More than 229,900 men were diagnosed with prostate cancer in the United States during 2004 (American Cancer Society [ACS], 2004a). This makes prostate cancer the second leading cause of cancer death among men in the United States, accounting for 10% of male cancer-related deaths (ACS, 2004b). Treatments for localized prostate cancer range from watchful waiting to radical surgery, with each treatment option demonstrating a similar survival curve (Jemal et al., 2003). A 5-year relative survival rate of 100% can be expected for the 85% of prostate cancers diagnosed while still localized, with relative 10-year survival rates of 79% now being reported (ACS, 2004c).

Frequently, treatment options are presented to patients as equal. While the overall survival rate may not vary among treatments, research related to treatment side effects is beginning to demonstrate differences between treatments. The American Urological Association’s Practice Guidelines Committee has made quality of life (QoL) a research priority, recommending that it should be measured as an outcome in any study of prostate cancer (Schellhammer et al., 1997). Research that evaluates the side effects of each treatment has been performed, but few studies exist that evaluate the impact of these side effects on quality of life, from the patient’s perspective.

### Introduction

The concept of Quality of Life (QoL) is as important as cure for those undergoing treatment for prostate cancer.

### Purpose

The purpose of this longitudinal study was to allow men with localized prostate cancer who chose radiation therapy treatment to self-evaluate their QoL before and after treatment.

### Method

Using a longitudinal survey design, a convenience sample of 59 participants completed a QoL instrument before treatment and at 3, 6, and 12 months post-treatment.

### Results

Analysis revealed statistical significance within the physical, social well-being subscales of the instrument. Statistical significance was also obtained within the prostate cancer specific concerns subscale between pre-treatment and 3 months after treatment.

### Conclusion

External beam radiation therapy as treatment of localized prostate cancer affects QoL.

---

**Prostate cancer continues to affect an increasing number of men in the United States. When diagnosed, these men may not have access to information that differentiates the long-term outcomes of one method of treatment from another. This study evaluated the impact of external beam radiation on several domains of quality of life, including physical, social/family, emotional, and functional well-being domains.**

---

**Peggy Ward-Smith, PhD, RN, is an Associate Professor, School of Nursing, University of Missouri, Kansas City, MO.**

**Deborah Kapitan, BSN, RN, is a Master’s in Nursing Student, University of Missouri, Kansas City, MO.**

**Note:** Funding for this study was obtained through the University of Missouri – Kansas City Faculty Research Grants Program.
cal treatment (Masalinska et al., 2001; Talcott et al., 2003). The Prostate Cancer Outcomes Study (Hamilton et al., 2001) obtained longitudinal data from 497 Caucasian, Hispanic, and African-American men treated with external-beam radiotherapy. These participants were interviewed at 6, 12, and 24 months after treatment. Sexual functioning was the most adversely affected QoL domain, with problems continuing to increase between 12 and 24 months after completing treatment. Bowel function problems increased 6 months after treatment, with partial resolution observed 24 months after completing treatment. Despite these side effects, the participants were generally satisfied with their treatment.

Researchers in the Netherlands (van Andel, Visser, Hulshof, Horenblas, & Kurth, 2003) assessed baseline health-related QoL and psychosocial data prior to prostate cancer treatment. A comparison of data between those scheduled for radical prostatectomy and those scheduled for external radiation therapy was performed. These data revealed that those scheduled for radiation therapy reported worse physical, role, cognitive, and social function, more fatigue, more pain, and a lower overall urinary and bowel function. The knowledge that these domains are affected prior to treatment provides the basis for performing longitudinal studies, using each patient as his own control.

Research performed in France by Almeras, Zerbib, Eschwege, and Debre (2003) used the UCLA/RAND Cancer Prostate Index questionnaire to retrospectively allow 108 patients with localized prostate cancer, treated with external beam radiotherapy, to self-evaluate their QoL. When comparing these participants to a control group, the participants who underwent external beam radiotherapy demonstrated functional alterations and decreased tolerance to the impairments of sexual, gastrointestinal, and urinary factors. Thus, these researchers concluded that external beam radiotherapy alters QoL.

In a qualitative study, van Andel et al. (2004) compared the self-evaluated quality of life measurements between men undergoing radical prostatectomy and men receiving external radiation therapy. This longitudinal study allowed 138 men to self-evaluate their QoL before and 1 year after treatment. The results of this study indicate that those who received surgical treatment suffered more from incontinence than those who received radiation therapy.

While acknowledging that the physical effects of treatment may be most appropriately evaluated by health care professionals, QoL is a great concern to patients considering treatment options. In the absence of clinical trial data clearly demonstrating that a particular treatment is superior to another for localized prostate cancer, in terms of specific survival, patients may value QoL as much as quantity of life (Penson, Litwin, & Aaronson, 2003). QoL is personal and subjective, yet established instruments that are psychometrically sound and measure concerns specific to the prostate cancer individual exist. Only the individual undergoing the specific cancer treatment can determine how that treatment affected individual QoL. Differences between patient and physician assessment of QoL among those with prostate cancer have been documented (Litwin, Lubeck, Henning, & Carroll, 1998). The American Urological Association has developed practice guidelines that include QoL as a treatment outcome and as a research priority (Schellhammer et al., 1997). This information is important because individuals with newly diagnosed localized prostate cancer are assisted in making treatment choices. Thus, self-evaluation of QoL as an outcome measure, using standardized questionnaires specifically developed to capture QoL, is appropriate (Holmboe & Concato, 2000). Much of the current research has been performed outside of the United States and does not provide QoL self-assessment prior to and after treatment. No study was located that allowed patients with localized prostate cancer to self-evaluate their QoL prior to, and after receiving external radiotherapy.

The Functional Assessment of Cancer Therapy-Prostate (FACT-P) is a 39-item Likert scale instrument that measures QoL among those with prostate cancer (Esper et al., 1997). The instrument is divided into five sections: physical well-being, social/family well-being, emotional well-being, functional well-being, and prostate cancer specific concerns. Participants are directed to rate their responses to each of the 39 items reflecting on the previous 7 days. The scale has five possible responses:

- 0 corresponds to “not at all.”
- 1 corresponds to “a little bit.”
- 2 corresponds to “some-what.”
- 3 corresponds to “quite a bit.”
- 4 corresponds to “very much.”

The instrument has been validated by the authors, obtaining an internal consistency of the prostate’s specific concerns subscale of 0.65 to 0.69, with coefficients for the subscales and aggregate scores ranging from 0.61 to 0.90. Concurrent validity was confirmed by the instrument’s ability to discriminate patients by their disease stage, performance status, and baseline prostate-specific antigen (PSA) level. Sensitivity to change in performance status and PSA score over a 2-month period suggested that some subscales of the FACT-P are sensitive to meaningful clinical change (Esper et al., 1997).

The FACT-P has been used in a longitudinal study among men with localized prostate cancer treated with brachytherapy (Ward-Smith, Wittkopp, & Sheldon, 2004). Internal consistency of the FACT-P, measured by Cronbach’s alpha, from data obtained in this study, was 0.92.
Cronbach’s alpha values range from 0 to 1 and measure the reliability of the instrument to measure the concept under investigation (Polit & Beck, 2004). The higher the alpha score, the more reliable the instrument. Nunnally and Bernstein (1994) indicated that a score of 0.70 or above demonstrates acceptable reliability. A Cronbach’s alpha of 0.92 indicates that the FACT-P provides an excellent method for evaluating QoL among men with prostate cancer. The instrument detected changes within each dimension over time, with a statistically significant difference noted within the emotional well-being subscale between the pre-treatment and the 12-month post-treatment data collection interval. A statistically significant difference was also noted in the prostate cancer specific concerns subscale between the pre-treatment and the 3-month after-treatment interval (p<0.005).

Method

A longitudinal survey design with descriptive, correlational, and comparative elements was used in this study. The study population consisted of a convenience sample that was treated at one of three radiation therapy care facilities in a Midwestern urban city. A power analysis revealed 54 subjects were needed to attain a power of 80%. The criterion for rejection was set at 0.05 using a two-tailed test and assuming a moderate effect sized covariance (Cohen, 1977). Data were analyzed using repeated-measures analysis of variance (ANOVA) and multiple t-tests performed through the Least Significant Difference Post-Hoc Post Test. A total of 72 men were enrolled in the study to provide for a possible 15% attrition rate. Of these individuals, 59 agreed to participate with 10 individuals citing disinterest as a reason for non-participation. In addition, three participants were lost to followup, and their incomplete data were eliminated prior to analysis. Missing data accounted for less than 1% of all data. Where necessary, Tabachnick and Fidell’s (1988) regression method was used to construct a regression equation that predicted the replacement value for all missing variables. This provided complete data sets without altering the means.

Data were collected from three different treatment centers, which used two different staging systems. To ensure that participants were homogeneous, inclusion criteria consisted of patients who were scheduled to undergo conventional radiation therapy as a treatment for localized prostate cancer. Localized prostate cancer is defined as cancer cells that are found only in the prostate gland (National Institutes of Health, 1987). Participation in this study was limited to individuals diagnosed with a cancer of stage B2 or less under the Jewett-Whitmore staging system (Kantoff, Carroll, & D’Amico, 2001). Using the tumor, node, metastases (TMN) system, study participation was limited to those diagnosed with a T2c lesion or less (Caudell, Castron, & Gallucci, 1996). Lesions at these stages are palpable yet intracapsular, approximately 1.5 cm in size, and may involve both lobes of the gland (Metlin, 1997). No race or age limitations were required for participation. The participants were able to read and understand English and were not suffering from any mental disorder that would make participation a hardship.

Instruments

Quality of life instrument. The Functional Assessment of Cancer Therapy-Prostate (www.facit.org/qview/alist.aspx) instrument is a 39-item Likert scale instrument which measures QoL among those with prostate cancer (Esper et al., 1997). The instrument is divided into five subscales, which assess physical, social/family, emotional and functional well-being, as well as prostate cancer specific concerns. This instrument was used in this study to allow for comparison between treatments from data of a previous study (Ward-Smith et al., 2004).

The instrument and demographic sheet may be completed in approximately 10 minutes and previous participants required no assistance in completing the instrument.

Each participant was asked to provide descriptive information which included age, ethnicity, marital status, current employment, mailing address, and income level at the time of completion of the first instrument (pre-treatment). These data were reported in aggregate form and used to describe the study population.

Procedure

Each participant who was recruited had selected conventional radiation therapy as treatment for localized prostate cancer. The patient care coordinator at each study site explained the nature and purpose of the study, obtained written consent, and provided the initial FACT-P, demographic data sheet, and a stamped self-addressed envelope. Each participant completed the forms and mailed them to the principal investigator. Health information was provided by each participant and the consent explained how confidentiality of this information was maintained in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All followup FACT-P instruments, with stamped self-addressed envelopes, were mailed by the principal investigator to each participant at 3, 6, and 12-month intervals after treatment was completed.

Findings

Demographic data. Study data were completed by 59 participants. The age of the participants in this study ranged from 49 to 82 years (mean 65.1 years). All of the participants were Caucasian. Of the participants, 75% were married, 17% were single, and 8% were divorced. The education level of these participants ranged from 12 to 20 years of schooling (mean 15.25 years). Work status at time of
diagnosis was self-disclosed as working at present (61%), with 22% stating they were not working at present and 17% reporting their work status as retired. Income for these participants ranged from less than $10,000 per year (18%) to greater than $90,000 (12%), with 51% of the participants reporting an income of less than $60,000 per year. The length of time between diagnosis and treatment initiation ranged from 1 to 21 weeks. No participant expired during the course of this study.

**Quality of life.** Internal consistency (Cronbach’s alpha) of the FACT-P score in this study ranged from 0.85 to 0.88, with a mean of 0.86. The total scores possible from the 39-item FACT-P range from 0 to 156. Mean pretreatment score on the FACT-P was 131.46 (range 99 to 153, SD 14.13). Evaluating these scores by frequency revealed that 25% of the scores (n=15) were in the 1st and 3rd quartile. These quartiles achieved scores between 99 and 113 or between 128 and 140. The 2nd quartile encompassed scores between 114 and 127 and were reported 22% of the time (n=13). The 4th quartile, or scores between 140 and 153, were reported 27% of the time (n=16). The distribution of scores remained evenly distributed and constant during data collection. Thus, these scores indicate that QoL was affected for each participant. The clinical implication from these scores is that a decrease in QoL can be expected and appears to be treatment, rather than co-morbidity, related. Table 1 describes the quartile distribution of the scores from each data-collection interval. Mean scores for each subscale of the FACT-P at each collection interval are given in Table 2.

The social/family well-being subscale consists of seven questions with a possible range of 0 to 28. One item on this scale (Q1) regarding sexual activity was optional for participants to answer. Five participants decided not to respond and mean scores were adjusted to reflect

---

**Table 1. FACT-P Quartile Scores of Participants Over Time**

<table>
<thead>
<tr>
<th></th>
<th>1st Quartile</th>
<th>2nd Quartile</th>
<th>3rd Quartile</th>
<th>4th Quartile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Treatment</td>
<td>15</td>
<td>13</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>3 Months</td>
<td>14</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>6 Months</td>
<td>15</td>
<td>14</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>12 Months</td>
<td>13</td>
<td>12</td>
<td>18</td>
<td>16</td>
</tr>
</tbody>
</table>

**Table 2. Mean Scores for Each Subscale of the FACT-P Over Time**

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Pre-Treatment</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Well-Being</td>
<td>26.1</td>
<td>24.8</td>
<td>24.1</td>
<td>24.6</td>
</tr>
<tr>
<td>Social Well-Being</td>
<td>24.3</td>
<td>22.0</td>
<td>21.5</td>
<td>21.9</td>
</tr>
<tr>
<td>Emotional Well-Being</td>
<td>20.4</td>
<td>20.2</td>
<td>20.8</td>
<td>20.6</td>
</tr>
<tr>
<td>Functional Well-Being</td>
<td>23.6</td>
<td>22.6</td>
<td>23.5</td>
<td>23.7</td>
</tr>
<tr>
<td>Prostate Concerns</td>
<td>37.0</td>
<td>33.6</td>
<td>35.1</td>
<td>36.5</td>
</tr>
<tr>
<td>Total FACT-P</td>
<td>26.3</td>
<td>24.6</td>
<td>25.0</td>
<td>25.4</td>
</tr>
</tbody>
</table>

**Figure 1. Mean Quality of Life Scores**
their decision. Graphic displays of the mean scores for each subscale over time are shown in Figure 1.

Repeated-measures analysis of variance (ANOVA) was performed to test differences among each group. Statistical differences were noted among the physical well-being subscale (0.002), the social well-being subscale (0.000), and the prostate concerns subscale (0.023). No statistical differences were determined from the data obtained within the emotional well-being subscale (0.655) and the functional well-being subscale (0.357). Thus, the hypothesis that QoL changes with radiation therapy treatment is partially accepted. When partially accepting the hypothesis, the possibility that each group may differ is a reality. Multiple correlation analysis is helpful in determining both the overall significance and the significance of each subscale. When data are from more than two groups, an ANOVA does not provide information regarding which groups differ from each other. Pooling the estimate of variance through data modification, rather than using the variance common to each group under comparison, is appropriate. Multiple t-test, performed through the Least Significant Difference Post-Hoc Post Test, provides this information. The results from this analysis support the finding that the physical and social well-being subscales remain statistically different across time. Data obtained from the prostate cancer specific concerns subscale were statistically different only when comparing pre-treatment to the 3-month post-treatment measure. Data obtained during the 6 and 12 month post-treatment measure were not statistically significant. These data are located in Table 3.

Conclusions and Clinical Implications

The results of this study indicate that external beam radiation therapy, as a treatment for localized prostate cancer, affects QoL. Analysis of self-evaluation QoL data, provided by those undergoing treatment, indicate that physical and social well-being changes significantly after external beam radiation therapy. Changes within the physical well-being aspects of the FACT-P are noted 6 months after treatment and remain altered 1 year after completion of treatment. The changes with the social well-being assessment of QoL appear within 3 months after treatment is concluded and remains altered during the first year after treatment. Significant changes identified in the specific prostate concerns subscale include bowel, bladder, and sexual functioning. These functions are significantly worse 3 months after treatment is completed, but reverse themselves by 6 months after treatment is completed, becoming not statistically significant.

The outcome of this study is to provide research data which evaluates external beam radiation therapy treatment effects on QoL. Data were obtained from the men undergoing the treatment, in a longitudinal fashion, to determine if the changes remain over time. The results of this study indicate that external beam radiation therapy does affect the physical and social well-being as well as concerns specific to those with prostate cancer during the first year after treatment.

The physical and social well-being aspects of QoL remain affected 1 year after treatment. The relatively small sample size, lack of diversity in racial and ethnic backgrounds among the participants, and the collection of data within one city are recognized as limitations for the study findings. Certainly larger sample sizes, different study settings, and the collection of data over a longer period of time are warranted. It remains unknown if the changes noted within the physical and social well-being scales lose their significance beyond 1 year after treatment is completed.

In comparing the findings of this study to a previous study evaluating QoL among those with prostate cancer treated with brachytherapy, differences were found (Ward-Smith et al., 2004). Both studies used similar populations, with those treated with brachytherapy slightly older (mean 67.83 versus 65.1 years of age). When comparing quartile scores obtained on the FACT-P, no differences were noted between the two studies. Data from those

<table>
<thead>
<tr>
<th>Table 3. Post-Hoc Participant Scores Over Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dependent Variable</strong></td>
</tr>
<tr>
<td>Physical Well-Being</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Social Well-Being</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Emotional Well-Being</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Prostate Specific Concerns</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

* p<0.01
treated with brachytherapy were statistically significant within the emotional well-being subscale between the pre-treatment and the 12-month post-treatment scores. This finding was not replicated among those treated with external beam radiation therapy, for there were no statistical differences noted during any of the data collection intervals on this subscale.

Data from the present study revealed physical well-being changes that began 6 months after treatment and remained a concern 1 year after treatment was completed. Data from the present study also revealed social well-being concerns occur through all data collection intervals. These concerns were not uncovered from the data obtained from those undergoing brachytherapy as treatment for prostate cancer. The prostate cancer specific concerns subscale achieved statistical significance between the pre-treatment and the 3-month post-treatment scores within both populations. All differences were not significant by 12 months after treatment. Thus, it may be concluded that QoL is affected by either treatment, specifically in the area of specific concerns related to prostate cancer. Thus individuals treated with brachytherapy suffer emotional distress associated with their treatment choice, while social and physical well-being concerns affected the QoL among those treated with external beam radiation.

Understanding the QoL effects of treatment and being able to provide data to patients making treatment decisions is an important aspect of health care education. A diagnosis of localized prostate cancer carries a high likelihood of survival, with few research studies available that provide information regarding the quality of that survival. Patients are asking for, and need, QoL data that will assist them in making the appropriate treatment choice.

References