

Research Article

Let's Make Implantation of Testicular Prostheses in Boys More Standardized and Feasible - Thoughts of Pediatric Urologist

Pawel Osemlak*

Department of Pediatric Surgery and Traumatology, Medical University of Lublin, Poland

***Corresponding author**

Pawel Osemlak, Department of Pediatric Surgery and Traumatology, Medical University of Lublin, Poland, Tel: 0048 606 792 901; Email: poseml@poczta.onet.pl

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Abstract

Background: There were discussed different aspects of implantation of testicular prostheses in boys with lack of testes, in particular use of Foley's catheter.

Aim: Determining suitability of the balloon of Foley's catheter to create space in the scrotum for the placement of a testicular prosthesis.

Materials and methods: A study group consisted of 385 boys operated on due to lack of a testis – implanted testicular prostheses. Patients divided into 2 groups: I group consisted of 290 boys, treated 2000 - 2014, silicone gel filled implants, different surgical accesses, II group consisted of 95 boys, treated 2015 - 2020, solid silicone elastomer, one access (supra-scrotal). Every patient has been operated using the Foley's catheter acting as an expander and hemostatic device. At least 2-year observation period for long-term results, majority of patients were in regular follow-up until adulthood. Late complications: displacement of the prosthesis to the groin, partial unveiling or its prolapse. Statistical analysis using an X^2 test.

Outcomes: The advantages of the scrotal space-generating balloon of Foley's catheter for testicular prostheses were presented and the good long-term results of implants in cases of testicular agenesis or loss in boys were pointed out.

Results: In I group of patient's late complications concerned 23 boys (8%). Displacement of the prosthesis to the groin was noted in 14 cases, partial unveiling – 5 cases, prolapse of the prosthesis – 4 cases. Late complications concerned 13% of patients operated on with transverse scrotal incision, 9% - inguinal, 4% - trans-septal scrotal and 3% - supra-scrotal incision. The supra-scrotal incision was the safest access. Late complications in supra-scrotal incision were statistically less frequent than in transverse scrotal one ($P = .01$).

In II group of patients late complications concerned 4 boys (3%) in form of implant's displacement.

Clinical Implications: Results and conclusions recognize use of the Foley's catheter as a gold standard in implantation of testicular prostheses.

Strengths & Limitations: This publication and the previous one present and discuss the use of the Foley's catheter in implantations of testicular prostheses in boys. The survey group is quite large - 385 cases. However, studies were observational, which could have a limiting effect on statistical conclusions.

Conclusion: The balloon of Foley's catheter is good surgical device, very useful in implantations of testicular prostheses because it's low-cost, widely available, slightly prolongs the operation time, ensures proper expansion of the scrotal sac and good hemostasis.

INTRODUCTION

Testicular prostheses are widely implanted in boys and adult men for many years and for many reasons: testicular agenesis or hypoplasia, orchidectomy due to torsion and necrosis, orchidectomy due to neoplasm, after injury or atrophy after orchidopexy, necessity of gonadectomy in disorders of sex differentiation like Congenital Adrenal Hyperplasia 46 XX or Kallman's syndrome [1-9].

There are many questions about biochemical components,

shape or physical features of prostheses, timing of the operation, surgical access and long-term results. But also an important issue is the proper preparation of the lodge in empty scrotal sac that will accommodate the prosthesis.

This thesis is an extension of the own study "The use of testicular prostheses in boys" published in 2018 [10]. Its thrust focuses on the use of the Foley's catheter balloon during implantation of testicular prostheses. The paper aimed to indicate the advantages of this catheter as an expander during

implantation of testicular prostheses and which surgical access is the best one.

MATERIALS AND METHODS

Testicular prostheses were implanted the first time in 385 boys, which had been hospitalized in the Department of Pediatric Surgery and Traumatology from 2000 to 2020 due to lack of the testis. Patients were 1 to 16 years old at the moment of operation, mean age 8 years. The indications for prosthesis implantation were as follows: testicular agenesis or hypoplasia, torsion and necrosis of a testis, atrophy after orchidopexy of undescended testis, injury or neoplasm.

In 290 boys (I group) operated on from 2000 to 2014, five sizes of testicular prostheses were available: 20 x 22 mm, 26 x 33 mm, 32 x 42 mm, 33 x 48 mm and 39 x 50 mm [10]. Prostheses produced by Polytech Health & Aesthetics GmbH® Germany were filled with a liquid silicone and coated with a highly-polymerized silicone. They had special "eyelet" for dragging a stay suture and anchoring to the bottom of scrotal sac.

In 95 boys (II group) operated on from 2015 to 2020, four sizes of testicular prostheses were available: 23 x 31 mm, 28 x 37 mm, 32 x 42 mm, 34 x 47 mm. Prostheses produced by Promedon N&S® Argentina consisted of solid silicone elastomer. Prostheses had no "eyelet".

The type of prostheses was changed from liquid to solid silicone by leading urologist (the author) due to shrinking of implants, noted in some of patients when prostheses were replaced with larger ones.

Size of the implant was determined by preoperative ultrasound of the opposite testis.

Surgical procedure

In the I group of patients prostheses were implanted through one of four incisions: inguinal – 107 cases (37%), supra-scrotal – 86 cases (25%), transverse scrotal – 72 cases (25%), or trans-septal scrotal – 25 cases (8%). In the II group prostheses were implanted via supra-scrotal incision only. The operation was conducted in general anesthesia. Standard cleaning of the operative field with Kodan® (Alcohol isopropyllicus + 1-Propanolum + 2-Biphenylol). At the beginning of procedure the implant was immersed in 50 ml of isotonic solution of sodium chloride with addition of 2 ml of gentamycin (40 mg/ml). The space for the prosthesis was created with a blunt dissector and fingertip, and then enlarged with the balloon of Foley's catheter. The balloon was very slowly filled with water and left in the scrotal sac for 5 minutes. It acted as an expander and hemostatic device. After removing of the catheter there was no bleeding. The prosthesis was inserted into the scrotum and the wound was closed in 3 layers: vaginal testicular tunica, subcutaneous tissue and skin (absorbable sutures). In I group; the prosthesis had a special "eyelet" for anchoring it to the bottom of the scrotal sac with a stay suture.

General management

Antibiotic treatment consisted of administration of amoxycillin with clavulanic acid administered intravenously

every 8 hours on the day of surgery and the day after, then orally for the next 5 days. Dressing was changed every 2 days, after one week the wound was healing without dressing; the patient could take a shower.

Follow up

The first visit in the outpatient clinic was scheduled 7 days after discharge from the hospital, the next – according to patient's condition. Physical activity was reduced for 1 month. Patients were observed for at least 2 years after operation for late complications and long-term results, considering location of the implant, symmetry of the scrotum and post-operative scar. Low position of the implant, scrotal symmetry and smooth scar were considered as good result. Late complications as displacement of the prosthesis to the groin, partial unveiling or its prolapse meant bad result.

Statistical analysis

Complications of treatment were statistically analyzed using software Excel Statistica Statsoft 8.0. The categorical variables were presented as counts and percentage. They were compared using an X^2 test with Yates amendment. A P -value of $< .05$ was considered significant.

Ethics in publishing

The study was conducted according to the protocol and informed consent approved by the Research Bioethics Committee of Medical University of Lublin (No. KE-0254/247/2017).

RESULTS

In the first 15-year period we operated 19 boys per year, in the second 6-year period – 15 boys per year. In the whole study group the indications for prosthesis implantation were as follows: testicular agenesis or hypoplasia – 54% of cases, torsion and necrosis of a testis – 27%, atrophy after orchiopexy of undescended testis – 10%, injury – 6% and neoplasm – 3%.

In I group of patient's late complications concerned 23 boys (8%) (Table 1). Displacement of the prosthesis to the groin was noted in 14 cases, partial unveiling – 5 cases, prolapse of the prosthesis – 4 cases. Late complications concerned 13% of patients operated on with transverse scrotal incision, 9% - inguinal, 4% - trans-septal scrotal and 3% - supra-scrotal incision. So, the supra-scrotal incision was the safest access. Late complications in supra-scrotal incision were statistically less frequent than in transverse scrotal one ($P = .01$).

In II group of patients late complications concerned 4 boys (3%) in form of implant's displacement.

DISCUSSION

From the 1980s of the 20th century, there has been gradual change in the materials used for manufacturing of testicular prostheses - solid rubber at the beginning, through silicone sheath filled with saline, silicone sheath filled with silicone gel to solid silicone elastomer nowadays [2,11-19]. The author of this paper used prostheses filled with silicone gel to 2014, later silicone elastomer only, because the first ones were gradually shrinking, so the long-term results have improved.

Table 1: Complications related to surgical access, group I.

Complications	Surgical access			
	Inguinal Cases (%)	Supra-scrotal Cases (%)	Transverse scrotal Cases (%)	Trans-septal scrotal Cases (%)
Displacement of a prosthesis	10	3	1	-
Partial unveiling of a prosthesis	-	-	4	1
Prolapse of a prosthesis	-	-	4	-
Together	10 (9)	3 (3)	9 (13)	1 (4)
χ^2 test		$P = .46$	$P = .01$	$P = .80$

The long-term results of treatment vary according to the experience of different authors. According to Adshead et al. 27% of patients reported an average or unsatisfactory result due to the high position of the prosthesis and asymmetry of the scrotum. The other authors have got good long-term results in over 90% of [2,5,11,12,18,19]. According to Clifford et al., Martinez et al. and Schönberger et al. 40-50% of patients consider the prosthesis too hard or in the wrong position, or the manufacturer offers few implant sizes. It is even possible for the implant to be rejected and prolapsed [20,21]. Henderson et al., and Pidutti et al., believe that there is a possible systemic reaction to silicone or only the presence of specific antibodies in laboratory tests. In contrast, Ku et al., believe there is no risk of developing systemic connective tissue disease as a reaction to silicone. Chen et al., say that is necessity of observation for many years due to long-term complications. Based on own observations of patients, it was found that long-term results were good in vast majority of cases, with complications concerning a few percent of patients. Few boys find silicone elastomer prostheses too hard. In own material, the observation period was at least 2 years but a lot of boys were under ambulatory follow-up for many years up to adulthood.

Operative access depends on the surgeon's preferences: inguinal or scrotal – Boy et al., scrotal – Martinez et al., Rose et al., Hampl et al., trans-septal scrotal - Bush et al. Libman et al. proposed so called “wink” incision (semilunar incision about 2 cm long, above the scrotum, 2-3 cm laterally to the penis) because the scar is hidden in pubic hair, there is big distance between the prosthesis and skin suture line and low risk of long-term complications. The results of own study show that in I group of patients, mainly inguinal access was used, less often supra-scrotal. Supra-scrotal incision is synonymous with above mentioned “wink” incision. In II group only supra-scrotal access was used, which was associated with fewer long-term complications.

As for other aspects of surgical technique, according to several authors, the prosthesis should be anchored in the scrotum [19,20,22-30].

The most important moment during the surgery is the creation of adequate space for the prosthesis, which is the main subject of this dissertation. Izquierdo et al., state that gradual stretching of the scrotum through multiple injections of hyaluronic acid in gel form is appropriate. Lattimer et al., place a tissue expander used in plastic surgery prior to prosthesis implantation, which is systematically filled with water. Analyzing the literature it was found, that the Foley's catheter balloon was used by Chadha et al., as an expander during reconstruction of the scrotal sac for

different reason and only by Simms et al. for implantation of testicular prostheses.

The author of this paper has always used the Foley's catheter balloon to produce a scrotal lodge and to control hemostasis, which has had a favorable effect on long-term results. In the first study period, the prosthesis was always anchored to the scrotal bottom, while in the second it was not. The tendency of the prosthesis to migrate toward the groin was not affected by anchoring or not-anchoring, as migration was found in the same percentage of cases in I and II group.

Summarizing own research, it should be concluded that the described technique of enlarging the scrotal sac using the Foley's catheter balloon is worth using and should be the standard in implantation of testicular prostheses. In particular, the two publications discussing the use of this technique concern exclusively adult men [23-30], and a meta-analysis (done by the author) of more than 370 publications available in the PubMed database found no such article concerning the developmental period.

CONCLUSION

Supra-scrotal incision is the best one for implantation of testicular prostheses in boys due to the least number of late complications. The balloon of Foley's catheter is good surgical device, very useful in aforementioned operations. It's low-cost, widely available, slightly prolongs the operation time, and ensures proper expansion of the scrotal sac and good hemostasis.

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