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Comparison of penile prosthesis types' complications: A retrospective analysis of single center

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Summary
Objectives: The aim of this study was to compare clinical outcomes and complication rates associated with semirigid (malleable) and inflatable penile prostheses (PPs) and investigate the factors that influence these complications.
Material and methods: The records of 131 patients who had undergone penile prosthesis implantation (PPI) in our clinic due to erectile dysfunction (ED) between January 2010 and March 2019 were retrospectively reviewed. The initial surgery included 116 primary implants and 15 men had two revision operations. Patients were assigned to two groups as semirigid (malleable) PPI (group 1) and inflatable PPI (group 2) patients, and obtained data were compared across these two groups.
Results: Group 1 included 93 patients, while Group 2 included 38 patients. Postoperative complication rates of Group 1 were 8.6% (n = 8), and Group 2 were 21% (n = 8), and the comparison of postoperative complication rates revealed a statistically significant difference between the two groups (p = 0.025). The majority of these complications (50%) was constituted by mechanical failure associated with inflatable PPs. When patients were further segregated as those with and without diabetes type 2 (DM) and those who had and had not undergone radical pelvic surgery (RPS), the comparison of complication rates across these subgroups did not yield any significant difference.
Conclusions: We determined in this study that semirigid (malleable) PPs were associated with lower complication rates compared to the inflatable group, particularly with regard to mechanic failure, and that DM and history of RPS did not make a difference in complication rates in patients planned to undergo PPI.

KEY WORDS: Penile prosthesis; Penile prosthesis implant; Erectile dysfunction; Impotence; Radical surgery; Satisfaction.

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INTRODUCTION

Penile prosthesis implantation (PPI) treatment has been offered for over 40 years with high surgical success in patients with *erectile dysfunction* (ED) who either do not respond to pharmacological treatments such as oral phosphodiesterase type 5 (PDE5) inhibitors and less invasive intracavernosal vasoactive agents or reject these treatments (1). *Penile prostheses* (PPs) are categorized into two groups as non-inflatable and inflatable prostheses. Non-inflatable PPs are also referred to as "semirigid (mal-leable)". Inflatable prostheses are further classified into two groups as two-piece and three-piece prostheses. Although semirigid (malleable) PPs are more durable and less expensive, they can experience more erosion as they are constantly rigid. On the other hand, inflatable PPs allow use in flaccid and erect states and offer cosmetic advantage, however, possessing a more complex structure may result in mechanical failure over time (2-6). Currently, two-piece and three-piece PPs constitute 75% of PPI surgeries worldwide, while in our country, semi-rigid (malleable) PPs are used at higher rates due to the reimbursement conditions of the social security institution and the higher cost of inflatable PPs (7-11).
Although PPI surgery is associated with patient and partner satisfaction, certain complications may arise during and after this operation (12-14). These include; intraoperative complications such as urethra perforation, cavernosal crossover, and crural perforation, as well as complications encountered in the postoperative period such as wound site infection, hematoma, lower urinary tract symptoms, bending during intercourse, breakage of the prosthesis, concorde deformity, and mechanical failure, particularly in multi-piece types. Among factors that influence these complications, the role of diabetes type 2 (DM) and history of *radical pelvic surgery* (RPS) has been contended in the literature (10, 15-17).
The aim of this study was to evaluate the clinical outcomes and surgical complications after PPI performed at our institution on patients with various causes of ED, compare complication rates associated with semirigid (malleable) and inflatable PPs, and investigate the factors that influence these complications.

MATERIALS AND METHODS

Approval of the institutional ethics committee was obtained. We retrospectively reviewed the records of 116 men with ED who had 131 penile prostheses implanted in our clinic due to end-stage ED between January 2010 and March 2019. The initial surgery included 115 primary implants and one revision case, who had undergone the initial operation at another institution. A further 15 men had two revision operations. Three patients with insufficient data and two cases, who had PPs implanted at another centre and demanded removal without replacement, were excluded from the study. For all the patients, demographic characteristics, duration of ED time, size of implanted PP, complications data, and patient satisfaction

were evaluated. Patients were assigned to two groups as semirigid (malleable) PPI (group 1) and inflatable PPI (group 2) patients, and obtained data were compared across these two groups.

Indications for PPI were failure or intolerance of medical treatment, confirmation of ED by Doppler ultrasound, and severe ED. All men routinely underwent medical and psychiatric consultation before the surgery. The operative field was disinfected with povidone-iodine 10 min before the surgical intervention. Preoperative antibiotic prophylaxis, such as vancomycin, was given the night before the surgery and for 3 days postoperatively. Oral antibiotic prophylaxis with ciprofloxacin was continued through the 7th postoperative day. All the PPs were implanted through penoscrotal incisions. The implant and surgical sites were irrigated with gentamicin in saline prior to implantation. The corpus cavernosum usually was dilated with Hegar dilators, though an Otis urethrotome was deemed necessary in two cases. A Foley catheter was inserted at the end of the procedure and removed 1 day later. The patients were discharged 1-2 days postoperatively.

Surgical complications were recorded in detail. Peroperative and postoperative complications were evaluated separately and compared between the groups. Postoperative complications were divided into two groups as 'early' (complications occurring within 30 days of surgery) and late (complications occurring after 30 days of surgery).

Prosthesis function was evaluated 1 month after surgery and then annually until lost to follow-up. Our patients were asked during control visits if they were satisfied, or unsatisfied with the prosthesis in general. They were evaluated at or within 12 months of the postoperative period, in most cases through face-to-face interviews. However, in some patients who failed to visit the clinics, follow-up was assessed through telephone interviews.

Statistical analyses

The groups were assessed for normal distribution using the Shapiro Wilk test. Statistical difference between the groups were analyzed with independent sample t test Mann Whitney U test. Chi-square test was used for cross comparison. A p-value < 0.05 was considered statistically significant. All analyses were made by IBM SPSS V22.

RESULTS

Data obtained from all patients were reviewed to determine duration of ED time, causes of ED, pre-prosthetic treatment of primary patients, type of implanted PP, size of implanted PP, perioperative and postoperative complications (Table 1). The most common factor implicated in the ED etiology of patients was DM with a rate of 41.2% (n = 54), followed by RPS with a rate of 20.6% (n = 27). Of 54 DM patients, 26 (48.1%) were on oral antidiabetics and 28 (51.8%) on insulin therapy. Overall perioperative complication (urethra perforation and cavernosal crossover) rate was 1.5% (n = 2). In one of these, where urethra perforation had been encountered during the cavernousal dilation stage of PPI and the procedure had been postponed, only one side of the semirigid (malleable) PP could be implanted in the second surgical session

sion due to difficulty in dissection. All perioperative complications were resolved during surgery, and the operations were completed successfully. The overall postoperative complication rate was 12.2 % (n = 16).

Table 1.

Demographics; duration, etiology and treatment of erectile disfunction (ED); characteristics, complications and satisfaction of penile prostheses (PPs).

Number of patients	131
Median age, year (min-max.)	59 (28-74)
Mean ± SD	58.4 ± 8.3
Median duration of ED time, year (min-max.)	3 (1-21)
Mean ± SD	4 ± 3.6
Causes of ED of primary patients, n, (%)	
· Idiopathic	22
· Comorbidity	
DM (Diabetes type 2)	54 (41.2%)
Hypertension	26
Myocardial infarction	11
By-pass surgery	5
Chronic obstructive pulmonary disease	2
Cerebrovascular occlusion	1
· RPS (Radical pelvic surgery)	
Radical prostatectomy	24 (18.3%)
Radical cystectomy	3 (2.2%)
· Pelvic radiotherapy	7
· Priapism	1
· Peyronie's disease	9
Penis fracture	1
Pre-prosthetic treatment of primary patients	
· Phosphodiesterase 5 (PDE5) inhibitors	114
On-demand	101
Daily	13
· Cavernosal injection	1
· Vascular surgery	1
PPI	
· Primary implants	116 (88.5%)
· Revision implants	15 (11.4%)
Type of implanted PP, n, (%)	
· Semi-rigid (Malleable) prostheses	93 (70.9%)
· Inflatable prostheses	38 (29%)
Two-piece	36 (94.7%)
Three-piece	2 (5.2%)
Size of implanted PP, n, (%)	
· Median size, diameter, cm (min-max.)	10 (9-13)
· Median size, length, cm (min-max.)	18.5 (12-25)
Perioperative complications, n (%), Note	2 (1.5%)
· Urethra perforation	1, During dilatation, postpone
· Cavernosal crossover	1, During dilatation
· Crural perforation	0
Postoperative complications	14 (10.6%)
· Early	
Superficial wound infection	4, Resolved with antibiotherapy
Hematoma located on scrotum	1, Resolved at follow-up
· Late	
Bending during intercourse	1, Revision
Lower urinary tract symptoms	1, History of TURP
Penile prosthesis breakage	2, Revision
Concord deformity	1, Revision
Mechanical failure	4, Revision
Overall complications	16 (12.2%)
Patient satisfaction, n (%)	
Satisfied	105/131 (80.1%)
Not satisfied	16/131 (19.8%)

Revision surgery was needed for 11.4% (15/131) of the PPs inserted. Of these 15 patients who underwent revision PPI, 12 had undergone the primary surgery at our clinic and three at external centers. The median time until PPI revision was determined as 36 months (1-192 months). Overall, 80.1% (105/131) of the men were satisfied with the results.

Group 1 included 93 patients, while Group 2 included 38 patients. The comparison of data from Group 1 and Group 2 patients have been summarised in Table 2. In Group 1, one patient had to be implanted with different-sized PPs on the right and left sides, whereas in Group 2, six patients were implanted with PPs of discrepant sizes. Postoperative complication rates of Group 1 were 8.6% (n = 8), and Group 2 were 21% (n = 8), and the comparison of postoperative complication rates revealed a statistically significant difference between the two groups (p = 0.025).

Table 2.
Study outcomes by type of prosthesis.

	Semirigid PPI (n = 93)	Inflatable PPI (n = 38)	p
Median age, year (min-max.)	59 (38-74)	61 (28-69)	0.667
Mean ± SD	58.6 ± 7.5	58.1 ± 9.8	
Median duration of ED time, year (min-max.)	3 (1-20)	2 (1-21)	0.229
Mean ± SD	4.2 ± 3.5	3.7 ± 4	
Size of implanted PP, n, (%)			
· Median size, diameter, cm (min-max.)	10 (9-13)	18.5 (12-25)	0.256
· Median size, length, cm (min-max.)	12.5 (12-12.5)	19 (14.5-22)	0.349
Perioperative complications, n (%)	2 (2.1%)	0	0.502
· Urethra perforation	1 (1%)	0	
· Cavernosal crossover	1 (1%)	0	
· Crural perforation	0	0	
Postoperative complications	6 (6.4%)	8 (21%)	0.025
- Early			
Superficial wound infection	2	2	
Hematoma located on scrotum	0	1	
- Late			
Bending during intercourse	1	0	
Lower urinary tract symptoms	1	0	
Penile prosthesis breakage	2	0	
Concord deformty	0	1	0.074
Mechanical failure	0	4	
Overall complications	8 (8.6)	8 (21%)	

Table 3.
Comparison of overall complication rates of patients with and without diabetes type 2 (DM).

	DM (n = 73)	DM (n = 58)	p
No complication	66 (90.4%)	49 (84.4%)	0.421
Overall complications	7 (9.5%)	9 (5.5%)	

Table 4.
Comparison of overall complication rates of patients with and without radical pelvic surgery (RPS).

	DM (n = 73)	DM (n = 58)	p
No complication	86 (86%)	29 (93.5%)	0,356
Overall complications	14 (14%)	2 (6.4%)	

Among postoperative complications, mechanical failure was detected in four patients, all of whom were Group 2 patients who had inflatable (two-piece) PPIs.

When patients were further segregated as those with and without DM and those who had and had not undergone RPS, the comparison of complication rates across these subgroups did not yield any significant difference (Tables 3, 4).

DISCUSSION

PPI has been used effectively in patients who do not respond to oral therapies such as PDE5 inhibitors and to intracavernosal injection therapy (1). Although this treatment method offers high patient and partner satisfaction, it may be associated with certain perioperative and postoperative complications (2-13). Among these complications, most notable are the PP infections and mechanical failure that arise in the postoperative period. In the recent years, technological advancements in PPs and advances in the surgical procedure technique have resulted in a partial decrease in these rates (18). Although inflatable PPs are utilized more commonly across the world, semirigid (malleable) PPs have been utilized at greater rates in our country due to low economic status of the patients, high cost of inflatable PPs, and reimbursement conditions of the social security institution (7-11). In this study, we aimed to compare the complication rates associated with semirigid (malleable) and inflatable PPs that we implant at our clinic as well as to compare these rates between patients with and without DM and patients with and without history of RPS. The two groups demonstrated no statistical differences with regard to perioperative complications. Comparison of postoperative complication rates across groups revealed a statistically higher rate for the inflatable group. The majority of these complications was constituted by mechanical failure associated with inflatable PPS. Also, the comparison of complication rates in patients with or without DM or history of RPS showed no difference of overall complication rates.

Although semirigid (malleable) PPs are less expensive and more durable, they are disadvantaged in terms of cosmetic appearance due to a constant state of erection. On the other hand, inflatable PPs offer more physiological erections but may lead to mechanical failure in the postoperative period. In the literature, mechanical failure rates vary from 0-5% for semirigid (malleable) PPs to 23% for inflatable PPs (2, 3, 10, 13). A study conducted by *Lotan et al.* reported that the complication-free rate was 87% for semirigid (malleable) PPs, whereas it was 50% for inflatable PPs (19). In our study, while no difference was detected between the groups with regard to perioperative complications, a statistically higher postoperative complication rate was determined in the inflatable group (21%) compared to the semirigid (malleable) group (6.4%). Half of the postoperative complications in the inflatable group were accounted by mechanical failure.

In the literature, whether post-PPI infective complications are more prevalent among patients with DM has been controversial. Although there are publications that corroborate the role of DM as a risk factor for postoper-

ative infections, there are also contradictory studies. Penidri et al. stated in their metanalysis that DM could be a risk factor for PP infection, although this could not be completely clarified (15). The relation of RPS history with perioperative and postoperative complication rates has also been contended in the literature. In a study by *Cuneyd et al.*, erosion rates in semirigid (malleable) PPs were higher in the RPS group, compared to patients with other comorbidities, however, postoperative complication rates were reported to be similar across groups. They connected these high erosion rates to fibrosis that develops in the cavernosal tissue after RPS (10). On the other hand, in a study by *Lane et al.*, it was stressed that three-piece PP surgery had comparable postoperative complication rates in patients with and without RPS history, and therefore, could be utilized safely in these patients (17). In our study, there were no differences between patients with and without DM and between patients with and without history of RPS with regard to perioperative and postoperative complication rates.

The limitations of our study include its dependence on retrospective data, lack of partner satisfaction data as it could not be evaluated for all patients, and absence of long-term follow up data of patients.

Conclusions

PPI surgery has been performed worldwide in the treatment of ED, on patients who do not respond to oral and intracavernosal therapies. Although inflatable PPs possess a more cosmetic and physiological structure, they cannot be used in all patients in our country due to their higher cost and the reimbursement conditions of our social security system. Semirigid (malleable) PPs constitute the most commonly utilized PPs at our clinic despite certain disadvantages. In conclusion, we determined in this study that semirigid (malleable) PPs were associated with lower complication rates compared to the inflatable group, particularly with regard to mechanic failure, and that DM and history of RPS did not make a difference in complication rates in patients planned to undergo PPI.

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