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ORIGINAL RESEARCH ARTICLE

Erectile and urinary function in patients on active surveillance for prostate cancer: results from the Finnish arm of the PRIAS trial

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ABSTRACT

Objective: To evaluate longitudinal changes in urinary function (UF) and erectile function (EF) in a prospective active surveillance (AS) cohort of men with low-risk prostate cancer (PC), and to correlate urinary and sexual satisfaction with quality of life (QoL).

Material and methods: The final cohort consisted of 359 men from the Finnish arm of the Prostate Cancer Research International: Active Surveillance (PRIAS) trial. Erectile function was assessed using the International Index of Erectile Function (IIEF-15) questionnaire and UF using the International Prostate Symptom Score (IPSS) questionnaire at baseline and at 1, 3, 5, 7, 9, 11, 13, and 15 years. Correlation analyses were performed between EF, UF, and QoL. Factors influencing EF and UF, including age, prostate-specific antigen (PSA), prostate volume, and number of biopsies, were analysed.

Results: In all, 255 (71%) men completed the IIEF-15 and 262 (73%) the IPSS questionnaires at baseline and at least once during follow-up. The median IIEF-15 score at baseline was 56 (interquartile range [IQR] 28–65), decreasing to 42 (IQR 12–62) after 5 years. Median IPSS scores increased from 7 (4–13 IQR) at baseline to 10 (5.5–14.5 IQR) at 3 years. Overall sexual satisfaction and IPSS QoL remained stable throughout follow-up.

Conclusion: AS did not cause short-term disturbances in EF or UF, as measured by standardised IIEF-15 and IPSS questionnaires. Although EF and UF significantly declined over the longest follow-up reported in the literature, overall sexual satisfaction and urinary QoL remained unaffected, suggesting that functional deterioration did not substantially impact patient-perceived QoL during AS.

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Introduction

Active surveillance (AS) is the preferred management option for low-risk prostate cancer (PC) [1]. In AS, patients are regularly monitored to detect cancer progression and typically undergo repeated prostate-specific antigen (PSA) tests, prostate biopsies, and magnetic resonance imaging (MRI) scans. The aim of AS is to reduce overtreatment and treatment-related side effects by postponing or even avoiding radical treatments, such as radical prostatectomy (RP) and radiotherapy (RT), which are known to have negative effects on both erectile function (EF) and urinary function (UF). AS is continued until signs of aggressive disease are detected, such as a rapid rise in PSA levels, an increase in cancer stage or grade, or when the patient is no longer considered to benefit from curative treatment due to ageing or comorbidities. Consequently, AS can be maintained for decades in some men.

One concern sometimes associated with AS is the potential anxiety and stress related to living with an untreated cancer. However, recent studies have shown that men on AS generally report a good overall quality of life (QoL), often superior to those undergoing radical treatments [2–4]. Both RP and RT are known to negatively impact UF and EF, but these functions naturally decline with age, even without intervention [5–7]. Erectile function and UF should be evaluated using standardised patient-reported outcome measures (PROMs). The treatment of PC can affect patients in many ways, making it crucial to discuss potential side effects and QoL when selecting a treatment modality. Some patients prioritise QoL above all, while others may accept a modest improvement in survival despite potential QoL impairments [8]. Therefore, it is essential to provide accurate data to guide decision making. Long-term prospective reports on EF and UF in men on AS are, however, scarce. In this study, we present data on validated PROMs that investigate changes in EF and UF in men on AS, with follow-up periods of up to 15 years.

Materials and methods

The International Index of Erectile Function (IIEF-15) questionnaire consists of 15 questions across five domains: EF, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. The maximum score is 75, with higher scores

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indicating better sexual desire and EF [9]. The domain scores range from 10 to 30 points each (EF 30 points, orgasmic function 10 points, sexual desire 10 points, intercourse satisfaction 15 points, and overall satisfaction 10 points). The International Prostate Symptom Score (IPSS) questionnaire is an eight-question tool used to assess lower urinary tract symptoms (LUTS), with seven questions focusing on LUTS and one on QoL. The IPSS score ranges from 0 to 35, with higher scores indicating more severe symptoms: scores of 1 to 7 indicate mild symptoms, 8 to 19 moderate symptoms, and 20 to 35 severe symptoms [10].

All patients from the Finnish arm of the Prostate Cancer Research International: Active Surveillance (PRIAS) trial were included in this study. The PRIAS is a multinational prospective AS study that was initiated in 2006 [11]. Patients enrolled in PRIAS have low-risk PC, and are followed according to a standardised surveillance schedule. In our centre, during surveillance, the IIEF-15 and IPSS questionnaires were completed regularly at 1, 3, 5, 7, 9, 11, 13, and 15 years of follow-up. The PROMs questionnaires coincided with the AS visits. Results are presented as medians with interquartile ranges (IQRs). Comparisons between two time points were performed using either a paired t-test or a non-parametric alternative depending on the data distribution. In our study, we used the minimal important difference (MID) of 3.0 points for the IPSS and 2–4 points for the IIEF-15 questionnaire. A more recent observational cohort study conducted in Dutch primary care [12] reported higher MID values depending on baseline symptom severity. Since the majority of our patients had mild symptoms, we chose these MID values accordingly.

Changes in EF and UF during AS, as assessed by the IIEF-15 and IPSS questionnaire scores. A correlation analysis using Pearson correlation coefficient was performed between EF, UF, and QoL at various timepoints. In addition, a correlation analysis was conducted between factors often described in relation to EF and UF: age, prostate volume, number of prostate biopsies, and number of biopsy cores. Information on the use of prescription urological drugs for erectile dysfunction (ED) and LUTS was collected via the electronic prescription data. Erectile dysfunction medications were phosphodiesterase-5 inhibitors, and alprostadil; LUTS medications were alpha-blockers, 5-alpha-reductase inhibitors (5ARIs), antimuscarinic agents, and mirabegron. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS for Windows, Release 28). A p-value of < 0.05 was considered statistically significant for all tests.

All patients in the PRIAS trial signed an informed consent upon entering the study. The ethics committee of Helsinki University Hospital has approved the PRIAS study (HUS 276/E6/06).

Results

The final cohort consisted of 359 men, with a median surveillance time of 49 months (IQR 15–96). Of these, 160 men (44.4%) received radical treatments: 116 (32%) underwent RP at a median of 17.4 months, and 44 (12%) underwent RT at a median of 26 months. Additionally, 22 men (7%) transitioned to watchful waiting (WW) at a median of 48 months. The cohort characteristics and follow-up data are presented in Table 1.

Erectile function

A total of 255 patients (71%) completed the IIEF-15 questionnaire at baseline and at least once during follow-up. While the IIEF-15 scores remained stable in the short term, a significant decline over the course of follow-up was found (Table 2). At baseline, the median IIEF-15 score was 56 (IQR 28–65), which decreased to 39 (IQR 12–62) at 5 years. By 7 years, the decline in the EF domain was particularly notable, with median scores dropping to 13 (IQR 4–25). Scores in other domains of the IIEF-15 also showed significant decreases over longer follow-up. Increasing age correlated with declining IIEF-15 scores, whereas PSA levels, prostate volume, number of prostate biopsies, and number of biopsy cores did not (Supplementary Tables 1 and 2). Despite the overall decline in scores, overall sexual satisfaction remained stable throughout follow-up. The total IIEF-15 scores and domain-specific scores are presented in Table 2.

Urinary function

A total of 262 men (73%) completed the IPSS questionnaire at baseline and at least once during follow-up. At baseline, the median IPSS score was 7 (IQR 4–13), indicating mild symptoms. After 1 year of follow-up, the median IPSS score increased to 9

Table 1. Clinical characteristics of men on active surveillance for low-risk prostate cancer in the Finnish arm of the Prostate Cancer Research International Active Surveillance (PRIAS) trial.

No. of cases	**359**
Age at diagnosis, median, years (IQR)	63 (59–68)
PSA at diagnosis, ng/ml, median, (IQR)	5.6 (4.2–7.0)
fPSA, ng/ml, median (IQR)	0.7 (0.4–1.1)
%fPSA, median (%)	13.4 (9.8–18.3)
Prostate volume at diagnosis, ml, median (IQR)	41 (33–51)
PSA density, ng/ml/ml, median (IQR)	0.13 (0.1–0.16)
Clinical stage at diagnosis, *n* (%)	
T1	350 (97)
T2	9 (3)
Number of positive cores at diagnosis, *n* (%)	
One	236 (66)
Two	116 (32)
Discontinued active surveillance, *n* (%)	230 (64)
Radical prostatectomy	116 (32)
Radiotherapy	44 (12)
Watchful waiting	22 (6)
Lost to follow-up	10 (3)
Died during follow-up	16 (5)
Died of prostate cancer	0 (0)
Time to discontinuation of active surveillance, median, months (IQR)	
Time to radical prostatectomy	17.4 (13.3–43.9)
Time to radiotherapy	26.1 (15.6–66.5)
Time to start watchful waiting	48 (17.2–88.7)
Time to death	98.8 (60.4–132.2)

IQR: interquartile range; PSA: prostate-specific antigen; fPSA: free/total prostate-specific antigen ratio.

Table 2. Longitudinal changes in erectile and urinary function assessed with IIEF-15 and IPSS questionnaires in men on active surveillance for prostate cancer in the Finnish arm of the Prostate Cancer Research International Active Surveillance (PRIAS) trial.

	Baseline	1 year	3 years	5 years	7 years	9 years	11 years	13 years	15 years
No. of returned IIEF-15 questionnaires	255	191	130	75	65	38	25	11	2
IIEF-15 Score, median (IQR)	56 (28–65)	53.5 (23.2–65)	54.5 (21–64.2)	42 (12–62)	30 (11.5–56.5)	43 (17–60)	39 (16–60)	27 (21–55)	26 (7–26)
Erectile function, median (IQR)	19.5 (10–29)	23 (9–29)	23 (9.2–29)	18 (3–26)	11 (2–24)	14 (4.2–25)	16.5 (6.2–26)	13 (6–23)	9.5 (1–9.5)
Orgasmic function, median (IQR)	7.2 (5–10)	9 (4–10)	8 (4–10)	6 (0–10)	6 (0–10)	6 (1.5–9.2)	6 (1.5–9.5)	2 (0–8)	2 (0–2)
Sexual desire, median (IQR)	5.9 (5–7)	6 (4–7)	6 (4–7)	6 (4–7)	5 (3–7)	6 (1.5–9.2)	5 (4–7)	5 (4–6)	4 (2–4)
Intercourse satisfaction, median (IQR)	7.7 (0–12)	9 (0–11.5)	10 (0–11)	7 (0–10)	5 (0–10)	6.5 (0–11)	7 (0–10)	5 (0–10)	4.5 (0–4.5)
Overall satisfaction, median (IQR)	6.8 (5–8)	7.5 (5–8)	8 (6–8)	7 (5–8)	6 (4–8)	8 (4.2–8)	8 (6–8)	8 (4–9)	6 (4–6)
No. of returned IPSS questionnaires	262	203	136	77	68	47	26	11	2
IPSS Score median (IQR)	7 (4–13)	9 (4–13)	10 (4–15)	10 (5.5–14.5)	10 (5–17)	12 (6.25–16)	8.5 (4–19.5)	7 (4–11)	16.5 (10–23)
IPSS QoL, median (IQR)	2 (1–3)	2 (1–2.75)	2 (1–2)	1 (1–3)	2 (1–3)	2 (1–3)	2 (1–3)	2 (1–2)	1.5 (1–.)

IIEF-15: International Index of Erectile Function questionnaire; IPSS: International Prostate Symptom Score; IQR: interquartile range.

(IQR 4–13), suggesting moderate symptoms. The scores continued to rise over time, with the median IPSS score increasing to 10 (IQR 4–15) at 3 years of follow-up reaching a statistically significance change ($p < 0.001$, Supplementary Table 3). However, IPSS-related QoL scores remained stable throughout the follow-up period. A significant correlation between total IPSS scores and IPSS QoL was observed at every time point during AS (Supplementary Table 1).

Medication

At baseline, 4 men were using ED medications. During surveillance, 117 additional men were prescribed ED drugs, with a median initiation time of 19.6 months. For benign prostatic hyperplasia (BPH), 80 men were using medications at baseline, and 91 new men were prescribed drugs during surveillance, with a median initiation time of 17.7 months. For overactive bladder (OAB), 2 men were on medication at baseline, and 19 additional men were prescribed OAB drugs during surveillance, with a median initiation time of 12 months. At baseline, 277 men (77%) were not taking any prescription medications for BPH or OAB. Interestingly, there was no significant difference in IIEF-15 scores between 5ARI users and non-users, although 5ARI users were more frequently prescribed ED medications.

Discussion

We observed no short-term disturbances in EF or UF in our AS cohort using validated PROMs during follow-up. Although both EF and UF declined over longer follow-up, overall sexual satisfaction and urinary-related QoL remained stable. This finding is important because it suggests that, despite functional deterioration, men on AS may not perceive significant declines in their QoL.

Several previous studies have reported QoL in patients on observation for PC, though most did not use validated PROMs. There are a few exceptions. The Scandinavian Prostate Cancer Group (SPCG)-4 trial [13] and the Prostate Cancer Intervention Versus Observation Trial (PIVOT) [14] both reported outcomes on EF and UF, finding functional declines, especially after RP. However, neither used IIEF-15 and IPSS questionnaires, limiting the comparability to our study. The Prostate Testing for Cancer and Treatment (ProtecT) trial reported outcomes on EF and UF for men with PC treated with surveillance, RP or RT [6]. However, the surveillance in this trial was very different to ours. Men in our trial underwent several routine follow-up biopsies, whereas men in the surveillance arm of the ProtecT only underwent PSA tests without biopsies. Men in surveillance arm of ProtecT experienced gradual declines in both EF and UF, whereas men undergoing RP saw a more immediate deterioration [7]. The surveillance arm of ProtecT experienced gradual declines in both EF and UF, whereas men undergoing RP saw a more immediate deterioration [7]. The gradual functional decline observed in the surveillance arm aligns with our findings. Particularly the significant drop in EF seen after 6 years in our cohort is similar to findings in the ProtecT trial. However, the follow-up schedules are very different.

In our study, EF seemed to be unaffected during AS for the first 5 years, declining significantly thereafter. It is known that EF decreases with increasing age and elderly men are known to often experience ED [15]. This phenomenon was also demonstrated in the Massachusetts Male Aging Study, where an annual increase of 26 new cases of ED per 1,000 men was observed [16]. Erectile dysfunction was more commonly associated with a lower level of education, diabetes, heart disease, and hypertension. Advancing age and a higher PSA level have also been associated with ED [16, 17]. In our study, we did not have access to information on comorbidities. However, in general, patients in the PRIAS trial can be considered healthy since they must be suitable for curative treatment and have life expectancy of more than 10 years to be included in the study.

In our study, increasing age correlated with declining IIEF-15 scores, whereas PSA levels, prostate volume, number of prostate biopsies, and number of biopsy cores did not. Similarly, rising IPSS scores were observed over time. The awareness of having an underlying malignant condition, even one with a good prognosis, may contribute to increasing urinary symptoms or ED in some patients.

Repeated prostate biopsies, a routine part of AS, may also contribute to declining EF. Studies have suggested that repeated biopsies can negatively impact EF [18, 19]. Our data did not, however, demonstrate a correlation between repeated biopsies and EF decline. Nevertheless, a less frequent biopsy schedule, facilitated by the increasing use of MRI and targeted biopsies, might mitigate the possible adverse effects of biopsies on EF. An AS strategy with less frequent biopsies may also increase the compliance for surveillance [20]. Ongoing studies such as the SPCG-17 trial are currently investigating whether reducing biopsy frequency can help preserve EF while maintaining surveillance accuracy [21] The PRIAS protocol contains frequent re-biopsies, known to be bothersome for patients. However, it is not clear that this translates into lower QoL [3, 20].

Both ED and LUTS have a negative impact on QoL, and are prevalent in ageing males [22]. Erectile dysfunction and LUTS may even share common pathophysiological pathway [23]. Despite the decline in EF over time, we found that overall sexual satisfaction scores remained stable, a finding supported by previous studies such as the CaPSURE trial [24]. This suggests that, for many men, the decline in physical EF does not necessarily translate into lower sexual satisfaction. Sexual satisfaction in older men is a multifaceted phenomenon, influenced more by psychological and relational factors, such as desire, intimacy, adaptation, and expectation, rather than by sexual function alone. Erectile dysfunction does not necessarily correlate with decreased life satisfaction. Age-related declines in libido, emotional well-being, and the quality of intimate relationships all play a significant role in shaping sexual satisfaction in later life. In addition, while 5ARI users were more frequently prescribed drugs for ED, no significant difference was observed in IIEF-15 scores between 5ARI users and non-users, adding to the ongoing debate on the impact of 5ARIs on sexual function [25].

In terms of UF, we observed a gradual increase in IPSS scores over time, indicating a worsening of LUTS. However, the stability of IPSS QoL scores suggests that men adapt to these changes, potentially perceiving them as part of the normal ageing process. LUTS are common in older men, and when symptoms remain mild, the perceived bother is also low [26]. Other studies, such as the Olmsted County Study and a large community-based study in Japan, have similarly reported increasing urinary symptoms with age [15, 27].

In this study, 44% of patients received radical treatments and an additional 7% switched to WW during surveillance. Most of the transitioning into active treatment was based on protocol-defined criteria, such as a short PSA doubling time or an upgrade in Gleason score on repeat biopsies. In the Finnish arm of the PRIAS study, only a few patients discontinued surveillance due to anxiety or depressive symptoms or opted straight for radical prostatectomy influenced by bothersome urinary symptoms [3].

The patients in our cohort all had low-risk PC and today there is strong consensus that these cancers should be treated with AS [1] The use of AS as a management option in PC has increased greatly in the past decades [28]. The PRIAS study was initiated at a time when MRI was only beginning to emerge in the diagnostic pathway for PC. Since then, the integration of MRI and targeted biopsies into clinical routine has significantly reduced the detection of low-risk Gleason 6 PC and increased the detection of intermediate-risk Gleason 7 PC. Today, the discussion of AS as a management option has shifted to these favourable intermediate-risk cancers and patients with these cancers can now be recommended AS, with certain reservations.

A key limitation of this study is the lack of a control group, which makes it difficult to disentangle the effects of AS from natural age-related declines in EF and UF. In addition, although the PRIAS study was prospectively designed, data on medications were collected retrospectively, which may affect the reliability of these findings. Further, our cohort in this study is selected. Patients were thoroughly informed about all treatment options, and AS was only offered to those who appeared mentally prepared to accept the concept of a potentially indolent cancer without immediate treatment. Consequently, individuals deemed unlikely to cope with AS were excluded based on clinical judgement. If a patient experienced significant LUTS, it is likely that this also contributed to selection bias, as such patients were more often directed towards radical surgery rather than AS.

The strengths of our study lie in its long follow-up period, the use of validated PROMs, and the relatively large cohort size. The IIEF-15 and IPSS questionnaires are widely used, validated tools for assessing ED and the severity of LUTS, adding robustness to our findings [29, 30].

Conclusion

In conclusion, in this study with the longest follow-up reported to date in a contemporary AS setting, we observed that although EF and UF gradually decline over time, overall QoL remains largely unaffected. These findings support AS as a viable option for men with low-risk PC who wish to avoid the immediate side effects of more aggressive treatments.

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Author contributions

Protocol/project development: Rannikko, Vasarainen
Data collection or management: Rannikko, Vasarainen, Lokman
Data analysis: Kerro, Kalalahti, Vasarainen
Manuscript writing/editing: All authors

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