Andrology-Open Access
ISSN: 2167-0250

Nomura et al., Andrology (Los Angel) 2016, 5:1
DOI: 10.4172/2167-0250.1000160

Research Article Open Access

Comprehensive Evaluation of the Health-Related Quality of Life after Ultrasound-Guided Prostate Needle Biopsy: A Prospective Study

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Received date: May 31, 2016; **Accepted date**: June 07, 2016; **Published date**: June 15, 2016

Abstract

Objectives: Prostate biopsy is considered a common procedure for the diagnosis of prostate cancer, with few major complications. There are some reports on complications, voiding function, and health-related quality of life (HRQOL) after prostate biopsy, but the association between prostate biopsy and erectile function, anxiety, and depression has been only sparsely investigated. With the aim of improving patient counseling and informed consent, we prospectively evaluated HRQOL outcomes, including sexual function and mental health, after prostate biopsy.

Methods: In total, 207 patients who underwent initial prostate needle biopsy were evaluated. All patients completed the following measurements before and 2-4 weeks after the procedure: Medical Outcomes Study Short-Form 8 (SF-8), Expanded Prostate Cancer Index Composite (EPIC), International Prostate Symptom Score (IPSS), International Index of Erectile Function-5 (IIEF-5), and Self-Rating Depression Scale (SDS).

Results: No significant differences were evident between baseline and post biopsy scores for SF-8. The EPIC scores for the general urinary domain and all its subscales dropped significantly, and the scores for the general sexual domain and its function decreased significantly after biopsy. Positive correlations between function and bother subscales within domains, including urinary and bowel components were high, but no positive correlation was observed between sexual function and bother. The IPSS was not significantly increased, but the QOL score was significantly decreased after biopsy. A significant difference between baseline and post biopsy was noted for the IIEF-5 score, and in particular, patients who were initially potent significantly developed erectile dysfunction (ED) after biopsy. The SDS score was significantly different between baseline and post biopsy, and patients aged 73 years or older showed clinically significant depression after the procedure.

Conclusion: Based on these data, urologists should pay attention not only to physical and short-lasting complications related to the biopsy procedure but also to HRQOL, including sexual function and mental health after prostate biopsy.

Keywords: Prostate biopsy; Quality of life; Erectile function; Depression; Mental health

Introduction

Prostate biopsy is commonly performed and imperative for diagnosing prostate cancer. This procedure is thought to be a simple and technically secure examination that can be completed in a short time period. Minor complications such as pain, hematuria, and hematospermia are frequently observed but are generally understood to be conceivable complications after prostate biopsy [1,2]. On the other hand, major complications are very rare, but life-threatening sepsis has been occasionally reported [3]. Therefore, most urologists tend not to pay careful attention to the morbidity secondary to prostate biopsy. Recently, the concept of health-related quality of life (HRQOL) has been noted in every aspect of medical care. Indeed, HRQOL definitions are multidimensional but generally include physical and mental wellbeing [4]. It is well known that patients who are diagnosed with cancer often experience significant anxiety and depression, which may be associated with personal discomfort, increased potential of admission to emergency treatment, hospitalization, outpatient visits, death, and suicide [5-7]. These psychological and spiritual reactions may be induced not only by the disease itself but by the diversity of treatment components. In particular, patients with prostate cancer are worried about the impact on sexual function because, in addition to the fear of the cancer, treatment for prostate cancer affects sexual function in varying degrees [8]. It is reasonable to suppose that prostate cancer-bearing patients experience psychological distress, but little investigation has taken place concerning HRQOL at the time of screening biopsy.

We have not fully considered the mental health and emotions of patients undergoing prostate biopsy. In fact, we often encounter patients who complain of anxiety, distress, and/or fear related to the

biopsy and expected results in everyday practice. It is also well known that mental distress greatly affects sexual function. Until recently, the clinical importance of mental distress has received little attention because prostate biopsy is a routine inspection. In general, much attention has been focused on treatment for disease, and the important issue of HRQOL has been largely neglected compared with the medical components. However, recently, the concept of HRQOL is widely accepted among non-healthy people as well as healthy people because even patients with cancer can obtain comparable HRQOL to their general population peers.

To date, some reports on physical complications, including bleeding, infection, and voiding function, after prostate biopsy have been noted, but there are few reports on HRQOL, and the knowledge of the effect of prostate biopsy on sexual function and mental health is limited [1-3]. Therefore, familiarity with HRQOL after prostate biopsy is essential for good management. With the aim of improving patient counseling and informed consent, we prospectively evaluated the association between prostate biopsy and HRQOL, including general health, erectile function, anxiety, and depression, using the Medical Outcomes Study Short-Form 8 (SF-8), Expanded Prostate Cancer Index Composite (EPIC), International Prostate Symptom Score (IPSS), International Index of Erectile Function-5 (IIEF-5), and Self-Rating Depression Sale (SDS).

Materials and Methods

The protocol for the present study was approved by the institutional review board. We studied 289 consecutive patients primarily undergoing 10 to 12-core transrectal or transperineal ultrasound-guided prostate needle biopsy between October 2011 and September 2014. Prior to the biopsy, verbal and written informed consent was obtained from all study participants. Prostate biopsy was performed with local or lumbar anesthesia in a hospital setting, as routinely reported in the literature [9]. Antibiotic prophylaxis consisted of fluoroquinolone prior to prostate biopsy and continued for 2 days. In addition to the original sextant biopsy [10], 4 to 6-extended cores in the posterolateral peripheral zone were sampled.

The SF-8, EPIC, IPSS, IIEF-5, and SDS questionnaires were administered before the biopsy (baseline) and during the 2 to 4-week waiting period before the biopsy result. For HRQOL assessment, 2 types of internationally validated generic HRQOL questionnaires were used (SF-8 and EPIC). The SF-8 includes eight-item scales of physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH). Based on these eight-item scales, two scores representing physical component summary (PCS) and mental component summary (MCS) are calculated. The Japanese version of SF-8 was validated by Fukuhara et al. [11]. The EPIC Quality of Life (QOL) scoring designed to measure QOL issues in patients with prostate cancer consists of 50-item questionnaires classified into four domains, including urinary, bowel, sexual, and hormonal domains [12]. In addition to four HRQOL domain summary scores, the domain-specific HRQOL subscales, including urinary, bowel, sexual, hormonal, and satisfaction, are evaluated. The urinary domain consists of four subscales, including urinary function, bother, incontinence and irritation/obstruction, but the domain subscales other than the urinary domain are composed of function and bother. The Japanese version of EPIC was validated by Takegami et al. [13]. The urinary symptom status was analyzed using IPSS [14].

HRQOL Domain	Baseline	Postbiopsy	P*
SF-8 Domains			
Physical functioning (PF)	48.69 ± 7.08	49.16 ± 5.93	0.404
Role physical (RP)	49.16 ± 7.25	49.28 ± 6.22	0.404
Bodily pain (BP)	52.43 ± 8.13	52.76 ± 8.04	0.287
General Health (GH)	49.22 ± 6.72	49.99 ± 7.11	0.272
Vitality (VT)	51.76 ± 6.14	51.89 ± 5.79	0.391
Social functioning (SF)	49.96 ± 8.30	49.61 ± 7.77	0.287
Role emotional (RE)	50.46 ±7.42	49.96 ± 6.74	0.182
Mental Health (MH)	50.47 ± 5.98	50.92 ± 6.47	0.207
Physical Component Summary (PCS)	48.52 ± 7.18	49.00 ± 6.41	0.155
Mental Component Summary (MCS)	50.10 ± 6.27	49.88 ± 6.54	0.347
EPIC Domains			
HRQOL Domain Summary Scores			
Urinary	90.9 ± 11.0	84.8 ±15.2	<0.001
Bowel	93.6 ± 8.4	93.9 ± 8.6	0.746
Sexual	41.4 ± 15.1	39.8 ± 16.3	0.018
Hormonal	94.0 ± 7.8	94.2 ± 8.3	0.696
Domain-Specific HRQOL Subscales			
Urinary subscales			
Functions	95.6 ± 9.9	87.5 ± 16.4	<0.001
Brother	86.5 ± 14.0	82.7 ±17.0	<0.001
Incontinence	95.0 ± 11.8	93.1 ± 13.9	0.014
Irritation/Obstruction	89.4 ± 11.9	81.5 ± 18.9	<0.001
Bowel subscales			
Function	92.2 ± 9.7	92.6 ± 9.6	0.733
Brother	94.9 ± 8.8	95.4 ± 9.8	0.756
Sexual Subscales			
Functions	22.3 ± 20.0	20.6 ± 20.9	0.031
Brother	84.4 ± 22.1	83.4 ± 24.9	0.225
Hormonal subscales			
Function	91.7 ± 11.0	92.0 ± 11.4	0.677
Brother	95.9 ± 9.0	95.8 ± 10.4	0.448
Satisfaction	60.1 ± 15.4	62.7 ± 17.8	0.965
Mean ± SD; *: Paired *t* test			

Table 1: Changes in HRQOL after prostate biopsy.

For IPSS assessment, question 1 was defined as the post voiding symptoms, and the sum of questions 3, 5, and 6 and sum of questions 2, 4, and 7 were defined as the voiding symptoms and storage symptoms, respectively. The QOL score was also evaluated. Erectile function was evaluated using IIEF-5 [15]. The IIEF-5 questionnaire is designed to measure erectile function and overall satisfaction. IIEF-5 scores of 22 or above indicate normal erectile function. To evaluate mental health, the SDS scores were examined [16]. SDS covers all the items related to major depressive disorder. A score of 40 or above indicates the presence of clinically significant depression. Statistical analysis was performed using Statcel3 (OMS publishing Inc., Tokyo, Japan). Values were expressed as mean ± standard deviation. Paired *t* test was applied to evaluate the differences between the results before and after prostate biopsy. Peason's correlation coefficient test was used to assess correlation between EPIC function and bother subscales. The limit for statistical significance was $p<0.05$.

Results

Of 289 patients who returned questionnaires, 82 were excluded from the present study because of insufficient data collection. The remaining 207 patients who returned completed questionnaires were analyzed. The median age of the subjects was 70 years (range, 42–83 years), and the median prostate specific antigen (PSA) value was 7.05 ng/ml (range, 3.20–919.0 ng/ml). The median volume of the prostate gland was 29 ml (range, 10–191 ml).

	Urinary function	Urinary bother	Bowel function	Bowel bother	Sexual function	Sexual bother	Hormonal function	Hormonal bother
Urinary function	1	0.63	0.17	0.21	0.1	0.08	0.15	0.07
Urinary bother	0.63	1	0.35	0.4	0.19	0.09	0.22	0.16
Bowel function	0.17	0.35	1	0.58	0.02	0.03	0.1	0.13
Bowel bother	0.21	0.4	0.58	1	0.06	0.14	0.15	0.2
Sexual function	0.1	0.19	0.02	0.06	1	0	0.04	0.05
Sexual bother	0.08	0.09	0.03	0.14	0	1	0.18	0.19
Hormonal function	0.15	0.22	0.1	0.15	0.04	0.18	1	0.37
Hormonal bother	0.07	0.16	0.13	0.2	0.05	0.19	0.37	1

Table 2: Interscale correlations between EPIC function and bother subscale after prostate biopsy.

Questionnaire	Baseline	Postbiopsy	P*
IPSS questions			
Post voiding symptoms (0-5)	1.1 ± 1.4	1.1 ± 1.5	0.478
Voiding symptoms (0-15)	3.9 ± 4.0	4.2 ± 4.3	0.888
Storage symptoms (0-15)	4.5 ± 3.2	4.6 ± 3.3	0.624
Total IPSS (0-35)	9.5 ± 8.6	9.9 ± 9.1	0.734
QOL score (0-6)	3.0 ± 1.7	2.8 ± 1.6	0.016
Mean ± SD; *: Paired t test			

Table 3: Changes in International Prostate Symptom Score and quality of life question score after prostate biopsy.

HRQOL

As shown in Table 1, deviation scores in PF, RP, BP, GH, VT, MH, and PCS scales increased, but the scores in SF, RE, and MCS decreased after prostate biopsy. Scores were comparable to the age/sex-adjusted national norms (50) for all items in baseline and post biopsy, and there were no statistically significant changes in SF-8 HRQOL scores between baseline and post biopsy. In contrast, baseline EPIC scores in the urinary, bowel, and hormonal domain summary ranged from 90.9 to 94.0, with lower baseline sexual domain summary scores (41.4). The post biopsy urinary and sexual domain summary scores were significantly lower than the baseline score ($p<0.001$ and $p=0.018$, respectively). For domain-specific EPIC HRQOL subscales, a significant decline occurred in urinary function ($p<0.001$), urinary bother ($p<0.001$), urinary incontinence ($p=0.014$), and urinary irritation/obstruction ($p<0.001$) after biopsy. The sexual function score was also significantly decreased ($p=0.031$) after biopsy, but the sexual bother score was not changed. There were no significant differences in the bowel and hormonal domain-specific subscales before and after biopsy. Next, correlations between EPIC domain function and bother subscales after biopsy were evaluated (Table 2). There were positive correlations between function and bother in urinary ($r=0.63$) and bowel ($r=0.58$) subscales, respectively. In contrast, no correlations were found in sexual and hormonal subscales. As expected, correlations between bother and function subscales among different HRQOL domains were weak or not observed.

Urinary symptoms

Of 207 patients, 48 patients were treated with α_1-adrenergic blockers, and another 12 patients with overactive bladder symptoms were treated with a combination of α_1-adrenergic blockers and anticholinergics. There were no patients with urinary retention, acute prostatitis, and sepsis. As shown in Table 3, urinary symptoms, including post voiding, voiding, and storage, as measured by IPSS, were worse after prostate biopsy, but significant differences were not observed. For unknown reasons, there was a slight but significant decrease ($p=0.016$) in the QOL score after biopsy.

Erectile function

The mean IIEF-5 score significantly decreased from 10.9 at baseline to 9.9 after biopsy (p<0.001) (Table 4). Among 19 patients (9.7%) who were initially potent (IIEF score>22), a significant difference was noted after biopsy (p=0.001).

	Number	Baseline	Postbiopsy	P*
Overall	196	10.9 ± 5.7	9.9 ± 5.6	<0.001
Normal EF (>22)	19	22.6 ± 2.1	18.1 ± 6.0	0.001
Mean ± SD; *: Paired *t* test				

Table 4: Changes in International Index Erectile Function 5 score after prostate biopsy.

Mental health

Of 207 patients, 18 patients treated with antidepressants or psychotropics were excluded from SDS; thus, a total of 189 patients were evaluated by measuring SDS scores. At baseline, 68 patients (36.0%) showed depression (SDS score>40), but 78 patients (41.3%) showed "clinically significant depression" after biopsy. As shown in Table 5, the overall mean SDS score significantly increased from 36.2 at baseline to 37.4 after biopsy (p=0.012). The SDS score increased among all age groups by a permissible margin but was only significant in 75–79 year olds (p=0.049). Next, we identified the cut-off age for risk of depression (Table 6). Patients aged 73 years or older fulfilled diagnostic criteria for depression after biopsy, indicating that older patients who undergo prostate biopsy may be at greater risk for depression with increasing age.

	Number	Baseline	Postbiopsy	P*
Overall	189	36.2 ± 8.5	37.4 ± 9.3	0.012
-59	15	32.9 ± 6.7	32.1 ± 7.3	0.329
60-64	25	34.9 ± 7.6	36.1 ± 8.2	0.134
65-69	47	35.4 ± 8.6	36.2 ± 9.4	0.245
70-74	53	37.7 ± 8.6	38.5 ± 9.4	0.207
75-79	32	36.6 ± 9.3	39.5 ± 9.4	0.049
80-	17	38.4 ± 8.7	39.6 ± 9.4	0.207
Mean ± SD; *: Paired t test				

Table 5: Changes in Self-Rating Depression Scale score after prostate biopsy.

Discussion

The clinical importance of screening for prostate cancer is widely recognized because prostate cancer is rarely symptomatic in the early stages. Screening tests consist of blood test for PSA, digital examination, and transrectal ultrasound. Prostate biopsy to make a histological diagnosis is scheduled if the patients have suspicious results in any one of the screening tests. Most urologists consider prostate biopsy to be a simple and technically secure examination that can accomplished in a short time period. Bleeding such as hematuria, hematochezia, and hematospermia is the common complication observed after biopsy and is typically minor and clinically immaterial [1,2]. Indeed, fatal sepsis after biopsy has been rarely reported; infectious complications are infrequent and mild and are easily controlled [3]. This procedure is fully thought to be extremely safe and minimally invasive for patients; therefore, meticulous attention is not necessarily given to the morbidity secondary to prostate biopsy. Published reports on HRQOL effects of prostate cancer screening by biopsy remain scarce. Therefore, we evaluated patient-reported HRQOL outcomes related to prostate biopsy to improve informed consent, patient counseling, and support during the screening process.

	Number	Baseline	Postbiopsy	P*
Overall	189	36.2 ± 8.5	37.4 ± 9.3	0.012
50-	188	36.3 ± 8.5	37.5 ± 9.3	0.019
60-	174	36.5 ± 8.6	37.8 ± 9.4	0.012
65-	148	36.8 ± 8.8	37.5 ± 9.3	0.022
70-	102	37.4 ± 8.8	39.0 ± 9.3	0.025
71-	90	37.7 ± 8.6	39.4 ± 9.2	0.02
72-	80	37.8 ± 8.6	39.5 ± 9.1	0.031
73-	69	38.2 ± 8.6	40.1 ± 9.0	0.032
74-	59	38.1 ± 8.8	40.2 ± 9.0	0.029
75-	49	37.2 ± 9.0	40.1 ± 9.3	0.031
76-	43	37.3 ± 8.9	40.0 ± 9.2	0.031
77-	36	37.1 ± 9.0	40.3 ± 9.7	0.029
78-	28	37.3 ± 8.7	41.8 ± 8.9	0.005
79-	22	38.4 ± 8.6	41.6 ± 9.5	0.042
80-	17	38.4 ± 8.7	39.6 ± 9.4	0.207
Mean ± SD; *: Paired t test				

Table 6: Changes in Self-Rating Depression Scale score after prostate biopsy.

There is a rapidly growing concern about HRQOL in every aspect of medical care. QOL is a broad, multidimensional concept that includes physical, material, social, and emotional wellbeing, in addition to development and activity [4]. Evaluation of HRQOL includes self-reported measures of physical and mental health. It is well known that patients with cancer often feel excessive anxiety and fear, with resulting poor HRQOL. In addition to the fear of the disease itself, patients with prostate cancer experience not only physical but also mental burdens accompanying therapy, including surgical, radiological, and hormonal treatment [8]. Because any of the treatments for prostate cancer may affect sexual function, urologists are always vigilant regarding sexual distress. However, limited research, except for physical discomfort, has taken place with respect to HRQOL at the time of screening for prostate cancer because prostate biopsy is considered to be convenient and minimally invasive. Nevertheless, we encounter patients complaining of discomfort and/or emotional distress after prostate biopsy. In severe cases, the patient may show signs of confusion and marked emotional disturbance of anxiety and irritation while waiting

for the scheduled procedure and/or waiting for histological diagnosis to be determined. In addition to the physical discomfort caused by procedure itself, patients who undergo prostate biopsy may be distressed by serious psychological burden.

In this study, we first analyzed general HRQOL using SF-8 to measure non-disease-specific HRQOL. As reported by Ishihara et al., no statistical differences in changes of SF-8 after prostate biopsy were observed after a comprehensive survey questionnaire for HRQOL [17]. Next, the patients were evaluated with the EPIC questionnaire, measuring HRQOL specific to prostate cancer. The significant worsening in sexual domain summary scores with the addition of urinary domain was an important finding. Although all urinary subscales in EPIC were significantly reduced, no marked worsening in condition was shown in the IPSS questions and QOL score in this series. Indeed, several investigators have reported difficult voiding, persistent dysuria, and urinary retention directly related to prostate biopsy, but considering the high scores of urinary subscales in EPIC, even if the scores are significantly decreased postbiopsy, the urinary condition after prostate biopsy may be acceptable in this series [2,18]. For sexual subscales, poorer sexual function was remarkable at baseline.

A significant decline occurred in sexual function postbiopsy, but it is doubtful whether this presented a clinically serious problem because the difference was only 1.7 points. In addition, no correlation between sexual function and bother was found after prostate biopsy, suggesting that an obvious dissociation existed between sexual function and its burden. These results indicate that poorer sexual function was of little concern to the patients who underwent prostate biopsy in this series. Interestingly, sexual function also did not correlate with bother at baseline (data not shown). In other words, the elderly Japanese patients undergoing prostate cancer screening may not necessarily pursue sexual function because they considered sexual dysfunction to be a natural, age-related change. This may be affected by cultural characteristics in Japan, however, this clinical importance should be stressed in European and American population because they wish for satisfactory sexual activity even in the elderly [19].

The findings regarding sexual function in EPIC were thought to be supported by the results of IIEF-5. For erectile function, the mean IIEF-5 score at baseline was 10.9, suggesting that the patients in this study had potentially moderate erectile dysfunction (ED). The lower IIEF-5 scores after prostate biopsy negatively reflected worsened sexual burden because of the lower sexual activity of Japanese men. Even so, it is important to recognize that the IIEF-5 score of potent patients was significantly decreased after prostate biopsy, suggesting that prostate biopsy was associated with increased risk of ED for men with normal sexual activity. There is continuing controversy as to whether prostate biopsy causes ED. Some reports have indicated that prostate biopsy did not significantly worsen ED and no relationship existed between worsened ED and the number of cores and biopsies [20,21]. In contrast, there are several reports suggesting that ED following prostate biopsy is associated with the number of needle cores and/or number of biopsies [22,23]. In addition, recent reports on ED following prostate biopsy have indicated that anxiety and local anesthesia for periprostatic nerve block led to ED [24,25]. It is easily conceivable that ED causes decreased libido and sexual impairment. Indeed, ED may be transient and recover at 3-6 months after the procedure, but special attention should be given to ED and/or sexual dysfunction following prostate biopsy because ED may be a psychological reaction induced by an emotional stressful event. Furthermore, ED following prostate biopsy may trigger emotional stress for patients with normal erectile function. This seems to be a vicious cycle for men with high potency and normal sexual activity.

With regard to the psychological status, a depressive tendency in baseline was apparent with increasing age. This result indicated that depressive symptoms were frequent in patients suspected of having prostate cancer with aging. There seems little doubt that the elderly patients often experience not only disease-specific anxiety but also age-related anxiety. In addition, pre biopsy anxiety may be associated with expected intraoperative pain for the initial procedure. Pre biopsy anxiety was reported to be an independent factor for predicting intraoperative pain [24]. Even if the overall SDS score after prostate biopsy was within the normal range, this seems to pose problems in clinical practice because 78 patients (41.3%) showed "clinically significant depression" after biopsy. From the results of SDS, there is a strong tendency toward depressive change after prostate biopsy with increasing age. In other words, the elderly patients with psychological distress associated with aging and/or suspicion of having prostate cancer may further suffer from depression following prostate biopsy. The possibility exists that the patients receiving prostate biopsy have significant mental distress caused by relevant physical discomfort and/or anxiety while waiting for the biopsy result. Therefore, it should be kept in mind that the genesis of depression in elderly patients is not simple but appears to be multifactorial. In general, a screening by biopsy was reported to be seldom associated with psychological distress, but Carlsson et al. reported that severe anxiety affected a small group of susceptible individuals [26]. There is a likelihood that patients suspected of cancer become more nervous about the biopsy result. Considering the results of SF-8, a generic HRQOL questionnaire seems inadequate to assess the mental health, including depression. In addition to generic HRQOL assessment, specific multinomial analysis should be performed to precisely evaluate psychological distress and to manage the individual patient.

In conclusion, we found that the screening by prostate biopsy had a relevant impact on sexual function and mental health, as measured with EPIC, IIEF-5, and SDS. The patients require to be appropriately informed of morbidities secondary to prostate biopsy, and we should be fully aware of these serious complications to improve patient counseling and informed consent. Proper medication and mental care are also essential so that appropriate management of complications related to prostate biopsy is rationally planned.

Conflict of interest

None declared.

Acknowledgements

The authors would like to thank Enago (www.enago.jp) for the English language review.

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