A prospective study of the short-term quality of life outcomes of patients undergoing transperineal prostate biopsy.

Dr Adam S. Dowrick, PhD, MAppSc, BAppSc, Research Fellow ^{*^}
(drdowrick@gmail.com)

Dr Addie C. Wootten, DPsych, BBehavSc ^{#^} (addie.wootten@mh.org.au)

Mr Nicholas Howard [#], EEN (nick.howard@hotmail.com)

Mr Justin S. Peters, MBBS, FRACS [^] (jspeters@netspace.net.au)

A/Prof Declan G. Murphy, MB BCH, BaO, FRACS, FRCS (Urol) ^{†^}
(declan.murphy@petermac.org)

* Norwegian University of Science and Technology, Department of Cancer Research and Molecular Medicine

Australian Prostate Cancer Research Centre Epworth

[^] Royal Melbourne Hospital, Department of Urology

[†] Peter MacCallum Cancer Centre, Division of Cancer Surgery, University of Melbourne, Melbourne, Australia

Correspondence:

Dr Adam Dowrick

Department of Cancer Research and Molecular Medicine

Postboks 8905

7491 Trondheim

Norway

Phone: +47 7283 6749

Email: drdowrick@gmail.com

Conflicts of Interest

Declan Murphy is an Associate Editor of BJU International. The authors have no other conflicts of interest to declare in relation to the work described.

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as doi: [10.1111/BJU.13413](https://doi.org/10.1111/BJU.13413)

This article is protected by copyright. All rights reserved

Received Date : 03-Nov-2015

Revised Date : 09-Dec-2015

Accepted Date : 04-Jan-2015

Article type : Original Article

Article category: Urological Oncology

Abstract

A prospective, observational study to investigate whether transperineal prostate biopsy (TPbx) results in patient-reported quality of life changes from baseline in the first three-months after the procedure.

Patients and methods

Consenting patients completed the Expanded Prostate cancer Index Composite (EPIC-26), the Sexual Health Inventory for Men (SHIM), the International Prostate Symptom Score (IPSS), the Generalised Anxiety Disorder (GAD-7), the Patient Health Questionnaire (PHQ-9) and a global question about willingness to have a repeat TPbx in a years' time. The instruments were scored using published scoring methods. Wilcoxon signed ranks tests and Mann-Whitney U tests were used to investigate statistically significant differences. Clinically significant differences were also investigated defined by published minimal important differences for the EPIC and changes in established categorical groups for the other instruments.

Results

Fifty-three participants consented to participate and completed the baseline questionnaire in addition to at least one of the 1- or 3-month follow-up questionnaires. We found that most patients having a TPbx had no clinically significant change in quality of life in the first three months following the procedure. However, 24% exhibited clinically worse urinary function and 18% had worse sexual function at one-month. At three-months, 3% of patients had

clinically worse urinary function and 25% continued to have worse sexual function compared with baseline. Patients who were subsequently diagnosed with cancer on the basis of the results of the TPbx exhibited statistically significantly reduced quality of life for the EPIC urinary scales and reduced improvements in scores on the psychological scales at one-month follow-up compared with those who were not diagnosed with cancer.

Conclusions

Most patients having a TPbx had no clinically significant change in quality of life in the first three months following the procedure. However, patients should be advised that a quarter may have clinically worse urinary function and nearly 20% have clinically worse sexual function in the first month and that sexual function deficits may continue up to three-months. The results of this study provide a resource that the clinician can use when discussing TPbx with patients.

Introduction

Diagnosis of prostate cancer is confirmed by prostate biopsy which can be performed either using a transrectal (TRUSbx) or transperineal (TPbx) approach. There is a higher risk of infection with the TRUSbx approach as the needle can inoculate bacteria from the rectum into the prostate [1]. For this reason, along with putative improved staging accuracy [2], some authors have suggested that TPbx should be the standard approach for all prostate biopsies [3]. However, there is little data available to physicians to accurately counsel patients prior to the TPbx procedure regarding possible quality of life changes in the months after the biopsy. Whilst there may be conflicting evidence, it is becoming increasingly recognised that some TRUSbx patients experience varying degrees of urinary dysfunction, erectile dysfunction and mental health changes in the early period following the biopsy procedure [4-9]. Given this, it is possible that the TPbx approach will also result in short-term deficits in quality of life. It is important that patients are counselled regarding the likelihood of any short-term effects to facilitate informed decision-making and to ensure that patient expectations are in line with the

actual experiences of previous patients. It has previously been shown that 25% of biopsy patients reported being under-informed of what to expect after the biopsy and that this increased patient stress and anxiety levels [10]. Further, patient expectation has been shown to have an effect on patient satisfaction with their healthcare experiences [11].

The issues surrounding the quality of life of patients having a prostate biopsy for the diagnosis of prostate cancer are increasingly relevant with the escalating management of patients with low volume, slow growing, localised tumours using active surveillance (AS) [12-15]. Most protocols call for a repeat biopsy within a year of being put on to AS [16]. While AS has been shown to be psychologically safe [17], as the adoption of AS increases, adherence to the management regime may be complicated by issues related to the multiple biopsies required, where patients who experience quality of life changes may be less willing to attend for future repeat biopsies. We undertook a prospective, observational study to investigate whether TPbx results in patient-reported quality of life changes from baseline in the first three-months after the procedure.

Patients and methods

Patients having a diagnostic prostate biopsy performed by urologists at two recruitment sites (one a public cancer centre and the other the private practice of one of the investigators (JSP)) were invited to participate in the study. The study was approved by the Institutional Ethics Committee and written informed consent was obtained from each patient. Patients were enrolled at the public hospital site between October 2013 and July 2014 and at the private practice site between March 2014 and July 2014. Patients were scheduled for TPbx as determined by the urologist for reasons including elevated prostate-specific antigen (PSA), rising PSA, abnormal digital rectal exam (DRE), being on an active surveillance protocol, elevated prostate health index (PHI) test or abnormal magnetic resonance imaging (MRI). All TPbx were performed under general anaesthesia using the standardised technique defined by the Ginsburg Study Group [18]. Patients had 24 or 32 cores taken depending on the size of the prostate. Patients who were less

than 40 years old, had a history of previous prostatic surgery, active urinary tract infection, any urologic malignancy, or if they would be unable to complete the questionnaires (due to their primary language being other than English or if they had an intellectual disability) were excluded. Patients were excluded from further follow-up if they had a prostatectomy during the study period.

Patients were asked to complete a set of questionnaires that were designed to measure demographics, urinary function, sexual function, bowel function, hormonal function, anxiety, depression and willingness to have a repeat TPbx. Clinical data was also obtained from the medical record. The demographics questionnaire included items related to age, comorbidities, smoking status, work status, and marital status. The Expanded Prostate cancer Index Composite (EPIC)-26 is a comprehensive instrument composed of 26 items [19]. Domains assessed include urinary incontinence, urinary irritation and obstruction, sexual function, bowel function, hormonal function, urinary bother, sexual bother, bowel bother, and hormonal bother [19]. Each domain is measured on a linearly transformed scale from zero to one hundred with higher scores representing better quality of life. No categorical group cut-off's have been defined for the continuous scales, however, minimally important clinical differences have been published of 6-9 for the urinary incontinence scale, 5-7 for the urinary obstruction scale, 4-6 for bowel, 10-12 for sexual, and 4-6 for the hormone scale [20]. The Sexual Health Inventory for Men (SHIM) (also known as the International Index of Erectile Function-5 or IIEF-5) is the single most frequently used measure of potency in the urologic literature and consists of five items that measure erectile function and intercourse satisfaction [21]. It was originally designed to measure erectile dysfunction in pharmaceutical trials of sildenafil citrate with higher scores indicating better function. Five categories of erectile dysfunction have been defined based on the SHIM: severe (5-7), moderate (8-11), mild to moderate (12-16), mild (17-21), and none (22-25)[21]. The International Prostate Symptom Score (IPSS) (also known as the American Urological Association-7 (AUA-7) or the AUA-Symptom Index (AUA-SI)) is made up of seven items and was developed to assess the severity of lower urinary tract symptoms in patients with benign

prostatic hyperplasia (BPH) [22]. Three categories of symptom severity have been defined, with scores of less than or equal to 7 corresponding to mild, 8 to 19 moderate, and greater than or equal to 20 severe LUTS. The Generalised Anxiety Disorder-7 (GAD-7) consists of seven items and is one of the few generalised anxiety disorder instruments that is specifically linked to DSM-IV criteria [23, 24]. Scores of 0-4, 5-9, 10-14, 15-19 and 20 or greater represent minimal, mild, moderate, moderately severe and severe levels of anxiety [23]. The Patient Health Questionnaire-9 (PHQ-9) was designed to measure depression severity [25]. The individual items are based on the nine criteria that define a diagnosis of a depressive disorder according to DSM-IV [24]. Similarly to the GAD-7, cut points of 5, 10, 15 and 20 represent minimal, mild, moderate, moderately severe and severe levels of depression. One additional item asks patients who did have any problems (as indicated by the diagnosis questions) about how difficult these problems have made it to do their usual activities [25]. At the one-month follow-up, patients were also asked to complete a global question that asked, “given your experience with your biopsy, would you have a problem having another biopsy in a years’ time?”

Patients were asked to complete the questionnaires at three time points: pre-biopsy (baseline) and at one- and three-months post-biopsy. The instruments were scored using the published scoring methods. Wilcoxon signed ranks tests were used to investigate overall differences in urinary function, erectile function, anxiety and depression from baseline to one-month and from baseline to three-months. Mann-Whitney U tests were used to analyse statistically significant differences between groups at the same time point. All analyses were performed using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY). In all tests statistical significance was defined as $p < .05$. To investigate clinically significant changes from baseline, a patients’ EPIC scores were defined as being better, worse or the same based on the upper limit of the minimal important clinical difference defined by Skolarus et al. [20]. Those with changes greater than the upper limit were defined as better, those with changes less than the additive inverse of the upper limit were defined as worse, and those between these two limits were defined as being the same.

Clinically significance changes in SHIM, IPSS, GAD and PHQ were defined as being better, worse or the same based on whether the patients score moved from one categorical group to another at follow-up. Because the SHIM was designed for use and has been validated in patients who are sexually active [21], results for the SHIM and EPIC sexual scale are only presented for those that indicated they were sexually active at baseline.

Results

During the study enrolment period 118 patients had biopsies at the hospital or privately with the investigator. Of these, 53 consented to participate and completed the baseline questionnaire and at least one other follow-up questionnaire. Twenty-one patients were excluded (18%), 18 refused participation (15%), and 22 did not complete a baseline questionnaire (19%). Removing those patients who met the exclusion criteria, the overall enrolment rate was 59%. Questionnaires were returned by 41 patients at one-month (77% participation rate) and 36 patients at three-months follow-up (88% participation rate). The baseline characteristics of the enrolled patients are shown in Table 1. The median age was 64 (IQR, 53.5 – 67.8) and the median diagnostic PSA was 6.6 (IQR, 4.5 – 9.1). At the time of baseline measurement 43% of patients had some degree of erectile dysfunction according to the SHIM score and 34% of patients had moderate or severe LUTS according to the IPSS, though no patients reported using a pad prior to biopsy. Prostate cancer was subsequently diagnosed as unilateral in 32% and bilateral in a further 32% of patients. Fifty-five per cent of patients reported having haematuria in the days after the biopsy (range, 1 to 21 days, median 2.5 days) and 53% reported having haemospermia (range, 1 to 30 days, median 7 days).

The median (IQR) scores for the quality of life measures at the different time points can be seen in Table 2. Overall, patients had statistically significantly reduced scores from baseline on the GAD at one-month follow-up (indicating improved function, $p = .009$) and on the EPIC urinary incontinence scale at three-months (indicating reduced function, $p = .045$). Table 3 shows clinically significant differences at each follow-up from baseline. Approximately 25% of

patients had clinically worse urinary incontinence scores at one-month follow-up compared with only 3% at three-months. Over 20% of patients had a clinically significant improvement in their EPIC bowel, sex and hormone scale scores at one-month. At three-months follow-up, a quarter of patients had clinically worse EPIC sexual scale scores and 17% had worse SHIM scores than at baseline. Aside from the EPIC sexual and SHIM scales, fewer than 15% of patients had worse function for any of the other measures at the 3-month follow-up. Overall, most patients reported no clinically significant changes to their quality of life following the TPbx.

There were no significant differences in quality of life scores between patients diagnosed with cancer or not on the TPbx at baseline (data not shown). Patients who were diagnosed with cancer on the basis of the results of the TPbx exhibited a significantly greater change (reduction) in scores at one-month compared with baseline than those who were not diagnosed with cancer for the EPIC urinary incontinence ($p = .020$), EPIC urinary obstruction ($p = .038$), and EPIC urinary bother ($p = .017$) scales (Table 4). In addition, patients diagnosed with cancer had significantly less of a change (reduction) in GAD ($p = .037$) and PHQ ($p = .034$) scores than those who were not diagnosed with cancer. When comparing changes between the cancer diagnosis groups from baseline to three-months there were no significant differences.

When patients were asked, “given your experience with your biopsy, would you have a problem having another biopsy in a year’s time?”, 51% answered that they would have “no problem” (64% of respondents), 23% a “minimal problem” (29% of respondents) and 6% (7% of respondents) indicated that they would have a “moderate” or “major” problem.

Discussion

Assessing whether there are any changes in the quality of life of patients having a prostate biopsy for the diagnosis of prostate cancer are increasingly relevant with the escalating management of patients with low volume, slow growing, localised tumours using an active surveillance (AS) protocol

requiring repeat biopsies [12, 16]. The adoption of the transperineal route for prostate biopsy is increasing due to its reduced infection rate and better sampling of the anterior part when compared with the traditional transrectal route [2]. Further, some authors have suggested that the reduced infection rate with the TPbx approach means that this should be the standard approach for all prostate biopsies [3]. However, there is little data available to help physicians counsel patients as to possible clinically significant changes in quality of life that they may face following the TPbx procedure. It is particularly important that patients are fully informed of any possible functional deficits, regardless of how transient these are, for a diagnostic test as patients whose results show no known disease but who have functional deficits may be more likely to be dissatisfied with their decision to have the procedure and may be less likely to have repeat diagnostic tests in the future [10]. We found that most patients having a TPbx had no clinically significant change in quality of life in the first three months following the procedure. However, 24% exhibited clinically worse urinary function and 18% had worse sexual function at one-month. At three-months, 3% of patients had clinically worse urinary function and 25% continued to have worse sexual function compared with baseline. Patients who were subsequently diagnosed with cancer on the basis of the results of the TPbx exhibited statistically significantly greater changes from baseline, indicating reduced quality of life, for the EPIC urinary scales and reduced improvements in scores on the psychological scales at one-month follow-up compared with those who were not diagnosed with cancer.

There are two studies in the literature that are most similar to ours in that they aimed to investigate patient-reported quality of life outcomes after TPbx. Both of these studies obtained more cores per patient than in our study. Losa et al. [26] assessed the quality of life and complications of patients eligible for focal therapy who underwent template-assisted TPbx under spinal anaesthesia. Patients had a median of 40 cores (range, 29-70). Merrick et al. [27] investigated the quality of life and clinical outcomes of patients having transperineal template-guided prostate mapping saturation biopsy. Patients had a median of 56 cores. Cancer was detected in fewer patients in the Merrick study (46%) than in our study (64%) or Losa's (62%). The median

baseline IPSS score of 9 was higher in the Merrick sample than in ours (5.5) or Losa's study (6). When investigating sexual function, both the Losa and Merrick studies analysed their data on all patients according to whether the patient was classified as having any erectile dysfunction (ED) or not. We followed the scoring principle in the validation paper for the SHIM of including only those who were sexually active [21]. When looking at outcomes after TPbx, Losa and our study found no significant differences in IPSS scores from baseline while Merrick found a change (improvement) in median IPSS score from baseline to one-month (9 to 2). This may be caused by the high baseline IPSS score or differences in alpha-blocker use, where Merrick's study prophylactically initiated 0.8mg of tamsulosin daily and for two weeks after the procedure. No significant differences were found in IIEF/SHIM scores from baseline to one-month in any of the three studies.

In a systematic review of complications following TRUSbx, it was suggested that up to 25% of patients will experience a temporary decrease in urinary function after the procedure [7]. Of those patients who do endure urinary function deficits after a TRUSbx, most will have resolved by one-month [5, 9]. For example, Murray found a statistically significant change in IPSS score from baseline to one-month but not three-months [9]. However, the mean scores in this study at baseline, one-month and three-months were 10.2, 9.4 and 9.3, respectively, suggesting that the clinical significance of these changes is doubtful. This finding underpins the importance of considering the clinical significance of scores and not just the statistical significance when using standardised questionnaires to investigate patient-reported quality of life outcomes. Further, the mean baseline scores for the Murray sample of patients indicate they had underlying moderate urinary dysfunction prior to the procedure which could affect the external validity of these results when comparing to other patient samples that have better baseline urinary function. Our analysis indicates that few patients have clinically significant changes in IPSS scores after TPbx (Table 3), however, using the EPIC urinary function scale we found that 24% had a clinically significant reduction in function at one-month that reduced to 3% of patients at three-months. This suggests that patients should be counselled that a quarter could expect to encounter a

urinary function deficit that resolves in most of those patients by three-months. The IPSS was designed for use in patients with BPH [22] while the EPIC was designed for use in patients with prostate cancer [19]. Hence, the differences in the wording of the questions may explain this difference in findings. Further, it must be considered that none of the questionnaires used in the literature have been formally validated for use in prostate biopsy populations, which may have led to measurement error that could explain the discrepancies in findings in the same samples using different instruments [28].

Comparisons across studies relating to erectile function after biopsy are complicated by differences in inclusion criteria for analyses, for example, whether patients were potent at baseline or not or whether questions were answered as the patient would be with or without the use of sexual aids. When investigating sexual function following TRUSbx, Zisman et al. using their own questionnaire showed that 10% of previously potent men who had no known risk factors (e.g., anxiety, subsequent prostate cancer diagnosis, diabetes) had ED at one-month post TRUS-bx [6], compared to the 5-6% ED rate in previously fully-potent men having TPbx [26, 27]. Using the SHIM in a study where over 80% of participants had some degree of baseline ED, Chrisofos showed no statistically significant change in TRUSbx patients from baseline to one- or three-months [29]. This compares with our sexually active group, where we found that 18% had clinically worse SHIM and EPIC sexual scores at one-month and 25% had clinically worse EPIC sexual scores at three-months.

There is growing evidence to suggest that there is a psychosomatic effect of having the diagnostic prostate biopsy which affects the urinary and sexual function of some patients [4, 6, 7, 30]. This may act in a positive direction for some. For example, Losa found that of the patients who were classified as having ED at baseline and who were not sexually active, 14% reported an increase in IIEF score and an accompanying resumption in sexual activity at one-month follow-up [26]. Similarly, though we found worse sexual function in up to a quarter of patients, we also found that more patients have clinically significantly better bowel, sexual and hormonal scores at one-month than do

patients who have reduced function. This could be as a result of the statistically significantly improved anxiety that we observed at 1-month. This finding is supported by the results of the study by Gustafsson et al. who measured cortisol levels in men attending for prostate cancer screening [30]. They found that cortisol levels were highest in men before they received the results of the biopsy and that after the result of the biopsy was known, anxiety levels fell no matter what the results of the biopsy were. Such results suggest that measurement of psychological domains at baseline and follow-up may be necessary in future studies. In addition, studies should be conducted to investigate whether those with high baseline anxiety levels benefit from pre-procedural interventions.

Due to its effects on psychological status (particularly anxiety [8]), cancer diagnosis could be expected to have an effect on patient quality of life in the months after a prostate biopsy. Using the IPSS and SHIM, we found no difference in change from baseline scores based on whether they were diagnosed with cancer or not at either follow-up. Similar results have been found at one-month in a sample of TRUSbx patients [31]. However, our results indicate that patients who are diagnosed with cancer have greater changes (reductions) in their urinary incontinence and obstruction and an associated greater bother with their urinary symptoms at one-month post-procedure than those patients who were not diagnosed with cancer when measured using the EPIC scales. Similarly, Helfand et al. found significant differences across all scales of the 15-item IIEF [31]. This again reflects differences in results when assessed using different questionnaires in the same sample of patients. The SHIM and the erectile function scale of the IIEF-15 have as their focus the measurement of potency, whereas the EPIC sexual scale and the full 15-item IIEF consist of items that have greater coverage of other aspects of sexual function that may have greater precision in capturing changes in quality of life from the patients' perspective. Anxiety has been shown to affect the urinary function of patients being screened for prostate cancer [32] and this relationship may be why we saw greater reduction in urinary function scores and less of a reduction in anxiety and depression in those diagnosed with cancer. This finding adds further weight to

the possibility that any changes after biopsy are more related to the patients' psychological status than to any direct trauma or inflammation that are a result of the biopsy itself.

Overall, 36% of patients indicated that they would have a problem with having a repeat biopsy in 12-months' time. Considering the possibility of a requirement for a repeat biopsy for those who had negative biopsies, it is concerning that 46% of those not diagnosed with cancer indicated that they would have a problem with having the repeat TPbx. Rosario et al. reported up to 20% of patients undergoing TRUSbx in a prospective study similarly reported that they would consider a further biopsy to be a major problem[33]. Unlike previous studies, none of the patients had infections that could influence this result [10]. Further research is needed to ascertain why the patients' feel this way and what could be implemented to reduce the negative attitudes of patients to having a repeat biopsy. It is possible that the data from this study could be used by the physician to inform patients of the likelihood of any deficits and that this will improve patient expectation and in turn satisfaction rates and a willingness to have a repeat TPbx [10].

This study's strength is in its prospective data collection which overcomes the problem of patient recall biases in retrospective, observational studies. However, it is limited by the small number of patients enrolled and the use of patient-reported quality of life instruments that have not been validated for use in this particular population of interest. Also, the study design is limited to patients undergoing TPbx and comparisons with outcomes following TRUSbx cannot be made. Nevertheless, the data fills a gap in the literature that can be used by physicians to counsel patients as to what they could expect with regard to quality of life changes in the first three months after the procedure.

In conclusion, we found that most patients having a TPbx had no clinically significant change in quality of life in the first three months following the procedure. However, patients should be advised that a quarter may have clinically worse urinary function and nearly 20% have clinically worse sexual function in the first month and that sexual function deficits may continue up to

three-months after the procedure. The results of this study provide a resource that the clinician can use when discussing TPbx with patients. Clinical researchers are encouraged to consider clinical significance as well as statistical significance when reporting results.

Acknowledgements

Adam Dowrick was supported by a Neil Hamilton Fairley Overseas Clinical Fellowship from the National Health and Medical Research Council (NHMRC) of Australia (581510).

We thank Emma Birch, Barbara Hartmann and Pina Grasso for their assistance with the conduct of this study.

References

- [1] Lindert K, Kabalin J, Terris M. Bacteremia and bacteriuria after transrectal ultrasound guided prostate biopsy. *J Urol*. 2000; **164**:76-80
- [2] Vyas L, Acher P, Kinsella J, et al. Indications, results and safety profile of transperineal sector biopsies (TPSB) of the prostate: a single centre experience of 634 cases. *BJU Int*. 2014; **114**:32-7
- [3] Grummet J, Weerakoon M, Huang S, et al. Sepsis and 'superbugs': should we favour the transperineal over the transrectal approach for prostate biopsy? *BJU Int*. 2014; **114**:384-8
- [4] Glaser AP, Novakovic K, Helfand BT. The impact of prostate biopsy on urinary symptoms, erectile function, and anxiety. *Curr Urol Rep*. 2012; **13**:447-54
- [5] Zisman A, Leibovici D, Kleinmann J, Cooper A, Siegel Y, Lindner A. The impact of prostate biopsy on patient well-being: a prospective study of voiding impairment. *J Urol*. 2001; **166**:2242-6
- [6] Zisman A, Leibovici D, Kleinmann J, Siegel Y, Lindner A. The impact of prostate biopsy on patient well-being: a prospective study of pain anxiety and erectile dysfunction. *J Urol*. 2001; **165**:445-54
- [7] Loeb S, Vellekoop A, Ahmed H, et al. Systematic review of complications of prostate biopsy. *Eur Urol*. 2013; **64**:876-92
- [8] Wade J, Rosario D, Macefield RC, et al. Psychological impact of prostate biopsy: physical symptoms, anxiety, and depression. *J Clin Oncol*. 2013; **31**:4235-41

- [9] Murray K, Bailey J, Zuk K, Lopez-Corona E, Thrasher J. A prospective study of erectile function after transrectal ultrasonography-guided prostate biopsy. *BJU Int.* 2015; **116**:190-5
- [10] Wade J, Rosario D, Howson J, et al. Role of information in preparing men for transrectal ultrasound guided prostate biopsy: a qualitative study embedded in the ProtecT trial. *BMC Health Serv Res.* 2015; **15**:80
- [11] Boudreaux E, Mandry C, Wood K. Patient satisfaction data as a quality indicator: a tale of two emergency departments. *Acad Emerg Med.* 2003; **10**:261-8
- [12] Weiner A, Patel S, Etzioni R, Eggener S. National trends in the management of low and intermediate risk prostate cancer in the United States. *J Urol.* 2015; **193**:95-102
- [13] Cooperberg M, Carroll P. Trends in management for patients with localized prostate cancer, 1990-2013. *JAMA.* 2015; **314**:80-2
- [14] Murphy D, Loeb S. Prostate cancer: growth of AS in the USA signals reduction in overtreatment. *Nat Rev Urol.* 2015; **in press**
- [15] Weerakoon M, Papa N, Lawrentschuk N, et al. The current use of active surveillance in an Australian cohort of men: a pattern of care analysis from the Victorian Prostate Cancer Registry. *BJU Int.* 2015; **115**:50-6
- [16] Filson C, Marks L, Litwin M. Expectant management for men with early stage prostate cancer. *CA Cancer J Clin.* 2015; **65**:264-82
- [17] Anderson J, Burney S, Brooker J, et al. Anxiety in the management of localised prostate cancer by active surveillance. *BJU Int.* 2014; **114**:55-61
- [18] Kuru T, Wadhwa K, Chang R, et al. Definitions of terms, processes and a minimum dataset for transperineal prostate biopsies: a standardization approach of the Ginsburg Study Group for Enhanced Prostate Diagnostics. *BJU Int.* 2013; **112**:568-77
- [19] Szymanski KM, Wei JT, Dunn RC, Sanda MG. Development and Validation of an Abbreviated Version of the Expanded Prostate cancer Index Composite instrument (EPIC-26) for measuring health-related quality of life among prostate cancer survivors. *Urology.* 2010; **76**:1245-50
- [20] Skolarus T, Dunn R, Sanda MG, et al. Minimally important difference for the Expanded Prostate Cancer Index Composite Short Form. *Urology.* 2015; **85**:101-5
- [21] Rosen RC, Cappelleri JC, Smith MD, Lipsky J, Peña BM. Development and evaluation of an abridged, 5-item version of the International Index of Erectile

Function (IIEF-5) as a diagnostic tool for erectile dysfunction. *Int J Impotence Res.* 1999; **11**:319-26

[22] Barry M, Fowler F, Chang Y, Liss C, Wilson H, Stek M, Jr. The American Urological Association symptom index: does mode of administration affect its psychometric properties? *J Urol.* 1995; **154**:1056-9

[23] Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder. The GAD-7. *Arch Intern Med.* 2006; **166**:1092-7

[24] American Psychiatric Association. Diagnostic and statistical manual of mental disorders: DSM-IV. Fourth edn, Washington DC: American Psychiatric Association, 1994

[25] Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. Validity of a brief depression severity measure *J Gen Intern Med.* 2001; **16**:606-13

[26] Losa A, Gadda G, Lazzeri M, et al. Complications and quality of life after template-assisted transperineal prostate biopsy in patients eligible for focal therapy. *Urology.* 2013; **81**:1291-6

[27] Merrick G, Taubenslag W, Andreini H, et al. The morbidity of transperineal template-guided prostate mapping biopsy. *BJU Int.* 2008; **101**:1524-9

[28] Dowrick A, Wootten A, Murphy D, Costello A. "We used a validated questionnaire": what does this mean and is it an accurate statement in urologic research? *Urology.* 2015; **85**:1304-11

[29] Chrisofos M, Papatsoris A, Dellis A, Varkarakis I, Skolarikos A, Deliveliotis C. Can prostate biopsies affect erectile function? *Andrologia.* 2006; **38**:79-83

[30] Gustafsson O, Theorell T, Norming U, Perski A, Öhström M, Nyman CR. Psychological reactions in men screened for prostate cancer. *Br J Urol.* 1995; **75**:631-6

[31] Helfand BT, Glaser AP, Rimar K, et al. Prostate cancer diagnosis is associated with an increased risk of erectile dysfunction after prostate biopsy. *BJU Int.* 2013; **111**:38-43

[32] Brindle L, Oliver S, Dedman D, et al. Measuring the psychosocial impact of population-based prostate-specific antigen testing for prostate cancer in the UK. *BJU Int.* 2006; **2006**:777-82

[33] Rosario D, Lane JA, Metcalfe C, et al. Short term outcomes of prostate biopsy in men tested for cancer by prostate specific antigen: prospective evaluation within ProtecT study. BMJ. 2012; **344**:d7894

Author Manuscript

Table 1. Demographic and clinical data.

Variable	TP bx pts (n=53)
Age, median (IQR)	64.0 (53.5 – 67.8)
Partnership status, n (%)	
Partnered	41 (77)
Unpartnered	11 (21)
missing	1 (2)
Education, n (%)	
School education only	22 (41)
Undergraduate degree	3 (6)
Postgraduate training or degree	19 (36)
Trade qualification	8 (15)
missing	1 (2)
Employment prior to biopsy, n (%)	
Full time	28 (53)
Part time	4 (7)
Unemployed, not interested in returning to work	1 (2)
Unemployed, disabled	2 (4)
Retired	18 (34)
Smoking status, n (%)	
Never	33 (62)
Current	4 (8)
Stopped	16 (30)
BMI, median (IQR)	27.1 (25.5 – 30.6)
Number of comorbidities, n (%)	
0	17 (32)
1	13 (25)
2	15 (28)
>2	8 (15)
Pre-biopsy PSA, median (IQR)	6.6 (4.5 – 9.1)

Malignancy diagnosed on biopsy,

n (%)

Yes, unilateral 17 (32)

Yes, bilateral 17 (32)

No 19 (36)

Haematuria post biopsy, n (%)

Yes 29 (55)

No 24 (45)

Haematuria days, median (IQR) 2.5 (2.0 – 6.8)

Haemospermia post biopsy, n (%)

Yes 28 (53)

No 25 (47)

Haemospermia days, median (IQR) 7 (5.0 – 18.5)

Sexually active at baseline, n (%)

Yes 40 (76)

No 13 (24)

Erectile dysfunction at baseline,
SHIM < 22, n (%) (for patients who
indicated they were sexually active
at baseline only)

Yes 17 (43)

No 22 (55)

missing 1 (2)

LUTS at baseline, IPSS > 8, n (%)

Yes 18 (34)

No 34 (64)

missing 1 (2)

nb: IQR = interquartile range; BMI = body mass index; PSA = prostate-specific antigen; SHIM = Sexual Health Inventory for Men; LUTS = lower urinary tract symptoms; IPSS = International Prostate Symptom Score

Table 2. Patient-reported quality of life data (all patients) (nb: figures at different time points are median (IQR)).

Variables	Baseline (n = 53)	1-month (n = 41)	p-value *	3-months (n = 36)	p-value **
EPIC-UI	100 (85.5 – 100)	100 (85.5 – 100)	.35	100 (66.8 – 100)	.045
EPIC-UO	93.8 (81.2 – 100)	87.5 (75.0 – 93.8)	.23	93.8 (76.6 – 100)	.70
EPIC-UB	100 (75.0 – 100)	100 (75.0 – 100)	.92	100 (75.0 – 100)	.62
EPIC-B	100 (83.3 – 100)	100 (91.2 – 100)	.10	100 (92.7 – 100)	.14
EPIC-SEX	83.3 (70.8 – 100)	83.3 (52.8 – 95.8)	.26	95.8 (66.7 – 100)	.43
EPIC-H	95.0 (85.0 – 100)	97.5 (88.8 – 100)	.12	100 (80.0 – 100)	.88
SHIM	23 (18 – 25)	22 (15.5 – 25)	.09	24 (24 – 25)	.86
IPSS	5.5 (3 – 12)	6 (2.8 – 12)	.79	5 (1 – 14)	.80
GAD-7	1 (0 – 6)	1 (0 – 2)	.009	0 (0 – 3.7)	.42
PHQ-9	3 (1 – 5)	1 (0 – 4)	1.0	0 (0 – 4.2)	.15

nb:

* = p-value for Wilcoxon signed rank test between baseline and 1-month

** = p-value for Wilcoxon signed rank test between baseline and 3-months

EPIC = Expanded Prostate cancer Index Composite; UI = urinary incontinence domain; UO = urinary obstruction domain; UB = urinary bother domain; B = bowel domain; SEX = sexual domain; H = hormonal domain; SHIM = Sexual Health Inventory for Men (also known as IIEF-5); IPSS = International Prostate Symptom Score; GAD = Generalised Anxiety Disorder; PHQ = Personal Health Questionnaire; IQR = interquartile range

Table 3. Clinically significant changes observed for EPIC scales at different time points (nb: figures at different time points are n (%)).

Variables	Clinically significant change from baseline to 1-month			Clinically significant change from baseline to 3-months		
	n (%)			n (%)		
	Better	No difference	Worse	Better	No difference	Worse
EPIC-UI	2 (6)	23 (70)	8 (24)	4 (10)	33 (87)	1 (3)
EPIC-UO	5 (14)	25 (72)	5 (14)	6 (15)	27 (70)	6 (15)
EPIC-B	9 (25)	24 (67)	3 (8)	10 (25)	26 (63)	5 (12)
EPIC-SEX	9 (26)	19 (56)	6 (18)	9 (23)	21 (52)	10 (25)
EPIC-H	7 (20)	21 (62)	6 (18)	7 (18)	29 (76)	2 (5)
SHIM	3 (7)	30 (75)	7 (18)	0	25 (83)	5 (17)
IPSS	6 (16)	28 (76)	3 (8)	4 (12)	26 (76)	4 (12)
GAD-7	8 (21)	29 (76)	1 (3)	4 (11)	28 (78)	4 (11)
PHQ-9	5 (14)	28 (80)	2 (6)	5 (16)	22 (71)	4 (13)

nb: EPIC = Expanded Prostate cancer Index Composite; UI = urinary incontinence domain; UO = urinary obstruction domain; UB = urinary bother domain; B = bowel domain; SEX = sexual domain; H = hormonal domain; SHIM = Sexual Health Inventory for Men (also known as IIEF-5); IPSS = International Prostate Symptom Score; GAD = Generalised Anxiety Disorder; PHQ = Personal Health Questionnaire

Table 4. Median changes from baseline scores for patient-reported quality of life by whether patients were diagnosed with cancer on transperineal biopsy.

Variables	Median (IQR) change from baseline to 1-month			Median (IQR) change from baseline to 3-months		
	Cancer	No cancer	p-value	Cancer	No cancer	p-value
EPIC-UI	0 (-36.4 – 0)	0 (0 – 6.2)	.020	0 (-1.6 – 0)	0 (0 – 7.8)	.08
EPIC-UO	-3.1 (-7.8 – 0)	6.2 (-3.1 – 9.4)	.038	0 (-6.2 – 0)	-3.1 (-10.9 – 0)	.62
EPIC-UB	0 (-25 – 0)	0 (0 – 25)	.017	0 (0 – 0)	0 (0 – 0)	.81
EPIC-B	0 (0 – 8.3)	0 (0 – 8.3)	.80	0 (0 – 4.2)	0 (-2.1 – 10.4)	.97
EPIC-SEX	0 (-1.0 – 8.3)	0 (0 – 3.4)	.68	0 (-20.2 – 8.3)	0 (-13.9 – 4.2)	.57
EPIC-H	0 (-7.5 – 7.5)	0 (0 – 2.5)	.65	0 (-2.5 – 5.0)	0 (0 – 5)	.63
SHIM	0 (0 – 1)	0 (0 – 0)	.73	0 (-1.5 – 1.0)	0 (-3.0 – 0)	.98
IPSS	0 (-2.0 – 2.5)	0 (-4.5 – 0.5)	.19	1 (-1.5 – 2.0)	-1 (-5 – 1.7)	.38
GAD-7	0 (-1.0 – 2.0)	-1.0 (-3.5 – 0)	.037	0 (-3 – 0)	0 (-2.5 – 0)	.76
PHQ-9	0 (-2.2 – 2.2)	-1.0 (-3.5 – -0.5)	.034	0 (-2 – 0)	0 (-1.7 – 0)	.82

nb: EPIC = Expanded Prostate cancer Index Composite; UI = urinary incontinence domain; UO = urinary obstruction domain; UB = urinary bother domain; B = bowel domain; SEX = sexual domain; H = hormonal domain; SHIM = Sexual Health Inventory for Men (also known as IIEF-5); IPSS = International Prostate Symptom Score; GAD = Generalised Anxiety Disorder; PHQ = Personal Health Questionnaire; IQR = interquartile range

Minerva Access is the Institutional Repository of The University of Melbourne

Author/s:

Dowrick, AS;Wootten, AC;Howard, N;Peters, JS;Murphy, DG

Title:

A prospective study of the short-term quality-of-life outcomes of patients undergoing transperineal prostate biopsy

Date:

2016-07-01

Citation:

Dowrick, A. S., Wootten, A. C., Howard, N., Peters, J. S. & Murphy, D. G. (2016). A prospective study of the short-term quality-of-life outcomes of patients undergoing transperineal prostate biopsy. *BJU INTERNATIONAL*, 118 (1), pp.60-67. <https://doi.org/10.1111/bju.13413>.

Persistent Link:

<http://hdl.handle.net/11343/290971>