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Safety and Efficacy Outcomes of ZSI 100 Semirigid Penile Prosthesis

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Abstract

Objective: *Demonstrate safety and efficacy of ZSI 100 malleable/semirigid penile implant.*

This study was conducted from May 2018 to March 2020.

Patients and method: *From May 2018 to March 2020, 52 ZSI 100*

Malleable-semirigid penile prostheses were implanted by 4 surgeons in 52 patients in three centres of the Islamic Republic of Iran. Mean age of patients was 54 years old [26-88]. Standard procedure was performed for the 52 patients. Erectile function was assessed by a questionnaire including desire, penile rigidity, orgasm, and frequency of intercourse.

Results: *Median follow-up was 13.23 months [6-28]. Complications were limited to 2 erosions (3.84%). At the end of follow-up, 92.30% of patients had a functional prosthesis and were satisfied.*

Conclusion: *Implantation, risks of complications, functional outcome and patient satisfaction with penile implant ZSI 100 are similar to standard malleable- semirigid penile implants.*

Key words: *Erectile dysfunction, penile prosthesis ZSI 100*

Introduction

The prevalence of erectile dysfunction [ED] is more than 40% after 40 years (1,2).

Erectile dysfunction is a common problem whose support is well codified. Neglecting the management of this disorder can lead patients to depression (3). The penile implant is proposed after the failure of other techniques such as oral treatments, vacuums, and intra-cavernous injections. Malleable penile implants are well accepted with simple surgical procedure, rare mechanical failure, and low cost. We are now able to evaluate its efficiency with standard questionnaire and we know more about intra-operative complications and post-operative complications of malleable penile implants.

We present the results of a study about 52 patients implanted with ZSI 100 penile implants (Zephyr Surgical Implants, Geneva, Switzerland). The ZSI 100 is designed as a standard malleable-semirigid penile prosthesis. We studied preparation, surgical procedure, post-operative events and functional outcome.

Material and method

Population

From May 2018 to March 2020, 52 malleable penile implants ZSI 100 were implanted in 52 patients by 4 operators from three centres in Islamic Republic of Iran.

Mean age of patients was 54 years old [26-88]. The indication of ZSI 100 penile implants procedure was proposed after failure or refusal of other treatments as oral treatment vacuum and intra-cavernous injections. All 52 patients didn't have penile implant surgery history. Satisfaction rate regarding rigidity was 92.30%.

Prosthesis

All penile prosthesis implanted were ZSI 100 D9 (diameter 9 mm), ZSI 100 D11 (diameter 11 mm), ZSI 100 D13 (diameter 13 mm).

ZSI 100 D9, D11 and D13

Surgical procedure

The surgical procedure was similar to implantation of standard malleable penile prosthesis. The patient had a shower with Povidone-iodine scrub solution the day before and the morning of surgery. At surgical theatre, the patient had a skin preparation with Povidone-iodine again. The incision was peno-scrotal or bilateral with transversal exposure of the corpora cavernosa.

After corpora cavernosa dilatation with dilators, corpora cavernosum length was measured and the right diameter of malleable prosthesis was elected. The device was cut at the right length and inserted

in the Corpora cavernosa were closed. In two patients a drainage was introduced to prevent a haematoma.

During procedure, antibiotic prophylaxis consisted of a single dose of 2 g cefazolin intravenously. Antibiotic therapy was continued for seven days postoperatively.

Follow up

The study was conducted retrospectively. Median follow-up was 13.23 months [6-28]. Postoperative consultations were one month after procedure, and one consultation for the study.

Erectile function was assessed by a questionnaire including desire, penile rigidity, orgasm and frequency of intercourse. preoperatively and postoperatively to evaluate the quality of erections and comfort of the implant.

Results

Intraoperative complications

The intraoperative period was uneventful for the 52 patients.

Postoperative complications

There was no postoperative scrotal hematoma. Hematomas occur in 7.3% with other penile prostheses, more often with inflatable penile prosthesis (4).

There was no infection for the 52 patients, but usual perineal pain in 2 patients from 15 days to three weeks. The patients didn't suffer a long-term pain: Pain after three months is present in 5% of cases especially with Coloplast prosthesis (4). One patient presents discomfort.

The main complications associated with inflatable prosthesis is infection with a rate of 3.2% to 11.5% within 2.9 months (4). With Promedon Tube's malleable penile implants the rate reach 5.5%. (8)

Depending on series (4;5) revisions, except for infection, are due mostly to a mechanical problem.

During the follow-up of the 52 patients with penile implant ZSI 100, complications were limited to two erosions (3.84%).

Functional results and patient satisfaction

Erectile function was assessed by a questionnaire including desire, penile rigidity, orgasm, and frequency of intercourse. preoperatively and postoperatively to evaluate the quality of erections and comfort of the implant.

Postoperatively, the satisfaction and penile rigidity rate was good for 48 patients [92.30%], two devices were removed, one complaint about difficulties to bend the device and one present discomfort.

Discussion

First months remains the most critical period for the implantation of prosthesis. This clinical trial shows safety and effectiveness of ZSI 100 prosthesis equivalent to other malleable prosthesis.

Intraoperative

The major intraoperative complications with implants are urethral perforation [unusual], perforations of a corporacavernosum [1-11%] or crosses of cavernous prostheses during the procedure 2.3% (6,7, 8). None of these complications arose in our group of 52 patients.

Postoperative

Bleeding/hematoma: regarding the risk of bleeding, the rate of postoperative hematoma is 7.3%, mainly with inflatable implants three components (4). The patients didn't present such a complication.

Pain: Usual perineal pain in 2 patients for 15 days to three weeks as standard malleable and inflatable penile implant. Pain after three months is present in 5% of cases especially with Coloplast prosthesis (4). From the 52 patients implanted, none of them presented a long-term perineal pain. Only one presented a discomfort.

Infection: the most serious complication is infection because it leads to the removal of the prosthesis (9). Regarding factors of risk for postoperative infection, diabetes is being discussed as an aggravating factor (5,10), other studies do not show relation with diabetes and infection (4,11). The patients in our series didn't have any infection. Our diabetic patient did not present infection. To reduce the risk of infection our patients did have a strict control of blood sugar and diet.

The advantage of the use of prostheses with a hydrophilic coating for reducing the risk of infection remains controversial. A study showed an equivalent result with and without local antibiotic (4). The ZSI 100 are coated with hydrophilic PVP and were immersed in a bath of antibiotics to fight against infection.

Migration: regarding the risk of prosthesis postoperative migration, it occurs more than 6 months after procedure (4), especially in implanted patients after priapism, may be due corpora cavernosa fibrosis (10). During follow up, we did not observe migration with the ZSI 100 prostheses.

Reliability: 68.5% of Inflatable Penile implants (first implantation) work for ten years without any revision and 59.7% work for 15 years (11). The overall incidence of mechanical failure in penile prosthesis is 5% (8). During our follow-up we didn't observe any cable breakage. Inflatable penile prostheses obtain a satisfaction score of 93% (12) when malleable penile implant such as Promedon present a satisfaction rate of 77.3% in diabetic patients and 79.4% in non-diabetic patients (8).

The functional results for our 52 patients implanted with ZSI 100 is over this score with 92.30% of satisfaction. Unfortunately, one patient got difficulties to bend the prosthesis, one patient present discomfort and two patients have had erosion leading to devices removal.

Conclusion

ZSI 100 is a reliable penile prothesis with good result in term of erection with few complications. No learning curve is needed. Our median follow-up of 13.23 months [6-28 months] is long enough to show ZSI 100 safety efficiency as main complications arose during this period. A longer follow-up and a larger group of patients are needed to confirm these good early results.

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