Utilization of penile prosthesis and male incontinence prosthetics in Saudi Arabia

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Background: Erectile dysfunction is a prevalent disease affecting over 50% of men between the ages of Abstract 40 and 70 years. Penile prosthesis represents the end of the line treatment when other less invasive therapies fail or are contraindicated. Male stress urinary incontinence can significantly diminish quality of life and lead to embarrassment and social withdrawal. Surgical therapies, such as male urethral slings and artificial urinary sphincters (AUS), are considered effective and safe treatments for male stress incontinence. No data exist on the utilization of penile prosthesis or male incontinence surgical treatment in Saudi Arabia. Generally, urological prosthetic surgery is performed either in private hospitals or in government hospitals. Our aim was to assess the trend of penile prosthesis and male incontinence device utilization in Saudi Arabia. Materials and Methods: We utilized sales' data of penile prosthetics, male slings, and AUS from the only two companies selling these devices in Saudi Arabia (AMS® and Coloplast®), from January 2013 to December 2016. Results: There were 2599 penile prosthesis implantation procedures done in the study period, with 67% of them performed in private institutions. There was a progressively increased use of penile prosthetics which nearly doubled from 2013 to 2016. The main type of prosthesis utilized was the semirigid type 70% versus 11% of the 2-piece inflatable and 17% of the 3-piece inflatable device. Only 10 slings and 31 AUS were inserted during the same study period.

Conclusions: There is an increased utilization of penile prosthetics in Saudi Arabia. The private sector performs the majority of penile prosthesis procedures, and most of them are of the semirigid type. The governmental sector is more likely to perform inflatable penile prosthesis and male incontinence device procedures. Male incontinence prosthetics' use is very limited in Saudi Arabia.

Keywords: Erectile dysfunction, penile prosthesis, Saudi Arabia, urinary incontinence

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INTRODUCTION

Over half of the men between the age of 40 and 70 years are affected with erectile dysfunction (ED).^[1] There are several predisposing factors for ED including aging, diabetes mellitus, hypertension, dyslipidemia, Peyronie's disease, and priapism. The introduction

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of type-5 phosphodiesterase inhibitors (PDE5Is) has revolutionized the treatment of ED, given its effectiveness and high safety profile. However, PDE5Is are not for every patient as it can be contraindicated, ineffective, or intolerable to certain groups of patients. Several treatment options are available for these patients

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with varying degrees of success such as intracavernosal injections, vacuum erection device, intraurethral prostaglandin E1, and penile prosthesis.^[2]

Penile prosthesis insertion is highly successful in treating ED regardless of the underlying etiology. They are associated with relatively low risk of complications. They fill the cavernosal bodies to provide adequate rigidity for penetration. They could be of the solid (semirigid) type or the inflatable type. There are 2 types of inflatable prosthetics; 3-piece inflatables (AMS[®] 700 and Coloplast[®] Titan) or 2-piece inflatables (AMS[®] Ambicor).^[3] Despite the introduction of PDE5Is and their widespread use, recent reports have demonstrated the increased utilization of penile prosthetics in the United States from 17,540 in 2000 to 22,420 in 2010.^[4,5]

Urinary incontinence affects nearly 15%–20% of patients postradical prostatectomy, with significant impact on quality of life and emotional well-being of individuals.^[6] Several options are available for treatment including pelvic floor exercises, injection of bulking agents, and insertion of prosthetics such as urethral slings and artificial urinary sphincters (AUS).^[7,8]

Healthcare in Saudi Arabia is provided through both the government sector and private sector. No data until now has been published on the utilization of penile and male incontinence prosthetics. This article examines the utilization of these devices in Saudi Arabia in both sectors and attempts to identify the patterns for their use and the types commonly utilized.

MATERIALS AND METHODS

Two companies provide penile and male incontinence prosthetics in Saudi Arabia; Coloplast® and American Medical Systems (AMS®). Data were provided by their distributors in Saudi Arabia for the 4-year period from January 2013 to December 2016. The data were provided for the types of penile prosthetics (semirigid, 2-piece inflatables, and 3-piece inflatables). In addition, the types of male incontinence devices were provided (male slings and AUS). Data wee categorized into private sector or governmental sector. Governmental sector refers to all the different branches of government hospitals including Ministry of Health, Armed Forces Hospitals, National Guard Hospitals, and University Hospitals. No data is available before January 2013. Due to the lack of centralized database, no patient information or outcome data was available for analysis.

RESULTS

There were 2599 penile prosthetics performed during the study period (January 2013 to December 2016). Most of these prosthetics were performed in the private sector (67%), while 33% were performed in the governmental sector [Table 1]. This percentage has remained nearly constant during the study period: 27% in 2013, 35% in 2014, 34% in 2015, and 35% in 2016 for the governmental sector and 73% in 2013, 65 in 2014, 66% in 2015, and 65% in 2016 for the private sector.

There was an overall progressively increased use of penile prosthetics during the study period which nearly doubled from 2013 to 2016 [Figure 1]. The increase was seen in both sectors; a total of 382 prosthetics in 2013, 584 in 2014, 805 in 2015, and 828 in 2016. Most of the penile prosthetics were of the semirigid type (70%), while 2-piece inflatables and 3-piece inflatables constituted 11% and 19% of the prosthetics used, respectively. This percentage has also remained nearly constant over the years: semirigid (70% in 2013, 69% in 2014, 71% in 2015, and 68% in 2016), 2-piece inflatables (7% in 2013, 13%, 12%, and 11% in 2016), and 3-piece inflatables (23% in 2013, 18% in 2014, 17% in 2015, and 21% in 2016) [Figure 1].

The private sector was more likely to perform semirigid penile prosthesis (75% of the semirigid prosthetics inserted), while the governmental sector was overall more likely to perform the inflatable prosthetics (57% of the 2-piece inflatables and 50% of the 3-piece inflatables) [Figure 2]. There were very few male incontinence devices inserted

Table 1: Total number of penile prosthetics performed inSaudi Arabia from January 2013 to December 2016

Sector	Semirigid	2-piece inflatable	3-piece inflatable	Total (%)
Governmental	454	162	253	869 (33)
Private	1354	124	252	1730 (67)
Both (%)	1808 (70)	286 (11)	505 (19)	2599 (100)



Figure 1: Types of penile prosthetics performed in Saudi Arabia by year



Figure 2: Types of penile prosthetics performed in Saudi Arabia by sector

(31 AUS and 10 slings). Most of them were performed in government hospitals (7 slings and 23 AUS).

DISCUSSION

Penile prosthesis represents the gold standard surgical treatment for ED, with the highest patient and partner satisfaction rate and a low complication rate.^[2] Chung *et al.* showed 90% satisfaction rate for penile prosthesis and 1.2% complication rate.^[9] Large studies on penile prosthesis in Saudi Arabia are absent, and most of the published literature focus on case reports and case series from single centers. Kattan in 2002 examined patient acceptance and satisfaction rate with intracavernosal injection, vacuum erection device, and penile prosthesis in 210 Saudi men. He showed that penile prosthesis was the least accepted modality of treatment but had by far the highest satisfaction rate of 87% at 12 months.^[10]

Healthcare in Saudi Arabia is provided through either the private sector, which could either be self-funded or covered by private insurance, or through the governmental sector. The governmental sector provides free healthcare to all citizens. However, when it comes to penile prosthesis insertion, private insurance companies do not provide coverage for the procedure and the patient would have to pay for it out of pocket. In addition, most government hospitals do not cover for this procedure, and those that do cover it either they do not provide the device in some situations or they have very long waiting lists. This is different from Medicare, for instance, which covers the procedure in its entirety from the perspective that it is an Food and Drug Administration-approved functional treatment not a cosmetic procedure.^[11]

Our data show that nearly two-thirds of penile prosthesis in Saudi Arabia are done in the private sector. This is not surprising given the above-mentioned factors. The patients would likely prefer to pay out of pocket to avoid long waiting lists. This also explains the fact that most of the penile prosthetics performed in the private sector are of the semirigid type because it is cheaper and less likely to require reoperation due to mechanical failure than the inflatable type. This probably makes the device more convenient to the patient financially and the performing private institution medicolegally. On the other hand, the governmental sector performs 57% of the inflatable cases as the inflatables are more physiologically acceptable to the patient, and he would not be required to pay for this expensive device in the majority of situations, while reoperations are still covered by the same institution. Of note, nearly one-third of the inflatables used were of the 2-piece inflatable type. This type of device (AMS® Ambicor) has been traditionally applied to patients with previous pelvic surgery where it is difficult to place the pump; however, due to the development of the ectopic flat reservoir, many surgeons has now shifted to the 3-piece inflatables with ectopic reservoir instead.[12-14]

Our data also show very limited utilization of male incontinence surgical devices. This could be attributed to either very low utilization of the device due to patient low acceptance or limited recommendation of these devices by the surgeons, or it could be attributed to the limited number of radical prostatectomies performed in Saudi Arabia.^[15] Most of these devices were performed in government hospitals, which might be the same hospitals that perform the radical prostatectomies.

The main limitation of this study is its limited scope, which is due to the lack of centralized database for penile prosthetics and male incontinence devices in Saudi Arabia. The only data source available was the distributors' sales data, which includes only the sales for 2013 onwards and no patient clinical information. No data is available on whether the devices are primary or revision devices. Since this is a purely descriptive study, no information is available on outcomes or complications. However, it remains the first national study on penile prosthesis and male incontinence device utilization in Saudi Arabia. Future studies should focus on multicentric analysis of penile and male incontinence prosthetics in Saudi Arabia in terms of clinical outcomes and hopefully establish a national database on those prosthetics usage.

CONCLUSIONS

This is a descriptive study showing the progressive increase in penile prosthesis utilization in Saudi Arabia and the dominance of the private sector in performing those procedures with a higher tendency to insert the semirigid type. The governmental sector, however, is more likely to perform inflatable penile prosthesis and male incontinence device insertion. We hope that more multicentric prospective studies and a national database are established, and we wish the private insurance would cover these cases as functional cases, not cosmetic ones.

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Conflicts of interest

There are no conflicts of interest.

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