LUGPA 2022 Annual Meeting:

Independent Urology Powered by Innovation

CME Program

Leading the Way to Optimizing Care in the Urology Practice

November 10, 2022

Chicago Marriott Downtown Magnificent Mile Hotel | 540 N Michigan Ave | Chicago

LUGPA
Integrated Practices
Comprehensive Care

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Welcome from the Program Chairs

Dear Colleagues:

Welcome to Chicago and the LUGPA 2022 CME Program. This year's theme, **Leading the Way to Optimizing Care in the Urology Practice**, will deliver an outstanding educational experience.

The program begins with recent breakthroughs to optimize ASC utilization. First, Michael Fabrizio, MD, will lead and moderate this session that will highlight the latest findings on Robotic Surgery from Ronney Abaza, MD, Transitioning to Ambulatory PCNL by Julio Davalos, MD and Urethral Reconstruction from Brad Figler, MD. This session will conclude with a presentation on Focal Therapies and Sherita King, MD will discuss Penile Implant-Post Prostatectomy, followed by a question and answer period.

Next, we will hear from Steven Kaplan, MD who will review the latest on BPH Treatments and Deobstructing Mouse Traps and Sandeep Bagla, MD will discuss Prostrate Artery Embolization. This session will feature Samuel Hakim, MD and David Morris, MD as panelists.

We are looking forward to the discussion about PSMA-PET moderated by Evan Goldfischer, MD. Phillip Koo, MD will provide the insight on the Clinical and Economic Utilization and panelists E.Scot Davis, Jeffrey Spier, MD and David Albala, MD will discuss independent practice perspectives.

For the second half of the program, we have planned a very important session on Appreciating Diversity in Urology Care. First, Brad Figler, MD will discuss data and findings on Gender Reassignment. Channa Amarasekera, MD and Diana Bowen, MD will share their research about LGBTQ Concerns for the independent urology practice. Panelists for this session include Guy Manetti, MD, Michael Fabrizio, MD and Benjamin Lowentritt, MD.

A session on the Advanced Prostate Cancer Clinic Optimization will feature Alicia Morgans, MD who will discuss mCSPC Couplet vs. Triplets, Evan Yu, MD who will discuss mCRPC Combining and Sequencing and the ever-enlightening information on Genetic Testing from Emmanuel Antonarakis, MD. Panelists for this session include Jonathan Henderson, MD, Scott Sellinger, MD and Jason Hafron, MD.

The Optimization of Advanced Bladder Cancer Clinic session will provide insight and discussion on Intravesical Explosion from Colin Dinney, MD and Systemic Therapies from Artene Siefker-Radtke, MD. Josuha Meeks, MD and Suzanne Merrill, MD will conduct the interactive question and answer session.

Advanced Bladder Cancer Clinic session will provide insight and discussion on Intravesical Explosion from Colin Dinney, MD and Systemic Therapies from Artene Siefker-Radtke, MD. Josuha Meeks, MD and Suzanne Merrill, MD will conduct the interactive question and answer session.

Finally, we will conclude the program with a spirited discussion lead by Gordon Brown, DO on the topic of Spacer Wars. Neil Mariados, MD, Parthiv Mehta, MD will provide their perspectives on Barrigel and SpacerOAR. Afterwards, Shawn Zimberg, MD with join Neil Mariados, MD and Pathiv Mehta, MD to answer questions o this important topic.

We look forward to your attendance and participation at the 2022 Annual CME meeting.

Neal Shore

Neal D. Shore, MD, FACS
Chair, LUGPA Practice Administrators Committee

Gordon Brown

Gordon Brown, DO, FACOS
Co-Chair, LUGPA

Program Faculty

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Neal D. Shore, MD, FACS
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Educational Needs/Objectives

Educational Needs

The specialty of urology has been developing with exceptional rapidity as evidenced by the multitude of FDA approved diagnostic, imaging and therapeutics for both oncologic and nononcologic management of prostate, bladder, kidney diseases and other genitourinary diseases. Concomitantly, urology practices are recognizing the importance of providing state-of-the-art care for these patients which can involve both multidisciplinary care as well as maintaining their existing expertise and strengthening their clinics of excellence, and thus allow them to remain competitive with large health systems and private equity acquisitions of independent practices. Challenges involve providing ongoing education to address not only the most recently presented/published trial data of these above mentioned advances and innovations but also how to best understand and optimize diagnosis, reduce complications, evaluation, therapeutic selection and patient management. Thus, the course will address these issues specifically focusing on advanced technologies which may change current practice patterns for genitourinary patients with both malignant and non-malignant conditions and issues that impact the independent practice urologist.

Educational Objectives

At the conclusion of the LUGPA 2022 CME Program, attendees will be able to:

1. Evaluate the differences in therapies and genetic testing used to treat urologic cancers.
2. Analyze the optimal way to use sequencing and genetic testing for the treatment prostrate cancer.
3. Adopt and develop best practices to treat complications for those who underwent gender reassignment.
4. Identify the adverse event and toxicity profile, indications and administration of bladder cancer therapies in order to best establish an Advanced Bladder Cancer clinic of excellence.
5. Describe the various treatment options and outcomes for BPH.
6. Review and appraise the use of rectum spacers and radiotherapy to treat metastatic prostate cancer.

Accreditation and Designation Statements

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of PeerPoint Medical Education Institute and the LUGPA. PeerPoint Medical Education Institute is accredited by the ACCME to provide continuing medical education for physicians.

PeerPoint Medical Education Institute designates the live format for this educational activity for a maximum of *3.75 AMA PRA Category 1 Credits*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Live activity date: November 10, 2022

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Ronney Abaza, MD	VTI, Veracyte Conmed Inc, Intuitive Surgical	Speaker Investigator
David Albala, MD	Biotechne, Boston Scientific Applied Medical Mdx Health, Exact Sciences	Consultant Consultant/Stock Speaker
Channa Amarasekera, MD	Nothing to Disclose	
Emmanuel Antonarakis, MD	Blue Earth Diagnostics, Janssen, Merck, Sanofi, Aikido Pharma, Amgen, Constellation, EcoR1, Exact Science, Foundation Medicine, Ismar, KeyQuest Health, Orion, Projects in Knowledge, Tempus Astrazenca Celegene, Clovis Qiagen	Consultant Research Grant Recipient/Consultant Research funding Patent holder
Sandeep Bagla, MD	Terumo Medical, Merit Medical, CranMed Ashahi Medical	Consultant Speaker
Fernando Bianco, MD	Smartblate, Francis Medical, Clinical Laser System Focalyx Janssen Pharmaceuticals	Advisor, Researcher Executive Role/Ownership Advisor
Diana Bowen, MD	Nothing to Disclose	
Gordon Brown, DO	Janssen, Astellas, Bayer, Astra Zeneca, Lantheus Engene	Speaker, Consultant, Research, Advisor Research, Advisor
Julio Davalos, MD	Karl Storz Endoscopy America, Boston Scientific, Monarch Lumenis, EMS	Consultant Contracted Research
E. Scot Davis	Bayer, Dendreon, Pizer, Specialty Networks, Boston Scientific, Myovant, Abbvie, Urogen	Speaker, Consultant
Colin Dinney, MD	Nothing to Disclose	

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	Merck	Speaker, Scientific Advisor
Brad Figler, MD	Nothing to Disclose	
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	Myovant Sciences, Inc.	Consultant/Advisor,
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	Promaxo, Lynx DX	Consultant/Advisor
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Jonathan Henderson, MD		
Tom Jayram, MD	Specialty Networks, Merck, Blue Earth, Tempus, Bristol Myers Squib, Photocure, Aura, KDx, Codiak	Consultant
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	Telix	Speaker
Benjamin Lowentritt, MD	Pfizer, UroGen	Consultant
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Alicia Morgans, MD	AstraZeneca, Janssen, Exelixis, Novartis Astellas, Bayer AAA, Sanofi, Myovant Pfizer Telix	Consultant Consultant/Research Research Speaker
David Morris, MD	Merck, Astellas, Janssen, Bayer, AstraZeneca, Clovis, Lantheus, Urogen Specialty Networks	Consultant Consultant/Stockholder
Scott Sellinger, MD	Bayer, Astellas, Pfizer, Janssen, Lantheus, Tolmar Astra-Zeneca, Exact Sciences	Consultant/Speaker Speaker
Neal Shore, MD	Nothing to Disclose	
Arlene Siefker-Radtke, MD	AstraZeneca, Bavarian Nordic, Genentech, G1 Therapeutics, Gilead, Ideeya, Immunomedics, Loxo, Seattle Genetics, Taiho Bristol Myers Squibb, Merck, Mirati, Nektar Therapeutics Janssen Basilea Pharmaceutica, Millennium	Advisory Board Advisory Boards/Clinical Trials Advisory Boards/Clinical Trials/Speaker Clinical Trials
Edward Soffen, MD	Boston Scientific Bioprotect	Consultant and Proctor Consultant
Jeffrey Spier, MD	Nothing to Disclose	
Evan Yu, MD	Advanced Accelerator Applications, Oncternal, Exelixis, Janssen Merck, Bayer Dendreon, Daiichi-Sankyo, Taiho, Seagen, Blue Earth, Lantheus	Consultant Consultant, Research Funding to Institution Research Funding to Institution
Shawn Zimberg, MD	Bayer Pharmaceuticals Boston Scientific Bioprotect, LTD	Speaker Consultant Research

CME Program Agenda

Thursday, November 10, 2022 Grand Ballroom Salons I & II (7th Floor)

TIME	SESSION TITLE
12:45pm – 1:00pm	**Welcome and Introductions** **Neal Shore, MD, FACS** Chair, LUGPA Education Committee and Co-Chair, CME Program **Gordon Brown, DO, FACOS** Co-Chair, CME Program
1:00pm – 1:58pm	**Optimizing ASC Utilization** Moderator: Michael Fabrizio, MD **Robotic Surgery (prostatectomy and nephrectomy)** Ronney Abaza, MD **Transitioning to Ambulatory PCNL** Julio Davalos, MD **Urethral Reconstruction** Brad Figler, MD **Focal Therapies** Fernando Bianco, MD **Penile Implant-Post Prostatectomy** Sherita King, MD **Question and Answer**
1:58pm – 2:26pm	**BPH Treatments** Moderator: Steven Kaplan, MD **Deobstructing Mouse Traps** Steven Kaplan, MD **Prostate Artery Embolization** Sandeep Bagla, MD **Question and Answer** Panelists: Samuel Hakim, MD David Morris, MD
2:26pm – 2:46pm	**PSMA- PET** Moderator: Evan Goldfischer, MD **Clinical and Economic Utilization** Phillip Koo, MD **Question and Answer** Panelists: E. Scot Davis Jeffrey Spier, MD David Albala, MD
2:46pm – 3:20pm	**Break in the Exhibit Hall – Grand Ballroom Foyer (7th Floor)**

**Please note that speakers and agenda topics are subject to change.*

CME Program Agenda: Thursday, November 10, 2022

TIME	SESSION TITLE
3:20pm – 3:50pm	**Appreciating Diversity in Urology Care** Moderator: Neal Shore, MD, FACS **Gender Affirming Surgery** Brad Figler, MD **LGBTQ Concerns** Channa Amarasekera, MD Diana Bowen, MD **Question and Answer** Panelists: Guy Manetti, MD Michael Fabrizio, MD Benjamin Lowentritt, MD
3:50pm – 4:30pm	**APCC Optimization** Moderator: David Morris, MD **mCSPC couplet vs triplets** Alicia Morgans, MD **mCRPC combining and sequencing** Evan Yu, MD **Genetic Testing** Emmanuel Antonarakis, MD **Question and Answer** Panelists: Jonathan Henderson, MD Scott Sellinger, MD Jason Hafron, MD
4:30pm – 5:00pm	**ABCC Optimization** Moderators: Tom Jayram, MD **Intravesical Explosion** Colin Dinney, MD **Systemic Therapies** Arlene Siefker-Radtke, MD **Question and Answer** Panelists: Joshua Meeks, MD Suzanne Merrill, MD

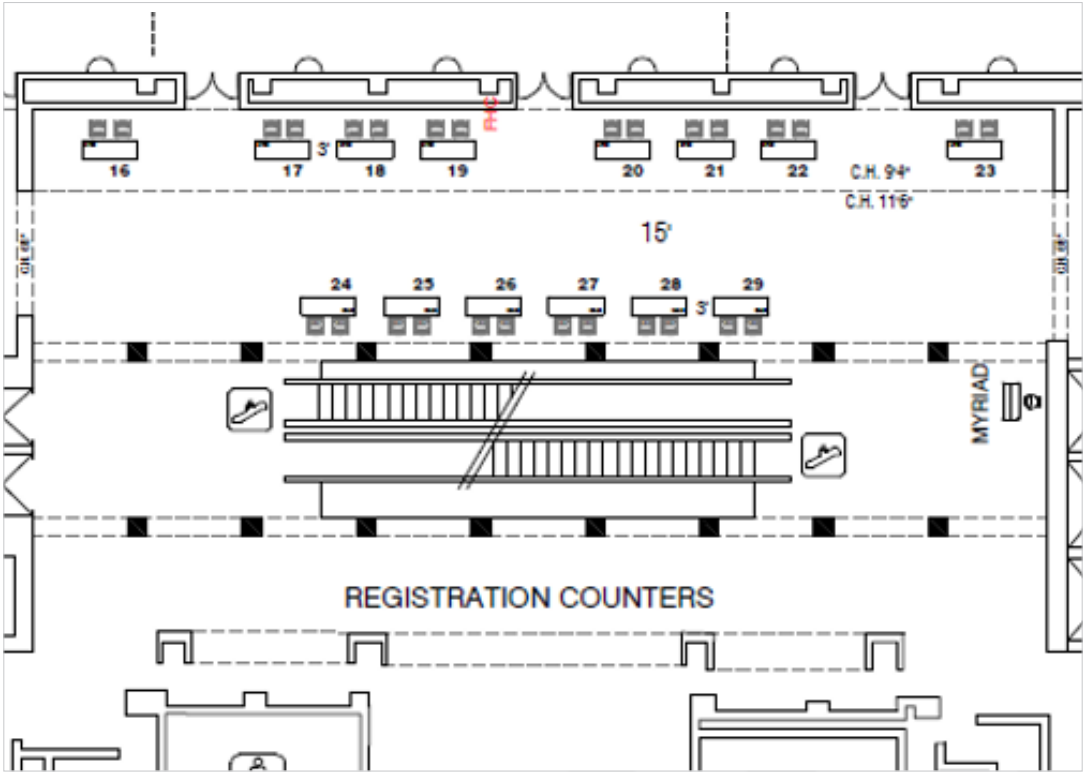
**Please note that speakers and agenda topics are subject to change.*

Agenda: Thursday, November 10, 2022

TIME	SESSION TITLE
5:00pm – 5:25pm	**Spacer Wars** Moderator: Gordon Brown, DO, FACOS **Barrigel** Neil Mariados, MD **SpaceOAR** Parthiv Mehta, MD **Bioprotect** Edward Soffen, MD **Question and Answer** Panelists: Neil Mariados, MD Shawn Zimberg, MD Edward Soffen, MD Parthiv Mehta, MD
5:25pm – 5:30pm	**Conclusion and Thank You** Neal Shore, MD, FACS Gordon Brown, MD, FACOS

**Please note that speakers and agenda topics are subject to change.*

Exhibit Hall Floor Plan



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Special Guest

ZERO – The End of Prostate Cancer

Faculty Biographies

Neal Shore, MD, FACS

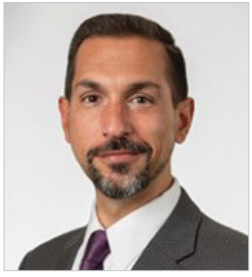
Chair, Education Committee

Dr. Neal Shore graduated both Duke University and Duke University Medical School. He completed his general surgery/urology residence at New York Hospital-Cornell Medical Center/ Memorial Sloan Kettering Cancer Center. He is the Medical Director, for the Carolina Urologic Research Center. He practices with Atlantic Urology Clinics in Myrtle Beach, South Carolina. Dr Shore has conducted more than 400 clinical trials, focusing mainly for GU Oncology indications. He is the Chief Medical Officer, Surgery/Urology, for GenesisCare,US. He has more than 250 peer reviewed publications and numerous book chapters. He serves on the SITC Guidelines Committee for Bladder Cancer as well as the boards of the Bladder Cancer Advocacy Network and the Duke Global Health Institute. He is the Chair of the LUGPA Education Committee. He is on the editorial boards of Reviews in Urology, Urology Times, Chemotherapy Advisor, OncLive, PLOS ONE, Urology Practice, World Journal of Urology, and also serves as Editor, Everyday Urology-Oncology. He is a Fellow of the American College of Surgeons.

Gordon A. Brown, DO, FACOS

Co-Chair LUGPA CME Program

Gordon Brown, DO, FACOS, is an Associate Professor at Rowan University School of Osteopathic Medicine. He serves as Program Director of Urologic Surgery at Rowan University School of Osteopathic Medicine as well as Director of New Jersey Urology's Center for Advanced Therapeutics, specializing in the treatment of prostate cancer. Board certified by the American Osteopathic Association, Dr. Brown completed a Urologic Oncology Fellowship at the UTMD Anderson Cancer Center in Houston, TX. He has been published in a variety of academic journals including *JAMA Oncology, BJU International*, and *Prostate Cancer and Prostatic Diseases*. Dr. Brown is a member of the American Society of Clinical Oncology, the American Association for Cancer Research, and the American Urological Association.



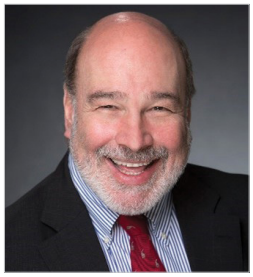
Ronney Abaza, MD

Dr. Ronney Abaza is a world-renowned expert in robotic surgery for prostate, kidney and bladder cancers and other urologic conditions. His practice has been dedicated solely to robotic surgery since 2008, and he has performed over 6,000 robotic surgeries making him the most experienced robotic surgeon in Ohio in any specialty and one of the top five in the world.

Dr. Abaza is a pioneer in robotic surgery as the first in the world to perform robotic surgery for adrenocortical carcinoma, kidney cancer with caval thrombi, ureteroileal anastomosis revisions after cystectomy, and renal autotransplantation, among other procedures he developed and performed for the first time. He has presented his work at national and international medical meetings, including more than 200 presentations at various meetings on robotic surgery, and has won numerous awards for his research. Dr. Abaza has authored over 130 publications and book chapters in the fields of robotic surgery and urologic cancers and is editor of the only textbook dedicated to robotic kidney surgery. His work has been featured on the covers of *Urology, European Urology* and the *Journal of Endourology*.

Dr. Abaza has given hundreds of lectures on robotic surgery and serves as faculty at medical society meetings and for educational courses both in the U.S. and internationally. He has performed live robotic surgery demonstrations broadcasted to the American Urological Association (AUA) Annual Meeting, the World Congress of Endourology, European Robotic Urology Symposium, North American Robotic Urology Symposium, International Robotic Urology Symposium, and the Society of Robotic Surgery Annual Meeting, among others. He has led the development of multidisciplinary robotic surgery programs at three institutions. He was director of a robotic urologic surgery fellowship program for 10 years training new urologists in robotic surgery. He has served as a visiting professor at several academic urology departments and has welcomed over 100 surgeons from around the world into his operating room for case observations to learn his techniques. Dr. Abaza's educational YouTube channel of surgeries he has performed for other surgeons was started only one year ago and already has thousands of views.

Dr. Abaza has served as President of the Ohio Urological Society and currently serves as the Ohio representative to the board of the North Central Section of the American Urological Association. He also serves on the editorial boards of several medical journals. Dr. Abaza has been chosen by peer nomination for the Best Doctors in America every year since 2011.



David M. Albala, MD

Dr. David M. Albala graduated with a geology degree from Lafayette College in Easton, Pennsylvania. He completed his medical school training at Michigan State University and went on to complete his surgical residency at the Dartmouth- Hitchcock Medical Center. Following this, Dr. Albala was an endourology fellow at Washington University Medical Center under the direction of Ralph V. Clayman. He practiced at Loyola University Medical Center in Chicago and rose from the ranks of Instructor to full Professor in Urology and Radiology in eight years. Ten years later, he became a tenured Professor at Duke University Medical Center in North Carolina. At Duke, he was Co-Director of the Endourology fellowship and Director for the Center of Minimally Invasive and Robotic Urological Surgery. He has over 217 publications in peer-reviewed journals and has authored three textbooks in endourology and five in general urology. He is the Editor-in-Chief of the Journal of Robotic Surgery. He serves on the editorial board for *Medical Reviews in Urology, Current Opinions in Urology* and *Urology Index and Reviews*. He serves as a reviewer for eight surgical journals. He currently sits on the Board of Directors for the Large Urology Group Practice Association (LUGPA) as well as US Urology Partners (USUP). He is a Visiting Professor in

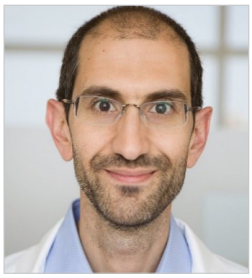
the Department of Urology at SUNY Downstate Health Sciences University. In addition, he was ranked among the top 2% of urologists in the world by a Stanford University study done in May, 2021.

At the present time he is Chief of Urology at Crouse Hospital and a member of Associated Medical Professionals in Syracuse, New York. He is considered a national and international authority in laparoscopic and robotic urological surgery and has been an active teacher in this area for over 20 years. His research and clinical interests have focused on robotic urological surgery. In addition, other clinical interests include minimally invasive treatment of benign prostatic hypertrophy (BPH), biomarkers in prostate cancer, and the use of fibrin sealants in surgery. He has been a Visiting Professor at numerous institutions across the United States as well as overseas in countries such as India, China, Iceland, Germany, France, Japan, Brazil, Australia, and Singapore. In addition, he has done operative demonstrations in over 32 countries and 23 states. He has trained 19 fellows in endourology and advanced robotic surgery.

In addition, Dr. Albala is a past White House Fellow who acted as a special assistant to Federico Pena, Secretary of Transportation, on classified and unclassified public health related issues.

Channa Amarasekera, MD

Dr. Amarasekera is an Assistant Professor of Urology at Northwestern University Feinberg School of Medicine with a clinical and research focus on Peyronie's disease, erectile dysfunction, prostate cancer survivorship, and identifying and addressing urologic healthcare disparities faced by members of sexual minorities. He graduated *Summa Cum Laude* from the University of Maryland with a degree in Cell Biology and Molecular Genetics and attended medical school at Harvard Medical School. He later went on to complete residency training at Northwestern. After residency, he pursued fellowship in Sexual Medicine and Reconstructive Urology at Rush University Medical Center. Following fellowship, he joined the faculty at Northwestern. In addition to serving as an Assistant Professor at the Feinberg School of Medicine, Dr. Amarasekera is the director of the Gay and Bisexual Men's Urology Program. He is actively involved in numerous national and international organizations, including the Sexual Medicine Society of North America (SMSNA), and the American Urologic Association (AUA).



Emmanuel S. Antonarakis, MD

Dr. Antonarakis is the Clark Endowed Professor of Medicine and the Director of Genitourinary Oncology in the Division of Hematology/Oncology and Transplantation at the University of Minnesota. He also serves as the Associate Director for Translational Research at the Masonic Cancer Center. Previously he was Professor of Oncology and Urology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, the Director of Prostate Cancer Medical Oncology Research, and the Co-Director of the Prostate Cancer Multi-Disciplinary Clinic at Johns Hopkins. Dr. Antonarakis an expert on the clinical management of prostate cancer and other genitourinary malignancies. He has received numerous awards for his translational research and his teaching skills. He is involved in mentoring fellows and junior faculty in the clinical care of genitourinary cancers and the development of translational clinical trials related to prostate cancer.

Dr. Antonarakis' research focuses on drug development and clinical trial design for patients with prostate cancer, as well as cancer genomics. More specifically, he is exploring novel androgen-directed therapies, genetically targeted therapies, and immunotherapies for men with recurrent or advanced prostate cancer, and using germline and cancer genomics to inform precision oncology approaches. He also has an interest in liquid biomarker development, specifically the clinical validation of the AR-V7 marker as well as DNA repair markers and their therapeutic implications. He is currently the PI of several phase II and III prostate cancer trials, and is an active member of the Prostate Cancer Clinical Trials Consortium (PCCTC) and the ECOG-ACRIN and Alliance Cooperative Groups, as well as the NCI Prostate Cancer Task Force and the NCCN Prostate Cancer Panel. He serves on the Editorial Board of several oncology journals, including the *Journal of Clinical Oncology*. He is the author of over 300 peer-reviewed articles, several book chapters, and has edited a textbook about AR signaling in cancer.

Sandeep Bagla, MD

Dr. Sandeep Bagla graduated with Honors from St. Georges University School of Medicine in 2002 before completing residency at Albany Medical Center in NY in Diagnostic Radiology, including being selected as Chief Resident. Dr. Bagla completed subspecialty training in Vascular & Interventional Radiology at George Washington University in 2008 and completed his Certificate of Added Qualification (CAQ) in Vascular & Interventional Radiology.
He has personally pioneered research in the fields of Benign Prostatic Hyperplasia, Knee Arthritis and Minimally Invasive Cancer Therapy.. Dr. Bagla has served as the Principal Investigator of numerous clinical trials and continues to improve novel methods to treat conditions that affect tens of millions of people.

He has numerous publications in peer-reviewed journals, has co-authored books and chapters on multiple topics. Dr. Bagla currently sits on the physician advisory board of multiple worldwide medical device companies providing his advice for the future of embolization therapy, while also working to advance the mission of the Society of Interventional Radiology with multiple roles for the organization.

Fernando J. Bianco, MD

Dr. Bianco, is a urologist specializing in pelvic floor reconstruction, the treatment of prostate conditions, and robotic surgery for cancers of the prostate, kidney, and bladder. Dr. Bianco is part of the team at Urology Specialist Group, serving the greater Miami and Fort Lauderdale areas of South Florida at their offices in Hialeah and Miami Lakes, Florida.

Dr. Bianco obtained his medical degree from the Central University of Venezuela in Caracas, Venezuela, in 1995. He then continued his education in urology at Wayne State University in Detroit from 1997-2003. Dr. Bianco further honed his skills from 2003-2006 in urologic oncology and laparoscopy at Memorial Sloan Kettering Cancer Center in New York City. With more than 20 years experience, Dr. Bianco has had the opportunity to serve in many professional appointments and is a former professor of urology at George Washington University in Washington, D.C. and at Columbia University in New York City. Currently, Dr. Bianco practices at Urology Specialist Group and Lyx Health in South Florida. He's the investigator-in-chief for the Urology Research Network in Miami and is a professor of urology at Nova Southeastern University in Fort Lauderdale. Throughout his medical career, Dr. Bianco has published numerous peer-reviewed professional research articles.

Diana Bowen, MD

Dr. Bowen is an Assistant Professor of Pediatric, Adolescent, Transitional and Adult Urology at Northwestern. She provides care at both Ann & Robert H. Lurie Children's Hospital in the multidisciplinary spina bifida clinic, as well as at Northwestern Memorial Hospital and the adult spina bifida clinic at Shirley Ryan Ability Lab (formerly RIC). She is also a principal founding member and surgeon in Northwestern's multidisciplinary program for Transgender Care and Gender-Affirmation Surgery. After obtaining a Bachelor of Arts in Biologic Anthropology from Harvard College in Cambridge, Massachusetts, she attended the University of Michigan Medical School and completed residency in Urologic Surgery at Northwestern Memorial Hospital in Chicago. She then underwent further training with a two-year fellowship in Pediatric Urology at The Children's Hospital of Philadelphia.

Julio G. Davalos, MD

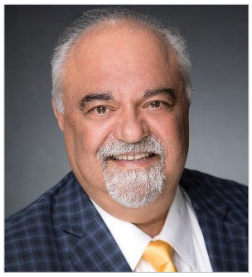
Dr. Davalos has been a practicing urologist since 2005 and he treats all aspects of adult urology. His special interest is in kidney stone disease and he specializes in providing comprehensive surgical, medical and preventive care for kidney stones with the treatment goal of rendering patients 100% stone free.

A national and international leader in the treatment of large kidney stones performing Percutaneous Nephrolithotomy (PCNL) and ambulatory percutaneous nephrolithotomy (PCNL), Dr. Davalos serves as the Director of Chesapeake Urology's Advanced Kidney Stone Program. Under his leadership, Chesapeake Urology's program was the first in the world to perform PCNL safely and effectively as an outpatient surgery in a free-standing ambulatory surgical center in 2015. Since then, Dr. Davalos continues to be a leader in ambulatory and outpatient PCNL surgery in the U.S., and globally.

While most general urologists treat stone disease, Dr. Julio Davalos is one of the region's foremost specialists in the diagnosis, treatment, and metabolic management of kidney stone disease to help prevent future stones from impacting your life. Specially trained in the most advanced surgical techniques, including PCNL and Tubeless PCNL, Dr. Davalos is a pioneer in the advanced treatment of kidney stones and focuses on the long term management of stone disease once a patient is stone free.

Dr. Davalos utilizes Percutaneous Nephrolithotomy (PCNL) for the surgical treatment of large and complex kidney stones. Dr. Davalos and his team are leaders in the tubeless PCNL technique, which is performed as a PCNL surgery but eliminates the need for the nephrostomy (drainage) tube. Patients go home the same day with no tube left in the kidney, resulting in an easier and quicker recovery.

In addition to kidney stones and all types of PCNL surgery, Dr. Davlos specializes in renal access (fluoroscopic-guided, ultrasound-guided, and endoscopic-guided), flexible Ureteroscopy, metabolic evaluation for stone prevention, percutaneous and endoscopic management of upper tract urothelial cancer, as well as endoscopic management of upper tract stricture disease.



E. Scot Davis

As its CEO, E. Scot Davis has played an instrumental role in the development and evolution of Arkansas Urology, located in Little Rock. Davis joined the practice as its CEO in May of 2013. Davis' extensive contributions to healthcare prior to Arkansas Urology include service as the CFO of Baptist Medical Group and CFO of Northeast Arkansas Clinic in Jonesboro. Davis is also a member of the Arkansas Medical Group Management Association and the American Medical Group Association.

Davis received a Bachelor of Arts in Political Science and a Master of Public Administration from Memphis State University. He also earned a Master of Business Administration from Christian Brothers University. Davis has over 25 years of physician practice management experience with expertise in operational efficiency, physician recruitment, joint venture arrangements and compensation modeling.

Colin P. N. Dinney, MD

Dr. Dinney is a Professor and Chairman of Urology. He maintains an active clinical practice specializing in bladder cancer and a research laboratory focused on understanding the biology of bladder cancer metastases and on the development of novel therapy for bladder cancer. His group played a pioneering role in developing preclinical models of spontaneous bladder cancer metastasis and used these models to identify the mechanisms regulating metastasis and for preclinical therapeutic studies.

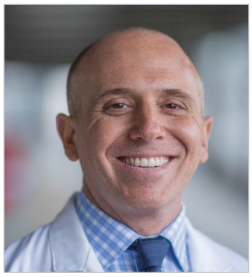
His group developed intravesical Nadoferigene Firadenovec (adenoviral-mediated interferon-α gene therapy) for the treatment of BCG Unresponsive NMIBC. A Phase 3 trial was conducted by the SUO-CTC. His laboratory is currently working to improve interferon gene therapy by identifying biomarkers that predict sensitivity or resistance. These testing novel vectors might improve transfection efficiency and activity and evaluating novel combination strategies.

Dr. Dinney served on the Society of Urologic Oncology Executive Committee, was the Founding President of the SUO's Clinical Trial Consortium, and is the current Chair of the SUO CTC Bladder Cancer Committee. Dr. Dinney is the SPORE's Liason to SWOG's GU Executive Committee. He is also a former member of the National Institutes of Health and Genitourinary Steering Committee and served as the Urology Chair for the Bladder Cancer Task Force from 2016-2019.

Michael D. Fabrizio, MD, FACS

A graduate of The College of William and Mary, Williamsburg, Virginia, and Medical College of Virginia, Richmond, Va., Dr. Fabrizio completed his residency at Thomas Jefferson University Hospital, Philadelphia, Pa. Dr. Fabrizio was awarded a fellowship in endourology and laparoscopic surgery at The Johns Hopkins University, Brady Urological Institute in Baltimore, MD. Dr. Fabrizio was involved in the FDA trials for the Zeus Robotic system, and an early adopter of robotic surgery.

Dr. Fabrizio has served as the CEO of Urology of Virginia since 2008. He specializes in urological laparoscopy for benign and malignant conditions including prostate and kidney cancer, adrenal surgery, kidney donation and complex kidney and ureteral stone surgery. With the support of his partners, he created the laparoscopic radical prostatectomy and robotic assisted prostatectomy program as well as the laparoscopic kidney donor program in Norfolk, Va. He also started a training fellowship in endourology and laparoscopy in 2003 which has received national recognition in Quality of Life Outcomes research for prostate cancer treatments. The fellowship has won awards for publications and been cited by *USA Today* and *Reuters News*. He has published many peer reviewed articles and book chapters as well as lectured around the world on topics in endourology and outcomes. Dr. Fabrizio is board certified by the American Board of Urology and the National Board of Medical Examiners and is a fellow in the American College of Surgeons. He is a member of The American Urological Association, Mid-Atlantic Section of the American Urological Association, Endourology Society, and the Society of Urologic Oncology. In addition to being the Chief Executive Officer of the practice and the endourology fellowship director, he is the President-elect of the Mid-Atlantic Section of the American Urological Association and on the board of LUGPA (Large Urology Group Practice Association).

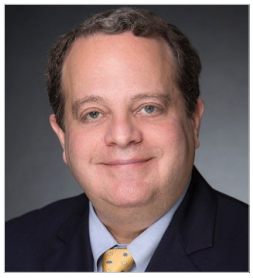


Brad Figler, MD

Dr. Figler is a board-certified Urologist and leader in the field of Genitourinary Reconstruction. Dr. Figler's practice specializes in complex genital reconstruction, including urethral reconstruction (for strictures and fistulas), genital skin deficiency (after infection and trauma), penile/genital cancer, gender affirming bottom surgery, and surgery for incontinence and erectile dysfunction. In addition to providing comprehensive care for all patients requiring complex genitourinary reconstruction, Dr. Figler specializes in the following conditions:

- Urethral strictures, including after trauma, radiation, and failed surgery.
- Rectourethral fistula
- Lichen sclerosus.
- Buried penis
- Penile/genital cancer – including Extramammary Paget's Disease (EMPD). A comprehensive team, including Dr. Marc Bjurlin in uro-oncology and Dr. Brad Merritt in Dermatology/Mohs surgery, utilize an innovative set of techniques to maximize chances of curing the cancer, preserve as much genital tissue as possible, and maximize quality of life.
- Vaginoplasty. Dr. Figler developed an innovative "graft only" approach for patients with sufficient genital skin and, in coordination with Dr. Marc Bjurlin, performs robot assisted peritoneal flap vaginoplasty for patients with insufficient genital skin.
- Metoidioplasty. Dr. Figler utilizes the "ring flap" approach to achieve excellent functional and aesthetic results.
- Phalloplasty. Dr. Figler and Dr. Yemi Ogunleye (plastic surgery) perform radial forearm free flap and anterolateral thigh (ALT) phalloplasty for transgender patients and cis-gender patients after penile cancer and trauma.
- Hidradenitis. As part of a comprehensive team, including Dr. Chris Sayed in dermatology, Dr. Figler offers comprehensive genital reconstructive surgery to reduce disease burden and improve quality of life.

Dr. Figler received his medical degree from Case Western Reserve University School of Medicine and completed his residency training in Urology at Emory University Hospital in Atlanta, GA. Following residency, Dr. Figler completed a two-year fellowship in Genitourinary Trauma and Male Reconstruction at the University of Washington and Harborview Medical Center with Dr. Hunter Wessells, a pioneer in Genitourinary Trauma and Male Reconstruction.



Evan P. Goldfischer, MD, MBA, CPI

Dr. Goldfischer received his BA from Tufts University and his MD from Cornell University Medical College. He completed his internship in general surgery and his residency in urology at the University of Chicago. He completed a fellowship in endourology under the direction of Arthur Smith at Long Island Jewish Medical Center. Dr. Goldfischer received his MBA from the University of Massachusetts and is a Certified Physician Executive. He served as the co-founding CEO of Premier Medical Group of the Hudson Valley, as well as founding Director of Research.

Dr. Goldfischer has written over 100 peer-reviewed abstracts and publications and has lectured on six continents. In addition, he was elected to the LUGPA Board of Directors in 2014 currently serving as President-Elect. He is the Editor-in-Chief of *Practice Management for Urology Groups: LUGPA's Guidebook Second Edition* published in 2020 and is the author of *Even Urologists Get Kidney Stones – A Guide to Prevention and Treatment*, published in 2018.

Jason M. Hafron, MD

Dr. Hafron is the Chief Medical Officer and Director of Clinical Research at the Michigan Institute of Urology (MIU). Dr. Hafron is a Professor of Urology at the William Beaumont School of Medicine, Oakland University, Royal Oak, Michigan. He is experienced in all areas of adult urology, specializing in the minimally invasive treatment of cancers involving the prostate, kidney and bladder utilizing robotic surgery.

Dr. Hafron received his Bachelor of Science degree from the University of Michigan and his Doctor of Medicine degree from Loyola University Chicago-Stritch School of Medicine. Dr. Hafron completed his General Surgery and Urology Residency at Albert Einstein College of Medicine, Montefiore Medical Center in New York City. He continued his training as a Fellow in Advanced Laparoscopic and Robotic Surgery at the Cleveland Clinic Foundation, Glickman Urological and Kidney Institute, Cleveland, Ohio. Dr. Hafron has published numerous peer reviewed journal articles on topics related to his expertise and presented his work at many national and international scientific meetings. He is the recipient of many clinical research awards. He is on the Editorial Board of the journal International Urology and Nephrology, Urologists in Cancer Care and Advances in Urology. He previously served on the Board of Directors of United Physicians Organization. Dr. Hafron is board certified in the specialty of Urology by the American Board of Urology.

Samuel Hakim, MD

Dr. Samuel Hakim cares for adults' general urologic concerns and focuses on minimally invasive laparoscopic and robotically assisted surgeries. He also specializes in performing vasectomy reversals using a surgical technique that he helped pioneer.

He joined Urology San Antonio in August 2009 after concluding 24 years of service in the U.S. Air Force Medical Corps. Prior to his military retirement, Dr. Hakim was a lieutenant colonel and the urology flight commander at Wilford Hall Medical Center.

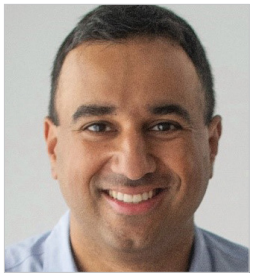
When he retired from the military in 2009, Dr. Hakim entered private practice with Urology San Antonio and helped the practice open a location in the Westover Hills area where he continues to see patients. Additionally, he spearheaded an initiative to make the practice one of the first civilian clinics in the United States offering couples the fibrin glue vasectomy reversal technique.

When he is not working in the clinic or the operating room, Dr. Hakim enjoys being physically active. In 2004, he completed the Ironman Florida Triathlon. He also enjoys the more leisurely sport of golf. Dr. Hakim and his wife Toni are blessed with three children.

Jonathan Henderson, MD

Dr. Henderson earned a Bachelor of Science Degree at LSU in Baton Rouge in microbiology. After receiving his MD at LSU Medical Center in Shreveport, he completed his internship and residency in Urology at LSUMC Hospital.

Dr. Henderson spent the next six years in practice in Alabama where he pioneered urologic laparoscopy. In 2002, Dr. Henderson was asked to return to Shreveport to join the nascent Regional Urology and served as CEO. In March 2022 Dr. Henderson joined Arkansas Urology in Little Rock, Arkansas Dr. Henderson is certified by the American Board of Urology. He is a member of the American Urologic Association (and sits on many committees for that organization), Shreveport Medical Society, Louisiana State Medical Society, and the Alpha Omega Alpha Medical Honor Society. He has been on the LUGPA Board of Directors since 2011 and is currently serving as President of LUGPA.



Gautam Thomas Jayram, MD

Dr. Jayram was born and raised in suburban Chicago and completed his urology residency including a year of research at the University of Chicago Hospitals. Following this he completed a fellowship at the Brady Urological Institute at Johns Hopkins. As a clinical instructor at Johns Hopkins, Dr. Jayram gained tremendous experience with kidney, prostate and bladder surgery with an emphasis on minimally invasive cancer surgery.

At Urology Associates in Nashville, Dr. Jayram has become one of the busiest urologic cancer surgeons in the region. He is co-director of the Advanced Therapeutics Center where he treats patients with advanced cancers and participates in cutting edge clinical trials. Dr. Jayram has spearheaded the immunotherapy program at Urology Associates where patients with complex urinary tract cancers from across the region can receive novel therapies or trials which can significantly impact their life. He is a Clinical Associate Professor of Urology at Vanderbilt and mentors resident physicians during their training. Dr. Jayram has written numerous journal articles and book chapters and is an editorial contributor to the popular website Practice Update. He is passionate about integrating novel technologies and therapeutics in community urology and promoting high-value care in independent group practice.

Steven Kaplan, MD, FACS

Dr. Steven Kaplan graduated from Mount Sinai School of Medicine in 1982 and was elected to the AOA Honor Society. Dr. Kaplan's postgraduate training included an internship and residency in the Department of Surgery at Mount Sinai Hospital as well as a residency in Urology at the Squier Urologic Clinic, Columbia University. He was an American Urologic Association Scholar between 1988 – 1990 that focused on identifying molecular markers and urodynamic parameters that herald bladder and prostate dysfunction.

Dr. Kaplan was the Given Foundation Professor of Urology and Administrator, as well as Vice Chairman of the Department of Urology at Columbia University from 1998 – 2005. And then, the E Darracott Vaughan Jr. Professor of Urology and Chief, Institute for Bladder and Prostate Health at Weill Cornell Medical College and Director, Iris Cantor Men's Health Center at New York Presbyterian Hospital. Currently, he is Professor of Urology at the Icahn School of Medicine at Mount Sinai and Director of The Men's Health Program of the Mount Sinai Health System.

He is a serial entrepreneur and a founder of Medidata Solutions Inc., a publicly held corporation and one of the premier electronic data capture companies in the world; Medivizor, Inc., a medical informatics enterprise; and InspiReN, a digital interface analyzing and enhancing the patient experience with health care professionals.

Dr. Kaplan is a Diplomat of the American Board of Urology and a Fellow of the American College of Surgeons. He is a recognized authority on the study of benign diseases of the prostate, the association of metabolic factors and voiding dysfunction and a thought leader on digital Men's Health. He has published more than 1200 articles, 170 abstracts, and has made over 340 presentations in more than 35 countries. He is the co - author of five books and is on the Editorial Board of *Urology, Journal of Urology*, and *Urology Times*.

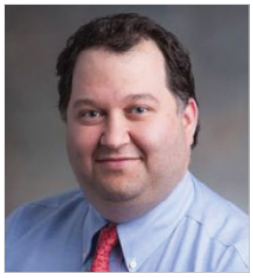
Dr. Kaplan has been a member of more than 30 professional organizations, been awarded 5 NIH grants and has received over 13 million dollars in research funding. He was awarded the John K. Lattimer Award for Lifetime Achievement in Urology by the National Kidney Foundation. Currently, he is the Chair of Research of the of American Urologic Association and is on the AUA BPH Guidelines Committee.

Sherita A. King, MD

Dr. King is a fellowship-trained and board-certified urologic surgeon specializing in male and female sexual medicine and prosthetic urology. She was raised in Augusta, GA and attended the University of Georgia. She completed medical school and urology residency at the Medical College of Georgia.

Phillip J. Koo, MD

Dr. Koo is the Chief of Diagnostic Imaging and Physician Executive of Oncology at the Banner MD Anderson Cancer Center in Phoenix, AZ. Prior to this, he was Chief of Nuclear Medicine and Associate Professor of Radiology at the University of Colorado School of Medicine. Dr. Koo completed his transitional internship at the University of Pennsylvania Medical Center-Presbyterian, radiology residency at Pennsylvania Hospital of the University of Pennsylvania Health System, and fellowship at the Harvard Medical School Joint Program in Nuclear Medicine. He is a diplomate of both the American Board of Radiology (ABR) and American Board of Nuclear Medicine. Dr. Koo's academic interests have focused on PET imaging in prostate cancer, response to novel therapies using PET, and data-driven image processing.



Benjamin Lowentritt, MD

Dr. Benjamin Lowentritt is Director of Prostate Cancer Services at United Urology Group, Director of the Comprehensive Prostate Cancer Care Program and Director of Minimally invasive Surgery and Robotics at Chesapeake Urology, a member of United Urology's group practices. He has been a leader of incorporating advanced prostate cancer treatments into community urology practices. He has authored numerous articles on the use of biomarkers, active surveillance, advanced prostate cancer, robotic surgery, erectile dysfunction and the urological management of patients after renal transplantation.

Dr. Lowentritt received his AB from Harvard University and Doctor of Medicine degree from Baylor College of Medicine. He completed his medical residency at the University of Maryland School of Medicine and a fellowship in Robotic, Laparoscopic and Endoscopic Urology at Tulane University. Dr. Lowentritt has served on the board of the Mid-Atlantic Section of the American Urological Association and is currently President-Elect. He also serves on the Board of Directors for MedChi, the Maryland State Medical Society and the Baltimore City Medical Society. He has been recognized as a Top Doctor in multiple publications over multiple years.

Guy Manetti, MD

Dr. Manetti graduated from the University of Pennsylvania and earned his Medical Degree from the University of Medicine & Dentistry of New Jersey. He completed his general surgery internship and urology residency at Yale New Haven Hospital in New Haven, Connecticut, where he served as chief resident of Urology. Dr. Manetti has published numerous peer-reviewed articles and was awarded a research grant from the Department of Surgery at Yale University. In addition to general urology, Dr. Manetti's areas of special expertise and interest are minimally invasive surgery of the kidney, robotic prostate surgery, management of stone disease and erectile dysfunction. He is a member of American Urological Association and an attending at Danbury Hospital/Western Connecticut Health Network.

Neil Mariados, MD

Dr. Mariados has fellowship trained expertise in stereotactic radiosurgery and brachytherapy for head and neck, GI, breast, and prostate cancers. He works closely with thoracic surgeons regionally in utilizing stereotactic radiosurgery for lung tumors as well as IMRT.

Joshua Meeks, MD

Dr. Meeks is an Associate Professor of Urology, Biochemistry and Molecular Genetics at the Northwestern University Feinberg School of Medicine, as well as Section Chief of Robotic Surgery at the Jesse Brown VA Medical Center. He is a urologic surgeon with expertise in the diagnosis, treatment and management of bladder cancer. He received his MD and PhD degrees from Northwestern University in 2005, completed urology residency at Northwestern University in 2011, and a urologic oncology fellowship at Memorial Sloan-Kettering Cancer in 2012.

His research interests focus on both the epigenetics and genetic mutations associated with cancer biology. Specifically, he is studying how chromatin remodeling genes play a role in bladder cancer. In addition, he is investigating the “driver mutations found in bladder cancer. In the future, he hopes to develop novel systemic and intravesical therapies to improve survival of patients with bladder cancer.

Parthiv Mehta, MD

Par Mehta, MD is a Board Certified Radiation Oncologist specializing in the treatment of prostate cancer. He possesses the expertise and advanced training in intensity-modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT), and prostate brachytherapy. Additionally, he is an expert in utilizing The Calypso® 4D Localization System (GPS for the body).

After earning his bachelor’s degree in engineering from the University of Michigan, Dr. Mehta entered the Medical Scholars Program at the University of Illinois where he completed an M.D as well as an M.B.A degree. He completed his residency in radiation oncology at Rush University Medical Center and entered into a brachytherapy fellowship program at Beth Israel Medical Center in New York City. During this time he completed research that has been published in several clinical journals.

Dr. Mehta is a member of the American Society for Therapeutic Radiology and Oncology, the American Society of Clinical Oncology, the American Medical Association, the Radiological Society of North America, the American College of Radiation Oncology, and the American Brachytherapy Society. Dr. Mehta is not only committed to providing his patients with the highest quality cutting edge treatment options, but he also ensures they are thoroughly informed about their treatment choices. He also speaks multiple languages, including Spanish and Gujarati.

Suzanne B. Merrill, MD, FACS

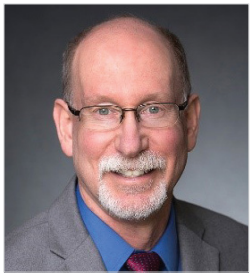
Dr. Merrill is a Urologic Oncologist affiliated with Colorado Urology and the United Urology Group. Dr. Merrill graduated summa cum laude from The University of Delaware where she received a bachelor of arts with honors in biology and chemistry. She attended The University of North Carolina Chapel Hill School of Medicine where she graduated with AOA honors. Dr. Merrill completed her urology residency at Duke University followed by a SUO accredited urologic oncology fellowship at The Mayo Clinic in Rochester, Minnesota. While at Mayo she also received a certificate in clinical and translational research science. Dr. Merrill’s clinical practice focuses on utilizing both open and minimally-invasive techniques to treat all primary/recurrent urologic cancers.

Alicia Morgans, MD, MPH

Dr. Morgans is a Genitourinary Medical Oncologist and the Medical Director of the Survivorship Program at Dana-Farber Cancer Institute. A clinician and investigator, she has expertise in clinical trials and patientreported outcome measures, as well as incorporating patient preferences and beliefs into clinical decision making. Her research has investigated complications of systemic therapy for prostate cancer survivors, including the study of skeletal, cardiovascular, diabetic, and cognitive complications. Her work has been funded by grants from the Prostate Cancer Foundation and the Department of Defense. She is a member of the advanced and localized prostate cancer treatment guidelines committee of the American Urologic Association, and is a member of the cardio oncology committee of the American Heart Association. Since 2016, she has been President of the Medical Advisory Board for ZERO, a non-profit organization dedicated to supporting education and research funding for prostate cancer research. She attended the University of Pennsylvania, Perelman School of Medicine, and completed her residency at the Hospital of the University of Pennsylvania. Her Fellowship in Medical Oncology was completed at the Dana-Farber Cancer Institute/Massachusetts General Hospital.

David S. Morris, MD

Originally from Cleveland in East Tennessee, Dr. Morris attended The Baylor School in Chattanooga, TN. He graduated Summa Cum Laude from Vanderbilt University and then earned his doctorate from Vanderbilt University School of Medicine. Dr. Morris completed his residency training at The University of Michigan in Ann Arbor, MI with a special research interest in genetics that predict the aggressiveness of prostate and bladder cancers. Since completion of training, he has been with Urology Associates in Nashville, Tennessee. He serves the group President and the Co-director for the Advanced Therapeutics Center. The ATC center also works closely with the Clinical Research Department as a center for multiple phase 2 and 3 trials primarily focused on GU oncology.



Scott Sellinger, MD

Dr. Sellinger has been a partner at Southeastern Urological Center, now a division of Advanced Urology Institute, since 1991. He received his B.S. degree in Chemistry from Syracuse University, and attended Medical School at the University of Florida in Gainesville. He completed his Urology residency at the University of Florida and has lived in Tallahassee for over 30 years. He was President of the Capital Medical Society in 2003, and served as President of the Florida Urological Society in 2005. In 2018, he served as President of the Southeastern Section of the American Urological Association (SESAUA). In 2019, he served as President of the American Association of Clinical Urologists (AACU). In addition to his urology specific work, Dr. Sellinger has developed a special interest in risk management and prevention of medical errors and has lectured extensively on this subject matter. He is also interested in large group practice development and management. For several years, Dr. Sellinger has served on the board of Advanced Urology Institute (AUI) representing his care center in Tallahassee. In January 2021, he became the second President of AUI, now one of the largest independent urology practices in the United States. Dr. Sellinger currently chairs the Advanced Prostate Cancer (APC) Committee and oversees seven APC clinics within AUI. Since 2015, has also served on the Large Urology Group Practice Association (LUGPA) Board of Directors, where he currently serves as Secretary. At LUGPA, he is proud to represent over 2300 Urologists by working to preserve and advance the independent practice of urology.

Arlene Siefker-Radtke, MD

Dr. Siefker-Radtke is a Professor of Genitourinary Medical Oncology at the University of Texas, M. D. Anderson Cancer Center, and is a Clinical Co-Leader of the M. D. Anderson Bladder SPORE. Her research focus is on developing effective therapies in the treatment of urothelial cancer and other rare tumors of the bladder and upper tract. She is well-known for her novel clinical trial designs, development of novel agents and targets including immunotherapy, FGFR inhibitors, and proteasome inhibitors, development of neoadjuvant chemotherapy, and expertise in treating even those most rare tumors of the bladder.

Edward Soffen, MD

Dr. Soffen received his Bachelor of Arts degree in biology, graduating Phi Beta Kappa, from Johns Hopkins University, Baltimore, before obtaining his medical degree and his selection to Alpha Omega Alpha Society from Temple University School of Medicine, Philadelphia. He completed his residency in radiation oncology at the Hospital of the University of Pennsylvania, Philadelphia. Dr. Soffen served on the faculty of the University of Pennsylvania and at Fox Chase Cancer Center. He is currently on the faculty of Rutgers University Medical School, New Brunswick, New Jersey. He has authored numerous publications and has received many awards including being selected by his peers as a “Top Doctor” in New Jersey for over 15 years, and as one of the “Best Doctors in America”.

Jeffrey Spier, MD

Dr. Spier is President of Rio Grande Urology (RGU) founded in 2008 serving West Texas and Southern New Mexico. RGU has 23 providers with 5 offices and 2 radiation centers employing over 250 staff in El Paso, Texas and Las Cruces, New Mexico. Dr. Spier has overseen the tremendous growth of RGU, becoming the largest private practice physician group in the region. Rio Grande Urology continues to expand with the formation of the Rio Grande Cancer Specialists (RGCS) providing radiation therapy as well as the RGCS Advanced Prostate Cancer. This center of excellence includes clinical research with ongoing expansion into other genitourinary oncologic conditions. RGU is committed to serving the urologic and oncologic needs of our patients, providing state of the art and compassionate care.

Dr. Spier is board certified by the American Board of Urology and member of the American Urological Association and South Central Section of the AUA. He graduated from the University of Texas Medical Branch in Galveston, Texas where he also completed his Urology residency training. He currently serves on the Large Urology Group Practice Association (LUGPA) Board of Directors where he has served on multiple committees and is current chair the Membership Committee. He is currently President of the El Paso County Medical Society, board member of the University of Texas at Galveston Alumni Board of Trustees and has served on the board of the Texas Urological Society.

Evan Y. Yu, MD

Dr. Yu is a medical oncologist specializing in GenitoUrinary malignancies, specifically prostate, bladder and testicular cancer treatment and research. He serves as the Medical Director for Clinical Research at the Fred Hutchinson Cancer Consortium. He is the institutions Principal Investigator for the National Cancer Trials Network Lead Academic Performance Site (LAPS) Grant, SWOG, and ECOG/ACRIN. Dr. Yu is also the Clinical Research Director for GenitoUrinary malignancies, Core Director for the Pacific Northwest Prostate Cancer SPORE and co-PI of the DoD Prostate Cancer Clinical Trials Consortium for his institution. He graduated Alpha Omega Alpha from the University of Washington School of Medicine. His research focuses on testing the next wave of novel molecular targeted therapies and immunotherapy techniques, with a complementary focus on imaging biomarkers. Previously, he served as a Hematology/Oncology Fellowship Program Director for a decade at the Fred Hutchinson Cancer Research Center. He has regularly been voted a “Top Doctor” by Castle Connolly, U.S. News and World Report, Seattle magazine, and Seattle Met magazine. He has served for many years on the National Cancer Institute Genitourinary Cancers Steering Committee and is currently the Co-Chair for the National Cancer Institute Prostate Cancer Task Force. Dr. Yu has held various leadership/committee roles within ASCO, AACR, and also serves as a senior editor for Clinical Cancer Research and Uro-Today.

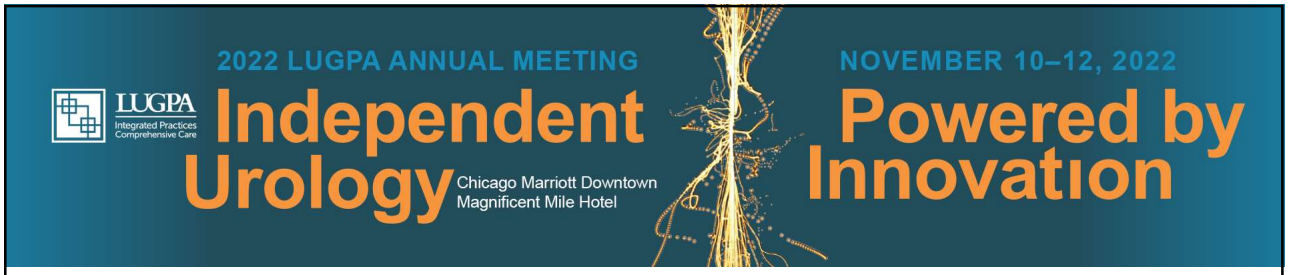
Shawn Zimberg, MD

Dr. Zimberg is the Director of Radiation Oncology services at Integrated Medical Professionals. He board-certified in Radiation Oncology and has additional experience in investment banking. In the NY metropolitan area, he is recognized as a leader in the treatment of prostate, breast and head & neck cancers. He completed his residency at Memorial Sloan-Kettering Cancer Center, where he was awarded the American Cancer Society’s Clinical Oncology Fellowship. More recently, he was the recipient of the American Cancer Society’s Cancer Control Award and currently serves on their Eastern Division’s Advisory Board, where he held the position of Medical Spokesman from 2004-2006. Dr. Zimberg is a principal in Foundation Ventures, LLC, a NYC investment and merchant banking firm, where he is currently serving on their Health Science Advisory Board. Prior to residency, Dr. Zimberg was a medical advisor to Advanced Capital Resources, a private banking concern, where he specialized in medical device and biotechnology sectors. Dr. Zimberg received both his undergraduate and MD degrees from the University of Michigan, Ann Arbor.

LUGPA
Integrated Practices
Comprehensive Care

LUGPA 2022 CME Program

Presentations



2022 CME PROGRAM

Leading the Way to Optimizing Care in the Urology Practice

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David Morris, MD

2022 CME PROGRAM AND FACULTY

Session	Moderator/Presenters	Question & Answer Panelists
Optimizing ASC Utilization • Robotic Surgery (prostatectomy and nephrectomy) • Percutaneous Upper Tract Management • Urethral Reconstruction • Focal Therapies • Penile Implant-Post Prostatectomy	Michael Fabrizio, MD Ronney Abaza, MD Julio Davalos, MD Brad Figler, MD Fernando Bianco, MD Sherita King, MD	Michael Fabrizio, MD Ronney Abaza, MD Julio Davalos, MD Brad Figler, MD Fernando Bianco, MD Sherita King, MD
BPH Treatments • Deobstructing Mouse Traps • Prostate Artery Embolization	Steven Kaplan, MD Steven Kaplan, MD Sandeep Bagla, MD	Samuel Hakim, MD David Morris, MD
PSMA-PET • Clinical and Economic Utilization	Evan Goldfischer, MD Phillip Koo, MD	E. Scot Davis Jeffrey Spier, MD David Albala, MD

2022 CME PROGRAM AND FACULTY

Session	Moderator/Presenters	Question & Answer Panelists
Appreciating Diversity in Urology Care • Gender Affirming Surgery • Diversity in Urology: Care for Transgender and Gender Diverse Patients • Urologic Care for the LGBT Community	Neal Shore, MD, FACS Brad Figler, MD Diana Bowen,MD Channa Amarasekera, MD	Guy Manetti, MD Michael Fabrizio, MD Benjamin Lowentritt, MD
APPC Otimization • mCSPC couplet vs triplets • mCRPC combining and sequencing • Genetic Testing	David Morris, MD Alicia Morgans, MD Evan Yu, MD Emmanuel Antonarakis, MD	Jonathan Henderson, MD Scott Sellinger, MD Jason Hafron, MD

2022 CME PROGRAM AND FACULTY

Session	Moderator/Presenters	Question & Answer Panelists
ABCC Optimization • Intravesical Explosion • Systemic Therapies	Tom Jayram, MD Colin Dinney, MD Arlene Siefker-Radtke	Joshua Meeks, MD Suzanne Merrill, MD
Spacer Wars • Barigel • SpaceQAR • Bioprotect	Gordon Brown MD Niel Mariados, MD Parthiv Mehta, MD Edward Soffen, MD	Neil Mariados, MD Shawn Zimberg, MD

BIG THANKS TO OUR 2022 CME PROGRAM SPONSORS AND EXHIBITORS

FEATURED PARTNERS

Myovant Sciences, Inc. & Pfizer Oncology, Inc.
Prostate Centers USA

COLLABORATING PARTNERS

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EXHIBITOR

Bristol Myers Squibb

SPECIAL GUEST

ZERO – The End of Prostate Cancer

8

UPCOMING LUGPA MEETINGS

BLADDER & KIDNEY CANCER ACADEMY
December 8 -10, 2022
Hotel ZAZA Memorial City, Houston, TX

REGIONAL MEETINGS
January 21-21, 2023
Location: Grand Hyatt, Vail, CO

March 31- April 1, 2023
Location: Willard InterContinental,
Washington, DC

May 5-6, 2023
Location: Camelback Inn, Scottsdale, AZ

LUGPA UROLOGY 2023 RESIDENT SUMMIT AND JOB FAIR
March 3-4, 2023
Location: Fairmont Hotel, Chicago, IL

LUGPA 2023 ANNUAL MEETING
November 2-4, 2023
Location: Disney's Yacht & Beach Club Resort, Orlando, FL

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LUGPA
November 2022

ASC Robotic Urologic Surgery

Ronney Abaza, MD, FACS
Central Ohio Urology Group
Columbus, Ohio

central ohio UROLOGY group

Disclosures

- Conmed
- Covidien
- Intuitive Surgical
- VTI

ASC Challenges

- All of the hospital challenges for starting a robotics program and more

Step #1: Financial Feasibility

- Medicare not eligible for robotics (Jan 1)
- Insurance contracting critical
- Assess feasibility from current hospital volume of eligible cases
- Necessary monthly volume is low if contracted rates favorable

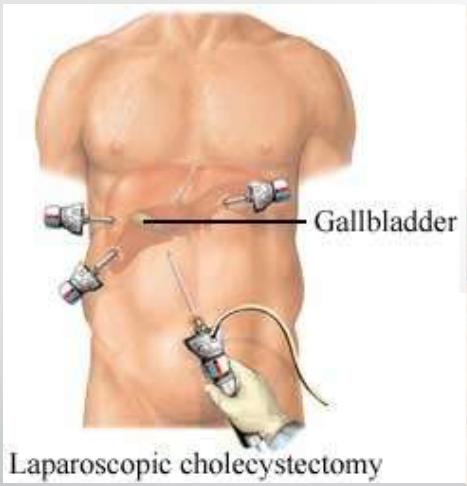
Physical Plant

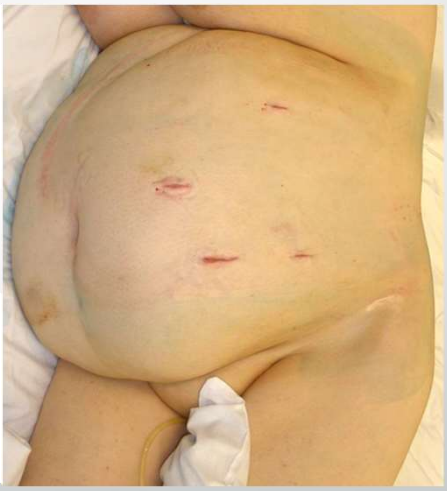
- Space for robot
  - Surprisingly small
  - Overhead clearance
- CO_2 wall vs. tank gas
- Specialized sterilization equipment for robotic instruments (not scopes)

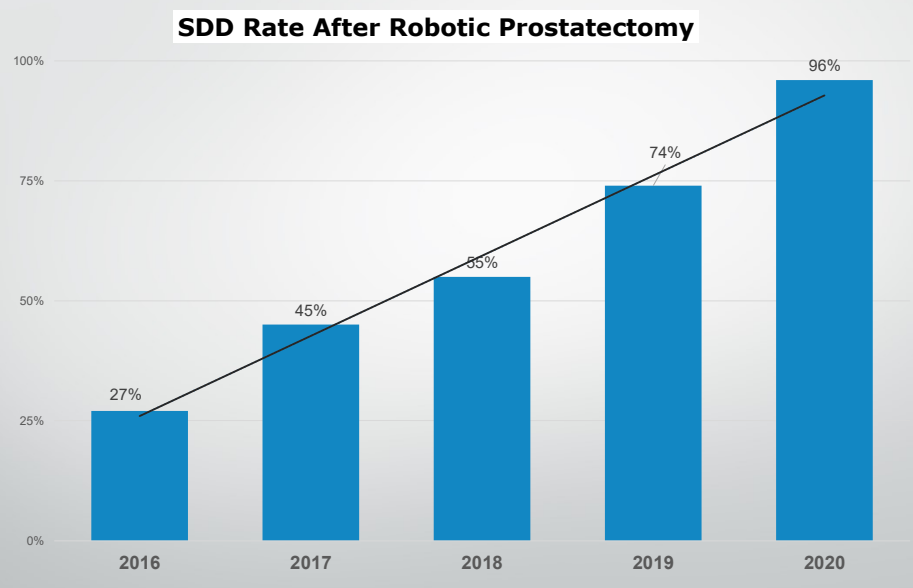
Other Logistics

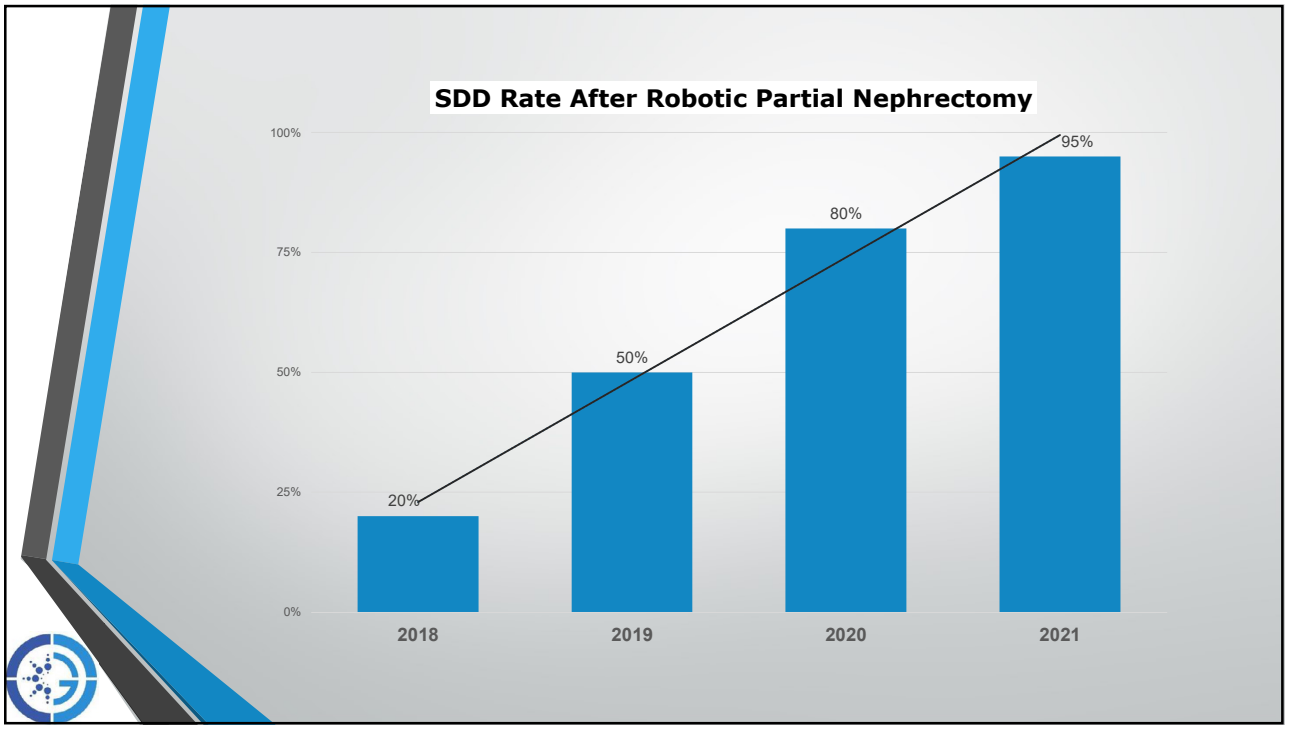
- Overnight capabilities vs. SDD
  - Backup planning
  - Start SDD in hospital
- OR time/scheduling
  - All new volume unlike hospital
  - Opportunity cost vs other procedures favorable

Why Not Same-Day???



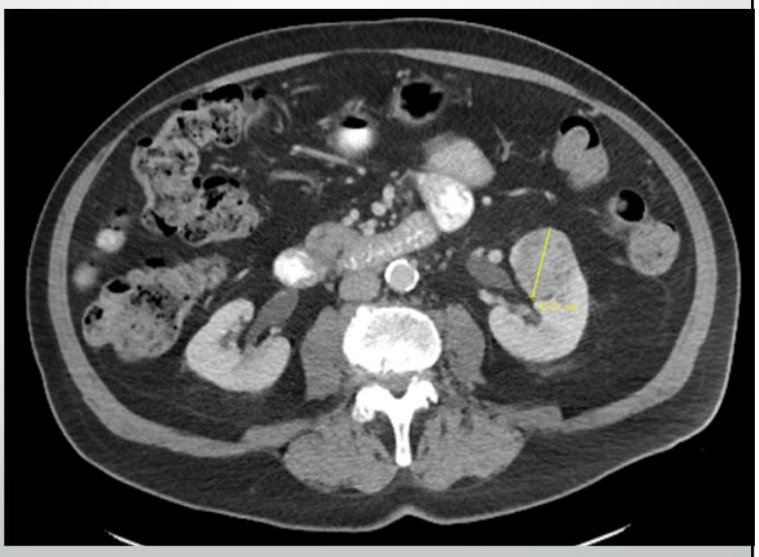






Example Case

- 80YO Male
- 4.1cm hilar mass
- Partial Nx
- 3rd case of day
- Home same day



COVID-19

Impact of the COVID-19 Crisis on Same-day Discharge After Robotic Urologic Surgery

Ronney Abaza, Paul Kogan, and Oscar Martinez

OBJECTIVE To assess the impact of the COVID-19 pandemic on the rate of same-day discharge (SDD) after robotic surgery

METHODS We reviewed our robotic surgeries during COVID-19 restrictions on surgery in Ohio between March 17 and June 5, 2020 and compared them with robotic procedures before COVID-19 and after restrictions were lifted. We followed our formerly described protocol in use since 2016 offering the option of SDD to all robotic urologic surgery patients, regardless of procedure type or patient-specific factors.

RESULTS During COVID-19 restrictions (COV), 89 robotic surgeries were performed and compared with 1667 of the same procedures performed previously (pre-COV) and 42 during the following month (post-COV). Among COV patients 98% (87/89 patients) opted for same-day discharge after surgery versus 52% in the historical pre-COV group ($P < .00001$). Post-COV, the higher rate of SDD was maintained at 98% (41/42 patients). There were no differences in 30-day complications or readmissions between SDD and overnight patients with only 2 COV (2%) and no post-COV 30-day readmissions. SDD after robotic surgery was safely applied during the COVID-19 crisis without increasing complications or readmissions. SDD may allow continuation of robotic surgery despite limited hospital beds and when minimizing hospital stay is important to protect postoperative patients from infection. Our experience suggests that patient attitude is a major factor in SDD after robotic surgery since the proportion of patients opting for SDD was much higher during COV and continued post-COV. Consideration of SDD long-term may be warranted for cost savings even in the absence of a crisis. UROLOGY 149: 40–45, 2021. © 2021 Elsevier Inc.

The emergence of the COVID-19 pandemic has affected health care delivery worldwide. A massive reallocation of health care resources created major obstacles to routine medical care in addition to the need to limit nosocomial disease transmission as infected patients filled hospital beds.[1]

The care of surgical patients required adaptation to this novel situation at every phase of the surgical process (pre-, intra-, and postoperatively).[1,2] Among the realities that was imposed by the COVID-19 crisis was a need to postpone elective surgeries and prioritize procedures by acuity of need in order to maintain hospital vacancies for infected patients as well as to preserve personal protective equipment (PPE) and other medical supplies. This unfortunately created a competing priority between managing the COVID-19 crisis and being able to surgically treat patients with cancers that might progress if indefinitely delayed.[3]

Effective from March 17, 2020, the Governor of Ohio ordered the suspension of all elective surgery,[3] and while Ohio was one of the first states in the country to do so, many other states quickly followed. Among the resulting difficulties for surgeons treating urologic cancers was the uncertainty regarding how long this would last and the need to make difficult decisions regarding which cancer operations should be delayed or still performed and how to do so safely for the patients chosen to still have surgery.

One of the measures to potentially reduce the risk of nosocomial COVID-19 transmission as well as to conserve hospital resources is decreasing postoperative length of stay (LOS) among those still having surgery during the pandemic. We began integrating clinical-care pathways into robotic urologic surgical care with the aim of decreasing postoperative stays over a decade ago.[4] Our recent report of same-day discharge (SDD) in the majority of robotic prostatectomy patients became very relevant once the COVID-19 crisis began.[5] Additionally, while our work to limit LOS after robotic kidney surgery to one night was met with initial criticism,[6,7] it has since gained its acceptance,[7] and we have since extended our robotic kidney surgery pathway to also allow for SDD.

Financial Disclosures: The authors declare that they have no relevant financial interests.

From the Robotic Surgery, OhioHealth Dublin Methodist Hospital, Dublin, OH, and the Ohio University Heritage College of Osteopathic Medicine, Dublin, OH

Address correspondence to Ronney Abaza, M.D., F.A.C.S., OhioHealth Robotic Urologic and Cancer Surgery, 7450 Hospital Dr. Dublin, OH 43016. E-mail: Ronney.Abaza@OhioHealth.com

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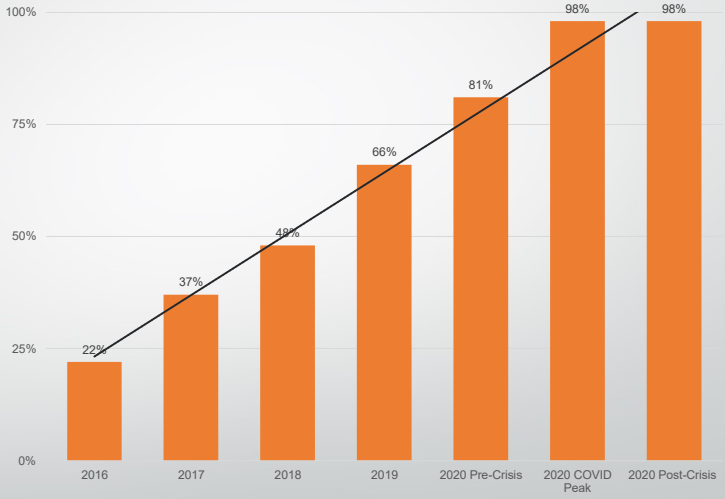
https://doi.org/10.1016/j.urology.2021.01.012
0090-4295

Rate of SDD for All Robotic Urologic Surgeries



Same Day Robotic Surgery

Same Day Discharge after Robotic Radical Prostatectomy

Ronney Abaza,*,† Oscar Martinez, Matthew C. Ferroni, Aya Bsatee and Robert S. Gerhard

From Robotic Surgery, OhioHealth Dublin Methodist Hospital (OM, MCF, RSG) and Ohio University Heritage College of Osteopathic Medicine (AB), Dublin (RA), Ohio

Purpose: The typical mean length of stay following robot-assisted laparoscopic prostatectomy is 24 to 48 hours. We began routinely offering same day discharge from the hospital after robot-assisted laparoscopic prostatectomy. We evaluated the success rate, safety and cost implications in what is to our knowledge the only large series of same day discharge to date.

Materials and Methods: Beginning in September 2016 all patients were given the option of same day discharge without it being mandated. After allowing 3 months to solidify the protocol we evaluated our prospective database for the next 500 patients.

Results: Of the 500 consecutive men who underwent robot-assisted laparoscopic prostatectomy performed by 1 surgeon in 18 months 246 (49.2%) were discharged home the day of surgery and all of the remaining 254 were discharged the next day for a mean 0.51-day length of stay. Mean patient age was 62 years (range 42 to 81) and mean body mass index was 29.7 kg/m^2 (range 20 to 53). Of the patients 34 (6.8%) had a Clavien-Dindo grade I-III complication within 90 days but there were no grade IV-V complications. Only 5 patients (1%) required an emergency department visit and only 8 (1.6%) required readmission. Only 1 of the patients who elected same day discharge was rehospitalized and only 1 presented to the emergency department. The estimated charge for an overnight stay at our institution is $2,109. The approximate reduction in charges was $518,814 during 18 months ($345,876 per year) with no increased cost due to emergency department visits or hospital readmissions compared with that of overnight patients. In

Abbreviations and Acronyms

ASA™ = American Society of Anesthesiologists™

BMI = body mass index

PLND = pelvic lymph node dissection

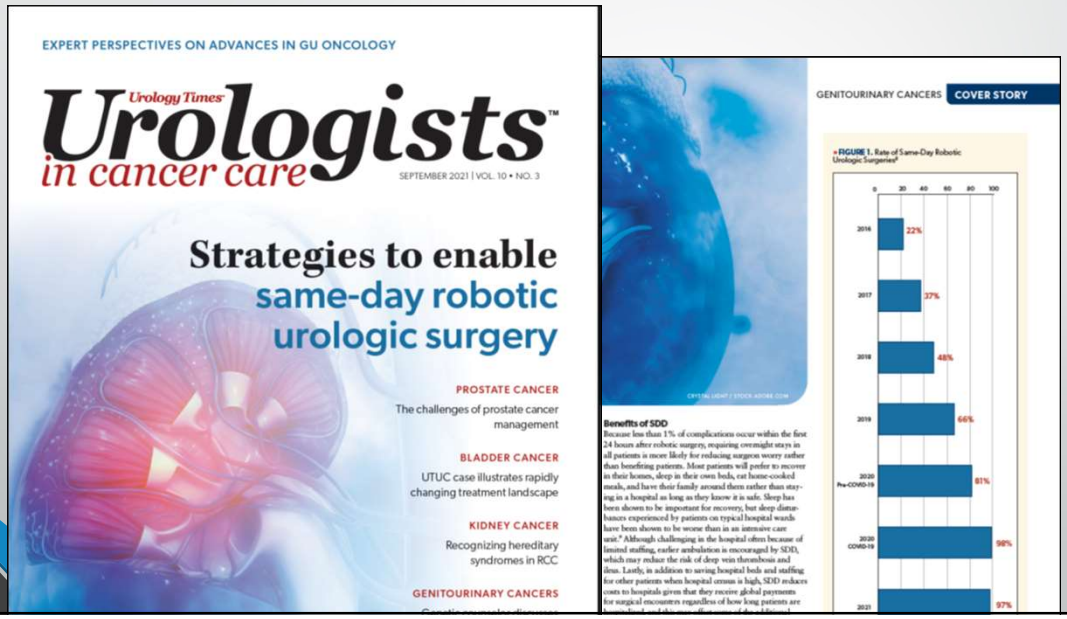
RALP = robot assisted laparoscopic prostatectomy

SDD = same day discharge

Accepted for publication May 9, 2018.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

Same Day Robotic Surgery



Personal Experience: Hospital vs. ASC

- First 739 cases over 17mos
- 527 Hospital Patients (excl. 12 cystectomy & 2 inpts)
  - 338 RALP, 78 RPN, 55 Nx/NephU, etc
  - 522/527 SDD (99%)
  - 30-day readmissions: 8 (1.5%)
- 212 ASC Patients
  - 163 RALP, 19 RPN, etc.
  - 212/212 same day (100%)
  - 30-day readmissions: 3 (1.4%)

ASC Year #1 (all surgeons)	Cases, *N*
Prostatectomy	165
Partial Nephrectomy	19
Pyeloplasty	12
Adrenalectomy	4
Simple Prostatectomy	3
Simple Nephrectomy	3
Ureteral reimplantation	3
Radical Nephrectomy	2
Nephroureterectomy	2
Renal Cyst Decortication	2
Sacrocolpopexy	2
Renal Vein Stent (Nutcracker Synd.)	2
Inguinal hernia repair (only)	1
Total	220

	N	Mean age (yrs)	Mean BMI (kg/m^2)	OR time (min)	Recovery Time (hrs)	Total LOS (hrs)
Prostatectomy	165	61	29	133	1.7	5.7
Partial Nephrectomy	19	59	26	110	1.3	5.4
Pyeloplasty	12	46	26	82	1.4	4.8
Nephrectomy	7	47	29	140	1.7	6.1
Adrenalectomy	4	57	32	62	1.4	4.8

	N	Mean age (yrs)	Mean BMI (kg/m^2)	OR time (min)	Recovery Time (hrs)	Total LOS (hrs)
Prostatectomy	165	61	29	133	1.7	5.7
Partial Nephrectomy	19	59	26	110	1.3	5.4
Pyeloplasty	12	46	26	82	1.4	4.8
Nephrectomy	7	47	29	140	1.7	6.1
Adrenalectomy	4	57	32	62	1.4	4.8

Conclusions

- ASC robotic surgery has challenges
- Can be done with limited resources
- Same rationale as all ASC surgery:
  - Independence from hospitals
  - Control (scheduling, staffing, turnovers, etc)
  - High patient satisfaction (100%)

Resources

- Sponsored ASC observations (ronneyabaza@hotmail.com)
- NARUS and LUGPA collaboration

Thank You

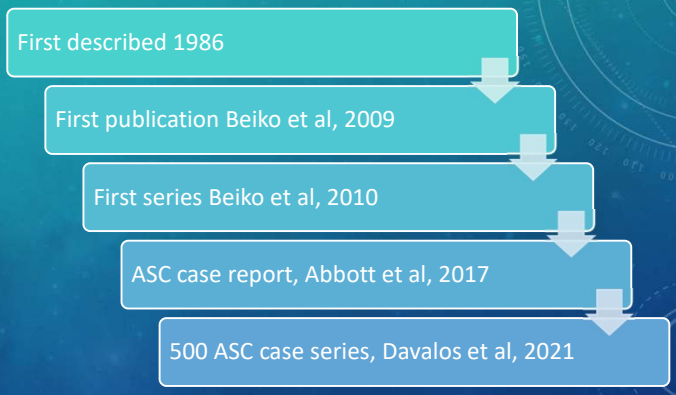
TRANSITIONING TO AMBULATORY PCNL

JULIO G. DAVALOS, MD
DIRECTOR, CLINICAL FELLOWSHIP IN ADVANCED ENDOUROLOGY, UNIVERSITY OF MARYLAND | CHESAPEAKE UROLOGY
CLINICAL PROFESSOR, UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE
DIRECTOR, KIDNEY STONE PROGRAM, CHESAPEAKE UROLOGY
DIRECTOR, KIDNEY STONE PROGRAM, UNIVERSITY OF MARYLAND BALTIMORE WASHINGTON MEDICAL CENTER

OVERVIEW

- Recommendations
- Transition planning
- Financial considerations
- Our experience

HISTORY



WHAT IS AMBULATORY PCNL?

- "Outpatient" PCNL - includes 1 overnight stay
- *Outpatient same day discharge PCNL – option to admit the patient
- **ASC PCNL – free standing surgery center without hospital resources

RECOMMENDATIONS

High volume of cases =
Experienced surgeon

Single center =
Experienced Team

- Surgical technologist
- Circulating OR nurse
- Pre-op and PACU nurses
- Radiation technologist
- Anesthesia provider

Limited number of providers =
Efficiency and Consistency

- Do not “dabble” in ambulatory PCNL
- ASC Credentialing process

TRANSITION PLANNING

CLINICAL

OPERATIONAL

FINANCIAL

CLINICAL

CLINICAL CONSIDERATIONS PRE-PROCEDURE

Medical considerations

- Cardiac
- Pulmonary
- BMI
- Chronic pain
- Infection risk
- Bleeding risk

Surgical considerations

- Stone burden
- Stone location
- Stone density
- Peri-renal anatomy
- Supra vs sub-costal access

CLINICAL

- Urologist obtained renal access
- Extensive experience with Outpatient PCNL in hospital setting
- Pain management

CLINICAL CONSIDERATIONS POST-PROCEDURE

PATIENT INSTRUCTIONS

POST-PROCEDURE MEDICATIONS

DRAINAGE TUBE(S) POST PROCEDURE

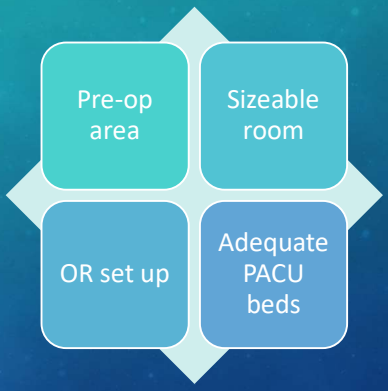
SETTING EXPECTATIONS

OPERATIONAL

OPERATIONAL

- ASC Infrastructure
- Equipment / Technology
- Operating Room set-up
- Disposables
- Work flow

ASC INFRASTRUCTURE



EQUIPMENT AND TECHNOLOGY

- OR bed
- Nephroscopes
- C-Arm
- High power laser
- Lithotriptor
- Fluid management system

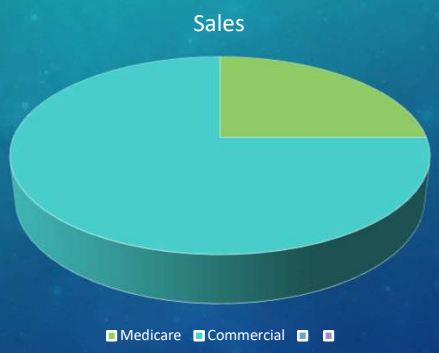
OPERATING ROOM SET-UP

WORK FLOW

- Pre-operative clearance
- Check-in process
- Operating Room set-up and turn-over
- Instrumentation needs and cleaning time
- Back-up equipment
- Discharge criteria
- Experienced PACU nurse

FINANCIAL

FINANCIAL
PAYOR MIX



FINANCIAL

- Determine fixed costs
- Track variable costs
- Determine Profitability

FINANCIAL

Medicare

- CPT codes 50080 and 50081 = same facility fee
- Add-on codes
- Rates are pre-set

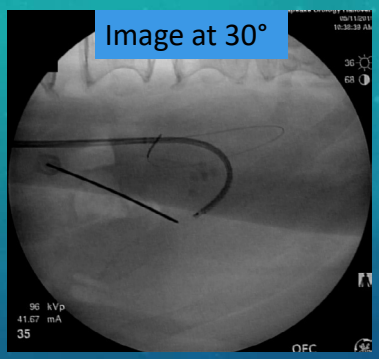
Commercial

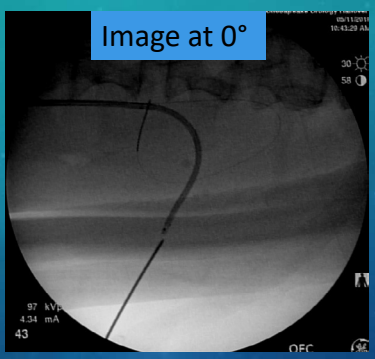
- CPT codes 50080 and 50081 may have different facility fees
- Add-on codes may be more limited
- *MUST negotiate rates*

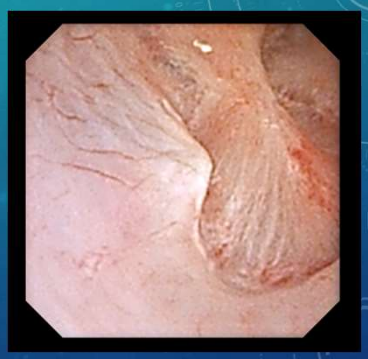
Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

CLINICAL SCENARIOS

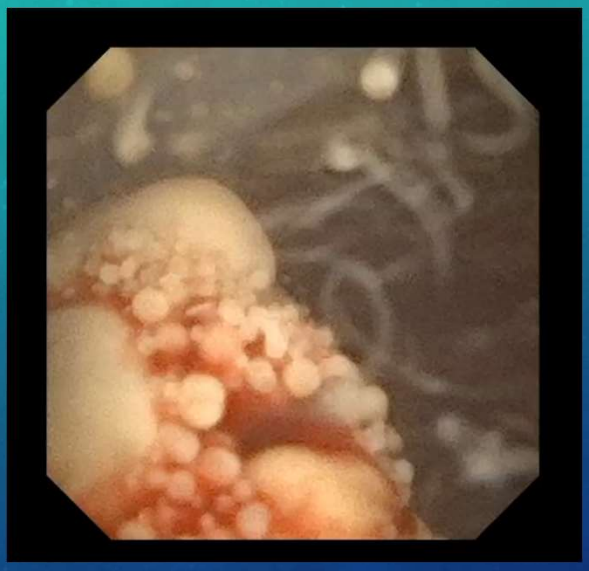
ECIRS/ FLUOROSCOPY RENAL ACCESS IMAGES



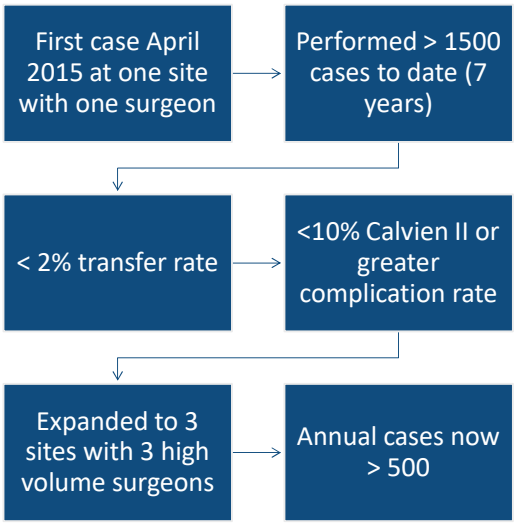




ECIRS RENAL ACCESS VIDEO



OUR ASC EXPERIENCE

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Urethral Reconstruction

Brad Figler MD FACS
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University of North Carolina-Chapel Hill

November 10, 2022

LUGPA 2022 - Chicago

Outpatient Urethral Reconstruction: Outline

- Patient selection
- Procedure selection
- Optimize
- Urethral reconstruction
  - Penis
  - Bulbar urethra
  - Posterior urethra, bladder neck and vesicourethral anastomosis

Outpatient Urethral Reconstruction: Patient Selection

- Comorbidities (e.g., CAD, obesity, sleep apnea)
- Age
- Anti-coagulants
- Opioid use
- Responsible individual to receive discharge instructions
- Transportation
- Post-discharge care
- Health literacy (patient and caregiver)

Outpatient Urethral Reconstruction: Procedure Selection

- Invasiveness
- Duration
- Potential blood loss & need for transfusion
- Post-operative pain control
- Need for specialized postoperative care

Outpatient Urethral Reconstruction: Optimize

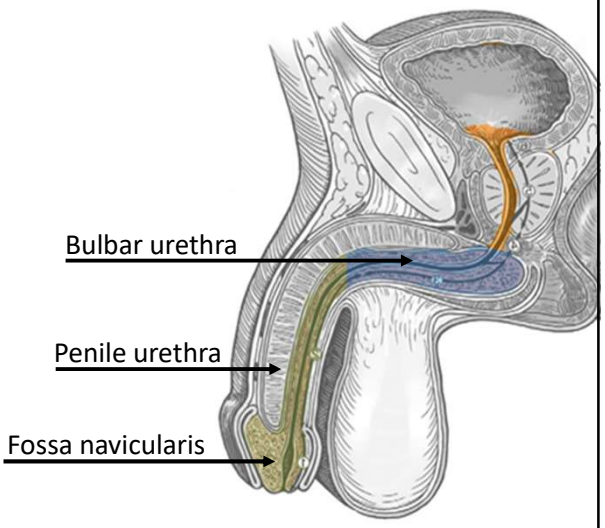
- Before surgery
  - Communicate pre/post needs to patient & caregiver
  - Communicate concerns with anesthesia
  - Diagnostic workup (cystoscopy, urethrogram, dilation, suprapubic tube)
- During surgery
  - Efficient
  - Minimize bleeding
  - Local anesthesia
- After surgery
  - Knowledgeable PACU staff
  - Accurate and detailed discharge information
  - Phone calls and MyChart messages

Urethral Reconstruction: Management options

- Self intermittent catheterization
- Endoscopic (e.g., dilation, incision, Optilume)
- Diversion (e.g., perineal urethrostomy, suprapubic tube)
- Urethroplasty

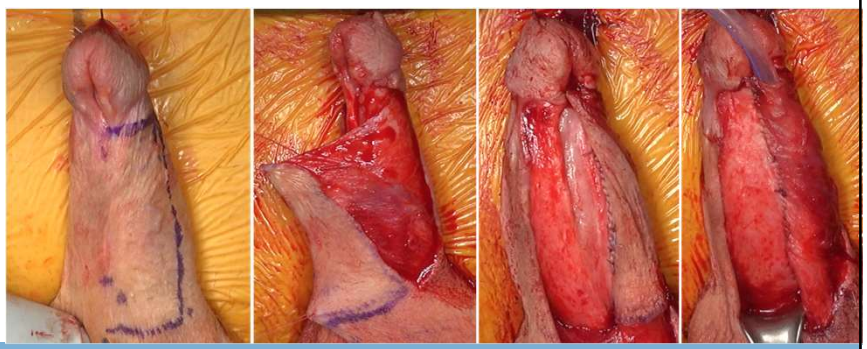
Urethral Reconstruction

- Meatus/fossa navicularis
- Penile
- Bulbar urethra
- Membranous
- Prostate/bladder neck
- Vesicourethral anastomosis



Outpatient Urethral Reconstruction: Penis

- Etiology: Lichen sclerosus, BPH surgery
- Work-up: RUG, VUG or pbRUG
- Urethral reconstruction
  - One-stage (shaft) – graft or flap
  - One-stage (meatus and fossa) - graft
  - Staged - graft



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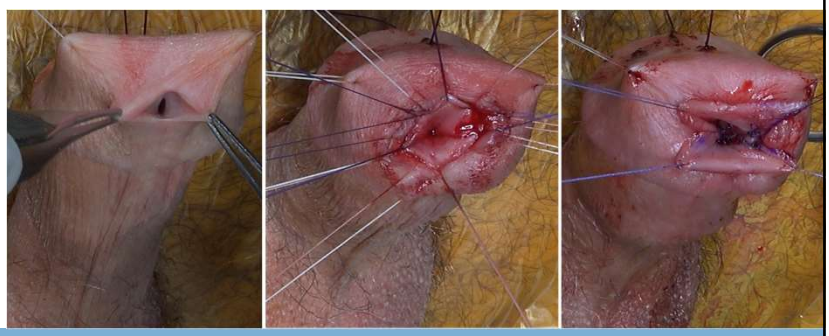

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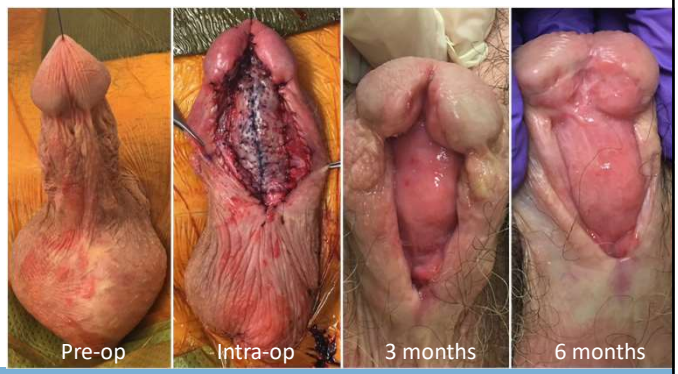
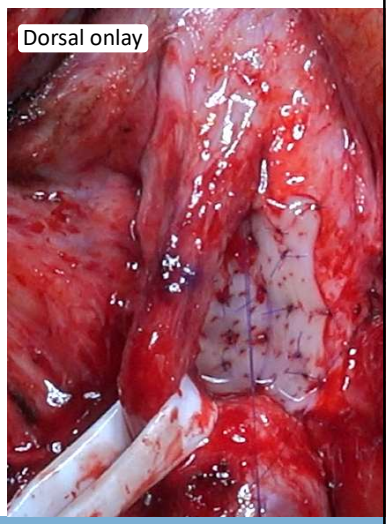


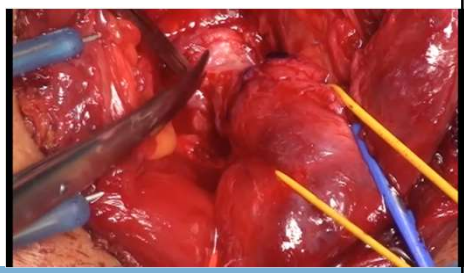
Outpatient Urethral Reconstruction: Bulbar Urethra

- Etiology: Trauma, instrumentation/surgery, radiation
- Work-up: RUG
- Management options
- Urethroplasty
  - Excision & primary anastomosis
  - Dorsal onlay
  - Ventral onlay



Urethral Reconstruction: Posterior Urethra

- Membranous stricture (e.g., radiation, brachytherapy, TURP)
  - Etiology: Radiation, brachytherapy, TURP
  - Urethroplasty: Spare external sphincter
- Prostatic apex (e.g, brachytherapy)
  - Etiology: Brachytherapy
  - Urethroplasty: Excision & anastomosis
- Pelvic fracture-association urethral disruption: Excision & anastomosis
- Bladder neck & vesicourethral anastomosis



Video: Reynaoldo Gomez (Santiago)

Urethral Reconstruction: Posterior Urethra

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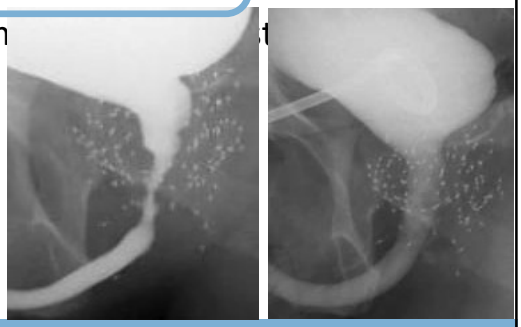

Urethral Reconstruction: Posterior Urethra

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Urethral Reconstruction: Posterior Urethra

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  - Urethroplasty: Excision & anastomosis
- Pelvic fracture-association urethral disruption: Excision & anastomosis
- Bladder neck & vesicourethral anastomosis
  - Etiology: post-TURP, post-prostatectomy
  - Urethroplasty: TUIMR, robotic YV, pre-rectal

Focal Therapy

Under a paradigm of certainty

Fernando J. Bianco, MD
Investigator in-Chief, Urological Research Network. Miami FL
Professor of Urology, NOVA Southeastern University. Hollywood, FL

Disclosure Statement

- Founder Focalyx
  - Currently serve as scientific advisor, proctor and shareholder
- Principal Investigator of Industry funded clinical study
  - TRANBERG Transperineal MR/US Fusion Laser--Induced Thermal Therapy for Men with Prostate Cancer
  - Protocol ID: URN-2022-002
  - Sponsored by Clinical Laserthermia Systems, AB
- Investigator - Advisor
  - Janssen, Imaging Medical, Francis Medical, Elesta SPA

FOCAL THERAPY RATIONALE

What has Changed in the last 10 years

Overcoming the pervasive uncertain bias

How has our thinking evolved, how we do it, in the Office

Whats the Data telling us

Final Comments

3

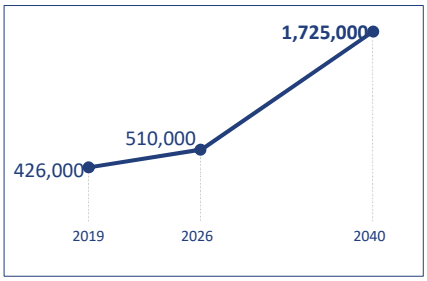
Intervention vs Observation

Evidence Level 1

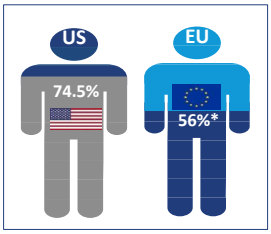
- Scandinavian Prostate Cancer Group 4 (SPCG)[1]
- The Prostate Intervention versus Observation Trial (PIVOT)[2]
- 10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer.(ProtecT)[3]

1- SPCG-4 Bill-Axelson, A et al New Engl J Med (2002,2008,2014,2018)
2- Wilt et al N Engl J Med, (2012, 2017) Eur Urol 2020
3- Hamdy et al N Engl J Med. (2016) Neal et al Eur Urol (2020)

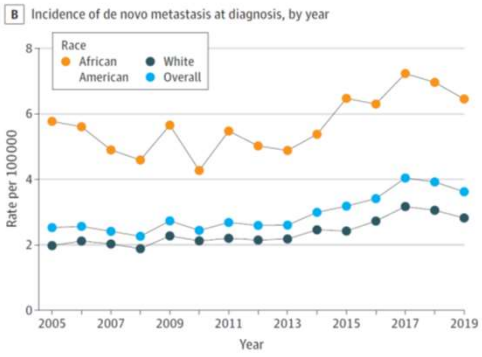
Localized Prostate Cancer is on the Rise



Anticipated total men in Europe and United States diagnosed with PCa in Localized stage



Percentage of men diagnosed with PCa in Localized stage



yet

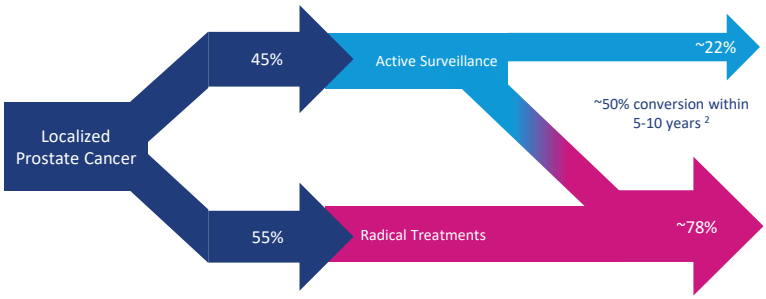
M1 at Dx as well…

JAMA Network Open. 2022;5(1):e2144027

* Average (corrected for country size population) of found reported percentages of all men diagnosed with prostate cancer at localized stage

Active Surveillance Often Leads to Radical Therapy

In the total Localized Prostate Cancer groups (Very low Risk, Low Risk, Intermediate Risk), Active Surveillance takes an important position although it often [1] still converts to Radical Treatment.



Source:
1. Klotz L, Vesprini D, Sethukavalan P, Jethava V, Zhang L, Jain S, et al. Long-term follow-up of a large active surveillance cohort of patients with prostate cancer. J Clin Oncol. 2015;33(3):272-7.
2. Tosoian JJ, Mamawala M, Epstein JI, Landis P, Macura KJ, Simopoulos DN, Carter HB, Gorin MA. Active Surveillance of Grade Group 1 Prostate Cancer: Long-term Outcomes from a Large Prospective Cohort. Eur Urol. 2020 Jun;77(6):675-682.

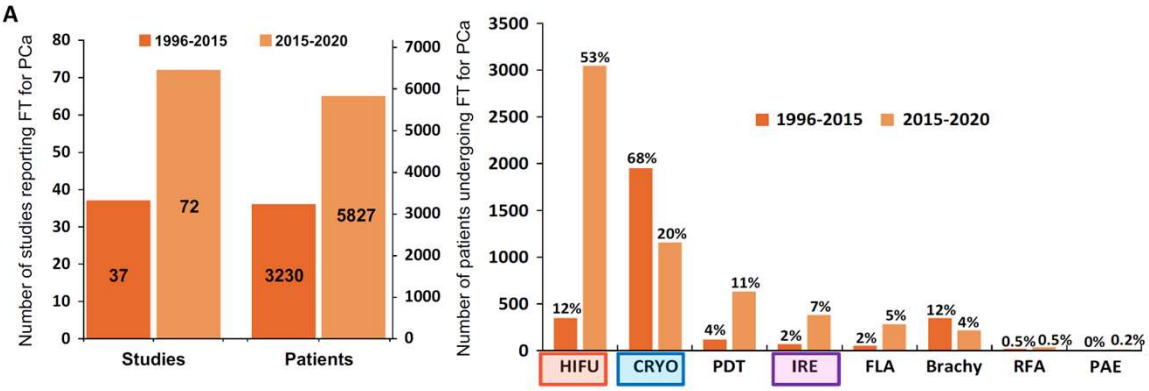
European Association of Urology

Platinum Priority – Editorial
Referring to the article published on pp. x–y of this issue

Focal Therapy for Prostate Cancer: Getting Ready for Prime Time

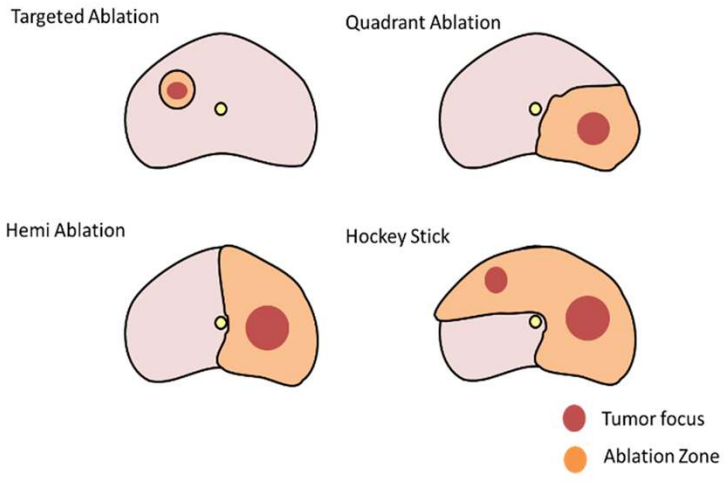
Andre Luis Abreu [a,], Masatomo Kaneko [a,b], Giovanni E. Cacciamani [a], Amir H. Lebastchi [a]*

[a] USC Institute of Urology, Center for Image-Guided Surgery, Focal Therapy and Artificial Intelligence for Prostate Cancer, Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; [b] Department of Urology, Kyoto Prefectural University of Medicine, Kyoto, Japan



Abreu et al Eur Urol (2022) 81:34

What is Focal Therapy? A Real-Time Opportunity



The Arsenal for Partial Gland Ablation

Office - Perineal Access - Local Anesthesia

Current
- Cryoablation
- Laser Ablation

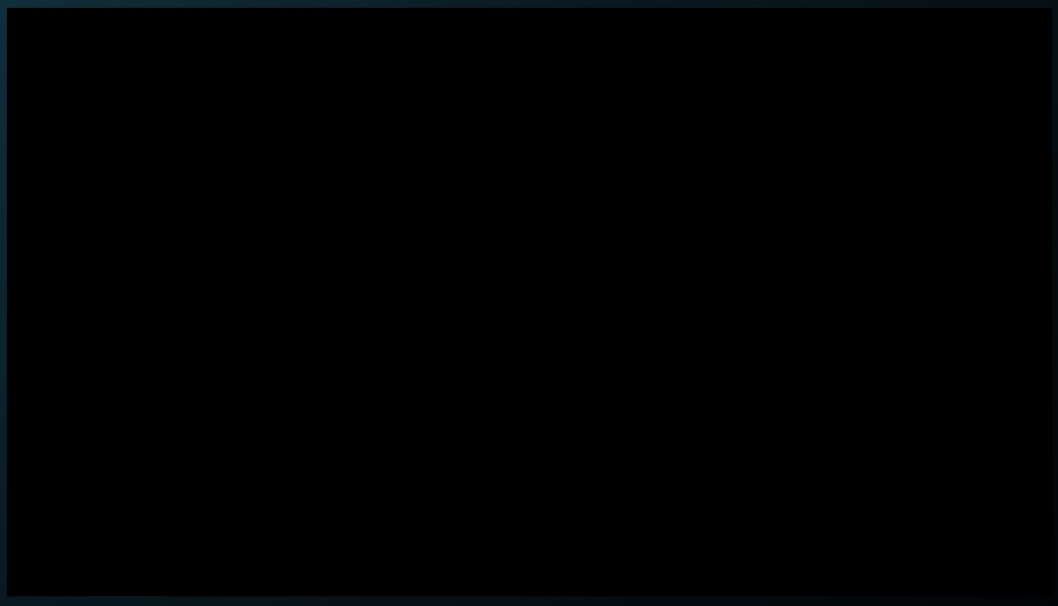
Future
- Radiofrequency – Coil
- Water Ablation
- Nano-particles
- Vascular –photodynamic

ASC / Hospital

All on the Office panel plus

- HIFU
- IRE

Certainty: Taking down the bias



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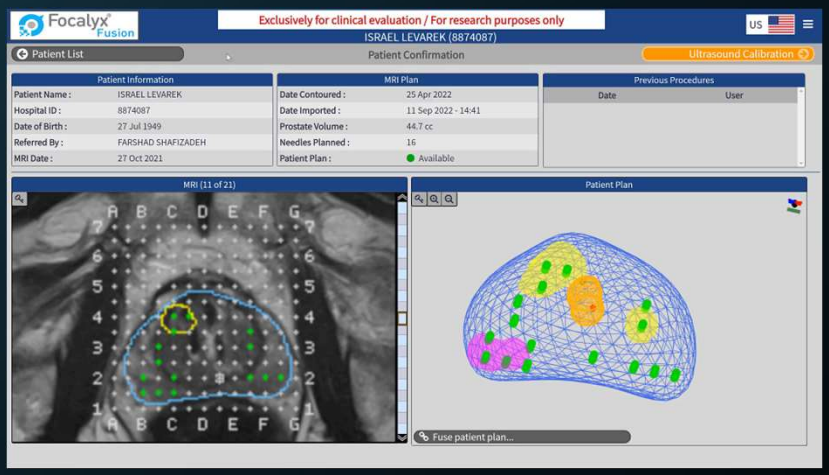
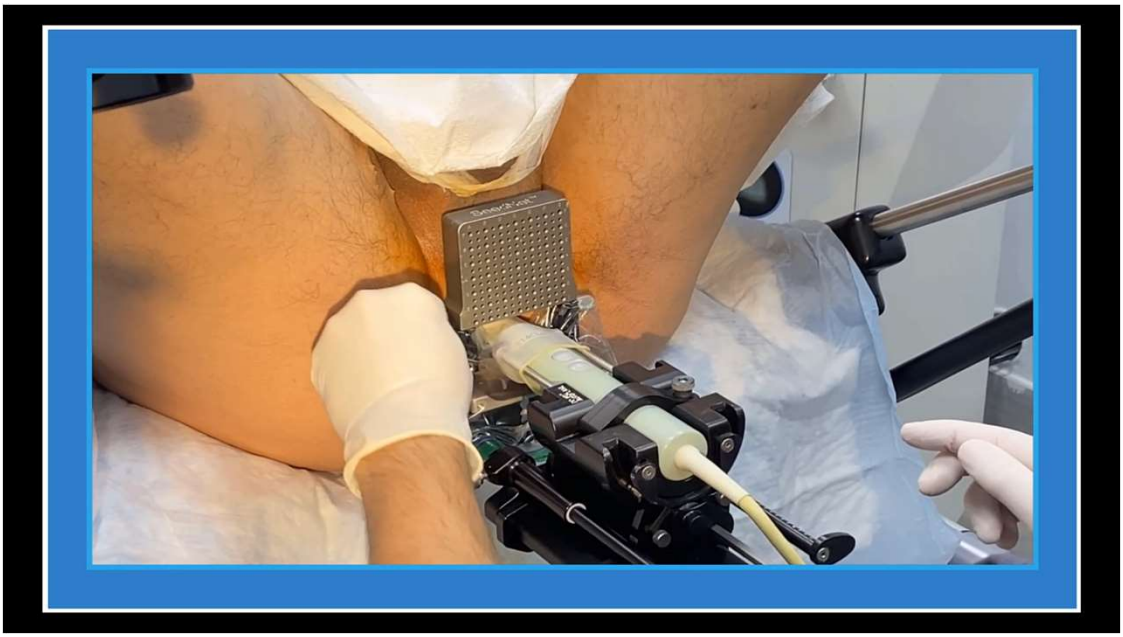
Certainty: Precise Knowledge



- Currently
- We know WHERE is
- We know what TYPE
- We Know the boundaries
- We know Ablation Success
- Futurel Opportunities
- Positive Core Molecular Profile
- Molecular target Management
- Immunotherapy Boost



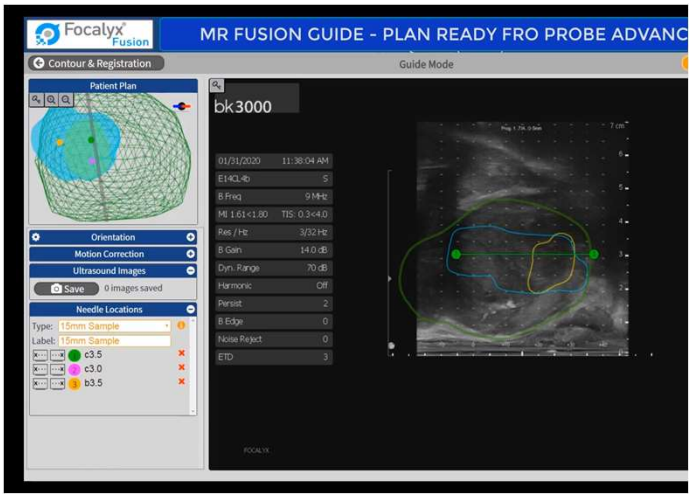
TARGETED FUSION: MRI to TRUS to Targets

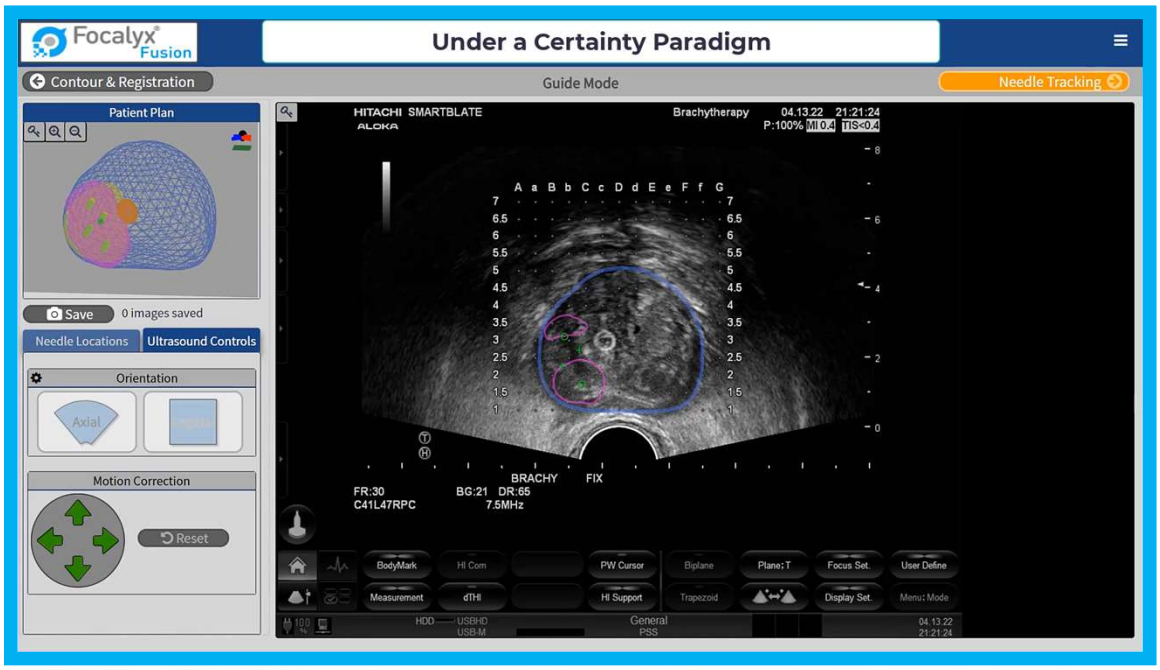
Planning – Areas of suspicious tissue are identified and contoured on MR images.

Modelling –GPS - accurate deformable model of the prostate.

Fusion – The patient model is mapped to the dynamic ultrasound images.

Guidance – The patient plan is updated in real-time enabling precise targeting of MR defined locations.





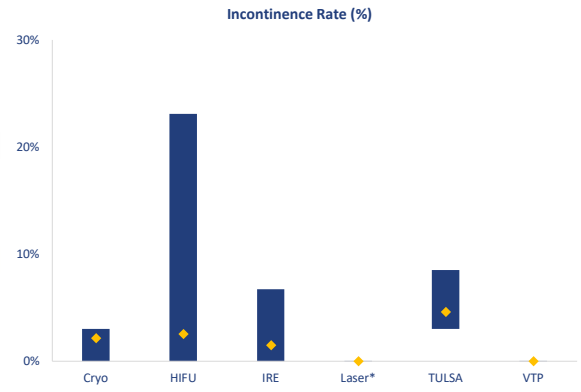
Results and Data Discussion

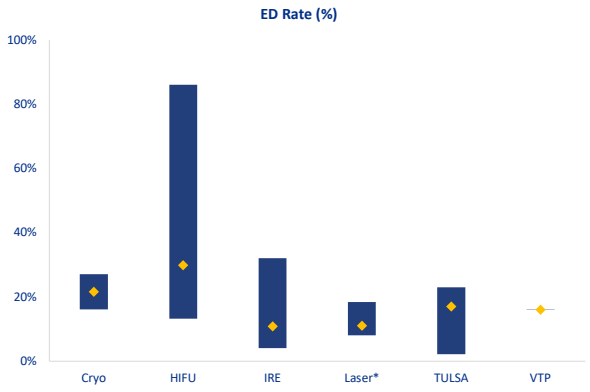
Efficacy & Complication Rates of PGA in the Current Academic Literature

Energy Source	# of Study Populations Included (> 25 pts)	Total Sample Population
Cryotherapy	5	582
High-Intensity Focused Ultrasound (HIFU)	16	3,635
Irreversible Electroporation (IRE)	6	722
Laser	2	169
Transurethral Ultrasound Ablation (TULSA)	2	162
Vascular Targeted Photodynamic Therapy (VTP)	1	68
Total	**32**	**5,338**

* One citation had two study populations with different treatment modalities (cryotherapy and HIFU)

Complication Rates of PGA in the Current Academic Literature



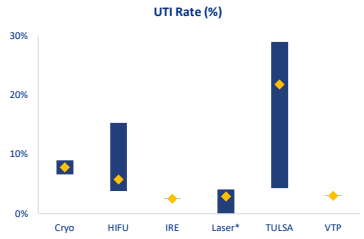


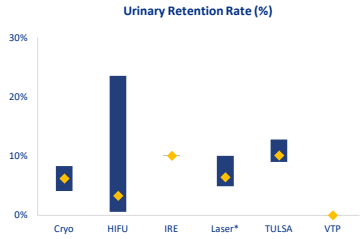
Weighted Average

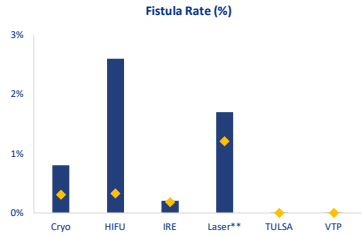
* All laser data was generated using in-bore MRI guidance

Methodology adopted from: Klotz et al. Current evidence for focal therapy and partial gland ablation for organ-confined prostate cancer: systematic review of literature published in the last 2 years. Curr Opin Urol. 2021 Jan;31(1):49-57.

Complication Rates of PGA in the Current Academic Literature







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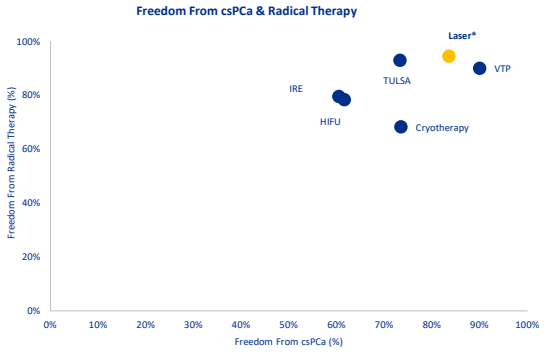
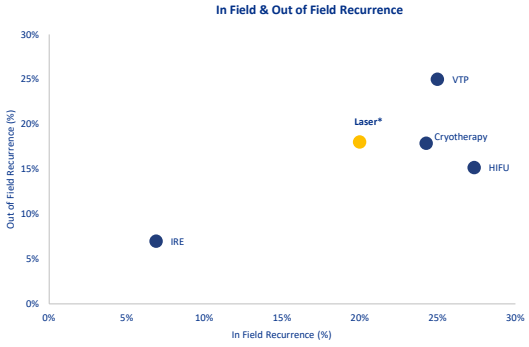
Efficacy of PGA in the Current Academic Literature





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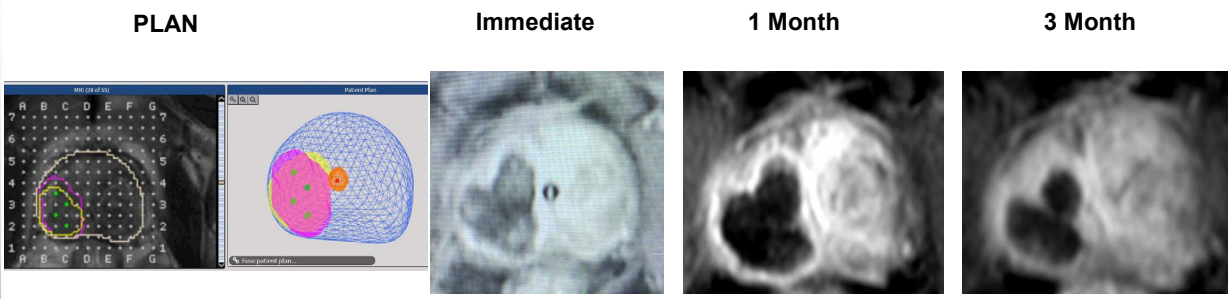
MR Fusion Laser Ablation: Phase 1 trial

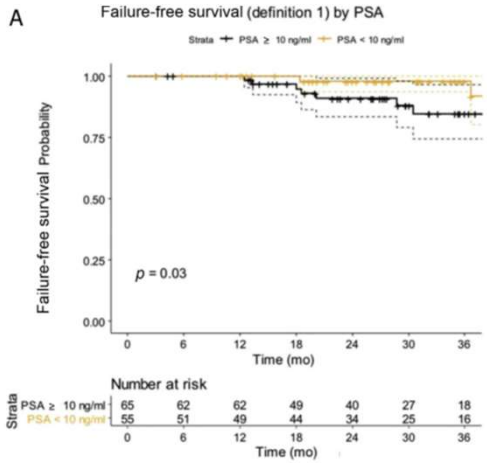


		PSA	ProstVol	TxVol	piRADS	piRadVol	Test	PSAD	PSAdelta	pVol Delta
Baseline		8.70	51.5	12.2	3	6.3	314	0.17		
DOP	4/14/2022	8.70	65.4	13.7						127%
m1	5/12/2022	9.90	44.6	7.7			307	0.22	-14%	87%
m3	7/19/2022	5.50	41.4	2.7			323	0.13	37%	80%

Early-Medium-Term Outcomes of Primary Focal Cryotherapy to Treat Nonmetastatic Clinically Significant Prostate Cancer from a Prospective Multicentre Registry

Taimur T. Shah[a,b,c,], Max Peters[d], David Eldred-Evans[a], Saiful Miah[a,b,c], Tet Yap[e], Nicholas A. Faure-Walker[e], Feargus Hosking-Jervis[a], Benjamin Thomas[c], Tim Dudderidge[f], Richard G. Hindley[g], Stuart McCracken[h], Damian Greene[i], Raj Nigam[i], Massimo Valerio[j], Suks Minhas[b], Mathias Winkler[a,b], Manit Arya[a,b,c,k,i], Hashim U. Ahmed[a,b,i]*

- 122 Patients
  - Median Age 68
  - Median PSA 10.8 ng/ml
  - Median Volume 45 cc
  - NCCN Intermediate Risk 87 pts (71%)
  - NCCN High Risk 35 pts (29%)
  - Median FU 28 months
- Primary endpoint: FFF
  - FFF = transition to radical, whole-gland, or systemic therapy, or metastases/death



Shah et al Eur Urol. (2019) 76:98

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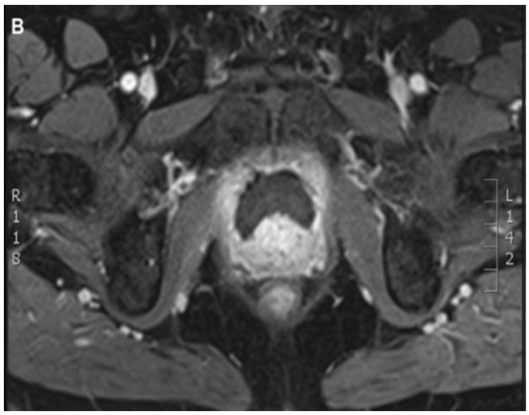
- 122 Patients
- 34 Adverse Events (28%)
  - Grade 3 – Cystoscopic intervention – in 2 pts (1.6%)
  - Grade 2 – UTI in 11 pts (9%)
  - Grade 2 – Osteitis Pubis in 1 pts (0.8%)
  - Grade 1 – Penile Numbness in 12 pts (10%)
  - Grade 1 – AUR in 5 pts (4.1%)
- By 3 months
  - Potency 84%
  - Incontinence 0%



Shah et al Eur Urol. (2019) 76:98

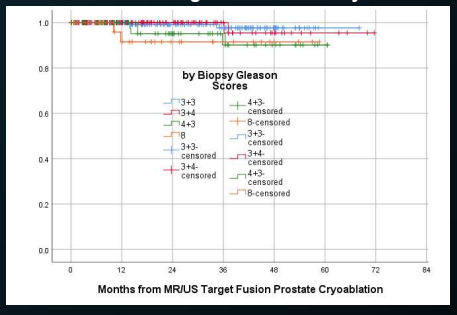
American Urological Association

MRI/US fusion guided Prostate Biopsy and Cryotherapy in a Clinical Office setting.

Fernando Bianco, Eusebio Luna*, Luanda Perez, Alberto Lopez-Prieto, Edward Gheiler, Ariel Kaufman, Miami, FL, Farshad Shafizadeh, New York, NY, Michael Zachareas, Beverly, MA, Juan Martinez-Salamanca, Madrid, Spain, Gloria Egui-Benatuil, Miami, FL, Michael Kattan, Claveland, OH

Total patients: 1,146

Freedom from salvage RP or XRT at 5 years



MR Fusion Cryo: 874 (76%)

- > 90% of Focalyx patients did not require any additional surgical intervention or radiation therapy at 5 years.
- > 95% without urinary incontinence or other GU / GI AEs.
- ~ 75% improvement in mean urinary flow rates.
- Median IPSS scores ignorantly decreased from 11 to 5.
- 86% transient ED returned to baseline after 6 months.

The Focalyx Clinical Registry continues to collect follow-up data on all patients and represents one of the largest trans-perineal MR/US fusion databases with >5000 patients followed 5+ years.

Focalyx

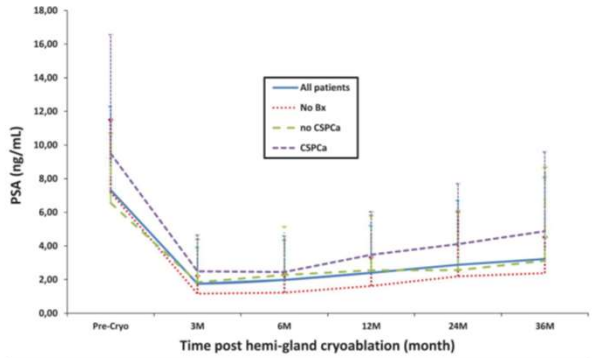
2

Hemigland Cryoablation of Localized Low, Intermediate and High Risk Prostate Cancer: Oncologic and Functional Outcomes at 5 Years

Masakatsu Oishi, Inderbir S. Gill, Alessandro Tafuri, Aliasger Shakir, Giovanni E. Cacciamani, Tsuyoshi Iwata, Atsuko Iwata, Akbar Ashrafi, Daniel Park, Jie Cai, Mihir Desai, Osamu Ukimura, Duke K. Bahn and Andre Luis Abreu*

Table 1. *Baseline data on PCa hemigland cryoablation*

No. pts	160	
Median age (IQR)	67	(60–74)
Median ng/ml PSA (IQR)	6.3	(4.2–9.0)
Median cc prostate vol (IQR)	40	(31–50)
Median ng/ml/cc PSA density (IQR)	0.16	(0.09–0.24)
No. clinical stage (%):		
T1c	98	(61)
T2a	49	(31)
T2b	13	(8)
No. Gleason Grade Group (%):		
1	39	(24)
2	55	(34)
3	45	(28)
4	17	(11)
5	4	(3)
No. D'Amico risk group (%):		
Low	29	(18)
Intermediate	106	(66)
High	25	(16)
No. pos biopsy side (%):		
Unilat	151	(94)
Bilat	9	(6)
No. neoadjuvant ADT (%)	29	(18)
Median study entry biopsy results (IQR):		
No. pos biopsy cores	2	(2–3)
Max Ca core length/core (mm)	6	(2.5–9)
Max % Ca/core	40	(20–65)



	Pre		3M		6M		12M		24M		36M	
	n	PSA	n	PSA	n	PSA	n	PSA	n	PSA	n	PSA
All patients	160	7.3 (5.0)	123	1.7 (2.2)	138	2.0 (2.4)	124	2.4 (2.8)	112	2.9 (3.8)	88	3.2 (4.8)
Follow-up biopsy status												
No Biopsy	56	7.2 (4.3)	38	1.2 (1.1)	43	1.2 (1.1)	39	1.6 (1.7)	31	2.2 (3.9)	18	2.4 (2.1)
No CSPCa	75	6.6 (4.1)	64	1.9 (2.5)	70	2.3 (2.8)	65	2.6 (3.3)	61	2.6 (3.5)	55	3.1 (5.5)
CSPCa	29	9.6 (7.2)	21	2.5 (2.2)	26	2.5 (2.1)	20	3.5 (2.6)	20	4.2 (3.7)	15	5.0 (4.9)

Oishi et al J Urol. (2019) 202:1188

The Role of Percentage of Prostate-specific Antigen Reduction After Focal Therapy Using High-intensity Focused Ultrasound for Primary Localised Prostate Cancer. Results from a Large Multi-institutional Series

Armando Stabile [a,b,c,], Clement Orczyk [b,d], Francesco Giganti [d,e], Marco Moschini [c,f], Clare Allen [e], Shonit Punwani [e], Nathalie Cathala [c], Hashim U. Ahmed [g,h], Xavier Cathelineau [c], Francesco Montorsi [a], Mark Emberton [b,d], Alberto Briganti [a], Rafael Sanchez-Salas [c], Caroline M. Moore [b,d]*

Table 1 – Descriptive characteristics of 703 patients receiving focal therapy with high-intensity focused ultrasound for clinically localised prostate cancer.

Variables	Overall (*n* = 703)
Age at biopsy (yr)	
Median	64
IQR	59–70
PSA value (ng/mL)	
Median	7.0
IQR	5.2–9.4
Prostate volume (ml)	
Median	35
IQR	28–45
Clinical stage, *n* (%)	
T1	119 (17)
T2	584 (83)
PSAd (ng/mL/mL)	
Median	0.2
Range	0.1–0.3
Number of Bx cores	
Median	26
IQR	12–48
Number of positive Bx cores	
Median	5
IQR	3–9
Maximum cancer core length (mm)	
Median	6
IQR	4–8
Gleason score, *n* (%)	
3 + 3	185 (26)
3 + 4	434 (62)
4 + 3	84 (12)

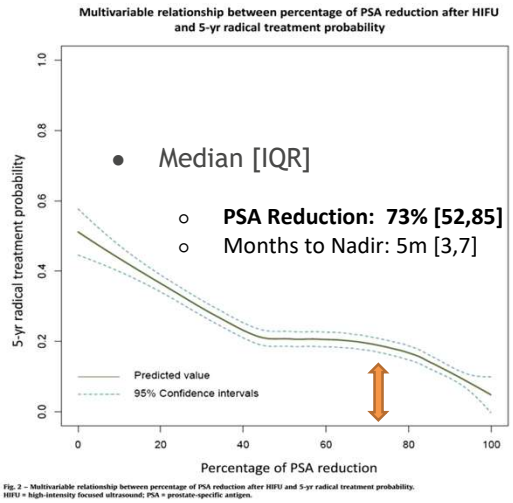


Fig. 2 – Multivariable relationship between percentage of PSA reduction after HIFU and 5-yr radical treatment probability. HIFU = high-intensity focused ultrasound; PSA = prostate-specific antigen.

Stabile et al Eur Urol. (2020) 78:155

POST MR FUSION CRYO PSA RESPONSE OUTCOMES:

659 men minimum of 6 months follow up

Aug 2013 Jul 2021		preTx PSA	Last PSA	Delta
N	Valid	734	659	
Mean		**7.6**	**1.9**	**75%**
Median		**6.4**	**1.7**	**73%**
Percentiles	25	4.6	0.8	83%
	50	6.4	1.7	73%
	75	9.2	3.4	63%

MR Fusion TX Cryoablation: AUA 2020

1 Year MRI piRADS with TPMRFBx

1Yr RM piRADS	1YrBxNeg	(%)	1YrBxPos	(%)	Totals
piRADS 1-2	93	94%	6	6%	99
piRADS 3	73	66%	38	34%	111
piRADS 4-5	15	26%	39	74%	53
Totals	181	61%	83	31%	264

p=0.001

What about reimbursement

Hospital Outpatient Medicare Payments FACILITY FEE for Focal Therapy Energies PCa Procedures (2023 Proposed rule vs 2022)

Procedure	Code	2022 Payment	2023 Proposed	% change	ASC
Prostate Brachytherapy	55875	$4,506	$4,784	6.2%	$4,506
Cryo	55873	$8,429	$8,711	3.3%	$6,443
Fusion Laser Ablation	0655T*	$9,100	$9,100	0%	$9,100
HIFU	55880	$4,506	$8,711	93.3%	$5,615
TULSA –Intraurethal HIFU	C-9734*	$12,593	$12,593	0%	?
IRE - Nanoknife	0600T*	$9,096	$9,096	0%	$6,244
Laparoscopic Prostatectomy (with or without Robotic Assistance)	55866	$9,096	$9,253	1.7%	$8,102

*CPT3 Codes

Sources: Focalyx, EDAP-tms, Angiodynamics, Profound Medical, USG

Hospital/ASC Outpatient Medicare Payments PHYSICIAN FEE for Focal Therapy Energies PCa Procedures (2023 Proposed rule vs 2022)

Procedure	Code	2022 Payment	2023 Proposed	% change	RVUs
Prostate Brachytherapy	55875	$785	$766	-2.4%	23
Cryo	55873	$774	$750	-3.1%	23
Fusion Laser Ablation	0655T*	Pt-PH	Pt-PH	0%	
HIFU	55880	$992	$960	-3.2%	29
TULSA –Intraurethal HIFU	C-9734*	Pt-PH	Pt-PH	0%	
IRE - Nanoknife	0600T*	Pt-PH	Pt-PH	0%	
Laparoscopic Prostatectomy (with or without Robotic Assistance)	55866	$1,455	$1,170	-20%	35

*CPT3 Codes **Negotiated Sources: Focalyx, EDAP-tms, Angiodynamics, Profound Medical, USG

OFFICE BASED - NON-FACILITY Medicare Payments PRACTICE FEE for Focal Therapy Energies PCa Transperineal Procedures

Procedure	Code	2022 Payment
Prostate Brachytherapy	55875	$4,506
MR Fusion Cryo	**55873-22**	**$7,700**
MR Fusion Laser Ablation	**0655T***	**$9,100**
MRI Guidance	77021	$441
TULSA, HIFU, IRE, Robotic Prostectomy	**NA**	**NA**

*CPT3 Codes Sources: Focalyx, USG, NY Urologic, Maiden Lane Medical, NYHealth, NE Urology

What do I tell patients?

Discuss RCT data, surveillance option, and that we have treated >800 assess their views of what's important in life for them

- **Confident:** Tumors will be destroyed
- **Confident:** Not burning any bridges
- **Very Confident:** QOL will improve
- **Very Confident:** Return to usual activities ~ 1 week
- **Very Confident:** Not burning any Tx bridges
- **I Stress that:** Cancer may come back, surveillance is key, MR at 1 year mandatory and Bx will depend of MR and PSA dynamics

Focalyx

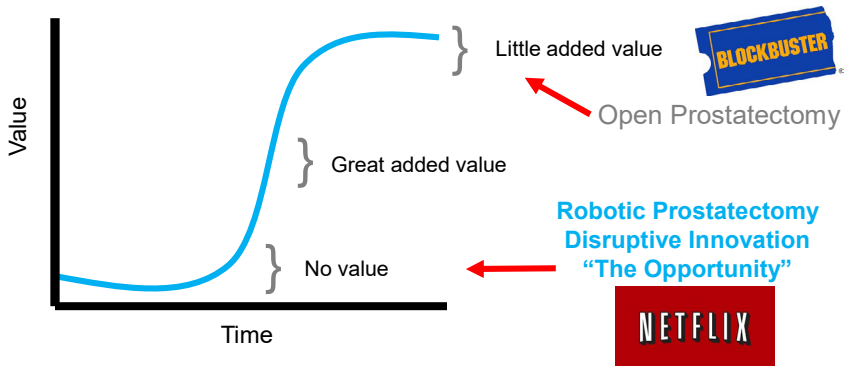
The last shift: Year 2000 – Open Prostatectomy most popular

Open Prostatectomy

- Loupes
- Minimal incisions
- Epidural
- Pfannenstiel

Robotic Prostatectomy

- More expensive
- Devastating Complications
- Long Procedure
- Technology on its side

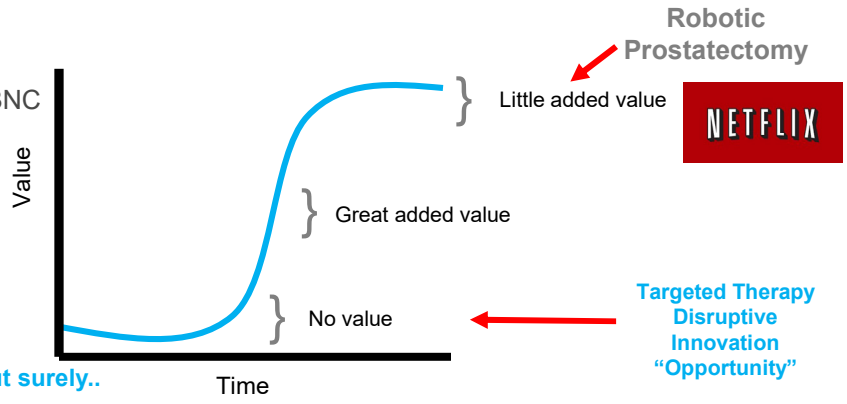


Clayton M. Christensen, *The Innovator's Dilemma*

The next shift: 2020s Targeted Therapy

Robotic Prostatectomy
- Xi, X, Single port
- Marketing, Exclusive
- Hard data is same without BNC

Targeted Therapy
- Office based, Inclusive
- Local Anesthesia
- Preservation of function
- Less costs

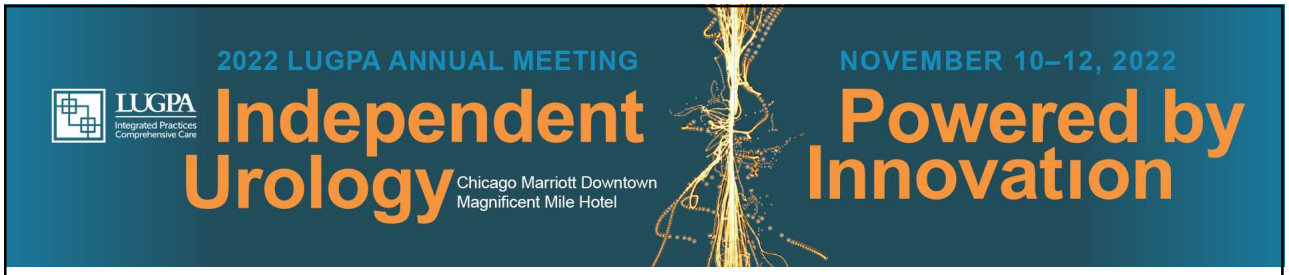


The market moves slowly but surely.. until… BANG!

Clayton M. Christensen, *The Innovator's Dilemma*

Thanks ☺

Any ? Email me drbianco@research.surgery



OPTIMIZING ASC UTILIZATION: PENILE IMPLANT-POST PROSTATECTOMY

Sherita A. King, MD
Director of Prosthetics and Sexual Medicine
Assistant Professor

KingUrology

I have at the present or have had within the last 24 months, the following affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest to the design, implementation, presentation, evaluation, etc. of CME Activities:

Coloplast Consultant

2

OTHER DISCLOSURES

- I do NOT do IPPs at my institution's ASC…

OBJECTIVES

- Preop
- Intraop
- Postop

4

PREOP

PREOP – FIND THE PATIENTS

- Referrals
  - Partner with GU onc surgeons
    - Prostate Cancer Survivorship Program
- Everyone is a potential ED patient
- Expedited treatment pathway
  - Manage expectations and educate patients

PREOP – PATIENT SELECTION

Minimal co-morbidities	
No PSH that will alter IPP placement	• i.e., IHR, cystectomies
Lower BMI	
Does not need concomitant procedures	• i.e., Peyronie's disease

7

BENEFITS VERIFICATION & CANCELLATION PREVENTION

Elective Surgery Cancellations

A multi-factorial problem, documented world-wide, averaging between 6-39%, varying from hospital type and specialty.

Hospital Related

- 60-80%
- OR time, PACU availability, etc.

Patient Related

- 20-40%
- Inadequate pre-op assessments, patient absenteeism, financial constraints, medical reasons

1 Narmeen Al Talalwah, BSN, MSc, DNP, RN, Kimberly H. McIltrot, DNP, CPNP, CWOCN. *Cancellation of Surgeries: Integrative Review*. Journal of PeriAnesthesia Nursing, Vol 34, No 1 (February), 2019: pp 86-96

BSC PRE-AUTHORIZATION PORTAL

- On-demand access to a portal dashboard for ***Prosthetic Urology***, Rezum and SpaceOAR
- You will receive the patients BV results within 2 business days
- Employer Exclusion Support

BOSTON SCIENTIFIC
PRE-AUTHORIZATION PORTAL
STREAMLINE SUCCESS

Boston Scientific's digital solution is designed to help your offices with benefit verifications and pre-authorizations – creating efficiencies and helping more patients gain access to therapy.

- Online digital tool to submit and track benefit verification and pre-authorization cases
- Expertise in pre-authorization services including handling denials*
- 50% reduction in turnaround time over fax submissions**
- Simple and intuitive to use
- Helps save time in handling benefit verifications and pre-authorizations
- Easily track case status and connect with BSC specialists and BSC clinical representatives through Portal

BOSTON SCIENTIFIC'S PRE-AUTHORIZATION TEAM HAS BEEN HELPING OFFICES IN THE UNITED STATES SINCE 2004

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At Boston Scientific, Reimbursement Managers cover specific regions of the US and are here to provide assistance to all of our provider partners (Physician, ASC, and Hospital):

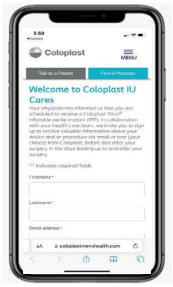
- Reimbursement education
- Billing and coding support
- Claim reviews
- Pre-authorization and claim denial feedback
- Payer coverage
- Field based and geographically focused

Contact your local Boston Scientific Territory Manager to learn more.

Coloplast
Informed Patient Program: Educate patients on common mishaps related to last minute cancellations

Patients opt into program

Receive notifications regarding their surgery



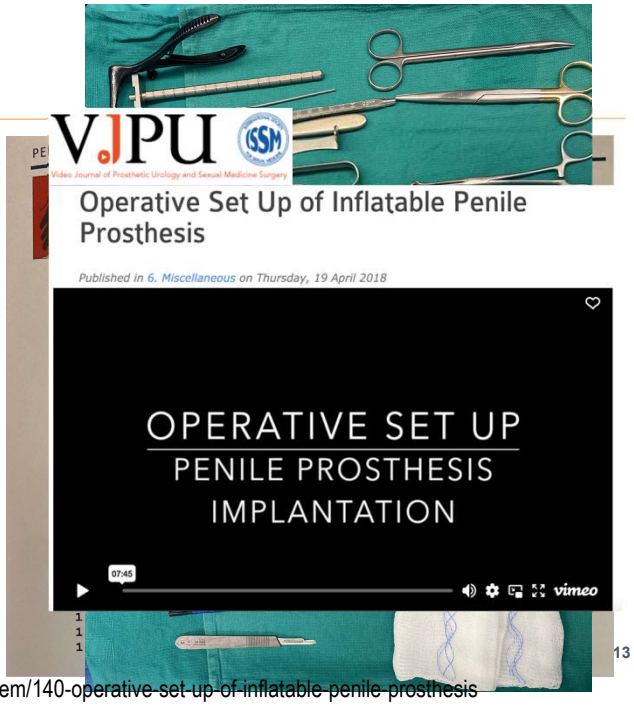
Notifications related to common reasons for last minute cancellations

- Pre-surgery checklist
- Patient Education
- Insurance Information
- Connect w/educators
- Medical Clearance
- What to expect after surgery

INTRAOP

INTRAOP – KIS MODEL

- Streamline preference card
- Peel pack essential disposable items
- Consistent OR staff–circulator and tech
  - Have picture of mayo setup
  - VJPU – setup video



https://www.vjpu-issm.info/videos/peer-reviewed/5-miscellaneous/item/140-operative-set-up-of-inflatable-penile-prosthesis

IJIR: Your Sexual Medicine Journal www.nature.com/ijir

ARTICLE

Pudendal nerve block prior to inflatable penile prosthesis implantation: decreased intra-operative narcotic requirements

Rashid K. Sayyid[1]✉, Nathaniel S. Taylor[2], Jeunice Owens-Walton[2], Michael D. Oberle[1], Katherine L. Fratino[1], Martha K. Terris[1], Zachary Klaassen[1] and Sherita A. King[1]

Table 2. Study cohort intra- and post-operative outcomes ($n = 122$).

Study variable	Pudendal nerve block group ($n = 35$)	No pudendal nerve block group ($n = 75$)	*P* value
Intra-operative narcotic requirements in morphine milligram equivalents, median (IQR)	16.3 (13.0–32.5)	25.8 (14.9–35.3)	**0.037**[a]
Post-operative narcotic requirements in morphine milligram equivalents, median (IQR)	37.5 (15.3–46.8)	37.2 (22.3–50.7)	0.18

23rd Annual Fall Scientific Meeting of SMSNA

23rd ISSM Scientific Meeting

OCTOBER • 27-30 • 2022
MIAMI • FL • USA

Narcotic requirements and operative outcomes of a pudendal nerve block prior to primary inflatable penile prosthesis implantation in a multiethnic population

Kevin Labagnara[1], Justin Loloi[2], Mustufa Babar[1], Arshia A. Harandi[1], Michael Zhu[1], Azizou Salami[1], Meenakshi Davuluri[2], Pedro Maria[2]

1: Albert Einstein College of Medicine; 2: Montefiore Medical Center

Introduction

There are various analgesic regimens for post-operative pain control following inflatable penile prosthesis (IPP) implantation. Specifically, post-operative pain control with opioids is a common practice, but efforts to minimize narcotic usage are vital given the current opioid epidemic in the United States. Pudendal nerve block (PNB) provides regional perineal and penile anesthesia and represents an attractive option to maximize pain control while minimizing post-operative narcotic use. However, there is a paucity of studies describing whether utilization of PNBs decreases intra- and post-operative narcotic requirements following IPP implantation

Aim

To determine whether PNB utilization in a multiethnic population undergoing primary IPP implantation can decrease rates of post-operative opiate usage. Secondary objectives were to assess PNB utilization on intra-operative and 30-day safety outcomes.

Method

A single institution retrospective study was conducted of patients who underwent primary IPP implantation between December 2015 and February 2022. Demographic data, intra-operative characteristics, and outcome measures were extracted from electronic medical records. Baseline characteristics of PNB (yes or no) were summarized and analyzed using a Student's t-test, Chi-square test, or Mann-Whitney U for non-normally distributed variables. PNB usage and PACU opioid administration (yes or no) were analyzed using binary logistic regression for univariate and multivariate analysis.

Intra-operative/Recovery Outcomes	All	No PNB	PNB	P value
Operative Time (minutes), median (IQR)	64 (52-80)	67 (56-81)	63 (51-79)	0.11
Post-induction Opiate Use ≥100mg, N (%)	179 (50.4)	36 (59.0)	143 (48.6)	0.14
Estimated Blood Loss ≥ 50ml, N (%)	55 (26.4)	25 (43.1)	30 (20.0)	<0.001
Surgical Drain, N (%)	17 (4.7)	1 (1.4)	17 (4.7)	0.16
Time spent in PACU (minutes), median (IQR)	152 (118-210)	238 (162-307)	144 (111-185)	<0.001
Narcotics given in PACU, N (%)	227 (63.9)	46 (75.4)	181 (61.6)	0.040
Post-operative Outcomes				
Discharged with catheter, N (%)	31 (8.5)	5 (7.2)	26 (8.8)	0.67
Retention, N (%)	7 (1.9)	2 (2.9)	5 (1.7)	0.52
Infection, N (%)	15 (4.5)	5 (8.9)	10 (3.6)	0.078
30-day call for opiate refill, N (%)	53 (14.6)	15 (21.7)	38 (12.9)	0.062
30-day ED visit for pain, N (%)	37 (10.2)	7 (10.1)	30 (10.2)	0.99
30-day Readmission, N (%)	13 (3.6)	3 (4.3)	10 (3.4)	0.70

Table 1: Intra- and post-operative outcomes of pudendal block vs non-pudendal block groups.

Results

A total of 363 patients were included, 294 (81.0%) in the PNB group and 69 (19.0%) in the non-PNB group. The majority of patients were of Hispanic race (62.3%). History of chronic pain (17.7% vs. 7.2%, p=0.03) and hyperlipidemia (52.0% vs. 34.8%, p=0.01) were more prevalent in the PNB group. Significantly more IPPs in the PNB group had cylinders measuring 20 centimeters or greater (57.1% vs 41.2, p=0.017).

Estimated blood loss of 50ml or greater (43.1% vs. 20.0%, p<0.001), PACU narcotic usage (61.6% vs. 75.4%, p=0.040) and time (minutes) spent in the PACU (144 [111-185] vs. 238 [162-307], p<0.001) were all significantly lower in the PNB group. There were no significant differences in postoperative and 30-day safety outcomes. On univariate analysis, both PNB (OR=0.52, p=0.043) and age above 65 (OR=0.53, p=0.004) were associated with a lower likelihood of receiving opiates in the PACU, while only age remained significant (OR=0.53, p=0.006) on multivariate analysis.

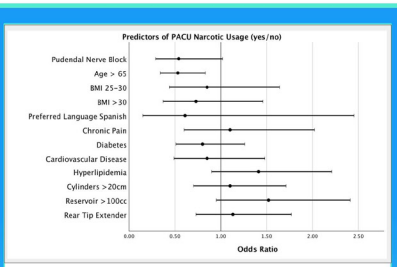


Table 1: Predictors of PACU narcotic usage (yes or no) on univariate and multivariate logistic regression analysis. Multivariate controls for age, chronic pain history, BMI, and pudendal nerve block. Reference categories set to BMI<25 and English for preferred language.

Conclusion

Pre-operative PNB decreases intra-operative estimated blood loss, post-operative opioid analgesic requirements and time spent in PACU in patients undergoing a primary IPP implantation. Thus, PBN represents a potentially attractive, non-opioid means of analgesia in patients undergoing primary IPP surgery.

Acknowledgements

Thank you to Dr. Pedro Maria and everyone in the Montefiore Department of Urology for making this project possible!

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Table 1: Intra- and post-operative outcomes of pudendal block vs non-pudendal block groups.

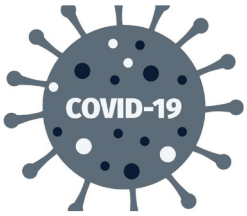
POSTOP

POSTOP – MOVE TO OUTPATIENT SURGERY

Partnered with home health

- d/c Foley POD#1
- d/c JP POD#3

Accelerated by



Hindered by

Empowered/Educated Patients in Post Op Care

- d/c Foley POD#1
- d/c JP POD#3
  - by pt vs nursing clinic visit

18

SUMMARY

- Time is money!

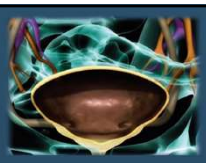
PreOp
- Find the patients and get to the OR
- Setup yourself up for surgical success with patient selection
- Benefits Verification
- Reduce Cancellations

IntraOp
- Simplify surgery
- Pudendal block

PostOp
- No admissions – partner with home health/teach patients aftercare
- Patient educators

19


LUGPA
Integrated Practices
Comprehensive Care



Deobstructing Mouse Traps

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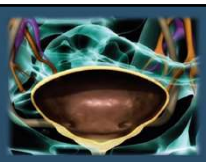
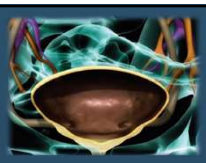
Professor of Urology
Icahn School of Medicine at Mount Sinai
Director, Men's Health Program
Mount Sinai Health System



Disclosures

- **Principal Investigator**
  - Urotronics
  - Proverum



Surgical Options

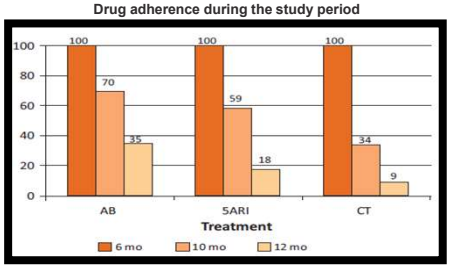
- **Minimally invasive options**
  - Office based
  - Ambulatory based
  - Minimal anesthetic
  - High risk patients
  - Low morbidity
- **Advanced Invasive Options**
  - Improved versions of prostatectomy

Low Adherence to Medications Supported by Multiple Studies

The Cindolo Study

1.5 million men ≥ 40 years with BPH-associated LUTS, administered alpha-blockers (AB) and 5alpha-reductase inhibitors (5ARIs), alone or in combination (CT)

Drug adherence during the study period

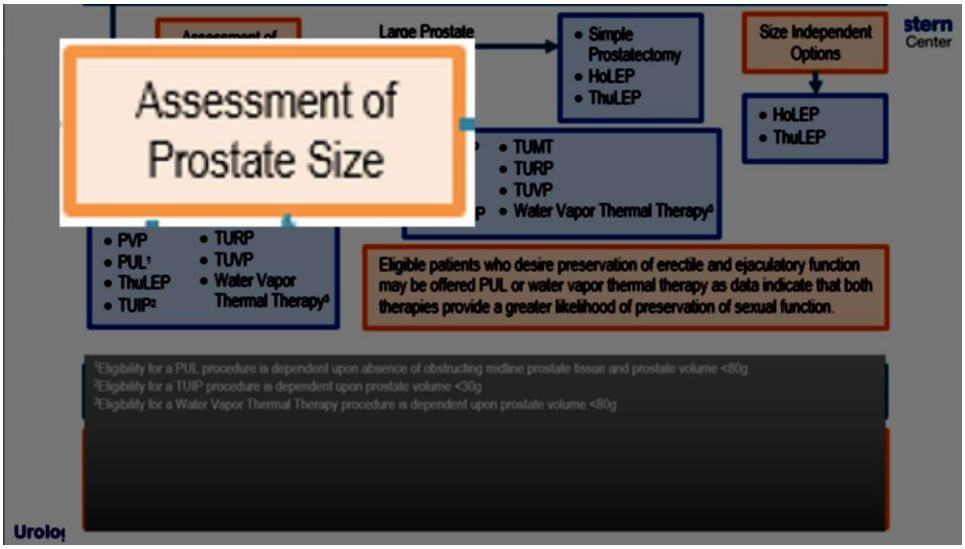


- Retrospective study that reviewed a national drug prescription database and hospital discharge codes of 1.5 million men in Italy
- **Aim:** to understand the difference in patient adherence with monotherapy and combination drug therapy for BPH
- Patients exposed to at least 6 months of therapy had a 1-year overall adherence of 29% (monotherapy AB 35%, monotherapy 5ARI 18%, CT 9%), i.e. **up to a 71% discontinuation rate**

Cindolo et al. BMC Urology 2015

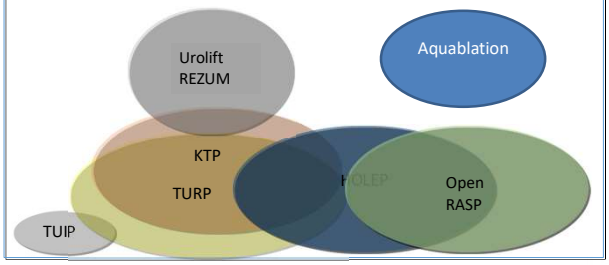
New Statement
Need for secondary treatment

6. Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally-invasive treatments for LUTS secondary to BPH. (Clinical Principle)



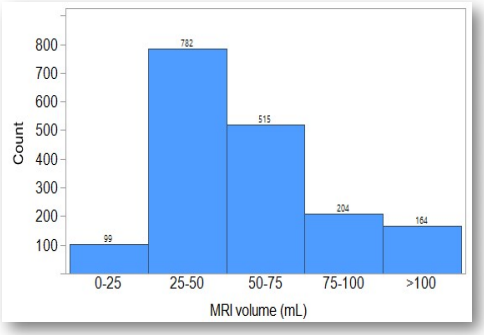
Choice of Surgical Techniques Based on Size

The tissue that is removed is mostly 'transition zone' by ultrasound The TZ ranges from 30 to 80% of total size
Strictly speaking the TZ is relevant when setting time/size limits for TURP
Guidelines suggest to not resect beyond 60 min or approximately 60 gm



< 30 gm 30 - 60 gm 60 – 100 gm > 100 gm > 200 gm

MRI measured prostate volume in 1764 men undergoing mpMRI imaging (Histogram and number and percent in categories)



MRI volume cutpoints, mL	Percent
<25	99 (6%)
25-50	782 (44%)
50-75	515 (29%)
75-100	204 (12%)
>100	164 (9%)

13

Five Year Durability Established

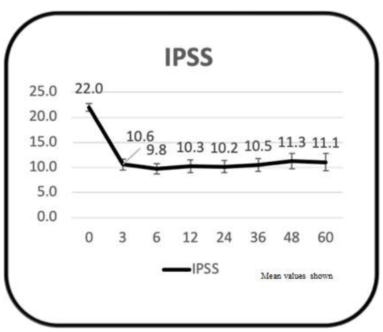
- **Prostatic Urethral Lift shows 5 year durable effect:**
  - ✓ **AUASI, QoL, Qmax remain improved 36%, 50%, and 44% from baseline, respectively.**
  - ✓ **Retreatment rate was 2% to 3% per year over 5 years**

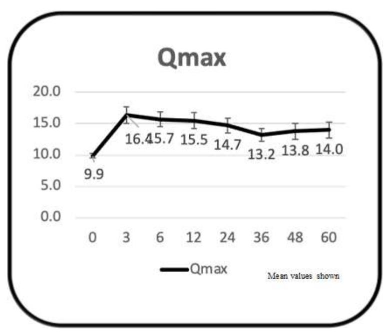
Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study

Claus G. Roehrborn, MD,[1] Jack Barkin, MD,[2] Steven N. Gange, MD,[3] Neal D. Shore, MD,[4] Jonathan L. Giddens, MD,[5] Damien M. Bolton, MD,[6] Barrett E. Cowan, MD,[7] Anthony L. Cantwell, MD,[8] Kevin T. McVary, MD,[9] Alexis E. Te, MD,[10] Shahram S. Gholami, MD,[11] William G. Moseley, MD,[12] Peter T. Chin, MD,[13] William T. Dowling, MD,[14] Sheldon J. Freedman, MD,[15] Peter F. Incze, MD,[16] K. Scott Coffield, MD,[17] Sean Herron, MD,[18] Prem Rashid, MD,[19] Daniel B. Rukstalis, MD[20]

Water Vaporization IPSS and Qmax

Significant improvement from baseline through 5 yrs





HEMOSTASIS AND POST-OPERATIVE MANAGEMENT

AQUABLATION Therapy by PROCEPT BioRobotics

HEMOSTASIS METHOD

- Clot Evacuation
- Removal of "fluffy tissue"
- Focal bladder-neck cautery
- Continuous bladder irrigation

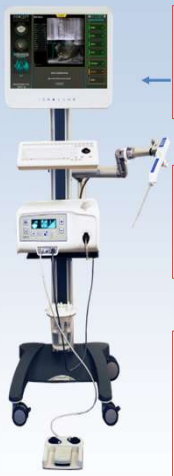
RESULTS

- In 1,116 Aquablation therapy procedures
- Across prostates ranging from 20 to 300 mL
- Aquablation therapy with focal bladder-neck cautery had a 0.6% transfusion rate

FLUFFY TISSUE | USE LOOP TO REMOVE FLUFFY TISSUE | FOCAL CAUTERY AT BLEEDERS

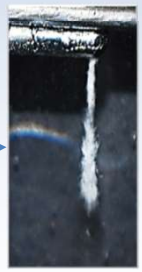
Elterman D. et al. Contemporary Transfusion Results from 1,116 Aquablation Procedures using the Focal Bladder Neck Cautery Method. – Submitted for Publication

THE WATERABLATION System



Conformal Planning Unit
- Surgical planning & mapping
- Controlled depth of resection
- Integrated TRUS display

Handpiece
- 24 Fr, precise sapphire nozzle
- Cystoscopic visualization
- Aspiration for tissue collection

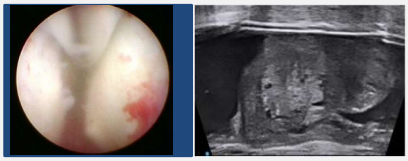


WaterAblation
- Submerged high velocity saline jet
- Tissue selectivity & depth control
- Non-thermal (room temperature)

CLARITY

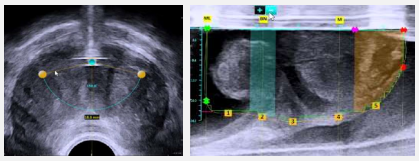
VISUALIZATION OF THE ENTIRE PROSTATE FOR CUSTOMIZED TREATMENT PLANNING

SIMULTANEOUS IMAGING



Visualization of the entire prostate through cystoscope and ultrasound

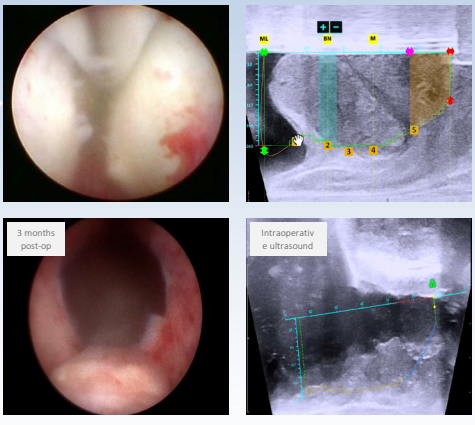
INTRAOPERATIVE SURGICAL PLANNING



Identify critical anatomy and customize resection contour

WATER ABLATION THERAPY RESULTS

BEFORE
Obstructed Prostatic Urethra



AFTER
Open Prostatic Urethra

Sample results shown here

CLINICALLY PROVEN OUTCOMES

	WATER STUDY	WATER II STUDY	OPEN WATER STUDY
OUTCOMES	Superior safety and non-inferior efficacy compared to TURP Sub-group of prostates over 50 mL were SUPERIOR in safety AND efficacy over TURP	Safe and effective without significant increase in procedure or resection time	Safe and effective without significant increase in procedure or resection time
DESCRIPTION	Only FDA pivotal study randomized to the gold standard	Only successful FDA multicenter study for large prostates	Largest commercial trial evaluating safety and efficacy
DESIGN	Prospective, double-blind, randomized controlled clinical trial	Prospective, multicenter clinical trial	Prospective, multicenter, all-comer trial
POPULATION	Prostates 30 – 80 mL N = 181 17 Sites | US, UK, AU, NZ	Prostates 80 – 150 mL N = 101 16 Sites | US and CA	Prostates 20 – 150 mL N = 178 6 Sites | DE, AU, NZ, UK, LB

Gilling P. et al. Three-year outcomes after Aquablation® therapy compared to TURP: results from a blinded randomized trial. Can J Urol. 2020 Feb;27(1):10072-10079

Desai M, et al. Aquablation for benign prostatic hyperplasia in large prostates (80-150 cc): 2-year results. Canadian Journal of Urology. 27(2):10147-10153. Apr 2020

Bach T. et al. First Multi-Center All-Comers Study for the Aquablation Procedure. J Clin Med. 2020 Feb;9(2):603.

HEMOSTASIS AND POST-OPERATIVE MANAGEMENT

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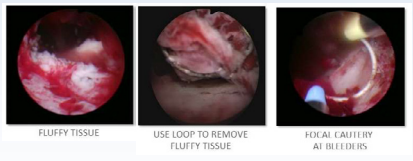
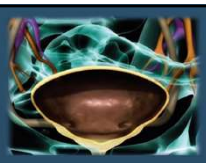


Efterman D. et al. Contemporary Transfusion Results from 1,116 Aquablation Procedures using the Focal Bladder Neck Cautery Method. – Submitted for Publication



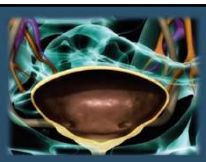
Water Ablation
Mount Sinai Experience

Population:

- N = 182 (Retention = 93)
- 1 – 36 month follow up
- Prostate size: 38 – 265 cc

Results

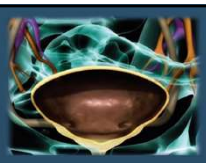
- 90 / 93 retention patients voided
- 111/112 antegrade ejaculation



Water Ablation
Mount Sinai Experience

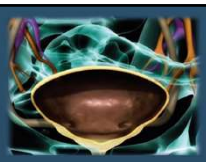
Results

- 7 previous TURP
- 9 previous Rezum
- 8 previous UroLift
- 17 previous PAE (all had IPP > 1 cm)
- 1 combo (PAE and AqB)



Water Ablation
Mount Sinai Experience

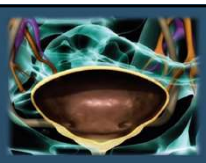
	N	IPSS	Qmax (ml/sec)	PVR (ml)
Baseline	182*	23.4	6.1	103
6M	147	7.7	19.3	43
12M	109	6.9	18.7	37
24M	54	6.7	19.0	45
36M	10	5.9	18	51



Water Ablation
Mount Sinai Experience

Complications

- 2 /182 for post op bleeding / fulguration
- 1/182 undermine bladder neck (require SPT)
- 1 retreatment (anterior lobe)
- 3 transfused (none in last 90)



Water Ablation Summary

Evolving

- Fast (average Aqb time was 7: 21 minutes)
- Prostate size not a barrier
- Easy to learn (need good TRUS skills)

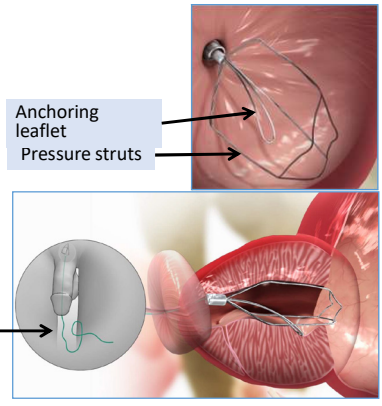
Issues

- Cost
- Durability
- Where it fits (HoLEP, simple prostatectomy)

The Device

The is a single-use device supplied on a dedicated delivery system comprised of:

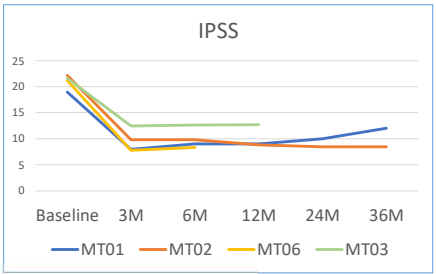
- Three nitinol cutting struts at 12, 5 and 7 o'clock positions
  - 5cm length
  - 3.5cm height
- An anchoring leaflet at the 6 o'clock position to prevent device migration
- A retrieval suture anchored to the distal part of the device for easy retrieval

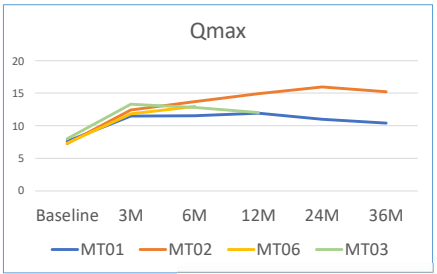


Clinical Data

Three published clinical studies including 280 patients

- IPSS reduction of -45% to -60%
- Qmax increase of 50% to 100%
- Durable effect to 3 years with <9% re-intervention
- Catheter-free procedure
- Erectile and ejaculatory function preserved
- Lowest rate of adverse events of any MIST
- Zero late occurring adverse events





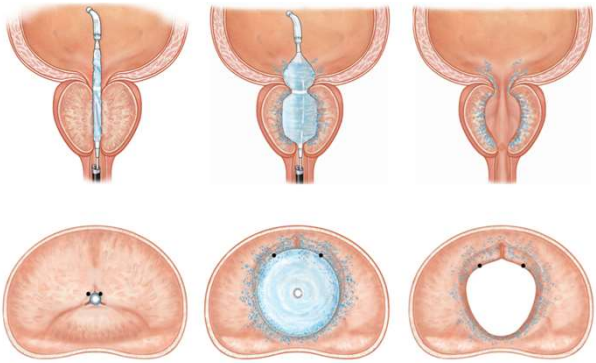
Weill Cornell Medicine NewYork-Presbyterian

Table 3. Overview of adjudicated adverse events

	iTind Group 0-30 days			Sham Group 0-30 days			iTind Group 1-3 months			iTind Group 3-12 months		
	Events (n)	Subjects (n)	Subjects (%)	Events (n)	Subjects (n)	Subjects (%)	Events (n)	Subjects (n)	Subjects (%)	Events (n)	Subjects (n)	Subjects (%)
Serious AEs	16	10	7.8	2	2	3.5						
Related serious	5	3	2.3									
All AEs	109	45	38.1	19	10	17.5						
Related AEs	81	39	33.1	4	4	7	2	2	1.6	1	1	0.8
Dysuria		27	22.9		5	8.8						
Hematuria		16	13.6									
Mictuition urgency		6	5.1		1	1.8						
Pollakiuria		8	6.8		1	1.8						
Urinary retention		7	5.9				1	1	0.8			
Urinary tract infection		2	1.7				1	1	0.8		1	0.8
Sepsis		1	0.8									
Pain		1	0.8									

Weill Cornell Medicine NewYork-Presbyterian

Balloon BPH Catheter System Mechanism of Action



Primary Mode of Action: Splitting of the lateral lobe commissure to create increased cross-sectional area

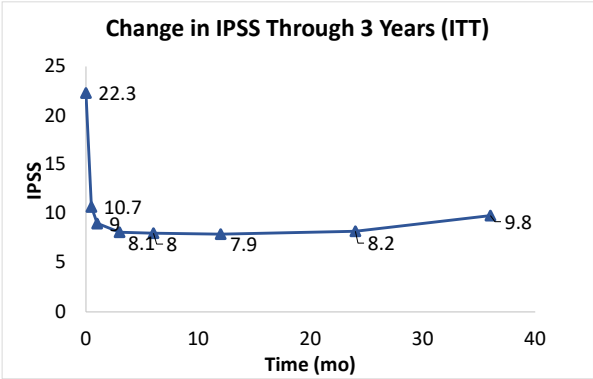
Secondary Mode of Action: Delivery of paclitaxel to the prostatic urethra to prevent short term growth of prostatic adenoma while re-urothelialization occurs.

Patented balloon shape locks on to the bladder neck, preventing slippage into the bladder during inflation.

Symptom Scores

Patients showed an immediate and sustained improvement in IPSS over the course of 3 years, with minimal fallout for additional BPH therapy.

Retreatment Rate - 3 Years	
Overall	**3.8%**
BPH Meds	*2.5%*
Surgical	***1.3%***



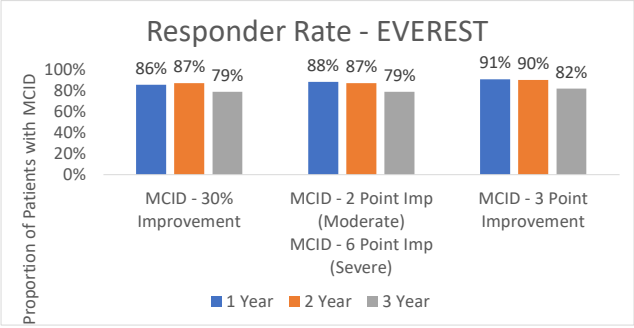
Minimum Clinically Important Difference (MCID)

Barry et al (1995)

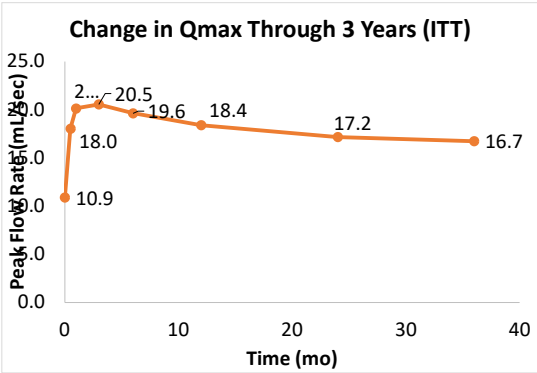
- Overall MCID for IPSS was a 3 point improvement
- Subjects with moderate IPSS at baseline (8 to 19) had an MCID of 2 point improvement
- Subjects with severe IPSS at baseline (≥20) had an MCID of 6 point improvement

FDA Guidance BPH Trials

Defined MCID of at least a 30% improvement from baseline IPSS scores based on CombAT study sub-analyses.



Qmax Through 3 Years (ITT)



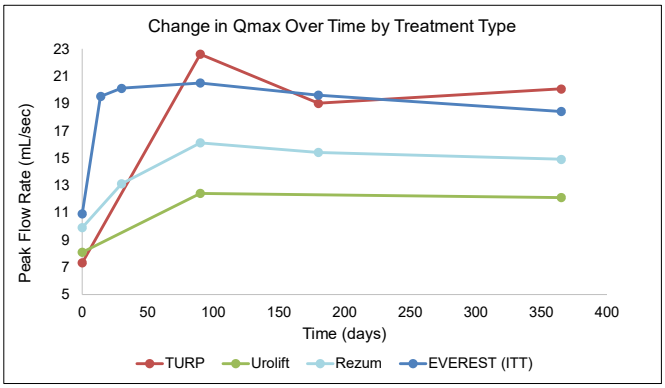
Peak Urinary Flow Rate (Qmax)

Significant increase in Qmax observed immediately post treatment and sustained through 3 year follow-up.

American Urological Association Education & Research, Inc.

AUA VIRTUAL EXPERIENCE

EVEREST QMAX RESULTS



- Improvement in symptoms more pronounced than other MIST therapies[1,2] and more immediate than TURP[3,4].

[1]Roehrborn CG, Gange SN, Shore ND, et al. *J Urol.* 2013;190:2161-67
[2]McVary KT, Gange SN, Gittelman MC, et al. *J Urol.* 2016;195:1529-38
[3]Sonksen J, Barber NJ, Speakman MJ, et al. *Eur J Urol.* 2015;68:643-52.
[4]Kumar N, Vasudeva P, Kumar A, Singh H. *LUTS.* 2018;10(1):17-20

EAU22
AMSTERDAM
1-4 July 2022

Cutting-edge Science at
Europe's largest Urology Congress

De Novo BPH Prescription Rates are Higher After TURP and PVP Compared to PUL: a US Healthcare Claims Analysis

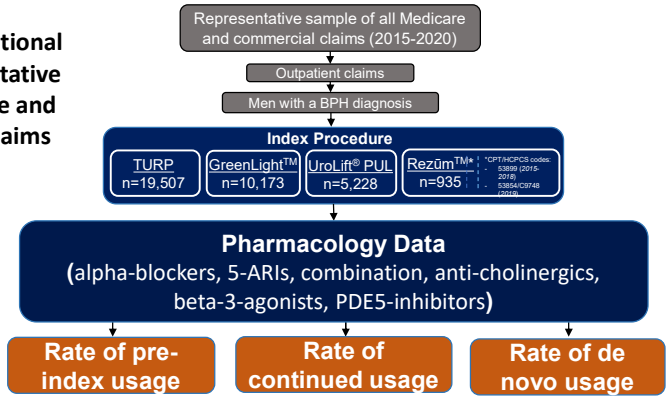
Steven Kaplan, MD

www.eau22.org

European Association of Urology

Healthcare utilization study

Retrospective observational analysis on a representative sample of US Medicare and commercial medical claims



EAU22 | AMSTERDAM 1-4 July 2022

Prior Usage

	PVP	TURP	PUL
Total patients that underwent procedure	11,158	22,021	7,088
- With medical records for BPH medication	3,162 (28.3%)	5,803 (26.4%)	1,497 (21.1%)
Prior Med Usage: n (% patients with med records)	**2,533 (80.1%)**	**4730 (81.5%)**	**1,301 (86.9%)**
	n (% prior med users)	**n (% prior med users)**	**n (% prior med users)**
5-ARI	749 (29.6%)	1,306 (27.6%)	328 (25.2%)
α-blocker	2,230 (88.0%)	4,111 (86.9%)	1,115 (85.7%)
Combination	64 (2.5%)	100 (2.1%)	32 (2.5%)
Anti-cholinergic	389 (15.4%)	787 (16.6%)	221 (17.0%)
Beta-3-agonist	360 (14.2%)	572 (12.1%)	225 (19.6%)
PDE5-inhibitor	361 (14.3%)	653 (13.8%)	293 (22.5%)

Of patients with medical records for BPH medication:

- Slightly more PUL patients were on medical therapy prior to their procedure compared to PVP and TURP
- α-blockers were the most utilized medical therapy prior to all procedures

www.eau22.org

European Association of Urology

Continued Usage

	PVP	TURP	PUL
Stopped Upon Procedure: n (% prior med users)	1,467 (57.9%)	2,860 (60.5%)	858 (65.9%)
Continued After Surgery: n (% prior med users)	1,066 (42.1%)	1,870 (39.5%)	443 (34.1%)
Avg duration post-procedure (procedure to final med record)	*260d*	*200d*	*222d*
	n (% continued med users)	**n (% continued med users)**	**n (% continued med users)**
5-ARI	309 (29.0%)	504 (27.0%)	99 (22.3%)
α-blocker	790 (74.1%)	1,414 (75.6%)	306 (69.1%)
Combination	17 (1.6%)	27 (1.4%)	10 (2.3%)
Anti-cholinergic	246 (23.1%)	491 (26.3%)	122 (27.5%)
Beta-3-agonist	267 (25.0%)	395 (21.1%)	159 (35.9%)
PDE5-inhibitor	206 (19.3%)	346 (18.5%)	129 (29.1%)
Odds Ratio for Continued Usage (vs. PUL)	1.58	1.39	--

- Slightly more PUL patients stopped medical therapy after their procedure compared to PVP and TURP
  - α-blockers were the most continued medical therapy
- **Odds Ratio** indicates 58% and 39% higher likelihood of continuing medical therapy after PVP and TURP compared to PUL

De Novo Usage

	PVP	TURP	PUL
De Novo Med Usage:			
n (% of patients with med records)	629 (19.9%)	1,073 (18.5%)	196 (13.1%)
Avg time from procedure to first med record	*123d*	*94d*	*150d*
Avg duration of de novo usage	*51d*	*36d*	*30d*
	n (% de novo med users)	**n (% de novo med users)**	**n (% de novo med users)**
5-ARI	110 (17.5%)	204 (19.0%)	23 (11.7%)
α-blocker	302 (48.0%)	501 (46.7%)	76 (38.8%)
Combination	3 (0.5%)	4 (0.4%)	0 (0.0%)
Anti-cholinergic	297 (47.2%)	674 (62.8%)	136 (69.4%)
Beta-3-agonist	348 (55.3%)	485 (45.2%)	139 (70.9%)
PDE5-inhibitor	160 (25.4%)	253 (23.6%)	58 (29.6%)
Odds Ratio (vs. PUL)	1.89	1.63	--

- Fewer PUL patients began *de novo* medical therapy after their procedure compared to PVP and TURP
- Beta-3-agonists, anti-cholinergic, α-blockers were the most utilized *de novo* medical therapy
- **Odds Ratio** indicates 89% and 63% higher likelihood of de novo medical therapy after PVP and TURP compared to PUL

WJ2

[@Najafi, Allison], should this say "higher likelihood of de no
rather than "continuing"
Welch, Jacqueline, 5/27/2022

Conclusions

Limitations:

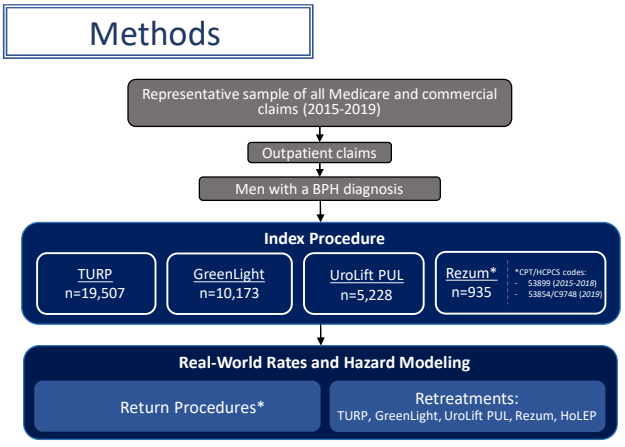
- Patient selection, inability to assess disease severity, and lack of other important baseline variables may create cohort biases within claims database
- Medication prescription rate may be less than in the real-world due to method of data capture

Summary:

- Higher likelihood of continued medication usage after PVP and TURP compared to PUL
  - α-blockers were the most likely drug class to be continued
- Higher likelihood of de novo medication usage after PVP and TURP compared to PUL
  - Beta-3-agonists, anti-cholinergic, α-blockers were the most likely drugs classes to be newly prescribed

Methods

Retrospective observational analysis on a representative sample of US Medicare and commercial medical claims



AUA-2021

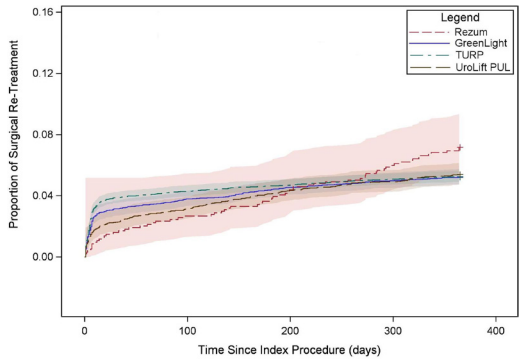
*procedure performed during a return visit to an outpatient setting

Certain data used in this study were supplied by International Business Machines Corporation as part of one or more IBM MarketScan Research Databases. Any analysis, interpretation, or conclusion based on these data is solely that of the authors and not International Business Machines Corporation.

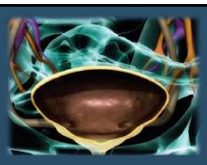
Results: 1-Year Retreatment Rates

- **Real-world rate**: At 365d, rate of surgical retreatment was similar between GreenLight, TURP, and PUL
  - Rate of 1-year retreatment was higher for Rezum vs PUL (p=0.04)

Rate of retreatments through 1 year	
Rezum	7.2%
GreenLight	5.2%
TURP	5.3%
UroLift PUL	5.4%

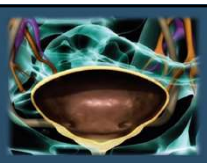


AUA 2021



Summary

- All procedures do well in the hands of the specialized committed expert
- Energy-based surgical techniques require comprehension of their unique tissue effects with specific technology



No one has a monopoly on truth, and science continues to advance. Yesterday's heresies may be tomorrow's conventional wisdom.

Dean Ornish

PROSTATEEMBOLIZATION

LUGPA MEETING NOVEMBER 2022

Disclosures

- Terumo
- Boston Scientific
- Guerbet
- Merit Medical
- CranMed

PROSTATE CENTERS
COMPREHENSIVE MEN'S HEALTH CARE

Re: Comparison of Clinical Outcomes of Prostatic Artery Embolization with 50-μm plus 100-μm Polyvinyl Alcohol (PVA) Particles versus 100-μm PVA Particles Alone: A Prospective Randomized Trial

M. Q. Wang, J

Department of Interven

J Vasc Interv Radiol 20

Abstract availab

Editorial Com

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Re: Early Results from a United States Trial of Prostatic Artery Embolization in the Treatment of Benign Prostatic Hyperplasia

S. Bagla, C. P. Martin, A. van Breda, M. J. Sheridan, K. M. Sterling, D. Papadouris, K. S. Rholl, J. B. Smirniotopoulos and A. van Breda

Cardiovascular and Interventional Radiology Department, Inova Alexandria Hospital, Alexandria, Inova Research Center, Falls Church and Inova Health System, Springfield, Virginia, and Georgetown University School of Medicine, Washington, D.C.

J Vasc Interv Radiol 2014; ***25:*** *47–52.*

Abstract for this article http://dx.doi.org/10.1016/j.juro.2015.01.027 available at http://jurology.com/

Editorial Comment: Those of us who have been involved in investigative trials for new therapeutic interventions for benign prostatic hyperplasia have become a bit skeptical regarding the long-term viability of these new, miraculous cures. Too often initial data in a few select patients have not translated to more widespread efficacy and safety. A relatively new player has been prostatic artery embolization (PAE). It is noteworthy that the authors are interventional radiologists, which suggests that urologists will not be the driving force behind this technology, although, ironically, we are the major source of patient referrals.

In this preliminary analysis a number of items stand out. First, only 20 of 72 men screened underwent the procedure, with exclusions ranging from, "I just do not want to do this" to opting for watchful waiting. However, the results demonstrate the disconnect between reduction in prostate volume and lower urinary tract symptoms. At 3 months there was a significant decrease in prostate volume (from 82.7 to 56.7 cm^3). There was also a symptom score decrease of about 12 points. However, at 3 months most men still had moderate or significant symptoms and would have been eligible for entry into a clinical trial for benign prostatic hyperplasia.

As the authors note, this was a small cohort with limited followup. If this technology continues to evolve, it will be interesting to see how clinical trials will be developed. To gain approval, one suspects

BENIGN PROSTATIC HYPERPLASIA 1317

that a placebo/sham study will be required, and recruitment for that type of study will be quite challenging. That being said, the role of PAE remains to be defined but I suspect that, like the ethanol injection experience, there will be reports of something besides prostate that was embolized. If that occurs, PAE will join other putative technologies in the dustbin.

Steven A. Kaplan, MD

Re: Efficacy and Safety of Prostate Artery Embolization for Benign Prostatic Hyperplasia: An Observational Study and Propensity-Matched Comparison with Transurethral Resection of the Prostate (the UK-ROPE Study)

well, M. J. Speakman, N. T. Longford, R. DasGupta, T. Bryant, S. Modi, is, G. Carolan-Rees and N. Hacking

ogy Research Centre, Cardiff and Vale University Health Board, Cardiff University, Cardiff, Centre for Health Technology ute for Health and Care Excellence, SNTL Statistics Research and Consulting, Department of Medicine, Imperial College f Urology, St. Mary's Hospital, Imperial College Healthcare NHS Trust, London, Nuffield Department of Primary Care Health xford, Oxford, Department of Urology, Taunton and Somerset NHS Trust, Taunton, and Departments of Interventional uthampton General Hospital, University Hospital Southampton NHS Foundation Trust, Southampton, United Kingdom

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Re: In-Hospital Cost Analysis of Prostatic Artery Embolization Compared with Transurethral Resection of the Prostate: Post Hoc Analysis of a Randomized Controlled Trial

G. Müllhaupt, L. Hechelhammer, D. S. Engeler, S. Güsewell, P. Betschart, V. Zumstein, T. M. Kessler, H. P. Schmid, L. Mordasini and D. Abt

Department of Urology, Department of Radiology and Nuclear Medicine, and Clinical Trials Unit, St. Gallen Cantonal Hospital, St. Gallen and Department of Neuro-Urology, Balgrist University Hospital, University of Zürich, Zürich, Switzerland

BJU Int 2019; **123:** *1055–1060* doi: 10.1111/bju.14660

Abstract available at http://www.ncbi.nlm.nih.gov/pubmed/30578705

Re: Prostatic Artery Embolization: Adding to the Arsenal against the Hapless Prostate

P. Chin

South Coast Urology, Wollongong, New South Wales, Australia

BJU Int 2019; **123:** *911–912.* doi: 10.1111/bju.14743

No Abstract

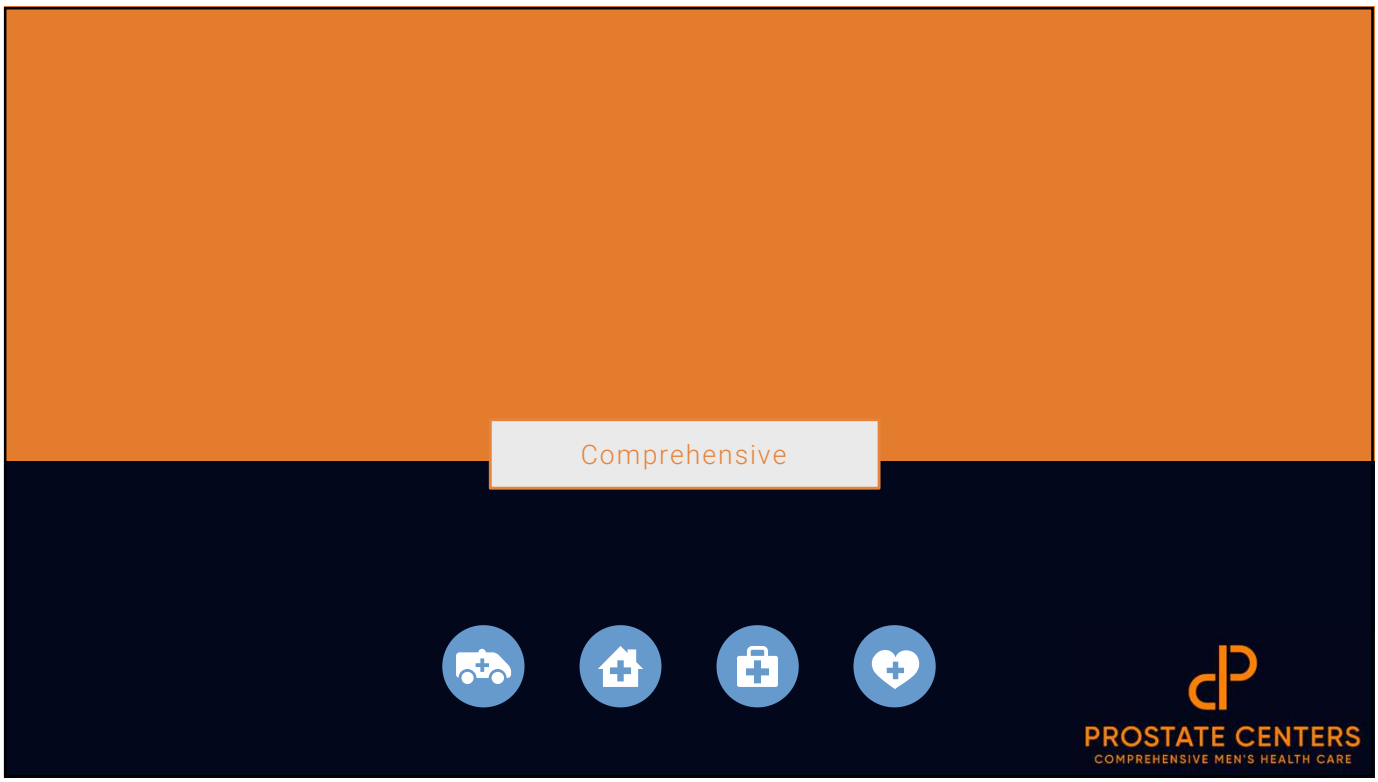
Editorial Comment: A number of patients have asked about whether prostatic artery embolization (PAE) is a reasonable therapeutic option for them. Based on their extensive Dr. Google search, they come away with the notion that PAE is safe, effective, easy and the best thing since sliced bread. One can well imagine their disappointment when they are informed about the efficacy, applicability and heretofore hardly discussed radiation exposure. This article and the accompanying editorial highlight the incongruity of post hoc analyses and real-world safety and efficacy. The study compares the in hospital costs of PAE and transurethral prostatectomy (TURP). The authors conclude that PAE costs less than TURP (as an inpatient procedure in Switzerland), although the difference is not statistically significant. Most of the PAE costs are related to supplies, while for TURP they are related to anesthesia and in hospital stay. One could surmise a different result in the United States, where TURP has become an outpatient procedure. Of note, PAE appears to be involve more postprocedural pain requiring analgesia, perhaps secondary to prostatic infarction.

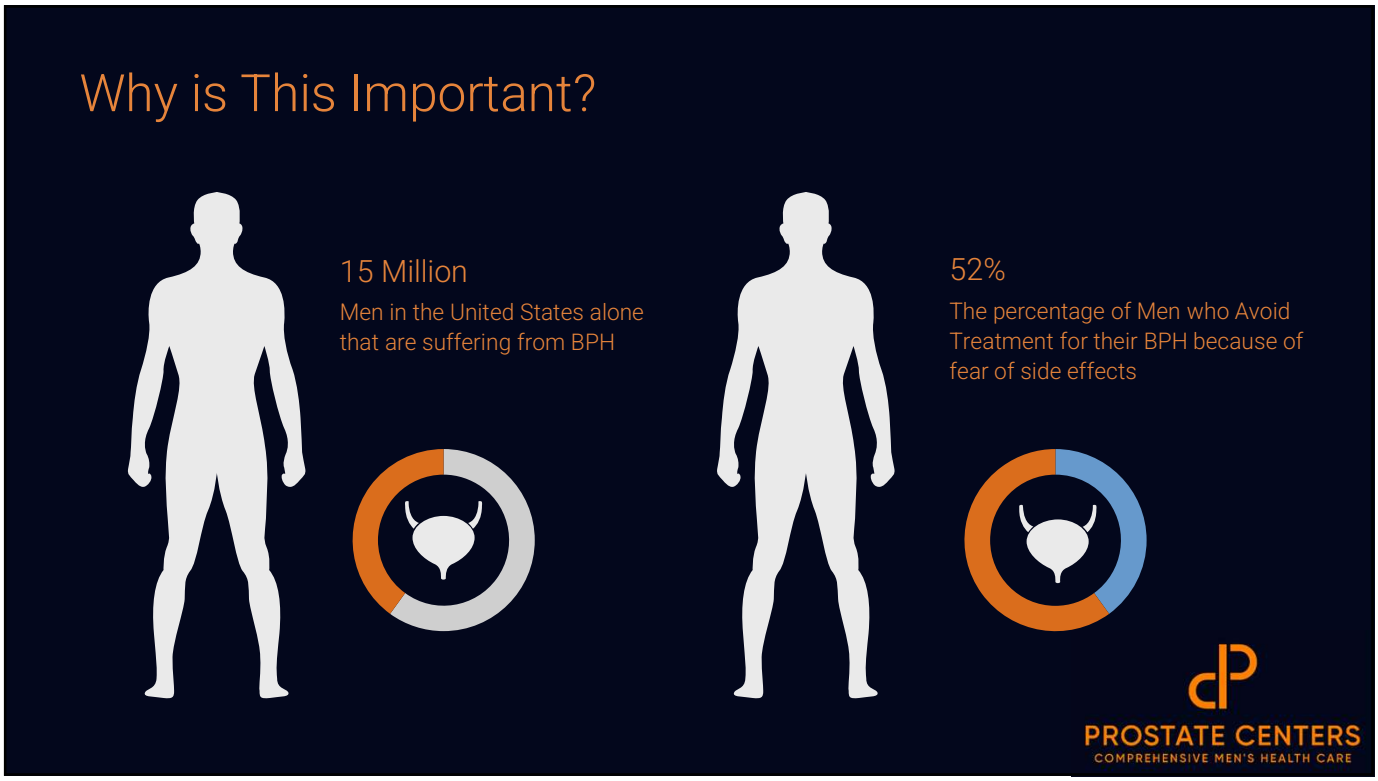
A number of interesting findings are mentioned by the authors, including unilateral embolization in about 25% of cases. Other studies have indicated similar findings. How do these results compare to bilateral embolization? As pointed out in the scholarly editorial by Chin, a heretofore less discussed aspect of PAE is the dose area product, which is a quantity used to assess radiation risk from diagnostic x-ray and interventional procedures. It is defined as the absorbed dose multiplied by the area irradiated and expressed in gray-centimeters squared. In this study the mean dose was 176.5 $Gy \cdot cm^2$. To put it in perspective, that is the equivalent of 5 to 10 abdominal computerized tomograms or 586 chest x-rays. As indicated by Chin, in a recent study in the vascular surgery literature there was a significant increase in abdominal cancers in patients who had undergone endovascular aneurysm repair, and in that study the mean radiation exposure was only 79.48 $Gy \cdot cm^2$.

The bottom line is that the long-term effects of radiation exposure with PAE are an important area to explore. For my part I would rather receive a urethral lift implant or Rezūm® heat therapy than chance such high radiation doses. The potential risk for treating a quality of life disorder is simply too high!

Steven A. Kaplan, MD

COMPREHENSIVE MEN'S HEALTH CARE




Why is This Important?
15 Million
Men in the United States alone that are suffering from BPH
52%
The percentage of Men who Avoid Treatment for their BPH because of fear of side effects
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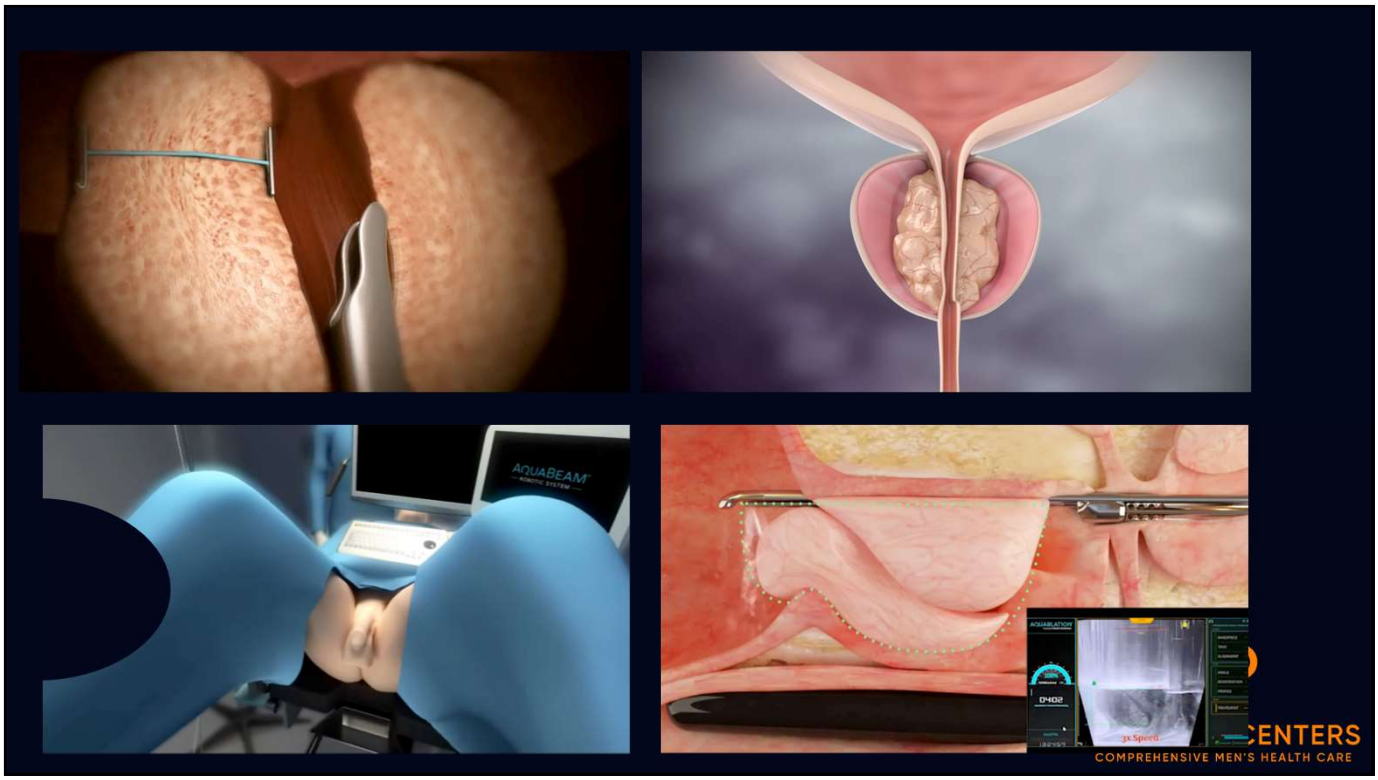
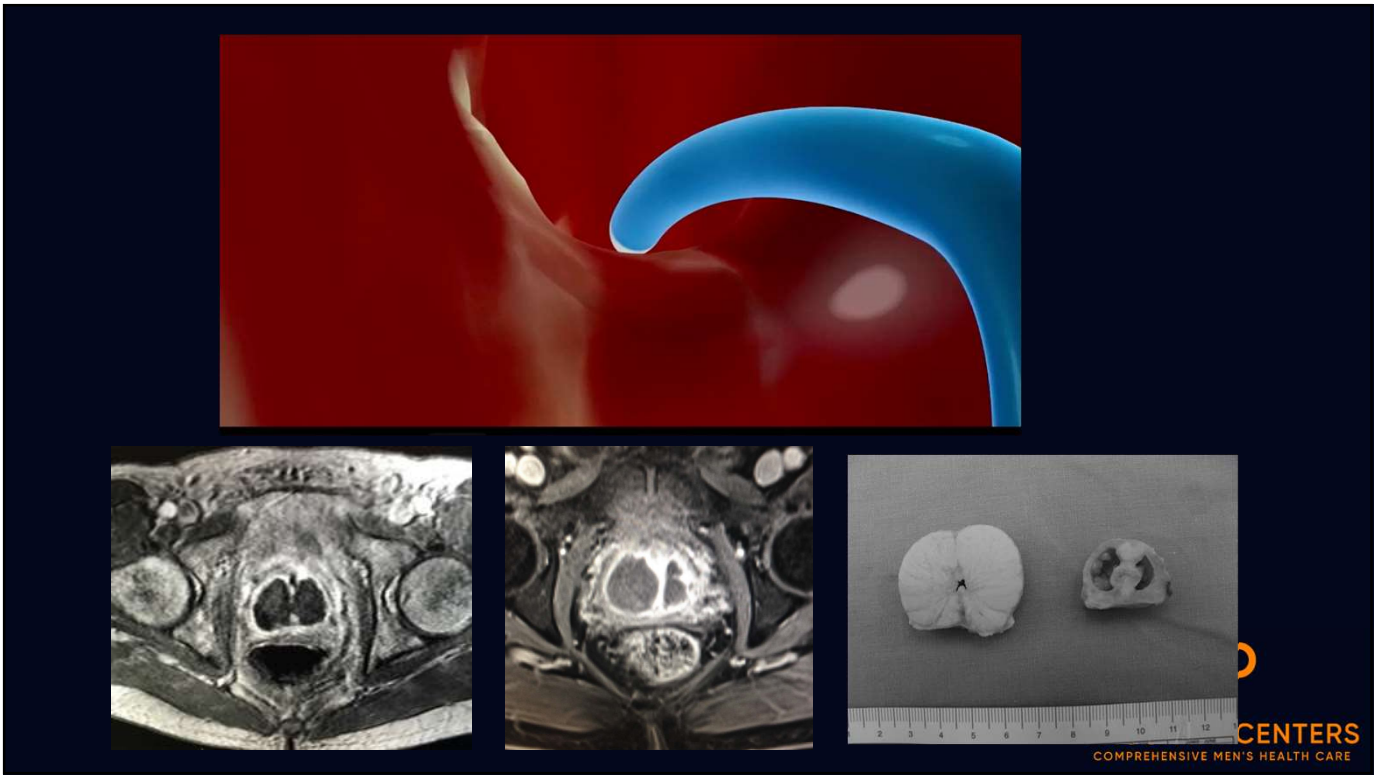
COMPREHENSIVE MEN'S HEALTH CARE

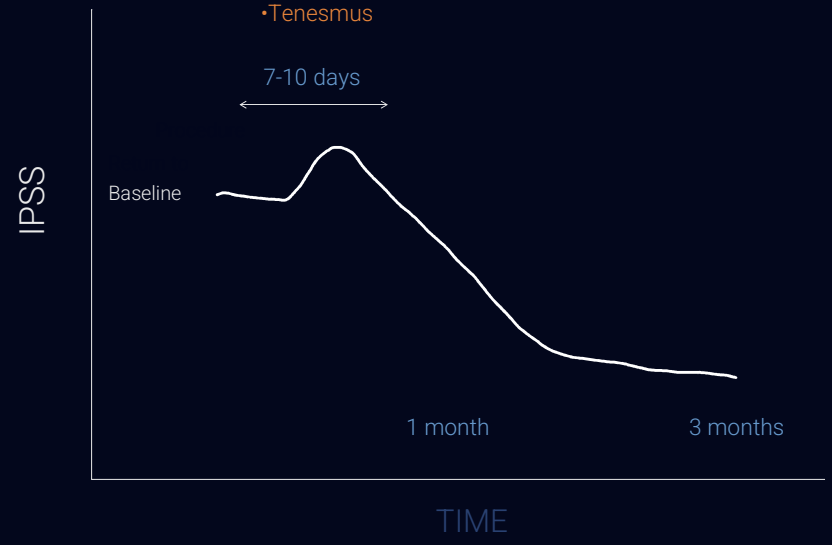

AQUABEAM
COMPREHENSIVE MEN'S HEALTH CARE

	Advantages	Disadvantages
Medications	Non-Invasive	Side Effects Cost Compliance
TURP	Long Term Efficacy Largest increase in flow rates	Surgical Risk Retrograde Ejaculation Catheter Hospitalization Cost
Urolift	Office Based No Impact on Erectile Function Non-Anesthesia	Shorter Term Results Limited to Size < 80 cc
Rezum	Office/ASC Based No Impact on Erectile Function	Shorter Term Results Limited to Size < 80 cc Post Rezum Pain Syndrome
PAE	Office Based Longer Term than MISTs No Impact on Erectile Function No Penile Route of Treatment No Upper Limit on Gland Size	Limited Effectiveness in < 50 cc Shorter Term than TURP
Aquablation	Increased Flow Rate Response Similar to TURP Results Low Likelihood of Ejaculatory Effect	Bleeding Risk Hospital-Based Post procedure Urgency Size Limited



What is Recovery?

- Frequency
- Nocturia
- Dysuria
- Tenesmus



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EVIDENCE-BASED REVIEW

Minimally Invasive Treatments for Benign Prostatic Hyperplasia: Systematic Review and Network Meta-Analysis

Abin Sajan, MD, Tej Mehta, MD, Pratik Desai, MD, Ari Isaacson, MD, and Sandeep Bagla, MD

ABSTRACT

Purpose: To review and indirectly compare the outcomes of minimally invasive therapies for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia.

Materials and Methods: A literature search via Medline and Cochrane Central databases was completed for randomized control studies published between January 2000 to April 2020 for the following therapies: Rezum, Urolift, Aquablation, and prostatic artery embolization (PAE). Data on the following variables were included: International prostate symptom score (IPSS), maximum urinary flow rate, quality of life, and postvoid residual (PVR). Standard mean differences between treatments were compared through a meta-analysis using transurethral resection of the prostate (TURP) to assess differences in treatment effect.

Results: There was no significant difference in outcomes between therapies for IPSS at the 3, 6, and 12-month follow ups. Although outcomes for Rezum were only available out to 3 months, there were no consistently significant differences in outcomes when comparing Aquablation versus PAE versus Rezum. TURP PVR was significantly better than Urolift at 3, 6, and 12 months. No significant differences in minor or major adverse events were noted.

Conclusion: Although significant differences in outcomes were limited, Aquablation and PAE were the most durable at 12 months. PAE has been well studied on multiple randomized control trials with minimal adverse events while Aquablation has limited high quality data and has been associated with bleeding-related complications.

ABBREVIATIONS

AE = adverse events, AUA = American Urological Association, BPH = benign prostatic hyperplasia, CI = confidence interval, IPSS = international prostate symptom score, IRR = incidence rate ratio, MIST = minimally invasive surgical therapies, PAE = prostatic artery embolization, PVR = postvoid residual, QoL = quality of life, RCT = randomized controlled trials, SMD = standardized mean difference, TURP = transurethral resection of the prostate

Minimally invasive surgical therapies (MISTs) have been developed to relieve symptomatic benign prostatic hyperplasia (BPH) to offer both in-office and ambulatory alternatives to transurethral resection of the prostate (TURP). Other advantages of MISTs include lower erectile or ejaculatory side effects and a potentially faster recovery time (1,2). Some of these therapies include Rezum, Urolift, Aquablation and prostatic artery embolization (PAE). While these techniques have been compared to TURP or sham in limited clinical studies (3–5), there is a paucity of high-level evidence comparing the MISTs to one another (3–6).

Preliminary comparisons between TURP and MISTs suggest that the major advantages of Urolift and Rezum include the preservation of erectile and ejaculatory function (7). Unlike Urolift, Rezum, or PAE, Aquablation requires general anesthesia and has been considered similar in mechanism to TURP (8). Although PAE demonstrates similar urinary domain scores, such as international prostate symptom score (IPSS), maximum urinary flow rate (Qmax), quality of life (QoL), and postvoid residual (PVR), compared with TURP in multiple randomized control trials (RCTs), the American Urological Association (AUA) considers PAE an experimental procedure with limited research and citations in PAE (9). Alternatively, the AUA recommends Rezum, Urolift, and Aquablation in the appropriate clinical setting despite similarities in scientific evidence presented for PAE, Rezum, Urolift, and Aquablation. The aim of this systematic review and meta-analysis was to investigate the comparative effectiveness of these MISTs from published RCTs.

Figures E1 to E16 can be found by accessing the online version of this article at www.jvir.org and clicking on the Supplemental Material tab.

J Vasc Interv Radiol 2022; xxx:1–9
https://doi.org/10.1016/j.jvir.2021.12.029

The Evidence

Six RCT's comparing PAE to TURP have demonstrated substantial symptomatic reduction with less Adverse Events than TURP

When a patient demonstrates severe LUTS (IPSS>19), PAE consistently reduces IPSS by 10-15 points

The mean durability of symptomatic relief after PAE is 5-7 years, based on longitudinal data sets

In most well performed studies, PAE has no effect on Erectile Function or Ejaculatory Function

In a Randomized Sham Controlled Study, PAE produced a substantially greater effect on IPSS reduction than Sham

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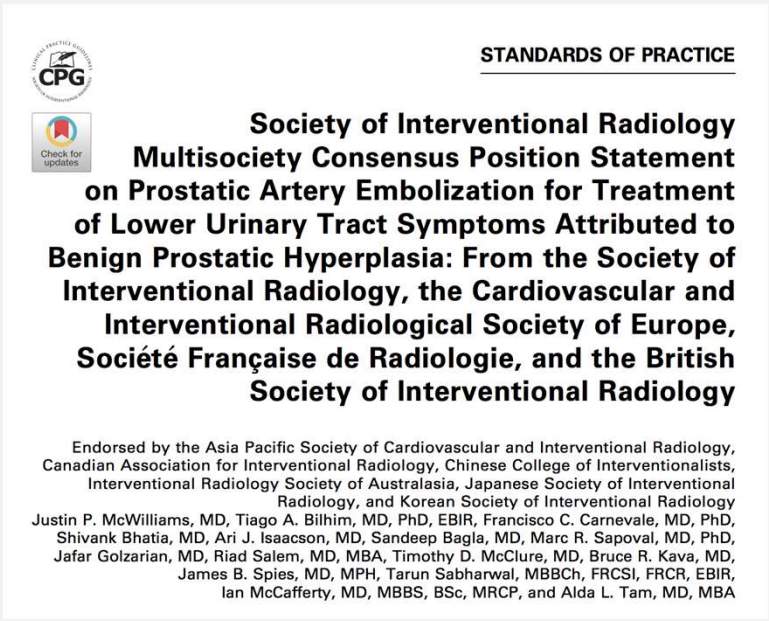


STANDARDS OF PRACTICE

Society of Interventional Radiology Multisociety Consensus Position Statement on Prostatic Artery Embolization for Treatment of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: From the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, Société Française de Radiologie, and the British Society of Interventional Radiology

Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology

Justin P. McWilliams, MD, Tiago A. Bilhim, MD, PhD, EBIR, Francisco C. Carnevale, MD, PhD, Shivank Bhatia, MD, Ari J. Isaacson, MD, Sandeep Bagla, MD, Marc R. Sapoval, MD, PhD, Jafar Golzarian, MD, Riad Salem, MD, MBA, Timothy D. McClure, MD, Bruce R. Kava, MD, James B. Spies, MD, MPH, Tarun Sabharwal, MBBCh, FRCSI, FRCR, EBIR, Ian McCafferty, MD, MBBS, BSc, MRCP, and Alda L. Tam, MD, MBA

Prostatic Artery Embolization

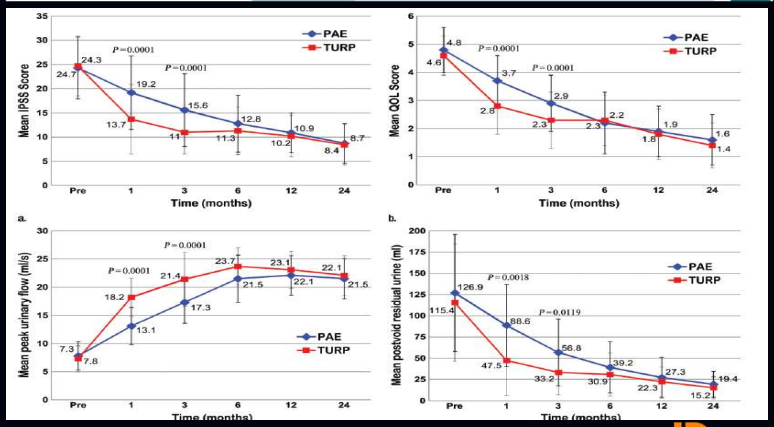
State of the Art to Standard of Care

Clinical Data

- 57 PAE vs 57 TURP→24 mo F/U
- PAE 15.6 IPSS, 3.2 QoL
- IPSS, QoL, Qmax, PVR equivalent @ 12, 24 mos
- PAE more adverse events
  - 52.6% v 29.8% P=0.03
- Signifcantly fewer pts requiring foley catheter or hospital stay with PAE
  - 2.9 v 4.8 days P<0.001
- Retreatment rates: 9% PAE vs 3.8% TURP
- No assessment of sexual function

Benign Prostatic Hyperplasia:
Prostatic Arterial Embolization versus Transurethral Resection of the Prostate—A Prospective, Randomized, and Controlled Clinical Trial[1]

Radiology



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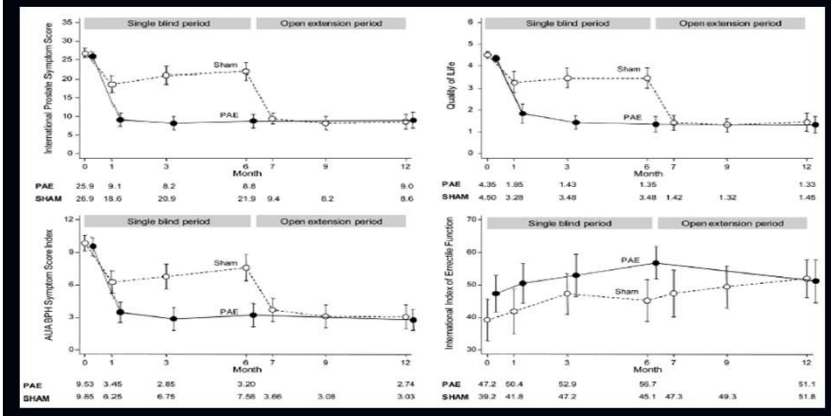
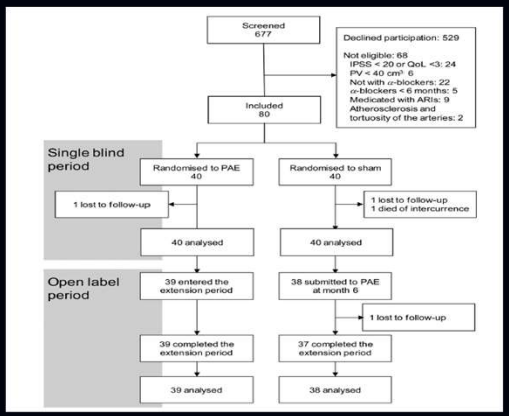
Randomised Clinical Trial of Prostatic Artery Embolisation Versus a Sham Procedure for Benign Prostatic Hyperplasia

João Martins Pisco[a,y], Tiago Bilhim[a,b,c], Nuno V. Costa[a,b,c], Daniel Torres[a,b,c], Joana Pisco[a], Luis Campos Pinheiro[c,d], Antonio Gouveia Oliveira[e,*]





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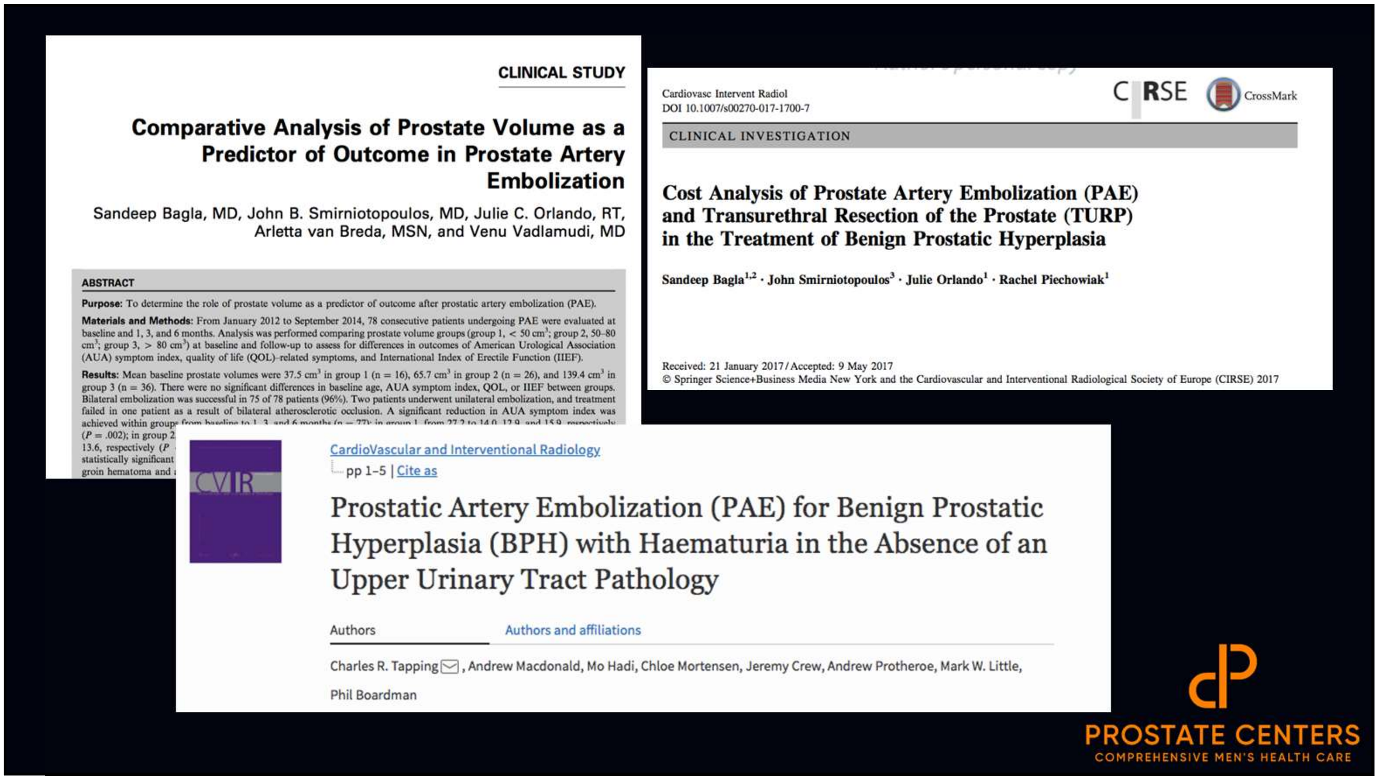


CLINICAL STUDY

Comparative Analysis of Prostate Volume as a Predictor of Outcome in Prostate Artery Embolization

Sandeep Bagla, MD, John B. Smirniotopoulos, MD, Julie C. Orlando, RT, Arletta van Breda, MSN, and Venu Vadlamudi, MD

ABSTRACT

Purpose: To determine the role of prostate volume as a predictor of outcome after prostatic artery embolization (PAE).

Materials and Methods: From January 2012 to September 2014, 78 consecutive patients undergoing PAE were evaluated at baseline and 1, 3, and 6 months. Analysis was performed comparing prostate volume groups (group 1, < 50 cm^3; group 2, 50–80 cm^3; group 3, > 80 cm^3) at baseline and follow-up to assess for differences in outcomes of American Urological Association (AUA) symptom index, quality of life (QOL)–related symptoms, and International Index of Erectile Function (IIEF).

Results: Mean baseline prostate volumes were 37.5 cm^3 in group 1 (n = 16), 65.7 cm^3 in group 2 (n = 26), and 139.4 cm^3 in group 3 (n = 36). There were no significant differences in baseline age, AUA symptom index, QOL, or IIEF between groups. Bilateral embolization was successful in 75 of 78 patients (96%). Two patients underwent unilateral embolization, and treatment failed in one patient as a result of bilateral atherosclerotic occlusion. A significant reduction in AUA symptom index was achieved within groups ... (P = .002); in group 2 ... 13.6, respectively (P ... statistically significant ... groin hematoma and ...

Cardiovasc Intervent Radiol
DOI 10.1007/s00270-017-1700-7

CIRSE CrossMark

CLINICAL INVESTIGATION

Cost Analysis of Prostate Artery Embolization (PAE) and Transurethral Resection of the Prostate (TURP) in the Treatment of Benign Prostatic Hyperplasia

Sandeep Bagla[1,2] · John Smirniotopoulos[3] · Julie Orlando[1] · Rachel Piechowiak[1]

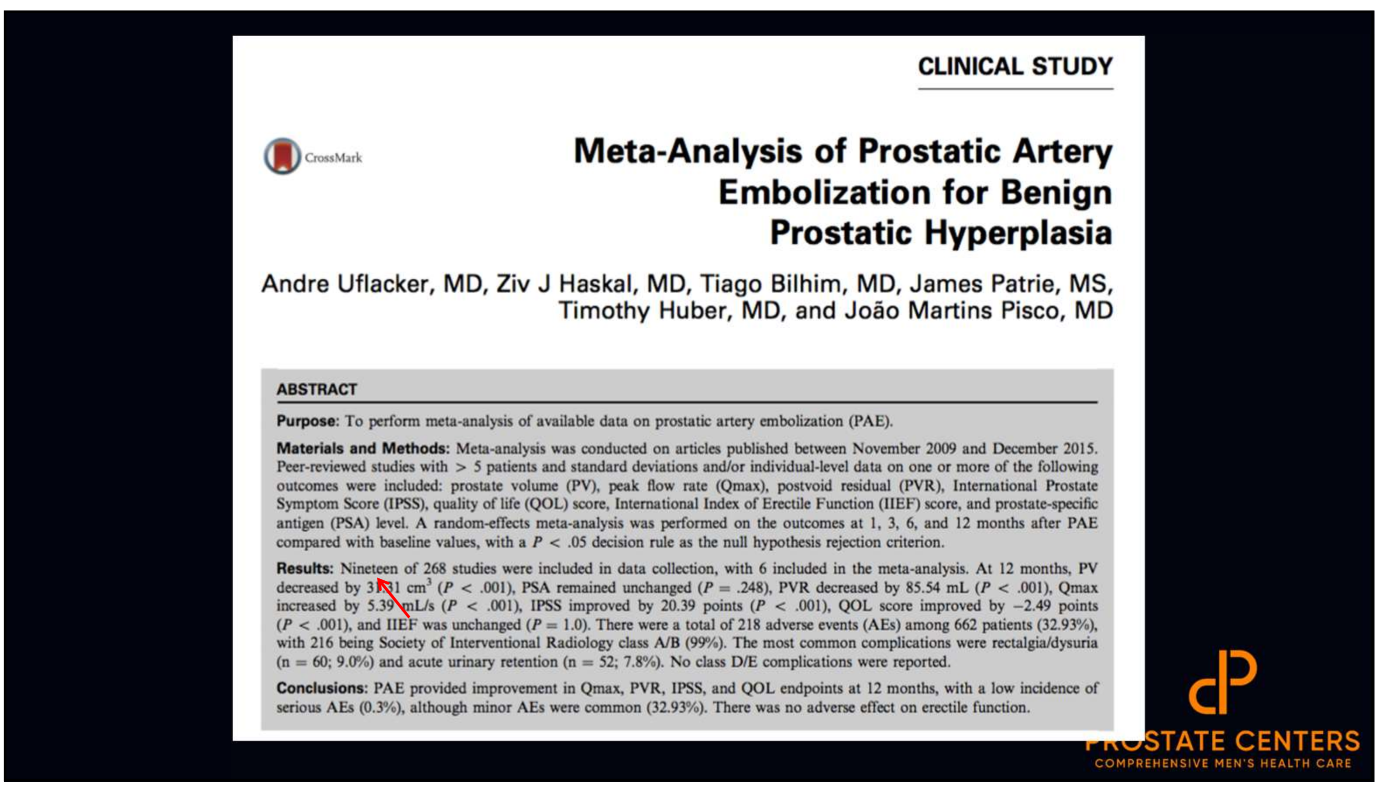
Received: 21 January 2017 / Accepted: 9 May 2017
© Springer Science+Business Media New York and the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) 2017

CardioVascular and Interventional Radiology
pp 1–5 | Cite as

Prostatic Artery Embolization (PAE) for Benign Prostatic Hyperplasia (BPH) with Haematuria in the Absence of an Upper Urinary Tract Pathology

Authors | Authors and affiliations

Charles R. Tapping, Andrew Macdonald, Mo Hadi, Chloe Mortensen, Jeremy Crew, Andrew Protheroe, Mark W. Little, Phil Boardman



CLINICAL STUDY

CrossMark

Meta-Analysis of Prostatic Artery Embolization for Benign Prostatic Hyperplasia

Andre Uflacker, MD, Ziv J Haskal, MD, Tiago Bilhim, MD, James Patrie, MS, Timothy Huber, MD, and João Martins Pisco, MD

ABSTRACT

Purpose: To perform meta-analysis of available data on prostatic artery embolization (PAE).

Materials and Methods: Meta-analysis was conducted on articles published between November 2009 and December 2015. Peer-reviewed studies with > 5 patients and standard deviations and/or individual-level data on one or more of the following outcomes were included: prostate volume (PV), peak flow rate (Qmax), postvoid residual (PVR), International Prostate Symptom Score (IPSS), quality of life (QOL) score, International Index of Erectile Function (IIEF) score, and prostate-specific antigen (PSA) level. A random-effects meta-analysis was performed on the outcomes at 1, 3, 6, and 12 months after PAE compared with baseline values, with a $P < .05$ decision rule as the null hypothesis rejection criterion.

Results: Nineteen of 268 studies were included in data collection, with 6 included in the meta-analysis. At 12 months, PV decreased by 31.31 cm^3 ($P < .001$), PSA remained unchanged ($P = .248$), PVR decreased by 85.54 mL ($P < .001$), Qmax increased by 5.39 mL/s ($P < .001$), IPSS improved by 20.39 points ($P < .001$), QOL score improved by –2.49 points ($P < .001$), and IIEF was unchanged ($P = 1.0$). There were a total of 218 adverse events (AEs) among 662 patients (32.93%), with 216 being Society of Interventional Radiology class A/B (99%). The most common complications were rectalgia/dysuria (n = 60; 9.0%) and acute urinary retention (n = 52; 7.8%). No class D/E complications were reported.

Conclusions: PAE provided improvement in Qmax, PVR, IPSS, and QOL endpoints at 12 months, with a low incidence of serious AEs (0.3%), although minor AEs were common (32.93%). There was no adverse effect on erectile function.

Table 1. Data Summary (5,8,11,14,16,17)

	Summary Demographic Data					
Study	No. of Pts.	Unilateral PAE (%)	Embolic Agent	Particle Size (μm)	Country of Origin	Mean Age (y)
Pisco et al (5)	250	18	PVA	100–200	Portugal	65.5
Bagla et al (8)	77	2.60	Embozene	100–400	United States	65.2
Carnevale et al (11)	11	18.18	Embosphere	300–500	Brazil	68.5
Wang et al (14)	109	0	PVA	50 and 100	China	71.5
Li et al (16)	22	13.64	PVA	50 and 100	China	74.5
Grosso et al (17)	12	25	Embozene	300–500	Italy	75.9

IIEF = International Index of Erectile Function, IPSS = International Prostate Symptom Score, PAE = p
volume, PVA = polyvinyl alcohol, PVR = postvoid residual, Qmax = maximum urinary flow rate, QOL

Baseline Outcome Parameters							
UR (%)	PV (cm^3)	Qmax (mL/s)	PVR (mL)	IPSS	QOL Score	IIEF Score	PSA (ng/mL)
13	83.5	9.2	102.9	24	4.4	18.9	5.68
0	93.89	7.11	NR	26.3	4.9	14	4.7
100	69.7	4.2	NR	NR	6	NR	9.8
0	118	8.5	125	26	5	11	4
0	110	6	140	27	4.5	20	3.8
58	87.4	NR	NR	29.25	4.33	8.83	NR

rostatic artery embolization, PSA = prosta pecific antigen, PV = prostate
= quality of life, UR = urinary retention.

PROSTATE CENTERS
COMPREHENSIVE MEN'S HEALTH CARE

Table 3. IPSS Study-Specific Effects (ie, Change from Baseline Δ) and Summary-Weighted Average Effect (Δ Points) (5,8,14,16,17)

Study	No. of Pts.	Effect	LCL	UCL	Weight*
Month 1					
Pisco et al (5)	236	−11.69	−12.77	−10.61	0.209
Wang et al (14)	105	−16.50	−17.91	−15.09	0.204
Li et al (16)	20	−15.00	−18.12	−11.88	0.163
Bagla et al (8) 1	14	−13.20	−17.28	−9.12	0.138
Bagla et al (8) 2	21	−8.46	−12.83	−4.09	0.131
Bagla et al (8) 3	31	−11.27	−14.70	−7.84	0.155
Summary	427	−12.93	−15.44	−10.42	$P^{\dagger}$ < .001
$\tau^{2\ddagger}$			7.55 (P < .001)		
$I^{2\S}$			86.0% (95% CI, 71.6%-93.1%)		
Month 3					
Grosso et al (17)	10	−13.40	−18.36	−8.44	0.109
Pisco et al (5)	221	−12.98	−14.08	−11.88	0.181
Wang et al (14)	60	−17.50	−19.01	−15.99	0.175
Li et al (16)	20	−20.00	−22.49	−17.51	0.158
Bagla et al (8) 1	13	−15.28	−19.40	−11.16	0.125
Bagla et al (8) 2	17	−9.31	−14.52	−4.10	0.104
Bagla et al (8) 3	28	−13.96	−17.00	−10.92	0.147
Summary	369	−14.98	−17.51	−12.45	$P^{\dagger}$ < .001
$\tau^{2\ddagger}$			8.92 (P < .001)		
$I^{2\S}$			86.5% (95% CI, 74.3%-93.0%)		
Month 6					
Grosso et al (17)	5	−17.20	−26.53	−7.87	0.064
Pisco et al (5)	167	−12.88	−14.27	−11.49	0.192
Wang et al (14)	60	−18.50	−20.13	−16.87	0.189
Li et al (16)	15	−19.00	−21.72	−16.28	0.170
Bagla et al (8) 1	11	−11.29	−17.19	−5.39	0.108
Bagla et al (8) 2	14	−12.10	−16.98	−7.22	0.127
Bagla et al (8) 3	19	−12.92	−16.66	−9.18	0.150
Summary	291	−15.00	−17.84	−12.15	$P^{\dagger}$ < .001
$\tau^{2\ddagger}$			10.45 (P < .001)		
$I^{2\S}$			84.5% (95% CI, 69.8%-92.0%)		
Month 12					
Grosso et al (17)	2	−29.50	−30.48	−28.52	0.254
Pisco et al (5)	101	−14.45	−16.17	−12.73	0.252
Wang et al (14)	54	−18.00	−19.78	−16.22	0.252
Li et al (16)	10	−19.50	−23.22	−15.78	0.243
Summary	167	−20.39	−28.79	−11.98	$P^{\dagger}$ < .001
$\tau^{2\ddagger}$			72.21 (P < .001)		
$I^{2\S}$			99.0% (95% CI, 98.4%-99.3%)		

PROSTATE CENTERS
COMPREHENSIVE MEN'S HEALTH CARE

Study ID	Method	Patient Characteristics	Intervention(s)	Results primary outcome	Results secondary and other outcomes	Level of Evidence & Journal	Summary
Bilhim T, Pisco J, Campos Pinheiro L, Rio Tinto H, Fernandes L, Pereira JA, Duarte M, Oliveira AG. Does polyvinyl alcohol particle size change the outcome of prostatic arterial embolization for benign prostatic hyperplasia? Results from a single center randomized prospective study. J Vasc Interv Radiol. 2013 Nov;24(11):1595-602.e1. doi: 10.1016/j.jvir.2013.06.003. Epub 2013 Aug 3. PMID: 23916874.	Design: Prospective Randomized Study N = 80 Primary Outcome: IPSS and QoL Funding: None	Group 1: 40 patients. Age: 64.4 ± 6.9 IPSS: 22.8 ± 4.8 Group 2: 40 patients. Age: 63.4 ± 6.8 IPSS: 22.7 ± 5.1	Group 1: Mean 100 µm PVA Prostate Artery Embolization Group 2: Mean 200 µm PVA Prostate Artery Embolization	IPSS: Group 2 had a greater decrease in IPSS (3.64 points; 95% CI, −0.03 to 7.31; P = .052). QoL: Group 2 had a greater decrease in QoL severity score (0.57 points; 95% CI, −0.06 to 1.20; P = .07).	PSA: Group 1 had significantly greater decrease in PSA level (2.09 ng/mL; 95% CI, 0.96–3.21; P < .001). AEs: No major adverse events in either group.	Level of Evidence: Level II. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2013	100um PVA particles resulted in greater prostate volume reduction than 200um without additional adverse events. However, 200 um particles resulted in better clinical outcomes.
Gao YA, Huang Y, Zhang R, Yang YD, Zhang Q, Hou M, Wang Y. Benign prostatic hyperplasia: prostatic arterial embolization versus transurethral resection of the prostate--a prospective, randomized, and controlled clinical trial. Radiology. 2014 Mar;270(3):920-8. doi: 10.1148/radiol.13122803. Epub 2013 Nov 13. PMID: 24475799.	Design: Prospective Randomized Study N = 114 Primary Outcome: IPSS, QoL, Qmax, PVR Funding: None	Group 1: 57 patients. Age: 67.7 ± 8.7 IPSS: 22.8 ± 5.9 Group 2: 57 patients. Age: 66.4 ± 7.8 IPSS: 23.1 ± 5.8	Group 1: Prostate Artery Embolization Group 2: Transurethral Resection of the Prostate	Functional Outcomes (IPSS, QoL, Qmax, PVR): Comparable improvements between PAE and TURP. Degree of Improvement was higher with TURP.	AEs: PAE: 22 minor and 8 major AEs TURP: 13 minor and 4 major AEs TURP: Significantly longer hospital stay (p<0.001) and higher risk of blood loss (p<0.001).	Level of Evidence: Level II. *Radiology* Impact Factor: 11.1 2013	RCT comparing PAE to TURP demonstrated similar symptomatic reduction starting at 6 months follow-up out to 2 years.
Carnevale FC, Iscaife A, Yoshinaga EM, Moreira AM, Antunes AA, Srougi M. Transurethral Resection of the Prostate (TURP) Versus Original and PErfecTED Prostate Artery Embolization (PAE) Due to Benign Prostatic Hyperplasia (BPH): Preliminary Results of a Single Center, Prospective, Urodynamic-Controlled Analysis. Cardiovasc Intervent Radiol. 2016 Jan;39(1):44-52. doi: 10.1007/s00270-015-1202-4. Epub 2015 Oct 27. PMID: 26506952.	Design: Prospective Randomized Study N = 45 Primary Outcome: IPSS, QoL, Qmax, PVR Funding: None	Group 1: 15 patients. Age: 66.4 ± 5.6 IPSS: 27.6 ± 3.2 Group 2: 15 patients. Age: 63.5 ± 8.7 IPSS: 25.3 ± 3.6 Group 3: 15 patients. Age: 60.4 ± 5.2 IPSS: 24.6 ± 3.6	Group 1: Transurethral Resection of the Prostate Group 2: Prostate Artery Embolization Group 3: Proximal Embolization First, Then Embolize Distal technique (PErfecTED)	Functional Outcomes (IPSS, QoL, Qmax, PVR): All parameters were significantly improved with TURP, PAE, and PErfecTED. TURP and PErfecTED resulted in significantly lower IPSS than PAE. TURP resulted in significantly better Qmax and PV than PErfecTED or PAE.	AEs: No major adverse events with TURP or PErfecTED. TURP: Significantly longer hospital stay (p<0.0001). TURP Major AE: Rupture of the prostatic capsule and readmission for hematuria.	Level of Evidence: Level II. *CardioVascular and Interventional Radiology* Impact Factor: 1.9 2016	Outcomes after TURP were superior to outcomes after "original" PAE. However, "Perfected" PAE outcomes were similar to TURP.

Study ID	Method	Patient Characteristics	Intervention(s)	Results primary outcome	Results secondary and other outcomes	Level of Evidence & Journal	Summary
Abt D, Hechelhammer L, Müllhaupt G, Markart S, Güsewell S, Kessler TM, Schmid HP, Engeler DS, Mordasini L. Comparison of prostatic artery embolisation (PAE) versus transurethral resection of the prostate (TURP) for benign prostatic hyperplasia: randomised, open label, non-inferiority trial. BMJ. 2018 Jun 19;361:k2338. doi: 10.1136/bmj.k2338. PMID: 29921613; PMCID: PMC6006990.	Prospective Randomized Study N = 103 patients Primary Outcome: IPSS Funding: None	Group 1: 48 patients. Age: 65.7 ± 9.3 IPSS: 19.4 ± 6.4 Group 2: 51 patients. Age: 66.1 ± 9.8 IPSS: 17.6 ± 6.2	Group 1: Prostate Artery Embolization Group 2: Transurethral Resection of the Prostate	IPSS: PAE: -9.2 reduction in IPSS at 12 weeks. TURP: -10.8 reduction in IPSS at 12 weeks.	Qmax, PSA, and PVR: No significant overall difference. AEs: No major AEs between groups. TURP: Significantly shorter procedure time. PAE: Significantly better blood loss and hospital stay.	Level of Evidence: Level II. *The British Medical Journal* Impact Factor: 39.9 2018	When compared to TURP in RCT, PAE was inferior, but still resulted in substantial symptomatic reduction with fewer AE's compared to TURP
Wang MQ, Zhang JL, Xin HN, Yuan K, Yan J, Wang Y, Zhang GD, Fu JX. Comparison of Clinical Outcomes of Prostatic Artery Embolization with 50-µm Plus 100-µm Polyvinyl Alcohol (PVA) Particles versus 100-µm PVA Particles Alone: A Prospective Randomized Trial. J Vasc Interv Radiol. 2018 Dec;29(12):1694-1702. doi: 10.1016/j.jvir.2018.06.019. Epub 2018 Oct 5. PMID: 30297313.	Prospective Randomized Study N = 110 patients Primary Outcome: IPSS, QoL, Qmax, PVR Funding: None	Group 1: 55 patients. Age: 67.5 ± 10.5 IPSS: 25.0 ± 5.5 Group 2: 55 patients. Age: 68.0 ± 11.5 IPSS: 24.5 ± 6.5	Randomized Allocation Group 1: 50-µm + 100-µm PVA Prostate Artery Embolization Group 2: 100-µm PVA Prostate Artery Embolization	Functional Outcomes (IPSS, QoL, Qmax, PVR): No significant difference in IPSS, QoL, Qmax, and QoL.	AEs: No major complications. IIEF: No significant difference between groups.	Level of Evidence: Level II. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2018	There was no significant difference in clinical outcomes when comparing 50 + 100 um PVA vs 100 um PVA alone.
Torres D, Costa NV, Pisco J, Pinheiro LC, Oliveira AG, Bilhim T. Prostatic Artery Embolization for Benign Prostatic Hyperplasia: Prospective Randomized Trial of 100-300 µm versus 300-500 µm versus 100- to 300-µm + 300- to 500-µm Embospheres. J Vasc Interv Radiol. 2019 May;30(5):638-644. doi: 10.1016/j.jvir.2019.02.014. PMID: 31029381.	Prospective Randomized Study N = 138 patients Primary Outcome: IPSS and QoL Funding: None	Group 1: 43 patients. Age: 67.5 ± 8.9 IPSS: 23.0 ± 5.6 Group 2: 46 patients. Age: 65.9 ± 7.9 IPSS: 23.0 ± 5.2 Group 2: 48 patients. Age: 65.1 ± 8.4 IPSS: 24.2 ± 4.9	Group 1: 100-300 µm Prostate Artery Embolization Group 2: 300-500 µm Prostate Artery Embolization Group 3: 100-500 µm Prostate Artery Embolization	IPSS and QoL: No significant difference in outcomes between the groups.	AEs: No major adverse events. PVR, Qmax, PSA, IIEF: No significant difference in outcomes between groups.	Level of Evidence: Level II. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2019	There was no significant difference in clinical outcomes between the 3 groups. However, there was a higher rate of minor AEs when embolization was performed with the smaller particles alone.

Study ID	Method	Patient Characteristics	Intervention(s)	Results primary outcome	Results secondary and other outcomes	Level of Evidence & Journal	Summary
Bilhim T, Costa NV, Torres D, Pisco J, Carmo S, Oliveira AG. Randomized Clinical Trial of Balloon Occlusion versus Conventional Microcatheter Prostatic Artery Embolization for Benign Prostatic Hyperplasia. J Vasc Interv Radiol. 2019 Nov;30(11):1798-1806. doi: 10.1016/j.jvir.2019.06.019. Epub 2019 Oct 3. PMID: 31587950.	Prospective Randomized Study N = 89 patients Primary Outcome: IPSS Funding: None	Group 1: 43 patients Age: 67.3 ± 8.02 IPSS: 20.0 ± 6.6 Group 2: 46 patients. Age: 65.8 ± 7.93 IPSS: 20.6 ± 6.7	Group 1: Conventional Microcatheter Prostate Artery Embolization Group 2: Balloon Occlusion Prostatic Artery Embolization	IPSS: No significant difference between groups.	QoL, IIEF, Qmax, PVR, PSA: No significant difference between groups. AEs: No major adverse events.	Level of Evidence: Level II. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2019	There was no significant difference in clinical efficacy for conventional versus balloon occlusion embolization for PAE. However, there were more AEs with conventional embolization.
Pisco JM, Bilhim T, Costa NV, Torres D, Pisco J, Pinheiro LC, Oliveira AG. Randomised Clinical Trial of Prostatic Artery Embolisation Versus a Sham Procedure for Benign Prostatic Hyperplasia. Eur Urol. 2020 Mar;77(3):354-362. doi: 10.1016/j.eururo.2019.11.010. Epub 2019 Dec 10. PMID: 31831295.	Prospective Randomized Study N = 80 patients Primary Outcome: IPSS and QoL Funding: None	Group 1: 40 patients Age: 64.0 IPSS: 27.5 Group 2: 40 patients. Age: 64.0 IPSS: 25.5	Group 1: Sham Embolization Group 2: Prostate Artery Embolization	IPSS: Significantly decrease with PAE (p < 0.0001). QoL: Significantly greater with Sham (p < 0.0001).	BPH-II, PSA, Qmax, PVR, PV: Significantly greater improvement with PAE. AEs: 1 major AE: hematuria treated with TURP.	Level of Evidence: Level II. *European Urology* Impact Factor: 17.6 2019	The symptomatic improvement after PAE was significantly greater than after a sham procedure.
Zhang JL, Wang MQ, Shen YG, Ye HY, Yuan K, Xin HN, Zhang HT, Fu JX, Yan JY, Wang Y. Effectiveness of Contrast-enhanced MR Angiography for Visualization of the Prostatic Artery prior to Prostatic Arterial Embolization. Radiology. 2019 May;291(2):370-378. doi: 10.1148/radiol.2019181524. Epub 2019 Feb 26. PMID: 30806596.	Prospective Randomized Study N = 100 patients Primary Outcome: Procedural Time, Radiation Dose, IPSS Funding: None	Group 1: 50 patients Age: 71.7 ± 11.9 IPSS: 24.7 ± 5.7 Group 2: 50 patients. Age: 72.3 ± 12.2 IPSS: 24.9 ± 5.3	Group 1: Prostate Artery Embolization without MR Angiography Group 2: Prostate Artery Embolization with MR Angiography	Time and Dose: Significant reduction in procedure time and radiation dose with MRA before PAE. IPSS: No significant difference between groups.	Contrast Volume: No significant difference between groups. QoL, Qmax, P, and PVR: No significant difference between groups. AEs: No major adverse events.	Level of Evidence: Level II. *Radiology* Impact Factor: 11.1 2019	Obtaining pre-PAE MRA of the pelvis reduced procedure time and procedural radiation dose compared to not obtaining MRA.
Insausti I, Sáez de Ocáriz A, Galbete A, Capdevila F, Solchaga S, Giral P, Bilhim T, Isaacson A, Urtasun F, Napal S. Randomized Comparison of Prostatic Artery Embolization versus Transurethral Resection of the Prostate for Treatment of Benign Prostatic Hyperplasia. J Vasc Interv Radiol. 2020 Jun;31(6):882-890. doi: 10.1016/j.jvir.2019.12.810. Epub 2020 Apr 2. PMID: 32249193.	Prospective Randomized Study N = 45 patients Primary Outcome: IPSS and Qmax Funding: None	Group 1: 23 patients Age: 72.4 ± 6.2 IPSS: 25.8 ± 4.6 Group 2: 22 patients. Age: 71.8 ± 5.5 IPSS: 26.0 ± 7.3	Group 1: Prostate Artery Embolization Group 2: Transurethral Resection of the Prostate	IPSS: No significant difference between groups. Qmax: No significant difference between groups.	QoL: Significantly improved with PAE. PV and PSA: Significantly greater improvement with TURP. AEs: TURP Major AE: urethral stricture treated with dilation. Minor AEs: Significantly more minor AEs with TURP.	Level of Evidence: Level II. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2020	When compared to TURP in an RCT, PAE resulted in greater symptomatic reduction.

Study ID	Method	Patient Characteristics	Intervention(s)	Results primary outcome	Results secondary and other outcomes	Level of Evidence & Journal	Summary
Torres D, Costa NV, Pisco J, Pinheiro LC, Oliveira AG, Bilhim T. Prostatic Artery Embolization for Benign Prostatic Hyperplasia: Prospective Randomized Trial of 100-300 µm versus 300-500 µm versus 100- to 300-µm + 300- to 500-µm Embospheres. J Vasc Interv Radiol. 2019 May;30(5):638-644. doi: 10.1016/j.jvir.2019.02.014. PMID: 31029381.	Prospective Randomized Study N = 138 patients Primary Outcome: IPSS and QoL Funding: None	Group 1: 43 patients. Age: 67.5 ± 8.9 IPSS: 23.0 ± 5.6 Group 2: 46 patients. Age: 65.9 ± 7.9 IPSS: 23.0 ± 5.2 Group 2: 48 patients. Age: 65.1 ± 8.4 IPSS: 24.2 ± 4.9	Group 1: 100-300 µm Prostate Artery Embolization Group 2: 300-500 µm Prostate Artery Embolization Group 3: 100-500 µm Prostate Artery Embolization	IPSS and QoL: No significant difference in outcomes between the groups.	AEs: No major adverse events. PVR, Qmax, PSA, IIEF: No significant difference in outcomes between groups.	Level of Evidence: Level II. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2019	There was no significant difference in clinical outcomes between the 3 groups. However, there was a higher rate of minor AEs when embolization was performed with the smaller particles alone.
Bilhim T, Costa NV, Torres D, Pisco J, Carmo S, Oliveira AG. Randomized Clinical Trial of Balloon Occlusion versus Conventional Microcatheter Prostatic Artery Embolization for Benign Prostatic Hyperplasia. J Vasc Interv Radiol. 2019 Nov;30(11):1798-1806. doi: 10.1016/j.jvir.2019.06.019. Epub 2019 Oct 3. PMID: 31587950.	Prospective Randomized Study N = 89 patients Primary Outcome: IPSS Funding: None	Group 1: 43 patients Age: 67.3 ± 8.02 IPSS: 20.0 ± 6.6 Group 2: 46 patients. Age: 65.8 ± 7.93 IPSS: 20.6 ± 6.7	Group 1: Conventional Microcatheter Prostate Artery Embolization Group 2: Balloon Occlusion Prostatic Artery Embolization	IPSS: No significant difference between groups.	QoL, IIEF, Qmax, PVR, PSA: No significant difference between groups. AEs: No major adverse events.	Level of Evidence: Level II. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2019	There was no significant difference in clinical efficacy for conventional versus balloon occlusion embolization for PAE. However, there were more AEs with conventional embolization.
Pisco JM, Bilhim T, Costa NV, Torres D, Pisco J, Pinheiro LC, Oliveira AG. Randomised Clinical Trial of Prostatic Artery Embolisation Versus a Sham Procedure for Benign Prostatic Hyperplasia. Eur Urol. 2020 Mar;77(3):354-362. doi: 10.1016/j.eururo.2019.11.010. Epub 2019 Dec 10. PMID: 31831295.	Prospective Randomized Study N = 80 patients Primary Outcome: IPSS and QoL Funding: None	Group 1: 40 patients Age: 64.0 IPSS: 27.5 Group 2: 40 patients. Age: 64.0 IPSS: 25.5	Group 1: Sham Embolization Group 2: Prostate Artery Embolization	IPSS: Significantly decrease with PAE (p < 0.0001). QoL: Significantly greater with Sham (p < 0.0001).	BPH-II, PSA, Qmax, PVR, PV: Significantly greater improvement with PAE. AEs: 1 major AE: hematuria treated with TURP.	Level of Evidence: Level II. *European Urology* Impact Factor: 17.6 2019	The symptomatic improvement after PAE was significantly greater than after a sham procedure.
Zhang JL, Wang MQ, Shen YG, Ye HY, Yuan K, Xin HN, Zhang HT, Fu JX, Yan JY, Wang Y. Effectiveness of Contrast-enhanced MR Angiography for Visualization of the Prostatic Artery prior to Prostatic Arterial Embolization. Radiology. 2019 May;291(2):370-378. doi: 10.1148/radiol.2019181524. Epub 2019 Feb 26. PMID: 30806596.	Prospective Randomized Study N = 100 patients Primary Outcome: Procedural Time, Radiation Dose, IPSS Funding: None	Group 1: 50 patients Age: 71.7 ± 11.9 IPSS: 24.7 ± 5.7 Group 2: 50 patients. Age: 72.3 ± 12.2 IPSS: 24.9 ± 5.3	Group 1: Prostate Artery Embolization without MR Angiography Group 2: Prostate Artery Embolization with MR Angiography	Time and Dose: Significant reduction in procedure time and radiation dose with MRA before PAE. IPSS: No significant difference between groups.	Contrast Volume: No significant difference between groups. QoL, Qmax, P, and PVR: No significant difference between groups. AEs: No major adverse events.	Level of Evidence: Level II. *Radiology* Impact Factor: 11.1 2019	Obtaining pre-PAE MRA of the pelvis reduced procedure time and procedural radiation dose compared to not obtaining MRA.

Study ID	Method	Patient Characteristics	Intervention(s)	Results primary outcome	Results secondary and other outcomes	Level of Evidence & Journal	Summary
Radwan A, Farouk A, Higazy A, Samir YR, Tawfeek AM, Gamal MA. Prostatic artery embolization versus transurethral resection of the prostate in management of benign prostatic hyperplasia. Prostate Int. 2020 Sep;8(3):130-133. doi: 10.1016/j.prnil.2020.04.001. Epub 2020 Apr 23. PMID: 3310239	Prospective Randomized Study N = 60 patients Primary Outcome: IPSS, QoL, Qmax, PVR Funding: None	Group 1: 20 patients Age: 63 years Group 2: 20 patients Age: 63 years Group 3: 20 patients Age: 63 years	Group 1: Monopolar Transurethral Resection of The Prostate Group 2: Bipolar Transurethral Resection of The Prostate Group 3: Prostate Artery Embolization	IPSS: M-TURP and B-TURP demonstrated significantly better IPSS reduction than PAE.	Qmax: M-TURP/B-TURP demonstrated significantly improved Qmax than PAE. Size: Significantly more reduced with M-TURP/B-TURP. PVR: No significant difference between groups.	Level of Evidence: Level II. *Prostate International* Impact Factor: 2.3 2020	Both mono- and bipolar TURP reduced urinary symptoms more significantly than PAE. However, PAE resulted in less AEs.
Abt D, Müllhaupt G, Hechelhammer L, Markart S, Güsewell S, Schmid HP, Mordasini L, Engeler DS. Prostatic Artery Embolisation Versus Transurethral Resection of the Prostate for Benign Prostatic Hyperplasia: 2-yr Outcomes of a Randomised, Open-label, Single-centre Trial. Eur Urol. 2021 Jul;80(1):34-42. doi: 10.1016/j.eururo.2021.02.008. Epub 2021 Feb 19. PMID: 33612376.	Prospective Randomized Study N = 103 patients Primary Outcome: IPSS Funding: None	Group 1: 34 patients. Age: 66.2 ± 9.0 IPSS: 18.9 ± 6.3 Group 2: 47 patients. Age: 66.0 ± 10.0 IPSS: 17.3 ± 5.8	Group 1: Prostate Artery Embolization Group 2: Transurethral Resection of the Prostate	IPSS: PAE w/ 9.2 and TURP w/ 12.1 reduction. TURP significantly better than PAE at 24 months.	Qmax, PVR, and PV: Significantly more improved with TURP. AEs: Minor adverse significantly higher with TURP. No major adverse events.	Level of Evidence: Level II. *European Journal* Impact Factor: 17.6 2021	TURP was superior to PAE in reducing urinary symptoms at 2 year follow-up. However, PAE resulted in less adverse events.
LaRussa S, Pantuck M, Wilcox Vanden Berg R, Gaffney CD, Askin G, McClure T. Symptomatic Improvement of Lower Urinary Tract Symptoms of Benign Prostatic Hyperplasia: A Comparative Systematic Review and Meta-Analysis of 4 Different Minimally Invasive Therapies. J Vasc Interv Radiol. 2021 Sep;32(9):1328-1340.e11. doi: 10.1016/j.jvir.2021.06.019. Epub 2021 Jul 10. PMID: 34256123.	Systematic Review and Meta-Analysis N = 2653 patients Review of Prospective Randomized and Retrospective Studies Funding: None	Prostatic artery embolization (PAE) Photoselective vaporization (PVP) Prostatic urethral lift (PUL) Water vapor thermal therapy (WV).	PAE vs PVP vs PUL vs WV IPSS, QoL, and IIEF-5 compared at 6 and 12 months.	IPSS and QoL: Statistically improved with all 4 therapies. Degree of improvement largest with PVP and PAE.	IIEF-5: Only PAE demonstrated improvement. AEs: N/A.	Level of Evidence: Level I. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2021	Meta-analysis comparing symptomatic improvement after 4 minimally invasive BPH therapies. PAE and PVP demonstrated the greatest effect size

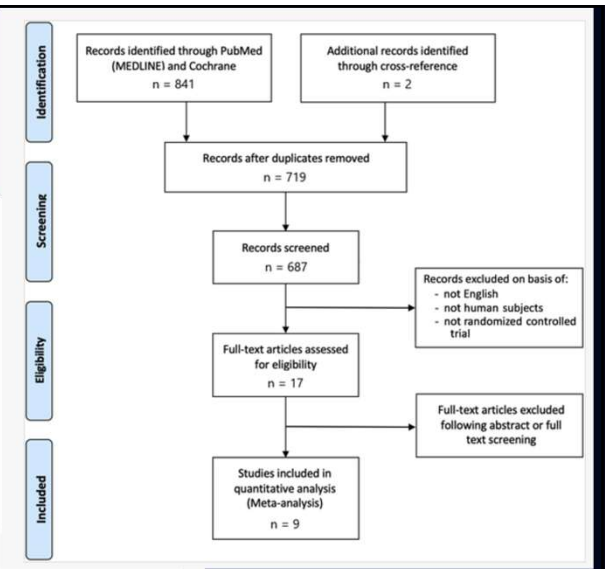
Study ID	Method	Patient Characteristics	Intervention(s)	Results primary outcome	Results secondary and other outcomes	Level of Evidence & Journal	Summary
Dahm P, MacDonald R, McKenzie L, Jung JH, Greer N, Wilt T. Newer Minimally Invasive Treatment Modalities to Treat Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia. Eur Urol Open Sci. 2021 Feb 24;26:72-82. doi: 10.1016/j.euros.2021.02.001. PMID: 34337510; PMCID: PMC8317814.	Systematic Review and Meta-Analysis N = 2653 patients Review of Prospective Randomized and Retrospective Studies Funding: None	Prostatic urethral lift (PUL) Transurethral prostate convective radiofrequency water vapor (Rezūm) Aquablation Prostatic arterial embolization (PAE)	PUL vs Rezum vs Aquablation vs PAE	IPSS: PUL and PAE were most similar in reduction to TURP.	AEs: No significant difference between groups.	Level of Evidence: Level I. *European Urology Open Science* Impact Factor: 1.2 2021	Meta-analysis comparing minimally invasive BPH procedures to TURP concluding that PAE and PUL reduce urinary symptoms most similarly to TURP
Sajan A, Mehta T, Isaacson A, Bagla S, Minimally Invasive Treatments for Benign Prostatic Hyperplasia: Systematic Review and Network Meta-Analysis *Accepted, Pending Publication in JVIR*	Systematic Review and Meta-Analysis N = 1034 patients Review of Prospective Randomized Studies Funding: None	Prostatic artery embolization (PAE) Prostatic urethral lift (PUL) Aquablation Transurethral prostate convective radiofrequency water vapor (Rezūm)	PAE vs PUL vs Aquablation vs Rezum IPSS, Qmax, QoL, PVR at 1, 3, 6, and 12 months Short- and Long-Term AEs	IPSS: No significant difference between groups.	Qmax/QoL: No significant difference between groups. PVR: Urolift significantly worse than Aquablation and PAE. AEs: No significant difference between groups.	Level of Evidence: Level I. *Journal of Vascular and Interventional Radiology* Impact Factor: 2.8 2021	Meta-analysis comparing symptomatic reduction after minimally invasive BPH therapies and concluding that there is no significant difference in effect size.

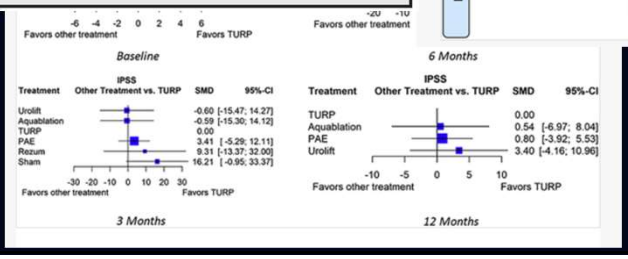
Evidence-Based Review

Minimally Invasive Treatments for Benign Prostatic Hyperplasia: Systematic Review and Network Meta-Analysis

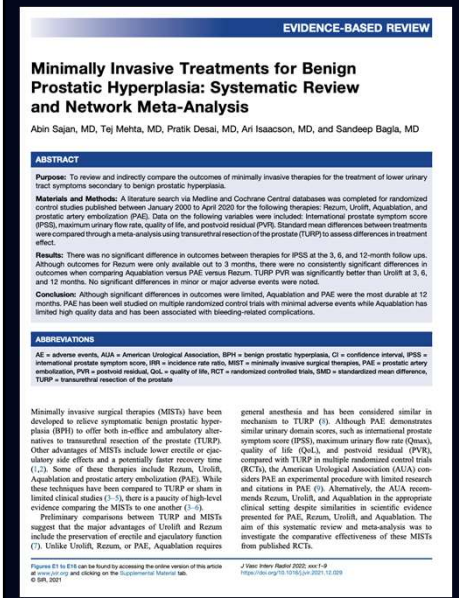
Research Highlights

- The American Urologic Association has recommended against prostatic artery embolization (PAE) while supporting the use of other minimally invasive therapies such as Rezum, Urolift, and Aquablation.
- This meta-analysis of randomized controlled trials studying PAE (N = 5), Rezum (N = 1), Urolift (N = 2), and Aquablation (N = 1) demonstrated no significant differences in international prostate symptom score between these therapies at the 3-, 6-, and 12-month follow ups.
- Aquablation and PAE had the most durable results at 12 months, but Aquablation has been associated with more bleeding adverse events, and had little randomized controlled trial data.





PROSTATE CENTERS
COMPREHENSIVE MEN'S HEALTH CARE



EVIDENCE-BASED REVIEW

Minimally Invasive Treatments for Benign Prostatic Hyperplasia: Systematic Review and Network Meta-Analysis

Abin Sajan, MD, Tej Mehta, MD, Pratik Desai, MD, Ari Isaacson, MD, and Sandeep Bagla, MD

ABSTRACT

Purpose: To review and indirectly compare the outcomes of minimally invasive therapies for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia.

Materials and Methods: A literature search via Medline and Cochrane Central databases was completed for randomized control studies published between January 2000 to April 2020 for the following therapies: Rezum, Urolift, Aquablation, and prostatic artery embolization (PAE). Data on the following variables were included: International prostate symptom score (IPSS), maximum urinary flow rate, quality of life, and postvoid residual (PVR). Standard mean differences between treatments were compared through a meta-analysis using transurethral resection of the prostate (TURP) to assess differences in treatment effect.

Results: There was no significant difference in outcomes between therapies for IPSS at the 3, 6, and 12-month follow ups. Although outcomes for Rezum were only available out to 3 months, there were no consistently significant differences in outcomes when comparing Aquablation versus PAE versus Rezum. TURP PVR was significantly better than Urolift at 3, 6, and 12 months. No significant differences in minor or major adverse events were noted.

Conclusion: Although significant differences in outcomes were limited, Aquablation and PAE were the most durable at 12 months. PAE has been well studied on multiple randomized control trials with minimal adverse events while Aquablation has limited high quality data and has been associated with bleeding-related complications.

ABBREVIATIONS

AE = adverse events, AUA = American Urological Association, BPH = benign prostatic hyperplasia, CI = confidence interval, IPSS = international prostate symptom score, IRR = incidence rate ratio, MIST = minimally invasive surgical therapies, PAE = prostatic artery embolization, PVR = postvoid residual, QoL = quality of life, RCT = randomized controlled trials, SMD = standardized mean difference, TURP = transurethral resection of the prostate

Minimally invasive surgical therapies (MISTs) have been developed to relieve symptomatic benign prostatic hyperplasia (BPH) to offer both in-office and ambulatory alternatives to transurethral resection of the prostate (TURP). Other advantages of MISTs include lower erectile or ejaculatory side effects and a potentially faster recovery time (1,2). Some of these therapies include Rezum, Urolift, Aquablation and prostatic artery embolization (PAE). While these techniques have been compared to TURP or sham in limited clinical studies (3–5), there is a paucity of high-level evidence comparing the MISTs to one another (3–6).

Preliminary comparisons between TURP and MISTs suggest that the major advantages of Urolift and Rezum include the preservation of erectile and ejaculatory function (7). Unlike Urolift, Rezum, or PAE, Aquablation requires general anesthesia and has been considered similar in mechanism to TURP (8). Although PAE demonstrates similar urinary domain scores, such as international prostate symptom score (IPSS), maximum urinary flow rate (Qmax), quality of life (QoL), and postvoid residual (PVR), compared with TURP in multiple randomized control trials (RCTs), the American Urological Association (AUA) considers PAE an experimental procedure with limited research and citations in PAE (9). Alternatively, the AUA recommends Rezum, Urolift, and Aquablation in the appropriate clinical setting despite similarities in scientific evidence presented for PAE, Rezum, Urolift, and Aquablation. The aim of this systematic review and meta-analysis was to investigate the comparative effectiveness of these MISTs from published RCTs.

Figures E1 to E16 can be found by accessing the online version of this article at www.jvir.org and clicking on the Supplemental Material tab.

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https://doi.org/10.1016/j.jvir.2021.12.029

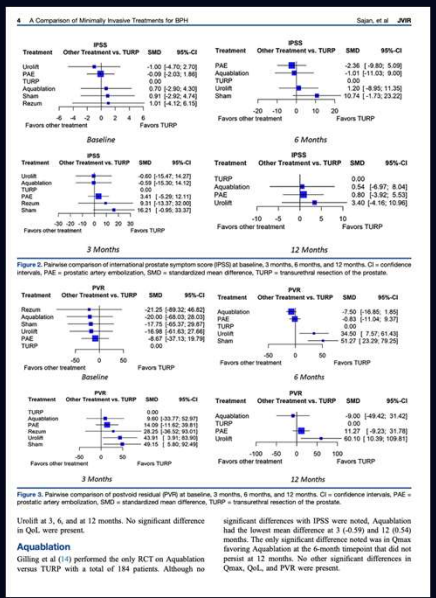


Figure 2. Pairwise comparison of international prostate symptom score (IPSS) at baseline, 3 months, 6 months, and 12 months. CI = confidence intervals, PAE = prostatic artery embolization, SMD = standardized mean difference, TURP = transurethral resection of the prostate.

Figure 3. Pairwise comparison of postvoid residual (PVR) at baseline, 3 months, 6 months, and 12 months. CI = confidence intervals, PAE = prostatic artery embolization, SMD = standardized mean difference, TURP = transurethral resection of the prostate.

Urolift at 3, 6, and at 12 months. No significant difference in QoL were present.

Aquablation

Gilling et al (14) performed the only RCT on Aquablation versus TURP with a total of 184 patients. Although no significant differences with IPSS were noted, Aquablation had the lowest mean difference at 3 (-0.59) and 12 (0.54) months. The only significant difference noted was in Qmax favoring Aquablation at the 6-month timepoint that did not persist at 12 months. No other significant differences in Qmax, QoL, and PVR were present.

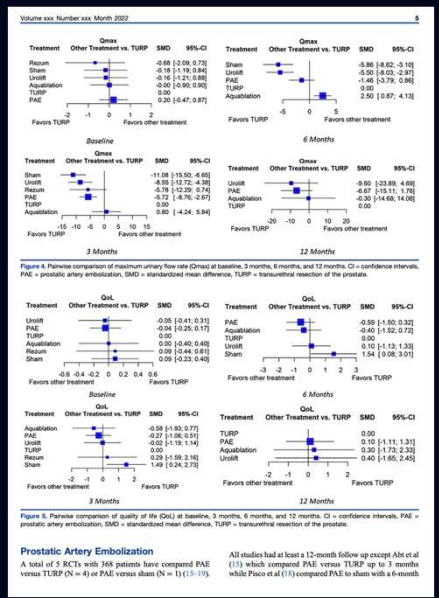


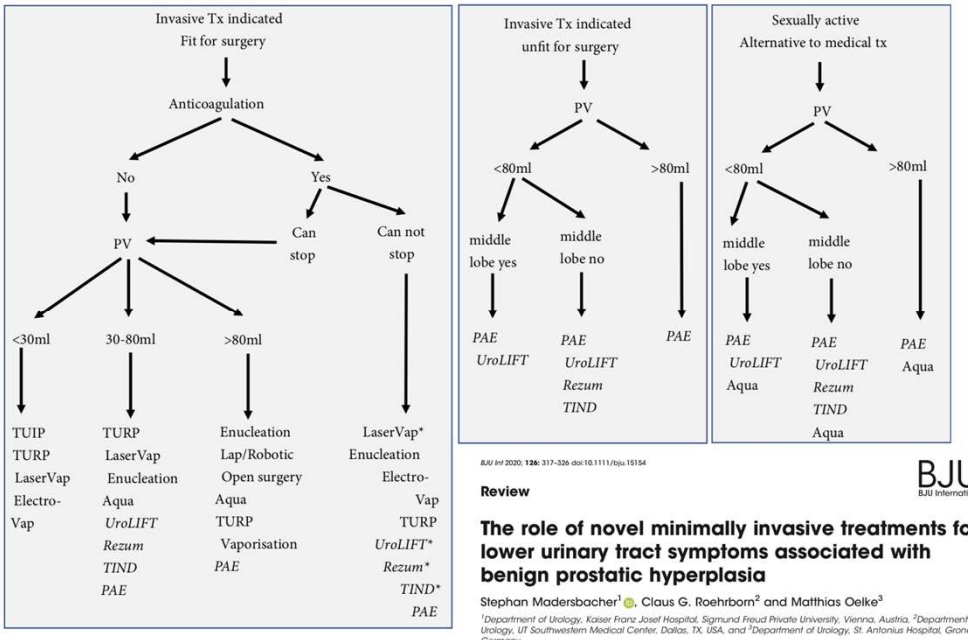
Figure 4. Pairwise comparison of maximum urinary flow rate (Qmax) at baseline, 3 months, 6 months, and 12 months. CI = confidence intervals, PAE = prostatic artery embolization, SMD = standardized mean difference, TURP = transurethral resection of the prostate.

Figure 5. Pairwise comparison of quality of life (QoL) at baseline, 3 months, 6 months, and 12 months. CI = confidence intervals, PAE = prostatic artery embolization, SMD = standardized mean difference, TURP = transurethral resection of the prostate.

Prostatic Artery Embolization

A total of 5 RCTs with 368 patients have compared PAE versus TURP (N = 4) or PAE versus sham (N = 1) (15–19). All studies had at least a 12-month follow up except Abt et al (15) which compared PAE versus TURP up to 3 months while Pisco et al (18) compared PAE to sham with a 6-month

Fig. 1 Algorithm for minimal invasive and surgical management in different clinical scenarios. Aqua, aquablation; Lap, laparoscopic; Tx, treatment; Vap, vaporistaion.



BJU Int 2020; 126: 317–326 doi:10.1111/bju.15154

BJUI
BJU International

Review

The role of novel minimally invasive treatments for lower urinary tract symptoms associated with benign prostatic hyperplasia

Stephan Madersbacher[1], Claus G. Roehrborn[2] and Matthias Oelke[3]

[1]Department of Urology, Kaiser Franz Josef Hospital, Sigmund Freud Private University, Vienna, Austria, [2]Department of Urology, UT Southwestern Medical Center, Dallas, TX, USA, and [3]Department of Urology, St. Antonius Hospital, Gronau, Germany

PROSTATE CENTERS
COMPREHENSIVE MEN'S HEALTH CARE

Aquablation

- Bleeding Risk
- Prolonged Catheter
- Hospitalization
- Size Limited
- Improved Flow Rates

PAE

- Devascularization
- Outpatient
- Not Size Limited
- Gland Size Reduction

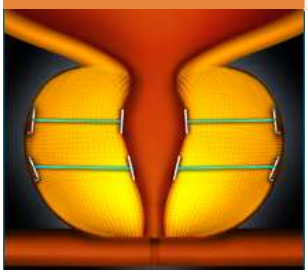
Combination Therapy

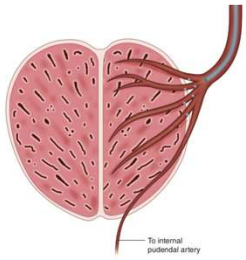
- Decreased Bleeding Risk
- Outpatient
- Increase Size Candidates
- Longer Term Results

PROSTATE CENTERS
COMPREHENSIVE MEN'S HEALTH CARE

Collaboration

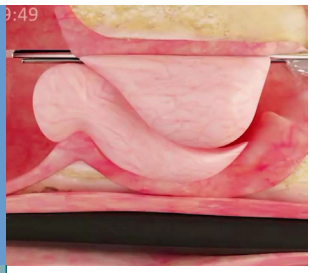
Urolift

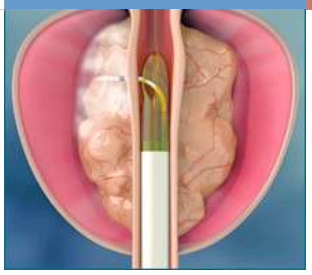




Prostate Artery Embolization (PAE)

Rezum





Aquablation

Thank You

PROSTATE CENTERS
COMPREHENSIVE MEN'S HEALTH CARE

Banner MD Anderson Cancer Center

Clinical and Economic Utilization

Phillip J. Koo, MD
Physician Executive of Oncology
Chief of Diagnostic Imaging

Banner MD Anderson Cancer Center

Disclosures

- Bayer
- AAA/Novartis
- Merck
- Janssen
- AstraZeneca
- Astellas
- Blue Earth
- Lantheus
- Clarity
- Telix
- ConcertAI

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PART 1

Clinical Utilization

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Diagnostic Radiopharmaceuticals

- Ga68 PSMA-11
- F18 Pyl
- FDG
- Fluciclovine

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RADAR/NCCN/Appropriate Use Criteria

- Text

Table 2

Clinical Scenarios for PSMA PET

Scenario no.	Description	Appropriateness	Score
1	Patients with suspected prostate cancer (e.g., high/rising PSA levels, abnormal digital rectal examination results) evaluated for targeted biopsy and detection of intraprostatic tumor	Rarely appropriate	3
2	Patients with very low, low, and favorable intermediate-risk prostate cancer	Rarely appropriate	2
3	Newly diagnosed unfavorable intermediate, high-risk, or very high-risk prostate cancer	Appropriate	8
4	Newly diagnosed unfavorable intermediate, high-risk, or very high-risk prostate cancer with negative/equivocal or oligometastatic disease on conventional imaging	Appropriate	8
5	Newly diagnosed prostate cancer with widespread metastatic disease on conventional imaging	May be appropriate	4
6	PSA persistence or PSA rise from undetectable level after radical prostatectomy	Appropriate	9
7	PSA rise above nadir after definitive radiotherapy	Appropriate	9
8	PSA rise after focal therapy of the primary tumor	May be appropriate	5
9	nmCRPC (M0) on conventional imaging	Appropriate	7
10	Posttreatment PSA rise in the mCRPC setting in a patient not being considered for PSMA-targeted radioligand therapy	May be appropriate	5
11	Evaluation of eligibility for patients being considered for PSMA-targeted radioligand therapy	Appropriate	9
12	Evaluation of response to therapy	May be appropriate	5

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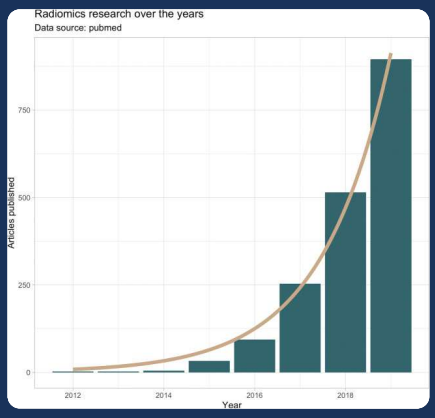
Future Applications

- Treatment response
  - RECIP
- Prognosis??
- **Multi-parametric Diagnostics**

Rise of Radiomics



EUROPEAN RADIOLOGY 2021
A decade of radiomics research: are images really data or just patterns in the noise?
Daniel Pinto Dos Santos[1], Matthias Dietzel[2], Bettina Baessler[3]

RADIOMICS

- Extraction and use of high-dimensional data from clinical images
- Discover imaging biomarkers or features that can be useful for predicting diagnosis and therapeutic response for various cancer types

ABSTRACT

- There is a translation gap in radiomics research, with many studies being published but so **far little to no translation into clinical practice**.
- Going forward, **more studies with higher levels of evidence are needed**, ideally also focusing on prospective studies with relevant clinical impact.

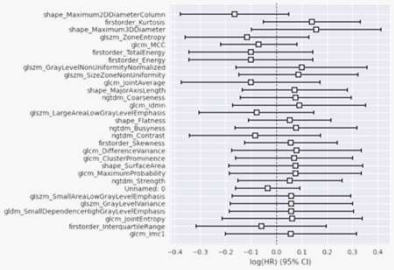
Modeling Case Study

Radiomics: Pipeline for processing medical images

1,000+ sample CT scans from public data sources and real-world settings

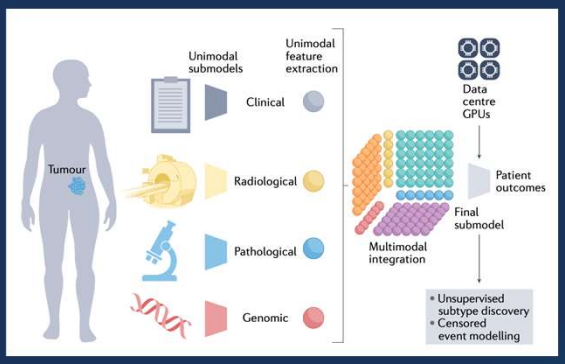
Pipeline for extracting radiomic features as part of a vector quantization scheme.

Compare each feature's values to overall survival, obtaining the "predictive power" of each feature.



Results hint at the potential of radiomics features in predicting progression of ICI treated patients within 3 months of the scan

Multimodal Biomarkers and Predictive Tools



NATURE REVIEWS CANCER 2021
Harnessing multimodal data integration to advance precision oncology
Boehm et al

- Most data-driven insights for patients with cancer are limited to a single mode of data, leaving integrated approaches across modalities relatively underdeveloped.
- Multimodal integration of advanced **molecular diagnostics, radiological and histological imaging, and codified clinical data** presents opportunities to advance precision oncology beyond genomics and standard molecular techniques.
- Modalities with fully orthogonal info **dramatically improves inference**.
- Reimagined class of multimodal biomarkers to propel the field of precision oncology in the coming decade.

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PART 2

Financial Considerations

PET

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Hardware

- PET/CT
  - Mobile
  - CT
- Buy
- Leasor
- Leasee
- Joint Venture

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Software

- Radiopharmaceuticals
  - Drug vs supply?

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Physical Space

- PET/CT
- Control Room
- Hot lab
- Uptake rooms
- Bathroom

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Human Resources

- Technologists
- Physicist
  - QC
  - Radiation Safety
- Professional Services

Benefits

- FFS
  - Financial
- Value
  - Quality and Patient Experience
    - Alignment
    - Integration
  - Data

ConcertAI

Banner MD Anderson ~~Cancer~~ Center

Thank you.

Gender Affirming Surgery

Brad Figler MD FACS
Associate Professor (Urology/Plastic Surgery)
University of North Carolina-Chapel Hill

November 10, 2022

LUGPA 2022 - Chicago

Transgender in the News

Texas Investigates Parents of Trans Teen Under Abuse Law, ACLU Sues

Virginia Bill Seeks to Restrict Trans Students' Restroom Access

Utah Legislature Passes Anti-Trans Bill, Republican Gov. Vows to Veto

Trans Woman Paloma Vazquez Fatally Shot in Houston

Study: Hormone Therapy Connected to Lower Suicide Risk in Trans Youth

Iowa Medicaid Program Must Cover Gender-Affirming Care, Judge Rules

North Carolina Health Care Discrimination Suit Can Move Forward

5 Steps Biden Administration Promises to Take to Protect Trans Kids

@BradFiglerMD | @TransUNC

Department of Urology

Outline

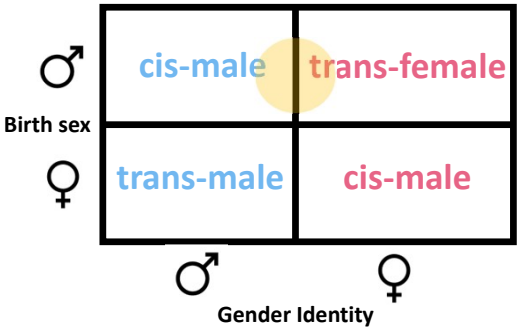
- Transgender overview
  - Terminology
  - Barriers and access
  - UNC Transgender Health Program
- Bottom surgery
  - General considerations
  - Feminizing bottom surgery (vulvoplasty & vaginoplasty)
  - Masculinizing bottom surgery (metoidioplasty & phalloplasty)

Terminology

Cis-gender
Gender identity = birth sex

Transgender
Gender identify ≠ birth sex

Gender non-conforming
Deviate from cultural gender norms



Terminology

Gender dysphoria
Distress due to gender identity ≠ birth sex

Gender affirming surgery/hormones
Make body = gender identity

Top surgery
Breast reduction (masculinizing)
Breast augmentation (feminizing)

Bottom surgery
Vulvoplasty/vaginoplasty (feminizing)
Metoidioplasty/phalloplasty (masculinizing)

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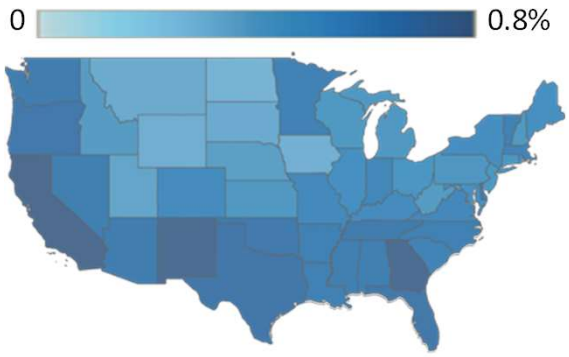
Epidemiology: Adults Who Identify as Transgender

- United States: 1.4 million (0.6%)
- North Carolina: 44,750 (0.6%)

- Gender affirming hormones: ~50%
- Gender affirming surgery in ~25%
  - Transgender men: 42%
  - Transgender women: 23%
  - Non-binary: 9%

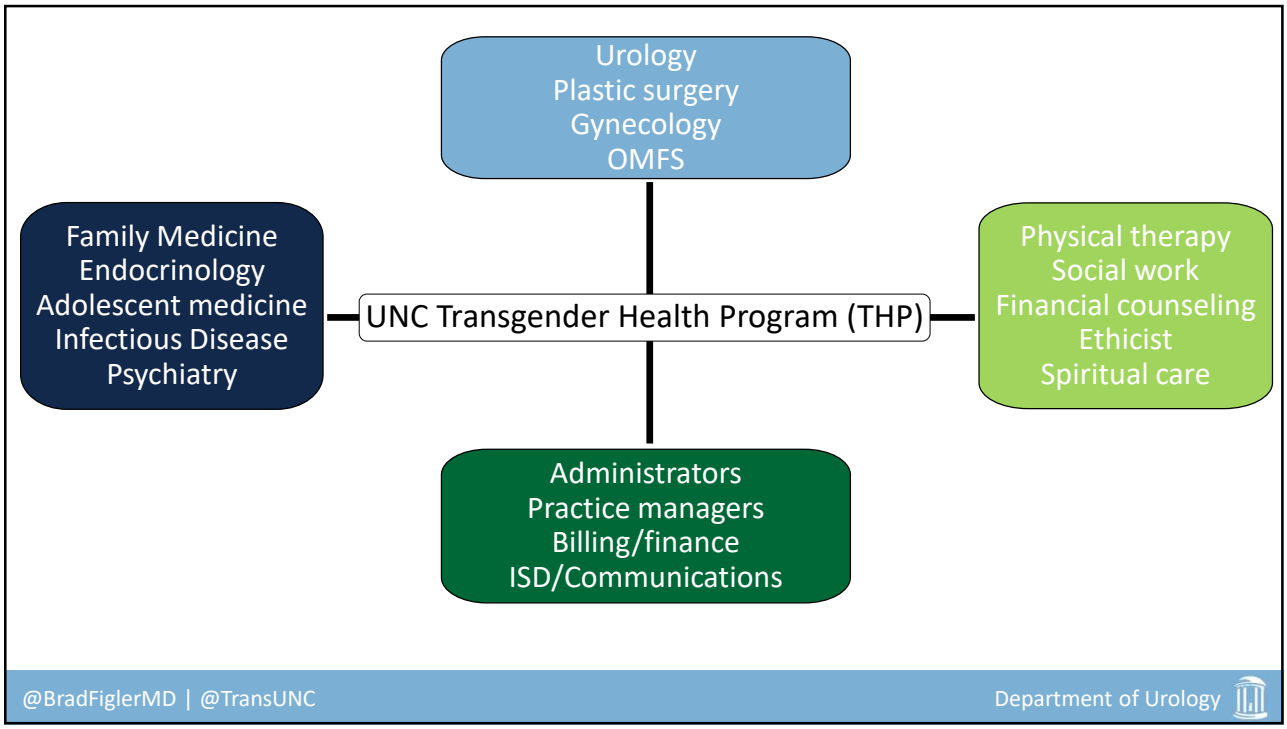


Source: USTS 2015 (p 96-103))

Barriers to Transgender Healthcare

- Living in poverty: 29% (U.S. population: 12%)
- Insurance coverage
  - Denial for gender affirming surgery: 55%
  - Denial for gender affirming hormone: 25%
- Negative experience with a healthcare professional: 33%
- Avoid medical care for fear of being mistreated: 23%
- Lack of qualified healthcare professionals

Source: USTS 2015 (p 96-103))



WPATH Standards of Care – Bottom Surgery

- Two referrals from mental health providers
- Persistent, well-documented gender dysphoria
- Capacity for informed consent
- Medical/mental issues well controlled
- 12 continuous months of hormone therapy
- 12 continuous months living in gender role

WPATH WORLD PROFESSIONAL ASSOCIATION for TRANSGENDER HEALTH

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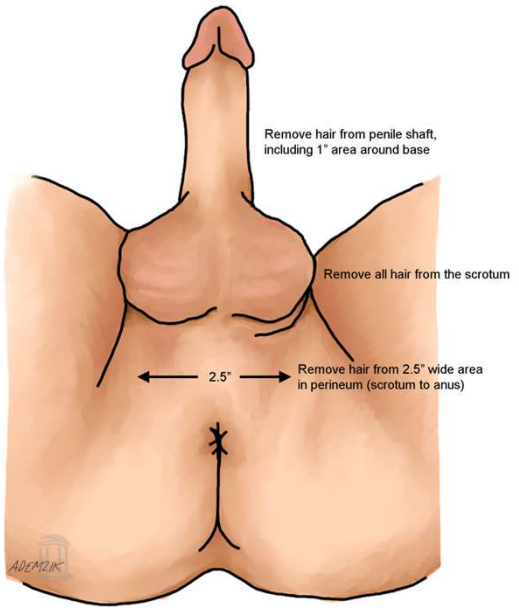
Department of Urology

Pre-Operative Considerations

- Smoking/nicotine cessation
- Diabetes
- Social support
- Fertility
- Hair removal
  - Scrotum/perineum (vaginoplasty)
  - No hair removal for metoidioplasty
- Vulvoplasty & vaginoplasty: Continue estrogen therapy
- Metoidioplasty: Testosterone therapy ≥ 2 years

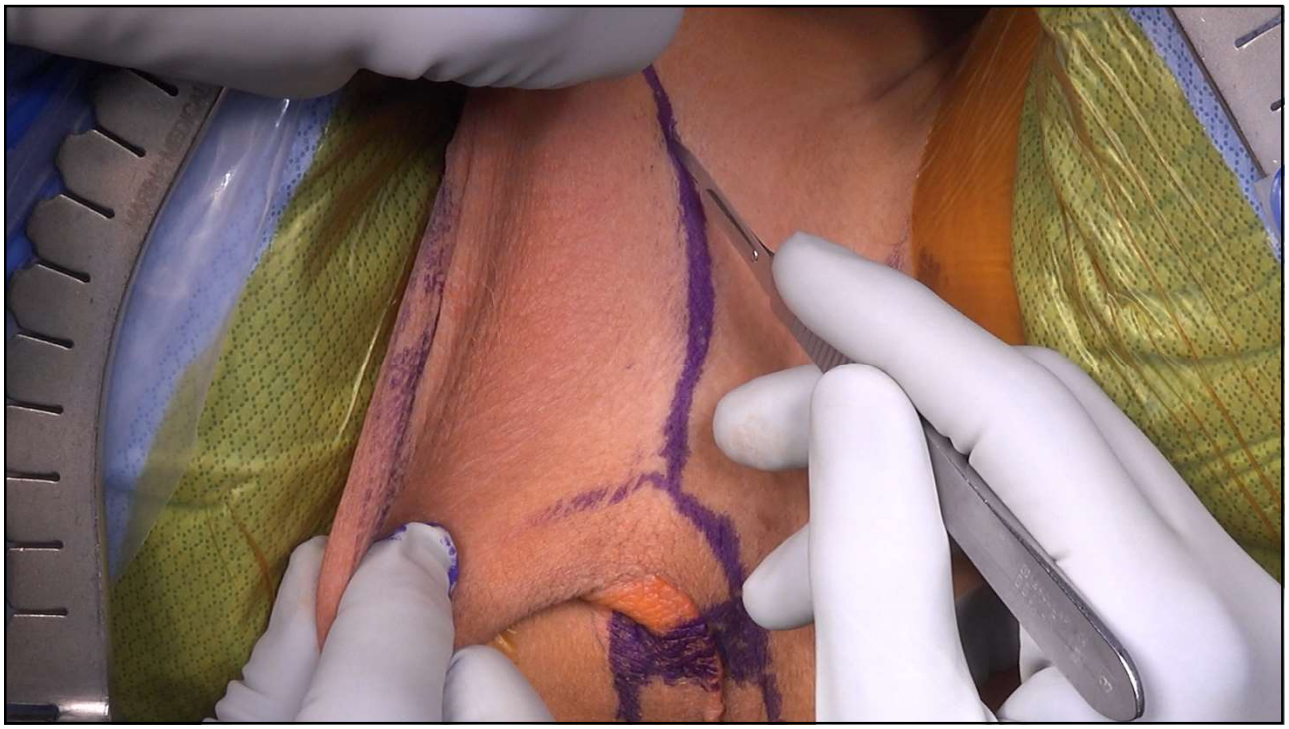


Gender Affirming Bottom Surgery (feminizing)

- Vulvoplasty: Creation of external female genitalia
  - Orchiectomy
  - Labia minora (penile skin)
  - Labia majora (scrotal skin)
  - Clitoris (corpora cavernosa, glans penis)
  - Perineal urethrostomy
- Vaginal canal (anterior to rectum, lined with graft)

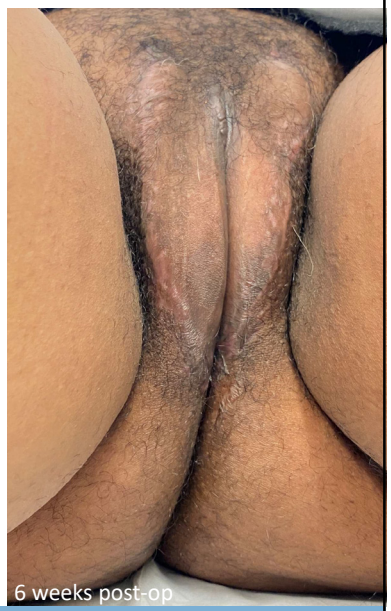
Vaginoplasty

- Goals
  - Natural appearing, minimal maintenance
  - Unobstructed urine stream
  - Erogenous
  - Receptive intercourse (if desired)



Vaginoplasty: Post-Op

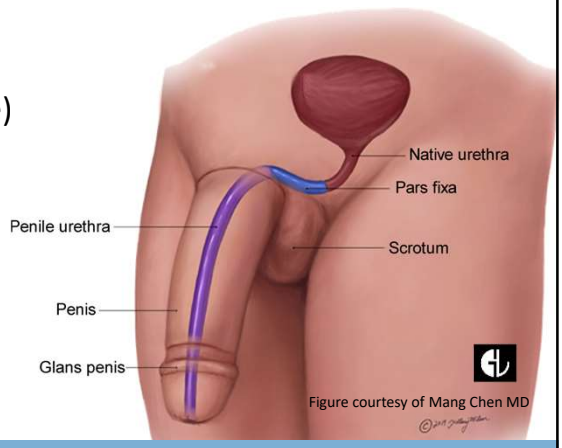
- Discharge POD 1-2
- Early and frequent ambulation
- Bolster/catheter removal: POD 6
- Dilation teaching: 2 weeks (twice daily then weekly)
- Close follow-up for 1 year
  - Wound healing
  - Dilation
  - Sexual function
  - Urination (stream, obstruction, infection)

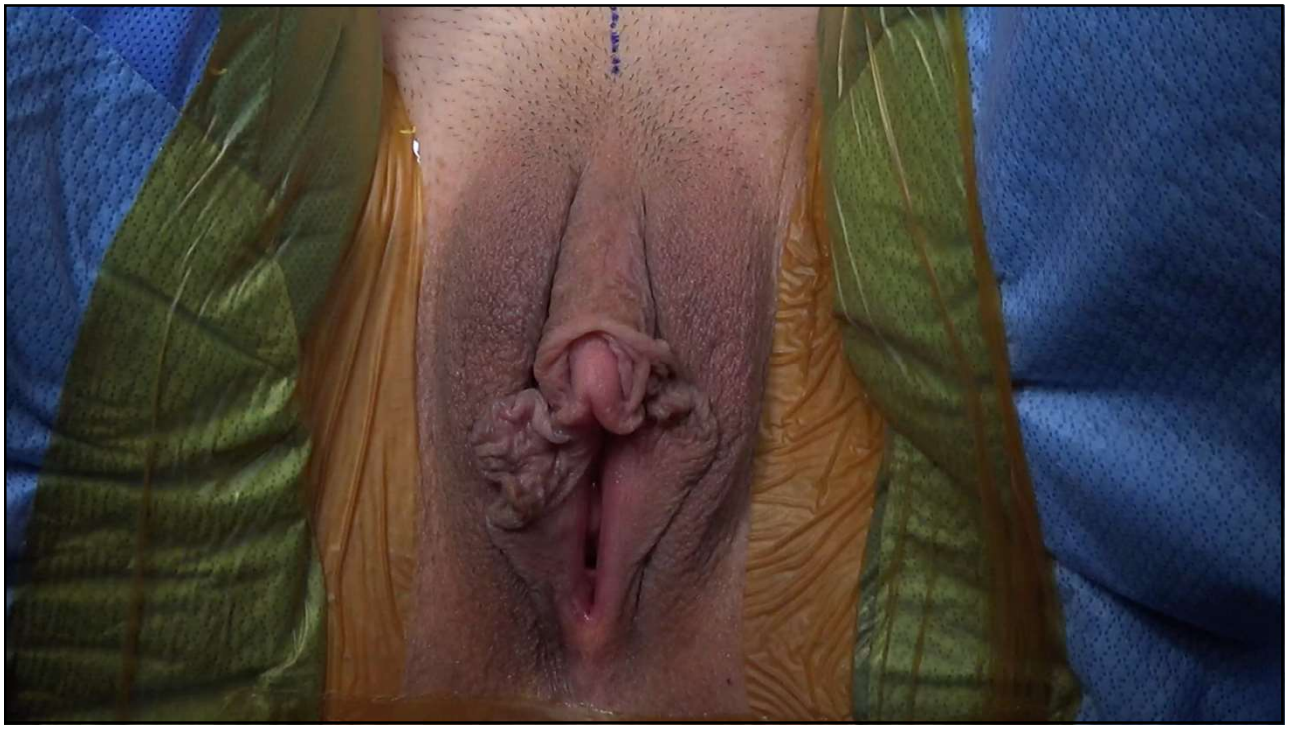


Bottom Surgery (FTM): Overview

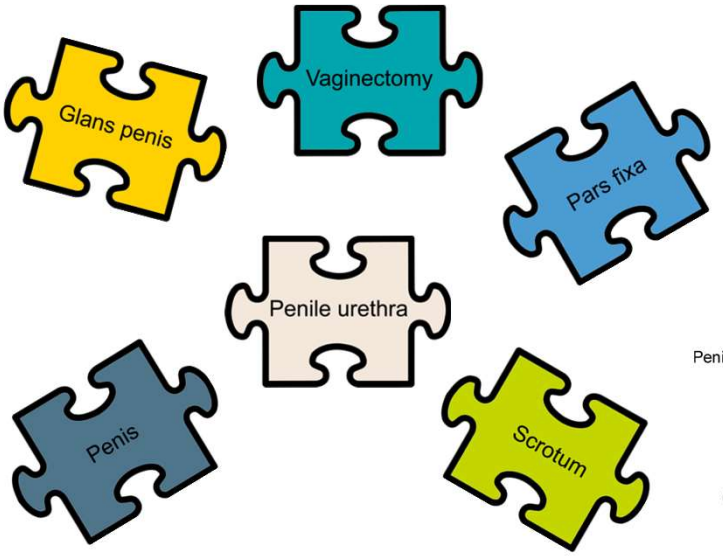
- Many options, including
  - Metoidioplasty (smaller penis, less invasive)
  - Phalloplasty (larger penis, more invasive)

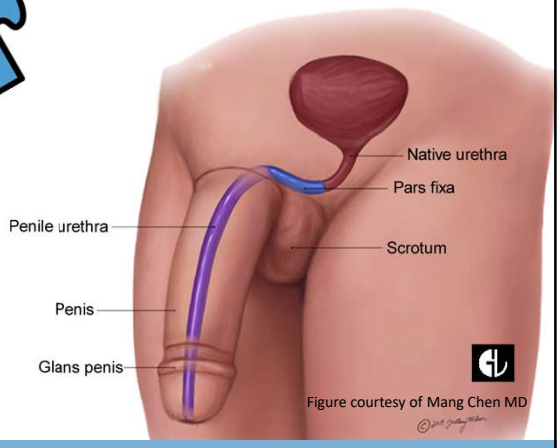
- Choice of surgery depends on
  - Goals (e.g., standing urination, intercourse)
  - Patient-specific factors (e.g., obesity)
  - Risk tolerance





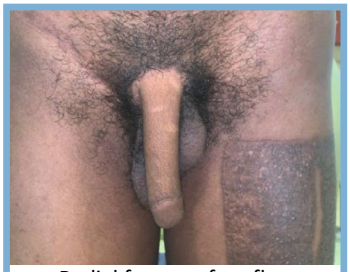
Bottom Surgery (FTM): Overview

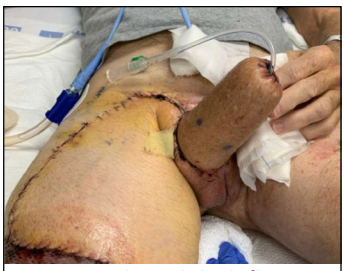




Bottom Surgery (FTM): Penis

	Advantage	Disadvantages
Radial forearm free flap (RFFF) phalloplasty	Physiologic length/girth Thin Well vascularized	Visible, functional donor site (arm)
Anterolateral thigh (ALT) phalloplasty - Free or pedicled	Inconspicuous donor site (leg) ↑phallic length/girth	↑ flap/urethral complications ↑phallic length/girth
Metoidioplasty (local tissue)	Minimally invasive No donor site	Small phallus No penetrative intercourse


Radial forearm free flap


Anterolateral thigh flap

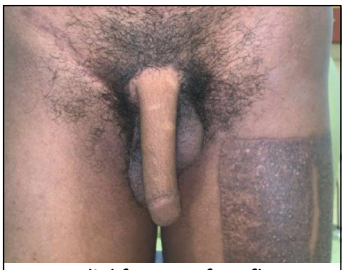

Metoidioplasty

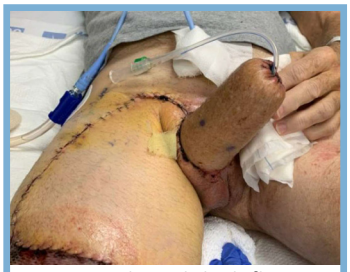
@BradFiglerMD | @TransUNC

Department of Urology

Bottom Surgery (FTM): Penis

	Advantage	Disadvantages
Radial forearm free flap (RFFF) phalloplasty	Physiologic length/girth Thin Well vascularized	Visible, functional donor site (arm)
Anterolateral thigh (ALT) phalloplasty - Free or pedicled	Inconspicuous donor site (leg) ↑phallic length/girth	↑ flap/urethral complications ↑phallic length/girth
Metoidioplasty (local tissue)	No donor site Minimally invasive	Small phallus No penetrative intercourse


Radial forearm free flap


Anterolateral thigh flap


Metoidioplasty

Bottom Surgery (FTM): Penis

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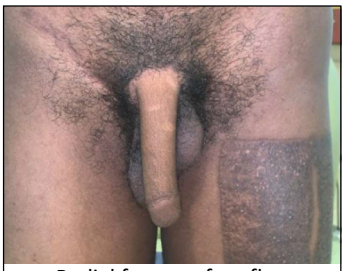
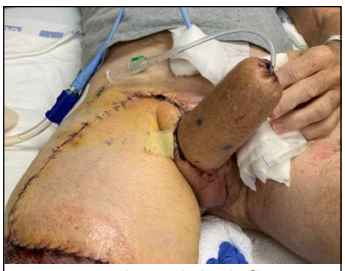

Radial forearm free flap


Anterolateral thigh flap


Metoidioplasty

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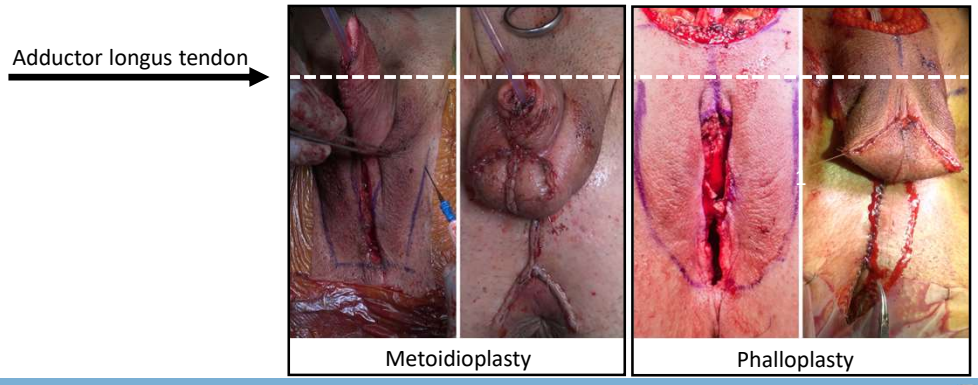
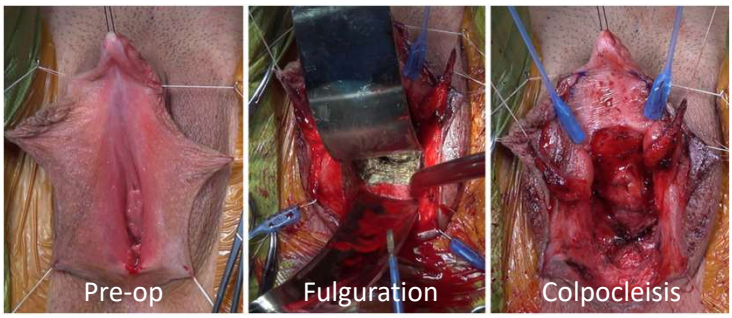
Bottom Surgery (FTM): Scrotum

- "Ghent scrotoplasty"
- Anteriorly based flap labia majora flaps
  - Phalloplasty: Entire labia majora
  - Metoidioplasty: Inferior 50% of labia majora



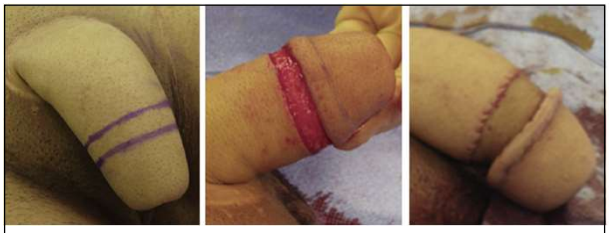
Bottom Surgery (FTM): Vaginectomy

- Vaginal excision or fulguration (perineal)
- Vaginal excision (abdominal – lap/robot)
- Hysterectomy prior

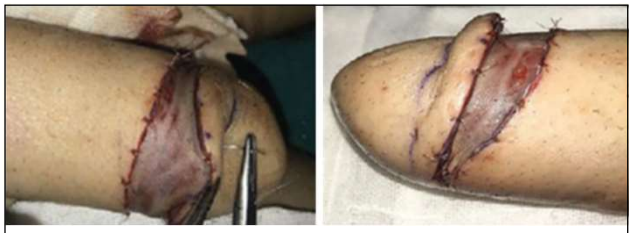


Bottom Surgery (FTM): Glansplasty

- Advance skin on distal penis 1cm distal
- Norfolk:
  - Edge of flap sutured to base
  - Full thickness skin graft for defect
- Ghent
  - Full thickness skin graft for defect and raw under-surface of flap



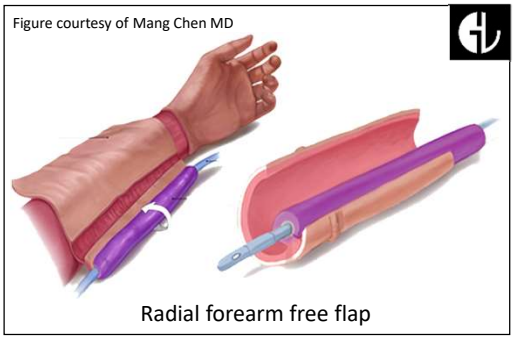
Norfolk



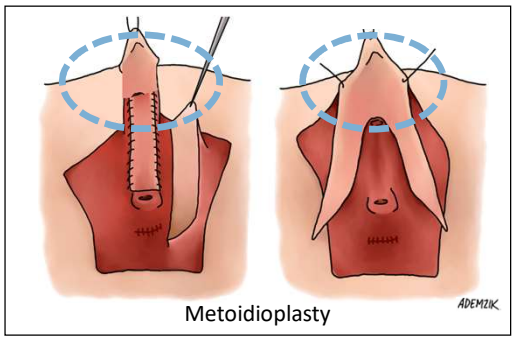
Ghent

Bottom Surgery (FTM): Penile Urethra

- Radial forearm free flap
  - Tube within a tube
- Metoidioplasty
  - Tubularized clitoral skin



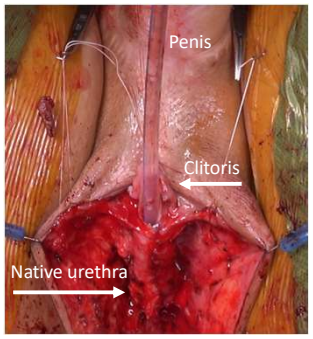
Radial forearm free flap

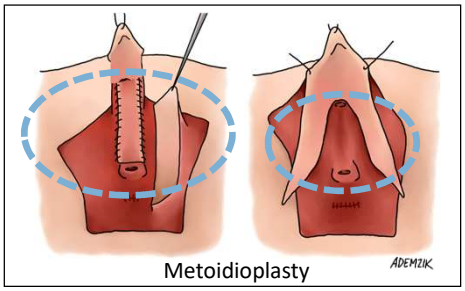


Metoidioplasty

Bottom Surgery (FTM): Pars Fixa

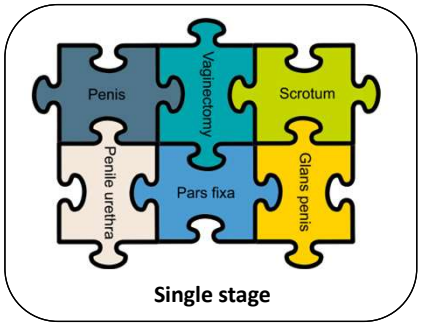
- Phalloplasty
  - Tubularized labia minora
  - "Ring flap" (anteriorly based labia minora flaps)
- Metoidioplasty
  - Buccal graft + labia minora flap
  - "Ring flap"



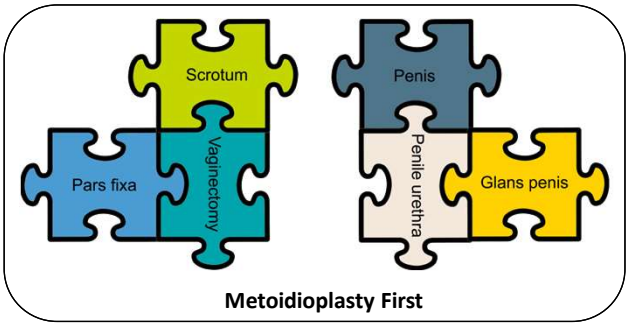


Metoidioplasty

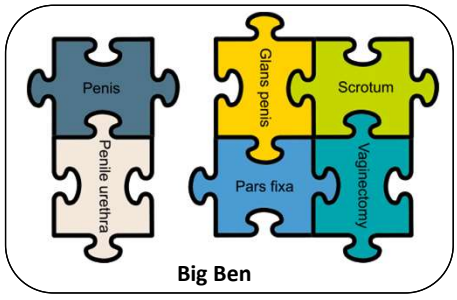
Bottom Surgery (FTM): Variations



Single stage



Metoidioplasty First



Big Ben

Disclosures

- I have no disclosures

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Urologic Care for Transgender and Gender Diverse (TGD) Patients

- How do I provide the best urologic are for TGD patients?
  - Making your clinic an affirming, safe space
  - Staff competency trainings
  - The EMR
- The Urologist's Role (*outside of Gender-Affirming Surgery*)
  - Sexual Health
  - Fertility
  - Lower Urinary Tract Dysfunction
  - Cancer screening
- Resources

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Gender Pathways Program at NM

Gender Pathways Program

Clinical Operations

- Surgeon-led Program of ~30 providers
- Partnership with Primary Care, Mental Health, Endocrinology
- System-wide Cultural Competency trainings
- Transitional care work with the children's hospital

Quality

- Medical and surgical guidelines for 11 hospital system
- Pronoun collection across the health system
- Access to care

Research

- Quality Outcomes
- Patient reported outcomes
- Sexual function
- Cancer screening

Community Engagement

- Community advisory board
- Local LGBTQ+ Organizations

Education

- Resident training
- T32 Grant for postdoctoral training

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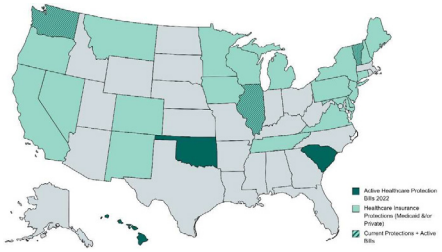
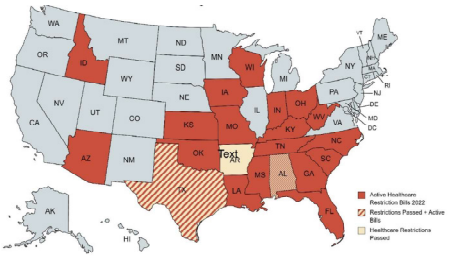
Transgender Health: A Growing Field

- Increasing acceptance = ↑ TGD individuals seeking urologic care

States with Gender Expansive Legislation



States with Gender Restrictive Legislation



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2015 U.S. TRANSGENDER SURVEY

- **33%** reported at least one **negative healthcare experience**
- **23%** did not see a doctor out of **fear of being mistreated**
- **29% reported having to teach their healthcare provider about trans issues and gender affirming care**

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James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality.

Keys to an Affirming Clinic Space

Physical Environment	Workforce	Patient Information
• Gender neutral bathrooms • Inclusive waiting areas • Safe space signage	• Terminology and pronouns • Cultural competency trainings	• Pronoun/gender identity options for: 1. Intake sheets 2. Electronic medical record

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Things to keep in mind

- It is important that affirming care goes beyond just when speaking to gender diverse clients. You most likely have gender diverse staff, but they may not be out to you.
- Patients may not be out to you as a medical care provider. Do not assume that you are not causing harm simply because it is not being stated directly to you.
- Being Trans or non-binary is not new or a trend, and does not mean you will necessarily visibly or medically transition

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Cultural Competency Trainings

- 7 Departments
- 92 Participants
- Focused on terminology, documentation in the EMR, and understanding how to create a welcoming environment for transgender and non-binary patients

Comment Themes

- Eager to learn, just want the resources,
- Enjoyed training and would appreciate more training
- Time to practice scenarios, especially sticky situations

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Prepared by NM Human Resources

Cultural Competency Trainings – Staff Tip Sheets

"Hi, my name is _____. I use (he/him, she/her, they/them) pronouns.

What pronouns do you use?"

"This is a question that we ask everyone because it's important to us to respect how you'd like to be addressed."

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Inclusive Intake Forms

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675 North Saint Clair Street, Ste 19-250
Chicago, IL 60611-5964
312-695-6022
nm.org

REGISTRATION FORM FOR PLASTIC AND RECONSTRUCTIVE SURGERY

TODAY'S DATE _____/_____/_____

LEGAL NAME _____

PREFERRED NAME_____ PRONOUNS (optional) _____

DATE OF BIRTH _____/_____/_____ AGE _____

LEGAL SEX: MALE_____ FEMALE_____ GENDER IDENTITY (optional): _____

MARITAL STATUS: SINGLE _____ MARRIED _____ WIDOWED _____ DIVORCED _____

ADDRESS_____

CITY_____STATE_____ ZIP CODE_____

HOME #_____ WORK #_____ CELL #_____

E-MAIL_____

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The Electronic Medical Record (EMR)

- Most TGD patients desire opportunities for EMR-wide preferred name and pronoun documentation, regardless of legal name
  - Especially younger patients
- Contact your EMR provider for latest updates and ability to capture sexual orientation and gender identity (SOGI) data
- Organ inventories may be particularly helpful as patients start to select their own gender identity within MyChart (i.e. Female instead of Trans-Female)

Sequeira GM et a. Affirming Transgender Youths' Names and Pronouns in the EMR. JAMA Pediatr, 2020.

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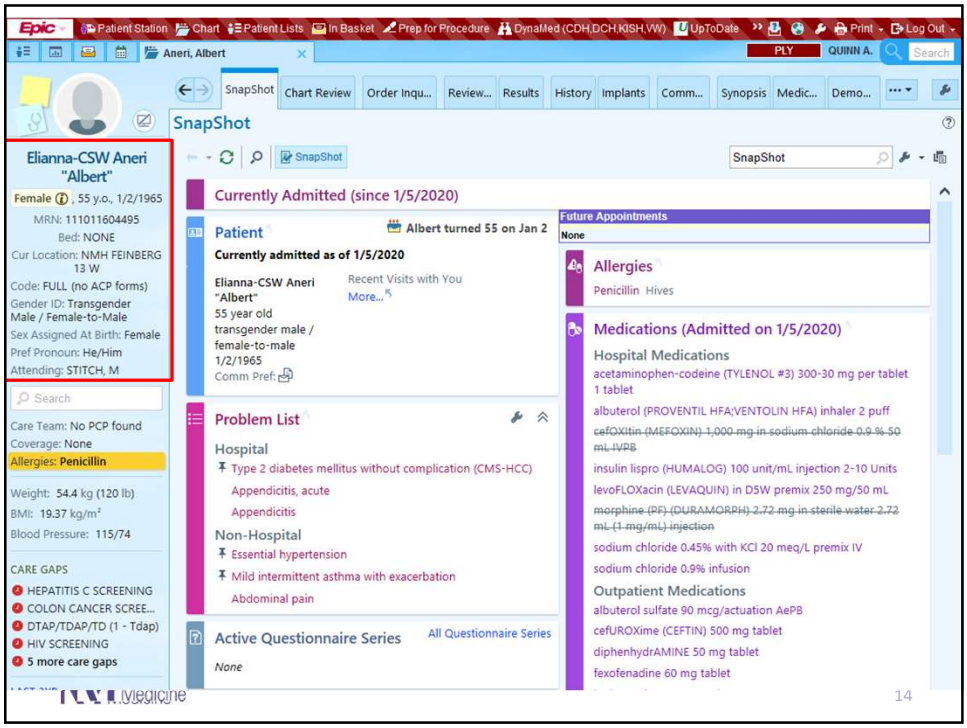
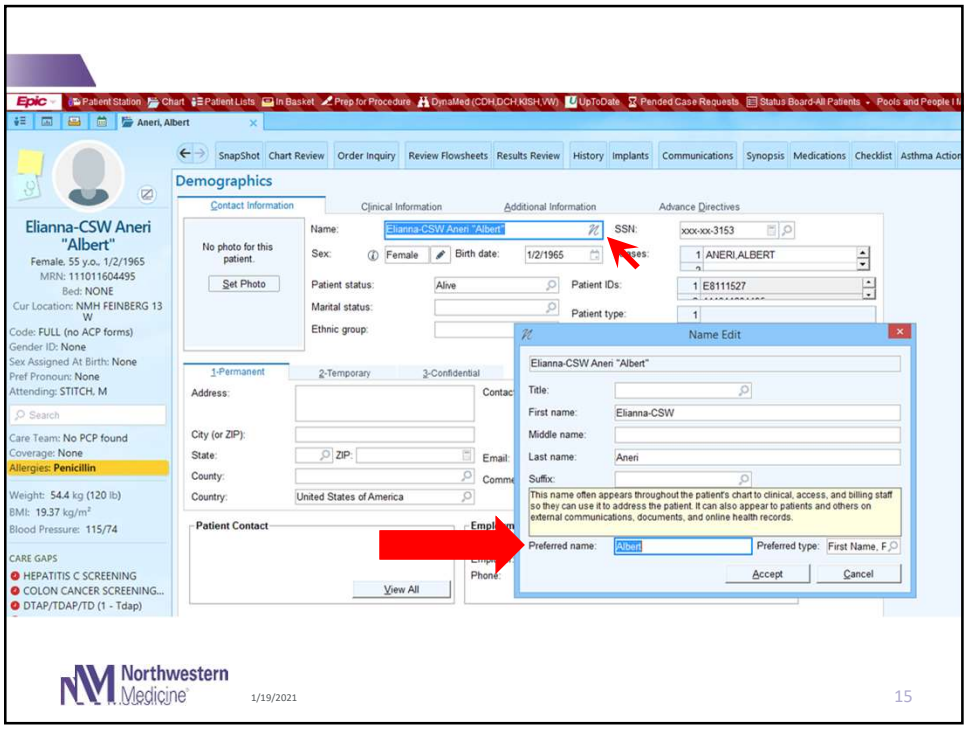
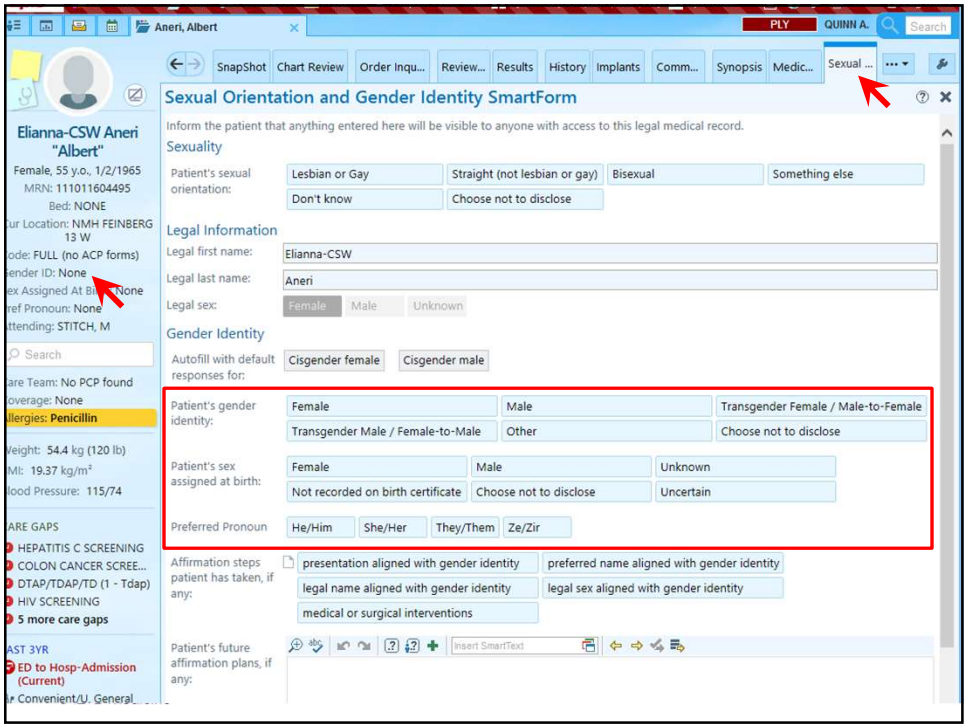
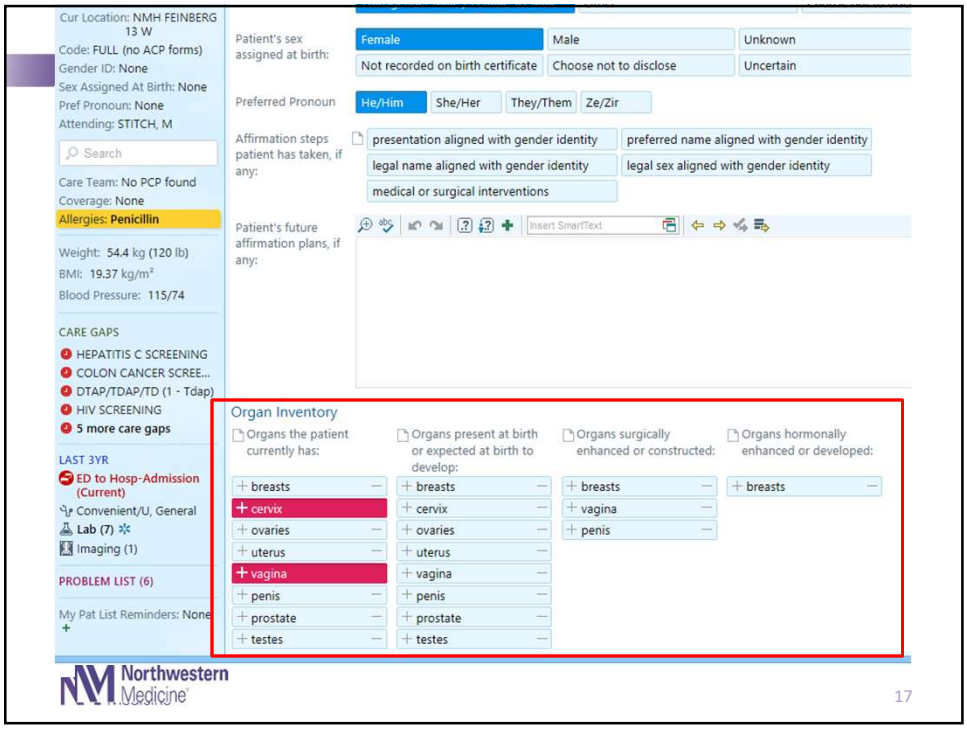



Demographics
Elianna-CSW Aneri "Albert"
Female, 55 y.o., 1/2/1965
MRN: 111011604495
Name Edit
Elianna-CSW Aneri "Albert"
First name: Elianna-CSW
Last name: Aneri
Preferred name: Albert
Accept
Cancel


Sexual Orientation and Gender Identity SmartForm
Inform the patient that anything entered here will be visible to anyone with access to this legal medical record.
Sexuality
Legal Information
Gender Identity
Elianna-CSW Aneri "Albert"


Cur Location: NMH FEINBERG 13 W
Code: FULL (no ACP forms)
Gender ID: None
Sex Assigned At Birth: None
Pref Pronoun: None
Attending: STITCH, M
Search
Care Team: No PCP found
Coverage: None
Allergies: Penicillin
Weight: 54.4 kg (120 lb)
BMI: 19.37 kg/m²
Blood Pressure: 115/74
CARE GAPS
HEPATITIS C SCREENING
COLON CANCER SCREE...
DTAP/TDAP/TD (1 - Tdap)
HIV SCREENING
5 more care gaps
LAST 3YR
ED to Hosp-Admission (Current)
Convenient/U, General
Lab (7)
Imaging (1)
PROBLEM LIST (6)
My Pat List Reminders: None
Patient's sex assigned at birth:
Female
Male
Unknown
Not recorded on birth certificate
Choose not to disclose
Uncertain
Preferred Pronoun
He/Him
She/Her
They/Them
Ze/Zir
Affirmation steps patient has taken, if any:
presentation aligned with gender identity
preferred name aligned with gender identity
legal name aligned with gender identity
legal sex aligned with gender identity
medical or surgical interventions
Patient's future affirmation plans, if any:
Insert SmartText
Organ Inventory
Organs the patient currently has:
breasts
cervix
ovaries
uterus
vagina
penis
prostate
testes
Organs present at birth or expected at birth to develop:
breasts
cervix
ovaries
uterus
vagina
penis
prostate
testes
Organs surgically enhanced or constructed:
breasts
vagina
penis
Organs hormonally enhanced or developed:
breasts
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17


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How can I provide the best care for TGD patients?
Specific Urologic Considerations

What is the Urologist's Role?

- Any urologic complaint!

- Lower urinary tract dysfunction
- Cancer screening
- Sexual dysfunction
- Fertility

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Generalities

- Think about the disease process as you would for any patient (phimosis, hydrocele, stones hematuria…)
  - Important to collect a detailed history of any relevant gender-affirming interventions – don't assume

- Genital exams
  - Heightened anxiety due to dysphoria, past experiences
  - Practice trauma-informed care
  - Demonstrate that it is a safe environment and discuss why there is a need for the exam
    - Spending the extra time and effort is important

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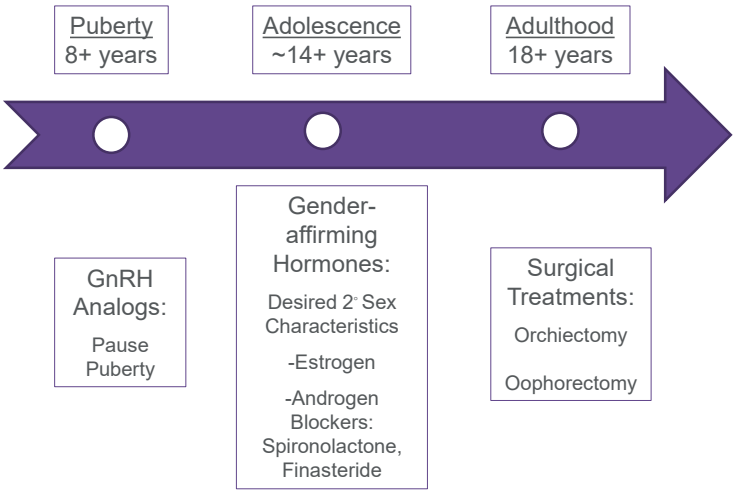
Hormonal Interventions throughout the Lifespan



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21

Lower Urinary Tract Dysfunction

- TGD patients often feel uncomfortable using public restrooms and may hold their urine for long periods of time
- Common co-existing mental health issues include anxiety, depression, and eating disorders
- Hormone initiation can trigger lower urinary tract symptoms that may require working with the patient's hormone provider to adjust dosing.
  - Feminizing hormones
  - Anti-androgen such as spironolactone may cause a diuretic effect and may compound underlying voiding dysfunction

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Lower Urinary Tract Dysfunction

- Tucking - practice used by trans-women to conceal the testicles and penis, pushing the testicles up into the inguinal canal and the penis down
  - Testicular pain
  - Epididymo-orchitis
  - UTIs
  - Genital skin irritation
- No robust literature

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Cancer screening

- Currently no WPATH guidelines on prostate cancer screening

Review Article
Prostate cancer in transgender women
Matthew D. Ingham, M.D.[a,b], Richard J. Lee, M.D., Ph.D.[c], Dhara MacDermed, M.D.[d], Aria F. Olumi, M.D.[e,*]

- Absence of many reports of CaP among transgender women in the literature suggests those on feminizing hormones/post orchiectomy are at lower risk, but the risk is not zero [1, 2]
  - Risk varies by stage/state of transition (medical)
- Prostate exams via Neovagina vs Rectal
- Unclear what age screening should begin and PSA cutoff
  - Suggested PSA of 1.0?

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Sexual Function

- WPATH Standards of Care Version 8.0
  https://www.wpath.org/soc8

International Journal of Transgender Health

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/wijt21

Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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Fertility

- WPATH SOC 8
  - AMAB TGD patients, especially those who have not already reproduced, should be informed about sperm preservation options and encouraged to consider banking their sperm prior to hormone therapy
- Generally, sperm parameters are decreased compared to cis-gender
- Ideally, sperm banking should occur *before* hormone therapy
  - After stopping therapy until sperm count rises again
  - Cryopreservation should be discussed even if poor semen quality
- There are multiple options to cryopreserve

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Takeaways

- Awareness that TGD patients will seek care for general urology issues
  - Not all TGD patients will elect same medical and surgical transition
- Don't make assumptions about gender identity, sexual preferences and activity, external genital anatomy or organs – ask!
  - If you make a mistake, just apologize
- Utilize available resources
  - WPATH guidelines, AUA Core Curriculum and Updates
- Find your champions to refer to
  - Sexual Health
  - PFPT
- If you do not think you can manage the condition, refer
  - May be best handled with a multidisciplinary approach

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Resources for your clinic

- Online educational modules are available at The Fenway Institute
  - https://fenwayhealth.org/the-fenway-institute/
- The AUA Core Curriculum
  - https://university.auanet.org/core/care-of-transgender-and-gender-non-confirming-patients/genital-gender-affirming-surgery-and-care-of-transgender-and-gender-diverse-patients
- WPATH Standards of Care Version 8.0
  - https://www.wpath.org/soc8
- Asking for and Using Pronouns
  https://www.brynmawr.edu/sites/default/files/asking-for-name-and-pronouns.pdf

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Work to be done – EMR Study

Project RECOGNIZE EMR Survey Link

https://bostonu.qualtrics.com/jfe/form/SV_8dCmixg08VfoGqy

Thank you! If you have any questions/concerns, do not hesitate to email carl.streed@bmc.org or maylene.navarra@bmc.org

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Thank you!

Feel free to contact me at dbowen@nm.org

@dkbowen_md

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Appendix C GENDER-AFFIRMING HORMONAL TREATMENTS

Table 1. Expected time course of physical changes in response to gender-affirming hormone therapy

Testosterone Based Re	
Effect	**Onset**
Skin Oiliness/acne	1–6 months
Facial/body hair growth	6–12 months
Scalp hair loss	6–12 months
Increased muscle mass/ strength	6–12 months
Fat redistribution	1–6 months
Cessation of menses	1–6 months
Clitoral enlargement	1–6 months
Vaginal atrophy	1–6 months
Deepening of voice	1–6 months

Estrogen and testosterone-lowering based regimens		
Effect	**Onset**	**Maximum**
Redistribution of body fat	3–6 months	2–5 years
Decrease in muscle mass and strength	3–6 months	1–2 years
Softening of skin/ decreased oiliness	3–6 months	Unknown
Decreased sexual desire	1–3 months	Unknown
Decreased spontaneous erections	1–3 months	3–6 months
Decreased sperm production	Unknown	2 years
Breast growth	3–6 months	2–5 years
Decreased testicular volume	3–6 months	Variable
Decreased terminal hair growth	6–12 months	> 3 years
Increased scalp hair	Variable	Variable
Voice changes	None	

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WPATH Standards of care Version 8.0;
Adapted from Hembree et al 2017

Urologic Care for the LGBT Community

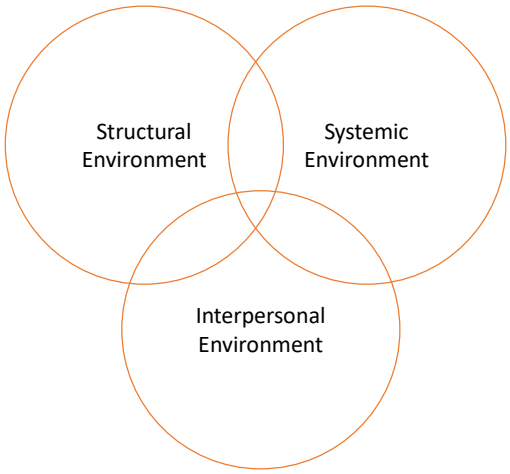
Channa Amarasekera, MD

Assistant Professor
Director, Gay and Bisexual Men's Urology Program
https://www.nm.org/conditions-and-care-areas/urology/gay-and-bisexual-mens-urology-program
Northwestern University
Feinberg School of Medicine

LGBTQ+ Marginalization in Healthcare

- History of mistrust and discrimination at community level (AIDS epidemic) and personal level
- Heteronormative attitudes in clinic
- Direct impact of stigma and chronic stress on health outcomes

Creating an Inclusive Clinic Environment



Wilkerson, 2011

Talking about Sexuality in the Clinic

Sexual orientation and identity are frequently not discussed in the clinical setting, due to gaps in providers' knowledge and comfort (Kitts, 2010)

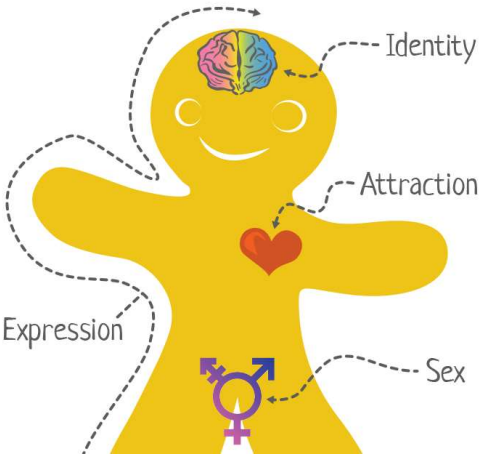
There is a significant rate of nondisclosure among LGBT patients in GU oncology clinics, burden often falling upon the patient (Rosser, 2021) Providers may be trained to:

- Provide a safe environment for disclosure
- Respond with affirmation to foster patient-physician trust

Adding sexuality and gender information in EMR has been found to be acceptable and feasible among LGBT patients (Rosser, 2021)

Sexuality is an important domain for patients and for effective physician decisions but the discomfort and gap in competence in addressing it needs to be addressed (Bauer, 2015)

Understanding LGBT Identity



A person's internal sense of their gender. Male, Female, Both or Neither

How a person identifies their physical, sexual and emotional attraction to others

How an individual presents themself via behavior, mannerisms, speech, dress. Exists as a spectrum

Assigned at birth. Male, Female or Intersex. May not be relevant to the patient but may be relevant to provider

Credit: The Genderbread Person

LGBT-inclusive Language in Clinics

- Not assuming that the patient is heterosexual/cisgender/ – asking open ended questions to give the patient the space to disclose sexual identity
- Normalizing affirmative language such as pronouns, sexual orientation and gender identity information in EMR, intake and physician-patient conversations
- Using gender-neutral terms (partner, instead of husband/wife) to document patient social history

LGBT Identity and Urologic Care

- LGBT patients may prioritize sexual health and specific aspects of sexual health more than non-LGBT patients. Ex. GBM PCa patients may be more concerned with certain side effects that should be considered when making treatment decisions:
  - Urinary incontinence
  - Erectile function
  - Loss of ejaculatory function
  - Rectal health, radiation concerns
- LGBT patients often take on the burden of being informed of how treatment decisions may affect their QOL.
- Awareness of LGBT-specific aspects of urologic conditions 1. increases trust 2. aids decision-making and 3. improves health outcomes (physical and mental health)

Resources for patients and providers

- Northwestern GBM Urology Program
- Fenway Guide to LGBT Health Textbook
- National LGBT Health Education Center Guide for Healthcare Staff
- The Joint Commission LGBT Health Field Guide
- Health Professionals Advancing LGBTQ Equality

mCSPC: Couplets vs Triplets

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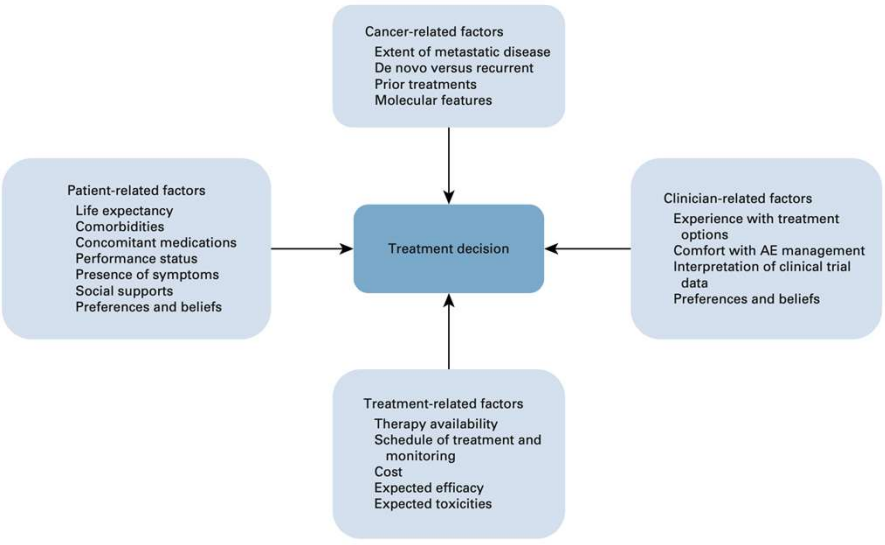
Dana-Farber Cancer Institute
Associate Professor. Harvard Medical School

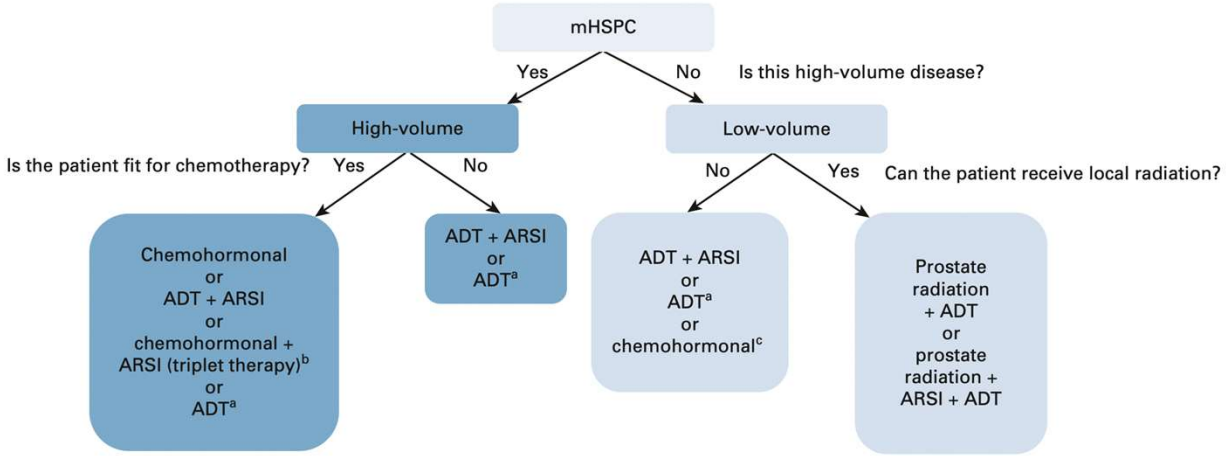
Dana-Farber Cancer Institute

Factors Contributing to Treatment Decisions



1. Morgans AK et al. *J Clin Oncol*. 2022;40:818-824.

Decision Algorithm for Treatment of mHSPC



[a] ADT monotherapy is not the preferred approach unless patient or clinical factors make combination treatment contradicted. [b] Triplet therapy with chemohormonal therapy + ARSI is associated with a survival benefit in men with de novo high-volume mHSPC. Data for men with recurrent high-volume mHSPC are not available.
[c] Chemohormonal therapy can be used in men with low-volume de novo mHSPC, but is not consistently beneficial across trials.
1. Morgans AK et al. *J Clin Oncol*. 2022;40:818-824.

National Comprehensive Cancer Network®

NCCN Guidelines Version 1.2023
Prostate Cancer

SYSTEMIC THERAPY FOR CASTRATION-SENSITIVE PROSTATE CANCER[rr]

ADT + docetaxel is no longer recommended!

M1[vv,ww,xx,yy,zz] →

ADT[u] with one of the following:
- **Preferred regimens:**
  - **Abiraterone (category 1)[u,ee]**
  - **Apalutamide (category 1)[u]**
  - **Enzalutamide (category 1)[u]**

or

ADT[u] with docetaxel and one of the following[aaa]:
- **Preferred regimens:**
  - **Abiraterone (category 1)[u,ee]**
  - **Darolutamide (category 1)[u]**

or

ADT[u] with EBRT[p] to the primary tumor for low metastatic burden M1[bbb]

or

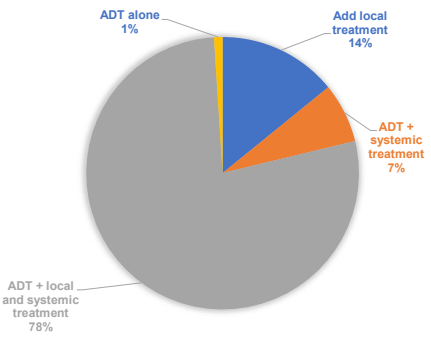
ADT[u,uu,ccc]

Schaeffer TE, et al. NCCN Prostate Cancer V 1.2023

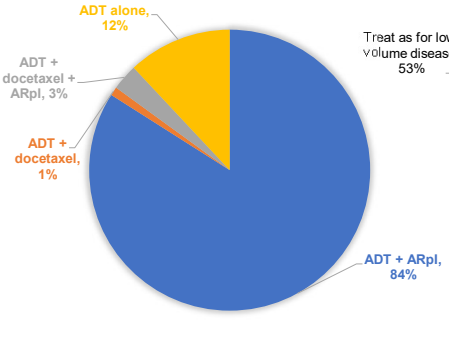
mHSPC: Couplet Therapy

APCCC Panel 2021: Recommendations for the Treatment of Low-Volume mHSPC

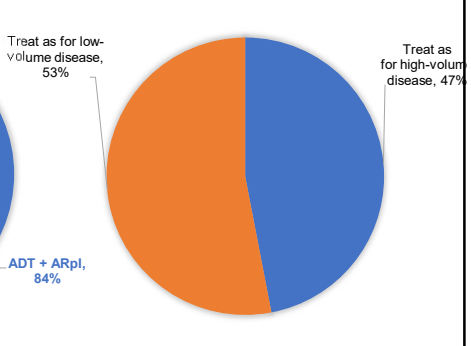
Asymptomatic, Synchronous, Low-Volume mHSPC



Asymptomatic, Synchronous, Low-Volume mHSPC, in Case Radical Local Treatment of the Primary Tumour is Recommended



Low-Volume mHSPC on Conventional Imaging but High Volume on NGI

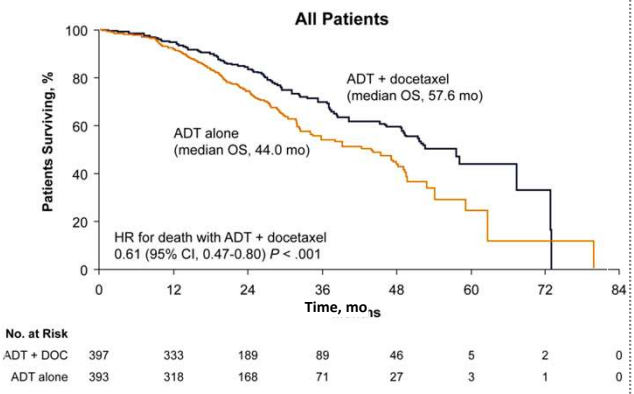


Percentage of Panellists Voted

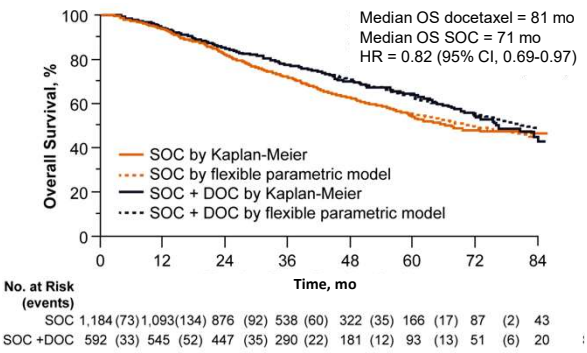
APCCC: Advanced Prostate Cancer Consensus Conference; NGI: next-generation imaging; ARpI = androgen receptor pathway inhibitor
Gillessen S et al. *Eur Urol*. 2022;82:115-141.

Chemohormonal Therapy

CHAARTED



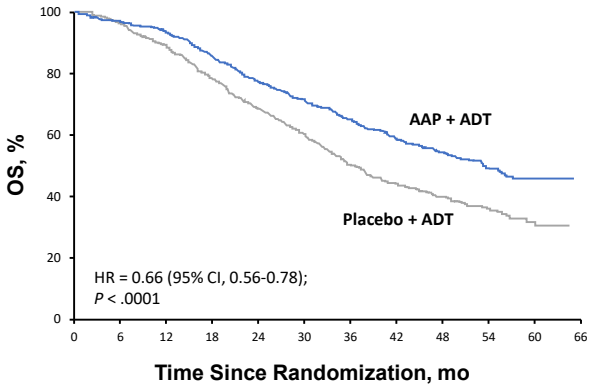
STAMPEDE



Sweeney C et al. *N Engl J Med.* 2015;373:737-746.
James ND et al. *Lancet.* 2016;387:1163-1177.

OS Benefit Confirmed in Long-Term Analyses

LATITUDE



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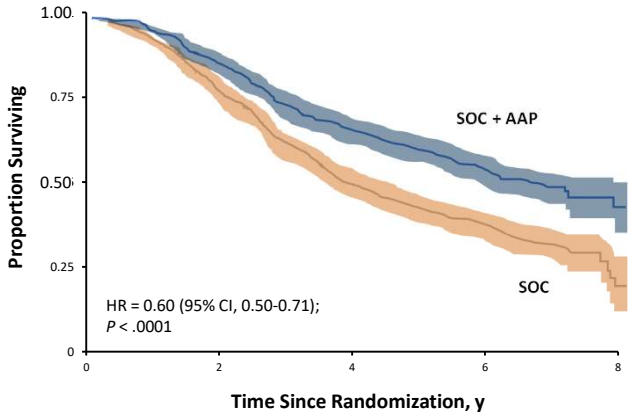
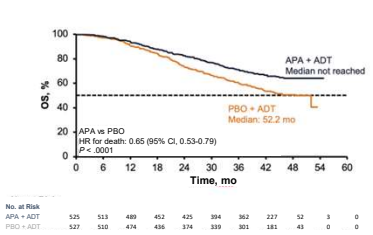


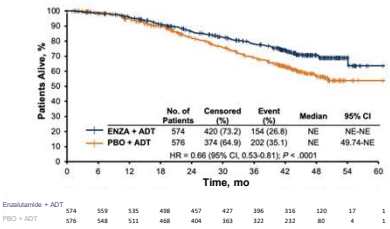
Fizazi K et al. *Lancet Oncol.* 2019;20:686-700.
James ND et al. ESMO 2020. Abstract 611O.

OS Benefit Confirmed With the Addition of ARSI

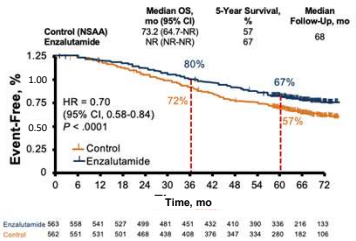
TITAN (apalutamide)



ARCHES (enzalutamide)



ENZAMET (enzalutamide)

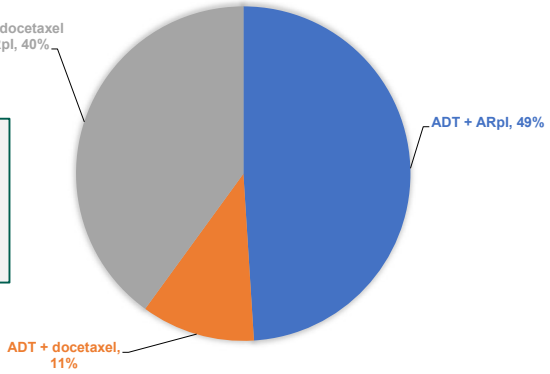


Chi KN et al. *J Clin Oncol*. 2021:39:2294-2303.
Armstrong AJ et al. *J Clin Oncol*. 2022;41:1616-1622.
Davis ID et al. ASCO 2022. Abstract LBA5004.

mHSPC: Triplet Therapy

APCCC Panel 2021: Recommendations for the Treatment of High-Volume mHSPC

Recommendation for the treatment of synchronous, high-volume mHSPC (as defined by conventional imaging or unequivocal NGI)

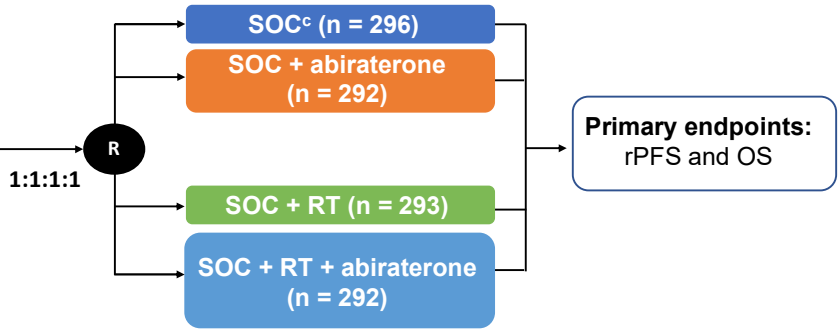


Gillessen S et al. *Eur Urol.* 2022;82:115-141.

PEACE-1: Abiraterone + Prednisone in Men With De Novo mCSPC

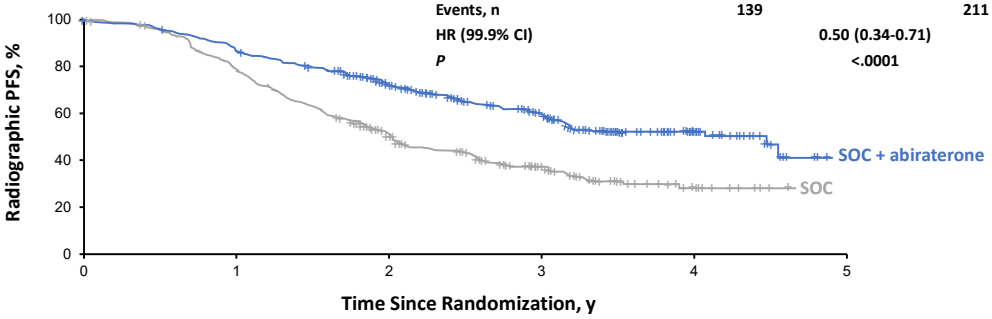
Key Eligibility Criteria
- De novo mCSPC
- Distant metastatic disease
- On-study requirement of continuous ADT
- ADT ≤3 months permitted

Stratification Factors
- ECOG PS 0 vs 1-2
- Site of metastases (LN vs bone vs viscera)
- Castration type (orchiectomy vs GnRH agonist vs GnRH antagonist)
- Docetaxel (yes vs no)



Fizazi K et al. *J Clin Oncol*. 2021;39(suppl 15):5000. Fizazi K. ESMO 2021. Abstract LBA5_PR.

PEACE-1: Improved rPFS With Abiraterone in the ADT + Docetaxel (+/- RT) Population



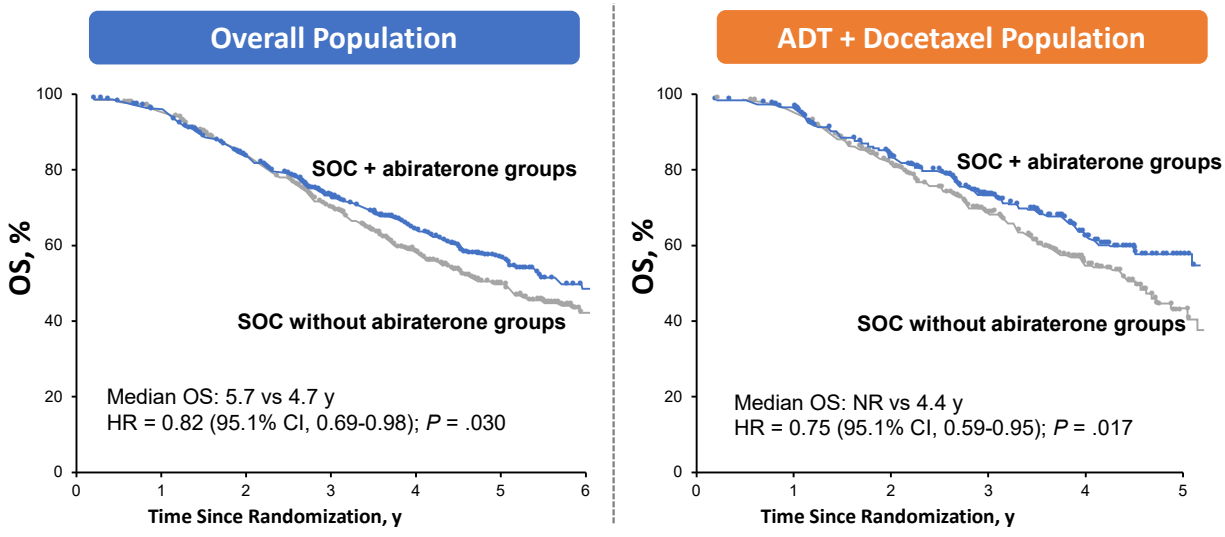
	SOC + Abiraterone (n = 355)	SOC (n = 355)
Median, y (IQR)	4.46 (1.9-NR)	2.03 (1.09-NR)
Events, n	139	211
HR (99.9% CI)	0.50 (0.34-0.71)	
P	<.0001	

No	355	274	137	61	16	0
Yes	355	303	200	105	35	0

Adding abiraterone to ADT + docetaxel significantly improved rPFS

Fizazi K et al. *Lancet*. 2022;399:1695-1707.

Phase 3 PEACE-1: Improved OS in Men With De Novo mCSPC



Fizazi K et al. *Lancet*. 2022;399:1695-1707.

ARASENS: Phase 3 Trial

International trial conducted at >300 sites in 23 countries

Key Eligibility Criteria
- Newly diagnosed metastatic disease
- ECOG PS 0 or 1
- Planned N = 1,300

Stratification Factors
- Extent of disease and ALP level

R

1:1

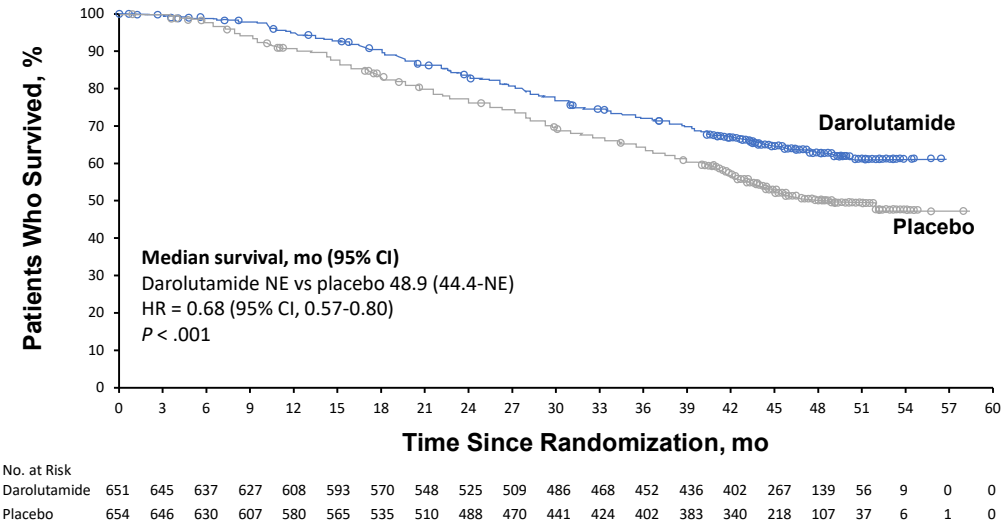
ADT + docetaxel (x 6 cycles) + darolutamide (600 mg by mouth twice daily)

ADT + docetaxel (x 6 cycles) + placebo

- **Primary endpoint:** OS
- **Key Secondary endpoints:** time to mCRPC, time to initiation of subsequent anticancer therapy, time to SSE-free survival, time to first SSE, time to pain progression

https://clinicaltrials.gov/ct2/show/NCT02799602. Smith MR et al. ASCO GU 2022. Abstract 13. Smith MR et al. *N Engl J Med*. 2022;386:1132-1142.

ARASENS: Overall Survival



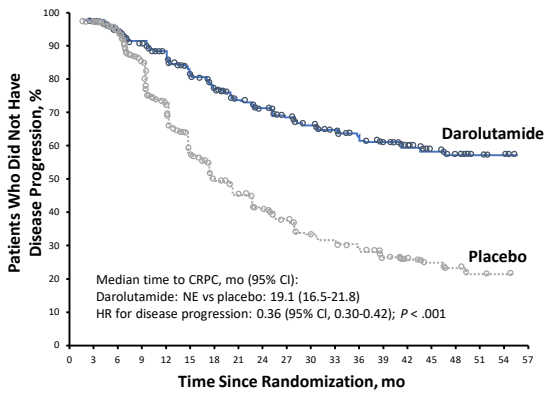
No. at Risk

Darolutamide	651	645	637	627	608	593	570	548	525	509	486	468	452	436	402	267	139	56	9	0	0
Placebo	654	646	630	607	580	565	535	510	488	470	441	424	402	383	340	218	107	37	6	1	0

Smith MR et al. *N Engl J Med*. 2022;386:1132-1142.

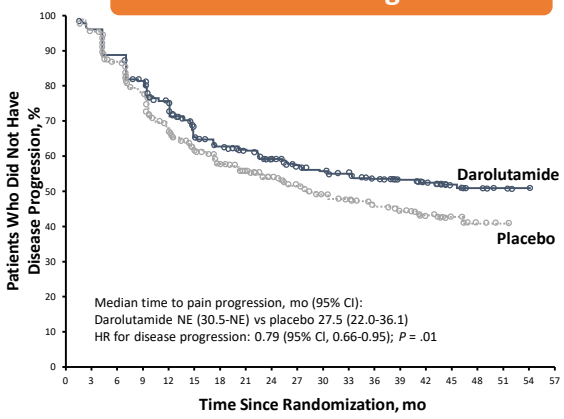
ARASENS: Key Secondary Endpoints

Time to CRPC



No. at Risk																			
Darolutamide	651	616	567	537	496	465	433	401	380	358	340	325	308	292	211	132	54	18	5	0
Placebo	654	613	533	425	348	289	242	215	185	165	143	134	120	105	79	38	14	4	1	0

Time to Pain Progression



No. at Risk																			
Darolutamide	651	447	401	363	327	284	265	249	228	211	202	189	175	159	106	67	31	6	1	0
Placebo	654	442	395	332	288	255	221	188	160	134	119	107	93	86	62	35	8	1	0	0

Smith MR et al. *N Engl J Med.* 2022;386:1132-1142.

ENZAMET: SOC ± Enzalutamide in mHSPC

Stratification Factors
- Volume of metastasis:[a] high vs low
- Planned early docetaxel: yes vs no
- ECOG PS: 0-1 vs 2
- Antiresorptive therapy: yes vs no
- Comorbidities (ACE-27): 0-1 vs 2-3
- Study site

R

ADT + enzalutamide 160 mg/d → Evaluate every 12 weeks

ADT + standard NSAA → Evaluate every 12 weeks

CRPC therapy at investigator's discretion at progression

Follow for time to progression and OS

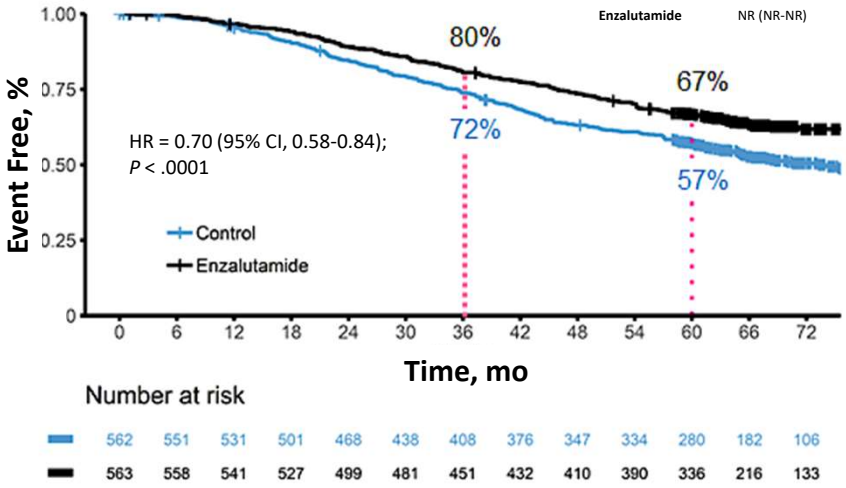
Primary endpoint: OS

- Prior to randomization, testosterone suppression up to 12 weeks and two cycles of docetaxel were allowed
- Intermittent ADT and cyproterone were not allowed
- NSAA: bicalutamide, nilutamide, flutamide

Davis ID et al. New Engl J Medicine. 2019.

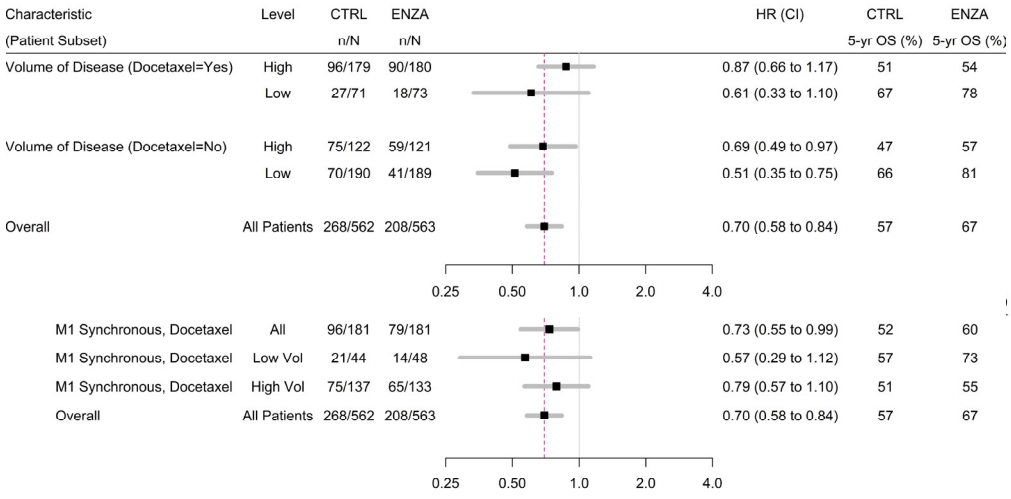
ENZAMET: OS Update

	Median OS, mo (95% CI)	5-Year Survival, %	Median Follow-Up, mo
Control (NSAA)	73.2 (64.7-NR)	57	68
Enzalutamide	NR (NR-NR)	67	



Davis ID et al. ASCO 2022, Abstract LBA5004

ENZAMET: Overall survival



Davis ID et al. ASCO 2022, Abstract LBA5004

Conclusions

- **ADT intensification for patients with mCSPC is the standard of care**
- **ADT alone is not recommended for the large majority of patients**
  - Treatment of patients with de novo, high volume mCSPC
    - Fit for docetaxel: ADT + docetaxel + abiraterone/prednisone or darolutamide or enzalutamide
    - Unfit for docetaxel: ADT + ARSI
  - Treatment of patients with low volume mCSPC
    - ADT + ARSI + RT
    - Discuss triplet therapy on a case by case basis (young, fit)

FRED HUTCH / UNIVERSITY OF WASHINGTON
CANCER CONSORTIUM

Metastatic Castration-Resistant Prostate Cancer: Combining and Sequencing

LUGPA 2022 CME
Chicago, IL

November 10, 2022

Evan Y. Yu, MD
Professor of Medicine and Oncology
Clinical Research Director, Genitourinary Oncology
Medical Director, Clinical Research Services
Fred Hutch Cancer Consortium

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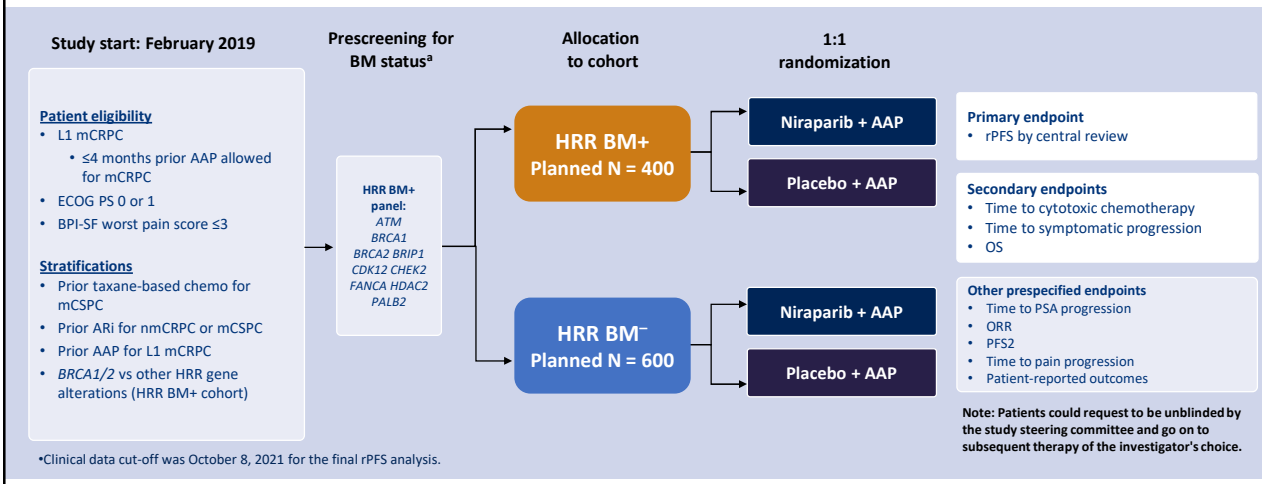
1

Disclosures

- Consulting – Advanced Accelerator Applications, Bayer, Exelixis, Janssen, Merck, Oncternal
- Research Funding to Institution – Bayer, Blue Earth, Daiichi-Sankyo, Dendreon, Lantheus, Merck, Seagen, Taiho

Randomized Phase 3 MAGNITUDE Trial Design

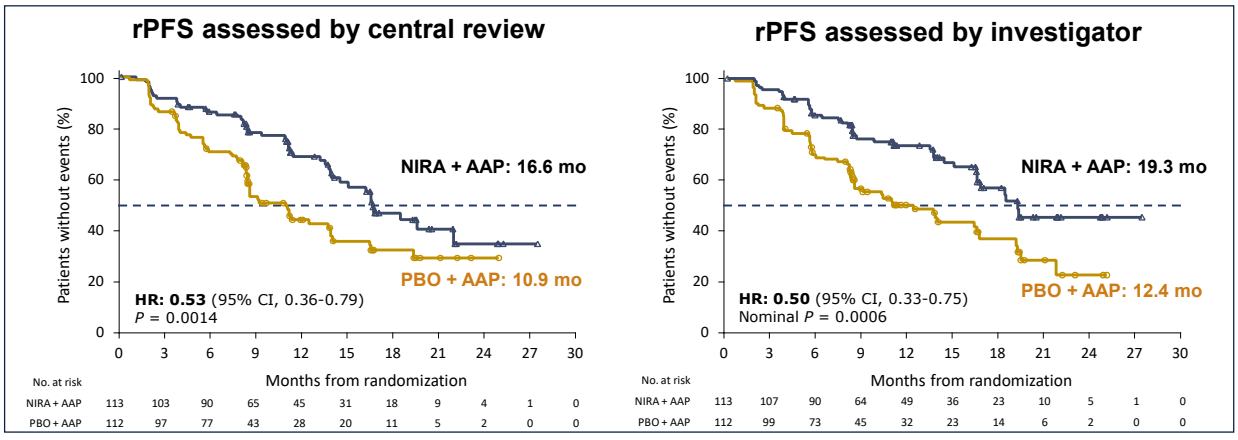


•Clinical data cut-off was October 8, 2021 for the final rPFS analysis.

AAP, abiraterone acetate + prednisone/prednisolone; AR, androgen receptor; ARi, androgen receptor inhibitor; BM, biomarker; BPI-SF, Brief Pain Inventory–Short Form; ctDNA, circulating tumor deoxyribonucleic acid; ECOG PS, Eastern Cooperative Oncology Group performance status; HRR, homologous recombination repair; L1, first line; mCRPC, metastatic castration-resistant prostate cancer; mCSPC, metastatic castration-sensitive prostate cancer; nmCRPC, nonmetastatic castration-resistant prostate cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival on first subsequent therapy; PSA, prostate-specific antigen; rPFS, radiographic progression-free survival.
[a]Tissue and Plasma assays: FoundationOne tissue test (FoundationOne®CDx), Resolution Bioscience liquid test (ctDNA), AmoyDx blood and tissue assays, Invitae germline testing (blood/saliva), local lab biomarker test results demonstrating a pathogenic germline or somatic alteration listed in the study biomarker gene panel.

Chi KN, et al. *GU ASCO* 2022.

MAGNITUDE *BRCA 1/2*-mutated: Primary Endpoint

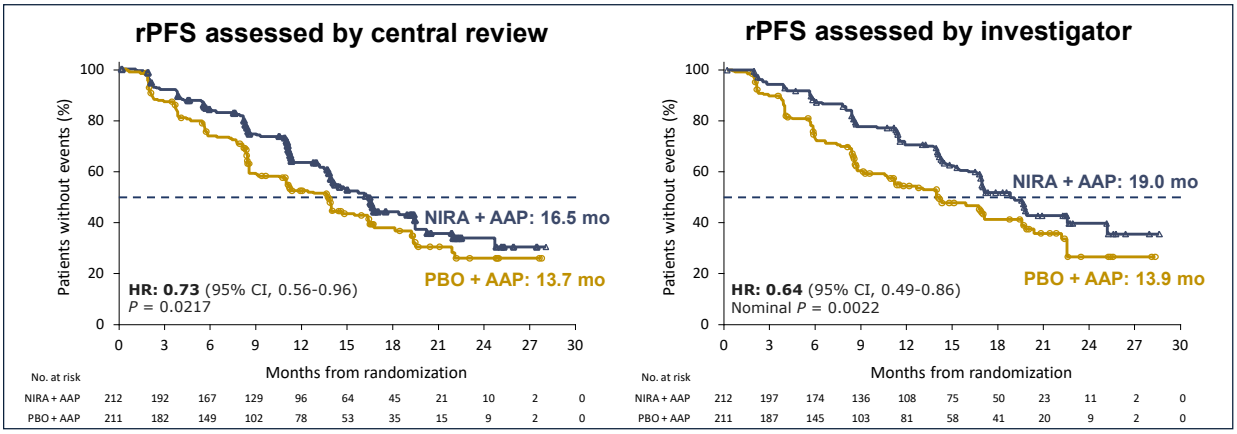


Median follow-up 16.7 months

AAP, abiraterone acetate + prednisone/prednisolone; CI, confidence interval; HR, hazard ratio; NIRA, niraparib; PBO, placebo; rPFS, radiographic progression-free survival.

Chi KN, et al. *GU ASCO* 2022.

MAGNITUDE ALL HRR BM+: Primary Endpoint



Median follow-up 18.6 months

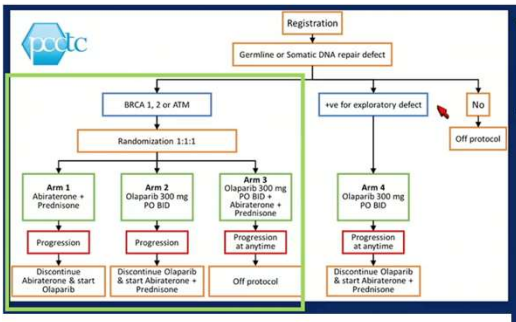
AAP, abiraterone acetate + prednisone/prednisolone; BM, biomarker; CI, confidence interval; HR, hazard ratio; HRR, homologous recombination repair; NIRA, niraparib; PBO, placebo; rPFS, radiographic progression-free survival.

Chi KN, et al. *GU ASCO* 2022.

MAGNITUDE Take Home Message

- In a biomarker selected trial for HRR+ mCRPC patients receiving first-line abiraterone, adding niraparib leads to a rPFS benefit
- Biomarker negative patients had no composite endpoint (radiographic or PSA progression) benefit to addition of niraparib to abiraterone
- Overall survival data is not mature
- The unanswered question is whether the addition of niraparib to abiraterone for HRR+ patients offers advantage to sequential use of abiraterone followed by niraparib

BRCAAway

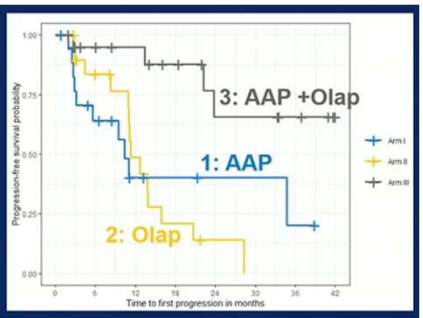


20 patients per arm

- Provides some hints that combination may be better than sequential
- Small patient numbers
- No overall survival data

Arm 1: AAP -> Olap
Arm 2: Olap -> AAP
Arm 3: AAP+Olap

➢ The crossover design allows comparison of combination vs sequential single agents



Arm (evaluable pts)	Median PFS (95% CI) in mos	12-month PFS rate (95% CI)	Unadjusted hazard ratio (Arm 3 vs Arms 1+2)
AAP (19)	10.4 (5.6, NA)	40% (0.21, 0.77)	0.17 (95% CI: 0.05, 0.56)
Olap (21)	11.3 (11.0, NA)	49% (0.29, 0.82)	0.15 (95% CI: 0.05, 0.49)
AAP + Olap (21)	NA (23.8, NA)	95% (0.86, 1.0)	-

Hussain M, et al. J Cin Oncol 40, 2022 (suppl 16; abstr 5018).

PROpel Randomized, Double-Blind Phase 3 Trial Design

Patient population
- 1L mCRPC
- Docetaxel allowed at mHSPC stage
- No prior abiraterone
- Other NHAs allowed if stopped ≥12 months prior to enrollment
- Ongoing ADT
- ECOG 0–1

Stratification factors
- Site of distant metastases: bone only vs visceral vs other
- Prior taxane at mHSPC: yes vs no

1:1

Olaparib 300 mg bid + abiraterone 1000 mg qd* n=399
Full dose of olaparib and abiraterone used

Placebo + abiraterone 1000 mg qd* n=397
Full dose of abiraterone used

Primary endpoint
- Radiographic progression or death (rPFS) by investigator assessment

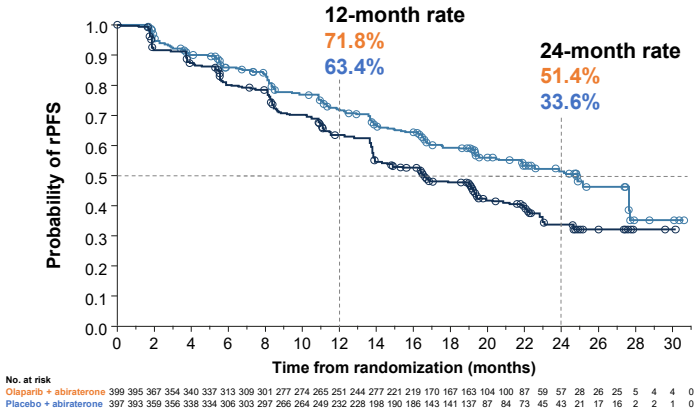
Key secondary endpoint
- Overall survival (alpha control)

Additional endpoints
- Time to first subsequent therapy or death (TFST)
- Time to second progression or death (PFS2)
- Objective response rate (ORR)
- HRRm† prevalence (retrospective testing)
- Health-related quality of life
- Safety and tolerability

First patient randomized: Nov 2018; Last patient randomized: Mar 2020; DCO1: July 30, 2021, for interim analysis of rPFS and OS.
Multiple testing procedure is used in this study: 1-sided alpha of 0.025 fully allocated to rPFS. If the rPFS result is statistically significant, OS to be tested in a hierarchical fashion with alpha passed on to OS.
Please access the ***Supplement*** via the QR code at the end of this presentation for more details.
*In combination with prednisone or prednisolone 5 mg bid. †HRRm, homologous recombination repair mutation, including 14 genes panel.
ADT, androgen deprivation therapy; bid, twice daily; ECOG, Eastern Cooperative Oncology Group; mHSPC, metastatic hormone sensitive prostate cancer; qd, daily

Saad F, et al. *GU ASCO* 2022.

PROpel Primary Endpoint: rPFS by Investigator Assessment



Events: 394; Maturity 49.5%
*In combination with prednisone or prednisolone
CI, confidence interval; HR, hazard ratio.

	Olaparib + abiraterone (n=399)	Placebo + abiraterone (n=397)
Events, n (%)	168 (42.1)	226 (56.9)
Median rPFS (months)	24.8	16.6
HR (95% CI)	0.66 (0.54–0.81); *P*<0.0001	

Pre-specified 2-sided alpha: 0.0324

Median rPFS improvement of 8.2 months favors olaparib + abiraterone*

Saad F, et al. *GU ASCO* 2022.

PROpel Pre-Specified Subgroup Analyses of rPFS

	Number of patients, n	Median rPFS, months		HR (95% CI)
All patients	796	24.8	16.6	0.66 (0.54–0.81)
Age at randomization				
<65	227	NR	16.4	0.51 (0.35–0.75)
≥65	569	22.0	16.7	0.78 (0.62–0.98)
ECOG performance status at baseline				
0	558	24.9	16.8	0.67 (0.52–0.85)
1	236	17.5	14.6	0.75 (0.53–1.06)
Site of distant metastases				
Bone only	434	27.6	22.2	0.73 (0.54–0.98)
Visceral	105	13.7	10.9	0.62 (0.39–0.99)
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Docetaxel treatment at mHSPC stage				
Yes	189	27.6	13.8	0.61 (0.40–0.92)
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Baseline PSA				
Below median baseline PSA	396	25.2	22.0	0.75 (0.55–1.02)
Above or equal to median baseline PSA	397	18.5	13.8	0.63 (0.48–0.82)
HRRm status*				
HRRm	226	NR	13.9	0.50 (0.34–0.73)
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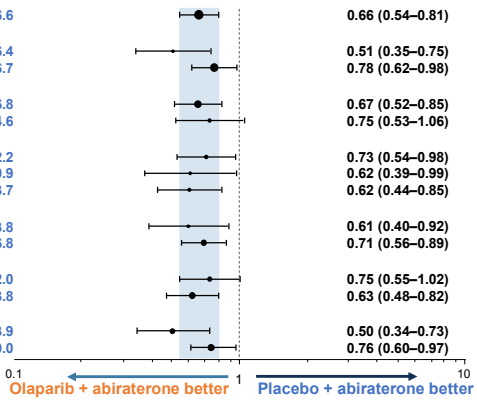

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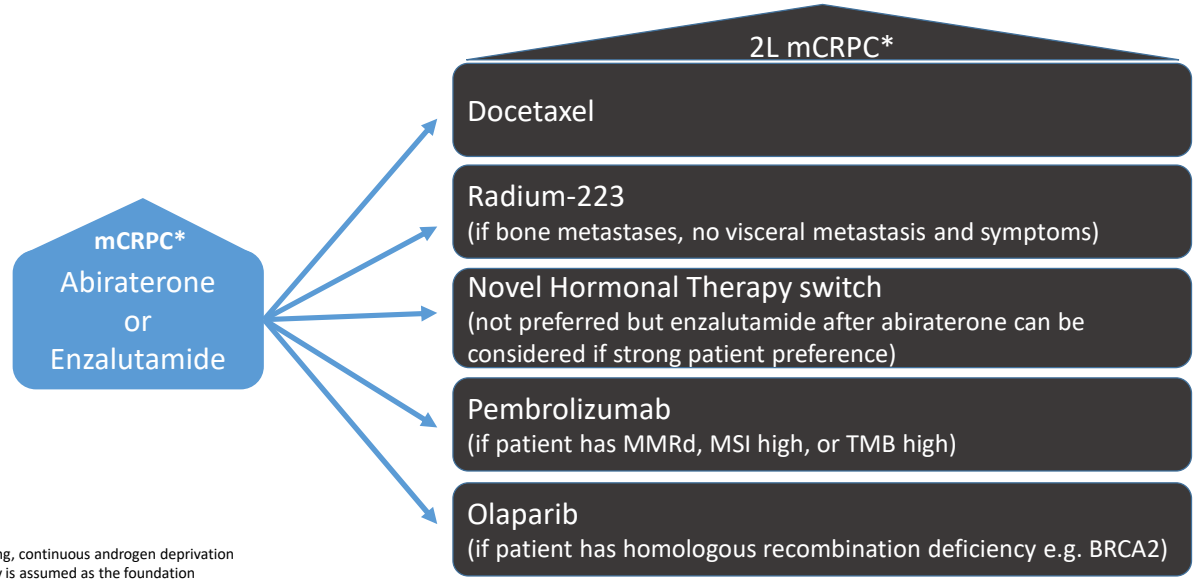
Traditional Path for Novel Hormonal Therapy Agents – 1st Line mCRPC



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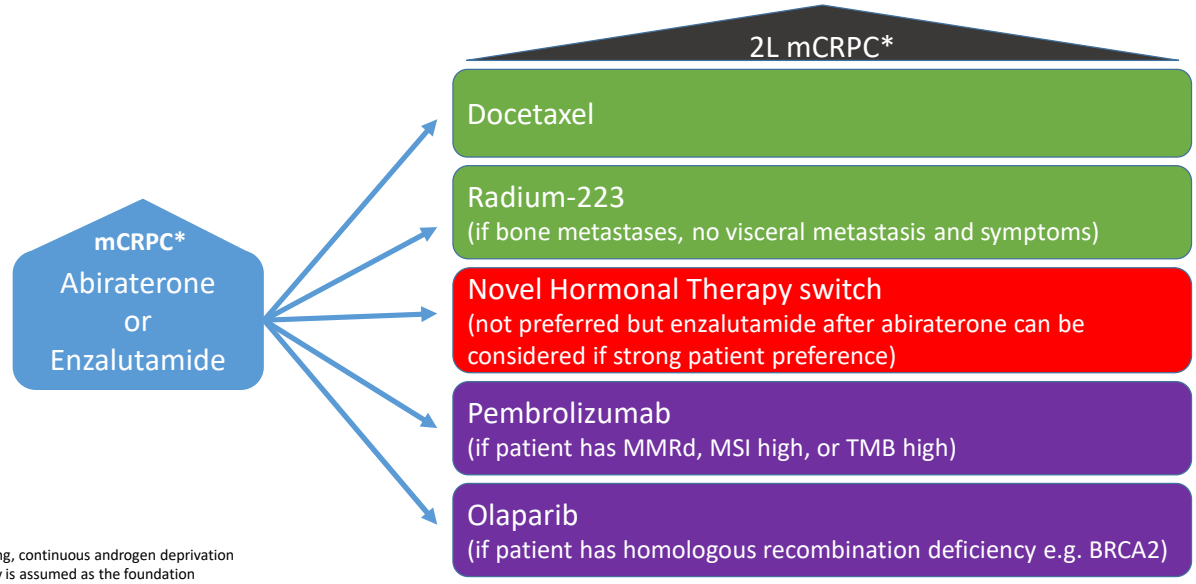

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Abiraterone Followed by Enzalutamide is the Better Sequence but Back-to-Back NHAs Yield Poor Results

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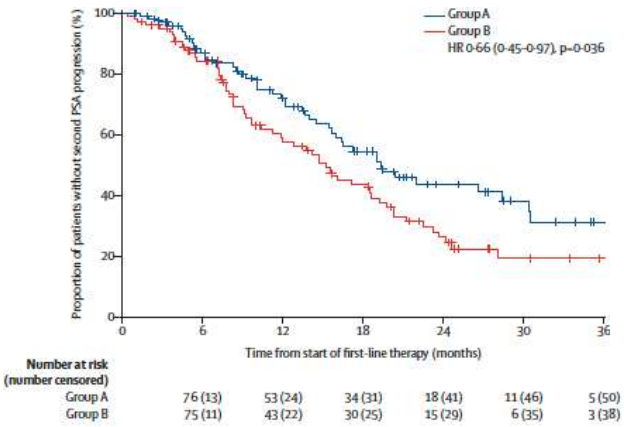

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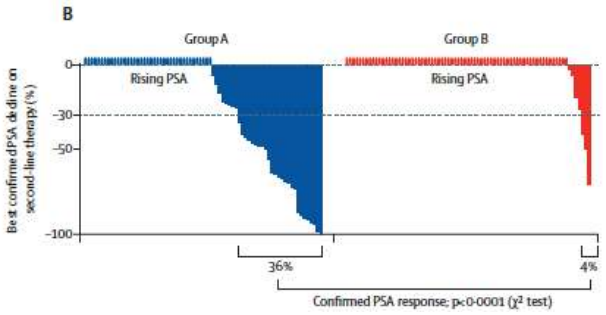

Khalaf DJ et al. *Lancet Oncol.* 2019;Epub November 11, 2019.

Should Radium-223 be Used Before or After Chemotherapy?

- Only FDA approved for patients lacking visceral metastasis
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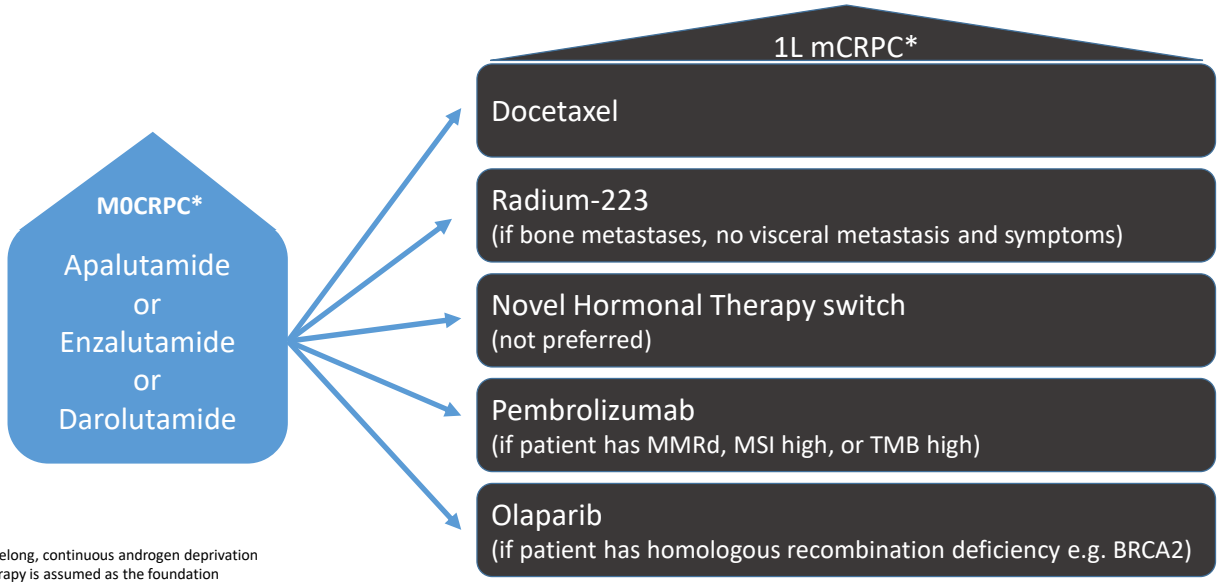
- Prior use of docetaxel increases likelihood of challenges with neutropenia and/or thrombocytopenia
- Requires pre-authorization, while chemotherapy with docetaxel does not
- More likely to be able to administer all 6 doses in the pre- vs. post-chemotherapy setting

Traditional Path (What Next for Patients Who Received 1st line NHA for mCRPC?) – Evan's Thoughts

- Precision therapy when possible
- Back-to-back NHA yields poor results…if one must do it, it is better to go abiraterone to enzalutamide than visa versa
- Radium-223 can ideally be administered here before docetaxel if the patient has bone metastases, lacks visceral metastasis, and has symptoms
- Docetaxel will be your best shot at response and should be the most frequently relied upon path

M0 CRPC Path for Novel Hormonal Therapy Agents



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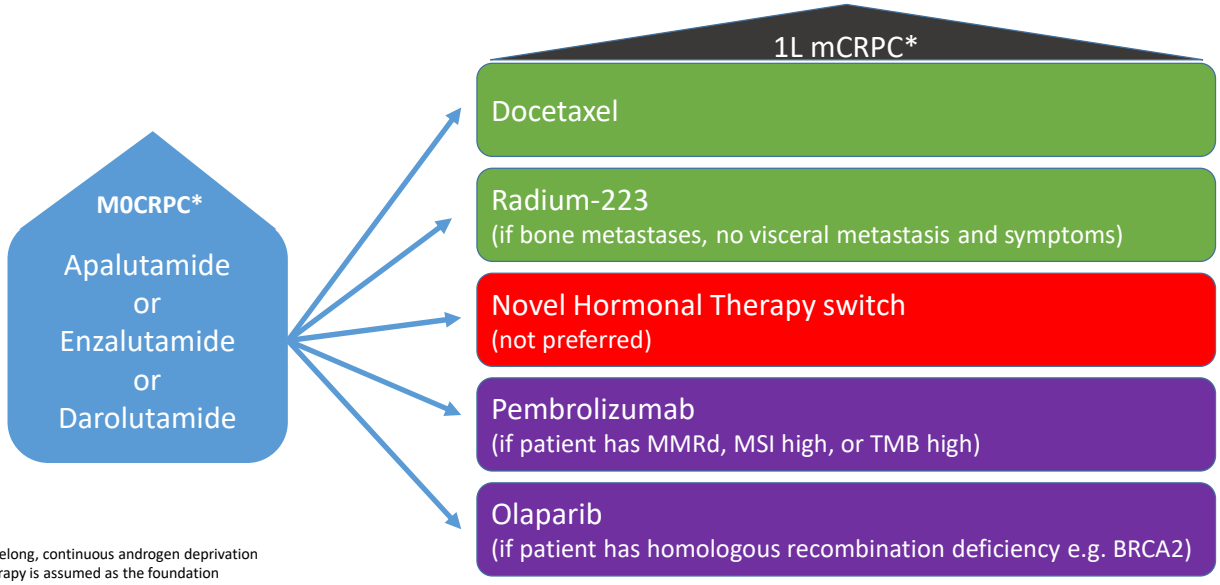

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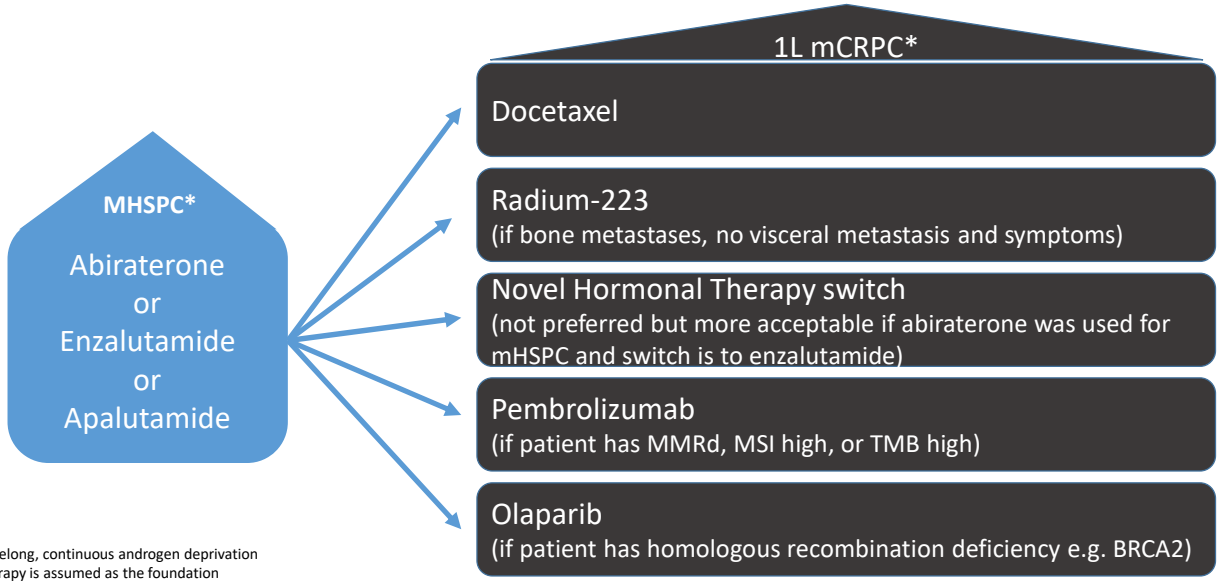
What Next for Patients who Received 1st Line NHA Administered for M0 CRPC? – Evan's Thoughts

- Precision therapy when possible
- Back-to-back NHA is something I never do because it would essentially have to be abiraterone, and that yields extremely low response rates
- Radium-223 can ideally be administered here before docetaxel if the patient has bone metastases, lacks visceral metastasis, and has symptoms
- Docetaxel will be your best shot at response and should be the most frequently relied upon path

Metastatic *Hormone Sensitive* Prostate Cancer Path for 1st Line NHA



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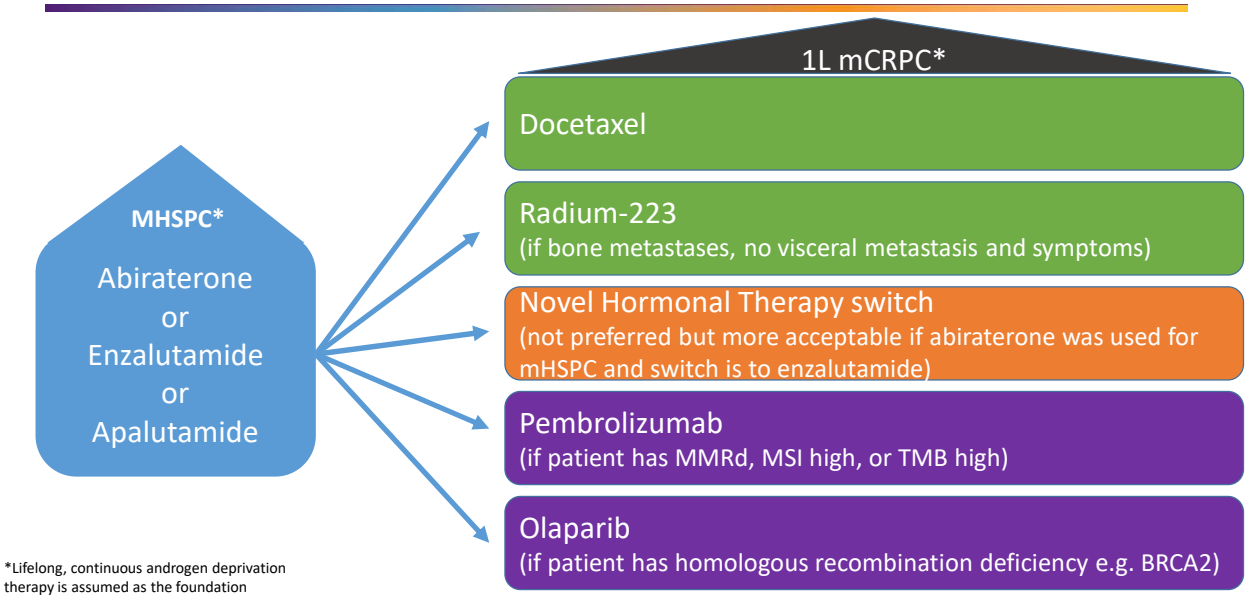

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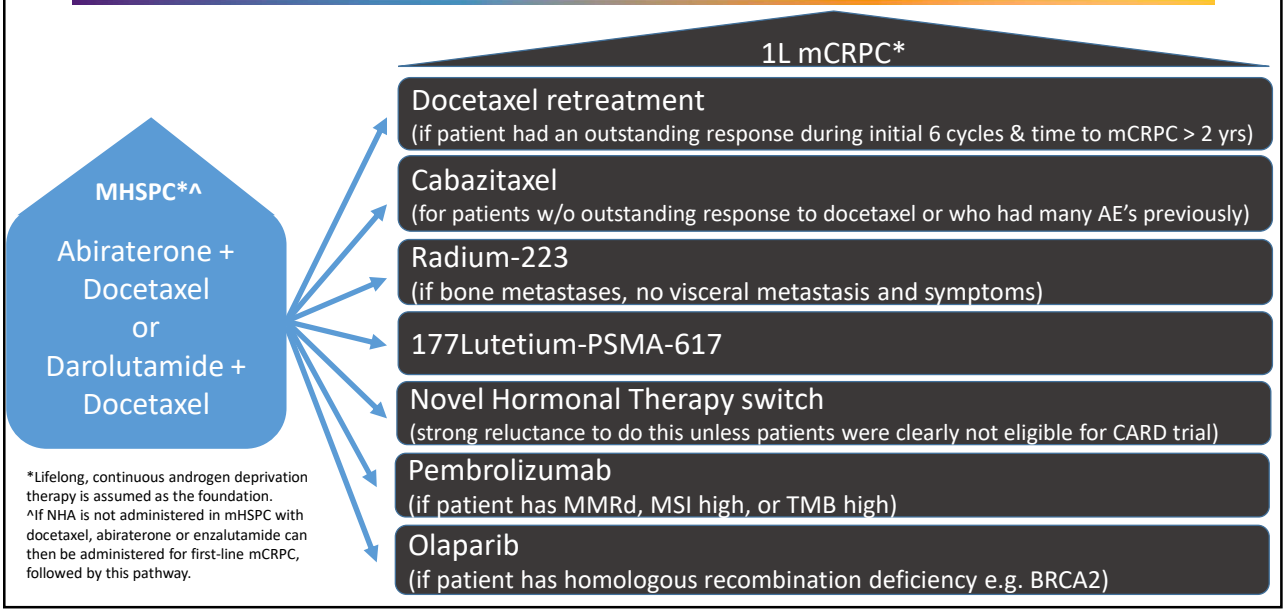
What Next for Patients Who Received 1st Line NHA Administered for mHSPC? – Evan's Thoughts

- Precision therapy when possible
- Radium-223 can ideally be administered here before docetaxel if the patient has bone metastases, lacks visceral metastasis, and has symptoms
- Docetaxel will be your best shot at response and should be the most frequently relied upon path
- However, if the NHA was abiraterone, I might try switch to enzalutamide for select patients who have slower rise in PSA, are asymptomatic, have no new metastases on imaging, and who are reluctant to move on to chemotherapy

Docetaxel +/- NHA Administered for Metastatic Hormone Sensitive Prostate Cancer



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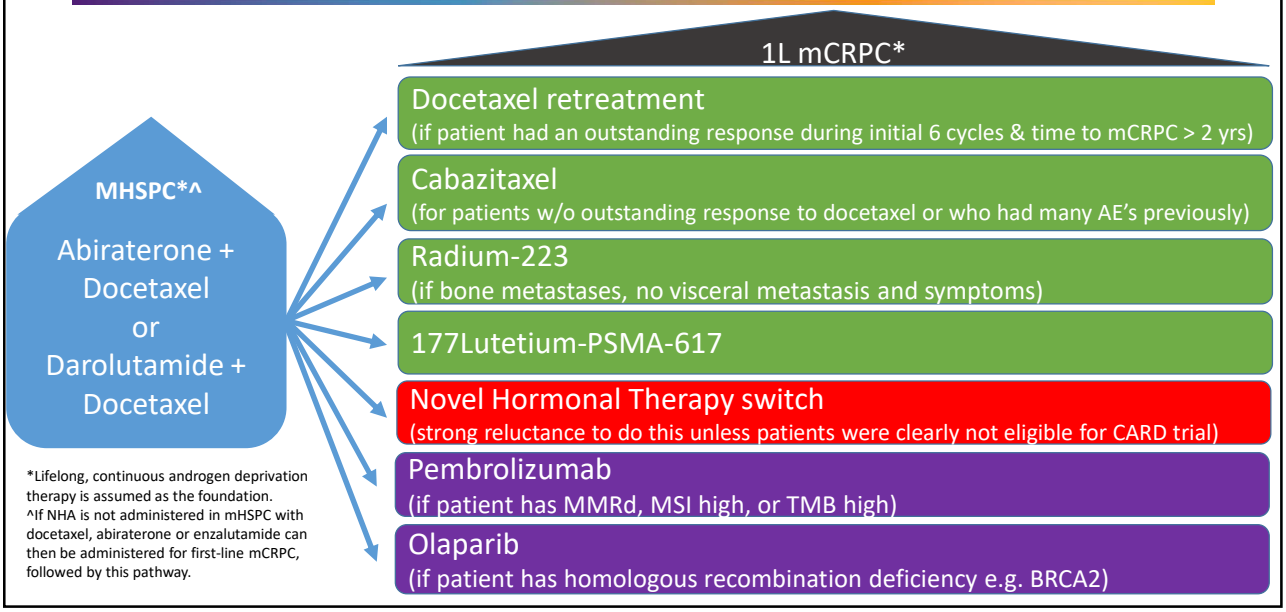
^If NHA is not administered in mHSPC with docetaxel, abiraterone or enzalutamide can then be administered for first-line mCRPC, followed by this pathway.

Docetaxel +/- NHA Administered for Metastatic Hormone Sensitive Prostate Cancer



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^If NHA is not administered in mHSPC with docetaxel, abiraterone or enzalutamide can then be administered for first-line mCRPC, followed by this pathway.

What Next for Patients Who Received Docetaxel + NHA Administered for mHSPC or Docetaxel followed by NHA for 1st Line mCRPC – Evan's Thoughts

- Precision therapy when possible
- Radium-223 can ideally be administered here if the patient has bone metastases, lacks visceral metastasis, and has symptoms
- Docetaxel retreatment can be considered if the patient had a good initial response for mHSPC and a long period before mCRPC developed
- Cabazitaxel and ^{177}Lutetium-PSMA-617 (these patients fit the FDA label!) may be the ideal agents to use in this situation
  - I may lean slightly towards ^{177}Lutetium-PSMA-617 because the TheraP trial showed superior PSA50 decline, composite PFS, and a better adverse event profile
- NHA switch should be strongly discouraged, given the other good available options

Take Home Points

- Combination therapy for mCRPC has generally been unremarkable, although there are early hints for combining abiraterone with PARP inhibitors
- There are many options for patients who progress on a NHA
- There are now many settings where a NHA can be received, and when it is administered and whether docetaxel has been given or not affects downstream options
- There is no definitive pathway, and patient individualization and clinical judgment should be applied
- Switch from one NHA to another generally does not lead to good outcomes, hence, change in mechanism of action is encouraged
- Clinical trial accrual is encouraged and standard of care is likely to change in the future

FRED HUTCH / UNIVERSITY OF WASHINGTON
CANCER CONSORTIUM

Metastatic Castration-Resistant Prostate Cancer: Combining and Sequencing

LUGPA 2022 CME
Chicago, IL

November 10, 2022

Evan Y. Yu, MD
Professor of Medicine and Oncology
Clinical Research Director, Genitourinary Oncology
Medical Director, Clinical Research Services
Fred Hutch Cancer Consortium

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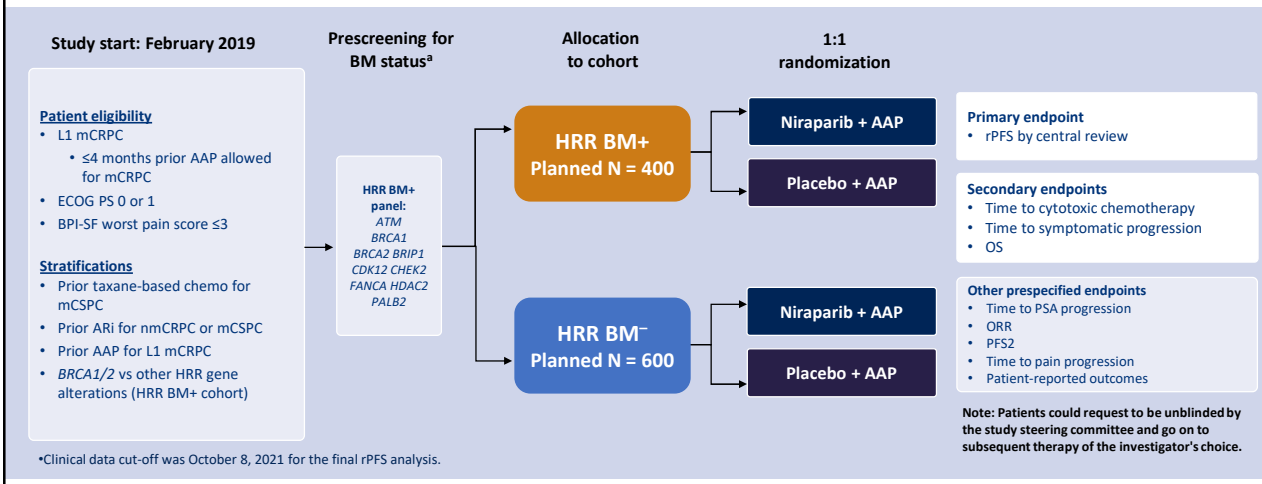
1

Disclosures

- Consulting – Advanced Accelerator Applications, Bayer, Exelixis, Janssen, Merck, Oncternal
- Research Funding to Institution – Bayer, Blue Earth, Daiichi-Sankyo, Dendreon, Lantheus, Merck, Seagen, Taiho

Randomized Phase 3 MAGNITUDE Trial Design

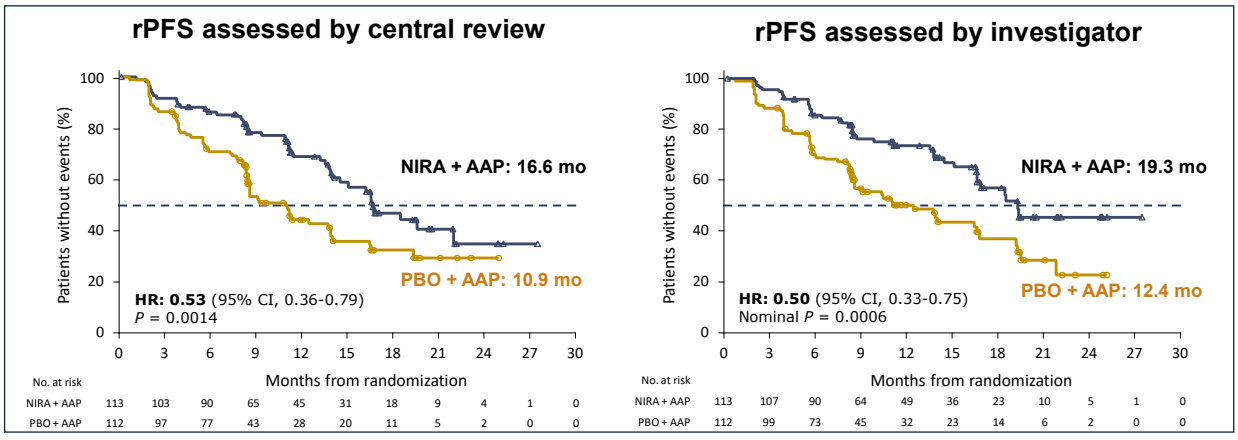


•Clinical data cut-off was October 8, 2021 for the final rPFS analysis.

AAP, abiraterone acetate + prednisone/prednisolone; AR, androgen receptor; ARi, androgen receptor inhibitor; BM, biomarker; BPI-SF, Brief Pain Inventory–Short Form; ctDNA, circulating tumor deoxyribonucleic acid; ECOG PS, Eastern Cooperative Oncology Group performance status; HRR, homologous recombination repair; L1, first line; mCRPC, metastatic castration-resistant prostate cancer; mCSPC, metastatic castration-sensitive prostate cancer; nmCRPC, nonmetastatic castration-resistant prostate cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival on first subsequent therapy; PSA, prostate-specific antigen; rPFS, radiographic progression-free survival.
[a]Tissue and Plasma assays: FoundationOne tissue test (FoundationOne®CDx), Resolution Bioscience liquid test (ctDNA), AmoyDx blood and tissue assays, Invitae germline testing (blood/saliva), local lab biomarker test results demonstrating a pathogenic germline or somatic alteration listed in the study biomarker gene panel.

Chi KN, et al. *GU ASCO* 2022.

MAGNITUDE *BRCA 1/2*-mutated: Primary Endpoint

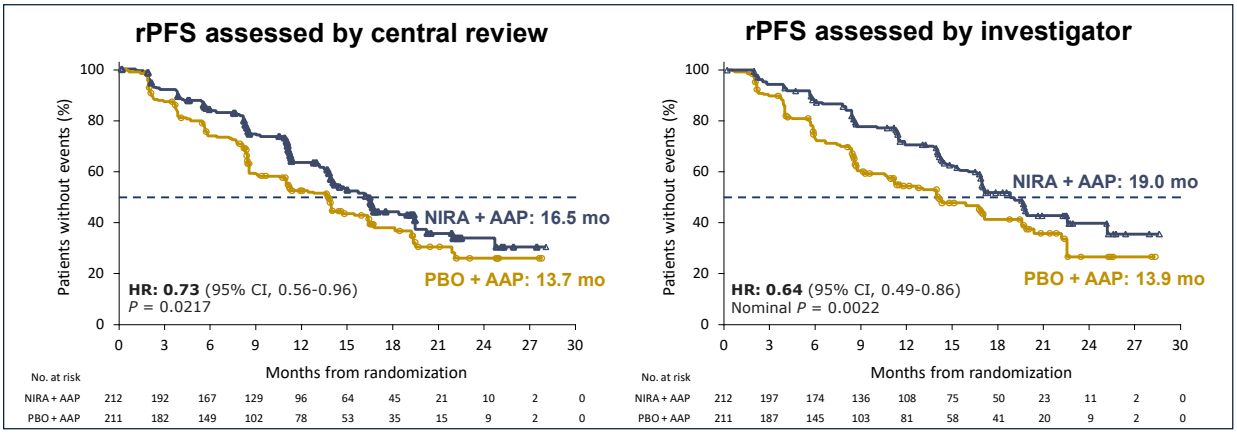


Median follow-up 16.7 months

AAP, abiraterone acetate + prednisone/prednisolone; CI, confidence interval; HR, hazard ratio; NIRA, niraparib; PBO, placebo; rPFS, radiographic progression-free survival.

Chi KN, et al. *GU ASCO* 2022.

MAGNITUDE ALL HRR BM+: Primary Endpoint



Median follow-up 18.6 months

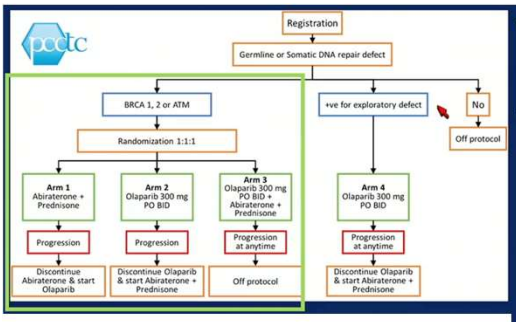
AAP, abiraterone acetate + prednisone/prednisolone; BM, biomarker; CI, confidence interval; HR, hazard ratio; HRR, homologous recombination repair; NIRA, niraparib; PBO, placebo; rPFS, radiographic progression-free survival.

Chi KN, et al. *GU ASCO* 2022.

MAGNITUDE Take Home Message

- In a biomarker selected trial for HRR+ mCRPC patients receiving first-line abiraterone, adding niraparib leads to a rPFS benefit
- Biomarker negative patients had no composite endpoint (radiographic or PSA progression) benefit to addition of niraparib to abiraterone
- Overall survival data is not mature
- The unanswered question is whether the addition of niraparib to abiraterone for HRR+ patients offers advantage to sequential use of abiraterone followed by niraparib

BRCAAway

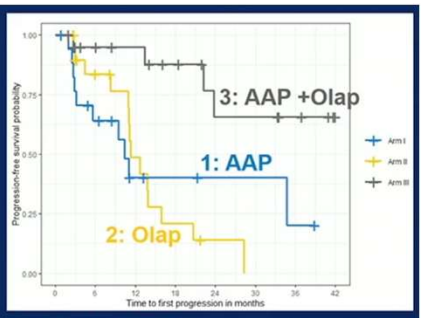


20 patients per arm

- Provides some hints that combination may be better than sequential
- Small patient numbers
- No overall survival data

Arm 1: AAP -> Olap
Arm 2: Olap -> AAP
Arm 3: AAP+Olap

➢ The crossover design allows comparison of combination vs sequential single agents



Arm (evaluable pts)	Median PFS (95% CI) in mos	12-month PFS rate (95% CI)	Unadjusted hazard ratio (Arm 3 vs Arms 1+2)
AAP (19)	10.4 (5.6, NA)	40% (0.21, 0.77)	0.17 (95% CI: 0.05, 0.56)
Olap (21)	11.3 (11.0, NA)	49% (0.29, 0.82)	0.15 (95% CI: 0.05, 0.49)
AAP + Olap (21)	NA (23.8, NA)	95% (0.86, 1.0)	-

Hussain M, et al. J Cin Oncol 40, 2022 (suppl 16; abstr 5018).

PROpel Randomized, Double-Blind Phase 3 Trial Design

Patient population
- 1L mCRPC
- Docetaxel allowed at mHSPC stage
- No prior abiraterone
- Other NHAs allowed if stopped ≥12 months prior to enrollment
- Ongoing ADT
- ECOG 0–1

Stratification factors
- Site of distant metastases: bone only vs visceral vs other
- Prior taxane at mHSPC: yes vs no

1:1

Olaparib 300 mg bid + abiraterone 1000 mg qd* n=399
Full dose of olaparib and abiraterone used

Placebo + abiraterone 1000 mg qd* n=397
Full dose of abiraterone used

Primary endpoint
- Radiographic progression or death (rPFS) by investigator assessment

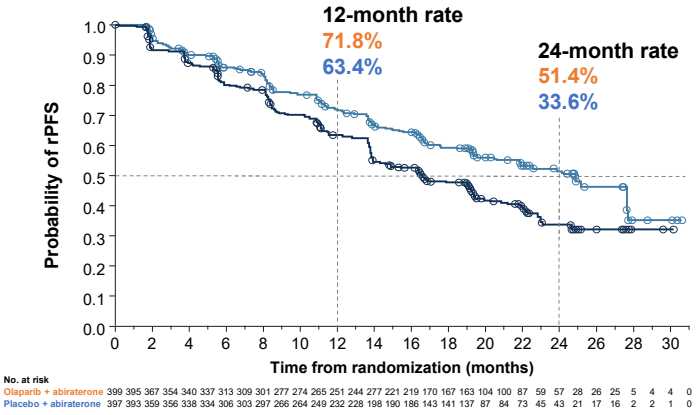
Key secondary endpoint
- Overall survival (alpha control)

Additional endpoints
- Time to first subsequent therapy or death (TFST)
- Time to second progression or death (PFS2)
- Objective response rate (ORR)
- HRRm† prevalence (retrospective testing)
- Health-related quality of life
- Safety and tolerability

First patient randomized: Nov 2018; Last patient randomized: Mar 2020; DCO1: July 30, 2021, for interim analysis of rPFS and OS.
Multiple testing procedure is used in this study: 1-sided alpha of 0.025 fully allocated to rPFS. If the rPFS result is statistically significant, OS to be tested in a hierarchical fashion with alpha passed on to OS.
Please access the ***Supplement*** via the QR code at the end of this presentation for more details.
*In combination with prednisone or prednisolone 5 mg bid. †HRRm, homologous recombination repair mutation, including 14 genes panel.
ADT, androgen deprivation therapy; bid, twice daily; ECOG, Eastern Cooperative Oncology Group; mHSPC, metastatic hormone sensitive prostate cancer; qd, daily

Saad F, et al. *GU ASCO* 2022.

PROpel Primary Endpoint: rPFS by Investigator Assessment



Events: 394; Maturity 49.5%
*In combination with prednisone or prednisolone
CI, confidence interval; HR, hazard ratio.

	Olaparib + abiraterone (n=399)	Placebo + abiraterone (n=397)
Events, n (%)	168 (42.1)	226 (56.9)
Median rPFS (months)	24.8	16.6
HR (95% CI)	0.66 (0.54–0.81); *P*<0.0001	

Pre-specified 2-sided alpha: 0.0324

Median rPFS improvement of 8.2 months favors olaparib + abiraterone*

Saad F, et al. *GU ASCO* 2022.

PROpel Pre-Specified Subgroup Analyses of rPFS

	Number of patients, n	Median rPFS, months		HR (95% CI)
All patients	796	24.8	16.6	0.66 (0.54–0.81)
Age at randomization				
<65	227	NR	16.4	0.51 (0.35–0.75)
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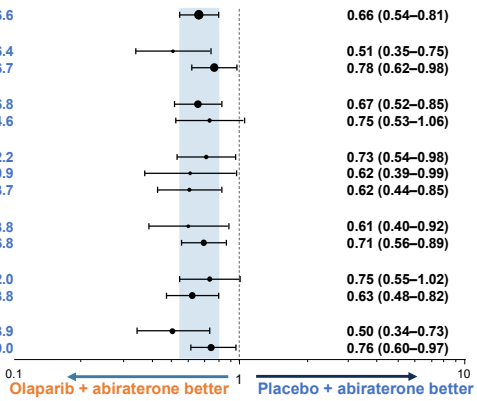

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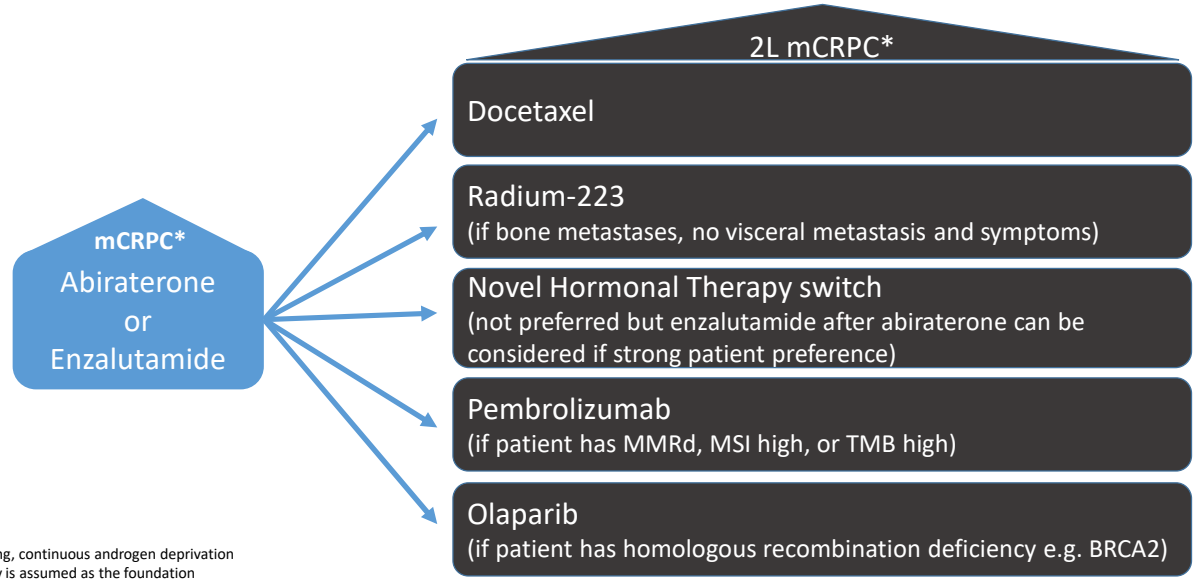

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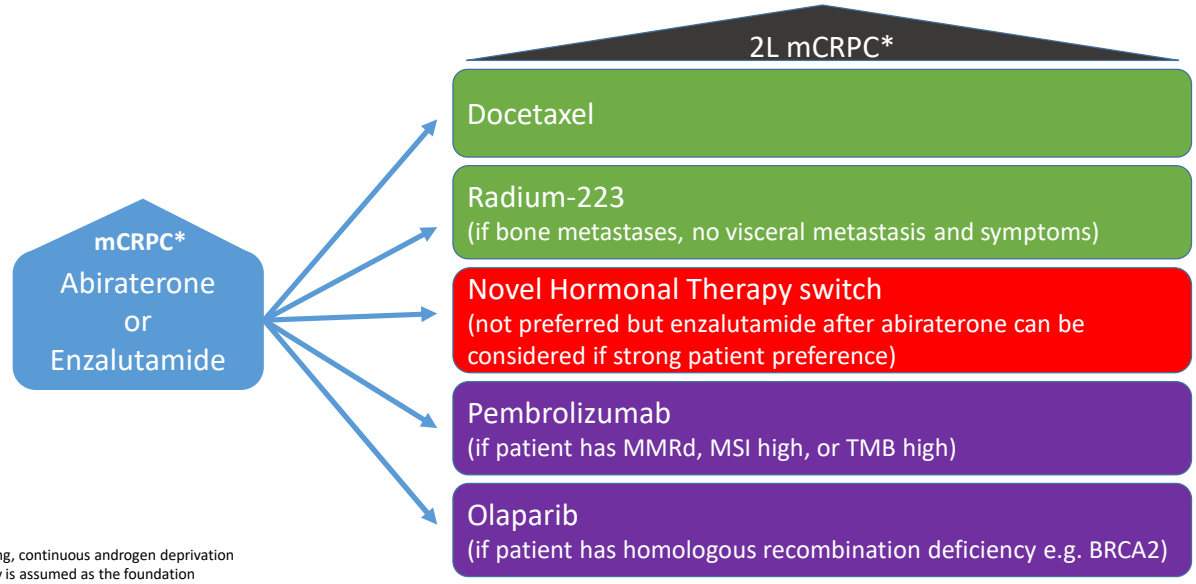

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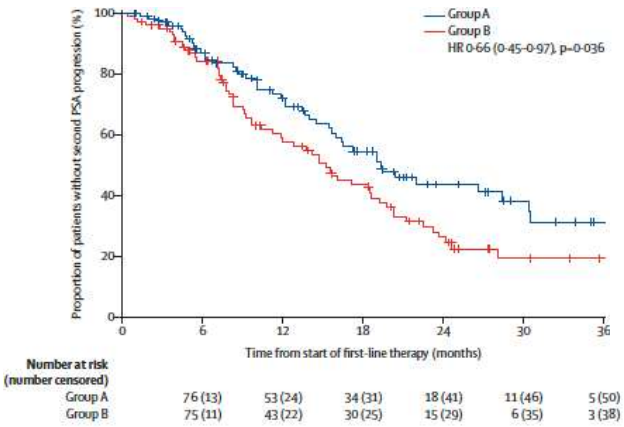

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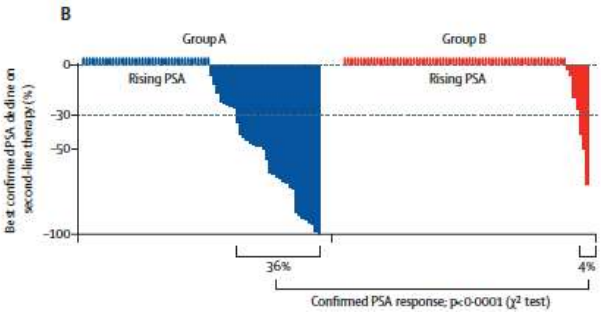

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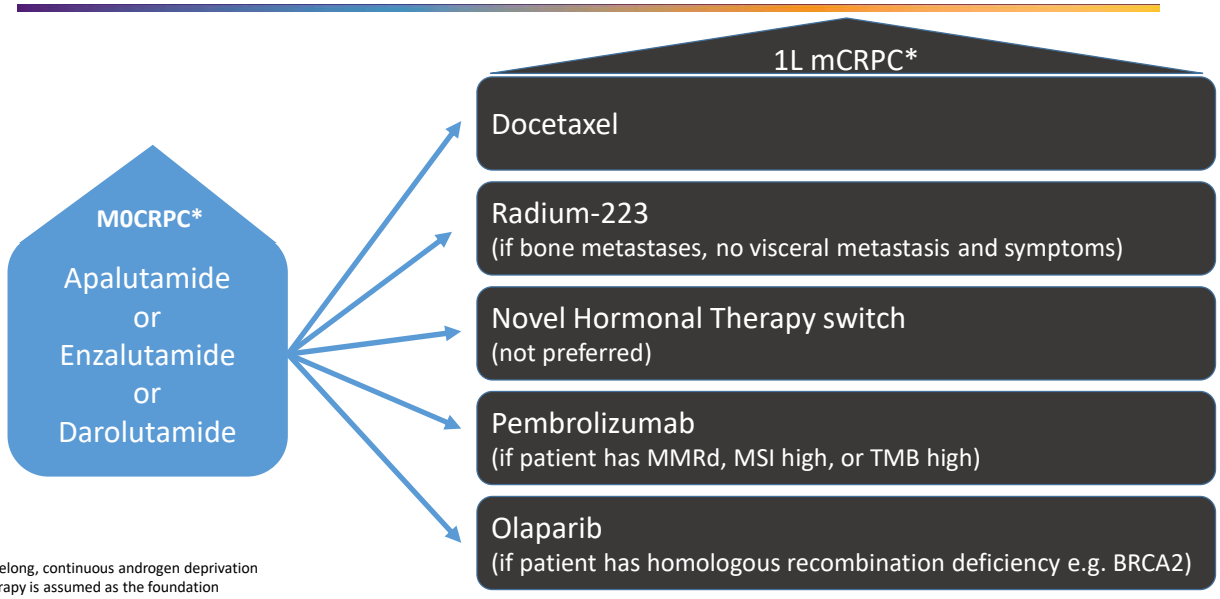
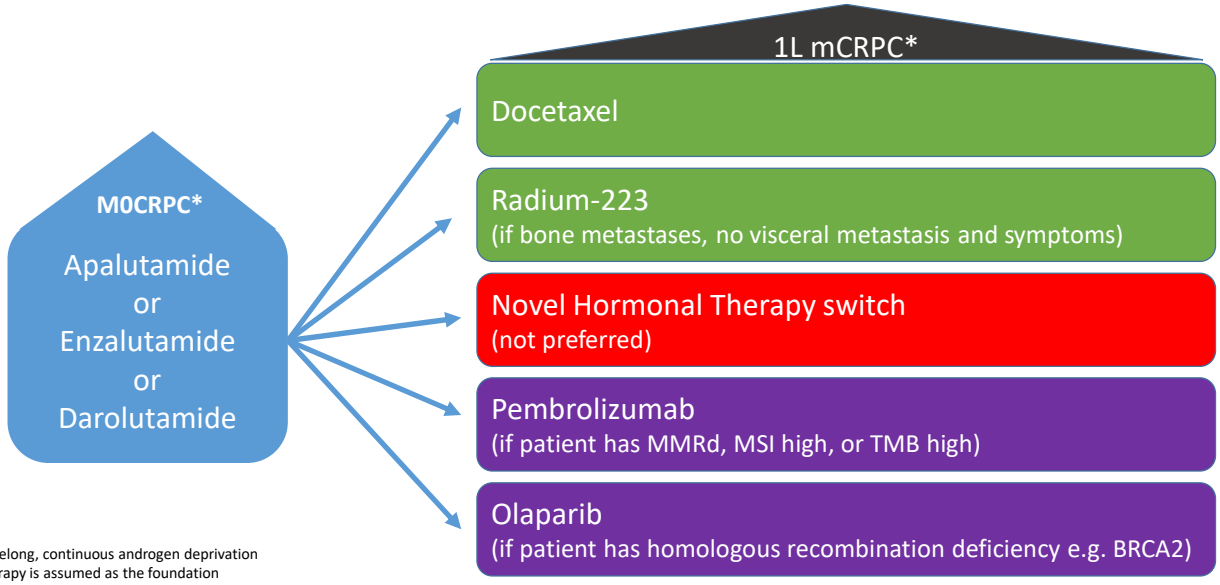


*Lifelong, continuous androgen deprivation therapy is assumed as the foundation

M0 CRPC Path for Novel Hormonal Therapy Agents

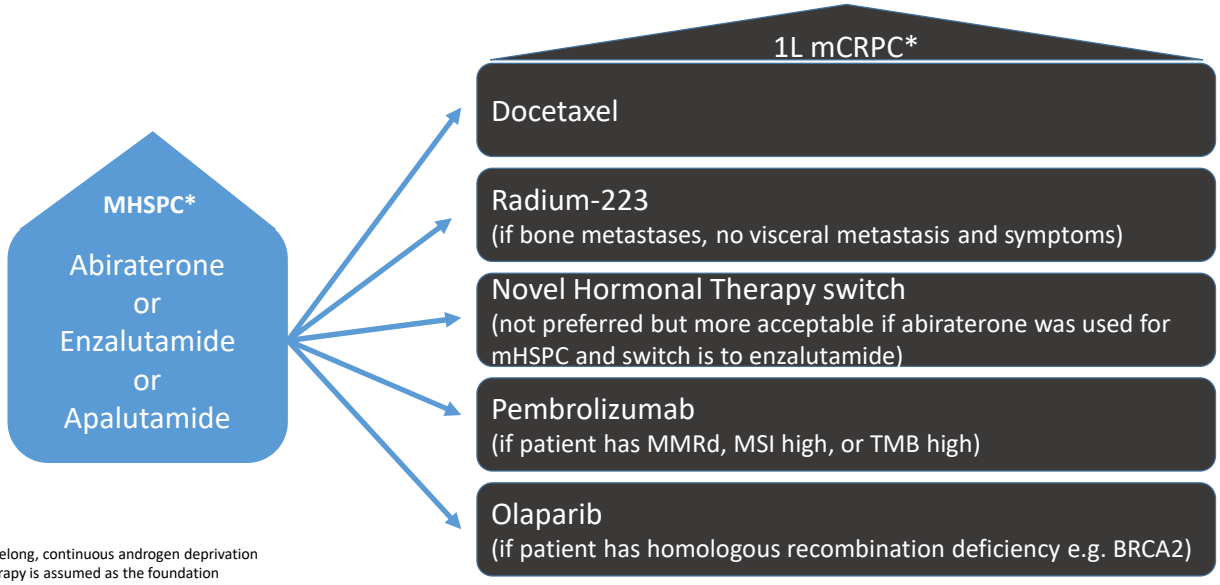


*Lifelong, continuous androgen deprivation therapy is assumed as the foundation

What Next for Patients who Received 1st Line NHA Administered for M0 CRPC? – Evan's Thoughts

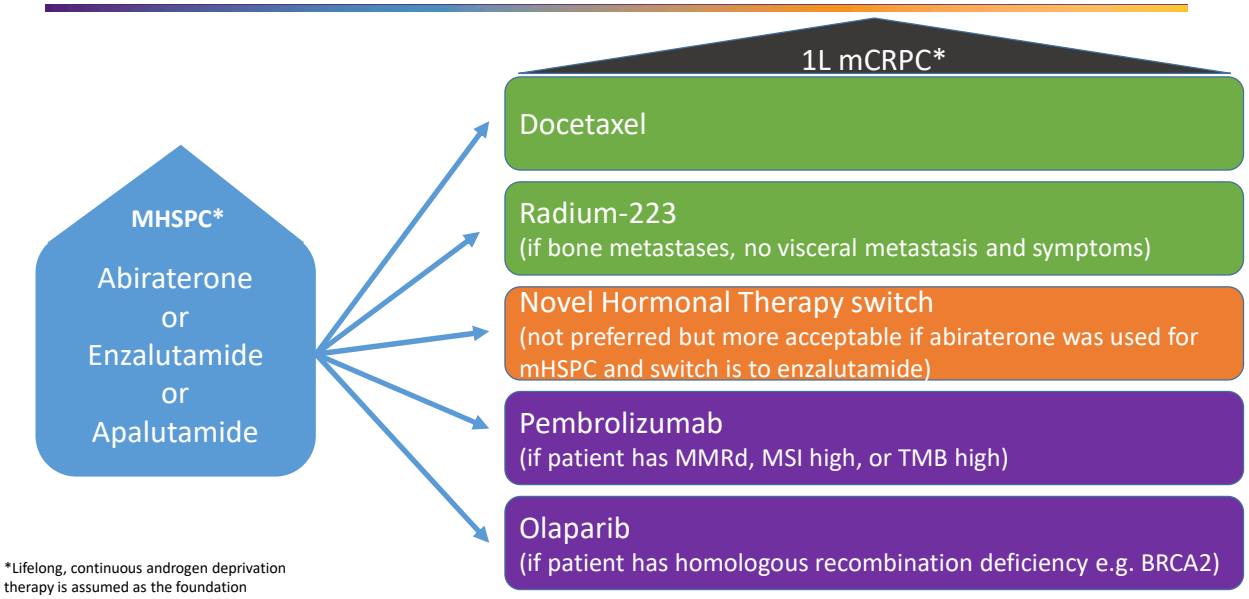
- Precision therapy when possible
- Back-to-back NHA is something I never do because it would essentially have to be abiraterone, and that yields extremely low response rates
- Radium-223 can ideally be administered here before docetaxel if the patient has bone metastases, lacks visceral metastasis, and has symptoms
- Docetaxel will be your best shot at response and should be the most frequently relied upon path

Metastatic *Hormone Sensitive* Prostate Cancer Path for 1st Line NHA



*Lifelong, continuous androgen deprivation therapy is assumed as the foundation

Metastatic *Hormone Sensitive* Prostate Cancer Path for 1st Line NHA

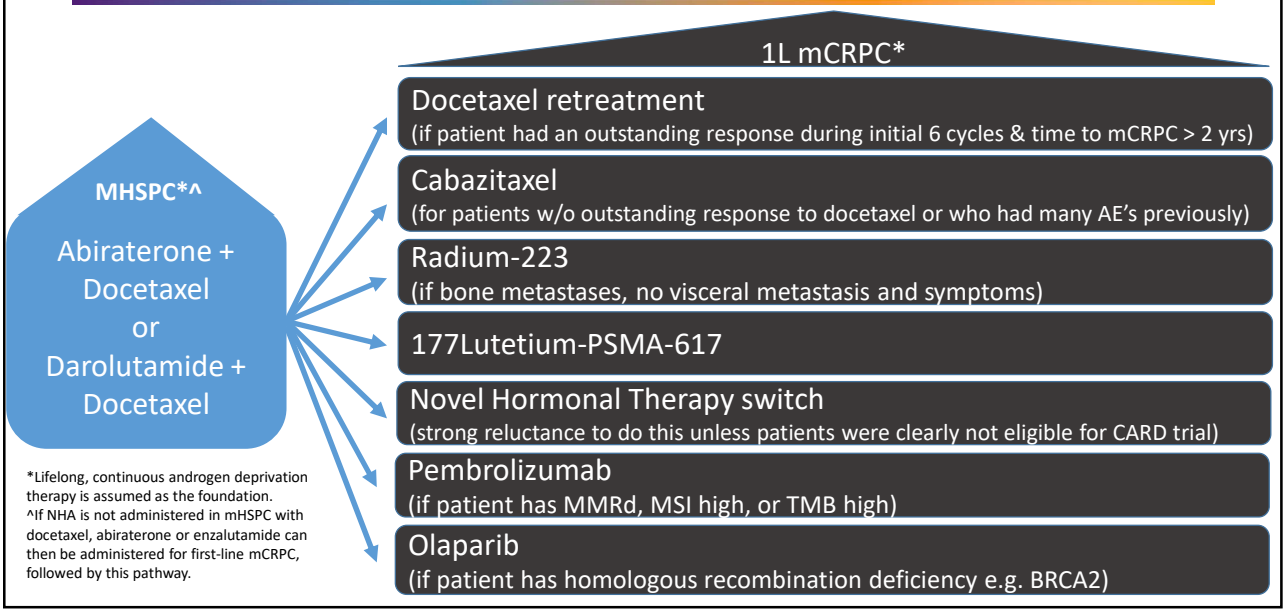


*Lifelong, continuous androgen deprivation therapy is assumed as the foundation

What Next for Patients Who Received 1st Line NHA Administered for mHSPC? – Evan's Thoughts

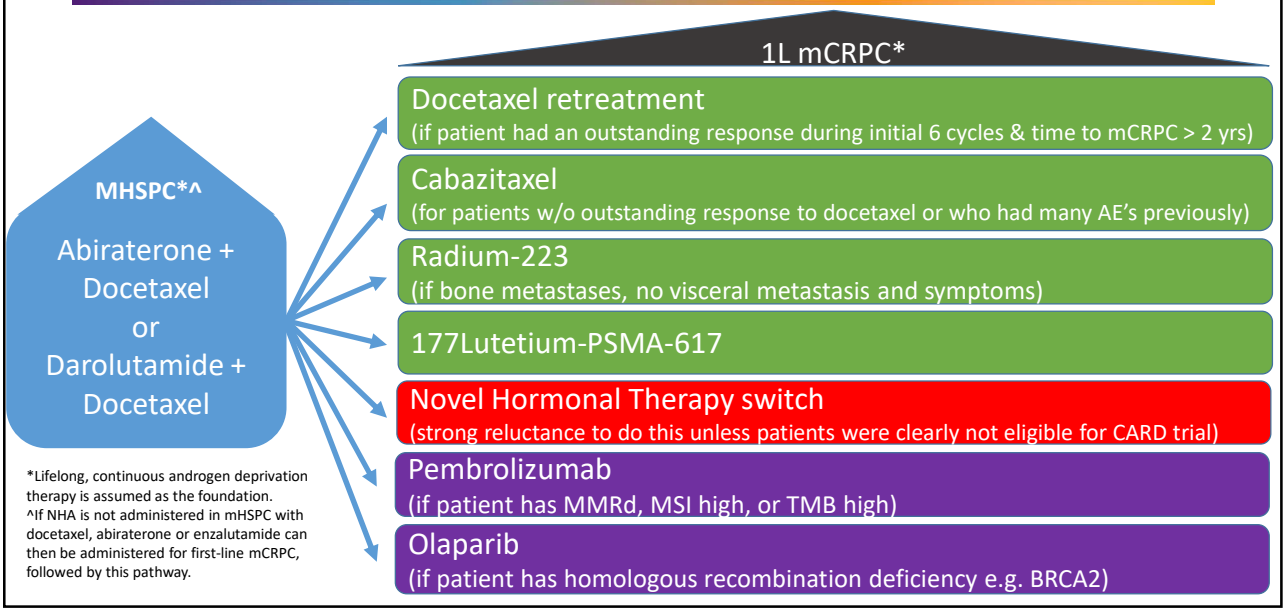
- Precision therapy when possible
- Radium-223 can ideally be administered here before docetaxel if the patient has bone metastases, lacks visceral metastasis, and has symptoms
- Docetaxel will be your best shot at response and should be the most frequently relied upon path
- However, if the NHA was abiraterone, I might try switch to enzalutamide for select patients who have slower rise in PSA, are asymptomatic, have no new metastases on imaging, and who are reluctant to move on to chemotherapy

Docetaxel +/- NHA Administered for Metastatic Hormone Sensitive Prostate Cancer



*Lifelong, continuous androgen deprivation therapy is assumed as the foundation.
^If NHA is not administered in mHSPC with docetaxel, abiraterone or enzalutamide can then be administered for first-line mCRPC, followed by this pathway.

Docetaxel +/- NHA Administered for Metastatic Hormone Sensitive Prostate Cancer



*Lifelong, continuous androgen deprivation therapy is assumed as the foundation.
^If NHA is not administered in mHSPC with docetaxel, abiraterone or enzalutamide can then be administered for first-line mCRPC, followed by this pathway.

What Next for Patients Who Received Docetaxel + NHA Administered for mHSPC or Docetaxel followed by NHA for 1st Line mCRPC – Evan's Thoughts

- Precision therapy when possible
- Radium-223 can ideally be administered here if the patient has bone metastases, lacks visceral metastasis, and has symptoms
- Docetaxel retreatment can be considered if the patient had a good initial response for mHSPC and a long period before mCRPC developed
- Cabazitaxel and ^{177}Lutetium-PSMA-617 (these patients fit the FDA label!) may be the ideal agents to use in this situation
  - I may lean slightly towards ^{177}Lutetium-PSMA-617 because the TheraP trial showed superior PSA50 decline, composite PFS, and a better adverse event profile
- NHA switch should be strongly discouraged, given the other good available options

Take Home Points

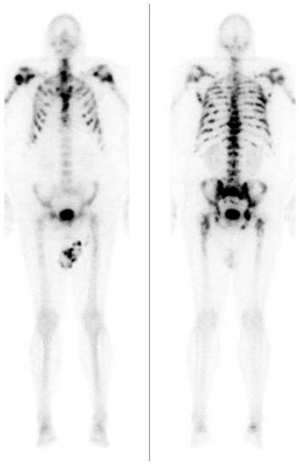
- Combination therapy for mCRPC has generally been unremarkable, although there are early hints for combining abiraterone with PARP inhibitors
- There are many options for patients who progress on a NHA
- There are now many settings where a NHA can be received, and when it is administered and whether docetaxel has been given or not affects downstream options
- There is no definitive pathway, and patient individualization and clinical judgment should be applied
- Switch from one NHA to another generally does not lead to good outcomes, hence, change in mechanism of action is encouraged
- Clinical trial accrual is encouraged and standard of care is likely to change in the future

LUGPA 2022
APCC Optimization

Case 1

- 45yo PSA 5.9, T1c 3+4 10/2012
- Morbidly obese
- Elected brachytherapy, no ADT
- PSA nadir 0.4 5/2020, PSA 0.8 5/2021
- Present with retention, voiding symptoms spring 2022
- PSA 99
- New imaging obtained

Case 1



- No current pain symptoms
- CT with no visceral disease

- 55yo mCSPC high-volume

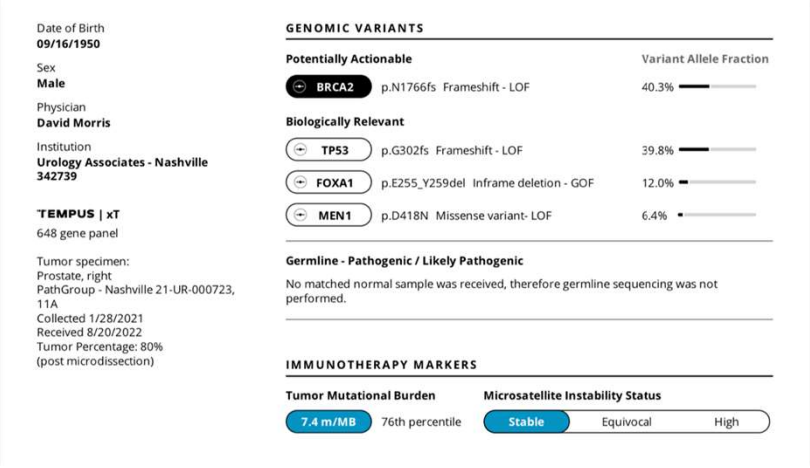
- Ideal markers for “triplet” vs “doublet” therapy
  - Age?
  - Visceral?
  - Certain comorbidities?
- For borderline cases, would you recommend “triplet” because of the improved 2nd line options available for that patient on progression?
- With good data for combination with abiraterone and darolutamide, do you think we would likely get same benefit with apalutamide/enzalutamide triplet?
- What toxicity concerns should urologists be focused on if co-managing patients during the docetaxel therapy?

Case 2

- 72yo; PSA 3.2, prostate nodule
- G 4+4 2/2021 biopsy; CT and BS negative
- PBT with ADT summer 2021
- PSA nadir to 0.1 now rising to 11
- CT with lung nodule, RP node, sclerosis in bones, but BS with no uptake
- FH: no PCA, no other cancer

Case 2

- PSA now rising to 11. mCRPC by conventional imaging
- Somatic on primary:



Date of Birth
09/16/1950

Sex
Male

Physician
David Morris

Institution
Urology Associates - Nashville
342739

TEMPUS | xT
648 gene panel

Tumor specimen:
Prostate, right
PathGroup - Nashville 21-UR-000723, 11A
Collected 1/28/2021
Received 8/20/2022
Tumor Percentage: 80%
(post microdissection)

GENOMIC VARIANTS

Potentially Actionable		Variant Allele Fraction
BRCA2	p.N1766fs Frameshift - LOF	40.3%
Biologically Relevant		
TP53	p.G302fs Frameshift - LOF	39.8%
FOXA1	p.E255_Y259del Inframe deletion - GOF	12.0%
MEN1	p.D418N Missense variant- LOF	6.4%

Germline - Pathogenic / Likely Pathogenic

No matched normal sample was received, therefore germline sequencing was not performed.

IMMUNOTHERAPY MARKERS

Tumor Mutational Burden		Microsatellite Instability Status		
7.4 m/MB	76th percentile	Stable	Equivocal	High

- When would you consider combination therapy with AR + PARPi
  - All-comers?
  - HRR+ patients?
  - BRCA2 patients?
  - "Depends on the label"
- Do you think there will be measurable clinical differences between the PARPi?
  - olaparib, rucaparib, niraparib, talazoparib
- Do you have a preference for testing sequence?
  - Germline early, somatic and liquid on progression?
  - Archival somatic first, germline confirmatory and liquid after progression?

Case 3

- 2004 60yo elevated PSA, biopsy 3+4
- RALP 2004, salvage XRT in 2009
- Continuous ADT and then abi addition in 2019
- 2nd line: enzalutamide 2021
- 3rd line: docetaxel 2021
- 4th line: cabazitaxel 2021 to 2022
- Progressing currently
- Guardant360 testing without actionable mutations.

- Any role for continued AR agent use during chemotherapy or alpha-radium?
- Progressed on 2 rounds of AR and 2 rounds of chemotherapy
  - Consideration for next round of therapy
- Lutetium vs alpha-radium
  - Production delays for Lutetium have prevented next line of therapy
  - Would you consider alpha-rad therapy in the meantime if bone marrow function is good enough?

General questions for the experts

- How do you manage patients that are conventional imaging non-metastatic while PET metastatic?
- What next combination therapy or MOA has you the most excited?
  - I/O therapy with other agents
  - PI3K/Akt inhibitors: Capivasertib / ipatasertib

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Explosion of intravesical therapy for NMIBC

Colin P. N. Dinney MD
Dept. of Urology
MD Anderson Cancer Center

Disclosures

- Research funding and personal compensation from FKD Therapies Oy for consulting and advisory services
- Research collaboration with AIV.
- I will discuss the investigational use of interferon gene therapy in my presentation.

Approved agents for NMIBC

- Until recently the history of drug development for NMIBC has been bleak
- Only 5 agents approved since 1959

Agent	Indication	Year of registration
Thiotepa	superficial papillary carcinoma of the urinary bladder	1959
Doxorubicin	superficial papillary carcinoma of the urinary bladder	1974
BCG	carcinoma in situ and for the prophylaxis of recurrent papillary tumors TICE (Organon) TheraCys (Sanofi)	 1989 1990
Valrubicin	BCG-refractory CIS in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality	initially approved in 1998, removed from market in 2002 due to a formulation issue with an inactive component and re-approved in February 2007
Pembrolizumab	BCG unresponsive CIS	2019

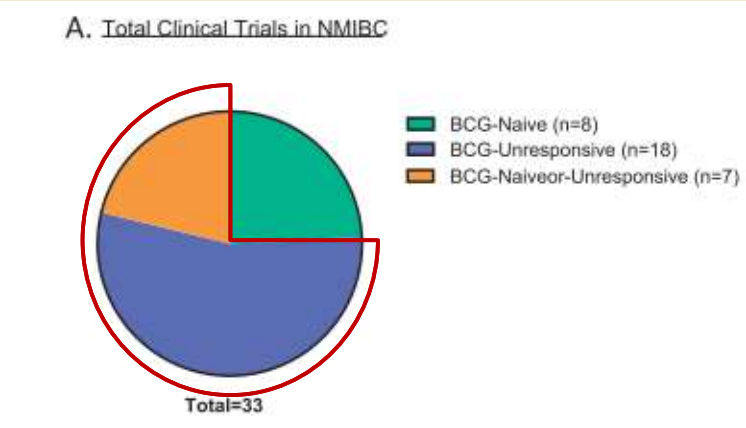
History of drug development for NMIBC has been bleak

- In 2012 the SUO, AUA, and the FDA launched a collaborative effort to address this deficiency.
- Initial focus was to define a pathway for drug registration for BCG Unresponsive NMIBC and stimulate activity in this space.
- At the same time, Bioniche announced the closing of its 2nd randomized trial with Urocidin, emphasizing that randomized trials were not feasible in this patient popuation.

What does a registration trial look like today?

- Trial design evolved over time (2012-2018).
- FDA will accept a single-arm trial (feasibility and lack of a comparator) with a mixed population of patients that meet the stringent definition of BCG Unresponsive NMIBC.
- Primary endpoint: CR rate for patients with CIS.
- FDA approval will be for CIS.
- Once an agent is approved the label could be extended to HG Ta/T1 disease or patients may be treated off-label.

The majority of current trials are now in this space



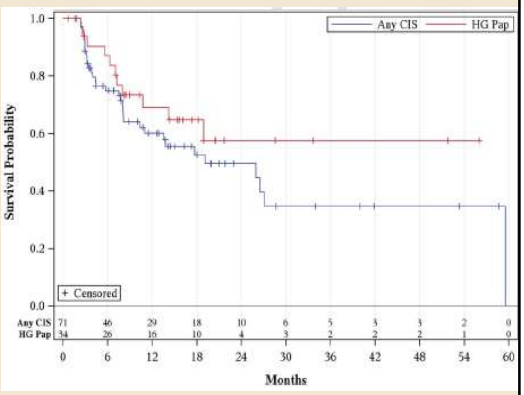
Siddqui et al. Urol Oncol 2017

Alternatives to cystectomy that are under development

- BCG plus something else
- Other immunotherapy
- Toxins
- Chemotherapy
- Gene therapy

Sequential gemcitabine and docetaxol

- 276 patients with BCG failure with median f/u of 23 mo.
- 37% were BCG-unresponsive.
- Gem/Doc x 6 weeks then mo. maintenance x 24 mo.
- 1- and 2-yr HG-RFS 65% and 52%
- 8% progressed to ≥pT2 at TURBT or cystectomy.

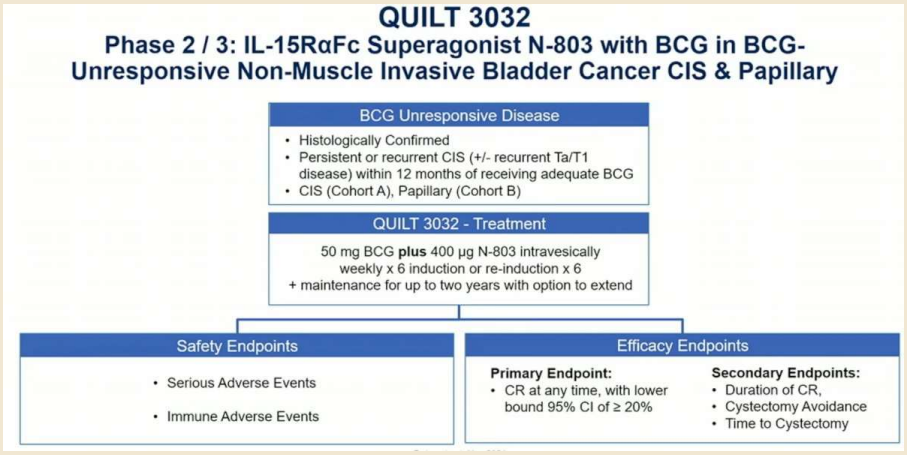


Steinberg et al, J Urol 2020

Intravesical agents that have completed Phase 3 trials

- Oportuzumab monatox (Vicinium)
- ALT 803 + BCG
- Nadofaragene firadenovec (Adstiladrin)

Quilt 3032



Results

Cohort A (CIS +/- papillary tumors): N = 82

- CR = 71% (95% CI: 59.6 – 80.3), median FU = 23.9 months
- Median duration of response = 26.6 months (95% CI: 9.9 – NR)
- Overall RC rate = 16%, Responders-only RC rate = 9%
- Well tolerated with SAE's in 1%, and treatment discontinued in 2%

Results

Cohort B (Papillary tumors – 7% with CIS): N = 77

- 12-mo. DFS = 55% (95% CI: 42% - 67%)
- Median DFS = 19.3 months, median FU = 20.7 mo.
- Overall RC rate = 5%
- Well tolerated with no SAE's, and treatment discontinued in 6%

Results

- Inactive as a monotherapy
- Combination with BCG compares favorably to other FDA-approved drugs
  - Pembrolizumab (CR 41%)
  - Valrubicin (CR 18%)
- Study design considerations
  - Combination trial with BCG but no BCG comparator
  - Retreatment allowed at 3 mo. for non-responders improved CR by 25%

Phase 3 trial of Nadofaragene firadenovec

Intravesical nadofaragene firadenovec gene therapy for BCG-unresponsive non-muscle-invasive bladder cancer: a single-arm, open-label, repeat-dose clinical trial

Stephen A Boorjian, Mehrdad Alemozaffar, Badrinath R Konety, Neal D Shore, Leonard G Gomella, Ashish M Kamat, Trinity J Bivalacqua, Jeffrey S Montgomery, Seth P Lerner, Joseph E Busby, Michael Poch, Paul L Crispen, Gary D Steinberg, Anne K Schuckman, Tracy M Downs, Robert S Svatek, Joseph Mashni Jr, Brian R Lane, Thomas J Guzzo, Gennady Bratslavsky, Lawrence I Karsh, Michael E Woods, Gordon Brown, Daniel Canter, Adam Luchey, Yair Lotan, Tracey Krupski, Brant A Inman, Michael B Williams, Michael S Cookson, Kirk A Keegan, Gerald L Andriole Jr, Alexander I Sankin, Alan Boyd, Michael A O'Donnell, David Sawutz, Richard Philipson, Ruth Coll, Vikram M Narayan, F Peter Treasure, Seppo Yla-Herttuala, Nigel R Parker, Colin P N Dinney

Boorjian et al, Lancet Oncol. 2020

Phase 3 trial of Nadofaragene firadenovec for BCG Unresponsive NMIBC

- Primary endpoint: 53% CR rate at 3 mo. for CIS.
- Secondary endpoints:
  - 46% with CIS remained HGRF through 12 mo.
  - 73% HG RFS for HG Ta/T1 at 3 mo.
  - 60% remained HG recurrence free at 12 mo.
  - 27% CR for CIS and a 48% RFS for HG papillary disease at 12 mo. based on clinical features alone.
- Late recurrences beyond 12 months were rare.
- Increase in anti-adenoviral Ab levels correlated with HG RFS at 15 mo.
- 8 progressed (5%), 6 (75%) had history of T1HG.

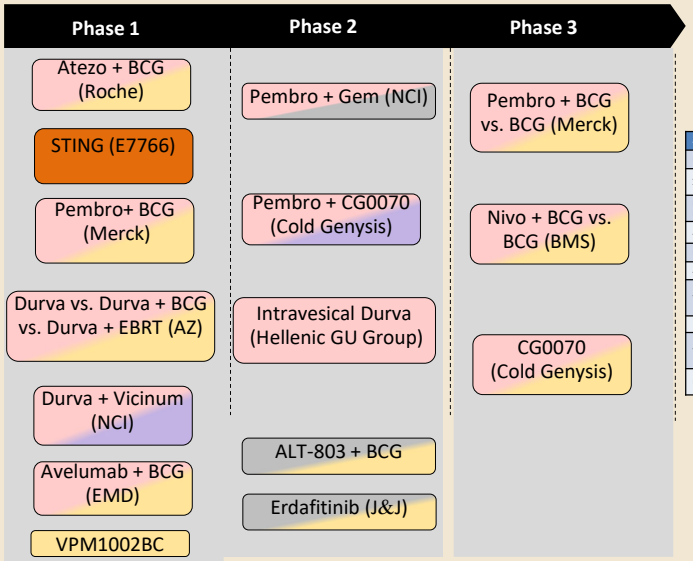
Phase 3 trial of Nadofaragene firadenovec for BCG Unresponsive NMIBC

- Acceptable safety and tolerability with one Grade 4 and no Grade 5 drug/procedure related AE's.
- Only 3 treatment related SAE (2%).
- Only 3 patients (2%) stopped treatment due to a treatment related AE.
- No pattern of immune-related adverse events, no treatment related deaths, and no deaths from bladder cancer.
- Convenient dosing schedule (one intravesical treatment/q3 mo).
- **Nadofaragene firadenovec provides a favourable benefit-risk profile for patients facing cystectomy.**

Specific considerations for single arm trials

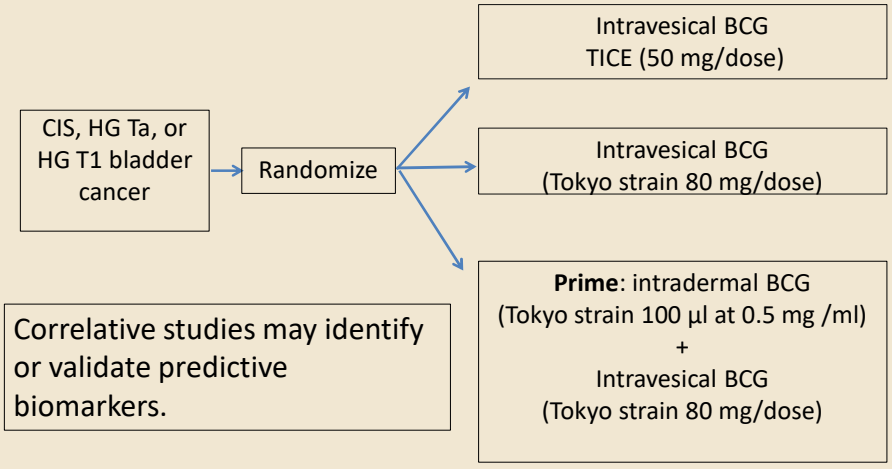
- The timepoint for defining a CR or HG RFS following the first dose of study drug will determine the response rate.
- CR rate improved as much as 25% by using a 6 mo. endpoint that allows for retreatment of persistent disease at 3 mo.
- When comparing trials that employ combination therapy (often with BCG) vs. those with monotherapy consider the contribution of the second drug to the response rate.
- Even in patients with BCG unresponsive disease at least 20% will achieve a CR secondary to BCG.
- Consider an end of study biopsy as it identifies occult disease and minimizes investigator bias.

Intravesical agents in development for BCG unresponsive NMIBC



Agent	Class of drug	Sponsor
Pembrolizumab	Anti-PD-1	Merck
Atezolizumab/ Tecentriq	Anti-PD-L1	Roche Genentech
Durvalumab/ Imfinzi	Anti-PD-L1	AstraZeeneca
Avelumab/ Bavencio	Anti-PD-L	Merck Serono, Pfizer
Nivolumab/ Opdivo	Anti-PD-1	BMS
ALT-803	IL-15 agonist	Altor Biosci.
VPM1002BC	genetically modified BCG	Swiss Group for Clinical Cancer Research
BMS-986205	IDO inhibitor	BMS
Vicinium	EpCAM ab fused w Pseudomonas exotoxin A	Viventia Bio
E7766	Stimulator of Interferon Genes	Eisai

BCG naïve: PRIME (S1602) trial schema (PI: Svatek)

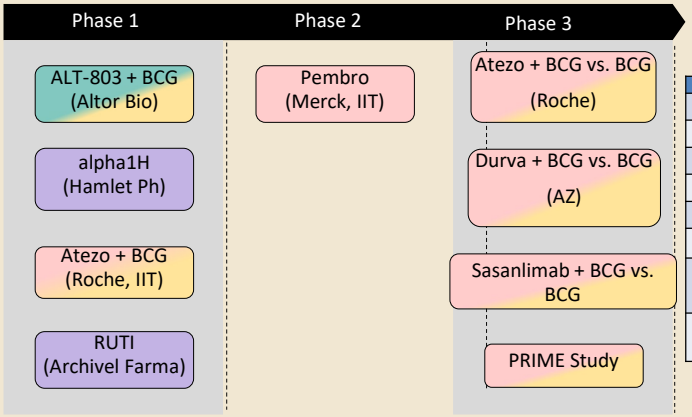


May lead to the approval of another strain of BCG in the USA.

Summary

- Efforts to establish a pathway for registration for BCG unresponsive CIS successful but patients with BCG unresponsive HG Ta/T1 NMIBC largely neglected.
- Recent FDA workshop recommended randomized registration trials for "BCG exposed" NMIBC.
- Most trials in the BCG naïve state combine BCG with an IO and will not address the BCG shortage.
- Approval of the Tokyo strain would alleviate the risk to patients with HR NMIBC imposed by the BCG shortage.
- Activity in Intermediate Risk NMIBC picking up.

Agents under development for BCG naïve NMIBC



Agent	Class of drug	Sponsor
Pembrolizumab	Anti-PD-1	Merck
Atezolizumab/ Tecentriq	Anti-PD-L1	Roche Genentech
Durvalumab/ Imfinzi	Anti-PD-L1	AstraZeeneca
Sasanlimab	Anti-PD-1	Pfizer
ALT-803	IL-15 agonist	Altor Biosci.
RUTI	Vaccine (frag. TB cells)	Archivel Farma
alpha1H	Vaccine: detoxified, fragmented mycobacterium tuberculosis cells, delivered in liposomes	Hamlet Pharma
BCG Tokyo-172	BCG derived from Mycobacterium bovis obtained from the Pasteur Institute in 1924	Southwest Oncology Group, NCI

Most new approaches combine a checkpoint inhibitor with BCG.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

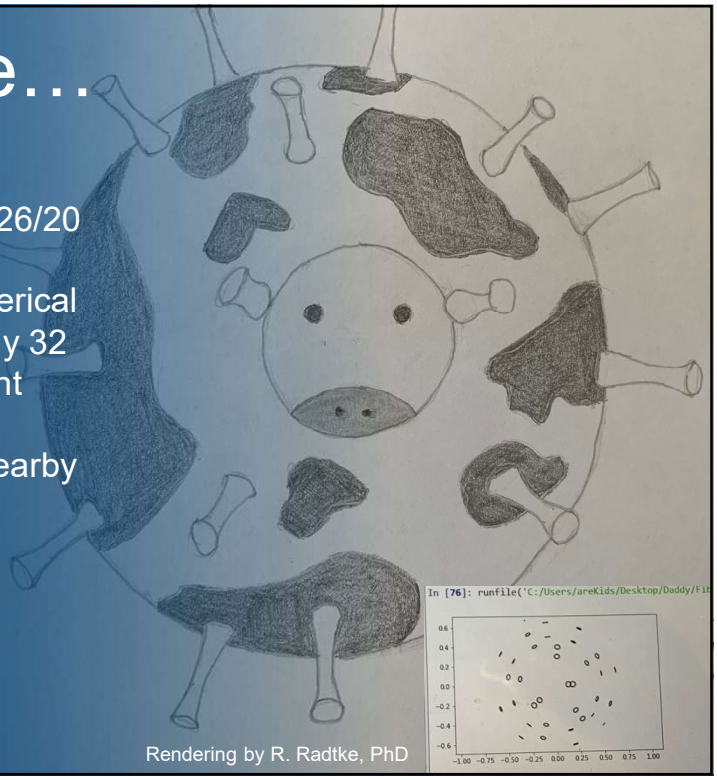
Systemic Treatment Options for MIBC and NMIBC

Arlene Siefker-Radtke, MD
Professor
Department of Genitourinary Medical Oncology

COVID will mutate…

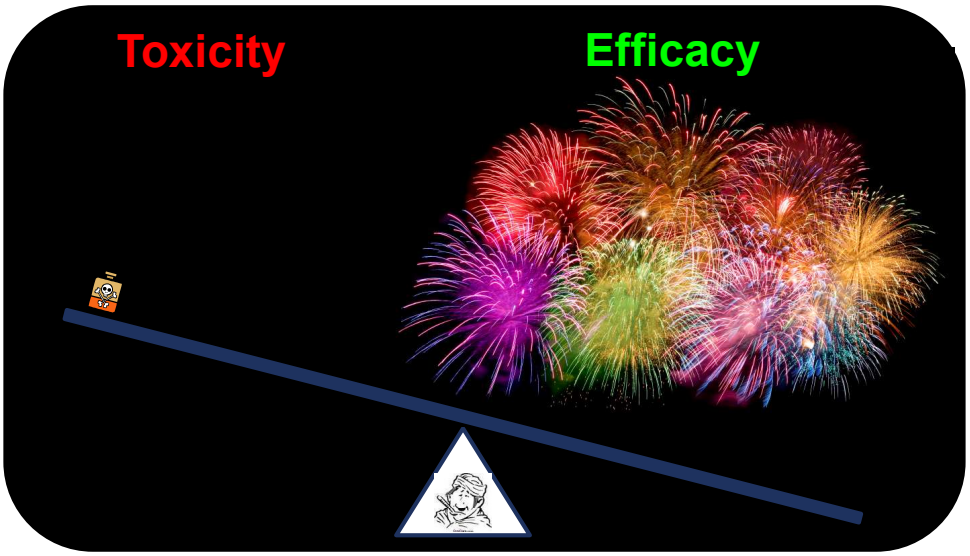
COWVID V.32

- First observation: Silverlake, Tx 12/26/20
- Designation V.32
  - Computer modeling using a spherical Fibonacci lattice suggests exactly 32 equidistant spike proteins present
- Virulence: R(t)=0
- No apparent similarities to typical nearby longhorns
- Current status: observation
  - Still munching on nearby lake grass



Rendering by R. Radtke, PhD

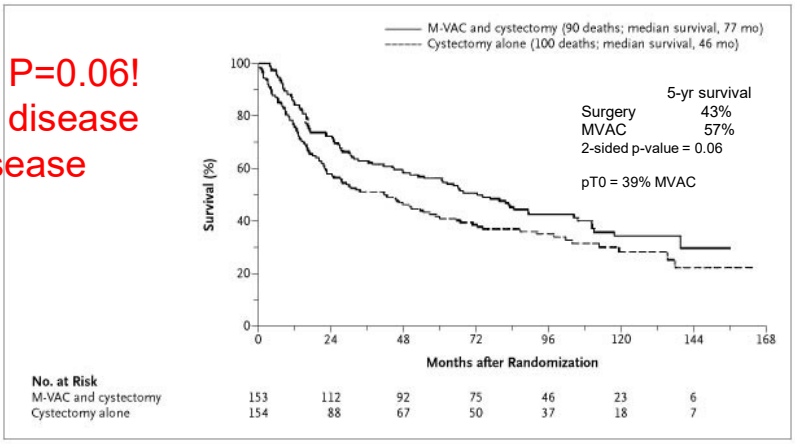
The Goal:



The Impression: Chemotherapy

SWOG Intergroup Trial – Current Standard

Double-sided P=0.06!
40% had cT2 disease
60% cT3b disease

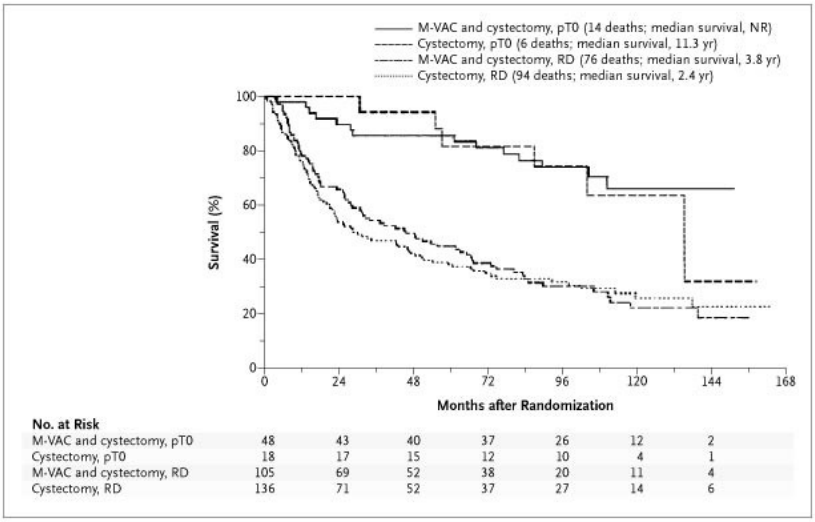


Grossman et al. NEJM 349;9: 859-866, 2003

No Chemotherapy in cT2N0 (or pT2N0) Patients

- Neoadjuvant chemotherapy associated with morbidity
  - Not tolerable in almost 50% of patients
  - Side effects can be long term – neuropathy/hearing loss
- Some patients are downstaged from TUR alone
  - No substantial benefit from chemotherapy

SWOG Intergroup Trial – Current Standard



- NO difference in survival for those downstaged by chemotherapy or TUR!
- 50% of cT2 tumors were pT0N0 in the surgery alone group

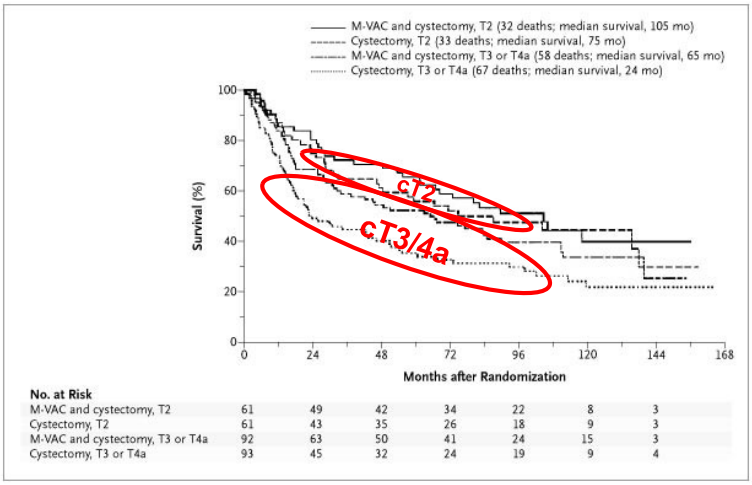
Grossman et al. NEJM 349;9: 859-866, 2003

No Chemotherapy in cT2N0 (or pT2N0) Patients

- Neoadjuvant chemotherapy associated with morbidity
  - Not tolerable in almost 50% of patients
  - Side effects can be long term – neuropathy/hearing loss
- Some patients are downstaged from TUR alone
  - No substantial benefit from chemotherapy
- pT2N0 patients have a high cure fraction from surgery alone
  - Greatest impact on improving outcomes for the ≥cT3b or N+ disease

SWOG Intergroup Trial – Current Standard

- Biggest difference is between the >= cT3bN0 tumors, little difference between the cT2N0



Grossman et al. NEJM 349;9: 859-866, 2003

The Age-Old Question:DDMVAC vs GC?

VESPER: DDMVAC vs GC

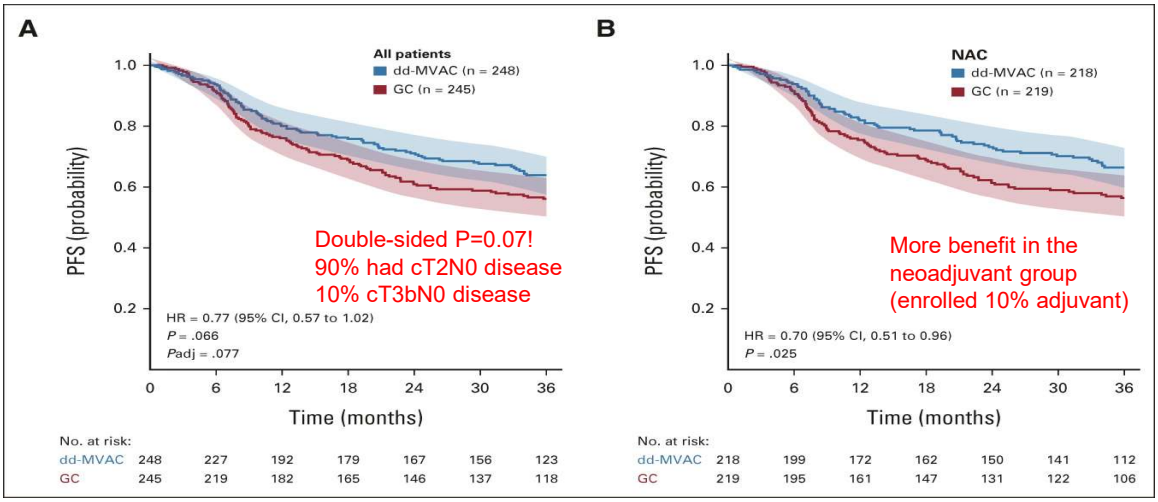


FIG 2. 3-year PFS Kaplan-Meier curves by chemotherapy arm (GC or dd-MVAC) for (A) the whole population of VESPER trial and (B) the NAC group. HR, dd-MVAC/GC HR with 95% CI. P, log-rank test P value. Padj, log-rank test P value stratified for therapeutic option (neoadjuvant or adjuvant) and the lymph nodes involvement (only for A). dd-MVAC, dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin; GC, gemcitabine and cisplatin; HR, hazard ratio; NAC, neoadjuvant chemotherapy; PFS, progression-free survival.

Published in: Christian Pfister; Gwenaelle Gravis; Aude Fléchon; Christine Chevreau; Hakim Mahammedi; Brigitte Laguerre; Aline Guillot; Florence Joly; Michel Soulié; Yves Allory; Valentin Harter; Stéphane Culine; *Journal of Clinical Oncology* 2022 402013-2022.
DOI: 10.1200/JCO.21.02051

VESPER: DDMVAC vs GC OS

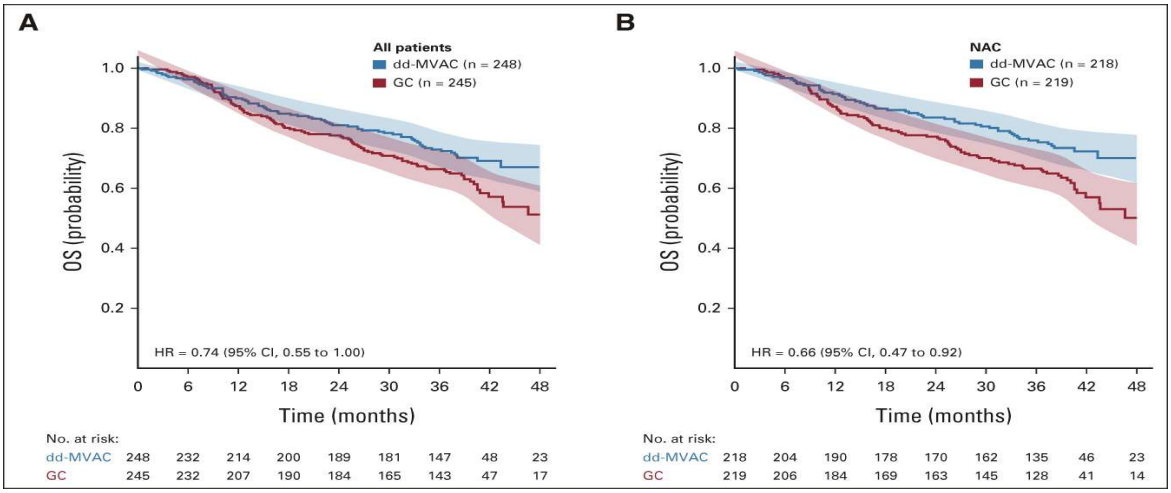
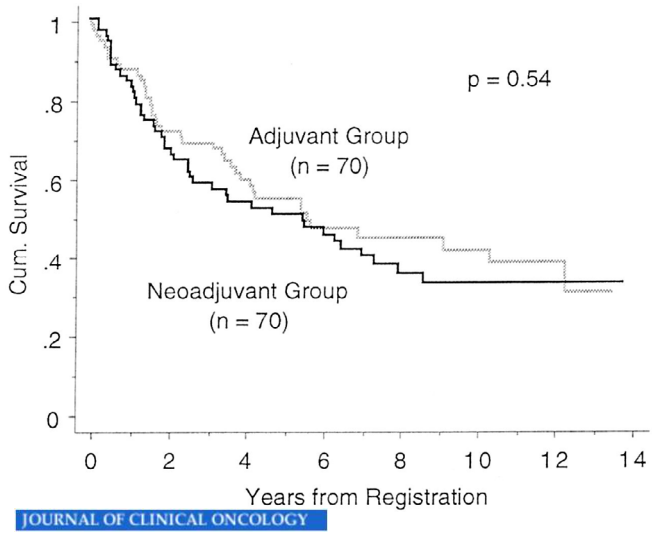


FIG 4. VESPER trial OS estimated with monitored data and 40-month follow-up for (A) the whole population of VESPER trial and (B) the NAC group. dd-MVAC, dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin; GC, gemcitabine and cisplatin; HR, hazard ratio; NAC, neoadjuvant chemotherapy; OS, overall survival.

Published in: Christian Pfister; Gwenaelle Gravis; Aude Fléchon; Christine Chevreau; Hakim Mahammedi; Brigitte Laguerre; Aline Guillot; Florence Joly; Michel Soulié; Yves Allory; Valentin Harter; Stéphane Culine; *Journal of Clinical Oncology* 2022 402013-2022.
DOI: 10.1200/JCO.21.02051

Do we lose efficacy or have worse outcomes when giving chemotherapy in the adjuvant setting?

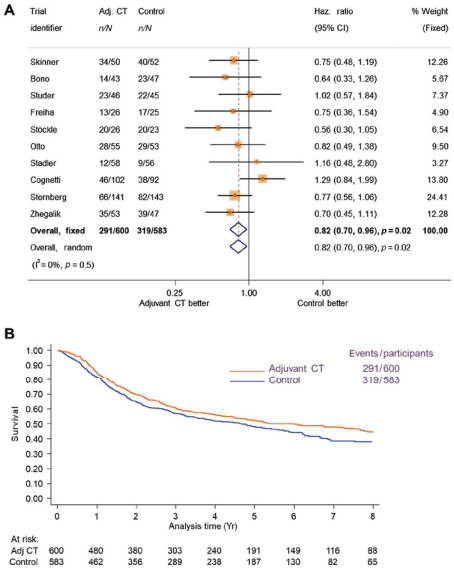
MVAC, Pre vs. Post-Surgery: Clinical Trial

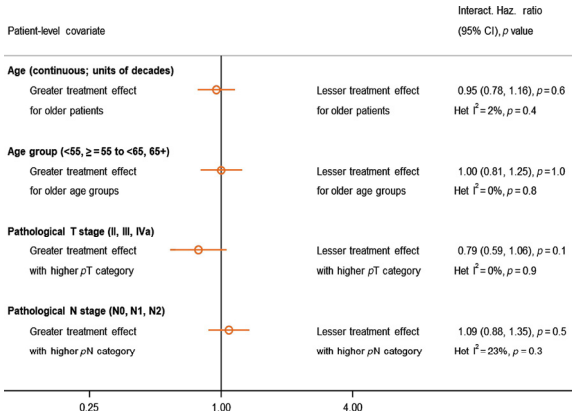


- Neoadjuvant MVAC (2 cycles pre, 3 cycles post surgery)
- Initial surgery (5 cycles adjuvant chemotherapy)
- High risk features in all
  - LVI
  - Hydronephrosis
  - 3-D mass on EUA despite thorough TUR
  - micropapillary
- NO difference in survival for those despite high risk features present in all
- Upstaging in over 80% treated with initial surgery

Millikan, R. et al. J Clin Oncol; 19:4005-4013 2001

Adjuvant Chemotherapy MIBC: Meta-analysis

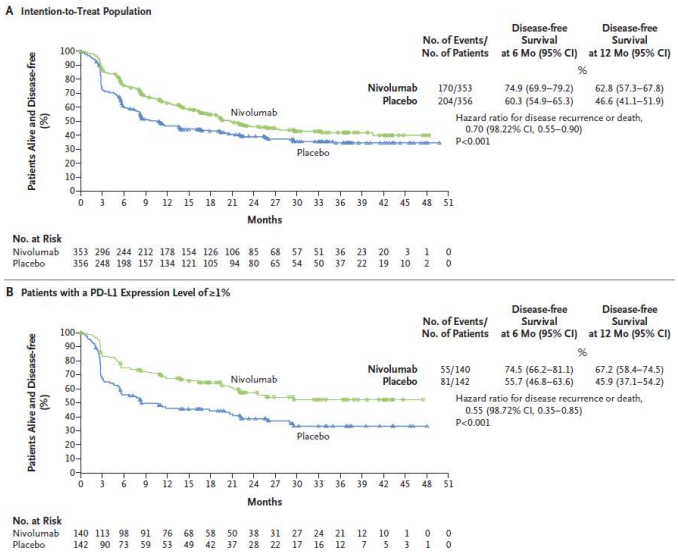




European Urology 2022 8150-61DOI: (10.1016/j.eururo.2021.09.028)

Does Adjuvant Nivolumab Cure Patients?

Adjuvant Nivolumab – Delay or Cure?



- N=709, "high-risk"
  - Post cisplatin:ypT2-4a or N+
  - No chemo:pT3-4a or N+
- Must have negative margin surgery
- Adjuvant to start within 120 days
- Disease-free by imaging within 4-weeks
- 1 year adj. nivo
- Median f/u: ~ 20 mo
- Improvement in DFS:
  - Nivo: 20.8 mo
  - Placebo: 10.8
- No survival data presented
- PDL-1 low subgroup data/figures not presented

Bajorin, et al. NEJM 2021

Selection Factors for Risk of Upstaging

National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2022
Muscle Invasive Bladder Cancer

NCCN Guidelines Index
Table of Contents
Discussion

ADJUVANT TREATMENT

Following cystectomy →

- Based on pathologic risk,
  - If no cisplatin neoadjuvant treatment given and pT3, pT4a, or pN+
    - ◊ Adjuvant cisplatin-based chemotherapy should be discussed (preferred)[x] or
    - ◊ Consider adjuvant nivolumab[x]

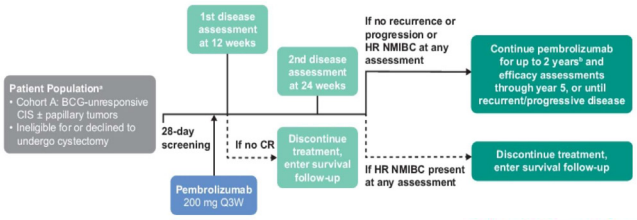
  or
  - If cisplatin neoadjuvant chemotherapy given and ypT2-ypT4a or ypN+, consider nivolumab[x,bb]

  or
  - Consider adjuvant RT in selected patients (T3–4, positive nodes/margins)[z] (category 2B)

→ See Follow-up (BL-E)

Pembrolizumab in NMIBC?

Keynote-057: Pembrolizumab for BCG-unresponsive NMIBC



- 3 month CR: 40%
- Median DOCR: 16.2 mo.
- Pembrolizumab given up to 2 years

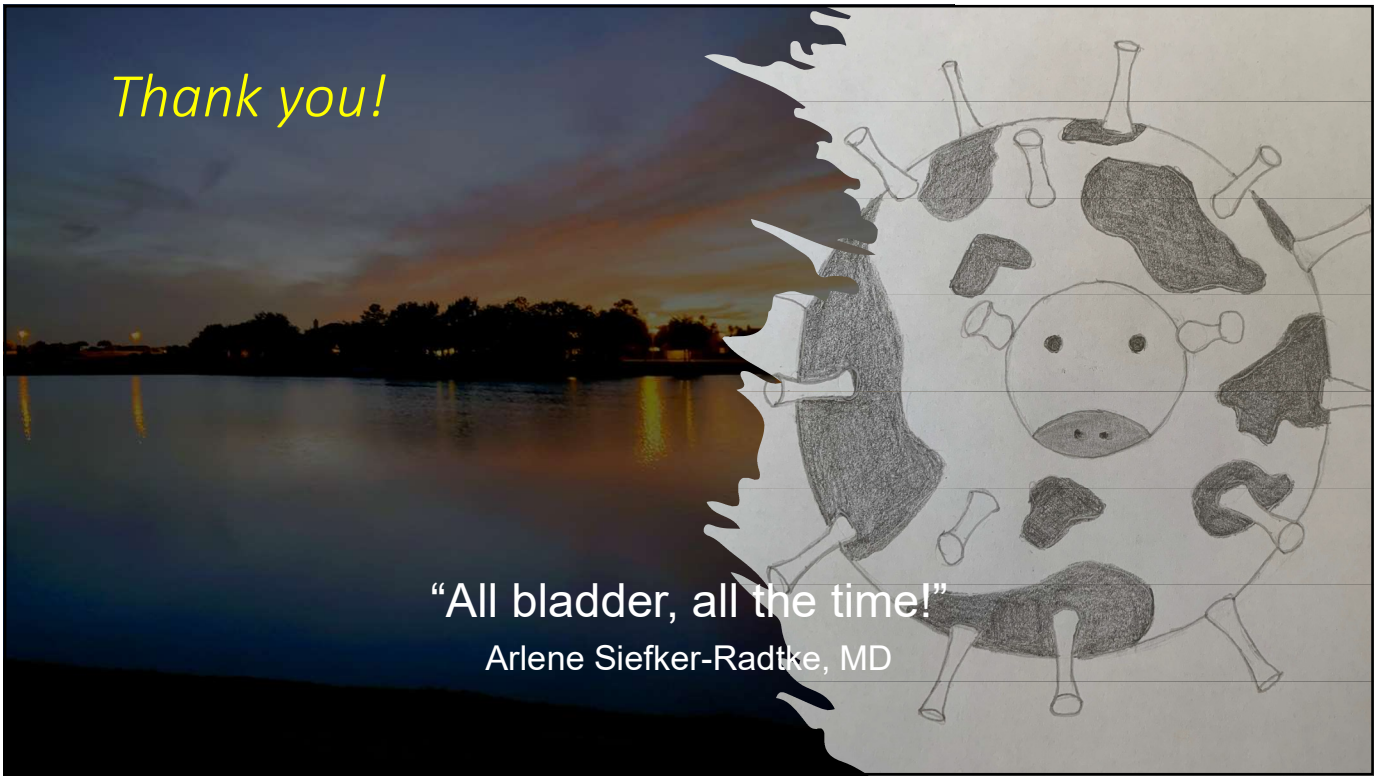
Table 1. Overall Response Rate at First Evaluable Assessment

N = 96	n	%	95% CI
CR	**39**	**40.6**	**30.7-51.1**
Non-CR	**56**	**58.3**	**47.8-68.3**
Persistent[a]	40	41.7	31.7-52.2
Recurrent[b]	6	6.3	2.3-13.1
NMIBC stage progression[c]	9	9.4	4.4-17.1
Non–bladder malignancy[d]	1	1.0	0.0-5.7
Progression to T2	0	0	NA-NA
Nonevaluable[e]	**1**	**1.0**	**0.0-5.7**

Balar et al, ASCO, 2020

Conclusion:

- Neoadjuvant, cisplatin-based chemotherapy remains the standard for cT2-T4aN0 urothelial carcinoma
  - DDMVAC may be favored
- Give adjuvant chemotherapy if they are upstaged at surgery to ≥ pT3b or N+ disease rather than adjuvant nivolumab
- Currently, adjuvant nivolumab may delay recurrence rather than cure
  - PD-L1 high?
  - Risk of overtreatment already cured patients
- Pembrolizumab is an option for BCG unresponsive NMIBC



BARRIGEL – THE FUTURE OF RECTAL SPACING

How Control Over Placement Is Delivering Optimized Anatomical Coverage With High Patient Safety

Neil Mariados, MD
Radiation Oncologist
Cancer Care of Western New York

DISCLOSURES

Bayer – consultant/ speaker; Jansen – consultant/ speaker ; PLS – consultant /speaker/non-direct interest;

2

BARRIGEL BENEFITS OVER PEG HYDROGEL

Comparison Of Rectal Spacers With FDA Clearance

	Barrigel	SpaceOAR	SpaceOAR Vue
Controllable, Sculptable Gel	✓	No	No
Physician Controlled Placement	✓ (remains viscous)	No (polymerization in 8-10 seconds)[1]	No (polymerization in 10-15 seconds)[2,3]
No Injection Time Constraints	✓	No	No
Reversible	✓ (dissolvable with hyaluronidase)	No	No
Single-Step Assembly	✓	No 14 steps[4]	No 14 steps[4]
IMAGING VISIBILITY			
TRUS	High (image-guided procedure)	Low (frequent artifact after deployment)[1]	Low (frequent artifact after deployment)[1]
CT	✓ (settings dependent)	No[5]	✓
MR	✓	✓	✓

3

[1]Montoya J et al, Can J Urol, (2018). [2]Boston Scientific. SpaceOAR™ Hydrogel: Advancing radiation therapy – SpaceOAR™ Vue across different radiation modalities, (2021). [3]Dempsey PJ et al, Clin Radiol, (2022).[4]SpaceOAR® System Instructions for Use. (Rev C).[5]2018 Urology Times Supplement (SpaceOAR).

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CONTROL OVER PLACEMENT OF THE IMPLANT RESULTS IN EVEN AND CONSISTENT COVERAGE

Barrigel –
Even coverage over the whole posterial rectal/prostate interface from the lateral aspect of one lobe to the other

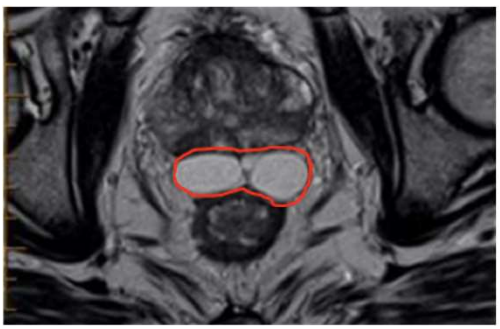
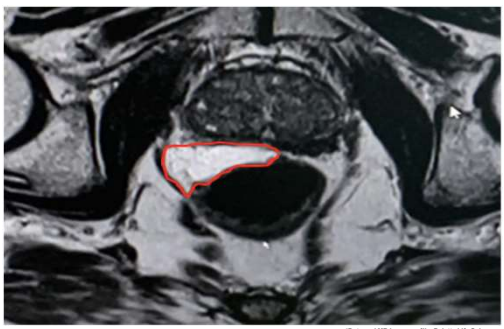


Image provided by Palette Life Sciences

SpaceOAR –
Lack of control over placement of the implant can result in uneven and inconsistent coverage and suboptimal dose distribution*



*Data and MR image on file. Palette Life Sciences.

BARRIGEL ACHIEVES CONTROLLED PLACEMENT FROM APEX TO BASE

1. Sculptable Gel (Non-Polymerizing)

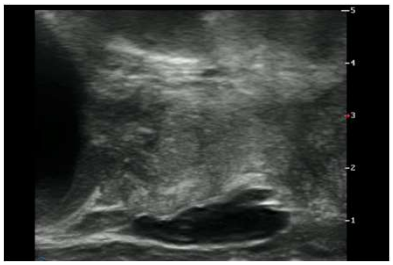
- The non-polymerizing gel allows or sculpting the implant to the anatomy
- Can perform touch-ups as needed
- Can reconfirm needle tip throughout the procedure

2. High TRUS Visibility

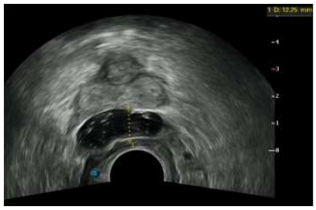
- Barrigel is highly hypoechoic, so you can see exactly where you are placing the implant in real time
- Fewer surprises on CT

3. Lifting Power

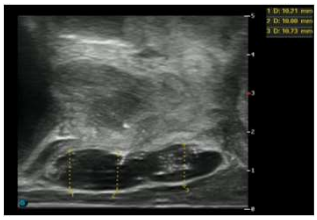
- Lifting strength creates and maintains adequate space in thin, hard-to-space areas from apex to base



Procedure video and images courtesy of Dr. Daniel Welchons, AMP of NY; NY, USA



12.25mm



10.21mm, 10.00mm, 10.73mm

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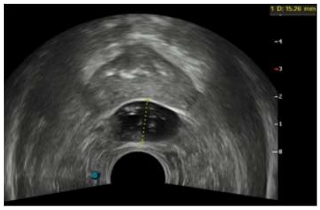
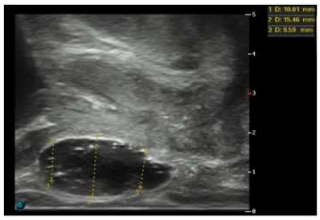
BARRIGEL COMMERCIAL SAME DAY CASES – NEW USER (SECOND DAY INJECTING)

All Cases: 09-08-22, Dr. Daniel Welchons of AMP of NY; NY, USA

PATIENT #1

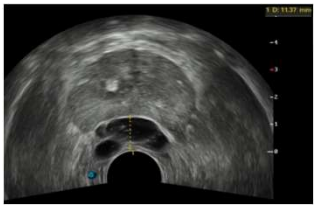


15.26mm

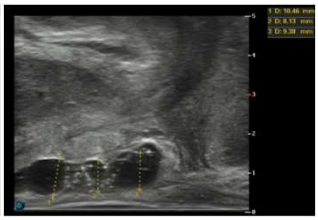


10.01mm, 15.46mm, 9.59mm

PATIENT #2

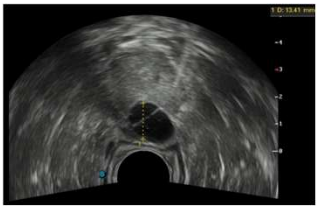


11.37mm

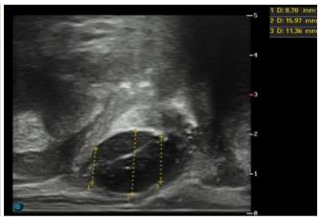


10.46mm, 8.13mm, 9.38mm

PATIENT #3

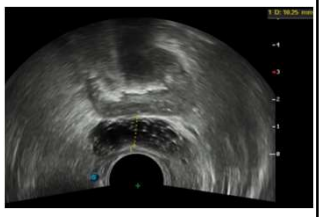


13.41mm

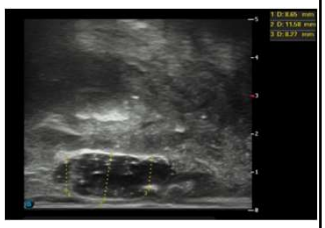


8.70mm, 15.97mm, 11.36mm

PATIENT #4



10.25mm

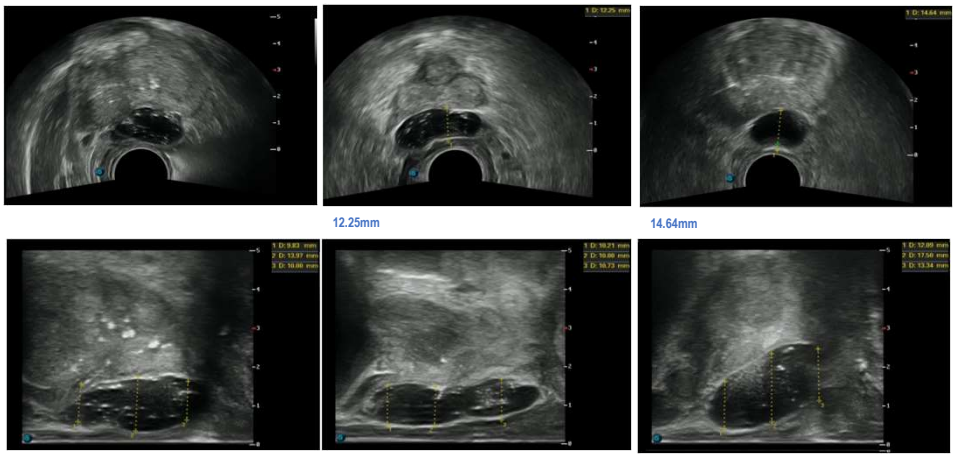


8.65mm, 11.58mm, 8.27mm

BARRIGEL COMMERCIAL SAME DAY CASES – NEW USER (SECOND DAY INJECTING) - CONTINUED

All Cases: 09-08-22, Dr. Daniel Welchons of AMP of NY; NY, USA

PATIENT #5 | PATIENT #6 | PATIENT #7



12.25mm | 14.64mm

9.83mm, 13.97mm, 10.00mm | 10.21mm, 10.00mm, 10.73mm | 12.09mm, 17.50mm, 13.34mm

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BARRIGEL ELIMINATES THE NEED FOR HYDRODISSECTION

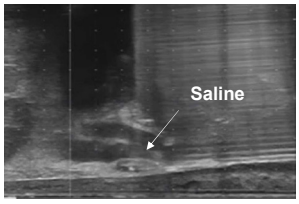
Barrigel Trial

7 Total Hydrodissections Performed

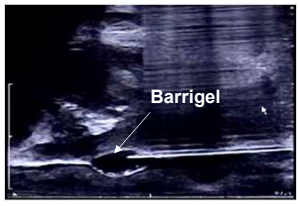
- 6 training patients
- 1 randomized patient

- **ZERO reports of embolism with Barrigel in the trial, commercial use, or MAUDE database (>5000 cases worldwide)**

PEG Hydrogel - Saline dissection (hydrodissection)



Barrigel - Gel dissection



Images provided by Palette Life Sciences

High TRUS visibility allows the injector to confidently locate the needle tip and inject a bolus amount of gel to confirm placement before proceeding with injection.

BARRIGEL PROSTATE TRIAL RESULTS – FDA CLEARED 05.27.22

Study Regimen (Hypofractionated)

The first randomized FDA-reviewed prostate hyprofractionated trial with a rectal spacer

60 Gy , 20 Fractions (3 Gy/Fraction)

Enrollment

201 Patients (136 Barrigel, 65 Control)
13 Sites

Primary Effectiveness

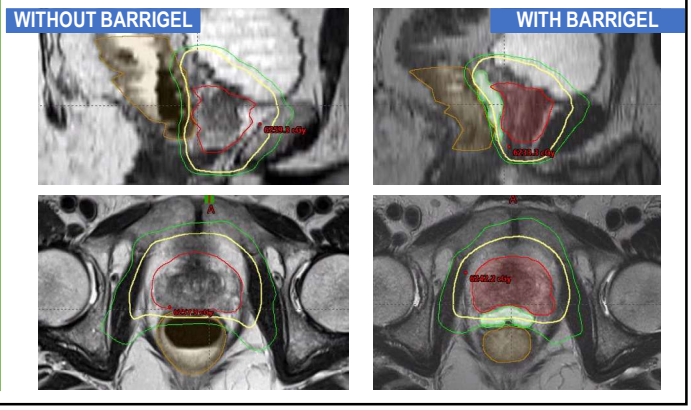
All run-in patients had identical outcomes to the randomized patients

98.5% Percent achieving a 25% reduction in rectum V90 (V54 Gy)
85% Average V90 reduction

Spacing

From midline of prostate to rectal wall

- **12.9mm** Immediate post-injection
- **12.6mm** 3 month post-injection



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BARRIGEL PROSTATE TRIAL RESULTS – FDA CLEARED 05.27.22

Safety Endpoint

Barrigel is superior in the reduction of acute Grade 2+ GI toxicity within 3 months compared to control subjects (p=0.006)

NO **Barrigel-Related UADEs, SAEs or AEs**

*Unanticipated Adverse Device Effects **(UADEs)**, Serious Adverse Events **(SAEs)** or Adverse Events **(AEs)***

ADDITIONAL BARRIGEL SAFETY

Global Commercial Safety Profile

- **5,000+** Global Barrigel Cases
- **0** Barrigel-related AE's

MAUDE Database Reporting

NO Barrigel-related reports as of 10/30/2022

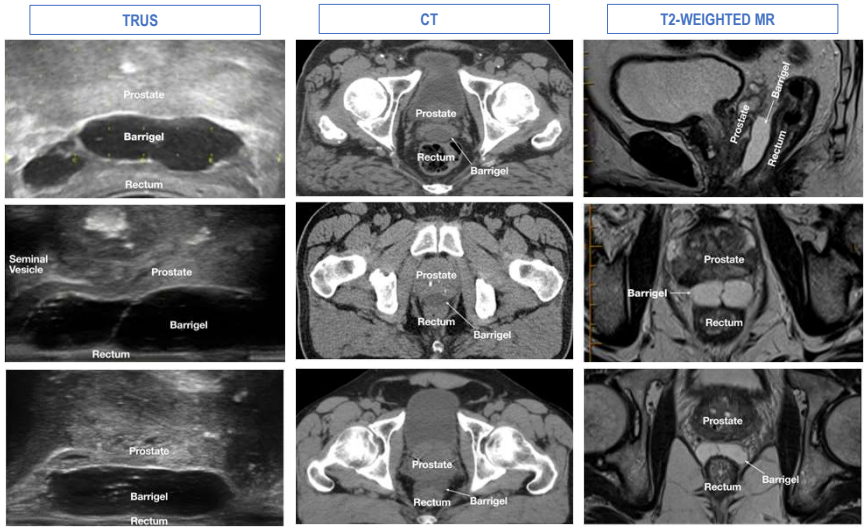
MAUDE = Manufacturer and User Facility Device Experience (Houses medical device reports submitted to the FDA)

BARRIGEL IS VISIBLE ON ALL MODALITIES

In my experience:

- Seeing the rectal spacer clearly on TRUS and being able to determine its final placement has been clinically superior to viewing on CT when it is too late to optimize anatomical coverage
- The treating therapists on the LINAC have no issue in visualizing Barrigel and treating patients

Images provided by Palette Life Sciences



LUGPA
Integrated Practices
Comprehensive Care

Spacer Wars

Par Mehta

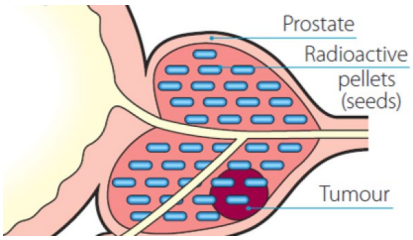
Uropartners

Chicago

Radiation Oncology

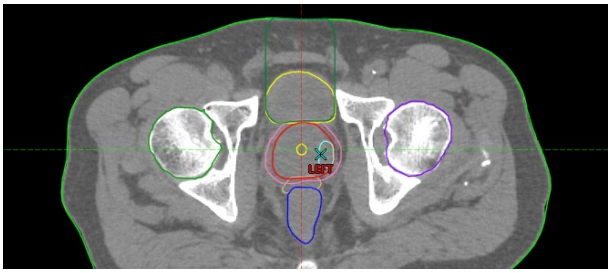
- Use radiation (particles, ionizing radiation) to kill cancer

- Minimize damage to normal tissues



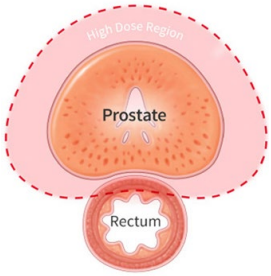
Prostate Cancer Radiation

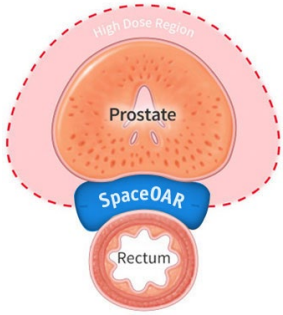
- Maximize dose to the prostate – Better cancer control
  - Dose Escalation
  - Hypofractionation
- Minimize dose to normal tissues – Reduce toxicity
  - Rectum
  - Bladder
  - Penile Bulb
  - Femoral Heads



Peri-rectal Spacers

- 1st FDA Approved 2015
- Physically displace the rectum from the prostate
  - Reduce dose to a critical structure
  - Allow for further dose intensification





“Perfect” Perirectal Spacer

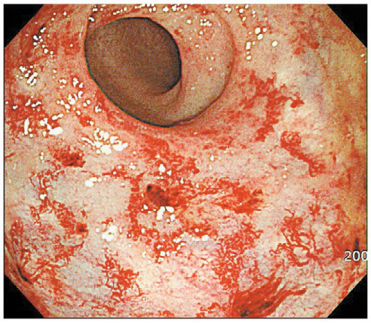
- SpaceOAR vs. The Rest

- Effective
- Safe
- Cost
- Ease of Use

Effectiveness

- SpaceOAR has over 225 articles published in peer reviewed journals

- INSERT TABLE FOR EFFECTIVENESS
- PIVOTAL STUDY
- Zelefsky, et al. SBRT

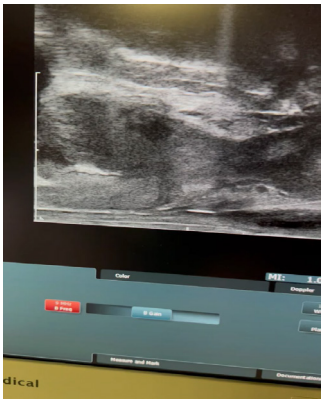


Safety

- Over 220,000 procedures done worldwide
- Published complication rates of < 0.1%
- Complications arise from misplacement
  - Insertion into the rectal wall
  - Embolism – 1 in 17,000 (MAUDE Database)

The “KEY” Differentiator

- Only SpaceOAR includes hydrodissection as part of the insertion
- Allows verification of peri-rectal fat layer prior to placement



Cost

- Covered by most insurances
- Similar in cost to competitors
  - Added benefit of SpaceOAR Vue includes ability to avoid another costly MRI for treatment planning due to visualization
  - INSERT CT CUTS OF SPACEOAR CLASSIC VS VUE

Ease of Use

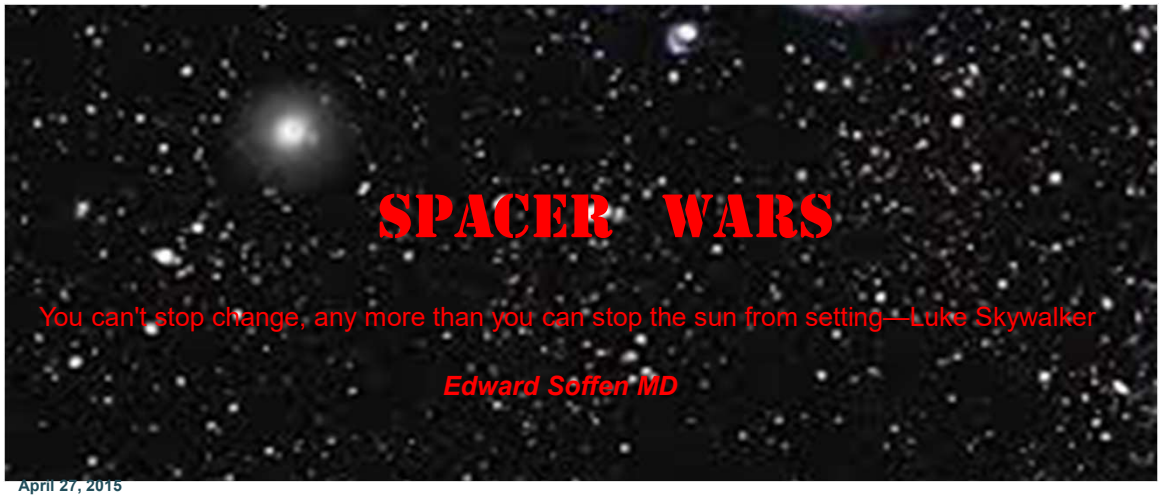
- Quickest peri-rectal spacer placement
  - Limit patient discomfort
  - Most efficient peri-rectal spacer placement
- Visualization of target area through hydrodissection
- No incision and no stitches

Summary

- SpaceOAR meets or beats the competition for optimal peri-rectal spacer
  - Effectiveness
  - Safety
  - Cost
  - Ease of Use

SpaceOAR
So Easy a Radiation Oncologist can do it

- Insert Video of SpaceOAR Placement



April 27, 2015

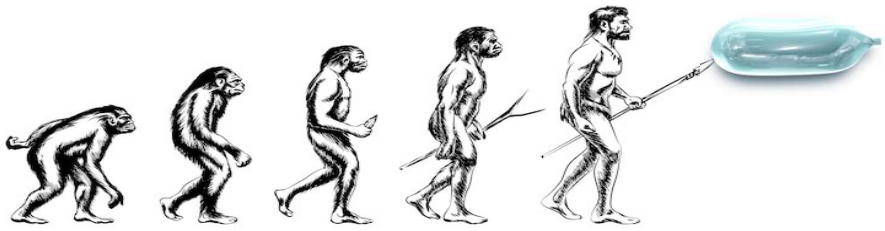
DISCLOSURE

I have at the present or have had within the last 24 months, the following affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest to the design, implementation, presentation, evaluation, etc. of CME Activities:

Boston Scientific—consulting fees
Bioprotect—consulting fees

I was an investigator in each of the above pivotal studies (Augmenix and Bioprotect) and have tried Barrigel since it was FDA approved this summer.

SPACER WARS—CHANGE IS EVOLUTION



Space OAR SpaceOAR Vue Barrigel Balloon

3

BIOPROTECT BALLOON PIVOTAL STUDY OVERVIEW

- Prospective randomized multicenter trial, subjects blinded (8 US sites)
- 222 patients randomized 2:1 at 16 sites (academic and private centers)
- Dates: Jan 2018-Dec 2021
- Efficacy endpoint—reducing at least 25% rectal volume receiving 70Gy in 75% patients
- Safety endpoints—rectal and implantation procedure related AEs
- Secondary endpoints—distance of rectal wall from the prostate and last RT visit, dosimetry and QOL
- Balloon resorbtion at 6 months

4

BIOPROTECT BALLOON RESULTS

- 97.9% % of subjects gained rectal dose reduction >25% in V70 post implantation (139/142)
- rectal volume receiving 70Gy pre-implantation 7.0%
- rectal volume receiving 70Gy post-implantation 1.1%
- mean V70 relative reduction 84.8%
- V60, V50, V40 all reduced—What does this mean? Decrease in rectal frequency, urgency-maybe!!
- No unanticipated adverse device effects!
- Overall absolute 5% reduction in grade 1 or 2 rectal toxicity in balloon group vs control
- Mean change in balloon height through last dose of radiation (1mm—3.6%)
- At 6 months, 98.5% of patients showed complete balloon resorption, the remaining two were almost completely gone.

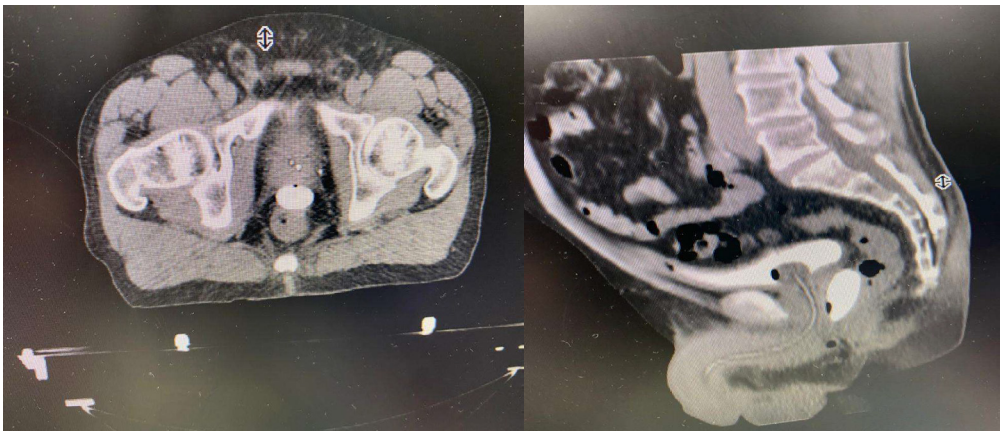
5

BIOPROTECT BALLOON ADVANTAGES

- Uniform and symmetrical separation from base to apex. If you don't like the position, deflate balloon and move position and reinflate
- 15-17 mm average separation --cannot be achieved with the other spacers. This will translate to better dose relationship to rectum AND bladder
- Stable configuration for 3 months, gone by six months
- Balloon can be deflated easily
- Virtually impossible to place in rectal wall
- Patient comfort—no complaints of rectal discomfort after procedure
- Highly visible under ultrasound and CT
- Do not need post implantation MRI
- Simple to contour. Visible with CBCT and KV imaging. (easier for physician, physics and therapist)

6

HIGHLY VISIBLE FOR CT PLANNING AND DAILY CBCT



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SPACER WARS COMPARISON

Feature	Balloon	Space OAR/Vue	Barrigel
Spacing	@15-18mm (17cc saline)	@10mm (10cc)	@10mm (9 or 12 cc)
Symmetry, consistency	+++	+	++
Visible under CT/ultrasound	+++/+++	+/+ +++/+	+(+) /++
Control positioning	+++	+	++
Safety-no beveled needle	+++	Possible rectal infiltration	Possible rectal infiltration
Safety-can be deflated/removed	YES	NO	Perhaps
Material can spread where you don't want it to go	NO	YES	Probably NOT

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If you believe that rectal spacing is important in the treatment of prostate cancer with radiation, it should be considered a standard of care to offer a spacer for those patients with few exceptions.

It improves dosimetric reduction to the rectum, and bladder with significant decrease in grade 2 and greater toxicity in these tissues.

The most symmetric, robust and visible product with the most precise predictable decay is clearly the balloon

A phase 3 randomized trial is being planned once the balloon is FDA approved (early 2023) which will settle once and for all—the SPACER WARS

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