LISTENING TO MUSIC DURING FLEXIBLE CYSTOSCOPY DOES NOT DECREASE ANXIETY OR PAIN: A VETERANS AFFAIRS PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

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(Presentation to be made by Dr. Mirheydar)

Objective: There is emerging evidence that listening to music during rigid cystoscopy decreases patient anxiety and pain, however, no studies to date have evaluated the effect of music on these outcomes following flexible cystoscopy. Our objective was to determine if music decreases pain or anxiety in a Veterans Affairs population undergoing flexible cystoscopy.

Methods: Patients at the Veterans Affairs San Diego Medical Center were enrolled prospectively between August and November 2012, and randomized to receive classical music or no music during cystoscopy. Primary outcomes included post-procedural anxiety and pain scores quantified by State-Trait Anxiety Inventory and visual analog pain scale. Secondary outcomes of this study included pre and post procedure systolic and diastolic blood pressure, pulse, and respiratory rate. In addition, clinical and demographic variables including age, race, gender, history of cystoscopy, and hematuria were examined. Sub-analyses were performed for men versus women, and patients with history of cystoscopy versus no history. Prior to cystoscopy, the urethra was disinfected with povidone-iodine and anesthetized with 10 mL of 2% lidocaine jelly (dwell time 10 minutes).

Results: Eighty patients underwent flexible cystoscopy (no music group, n=46 and music group, n=34). Age, race, gender, and hematuria were statistically similar between the two groups. Post-procedure median pain scores (1 vs. 0, p=0.05) and mean systolic blood pressure (144 vs. 132, p=0.005) were higher in the music group. There were no differences in the post-procedure mean anxiety scores between the music and no music groups. In sub-analysis, the pre-procedure (36.9 vs. 22, p<0.001) and post-procedure mean anxiety levels (34.9 vs. 22, p<0.001) were significantly higher in men than women. Also, the pre-procedure anxiety level was significantly higher in patients undergoing first cystoscopy versus patients with history of cystoscopy (37.6 vs 30.3, p=0.014). Music did not decrease anxiety or pain in men versus women, or in patients undergoing first cystoscopy versus patients with history of cystoscopy.

Conclusions: This is the first prospective randomized study in the Veterans Affairs population demonstrating that listening to music during flexible cystoscopy does not decrease anxiety or pain. Men undergoing cystoscopy are more anxious than women. Patients with history of cystoscopy are less anxious. Further investigation is required to explain the observed differences in pre-procedural anxiety scores among our subgroups.

Source of Funding: None
CAUSE OF CANCER DEATH AMONG PATIENTS WITH NON-INVASIVE BLADDER CANCER
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(Presentation to be made by Joshua O. Ness)

Background/Objectives: With current treatment modalities, patients with non-invasive bladder cancer (NIBC) experience prolonged survival when compared to patients with invasive bladder cancer (IBC), despite frequent recurrences. Because bladder cancer is a smoking related disease, NIBC patients are at increased risk of smoking related morbidity, including secondary cancers. We sought to determine cancer cause of death among bladder cancer patients using the Oregon State Cancer Registry (OSCaR).

Methods: We utilized OSCaR to identify bladder cancer diagnoses between 1996 and 2012. The Oregon Center for Health Statistics provided cause of death information for patients that died of any cancer. Designation of IBC and NIBC was determined using stage and grade data from OSCaR, where stage T1, T2, T3 and T4 were defined as invasive while Ta and Tis were defined as noninvasive. Only patients with known stage, grade, and cause of death were included in analysis. For both groups, multiple logistic regression was performed to determine the odds of dying from bladder cancer compared to other cancers.

Results: 14,064 patients were diagnosed with bladder cancer, of which 13,121 met the inclusion criteria. The median time from diagnosis was 103.3 months, though this time for NIBC patients was significantly longer than for IBC patients (106.4 vs 100.8 months, p<0.01). In patients diagnosed with NIBC (N=7445), 2,741 (37%) died during the study interval. Of these deaths, 1009 (37%) were cancer related, with bladder (12% of deaths), lung (7%) and GI (6%) cancers being the most common. In patients diagnosed with IBC (N=5676), 3,537 (62%) died during the study interval. Of these deaths, 2160(61%) were cancer related, with bladder (46% of deaths), lung (4%) and GI (2%) cancers being the most common. For NIBC patients, after controlling for gender, the odds of death due to other cancers was 2.06 times greater than death due to bladder cancer (95%CI:1.78-2.38;p<.001). Among IBC patients, cause of death due to other cancers was lower than death due to bladder cancer, with an odds ratio of 0.39 (95%CI:0.35-0.44;p<.001).

Conclusions: Patients with NIBC are at higher risk of dying from other smoking related cancers than they are of bladder cancer. Smoking related cancers are a significant competing risk for cancer mortality among patients with NIBC. Survivorship programs focused on other smoking related cancers may be indicated in this population.

Source of Funding: None
Objective: To evaluate the role of pre-operative serum tumor markers to predict locally advanced UCB.

Materials and Methods: Between June 2004 and Oct 2012, serum samples of 280 patients with UCB who underwent curative radical cystectomy and did not receive neoadjuvant chemotherapy were used to measure pre-operative carbohydrate antigen (CA) 19-9, CA 125, and carcinoembryonic antigen (CEA) levels. Based on post-operative pathology, patients were divided into organ-confined (≤T2 stage) lymph-node-negative (OC LNN), and locally-advanced (≥T3 stage and/or positive nodal disease). Multivariable logistic regression model was used to identify independent predictors of locally-advanced UCB.

Results: A total of 217 patients (144 male) with mean age of 69 yrs (range, 36–95) were included. 100(46%) patients had pathologic locally-advanced UCB. Serum levels were abnormal in 12(5.5%) for CA19-9 (>35U/mL), 5(2%) for CA125 (>35U/mL), and 31(14%) for CEA (>3.8ng/mL). Abnormal CA19-9 level was significantly associated with locally-advanced UCB (HR=6.3, 95%CI: 1.3–29.8; P=0.01). However, abnormal CA125 and CEA were not associated with pathologic stage. In multivariate logistic regression model, serum CA 19-9 was an independent predictor of pathologic stage. (Table 1)

Conclusions: Pre-operative serum CA 19-9 level maybe used to identify proper candidates for neoadjuvant systemic chemotherapy in patients with UCB.

| Table1. Multivariable logistic regression model for independent predictors of locally-advanced UCB |
|--------------------------------------------------|-----------------|--------------------------|
| Serum CA 19-9                                    | HR              | 95% CI                  | P value   |
| Normal (≤ 35 U/mL)                               | 1               | -                       | 0.001     |
| Abnormal (>35 U/mL)                              | 5.5             | 1 – 28.5                |           |
| Clinical stage                                    |                 |                         |           |
| LNN OC                                           | 1               | -                       | 0.04      |
| Locally-advanced                                 | 27              | 3.5 – 209               |           |
| Gender                                           |                 |                         |           |
| Male                                             | 1               | -                       | 0.004     |
| Female                                           | 2.5             | 1.4 – 5                 |           |
| Lymphovascular invasion                          | 2.2             | 1.1 – 4.7               | 0.02      |
STANDARDIZED CARE PATHWAY FOR PATIENTS UNDERGOING RADICAL CYSTECTOMY

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Introduction: Despite significant advances in many areas of surgical care, patients that undergo radical cystectomy for bladder cancer continue to require significant inpatient hospital care. Recent protocols have been offered with the aim of standardizing perioperative care, reducing length of stay, and minimizing post-operative complications. We instituted a standardized protocol at our institution and present our early experience.

Methods: Our standardized protocol focuses on elimination of all preoperative bowel preparation and routine use of nasogastric tubes, early oral feeding, and minimization of narcotic pain medication. We compared the outcomes for the first 11 consecutive patients who underwent radical cystectomy for bladder cancer under this care pathway to the most recent 26 patients previous to institution of this protocol. We evaluated length of stay, 90-day readmission rates, and 90 day complication rates.

Results: Patient characteristics were similar between groups including age, comorbidities, and proportion of female gender. Standardized protocol patients had a median length of stay of 6 days (range 4-43) compared to 9 days (range 5-21) for pre-protocol patients (p=0.025). A larger proportion of protocol patients were discharged from the hospital within one week compared to pre-protocol patients (63.6% versus 23.1%, p=0.018). Ninety-day readmission rates (27.3% versus 23.5%, p=0.79) and complication rates (36.4% versus 61.5%; p=0.162) were not different between the groups.

Conclusion: Our standardized protocol for patients undergoing radical cystectomy safely eliminates pre-operative bowel preparation without an increase in 90-day complication rates. Further, this protocol is successful at reducing hospital inpatient stay without increasing readmission and complication rates.

Source of Funding: None
EFFECT OF ALVIMOPAN ON RETURN OF BOWEL FUNCTION AFTER ROBOTIC ASSISTED RADICAL CYSTECTOMY
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(Presentation to be made by Dr. Heinlen)

Introduction and Objective: Alvimopan is a peripherally acting mu-opioid antagonist marketed as Entereg™. It has been shown to improve time to return of bowel function in patients undergoing bowel resection. The objective of this study is to determine if alvimopan has an effect in return of bowel function for patients undergoing Robot Assisted Radical Cystectomy (RARC).

Methods: All consecutive RARC cases were reviewed from a period of January 2008 until March of 2012. Patients were included where data was available on date of first bowel movement and time to tolerance of regular diet. Patients were grouped based on whether they received alvimopan or not. All patients receiving alvimopan received a pre-operative dose of 12mg PO and then were re-dosed twice daily until their first bowel movement. One-sided Wilcoxon rank sum test was used to assess the advantage of treated patients over untreated patients for these functional outcomes.

Results: One hundred seventeen (117) RARCs were performed during the study period meeting criteria. All urinary diversions were performed extracorporeal. Fifty patients had Studer ileal neobladder, 22 had Indiana pouch, 45 had ileal conduit. Fifty four (54) received alvimopan and 63 did not. There was no difference in urinary diversion between groups. The median time to first bowel movement (BM) was 5 days in the treated group and 6 days in the untreated group (p = 0.03). Median time to tolerance of regular diet was 6 days in the treated group and 7 days in the untreated group (p=0.03). Time to discharge was similar between the two groups (8 treated, 9 untreated, p=0.07).

Conclusions: Alvimopan has a positive effect on bowel function after RARC resulting in quicker return of bowel function post-operatively.

Source of Funding: None

<table>
<thead>
<tr>
<th></th>
<th>Alvimopan</th>
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<th>p</th>
</tr>
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<tr>
<td># of Patients</td>
<td>54</td>
<td>63</td>
<td></td>
</tr>
<tr>
<td>Time to Bowel Movement</td>
<td>5 (4-7)</td>
<td>6 (5-7)</td>
<td>0.03</td>
</tr>
<tr>
<td>(days), median (IQR)</td>
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<tr>
<td>Time to Regular Diet</td>
<td>6 (5-8)</td>
<td>7 (5-9)</td>
<td>0.03</td>
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<tr>
<td>(days), median (IQR)</td>
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<tr>
<td>Time to Discharge</td>
<td>8 (6-10)</td>
<td>9 (7-12)</td>
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<td>(days), median (IQR)</td>
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No conflicts of interest
ENHANCED POSTOPERATIVE RECOVERY IN PATIENTS WHO UNDERGO ROBOTIC RADICAL CYSTECTOMY AND TOTAL INTRACORPOREAL URINARY DIVERSION

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(Presentation to be made by Dr. Ahmadi)

Purpose: To report our initial experience with a peri-operative protocol to enhance the return of bowel function and decrease length of hospital stay (LOS) following robotic-assisted radical cystectomy (RARC) and total intracorporeal urinary diversion (ICUD) in patients with bladder cancer.

Materials and Methods: From May 2012 to March 2013, 40 (36 male) consecutive patients were enrolled and meticulously followed for 30 days postoperatively. Major components of the protocol were stimulating bowel movement, use of non-narcotic pain medications, and early postoperative feeding. Time to bowel movement (BM), LOS, and 30-day readmission and complication rates were recorded. Based on the caregivers’ adherence to the protocol, patients were divided in two groups of full-adherence (FA) and non-Full adherence (non-FA). Non-FA was considered when at least one of the major components of the protocol was missing in postoperative care. The measured outcomes were compared between two groups.

Results: Median age of patients was 73 y/o (range, 48 – 90). Median time to BM and LOS was 3 and 5 days, respectively. Other measured outcomes are summarized in Table 1. Most common complications were infections and genitourinary tract-related complications (acute renal failure/urinary diversion-related complications) in 14 (35%) and 12 (30%) patients, respectively. Patients in FA group had significantly shorter median LOS (5 days vs. 6 days; P=0.03) and showed a trend toward lower overall 30-day complication rate (86% vs. 60%; P=0.07) compared to non-FA group.

Conclusion: Current multimodal postoperative recovery protocol successfully enhances the return of bowel function and shortens the length of hospital stay following RARC and ICUD. Full adherence to this multimodal protocol is critical to obtain ideal outcomes.

Table1. Intra- and post-operative outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median operative time</td>
<td>450 min</td>
</tr>
<tr>
<td>Median estimated blood loss</td>
<td>200 ml</td>
</tr>
<tr>
<td>30-day readmission rate, n (%)</td>
<td>14 (35)</td>
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<tr>
<td>Median time to readmission</td>
<td>7 days</td>
</tr>
<tr>
<td>30-day complication rate, n (%)</td>
<td>28 (70)</td>
</tr>
<tr>
<td>Low grade (≤ II Clavien grade)</td>
<td>28 (70)</td>
</tr>
<tr>
<td>High grade (≥ III Clavien grade)</td>
<td>10 (25)</td>
</tr>
<tr>
<td>Median time to first complication</td>
<td>4 days</td>
</tr>
</tbody>
</table>
Background: Rural living is associated with disparities in cancer diagnosis and treatment. Oregon has a diverse spectrum of population density ranging from densely populated urban counties to extremely vast rural counties. The comprehensive, state-mandated Oregon State Cancer Registry (OSCaR) database provides an ideal model to analyze differences between urban and rural bladder cancers (BC).

Objective: Our primary objective was to determine BC specific survival between urban and rural Oregonians. Our secondary objectives were: determine the relative risk of developing BC in rural counties compared to urban counties, analyze differences in stage and grade at presentation, and compare initial treatments for patients from rural and urban counties.

Materials/Methods: We retrospectively analyzed a cohort of BC cases diagnosed in Oregon from 1996-2012 from the OSCaR database. Trends in cancer presentation, including stage, grade and socioeconomic factors were evaluated, as were treatment and survival data. Death certificate data were available and reviewed. US Census data were used by the Oregon Office of Rural Health to define urban, rural, and frontier counties. County level socioeconomic data from the 2012 County Health Rankings, County numbers of primary physicians, oncologists, and urologists from the Oregon Medical Board were analyzed. Pearson’s Chi-square tests were used to evaluate the general association between county categories and other categorical variables, while Kruskal-Wallis tests were used to assess the differences of continuous variables across county categories. The Kaplan-Meier method was used to estimate BC specific survival functions. Univariate Cox Regression model was used to evaluate the association between BC-specific survival with all collected covariates. Multivariable Cox Regression was used to evaluate all important covariates identified on univariate analysis.

Results: There were 14061 Oregonians diagnosed with BC between 1996 and 2012, and 74%, 23%, and 3% of cases were from urban, rural, and frontier counties respectively. The relative risk for developing BC in rural counties compared to urban counties was 1.563 (95%CI: 1.493-1.616), and frontier counties had a relative risk of 1.364 (95%CI: 1.171-1.429) compared to urban counties. Patients from rural and frontier counties were significantly older (p=.012) Rural patients were less likely to have private insurance (p<.001), a higher stage (p<.001) and higher grade (p<.001) at presentation, and a higher risk of death due to any cause (p=.001). In our cohort, 7129 (51%) patients were deceased, of which 2,192 deaths were due to bladder cancer. The 5-year bladder cancer specific survival for urban, rural, and frontier counties was 72%, 71%, and 69%, respectively. While showing a decreasing trend, the estimated survival rates were not significantly different from each other. There was not a significant difference in overall BC specific survival (p=0.125) or in invasive BC specific survival (p=0.707) between urban, rural, and frontier county categories after controlling for important confounders (ie: age at diagnosis, sex, insurance status) and other risk factors (ie: grade, stage and histology). Cystectomy rates and time from diagnosis to cystectomy were no different among the urban, rural and frontier groups.

Conclusions: Rural and frontier bladder cancer patients had a higher relative risk for developing BC and present with higher stage and grade BC. They do not have significant differences in treatment or bladder cancer specific survival compared to their urban counterparts.

Source of Funding: None
Introduction: Controversy exists over the effect of obesity on surgical outcomes after cystectomy. We aimed to examine the effects of BMI ≥ 30 on perioperative outcomes after cystectomy.

Materials and Methods: The American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database was used to acquire 1,293 cystectomies performed from 2005 to 2011. Patients were divided into 2 groups: body mass index (BMI) < 30 kg/m² and ≥ 30 kg/m². A propensity score (PS) matched analysis of perioperative outcomes was performed.

Results: Before PS matching, 869 patients had a BMI of < 30 while 424 had a BMI ≥ 30. Unadjusted comparisons revealed higher rates of superficial surgical site infections (8.7% vs. 5.3%, p=0.04), renal insufficiency (4.0% vs. 1.7%, p=0.01) and increased operative times (365.7 min vs. 338.6, p<0.001) in the obese patients but interestingly lower rates of pneumonia (2.4% vs. 4.8, p=0.03) and cerebral vascular accidents (0.0% vs. 0.9%, p=0.05). However, the latter two observations may be explained by more tobacco use among nonobese patients (26.6 mean pack-years vs. 20.0, P=0.004). Notably, no differences in 30-day mortality were noted. After adjusting for demographic and preoperative clinical data using PS matching methods, there were no observed differences in perioperative complications between the two cohorts.

Conclusions: Obesity may not be independently associated with an increased risk of perioperative complications or 30-day mortality after cystectomy.

Source of Funding: None
A RESTRICTIVE TRANSFUSION APPROACH IS SAFE IN OPEN RADICAL CYSTECTOMY
Sumeet Syan-Bhanvadia, M.D., Siri Drangsholt, MS4, Jie Cai, Gus Miranda, Siamak Daneshmand, M.D.: Los Angeles, CA
(Presentation to be made by Dr. Syan-Bhanvadia)

Purpose: Recent data suggests that perioperative blood transfusion (PBT) at time of radical cystectomy (RC) for urothelial carcinoma is associated with poorer overall and oncologic outcomes. By refining our RC technique and employing a judicious approach to perioperative use of blood products we aim to minimize PBT in an operation that is historically associated with high rates of transfusion. Herein we compare perioperative outcomes of patients undergoing RC in a restrictive transfusion approach to a matched cohort undergoing RC during an earlier period of liberal transfusion use at the same institution.

Materials and Methods: From April 2010 to December 2012, 104 consecutive RC were performed by a single surgeon using a restrictive transfusion approach. A historical cohort of patients undergoing RC at our institution between February 2003 and 2010 (Era 1) was matched for age, sex, co-morbidities, clinical stage and neoadjuvant chemotherapy status to the contemporary restrictive transfusion cohort (Era 2) (n=87). Retrospective review of perioperative data and 90 day complications was performed. Complications were graded using Clavien-Dindo classification. Student t-test and stepwise and logistic regression modeling were used to compare outcomes.

Results: A tissue sealant device and hemostatic agents were used intra-operatively in all Era 2 patients. There were no differences between cohorts in regards to age, sex, co-morbidities, clinical stage or neoadjuvant chemotherapy status. Median EBL was significantly lower in Era 2 versus Era 1 at 1000 mL (range = 500-4300) and 400 mL (150-1200) respectively (p<0.0001). Mean operative time was shorter in Era 2 at 319 min (183-509) versus 355 min (193-682) in Era 1, p=0.001. Length of stay was significantly shorter in Era 2 with a median of 6 days (3-23) versus 9 days (5-29) in Era 1 (p<0.05). Median preoperative, immediate post-operative and discharge hematocrits were higher in Era 1 at 37.6 g/dL, 34.77 g/dL and 33.1 g/dL compared to 30.9, 29.3 and 28.1, respectively, in Era 2 (p<0.0001 for all). Overall rates of PBT were significantly different at 92% in Era 1 and 31% in Era 2. Mean PBT in Era 1 was 4.63 (0-22) units pRBC compared to 0.60 (0-7) units in Era 2 (p<0.0001). However, no significant difference was seen between total, cardiac, or high grade complications between groups (p=0.1). Stepwise and logistic regression of Era 2 patients revealed predictors of PBT to be age (OR=1.09, p<0.05), having undergone neoadjuvant chemotherapy (OR=4.4, p<0.05) and preoperative hematocrit (OR=0.86, p<0.05). Co-morbidities, clinical stage, EBL and history of prior pelvic radiation were not predictors of PBT.

Conclusions: The minimization of intraoperative bleeding through the enhancement of surgical technique and use of surgical adjuncts can be coupled with a restrictive transfusion approach to safely minimize PBT in RC. This approach is not associated with an increased rate of cardiovascular or total perioperative complications.

Source of Funding: None
Background and Objective: In patients with invasive bladder cancer (BC), lymph node dissection (LND) at the time of cystectomy and the number of lymph nodes dissected are commonly used as surgical quality measures because of the survival benefit previously demonstrated. We sought to investigate if surgical disparities exist for Oregon’s rural bladder cancer patients that require cystectomy.

Methods: We used the Oregon State Cancer Registry (OSCaR) to identify BC cases and their county of residence from 1996 to 2012. We defined rural using the Oregon Office of Rural Health’s definition to stratify counties into two groups. Urban counties were any county with a census defined urban area within its borders. Rural counties have no urbanized area, and are 10 or more miles from the centroid of a population center of 40,000 or more. BC cases were included if they were non-metastatic (any stage≤M0) and underwent cystectomy. Time from initial diagnosis to cystectomy was compared using the Kruskal-Wallis test. We used both logistic and linear regression models to test if rural patients are less likely to undergo LND, and if there was a difference in the number of lymph nodes examined when LND was performed.

Results: During the study period 14,061 cases of BC were diagnosed, of which 1,252 patients with non-metastatic BC underwent cystectomy. There were 1,058 (84.5%) patients that underwent LND. The median number of nodes dissected was 10 (IQR: 6-18). Univariate logistic regression identified age, sex, grade, and stage as significant predictors (P<.10), and were included in multivariate analysis. There was no difference in the proportion of rural and urban patients that underwent LND at the time of cystectomy were 82% vs 86%, respectively. When controlling for stage, grade, age, and sex on multi-variable logistic regression rural patients were 33% less likely to undergo LND (OR=.67; 95%CI: .047-0.95; p=.025). Controlling for the same variables, on multi-variable logistic regression there was no significant difference in proportion of urban and rural patients that received >10 lymph nodes examined (p=.094). The time from diagnosis to cystectomy was not different for rural patients compared to urban (p=.93).

Conclusions: Rural residence is associated with a decreased rate of lymph node dissection, but when a lymph node dissection occurs there is no difference in the extent of LND. Rural patients are not treated any later than their urban counterparts.

Funding source: This project was made possible by the Oregon Health and Science University Knight Cancer Institute pilot project fund.
Purpose: Prior studies have reported that females experience worse outcomes than males following radical cystectomy for urothelial carcinoma of the bladder (UCB). However, the oncological basis behind this differential behavior is unclear. This study used a balanced case-control approach to examine the sole impact of gender on prognosis following radical cystectomy for UCB.

Patients and Methods: A review of 2,567 patients who underwent open radical cystectomy for primary UCB at our institution between 1971 and 2009 was conducted. Patients with ≥80% non-UCB histology, urethral or upper tract primary, or distant metastasis at diagnosis were excluded. Female UCB patients were matched 1:1 for demographic, tumor and treatment characteristics with their male UCB counterparts. Tumor characteristics and outcomes of female patients were also compared to an unmatched independent male UCB cohort.

Results: A total of 414 female UCB cases were identified and matched 1:1 to 414 male UCB controls (median follow-up, 9.6 years). Cases were matched perfectly with controls for tumor and nodal stages, and lymphovascular invasion status (all, p=1.0). The subgroups were also nearly identical for surgical margin status (p=0.61), age (p=0.94), prior intravesical treatment (p=1.0), and neoadjuvant (p=0.64) and adjuvant chemotherapy (p=0.96) administration. Cases were also balanced with controls for tumor grade, p53 status, nodal yield, ASA score, presence of hydronephrosis, and time durations to diagnosis and cystectomy (p≥0.14). When thus balanced for presentation, tumor and treatment characteristics, no differences in recurrence-free (RFS, p=0.45), cancer-specific (CSS, p=0.34) and overall survival (OS, p=0.71) were noted between the genders. Female UCB cases were then compared to an unmatched independent cohort of 1,166 male UCB patients (median follow-up, 13.5 years). In this comparison, female gender was associated with worse RFS (p=0.004), CSS (p=0.001) and OS (p=0.006). When characteristics were compared between these subgroups, greater proportion of females was observed to present with ≥pT3 tumors than males (41% versus 33.7%, p<0.001). A greater proportion of females also had node-positive disease (25.6% versus 20.9%, p=0.049), and did not receive intravesical therapy prior to cystectomy (74.6% versus 69%, p=0.032) than males. However, time to presentation and cystectomy did not differ significantly between genders.

Conclusions: Females have similar UCB outcomes to males when matched for demographic, clinicopathological, and management characteristics. However, they present with more advanced tumors, thus probably explaining the general observation of poor outcomes.

Source of Funding: None
PERIOPERATIVE AND PATHOLOGIC OUTCOMES COMPARING OPEN AND ROBOTIC-ASSISTED RADICAL CYSTECTOMY AT A SINGLE INSTITUTION

(Presentation to be made by Dr. Zhuang)

Purpose: Recent series report the surgical feasibility of robotic cystectomy with the potential of lower surgical blood loss, more rapid return of bowel function and earlier hospital discharge compared to open cystectomy. We compared the perioperative and pathologic outcomes of robotic versus open radical cystectomy at our institution where there is an equal distribution of patients receiving an open or robotic cystectomy and no predetermined selection criteria for either approach.

Materials and Methods: Between 1/2010 and 5/2013, a total of 142 patients with urothelial cancer underwent radical cystectomy and urinary diversion. Of these, 62 patients received an open cystectomy and 80 underwent a robotic-assisted approach. We compared these groups with regard to perioperative and pathologic outcomes, and early (within 30 days of surgery) postoperative complication rates. The demographic and cancer-specific characteristics of the open and robotic groups were compared statistically using chi-square and t-tests. Linear regression models were used to compare perioperative outcomes including blood loss, transfusion rates, intraoperative fluid requirements, postoperative hematocrit levels, lymph node count, hospital length of stay (LOS) and perioperative complications.

Results: Comparing open and robotic cystectomy patients, there was no difference between age, ASA score, BMI and the number receiving neoadjuvant chemotherapy. In the open cystectomy group, there were a greater number of neobladder diversions (p=0.014) and more female patients (p=0.028). Despite similar operative time between open (7.0 hours), and robotic (6.6 hours) groups (p=0.094), estimated blood loss (225 versus 1291 mL, p<0.001) and intraoperative fluid requirements (4.03 versus 8.02 liters, p<0.001) were significantly less in the robotic group. Perioperative blood transfusion was required in 34% of open versus 7% of the robotic cystectomy patients (p<0.001). Despite more frequent blood transfusion in the open surgery group, postoperative day #4 hematocrit levels were significantly higher in the robotic cystectomy group (p=0.001). Lymph node count was no different between open (30) and robotic (26) groups (p=0.32) and pathologic stage distribution was similar. While most perioperative complications including readmission rates were no different between the groups, pulmonary embolus was more commonly seen (6% versus 0%, p=0.011) in the open cystectomy cohort. Hospital LOS was significantly shorter (median 4.99 versus 8.00 days, p<0.001) in robotic cystectomy patients.

Conclusions: In our experience, robotic cystectomy compares favorably to an open approach with equal operative times, no difference in lymph node counts and similar perioperative complications. In addition, robotic cystectomy may be superior to an open approach in terms of intraoperative blood loss, less requirement for intraoperative fluid support, lower blood transfusion rates and a significantly shorter hospital stay.

Source of Funding: None
PELVIC RECURRENCE FOLLOWING RADICAL CYSTECTOMY FOR UROTHELIAL CARCINOMA OF THE BLADDER

Anirban P. Mitra, M.D., Ph.D., Anne K. Schuckman, M.D., Eila C. Skinner, M.D., Siamak Daneshmand, M.D.: Los Angeles, CA
(Presentation to be made by Dr. Daneshmand)

Purpose: Pelvic recurrence of bladder cancer following cystectomy portends a poor prognosis. The risk of developing pelvic recurrence with no evidence of distant metastasis (PRwoDM) after radical cystectomy with extended pelvic lymphadenectomy is not well characterized. This study examined factors associated with PRwoDM and its impact on clinical outcome.

Patients and Methods: Data on patients who underwent open radical cystectomy and extended pelvic and lower retroperitoneal lymph node dissection for bladder cancer under a standardized surgical protocol during 1971-2009 were reviewed. Patients with upper tract/urethral recurrence were excluded from analysis. We determined the influence of clinicopathologic and treatment characteristics on PRwoDM rates, and the impact of such recurrence on patient survival.

Results: Recurrence data was available on 1,817 patients (median age, 67 years; median follow-up, 11.7 years; 78.9% males). 81 (4.5%) patients had PRwoDM, and 437 (24.1%) recurred at distant sites without/pelvic recurrence at last follow-up. Compared to those who did not recur, a greater proportion of patients experiencing PRwoDM were female (19.2% vs. 28.4%; p=0.045), had hydronephrosis (18.9% vs. 36.4%; p=0.001), positive surgical margins (3.2% vs. 9.9%; p=0.006), lymphovascular invasion (34.4% vs. 56.7%), and were pathologically upstaged (36.6% vs. 79%; both p<0.001). 0.6% of non-muscle invasive; 3.8% organ-confined, muscle invasive; 7.4% pT3N0M0; 7.1% pT4N0M0; and 9% node-positive disease patients experienced PRwoDM. Corresponding proportions for patients experiencing pelvic recurrence with distant metastasis were 0.7%, 2.2%, 7.4%, 1.2% and 8.5%. Nodal yields in PRwoDM patients vs. those who did not recur were comparable (both, median=37; p=0.35). Median time to PRwoDM was 12 months in patients not receiving adjuvant chemotherapy vs. 14.6 months in those who did (p=0.39). Median post-recurrence survival for patients with PRwoDM was 6.7 months vs. 5.6 months for distant metastasis (p=0.037).

Conclusions: Local control is excellent for patients with organ-confined bladder cancer; however, patients with extravesical and/or node-positive disease have PRwoDM rates of 8.2% despite an extended node dissection. Pathological stage, hydronephrosis, positive surgical margins, lymphovascular invasion, and upstaging are associated with greater probability of disease recurrence. Pelvic recurrence is an ominous sign with median post-recurrence survival under 7 months. These patients may be candidates for adjuvant local therapy.

Source of Funding: None
BENIGN URETEROENTERIC STRICTURE IN PATIENTS UNDERGOING RADICAL CYSTECTOMY AND URINARY DIVERSION

Kamran Movassaghi, M.D., Anh Huy Nguyen, M.D., Hamed Ahmadi, M.D., Eila Skinner, M.D., Siama Daneshmand, M.D., Hooman Djaladat, M.D.: Los Angeles, CA (Presentation to be made by Dr. Djaladat)

Purpose: To evaluate the risk factors, management and outcome of benign ureteroenteric strictures (UES) in patients undergoing open radical cystectomy (RC) and urinary diversion for urothelial bladder carcinoma (UBC).

Material and methods: Using our IRB approved institutional bladder cancer database we identified 1,964 patients who underwent RC for UBC at our institution between 1971 and 2008. We reviewed clinicopathological variables, stricture management and their outcome per renal unit. A multivariate logistic regression model was used to identify independent predictors of UES.

Results: 49 patients and 51 renal units were retrospectively identified with benign UES (2.6%). Their clinicopathologic characteristics are summarized in table 1. All the ureteral reimplants were refluxing to ileum. Median follow up was 12.4 years (0.2 – 27.3 yrs) and median time from cystectomy to stricture diagnosis was 10 months (range 2 months-10 years). Most patients were asymptomatic, but common presentations were flank pain (22%) and urinary tract infection (9%). Using available data, 31 patients underwent primary endoscopic treatments including dilatation and stenting. Of those, 13 (42%) required secondary endoscopic treatment and 9 (29%) eventually needed open revisions. Three patients underwent primary open surgical management. Median eGFR (Glomerular filtration rate) did not change significantly post surgical management of the stricture (47 mL/min to 44 mL/min, P > 0.05), but imaging studies showed improvement in 50% of cases. A multivariate logistic regression model did not reveal any role for age, body mass index, Charleson comorbidity index, perioperative radiation/chemotherapy, or pre-operative serum albumin to predict UES.

Conclusion: Benign ureteroenteric strictures are uncommon after cystectomy and urinary diversion. It is mostly seen on the left side and usually present few months after cystectomy. Although no specific predisposing factor has been determined, surgical technique may play an important role.

Source of Funding: None

Table 1: Clinicopathologic characteristics of UES Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (range)</td>
<td>63 (42-84)</td>
</tr>
<tr>
<td>Gender (%)</td>
<td>Male 42 (86%)</td>
</tr>
<tr>
<td>Median BMI (Kg/m²) (range)</td>
<td>26.2 (21.5-32.4)</td>
</tr>
<tr>
<td>Charlson Comorbidity Index (CCI)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>68%</td>
</tr>
<tr>
<td>1</td>
<td>24%</td>
</tr>
<tr>
<td>≥2</td>
<td>8%</td>
</tr>
<tr>
<td>Hx of pre-cystectomy pelvic radiation (%)</td>
<td>6 (12%)</td>
</tr>
<tr>
<td>Previous abdominopelvic surgery (%)</td>
<td>16 (33%)</td>
</tr>
<tr>
<td>Stricture Side</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>66%</td>
</tr>
<tr>
<td>Right</td>
<td>29%</td>
</tr>
<tr>
<td>Bilateral</td>
<td>5%</td>
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<tr>
<td>Median Stricture Length (range)</td>
<td>1-5.5cm</td>
</tr>
<tr>
<td>Pathologic stage</td>
<td></td>
</tr>
<tr>
<td>OC (=&lt; T2)</td>
<td>23 (46%)</td>
</tr>
<tr>
<td>EV (T3,T4)</td>
<td>27 (54%)</td>
</tr>
<tr>
<td>AnyT N+</td>
<td>16 (32%)</td>
</tr>
<tr>
<td>Ureteral Positive Margin</td>
<td>3 (6%)</td>
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</tbody>
</table>
A COMPARISON OF 30-DAY SURGICAL OUTCOMES FOR MINIMALLY INVASIVE AND OPEN SACROCOLPOPEXY

Mark D. Tyson, M.D., Christopher E. Wolter, M.D.: Phoenix, AZ
(Presentation to be made by Dr. Tyson)

**Purpose:** Minimally invasive sacrocolpopexy (MISC) has gained widespread acceptance without randomized or population-based data to support its use. This study compares 30-day outcomes after MISC and open sacrocolpopexy (OSC) using population-based data.

**Materials and Methods:** The National Surgical Quality Improvement Program (NSQIP) database was used to acquire 1,786 sacrocolpopexy operations (659 OSC and 1,127 MISC) performed from 2005 to 2011. A propensity-weighted comparative analysis of perioperative morbidity was performed.

**Results:** Among women undergoing sacrocolpopexy, the proportion of MISC procedures increased from 7.1% in 2006 to 68.8% in 2011. Women undergoing OSC were older ($P<.001$) and had somewhat higher American Society of Anesthesiologists classifications ($P=.11$). Unadjusted comparisons between groups revealed higher rates of superficial ($P<.001$) and deep surgical ($P=.009$) site infections in the OSC group. There was also a higher rate of blood transfusions ($P=.02$), a longer length of hospitalization ($P<.001$), and a shorter operative time ($P<.001$) among patients undergoing OSC. In the propensity-weighted analysis, MISC was associated with lower rates of wound infections (1.1% vs 3.0%; $P=.01$), lower blood transfusion rates (0.7% vs 2.3%; $P=.01$), a shorter mean hospitalization (1.4 vs 3.0 days; $P<.001$), and a longer mean operative time (224.8 vs 188.6 minutes; $P<.001$). No differences were noted among renal, infectious, or neurologic complications, although pulmonary complications were higher in the OSC group (0.3% vs 1.0%; $P=.08$). No differences in 30-day mortality were noted (0.1% vs 0.2%; $P=.61$).

**Conclusions:** MISC was associated with lower perioperative morbidity in this propensity-weighted analysis.

**Source of Funding:** None

Keywords: pelvic organ prolapse; sacrocolpopexy; surgical outcomes

**Abbreviations**
MISC, minimally invasive sacrocolpopexy
NSQIP, National Surgical Quality Improvement Program
OSC, open sacrocolpopexy
POP, pelvic organ prolapse
SSI, surgical site infection
Objective: Artificial urinary sphincter (AUS) placement has been the “gold standard” procedure for treatment of significant male stress urinary incontinence (SUI). The reported success rate of AUS ranges 60-90%. AUS revision procedures for persistent incontinence include complete replacement of AUS, cuff down-size, and tandem cuff. Replacement of the standard 61-70 cm H2O pressure regulating balloon (PRB) with a 71-80 cm H2O balloon has not been widely reported. We retrospectively reviewed initial clinical outcomes data from patients who underwent AUS revision with this technique.

Materials and Methods: Clinical outcomes data, including standardized questionnaires for Urinary Incontinence Symptoms Index (ISI) and Quality of Life (QOL), were collected from patients who underwent PRB upsize for persistent incontinence within 12 months of AUS placement.

Results: Eight patients were identified and underwent PRB upsize 2 to 12 months after AUS placement. Six had SUI after radical prostatectomy, of whom two also had radiation therapy. One patient had pelvic fracture with distraction injury to the bladder neck; another had spina bifida with neurogenic bladder. All but two patients had undergone previous AUS placements. Three had urethral slings, and 3 attempted bulking agent injections at the bladder neck. During the latest AUS placements, three patients underwent transcorporal cuff placement, and one had double transcorporal cuffs. Cuff size ranged from 4-5.5 cm. Mean follow up period was 7 months (range 2-20 months). One patient developed superficial surgical site infection treated with oral antibiotics; one died of non-urologic causes two months after PRB upsize. The three patients who achieved minimal leakage (0-1 pad per day) had an average of 2 prior SUI procedures. Of the four patients with persistent leakage, two had significant urge incontinence; one had a persistent cough; and another developed abrupt worsening of leakage after prolonged AUS inactivation. These patients had a mean of 3.75 prior SUI procedures.

Of the four patients who had complete ISI and QOL data, two patients had significant improvement of leakage with PRB up-regulation, and their mean pre-AUS ISI of 37.5/41 improved to 17/41 post-AUS and to 9.5/41 post-PRB revision. Their mean pre-AUS QOL of 21/28 improved to 8/28 post-AUS and 0.5/28 post-PRB revision. The two patients with persistent leakage after PRB upsize had an ISI of 33/41 pre-AUS, 25.5/41 post-AUS, and 24.5/41 post-PRB revision. Their mean QOL was 24/28 pre-AUS, 15/28 post-AUS, and 12.5/28 post-PRB revision.

Conclusion: AUS revision with PRB upsize may be considered as a possible option in carefully selected patients with persistent SUI after AUS placement. Increased number of prior SUI procedures and diminished symptom reduction with the AUS placement appear to decrease the continence rate of PRB up-regulation. We are currently developing a standardized approach to prospectively study this technique.

Source of Funding: None
NONSURGICAL TRANSURETHRAL RADIOFREQUENCY COLLAGEN DENATURATION (LYRETTÉ) IN THE TREATMENT OF MILD TO MODERATE FEMALE STRESS URINARY INCONTINENCE

James C. Lukban D.O.*, Monisha S. Crisell, M.D.,
Douglas Van Drie, M.D.*, Denise M. Elser, M.D. *,
Phillip L. Bressman, M.D. *, Royce T. Adkins, M.D. *,
Randall C. Kahan, M.D.*: Norfolk, VA
(Presentation to be made by Dr. Lukban)

Objective: To determine the efficacy of Lyrette in women with mild to moderate stress urinary incontinence (SUI).

Materials and Methods: On-going, prospective, 36-month, open-label, multi-center clinical study enrolling women with anatomic SUI and urodynamic indices of Valsalva Leak-point Pressure (VLPP) >= 90 cm H2O and Maximum Urethral Closure Pressure (MUCP) >= 45 cm H2O. Intervention was in the form of transurethral radiofrequency energy delivered to the bladder neck and proximal urethra at 65 degrees C° to a total of 36 foci. Primary endpoint was the percentage of patients deemed to be “dry” at 6 months as defined by <= 1 leak on 3-day diary or <= 1 gram of leak on 1-hour pad weight test (PWT). Secondary endpoints included the proportion of patients with >= 50% decrease on PWT; cough stress test (CST); quality of life (QOL) measures including the Incontinence Quality of Life (I-QOL) and Urogenital distress Inventory (UDI-6); post-treatment pain as per the Visual Analog Scale (1 minimum – 10 maximum); and patient satisfaction.

Results: Fifty-two patients underwent treatment and had follow-up through 6 months. Subjects were analyzed by Intent-to-Treat. Dry rate was 76%; 73% had a >=50% decrease on PWT; and 65% exhibited a negative CST. Seventy-five percent had an improvement in I-QOL with significant improvement (P < 0.001) observed in mean UDI-6 scores. No significant post-treatment pain was recorded with a mean VAS score of 1.7 ± 1.8. Seventy-nine percent were “very” or “somewhat” satisfied and 87% would “…refer this treatment to a friend…”. No serious adverse events were recorded.

Conclusion: At 6 months, treatment of women with mild to moderate SUI employing Lyrette yielded favorable efficacy, improvement in QOL and high patient satisfaction.

Source of Funding: Verathon, Washington, USA
With the increasing concerns regarding mesh complications, there has been renewed interest in pelvic organ prolapse repairs without mesh. Since 2000 we have performed the cadaveric prolapse repair with sling procedure (CaPS) which involves an anterior repair utilizing a solvent dehydrated non-frozen cadaveric fascia lata (Tutoplast fascia). Our objective is to present the long-term data for the CaPS procedure.

A retrospective review of 610 patients who have undergone a CaPS procedure was performed. The outcomes measured included prolapse recurrence, complications, pre and post operative SEAPI scores, and patient satisfaction questionnaire. Failure was defined as recurrence of cystocele grade 2 or higher using the Baden-Walker system.

510 out of 610 (83.6%) patients have follow-up. The average follow-up period with a questionnaire was 4.05 years (Range: 3–136 months). 110 (21.6%) patients have at least five-years of follow-up. Average patient age at the time of surgery was 62.6 years (Range: 29–89 years). There were 598 concomitant surgeries performed which included 241 vaginal vault suspensions. The complication rate was 0.1% (5/510) which included: 1 bowel injury, 1 ureteral obstruction, and 3 fascia extrusions. Cystocele recurrence occurred in 39/510 (7.6%) patients. 10 of the 39 patients (2%) underwent a repeat cystocele repair. Prolapse failure occurred at an average of 33.7 months postoperatively (Range: 3-107 months). Vaginal vault prolapse recurrence occurred in 15 (2.9%) patients. Uterine prolapse occurred in 5 (0.9%) patients. Durable and statistically significant improvement was observed in the total SEAPI score. Pre-operative SEAPI score average was 6.6 and the post-operative score decreased to 2.5 for a 62.1% improvement (p<0.05). Of the 79/510 (15.5%) women who were sexually active, 44/79 (55.7%) reported no discomfort with intercourse. At the time of each patient’s last questionnaire, 370 (72.5%) patients would recommend the surgery and 379 (74.3%) patients would repeat the surgery. Self-reported patient satisfaction on a visual analogue scale was high with a 68% improvement from baseline.

With a maximum follow-up of more than 11 years and an average follow-up of over 4 years, patients undergoing the CaPS procedure have results which are excellent and durable. 92.4% of patient’s had no significant cystocele recurrence. There was high patient satisfaction and no significant morbidity.

Source of Funding: Coloplast
OBESITY AND PREVIOUS MAJOR ABDOMINAL SURGERY SHOULD NOT INFLUENCE OUTCOMES IN ROBOTIC ASSISTED SACROCOLPOPEXY: THE MAYO CLINIC EXPERIENCE
Daniel E. Schneider, M.D., Christopher Wolter, M.D.: Phoenix, AZ
(Presentation to be made by Dr. Schneider)

**Introduction:** Robotic Assisted Sacrocolpopexy (RASC) has been shown in observational studies to be a highly effective procedure for high grade apical pelvic organ prolapse. The purpose of this review is to evaluate a single surgeon’s experience to add to the body of knowledge regarding the efficacy of this procedure.

**Methods:** A retrospective analysis was completed on patients with high grade prolapse from the 2009-2012 for a median follow up of 9 (+/- 9 months). Demographical data was collected along with operative outcomes. We used univariate analysis to evaluate whether or not obesity, previous pelvic surgery or previous major abdominal surgery had an effect on operative time, blood loss, hospital stay or operative outcomes.

**Results:** A total of 81 patients were included in the analysis for a median follow up of 9 +/- 9 months. Thirty six (44%) had a previous prolapse repair, twenty three (28%) had a previous incontinence procedure and thirty four (42%) had previous major abdominal surgery, and the average BMI was 26.8 (+/-4.6 range 19.5-47.2), with fifteen patients being morbidly obese (19%). Twenty one (26%) reported stress incontinence, fifteen (18%) reported urge incontinence, and nineteen (23%) reported mixed incontinence. Average blood loss was 78.2 +/-51 mL, operative time 227 (+/-101 minutes), average hospital state 1.41 (+/-0.59 days). Major complication rate was 4%, 4 (5%) went in to prolonged urinary retention and 1 (1%) had mesh extrusion that had to be managed surgically. Operative success was demonstrated in 93%, 73% of those with preexisting urge incontinence demonstrated improvement, 87% with preoperative stress incontinence demonstrated improvement. No case had to be converted to an open procedure. There was no difference in operative outcomes after controlling for BMI, previous abdominal surgery, or previous pelvic surgery.

**Conclusions:** In this retrospective single institutional/single surgeon study, RASC proved to be an effective operation, even in a surgically complex patient cohort. Previous major abdominal surgery and obesity appears to have no effect on complication rates in this cohort, and all cases were successfully able to be completed laparoscopically. Long term follow up is necessary to determine the durability of the outcomes.

**Source of Funding:** None
ONABOTULINUMTOXINA SIGNIFICANTLY REDUCES URINARY INCONTINENCE AND IMPROVES QUALITY OF LIFE IN PATIENTS WITH IDIOPATHIC OVERACTIVE BLADDER: A POOLED ANALYSIS OF TWO PHASE III, PLACEBO-CONTROLLED PIVOTAL TRIALS
Stephen Auerbach, M.D., Christopher Nardo, Ph.D*, Jihao Zhou, Ph.D*, Victor Nitti, M.D.: Newport Beach, CA
(Presentation to be made by Dr. Auerbach)

Objectives: To assess the efficacy and safety of onabotulinumtoxinA (onabotA) in patients with overactive bladder (OAB) with urinary incontinence (UI) who were inadequately managed with oral anticholinergic (ACH) therapies.

Methods: Data from two phase 3 studies were pooled for analysis. OAB patients with ≥3 urgency UI episodes over a 3-day period and ≥8 micturitions/day who had either insufficient efficacy or intolerable side effects with prior ACH therapy were randomized 1:1 to receive 20 cystoscopic intradetrusor injections (0.5 mL/injection) of onabotA 100U (n=557) or placebo (n=548), sparing the trigone. All injections were performed in the investigator's office by instillation of local anesthesia to the bladder and/or sedation. Patients with a predominance of stress UI were excluded. Change from baseline at week 12 in UI episodes/day and proportion of patients reporting a positive response (condition ‘greatly improved’ or ‘improved’) on the treatment benefit scale (TBS) were evaluated. Other OAB symptoms (including episodes of micturition, urgency and nocturia) and volume voided/micturition were also assessed. Health-related quality of life (HRQOL) outcomes were evaluated using the Incontinence-Quality of Life instrument and King’s Health Questionnaire. Adverse events (AEs) were assessed.

Results: Mean daily UI episodes at baseline in onabotA and placebo groups were 5.5 and 5.4, respectively. At week 12, significant reductions from baseline in daily UI episodes were observed with onabotA 100U, compared with placebo (−2.80 vs. −0.95 episodes/day; p<0.001). A corresponding significant increase in positive TBS responders was noted in the onabotA group vs. placebo (61.8% vs. 28.0%; p<0.001). All other OAB symptoms were significantly improved following treatment with onabotA 100U vs. placebo, with significant reductions from baseline in daily episodes of micturition (−2.35 vs. −0.87), urgency (−3.3 vs. −1.2) and nocturia (−0.49 vs. −0.24) (p<0.001 vs. placebo at week 12 for all parameters). Volume voided/micturition was significantly increased with onabotA vs. placebo (42.1 ml vs. 11.2 ml; p<0.001). Significant and clinically meaningful improvements in patients’ HRQOL were noted with onabotA in all domains, apart from General Health. AEs were primarily localized to the bladder. The most common AE was urinary tract infection (UTI) (25.5% with onabotA vs. 9.6% with placebo). All but one case of UTI were uncomplicated with no upper urinary tract involvement. A low rate of urinary retention was observed (5.8% with onabotA vs. 0.4% with placebo).

Conclusions: In OAB patients who were inadequately managed with ACH therapy, onabotA 100U was well tolerated and demonstrated significant and clinically relevant improvements in all evaluated symptoms of OAB, which were reflected in patients’ perception of treatment benefit, including a significant positive impact on their HRQOL.

Source of funding: Allergan, Inc.
THE MINIARC\textsuperscript{R} SLING – LONG TERM SUCCESS
Saad Juma, M.D.: Encinitas, CA
(Presentation to be made by Dr. Juma)

Objectives: The success of MINIARC\textsuperscript{R} in the management of SUI is reported to be 78-94% at short and intermediate follow-up. Dry rates and patient satisfaction rates are two distinct outcome measures. Dry rate is a precise end point measure for the outcome, and reflects one perspective of the outcome. Patient satisfaction rate is as important outcome measure as dry rate. It encompasses the patient’s overall experience with the procedure and not merely being dry. The objective of this retrospective analysis is to evaluate the long-term success of MINIARC\textsuperscript{R} in the surgical management of patients with SUI using patients’ reported dry rates and patients’ reported satisfaction rates.

Methods: Sixty-nine patients who had MINIARC\textsuperscript{R} (± pelvic organ prolapse repair), and who completed a minimum follow up of 12 months were the subjects of this review. Pre and postoperative evaluation included; history [including pads used per day (PPD)], examination, and QOL [Incontinence impact questionnaire (IIQ), Urogenital distress inventory (UDI), and patient satisfaction visual analog scale (VAS)]. All patients had preoperative urodynamic studies and cystoscopy.

Results: Their mean age was 63.6 (30-89) years, and mean BMI 26.42 (19-42). History of SUI was reported by 79% and 89% had history of urge urinary incontinence (UUI). PPD was 2.32 (0-8). Their QOL score were IIQ 10.18 (0-28), UDI 9.41(0-16), and VAS 2.84 (0-10). All patient had the MINIARC\textsuperscript{R} sling procedure. Fifty-six (81%) had cystocele repair, 9 (13%) enterocele repair, 36 (52%) rectocele repair, 11 (16%) hysterectomy, 21 (30%) sacrospinous suspension, and 7 (10%) abdominal sacrocolpopexy. At a mean follow up of 26.9 months (12-60), SUI was reported in 13% {P<0.05}, and UUI in 39% {P<0.05}. Mean PPD use was 0.54 (0-3){P<0.05}, and their QOL scores were, IIQ 4.14 (0-28) {P<0.05}, UDI 3.75 (0-16) {P<0.05}, and VAS 6.12(0-10){P<0.05}. Forty eight percent were dry (no SUI or UUI). No sling extrusion was seen in this series though 3 patients (4.34%) had extrusion of pelvic prolapse repair mesh, 1 (1.44%) patient required urethrolysis.

Conclusions: These data demonstrate the efficacy of the MINIARC\textsuperscript{R} Sling in the surgical management of patients with SUI at long-term follow-up. Patients reported dry rates and patients’ satisfaction remains high. It further demonstrates the safety of the procedure with low morbidity.

Source of Funding: None
INTERNAL URETHROTOMY AND VAGINAL FLAP URETHROPLASTY FOR FEMALE URETHRAL STRICTURE DISEASE - THE STANFORD EXPERIENCE

Ying H. Jura, M.D., Christopher S. Elliott, M.D., Craig V. Comiter, M.D., Christopher K. Payne, M.D.: Stanford, CA
(Presentation to be made by Dr. Jura)

Objectives: Female urethral stricture is a rare problem with limited consensus to guide management. Treatment options include dilation, direct vision internal urethrotomy (DVIU) or urethral reconstruction. A simple technique for urethral reconstruction is a single stage vaginal flap urethroplasty (VFU) first described by Dr. John Blandy. To date, there are few series documenting the outcome of DVIU or VFU for female urethral stricture treatment.

Methods: We retrospectively reviewed the charts of all women who underwent a DVIU or a VFU for urethral stricture between 2005 and 2011. DVIU was performed using a holmium laser, often with concurrent urethral dilation. VFU consisted of: raising an inverted U-shaped anterior vaginal wall flap; incising the posterior aspect of the stricture; and then advancing the flap into the urethra so that the apex of the flap is approximated to the apex of the urethral incision.

Results: Twelve patients were identified for review with ages ranging from 32 to 59 years. Mean follow-up was 28 months (range 7-91). These patients underwent eleven DVIUs and eight VFUs (See Table 1), with an individual patient often having undergone more than one of the study treatments. All but one patient had undergone prior urethral procedures. The stricture involved only the distal urethra in nine patients. The mean preoperative urethral caliber was 12 French (range pinhole to 21) for DVIUs and 11 French (range 5-16) for VFUs. Following DVIU, all but one patient reported improvement in their symptoms. Symptomatic recurrent strictures (range 12-21 French) requiring repeat intervention occurred following seven DVIUs after a mean of 8 months (range 1-23). Following VFUs, all patients reported improvement in their symptoms. Symptomatic recurrent strictures (range 12-16 French) requiring repeat intervention occurred in four VFUs after an average of 42 months (range 17-90). There were no cases of de-novo stress incontinence after any of the procedures.

Conclusions: In our experience, DVIU has up to a 25% success rate for treatment of distal female urethral strictures while VFU has up to a 50% long term success rate. Recurrences after DVIU typically occur within the first year whereas recurrences after VFU can occur anywhere from 1.5 to 7 years after surgery and long-term follow-up is advisable.

Source of Funding: None

Table 1. Treatment and Follow-up

<table>
<thead>
<tr>
<th>Pt. No.</th>
<th>Stricture Site</th>
<th>Prior Treatment</th>
<th>1° Follow-up</th>
<th>2° Follow-up</th>
<th>3° + 4° Follow-up</th>
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<td>DVIU</td>
<td>VFU</td>
<td>4</td>
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<tr>
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<td>distal</td>
<td>Bladder Neck Incision</td>
<td>DVIU 8</td>
<td>VFU 15</td>
<td>DVIU + Dilation (office) 1 + 7</td>
</tr>
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<td>Dilation, DVIU</td>
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<td>VFU 2</td>
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<tr>
<td>4</td>
<td>proximal</td>
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<td>VFU 17</td>
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<td>8</td>
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<td>DVIU 10</td>
<td>DVIU 9</td>
<td>DVIU 2</td>
<td></td>
</tr>
</tbody>
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