NOT ALL NOTCH IS CREATED EQUAL: THE ONCOGENIC ROLE OF NOTCH2 IN BLADDER CANCER

(Presentation to be made by Peter C. Black)

Objectives: In the context of recent molecular analyses of bladder cancer (BC) that open the door to significant advances in targeted therapies, Notch has been identified as a suspected tumor suppressor. The objective of this project, however, was to demonstrate the oncogenic role of Notch2 in BC.

Materials & Methods: We investigated genomic aberrations of Notch1, 2 and 3 in patients with muscle invasive bladder cancer and correlated these to survival. Molecular analysis of Notch2 function was studied in preclinical models of BC.

Results: We report a high rate of Notch2 copy number gain in BC. High Notch2 expression was identified especially in the basal subtype and in mesenchymal tumors. Notch2 activation correlated with adverse disease parameters and worse prognosis by immunohistochemistry. Forced over-expression of the intracellular domain of Notch2 (N2ICD) induced growth and invasion by cell cycle progression, maintenance of stemness and epithelial-to-mesenchymal transition (EMT). These effects were abrogated by silencing of CSL, indicating mediation of these effects through the canonical Notch signaling pathway. In an orthotopic xenograft model, forced over-expression of N2ICD increased growth, invasion and metastasis. In order to explore the potential for therapeutic targeting of Notch2, we first silenced the receptor with shRNA and subsequently treated with a specific inhibitory monoclonal antibody. Both interventions decreased cell growth, invasion and metastasis in vitro and in the orthotopic xenograft model.

Conclusions: We have demonstrated that Notch2 acts as an oncogene that promotes BC growth and metastasis through EMT, cell cycle progression and maintenance of stemness. Inhibition of Notch2 is a rational novel treatment strategy for invasive BC.

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THE IMPACT OF TUMOR STAGE AND NODE STATUS ON SURVIVAL FOLLOWING CYSTECTOMY: THE COBRA (CANCER OF THE BLADDER RISK ASSESSMENT) SCORE
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(Presentation to be made by Dr. Porten)

Purpose: The American Joint Committee on Cancer (AJCC) staging system for bladder cancer classifies all lymph node (LN) positive patients as stage IV, with estimated 5-year cancer specific survival (CSS) of 15%. However, other factors such as extent of node involvement and tumor stage (T stage) may influence CSS. The objective of this study is to 1) assess the impact of primary T stage on CSS in LN positive patients using a large population based registry 2) create an accurate, straightforward risk assessment score based on whole integers that accurately integrates readily available clinical and pathologic information.

Materials and Methods: We identified cases of urothelial carcinoma of the bladder from the SEER national cancer registry treated with cystectomy and lymph node dissection between 1988 and 2011. The primary outcome was death due to bladder cancer. Covariates examined included year of diagnosis, age at diagnosis, race, gender, tumor grade, tumor stage, nodal stage, total number of lymph nodes removed, number of positive lymph nodes, and lymph node density. Adjusted survival analysis was performed using Cox proportional hazards analysis stratified by stage and node status. The cohort was then randomly divided 1:1 into discovery and validation sets. Variables included in COBRA were those of maximal log hazard ratios and then validated with Cox proportional hazard analysis with bootstrapping. Predictive accuracy was confirmed using Harrell’s concordance index.

Results: A total of 14,828 patients were identified and 3,649 (25%) were node positive (N+). A median of 10 LN (IQR 5-18) were removed per patient and did not differ between groups (N+ vs N-). Within each respective T stage, N+ patients had worse CSS than N- patients. However, 5-year CSS of low T stage, N+ patients was similar to that of high T stage, N- patients (49% vs 56%). The population was then split into discovery and validation cohorts (7,414 each) for COBRA and was not significantly different in demographic and pathologic variables. Variables with the highest hazard risk ratios (age, tumor stage, and lymph node density) were condensed so that a coefficient of approximately 0.5 was associated with 1 point. The full score ranged from 0 (lowest risk) to 7 (highest risk), with a maximum of 1 point for age, 3 points for stage, and 3 points for lymph node density. Each point increase in the newly developed COBRA score was associated with a HR of 1.61 (95% CI 1.56-1.65), translating to a roughly 3-fold increase in the risk of bladder cancer death for every two-point increase. The c-index for the model in the discovery cohort was 0.712 and 0.705 in the validation cohort.

Conclusions: CSS among node positive patients is heavily influenced by primary tumor stage. The novel COBRA score is a simple risk stratification tool with readily available patient data incorporating the relative contribution of tumor stage and lymph node involvement to patient prognosis following cystectomy.

Source of Funding: Goldberg-Benioff Program in Cancer Translational Biology
PROPHYLACTIC ANTIBIOTICS IN THE FIRST 30 DAYS FOLLOWING RADICAL CYSTECTOMY WITH URINARY DIVERSION LEADS TO FEWER URINARY TRACT INFECTIONS

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Introduction and Objectives: Urinary tract infections and sepsis from a urinary source contribute significantly to the morbidity associated with cystectomy and urinary diversion. Many of these urinary tract infections and readmissions for urosepsis occur in the first 30 days following surgery and around the time of ureteral stent removal. Currently, there is little data and no AUA guidelines that address the use of prophylactic antibiotics in the first 30 days following radical cystectomy with urinary diversion. The purpose of this study was to determine if prophylactic antibiotics decreases urinary tract infections in the first 30 days following radical cystectomy.

Methods: Subjects were identified utilizing using our IRB approved electronic database. From 2014-2015, 84 consecutive patients who underwent a radical cystectomy with urinary diversion for bladder cancer were included in the study. The indwelling ureteral stents were left in place for 3 weeks in both groups. The first 42 patients did not receive daily prophylactic antibiotics. We then altered our postoperative protocol to include a urine culture on discharge followed by 4 weeks of daily oral antibiotics. Patients with a prolonged hospital course, those who died of other causes, or who had been on antibiotics for a known uropathogen preoperatively were excluded from the study. We retrospectively evaluated for urinary tract infections in the first 30 days following surgery. A urinary tract infection was defined as clinical symptoms or signs (i.e. sepsis, pyelonephritis, malaise, elevated wbc count) and a documented culture positive organism. Simple T tests were used to determine the association between 4 weeks of postoperative antibiotics and 30 day risk of urinary tract infection.

Results: A total of 84 patients were enrolled in the study between 1/2014 and 5/2015. There was no significant difference in age, BMI, or stage between the two groups. A total of 81% received an ileal conduit urinary diversion in the prophylactic antibiotic group and 84% in the no antibiotic group. A total of 10% (4 patients) in the prophylactic antibiotic group had a documented urinary tract infection, whereas 31% (13 patients) in the no antibiotic group had a urinary tract infection. On univariable analysis, this was statistically significant with P=0.01. Clostridium difficile occurred in 1 patient from the no antibiotic group. No clostridia infections were noted in the prophylactic antibiotic cohort. One patient in the prophylactic group developed a resistant organism and 2 patients in the no antibiotic group developed a resistant organism. In the patients receiving antibiotics, 8 patients had discharge positive urine cultures, but only 1 patient had a symptomatic urinary tract infection. There was no association noted between urine culture at discharge and the development of UTI in the 30 day post discharge period. A total of 7 patients in the no antibiotic group were admitted for sepsis from a urinary source compared to 2 patients in the antibiotic group (P=0.06).

Conclusion: Prophylactic antibiotics in the 4 weeks following radical cystectomy is associated with a significant decrease in urinary tract infections in the 30 days after surgery, without an increase in antibiotic associated complications. A discharge positive urine culture was not associated with the development of a urinary tract infection in the first 30-days following cystectomy. In the antibiotic group, fewer patients were admitted for sepsis from a urinary source, but these results were not significant.
STATE OF THE ART

PROSPECTIVE EVALUATION OF CONTINENCE AFTER OPEN RADICAL CYSTECTOMY AND ORTHOTOPIC URINARY DIVERSION

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(Presentation to be made by Dr. Swar H. Shah)

Objective: We evaluated the continence outcomes in patients undergoing orthotopic neobladder (ONB) diversion following radical cystectomy using validated pad usage questionnaires.

Materials and Methods: Using our IRB approved database, we identified 1545 patients that underwent open radical cystectomy from 2000 to 2014. ONB was constructed in 1057 (68%) patients, of whom 892 (84%) were male. Beginning in 2012, patients were prospectively followed, completing a validated, pictorial pad usage questionnaire, assessing the number, size, and wetness of pads, as well as catheter use, at follow up visits. Continence was defined as no pad usage, or pads as “almost dry.” Questionnaires were stratified into distinct postoperative time intervals. Patients with artificial urinary sphincters, a history of radiotherapy, or female gender were excluded.

Results: A total of 161 patients with available pad usage questionnaires were followed from August 2012 to March 2015. A total of 345 pad usage questionnaires were collected, with 283 interval distinct pad usage questionnaires separated into intervals of < 3 months, 3-6 months, 6-12 months, 12-18 months, 18-36 months, and more than 36 months after surgery (n= 48, 45, 46, 37, 52, and 51, respectively). Daytime continence rates increase from 58% at <3 months to 89% by 12-18 months postoperatively. Nighttime continence rates increase from 25% at <3 months to 52% by 18-36 months postoperatively. Fifty percent of patients reported day and nighttime continence by 18-36 months postoperatively. Catheterization rate was 13.9% for the entire cohort, with a median time to catheterization of 15.9 months.

Conclusions: Following ONB, continence improves significantly by 6 months, and plateaus with 89% of patients achieved daytime continence by 12-18 months. ONB represent an excellent functional option for urinary diversion.

Source of Funding: None
Objectives: Urothelial carcinoma of the bladder (UCB) or upper urinary tract (UCUT) and renal cell carcinoma (RCC) are smoking-related genitourinary malignancies. A new diagnosis of smoking-related genitourinary cancer is a clinical moment when smoking cessation interventions may have increased effectiveness. Underuse or underreporting of cessation tools in this setting represents potential for quality improvement. We estimated utilization of smoking cessation in new smoking-related genitourinary cancer visits.

Methods: From MarketScan® data, over 34 million enrollees aged 18-65, calendar years 2007-2012 were screened for billing codes for index UCB/UT or RCC and tobacco use disorder. Qualifying individuals were assessed for pharmacologic or counselling smoking cessation interventions in the 12 months following diagnosis using CPT and ICD-9 codes. Multivariable logistic regression identified factors associated with smoking cessation intervention.

Results: 5,777 smokers with tobacco-related genitourinary malignancy were identified by billing claims (40% UCB, 46% RCC, 4.2% UCUT and 9.8% multiple cancers). Claims for intervention were rare (5.3%). Among intervention recipients, 240 (80%) had UCB and 92% had claims for either counselling or medications, only 8% had both. The majority (61%) of intervention claims were within 3 months after genitourinary cancer diagnosis. On multivariable analysis UCB was associated increased odds of intervention claims (OR 6.27;95%CI 4.57,8.60) compared with UCUT and RCC. Other significant factors included more co-morbidities (Charlson 1 OR 1.50, 95%CI 1.06,-2.13; Charlson ≥2 OR 1.89, 95% CI 1.19-3.02 compared with Charson 0). Age, gender, region, provider specialty and care setting were not associated with billing claims for cessation interventions.

Conclusions: Although a new diagnosis of a smoking-related genitourinary malignancy diagnosis offers greater opportunity for provider-driven smoking cessation claims, timely multi-modal cessation interventions are underreported and/or underutilized.
SURVEILLANCE AFTER NEOADJUVANT CHEMOTHERAPY FOR THE TREATMENT OF MUSCLE-INVASIVE BLADDER CANCER: LONG TERM FOLLOW-UP AND UPDATE

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(Presentation to be made by Dr. Stanley Yap)

Introduction and Objectives: Initial single-institution studies show that surveillance after neoadjuvant chemotherapy (NAC) for the treatment of muscle-invasive bladder cancer (MIBC) may be a reasonable option for patients who are cT0 on transurethral resection (TUR) following NAC. We update our experience with this treatment modality and provide long-term follow-up data.

Methods: We performed a retrospective review of patients diagnosed with MIBC undergoing NAC at our institution from 1997-2007. This cohort was separated into two groups based on post-NAC TUR pathology: those who were cT0 and those with persistent disease (>cT0). Patients with cT0 disease were offered the option of surveillance, without immediate radical cystectomy (RC). Kaplan-Meier analysis was utilized to assess overall survival (OS), cancer-specific survival (CSS), and metastasis-free survival (MFS), and stratified by disease status following NAC. Cox proportional hazards (PH) models were utilized to assess the association between disease status post-NAC and survival (OS, CSS, MFS).

Results: Fifty-six patients were included; 32 (57%) were cT0 on post-NAC TUR, and 24 (43%) had persistent disease. Mean follow-up is 62 months. All 32 patients with cT0 disease opted for initial bladder preservation and surveillance. Of these patients, 16 (50%) maintained their bladder without evidence of recurrence. Five-year OS, CSS, and MFS for the overall cohort were 65%, 73%, and 66%, respectively. CSS at five years for those with >cT0 disease on post-NAC TUR was 50%, compared to 89% among those with cT0 disease. MFS at five years for those with >cT0 disease on post-NAC TUR was 37%, compared to 89% among those with cT0 disease. Kaplan Meier analysis demonstrated significantly better OS, CSS, and MFS for those free of disease (and undergoing initial bladder preservation) on post-NAC TUR (cT0) compared to those with >cT0 disease (p<0.05). Cox PH analysis identified a significant association between persistent disease post-NAC (c>T0) and worse OS (Hazards ratio (HR) 3.53, CI 1.28 – 9.80), CSS (HR 6.27, 1.69 – 23.30), and MFS (HR 5.18, 1.98 – 13.60).

Conclusions: Long-term follow-up demonstrates that surveillance after NAC is a reasonable option for patients who are disease free on TUR after NAC, and bladder preservation was maintained in the majority. Patients with persistent disease on TUR after chemotherapy have poor outcomes and should not be candidates for surveillance protocols.

Source of Funding: None
OUTCOMES IN NEUROENDOCRINE BLADDER CANCER TREATED WITH RADICAL CYSTECTOMY
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(Presentation to be made by Vivian Pham)

Objective: Management of localized or locally-advanced neuroendocrine (NE) bladder cancer is difficult as data is sparse and outcomes tend to be poor regardless of treatment approach. We sought to characterize our institutional experience with NE cancer of the bladder to determine factors associated with survival.

Materials and Methods: We utilized our bladder cancer database to identify patients with any NE component to their bladder cancer who underwent radical cystectomy (RC) (1977-2012). Patients with distant metastasis were excluded. Clinical and pathologic data were obtained. Kaplan-Meier curves were used to estimate recurrence-free survival (RFS) and overall survival (OS) and were compared with the log rank test. Multivariable Cox proportional hazards adjusting for age, gender, smoking status, and histology determined factors associated with RFS and OS.

Results: A total of 86 patients met the inclusion criteria with a median age of 68 years (range 37-89). The highest clinical stage prior to RC was ≤T2 in 71 patients, >T2 in 8 patients, and lymph node positive in 7 patients. There were 35 (41%) patients with predominant NE histology (small cell n=30, large cell n=5) and the remaining 51 (59%) patients had <50% NE components on histology. Twenty-two patients (26%) underwent neoadjuvant chemotherapy (NACHt) with cisplatin/etoposide representing the most common regimen. Rates of pathologic upstaging are shown in the Figure 1. Lymph node upstaging was significantly higher in patients who did not receive NACHt when compared with patients who receive NACHt (51% vs. 19%, p<0.02). The median OS and RFS for the entire cohort were 2.0 and 1.4 years, respectively. Patients with predominant NE histology had worse OS when compared with patients with <50% NE histology (p=0.002, Figure 2). A response to NACHt on imaging was associated with improved OS (median 30.5 months) when compared with patients who had no response to NACHt (median 10 months, p=0.13). On multivariable analysis, a predominant NE histology, presence of pathologic upstaging, and not receiving adjuvant chemotherapy were independently associated with worse OS.

Conclusions: Survival in patients with bladder cancer with NE histology is poor and occult LN positive disease is identified in almost half of patients at the time of RC. A predominant NE histology is independently associated with worse survival. Further investigation into the optimal timing of multimodal therapies is required to improve outcomes in this population.

![Pathologic Upstaging (%)](image1)

![Overall Survival After Radical Cystectomy](image2)
EFFECT OF NEOADJUVANT CHEMOTHERAPY ON RENAL FUNCTION FOLLOWING RADICAL CYSTECTOMY: IS THERE A MEANINGFUL IMPACT?

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(Presentation to be made by Dr. Chandrasekar)

Introduction and Objective: While neoadjuvant chemotherapy (NAC) prior to radical cystectomy (RC) for muscle-invasive bladder cancer is a guideline practice supported by level 1 evidence, it is accepted to be nephrotoxic and typically reserved for patients with good baseline renal function. We evaluate the patterns of impact of NAC on renal function across the initial year following treatment.

Methods: We reviewed the charts of 241 patients who underwent RC for urothelial carcinoma of the bladder from 2003-14 at our institution. Renal function was evaluated at multiple time points (pre-chemotherapy, pre-operatively, post-operatively, 6-12 months follow-up), and then classified by CKD staging. Univariable and multivariable logistic regression analyses were performed to determine relationship between NAC and change in CKD stage. Confounders controlled for included demographic variables, pathologic characteristics, and patient comorbidities.

Results: Of the 241 patients who underwent RC for urothelial carcinoma of the bladder, 66 (27%) received NAC prior to RC and 175 (73%) underwent RC alone. In multivariable analysis, NAC was associated with a decrease of at least one CKD stage from baseline to both post-op (p≤0.05) and 6-12 months follow-up (p≤0.05). The loss of GFR in the NAC cohort occurs up-front with chemotherapy (mean GFR pre-chemo [73.9], pre-op [65.5], 6-12 month follow-up [59.2]), while patients who underwent cystectomy alone had stable GFR (mean GFR pre-op [63.4], 6-12 month follow-up [62]). Of the patients who had normal renal function initially (CKD stage 1-2), NAC was associated with a trend towards worsening to CKD 3-5 at postop, though statistical significance was not achieved (OR 2.13, CI 0.93 - 4.86, p = 0.07). Of the 15 NAC patients (26.8%) who were Stage 3 CKD prior to chemotherapy, none progressed to a higher stage CKD.

Conclusion: NAC is associated with an initial decline in GFR, which then remains stable through the first year following RC. Despite an initial insult, patients receiving NAC are not vulnerable to further deterioration. When appropriately selected, NAC does not appear to result in a clinically significant deterioration of renal function.

Source of Funding: None
TREATMENT TRENDS FOR CLINICAL STAGE I TESTICULAR SEMINOMA IN A LARGE, EQUAL-ACCESS MEDICAL SYSTEM: AN EXAMINATION OF ADJUVANT TREATMENTS FROM 2001-2011 IN THE DEPARTMENT OF DEFENSE TUMOR REGISTRY
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(Presentation to be made by Dr. Jonathan Wingate)

Purpose: Treatment for clinical stage I testicular seminoma is variable, and in many cases, may relate to the nuances of access that are available at the treating facility. The landscape for adjuvant treatment in clinical stage IA/IB seminoma is rapidly evolving, and now, single-use carboplatin is commonly used for adjuvant treatment. The Military Health System is an equal-access system with tri-service medical facilities located throughout the world. These facilities are charged with caring for our service members—a patient-base rich with men in their 20’s, and largely a transitory population, with frequent deployments and transfers. We sought to examine the trends for use of adjuvant therapies for clinical stage IA/IB seminoma in this setting.

Materials and Methods: The ACTUR (Automated Central Tumor Registry) database was queried for cases of clinical stage IA/IB seminoma diagnosed between 2001-2011. The ACTUR database is the cancer registry system for the Department of Defense, and it is maintained by the Joint Pathology Center in the National Capital Region. A total of 412 men were identified with clinical stage IA/IB testicular seminoma from 2001 to 2011 that had records adequate for inclusion. Models were created to analyze the association of year and age with the administration of adjuvant radiotherapy, chemotherapy, and active surveillance.

Results: The use of adjuvant radiotherapy in this population decreased significantly from 2001 to 2011. In 2001, 83.3% of patients received radiation, compared to only 24.0% in 2011 (P < 0.01). During this time, the use of chemotherapy increased significantly. In 2001, 0% of patients received chemotherapy, compared to 40.0% in 2011 (p < 0.01). Later year of diagnosis was significantly associated with increasing odds of receiving chemotherapy than radiation (p<0.001, 2001 to 2005 vs 2006 to 2011, OR 7.40, 95% CI 4.13-13.3). Later year of diagnosis was not significantly associated with odds of receiving surveillance versus chemotherapy or radiotherapy (p=0.542, 2001 to 2005 vs 2006 to 2011, OR 1.16, 95% CI 0.72-1.88).

Conclusions: The use of adjuvant radiotherapy for clinical stage I testicular seminoma has decreased significantly in contemporary times in an equal-access system. This is contrasted by a steady rise in the use of chemotherapy. The use of active surveillance has maintained relatively steady. The relatively low utilization of active surveillance may relate to the transitory nature of this patient base.
PERIOPERATIVE OUTCOMES AND COMPLICATION RATES FOLLOWING ROBOT ASSISTED RETROPERITONEAL LYMPH NODE DISSECTION FOR TESTICULAR CANCER: A MULTI-INSTITUTIONAL UPDATE

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(Presentation to be made by Haidar Abdul-Muhsin MD)

OBJECTIVE: Retroperitoneal Lymph node dissection (RPLND) is an established treatment option for metastatic testicular cancer. The robotic approach has the potential to decrease the morbidity associated with this procedure and to enhance the recovery while maintaining safe oncological outcomes. The objective of this study is to evaluate the perioperative outcomes and postoperative complication rates for robot assisted retroperitoneal lymph node dissection (RA-RPLND) in a large multi-Institutional cohort.

METHODS: After individual institutional review board approval in four participating institutions, the data of all testicular cancer patients treated with RA-RPLND at these tertiary institutions were collected and retrospectively analyzed. The institutions were Mayo Clinic in Arizona, Naval Medical Center in San Diego, Swedish Medical Center and University of North Carolina. The procedures were performed by a single experienced robotic surgeon at each participating institution. All demographic, Intraoperative variables, post-operative pathological outcomes and complications were reported. Additionally, Recurrence rates at the time of this analysis conduction were reported.

RESULTS: There were 97 patients who underwent RA-RPLND. The mean patients' age was 28.9 years (SD±8.3), mean BMI was 26.4 Kg/m² (SD±5.1). Bilateral Full template dissection was performed in 63 (65%) patients compared to 34 patients (35%) who had modified template of dissection. Nerve sparing was attempted in 69 (71%) patients. There were 65 (67%) patients who underwent primary RA-RPLND compared to 32 (33%) patients who received previous chemotherapy. Mean operative time was 339 min (SD±108). Estimated blood loss was 276.1 ml (SD±506). Length of postoperative hospital stay was 2.2days (SD±1.7). There were five conversions (5.2%) to open RPLND. Postoperatively, there were 27 total complications (Grade I=21, II=5, III=1). From oncological point of view, mean lymph node (LN) yield was 25.3 LNs (SD±13.8) with positive LN identified in 27 patients (27.8%). Among the primary RA-RPLND patients who had positive LNs, there were only 5 patients who received adjuvant chemotherapy. There were two intraoperative complications (renal artery injury requiring conversion and open nephrectomy and ureteral injury requiring repair and stenting). There were four recurrences (4.1%) identified at a median follow up of 27.2 months (IQR 8.3-43.6).

CONCLUSION: To our knowledge this study represents the largest study of RA-RPLND outcomes in testicular cancer patients. It demonstrates that this procedure is safe, reproducible. When performed by the hand of experienced surgeons it may provide improved morbidity and less convalescence.
STATE OF THE ART

Practical Approach to the Management of Urethral Strictures.

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