ROBOT-ASSISTED RADICAL CYSTECTOMY IN OCTOGENARIANS AND THE EFFECT OF AN ENHANCED RECOVERY PATHWAY ON PERI-OPERATIVE INDICES
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(Presentation to be made by Dr. Chennamsetty)

Introduction: The management of aggressive bladder cancer poses a unique challenge due to the often-advanced age at diagnosis. This is becoming more common with the increasing longevity of the general population and incidence of bladder cancer as a whole. Robot-assistance may offer decreased peri-operative morbidity in comparison to open surgery, especially important in the elderly. Further, enhanced recovery protocols can offer added benefits on operative outcomes in this population. Thus, we present our experience with robot-assisted radical cystectomy in a strictly octogenarian population and the effect of the City of Hope Cystectomy Pathway on peri-operative indices.

Methods: We identified all patients who were >80 years at the time of their robot-assisted radical cystectomy performed at our institution between October 2003 to present. Demographic and peri-operative data were collected in an IRB-approved database. Patients were then stratified by whether or not they were subject to the City of Hope Cystectomy Pathway that was instituted in April 2014 and these cohorts were compared.

Results: A total of 87 octogenarians underwent robot-assisted radical cystectomy during our study period. 20 of these were subject to the pathway. The total mean age was 83.9 years, and the vast majority were unhealthy with 91.9% of the cohort having an ASA ≥ 3. Most patients (85.1%) underwent ileal conduit diversions. Median estimated blood loss was 250 cc. 63.2% of patients required blood transfusions. There were 3 (3.4%) open conversions. Median length of stay was 10 days. 31.0% of patients experienced major complications at 90 days. The 30 and 90-day mortality rate was 3.4% and 12.6%, respectively. The 30 and 90-day readmission rate was 32.2% and 42.5%, respectively. Pathway patients had a higher ASA and lower estimated blood loss. Use of the pathway reduced length of stay by 3 days. There was no difference observed in the rate of complications, peri-operative mortality or early readmission.

Conclusions: Robot-assisted radical cystectomy is safe and feasible in octogenarians with an acceptable peri-operative morbidity profile that can potentially be an improvement when compared to open surgery. The City of Hope cystectomy pathway was not associated with a reduction in the rates of early complications, mortality or readmissions but a shorter length of stay was observed. Larger randomized, prospective trials are needed to further investigate our findings.

Source of Funding: None
SINGLE STAGE REPAIR OF WATERING CAN PERINEUM: AVOIDING TRADITIONAL 2 STAGE APPROACH

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INTRODUCTION AND OBJECTIVES: Adult non-hypospadias-associated urethral fistula is a rare, but it is a documented pathologic entity. Urethral fistulas associated with urethral stricture are usually multiple and infected. A 2 stage approach is generally adopted for the treatment of such cases. In this study, we retrospectively reviewed 10 cases with urethral stricture and urethrocystaneous fistula for whom we did single stage repair.

METHODS: Ten patients were included in the study with age range 21-58 years. Aetiology included infection, trauma, idiopathic and Lichen Sclerosis. Fistulas were always associated with stricture. Hence excision of fistula tract was required along with urethroplasty. The urethroplasty was done using dorsal onlay approach with buccal graft augmentation. Follow up ranged from 6 months to 3 years. Postoperative work up included AUA symptom score, postvoiding residue and uroflowmetry. Retrograde urethrography was done when any of the previous findings deemed abnormal. Success was defined by the lack of any maneuvers after urethroplasty.

RESULTS: All patients had multiple fistula at beginning except one patient who had a single fistula. Eight patients had successful outcome. Closure of all fistulas were achieved and patients had normal urine flow. Two cases had suboptimal success in regard to passing few drops of urine from one fistula site. Out of these 2 patients, one had prior radiation for prostate cancer and the other had prior failed urethroplasty. They had expectant management with long broad spectrum antibiotic coverage and fistulas healed over 3 month’s duration.

CONCLUSIONS: One stage repair of watering can perineum is feasible and successful. Clearing infection and urine diversion in form of suprapubic catheter for a short duration before graft urethroplasty may be needed to optimize the outcome in case of augmentation urethroplasty. Prospective randomized study with larger number of cases and longer follow up is mandated.
THE UNIVERSITY OF ARIZONA RADICAL CYSTECTOMY
POSTOPERATIVE CARE PATHWAY

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(Presentation to be made by: Dr. John Michalak)

Introduction: Standardizing postoperative care reduces complications, length of stay, and readmission rates. In an effort to improve the outcomes of patients undergoing open radical cystectomy and ileal conduit urinary diversion (RC/IC), we designed and implemented a standardized postoperative care pathway for patients undergoing this procedure.

Methods: The University of Arizona Radical Cystectomy Postoperative Care Pathway was implemented into our institution’s electronic medical records system, standardizing postoperative nursing care, drain removal, dietary advancement, and ambulation/activity. (Table 1) The study group consisted of 20 consecutive patients undergoing RC/IC from March 2015 to July 2016 after implementation of the postoperative care pathway. A historical control group was comprised of 29 consecutive patients who underwent RC/IC from 10/2014 to 3/2015 prior to implementation of the care pathway. The study group patients were compared to controls with regard to length of hospital stay, time to return of bowel function, time to regular diet, time to first ambulation, incidence of nausea and vomiting, incidence of ileus, rate of low and high grade Clavien complications, and readmission rate within 30 days of surgery.

Results: There were no significant demographic differences between the two groups. (Table 2) In comparison to the historical control group, the postoperative care pathway group had shorter length of stay (7.5 vs 8.4 days), decreased rates of both low and high grade complications (30.0% vs 55.0% and 10.0% vs 14.0%, respectively) decreased time to regular diet (6.3 vs 6.8 days), and decreased time to first ambulation (1.1 vs 1.4 days). The improvements experienced by the study group in this relatively small cohort did not achieve statistical significance.

Conclusions: Our prospective trial on a small group of patients undergoing RC/IC demonstrates that standardization of their postoperative care may reduce complication rates, shorten length of stay, and decrease time to return of bowel function. However, a larger, randomized study is required to confirm these findings.
THE EFFICACY OF BLADDER CANCER SCREENING IN SPINAL CORD INJURY PATIENTS: A SINGLE CENTER’S EXPERIENCE.


(Presentation to be made by Dr. Mittakanti.)

Objectives: The incidence bladder cancer has been reportedly higher, at roughly 6%, in patients with spinal cord injury or disease (SCI/D). Current guidelines regarding bladder cancer screening in this patient population are vague recommending any combination of cystoscopy, cytology and random bladder biopsy. There is paucity of data regarding the optimal time to initiate screening, how frequently to screen, and the preferred screening modality based on safety, efficacy and cost. We sought to characterize veterans with spinal cord injury disease and bladder cancer at the Veterans Integrated Service Network (VISN) 21 center and whether bladder cancer was found by screening or by clinical presentation.

Methods: Veterans with SCI/D from 1999-2012 were identified by abstraction from the Veterans Affairs (VA) electronic medical data using International Classification of Diseases Version 9 (ICD-9) codes. A cohort of veterans with SCI/D who received care at VISN 21 was identified after correlating the initial subset of veterans with the VISN21 spinal cord injury database. Clinical encounters for each patient were then searched for a diagnosis, via ICD-9 coding, of bladder cancer, CIS or a history of bladder cancer. The electronic medical record was then examined, confirming the diagnosis and details were extracted regarding detection due to screening versus clinical presentation, patient demographic factors, risk factors, treatment, clinical outcomes, and pathologic diagnosis.

Results: Thirty-eight veterans from the initial cohort of 1,938 veterans were identified as having both SCI/D and bladder cancer diagnoses over the 13-year study period. After chart review, a final cohort of 21 patients were identified as having accurate diagnoses for both bladder cancer and SCI/D. Two-thirds of these patients had cancer detected upon workup for gross hematuria or other clinical symptoms. Two of these patients were detected upon cystoscopy performed for “bladder stones”. The remaining five patients were detected incidentally on renal-bladder ultrasounds. None were detected by screening cytology, routine screening cystoscopy, or by other standardized surveillance methods. All these veterans were male and the mean age of presentation was 68.1 ± 11.8 years. The age adjusted incidence rate was 39.9/100,000 person years, which is roughly twice the incidence rate of the general population based on Surveillance, Epidemiology, and End Results Program data. The vast majority of patients, roughly 95%, had urothelial carcinoma and the overall 5-year survival was 33%.

Conclusions: Veterans with SCI/D have a higher incidence of bladder cancer. These patients typically present at a younger age with lower survival. Those who were found to have bladder cancer were detected mostly by clinical presentation or incidentally discovered by other means such as ultrasound. None were detected on routine screening by cytology or cystoscopy. More studies need to be performed to see if there is any benefit to screening in this patient population and what screening modalities should be used.

Sources of Funding: none.
OBJECTIVES: In order to investigate disparities in the incidence and demographics of bladder cancer (BC) in Latinos and Latino subpopulations, we used data from the California Cancer Registry (CCR) to compare cases of Latinos with BC living in California during 1977-2012 with non-Latino whites (NLW), non-Latino blacks (NLB), and Asian/Pacific Islanders (API).

METHODS: BC cases were identified by the Surveillance, Epidemiology, and End Results Program (SEER) site recodes (29010). Latino status and country of origin were identified by the NAACCR Hispanic Identification Algorithm (NHIA) and birthplace variable. Latino subpopulations were defined as Mexican (2,696), Central or South American (CSA) (737), Caribbean (324), and unknown origin (6,044). Annual age-adjusted incidence rates (AAIRs) were calculated.

RESULTS: 107,564 cases were recorded: 87,436 NLW (81.3%), 9,801 (9.1%) Latinos, 6,035 (5.6%) API and 4,292 NLB (4.0%). Male to female ratio was 3:1 in all groups except NLB and CSA Latinos where it was 2:1. AAIRs were consistently lower for Latinos vs. NLW and NLB, but higher than those in API (Fig 1). Mexican Latinos had lower AAIR than Caribbean or CSA Latinos (6 vs. 17 per 100,000) (Fig 2). By stage Latinos presented similarly to NLW; NLB presented with higher stage disease vs. all groups (p<0.001). There was no difference in the incidence of low vs. high-grade cancer between Latinos and NLW but the rate of non-urothelial histology was double. 50% of NLW received some type of treatment within 30 days of diagnosis vs. 43% of Latinos. 31% of Latinos received treatment >180 days of diagnosis vs. 26% of NLW. Females in all groups were more likely to receive treatment >180 days (30% vs. 25%) than males. Low SES status was more common amongst Latinos and NLB (>50%) than NLW (26%) or API (31%).

CONCLUSIONS: Differences in BC incidence, tumor characteristics and treatment patterns were observed in Latinos vs. NLW, as well as within Latino subpopulations in California. Further analyses are warranted to understand the causes underlying these disparities.

Source of Funding: none
SUTURE TO CLOSE PART OF THE URINARY MEATUS: A NOVEL ANIMAL MODEL OF BLADDER OUTLET OBSTRUCTION

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Keywords: Bladder outlet obstruction, Animal study, surgery, voiding dysfunction

Aims of study: Traditional open surgery causes some complications such as incision infection and bladder stone formation in mouse BOO model. It is also difficult to standardize the firmness of ligation, or exclude foreign material from rings in surgery models such as bladder ischemia. Mouse bladders are oval shaped, and bladder vessels depart from the bladder neck. The posterior urethra, which can be ligated, is short and difficult to identify unless operating under a microscope. If the bladder neck were pulled over or ligated, bladder ischemia would occur. We produced a novel model of bladder outlet obstruction (BOO) by suture to close part of the urinary meatus and compared the cystometric features, postoperative complications, and histopathological changes of that model between different degrees of obstruction.

Materials and methods: Six to 8-week-old female BALB/c mice were divided into four groups. In all the groups, the pediatric venous indwelling catheter (26G, i.d.=0.4 mm, o.d.=0.6mm, 16mm length) was used for urethral catheterization, and then the needle for suture was entering the urinary meatus at the 3 o’clock position. We withdraw the needle slightly and aim for the 9 o’clock position (1/2 closed group and sham-operated group), 11 o’clock position (1/3 closed group) or 12 o’clock position (1/4 closed group) respectively. In the sham-operated group, we just slightly tied a knot but not ligated the urinary meatus. After 1, 2 and 4 weeks, filling cystometry, postoperative complications, and histopathological features were evaluated in each group.

Results: In 1/2 closed group and 1/3 closed group, we tested increased maximum cystometric capacity, maximum bladder pressure, micturition interval, and post-void residual urine volume compared with control (p < 0.01). The closed groups had significantly shorter operative time, less incidence of incision infection compared with the traditional surgery according to the previous research. Smooth muscle hypertrophy was showed by Hematoxylin and eosin (HE) staining and Proliferating cell nuclear antigen (PCNA) qualified by Western Blot was increased in both closed groups. In 1/2 closed group and 1/3 closed group, as observed in masson trichrome staining, the collagen deposition in partial detrusor muscle bundles increased compared to the control group.

Interpretation of results: Smooth muscle hypertrophy and cell proliferating were the marker of early stage of BOO, and our results shows that close 1/3 part of external orifice of urethra, which are closely and reliably mimics the human condition of chronic BOO than the other groups, while avoiding open surgery and its complications. It also indicated that was in the early stage of BOO without large number of collagen deposition due to masson trichrome staining in 1/3 closed group compared with 1/2 closed group.

Concluding message: Suture to close part of the urinary meatus is a minimal invasive and accurate method to generate animal model of BOO compared with traditional method.
THE NODES OF SCYLLA AND CHARYBDIS: BALANCING THE RISKS OF THROMBOSIS & INFECTION AFTER INGUINAL LYMPHADENECTOMY

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Introduction: Inguinal lymphadenectomy (ILND) is the standard of care for many malignancies of the groin, perineum and lower extremities. It is a surgery that is also associated with increased risk of both thromboembolic event (TE) and wound complications. However, many of the prophylactic measures for these complications are opposing, such as ambulation versus bedrest or the use of heparin prophylaxis. Using data from the National Surgical Quality Improvement Project (NSQIP) database, we address this by identifying rates of occurrence and risk factors associated with ILND.

Methods: Using CPT codes, we queried the NSQIP database for the years 2003 to 2014 for any patient undergoing superficial or deep inguinal ILND for malignancy. The effect of covariates on the occurrences of complications or readmission were analyzed using logistic regression. Times to occurrences of these events were analyzed using negative binomial regression.

Results: A total of 1,413 patients were analyzed, of which 539 underwent deep inguinal node dissection. The overall readmission rate was 7.4%, and 18.2% for urologists, though on multivariable analysis type of surgeon was not a significant predictor. Overall rate of wound infection was 13.9%, compared to a 1.1% rate of TE.

Diabetic patients (odds ratio [OR] = 2.26, P = 0.003), obese patients (OR = 2.15, P = 0.014) and patients undergoing deep inguinal node dissection (OR = 1.94, P = 0.005) had significantly higher odds of developing a wound infection. Higher serum creatinine was associated with a statistically significantly but only marginal longer time to any infection (rate ratio = 1.55; P = 0.04). Patients with preoperative serum albumin of 4 or higher had a significantly longer time to superficial surgical site infection (rate ratio = 1.32; P = 0.018). Obese patients had significantly higher odds of readmission than normal weight patients (OR = 2.59; P = 0.03). We found no significant difference between peri-operative events and surgeon specialty.

Conclusion: Though arguably a more morbid complication, TE's are very uncommon in the first 30 days following ILND, while rates of wound complication are high. With a better understanding of factors associated with each of these complications, we can better stratify patients to most effectively reduce risks and improve peri-operative outcomes following ILND.

Source of Funding: None
Introduction: Metastatic urothelial carcinoma presents a dismal prognosis despite multimodal therapies. The role of surgical intervention in the setting of residual or recurrent nodal disease has not been well-described. We sought to determine outcomes among patients undergoing consolidative retroperitoneal lymph node dissection for metastatic nodal disease following primary treatment for urothelial carcinoma.

Methods: Retrospective review of our prospectively maintained IRB approved bladder cancer database was completed. Patients who underwent initial radical cystectomy or nephroureterectomy for urothelial carcinoma and subsequent resection of metastatic disease with curative intent were identified. Records were examined for patient clinical and pathologic characterization as well as long term outcomes.

Results: We identified six patients with limited metastatic disease treated with surgical resection following primary therapy for urothelial carcinoma between 9/2003 and 10/2014. Three patients underwent initial surgical resection and experienced nodal recurrence at 4, 12, and 23 months respectively. Two patients received adjuvant chemotherapy following initial resection and experienced disease recurrence at 13 and 60 months. The final patient had residual evidence of disease following surgical excision and adjuvant chemotherapy prompting repeat lymph node dissection. All patients received cisplatin based chemotherapy prior to consolidative lymph node dissection. RPLND was completed without complication in all patients. Pathology from RPLND revealed metastatic urothelial carcinoma in three of six patients. Two patients without carcinoma at resection and known follow-up remain disease free at 10 months and 73 months. All patients with residual disease at RPLND recurred at 4, 15, and 25 months but are alive and are receiving continued systemic therapy.

Conclusion: Management of urothelial carcinoma recurrence following radical cystectomy is difficult. Resection of limited metastatic disease following systemic therapies is feasible and can result in long-term survival among carefully selected patients. Further study is needed to determine the role of surgical intervention in this population.

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FACTORS IMPACTING ENROLLMENT IN A PROSPECTIVE RANDOMIZED SURGICAL TRIAL

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Objective: Prospective randomized surgical trials are challenging to perform for a number of reasons. A randomized trial evaluating the prevention of parastomal hernia following radical cystectomy and ileal conduit using biologic mesh is ongoing at our institution (NCT02439060). We sought to evaluate proficiency in trial enrollment and determine any identifiable contributing factor to non-enrollment of eligible patients in this trial.

Methods: A retrospective review of our IRB approved prospectively maintained radical cystectomy database was completed. We identified all patients who underwent radical cystectomy with ileal conduit urinary diversion during the period of open trial enrollment, 12/2015-6/2016. Patients not meeting criteria for enrollment including those without diagnosis of bladder cancer, predicted survival less than 12 months after surgery, and prior scar or mesh at the level of ileal conduit were excluded. Factors including patient age, race, gender, preferred language, prior intervention at our institution, clinical stage, receipt of neoadjuvant chemotherapy and operative start time (first case versus not) were evaluated for those patients enrolled and those deemed eligible but not enrolled in the trial.

Results: 58 patients underwent radical cystectomy with ileal conduit in this time span (39 open and 19 robotic); 34 were not enrolled in the trial. 7/34 patients failed to meet basic eligibility criteria due to pathologic diagnosis or poor pre-operative prognosis. Comparing to non-enrolled patients, enrolled cohort were significantly more likely to speak English as their primary language (p=0.04) and to undergo an open procedure (p=0.008). No significant difference was determined in other examined factors. (Table 1)

Conclusion: Patient enrollment in surgical trials is dependent on multiple factors involving both patient and surgeon. Potential barriers to enrollment including language and planned surgical approach should be recognized and addressed as able in order to optimize enrollment opportunities for patients and overall trial accrual.

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INTERACTION BETWEEN HISTOLOGIC SUBTYPE AND ETHNICITY ON BLADDER CANCER OUTCOME

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(Presentation to be made by Dr. Samuel Washington)

Objective: Bladder cancer is a major contributor to cancer-related morbidity and mortality with higher incidence among minorities. We aim to evaluate the relationship between race and non-urothelial carcinoma (UC) variant histology on bladder cancer outcomes using the National Cancer Database.

Methods: We compiled data on patients with bladder cancer and treated with radical cystectomy from 2004 to 2013. Univariate analyses identified differences between UC and variant histology. Multivariable Cox regression was used for analysis of overall survival, with hazard ratios (HR) and 95% confidence intervals (CI).

Results: Of the 362,091 patients included, black patients comprised 5.1% with a higher proportion of women (35.6% vs 24.7%) compared to white patients (p<0.05). Black patients had higher rates of variant histology: squamous cell carcinoma (2.9% vs 1.2%, p<0.05), undifferentiated carcinoma (2.7 vs 1.4%, p<0.05) and adenocarcinoma (1.5 vs 0.5%, p<0.05). In adjusted models squamous cell carcinoma (HR 1.3, 95% CI 1.2-1.4, p<0.05), small cell carcinoma (HR 1.5, 95% CI 1.3-1.7, p<0.05) and black ethnicity (HR 1.2, 95% CI 1.1-1.2) independently predicted increased mortality while chemotherapy was associated with decreased risk (HR 0.8, 95% CI 0.7-0.8, p<0.05).

Conclusions: Non-urothelial histology was more prevalent in black patients and associated with worse overall survival in patients with bladder cancer treated with radical cystectomy. In addition, black ethnicity was also a predictor of worse survival, independent of histology, in patients treated with cystectomy.

Further investigation is needed to explore the interplay between race and variant histology on survival in post-cystectomy patients.

Source of Funding: None
ASSESSMENT OF PERINEAL PAIN AFTER URETHROPLASTY FOR MALE URETHRAL STRICTURES

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Purpose: To assess and characterize perineal and bladder pain after urethroplasty.

Methods: We identified male patients at the University of Utah that underwent urethroplasty for urethral strictures from 12/2014 – 06/2016. Patients completed surveys before their surgical procedure and at follow up appointments at least 90 days after the procedure. The surveys included questions concerning perineal and urethral pain, quality of life, pain frequency, and if their condition limited exercise, work, and home tasks. Perineal pain was assessed on a scale from 0-10, with 0 representing no pain. Quality of life was assessed using the 7-point Andrews & Withey's ‘Delighted-Terrible’ Scale. Limitations and pain frequency were assessed using a 4-point Likert Scale ranging from Never to Often. Information reviewed included administrative data. Data was analyzed using descriptive statistics.

Results: Thirty-five patients were identified with a mean age of 46.5 years old (SD±15.1, range 18-74) and mean BMI of 30.7 (SD±5.0, range 21.6-40.5). Thirty-four patients left the hospital the day after surgery. Follow-up surveys were completed at a mean follow-up of 466 days (SD±210, range 90-810). Pre-operatively 69% of patients rated their quality of life as unhappy (13) or terrible (11) as compared to 2.9% (1) postoperatively. Before surgery, zero patients reported being pleased or delighted with their current condition while post-operatively, 69% rated their quality of life as being pleased (13) or delighted (11) with their current condition. 54% of patients reported penile or urethral pain sometimes or often before surgery compared to 14% after surgery. 14% of patients reported pre-operative perineal pain sometimes or often, compared to 8.6% post-operatively. The pre- and post-surgery perineal and scrotal pain was minimal, with a pre-op mean score of 1.2 (SD±2.0, range 0-8) and post-op mean of 0.9 (SD±1.6, range 0-7) on a 10-point scale. Before surgery, 14.3% of men had pain that limited them in work, exercise, or tasks at home sometimes or often compared to 5.7% after surgery.

Conclusion: Urethroplasty is a safe procedure that improves patient quality of life as well as domestic and exercise limitations. Pain associated with the procedure is minimal after recovery.

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PALLIATIVE CYSTECTOMIES FOR METASTATIC BLADDER CANCER- IS THERE A BENEFIT?
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Presentation to be made by Dr. Siamak Daneshmand

Introduction: Palliative cystectomy for metastatic bladder cancer is usually only performed in the face of progressive disease with significant dysuria, hematuria, urinary obstruction, or mass effect-related pain unresponsive to conservative treatment options. The procedure carries high risk of peri-operative complications and is invariably performed on patients with substantial disease burden and medical comorbidities. Whether the procedure truly provides palliation, and whether palliation justifies the risks of surgery, is not well defined in the literature.

Methods: Using our IRB approved bladder cancer database we identified patients with primary bladder cancers who underwent palliative cystectomy with urinary diversion at our institution. We defined palliative cystectomy as a cystectomy done with the primary intent of alleviating symptoms and without the goal of prolonging life.

Results: Eleven patients (2 female, 9 male) were identified in our database, ages 53 to 81 (mean 70), that underwent palliative cystectomy between 2004 and 2016 at our institution for bladder cancer. All patients except one received neoadjuvant chemotherapy (91%). Indications for surgery included pelvic pain (6/11), severe LUTS (6/11), hematuria (4/11), dysuria (1/11), and colovesical fistula (1/11). The majority of patients (91%) experienced substantial reduction or elimination of their pre-operative symptoms (intractable dysuria, hematuria, or mass-effect pain). However, most patients suffered a post-operative complication and experienced prolonged recovery from surgery. There were 5 Clavien I (45%), 2 Clavien II (18%), 3 clavien IVa (27%), and 1 Clavien V (9%) complications consisting of prolonged nausea, anorexia and weight loss, *Clostridium diffficile* infection, acute kidney injury leading to end-stage renal disease, loss of ambulation, and death. Only two patients (18%) fully returned to their pre-operative level of health. The median hospital length-of-stay on admission for palliative cystectomy was 7 days (range: 3-27). All patients expired or were lost to follow-up within one year of surgery. Median survival at the time of censorship was 92 days (range: 26-153) from the date of surgery.

Conclusions: Palliative cystectomy usually results in symptomatic palliation, however, it is accompanied by significant risk of post-operative complication and decreased quality-of-life. Surgical candidates should be selected extremely carefully.
Objective: To investigate the prevalence of urinary retention in male bladder cancer patients who underwent radical cystectomy and orthotopic neobladder and to identify potential predictors of retention after the procedure, if any.

Methods: Using an IRB approved, prospectively maintained bladder cancer database, we identified 265 males who underwent radical cystectomy with neobladder at our institution from 3/2000 to 6/2015 and completed post operative questionnaires regarding catheterization. The mean age at surgery was 65.7 years (SD 9.91) and mean BMI was 27.42 (SD 4.51). Univariate logistic analysis was performed for potential predictors of catheterization and urinary retention. Retention was defined as 3 or more catheterizations per day or self-reported inability to void without catheterizing.

Results: The need to catheterize at all was noted in 33 of the 265 (12.4%) patients included in the study. Of these, 11 (4.2% of the total patients) were determined to be in retention or required catheterization to void. Data regarding the number of catheterizations per day was available in 32 of these patients (Table 1). Univariate analysis showed that increasing BMI significantly predicted the need for catheterization (p = 0.009, coefficient = 0.097). Diabetes and moderate-to-severe renal disease approached significance as predictors (p-value = 0.075 and 0.09, respectively), but there were otherwise no significant predictors of the need to catheterize. Additionally, no significant predictors of urinary retention were found (Table 2).

Conclusion: In males undergoing radical cystectomy with orthotopic neobladder, retention requiring catheterization to void is uncommon. In this large cohort, the rate of any catheterization at all was 12.4%, of which a small fraction (4.2%) had complete urinary retention. BMI was found to significantly correlate with the need to catheterize, but age, medical comorbidities, pathologic stage, and receiving neoadjuvant chemotherapy did not have significant correlations with urinary retention in bladder cancer patients who underwent cystectomy. Larger power studies are required to further evaluate these predictors.
THE USE OF LITHOVUE™, A DISPOSABLE FLEXIBLE URETEROSCOPE, REDUCES SCOPE REPROCESSING TIME AND TECHNOLOGIST LABOR

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(Presentation to be made by Mr. Dylan Isaacson)

Introduction: The use of LithoVue™ (Boston Scientific, Marlborough, MA), a single-use digital flexible ureteroscope may disrupt cost paradigms for the diagnosis and treatment of upper urinary tract pathology. Reusable ureteroscopes require sterilization, processing and repair, rendering those scopes unusable for a period after case completion. Single-use ureteroscopes require much less time for recycling or disposal. The objectives of this study were to quantify the steps involved in processing reusable flexible ureteroscopes and to identify the time and labor saved when utilizing disposable scopes.

Methods: From July-August 2016, a prospective time-motion study was performed involving the intraoperative use and postoperative processing of reusable (URF-P6, Olympus, Tokyo, Japan) and LithoVue™ single-use flexible ureteroscopes used in treatment of stone pathology at UCSF. Observers timed intraoperative events and all steps involved in scope reprocessing. The subset of steps requiring human personnel was noted. Turnover time between cases was abstracted from anesthesia records.

Results: Fifteen cases utilizing reusable flexible ureteroscopes and ten cases utilizing LithoVue™ were characterized. Seven reusable scopes were followed through reprocessing. Reusable scope cases duration was 52.3 ± 31.2 minutes as compared to 43.2 ± 7.2 minutes for LithoVue™ cases (p=0.37). Mean patient preparation time in the operating room was 34 ± 10 minutes. Room turnover averaged 43 minutes between cases. Reusable scope reprocessing averaged 212 minutes of which 57 minutes required central processing personnel interaction (shaded bars, Figure 1). Processing of LithoVue™ required 4.4 minutes of labor when recycled and 0.33 minutes when disposed.

Conclusions: Reprocessing of reusable scopes at UCSF requires 3.5 hours, of which one hour is labor-dependent. Accounting for room turnover and patient preparation time, a reusable scope utilized during the first case of the day would not be ready for use until midway through the third case. Use of Lithovue™ nearly eliminates this time and labor requirement and may facilitate an increased number of cases per day with fewer ureteroscope resources invested.

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HIGH USER SATISFACTION WITH TELEMEDICINE TO MANAGE NEUROGENIC BLADDER AND PREVENT URINARY TRACT INFECTIONS IN INDIVIDUALS WITH TRAUMATIC AND NON-TRAUMATIC SPINAL CORD INJURY

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INTRODUCTION: Urinary tract infection (UTI) is the most frequent secondary health complication following spinal cord injury (SCI). It is associated with septicemia, resistant organisms, autonomic dysreflexia, and reduced quality of life. In the SCI population access to specialists is impeded by distance of clinics, economic burden and traveling with assisted ventilation. The SCI community has identified UTI as a priority area for their healthcare improvement. The objective of this study is to determine the feasibility of home-based monitoring using telemedicine to improve management of neurogenic bladder and prevent UTIs in SCI individuals. Outcome measures to determine feasibility are: (1) participant compliance (2) functionality of telemedicine software (3) user satisfaction and (4) incidence of UTIs pre and post telemedicine intervention. METHODS: A prospective cohort study including SCI participants presenting to a specialty ambulatory care centre with history of symptomatic UTIs. Participants served as their own controls for a 6-month run in, then were assessed in clinic, instructed on how to operate telemedicine software and given supplies to facilitate home monitoring of neurogenic bladder (blood pressure cuff, thermometer and urine dipsticks). Participants required internet access and a personal computer device to use telemedicine at home. Once at home participants received standardized telemedicine appointments monthly for 6-months. Upon initiation and completion of telemedicine intervention validated symptom scores were performed; The Neurogenic Bladder Symptom Score, SF-36 and Qualiveen-30. Feasibility assessment of telemedicine included: number of completed visits, satisfaction survey (Likert scale 6) and 6 aspects of software functionality (Likert scale 6). UTIs confirmed with positive culture during telemedicine intervention were frozen for genetic analysis.

RESULTS: Total study population of N = 55, 41 male, 14 female, with an age range of 23-70. Of these subjects 47 have SCI (30 ASIA-A, 9 ASIA-B, 5 ASIA-C, 2 ASIA-D, 1 ASIA-E), 4 have multiple sclerosis and 4 have spina bifida, as their cause of neurogenic bladder. Two subjects used adaptive mouth technology to operate computer and run telemedicine software. Eight subjects were required to travel over 100km to access specialty urological care for their neurogenic bladder. Eighteen subjects have completed the telemedicine intervention, 13 are actively participating, 17 are still in control phase, 1 withdrew after initiation of telemedicine and 6 withdrew from study after initial contact. Of 204 telemedicine appointments scheduled with subjects, 183 were completed, yielding 89.7% compliance rate. Twenty-one telemedicine appointments failed due to participants not signing in online for scheduled appointments, yielding 10.3% non-compliance rate. Of the completed telemedicine appointments, 59.8% had no operational challenges, 21.1% required troubleshooting, 8.8% required assistance with telephone, 15.2% had poor audio video quality and 8.3% had software incompatibility issues. The video component allowed study personnel to guide participants through proper home-monitoring of blood pressure, temperature, urine dipsticks and urine sample collection. The telemedicine satisfaction survey determined that the majority of subjects agreed or strongly agreed that: discussions on UTI prevention was helpful (75%), telemedicine increased motivation to monitor their health (88%), would recommend it to others (100%), and would consider it for future health services (94%). Furthermore, 100% agreed or strongly agreed that they were overall satisfied with telemedicine home-based monitoring service.

CONCLUSIONS: The telemedicine platform was successful with regards to compliance, software functionality and high user satisfaction. Telemedicine was even successful for high tetraplegics requiring adaptive mouth technology to operate computers. Based on these findings telemedicine could be an effective tool to promote better neurogenic bladder management through home-based monitoring and increase accessibility to healthcare for the SCI population. Participant feedback identified areas for software improvement including simplified login and reminder prompts for completing follow up assessment tasks. ACKNOWLEDGEMENTS: We would like to thank the Rick Hansen Institute for funding this research project.
PERCUTANEOUS EXTERNALLY ASSEMBLED LAPAROSCOPIC (PEAL) VERSUS TRADITIONAL LAPAROSCOPIC INSTRUMENTS: A COSMESIS AND PAIN COMPARISON

Isaac L Kelly MD, Matthew A Pierce MD, Julie W Cheng MD, Samuel R Abourbih MD, Hillary Wagner MD, D Duane Baldwin MD; Loma Linda, CA
(Presentation to be made by Dr. Julie Cheng.)

Introduction: A novel Percutaneous Externally Assembled Laparoscopic (PEAL) paradigm was developed to decrease incisional pain and laparoscopic scars. The aim of this study is to compare post-operative cosmesis and pain between the PEAL instrument site and traditional 5 and 12 mm port sites.

Methods: Six healthy kidney donors consented to use of the PEAL instruments during their nephrectomy from July 2016 to March 2017. Nephrectomies were performed using the hand-assisted technique with a PEAL instrument replacing one of the traditional laparoscopic ports, along with an additional 12 mm working port and a 5 mm port for the laparoscopic camera. The primary outcomes were post-operative comparative cosmesis between scars as determined by the patient and surgeon along with scar length. A secondary outcome was immediate post-operative pain. Cosmesis was rated using a Likert scale from 1 to 10 with 10 being best cosmesis. Pain was rated on a numeric rating scale from 0 to 10, with 10 being the worst pain. One-way ANOVA was calculated using SPSS with a p-value <0.05 considered significant.

Results: Each patient had a 2.96 mm PEAL instrument site, 5 mm and 12 mm traditional laparoscopic ports, and an 8 cm periumbilical midline hand-assist incision. Each patient acted as their own control. There were no complications. At mean follow-up of 6.8 months, both patients and surgeon significantly preferred the PEAL site as the most cosmetically appealing, followed by the 5 mm, 12 mm, and hand-assist sites, (Table 1, p<0.03 for PEAL site compared to all other sites). Scar length was also significantly smaller for the PEAL site compared to each other incision (Table 1, p<0.02) Additionally, immediate post-operative pain was lower at the PEAL site, followed by the 12 mm, 5 mm, and hand-assist ports, respectively, but this did not reach significance (2.0, 4.3, 4.0, and 5.3, respectively).

Conclusions: The PEAL incisions show significantly improved cosmesis and scar size compared to traditional 5 and 12 mm laparoscopic ports. Additional substitution of PEAL instruments for traditional instruments will likely significantly improve cosmetic outcomes.

Source of Funding: None

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Table 1: Cosmesis and Scar Size Comparison
OPERATING ROOM SUPPLY COST AWARENESS: A CROSS-SECTIONAL ANALYSIS

Bogdana Schmidt M.D., M.P.H., Lindsay A. Hampson M.D., M.S.: San Francisco, CA.
(Presentation to be made by Bogdana Schmidt)

Objective: Medical supplies comprise the second largest hospital expenditure, and while surgeons often drive the selection of supplies in the operating room, studies demonstrate that they are unaware of costs. Our study aimed to evaluate the operating room supply cost awareness in an academic urology practice. Our objectives were: 1) to assess surgeon knowledge of commonly used instruments and disposable items and 2) to describe attitudes toward incorporating cost data into daily practice.

Methods: A REDCap survey was distributed to faculty and trainees in the UCSF Department of Urology. Response rate was 71% among faculty (n=12) and 90% among trainees (n=18). The survey assessed qualitative opinions toward operating room supply cost information and assessed knowledge of cost of supplies used in a laparoscopic nephrectomy. A response was considered accurate when it fell within 50% of the actual cost. Analyses were conducted using Chi-squared tests and stratified by level of training.

Results: Of the faculty and trainees surveyed, 55% and 82%, respectively, considered their knowledge of costs “fair” or “poor”. Further, 69% and 35%, respectively, reported that it is “somewhat” or “very” difficult obtain cost data. The overall accuracy of cost estimation for ten commonly-used supply items was 27% (standard deviation 45%), with no significant difference between trainees and faculty (p=0.70). Accuracy was not associated with self-reported cost knowledge (p=0.25) or number of laparoscopic nephrectomies performed (p=0.47). 42% of faculty and 41% of trainees reported that having more knowledge of costs would motivate them to decrease their operating room supply costs. 42% of faculty felt that an incentive program would motivate them, while only 24% of trainees cited incentives as motivation.

Conclusions: Trainees and faculty generally have poor knowledge of operating room supply costs. In our academic setting we noted an interest among both faculty and residents to make cost data more readily accessible. These data would provide an opportunity for surgeons to act as cost arbiters in the operating room.
ENDOSCOPIC MANAGEMENT OF PRIMARY OBSTRUCTIVE MEGAURETER: A SYSTEMATIC REVIEW

Alexander D. Doudt D.O., Chad R. Pusateri D.O., Matthew S. Christman M.D.: San Diego, CA
(Presentation to be made by Dr. Alexander Doudt)

Background: The gold standard treatment for primary obstructive megaureter (POM) with declining renal function, worsening obstruction, or recurrent infections is ureteral re-implantation with or without tapering. However, open surgery is technically demanding and associated with significant morbidity. We conducted a systematic review of the literature with special interest in endoscopic management of POM and its outcomes.

Methods: A search was conducted of the MEDLINE/Ovid, PubMed, Embase, and Web of Science databases. Only full-text articles written in the English language and involving greater than one reported pediatric case per publication were included. Two authors independently extracted data and assessed strength of evidence for each study.

Results: We found 12 retrospective and one prospective, single institution case series that met selection criteria, describing 235 patients with 250 obstructed renal units. The mean age at time of surgery was 23.1 months. The most common endoscopic approaches were cystoscopy + high pressure balloon dilation (HPBD) + double-J ureteral stent placement (48%), cystoscopy + incisional ureterotomy + double-J ureteral stent placement (24.8%), and cystoscopy + double-J ureteral stent placement (16.4%). There was significant heterogeneity regarding primary endpoints between studies. For all approaches, there was complete or significant improvement of hydroureteronephrosis in 79.7% (157/197) of renal units and resolution of functional obstruction and/or preserved/improved differential renal function in 75.3% (156/207) of renal units. Endoscopic re-treatment was performed in 14.4% of cases with a 37.6% overall surgical re-intervention rate. Forty-four ureters progressed to ureteral re-implantation. Complications were generally mild (Clavien-Dindo Grades I-II), but 14 ureters did develop vesicoureteral reflux. Mean follow-up period was 3.1 years.

Conclusions: Endoscopic management for primary obstructive megaureter is an effective, minimally invasive alternative to ureteral re-implantation. However, approximately 1/3 of patients require surgical re-intervention. Prospective, multi-institutional studies with longer follow-up are needed to validate these findings.

Source of Funding: None
Introduction: Robot-assisted laparoscopic pyeloplasty is an established treatment for ureteropelvic junction (UPJ) obstruction. However, the literature in children is limited to short-term follow-up. We report our 10 year experience with robotic pyeloplasty, including long term outcomes.

Methods: We performed a retrospective review of all patients with available imaging who underwent robotic pyeloplasty at our institution since 2006. Success was defined as improvement in imaging, improvement in pain with stable imaging or if a MAG3 Lasix renogram was non-obstructive.

Results: 139 patients met inclusion criteria from 2006 and 2016. Most were boys (73%) and most presented due to flank pain (57%). Sixteen (11%) patients had prior procedures on the UPJ, some multiple. Mean age at time of surgery was 101 months (4 – 229). One surgeon performed 91% of the operations and the dismembered pyeloplasty technique was primarily used (89%). Mean operative time was 204 minutes (99 – 402) and mean length of stay was 2 days (1 – 10) with 47% of patients discharged POD1. Twenty-one (15%) patients experienced post-operative complications, some multiple. Overall, 93% of pyeloplasties were successful with mean length of follow-up about 3 years. A subset of patients (30/139) with greater than 5 year clinical follow-up had a similar success rate (90%) with mean length of follow up almost 7 years.

Conclusions: Robot-assisted laparoscopic pyeloplasty is safe and durable in pediatric patients. Continued study will be required to truly understand the comparative effectiveness of robotic pyeloplasty.

Source of Funding: None

Table: Outcomes

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**PERIPHERAL RAPID INFUSION VIA CORPUS CAVERNOSUM (PRICC): AN ALTERNATIVE ROUTE OF VASCULAR ACCESS**

Nathan Osbun, Thomas Walsh, Marc Rogers, Claire Yang, Seattle, WA

**Introduction and Objectives:** Securing vascular access is crucial in the initial resuscitation of traumatically injured and critically ill patients. Peripheral vascular access can be difficult in these patients for a variety of reasons such as venous collapse or sclerosis, obesity, burns, or limb trauma. Obtaining central venous access can have a high complication rate in the emergent setting. Intraosseous catheter placement requires specialized equipment and training. The corpora cavernosa of the penis provide robust access to the systemic vasculature and may be ideal for the resuscitation of male patients with compromised peripheral access. We performed this study to evaluate the flow rates possible with intracavernosal infusion using standard peripheral intravenous (IV) catheter equipment.

**Methods:** Men undergoing inflatable penile prosthesis placement were consented for intracavernosal insertion of a 16 gauge angiocatheter, just after exposure of the tunica albuginea. The angiocatheter was placed at the base of the penile shaft, on the lateral aspect and advanced proximally. Normal saline 100 cc was infused under 100 cmH2O (gravity) pressure, followed by a 60 second infusion of normal saline under 300 mmHg pressure. Time to catheter insertion, vital signs, degree of penile tumescence, and flow rates were recorded.

**Results:** Ten men underwent corpus cavernosum infusion. All angiocatheters were placed into the corpus cavernosum in less than 5 seconds. Mean patient age was 67 (range 54-75). Mean flow rate of normal saline under gravity pressure was 64 cc/min (range 18-150). Mean flow rate at 300 mmHg pressure was 159 cc/min (range 85-265). Average maximal penile tumescence was 26% (range 5-75) at gravity pressure and 54% (range 10-100) at 300 mmHg pressure. All patients experienced rapid detumescence with infusion cessation. Heart rate and blood pressure under anesthesia did not vary with infusion. No 30-day complications occurred.

**Conclusions:** Fluid delivery via the corpus cavernosum appears safe and expedient. Intracavernosal flow rates using standard peripheral IV equipment are comparable or surpass that of traditional peripheral vascular access routes. The penis should be considered as a simple, efficient alternative in the rapid fluid resuscitation of male patients with compromised peripheral vasculature.
EVALUATION OF GOPRO TO INDUSTRY STANDARD SURGICAL CAMERAS FOR ABILITY TO DEMONSTRATE SURGICAL PRINCIPALS IN RESIDENT EDUCATION

Wayne G. Brisbane, MD, Saneal Rajanahally, MD, Marc J. Rogers, MD, Lauren Trew, MM, Kevin A. Ostrowski, MD, MPH, George R Schade, MD, Hunter B. Wessells, MD, Thomas J. Walsh, MD
(Presentation to be made by Dr. Wayne Brisbane)

Introduction: We have previously demonstrated that viewing videos in preparation for surgery is an efficient means of conveying anatomy, procedural steps and technique. Industry-leading loupe-mounted cameras cost around $5000, and require direct connection to a laptop computer for power and data storage. While this works well, it requires cooperation from the operating room staff and adequate time for setup. Conversely, GoPro’s latest Session camera is self-contained, voice-operated, and low-cost (~$300). We compared two industry-leading loupe-mounted cameras to the GoPro for video quality in the operating room. Secondary outcomes included assessment of how residents use video and barriers to resident utilization of video recording in the operating room.

Methods: We utilized three camera systems, LoupeCam (LoupeCam, Scottsdale, AZ), NanoCam (Designs for Vision, Long Island, NY), and GoPro Hero 5 Session (GoPro, San Mateo, CA) to record a varicocelectomy. The stock lens and first take recording was used for each camera. Magnification was highest for the NanoCam, followed by the LoupeCam, and finally the GoPro. Videos were edited and distributed with an evaluation survey to 20 urology residents from the University Washington and Virginia Mason Hospital. The video clips and survey are available for review at: https://goo.gl/BP3VJg. The survey initially blinded residents to the cameras and asked which camera best demonstrated 6 surgical principles as shown in the table. Residents were then un-blinded to cost differences and asked which surgical principles could adequately be demonstrated with the GoPro alone.

Results: The survey response rate was 85%. Residents felt the LoupeCam best demonstrate surgical anatomy (59%), tissue handling (76%) and surgical exposure (59%). The GoPro was felt to best demonstrate economy of motion (65%), and was equal to the LoupeCam in demonstrating procedural steps (47%) and instrument handling (47%). When un-blinded, 100% of residents felt that the GoPro adequately demonstrated procedural steps. Regarding use, 94% wanted to use the video to review procedural steps, and 76% though the clips could improve surgical technique and case presentations. Lack of time was a barrier to implementing video for 94% of residents.

Conclusions: We demonstrated that compared to other surgical cameras, the GoPro Hero 5 Session is preferable or equal in demonstrating procedural steps, instrument handling, and economy of motion. Anatomy, tissue handling and surgical exposure require increased magnification. Residents likely preferred the magnification level rather than the actual camera system. Residents felt that they would most likely use OR video for evaluating procedural steps; in this domain, GoPro performed equally to more expensive cameras. Limited time was the most commonly cited barrier to implementation of surgical video review.

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RETROPUBIC RADICAL PROSTATECTOMY WITH ONE NIGHT HOSPITAL STAY: WHICH IS THE BEST ANAESTHESIA?

Alessandra Ambu*, MD, Stefano Guercio*, MD, Mauro Mari*, MD, Mariateresa Carchedi*, MD, Francesco Mangione*, MD, Maurizio Bellina*, MD; Turin, Italy.
(Presentation to be made by dr. Alessandra Ambu)

Introduction: In recent years, the need to decrease healthcare costs has encouraged the practice of early discharge after prostate cancer surgery. During the last decades, radical retropubic prostatectomy (RRP) has refined its technique, becoming in selected patients a “limited” procedure. Combined spinal-epidural anaesthesia (SEA) is considered the gold standard for RRP, thanks to the optimal analgesia in the immediate postoperative course. Nevertheless, as known, this technique requires a proper observation period (at least 24 hours) after the epidural catheter removing, due to the risk for epidural haematoma. Several Authors recently described their experience with early discharge after laparoscopic or robot-assisted radical prostatectomy under general anaesthesia (GA). Aim of our study was to evaluate whether spinal anaesthesia (SA) plus oral oxycodone/naloxone could facilitate discharge within 24 hours after RRP, compared to GA plus oxycodone/naloxone.

Methods: From January 2015 to February 2016, 20 selected patients with localized prostate cancer were proposed to undergo to “limited” RRP (LRRP), with the possibility to be discharged after 1 night of postoperative hospital stay. LRRP includes minimal skin incision (about 8 cm), and nerve- and seminal sparing procedure (Hauri, Urology 2000), with the aid of a water-jet dissector and without lymphadenectomy. Patients inclusion criteria: PSA <10 ng/ml, GS≦ 7 (3+4); <30% biopsy positive cores; MRI negative for extracapsular disease; age ≦ 65 ys; ASA < 3.

Patients were randomized into two groups, according to the received anaesthesia. Group 1 (GP1) received a SA with 15 mg bupivacaine plus oral oxycodone/naloxone 10 mg twice a day, starting 2 hours prior the LRRP, and then repeated every 12 hours for 2 days postoperatively. Group 2 (GP2) received a GA, with oral administration of oxycodone/naloxone 10 mg twice a day, starting 2 hours prior the LRRP, and then repeated every 12 hours for 2 days postoperatively.

At 24 hours postoperatively, immediate discharge was evaluated, under following conditions: absence of medical complications; visual analogue score for pain (VAS) score <4; drainage of less than 50 mL; normal oral feeding tolerance; bowel function return, no haematuria.

Patients satisfaction was evaluated 15 days postoperatively by means of the validated PSQ-18 questionnaire, which includes 18 items, each scored 1-5, high scores reflecting satisfaction with medical care.

Results: Mean VAS score for GP1 and GP2 on 1st day postoperatively was 2.44 and 2.22 respectively. In group 1: all patients could be discharged 1 day postoperatively; no major or minor complications occurred during the hospital stay. In group 2: only 6 patients (60%) could be discharged on the day after surgery; 1 patient had postoperative nausea and vomiting; 2 patients had delayed bowel function return; 1 patient had difficult unassisted ambulation. After discharge, no early or late hospital readmission was recorded. In GP1, patients satisfaction was extremely high: mean PSQ-18 score was 85 (range 72-90). In GP2, patients satisfaction mean score was 80 (range 70-87).

Conclusions: In our preliminary study, LRRP with SA+oxycodone/naloxone permits discharge within 24 hours postoperatively in a larger number of patients compared to GA, with high patients satisfaction and hospital costs reduction.
THE EFFICACY OF THE COMBINATION OF FOSFOMYCIN AND AMIKACIN ANTIBIOTIC PROPHYLAXIS REGIMEN PRIOR TO TRANSRECTAL ULTRASOUND GUIDED NEEDLE BIOPSY OF THE PROSTATE ON THE INFECTIOUS COMPLICATIONS OF THIS PROCEDURE

Younis Taher*md,Phd, Haluk Ozen md Prof, Bulent Akdogan md,Ass Prof, Serhat Unal md,Prof, Hakan Haberal,md

INTRODUCTION AND OBJECTIVES: Infectious complications of transrectal ultrasound guided needle biopsy of the prostate are one of the major morbidities of the procedure as it may necessitate hospitalization and further management. Antibiotic prophylaxis plays an important role in decreasing such complications. The aim of this study is to compare the efficacy of two different antibiotic prophylaxis regimens on hospitalization rate due to infectious complications.

METHODS: Patient files between January 2011 and March 2016 were retrospectively reviewed. There were 2 groups regarding prophylactic regimens. First group between January 2011 and December 2012 received Ampicillin/Sulbactam where the latter group between January 2013 and March 2016 received fosfomycin + amikacin prior to the procedure. Hospitalization rates due to infectious complications were the main comparative parameter. Patient characteristics (age, total and free PSA levels, prostate size, biopsy pathology, number of cores, comorbidities) were noted.

RESULTS: A total of 831 patients were found in the first group and 540 patients were found in the second group. Fifty-two patients were hospitalized in the first group while only 20 patients required hospitalization due to infectious complications in the latter group. The hospitalization rates after procedure due to infectious complications were 6.2% and 3.7%, respectively indicating a %41 decrease in hospitalization rate in amikacin + fosfomycin group.

CONCLUSIONS: Our results indicate fosfomycin+amikacin antibiotic prophylaxis regimen when compared with Ampicillin/Sulbactam, decreases hospitalization rates due to infectious complications by 41%.
HEMI-ABLATION OF THE PROSTATE USING HIFU FOR THE MANAGEMENT OF PROSTATE CANCER
Ashok J Kar MD: Orange, CA

Introduction: Prostate Cancer is the most common cancer in American Males. Traditional treatments using Surgery and Radiation are effective but have significant resulting morbidity including Incontinence, ED and Ejaculatory dysfunction. With the introduction of newer modalities of diagnosis and treatment, we present a novel method of treating Prostate Cancer while minimizing resultant morbidity.

Methods: We reviewed the outcomes of 20 patients with Prostate Cancer treated with Hemi-ablation of the Prostate over the past 4 years. All patients were diagnosed using in-office biopsies or MRI-Fusion biopsies using Koalis equipment. After diagnosis, all biopsies were sent for Genomic testing and based on the results, patients were counseled about Active Surveillance or active management. If the MRI showed significant disease bilaterally they were treated with Robotic Surgery and/or IMRT. For patients with unilateral involvement and MRI showing lesions with PIRADS IV or V lesions corresponding to the side of positive biopsies, they were counseled about Unilateral HIFU. Patients were treated with the Sonacare HIFU Equipment in the Bahamas and recently in Tustin CA and all follow-up was done locally. All procedures were done as an outpatient and a Foley catheter was left indwelling for 5-18 days. All patients had follow-up PSA every 3 months and follow-up MRI with fusion biopsies at 6 months.

Results: Of the 20 patients the results are as follows:
1 has residual cancer on the treated side with Gleason 6 and has opted for Active Surveillance. No progression 4 years after initial hemi-ablation. 1 was treated with HIFU for a Gleason 7 lesion. He was subsequently biopsied bilaterally and has no residual cancer on the treated side but developed a Gleason 6 lesion on the contralateral side which is being followed with AS.
All patients had a baseline PSA between 6 and 18 and Gleason scores between 6 and 8. Follow-up PSAs are in the range of 0.4 to 2.1. All patients have had a reduction of at least 60 percent of the baseline PSA levels. 12 of 16 patients continue to have Erectile and ejaculatory function. 4 patients developed ED inspite of oral agents. 4 patients had ED prior to therapy. 1 patient developed a urethral stricture which is being managed with self-dilations.

Conclusion: Hemi-ablation with HIFU is an effective treatment for selected patients with Prostate Cancer and is associated with minimal morbidity.
Introduction: The Urolift Prostatic Urethral Lift is a minimally invasive procedure approved to treat lower urinary tract symptoms due to benign prostatic hyperplasia. We have used Urolift exclusively in the office setting and present our results treating Acute Urinary Retention using the Urolift system.

Methods: We reviewed the outcomes of using Urolift in 20 patients with acute urinary retention due to BPH over the past 18 months. All patients had indwelling foley catheters in place and had failed attempts at voiding using alpha blockers and 5Alpha reductase inhibitors. All patients were evaluated with in-office flexible cystoscopy to determine prostate size and anatomy. The Urolift was done in the office using a local anesthesia protocol and oral sedation with benzodiazepines. At the conclusion of the procedure the bladder was filled and patients were discharged without a catheter if able to void. If unable to void a catheter was reinserted and a voiding trial was given 3-5 days later. Alpha blockers were discontinued 2 weeks after therapy. Follow-up was done at regular intervals and most patients are at least 3 months since treatment. Follow-up consists of completion of an IPPS score and post-void residuals.

Results: Of the 20 patients treated with urinary retention, 8 (40 pct) voided after the procedure and were sent home without a catheter. Of the 12 remaining patients 10 voided at a second voiding trial and are catheter free. 2 (10 pct) failed therapy and multiple voiding trials and required subsequent Bipolar TUR-P. The post-void residuals on these patients are between 4 and 180 ml. Significant improvement in IPPS and QOL scores were seen in 60 pct of patients. 6 patients (30 pct) have continued alpha blockers and 5ARIIs. 2 patients experienced bleeding after treatment and required temporary catheter placement. None requiring hospitalization. No cases of Incontinence occurred. Irritative voiding symptoms were recorded in 8 (40 pct) but resolved after several weeks. 2 patients with Radiation after prostate cancer were treated with good outcomes.

Conclusion: In-Office Urolift is an effective treatment in the management of acute urinary retention and can be safely performed in the office setting with minimal morbidity.

Disclosure: Dr Kar is a Proctor for Neotract but does not receive any compensation for this study.
RISK ASSESSMENT IN PATIENTS WITH LOW LEVEL PSA DETECTION AFTER ROBOT-ASSISTED LAPAROSCOPIC PROSTATECTOMY

Matthew N. Simmons, Timothy Krigbaum, Michelle Fitts, Andrew D. Neeb
Urology Specialists of Oregon, Bend, Oregon, USA

Introduction: Ultrasensitive PSA assays allow for detection of sub-0.1ng/dL PSA levels after robot-assisted laparoscopic prostatectomy (RALP). This can result in anxiety and possible unnecessary secondary therapy in these patients. This study aimed to better characterize PSA trends after RALP in patients with low-level PSA detection, and to identify risk factors for development of biochemical recurrence.

Methods: Patient data was reviewed for 130 patients who underwent RALP between January 2013 through May 2016. A control group was composed of 74 patients with undetectable PSA for ≥12 months after RALP. The study group included patients with localized node-negative disease who had PSA levels between 0.014-0.2ng/dL at initial detection. Analysis was conducted using rising PSA trend as an endpoint to identify risk factors for recurrence. Student’s t-test and univariate and multivariate linear regression analyses were used to compare differences among study groups.

Results: Three clear PSA trends were observed: fizzle, stability and rise. The mean PSA in each group at initial detection was equivalent and ranged from 0.038-0.058ng/dL. Mean rate of decrease in the fizzle group was 0.005ng/dL/month. Mean rate of rise in the rising PSA group was 0.01ng/dl/month. Patients with a rising PSA trend had higher preoperative PSA (p=0.006), Gleason score (p=0.004), positive margin rate (p=0.002) and genetic test score (GTS; p=0.004). Detection of PSA at 6 weeks after RALP, and/or an initial PSA level ≥0.1ng/dL were associated with a rising PSA trend. Risk-stratified multivariate regression analysis identified early PSA detection <6month after surgery as the factor most strongly associated with PSA rise (p<0.001), followed by GTS (p=0.006) and initial PSA level >0.1ng/dL (p=0.003) as strong secondary risk factors.

Conclusions: Low level PSA <0.1ng/dL after RALP does not uniformly equate to biochemical recurrence. Of patients with detectable PSA ≤0.1ng/dL in this cohort 61% exhibited a rising PSA level, while the remaining 39% exhibited stability or fizzle. It is important to follow PSA levels for at least 12 months after RALP to clearly identify a trend prior to commitment to secondary therapy. Risk factors for rising PSA include initial PSA detection <6 months after RALP, an initial PSA level >0.05 and high GTS. Future studies may validate genetic testing as a principal adjunct for management of sub-0.1ng/dL PSA recurrence after RALP.
Objective: The male genitourinary (GU) exam, which includes the testicular (TE) and the digital rectal examinations (DRE), is generally taught in the pre-clinical years with the expectation that students will practice during clerkships. Unfortunately, studies show significant variation in student experience. Thus, our objective was to measure students' experiences, attitudes, and confidence with the male GU exam and to identify the clinical settings where they practice this skill.

Methods: Using Qualtrics, we created a web-based survey which was distributed to students in their final year at the Saint Louis University School of Medicine. Subjects were asked about their training, experience, attitudes, confidence, and barriers with respect to the TE and DRE. Subjects were also asked to identify career interests, relevant rotations, indications for the exam, and beliefs about prostate cancer screening. Likert Scale questions were used to assess attitudes and confidence.

Results: 40 students completed the survey. All students were trained on the GU exam. 90% performed between 0-10 TEs and 0-5 DREs, with a median of 3 TEs and 1 DRE. 47% performed less than 2 TEs and 42% never performed a DRE. Female gender was associated with less TE and DRE experience (p = .022) and reduced confidence (p<0.001). Less than 15% of students reported attending physician supervision. The majority of TEs were done on pediatric, family medicine, and surgery rotations. Most DREs were performed on family medicine, internal medicine, and surgery rotations. 50% felt confident in identifying an abnormal TE, compared to 30% with the DRE. Female gender was also correlated with lower confidence in performing TEs (p=.001) and DREs (p=.003). Barriers included lack of opportunities (90%) and comfort (57%). 75% believed the DRE should be offered to men with a family history of prostate cancer, but 37.5% were unsure if a DRE should be offered to Latino/African-American men. 70% also believed the USPSTF recommendations for PSA screening also extend to DREs.

Conclusions: The data demonstrate a dearth of experience with the male GU exam that impacts student’s confidence in initiating, performing, and interpreting exams. Our study also specifies significant barriers alongside potential avenues for improvement, including concentrated teaching efforts by higher-yield clerkships and clearer education around the role of the DRE in clinical practice.
DIAGNOSTIC ACCURACY OF MULTIPARAMETRIC MAGNETIC RESONANCE IMAGING FOLLOWING PROSTATE CANCER FOCAL THERAPY WITH IRREVERSIBLE ELECTROPORATION

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Sydney, Australia & Amsterdam, the Netherlands.
(Presentation to be made by Dr. Matthijs J Scheltema)

Background and objectives: Follow-up after primary focal therapy for localized prostate cancer (PCa) includes monitoring with multiparametric Magnetic Resonance Imaging (mpMRI). However, no diagnostic accuracy studies have been published on mpMRI following focal therapy. The objective of this study was to determine the diagnostic accuracy of mpMRI in the follow-up after FT with irreversible electroporation (IRE).

Methods: Seventy-six patients with biopsy-proven localized PCa underwent primary IRE between February 2013 and March 2016. Fifty patients received consecutive follow-up mpMRI at 6 months, serial PSA testing and transperineal template mapping biopsies (TTMB) at 12 months in one referral center. mpMRI were reported for outfield regions of interest (ROI) using the second version of PI-RADS. A binary outcome was given for the infield ablation zone (suspicious vs. non-suspicious). Sensitivity, specificity, positive (PPV) and negative predictive values (NPV) were primarily evaluated for definition 1 significant PCa (Gleason ≥4+3 or maximum cancer core length (MCCL) ≥6 mm) for both outfield and infield ROI. Secondary evaluation was performed for definition 2 significant PCa (Gleason ≥3+4 or MCCL ≥4 mm). Multivariate linear regression analyses were performed to evaluate the additional value of nadir PSA.

Results: Sensitivity, specificity, PPV and NPV of infield ROI for definition 1 was 43%, 86%, 33%, 90% and 38%, 86%, 33%, 88% for infield definition 2 respectively. For outfield ROI this was 33%, 82%, 20%, 90% for definition 1 and 38%, 86%, 50%, 80% for definition 2, respectively. Nadir PSA could not significantly predict residual PCa.
In 10 patients with a negative mpMRI, 7 regions with definition 1 and 10 regions with definition 2 significant PCa were detected on TTMB. Anatomical discordance was present in 3 patients with a positive mpMRI. Only 3 regions in 2 patients had a Gleason Score ≥7 that contained a MCCL of ≥4mm.

Conclusions: mpMRI could accurately predict the absence of definition 1 significant PCa with NPVs of 90%. Follow-up biopsies should not be deferred due to the low sensitivity and PPV of identified ROI.

Source of Funding: M. Scheltema received a PhD grant from the Cure for Cancer Foundation and a fellowship grant the Australian Prostate Cancer Research Centre-NSW.
GENITO-URINARY FUNCTION AND QUALITY OF LIFE AFTER FOCAL IRREVERSIBLE ELECTROPORATION OF DIFFERENT PROSTATE SEGMENTS

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Sydney, Australia & Amsterdam, the Netherlands.
(Presentation to be made by Dr. Matthijs J Scheltema)

Background and objectives: Several ablative modalities are available for focal therapy of localized prostate cancer (PCa). To improve this PCa treatment option it is essential to identify per available modality the ideal prostate segments and system settings. This study evaluates genito-urinary function and quality of life (QoL) following ablation of different prostate segments using irreversible electroporation (IRE).

Methods: Patients that received primary focal IRE for organ-confined PCa were analysed on genito-urinary function and QoL per prostate segment treated (anterior vs. posterior, apex vs base vs apex-to-base, unilateral vs bilateral). IRE system settings and patient characteristics were compared between patients with preserved versus deteriorated genito-urinary function. Data was prospectively collected at baseline, 3, 6 and 12 months using the Expanded Prostate Cancer Index Composite, AUA symptom score, SF-12 Physical and Mental Component Summary surveys. The Wilcoxon’s Signed Rank Test and Mann-Whitney U Test were performed to evaluate significant differences within segments over time or between segments in paired and unpaired continuous variables.

Results: Sixty patients were included. There were no significant changes in the entire cohort for overall urinary, bowel, physical and mental genito-urinary function scores and QoL domains at 6 months. Deterioration of sexual function scores was demonstrated at 6 months within all prostate segments. There were no significant differences found in genito-urinary function or QoL between prostate segments or applied system settings. Patients with poor baseline sexual function or higher age at time of treatment were significantly more at risk to develop erectile dysfunction following IRE.

Conclusions: IRE is able to preserve genito-urinary function and QoL in all prostate segments, with promising rates of preserved urinary continence and erectile function. Future studies with larger cohorts may result in the optimization of system settings to further improve the ability to preserve genito-urinary function.

Source of Funding: M. Scheltema received a PhD grant from the Cure for Cancer Foundation and a fellowship grant the Australian Prostate Cancer Research Centre-NSW.
Objective: Magnetic resonance imaging (MRI)-guided prostate biopsy has been shown in a number of studies to improve the detection of clinically significant prostate cancer (csPCa). In this study, we aim to review our initial experience with the UroNav system (In Vivo Corp./Philips) for MRI-transrectal ultrasound fusion prostate biopsies.

Methods: Consecutive patients were registered into a prospective institutional review board–approved database (DSRB 2015/01252) assessing MRI-targeted prostate biopsy in our institution. We reviewed patients who underwent biopsy from 1 May 2016 to 26 February 2017. Inclusion criteria for our study were patients with at least one Prostate Imaging – Reporting and Data System (PIRADS) 3 or higher lesion on multi-parametric (mp) MRI and who underwent both targeted and systematic prostatic biopsies in the same sitting. The primary objective was to compare targeted and systematic biopsy approaches for the detection of csPCa (which we defined as any Gleason score ≥ 7 cancer).

Results: 71 patients were included in the study. 56 patients (78.9%) had a previous negative prostatic biopsy. The number of patients with at least one PIRADS 3, 4 or 5 lesion were 39 (54.9%), 23 (32.4%) and 9 (12.7%) respectively. The detection rates for csPCa for patients with PIRADS 3, 4 or 5 lesions were 7.7%, 39.1% and 77.8% respectively. In comparison, 18.3% of patients had csPCa detected on systematic biopsy. Targeted biopsies demonstrated higher sensitivity for the detection of csPCa compared to systematic biopsies (90.5% versus 61.9% respectively, p=0.03). If only targeted biopsy was performed, 2 (9.5%) cases of csPCa would have been missed. On the other hand, systematic biopsy missed 8 (38.1%) cases of csPCa.

Conclusions: Targeted prostate biopsies demonstrated higher sensitivity for the detection of csPCa compared to systematic biopsies, with a significant proportion (38.1%) of csPCa detected on targeted biopsies only. However, systematic biopsies should not be omitted as a proportion (9.5%) of csPCa may otherwise be missed with a targeted biopsy-only approach.
COMMUNITY-BASED OUTREACH: A Viable Model for Prostate Cancer Screening in Marginalized, High-Risk Communities

Neil A. Mistry, MPH, Sameer Siddiqui, MD, Ricardo Wray, PhD, Carl Freter, MD PhD, Delphine Yates, Michell Nickerson: St. Louis MO

(Presentation to be made by Mr. Neil A. Mistry)

Objectives: Prostate cancer (PC) is the second most common cancer in males. However, screening for PC is controversial as the United States Preventative Services Task Force recommended against universal Prostate Specific Antigen (PSA) testing. In spite of this, both the AUA and the American Cancer Society recommend to clinicians to engage patients in shared-decision-making (SDM) to discuss the risks and benefits screening, recognizing that certain high-risk groups like African Americans face a greater risk of both being diagnosed and dying from PC and may benefit from early detection. To this end, community-based outreach that includes community stakeholders has gained traction as a potential avenue to increase access to screening. Our objective is to share our experiences from 6 years of outreach and demonstrate effectiveness in offering services to medically underserved communities.

Methods: Since 2010, the Saint Louis University Cancer Center and The Empowerment Network – a PC survivor support group, have partnered with local employers, churches, and community groups to organize outreach events throughout the St. Louis area that offer men in the community a free PSA-blood test. The process involves a short presentation from a PC survivor and a SDM encounter with a trained clinical educator where topics such as the value, interpretations, and risks of PSA screening are discussed. Participants are then given a choice to get screened. Those who choose to get screened receive a letter in the mail with their results and follow-up calls to determine their course.

Results: A total of 1,831 men were screened over a 6-year period. The majority of participants had private insurance (57.7%), Medicare/Medicaid (22.9%), or were uninsured (15.1%). 12.6% of participants had a family history and 1.6% had a personal history of PC. After SDM, more than 84% indicated understanding the PSA’s purpose and interpretation and PC mortality and treatment. In regards to the potential side effects of PC treatment and risk of overtreatment, 75% indicated understanding. Overall, 8.93% (157) of men screened had an abnormal PSA that was greater than 2.5 ng/mL, with 3 men reporting undergoing a biopsy and one case of PC identified (Gleason grade 6).

Conclusion: Applying a community-based approach to involve the relevant stakeholders and using survivor groups in conjunction with clinical educators provides a viable model through which free PSA screenings can be offered to help address local-level health disparities in a manner that empowers patients.
CONCURRENT VALIDATION OF AUTOMATED EVALUATION OF ROBOTIC SURGERY PERFORMANCE: CORRELATION OF PERFORMANCE METRICS TO GLOBAL EVALUATIVE ASSESSMENT OF ROBOTIC SURGERY (GEARS)

Jian Chen* M.D., Los Angeles, CA, Anthony Jarc Ph.D., Sunnyvale, CA, Hooman Djaladat M.D., Los Angeles, CA, David Hatcher M.D., Los Angeles, CA, Inderbir S. Gill M.D., Los Angeles, CA, Andrew J. Hung M.D.: Los Angeles, CA

Introduction: Global Evaluative Assessment of Robotic Skills (GEARS) is an extensively validated but subjective and time consuming robotic surgical performance evaluative method. With a novel recording solution (“dVLogger”), we correlated objective surgeon performance metrics to GEARS during select steps of the robotic radical prostatectomy (RRP), attempting to standardize and objectify robotic surgical performance evaluation.

Methods: Performance data were captured, and surgical footage were recorded from surgeons performing two steps of RRP: seminal vesicles dissection (SVD), anterior vesicourethral anastomosis (AA), using the “dVLogger” provided by the research team at Intuitive Surgical. Also, the video clips of these surgical steps were blindly evaluated by three expert robotic surgeons using GEARS. Inter-observer reliability among raters was estimated using intraclass correlation (ICC). Performance metrics were correlated to GEARS using the Spearman’s analysis.

Results: We evaluated 70 cases of robotic radical prostatectomy. Eighteen surgeons participated. The ICC of three evaluators was 0.6 for SVD and 0.7 for AA. For both steps, task completion time was negatively correlated to all GEARS items and total score (p<0.05), and dominant instrument moving velocity was correlated to all GEARS items and total GEARS score (p<0.05). For SVD, instrument economy of motion was negatively correlated to depth perception (p=0.001), bimanual dexterity (p=0.001), efficiency (p<0.001) and total GEARS score (p=0.001). Frequency of energy apply was correlated to efficiency (p=0.04), robotic control (p=0.037). For AA, frequency of camera position adjustment was correlated to depth perception (p=0.016), efficiency (p=0.01), robotic control (p=0.025) and total GEARS score (p=0.01) (Table).

Conclusion: Statistical correlation was found between key automated metrics and subjective GEARS scores during a dissection and suturing step of RRP. Strong correlation between metrics and GEARS scores may suggest agreement in evaluation of a surgeon’s performance, disagreement or lack of statistical correlation does not infer that automated assessment or GEARS is superior. Further refinement of this analysis with more tailored performance metrics as well as correlation to clinical outcomes may better delineate the relative value of automated assessment to GEARS.
**THE LEARNING CURVE OF SELECTIVE STEPS OF ROBOTIC RADICAL PROSTATECTOMY BASED ON OBJECTIVE SURGICAL PERFORMANCE METRICS**

Jian Chen* M.D., Los Angeles, CA, Anthony Jarc Ph.D., Sunnyvale, CA, Inderbir S. Gill M.D., Los Angeles, CA, Andrew J. Hung M.D.
Los Angeles, CA

**Introduction:** During its initial diffusion period, robotic radical prostatectomy (RRP) was associated with an increased adjusted risk for patient safety. Limited duty hour and increasing patient safety consideration put urological residents in the situation of further lack of solid training. With the “dVLogger” provided by Intuitive Surgical, we can objectively study the learning pattern of robotic surgery. Herein, we present the learning curve of selective steps of robotic radical prostatectomy based on objective surgical performance metrics.

**Methods:** We selectively chose 4 RRP steps performed on da Vinci Si systems: bladder mobilization (BM), seminal vesicles dissection (SVD), anterior vesicourethral anastomosis (AA) and right pelvic lymph nodes dissection (RLD). Surgical performance metrics captured by “dVLogger” during these steps, such as, step completion time, instruments economy of motion, and dominant instrument moving velocity were studied. These performance metrics were plotted against the prior console cases experience of the conducting surgeons for each surgical step, and trend lines were generated based on the scatter plots. Caseloads needed for 50% and 75% of performance improvement were calculated based on the trend line formula. The characteristics of each learning curve were analyzed and compared across different steps. One way ANOVA was used to compare the caseloads needed for improvement of all 4 steps.

**Results:** Four surgical steps of 60 RRP performed by 15 surgeons (median 55 (range 5-450) console case experience) were analyzed. Surgical performance metrics learning curves show consistent trends (Figure). With increasing experience, each of the 4 steps took less time to complete, surgeon’s instruments economy of motion improved, and average dominant instrument velocity increased. For BM, SVD, AA, RLN, the caseloads needed for 50% improvement of task completion time were 23, 40, 32, 75 respectfully; the caseloads needed for 50% improvement of instrument economy of motion were 28, 81, 43, 85; the caseloads needed for 50% improvement of dominant hand velocity were 41, 55, 70 and 111 (p=0.02). Of the above 3 surgical performance metrics, the caseloads needed for 75% improvement for BM was 74-117, 109-244 for SVD, 85-180 for AA, and 145-215 for RLN (p=0.17).

**Conclusion:** The learning curves showed that surgical performance improved with increasing experience. Although some steps required more caseloads to improve than others, proficiency of all 4 surgical steps could be achieved after 80 to 200 RRP cases.

**Figure.** Learning curve for BM, SVD, AA, and RLN
THE INFLUENCE OF DECISION AIDS ON PROSTATE CANCER SCREENING: IS PROVIDER RELATIONSHIP IMPACTFUL?


(Presentation to be made by Andrew Stamm)

Introduction: Shared decision making (SDM) is widely encouraged by both the American Urological Association (AUA) and Choosing Wisely for prostate cancer (CaP) screening. Implementation of SDM is challenging secondary to time constraints and competing patient priorities. One strategy to mitigate the difficulties in implementing SDM is to utilize a decision aid (DA). Here we update our series evaluating whether a DA improves a patient’s CaP knowledge and affects PSA screening rates. Additionally, we investigate the impact of the length of the patient-provider relationship in this context.

Methods: Patients were randomized to usual care (UC), DA, or DA+SDM. Perception of quality of care was measured using the CAHPS survey. Outcomes were stratified by long-term provider relationship (LTPR, >3 years) versus short-term provider relationship (STPR, <3 years). Knowledge of CaP screening and the decision regarding screening were assessed. Groups were compared using ANOVA and logistic regression models.

Results: A total of 329 patients were randomized. Patients in the DA+SDM arm were significantly more likely to report discussing the implication of screening (33% DA+SDM, 22% UC, 16% DA, p=0.0292) and answered significantly more knowledge questions correctly compared to the UC arm (5.03 vs 4.46, p=0.046). Additionally, those in the DA arm were significantly less likely to report that they always felt encouraged to discuss all health concerns (72% DA, 78% DA+SDM, 87% UC, p=0.0285). Interestingly, STPR patients in the DA arm were significantly more likely to undergo PSA-based CaP screening (41%) than the UC arm (8%, p=0.019). This effect was not observed in the LTPR group.

Conclusions: Providing patients a DA without a personal interaction resulted in a greater chance of undergoing PSA-based screening without improving knowledge about screening or understanding of the consequences of this decision. This effect was exacerbated by a shorter-term provider relationship. With complex issues such as the decision to pursue PSA-based CaP screening, tools cannot substitute for direct interaction with a trusted provider.
TRANSURETHRAL RESECTION OF THE PROSTATE (TURP): A COST ANALYSIS OF BIPOLAR AND MONOPOLAR TECHNOLOGIES

David A. Gregory*, MPA, Brittany E. Blau*, MPH, Christina L. Cool*, MPH, New York, NY
(Presentation to be made by Ms. Christina Cool)

Introduction: Literature comparing clinical outcomes of patients undergoing bipolar and monopolar transurethral resection of the prostate (TURP) procedures find bipolar TURP procedures have lower rates of TUR syndrome, blood transfusions, and clot retention. The National Institute for Health and Care Excellence concluded bipolar TURP is associated with fewer complications and lower overall costs when considering the cost of adverse events. To determine the economic impact of clinical differences observed in the literature for procedures in the United States, the present study evaluated hospital cost differences between bipolar and monopolar TURP procedures, comparing procedure setting, length of stay (LOS), and total cost.

Methods: TURP procedures were identified and then examined in the Medicare Inpatient and Outpatient Standard Analytic Files (01/01/2014-09/30/2015). Procedure setting, total cost (treatment, complications, and device costs), and LOS were analyzed for 416 bipolar and 539 monopolar procedures in 34 hospitals.

Results: Bipolar cases were admitted 41% less than monopolar (p<.001). When admitted, bipolar cases were 27% less expensive (p<.008) and had a shorter LOS (p=.064). Bipolar inpatient cost savings of 22%-48% were seen in laboratory, operating room, pharmacy and room costs, with over 60% savings in intensive care. Outpatient costs were 66% less than inpatient (p<.001). Bipolar index outpatient costs were not statistically different from monopolar after removing hospitals with substantially different costs than the average (“outlier hospitals”) (p=.179). Modeled savings show overall bipolar procedure costs were $667.78 less per patient than monopolar ($1,099.66 less for inlier hospitals).

Conclusion: Bipolar TURP generates cost-savings when accounting for procedure setting and care efficiencies. Clinical evidence of reduced complication rates among bipolar TURP procedures compared to monopolar TURP help to explain procedure setting differences and the large differential among inpatient costs. This is the first US study to show how care efficiency benefits can offset cost differences between TURP technologies while also improving patient experience.

<table>
<thead>
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<th>Measure</th>
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</table>

Source of Funding: Funded by Olympus Corporation of the Americas.
Background: Androgen deprivation therapy (ADT) is the standard of care for metastatic prostate cancer. Previously, in a head-to-head comparison of long-acting, polymer-delivered, subcutaneously administered leuprolide acetate (SC-LA) and microsphere intramuscularly administered LA depot (IM-LA) in healthy subjects, SC-LA demonstrated extended drug delivery compared to IM-LA (duration of serum leuprolide detection above the level of quantitation ranged from 42-56 days vs 14-35 days, respectively), as well as prolonged testosterone (T) suppression (median serum T began to increase by Day 35 in IM-LA group vs Day 56 for SC-LA). The objective of this study was to evaluate the safety and pharmacokinetics (PK) of SC-LA in orchiectomized, advanced prostate cancer patients to confirm and compare the PK results from the prior head-to-head study¹. Orchiectomized patients were chosen to identify treatment emergent events attributed to the effects of the study drug itself vs the effects of lowering T to castrate levels, which had already been achieved by orchiectomy.

Methods: In this open label, single dose study, male, orchiectomized prostate cancer patients (ages 45-85) received a single dose of 7.5 mg SC-LA (labeled for 1 month dose interval). Blood samples were taken at baseline and at scheduled visits up to day 56. LA concentration in serum was analyzed by high performance liquid chromatography. PK parameters area under the curve (AUC), maximum concentration (Cmax), time to Cmax (Tmax), t1/2 and concentration-time data were evaluated and adverse events (AEs) were assessed.

Results: The study was conducted in 8 males with prostate cancer (mean age=72.5 y). Following administration, there was an initial rapid absorption phase with maximal concentrations observed at 2-6 hours. Serum LA declined slowly over 4-6 days and remained above 0.1 ng/mL, the level associated with T suppression, for a mean of 37 days (range 28-49). Mean Cmax was 26.3 ±12.6 ng/mL with a mean Tmax of 3.79 ±1.39 h. AUC was 999 ±247 ng*h/mL. There were no serious treatment-related AEs and no subjects discontinued the study due to an AE.

Conclusions: LA administered as a single, monthly SC dose via a polymer in situ forming delivery system in orchiectomized prostate cancer patients demonstrated extended drug delivery and T suppression 3 weeks past the dosing interval, mirroring extended PK in healthy subjects, which may be attributed to the ATRIGEL® Delivery System technology. The pharmacokinetic profile of SC-LA demonstrates effective drug release throughout and beyond the labelled dosing interval.


Funding Source: TOLMAR, Inc.
POLYMER DELIVERED, SUBCUTANEOUSLY ADMINISTERED LEUPROLIDE ACETATE PROVIDES STABLE AND LONG-TERM DRUG DELIVERY ABOVE 0.1 NG/ML TO SUPPRESS TESTOSTERONE BELOW 20 NG/DL ACROSS 4 PIVOTAL TRIALS


(Presentation to be made by Dr. Dan Barocas)

Background: The optimal treatment strategy in advanced prostate cancer, an androgen sensitive tumor, is using androgen deprivation therapy (ADT) to suppress testosterone (T) thus inhibiting proliferation of malignant cells. The target for T suppression levels with ADT should be comparable to those seen following bilateral orchiectomy. Although the historical threshold definition of castration is T ≤50 ng/dL, increasing evidence suggests a T lower than 20 ng/dL may improve clinical outcomes, including increased cancer specific survival and delayed disease progression. However, it has not been established what level of serum leuprolide acetate (LA) is required to achieve T suppression below this more rigorous threshold. To determine the level of serum leuprolide required to maintain T suppression ≤20 ng/dL in prostate cancer patients, data from 4 trials evaluating long-acting, subcutaneously (SC) administered LA formulated with a biodegradable polymer were pooled.

Method: 438 eugonadal prostate cancer patients (age 40-86) were treated with SC-LA 7.5, 22.5, 30, or 45mg delivered with a single dose lasting over 1, 3, 4, or 6 months (n=120, 117, 90, 111, respectively) in 4 open-label, fixed-dose, pivotal trials. Descriptive statistics were used to summarize the median concentration of leuprolide acetate at each time point as well as to determine level of T suppression.

Results: Over the dosing intervals of the 1, 3, 4 and 6-month SC-LA formulations, median serum leuprolide levels were consistent. Of all patients (n=438), 90-96% achieved T ≤20 ng/dL by week 6 and 90-97% maintained T ≤20 ng/dL from weeks 6-24. Pharmacokinetic (PK) assessments were done via frequent blood testing on a sub-set of 66 patients. In the pooled analysis, all 66 patients had a serum leuprolide level above 0.1 ng/mL within 4 hours of administration through week 12 with 91% (60/66) of patients achieving T≤20ng/dL by week 5 after administration.

Conclusions: These data suggest that across all doses, SC-LA achieves consistent and prolonged drug delivery and that serum LA levels above 0.1 ng/mL provide favorable T suppression below 20 ng/dL from week 6 and lasting until week 24. Consistent achievement of these levels may have implications for improved clinical outcomes, such as increased cancer specific and progression free survival.

Source of Funding: TOLMAR, Inc.
MULTI-CENTER, REAL WORLD EXPERIENCE WITH THE PROSTATIC URETHRAL LIFT (PUL)

Authors: L. Walsh, D. Grier, S. Gange, P. Cozzi

**Introduction and Objectives:** The practical value of a new medical device technology may be discerned through widespread “real-world” experience with the technology. The Prostatic Urethral Lift (PUL) is a minimally invasive treatment for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) that has been well-documented in numerous published clinical studies and has been shown to provide rapid, significant improvement with low morbidity. Here we report on the clinical experience with PUL in a retrospective, multi-center study of real world, commercial cases.

**Methods:** During the PUL procedure, small UroLift® system implants are placed transurethrally to lift the encroaching lateral lobes and restore patency to the urethral lumen. Data pooled from 197 commercial cases performed at multiple centers in North America and Australia were examined retrospectively. 8% of patients were in urinary retention at the time of the procedure. Post-operative outcomes were assessed through measurements including the International Prostate Symptom Score (IPSS), quality of life score (QOL) and peak urinary flow rate (Qmax). Peak flow rates were only included in the analysis if the voided volume was at least 75mL.

**Results:** The average age was 67 years (range 40-101). Average prostate size was 54.1cc (19-160cc). Average number of implants was 3.8 (2-10). LUTS improvement was significant, with 29-42% average improvement during the follow up periods (Table 1, p values < 0.0001). QOL improved by 61% at 1 year (4.3 at baseline vs. 1.7 at 1 year, p<0.0001). Qmax improvement was slight throughout.

**Conclusions:** In this largest retrospective study of pooled, real world PUL cases, the data show that PUL offers rapid, significant improvement by 1 month that is stable through 12 months. These findings corroborate those published formal clinical studies demonstrating that PUL is an effective treatment option for millions of men suffering from LUTS due to BPH.

**Source of Funding:** None

Table 1: Paired outcome measures for treated patients.
Introduction and Objectives: The Prostatic Urethral Lift (PUL) uses small implants to mechanically relieve urethral obstruction and treat lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). Prior studies have shown that PUL provides rapid, significant and durable relief with minimal morbidity. Here we present the 4 year data from a crossover study in which subjects served as their own control.

Methods: 53 men underwent a control sham procedure (rigid cystoscopy) as part of a blinded, controlled study. After 3 months, when subjects and assessors were unblinded, these men crossed over to being treated with PUL. Small implants were placed transurethrally to retract the obstructing lateral prostatic lobes. They were followed for 4 years using validated measurements including the International Prostate Symptom Score (IPSS), quality of life score (QOL), BPH Impact Index (BPH II), peak flow rate (Qmax) and sexual function scores.

Results: 4 years after crossover PUL, average scores for IPSS, QOL and BPHII remained improved 39%, 42% and 35% from baseline, respectively (p<0.001). Average Qmax increased over 97% as compared to baseline (p=0.02). In contrast, average IPSS improved but returned to near baseline 3 months after sham, and Qmax remained slightly elevated. Morbidity after PUL was low; related adverse events were typically mild-moderate and transient. On average, PUL subjects returned to normal activity within 7 days. There were no reports of new onset sustained erectile or ejaculatory dysfunction.

Conclusions: The 4 year results from the crossover study confirm prior studies that show that PUL rapidly and significantly improves symptoms, quality of life and peak flow rate. Patients achieve stable, non-placebo relief that in a procedure that allows fast recovery with no compromise to sexual function.

Source of Funding: NeoTract, Inc.
DEFINING ENDPOINTS OF RECOVERY OF URINARY HEALTH AFTER PROSTATE CANCER SURGERY

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(Presentation to be made by Dr. Tristan Nicholson)

Introduction: Prostate cancer surgery, or radical prostatectomy (RP), can lead to long-term urinary health issues. “Pad-Free” is a common definition of successful outcome after RP. The purpose of this study was to compare “Pad-Free” reporting with a calculated “return to baseline” (RTB) using a standard instrument for prostate cancer urinary health related quality of life (HRQOL) outcomes.

Methods: This was an IRB-approved prospective cohort study of 105 men with clinically organ confined prostate cancer who underwent RP between 2009 and 2013 (radical retropubic prostatectomy, n = 67 or robot-assisted laparoscopic prostatectomy, n = 38). Men completed the Expanded Prostate Cancer Index Composite (EPIC) survey prior to surgery and annually thereafter. All forms were completed and returned to a data center anonymously and outside of the healthcare institution. Pad-free was defined as use of 0 pads per day on the single item survey question on pad usage. The urinary function, urinary continence, obstructive/irritative and urinary bother scores were then used for comparative analysis. RTB in these scores was defined as a post-surgery score at least 90% of the baseline score. All men had a minimum of two years of follow-up (range 2-4 years).

Results: The overall pad-free rate was 80%. Table 1 shows the percentage of pad-free men who also reported return to baseline (RTB) in urinary function, urinary continence, obstructive/irritative and bother scores.

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Urinary Function</th>
<th>Urinary Continence</th>
<th>Obstructive Irritative</th>
<th>Urinary Bother</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pad-Free (n = 84)</td>
<td>78%</td>
<td>56%</td>
<td>83%</td>
<td>71%</td>
</tr>
</tbody>
</table>

Among pad-free men, complete recovery of urinary health, as defined by RTB in all four scores was achieved in 48%.

Conclusions: Our effort at long-term cancer control with RP carries with it the potential for long-term declines in urinary HRQOL. Our study found that the use of a pad-free endpoint to define success after RP appears to overestimate the actual preservation of urinary health, with less than half of men who reported being pad-free also achieving RTB in all four urinary health scores. For future reporting and patient counseling, the RTB endpoint more accurately reflects successful recovery of urinary health after RP than simply “Pad-Free”.
MINORITIES WITH HIGH RISK PROSTATE CANCER DO NOT EXHIBIT MRI DETECTABLE DIFFERENCES

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Introduction and Objective: African-American, Latino and Asian-American prostate cancer patients often exhibit more aggressive disease than Caucasian patients. We sought to determine if any differences in multiparametric prostate MRI (mpMRI) features exist between ethnicities in a cohort of patients with high risk prostate cancer.

Methods: Natural language processing software was used to query a database of men who underwent mpMRI (1.5 Tesla, multi-phased array surface coil) for high risk prostate cancer. 168 patients were identified and retrospectively evaluated. Charts were retrospectively reviewed for demographics clinicopathological data and MRI characteristics. MRI features were compared between ethnic strata (Caucasian vs other) using the Student’s T-test for continuous variables and Fisher’s exact test for categorical variables.

Results: 168 patients with high risk prostate cancer were identified; 67 were Caucasian and 106 were African-American, Latino or Asian. There was no significant difference between age (68 versus 67), family history (30% versus 33%), Gleason group (p=0.74) or PSA (29.4 versus 19.3, p=0.19) between groups. Non-caucasian patients more commonly had an abnormal digital rectal exam (55% vs 38%, p=0.04). Early contrast enhancement more prevalent between ethnicities (Caucasian vs non-Caucasian (97% vs 85%, p = 0.011). There was no difference in the presence of T2 hypointensity (p=0.55), diffusion restriction (p=0.42), extracapsular extension (p=0.55), seminal vesicle invasion (p=0.34) lowest ADC value (776 vs 757. p=0.47), or lymphadenopathy between the groups.

Conclusions: Caucasian patients demonstrated abnormal early contrast enhancement on mpMRI of the prostate more frequently than non-caucasian patients. There were no other MRI features that were ethnically unique.
EXPLORATION OF TECHNICAL NUANCES IN VESICOURETHRAL ANASTOMOSIS IN ROBOTIC RADICAL PROSTATECTOMY

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Introduction: Vescicourethral anastomosis (VUA) is one of the most critical steps of robotic radical prostatectomy (RP) because it directly affects patient post-operative recovery and quality of life. Inadequate technique during VUA can result in urine leakage and compromise urinary continence. VUA is one of the most technically demanding, but also fastest improved surgical steps of RRP. In order to improve VUA technique among robotic surgical trainees, we broke down the whole VUA into individual movements, analyzed the technical metrics, and explored the trend in behaviors of surgeons with varying experience.

Methods: We studied the first 4 stitches of VUA in RRP. With the “dVLogger,” a novel recording device provided by the research team at Intuitive Surgical, surgical footage of RRP performed on da Vinci Si systems were recorded along with instrument kinematic and events data during live surgery. Performing surgeons were categorized into experts and trainees based on their prior robotic surgical experience (trainees: <200 console cases experience, experts: >200 console cases experience). Post-operatively, we reviewed the VUA footage and annotated each individual anastomosis stitches. The moment when the needle driver first grab the needle was recorded as suturing start time (time point 1). When the needle first touches the tissue (bladder neck or urethral stump), that moment was marked as time point 2. Once the entire needle passed through the tissue, the moment was marked as time point 3. After the needle passed through and the suture was cinched down, the whole suturing movement was counted finished (time point 4) (Figure 1). Kinematic metrics (suturing completion time, instruments path distance, and instrument moving velocity), system events metrics (frequency of camera control, master clutch usage), and endo-wrist metrics (range of instrument articular movement) were captured and analyzed. Also, information such as needle-needle driver position, number of attempts to successful needle throw, tissue trauma or tear were manually recorded. These metrics were compared between expert and training groups using statistical mixed effect models.

Results: Five surgeons including 3 experts (median 450 (300-2000) console cases experience) and 2 novices (median 100 (50-150) cases) participated in this study. Thirteen RRP cases were recorded by the “dVLogger”. For each case, 8 suturing movements of the first 4 stitches of vesicoureteral anastomosis were analyzed. For the entire suturing process (time point 1 to 4), experts outperformed trainees in suturing completion time (34 s vs 157 s, p<0.001), instruments path distance (113 cm vs 268 cm, p<0.001), and movement velocity of dominant (1.9 cm/s vs 1.1 cm/s, p<0.001) and non-dominant (1.7 cm/s vs 1.2 cm/s, p<0.001) instruments. During the process of preparing to throw the needle (time point 1 to 2), experts spent less time (10 s vs 53 s, p<0.001) but adjusted better needle-needle driver (p=0.004) than trainees. When throwing the needle through the tissue (time point 2 to 3), experts articulated both dominant and non-dominant instruments with greater range of motion in all three joints compared to trainees (dominant instrument: 58° vs 37° in roll, 35° vs 18° in pitch, 33° vs 21° in yaw, p<0.05; non-dominant instrument: 39° vs 27° in roll, 25° vs 16° in pitch, 25° vs 18° in yaw, p<0.05) (Figure 2). Experts achieved successful needle throw with fewer attempts compared to novices (1 attempt vs 2 attempts, p<0.001) and caused less incidences of tissue trauma (p=0.01). During the final movement of suturing (time point 3 to 4), expert spent less time cinching the suture (12 s vs 66 s, p<0.001) with more efficient instrument movement (38 cm vs 109 cm, p<0.001) and camera movement (3 cm vs 12 cm, p=0.002).

Conclusions: Expert surgeons were not only faster and more efficient in manipulating the instruments, but also more flexible with wrist rotations in suturing movement compared to the trainees. They also had more proper needle positioning and fewer incidences of tissue injury. By identifying the suturing movement characteristics of robotic surgical experts, we hope to mentor trainees more efficiently and effectively.
A 17-GENE RTPCR ASSAY TO AID DECISION MAKING IN CLINICALLY LOW RISK PROSTATE CANCER

Fredrick Wolk, Franklin Gaylis, Neyssan Tebyani, Bryan Mehlhaff, Ruixiao Lu*, John Bennett*, Alan W. Shindel, Phil G. Febbo*, Bela S. Denes

(to be presented by Fredrick Wolk)

Objectives: Genomic testing provides actionable novel information to help inform decisions on whether to pursue Active Surveillance (AS) or Immediate Treatment (IT) in men with clinically low risk prostate cancer (PCa). This study explores the impact of genomic testing in a large prospective study conducted in community practices.

Methods: Men with NCCN Very Low-, Low-, and Intermediate-Risk PCa were enrolled in a large, prospective, nationwide study of a validated 17-gene tissue-based RT-PCR assay (Genomic Prostate Score™; GPS). The primary endpoint was rate of change in management (i.e. from AS to IT and vice versa) before and after GPS testing. Secondary endpoints included provider rating of increased recommendation confidence based on GPS, patient perceived utility of GPS, and the patient Decisional Conflict Scale (DCS) before and after testing.

Results Obtained: 796 patients from 25 centers were included in this analysis. Of the 796 men, 502 (63%) pursued AS and 294 (37%) pursued IT as initial disease management. In terms of specific treatment 148 (50%) elected surgery and 140 (48%) elected radiation/brachytherapy. Following GPS testing, a change in initial management recommendation occurred in 25% (202/796) of patients. In the NCCN Low Risk patient cohort, changes in management were bidirectional, with 58 (53%) of the 110 who had IT initially recommended changing to AS, and 44 (17%) of the 253 who had AS initially recommended changing to IT. In 88% (90/102) of NCCN Low Risk cases, change in management was directionally consistent with GPS results. Physicians reported greater confidence after GPS in 92% of cases. Patients found GPS useful in 94% of cases. In terms of patient decisional conflict, Mean DCS scores declined by 13 points (scale 0-100) after GPS; the number of patients reporting low DCS (<25) increased from 287 (37%) pre-GPS to 501 (65%) post-GPS.

Conclusions: Incorporation of GPS into clinical decision making provides an individualized risk assessment which in turn results in a change of initial disease management for 1 in 4 men. Both urologists and patients reported that the test was useful in decision making. Use of GPS reduced decisional conflict, regardless of final shared decision for management.
SELECTMDx™ TEST ACCURATELY PREDICTS HIGH GRADE PROSTATE CANCER AT BIOPSY THAN PROGENSA® PCA3 TEST
E. David Crawford, MD, Salvatore Catarinichia, MD, Joshua K. Romero, Paul Arangua, John Hoenemeyer, MD, Francisco G. La Rosa, MD, Adrie van Bokhoven, PhD, M. Scott Lucia, MD, Wendy Poage, Nelson D. Stone, MD, Jack A. Schalken, Ph.D., and Priya N. Werahera, PhD: Aurora, CO
(Presentation to be made by Dr. E. David Crawford)

Introduction and Objective: Urine-based molecular diagnostic tests, SelectMDx™ and Progensa® Prostate Cancer Gene 3 (PCA3), can be used for risk assessment of prostate cancer (PCa) patients. The objective of these tests is to identify patients with either PCa or high-grade (HG) PCa and thereby increase the chance of diagnosing the disease at biopsy. The SelectMDx™ test provides the likelihood of detecting PCa upon biopsy and the probability for HG disease. The test measures the mRNA levels of the homeobox C6 (HOXC6) and distal-less homeobox 1 (DLX1) biomarkers in urine samples and higher expression levels are associated with an increased probability for HG PCa. PCA3 test measure mRNA levels of PCA3 and higher expression levels are associated with PCa. We investigated the clinical utility of SelectMDx and PCA3 tests using histopathological data of patients opting for template-guided transperineal mapping biopsy (MB) as the reference.

Methods: In this retrospective study, a cohort of patients at the University of Colorado Hospital chose MB to confirm the histopathological findings of their initial TRUS biopsies. Post-DRE, first-v oid urine specimens were collected from each patient prior to MB. Histopathology of MB was independently read by a genitourinary pathologist. Patients with HG disease have Gleason Score (GS) ≥7 tumors with Gleason grades 4 & 5 and low grade (LG) disease have GS = 6 tumors Gleason Grade 3. MB histopathology data was compared against SelectMDx™ and PCA3 test results for risk of PCa and HG PCa at biopsy. For SelectMDx test, a probability (p) > 0 is considered as an indication of the respective disease within each category. The cutoff for PCA3 test has been revised and a score ≥ 25 now indicate patients at risk for PCa. Standard statistical measures were used to determine the accuracy of tests including receiver operating curves (ROC) and logistic regression (LR) analyses.

Results: A total of 64 patients were included in this study with mean age of 62.8 ± 8.3 (34 - 78) yrs, PSA 7.0 ± 8.2 (0.32 - 41.82) ng/mL, and PCA3 40.0±42.6 (1.5-181.6). MB histopathology data indicated 44/64 (67%) patients had PCa including 25 with GS = 6, 19 with GS ≥ 7 and, 9 with GS ≥ 4+3 tumors. Based on indication to biopsy, 18/24 and 23/30 patients were diagnosed with PCa by SelectMDx and PCA3 tests, respectively. SelectMDx correctly diagnosed 4 with GS = 6, 14 with GS ≥ 7, and 9 with GS ≥ 4+3 patients. PCA3 correctly diagnosed 13 with GS = 6, 10 with GS ≥ 7, and 6 with GS ≥ 4+3 patients. LR analysis found SelectMDx significantly better than PCA3 for diagnosing patients with GS ≥ 7 disease (β=8.99, p=0.0003). ROC analysis in the figure show that area- under-the-curve (AUC) of SelectMDx is larger than PCA3 (0.81 vs 0.52, p=0.0012). Sensitivity and NPV reached 100% for SelectMDx test when limited to patients with GS ≥ 4+3 PCa with AUC larger than PCA3 (0.91 vs 0.59, p=0.0002).

Conclusions: SelectMDx™ is a better predictor of PCa patients with HG disease than Progensa® PCA3, particularly for patients with primary Gleason grade 4 and higher tumors. Additional studies are needed to confirm our findings.

Source of Funding: The study was supported in parts by the Bingham Research Fund and MDx Health
Introduction: Previous studies have identified PSA of 1.5 as a more appropriate cut-off than the standard 4 to identify patients at risk when screening for prostate cancer (PCa) (1,2). Our institution provides annual screening for the members of our community during Prostate Cancer Awareness Week (PCAW). Last year, we offered Select MDx™ test as part of the screening protocol during PCAW. The SelectMDx™ urine test provides the likelihood of detecting PCa and high grade prostate cancer (HG PCa) with Gleason pattern 4 and 5 upon subsequent biopsy (3). The test measures the mRNA levels of the homeobox C6 (HOXC6) and distal-less homeobox 1 (DLX1) biomarkers in urine samples post-DRE. Higher expression levels of HOXC6 and DLX1 are associated with an increased probability for HG PCa. We investigated whether Select MDx™ test was predictive of PCa and HG PCa in patients using a PSA of 1.5 as a cut-off.

Methods: Our institution advertised prostate PCAW to the members of our community with mail-out materials. We collected serum samples and post-DRE, first-void urine specimens from each participant. We compared PSA results against SelectMDx™ test results for probability of PCa and HG PCa at biopsy. Likelihood of diagnosing PCa and HG PCa at biopsy is reported as a probability (p) between 0 - 100%.

Results: We had 199 participants and successfully collected post-DRE first-void urine samples from all but 13. Average age of the 186 patients was 66 and PSA was 2.17. 81 patients had a PSA <1.5 and none of these men were predicted to have PCa by Select MDx. However, 6/81 had a positive DRE. 109 patients had a PSA >1.5. Select MDx test predicted 7 of these patients at risk for PCa. The average risk predicted by SelectMDx™ was 43% for PCa and 17% for HG PCa. However, 3/7 had a positive DRE and 6/7 had a PSA > 4. Only one patient had a PSA < 4 (2.39) with a negative DRE.

Conclusions: Select MDx test reinforced the original data that a PSA < 1.5 is a more appropriate screening cut-off that represents a low-risk subset of patients. Additionally, our data also supports referring patients with a PSA >1.5 to further urologic intervention. Patients with PSA >1.5 in our population were the only positive Select MDx results. While SelectMDx test has sufficient sensitivity and NPV(3) to indicate patients with high grade prostate cancer, the test may also produce false positives.


3. Dijkstra et al, Validation of a New Urine Test for the Early Diagnosis of Clinically Significant Prostate Cancer. Proceedings from SIU 2015, MP0302, p10
Introduction: Clinical observations suggested that patients with larger prostate size were more prone to urinary leakage or longer recovery of urinary continence after robotic assisted radical prostatectomy (RALP). We sought to determine if patient factors such as prostate volume, BMI, or age predicted urinary continence status-post robotic-assisted laparoscopic prostatectomy (RALP). We hypothesize that prostate volume is correlated to urinary pad usage following RALP.

Methods: We retrospectively reviewed patients who underwent RALP by a single surgeon. Patients were included if they completed EPIC questionnaires 2- and 6-months after surgery. Prostate volume was used from the pathology report. Questionnaires included pre- and post-op urinary pad usage and was differentiated between 0, 1, 2, 3 or more pads per day. Final analysis included 101 patients.

Results: Our data did not show any correlation between pathologic prostate volume and urinary pad usage at either two or six months post-operatively. Additionally BMI did not have a significant effect on urinary pad use post-operatively. We did find a statistically significant association between age and no urinary pad usage at six months post-op. There were 18 patients younger than 55y, and 77.8% were not using any pads at the six month post-op period. Of the 47 patients between the age of 55-64, 70.2% were not using any urinary pads at six months. However, Of the patients older than 65, only 36.4% were not using any urinary pads at six months (chi squared p<0.002). Conversely, no statistically significant relationship was found related to age and two or more pad use per day. At six months, 5.6% of those younger than 55 years old were still using 2 or more pads per day, while 6.4% of those 55-64 years old and 15.2% of those 65 years and older were still using two or more pads per day (chi squared p=0.34). Although not statistically significant, there was a suggestive trend of 2 or more pad use per day with gland size greater than 40 grams (chi squared p = 0.14).

Conclusion: Age, but not BMI or prostate size are related to pad usage at six months after RALP by a single surgeon. Our original hypothesis was not supported by the data, which is perhaps secondary to the study being underpowered. That said, this study should be large enough to provide clinically relevant information for patient counseling.
EVALUATING THE PROGNOSTIC UTILITY OF THE CCP SCORE FOR PREDICTING PROSTATE CANCER AGGRESSIVENESS IN AFRICAN AMERICAN MEN

Stephen Bardot¹, MD; Julia Reid*², MStat; Maria Latsis¹, MD; Margaret Variano¹, MPH; Shams Halat¹, MD; Daniel Canter¹, MD; Zaina Sangale², MD; Michael Brawer², MD; Steven Stone², PhD

¹Ochsner Clinic Foundation, Gayle and Tom Benson Cancer Center, New Orleans, LA
²Myriad Genetics, Inc., Salt Lake City, UT

Objectives: The cell cycle progression score (CCP score, based on measuring the expression levels of CCP genes) has proven to be a robust predictor of prostate cancer outcomes in various clinical settings and patient populations. However, data regarding the ability to predict outcomes in African American (AA) men are sparse. Here, we evaluate the utility of the CCP score generated from diagnostic biopsy to predict BCR and metastatic disease in a large cohort of treated patients at an academic teaching institution that is highly enriched with AA patient population.

Methods: Patients were diagnosed with clinically localized adenocarcinoma of the prostate and treated at the Ochsner Clinic (New Orleans, LA) between January 2006 and December 2011 who had available FFPE biopsy tissue. The final cohort consisted of 694 men with both a passing CCP score and complete clinical information for calculation of CAPRA. Thirty-eight (38) percent of the cohort was AA. Study outcomes included time from disease diagnosis to either metastatic disease (N= 33, 5%), or time to BCR (N= 94, 17%) after primary treatment (EBRT or RP). Median follow-up time for patients who did not experience an event or death before the study end was 6 years. Association with outcomes was evaluated by CoxPH survival analysis and likelihood ratio tests.

Results: The CCP score distribution was not different by race (p= 0.66) and had an overall mean of 0.42 (IQR = -0.20, 1.00). The primary pre-planned analysis called for evaluating the association of CCP score with outcome after adjusting for CAPRA and race. In this multivariable analysis the CCP score strongly predicted both BCR [HR per unit score = 1.50, 95%CI (1.22, 1.86), p= 0.00029] and metastatic disease [HR per unit score = 2.02, 95%CI (1.48, 2.77), p= 4.2 x 10⁻⁵]. Race was not significantly associated with either outcome (p= 0.51 for BCR; p= 0.28 for metastatic disease). Further, there was no interaction between CCP score and race (p= 0.21), indicating that a unit increase in the score confers the same relative increase in risk to either Caucasian or African American patients. There was also no interaction between CCP score and treatment type (p = 0.34).

Conclusions: The CCP score provides significant prognostic information to AA patients that cannot be obtained from clinicopathologic variables. Therefore, the score is a useful tool to help differentiate risk among AA men and enables more informed clinical management of their disease.

Disclosure: Research was, in part, funded by Myriad Genetics, Inc.
PATIENT RISK RECLASSIFICATION BASED ON COMBINED CLINICAL CELL CYCLE RISK (CCR) SCORE

Edward Uchio¹, MD, FACS, CPI; Steven Stone,² PhD; Julia Reid,² MStat; E. David Crawford,³ MD, Michael Brawer⁴, MD

Objectives: Improved prognostic tools for newly diagnosed prostate cancer are needed to more appropriately match treatment to a patient’s risk of progression. The CCR score is a validated prognostic tool that estimates 10-year prostate cancer mortality (PCM) based on prognostic information from both molecular (cell cycle progression (CCP) gene expression) and clinical (CAPRA) variables. We evaluate how the CCR score can reclassify PCM-risk for men tested within the AUA Western section relative to NCCN and AUA risk categories.

Methods: Prostate biopsy samples from 4568 men within the AUA Western section were submitted for commercial testing. The CCR score was previously validated and is calculated as a linear combination of CAPRA and CCP score (0.39 x CAPRA + 0.57 x CCP). Patients were assigned to NCCN and AUA risk categories using clinicopathologic data obtained from test request forms. Interquartile ranges (IQR) for each NCCN/AUA risk category were determined from the full commercial cohort (N=20,958). Patients whose CCR-based PCM risks were outside the IQR of their NCCN/AUA risk category were reclassified according to whether their PCM risk fell within the IQR of another risk category.

Results Obtained: Based on NCCN guidelines using clinicopathologic features alone, the commercial cohort was classified as low (n=2277, 49.8%), favorable intermediate (n=981, 21.5%), intermediate (n=898, 19.7%), and high risk (n=412, 9.0%). After calculating PCM-risk based on CCR, 36.2% of men were reclassified to a different risk category relative to NCCN criteria (12.5% lower, 23.7% higher; see Table). Similarly, men were classified as AUA low (n=2285, 50.0%), intermediate (n=1739, 38.1%), and high risk (n=544, 11.9%) based on clinical features. PCM-risk based on CCR scores resulted in the reclassification of 31.2% of men relative to AUA criteria (10.4% lower, 20.9% higher; see Table).

Conclusion: The prognostic information in the CCR score results in significant risk reclassification for all patients with localized disease when compared to stratification based only on clinicopathologic criteria.

Funding was partly provided by Myriad Genetics, Inc. All Myriad Authors Receive Salary and Stock Options.
ROBOT-ASSISTED LAPAROSCOPIC CYTOREDUCTIVE PROSTATECTOMY: SINGLE INSTITUTIONAL EXPERIENCE

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(Presentation to be made by Dr. Chennamsetty)

Introduction: The current treatment paradigm for metastatic prostate cancer involves hormone therapy with or without systemic treatments. There is some evidence that suggests local control of prostate cancer may help prolong survival or help with symptomatic disease. As part of an ongoing multi-institutional Phase I trial, we reviewed our single institutional experience of performing robot-assisted laparoscopic cytoreductive prostatectomy with extended pelvic lymph node dissection.

Methods: Between 2012 and 2016, 11 men with radiographic metastatic prostate cancer (clinical T1-3N1M0 or T1-3N0M1a-b) were offered cytoreductive prostatectomy, and of those 11, seven were part of an ongoing multi-institutional Phase I trial. All patients received an extended pelvic lymph node dissection. Following surgery, patients received the standard systemic androgen deprivation therapy. Primary outcome was to determine the incidence of major peri-operative complications, defined as Clavien-Dindo grade III or higher, within 90 days following cytoreductive prostatectomy.

Results: Of the 11 patients, the median age at surgery was 60 years (R: 47-73), median BMI was 28.5 (R: 22.4-37.8), median pre-op PSA was 27.5 ng/ml (R: 5.1-217), and the median operative time was 237 minutes. 10/11 patients had positive lymph nodes. The median lymph node yield was 25.5 (R: 10-41) and 21.1% of lymph nodes removed were positive. Positive margin rate was 63.6%. The majority of patients were discharged home on the first post-operative day and recovered similar to patients with localized disease. 3/11 (27.3%) patients had a 90-day complication. All three complications were urinary anastomotic leaks requiring prolonged Foley catheter drainage. No major (Clavien-Dindo grade ≥ III) 90-day complications were reported. Of the 7 patients that had 6-month follow-up, 5 patients (71.4%) had PSA < 0.2.

Conclusions: In patients with low metastatic burden undergoing cytoreductive prostatectomy, we report a low morbidity rate. Long-term evaluation is necessary to determine definitive impact on survival.

Source of Funding: None
USE OF PSMA PET/CT SCANNING WITH MRI/ULTRASOUND FUSION TARGETED PROSTATE BIOPSY TO DETECT OCCULT PROSTATE CANCER

Fuad F. Elkhoury, MD; Demetrios N. Simopoulos, MD; Shyam Natarajan, PhD*; Alan M. Priester, PhD*; Wolfgang P. Fendler, MD*; Matthias Eiber, MD*; Ely R. Felker, MD*; Leonard S. Marks, MD : Los Angeles, CA
(Presentation by Dr. Fuad F. Elkhoury, MD)

Purpose: A patient with a persistently rising PSA despite several negative prostate biopsies and negative multiparametric prostate MRI (mpMRI) poses a diagnostic challenge to urologists. In this case report, we present the use of PSMA PET/CT scanning to identify index prostate cancer lesions that can be targeted and biopsied with MR/US fusion technology, thus impacting subsequent management.

Case Presentation
A 71 year old Caucasian male is in the UCLA active surveillance program for very low risk prostate cancer, first diagnosed with a micro-focus of Gleason 3+3 prostate cancer (0.5 mm in one core) in 2013 using the Artemis mpMRI Fusion biopsy system, with the mpMRI detecting a PIRADS 3 target. Screening PSA was 8.5 ng/ml. Confirmatory MR fusion biopsy 6 months later was negative. Prior to this, he underwent two negative transrectal ultrasound guided needle biopsies and a TURP. His PSA continued to rise to 27.6 ng/ml in November of 2014 and mpMRI Fusion biopsy demonstrated a single micro-focus (1 mm on one core) at the left lateral apex and the region of prior positive biopsy. Over the next two years, his PSA rose to 49.0 ng/ml with a 6% free component. Repeat mpMRI was negative in February 2016 and January 2017. Pelvic MRI, bone scan, and CT chest/abdomen/pelvis were negative.

In January 2017, a $^{68}$Ga HBED PSMA PET/CT was performed that demonstrated radiotracer uptake in the anterior prostate and near a prior TURP defect, with no evidence of local or distant metastasis (Figure 1). mpMRI was again done and read as negative for malignancy by our expert radiologist. Using ProFuse imaging software for the Artemis biopsy system, the PSMA region of interest was identified on MRI images (Figure 2).

The Artemis system was used to construct a three-dimensional model of the target, fuse this with real-time ultrasound, and biopsy cores precisely from the target lesions originally identified by PSMA scanning (Figure 3). Of the six cores taken, one core demonstrated Gleason 4+3 cancer and five cores demonstrated Gleason 3+4 cancer. Consequentially, the patient proceeded to definitive management of his prostate cancer.

Conclusion: This is the first reported case of combining PSMA PET/CT scanning with MR/US fusion targeted prostate biopsy to detect mpMRI-invisible, clinically significant prostate cancer. This can augment our diagnostic capabilities to optimally manage men suspected of having prostate cancer.
THE INTENSITY AND FOCUS OF UROLOGICAL PRACTICE IN THE UNITED STATES: INSIGHTS FROM THE AQUA REGISTRY

Matthew R Cooperberg, Raymond Fang, Stuart Wolf, Heddy Hubbard, Mary Nolin, Kimberly Ross, Steven Schlossberg, Quentin Clemens.
San Francisco, CA

(Presentation to be made by Dr. Cooperberg)

Purpose: Most traditional analyses of national urologic practice patterns have relied on data sources which suffer from limited representativeness and/or variable accuracy. The AUA Quality (AQUA) Registry was launched in 2013 to document practice patterns and quality of care for a range of urologic conditions. As the number of participating practices has grown, we aimed to provide an initial description of contemporary urologic practice in the US.

Methods: AQUA collects data from participating practices via automated data extraction from local electronic health record systems. Data are collected from both structured (e.g., billing codes, prescriptions) and unstructured (e.g., pathology reports, physician notes) chart elements. Practice size was categorized by tertile. Patients were categorized by race/ethnicity, and by adult vs. pediatric status based on age under vs. at least 18. The primary diagnoses reported at each patient encounter was identified and analyzed, as were common procedural codes.

Results: As of December 31, 2016, 426 urology practices from 48 US states and territories, representing 2,614 providers, had signed up with the AQUA registry. Data were available for analysis from 88 (21%) of these practices, and 961 (37%) of the providers. Small, medium, and large practices were defined by the cutpoints of 10 and 24 urologists. From January 2014 to December 2016, AQUA collected data on 2,481,828 unique patients at these practices. The median (interquartile range [IQR]) age was 64 (51-74). 1.4% of the patients were pediatric. 78% were Caucasian, 10% African-American, 6% Hispanic, 2% Asian / Pacific Islander, and 3% other. The median (interquartile range [IQR]) number of patient visits per urologist per month was 258 (161-387). Median visits per month by practice size tertile were 227, 256, and 288. Median (IQR) new patients seen per month was 26 (13-40). 9% of the adult urologic visits were for oncologic diagnoses, and the remainder for benign conditions. Common conditions and procedures have been summarized.

Conclusions: As the AQUA Registry continues to develop, it will allow unprecedented analyses of practice patterns across the breadth of urologic practice in the US.

Source of Funding: American Urological Association Education and Research
A COST-BASED ANALYSIS OF MODIFICATIONS TO PROSTATE CANCER SCREENING: ASSESSING THE COST OF CARE
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Introduction and Objectives: In response to the USPTF recommendation against routine prostate cancer screening with PSA, researchers focused on determining a screening paradigm that balanced cost effectiveness with the benefits of screening. Retrospective analysis had highlighted the costly price tag of comprehensive screening with the majority of costs associated with the screening and treatment of men with low-risk disease. To combat the issue of overtreatment, the pendulum swung towards the development of screening and treatment tools, which attach risk-stratification to prostate cancer screening protocols. A combination of cost-effectiveness research and application of the USPSTF recommendation has led to a similar conclusion, that men should be screened less frequently for prostate cancer. However, early reports have suggested that these changes to screening protocols have had downstream effects on prostate cancer characteristics. Data has demonstrated stage migration—an increase in PSA value at the time of diagnosis accompanied by a higher stage and grade at presentation. The goal of this study is to use cost-effectiveness analysis to evaluate the financial ramifications of potential shifts in prostate cancer at presentation as men are screened less and potentially presenting with more advanced or metastatic disease.

Methods: Three models were created to determine the costs of PCa screening and treatment based on different screening criteria: screening all men aged 50 to 75 (Model A), screening 50% of men aged 50 to 75 (Model B), and forgoing routine screening (Model C). The models were evaluated at two time points, 2010 and 2020 and were limited to Caucasian men due to the increased risk of prostate cancer among African American men. PCa-specific data for the cost-analyses was obtained from the PLCO Cancer Screening Trial and the Medicare SEER database. Data was statistically analyzed utilizing ANOVA.

Results: The costs per year for Model A was $11.2 billion, $4.9 billion for Model B and $8.7 billion for Model C. Costs for each model nearly doubled when calculated with respect to 10-year projections. The majority of PCa-related costs were attributable to the costs of a new PCa diagnosis. PSA tests represented the second most costly PCa expenditure. In comparison to Models B and A, Model C had the greatest percentage of expenditure dedicated to new prostate cancer diagnoses (95% vs 66% vs 76%, p < 0.0001 ). Model C has the lowest expenditure for PSA screening and prostate biopsy (0% and 3.5%). Model B had the highest relative cost expenditure on PSA testing (12.9% ).

Conclusions: This cost-analysis demonstrates that there are substantial yearly costs associated with all aspects of the treatment of prostate cancer from screening to treatment and retreatment, as well as complications. The data suggest that for low-risk populations, for example excluding those of African-American race or a positive family history, a narrower prostate cancer screening protocol may be cost effective and reduce morbidity. A balance must be struck between shifting costs to treatment of likely more advanced cancers at the expense of cutting back on the costs of screening. Remaining questions surround the impact on mortality and how to select which “low-risk” men are appropriate for screening.

Source of Funding: None
SPINDLE CELL TUMOR OF THE SPERMATIC CORD: A CASE REPORT

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Abstract: R.S. and 84 year old Caucasian male presented with a mass in the right spermatic cord slowly increasing in size for several years. The lesion was causing some discomfort and he wanted it resected. Examination revealed a rubbery soft lesion of the cord. The patient was taken to surgery with the preoperative diagnosis of a cord lipoma. Upon exploration of the scrotum the lesion did not have the usual appearance of a lipoma so a radical orchiectomy was performed. The pathology revealed a spindle cell tumor of the cord; the second reported case. Pathology and management are reviewed.
Objective: Coinciding with the increasing number of female medical students, the number of women entering the field of urology has increased significantly. Additionally, 33% of students matching in urology are now female. Despite these increases, urology remains a predominantly male dominated field. However, interest has emerged regarding the impact of gender on job satisfaction. Contrary to the civilian workforce, the military poses equal pay between genders of similar rank, and all active duty urologists are considered full-time employees. Our objective was to characterize the female workforce in military urology with regard to income, workload, and job satisfaction and compare these factors to their male counterparts.

Methods: A total of 182 military urologists (30 women and 152 men) were sent survey invitations via e-mail. The survey consisted of 27 questions (22 multiple choice and 5 open-ended) and took approximately 15 minutes to complete. Linear regression models were used to evaluate bivariable and multivariable associations with job satisfaction and compensation.

Results: A total of 106 responses were collected (21 female and 85 male), for a total response rate of 58%. The 21 female respondents represented 70% of the total female cohort, while the 85 male respondents represented 56% of the male cohort. Of the female respondents, 35% were residents and 65% were staff urologists, while 22% of the male respondents were residents and 78% were staff urologists. The age distribution of respondents did not differ significantly between genders. Despite an equal proportion of residents and staff in each cohort, women military urologists reported working more hours than males, with 42% vs. 19% reporting 70+ hour weeks. When adjusting for the other predictors of income, women reported a lower average military income ($=0.016) and were less likely to have ancillary income ($= 0.06). When adjusted for fellowship training and resident status, the reported pattern of lower compensation for females is consistent by rank. When accounting for ancillary income and adjusting for rank, there is a larger gender difference since female urologists make $20,000 less on average than male urologists ($=0.015, 95% CI: $4,000-$36,000 less). All 21 female respondents stated that career has compromised family and personal life at least somewhat, while 26% of men stated that it compromised little to none. Moreover, if given the opportunity, 44% of women would choose a career outside of medicine vs. 19% of men ($= 0.047). Despite these findings, women and men have similar rates of job satisfaction. Overall, 67% of women and 81% of men were very or mostly satisfied with their jobs. Males and females cited similar reasons for job dissatisfaction. The top 5 reasons cited for job dissatisfaction in both genders included increased administrative burden (51%), dissatisfaction with facilities and support staff (24%), underutilization of urology training (13%), salary (18%), and limited opportunity for career development (16%).

Conclusions: Income disparities between male and female physicians in the civilian workforce are well established and have been reported in urology. The military system poses equal pay between genders of similar rank and all are full time employees. Despite this, female military urologists reported a lower income compared to their male counterparts. This finding within a gender neutral equal pay system may reflect a large reporting bias, or the perception held by female urologists of a difference in compensation. If so, this would call into question the findings of numerous studies reporting an actual difference in physician compensation based on gender alone. Despite the perception of lower income compared to male urologists, job satisfaction between male and female military urologists did not differ, suggesting that although the two are thought to be positively correlated, income is not interchangeable with job satisfaction. Further studies on actual income discrepancies between genders and job satisfaction are warranted.
EXPERIENCE AT THE JEEV SEEWA SAMITI HOSPITAL UROLOGY CAMP IN AJMER, INDIA

Pooya Banapour, MD

India Narrative

As I arrived at the bustling and vibrant city center in the heart of Ajmer, I was immediately greeted by the sights of speeding rickshaws, chaotic crowds scurrying through markets and animated street vendors displaying their collection of prized Hindu relics. Little did I know that Rajasthan’s most important Muslim pilgrimage center was also home to one of the busiest and most popular annual medical camps in all of India: the Jeev Sewa Samiti Ajmer urology camp.

Our instructions were very brief: take a taxi to the Khadim bungalow, check into your room and be ready by 8AM. After a much-needed rest, we were picked up the next morning and taken directly to the camp. It was located inside the Jawahar Lal Nehru hospital, home to a medical school and graduate medical training program. Crowds of patients filled the streets outside of the hospital with their family members and medical records clasped tightly to their bodies. As soon as they made eye contact with our team, their looks of despair became replaced with a namaskar, a traditional Indian greeting of admiration. They had been patiently waiting our arrival and were now bewildered yet relieved by our appearance.

Dr. Rohit Ajmera and Dr. Gopal Badlani were the first to welcome us to the camp. Dr. Ajmera warned us that it would be a busy week ahead as he hurried through our brief orientation. I was almost certain that he had made a mistake when Dr. Ajmera repeated himself clearly: “We will be performing 25-30 cases per day using two beds in one room.” As I peered at the week’s case list, I saw that we had a wide variety of operations ahead of us: DVIUs, TURPs, TURBTs, Ureteroscopies, PCNLs, retropubic slings, cystolithotomies, orchidopexies and more. I became immediately excited about the mission at hand but doubtful about its execution.
A RARE CASE OF CARCINOMA BLADDER IN A YOUNG PATIENT WITH XERODERMA PIGMENTOSA

Introduction: Carcinoma bladder is the ninth most common malignancy worldwide and is the 13th most common cause of cancer death. The median age of carcinoma bladder is 70-years of age, and the incidence and mortality increase with age. Xeroderma pigmentosa is a rare autosomal recessive disorder, having increased risk of bladder malignancy. But only a few case reports available in the literature.

Case report: A 23-year male, a known case of xeroderma pigmentosa with diabetes and hypertension developed blood in urine. He was evaluated at an outside hospital and found to have carcinoma bladder, hence underwent Transurethral resection of bladder tumor. He was referred to us as the resected specimen showed invasive tumor. We evaluated him further to find residual lesion with stricture urethra. We did radical cystectomy, neobladder creation and buccal mucosal urethroplasty for the stricture at the same setting. On 1.5-year follow-up, he has controlled voiding, normal sexual life, and no upper tract changes.

Discussion: Xeroderma pigmentosa is uncommon, autosomal recessive disorder characterized by increased risk of malignancy. Skin and mucus membrane malignancies are common. The polymorphism of xeroderma pigmentosa gene leads to impaired DNA repair resulting in increased chances of carcinoma bladder. Despite the advanced treatment, the 5-year survival in invasive carcinoma bladder is only 47%.

Conclusion: Carcinoma bladder in a 23-year male with xeroderma pigmentosa is a rare entity. Early diagnosis and adequate treatment improve outcome.
**UROLOGIC CANCER DISPARITIES AMONG HISPANIC AMERICANS AND NATIVE AMERICANS IN FOUR U.S.-MEXICO BORDER STATES**

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**Background:** Overall cancer incidence and mortality rates among Hispanic Americans (HAs), Native Americans (NAs), and Alaskan Natives are lower compared to European Americans (EAs) of non-Hispanic origin. However, NAs and HAs are very heterogeneous groups. Cancer incidence and mortality rate vary among HA subgroups and regionally among NAs. The objective of this study was to assess the extent of urologic cancer disparities among HAs and NAs compared to EAs in four U.S.-Mexico border states (Arizona, California, New Mexico, and Texas).

**Methods:** We obtained prostate, kidney, and bladder cancer incidence rates (age-adjusted incidence rates per 100,000 using 2000 US standard population) between 2009 and 2013 from the North American Association of Central Cancer Registries.

**Results:** Prostate cancer was more common than kidney and bladder cancer in all three race/ethnicity groups. Prostate cancer incidence rate was higher in EAs than NAs or HAs, but HAs and NAs were more likely to be diagnosed with metastatic prostate cancer than EAs. The proportion of NA men diagnosed with metastatic prostate cancer was 17% and 19% in Arizona and New Mexico respectively, while only 5% of EA men were diagnosed with metastatic prostate cancer. Kidney cancer was more common than bladder cancer in NAs and HAs. HAs had significantly higher kidney cancer incidence rate than EAs in all border states. Kidney cancer incidence rate in NAs was significantly higher than EAs in Arizona and New Mexico, but lower in California. In EAs, bladder cancer was more common than kidney cancer, and bladder cancer incidence rate was significantly higher than in NAs and HAs. Incidence rates were compared between races/ethnicities and further stratified by age group (<65 and ≥65). Prostate cancer incidence rates were significantly lower in HAs and NAs than in EAs in the younger age group. The differences in incidence rates were smaller in the older age group, while statistically significant for many comparisons. In Arizona, the prostate cancer incidence rate was similar in NAs and EAs in the older age group (NA/EA incidence rate ratio of 1.05). Incidence rate ratios between HAs and EAs and between NAs and EAs were similar in older and younger age groups for kidney and bladder cancer.

**Conclusion:** Although HAs and NAs showed lower prostate cancer incidence rates among the younger age group, HAs and NAs showed higher incidence rates for metastatic prostate cancer, possibly due to differences in screening participation compared to EAs. NAs and HAs in border states were also found to have a heavier burden of kidney cancer than EAs. These findings indicate a need for greater understanding and exploration of the underlying causes of these disparities.
Background: Bladder cancer (BC) is rarely seen in young adults and is poorly understood in this population. With the use of National Cancer Database, we characterize the clinicopathological outcomes in patients less than 40 years old.

Methods: We identified 362,091 BC patients. We compared adults less than 40 (Group A) to those over 40 (Group B) with univariate analysis using Chi-square tests. Reported differences were significant. Multivariable Cox regression was used for overall survival (OS) analysis with hazard ratios (HR) and 95% confidence intervals (CI).

Results: 3,799 patients (1.1%) were in Group A, mean age was 34.5 versus 71.5 years in Group B. Group A had more low stage disease 51.4% Ta versus 38.3% Ta in Group B; and less MIBC 9.9% versus 15.9%. Variant histology (VH) was more common in Group A 8.74% versus 5.31%. Age less than 40 and NMIBC were associated with decreased mortality (HR 0.3, 95% CI 0.2-0.3 and HR 0.9, 95% CI 0.9-0.9), while VH with worse mortality (HR 1.9, 95% CI 1.9-2.0). In subgroup of patients post-cystectomy Group A had more nodal and distant disease 30.4% versus 23.9% and 3.6% versus 1.9% respectively. In the post-cystectomy sub-group, Group A again had more VH 24.2% versus 10.3%. VH patients in Groups A and B post-cystectomy were more likely to have nodal or distant disease.

Conclusions: Most young adults with BC have low risk disease and good prognosis however a small subset have aggressive disease with early nodal and metastatic disease associated with VH.
MONOCYTE-TO-LYMPHOCYTE RATIO (MLR) AS AN INDICATOR OF POOR PROGNOSIS IN MUSCLE-INVASIVE BLADDER CANCER

Abstract Introduction: A biological marker of inflammation has been associated with poor survival for various cancer. We focused on Monocyte-to-Lymphocyte Ratio (MLR). The aim of this study is to investigate the clinical MLR as a prognostic factor in muscle-invasive bladder cancer (MIBC) patients.

Methods and Patients: MIBC patients diagnosed in Nagoya daini Red Cross Hospital between April 2009 and March 2015 were retrospectively reviewed. Potential prognostic factors such as age, gender, vascular invasion, N-stage, and MLR were analyzed. MLR was assessed before radical cystectomy. Overall survival (OS) were calculated by the Kaplan–Meier method.

Results: A total of 94 patients were included in the study. The average of MLR before RC was 0.256 (0.104 -0.754). MLR of 0.23 was identified according to the ROC.

45 patients (47.9%) presented MLR>0.23. Median survival for the entire cohort was 32 months. We found that patients with MLR>0.23 had worse survival. Median OS of patients with MLR>0.23 was 28 months and in patients with MLR<0.23 was 36 months (p = 0.047)

Multivariate analysis showed that elevated MLR was independent predictors of OS in patients undergoing RC based on hazard ratio (HR 2.56 95%CI:1.02 -6.59 P=0.047)

Conclusion: In our analysis, elevated MLR is a predictor of shorter survival in patients with MIBC. MLR is an easily measured, reproducible test that could be considered to be incorporated in the routine practice in MIBC patients.
CHANGE IN NEUTROPHIL TO LYMPHOCYTE RATIO AS A PROGNOSTIC MARKER IN PATIENTS UNDERGOING RADICAL CYSTECTOMY FOR MUSCLE INVASIVE BLADDER CANCER

Introduction & Objectives: Several inflammatory response markers are used as prognostic indicators for various cancers. The neutrophil to lymphocyte ratio (NLR) has been introduced for prognostic scoring and there are some reports about this ratio in bladder cancer. We hypothesized that elevation of the NLR was associated with progression of bladder cancer, and we focused on the increase in the NLR before radical cystectomy (RC). The aim of this study was to assess the potential value of the change in NLR as a prognostic factor for patients with muscle invasive bladder cancer (MIBC).

Methods: Patients undergoing RC for MIBC at Nagoya Daini Red Cross Hospital between 1994 and 2015 were analyzed retrospectively. However, patients receiving neoadjuvant chemotherapy and those without transurethral resection of bladder tumor (TURBT) were excluded. Accordingly, we calculated the NLR just before TURBT and RC in 102 patients. The NLR doubling time (NLR-DT) was determined. Univariable and multivariable Cox proportional hazards regression analysis was used to identify factors influencing overall survival (OS). In these analyses, covariates included the age, gender, pathological T stage, pathological N stage, lymph vascular invasion, adjuvant chemotherapy, NLR before TURBT and RC, and NLR-DT.

Results: The median age was 72 (35-83) years with a median follow up period of 32 (1-133) months. Death from MIBC occurred in 40 patients. The average NLR before TURBT was 2.84 (0.77-33) and the average NLR before RC was 2.88 (0.71-12.22). The median span between TURBT and RC was 60 (11-152) days. An NLR-DT of 120 days was used to divide the patients into two groups. In 24 of the 102 patients, NLR-DT was less than 120 days. Univariate analysis showed that NLR-DT, NLR before RC, T stage, N stage, and lymph vascular invasion were significantly associated with a poor outcome. Multivariate analysis confirmed that NLR-DT and N stage were independent predictors of OS in patients undergoing RC. A shorter NLR-DT was associated with a higher risk of short OS (HR 11.33, 95% CI: 2.58-66.83, P=0.009).

Conclusions: NLR-DT < 120 days may be a biomarker of poor overall survival in patients undergoing RC for MIBC, but further investigation is needed to better understand the impact of NLR in bladder cancer.
SOLITARY FIBROUS TUMOR OF THE RENAL VEIN PRESENTING AS RENAL ARTERY ANEURYSM: A CASE REPORT
(Presentation to be made by Dr. Hertz)

Introduction: Solitary fibrous tumor (SFT) is a mesenchymal tumor with fibroblastic components originally thought to only arise in the pleura. However, they are now known to occur in many extra-thoracic sites. Giant renal artery aneurysms (RAA) are an uncommon condition with less than 30 cases reported in the literature. They are notable for their large size and proclivity for rupture. Presented here is the first reported case, to the author’s knowledge, of SFT originating from the renal vein, but presenting as a giant RAA.

Case Report: A 56-year-old man presented to the emergency department with acute onset of epigastric pain and hypertension. The patient was tender to palpation in the epigastric region. He had no costovertebral angle tenderness. He was recently diagnosed with hypertension as an outpatient which was managed with one oral anti-hypertensive. The patient had a remote history of multiple motorcycle crashes, but no known intra-abdominal injuries. Renal function was within normal limits with a creatinine of 1.2 mg/dl. Computed tomography (CT) images were obtained and radiology reported a 10cm left renal artery aneurysm with contained rupture. Segmental infarcts were also noted, suggesting showering of emboli. There was visible renal vein thrombus. CT demonstrated standard renal vascular anatomy with one artery and vein. The vascular surgery, interventional radiology, and urology services were immediately consulted.

Immediate beta-blockade with esmolol was used for blood pressure control. The patient was taken for coil embolization of the renal artery aneurysm with a multidisciplinary team of interventional radiologists and vascular surgeons. Three endovascular coils were used. The patient remained hemodynamically stable throughout the procedure.

The patient was transferred directly to the operating room where vascular and urologic surgeons prepared for a radical nephrectomy. Using a modified anterior subcostal incision, vascular control was achieved. The renal artery and ureter were divided using a vascular stapler. During subsequent hilar dissection the left renal vein was partially torn and extruded thrombus noted in its lumen. A renal pedicle clamp was placed proximal to the injury and the vein divided using a vascular stapler. The kidney was passed off as specimen, the renal vein tear repaired.

The patient’s post-operative recovery was unremarkable. He was discharged home on postoperative day 5 with stable renal function and no change in anti-hypertensive medication.

Pathology reviewed the specimen and histologically saw a spindle cell neoplasia consistent with solitary fibrous tumor. Immunohistochemical staining was positive for CD34, bcl2, SMA (focally), and PanCK (weakly focally positive). The case was referred to the Joint Pathology Center for further review. Expert pathologists agreed with the finding of solitary fibrous tumor. They additionally noted that the tumor was likely originating from the renal vein and not the artery. This finding has not previously been noted in the literature.

Conclusion: This case represents the first finding of solitary fibrous tumor of the renal vein and illustrates its potential to masquerade as a giant renal artery aneurysm.
LONG-TERM FOLLOW-UP FROM STAMP, A PHASE 2 TRIAL, EVALUATING SIPULEUCEL-T AND CONCURRENT VS SEQUENTIAL ABIRATERONE ACETATE + PREDNISONE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER PATIENTS

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(Presentation to be made by Dr. Lawrence Karsh)

Introduction: The optimal sequence and combination of life-extending anticancer therapies in metastatic castration-resistant prostate cancer (mCRPC) patients remains unknown. Sipuleucel-T (sip-T), an autologous cellular immunotherapy approved for the therapy of asymptomatic or minimally symptomatic mCRPC patients, was evaluated in combination with abiraterone acetate and prednisone (abi) in the phase 2 STAMP trial (NCT01487863), with patients randomly assigned to receive concurrent (CON) sip-T + abi or sequential (SEQ) sip-T followed by abi. The combination was well tolerated and did not alter the immune response parameters that correlate with overall survival (OS; Clin Cancer Res 2015;21:3862). Here, we present long-term follow-up of clinical outcomes, including OS.

Methods: mCRPC patients were randomized 1:1 to CON or SEQ therapy with sip-T and abi. Abi began 1 day after (CON) or at week 10 (SEQ) after the first sip-T infusion and continued for 26 weeks of therapy, after which continued abi therapy was permitted. Long-term clinical outcomes included OS, disease-specific death, progressive disease, time to first anticancer intervention, and safety.

Results: Sixty-nine patients were enrolled (35 CON; 34 SEQ), with a median follow-up of 36.2 months. Median OS was 34.0 months (95% CI, 24.4—not estimable; 30.0 months CON; 34.2 months SEQ; p=0.921), and median time to disease-specific death was not reached (CON vs SEQ; p=0.733). Median time to progressive disease was 17.3 months (95% CI, 9.7—not estimable; 17.7 months CON vs 13.9 months SEQ; p=0.914; consistent with higher rates of abi discontinuation due to progressive disease in SEQ [26.5% vs 14.3% in CON]). Time to first anticancer intervention was similar between arms at 15.4 months (95% CI, 11.0–19.9). No new safety signals were observed with the combination, and no discernable difference in clinical outcomes was observed with CON or SEQ treatments.

Conclusions: Long-term follow-up data confirm that sip-T + CON or SEQ abi is well tolerated, with no new safety signals. No clear differences were observed in clinical outcomes between arms, although the study was not powered to detect these differences. Future and more appropriately powered studies on the effect of sip-T + continuous abi for responding patients may provide further insights on the benefit of combination therapy.

Funding Source: Dendreon Pharmaceuticals, Inc.
DEVELOPMENT AND VALIDATION OF A NOVEL CLINICAL-GENOMIC RISK GROUP CLASSIFICATION FOR PROSTATE CANCER INCORPORATING GENOMIC AND CLINICOPATHOLOGIC RISK


(Presentation to be made by Kasra Yousefi)

Objectives: Treatment of localized prostate cancer is currently founded within the framework of risk groups, such as those defined by the National Compressive Cancer Network (NCCN) practice guidelines. Genomic risk assessment in prostate cancer has rapidly emerged as a tool to improve stratification, but for many providers it is clinically challenging to integrate genomic classifier results that report a numerical risk of recurrence into treatment recommendations for patients. We aimed to develop a novel clinical-genomic risk grouping system that can be easily incorporated into treatment guidelines for localized prostate cancer.

Materials and Methods: Four multi-center cohorts (n=6928 patients) were utilized to characterize, and validate a novel clinical-genomic risk system in radical prostatectomy (RP) samples, and subsequently in diagnostic biopsy samples. Fine-Gray competing risks analysis was used to estimate the risk of metastasis. Time-dependent c-indices were constructed to compare NCCN and Cancer of the Prostate Risk Assessment (CAPRA) risk to the clinical-genomic risk system.

Results: With a median follow-up of 8 years for men in our RP cohort, the 10-year distant metastasis rates for NCCN low, favorable-intermediate, unfavorable-intermediate, and high-risk were 7.8%, 9.4%, 40.1%, and 41.4%, respectively. Our 3-tier clinical-genomic risk groups had 10-year distant metastasis rates of 3.7%, 30.7%, and 57.7%, for low, intermediate, and high-risk, which were validated in our pre-treatment biopsy cohort with 10-year rate of distant metastasis of 0%, 30.3%, and 63.2%, respectively. C-indices for the clinical-genomic system (0.84, 95%CI 0.62-0.92) were significantly improved over NCCN (0.71, 95%CI 0.59-0.84) and CAPRA (0.71, 95%CI 0.60-0.81) score. A total of 33.4% of men would be reclassified by the clinical-genomic system, and specifically 17.1%, 41.3%, and 19.4% of men in NCCN low, intermediate and high risk groups would be reclassified by our new system.

Conclusions: A commercially available genomic-classifier in combination with standard clinicopathologic variables can generate a simple to use 3-tier clinical-genomic risk grouping system that is highly prognostic for survival outcomes, more accurately identifies patients at low, intermediate, and high risk of metastasis, and can be easily incorporated into current NCCN guidelines to inform treatment decisions.

Source of Funding: GenomeDx Biosciences
BOOSTING LONG-TERM IMMUNE RESPONSES TO SIPULEUCEL-T (SIP-T) BY RETREATMENT OF PATIENTS (PTS) WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC)

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(Presentation to be made by Dr. Corman)

Objective: Sip-T induces immune responses to target antigens PAP and PA2024 (a recombinant of PAP and granulocyte macrophage colony-stimulating factor). PROTECT (NCT00779402) assessed sip-T in biochemically recurrent androgen-dependent PC; pts who subsequently developed mCRPC were eligible for P10-1 (NCT01338012). Immune memory prior to retreatment was assessed and compared to treatment-naïve mCRPC pts.

Methods: PROTECT pts (sip-T arm) were retreated with sip-T in mCRPC, as part of P10-1. Antigen presenting cell (APC) activation, cellular (PA2024/PAP ELISPOT; T cell proliferation) and humoral responses were assessed and compared with treatment-naïve mCRPC pts (IMPACT NCT00065442; STAMP NCT01487863; STRIDE NCT01981122).

Results: Caucasian men (n=8), median follow-up 8.9 y and aged 74 y, had an ECOG PS ≤1. Median APC activation with sip-T infusion 1 was ~3-fold higher in P10-1 vs treatment-naïve pts. In P10-1, higher magnitude cellular and humoral responses were preexistent at baseline (BL). Sip-T retreatment further boosted cellular and humoral responses. Immune responses were maintained up to wk 52, and were higher vs 1st time treated mCRPC pts.

Conclusions: Sip-T in an earlier disease setting generated sustained antigen-specific immune memory lasting up to 10 y. Consistent with immune responses to vaccines, sip-T retreatment rapidly boosted cellular and humoral antigen-specific responses in mCRPC pts.

Source of Funding: Dendreon Pharmaceuticals, Inc.

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Purpose: Positive surgical margins after radical prostatectomy are a significant predictor for biochemical failure. Close surgical margins however represent a diagnostic challenge for surgeons. We sought to evaluate the biochemical recurrence patterns among men with radical prostatectomy specimens having negative, positive, and close surgical margins from the Shared Equal Access Regional Cancer Hospital (SEARCH) cohort.

Materials and Methods: Men undergoing radical prostatectomy between 1988 and 2015 with known final pathologic margin status were evaluated. The cohort was divided into 3 groups based on margin status; negative, positive, and close. Close margins were defined by distance of tumor ≤1mm from the surgical margin or by pathologic description from reports. Biochemical recurrence was defined as PSA >0.2ng/ml, 2 values at 0.2ng/ml, or secondary treatment for an elevated PSA. Predictors of PSA recurrence and prostate cancer specific death were analyzed using Cox-proportional Hazard models.

Results: Of 5,416 men in the SEARCH database, 4,224 (78%) men met criteria for inclusion in the analysis. Of these, 2,016 (48%) had negative margins, 1,851 (44%) had positive margins, and 357 (8%) had close margins. On multivariable analysis, relative to negative margins, men with close margins had a higher risk of biochemical recurrence (HR=1.57, 95%CI=1.41–2.10, P<0.001). However, this risk was lower than that of men with a positive margin (HR=2.16, 95%CI=1.91-2.44, P<0.001). However, both close (p=0.25) and positive margins (p=0.95) were unrelated to disease-specific survival.

Conclusion: Close but negative margins are associated with an intermediate risk of BCR – greater than negative margins, but less than men with positive margins. However, consistent with prior studies from our group, all margin categories were unrelated to disease-specific survival. Close or positive margins, in the absence of other high-risk features, do not increase the risk of death and should not be used alone to make adjuvant therapy decisions.
RADICAL PROSTATECTOMY UTILIZATION AFTER THE USPTF PRONOUNCEMENT IN THE SOUTHERN SAN JOAQUIN VALLEY OF CALIFORNIA. DOES THE CULTURE TRUMP SCIENCE THERE?

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Introduction: The southern San Joaquin Valley was established as high utilization area for radical prostatectomy typical of far western culture along with high rates of suicide, teenage pregnancy, back surgery and auto-accidents. But, utilization of the ‘radical’ decreased markedly in 1992 when the Medicare administration said they were going to audit all radical prostatectomies over age 75. This report answers the question,”Will this high utilization area have a dramatic decrease in utilization, as in 1992, after USPTF opined in October 2011 that screening with PSA did more harm than good?”

Materials and Methods: Data on the number of prostate cancer cases and the percent radical prostatectomized was requested from the state of California Cancer Reporting and Epidemiological Surveillance group for 2006-2014 and for Madera, Fresno, Kings, Tulare and Kern counties.

Results: As shown in the graph, there was a slow, 35% decrease in case finding from a peak in 2007 to 2014. That year was 15% below 2013. But, there was only a 3% drop in the number of radical prostatectomies performed 2013 to 2014 and only a 5% drop from the peak year of 2007.

Discussion: There is little dispute in academia that the USPTF decision was overdue. For example, a consortium of academic practices has reported at the AUA in San Diego a 47% drop in numbers of radical prostatectomies between the periods 2012-2013 and 2014-2015. By contrast, the southern San Joaquin Valley has been obdurate in its response to USPTF. Case finding has declined 35% since 2007 but its radical prostatectomy rate responded only a little (-3%) compared to the academic group cited above.

Conclusion: An activist, ‘cowboy’ culture trumps the culture of science in the southern San Joaquin Valley.
SURVIVAL OUTCOMES FOR AFRICAN-AMERICAN (AA) VS MATCHED CAUCASIAN (CAU) PATIENTS (PTS) WITH METASTATIC CASTRATE-RESISTANT PROSTATE CANCER (mCRPC) TREATED WITH SIPULEUCEL-T (SIP-T)

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(Presentation to be made by Dr. Freedland)

Objective: Prostate cancer risk and mortality is higher in AA vs CAU men. In an analysis of three phase 3 mCRPC trials, AA pts appear to derive greater survival benefit with sip-T, an autologous cellular immunotherapy for asymptomatic/minimally symptomatic mCRPC. AA pts on sip-T had a 30.7-month (mo) median overall survival (OS) benefit vs control (AUA 2012 P953), in contrast to a 4.1-mo OS benefit with sip-T vs control for all pts in IMPACT (NEJM 2010;363:411). As the prior analysis did not adjust for baseline differences between races, we matched AA to CAU pts treated with sip-T to better assess racial differences in sip-T OS benefit and product cumulative antigen presenting cell (APC) activation, which correlates with OS (CII 2013;62:137).

Methods: Data were from phase 3 mCRPC trials that randomized pts 2:1 to sip-T or control (D9901 [NCT00005947]; D9902A [NCT01133704]; IMPACT [NCT00065442]). Thirty-three AA sip-T pts were matched with 66 CAU sip-T pts based on predicted Halabi survival. Data were evaluated by the Kaplan-Meier method (event rates) and ANOVA (APC activation).

Results: Median follow-up was 36 mos. AA pts on sip-T had a 20.6-mo longer median OS (45.3 mos; 95% CI 23.4–NE) vs CAU pts (24.7 mos; 95% CI 18.1–29.4) (HR=0.49; 95% CI 0.26–0.91; p=0.02). Median event-free survival (time to death or anticancer intervention [ACI]) was 10.7 mos for AA pts (95% CI 8.5–21.5) vs 8.7 mos for CAU pts (95% CI 6.6–11.5) (HR=0.74; 95% CI 0.47–1.18; p=0.20). Median time to next ACI was 23.5 mos in AA pts (95% CI 9.4–NE) vs 16.3 mos in CAU pts (95% CI 9.7–25.6) (HR=0.78; 95% CI 0.42–1.43; p=0.42). In AA pts, median APC activation was higher with sip-T infusion 1 vs CAU pts (7.0 vs 5.5, p=0.004). Median cumulative APC activation over the three infusions was 27.7 (22.6–42.4, AA) vs 25.7 (21.5–33.9, CAU) (p=0.083).

Conclusions: Prior studies found sip-T provides OS benefit to both AA and CAU mCRPC pts. Herein, for men treated with sip-T, AA had longer survival, suggesting sip-T may provide greater OS benefit in AA. The basis for this may be biologic (greater APC activation). Further studies with larger sample sizes are needed to confirm if AA pts derive greater OS benefit from sip-T.

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