ARTIFICIAL URINARY SPHINCTER VS. MALE URETHRAL SLING FOR MILD-MODERATE POST-PROSTATECTOMY URINARY INCONTINENCE: A COST EFFECTIVENESS ANALYSIS
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(Presentation to be made by: Dr. Bogdana Schmidt)

Introduction/Objective: Stress urinary incontinence (SUI) following radical prostatectomy for prostate cancer is a well-established but treatable consequence of surgery. We performed a cost-effectiveness analysis of AMS Artificial Urinary Sphincter (AUS) and Advance male urethral sling (MUS) for the treatment of mild-moderate post-prostatectomy SUI.

Methods: A decision model was created to simulate treatment of SUI with AUS or MUS. Cost data was obtained from the Medicare Resource-Based Relative Value Scale. Success and complication rates of AUS and MUS and utility rates of continence and incontinence were obtained from peer-reviewed literature and expert opinion. We excluded patients with prior pelvic radiation or prostate procedures. A discount rate of 3% per year was applied to utilities and a time horizon of 20 year was used. The incremental cost effectiveness ratio (ICER) was calculated and compared using $50,000 as a cutoff for cost-effectiveness. Sensitivity analyses were performed varying continence outcome, utility and cost for both procedures.

Results: The Cost/QALY gained was $19,063 for MUS and $11,378 for AUS with an ICER of $295,622 favoring MUS. Sensitivity analysis showed that MUS remained more cost effective than AUS when continent outcomes of MUS are >0.44 and when the utility of continence is <0.94. When the utility of continence decreases <=0.91 there are no instances where AUS is cost effective. Our model remained insensitive to the utility of incontinence and cost of MUS and AUS.

Conclusion: MUS is more cost effective than AUS in men with mild-moderate post-prostatectomy SUI. Our model is relatively sensitive to primary continent outcome of MUS and utility of continence. Limitations inherent to cost-effectiveness analysis and heterogeneity of outcomes reported in the literature are acknowledged.
DEMOGRAPHICS AND PREDICTORS FOR LONG-TERM CONVERSION TO NORMAL VOIDING IN SPINAL CORD INJURY PATIENTS

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(Presentation to be made by Dr. Dimitar Zlatev)

Introduction: The majority of patients with spinal cord injury (SCI) have bladder dysfunction associated with their injury and are initially unable to volitionally void. Nonetheless approximately 10-15% of these patients convert to normal voiding on long-term followup. We sought to characterize the demographics of this subgroup of patients and assess for predictors of long-term conversion to normal voiding in SCI patients.

Methods: We assessed Form I and II data from the 2000-2013 National Spinal Cord Injury Database. Bladder management was determined at initial discharge from rehabilitation and at 1-year followup. Upper extremity (UE) motor scores were transformed using a previously published algorithm to predict a patient's ability to independently self-catheterize. Logistic regression modeling was performed to assess risk factors affecting the conversion from non-volitional voiding at initial discharge from rehabilitation to normal voiding at 1-year followup.

Results: Of the 5,112 patients evaluated who could not volitionally void at initial discharge, 14% converted to normal voiding at 1-year followup. Demographic characteristics were similar between all patients and the subgroup of patients who converted to normal voiding at 1-year followup. Patients were more likely to convert to normal voiding if they had a lower overall SCI level or if they had milder impairment in UE motor function (p ≤ 0.001 for both). Significant predictors of long-term conversion to normal voiding included increasing age (OR 1.01 - 1.02, p ≤ 0.001), married marital status (OR 1.6, p ≤ 0.001), thoracic or lumbar level of neurological deficit (OR 1.7 - 1.9, p ≤ 0.001), neurologic scale of SCI impairment (OR 21 - 69, p ≤ 0.001), and UE motor function sufficient for possible self-catheterization (OR 1.4, p ≤ 0.001).

Conclusions: The most powerful predictors for long-term conversion to normal voiding in SCI patients include neurologic scale of impairment, lower level of neurological deficit, and UE motor function. Additional significant predictors include married marital status and increasing age.

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FACTORS AFFECTING CONTINENCE AFTER RADICAL CYSTECTOMY AND ORTHOTOPIC NEOBLADDER

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(Presentation to be made by Thomas G. Clifford)

Introduction: Orthotopic neobladder (ONB) is the gold standard form of urinary diversion following radical cystectomy (RC) at our institution. However, counseling patients on postoperative continence rates is a challenge as the literature is outdated. Herein we evaluate factors affecting continence in patients after RC and orthotopic diversion using a validated pad usage questionnaire.

Materials and Methods: Using our IRB approved database, we identified 1786 patients that underwent open RC from 2001 to 2015. ONB was constructed in 1128 (63.2%) patients, of whom 954 were male (84.6%). Starting in 2012, these patients were prospectively followed and asked to complete a validated, pictorial questionnaire at their follow up visits to assess the number, size, and wetness of pads used at day and night. Mucus leakage and catheterization frequency were also assessed. Patients were defined as continent if they reported no pad usage or pads as "almost dry." Questionnaires were stratified into distinct postoperative time intervals. Female patients and those with artificial urinary sphincters or a history of radiation were excluded. Multivariable logistic regression was performed.

Results: A total of 189 male patients with available pad usage questionnaires were followed from September 2012 to August 2015. A total of 447 pad usage questionnaires were collected, with 351 interval distinct when separated into intervals of <3 months, 3-6 months, 6-12 months, 12-18 months, 18-36 months, and more than 36 months (n=64, 61, 58, 49, 61, 58 respectively). Day and nighttime continence rates are shown in Figure 1. In multivariate analysis, age less than 65 was associated with greater likelihood of daytime (OR 2.77, CI 1.65-4.61, p<0.0001) and nighttime continence (OR 1.72, CI 1.13-2.63, p<0.01) while diabetes was associated with worse daytime continence (OR 0.49, CI 0.27-0.91, p<0.02). Overall catheterization rate was 13.1%.

Conclusions: Daytime continence after RC and ONB is excellent, although nighttime continence remains problematic. Older age and diabetes are associated with worse daytime continence after radical cystectomy and ONB. Of these factors, only age is significantly associated with worse nighttime continence.
OUTCOMES AND MORBIDITY OF RIGHT COLON POUCH URINARY DIVERSION: A SINGLE CENTER RETROSPECTIVE CASE SERIES

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Introduction: Right colon pouch is a primary option for urinary diversion. The procedure creates a large low-pressure urinary reservoir and has well-established excellent continence rates. We present a contemporary retrospective case series of right colon pouch outcomes from a single institution and hypothesize that it is a sustainable option for urinary diversion for a variety of clinical problems.

Methods: We identified patients that underwent creation of a right colon pouch for urinary diversion at the University of Utah from 1/2010-4/2016, excluding those undergoing revision of previously created right colon pouches. Information collected included: patient demographics, Charlson comorbidity index, past medical and surgical history, surgical indication, post-operative complications as measured by the Clavien-Dindo classification, and long-term surgical complications. Descriptive statistics were used for analysis.

Results: Fifty patients had creation of a right colon pouch. The mean age, BMI, and Charlson comorbidity index was 56 years old (SD± 13, range 32-81), 30 kg/m² (SD± 9, range 14-60), and 4 (SD± 2, range 0-9) respectively. The mean number of previous abdominal surgeries in our cohort was two (SD± 2, range 0-7) including 8 (16%) patients with prior urinary diversion or augmentation cystoplasty. Surgical indications varied and included patients with: neurogenic bladder (n= 14, 28%), urologic radiation injury (n=16, 32%), bladder cancer (n= 10, 20%), intractable interstitial cystitis (n= 5, 10%), and other indications (n=5, 10%). Twenty (40%) patients had an indwelling catheter prior to surgery for greater than 3 months (SD± 7, range 0-30). Mean pre-operative creatinine was 0.96 (SD± 0.84, range 0.3-5.87). During the operation, the mean estimated blood loss was 433mL (SD± 413, range 100-2300). Within the perioperative period (6 weeks), 11 (22%) patients had Clavien-Dindo complications of grade 3 or higher. These complications were 3a (n=4, 8%), 3b (n=6,12%), and 5 (n=1, 2%). Reoperations included incision and drainage of complex abscesses (n=3, 6%), repair of incarcerated abdominal hernia (n=1, 2%), repair of perforated pouch (n=1, 2%), and direct vision internal urethrotomy for difficult catheterization (n=1, 2%). Death in one patient was the result of urinary sepsis. Readmissions rate within 6 weeks was 40% (n=20). Sepsis (n=6, 12%) and wound abscesses (n=5, 10%), comprised the most frequent indications for readmission. Median follow up was 14 months (SD± 15, range 0-62) with 25 (50%) of patients requiring further operative management. These procedures included stomal revision (n=8, 16%), wound incision and drainage (n=6, 12%), pouch revision (n=6, 12%), deep catheter channel revision (n=5, 10%), ureteral stent placement (n=4, 8%), hernia repair (n=2, 4%), and unilateral nephrectomy (n=2, 4%). Median time between right colon pouch creation and initial surgical revision was 8 months (SD± 13, range 3-45). 86% of patients still utilized their pouch. 14% of patients were reliant on a SPT permanently (n=7) because of difficulty with catheterization, and refusal to catheterize in 2. An additional pouch was removed in the perioperative period for total necrosis. There were no associations between gender, age, BMI, Charlson comorbidity index, surgical history, surgical indication, or radiation history that resulted in a higher short, or long-term complications.

Conclusions: The creation of a right colon pouch provides a continent alternative when undergoing urinary diversion. Our study suggests there is high morbidity associated with this procedure regardless of the etiology or comorbidities. Despite the high morbidity, 86% of patients utilize their pouch as intended. Patients considering this procedure need to be aware of the risks in the perioperative period and long-term.

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PERIPHERAL NERVE EVALUATION CONVERSION RATES WITH AND WITHOUT THE USE OF FLUOROSCOPY

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Presentation to be made by Dr. Steve Rivera

Objectives: Peripheral nerve evaluation (PNE) is a minimally invasive procedure, performed in the clinic under local anesthesia, to determine eligibility for permanent InterStim implantation in patients experiencing significant urinary urgency, frequency, urge incontinence, or non-obstructive urinary retention. We sought to determine whether a difference in conversion rates to full implantation is seen between patients undergoing PNE with and without the use of fluoroscopy.

Methods: A retrospective review was performed in two consecutive series of patients undergoing PNE with and without fluoroscopy use. Temporary leads were placed along the S3 nerves bilaterally, in the routine manner. Physical landmarks were used to determine the location of needle insertion. When used, fluoroscopy confirmed temporary lead location in the S3 foramina bilaterally. After lead placement for all patients, both verbal feedback (vibration or pulling sensation in the scrotum, vagina, or rectum) and motor responses (plantar flexion of the great toe and bellows contraction) confirmed stimulation of the S3 nerves. When inconclusive, a staged InterStim trial was performed. If the patient documented a 50% or greater reduction in symptoms, they proceeded with permanent device implantation. N-1 Two Proportion test compared significance between groups.

Results: 42 patients underwent PNE: 28 with and 14 without fluoroscopy use. There were no differences in patient age, BMI, or stress incontinence rates between the groups. No significant difference was noted between the 11/28 (39.3%) patients that underwent InterStim implantation with fluoroscopy use and the 5/14 (35.7%) patients that underwent implantation without fluoroscopy use (p = 0.41). Similarly, no difference was seen between groups when including patients undergoing staged InterStim trials: 14/28 (50%) implantations with fluoroscopy use versus 6/14 (42.9%) implantations without fluoroscopy use (p = 0.33).

Conclusions: Fluoroscopy may not be available in all settings and this limitation might hinder clinic peripheral nerve evaluations. Our preliminary data suggests that fluoroscopy use does not affect conversion rates to full InterStim implantation. While our fluoroless arm of patients expands to make the data more meaningful, we hope to continue seeing results that support the fluoroless technique which completely removes radiation exposure to patients and staff.
Objective: Current practice at our high-volume tertiary referral hospital aims to optimize lead placement at the superior medial aspect of the S3 foramen and achieving lead thresholds under 2mA for all electrodes sites. This analysis aims to summarize our intraoperative characteristics and evaluate the impact of demographic, clinical and intraoperative factors on progression to stage 2 SNM implant.

Methods: This is an observational study of all stage 1 lead placement SNM cases at our institution from August 2014-April 2016. After a 1-2 week trial period, patients received a stage 2 SNM pulse generator if their voiding diaries reflected ≥50% symptom improvement. Demographic, clinical and intraoperative factors were compared between those who progressed to stage 2, and those whose leads were removed. Statistical analysis was performed using Excel.

Results: A total of 101 stage 1 lead placements were performed, and 90% of subjects progressed to stage 2. 90% of subjects were female. Indications for implant were 94% refractory urgency, 9.9% idiopathic urinary retention, and 13.9% fecal incontinence. Female gender was associated with progression to stage 2 implant (p=0.023). History of failed 3rd line therapy was associated with non-progression to stage 2 (p=0.018). The impact of other factors on progression was not significant (see table 1). With mean 12.9 months follow up, 4.4% and 4.4% of SNM implants were subsequently revised or removed, respectively, including 1.1% for infection. 1.1% of patient in the progression group and 10% in the removal group subsequently had intravesical chemodenervation. The UDI6 scores for the progression group were significantly improved at 7 months (40.0 vs 60.8, p=0.001).

Conclusions: Using contemporary surgical techniques in which SNM lead placement is optimized, our institution’s lead thresholds, placement time, fluoroscopy time, and surgeon report of difficulty are low. However, these intraoperative factors, as well as most tested clinical and demographic variables, were not associated with progression to stage 2 SNM implantation in this preliminary analysis. Female gender and absence of history of prior failed 3rd line therapy were associated with progression to stage 2 in this population. Short term follow-up reveals significantly improved bother scores after stage 2 implantation, as well as low rates of subsequent chemodenervation, device revision, subsequent removal, or infection.

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SACRAL NEUROMODULATION IN CALIFORNIA FROM 2005 TO 2011: WHAT ARE THE REAL-WORLD SUCCESS RATES?

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(Presentation to be made by Dr. Amy Dobberfuhl)

Introduction: Sacral neuromodulation (SNS) is approved by the Food and Drug Administration as a third-line treatment for refractory overactive bladder, idiopathic urinary retention and fecal incontinence. Prior to implantation of a working device, all patients undergo a trial phase to ensure improvement in their symptoms. The success rates of staged SNS implantation of a pulse generator (moving from the test phase to permanent implant) vary greatly in the literature (ranging from 40 to 90%). We sought to characterize this using a statewide registry.

Methods: With prior approval we accessed non-public records from the California Office of Statewide Health Planning and Development (OSHPD) Ambulatory Surgery Database for the years 2005 to 2011. This dataset captures all non-federal ambulatory surgical visits within the state. Appropriate Current Procedural Terminology, 4th edition (CPT) procedure codes and International Classification of Disease, 9th edition (ICD-9) diagnosis codes were used to analyze all SNS procedures and their indication. Patients were followed longitudinally using unique patient record linkage numbers. Staged success was defined as the proportion of patients who received a stage-2 SNS generator implantation after their stage-1 SNS trial.

Results: We identified 4,098 patients with SNS procedure codes. After excluding patients who only underwent battery changes, lead revisions or lead explants, our final cohort included 2,765 patients. The majority of patients were female (77%), over 60 years of age (68%), Caucasian (74%) and had Medicare (60%). A total of 1,396 patients underwent a trial of staged implantation, of which 962 subsequently underwent SNS stage-2 generator placement (overall staged success rate of 69%). Staged success rates were 72% for overactive bladder wet, 69% for urgency frequency, 57% for urinary retention, 68% for interstitial cystitis and 67% for neurogenic bladder. Success rates were similar after stratification by race/ethnicity and insurance.

Conclusions: While the success rates for staged SNS implantation in the state of California were less than that observed in many single center academic series; they are better than previously reported for Medicare patients and suggestive of an acceptable level of real world success.

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META-ANALYSIS TO ASSESS THE TREATMENT EFFECT OF ONABOTULINUMTOXINA, MIRABEGRON AND ANTICHOLINERGICS VERSUS PLACEBO FOR OVERACTIVE BLADDER

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(Presentation to be made by Dr. David A. Ginsberg)

Objective: Pharmacotherapy is the second-line treatment for overactive bladder (OAB) after behavioral therapy, but there is a high discontinuation rate due to inadequate efficacy and/or intolerable side effects. OnabotulinumtoxinA provides an additional treatment option for OAB in patients who are inadequately managed by an anticholinergic. Our objective was to perform a comparison of the efficacy of all licensed doses of anticholinergics, mirabegron, and onabotulinumtoxinA versus placebo in adults with idiopathic overactive bladder using network meta-analysis (NMA) and meta-regression (NMR).

Methods: Electronic databases, review documents, guidelines, and websites were searched for randomized blinded trials of ≥2 weeks duration comparing any dose of onabotulinumtoxinA, mirabegron, or oral/transdermal anticholinergics with each other or placebo. Networks were developed for outcomes of interest based on studies of similar quality of study methods, confounding factors, common treatment arms, and outcomes measured. Bayesian random effects NMA (for the outcome of 100% reduction in urinary incontinence episodes [UIE]) and NMR (for outcomes on changes from baseline in UIE, urgency episodes, and micturition frequency) models were used to synthesize results at week 12. Safety outcomes were not compared due to differences in adverse event profiles.

Results: 102 trials were assessed. NMRs indicated that, after adjusting for differences in baseline severity between trials, all treatments were more efficacious than placebo. Patients who received onabotulinumtoxinA 100U had the greatest mean reductions in UIE (1.55 episodes/day more than placebo [95% credible interval (CrI): 1.10, 2.01]), urgency (2.01 episodes/day more than placebo [CrI: 1.48, 2.54]) and micturition frequency (1.37 episodes/day more than placebo [CrI: 1.03, 1.70]). OnabotulinumtoxinA patients also had the highest likelihood of achieving 100% UIE reduction (OR 4.30 versus placebo [CrI: 3.03, 6.23]).

Conclusion: This analysis suggests that onabotulinumtoxinA 100U provides the greatest reduction in OAB symptoms and higher likelihood of being dry, relative to placebo, than all licensed doses of anticholinergics and mirabegron in the network. Additional studies should also evaluate the cost-effectiveness of onabotulinumtoxinA versus other OAB treatments.

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PERINEAL PRESSURE CHANGES WITH VARYING OSCILLATION WHILE CYCLING

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Objectives: Up to 31% of endurance cyclists experience perineal and penile paresthesias and up to 21% experience short-term erectile dysfunction. The effect of constant seated perineal pressure on penile blood flow has been well-described, but the effect of road conditions on perineal pressure remains unclear. Our aim is to evaluate the changes in distribution of perineal pressure with increasing levels of oscillation of the bicycle to simulate what cyclists experience when riding in real world conditions.

Materials and Methods: We recruited healthy subjects between ages 18-50 without any known genitourinary disease or symptoms. We used a Tekscan pressure sensor system secured to a bicycle saddle to measure the pressure directly on the perineum while subjects cycled on a road bicycle placed on a stationary trainer. We assessed changes in perineal pressure from small, medium and large oscillations defined as drop from 1, 2, and 3cm, respectively. Measurements were taken with the cyclist in the seated position while riding with watts set at 100 for a total of 45 seconds. We repeated these measurements after the addition of a seat-post shock-absorber. We summed the total force applied to the perineum at baseline and during oscillation. We compared the changes in pressure following addition of the shock-absorber.

Results: Twenty-two volunteers were enrolled – 17 men and 5 women. The average BMI was 24 (range 18.9 -29.8). Small oscillations created a 28% increase in perineal pressure over baseline, while medium and large oscillations created a 37% and 42% increase, respectively. Computer generated heatmaps (Figure) comparing pressure before (A) and after (B) the use of a shock-absorber demonstrated that the shock-absorber decreased peak pressures around the ischial tuberosities and symphysis pubis. It additionally produced a 15% reduction in pressure change across the perineum.

Conclusion: There are notable increases in perineal pressure with oscillations while riding a bicycle. These pressure increases may cause microtrauma to the perineal nerve which could lead to paresthesias and nerve palsy that decrease penile blood flow. The addition of a shock-absorber may decrease the impact of these issues, particularly in areas most susceptible to peak-pressure.

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Figure
PATIENT FACTORS AND RESPONSE TO BLADDER HYDRODISTENTION

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(Presentation to be made by Kelli X. Gross, M.D.)

Introduction: Interstitial cystitis/bladder pain syndrome (IC/BPS) is a condition that can have severe impact on patients’ quality of life. Research of outcomes of treatments, including hydrodistention, for IC/BPS have reported varying response rates, leading to difficulty in standardizing the clinical utility of hydrodistention. We aim to better delineate the patient characteristics that are involved in the symptomatic response to bladder hydrodistention.

Methods: Between March 2008 and March 2016, 77 patients underwent bladder hydrodistention at our institution. A retrospective chart review was performed. All procedures were done in the operating room under anesthesia, with filling of the bladder at a water pressure of 60-80 cm H2O. Patients were assessed on improvement of their symptoms at routine follow up visits.

Results: Of 77 patients who underwent bladder hydrodistention, 62 (80.5%) were female and 15 (19.5%) were male. The mean age was 53.2 ±15.4 years. Of the 64 patients who had follow up after hydrodistention, 41 (53.2%) had improvement in symptoms and 23 (29.9%) did not. Ulceration was present on cystoscopy in 20 (26%) and was not present in 57 (74%). Of the 41 patients who responded to hydrodistention, 16 had ulcers and 25 did not, while in non-responders, 2 had ulcers and 21 did not (p<0.01). Patients who responded to hydrodistention had lower mean anesthetic bladder capacity during filling (496.0ml±235.4) versus non-responders (747.4ml±276.05) (p=0.22). There was no difference in responders and non-responders in the presence of involuntary detrusor contractions on urodynamic testing (p=0.80), in bladder capacity on urodynamic testing (p=0.41), or in likelihood of having tried, 2nd line, 3rd line, or 4th line treatments for IC/BPS prior to hydrodistention (p=0.64, 0.88, and 0.22 respectively).

Conclusions: Patients with lower anesthetic bladder capacity as well as patients who have ulceration on cystoscopy may be more likely to have relief of symptoms. Further investigation to characterize which patients are more likely to respond to bladder hydrodistention will help predict response and limit side effects from treatment of IC/BPS.

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