



THE MID-ATLANTIC SECTION
of the
AMERICAN UROLOGICAL ASSOCIATION



MA-AUA

67th Annual Meeting October 1-4, 2009

*The Canadian Journal of Urology
is pleased to publish the following abstracts
from the 2009 Mid-Atlantic Section
AUA Meeting,
October 1-4, 2009*

Williamsburg Lodge - Williamsburg, Virginia

P1

First Long-Acting Testosterone Undecanoate Injection to Treat Male Hypogonadism: 21-Month Safety and Efficacy Outcome

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Introduction: Pharmacokinetic data up to 24 weeks were previously reported from a phase 3 study of testosterone undecanoate (TU) 750 mg for hypogonadism. This study reports data up to 21 months.

Materials and methods: For this multicenter, US-based study, TU 750 mg was injected at initial dose, at week 4, and every 10 weeks thereafter through 84 weeks. Men ≥18 years of age with primary or secondary hypogonadism and screening serum testosterone concentrations <300 ng/dL were eligible. Blood was collected frequently during weeks 14-24 (after third injection) and 24-34 (after fourth injection). Trough testosterone samples were collected at each injection. Safety monitoring included clinical labs, prostate health, and AEs.

Results: Of 130 patients (mean age, 54 y), >75% completed all injections. Mean 10-week testosterone concentration during weeks 14-24 was 494.6 ng/dL (SD, 141.46 ng/dL). Similar testosterone concentrations across injection intervals, with nearly identical peaks and nadirs, indicated consistent testosterone therapy. Mean trough testosterone concentrations were within normal range (300-1000 ng/dL). Injections were well tolerated. AEs were minor and nonserious; 36.7% experienced at least one possibly treatment-related AE, with acne (6.2%) and increased PSA (5.4%) most common. Three (2.3%) had increased hematocrit and/or hemoglobin, and 2 (1.5%) were diagnosed with prostate cancer during the study.

Conclusions: TU 750 mg every 10 weeks for 21 months effectively provides consistent testosterone concentrations within normal range, a favorable safety profile, and a high level of patient tolerability.

P2

mTOR/p70S6 Pathway in Clear Cell Renal Cell Carcinoma (cc-RCC): Comparison of Activation in Primary Tumor and Matched Metastatic Deposits

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Introduction: The mTOR/p70S6 kinase pathway regulates cell growth, proliferation, motility, and survival. Here we assess and compare its activation in primary cc-RCC and matched metastases (n=34).

Methods: Tissues from primary renal tumors and matched resected/biopsied metastatic deposits were obtained from our institutional biosample repository. Tissue microarray (TMA) slides were constructed to include normal kidney controls. TMAs were incubated with rabbit polyclonal antibodies against Ser2448 of p-mTOR and Ser235/236 of p-ribosomal protein S6. Semiquantitative assessments of immunohistochemical staining were made, and Spearman rank correlation coefficients were used to assess associations between variables.

Results: Both primary tumors and matched metastases exhibited heterogeneous levels of staining for p-mTOR and for p-S6. We observed a strong relationship between phosphorylation of S6 in primary tumors and their matched metastases (p<0.0001, Figure 1); however in clear cell tumors we did not identify statistically significant relationships between staining for p-mTOR in the primary tumors and their matched metastases (p=0.179). No statistically significant association was seen between level of p-mTOR expression and p-S6 in primary cc-RCC (p=0.470), nor within metastatic lesions (p=0.368).

Conclusions: Our data suggest that mTOR/p70S6 kinase pathway activation is common, but not ubiquitous in patients with metastatic cc-RCC. We document a strong relationship between phosphorylation of S6 in primary clear cell tumors and their matched metastases. These findings are novel and deserve further study.

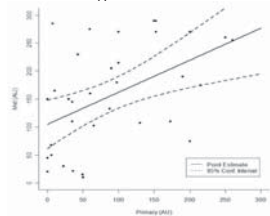


Figure 1. Plot of p-S6 expression in metastatic cc-RCC. Legend: solid line represents the identity line (y=x), dashed line represents the regression line.

P3

Prostaglandin Production by Interstitial Cells of Cajal Regulates Spontaneous Rhythmic Contraction of the Urinary Bladder

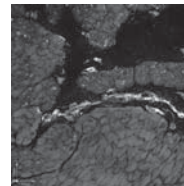
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Introduction: Bladders from patients and animals with overactive bladder display increased spontaneous rhythmic contraction (SRC). We tested the hypothesis that Interstitial Cells of Cajal (ICC) express cyclooxygenase (COX) and produce prostaglandins that cause SRC.

Materials and methods: In muscle experiments using strips of rabbit detrusor free of urothelium, SRC was measured after addition of COX inhibitors and prostaglandin receptor antagonists. Fluorescence immunohistochemistry with scanning confocal microscopy investigated the presence of ICC in bladder and COX. Using enzyme immunoassay (EIA), PGE2 production was determined in tissues incubated for 1, 5, and 15 minutes in physiologic salt solution, and effects on production were studied after pre-treatment with COX inhibitors.

Results: Maximum inhibition of SRC was achieved with a selective PGE2 receptor antagonist (~90%) with slightly less inhibition achieved using COX inhibitors (~80-85%). Confocal microscopy revealed that ICC markers (c-Kit and vimentin) co-localized to cells surrounding detrusor smooth muscle (DSM) bundles (Fig1, purple with blue nuclei), indicating the presence of extensive ICC. COX-1 (Fig1-yellow/orange) and COX-2 co-localized with interstitial cells expressing vimentin, an ICC marker. EIA analysis revealed a 4.8 fold increase in PGE2 production at 15 minutes (p<0.05). PGE2 production was reduced by pre-treatment a non-selective COX inhibitor (ibuprofen: 88%, p<0.05), COX-1 inhibitor (SC560: 45%, p<0.05) and COX-2 inhibitor (NS-398: 47%, p=0.065).

Conclusions: These data suggest that basal synthesis of prostaglandins by COX-1 and COX-2, expressed by ICC, regulates SRC. Additional studies may identify novel targets for the treatment of overactive bladder.



P4

Genomic Study on Prostate Cancer Disparities Associated with the African American Population

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Introduction: African Americans (AA) have the highest risk of developing prostate cancer with aggressive disease compared to Caucasian Americans (CA). To identify the genetic predisposition and oncogenic signatures, we applied genomic approaches to compare RNA expression profiles and DNA copy number variations (CNVs).

Materials and methods: Prostate cancer biopsy cores and adjacent benign cores from 6 AA and 4 CA were collected. The purified RNA and DNA samples were processed and hybridized onto Affymetrix Exon and SNP 6.0 arrays to examine the RNA expression profiles and DNA CNVs, respectively.

Results: 95 genes were differentially expressed in the benign cores from normal AAs and CAs. These genes were selected for further clustering analysis and functional classification. These genes could be functionally classified into four major networks involving in ERK, NF-κB, insulin/INS1 signaling and androgen metabolism. Comparisons of the expression profiles from cancer with the adjacent benign tissues revealed that 289 differentially expressed genes were involved in the regulation of several oncogenic and inflammatory pathways in AA patients. STAT1 and RHOA genes were highly expressed in AA, suggesting the more aggressive tumor. Exon array results further revealed the alternative splicing variants in three genes associated with prostate cancer progression; including TMG4 and ESRRC in normal AA, and STAT1 in cancer AA.

Conclusions: The exon and SNP profiling reveals differential expression patterns and CNVs in normal and cancer biopsies in two ethnic groups, suggesting that differences in inflammatory responses, oncogenic pathways, and insulin and androgen metabolisms may account for the observed disparities.

MODERATED POSTER SESSION I

P5

MALDI Mass Spectrometry Tissue Imaging and Clinical Applications for Renal Cell Carcinoma

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Introduction: Matrix-assisted laser desorption/ionization mass spectrometry imaging (MALDI MSI) is a novel tool for investigating tumor biology as it allows analysis of protein distribution directly from intact tissue sections. We report a pilot study evaluating MALDI MSI in clear cell renal cell carcinoma (cRCC) and papillary renal cell carcinoma (pRCC).

Materials and methods: Frozen tissue from surgical specimens of pathologically confirmed cRCC and pRCC were used for analysis. Adjacent tissue sections were prepared for IHC analysis and MALDI MSI from 10 specimens of cRCC and pRCC. 5 specimens of normal renal parenchyma were used as a control. A Bruker Daltonics Ultraflex III MALDI time of flight (TOF) system was used to generate spectra from the 3 tissue groups. Differences in protein expression were determined using Flex Imaging software.

Results: Significant differences in spectra obtained from the 3 groups. For cRCC the spectra revealed high intensity protein peaks at 4632.23 m/z (mass to charge ratio) and 9261.06 m/z that were less in the spectra for pRCC and normal renal parenchyma. Unique to pRCC and cRCC was a peak at 3443.55 m/z which was significantly more intense in pRCC compared to cRCC. This was not seen in the spectra for normal renal parenchyma.

Conclusions: We report the novel use of MALDI MSI as a potential adjunct to pathologic examination of RCC. Clear differences in protein expression were seen between cRCC and pRCC. Future evaluation of this technology will focus on all RCC histologic subtypes and its potential application to percutaneous renal biopsies.

P7

Concordance in the Perception of Couples Recovering from Primary Surgical Treatment of Prostate Cancer

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Introduction: Urologists have focused on prostate cancer control and patient outcomes; however, it has been labeled a "relationship disease" as research shows effects on the couple. Studies have found that psychological distress is equivalent regardless of whether the person is the patient or partner. We hypothesized that the couple would perceive the recovery from primary surgical treatment of PCA differently.

Methods: Retrospective sexual survey packets (RSS) were sent to patients undergoing surgical procedure for prostate cancer by a single surgeon. One follow-up call was utilized per patient. If no interest was shown, no further contact was pursued. RSS packets include IRB-approved consent forms, a RSS, and a validated sexual function questionnaire the International Index of Erectile Function (IIEF) for male partner and the Female Sexual Function Index (FSFI) for female partner. We analyzed couples' concordance in psychological domains including emotional status, relationship, self-image, partnership quality, and support.

Results: 28 heterosexual couples (56 people) were enrolled. Patients were treated between February 2002 and March 2007 with a median follow-up of 26 (range: 4-59) months. When polled on psychological aspects that may have been affected by treatment, overall concordance was 75.0%. Partnership had the highest concordance (92.2%) with treatment satisfaction questions following in second (90.7%). Subcategories focused on self-image (77.5%), the relationship (67.3%), support (66.4%), and emotional status (55.6%), were less concordant.

Conclusions: Although couples report relationships as strong, misconception between partners is widespread. Further research concerning the effect of such disparities in couples might provide additional insight into improving recovery.

P6

Utilization of Helical Computer Tomography as a Replacement for Intravenous Urography: Cost of Progress?

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Introduction: Radiographic imaging is essential to the urologist to make clinical diagnosis. Intravenous urography (IVU) has been integrated for the work up of calculi and hematuria. Advancement of computerized tomography (CT) has changed urologists' practice patterns and impacted usage of IVU. The degree of utilization and the cost of CT scanning as the imaging modality are evaluated.

Materials and methods: A large single-specialty urology practice database was reviewed from 1/2000 to 1/2008, comparing utilization of IVU and helical CT scan imaging. Utilization of imaging modalities over time was done by annual data analysis. 2007 regional Medicare fee schedule was used to compare the facility payment of imaging per year. (IVU payment: \$76.04 and CT Abdomen/Pelvis payment: \$343.31)

Results: IVU utilization was consistent until 2002. Between 2002 and 2004, IVU utilization dropped from 56% of the imaging to 24% and continued to decrease. In 2000, 3905 radiology studies (CT & IVU) were ordered; 55% were IVUs. In 2007, 4292 radiology studies were ordered; only 3% were IVUs. Total number of studies (IVU and CT) ordered per year remained relatively constant over the study period. Annual total imaging cost, based on 2007 Medicare fee schedule, between 2000 and 2007 increased 48%, from \$766,338 in 2000 to \$1,481,851 in 2007.

Conclusions: Imaging of patients shifted from IVU to CT over the study period. Cost of imaging increased as practice patterns changed. The change in practice pattern was most likely driven by the substitution of a better modality (CT scan) for a lesser modality (IVU).

P8

Focal/Partial Gland Prostate Cryoablation: Results of 795 Patients from Multiple Centers Tracked with the COLD Registry

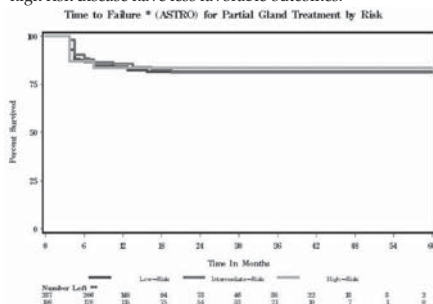
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Introduction: Cryotherapy for prostate cancer traditionally targets treatment of the whole gland. While efficacious, this ablates healthy tissue thereby increasing morbidity. Focal prostate cryo addresses only known cancerous foci. We report the outcomes of focal cryo at a number of centers participating in the Cryo On-Line Database (COLD). These early data on 795 men comprise the first multicenter report.

Methods: 795 focal cryo patients were stratified by D'Amico risk classifications. Biochemical failure was determined by the ASTRO definition. Biopsy was performed at the physician's discretion. Incontinence was the use of any pads. Intercourse was the ability to penetrate and complete with or without assistance.

Results: Median age of patients was 68 (37-85). Median follow up is 1 year. Actuarial disease free survivals are reported in the figure. Positive biopsies were reported in 36 patients (4.5% of the cohort, 25% of patients undergoing biopsy). 3 (0.4%) rectal fistulas were reported between 6 weeks and 12 months postop. Incontinence was reported in 11 pts (2.8%). Of the 134 patients potent prior to cryo, 87 (65%) were sexually active 12 months postop.

Conclusions: Focal prostate cryo is controversial. It is associated with low morbidity - most notably, a majority of men resume intercourse. Early efficacy is supported by encouraging 60 month BDFS rates in men with low and intermediate risk, but men with high risk disease have less favorable outcomes.



P9

Utilization of Systemic Therapy and Factors Impacting Survival in Patients Undergoing Cytoreductive Nephrectomy

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Introduction: A survival benefit to cytoreductive nephrectomy (CN) in patients with metastatic renal cell carcinoma (RCC) treated with immunotherapy has been demonstrated, and these data have been extrapolated to support CN in the targeted therapy era as well. Nevertheless, the likelihood that patients undergoing CN will receive systemic treatment remains poorly defined. Here, we present a multi-institutional experience evaluating the utilization of systemic therapy in patients undergoing CN.

Materials and methods: 141 patients who underwent CN between 1990 and 2008 were identified from our Institutional Kidney Cancer Registries. Kaplan Meier analyses and Cox regression models were used to assess the impact of clinicopathological variables on utilization of systemic therapy and survival.

Results: Overall, 98 patients (69.5%) received systemic therapy, at a median of 2.5 months (range 0.1-61.5) after CN. In this group, 52 (53%) patients received immunotherapy, 34 (35%) targeted agents, and 12 (12%) other regimens. By contrast, 43 patients (30.5%) did not receive systemic therapy, because of rapid disease progression (n=13, 30%), decision for surveillance (n=9, 21%), patient refusal (n=10, 23%), perioperative death (n=8, 19%), and unknown reasons (n=3, 7.0%). Median survival after CN was 16.7 months (range 0-120). The risk of death after CN correlated with symptoms at presentation (p=0.006), performance status (p=0.001), tumor grade (p=0.006), number of metastatic sites (p=0.012), and sarcomatoid histology (p<0.001).

Conclusions: Nearly 1/3 of patients undergoing CN never received systemic treatment. Studies are needed to identify those patients at highest risk for rapid disease progression who might benefit from a neoadjuvant treatment approach.

P11

Flash Replenishment Imaging with Contrast-enhanced Ultrasound Identifies High Volume/High Grade Prostate Cancer

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Introduction: To evaluate the detection of prostate cancer using contrast-enhanced ultrasound with an advanced flash replenishment technique - MicroFlow Imaging (MFI).

Materials and methods: 136 patients referred for prostate biopsy were evaluated by transrectal US. The microbubble agent Definity (Bristol-Myers Squibb) was diluted into concentration of 49.4uL/mL and infused at a rate of 4 mL/min. MFI uses high power flash pulses to destroy bubbles, followed by low power pulses to demonstrate contrast replenishment and depict vascular architecture. Up to 6 targeted biopsy cores were obtained from areas of abnormal vascular enhancement or morphology on MFI, followed by a systematic 12 core biopsy protocol.

Results: Enhancement of capsular and intraprostatic vessels was observed in all patients. Positive biopsies were obtained in 137/1632 (8.4%) of systematic cores and 93/555 (16.8%) of targeted cores (OR=3.3, p<0.001). Among the 49 patients detected by systematic biopsy, those 30 patients with a positive targeted core demonstrated an average of 3.7 positive systematic cores while those 19 patients who were missed by targeted biopsy demonstrated an average of 1.5 positive systematic cores (p=0.001). Mean percentage of systematic biopsy core involvement was 32% among patients with a positive targeted core, compared with 15% among patients who were missed by targeted biopsy (p=0.01). Higher grade cancer (Gleason score >6) was more common among patients with a positive targeted biopsy (47% versus 16%; p=0.03).

Conclusions: Targeted biopsy of the prostate using contrast-enhanced MFI imaging of the prostate identifies high volume/grade cancers which are most likely to be clinically significant.

P10

The Impact a Family History of Prostate Cancer has on PSA Recurrence-free Survival in Obese Men

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Introduction: Obesity has been suggested as a risk factor for PSA recurrence in men after radical prostatectomy (RP). However a family history (FH) of prostate cancer has been shown not to increase this risk. We examined a prospectively maintained RP database (1991-2005) to determine the impact of FH on PSA recurrence-free survival (PSARFS) in obese men.

Materials and methods: 2113 patients were analyzed. FH of prostate cancer was defined as >1 primary or secondary relative with prostate cancer. PSA recurrence was defined as a postoperative elevation in serum PSA >0.2 ng/mL. Chi-square, Fisher's exact and T-tests were used to compare variables. Multivariate regression analysis was performed to determine variables impact of on PSARFS.

Results: The mean follow-up was 62.2 months. The mean age and pathological Gleason score were 59.6 years and 6.5 respectively. 63% of men had no FH of prostate cancer, 19.8% had one relative with prostate cancer and 4.9% had >2 relatives with prostate cancer. FH was not an independent predictor of PSARFS on multivariate analysis. However, when subgroup analysis was performed, FH was a negative predictor of PSARFS in obese men, but not in non-obese men (HR=1.47, 95% CI 1.07, 2.04; p=0.02 and HR=0.80, 95% CI 0.42-1.43; p=0.45, respectively).

Conclusions: A FH of prostate cancer does not impact PSARFS after RP in non-obese men, but it does have a negative impact in obese men. More work is needed to define the potential biological mechanism of this relationship. Studies on hereditary prostate cancer should consider analyzing BMI data.

P12

Which Men Benefit Most in Improvement of LUTS after Robotic Prostatectomy?

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Introduction: We attempted to identify pre-operative predictors for reduction in lower urinary tract symptoms (LUTS) after robotic-assisted laparoscopic radical prostatectomy (RALRP).

Methods: A retrospective analysis was performed on men who underwent RALRP for prostate cancer (PCa). Variables examined by descriptive and univariate analyses include age, prostate size, inflammation on biopsy, and change in International Prostate Symptom Score (IPSS).

Results: Our study identified 121 men between 2003 and 2009 who had RALRP with at least 6 months follow-up (average 29 months). Fifty-one men had a pre-operative moderate-to-severe LUTS. Of these men, 80% had improvement of their LUTS (mean of 7.6 points). Men with high pre-operative IPSS (>=8) had greater reduction in IPSS (p<0.0001). When stratified into age groups, reductions in IPSS directly correlated; with age <50=33% (n=6), 50-60=43% (n=60), 60-70=61% (n=44), and >70=64% (n=11). Men with prostate size >35g experienced greater improvement in LUTS (37% vs 19%, p=0.02). Men with inflammation on pre-operative biopsy trended towards greater reduction in IPSS (5.7 vs 2.9, p=0.15). Five men predicted to improve by the above criteria fail to do so, but four had longstanding specific risk factors including stroke, low-compliance bladder, and detrusor overactivity.

Conclusions: Our data suggests that 80% of older men with significant pre-operative LUTS and large prostates can expect significant improvement of their LUTS post-operatively. Men with certain conditions known to impact bladder function are less likely to improve. Whether this degree of improvement offers an advantage of RALRP over other treatments for PCa is the subject of future study.

P13

Quality of Life after Open or Robotic Prostatectomy, Cryoablation, or Brachytherapy for Localized Prostate Cancer

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Introduction: Health related quality of life (HRQOL) concerns factor prominently in prostate cancer management. We describe HRQOL impact and recovery profiles of four commonly used invasive treatments for localized prostate cancer.

Methods: Beginning February 2000, all patients undergoing treatment by open radical prostatectomy (ORP), robot-assisted laparoscopic prostatectomy (RAP), brachytherapy (BT), or cryotherapy (CT) were asked to complete the UCLA Prostate Cancer Index questionnaire before treatment and at 3, 6, 12, 18, 24, 30, and 36 months following treatment. Outcomes were compared across treatment types with statistical analysis utilizing univariate and multivariate models.

Results: 785 patients treated between February 2000 and December 2008 were included in the analysis, with a mean follow-up of 24 months. All HRQOL domains were adversely affected by all treatments, and recovery profiles varied significantly by treatment type. Overall, urinary function and bother outcomes were significantly better after BT and TCAP compared to ORP and RAP. BT and CT had a three-fold higher rate of return to baseline urinary function compared to ORP and RAP (Cox proportional hazards). Sexual function and bother outcomes were best after BT, with a five-fold higher rate of return to baseline function compared to TCAP, ORP, and RAP. Bowel function and bother scores suggested mild and transient negative impact for all four treatments.

Conclusions: Based on sequential HRQOL assessments, BT and CT are associated with superior urinary function and bother outcomes compared to ORP and DVP. BT is associated with superior sexual function and bother outcomes compared to ORP, RAP, and CT.

P15

Urinary Quality of Life Following Radical Prostatectomy is Positively Impacted by Placement of a Male Sling

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Introduction: The treatment of prostate cancer has well known morbidities which dramatically affect quality of life (QoL). A longitudinal comparison using validated QoL instruments is valuable in evaluating outcomes. We evaluated QoL changes from pre-treatment in patients receiving radical prostatectomy (RP) and subsequent AdVance® sling placement for post-prostatectomy incontinence (PPI).

Methods: We included 21 patients who underwent both RP and subsequent AdVance® sling placement for PPI. QoL scores were collected prospectively for 36 months following RP using the self-administered UCLA-PCI questionnaire. We compared pre-treatment, post-RP, and post-sling scores for urinary and sexual function/bother. Post-RP/pre-sling and post-sling pad counts were collected retrospectively by chart review.

Results: 21 patients met inclusion criteria. Mean patient age at time of RP was 62. Mean follow-up was 19 months post-RP and 11 months post-sling placement. Significant declines from baseline in both urinary and sexual function (p<0.001) and bother (p<0.001) were found post-RP. Patients did receive significant increases in urinary QoL scores (p<0.001, p<0.002) after treatment with AdVance® sling placement, although not back to pre-treatment levels. Patients demonstrated significant decreases in pad counts after sling placement (p<0.001). Sexual QoL scores were not affected. Pad counts reported at time of follow-up correlated well with post-RP and post-sling urinary function QoL (p<0.001, p<0.005).

Conclusions: Men undergoing RP have significant declines in urinary and sexual QoL. Their urinary QoL scores improve significantly after AdVance® sling placement, however they do not regain their baseline. Patient reported pad counts at time of follow-up are a surrogate for self-reported urinary function QoL scores.

P14

Interstim II Implantable Generator Improves Surgical Time and Postoperative Pain After Neuromodulation

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Introduction: Sacral neuromodulation (Interstim) is an FDA-approved treatment modality for refractory urgency/frequency, refractory urgency incontinence, and non-obstructive urinary retention. A new, smaller implantable generator (IPG) was FDA approved in August 2006. The purpose of this study is to present the authors' experience with this new IPG.

Materials and methods: Patients who underwent successful Stage II sacral neuromodulation with Interstim II were followed prospectively. All patients underwent upper tract evaluation, cystoscopy, and urodynamic evaluation before the Interstim Stage I procedure. Patients were deemed eligible for Stage II implantation if they demonstrated a 50% improvement in urinary frequency, urgency, and urgency incontinence. Patients with nonobstructive urinary retention were eligible for Stage II implantation if they demonstrated a significant reduction in need for self-intermittent catheterization, or were not using this modality and voiding on their own.

Results: The mean patient age was 46 years (n=58 females). All patients had refractory urgency/frequency or urgency incontinence. The operative time for Stage II implant was 22 minutes compared to 32 minutes for the prior larger IPG (Interstim I). Two patients (3%) had infections of their IPG. Eight patients with previously significant IPG pocket pain from the larger IPG were implanted with Interstim II. Their mean pocket pain score (scale 1-10) improved from eight with Interstim I to 2.5 with Interstim II.

Conclusions: Sacral neuromodulation with Interstim II improves surgical time and pocket-related pain compared with the larger Interstim I IPG. In addition, there is a low infection rate and no revisions have been required to date.

P16

Effect of Age on the Efficacy and Safety of Silodosin in Men With Symptoms of Benign Prostatic Hyperplasia

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Introduction: Efficacy and safety data from 2 US phase 3 studies in men with BPH symptoms were combined and analyzed by age group

Materials and methods: Men aged ≥50 years with International Prostate Symptom Scores (IPSS) ≥13 received 8 mg silodosin or placebo once daily for 12 weeks. Endpoints were changes from baseline to last observation in IPSS (primary) and Qmax (secondary). Treatment effects were compared by analysis of covariance, with patients stratified by age (≥65y, <65y).

Results: Most (55%) study participants (N=923) were aged <65y. Among patients receiving silodosin (n=466), discontinuation due to adverse events was 8.1% for those <65y and 4.3% for those ≥65y. Improvement in IPSS, including irritative and obstructive subscores, and in Qmax was significantly greater for silodosin than placebo in both age groups (Table). The percentage of patients reporting silodosin-related retrograde ejaculation decreased with age (<65y, 38.6%; ≥65y, 15%). Treatment-related orthostatic hypotension was more common in the older than the younger age group, but incidence overall was similar for silodosin vs placebo (<65y, 1.5% vs 1.2%; ≥65y, 2.4% vs 1.9%). No treatment-related cardiac events occurred. The single serious drug-related event (syncope) occurred in a patient (85y) who took a prohibited concomitant medication (prazosin).

Conclusions: Silodosin promoted significant symptom relief and was well tolerated, regardless of patient age, with a cardiovascular safety profile similar to that of placebo.

TABLE. Summary of Treatment Effects (Silodosin vs Placebo) by Age Group

| | <65 years n=508 | <65 years n=508 | ≥65 years n=415 | ≥65 years n=415 |
|------------------|--------------------|--------------------|--------------------|--------------------|
| | LSM (95% CI) | P value | LSM (95% CI) | P value |
| IPSS Total | -2.9 (-4.0, -1.8) | <.001 | -2.7 (-3.8, -1.6) | <.001 |
| IPSS Irritative | -1.0 (-1.5, -0.5) | <.001 | -0.9 (-1.4, -0.4) | <.001 |
| IPSS Obstructive | -1.9 (-2.6, -1.2) | <.001 | -1.8 (-2.5, -1.1) | <.001 |
| Qmax, mL/s | 1.0 (0.2, 1.8) | .020 | 0.9 (0.2, 1.7) | .014 |

MODERATED POSTER SESSION II

P17

Does Hospital TURP Case Volume Predict Patient Outcomes?

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Introduction: The surgical literature evaluates hospital volume-outcome relationships using death as an endpoint but limits application to urology, as mortality rates are low. Patient safety indicators (PSI) have recently been shown as a novel method for measuring urologic surgical outcomes. PSIs are validated measures of quality of care developed by the Agency for Healthcare Research and Quality. We hypothesize that there is a volume-outcome relationship in the care of transurethral resection of the prostate (TURP) cases using PSIs as the outcome measure.

Methods: Retrospective analysis of the Nationwide Inpatient Sample was performed (2001-2005). TURPs were identified by ICD-9 procedure codes. Primary outcome variables were mortality and PSI events. Other variables included patient demographic variables and hospital characteristics.

Results: A total of 104,494 TURP patients were identified. Mean age was 73 years, 81.6% white, 6.8% black, and 7.1% Hispanic. Mortality was 0.3% and overall PSI rate was 0.81%. Median annual hospital TURP volume was 21 (range 7-43). After adjusting for potentially confounding patient and hospital variables, TURP volume was found to be significantly associated with one or more PSI events. A ten-case increase in annual volume decreases the overall PSI event rate by 4.0%. The volume-outcome relationship was mostly influenced by PSIs regarding hip fracture, DVT, and sepsis.

Conclusion: Hospital TURP volume was inversely correlated with patient outcomes as measured by PSI, many related to post operative care. Future work should focus on defining the minimum number of cases that a hospital should perform to maintain high quality urologic outcomes.

P19

Is Cystoscopy Indicated for Bladder Wall Thickening Identified Incidentally on Computerized Tomography?

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Introduction: Bladder wall thickening is identified incidentally on many computerized tomography (CT) reports, prompting urologic consultation for cystoscopy. The goal of this investigation was to determine the value of cystoscopy for this indication.

Materials and methods: Using a cystoscopy log and the medical record, indications for cystoscopy were reviewed on 1000 consecutive patients from January, 2007 to March, 2009 to identify patients whose sole indication for the procedure was incidentally identified bladder wall thickening on CT. Patients were excluded if found to have concurrent history of microscopic or gross hematuria or bladder cancer. Data collected included age, gender, race, cystoscopic findings, AUA symptom score, medical history, social history, and follow-up.

Results: 12 patients underwent cystoscopy for incidentally identified bladder wall thickening on CT for a total incidence to 1.2%. Of these, eight (66.7%) had diffuse and four (33.3%) had focal bladder wall thickening. Average patient age was 65.1 years and 53% reported smoking history. None of the eight patients with diffuse bladder wall thickening (0%) were found to have suspicious lesions on cystoscopy. Suspicious lesions were identified in 2 of 4 patients (50%) with focal bladder wall thickening; however subsequent biopsies were negative for malignancy. Overall, no patients with incidentally identified bladder wall thickening on CT were found to have malignancy and 2 of 12 (16.7%) underwent unnecessary biopsies.

Conclusions: In this initial series, incidentally identified bladder wall thickening on CT does not provide sufficient justification for cystoscopy.

P18

Silodosin Promotes Urodynamically and Symptomatic Improvement in Men With Symptoms Secondary to Benign Prostatic Hyperplasia: Relationship Between Efficacy and Retrograde Ejaculation

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Introduction: Alpha-blockers are thought to improve urine flow and symptoms related to benign prostatic hyperplasia (BPH) through smooth muscle relaxation in the bladder neck and prostate. We wondered whether the occurrence of retrograde ejaculation (RE), an indirect indicator of smooth muscle relaxation, is related to improvement in symptoms or flow rate.

Materials and methods: In two 12-week, randomized, placebo-controlled studies, silodosin (8 mg/day), a selective α 1A-adrenergic antagonist, was given to patients (age >50y) with moderate to severe BPH-related symptoms (IPSS \geq 13; peak flow rate [Qmax] between 4 and 15 ml/sec; voided volume >125 ml; postvoid residual <250 ml). For this analysis, patients were stratified by whether they experienced RE during the study.

Results: Of 466 silodosin-treated patients, 131 (28.1%) experienced RE (SIL+RE) and 335 experienced no RE (SIL-RE). Both groups had similar baseline values for IPSS and Qmax and, compared with placebo, experienced significant improvement (P < .02) in IPSS and Qmax after 12 weeks of treatment; mean improvement in IPSS and Qmax was greater in the SIL+RE compared with the SIL-RE group (Table).

Conclusions: On average, retrograde ejaculation was associated with greater improvement in symptoms and Qmax, with a clinically meaningful difference between SIL+RE and SIL-RE for Qmax. Superior relaxation of smooth muscle in genital and lower urinary tracts may result in both RE and greater efficacy in "unobstructing" urinary flow.

TABLE. Efficacy in patients with and without silodosin-related retrograde ejaculation

| Mean (SD) | P value SIL+RE | | | P value SIL-RE | | |
|---------------------|----------------|------------|---------|----------------|---------------|-----------|
| | PLA | SIL-RE | P value | SIL-RE vs PLA | SIL+RE vs PLA | vs SIL-RE |
| IPSS | | | | | | |
| Baseline | 21.3 (4.9) | 21.0 (5.1) | | 22.2 (5.0) | | |
| CFB to wk 12 (LOCF) | -3.5 (5.8) | -6.1 (6.4) | <.0001 | -7.2 (7.2) | <.0001 | .3856 |
| Qmax, ml/sec | | | | | | |
| Baseline | 8.9 (2.8) | 8.6 (2.6) | | 8.9 (2.4) | | |
| CFB to wk 12 (LOCF) | 1.5 (4.4) | 2.4 (4.3) | .0184 | 3.1 (4.8) | .0003 | .0699 |

P20

The Effect of the Combination of Dutasteride and Tamsulosin on the Transition Zone of the Prostate

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Introduction: Dutasteride decreases total prostate volume (PV) and transition zone volume (TZV) in BPH. However, the combination of dutasteride with an alpha-blocker and its effect on these two areas is unknown. We determined the effects of combination therapy on PV, TZV and the transition zone index (TZI).

Materials and methods: A total of 4,844 men \geq 50 years with BPH, AUA symptom score of \geq 12, PV \geq 30 cc, PSA \geq 1.5 ng/ml, and \leq 10 ng/ml, and peak urinary flow rate \leq 15 ml/second were randomized to dutasteride 0.5 mg, tamsulosin 0.4 mg or the combination of the two daily for 2 years. Prostate TZV was measured in a 10% subset of the subjects with transrectal ultrasound at baseline and after 1 and 2-years. PV, TZV and the TZI (TZV/PV ratio) were calculated. Patients were stratified into tertiles according to baseline PV. Treatment comparisons within PV tertiles were performed using a Wilcoxon rank-sum test.

Results: Within each PV tertile, combination therapy and dutasteride monotherapy significantly (p < 0.001) decreased PV and TZV compared with tamsulosin monotherapy. However, there was no significant difference between combination therapy and dutasteride monotherapy.

Conclusions: Dutasteride and combination therapy significantly decreased total PV and TZV compared with tamsulosin monotherapy regardless of baseline PV value.

TABLE. Percent Change From Baseline in Total Prostate Volume and Transition Zone Volume (LOCF) at Month 24

| Median [n] | Dut 0.5 + Tam 0.4 mg N = 153 | Dut 0.5 mg N = 164 | Tam 0.4 mg N = 160 |
|------------------------|---------------------------------|-----------------------|-----------------------|
| PV | | | |
| Baseline PV <44cc | -25.1 [54] | -28.8 [50] | -7.0 [54] |
| Baseline 44cc to <63cc | -24.0 [51] | -25.9 [53] | 5.6 [53] |
| Baseline PV > 63cc | -20.3 [48] | -29.8 [61] | 3.0 [53] |
| TZV | | | |
| Baseline PV <44cc | -24.1 [54] | -29.7 [50] | -0.5 [54] |
| Baseline 44cc to <63cc | -24.0 [51] | -26.6 [53] | 11.6 [53] |
| Baseline PV > 63cc | -24.0 [48] | -31.2 [61] | 2.8 [53] |

MODERATED POSTER SESSION II

| P21 | P23 |
|---|---|
| <p>Abstract not available</p> | <p>Abstract not available</p> |
| P22 | P24 |
| <p>Radiation Dose in CT-Guided Cryoablation of Renal Masses <i>Amy S. Burns, *Allen R. Goode, *Matthew J. Bassignani, Noah S. Schenkman</i> <i>University of Virginia, Charlottesville, VA</i></p> <p>Introduction: The use of image-guided therapy is increasing while health risks from exposure to ionizing radiation are increasingly reported. Our goal was to calculate the effective radiation dose received during CT-guided cryoablation of renal tumors and to compute the learning curve for the procedure.</p> <p>Materials and methods: A retrospective chart review from January 2008 to February 2009 found 17 patients that underwent renal mass percutaneous cryoablation. Using radiation dose estimates based on a standard anthropomorphic phantom from each procedure, the average effective radiation dose was estimated.</p> <p>Results: A total of 11 males and 6 females underwent cryoablation. There were 10 right- and 9 left-sided renal masses (one patient had ablation of three left tumors). Average mass size was 2.7 cm (range 0.9 cm-5.9 cm), average fluoroscopy time was 55.8 seconds (range 25.1-143.4 seconds), and average effective dose was 8.13 mSv for the fluoroscopy portion and 19.67 mSv for the total procedure. Average effective fluoroscopy dose and total dose for the first five cases were 12.56 mSv and 21.56 mSv, respectively. For the last five cases, average effective dose for the fluoroscopy portion and total procedure were 4.12 mSv and 15.78 mSv, respectively.</p> <p>Conclusions: Average effective radiation dose for the entire procedure was 19.67 mSv. For comparison, the effective dose for three-phase renal CT is 23.7 mSv. Average effective radiation dose in the first five is higher compared to the last five cases. Patients should be informed of potential radiation risks when selecting this treatment modality</p> | <p>Novel Management of Inverted-Y-Ureteral Duplication <i>Jyoti Upadhyay¹, *Amanda Burnette¹, *Greg Spana², *Margaret Roth², Maryellen Sheridan, RN²</i> <i>*Bijan Shekarritz¹</i> ¹<i>Children's Hospital of the Kings Daughter, Eastern Virginia Medical School, Norfolk, VA;</i> ²<i>University Hospital of New York, Syracuse, NY</i></p> <p>Introduction: There are no reported studies on the appropriate modality of detection of urinary incontinence caused by inverted-y-duplications. MRI/MRU (Magnetic Resonance Imaging with Urogram), with exam under anesthesia is the modality of choice for ectopic ureters in duplex systems. The best modality for detection of inverted-y-duplication, is not clear.</p> <p>Materials and methods: We report on a series of five consecutive adolescent females (ages 14-17, mean 16) treated by one surgeon from 2002-2009 for refractory continuous urinary incontinence after lengthy negative diagnostic workup. High pressure vaginograms were performed with installation volumes ranging from 150-300cc diluted contrast with a large Foley catheter with the balloon inflated (20-30cc). Upon detection of inverted-y-duplication, laparoscopic excision was utilized.</p> <p>Results: In three of the five patients, high pressure vaginogram detected an inverted-y-duplication with ectopia to the vaginal fornical cuff. In two of the five patients, vaginograms detected ectopic ureter of a duplex system. Two of the three inverted-y-duplications were treated laparoscopically with ectopic segment excision. One patient was lost to follow-up. Two patients underwent partial nephrectomy for poor functioning upper pole. All four patients who underwent surgery had complete resolution of urinary incontinence. In all three inverted-y-duplications, MRI/MRU failed to detect the anomalie.</p> <p>Conclusion: We report the first utilization of high pressure vaginogram in detection of inverted-y-duplications in a subset of patients with continuous urinary incontinence. We also present a novel, minimally invasive laparoscopic approach to the treatment of this anomalie. High pressure vaginogram and laparoscopy should be in the armamentary of treatment of inverted-y-duplication.</p> |

P25

Novel Reconstructive Repair of Ileal Loop Stomal Stenosis or Left Ureteroileal Anastomotic Stricture with a New Segment of Ileum

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Introduction: Creation of an ileal loop urinary conduit can be complicated by stomal stenosis and left ureteral stricture. These complications can be difficult to manage, especially for left ureteroileal anastomotic strictures since primary re-anastomosis may be impossible due to insufficient ureteral length. Reconstruction with another segment of ileum can treat these complications.

Materials and methods: Two patients with stomal stenosis and concomitant parastomal hernia underwent repair. The order of the surgery was: exploratory laparotomy, takedown of urostomy, excision of the stomal stenosis, repair of the parastomal hernia, harvest of a new ileal segment, re-establishment of bowel continuity, end-to-end ileoileostomy (old loop to new loop) and maturation of new stoma on contralateral abdominal wall. We coined this repair an "extend-a-loop". Three other patients with left uretero-ileal anastomotic ureteral strictures (between 2-8 cm in length) had reconstruction by harvesting a new ileal segment, re-establishment of bowel continuity, anastomosing the patent proximal left ureter to the new ileal segment, and performing end-to-side ileoileostomy (old to new loop).

Results: Both patients with stomal stenosis have functional, viable stomas with a minimum of 24-months follow up. The 3 patients with left ureteral reconstruction have unobstructed left ureters between 6 months to 5 years follow up.

Conclusions: Surgical management of stomal stenosis or left ureteral stenosis after ileal loop urinary conduit is technically complex. Reconstruction with additional ileal segment is an option with excellent outcomes. A caveat is that extensive operative dissection (complete enterolysis and left retroperitoneal exploration) is required and the urologist has to be prepared for this.

P27

Anterior versus Posterior Approach to Seminal Vesicle Dissection During Robotic Assisted Laparoscopic Prostatectomy

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Introduction: We compare our experience with both anterior and posterior approaches to RALP, and evaluate both perioperative and postoperative factors for each technique.

Materials and methods: A retrospective analysis was obtained on a consecutive series of 105 patients undergoing RALP, performed by 2 surgeons (JJ and JH), at a single institution. Patients were divided into 2 groups: anterior approach (AA) and posterior approach (PA). Patient demographics, operative parameters, pathological characteristics and complications were compared between groups.

Results: Preoperative factors among the AA and AP groups were similar with mean age of 60 years [range 40-74], mean PSA of 6.3ng/mL [range 0.5-22.3], and similar clinical stage. The pathologic staging, Gleason scores, and margin status were not significantly different (p>0.05) in both groups. The factors that proved to be of statistical significance included a lower console time for PA of 162.1 minutes versus 193.8 minutes in AA group (p=0.01) and a lower transfusion rate (p < 0.0001) in the PA group. There was one rectal injury in both groups repaired robotically. In addition, all patients in the PA group were able to undergo a pure RALP without conversion to LRP. Hospital stay and length of foley catheter duration were similar in both groups, a reflection of the surgeons' practice.

Conclusions: With preoperative factors being similar, the posterior approach to a RALP is associated with lower console time and a lower transfusion rate. Perhaps this approach may facilitate in shortening the learning curve for RALP.

P26

Oxidative Stress in the Penis: Friend or Foe?

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Introduction: Erectile dysfunction affects 30 million men in the U.S. Oxidative stress (OS) in certain organs results in tissue injury culminating in cell death. We sought to determine effects of OS on cavernosal tissue.

Materials and methods: OS to the murine penis was induced via two models: 1) hydrogen peroxide (H2O2) was microinjected directly into the corpus cavernosum and 2) a priapism model in which the base of the penis was ligated following a vacuum-induced erection. OS was assessed by 8-hydroxy-2'-deoxyguanosine (8-OHdG) immunostaining and histological examinations to assess for neutrophil recruitment, vasculitis, cavernosal damage, and apoptotic cells. Intracavernosal pressures (ICP) were obtained before and during cavernosal nerve electrical stimulation (CNES) in both control and H2O2 injected penes.

Results: Microinjection of H2O2 into the corpus cavernosum caused an increase in OS as determined by 8-OHdG immunostaining at 24, 48, and 72 hours post-injection. However, there was no increase in apoptotic cell death or neutrophil recruitment to the corporal tissue in either the H2O2 injected or the priapism model. Neither was a difference observed in erectile function between control mice and those subject to intracavernosal H2O2 injection.

Conclusions: These results support the hypothesis that, unlike other organs that are profoundly affected by OS, the penis is refractory to damage induced by single or prolonged episodes of OS. Since normal erections cause periods of hypoxia and potential OS, the penis may have protective mechanisms against OS that may account for the relative lack of tissue damage after prolonged erections or priapism.

P28

Tandem-Robot Assisted Laparoscopic Radical Prostatectomy (T-RALP) to Improve the Neurovascular Bundle Visualization: a Feasibility Study

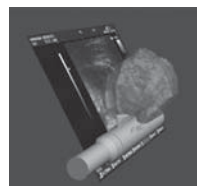
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Introduction: Robot-assisted laparoscopic radical prostatectomy (RALP) is a commonly performed surgery for prostate cancer treatment. The preservation of the neurovascular bundle (NVB) during the surgery improves the postoperative recovery of sexual potency. The blood vessels in the NVB, which are visible with Doppler ultrasound, can serve as a macroscopic landmark to localize the microscopic cavernous nerves in the NVB. In this feasibility study, a novel, robotic-transrectal ultrasound probe manipulator (TRUS Robot) and 3-D reconstruction software were used concurrently with the daVinci® robot in a tandem robot approach (T-RALP) to enable the intraoperative use of TRUS for image-guidance navigation.

Materials and methods: After IRB and FDA approval, we performed T-RALP on three subjects with prostate cancer. TRUS Robot provided a steady holding of the TRUS probe and allowed remote manipulation using a joystick located next to the daVinci® console.

Results: All subjects underwent T-RALP without associated complications. TRUS Robot was able to track the accurate position of the TRUS probe, allowing 3-D reconstruction of the images. Image navigation was then performed by observing the surgical instruments in the live TRUS image. NVBs were clearly visualized in the 3-D reconstruction.

Conclusions: In this feasibility study, intraoperative 3-D image-guided navigation system was developed. TRUS imaging during surgery can potentially improve the visualization of the NVB and provide accurate guidance of surgical landmarks to the surgeon.



P29

Native Nephrectomy for Renal Cell Carcinoma in Transplant Recipients

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Introduction: Renal cancer is one of the top ten causes of cancer death among adults in the United States. Dialysis and acquired cystic kidney disease (ACKD) increase the risk of renal cell carcinoma (RCC). This risk continues after transplantation. We report our experience in 15 post-transplant patients who underwent native nephrectomy for renal masses.

Materials and methods: IRB-exempt retrospective chart review was performed on transplant recipients who underwent native nephrectomy for suspicious masses.

Results: Twenty-two kidneys were removed from 15 patients, 18 laparoscopically and 4 open. Seventeen units (77%) from 13 patients contained RCC. One kidney had two cancers, for a total of 18 cancers. The distribution of RCC follows: 11 papillary, 4 clear cell, and 3 chromophobe. Most patients were low stage: 10 stage T1N0M0, 2 stage T2N0M0, and 1 stage T3N0M0. The median length of stay (LOS) for laparoscopic nephrectomy was 61 hours. Open bilateral nephrectomies for masses within polycystic kidneys were performed on two patients, with an 18 day average LOS. Complications (20%) included a delayed extraction site hernia, bronchitis, and bacteremia. There were no episodes of rejection, dialysis or injury to the kidney. No patients have recurred, with an average follow up of 36 months.

Conclusions: Renal transplant recipients can safely undergo native nephrectomy without jeopardizing their grafts. The cancers may be found at an earlier stage because of frequent imaging of transplant recipients. Immunosuppression does not seem to promote metastasis or recurrence, although longer follow up is required.

P31

Does Practice Environment Affect the Management of Small Renal Masses?

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Introduction: Renal preservation strategies have historically been underutilized when managing small renal masses (SRMs). We evaluated contemporary practice patterns for the management of SRMs in the context of urologist's practice environment.

Materials and methods: A survey instrument querying practice type (private vs. academic/academic affiliation) and management of three case scenarios (SRM in a healthy 55 year old, healthy 75 year old, and comorbid 75 year old patient) was distributed to attending physicians of the Mid-Atlantic American Urological Association (MA-AUA).

Results: Of the 287 responding urologists who managed kidney cancer, 92 (33%) practiced in an academic environment, and 189 (67%) were private practitioners. For SRMs in a healthy 55 year old, private practice physicians were more likely to perform a radical nephrectomy (5% vs. 0%, p=0.03) and less likely to perform a partial nephrectomy (82% vs. 91%, p=0.04) when compared to those in an academic environment. Management of SRMs in a comorbid 75 year old patient was similar irrespective of practice type with over 80% of urologists selecting ablative or surveillance strategies. Interestingly, for SRMs in a healthy 75 year old patient, private practitioners were less likely to choose surveillance strategies than academic physicians (1% vs. 14%, p=0.001).

Conclusions: Although urologists responding to this survey largely espouse renal preservation treatments, private practitioners are still more likely to perform a radical nephrectomy for SRMs. Surveillance has become a mainstream management for SRMs in the elderly, comorbid patient; interestingly, this strategy is infrequently employed by private practitioners for older, but healthy patients.

P30

Fluorescence Optical Imaging of Ureters: a Pilot Feasibility Study

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Objective: To test the feasibility of fluorescence-enhanced optical imaging associated with intravenous methylene blue to assist in the intraoperative visualization of ureters.

Methods: Ten patients undergoing open abdominal surgery were enrolled. Real-time fluorescent images of distal ureters were acquired with an investigational Fluorescence Guided Surgery (FiGS) system (GE Healthcare, Milwaukee, WI) after intravenous injection of 1% Methylene blue (2 mg/kg). The ability to identify the ureteral segments, with and without fluorescence-enhanced optical imaging, was visually scored and assessed independently by 2 reviewers for visual conspicuity at 2 different time points on a 5-point scale (1 to 5; worst to best). The duration of contrast enhancement was determined. A non-parametric, Wilcoxon signed-rank test was used to compare the results with and without fluorescent dye.

Results: A total of 20 ureters were evaluated with and without fluorescent imaging. Real-time fluorescent imaging clearly demonstrated dye-enhanced distal ureters with peristalsis. Mean score was 2.4±1.71 for reviewer 1 and 2.4±1.57 for reviewer 2 on non-fluorescence imaging while the mean FiGS score was 3.7±1.70 and 3.5±1.77 for reviewers 1 and 2. There was a trend toward significance for higher FiGS scores compared to regular images (p<0.08). There were no differences between the scores of the reviewers (p>0.15). There were 4 ureters not visualized by fluorescent imaging due to overlying inflammatory tissue or lesions (endometriosis). The duration of the positive enhancement exceeded 120 minutes. No complications occurred.

Conclusion: A new fluorescence-based optical imaging technique has the potential for improving the localization of the ureter during intra-abdominal surgery.

P32

Abstract not available

P33

The Risk of Stone Formation in Tissue Engineered Bladder

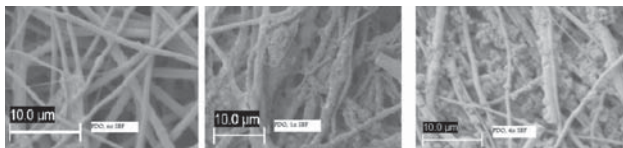
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Introduction: Bladder replacement therapies have known complications of malignant transformation, electrolyte disturbance, and stone formation. With the advancement of biotechnology, there is increasing opportunity to develop the ideal tissue engineered bladder. By using the electrospinning technique, we have previously demonstrated the ability of such nanofiber matrices to facilitate bladder smooth muscle growth. Our goal in this study was to evaluate the degree of mineralization and possible risk of subsequent stone formation in tissue engineering scaffolds for use in urologic applications.

Materials and methods: Synthetic polymers of varying concentrations were electrospun and incubated in a bioreactor for seven days with a simulated body fluid (SBF) solution and a 4x SBF solution to simulate the electrolyte concentrations found in urine. Scaffolds were evaluated with scanning electron microscopy (SEM) to determine the qualitative degree of calcification.

Results: SEM analysis revealed subjective mineralization of both the 1x and 4x SBF after one week of scaffold incubation, with a larger degree observed at higher concentrations.

Conclusions: We have successfully demonstrated electrospun tissue engineering scaffolds' tendencies to promote mineralization. Chronic exposure to elevated levels of urinary electrolytes could render implanted scaffolds more susceptible to becoming a nidus for stone formation, infection, and possible graft failure. Future experiments will involve SBF incubation of scaffolds with existing bladder smooth muscle cells to determine if cell growth is inhibited in such an environment.



P35

Feasibility and Safety of Ultrasound-Guided Percutaneous Renal Cryoablation: a Novel Approach

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Introduction: Our Department of Urology has established intensive ultrasound training for both residents and faculty that has resulted in performance of greater than 500 proctored ultrasound examinations during training. These skills have facilitated the development of percutaneous renal cryoablation (PRC) under ultrasound guidance. We previously published our novel technique for ultrasound-guided PRC utilizing the CIVCO assist positioning system. We are now presenting the feasibility and safety in 41 patients undergoing ultrasound-guided PRC using this technique.

Materials and methods: An IRB-approved retrospective analysis of a prospective quality improvement database was performed for pertinent clinical outcomes.

Results: Forty-one of 288 (14%) procedures were performed percutaneously. Selection criteria resulted in a median BMI of 29.4, with 77% of masses being exophytic and 93% being posterior or lateral in location. Median operative time was 48.5 minutes with 2 (1-3) cryoprobes used. Length of stay was 23 hours. Major complications developed in 3 of 41 (7.3%) patients, with 1 patient (2.4%) requiring transfusion. Importantly, one patient treated for a left upper pole lesion suffered a delayed splenic hemorrhage, while another patient treated for a medial lower pole lesion developed an acute ureteral obstruction which resolved with stent placement.

Conclusions: With appropriate ultrasound training, urologists are capable of performing ultrasound-guided PRC in a safe manner for appropriately selected patients. Ultrasound represents an attractive imaging modality for this procedure due to the absence of radiation exposure and the potential cost reduction.

P34

Does In-sourcing Pathology Services in a Large Private Practice Urology Group Increase the Utilization of Prostate Biopsy?

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Introduction: Addition of ancillary services to a urology practice can increase utilization of these services. Does addition of integrated pathology services (as partner) in a large single-specialty urology practice increased utilization of prostate biopsy and detection of prostate cancer (CaP)?

Materials and methods: The practice's database was used to analyze 23,019 consecutive patients undergoing prostate biopsy over 13 years (1/95 to 1/08). All biopsies were done by urologist in the practice. During study period, the number of practicing urologists increased 42% from 19 to 27. In 2004, biopsy protocol was changed from 6/8 cores to 12 cores. Comparison was made over time (yearly) of numbers of patients biopsied, positive biopsies, and urology full time equivalents (FTE) to determine if inclusion of pathology services impacted biopsy and CaP rate. Patient data (age and PSA) was compared to detect variation in the population.

Results: Over study period, number of patients biopsied per year increased 132% (1076 in 1995 to 2497 in 2007). Detection of prostate cancer increased from 31% in 1995 to 41% in 2007. Number of patients biopsied per urologist increased from 56.6/FTE to 92.5/FTE and CaP detection increased from 17.5/FTE to 38.7/FTE. Age and PSA at biopsy and at detection of CaP decreased over the study period.

Conclusions: During study period, volume of prostate biopsies performed per FTE has increased as has CaP detection. These variations in utilization are most likely related to other factors such as increased practice volume and changes in biopsy protocol and PSA sensitivity.

P36

Solifenacin Significantly Improves Symptom Bother in Patients with Overactive Bladder

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Introduction: To assess the efficacy of solifenacin on symptom bother, health-related quality of life (HRQL), and overactive bladder (OAB) symptoms in patients with OAB using the Overactive Bladder Questionnaire (OAB-q) and bladder diaries.

Materials and methods: Patients with OAB for ≥3 months were randomized to flexibly dosed (5 or 10 mg) solifenacin or placebo for 12 weeks. At baseline and at 4-week intervals, patients completed the OAB-q (Symptom Bother and HRQL) and 3-day bladder diaries. The primary efficacy variable was mean change from baseline to Week 12 in Symptom Bother score. Secondary variables included changes in HRQL and OAB symptoms.

Results: At Weeks 4, 8, and 12, solifenacin significantly reduced mean Symptom Bother score versus placebo as well as all HRQL domains and all OAB symptoms except nocturia versus placebo. Expected treatment-related adverse events in solifenacin versus placebo patients included dry mouth (13% versus 2%), constipation (8% versus 2%), dry eye (2% vs <1%), and blurred vision (1% versus 1%).

TABLE. Summary of results for OAB-q and bladder diary variables

| OAB-q scale Domain | Mean at Baseline Placebo (n=374) | Solifenacin (n=377) | Mean Change From Baseline to W12 Placebo (n=374) | Solifenacin (n=377) | P-Value [‡] |
|-------------------------------|----------------------------------|---------------------|--|---------------------|----------------------|
| Symptom Bother* | 57.9 | 58.2 | -20.4 | -29.9 | <0.0001 |
| Total HRQL (all 4 domains) | 57.8 | 56.4 | 16.7 | 25.3 | <0.0001 |
| Coping | 53.7 | 52.2 | 18.6 | 28.5 | <0.0001 |
| Concern | 52.0 | 51.9 | 19.3 | 29.2 | <0.0001 |
| Sleep | 51.3 | 47.3 | 17.4 | 26.6 | <0.0001 |
| Social Interaction | 78.9 | 78.7 | 9.3 | 13.6 | <0.0001 |
| Bladder diary variable | | | | | |
| Urgency* | 5.7 | 5.7 | -1.84 | -3.05 | <0.0001 |
| Frequency* | 11.9 | 11.7 | -1.36 | -2.23 | <0.0001 |
| Incontinence* | 2.8 | 2.9 | -1.24 | -1.85 | 0.0024 |
| Nocturia* | 1.6 | 1.7 | -0.48 | -0.63 | 0.3408 |

*A negative value indicates improvement.

[‡]Based on ANCOVA model including terms for treatment, pooled center, and baseline value.

Conclusions: As early as Week 4 and through Week 12, flexibly dosed solifenacin significantly improved symptom bother and HRQL, as well as urgency, frequency, and incontinence compared with placebo. Solifenacin was well tolerated.

P37

Radical Nephrectomy for Renal Cell Carcinoma before Renal Transplantation

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Introduction: Traditionally patients with cancer are observed for at least two years after treatment before considered eligible for transplantation. However, for non-invasive low-grade cancers, the risk of death from renal failure may exceed that of the cancer. We present nine patients who had nephrectomies for RCC and subsequently received a renal transplant.

Materials and methods: IRB-exempt retrospective chart review was performed on patients with RCC who subsequently received a renal transplant.

Results: Eleven renal units were removed from nine patients; all were attempted laparoscopically with one conversion to open. Eleven malignancies were found within 10 kidneys. All patients had stage T1N0M0 RCC: five papillary, five clear cell and one cystic. Tumor grade was known for 10 of the 11 masses: eight Furhman grade 2 and two Furhman grade 3. The average length of stay following nephrectomy was 55 hours. The two surgical complications (22%) included one delayed extraction site hernia and one dehiscence. The median time to transplant after nephrectomy was 5 months. The two Furhman grade 3 patients were observed 24 and 29 months before transplant. At an average follow up of 29 months, no patients have recurred.

Conclusions: It may be safe to transplant selected patients with low stage, low grade RCC without the traditional two years of observation. Although papillary RCC is the most common histology in dialysis patients, our patients were just as likely to develop clear cell carcinoma. Subsequent immunosuppression does not appear to increase the risk of recurrence.

P39

Improvement in Breast Tenderness Demonstrated in Men on Toremifene 80 mg Compared to Placebo in Phase III ADT Trial

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Introduction: Androgen deprivation therapy (ADT) results in castrate levels of testosterone and estrogen which lead to estrogen deficiencies; e.g., gynecomastia. A recent randomized, double-blind placebo controlled trial showed toremifene 80 mg prevents fractures in men on ADT. Because of the prevalence of gynecomastia in this population, we assessed the effect of toremifene on the incidence and severity of breast enlargement and tenderness.

Materials and methods: 1389 men with PCa were randomized to receive toremifene or placebo. The primary endpoint was new morphometric vertebral fractures. Secondary endpoints included gynecomastia, hot flashes and changes in BMD and lipids. The modified intent to treat (MITT) population (446 toremifene and 467 placebo subjects) was defined as men who received at least 1 dose of study medication and had at least 1 on-study radiograph. Breast tenderness was assessed on initial physical examination and subsequently scored as 1st or 2nd degree worsening, unchanged, or 1st or 2nd degree improved. Each assessment was performed at baseline and months 3, 6, 12, 18, and 24.

Results: A positive effect on breast tenderness was observed with more subjects scored as improved and fewer subjects scored as worsened in the toremifene group compared to placebo (p=0.0034). In subjects with documented use of bicalutamide (toremifene=99, placebo=101) there was a highly significant improvement in breast tenderness (p=0.0008).

Conclusions: Toremifene demonstrated a positive effect on mastalgia in men on ADT. These results suggest that treatment with a SERM can reduce breast tenderness in this patient population.

P38

Phase III Trial of Toremifene 80 mg Compared to Placebo in Men on ADT Demonstrates a Positive Impact on Lipid Profile

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Introduction: Many men are on ADT for 10 or more years subjecting them to estrogen deficiency side effects such as adverse changes in lipoproteins. We conducted a double-blind, randomized, placebo-controlled trial to determine if toremifene 80 mg would prevent fractures in men on ADT and also assessed the effect of toremifene on lipoproteins

Materials and methods: 1389 men with prostate cancer were randomized to receive toremifene or placebo orally. The primary endpoint was new morphometric vertebral fractures. Secondary endpoints included change in lipoproteins, BMD, worsening vertebral fractures, breast pain, and hot flashes.

Results: Changes in lipoproteins differed significantly between the toremifene and placebo groups. At 24 months, total cholesterol, LDL, and triglycerides decreased by 10.0% (95% CI, 8.1% to 11.9%), 16.6% (95% CI, 13.8% to 19.4%), and 7.9% (95% CI, 3.2% to 12.5%), respectively, in the toremifene group as compared to the placebo group (p<0.001 for all comparisons). In contrast, HDL increased by 10.1% (95% CI, 7.5% to 12.6%) in the toremifene group as compared to the placebo group (p<0.001).

Conclusions: Adverse lipid changes are a common asymptomatic side effect of ADT. In this randomized, placebo controlled trial, toremifene 80 mg demonstrated a reduction in total cholesterol, LDL, and triglycerides; and an increase in HDL. These results suggest that men on toremifene for the prevention of fractures due to ADT may benefit from a statistically significant improvement in their lipid profile

P40

High Risk Prostate Cancer Biochemical Recurrence with Robotic Radical Prostatectomy

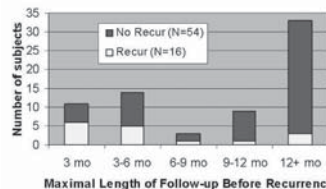
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Introduction: Prior studies have demonstrated feasibility of open radical prostatectomy in the high-risk setting. Management of high risk disease with robotic assisted laparoscopic radical prostatectomy (RALP) is controversial. We examined biochemical recurrence in a select cohort of high risk patients undergoing RALP.

Methods: From an IRB-approved, prospectively maintained database, men with high risk prostate cancer who underwent RALP by a single surgeon without adjuvant or neoadjuvant therapy were identified. High risk was defined by preoperative PSA>10 ng/dl, Gleason score ≥ 8 on final pathology or stage ≥ pT3. Postoperative PSA ≥ 0.2 defined biochemical recurrence. Two-tailed t-tests, Chi-squared and ANOVA tests analyzed cohort characteristics and biochemical survival.

Results: We identified 71 high-risk men. There was no significant difference in surgical margin positivity (38% overall), prostate size or cancer volume on final pathology between recurrence and non-recurrence cohorts. Biochemical recurrence occurred significantly earlier than later (p=0.017) with most recurring by 3 to 6 months (Graph) at follow-up to 49 months (mean 15 months). Biochemical failure was significantly associated with higher preoperative PSA (mean PSA 13.7, p=0.039), pathological stage (p=0.037) and Gleason score (p=0.048).

PSA Recurrence and Survival vs. Maximal Follow-up Length (p=0.017)



Conclusions: Using a stringent definition of high risk prostate cancer, men undergoing RALP have similar short-term biochemical outcomes and associations to those previously reported for open prostatectomy. Our data suggests that RALP is feasible in a select cohort of high-risk prostate cancer patients.

P41

Cost Comparison of Disposable Equipment Used in Laparoscopic versus Robot-assisted Laparoscopic Radical Prostatectomy

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Introduction: The operative cost of radical prostatectomy (RP) has increased as minimally-invasive technology has been successfully applied to RP. Operating room disposables represent variable costs that may differ between minimally-invasive surgical approaches. We chose to compare the costs of disposables used in laparoscopic RP (LRP) and robot-assisted laparoscopic RP (RARP).

Materials and methods: A review of instruments pulled for LRP and RARP cases at Johns Hopkins Medical Institutions in 2007-08 was performed. Costs for single-use and multi-use disposables were tabulated, and for multi-use disposable costs, were allocated by case volumes. We assessed actual operating room disposable costs rather than final charges.

Results: Per case, RARP was more expensive than LRP. The disposable cost of a typical LRP case was \$1,505 and for a typical RARP case was \$ 2,260. RARP thus carried a cost premium of \$755/case in disposable materials alone. The most expensive disposable items used in RARP were the Da Vinci instruments. The most expensive disposable used in LRP was the harmonic scalpel (\$417/case). Costs for LRP could be decreased by another \$180/case if certain optional instruments were either not used or replaced by reusables (e.g. screw trocars), whereas the costs for RARP may have been underestimated given that on occasion, an instrument may fail prior to its 10-case lifespan.

Conclusions: RARP presents higher variable costs (supplies) to an operating room than does LRP by more than \$750/case. This consideration may be of increasing importance given the difficult economic environment facing United States healthcare at present.

P43

Percent of Prostate Positive Biopsy Cores and Density Analysis in Predicting Prostate Cancer Outcomes

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Introduction: We investigated the prognostic value of percent positive biopsy (PPB) cores and prostate density on outcomes following radical retropubic prostatectomy (RRP).

Materials and methods: A cohort of 985 patients who underwent RRP with available biopsy information on number of cores, number of positive cores, and prostate volume was retrospectively reviewed. The PPB cores and prostate density were evaluated for association with 3 outcomes: extracapsular extension (ECE), seminal vesicle invasion (SVI), and biochemical recurrence (BCR) by using logistic and Cox proportional hazards regression, first in univariate models as continuous and then by increasing cutoffs. Independent prognostic ability was assessed by adjusting for biopsy Gleason score, clinical stage, preoperative PSA, and race.

Results: Continuous PPB cores and prostate density were significantly associated with ECE, SVI, and BCR in univariate analysis and independently after adjustment for Gleason score, clinical stage, and preoperative PSA. Men with 25-40% and >40% PPB cores or 0.0025-0.0060 and >0.0060 densities had significantly increased risk of ECE after adjustment, with odds ratios ranging from 2.09-5.02. Men with 25-50% and >50% PPB cores or density >0.0060 had significantly increased risk of SVI after adjustment, with odds ratios of 5.16-15.3. Men with >40% PPB cores or density > 0.0130 had significantly increased risk of BCR after adjustment, with hazard ratios of 1.69-2.38. Race was not associated with ECE or SVI, but was marginally associated with BCR.

Conclusions: Greater PPB cores and prostate density are independently associated with an increased risk of ECE, SVI, and BCR following RRP.

P42

Adult Robotic-assisted Ureteral Reimplantation: Single Institution Evaluation

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Introduction: Distal ureteral obstruction caused by ureteral tumors or strictures require reconstruction with ureteral reimplantation. Use of the daVinci robot facilitates laparoscopic reconstruction in these patients. We review our experience with robot-assisted ureteral reimplantation to treat distal ureteral obstruction.

Materials and methods: 8 consecutive patients underwent robotic-assisted ureteral reimplantation between 8/2007-4/2009. Indications for ureteral reimplantation included ureteral stricture (n=5) and tumor (n=3). Patient characteristics, intraoperative parameters, short and long-term outcomes were retrospectively reviewed. Univariate and multivariate analysis were conducted to determine parameters related to adverse outcomes.

Results: Mean age was 54 (30-82). Mean BMI was 32 (21-41). Mean hospital stay was 3.1 days (2-5). The mean blood loss was 175ml (50-400). Two patients required blood transfusions. The conversion to open rate was 38% (3/8). The reasons for conversion included: intra-abdominal adhesions and failure of progression. Five patients had previous abdominal surgeries and all of the patients that were converted to open had previous abdominal surgery (3/3). The mean follow-up was 208 days (4-600). No patients had positive margins or tumor recurrence. Two had long-term adverse outcomes including: pyelonephritis (n=1) and ureteral stricture (n=1). Univariate and multivariate analysis identified BMI as associated with conversion to open surgery (p=0.011). The mean BMI in patients who remained laparoscopic and patients who were converted to open surgery were 27.5 and 38.5 respectively.

Conclusions: Robot-assisted ureteral reimplantation is safe and effective. Based on our series, patient selection especially with regard to previous abdominal surgery and BMI are important to minimize conversion to open surgery.

P44

Impact of Urologist's Reimbursement on the Initial Treatment of Prostate Cancer in a Community Practice

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Introduction: The purpose of this paper is to determine if a change in urologists' reimbursement influences the initial treatment for CaP.

Materials and methods: A private practice tumor registry of 7993 consecutive, newly diagnosed patients with CaP was used to determine initial treatment choices before and after two financial events. 1) Radioactive seed implantation (RASI) moved to a urologist owned ambulatory surgery center (ASC) (\$2,130 per case in facility fee) and 2) Medicare fee schedule reduction in the payment for chemical androgen deprivation (ADT) (\$2,670 in loss per patient per year) A total of 1,970 consecutive patients with RASI or external beam radiation therapy (EBRT) were divided evenly before and after the availability of the ASC and 962 consecutive patients with primary ADT (PADT) or active surveillance/watchful waiting (WW) were divided evenly before and after Medicare fee reduction. The age, PSA and Gleason scores were compared.

Results: After availability of ASC, patients choosing RASI increased from 529 to 615 [not statistically significant, OR 1.081, 95% CI (0.881-1.326)]. The revenue increased \$1,018,140. After Medicare decreased fee schedule for ADT, the patients choosing PADT decreased from 301 to 237 [not statistically significant, OR 0.810, 95% CI (0.573-1.144)] Resulting decrease in revenue of \$632,790.

Conclusions: A change in urologist reimbursement did not change the treatment for their CaP patients. One of the reasons for this outcome may be the salary payment system for the urologist instead of a fee for service model.

SCIENTIFIC SESSION III

†Resident Prize Essay

| †1 | †3 |
|--|--|
| <p>Evaluation of the Prostate Cancer Prevention Trial Risk Calculator in a High-risk Screening Population <i>David J. Kaplan, Stephen A. Boorjian, *Karen Ruth, *Brian L. Egleston, David Y.T. Chen, Rosalia Viterbo, Robert G. Uzzo, *Mark K. Buyyounouski, *Susan Raysor, *Veda N. Giri Fox Chase Cancer Center, Philadelphia, PA</i></p> <p>Introduction: Clinical factors in addition to PSA have been evaluated to improve risk assessment for prostate cancer (CaP). The Prostate Cancer Prevention Trial (PCPT) risk calculator provides an assessment of CaP risk based on age, PSA, race, prior biopsy, and family history. This study evaluated the risk calculator in a screening cohort of young, racially-diverse high risk men with a low baseline PSA.</p> <p>Materials and methods: Our Prostate Risk Assessment Program (PRAP) enrolls men age 35-69 who are African-American, have a family history of CaP, or have a known BRCA1/2 mutation. PCPT risk scores were determined for PRAP participants, and were compared to observed CaP rates.</p> <p>Results: 624 patients fit inclusion criteria, including 382 (61.2%) African-American men and 375 (60%) men with a family history of CaP. Median age was 49.0 years (range 34.0-69.0), and median PSA was 0.9 (range 0.1-27.2). PCPT risk score correlated with CaP diagnosis, as the median baseline risk score in patients diagnosed with CaP was 31.3%, versus 14.2% in patients not diagnosed with CaP (p<0.0001). The PCPT calculator similarly stratified the risk of diagnosis of Gleason score ≥ 7 disease, as the median risk score was 36.2% in patients diagnosed with Gleason ≥ 7 CaP versus 15.2% in all other participants (p<0.0001).</p> <p>Conclusions: The PCPT risk calculator score was found to stratify CaP risk in a cohort of young, primarily African-American patients with a low baseline PSA. These results support the application of this predictive tool for CaP risk assessment in high-risk men.</p> | <p>Does the Yield of Random Bladder Biopsies Justify Their Use in the Assessment of Patients Following Intravesical BCG Therapy?? <i>*Matthew J. Resnick, *Daniel J. Canter, *Thomas J. Guzzo, *Laurie Magerfleisch, S. Bruce Malkowicz University of Pennsylvania School of Medicine, Philadelphia, PA</i></p> <p>Introduction: In this study we assessed the utility of random bladder biopsies in the evaluation of treatment failure following BCG therapy for non muscle-invasive (NMI) TCC.</p> <p>Methods: We reviewed our database of patients with NMI bladder cancer and isolated 253 patients with TCC who underwent a 6-week course of BCG. Patients underwent cystoscopy and directed or random bladder biopsies based upon the presence or absence of suspicious findings on cystoscopy. The results were analyzed to assess the yield of random biopsies in the detection of treatment failure.</p> <p>Results: A total of 253 patients were treated with 6-weeks of BCG for NMI TCC. Of the 84 patients who underwent directed biopsies, 13 (15.5%) were found to have TCC on pathologic evaluation as compared to 10 of 169 (5.9%) patients with a normal cystoscopic examination who underwent random bladder biopsies. The relative risk of cancer diagnosis was found to be 2.6 (95% CI 1.19-5.71, p<0.01). Positive urine cytology did not improve the yield of random biopsies. The overall sensitivity and specificity of cystoscopy for the identification of TCC were 56.5% and 69.1%, respectively. The positive predictive value of suspicious findings on cystoscopy was found to be 15.4% and the negative predictive value of a normal cystoscopy 94.1%.</p> <p>Conclusions: While the use of directed biopsies is required to evaluate for the presence of persistent disease, the yield of random bladder biopsies is limited. Accordingly, careful consideration of the utility of such a practice is necessary in the evaluation of patients following BCG therapy.</p> |
| †2 | †4 |
| <p>Endorectal MRI does not Differentiate between Favorable and Adverse Pathologic Features in Men with Prostate Cancer who would Qualify for Expectant Management <i>Matthew J. Resnick¹, Thomas J. Guzzo¹, Daniel J. Canter¹, Trinity J. Bivalacqua², *John E. Tomaszewski¹, Alan J. Wein¹, S. Bruce Malkowicz¹</i> ¹The University of Pennsylvania, Philadelphia, PA; ²The Johns Hopkins Medical Institutions, Baltimore, MD</p> <p>Introduction: With the increased diagnosis of potentially non-lethal tumors the concept of active surveillance (AS) has become an increasingly popular alternative for select men with prostate cancer. The lack of precise clinical staging modalities currently makes it difficult to predict exactly which patients are most appropriate for AS. The goal of our study was to evaluate the ability of endorectal MRI (eMRI) in predicting adverse pathologic features for those who would otherwise qualify for AS.</p> <p>Materials and methods: We retrospectively reviewed our radical prostatectomy (RP) database from 1991-2007, identifying 172 patients who would have qualified for AS and had a pre-operative staging eMRI. eMRI findings were correlated to final pathology to access its ability to predict adverse pathologic features in this patient population.</p> <p>Results: The mean age of our cohort was 59.8+6.2 years. The mean PSA at the time of diagnosis was 5.2+2.2 ng/ml. Fifty-one percent had no tumor visualized on eMRI and 49% had a tumor detected. At the time of RP, Patients with a documented tumor on eMRI did not have an increased incidence of adverse pathologic findings with regard to tumor volume (p=0.31), extra-capsular extension (p=0.82), Gleason upgrading (p=0.92), seminal vesicle invasion (p=0.97) or positive margin rate (p=0.95) compared to those in which no tumor was seen.</p> <p>Conclusions: Discrete tumor identification on eMRI is not predictive of adverse pathologic features in patients who would otherwise qualify for AS. eMRI likely does not provide additional information when evaluating prospective patients for AS.</p> | <p>Pelvic Lymph Node Dissection is Associated with Venous Thrombo-embolism Risk during Laparoscopic Radical Prostatectomy <i>*John B. Eifler, Jr., *Adam W. Levinson, Patrick C. Walsh, Christian P. Pavlovich Brady Urological Institute, Baltimore, MD</i></p> <p>Introduction: Venous thrombo-embolism (VTE) is a source of serious morbidity and mortality after radical prostatectomy (RP). It is unknown whether pelvic lymph node dissection (PLND) is related to the development of VTE. Given that PLND may not be necessary in most contemporary surgical patients, we wondered whether omitting PLND might decrease the incidence of VTE.</p> <p>Materials and methods: The records of 698 consecutive men who underwent laparoscopic radical prostatectomy (LRP) by a single surgeon between 2001 and 2007 were reviewed for postoperative VTE. All had at least 3 months of follow-up. All patients underwent transperitoneal or extraperitoneal LRP +/- laparoscopic PLND. Only those at increased risk for lymph node metastasis by Partin nomogram and those who requested PLND received simultaneous limited pelvic lymphadenectomy.</p> <p>Results: 417 patients (60.1%) received LRP+PLND; 281 received LRP only (39.9%). VTE occurred in 6/417 LRP+PLND patients (1.4%), and in 0/281 LRP only patients (0%) (p =0.046). Patients who underwent LRP+PLND and developed VTE had significantly greater BMI (31.0 vs. 27.0, p<0.05), higher lymph node counts (6.5 vs. 5.7, p=n.s.) and longer operative times (3.9 vs. 3.3hrs, p=n.s.) than those who underwent LRP+PLND who did not develop VTE. Only 3/417 (0.7%) LRP+PLND patients had positive lymph nodes.</p> <p>Conclusions: PLND may increase the risk of VTE without providing a cancer control benefit in most patients undergoing RP for clinically localized prostate cancer. Our data argue that lymphadenectomy should be judiciously rather than routinely performed for patients at low risk for LN metastasis.</p> |

t5

Magnetic Resonance Imaging Better Predicts Pathologic Renal Tumor Size Prior to Radical or Partial Nephrectomy

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Introduction: Magnetic resonance imaging (MRI), computed tomography (CT) and ultrasound are all reliable methods for determining renal tumor size. We examined which modality was best at determining pathologic tumor size prior to radical or partial nephrectomy for RCC.

Materials and methods: The data of 776 patients who underwent radical or partial nephrectomy was reviewed. The maximum reported diameter of the tumor was compared to the maximum diameter of the tumor after resection. Benign lesions and patients with incomplete data were eliminated from analysis. Data was analyzed by paired student T-test, Spearman rank correlation and linear regression analysis.

Results: 647 patients had available data for analysis, including 385 CT scans, 112 ultrasounds, and 421 MRIs. Average time from imaging to surgery was 87.1 days. When tumor size was compared to preoperative size on ultrasound, CT, and MRI, there was no significant difference between the estimated preoperative tumor size and pathologic tumor size (Table 1.) Pathologic tumor size was well correlated with all three modalities (p<0.001). When all three modalities were performed in the same patient preoperatively, only MRI remained a significant predictor of tumor size in multivariable analysis.

Conclusions: All three standard renal imaging modalities appear to accurately predict pathologic tumor size in patients with primary malignant RCC. When comparing all three modalities against each other, MRI appears to perform better in predicting pathologic tumor size.

TABLE

| Modality | Preoperative Tumor Size | Pathologic Tumor Size | Difference | p value* |
|------------------------------|-------------------------|-----------------------|----------------------|----------|
| Ultrasound (n=112) | 4.76 cm | 4.60 cm | -0.14cm (S.D = 2.48) | p = 0.54 |
| Computed Tomography (n= 385) | 4.93 cm | 4.98 cm | 0.05 cm (S.D = 1.84) | p =0.62 |
| Magnetic Resonance (n= 421) | 4.61 cm | 4.67 cm | 0.05cm (S.D = 1.78) | p = 0.56 |

* p value determined by paired Student T-test, S.D. = Standard Deviation

7

The Impact of Fibrin Clot Inhibitor Medications on the Efficacy of Bacillus Calmette-Guerin Therapy for Urothelial Carcinoma of the Bladder

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Introduction: Studies have suggested that the antitumor effect of BCG is dependent upon attachment of BCG to fibronectin at sites of fibrin clot formation, and that medications which impact fibrin clot formation may modify BCG activity. We evaluated the impact of fibrin-clot inhibitors on the clinical efficacy of BCG.

Materials and methods: We reviewed 907 consecutive patients treated with BCG between 1990-2006. Time to disease recurrence and progression to surgery were compared for patients taking and not taking fibrin-clot inhibitors by Kaplan-Meier methods and multivariate Cox regression models.

Results: Overall, 221 (24%) patients were taking at least one fibrin-clot inhibitor, including 170, 34, and 52 patients taking aspirin, clopidogrel, and warfarin, respectively. Patients taking warfarin had a shorter time to progression than patients not taking warfarin (median 2.1 vs 9.0 years, p<0.005), while patients taking aspirin had a significantly improved 5-year probability of freedom from surgery (66% vs 56%, p=0.029). On multivariate analysis, warfarin use was associated with an increased risk of progression to surgery (HR 1.89;95% CI 1.31, 2.74; p=0.0007), and aspirin use was associated with a decreased risk (HR 0.71;95% CI 0.52, 0.96; p=0.024). Use of warfarin alone was associated with an increased risk of tumor recurrence (HR 1.39;95% CI 1.00, 1.94; p=0.048).

Conclusions: These data suggest that the risks of recurrence and progression to surgery following BCG are higher in patients taking warfarin, while the risk of progression is lower in patients on aspirin. These findings may have important implications for the management of such patients in whom BCG is being contemplated.

t6

Quantitative mRNA Expression Analysis of c-MYC Oncogene in Human Prostate Cancer

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Introduction: Alterations in the expression of chromosome 8 genes have been recently identified in prostate cancer (CaP). Amplification at the locus 8q24 which includes the c-myc proto-oncogene draws current attention as a promising prognostic factor. This study evaluates the prognostic features of c-MYC expression in primary prostate cancer.

Materials and methods: RNA of the paired benign and neoplastic prostate epithelial cells was extracted from 105 patients who underwent radical prostatectomy at a single institution. All 210 study samples represented hormone naive disease and were obtained via laser capture microdissection technique. Quantitative expression of the c-MYC mRNA was examined using duplex real-time reverse transcription-PCR.

Results: Paired t-test analysis revealed significantly higher c-MYC (in 37.4% of patients) expression levels in tumor than in matched benign epithelial cells (p=0.0105). The elevated c-MYC expression levels in tumor tissues demonstrated a strong relationship to patients' biochemical recurrence (OR = 0.836; p = 0.0085, multivariate Cox proportional hazards model).

Conclusions: This study identified elevated c-MYC expression in primary prostate tumor as a predictor of biochemical recurrence. As the deregulated c-MYC expression has been previously demonstrated in more aggressive subtypes of prostate cancer, its role as potential prognostic indicator necessitates further investigation.

8

Preoperative Prediction of Invasive Upper-Tract Urothelial Carcinoma Stage Using Hydronephrosis, Ureteroscopic Biopsy Grade, and Urinary Cytology

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Introduction: Hydronephrosis, ureteroscopic (URS) biopsy grade, and urinary cytology are suggested to correlate with advanced pathologic stage for upper-tract urothelial carcinoma (UTUC). In isolation, however, their accuracy remains suboptimal. We hypothesized that combining these variables would allow more accurate preoperative prediction of UTUC stage.

Methods: Data on hydronephrosis (present vs. absent), urinary cytology (positive or atypical vs. negative), and URS grade (high vs. low) was available in 172 patients who underwent radical nephroureterectomy or segmental ureterectomy for clinically localized UTUC.

Results: 110 men and 62 women were evaluated. Preoperatively, 54% had hydronephrosis, 43% had high grade disease on URS biopsy, and 80% had positive urine cytology. Overall, 45% had > pT2 disease, and 34% had non-organ confined disease (> pT3 or N+). On multivariate analyses, the presence of hydronephrosis (p<0.001) and high URS grade (p<0.001) were associated with muscle-invasive disease and non-organ confined disease, while positive cytology was only associated with the latter (p=0.025). Combining all three variables allowed stratification of patients into risk groups for predicting UTUC stage. Specifically, abnormality of all three features had a positive predictive value of 89% for muscle-invasive and 73% for non-organ confined UTUC. Conversely, normality of all three variables had a negative predictive value of 100% for > pT2 and non-organ confined disease.

Conclusion: Preoperative hydronephrosis, URS grade, and cytology can be used in conjunction to create a "triple screen" model with high accuracy for prediction of advanced UTUC, which may facilitate improved preoperative stratification to guide clinical decision making regarding treatment options.

9

Incidence and Survival of Patients with Carcinoma of the Ureter and Renal Pelvis in the United States, 1973-2005

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Introduction: Outcomes data for upper tract urothelial carcinoma (UTUC) are somewhat limited due to its infrequent presentation. We evaluated epidemiologic and survival patterns of UTUC over the past 30 years through review of a large, population based database.

Materials and methods: Data from the Surveillance, Epidemiology, and End Results (SEER) database from 1973 to 2005 were reviewed in 10-year increments to evaluate for disease trends. Univariate and multivariate survival analyses identified prognostic variables for outcomes.

Results: 13,800 SEER-registered cases of UTUC were included. The overall incidence of UTUC increased from 1.88 to 2.06 (cases per 100,000 person-years) during the period studied with an associated increase in ureteral disease (0.69 to 0.91) and a decrease in renal pelvic cancers (1.19 to 1.15). The proportion of in-situ tumors increased from 7.2% to 31.0% (p<0.001), while local tumors declined from 50.4% to 23.6% (p<0.001). There was no change in the proportion of patients presenting with distant disease. On multivariate analysis, increasing age (p<0.001), male gender (p<0.001), black non-hispanic race (p<0.001), bilateral UTUC (p=0.001), and regional/distant disease (p<0.001) were all associated with worse survival outcomes.

Conclusions: The incidence of UTUC has slowly risen over the past 30 years. Increased use of bladder cancer surveillance regimens and axial imaging may contribute to the observed stage migration towards more in-situ lesions. While pathologic disease characteristics impact cancer outcomes, certain sociodemographic factors appear to portend worse prognosis. Further investigation on this front is necessary.

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Abstract not available

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The Impact of Preoperative Erectile Dysfunction on Survival after Radical Prostatectomy

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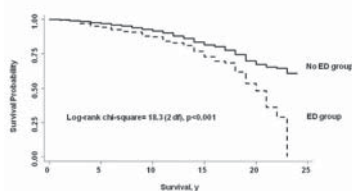
Introduction: Erectile dysfunction (ED) and cardiovascular disease share etiology and pathophysiology. Preoperative ED may adversely affect survival following radical prostatectomy (RP). We examined the association between preoperative ED and survival following RP.

Materials and methods: Between 1983 and 2004, a single surgeon performed RP on 2,515 men, with preoperative ED (ED group, n=234) or without ED (No ED group, n= 2,281). We retrospectively analyzed their prostate cancer-specific survival (PCSS), non-PCSS (NPCSS) and overall survival (OS) from time of surgery.

Results: With median follow-up of 12 years after prostatectomy, 450 men (18%) died (140 from prostate cancer, 310 from other causes). Kaplan-Meier analyses demonstrated significant differences in both NPCSS (p<0.001) and OS (p<0.001), but not in PCSS (p=0.18), between ED group vs. No ED group. In univariate proportional hazards analyses, preoperative ED was associated with a significant decrease in NPCSS, hazard ratio [HR], 0.52 (95% confidence interval [CI], 0.38-0.70), p<0.001, and in OS, HR, 0.58 (95% CI, 0.45-0.74), p<0.001. However, in multivariate analyses, the effect of ED on NPCSS and OS became insignificant after adjusting for other prognostic factors, such as age, PSA, Gleason score, pathologic stage, body mass index (BMI), and comorbidity.

Conclusions: Men with preoperative ED experience significant decrease in NPCSS and OS following RP. However, preoperative ED is not an independent predictor of survival after adjusting for other predictors of survival following RP.

Figure. Overall Survival After Radical Prostatectomy (1983-2004) by Preoperative Erectile Dysfunction Status



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Toremifene 80 mg Demonstrates a Reduction in Hot Flashes in Phase III Trial Compared to Placebo in Men on ADT

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Introduction: ADT results in castrate levels of testosterone leading to estrogen deficiency side effects such as hot flashes. In a randomized, double-blind, placebo controlled trial to determine if toremifene 80 mg prevents fractures in men on ADT, we assessed the effect of toremifene on hot flashes.

Materials and methods: 1389 men with prostate cancer were randomized to toremifene or placebo for up to 24 months. Hot flashes were reported using a 7-day diary at baseline and every 3 months. Severe hot flashes and flushing were recorded as AEs and analyzed between treatment groups based on the ITT population.

Results: US subjects with ≥ 6 hot flashes/day, not on Megace®, were analyzed (toremifene=18 subjects, placebo=19 subjects). Toremifene reduced the incidence of hot flashes from baseline at 6 months by 42% (26% decrease placebo) with a trend in favor of toremifene (p=0.0597). At 9 months, toremifene significantly reduced the incidence of hot flashes from baseline by 42% compared to an 18% decrease in placebo (p=0.0457). The effect was maintained for the duration of the study. The incidence of severe hot flashes and flushing reported as AEs was lower in the toremifene group (3.9%) compared to placebo (5.8%), showing a statistical trend in favor of toremifene (p=0.1188).

Conclusions: Toremifene 80 mg demonstrated the ability to reduce hot flashes in a subset population that experienced on average a higher number of hot flashes at baseline than that observed in the ITT population. Additionally, fewer subjects reported severe hot flashes and flushing as AEs.

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| <p style="text-align: center;">13</p> <p>Abstract not available</p> | <p style="text-align: center;">15</p> <p>Is Bladder Cancer Severity or Long Term Outcomes after Radical Cystectomy Affected by Body Mass Index? <i>*Andrew Harris, *Phillip Mucksavage, *Meredith Bergey, Bruce Malkowicz Hospital of the University of Pennsylvania, Philadelphia, PA</i></p> <p>Introduction: Obesity is a growing problem in the developed world. Although obesity has been shown to influence many types of cancer, there is very little data examining the effect of body mass index (BMI) on bladder cancer. We evaluated the effects of BMI on pathologic bladder cancer stage in patients undergoing radical cystectomy for bladder cancer.</p> <p>Materials and methods: The clinical and pathologic data on 356 patients available in a prospectively maintained radical cystectomy database were reviewed with respect to BMI. Patients were divided into the WHO categories of normal weight (BMI <25 kg/m²), overweight (BMI 25 kg/m² to 29.9 kg/m² and obese (BMI > 30 kg/m²). Analysis was performed using Chi squared analysis, Kaplan-Meier survival curves, and log-rank test.</p> <p>Results: Overall, 110 patients (27%) had a normal weight, 142 (35%) overweight, and 84 (21%) obese. Patients were divided into lower pathological stages (less than or equal to pT2, 194 patients) and higher pathological stage (higher than pT2, 162 patients). When BMI was compared to higher and lower pathological stage, there was no significant difference (p=0.19). Kaplan-Meier survival analysis showed a median overall survival in normal weight individuals to be 42.7 months, 44.7 months in overweight individuals, and 47.3 months in obese individuals, which was not significant (p=0.53).</p> <p>Conclusions: There is little or no data concerning the effects of obesity on outcomes after radical cystectomy. This data suggests obesity may not play a role on the severity of bladder cancer or long term outcomes after radical cystectomy.</p> |
| <p style="text-align: center;">14</p> <p>Diagnostic Accuracy of Urinary Cytology for Upper-Tract Urothelial Carcinoma (UTUC) <i>Jamie C. Messer¹, James Brien¹, Shahrokh Shariat², Casey Ng³, Benjamin Scoll⁴, Stephen Boorjian⁴, Robert Uzzo⁴, Scott Eggener⁵, John Terrell⁶, Jay Raman¹</i> ¹Penn State Milton S Hershey Medical Center, Hershey, PA; ²Memorial Sloan Kettering Cancer Center, New York, NY; ³Cornell University, New York, NY; ⁴Fox Chase, Philadelphia, PA; ⁵University of Chicago, Chicago, IL; ⁶University of Texas Southwestern, Dallas, TX</p> <p>Introduction: Urinary cytology has proven benefit for the diagnosis and staging of urothelial carcinoma of the bladder. Its role, however, is less well defined for patients with upper-tract malignancies.</p> <p>Materials and methods: The records of 335 patients who underwent a radical nephroureterectomy or a segmental ureterectomy at 5 academic medical centers for UTUC were reviewed. Urinary cytology data (reported as positive, atypical, and negative) was correlated with the final pathology from surgical specimens.</p> <p>Results: 126 women and 209 men with a median age of 70 years were included. 3% had pT0 disease, 52% had superficial UTUC (pTa, pTis, pT1), and 46% had invasive disease (> pT2 or greater). Low grade UTUC was present in 34% and high grade disease in 66% of patients. Overall, positive, atypical, and negative urine cytologies were noted in 42%, 38%, and 20% of cases, respectively. Positive urinary cytology had a sensitivity of 56%, specificity of 14%, and a positive predictive value (PPV) of 54% for high grade UTUC. When including atypical with positive cytologies, sensitivity and PPV increased to 74% and 64%, although specificity decreased to 10%. For pathologic stage, a positive cytology had a sensitivity of 62%, specificity of 29%, and PPV of 44% for invasive UTUC. Similar to pathologic grade, including atypical cytologies improved sensitivity (77%) and PPV (45%) at the expense of specificity (18%).</p> <p>Conclusions: For patients with UTUC, cytologic data in isolation is limited in its accuracy to predict final pathologic stage and grade.</p> | <p style="text-align: center;">16</p> <p>In Patients with Biochemical Recurrence Post-Prostatectomy, Early Recurrence and Faster PSA Doubling Time Predict for Metastatic Development <i>*Michael B. Williams, *Bethany Barone, Paul F. Schellhammer, Raymond S. Lance Eastern Virginia Medical School, Norfolk, VA</i></p> <p>Introduction: Biochemical recurrence (BCR) following radical prostatectomy (RP) identifies patients at risk for metastases and death from prostate cancer. We hypothesize that patients with early BCR and faster PSADT have the highest risk of developing metastases and death.</p> <p>Materials and methods: All patients who received RP from 1989-2003 and developed BCR ≥ 0.2 formed the population. Primary endpoints were death and metastases. Cox proportional regression analysis was performed to calculate a hazard ratio for risk of metastasis and death.</p> <p>Results: 206 patients with mean age of 61.5 years met the inclusion criteria with median follow-up of 93.7 months. RP specimens demonstrated $\geq pT3$ in 62.5%, Gleason ≥ 7 in 50%, and EPE in 60%. Forty-nine percent received androgen deprivation prior to metastasis and 32% received salvage radiotherapy. With only ten events, no factors were associated with death. Metastatic disease was associated with pN+, time to BCR (<12mon v. >12mon), and not achieving an undetectable PSA post RP (30%). 10-year freedom from metastases based on time to BCR (<12mon v. >12mon) was 78.0% and 90.8%, respectively. PSADT <10 months had a 3.8 fold increased risk of developing metastases over a PSADT >10 months (p=0.002).</p> <p>Conclusions: BCR within the first year after RP and PSADT <10 months increases the risk of developing metastases among patients with BCR. Remarkably, with 9-year median follow up and androgen deprivation in 49.5% prior to metastasis, only 15% of patients with BCR following RP developed metastases. All cause mortality was 4.8% and prostate cancer mortality was only 2.4%.</p> |

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Are Urology Residents Adequately Exposed to Treatment Modalities for Small Renal Masses?

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Introduction: The increasing diagnosis of small renal masses (SRMs) necessitates urology trainees to be familiar with available therapies. We evaluated resident exposure to treatments and management patterns for SRMs.

Materials and methods: The survey was distributed electronically to resident members of the American Urological Association (AUA) and queried exposure to ablation and surveillance for SRMs. Three case scenarios (SRM in a healthy 55 year old, healthy 75 year old, and comorbid 75 year old patient) were presented.

Results: 257 residents responded with equal distribution across AUA sections and levels of training. 234 (91%) reported ablation was offered at their institution; only 140 (54%) participated in this procedure. Of these, 80 (57%) were involved in fewer than 5 procedures. Experience with ablation did not increase with level of training (U3 - 61%, U4 - 66%, U5 - 63%). 224 (87%) residents noted exposure to surveillance for managing SRMs, increasing from 70% in U1 to 94% in U5. When considering case scenarios, management shifted significantly from extirpation to ablation or surveillance as the comorbidity profile increased. (Table 1).

Conclusions: While most residents have exposure to surveillance for SRMs, only 54% participated in ablation. Despite this lack of exposure, a significant percentage recommended ablation to manage SRMs in comorbid patients suggesting that training should be adapted such that urologists completing residency are better exposed to therapies they recommend.

TABLE. Resident responses to case scenarios of patients with SRMs (n=257 total)

| Treatment | 55 year old | | 75 year old | |
|---|-----------------|----------------|-----------------------|-----------------------|
| | Healthy No. (%) | Health No. (%) | comorbidities No. (%) | comorbidities No. (%) |
| Radical nephrectomy (open or lap) | 0 (0) | 2 (0.8) | 0 (0) | |
| Partial nephrectomy (open or lap) | 251 (97.7) | 159 (61.9) | 40 (15.6) | |
| Thermal ablation (RFA or Cryo; perc or lap) | 5 (1.9) | 69 (26.8) | 123 (47.9) | |
| Active surveillance | 2 (0.8) | 21 (8.2) | 94 (36.6) | |

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Prostaglandin Production by Interstitial Cells of Cajal Regulates Spontaneous Rhythmic Contraction of the Urinary Bladder

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Introduction: Prostaglandins (PGs) are suggested to cause spontaneous rhythmic contractions (SRC) in detrusor smooth muscle (DSM). Patients with overactive bladder (OAB) display elevated SRC. Cyclooxygenase (COX)-1 and COX-2 produce PGs. We determined that bladder interstitial cells of Cajal (ICC) express both COX isotypes. Elevated SRC in OAB is associated with elevated COX activity.

Materials and methods: Rabbit DSM strips free of underlying urothelium were incubated in a physiological salt solution (PSS) with or without the non-selective COX inhibitor, ibuprofen, the selective COX 1 inhibitor, SC-560, and the selective COX 2 inhibitor, NS-398. Enzyme immunoassays were used to measure PG production. The subsequent bioassay included the addition of the ventral aspect of the bladder. Indomethacin and SC-51089, a PGE2 antagonist, were drugs utilized in this phase.

Results: Analysis revealed a 2.5 fold increase in PG production and 4.8 fold increase in PGE2 production. In the PG group ibuprofen reduced production by 56%. Reduction in PGE2 production was seen among all 3 COX inhibitors. Consistent qualitative results indicate a complete inhibition of SRC with indomethacin and the return of rhythm with addition of "superfustate" from the isolated ventral DSM.

Conclusions: PGs, specifically PGE2, were produced by DSM strips. Ibuprofen inhibited PG production. PGE2 production was inhibited by ibuprofen and low concentrations of COX 1 inhibitor. The COX2 inhibitor demonstrated a strong trend towards inhibiting PGE2 production. Our preliminary bioassay results revealed trends similar to those previously obtained. These results are a step forward in discovering novel rational therapies targeting OAB.

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Ureteroscopic Management of Large Intrarenal Calculi - a Comparison of Techniques

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Introduction: Retrograde intracorporeal lithotripsy represents a viable alternative to percutaneous nephrostolithotomy for the treatment of large intrarenal calculi. We compare the outcomes of differing ureteroscopic techniques, including holmium laser and electrohydraulic lithotripsy, in the setting of intrarenal calculi >2cm.

Materials and methods: A total of 79 consecutive patients underwent ureteroscopic lithotripsy of intrarenal calculi >2cm by one of three at surgeons at two separate institutions. Demographic data, intraoperative techniques, success rates and complications were compared. Successful clearance of stones was defined as an absence of residual fragments measuring larger than 2mm on post-operative imaging or last ureteroscopy.

Results: Mean stone size for all patients was 29.6mm. Mean operative time was 111.1 minutes. Successful stone clearance was achieved in 76 patients (96.2%), and required an average of 1.4 ureteroscopic lithotripsy treatment episodes per patient. Primary electrohydraulic lithotripsy resulted in shorter operative times (p=0.0000) and required fewer treatment episodes (p=0.0024) compared to primary laser lithotripsy. The final success rate was similar for each group (p=0.332). There was no difference in the number of unplanned ancillary procedures performed for post-operative complications (p=0.4103).

Conclusions: Retrograde ureteroscopic lithotripsy offers excellent success and retreatment rates for the treatment of large intrarenal calculi >2cm, similar to gold-standard percutaneous nephrostolithotomy. Significantly shorter operative times and higher initial success rates were obtained when electrohydraulic lithotripsy was the primary treatment modality, but overall success was not significantly different when compared to holmium laser lithotripsy. Complimentary use of both techniques can help to achieve optimal results.

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Small Integrin Binding Proteins as Serum Markers for Prostate Cancer Detection

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Introduction: The SIBLING (Small Integrin Binding Ligand N-linked Glycoprotein) gene family includes bone sialoprotein (BSP), dentin matrix protein-1 (DMP1), dentin sialophosphoprotein (DSPP), matrix extracellular phosphoglycoprotein (MEPE), and osteopontin (OPN). Previous studies have separately reported elevated expression of BSP, OPN or DSPP in prostate tumor paraffin sections. We hypothesized that SIBLINGs may be informative markers for prostate cancer.

Methods: Expression levels of SIBLINGs in biopsy normal tissue and tumor were determined by cDNA array and by immunohistochemistry. Competitive ELISAs for total BSP, DSPP, MEPE and OPN were applied to a group of 102 subjects with prostate cancer and 110 normal subjects and a validation group of 90 subjects.

Results: The SIBLINGs BSP, DMP1, DSPP and OPN exhibited elevated mRNA expression and protein levels in biopsies. BSP, DSPP and OPN were elevated in serum from prostate cancer subjects, with serum DSPP exhibiting the greatest difference, yielding an area under the receiver operator characteristic curve value of 0.98. Serum BSP and OPN levels were significantly elevated only in late stages, while DSPP was significantly elevated at all stages. The elevated level of DSPP in serum was confirmed by SDS PAGE/Western blot analysis. Optimal serum value cut-off points derived for BSP, OPN and DSPP were applied as a validation test to a new group of 90 subjects and DSPP yielded a sensitivity of 90% and a specificity of 100%.

Conclusion: Of the SIBLING gene family members, DSPP appears to be a strong candidate for use in serum assays for prostate cancer detection.

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Hexaminolevulinate Fluorescence Cystoscopy Improves Detection and Resection of Papillary Bladder Cancer Lesions and Reduces Early Recurrences

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Introduction: Fluorescence guided diagnosis using hexaminolevulinate (HAL) can identify tumors not visible under white light cystoscopy. Comparison of HAL guided and white light cystoscopy in the detection of non-muscle invasive papillary bladder cancer (NMIBCs), and its early recurrence rates were studied.

Materials and methods: A prospective, controlled, randomized, phase III multi-center study consisted of patients with likely recurrence within nine months of initial tumor resection. Patients having one or multiple papillary tumor recurrences, within 12 months of their last tumor diagnosis were randomized to white light or HAL fluorescence cystoscopy. All patients were first inspected under white light with visible lesions recorded. Patients randomized to HAL underwent second mapping under blue light. All suspicious areas were resected in both groups. Completeness of resection was checked in blue light for HAL group. Follow up at 3, 6 and 9 months was with white light, with recurrence verified by histology.

Results: 766 patients were randomized. In the HAL group, 278 were diagnosed as Ta/T1. 16.9% of these patients had at least 1 additional Ta/T1 tumor detected with HAL compared to white light (p= 0.0005). 32% (13/41) of CIS patients were diagnosed only with HAL, an improvement in CIS detection rate of 46%. Significant reduction in tumor recurrence was seen in the HAL arm (n=200): 72 (36%) compared to 92 (46%) in the white light group (n=202) (p = 0.029).

Conclusions: This is the first demonstration that HAL fluorescence cystoscopy improves detection and resection of NMIBCs, with reduced recurrence rates at nine months.

Renal Functional Outcomes Following Percutaneous and Laparoscopic Cryoablation of Small Renal Masses

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Introduction: Renal functional outcomes after renal cryosurgery have not been widely scrutinized. We report two-year renal functional outcomes from a single-center cohort of patients treated with cryoablation of small renal masses.

Methods: We performed a retrospective review of our laparoscopic and percutaneous renal cryoablation experience between 1/2003 and 4/2007. Global renal function was assessed using measured serum creatinine and estimated GFR (MDRD equation). Chronic kidney disease (CKD) was defined as serum creatinine > 2.0 mg/dL or eGFR < 60 ml/min/1.73m².

Results: 62 patients were included in the analysis. Mean follow-up was 30 months (range: 13-63). Mean tumor size was 2.33 cm (range: 1-4.6cm). Comorbid conditions were prevalent: 77% HTN, 35% HLD, 31% DM, 39% tobacco use, and 32 % heart disease (CAD/CHF). Based on eGFR calculations, preoperative CKD was noted in 17 of 62 (27%) patients. De novo CKD developed in 5 of 45 patients (11%). Patients developing de novo CKD had lower pretreatment eGFR (71.0 vs. 98.4 ml/min/1.73m², p = 0.03) and larger tumor size (2.94 vs. 2.19 cm, p = 0.04) compared to patients maintaining normal renal function. When CKD was defined as Cr > 2.0 mg/dL, only 1 and 6 patients were identified with preoperative and de novo CKD, respectively.

Conclusions: In a cohort of renal cryosurgery patients characterized by highly prevalent medical comorbidities, renal function was generally well maintained, with a low rate of de novo CKD based on eGFR calculations. Serum creatinine > 2.0 mg/dL was a less sensitive measure of CKD.

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A Multi-institutional Comparison of Radical Retropubic Prostatectomy, Radical Perineal Prostatectomy, and Robotic Assisted Laparoscopic Prostatectomy for the Treatment of Localized Prostate Cancer

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Introduction: To evaluate the pathological stage and margin status of patients undergoing radical retropubic prostatectomy (RRP), radical perineal prostatectomy (RPP) and robotic assisted laparoscopic prostatectomy (RALP).

Materials and methods: We performed a retrospective analysis of 196 patients who underwent RRP, RPP and RALP as part of our multi-institution program. 57 patients underwent RRP, 41 RPP, and 98 RALP. Patient age, preoperative PSA, preoperative Gleason score, preoperative clinical stage, pathological stage, postoperative Gleason score, and margin status were reviewed.

Results: All preoperative factors except for PSA were similar. Margins were positive in 12%, 24%, and 36% of patients from RALP, RRP, and RPP (p=0.004). The positive margin rates in patients with pT2 tumors were 4%, 14%, and 19% in the RALP, RRP, and the RPP groups (p=0.03). Controlling for age and pre-operative PSA and Gleason score, the rate of positive margins was statistically lower in the RALP vs. both the RRP (p=0.046) and the RPP groups (p=0.02). In the patients with pT3 tumors, positive margins were observed in 36% of patients undergoing the RALP and 53% and 90% of patients undergoing the RRP and RPP (p=0.015). Controlling for the same factors, the positive margin rate was statistically lower in the RALP vs. the RPP (p=0.01) but not compared to the RRP patients (p=0.32).

Conclusions: The percentage of positive margins was lower in RALP than in RPP for both pT2 and pT3 tumors. RRP had a higher percentage of positive margins than RALP among pT2 tumors but not for pT3 tumors.

Robotic Assisted Laparoscopic Partial Nephrectomy: a Review of Surgical Outcomes from a Single Institution's Initial Experience

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Introduction: With recent advances in robotic surgical technology, robot assisted laparoscopic partial nephrectomy is quickly gaining widespread acceptance in managing small renal tumors. Herein, we report on the initial 2 year experience with robotic assisted laparoscopic partial nephrectomy (RLPN) at one institution and compare the outcomes to that of laparoscopic partial nephrectomy (LPN) and open partial nephrectomy (OPN) approaches during the concurrent time period.

Materials and methods: A retrospective review was conducted on all partial nephrectomies performed at a single institution from July 2006 to September 2008. Records were compared between 21 pts undergoing RLPNs, 20 pts undergoing LPNs and 26 pts undergoing OPNs. Various parameters analyzed included tumor size, estimated blood loss, operative and ischemia time, length of stay (LOS), final pathology and perioperative complications.

Results: The mean tumor sizes of patients treated were 3.1 cm in RLPN group, 2.6 cm in LPN group and 3.4 cm in OPN group. Overall, there was no significant difference among the three groups in regard to the operative time, ischemia time, positive margin rate and complication rates. The EBL and length of stay were significantly less in the RLPN and LPN groups compared to the OPN group. There were no conversions from RLPN to open and only one conversion from lap to open in this series.

Conclusions: Robotic assisted laparoscopic partial nephrectomy is an acceptable and feasible approach for T1 renal lesions. In our experience, RLPN can provide patients the benefit of minimally invasive nephron sparing surgery without compromising any oncological principles.

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Belt and Suspenders: Division of the Cremaster During Orchiopexy is Safe and Effective

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Introduction: It has been shown that suture fixation of the testicle can be associated with severe parenchymal damage. We describe an alternate technique that blunts the Cremaster reflex, eliminating a mechanism that can contribute to failed fixation.

Methods: Depending on the exam, we utilize a transverse inguinal and/or high scrotal incision. The underlying tissues are opened with cautery and the testicle is delivered into the wound. The spermatic cord is skeletonized, addressing any hernias. Using cauterization, cremaster fibers are divided superior to the testicle, and stripped to the external ring. The tunica vaginalis is opened widely and everted. A subdartos pocket is created, and absorbable sutures are used to affix the everted tunica to the dartos, keeping the testicle dependent. The scrotum is then closed.

Results: A retrospective review identified 77 patients over one year for which 5 year follow-up was possible. 92 testicles were operated upon. Average age was 69 months, with an average follow-up of 9.25 months. No patients experienced subsequent torsion, recurrence of retractile testis, or testicular ascent. There were no major complications. The modified technique was used to address a variety of indications.

Conclusions: We present a modified orchiopexy technique that is safe, effective, and blunts the Cremaster reflex. The testicles remained in their dependent positions during follow-up. Our technique may provide an alternative to those still utilizing suture fixation techniques.



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Intramuscular Detrusor Injection of Botulinum Toxin Type A as a Therapeutic Option for Bladder Preservation in Patients with Severe Neurogenic Detrusor Overactivity

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Aims: Botulinum toxin type A (BoNT-A) has shown promise in treating neurogenic detrusor overactivity (NDO), but studies conducted to date have not been in patients with severe urge urinary incontinence (UUI). This study examines our experience using BoNT-A in such patients.

Methods: This was a retrospective review of patients with UUI secondary to NDO who were treated with BoNT-A. Patients had almost constant urine leakage. BoNT-A 200U was injected transurethraly into 30 detrusor sites. Patients could receive repeated BoNT-A injections at the treating physician's discretion. Follow-up was 3-weekly for the first 6 weeks, then 6-weekly for up to 18 months. Urodynamic examination was conducted at follow-up visits in patients who did not experience clinical improvement.

Results: A total of 21 patients (9 men, 12 women) with proven NDO and UUI were included in the study. Patients received one (n=6), two (n=5), three (n=5), four (n=3) or five (n=2) treatments with BoNT-A (interval between injections approximately 1-17 months) and were followed-up for ≥12 months. At the end of follow-up, MCC had improved from baseline in all patients (mean change +xxx mL; p<0.xx). Treatment was considered successful in 17 patients who achieved MCC of >200 mL; these patients could be managed by suprapubic catheter placement; timed voiding + clean intermittent catheterization (CIC) or medications; or sling + CIC or suprapubic catheterization.

Conclusions: In patients with endstage NDO, intradetrusor injection of BoNT-A improves urodynamic parameters and circumvents the need for major surgical urinary diversion.

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Overactive Bladder Medication Adherence When Medications are Free to the Patients

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Introduction: In order to examine the effect of medication cost on medication compliance, we examined overactive bladder medication compliance in a healthcare system where patients do not pay for their medications.

Materials and methods: Pharmacy dispensing records were reviewed for antimuscarinic agents from January 2003 to December 2006 for the National Capital Region of the U.S. Military Health System. Medication non-persistence, switching, and adherence were examined. Kaplan Meier survival analysis was performed to compare medication persistence duration.

Results: Overactive bladder medications were dispensed to 7,879 adults. Tolterodine extended release (4,716 prescriptions) and oxybutynin immediate release (2,003 prescriptions) were most commonly prescribed. The medication non-persistence rate was 35.1% (2,760/7,858). Of 5,098 subjects who refilled their prescriptions, 1,305 changed their medication or dosage at least once, for a medication switch rate of 25.6%. The overall median Medication Possession Ratio (MPR) was 0.82 for all subjects. Men had a significantly higher median MPR than women (0.86 vs. 0.81, p<0.001). However, among patients who obtained at least one refill, women stayed on medications longer than men (Median 606 days vs. 547 days, p=0.01). Patients on tolterodine extended release had a higher MPR than those on oxybutynin immediate release (0.89 vs. 0.68, p<0.01). There was no difference between any different extended release medications.

Conclusions: In a health care system in which patients do not pay for medications, 35% of patients do not refill their prescription for overactive bladder medications. Other measures of medication compliance are higher than those published previously in systems with co-pays.

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Recovery of Erectile Function Following Nerve-sparing Radical Prostatectomy after Penile Rehabilitation with Nightly Intraurethral Alprostadil vs Sildenafil Citrate

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Introduction: Radical prostatectomy can cause longstanding erectile dysfunction. The current clinical trial was conducted to assess if early, consistent use of intraurethral alprostadil (IUA) vs sildenafil citrate (SC) hastened return of erectile function after nerve sparing radical prostatectomy (NSRP).

Materials and methods: Subjects with normal erectile function scheduled for bilateral NSRP were enrolled in this prospective, randomized, open label, multicenter study. They initiated nightly IUA, 125 mcg (started 250 mcg at 1 month), or SC, 50mg, within 1 month of surgery and continued for 9 months. Subjects were seen throughout the study and completed the International Index of Erectile Function (IIEF) erectile function domain, global assessment question (GAQ) sexual encounter profile and measured stretched penile length (SPL). After one month washout period (month 9) they self-administered SC, 100mg, 6 times prior to sexual activity. The Erectile Dysfunction Inventory of Treatment Satisfaction was completed at 11 months.

Results: 100 IUA and 61 SC subjects completed the trial. IUA increased the IIEF and GAQ by 12-14% and 11-27% at 3 and 6 months, respectively, vs SC (p<0.02 for GAQ at 6 months). Intercourse success rate was improved by IUA, and SPL decreased less for the IUA group (months 6 and 9). There were no differences between IUA and SC at study termination. Treatments were well tolerated.

Conclusions: Early, consistent use of low dose IUA after NSRP produced a quicker return of erectile function than SC. Early initiation of IUA after RP may hasten penile rehabilitation, providing for a better, earlier sexual response.

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Protection from Ischemia-reperfusion Induced Testis Injury by Blocking P-selectin

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Introduction: Germ cell specific apoptosis after ischemia-reperfusion (I/R) induced testicular injury is dependent on neutrophil recruitment to the testis. Intravascular adhesion molecules like the P- and E- selectins play an important role in this recruitment. The purpose of this study was to inhibit neutrophil recruitment in I/R induced testicular injury by using a function-blocking monoclonal anti-mouse P-selectin antibody.

Materials and methods: Adult mice were subjected to a 2 h period of testicular torsion (ischemia) followed by detorsion (reperfusion). Ten minutes after the onset of reperfusion, mice received either 100 µg of a function-blocking monoclonal P-selectin antibody (FBMAB group) or isotype-matched control antibody (IMCA group). Separate groups of mice underwent sham-operation (SO group) or received 500 ng of TNFα (IF group) to induce inflammation. Mice were sacrificed 24 h after reperfusion and testicular interstitial cells were isolated and analyzed for the presence of neutrophils by means of flow cytometry.

Results: The function-blocking monoclonal P-selectin antibody reduced neutrophil recruitment in I/R induced testicular injury significantly (FBMAB group as compared to the IMCA group 26 ± 4 vs. 52 ± 10% Gr-1+CD11b+ of total leucocytes; P < 0.001).

Conclusions: Blocking P-selectin may be therapeutically beneficial to protect postischemic testis.

Clinical Impact of Delaying 5ARI Therapy in Men on Alpha Blockers for Symptomatic BPH in a Managed Care Population

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Introduction: Pharmacologic treatment of LUTS from an enlarged prostate (EP) commonly includes an alpha blocker (AB) and a 5-alpha reductase inhibitor (5ARI). Many clinicians use an AB for rapid symptom improvement and a 5ARI in men who continue to have bothersome symptoms and/or to modify long-term disease progression. The purpose of this study was to assess the clinical impact of delayed 5ARI therapy in patients treated with ABs for LUTS.

Materials and methods: Using a nationally representative database, a retrospective analysis was conducted including men aged ≥50 years treated for BPH between 2000 and 2004. Clinical outcomes for those using 5ARI therapy early (within 30 days of initiating AB) and late (>30 days after initiating AB) were compared. The likelihood of clinical progression, defined as occurrence of acute urinary retention (AUR) or prostate surgery, was assessed for each group over a 1-year period following AB initiation.

Results: Of 2,636 men in the analysis, 60.6% initiated 5ARI therapy within 30 days of AB therapy (the early cohort). Patients receiving 5ARIs early were less likely to have clinical progression (11.2% vs 19.0%, P<0.0001), AUR (8.1% vs 13.2%, P<0.0001) and surgery (4.8% vs 9.5%, P<0.0001) than those treated later. Each 30-day delay in starting 5ARI therapy resulted in an average 21.1%, 18.6% and 26.7% increase in the likelihood of clinical progression, AUR and prostate surgery, respectively.

Conclusions: These results suggest that delaying 5ARI therapy in men with LUTS from EP may increase the risk of AUR and prostate surgery over the ensuing 12 months.

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The Longitudinal Effects on Penile Oxygen Saturation from a Prospective Randomized Study of the Nightly Use of Intraurethral Alprostadil vs Sildenafil Following Nerve Sparing Radical Prostatectomy (NSRP)

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Introduction: Early penile rehabilitation is recognized as an important part of the recovery of erectile function after RP. Postoperative intracorporal and intraurethral alprostadil as well as oral sildenafil have been reported to improve recovery of erectile function. Enhanced penile oxygenation is believed to be an important factor in the observed beneficial effect. The purpose of this study was to examine the longitudinal effect of nightly sildenafil or intraurethral prostaglandin on flaccid penile oxygen saturation.

Methods: A subgroup of 50 men enrolled in a larger (78 men) randomized comparative 11 month penile rehabilitation trial of nightly alprostadil (MUSE®) 250 mcgm vs sildenafil 50 mgs, underwent preoperative penile oximetry and at post op visit week one, and months 1, 2, 3, 6, 9 and 11. Medications were started at catheter removal and continued through month 9. At each visit penile oximetry was done with a FDA approved tissue oximeter.

Results: All men were preoperatively potent (Avg IIEF 29) and underwent nerve sparing prostatectomy by two surgeons. Corporal oximetry in the IUA cohort increased over 9 months, achieving statistical significance over the second visit nadir throughout the treatment period. Corporal gradually decreased from baseline in the Sildenafil group but returned to baseline by the end of the study.

Conclusion: Despite the short half life of intraurethral alprostadil, nightly alprostadil increased flaccid penile oximetry throughout the study. Flaccid penile oximetry in the sildenafil cohort decreased in the same period. This supports the early incorporation IUA for penile rehabilitation after RP to maintain corporal oxygenation.

Ileovesicostomy for Neurogenic Bladder Dysfunction

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Introduction: The purpose of this investigation was to characterize the results and complications of a series of patients treated with ileovesicostomy for neurogenic bladder dysfunction.

Methods: Fifteen patients who underwent ileovesicostomy for neurogenic bladder dysfunction from June, 2005 to January, 2009 at two academic medical centers were identified retrospectively. Patient data including medical co-morbidities, prior surgery, preoperative bladder management as well as operative factors, postoperative complications, and degree of incontinence were collected. Data is reported as means ± SEM.

Results: Fifteen patients underwent ileovesicostomy with a mean age of 43.8 ± 3.2 years; eight of fifteen (53%) were white with an average BMI of 24.3 ± 1.4. Fourteen of fifteen (93%) managed their bladders with indwelling catheters preoperatively for a mean duration of 6.44 ± 1.36 years. Mean operative time was 282 ± 47.4 minutes with an average estimated blood loss of 217 ± 25 ml. Average length-of-stay was 9 ± 1.25 days with the most common postoperative complication being ileus (53.3%). Three patients had serious complications, including one with a bladder anastomotic leak that was managed conservatively, and two with sepsis. There were no deaths and no thromboembolic events. One patient (6.7%) required reoperation with conversion to ileoconduit for persistent incontinence. At last follow up, 66.7% were continent per urethra. Average follow up time was 19.3 ± 3.4 months.

Conclusions: Ileovesicostomy is an effective option for management of neurogenic bladder dysfunction with excellent urethral continence (67%) despite high, but acceptable, rates of postoperative morbidity.

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Abstract not available