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A longitudinal study of anxiety, depression and distress as predictors of sexual and urinary quality of life in men with prostate cancer

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Objective

- To evaluate the prevalence of depression, anxiety and distress among active surveillance (AS) and radical prostatectomy (RP) patients.
- To evaluate the impact of these symptoms at baseline on urinary and sexual quality of life at follow-up.

Patients and Methods

- Patients managed with AS or RP who completed validated questionnaires assessing levels of depression, anxiety, distress and urinary (UF) and sexual function (SF) and bother comprised the final analytic cohort.
- These measures were completed at baseline, within 1 year, and between 1 and 3 years from baseline.
- Mixed model repeated measures analysis was used to examine associations between mental health at baseline and sexual and urinary outcomes in a subset of RP patients with complete follow-up.

Results

- Among 679 men who comprised the study cohort, baseline prevalence of moderate or higher levels of depression or anxiety were low (<5%), while levels of mild depression or anxiety ranged from 3–16% over time.

- Baseline levels of elevated distress ranged from 8–20%.
- Among men who provided data at baseline and follow-up, there were no significant differences between AS and RP patients in the proportion of men with elevated levels of depression, anxiety, or distress.
- Among 177 men who underwent RP and had complete follow-up moderate or higher levels of depression or anxiety appeared to be associated with post-treatment SF and bother, while elevated levels of distress were associated with post-treatment UF.

Conclusion

- Moderate or higher levels of depression or anxiety were low in men with localised prostate cancer but were associated with sexual outcomes, while elevated distress was associated with urinary outcomes.
- Greater attention should be paid to mental health symptoms among men with prostate cancer, as these symptoms may be associated with quality of life outcomes.

Keywords

prostate cancer, mental health, active surveillance, radical prostatectomy

Introduction

Despite an increased focus on disease-specific health-related quality of life (HRQL) among men with prostate cancer, less attention has been given to the psychological well-being of these patients. A recent study reported that men diagnosed with prostate cancer had significant declines in mental HRQL compared with propensity score matched controls without prostate cancer [1]. Furthermore, previous studies have reported an increased risk of suicide, especially in the first 3

months after diagnosis [2]. Although some studies have suggested that declines in mental health status vary by treatment type, other studies have failed to find such an association [3,4]. Clearly, any increased risk of psychological morbidity in patients undergoing active surveillance (AS) is important as psychological symptoms may influence men's likelihood to pursue or continue AS [5]. Given the consequences of poor psychological wellbeing in men with prostate cancer, it is worrisome that elevated levels of distress, depression, and anxiety frequently remain undetected and untreated [6].

Previous studies have shown an association between poor psychological wellbeing and worse urinary and sexual HRQL in men with prostate cancer [7]. However, because these studies have been cross-sectional, it is difficult to elucidate whether poor mental health preceded or succeeded worse urinary and sexual outcomes. Thus, clarifying the nature of the relationship between psychological wellbeing and sexual and urinary outcomes over time could help identify targets for improving HRQL in men with prostate cancer.

There is now wide recognition that psychosocial care is a critical part of high-quality cancer care [8]. The goal of the present study was to evaluate the prevalence of depression, anxiety and distress over time using validated self-report questionnaires in men with prostate cancer. First, we assessed these mental health measures over time in men who were on AS or underwent radical prostatectomy (RP). Secondly, we aimed to evaluate the impact of depression, anxiety, and distress on urinary and sexual HRQL in a subset of men who underwent RP and had complete follow-up.

Patients and Methods

Data for this prospective cohort study were part of a longitudinal, comprehensive assessment of patients with newly diagnosed prostate cancer managed with AS or RP in the Department of Urology at The University of California, San Francisco (UCSF). All men provided written informed consent for research participation. Data collection for this comprehensive assessment was approved by the UCSF Institutional Review Board. Demographic, clinical, and treatment information was derived from the institutional Urologic Oncology Database. Clinical risk at diagnosis was measured using the Cancer of the Prostate Risk Assessment (CAPRA) score [9]. For this study, AS patients were followed with no active treatment for at ≥ 6 months after initial diagnosis.

Mental and physical health self-report symptom questionnaires were administered through UCSF's web-based patient-reported outcomes system, which has been previously described [10]. Since 2007, all patients managed for prostate cancer at UCSF have been asked to report their HRQL via on-line administration of validated questionnaires as part of routine clinical care. New patients were emailed questionnaires to be completed via a secure web portal before their initial clinic appointment and at regular follow-up intervals after diagnosis and treatment. Follow-up intervals ranged from every 3–6 months initially after treatment or diagnosis and then every 12–24 months thereafter depending on the preference of the treating physician.

The questionnaires consisted of six instruments used to assess relevant HRQL domains. Depressive symptoms were assessed using the Patient Health Questionnaire (PHQ-9), a well-validated and reliable self-administered screening tool whose items represent the diagnostic criteria for major depression [11–13]. The PHQ-9 consists of nine items, each scored from 0 to 3 (possible range 0–27). Threshold points of 5, 10, 15 and 20 correspond to mild, moderate, moderately severe, and severe levels of depression, respectively [11].

Anxiety symptoms were measured using the General Anxiety Disorder scale 7 (GAD-7), a self-administered questionnaire with excellent validity and reliability for measuring generalised anxiety in medical populations [14]. Each of the seven items is scored from 0 to 3 (possible range 0–21). Threshold points of 5, 10 and 15 correspond to mild, moderate and severe anxiety, respectively.

Distress was ascertained using the Distress Thermometer (DT), a single-item screening tool that has been validated for detecting distress in patients with cancer and correlates well with other validated instruments [15]. The DT is self-rated on a scale from 0 (no distress) to 10 (extreme distress). Scores ≥ 4 have been shown to differentiate between elevated vs none-to-mild levels of distress [16]. These questionnaires have been added to the manuscript supplemental material for reference.

Physical HRQL outcomes were ascertained in both urinary and sexual domains. The IPSS is a frequently used eight-item questionnaire assessing a patient's magnitude of urinary problems with higher scores (scaled from 0 to 35) suggesting a greater degree of obstructive and irritative urinary problems. An additional question relates to the patient's satisfaction with current urinary function (UF), measured on a scale from 0 to 6, with higher scores suggesting worse HRQL [17]. The Sexual Health Inventory for Men (SHIM) score is computed from seven items and assesses erectile dysfunction among men on a scale of 0 to 25, with higher scores indicating better sexual function (SF) [18]. The Expanded Prostate Cancer Index Composite Short Form (EPIC-26) is a 26-item measure that assesses urinary, sexual, bowel, and hormonal domains and was used in this study to provide an assessment of urinary bother (UB) and sexual bother (SB). Each item is scored from 0 to 100; higher scores indicate better function and less bother [19]. These tools are all well validated and widely used to assess HRQL in prostate cancer.

Comparisons of baseline characteristics between AS and RP patients were made using chi-square for categorical variables, ANOVA for normally distributed continuous variables, and the Kruskal–Wallis test for continuous variables without normal distribution. Assessment time was divided into baseline (before RP for surgical patients or ≤ 6

months after diagnosis for AS patients), within 1 year after baseline, and between 1 and 3 years after baseline. These time-points were chosen to account for different follow-up periods between AS and RP patients. Patients were excluded if they did not complete the questionnaires at baseline. Established thresholds for levels of depression, anxiety and distress based on the PHQ-9, GAD-7 and DT were used. Differences in the proportions of AS and RP patients with elevated levels of mental health symptoms at each time-point were evaluated using chi-square tests. Men who progressed on AS remained in the AS group regardless of whether they eventually underwent active treatment. All questionnaire data were used, whether before or after active treatment, and regression models were adjusted for receipt of active treatment.

Mixed model repeated measures analysis was used to examine associations among baseline mental health symptoms (depression, anxiety, and distress) and UF and SF and bother scores over time in a subset of RP patients with complete follow-up. These models were adjusted for age at diagnosis, race/ethnicity, relationship status, year of diagnosis, CAPRA score, receipt of salvage treatment, and time of assessment after baseline. Repeated measures mixed modelling includes baseline assessments as part of the outcome HRQL measure rather than treating them as individual covariates in the model. We used mixed modelling with likelihood-based estimation to account for both fixed and random effects parameters. This approach models the response mean as a linear function of the explanatory variables (i.e. fixed effects) with repeated measures analysis that accounts for within-subject variability. Compound symmetry was specified as the covariance structure because variance and covariance among repeated measures within individual patients were assumed to be constant. Mixed models also uses all available HRQL data by accommodating data that are randomly missing, rather than excluding patients with incomplete follow-up. A two-sided $P < 0.05$ was considered to indicate statistical significance.

Results

Of 864 men treated with AS or RP who were sent a questionnaire between 2007 and 2010, 679 (77%) completed a baseline survey and were included in this study. Among these men, 557 (82%) were managed with RP and 122 (18%) with AS. Among the men on AS, 27 were eventually treated for prostate cancer. Table 1 shows the baseline demographic and clinical information for RP and AS patients. The mean (SD) age was 60.1 (6.7) years. Men who were managed with AS had lower CAPRA risk scores, as expected, and higher baseline SHIM and EPIC UB scores than men managed with RP. Men excluded due to lack of baseline surveys were similar in age and treatment type but

Table 1 Baseline demographics, clinical characteristics and physical HRQL scores of men treated with RP and AS.

Patient characteristic	RP group	AS group	P
Number of patients	557	122	
Mean (SD)			
Age at diagnosis, years	60.0 (6.7)	60.5 (6.5)	0.50
N (%):			
Race/ethnicity:			0.05
Caucasian	508 (91)	114 (93)	
Asian or Pacific Islander	28 (6)	3 (2)	
African American	8 (1)	1 (1)	
Latino	8 (1)	0 (0)	
Native American	1 (<1)	0 (0)	
Mixed	3 (1)	1 (1)	
Other	1 (0)	3 (2)	
Relationship status:			0.19
Married or partnered	486 (87)	101 (83)	
Single	71 (13)	21 (17)	
CAPRA clinical risk			<0.01
Low (0–2)	174 (37)	99 (84)	
Intermediate (3–5)	227 (48)	16 (14)	
High (6–10)	70 (15)	2 (2)	
Mean (SD):			
IPSS HRQL	1.66 (1.49)	1.49 (1.29)	0.06
SHIM	16.2 (9.1)	18.2 (8.3)	0.04
EPIC UB score	87.2 (14.3)	90.9 (11.8)	0.03
EPIC SB score	79.9 (25.6)	73.5 (28.8)	0.10

had lower clinical risk (CAPRA 2 vs 3) and fewer patients were Caucasian (85% vs 92%)(both $P < 0.01$).

Table 2 shows the severity of PHQ-9, GAD-7, and DT symptoms in the RP and AS groups at each assessment interval. In all, 40–60% of the cohort provided follow-up data at the <1 year time-point, while 13–30% provided assessments at the 1–3 years time-point. There were no significant differences in patients who provided complete data vs those who did not, with the exception of higher levels of distress among those who provided complete follow-up. Among those who provided baseline and follow-up assessment there was no significant difference between RP and AS patients in the degree of depression. Rates of moderate-to-severe depression were <5% in both groups, while rates of mild depression ranged from 3% to 12%. Among the 25 men who had moderate or higher depression at baseline, five (20%) men still reported moderate–severe depression within 1 year, among whom none filled out the questionnaires at 1–3 years.

The AS and RP groups likewise did not differ in severity of anxiety. Moderate to severe levels of anxiety were also <5% in each group, while levels of mild anxiety ranged from 4% to 16% among RP and AS patients. Among the 23 men with moderate-to-severe anxiety at baseline, two (9%) men still had moderate-to-severe anxiety at the <1 year time-point, neither of whom completed a questionnaire at the 1–3 years time-point.

Finally, the AS and RP groups did not differ in the proportion of men with elevated DT scores (i.e. ≥ 4). Levels

Table 2 Distribution of PHQ-9, GAD-7 and DT levels among RP and AS patients at baseline, within 1 year, and from 1 to 3 years.

Mental health measure	Baseline			Within 1 year			1–3 years		
	RP group	AS group	P	RP group	AS group	P	RP group	AS group	P
PHQ-9									
Number of patients	508	108		222	32		61	24	
N (%):			0.98			0.65			0.77
None (0–4)	429 (84)	92 (85)		189 (85)	29 (91)		58 (95)	22 (92)	
Mild (5–9)	58 (12)	12 (11)		26 (12)	2 (6)		2 (3)	1 (4)	
Moderate (10–14)	15 (3)	3 (3)		7 (3)	1 (3)		1 (2)	1 (4)	
Moderately severe (15–19)	6 (1)	1 (1)		0	0		0	0	
Severe (20–27)	2 (<1)	0		0	0		0	0	
GAD-7:									
Number of patients	506	106		225	32		64	23	
N (%):			0.94			0.89			0.17
None (0–4)	412 (81)	88 (83)		190 (84)	27 (84)		57 (89)	21 (91)	
Mild (5–9)	74 (15)	15 (14)		31 (14)	5 (16)		7 (11)	1 (4)	
Moderate (10–14)	15 (3)	2 (2)		3 (1)	0		0	1 (4)	
Severe (15–21)	5 (1)	1 (1)		1 (<1)	0		0	0	
DT									
Number of patients	557	122		341	59		149	57	
N (%):			0.12			0.32			0.35
None -mild (<4)	445 (80)	105 (86)		309 (91)	51 (86)		137 (92)	50 (88)	
Elevated (≥4)	112 (20)	17 (14)		32 (9)	8 (14)		12 (8)	7 (12)	

of elevated distress ranged from 8% to 20% over time. Among the 129 men with elevated distress at baseline, 20 (15.5%) men still had elevated distress at <1 year. Of those, five (25%) had elevated distress at 1–3 years, five had no-to-mild distress (i.e. DT scores of <4), and 10 did not complete questionnaires.

Mixed models repeated measures analysis tested the relationships between baseline mental health scores and disease-specific physical HRQL over time in a subset of 177 men who underwent RP and had complete follow-up. Elevated baseline PHQ-9 depression scores were associated with change in SHIM and SB scores (Fig. 1). Higher GAD-7 scores were associated with change in UB, SHIM, and SB scores (Fig. 2). Neither was associated with IPSS HRQL scores. Finally, higher DT scores were not associated with SHIM scores, but were associated with change in IPSS HRQL, UB and SB scores (Fig. 3).

Discussion

Using well-validated measures, the present study found that patients with prostate cancer managed with AS or RP had similar prevalence rates of depression, anxiety, and distress over time. In both AS and RP groups, <5% of patients had moderate or high levels of depression or anxiety, whereas elevated levels of distress ranged from 8% to 20%. We also found that higher levels of depression or anxiety were associated with worse SF and bother, while elevated levels of distress were associated with worse UF on follow-up.

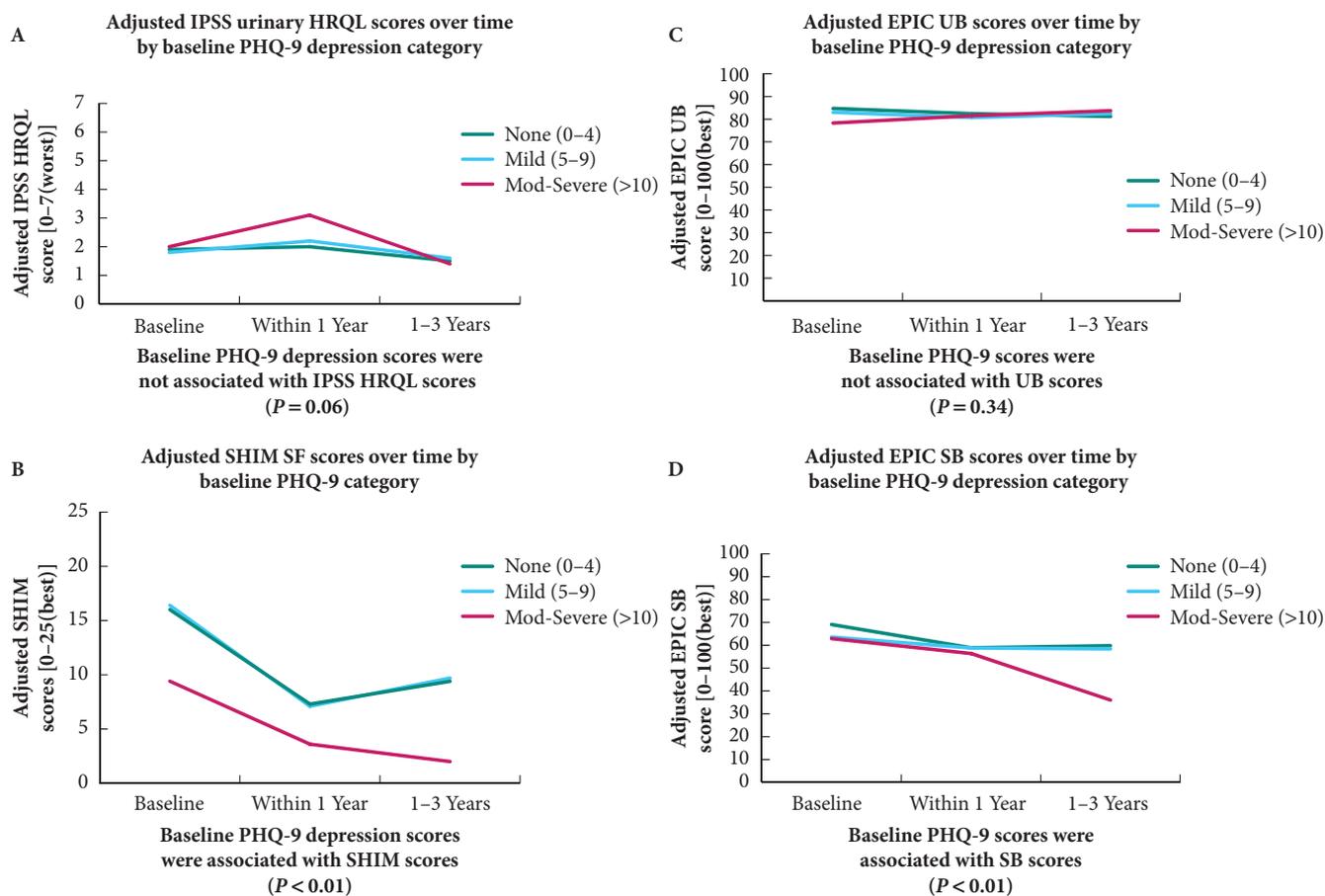
The prevalence of mild depression or anxiety ranged from 3% to 16% over time, consistent with previous studies [20].

Although the prevalence of moderate-to-severe depression or anxiety was relatively low, these rates are still much higher than those seen in similarly aged men without a diagnosis of prostate cancer [21]. However, other studies have not confirmed higher levels of depression or anxiety among men with prostate cancer [22]. These divergent findings are probably due to varying demographic (e.g. age, ethnicity) and treatment characteristics across samples, as well as to heterogeneous symptom assessment methods.

Although rates of elevated distress did not statistically differ between men undergoing AS or RP at any time-point there appeared to be a greater reduction in the proportion of distressed patients in the RP arm. Furthermore, there appeared to be 14 new cases of distress that were seen in later years among patients who were not distressed at baseline. This suggests that some men with prostate cancer will benefit from more psychosocial attention as part of their routine clinical care. This is especially applicable to men on AS whose elevated levels of anxiety or distress often prompt change from AS to active treatment in the absence of clinical progression [5].

The present findings corroborate and expand on two previous studies of the prevalence of mental health symptoms among patients with prostate cancer undergoing different treatments. One study involving 100 AS patients and 229 patients who received localised treatment for prostate cancer found no differences in levels of depression or anxiety between the groups [3]. Another study found that patients who were actively treated for localised prostate cancer had greater dysfunction at work and in daily

Fig. 1 The effect of baseline PHQ-9 depression scores on (A) IPSS, (B) SHIM, (C) UB, and (D) SB scores at follow-up. Models are adjusted for age, relationship status, ethnicity, CAPRA, receipt of salvage treatment, and year of diagnosis.



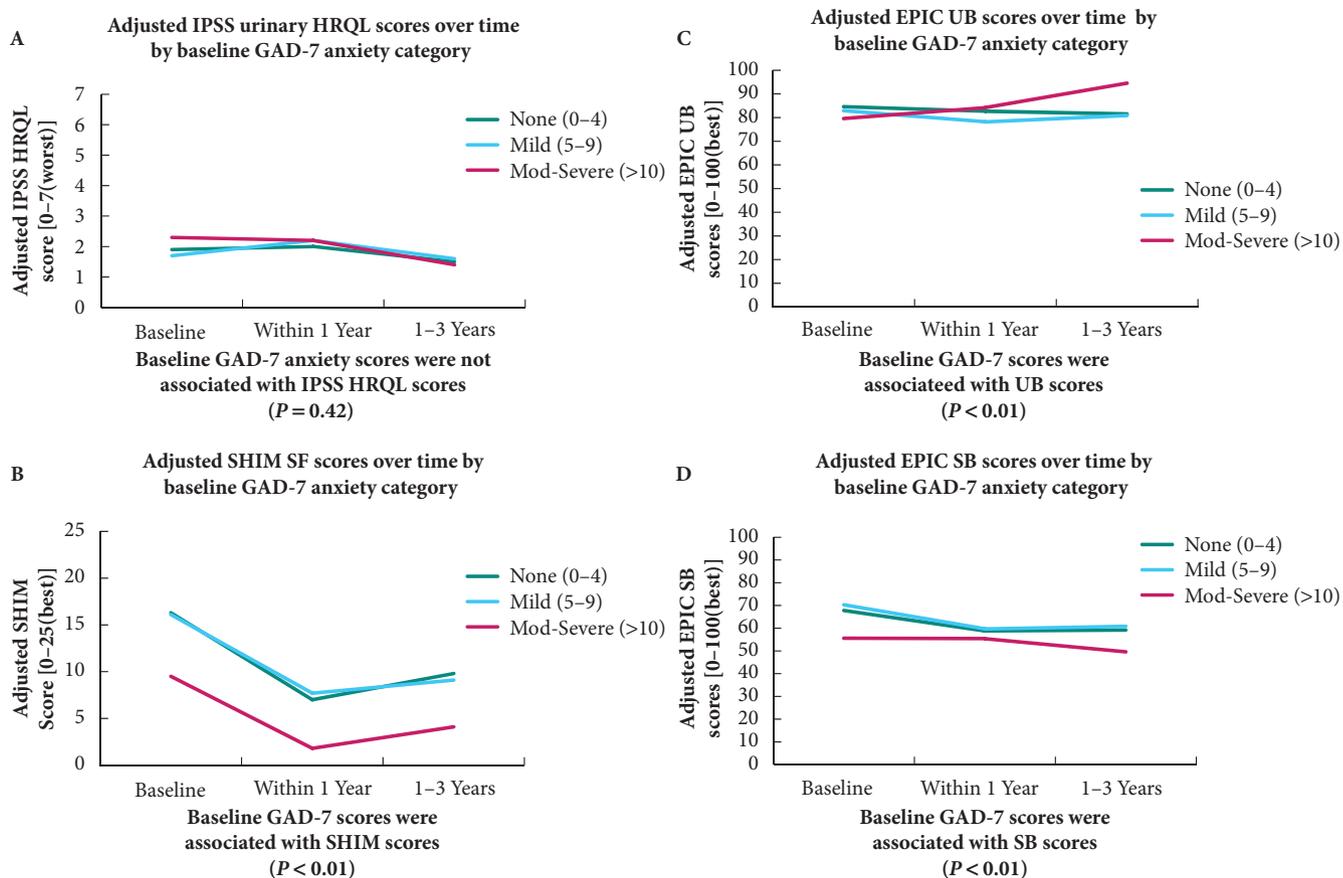
activities early after treatment than patients on AS, but after 1 year they were similar to AS patients in HRQL and psychological status [4].

A substantial amount of data from patients with cancer documents the importance of mental health in the recovery of functional outcomes [23]. Patients with increased levels of distress may not comply with follow-up and treatment protocols, which may in turn impede their recovery [24]. Perhaps men with worse psychological wellbeing are less likely to undergo penile rehabilitation programmes or do Kegel exercises, which may in turn affect their sexual and urinary recovery, respectively. Secondly, the present HRQL outcomes were based on self-reported patient questionnaires. It is possible that men with poor mental health may be more likely to report worse satisfaction with their recovery and HRQL, providing another explanation for the present findings. Although it was beyond the scope of the present study to hypothesise or investigate all the potential mechanisms of this dynamic relationship between mental health and HRQL, future research focused in this area may help us to understand how we can best help these men.

Only one other study was found that examined the relationship between mental health and urinary and sexual HRQL over time. Mohamed et al. [25] reported that among a cohort of men with prostate cancer, those patients with pre-treatment depression were at risk of worsened urinary and sexual HRQL after 6 months. The present study confirms their findings for sexual HRQL but did not find a significant association between depression and urinary domains. In addition, the present study provides longer follow-up of patients and adds information on the impact of anxiety and distress.

To analyse a more consistent cohort for our longitudinal analysis, we focused on only RP patients who had complete follow-up at each of the three assessment intervals. Although the present study found a statistically significant association between various mental health measures at baseline and UF and SF and both in follow-up, the clinical significance of some of these findings may be relatively minor. For instance, we observed a statistically significant association between higher distress scores and worse UB and SB. However, the difference in both scores between men with low distress and those with elevated

Fig. 2 The effect of baseline GAD-7 anxiety scores on (A) IPSS, (B) SHIM, (C) UB, and (D) SB scores at follow-up. Models are adjusted for age, relationship status, ethnicity, CAPRA, receipt of salvage treatment, and year of diagnosis.



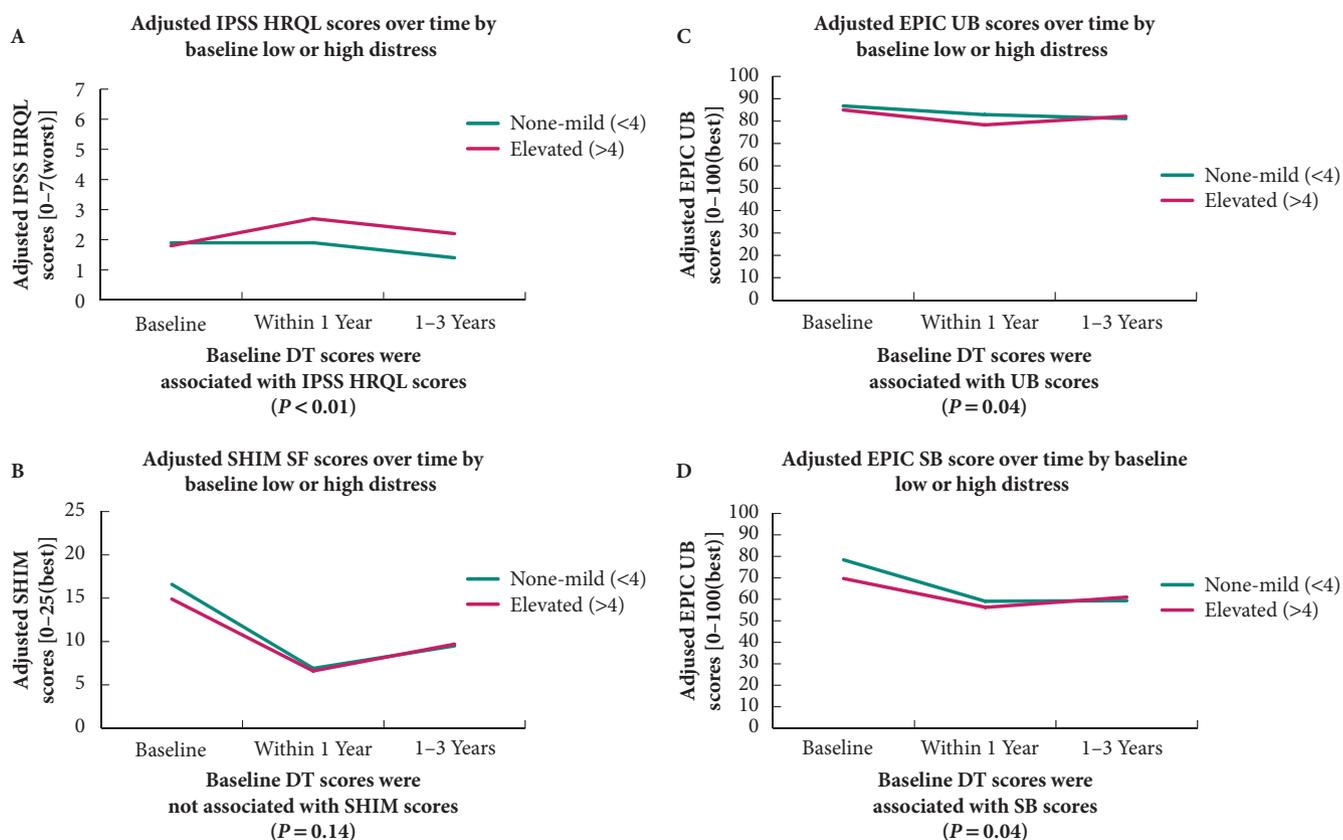
distress were less than a one half standard deviation from the mean suggesting that the clinical impact may be minimal (Fig. 3). Although other associations such as the impact of depression on SF and bother appear more clinically meaningful (Fig. 1), the clinical relevance of these associations cannot be definitively determined in this exploratory analysis. In addition, although we clarify the nature of the association between mental health at baseline and HRQL at follow-up in the present longitudinal analysis, we cannot exclude the possibility that declines in HRQL after diagnosis or treatment of prostate cancer may have an adverse impact on mental health.

There is wide acknowledgement that psychosocial support is an important component in the comprehensive care of patients with cancer. A first step in this comprehensive care is the identification of those men who may need additional support or resources. Our approach, namely, routinely screening patients with prostate cancer for potential mental health concerns, recognises that some men with prostate cancer may have psychological symptoms that will affect sexual and urinary HRQL. Next steps include intervention-based research directed towards improving

psychological wellbeing, to enhance treatment adherence and improve mental and physical HRQL. A recent meta-analysis of patients with prostate cancer found that men who used problem- and emotion-focused coping strategies had better psychological and physical outcomes than those who used avoidant coping strategies [26]. Other studies have suggested that psychosocial interventions delivered to the patient and his intimate family may improve and help maintain HRQL [27]. Thus, intervention research aimed at helping men cope more effectively is critically important to enhancing the comprehensive care of men with prostate cancer [28].

The present study had several limitations. Although the measures used to assess depression, anxiety, and distress have been well-validated, they do not substitute for a careful diagnostic interview or assess past history of depression or anxiety disorders, which are risk factors for depression in the context of cancer treatment. Furthermore, men may be less likely to endorse mental health symptoms on an online questionnaire, particularly when they may not see this information as relevant to their prostate cancer management. Thus, the ability of these questionnaires to

Fig. 3 The effect of baseline DT distress scores on (A) IPSS, (B) SHIM, (C) UB, and (D) SB scores at follow-up. Models are adjusted for age, relationship status, ethnicity, CAPRA, receipt of salvage treatment, and year of diagnosis.



appropriately characterise men with elevated levels of depression, anxiety, or distress presents a limitation to the interpretation of our findings. However, such limitations are inherent in questionnaire-based research. Attrition was also an issue, with fewer men completing questionnaires at later follow-up time-points (40–60% at <1 year and 13–30% at 1–3 years), resulting in a potential ascertainment bias. These attrition rates over time also limit a full assessment of psychological outcomes among men with moderate-to-severe anxiety, depression or distress at baseline. The assessment of psychological wellbeing in men with prostate cancer at our institution was not driven by a formal research protocol, but rather was part of the routine clinical care of patients with cancer and is therefore subject to both the advantages and limitations of observational research. We attempted to manage this problem by focusing the present longitudinal analysis on patients who had complete follow-up. We acknowledge that the results of the present analysis are only applicable to these 177 men with complete follow-up, creating a potential for selection bias. In addition, we looked for any differences between men who provided complete follow-up and those who did not and found no significant difference in any demographic, clinical, mental, or HRQL characteristic assessed, with the

exception of baseline distress. We noticed that complete responders were more likely to have higher levels of distress than those who did not have complete follow-up. Although this may question the validity of the present findings for distress, it provides support to the validity of our findings about depression and anxiety. Furthermore, although our institutional database had complete data on various clinical and demographic characteristics pertinent to the present analysis, there are many other variables (e.g. cumulative life stress, coping style, personality traits) that were not available or measured. Such limitations are inherent to research using clinical databases. However, as a result it was difficult for the present study to properly identify men who are particularly vulnerable to impairments in psychosocial HRQL. However, we have confirmed and expanded upon associations seen between psychological wellbeing and HRQL among men with prostate cancer, which is an area that has currently not received its deserved attention. We hope the present study and others of its kind will provide the platform for much more in depth investigation into the dynamic relationship between mental health and HRQL, to provide us with a better understanding of how to help these men. Despite these limitations, the present study is one of few to examine

associations between baseline mental health and later physical HRQL outcomes in men with prostate cancer. Moreover, the present study used widely accepted mental health-assessment instruments, had a reasonable sample size, and followed patients longitudinally.

The use of validated measures of distress, depression, and anxiety to identify patients with cancer with elevated mental health symptom levels is a critical patient-centred mission for cancer providers. Although levels of moderate or severe depression, anxiety and distress appeared to be low in men with newly diagnosed prostate cancer, they were associated with various urinary and sexual outcomes in the present study. These findings suggest the need for heightened attention to the mental health status of men with prostate cancer.

Conflict of Interest

None declared.

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Abbreviations: AS, active surveillance; CAPRA, Cancer of the Prostate Risk Assessment; DT, Distress Thermometer; EPIC-26, Expanded Prostate Cancer Index Composite Short Form; GAD-7, General Anxiety Disorder scale; HRQL, health-related quality of life; PHQ-9, Patient Health Questionnaire; RP, radical prostatectomy; SB, sexual bother; SF, sexual function; SHIM, The Sexual Health Inventory for Men; UCSF, The University of California, San Francisco; UB, urinary bother; UF, urinary function.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

- Appendix S1** Distress thermometer (DT).
Appendix S2 Generalized anxiety disorder scale (GAD-7).
Appendix S3 Patient health questionnaire (PHQ-9).
Appendix S4 Patient characteristics and demographics among those who provided complete follow up and those who did not.