ERECTILE DYSFUNCTION

Comparison of Satisfaction With Penile Prosthesis Implantation in Patients With Radical Prostatectomy or Radical Cystoprostatectomy to the General Population



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ABSTRACT

Introduction: Penile prosthesis implantation is a widely used treatment option for erectile dysfunction. Data is limited with regard to patient satisfaction with a penile prosthesis following radical prostatectomy/cystoprostatectomy vs patients with erectile dysfunction of other etiologies.

Aim: To examine patient satisfaction with penile prosthesis implantation and determine if a difference in satisfaction exists in post-prostatectomy/cystoprostatectomy patients vs patients with erectile dysfunction of other etiologies. We hypothesize that etiology does not affect satisfaction.

Methods: A total of 164 patients underwent penile prosthesis implantation at our institution between August 2017 and December 2019, with 102 patients completing a validated 14 item questionnaire, Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS), at 6 months postoperation. Demographics, surgical characteristics, and erectile dysfunction etiology were recorded. Patients were assigned to one of 2 groups: postprostatectomy/ postcystoprostatectomy erectile dysfunction or other etiologies. The study group was further analyzed between radical prostatectomy or radical cystoprostatectomy.

Main Outcome Measures: Satisfaction based on key EDITS questions with postradical prostatectomy/cystoprostatectomy vs patients with erectile dysfunction of other etiologies.

Results: Responses to 3 questions were analyzed: overall satisfaction, expectations met in the past 4 weeks, and confidence in the ability to participate in sexual activity. Chi-square analysis was performed to determine the difference in responses. No difference was seen in overall satisfaction (P= .96), expectations (P= .78), or confidence (P= .78) between groups. On subgroup analysis, there was no difference in reported overall satisfaction (P= .47) or confidence (P= .080) between postprostatectomy and postcystoprostatectomy patients. Postprostatectomy and postcystoprostatectomy patients differed in whether the penile prosthesis implantation met expectations (P= .033). Postprostatectomy patients reported a mean score of 3.5/4 compared to postcystoprostatectomy patients, who reported a mean of 3.0/4.

Conclusions: Our analysis suggests that key erectile function scores are not significantly different between postprostatectomy/postcystoprostatectomy patients compared to other etiologies. The difference in measures between postprostatectomy and postcystoprostatectomy patients is not significant or of unclear significance. Registration # of clinical trial: HSC-MS-19-0320 Howell S, Palasi S, Green T, et al. Comparison of Satisfaction With Penile Prosthesis Implantation in Patients With Radical Prostatectomy or Radical Cystoprostatectomy to the General Population. Sex Med 2021;9:100300.

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Key Words: Penile Implantation; Erectile Dysfunction; Prostatectomy; Patient Satisfaction; Penile Prosthesis

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INTRODUCTION

Prostate cancer and bladder cancers are commonly diagnosed cancers in men. ¹ As diagnosis and treatment improve, survival increases, and management of treatment complications increases in importance. Erectile dysfunction (ED), or the persistent inability to achieve or maintain an erection satisfactory for sexual performance, ² is one major side effect of bladder cancer treated with radical cystoprostatectomy (RCP) or prostate cancer treatment with radical prostatectomy (RP), pelvic radiation therapy (RT), and androgen deprivation therapy (ADT). RP or RCP, in particular, may induce ED via several mechanisms that impair cavernosal nervous function, including direct trauma to nerves, damage from surgical electrocautery, neurovascular disruption, or local inflammation. ³ Regardless of the specific etiology, neurological impairment causes oxygenation dysfunction and leads to chronic hypoxia, inflammation, and fibrosis. ^{4,5}

Post-RP or RCP ED has previously been managed conservatively with oral type 5 phosphodiesterase inhibitors (PDE5i) or locally-acting therapies (intracavernosal injections, intraurethral alprostadil, or vacuum erection devices), only moving to surgery when patients did not respond. However, penile prosthesis implantation (PPI) can now be considered as an initial treatment option for ED based on patient needs.⁶

Independent of implant type, studies report high (87–91%) patient and partner satisfaction rates with PPI, ^{7,8} and some suggest satisfaction with the prosthesis is even higher than with oral medication or local therapy. ⁹ In the special population of ED patients who are post-RP, high patient satisfaction and low morbidity are reported; one study found no significant difference in overall satisfaction between post-RP ED patients and vasculogenic ED controls. ¹⁰ A second study found that in patients with post-RP ED receiving PPI, erectile function scores increased commensurate to other patient groups, but the increase in satisfaction was significantly less. ¹¹ Thus, while post-RP ED patients do report higher satisfaction with PPI, it is unclear to what degree they benefit from this procedure compared to other ED patients. Furthermore, it is unknown if men with post-RCP ED receiving PPI are more, less, or equally satisfied compared to men who receive PPI after RP.

Therefore, this study has 3 objectives: first, to report satisfaction rates to corroborate current literature for ED patients receiving PPI; second, to determine if a difference in PPI satisfaction exists in post-RP or RCP patients compared to the general population and potential reasons for this difference; and third, to find whether a difference in satisfaction exists between post-RP and RCP patients receiving PPI for ED. The ultimate goal of our paper was to answer the question if we can identify the etiology of ED to correlate with postoperative satisfaction after PPI and to provide guidance for patient expectations.

MATERIALS AND METHODS

The 164 patients who received PPI by a single surgeon at our institution from August 2017 to December 2019 were given a

validated 14-item questionnaire, Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS), to assess their satisfaction with PPI. ¹² Only patients who were receiving their first implant were administered the questionnaire, and any reoperative patients were excluded. Patients who did not complete the EDITS questionnaire were also excluded, for reasons consisting of failure to contact (30), death or hospice placement (5), incomplete questionnaire (4), complications preventing use of the prosthesis (4), refusal (2), or language barrier (1). One hundred and 2 patients completed the questionnaire at 6 months following surgery and were enrolled in this study. All patients were aggressively measured and sized during PPI to allow for the largest sized implant possible for the patient to be placed.

Patient charts were retrospectively reviewed for demographic information, information related to PPI, and information regarding ED etiology. Demographic information collected included age, body mass index (BMI), self-reported ethnicity, and penile Doppler results. PPI information collected included surgical approach, location of reservoir placement, and device type.

Patients with post-RP or RCP ED were assigned to the study group. Patients with ED who had not received either of these procedures were assigned to the control group. Patients in the study group were further assigned to a subgroup based on the specific procedure they had received: RP or RCP. All patients received a robotic-assisted laparoscopic radical prostatectomy in the post-RP group except for 1 patient in the study group and 2 patients in the control group. These 3 patients received an open surgical procedure instead. All patients underwent open radical cystoprostatectomy except for 1 patient in the study group who received it robotically assisted. A nerve-sparing approach was used whenever feasible, which was in greater than 90% of patients in our study population.

All patients were offered post-RP and post-RCP rehabilitation with a vacuum erection device and daily PDE5i if they had nerve-sparing surgery. If ED persisted despite PDE5i therapy and VED, patients were considered for ICI therapy. All patients failed ICI therapy or were unwilling to use ICI before PPI. Time from RP or RCP to PPI varied from 6 months to 5 years. No significance was found between satisfaction rates and time from cancer surgery to PPI. After PPI, patients were seen in the clinic 6 weeks postoperatively. At that time, patients were instructed on how to use the device and were told to cycle the device at least 3 times per week for the first 6 months after implantation. Implants used were the AMS 700 TM LGX/CX/CXR (Boston Scientific; Marlborough, MA, USA) and the Titan (Coloplast; Minneapolis, MN, USA).

Responses to 3 key EDITS items were analyzed, focusing on (1) overall satisfaction with treatment; (2) the degree to which treatment had met patient expectations over the past 4 weeks; and (3) patient's confidence in their ability to engage in sexual activity. Possible responses were based on a Likert-type scale and were codified using 0-4, with 4 showing higher satisfaction, a meeting of expectations, and confidence. Response distributions

Table 1. Clinical characteristics of the PPI cohort stratified by ED etiology (post-RP vs non-post-RP)

Variable*	Overall (n = 102)	Study (n = 79)	Control (n = 23)	P
Age in years	67 (63, 71)	66 (63, 71)	67 (64.5, 73)	.1
BMI	29.7 (26.1, 31.7)	29.6 (26.3, 31.6)	30.6 (25.3, 32.8)	.8
Ethnicity				.2
African-American	31 (30%)	21 (27%)	10 (43%)	
Asian	2 (2%)	2 (3%)	0 (0%)	
Caucasian	59 (58%)	46 (58%)	13 (57%)	
Hispanic	10 (10%)	10 (13%)	0 (0%)	
Penile Doppler				.07
Arterial insufficiency	58 (57%)	61 (77%)	13 (56%)	
Mixed vasculogenic	15 (15%)	10 (13%)	5 (22%)	
Not applicable	22 (22%)	5 (6%)	1 (4%)	
Venous leakage	7 (7%)	3 (4%)	4 (18%)	
Surgical Approach				.9
Infrapubic	5 (5%)	4 (5%)	1 (4%)	
Penoscrotal	97 (95%)	75 (95%)	22 (96%)	
Reservoir Placement				.1
Retzius	3 (3%)	1 (1%)	2 (9%)	
Submuscular	88 (86%)	68 (86%)	20 (87%)	
Subscarpas	11 (11%)	10 (12%)	1 (4%)	
Device				.3
AMS 700 (LGX/CX/CXR)	48 (47%)	35 (44%)	13 (57%)	
Coloplast (Titan/NB)	54 (53%)	44 (56%)	10 (43%)	

^{*}Continuous variables are reported as median and interquartile range; categorical variables are reported as number and percent.

between study groups were compared to determine fit with respect to each other: post-RP and post-RCP responses were compared to all other etiologies, and post-RP and post-RCP responses were also compared to each other.

Response distribution comparisons were performed using chisquare analysis. This test was selected in order to compare whether the distribution of the study group fit the distribution of the control group. Distributions were not assessed for normalcy or compared to a third master distribution. All other categorical variables were assessed using the chi-square test. All continuous variables were assessed using Student's *t*-test. A *P*-value of less than 0.05 was considered statistically significant. Descriptive statistics, including mean response and standard deviation, were calculated to assist in the analysis of the clinical difference between groups. All statistics were performed using Microsoft Excel (version 365; Microsoft Corporation; Redmond, WA, USA).

Trial Registration- This trial is registered and approved by the IRB committee at our institution, ID: HSC-MS-19-0320. Surgical and research-informed consent was signed by all patients prior to surgery.

RESULTS

The complete cohort of interest included 102 patients, with 79 patients assigned to the study group (77%) and 23 assigned to the control group (23%). Demographic and clinical/surgical characteristics are reported in Table 1. No significant differences

in any of these characteristics were found when comparing the study group to the control group.

The median age of men in the study group was 66 (IQR 63-71) and 67 (IQR 64.5-73) in the control group. There was no difference in mean age (P=.1). The median BMI was 29.6 (IQR 26.3-31.6) for men in the study group and 30.6 (25.3-32.8) for men in the control group. The distribution of ethnicity (P=.2), penile Doppler results (P=.07), surgical approach (0.9), location of the reservoir (0.1), and device type (0.3) did not differ significantly between the study and control groups. ED etiologies of patients in the control group can be found in Table 2. Of note, some patients' histories included multiple contributing etiologies.

EDITS questionnaire items, along with the measures of significance in the distribution differences between study and control

Table 2. Non-RP and Non-RCP Etiologies of ED in the control group

Etiology	N
Diabetes Mellitus	7
Hypertension	
Organic (unspecified)	
Radiation Therapy	4
Abdominopelvic Resection	
Peyronie's Disease	
Coronary Artery Disease	
Spinal Cord Injury	

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Table 3. EDITS questionnaire components and results of chi-square analysis by item, study vs control

Item	Р	
Q1. Overall, how satisfied are you with this treatment?		
Q2. During the past 4 weeks, to what degree has the treatment met your expectations?		
Q3. How likely are you to continue using this treatment?		
Q4. During the past 4 weeks, how easy was it for you to use this treatment?	-	
Q5. During the past 4 weeks, how satisfied have you been with how quickly the treatment works?	.53	
Q6. During the past 4 weeks, how satisfied have you been with how long the treatment lasts?	.72	
Q7. How confident has this treatment made you feel about your ability to engage in sexual activity?		
Q8. Overall, how satisfied do you believe your partner is with the effects of this treatment?		
Q9. How does your partner feel about your continuing to use this treatment?		
Q10. How natural did the process of achieving an erection feel when you used this treatment over the past 4 weeks?	.76	
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?	.41	
Q12. Do you remember the length of your penis when it was measured in your previous (postoperative) appointment? (% Yes)	.92	
Q13. How satisfied are you with the size of your penis after surgery?		
Q14. Do you believe your overall sexual satisfaction is affected by penile length? (% Yes)	.55	

groups, are recorded in Table 3. Key study questions are shown in bold. Responses to other questions not evaluated in this study are included for completeness. Mean response scores for overall satisfaction with treatment were 3.57 vs 3.48 in the study vs control group, respectively. No significant difference in the distribution of responses was found (P = .96). Mean scores for the meeting of treatment expectations were 3.40 vs 3.35 in the study vs control group, respectively. Again, no significant difference in the response distribution was found (P = .78). Mean scores for confidence in the ability to participate in sexual activity were 3.62 vs 3.52 in the study vs control group, respectively. No significant difference in the response distribution was found (P = .78). Mean responses to key questions are illustrated in Figure 1.

Of the study group, 85% received RP, while 15% received RCP. Responses to key EDITS questions for overall satisfaction,

treatment expectations, and confidence were compared in these 2 populations. These items, along with their corresponding measures of significance, are displayed in Table 4. Mean response scores for overall satisfaction with treatment were 3.64 vs 3.17 in the RP vs RCP group, respectively. No significant difference in the distribution of responses was found (P = .47). Mean scores for the meeting of treatment expectations were 3.48 vs 3.00 in the RP vs RCP group, respectively. A statistically significant difference was found (P = .03), but the clinical significance cannot be established due to the mean responses falling in the same category. Mean scores for confidence in the ability to participate in sexual activity were 3.64 vs 3.50 in the study vs control group, respectively. We observed no significant difference in this response comparison (P = .08). Mean responses to key questions are illustrated in Figure 2.

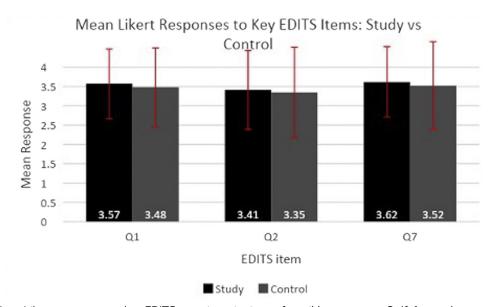


Figure 1. Mean Likert responses to key EDITS questionnaire items (possible responses: 0-4) for study vs control groups.

Table 4. EDITS questionnaire components and results of chi-square analysis by item, RP vs RCP

Item	Р
Q1. Overall, how satisfied are you with this treatment?	.47
Q2. During the past 4 weeks, to what degree has the treatment met your expectations?	
Q7. How confident has this treatment made you feel about your ability to engage in sexual activity?	

DISCUSSION

PPI is now used in the discussion as a treatment option for ED at the initial encounter in our practice, whereas in the recent past, it was used only when conventional treatments had failed. This paradigm shift has occurred at a time when prostate and bladder cancer is increasing in both incidence and prevalence due to better diagnosis, as well as increased survival. As a result, complications of treatment, including post-RP and RCP ED, are becoming more crucial to manage, and PPI has established its place among treatment options. High patient and partner satisfaction is already well-documented in the general population, but it is important to understand any difference in the satisfaction that RP or RCP related ED might be associated with. Our study analyzed patient satisfaction in a granular way, focusing on overall satisfaction with surgery, whether treatment met expectations at a specific point in time postoperatively, and how confident patients are in participating in sexual activity.

Patient Satisfaction

PPI as a treatment for ED has been well-studied, and high satisfaction is reported in the literature. One study followed 126 patients receiving PPI with various etiologies of ED refractory to medical treatment and assessed their satisfaction with the surgery 1 year postoperatively. This study evaluated both patient and

partner satisfaction using one question only. The results of this article demonstrate high satisfaction rates for both patients (83.2%) and partners (85.4%). This article corroborated the high satisfaction rates achieved with PPI and demonstrated that various etiologies of ED could have high satisfaction. Although nearly a quarter of participants in this study (23%) had post-RP ED, the study did not specifically analyze satisfaction by etiology. Our study corroborates these findings by reporting a high mean item response for the EDITS satisfaction question in both study and control groups.

2 studies evaluated PPI satisfaction rates in patients specifically with post-RP ED. The first study compared these patients to a control group with vasculogenic ED. Patients in the post-RP study group had lower satisfaction scores both before and after prosthesis implantation compared to those in the vasculogenic control group. However, there was no significant difference in overall satisfaction. This data reveals possible underlying confounders as to why post-RP patients may be thought to have lower satisfaction; they may have a lower quality of life at baseline. However, PPI therapy in particular remains a treatment option that nevertheless functions extremely well as a tool for increased patient quality of life regardless of ED etiology. The second study consisted of patients with solely post-RP ED and evaluated their satisfaction with PPI treatment using a combination of metrics, including erectile function (EDITS), quality of

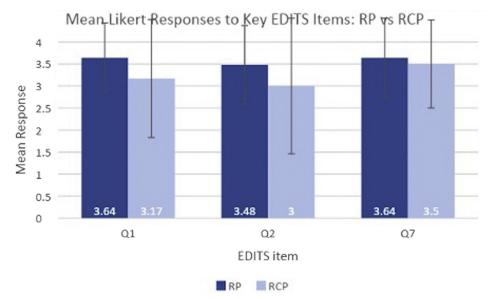


Figure 2. Mean Likert responses to key EDITS questionnaire items (possible responses: 0-4) for RP vs RCP subgroups.

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life assessments, and mental health questionnaires (GAD-7, PHQ-9). Results demonstrated high satisfaction and erectile function scores but noted that better scores were correlated with mental health function, suggesting that adjunct mental health therapy may be of use in increasing patient satisfaction following PPI for post-RP ED. ¹⁴ Our study revealed high satisfaction with no significant difference in response distribution between study and control groups, findings that are in agreement with the literature.

Patient Expectations

Whether a particular treatment meets expectations is not quite the same as satisfaction. For example, a patient who has received a prosthetic for ED may be able to penetrate, perceive appropriate length, or have a satisfied partner. However, they may have had expectations beyond their reality, even if they are able to satisfactorily participate in sexual activity. Studies show that proper management of patient expectations prior to prosthesis implantation yields better satisfaction following the surgery. 6 Conversely, patients whose expectations are not managed appropriately may have lower postoperative satisfaction. This study, in part, sought to examine whether post-RP or RCP patients are less satisfied as a result of their expectations. One study suggests that patients who are post-RP may tend toward unrealistic expectations in terms of sexual function. The authors concluded that this might be a result of patients not remembering, or being insufficiently aware of, information that was given prior to surgical intervention. This creates a problem for men with post-RP or RCP ED because the unrealistic expectations are being generated at the level of the RP or RCP, not the PPI. 15 However, these results were not found in our patient population. PPI treatment appears to meet patient expectations equally, whether post-RP or RCP or otherwise. Interestingly, a significant difference in response distribution did exist between post-RP and post-RCP patients themselves. Combined with the lack of significant difference between post-RP and RCP vs other etiologies, this provides further support for the idea that expectations are dependent on surgical counseling at the time of ablative surgery, rather than the PPI. Notably, this significant difference in response distribution has unclear clinical significance, as the mean response fell into the same category.

Patient Confidence

Several of the studies performed in men with ED and particularly post-RP ED have touched on the underlying psychological issues that may play a role in sexual dysfunction. In particular, ED patients who are suffering from a severe disease like prostate cancer may be more susceptible due to the increased stresses in their day to day life. As a result, it is reasonable to expect that confidence in sexual activity could be decreased at baseline in these patients. However, this has not been reported in the literature, and our own data suggest that the reality is the

opposite; men with post-RP ED in our study report similar confidence in their ability to participate in sexual activity as those with other etiologies of ED following PPI.

Cystoprostatectomy

The literature is lacking in studies that specifically report PPI satisfaction after RCP. However, it is important to identify the unique challenges faced by these patients in terms of sexual function. One study evaluated the quality of life in Tunisian men receiving RCP. According to this study, these patients tend to have a low quality of life following RCP, with 77.5% of patients reporting a "very low" quality of life. 16 There are several explanations provided for this finding. Patients not only have sexual issues from the surgical procedure but are required to deal with a multitude of urinary problems, physical difficulties, and social limitations due to their new urinary diversion. Psychological issues exist as well, including feelings of being unwanted or a burden on their families or caregivers. Penile rehabilitation in post-RCP patients has been described, but these strategies consisted of medical therapy with sildenafil rather than a surgical intervention with PPI.¹⁷ Our study included patients with post-RCP ED as part of the study group; it is the first study, to our knowledge, that revealed no statistically significant differences between overall satisfaction and sexual confidence between post-RP and post-RCP patients, although there was a statistically significant difference, with unknown clinical impact, in whether treatment met expectations between these groups.

Limitations

There are several limitations to this study. First, many of our patients received PPI at an institution focused on cancer care. Therefore, the distribution of ED etiology differed significantly from the general population, with postprostatectomy ED heavily over-represented.¹⁸ This led to a small control group with potentially limited generalizability compared to the general population. Our analysis demonstrated no significant differences between the 2 populations studied, but the further multicenter study would benefit from a larger sample size for patients with more diverse etiologies. Second, the study was dependent on patient responses for data, which presents a challenge since this introduces the possibility of reporting bias. For example, patients who were truly more satisfied with their results may have been more likely to respond, while those who were dissatisfied may have been lost to follow up and disregarded the survey request. The converse may be true as well, with those who were more dissatisfied potentially more inclined to let their thoughts be known compared to those who were moderately or greatly satisfied. Finally, due to the relatively short follow-up time, this study did not consider complications and the possible effects these might have had on satisfaction. Further studies may more closely examine the role of infection, mechanical complication, erosion, and other complications of treatment on long-term satisfaction.

CONCLUSIONS

Our analysis suggests that the distribution of responses to the EDITS questionnaire regarding overall satisfaction and confidence following PPI are not significantly different between patients whose etiology of ED is postprostatectomy compared to all other etiologies. However, patients with a history of radical cystoprostatectomy may benefit from more consultation prior to PPI since they have a greater tendency to report unmet expectations compared to those with a history of radical prostatectomy. Further studies may focus on long-term satisfaction with larger cohort sizes and increased time surveillance.

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