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Sexual Function and the use of Medical Devices or Drugs to Optimize Potency after Prostate Brachytherapy

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Abstract

Purpose—Prospective evaluation of sexual outcomes after prostate brachytherapy with iodine-125 seeds as monotherapy at a tertiary cancer care center.

Methods and Materials—Subjects were 129 men with prostate cancer with I-125 seed implants (prescribed dose, 145 Gy) without supplemental hormonal or external beam radiation therapy. Sexual function, potency, and bother were prospectively assessed at baseline and at 1, 4, 8, and 12 months using validated quality-of-life self-assessment surveys. Postimplant dosimetry values, including dose to 10% of the penile bulb (D10), D20, D33, D50, D75, D90, and penile-volume receiving 100% of the prescribed dose (V100) were calculated.

Results—At baseline, 56% of patients recorded having optimal erections; at 1 year, 62% of patients with baseline erectile function maintained optimal potency, 58% of whom with medically prescribed sexual aids or drugs. Variables associated with pretreatment-to-posttreatment decline in potency were time after implant ($p=0.04$) and age ($p=0.01$). Decline in urinary function may have been related to decline in potency. At 1 year, 69% of potent patients younger than 70 years maintained optimal potency, whereas 31% of patients over 70 maintained optimal potency ($p=0.02$). Diabetes was related to a decline in potency ($p=0.05$), but neither smoking nor hypertension were. For patients with optimal potency at baseline, mean sexual bother scores had declined significantly at 1 year ($p<0.01$). Sexual potency, sexual function, and sexual bother scores failed to correlate with any dosimetric variable tested.

Conclusions—Erections firm enough for intercourse can be achieved at 1 year after treatment, but most men will require medical aids to optimize potency. Although younger men were better able to maintain erections firm enough for intercourse than older men, there was no correlation between potency, sexual function, or sexual bother and penile bulb dosimetry.

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Keywords

erectile dysfunction; radiation therapy; brachytherapy; prostate cancer; sexual aids; sexual function; penile rehabilitation

INTRODUCTION

Prostate brachytherapy is considered an ideal option for some men with localized prostate cancer because of its low cost, convenience, high cure rates, and good quality of life after treatment [1–2]. However, rates of erectile dysfunction after permanent seed implantation have been as high as 50% within the 6 years after treatment [3]. Acute erectile dysfunction after brachytherapy among men with good sexual function before the procedure has been attributed to regional trauma with vascular and neurogenic damage, radiation effects, and psychogenic effects [4].

Evaluation of the extent of erectile function during the first year after the brachytherapy is often confounded by competing factors such as comorbid conditions or use of anti-androgenic therapies or supplemental therapies. Many studies have also failed to adequately define and document potency before seed implantation, which limits the validity of the postimplant findings and produces uncertainty as to the true effect of brachytherapy on sexual function [4]. Moreover, many studies of sexual function after brachytherapy have concentrated on long-term sexual difficulties [5,6]. Although long-term follow-up is valuable, interpretation of such findings can be further complicated by the effects of aging.

Attempts to correlate various dosimetric variables with erectile function have produced conflicting results. Owing to their close proximity to the prostate, several non-target structures such as the neurovascular bundles, crura, and penile bulb often receive significant radiation doses, and radiation injury to these structures has been postulated to be responsible for erectile dysfunction after definitive treatment for prostate cancer [5–10]. Although the penile bulb is not essential for achieving an erection [11], Mulhall *et al.*, among others, have hypothesized that the penile bulb could be a surrogate for some of the adjacent structures that are critical for achieving and maintaining erections [12].

To clarify the relationship between preimplant and postimplant sexual function, and to clarify potential associations between dosimetric variables and sexual function after treatment, we undertook this study to evaluate sexual outcomes before and after prostate brachytherapy with iodine-125 (^{125}I) stranded seeds as monotherapy for prostate cancer at a single tertiary cancer care center.

METHODS AND MATERIALS

Patients for this analysis were identified through an institutional review board–approved protocol by retrospectively identifying the medical records of all men with adenocarcinoma of the prostate treated with ^{125}I stranded-seed implants as monotherapy for prostate cancer between October 2005 through December 2007. To minimize the confounding influence of other treatment-related factors on sexual function, we excluded men who had received any external beam radiation therapy or hormone therapy. A total of 129 men treated with ^{125}I -seed monotherapy to a prescribed dose of 145 Gy with at least 8 months of follow-up were the subjects of this analysis. Information on tumor stage and grade, initial serum prostate specific antigen level, disease status, race, age, medical comorbidities, and current medications was extracted from the medical records and incorporated into a study database.

All men were offered a prescription for a phosphodiesterase (PDE) inhibitor at the time of implantation unless such drugs were contraindicated.

Penile Bulb Localization and Dosimetry

CT-based dosimetric measurements were obtained on the day of the implant (day 0) and one month afterward (day 30). CT-MRI fusion was used to contour pelvic structures. The anatomic relationship of the penile bulb and adjacent structures and their appearance on various imaging modalities are described by Wallner *et al.* [13]; landmarks include the laterally paired crura, the corpus cavernosa anteriorly, and the levator ani posteriorly. For this study, the bulb was identified on one 0.25-cm slice below the apex of the prostate. To limit ambiguity in distinguishing corpus spongiosum from penile bulb, a maximum of 2 cm of the proximal enlargement of the central midline penis, which is secured to the urogenital diaphragm and covered by the bulbospongiosum muscle, was considered the penile bulb [13]. The penile bulb was outlined on the day 0 and day 30 CT scans by one investigator (J.T.W.) and reviewed by another (S.J.F). Dose-volume histograms were used to calculate absolute mean dose delivered to the entire penile bulb (D_{100}) and the mean dose delivered to 10%, 20%, 33%, 50%, 70%, and 90% of the penile bulb. Penile bulb V_{100} , the penile bulb volume receiving 100% of the prescription dose, was calculated as an objective measure of radiation dose.

Assessment of Erectile Function: Sexual Potency, Sexual Function, and Sexual Bother

A validated quality-of-life self-assessment instrument, the Expanded Prostate Index Composite (EPIC) [14], was used to prospectively collect data on sexual function at baseline (before the implant), at 1, 4, 8, and 12 months after the implant, and at 6-month intervals thereafter. For this study, potency was defined as optimal or suboptimal according to the patient's response to question 32 of the EPIC, "erections firm enough for intercourse" and "erections firm enough for masturbation and foreplay only". All questions regarding sexual function and associated "bother" were to be answered on a 5-point scale with 5 being the best score possible for both sexual function and bother. A sexual summary score for each grouping was constructed and plotted in a linear regression model.

Use of Erectile Function Aids

To document the use of medical devices or pharmaceutical agents to aid erectile function, we gave each patient a four-question survey at the same time as the EPIC questionnaire [15]. Patients reported sexual potency without the use of sexual medical devices in the final question of that survey.

Statistical Analyses

Statistical analyses were performed with SAS v9.2 (SAS Institute, Inc., Cary, NC) and Stata (release 11) (StataCorp LP, College Station, TX). Longitudinal analyses were done with Stata's *xtmixed* routine (for continuous variables) or *xtmelogit* routine (for binary variables). For all statistical tests, a *p* value of 0.05 indicated statistical significance.

RESULTS

Patient characteristics

Of 188 men who underwent ^{125}I brachytherapy for localized prostate cancer from October 2005 through December 2007 at MD Anderson, 129 had completed the EPIC surveys and had not received hormonal ablation or external beam radiation therapy. Demographic and clinical characteristics are listed in Table 1. The mean age ($\pm$ standard deviation [SD]) was 65.3 ± 8.1 years; median follow-up time was 18 months (range 1–41). At baseline, 72 men

(56%) had erections firm enough for intercourse (20 [28%] of whom were using [PDE] inhibitors at that time); 18 men (14%) had erections firm enough for masturbation and foreplay only; and 16 men (12%) had no sexual activity at baseline. Twenty-three patients (18%) had no erectile function at baseline (Fig. 1). Of patients <70 years, 69% were potent at baseline, whereas only 31% of patients >70 were potent at baseline ($p<0.01$). Among 17 men with diabetes, 41% were potent at baseline versus 57% of 112 men without diabetes ($p=0.22$). Of 80 men with hypertension, 52% had baseline optimal potency versus 63% of 49 men without hypertension ($p=0.21$). Of 22 men with a history of smoking, 59% reported optimal potency at baseline versus 56% of nonsmokers ($p=0.78$).

Sexual potency before and after brachytherapy

Variables independently associated with a change in potency after brachytherapy were number of months after implant ($p=0.04$) and age at implant ($p=0.01$); an interaction between days after implant and age at implant was also noted ($p=0.04$). Declines in urinary function after treatment seemed to be related to potency but this apparent trend was not statistically significant.

Of the 72 men reporting optimal potency (erections firm enough for intercourse) at baseline, 68% maintained optimal potency after treatment, 67% at 4 months and 62% at 12 months ($p=0.56$). At 1 year, 69% of potent men <70 years maintained optimal potency, whereas 30% of patients >70 maintained optimal potency ($p=0.02$). Of the 17 men with diabetes, 41% reported optimal potency at baseline and 14% at 1 year; 57% of men without diabetes were potent at baseline compared with 31% at 1 year; in other words, 55% of optimally potent, nondiabetic men maintained optimal potency at 1 year ($p=0.05$). Of the 71 patients with hypertension, 40 (52%) were potent at baseline; 62% were optimally potent at 1 year. Of the 22 patients with a history of smoking, optimal potency rates were 59% at baseline and 41% at 1 year.

Sexual function before and after brachytherapy

The mean ($\pm$ SD) baseline sexual function scores on the EPIC survey were 65.7 ± 16.1 for men with optimal potency at that time and 24.1 ± 20.1 for men with suboptimal erections at that time. The presence of (patient-reported) nocturnal erections correlated positively with sexual function at baseline ($r=0.74$, $p<0.01$) and at 8 months ($r=0.71$, $p<0.01$).

Sexual Bother Before and After Brachytherapy

For men with optimal potency at baseline, mean sexual bother scores declined between baseline (81.3, 95% confidence interval [CI] 76.0–86.6) and 1 year (65.6, 95% CI 58.8–74.4, $p<0.001$). Sexual bother was less common among men with optimal potency than among those with suboptimal potency or no sexual activity at each measurement point (Fig. 2). The extent of sexual bother was no different for men with suboptimal potency versus those with no sexual activity (data not shown). However, the SD for sexual bother for men with no erectile function was wide, indicating considerable differences in the amount of bother associated with erectile dysfunction among individual patients.

Sexual function correlated with sexual bother at several points (Pearson's $r=0.66$ at baseline, 0.49 at 1 month, 0.50 at 4 months, and 0.57 at 8 months [$p<0.01$ for all]).

Penile Bulb Dosimetry and Sexual Outcomes

The penile bulb V_{100} ranged from 0 to 1.43 cm^3 (mean, 0.23 cm^3); the mean penile bulb D_{10} was 110 cGy on day 30. For men with optimal potency at baseline, neither potency nor

sexual function nor sexual bother correlated with any dosimetric variable tested on postimplant day 30 (Fig. 3).

No correlations were found between potency or sexual function and dosimetric variables at other points; specifically, at 1 year, the Pearson's r for potency and penile bulb V_{100} was 0.14 ($p=0.30$) and that for potency and D_{50} was 0.0713 ($p=0.30$). Sexual function did not correlate with penile bulb D_{10} at 1 month (0.032, $p=0.55$) or at 1 year (0.55, $p=0.58$). Pearson coefficients for sexual bother and dosimetric values were 0.042 ($p=0.71$) at 1 month and 0.385 ($p=0.38$) at 8 months. In short, we found no correlations between any dosimetry variable and any aspect of sexual health.

Use of devices or drugs to aid erectile function

Use of sexual aids or drugs was reported by 29% of men with optimal potency at baseline (Fig. 4) and 24% of all men. The proportion of men who reported both optimal potency and use of medical devices rose throughout the study period, with 49% reporting use at 1 month and 58% at 1 year (Fig. 4). Approximately 14% of men with no erectile function at baseline reported using sexual aids at both baseline and 1 year following treatment. Of all men using PDE inhibitors at 1 year, 45% reported improved potency over baseline. Overall, 70 men (54% of all patients) reported using some form of medication or device to aid erectile function at 1 year.

DISCUSSION

To our knowledge this is the first prospective evaluation of potency to consider medically prescribed sexual aids and dosimetry during the first year after brachytherapy. Of men with optimal potency at baseline, 62% maintained optimal potency at 1 year, and 58% of them used sexual aids. Using a validated, patient-reported quality-of-life questionnaire, we found that maintaining potency during the first year after treatment is age-dependent: men <70 years old are more likely to be able to sustain erections firm enough for intercourse at 1 year after prostate brachytherapy than are older men. Other than a potential association with diabetes, we found no associations between comorbid conditions and sexual potency. We further found no correlations between penile bulb dosimetric variables and erectile function, sexual potency, sexual function, or sexual bother.

Our study was unique in that we prospectively analyzed sexual outcomes among men who reported optimal vs. suboptimal potency at baseline; other studies [16] have not included measures of potency before treatment. In terms of quality of life, erectile dysfunction is a top concern for men, particularly potent men, in choosing a treatment for prostate cancer. We showed that most potent men could maintain erections firm enough for intercourse after prostate brachytherapy.

'Sexual health' in this study had three components—potency, function, and bother. We used the term potency to encompass the American Urological Association's definition of erectile dysfunction, that is, the inability to achieve and or maintain an erect penis adequate for sexual function. Sexual function, in the EPIC survey, refers to both function and bother. We found, not surprisingly, a correlation between overall erectile function and potency; however, a more interesting finding was the lack of correlation between sexual potency and bother. In other words, patients with optimal potency noted less sexual bother, but patients with suboptimal potency had no less bother than patients with complete lack of sexual activity. However, when we analyzed sexual *function*, a more comprehensive term that incorporates potency, we found a correlation between sexual function and sexual bother. The presence of nocturnal erections correlated with sexual function, suggesting that using only self-reports of erectile function to estimate the impact of treatment on sexual health

may miss important facts affecting patients' quality of life. Further, although sexual bother correlated with sexual functioning throughout the study, sexual bother did not increase as time passed.

We also found that having diabetes may be associated with worse sexual function, a finding consistent with other reports of decreased erectile functioning among men with hypertension, vascular disease, diabetes mellitus, and smoking [17]. Longer prospective follow-up may reveal additional declines in potency as a consequence of the long-term vascular effects of these conditions.

The mechanism underlying radiation-induced erectile dysfunction has been much debated. Several critical erectile structures, including neurovascular bundles, pudendal arteries, and corpus cavernosa, often receive substantial irradiation because of their proximity to the target volume [4, 18, 19]. Suboptimal radiation planning and delivery techniques can lead to elevated radiation doses to the penile bulb [13], which may be a surrogate for adjacent structures necessary for maintaining erection [12]. Attempts to correlate dosimetric variables with erectile functioning after brachytherapy have produced conflicting results (Table 2). We found no correlation between penile bulb dosimetric variables and erectile function, sexual potency, sexual function, or sexual bother. In contrast, Merrick *et al.* reported that doses to the penile bulb strongly correlated with erectile dysfunction after brachytherapy [8], leading them to conclude that the proximal penis is important in radiation-induced erectile dysfunction [8]. Other studies have not found correlations between postirradiation erectile dysfunction and the dose to various penile structures [6, 9, 20, 21]. The numerous critical elements involved in achieving and maintaining an erection, many of which are difficult to visualize (e.g., the internal pudendal arteries, neurovascular bundle, and other microvasculature) undoubtedly contribute to the inconsistency of these results.

In a recent study of a larger number of patients, we noted a correlation between decreased sexual function and worse urinary outcomes [22]. Previous studies have also noted correlations between urinary symptoms and erectile functioning, including one in which flares in lower urinary tract symptoms correlated with declining erectile function [22] and another in which peaks in urinary irritation and incontinence during the first 6 months closely correlated with the peak in erectile dysfunction [24].

Erectile functioning after prostate brachytherapy may be related to the quality of the treatment planning techniques and imaging capabilities. Although the prostatic apex harbors disease in up to 83% of cases, proper planning with improved imaging can lead to more precise irradiation and thus better erectile functional [25, 26, 27]. The delicate neurovascular structures adjacent to the apex of the prostate, combined with less than optimal planning or poor intraoperative technique in the placement of periapical seeds, may lead to unnecessary damage to erectile tissues [28]. In one study, the mean distance between the prostate apex and penile bulb was 1.45 cm but the range was large (0.7–2.1 cm) [29]. The imaging modality used can contribute to interobserver variability; other studies have shown less such variability with MRI-derived dose-volume histograms than with CT-derived values [30, 31], leading some to argue that use of MRI, with or without angiography, may help to make “erection-sparing” prostate brachytherapy a reality. Another small study suggested that using MRI for treatment planning could selectively increase the radiation dose delivered to biologically determined locations of tumor foci within the gland [32]. However, few data on MRI-based planning are available in conjunction with penile bulb dosimetry. We are currently investigating the use of MRI for treatment planning and its subsequent effect on quality of life after treatment.

This study had several limitations, among them the short follow-up period. However, the immediate effects on quality of life of the various treatment options are germane, particularly for men with localized disease. We chose to focus on short-term functioning to elucidate the potential mechanisms involved in early effects on erectile function after seed implantation. We noted that The largest decline in sexual potency occurred during the first month after the implant (Fig. 1); others have noted loss of erectile function as early as a mean of 2.6 months [5, 8] and a universal decline in sexual function during the first 6 weeks that then stabilized by 6 months of follow-up [24]. We found no correlation between penile bulb dosimetry and sexual outcomes after brachytherapy, and therefore, we believe the decline at 1 month is probably related to trauma and the psychogenic effects of the procedure. The mechanism underlying the long-term erectile dysfunction associated with all forms of radiation therapy may be vascular or neurologic [4–10]; however, in the context of this study, the impact of radiation damage secondary to brachytherapy is not likely to occur during such a short interval; rather, the effects of radiation would accumulate for years after treatment.

CONCLUSIONS

Erections firm enough for intercourse are possible at 1 year after prostate brachytherapy, however, many men will require medical aids for optimal potency. Younger men have better baseline sexual potency and generally are better able to maintain erections firm enough for intercourse than older men. We are investigating whether the routine use of PDE inhibitors for erectile rehabilitation will further optimize potency and improve sexual quality of life.

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Fig. 1.
Potency after prostate brachytherapy as a function of time; month 0, baseline; column widths, number of patients completing the questionnaires at that time.

Fig. 2.

Sexual bother as a function of sexual potency. Sexual bother was scored on a 100-point scale at each point; higher scores indicate less sexual bother and improved quality of life; bars, standard deviation; month 0, baseline values.

Fig. 3.

Penile bulb dosimetric variables and sexual function at 1 year after brachytherapy. Sexual function was scored on a 100-point scale. Each plot represents a unique dosimetric value of interest; each point indicates a patient. Green lines, least squares fit; red lines, lowest fit curve.

Fig. 4.

Use of medically prescribed sexual devices or drugs over time after brachytherapy. Blue bars, proportions of those who have not used such devices or drugs; red bars, proportions of those who have used such drugs or devices at some time. Month 0, baseline values; column widths, the number of patients completing the questionnaires at that time.

Table 1

Pre-Treatment Patient Baseline Characteristics

Age	
Mean	65
Range	46–86
Race	
Caucasian	104 (80.6%)
African-American	16 (12.4%)
Hispanic	7 (5.4%)
Other	2 (1.5%)
Pre-Treatment AUA Score (Mean)	6.28
Pre-Treatment Prostate Volume (Mean)	51
AJCC Stage 1992	
T1c	104 (80.6%)
T2a	23 (17.8%)
T2b	2 (1.5%)
Gleason Score	
6	68 (52.7%)
7	60 (46.5%)
8	1 (0.8%)
Presence of Diabetes	17 (13 %)
Presence of Hypertension	80 (62%)
History of Smoking	22 (17%)
Presence of Peripheral Vascular Disease	23 (17.8%)

Table 2
Correlation for Dosimetry to Penile Bulb and RIED: Previous Literature Results

Authors	Year	Prospective Evaluation	#	Follow-up (months)	Sign Correlation	Results
Merrick et al.	2001	No	46	Mean 35	Yes	Minimum D25, D50, D70, D75, D90 and D95 of the PB
Merrick et al.	2002	No	60	26–79	Yes	Minimum D50 of the PB
Merrick et al.	2005	Yes	128	13–42	No	Minimum D50 of the proximal crura
Kiteley et al.	2002	Yes	50	24–45	No	No significant correlations
Wright et al.	2004	No	41	12–41	Yes	Minimum D90 with a 10% cutpoint of the prescribed dose.
MacDonald et al.	2005	Yes	226	>24	No	No significant correlations
Present Study	2011	Yes	126	Median 18	No	No significant correlations