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Authors
Cooperberg, MR
Master, VA
Carroll, PR

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HEALTH RELATED QUALITY OF LIFE SIGNIFICANCE OF SINGLE PAD URINARY INCONTINENCE FOLLOWING RADICAL PROSTATECTOMY

MATTHEW R. COOPERBERG, VIRAJ A. MASTER AND PETER R. CARROLL*†

From the Department of Urology, Program in Urologic Oncology, Urologic Outcomes Research Group, University of California-San Francisco/Mt. Zion Comprehensive Cancer Center, University of California, San Francisco, California

ABSTRACT

Purpose: Continence outcomes after radical prostatectomy are frequently reported as the proportion of men using 1 urinary pad or less daily. We postulated that underappreciated health related quality of life (HRQOL) differences may exist between patients requiring 1 pad daily and those who do not require pads.

Materials and Methods: A total of 168 patients who underwent radical prostatectomy performed by a single surgeon in a 2-year period were surveyed at a mean of 75 ± 30 weeks postoperatively using the urinary function and bother scales of the University of California-Los Angeles Prostate Cancer Index (PCI), the American Urological Association symptom index and a question assessing satisfaction. To establish patient groups the levels of the PCI question assessing pad use were redefined to 0, 1, or 2 or greater pads daily. The remaining 4 urinary function questions were used to calculate the summary function score.

Results: Of the patients 146 (86.9%) reported no pad use and 20 (11.9%) used 1 pad daily. The mean function score ±SD was 81.7 ± 19.5 and 51.5 ± 26.5 for the no and 1 pad groups, respectively (p <0.0001). The mean bother score was 86.8 ± 18.8 and 54.2 ± 30.0 (p <0.0001).

There were sharp differences between the 2 groups for each of the individual PCI questions and for the satisfaction question but no differences in American Urological Association symptom index scores.

Conclusions: We noted significant differences in urinary HRQOL between patients who do not require urinary pads after surgery and those who use a single pad daily across several domains of urinary function and bother. We believe that these findings underscore the need for more comprehensive HRQOL assessment in urinary outcome assessment after prostatectomy.

KEY WORDS: prostate, prostatic neoplasms, prostatectomy urinary incontinence, quality of life

Anatomical radical prostatectomy (RP) is a safe and effective treatment for localized prostate cancer. Urinary incontinence is a well established potential side effect of this treatment, one which has been the subject of extensive study. Incontinence is a critical determinant of postoperative health related quality of life (HRQOL). Moreover, patients rate the possibility of incontinence as the greatest perceived drawback to surgical treatment for prostate cancer. Estimates of postoperative incontinence frequency vary dramatically, ranging from 2.5% to 87%, depending on a number of factors related to study design, including definition, assessment method, time since surgery, patient vs physician reporting and practice setting.

In published series some groups consider patients to be continent after RP if they report using urinary pads no more frequently than once daily, whereas others have used a stricter criterion of no pad use. A growing body of literature in the last several years has underscored the need for more comprehensive, patient centered assessment of HRQOL as it relates to continence after treatment for prostate cancer. To address this need Litwin et al developed the University of California-Los Angeles Prostate Cancer Index (PCI), a well validated, patient reported questionnaire designed to assess several domains of HRQOL after prostate cancer treatment. Two of these domains, urinary function and urinary bother, ask questions that assess the impact of incontinence on patient daily life. As such, they may better characterize patient feelings about continence status. We determined whether there is in fact an ascertainable difference in urinary HRQOL between patients who use a single pad daily and those who use no pads.

MATERIALS AND METHODS

All patients who underwent radical retropubic prostatectomy performed by a single surgeon (PRC) at our institution between 1999 and 2000 were contacted under supervision of the institutional review board in July 2001 at a mean ± SD of 75 ± 30 weeks postoperatively. Basic clinical data, including age, preoperative prostate specific antigen (PSA), Gleason score and nerve sparing techniques, were collected. These variables were compared between the 2 groups using the Student t or chi-square test as appropriate. In no cases were bladder neck sparing techniques applied. Patients were mailed a questionnaire that included the urinary function and bother subscales of the PCI, the American Urological Association Symptom Index (AUASI) and a single question asking patients to rate satisfaction with their continence status on a scale of 0—delighted to 6—terrible. AUASI survey results were also compared to preoperative scores collected routinely from all patients before surgery. Demographic and clinical data were compared between participating and nonparticipating patients to ascertain any potential response bias.

The urinary function subscale of the PCI comprises 5 questions assessing urinary control, frequency of urine leakage,
number of pads or diapers used daily, problems attributable to leakage and interference of leakage with sexual activity. The sexual bother subscale is measured with a single question. Each question is scored on a scale of 0 to 100 points with higher values representing better quality of life, that is a higher sexual function score indicates better function and a higher sexual bother score indicates less bother. The mean of individual question scores per subscale defines the summary score. The satisfaction question was likewise scored from 0 to 100.

For this study the PCI was modified slightly, such that the levels of the question assessing pad use were redefined from 0, 1 to 2, or 3 or greater pads/diapers daily to 0, 1, or 2 or greater pads (not diapers) daily. This question was used to categorize patients by pad use and the remaining 4 urinary function questions were used to calculate the urinary function summary score. This abbreviated 4 item instrument, which was scored on the same 0 to 100 scale as the full subscale, was re-validated by measuring Cronbach’s α.

Differences in scores among groups were tested with the Wilcoxon rank sum test. Correlation coefficients were calculated to assess agreement among select measures. All analyses were done using commercially available software.

RESULTS

A total of 168 patients completed the survey in its entirety for a 77% response rate. When comparing nonresponders to responders, few significant differences were found in demographic or clinical parameters. Nonresponding patients tended to be younger than responders (mean age 56.6 vs 60.6 years, \( p = 0.0002 \)) and underwent surgery earlier (97 vs 75 weeks of followup, \( p < 0.0001 \)). There were no significant differences in PSA (mean 7.3 vs 6.3 ng/ml, \( p = 0.3 \)), Gleason score (6.6 in each group, \( p = 0.63 \)) or preoperative AUASI (mean score 7.8 vs 7.0, \( p = 0.9 \) and QOL mean score 1.6 vs 1.7, \( p = 0.54 \)). Nonresponders were no more or less likely to have been treated with nerve sparing surgery than responders (\( p = 0.59 \)).

Of the patients completing the survey 146 reported no pad use and 20 reported using 1 pad daily. Two men who reported 2 or greater pads/diapers daily were not included in this analysis. Mean time since surgery was 60.4 ± 6.5 years in the no pad group and 61.5 ± 7.5 years in the 1 pad group. Mean PSA and Gleason score were 7.14 ± 6.17 ng/ml and 6.65 ± 0.74 in the no pad group, and 8.76 ± 4.20 ng/ml and 6.56 ± 0.62 in the 1 pad group, respectively. Mean time since surgery was 74 ± 30 and 81 ± 33 weeks in the no and 1 pad groups, respectively. Data on nerve sparing were available on 118 patients (71%). In the no pad group 71%, 16% and 13% of patients received bilateral, unilateral or no nerve sparing, respectively. In the 1 pad group the corresponding proportions were 70%, 20% and 10%, respectively. None of these differences was statistically significant. Among all patients time since surgery was 7.9 to 135.4 weeks. The abbreviated, 4 item urinary function score demonstrated excellent internal consistency in our data set with a Cronbach’s α of 0.86, comparable to the value of 0.87 originally reported for the urinary function domain of the PCI.9

The figure shows the range of summary urinary function and bother scores for the 2 patient groups. Mean urinary function and bother scores were 81.7 ± 19.5 (range 11 to 100) and 86.8 ± 18.8 (range 25 to 100) in the no pad group, and 51.5 ± 26.5 (range 15 to 100) and 54.2 ± 30.0 (range 0 to 100) in the 1 pad group (each score \( p < 0.0001 \)). The table lists individual question results. There were sharp differences between the 2 groups in each of the questions comprising the PCI subscales and in the assessment of satisfaction. There were no differences in AUASI scores preoperatively or postoperatively but there was a significantly greater decrease (ie improvement) in the AUASI quality of life score in patients reporting no pad use.

In response to the PCI question assessing urinary control no patient indicated a total lack of control. Of the 1 pad group 25% of patients reported frequent dribbling, 65% reported occasional dribbling and 10% reported total control. Of the no pad group 1% of patients reported frequent dribbling, 41% reported occasional dribbling and 58% reported total control. The difference among the groups was significant (Mantel-Haenszel chi-square test \( p < 0.0001 \)). As assessed by the PCI, urinary bother correlated well with satisfaction (\( r = 0.77, p < 0.0001 \)) as well as with HRQOL on the AUASI (\( r = 0.77, p < 0.0001 \)). As assessed by the AUASI, HRQOL also correlated well with satisfaction (\( r = 0.88, p < 0.0001 \)).

DISCUSSION

The natural history of localized prostate cancer is prolonged and many patients may live for years even without treatment.31 Therefore, it is essential, even more so than in other areas of oncology, that treatments aimed at prolonging life exert a minimal decremental impact on quality of life because any such negative impact may be experienced by patients for an extended time. More than other areas of HRQOL after prostate cancer treatment, incontinence is a concern particularly relevant to men undergoing RP because surgery more frequently negatively impacts continence than do other treatment modalities, and because patients rate urinary status as one of their greatest concerns regarding
HRQOL after treatment. Patients using pads or clamps to control incontinence after RP report significantly greater urinary bother and fewer would select surgery given the choice.

Recent studies show a significant discordance between HRQOL outcomes as assessed by physicians and as reported by patients. For example, a recent community based analysis found dramatically higher rates of urinary impairment, as indicated by responses on the PCI versus those determined by treating physicians. Indeed, the PCI was developed to address the need for HRQOL measurement based on patient perceptions and it has become the gold standard instrument for this purpose. More recently, studies have attempted to relate specific questions from the urinary domains of the PCI to ostensibly more objective measures of postoperative continence.

For example, the series of Kielb et al analyzing the early recovery of continence after radical prostatectomy used 3 measures of continence, including urinary control assessed by the same PCI question used in the current analysis, the number of pads used daily and urinary bother. They found that a standard of no or 1 pad daily as a measure of continence resulted in nearly twice the rate of continence recovery as a response of total control on the PCI control question. Although this abbreviated version had internal consistency comparable to that of the full measure, it has not been as extensively validated and may not be as accurate a reflection of HRQOL referable to urinary function.

**CONCLUSIONS**

Patients dependent on 1 pad daily for urinary control after radical prostatectomy experience a significant degree of HRQOL impairment relative to those using no pads. With ongoing refinements in the techniques of anatomical RP we should expect standards of excellence to continue to increase. Thus, single pad incontinence postoperatively can no longer be considered a result equivalent to true continence. However, we emphasize that no single question adequately assesses urinary HRQOL outcomes after treatment for prostate cancer. Instruments such as the PCI should likely be used routinely in clinical practice as well as in research series. Monitoring HRQOL outcomes more accurately and across multiple domains would facilitate treatment planning and better enable urologists to address patient concerns about quality of life as they weigh their options for treating localized prostate cancer.

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* PCI subscales:
  - Leak frequency
  - Urinary control
  - Drop/wet problems
  - Sexual interference
  - Urinary bother

<table>
<thead>
<tr>
<th>Questionnaire results in the 1 and no pad groups</th>
<th>Mean 1 Pad Group</th>
<th>Mean No Pad Group</th>
<th>Difference</th>
<th>p Value (Wilcoxon rank sum test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop symptom score</td>
<td>8.06 ± 5.33</td>
<td>7.77 ± 5.33</td>
<td>-0.29</td>
<td>0.4939</td>
</tr>
<tr>
<td>Postop symptom score</td>
<td>7.26 ± 5.60</td>
<td>5.86 ± 5.60</td>
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<tr>
<td>Symptom score change</td>
<td>-1.00 ± 7.23</td>
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<tr>
<td>AUASI†</td>
<td>1.06 ± 1.06</td>
<td>1.65 ± 1.06</td>
<td>0.69</td>
<td>0.1601</td>
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<tr>
<td>Postop</td>
<td>2.95 ± 2.96</td>
<td>1.01 ± 1.96</td>
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<td>&lt;.0001</td>
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<tr>
<td>Change</td>
<td>1.81 ± 2.10</td>
<td>-0.58 ± 2.10</td>
<td>-2.39</td>
<td>&lt;.0001</td>
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<tr>
<td>Satisfaction‡</td>
<td>50.9 ± 32.4</td>
<td>87.1 ± 14.2</td>
<td>36.2</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

* PCI scales are scored from 0 to 100 with higher scores indicating better function or less bother.
† AUASI is scored from 0 to 35 with higher scores indicating greater impairment.
‡ AUASI HRQOL measure is scored from 0 to 6 with higher scores indicating worse HRQOL.
§ The satisfaction question is scaled from 0 to 100 with higher scores indicating greater satisfaction.
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