

INFRAPUBIC VERSUS SUBCORONAL SEMI-RIGID PENILE PROSTHESIS IMPLANTATION: A PROSPECTIVE STUDY

By

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ABSTRACT

Background: Medical treatment accomplished good results in the treatment of erectile dysfunction (ED). However, these results were temporary, whereby approximately 80% of the patients experienced drop out. Penile prosthesis insertion is an outstanding treatment for patients with ED who are refractory to medical treatment or those who desired to leave off pharmacotherapy to gain lasting treatment.

Objectives: To assess the safety, efficacy, and sexual and psychological satisfaction among patients with ED who were subjected to subcoronal or infrapubic penile prosthesis implantation.

Patients and Methods: The present study was a prospective case-control study that was carried out at Al-Azhar University Hospitals through the entire period of 2016 to 2020. Men with ED that did not respond to medical treatment and had vasculogenic impotence based on penile duplex were included in the study. All patients were submitted to clinical evaluation comprised of detailed sexual and urological history, and physical evaluation. All patients were subjected to frequent follow-up assessment visits for six months after the surgery.

Results: This study included a total of 18 patients with ED. Out of them, 9 (50%) patients were subjected to the infrapubic approach, while 9 (50%) patients were treated with the subcoronal approach. Three months postoperatively, all men revealed an average penile length at maximum inflation of 13.4 cm (9.3-17.5 cm). This status was continued for six months in which no patient lost his penile length. Among patients treated with the subcoronal approach, one patient developed penile extrusion one and half months post-operatively due to wound dehiscence secondary to uncontrolled DM. As for the infrapubic group, a patient developed superficial infection and wound dehiscence and responded to antibiotic use and secondary suturing. Another case developed a hypertrophic scar.

Conclusion: Erectile dysfunction can be safely and effectively treated by implantation of the penile prosthesis by the subcoronal approach. This approach achieved high satisfactory functional, aesthetic, and psychological outcomes relative to the infrapubic approach.

Keywords: Erectile Dysfunction. Subcoronal, Infrapubic, Penile Prosthesis.

INTRODUCTION

Penile prosthesis accomplished superior sexual satisfaction for both patient and partner when compared with other therapeutic methods of ED

(Bettocchi *et al.*, 2010). Based on these benefits, the American Urological Association proposed that all erectile dysfunction patients should be aware of the potential advantages of penile

prosthesis as a therapeutic approach (Burnett *et al.*, 2018).

Abundant variations of the inflatable prosthesis procedures have been evolved comprehending penoscrotal, suprapubic, perineal, infrapubic and subcoronal approaches (Trost *et al.*, 2015). The subcoronal approach has the benefits of low risk of crossover during corporal dilatation along with preferable cosmetic results and low risk of infection (Weinberg *et al.*, 2016). The infrapubic approach has two main advantages apart from the capability to implant the reservoir more quickly under immediate vision via the same incision, as well as avoidance of additional incisions to the scrotum (Karpman, 2012 and Vollstedt *et al.*, 2017). Conversely, numerous disadvantages had been reported such as restricted distal corporal exposure, damage to the dorsal nerve of the penis, and difficulties to access to the most dependent portion of the scrotum to fix the pump (Kramer & Chason, 2010 and Antonini *et al.*, 2016). Throughout the literature search, no study has been implemented to compare the outcomes of the subcoronal and the infrapubic approaches for the treatment of ED.

The current investigation was conducted to reveal the safety, efficacy, and sexual and psychological satisfaction among patients with ED who were subjected to the subcoronal or the infrapubic penile prosthesis implantation.

PATIENTS AND METHODS

The present study was a prospective case-control study that was carried out at Al-Azhar University Hospitals through the entire period of 2016 to 2020. All clinical

and surgical procedures were conducted along with the recommendations of the ethical research board committee of the Faculty of Medicine, Al-Azhar University, Cairo, Egypt, after an obvious explanation of the probable consequences and adverse events of the surgical procedures. All patients were aware of the potential adverse events apart from the loss of penile length, mechanical reliability, infection rates, and the risk of injury to adjacent structures such as the urethra, bladder, bowel, and vessels.

Prior to study implementation, all patients assigned informed consents to elucidate their agreement to participate in the current investigation and their prior knowledge of the possible sequels. Men with ED who did not respond to medical treatment for at least six months and had vasculogenic impotence based on penile duplex were included in the study. Penile duplex was performed by the andrologist who interpret the results of it. On the other hand, patients with urinary incontinence, penile deformities, patients subjected to previous penile or urethral surgery, patients subordinated to simultaneous surgeries for congenital or acquired recurvatum, marked obese candidates, patients with neurogenic impotence, and patients with massive obstructive urinary tract symptoms were omitted. Prior to the surgical intervention, patients with intense infection, principally urinary tract infection or genital skin infection or those who unfit for surgery, were excluded.

Preoperative detailed counseling with patients about their medical condition and details of surgical intervention was implemented. They received post-operative instructions discussing the

benefits of the procedure to realize the satisfaction of the patient and outcomes which normalize the sexual cycle. In some cases, we required counseling in the presence of his wife after his permission. The counseling was done in three sessions from the first meeting, the second session after obtaining the results of the investigations, and the last preoperative to roll out any criteria of psychological illness. All clinical complaints from the wife about vaginal looseness or widening, especially in repeated pregnancy cases, were put into consideration to achieve the normal sexual cycle to correct the problem from a comprehensive overview of both partners.

All patients were submitted to clinical evaluation comprised of detailed sexual and urological history and physical evaluation. The laboratory assessment was executed, including urine analysis, serum testosterone, prolactin, prostate-specific antigen levels, blood profile, liver functions, renal functions, fasting blood sugar, and glycosylated hemoglobin.

Preoperatively, a doppler ultrasound assessment was done for all patients to appreciate the penile hemodynamics before and after intracavernous injection

of prostaglandin E1. Additionally, erectile length was assessed via a flexible tape that extended from the penis up to the coronal sulcus.

Surgical procedure:

Infrapubic approach: Closure to the penile root, a transverse skin incision of 2.5-4 cm was performed at the level of the lower border of the symphysis pubis. The corpora were exposed using two retractors, emphasizing avoiding the injury of the neurovascular bundle and suspensory ligaments. Two lateral stay silk sutures were applied in the starting corpora then corporotomy vertical incision (2 cm) was performed. Furthermore, subtunical dilation of the corpora with penile stretching using heggar dilators in an upward and lateral direction to avoid urethral injury. The measurements were taken while the penis was maximally lengthened. Continuous irrigation with gentamycin and saline proximally and distally was implemented. After adequate measurements, the cylinder was positioned. Corpora were closed in a continuous pattern followed by the closure of the remaining layers separately (**Figure 1**).



Figure (1): Patient with ED who subjected to infrapubic approach. A. During pre-operative evaluation, B. Immediate post-operative results with transverse skin incision after implant positioning.

Subcoronal approach: A distal dorsal semi circumcisional " subcoronal" skin incision was performed 2 cm proximal to the coronal sulcus of glans penis. The glans penis was, subsequently, grasped in the surgeon's non-dominant hand, and a special gauze was used to dissect in the subdartos plan towards the penis base. Stay sutures of braided polyglactin (Vicryll 00) were positioned to retract the dissected flap followed by corpotomy. Furthermore, Metzenbaum scissors were

passed away in a posterior direction to the mid glans. The furrow instrument was passed proximally and distally into the channel opened by the scissors to assess the distal and proximal measurements. After adequate measurements, the proximal end of the prosthesis was embedded into the corpora close to the penoscrotal junction. The distal end of the prosthesis was pulled through the remaining corpora towards the mid glans (**Figure 2**).

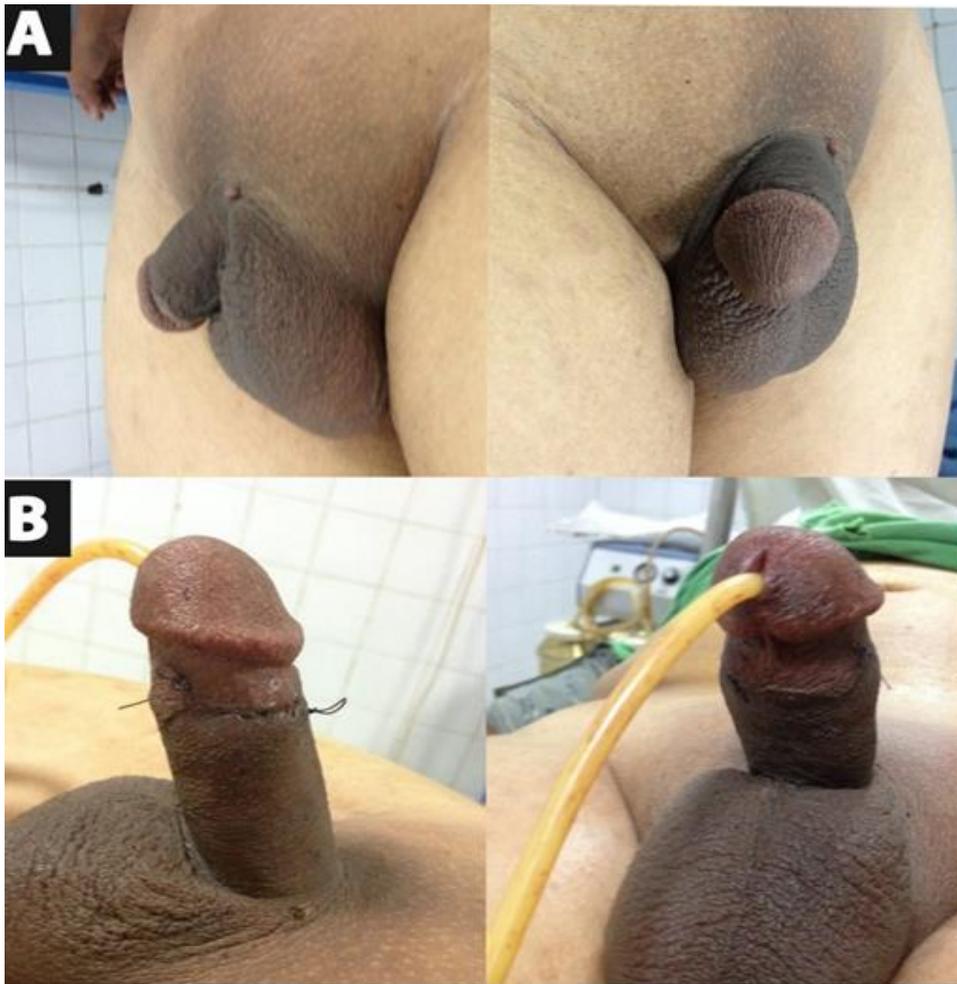


Figure (2): Patient with ED who was subjected to subcoronal approach. A. During Preoperative evaluation, B. Immediate results after closing of the subcoronal incision at the end of surgery.

All patients received broad-spectrum antibiotics and alpha-blockers to decrease post-intervention urinary manifestations. All patients were subjected to frequent follow-up assessment visits for six months after the surgery.

Statistical analysis:

Continuous normally distributed data were reported in the form of mean, and standard deviation (SD), and its related groups were compared using independent

sample t-test. Categorical variables were expressed using number and percentage and its particular groups were compared using Fisher's exact test. The overall statistically significant difference was established at $p < 0.05$. Statistical analysis was performed using SPSS software version 25 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

Patients' demographic characteristics:

This study included a total of 18 patients with ED. Out of them, 9 (50%) patients were subjected to the infrapubic approach, while 9 (50%) patients were treated with the subcoronal approach. The mean age of the included patients was 53.5 ± 9.8 and

52.1 ± 10.6 years among the infrapubic and the subcoronal groups, respectively. There were 2 (22.22%) diabetic cases within the infrapubic group, in contrast to 3 (33.33%) patients within the subcoronal group (**Table 1**).

Table (1): Baseline demographic characteristics of the included patients

Variables	Groups		P-Value
	Infrapubic approach	Subcoronal approach	
	Mean +SD/Number (%)	Mean +SD/Number (%)	
Number	9	9	
Age	53.5 ± 9.8	52.1 ± 10.6	0.61
BMI (Kg/m²)	28.5 ± 5.4	27.6 ± 4.8	0.78
Comorbidities			
Diabetes	2 (22.22%)	3 (33.33%)	1
Hypertension	1 (11.11%)	2 (22.22%)	1
BMI=Body mass index			

Surgical outcomes:

Three months postoperatively, all men revealed an average penile length at maximum inflation of 13.4 cm (9.3-17.5

cm). This status was continued for six months in which no patient lost his penile length (**Figures 3 and 4**).



Figure (3): The length of the penis one week after positioning of semi-rigid implant through infrapubic approach



Figure (4): The length of the penis one week after positioning of semi-rigid implant through Subcoronal approach

Among patients treated with the subcoronal approach, one patient developed penile extrusion one and half months postoperatively due to wound dehiscence secondary to uncontrolled DM. Furthermore, three patients were unsatisfied with the penile girth, and after psychiatric consultation, they suggested enhancement penile girth if available to achieve the desired patient's outcome. As the mainline of psychological treatment of these cases, we used autologous fat transfers to augment the girth and giving soft padding around the prosthesis. The fat harvested by Coleman's harvesting cannula from trochanteric area without any use of the tumescent solution and transferred in subcutaneous plan with blunt tip fat injection cannula. The three cases accepted limited fat absorption, which did not exceed 20% of the injected

DISCUSSION

The inflatable penile prosthesis and implantation techniques witnessed a significant increase with better surgical outcomes and broader acceptance (*Bajic et al., 2020*). The infrapubic approach is widely used with excellent results;

amount with the achievement of patient satisfaction.

As for the infrapubic group, a patient developed a superficial infection and wound dehiscence and responded to antibiotic use and secondary suturing. Another case developed hypertrophic scar and responded to topical intralesional steroid injection one setting followed by three sessions of fractional Co2 laser for resurfacing. Another patient developed paranesthesia at the incision site. Two cases were unsatisfied by penile girth despite adequate preoperative counseling in the three sessions, but disclosure was mainly due to partner dissatisfaction. There was no need for girth enhancement, but the wife of both patients was complaining of vaginal looseness grade 2, requiring intravaginal fat transfer.

however, the debate existed regarding which approach is the most feasible, safe, and effective. Throughout the era of penile prosthesis, manufactures have continued to improve the outcomes of the penile prosthesis by improving the prosthesis design. Conversely, minimal changes have been proposed for the

operative techniques to implant the components (*Otero et al., 2020* and *Saavedra-Belaunde et al., 2020*). Therefore, this study was conducted to reveal the outcomes of the subcoronal and the infrapubic approaches for penile prosthesis in patients with ED.

In this study, patients with the subcoronal approach accomplished better functional, cosmetic, and psychological satisfaction relative to those who received the infrapubic approaches. These significant surgical outcomes were also associated with fewer patterns of complications. These findings were concomitant with Weinberg *et al.*, 2016 who reported that modified non-touch subcoronal approach allows easier access to the entire corporal body, allowing the operator to carry out different penile reconstruction surgeries via a single incision (*Weinberg et al., 2016*). The subcoronal approach is a simple approach with easy accessibility for implant insertion and fitting with a short operative time. The infrapubic procedure is totally away from penile skin, limiting the susceptibility of paresthesia or other wound problem in the penile skin, which hinder the normal sexual act of the patient. It also helps in penile lengthening in cases of the short penis and some cases with excess infrapubic skin, which causes burying of the penile root, and clinical shortening can be excised in a crescentic manner with its doom upward. The excessive skin excision can be advanced in the cephalic direction in a lazy S-shaped scar. In some cases, this approach helps to reduce excess fat in this area, but it requires meticulous dissection. However, the infrapubic approach has golden advantages not solving the ED

problem but also helps restore as much as we can the normal anatomy with excellent functional and aesthetic outcomes.

Infection is the most feared complication after penile prosthesis procedures. It is associated with penile shortening, urethral injury, erosions, mechanical failure, and tissue loss. This finding was in parallel with *Eid (2011)*, who found fewer infection patterns associated with the non-touch technique. While the dartos muscle is fully retracted off the corpora during the procedure, many reconstructive surgeries could be performed. These reconstructive procedures previously required further incisions, allowing the surgeon to improve the cosmetic outcomes by performing a single incision. The infrapubic approach is associated with a higher risk of neurovascular bundle injury. To avoid such injury, the infrapubic approach through the dorsal surface of the corpora cavernosa may provide anatomical protection against the injury (*Berg, 2011*).

The rapidly evolving technology beneath the complexity of penile prosthesis continued to minimize the complications associated with implantation. This makes the prosthesis more effective, reliable, safe, and widely accepted for the treatment of ED with the accomplishment of desired functional outcomes with high satisfaction rates. Despite the evidence obtained in this study, it represents an experience of limited cohort size. Additionally, the short follow-up period limited the capability to assess the long-term outcomes of penile prosthesis with the infrapubic and subcoronal approaches.

Despite the great satisfaction associated with inflatable devices, certain drawbacks stand barriers against their use. Mechanical deflation, costs, lengthy operative time, more dissection, and experience to avoid nerve injury are all barriers against its employment. With the semi-rigid implants, cost-effectiveness, shorter operative time, and easy applicability are the main advantages.

CONCLUSION

Erectile dysfunction can be safely and effectively treated by implantation of the penile prosthesis by the subcoronal approach. This approach achieved high satisfactory functional, aesthetic, and psychological outcomes relative to the infrapubic approach. Further studies with randomized controlled design and adequate follow-up periods are required to address the potential limitations of this study.

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دراسة مستقبلية لتقييم نتائج زراعة الدعامة القضيبية شبه الجامدة في النسيج الكهفي للقضيب بالطريقة تحت التاجية وتحت العانة للمرضى الذين يعانون من ضعف الانتصاب

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خلفية البحث: ضعف الانتصاب له تداعيات متعددة على السلوك الاجتماعي والنفسي والجسدي للمرضى. لم يكن هؤلاء المرضى قادرين على تحقيق أو الحفاظ على انتصاب كافٍ لتحقيق حياة جنسية مُرضية. تم وضع مناهج علاجية كثيرة لعلاج الضعف الجنسي. حقق العلاج الطبي نتائج جيدة في علاج الضعف الجنسي؛ ومع ذلك، كانت هذه النتائج مؤقتة، حيث عانى ما يقرب من 80% من المرضى من ضعف الانتصاب من حين لآخر. تعتبر الدعامة القضيبية علاجًا متميزًا للمرضى الذين يعانون من الضعف الجنسي و الذين يرغبون في ترك العلاج الدوائي من أجل الحصول على علاج دائم.

الهدف من البحث: تم إجراء الدراسة الحالية للكشف عن السلامة والفعالية والرضا الجنسي والنفسي بين المرضى الذين يعانون من الضعف الجنسي والذين خضعوا لزراعة دعامة قضيبية شبه جامدة للنسيج الكهفي للقضيب بالطريقة تحت التاجية وبطريقة تحت العانة.

المرضى وطرق البحث: الدراسة الحالية عبارة عن دراسة مستقبلية تم إجراؤها في مستشفيات جامعة الأزهر طوال الفترة من 2016 إلى 2020. تضمنت الدراسة الرجال الذين يعانون من الضعف الجنسي ولا يستجيبون للعلاج الطبي والذين يعانون من ضعف فى الانتصاب أيضاً. خضع جميع المرضى لتقييم سريري يتكون من التاريخ الجنسي والفحص التناسلى الدقيق والتقييم البدني بالإضافة إلى زيارات متكررة للمتابعة وتقييم لمدة 6 أشهر بعد الجراحة.

نتائج البحث: شملت هذه الدراسة 18 مريض يعانون من الضعف الجنسي. تم تقسيمهم إلى مجموعتين حيث خضع 9 مرضى لتقنية تحت العانة و 9 لتقنية تحت

التاجي. تم تقييم مستوى طول القضيب عند التضخم حيث بلغ 13.4 سم (9.3-17.5 سم) كحد أقصى. وخلال فترة المتابعة، لم يفقد أي مريض هذه النتيجة. بالنسبة للمرضى الذين عولجوا بنهج تحت التاج، عانى مريض واحد من خروج الدعامة القضيبية من الجرح بعد شهر ونصف من الجراحة نتيجة مرض السكري الغير منضبط. أما بالنسبة للمجموعة التي خضعت لطريقة تحت العانة، فقد أصيب مريض بعدوى سطحية وتفزر بالجرح واستجاب لاستخدام المضادات الحيوية والخياطة الثانوية بينما عانت حالة أخرى من ظهور ندبة تضخمية.

الإستنتاج: يمكن علاج ضعف الانتصاب بأمان وفعالية عن طريق زرع طرف اصطناعي للقضيب من خلال نهج تحت التاجي حيث حقق هذا النهج نتائج وظيفية وجمالية ونفسية مرضية عالية، مقارنة بالنهج تحت العانة.

الكلمات الدالة: ضعف الانتصاب، نهج تحت التاجي، نهج تحت العانة، زرع نسيج قضيبى.