Moderated Posters 1: Prostate Cancer (Surgery/Active Surveillance/ Miscellaneous)
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MP-01.01
Comparative Effectiveness of Robotic-assisted versus Open Radical Prostatectomy Cancer Control Outcomes

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Introduction and Objectives: Robotic-assisted surgery remains controversial due to exaggerated marketing claims, higher costs, hidden risks and few clinically significant benefits; We sought to examine the comparative effectiveness of robotic-assisted RP (RARP) vs. open RP (ORP) for surgical margin status and use of additional cancer therapy.

Methods: We identified 13,434 men with a histologically confirmed, non-metastatic prostate cancer treated with RARP versus ORP during 2004 and 2009 from Surveillance, Epidemiology, and End Results (SEER)--Medicare linked data. Propensity-based analyses were performed to minimize treatment selection biases. Generalized linear regression models were computed for comparison of RP surgical margin status and use of additional cancer therapy (radiation and/or androgen deprivation therapy) by surgical approach.

Results: During the study period, 5,556 and 7,878 men underwent RARP and ORP, respectively. In the propensity-adjusted cohort, the incidence of positive surgical margins was significantly lower among men undergoing RARP vs. ORP (13.7% vs. 18.4%, odds ratio [OR]: 0.68, 95% confidence interval [CI]: 0.63--0.73), and this was driven by differences in intermediate (15.1% vs. 21.7%; OR 0.66; 95%CI 0.58--0.74) and high-risk (15.1% vs. 21.7%; OR 0.69, 95%CI 0.64--0.75) disease. Additionally, RARP was associated with less use of additional cancer therapy within 6 (4.7% vs. 6.6%; OR 0.74; 95%CI 0.66-0.82), 12 (OR 0.74 95%CI 0.63-0.86) and 24 (OR 0.68; 95%CI 0.58-0.79) months of surgery.

Conclusions: RARP was associated with improved surgical margin status relative to ORP among men with intermediate and high-risk disease. This has important implications for patient quality of life, health care delivery and costs particularly with greater acceptance of active surveillance for low-risk disease and greater adoption of adjuvant radiotherapy for positive surgical margins, consistent with level-one evidence.

MP-01.02
Comparative Effectiveness of Robotic-assisted and Open Radical Prostatectomy in the "Post-Learning Curve" Era

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Introduction and Objectives: Despite limited evaluation of the comparative effectiveness between robot-assisted radical prostatectomy (RARP) and open radical prostatectomy (ORP), RARP was rapidly adopted to become the main surgical approach for the treatment of localized prostate cancer. The aim of our study was to re-examine the outcomes of these techniques using a cohort of patients less likely to be affected by the learning curve of early adopters.

Methods: Relying on the Surveillance Epidemiology and End Results Medicare-linked database, 5915 patients with prostate cancer treated with ORP (n=2439) vs. RARP (n=3476) between October 2008 and December 2009 were evaluated. Postoperative complications, blood transfusions, length of stay (LOS), readmission rates, use of additional cancer therapies, and total costs of care within the first year after surgery were compared between the two surgical approaches. To decrease the effect of unmeasured confounders associated with treatment selection, instrumental variable analysis was performed.

Results: No significant differences were observed in 30- and 90-day postoperative complications, readmission rates, and additional cancer therapies between the two surgical approaches, after adjusting for confounders (all $p \geq 0.1$). Patients undergoing RARP had higher probability of experiencing 30- and 90-days genitourinary and miscellaneous medical complications compared to their open counterpart (all $p \leq 0.02$). However, RARP was associated with lower risk of receiving blood transfusion and with shorter LOS (all $p<0.001$). Finally, first-year reimbursements were greater for patients undergoing RARP compared to their ORP counterpart ($p=0.002$).

Conclusions: RARP and ORP have comparable rates of complications and additional cancer therapies, even in the "post-learning curve" era. Despite the lower risk of blood transfusions and prolonged LOS, RARP was associated with higher costs.

MP-01.03
Metabolic Syndrome and Oncologic Outcomes in Men Undergoing Radical Prostatectomy for Prostate Cancer

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Introduction and Objectives: Metabolic syndrome (MetS) is associated with an increased risk of prostate cancer (PC) overall and high grade disease on biopsy pathology. In the present study, our objective was to determine if MetS is associated with adverse pathology and risk of treatment failure in men undergoing radical prostatectomy (RP).

Methods: Patients undergoing RP (2004-2013) were identified using our prospectively maintained institutional database. Salvage RPs and men those who received neo-adjuvant therapies were excluded. MetS required any 3 of 5 components (obesity, diabetes or impaired fasting glucose, hypertension, low HDL-cholesterol, and high triglycerides), and was ascertained using electronic chart review. The outcomes were PC stage and grade on final RP pathology, and RP treatment failure, defined by a post-RP serum PSA ≥0.2, or use of adjuvant or salvage therapies such as radiation or androgen deprivation therapy. Multivariable logistic regression models, Kaplan-Meier analyses, and Cox-proportional Hazards models were used.

Results: The final cohort consisted of 1939 men, of which 439 (22.6) had MetS. Median follow-up was 36 months. On RP pathology, there were 663 (34.2%) men with extraprostatic disease (≥pT3), 505 (26%) with Gleason ≤6 disease, 1321 (68.1%) with Gleason 7 disease, and 113 (5.8%) with Gleason 8-10 disease. There were 357 (18.4%) considered as RP treatment failures. MetS was associated with an increased risk of extraprostatic disease (adjusted OR=1.29, 95%CI=1.03-1.62, p=0.030) and Gleason 8-10

disease (adjusted OR=1.61, 95%CI=1.06-2.45). Although there was a high rate of treatment failure among men with MetS (19.1% vs. 18.2%), differences did not reach statistical significance in Kaplan Meier analyses and Cox models.
Conclusions: Metabolic syndrome is associated with an increased risk of harbouring extraprostatic and high-grade disease. Longer follow-up will be required to see how this translates into treatment failure outcomes.

MP-01.04

Obesity Is Associated with an Increased Risk of Progression for Men on Active Surveillance for Low Risk Prostate Cancer

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Introduction and Objectives: While obesity is associated with high grade prostate cancer (PC), its impact on progression in the active surveillance population is not well characterized. Our objective was to determine if obesity is associated with progression in men on AS for low-risk PC.
Methods: Men undergoing AS for low risk PC (no Gleason pattern ≥4, ≤3 cores involved or ≤1/3 of total number of cores involved, and no core with >50% cancer involvement) were identified at our institution. The outcomes were pathologic progression (defined as no longer meeting low risk criteria on follow-up biopsy) and therapeutic progression (defined as intent to initiate active treatment). Kaplan Meier (KM), logistic regression and Cox–proportional hazards analyses were performed. Separate models for reclassification at confirmatory biopsy (first biopsy after diagnostic biopsy) and progression beyond confirmatory biopsy were used.
Results: In this cohort of 565 men, 124 (21.9%) were obese (BMI≥30 kg/m2). Pathological and therapeutic progression occurred in 168 (29.7%) and 174 (30.8%) men, respectively. There was no association between obesity and progression at the confirmatory biopsy. However, beyond confirmatory biopsy, obesity was associated with greater probability of pathological (p=0.007) and therapeutic (p=0.009) progression in KM analyses. In adjusted Cox models, obesity was associated with an increased risk of pathologic (HR=2.01, 95%CI=1.13-3.57, p=0.018) and therapeutic progression (1.86, 95%CI=1.12-3.09, p=0.017). The corresponding increase in risk of pathologic and therapeutic progression was 9% (HR=1.09, 95%CI=1.03-1.16, p=0.003) and 8% (1.08, 95%CI=1.02-1.14, p=0.014), respectively, per 1-unit increase in BMI, beyond the confirmatory biopsy.
Conclusions: Obesity was associated with a significantly increased the risk of progression beyond the confirmatory biopsy, suggesting an increased risk of long-term biologic progression rather than solely misclassification.

MP-01.05

Prostate Cancer Is Not Associated with Lower Urinary Tract Symptoms in the Modern Era: Analysis of a Contemporary Propensity Score-matched Cohort

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Introduction and Objectives: Prostate cancer (PC) often enters in the differential diagnosis for lower urinary tract symptoms (LUTS), based on data from the pre-PSA era. Our aim was to determine if PC is associated with worse LUTS, with attention to cancer volume and grade, in a contemporary cohort.
Methods: Men diagnosed with PC on biopsy were matched 1:1 to controls with negative biopsy on age, prostate volume, and a propensity score predicting the probability of PC diagnosis. IPSS was compared between PC cases and controls using paired statistics, stratifying on grade and cancer volume (low volume: ≤3 cores or ≤1/3 of total number of cores involved, and no core with >50% cancer involvement; high volume: >50% of cores involved and >50% cancer involvement in ≥1 core; intermediate volume: cancers not meeting low/high volume criteria). A sensitivity analysis was performed repeating the match for high volume cancers only, and excluding users of BPH meds.
Results: In our cohort of 1300 men, there were 275 (42.3%) Gleason 6 cancers, 313 (48.2%) Gleason 7 cancers, and 62 (9.5%) Gleason 8-10 cancers. There was no difference in IPSS between PC cases and matched benign controls (PC: median 6.5 (IQR=3-12) vs. controls: 7 (IQR=3-13), p=0.34; 90% power to detect a difference of 1.08 IPSS points). No stratum of volume or grade was significantly worse than matched controls. The sensitivity analysis yielded a matched cohort of 292 men. High-volume PC was again not significantly associated with IPSS (PC: median=6 (IQR=6-12) vs. controls: median=5.5 (IQR=2-10), p=0.16).
Conclusions: In our contemporary cohort of patients without prior PC diagnosis, newly diagnosed PC was not associated with worse LUTS as measured by the IPSS compared to benign controls. This suggests that PC is an uncommon cause of LUTS in the modern era. Outlet obstruction from cancer is likely a late event in the natural history of PC progression, occurring sometime later beyond initial diagnosis.

MP-01.06

A Comparison of Patients Comfort and Satisfaction after Robotic Prostatectomy with Suprapubic Tube versus Urethral Catheter Drainage

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Introduction: RALP with suprapubic tube (SPT) compared to urethral catheter (UC) drainage, has been proposed to improve patient comfort and recovery. We sought to compare short-term outcomes for pain and satisfaction with urinary function after RALP with SPT versus UC.
Methods: 93 men underwent a RALP and completed a series of questionnaires addressing postop discomfort. Group 1 (n= 57) underwent a RALP by a single surgeon who placed only a UC and removed it postop day (POD) 7-10. Group 2 (n= 36) underwent a RALP by a single surgeon who placed a percutaneous SPT and UC. On POD 1 the UC was removed and the SPT was left to drainage. On POD the SPT was removed. Both surgeons preserved bladder neck, performed a single layer anastomosis, and did not perform a Rocco stitch reconstruction.
Results: There were no statistically significant differences between groups for pre-op mean age, BMI, ASA scores, PSA, total score on continence questionnaire, nerve sparing, EBL and prostate volume. The mean OR time (mins) for Group 1 (173.8) was significantly shorter than for Group 2 (223.1) (p< 0.0001). Both groups had a median postoperative Gleason sum of 7. Pathologic T3a or less was found in 95.2% of Group 1 and 94.4% of Groups 2. One week after surgery the mean penile pain score was statistically significantly lower in Group 2 (14% reported moderate to severe pain) compared to 23% in Group 1 (p<0.0001). Bladder spasms were significantly higher for Group 1 compared to Group 2 (26.3% vs. 16.7%, p<0.0001). When asked about overall pain, 33.4% of patients in Group 1 reported moderate to severe pain compared to 30.6% in Group 2 (p<0.0001). When asked "How big a problem has your urine storage device been?" 17.6% of patients in Group 1 reported it as a 'moderate to big' problem compared to 13.9% in Group 2 (p<0.0001).
Conclusions: SPT is associated with less penile pain, better patient satisfaction and better perception of their urinary function compared to UC. Data accrual is underway to assess trends in larger populations.

MP-01.07

Oncological and Function Outcomes of 720 RARP Cases and Assessment of the Oncological and Surgical Learning Curve - Largest Canadian Experience

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Introduction and Objectives: Despite RARP (Robotic assisted radical prostatectomy) becoming more popular as a surgical treatment for prostate cancer, there is a paucity of data in the Canadian literature concerning its oncological and functional outcome. Hence, the objective of this study is to report the largest RARP Canadian experience.

Methods: Data from 722 patients who underwent RARP performed by 4 surgeons were collected prospectively from October 2006 to December 2013. Preoperative and perioperative data, surgical outcomes and pathological parameters were collected. Follow-up PSA, erectile function and continence were also assessed up to 72 months postoperative.

Results: Median follow-up (IQR) was 18 months (9-36). D'Amico risk stratification distribution was 31% low, 58% intermediate and 11% high-risk. Median operative time was 178min (142-205), estimated blood loss was 200mL (150-300) and postoperative hospital stay (range) was 1 day (1-23). Transfusion rate was only 0.7%. There were 0.7% major (Clavien III-IV) and 10.4% minor (Clavien I-II) postoperative complications, and no mortality. 445 patients (62%) were classified as pT2, 81 (18%) with PSM. 189 patients (26%) were classified as pT3, 87 (59%) with PSM. Return of urinary continence (0-pads/day) at 3, 6, and 12 months was 68%, 80%, and 90% respectively. Potency rate (successful penetration) for all men at 6, 12, and 24 months was 37%, 52%, and 59% respectively. 31 patients (4.3%) had biochemical recurrence (PSA>0.2 ng/mL), 15 patients (2%) received early salvage radiotherapy (PSA<0.2 ng/mL). In total, 47 patients (6.5%) underwent radiotherapy treatment.

Conclusions: Our results compare favourably with other high-volume RARP programs. Being the largest RARP data and experience in Canada, we report that RARP is safe with acceptable oncologic outcomes in Canadian settings.

MP-01.08

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

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Introduction and Objectives: 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 extraprostatic extension. We aim to assess the incidence and risk factors of contralateral EPE (cEPE) and contralateral positive surgical margins (cPSM) in patients diagnosed preoperatively with unilateral disease.

Methods: This multicentre cohort consisted of 331 men diagnosed with unilateral PCa who underwent RARP. Localization and occurrence of positive cores from biopsy, cEPE, cPSM and SVI was noted (Table 1). cEPE+ and cEPE- groups were compared for preoperative predictive parameters.

Results: Pathology reported cPCa in 50.2% and cEPE in 4% of the cohort. PSA levels of cEPE+ and cEPE- patients was 6.4 µg/L (5.1-14.6) and 5.2 µg/L (4.0-7.1) respectively (p=0.026). 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 also assessed. Logistic regression also identified PSA as a predictive factor of cEPE with an OR of 1.138 (CI 95% 1.032-1.255, p=0.01) per one-unit increase in PSA. Lastly, in the pT3 subgroup the presence of positive biopsies at the apex demonstrated an increased risk of cPCa and cEPE (p=0.007).

Conclusions: Despite the 50% chance of bilateral disease, the risk of cPSM associated with cEPE 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. MP-01.08

(%)	cPCa-, cEPE- n=165 [50%]	cPCa+, cEPE- n=153 [46%]	cPCa+, cEPE+ n=13 [4%]	*p* value
PSM	14.5	26.8	38.5	0.008
cPSM	0.0	10.5	23.1	<0.001
SVI	3.0	5.2	38.5	<0.001

MP-01.09

Emergency Visits Following Radical Prostatectomy in Ontario: Disturbing Prevalence and Novel Insights

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Introduction: Radical prostatectomy (RP) is a common procedure utilized to treat localized prostate cancer. We set out to determine the population-based rate of emergency room (ER) visits 30 days following RP.

Methods: Two studies were performed using Cancer Care Ontario's available databases (Ontario Cancer Registry and the National Ambulatory Care Reporting System Discharge Abstract Database). We developed an inception cohort of all men who underwent RP in Ontario in 2008-09 (n=2691) and 2010-11 (n=2280). We then linked the cohort with Ontario ER visits over a 30-day period. Local Health Integration Network (LHIN), a government-based geographic stratum for healthcare services delivery, examined variation. A questionnaire/interview-based study was then performed of randomly selected men (n=114) treated at University Health Network (UHN) to determine our hospital-specific rates as well as the epidemiology of this outcome.

Results: From the provincial cohort, 20 and 21% of patients visited an ER within 30 days of RP in 2008/09 and 2010/11, respectively. There were no differences noted between years (p>0.05). Ranges of ER visits were between 16-43% by LHIN in 2008/09 and 20-32% in 2010/11. Based upon these data, UHN specific rate of ER visits was 19.2%. Of the visits, 59.1% were in the first 2 postoperative weeks (before catheter removal) with the remainder in weeks 3 and 4. Specifying the reason for ER visits, leg complaints (real or suspected blood thromboses) (36.4%) and catheter-related issues (27.3%) dominated, attributed mostly to bladder spasms or poor Foley drainage. On further inquiry, of men with leg complaints, 83% were deep venous thrombosis (DVT) concerns on the ipsilateral side of the straps for catheter security.

Conclusions: A disturbingly high proportion of men in Ontario return to ER following RP. Better education about catheter management, especially bladder spasms is needed. Daily shifting of the Foley catheter between legs may help as well.

MP-01.10

Natural History of a Large Active Surveillance Cohort of Prostate Cancer Patients with 5-year Median Follow-up: Predictors of Undergoing Treatment and Surgical Outcomes in a Real-world Setting

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Introduction and Objectives: Active Surveillance (AS) is an alternative to radical treatment for patients diagnosed with low risk prostate cancer (PCa). These patients are monitored with the intent to treat if the cancer progresses or by patient preference. We assessed our centre's experience with AS.

Methods: In this retrospective study with institutional board ethics, patients with an active diagnosis of PCa with Gleason ≤3+4, ≤t2b, and PSA <20 and patients who chose AS were included. Data analyzed included patient, biopsy, and surgical pathology characteristics, and disease outcomes. Multivariate analysis was utilized to identify predictors of undergoing radical treatment on AS using SAS software.

Results: Over a median follow-up of 5.6 years, 289 patients were on AS at our centre with 114 (39%) patients ultimately requiring treatment. Of the treated patients the median age was 65 with each patient requiring a median of 2 biopsies. Median interval to first follow-up biopsy was 12 months, and 20 months between all subsequent biopsies. 71% of patients had Gleason 3+3 when starting on active surveillance. In our multivariate model Gleason upgrade on surveillance biopsy ($p<0.0001$), PSA change ($p=0.0125$), and absolute change in cancer length among all cores (p less than 0.0001) was predictive of failing active surveillance. PSA doubling time approached significance ($p=0.0535$). Age, year of diagnosis, and PSA density were not predictive of receiving treatment. 23% of patients were found to have Gleason upgrade on final surgical pathology. In addition, of the 114 treated patients 30 percent developed biochemical recurrence. No patient died of PCa in our study period.

Conclusions: In our study period, thirty nine percent of patients went on to treatment from AS. Total cancer linear distance change, PSA change, and Gleason upgrade were predictive of treatment. In terms of surgical pathology, 23% were upgraded. No patient died of PCa.

MP-01.11

5-year Follow-up of Active Surveillance for Prostate Cancer: A Canadian Community-based Urological Experience

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Introduction and Objective: Active surveillance ("AS") is an accepted alternative to radical treatment of favorable-risk prostate cancer. We present oncological outcomes for AS through a retrospective analysis of a community-based urological database with intermediate term follow-up, and indicate predictors of disease reclassification on surveillance biopsy.

Methods: Retrospective chart review was performed on 200 men followed by AS. PSA was measured every 3 - 6 months. Repeat biopsies were performed at individual physician discretion and every 1 - 4 years. Reclassification was defined as cT1 to cT2 progression, > 2 cores positive, Gleason score > 6, or > 50% core involvement on surveillance biopsy. Multivariate Cox regression analysis was used to evaluate predictors of reclassification at surveillance biopsy. Kaplan-Meier survival analysis was applied.

Results: A cohort of 86 patients, median age 67.2 years, received ≥ 1 surveillance biopsies. Median follow-up was 5.2 years (range, 0.81 - 14.95 years). Median times to 1st and 2nd surveillance biopsies were 2.0 and 2.1 years, respectively. Seventy-one percent of patients met PRIAS criteria, and 53% met Epstein criteria at baseline. Overall, 47% of patients were reclassified on surveillance biopsy and offered definitive therapy. Median time to reclassification was 2.1 years. At diagnosis, PSA density > 0.20 was associated with 4.55 times risk of disease progression. Predictors of progression at time of surveillance biopsy were number of positive cores and clinical stage. A total of 25 (29%) patients went forward for intervention, with median time to intervention 2.55 years. Overall survival was 95%. Prostate cancer-specific survival was 100%. Median time on active surveillance was 4.4 years.

Conclusions: Our data support AS as a strategy to reduce overtreatment of prostate cancer. PSA density > 0.20 is a strong predictor of disease progression on surveillance biopsy.

MP-01.12

Magnetic Resonance Imaging (MRI)-guided Transurethral Ultrasound Ablation of Prostate Cancer: Preliminary Outcomes of a Phase I Clinical Trial

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Introduction and Objectives: MRI-guided transurethral ultrasound ablation (TULSA) is a new minimally-invasive modality to ablate prostate tissue using real-time MRI monitoring and active temperature feedback control. Aim of this multicentre phase I clinical study is to determine the safety and feasibility of MRI-guided TULSA, and to assess initial efficacy for treatment of localized prostate cancer (PCa).

Methods: Patients with low-risk PCa are enrolled (cT1c-T2a, N0, M0; PSA≤10ng/mL; GS≤6). Under general anesthesia, suprapubic catheter (SPC) is inserted and left in for 2 weeks. The TULSA device (PAD-105, Profound Medical Inc.) is inserted over a guidewire and positioned in the prostatic urethra with MRI guidance. Treatment planning is performed under MRI prostate visualization, with therapeutic intent of whole-gland ablation. Treatment is delivered under continuous MR thermometry feedback control. Primary study endpoints are safety and feasibility with follow-up to 12 months. Complete clinical monitoring is 5 years, including serial PSA, TRUS biopsy and QoL questionnaires (IPSS, IIEF, UCLA-PCI-SF bowel domain).

Results: To-date, 21 patients have been treated with no intraoperative complications. Median treatment time was 33 (24-61) min and prostate volume 45 (33-95) cc. Clavien II complications included urinary tract infections (6), and epididymitis (1), resolved with antibiotics. Clavien I complications included hematuria (9), and acute urinary retention after SPC removal (3) resolving after SPC re-insertion. Median PSA reduced by 90% (60-99%) to 0.7 ng/ml at 1 month (n=17) and remained stable to 0.8 ng/ml at 6 months (n=5). Normal micturition returned after SPC removal, with return to baseline QoL by 3 months (n=11).

Conclusions: MRI-guidance enables accurate planning and real-time dosimetry and control of the thermal ablation volume. Initial results indicate that MRI-guided TULSA is safe and clinically feasible with a well-tolerated, low side effect profile.

MP-01.13

The Effect of Energy Drinks on LHRH-Induced Fatigue: Results of a Pilot Study

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Introduction: A large proportion of men treated with luteinizing hormone-releasing hormone (LHRH) agonist for prostate cancer suffer from fatigue. Despite being common, they are currently no universally accepted treatment option. Energy drinks were developed for use during periods of increased mental and physical exertion. There effect among men with prostate cancer has never been study. The objectives of our study were to assess whether Red Bull® Sugar-Free Drinks improve fatigue levels and quality of life among men treated with LHRH agonist for a period of at least six months.

Methods: We performed a single-centre, phase II, open-label trial in which men with LHRH agonist-related fatigue were given 2 daily cans of Red Bull® Sugar-Free energy drinks for a period of 4 weeks. Fatigue levels were evaluated using the Bruera global fatigue severity scale while quality of life was evaluated using the RAND 36-Item Health Survey 1.0 (SF-36).
Results: Twenty men were recruited to participate to the trial. One was excluded before the start of the trial because of medical issues while 1 dropped-out because of an adverse event. The average age of the cohort was 69 (±8) years old. More than half were on LHRH agonist alone (68%) and the majority were on it because of biochemical failure (68%). After a 4-week treatment period, the average fatigue levels were significantly improved (p=0.001) in comparison to baseline levels from 6 (IQR: 3-8) to a 3.1 (±2.1). In the SF-36 survey, the vitality domain, an assessment of energy and fatigue, was significantly improved at week-4 (p=0.006). No significant difference was observed among the subjects with regards to the blood pressure measurements and the heart rates during the study period.
Conclusions: Energy drinks appear to have a significant effect on fatigue level and on quality of life in men treated with LHRH agonist for prostate cancer in this phase II trial. In addition, they appear to be safe and well tolerated.

MP-01.14

Impact of Initiation of a Robotic Surgery Program on Radical Prostatectomy at an Academic Centre

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Introduction and Objectives: Robotic surgery may impact patient selection for open prostatectomy and resident training. We describe radical prostatectomy (RP) during the first year of a robotic surgery program in Canada.
Method: We reviewed radical prostatectomy between October 31, 2011 and October 31, 2012. An independent data collector obtained pre- and postoperative information from the medical record.
Results: A total of 225 RPs were performed during the study period (104 robotic (RALRP) and 121 open (ORP). For RALRP and ORP, the respective mean PSA was 7.9±5.6 and 8.5±6.9 ng/ml and prostate volume was 31.9±13 and 36.5±24 cc. For RALRP, the number of Gleason sum 7 was 64 (61.5%) and Gleason 8-10 in was 14 (14%). For ORP, Gleason sum was 7 in 70 (57.8%) and 8-10 in 24 (20%). Mean total operative time was 282±63 and 268± 65 minutes (p=0.1). The hospital stay and blood loss were significantly lower in the RALRP (1.4 vs. 2.5 days, and 282.2 ml vs. 737 ml, respectively). There were no conversions to an open approach in the RALRP group. Postoperative complications in the RALRP vs. ORP were, blood transfusion (1 vs. 15), anastomotic leak (5 vs. 2), urinary tract infection (3 vs. 2), and bladder neck contracture (0 vs. 6). Overall, 38 (36.5%) vs. 52 (43%) patients had a positive surgical margin in the RALRP and ORP groups, respectively (p=0.05). The rate of complete continence at 3 months was 62% and 38% in the RALRP and ORP. At last follow-up, 61% and 50% of patients with bilateral nerve preservation in the RALRP and ORP, respectively, had satisfactory return of erectile function for sexual intercourse with or without PDE-5 inhibitors.
Conclusions: Introduction of RALRP to our institution significantly reduced ORP during the first year of implementation. Patient characteristics and outcomes were similar between treatment cohorts.

MP-01.15

Circulating Tumour Cells in Metastatic Prostate Cancer Patients: Isolation and Three-dimensional Molecular Characterization

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Introduction and Objectives: Circulating tumour cells (CTCs) are emerging as a promising bio-marker in prostate cancer screening and monitoring of disease progression. An efficient and reliable method of CTC isolation must be developed in order to utilize CTCs clinically. Stratification and profiling of prostate cancer patients can be achieved with isolation of CTCs and analysis of the three-dimensional (3D) nuclear organization of telomeres. The relative aggressiveness of a tumour can be correlated to the degree of chromosomal instability (CIN) seen within a given cell. We show that metastatic prostate cancer patients display CTCs and telomeric profiles that correlate to high-risk prostate cancer phenotypes.
Methods: CTCs from ten consecutive patients presenting with metastatic prostate cancer were isolated using size based ScreenCell filtration. Cytokeration 8,18, 19 immunostaining and 3D quantative fluorescence in situ hybridization was performed on the isolated CTCs followed by 3D image acquisition using a Carl Zeiss AxioImager Z2 microscope. Quantitative image analysis with Teloview and Teloscan were then preformed to obtain 3D telomere profiles and to identify the number of CTCs.
Results: Our data shows that a significant number of CTCs are present and can be isolated in patients with metastatic prostate cancer. Furthermore, these CTCs have similar telomere profiles when comparing the following statistical parameters: percentage of cells with aggregates, average number of telomeres per cell, average number of aggregates per cell and average nuclear volume.
Conclusions: This proof of principle study shows for the first time that CTCs in metastatic prostate cancer patients can be reliably isolated and characterized by 3D nuclear telomere profiling using ScreenCell filters as well as presenting similar telomeric profiles. These findings show that prostate cancer CTCs and telomeric analysis have the potential to become a biomarker for tumour stage and progression.

MP-01.16

Denosumab for the Prevention of Symptomatic Skeletal Events in Patients with Castration-resistant Advanced Prostate Cancer: A Comparison with Skeletal-related Events

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Introduction and Objectives: In a randomized controlled trial of men with castration-resistant prostate cancer (CRPC) and bone metastases, denosumab was superior to zoledronic acid (ZA) for reducing skeletal-related events (SRE, defined as pathological fracture, surgery or radiation to bone [including the use of radioisotopes], or spinal cord compression) (Fizazi et al, Lancet 2011;377:813-822). Recently, the composite endpoint of symptomatic skeletal event (SSE, defined as symptomatic fracture, surgery or radiation to bone, or spinal cord compression) was introduced as an alternative term/clinical trial endpoint to describe skeletal morbidity. Here we report on the impact of the endpoint definition on the risk of skeletal events in men with CRPC.
Methods: Men with CRPC, ≥1 bone metastasis, and no prior intravenous (IV) bisphosphonate use received either subcutaneous denosumab 120 mg or IV ZA 4 mg (adjusted for creatinine clearance) in a blinded fashion

every 4 weeks. Oral calcium and vitamin D supplements were recommended. SSEs included pathologic fractures considered symptomatic by the investigator, spinal cord compression and surgery and radiation to bone.

Results: As previously reported, the risk of first SRE and multiple SREs in men who received denosumab was significantly lower than in men who received ZA (Table 1). Similarly, the risk of first SSE and multiple SSEs was lower in the denosumab group than the ZA group. The median (95% CI) estimate of time to first SSE (superiority analysis) for denosumab was not reached (28.8 mo, not estimable), and for ZA it was 24.2 (20.7, 30.2) months (HR = 0.78 (0.66, 0.93) p=0.01).

Conclusions: Denosumab reduced the risk of skeletal events in men with CRPC regardless of endpoint definition as SRE or SSE. The risk of developing SSEs was reduced by up to 22% when comparing denosumab with ZA.

Table 1. MP-01.16

Number of confirmed skeletal events, n (%)	Denosumab (N = 950)	ZA (N = 951)	Hazard or rate ratio (95% CI)
First SSE	241 (25.4%)	289 (30.4%)	HR = 0.78 (0.66, 0.93) P < 0.01
First SRE	341 (35.9%)	386 (40.6%)	HR = 0.82 (0.71, 0.95) P < 0.01
Multiple SSEs	329	409	RR = 0.78 (0.65, 0.92) P < 0.01
Multiple SREs	494	584	RR =0.82 (0.71, 0.94) P < 0.01