Patient Reported Outcome Measures for transperineal template prostate mapping biopsies in the PICTURE study

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Abstract

Purpose:

Transperineal prostate mapping (TTPM) biopsy is an increasingly utilized method of procuring tissue from men with suspected prostate cancer. We sought to report the patient related outcome measures (PROMs) and adverse events in men undergoing this diagnostic test within the PICTURE trial.

Material and Methods:

249 men underwent a mpMRI followed by a TTPM biopsy as a validation study. Pre-and post-TTPM functional outcomes were prospectively collected and recorded using IPSS, IPSS-QoL, IIEF-15 and EPIC-Urinary function questionnaires.

Results:

Mean age, median PSA and median gland size was 62 years, 6.8 ng/ml and 37ml, respectively. **At TTPM biopsy, a median (IQR) 49 (40-55) cores were taken**. Mean time for completion of post-procedure PROMs questionnaires was 46 days. Adverse events included post procedure acute urinary retention (24%), rectal pain (26%) and perineal pain (41%). TTPM-biopsy resulted in a statistically significant increase in IPSS (10.9 to 11.8; p=0.024) and IPSS-QoL score (1.57 to 1.76; p=0.03). The erectile function score on IIEF-15 declined by 23.2% (47.7 to 38.7; **p<0.001**). Significant deterioration in all 5 functional domains of IIEF-15 (erectile and orgasmic function, sexual desire, intercourse and overall satisfaction; **p<0.001**) occurred. EPIC-Urinary scores showed no overall change from baseline.

Conclusions:

TTPM-biopsy causes a high urinary retention rate and a detrimental impact on genitourinary functional outcomes including deterioration in urinary flow and sexual function. Our findings can be used to ensure adequate counselling about TTPM-biopsies and point to a need for strategies such as mpMRI and targeted biopsies to minimize harms of TTPM-biopsy.

Introduction

Men who have had a transrectal ultrasound guided prostate cancer can sometimes be miss-classified **due to the diagnostic inaccuracy of this test**.[1] [2] As a result, in many healthcare settings, transperineal template sectoral or prostate mapping (TTPM) biopsies are increasingly used as a second biopsy technique in men with an initial TRUS biopsy where diagnostic uncertainty remains.[3] [4] TTPM-biopsy is an accurate technique but is more invasive in that multiple biopsies (on average between 30-60 cores) are taken under general **or spinal** anaesthesia. The impact of this test on quality of life has been poorly reported. **The clinical risks associated with prostate biopsies include hemorrhagic complications including hematuria, hematospermia, and rectal and perineal bleeding.[5] TRUS biopsy also incurs a significant sepsis risk and the promotion of global antibiotic resistance.[6]**

Traditional clinical ways of measuring health and the effects of treatment are increasingly accompanied by patient reported outcome measures (PROMs)[7]. These are directly reported by the patient without interpretation of the patient's response by a clinician[8]. **PROMs** have become the new standard for evaluating the patient experience, and progressively being used to shape the way healthcare is funded, provided and managed.[7] This has included studies using PROMs for various modalities of prostate cancer treatments across all grades of disease including active surveillance, watchful waiting, brachytherapy, radical radiotherapy, prostatectomy have also been extensively reported in literature[9-12].

The Prostate Imaging Compared to Transperineal Ultrasound-guided biopsy for significant PCa Risk Evaluation (PICTURE) was a paired-cohort confirmatory study designed to assess the diagnostic accuracy of multi-parametric resonance imaging (mpMRI) in men requiring a repeat biopsy.[13] [14] PICTURE prospectively provided evidence on the diagnostic performance of the mpMRI, MRI-targeted biopsies and validated this index test against the reference test of TTPM-biopsy.

Here we report adverse events as well as changes in **PROMs** for **the largest series** of men undergoing TTPM within the PICTURE trial.

Material and Methods

Study design and participants

The PICTURE trial design, baseline demographic and clinical results have been fully reported elsewhere in detail (**table 1** and 2)[13 14]. Ethics committee approval for the study was granted by London City Road and Hampstead National Research Ethics Committee (reference 11/LO/1657). The study opened to recruitment on 11 January 2012 and completed recruitment on 29 January 2014. All men had already undergone a TRUS-biopsy previously. **The study was conducted in a single-centre by three experienced operating surgeons.** Pre TTPM-biopsy, patients received intravenous antibiotics in the form of a combination of intravenous gentamicin (120mg) and cefuroxime (1.5g). In brief, the mapping protocol utilized for TTPM-biopsy was undertaken using 5mm intervals **for the purposes of the validation of a new diagnostic test. This was** obtained using core needles inserted via a brachytherapy grid fixed on a stepper. In most prostates, two biopsies at each grid point were required to sample the full craniocaudal gland length. Post-procedure patients were given a metronidazole (500mg) suppository and analgesics in the form of NSAID and paracetamol/codeine combinations. Routine oral antibiotics were not given to patient's post-procedure.

Patient Reported Outcome Measures

Adverse events following TTPM were monitored and recorded including established and recognized side effects for this procedure. Validated PROMs questionnaires included the International Prostate Symptom Score (IPSS), IPSS Quality of Life (IPSS-QoL), Item International Index of Erectile Index Function (IIEF-15), Expanded Prostate Index Composite (EPIC) Urinary Function questionnaire given before and after TTPM-biopsy **(appendices 1, 2 and 3)**.

Data Collection and Analysis

All participants were provided with paper-based questionnaires at initial trial recruitment. Questionnaires were filled in private by the patients without any clinical or research team present. All participants were provided with a paper-based questionnaire pack via post and asked to return these via a pre-paid postal service or during their next clinical consultation which equated to 6 to 8 weeks post TTPM-biopsy.

Only those men who completed each pre-and-post questionnaire in full were included in the study for further analysis for each validated questionnaire type. All questionnaire responses and data were entered into an SPSS database (SPSS Statistics Version 24).

Descriptive statistics were used to describe the baseline and follow-up values of all parameters. For **PROMs** outcomes, a paired t test was used to evaluate the change from baseline for each measure. All statistical tests were 2-tailed and P values of < 0.05 were considered statistically significant. All analyses were carried out by using SPSS statistical software version 24.0 (SPSS Inc., Chicago, USA).

Results

Three-hundred and thirty men were enrolled, and following 81 withdrawals (gland> **80ml** n=61, patient choice n=9, medical reason n=4, miscellaneous n=7) we had 249 who completed both mpMRI and TTPM biopsies. Patient demographics and histological characteristics are summarized in table 1. Men eligible for analysis had a mean age of 62 years, median (IQR) PSA of 6.8 ng ml^{-1} (4.8-9.8), median (IQR) number of previous TRUS-biopsies 1 (1-2) and median gland size of 37ml (26.8-50.0). At TTPM biopsy, a median (IQR) 49 (40-55) cores were taken.

Mean time for completion of post-procedure PROMs questionnaires was 46 days. Of the 249 included in the PICTURE study, 203, 203, 164 and 176 men completed the IPSS, IPSS-QoL, IIEF-15 and the EPIC urinary questionnaires in full pre-and post TTPM-biopsy making our response rate 81.5%, 81.5%, 65.8% and 70.1%, respectively

Adverse events

Adverse events were captured in 236/249 (94.8%) patients in a median of 38±56 days after biopsy **(table 3)**. Haematuria was experienced by 220/249 (88.4%) post TTPM-biopsy with two (0.8%) requiring hospital admission due to clot urinary retention. Poor urine flow was reported in 108/249 (43.8%). Following TTPM-biopsy 56/249 **(22.55%) of men went into acute urinary retention. On average the urethral catheter remained in-situ for 8 days prior to successful removal.** No patient remained catheter dependent for more than 28 days or required a transurethral

resection following TTPM-biopsy. Post-procedure rectal and perineal pain and perineal bruising were reported in 59/249 (23.7%), 95/249 (38.1%), and 136/249 (54.6%), respectively. Urinary tract infection occurred 23/249 (9.2%) and perineal skin infection in 8/249 (3.2%). No patients were admitted into hospital with post-procedure urinary sepsis. Serious **related** adverse events resulting from TTPM biopsy occurred in **8**/249 (3.2%) **which were 2 urinary clot retentions, 5 acute urinary retentions (3 immediate<24hr and 2>24hrs ((day 14 and day 19)) and 1 hospital admission for monitoring with slow urinary flow where a catheter was not required.**

Urinary function

No men filled in the PROMs questionnaires with a catheter in-situ. TTPM-biopsy resulted in a statistically significant increase in IPSS (10.9 to 11.8; p=0.024 [2-tailed t-test]) (table 4). With regards to baseline urinary symptoms score, 33.5%, 54.8% and 11.7% fell into the IPSS mild, moderate and severe symptom groups, respectively. **There were no major chances on this** following TTPM-biopsy with 28.6%, 57.8% and 13.6% **in the mild, moderate and severe categories respectively**. TTPM-biopsy also resulted in a statistically significant sustained increase in IPSS-QoL score (1.57 to 1.76; p=0.03 [2-tailed t-test] [table 2]).

Sexual function

There was a statistically significant negative impact on sexual function, with erectile function scores on IIEF-15 decreasing (47.7 to 38.7; **p<0.001**(2-tailed t-test)) (table 5). There was a significant deterioration in all 5 functional domains of IIEF-15 (erectile and orgasmic function, sexual desire, intercourse and overall satisfaction; **p<0.001**) (table 2). De novo erectile dysfunction occurred in 49/249 (19.7%) with 2 men requiring oral medication.

EPIC-Urinary scores

The total EPIC urinary function scores showed no statistically significant change from baseline and post-TTPM-biopsy (24.28 to 24.78; p=0.69 [2-tailed t-test]) (table 6).

Overall urinary function did demonstrate a statistically significant deterioration (2.02 to 2.28 **p<0.001** (2-tailed paired t-test).

Discussion

In summary, our study shows that TTPM-biopsy has high adverse event rates including a high post-operative urinary retention rate in nearly 1 in 4 men. Furthermore, we have shown that there is a sustained detrimental impact on genitourinary **function including** deterioration in lower urinary tract symptoms and all aspects of sexual function persisting for several weeks.

Our study adds to literature on PROMs following prostate biopsies through the transperineal route.[15-17] Our study differs in that it is the first to report PROMs on men who exclusively underwent a TTPM-biopsy **following a prior TRUS-biopsy**. The first prospective collection of PROMs data for transperineal biopsies was reported by Wadhwa et al. [17] This study only evaluated the short-term PROMs (7-14 days) after transperineal prostate biopsy in 201 men. Again, this group demonstrated that transperineal prostate biopsy resulted in a significant detrimental change in erectile function score as was the case in our study but no difference in the IPSS and IPSS QoL scores. The major limitation in using this study as a comparator to ours was the heterogeneous non-standardized method of transperineal prostate biopsy across various centers which was not exclusively in a template mapping manner. Bhatt et al. [15] reported from a cohort of 27 patients all undergoing TTPM-biopsies with similar post-operative pain outcome and haematuria rate to our study. This group also demonstrated that there was a significant deterioration on sexual function score longer in duration due to the median follow-up questionnaire completion of 37-weeks in their study **which was significantly longer than our shorter follow-up period of 6-8 weeks**. **Pepe et al reported on 1 050 men undergoing a transperineal prostate biopsy and their sexual adverse events.[18] They reported the performance of transperineal prostate biopsy did not significantly worsen erectile function at 3-6 months from the procedure. [18] Their study did however used the shorter form of the IIEF questionnaire and also performed a lower number of cores in**

comparison to our study which was 5mm mapping biopsy of each prostate. TTPM-biopsies in our study would have included those grid-points 5mm from the urethra but biopsies were not taken through the midline grid-points anterior to the urethra in order to not traverse the urethra. We think the high retention rate will be due to biopsy-related swelling from the high number of cores.

Implementation of PROMs has transitioned from being primarily descriptive in nature to producing actionable findings.[19] Healthcare policy-makers now rely on these measures to determine whether specific procedures are worthwhile supporting and to compare outcomes between institutions. [20] Our findings can be used to ensure adequate counselling about TTPM-biopsies and point to a need for strategies such as mpMRI and targeted biopsies to minimize harms of TTPM-biopsy.

Nonetheless, TTPM-biopsy has advantages over TRUS biopsy with lower infection and sepsis rates and improved diagnostic information.[1] Furthermore TRUS biopsy has been shown be associated with significant pain and distress and a major causative factor of the globally increasing incidence of anti-microbial resistance to micro-organisms in the rectal flora .[21] [22] [23] Clearly, use of TTPM-biopsy on a larger scale would be expensive, resource intensive and, as we have shown, significant toxicity. The results of PROMIS has now provided level 1 evidence for the application of pre-biopsy mpMRI.[1] This is now the emerging standard of care throughout the major institutions across the U.K and beyond with other centres closely following suite due to a national strategy to deliver this change. [24]

The combination of pre-biopsy MRI and targeted biopsies has resulted in the use of image guided transperineal prostate biopsy as an increasing method of sampling from those men with suspected PCa.[25] Targeted transperineal biopsies with limited sampling means fewer cores than TTPM-biopsy, minimal toxicity and low retention rates of 1% or less done under local anaesthetic or conscious sedation.[24] TTPM-biopsy biopsies can be carried out in equivocal cases where imaging may be contraindicated or unclear, or where diagnostic doubt remains for some other reason.

The avoidance of TTPM and replacement with a targeted transperineal approach will also result in improved efficiency and optimization of the diagnostic pathway. Limiting the number of cores taken will result in efficiency- and cost-savings. It would liberate more operating time, reduce the number of consumables used, decrease the burden of technical time and work-load on pathology departments. [26] [27] This will additionally release more resources that could potentially be steered towards a greater number of men undergoing a contemporary PCa diagnostic pathway in a more timely manner. These potential outcomes in addition to the unfavorable PROMs are important issues that should be highlighted when engaging stakeholders in those units who are in the process or planning to re-structure their diagnostics pathways to a more up-to-date and patient centred model.

Our study limitations include the exclusion of those prostate glands larger than 80cc due to inability to accurately sample the lateral and anterior parts of the gland due to the bony pelvis. However, it is likely that our retention rates would have been much higher were larger glands included. **Our study did not assess the rates of post-procedural haematospermia and haematochezia.** Our **PROMs** response rate was not complete but higher than the majority of comparable studies in which response rates were 51.6-60%. [15] [17]. **With regards to the urinary function following a TTPM-biopsy, we believe that these differences though small are clinically relevant given the correlating changes in QoL scores**. The PICTURE study did not incorporate longitudinal follow-up beyond the 6-8-week period and this will be clearly needed to assess the time required by patients to return to their baseline genitourinary function following a TTPM-biopsy.

Conclusion

Our study has revealed that men who undergo a TTPM-biopsy will suffer a significant sustained detrimental erectile and urinary function with a high risk of requiring a urinary catheter due to urinary retention. Patients and their physicians should be aware of these detrimental effects and look to incorporate targeting and limited sampling to maintain accuracy and the benefits of low infection rates that transperineal biopsies confers.

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Legends

Table 1: Inclusion and exclusion criteria for the PICTURE study.

Table 2: Patient demographics and histological characteristics. IQR – interquartile range, MCCL = maximum cancer core length.

Table 3: Type and rate of adverse events following TTPM-biopsy

Table 4: Pre-and post-TTPM-biopsy IPSS and IPSS QoL.

Table 5: Pre-and post-TTPM-biopsy IIEF-15 scores including scores of all 5 domains.

Table 6: Pre-and post TTPM-biopsy UCLA-EPIC urinary function scores

Inclusion and exclusion criteria	
Inclusion	Men who have undergone prior trans-rectal biopsies.
	Men undergoing further evaluation of their prostate and who are suitable for characterisation using transperineal Template Prostate Mapping biopsy.
Exclusion	Previous history of prostate cancer treatment
	Men unable to have MRI scan, or in whom artefact would reduce quality of MRI.
	Men unable to have general or regional anaesthesia
	Men unable to give informed consent
	Men with a prostate size > 80g
Withdrawal	Men who are unfit or choose to not undergo Prostate Mapping biopsies after undergoing either or both index test.
	Men in whom either of the Index tests are inadequate for analysis due to artefact or image acquisition problems.
	Men in whom the reference test is inadequate for analysis due to lack of complete gland sampling or inadequate sampling density.

Table 1. Inclusion and exclusion criteria for the PICTURE study.

		Men Enrolled n=330	Men eligible for analysis following withdrawals, n=249
Characteristics			
Age (years), mean (s.d)		63 (7)	62 (7)
PSA (ng ml^{-1}) median (IQR)		7.4 (5.3-10.7)	6.8 (4.8-9.8)
No. of previous biopsies, median (IQR)		1 (1-2)	1 (1-2)
MRI prostate volume (cm^3), median (IQR)		42 (28-50)	37 (26.8-50)
Histological characteristics median (IQR)	Total no. of cores		49 (40-55)
	No. of cancer cores		6 (2-11)
	MCCL (mm)		4 (2-7)
	Gleason score		**N (%)**
	Benign		40 (16.1)
	3+3		66 (26.5)
	3+4		110 (44.2)
	4+3		29 (11.7)
	≥ 4+4		3 (1.2)
	3+5		1 (0.4)

Table 1: Patient demographics and histological characteristics. IQR – interquartile range, MCCL = maximum cancer core length.

Adverse Events	
Type	Rate
Haematuria	220/249 (88.4%)
Poor urine flow	108/249 (43.8%)
Acute urinary retention	56/249 (22.55%)
Rectal pain	59/249 (23.7%)
Perineal pain	95/249 (38.1%)
Perineal bruising	136/249 (54.6%)
Urinary tract infection	23/249 (9.2%)
Perineal skin infection	8/249 (3.2%)

Table 3. Type and rate of adverse events following TTPM-biopsy

	IPSS				IPSS QoL
	Total score (+/- sd)	**Mild (%)**	**Mod (%)**	**Sev (%)**	**Score (+/- sd)**
Pre-Biopsy	10.93 (6.77)	33.5	54.8	11.7	1.57 (1.28)
Post-Biopsy	11.76 (6.56)	28.6	57.8	13.6	1.76 (1.39)
P-value	0.024				0.03

Table 2. Pre-and post-TTPM-biopsy IPSS and IPSS QoL.

	IIEF-15					
	Overall score (+/- sd)	**Erectile Function (+/- sd)**	**Orgasmic Function (+/- sd)**	**Sexual Desire (+/- sd)**	**Intercourse Satisfaction (+/- sd)**	**Overall Satisfaction (+/- sd)**
Pre-Biopsy	47.73 (21.23)	19.66 (9.67)	7.19 (3.51)	6.51 (2.01)	7.56 (5.15)	6.81 (2.67)
Post-Biopsy	38.71 (22.64)	15.62 (10.42)	5.86 (3.87)	5.70 (2.38)	5.83 (5.37)	5.71 (2.82)
P-value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 3. Pre-and post-TTPM-biopsy IIEF-15 scores including scores of all 5 domains.

	UCLA- EPIC urinary function total score (+/- sd)
Pre-biopsy	24.28
	(3.65)
Post-biopsy	24.78
	(4.2)
P-value	0.69

Table 4: Pre-and post TTPM-biopsy UCLA-EPIC urinary function scores

International Prostate Symptom Score (IPSS)

Please Circle Answers

How often over the past month,	Not at all	Rarely	Less than half	About half	More than half	Almost always
Have you felt that you did not empty your bladder completely?	0	1	2	3	4	5
Have you had to pass water more than once in two hours?	0	1	2	3	4	5
Has the flow stopped and started?	0	1	2	3	4	5
Did you have to rush quickly to get to the toilet?	0	1	2	3	4	5
Was the force of the stream reduced?	0	1	2	3	4	5
Did you have difficulty starting to pass water?	0	1	2	3	4	5
At night, did you get up to pass water?	0	1	2	3	4	5

Total IPSS Score (Maximum: 35)……..

IPSS-Quality of Life

How would you feel if you had to spend the rest of your life with your waterworks the same as they are now?

Mostly satisfied	Satisfied	Mixed	Dissatisfied	Mostly Dissatisfied	Unhappy	Terrible
0	1	2	3	4	5	6

Item International Index of Erectile Function (IIEF-15)

Please answer the following questions as honestly and clearly as possible.
In answering these questions, the following definitions apply:

- Sexual activity includes intercourse, caressing, foreplay and masturbation
- Sexual intercourse is defined as vaginal penetration of the partner (you entered your partner)
- Sexual stimulation includes situations like foreplay with a partner, looking at erotic pictures, etc.
- Ejaculate is the ejection of semen from the penis (or the feeling of this)

Please Circle One Number

1. Over the past 4 weeks how often were you able to get an erection during sexual activity?

No sexual activity	0
Almost never/never	1
A few times (much less than half the time)	2
Sometimes (about half the time)	3
Most times (much more than half the time)	4
Almost always/always	5

2. Over the past 4 weeks when you had erections with sexual stimulation, how often were your erections hard enough for penetration?

No sexual activity	0
Almost never/never	1
A few times (much less than half the time)	2
Sometimes (about half the time)	3
Most times (much more than half the time)	4
Almost always/always	5

3. Over the past 4 weeks when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?

Did not attempt intercourse	0
Almost never/never	1
A few times (much less than half the time)	2
Sometimes (about half the time)	3
Most times (much more than half the time)	4
Almost always/always	5

4. Over the past 4 weeks during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

Did not attempt intercourse	0
Almost never/never	1
A few times (much less than half the time)	2
Sometimes (about half the time)	3
Most times (much more than half the time)	4

Almost always/always	5

5. Over the past 4 weeks during sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

Did not attempt intercourse	1
Very difficult	2
Difficult	3
Slightly difficult	4
Not difficult	5

6. Over the past 4 weeks how many times have you attempted sexual intercourse?

No attempts	0
One to two attempts	1
Three to four attempts	2
Five to six attempts	3
Seven to ten attempts	4
Eleven + attempts	5

7. Over the past 4 weeks when you attempted sexual intercourse, how often was it satisfactory for you?

Did not attempt intercourse	0
Almost never/never	1
A few times (much less than half the time)	2
Sometimes (about half the time)	3
Most times (much more than half the time)	4
Almost always/always	5

8. Over the past 4 weeks how much have you enjoyed sexual intercourse?

No intercourse	0
No enjoyment	1
Not very enjoyable	2
Fairly enjoyable	3
Highly enjoyable	4
Very highly enjoyable	5

9. Over the past 4 weeks when you had sexual stimulation or intercourse, how often did you ejaculate?

No sexual stimulation/intercourse	0
Almost never/never	1
A few times (much less than half the time)	2
Sometimes (about half the time)	3
Most times (much more than half the time)	4
Almost always/always	5

10. Over the past 4 weeks when you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax?

No sexual stimulation/intercourse	0
Almost never/never	1
A few times (much less than half the time)	2
Sometimes (about half the time)	3
Most times (much more than half the time)	4
Almost always/always	5

11. Over the past 4 weeks how often have you felt sexual desire?

Almost never/never	1
A few times (much less than half the time)	2
Sometimes (about half the time)	3
Most times (much more than half the time)	4
Almost always/always	5

12. Over the past 4 weeks how would you rate your level of sexual desire?

Very low/none at all	1
Low	2
Moderate	3
High	4
Very high	5

13. Over the past 4 weeks how satisfied have you been with your overall sex life?

Very dissatisfied	1
Moderately dissatisfied	2
About equally satisfied and dissatisfied	3
Moderately satisfied	4
Very satisfied	5

14. Over the past 4 weeks how satisfied have you been with your sexual relationship with your partner?

Very dissatisfied	1
Moderately dissatisfied	2
About equally satisfied and dissatisfied	3
Moderately satisfied	4
Very satisfied	5

15. Over the past 4 weeks how do you rate your confidence that you could get and keep an erection?

Very low/none at all	1
Low	2
Moderate	3
High	4

Very high	5

UCLA-EPIC Urinary Function Questionnaire

Please answer the following questions as honestly and clearly as possible.

Please Circle One Number

1. Over the **past 4 weeks**, how often have you leaked urine?

More than once a day	1
About once a day	2
More than once a week	3
About once a week	4
Rarely or never	5

2. Over the **past 4 weeks**, how often have you urinated blood?

More than once a day	1
About once a day	2
More than once a week	3
About once a week	4
Rarely or never	5

3. Over the **past 4 weeks**, how often have you had pain or burning with urination?

More than once a day	1
About once a day	2
More than once a week	3
About once a week	4
Rarely or never	5

4. Which of the following best describes your urinary control **during the last 4 weeks**?

No urinary control whatsoever	1
Frequent dribbling	2
Occasional dribbling	3
Total control	4

5. How many pads or adult diapers per day did you usually use to control leakage **during the last 4 weeks**?

None	0
1 pad per day	1
2 pads per day	2
3 or more pads per day	3

6. How big a problem, if any, has each of the following been for you **during the last 4 weeks? (Circle one number on each line)**

	No problem	Very small problem	Small problem	Moderate problem	Big problem
a. Dripping or leaking urine	0	1	2	3	4
b. Pain or burning on urination	0	1	2	3	4
c. Bleeding with urination	0	1	2	3	4
d. Weak urine stream or incomplete emptying	0	1	2	3	4
e. Waking up to urinate	0	1	2	3	4
f. Need to urinate frequently during the day	0	1	2	3	4

7. Overall, how big a problem has your urinary function been for you **during the last 4 weeks**?

No problem	1
Very small problem	2
Small problem	3
Moderate problem	4
Big problem	5