# CUA 2022 Annual Meeting Abstracts – Poster Session 6: Oncology – Penis/Testis/Urethra, Prostate

## Saturday, June 25, 2022 • 16:00–17:30

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### MP-6.1

### Natural history of small testis masses

*James Hayes[1,2], Philippe Bedard[3], Eshetu Atenafu[4], Peter Chung[5], Di Maria Jiang[3], Padraig Warde[5], Martin O'Malley[6], Lynn Anson-Cartwright[1], Rachel Glicksman[5], Robert J. Hamilton[1]*

[1]Departments of Surgery (Urology) and Surgical Oncology, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; [2]Division of Urology, Department of Surgery, University of Ottawa, Ottawa, ON, Canada; [3]Department of Medical Oncology, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; [4]Department of Biostatistics, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; [5]Department of Radiation Oncology, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada; [6]Department of Medical Imaging, Princess Margaret Cancer Centre, University Health Network, Toronto, ON, Canada

**Introduction:** Increasing availability and sensitivity of ultrasound has led to burgeoning identification of small, non-palpable, intratesticular lesions. While the overall rate of malignancy of testicular lesions is high at 80–90%, for non-palpable lesions, the rate is much lower at 20%. Limited data exist regarding the natural history and malignant potential of small testicular masses.

**Methods:** We retrospectively reviewed all scrotal ultrasounds performed at the University Health Network in Toronto, Canada, between July 1996 and July 2015. In total, 2978 ultrasound reports met criteria and were reviewed manually. Patients were included in the final cohort if they had a non-cystic single or multifocal mass-like lesion(s) no larger than 1 cm. Long-term followup was conducted by cross-referencing with provincial health information system Cancer Care Ontario data of all orchiectomies with a diagnosis of testis cancer with a minimum two-year followup period.

**Results:** In total, 116 met inclusion criteria, of whom only 15 (12.9%) were found to have testis cancer. Twenty-five (21.6%) underwent orchiectomy for clinical concern of testis cancer. Of those undergoing orchiectomy, 11 (42%) were benign and 14 (58%) were malignant. One patient was diagnosed on retroperitoneal biopsy. Several factors were associated with finding testis cancer at orchiectomy, including younger median age (29.98 vs. 50.83 years, p=0.0001), prior history of contralateral testis cancer (87% vs. 2%, p<0.001), larger lesion size (6 mm vs. 4 mm, p=0.0015), multifocality (47% vs. 17%, p=0.0144), calcifications within the lesion (33.3% vs. 3.96%, p=0.0017), and calcifications in the testicle in general (46.7% vs. 11.9%, p=0.003) (Table 1).

**Conclusions:** Our findings underscore that most small lesions are benign and reflexive; immediate radical orchiectomy may be overtreatment. In select men, particularly in the absence of the above-noted risk factors, surveillance and/or partial orchiectomy is warranted.

### MP-6.2

### The use of salvage chemotherapy for patients with relapsed testicular germ cell tumor in Canada: A national survey

*Esmail Al-Ezzi[1], Carlos Stecca[1], Robert J. Hamilton[2], Michael Crump[1], John Kuruvilla[1], Lori A. Wood[3], Lucia Nappi[4], Christian Kollmannsberger[4], Scott North[5], Eric Winquist[6], Denis Soulieres[7], Sebastien Hotte[8], Srikala S. Sridhar[1], Di Maria Jiang[1]*

[1]Division of Medical Oncology and Hematology, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, ON, Canada; [2]Division of Urology, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, ON, Canada; [3]Division of Medical Oncology and Hematology, Queen Elizabeth II Health Sciences Centre, Dalhousie University, Halifax, NS, Canada; [4]Department of Medicine, British Columbia Cancer Agency, University of British Columbia, Vancouver, BC, Canada; [5]Division of Medical Oncology, Cross Cancer Institute, University of Alberta, Edmonton, AB, Canada; [6]Department of Oncology, London Health Sciences Centre, Western University, London, ON, Canada; [7]Département Hématologie-Oncologie, Centre Hospitalier de l'Université de Montréal, Montreal, QC, Canada; [8]Department of Oncology, Juravinski Cancer Centre, McMaster University, Hamilton, ON, Canada

**Introduction:** Although metastatic germ cell tumor (GCT) is highly curable, 10% of patients relapse after initial cisplatin-based chemotherapy and have a poorer prognosis. Salvage chemotherapy options include conventional (CDCT) and high-dose chemotherapy (HDCT). However, definitive comparative data are lacking. We aimed to characterize the contemporary practice patterns of salvage chemotherapy across Canada.

**Methods:** We conducted a 30-question online survey in August 2021 on medical (MO) and hematological oncologists (HO) with experience in treating GCT, assessing treatment availability, patient selection, and management strategies used for relapsed GCT patients.

**Results:** Respondents were 24 staff MO, 2 HO, 2 both; from British Columbia, Alberta, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, and PEI; 86% were from academic centers. Reported case volumes for salvage chemotherapy were <1 (18%), 1 (21%), 1–5 (39%), and 6–10 cases/year (21%). No active clinical trials were available at the time of the survey. The most common CDCT regimens used were TIP (64%) and VIP (25%). HDCT was available for 70%, and used as first- (67%, range 0–100), second- (33%, 0–100) or third-line/beyond (4%, 0–20) salvage therapy. Only some used the IPFSG risk classification for treatment selection. Assuming tolerability and feasibility, only one respondent indicated a clinical scenario precluding HDCT ("rising markers during platinum chemotherapy for mediastinal non-seminoma"). HDCT regimen used included carboplatin and etoposide (two cycles 76%; three cycles 6%), and the TICE protocol (two centers). "Bridging" CDCT was needed by 63% while waiting to access HDCT. Post-HDCT treatments considered include surgical resection for residual disease (n=13), maintenance etoposide (n=1), and surveillance only (n=1).

**Conclusions:** HDCT is the most commonly used GCT salvage strategy in Canada. Significant differences exist in the treatment availability, selection, and delivery of HDCT, highlighting the need for standardization of care for patients with relapsed testicular GCT requiring salvage chemotherapy.

**MP-6.1. Table 1. Baseline patient characteristics by outcome**

| | | Outcome | | |
|---|---|---|---|---|
| | Total | No orchiectomy | Orchiectomy (benign/SCST) | Orchiectomy or biopsy (malignant) |
| | (n=116) | (n=90) | (n=11) | (n=15) |
| Age, median years (IQR) | 48 (33–65) | 53 (37–67) | 39 (32–48.5) | 30 (28.5–36) |
| Testis cancer history, n (%) | | | | |
| Yes | 17 (15) | 4 (4) | 0 (0) | 13 (87) |
| No | 99 (85) | 86 (96) | 11 (100) | 2 (13) |
| # ultrasounds, median (IQR) | 2 (1–3) | 2 (1–3) | 1 (1–2) | 2 (1–3.5) |
| Indication, n (%) | | | | |
| Mass | 21 (18) | 16 (18) | 5 (45) | 0 (0) |
| Pain | 24 (21) | 20 (22) | 3 (27) | 1 (7) |
| Swelling | 17 (15) | 16 (18) | 0 (0) | 1 (7) |
| History of testis cancer | 15 (13) | 4 (4) | 0 (0) | 11 (73) |
| Other | 39 (34) | 34 (38) | 3 (27) | 2 (13) |
| Laterality, n (%) | | | | |
| Left | 53 (46) | 38 (42) | 8 (73) | 7 (47) |
| Right | 53 (46) | 42 (47) | 3 (27) | 8 (53) |
| Bilateral | 10 (9) | 10 (11) | 0 (0) | 0 (0) |
| Lesion size | | | | |
| Average size (mm) (SD) | 4.63 (2.33) | 4.08 (2.14) | 6.82 (2.09) | 6.33 (1.88) |
| Median size (mm) (IQR) | 4 (2.85–5) | 3.15 (2.85–5) | 6 (5–8) | 6 (5.5–7.5) |
| Multifocality, n (%) | | | | |
| Yes | 24 (21) | 17 (19) | 0 (0) | 7 (47) |
| No | 92 (79) | 73 (81) | 11 (100) | 8 (53) |
| Vascularity, n (%) | | | | |
| Yes | 37 (32) | 23 (26) | 8 (73) | 6 (40) |
| No | 79 (68) | 67 (74) | 3 (27) | 9 (60) |
| Any calcifications, n (%) | | | | |
| Yes | 19 (16) | 11 (12) | 1 (9) | 7 (47) |
| No | 97 (84) | 79 (88) | 10 (91) | 8 (53) |
| Calcifications lesion, n (%) | | | | |
| Yes | 9 (8) | 3 (3) | 1 (9) | 5 (33) |
| No | 107 (92) | 87 (97) | 10 (91) | 10 (67) |
| Echogenicity, n (%) | | | | |
| Hypoechoic | 96 (83) | 74 (82) | 9 (82) | 13 (87) |
| Hyperechoic | 15 (13) | 13 (14) | 1 (9) | 1 (7) |
| Isoechoic | 2 (2) | 1 (1) | 1 (9) | 0 (0) |
| Heterogeneous | 3 (3) | 2 (2) | 0 (0) | 1 (7) |
| Orchiectomy technique, n (%) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Radical | 16 (14) | 0 (0) | 7 (64) | 9 (60) |
| Partial | 9 (8) | 0 (0) | 4 (36) | 5 (33) |

SCST: sex cord stromal tumor.

## MP-6.3

### A quality assurance review of penile cancer diagnostic delays and advanced stage at presentation during the COVID-19 pandemic

William Janes[1], Jessica Henley[1], Matthew Andrews[2], Paul H. Johnston[2], Michael Organ[2]

[1]Faculty of Medicine, Memorial University, St. John's, NL, Canada; [2]Department of Urology, Memorial University, St. John's, NL, Canada

**Introduction:** Penile carcinomas are a rare, heterogenous subset of neoplasms that present with extraordinary potential for malignancy, with recent evidence supporting a global trend towards increased incidence over time. Penile cancer is a devastating occurrence causing significant psychosocial impacts that deter patients from seeking medical attention and further exacerbating consequences. The COVID-19 pandemic has necessitated a dramatic shift in healthcare delivery to virtual platforms, which has resulted in various reported diagnostic and treatment delays. It is suspected that prevalent psychosocial impacts of penile lesions have been further compounded by the pandemic, leading to several late-stage presentations engendering poorer outcomes.

**Methods:** A retrospective chart review was conducted for quality assurances purposes from December 2019 to December 2021 to identify

cases of penile cancer subject to pandemic-induced delays in diagnosis and treatment. Diagnostic delays were defined on a timeframe of delay greater than three months. Charts were examined for delays in diagnostic measures and treatments. Outcomes of interest aimed to identify areas of improvement for care, including virtual care and timeliness/urgency of reported urogenital concerns.
**Results:** Secondary to virtual care appointments, three patients were unable to receive an initial physical exam, which delayed primary care referral and subsequent diagnosis. One patient had a physical exam delayed six months while receiving virtual care. A further 12 patients underwent partial or total penectomy for late-stage presentation at our institution, 10 of which occurred in 2020.
**Conclusions:** In cases of concern for penile malignancy, virtual care cannot replace the necessity of physical exams in preventing diagnostic and treatment delays. In response, urologists at our center have altered practices for urgent examination of referred males with genital abnormalities to prevent further exacerbation of delays.

## MP-6.4

### Comparing and contrasting primary testicular lymphoma and germ cell tumors

*Mohamad Baker Berjaoui[1], Jaime O. Herrera-Caceres[1], Yazan Qaoud[1], Raj Tiwari[1], Mughda Khondker[1], Sumana Naidu[1], Danny Ma[1], Katherine Lajkosz[1], Miran Kenk[1], Khaled Ajib[1], Thenappan Chandraseka[1], Hanan Goldberg[1], Neil E. Fleshner[1]*
[1]Division of Urology, Department of Surgery, University of Toronto, Toronto, ON, Canada

**Introduction:** Testicular cancer represents 1% of adult neoplasms, with the vast majority being primary germ cell tumors (GCT). On the other hand, while primary testicular non-Hodgkin's lymphoma (PTL) is a very rare disease, comprising <5% of all cases of testicular tumors, it is considered the most common testicular malignancy in men older than 60 years. To our knowledge, no data have been published comparing survival rates between PTL and GCT. Our aim was to analyze the differences in clinical parameters and survival outcomes between patients with PTL and GCT.
**Methods:** The Surveillance, Epidemiology, and End Results (SEER) database was queried for all patients with testicular tumors from 1980–2013. Data collected consisted of demographic and clinical parameters, including staging, pathological, and survival data. Patients were stratified according to their tumor type and compared.
**Results:** The cohort included 51 269 patients comprising all testicular tumors managed during a period of 33 years. PTL patients (n=1745) accounted for 3.45% of all testicular tumors, compared to 96.6% (n=49 524) patients with GCT. The median age at GCT was 33 years (interquartile rage [IQR] 26–41), compared to 70 (IQR 59–77) with PTL (p<0.001). In terms of treatment, similar rates of radical orchiectomy and radiation were noted between the two cohorts, while a major difference was noted in chemotherapy rates. Among the GCT patients, 47 632 (96.2%) underwent radical orchiectomy, compared to 1632 (93.5%) patients in the PTL cohort. Furthermore, in terms of radiation, 33 032 (66.7%) of the GCT patients underwent radiation therapy compared to 1106 (63.4%) patients in the PTL cohort (p=0.012). There was a considerable difference with chemotherapy, with 34 905 of the GCT patients (70.5%) receiving chemotherapy compared to 546 patients (31.3%) in the PTL cohort (p<0.001). Twenty-year survival probabilities were 82.3% (95% confidence interval [CI] 81.8–82.9%) for GCT patients and 9.83% (95% CI 7.25–13.3%) for PTL patients (p<0.001), with the adjusted hazard ratio of 2.57 (95% CI 2.16–3.05, p<0.001).
**Conclusions:** Lower survival rates are noted among PTL patients when compared to GCT patients. Younger patients are more likely to receive chemotherapy and radiation and have better disease-specific survival outcomes. Reduced rates of chemotherapy in PTL patients may also be attributable to the blood-testis barrier creating sanctuaries for these tumors from systemic chemotherapy.

## MP-6.5

### Age-related differences in primary testicular lymphoma: A large, population-based cohort study

*Mohamad Baker Berjaoui[1], Jaime O. Herrera-Caceres[1], Yazan Qaoud[1], Raj Tiwari[1], Danny Ma[1], Mughda Khondker[1], Sumana Naidu[1], Katherine Lajkosz[1], Miran Kenk[1], Khaled Ajib[1], Thenappan Chandraseka[1], Hanan Goldberg[1], Neil E. Fleshner[1]*
[1]Division of Urology, Department of Surgery, University of Toronto, Toronto, ON, Canada

**Introduction:** Primary testicular non-Hodgkin's lymphoma (PTL) is a very rare disease, comprising 1% of all non-Hodgkin's lymphoma and <5% of all cases of testicular tumors. With a median age at diagnosis of 67 years, PTL is the most common testicular malignancy in men aged >60 years. However, scare data has been published on PTL in younger patients and their overall outcomes. Our goal was to compare clinical parameters and survival outcomes between patients older and younger than 60.
**Methods:** The Surveillance, Epidemiology, and End Results (SEER) database was queried for all patients diagnosed with PTL diagnosis from 1980–2013. Data collected consisted of demographic and clinical parameters, including staging, pathological, and survival data. Patients were stratified according to their age and compared.
**Results:** The cohort included 1679 patients comprising 3.45% of all testicular tumors detected during a period of 33 years. The fraction of PTL out of all testicular tumors had remained stable at 3.24% in the 1980–1984 and 3.73% in 2010–2013 periods, although the absolute number of cases has increased from 85 per year in 1980 to 378 in 2013. Overall 433 patients (25.8%) were older than 60 years of age, with 208 (12.4%) being <50 and 91 (5.4%) <40. Older and younger patients exhibited similar racial diversity, geographical origin, and T stage. Almost all patients in both groups had mature B cell lymphoma. A larger percentage of younger patients received radiation to the contralateral testicle (43.4% vs. 31.9% of older patients, p<0.001) and chemotherapy (82.2% vs. 66%, p<0.001). More older patients had insurance (97.8% vs. 88.2%, p<0.001). On average, younger patients were less likely to die of their disease (28.2% vs. 38.8%, p<0.001), with a median survival time of 283 months vs. 98 months (p<0.001). Fine and Grey competing risk multivariable analysis demonstrated that increasing age, worse T stage, and mature T cell histopathology conferred a worse cancer-specific outcome while receiving radiotherapy, chemotherapy, and being insured had a protective role.
**Conclusions:** PTL is the most common testicular malignancy in men older than 60 years of age, but more than a quarter of the patients are younger than 60 and more than 12% are <50. Younger patients are more likely to receive chemotherapy and radiation and overall do better in terms of disease-specific survival. Being younger, insured, having a lower T stage, and being treated with chemotherapy and radiotherapy increase the chances of survival.

## MP-6.6

### Holmium laser enucleation of the prostate to patients with bladder outlet obstruction, high prostate-specific antigen, and negative prostatic biopsy is a reliable tool for missed prostate cancer diagnosis

*Loay Abbas[1], Ahmed Kotb[1], Ahmed S. Zakaria[1], Walid Shahrour[1], Hazem Elmansy[1]*
[1]Division of Urology, Northern Ontario School of Medicine, Thunder Bay, ON, Canada

**Introduction:** The aim of this study was to report our experience doing holmium laser enucleation of the prostate (HoLEP) to patients with high prostate-specific antigen (PSA) and negative prostatic biopsy.
**Methods:** We conducted a retrospective study of all patients that had HoLEP because of refractory bladder outlet obstruction. The study included all patients with high PSA and negative prostatic biopsy.
**Results:** Thirty-one patients were identified. The mean age was 74 years. The mean preoperative PSA and PSA density were 8 ng/ml and 0.08 ng/ml/g, respectively. The mean prostate volume and resected weight were 106 cc and 72 g, respectively. The mean three-month postoperative PSA and the mean PSA reduction were 4.6 ng/ml and 79%, respectively. Prostate cancer was diagnosed in 27 patients (87%) with HoLEP; of these,

14 patients had 3+3, 11 had 3+4, and two patients had 4+5 prostate cancer. Thirteen patients with 3+3 prostate cancer were enrolled into active surveillance (AS) and 11 of them had repeat prostatic biopsy within a year of diagnosis showing stable disease or no evidence of cancer. One patient with 3+3 prostate cancer chose radical prostatectomy (RP). Eleven patients had 3+4 prostate cancer; of these, four chose AS and showed no warning criteria of progression to the current time. Three patients had RP and four patients had radiotherapy. Two patients had 4+5 prostate cancer and that was followed by computed tomography and bone scan showing a metastatic disease. The other four patients included one diagnosed with benign prostatic hyperplasia, two with high-grade prostatic intraepithelial neoplasia, and one with atypical small acinar proliferation. Prostate biopsy after six months identified prostate cancer in two of them, including 3+3 prostate cancer in one patient managed by AS and 4+5 in the second one managed by radiotherapy.

**Conclusions:** Prostatic biopsy can be very challenging for prostate cancer diagnosis in men with a markedly large prostate. HoLEP has a high degree of reliability to diagnose prostate cancer in men with a large prostate and negative prostatic biopsy. Prostatic volume reduction with HoLEP increases the diagnostic yield of further prostatic biopsies to men with persistently high PSA.

## MP-6.8

### Robotic-assisted radical cystectomy: Experiences from a high-volume robotic prostatectomy surgeon

*Raees Cassim[1], Yanbo Guo[1], Jen Hoogenes[1], Bobby Shayegan[1]*
[1]Division of Urology, McMaster, Hamilton, ON, Canada

**Introduction:** The recently published RAZOR trial demonstrated non-inferiority of robotic-assisted radical cystectomy (RARC) compared to open cystectomy.[1] While gaining popularity in the U.S., few centers in Canada use this technique. This may be related to the perceived challenges and learning curve of this procedure. We present outcomes from the largest Canadian cohort of RARC performed at a tertiary site with extensive robotic prostatectomy experience.

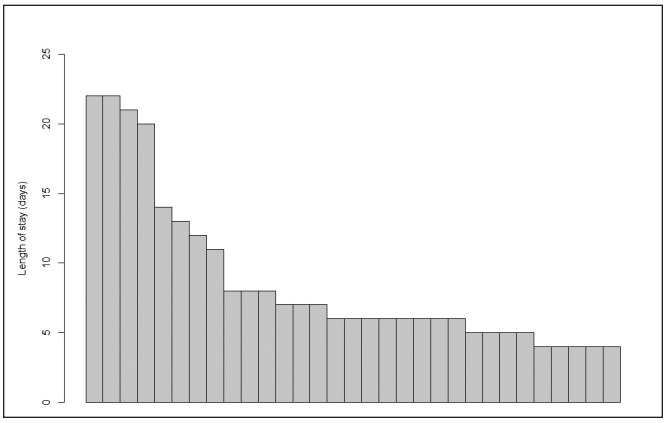
**Methods:** We conducted a retrospective chart review of all patients undergoing RARC at our institution from May 2020 to December 2021. These were performed by a single surgeon (BS). We collected information regarding patient demographics, intraoperative and postoperative factors, and complications in the first 90 days. Regression analysis was used to determine the relationship between case volume and operative time/lymph node yield.

**Results:** A total of 31 patients underwent RARC in our study period (Table 1). For ileal conduit diversions, decreasing operative time was weakly correlated with increased case volumes, whereas neobladder operative times were not (Figure 1). Median length of stay was six days (Figure 2). Surgical margins were positive in 12.9% (n=4) of patients. Average lymph node yield was 17.8±7.5 nodes and was not significantly affected by case volume (Figure 3). Forty-five percent (n=14) of patients were managed without an epidural or patient-controlled analgesia. Forty-five percent (n=14) of patients experienced postoperative complications, with only 12.9% (n=4) experiencing Clavien-Dindo grade 3 or greater complications. Two patients received intraoperative transfusions and two patients received postoperative transfusions. Reoperation rate was 3.2%. Ninety-day readmission and mortality rates were 17.2% (n=5) and 0%, respectively

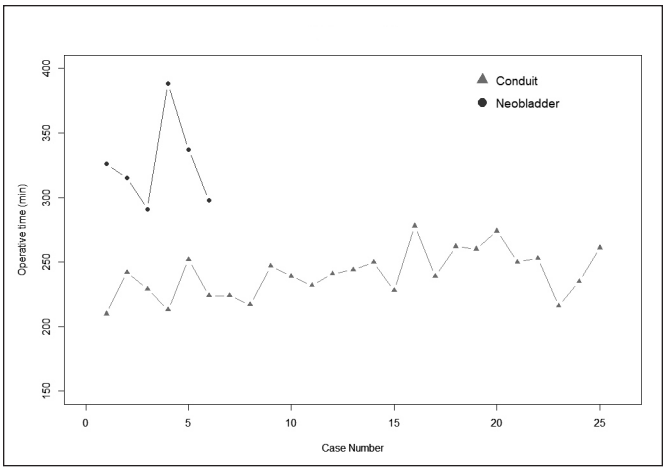
**Conclusions:** RARC, when conducted by an experienced robotic pelvic surgeon, is safe and provides satisfactory oncological outcomes. Prior experience with robotic pelvic surgery may have avoided a noticeable learning curve at our facility.

**MP-6.8. Table 1. Patient demographics**

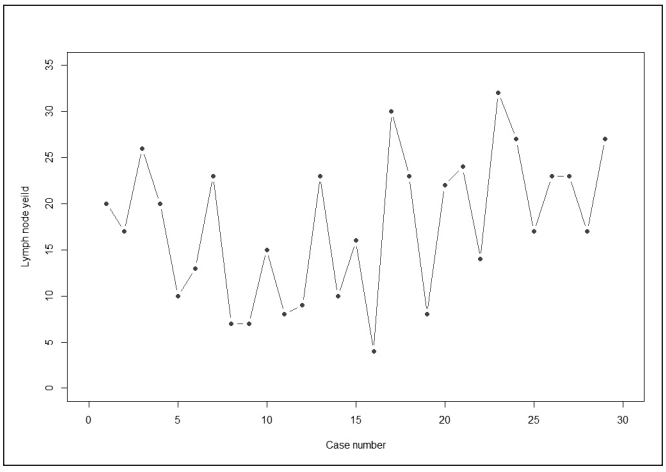
| | |
|---|---|
| Male, % (n) | 83% (26) |
| Age (years, mean±SD) | 66.7±10.2 |
| Length of stay (days, median±IQR) | 6±4.5 |
| BMI (mean±SD) | 25.8±3.8 |
| ECOG, % (n) | |
| 0 | 64.5% (20) |
| 1 | 32.2% (10) |
| ≥2 | 3.2% (1) |
| ASA class | |
| ≤2 | 3.2% (1) |
| 3 | 67.7% (21) |
| ≥4 | 29.0% (9) |
| Clinical stage | |
| CIS | 6.5% (2) |
| Ta | 3.2% (1) |
| T1 | 19.4% (6) |
| T2 | 48.4% (15) |
| T3 | 16.1 %(5) |
| T4 | 3.2% (1) |
| Metastatic | 3.2% (1) |
| Neoadjuvant chemotherapy, % (n) | 48.3% (15) |
| Estimated blood loss (mL, mean±SD) | 293.3±209.7 |
| Diversion, % (n) | |
| Incontinent | 80.6% (25) |
| Continent | 19.3% (6) |
| Complications | 45% (14) |
| Clavien-Dindo <3 | 32.2% (10) |
| Clavien-Dindo ≥3 | 12.9% (4) |
| Positive soft tissue margins, % (n) | 12.9% (4) |
| Lymph node yield (mean±SD) | 17.8±7.5 |
| Analgesia | |
| Epidural, % (n) | 9.7% (3) |
| Patient-controlled analgesia (PCA) | 45.2% (14) |
| No specific modality, % (n) | 45.2% (14) |
| Length of PCA/epidural (days, mean±SD) | 2.1±1.2 |
| Days till flatus (median±IQR) | 3.2±1.1 |




**MP-6.8. Figure 1.** Length of stay by patient.




**MP-6.8. Figure 2.** Operative time.




**MP-6.8. Figure 3.** Lymph node yield by case number.

**Reference**

1. Parekh DJ, Reis IM, Castle EP, et al. Robot-assisted radical cystectomy vs. open radical cystectomy in patients with bladder cancer (RAZOR): An open-label, randomized, phase 3, non-inferiority trial. *Lancet* 2018;391:2525-36. https://doi.org/10.1016/S0140-6736(18)30996-6

## MP-6.9

### Partial gland ablation with high-intensity focal ultrasound impact on urinary function and quality of life: Our initial experience

*Ioana Fugaru[1], Gautier Marcq[2], Alexis Rompré-Brodeur[1], Andrew Meng[3], Oleg Loutochin[1], George Loutochin[1], Maurice Anidjar[1], Franck Bladou[4], Raphael Sanchez-Salas[1]*

[1]Department of Surgery, Division of Urology, McGill University, Montreal, QC, Canada; [2]Department of Urology, Claude Huriez Hospital, CHU Lille, Lille, France; [3]Faculty of Medicine, McGill University, Montreal, QC, Canada; [4]Department of Urology, Claude Huriez Hospital, Pellegrin University Hospital, Bordeaux, France

**Introduction:** Partial gland ablation (PGA) using high-intensity focal ultrasound (HIFU) is emerging as an option for localized prostate cancer (PCa). Our goal was to present the urinary side effects and the impact of PGA on quality of life (QoL) in the initial prospective cohort of men who underwent PGA at our institution.

**Methods:** Twenty-five men with a diagnosis of low/intermediate PCa were enrolled prospectively in a single Canadian center between 2013 and 2016. Patients completed questionnaires at baseline, one, three, six, and 12 months after PGA. Statistical tests were performed using GraphPrism 8.0.

**Results:** Median age was 64 years. Baseline median International Index of Erectile Function-15 (IIEF-15) score was 50 and decreased to 18 at one month (p=0.0323). At three months, IIEF-15 score returned to baseline (51) and remained stable at six and 12 months (51; 52). At baseline, 16% of patients were delighted and 44% were pleased with their urinary condition, on the International Prostate Symptom Score (IPSS) QoL question. At one month, only 8% were delighted and 40% were pleased (p=0.5668). This increased to 32% delighted and 44% pleased at three months (p=0.0296). IPSS median at baseline was 8. This deteriorated at one month (12), and then improved to 7, 6, and 5 at three, six, and 12 months (p=0.0459). On the UCLA-Expanded Prostate Cancer Index Composite urinary function, 76% of patients had scores between 81 and 100, which decreased to 36% at one month (p=0.0313) but returned to 68% at three month. Concerning QoL, baseline median visual analogue scale (VAS) in EQ-5D questionnaire was 85 and was similar at followup (82.5, 90, 80, and 85, respectively, p=0.4002). Similarly, median Functional Assessment Cancer Therapy-Prostate (FACT-P) score at baseline was 136 and was stable at 134, 142, 135, and 131 at followup times, respectively (p=0.9418).

**Conclusions:** In our initial experience with PGA, patients had slight deterioration in urinary and erectile function at one month but then returned to baseline. Men did not have significant perturbation of QoL during followup.

## MP-6.10

### Evaluation of perioperative outcomes and predictors of successful same-day discharge after robot-assisted radical prostatectomy

*Braden Millan[1], Benjamin Bay[1], Raees Cassim[1], Bobby Shayegan[1]*

[1]Division of Urology, McMaster, Hamilton, ON, Canada

**Introduction:** Recent research has demonstrated that same-day discharge (SDD) robotic-assisted radical prostatectomy (RARP) can be safely conducted with comparable outcomes. We aimed to evaluate perioperative outcomes using our center's new SDD protocol for RARP. To our knowledge, we are the first center in Canada to implement this protocol.

**Methods:** This study was conducted at a single center, where eligible patients were offered voluntary SDD. Any cases that were deemed technically difficult were excluded from the SDD cohort per the surgeon's discretion. All patients initiated on the SDD pathway were included in the analysis. Descriptive statistics were calculated for each group. Differences between groups were evaluated using analysis of variance and multiple linear regression.

**Results:** Data were available for 82 patients, 41 (50.0%) patients on the SDD pathway and 41 (50.0%) on the inpatient pathway (IP-RARP). For patients in the SDD pathway, 26 (63.4%) were successfully discharged same-day (SDDD-RARP), while 15 (36.5%) failed SDD (SDDF-RARP). There were no significant differences between cohorts in regards to baseline demographics. Length of stay was shorter in the SDDS-RARP cohort (7.9 vs. 22.6 vs. 29.9 hours; p<0.0001). Five SDDS patients (19.2%), five SDDF patients (33.3%), and nine IP-RARP patients (22.0%) presented to the emergency department (p=0.4). There were no unscheduled office visits or hospital admissions in either SDD cohort, with two readmissions in the IP-RARP cohort (p=0.4). Multiple regression revealed that the only predictive factor for SDDS was case order, with the first case of the day resulting in the highest chance of successful discharge.

**Conclusions:** We demonstrated the feasibility and safety of implementing a SDD pathway in men undergoing RARP at a high-volume center. There were no significant differences in baseline characteristics, suggesting that same-day surgery can be offered to the majority of patients undergoing RARP.

## MP-6.11

### Health-related quality of life, pain and safety outcomes in the phase 3 VISION study of 177Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer

*Kim Chi[1], Karim Fizazi[2], Ken Hermann[3], Bernd J. Krause[4], Kambiz Rahbar[5], Michael J. Morris[6], Oliver Sartor[7], Scott T. Tagawa[8], Ayse T. Kendi[9], Nicholas Vogelzang[10], Jeremie Calais[11], James Nagarajah[12], Xiao X. Wei[13], Vadim S. Koshkin[14], Jean-Mathieu Beauregard[15], Brian Chang[16], Michelle DeSilvio[17], Richard A. Messmann[17], Johann de Bono[18]*

[1]British Columbia Cancer Agency, Vancouver Centre, Vancouver, BC, Canada; [2]Gustave Roussy Institute, University of Paris Saclay, Villejuif, France; [3]University Hospital Essen, Essen, Germany; [4]Rostock University Medical Center, Rostock, Germany; [5]University Hospital Münster, Münster, Germany; [6]Memorial Sloan Kettering Cancer Center, New York, NY, United States; [7]Tulane Medical School, New Orleans, LA, United States; [8]Weill Cornell Medicine, New York, NY, United States; [9]Mayo Clinic, Rochester, NY, United States; [10]Comprehensive Cancer Centers, Las Vegas, NV, United States; [11]University of California, Los Angeles, CA, United States; [12]Radboud University Medical Center, Nijmegen, Netherlands; [13]Dana-Farber Cancer Institute, Boston, MA, United States; [14]University of California San Francisco, Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, United States; [15]CHU de Québec - Université Laval, Québec, QC, Canada; [16]Radiation Oncology Associates, Parkview Hospital, Fort Wayne, IN, United States; [17]Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States; [18]The Institute of Cancer Research and Royal Marsden Hospital, London, United Kingdom

**Introduction:** [$^{177}$Lu]Lu-PSMA-617 ($^{177}$Lu-PSMA-617) delivers β-particle radiation to prostate-specific membrane antigen (PSMA) expressing cells and the surrounding microenvironment. In the phase 3 VISION study (NCT03511664), $^{177}$Lu-PSMA-617 plus protocol-permitted standard of care (SOC) prolonged radiographic progression-free survival (rPFS; hazard ratio [HR] 0.40; 99.2% confidence interval [CI] 0.29, 0.57), overall survival (OS; 0.62; 95% CI 0.52, 0.74), and time to first symptomatic skeletal event (SSE; 0.50; 95% CI 0.40, 0.62) vs. SOC (all p<0.001).

**Methods:** VISION was an international, open-label study of $^{177}$Lu-PSMA-617 in adults with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) previously treated with ≥1 androgen receptor pathway inhibitor and 1–2 taxane regimens. Patients were randomized 2:1 to $^{177}$Lu-PSMA-617 (7.4 GBq every six weeks, ≤6 cycles) plus SOC or to SOC alone. rPFS and OS were alternate primary endpoints; time to SSE was a key secondary endpoint. Other secondary endpoints included safety and patient-reported health-related quality of life (HRQoL) (Functional Assessment of Cancer Therapy – Prostate) and pain (Brief Pain Inventory – Short Form). Prespecified analyses included time to the first occurrence of HRQoL/pain worsening, disease progression, or death. Here, we present ad hoc analyses of time to worsening only (non-inferential).

**Results:** HRQoL was assessed in the prespecified rPFS analysis set comprising 581 of the 831 randomized patients ($^{177}$Lu-PSMA-617 arm, n=385; control arm, n=196). HRQoL and pain time-to-worsening analyses favored the $^{177}$Lu-PSMA-617 arm (Table 1), despite a higher incidence of grade ≥3 adverse events vs. SOC alone. No new or unexpected safety concerns were noted, including changes in creatinine clearance.

**Conclusions:** $^{177}$Lu-PSMA-617 plus SOC was generally well-tolerated and delayed time to HRQoL and pain worsening vs. SOC alone in patients with advanced mCRPC.

**MP-6.11. Table 1. Hazard ratios for time to worsening in Functional Assessment of Cancer Therapy – Prostate (FACT-P) and Brief Pain Inventory – Short Form (BPI-SF) scores**

| Outcome† | Hazard ratio (95% confidence interval) |
|---|---|
| FACT-P | |
| Total | 0.46 (0.35, 0.61)* |
| Pain-related subscale | 0.55 (0.42, 0.71)* |
| Prostate cancer subscale | 0.59 (0.46, 0.76)* |
| BPI-SF | |
| Pain intensity | 0.45 (0.33, 0.60)* |
| Worst pain intensity | 0.49 (0.37, 0.65)* |
| Pain interference | 0.60 (0.45, 0.80)* |

†Time to the first occurrence of the following from baseline. ≥10 point decrease in FACT-P total; ≥2 point decrease in FACT-P pain-related subscale; ≥3 point decrease in FACT-P prostate cancer subscale; ≥30% or ≥2 point increase in BPI-SF pain intensity; ≥30% or ≥2 point increase in BPI-SF worst pain intensity; ≥30% or ≥2 point increase in BPI-SF pain interference; *p<0.001 (nominal; non-inferential analysis).

## MP-6.12

### Darolutamide observational study in patients with non-metastatic castration-resistant prostate cancer

*Geoffrey Gotto[1], Evan Y. Yu[2], Christopher Pieczonka[3], Andrew J. Armstrong[4], Hiroyoshi Suzuki[5], James Bailen[6], Declan Murphy[7], Thierry Lebret[8], Murilo Luz[9], Antoine Thiery-Vuillemin[10], Jorge A. Ortiz[11], Javeed Khan[12], Alberto Briganti[13]*

[1]Southern Alberta Institute of Urology, University of Calgary, Calgary, AB, Canada; [2]University of Washington, Seattle, WA, United States; [3]Associated Medical Professionals of NY, Syracuse, NY, United States; [4]Duke University School of Medicine, Durham, NC, United States; [5]Toho University Sakura Medical Center, Chiba, Japan; [6]First Urology PSC, Jeffersonville, IN, United States; [7]Peter MacCallum Cancer Centre, University of Melbourne, Melbourne, Australia; [8]Hôpital Foch, Université Versailles St Quentin, Paris, France; [9]Hospital Erasto Gaertner, Curitiba, Brazil; [10]Centre Hospitalier Régional Universitaire, Besançon, France; [11]Bayer Healthcare, Whippany, NJ, United States; [12]Bayer Healthcare, Reading, United Kingdom; [13]Urological Research Institute, IRCCS Ospedale San Raffaele and Università Vita-Salute San Raffaele, Milan, Italy

**Introduction:** In ARAMIS (NCT2200614), darolutamide (DARO) improved metastasis-free survival and overall survival in non-metastatic castration-resistant prostate cancer (nmCRPC), with favorable tolerability. The DARolutamide ObservationaL (DAROL) trial (NCT04122976) is assessing real-world safety and effectiveness of DARO. We report the first interim analysis.

**Methods:** DAROL is an international, single-arm, non-interventional study. Eligible patients (pts) are DARO-naive, ≥18 years of age, with confirmed nmCRPC. Treatment dose/duration are per investigator's routine practice. The primary endpoint is safety. Prostate-specific antigen (PSA) response is an exploratory objective. Descriptive statistics are reported for the first prespecified interim analysis after ~100 pts (Canada, Japan, U.S.) completed ≥6 months of treatment/discontinued treatment.

**Results:** All 100 pts were evaluable for safety: median age 78.0 years; White/Black/Asian/other/not reported 59%/11%/27%/1%/2%; Canada/Japan/U.S. 24%/21%/55% (see baseline measures in Table 1). Most (79%) pts had ≥1 concomitant medication; those in ≥15% were HMG-CoA reductase inhibitors (30%), bone structure/mineralization agents (22%), oral platelet aggregation inhibitors (21%), angiotensin II receptor blockers (16%), alpha-adrenoreceptor antagonists (15%), and beta-blocking agents-antimigraine (15%). Median (Q1–Q3) DARO treatment duration was 11.3 months (8.4–14.4); median (Q1–Q3) followup time was 12.3 months (9.6–15.6). Twenty-eight percent had any grade treatment-emergent adverse events (TEAEs): 3% grade 3, no grade ≥4; 2% had serious adverse events (AEs). Incidence of AEs was low; those in ≥2% of pts were fatigue (5%), diarrhea (5%), asthenia (2%), muscle weakness (2%), anemia (2%), and rash (2%). TEAEs led to drug discontinuation in 7%. Of 93 pts, 81.7%, 77.4%, and 52.7% had PSA responses of ≥30%, ≥50%, and ≥90% (any time during followup), respectively.

**Conclusions:** Safety and tolerability of DARO were consistent with the favorable tolerability profile observed in ARAMIS.

**MP-6.12. Table 1. DAROL baseline measures and disease characteristics**

| Baseline measures and disease characteristics | Patients (n=100) |
|---|---|
| ECOG PS | |
| 0–1 | 72 (72) |
| 2–4 | 5 (5) |
| NR | 23 (23) |
| Time from initial diagnosis to castration resistant (months), median (Q1–Q3) | 89.1 (39.1–130.6)* |
| Gleason score at initial diagnosis | |
| ≤6 | 15 (15.8) |
| 7 | 37 (38.9) |
| 8–10 | 43 (45.3) |
| NR | 5 |
| PSA (ng/mL), n (%) | |
| ≤10 | 73 (75.3) |
| >10 | 24 (24.7) |
| NR | 3 |
| PSA doubling time | |
| ≤6 | 39 (58.2) |
| >6 | 28 (41.8) |
| NR | 33 |

*Assessed in 95 patients.