ANZUP ANNUAL SCIENTIFIC MEETING


# ABSTRACTS

WILEY

# List of Best of the Best Oral Abstracts

## Best of the best orals
## Monday 14 July 2014, 3:15 pm–4:15 pm

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Circulating microRNAs associated with docetaxel-resistant castration-resistant prostate cancer *abs#11*

**Kate Mahon**
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# INVITED PRESENTATIONS AND ORAL ABSTRACTS

abs#1

## KIDNEY CANCER TREATMENT: "WHAT, WHEN AND WHY?"

C. Kollmannsberger
*Div. of Medical Oncology, Dept. of Medicine, University of British Columbia, British Columbia Cancer Agency, Vancouver, BC Canada*

Great progress has been made over the past decade in the treatment of kidney cancer and the median survival of patients with metastatic disease is already exceeding 2 years. Several agents are now available including sunitinib, pazopanib, and temsirolimus for first-line therapy as well as everolimus and axitinib for second-line therapy. No predictive biomarkers are yet available for clinical practice which makes the choice of therapy challenging. Patient and agent specific factors, including performance status, co-morbidities, Heng classification and drug interactions, toxicity profiles, respectively, as well as efficacy and, most importantly, physician preference/experience may influence the choice of therapeutic agent. In order to achieve the maximum benefit from any targeted therapy in metastatic RCC, optimization of all treatment aspects is of utmost importance. Treatment optimization includes the cautious assessment of any potential progression and the impact of different types of progression on treatment decisions in particular the need for a change in treatment, the rationale integration of surgery and/or other local treatment methods, careful individualization of dose and schedule in order to achieve the maximum dose intensity and avoid premature discontinuation of treatment, as well as the best possible side effect management.

Complete remissions remain rare and the very vast majority of patients will eventually progress due to development of resistance and evolution of tumor heterogeneity. Assessment of progression remains difficult since patients may still derive clinical benefit despite some tumor growth and RECIST criteria may not always be the best tool to assess response in clinical practice. Different types of progression such as immediate progression (primary resistant disease), early, slow, delayed or solitary site progression may require different adjustments in treatment.

A clear dose-response and dose-survival relationship exists for all targeted agents in RCC. Optimal dosing is crucial in order to avoid under-dosing and ensure maximum efficacy. Side effects have been shown to be a biomarker for response and can be used to adjust dosing and schedule. A relationship between the occurrence of side effects and improved outcomes has been shown for virtually every side effect thus far.

Proactive side effect management is critical in order to avoid unnecessary dose reductions or discontinuations, ensure good quality of life and allow prolonged application of therapy.

After a decade of unprecedented success in the treatment of renal cell carcinoma, many questions and much work still remain to fully realize the potential of available targeted therapies and subsequent optimize outcomes.

abs#2

## TAKING THE BULL BY THE HORNS: THE MATADORS CONCEPT FOR PROSTATE CANCER TARGETED RADIOTHERAPY TRIALS

R. G. Bristow
*Radiation Medicine Program, Princess Margaret Cancer Center and Radiation Oncology, University of Toronto*

Prostate cancer (CaP) is the most commonly diagnosed malignancy in males in the Western world with one in six males diagnosed in their lifetime. Current clinical prognostication groupings use pathologic Gleason score, pre-treatment prostatic-specific antigen and Union for International Cancer Control-TNM staging to place patients with localized CaP into low-, intermediate- and high-risk categories. These categories represent an increasing risk of biochemical failure and CaP-specific mortality rates, they also reflect the need for increasing treatment intensity and justification to our patients for the increased side effects. Presently, despite elegant physical targeting of image-guided radiotherapy and robotic forms of surgery, 30–50% of patients will fail local therapy. Using novel, pre-treatment prognostic assays based on DNA signatures, RNA expression or cancer metabolism (e.g. hypoxia), it may be possible to triage patients at greatest risk of systemic failure to intensified treatment, such as the use of adjuvant ADT. Similarly, these markers may allow certain patients to forego ADT despite being classified as high-risk. More importantly, it is argued that these assays could be even more useful if combined and used on diagnostic biopsies a priori to drive forward precision cancer medicine for localized CaP. The ability to "intensify and de-intensify" therapy could be incorporated into novel Phase II clinical trials. This intensification schema (e.g. MATADORS: Molecular Adjuvant Therapies Adding to Optimized radiotherapy or Surgery) would be based on an individual patient's risk for aggression based on their innate tumour genomics and/or microenvironment.

abs#3

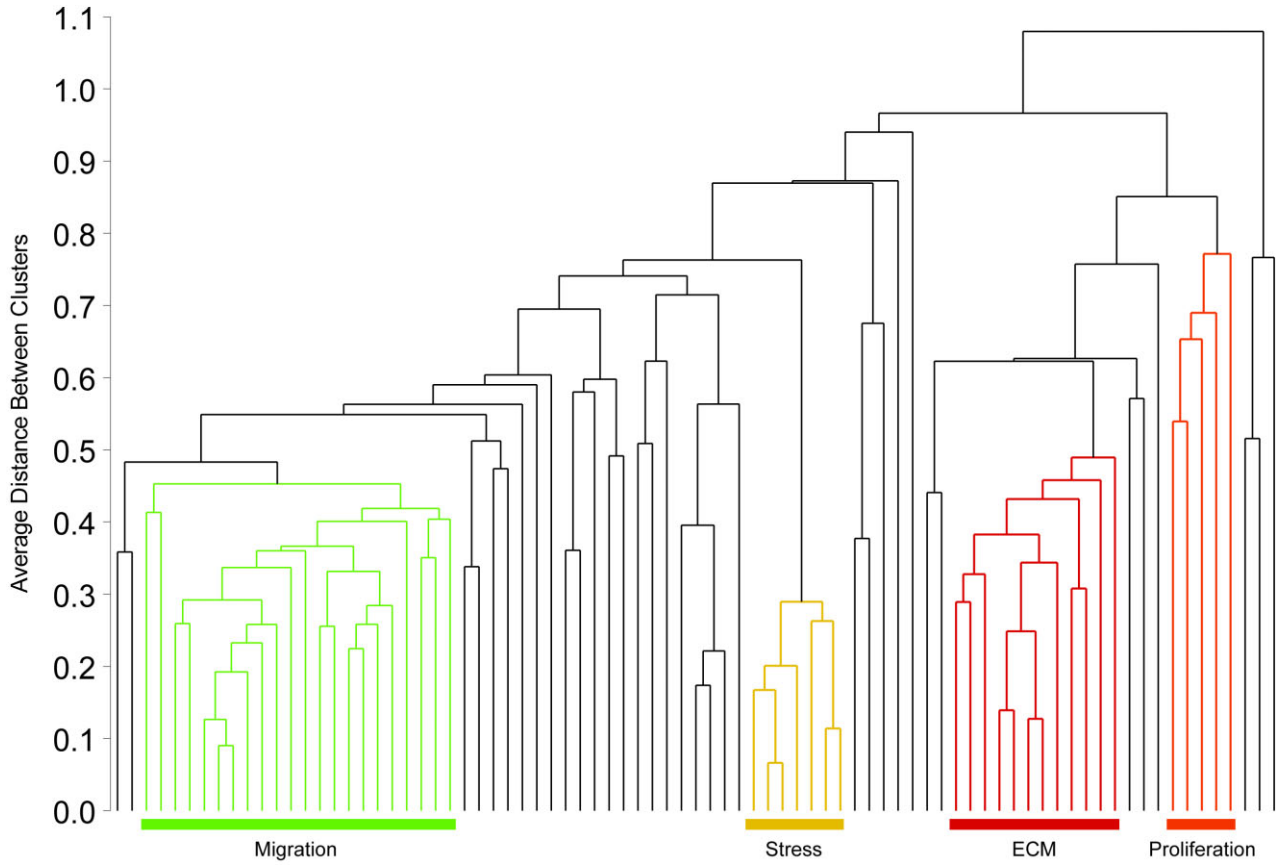
## GENE EXPRESSION PROFILING OF PROSTATE CANCER: FIRST STEP TO IDENTIFYING BEST CANDIDATES FOR ACTIVE SURVEILLANCE

Eric A. Klein
*Chairman, Glickman Urological and Kidney Institute, Cleveland Clinic*

The natural history of prostate cancer is unusual among visceral malignancies in that the majority of tumors are indolent and even if untreated will not progress to cause symptoms or death. In the PSA era two lines of evidence suggest a marked overdiagnosis of these non-lethal cancers: 1) a significant discrepancy between clinical incidence (US lifetime risk of diagnosis 17%) and tumor-related death (3% lifetime risk) and 2) estimates from large scale screening trials of the number needed to treat (NNT) to prevent one death ranging from 12 to 100. Despite the indolent nature of most prostate cancers and data suggesting no survival advantage to their treatment, more than 90% of men who are newly diagnosed with low-risk disease are treated by radiation or surgery with curative intent. Overtreatment of prostate cancer is associated with substantial cost and unnecessary morbidity, leading some public health agencies to question the value of routine screening. An important reason for the over-treatment of prostate cancer is the lack of prognostic tools that reliably distinguish indolent from potentially lethal cancers. The development of a biopsy-based tool could help identify newly diagnosed men who are likely to benefit from immediate therapy versus those who may safely consider initial surveillance with intervention delayed to the time of tumor progression, a strategy that has been associated with a minimal risk of cancer-specific mortality in appropriately selected patients.

Working with Genomic Health, we have studied a large number of prostate cancers from radical prostatectomy specimens to determine if a gene expression signature could predict clinical recurrence or death from prostate cancer as an initial step toward developing a biopsy-based molecular test that can help determine whether a newly diagnosed patient can safely adopt a strategy of active surveillance. The study included 501 men who underwent prostatectomy between 1987–2004. The tumors were microdissected and the isolated RNA was assayed for the expression of 726 candidate genes by quantitative real-time RT-PCR. Gene expression signatures were then correlated with clinical outcomes including PSA recurrence, clinical recurrence (local recurrence or metastasis), and death due to prostate cancer.

The results demonstrated that the expression profiles of 295 genes can predict these outcomes – increased expression of proliferation, basal epithelial, and extracellular matrix genes are associated with increased risk of clinical recurrence, while increased expression of cytoskeletal/migration, PSA-related, and stress genes are associated with decreased chance of clinical recurrence. The results indicated that 1) specific expression profiles predicted outcome independent of the usual preoperative parameters (biopsy grade, stage and PSA); 2) a subset of these genes predicted outcomes independent of the Gleason grade in the prostatectomy specimen; and 3) gene expression signatures were similar across different tumor foci in the same patient.




The results of this study demonstrate that gene expression profiling can reveal an underlying biology that provides value beyond Gleason grading, and serve as a first step in the development of a biopsy based assay that may be able to distinguish indolent from aggressive disease. Our ultimate goal is to develop this test to help clinicians and patients decide on the need for immediate therapy versus active surveillance.

Genes Associated With Clinical Outcome Cluster Into Gene Families with Related Biological Functions

abs#4

## OUTCOMES THAT MATTER: COPING WITH TREATMENT

T. Wiseman
*The Royal Marsden NHS Foundation Trust, London UK*

Advances in diagnostics and treatment modalities have largely changed the trajectory of cancer to a chronic disease which includes acute phases and periods of chronic disease management. People are living longer with and beyond cancer treatment. This paper is a synthesis of findings from three qualitative studies of patient experience to elucidate outcomes that matter to patients and their families. Patients and their families stress the importance of "living life not just living" and the centrality of real choice within treatment. This meta-synthesis emphasises the need for support for changing expectation, managing uncertainty, flexibility in treatment and effective practical knowledge within symptom management. Ways to incorporate this into usual care are suggested.

abs#5

## THE EVOLUTION OF GLEASON GRADING

J. Kench
*Department of Tissue Pathology and Diagnostic Oncology, Royal Prince Alfred Hospital, Camperdown, Sydney, NSW*

The Gleason grading system in various forms has been in use for almost 50 years with the latest International Society of Urological Pathology (ISUP) endorsed modifications (2005) enjoying almost universal acceptance in contemporary practice. However, the impact of these changes on the clinical management of prostate cancer, as well as the significant implications for research and clinical trials, is often poorly appreciated.

Donald Gleason developed the first version of his grading system for prostatic adenocarcinoma in 1966 based on the 270 patients forming the Veterans Administration Cooperative Urological Research Group (VACURG) series. Initially 9 grades were defined, but these were soon consolidated into 5 grading categories, also known as patterns, based on similarities in outcome. Since more than one morphological pattern was identified in most cases (designated primary and secondary based on the extent of each), and as the prognosis of cases with mixed grades/patterns was intermediate between that of either the primary or secondary grade alone, Gleason advocated the use of a combined score to give more comprehensive prognostic information. By 1974 his cohort had increased to 1032 patients and Gleason made several modifications to the definitions of grades/patterns 1–4. With only minor local modifications this was the system in general use worldwide for two decades, supported by evidence from a number of independent that studies showed Gleason score correlated with biochemical

relapse, development of metastatic disease, survival following radiotherapy, disease specific and overall survival.

However, by 2005 it was clear that significant changes in clinical and pathological practice necessitated review of the Gleason grading system; for example widespread PSA screening had led to well documented grade and stage migration of prostate cancer at diagnosis, while the availability of immunohistochemical stains for basal cells had demonstrated that the vast majority, if not all, of Gleason pattern 1 (score 1 + 1 = 2) cancers were actually benign lesions, representing adenosis (atypical adenomatous hyperplasia), rather than malignancies. In response, ISUP convened a consensus conference to modernise and standardise grading/scoring for prostatic adenocarcinoma. The resulting modified Gleason grading system made several major changes: for instance the range of morphological appearances included in grade/pattern 4 was very significantly expanded with poorly formed discrete glands and most cribriform glands moving from pattern/grade 3 into 4. The method of scoring core needle biopsy specimens was also radically altered with Gleason categories 1 and 2 being virtually eliminated and the method of calculating the Gleason score overhauled. These changes were based on limited evidence and were (arguably) poorly communicated to clinicians and prostate cancer researchers. Crucially, they raised issues regarding the validity of widely utilised nomograms guiding patient management decisions, the selection of patients for active surveillance, reproducibility, and research using previously collected cohorts.

abs#6

## IMPLEMENTING CANCER GENOMICS IN INDIVIDUAL PROSTATE CANCER RISK STRATIFICATION

R. G. Bristow
*Radiation Medicine Program, Princess Margaret Cancer Center and Radiation Oncology, University of Toronto*

Prostate cancer (CaP) is the most commonly diagnosed malignancy in men in the Western world. In North America, more than 275,000 men are diagnosed annually, whereby approximately 1 in 6 men will be diagnosed with CaP in their lifetime, and 1 in 34 men will die from castration-resistant metastatic disease. Unfortunately, current clinical prognostic factors explain only a proportion of the observed variation in clinical outcome from patient to patient (e.g. 30–50% biochemical failure rates after precision radiotherapy or surgery). As such, better predictors of individualized prognosis and treatment response are urgently needed to triage patients to stratify patients into personalized treatment protocols. Recent developments in next-generation sequencing have made it possible to identify prognostic and predictive signatures based on genomic profiles. The genetic basis of CaP progression from localized to systemic disease can now be described by a series of point mutations, copy-number alterations, and structural variants. However, challenges still exist based on the unique features of CaP biology, including intraprostatic and interprostatic heterogeneity, multifocality and multiclonality, and controversy regarding the importance of TMPRSS2:ERG in tumour progression. However, by harnessing these features, there is great potential for prostate cancer genomics to provide the identification of novel molecular targets for therapy.

abs#7

## TO CURE THE INCURABLE CAN WE JUSTIFY "AGGRESSIVE MANAGEMENT" OF PROSTATE CANCER WITH ADVANCED OR OLIGOMETASTATIC DISEASE?

A. Kneebone
*Northern Sydney Cancer Centre*

Two recent randomised trials have demonstrated a significant survival benefit with the addition of pelvic radiotherapy to hormone therapy alone for men with very high risk prostate cancer previously thought to be incurable due to the likely presence of micro-metastases. With the development of advanced radiotherapy techniques such as Stereotactic Body Radiotherapy (SBRT) which can deliver ablative doses of radiotherapy to sites of metastatic disease with relative safety, attention is now being directed at men with oligometastases who are thought to have a different natural history to those with more widespread disease. Series incorporating SBRT in this group of men are now demonstrating promising disease control and can allow a meaningful time off androgen deprivation. This is an area warranting research by the ANZUP community.

abs#8

## SCREENING AND HOW WE NEED TO CHANGE THE PARADIGM

E. Klein
*Chairman, Glickman Urological and Kidney Institute, Cleveland Clinic*

The use of PSA as a screening test has had the greatest impact on the incidence and potentially mortality of prostate cancer worldwide. Since the introduction of PSA, lifetime risk of prostate cancer in the US has doubled from 7.8% to 15.3% while the risk of dying from has decreased from 3% to 2.6%. In the PCPT, 14% of men in the placebo arm were diagnosed by annual PSA screening within 7 years of enrollment, suggesting that lifetime risk for regular screening may approach 20%. The discrepancy between incidence and mortality is one piece of evidence that screening primarily detects non-lethal cancers that may be best managed expectantly to avoid the cost and morbidity of therapy. Identifying which tumors on biopsy may be safely managed by active surveillance is one of the major challenges in prostate cancer today.

Recently, the results of 2 large randomized trials assessing the effect of PSA screening on prostate cancer mortality were published. The U.S. Prostate, Lung, Colorectal, and Ovarian (PLCO) cancer screening trial reported on 76,685 US men aged 55–74 randomized between annual screening or usual care. Through 13 years of follow-up the incidence of prostate cancer in the screening group was 12% higher than in the control group (108 vs. 97 per 10,000 person-years, respectively). However, there was no difference in prostate cancer mortality between the groups (3.7 vs 3.4 deaths per 10,000 person-years in the screening and control groups, respectively; HR = 1.09; 95% CI: 1.87–1.4). The trial has been criticized for high rates of pre-screening (44% reported undergoing PSA testing prior to enrollment), poor compliance with prostate biopsy, and 52% contamination by ad hoc screening in the control arm. There were also identical rates of non-compliance with PSA-screening (15%) in the control and screening arms. Thus, the trial does not fairly compare annual screening versus none and was likely underpowered to detect meaningful differences in prostate cancer mortality between the groups. The European Randomized Study of Screening for Prostate Cancer (ERSPC), included 162,243 men between the ages of 55–69 randomized between PSA screening every 4 years or no screening (Schroder et al, 2012). After a median follow-up of 11 years, men in the screening arm had a 63% (95% CI: 57–69) increased incidence of prostate cancer compared to controls (97 vs. 56 cancers per 10,000 person-years) and a 21% (95% CI: 9–32) relative reduction in death from prostate cancer (3.9 vs. 5 cancer deaths per 10,000 person-years). Extrapolating the ERSPC results to the long-term U.S. setting suggests an absolute mortality reduction up to 5 times greater than that observed in ESRPC.

Soon after publication of PLCO and ERSPC, the U.S. Preventive Services Task Force (USPSTF) in 2011 recommended against routine PSA screening in healthy men regardless of age, race, or family history. It gave PSA a grade 'D' recommendation, meaning that there was a moderate-to-high certainty that the service has no net benefit or that the harms outweigh the benefits. The future impact of these recommendations on PSA screening practices and national prostate cancer incidence rates is uncertain. Conflicting results of the impact of the publication of PLCO and ERSPC in 2009 and the 2008 USPSTF recommendations to discontinue screening among men >75 have been reported. No differences in self-reported PSA testing were identified among men aged >75 in the National Health Interview Survey between 2005–2010, while in the SEER-Medicare population and VA Pacific Northwest Network, a small but statistically significant reduction in PSA testing (29.4% vs. 27.8% and 25.4% vs. 24.3%, respectively) was observed in the periods before and after the 2008 USPSTF recommendations. This may have explained part of the 25% reduction in prostate cancer incidence reported in

the SEER registry among men ≥ 75 between 2007–2009. Among men <75, the PLCO and ERSPC results appeared to have had minimal impact on PSA testing rates among men in a commercial insurance database (–0.7%–1.5% change after 2009) and VA (–3% change after 2009). In a survey of primary care practitioners in university-affiliated practice after the 2011 USPSTF recommendations, approximately half agreed with the committee's recommendations but >75% reported that they would be somewhat less likely to change their PSA screening practice or that it would not change at all. Even among clinicians who agreed strongly with the recommendations, only 42% stated they would no longer order a PSA test or would be much less likely to do so.

These observations suggest the need to develop a new paradigm for screening, that includes behavioral change by physicians and patients, and the incorporation of new markers that have improved sensitivity and specificity for the detection of biologically significant cancers.

abs#9

## POOR ADHERENCE AND THE IMPORTANCE OF PATIENT SELF-MANAGEMENT IN ADOLESCENT AND YOUNG ADULT (AYA) ONCOLOGY CARE

K. Thompson
*Program Director, ONTrac at Peter Mac Victorian AYA Cancer Service*

Young people with cancer are a unique oncological cohort that faces significant physical and psychosocial impacts as the result of a diagnosis during the most complex developmental life-stage. They are often isolated within a health system which is traditionally dichotomised into adult and paediatric care; face a unique spectrum of disease and; are dually expected to manage the significant developmental milestones associated with the transition to adulthood, including evolving relationships, developing sexual and personal identity, managing education and vocational tasks and negotiating the transition to independence.

In recent years there has been increasing recognition of the issue of poor adherence in the AYA oncology population. Largely related to life-stage factors, poor adherence can present challenges for healthcare professionals caring for young people and can impact treatment response and survival outcomes. In response, it has become evident that supporting young people to develop self-management skills is essential to empower them in directing their own care and in improving adherence. With developing cognitive capacity, AYA patients often do not have the same skills as adults in relation to self-management and advocating for their needs. For this reason, supporting patient self-management is a cornerstone of AYA oncology care to ensure the best health and wellbeing outcomes both during cancer treatment and into the future.

This presentation will provide an overview of the defining characteristics of adolescent oncology and care. It will review what is known about the poor adherence of young people to cancer treatment. It will also discuss the importance of self-management and the ways healthcare professionals may promote self-management skill development with young people facing a diagnosis of cancer.

abs#10

## DOVITINIB IN 1ST-LINE METASTATIC RENAL CELL CARCINOMA AND CORRELATION OF EFFICACY WITH TUMOR GENE STATUS: A PHASE II CLINICAL TRIAL

R. J. Broom[1], F. Hanning[1], C. Fraser-Browne[1], S. Duffey[1], G. Wilson[1], K. Thompson[1], N. Mitchell[1], J. Zwi[1], M. McKeage[2], G. Dranitsaris[1], P. Oei[3], P. Fong[1]
*[1]Auckland City Hospital, Grafton, Auckland, New Zealand, [2]University of Auckland, Auckland, New Zealand, [3]IGENZ Ltd., Auckland*

**Background:** Dovitinib is an anti-VEGFR tyrosine kinase inhibitor which also inhibits FGFR-1,-2,-3 and PDGFRβ. We studied its activity as 1st-line therapy in patients with metastatic clear-cell renal cell carcinoma (mCCRCC) and correlated genes related to its action mechanism with clinical outcomes.

**Methods:** The 31 treatment naïve patients with mCCRCC enrolled in this single-arm, single-site, phase II study received dovitinib at 500 mg 5 days on/2 days off until progression. An optional post-treatment biopsy was offered to study resistance mechanisms. The primary endpoint was progression free survival (PFS) using RECIST 1.1. Secondary endpoints included response rate and efficacy by gene status (FISH and DNA sequence).

**Results:** Accrual occurred over 15 months from March 2012. Median patient age was 64 and 72% were male. ECOG performance status was 0 in 45% and 1 in 55%. Heng prognostic group was favorable risk in 38%, intermediate risk in 52% and poor risk in 10%. 38% had bone metastases. 4 patients stopped treatment due to toxicity and 1 patient withdrew. Median PFS was 6.2 months (inter quartile range: 3.3 to 8.2). Of 28 evaluable patients, best response was: PR (29%), SD (53%) and PD (18%). All-cause grade 3/4 adverse events (AE's) occurring in ≥5% of patients were: fatigue (16%), abdominal pain (13%), pancreatitis (10%), gout (7%), diarrhea (7%), bone pain (7%), hypercalcemia (7%), elevated lipase (7%) and pulmonary embolism (7%). Pre-treatment metastatic and primary tumor tissue was available from 93% and 54% of patients respectively. 6 patients donated post-progression tissue. Gene status (FISH) for FGFR-1,-2,-3, PDGFβ and PDGFRβ was available for 20 primary and 17 metastatic specimens. FGFR-1 showed a trend towards positive correlation between gene gain/amplification and response (Spearman's rho = 0.32, p = 0.17). FGFR-2, FGFR-3, PDGFR-β and PDGF-β showed no statistically significant associations.

**Conclusions:** Dovitinib has activity in the first line setting of mCCRCC with a tolerable safety profile at the given dosing schedule. A non-significant correlation of this activity with FGFR-1 gene gain/amplification was seen and further study with a larger sample size is warranted.

abs#11

## CIRCULATING MICRORNAS ASSOCIATED WITH DOCETAXEL-RESISTANT CASTRATION-RESISTANT PROSTATE CANCER

K. L. Mahon[1,2], K. Chiam[2], B. Y. Lee[3], Q. Nguyen[2], M. J. Boyer[1], M. Stockler[1,4], N. Pavlakis[5], G. Marx[6], G. Mallesara[7], H. Gurney[8], S. Clark[2], A. Swarbrick[2], R. Daly[9], Lisa Horvath[1,2]
*[1]Chris O'Brien Lifehouse, Camperdown, NSW, Australia, [2]Cancer Research Division, The Kinghorn Cancer Centre / Garvan Institute for Medical Research, Sydney, NSW, Australia, [3]Cancer Research Division, The Kinghorn Cancer Centre / Garvan Institute for Medical Research, Sydney, NSW, Australia, [4]NHMRC Clinical Trials Centre, Sydney, NSW, Australia, [5]Department of Medical Oncology, Royal North Shore Hospital, Sydney, NSW, Australia, [6]Northern Haematology and Oncology Group, Sydney Adventist Hospital, Sydney, NSW, Australia, [7]Calvary Mater Hospital , Newcastle, NSW, Australia, [8]Westmead Hospital, Sydney, NSW, Australia, [9]Monash University, Melbourne, VIC, Australia*

**Background:** Despite a range of new treatments, docetaxel remains the first-line chemotherapy for metastatic castration-resistant prostate cancer (mCRPC). However, only 50% of patients respond to docetaxel at the cost of potentially significant toxicity. Therefore, there is a need for new biomarkers to identify early response to therapy. This study aims to determine if circulating microRNAs are associated with docetaxel chemotherapy outcome in CRPC.

**Methods:** Global microRNA profiling was performed on docetaxel-resistant and sensitive cell lines to identify candidate circulating microRNA biomarkers. Custom Taqman Array MicroRNA cards were used to measure the levels of 46 candidate microRNAs in plasma/serum from 97 CRPC patients, collected pre- and post-cycle 1 of docetaxel (1 cycle = 3 weeks). Responses were defined by the PCWG2 serum prostate-specific antigen (PSA) response criteria; partial response (PR), stable disease (SD), progressive disease (PD). Multiple T-test, Mann-Whitney U, Kaplan-Meier, Receiver Operating Characteristic (ROC) and Cox regression analyses were used to assess the associations between microRNA levels and clinical outcomes.

**Results:** The patient cohort had a median follow-up of 12 months (range 3–62 months) with 57% of men dead at the time of analysis. 63% of the cohort had a PSA PR to docetaxel, 26% had SD and 11% PD. Sixteen microRNAs were associated with PSA response or overall survival ($p < 0.05$).

Patients with shorter survival had high pre-docetaxel levels of miR-200 family members – miR-200a (HR 2.8 95%CI 1.6–5.0; $p = 0.0004$), miR-200b (HR 3.2 95%CI 1.7–5.9; $p = 0.0001$), miR-200c (HR 2.3 95%CI 1.3–4.1; $p = 0.006$), miR-429 (HR 3.5 95%CI 1.8–6.9; $p = 0.0003$) – or decreased/unchanged post-docetaxel levels of miR-17 family members – miR-20a (HR 0.30 95%CI 0.16–0.58; $p = 0.0004$), miR-20b (HR 0.39 95%CI 0.20–0.74; $p = 0.004$).

Docetaxel PSA non-responders (PD+SD) tended to have higher pre-docetaxel levels of miR-200c or miR-200b, or lower pre-docetaxel levels of miR-146a ($p < 0.05$). After docetaxel treatment, non-responders tended to have a decrease/no change in post-docetaxel levels of miR-222 or miR-20a, or an increase in post-docetaxel levels of miR-301b ($p < 0.05$). The combined levels of miR-20a, miR-146a, miR-200b, miR-200c, miR-222 and miR-301b predicted PSA response to docetaxel (ROC AUC 0.73, 95% CI 0.62–0.84; $p = 0.001$).

Pre-docetaxel miR-200b levels (HR 3.1 95%CI 1.6–6.0; $p = 0.001$) and post-docetaxel change in miR-20a (HR 0.29 95%CI 0.15–0.58; $p = 0.0005$) were independent predictors of overall survival when modeled with hemoglobin levels (HR 0.38, 95%CI 0.20–0.73; $p = 0.004$) and visceral metastases (HR 2.0, 95%CI 1.1–3.7; $p = 0.02$).

**Conclusions:** Circulating microRNAs are potential early predictors of docetaxel chemotherapy outcome and may be useful in stratifying patients in future clinical trials. These microRNAs may also be involved in docetaxel resistance and represent potential therapeutic targets.

abs#12

## METHYLATED GLUTATHIONE S-TRANSFERASE 1 (MGSTP1) ASA POTENTIAL PLASMA EPIGENETIC MARKER OF PROGNOSIS AND RESPONSE TO CHEMOTHERAPY IN CASTRATE-RESISTANT PROSTATE CANCER (CRPC)

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**Background:** GSTP1 is inactivated and displays aberrant CpG island promoter methylation in the majority of prostate cancers (PCs). The aim of this study was to assess whether changes in methylated glutathione s-transferase 1 (mGSTP1) levels are predictive of response to chemotherapy and overall survival (OS).

**Methods:** Plasma samples were collected prospectively from a phase I exploratory cohort of 75 men with castration-resistant prostate cancer (CRPC) (40 treated with chemotherapy) and a phase II independent validation cohort ($n = 51$). Plasma samples were collected at presentation with CRPC and pre- and post-cycle one of chemotherapy (90% Docetaxel). mGSTP1 levels were measured using a methylation-specific head-loop PCR assayfrom DNA isolated from either (1) immunomagnetic separation of circulating tumor cells (CTCs) or (2) free plasma DNA. The associations between plasma mGSTP1 levels, PSA response (defined by PCWG1 criteria), and OS were tested using non-parametric tests and survival analyses.

**Results:** The ability to detect mGSTP1 was significantly higher for the plasma free DNA assay compared to DNA from CTCs ($p < 0.0001$), so for the remainder of the study the plasma free DNA assay was used. The phase I exploratory cohort identified that detectable mGSTP1 at CRPC presentation predicted for poorer OS (HR 4.2, 95% CI 2.1–8.2; $p < 0.0001$). In the 40 men treated with chemotherapy, a decrease in mGSTP1 levels after cycle one predicted a subsequent more than 50% decrease in PSA prior to cycle 4 ($p = 0.008$). The phase II validation cohort demonstrated that undetectable plasma mGSTP1 after one cycle of chemotherapy predicted for a clinical benefit from treatment (PR+SD vs. PD) ($p = 0.007$). Furthermore, an undetectable plasma mGSTP1 after one cycle of chemotherapy was a better predictor of death within 12 months than change in PSA after three months (AUC 0.87, 95% CI 0.77–0.98; $p = 0.006$).

**Conclusions:** We have identified plasma mGSTP1 levels as a potential prognostic marker in men with CRPC as well as a potential surrogate therapeutic efficacy marker for cytotoxic chemotherapy and validated these findings in an independent phase II cohort. Prospective phase III assessment of mGSTP1 as a biomarker of therapeutic response is now warranted.

abs#13

## MY ROAD AHEAD: PRELIMINARY RESULTS FROM A RANDOMISED CONTROLLED TRIAL OF AN ONLINE PSYCHOLOGICAL SUPPORT PROGRAM FOR MEN WITH PROSTATE CANCER

A. C. Wootten[1,2], J. M. Abbott[3], D. Austin[4], B. Klein[5], K. Chisholm[4], M. McCabe[4], D. Murphy[6,7], A. J. Costello[1,2,7]
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**Objective:** This study aimed to develop and assess the efficacy of a unique online psychological intervention that is accessible, user friendly and engaging to men with prostate cancer and that reduces the stigma of psychological distress in the context of prostate cancer.

**Methods:** My Road Ahead is an online CBT-based self-directed intervention which aims to provide experiential as well as information and psychoeducational material to men diagnosed with prostate cancer across a range of topic areas delivered across 6 modules. The topics explored include identifying emotions and feelings; an introduction to CBT and the role of thought processes and beliefs; communication; coping with physical changes; sexuality and masculinity; sexuality and intimacy and relationships; fear of recurrence and planning for the future.

Participants were randomly assigned to one of three (3) intervention arms. Group 1: online intervention, group 2: online intervention plus access to the moderated forum; Group 3: moderated forum only. Participants completed the DASS-21 (Lovibond & Lovibond, 1995), the Prostate Cancer-Related Quality of Life scale (PCa-QoL; Clark et al., 2003), the IIEF (Rosen et al., 1997), the Dyadic Sexual Communication Scale-short form (Catania, 1998), the Communication Pattern Questionnaire – Short Form (CPQ-SF; Christensen & Heavy, 1990) and the Kansas Martial Satisfaction Survey (Schumm, Nichols, Schectman & Grigsby,1985).

**Results:** Preliminary results will be presented and discussed. 144 patients were recruited and randomly assigned to the three groups. 63% of patients were referred by a doctor or other health professional and 13% were referred by a support group. The majority of men had undergone a radical prostatectomy (88%). There was a significant reduction in psychological distress for those participants who received the program and forum as compared to those who received the program or the forum alone. The impact of the program on QoL, relationship satisfaction and erectile functioning will be discussed as well as mediation and moderation effects.

**Conclusions:** This is the first randomized controlled trial to assess the efficacy of a self-directed online psychological intervention for men with prostate cancer that we are aware of. These preliminary results indicate that the intervention in combination with access to a moderated forum provides an effective program in reducing psychological distress. The anonymity of the online medium could also provide a forum for men to access appropriate support without fear of stigma that still surrounds psychological or emotional distress in the wider community.

abs#14

### TOXICITY-ADJUSTED DOSE (TAD) OF SUNITINIB GIVES LOW INTRA-PATIENT VARIATION OF TROUGH LEVELS: A LONGITUDINAL STUDY IN METASTATIC RENAL CELL CANCER (MRCC)

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**Background:** It has been proposed that trough levels of sunitinib + metabolite of >50 ng/mL may be associated with better anti-cancer effect. Large inter-patient variations of trough S have been reported in patients with mRCC at standard doses. However, little is known about the intra-patient variation of sunitinib levels over time.

**Methods:** Dose and schedule of sunitinib was adjusted to ensure grade 1 or 2 toxicity on >10 days (d) of each 42 d cycle. Trough levels of sunitinib and its active metabolite, N-desethyl-sunitinib (NdS) were determined by HPLC-mass spectrometry every 6 weeks. Total trough level (TTL) was defined as the sum of sunitinib + NdS. Pts achieving a TTL target of >50 ng/mL at stable dose were determined.

**Results:** 36 patients with mRCC received sunitinib for a median of 14.8 months (range 2 to 25 months) with doses ranging from 25 to 87.5 mg/day in the dose adjustment period. There was no correlation between dose and sunitinib trough level ($r = 0.10$; $P = NS$). However there was a positive correlation between dose and NdS level ($r = 0.40$; $P < 0.001$), and dose and TTL ($r = 0.31$; $P < 0.001$). The mean stable dose was 42.8 mg (range 25–75 mg) usually on a 14/7 schedule. Dose was significantly lower for females (34.7 vs 44.7 mg; $P = 0.05$). Between patients, TTL ranged from 3.61 to 190.8 ng/mL (mean 69.0 ng/mL, coefficient of variation 48.6%). In contrast, mean intra-patient variability of TTL in patients at stable dose was 16.2% (range 0.4% to 32.2%). 33/36 patients (91.2%) reached the target TTL > 50 ng/mL using the TAD protocol.

**Conclusion:** Using a novel TAD protocol over 90% of patients achieved the target TTL. This study demonstrates that individuals on stable dose had negligible variation in trough level over time and has implication for therapeutic drug monitoring. The study is ongoing to correlate TTL at stable dose with outcome.

abs#15

### PLANNING YOUR TRIAL – PROFORMAS FOR REPORTING CLINICAL TRIALS

V. Chalasani
*[1]University of Sydney, [2]ANZUP*

Writing a clinical trial report for publication is the culmination of a randomised controlled trial. Discovering at this stage that steps were not taken to ensure editorial requirements were met is often too late. This talk will summarize the mostly commonly recommended reporting guidelines.

abs#16

### CURRENT ISSUES IN PSYCHO-ONCOLOGY RESEARCH

S. Chambers
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Psycho-oncology has been described as one of the newest subspecialties of oncology. While definitions of what psycho-oncology research vary widely in emphasis, common elements include: the application of behavioural, psychological and social research to improve outcomes for cancer patients through cancer prevention and early detection; improving adherence to treatment and improving symptom control; improving psychological and quality of life outcomes for cancer patients and their families across the illness continuum. As in other specialty areas psycho-oncology researchers face challenges associated with dramatic increases in the cancer burden parallel with fiscal constraints and demands for translation of research into practice as evidence of social benefit from this investment. An exemplar of this issue is in the movement towards routine screening for distress and the implementation of psychosocial care in cancer on a population level. A brief summary of challenges ahead will be overviewed including the emerging chronic and non-communicable disease paradigm. Multidisciplinary trials groups will be of increasing importance in this context as a platform for psycho-oncology research.

abs#17

### EPIGENETIC REMODELING AND REPLICATION TIMING IN CANCER

S. J. Clark
*Epigenetics Program, Cancer Division, Garvan Institute of Medical Research, Darlinghurst, New South Wales, 2010, Australia*

Epigenetic deregulation is involved in cancer initiation and progression, but most studies have concentrated on gene repression and hypermethylation of tumour suppressor genes. Therefore the mechanism underpinning epigenetic-based gene activation in carcinogenesis is still poorly understood. We reported that epigenetic changes could occur over large domains, resulting in concordant gene repression by Long Range Epigenetic Silencing (LRES) and more recently we reported that concordant gene activation by Long Range Epigenetic Activation (LREA)1 of multiple adjacent genes also is common in cancer. By an integrative epigenome-wide sequencing analysis of prostate cancer and normal cells, we found the epigenetic deregulated domains are characterised by an exchange of active (H3K9ac and H3K4me3) chromatin marks, and repressive (H3K9me2 and H3K27me3) marks. Notably, whilst promoter hypomethylation did not often contribute to gene activation, extensive DNA hypermethylation of CpG islands or "CpG island borders" was strongly related to both gene repression and cancer-specific gene activation or a change in promoter usage. We also found that the epigenetic deregulated domains change in the replication timing in cancer, with a clear shift to late replication in LRES regions and conversely early replication in LREA regions. These findings have wide ramifications for cancer diagnosis, progression and epigenetic-based gene therapies.

(1) Bert SA, Robinson MD, Strbenac D, Statham AL, Song JZ, Hulf T, Sutherland RL, Coolen MW, Stirzaker C, Clark SJ. Regional Activation of the Cancer Genome by Long Range Epigenetic Remodelling (2013) Cancer Cell 23: 9–21

abs#18

### BIOMARKERS: MAKING SENSE OF RISK, PROGNOSTIC, PREDICTIVE AND OTHER PERPLEXING FACTORS

M. Stockler[1], S. Yip[1]
*[1]NHMRC Clinical Trials Centre, Camperdown, NSW, Australia*

Clinical studies frequently include the assessment of biomarkers as possible risk, prognostic and predictive factors. The purpose of this short presentation is to help clinicians and researchers make sense of this confusing area by providing definitions, explanations, and aids to the analysis and interpretation of such studies.

A biomarker is a characteristic that can be measured as an indicator of: normal or pathological biological processes; the likelihood of developing a disease or specific outcomes; or, the likelihood of a response to treatment. A risk factor is a characteristic associated either with the likelihood of developing a disease, or with the likelihood of suffering an adverse outcome of the disease. A prognostic factor is a characteristic that is associated with the

 

outcome of a disease, independent of its treatment, for example Gleason score and nodal status in early prostate cancer. A predictive factor is a characteristic that is associated with the response to a particular treatment, for example HER2 status in breast cancer.

There are many sources of confusion. Biomarkers can be prognostic and/or predictive, and the prognostic and predictive effects can be in the same direction, or in opposite directions. For example, HER2 positivity is associated with shorter survival in women with breast cancer who are not treated with anti-HER2 therapy. But HER2 positivity is predictive of a response, and longer survival, with anti-HER2 therapy.

A statistical interaction is when the effect of one thing (e.g. a treatment) depends on the effect of another thing (e.g. a biomarker). For example the effect of trastuzumab depends on HER2 status. Analyses of predictive factors, and of subgroups in clinical trials, are best understood as assessments for interactions between the effect of the factor and the effect of the treatment.

abs#19

## IMPROVING OUTCOMES: WHAT ARE WE MISSING IN TRIALS

T. Wiseman
*The Royal Marsden NHS Foundation Trust, London UK*

The importance of clinical trials to the knowledge of cancer and progress of treatments is widely accepted. Cancer trial participants have access to the latest drugs, procedures, and other types of treatment. If a new treatment is effective, patients in clinical trials are among the first to receive it. Translational research stresses the importance of from the bench to the bedside. Yet, in addition to knowing the outcomes of a trial (that is treatment efficacy, safety, and health economics), it is important to consider the experiences of participants receiving the treatment and the impact on the person and their family. Health service research alongside translational research offers the opportunity to not just consider from the bench to the bedside but also from the bedside and beyond. Historically, although the importance of patient experience is recognised to an extent within clinical trials, efforts to capture such impact have been restricted to Quality of Life tools. Qualitative approaches incorporated within the trial provide an opportunity to generate more detailed and in-depth insights into patient experience. There are a number of empirical studies that demonstrate how incorporating a qualitative element within the trial can improve the design and running of the trial. Areas of particular interest could include: delays in diagnosis and seeking treatment, uptake and adherence to trials, overall experience of the trial treatment and living and beyond the trial.

abs#20

## RETURNING TO IMMUNOTHERAPY IN KIDNEY CANCER

C. Kollmannsberger
*Div. of Medical Oncology, Dept. of Medicine, University of British Columbia, British Columbia Cancer Agency, Vancouver, BC Canada*

Prior to the development of targeted therapies, immunotherapy with interleukin-2 (IL-2) and interferon-a (IFN-a) was the standard of care in patients with advanced RCC. The benefit from treatment with these agents is modest in a small number of patients but HD-IL-2 remains one of the only treatments capable of curing advanced disease in a very highly selected population. Treatment with IFN-a and in particular with HD-IL-2 is associated with substantial toxicities and with the advent of targeted agents, the use of immunotherapy with IFN-a and HD-IL-2 has been greatly declining.

Despite the substantial improvement in outcomes with targeted therapies, durable or complete remissions are rare and almost all patients ultimately develop resistance and disease progression.

Increasing insight into the complex mechanisms of immune response have let to the development and exploration of a number of novel immunotherapy agents includingamongst others antibodies against immune checkpoint proteins that block downregulation of effector T cells (eg, programmed death-1 and cytotoxic T-lymphocyte antigen-4), inhibit tumor-induced immunosuppression (eg, trans- forming growth factor-beta [TGF-β] antibody, programmed death ligand 1 [PD-L1] antibody), more specifically activate T cells (eg, CD137anti- body, IL-21), and several novel vaccines including genetically modified tumor vaccines, DC-based vaccines, autologous tumor-cell vaccines, and peptide-based vaccines (e.g. IMA901; AGS-003).

Clinical experience thus far is limited but very promising results have been reported in early clinical studies and a number of large randomized trials are now underway.

The CTLA-4 antibody ipilimumab demonstrated objective tumor responses in a phase II study in metastatic patients but also significant toxicities. The PD-1/PD-L1 pathway is one of the most critical pathways in RCC and responsible for tumor-induced immune suppression. Kidney cancers that express PD-L1 have a worse prognosis. Ten of 34 heavily pretreated RCC patients treated in a larger phase I trial experienced objective tumor responses and nine other patients had stable disease that lasted at least 24 weeks. Five patients remained progression free for 1 year and one patient had a complete remission. Of note, significantly more patients with PD-L1 positive tumors responded compared to PD-L1 negative patients. Side effects appeared acceptable, although 3 patients in the entire phase I patient cohort died of pulmonary complications.

Many questions remain regarding how to best integrate these agents into current treatment patters, how to best utilize these agents, and whether to combine them with targeted to give these drugs. Theoretically, the best effect with immunotherapy should be achievable when used early when the immune system has not yet been impacted by therapy and in a situation of minimal disease burden, e.g. in the adjuvant setting.

abs#21

## ROBOTIC PARTIAL NEPHRECTOMY – TECHNIQUE, OUTCOMES AND THE FUTURE

D. Pan
*Monash Medical Centre, Austin Health in Victoria*

Robotic partial nephrectomy RPN is an established and safe option for patients undergoing nephron sparing surgery NSS. The intraoperative and perioperative outcomes of RPN will be discussed and compared to laparoscopic partial nephrectomy. As the technique matures, reduction in warm ischaemia time can be achieved without compromising oncological efficacy.

abs#22

## MINIMALLY INVASIVE TREATMENTS FOR PRIMARY RCC

N. Brook
*Royal Adelaide Hospital, Thorngate, SA, Australia*

Standard treatment of localised kidney cancer is with partial or radical nephrectomy, with minimally invasive ablative techniques reserved as a 'Plan B' if established treatments cannot be used in unfit patients. The technology has been available for many years, but uptake and utilization is low. This session will discuss results of cryo-, radiofrequency- and microwave – ablation, and summarise an exciting newcomer to the scene, Stereotactic Ablative Body Radiotherapy (SABR), currently undergoing clinical study in Australia.

abs#23

## FUTURE DIRECTIONS IN THE TREATMENT OF BLADDER CANCER

K. Sridhar
*Princess Margaret Cancer Center, GU Medical Oncology Site Group Head, Assistant Professor, University of Toronto*

Bladder cancer is the 4th most common malignancy in American men and the 9th most common in women. Unlike other genitourinary cancers such as

 

prostate and kidney cancer, there has been limited progress in this disease over the last three decades. In this talk I will provide an overview of the current management of bladder cancer by stage; strategies used to improve outcomes; and discuss planned or ongoing clinical trials of novel targeted therapies.

abs#24

## LIVING WITH BLADDER CANCER AND THE CONSEQUENCES

A. Clarke
*WA Cancer & Palliative Care Network, Perth, WA, Australia*

**Background:** Worldwide Bladder Cancer Incidence is estimated at over 12 million new cases[1]. In WA alone there was an incidence of 285 with 104 deaths; making it the 6th most commonly diagnosed cancer in males.[2]

It is estimated that 70–80% of cases present with Non-muscle Invasive Bladder Cancer however 50–70% who have treatment can experience cancer recurrence with 10–30% progressing to Muscle Invasive disease.[3]

The treatments available for both Non-muscle and Muscle Invasive bladder cancer are effective at managing this disease however these therapies come with physical, psychosocial and psychosexual impacts. This presentation will highlight and discuss common sequelae associated with treatment from a nursing perspective.

**Aim:** To provide a 20 minute presentation on the given topic of "Living with Bladder Cancer and the consequences.

### References

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3. Jacobs BL, et al. (2010). CA: Cancer J Clin, 60(4); 244–72. doi:10.3322/caac.20077

abs#25

## TAKING NEW TECHNOLOGIES FROM THE FACTORY TO THE FRONTLINE – EXPERIENCES FROM THE TROG COOPERATIVE TRIALS GROUP

T. Kron
*Peter MacCallum Cancer Centre, Department of Physical Sciences,East Melbourne*

Radiation Oncology is a cancer treatment modality that relies heavily on technology for tumour delineation as well as daily radiation delivery. In recent years many different technical solutions for similar problems have been proposed and it is difficult to identify which technologies should be pursued for what patients and at what cost. Clinical trials play an important role in the introduction of technology as they help to:
– define the technology in the first place
– clearly identify a patient group in which it will be applied
– prospectively determine the benefit that ought to be expected and
– determine the cost and resources required to implement the technology.
The presentation will illustrate these concepts in the context of clinical trials of stereotactic ablative radiotherapy and adaptive radiotherapy for bladder cancer with particular emphasis on taking technological solutions from a single institution to the broader community in multicentre trials.

 

# POSTER ABSTRACTS

abs#100

## A GLOBAL PERSPECTIVE ON TRUS BIOPSY SEPSIS

E. Anderson[1], A. Cheng[2], J. Grummet
[1]*Monash University, Melbourne,* [2]*Alfred Health, Melbourne*

**Objective:** In response to increasing rates of sepsis following TRUS biopsies there have been recent concerns regarding the standard of fluoroquinolone antibiotic prophylaxis. Our objective was to assess the worldwide prevalence and trend of infectious complications, as well as their prevention and possible risk factors.

**Methods:** A literature review was performed using the electronic databases, Central, Embase and Medline. The search terms used were "Transrectal, prostate, biopsy, infection, sepsis, risk-factors, complications" from 2005 until present. Studies were rated for quality.

**Results:** Increasing infectious complications following TRUS biopsy have been reported in North America and Europe. Current prevalence rates of sepsis vary from 0–6.3%, with an average of 2.32%. Patient, procedure and outcome risk factors for infection have been investigated and significant risk factors include: endogenous fluoroquinolone-resistant rectal flora, recent antibiotic use and recent overseas travel. Fluoroquinolone-resistant rectal flora is increasingly identified as serogroup O25b-ST131 E.coli. This organism easily disseminates and is highly resistant, highly virulent and evolving, with a carbapenem-resistant isolate recently identified. Three strategies to neutralize this risk are described: 1) Antibiotic prophylaxis based on geographical antibiotic resistance patterns 2) Pre-biopsy rectal swab enabling "tailored" antibiotic prophylaxis 3) Transperineal prostate biopsy. All procedures have reported sepsis rates lower than the standard fluoroquinolone prophylaxis average.

**Conclusion:** The rate of infectious complications following TRUS biopsy is increasing. A number of significant risk factors have been identified and should be considered in clinical practice. As ST131 E.Coli becomes more prevalent, standard fluoroquinolone prophylaxis becomes less effective. An alternative prophylaxis strategy or biopsy approach is therefore advisable.

abs#101

## COMPARISON OF TWO NOVEL METHODS OF TRUS BIOPSY ANALGESIA: METHOXYFLURANE ALONE VERSUS METHOXYFLURANE PLUS LOCAL ANAESTHETIC INFILTRATION

W. L. Ong[1,2], S. Huang[1], E. Anderson[3], L. Pepdjonovic[4], A. Konstantantos[1,5], M. Frydenberg[4,6,7], J. Grummet[1,4,7]
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**Introduction & Objectives**
- Transrectal ultrasound guided (TRUS) biopsy of the prostate is well-recognized as a potential source of pain and distress for patients
- Currently, peri-prostatic infiltration of local anaesthetic (PILA) is described as the 'gold standard' of analgesia for TRUS biopsy
- However, this technique is not widely practised in Australia and NZ. Our survey in 2012 showed that less than 27% of urologists in our region reported using PILA alone as analgesia for TRUS biopsies
- As the resource-intensive transperineal biopsy approach continues to gain momentum, the search continues for an improved analgesic method for TRUS biopsy that does not require the use of the operating theatre.
- Recently, we reported a safe and feasible novel methods of analgesia for TRUS using only the inhaled methoxyflurane (PenthroxTM) – the 'green whistle'
- In this study we aimed to compare patient-reported analgesia of methoxyflurane alone versus methoxyflurane with PILA for TRUS biopsy

**Methods**
- Two consecutive series of patients who underwent TRUS biopsy at a Victorian regional hospital from August 2010 to August 2013 were included
- All patients were provided with, and instructed on the use of, a Penthrox inhaler (3 mL methoxyflurane) immediately prior to TRUS biopsy
- For patients in the combination analgesia group, 2.5 ml of 2% of lignocaine was also injected into the junction of prostate base and seminal vesicle bilaterally using a 23 G needle (total 5 ml)
- Immediately following the TRUS biopsy, the overall pain of the procedure was assessed using the verbal rating scale, with 0 being no pain and 10 being the worst pain imaginable
- Student t-test (or Wilcoxon rank-sum test as appropriate) was used to compare characteristics and pain scores between the two groups

**Results**
- 72 patients underwent TRUS prostate biopsy during the study period, of which the first 42 had methoxyflurane alone (Group 1) while the following 30 had a combination of methoxyflurane plus PILA (Group 2)
- Patients in Group 1 reported a mean pain score of 3.7 (± 2.3) while patients in Group 2 reported a statistically significantly lower mean pain score of 2.3 (± 2.0) (P = 0.008)
- All patients in both groups reported that they would be happy to undergo the same procedure again

**Conclusions**
- Whilst methoxyflurane alone appeared to provide safe and promising control for TRUS biopsy, in this small initial comparative experience, the combination of methoxyflurane plus PILA provided significantly better analgesic control
- Planning for a multi-centre double-blind randomized controlled trial comparing methoxyflurane plus PILA versus PILA alone for TRUS biopsy analgesia is presently underway

abs#102

## THE STATE OF TRUS BIOPSY SEPSIS. READMISSIONS TO VICTORIAN HOSPITALS WITH TRUS BIOPSY-RELATED INFECTION OVER 5 YEARS

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**Introduction & Objectives:** The incidence of infectious complications following trans-rectal prostatic biopsy is reported to be increasing, which may be attributed to a rise in resistant organisms. This retrospective observational study aimed to describe the burden of biopsy-related infections requiring hospital admission in the state of Victoria.

**Method:** The Department of Health's Victorian Admitted Episodes Data Set was used to identify those patients who underwent TRUS biopsy in Victoria who were subsequently readmitted within 7 days to any Victorian hospital with infective complications from July 2007 to June 2012. All Victorian public and private hospitals were included. Patients were excluded if their biopsy was performed during a multi-day admission. Length of stay (LOS), ICU admission and mortality were noted. Linear regression analysis was performed to assess for a significant trend in sepsis rates over the 5 years. Institutional ethics committee approval was granted for this study.

**Results:** 34,865 TRUS biopsies were performed in the 5-year period. 1276 (3.66%) were readmitted to a Victorian hospital within 7 days. 604 (1.73%) of these were readmitted with a biopsy-related infection. No significant trend in sepsis rates was seen in five years. The median readmission LOS was 4 days. The total burden of readmission was 3,686 days

over 5 years. 38 (0.11%) required ICU admission, with a median ICU stay of 37 hours. One patient readmitted with a biopsy related infection died during that episode of care. 20,051 (57.51%) of biopsies resulted in a diagnosis of prostate cancer.

**Conclusions:** Infection following TRUS biopsy required hospital admission in 1.73% of cases with a total burden of 3,686 admission days. The incidence was stable over the period examined.

abs#103

### IMPROVING PATIENT OUTCOMES IN ROBOTIC PROSTATECTOMY PATIENTS USING A NURSE-LED CLINIC

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**Background:** The robotic prostatectomy clinic (RoCaP) at Peter MacCallum Cancer Centre (Peter Mac) is designed to provide a forum for men and their families to receive information, basic anatomy and the impact surgery will have on their urinary, sexual and psychological health. This is led by a Robotic Surgery Nurse Coordinator and invloves the multidisciplinary team: Urologist, Nurse Practitioner, Physiotherapist and Psychologist. RoCaP clinic's aim is to decrease anxiety levels and manage expectations of outcomes.

**Method:** Between May 2012 and August 2013, 74 patients attended RoCaP and completed the evaluation questionnaire. All questions were completed on a five-point scale with high scores indicating more severe symptoms or greater satisfaction. Patients scoring 4 or 5 were defined as having "high" symptoms or satisfaction.

**Results:** No patient indicated that they did not feel well supported once referred to Peter Mac. On diagnosis, 52.7% of men indicated that they had a high level of anxiety with 70.3% of men saying that the RoCaP clinic decreased their anxiety. In addition, 89.2% felt well supported by the nurse telephone calls the day after the operation and 81.1% of patients felt that the RoCaP clinic was useful as part of their prostate cancer treatment pathway.

**Conclusion:** The RoCaP clinic is a useful tool for managing patient expectations and decreasing anxiety following their robotic prostatectomy.

abs#104

### E-TC: DEVELOPMENT AND PILOT TESTING OF A WEB-BASED INTERVENTION TO REDUCE ANXIETY AND DEPRESSION IN SURVIVORS OF TESTICULAR CANCER

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**Background:** Despite a good prognosis, many testicular cancer (TC) survivors report anxiety, depression and unmet needs in the longer term[1]. Many barriers to seeking support, such as stigma, inconvenience and cost[2], may be overcome using online interventions, which have been effectively utilised in other settings and patient groups[3].

**Aim:** To develop and pilot test e-TC, a tailored, online psychosocial intervention targeting anxiety and depression in testicular cancer survivors.

**Method:** e-TC incorporates psychoeducational, cognitive-behavioural and metacognitive approaches based on evidence-based clinical therapies, psychosocial interventions for cancer patients and survivors, and expert advice. The intervention is tailored based on participants' goals in using e-TC, relationship status and current physical concerns. A panel of expert advisers, including consumers and ANZUP clinicians, was involved in an iterative feedback process throughout development of e-TC. The pilot study will assess feasibility of, and satisfaction with, e-TC in 40 TC survivors who completed active treatment 6 months-5 years ago. Participants will use e-TC for up to 10 weeks and provide feedback on the utility, comprehensiveness, relevance, simplicity and length of each module and the intervention as a whole. At baseline, participants will complete demographic and disease-related questions, the QLQ-TC26 (quality of life)[4], Distress and Impact thermometers (DIT)[5], the Hospital Anxiety and Depression Scale (HADS)[6], the Fear of Recurrence Scale (FRS)[7], the Duke Social Support scale (DSS)[8], and the Casun unmet needs scale (CASUN)[9]. The DIT and HADS will be repeated throughout the intervention. Post-intervention, participants will complete the QLQ-TC26, HADS, FRS and CASUN.

**Feasibility and acceptability outcomes:** 1) proportion of e-TC completed and 2) satisfaction with e-TC. Qualitative interviews with ten randomly chosen participants will be conducted and content-analysed to describe the attitudes and experiences of men using e-TC.

A detailed overview of e-TC, up-to-date pilot study data and intervention feedback will be reported.

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abs#105

### PATIENT-DERIVED XENOGRAFTING IDENTIFIES CASTRATE-TOLERANT STEM CELLS THAT RESIDE IN LOCALISED PROSTATE CANCER SPECIMENS

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Prostate cancer is a heterogeneous disease and it is proposed that the subpopulation of cancer cells that survive androgen deprivation possess a lethal phenotype. Identifying the unique biological characteristics of these cells that reside in the primary cancer lesion is essential to determine their role in tumour progression and susceptibility to novel therapeutic agents. We recently identified a population of castrate-tolerant cancer cells that

 

'pre-exist' in prostate cancer specimens using patient-derived xenografts (PDX). We hypothesised that the castrate-tolerant cells represent a select clone that evades treatment without the need to evolve under this selective pressure. To test this, we established PDX of human primary specimens from 3 men with localised (Gleason 7) prostate cancer. For each patient, we performed a series of grafts to compare the role of castrate-tolerant cells in regenerating tumours following testosterone (T) replacement. Similar to previous studies, the castrate-tolerant cancer cells from all patients expressed stem cell markers including Oct-4, Sox2, NANOG and ALDH1, and possessed regenerative potential based on their ability to repopulate tumours with re-administration of testosterone. Using immunohistochemistry, we showed that the localisation and expression of PTEN, FoxA1, ERG and p21 were similar in T-restored grafts compared to intact controls, indicating that the castrate-tolerant stem cells faithfully repopulate the original tumour. We are now using laser capture microdissection to subject the same tumours to expression profiling by DNA copy number analysis to determine whether the same molecular signature can be detected in intact and T-restored tumours. In summary, this ongoing study is identifying biomarker and molecular profiles of castrate-tolerant prostate cancer cells that exist in untreated localised disease, survive androgen withdrawal and are potential therapeutic targets. Specific eradication of these regenerative stem-like tumour cells that evade castration therapy could improve patient survival.

abs#106

## PATTERNS OF CARE IN AUSTRALIAN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA (MRCC)

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**Aim:** Large registration trials have demonstrated that sunitinib provides significant clinical benefits for mRCC patients. It remains unclear how these benefits translate in the Australian context. This observational, retrospective study examines patterns of care and survival benefits associated with sunitinib use in Australian mRCC patients.

**Methods:** Patients with mRCC diagnosed between 2006–2012 were identified from four hospitals in Victoria and ACT. Demographics, clinicopathologic features, treatment data and survival data were recorded by chart review. Detailed data regarding sunitinib dosage and toxicity were also recorded. Descriptive statistics were used to report findings. Survival was estimated by the Kaplan-Meier method and compared using log-rank test. Although, the project was supported by a grant from Pfizer Australia, Pfizer has not been involved in the interpretation and reporting of the data.

**Results:** Our study identified 212 mRCC patients for analysis. Patients predominantly had mRCC of clear cell histology (75%), ECOG performance status 0–1 (67%) and favourable/intermediate MSKCC risk (68%). 163 (77%) patients received first-line systemic therapy, while 49 (23%) received best supportive care (BSC). The most frequently used first-line treatment was sunitinib (n = 125, 77%). Most patients (80%) started at 50 mg daily on a 4-weeks-on/2–weeks-off schedule (79%); 42% required dose reductions. Median time on sunitinib was 8.9 months. Patients receiving sunitinib had superior overall survival (OS) compared to BSC (median 27.6 mo versus 7.9 mo, $p = 0.03$). Our data also validated the MSKCC risk classification, stratifying OS for favourable, intermediate and poor risk groups in patients who received first-line sunitinib (median 56.3 mo; 23.8 mo; 7.7 mo, $p < 0.0001$).

**Conclusion:** Our study confirms that a high proportion of Australian mRCC patients in this cohort received sunitinib, typically delivered at standard doses and schedule. Our survival analyses suggest outcomes reported in clinical trials can be reproduced in an Australian mRCC population.

abs#107

## GALLIUM-68 NANOCOLLOID PET/CT FOR IDENTIFICATION OF SENTINEL LYMPH NODES IN PROSTATE CANCER – FIRST IN-MAN FINDINGS

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**Aims:** To use high resolution PET/CT imaging to identify pathways of prostate cancer metastasis. To contribute to evidence for rational treatment of pelvic lymph nodes in high risk prostate cancer.

**Method:** This is a pilot study to assess feasibility of using a novel gallium-68 nanocolloid tracer to identify sentinel lymph nodes and other potential pathways of spread in prostate cancer. Participants: Men who require gold fiducial placement for radiation therapy to the prostate. The tracer is injected intra-prostatically at time of gold fiducial implantation using trans-rectal ultrasound and template guidance. The first three participants were administered the standard technetium-99m nanocolloid tracer and underwent SPECT/CT imaging to allow optimisation of technique. The latter participants were studied with the novel PET tracer.

**Results:** The first three cases using technetium provided results similar to those previously described[1, 2] and allowed the dose, timing and injection technique to be refined before using the gallium-68 radiotracer. Following intra-prostatic injection of gallium-68 nanocolloid, the first patient has been successfully imaged. PET/CT was successful in identification of sentinel lymph nodes.

**Conclusion:** A novel gallium-68 nanocolloid has been developed and used for in-human evaluation of lymph node drainage in patients with prostate cancer. PET/CT imaging to assess pathways of metastatic spread is achievable and may contribute new information regarding the behavior of prostate cancer.

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abs#108

## SURVIVAL OUTCOMES FOR MEN WITH CASTRATE-RESISTANT PROSTATE CANCER (CRPC) TREATED WITH A DENDRITIC-CELL BASED VACCINE IN A RANDOMIZED CONTROLLED TRIAL

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**Introduction & Objectives:** Between 2000 and 2007, we undertook a randomised controlled study of men with CRPC receiving androgen deprivation therapy (ADT) with biochemical escape in the absence CT or bone scan evidence of metastases to compare intravenous and intradermal delivery of peptide vaccine.

**Methods:** Ineligibility criteria included previous radical prostatectomy, prostatic radiotherapy and a HLA-A2 negative phenotype. Vaccines were prepared using prostate-specific membrane antigen (PSMA) peptides to prime the patients' own monocyte-derived dendritic cells (DCs).

Eligible patients were randomised to receive vaccine IV (with placebo ID), vaccine ID (with placebo IV) or placebo IV and ID 4 weekly for 28 weeks to determine the more effective route of delivery. Men randomised to placebo both IV *and* ID were offered vaccine (IV *or* ID after re-randomization) at 28 weeks if still eligible.

Prostatic biopsies were performed at baseline and 6 months to evaluate vaccination effects on the primary tumour.

**Results:**

| Age | Randomised treatment | Initial PSA | PSA d'bling time: entry & 6 months | | Months to metastases | Months to death |
|---|---|---|---|---|---|---|
| 81 | IV | 13 | 3.2 | 2.5 | 9 | 20 |
| 75 | IV | 57 | 13.4 | 9.9 | 6 | 77 |
| 74 | IV | 17 | 1.92 | 13.3 | 6 | 6 |
| 73 | IV | 12 | 5.8 | 2.7 | – | 5 CVA |
| 71 | IV | 9.6 | 6.3 | 8.6 | 6 | 35 |
| 72 | IV | 20 | 7.2 | 3.3 | 6 | 31 |
| 56 | Placebo | 5.8 | 7.2 | 7.7 | 32 | 89 Alive |
| | IV | 7.6 | 7.3 | | | |
| 74 | IV | 6.4 | 4.1 | 2.9 | – | 13 CVA |
| 74 | ID | 25.3 | 14.2 | 10.6 | 36 | 46 |
| 79 | Placebo | 20 | 3.1 | 4.7 | 6 | 18 |
| | ID | 80 | 3.7 | | | |
| 70 | ID | 12 | 20.7 | 9.8 | 92 | 158 |
| 83 | Placebo | 24 | 2.6 | 6.5 | 6 | 32 |
| 84 | ID | 91 | 4.2 | | | |
| 73 | ID | 11 | 1.6 | 2.5 | 6 | 24 |
| 80 | Placebo | 11 | 49.2 | 10.7 | 27 | 39 melanoma |
| | ID | 10 | –17.1 | | | |
| 85 | ID | 13 | 4.2 | 4.2 | 6 | 10 |
| 77 | ID | 31 | 6.8 | 5.3 | 12 | 49 |
| 81 | Placebo | 61 | 1.8 | 1.5 | 6 | 17 |

**Conclusions:** Although these results do not provide a clear indication of which was the better mode for delivering this DC vaccine , they indicate that patients with sub-terminal prostate cancer were prepared to be randomised in a placebo controlled trial for this very-well tolerated therapy and that, notwithstanding the variable natural history of CRPC, some patients lived for exceptionally long periods before their demise.

abs#109

## MESENCHYMAL DIFFERENTIATION PROGRAMS GOVERN VHL-MUTANT CLEAR CELL RENAL CANCER BIOLOGY

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**Background:** Cancers are internally heterogeneous. Epigenetic heterogeneity has been modeled as epithelial-mesenchymal transition (EMT), phenotypic plasticity or hierarchically in terms of the cancer stem cell (CSC) hypothesis. To examine heterogeneity in clear cell renal cell carcinoma (ccRCC) one must account for all stromal non-malignant cell populations within the tumour. The existence of CSC in ccRCC has not been examined in *ex vivo* patient samples.

**Methods:** We established reproducible procedures to procure and process patient RCC samples to generate viable single cell suspensions. We used multiplex flow cytometry (FC) to reliably identify and isolate tumour cell and stromal cell subpopulations including CD45+ immune and CD31+/CD144+ endothelial cells. Using CD34 and a cell surface fibroblast marker (FBM) we were also able to identify cancer-associated fibroblasts (CAF), leaving presumed lineage negative ($LIN^{neg}$) ccRCC tumour cells. Immunofluorescence (IF), high-throughput FC (HT-FC), FC cell sorting (FACS) and functional assays were used to examine and characterize cell populations. Targeted re-sequencing of patient-specific *VHL* mutations, and copy-number variation (CNV) analysis by Cytoscan® HD arrays were used to identify malignant and non-malignant cell populations.

**Results:** FC and HT-FC identified clearly defined immune, endothelial and CAF populations, but also revealed a population of $CD34^{neg}FBM+$ positive cells in all ccRCC patients' samples. This $CD34^{neg}FBM+$ population demonstrated a phenotype intermediate between CAF and $LIN^{neg}$ tumour cells, and specifically expressed multiple mesenchymal markers including CD49f, CD90, CD146, and very weakly, CD105. Both $LIN^{neg}$ and $CD34^{neg}FBM+$ cells strongly expressed ccRCC markers including cytokeratin, vimentin, CD10 and CAIX. 12/18 patient tumor samples tested had *VHL* exome mutations. Targeted re-sequencing of FC sorted subpopulations from these patients' samples revealed that while CD45+, CD31+/CD144+ and CD34+FBM+ cells were genetically normal, $CD34^{neg}FBM+$ positive cells were predominantly *VHL*-mutant in every patient's tumour, while $LIN^{neg}$ cells were reliably *VHL*-mutant. CNV analysis of separated cell populations from 6 *VHL*-null patients showed essentially identical copy-number changes in $LIN^{neg}$ and $CD34^{neg}FBM+$ cells. IF showed that $CD34^{neg}FBM+$ cells tended to be closer to blood vessels than $LIN^{neg}$ cells, and expressed cytokeratin and PAX8. Freshly isolated $LIN^{neg}$ cells demonstrated abnormal morphology with clear cell differentiation while $CD34^{neg}FBM+$ cells appeared more fibroblastic, but also developed some clear cell morphology after culture *in vitro*. Established RCC cell lines could be induced to undergo adipogenic differentiation under 'replete' cell culture conditions, and conversely could be induced to de-differentiate to a more fibroblastic morphology, phenotype, and function under 'starvation' conditions. Sorted *ex vivo* $CD34^{neg}FBM+$ *VHL*-mutant cells showed higher expression of Ki-67, proliferated extensively in mesenchymal culture conditions, were tumorigenic, showed enhanced motility, migration, transendothelial invasion and non-adherent clonogenicity *in vitro*, and secreted pro-angiogenic and immunoregulatory cytokines compared to $LIN^{neg}$*VHL*-mutant tumor cells.

**Conclusions:** We demonstrate that ccRCC tumour cells exhibit a spectrum of mesenchymal phenotypes, with a previously unappreciated population of de-differentiated $CD34^{neg}FBM+$*VHL*-mutant cells present in every patient studied. These more fibroblastic tumour cells show enhanced migration, invasion, proliferation and angiogenic properties. This spectrum of phenotypes suggests a mesenchymal differentiation program in ccRCC, with implications for the classification and treatment of *VHL*-mutant renal cancer.

abs#110

## COMPLIANCE OF MALES WITH STAGE 1 TESTICULAR GERM CELL TUMOURS (TGCT) ON AN ACTIVE SURVEILLANCE (AS) PROTOCOL

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**Background:** Management options for stage I TGCT after orchidectomy include AS or adjuvant therapy. Recurrence rates on AS are about 50% for high-risk non-seminoma, 20% for low-risk non-seminoma, and 17% for seminoma; and after adjuvant therapy about 5%. AS is preferred in our institution on basis of reduced toxicity for most and equivalent survival, but requires excellent compliance to avoid late detection of recurrence.

**Aim:** To determine compliance of males with stage 1 TGCT on an active surveillance protocol. Methods: In this retrospective study, we determined compliance with local histology-specific AS protocols incorporating a defined schedule of visits, amongst all males age 18 or older presenting to a large Sydney tertiary referral hospital with a new diagnosis of stage 1 TGCT managed with AS between 2009 and 2012. Patients failing to attend appointments were contacted by letter +/– clinician phone call. Adequate

 

protocol compliance was defined as attendance at all visits, with ≤1 later than 4 weeks after the scheduled appointment.

**Results:** 57 of 75 patients (76%) with stage 1 TGCT were managed with AS. Median follow up was 24 months (range 2–54). Eleven patients (19%) relapsed, none between protocol visits. 46 (81%) had adequate protocol compliance. Seven (12%) were lost to follow up, two after less than 6 months, with none known to have relapsed. Four (7%) missed ≥1 appointment. In addition, six (11%) were more than 4 weeks late to one visit. Compliance rates varied by subgroups including non-seminoma (20/27,74%), seminoma (26/30,87%), age <30 (23/26,88%), age >30 (23/31,74%).

**Conclusion:** Active surveillance is a viable option for males with stage 1 TGCT, but requires efforts to maintain adequate compliance with follow-up. We recommend tracking compliance, clinician phone calls for non-attenders, and research into the utility of novel nurse-led and web-based AS protocols.

abs#111

## SUNITINIB THERAPY FOR METASTATIC RENAL CELL CARCINOMA (MRCC) IN ELDERLY PATIENTS (AGE 70 AND OVER): A MULTI-INSTITUTIONAL AUSTRALIAN EXPERIENCE

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**Aim:** Elderly patients with mRCC treated with sunitinib in prospective trials derived survival benefits comparable to younger patients with acceptable tolerability [1]. We compared the usage and outcome of sunitinib between mRCC patients aged <70 yo and ≥70 yo treated in five Australian centres.

**Methods:** mRCC patients from hospitals across Victoria and ACT diagnosed between 2006–2012 were studied retrospectively. Patients <70 yo and ≥70 yo were compared with regards to demographics, clinicopathologic features, treatment and survival, as estimated by the Kaplan-Meier method. Median time on first line sunitinib was used as a surrogate for progression free survival (PFS). Survival differences between groups were compared using the log-rank test.

**Results:** The cohort of 212 patients included 50 (24%) ≥ 70 yo. There were no significant differences in baseline characteristics including predominance of clear cell histology (60%), ECOG < 2 (52%) and favourable/intermediate MSKCC risk (66%), compared with <70 yo patients. Elderly patients were more likely to receive best supportive care only compared with younger patients (46% vs 16%, $p < 0.0001$). Of those who received systemic therapy most received sunitinib (n = 20, 74%). More elderly patients commenced at an attenuated dosage of 25 mg or 37.5 mg/day than younger patients (6/20, 30% vs 8/105, 8%, $p = 0.0261$), with the majority (75%) on a 4 weeks on, 2 weeks off schedule. Dose reductions were required more frequently in ≥70 yo than <70 yo (9/20, 45% versus 34/105, 32%, p = NS). Median PFS was similar between <70 and ≥70 yo patients on sunitinib (7.80 m vs 10 m, $p = 1.0$) whilst overall survival was also similar (28 m vs 33 m, $p = 0.5$). Our observed survival is similar to that observed for elderly patients from clinical trials (median PFS 11 m, median OS 25.6 m) [1].

**Conclusion:** Elderly patients were more likely to be treated with a lower dose intensity of sunitinib, however, survival outcome does not appear to be inferior to younger patients.

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**Acknowledgements:** Data analysis was conducted by BioGrid Australia. The project was supported by a grant from Pfizer Australia.

abs#112

## INTRAVESICAL GEMCITABINE VERSUS INTRAVESICAL BACILLUS CALMETTE-GUÉRIN FOR THE TREATMENT OF NON-MUSCLE INVASIVE BLADDER CANCER: AN EVALUATION OF EFFICACY AND TOLERANCE

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**Background:** A considerable proportion of patients with non-muscle invasive bladder cancer (NMIBC) experience disease recurrence after tumour resection. Adjuvant intravesical Bacillus Calmette-Guérin (BCG) and gemcitabine (GEM) had both been found to be superior than mitomycin C in prolonging disease-free survival. To date there has not been any randomised controlled trial (RCT) comparing the efficacy and tolerance between BCG and GEM.

**Methods:** A retrospective review of patients with NMIBC treated with intravesical BCG or GEM at The Canberra Hospital during 2010 to 2013 was performed. The aim of the study was to compare the efficacy (measured by disease-free survival and 2-year recurrence rate) and tolerability (measured by incidence of overall adverse events) between the two regimens. Cystoscopy finding at 6 weeks was also reviewed. Patients were followed up until disease recurrence, or two years after completion of adjuvant treatment.

**Results:** 68 patients were identified and included in the analysis: 37 received BCG and 31 received GEM. Interim results at a median of 24-month follow up found the 1-year recurrence rate to be significantly higher in the BCG group than the GEM group. There was a trend toward a better disease-free survival in the GEM group. Treatment outcome at 6 weeks was also better in the GEM group. Overall adverse events occurred more frequently in the BCG group; haematuria, urosepsis and systemic toxicities occurred only in the BCG group.

**Conclusion:** Interim results suggested the efficacy of intravesical GEM to be comparable to that of BCG with a better tolerability. We believe intravesical GEM can safely replace BCG in whom BCG cannot be administered. Two-year recurrence rate will be updated. A prospective RCT is needed to validate these findings.

abs#113

## CAN SUPPORTIVE CARE SCREENING PREDICT TESTICULAR CANCER SURVEILLANCE COMPLIANCE?

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**Background:** Testicular germ cell tumours (GCTs) are the most common solid malignancy (excluding skin cancers) affecting males between 15 and 35 years of age. But unlike most solid malignancies, cure rates are extremely high even in the presence of metastatic disease. In recent times, there has been increased awareness of the significant psychological stress that this element of cancer survivorship places on this population of relatively young men. Given the often young age at presentation, surveillance of tumours following resection is preferable to avoid unnecessary long term morbidity from adjuvant chemotherapy. Poor compliance with surveillance protocols can compromise care. Development of a support tool that could accurately predict patients less likely to comply with recommended surveillance may assist health professionals develop care plans to promote attendance or tailor treatment recommendations for adjuvant therapies.

**Aim:** This retrospective study examines patterns in data from the Supportive Care Screening (SCS) tool and subsequently assesses the tool's ability to accurately predict the likelihood of surveillance compliance.

**Method:** Supportive care screening data (distress scale and social support scale) was retrospectively collected on patients scheduled for testicular cancer surveillance appointments in the last 12 months in a single inner city

 

Victorian Hospital. This was subsequently correlated with rates of attendance to outpatient clinic review. Non-attendance was defined as missing two or more consecutive clinic appointments despite telephone follow-up from first fail to attend.

**Results:** Results from this analysis will be presented and will have significant implications for designing strategies to improve compliance in this patient group.

**Disclosures:** the authors declare no competing financial interests or signficant conflicts of interest.

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abs#114

## RADICAL PROSTATECTOMY- INSTITUTIONAL OUTCOMES COMPARED TO A POPULATION-BASED DATABASE

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**Introduction:** Registry data provides extremely useful institutional and surgical benchmarks as well as informing on patterns of practice. However, based on selection criteria and data collection practices a registry and its findings may differ from institutional data. In particular active surveillance and its impact with repeat biopsy leading to reclassification from low to higher risk disease may account for patients transitioning from low-risk to surgery which is not generally appreciated in the registry due to data collection time-lag. As such, our aim was to compare risk-classification of men with prostate cancer from institutional data of Austin Hospital (AH) to a population-based registry, Prostate Cancer Registry, (PCR) Victoria of AH's data for any insight into registry generalizability.

**Methods:** The audit compares radical prostatectomy data of men (aged 49-82) with prostate cancer from Austin Hospital (n = 209) and PCR (n = 209) from June 2009 to November 2011. Data was obtained from patient clinical records from both PCR and Austin Hospital database. All patients were classified by NCCN criteria for risk of disease progression into low, intermediate, high, very high or metastatic. Surgical margin rates post prostatectomy compared according to organ-confined groups.

**Results:** Twelve patients from AH, and 5 patients from PCR were unable to be classified due to incomplete data resulting in 198 vs 182 patients analysed respectively. AH in comparison to PCR showed risks of Low (n = 10 vs 31), Int (n = 90 vs 105), High (n = 72 vs 43), very high (n = 16 vs 2) and metastatic (n = 9 vs 1) respectively. Positive surgical margins rates for organ-confined disease were lower in the Austin group than the registry (20% vs 33%). Non-organ-confined were not compared as surgical margin rates were not available with accuracy in those groups.

**Conclusions:** Misclassification of patients as low-risk appears to be common with registry versus institutional data. This likely indicates that patients who may start as low-risk on surveillance will have a confirmatory biopsy reclassifying them leading to surgical intervention. However, without interim biopsy results reported into the registry this appears to alter actual data reported. These findings need to be accounted for with registry data collection and reporting to closer reflect institutional data.

abs#115

## EFFECTS OF A CLINICIAN'S REFERRAL AND PHYSICAL ACTIVITY PROGRAM FOR MEN WHO HAVE COMPLETED TREATMENT FOR PROSTATE CANCER: A MULTICENTRE CLUSTER RANDOMIZED CONTROLLED TRIAL [ENGAGE]

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**Objective:** We tested the efficacy of a clinician's referral and physical activity program to improve physical activity levels, quality of life and psychosocial outcomes among men who had completed active treatment for prostate cancer.

**Patients and Methods:** A multicentre, cluster randomised controlled trial was conducted in Melbourne Australia. Overall, 13 clinicians were randomised to either refer men with prostate cancer to a 12 week, supervised physical activity program (n = 54), which included two gym sessions and one home based session per week, or assigned to usual care (n = 93). The primary end point was self-report participation in physical activity. Secondary end points were quality of life, anxiety and depression.

**Results:** Overall, 147 (46%) agreed to participate. At 12 weeks, significant intervention effects were observed for strenuous exercise only (intervention group: 94.41 minutes per week compared to 41 minutes per week for the control condition; p = 0.01); the intervention group was 3.5 times (95% CI:1.2–9.8) more likely to have one or more sessions of strenuous exercise per week compared with the control group; significant intervention effects were not observed for combined moderate, strenuous physical activity levels (p = 0.48); a suggested intervention effect was observed with depression levels decreasing (p = 0.06), while cognitive functioning improved (p = 0.06) in the intervention group. The program was acceptable among participants with an 85% adherence rate to the gym sessions and 81% to the home based session; 80% of participants reported they were influenced by the clinician's recommendation to attend the 12 week program.

**Conclusion:** The ENGAGE intervention program could form part of a patient's treatment regime and be integrated into standard care for men following active treatment for prostate cancer.

abs#116

## CURRENT CLINICIAN PRACTICES IN UTILISING RADIOTHERAPY AND TARGETED THERAPIES IN TREATING PATIENTS WITH METASTATIC RENAL CELL CARCINOMA – A SURVEY OF AUSTRALIAN AND NEW ZEALAND CLINICIANS

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In recent years there has been a significant change in treatment options for metastatic renal cell carcinoma. Current management includes the availability of metastasectomy, cytoreductive nephrectomy, stereotactic radiotherapy and systemic therapies including targeted therapies like Sunitinib, Sorafenib and Everolimus.

There are no clear guidelines regarding the role and effectiveness of radiation, in particular stereotactic radiotherapy in managing renal cell carcinoma nor are there guidelines or consensus for the simultaneous use of targeted therapies and radiotherapy. Further, it is unclear if the possible interactions between treatment modalities e.g. radiotherapy and targeted therapies are beneficial or detrimental. These drugs are radiosensitisers and may increase clinical effect but alternatively the toxicity may also be increased significantly.

 

**Aim:** The aim of this questionnaire is to assess current practices amongst clinicians treating metastatic renal cell carcinoma in particular their use of stereotactic radiotherapy and the concurrent use of targeted therapies with radiotherapy. This survey also aims to determine the potential level of support for future clinical trials in this area. This study was approved by the Ethics Review Committee of the Sydney Local Health District.

The primary objective was to evaluate the proportion of clinicians utilising radiotherapy in treating metastatic renal cell carcinoma. Secondary objectives were the proportion of clinicians utilising targeted therapies and radiotherapy simultaneously, proportion of clinicians stopping targeted therapies for radiotherapy, proportion of clinicians happy to support further research in this area and the variation in practice amongst clinicians across Australasia and different specialty fields.

**Methods:** An online survey was created using Surveymonkey and distributed to members of Australia and New Zealand Urological and Prostate Cancer Clinical Trials Group (ANZUP), Faculty of Radiation Oncology Genito-Urinary Group (FROGG) and the Urological Society of Australia and New Zealand (USANZ) via email which included an explanation and link to online version of the survey. Descriptive statistics will be performed to analyse the data and presented as proportions, percentages, means or medians.

**Results and Conclusion:** will be presented at ANZUP ASM.

abs#117

## MANAGEMENT OF PATIENTS WITH NON-METASTATIC MUSCLE INVASIVE BLADDER CANCER. A SURVEY OF CLINICIANS' PRACTICE

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**Background:** Bladder cancer is the 7th most common cancer worldwide in men and affects men 4 x more frequently than women. Chemotherapy improves survival when given before or after surgery for muscle-invasive urothelial cancer but the optimal strategy is unknown. Preoperative regimens are the best tested, but have modest benefits (hazard rate 0.88), whereas postoperative regimens are less well tested, with smaller sample sizes and heterogeneity in methodology, but seem to have larger benefits (hazard rate 0.77). MVAC, CMV and cisplatin and gemcitabine (CG) are the most widely used regimens while Accelerated MVAC (accMVAC) is the most active regimen. We believe clinical practice in this area is heterogenous as there is little consensus. It is important to describe current practices amongst clinicians so that future research will address the most pertinent questions.

**Methods:** An online survey was developed and constructed using Survey Monkey. It was initially piloted with a small group of clinicians to test validity and clarity. After refinement and Ethics approval the survey was distributed to Australian and New Zealand medical oncologists, urologists and radiation oncologists who were contacted through their membership groups Australia and New Zealand Urological and Prostate Cancer (ANZUP) Trials Group and Urological Society of Australia and New Zealand (USANZ). All responses were de-identified. Data analyses was conducted with IBM SPSS v 22.

**Results:** N = 45 respondents (32 medical oncologist, 1 radiation oncologist and 12 urologist). 71% practicing in the Metro area while the rest in rural or regional practice. 71% suggested that they would consider "most" of their patients for Peri-operative chemotherapy. 19 respondents preferred Cis / Gem Q3 weekly to other forms of chemotherapy in this patient group with only 5 respondents supporting MVAC and 2 respondents supporting CMV. 100% of surgical respondents carried out lymph node dissections when performing a cystectomy.

**Conclusions:** Clinical practice in this area is diverse and subject to clinician preferences.

abs#118

## OUTCOMES FROM CYSTECTOMY IN PATIENTS OVER THE AGE OF 80

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**Introduction:** Life expectancy in developed countries is continuosuly increasing. That fact justifies why the elderly patients are becoming more common in our clinical practice. Currently, one of the challenges of medicine remains the question wether patients should undergo aggressive treatments given the significant risk that entails.

**Objective:** To describe the results and complications of surgical patients over 80 years undergoing radical cystectomy for bladder tumor.

**Material and methods:** A total of 34 cystectomy in patients older than 80 years have been carried out in the Hospital Clinic of Barcelona (Spain ) during the period between 1991 and 2010. The reason for the radical surgical treatment was bladder tumor. A retrospective review of these patients was performed by evaluating the clinical and pathologic features and complications.

**Results:** The median age of the series was 82.3 years. Seven of them were women and 27 men. Regarding the ASA classification, 15 patients were ASA II , 15 patients ASA III and 4 ASA IV. Prior to surgery, 16 patients had hydronephrosis. The mean creatinine series was 1.8 ng/dl. In 32 cases ileal conduit was performed, 1 case ureterosigmoidostomy and 1 cutaneous ureterostomy case. The mean operative time was 210.3 minutes and a total of 20 patients required blood transfusion. The average hospital staying was 10.4 days. Concerning early complications: 9 cases of paralytic ileus, 4 surgical wound infections, 1 lymphocele and 1 urinary fistula. A total of 4 patients required surgical reintervention (2 evisceration, 1 bleeding and 1 case of urinary fistula). Two patients died in the immediate postoperative period. Regarding late complications: 6 cases of sepsis and 1 case of ureteral stenosis. The mean follow-up of the series was 20.3 months (0.03–134.7 months). During this period 22 of the 18 patients died due to the tumor, 2 patients in the immediate postoperative period, 1 case due to heart disease and 1 case of respiratory infection.

**Conclusion:** Radical cystectomy is an aggressive treatment with a non-negligible complication rate. Careful selection of patients is necessary in order to minimize the complications of this surgery.

abs#119

## BASELINE CHARACTERISTICS OF THE PARTICIPANTS IN A TELEPHONE-DELIVERED MINDFULNESS INTERVENTION FOR MEN WITH ADVANCED PROSTATE CANCER

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**Introduction/Objective:** There has been limited psychological intervention research conducted that specifically targets men with advanced prostate

cancer. Mindfulness-Based Cognitive Therapy (MBCT) is thought to be an effective approach to reduce psychological distress in this population. This presentation examines the baseline characteristics of the participants in a multi-state randomised controlled trial of a telephone-delivered MBCT intervention for men with advanced prostate cancer.

**Methods:** This trial has recruited 128 of its 190 man target across over 30 sites around Australia. The target population of the trial is men with proven metastatic disease or endocrine resistant biochemical progression. Recruited men have completed baseline questionnaires assessing their quality of life and levels of psychological distress as well as interviews assessing their medical history, demographics and support use. A larger dataset will be available at the time of presentation.

**Results:** Men in the trial had an average age of 69.2 (SD = 8.9) and their length of time since diagnosis ranged from 1 month to 26 years. Seventy-eight percent of the men were overweight or obese (BMI over 25) and almost all men reported comorbid health conditions in addition to their prostate cancer. Seventy-three percent of the men were in a married or de-facto relationship and had predominantly received support for their prostate cancer through brochures from their doctor (16%), prostate cancer support groups (16%) and self-led internet research (14%). Forty-two percent of men indicated they hadn't accessed any support for their prostate cancer in the last 6 months. Twenty percent of the men had clinically significant levels of distress at recruitment and 21% had experienced a powerful or severe impact on their lives due to their illness indicating a risk of post-traumatic stress related concerns.

**Conclusion:** Men involved in the trial are experiencing multiple medical concerns and many are not accessing support for their prostate cancer, despite the presence of clinically significant distress and a risk of future mental health concerns. Further assessments of men participating in this trial of a telephone-delivered MBCT intervention will reveal the utility of this therapeutic approach and hopefully lead to a reduction in psychological distress for these men.

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abs#120

## SETUP AND INITIAL EVALUATION OF A NURSE-LED SURVEILLANCE FLEXIBLE CYSTOSCOPY PROGRAM

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**Background:** Nurse-led cystoscopy services provide additional resources for busy urology units, but need to be set up with care to ensure appropriate training and oversight. The objective of this study is to present the process and initial evaluation of the establishment of such a service at our institution.

**Methods:** An experienced urology clinical nurse consultant undertook in excess of 500 flexible cystoscopies with experienced urology fellows as preparation prior to the commencement of the service. Independent nurse-led cystoscopies started in September 2012, enrolling only patients returning for surveillance of urothelial carcinoma. Formal urology operating lists run at the same time in an adjacent operating suite, providing ready access to a urology trainee and consultant for advice and assistance as required. All suspected recurrences are documented photographically and booked for rigid cystoscopy. The six-month period from September 2012 to March 2013 has been assessed as part of the initial evaluation of the service.

**Results & Findings:** Surveillance flexible cystoscopy was undertaken on 125 patients after prior bladder cancer treatment (74 low-grade, 40 high-grade, 7 CIS) and 3 after prior nephro-ureterectomy. Eighteen patients were suspected to have recurrences and referred for rigid cystoscopy. Biopsies were obtained in 10 of these patients, with 5 proving to be malignant (1 high-grade), while an additional 4 patients had lesions that were treated by diathermy, yielding a true positive rate of 9/18 (50%).

**Conclusions:** Initial evaluation suggests that a nurse-led surveillance flexible cystoscopy service is feasible to set up with appropriate training and supervision. Further evaluation is ongoing.

abs#121

## RETROSPECTIVE COMPARISON OF PATHOLOGICAL COMPLETE RESPONSE RATES IN PATIENTS RECEIVING GC OR MVAC NEOADJUVANTLY FOR MUSCLE INVASIVE UROTHELIAL BLADDER CARCINOMA

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**Aim:** To evaluate outcomes for patients receiving neoadjuvant chemotherapy for muscle invasive urothelial bladder cancer (MIBC) in New Zealand centers. Furthermore, to compare pathological complete response rates (pT0) following neoadjuvant gemcitabine-cisplatin (GC) and methotrexate, vinblastine, doxorubicin, cisplatin (MVAC) in MIBC.

**Background:** MIBC is a disease occurring predominantly in male patients in their 60 s and over. The most common pathology is urothelial carcinoma. Previous meta-analysis of randomized controlled trials using platinum-based combination neo-adjuvant chemotherapy has demonstrated an improved overall survival at 5 years from 45 to 50% with treatment (P = 0.003). It has also been reported that pT0 rate is higher with neoadjuvant chemotherapy (NAC) followed by radical cystectomy (RC) than with RC alone. The higher pT0 rate correlates with improved overall survival.

**Method:** Retrospective collection of data on 42 patients treated with NAC between 2006 and current at two oncology centers with functional genito-urinary multi-disciplinary meetings, one in Auckland and one in Palmerston North. Patients were identified from pharmacy database and data collected from chart review. Patients included were stage cT2-4aNxMO and had urothelial carcinoma. The primary intention was to assess rate of pT0 in both in the two treatment groups and the whole cohort. Secondary intentions were assessment of ≤pT1 rate, OS, PFS, rate of progression on chemotherapy and rate of treatment cessation due to toxicities in these groups. All p values were obtained using a 2-sided statistical test, proportions were analyzed using the Chi-square test.

The GC protocol was for three 4-weekly cycles with gemcitabine given on day 1, 8 and 15 at a dose of 1000 mg/m2, and cisplatin given on day 1 only at a dose of 70 mg/m2. The MVAC protocol was for three 4-weekly cycles of methotrexate 30 mg/m2 day 1,15 and 22, vinblastine 3 mg/m2 day 2, 15 and 22, doxorubicin 30 mg/m2 day 2, and cisplatin 70 mg/m2 day 2.

RC with standard lymph node dissection (LND) was performed in the majority of patients, there was only one patient who received extended LND. In those who went forward for RC the average number of lymph nodes removed was 13 in the GC group and 14 in the MVAC group. Mean time from start of chemotherapy to RC was 3 months in the GC group and 3.3 months in the MVAC group.

**Results:** There were 21 patients in the GC group and 21 in the MVAC group. All but one patient in the GC group were treated in Auckland, all patients in the MVAC group were treated in Palmerston North. In the entire cohort 79% (33/42) of patients were male, 62% (26/42) were ≥60 years old and 55% (23/42) had a history of smoking. With respect to clinical T stage 50% (21/42) had T2 disease, 31% (13/42) had T3 disease and 19% (8/42) had T4a disease. Overall 76% (32/42) were clinically node negative. The 2 groups were well matched with respect to baseline characteristics of age, sex, smoking status and clinical T stage. In the GC group 33% (7/21) of patients had clinical node involvement compared with 14% (3/21) in the MVAC group. Median follow-up time in the GC group was 6.5 months (range 3 to 53 months), median follow-up time in the MVAC group was 13.7 months (range 5 to 81 months).

The total pT0 rate was 21.5% overall. There was a trend towards higher pT0 in the GC group, which had a rate of 33% (7/21), compared with only 9.5% (2/21) in the MVAC group, although this did not reach statistical significance (P = 0.06, OR 4.75, 95% CI 0.85 to 26.5). Rate of ≤pT1 was 26% overall, 38% (8/21) in the GC group and 14% (3/21) in the MVAC

 

group, the difference in rate between the two treatment groups was not statistically significant (P = 0.08, OR 3.7, 95% CI 0.8 to 16.7). In the GC group 3/7 clinically node positive patients were down-staged to node negative pathologically. In the MVAC group 1/3 patients clinically node positive disease was down-staged to pathologically node negative. The rate of progression on chemotherapy was 14% (3/21) in the GC group and 9.5% (2/21) in the MVAC group. Of the 3 patients who progressed in the GC group, two had clinical stage T4aN2 disease and developed new distant metastases on chemotherapy. The third patient had low grade T4a disease felt to be of borderline operability prior to neoadjuvant chemotherapy and subsequently progressed locally on treatment thereby becoming inoperable. These 3 patients were spared RC, all other patients in the GC group proceeded to RC. One patient in the MVAC group had clinically stable disease on chemotherapy and was found at the time of planned RC to have widespread intra-abdominal disease therefore did not proceed. All other patients in the MVAC group proceeded to RC including 2 patients who progressed locally on treatment and were found on histology to have T3 or T4a node negative disease. Chemotherapy was stopped due to toxicity in 24% (5/21) in the GC group and 19% (4/21) in the MVAC group. Median OS in the MVAC group was 37 months. Median OS in the GC group and median PFS in both groups were not reached during the follow-up period. In both groups all mortalities were due to disease. There were 3/21 documented deaths in the GC group and 7/21 in the MVAC group. One patient in the GC group and two in the MVAC group with documented progression were subsequently lost to follow-up and censored at that point.

**Discussion:** There was a strong trend towards improved pT0 with use of GC compared with use of the more widely accepted MVAC regimen. This was despite a trend towards more patients with clinical nodal involvement in the GC group compared with the MVAC group, in otherwise well-matched groups. Although the benefit of GC over MVAC did not reach statistical significance, this research supports the use of GC neoadjuvantly. These results have to be interpreted with caution due to the small numbers and in recognition that despite advances in technology it is well recognized that clinical staging is inaccurate. Previous studies report a pT0 rate of approximately 30–45% with neoadjuvant cisplatin-based combination chemotherapy, compared with a pT0 rate of 15% observed following RC without chemotherapy, for patients with T2-T4aN0M0 disease. The rate in our cohort overall was lower than this, which may be explained by the inclusion of node positive patients in this study. It would be interesting to evaluate the rate of pT0 in those patients in our region who have been treated with RC only for MIBC. Median PFS and OS could not be assessed due to short follow-up time, however these will be evaluated when the data matures.

abs#122

## OUTPATIENT LETTERS: WHEN ARE THEY SENT?

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**Introduction:** When a patient is seen in an outpatient clinic in a large tertiary referral hospital, correspondence from the treating clinician to the patient's referring GP helps communicate clinical findings, investigation results and planned management. However, not all patient visits result in an outpatient letter being sent. The aim of this study was to assess the completion of letters to GP's at our Uro-Oncology clinic, and factors affecting this.

**Patients & Methods:** Using the outpatient bookings system, patients attending the weekly Uro-oncology clinic at Austin Health between January and June 2013 were identified. A retrospective chart review was carried out to assess whether the outpatient visit led to a dictated letter being sent to the GP. Factors potentially impacting letter dictation, including which doctor saw the patient, how many patients were seen at that clinic, the diagnosis, stage of treatment and inclusion in the subsequent multi-disciplinary meeting (MDT) were recorded. Associations were analysed using logistic regression, with statistical significance set at $p < 0.05$.

**Results:** Over 25 clinics, 1012 outpatient visits were recorded, with 818 (80.8%) of these being for a cancer diagnosis, majority being prostate cancer. A GP letter was dictated at 662 (65.4%) visits. Patients were more likely to have a letter dictated at the time of cancer progression (70%) or review after specific investigations (91%), but less likely at the first post-treatment review (57%) or pre-treatment (51%), $p < 0.0001$. Significant variations were also noted in the proportion of patients for whom each doctor dictated a letter, ranging from 13.5% to 100% ($p < 0.0001$), although there was no significant variation by seniority level. Inclusion in the MDT, number of patients seen at clinic and time to next appointment (Odds ratio [95% Confidence interval] 0.39 [0.23–0.66], 0.92 [0.87–0.97] and 1.09 [1.03–1.15]) were other factors that had a significant impact on letter dictation. On multivariate analysis, stage of treatment and number of patients seen no longer remained significant predictors of letter dictation, but treating doctor, MDT inclusion, time to next appointment and discharge from clinic all were.

**Conclusions:** At our Uro-oncology clinic, about two-thirds of patient visits are followed by dictated correspondence to GPs. Analysis of factors leading to a letter being dictated suggest that specific investigation results, evidence of cancer progression and discharge from clinic are well communicated to GPs. Clinic workload, doctors preferences and clinical complexity warranting MDT discussion may preclude letter dictation.

abs#123

## VICTORIAN NODE OF THE AUSTRALIAN PROSTATE CANCER BIOREOURCE- FACILITATING PROSTATE CANCER RESEARCH

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The Victorian Node of the Australian Prostate Cancer BioResource (APCB) is a tissue bank which collects and stores fresh prostate specimens and associated clinical data from prostate cancer (PC) patients undergoing surgical treatment. The tissue bank is facilitated by the Prostate Cancer Research Program at Monash University. Underpinning the collection of biological specimens is the collaboration between scientistics, clinincians and pathologists, which enables valuable tissue specimens to be used for subsequent experiments into PC and related diseases. The program is funded by the NHMRC and PCFA.

The Victorian Node has established a seamless tissue bank collection method that increases the quantity and quality of the biological specimens collected. The process involves mimimal intervention to normal clinical practice, pathologist time and patient care. By sampling fresh tissue immediately following radical prostatstecomy (RP), researchers at Monash can generate cell lines and xenograft models to address multiple research questions. The research program also focuses on niche collections, including TURP specimens from men with BPH and castrate-resistant disease, metastatic tissue from a rapid warm autopsy program and specimens from men with known genetic mutations and irregular pathology including intraductal carcinoma of the prostate.

To date, we have recruited more than 740 men to the research program who have subsequently donated biological samples, including tissue and blood specimens, to the tissue bank. Clinical data from these men illustrate a mean age of 62 at the time of RP (68% Open RP vs 32% Robotic Assisted RP). The majority of men in the repository reported a Gleason Score of 7 (82%) at RP and tumour stage of pT2 (67%) with most men presenting as having a multifocal tumour foci (81%).

In summary, the tissue bank established by the Victorian Node of the APCB is an essential tool for PC researchers nationally, providing quality assured

 

clinical resources and annotated clinical data. The program is open to accessing new clinical collaborations that will add value to the current resource that encompasses the spectrum of PC cases in Victoria.

abs#124

## RENAL CELL CANCER IN NATIVE KIDNEY OF TRANSPLANT RECIPIENTS A CASE SERIES

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**Background:** Renal Transplantation is now a routine treatment option considered in end stage renal failure patients in South Australia. Renal transplant recipients are at increased risk of malignancy, especially post-transplantation lymphoproliferative disorders. Cancer of the native kidney is seen increasing after 5 years of transplant surgery, with a 15-fold increase in incidence post-transplantation. Little guidance exists in the treatment of renal cell carcinoma (RCC) in this group of patients.

**Method:** This is a 4 case series of renal transplant recipients with clear cell RCC from South Australia. 2 patients had early disease and the other 2 patients had advanced RCC. Management of such patients is detailed in our institutions.

**Results:** In the first 2 case, native kidney RCC was detected on ultrasonography following abnormal urinalysis and renal function test. Radical nephrectomy was performed as no distant metastases were detected on staging. To date, both patients remain well with no recurrence.

The remaining 2 patients were ultrasound detected native kidney RCC, showed distant metastatic lesions on staging investigations. These patients did not undergo cytoreductive therapy, but were commenced on systemic management. Initially mammalian target of rapamycin (mTOR) inhibitors were utilised, then on disease progression a tyrosine kinase was added to their management. Loco-regional treatments were also used to treat bony metastases. The treatments did not affect the transplanted kidney. One patient remains alive at 3 years from the time of diagnosis.

**Conclusions:** Screening by ultrasonography may be considered to detect early stage RCC in the native kidney of renal transplant recipients, allowing curative nephrectomy to be undertaken. In late stage / advanced RCC of the native kidney, an algorhythm for treatment approach is proposed that is well tolerated and safe in the renal transplant recipients.

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abs#125

## ZINC PRECONDITIONING PROTECTS THE RAT KIDNEY AGAINST ISCHEMIC INJURY

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**Introduction:** Approximately 2000 new cases of kidney cancer are diagnosed in Australia each year. Nephron sparing partial nephrectomies are being increasingly performed to preserve renal function but are associated with a risk of acute renal failure due to ischemic injury, particularly in patients with underlying renal disease. Zinc and Cobalt preconditioning have been shown to protect brain, heart and liver tissue against ischemic injury possibly through up-regulation of Hypoxia Inducible Factor (HIF) and metallothionein.

Our aim was to investigate the protective effects of Zinc against renal ischemic injury.

**Patients & Methods:** 25 Sprague Dawley rats were assigned to control (5); Cobalt 30 mg/kg (5); Zinc 5 mg/kg (5), Zinc 10 mg/kg (5), and Zinc 30 mg/kg (5) groups. All rats underwent a right nephrectomy and were allowed to recover for 7 days, before 60 min occlusion of the left renal pedicle. Rats in interventional groups were preconditioned with subcutaneous Zinc or Cobalt injections 24 hr and 4 hr prior to occlusion. Serial serum urea and creatinine measurements were used to assess renal function. Rats were monitored using animal health scores. A blinded independent pathologist analyzed H&E stained cross sections of each kidney.

**Results:** The mean creatinine (mmol/L) was significantly lower in the Zinc 10 mg/kg group than in the control group (Day 1: 207 vs 390; Day 3: 79 vs 403; Day 5 67 vs 234; Day 7 53 vs 104) ($p < 0.05$). Preconditioning with Cobalt 30 mg/kg or Zinc 30 mg/kg also resulted in lower creatinine values but the differences were not statistically significant. Control group kidneys displayed significantly greater renal injury as evidenced by tubular damage and coagulative necrosis compared to cobalt and zinc 10 mg/kg. Histology of the zinc 10 mg/kg kidneys had the lowest Jablonski score of all groups.

**Conclusion:** Zinc preconditioning protects the rat kidney against ischemic injury in a dose dependant manner. Further studies are warranted to determine the possible mechanisms involved and assess the benefit of zinc preconditioning for clinical application.

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## STANDARDIZING PATIENT-CENTERED OUTCOMES MEASUREMENT IN PROSTATE CANCER: AN INTERNATIONAL, CROSS-DISCIPLINARY EFFORT

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**Background:** The prospective collection of standardized, patient-centered outcomes for men with prostate cancer will allow intra- and inter-institutional comparisons, patient education, self-assessment and dissemination of best practices. We lack recommended standardized sets of such outcomes.

**Methods:** Through the International Consortium for Health Outcomes Measurement, a working group of urologists, radiation oncologists, registry representatives and patient advocates convened to develop a recommended minimum set of measures which institutions would collect on all prostate patients. Using a modified Delphi method over a series of in-person meetings and conference calls, a final set of recommendations was developed.

**Results:** Approximately 30 experts in prostate cancer care from North America, Europe, Australia, and the Middle East participated in the process, representing academic centers, registries and patients. We defined the scope of this initial effort as outcomes related to the management of localized prostate cancer. The group recommended cross-disciplinary measures applicable to a variety of treatment approaches from surveillance to radiation and prostatectomy. Standards were identified for disease control definitions as well as baseline patient and disease-specific risk stratification factors. Domains of patient reported outcomes to be tracked in follow up were identified including urinary incontinence, urinary irritation, bowel irritation, sexual function, and symptoms related to hormonal therapy. Finally, specific tools to assess these domains and gaps in our current tools were identified. The final recommended set is available at http://www.ichom.org/project/localized-prostate-cancer/.

 

**Conclusions:** Standardized outcome reporting is a necessary component in the movement towards high-value health care. Patient-centered outcomes related to toxicity and disease control can be identified and systemized by a multidisciplinary group of experts. The result of this project is an initial step in what will be an iterative process with the goal of improving the care of all men with prostate cancer. An pilot global comparisons project has been proposed based on implementing the final set of recommendations.

abs#127

## A COMPARISON OF MEN TREATED FOR PROSTATE CANCER WHO ENROLLED IN A RANDOMIZED CONTROLLED TRIAL COMPARED WITH THOSE WHO DID NOT: DATA FROM THE ENGAGE STUDY

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**Introduction:** Randomised controlled trials (RCT) provide high quality evidence that can inform clinical practice. However, the applicability of findings may be limited if patients who participate differ significantly from those who did not participate in the study. The aim of this study was to compare patients with prostate cancer who did or did not enroll in a prospective RCT.

**Methods:** Patients who had completed curative treatment for prostate cancer at participating centers (Austin health, Eastern Health, Peter Maccallum Cancer Centre and private urologist rooms) 3–12 months prior, were approached to participate in the ENGAGE trial (randomized to a prescribed exercise program versus usual care) between June 2011 and June 2013. Patient socio-demographic and clinical characteristics were compared between patients who did and did not consent to participate in the trial. Comparisons were carried out using Chi-square or Mann-Whitney tests as appropriate, with statistical significance ascribed to p-values <0.05.

**Results:** One-hundred and forty-seven (45.9%) of 320 eligible patients who were approached agreed to participate in the trial. Compared to patients who refused, trial patients were of similar age, but had a higher socio-economic index for area, with a median of 1050 (range: 867 to 1151) compared to 1024 (range: 805 to 1130), $p < 0.001$; were less likely to have been treated in the public sector (73.5% vs 84.4%, $p < 0.02$), undergone radiotherapy (49.0% vs 60.7%, $p < 0.05$) or had androgen deprivation therapy (17.0% vs 27.2%, $p < 0.003$). There were no significant differences in PSA at diagnosis, clinical stage or biopsy Gleason score distribution.

**Conclusions:** We have found significant socio-demographic and clinical differences between patients who participated in the ENGAGE RCT and those who did not. Selection bias of this nature will need to be considered when extrapolating RCT findings to the general population.

abs#128

## POLYMER FIDUCIAL MARKERS FOR PROSTATIC RADIOTHERAPY – A COMPARISON WITH THE "GOLD" STANDARD: THE POLYGOLD TRIAL

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**Introduction:** Gold fiducial markers are frequently used for the delivery of external beam radiotherapy to the prostate using X-ray image guidance. However, they can be susceptible to problems such as artifact on CT imaging, and lack of visibility on MRI. The aim of this study was to assess the use of polymer fiducials as a potential alternative.

**Methods:** Initial assessment of the polymer fiducials was carried out using phantom studies. With ethics approval, a prospective matched comparison was carried out of polymer fiducials in 14 patients and standard gold seeds in 14 patients matched for BMI and prostate size, all with prostate cancer of NCCN high-risk or very high-risk features. Following the insertion of fiducials, patients underwent imaging by CT and MRI, with qualitative assessment by experienced radiotherapy staff and quantitative assessment using the Image-J software, aiming to assess visibility, artifact and migration.

**Results:** The phantom studies have demonstrated that the polymer fiducials have less artifact on CT scans compared to gold fiducials, but while visible on cone-beam CT, they were not visible on 2D MV CT. Insertion of the polymer fiducials have been well tolerated, with no significant bleeding, infection or pain. Imaging findings have confirmed the findings from the phantom studies.

**Conclusions:** We have found significant socio-demographic and clinical differences between patients who participated in the ENGAGE RCT and those who did not. Selection bias of this nature will need to be considered when extrapolating RCT findings to the general population.

abs#129

## SUBMUCOSAL CONTRAST INJECTION TO FACILITATE IMAGE-GUIDED DELIVERY OF EXTERNAL BEAM RADIOTHERAPY POST-PROSTATECTOMY – A PILOT STUDY

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**Introduction:** Image-guidance in the delivery of external beam radiotherapy to the prostate has become standard, but has been challenging in the post-prostatectomy setting, given the absence of a definable target. The aim of this pilot study was to develop a technique for submucosal contrast injection to enable CT-guided targeting of the anastomosis & prostatic bed.

**Methods:** For men being planned for post-prostatectomy radiotherapy at our institution, a cystoscopy was carried out, with the aim of injecting lipid-based radiologic contrast (Lipiodilä). Submucosal injections of approximately 0.2–0.3 mL of contrast were made at 6 o'clock and 12 o'clock at the anastomosis, 3 o'clock and 9 o'clock about 1–2 cm in from the anastomosis, and midline on the inter-ureteric bar (video of technique will be presented). Patients then underwent a routine planning CT-scan, with external beam radiotherapy target volume defined using the visible contrast.

**Results:** To date, 10 patients have been treated, with no intra-operative or post-operative problems documented. In the first 3–4 cases, as the technique was being developed, the lessons learnt included: injection via flexible cystoscopy is challenging; submucosal location is important, to avoid contrast spreading too widely along extravesical planes; too little or too much contrast makes it difficult to utilize the markers.

**Conclusions:** Cystoscopic injection of submucosal contrast is a safe and feasible technique to assist image-guided planning of post-prostatectomy delivery of external beam radiotherapy. Further study is required to assess its impact on dosimetry, oncological outcomes and morbidity.

abs#130

## TRENDS IN SURVIVAL FOR UPPER URINARY TRACT CANCERS IN VICTORIA

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**Introduction:** The incidence of renal cancers in Australia has doubled over the last 2 decades, but this has resulted in improved rates of survival1. However there is no data looking at the trends of the different types of upper

tract cancers in Australia. We aimed to investigate the mortality trends of renal cell carcinoma (RCC) in Victoria and compare this with the transitional cell carcinomas(TCC) of the renal pelvis.

**Methods:** The numbers of deaths from upper tract renal malignancies were identified using the Victorian cancer registry for the time period 1987–2011. TCC diagnoses were coded separately from 2001 onwards, therefore relative survival rates for RCC and TCC were calculated, by age at diagnosis and sex comparing the periods from 2001–06 with 2007–2011.

**Results:** There were 1290 deaths from RCC and 548 deaths from TCC from 2001–11. Although there was a 17% improvement in the 5-year survival rates for RCC from 1987 for 2011 for RCC($p < 0.05$), there was no significant improvement in survival from 2001–06 to 2007–11 for TCCs (30 vs 36%) and the 5-year survival for TCC was much lower. Lower age at diagnosis improved survival in both RCCs and TCCs ($p < 0.01$) but there was no difference in in survival between males and females.

**Conclusions:** The survival rates for RCCs have improved significantly, in keeping with the overall Australian trends. However, there were only small improvements 5-year survival rates for upper tract cancers TCC and had much worse outcomes compared with RCCs.

1. Luke, C., Sargent, N., Pittman, K. et al.: Epidemiology of cancers of the kidney in an Australian population. Asian Pac J Cancer Prev, 12: 2893, 2011

abs#131

## MANAGEMENT OF BRAIN METASTASES IN PATIENTS WITH RENAL CELL CARCINOMA IN THE ERA OF TYROSINE KINASE INHIBITORS AND STEREOTACTIC RADIOTHERAPY

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**Introduction:** There are no consensus guidelines for the treatment of patients with metastatic renal cell carcinoma (mRCC) and brain metastases (BM). The necessity for screening, best central nervous system (CNS) directed therapy, and sequence and effectiveness of targeted therapy (TT) in this setting is not yet established. Survival of patients with metastatic RCC has improved with TT, making optimal CNS control and minimisation of neurotoxicity increasingly important.

**Methods:** Medical records of patients with mRCC and a diagnosis of BM were examined under an ethics approved protocol at a single institution between 2005 (when sunitinib expanded access program opened) and present. A database of all patients with mRCC from 2013–2014 was also reviewed. Data was collated on histology and prior nephrectomy, symptoms associated with BM, treatment of BM, use of TT, and survival from time of diagnosis of mRCC (OS-mRCC), and from time of diagnosis of BM (OS-BM). The Kaplan-Meier method was used for survival analysis.

**Results:** Thirty eight patients were identified with mRCC and BM from 2005 to 2014. It was possible to calculate the proportion of patients with mRCC and BM from only the most recent 2013–2014 period (4/48, 8%). Routine imaging of the brain was not practiced outside requirements of some clinical trials. Median age was 59 years at time of diagnosis of mRCC (range 43–90), 74% were male and 74% had clear cell histology. Of patients with BM, 26% had BM documented at the time of diagnosis of mRCC. For the remaining 74%, median time from diagnosis of mRCC to development of BM was 29 months. Median number of BM was 1, mean size was 19 mm. Of the 32% presenting with haemorrhagic BM, two patients were on TT at this time. 87% had >1 CNS-directed therapies. Of the 58% who had neurosurgery, 56% had whole brain radiotherapy (WBRT) as well. Overall, median OS-mRCC was 34.3 months and 6.8 months from the time of diagnosis of BM (OS-BM). Patients with asymptomatic BM had a median OS-BM of 13.2 months relative to OS-BM of 5.9 months for patients with symptomatic BM. Patients treated with TT had a median OS-BM of 7.5 months relative to median OS-BM of 4.1 months for patients never treated with TT. Patients treated with stereotactic radiotherapy (SRT) had a median OS-BM of 23.6 months.

Table 1: Overall survival (OS) in subgroups of mRCC with BM

| | Number | % | OS-RCC (months) (95% Cl) | OS-BM (mths) (95% Cl) |
|---|---|---|---|---|
| **mRCC+BM** | 38 | 100 | 34.3 (19.2–49.6) | 6.8 (4.2–13.2) |
| **Symptomatic*** | 28 | 74 | 35.9 (18.2–52.4) | 5.9 (4.2–13.2) |
| **Asymptomatic*** | 8 | 21 | 29.1 (18.9–80.1) | 13.2 (2.1–33.9) |
| **Ever had TT** | 24 | 63 | 34.2 (18.2–54.2) | 7.5 (5.3–15.9) |
| **Never had TT** | 14 | 37 | 35.9 (14.9–53.2) | 4.1 (2.3–14.6) |
| **Neurosurgery†** | 22 | 58 | 43.5 (23.9–61.6) | 12.6 (5.3–15.9) |
| **Whole brain radiotherapy (WBRT)†** | 19 | 50 | 30.5 (18.9–53.2) | 5.9 (4.1–13.2) |
| **SRT†** | 9 | 24 | 49.6 (34.2–61.6) | 23.6 (6.8–52.6) |

*2 patients had no documentation of symptom status and not included.
†Not mutually exclusive groups.

**Discussion:** This single centre retrospective series has limitations that restrict analysis. However this study shows that once brain metastases are diagnosed, survival is relatively poor. Use of TT may prolong survival following CNS directed therapy. Given 21% of BM patients were asymptomatic, consideration should be given to periodic CNS screening in mRCC. Earlier detection may allow use of SRT which in other studies is associated with lower rates of neurocognitive deficits compared with WBRT, provides durable local control and less morbidity than neurosurgery.

abs#132

## MANAGEMENT OF PROSTATE CANCER IN A REGIONAL CENTRE

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**Objective:** Prostate cancer is the commonest cancer in males and the third leading cancer-related mortality in Australia. We aim to describe the management of patients with prostate cancer in a regional centre at Goulburn Valley Health from 2011 to 2013 and elucidate potential clinical predictors for the different treatment modalities and patient outcome. Methods: This is a retrospective chart audit of hospital medical records.

**Results:** Out of 137 records with a diagnosis of prostate cancer, 96 were included for this analysis. Seventy-five (78%) patients have localised disease at diagnosis, of whom 18 (24%) underwent radical prostatectomy while another 18 (24%) received endocrine therapy as initial treatment. Fourteen (19%) patients with limited disease were referred for radical radiotherapy whilst 25 (33%) were kept on surveillance only. Patients who underwent surgery were younger (61 vs 69), had a lower median PSA (6.7 vs 34) and Gleason score (6–7 vs 8–9) than those who did not have surgery. Sixteen patients (21%) developed metastatic disease subsequently. Majority (88%) of the patients with metastatic disease have bone secondaries while only 5 (15%) have visceral disease. These patients received a median of 2 lines of endocrine therapy (range 2–3). All but 1 of the 35 patients who were referred to Medical Oncology had metastatic disease. Thirteen (38%) underwent systemic chemotherapy with docetaxel while 3 received second-line chemotherapy with carbazitaxel. Only 4 received abiraterone after its approval from August 2013 due to intolerance of docetaxel chemotherapy. Some of the patients could not receive abiraterone as they either refused or were unfit to receive chemotherapy. Others received radiotherapy for painful bone metastases. The median disease-free interval from initial diagnosis to development of metastatic disease as well as the median survival of patients with metastatic prostate cancer will be updated in the final abstract.

 

**Conclusion:** Despite selection bias and limited sample size within a retrospective chart audit, the treatment algorithms within a regional public institution are largely shaped by referral patterns and reimbursement guidelines. Patients not referred to Medical Oncology may potentially have less aggressive disease requiring either only local therapy or surveillance only. It would be worthwhile to systematically follow up the clinical parameters and treatment outcomes of patients treated in regional centres to compare with known benchmarks.

abs#133

## DOCETAXEL/PREDNISONE CHEMOTHERAPY IN METASTATIC CASTRATION RESISTANT PROSTATE CANCER: EXPERIENCE AT AUCKLAND, A NEW ZEALAND TERTIARY CANCER CENTER

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**Introduction:** Although the efficacy of docetaxel chemotherapy in metastatic castration resistant prostate cancer (mCRPC) was established since 2004 from the TAX327 trial, public funding for docetaxel chemotherapy in prostate cancer in New Zealand only began from July 2011. We present the local experience of the use of docetaxel in mCRPC in the Auckland region.

**Methods:** This is a retrospective review of all mCRPC patients treated with docetaxel/prednisone chemotherapy in the Auckland region from September 2009 to March 2013.

Docetaxel chemotherapy was administered in three weekly cycles (75 mg/$m^2$) with the addition of prednisone 5 mg twice daily.

Patient characteristics, previous and subsequent treatment records, treatment related toxicities and outcomes (50% PSA decline, progression free survival (PFS) and 1 year overall survival (OS)) were recorded.

**Results:** 54 patients were treated with docetaxel chemotherapy over this period. The median age of patients was 66 years (51–81 years). 49 patients (90%) had a performance status of 0 to 1 and 5 patients had a performance status of 2.

39 patients (72%) had a Gleason Score of ≥8. Visceral metastatic disease involvement was seen in 12 patients (22%), nodal disease in 32 patients (59%) and bone metastases in 49 patients (91%).

The median PSA was 81 microgram/L (0.6–2720). 22 patients (41%) had a PSA doubling time (PSADT) < 2 months, 46 patients (85%) had a PSADT < 6 months. 6 patients did not have PSADT records available.

All patients were symptomatic prior to docetaxel commencement. 45 patients (83%) had previous radiotherapy for symptomatic bone metastases.

The median number of chemotherapy cycles completed was six. 30 patients (56%) experienced Grade 3/4 neutropenia and four patients (7%) developed febrile neutropenia. There were no Grade 3/4 non-haematological toxicities.

The median PFS by either PSA or radiological assessment was 6 months. 33/54 patients (61%) achieved a 50% decline in PSA. 37/54 patients (68.5%) achieved a 1 year overall survival.

23 patients (43%) had subsequent lines of therapy, including cytotoxic agents, novel hormonal agents and clinical trial participation with 1 year OS of 18/23 (78%).

**Conclusion:** This is the first audit documenting the outcomes of the use of chemotherapy in mCRPC in New Zealand. Docetaxel/prednisone chemotherapy can be safely administered with good clinical efficacy in mCRPC. The clinical outcomes from our experience are in keeping with that of published literature, with a slightly greater proportion of our patients achieving ≥50% decline in PSA levels.

abs#134

## A DESCRIPTIVE STUDY OF PROSTATE CANCER IN OCTOGENARIANS – FINDINGS FROM A CLINICAL REGISTRY

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**Introduction:** Prostate cancer is the most common malignancy among Australian men. The median age at diagnosis is 67 years and the prevalence increases with age. Previous studies suggest that, prostate cancer is the cause of death in around half of the cases diagnosed with the disease. Data on elderly men especially men aged ≥80 with prostate cancer is scarce as they are underrepresented in the available studies. It is believed that elderly men with prostate cancer often have indolent disease with lower cancer specific mortality, which may lead to either under-treatment or overtreatment of the disease in the elderly population. Here we describe primary cause of death (prostate cancer versus non-prostate cancer) and patient and disease characteristics, in patients who were diagnosed when aged ≥80 from a population based disease registry and compared them with patients from the same registry who were diagnosed with prostate cancer at the age of 70–79.

**Patients and methods:** Data were obtained from the South Australian Prostate Cancer Clinical Outcome Collaborative (SA-PCCOC) database. This is a longitudinal, observational disease registry of men with biopsy-proven prostate cancer, treated at three major metropolitan hospitals and collaborating private institutions throughout South Australia since 1998. For this analysis, elderly men (≥70 years of age) with non-metastatic prostate cancer were selected from the database. Baseline demographics, disease characteristics and initial treatment information were extracted. Cause of death was identified from the death registry linked to the database. Patients were followed up for a minimum of 2 years (median 6.3 years range 1.3–17). Treatment groups were defined as: group 1: radical prostatectomy, group 2: radiotherapy and group 3: hormonal treatment. Proportions were compared using a Chi squared test or Fishers exact test.

**Results:** There were 601 patients in the ≥80 group, (median age at diagnosis = 84, range 80–101) and 1232 patients aged 70–79, (median age at diagnosis = 74, range 70–79). In the ≥80 group, 170 subjects (28%; 95% CI 25–32%) were still alive at the time of the study; of the 431 who died, in 187 (43%; 95% CI 39–48%) the underlying cause of death was prostate cancer. Patients who had a Gleason score of >7 at diagnosis, were significantly more likely to die of prostate cancer [OR 1.93 (1.14–3.31); p = 0.01].

In the 70–79 group, 942 (76%; 95% CI 74–79%) were alive, of those who died: in 142 (49%; 95% CI 43–55%) prostate cancer was the underlying cause of death. In this group of patients, death due to prostate cancer was significantly higher in: patients with clinical stage 3 (versus 1) [OR = 4.55, 95% CI, 1.73–12.97, p = 0.001], patients with Gleason score >7 [OR = 3.63, 95% CI 1.90–7.08, p = 0. 00006], patients receiving hormonal treatment (group 3) [OR = 4.38, 95% CI, 1.87–11.23, p = 0.0003].

Comparing the two groups, patients were significantly more likely to die if diagnosed with prostate cancer when ≥80 when compared to those 70–79 at diagnosis [OR of death: 8.24, 95% CI 6.56–10.33]. There was no statistically significant difference in the proportion of deaths caused by prostate cancer between the ≥80 and 70–79 groups (43% vs 49% respectively, OR 0.80 95% CI 0.59–1.09). In both groups, patients with Gleason score >7 were more likely to die of prostate cancer than other causes.

**Discussion:** This study suggests that a large proportion of elderly men with prostate cancer are likely to die from the disease. The underlying cause of death (prostate cancer versus non-prostate cancer) was not significantly different when comparing ≥80 group to the 70–79 cohort. We conclude that a significant proportion of octogenarian men die from prostate cancer related events. These findings challenge the commonly held belief that elderly men "die with prostate cancer than of it". The results should be considered in the management of this group of patients especially those with a high

Gleason score. To our knowledge this is the first study focusing on the population of patients older than 80 with prostate cancer, nonetheless we do acknowledge that as a retrospective analysis of already available data, our study has limitations.

abs#135

## CURRENT USE OF ACTIVE SURVEILLANCE IN AUSTRALIA- A PATTERNS OF CARE ANALYSIS FROM THE PROSTATE CANCER REGISTRY

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**Introduction and Objectives:** Prostate cancer is the leading cause of morbidity and mortality amongst Australian men, with more men being diagnosed with low- risk disease due to individualised opportunistic screening. In lieu of side effects of treatment, active surveillance has been established as a feasible management option with intent to curative treatment for disease progression. The Victorian Prostate Cancer Registry (PCR) was developed in 2008 and captures over 85% of all newly-diagnosed prostate cancers in Victoria. It is a valuable resource for patterns of care of prostate cancer in Australia today.

**Material and Methods:** De- identified data was obtained for 6633 men from the PCR. Patients were stratified using the NCCN risk grouping system and those who were not actively treated were identified. Men included in this study were diagnosed with prostate cancer from 2008 to August 2012 with a minimum of 12-month follow –up. Data was acquired to describe the trends and uptake of AS according to public (teaching hospital) vs private (non- teaching hospital) hospital sector, and regional vs metropolitan regions.

**Results:** A total of 1603/ 6633 (24%) of patients have not received active treatment including 1004 patients who were on AS (as opposed to watchful waiting). By risk category this includes 653/1816 (36%) of very low and low risk men and 251/2820 (9%) of intermediate-risk men and 76/1789 (4.2%) of high, very high and metastatic disease. Of the 1004 patients on AS, 146/1004 (14.5%) progressed to active treatment after 12 months. 96/146 (65.7%) underwent radical prostatectomy (RP), 30/141(20.7%) external beam radiation therapy (EBRT) , 8/146 (5.4%) brachytherapy (BT) and 12/146 (8.2%) androgen depravation therapy (ADT).

Patients were more likely to be on AS if they were treated in a private setting with 644/1004 (64.1%) patients being treated in the private sector, with 360/1004 (35.9%) in public ($p = 0.001$). Patients in the private sector were on average 1.9 years younger, had a lower PSA (0.2 ng/mL difference). They also had lower risk disease by clinical staging and biopsy Gleason score. All of these factors were statistically significant ($p = 0.001$).

The distribution of patients in Victoria was analysed by postcode according to the Australian Bureau of Statistics 2011 remoteness structure based on postcode correspondence. There were no significant differences in AS utilisation found in our cohort of men from urban to outer regional areas.

**Conclusion:** In this contemporary Registry- based population, AS is being used in a significant proportion of patients. The proportion of men progressing to intervention is lower than what is shown in current literature.

Overall, 36% of patients in our cohort of men with low risk disease are on AS, with a further 9% of men in the intermediate risk groups. Our progression to treatment rate was 14.5%, with majority of patients undergoing radical prostatectomy. Patients were more likely to be on AS if they were treated in the private setting (non- teaching). This can be attributed to patient characteristics, whereby private patients were of a younger age, had a lower PSA, clinical staging and biopsy Gleason score, all of which, were found to be significant. There was no difference, in the uptake of AS in our patients by demographic distribution. We acknowledge that longer-term follow- up is needed to further determine the outcomes of our AS cohort.

abs#136

## THE UTILISATION OF ACTIVE SURVEILLANCE IN A COHORT OF VICTORIAN MEN, ACCORDING TO PRIAS AND OTHER CONTEMPORARY ACTIVE SURVEILLANCE PROTOCOLS

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**Introduction/Objectives:** Active Surveillance (AS) is increasingly used in the management of men with low -risk prostate cancer. With the increased uptake of AS, several protocols are in place to manage such patients. Of these, PRIAS is currently the largest recruiting. The aim of this study was to look at the uptake and utilization of AS in this cohort of men according to PRIAS and other contemporary AS protocols.

**Material & Method:** De- identified data was obtained for 6633 men from the Victorian Prostate Cancer Registry (PCR). Men included in this study were diagnosed with prostate cancer from 2008 to August 2012 with a minimum of 12-month follow -up. Data was acquired to describe the current utilization of AS in Victorian men, according to the PRIAS and other contemporary AS protocols.

**Results:** The PRIAS criteria was analysed with the data sets from the registry. A total of 841 patients would have met the criteria for PRIAS to commence AS. Of these, 321/841 (38%) of patients were actually on AS with the remaining 520/841 (62%) of patients being treated with other modalities. Interestingly 683/1004 (68%) of patients currently on AS were not eligible for PRIAS.

Of the 520 patients undergoing other treatment modalities despite being eligible for PRIAS, 333/520 (64%) underwent radical prostatectomy (RP). 48/520 (9%) underwent external beam radiation therapy (EBRT), 61/520 underwent low- dose radiation therapy (LDR) and brachytherapy (BT), 6/520 (1%) received BT alone, 46/520 (8.8%) were classified as no treatment (and not on AS), 21/ 520 (4%) on watchful waiting, 2/520 (0.4%) on androgen depravation therapy alone and 3/520 (0.6%) on LDR alone. ($P = 0.000$)

Our findings were similar when comparing our cohort of men with six other contemporary AS protocols. According to our cohort of men, 610/958 (63.7%) of patients not on AS were eligible to be on Memorial Sloan Kettering Cancer Centre (MSKCC) AS protocol; 873/1249 (69.9%) according to Royal Marsden (UK); 431/742 (58%) for Epstein (John Hopkins); 576/929 (62%) with University of Miami; 484/797 (60.7%) by UCSF (University of California, San Francisco) and 950/1451 (65.5%) by the University of Toronto.

**Conclusion:** Our study suggests that despite the increased uptake of AS in a cohort of Victorian men, AS is not used in many men who would appear suitable by PRIAS criteria with majority (62%) of patients with low risk disease being actively treated with other modalities despite fulfilling the PRIAS criteria for AS. We also found our results to be consistent across the board when comparing utilisation with other AS protocols. We acknowledge that the increasing trends in utilisation of AS in recent years may influence our results, and that ongoing follow up will be required.

abs#137

## SURGERY OR SALVAGE CHEMOTHERAPY WHEN SERUM TUMOUR MARKERS FALL BUT FAIL TO NORMALISE WITH CHEMOTHERAPY FOR NON-SEMINOMATOUS GERM CELL TUMOURS?

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Post-chemotherapy surgery (PCS) to resect all residual masses is the standard of care for men with non-seminomatous germ cell tumours (NSGCT) if serum tumour marker (STM) levels are normal after chemotherapy . If STMs rise during or soon after chemotherapy, salvage chemotherapy (followed by surgery in most cases) is also the standard of care. However, optimal management is unclear for a small number of men who do not fit into either of

 

the above categories and have STM levels that remain mildly elevated but stable after chemotherapy. There are anecdotal reports that mildly raised alpha-fetoprotein levels may be due to secretion from teratoma, and surgery may be appropriate in such cases. However, there is little information available about how to manage men with mild elevation of human chorionic gonadotrophin (HCG) after chemotherapy.

We present a case series of five patients with metastatic NSGCT and poor prognosis features, including baseline HCG levels >250,000 IU/L, whose post-chemotherapy HCG was mildly elevated and stable (range 12–34 IU/L). All 5 cases proceeded to PCS and their HCG levels returned to normal after surgery. 3 of 5 patients received additional post-surgical chemotherapy with TIP (paclitaxel, ifosfamide and cisplatin). We present follow-up data for these patients including one patient who is disease free at 5+ years. Interestingly, histologic examination revealed only necrosis in 3 of 5 patients, despite a correlating fall to normal in HCG levels after surgery. This suggests that residual viable tumour cells were present in the resected tissue but not identified by pathologic examination.

We propose that initial PCS and 2 cycles of "adjuvant" chemotherapy is appropriate in selected cases with NSGCT when STM remain mildly elevated but stable after chemotherapy. This is likely to result in a reduced treatment burden compared to initial salvage chemotherapy followed by surgery. These cases should only be managed at high-volume centres by experienced clinicians. Additionally, resection of "necrotic" masses may not be therapeutically futile in all cases as viable malignancy may be present but unrecognised.

National and/or international registries of testicular cases, as trialled by Cancer Australia and supported by Australian and New Zealand Urogenital and Prostate Trials Group would allow analysis of uncommon clinical scenarios, such as cases presented here, and result in more informed treatment choices.[1]

abs#138

## AUSTRALIAN PROSTATE CANCER BIORESOURCE, 2014

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**Significance:** The vision of Australian Prostate Cancer BioResource (APCB) is to provide a unique quality assured facility for the collection, storage and access to tissue to support research into the treatment and improved clinical management of men with prostate cancer. The APCB manages four federated nodes located in Brisbane, Sydney, Melbourne and Adelaide.

The APCB is jointly funded by the National Health and Medical Research Council (NHMRC) and Prostate Cancer Foundation of Australia (PCFA).

**Results:** The APCB provides a significant number of unique services which include:
- fresh tissue (cancer/"benign" cores) from radical prostatectomies;
- paraffin embedded tissue sections,
- buffy coat cells, serum, plasma
- tissue microarrays

To date the APCB has collected **125,867** samples from **5,008** men (Oct 2005-Feb 2014) and has distributed samples to 45 different researcher groups on 80 occasions (since 2007).

The APCB is firmly embedded in translational prostate cancer research within Australia and importantly has provided resources to build and contribute Australasian cohorts in large scale genetic, genomic and proteomic biomarkers studies. This includes the following research programs; PRACTICAL Genome Wide Association Study, Irish Biomarker Consortium, International Cancer Genome Consortium, and the highly publicised Movember Global Action Plan initiative.

Our alliance with the ANZUP Clinical Trial group has facilitated an agreement with the clinical trial sponsor TROG, to provide expertise and infrastructure to bank samples from the Phase III multi-centre RAVES trial. As the APCB has collection nodes distributed nationally we are perfectly placed to fully support and collaborate with all major clinical trials for men with prostate cancer within Australia. **In addition the APCB has established a foundation to support long term clinical follow up studies – vital in the case of prostate disease due to its long natural history of disease progression.**
**Conclusions:** The APCB has a collection of high quality prospectively collected prostate cancer tissue with clinical and pathological data acquired at diagnosis and surgery. The APCB is a critical component of ANZUP by providing biobanking for biological sub studies of current and future clinical trials for prostate cancer.

abs#139

## PROSPECTIVE RANDOMISED CONTROLLED TRIAL OF WRITTEN VS VERBAL INFORMATION GIVEN TO PATIENTS AT THE TIME OF FLEXIBLE CYSTOSCOPY

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**Background and rationale:** Patients undergoing flexible cystoscopy (FC) for surveillance of bladder cancer are usually given information regarding the findings from the procedure and further treatment plans, either verbally (as is the usual practice at our institution) or in writing. We hypothesized that the provision of written information would aid patient understanding, and thereby reduce anxiety.

**Methodology:** All patients undergoing FC were invited to participate unless language, psychological or cognitive barriers were identified. Patients completed a pre-procedure questionnaire including self-rating of anxiety and understanding of the procedure on Likert scales (1–5). FC was conducted as per usual practice. The findings from the FC and plan of management were communicated to patients either verbally (Group 1) or on a standardized written template (Group 2), according to randomized allocation. On discharge, patients completed a post-procedure questionnaire including self-assessment of how well-informed and how anxious they felt.

**Results:** Two hundred patients were recruited, with 171 evaluable questionnaires returned (125 patients having surveillance for bladder cancer, remaining 46 investigation of symptoms), 88 from Group 1 and 83 from Group 2. The distribution of age, sex and prior FC as well as the pre-procedure self-assessment of anxiety and understanding were similar between the two groups. Post-procedure, all patients except 4 in Group 1 had an accurate understanding of the findings at FC and the proposed management plan. Patients in Group 2 reported feeling better informed (median [range] 5 [4–5] compared to 4 [1–5] out of 5, $p < 0.0001$) and lower anxiety levels (1 [1–4] compared to 2 [1–5] out of 5, $p < 0.005$).

**Conclusion:** The provision of written information at the time of FC detailing the findings and management plan leads to patients feeling better informed and less anxious. However, most patients appear to gain an accurate understanding from the provision of verbal information alone.

abs#140

## PSYCHOLOGICAL DISTRESS AND ADVANCED PROSTATE CANCER

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**Introduction:** It is estimated that approximately 20% of men with prostate cancer have locally advanced or advanced disease at diagnosis. By comparison with men with localised prostate cancer, men with advanced disease report higher levels of distress, greater unmet supportive care needs, poorer quality of life, and a greater risk of suicide. This presentation describes men's quality of life and psychological outcomes after diagnosis of locally advanced or advanced prostate cancer from baseline to 36 months follow-up.

**Method:** Participants were 81 men recruited as part of a larger longitudinal epidemiological study who were newly diagnosed with self-reported locally

advanced or advanced prostate cancer in Queensland. A series of previously validated self-report psychological distress and quality of life measures were administered to participants at baseline, 2, 6, 12, 24 and 36 month follow-up.

**Results:** Across time there were significant variations in participant psychological distress and quality of life. Specifically, mean responses indicated that decisional conflict was significantly higher at baseline compared to each of the following time points; distress thermometer ratings were higher at baseline than at 12 month follow-up; and decision regret related to treatment choice increased overtime. Quality of life, measured by the SF-36 physical functioning domain and satisfaction with life scale, decreased overtime. Sixty-one percent of men were categorised as distressed according to the Decisional Conflict Scale classification rule and 44% fell in the distressed category on the Distress Thermometer. Based on case rules, a large proportion of participant distress persisted at 36 months (44% and 39% respectively). Bivariate correlation matrices revealed that decisional conflict was consistently significantly associated with baseline and prospective treatment decision regret ($r = 0.32$ to 0.67) and satisfaction with life ($r = -0.31$ to $-0.46$).

**Conclusion:** Even though distress predominantly decreased overtime a substantial proportion of men were still classified as distressed according to the Distress Thermometer and Decisional Conflict Scale case rules at 36 month follow-up. Consistent with expectations, quality of life decreased overtime. This data has implications related to targeting psychological service delivery for men who have been diagnosed with locally advanced or advanced prostate cancer.

abs#141

## PHARMACODYNAMIC EFFECTS OF THE HEAT SHOCK PROTEIN 90 (HSP90) INHIBITOR, AUY922, IN HIGH-RISK, LOCALISED PROSTATE CANCER

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**Background:** Prostate cancer (PC) is the most commonly diagnosed cancer and despite advances in treatment options, remains the second-most common cause of cancer-death in Australia [1]. Prostate epithelial cells are dependent on androgen signalling, mediated by the androgen receptor (AR). Hsp90 is over-expressed in PC and Hsp90 is a chaperone protein for the androgen receptor. Therefore there is a strong rationale for using Hsp90 inhibitors in PC. The novel agent, NVP-AUY922, is significantly more potent than the first-in-class inhibitors, showing improved preclinical efficacy in numerous cancer cell types [2]. It has been demonstrated to be particularly effective at decreasing proliferation and inducing apoptosis in ex vivo cultures of human prostate tumours [3]. The pre-prostatectomy setting provides a unique opportunity to evaluate matched patient tissue before and after 4 weeks treatment with NVP-AUY922. This allows analysis of target inhibition, tumour levels of the agent, biological efficacy and identification of biomarkers of response.

**Aim:** To determine the pharmacodynamic activity of the Hsp90 inhibitor, AUY922, in men with high-risk localised PC undergoing radical prostectomy (RP).

**Methods:** This is a two-arm, randomised, open-label pharmacodynamic study of adult men with high-risk localised PC (stage $^3$T3A, Gleason score 8–10 or with a pre-operative PSA >20 ng/mL) who are planned for RP. Patients will undergo 1:3 randomisation to no treatment versus NVP-AUY922 given at a dose of 70 mg/m2 intravenously on Days 1, 8, 15, 22 in a 28-day cycle. RP will be performed on Day 29.

The primary outcome is to determine the frequency of a 50% reduction in the Ki-67 proliferation index from the pre-treatment prostate biopsy compared to prostate cancer tissue from RP. The secondary endpoints are (1) levels of Hsp70 induction in prostate tissue and peripheral blood mononuclear cells, (2) levels of cleaved caspase-3 induction as a marker of apoptotic cell death, (3) changes in serum and tumour levels of PSA, (4) pathological regression and (5) the frequency/severity of adverse events. Exploratory biomarker endpoints will be identified from ongoing prostate cancer explant studies.

This is a trial-in-progress. The study has been submitted for HREC approval as of April 2014. Patient recruitment is to commence from May 2014 with a 2-year accrual period. Based on analysis of the experimental arm using a Simon's 2-stage minimax approach, a total of 41 treatment patients and 14 control patients will be recruited, assuming 3 or more responses are observed in the first 25 treated patients. The null hypothesis will be rejected if there are 8 or more PD responses in the 41 treated patients.

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abs#142

## USING WEB-ENABLED TECHNOLOGY TO SUPPORT MEN WITH PROSTATE CANCER

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**Introduction:** Access to appropriate information and support remains problematic for many men diagnosed with prostate cancer, especially in rural and remote areas of Australia. We have developed an online clinical support program, PROSTMATE, which aims to overcome these barriers to access.

**Aims:** PROSTMATE is a secure portal that provides telehealth consultations with nurses and psychologists, tailored information, a place to record treatments, test results and appointments, online tracking tools and self-directed support programs to improve health and wellbeing.

**Methodology:** PROSTMATE (www.prostmate.org.au) is freely accessible to men affected by prostate cancer, their families and others interested in prostate cancer. PROSTMATE launched in November 2013 and we have monitored its uptake, user engagement and participant feedback.

**Results:** Over 600 people have registered. 72% of members are from metropolitan areas, 22.5% from regional or remote areas. The majority of members (56.5%) are men who have been diagnosed with prostate cancer. Self-reported problems at registration indicated that 17.2% of men with prostate cancer reported at risk levels of mood problems and 41.4% reported at risk levels of sexual intimacy problems. 23.5% of partners reported at risk levels of relationship problems and 41.2% reported at risk levels of sexual intimacy problems. Telehealth consultations have steadily grown and appear to be an acceptable delivery mode for men and their families.

**Conclusions:** PROSTMATE shows promise in supporting men and offering access to specialist prostate cancer nurses and allied health services. This paper will explore how PROSTMATE could provide a novel way of improving care, and potentially see the integration of these systems into routine care.

[Correction added on 16 July after print and first online publication: The Poster Abstracts section has been updated to include two additional abstracts, abs#141 and 142.]

 