

Penile prosthesis – a viable solution for erectile dysfunction refractory to conservative therapy

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Abstract: Introduction: Erectile dysfunction(ED) is a serious condition which can affect men of all ages, with an important impact over the quality of life. When conservative therapy fails, a viable solution is the penile prosthesis implantation (PPI).

Objective: The purpose of this paper is to present data from recent literature regarding the satisfaction rates of men who have undergone penile PPI and as well as the partners satisfaction rates, ease of use, informations regarding long term survival of these prosthesis, postoperative complications and long distance complications, the effectiveness and the way that penile prosthesis have influenced the quality of life of the men who have opted for this solution.

Material and methods: We have analyzed recent long term studies concerning the outcomes of the PPI, studies which were made retrospectively, over a period of time of 10 to 15 years.

Results: Compared with the conservative treatment for ED, the satisfaction rates achieved after penile prosthesis implantation are higher. According to these studies, the overall patient's satisfaction is 70-90%. The difference between patient and their partners' satisfaction rate is negligible, this difference ranging between 2 to 8%. The satisfaction rate regarding the adequate erection for sexual intercourse is 80-90%. The overall satisfaction rates for the malleable prostheses are lower compared with inflatable devices, 30-75%, respectively 75-90% for the inflatable prosthesis. The mechanical and overall survival rates for the malleable prosthesis range between 65-80% at 10 years, and 58-75% for the inflatable devices. Overall ease of use is rated as 78%. Complications after implantation can be encountered in less than 5% of cases and infections in less than 2%. The likelihood of continued use is higher in the group of the patients with the inflatable prosthesis compared with the malleable ones 70-80%, respectively 50-60%. Up to 85-90% of patients with inflatable prosthesis would recommend them.

Conclusions: PPI is a high effective treatment for erectile dysfunction, refractory to pharmacological treatment. The inflatable penile prosthesis (IPP) provides more overall satisfaction than the malleable ones. The patients with IPP are more likely to continue using their devices than those with the malleable prosthesis. PPI improves significantly the quality of life for patients with erectile dysfunction.

INTRODUCTION

Erectile dysfunction is defined as the inability to obtain and maintain an erection with sufficient penis rigidity, adequate for successful sexual contact.

Although ED decreases significantly the quality of life for both men and their partners, in many countries

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ED is understated because of cultural aspects.

ED can affect men of all ages, but as life expectancy continues to increase, so does its prevalence. It is estimated that the prevalence of ED in men over the age of 50 years is higher than 50 percent, and this prevalence grows as the age increases. This condition is not exclusively encountered in men over the age of 50. It is estimated 3-5 percent of young men with ages between 15 and 25 years may suffer from this condition and 7 to 10 percent of those with ages between 25-45 [1].

Despite initial beliefs that the most common cause for ED was the psychological factor, especially in young men, it is now proven that organic causes are responsible for 70 to 90 % of ED. There are several proven pathologies proven in ED [2]:

a) Diabetes Mellitus-is a frequent cause of ED. Men with DM compared with general population may have ED at an earlier age. The prevalence of ED in the population of men with DM can be as high as 70-80%. The peripheral polyneuropathy, microangiopathy and arterial insufficiency encountered in DM evolution can explain the earlier age of ED appearance and a higher prevalence than individuals without DM [3].

b) Vascular causes-atherosclerosis plays an important role in ED physiopathology. The presence of aortic or iliac atheromatosis can decrease the blood inflow, thus explaining the ED prevalence of up to 50 % in patients with atheromatosis. Another vascular cause may be the increased venous outflow, which depends on the trabecular smooth muscle relaxation and on the erectile tissue's capacity of expandability.

c) Iatrogenic causes responsible for ED- renal transplantation, aortic or peripheral surgery, abdominal perineal resection of the rectum, perineal irradiation, cystoprostatectomy or radical prostatectomy (RP). Erectile dysfunction secondary to cystoprostatectomy and radical prostatectomy may be encountered in up to 80% of cases. Since the nerve sparing RP was introduced by Walsh over years ago, the incidence of ED was decreased to 40-60% [4]. The incidence of ED post RP depends on patient age, comorbidities, preoperative potency status, type of surgery, surgical technique (open, laparoscopic or

robot assisted RP), surgical experience, extensive nerve sparing (unilateral or bilateral) [5]. Although some patients believe that radiotherapy may be associated with a lower risk of ED, it has been proven that ED may be encountered in 20-80% of patient who has undergone radiotherapy. Studies have shown that the incidence of cavernosal fibrosis and ED are similar between RP and radiotherapy [6,7].

d) Trauma – pelvic fractures may affect the internal pudendal or common penile artery or the neurovascular bundle.

e) Endocrinological causes such as: hypogonadotropic hypogonadism, hypergonadotropic hypogonadism, hyperprolactinemia and hyperthyroidism.

It is known that testosterone increases sexual interest and the frequency of sexual acts, as well as the frequency of nocturnal erections, but it's role on visual or fantasy induced erections is little to none.

f) Neurological causes:

- CNS: Parkinson's disease, encephalitis, temporal lobe epilepsy, stroke, multiple sclerosis (50-70% of patients with MS may have ED), tumors, myelodysplasia;

- peripheral nerves (trauma, diabetic polyneuropathy, alcoholic neuropathy and radiopelvic surgery).

g) Penile diseases: Peyronie's disease, trauma, priapism (vascular lesions).

h) Drugs: Marijuana, Opioids, Ethanol, Antimuscarinic drugs, Antihistamine, Tricyclic antidepressants, Estrogens, Spironolactones, Ketoconazole, and many other drugs.

i) Renal failure-up to 40-50% patients on dialysis suffer from ED.

TREATMENT

Currently there are three lines of treatment for ED. The first line and the most used one is oral medication, especially phosphodiesterase 5 inhibitors. Since 1998, when the first PDE-5 inhibitor was introduced, Sildenafil (Viagra), the management of ED was revolutionized due to its high efficacy and few adverse effects. As time passed other drugs with higher efficiency and superior safety profiles became

available, such as: Vardenafil (Levitra) and Tadalafil (Cialis). These drugs block the hydrolysis of cyclic GMP, increasing the accumulation of GMPC and potentiating the effect of NO [2]. For many men the treatment with PDE-5 inhibitors has allowed them to regain normal sexual function and regain self-confidence.

The second line treatment is the intracavernous injection of vasoactive drugs such as papaverine, prostaglandin E1 or phentolamine. The efficacy of this therapy is high, but the pain and the risk of ischaemic priapism limit its utilization [8]. The third line of treatment is the surgical implantation of a penile prosthesis. When the conservative therapy fails (PDE 5 inhibitors, intracavernosal injections, vacuum erection device, intraurethral suppositories with alprostadil – Is a PGE1 which increases corporeal oxygenation by promoting blood inflow) or when the patients are reluctant to any form of conservative therapy, the solution is the penile prosthesis implantation. The first penile prosthesis were introduced at the beginning of the 1970s. Since then they have been greatly improved and the surgical techniques for placement have evolved and made penile prosthesis implant a very effective treatment for ED [9]. This kind of treatment is effective and safe, and it also offers high satisfaction rates for patients and for their partners. With the technical improvement the number of complications and revision surgeries decreased, thereby the popularity and use of penile prosthesis for the treatment of ED increased.

The penile prosthesis available on the market include the one piece malleable and the two or three piece inflatable versions, each type of prosthesis having its own advantages and disadvantages. Malleable prosthesis is easier to use and have fewer mechanical problems compared with the inflatable prosthesis and they are also less expensive. The disadvantage of malleable implants is that complete penile detumescence cannot be achieved and this may be an important factor for patient dissatisfaction [10]. The inflatable prosthesis permit flaccidity and have a better functional result, but not all patients have the dexterity to use them, especially older men. Despite

the implantation of penile prosthesis has been well documented, many urologists are reluctant to this form of treatment in older patients, due to the concern that older men have less dexterity and ability to operate an inflatable device [11]. The patients' satisfaction regarding the penile prosthesis implant is associated with their expectations and the performance of the implanted prosthesis [12]. Therefore, the decision regarding the type of prosthesis should be made by the doctor and by the patient, during a discussion where the doctor explains the advantages and disadvantages of every type of prosthesis, the risk of complications, the rate of satisfaction and dissatisfaction that both patient and his partner may have from this type of treatment, thus making sure that the patients will have expectations in line with reality.

The three piece inflatable penile implants are currently the most used prosthesis and their results regarding patient satisfaction are very good. The malleable and two piece penile prosthesis can be used in selected cases, where the three piece prosthesis has questionable indications (like in the case of elderly men who may have low dexterity and ability to operate such devices) [13,14].

Partners' satisfaction is questionable because few studies have investigated this problem during a long term follow-up period; although in literature the rate of partners' satisfaction is similar with men satisfaction. For more realistic results regarding this problem, evaluating the two partners separately during the follow-up period should bring out interesting results (in line with reality) [15].

Hakan Kilicarslan et. al in a recent study regarding the comparison of patient satisfaction for the malleable prosthesis (AMS 600-650) and two piece inflatable penile prosthesis (AMS Ambicor) concluded that the two piece inflatable prosthesis was found to be more successful and more likely for continuous use when compared to the malleable device. A total of 72 patients had either AMS 600-650 or AMS Ambicor, but only 46 patients were reviewed during a long time follow-up. The percentages of patients with AMS 600-650 who reported to be satisfied, very satisfied and unsatisfied after the implant were 34,78% (8

patients out of the total of 23 questioned after the operation), 30.43% (7 patients out of 23) and 34.78% (8 patients out of 23). For the patients with the two piece inflatable penile prosthesis the results were: 73.91% (17 out of 23), 13.04% (3 out of 23) and 13.04%. The percentages of patients who reported to be very likely, unlikely or very unlikely to continue using the malleable implants were: 30.43% (7 patients), 34.78% (8 patients) and 34.78%; in the case of the patients with the two piece inflatable devices the results were: 65.21%, 21.33% and 13.04% [16].

A study made by Natali et. al revealed that the likelihood of continuous for the two piece device AMS Ambicor was 89% (59 patients) and for the malleable device AMS 600-650 was 56% (9 patients) [13].

In another comparative study Lux et. al reported that the partners satisfaction rated 79% with the two piece prosthesis [17].

Levine related an overall satisfaction rate of 90% for men and the 82% for their partners, of a total of 131 patients, patients which benefited from the AMS two piece Ambicor implant [18].

Minervini reported that the 71% of patients using the malleable AMS 600-650 were satisfied with the implant [19].

Yoon Seob Ji in a study made on 74 patients who underwent implantation of inflatable penile prosthesis reported that the overall satisfaction was 86,8% and that 81,1% said that the prosthesis improved their sexual life. 83% of the patients in the study would undergo surgery again and 88.7% would recommend it to a friend. Only 60.4% of the patients interviewed during the follow-up period reported that they had an orgasm [20].

Mario Paranhos and collaborators established that 86.3% of patients (120 patients questioned out of 249 operated) rated their satisfaction after the implant as good, excellent or very good. The partners' satisfaction percentages was similar. The follow-up period was 40 months [21].

Humberto G. Villarreal and LeRoy Jones, in a study about penile prosthesis in the elderly men, reported

that overall satisfaction was 4.3 (from a scale of 1 to 5, 5 meaning very satisfied), the ease of use was 4.1 (from a scale of 1 to 5.5 meaning very easy) and the mean use was 3,3 per month (0 to 7 times a month) [11].

Carson and associates evaluated satisfaction rate in 372 patients, group in which was used the AMS 700 CX prosthesis and it was stated that 79% used this prosthesis at least twice a month and that 88% would recommend the prosthesis for a friend [22].

There was little data regarding implantation of penile prosthesis in elderly people. As the life expectancy and longevity continuous to increase so does the ED problem refractory to first line treatment. Accordingly to Lindau, elderly couples remain sexual active even into the eight decade of life [23]. So the number of elderly men seeking penile prosthesis implantation will have a significantly increase. There are numerous potential complications of the inflatable penile prosthesis such as surgery related complications (haematoma, infections, erosion of the corpus cavernosum and even perforation) and mechanical failure (reservoir leakage, cylinder leakage, pump failure) [14,24].

The incidence of these complications depends on the follow-up period. In the immediate postoperative period, Paranhos stated that 24.5% patients reported pain, 7,9% had local infections and 8,6% had other complications such as wound dehiscence, difficulty voiding or local secretions without infection. In regards to late complications 8.6% of patients had to undergo revision surgery (12 patients out of 139 operated and followed up), of whom 4 the prosthesis had removed due to inefficacy and 8 had them exchanged. 2 of the 8 patients who had them exchanged had prosthesis fractured, 4 had inadequate size and the other 2 had extrusion of the cylinder. He remarked in his study that the risks of complication for the patients that have had radical prostatectomy previously was higher, 3,3 times higher. The rate of postoperative infections in this study was 7.9%. Paranhos explains that this high rate of infections compared to other studies is due to the experience of medical trainees, the high number of surgery in the operating rooms and the economic and

social conditions of the patients [21]. The rigorous preoperative asepsis has shown to reduce the incidence of infection to 4% from initial overall rate of 12% [25].

Jarow et. al [26] reported an infection rate of 1,8% and Gower a rate of 2.1% [27].

Merino in a meta-analysis related a lower infection rate in the case of malleable prosthesis compared to inflatable prosthesis (1.3% vs 3.5%) [28].

Menard in a study which examined over 400 patients with penile prosthesis after radical prostatectomy showed that the rate of complications for infection, revision or mechanical failure was less 5% and that the satisfaction rate was 86.1% [29]. The use of antibiotic impregnated penile prosthesis could significantly reduce the postoperative infection incidence and as well as the number of revision surgeries related to infectious complications. The overall postoperative complications are less than 5% and for infections is less than 2%. The incidence for mechanical failure is related of the follow-up period [30] and the overall incidence is around 5% [31]. Mechanical failure occurs more frequently in a case of multipiece inflatable prosthesis, due to their complexity. Malleable prosthesis due to the simple design are associated with a lower risk of mechanical problems. Lotan et al. related that the rate of survival (without technical problems) for malleable prosthesis compared to the inflatable ones is 87% vs 50% [32]. Paranhos encountered during his study a rate of mechanical problems in 3.59% of cases [21].

Atienza, in a meta-analysis regarding this problem found that the overall rate of mechanical failure was 1.4% [33]. He also found a rate of prosthesis exchange or withdrawal of 7.1%, which was similar to the rate that Paranhos described in his study of 8,68% [21]. The causes of exchange or withdrawal were inadequate cylinder size, fracture of bioprosthesis (very rare, Paranhos [21] reported 2 cases of patients with prosthesis fracture that didn't know of their problem and they had a normal sexual activity, this issue was found during check-ups).

Yoon Seeob Ji [20] related that 21.6% of patients (16 patients) experienced mechanical problems and 5.4%

(4 patients) mechanical problems. The mean follow-up period was 98 months. The mechanical problems encountered were caused by cylinder leakage 8.1% (6 patients), reservoir leakage 1.4% (1 patient out of 16) and pump failure 1.4%. In the case of the other 8 patients with mechanical failure the cause was not found because they didn't undergo reoperation. The nonmechanical failure was due to erosion, infection of the prosthesis and other medical problems. All the patients with non mechanical failure underwent implant removal and surgical exploration. The survival rate of the inflatable prosthesis during the follow-ups over 5.10 and 15 years were 67.6%, 43.2% and 23%.

RESULTS

Compared with the conservative treatment for ED, the satisfaction rates achieved after penile prosthesis implantation are higher. According to the studies that we have analyzed, the overall patients satisfaction is 70-90%. The difference between patient and their partners satisfaction rate is negligible, this difference ranging between 2 to 8%. The satisfaction rate regarding the adequate erection for sexual intercourse is 80-90%. The overall satisfaction rates for the malleable prostheses are lower compared with inflatable devices, 30-75%, respectively 75-90% for the inflatable prosthesis. The mechanical and overall survival rates for the malleable prosthesis range between 65-80% at 10 years, and 58-75% for the inflatable devices. Overall ease of use is rated as 78%.

Complications after implantation can be encountered in less than 5% of cases and infections in less than 2%. The likelihood of continued use is higher in the group of the patients with the inflatable prosthesis compared with the malleable ones 70-80%, respectively 50-60%. Up to 85-90% of patients with inflatable prosthesis would recommend them.

CONCLUSIONS

PPI is a high effective treatment for erectile dysfunction, refractory to pharmacological treatment. The technological improvements have decreased the rate of complications and revision surgeries which

may appear after implantation, making these devices a safe solution and with great results for the men who choose penile prosthesis implantation as an answer to their problem. Many studies have related that the satisfaction rate after the operation was high, both for the patients and their partners [20]. The patients' dissatisfaction after the implantation, was related to the unnatural feel of the sexual relations, due to the delayed ejaculation which was encountered in few cases and also because of the partners' dissatisfaction, situation that may be related to the fact that the expectations were higher than the results. Thus before the operation, the doctor should make sure that the patient and his partners will have expectations in line with reality. Today, the three-piece inflatable prosthesis is the most preferred one. Regarding the long-term survival and complications of the penile prosthesis, the malleable prosthesis have a lower rate of mechanical problems than the inflatable ones, due to their less complex technological design, but patients' satisfaction is higher in the group of

inflatable prosthesis because they permit flaccidity and they have a better functional result. Patients who undergo implantation for the first time have a lower risk of postoperative complications compared with the patients who have had several interventions for different complications related to the penile prosthesis implant. The likelihood of continued use is higher in the group of the patients with the inflatable prosthesis compared with the malleable ones. The success of the implantation is very important, because the surgical revision is associated with a worse prognosis and a higher rate of complications. Regarding diabetes, several studies have shown a small correlation between diabetes mellitus and postoperative infections [34,35]. Diabetes mellitus and radical prostatectomy are associated with a higher of postoperative complications. PPI enhances sexual capacity and self-confidence, therefore it should be considered as a final choice for patients with ED refractory to drugs.

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