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Original Article

The Clinical Results of Penile Prosthesis Implantation for the Treatment of Organic Erectile Dysfunction

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Abstract

Introduction: The aim of this study is to evaluate the clinical results of penile prosthesis implantation for the treatment of the patients with organic erectile dysfunction (ED).

Methods: Medical records of penile prosthesis implantation for the treatments of 36 patients with organic ED between January 2006 and December 2014 were retrospectively reviewed. The demographic data of the patients, the causes and duration of ED, operative time, hospitalization time, types of prosthesis, and intraoperative and postoperative complications were evaluated.

Results: The mean age of patients was 53.94±9.66 years and the mean body mass index of the patients was 27.23±4.02 kg/m2. The mean duration of ED was 48±26.52 months. The etiologic factors were diabetes mellitus in 21 patients (58%), caridovascular diseases in 8 patients (22%), radical pelvic surgery in 4 patients (11%), radiotherapy in 1 patient (2.7%), spinal surgery in 1 patient (2.7%), and genital travma in 1 patient (2.7%). 28 of patients (77.7%) were smoker. Mean operation time was 108.2±27.62 minutes and mean hospitalization time was 2.64±1.57 days. In 32 patients (88.8%) whom have implanted malleable penile prosthesis, two different trade mark malleable penile prostheses were used. Four (11.2%) inflatable penile prostheses were implanted in the remaining patients. The penile prosthesis implantation was performed under general anesthesia with antibiotic prophylaxis using vancomisine and gentamicine. It was not seen any peroperative complication. Postoperative complications were 1 acute urinary retantion, 1 penile pain, 1 reimplantation due to mechanical failure. Two prosthesis were completely removed due to infection. The patients were followed for 25.72±30.92 months. The satisfaction rate of the patients was 67%.

Conclusion: Although penile prosthesis implantation is an invasive treatment option for the patients with organic ED, it can be performed safely and effectively for these patients. Despite of appropriate surgical techniques, infection is most common complication of this operation provide patient and partners satisfaction.

Keywords: Erectile dysfunction, surgery, treatment, penile prosthesis, complication

Introduction

Erectile dysfunction (ED) is the second most common sexual dysfunction in men after premature ejaculation (1) and is defined as "the inability of a man to have and/or maintain adequate penile erection for sexual intercourse for at least 6 months" (2). In a community-based study conducted by the Turkish Society of Andrology on the prevalence of ED, its prevalence was found to be 69.2% (33.2% as mild, 27.5% as moderate, and 8.5% as advanced ED) (3). According to the findings of the *Massachusetts Male Aging Study* (MMAS), which is accepted to be a reference as one of the most important international epidemiological studies, of male patients between the ages of 40 and 70 years, 17% had mild ED, 25% had moderate ED, and 10% had severe ED (4). Based on these findings, it is estimated that the number of ED patients will increase to approximately 322 million worldwide in 2015 (5). It has been demonstrated that frequent ED can seriously affect the quality of life of the spouse as well as the patient (4).

In basic scientific and clinical studies conducted on the physiology and pathophysiology of erection, it has been revealed that ED is a vascular pathology associated with risk factors, such as cardiovascular diseases, hypertension, atherosclerosis, lipid disorders, smoking, diabetes mellitus, obesity, metabolic syndrome, and a sedentary lifestyle (2, 6). Apart from the abovementioned medical problems, iatrogenic factors, such as pelvic surgeries, particularly radical prostatectomy where even bilateral neuroprotective is applied, are also among the important factors that play a role in the occurrence of ED (7).

Currently, lifestyle changes and primary and secondary care conservative therapies, including medical treatment choices applied orally or through intracavernous injection, are the first techniques performed for patients with ED. Phosphodiesterase type-5 inhibitors, intracavernous injections, intraurethral alprostadil, and vacuum devices can fail in approximately 80% of patients because they discontinue the treatment (8, 9). In such a situation or in ED patients, particularly in the case of ED with an organic origin, with no adequate response to the treatment, despite invasive and costly intervention, flexible or inflatable penile prosthesis implantation, which has been

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developed over the last 25 years, is a commonly used treatment method that provides efficient and high patient and partner satisfaction (10, 11). Although all penile prostheses provide enough rigidity for penetration, inflatable ones seem to be a more appropriate choice for the individuals who actively join in daily life because they can be used when necessary compared to the flexible ones. In literature, there are many studies reporting the success rates and complications of the implantations of all penile prosthesis types with different surgical techniques.

In this study, it was aimed to present our findings on patient satisfaction with penile prosthesis implantation applied in organic ED patients with no response to primary and secondary care treatments and to report any complications that developed during or after operation.

Methods

In this study, 47 patients with organic ED who undergone flexible or inflatable penile prosthesis implantation in our clinic between January 2006 and December 2015 were evaluated retrospectively. The types of prostheses were recorded. All the patients included in the study had been treated with oral phosphodiesterase type-5 inhibitors and then with intracavernous injections, but they had given no response to the treatment before the operation. In the evaluation of the patients, penile Doppler ultrasonography was performed in addition to physical examination and routine biochemistry tests. All the patients undergoing radical prostatectomy due to prostate cancer in our clinic were administered neuroprotective treatment with 5 mg/day tadalafil for protecting the penile cavernosal tissue in order to prevent penile deformity and fibrosis-induced shortening. Patients who were assisted with penile prosthesis for the first time were included in the study, and all the operations were performed by the same surgeon. At the beginning, the patients were given general information about the operation, and they were informed about possible complications and alternative treatment methods. Written informed consent forms were received from the patients. After giving information to the patients, they were recommended inflatable or flexible penile prostheses depending on their mental status, manual skills, and the existence of narrowing in their urethras. Prostheses with the trademarks of AMS, Coloplast, and Mentor were used. *700*^{TM} models of AMS prostheses, which included a pump with a three-piece prosthesis reservoir and valve mechanism allowing easy deflation with a single touch and preventing auto-inflation, were utilized. *Genesis* model flexible Coloplast penile prostheses and *Acuform* model Mentor prostheses were used.

The Turkish version of the *International Index of Erectile Function* (IIEF), was used for evaluating the erectile functions of patients. IIEF was developed by Rosen et al. (12). It consists of 15 questions that evaluate erectile function and capacity and it is responded to by patients themselves. It evaluates sexual function in men under five sub-groups, including erectile function, orgasmic function, sexual desire, sexual satisfaction, and general satisfaction.

After shaving the pubic regions of 38 patients under general anesthesia and 9 under spinal anesthesia, they were disinfected with povidone iodine solution for 10 min. At the same time, all the patients were also administered intravenous vancomycin and gentamicin. Before operation, the presence of any pathology that had to be corrected was controlled by creating an artificial erection. Then, corpus cavernosa were reached through an approximately 3 cm skin incision from the penoscrotal region and a 2 cm bilateral corporotomy was performed. Next, *Furlow* dilators were used for creating areas in the corpus cavernosum where the prosthesis would be placed, and measurements were performed for the choice of device in its proper size. During all these processes, corpus cavernosa were washed with solution, including gentamicin. Supportive sutures were placed in the lateral region of the dorsal nerve in the corpus cavernosum. Patients were inserted inflatable prosthesis and the reservoir filled with 100 mL isotonic was placed in the posterior region of the transverse fascia in the craniocaudal position. After preparing the surgical area, cylinders were placed by using supportive sutures for retraction. Cylinders were filled immediately and evaluated in terms of the presence of any functional and cosmetic problem. A subdartos pouch was created in the scrotum and a pump was inserted. After performing a hydraulic test, corporotomies were closed with supportive sutures that had been previously placed. A drain was placed and the process was completed by closing the skin incision.

Inflatable prostheses were activated at the rate of 80% for preventing contraction during 72 h. Further, 8–10 days after the operation, the first activation was performed. Six weeks later, patients were allowed to have sexual intercourse. Oral cefazolin therapy was continued against infection for 10 days.

Demographic data of the patients [age, body mass index (BMI) and marital status], ED findings (etiology, duration, type of previous treatment), intraoperative (duration of operation, the type of prosthesis), and postoperative (duration of hospitalization, complications, and the rate of patients satisfied with the therapy) findings, and complications were evaluated. Patients were followed up for 21.04±28.72 months on average after operation.

Results

The mean age of patients was 54.63±9.69 years, (range 30-78 years). The mean BMI was 36.71±6.57 kg/m^2 (Table 1). Of 47 patients, 43 (91.4%) were married and 4 (8.6%) were single. In the evaluation of ED etiologies in patients, 30 (63.8%) were diabetes mellitus, 8 were cardiovascular disease, 4 were radical pelvic surgery, 2 were pelvic radiotherapy for prostate cancer, 2 were spinal surgery, and 1 was genital trauma (Table 2). Apart from all these reasons, 33 patients (70.2%) had a history of smoking. The mean duration of ED in patients was 45.36±24.82 months, ranging from 12 months to 120 months. The median IIEF score of patients was found to be 0. Before the application of penile prosthesis, all the patients had received oral phosphodiesterase type-5 inhibitors and intracavernosal papaverine therapies from the first and second care treatment alternatives, but they had not responded to these therapies.

Penile prosthesis implantation lasted for 109.6±28.41 min on average and no complication was observed during operation. Of 32 patients (88.8%) were placed flexible penile prosthesis, 26 were placed Coloplast, and 6 were placed Mentor prostheses. In 4 patients who were placed inflatable prostheses, an AMS penile prosthesis was used. The mean duration of hospitalization was 2.48±1.41 days. Early and late complications were observed only in 10 patients (21.2%) and 97% of these complications were re-

Table 1. Data of patients

Data	
Age of patient (years)	54.63±9.69
Marital status (married/single)	43/4
Duration of ED (months)	45.36±24.82
BMI (kg/m^2)	36.71±6.57
Median IIEF score	0

ED: erectile dysfunction; BMI: body mass index; IIEF: International Index of Erectile Function

Table 2. Etiological factors in patients

Etiology	n (%)
Diabetes mellitus	30 (64%)
Cardiovascular disease	8 (17%)
Radical pelvic surgery	4 (9%)
Pelvic radiotherapy for prostate cancer	2 (4%)
Spinal surgery	2 (4%)
Genital trauma	1 (2%)

Table 3. Intraoperative and postoperative complications

Complication	n
Intraoperative	0
Postoperative	
Infection in incision site	3
Infection	2
Mechanic damage	2
Acute urinary retention	1
Tension/pain	1
Scrotal hematoma	1

solved without any intervention (Table 3). Acute urinary retention developed in one patient applied spinal anesthesia in the early postoperative period and this patient was implemented short-term urethral catheterization. In the late postoperative period, 3 patients had an infection in the skin incision that healed after antibiotic therapy, 1 patient had penile tension/pain, 1 had a problem in the prosthesis pump, and 1 patient had a mechanical problem in the device. Therefore, their devices needed to be changed. Prosthesis associated infection was observed in 2 patients. In one of these patients, an improvement was observed after the removal of the prosthesis. However, in the other patient, infection did not regress and penile amputation was performed. Besides that, no problem associated with prosthesis, such as a mechanical defect or inadequate length, was observed. 67% of patients, who were followed up for 21.04±28.72 months on average, stated that they were satisfied with the treatment.

Discussion

Erectile dysfunction is an important sexual dysfunction in men, which can seriously affect quality of life and can be associated with vascular, neurogenic, and psychogenic factors. ED can be divided into two groups: organic and iatrogenic. ED can develop in approximately 30-87% of patients even if robotic and anatomic neuroprotective surgery is performed after radical prostatectomy, which is a gold standard treatment, especially for prostate cancer, today (7, 13). The most important pathophysiology underlying ED that develops after radical prostatectomy is neurovascular bundle dissection or neurapraxia (14). The recovery period can be prolonged by up to 18 months due to trauma because of suturing a prostatic branch of the prostato-vesicular artery, which supplies the prostate, and the neurovascular bundle, which innervates the penis, due to bleeding resulting from dorsal vein on the anterior prostate during operation, cutting the striated muscle during the placement of anastomosis sutures on the urethra, carelessly cutting the posterior urethra, and excessive hemostasis at the end of

Table 4. Methods that can be used in penile rehabilitation after radical prostatectomy

Pharmacological agents	Oral treatments (14–20 days/month)	PDE5 inhibitors Sildenafil, tadalafil, vardenafil
	Intracarvernous injections (3 times a week)	PGE_1 (alprostadil) Low dose Trimix Bimix (papaverine, phentolamine)
	Intraurethral injections (125 or 150 µg for 3 times a week)	
Non-pharmacological agents	Vacuum erection device (for 5–10 min a day, without using a ring)	
Combination of the abovementioned therapies		

PDE5: phosphodiesterase type 5; PGE_1: prostaglandin E_1

Table 5. Complications of penile prosthesis

Complication	Preventive action/treatment
Mechanical damage	Change of device
Infection	Use of devices covered with antibiotics
	Use of broad-spectrum antibiotics during operation
	Application of no-touch technique
	Removal of device and washing
Urethral perforation	Immediate repair
	Healing on urethral catheter
	Suprapubic diversion
	Waiting for urethral recovery
Reservoir herniation	Leaving in situ
	Placement in the perivesical region
Curvature/tear in the glans	Use of prosthesis in proper length
	Providing adequate dilatation
	Repair in serious cases
Corporal perforation	Repair
	Use of windsock patch
Erosion	Distal corporoplasty
	Repair

the operation and lacunar fibrosis developing as a result of this situation can cause erectile dysfunction (15).

Oral phosphodiesterase type-5 inhibitors are used in the primary care treatment of erectile dysfunction. Phosphodiesterase type-5 inhibitors, such as sildenafil, which was the first introduced into the market, vardenafil, tadalafil, and the more recently produced udenafil, avanafil, lodenafil, and mirodenafil are the drugs that are easiest to use, and that are effective and easily tolerated by patient. The aim of penile rehabilitation, which is performed for regaining spontaneous erections in ED developing after radical prostatectomy, is to provide sufficient tissue oxygenation during the neural regaining process and to prevent possible cavernous tissue damage. There is no consensus on the agents, their doses, their frequencies, or the program of penile rehabilitation to be applied for this aim (Table 4). There are some studies reporting that the most effective phosphodiesterase type-5 inhibitor is sildenafil, particularly for patients undergoing neuroprotective operation. Also in our study, oral phosphodiesterase type-5 inhibitors were used in the primary care ED treatment of all patients. In the studies, the success rates of sildenafil in ED after radical prostatectomy were reported to be between 35% and 75% in patients undergoing neuroprotective surgery and between 0% and 15% in patients not undergoing neuroprotective surgery (17, 18). In our clinic, all patients were initiated with 5 mg/day tadalafil in the early period after radical prostatectomy for reducing the rates of penile fibrosis and ED, which may develop due to operation.

In patients without a response to oral therapy, intracavernosal and intraurethral vasoactive agents can be used. The most commonly used vasoactive agent is prostaglandin E_1 alprostadil. Besides that, Bimix, which is the combination of papaverine and alprostadil, and Trimix, with the addition of fentolamin to this combination, are other alternatives. It was reported that intracavernosal injections were successful in 87%-93.5% of all ED patients and by 86%-90.3% of their partners (19, 20). However, 67% of patients discontinue the treatment due to some reasons, such as pain, prolonged erection, priapism, and fibrosis (21).

In ED patients not responding to primary and secondary care treatments, penile prosthesis implantation is recommended as a permanent and invasive method. Penile prostheses, which first began to be used in the 1970s, were modernized with the development of new prostheses with a silicon inner side and metal support in 1989. Then, with the production of inflatable and multiple-piece and even antibiotic-coated prostheses, devices that led to less complications and were more suitable for social life were developed (22, 23). An ideal penile prosthesis should be able to be implanted without leading to a serious complication during the operation, have an adequate length and rigidity for penetration, and provide the highest patient and partner satisfaction. However, the type of prosthesis can change depending on the patient's mental capacity and manual skill. All types of prostheses have different advantages and disadvantages that will affect the satisfaction levels. Flexible prostheses are advantageous for many as they comprise few pieces, their duration of operation is short, and their costs are lower. However, because they are always rigid, they are not suitable for endoscopic interventions in which a urethral passage is required. On the other hand, despite the occurrence of more mechanical defects, inflatable prostheses are more cosmetic and natural since they provide rigidity when necessary. Most patients are satisfied with penile prostheses because they offer nearly natural rigidity. In our study, 68% of patients stated that they were satisfied with penile prosthesis implantation in the 21-month follow-up period. Today, approximately 80% of patients can use their prostheses in the 5th year without any complication associated with the device (24). Only one of our patients underwent re-implantation due to a complication caused by the device. Infection, which is the most important complication, is seen at rates of between 1% and 2% owing to the antibiotics developed against gram positive and gram negative bacteria and antibiotic-coated devices (24). Although we used antibiotic-coated prosthesis in our study, infection was observed in only 2 patients. In one of these patients, infection could not be brought under control and penile amputation was considered.

In addition to the complications in the device, such as leakage of fluid, aneurysmal dilatations of the cylinders, a tear in the synthetic material, and corporaglanular deformity, in the penile prostheses providing satisfying results in patients with erectile dysfunction and their partners (25), infection is the most common and the most serious complication that can lead to penile shortening, urethral injury, and tissue loss (Table 5) (26, 27). Particularly, patients with diabetes mellitus, suppressed immunity, and an injured spinal cord are exposed to infection more frequently. In the studies conducted on penile prostheses removed due to infection, it was revealed that a biofilm layer was formed by microorganisms on the surface of the device and impaired the immune system and that antibiotics could not improve this situation (28). Therefore, new model devices were developed with the notion that postoperative infection risk could be reduced through coating the penile prostheses with antibiotics such as rifampicin and minocycline (29).

Conclusion

Penile prosthesis implantation is an efficient treatment method for ED whatever the ED results from. Tertiary care treatment, in which less mechanic damage and infection is seen with the new prostheses developed recently, is an alternative that can be applied successfully in every clinic and that provides a high level of satisfaction in patients and their partners.

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Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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