
An Assessment of Quality of Life Following Radical Prostatectomy, High Dose External Beam Radiation Therapy and Brachytherapy Iodine Implantation as Monotherapies for Localized Prostate Cancer

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Purpose: Monotherapy with radical prostatectomy, high dose external beam radiotherapy or a ^{125}I implant is reported to produce equivalent outcomes. We assessed the health related quality of life associated with these 3 treatment approaches. **Materials and Methods:** Extended Prostate Index Composite surveys were mailed to all 960 patients treated with a ^{125}I implant, high dose external beam radiotherapy or radical prostatectomy with or without hormonal therapy at our institution from 1998 to 2000. A total of 625 patients (65%) completed the surveys. Nerve sparing radical prostatectomy was performed when appropriate. The ^{125}I implant consisted of 145 Gy and high dose external beam radiotherapy consisted of 78 Gy. For urinary, rectal and sexual domains mean scores were calculated, compared by treatment modality and compared to normative values.

Results: A total of 234 patients with radical prostatectomy, 135 with external beam radiotherapy and 74 with a ^{125}I implant were treated with a monotherapy approach. Median age was 61 years in the radical prostatectomy group, 68 years in the high dose external beam radiotherapy group and 64 years in the ^{125}I implant group ($p < 0.001$). Of the patients 97% or greater had cT1-2 disease and Gleason score 7 or greater. Median time from treatment was 4.0 years for radical prostatectomy, 4.7 years for high dose external beam radiotherapy and 3.5 years for ^{125}I implantation. Radiation caused significantly worse bowel bother and bowel function than radical prostatectomy ($p \leq 0.018$). Patients with high dose external beam radiotherapy had significantly better urinary function than patients with radical prostatectomy ($p < 0.001$). While patients with radical prostatectomy had significantly worse urinary incontinence than those with a ^{125}I implant or high dose external beam radiotherapy ($p < 0.0001$), patients with a ^{125}I implant had more urinary irritation than those with high dose external beam radiotherapy and radical prostatectomy ($p < 0.01$ and < 0.0001 , respectively). Patients with a ^{125}I implant had significantly better sexual function than those with high dose external beam radiotherapy and radical prostatectomy ($p = 0.01$ and 0.0003 , respectively).

Conclusions: Of patients with prostate cancer treated with a monotherapy approach we noted better urinary continence in those who underwent radiation based therapies, and better bowel function and less urinary irritation in those who underwent surgery. Sexual function was impaired across all monotherapies but higher scores were seen in men who selected brachytherapy.

Key Words: prostate, prostatic neoplasms, quality of life, prostatectomy, radiotherapy, brachytherapy

Surgery and radiation therapy have equivalent outcomes when used as treatment for prostate cancer.¹ Contemporary patients tend to place equal emphasis on the expected prostate cancer survival outcomes and post-treatment quality of life associated with each treatment modality.² Numerous groups have compared HRQOL outcomes after RP with those of conventional low dose external beam radiation therapy.²⁻⁵ Brachytherapy has reemerged

as a treatment option for appropriately selected patients due to long-term reports of efficacy with acceptable morbidity and the convenience of a 1-time outpatient procedure.¹ Reports comparing monotherapy treatment approaches (without neoadjuvant, concurrent or adjuvant hormone therapy and/or a combination of external beam radiation with a brachytherapy implant) using modern treatment techniques with validated QOL instruments are limited. Instruments such as the validated EPIC survey are used to evaluate HRQOL outcomes, such as urinary, bowel and sexual side effects, to help patients better understand what their HRQOL may be following treatment.⁶ We used the EPIC survey to evaluate posttreatment HRQOL and treatment related side effects in patients treated for localized prostate cancer with monotherapy with RP, HDXRT or a permanent brachytherapy IMP.

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Study received institutional review board approval.

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METHODS AND MATERIALS

Patient Selection

From 1998 to 2000, 160 IMP procedures, 400 HDXRT procedures and 400 RPs were performed at our institution as treatment for prostate cancer. Nerve sparing RP was performed in some cases at surgeon discretion. Patients treated with IMP received 145 Gy to the prostate with ¹²⁵I seeds using a modified peripheral loading technique via a transrectal ultrasound guided transperineal approach. HDXRT consisted of 78 Gy to the prostate with the dose prescribed to the isocenter using 3-dimensional conformal radiotherapy. Patients who received hormonal therapy as part of treatment were included in the protocol database. In this study patients who received any form of combination therapy and/or hormone therapy were excluded. Only patients treated with a monotherapy treatment approach were included in the analysis.

Measures for Evaluation

Under an institutional review board approved protocol 960 patients were mailed an EPIC survey to assess disease specific HRQOL in men treated for localized prostate cancer. In addition to its use in compiling HRQOL data, the survey was used to collect information about patient sociodemographic status and current medications, and any treatment for erectile dysfunction. Tumor stage and grade, initial prostate specific antigen, disease status, race, age, hormone therapy and comorbidities were obtained from the medical record and included in the study database.

Statistical Analysis

The standard EPIC scoring system was used to calculate a score for certain domains, including urinary function, urinary bother, urinary incontinence, urinary irritation, bowel function, bowel bother, sexual function and sexual bother. For each survey domain mean scores were calculated and compared by treatment modality and by EPIC normative mean values. An SAS® macro (<http://roadrunner.cancer.med.umich.edu/epic/>) was used to calculate these scores. For each domain ANOVA was used to compare mean scores among the treatment arms. For this analysis the Tukey LSD procedure was used to adjust for the 3 pairwise comparisons that were made. In addition, as a confirmatory analysis, ANOVA was used to compare mean scores among the 3 treatment arms after adjusting for age at diagnosis, Gleason

score and clinical stage. Mean scores were compared with normative controls using the t test. For this analysis the Bonferroni method was used to adjust for multiple comparisons. All statistical tests were performed 2-sided at an $\alpha = 0.05$ level. No adjustment was made for the fact that multiple domains were assessed in the study.

RESULTS

EPIC surveys were mailed to 960 patients who received definitive treatment for prostate cancer at our institution from 1998 and 2000. A total of 625 patients (65%) completed the surveys during the study course (2001 to 2004), including 254 who underwent HDRT, 261 who underwent RP and 108 who received an IMP. Returned surveys indicated that 71% of the patients were treated with a monotherapy approach and they represent the study group, including 234 (59%) with RP, 135 (34%) with HDRT and 74 (46%) with IMP. The remaining patients received a form of combination therapy consisting of the addition of hormone therapy or external beam radiotherapy and they were not included in our analysis. Patient numbers were adequate for appropriate statistical power.

Median patient age was 61 years in the RP group, 68 years in the HDXRT and 64 years in the IMP group ($p < 0.001$). Patients with RP were significantly younger than patients treated with radiotherapy. Patients treated with HDRT had the longest median time from treatment to survey compared with those treated with RP and IMP (4.7 vs 4.0 and 3.5 years, respectively). Most patients treated in this study had organ confined, clinical stage T1–2 disease, including 227 of 233 with RP (97.4%), 131 of 135 with HDRT (97.0%) and 74 of 74 (100%) with IMP. Of all patients treated with a monotherapy approach 97% had Gleason score 7 or less. The table lists EPIC survey results, including the mean, SD and 95% CI of the normative and monotherapy treatment modalities.

Urinary Function

Figure 1 shows a comparison of mean urinary function scores. Patients treated with HDRT had significantly better urinary function than those treated with RP ($p < 0.001$). There was no significant difference in urinary function between patients with IMP, and patients with RP and HDXRT ($p = 0.38$ and 0.09 , respectively). The normative group had

EPIC domain specific prostate cancer HRQOL scores

| HRQOL Domain | Mean ± SD IMP (95% CI) | Mean ± SD HDXRT (95% CI) | Mean ± SD RP (95% CI) | Mean ± SD Control (95% CI) ¹⁰ |
|--------------|---------------------------|-----------------------------|--------------------------|---|
| No. pts | 74 | 135 | 234 | 112 |
| Urinary: | | | | |
| Function | 85.8* ± 24.3 (80.1–91.4) | 90.1* ± 15.3 (87.5–92.7) | 83.7* ± 15.8 (81.7–85.7) | 95.5 ± 9.5 (93.7–97.3) |
| Bother | 78.0* ± 19.6 (73.5–82.6) | 80.4 ± 18.0 (77.4–83.5) | 83.2 ± 16.1 (81.1–85.3) | 85.2 ± 14.1 (82.6–87.8) |
| Incontinence | 85.9 ± 23.0 (80.6–91.2) | 85.5* ± 18.9 (82.3–88.7) | 73.4* ± 25.1 (70.2–76.6) | 92.9 ± 14.6 (90.2–95.6) |
| Irritation | 79.6* ± 19.0 (75.2–84.0) | 85.2 ± 12.8 (83.0–87.4) | 89.9 ± 11.6 (88.4–91.4) | 88.2 ± 11.0 (86.2–90.2) |
| Bowel: | | | | |
| Function | 89.4 ± 11.5 (86.8–92.1) | 85.8* ± 14.2 (83.4–88.2) | 93.0 ± 9.0 (91.8–94.2) | 92.1 ± 8.5 (90.5–93.7) |
| Bother | 86.4* ± 16.8 (82.5–90.3) | 85.1* ± 19.8 (81.7–88.5) | 94.6 ± 10.4 (93.2–95.9) | 92.8 ± 11.1 (90.7–94.9) |
| Sexual: | | | | |
| Function | 37.8* ± 27.2 (31.5–44.1) | 28.0* ± 27.9 (23.3–32.8) | 25.1* ± 24.5 (21.9–28.2) | 55.8 ± 24.1 (51.3–60.3) |
| Bother | 49.4* ± 31.9 (42.0–56.8) | 50.2* ± 36.7 (43.9–56.4) | 44.7* ± 31.8 (40.6–48.8) | 74.3 ± 27.7 (69.2–79.4) |

Higher scores indicate more favorable HRQOL outcomes.
* Significantly different vs control ($p < 0.05$).

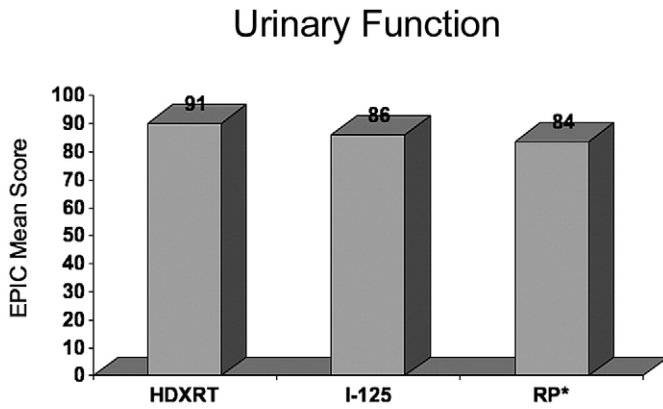


FIG. 1. HRQOL domain considered not clinically significant, that is less than 10 point difference among treatment subgroups. Asterisk indicates statistically worse HRQOL vs HDXRT. *I-125*, IMP.

significantly better urinary function than all patients treated with a monotherapy approach ($p < 0.005$).

Urinary Bother

There was no statistically significant difference in urinary bother among the 3 monotherapy approaches, although patients treated with RP trended toward less urinary bother than those treated with radiotherapy ($p = 0.058$). Compared to the normative group the IMP group had more urinary bother ($p < 0.01$).

Urinary Incontinence

RP treated patients had significantly worse urinary incontinence than IMP or HDRT treated patients ($p < 0.0001$, fig. 2). Compared to the normative group patients treated with RP and HDXRT had significantly worse urinary incontinence ($p < 0.001$).

Urinary Irritation

HDRT and IMP caused significantly more urinary irritation than RP ($p < 0.0001$, fig. 3). Patients with IMP had more urinary irritation than HDXRT treated patients ($p < 0.01$). Patients who underwent brachytherapy experienced significantly greater urinary irritation than those in the normative group ($p < 0.001$).

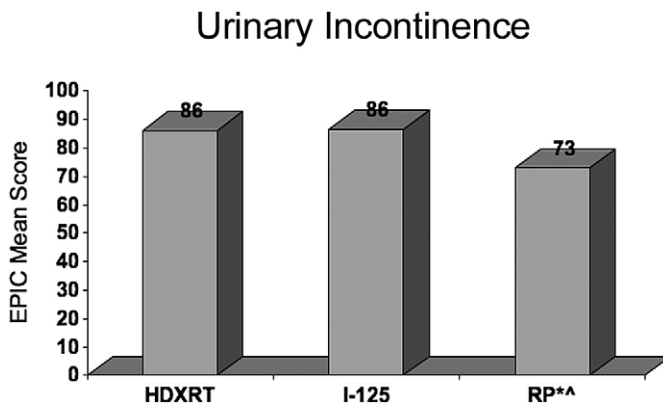


FIG. 2. HRQOL domain considered clinically significant, that is 10 point or greater difference among treatment subgroups. Asterisk indicates statistically worse HRQOL vs HDXRT. Caret indicates statistically worse HRQOL vs IMP (*I-125*).

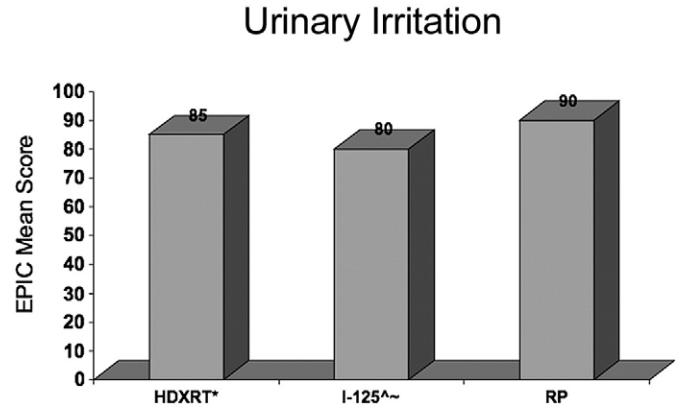


FIG. 3. HRQOL domain considered clinically significant, that is 10 point or greater difference among treatment subgroups. Asterisk indicates statistically worse HRQOL vs HDXRT. Caret indicates statistically worse HRQOL vs IMP (*I-125*). Tilde indicates statistically worse HRQOL vs HDXRT.

Bowel Function

Although all treatment modalities maintained relatively high bowel function, IMP and HDRT monotherapies caused significantly worse bowel function than RP ($p = 0.018$ and < 0.0001 , respectively, fig. 4). HDXRT caused worse bowel function than IMP ($p = 0.03$). Compared to the normative group patients who underwent HDXRT had significantly worse bowel function ($p < 0.001$).

Bowel Bother

IMP and HDRT monotherapies caused significantly more bowel bother than RP ($p < 0.0001$, fig. 5). Compared to the normative group patients who underwent radiotherapy had significantly worse bowel bother than patients treated with IMP and HDRT ($p < 0.005$ and < 0.001 , respectively).

Sexual Function

Patients treated with IMP had significantly better sexual function than patients treated with HDRT and RP ($p < 0.01$ and < 0.001 , respectively, fig. 6). However, the difference in sexual function in patients who underwent RP and in those who underwent HDRT was not statistically significant.

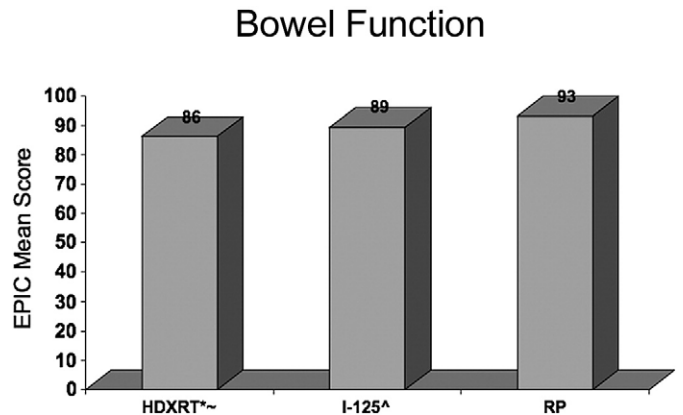


FIG. 4. HRQOL domain considered not clinically significant, that is less than 10 point difference among treatment subgroups. Asterisk indicates statistically worse HRQOL vs RP. Caret indicates statistically worse HRQOL vs RP. Tilde indicates statistically worse HRQOL vs HDXRT. *I-125*, IMP.

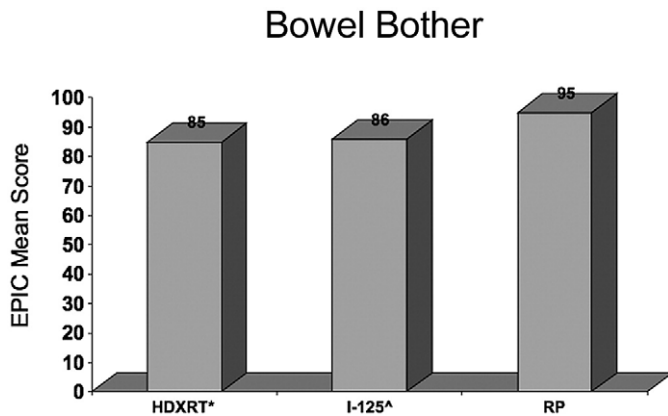


FIG. 5. HRQOL domain considered clinically significant, that is 10 point or greater difference among treatment subgroups. Asterisk indicates statistically worse HRQOL vs RP. Caret indicates statistically worse HRQOL vs HDXRT. *I-125*, IMP.

cant ($p = 0.3$). Compared to the normative group patients in all 3 monotherapy groups had significantly worse sexual function ($p < 0.0001$).

Sexual Bother

There was no statistically significant difference in sexual bother among the 3 monotherapy modalities ($p = 0.35$). However, compared to the normative group all 3 groups experienced significantly more sexual bother ($p < 0.0001$).

DISCUSSION

To our knowledge this study is the first to compare HRQOL following prostate cancer treatment with modern monotherapy approaches with RP, HDRT and IMP. In this study patients treated with radiotherapy for localized prostate cancer had better urinary function and less urinary incontinence but more urinary irritation than patients treated with RP. RP treated patients had better bowel function and less bowel bother than those treated with radiotherapy. Finally, patients treated with ^{125}I had better sexual function than HDRT or RP treated patients. The results of our study are consistent with the growing body of HRQOL literature on patients with prostate cancer.

In this study normative controls were defined by the authors of the EPIC survey and reported in the study by Wei et al.³ All monotherapy treatment modalities had worse urinary function, sexual function and sexual bother than controls. While patients with RP and HDXRT had worse urinary incontinence, patients with IMP had more urinary bother and irritation. Bowel bother was noted to be worse for the 2 radiation treatment modalities compared to the normative control but only HDXRT showed a decrease in bowel function.

Wei et al first reported a comprehensive comparison of HRQOL for patients treated for localized prostate cancer using EPIC.³ While that study showed no long-term difference in urinary incontinence between RP and brachytherapy treated patients, our study revealed worse urinary function, urinary incontinence and sexual function for RP compared to either radiation modality. Similar to the study by Wei et al, bowel function was better in patients with RP than in radiation treated patients, while patients with RP had less

urinary irritation than those with IMP. Interestingly our data indicated that sexual function was significantly better in patients with IMP than in patients with RP and HDXRT.

There were some important differences between the brachytherapy treated cohorts. 1) Of brachytherapy treated patients 51% received hormone therapy in the study by Wei et al.³ 2) The number of patients with brachytherapy who received a combination of external beam radiotherapy and brachytherapy is not specifically defined but approximately 32% of those with brachytherapy had Gleason score greater than 6, which at our institution would not have been treated with a monotherapy approach. 3) In our study all brachytherapy treated patients had a Gleason score of 6, which is consistent with our monotherapy treatment approach for patients with early stage localized disease. 4) Higher International Prostate Symptom Score, larger gland size, higher activity, and wider posterior and apical margins may be additional factors contributing to their worse outcomes.

Wei et al defined the clinical significance of the domain summary scores by comparing the EPIC bother subscales that measure impairment related to each prostate specific HRQOL.³ They concluded that brachytherapy was significantly bothersome for urinary, sexual and bowel bother domains. In contrast, our study did not show any significant differences with sexual or urinary bothersome effects for IMP. External beam radiation treated patients had significantly bothersome bowel and sexual effects, and patients with RP had significantly bothersome long-term sexual effects.

In a retrospective cross-sectional study Davis et al studied patients treated for localized prostate cancer with RP, a ^{103}Pd implant or external beam radiotherapy from 1995 to 1999 at Eastern Virginia Medical School.⁴ Urinary function was less in RP treated patients because of incontinence symptoms but ^{103}Pd treated patients who underwent treatment less than 1 year from the study reported higher American Urological Association symptom scores. All groups showed decreased sexual function compared to controls with the RP group showing a significantly greater decrease than the ^{103}Pd and radiotherapy groups.

In a study by Downs et al the validated RAND 36-Item Health Survey and UCLA-PCI were used to measure HRQOL in patients from the CaPSURE™ database who

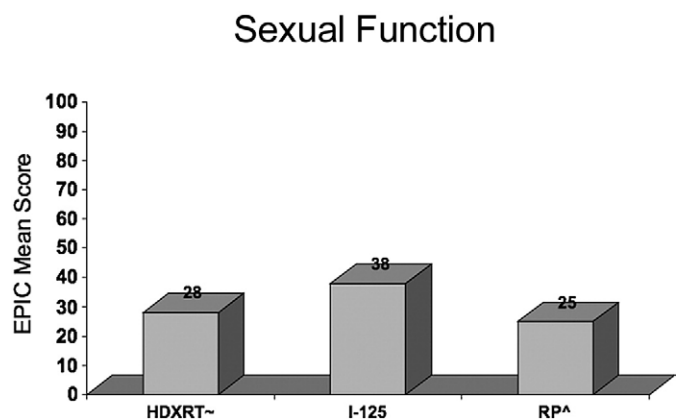


FIG. 6. HRQOL domain considered clinically significant, that is 10 point or greater difference among treatment subgroups. Caret indicates statistically worse HRQOL vs RP. Tilde indicates statistically worse HRQOL vs HDXRT. *I-125*, IMP.

underwent brachytherapy monotherapy and RP.⁷ They concluded that general HRQOL and urinary bother did not differ between the groups in the first 6 months following treatment but urinary function was worse in RP treated patients. Miller et al prospectively reevaluated a cohort of 709 survivors of prostate cancer 4 to 8 years after primary treatment with RP, radiotherapy or brachytherapy.⁸ They concluded that urinary irritative-obstructive and bowel QOL assessments improved in brachytherapy treated patients. However, in the 4-year interval after HRQOL assessment a subsequent study revealed that urinary incontinence appeared to worsen in the brachytherapy and radiotherapy (3-dimensional conformal radiotherapy) treated groups. Additionally, overall sexual HRQOL continued to decrease in the radiotherapy group, while significant changes in sexual HRQOL in patients with RP were not observed.

Reis et al reported a nonvalidated self-reporting questionnaire in 158 patients treated with RP or low dose rate brachytherapy from 1992 to 2001.⁹ Five questions were related to sexual function, 4 addressed urinary continence and 2 addressed satisfaction with definitive treatment and willingness to undergo treatment again. Perhaps one of the most relevant questions for patients with newly diagnosed prostate cancer is about satisfaction with the treatment and willingness in retrospect to undergo the same treatment again. In this cohort of 56 patients (43%) who answered the questionnaire 88% said that they would elect surgery again and 96% said that they would elect brachytherapy again. These data suggest that surgery and low dose rate brachytherapy provide a relatively high posttreatment quality of life in patients with prostate cancer.

Although men who undergo RP generally report more urinary and sexual problems compared to those undergoing either form of radiotherapy,¹⁰ bowel function and bother are consistently worse with radiotherapy.¹¹ Similarly in our study patients treated with RP had better bowel function than HDXRT treated patients and less bowel bother than those treated with HDXRT or IMP.

Limitations to our retrospective study include the lack of initial baseline data collected on each cohort before the initiation of therapy. Randomized clinical trials such as the Surgical Prostatectomy Interstitial Radiation Intervention Trial and the Radiation Therapy Oncology Group trial comparing an implant alone vs external beam followed by an implant failed to accrue or are slow to accrue, respectively. Therefore, future prospective studies, such as those that are ongoing at our institution with all local therapy modalities, may help provide patients with the appropriate information to help guide their treatment decisions. Data on erectile dysfunction medications and/or sexual medical devices were not comprehensively obtained in this retrospective study. Additionally, there may be inherent treatment related biases in the evaluation of sexual function and bother in the subset of patients treated with nerve sparing vs nonnerve sparing RP.¹² The HRQOL evaluation of sexual function with nerve sparing RP was studied by Talcott et al.¹³ In a prospective study with baseline pretreatment data they found little apparent improvement in sexual function with the nerve sparing RP surgical technique. Similarly Litwin et al used the UCLA-PCI validated instrument and also failed to note improved sexual function in men undergoing nerve sparing vs standard prostatectomy but the power to detect a difference was low.¹⁴ In contrast, in a study by

Hollenbeck et al an improvement in sexual health outcome was noted in a high volume urological practice with nerve sparing RP.¹² Finally, the use and type of erectile function aids were not controlled for among the treatment groups. Reports of the ability to preserve potency following prostate cancer treatment vary (range 10% to 90%) and the use of aids with varying efficacies, such as oral drugs, intraurethral alprostadil, vacuum devices, intracavernous injections and penile prostheses, further confound the data.^{15,16} In this study significantly worse erectile function in the younger, RP treated patients compared to that in IMP treated patients appears noteworthy.

Clinically Significant vs Statistically Significant

While the validated EPIC instrument provides important insight into HRQOL outcomes following local prostate cancer treatment, clinicians and patients find the interpretation of these statistically significant results into clinically significant results somewhat arbitrary. In our study a mean difference of 10 points was used to define clinical significance because this represents 1 SD from the mean according to the authors of the original EPIC. Two domains had statistically significant results but mean point differences were less than 10 points among the treatment groups (figs. 1 and 4). For example, in this study urinary function was statistically worse in the RP group compared to that in HDXRT treated patients but mean point differences between patients with RP and HDXRT was 7 points. Similarly bowel function was statistically worse in HDXRT and IMP treated patients compared to that in patients with RP but mean point differences between HDXRT and RP, and IMP and RP were 7 and 4 points, respectively. Other domains (urinary incontinence, urinary irritation, bowel bother and sexual function) had a mean point difference of 10 or greater among select treatment groups (figs. 2, 3, 5 and 6). However, to our knowledge the power of the clinical significance of this difference has not been well described. In fact, EPIC validation studies and subsequent clinical studies made no mention of the clinical vs the statistical significance with respect to mean point differences among treatment groups.^{3,17,18} Therefore, it is not surprising that, due to the inherent biases of urologists and radiation oncologists, patients often make treatment decisions following consultation with previously treated patients with prostate cancer. At our multidisciplinary clinic we attempt to minimize these inherent subspecialty biases by having patients evaluated by a urologist and a radiation oncologist to present unified treatment approaches and outcome discussions about prostate cancer.

CONCLUSIONS

The EPIC survey is an important validated instrument to help patients better understand what the potential treatment related side effects might be following definitive treatment for localized prostate cancer. Using the outcomes in this study from the EPIC survey appropriately selected surgical candidates may consider pursuing RP for prostate cancer treatment if they are concerned about bowel function and bowel bother following definitive treatment. Patients concerned about wearing daily pads and incontinence may want to consider definitive treatment with either radiation treatment monotherapy approach but they must be informed of the potential irritable and bothersome urinary side effects.

If sexual function and the convenience of a 1-time procedure is important in the patient decision making process, for appropriately selected patients a ^{125}I permanent prostate brachytherapy implant may be the optimal form of definitive treatment. These HRQOL parameters should continue to be reassessed and compared as treatment techniques improve and new treatment options become available.

Abbreviations and Acronyms

| | | |
|-------|---|---|
| EPIC | = | Expanded Prostate Cancer Index Composite |
| HDRT | = | high dose radiation therapy |
| HDXRT | = | high dose external beam radiation therapy |
| HRQOL | = | health related QOL |
| IMP | = | ^{125}I implant |
| QOL | = | quality of life |
| RP | = | radical prostatectomy |

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EDITORIAL COMMENT

These authors report HRQOL outcomes using the EPIC survey in patients treated with monotherapy, including brachytherapy, external beam radiotherapy and RP. The message from this and other HRQOL studies (reference 4 in article) is clear. Surgically treated patients have urinary leakage early following treatment, while patients with radiation therapy experience early irritative urinary symptoms and are at slightly higher risk for bowel symptoms. Urinary and bowel HRQOL side effects from either treatment typically resolve within 6 months of treatment (reference 7 in article). While posttreatment sexual function HRQOL scores were highest in brachytherapy treated patients (38 of 100) compared with patients treated with external beam radiotherapy (28) or radical prostatectomy (25), following prostate cancer treatment most patients require some assistance to improve sexual function. Anticipated HRQOL outcomes following surgery or radiation are well understood. Our daily challenge is to ensure that these anticipated HRQOL outcomes are conveyed to each patient clearly and with minimal bias.

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REPLY BY AUTHORS

With recent advances in technology in surgery and radiation oncology prospective evaluation of QOL following treatment will be important to help patients make appropriate decisions concerning prostate cancer therapy. Downs states that the side effects following definitive treatment with surgery and radiation therapy will usually resolve within 6 months. Our study, with a median followup of 4.0, 4.7 and 3.5 years for RP, HDRT and IMP, respectively, would suggest that patients continue to experience HRQOL changes years after treatment.