7041 POSTER

Men's Experiences of Regaining Urinary Continence Following Robotic Assisted Laparoscopic Prostatectomy (RALP) for Localised Prostate Cancer − a Qualitative Phenomenological Study

J. Waller[1], N.A. Pattison[2]. [1]*Royal Marsden Hospital − NHS Trust, Ellis Ward, London, United Kingdom;* [2]*Royal Marsden Hospital − NHS Trust, Nursing Risk and Quality Assurance, London, United Kingdom*

Background: Robotic-Assisted Laparoscopic Prostatectomy (RALP) is an innovative surgical technique in localised prostate cancer treatment, which is purported to minimise risks of long-term post-operative urinary incontinence. Current studies demonstrate that urinary function and quality of life domains are temporarily affected following RALP, but the impact on men's lives is not known.
Methods: Phenomenological in-depth interviews were conducted to describe and understand how men individually interpret their experiences of regaining urinary continence following RALP. Seven men who defined themselves as continent of urine at 12 weeks post-RALP participated. Participants' mean age was 64 years (range: 57−71) and all had confirmed stage pT2c prostate cancer. Taped interviews were transcribed ad verbatim and inductively analysed for themes using an adaption of Diekelmann et al's (1989) framework, based on hermeneutic-phenomenological principles.
Results: In the initial stages (1−6 weeks) men experienced both urge and stress incontinence. In latter stages men predominantly experienced stress incontinence (7−12 weeks). Despite defining themselves as continent at the time of interview, three men continued to experience some degree of stress incontinence. Four main themes were established: '*What was forecast*', which related to men's expectations; '*After sales service*' related to men's descriptions of post RALP care and discharge, catheter care; support and follow-up care. '*New plumbing*' referred to men's descriptions of regaining urinary continence. '*Sense of self*' refers to the psychosocial impact of RALP on men's personal identity and the individual processes men underwent to reconcile themselves to their new life situation. All men perceived psychological recovery of regaining continence to be more challenging than physical recovery as they had not been prepared for this − incontinence evoked feelings of shame and infantilised them.
Conclusion: There are implications for information-giving pre- and post-operatively and individual information requirements around regaining continence. Various coping strategies were employed to deal with incontinence. Support needs were, again, individual and regaining continence was an important hurdle to overcome to return to a sense of normality.

References

Diekelmann N L, Allen D, Tanner C A (1989) *The NLN Criteria for Appraisal of Baccalaureate Programs: A Critical Hermeneutic Analysis* New York: National League for Nursing

7042 POSTER

Validation of a Rating Scale to Assess the Effects of Testosterone Deficiency in Prostate Cancer Patients Taking Androgen Deprivation Therapy as an Adjunct to Radical Radiotherapy

R.A. Cox[1], E. Ferguson[2], S. Sundar[1]. [1]*Nottingham University Hospitals NHS Trust, Department of Clinical Oncology, Nottingham, United Kingdom;* [2]*The University of Nottingham, School of Psychology, Nottingham, United Kingdom*

Background: The self-administered Aging Males Symptom Scale (AMS) was originally developed to assess the magnitude of symptoms and the response to androgen replacement therapy in patients with age-related testosterone deficiency syndrome (TDS). Short course (SCADT) and long-course (LCADT) medical androgen deprivation therapies (ADT) given in combination with radiotherapy significantly affect the quality of life (QOL) in patients with localised prostate cancer. There is an unmet need for a rating scale to quantify the symptoms due to ADT.
Materials and Methods: After obtaining ethical approval, we prospectively evaluated the performance of AMS in patients undergoing ADT. AMS measures 3 sub-scales: psychological disturbance, somatic symptoms and sexual dysfunction, with the arithmetic sum giving a total symptom score. 77 men due to receive SCADT (3−6 months) or LCADT (2−3 years) completed a pack of five validated questionnaires (International Index of Erectile dysfunction, Whitney Index, 9-point Non-specific Symptom Scale, EORTC QLQ-C30, Hospital Anxiety and Depression Scale) and the AMS prior to commencing ADT, at 3−6 months, once testosterone levels had normalised in the SCADT group and whilst continuing ADT in the LCADT group.
Results: Median age 69 years (52−78); 91% stage T2/T3; 45% Gleason score 7; median pre-treatment PSA 13 (1.0 to 102); median baseline testoerone 13.0. After 3−6 months ADT there was deterioration in global QOL, erectile dysfunction (ED), fatigue and social functioning in both groups (all $p < 0.05$), with increased depression and insomnia seen only with SCADT. At the end-of-treatment follow-up (median 111 days) in the SCADT group, all QOL scores had improved with no significant difference to baseline except for fatigue ($p = 0.045$), impaired social function ($p = 0.007$), and the AMS somatic symptoms ($p = 0.01$), sexual dysfunction ($p = 0.034$) and total symptom scores ($p = 0.003$). In the LCADT group, there was no deterioration in QOL at late follow-up (median 407 days) other than for ED ($p = 0.02$) and AMS sexual dysfunction ($p = 0.029$) after continuing ADT for longer than 3−6 months.
Conclusions: The AMS scale has not yet been validated for use in prostate cancer patients. This study suggests that it reflects trends in psychological disturbance, somatic symptoms and sexual dysfunction as indicated by the 16 other validated measures. The deterioration in AMS somatic, sexual and total symptoms scores after the normalisation of testosterone levels in the SCADT group, was not reflected by the other scales; sexual distress other than ED is not assessed by the other scales. The change in the AMS total symptom score was mainly due to the significant deterioration in sexual dysfunction. With the cautious introduction of testosterone for symptoms of TDS on the completion of treatment in patients with very good prognosis prostate cancer, there is a need for a concise, validated and sensitive tool to assess response to therapy. Further investigation and analysis of the AMS is warranted. The study is currently on-going.

7043 POSTER

A Phase I/II Trial of AN-152 in Castration- and Taxane-Resistant Prostate Cancer

S.V. Liu[1], A.V. Schally[2], T.B. Dorff[1], S. Groshen[3], D. Hawes[4], D.I. Quinn[1], Y.C. Tai[5], N.L. Block[2], J. Engel[6], J. Pinski[1]. [1]*University of Southern California Norris Comprehensive Cancer Center, Medical Oncology, Los Angeles, USA;* [2]*University of Miami Miller School of Medicine, Hematology/Oncology, Miami, USA;* [3]*University of Southern California Norris Comprehensive Cancer Center, Preventive Medicine, Los Angeles, USA;* [4]*University of Southern California Norris Comprehensive Cancer Center, Pathology, Los Angeles, USA;* [5]*California Institute of Technology, Electrical Engineering, Pasadena, USA;* [6]*Aeterna Zentaris, Aeterna Zentaris, Frankfurt, Germany*

Background: Options for patients with castration-resistant prostate cancer (CRPC) are limited and targeted therapies should be explored. One potential target is the receptor for luteinizing hormone-releasing hormone (LHRH-R), which is expressed on most CRPC specimens but not on normal tissue. AN-152 [AEZS-108], designed to target LHRH-R, is an LHRH agonist coupled to doxorubicin. Its selectivity for cells expressing LHRH-R has been well documented and AN-152 has shown greater efficacy than either doxorubicin or LHRH agonists alone. Efficacy has been proven in patients with pretreated ovarian and endometrial cancer with a favorable safety profile. This trial will evaluate the safety and efficacy of AN-152 in men with taxane-resistant CRPC. Correlative studies will identify predictive markers, including LHRH-R expression on biopsy specimens and on circulating tumour cells (CTC). In addition, internalization of AN-152 will be measured in CTC by exploiting the auto-fluorescence of doxorubicin. We report results from the phase I portion, designed to confirm the dose used in female patients.
Methods: This trial is a single-arm study with a phase I lead-in to a phase II clinical trial. Enrollment began in November 2010 and is ongoing. Up to 18 men will be enrolled in the phase I lead-in. Eligibility criteria include adequate organ function and progression of disease despite prior therapy with an LHRH agonist and at least one taxane-based regimen. Patients will be required to discontinue LHRH agonists to avoid receptor competition. Due to potential cardiotoxicity, patients with an ejection fraction <50% or prior exposure to doxorubicin or mitoxantrone will be excluded. Pituitary function will be monitored. Patients will receive AN-152 every 21 days until progression or unacceptable toxicity for up to 6 cycles. The primary endpoint for the phase I portion is safety. The phase I portion follows a "3+3" model to confirm the dose established in a completed phase I trial in women.
Results: The first two of three planned dose levels has met accrual with no dose-limiting toxicities to date. Final results detailing safety, response and suggested dose for the phase II portion will be reported.
Conclusions: AN-152 has been well tolerated. The phase I portion of the study will continue to a maximum of 18 patients.