BEST OF AUA 2015
ΚΑΛΟΓΕΡΟΠΟΥΛΟΣ ΘΕΟΔΩΡΟΣ
ΕΠ Α' ΕΣΥ
ΟΥΡΟΛΟΓΙΚΗ ΚΛΙΝΙΚΗ
ΑΟΝΑ ΑΓ ΣΑΒΒΑΣ

1st Place Award Winning Video

Simulated Robotic Partial Nephrectomy Using a 3-D Printed Animated Physical Mode (S.I.M.P.L.E.)

Presenting Author: Ahmed Ghazi, MD, MSc
1st Place: V9-10: Simulated Robotic Partial Nephrectomy Using a 3-D Printed Animated Phased Mode (S.I.M.P.L.E.)
3D printed Kidney tumor models from individual CT scans (preop planning)

- Poly vinyl alcohol hydrogel
  - Face, content, construct validity measured

- Imported DICOM images
  - Different colored Resins mimic vasculature, collecting system, mass and parenchyma
  - Prospective Robotic PN on model prior to patient’s surgery

MP 23-09 Stone J, Ghazi A et al
MP 22-02 Kyung YS, Yoo S, et al

MP 22-3, 22-4 Maddox M, Silberstein J et al
V9-10 Ghazi AE et al
2nd Place Award Winning Video

Robot Assisted Flexible Ureteroscopic Laser Lithotripsy, with Avicenna Roboflex

Presenting Author: Jens Rassweiler, MD
Robotic Ureterorenoscopy

Summary

- The Avicenna Roboflex has been well designed
  - free rotatable manipulator
  - fine movements steerable at console
  - adjustable to US and European endoscopes
  - versatile for endoscopes and lasers
- The Avicenna Roboflex improves ergonomy
  - sitting at console with armrest
  - free control of all functions

The future of flexible ureterorenoscopy
3rd Place: V11-01: Notes-Assisted Laparoscopic Transvesical Bladder Diverticulectomy

3rd Place Award Winning Video

Notes-Assisted Laparoscopic Transvesical Bladder Diverticulectomy

Presenting Author: Ahmed Magdy, MSc
Cystogram:
3 Bladder Diverticulae
Cystogram Day 10: Smooth Bladder Outlines
Rectourethral Fistulas Secondary to Prostate Cancer Treatment: Management and Outcomes

Catherine R. Harris, Benjamin N. Breyer, Daniela Andrich, Alex J. Vanni, Ramon Virasoro, Oscar A. Storme, Gerald H. Jordan, Leonard N. Zinman, Anthony R. Mundy, J.W. McAninch
## Management

<table>
<thead>
<tr>
<th>Procedure</th>
<th>N</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fistulas</td>
<td>225</td>
<td>100%</td>
</tr>
<tr>
<td>Repaired</td>
<td>210</td>
<td>98.3%</td>
</tr>
<tr>
<td>Primary Urinary Diversion</td>
<td>7</td>
<td>3.3%</td>
</tr>
<tr>
<td>Muscle Flaps (gracilis, levator) or Omentum</td>
<td>193</td>
<td>91.9%</td>
</tr>
<tr>
<td>Bowel diversion prior to repair</td>
<td>155</td>
<td>73.8%</td>
</tr>
<tr>
<td>Subgroup Characteristics</td>
<td>RP (N)</td>
<td>%</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------</td>
<td>-----</td>
</tr>
<tr>
<td>Patients</td>
<td>106</td>
<td>50.4%</td>
</tr>
<tr>
<td>Bowel Diversion</td>
<td>69</td>
<td>65.0%</td>
</tr>
<tr>
<td>Muscle flaps or Omentum</td>
<td>98</td>
<td>92.4%</td>
</tr>
<tr>
<td>Buccal Mucosa graft</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Concomitant stricture</td>
<td>15</td>
<td>14.2%</td>
</tr>
<tr>
<td>Position</td>
<td>N</td>
<td>Percent</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----</td>
<td>---------</td>
</tr>
<tr>
<td>Lithotomy</td>
<td>174</td>
<td>82.8%</td>
</tr>
<tr>
<td>Prone</td>
<td>36</td>
<td>17.1%</td>
</tr>
<tr>
<td>Approach</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perineal</td>
<td>166</td>
<td>79%</td>
</tr>
<tr>
<td>Abdominoperineal</td>
<td>42</td>
<td>20%</td>
</tr>
</tbody>
</table>
## Outcomes

<table>
<thead>
<tr>
<th></th>
<th>RP (N)</th>
<th>%</th>
<th>Radiation/Ablation (N)</th>
<th>%</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>106</td>
<td>50.4%</td>
<td>104</td>
<td>49.6%</td>
<td></td>
</tr>
<tr>
<td>Initial Success</td>
<td>99</td>
<td>93.3%</td>
<td>84</td>
<td>80.7%</td>
<td>.006</td>
</tr>
<tr>
<td>Eventual Success</td>
<td>105</td>
<td>99%</td>
<td>90</td>
<td>86.5%</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

** Overall Success Rate 92.8% **
Take Home Message

- Bowel diversion
- Muscle/omental flaps
- Experienced surgeon
- Can avoid urinary diversion
- Success 92.8%
TAKE HOME MESSAGES
ΠΡΟΣΤΑΤΗΣ
Epidemiology and Natural Hx

Active Surveillance

- Retrospective cohort study of 44,292 pts
- Rates of expectant therapy: ↑ (26.4% in 2002 → 36.0% in 2010)
- AS rate ↑ (14.7% → 23.5%) over 8 yrs
- Overall, 61.9% received DT
- Cumulative probability of discontinuing AS: 1yr (39.6%) → 5yr (64.2%)

AS was frequently applied and the rates of AS seemed to increase over time. However, 61.9% of the pts eventually moved on to receiving DT.

(MP42-06, Richard)
Epidemiology and Natural Hx

Testosterone and Prostate Cancer
- Prospective cohort of 18 studies (5,091 pts with Pca and 11,930 controls)
- PSA difference: very minimal (0.11 ng/ml and 0.23ng/ml)
- A summary RR of Pca: 0.94 (not significant)
- PCa development: unrelated to endogenous s-T levels.
- Testosterone replacement therapy for symp. hypogonadism does not appear to increase PSA levels nor the risk of Pca development. (MP4-09, Boyle)

Metformin Use
- A nested case-control study using THIN database including 27,212 PCa pts and 105,940 controls, current Metformin use is associated with a significant decreased risk of PCa. (MP14-14, Kabarriti).
- Metformin use was associated with a significant survival advantage for diabetic veterans with PCa. (PD6-03, Reznick)
Prostate Cancer

Stage

N(+) PCa treated with RP and ePLD

- In a multi-institutional, conditional SA of 1,947 patients with LNI

<table>
<thead>
<tr>
<th></th>
<th>10-yr</th>
<th>15-yr</th>
<th>20-yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCR FS Rates</td>
<td>43.4%</td>
<td>37.9%</td>
<td>33.2%</td>
</tr>
<tr>
<td>MFS Rates</td>
<td>78.1%</td>
<td>69.4%</td>
<td>63.9%</td>
</tr>
<tr>
<td>CSS Rates</td>
<td>84.0%</td>
<td>74.8%</td>
<td>69.9%</td>
</tr>
</tbody>
</table>

- Even in the context of node positive PCa, pts may experience a long-term survival. (PD32-09, Moschini).
Late Breaking Abstract (PII-LBA10): A Multicenter Phase 2 Study of Enzalutamide (ENZA) versus Bicalutamide (BIC) in Men with Nonmetastatic (M0) or Metastatic (M1) Castration-Resistant Prostate Cancer (CRPC): the STRIVE Trial

STRIVE
A Multicenter Phase 2 Study of Enzalutamide versus Bicalutamide in Men with Nonmetastatic or Metastatic Castration-Resistant Prostate Cancer

David Penson, ¹ Andrew Armstrong, ² Raoul Concepcion, ³ Neeraj Agarwal, ⁴ Fong Wang, ⁵ Kenneth Wu, ⁵ Andree Amelsberg, ⁶ De Phung, ⁷ Celestia Higano ⁸

¹Vanderbilt Ingram Cancer Center, Nashville, TN; ²Duke University, Durham, NC; ³Urology Associates PC, Nashville, TN; ⁴Huntsman Cancer Institute, University of Utah, Salt Lake City, UT; ⁵Medivation, Inc., San Francisco, CA; ⁶Astellas Pharma Global Development, Inc., Northbrook, IL; ⁷Astellas Pharma Global Development, Inc., Leiden, The Netherlands; ⁸Fred Hutchinson Cancer Research Center, Seattle, WA

ClinicalTrials.gov identifier: NCT01664923
**STRIVE Study Design**

**Patient Population**
- M0 or M1 CRPC
- Asymptomatic/mildly symptomatic
- No prior bicalutamide or no progression on bicalutamide
- Chemotherapy-naïve

**Randomized 1:1**

**Enzalutamide**
- 160 mg/day (n = 198)

**Bicalutamide**
- 50 mg/day (n = 198)

**Primary Endpoint**
- Progression-free survival (PFS): PSA progression or Radiographic progression or Death

**Key secondary endpoints:**
- Time to PSA progression
- PSA response
- rPFS (M1 population only)

ADT = androgen deprivation therapy; CRPC = castration-resistant prostate cancer; M0 = nonmetastatic; M1 = metastatic; PSA = prostate-specific antigen; rPFS = radiographic PFS.

ClinicalTrials.gov identifier: NCT01664923.
Results

- 58 US investigators (majority urologists)
- 396 patients randomized from Aug 2012 to Mar 2014
  - 139 (35%) with M0
  - 257 (65%) with M1
- Progression at time of enrolment:
  - 52% PSA rise only
  - 32% PSA rise and imaging
  - 9% Imaging only
- Data cut-off occurred after 236 PFS events on Feb 9, 2015
  - A minimum of 231 PFS events for the primary efficacy endpoint of PFS was required with target hazard ratio of 0.65 to give 90% power
**Baseline Patient Characteristics**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Enalutamide (n = 198)</th>
<th>Bicalutamide (n = 198)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, median (range)</td>
<td>72 (46–92)</td>
<td>74 (50–91)</td>
</tr>
<tr>
<td>ECOG PS grade, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>148 (74.7)</td>
<td>145 (73.2)</td>
</tr>
<tr>
<td>1</td>
<td>50 (25.3)</td>
<td>53 (26.8)</td>
</tr>
<tr>
<td>Pain score of 0–1 on BPI-SF Q3, n (%)</td>
<td>165 (83.3)</td>
<td>158 (79.8)</td>
</tr>
<tr>
<td>Gleason score ≥ 8 at initial diagnosis, n (%)</td>
<td>100 (50.5)</td>
<td>97 (49.0)</td>
</tr>
<tr>
<td>Disease stage, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M0</td>
<td>70 (35.4)</td>
<td>69 (34.8)</td>
</tr>
<tr>
<td>M1</td>
<td>128 (64.6)</td>
<td>129 (65.2)</td>
</tr>
<tr>
<td>PSA, median (µg/L)</td>
<td>11.0</td>
<td>13.2</td>
</tr>
<tr>
<td>Alkaline phosphatase, median (U/L)</td>
<td>78.0</td>
<td>75.0</td>
</tr>
</tbody>
</table>

ECOG PS = Eastern Cooperative Oncology Group Performance Status; BPI-SF Q3 = Brief Pain Inventory Short Form, question 3; M0 = nonmetastatic; M1 = metastatic; PSA = prostate-specific antigen.
Late Breaking Abstract (PII-LBA10): A Multicenter Phase 2 Study of Enzalutamide (ENZA) versus Bicalutamide (BIC) in Men with Nonmetastatic (M0) or Metastatic (M1) Castration-Resistant Prostate Cancer (CRPC): the STRIVE Trial

**Progression-Free Survival**

- **Enzalutamide 160 mg**
- **Bicalutamide 50 mg**

**Median 5.7 months**
- (95% CI: 5.6, 6.1)

**Median 19.4 months**
- (95% CI: 16.8, NR)

**HR, 0.24 (95% CI: 0.18, 0.32); P < 0.0001**

Patients at Risk:
- Enzalutamide: 198, 171, 150, 131, 104, 66, 43, 24, 16, 5, 0
- Bicalutamide: 198, 138, 80, 51, 29, 17, 9, 5, 3, 1, 0

CI = confidence interval; HR = hazard ratio; NR = not reached.

ClinicalTrials.gov identifier: NCT01684923
Late Breaking Abstract (PII-LBA10): A Multicenter Phase 2 Study of Enzalutamide (ENZA) versus Bicalutamide (BIC) in Men with Nonmetastatic (M0) or Metastatic (M1) Castration-Resistant Prostate Cancer (CRPC): the STRIVE Trial

**Time to PSA Progression**

- **Enzalutamide 160 mg**
- **Bicalutamide 50 mg**

**Median 8.3 months**

- **HR, 0.19 (95% CI: 0.14, 0.26); P < 0.0001**

<table>
<thead>
<tr>
<th>Months</th>
<th>Patients at Risk Enzalutamide</th>
<th>Patients at Risk Bicalutamide</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>198</td>
<td>198</td>
</tr>
<tr>
<td>3</td>
<td>177</td>
<td>154</td>
</tr>
<tr>
<td>6</td>
<td>157</td>
<td>134</td>
</tr>
<tr>
<td>9</td>
<td>139</td>
<td>91</td>
</tr>
<tr>
<td>12</td>
<td>139</td>
<td>59</td>
</tr>
<tr>
<td>15</td>
<td>108</td>
<td>32</td>
</tr>
<tr>
<td>18</td>
<td>69</td>
<td>19</td>
</tr>
<tr>
<td>21</td>
<td>42</td>
<td>9</td>
</tr>
<tr>
<td>24</td>
<td>25</td>
<td>6</td>
</tr>
<tr>
<td>27</td>
<td>16</td>
<td>4</td>
</tr>
<tr>
<td>30</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

Cl = confidence interval; HR = hazard ratio; NR = not reached; PSA = prostate-specific antigen

ClinicalTrials.gov identifier: NCT01864923
Late Breaking Abstract (PII-LBA10): A Multicenter Phase 2 Study of Enzalutamide (ENZA) versus Bicalutamide (BIC) in Men with Nonmetastatic (M0) or Metastatic (M1) Castration-Resistant Prostate Cancer (CRPC): the STRIVE Trial
### Results by Baseline Population

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>M0 (35%)</th>
<th>M1 (65%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Enzalutamide</td>
<td>Bicalutamide</td>
</tr>
<tr>
<td>Median PFS, months</td>
<td>NR</td>
<td>8.6</td>
</tr>
<tr>
<td>HR (95% CI)</td>
<td>0.24 (0.14, 0.42)</td>
<td>0.24 (0.17, 0.34)</td>
</tr>
<tr>
<td>Median rPFS, months</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>HR (95% CI)</td>
<td>0.24 (0.10, 0.56)</td>
<td>NR</td>
</tr>
<tr>
<td>Median time to PSA progression, months</td>
<td>NR</td>
<td>11.1</td>
</tr>
<tr>
<td>HR (95% CI)</td>
<td>0.18 (0.10, 0.34)</td>
<td>0.19 (0.13, 0.28)</td>
</tr>
<tr>
<td>PSA response (≥ 50%), %</td>
<td>90.9</td>
<td>42.0</td>
</tr>
<tr>
<td>Difference, % (95% CI)</td>
<td>48.9 (35.3, 62.4)</td>
<td>50.8 (40.2, 61.4)</td>
</tr>
</tbody>
</table>

CI = confidence interval; HR = hazard ratio; M0 = nonmetastatic; M1 = metastatic; NR = not reached; PFS = progression-free survival; PSA = prostate-specific antigen; rPFS = radiographic PFS.

ClinicalTrials.gov identifier: NCT01684923.
Late Breaking Abstract (PII-LBA10): A Multicenter Phase 2 Study of Enzalutamide (ENZA) versus Bicalutamide (BIC) in Men with Nonmetastatic (M0) or Metastatic (M1) Castration-Resistant Prostate Cancer (CRPC): the STRIVE Trial

### Most Common Treatment-Emergent AEs*

<table>
<thead>
<tr>
<th>AE, n (%)</th>
<th>Enzalutamide (n = 197)</th>
<th>Bicalutamide (n = 198)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>74 (37.6)</td>
<td>56 (28.3)</td>
</tr>
<tr>
<td>Back pain</td>
<td>35 (17.8)</td>
<td>31 (15.7)</td>
</tr>
<tr>
<td>Hot flash</td>
<td>31 (15.7)</td>
<td>19 (9.6)</td>
</tr>
<tr>
<td>Constipation</td>
<td>20 (10.2)</td>
<td>33 (16.7)</td>
</tr>
<tr>
<td>Fall</td>
<td>27 (13.7)</td>
<td>16 (8.1)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>17 (8.6)</td>
<td>28 (14.1)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>24 (12.2)</td>
<td>14 (7.1)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>24 (12.2)</td>
<td>10 (5.1)</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>23 (11.7)</td>
<td>17 (8.6)</td>
</tr>
<tr>
<td>Anemia</td>
<td>13 (6.6)</td>
<td>21 (10.6)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>10 (5.1)</td>
<td>22 (11.1)</td>
</tr>
</tbody>
</table>

*At least 10% in either treatment group and a difference between treatment arms of at least 1%.

AE = adverse event.
Conclusions

- First head to head trial adding either enzalutamide or bicalutamide to ADT in M0 and M1 patients with CRPC. Compared to bicalutamide, enzalutamide resulted in highly statistically significant:
  - Prolonged PFS
  - Delay in time to PSA progression
  - Higher PSA response rates
  - Prolonged rPFS
- Consistent with more profound androgen blockade, enzalutamide resulted in more fatigue, hot flashes, and hypertension. There were also more falls and dizziness.
- In the bicalutamide arm, there was more constipation, diarrhea, anemia, and urinary tract infections.
- The PROSPER phase 3 trial that includes only M0 CRPC patients will further define the effect of enzalutamide in this specific population.
TERRAIN TRIAL: PROSTATE-SPECIFIC ANTIGEN KINETICS AND QUALITY OF LIFE RESULTS OF ENZALUTAMIDE VERSUS BICALUTAMIDE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

Neal Shore,1 Axel Heidenreich,2 Arnauld Villers,3 Laurence Klotz,4 Maha Hussain,3 Lawrence Karsh,6 Steve van Os,7 Benoit Baron,7 Fong Wang,8 David Forer,8 Simon Chowdhury,9 D. Robert Siemens10

1Carolina Urologic Research Center, Myrtle Beach, SC, USA; 2Department of Urology, Aachen University, Aachen, Germany; 3Department of Urology, Lille University, Lille, France; 4Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada; 5University of Michigan Comprehensive Cancer Center, Ann Arbor, MI, USA; 6The Urology Center of Colorado, Denver, CO, USA; 7Astellas Pharma Inc, Leiden, the Netherlands; 8Medivation, Inc., San Francisco, CA, USA; 9Guy’s, King’s and St Thomas’ Hospitals, London, UK; 10Centre for Applied Urological Research, Queen’s University, Kingston, Ontario, Canada; 1Presenting author
Late Breaking Abstract (PII-LBA4): TERRAIN Trial: Prostate-specific Antigen Kinetics and Quality of Life Results of Enzalutamide versus Bicalutamide in Metastatic Castration-resistant Prostate Cancer

**TERRAIN study design**

**Patient population**
- 375 men with progressive mCRPC
- Asymptomatic / mildly symptomatic
- Chemotherapy-naive
- No requirement for steroids

**Exclusion**
- Progression on anti-androgen therapy

**Randomized 1:1**

**ENZA 160 mg/day n=184**

**BIC 50 mg/day n=191**

**Primary endpoint:** Progression-free survival (PFS):
- Radiographic progression (central review)
- Skeletal-related events
- Change to a new anti-neoplastic therapy
- Death

**Other endpoints:**
- Time to PSA decrease
- PSA response
- Health-related QoL (FACT-P)

**Statistical design**
- The final analysis was planned at ≥220 progression events with 85% power to detect a target hazard ratio of 0.67 (assuming a median PFS of 9 months versus 6 months)
- The data cut-off date was October 19, 2014 with 240 events for the primary efficacy endpoint

TERRAIN trial: NCT01288911
ENZA, enzalutamide; BIC, bicalutamide; PSA, prostate-specific antigen;
QoL, quality of life; FACT-P, Functional Assessment of Cancer Treatment—Prostate
Late Breaking Abstract (PII-LBA4): TERRAIN Trial: Prostate-specific Antigen Kinetics and Quality of Life Results of Enzalutamide versus Bicalutamide in Metastatic Castration-resistant Prostate Cancer

PSA response by week 13

![Graph showing PSA response by week 13 for Enzalutamide (ENZA) and Bicalutamide (BIC). The graph indicates that Enzalutamide shows a significant decrease in PSA levels, with 82% of patients having at least a 50% decrease in PSA by week 13, compared to Bicalutamide where only 21% of patients showed a similar decrease.](image-url)

Heidenreich, A et al. EAU 2015
Progression-free survival

Median (95% CI)
ENZA: 15.7 months (11.5, 19.4)
BIC: 5.8 months (4.8, 8.1)

Hazard ratio (95% CI)
ENZA: 0.44 (0.34, 0.57)
BIC: p<0.0001

Patients at risk
ENZA: 184, 159, 131, 107, 86, 71, 52, 33, 21, 13, 8, 6
BIC: 191, 133, 85, 61, 44, 30, 13, 7, 4, 2, 2, 1

Heidenreich, A et al. EAU. 2015
Late Breaking Abstract (PII-LBA4): TERRAIN Trial: Prostate-specific Antigen Kinetics and Quality of Life Results of Enzalutamide versus Bicalutamide in Metastatic Castration-resistant Prostate Cancer

**Time to ≥90% PSA decrease**

- **Median (95% CI):**
  - **ENZA:** 5.4 months (3.0, 5.7)
  - **BIC:**

- **Hazard ratio (95% CI):** 13.9 (7.2, 26.8)

**Patients at risk**

- **ENZA:**
  - 184
  - 92
  - 50
  - 29
  - 19
  - 13
  - 8
  - 5
  - 3

- **BIC:**
  - 191
  - 133
  - 97
  - 58
  - 40
  - 26
  - 13
  - 8
  - 5

**Source:** AUA Annual Meeting, May 13–15, 2013, New Orleans, LA, USA
Late Breaking Abstract (PII-LBA4): TERRAIN Trial: Prostate-specific Antigen Kinetics and Quality of Life Results of Enzalutamide versus Bicalutamide in Metastatic Castration-resistant Prostate Cancer

FACT-P response analysis

*\( p < 0.05 \)

- PWB: physical well-being
- SWB: social well-being
- EWB: emotional well-being
- FWB: functional well-being
- PCS: prostate cancer subscale
- PCSP: PCS pain-related score
- FAPS: Functional Assessment of Cancer Therapy—Advanced Prostate Symptom Index
- TOI: Trial Outcome Index
- FACT-G: Functional Assessment of Cancer Therapy—General
- FACT-P: Functional Assessment of Cancer Therapy—Prostate

HRQoL domain

Patients with improvement at any time during the study (%)
Conclusions

- ENZA was associated with significantly longer PFS compared to BIC, with a difference of approximately 10 months in median PFS.
- ENZA was associated with a higher PSA response rate compared with BIC.
- ENZA was associated with a greater HRQoL benefit compared with BIC.
- ENZA demonstrated safety broadly consistent with its known safety profile in patients with mCRPC.
- In this large, double-blind, randomized, Phase II study, ENZA demonstrated greater efficacy compared to BIC in patients with asymptomatic / mildly symptomatic mCRPC.
Overview

- 123 abstracts in the BPH/LUTS section
  - 8 podium and poster sessions
  - 1 video session
- 2 Plenary Sessions
Conclusions

- Increased age and BMI predict 5AR2 methylation and decreased protein expression in symptomatic BPH

- 5AR2 expression is variable in the adult population
  - May explain why a subset of patients fail medical therapy
  - Sets the stage for personalized medicine

- Dynamic interplay of metabolic risk factors and methylation
  - Improvement in LUTS with lifestyle changes or gastric bypass surgery

- Future: evaluate global gene expression and define an epigenetic “signature” in BPH in response to 5ARI therapy

- Goal: identify those unlikely to respond to 5ARIs early on and develop an alternate targeted therapy

1 Bechis SK et al, J Urol 2014
Surgical Therapy & New Technology

• Thermo-expandable intraprostatic stent (MP13-13 Song)
  – Comparison of TURP (n=37) vs. Memokath™ stent (n=15) used in patients with significant comorbidities (ASA≥3) with similar improvements in IPSS scores (-8)
  – 33% complication rate (pain in 3, incontinence in 1, migration in 1)

• Laser prostatectomy
  – Holmium (MP13-05 Elkousy): 1216 HoLEP procedures with 1.3 day mean duration of stay with 4.3% (n=52) rate of reoperation for recurrent LUTS, 1.15% (n=14) for BNC, and 2.05% (n=25) for urethral stricture
    • Adenoma recurrence associated with smaller prostate size and previous surgery
    • BNC associated with smaller glands
    • Urethral stricture associated with longer operative time and catheterization
  – Thulium (MP13-10, -11, and -12, Netsch): 6 year follow-up for 500 patients undergoing ThuVEP shows durable outcomes (90 patients with prostates >80cc) in all age groups 60 and above
  – XPS (PDS-08 Thomas): 24 month results of Goliath RCT of Greenlight XPS vs. TURP shows noninferiority to TURP at 24mo (IPSS 6.9 vs. 5.9; Qmax 20.6 vs. 21.9)
Surgical Therapy & New Technology

- Prostatic Urethral Lift (MP3-01 Barber, PD5-01 Roehrborn, MP3-02 Woo)
  - RCT of PUL vs. TURP in 80 patients over 10 European centers: moderate improvement in IPSS scores compared to TURP with lower rates of retrograde ejaculation and faster postoperative recovery
  - 3 year results for RCT of 140 men treated with PUL vs. sham: 43% AUASS reduction with preserved sexual function, with 12/140 (9%) retreatment rate
  - Crossover study in 53 patients shows good symptom relief with PUL out to 2 years

- Rezum II (P11-LBA1 McVary):
  - RCT of 197 men treated with water vapor vs. sham with IPSS improvement (22 to 10.7) and Qmax improvement (+4.9mL/s) with only mild and transient adverse events

- Aquablation: image-guided, robotic-assisted water jet ablation of prostate (PD5-02 Gilling, MP3-03 Desai)
  - High velocity saline stream (AquaBeam®) controlled using real-time ultrasound and planning coregistration
  - n=21 patients and n=9 treated with LUTS improvement (IPSS 23 to 8.9, Qmax 8.6 to 21.7mL/s) at 6 months
Rezūm II Pivotal Study
Minimally Invasive Prostatic Vapor Ablation Multicenter RCT for the Treatment of LUTS/BPH

Kevin T. McVary, MD
SIU School of Medicine
Division of Urology
Springfield, IL
The Rezūm System

Rezūm System consists of a hand held delivery device and generator.

Caution: Investigational device. Limited by U.S. Law to investigational use.
Water Vapor Production

1. RF energy and sterile water are sent to the Delivery Device from the Generator.
2. RF power heats and converts sterile water flowing through the Delivery Device coil into stored thermal energy in the form of water vapor (steam).
3. Water vapor is delivered through the needle into the prostate.
Convective WAVE™ Technology

Transition Zone Boundary
0.42mL Water Vapor Injected

Rapidly disperses through tissue interstices
Condensation releases stored thermal energy denaturing cell membranes
Tissue coagulation and necrosis (cell death)

Time = 0 → Time = 9 sec/treatment
The Rezūm Procedure
The Rezūm II Pivotal Study

- 15 US Investigational Sites
- 197 subjects
- 2:1 Randomization Rezūm vs. Control
  - Control
    - Rigid cystoscopy w/ surgical screen,
    - Rezūm device operated external to subject to mimic system sounds
  - Blinding (subject and assessment personnel)
- Independent evaluation & adjudication of data
  - Data Monitoring Committee
  - Clinical Events Committee
Inclusion Criteria

- Males > 50 years of age with LUTS/BPH
- IPSS \( \geq 13 \)
- Qmax: \( \geq 5 - 15 \) ml/sec (voided \( \geq 125 \) ml)
- PVR \( \leq 250 \) ml
- Prostate volume \( \geq 30 \) and \( \leq 80 \) gm
- Middle lobes **NOT** excluded!
**Procedural Pain Management**

<table>
<thead>
<tr>
<th>Type of Medication</th>
<th># of Subjects (N=196)</th>
<th>Percentage of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Sedation</td>
<td>135</td>
<td>68.88%</td>
</tr>
<tr>
<td>Prostate Block</td>
<td>41</td>
<td>20.92%</td>
</tr>
<tr>
<td>IV Sedation</td>
<td>20</td>
<td>10.20%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedural Results</th>
<th>Treatment (N=136)</th>
<th>Control (N=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Time (min)</td>
<td>Mean ± SD (n)</td>
<td>Mean ± SD (n)</td>
</tr>
<tr>
<td></td>
<td>5.3 ± 3.5 (135)</td>
<td>3.3 ± 1.3 (61)</td>
</tr>
<tr>
<td>% with middle lobe treated</td>
<td>31.1% (42/135)</td>
<td>18.0% (11/61)</td>
</tr>
<tr>
<td>Number of treatments total</td>
<td>4.5 ± 1.8 (135)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
**Primary Efficacy Endpoint – As Treated**

Improvement in LUTS as measured by IPSS change for subjects in the Treatment Arm as compared to those in the Control Arm at 3 months post-treatment.

<table>
<thead>
<tr>
<th></th>
<th>Treatment Arm</th>
<th>Control Arm</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>3 Months</td>
<td>Change</td>
<td>Baseline</td>
<td>3 Months</td>
<td>Change</td>
</tr>
<tr>
<td>IPSS Score</td>
<td>22.0 ± 4.8</td>
<td>10.7 ± 6.5</td>
<td>-11.3 ± 7.6</td>
<td>21.9 ± 4.7</td>
<td>17.5 ± 7.6</td>
<td>-4.3 ± 6.9</td>
</tr>
</tbody>
</table>

Met pre-specified primary efficacy endpoint!
## Primary Safety Endpoint

Demonstrate that the composite observed rate of post-procedure device-related serious complications in the Treatment Arm is ≤12% at 3 months.

<table>
<thead>
<tr>
<th>Primary Safety Composite Endpoint:</th>
<th>Treatment Arm</th>
<th>Events</th>
<th>Patients % (n/N)</th>
<th>Upper CI</th>
<th>p-value</th>
<th>Endpoint Criteria</th>
<th>Endpoint Met?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Device perforation of rectum or GI tract</td>
<td>0</td>
<td>0.0% (0/136)</td>
<td>3.40%</td>
<td>&lt;0.0001</td>
<td>Upper CI ≤ 12%</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>2) Device related formation of fistula between the rectum and urethra</td>
<td>0</td>
<td>0.0% (0/136)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) De novo severe urinary retention lasting more than 21 consecutive days post treatment</td>
<td>1</td>
<td>0.7% (1/136)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹One-sided 95% Exact Binomial CI

Met primary safety endpoint!
Summary

- All primary and secondary endpoints met

- IPSS at 3 mo -11.3 or -50% from baseline

- Qmax at 3 mo +6.2 or +67% from baseline

- Durability to 1 year noted
  - IPSS at 12 mo -11.9 or -54% from baseline
  - Qmax at 12 mo +5.4 or +57% from baseline

- Rezūm:
  - Well tolerated with oral medication
  - Significant symptom relief
  - Significant improvement in Qmax
  - No impact on sexual function
  - Treats middle lobes
Efficacy and safety of mirabegron add-on treatment to solifenacin in incontinent OAB subjects with an inadequate response to initial 4-week solifenacin monotherapy

Marcus Drake (presenter)\textsuperscript{1}; Ahmet Adil Esen\textsuperscript{2}; Stavros Athanasiou\textsuperscript{3}; Claire Herholdt\textsuperscript{4}; Roberta Baronio\textsuperscript{5}; Tahir Saleem\textsuperscript{4}; Moses Huang\textsuperscript{4}; Emad Siddiqui\textsuperscript{4}; Scott MacDiarmid\textsuperscript{6}

\textsuperscript{1}Bristol Urological Institute, Dept. Urology, Bristol, UK; \textsuperscript{2}Dokuz Eylül University, Urology Department, Izmir, Turkey; \textsuperscript{3}University of Athens, Alexandra Hospital, Athens, Greece; \textsuperscript{4}Astellas Pharma Europe Ltd, Chertsey, Surrey, UK; \textsuperscript{5}FSP Chiltern International, Leiden, Netherlands; \textsuperscript{6}Alliance Urology Specialists, Greensboro, NC, USA
Study objectives

- **Primary objective**
  - To evaluate the efficacy of solifenacin (SOLI) 5 mg in combination with mirabegron 50 mg ("combination therapy") versus SOLI 5 mg monotherapy

- **Secondary objectives**
  - To evaluate the safety and tolerability of combination therapy versus SOLI 5 mg and SOLI 10 mg monotherapy
  - To evaluate the efficacy of combination therapy versus SOLI 10 mg monotherapy
Study design

- Male and female subjects ≥18 years of age, who had symptoms of OAB for ≥3 months, and who remained incontinent after treatment with SOLI 5 mg during a 4-week run-in period, were eligible for double-blind treatment.
**Summary**

- Combination therapy (mirabegron and solifenacin) was **superior** to SOLI 5 mg in reducing incontinence episodes and micturition frequency (primary and key secondary efficacy endpoints).
- The combination was **non-inferior** to SOLI 10 mg for both key secondary efficacy endpoints, and was **superior** to SOLI 10 mg in reducing micturition frequency.
- Combination was **superior** to both doses of solifenacin in reducing urgency episodes (grade 3 or 4)/24 h and increasing mean volume voided/micturition.
- All treatment arms were well tolerated; the AE profile for the combination appeared in general to be comparable with known SOLI and MIRA profiles.
- Vital signs in the combination group showed no additive/synergistic effects beyond those known for either monotherapy.
Conclusion

- In incontinent OAB patients with an insufficient response to solifenacin 5 mg, add-on treatment with mirabegron provides additional benefit compared to solifenacin 5 mg monotherapy or an increase to solifenacin 10 mg, and is well tolerated.
Durable Reductions in UI with Long-Term OnabotulinumtoxinA Treatment in Patients with Overactive Bladder Syndrome
Final Results of 3.5-Year Study

Victor Nitti¹, Dirk De Ridder², David Sussman³, Peter Sand⁴, Karl-Dietrich Sievert⁵, Christopher Chapple⁶, Brenda Jenkins⁷, Andrew Magyar⁶, Sidney Radomski⁹

¹New York University, New York, NY, USA; ²University Hospitals KU Leuven, Leuven, Belgium; ³Rowan University School of Osteopathic Medicine, Stratford, NJ, USA; ⁴Evanston Continence Center, Evanston, IL, USA; ⁵University of Tuebingen, Tuebingen, Germany; ⁶Royal Hallamshire Hospital, Sheffield, UK; ⁷Allergan Inc., Irvine, CA, USA; ⁸Allergan, Inc., Bridgewater, NJ, USA; ⁹University of Toronto, Toronto, Canada
Background and Objective

- Two phase 3, randomized, double-blind, placebo-controlled studies demonstrated that onabotulinumtoxinA (BOTOX®, Allergan, Inc.) 100U significantly decreased urinary incontinence (UI) and improved quality of life versus placebo in patients with overactive bladder (OAB) with UI who were inadequately managed by an anticholinergic.

- A multicenter extension study was performed to assess the long-term safety and efficacy of onabotulinumtoxinA in the treatment of OAB.
Study Design

Two 24-week, randomized, multicenter, double-blind, placebo-controlled phase 3 studies

OnabotA 100U vs placebo

First patient in 2009

Protocol amendment Aug 2012

Final patient out Aug 2014

3-year, long-term follow-up study OnabotulinumtoxinA 100U*

24 weeks
Up to 2 treatments

Up to 3 years
Multiple treatments, request for re-treatment initiated by patient

*Originally, a dose increase from 100U to 150U was permitted from treatment 3 onwards. Since the 150U dose did not provide additional efficacy, the protocol was amended to allow only the 100U dose. The current analyses include data for the 100U dose only.
Overall Population Results: Consistent Reduction in UI Episodes/day at Week 12

<table>
<thead>
<tr>
<th>Treatment Number</th>
<th>n</th>
<th>UI Episodes/Day (Mean Change From BL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>812</td>
<td>-3.3</td>
</tr>
<tr>
<td>2</td>
<td>597</td>
<td>-3.6</td>
</tr>
<tr>
<td>3</td>
<td>372</td>
<td>-3.8</td>
</tr>
<tr>
<td>4</td>
<td>264</td>
<td>-3.5</td>
</tr>
<tr>
<td>5</td>
<td>181</td>
<td>-3.3</td>
</tr>
<tr>
<td>6</td>
<td>136</td>
<td>-3.1</td>
</tr>
</tbody>
</table>

Error bars represent 95% confidence intervals.

n values denote the number of patients with data available at week 12. BL = baseline; UI = urinary incontinence.
Overall Median Duration of Effect Was 7.6 Months

<table>
<thead>
<tr>
<th>Duration</th>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤6 months</td>
<td>34.2%</td>
</tr>
<tr>
<td>&gt;6 to ≤12 months</td>
<td>37.2%</td>
</tr>
<tr>
<td>&gt;12 months</td>
<td>28.5%</td>
</tr>
</tbody>
</table>

*n= Median of the median duration for each patient. Includes data from complete treatment cycles (100U only) 4 weeks = 1 month. Total of 438 patients who received 100U only throughout the study and who had complete treatment cycles over the 3.5-year study.*
## Overall Population Results: Adverse Events ≥3% Through Week 12

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>OnabotulinumtoxinA 100U Treatment Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (n=829)</td>
</tr>
<tr>
<td></td>
<td>2 (n=608)</td>
</tr>
<tr>
<td></td>
<td>3 (n=388)</td>
</tr>
<tr>
<td></td>
<td>4 (n=27)</td>
</tr>
<tr>
<td></td>
<td>5 (n=185)</td>
</tr>
<tr>
<td></td>
<td>6 (n=139)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>141 (17.0)</td>
</tr>
<tr>
<td></td>
<td>98 (16.1)</td>
</tr>
<tr>
<td></td>
<td>68 (17.5)</td>
</tr>
<tr>
<td></td>
<td>40 (14.7)</td>
</tr>
<tr>
<td></td>
<td>25 (13.5)</td>
</tr>
<tr>
<td></td>
<td>20 (14.4)</td>
</tr>
<tr>
<td>Dysuria</td>
<td>46 (5.5)</td>
</tr>
<tr>
<td></td>
<td>28 (4.6)</td>
</tr>
<tr>
<td></td>
<td>16 (4.1)</td>
</tr>
<tr>
<td></td>
<td>7 (2.6)</td>
</tr>
<tr>
<td></td>
<td>7 (3.8)</td>
</tr>
<tr>
<td></td>
<td>8 (5.8)</td>
</tr>
<tr>
<td>Bacteriuriaa</td>
<td>32 (3.9)</td>
</tr>
<tr>
<td></td>
<td>21 (3.5)</td>
</tr>
<tr>
<td></td>
<td>18 (4.6)</td>
</tr>
<tr>
<td></td>
<td>12 (4.4)</td>
</tr>
<tr>
<td></td>
<td>6 (3.2)</td>
</tr>
<tr>
<td></td>
<td>4 (2.9)</td>
</tr>
<tr>
<td>Urinary retentionb</td>
<td>32 (3.9)</td>
</tr>
<tr>
<td></td>
<td>20 (3.3)</td>
</tr>
<tr>
<td></td>
<td>9 (2.3)</td>
</tr>
<tr>
<td></td>
<td>6 (2.2)</td>
</tr>
<tr>
<td></td>
<td>3 (1.6)</td>
</tr>
<tr>
<td></td>
<td>3 (2.2)</td>
</tr>
<tr>
<td>Leukocyturia</td>
<td>18 (2.2)</td>
</tr>
<tr>
<td></td>
<td>7 (1.2)</td>
</tr>
<tr>
<td></td>
<td>4 (1.0)</td>
</tr>
<tr>
<td></td>
<td>3 (1.1)</td>
</tr>
<tr>
<td></td>
<td>2 (1.1)</td>
</tr>
<tr>
<td></td>
<td>5 (3.6)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>8 (1.0)</td>
</tr>
<tr>
<td></td>
<td>10 (1.6)</td>
</tr>
<tr>
<td></td>
<td>7 (1.8)</td>
</tr>
<tr>
<td></td>
<td>2 (0.7)</td>
</tr>
<tr>
<td></td>
<td>6 (3.2)</td>
</tr>
<tr>
<td></td>
<td>1 (0.7)</td>
</tr>
</tbody>
</table>

*a Defined as a positive urine culture with a bacteriuria count of >10⁵ colony forming units/mL and leukocyturia of >5 high power field, regardless of symptoms.

*b Defined as PVR ≥350 ml, regardless of symptoms or PVR between ≥200 ml and <350 ml, with associated symptoms that required CIC in the investigator’s opinion.
Conclusions

- Patients with overactive bladder and UI treated with onabotulinumtoxinA up to 3.5 years showed consistent reductions in daily UI episodes.
- A consistently high proportion of patients (74.0–83.2%) reported their urinary condition as ‘improved’ or ‘greatly improved’ through 6 treatments.
- The overall median duration of effect was 7.6 months.
- No new safety signals were identified upon repeat treatment with onabotulinumtoxinA.
Overview

- 36 Podiums, 14 Videos, 179 Posters
- 5 PG Courses, 1 IC Course
- 11 Plenaries
  - Shock Wave Lithotripsy Should Be Retired (Crossfire)
  - Difficult Stone Cases (Second Opinion)
  - Percutaneous Nephrolithotomy (3 Live Surgeries, 1 Panel Discussion)
  - Ureteroscopy for Stones: To Dust or To Basket (Critical Discussion)
  - Pathophysiology & Management of Uric Acid Stones (State-of-the-Art)
  - Ultrasound Propulsion of Stones (State-of-the-Art Lecture)
  - Robot-Assisted Flexible Ureteroscopy (Award Winning Video)
  - Endourology and Stone Disease (Take Home Messages)
Countries Represented

USA  Brazil  New Zealand
Japan France  Germany
Canada  Spain  Venezuela
Turkey  Switzerland  Algeria
Egypt Italy  Portugal
Korea  Singapore  Netherlands
UK  UAE  Greece
Israel  Taiwan  Austria
China  India  Kuwait
PD13-01: Dusting vs Basketing During Ureteroscopic Lithotripsy  What is more efficacious? Interim analysis from a multi-center prospective trial

Prospective trial → 72 pts/arm (still recruiting)
Renal stones ≤ 2 cm → Experts in field, stented

Primary outcome → SFR (KUB/RUS) @ 4-6 weeks

**Dusting (n=52)**
- Stone area: 109.9(337.6) mm²
- Sheath 24.0%
- Op time: 38.3(14.9) min
- Laser energy: 38.6(209.9) kJ
- Residual fragments: 30.8%
  - > 4mm: 25.0%
  - < 2mm: 56.2%

**Basketing (n=68)**
- Stone area: 62.0(79.8) mm²
- Sheath: 100%
- Op time: 58.2(33.1) min
- Laser energy: 7.3(29.5) kJ
- Residual fragments: 8.8%
  - > 4 mm: 0
  - < 2 mm: 66.7%
**MP75-15: The Consequences of Delaying Stone Treatment**

County hospital billing data 2011–2013: 795 stone procedures

Presentation time to treatment → patient morbidity and cost (i.e. – 199 temporary drainage; 714 unplanned encounters)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>≤ 45 days (n=262)</th>
<th>&gt;45 days (n=533)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admissions</td>
<td>1.0 (0.96-1.1)</td>
<td>1.3 (1.2-1.5)</td>
<td>0.10</td>
</tr>
<tr>
<td>Mean length of antibiotics course, days</td>
<td>7.8 (6.2-9.4)</td>
<td>10.7 (9.3-11.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Clinic visits</td>
<td>1.0 (1.0-1.0)</td>
<td>1.5 (1.3-1.6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ER visits</td>
<td>1.2 (1.1-1.4)</td>
<td>1.9 (1.7-2.1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Imaging studies</td>
<td>1.1 (1.0-1.3)</td>
<td>1.6 (1.5-1.8)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Tube changes</td>
<td>1.0 (1.0-1.0)</td>
<td>1.4 (1.2-1.6)</td>
<td>0.004</td>
</tr>
<tr>
<td>Clavien grade ≥ 3a+</td>
<td>7 (2.7%)</td>
<td>18 (3.4%)</td>
<td>0.67</td>
</tr>
</tbody>
</table>
MP75-15: The Consequences of Delaying Stone Treatment

County hospital billing data 2011–2013: 795 stone procedures
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MP75-15: The Consequences of Delaying Stone Treatment

County hospital billing data 2011–2013: 795 stone procedures
Presentation time to treatment → patient morbidity and cost (i.e. – 199 temporary drainage; 714 unplanned encounters)

Multivariate adjusted analysis of time to treatment (ref. < 45 days)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>OR</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic courses (no.)</td>
<td>3.4</td>
<td>2.2-5.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Clinic visits (no.)</td>
<td>15.2</td>
<td>8.4-30.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ER visits (no.)</td>
<td>3.6</td>
<td>2.6-5.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Imaging studies (no.)</td>
<td>5.7</td>
<td>3.9-8.4</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Adjusted for age, gender, ASA, DM, BMI, stone size & location, recurrent stone former status, eGFR by MDRD, need for temporizing drainage at presentation, and infection at presentation.
Digital force gauge → perforation forces ex vivo before/after cleaving in a URS and pig ureter

Control, Ceramic Scissors, Scribe Pen, Scalpel, Diamond wheel (X)

Highest force (harder to perforate) and least tip damage
Urothelial cancers

- Detection/Screening/Pathology
- NMIBC (non muscle invasive bladder cancer)
- MIBC (muscle invasive bladder cancer)
- Upper tract urothelial cancer (UTUC)
- Basic science and translational research
NMIBC

- Nabbout et al reported that most patients with CIS of the bladder are not receiving BCG based on SEER database study (PD17-04)
  - A SEER-Medicare database study of 3782 patients
  - Only 10% of patients received BCG and 85% received no adjuvant treatment
  - BCG group had superior overall survival and delayed time to cystectomy
  - Despite being the standard of care, the delivery of intravesical BCG for CIS remains extremely low.
MIBC

- Robotic cystectomy series are maturing
  - Safe in elderly population (MP67-17, Winters et al.)
  - 437 patients from 2003-2014 by Wilson et al. (MP 67-18)

- Nguyen et al. presented a series of 383 patients (120 open RC, and 263 RARC)
  - Recurrence free survival similar for two groups
  - RARC with increased distant recurrences - extra pelvic lymph node recurrence and peritoneal carcinomatosis (MP65-3)
Abstract: MP60-18

Introduction and Objectives
To introduce the PCP-SMART study (Prostate Cancer Predictive Simulation Modeling, Assessing Risk, Technique) and its derivative PCRD Index (Prostate Cancer Risk Determinator), aiming to predict the probability of prostate cancer (PCA) in patients undergoing prostate biopsy.

Methods
PCP-SMART was applied to 371 men undergoing prostate biopsy. Model development was based on the facts: tPSA correlates to age and prostate volume, f/PSA is established predictor of PCA, tPSA > 50 ng/ml has 98.5% PPV for PCA diagnosis. We hypothesized that the correlation of two variables, each consisting of three ratios such as: PSA/age – PSA/prostate volume[PSAD] – Free/total PSA, with one including patient’s tPSA value and the other tPSA value 50ng/ml, could operate as a “PCA conditions imitating - simulating model”. Linear regression of these variables derived the coefficient of determination $R^2$ (signed + or - (equation slope)) considered potent estimator of the probability of biopsy outcome and was termed PCRD index. Statistics to quantify model’s predictive ability were performed using SPSS-22 including chi-square test, logistic regression analysis with equation formation for predicting probability of positive biopsy, calculation of sensitivity, specificity, PPV, NPV, likelihood ratio, accuracy and AUC-ROC curve analysis, $p<0.05$ statistically significant.

Results
Histologic examination was PCA(+) in 167 (45.1%) patients, negative in 164 (44.2%) while, in 40 (10.7%) it showed HGPIN/A5AP. PCRD index(+) was found in 89.82% PCA(+) and 10.18% PCA(-) cases while it was negative in 91.46% PCA(-) and 9.54% PCA(+) patients (chi-square $p<0.001$-RR.8,98). Sensitivity was 89.8%, specificity 91.5%, PPV 91.5%, NPV 89.8%, LR(+) 10.5, LR(-) 0.11 and accuracy 90.6%. Multiple logistic regression demonstrated PCRD index ($p<0.001$) and prostate volume ($p=0.039$) to be significant predictors of PCA diagnosis while, the logistic regression equation formed, predicted with 91% accuracy the probability of PCA(+) biopsy outcome. ROC curve analysis showed PCRD index AUC [0.926] was significantly greater ($p<0.001$) vs PSAD, prostate volume, f/PSA, fPSA, age, tPSA.

Conclusions
PCRD index predicted with high accuracy biopsy outcome, identifying correctly 9 in 10 patients with prostate cancer as well as, 9 in 10 without PCA. Its predictive power was significantly higher compared to established PCA predictors while, the logistic regression equation, calculated accurately the probability of PCA positive prostate biopsy outcome.