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Author

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Running head: Trajectories of distress in surgical prostate cancer patients

A Prospective Study of Psychological Distress after Prostate Cancer Surgery

Stefano Occhipinti PhD^a, Leah Zajdlewicz MORGPsyc^b, Geoffrey D. Coughlin FRACS^c, John W. Yaxley FRACS^c, Nigel Dunglison FRACS^c, Robert A. Gardiner MD^{c-f}, Suzanne K. Chambers PhD^{a,d,f,g}

^aMenzies Health Institute Queensland, Griffith University, Gold Coast, Australia

^bCancer Council Queensland, Brisbane, Australia

^cDepartment of Urology, Royal Brisbane & Women's Hospital, Brisbane, Australia

^dThe University of Queensland Centre for Clinical Research, Brisbane, Australia

^eFaculty of Medicine, The University of Queensland, Brisbane, Australia

^fEdith Cowan University, Perth, Western Australia

^gUniversity of Technology Sydney, Sydney, Australia

Correspondence to: Associate Professor Stefano Occhipinti, School of Applied Psychology, Mt Gravatt campus, Griffith University QLD 4122, Australia

Email: s.occhipinti@griffith.edu.au

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Abstract

Background: Men treated for prostate cancer experience heightened psychological distress and have an increased risk of suicide. Management of this distress and risk is crucial for quality urological care.

Objective: To identify risk indicators for poorer trajectories of psychological adjustment and health-related quality of life after surgery for localised prostate cancer.

Design, Setting and Participants: Patients were newly diagnosed with localised prostate cancer scheduled for surgical treatment. Patients were assessed at baseline (pre-surgery), and 6 weeks, 3mo, 6mo, 12mo and 24mo post-surgery.

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Measurements: Assessment measures included: sociodemographics, domain-specific and health-related quality of life, and psychological distress. Mixed effects regression models were used to analyse the data.

Results and Limitations: A total of 233 patients provided data for this analysis ($M_{\text{age}} = 60$ years, $SD = 4.02$; $M_{\text{PSA}} = 7.37$ ng/ml). At baseline the prevalence of high psychological distress was 28% reducing to 21% at 24mo. Before treatment younger age, more comorbidities and worse bowel function were related to greater psychological distress; and younger age, and better urinary, sexual and bowel function were related to better health-related QOL. By contrast, for changes over time only bowel function was important with better bowel function predicting decreasing psychological distress for men.

Conclusions: Regular distress screening is indicated over the 24mo after surgery for localised prostate cancer. Care pathways for men with prostate cancer need also to respond to age specific concerns and health problems associated with co-morbidities in aging men. Focussed symptom control for bowel bother should be a priority.

Introduction

The diagnosis of localised prostate cancer is a major life stress that for many men is followed by not only treatment-related symptomatology, but also heightened psychological distress. A recent meta-analysis reported that at diagnosis of prostate cancer and treatment, 15-27% of men experience anxiety and 15-18% report depression¹. In addition, men have an increased risk of suicide after prostate cancer by comparison with controls²⁻⁴, with the first year after diagnosis a period of heightened risk⁵. It is therefore advised that after the diagnosis of prostate cancer and regularly through treatment and surveillance men are screened regularly for distress and referred for evidence-based psychosocial intervention when indicated^{6,7}. However, while distress screening provides the capability to detect men who are experiencing high distress⁸, a clear understanding of what characteristics predict poorer outcomes not only at diagnosis but also over time would support better targeting of assessment and care planning for these men.

With regards to prediction of distress, a recent review of 36 studies suggested that younger age, baseline emotional distress, and neuroticism predicted higher distress in men with prostate cancer after twelve months, however domain-specific quality of life (such as urinary, sexual and bowel function), clinical characteristics, and co-morbidities were not considered⁹. Further, research to date is limited by being largely cross-sectional such that actual trajectories of distress over time are not well described nor understood. In our randomised controlled trial comparing outcomes for men with localised prostate cancer treated by either robotic or open prostatectomy followed men from baseline to 24 months, we found no long-term differences in psychological outcomes on the basis of surgical approach¹⁰. However, there was evidence of wide variation in psychological outcomes across men within groups and such heterogeneity at the individual level was not addressed by statistical analyses that compared groups. Prevalence of distress was high and persistent over time with one in five men reporting high distress at 24 mo. As well, cross-sectional analyses at each endpoint may mask differences in individual men's progression across time. Although many men may improve in functioning, some may either fail to improve or may worsen over time. This landmark study provides a unique opportunity to investigate men's long-term distress trajectories after surgery for prostate

cancer in a well characterised patient population. Accordingly, in the present study we investigate the trajectory of men's psychological adjustment over time from before surgery for localised prostate cancer to 24 mo to identify what sociodemographic and symptom profiles are associated with poorer outcomes.

Methods

2.1 Study design and participants

These data are from a randomised control trial comparing open radical retropubic prostatectomy with robot-assisted laparoscopic prostatectomy, with trial outcome data reported elsewhere^{10, 11}. Patients for this study were managed at the Royal Brisbane & Women's Hospital (RBWH) with referrals to the public clinics from general practice and the private practices of urologists in SE Queensland in Australia. Inclusion criteria were that men must: be newly diagnosed with clinically localised prostate cancer and have chosen surgery as their treatment approach; be able to read and speak English; have no previous history of head injury, dementia or psychiatric illness; have no concurrent cancer; have an estimated life expectancy of 10 years or more; be aged between 35 years and 70 years. Exclusion criteria were: evidence of non-localised prostate cancer clinically; prostate specific antigen greater than 20 ng/mL; previous laparoscopic hernia repair; previous pelvic radiotherapy or major pelvic surgery; and another malignancy within the past 5 years, with the exception of non-melanoma skin cancer. Ethical approval was obtained from the RBWH Human Research Ethics Committee (HREC/09/QRBW/320). Patients provided written informed consent.

Procedures and Measures

Men were sent self-administered questionnaires to collect predictor and outcome variable data at the following time points: baseline (pre-surgery), and 6 weeks, 3 mo, 6 mo, 12 mo and 24 mo post-surgery. Sociodemographic information collected included age at recruitment, highest level of educational attainment, employment status, income level, and number and type of comorbidities. Clinical information included pre-surgery prostate specific antigen level. Sociodemographic and clinical information was collected at baseline (pre-surgery).

Predictor and Outcome Variables

Predictor variables were age at recruitment, highest level of educational attainment, pre-surgery prostate specific antigen (PSA), and disease-specific quality of life (QoL; Expanded Prostate Cancer Index Composite). The outcome variables were psychological distress (Hospital Anxiety and Depression Scale (HADS)) and physical and mental health-related QoL (Short Form 36 Health Survey (SF-36)).

Disease-specific QoL was measured using the EPIC¹², a 50-item scale to assess urinary, bowel, and sexual domains (hormonal function was irrelevant for this patient group and therefore not reported in this study). All EPIC scores were standardised to a 0 to 100 scale. For each domain a summary score was constructed, with higher scores indicating better QoL.

The 14-item HADS (HADS-T) measured psychological distress¹³. Participants rated their experience of distress in the past week on 4-point scales scored 0 (e.g., not at all) to 3 (e.g., very often); higher scores indicate increased distress (range 0-42). In the current study, cut-off scores ≥ 11 ¹⁴ were used to indicate probable cases of clinical distress.

The SF-36 was used to assess health-related QoL^{15,16}. The SF-36 produces two global measures of mental health and physical health QoL (Mental Health Domain and Physical Health Domain) where higher scores indicate better health-related QoL.

Statistical analysis

Means with 95% CIs were used to report continuous variables. Frequencies and proportions were used to report categorical variables.

As there were no significant differences found between the two surgical groups for the randomised control trial in respect to domain-specific QoL, health related QoL and psychological distress^{10,11}, the

sample was combined for this analysis. Mixed effects regression models were used to assess the trajectories of health-related QoL and anxiety and depression across the 24 months of assessment.

Trajectories were assessed first as fixed effects of time (coded as number of months since study accrual), followed by random intercept and random coefficient models that allowed the effect of time to vary randomly across men. All analyses were performed with maximum likelihood estimation to account for missing data. Missingness varied across timepoints and generally increased over the time of the study as would be expected in a longitudinal design. At baseline, missingness varied from 3.9% (HADS-T) to 5.84% (SF36). By the 24 month assessment, missingness varied from 12.66% (EPIC) to 16.23% (SF36).

Predictors were then entered for random intercept models for all primary outcomes. Predictors were entered for random coefficient models only if likelihood ratio tests indicated significant individual variation in the time slope for that outcome. For random intercept models, mixed effects regression assessed whether age at recruitment, highest level of educational attainment, pre-surgery PSA, and disease-specific QoL predicted baseline and overall levels of health-related QoL and anxiety and depression. Disease-specific QoL measures were entered as time varying covariates as these had been measured at each assessment in the study. For random coefficient models, analyses tested whether the predictors accounted for variations across men in the rate of change (i.e., slope) of the outcomes across time. Where appropriate, likelihood ratio tests were used to examine differences between unconstrained models and models in which the effects of disease-specific quality of life predictors (i.e., bowel, urinary, and sexual) were constrained to be equal.

Significance level was set at a p value of <0.05 (two-tailed). Statistical analyses were performed using Stata 15.1 Software (College Station, TX, USA).

Results

Participants

Between Aug 23, 2010, and Nov 25, 2014, 326 men were enrolled, into the study. 18 withdrew and thus 308 patients continued to surgery. The first patient underwent surgery in October 2010, and the last in March 2015. A total of 233 patients provided data for this analysis. Mean age of patients was 60 years (SD = 6.27; range 40-70 years of age). Their average pre-surgery PSA was 7.37 ng/ml (SD=4.02; range 0.45-24ng/ml). Over half (53%) of the patients had a technical trade certificate or university degree as their highest form of educational achievement; 60% were employed full-time, and 61% had an annual household income of less than \$60 000AUD. Fifty-eight per cent of the patients reported between 1-3 comorbidities with hypertension (38%) and hypercholesterolaemia (33%) the most common. Thirty-six per cent reported no comorbidities. Relevant characteristics are reported in Table 1.

Psychological Distress and Quality of Life

Up to 28% of patients were distressed prior to their surgery for prostate cancer. The proportion of patients indicating psychological distress remained stable across time with 21% distressed 24 mo later (Table 2)¹⁰. The pattern of domain-specific quality of life scores across time are presented in Table 2 and 3. According to previous research, the threshold of discrimination for changes in health-related quality of life is half a standard deviation^{17, 18}. Applying this criterion, for urinary quality of life, 76% had worse functioning at 6 week follow up, and while this proportion decreased across the timepoints, 25% had not returned to baseline levels at 24 month follow up. For sexual quality of life, consistently over half the men had worse functioning at the follow up timepoints compared to baseline (between 52-77%). For bowel quality of life, between 16-33% of participants did not return to baseline functioning across the timepoints.

Trajectory of Psychological Distress

Average psychological distress trajectories remained stable across the 24 mo of the study (-0.02, $p < 0.24$, 95%CI -0.04-0.01). However, individual patient distress slopes varied significantly (LR Chi

square = 14.72, $p < .001$). Across the timepoints, between 27-40% of patients experienced an increase in psychological distress levels. Distress was associated negatively with age at recruitment (-0.2, $p < 0.01$, 95%CI -0.31 to -0.09) and bowel QoL (-0.14, $p < 0.01$, 95%CI -0.17 to -0.10), and positively with number of comorbidities (0.64, $p = 0.03$, 95%CI 0.07-1.21). Thus, at baseline the most distress was experienced by younger men, those with lower bowel-related QoL, and those with more comorbidities. Further, although average distress trajectories were stable across time overall, the slope was more negative, suggesting that distress declined significantly faster, for men with higher bowel QoL (-0.004, $p = 0.01$, 95%CI -0.008 to -0.001). Thus, higher bowel QoL across the 24 months of the study would be expected to lead to a faster return to premorbid functioning.

Trajectory of Mental Health QoL

Mental health QoL trajectories were stable across the 24 mo of the study (0.02, $p = 0.47$, 95%CI -0.03-0.06), and patient slopes did not vary significantly for this outcome. However, we found that age at recruitment (0.31, $p < 0.01$, 95%CI 0.16 -0.47), urinary QoL (0.07, $p < 0.01$, 95%CI 0.03-0.11), bowel QoL (0.20, $p < 0.01$, 95%CI 0.13-0.27), and sexual QoL (0.04, $p < 0.01$, 95%CI 0.02-0.06) were all associated positively with overall levels of mental health QoL. Of the QoL predictors, bowel QoL had the strongest effect (LR Chi square = 18.47, $p < 0.01$). Thus, higher mental health-related QoL was reported by older men and those with higher disease-specific QoL, especially bowel-related QoL.

Trajectory of Physical QoL

Physical health-related QoL trajectories decreased on average across the 24 mo of the study (-0.20, $p < 0.01$, 95%CI -0.24 to -0.16). However, patient slopes did not vary significantly for this outcome. We found that only urinary QoL (0.08, $p < 0.01$, 95%CI 0.05-0.11), bowel QoL (0.16, $p < 0.01$, 95%CI 0.10-0.21), and sexual QoL (0.06, $p < 0.01$, 95%CI 0.05-0.08) were associated positively with overall levels of physical QoL and of these, bowel QoL had the strongest effect (LR Chi square = 11.24, $p < 0.01$).

Discussion

In this prospective, longitudinal trial-based study of patients treated for prostate cancer with contemporary surgical techniques we observed a substantial subgroup of men who fare worse over time for psychological distress. Men differed significantly in their individual distress trajectories. That is, although most men gradually got better, some didn't get better and some got worse. Moreover, distress was worse for men who were younger, who had more co-morbidities, and in particular for men who experienced worse bowel function. This supports the overarching principle that psychosocial care for men needs to focus more broadly than the more common surgical side effects, such as erectile dysfunction and subsequent sexual concerns. In particular, there is a need to consider life course, and within this the problems that arise from diagnosis at a younger age, and from the co-morbidities that are common in older men. In addition, the particular meaning and distress that relates to difficulties in bowel functions changes need to be considered.

The relationship between younger age and a poorer psychological outcome has been previously reported, and likely relates to masculine constructions of what it means to be a young man, that are inconsistent with a diagnosis of prostate cancer¹⁹. For example, the psychological threat of prostate cancer in younger men, who have a financially dependent family, a developing career, and a self-image strongly connected to perceptions of strength and vitality, may loom large. For aging men who are affected by other common and often co-occurring chronic diseases, such as cardiovascular disease, diabetes or osteoarthritis, the burden of prostate cancer additional to these may be overwhelming. Our group has previously reported six-year outcomes in a large and heterogeneous group of men with prostate cancer and found younger age, lower income and co-morbidities to predict poorer psychological trajectories²⁰. This new study confirms these findings in a well characterised surgical population closely tracked over 24 mo and further supports the need for life course to be considered in men's risk profiles for poorer survivorship outcomes.

The finding of a singular effect of bowel function and bother on men's psychological trajectories in this patient group is novel. We have shown that, adjusting for sociodemographic and clinical

variables, bowel quality of life at any given point predicts a man's slope in distress better than sexual and urinary function. This result is consistent with recent evidence that urinary, sexual, and bowel Unmet supportive care need surveys of men with prostate cancer consistently report high levels of unmet need for psychosocial and sexual problems^{21,22}, yet in the present study the differentiating variable was bowel dysfunction. While the reasons for this are unclear, this may relate to the societal stigma and taboos associated with bowel complaints²³. This means that even mild bowel dysfunction may be highly distressing for men for whom these problems are embarrassing and difficult to openly discuss with their health care provider. This interpretation is consistent with recent evidence suggesting that reported emotional distress and bowel, urinary and sexual function have a bidirectional prospective relationship with emotional distress²⁴. Close attention to addressing bowel dysfunction in men's long-term care is warranted. In Litwin and colleagues' analysis, gastrointestinal disease was a co-morbidity for 16.7% of the radical prostatectomy group and this was equal to the radiation and brachytherapy groups, respectively²⁵. Men may easily associate salient bowel-related symptoms with medical treatment even in the absence of treatment-related bowel dysfunction and techniques such as cognitive behavioural therapy may be beneficial in addressing the concerns that men may have regarding bowel-related symptoms.

There are many cross-sectional studies suggesting the prevalence of distress in men with prostate cancer exceeds that of their population comparators. For this study, strengths include assessments at baseline before treatment, multiple assessment points (an average of seven), long term follow up, use of well validated measures, and a clearly defined patient population who received standardised high quality surgical care. Hence causes of unknown study bias are limited and strong conclusions can be drawn for a surgical patient group. Prospective longitudinal studies are now emerging to describe how this distress evolves over time. Over 1.1 million men are diagnosed with prostate cancer each year worldwide and most of them will be long term survivors²⁶⁻²⁸. The present study shows a substantial number of these men, one in five, will continue to be distressed over the long term (> 1 year), and this presents a public mental and men's health emergency in the context of an escalating global prostate cancer burden. We found that across outcomes younger age and worse disease-specific QoL,

particularly bowel QoL were associated with more distress and lower physical and psychological QoL. Brief distress screening in people with cancer is an accepted standard of optimal care ⁷ and has been well validated in men with prostate cancer ⁶. Effective psychosocial interventions have been identified ²⁹. What remains lacking is broad implementation of psychosocial care beyond specialist clinics.

Study Limitations

The current study is limited by not utilising a population-based sample, and from this these results may not be generalizable to different cultural groups and men who had a different clinical pathway.

Clinical Implications

Men treated surgically for prostate cancer are at risk of heightened psychological distress.

Survivorship care plans should include regular distress screening and take a broader perspective on men's health outside of prostate specific factors and consider life course factors that relate to age and aging.

Conclusion

A substantive group of men experience heightened psychological distress after prostate cancer that for some persists over the long term. Care pathways for men with prostate cancer need also to respond to age specific concerns and health problems associated with co-morbidities in aging men. Focussed symptom control for bowel bother should be a priority.

Conflict of Interest Statement

The authors declare that they have no competing interests.

Author Contributions

Concept and design: SO, JWY, ND, RAG and SKC; Acquisition of data: LZ; Analysis and interpretation of data: SO and SKC; Drafting the manuscript: SO and SKC; Critical revision of the

manuscript for important intellectual content: SO, LZ, GDC, JWY, ND, RAG, and SKC; Statistical analysis: SO, LZ and SKC; Obtaining funding: SO, GDC, JWY, ND, RAG, and SKC.

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Table 1

Summary of demographic details of participants

	Total
Age, years (M±SD)	60.01 ± 6.24
Education n (%)	
University	30 (12)
Technical	107 (41)
Senior high school	61 (24)
Junior high school	42 (26)
Primary school	13 (5)
Did not complete primary	6 (2)
Employment n (%)	
Employed – full time	144 (60)
Unemployed or looking for work	8 (3)
Retired	54 (22)
Unwilling to answer	2 (1)
Employed – casual	9 (4)
Employed – part time	19 (8)
Full time home duties or home carer	1 (0.40)
Permanently ill/disabled	11 (4)
Household income n (%)‡	
< \$20 000 to \$40 000	89 (34)
\$40 001 to \$60 000	70 (27)
\$60 001 to \$80 000	48 (19)
\$80 001 +	40 (15)
Unwilling to answer / Don't know	12 (5)
Comorbid condition n (%)	
Myocardial infarction	21 (7)
Heart failure	13 (4)
Angina or abdominal aortic aneurysm	14 (5)
Peptic ulcer disease	14 (5)
Cerebrovascular accident	7 (2)
Diabetes mellitus	28 (9)
Chronic obstructive pulmonary disease	18 (6)
Dementia	0 (0)
Connective tissue/autoimmune disease	4 (1)
Liver disease	6 (2)
Kidney disease	13 (4)
Bowel disease	10 (3)
Hypertension	117 (38)

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Table 2

Prevalence of psychological distress and failure to return to baseline domain specific quality of life functioning across timepoints

	Baseline	6 wks	3 mo	6 mo	12 mo	24 mo
Case* n (%)	87 (28)	62 (23)	59 (23)	59 (21)	61 (22)	57 (21)
Case EPIC urinary ** n (%)		162 (76)	89 (44)	70 (32)	60 (27)	54 (25)
Case EPIC sexual ** n (%)		161 (77)	146 (73)	156 (73)	136 (62)	112 (52)
Case EPIC bowel ** n (%)		70 (33)	33 (16)	35 (16)	38 (17)	35 (16)

*Psychological distress caseness was defined as ≥ 11 on the total score for the Hospital Anxiety and Depression Scale which indicates elevated psychological distress

** Expanded Prostate Cancer Index Composite (EPIC) cases were those where follow up domain specific quality of life mean scores did not return to baseline (i.e., >0.5 SD)

Table 3. Expanded Prostate Cancer Index Composite domain summary scores across timepoints

	Range	Baseline		6 weeks		3 months		6 months		12 months		24 months	
		M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Urinary domain	0-100	89.37	11.73	72.90	16.10	83.34	13.13	89.15	10.92	91.41	9.95	91.34	10.34
Sexual domain	0-100	62.80	23.99	32.36	21.93	37.45	23.09	38.44	22.62	42.37	25.57	45.89	26.59
Bowel domain	0-100	94.42	7.78	91.91	9.03	94.30	8.69	95.13	8.83	95.22	8.06	95.39	6.94

Data are M, SD Higher scores indicate better functioning on all scales.
 EPIC=Expanded Prostate Cancer Index Composite.

Table 4

Mixed effects regression results for mental and physical QoL and psychological distress outcomes

	regression weight	p	95% CI
Mental QoL			
Time	0.02	0.47	-0.03-0.06
Age	0.31	<0.01	0.16-0.47
High education	-0.50	0.59	-2.31-1.31
Comorbidities	-0.36	0.37	-1.16-0.43
Baseline PSA	-0.05	0.67	-0.30-0.19
Urinary QoL	0.07	<0.01	0.03-0.11
Bowel QoL	0.20	<0.01	0.13-0.27
Sexual QoL	0.04	<0.01	0.02-0.06
Physical QoL			
Time	-0.20	<0.01	-0.24--0.16
Age	0.02	0.75	-0.09-0.12
High education	0.36	0.57	-0.87-1.58
Comorbidities	-0.01	0.99	-0.54-0.53
Baseline PSA	-0.07	0.4	-0.23-0.09
Urinary QoL	0.08	<0.01	0.05-0.11
Bowel QoL	0.16	<0.01	0.10-0.21
Sexual QoL	0.06	<0.01	0.05-0.08
Psychological Distress			
Time	-0.02	0.24	-0.04-0.01
Age	-0.2	<0.01	-0.31--0.09
High education	0.26	0.7	-1.05-1.56
Comorbidities	0.64	0.03	0.07-1.21
Baseline PSA	-0.04	0.65	-0.22-0.14
Urinary QoL	-0.02	0.11	-0.04-0
Bowel QoL	-0.14	<0.01	-0.17--0.1
Sexual QoL	-0.01	0.07	-0.02-0
Bowel x Time	-0.004	0.01	-.008--0.001