Original Article

Comparison of satisfaction with penile prosthesis implantation in patients with prostate cancer radiation therapy versus radical prostatectomy

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Background: Penile prosthesis surgery (PPS) is a commonly used treatment for erectile dysfunction (ED), either as first-line therapy or in cases refractory to other treatment options. In patients with a urologic malignancy such as prostate cancer, surgical interventions like radical prostatectomy (RP) as well as non-surgical treatments such as radiation therapy can all induce ED. PPS as a treatment for ED has high satisfaction rates in the general population. Our aim was to compare sexual satisfaction in patients with prosthesis implantation for ED following RP versus ED following radiation therapy for prostate cancer.

Methods: A retrospective chart review from our institutional database was conducted to identify patients who underwent PPS at our institution from 2011 to 2021. Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire data at least 6 months from implant operative date available was required for inclusion. Eligible patients were placed in one of two groups depending on etiology of ED-following RP or prostate cancer radiation therapy. To prevent crossover confounding; patients with history of pelvic radiation were excluded from the RP group and patients with history of RP were excluded from the radiation group. Data were obtained from 51 patients in the RP group and 32 patients in the radiation therapy group. Mean EDITS scores and additional survey questions were compared between the radiation and RP groups.

Results: There was a significant difference in mean survey responses for 8 of the 11 questions in the EDITS questionnaire between the RP group and the radiation group. Additional survey questions administered also found RP patients reported significantly higher rate of satisfaction with size of penis post-operatively versus the radiation group.

Conclusions: These preliminary findings, while requiring large-scale follow-up, suggest that there is greater sexual satisfaction and penile prosthesis device satisfaction in patients undergoing IPP placement following RP versus radiation therapy for prostate cancer. Use of validated questionnaires should continue to be utilized in quantifying device and sexual satisfaction following PPS.

Keywords: Inflatable penile prosthesis; Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS); radical prostatectomy (RP); radiation therapy; prostate cancer

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Introduction

Prostate cancer is the second most common malignancy encountered in men worldwide, responsible for 3.8% of all deaths caused by cancer in men annually (1). Several treatment options exist in the management of prostate cancer, including radical prostatectomy (RP), radiation therapy, and systemic therapies (2). One of the most common complications following prostate cancer treatment, regardless of modality, is erectile dysfunction (ED) (3). Rates of ED can vary widely depending on treatment modality, from 14–90% reported following RP, 8–85% following external beam radiotherapy (EBRT), 14–61% following brachytherapy, and 74% following androgen deprivation therapy (ADT) (4-6). In prostate cancer treatment-induced ED, management options can include phosphodisesterase-5 inhibitors (PDE-5i), vacuum erection devices (VED), intracavernosal injection (ICI) therapy, or penile prosthesis surgery (PPS) (7). Often, in the setting of ED refractory to less invasive treatment options, definitive surgical management with PPS may be desired by patients.

Studies report high levels of satisfaction in patients with PPS for ED, with rates frequently reported above 90% (8-10). However, the wide variability in assessing patient attitudes post-prosthesis implantation has led to a paucity of validated questionnaire usage within the current literature.

Highlight box

Key findings

- In our retrospective cohort, we found that patients who underwent penile prosthesis surgery (PPS) following radiation therapy for prostate cancer treatment had a statistically significant lower mean score for 8 of the 11 EDITS questionnaire responses as well as in overall EDITS score versus post-radical prostatectomy (RP) patients.

What is known and what is new?

- Quantifying satisfaction following PPS has been frequently studied, and in the advent of new procedure-specific surveys such as the Satisfaction Survey for Inflatable Penile Implant, the accuracy of assessing patient-satisfaction should hopefully improve.
- There remains limited literature on PPS satisfaction stratified by ED etiology.
- We attempted to study if there exists a difference in post-PPS satisfaction when stratified by ED due to radiation or RP.

What is the implication, and what should change now?

- Work should continue in identifying if there are any unique considerations specific to post-radiation or post-RP patients that we may utilize in future to increase the PPS satisfaction of these groups.

There also remains limited data available regarding patient satisfaction with PPS stratified by etiology of ED including following prostate cancer treatment such as surgical management or targeted radiation therapy. Our group previously studied satisfaction levels of patients with PPS following RP or radical cystoprostatectomy (RCP) versus the general population (11). For clinically localized prostate cancer, both surgery and radiation can be available as options through shared decision making between clinicians and patients, therefore, many patients at our institution undergo radiation in their genitourinary cancer treatment (12).

There is a lack of literature available on patient satisfaction following PPS in patients with ED due to radiation therapy compared to other prostate cancer treatment modalities. As we had previously studied the sexual satisfaction of our PPS patients following RP/RCP, we sought to quantify the satisfaction of our patients with ED secondary to prostate cancer radiation treatment. Thus, the primary objective for our study was to determine if there is a significant difference in device and sexual satisfaction rates between patients receiving PPS for ED post-RP versus post-prostate cancer radiation therapy quantified via a validated questionnaire. We present this article in accordance with the STROBE reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-22-600/rc).

Methods

A retrospective chart review from our IRB-approved institutional database was conducted to identify 970 patients who underwent PPS by a single surgeon at our center from 2011 to 2021. Only patients that had completed the 11-item Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) validated questionnaire (13) and had response data available for review were eligible for inclusion. All EDITS questionnaires were administered at least 6 months from PPS operative date or later. Eligible patients were screened for placement into one of two groups depending on etiology of ED: following RP or following prostate cancer radiation therapy. To prevent crossover confounding; patients with history of pelvic radiation were excluded from the RP group and patients with history of RP were excluded from the radiation group. All patients included were impotent at time of PPS. Final data were obtained from 51 patients in the RP group and 32 patients in the radiation therapy group. Within the radiation therapy group, 26 patients underwent EBRT and 6 underwent prostate brachytherapy. A patient selection flowchart for inclusion is represented in *Figure 1*.

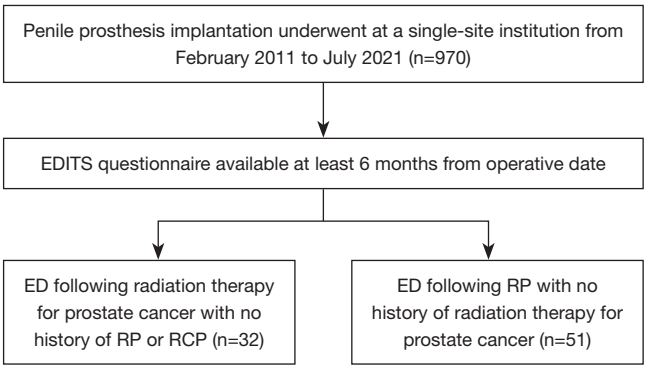

Figure 1 Diagram of patient selection for both groups. EDITS, Erectile Dysfunction Inventory of Treatment Satisfaction; ED, erectile dysfunction; RP, radical prostatectomy; RCP, radical cystoprostatectomy.

Additionally, patient charts were retrospectively reviewed for demographics, surgical information, and etiology of ED. Demographic information included age and BMI at time of implant operation, self-reported ethnicity, and pre-operative penile doppler results. Surgical information reviewed included surgical approach, location of reservoir placement, and penile prothesis implant used. Implants used were the AMS 700 TM LGX/CX/CXR (Boston Scientific; Marlborough, MA, USA) and the Titan (Coloplast; Minneapolis, MN, USA). Mean EDITS scores were calculated for both the total cohort as well as stratified by group. Mean responses to the 11-item EDITS questionnaire were compared between the two groups as a measurement of device and sexual satisfaction. Responses ranged from 0-4, with 4 indicating higher levels of satisfaction relevant to each specific question. All patients were also surveyed on three additional questions: (I) Do you remember the length of your penis when it was measured in your previous (postoperative) appointment? (Yes/No); (II) How satisfied are you with the size of your penis after surgery? (1-5, 5 being extremely satisfied); and (III) Do you believe your overall sexual satisfaction is affected by penile length? (Yes/No). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional review board of UTHealth - Houston (IRB # HSC-MS-19-0320) and individual consent for this retrospective analysis was waived.

Statistical analysis

Distribution of categorical variables was assessed using the chi-square test. Mean responses to EDITS and additional questions were compared between groups using Student's *t*-test. P<0.05 was considered statistically significant. All statistics were performed using R 3.6.2 (R Foundation For Statistical Computing, Vienna, Austria).

Results

The combined total of both cohorts included 83 patients, with 38.6% (n=32) in the radiation only group and 61.4% (n=51) in the RP group. Demographics, surgical information, implant device used, and mean EDITS score are reported in *Table 1*, both for the total cohort and stratified by group. Of the radiation group, 81.3% (n=26) underwent EBRT and 18.7% (n=6) underwent brachytherapy. Of the RP group, for those with specific RP operative reports available (n=44), 91% (n=40) underwent robotic RP and 81.8% (n=36) underwent unilateral or bilateral nerve-sparing RP. Specific breakdown of unilateral versus bilateral nerve sparing was not available.

The median age at PPS operation date was 70.1 years (IQR: 67.4–74.9) for the radiation group, and 67.6 years (IQR: 64.0–71.5) for the RP group. There was no significant difference found between the two groups (P=0.051). The median number of months from prostate cancer treatment, defined as date of RP or final radiation treatment, to PPS was 54.6 (IQR: 32.1–95.1) for the radiation group and 28.1 (IQR: 16.5–56.7) for the RP group, with a significant difference found between the two groups (P=0.002). ADT use at any time prior to completion of EDITS questionnaire was also assessed, with 62.5% (n=20) in the radiation group and 17.6% (n=9) in the RP group noting ADT use at any point, with a significant difference found between the two groups (P<0.001). Mean Charlson Comorbidity Index (CCI) was compared between the two groups, 5.2 versus 4.8 for the radiation and RP groups, respectively (P=0.17).

Additionally, there was a significant difference found in mean total EDITS score between the radiation group, 76.56 (range, 27.3–100), and RP group, 90.4 (13.6–100), respectively (P<0.001). There was no significant difference found in distribution of median BMI (P=0.87), ethnicity (P=0.92), penile doppler results (P=0.82), surgical approach (P=0.25), and device type (P=0.16) between the two groups. There was a significant difference found in the distribution of location of reservoir placement between the two groups (P=0.004).

EDITS questionnaire items are listed in *Table 2* along with measures of significance of mean responses

Table 1 Patient demographics and surgical characteristics

Variable	Overall (n=83)	Radiation only (n=32)	RP (n=51)	P
Age in years, median (IQR)	68.8 (65.3–72.5)	70.1 (67.4–74.9)	67.6 (64.0–71.5)	0.051
BMI, median (IQR)	29.7 (27.0–31.7)	29.4 (27.1–31.3)	29.7 (26.3–31.7)	0.87
Ethnicity, n (%)				0.92
Caucasian	48 (57.8)	20 (62.5)	28 (54.9)	
African American	24 (28.9)	11 (34.4)	13 (25.5)	
Hispanic	4 (4.8)	1 (3.1)	3 (5.9)	
Asian	7 (8.4)	0 (0.0)	7 (13.7)	
Penile doppler, n (%)				0.82
Arterial insufficiency	64 (77.1)	25 (78.1)	39 (76.5)	
Mixed vasculogenic	8 (9.6)	2 (6.3)	6 (11.8)	
Venous leakage	4 (4.8)	2 (6.3)	2 (3.9)	
Not applicable	7 (8.4)	3 (9.4)	4 (7.8)	
Months from PCa treatment[a] to PPS, median (IQR)	33.7 (20.4–81.1)	54.6 (32.1–95.1)	28.1 (16.5–56.7)	0.002
Surgical approach, n (%)				0.25
Infrapubic	6 (7.2)	1 (3.1)	5 (9.8)	
Penoscrotal	77 (92.8)	31 (96.9)	46 (90.2)	
Reservoir placement, n (%)				0.004
Space of Retzius	5 (6.0)	3 (9.4)	2 (3.9)	
Submuscular	73 (88.0)	24 (75.0)	49 (96.1)	
Subscarpas	5 (6.0)	5 (15.6)	0 (0.0)	
Device, n (%)				0.16
AMS 700 (LGX/CX/CXR)	31 (37.3)	15 (46.9)	16 (31.4)	
Coloplast (Titan/NB)	52 (62.7)	17 (53.1)	35 (68.6)	
ADT use, n (%)	29 (34.9)	20 (62.5)	9 (17.6)	<0.001
Charlson Comorbidity score, mean (range)	4.9 (3–8)	5.2 (3–8)	4.8 (3–8)	0.17
Mean EDITS score (range)	85.0 (13.6–100)	76.56 (27.27–100)	90.4 (13.6–100)	<0.001

[a], treatment refers to date of radical prostatectomy or date of final radiation treatment. BMI, body mass index; PCa, prostate cancer; PPS, penile prosthesis surgery; ADT, androgen deprivation therapy; EDITS, Erectile Dysfunction Inventory of Treatment Satisfaction; RP, radical prostatectomy.

between the two groups as well as three additional survey questions regarding patient satisfaction. There was a significant difference in mean survey responses for 8 of the 11 questions in the EDITS questionnaire between the RP group and the radiation group (P<0.05). For all 8 of these questions surveying key satisfaction metrics, the RP group had a significantly higher mean score versus the radiation group. These survey themes with a significant difference in mean score were overall treatment satisfaction (Question 1), likelihood to continuing use of treatment (Question 3), satisfaction with how quickly the treatment works (Question 5), satisfaction with how long the treatment works (Question 6), confidence regarding ability to engage in sexual activity (Question 7), perceived satisfaction of their partner with the device (Question 8), naturalness of the erection with the treatment (Question 10), and

Table 2 Comparison of mean EDITS and additional survey responses by question between RP patients and radiation patients

Item	RP mean score	Radiation mean score	P
Q1. Overall, how satisfied are you with this treatment?	3.65	3.13	0.007*
Q2. During the past 4 weeks, to what degree has the treatment met your expectations?	3.47	3.06	0.056
Q3. How likely are you to continue using this treatment?	3.78	3.28	0.007*
Q4. During the past 4 weeks, how easy was it for you to use this treatment?	3.71	3.34	0.052
Q5. During the past 4 weeks, how satisfied have you been with how quickly the treatment works?	3.78	3.25	0.002*
Q6. During the past 4 weeks, how satisfied have you been with how long the treatment lasts?	3.82	3.28	0.002*
Q7. How confident has this treatment made you feel about your ability to engage in sexual activity?	3.69	2.94	<0.001*
Q8. Overall, how satisfied do you believe your partner is with the effects of this treatment?	3.61	3.09	0.014*
Q9. How does your partner feel about your continuing to use this treatment?	3.65	3.31	0.064
Q10. How natural did the process of achieving an erection feel when you used this treatment over the past 4 weeks?	3.35	2.78	0.016*
Q11. Compared to before you had an erection problem how would you rate the naturalness of your erection when you used this treatment over the past 4 weeks in terms of hardness?	3.25	2.22	<0.001*
Q12. Do you remember the length of your penis when it was measured in your previous (postoperative) appointment? (% Yes)	48.5	34.4	0.098
Q13. How satisfied are you with the size of your penis after surgery? (1-5, 5 being very satisfied)	4.24	3.59	0.012*
Q14. Do you believe your overall sexual satisfaction is affected by penile length? (% Yes)	59.1	75.0	0.18

*, denotes statistically significant difference (P<0.05). EDITS, Erectile Dysfunction Inventory of Treatment Satisfaction; RP, radical prostatectomy.

naturalness of the erection in terms of hardness (Question 11). Comparison of means for all EDITS questions are displayed in *Figure 2*. Additional survey questions administered found no significant difference in rates of patients remembering the size of their penis measurement at their prior post-operative visit between the two groups (P=0.098) but did find a significant difference in patient satisfaction (rated 1–5 with 5 being very satisfied) with size of penis post-operatively, with a mean score of 4.24 for the RP group and 3.59 for the radiation group, respectively (P=0.01). Additionally, there was not a significant difference in proportion of patients with belief that overall sexual satisfaction is affected by penile length between the two groups (P=0.18).

Discussion

We found that patients who underwent PPS following radiation therapy for prostate cancer treatment had a statistically significant lower mean score for 8 of the 11 EDITS questionnaire responses as well as in overall EDITS score versus post-RP patients. Additional questions administered also found a significant difference in patient satisfaction with penile length after surgery.

Understanding why radiation patients were generally less satisfied relative to the surgical cohort of RP patients is of particular interest. Beginning from a possible mechanism-level etiology, ED following post-RP is generally more well understood versus radiation induced ED (7,14,15).

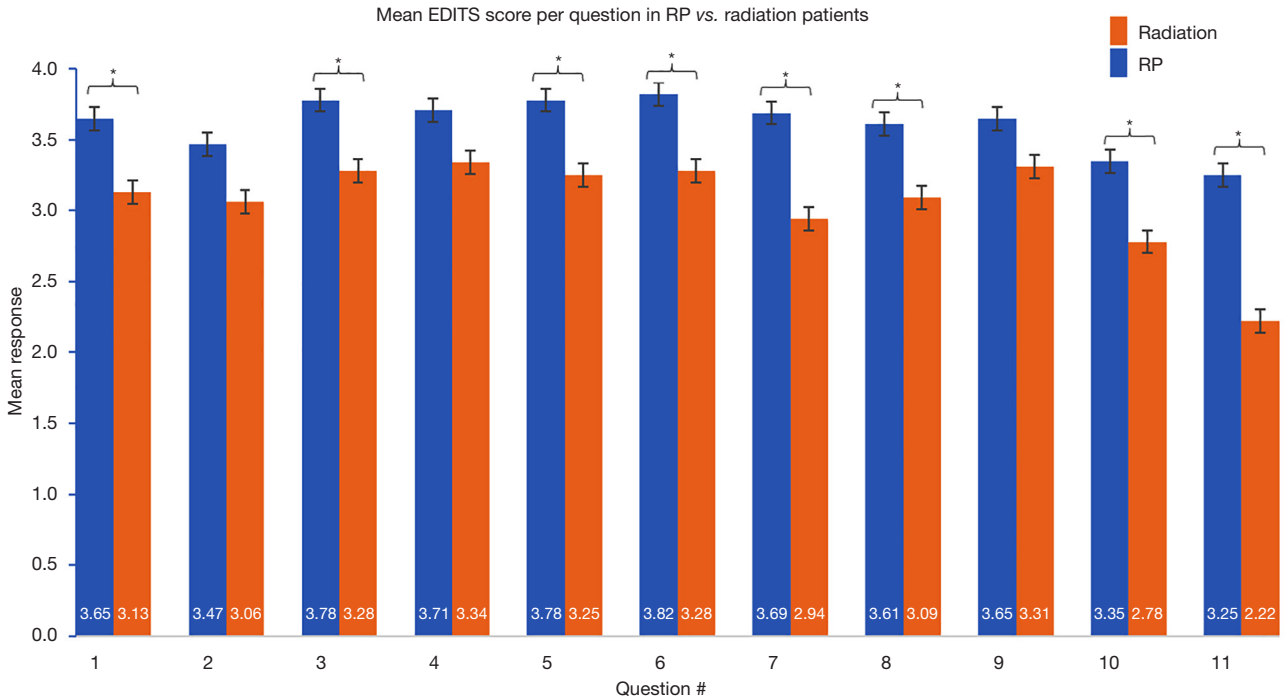

Figure 2 Mean EDITS score per question in RP *vs.* radiation patients. Comparison of mean EDITS score per question between RP and radiation groups (possible responses 0-4). *, denotes statistically significant difference (P<0.05). RP, radical prostatectomy; EDITS, Erectile Dysfunction Inventory of Treatment Satisfaction.

Studies on radiation induced ED are ongoing, and there are few published studies regarding this topic as it continues to be less definitively understood than following surgical management of prostate cancer (16,17). Secondly, patient characteristics may differ in the two cohorts. Specifically, understanding if there are differences in patients who opt for one modality versus the other may help elucidate the results we observed in our study. In our cohort, the median age of the radiation group was older than that of the RP group at time of PPS date although this difference was not statistically significant. Similarly, the mean CCI of our radiation cohort was greater than that of the RP group, although this difference was also not found to be statistically significant. However, even in the absence of statistical significance these absolute differences in median age at surgery and CCI may help explain some of the results observed. A large-scale population study following 17,570 men who underwent either RP or EBRT for prostate cancer treatment found EBRT patients were significantly older at time of treatment versus RP (18). Additionally, this EBRT group also had a significantly higher level of baseline comorbidities as quantified by the CCI. Although treatment modality selection in prostate cancer management is advised to be guided by health status versus chronological age, it has been reported the EBRT is delivered more frequently than RP in older men relatively (18,19). Further investigation into specific existing comorbidities between the two groups and whether significant differences exist may also help elucidate differences in survey responses and satisfaction given that both age and comorbidities have also been linked to prevalence of ED in general (20,21).

However, even with an understanding of why the radiation and RP groups differ in post-PPS sexual satisfaction, asking how this information can and should be applied moving forward to best serve our patients is one of great importance. The goal of our study was not to help guide treatment for a patient's prostate cancer via observed differences in sexual satisfaction following treatment for ED that may or may not result secondary to their treatment modality. Cancer treatment options should absolutely not change under the supposition of post-treatment ED. The goal, in addition to building off prior work our team has published, is that if there is indeed a difference in sexual satisfaction between the two groups, are there any unique

considerations we may utilize in the future to increase the PPS satisfaction of our patients.

The role that ADT may play in sexual satisfaction, or lack thereof, in our patient cohort is important in interpretation of our results. In our study, patients with any history of ADT use, including pre-PPS, were included in the "yes" category for both the RP and radiation cohorts. ADT use has been well-documented as increasing the risk for erectile dysfunction and decreased libido in patients. In some instances, it has also been noted to cause ED following discontinuation of use, which guided our rationale in defining ADT use as that of any point prior to survey (22,23). Furthermore, the downstream effects of ADT use, including the blockade of testosterone (T) production, leading to decreased sexual desire and satisfaction may impact the results of our study (24). The radiation-only cohort had a higher proportion of patients with any history of ADT use, and additionally, as a limitation, we did not have T levels at time of survey to be included in our analysis. Furthermore, the risk of hypogonadism in pelvic irradiation provides another possible factor in the decreased satisfaction our radiation-only cohort reported. We hypothesize that this may relate to the greater proportion of the radiation cohort reporting subjectively decreased penis size post-operatively, which has been found as being more common in patients undergoing RT/ADT versus RP (25,26).

While the advancement of prostate cancer screening has improved risk-stratification and potentially the confidence with which certain treatment modalities can be recommended based on relative risk of a patient's cancer, shared decision making remains essential in moving forward with treatment (27). Patients play a vital role in the clinician-patient decision making between surgery or radiation or alternative modalities in their treatment of prostate cancer (28-30). As prostate cancer treatment improves in the modern era, patients who undergo radiation therapy experience improved cancer-specific survival and overall survival compared to prior eras (31). Thus, management of quality-of-life and post-treatment complications are increasingly important, of which a penile prosthesis may play an essential role in. A 2018 study compared PPS patients with a history of radiation versus RP for prostate cancer similar to our study (32). They found that PPS is safe and effective in treatment of ED in patients with history of irradiation for prostate cancer, however, this study focused on reoperation rates rather than patient satisfaction. A previous study looked at possible determinants of patient satisfaction following PPS and did find reduced satisfaction in those with a history of RP, however, this was by comparing pre- and post-operative satisfaction rates as quantified by various scales (33). Research on optimizing treatment of sexual dysfunction in patients undergoing prostatic irradiation, which includes treatment via PPS, is ongoing and provides an opportunity to consequently improve patient satisfaction as well (17).

It is also important to note that the EDITS validated questionnaire, although one of the most commonly used in assessing patient satisfaction following PPS, is not without flaw in quantifying post-penile prosthesis sexual satisfaction and this may have affected our results. Until recently, there did not exist a survey specifically validated for PPS patients to capture true satisfaction, thus results may be limited in accuracy (34). A 2017 review found that over 66% of published studies in a 16-year time frame evaluating patient satisfaction following PPS did so using non-validated surveys or questionnaires (34). The Satisfaction Survey for Inflatable Penile Implant (SSIPI) has been developed and validated to assess post-PPS patient reported outcomes and satisfaction (35).

There are several limitations to our study in addition to those mentioned above. First, although our institution has a high-volume of patients undergoing PPS, all patients did not complete an EDITS questionnaire. Like as mentioned above, utilizing a validated survey in assessing sexual and device satisfaction is important when evaluating PPS patients (9,36,37). Many PPS satisfaction studies are limited by using non-validated assessments in capturing data. And with the promising new development of procedure-specific surveys such as the SSIPI, evaluation of post-operative outcomes and satisfaction should improve. The retrospective nature of our study introduces limitations, including continued utilization of the EDITS questionnaire which may now be considered a dated evaluation tool with the development of surveys such as the SSIPI. We therefore recommend more frequent utilization of questionnaires such as the SSIPI to provide greater external validity to future related studies, preferably in prospective studies. It is also possible that EDITS questionnaire participants had differing satisfaction levels from the high number of non-participants, introducing response bias to our study. Subsequently as a limitation, the three additional questions asked of patients following the EDITS questionnaire are currently unvalidated questions but had been used in evaluation of patients in our prior published work (11). Given the retrospective nature of our study we chose to include these answers as well. Additionally, an important

note is that although there may be statistically significant difference in EDITS scores, there may not be a clinical difference. The scores of the radiation-only cohort were lower versus the RP group, but as the radiation only cohort did have a mean EDITS score of 76.56, this is still considered an overall positive post-operative satisfaction level, albeit low in relation to the RP group. Additionally, our radiation-only cohort had a very small number of patients, 6 of the 32, who underwent brachytherapy versus EBRT. Another limitation includes lack of information regarding partner satisfaction with treatment in this cohort. Understanding if there is a relationship between partner satisfaction and patient device satisfaction rates is vitally important in post-PPS assessments going forward (38,39). Also, our radiation-only cohort had a significantly greater period of time from prostate cancer treatment to PPS date. Determining why or what caused this delay in time from treatment to penile prosthesis surgical implantation date may help elucidate the differences in our satisfaction findings. There is a possibility that patients in the radiation-only cohort opted for more non-invasive options for ED treatment with no success prior to finally opting for surgery, although we unfortunately did not have this information to be included in our analysis. Following years of interventions with limited success, this could certainly increase a patient's dissatisfaction with their sexual function, even following definitive treatment via PPS. This is a limitation to our study and addressing what led to this delay in time from treatment to PPS can help identify ways in which we can streamline our care for our patients. And finally, our study is limited by the sample size in our radiation-only group as compared to the RP group. Although ED due to radiation therapy for prostate cancer with no history of surgical intervention is less frequently encountered at our institution versus post-RP, attempting to procure a larger sample size may have provided a more generalizable patient view of PPS following radiation induced ED.

Looking forward, follow-up studies should be conducted on a larger scale with multi-institutional involvement using a validated questionnaire that also attempts to elucidate patient concerns or factors that may be associated with device or sexual dissatisfaction. An additional group of patients with history of both radiation and RP would be useful to provide comparison to the surgery or radiation only groups. In addition, further information on patient's prostate cancer and subsequent treatment should be investigated to allow stratification on prostate cancer stage/risk-level as well as type of surgery or radiation.

Conclusions

Patients who have underwent PPS have a higher level of sexual satisfaction and penile prosthesis device satisfaction following RP versus radiation therapy for prostate cancer. Future studies should further explore the impact that age and existing comorbidities at time of cancer treatment may have on subsequent device and sexual satisfaction. Additionally, it important that this data is gathered via validated questionnaires to increase external validity of findings.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-22-600/rc

Data Sharing Statement: Available at https://tau.amegroups.com/article/view/10.21037/tau-22-600/dss

Peer Review File: Available at https://tau.amegroups.com/article/view/10.21037/tau-22-600/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-22-600/coif). RW is a consultant for Boston Scientific and Teleflex. The other authors have no conflicts of interest to report.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional review board of UTHealth - Houston (IRB # HSC-MS-19-0320) and individual consent for this retrospective analysis was waived.

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