

Infrapubic Approach Versus Penoscrotal Approach For Malleable Penile Prosthesis Implantation As A Management Of Erectile Dysfunction: A Comparative Randomized Study

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ABSTRACT

Keywords: Infrapubic, penoscrotal, Erectile Dysfunction, Malleable Penile, Prosthesis, satisfaction.

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A. Alam 01009081997 undefined amr_uro2009@yahoo.com] **Background**: The implantation of malleable penile prosthesis is considered as third line for treatment of ED. The aim of the **study:** is to compare outcome of infrapubic and Penoscrotal approaches for implantation of malleable prosthesis. Patients and methods: 38 patients were divided into two groups and each group underwent one approach at Aswan university hospital **Results** superficial wound infection was 26.3% in penoscrotal and 10.5% infrapubic. urethral catheterization was 52.6% infrapubic and 100% in penoscrotal which was statistically significant (p value 0.001). The patients and their partner's satisfaction in both approaches using Moskovic questionnaire. Conclusion: Both approaches revealed there was no significant difference in both approaches for penile prosthesis implantation regards technique, complications, and patients and their partner's satisfaction. Implanting malleable prosthesis is an effective line for treatment of ED patients with high satisfaction rate for patients and their partners.

INTRODUCTION

The prevalence of ED was >40% among Arab men. Risk factors and medical comorbidities that negatively affect the cardiovascular system, endothelial function and ultimately erectile function were common in men in Arab countries¹. The implantation of penile prosthesis is an effective option for treating erectile dysfunction (ED), and nowadays it is used to treat those cases

where pharmacological agents have not provided a useful result². Currently, two existing types of penile prosthesis include inflatable and semi rigid (Malleable) devices³. Malleable penile prostheses are ideal for patients in whom the cosmetic advantages of the inflatable devices are not as important as the ease of use and the lower chances of mechanical failure in semi rigid implants ⁴ and more financial suitability for patients in developing countries⁵. The infrapubic

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approach allows the reservoir to be implanted under direct vision. Disadvantages of the infrapubic approach include possible damage to dorsal nerves of the penis with sensory loss, limited corporeal exposure⁶. The penoscrotal approach has concern that this approach might be associated with a higher infection rate than the infrapubic approach. The Advantages of the penoscrotal approach include avoidance of dorsal nerve injury, better corporeal exposure ⁶. Patient and partner satisfaction with the cosmetic appearance and the widespread use of prosthesis reflect their quality and the experience gained by surgeons in device implantation ². This study was designed compare Infrapubic Penoscrotal approaches for the implantation of malleable prostheses as regarding safety, efficacy, duration of recovery, time needed for return to sexual activity, complications and patients and their partner's satisfaction.

PATIENTS AND METHODS

2.1. Study Design and Settings

This study is prospective randomized comparative study It was carried out at Department of Urology, Aswan University, from Jan 2016 to Dec 2018.

2.2. Eligibility

Thirty-eight patients with erectile dysfunction were recruited according to inclusion and exclusion criteria. The inclusion criteria included men with erectile dysfunction not responding to medical treatment and men with vasculogenic impotence in penile duplex. The exclusion criteria were patients with previous history of penile prosthesis implantation, patients with history of mental impairment and patients who are unfit for surgery.

2.3.Conflict of Interest

No conflict of interest was declared by the authors.

2.4. Financial Disclosure

The authors declared that this study has received no financial support

2.5. Sample Size Calculation

The statistical power of the study was calculated using results from OpenEpi, version 3, open source calculator SS proper for RCT to determine an adequate sample size. With accuracy mode calculation and an effect size convention 7.9 for the independent samples t-test, with probability of 0.05, provided confidence level 95% at 80% power for sample size. H0 postulated to compare the infrapubic approach against Penoscrotal approach of 19 patients in each group. The estimated sample was 38 patients.

2.6. Randomization

Patients were randomly allocated into 2 groups in ratio 1:1; group I was treated with Infrapubic (IP) approach and group II was treated with Penoscrotal approach (PS). Randomization was done by using closed envelope.

2.7. Procedures

Preoperative: All pateints were given an antibiotic prophylaxis the night before surgery.

2.8. Surgical Techniques

Anesthesia was General or spinal. Patient's was in supine position. Scrubbing by povidone-iodine® solution and brushing from umbilicus till knee For 5 - 10 minutes (Fig.1) followed by fixation of urethral catheter (in some cases of infrapubic which we suspect impending obstructive lower urinary tract symptoms) & all cases of



penoscrotal approach under Complete aseptic conditions.

2.8.1. IP Approach

Transverse skin incision 2.5 - 3 cm was done just close to root of the penis at level of lower border of

symphysis pubis. Exposure of the corpora with two senn retractors to avoid suspensory ligaments and neurovascular bundle injury followed by dissection of the Buck's fascia until the tunica albuginea was reached. Two lateral stay sutures in starting corpora using silk sutures were applied then vertical 2 cm corporotomy incision was

done. Subtunical Corporeal dilatation using heggar dilators were directed upwards and laterally specially in non-catheterized patients to avoid injury of the urethra. Measurements were taken distally and proximally on both sides on maximal penile length and girth .frequent irrigation with saline and Gentamycin proximally and distally was applied. Insertion of both Rt and Lt (cylinder) rods and then Close corpora on each side in continuous fashion using vicryl 2/0 followed by closure of all layers separately. Good homeostasis was done then closure of skin in interrupted half mattress sutures. Then postoperative follows up urology outpatient clinic (Fig.1).















Fig.1. steps of infrapubic malleable penile prosthesis implantation.

2.8.2. PS Approach Incision was designed at penoscrotal junction about 2.5 to 3 cm in

length each corpus was accessed along the ventral aspect just lateral to the urethra and then we proceeds as infrapubic approach. (Fig.2).



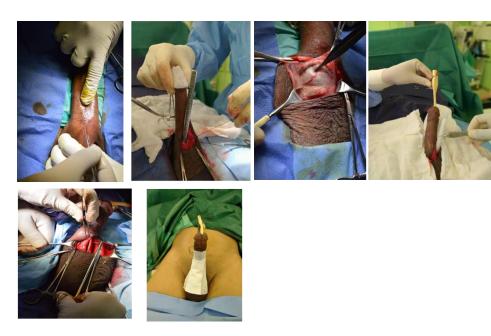


Fig.2. steps for Penoscrotal malleable penile prosthesis implantation

2.9. Post-Operative Care

Proper broad spectrum antibiotic covering gram positive, negative and anaerobic infections were given Compression around the penis was applied by wrapping the penis with goose Urethral catheter was removed then patient was discharged on the day after the operation or more according to patient stability. All patients were asked to follow up at outpatient urology & andrology clinic Aswan university hospital until complete wound healing to assess prosthesis function and complications and further follow up through control visits for any changes.

Follow-up strategy:-

In the first month follow up was weekly to recognize early signs or symptoms of local infection and treat it immediately. In the next 3 months follow up was monthly to make sure that the device working well and the patient can use it easily. Then the patient and partner were evaluated at 6 months to assess the degree of patient and partner satisfaction using modified

Moskovic questionnaire table for malleable penile prosthesis.

2.10. Ethical Issues

This study was approved by the local Aswan Ethical committee. All patients were counseled and informed consent was obtained from each patient and goals and risks of this study were thoroughly explained.

2.11. Data management and Statistical analysis

The demographic characters, operative details, intraoperative and postoperative complications were recorded. The success rate and patient satisfaction were also determined. All gathered data were statistically analyzed by Stastical Package of Social Science (SPSS) software version 20. Mean and Standard deviation was calculated for proposed variables numerical data independent student t-test. Categorical variables were analyzed using chi-square test. Quantitative data was expressed as means \pm SD while qualitative data was expressed as



numbers and percentages(%) A probability value (p-value) < 0.05 was considered statistically significant.

3. Results

This study was carried out in the Urology and Andrology department, Aswan University Hospital- Egypt from January 2016 to December 2018. Thirty eight patients were enrolled in the study Nineteen patients each group. Group I underwent PP implantation through infrapupic approach, while group II

underwent PP implantation through penoscrotal approach in our study the mean age of the patients in group 1 were 50.32 ± 10.25 while the mean age of patients in group II were 51.05 ± 8.75 . The number of diabetic patients in both groups were 11 in each group. There were 9 hypertensive patients in group I and $^{\lor}$ in group II. There were none statistically significant difference between both groups as regard HTN, DM and history of pharmacotherapy for ED. Venogenic ED was the most common type of ED in both group (table 1).

Table 1. Demographics and characteristics of both groups.

	Group I (19)	Group II (19)	P value			
	()	()				
Age (mean ±SD)	50.32± 10.25	51.05± 8.75	0.813*			
History of medical diseases						
HTN (No. %)	9 (47.4%)	7 (36.8%)	0.511^{Δ}			
DM	11 (57.9%)	11 (57.9%)	1^{Δ}			
History of pharmacotherapy for ED						
• Yes	16 (84.2%)	17 (89.5%)	1^{Δ}			
• No	3 (15.8%)	2 (10.5%)	1^{Δ}			
penile duplex						
venogenic	13 (68.4%)	13 (68.4%)	1^{Δ}			
mixed	6 (31.5 %)	6 (31.5 %)	1^{Δ}			

Non statistically significant differences were found between both groups in terms of operative time (table.2) and easiness of surgical approach . According to the easiness of the surgical approach (table.2) only one case was difficult during the surgery in infrapupic approach (5.3%) and 5 cases in penoscrotal

(26.3%) which was due to corporeal fibrosis and it is statistically non-significant. Also the mean of duration of the surgical approach was (67.37 ± 10.46) minutes in infrapubic approach and was (72.11 ± 10.32) minutes in penoscrotal approach which was statistically non-significant. the mean duration of hospital



stay/day for infrapubic approach was (2.16± 0.69) and the mean duration of hospital stay/day for penoscrotal approach (2.84±0.21) which was statistically significant (p value 0.039). twenty two patients (57.89%) from the total number of patients were diabetic (11 in each group) . the total incidence of post operative infection were 4 case from the diabetic group and 3 cases from the non diabetic group wound infections in PS approach was (5 cases) and with IP approach was (only 2 cases) .Most of postoperative infection were minor complications including superficial wound infection only one case was abcess formation. Scrotal and penile shaft edema was common with Penoscrotal approach (89.5%) in comparison with infrapubic approach (68.4%) which was statistically non significant (Table 3). Neither erosions nor urethral injury were

reported in this study. Non statistically significant diffrance in post operative pain in both groups. In the infrapubic approach the IIEF-5 preoperative was (6.00±0.94) and postoperative was (23.32±1.49) which was statistically significant (p value < 0.001) (table.3), also in the penoscrotal approach the IIEF-5 preoperative was (6.11±0.88) and postoperative was (22.26±1.19) which was statistically significant (p value < 0.001). There is statistically significant improvement in the IIEF-5 postoperatively for the infrapubic approach than the penoscrotal approach (p value = 0.022). The follow up period was 6 months for each patient. Satisfaction with the prosthesis was evaluated in details in this study, where patients and their partners were asked during their visits about their satisfaction using modified Moskovic questionnaire.

Table (2): pre and intra- operative data between group I & group II.

	Group I	Group II	P value	
duration of surgical approach/min (mean ±SD)	67.37 ±10.46	72.11 ±10.32	0.16*	
IIEF-5 Questionnaire before surgery	6.00 ±0.94	6.11 ±0.88	0.72*	
Ease of surgical approach				
easy	18 (94.7%)	14 (73.7%)		
difficult	1 (5.3%)	5 (26.3%)	0.18^{Δ}	
Urethral catheterization	•			
Catheterized patients	10 (52.6%)	19 (100.0%)	0.001^{Δ}	
Non catheterized patient	9 (47.4%)	0 (0.0%)	0.001	
Corporal cross over				
yes	2 (10.5%)	5 (26.3%)	0.40^{Δ}	
no	17 (89.5%)	14 (73.7%)		

Table (3): post-operative data in both groups.



	Group I	Group II	P value
post-operative pain	14 (73.7%)	15 (78.9%)	1^{Δ}
post-operative edema	13 (68.4%)	17 (89.5%)	0.23^{Δ}
post-operative erosion	0 (0.0%)	0 (0.0%)	
Post-operative infection	2 (10.5%)	5 (26.3%)	0.40^{Δ}
Post-operative infection / DM	2/11(18.1%)	2/11(18.1%)	1^{Δ}
IIEF-5 Questionnaire after surgery Mean ± SD	23.32 ±1.49	22.26 ±1.19	0.02*
hospital stay/day Mean ± SD	2.16 ±0.69	2.84 ±1.21	0.03*

Table (4): Comparison between group I and group II as regards patient and partners satisfaction using modified (Moskovic and Gittens, Questionnaire).

	Patient satisfaction		
	Group I	Group II	P value
Ease of use of PP	3.42 ±0.61	3.42 ±0.51	1
rigidity of PP	3.53± 0.61	3.47±0.61	0.792
Length of PP	3.37±0.60	3.05±0.40	0.064
width of PP	3.53± 0.51	3.63±0.50	0.524
orgasm with PP	3.63±0.60	3.33 ±0.59	0.137
sexual partner satisfaction with PP	3.42± 0.69	3.42±0.61	1
overall satisfaction with PP	3.63±0.83	3.37±0.60	0.27
No. of use per Month	10.26±3.33	9.47±2.63	0.423
Undergo PP again (yes)	18 (94.7%)	17(89.5%)	1
Undergo PP again (NO)	1(5.3%)	2(10.5%)	1
You recommend PP for other pt.(yes)	18 (94.7%)	17(89.5%)	1
You recommend PP for other pt.(No)	1 (5.3%)	2 (10.5%)	1
partner satisfaction			
Ease of use	3.32±0.89	3.84±0.96	0.087
rigidity	3.58±0.77	3.83±0.71	0.303
length	3.47±0.70	3.68±0.75	0.376
width	3.89±0.74	3.84±0.83	0.838
satisfaction with PP	4.00±0.94	3.84±0.96	0.612
pain from PP during sexual activity (1-10)	1.84±0.37	1.95±0.71	0.569
You recommend undergo PP again (yes)	18 (94.7%)	17 (89.5%)	1
You recommend undergo PP again (No)	1 (5.3%)	2 (10.5%)	1

DISCUSSION

In Egypt, the malleable penile implant is commonly used in the management of erectile dysfunction not only for its technical easiness to be applied and less incidence of mechanical failure but also due to low cost ⁵. Caution must be taken during implantation of inflatable and



malleable devices through the infrapubic access, to avoid the possibility of injury to the neurovascular bundle. On the other hand, the approach through the dorsal surface of the corpora cavernosa has a natural capability of anatomical protection of the urethra and not requiring urethral catheterization. advantage has a vital role when considering possible causes of pre and postoperative morbidity ⁷. The main purpose of the present study was to evaluate the outcome of the malleable penile implant using infrapubic comparison to penoscrotal approach in approach as regarding intraoperative and postoperative complications, patients and their partner's satisfaction. In this prospective randomized study thirty-eight patients with underwent erectile dysfunction management after failure of all medical lines of treatment or if it is contraindicated and fulfill all the inclusion and exclusion criteria. They were randomly allocated into two groups each group include 19 patients, all patients were treated with a malleable penile implants. The first group was treated with an infrapubic approach and the second group was treated with a penoscrotal approach. Patients in both groups were comparable regarding age, medical diseases such as (DM and HTN), history of pharmacotherapy for ED and its etiology according to penile duplex study. In this study the most common cause of ED according to penile duplex scanning in both groups was venogenic ED (68.4%) in each group. Our results were supported by 1 2011 who found that the most common cause of ED according to penile duplex was venogenic ED in nature. In this study the preoperative IIEF-5 in infrapubic approach was (6.00±0.94) while in the penoscrotal approach was (6.11±0.88) which was not statistically significant difference. Our result was similar to Vakalopoulos et al. 8,

Blewniewski et al. ⁹ and Antonini et al. ¹⁰ who reported that IIEF-5 was around (5-8). Urethral catheterization in our study was 52.6% in infrapubic patients and 100% in penoscrotal patients which was statistically significant (p value 0.001). These results were supported by Shebl and Ali¹¹ who reported that urethral catheterization was 12% in infrapubic patients and 100% in penoscrotal patient.

Urethral injury in our study was not reported in both infrapubic and penoscrotal approaches .Unlike our result Gupta et al. 12 reported 4 cases with urethral injury as a complication of penile prosthesis implantation. Also Vollstedt et al.¹³reported that distal urethral injuries were not uncommon because they did not focus on protecting the fossa navicularis during measurement with the Furlow inserter this may be due to our strict adherence to technical steps and caution to protect urethra. In the current study corporeal crossover was recognized intraoperativelly in 2 cases in infrapubic approach (10.5%) and 5 cases in penoscrotal approach (26.3%) which didn't interfere with the surgical technique and it was not statistically significant. These results were supported by Fathy et al.5 who reported that corporal cross over was one of the famous intraoperative complication of semi rigid implant and was (4%) which managed intraoperativelly. Also **Shebl and Ali**¹¹ reported that corporal crossover of semi rigid implant was an encountered complication during corporeal dilatation which was 12% infrapubic and 24% in penoscrotal approach. According to the surgical technique and its easiness or difficulty, only one case was difficult during the surgery in infrapubic approach (5.3%) which was due to excessive suprapubic fat, and five cases in penoscrotal approach (26.3%) due to excessive corporal



fibrosis and it is not statistically significant. Also the mean duration of the surgical approach was (67.37±10.46) minutes in infrapubic approach while it (72.11± 10.32) minutes in which was penoscrotal approach not statistically significant. Palmisano et al. 15 explained that easiness and duration of the technique depend on the surgeon knowledge and his team of both accesses and his capability of tailoring the incision strategy for complex cases. In this study postoperative pain which occurred in 73.7% of the infrapubic cases and 78.9% of the penoscrotal cases and relieved by analgesics. As regards scrotal and penile shaft edema it occurred in (68.4%) of infra pubic cases in comparison to penoscrotal cases where it occurred in (89.5%); It may be due to compression of lymphatic vessels and surgical manipulations. it was relieved by medical treatment. Both post-operative pain and edema were not statistically significant in both groups our result unlike Shebl and Ali¹¹ who reported that Scrotal and penile shaft edema was common with infrapubic approach (92%) in comparison with Penoscrotal approach (60%) be due which may to less surgical manipulations and good post-operative bandage Overall postoperative infection in the current study occurred in 7 patients out of 38 patients (18.5%). In the infra pubic group 2 patients (10.5%) had infection and they were diabetic. In the penoscrotal group 5 patients (26.3%) had infection 2 patients of them were diabetic The incidence of postoperative infection with DM was 57.2% (4 out of 7 post-operative infected cases) while the incidence of postoperative infection in non-diabetic patient was 42.8% (3 out of 7 post-operative infected cases). This difference in incidence between post-operative infection with and without DM was not statistically significant. However the incidence of postoperative infection was higher in

penoscrotal group but it was not statistically significant (p-value 0.40). Most of the postoperative infections in this study were superficial wound infection and all were appropriate broad-spectrum managed by antibiotics according to culture and sensitivity test. Only one patient in the penoscrotal group develops an infected hematoma formation and was managed by surgical drainage he didn't require implant removal and the function of the device was not affected. Similar results about postoperative infection were supported by **Shebl and Ali** ¹¹ who reported that superficial wound infection was significantly more with penoscrotal cases 6/25 (24%) in comparison with infra pubic cases 1/25 (4%), p-value = 0.041) with no significant correlation between diabetes and infections. Also, a similar lack of correlation between diabetes and penile prosthesis infection was reported by Mohamed et al.¹⁵, Montague et al. ¹⁶ and Jarow ¹⁷. Unlike our results, Garber and Marcus 18 in their study reported that the infection rate in the infrapubic cases higher was penoscrotal cases but this difference was not statistically significant (P = 0.15). In this study, the hospital stay was shorter in infrapubic patients in comparison to the penoscrotal patients which was statistically significant (pvalue 0.03), this may be due to more postoperative pain, and edema and infection in penoscrotal approach that need monitoring at hospital. In the current study there is statistically significant improvement in the IIEF-5 before and after surgical technique for both groups (p-value, 0.001). The postoperative IIEF-5 in the infra pubic group was (23.32±1.49) and in the penoscrotal group was (22.26±1.19) which was statistically significant (p-value < 0.022). Similar results was reported by Akdemir et al. 19 who found that the mean IIEF-5 score was (5.86±0.92)



before surgery, and it was (22.5±0.62) at the end of the follow-up which was statistically significant. Song et al. 20 reported that all of the patients could perform sexual intercourse post penile prosthesis implantation with the mean postoperative IIEF-5 (20.02 \pm 2.32), which was significantly improved compared with the preoperative scores $(6.29\pm1.5,$ P<0.01). Effective treatment of ED has been shown to improve sexual function and satisfaction between patients and their partners, which is due to treatment-related improvements in the man's erectile function ²¹. Casabé et al. ²² said that it is not easy to assess the satisfaction of patients with penile prostheses Patients' subjectivity makes it so difficult to analyze it. Patient satisfaction can be affected by many parameters, including patient expectations, partners' attitudes, the presence or absence of surgical complications, and premature device failure. In this study assessment of the patients and their partner's satisfaction using Moskovic questionnaire after modification by Roaiah et al. ²³ at KasrAlainy School of Medicine which is a simple questionnaire and have direct questions that can be easily understood by our patients and their partners in our society, with various domains related to the semi-rigid penile (e.g., overall satisfaction and prosthesis satisfaction related to length, girth, ease of use, and partner perception) scored from 1–5 as (1—

very unsatisfied, 2—moderately unsatisfied, 3—satisfied, 4—moderately satisfied, 5—very satisfied), Scores ≥ 3 were classified as satisfied. Patient's in both groups infrapubic and penoscrotal approaches were satisfied by prosthesis implantation with score (>3) and there is no statistically significant difference in satisfaction rate between the two surgical approaches where infrapubic approach group (94.7%) said they would undergo the procedure again if it was offered to them and would recommend this procedure to other patients as well as the penoscrotal approach group (89.5%) who said they would undergo the procedure again if it was offered to them and would recommend this procedure to other patients. Partner's in both groups were satisfied by their couples penile prosthesis implantation with score (>3) and there is not statistically significant difference in satisfaction rate between the two surgical approaches. Unlike our results Roaiah et al.23 found that satisfaction rates for patients was (69%) and their partners (53%) this may be due to less postoperative complications, with good implant function. The advantage of our study that, it was comparative randomized study and it highlighted the use of infrapubic approach as a technique for implantation of the malleable penile implant as it is used mainly for inflatable prosthesis implantation.

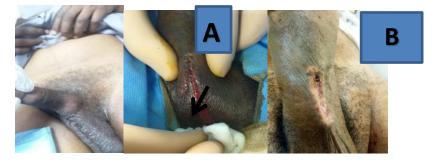


Fig.3. A- abscess formation and B- superficial wound infection in penoscrotal approach

Limatation of the study:



There were some limitations in our study such as a small sample size because in our community erectile dysfunction patients are embarrassed from seeking medical advice, difficulty in assessment of patients and their partner's satisfaction due to the same cause, and short-term follow-up.

4. Conclusion:

The infrapubic approach is an effective surgical technique with less infection rate and urethral catheterization when compared with penoscrotal approach, so it should be applied as a technical option for implanting malleable with prostheses cases erectile dysfunction.Implanting malleable penile prosthesis using the infrapubic and the penoscrotal approach are effective line of treatment in erectile dysfunction patients with high satisfaction rate for patients and their partners.

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