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Disclosures

- Consultant - AMS Men’s Health/Boston Scientific
  - Male Incontinence: Male Sling and AUS
- Employee (spouse): AMS Men’s Health/ Boston Scientific
Artificial Urinary Sphincter: Executive Summary of the 2015 Consensus Conference

X. Biardeau, S. Aharony, the AUS Consensus Group, L. Campeau, and J. Corcos
Department of Urology, Jewish General Hospital, McGill University, Montreal, Quebec, Canada

X Biardeau, S Aharony, KW Angermeier, TB Boone, WO Brant, E Chartier-Kastler, M Drake, DS Elliott, WJ Hellstrom, S Herschorn, KA McCammon, AF Morey, A Mourtzinos, VW Nitti, AC Peterson, JS Sandhu, OL Westney, FA Yafe, L Campeau and J Corcos
AUS Consensus Group Conference

• Initial thoughts, variations in technique and management of complications
• Multiple issues associated with AMS800™ implantation

NEED FOR A CONSENSUS!!!
AUS Consensus Group Conference

- Chicago, July 2015
- 19/25 experienced urologists-implanters
- Program construction and approval
- Approval by International Continence Society (ICS)
AUS Consensus Group Conference

**8-chapter structure:**

- Preoperative assessment
- Preoperative challenges
- Implantation technique
- Post-operative care
- Outcomes evaluation
- Trouble shooting
- Special populations
- Future of AUS
Excerpt of Topic Assignments

- Patient selection and evaluation: who is candidate for an AMS 800, who is not? LYSANNE CAMPEAU
- Teaching the patient LENAINE WESTNEY
- Pre op UTI, pre op antibiotics-(should all have a negative culture or is UA adequate) SANDHU JASPREET
- Radiation: does it change anything to the approach, to the consent? (next talk)
  - ALLEN MOREY
    - Done before implant
    - To be done at the same moment of AUS implant: which strategy?
    - Does radiation affect the already placed AUS
- Detrusor overactivity: pre op management? Impact on results? KURT McCAMMON
- Post-operative antibiotics, activation timing and Follow-up LENAINE WESTNEY
Preoperative assessment

• **Who?**
  - Stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD)
  - After conservative management failure

• **When?**
  - No earlier than 6 months after prostatectomy
  - Sufficient dexterity and cognitive function to operate the device.
Preoperative Assessment (cont)

- **Examination and information**
  - Careful history and physical examination
  - Pre-operative endoscopic evaluation

  Pre-operative endoscopic evaluation of the LUT is highly recommended prior to AUS placement as unrecognized urethral pathology can complicate surgical implantation and possibly affect expectations of long-term outcomes. *(Grade of recommendation D)*

  +/- UDS

  UDS should be carried out at the discretion of clinicians in cases where it will help with diagnosis or counseling and follow-up. Poor bladder compliance may pose a risk of upper tract damage after AUS placement and should be followed closely. *(Grade of recommendation C)*
Detrusor Overactivity

- Pre-op management?
- Impact on results?
A Prospective Study Evaluating the Efficacy of the Artificial Sphincter AMS 800 for the Treatment of Postradical Prostatectomy Urinary Incontinence and the Correlation Between Preoperative Urodynamic and Surgical Outcomes

- DH defined as involuntary detrusor contraction
- Reduced bladder compliance < 20ml/cm H20
  - 20% (8 Pts) low compliance
  - Low bladder capacity 4 patients 2 DH and 2 RBC
  - 25% (10 pts) DH
- Presence of DH not associated with worse continence (p>0.99)
- Reduced compliance
  - 2 remained incontinent
  - “although our data do not correlate a reduced bladder compliance with a worse continence prognosis (p=0.213)”

Urodynamic Testing in Evaluation of Postradical Prostatectomy Incontinence Before Artificial Urinary Sphincter Implantation

H. Henry Lai, Elias I. Hsu, and Timothy B. Boone

<table>
<thead>
<tr>
<th>Adverse urodynamic features (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence of DO</td>
<td>15.8</td>
</tr>
<tr>
<td>Volume of first sensation ≤75 mL</td>
<td>22</td>
</tr>
<tr>
<td>Volume of first urge ≤125 mL</td>
<td>14.8</td>
</tr>
<tr>
<td>Cystometric capacity ≤200 mL</td>
<td>9.6</td>
</tr>
<tr>
<td>ALPP ≤30 cm H₂O</td>
<td>21.1</td>
</tr>
<tr>
<td>Detrusor compliance ≤10 cm/mL</td>
<td>17.5</td>
</tr>
<tr>
<td>Qmax ≤10 mL/s</td>
<td>36.5</td>
</tr>
<tr>
<td>PdetQmax ≤10 cm H₂O</td>
<td>10.5</td>
</tr>
<tr>
<td>BCI ≤100</td>
<td>64.8</td>
</tr>
<tr>
<td>Postvoid residual urine volume</td>
<td></td>
</tr>
<tr>
<td>≥250 mL</td>
<td></td>
</tr>
<tr>
<td>≥3 adverse urodynamic features in same patient (%)</td>
<td>21.7</td>
</tr>
</tbody>
</table>
Adverse pre operative UDS features

- Did not negatively affect post AUS PPD usage
  - Presence of DO
  - Early sensation of bladder filling < 75ml
  - Early desire to void < 125ml
  - Reduced capacity < 200 ml
  - Poor bladder compliance < 10ml/cm
- Pts with poor compliance used more pads post op compared to normal compliance (p=.23)
- 37 patients with DO and/or poor bladder compliance
  - 13 using anticholinergics prior to AUS
  - 14 using anticholinergics after

• 23% pts developed de novo OAB
• 71% persistent OAB

Table 2. OAB and anticholinergic use before and after AUS surgery

<table>
<thead>
<tr>
<th></th>
<th>No. Yes After AUS</th>
<th>No. No After AUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>OAB:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes before AUS</td>
<td>24 (persistent OAB 71%)</td>
<td>10 (OAB resolved 29%)</td>
</tr>
<tr>
<td>No before AUS</td>
<td>22 (de novo OAB 23%)</td>
<td>73</td>
</tr>
<tr>
<td>Anticholinergic use:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes before AUS</td>
<td>20 (persistent use 69%)</td>
<td>9 (stopped using 31%)</td>
</tr>
<tr>
<td>No before AUS</td>
<td>19 (de novo use 19%)</td>
<td>81</td>
</tr>
</tbody>
</table>
Implantation of Artificial Urinary Sphincter in Patients With Post-Prostatectomy Incontinence, and Preoperative Overactive Bladder and Mixed Symptoms

H. Henry Lai* and Timothy B. Boone†

- Pts with pre op OAB continence similar to those with no OAB
- Post op OAB did negatively impact overall continence
DO Recommendations

- Treat OAB preoperatively
- Do not deny AUS to those with SUI and OAB
- Close observation for patients with decreased capacity or compliance <10ml/cm

Detrusor overactivity. Detrusor overactivity should be treated before surgery, but does not constitute a contraindication for AUS implantation. (Grade of recommendation D)
Implantation Technique (Skin Preparation)

- Lithotomy or supine position
- Razors or clippers

Surgeons should be permitted their choice of razors or clippers for pre-operative preparation of the male genitalia. (Grade of recommendation A)

- 5-minute pre-operative topical antimicrobial scrub
- Chlorexidine-alcohol skin preparation

Chlorexidine-alcohol skin preparation is superior to povidone-iodine. (Grade of recommendation A)
Implantation Technique (Infection Control)

- Pre-operative prophylactic antibiotics within 60 minutes of the incision
- Ensure urine low bacterial counts
- Inhibizone coated components

The results with InhibiZone® antibiotic coating are not better than those without coating, and device costs are higher. (Grade of recommendation B)
Best Practice Policy Statement on

UROLOGIC SURGERY ANTIMICROBIAL PROPHYLAXIS

- 2008, updated 2014

PANEL MEMBERS:
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Carol J. Bennett, M.D.
Roger R. Dmochowski, M.D.
Brent K. Hollenbeck, M.D., M.S.
Margaret S. Pearle, M.D., Ph.D.
Anthony J. Schaeffer, M.D.

AUA STAFF:
Heddy Hubbard, Ph.D.
Edith M. Budd
Michael Folmer
Katherine Moore
Kadiatu Kebe

Courtesy of Jaspreet Sandhu, MD
### TABLE 5.

**Prophylaxis for Upper Tract Instrumentation**

<table>
<thead>
<tr>
<th>Procedure (organisms)¹</th>
<th>Prophylaxis Indicated</th>
<th>Antimicrobial(s) of Choice²</th>
<th>Alternative Antimicrobial (s)²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal surgery (GU tract, skin and Group B Strep.)</td>
<td>All patients</td>
<td>1st/2nd gen. Cephalosporin Aminoglycoside + Metronidazole or Clindamycin</td>
<td>Ampicillin/Sulbactam Fluoroquinolone</td>
</tr>
<tr>
<td>Involving entry into the urinary tract (GU tract and skin)</td>
<td>All patients</td>
<td>1st/2nd gen. Cephalosporin Aminoglycoside + Metronidazole or Clindamycin</td>
<td>Ampicillin/Sulbactam Fluoroquinolone</td>
</tr>
<tr>
<td>Without entering urinary tract (skin)</td>
<td>Patients with risk factors³</td>
<td>1st gen. Cephalosporin (single dose)</td>
<td>Clindamycin (single dose)</td>
</tr>
<tr>
<td>Involving intestine⁴ (GU tract, skin, and intestine)</td>
<td>All patients</td>
<td>2nd/3rd gen. Cephalosporin, Aminoglycoside + Metronidazole or Clindamycin</td>
<td>Ampicillin/Sulbactam Ticarcillin/Clavulanate Piperillin/Tazobactam Fluoroquinolone</td>
</tr>
<tr>
<td>Involving implanted prosthesis (GU tract and skin)</td>
<td>All patients</td>
<td>Aminoglycoside + 1st/2nd gen. Cephalosporin or Vancomycin</td>
<td>Ampicillin/Sulbactam Ticarcillin/Clavulanate Piperillin/Tazobactam</td>
</tr>
</tbody>
</table>

Key: gen., generation; GU, genitourinary.

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Courtesy of Jaspreet Sandhu, MD
# Classification of wound

### Table 2: Surgical wound classification

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean</td>
<td>Uninfected operative site, with primary skin closure.</td>
</tr>
<tr>
<td>Clean-contaminated</td>
<td>Entry into respiratory, alimentary, genital, or urinary tracts.</td>
</tr>
<tr>
<td>Contaminated</td>
<td>Fresh accidental wounds, major break in sterile technique, gross spillage from gastrointestinal tract, or presence of acute but nonpurulent inflammation at the operative site.</td>
</tr>
<tr>
<td>Dirty-infected</td>
<td>Old accidental wound with devitalized tissue or presence of clinical infection or perforated viscera at the operative site. This definition implies that organisms that might cause postoperative infection were present at the operative site before surgery.</td>
</tr>
</tbody>
</table>

*Courtesy of Jaspreet Sandhu, MD*
Preoperative U/A versus Urine Culture

• Very little evidence to go on

• Some evidence in the female and orthopedic literature that U/A (using nitrites or leukocyte esterase positivity) very specific

• Sometimes, difficult to eradicate UTI – eg NGB

Courtesy of Jaspreet Sandhu, MD
Summary

• Eradicate UTI (remote infection associated with 3-5X higher rate of SSI)

• Consider not performing a cystoscopy at the time of AUS placement (clean-contaminated has 2-3 X higher rate of SSI)

• All patients need appropriate pre-op antibiotics

• Duration after procedure unclear

Courtesy of Jaspreet Sandhu, MD
Implantation technique

- Perineal approach (vs trans-scrotal)
- Sterile saline or contrast filling solution
- Isotonic
- 61-70 cmH2O pressure regulating balloon
- 94% of implanted PRB's
- Filling volume = 22-27 cc
Implantation Technique

- Urethral injury should systematically be ruled out
- Proper functioning by device cycling

*Intra-operative assessment of efficacy. Urethral injury should be ruled out and proper functioning should be confirmed by device cycling. (Grade of recommendation D)*
Post-operative care

• A 14 French urethral catheter should be left in place
  • Removed after a brief period (overnight)

• Oral analgesia
• Stool softener
• No evidence the administration of post-operative antibiotics

• AUS should be activated at 4 to 6 weeks post-implantation
Post-operative Prescriptions

- **POSTOPERATIVE PRESCRIPTIONS SHOULD CONSIST OF ORAL ANALGESIA AND STOOL SOFTENER (IF INDICATED BASED ON PATIENT HISTORY)**

- **Considerations:**
  - Consistency with AUA Best Practice Guidelines
  - Inconsistency in reported current protocols in AUS literature: 11/87 surgical series (1985-present)
“The implantation of foreign material raises the specter of disastrous infectious complication. Although there are no RCTs regarding antimicrobial prophylaxis for insertion of penile prostheses…

A prolonged course of antimicrobials has been used by many practitioners following penile prosthesis insertion, but evidence from the orthopedic literature suggests that prophylaxis for 24 hours or less is adequate.¹

  - 7 days, Cephalexin or Ciprofloxacin

Trigo Rocha F, Gomes CM, Mitre AI, Arap S, Srougi M. A prospective study evaluating the efficacy of the artificial sphincter AMS 800 for the treatment of postradical prostatectomy urinary incontinence and the correlation between preoperative urodynamic and surgical outcomes. Urology 2008;71:85–9
  - 14 days, Ciprofloxacin

  - 7 days, Cephalexin or Bactrim

  - 1 week, agent unspecified
Post-operative care

• Limit physical activity
• Avoid perineal pressure
• Wear a *MedicAlert* type of bracelet

• Physical long-term follow-up:
  • 3 and 6 months
  • Yearly thereafter

• Evaluation of symptoms consistent with:
  • Device malfunction
  • Infection
  • Erosion
Pre-activation Visits

- PRE-ACTIVATION VISITS SHOULD BE SCHEDULED AT THE DISCRETION OF THE SURGEON FOR THE PURPOSE OF EVALUATION OF THE INCISION OR ANY PATIENT CONCERNS
Pre-Activation Literature

- Very few references explicitly mention a pre-activation visit
  - Long-term follow-up: Different protocols over time
  - Multi-institutional variability
  - Technically focused manuscript: not germane

  - 2 week visit

  - 2 week visit
A VIRGIN ARTIFICIAL URINARY SPHINCTER SHOULD BE ACTIVATED AT FOUR TO SIX WEEKS POST-IMPLANTATION. ACTIVATION TIMES AFTER DEVICE REVISIONS AND INDIVIDUAL COMPONENT REPLACEMENT MAY BE ADJUSTED BASED ON THE CLINICAL SITUATION AND PATIENT COMFORT.
Activation Data – Overall

- Mean time of activation (weeks): 5.6 weeks, median: 6
### General Reactivation Protocol by Institution based on the literature

- Baylor (Boone): 4 weeks
- Mayo Clinic - Minnesota (Elliott): 6 weeks
  - Mayo (Jacksonville) (Petrou): 4 weeks
- Baylor/Mayo paper: 4-6 weeks
- U Mich: 6 weeks
- University of Chicago (Bales): 4-6 weeks
- Pitié-Salpétrieire Academic Hospital (Chartier-Kastler): 6 weeks
- MDACC (Westney): 6 weeks (virgin case)
Activation References

Adjusted Reactivation Time

• Klijn (Erasmus University) (1998)
  • “The sphincter was left deactivated for 3 days to 3 weeks, depending on the presence or absence of post-operative scrotal oedema or haematoma.”
  • Extrapolation to different types of cases:
    – Virgin
    – Removal/Replacement +/- Downsizing (without new dissection
    – Single Component replacement
      • Reservoir exchange


- Immediate Reactivation in cases of reservoir exchange only
Activation Visit

- **TEACHING:** THE PATIENT MUST DEMONSTRATE THE ABILITY TO PROPERLY CYCLE THE ARTIFICIAL URINARY SPHINCTER AND UNDERSTANDING OF THE DEACTIVATION PROCESS DURING THE ACTIVATION VISIT
Long-Term Follow-up

• PHYSICAL LONG-TERM FOLLOW-UP SHOULD BE PERFORMED AT 3 MONTHS, 6 MONTHS AND 1 YEAR POST-IMPLANTATION. SUBSEQUENTLY, YEARLY FOLLOW-UP MAY BE CONDUCTED IN-PERSON OR BY QUESTIONNAIRE WITH MANDATORY EVALUATION FOR SYMPTOMS SUSPICIOUS FOR DEVICE MALFUNCTION, INFECTION AND/OR EROSION
  – Hematuria, Decreasing Force of Stream, Abrupt Sustained Severe Incontinence
Follow-up Data Literature

- Variable reporting
  - 17/80+ mentioned follow-up strategy
    - Technique-focused
    - Short-term follow-up
- Most commonly reported follow-up periods:
  - 3 months and 1 year
  - 6 months
Follow-up Literature (cont)

• Patient/Complication Directed
  – “Following this, patients are followed via office evaluation on an as needed basis, as determined by their continence or other device concerns”
  – Teriitary Referral Reality
  – Possible Outside Intervening Visits
Outcomes evaluation

- The number of patients with no pad, occasional or regular pad

- Pads/shields/diapers type used

- Validated quality of life measurement

- Device survival
### Persistent/Recurrent Leakage

#### TABLE I. Management of Persistent Incontinence or Partially Functioning AUS

<table>
<thead>
<tr>
<th>Potential findings</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>History and examination</td>
<td>Urgency urinary incontinence</td>
</tr>
<tr>
<td></td>
<td>Sensation of incomplete emptying</td>
</tr>
<tr>
<td></td>
<td>Sensation without leakage</td>
</tr>
<tr>
<td></td>
<td>Post-micturition dribble</td>
</tr>
<tr>
<td></td>
<td>Distended bladder</td>
</tr>
<tr>
<td></td>
<td>Malfunction of pump chamber</td>
</tr>
<tr>
<td></td>
<td>Malfunction of inactivation button</td>
</tr>
<tr>
<td></td>
<td>Lack of confidence</td>
</tr>
<tr>
<td></td>
<td>Physically or mentally unable to use AUS</td>
</tr>
<tr>
<td>Flow rate and bladder scan</td>
<td>Review urodynamics done prior to AUS</td>
</tr>
<tr>
<td></td>
<td>Abnormal pattern of flow</td>
</tr>
<tr>
<td></td>
<td>Post void residual</td>
</tr>
<tr>
<td>Pelvic ultrasound</td>
<td>Empty reservoir</td>
</tr>
<tr>
<td>Abdomino-perineal X-ray*</td>
<td>Empty or under-filled reservoir, cuff or pump</td>
</tr>
<tr>
<td></td>
<td>Air bubbles</td>
</tr>
<tr>
<td>Cysto-urethroscopy</td>
<td>Cuff erosion</td>
</tr>
<tr>
<td>Urodynamics</td>
<td>Abnormal urethral pressure profile, storage or voiding</td>
</tr>
<tr>
<td>Further findings in surgery</td>
<td>Cuff tab not engaged</td>
</tr>
<tr>
<td></td>
<td>Urethral atrophy</td>
</tr>
</tbody>
</table>

ISC, intermittent self-catheterization.

*For contrast-filled AUS.
Infection/Erosion

- AUS infection

  Infection, device removal and delayed re-implantation are preferred over immediate salvage re-implantation. (Grade of recommendation D)

- Urethral cuff exposure / erosion
Definitive diagnosis of mechanical AUS failure is demonstrated by decreased fluid in the system, either by intra-operative aspiration or pre-operative radiologic evidence of diminished fluid in the PRB. *(Grade of recommendation D)*

Whole system replacement is generally preferred at the time of AUS replacement of a malfunctioning device. *(Grade of recommendation D)*
Special populations

• Inflated penile prosthesis placement

IPP placement after TC AUS cuff procedures should be considered a high risk. *Grade of recommendation D*

• AUS and urethral catheterization

In cases that require prolonged drainage (>48 hr), a suprapubic tube should be considered, with imaging guidance. *Grade of recommendation D*
Future of AUS

• The “ideal” AUS should:

  • Be easily manipulated and inactivated
  • Modify cuff pressure after implantation
  • Be able to adapt occlusive cuff pressure in a real-time manner
  • Have a simple and robust design
  • Be safely implanted via a minimally-invasive procedure
  • Be as cost effective as possible
That’s all folks

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