

Coping and Health-Related Quality of Life in Men With Prostate Cancer Randomly  
Assigned to Hormonal Medication or Close Monitoring

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Short Title: QUALITY OF LIFE IN PROSTATE CANCER

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\*\*PREPRINT. Final version published in *Psycho-Oncology* (2002), 11, 401-414 \*\*

This project was wholly financed by Queensland Cancer Fund

## Summary

Prostatic carcinoma and its treatment have been associated with adverse effects on health-related quality of life (HRQoL). Individual differences in appraisal and coping have been suggested to mediate these HRQoL outcomes. A randomized trial of 65 men with non-localized prostate cancer compared several treatments and tested associations between appraisal, coping, and HRQoL. These patients, and 16 community volunteers matched for age and general health, undertook psychosocial assessments before treatment and after 6 months of treatment. Compared with baseline assessments, men on hormonal treatments reported impaired sexual function. Groups did not differ on emotional distress, existential satisfaction, subjective cognitive function, physical symptoms, or social and role functioning. For individuals, hormonal treatments were more frequently associated with decreased sexual, social and role functioning, but were also associated with improved physical symptoms. In hierarchical regression analysis, HRQoL was lower for men who had more comorbid illnesses, a history of neurological dysfunction, higher threat appraisals, or higher use of coping strategies at baseline. These results showed that pharmacological hormonal ablation for prostate cancer can improve or decrease HRQoL in different domains. HRQoL in men with prostate cancer was associated more strongly with appraisal and coping than with medical variables.

**KEY WORDS:** prostate cancer, adverse effects, quality of life, coping, appraisal, self-efficacy

Management of chronic illnesses requires consideration of multiple health outcomes. Health-related quality of life (HRQoL) has been defined as the physical, mental, and social effects of illness on daily living and the impact of these effects on levels of subjective well-being, satisfaction and self-esteem [Bowling, 1991]. This study examined HRQoL for men with non-localized prostatic carcinoma. Prostate cancer is the most frequently diagnosed internal malignancy in men and the second most frequent cause of male cancer deaths in the United States and Australia [Jain, 1994; Landis *et al.*, 1998].

Urinary symptoms, pain, fatigue, and reduced overall quality of life are frequently reported by men with non-localized prostate cancer [Esper and Redman, 1999; Rossetti and Terrone, 1996; Tannock *et al.*, 1996; van Andel *et al.*, 1997]. Elevated emotional distress is reported by some but by no means all patients. Group means have shown no difference from general population means for depression and anxiety [Albertsen *et al.*, 1997; Bjorck *et al.*, 1999]. Palliative treatment using surgical or pharmacological androgen ablation is indicated at some time but the optimum timing for commencement is debated [Huben, 1992].

Beneficial effects reported for androgen suppression treatments include improved urinary symptoms, global HRQoL, physical functioning and appetite, and reduced pain [Albertsen *et al.*, 1997; Cassileth *et al.*, 1992; da Silva *et al.*, 1996]. Adverse effects include impaired sexual function, hot flushes, breast enlargement, osteoporosis, liver dysfunction, fatigue, and depression [Altwein *et al.*, 1997; Herr and O'Sullivan, 2000; van Andel *et al.*, 1997]. Most studies comparing treatments have focused on physical effects, have used non-random assignment to treatments, and have not included control groups or normative data. There is also insufficient information on

the HRQoL effects of clinical monitoring [delayed treatment; Altwein *et al.*, 1997; Frydenberg *et al.*, 2000]. The present study addressed these issues by assessing HRQoL before and during treatments to which patients were randomly assigned.

In addition to the external factor of treatment, we examined associations between HRQoL and patients' individual variability in coping. This component of the study was based on a stress and coping model [Folkman and Greer, 2000; Lazarus and Folkman, 1984]. According to stress and coping theory, outcomes that occur in response to a stressor are mediated by the individual's cognitive appraisal of the stressor and his or her coping resources and strategies. The theory distinguishes between primary appraisal (evaluating the extent to which an event is threatening), and secondary appraisal (evaluating the feasibility of coping, such as determining one's self-efficacy for carrying out specific coping strategies). If an event is appraised as threatening or harmful, stress and coping theory predicts that the individual will implement coping strategies that may include problem-focused coping (strategies directed at the external event) and emotion-focused coping (strategies directed at the individual's internal emotional reactions). Other ways coping strategies have been categorised include meaning-based coping [Folkman and Greer, 2000] and emotional approach versus avoidance [Stanton *et al.*, 1994].

The link between cognitive appraisals of an illness and distress has been well established. In 30 men with prostate cancer, appraisals of greater threat and loss were correlated with higher depression and anxiety [Bjorck *et al.*, 1999]. Appraisal of prostate cancer as a challenge was not correlated with depression or anxiety [Bjorck *et al.*, 1999]. Patients with other types of cancer have shown similar associations between primary appraisal and distress [Burgess and Haaga, 1998; Parle and Maguire, 1995].

The association between secondary appraisal (self-efficacy) and HRQoL in prostate cancer has also been supported. Self-perceived ability to cope with stress was a stronger predictor of higher global HRQoL in men with prostate cancer within 1-6 months of their initial treatment than stage of cancer or other psychosocial predictors [Krongrad *et al.*, 1997].

Evidence has supported an association between coping strategies and HRQoL in people with prostate cancer or other types of cancer. The association with higher HRQoL is especially robust for problem-focused coping [Bjorck *et al.*, 1999; Bloom, 1996; Osowiecki and Compas, 1998]. Emotion-focused coping has been associated with higher HRQoL in some studies [Glanz and Lerman, 1992], but with lower HRQoL in others [Osowiecki and Compas, 1998], especially when avoidant emotion-focused coping is used [Holahan *et al.*, 1996]. Use of meaning-based coping has been associated with psychological well-being in patients with cancer or other serious illnesses [Folkman and Greer, 2000]. This study addressed limitations from some of the previous research by distinguishing between appraisal and coping, examining patients with prostate cancer as a separate group, and measuring multiple HRQoL domains rather than focusing only on emotional outcomes.

The first aim of the present study was to compare effects on HRQoL of different pharmacological treatments for non-localized prostate cancer. The second aim was to examine the role of appraisal and coping in HRQoL in this patient group. Men with prostate cancer were randomly assigned to treatment with either a luteinizing hormone releasing hormone (LHRH) analog, steroidal antiandrogen, or clinical monitoring, and undertook psychosocial assessment before and during treatment. It was hypothesized on the basis of previous findings that, when on active treatment, men on androgen-

suppressing treatments (leuprorelin, goserelin, or cyproterone) would report impairment in sexual function compared with close clinical monitoring and community controls (Hypothesis 1). With respect to the second aim, it was predicted that lower threat appraisals, higher self-efficacy and greater use of problem-focused coping would be associated with better HRQoL (Hypothesis 2).

## Methods

### Participants

Men with non-localized prostate cancer, for whom palliative treatment by hormonal manipulation was considered to be optional, were eligible to participate in the randomized trial. Exclusion criteria were previous hormonal therapy, psychiatric impairment, severe lower tract symptoms (International Prostate Symptom Score > 7), or abnormal serum testosterone. Eighty-two men with prostate cancer agreed to participate and gave written consent. Seventy-seven patients, and 20 male community volunteers with no clinical evidence of prostate cancer, were assessed at baseline. Participants reassessed at 6 months were 65 men with prostate cancer, with a mean age of 73.3 years (SD = 6.4; range 56-86), and 16 community participants, with a mean age of 69.2 years (SD 6.3; range 59-83). Community participants were comparable with patients in age, marital status, occupational status [Australian Bureau of Statistics, 1997] and general health. However, mean education was significantly higher for the community participants (13.4, SD = 3.3) than patients (9.1, SD = 2.4).

Patients were recruited through 20 urologists or radiologists in Queensland, Australia over a 20-month period. Community participants were recruited through media releases that offered free memory testing to men aged 60 or above. Participation rates were not obtainable, due to use of these multiple recruitment sources. All

participants took part on a voluntary basis and received no financial benefit. Local transport costs for session attendance were paid on behalf of some participants.

### Measurement Instruments

Several instruments were used in order to measure specific dimensions of HRQoL, appraisal and coping. HRQoL dimensions were emotional distress (Depression Anxiety Stress Scales), existential satisfaction (Satisfaction With Life Scale), physical/urinary function (European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire [EORTC-QLQ-C30]), social/role function (EORTC-QLQ-C30), subjective cognitive function (EORTC-QLQ-C30), and sexual function (supplementary module to EORTC-QLQ-C30). Threat appraisal and self-efficacy were measured by questionnaires modelled on those from previous studies. Coping was measured with the COPE questionnaire. A half-hour interview by a clinical psychologist provided additional information on participants' general health. The interview and neuropsychological assessment undertaken by participants are reported elsewhere [Green *et al.*, 2001].

Health-related quality of life. Emotional distress was measured with the total score on the Depression Anxiety Stress Scales [Lovibond and Lovibond, 1995]. This 21-item Australian measure (Cronbach's alpha = .92) correlates highly with the Beck Depression and Anxiety Inventories [Lovibond and Lovibond, 1995].

Existential satisfaction was measured with the Satisfaction With Life Scale [Pavot and Diener, 1993]. This 5-item measure (alpha = .86) allows participants to subjectively weight dimensions of HRQoL in rating their overall satisfaction.

Other HRQoL measures came from the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 [EORTC QLQ-C30 Version

3; Aaronson *et al.*, 1993] and a supplementary module developed for men with prostate cancer [Borghede and Sullivan, 1996]. A factor analysis of the EORTC measures showed that physical and symptom items from the core questionnaire loaded with the urinary function items from the supplementary questionnaire. Thus, a combined score for physical symptoms and urinary function was computed (excluding a financial difficulties item; 22 items,  $\alpha = .89$ ). Similarly, the 4 social and role items from the EORTC QLQ-C30 loaded together, and were combined to produce a social and role function measure ( $\alpha = .87$ ). Subjective cognitive function was a separate factor and was operationalized as the conventional 2-item EORTC QLQ-C30 Cognitive Functioning subscale ( $\alpha = .76$ ). The 4-item sexual function scale from the supplementary module was also a separate factor and was used in its existing form [ $\alpha = .92$ ; Borghede and Sullivan, 1996]. All EORTC measures were rescaled in 0-100 format using the procedures in the scoring manual [Fayers *et al.*, 1997]. Maximum function was indicated by a score of 100, except for sexual function in which 100 represented maximum dysfunction.

Context for appraisal and coping items. In order to provide a context for patients' responses to measures of appraisal and coping, a list of 8 difficulties frequently reported by men with prostate cancer was constructed from qualitative and quantitative data [Burman and Weinert, 1997; Clark *et al.*, 1997; O'Rourke and Germino, 1998; Silveira and Winstead-Fry, 1997; Steele and Fitch, 1996]. Respondents were also encouraged to nominate up to 2 personal difficulties not on the list. Participants rated from 0 = have not experienced to 5 = extremely difficult how difficult each item had been for them to manage over the last 30 days. The highest degree of difficulty was the rating for "sexual difficulties" ( $M = 2.3 \pm SD = 2.0$ ). Next was "wife's worry about my



cancer”, rated  $M = 1.5 \pm 1.5$ , “worry about the future”, rated  $M = 1.3 \pm 1.3$ , and “other” (such as urinary problems or coping with diagnosis), rated  $M = 1.2 \pm 1.6$ . Other contextual items (“others are afraid to talk to me”, “lack of information”, “feeling less of a man”, “feeling like a burden to others”, and “carrying out doctor’s orders”) all had means of  $<1.0$ , although it should be noted that responses on every item ranged from 0-5, indicating that each of the items was “extremely difficult” for at least one participant. Respondents were asked to answer all the remaining questions (appraisal and coping items) in the context of the difficulties they had nominated. Community participants were asked to answer appraisal and coping items in the context of a recent health difficulty that they had nominated.

Appraisal. Appraisal items were developed for this study, to measure primary (threat) and secondary (self-efficacy) appraisals. In the absence of standardized measures of these constructs, items and response formats were constructed that were similar to those used in other studies of appraisal in people with cancer [Bjorck *et al.*, 1999; Burgess and Haaga, 1998]. Participants were instructed to rate, in relation to other difficulties they had experienced, the difficulties that had been caused by their illness in the last 30 days. Participants rated how stressful, disruptive, upsetting, difficult, and severe the difficulties were, on 5-point Likert scales (5 items,  $\alpha = .92$ ). Item 1 had endpoints of “not stressful” and “extremely stressful” and other items were worded similarly. Four self-efficacy items required participants to rate their anticipated success in coping with the nominated difficulties, on 5-point scales (1=not at all to 5=completely). The items asked how well the participant thought he would deal with these problems, how effective he thought his attempts to deal with problems would be, how certain he was that he would be able to deal with the problems, and how difficult

he thought it would be to deal with the problems. One reverse-scored item had a low item-total correlation and was omitted, leaving a 3-item scale ( $\alpha = .88$ ). A principal components factor analysis on threat and self-efficacy items showed that they loaded on two distinct factors and they were therefore analysed separately.

Coping. A 40-item version of the COPE scale was used, comprising 10 subscales with 4 items each [Carver *et al.*, 1989]. Items from different subscales were intermixed and administered in a fixed order. Participants were instructed to identify the extent to which they had used each of these coping strategies in the preceding 30 days, on a 4-point rating scale [1=Not at All to 4=A Lot; Carver *et al.*, 1989]. Problem-focused items were derived from the COPE subscales; Active Coping, Planning, and Seeking Social Support for Instrumental Reasons. Emotion-focused items came from the COPE subscales; Positive Reinterpretation and Growth, Seeking Social Support for Emotional Reasons, Religion, Acceptance, and Mental Disengagement. A sixth emotion-focused subscale replaced a COPE subscale (Focus on and Venting of Emotions) with four items from Stanton's Emotional Approach Coping measure, to avoid confounding emotional coping with psychopathology [Stanton *et al.*, 1994]. A factor analysis on problem-focused items indicated that a one-factor solution was satisfactory, and a separate analysis on emotion-focused items also found that a one-factor solution was adequate. Therefore, one problem-focused (12 items,  $\alpha = .94$ ) and one emotion-focused (24 items,  $\alpha = .91$ ) scale was constructed, each scaled with potential range 4-16 for comparison with previous COPE data [Carver *et al.*, 1989]. The Denial subscale from the COPE was omitted from further analysis due to low subscale reliability and low correlation with other coping items.

Medical history. Illnesses other than prostate cancer were coded from an interview by a clinical psychologist. The number of serious illnesses, injuries and operations reported by the participant was recorded, as at baseline interview (current illnesses) and over the participants' lifetime including any current illnesses (past illnesses). The interviewer also inquired about neurological illnesses, brain injury, and current and past levels of alcohol use.

#### Procedure

Randomization. Urologists explained the randomization treatment options to patients and obtained verbal consent. Patients were then referred to a research nurse who described the study in more detail, obtained written informed consent and randomly allocated participants to one of four management groups using a table generated by computer before study enrolments began. The four groups were close observation, goserelin (LHRH agonist), leuprorelin (LHRH agonist), and cyproterone acetate (antiandrogen). There were no significant differences among patient treatment groups in age, education, occupational status, marital status, or baseline prostate specific antigen levels [PSA, a prognostic marker; Garnick and Fair, 1996].

Data collection. A clinical psychologist conducted psychosocial assessments, in conjunction with assessments of cognitive function reported elsewhere [Green *et al.*, 2001]. The psychologist was blind to the patient's treatment group within participants with prostate cancer. The psychologist was not blind to the status of participants as being in the randomized study or the community comparison group. The baseline session of approximately 2.5 hours comprised a clinical interview, neuropsychological testing with appropriate rest breaks, and presentation of psychosocial questionnaires to be completed at home and returned by reply paid mail. The baseline session took place

approximately one week before patients commenced the assigned treatment.

Participants were telephoned if questionnaires were not returned within 2 weeks.

Assessments were repeated after 6 months of treatment.

## Results

A repeated measures Group (5) x Time (2) MANOVA was conducted with the 6 HRQoL measures. Wilk's Lambda was used as the criterion for significance, with alpha level .05. The MANOVA was followed by investigation of univariate ANOVAs. Clinically significant changes for individuals were identified using the Reliable Change Index [Hinton-Bayre *et al.*, 1999; Jacobson and Truax, 1991]. This measure compares an individual's change in score to the variability that would be expected, calculated from the community participants' variance at baseline and test-retest reliability. A significance level of .05 (2-tailed) was used.

Hierarchical multiple regressions were performed on the cross-sectional and longitudinal data to examine the relationship between appraisal and coping and each of the 6 HRQoL measures, for men with prostate cancer. Bivariate correlations were examined to identify demographic and medical variables that needed to be entered as covariates. An alpha level of .01 was used for regressions to control Type I error rate.

### Preliminary Analyses

Five patients who initially agreed to participate subsequently changed their treatment decisions or withdrew their consent before psychosocial assessment. Of 97 participants tested at baseline, 16 were unavailable at 6 month follow-up. Reasons for withdrawal were death (2 men assigned to cyproterone), illness (1 leuprorelin, 3 cyproterone and 3 monitoring), changed treatment decision (1 cyproterone), and refusal (1 cyproterone, 1 monitoring, 4 community participants). T-tests showed that

participants lost to follow up did not differ significantly from participants who attended Time 2 in baseline measures of age, years of education, occupational status, PSA, testosterone, and number of current or past illnesses. Therefore, the participants who were lost to follow-up were considered a random sample of baseline participants and their data were not analysed further.

Missing data also resulted from participants omitting to answer items. The proportion of participants with missing items ranged across all measures, from 10% (social/role and subjective cognition) to 40% (COPE). No increase in missing items occurred for potentially sensitive issues such as sexual function (20% with missing items). Because measures had high internal reliability, estimates were used to replace missing data. When possible, missing data of this type were replaced with the mean of the participant's completed items on the measure. If no items were completed but there was a score at the other time point, the score at the other time was used. If the score was unavailable at both time points, the Statistical Package for the Social Sciences (SPSS) expectation-maximization procedure was used to estimate the score from the participant's scores on other measures at that time point. If no questionnaires were completed, the group mean was used. A logarithmic transformation was used for PSA to correct this variable's high skew and kurtosis. Mild skew was found for emotional distress, physical/urinary function, Time 1 existential satisfaction, and Time 2 sexual function, and moderate skew for self-efficacy, social/role and subjective cognition. These variables were retained untransformed because they were thought to accurately reflect the distribution of scores in the population of interest.

### HRQoL Changes over Time

Changes within groups. Means and standard deviations for the 6 HRQoL measures are shown in Table 1. Comparisons with normative data from other studies, also in Table 1, indicated that mean HRQoL measures were close to norms both at baseline and on-treatment.

Insert Table 1 about here

There was a significant multivariate effect of Time,  $F(6, 71) = 6.08, p < .001, \eta^2 = .34$ , in the direction of worse HRQoL at Time 2. There was no main effect of Group and no Group x Time interaction, indicating that worse HRQoL over time affected all groups including the community group without prostate cancer. Univariate ANOVAs showed that the significant multivariate effect was largely due to worse Sexual Function at Time 2,  $F(1, 76) = 29.84, p < .001, \eta^2 = .28$ . Sexual function also showed significant effects of Group,  $F(4, 76) = 4.52, p = .003, \eta^2 = .19$ , and the Group x Time interaction,  $F(4, 76) = 3.06, p = .021, \eta^2 = .14$ . The interaction occurred because increased sexual difficulties over time were particularly pronounced for men assigned to goserelin,  $p < .001$ , and leuprorelin,  $p = .051$ , but did not change markedly for men on cyproterone, clinical monitoring or community comparison participants. This interaction is shown in Figure 1. No other measures had significant univariate results.

Insert Figure 1 about here

Changes within individuals. Change scores were computed for individuals and compared with the Reliable Change Index. The data in Table 2 show the proportion of individuals with significant changes. Worse HRQoL at Time 2, on at least one of the six measures, occurred in men from all groups. However, reliable decreases in 2 or more measures occurred almost exclusively in the hormonally treated groups. No man

on close monitoring, and only 1 community participant, a 77 year-old man who was undergoing diagnosis for suspected myeloma, reported reliable decreases on more than one measure of HRQoL.

Insert Table 2 about here

In descending order of frequency, reliable decreases for men on hormonal treatments occurred in sexual function (10 men), social/role (9), subjective cognition (8), physical/urinary (7), emotional distress (5), and existential satisfaction (3). Three men from the close monitoring group reported decreased HRQoL, for emotional distress, physical/urinary and subjective cognition respectively. Community reports of decreased HRQoL occurred for sexual function (2), cognitive (2), social/role (2) and physical/urinary (1). These numbers for the community group include one participant who reported reliable decreases for both sexual and physical/urinary function.

Since treatments have the potential to improve HRQoL, reliable increases were also examined. Improved HRQoL was more likely to be reported by hormonally treated men than men in close monitoring or community groups. For men on hormonal treatments, reliable improvements were reported for physical/urinary (9 men), social/role (6), emotional distress (3), subjective cognition (2), and existential satisfaction (1). One man on close monitoring reported improved cognitive function and existential satisfaction. Improvements in emotional distress and existential satisfaction respectively were each reported by one community volunteer.

#### Bivariate Correlations

Bivariate correlations were used to examine the extent to which predictors and criterion variables were related cross-sectionally and longitudinally. Background variables found to correlate with criterion variables were current illnesses, past illnesses,

and neurological history. Potential predictors that did not correlate with criterion variables were  $\log_{10}$  of baseline PSA, baseline testosterone, age, education, occupation, loss of consciousness, current alcohol use, past alcohol use, psychiatric history, and non-English speaking background.

Correlations with criterion variables, for the final set of predictor variables, are summarized in Table 3. Higher scores for HRQoL measures represented better function, except for DASS and sexual function on which higher scores represented greater dysfunction. Better HRQoL at Times 1 and 2 was significantly correlated with lower number of current illnesses, lower number of past illnesses, and lower threat appraisals. At Time 2, there was an additional finding of lower HRQoL associated with a history of neurological disturbance. Contrary to expectations, HRQoL at both Times 1 and 2 was poorer for men who reported higher use of either problem- or emotion-focused coping.

Insert Table 3 about here

#### Hierarchical Regression Analyses of the Effects of Stress and Coping Predictors

Cross-sectional analyses. Cross-sectional hierarchical regressions were performed for each of the 6 HRQoL measures. Covariates that correlated with a criterion variable ( $\alpha = .01$ ) were included in regressions with that criterion variable (see Table 3). Past illness was not included in regressions because it correlated with current illness ( $r = .57$ ) and would have decreased the ratio of cases to variables. Covariates were entered at Step 1, appraisal (threat and self-efficacy) at Step 2, and coping measures (problem- and emotion-focused) at Step 3. Results are summarized in Table 4. Tolerances were within acceptable limits, indicating no multicollinearity between predictors [Tabachnick and Fidell, 1989]. When all variables were in the equation,



significant amounts of variance were accounted for in distress (54%), physical/urinary function (32%), and social/role function (44%).

Current comorbid illness accounted for significant variance in distress (10%), physical/urinary (12%) and social/role (13%) function. Higher numbers of illnesses were associated with reports of higher distress and poorer physical/urinary and social/role functions. Appraisal accounted for a significant increment in variance of distress (37%), physical/urinary (20%), and social/role function (31%). Higher threat appraisals were associated with reports of higher distress, poorer physical/urinary and poorer social/role function. Similar effects were seen with existential satisfaction and subjective cognition, for which the overall variance accounted for was significant at .05 but not at the .01 cut-off level. Self-efficacy was associated with social/role function in the opposite direction to predictions, with higher self-efficacy associated with lower social/role function. After controlling for the effects of all other predictors, coping strategies explained significant additional variance in emotional distress (7%). Although the beta weights for individual coping strategies did not reach significance, the direction of association showed that higher use of either problem- or emotion-focused coping was associated with higher emotional distress.

Insert Table 4 about here

Longitudinal analyses. Results of regression analyses of the effects of Time 1 predictors on Time 2 HRQoL are summarized in Table 5. Longitudinal analyses used the same baseline predictor variables as cross-sectional analyses, except that Time 1 score on the dependent variable was entered as a preliminary step, to control for Time 1 HRQoL. Because Time 2 sexual function was significantly affected by treatment group, participants' assignment to active treatment (1) or close monitoring (2) was entered at

Step 2, for sexual function only. The medical variable of neurological history (coded 1=no, 2=yes) was added for analyses performed on distress, physical/urinary and social/role because it correlated significantly with Time 2 reports of these measures. The remaining stress and coping variables were entered in the same order as above.

When all variables were in the equation, significant amounts of variance were accounted for in all criterion variables (36-71%). Time 1 HRQoL accounted for the largest amounts of variance (28-57%). Treatment assignment accounted for a further 7% of variance in sexual function, with men on active treatments reporting higher sexual dysfunction than men on close monitoring. Medical variables accounted for a significant increment in variance in physical/urinary (8%) and distress (9%). Men with a history of neurological illness reported worse Time 2 distress and physical/urinary function. A similar trend was seen for social/role function. Unexpectedly, Time 1 appraisal was unrelated to all Time 2 criterion variables when all predictors were in the equations. However, the increment in variance in social/role function explained by appraisal approached significance, with higher threat appraisals associated with lower social/role function. When all other predictors were in the regression, Time 1 coping strategies explained a significant additional amount of variance in physical/urinary (6%) and subjective cognition (10%). Although beta weights for individual coping strategies did not reach significance, the directions of association showed that higher use of either emotion- or problem-focused coping at Time 1 was associated with worse Time 2 reports of physical/urinary and subjective cognitive function.

Insert Table 5 about here

## Discussion

The present study is one of the few that has used random assignment to compare the effects of prostate cancer management strategies on HRQoL. Patients who were assigned to pharmacological androgen ablation reported significantly worse deterioration in sexual function than patients assigned to close clinical monitoring or male community volunteers of comparable age and general health. Analysis of variance showed no difference between the groups over time in reports of emotional, existential, physical/urinary, social/role, or subjective cognitive functions. Examination of clinically significant HRQoL changes for individuals showed that androgen ablation treatments were more frequently associated with both decreases in HRQoL, particularly in sexual, social/role, and subjective cognitive functions, and increases in HRQoL, particularly in physical/urinary function. Cross-sectional hierarchical regression analysis showed that medical, appraisal, and coping variables were associated with HRQoL. Longitudinal hierarchical regression analysis showed that medical and coping variables from Time 1 also predicted HRQoL at Time 2.

Hypothesis 1 was supported; deterioration in sexual function over time was greater for men on androgen ablation treatments than men not receiving these treatments. The deterioration was demonstrable even though mean age at baseline was 72.5 years. This finding is consistent with those of other studies [da Silva *et al.*, 1996].

Because of conflicting reports in the literature of non-sexual HRQoL effects of prostate cancer treatments, it was difficult to predict how HRQoL in the other domains would be affected. The present study found that, as a group, men eligible for optional hormonal treatment for prostate cancer reported HRQoL comparable to normative data, in non-sexual domains, and that they maintained this level of HRQoL after 6 months of

treatment. Our findings on emotional distress contrasted with previous findings of either improvement [Cassileth *et al.*, 1992], or deterioration [Herr and O'Sullivan, 2000], in emotional function associated with androgen ablation treatments. The findings also contrasted with previous reports of improved urinary and physical function [Albertsen *et al.*, 1997; Cassileth *et al.*, 1992; da Silva *et al.*, 1996; Isurugi *et al.*, 1980], and increased fatigue [Altwein *et al.*, 1997; Daneshgari and Crawford, 1993; Herr and O'Sullivan, 2000; Isurugi *et al.*, 1980] during these treatments. Since these other studies did not use random allocation, they did not establish definitively that changes were caused by androgen ablation rather than other factors. Few previous data were available on social/role, existential and subjective cognitive function.

Although group analyses detected a difference between treatments in sexual function only, groups differed in the number of individuals showing reliable change in HRQoL. Compared with the close monitoring group and men without prostate cancer, androgen ablation treatments had greater potential to either decrease or increase HRQoL. This highlights the importance of understanding individual differences in treatment effects and of considering both benefits and costs of treatment.

Withdrawal from the study was highest for men assigned to cyproterone acetate; 35% withdrew by 6 month follow-up. Goserelin and leuprorelin had 0 and 5% withdrawal respectively, while 21% of close monitoring and 20% of community participants withdrew. The high drop out rate for cyproterone, especially compared with other active treatments, may indicate a less favourable profile of beneficial and adverse effects of this treatment when used as monotherapy. Previously, withdrawal from trials has been reported to be higher for nonsteroidal antiandrogens (4-10%) than for LHRH agonists [0-4%; Seidenfeld *et al.*, 2000]. The same meta-analysis found

withdrawal rates for the steroidal antiandrogen cyproterone acetate (1-4%) to be relatively comparable with LHRH agonists. In the present study, LHRH agonists appeared to be much better tolerated than cyproterone acetate.

Hypothesis 2 was partially supported. As predicted, lower threat appraisals were associated with better HRQoL at Time 1, in the domains of emotional, existential, physical/urinary, social/role and subjective cognitive function. Similar cross-sectional associations between lower threat appraisals and lower depression for people with prostate cancer [Bjorck *et al.*, 1999] or other types of cancer [Burgess and Haaga, 1998; Johnson *et al.*, 1997] have been reported. We additionally demonstrated an association between lower threat appraisals and higher self-reported existential satisfaction, physical/urinary, social/role and subjective cognitive function. With all variables entered in the regression analysis, threat appraisal was a much stronger predictor of patients' self-reported HRQoL than either Time 1 PSA or the number of comorbid illnesses. Similarly, other studies have found small or no associations between biological measures and self-reported HRQoL [Gleason and Schulz, 1996]. The cross-sectional relationship could also be interpreted as suggesting that patients with worse symptoms evaluate their cancer as more threatening than do patients with lower symptom levels.

Unexpectedly, higher self-efficacy was associated with lower social/role function at Time 1 and was unrelated to all other HRQoL measures. This contrasted with a previous finding of higher HRQoL associated with higher self-efficacy in men with prostate cancer [Krongrad *et al.*, 1997]. The latter study used a different measure of self-efficacy, and also included more early-stage patients. Another possible explanation is that this result is consistent with previous findings that unrealistically

positive views of the self are negatively correlated with behaviours necessary for positive social interaction [Colvin *et al.*, 1995].

Higher use of either emotion- or problem-focused coping was associated with higher emotional distress at Time 1, and with decreased physical/urinary, social/role and subjective cognitive function at Time 2. These findings contrasted with Hypothesis 2, which predicted higher problem-focused coping to be associated with better HRQoL. Others have found cancer patients who report higher use of emotion-focused coping to report lower HRQoL [Osowiecki and Compas, 1998]. For some samples, it seems that greater use of coping strategies is a marker of higher distress [Burgess and Haaga, 1998], and in our sample this was true for both problem- and emotion-focused coping. The measure of problem-focused coping may not have tapped the range of coping strategies used by men with prostate cancer. Coping was reduced to two broad dimensions, which may have obscured potential differential relations between more specific coping strategies and HRQoL. Gender differences in coping strategies may also help to explain the different findings between this and previous studies. For adolescents with cancer, boys with higher use of either emotion- or problem-focused coping had worse HRQoL. In contrast, girls' HRQoL was not affected by emotion-focused coping and had a positive association with problem-focused coping [Burgess and Haaga, 1998].

At Time 1, individuals who were experiencing health problems additional to prostate cancer reported higher distress and lower physical/urinary and social/role functions. Additionally, individuals who had experienced neurological illness or injury prior to the study reported higher distress and lower physical/urinary and social/role function at Time 2, although no such association emerged at Time 1. These findings

indicate the importance of the patient's overall health in determining HRQoL outcomes associated with prostate cancer treatment. The associations with neurological vulnerability are particularly interesting, since we are currently investigating whether androgen ablation treatments cause cognitive impairment in men with prostate cancer [Green *et al.*, 2001]. Cognitive impairment could affect patients' appraisals and coping, especially cognitively oriented problem-solving strategies, and could help to explain why problem-focused coping at Time 1 was associated with worse HRQoL at Time 2.

Cross-sectional and longitudinal regressions showed different results. Time 1 threat appraisal was a strong predictor of Time 1 HRQoL, but was unrelated to Time 2 HRQoL. One possibility is that appraisals may change over time. Although we were primarily interested in Time 1 appraisals, examination of Time 2 data showed a trend to decreased threat appraisals at Time 2 (see Table 1). Another difference was that neurological illness predicted Time 2 but not Time 1 HRQoL, which may suggest cumulative effects of neurological compromise that manifest over time. Coping was associated cross-sectionally with distress, but longitudinally with physical/urinary, social/role and subjective cognitive function. This suggests that coping strategies affect a number of HRQoL dimensions in addition to emotional distress, which has been the most widely studied domain.

Power for detecting effects in analysis of variance was adequate (>90%). Missing data may partly relate to study burden, but the high retention rate of participants suggests that they found the assessments manageable. Future research of this type could consider ways to reduce the burden on participants and increase the number of complete datasets. The study could also have been improved by a larger sample size for regression analysis, additional methods of data collection to supplement

self-report and interview measures, and finer-grained analysis of coping strategies. Other influences on HRQoL not addressed in this study include changes in coping over time, the quality of the patient-doctor relationship, the impact of uncertainty about treatment, and the patients' understanding of their illness and treatment. Nevertheless, in spite of its limitations, the study contributes significantly to the literature by using random allocation to treatments, assessing longitudinal as well as cross-sectional data, and measuring HRQoL in a range of domains. There were significant findings even with more stringent cut-offs and modest sample size. Furthermore, the pattern of results was largely consistent with previous research, which increases our confidence in the veracity of findings.

These results showed that androgen ablation treatments had beneficial as well as adverse effects on HRQoL. Factors found to predict lower HRQoL were comorbid illnesses, a history of neurological problems, high threat appraisals, and higher use of coping strategies at Time 1. These results imply that psychosocial interventions aimed at decreasing threat appraisals may help to decrease distress associated with prostate cancer and its symptoms. Potential interventions include providing information, facilitating patients' sense of control, or using reassurance. Indirect support for this approach has been reported [Johnson *et al.*, 1997]. It would also be valuable to identify effective coping strategies, since the coping strategies in this study were associated with reports of lower HRQoL. In summary, there was evidence of individual factors influencing HRQoL for men with prostate cancer, with appraisal and coping emerging as important psychological factors.



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Table 1.

Sample and Normative Data for Measures of HRQoL, Appraisal and Coping

Measure	Time 1		Time 2		Normative Data		
	Patients (n=65)	Community (n=16)	Patients (n=65)	Community (n=16)	Sample	N	Mean
	<u>M (SD)</u>	<u>M (SD)</u>	<u>M (SD)</u>	<u>M (SD)</u>			
Distress	7.1 ( 6.9)	9.0 (11.1)	8.9 ( 9.2)	9.3 (10.2)	University students <sup>a</sup>	717	11.5
Life satisfaction	26.2 ( 6.0)	24.3 ( 8.0)	25.8 ( 6.2)	24.5 ( 9.2)	Older Americans <sup>b</sup>	39	24.2
Physical/urinary	83.2 (14.5)	87.1 ( 9.6)	83.0 (14.1)	86.2 ( 9.3)	Men with prostate	186	89.1
Social/role	83.2 (24.2)	90.0 (13.4)	82.3 (23.8)	84.9 (20.5)	cancer, 1-3 years	186	85.5
Cognition	79.4 (21.7)	83.3 (14.1)	73.9 (20.6)	77.1 (19.1)	post-radiotherapy <sup>c</sup>	186	87.5
Sexual	52.7 (37.9)	25.0 (32.5)	75.1 (31.1)	33.3 (34.3)		186	54.5
Threat	2.1 ( 1.0)	3.2 ( 1.0)	1.6 ( 0.8)	3.0 ( 1.1)	Men with prostate cancer <sup>d</sup>	30	2.6
Self-efficacy	4.2 ( 0.9)	3.8 ( 0.8)	4.2 ( 1.0)	4.0 ( 1.0)	-	-	-
Emotion-focused coping	9.2 ( 2.5)	8.7 ( 2.4)	9.1 ( 2.4)	8.6 ( 2.4)	University students <sup>e</sup>	117	9.9
Problem-focused coping	10.2 ( 3.5)	9.7 ( 3.2)	8.7 ( 2.9)	9.5 ( 3.0)		117	10.8

<sup>a</sup> [Lovibond and Lovibond, 1995]

<sup>b</sup> [Pavot and Diener, 1993]

<sup>c</sup> [Borghede and Sullivan, 1996]

<sup>d</sup> [Bjorck *et al.*, 1999]

<sup>e</sup> [Carver *et al.*, 1989]

Table 2.

Frequency of Individuals Reporting Clinically Significant Changes in HRQoL as Measured by the Reliable Change Index

Group	Worse HRQoL		Improved HRQoL	
	1 or more measures <u>n</u>	2 or more measures <u>n</u>	1 or more measures <u>n</u>	2 or more measures <u>n</u>
Leuprorelin	6	3	4	2
Goserelin	8	5	5	3
Cyproterone	6	3	2	1
Monitoring	3	0	1	1
Community	6	1	2	0



Table 3.

Correlations Between Stress and Coping Predictors and Criterion HRQoL Variables in Men With Prostate Cancer

T1 Predictors	HRQoL Variables											
	DASS		SLS		PHYS/UR		SOC/ROLE		COG		SEXUAL	
	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
Illcurrent	.32**	.35**	-.26*	-.18	-.35**	-.27*	-.36**	-.23*	-.12	-.07	.07	.08
Illpast	.23*	.36**	-.19	-.20	-.34**	-.42**	-.32**	-.29**	-.15	-.20	.16	.14
Neurological history	.13	.35**	-.09	-.13	-.22	-.40**	-.16	-.30**	-.22	-.34	.05	.05
Threat appraisal	.67**	.52**	-.38**	-.33**	-.50**	-.38**	-.56**	-.53**	-.33**	-.36**	.14	.26*
Self-efficacy	-.01	-.11	-.04	-.03	-.09	.05	-.21	-.00	.06	.10	.04	.05
Emotion-focused coping	.48**	.43**	-.22	-.20	-.22	-.38**	-.27*	-.48**	-.17	-.38**	.27*	.19
Problem-focused coping	.48**	.37**	-.23*	-.23*	-.21	-.31**	-.28*	-.42**	-.08	-.31**	.09	.19

Note. T1 = Time 1; T2 = Time 2; DASS = Depression, Anxiety and Stress Scales; SLS = Satisfaction With Life Scale; Phys/Ur = Physical and Urinary Function; Soc/Role = Social and Role Function; Cog = Subjective Cognitive Function; Sexual = Sexual Function. Better HRQoL corresponded to higher scores on SLS, Phys/Ur, Soc/Role and Cognition, but lower scores on DASS and Sexual Function.

\* $p < .05$     \*\* $p < .01$

Table 4.

Hierarchical Regression Analysis of the Effects of Stress and Coping Predictors on Time 1 HRQoL

T1 Predictor	DASS		SLS		PHYS/UR		SOC/ROLE		COG		SEXUAL	
	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$
Medical	.10**		na		.12**		.13***		na		na	
Illcurrent		.19*		na		-.25*		-.26**		na		na
Appraisal	.37***		.15**		.20***		.31***		.11*		.02	
Threat		.49***		-.36		-.43***		-.49***		-.35**		.10
Self-efficacy		.02		-.06		-.16		-.28**		.03		.04
Coping	.07**		.00		.00		.00		.02		.08*	
Emotion-focused		.10		-.06		-.07		-.08		-.19		.41*
Problem-focused		.21		-.02		.05		.03		.22		-.26
Total R <sup>2</sup>	.54		.16		.32		.44		.14		.10	
Total F	(5, 71) = 16.31***		(4, 72) = 3.34*		(5, 71) = 6.64***		(5, 71) = 11.14***		(4, 72) = 2.81*		(4, 72) = 2.02	

\* $p < .05$     \*\* $p < .01$     \*\*\* $p < .001$

Note. T1 = Time 1; DASS = Depression, Anxiety and Stress Scales; SLS = Satisfaction With Life Scale; Phys/Ur = Physical and Urinary Function; Soc/Role = Social and Role Function; Cog = Subjective Cognitive Function; Sexual = Sexual Function; na = not applicable

Table 5.

Hierarchical Regression Analysis of the Effects of Stress and Coping Predictors on Time 2 HRQoL

Predictor	DASS		SLS		PHYS/UR		SOC/ROLE		COG		SEXUAL	
	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$	$\Delta R^2$	$\beta$
Time 1 HRQoL	.40***	.43**	.35***	.54***	.57***	.68***	.28***	.31*	.43***	.62***	.44***	.65***
Active/monitoring											.07**	-.25**
Medical	.09**				.08**		.06					
Illcurrent		.14				-.02		-.04				
Neurological		.29**				-.24**		-.24*				
Appraisal	.01		.01		.00		.07*		.02		.04	
Threat		.12		-.09		.09		-.18		.06		.15
Self-efficacy		-.01		-.02		.08		.01		.12		.06
Coping	.03		.00		.06**		.09*		.10**		.03	
Emotion-focused		.25		.01		-.23*		-.31*		-.14		-.24
Problem-focused		-.13		-.07		-.05		-.01		-.24		.26
Total R <sup>2</sup>	.53		.36		.71		.49		.54		.58	
Total F	(7, 57) = 9.29***		(5, 59) = 6.61***		(7, 57) = 19.52***		(7, 57) = 7.70***		(5, 59) = 14.05***		(6, 58) = 13.15***	

\* $p < .05$  \*\* $p < .01$  \*\*\* $p < .001$ Note. T1 = Time 1; DASS = Depression, Anxiety and Stress Scales; SLS = Satisfaction With Life Scale; Phys/Ur = Physical and Urinary

Function; Soc/Role = Social and Role Function; Cog = Subjective Cognitive Function; Sexual = Sexual Function

Figure Caption

Figure 1. Group x Time interaction for self-reported sexual dysfunction. The range of possible scores is 0-100, with 100 representing maximum dysfunction. Solid symbols represent groups of men with prostate cancer who were randomly assigned to treatments. Open squares represent male community volunteers matched for age and general health.

### Acknowledgements

This research was financed by Queensland Cancer Fund. Special thanks are due to Mrs V Allen and Mrs B Scells for coordinating recruitment, collating medical data, and providing exemplary contact and support for participants. Drs J Yaxley, D Nicol, P Mactaggart and R Watson assisted with preliminary conceptualization and recruiting and treating participants. Dr C Swanson's helpful suggestions for statistical analysis are acknowledged. We are indebted to the following colleagues who referred their patients to the study: Drs R Cheuck, A Clarke, N Dungleison, T Farrell, I Franklin, A Gallagher, J Greenland, P Heathcote, G Holmes, J Josey, S McClintock, J Munns, J Phillips, T Shar, P Swindle, G Wood. A related study submitted for publication has similar text describing methods and results of preliminary analyses.

