Impact of penile prostheses and intracavernosal injections on psychosocial functioning

Paul H. Chung, MD,¹ Andrew Salib, MD,¹ Taylor Tidwell, BS,¹ Kaitlin Berry, BS,¹ Joon Yau Leong, MD,¹ Rosemary Frasso, PhD²

¹Department of Urology, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania, USA ²College of Population Health, Thomas Jefferson University, Philadelphia, Pennsylvania, USA

CHUNG PH, SALIB A, TIDWELL T, BERRY K LEONG JY, FRASSO R. Impact of penile prostheses and intracavernosal injections on psychosocial functioning. *Can J Urol* 2022;29(1):10969-10975.

Introduction: Prior studies evaluating the efficacy of penile prostheses (PP) and intracavernosal injections (ICI) have focused predominantly on sexual function, not psychosocial health. We utilized the freelisting technique and the Self-Esteem and Relationship (SEAR) questionnaire to evaluate the impact of PP and ICI treatments on psychosocial functioning.

Materials and methods: IRB-approval was obtained to perform an evaluation of patients who underwent PP or ICI treatment for erectile dysfunction (ED). Using a modified freelisting approach, participants were asked to give three one-word responses to questions about sexual function and relationships. Participants also completed the SEAR questionnaire and results were calculated based on the previously described formulas.

Results: Fifty patients agreed to participate in the study (25 ICI, 25 PP). In the freelisting portion of the

Introduction

The interest in men's mental and physical health has increased in the past decades due to differences in life expectancy and health care seeking behavior between

Accepted for publication December 2021

Address correspondence to Dr. Paul H. Chung, Department of Urology, Sidney Kimmel Medical College, Thomas Jefferson University, 1025 Walnut St. Ste. 1100, Philadelphia, PA 19107 USA study, PP patients had more positive responses than ICI patients in 2 out of 3 questions. The freelisting study also identified important areas of concern for ED patients such as self-esteem, confidence, and treatment reliability. PP patients reported numerically higher SEAR total scores than ICI patients (63.9 vs. 53.9, p = 0.12), especially in confidence with duration of (p = 0.003), satisfaction with sexual performance (p = 0.02). SEAR confidence domain (p = 0.83), self-esteem subscale (p = 0.68), and overall relationship sub-scales (p = 0.90) were similar between PP and ICI patients.

Conclusions: PP appears to have a stronger psychosocial impact compared to ICI; however, both PP and ICI patients continue to struggle with self-esteem, confidence, and treatment reliability. Further patient counseling before and after treatment may help to address these concerns and improve patient satisfaction.

Key Words: erectile dysfunction, penile prosthesis, intracavernosal injections, psychosocial health

men and women.¹ With the passing of the affordable care act in 2010, multispecialty men's health centers were created to meet the demand of a newly insured population.² A common chief complaint seen by urologists in those health centers is erectile dysfunction (ED), which can have a strong impact on a patient's mental and physical health. ED can be the first sign of underlying cardiovascular disease (CVD) and can prompt evaluation of CVD risk factors. Beyond the physical health, ED can have significant psychosocial impact as it can affect patient's relationships, self-esteem, and confidence.²

ED treatments vary in invasiveness and are tailored based on disease severity and patient's treatment goals.³ Two treatments of interest in this study are penile prosthesis (PP) and intracavernosal injections (ICI) which are considered second line treatments after failure of behavior medication and oral phosphodiesterase 5 inhibitors.³ PP and ICI have been studied extensively to determine the success of each treatment on sexual function.^{4,5} Prior studies have suggested that PP patients have better erectile function than patients using ICI or oral phosphodiesterase 5 inhibitors.⁴ However, the psychosocial effects of the treatments have not been as well studied due to the subjective nature of the measurement and the lack of comprehensive questionnaires.

In this study we utilized a freelisting method and the Self-Esteem and Relationship (SEAR) questionnaire to delineate the impact of ED treatments on the psychological and social aspects of patients' lives.⁶ Feelisting is a research tool which quickly evaluates how particular groups of people think about a specific domain and can identify shared experiences.^{7,8} SEAR is a validated questionnaire which evaluates sexual relationship, confidence, self-esteem, and overall relationships.⁶ We hypothesized that PP would have a greater psychosocial impact on patients compared to ICI.

Materials and methods

Study design and patient population

This study was conducted with patients from the practice of a single surgeon at a tertiary academic center. Institutional review board approval was obtained to retrospectively identify patients who underwent treatment with either PP or ICI and contact them by phone. Patients who were willing to proceed with phone interviews provided verbal consent. Participants were informed that the interview responses would be transcribed and used for research purposes. All participants were given the opportunity to decline participation or terminate the interview at any point. Retrospective chart review was performed for patients who completed the telephone interview.

Data collection

An interview guide was developed and piloted by the research team. The interview included both a freelisting component and the SEAR questionnaire.⁶ The basis for freelisting is that individuals who had a shared experience will have a common understanding of a certain domain.⁹ A freelisting study was selected to distinguish perceptions of ED treatment within and between patients treated with PP and ICI. Participants generated a list of three words in response to the following questions during semi-structured interviews with a trained research assistant: what are some words 1) that describe how your current sexual function makes you feel, 2) that come to mind which describe your ability to have sex by yourself or with others, and 3) that describe your intimate relationships with others? The use of three single words has been utilized with precedence.¹⁰⁻¹²

Data analysis

Freelists for each question were reviewed by the research team to combine root words, synonyms, and words with similar meaning. For example, the words satisfying, satisfactory, and satisfied were all classified as satisfied.^{7,9} The lists were reviewed to determine the frequency of responses, and words that appeared at least four times were reported in this study. All words regardless of frequency, were then categorized as having positive or negative connotation. Additionally, lists were sorted by respondent type, that is separate lists were created for both PP and ICI participants to allow for comparisons.

Reponses to the SEAR questionnaire were recorded on a 1-5 scale.⁶ Domains (i.e., sexual relationship and confidence), subscales (i.e., self-esteem, overall relationships), and total score were computed by summing their respective items, Table 1. Each score was transformed onto a 0-to-100-point scale (0 = least favorable, 100 = most favorable) using the following formula [(raw score-lowest possible score)/raw score range] x100.

Demographics and transformed SEAR scores were compared between the PP and ICI groups using a twotailed T-test and chi-square analyses.

Results

Participant demographics

A total of 113 patients were identified as candidates for the study, out of which 64 (57%) patients spoke with our researchers and initiated the survey. Fifty participants (25 PP and 25 ICI) completed interviews between August 2020 and January 2021. Forty-six participants (22 PP and 24 ICI) were included in the final analysis. Three PP patients were excluded due to the following: two had not yet utilized their device and another participant had his device removed due to infection. One ICI patient was excluded due to incomplete data. Average age, ethnicity, relationship status were similar between the two cohorts, Table 2.

SEAR questions		Intracorporeal injections (Mean ± SD)	Penile protheses (Mean ± SD)	p value
1.	I felt relaxed about initiating sex with my partner.	3.3 ± 1.5	3.9 ± 1.5	0.23
2.	I felt confident that during sex my erection would last long enough.	2.8 ± 1.7	4.2 ± 1.4	0.004
3.	I was satisfied with my sexual performance.	2.7 ± 1.5	3.5 ± 1.5	0.06
4.	I felt that sex could be spontaneous.	3.0 ± 1.5	3.5 ± 1.5	0.26
5.	I was likely to initiate sex.	3.5 ± 1.4	4.0 ± 1.3	0.18
6.	I felt confident about performing sexually.	3.0 ± 1.4	4.1 ± 1.4	0.02
7.	I was satisfied with our sex life.	2.6 ± 1.6	3.2 ± 1.6	0.18
8.	My partner was unhappy with the quality of our sexual relations.	2.3 ± 1.4	2.1 ± 1.2	0.75
9.	I had good self-esteem.	3.8 ± 1.1	3.8 ± 1.4	0.97
10	. I felt like a whole man.	3.7 ± 1.3	4.1 ± 1.2	0.29
11	. I was inclined to feel that I am a failure.	2.0 ± 1.3	1.8 ± 1.2	0.55
12	. I felt confident.	3.6 ± 1.2	3.8 ± 1.3	0.60
13	. My partner was satisfied with our relationship in general.	3.9 ± 1.0	3.9 ± 1.1	0.96
14	. I was satisfied with our relationship in general.	3.9 ± 1.2	3.8 ± 1.5	0.80
D	omains scores			
Se	xual relationship (Q1-8)	47.5 ± 26.0	64.1 ± 27.1	0.04
Сс	onfidence (Q9-14)	62.5 ± 16.7	63.6 ± 18.9	0.83
Su	ibscale scores			
Se	lf-esteem (Q9-12)	57.6 ± 16.0	59.8 ± 20.1	0.68
	verall relationship (Q13-14)	72.4 ± 25.0	71.3 ± 31.6	0.90
То	tal SEAR score	53.9 ± 20.4	63.9 ± 22.4	0.12

Prostate cancer (n = 18, 39.1%) and DM (n = 7, 15.2%) were the leading causes of ED. PP patients on average suffered from ED for a longer period than patients on ICI (average 5.6 vs. 2.7 years, p = 0.005).

Freelisting questionnaire

Frequency of words with at least four responses are reported in Table 3. A sub analysis of the responses was then performed dividing the responses into overall positive or negative sentiments. For freelisting question 1 (What are some words that describe how your current sexual function makes you feel?) 50 responses were positive for PP compared to 40 for ICI (p = 0.53) while negative responses were 23 for PP and 42 for ICI (p = 0.36). For freelisting question 2, (What are some words that come to mind that describe your ability to have sex by yourself or with others?) positive responses for PP vs. ICI were 39 vs. 34, p = 0.41 compared to negative responses (14 vs. 22, p = 0.24). For freelisting question 3 (What are some words that describe your intimate relationships with others?) positive and negative responses for ICI compared to PP were 47 vs. 45, p = 0.96and 10 vs. 9, p = 0.91, respectively.

SEAR questionnaire

PP patients reported numerically higher total SEAR scores than ICI patients (63.9 vs. 53.9, p = 0.12), Table 3. PP patients reported higher sexual relationships domain scores than ICI patients (64.1 vs. 47.5, p = 0.04), especially in question 2 (I felt confident that during sex my erection

	Intracorporeal injections	Penile prostheses
Average age (years)	63.2	64.0
Ethnicity		
White	15	13
African American	6	7
Hispanic	1	2
Other	2	0
Relationship status		
Married/partner	18	14
Single	2	3
Other	4	5
Cause of erectile dysfunction		
Radical prostatectomy	10	8
Radiation for prostate cancer	0	2
Cardiovascular disease	4	2
Diabetes	5	2
Other	5	8
Duration of erectile dysfunction		
1-5 years	24	16
6-10 years	0	4
> 10 years	0	2
Total	24	22

TABLE 2. Demographics of patient population

would last long enough) (p = 0.003), question 3 (I was satisfied with my sexual performance) (p = 0.06), and question 6 (I felt confident about performing sexually) (p = 0.02). Confidence domain (p = 0.83), self-esteem subscale (p = 0.68), and overall relationship sub-scales (p = 0.90) were similar between PP and ICI patients.

Discussion

ED is a disease with significant psychological and social burden which can persist despite treatment. ED has emotional and psychological aspects and can lead to emasculation, depression, and decreased self-confidence.¹³⁻¹⁵ Erectile function is also meaningful, due to its integral nature with interpersonal relationships.⁶ Patients with ED often report that they are letting down their partners, have anxiety that their partners may go elsewhere, and are unable to discuss the problem with their partners. When patients undergo treatment for ED, they report happiness and a return to manhood, and conversely report severe disappointment when treatments fail .^{16,17} Outcomes of ED treatments have focused on the functional problem with good success in improving erectile function; however, few studies

have evaluated the psychosocial aspects of ED. In this study, we evaluate patients' psychosocial health post treatment using two well studied research methodologies.

Freelisting technique is a research method developed by the field of anthropology to examine the population's perception of a certain topic.⁸ Using this method, the researchers ask the subjects a series of open-ended questions and the answers are compiled and then frequency of different terms used in the answers is analyzed.8 Analysis of different answers provides insight into the subjects' perspective on the topic and is a helpful tool for the measurement of qualitative and subjective parameters. Freelisting technique has gained popularity in medicine to assess patients' perspectives on their disease states and treatment such as in the field of psychiatry evaluating depression and ADHD or in primary care evaluating factors preventing medication compliance.9 Drawing from the experience of previous studies, we utilized the freelisting technique to assess the effect of ED treatment on patients' psychosocial domain with the goal of uncovering treatment side effects which are poorly examined.

	-	
	Intracorporeal injections	Penile prostheses
Question 1: What are some words that describe how your current sexual function makes you feel?		
у у У	Positive $(n = 13)$ Satisfied $(n = 12)$ Confident $(n = 5)$ Dependable $(n = 5)$ Nervous $(n = 4)$ Nonfunctional $(n = 4)$ Unsatisfied $(n = 4)$	Positive $(n = 9)$ Satisfied $(n = 6)$ Excited $(n = 4)$ Fine $(n = 4)$ Nonfunction $(n = 4)$
Question 2: What are some words that come to mind that describe your ability to have sex by yourself or with others?		
	Positive (n = 7) Dependable (n = 5) Unsatisfied (n = 4) Confident (n = 4)	Nonfunction (n = 5) Dependable (n = 5) Positive (n = 4)
Question 3: What are some words that describe your intimate relationships with others?		
	Positive $(n = 7)$ Satisfied $(n = 7)$	Positive (n = 9) Satisfied (n = 8) Love (n = 8)

TABLE 3. Frequency of freelisting words with at least four responses

Our study utilized freelisting to shed light on ED patients' perspective on treatment success. We used 3 open-ended questions to evaluate patients post ED treatment. PP patients numerically had more positive and fewer negative responses than ICI patients. Freelisting also identified other important domains for patients. For example, having a dependable device and feeling confident and not nervous with using the device or injection are important factors that may not be regularly evaluated postoperatively by urology providers. This finding is consistent with Althof et al who identified that to an ED patient being able to obtain an erection might not be the sole measure of treatment success, and other factors such as ease of use, pain, partner comfort, self-esteem, lack of spontaneity, or feeling of being unnatural can lead to dissatisfaction with treatment.¹⁸ Pre-treatment counseling and discussion of treatment side effects and expectations can gauge patients' expectations and possibly lead to increased treatment satisfaction. Post-treatment, patients may benefit from continued counseling and a deeper dive into how the patient is doing on a deeper level, not just evaluating whether the PP cycles or how strong of an erection ICI may produce.

Many studies use patient questionnaires, administered at different treatment points to evaluate treatment success and side effects. In the field of sexual medicine, multiple questionnaires have been developed to assess treatment satisfaction, such as Erectile Dysfunction Treatment Inventory for Treatment Satisfaction (EDITS), Erectile Function Domain (EFD), International Index of Erectile Function (IIEF), Sexual Quality of Life Instrument for Men (SQoL-M), Quality of Life and Sexuality with Penile Prosthesis (QoLSPP), and SEAR.^{4,6,14,16,17,19,20-23} For this study, we chose SEAR due its comprehensive nature in evaluating the psychosocial impact of ED treatment within two domains (sexual relations and confidence), with the latter being divided into two subsets (selfesteem and overall relationships).

Using the SEAR questionnaire, PP patients had overall higher total scores and sexual relationship and self-esteem domain scores. Our study results are consistent with previous studies which used post treatment questionnaires to evaluate satisfaction between PP and ICI. Rajpurkar et al used three different questionnaires (EDITS, EFD, IIEF) to compare PP, ICI, and oral medications, with PP patient outscoring ICI and oral medications patients in all three questionnaires.⁴ Reduced satisfaction with ICI treatment can lead to noncompliance and treatment dropout.^{21,24} Sexton et al and Mulhall et al identified noncompliance factors such as lack of spontaneity, treatment cost, inadequate erections, and treatment side effects.^{21,24} Sexton et al also compared compliance rates in ICI to PP and found that only 41% of ICI were compliant with treatment as opposed to 70% PP patients.²¹

The freelisting method and the SEAR questionnaire uncovered the psychological side of ED that is not solely resolved by a stronger erection. In our study, PP had better response rates in the freelisting and SEAR questionnaire portion than ICI treatment; however, urologists need to take more steps to improve treatment satisfaction. Pre- and post-treatment sex therapy is one strategy that has been proposed by other studies to improve sexual satisfaction. Schover et al described pre-implantation and post-implantation sexual counseling with patients and their partners.²⁵ Pre-treatment sexual therapy can also identify patient who are at higher risk of negative psychological side effects of treatments and recommend closer follow up postoperatively to assess patient and partner satisfaction.²⁶ Sex therapy was also applied to ICI patients to reduce dropout rates and medications misuse with good success.

Limitations of our study include a small sample size and a short study period from a single institution which may limit generalization to other clinical settings. Differences in health literacy, health insurance status, and socioeconomic status may also differ in our cohorts. This may be a contributing factor as satisfactory treatment of ED may require several clinic visits and out of pocket expenses. PP are not always covered by insurance, while ICI are widely not covered. A longer study period could show changes in the patients' responses to the free listing questions as they become more familiar with PP or ICI. Freelisting is a rapid technique which infers ideas from word lists. Bias may have been introduced by the team during data cleaning. Furthermore, freelisting is limited in depth since only words or phrases are collected from the perspective of the individual. The SEAR questionnaire was validated in patients who underwent treatment with phosphodiesterase 5 inhibitors, but not intracavernosal injections or penile prostheses. The intent of this present study is to shed light on the experiences of patients undergoing ED treatment with PP and ICI and open the door for quantifiable and more generalizable studies in the future.

Conclusions

PP appears to have a stronger psychosocial impact compared to ICI. PP patients reported higher sexual function SEAR domain scores and appear to have greater positive sentiment of their sexual function. However, several participants were nervous, lacked self-confidence, and reported no improvements with treatment. Additional patient counseling before and after treatment in addition to close postoperative follow up may help to improve patient satisfaction and self-perception. More research is needed to identify patients at higher risk of treatment failure and to develop strategies to improve treatment success.

References

- 1. Weiner PR, Salib A. Developing a men's health program. *Can J Urol* 2020;27(S3):51-53.
- Lee RK, Chughtai B, Te AE, Kaplan SA. Sexual function in men with metabolic syndrome. Urol Clin North Am 2012;39(1):53-62.
- Burnett AL, Nehra A, Breau RH et al. Erectile dysfunction: AUA guideline. J Urol 2018;200(3):633-641.
- Rajpurkar A, Dhabuwala CB. Comparison of satisfaction rates and erectile function in patients treated with sildenafil, intracavernous prostaglandin E1 and penile implant surgery for erectile dysfunction in urology practice. *J Urol* 2003;170(1): 159-163.
- 5. Villarreal HG, Jones L. Outcomes of and satisfaction with the inflatable penile prosthesis in the elderly male. *Adv Urol* 2012;2012:240963.
- 6. Cappelleri JC, Althof SE, Siegel RL, Shpilsky A, Bell SS, Duttagupta S. Development and validation of the Self-Esteem And Relationship (SEAR) questionnaire in erectile dysfunction. *Int J Impot Res* 2004;16(1):30-38.
- 7. Keddem S, Barg FK, Frasso R. Practical guidance for studies using freelisting interviews. *Prev Chronic Dis* 2021;18:E04.
- Frasso R, Keddem S, Golinkoff JM. Qualitative Methods: Tools for Understanding and Engaging Communities. In: Cnaan RA, Milofsky C, eds. Handbook of Community Movements and Local Organizations in the 21st Century. Cham: Springer International Publishing, 2018:527-549.
- Fiks AG, Gafen A, Hughes CC, Hunter KF, Barg FK. Using freelisting to understand shared decision making in ADHD: parents' and pediatricians' perspectives. *Patient Educ Couns* 2011;84(2):236-244.
- John CC, Ayodo G, Musoke P. Successful global health research partnerships: what makes them work? *Am J Trop Med Hyg* 2016; 94(1):5-7.
- Holiday S, Norman MS, Cummins RG, Hernandez TN, Holland D, Rasmussen EE. Television advertising's influence on parents' gift-giving perceptions. J Consum Market 2018;35(7):665-675.
- Bower SD, Aas Ø, Arlinghaus R et al. Knowledge gaps and management priorities for recreational fisheries in the developing world. *Reviews in Fisheries Science & Aquaculture* 2020;28(4):518-535.
- 13. Althof SE. Quality of life and erectile dysfunction. *Urology* 2002;59(6):803-810.

- 14. Araujo AB, Durante R, Feldman HA, Goldstein I, McKinlay JB. The relationship between depressive symptoms and male erectile dysfunction: cross-sectional results from the Massachusetts Male Aging Study. *Psychosom Med* 1998;60(4):458-465.
- 15. Seidman SN, Roose SP. The relationship between depression and erectile dysfunction. *Curr Psychiatry Rep* 2000;2(3):201-205.
- Tomlinson J, Wright D. Impact of erectile dysfunction and its subsequent treatment with sildenafil: qualitative study. *BMJ* 2004;328(7447):1037.
- Chierigo F, Capogrosso P, Deho F et al. Long-term follow-up after penile prosthesis implantation-survival and quality of life outcomes. J Sex Med 2019;16(11):1827-1833.
- Althof SE, Corty EW, Levine SB et al. EDITS: development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. *Urology* 1999;53(4):793-799.
- Adrianne R, Pairoux J-F, Debois C, Mormont C, Coppens L, Kempeneers P. Patient satisfaction and retrospective evaluation of benefits of penile prosthetic implantation surgery: the OEDIPUS study. *Ann Med Medical Res* 2018;1:1002.
- 20. Kucuk EV, Tahra A, Bindayi A, Onol FF. Erectile dysfunction patients are more satisfied with penile prosthesis implantation compared with tadalafil and intracavernosal injection treatments. *Andrology* 2016;4(5):952-956.
- 21. Sexton WJ, Benedict JF, Jarow JP. Comparison of long-term outcomes of penile prostheses and intracavernosal injection therapy. J Urol 1998;159(3):811-815.
- 22. Jorissen C, De Bruyna H, Baten E, Van Renterghem K. Clinical outcome: patient and partner satisfaction after penile implant surgery. *Curr Urol* 2019;13(2):94-100.
- 23. Caraceni E, Utizi L. A questionnaire for the evaluation of quality of life after penile prosthesis implant: quality of life and sexuality with penile prosthesis (QoLSPP): to what extent does the implant affect the patient's life? *J Sex Med* 2014;11(4): 1005-1012.
- Mulhall JP, Jahoda AE, Cairney M et al. The causes of patient dropout from penile self-injection therapy for impotence. *J Urol* 1999;162(4):1291-1294.
- 25. Schover LR. Sex therapy for the penile prosthesis recipient. *Urol Clin North Am* 1989;16(1):91-98.
- 26. Schover LR, von Eschenbach AC. Sex therapy and the penile prosthesis: a synthesis. *J Sex Marital Ther* 1985;11(1):57-66.