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Long-term quality of life after radical prostatectomy in wives of men in the postoperative adjuvant androgen deprivation trial

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Abstract

Purpose—We examined quality of life in spouses of men in the Post-Adjuvant Androgen Deprivation trial after radical prostatectomy.

Methods—Men at high risk of prostate cancer recurrence were randomized to receive androgen deprivation therapy or observation. Forty-three couples completed telephone interviews every 6 months for 2 years assessing women's mood disturbance, mental and physical health, and sexual function and bother as well as men's symptoms and sociodemographic and marital variables. We used linear mixed modeling to explore relationships between wives' quality of life and time, treatment group, and men's symptoms.

Results—Women's mental health functioning improved over time ($p<0.05$). Furthermore, women with husbands in the observation group had worse mood disturbance ($p=0.01$) and poorer mental health ($p=0.02$) than women with husbands in treatment. Men's symptoms were associated with worse physical health in wives ($p=0.02$). Women also reported worse sexual function at 18 and 24 months compared with baseline ($p=0.02$), but ratings of sexual bother were unrelated to time, treatment, and symptoms.

Conclusions—These exploratory results are consistent with research demonstrating that spousal cancer-related distress decreases over time. Treatment group differences suggest that an examination of caregiving in the context of uncertainty is warranted. Also, the physical burden of

caregiving may intensify when men have more symptoms. To inform interventions, future studies should clarify how treatment and symptoms influence wives' distress by examining expectations and communication.

Keywords

Prostate cancer; Quality of life; Partners; Symptoms

Prostate cancer is the most common non-skin cancer in men in the USA; 192,280 new prostate cancer cases were estimated for 2009 [1]. A variety of treatment options with diverse side effects are available depending on stage at diagnosis and other clinical factors [2]. Men with locally advanced disease at high risk for recurrence after radical prostatectomy may face significant challenges from side effects associated with recovery from surgery [3] and the uncertain prognosis [4]. Men may undergo androgen deprivation therapy to lower levels of hormones thought to stimulate prostate cancer growth or instead may undergo careful monitoring without treatment. Prostatectomy patients commonly experience urinary incontinence and impotence during recovery [2, 3]. Men who have androgen deprivation therapy experience fatigue, hot flashes, and sexual side effects [5]. Treatment for men at high risk of recurrence remains controversial so trials are underway comparing survival and quality of life (e.g., [6]) for different treatments.

In addition to considering the clinical course of men at high risk of recurrence, it is important to consider quality of life. Regardless of treatment modality, men with prostate cancer report illness effects on their quality of life [7]; these effects vary by clinical and symptom experiences. For example, men reporting worse urinary and sexual function also report worse cancer-specific quality of life and bother [8], and men with advanced disease report worse health-related quality of life than men with localized disease [7]. A growing number of studies have acknowledged the importance of considering the perspectives of patients' spouses (e.g., [9]). This research has shown that spouses tend to experience similar or worse distress than patients [9], distress in couples tends to decrease in the year after diagnosis (e.g., [10]), and this distress may vary depending on the illness phase [11]. Less, however, is known about the influence of treatment and symptoms on spousal quality of life. To facilitate adaptive coping in couples, more research is needed to understand the mechanisms underlying spousal distress. For example, because treatment side effects can have a significant impact on couples [12] and because there is some evidence that partners may rate prostate cancer symptoms worse than patients (e.g., [9, 13, 14]), a better understanding about how men's symptoms affect spouses may highlight coping intervention strategies.

To gain insight into some of the factors influencing quality of life in wives of men with prostate cancer, we explored wives' quality of life over 2 years after their husbands' radical prostatectomy. We used data from a clinical trial in which men who were at high risk of recurrence were randomized to receive 12 months of androgen deprivation or observation. The aim of the current study was to examine relationships between wives' quality of life (mood disturbance, mental and physical health, sexual function, and sexual bother) and time (baseline and 6, 12, 18, and 24 months), treatment group (androgen deprivation and observation), and men's symptoms. We hypothesized that women's quality of life would improve over time and vary by treatment group and men's symptoms.

Methods

Sample and procedures

After completing radical retropubic prostatectomy at MD Anderson Cancer Center, men at high risk for recurrence were invited to participate in the Postoperative Adjuvant Androgen Deprivation Trial testing 5-year clinical outcomes in men receiving 1 year of androgen deprivation versus observation [6]. Married men in this trial and their spouses were invited to enroll in a companion study to examine quality of life. This study was approved by the Institutional Review Board of MD Anderson.

Trial participants were at high risk for cancer recurrence based on tumor stage, Gleason score, and surgical margin status [6]. This risk was consistent with a projected 5-year disease free survival rate of approximately 65% or less [15–17]. Men signed informed consent forms and enrolled into the trial within 90 days of surgery; if spouses were present at the clinic, they were also recruited and signed consent forms then. Women who were not present were contacted by telephone. As illustrated in Fig. 1, the majority of the 57 men in the parent trial (95%) were married and potentially eligible for the current study. Forty-three of these wives enrolled, and 11 either directly declined the study or were not reached.

Separate telephone interviews were conducted with partners at baseline and 6, 12, 18, and 24 months. We used telephone interviews to facilitate improved response rates and timely survey completion. Multiple calls were attempted at each timepoint, and interviews were conducted by a trained research assistant and lasted approximately 30 min. The majority of wives in the current sub-study ($n=33$, 77%) completed baseline surveys on the same day as or before their husband completed his survey prior to study randomization to treatment arm. The remaining women ($n=10$) completed baseline surveys between 1 and 23 days after their husbands ($M=7.6$ days).

The majority of participants in this sub-study were White (88% men, 90% women), the average age was 60 ($M=58$, $SD=7.6$ women, $M=61$, $SD=6.8$ men), and the majority of participants had completed at least some college (45% women and 28% men) or more education (28% women and 47% men). Women's husbands were randomized to the observation (56%) and androgen deprivation (44%) groups. Additional details about men's clinical status and quality of life are published elsewhere [6].

Measures

Our main outcome variables included women's mood disturbance, mental and physical health, and sexual function and bother. Our independent variables included time (baseline versus 6, 12, 18, and 24 months), treatment group (androgen deprivation versus observation), and men's symptoms. We also assessed women's sociodemographic variables and men's sexual function and bother.

Mood disturbance—The Profile of Mood States instrument [18] was used to examine mood disturbance in wives. This instrument has been widely used to study psychological aspects of cancer. Respondents rated 65 feelings they experienced (0=not at all to 4=extremely) during the past week. The six subscales (anger/hostility, confusion, depression/dejection, fatigue, tension/anxiety, and vigor) were combined for a total mood disturbance score at each timepoint; higher scores reflected worse mood disturbance ($\alpha=0.94$ in wives at baseline).

Mental and physical health—The SF-36 instrument [19] assesses eight health concepts (36 items) in wives at each timepoint: (1) limitations in physical activities, (2) physical

health role limitations, (3) bodily pain, (4) general health, (5) social limitations because of physical/emotional problems, (6) general mental health, (7) emotional health role limitations, and (8) vitality. The first four subscales comprise a mental health composite score, and the last four subscales comprise a physical health composite score [20]; higher scores reflected better mental ($\alpha=0.81$) and physical ($\alpha=0.80$) functioning. This instrument has been widely used in diverse populations with sound psychometric properties [21].

Sexual function and bother—The Sexual Function subscale of the University of California Los Angeles Prostate Cancer Index [22] was used to assess men's sexual function (eight items) and the degree to which their sexual function was a problem (one item; 1=no problem to 5=big problem) at each timepoint. Two single items from this instrument were used to assess women's sexual function and bother over the past 4 weeks at each timepoint; higher scores reflected better sexual function and worse bother, respectively.

Men's symptoms—The Southwest Oncology Group's Treatment-Specific Symptoms Scale [23] was used to assess urinary (three items), bowel (four items), and other (one item each for hot flashes, breast tenderness, and breast swelling/enlargement) symptoms experienced by men in the past week. Responses ranged from seldom (e.g., "I seldom if ever have crampy abdominal pain") to frequent (e.g., "I have crampy, abdominal pain several times a day"). We did not include those who had an indwelling catheter or colostomy for urinary and bowel items. We calculated a count of the number of concurrent symptoms experienced (*seldom, if ever* versus all other responses for bowel, hot flashes and gas pain symptoms, and *none* versus *any* for urine, breast tenderness/swelling symptoms) at each timepoint.

Dyadic adjustment—Respondents completed 32 items concerning their dyadic satisfaction, cohesion, consensus, and affectional expression using the Dyadic Adjustment Scale [24]. A composite adjustment score with higher scores reflecting better relationships was calculated at each timepoint ($\alpha=0.93$ in wives at baseline).

Sociodemographic variables—Participants reported age, race, income, and education at baseline.

Analysis

All analyses were conducted in SAS version 9.1 using linear mixed modeling. We chose this technique because it uses random effects to model the shared variability across timepoints and accounts for between and within person variability. In addition, this technique allowed us to use all participants' data even when some timepoints were missing [25, 26]. First, to describe men's symptom experiences by treatment group, we modeled time, treatment group, and a time-by-treatment group interaction as fixed effects and included a random intercept in the model to account for within-subject correlations. Next, we explored relationships between women's quality of life (i.e., mood disturbance, mental and physical health, and sexual function and bother) and time, treatment group, and men's symptoms. In these analyses, we modeled time, treatment group, men's symptoms, and a time-by-treatment group interaction as fixed effects. We included men's sexual function and bother in each model along with sociodemographic covariates that were associated with each outcome using Pearson correlations and ANOVA ($p<0.1$). Because this was a pilot study to generate hypotheses for future studies, we considered $p<0.05$ as evidence for significant factors in our models without correcting for multiple comparisons. Also, when we identified a significant time-by-treatment group interaction, we performed contrasts at each of the individual timepoints to test if the treatment group differences at each timepoint were significant, without adjusting for multiple comparisons.

Results

Descriptive statistics

In our analyses to identify covariates for inclusion in models, women's mood disturbance was associated with dyadic adjustment ($r=-0.49$, $p=0.001$) and education level ($F=2.6$, $p=0.07$). Women's mental health functioning was also associated with dyadic adjustment ($r=0.35$, $p=0.02$) and education level ($F=2.2$, $p=0.10$), and women's physical health functioning was associated with age ($r=-0.27$, $p=0.10$). Also, women's sexual function was associated with dyadic adjustment ($r=0.26$, $p=0.10$) and income level ($F=2.9$, $p=0.02$), and women's sexual bother was associated with dyadic adjustment ($r=0.44$, $p=0.003$), employment status ($F=3.2$, $p=0.02$), and race ($F=4.0$, $p=0.05$).

Men's symptoms

We found a significant main effect for treatment group ($\beta = -1.3$, $p=0.002$) and time ($p=0.009$) on men's symptoms (Fig. 2). Men in the observation group reported fewer symptoms than men in treatment. In addition, men in the full study sample experienced more symptoms at 6 ($\beta = 0.75$, $p=0.003$), 12 ($\beta = 0.52$, $p=0.04$), and 18 months ($\beta = 0.51$, $p=0.04$) when compared with baseline. Furthermore, we found a significant time-by-treatment-group interaction ($p=0.02$); as shown in Fig. 2, the average number of symptoms in the observation group remained relatively consistent during the study, while symptoms in the treatment group increased during the first 6 months and then slowly decreased during the next 18 months. Contrasts at each timepoint identified significant differences in groups at 6 ($p<0.001$), 12 ($p=0.002$), and 18 months ($p=0.007$).

Women's quality of life

We found a significant main effect for treatment group on women's mood disturbance ($\beta = 11.4$, $p=0.01$) controlling for dyadic adjustment ($p<0.0001$), education level ($p=0.0005$), and men's sexual function (not significant, ns) and bother (ns) (Fig. 3a). On average, women with husbands in the observation group experienced worse mood disturbance during the study when compared with women with husbands in treatment. Time, men's symptoms, and the time by treatment group interaction were not significant in this model.

We found a significant main effect for time ($p=0.02$) and treatment group ($\beta = -4.4$, $p=0.02$) on women's mental health functioning controlling for dyadic adjustment ($p=0.0002$), education level ($p=0.01$), and men's sexual function (ns) and bother (ns) (Fig. 3b). In the overall study sample, women's mental health functioning was better at 6 ($\beta = 4.45$, $p=0.004$), 12 ($\beta = 4.77$, $p=0.003$), and 24 months ($\beta = 3.98$, $p=0.03$) when compared with baseline. Also, women with husbands in the observation group had worse mental health functioning during the study than women with husbands in treatment. Men's symptoms and the time by treatment group interaction were not significant.

We found no significant main effects for time, treatment group, or the time by treatment group interaction on women's physical health functioning (Fig. 3c). We did find a significant main effect for men's symptoms on women's physical health functioning ($\beta = -0.93$, $p=0.02$), controlling for women's age ($p=0.02$), and men's sexual function (ns) and bother (ns). Wives whose husbands were experiencing more symptoms reported worse physical health.

We found a significant main effect for time on women's sexual function ($p=0.02$), controlling for dyadic adjustment ($p=0.03$), income level ($p=0.04$), and men's sexual function ($p=0.03$) and bother (ns) (Fig. 3d). Women in the full study sample reported significantly worse sexual function at 18 ($\beta = -13.0$, $p=0.02$) and 24 months ($\beta = -12.9$,

$p=0.02$) when compared with baseline. We also found a significant time-by-treatment group interaction in this model ($p=0.02$). For women with husbands in treatment, sexual functioning worsened in the first 6 months after surgery, improved by the first year, and then declined over the second year. For women with husbands in the observation group, sexual functioning declined between 12 and 18 months but recovered to near baseline levels by 24 months. None of the contrasts at the individual timepoints were statistically significant, but the largest contrast occurred at 24 months and was borderline ($p=0.053$). As shown in Fig. 3d, although the 24-month timepoint nears significance, the confidence intervals are overlapping. This is not inconsistent with the p value because for point-to-point comparisons of this type, the standard “non-overlapping confidence interval” rule is more conservative than standard statistical hypotheses tests at the $\alpha=0.05$ level, and confidence intervals that have less than 50% overlap can be associated with significant differences [27–31].

We found no significant main effects for time, treatment group, men’s symptoms, or the time-by-treatment group interaction on women’s ratings of sexual bother, controlling for dyadic adjustment ($p=0.0006$), employment status (ns), race (ns), and men’s sexual function (ns) and bother (ns) (Fig. 3e).

Discussion

It is critical to understand interpersonal cancer experiences as the number of cancer survivors rapidly increases [32] and families face complex treatment decisions and side effects. We examined quality of life in women whose husbands were at high risk of prostate cancer recurrence. These women may be at especially high risk for poor outcomes because they are caregiving in the context of an uncertain prognosis, which can be associated with poor outcomes (e.g., [33]). Previous research has shown that spouses reported more uncertainty than prostate cancer patients especially when men were at high risk of recurrence [11]. Consistent with prior research examining couples coping with prostate cancer [10–12], in this study, women’s mental health improved over time after men’s surgery despite men’s high recurrence risk.

To provide a context for what patients were experiencing, we examined men’s symptoms during the trial. Consistent with clinical expectations concerning recovery from surgery and androgen deprivation therapy, the total number of men’s symptoms was higher in the treatment group at 6, 12, and 18 months compared with the observation group. However, contrary to our expectations and previous studies (e.g., [34, 35]), women whose husbands were experiencing more symptoms did not have worse distress. Instead, wives of men in the observation group had worse mood disturbance and mental health functioning. These exploratory findings may highlight challenges related to watchful waiting for men’s caregivers; beyond the uncertainty of waiting [33], women may feel less helpless when their husbands are actively engaging in treatment. In addition, these concerns could be exacerbated when one’s spouse is randomized to the control arm of a clinical trial. Whether similar group differences would be observed outside of a trial is unknown.

In contrast to our pilot findings, other studies have found relationships between men’s symptoms and spouse’s well-being. However, these studies have varied in the measurement of symptoms and outcomes. For example, Siegal and colleagues [36] found that the number of patients’ symptoms was associated with objective and subjective caregiver burden (e.g., time spent and consequences of caregiving, respectively). While we assessed symptoms in a similar fashion, these authors assessed the impact of symptoms on specific aspects of caregiving rather than on more global measures of functioning such as women’s disturbance and mental health. In addition, Kornblith and colleagues [34] found that when men reported more problems with urinary frequency and fatigue (i.e., more direct measures of symptom

impact), their wives reported worse quality of life. Furthermore, in our study, we asked men to report their symptoms directly and therefore cannot make conclusions about women's perspectives concerning their husbands' symptoms. Perhaps patients' symptom-related distress is important to caregivers' well-being rather than the symptoms directly. For example, Sanda and colleagues [13] reported that changes in patient cancer-specific quality of life over 1 year (e.g., extent to which urinary symptoms were problematic) was associated with spousal distress.

Consistent with the caregiving literature in which the act of caregiving can entail a physical cost (e.g., [37]), we found that the number of men's symptoms was associated with worse physical functioning in women. The physical burden of caregiving may be increased for spouses when patients experience multiple symptoms due to disruptions in daily activities or shifts in responsibilities.

We found that women's sexual function ratings worsened during the study. Although it is not possible to determine whether this decline was associated with illness-specific concerns, we found that husband and wife reports of sexual function were associated. Despite the decline in wives' sexual function, women's ratings of sexual bother did not vary by time or treatment group in this study. Partners' sexual functioning has rarely been examined in detail in the context of prostate cancer. Previous studies have shown that women's satisfaction with their sexual relationship is positively associated with quality of life [38] and that partners rate patients' sexual function worse than patients themselves [39]. Our exploratory findings highlight that both partners' perceptions about sexual functioning during treatment may be important.

Our study results must be interpreted with caution because the study was small in scope and sample size and included a homogeneous sample of mostly White, well-educated couples. Because our goal was to generate future hypotheses, we did not control for the multiple comparisons we conducted. In addition, we were limited in our measurement of wives' sexual functioning and bother, using single items from an instrument that has been validated only in men. A further consideration for the interpretation of these results is that the women were not randomized to study arm. Some of the women completed baseline surveys after their husbands were randomized ($n=10$) and therefore likely knew which treatment plan their husband was following. Finally, despite the interdependent nature of spouses' illness-related emotions and behaviors [40], the analyses we conducted were not dyadic in nature.

Despite limitations, this study demonstrates the value of collecting quality of life data from spouses in the clinical trial setting and has several methodological strengths including our longitudinal design and use of validated questionnaires and mixed modeling. Future studies should build on these exploratory results to examine the mechanisms underlying distress in spouses of men who elect not to have treatment and strategies for alleviating that distress. For example, because patients report better outcomes when they understand what to expect during treatment [41], future research should examine the hypothesis that when wives understand their partners' care plans and know what to expect (e.g., symptoms and frequency of monitoring), they may also fare better. Likewise, future research should examine how men's symptoms affect wives' physical functioning to highlight ways to prepare women for caregiving. Future studies should explore couple's sexual functioning with more detailed instruments and consider women's perceptions about how their husbands' treatment and side effects influence their sexuality. The current research sets the stage for future studies to examine partner responses to prostate cancer together as a couple in larger, more diverse samples. Specifically, a direct consideration of each partner's uncertainty, self efficacy, and communication about cancer may highlight modifiable factors for intervention. Spouses with better self efficacy for caregiving have better psychological

outcomes [42] and communicating about cancer and its symptoms may alleviate caregiver distress [43, 44]. Understanding the impact of treatment on patient and partner quality of life can identify individuals at high-risk for poor outcomes and in need of psychoeducational interventions.

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Fig. 1.
Study enrollment and response rates

Fig. 2.
Men's symptoms over time by men's treatment group

Fig. 3. Women's quality of life over time by men's treatment group. All models controlled for the time×treatment group interaction term and men's sexual function and bother. **a** Controlling for dyadic adjustment and education; higher scores reflect worse mood disturbance. **b** Controlling for dyadic adjustment and education; higher scores reflect better mental health. **c** Controlling for age; higher scores reflect better physical health. **d** Controlling for dyadic adjustment and income; higher scores reflect better sexual functioning. **e** Controlling for dyadic adjustment, employment status, and race; higher scores reflect worse sexual bother