

Comparative investigation of two surgical techniques of orchiopexy in the post-operative recurrence rate and testicular size in children in clinical trial study

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Abstract

Background: Cryptorchidism is a common problem which is prevalent in 3% of male infants. This study aimed to determine the effect of both trans fixation and Dartos pouch fixation methods on the postoperative recurrence rate and testicular changes.

Materials and Methods: In a clinical trial study, 70 children were randomly divided into two groups. In the first group, the correction of cryptorchidism was done by Dartos pouch without suture and in the second group; testis was sutured using common trans fixation. The size of testicles was measured before and 6 months after surgery, children were followed on postoperative complications, trauma to testicles and recurrence of disease in both groups. Data were analyzed using SPSS soft ware.

Results: The mean size of testicles was $87.16 \pm 20.6 \text{ mm}^2$ in the group with fixed testicle and $182.4 \pm 37.9 \text{ mm}^2$ in the group with not-fixed testicle before operation and the difference between the two groups was significant ($P = 0.013$). After surgery, the mean size of testicles was $90.8 \pm 19.9 \text{ mm}^2$ in the group with fixed testicle and $183.7 \pm 41.2 \text{ mm}^2$ in the group with not-fixed testicle and the difference between them was significant ($P = 0.026$). The average of changes in testicular size was 3.62 ± 1.93 and $1.25 \pm 5.35 \text{ mm}^2$ in both fixed and not-fixed groups, respectively and changes in testicular size had no significant difference between the two groups. ($P = 0.68$).

Conclusions: Type of fixation had no effect on the size of testes or relevance to the level of retraction. The above management protocol did very well in our hands, and we recommend it for application in the management of undescended testis.

Key Words: Dartos pouch fixation, orchiopexy, postoperative recurrence rate, testicular size, trans fixation

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INTRODUCTION

Cryptorchidism is a common problem which is prevalent in 3% of male infants. Most cryptorchidism is normal at birth while irreversible and progressive changes occur at the end of the second year of life. So, it is widely recommended that orchiopexy be conducted near age 1 year.^[1] Moving testicles into the scrotum

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is important in terms of maintaining the appearance of the genitalia and preventing complications such as torsion of the testis, inguinal hernia,^[2] preservation of reproductively^[3] and reducing the risk of malignant cancer.^[4] And improve the endocrine function of testis^[1]

Orchiopexy in human aims to fix appropriately testicle into the scrotum for preventing torsion of the testis, spermatic cord or retractile testis and to achieve these objectives with minimal trauma in testicles.^[5]

The recurrence rate of cryptorchidism is different from 0.2% to 10%.^[6,7] Its main causes include insufficient release of components of cord into proximal, insufficient release of cord from its connections to the fascia,^[7,8] the lack of high ligation process of open vaginalis (releasing sac hernia increases the length of cord 6%),^[9] the lack of proper placement of testicles into and bottom of scrotum^[10] and generally, high tension and lack of proper fixation of testicles into the scrotum that in the secondary case, the lack of adequate and proper release of cord is created. By putting pressure on the cord, these factors result in loss of fixation, disorder of blood flow within the cord and testicular hypoplasia and atrophy.^[10]

In an experimental study on animals, it has been shown that by trans fixation method, classical orchiopexy causes to damage germ cells and stop spermatogenesis in the early stages while no damage has been reported in orchiopexy by Dartos pouch fixation.^[4] The most significant complication of orchiopexy is testicular atrophy, injury to the spermatic vessels or extensive downward traction during repair can cause postoperative venose congestion or ischemia with resultant testicular atrophy.^[11] Accordingly, given the high incidence of cryptorchidism and lack of sufficient studies in the country, this study aimed to determine the effect of both trans fixation and Dartos pouch fixation methods on the postoperative recurrence rate and testicular changes on human subjects.

MATERIALS AND METHODS

This study is a clinical trial study conducted in Imam Hossein Medical and Education Center in 2012-2014. The study population consisted of patients undergoing orchiopexy surgery and referred to the above-mentioned center in 2012-2014.

Inclusion criteria were the patients candidated for orchiopexy; no previous orchiopexy surgery; age <14 years and parental consent to participate in the study. Exclusion criteria were failure to follow up patients due to emigration, death, etc., withdrawing of parents to continue cooperation and testicular atrophy (which is determined at the time of surgery).

Using the formula for estimating the sample size and considering the confidence level of 95%, test power of 80%, the incidence of recurrence about 10%, the sample size required for the study was estimated to compare the ratios^[5,6] and the minimal significant difference between the two studied groups was considered 0.1 was estimated as 35 patients in each group.

The method is in a way that first referred children with cryptorchidism undergone surgery were evaluated so that patients were distributed into two groups by block randomization. The first group includes the patients with odd number admissions and second group include the patients with even number admission. and this randomization was done by admission unit who did not know any thing about the study. In the first group, the correction of cryptorchidism was done by Dartos pouch without suture and in the second group; testis was sutured using common trans fixation. The operation is usually performed as an outpatient procedure by using general anesthesia. The patient was supine. Intraoperative administration of an ilioinguinal nerve block with bupivacaine provides excellent postoperative analgesia. The incision should be made along one of Langer's lines, over the internal ring. The external oblique aponeurosis is incised laterally from the external ring in the direction of its fibers, avoiding injury to the ilioinguinal nerve. Once located, the testis and spermatic cord are freed. The testis and hernia sac are dissected from the canal. The tunica vaginalis is then dissected away from the vas deferens and the vessels before its division. The proximal sac is twisted, doubly suture-ligated, and amputated. Retroperitoneal dissection through the internal ring may provide additional cord length for the testis to reach the scrotum. A tunnel is created from the inguinal canal into the scrotum by using a finger or a large surgical clamp. The scrotum is bluntly enlarged. A sub-dartos pouch is created by placing the finger through the tunnel and stretching the skin in a dependent portion of the scrotum. A 1-cm to 2-cm incision is made in the skin over the finger, and a hemostat is inserted just under the skin and spread both superiorly and inferiorly to create the pouch. A clamp is then placed on the surgeon's finger in this scrotal incision, and its tip is guided into the inguinal canal by withdrawing the finger. The clamp is then used to grasp some adventitial tissue around the testis.

The clamp is then pulled back to guide the testis into the pouch. One should avoid grasping the testis or vas deferens directly, as this may cause scarring. Alternatively, a testicular transfixation suture may be used to deliver the testicle to the dartos pouch. Once the testis is in the dartos pouch, a suture is used to

narrow the neck of the pouch to prevent testicular retraction.

This suture also may be attached to the cut edge of the tunica. Testis measurements and biopsy may be performed at this time. The scrotal skin incision is closed. The external oblique aponeurosis is re-approximated with absorbable suture, and the skin and subcuticular tissue closed with interrupted subcuticular stitches. A flexible collodion dressing is useful in diapered boys. The patient is seen in the outpatient clinic after a few weeks for a wound check and again several months later for testicular examination. Final position and condition of the testicle should be noted. Although rare, complications include atrophy and retraction.^[12,13] In the first group we did not use any suture to fix the testis.

The size of testicles were measured by sonography before the surgery and at 6 months after surgery, patients were followed and postoperative complications, trauma to testicles and recurrence of disease were assessed in both groups by sonography that was done by the same sonographer. The required data including the age at the first admission, clinical protests upon admission, the urgency of clinical protests, the involvement side and testis position at the first visit were studied and recorded in the profile of each patient. The recurrence rate and changes of testicles were investigated and recorded in the subsequent follow-up.

After we had collected the data, we entered them into the computer and analyzed them by SPSS version 22, and then we ran statistical Student's *t*-test, paired *t*-test, Chi-square and ANOVA analysis tests.

RESULTS

In this study, 69 children undergoing orchiopexy surgery were studied in two groups of 34 individuals that during the follow up period, one patient was excluded from the study since he did not refer to the clinic (despite the performed follow-up). The mean age of all patients was 40.7 ± 37.3 months with the range of 6–168 months at the time of operation. Cryptorchidism was in 25 (36.2%) individuals on the right testicle, 32 (46.4%) ones on the left testicle and 12 (17.4%) cases on both sides. The site of the ectopic testis was inguinal in 46 (66.7%) patients and pre-scrotal in 23 (33.3%) subjects. Twenty-nine (42%) of these patients had hernia along with cryptorchidism.

The mean age of the two groups undergoing fixed as well as not-fixed testis methods were 58.8 ± 41.8 and 23 ± 21 months, respectively. Also, the mean age of

patients used non-fixed testis method was significantly higher ($P < 0.001$). The clinical sign observed in all studied patients was lack of testicles in the scrotum. The distribution of preoperative demographic and clinical data for patients in both groups is given in Table 1. Chi-square and Fisher's exact tests on the above-mentioned data indicated that the side of testicles suffered before surgery and the presence of simultaneous hernia have no significant difference in both groups ($P > 0.05$).

The mean size (length×width)–(mm²) area of testicles was 87.16 ± 20.6 mm² in the group with fixed testicle and 182.4 ± 37.9 mm² in the group with not-fixed testicle before operation and the difference between the two groups was significant ($P = 0.013$). After surgery, the mean size of testicles was 90.8 ± 19.9 mm² in the group with fixed testicle and 183.7 ± 41.2 mm² in the group with not-fixed testicle and the difference between them was significant ($P = 0.026$). The average of changes in testicular size was 3.62 ± 1.93 and 1.25 ± 5.35 mm² in both fixed and not-fixed groups, respectively and changes in testicular size had no significant difference between the two groups. ($P = 0.68$). In Figure 1, the mean size of testicles before and after surgery has been shown in both groups.

According to the conducted follow-up, the disease returned only in one (2.9%) patient of the group with fixed testicles and no case of recurrence was observed in not-fixed group while according to Fisher's exact test, the incidence of recurrence had no significant difference in both groups ($P = 0.99$). The recurrence of disease occurred in an infant at the age of 6 months who suffered from the right testicular ectopia in the inguinal side. The testicular size in patients suffered from recurrence was 129.5 mm² before surgery and 114 mm² after surgery and the change of testicular size was 115.5 mm² in our modified technique that we didn't use any suture to the scrotum was no difference

Table 1: Distribution of preoperative clinical signs for patients in both groups

Group Variable	Fixed testicle (35 cases)	Not-fixed testicle (34 cases)	P
Mean age (month)	23±21	58.8±41.8	<0.001
The involved side number (%)			
Right	13 (37.1)	12 (35.3)	0.4
Left	18 (51.4)	14 (41.2)	
Both sides	4 (11.4)	8 (23.5)	
Pre-operation testicles side			
Inguinal	23 (65.7)	23 (67.6)	0.99
pre-scrotal	12 (34.3)	11 (32.4)	
Simultaneous hernia			
Yes	17 (48.6)	12 (35.3)	0.26
No	18 (51.4)	22 (64.7)	

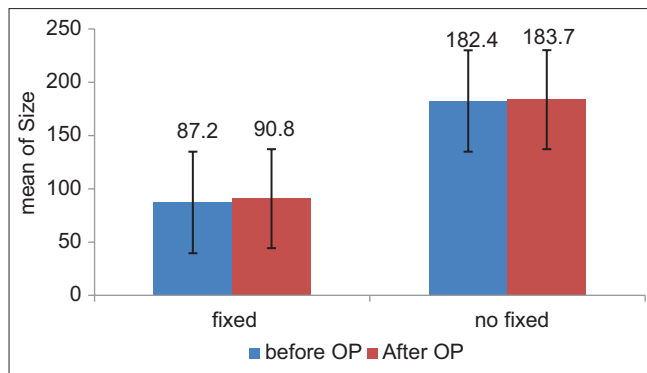


Figure 1: The mean size (length*width) (mm²) area of testicles before and after surgery in both groups

in size before and after surgery that demonstrate no damage to the testicle during surgery conversely recurrences risk did not increase.

DISCUSSION

The overall objective of this study was to compare the effect of two surgical techniques of orchiopexy on the recurrence rate and trauma on the testicles during and after surgery in children referred to Imam Hossein in Isfahan in 2012–2014. Due to risks in future for children with cryptorchidism, it is considered as a necessary surgery for children and to prevent the recurrence of the disease, orchiopexy had been performed along with suturing testicles to scrotum for a longtime. Since, during the surgery and suturing testicles to the scrotum, testicles were hurt in many cases, according to Dartos pouch's new technique, suturing testicles to scrotum was abandoned. Although there are criticisms about the recurrence of the disease on this technique, the results from the previous studies were controversial and there is no unified theory on the superiority of the mentioned method than the traditional one (suturing testicles to the scrotum). In our study, a 35-member group of patients selected for orchiopexy with suturing testicles to the scrotum along with a 34-member group of patients undergoing orchiopexy without suturing followed up for 6 months by examination and sonography and comparing result before surgery, (its necessary to emphasis that sonography before and after of surgery was done by one specified sonographer) that only one case of recurrence was observed in the group with fixed testicles while there were no cases of recurrence in the group without fixed testicles. Furthermore, during operation and up to 6 months after surgery, no cases of the incidence of testicular trauma were observed. In the study conducted in Saudi Arabia in 2013, by reviewing 670 cases of orchiopexy surgery over a period of 10 years, Osama concluded that patients treated by Dartos technique had no significant

difference with those treated by trans-fixation technique method in terms of recurrence and changes in testicular size.^[14] Therefore, it can be implied that orchiopexy surgery without suturing testicles to the scrotum is not associated with higher recurrence of the disease. On the other hand, in our study, there was no case of damage to the texture of testicles during suturing testicles to the scrotum and after surgery and this confirmed by doing sonography after surgery and there were not any significant changes in the size of the testicles; however, damage to the texture of testicles during and after surgery (the incidence of postoperative chronic pain, infection or rupture of suture site due to inappropriate suture, pressure on the texture of testicles and scrotum and microbial contamination of surgery site) highly depends up on the skill of the surgeon in doing the surgery. If the surgery of orchiopexy is also investigated at other hospitals, cases of trauma to testicles and other postoperative complications and recurrence will be observed too.

Our results were encouraging after the second redo-inguinal orchiopexy, with an acceptable deterioration in size and an acceptable scrotal position. Similarly the third orchiopexy showed good results. Therefore we concluded that our careful selection of patients, careful timing of repeat surgeries and meticulous surgery, the outcome of a repeat inguinal orchiopexy can be fruitful with encouraging results of having an acceptable risk which should be weighed against the current position of testis.

It is important to emphasize that the best chance to put an undescended testis is during the 1st orchiopexy which always should be done by an experienced surgeon.

Type of fixation had no effect on the size of testes or relevance to the level of retraction.

The above management protocol did very well in our hands and we recommend it for application in the management of undescended testis.

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