Moderated Poster Session 3: Oncology II
Friday, November 14, 2014
10:30 a.m. – 12:15 p.m.

P30
Renal Cell Carcinoma Recurrence: A Population-based Cohort of Patients Treated for Cure From Atlantic Canada

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Background: The goal of this study was to determine the recurrence/mortality rates as well as identify significant clinical and pathological characteristics associated with Renal Cell Carcinoma (RCC) recurrence in a modern day population based cohort of patients treated for cure.
Methods: This is a population-based study that identified all patients undergoing curative-intent surgery for RCC between 2006 and 2010 in mainland Nova Scotia(NS), Canada. Patients were identified through Cancer Care NS, and study approval was obtained at appropriate REBs. The primary outcome was the incidence of postoperative RCC recurrences in this cohort. Data collection included baseline demographics, type of surgery, pathology characteristics, how recurrences were detected and location of recurrences. Using a multivariate regression analysis we analyzed the significance of these variables within the recurrence and non-recurrence populations. Patient mortality was evaluated as a secondary outcome.
Results: 541 patients make up the study cohort. We identified 70 (13%) recurrences, 70 deaths (13%) and 104 (19%) recurrences or deaths. Recurrences were detected by routine imaging in 73% of patients and symptoms in 23%. 53% of pts recurred in only one site. Of those that recurred, 37% had initial stage 1, 19% stage 2, and 44% stage 3 RCC (p<0.0001). Clear cell pathology accounted for 75% of the entire cohort, and 87% of the recurrences. Multivariate regression analysis revealed that sarcomatoid differentiation, tumor necrosis and grade 3&4 pathology were associated with significantly higher recurrence rates, p<0.0001, p<0.0349 and p<0.0055 respectively. Among patients with recurrent disease, 86% had undergone radical nephrectomies vs. 14% partial nephrectomies (p<0.0001). The median time to progression from day of diagnosis was 2.5 years.
Conclusions: In our cohort of NS patients operated on between 2006 and 2010, the recurrence rate was 13%. With further follow up, this number will increase. Most recurrences were identified from routine imaging. The highest risk of relapse was shown for patients having undergone radical nephrectomies for stage 3 clear cell RCC, with positive pathology for sarcomatoid differentiation, tumor necrosis and grade 3&4 disease.

P31
Salvage Intravesical Therapy With Interferon-α2b Plus Bacillus Calmette-guerin (BCG) in Patients With BCG Refractory Superficial Bladder Cancer

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Background: Thirty percent of patients with non-muscle-invasive bladder cancer (NMIBC) fail to respond to intravesical therapy with bacillus Calmette-Guerin (BCG).There is no gold standard protocol for salvage intravesical therapy following BCG failure. The use of intravesical interferon-α2B in combination with BCG has been shown to be effective in a subset of patients with NMIBC BCG refractory disease. Here we present a contemporary series on the effectiveness and safety of intravesical interferon-α2B /BCG (IFN/BCG) therapy in patients with BCG refractory NMIBC.
Methods: From January of 2005 to April of 2014 we retrospectively found 46 patients who underwent intravesical induction with combination IFN/ BCG for the management of NMIBC. Patients with primary upper tract disease were excluded from the analysis. A chart review was performed to assess for initial pathological stage/grade, pathological stage/grade at the time of induction, time to IFN/BCG failure, pathological stage/grade at failure, therapy post failure and current disease state.
Results: 44 patients met criteria for the analysis of which 35 (79%) were male and 9 (20.5%) were female. Median age at time of diagnosis was 63 years (38-92). The most common histologies at induction were pTis (34.1%) and pTa (36.4%), with 88.4% of tumors presenting with high grade features. Of the 44 patients, 17 (38.6%) were disease free after induction therapy with median follow-up time of 26 months. 27 (61.4%) ultimately had disease recurrence. Median time to failure was 7.2 months. The most common histology after failure was pTa (25%), with only 3 (6.82%) patients presenting with pT2 disease. After failure, radical cystectomy was performed in 17 (63.0%) patients. Of the patients that failed BCG plus interferon- 2B therapy 70.4% remained disease free, with 2 (7.41%) developing metastatic disease.
Conclusions: Combination BCG plus interferon-α2B remains a reasonably safe alternative treatment for patients with BCG refractory disease prior to proceeding to radical cystectomy.

P32
Reducing Pain During Office Biopsy of the Prostate: A Randomized, Single Center Trial of the Effect of Extending Time from Peri-prostatic Lidocaine Injection to Onset of Transrectal Ultrasound-guided Prostate Biopsy on Patient-reported Pain Scores

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Background: Local anesthetics, widely used in transrectal ultrasound-guided prostate biopsies, are weak bases, consisting of a lipophilic aromatic ring, a link and a hydrophilic amine group. Lidocaine, the most commonly used local anesthetic in this setting, has a half-life of 1.6 hours. Although, the efficacy of peri-prostatic local anesthetic in terms of site, dosage and method of injection have been previously described in prospective randomized control trials elsewhere, the time from lidocaine injection to prostate biopsy has not been thoroughly investigated.
Methods: We conducted a randomized, single center trial of the effect of extending the time from peri-prostatic lidocaine injection to onset of transrectal ultrasound-guided prostate biopsy utilizing a pain visual analog scale (VAS) on prostate biopsy-naïve patients. Exclusion criteria include patients with significant pain syndromes or those who are on chronic analgesic medications. Patients were randomized to four different treatment arms: bibasilar injection at 2 minutes (A), bibasilar + single apical injection at 2 minutes (B), bibasilar injection at 10 minutes (C), and bibasilar + single apical injection at 10 minutes (D). Patients were asked to report their level of pain at the following intervals: probe insertion (baseline), after each core, post-procedure and post-visit.
Results: A total of 83 patients were randomized to the aforementioned treatment arms. The groups were comparable with respect to age, PSA, prostatic volume and number of cores taken. Although final statistical analysis is ongoing, preliminary data suggests patients in Groups C+D demonstrate favorable VAS scores when compared to Groups A + B.
Conclusions: Extending the time from lidocaine injection to prostate biopsy results in lower VAS scores, thereby reducing patient anxiety. Further subroup analysis of patients with higher baseline VAS scores, those with a co-morbid diagnosis of neuropathy, location and number of injections are in process. Results from this analysis could yield patient-specific protocols for location and time from lidocaine injection to prostate biopsy.

P33
Urinary Continence After Robotic Prostatectomy: Results From a Randomized, Double-blind Multi-center Phase 4 Clinical Trial Evaluating Solifenacin Succinate Versus Placebo

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Background: Deleterious bladder effects after radical prostatectomy such as reduced compliance, decreased capacity, and hyperactivity influence recovery of urinary continence. NCT01371994 (Vanguard Trial) a multi-center, randomized, double-blind study assessed the effects of postoperative Solifenacin succinate (SS) vs placebo on early return to continence after Robot Assisted, Laparoscopic Radical Prostatectomy (RALP).

Methods: Continence outcomes after RALP were assessed by the Vanguard Trial. Primary and secondary outcomes were collected daily with a smartphone device (SPH) provided to patients the day of Foley catheter removal. Digitally recorded, encrypted patient answers were transmitted to dedicated servers. The study had an initial 21 day screening phase. Those voiding spontaneously during the last week of screening - but reporting urinary incontinence that required 2 to 10 pads inclusive per day (PPD) - were eligible for 1:1 randomization ratio to either 5 mg SS daily or placebo. Randomized patients kept the SPH for another 12 weeks and answered daily inquiries, such as the number of PPD used over the prior 24 hours. The primary endpoint was the time interval from randomization to continence - defined as 0 pads use or a security pad completely dry for 3 consecutive days. Average PPD change from baseline to each visit was a secondary endpoint and the number of patients who reached 0-1 PPD use on any day of study was also analyzed as a post-hoc analysis.

Results: Of the 1125 screened patients, 1086 had SPH data and 837 (77.1%) wore one or less PPD by 15 weeks after RALP. 640 patients met randomization criteria and 622 patients had complete post-baseline SPH data. There was no significant difference in the continence time interval - primary endpoint (p=0.17). Mean change from baseline to end of treatment in average daily pad use was -2.9 and -3.2, for placebo and SS, respectively (p=0.033). By study end, 202/309 (65.4%) in placebo and 233/313 (74.4%) in SS reported 0-1 PPD use (p=0.0137). Dry mouth was the only common adverse event: 0.6% and 6.1% of placebo and SS, respectively.

Conclusions: Solifenacin succinate did not significantly affect time to continence following RALP, but was significantly associated with reaching the 0-1 PPD milestone by the end of the study. Among 1086 screened subjects with SPH data 77% reach the 0-1 PPD milestone 15 weeks after RALP (Level 1-B evidence).

P34
Reporting and Prognostic Significance of Lymphovascular Invasion in Muscle-invasive Bladder Cancer: A Population-based Study

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Background: Previous reports from centers of excellence have found lymphovascular invasion (LVI) to be a poor prognostic factor in bladder cancer. However, LVI assessment by pathologists is prone to over- and underreporting; this may be of particular significance in routine clinical practice. Here we present reporting patterns and outcomes associated with LVI in the general population of Ontario, Canada.

Methods: Electronic records of treatment were linked to the population-based Ontario Cancer Registry to identify all patients who underwent cystectomy for muscle-invasive bladder cancer (MIBC) in Ontario 1994-2008. Surgical pathology reports were analyzed for pathological variables including LVI. LVI reporting patterns were described over time and the association of LVI with cancer-specific (CSS) and overall (OS) survival

was evaluated using a Cox proportional hazards model controlling for patient-, disease-, and treatment-related characteristics.

Results: 2802 patients with MIBC who underwent cystectomy were included in this study. LVI status was reported in 75% of patients overall, and increased over time (57% 1994-1998; 76% 1999-2003; 85% 2004-2008, p < 0.001). Reporting LVI status was greater among cases treated by high volume surgeons (80% vs 74%, p=0.001) and among those treated at comprehensive cancer centers (78% vs 74%, p=0.032). Cases in which there were no lymph nodes submitted with the surgical specimen were less likely to report LVI (67%) than cases that were node positive (83%) or node negative (75%) (p<0.001). Patients with evidence of LVI had substantially lower survival than patients that were LVI negative or LVI unstated (5-year CSS 19% vs 55% vs 42%, p<0.001 and 5 year OS 18% vs 47% vs 37%, p<0.001). These differences were seen independent of lymph node status. Presence of LVI was strongly associated with reduced survival in adjusted analyses (HR CSS 1.99, 95% CI 1.72-2.31; HR OS 1.77, 95% CI 1.56-2.00). Age, co-morbidity, T & N stage, margin status, surgeon case volume, and use of adjuvant chemotherapy were also independently associated with patient survival.

Conclusions: Reporting of LVI among patients with MIBC treated in routine clinical practice has improved over time. LVI is an independent and strong prognostic factor for inferior CSS and OS in the general population.

P35
Utilization of Preoperative Imaging for Muscle-invasive Bladder Cancer: A Population-based Study

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Background: Practice guidelines for preoperative imaging of patients with muscle-invasive bladder cancer (MIBC) vary, and are often based on scant evidence.

Our objective was to test the a priori hypotheses that in routine clinical practice: a) the use of preoperative imaging for MIBC conforms to clinical practice guidelines; b) preoperative imaging, through stage selection is associated with improved surgical outcomes.

Methods: In this population-based cohort study, electronic records of treatment were linked to the Ontario Cancer Registry to identify all patients with MIBC treated with cystectomy from 1994-2008.

Utilization of chest, abdomen-pelvis and bone imaging were evaluated. Trends were evaluated over 3 study periods (1994-1998, 1999-2003, 2004-2008). Logistic regression was used to analyze factors associated with utilization. Cox model analyses were used to explore associations between imaging and survival.

Results: 2802 patients with MIBC underwent cystectomy during 1994-2008. There was an increase in utilization of: chest x-ray(CXR) (55%,64%,63%,p<0.001), CT chest(10%,10%,21%,p<0.001), bone scan(30%,34%,36%,p=0.04) and CT/MR abdomen/pelvis(80%,87%,90%, p=<0.001). Use of chest and bone imaging was independently associated with age, N-stage and geographic region. In adjusted analyses we found that patients who did not have preoperative chest imaging had inferior overall survival (OS) hazard ratio (HR) 1.12(95%CI 1.01-1.25) but not cancer specific survival (CSS) HR 1.09(0.97-1.22); those who did not have preoperative bone scan had inferior OS HR 1.11(1.01-1.22) and CSS HR 1.09(95%CI 1.01-1.25).

Conclusions: In routine clinical practice there is considerable variation in use of preoperative chest, body, and bone imaging. Preoperative chest and bone imaging is associated with improved outcomes; this association likely reflects better patient selection for cystectomy.

P36

Effect of Combined Sequential Treatment Of Sipuleucel-T Followed by Enzalutamide in Metastatic Chemo-Naïve Castration Resistant Prostate Cancer: Results of a Single Center Large Urology Group

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Background: Sipuleucel-T is the first autologous cellular vaccine approved by the FDA in 2010 for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer (mCRPC). Enzalutamide was approved in the treatment of post-chemotherapy mCRPC patients in August of 2012. The results of the IMPACT trial demonstrated that immunotherapy as monotherapy is not sufficient enough to hinder or stop progression of mCRPC especially with high baseline PSA level. Therefore, the timing and sequencing of combination therapy is becoming of outmost importance for the treatment of these patients. As a result our hypothesis has been to layer on enzalutamide very quickly after the completion of sipuleucel-T.

Methods: We collected the data of 84 patients with chemo-naïve mCRPC treated with sipuleucel-T at our practice from September 2011 to January 2014. Prior to the initiation of treatment the baseline status was recorded in all patients. We then selected and analyzed outcomes of 19 patients who received sequential enzalutamide treatment after completion of sipuleucel-T. The average timing for the initiation of enzalutamide was 2.5 ± 1.6 months after completion of the immune therapy. We believe this to be a very unique cohort as all of these patients were treated with enzalutamide off label (i.e. pre-chemo).

Results: The median time of enzalutamide therapy was 5.4 months (range: 1-13). In our cohort of 19 patients: 1 case showed radiographic full regression of metastatic lesions in bone, lung and lymph nodes. Another case showed radiographic full regression of bony metastatic lesions. 2 other cases - showed a partial regression radiographically of bony metastatic disease. 13 cases showed stable disease according to RECIST-criteria. The remaining 2 patients were deceased due to progression of mCRPC. The patients with full and partial response were in the lowest quartile of our cohort as defined as a PSA ≤ 3.87 ng/ml. On the contrary, all cases of progression and death were documented in highest (last) quartile as defined by a PSA level more than 84 ng/ml.

Conclusions: Our experience demonstrates a promising effect using sequential sipuleucel-T immunotherapy followed by enzalutamide for mCRPC. To our knowledge this will be the first case of complete radiographic regression of lung, bone, and extensive lymph node disease. Currently there are studies undergoing that will hopefully validate our experience with using enzalutamide at the initiation of sipuleucel-T.

P37

Our Experience of Radium-223 (xofigo) Treatment for Metastatic Castrate Resistant Prostate Cancer

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Background: The many advantages associated with Ra-223 cytotoxic mechanism of action and excretion makes it a stronger, less myelotoxic and nephrotoxic option than its counterparts (Sm153 and Sr89). We report the short-term pain evolution, side-effects and hematologic profile of patients with metastatic castrate-resistant prostate cancer (mCRPC) undergoing Ra-223 treatment.

Methods: Clinical data from 30 mCRPC patients treated with Ra-223 was collected from a large multi-disciplinary group. In accordance with the FDA's recommended dosage, Ra-223's monthly injections were composed of 1 dose of 50 kBq/kg, for 6 months. The World Health Organization's (WHO) ladder for cancer pain was assessed. Also, short-term incidence of side effects was reported together with the hematologic parameters at each injection.

Results: This cohort was composed of men aged 72(63-77) years old, and all suffered from bone metastasis. At baseline, all patients were symptomatic. During treatment, gradually more men graded their pain at 0. By the 6th injection, 43% of patients had no pain. The proportion of patients with severe pain (grade 3) tended to decline during treatment. A decline in white blood cell count was the only major myelotoxicity observed. 43% (n=6) of patients who received all 6 injections had a WBC count loss of >33% from baseline to the last injection. Blood markers such as albumin, LDH and PSA did not seem to vary during treatment. ALP serum levels tended to decrease during treatment. Major side-effects included diarrhea (35.7%), nausea (35.7%) and a flare response (28.6%).

Conclusions: Our short-term results demonstrated promising bone-pain relief effect of Ra-223 in 71% of patients during the course of treatment. Encountered side effects were mild including mostly gastro-intestinal symptoms. White blood cell count was reduced especially after the first injection.

P38

Prevalence and Risk Factors of Contralateral Extracapsular Extension in Men Undergoing Radical Prostatectomy for Localized Unilateral Disease at Biopsy: A Global Multi-institutional Experience

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Background: Interfascial nerve-sparing technique during RARP may be performed on the contralateral side of unilaterally diagnosed prostate cancer. Unsuspected bilateral disease could be associated with extracapsular extension (ECE), thus increasing the risk of postoperative positive margins and recurrence. We aim to assess the incidence and risk factors of contralateral ECE (cECE) and contralateral positive surgical margins (cPSM) in patients diagnosed preoperatively with unilateral disease.

Methods: This multicenter cohort consisted of 331 men diagnosed with unilateral PCa who underwent RARP. Localization and occurrence of positive cores from biopsy, cECE, cPSM and SVI was noted. cECE+ and cECE- groups were compared for preoperative predictive parameters.

Results: Pathology reported cPCa in 50.2% and cECE in 4% of the cohort (Table 1). PSA levels of cECE+ and cECE- patients was 6.4 µg/L (5.1-14.6) and 5.2 µg/L (4.0-7.1) respectively (p=0.026). Also proportion of positive cores (p=0.189), maximum cancer involvement in a core (p=0.168), clinical stage (p=0.327), Gleason score (p=0.178) and TRUS size (p=0.411) was assessed. Lastly, in the pT3 subgroup, the frequency of positive biopsies at the apex increased with contralateral cancer invasion (p=0.007) (Table 1).

Conclusions: Despite the 50% chance of bilateral disease, the risk of cPSM associated with cECE is only 1% in the cohort. Contralateral nerve-sparing procedures may be considered safe in patients with unilateral disease on preoperative biopsies, especially when associated with a low PSA and negative biopsies at the apex.

Table 1. P38

(%)	cPCa-,cECE- n=165 (50%)	cPCa+, cECE- n=153 (46%)	cPCa, cECE+ n=13 (4%)	p value
PSM	14.5	26.8	38.5	0.008
cPSM	0	10.5	23.1	<0.001
SVI	3.0	5.2	38.5	<0.01

P39
Intermediate Results of a Whole Gland HIFU for Localized Prostate Cancer: A Single Center Experience

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Background: We present an intermediate -term cancer control and morbidity of high intensity focused ultrasound (HIFU) from a single tertiary center.

Methods: A retrospective cohort of 99 patients underwent HIFU at the medical center "Zdorovie" for localized prostate cancer (T1-2, N0, M0, PSA at first diagnosis less than 15 ng/ml) and follow-up longer than 12 months. Those patients with previous long-term androgen deprivation therapy, locally advanced prostate cancer or any therapy influencing prostate specific antigen (PSA) were excluded from study. All patients were treated completely with an Sonablate 500® high intensity focused ultrasound device. Evaluation was performed in aggregate, and by stratification according to cohort group, risk group (D'Amico criteria), prostate specific antigen nadir and Gleason score. The Phoenix definition was used for biochemical failure. Statistical analysis was performed using the Kaplan-Meier method, and univariate and multivariate analysis was performed using a Cox model.

Results: Of 99 study patients 36 (36%) had intermediate or high risk disease. Mean follow-up was 3.03 years (range 1.0 to 5.5). Cancer specific survival was 100%, Biochemical disease free survival at 3 years of follow-up was 82% for low-risk, 63%- for intermediate risk and 45% - for high risk disease, respectfully.PSA nadir and Gleason score predicted biochemical failure and side effects were mild. In terms of continence, from 99 patients 89 (88)% are continent after procedure, in 10 cases a transient incontinence (up to 6 months) was revealed treated with Kegel exercises combined with physical therapy or biofeedback and 2 patients developed longer treatment (up to 18 months) with recovery of continence function. Regarding erectile dysfunction (ED) :74 (74%) patients had ED in postop although 65 (88%) of them had ED before procedure and 52 of them (70%) had not been interested in recovery of sexual function. That said, only 9 (9%) patients developed de novo ED after HIFU.

Conclusions: Our intermediate -term follow-up with HIFU whole gland ablation demonstrated a high overall rate of cancer specific survival and an exceptionally high rate of biochemical disease free survival in low risk patients.

P40
A Comparison of Time to Return to Baseline Lower Urinary Tract Symptoms among American Urological Association Symptom Index Severity Groups after Brachytherapy

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Background: Moderate to severe lower urinary tract symptoms (LUTS) have been considered a relative contraindication to prostate brachytherapy and has excluded patients that would have been otherwise well served by this more minimally invasive procedure. The short half-life of 131Cesium (131Cs) has been associated with a quicker resolution of symptoms in men undergoing prostate brachytherapy with 131Cs when compared to men undergoing prostate brachytherapy with Iodine 125 (125I) or Palladium 103 (103Pd). The present study evaluates the duration and severity of lower urinary tract symptoms in men with moderate to severe lower urinary tract symptoms who underwent prostate brachytherapy with 131Cs.

Methods: Four hundred and thirty one 131Cs prostate brachytherapy patients completed an American Urological Association Symptom Index (AUA-SI) and an Expanded Prostate Index Composite (EPIC) preoperatively and in follow up at 2-weeks, 3-, 6-, 12-, and 24-months. Their return to baseline AUA -SI and EPIC scores was compared amongst 4 groups: patients with mild, mild moderate (8-15), severe moderate (16-20), and severe (21-35) preoperative AUA-SI scores (Table 1).

Results: Patients with mild (0-7) and mild moderate symptoms (8-15) had a slower return to baseline symptoms than those with severe moderate (16-20) and severe (21-35) symptoms. At more distant follow up the gap narrowed and a predominance of all patients regardless of the preoperative AUA-SI and EPIC classification were back to their baseline symptoms.

Conclusions: Patients with more severe lower urinary tract symptoms have previously been discouraged from undergoing prostate brachytherapy as they were counseled they would have very bothersome voiding symptoms after their procedure. The results of the present study demonstrate that men who undergo prostate brachytherapy with 131Cs who have higher preoperative AUS-SI scores actually return to their baseline voiding pattern quicker than men with lower preoperative AUA-SI scores. These results suggest that men with more bothersome baseline lower urinary tract symptoms can undergo prostate brachytherapy with 131Cs without concern for excessively bothersome symptoms for a prolonged duration after their procedure.

P41
Sarcopenia Measured at L3 Vertebral Level Best Predicts 90-Day Complication Rate following Radical Cystectomy

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Background: Previous work has shown that sarcopenia, defined by measuring total psoas area (TPA) at the L3 vertebral level, correlates with outcomes following radical cystectomy. We sought to determine whether TPA measurements at different vertebral levels affected the prognostic ability of TPA.

Methods: After obtaining institutional review board approval, we retrospectively identified all patients who underwent cystectomy at our institution in 2011 or 2012. Patients with CT scans obtained within 30 days prior to cystectomy were included. TPA was measured as the cross-sectional area of both psoas muscles at the L2, L3 and L4 vertebral levels and then normalized for patient size using body surface area. Outcomes including 90-day complication rate as well as 1-year overall and cancer-specific mortality were examined. Receiver operating characteristic (ROC) curve analysis was used to examine the predictive ability of TPA as a biomarker. Multivariable logistic regression examining predictors of 90-day complication rate including age, gender, American Society of Anesthesiologist's (ASA) class, ECOG status, receipt of neoadjuvant chemotherapy, pathologic T stage and L3 TPA was completed.

Results: A total of 135 patients had data available for analysis. Average TPA values were higher in men than in women for all 3 vertebral levels examined (p < 0.01) but were not significantly different between patients

Table 1. P40. Percent of patients returned to baseline AUA-SI score at postoperative follow up intervals after Cesium-131 prostate brachytherapy

| AUA-SI Severity Classification | n | Percent back to baseline | | | | |
		2 weeks	3 months	6 months	12 months	24 months
AUA-SI Mild (0-7)	265	21.80%	57.04%	74.02%	75.41%	79.51%
AUA-SI Mild Moderate (8-15)	116	25.00%	64.41%	79.63%	80.00%	85.96%
AUA-SI Severe Moderate (16-20)	34	40.00%	94.12%	87.50%	71.43%	84.62%
AUA-SI Severe (21-35)	16	40.00%	88.89%	87.50%	75.00%	100.00%

who did and did not undergo neoadjuvant chemotherapy at any level. L3 TPA was significantly lower among patients who experienced a 90-day complication than those who did not (p = 0.043). Neither L2 TPA (p = 0.69) nor L4 TPA (p = 0.86) correlated significantly to 90-day complication rate. ROC AUC (area under the curve) for L3 was 0.602, which was superior to the AUC for L2 (0.48) and L4 (0.49). On multivariable analysis, TPA was the sole significant predictor of experiencing a complication during the first 90 postoperative days (OR 0.79, 95% CI 0.65 - 0.96, p = 0.015) of the variables examined. No TPA value was a significant predictor of 1-year overall or cancer-specific survival.

Conclusions: Low TPA measured at the L3 vertebral level independently predicts 90-day complication rate following radical cystectomy. L2 and L4 TPA values had no predictive value for our measured outcomes. ROC curves confirmed that L3 TPA had the best predictive value for 90-day complication rate among the measurements taken. These data suggest that future studies investigating sarcopenia in bladder cancer patients should measure TPA at the L3 vertebral level.

P42
Detecting Prostate Cancer on Repeat Biopsy: MRI/Ultrasound Fusion is Superior to Transrectal Ultrasound Alone

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Background: The role of multiparametric magnetic resonance imaging (MRI) technology is increasing in prostate cancer (CaP) diagnosis. We compared CaP detection rates in men undergoing repeat biopsy by MRI/Transrectal Ultrasound (TRUS) fusion guidance versus the standard TRUS.

Methods: We performed an IRB-approved retrospective analysis of men undergoing repeat prostate biopsy, as clinically indicated, from March 2013 to May 2014. Men without prior CaP and at least one prior prostate biopsy were included in the analysis. The most recent biopsy, either MRI/TRUS fusion (FBX) or standard TRUS (SBX), was evaluated for the primary outcome of CaP detection. The GE LOGIQ E9 machine was used to fuse prostate MRI data with a real-time ultrasound.

Results: N=150 men in the FBX cohort (median age at biopsy = 65). N=193 men in the SBX group (median age at biopsy = 69). CaP detection rate by FBX was 37.3% (56/150) versus 25.4% in SBX, p = 0.017, chi-square test. Gleason Score (GS) ≥ 8 by FBX was 25.0% (14/56) compared to 12.2% (6/49) in SBX. HGPIN was found more frequently in SBX (83/193 = 43.0%) compared to FBX (27/150 = 18.0%), p<0.001.

Conclusions: For men undergoing repeat biopsy, MRI/Ultrasound fusion guided prostate biopsy shows increased prostate cancer detection compared to conventional TRUS. A larger sample size may emphasize the improved detection of clinically significant prostate cancer by FBX seen in our study. FBX may increase the overall detection probability of prostate cancer, while maintaining outpatient practice efficiency.

P43
Characterization of Cystic Renal Cell Carcinoma

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Background: Bosniak's renal cyst classification has provided the current grading system for radiographic prediction of malignant histology among renal cysts, many of which are subsequently surgically resected. Increasing evidence suggests certain low risk renal malignancies may not represent clinically significant disease requiring treatment. It has also been suggested that cystic renal cell carcinoma (RCC) tumors may have little risk, though no study has yet thoroughly investigated the metastatic potential and histologic grades of cystic RCC. We sought to characterize the metastatic potential and histologic grade of renal cysts removed during surgery.

Methods: We performed a retrospective review of predominantly cystic masses removed by partial or radical nephrectomy between 2006-2009 at a single National Comprehensive Cancer Network designated cancer center. All cysts were reviewed and defined as greater than 50% cystic.

Each cyst was assigned a cystic composition grade ranging from 50%-100%. Statistical analysis was done to correlate the cystic grade with final pathology, incidence of metastasis at presentation, and recurrence of disease.

Results: A total of 16 tumors from 16 renal units in 15 patients were identified with predominantly cystic lesions. 81% were male with median age of 66 years (range 47-85 years). The mean and median cyst sizes were 5.72 and 4.05 cm respectively (range 1.9-12.9cm). The mean and median cystic scores were 76.9% and 85% respectively (range 50-95%). 14 cysts were classified as Bosniak grade IV while two were classified as Bosniak grade III. Furthermore, 11 cysts were classified as low histologic grade and 5 as high histologic grade. Representative histologies included 10 clear cell, 5 papillary including 2 type I and 3 type II, and one mucinous tubular and spindle cell carcinoma. All high grade cysts had either papillary type 2 histology or clear cell histology with no more than 50% cystic component. All clear cell cystic RCC with >50% cystic component were low grade. At a median follow up of 59.5 months, there was only one metastasis, which occurred in a patient with papillary type 2 RCC.

Conclusions: The Bosniak Renal Cyst Classification does not predict presence of clinically significant malignancy in renal masses. Our data suggests that predominantly cystic clear cell carcinoma is likely to be low grade. Conversely, papillary type 2 carcinomas were more likely to be high grade, even in setting of a small solid component. Measuring cystic composition will provide a new scoring system that correlates tumor grade and clinical outcomes.

P44
WITHDRAWN

P45
Lymph Node Positivity at Radical Prostatectomy and Clinical Outcomes at a Tertiary Care Referral Center

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Background: The extent of pelvic lymph node dissection (PLND) at the time of radical retropubic prostatectomy (RRP) varies among surgeons and institutions. Differences mainly focus on candidacy for node dissection and the limit of dissection (limited versus extended). We analyzed our local experience of lymph node outcomes.

Methods: In this retrospective study with institutional board ethics, data was collected on consecutive patients undergoing RRP with PLND from January 2003 to June 2013 by two academic Urooncologists. Extracted information included surgical pathology and patient, biopsy, and biochemical recurrence (BCR) characteristics. A univariate and multivariate analysis was conducted using SAS software.

Results: 420 consecutive patients, of whom 411 underwent a RRP with PLND and 9 aborted prostatectomies, had median followup of 46 months. Median patient age was 60 with a mean preoperative PSA of 11. Overall lymph node metastases rate was 16.1%. Of these N1 patients, the average number of positive nodes was 2.3 with an average removal of 13.4 nodes. Anatomic regions of positive pelvic lymph node metastasis were 54 percent in hypogastric area, 13 percent in obturator area, and 33 percent were external iliac. 2 patients with N1 disease died and 79 percent had BCR. Median time from treatment to BCR was 4.5 months with a median PSA of 0.28. Multivariate analysis showed that year of surgery (p = 0.04), Gleason ≥ 4+3 (p = 0.0003), and the biopsy ratio of total cancer length: total length of all cores (p less than .0001) was associated with node positivity.

Conclusions: This contemporary series of RRP for prostate cancer shows a high rate of lymph node metastases (16%). Performing a limited pelvic lymph node dissection would under stage 54% of our patients. To our knowledge, this study is the first to demonstrate that the ratio of preoperative biopsy total cancer length:total length of all cores was associated with node positivity

P99
Perioperative Predictors of Biochemical Recurrence at 48 Months After Radical Prostatectomy

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Background: Historically, biochemical recurrence (BCR) occurs in up to 35% of patients at 10 years after radical prostatectomy (RP) for clinically localized prostate cancer. Although all BCR may not lead to cancer-specific mortality, patients who experience earlier biochemical recurrence are more likely to suffer prostate cancer metastases and cancer-specific mortality. Thus, predictors of early biochemical recurrence are useful for prognostication. The objective of the present study was to determine what clinicopathologic factors predict BCR at a mean time to recurrence of 48 months.

Methods: The study cohort represents consecutive patients who underwent open RP by a single surgeon from 1999-2012. Patients were stratified by pathologic Gleason grade: pure 3+3=6, 3+3=6 with any higher tertiary grade, 3+4=7, 4+3=7, Gleason sum (GS) 8, and GS 9-10. Univariate and multivariable analyses were used to compare biochemical recurrence (defined as PSA ≥ 0.2 ng/ml or any adjuvant treatment) with preoperative and postoperative clinicopathologic features.

Results: Two thousand five hundred sixty-four patients were included in the study. The breakdown of patients by Gleason category is listed in Table 1. Independent predictors of biochemical recurrence included higher Gleason grade, preoperative PSA (HR 1.03, 1.01-1.04), seminal vesicle invasion (HR 1.81, 1.34-2.45), positive lymph nodes (HR 3.01, 2.14-4.23), and high percentage of tumor in gland (HR 1.02, 1.01-1.03). Within Gleason grade, there was a strong increase in biochemical recurrence for more poorly differentiated tumors, ranging from Gleason 3+4 (HR 3.02, 1.58-5.76) to Gleason 9-10 (HR 21.4, 10.8-42.8).

Conclusions: Gleason pattern component ≥4, preoperative PSA, seminal vesicle invasion, positive lymph nodes, and high percentage of tumor volume in gland independently predict BCR after RP at 48 months. High Gleason grade remains the strongest predictor of biochemical recurrence. These results can be used postoperatively to counsel patients regarding their risk of biochemical recurrence and identify patients who may derive benefit from earlier adjuvant therapies.

P100
Peripheral Blood Monocyte Subset Signature Predicts Patient Outcome in Stage IV Renal Cell Carcinoma Dendritic Cell Vaccination

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Background: Compared to conventional cancer treatments, immune-based therapy has the unique potential to provide systemic and tumor-specific responses. Clinical trials have demonstrated that dendritic cell (DC) vaccination can provide durable complete anti-tumor responses in a subset of patients, even in cases of aggressive metastatic disease including stage IV Renal Cell Carcinoma (RCC). In many DC vaccination approaches, peripheral blood monocytes serve as precursors to generate DC ex vivo. Recently, monocytes have been shown to consist of three distinct subsets (Mo1, Mo2, Mo3) with different functional properties. The role of each of these subsets in inducing anti-tumor immunity, particularly in the context of DC vaccination, is unclear. The goal of this study was to investigate whether the percentage of monocyte subsets in peripheral blood of RCC patients prior to vaccination could predict which patients had responses to treatment.

Methods: Pre-treatment peripheral blood monocytes from 13 patients who received intranodal autologous tumor lysate dendritic cell vaccinations

Table 1. P99. Cox Proportional Hazard Model (Outcome: Biochemical recurrence)

Predictor		Univariate Haz. Ratio (95% CI)	Univariate P > |z|	Multivariable Haz. Ratio (95% CI)	Multivariable P > |z|
Group					
Group I (pure 3+3, n=623)		(Reference)		(Reference)	
Group II (3+3=6 w/ HTG, n=143)		2.91 (1.13, 7.52)	0.027	2.38 (0.92, 6.16)	0.073
Group III (pure 3+4, n=1224)		4.65 (2.46, 8.77)	<0.001**	3.02 (1.58, 5.76)	0.001**
Group IV (4+3=7, n=350)		27.12 (14.54, 50.57)	<0.001**	9.04 (4.68, 17.48)	<0.001**
Group V (Gleason 8, n=105)		41.04 (21.13, 79.70)	<0.001**	12.9 (6.40, 25.98)	<0.001**
Group VI (Gleason 9-10, n=109)		91.18 (48.29, 172.18)	<0.001**	21.4 (10.8, 42.48)	<0.001**
Age (Years)		1.04 (1.02,1.05)	<0.001**	1.01 (0.99, 1.03)	0.441
Race					
White		(Reference)		(Reference)	
Non White		1.15 (0.73, 1.83)	0.546	0.88 (0.54, 1.43)	0.595
Comorbidity (Y/N)	Hypertension	1.09 (0.87, 1.37)	0.453	1.02 (0.80, 1.29)	0.870
	Diabetes	1.23 (0.81, 1.87)	0.324	1.15 (0.74, 1.79)	0.537
	Hyperlipidemia	0.87 (0.68, 1.12)	0.291	0.94 (0.72, 1.22)	0.628
	CAD	1.20 (0.75, 1.91)	0.444	0.83 (0.50, 1.35)	0.450
Pre-op PSA (ng/ml)		1.07 (1.06, 1.08)	<0.001**	1.03 (1.01, 1.04)	<0.001**
Organ confined (Y/N)		0.10 (0.08, 0.12)	<0.001**	0.14 (0.00, 45.26)	0.504
ECE (Y/N)		10.07 (7.89, 12.86)	<0.001**	0.37 (0.00, 119.5)	0.735
Seminal Vesicle Invasion (Y/N)		14.80 (11.67, 18.78)	<0.001**	1.81 (1.34, 2.45)	0.001**
Margin status (Y/N)		4.19 (3.22, 5.44)	<0.001**	0.85 (0.64, 1.14)	0.279
Positive nodal status (Y/N)		21.85 (16.24, 29.41)	<0.001**	3.01 (2.14, 4.23)	<0.001**
Largest tumor nodule (cm)		1.05 (1.03, 1.07)	<0.001**	1.02 (0.96, 1.08)	0.558
Percent of tumor gland (%)		1.06 (1.05, 1.07)	<0.001**	1.02 (1.01, 1.03)	<0.001**

were obtained and subsets were identified by differential expression of CD14 and CD16. Monocyte subsets from the peripheral blood of healthy donors were isolated, cultured into DC, and then analyzed for costimulatory molecule expression by flow cytometry.

Results: Stage IV RCC patients exhibiting complete responses to DC vaccination exhibited a unique monocyte subset signature in peripheral blood with approximately twice as many Mo3 (16.3% ± 2.6, mean ± SD) compared to partial responders (6.8% ± 2.8, P < 0.01 respectively), patients with progressive disease following vaccination (4.5% ± 3.9, P < 0.05), or healthy donors (7.2% ± 2.6 P < 0.005). Peripheral blood from complete responders contained decreased percentages of Mo1 (57.5% ± 6.4) compared to partial responders (78.2% ± 5.3, P < 0.01), progressive disease (81.0% ± 10.6, P < 0.08), and healthy controls (79.0% ± 4.8, P < 0.01). Interestingly, when Mo3 from healthy donors were cultured into DC ex vivo, these populations had elevated percent positive values for costimulatory molecules CD80 (96.4%) and CD86 (91.1%) as well as HLA-DR (99.1%) compared to Mo1-derived DC (64.6%, 54.4%, 60.2%, respectively), suggesting that DC cultured from mo3 are superior antigen presenting cells.

Conclusions: Collectively, these findings demonstrate that monocyte subsets in peripheral blood may be an important prognostic tool prior to DC vaccination. Future studies will evaluate whether enrichment of Mo3 populations prior to ex vivo culture into DC can improve DC-mediated T cell activation.

P101
Sipuleucel-t Therapy: Distribution of Baseline PSA as Defined as Quartiles in a Cohort of Large Urology Group Compared to the IMPACT Trial

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Background: Emerging scientific evidence from IMPACT trial suggested that survival advantage quoted to patients must take pretreatment PSA into consideration. We demonstrated that in community based practice may have mCRPC identified earlier in the treatment course that typical patient in the IMPACT study.

Methods: Electronic charts for 60 patients were reviewed. All patients were treated with Sipuleucel-T in an on-label fashion.

Results: The baseline PSA quartile distribution was remarkably different from IMPACT data. All four quartiles had much lower PSA cut-off. The lowest PSA threshold was ≤ 2.72 ng/ml for first quartile versus ≤22.1 ng/ml of IMPACT. From 2.73-10.35 vs. from >22.1 to 50.1 for second, from 10.36-33.65 vs. from >50.1 to 134.1 for third and >33.66 vs. >134.1 ng/ml for the fourth quartile of the treated patients, respectively.

The time elapsed from their first Sipuleucel-T injection date ranged from 3 to 1074 days, with a median of 417 days. Time to death ranged from 188 to 848 days, with a median of 334 days after immunotherapy.

Of those that expired, 5/9 (56%) died in the first 12 months, 1/9 patients (11%) in 12-18 months, and 3/9 patients (33%) died >18 months after the last injection of Sipuleucel -T.

Conclusions: Our experience demonstrates a different patient population than that of the IMPACT study, namely our patients had lower PSAs indicating earlier stage of mCRPC. It seems reasonable to initiate immunotherapy at this early stage with an attempt to drastically change the natural history of disease by improving OS that we plan to study further.

P102
Role of Fuhrman Grading in Renal Cell Carcinoma Recurrences

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Background: Guidelines for kidney cancer follow up are based on historic data. The guidelines are not specific regarding follow up for low and high grade kidney cancer and do not take into account the surgical approach (partial versus radical nephrectomy). We set out to investigate the role of Fuhrman nuclear grading in kidney cancer patients.

Methods: The prospectively populated IRB-approved kidney cancer database was queried for all patients who underwent radical or partial nephrectomy for renal cell carcinoma (RCC). Patients were grouped into low grade renal cell carcinoma (Fuhrman grade 1 and 2) and high grade RCC (Fuhrman grade 3 and 4). Patient characteristics, surgical approach, recurrences (local and distant) and survival data were collected. Data analysis was performed using Fischer's exact t-test and Kaplan Meier survival analysis.

Results: A total of 787 patients were identified matching our criteria. 44 of 439 patients (10.0%) with Fuhrman grade 1 or 2 developed local or distant metastatic disease, compared to 132 of 438 patients (30.1%) with Fuhrman grade 3 or 4 (p < 0.001). When Fuhrman grade 3 and 4 were analyzed, 33 out of 250 (13.2%) with grade 3 versus 29 out of 98 (30%) with grade 4 developed recurrent disease (p<.001). Average time to recurrence for Fuhrman grade 1 and 2 was 35.8 months, average time to death was 31.7 months and a range of time to death of 1-106 months. Patients with Fuhrman grade 3 had an average time to recurrence of 24 months, average time to death of 21.4 months and a range of time to death of 2-93 months, while Fuhrman grade 4 patients had an average time to recurrence of 2.5 months, average time to death 10.2 months and range of time to death of 0-54 months. No local or metastatic disease was observed in Fuhrman grade 1 patients. Local recurrence was seen in 8 patients with Fuhrman grade 2. There were a total of 7 patients with local recurrences in the Fuhrman grade 3 and 4 cohort. Surgical approach was not statistically significant in local recurrences.

Conclusions: In conclusion, Fuhrman grade 1 patients experience excellent prognosis and extremely low risk of kidney cancer recurrence, while high Fuhrman grade patients have a high chance of tumor recurrence and death from disease. These data support the use of a large RCC databases to adjust follow up guidelines in kidney cancer according to grade of disease.

P103
Five-year 131Cesium Brachytherapy Outcomes

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Background: We present our 5 year outcomes in men undergoing prostate brachytherapy with Cesium 131 (131Cs). Cesium 131 is a relatively newer isotope proposed to have a shorter duration of lower urinary tract symptoms compared to Iodine 125 (125I) and Palladium 103 (103Pd).

Methods: Four hundred and eighty five patients have undergone prostate brachytherapy with 131Cs at our institution. We present PSA outcomes in the first 367 patients who now have at least two years of follow up; 187 of those patients have five years of follow up. Biochemical recurrence defined as PSA nadir plus 2 ng/ml (Phoenix definition) was used as the primary outcome measure. Results are reported for the total cohort and stratified individually for low, intermediate, and high risk groups. Results are also reported for patient receiving monotherapy, combination therapy, and trimodal therapy.

Results: Of the 367 patient that underwent brachytherapy with 131Cs and had at least two years of follow up the biochemical freedom of disease (BFD) was 96.0% for low risk, 92.7% for intermediate risk, and 82.9% for high risk patients. Of all patients treated with monotherapy 95.7% were BFD. Those treated with combination therapy and trimodal therapy were 84.9% and 92.0% BFD respectively.

Conclusion: The BFD at 5 years for patients treated at a single institution with 131Cs rival or improve upon results achieved with 125I and 103Pd. These results, however, represent only intermediate follow up and longer term follow up is needed to confirm these results given the long natural history of this disease.