

## Trans-scrotal Incision Approach versus Traditional Trans-scrotal Incision Orchiopexy in Children with Cryptorchidism: A Randomized Trial Study

### Abstract

**Background:** Although undescended testis (UDT) is the most prevalent malformation in male neonates, the best mode of UDT treatment remains controversial. This study aimed to compare trans-scrotal incision approach with traditional trans-scrotal incision orchiopexy in children suffering from cryptorchidism. **Materials and Methods:** This single-blind randomized clinical trial was done on 100 children with UDT who needed surgery. The participants were alternately undergoing trans-scrotal incision orchiopexy (Group I) and traditional inguinal incision orchiopexy (Group II). The success rate and incidence of postoperative complications were evaluated 1 week and 1 month and 6 months after the operation in the two groups. **Results:** Both the groups were similar in baseline characteristics including age and laterality ( $P > 0.05$ ). There was no significant difference between the two groups in terms of the incidence of wound infection, testicular atrophy, testicular hypotrophy, and relapse ( $P > 0.05$ ). In addition, the success rates were 98% in Group I and 94% in Group II ( $P > 0.05$ ). **Conclusion:** Both surgical methods have a high success rate, and there is no significant difference in the incidence of complications; however, in terms of beauty, satisfaction, and shortening the duration of surgery and the duration of hospitalization, trans-scrotal approach was more successful than the traditional method.

**Keywords:** Cryptorchidism, orchiopexy, traditional trans-scrotal incision, trans-scrotal incision

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### Introduction

Cryptorchidism or undescended testis (UDT) is the most prevalent malformation in male neonates,<sup>[1]</sup> occurs in 2%–4% of them, and decreases to 1% in the 1<sup>st</sup> year of life.<sup>[2,3]</sup> Such abnormality occurs when the process of descending of testes is impaired and the testes stop along its descending path.<sup>[4]</sup> Most of the UDTs descend during the first 3 months of life, and a small percentage remains for the next 9 months.<sup>[5]</sup> UDT may involve one or both of the testes and is bilateral in approximately 10% of the cases.<sup>[6]</sup> Most of the UDTs are located in the superficial inguinal pouch of Denis Browne. This has led the UDT traditional method to the exploration through inguinal canal.<sup>[5]</sup>

UDT has a bulk of long-term complications. Males with a history of UDT have an increased risk of testicular cancer five times than the normal population.<sup>[6-8]</sup> About 10% of all testicular malignancies are associated

with UDT.<sup>[9]</sup> Infertility is more common among men with UDT.<sup>[10]</sup> Other long-term consequences include hernia, testicular twists, and mental stress.<sup>[11-13]</sup> The best approach to diagnose UDT is through clinical examination. UDTs go under the dichotomy of touchable and unobtrusive categories.<sup>[14]</sup> The proper diagnosis of UDT requires a skilled examiner.<sup>[15]</sup> Surgery is known as a golden standard in the treatment of UDT.<sup>[6]</sup>

The inguinal approach is the traditional method for correcting UDT. In this approach, two incisions are made: one inguinal or groin incision to open the inguinal canal to visualize the cord structure and a second scrotal incision to fix the testes within the scrotum.<sup>[16]</sup> It was believed that inguinal incision is helpful for sufficient mobilization of the spermatic cord, separation of the processus vaginalis or hernia sac, high ligation of the hernia sac, and to achieve an adequate length for the testes to be relocated to the dependent portion of the scrotum.

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To reduce morbidity, trans-scrotal approach was introduced, with only one cut on the cryptorchidism scrotal. The advantages of this method include shorter operating times, easier dissection, better wound healing, less pain, and better beauty. In this regard, some previous studies showed that single scrotal incision orchiopexy proved to be an effective technique and is associated with low rates of complications.<sup>[15,17]</sup>

In fact, the majority of previous studies have shown that single scrotal incision orchiopexy is a simple technique that is associated with a shorter operation time and hospital stay than the traditional method and that is more feasible cosmetically.<sup>[14,18]</sup> However, this method has not been widespread greatly, and studies have been carried out on a small scale, which may be due to the possibility of either failure or complication. To this end, the current study has compared trans-scrotal incision approach with traditional trans-scrotal incision orchiopexy in children suffering from cryptorchidism.

## Materials and Methods

The present randomized single-blind study was conducted among children with UDT who referred to Emam Hossein Hospital from May 2017 to May 2018 who needed surgery. The sample size of 50 patients in each group was determined based on a confidence level of 95%, a statistical power of test of 80%, a success rate of 0.85 in surgical patients with scrotal incision orchiopexy,<sup>[17]</sup> and a minimum difference of 0.15 between these two groups.

These children had cryptorchidism with the age range of 6 months–1 year whose UDT was tangible in the inguinal canal. These children had no history of systemic diseases such as immune deficiency, kidney disease, liver and heart disease, or lack of specific syndromes associated with cryptorchidism and had not had any previous history of surgery. On the other hand, the children were excluded from the study if the UDT was not touched in the inguinal and distal canal or if they had any congenital anomalies and taking medications such as corticosteroids and immunosuppressive drugs. These patients were selected using simple random sampling technique.

After obtaining the ethical code (IR.MUI.REC.1396.084) from the Ethics Committee of Isfahan University of Medical Sciences and obtaining written informed consent from the parents of eligible children, the participants were randomly divided into two groups of trans-scrotal incision orchiopexy (Group I) and traditional inguinal incision orchiopexy (Group II) by the same surgeon [Figure 1].

Before surgery, all patients undergo examination and ultrasound and were evaluated about the testicle location and the presence of hernial sac. In addition, the cord should be fixed at the lowest point in the channel close to the scrotum and should be re-operated at the later stages, which we have not encountered in our study fortunately.

In trans-scrotal method, a cross-sectional incision was performed on the scrotum for unilateral undescended cases, while a longitudinal incision was made on the scrotum for the case of bilateral undescended ones. After the placement of the testicle, the testicle was subjected to the same incision and pulled down and then placed in the desired position, and the surgical incision was restored. In the traditional method, two incisions were made in the inguinal area and the testes were subjected to an exploratory examination and then an incision in the scrotal area, and after creating a suitable site for the placement of the testes, the testis was drawn from the inguinal canal and placed in the desired position and the surgical incisions were restored [Figure 2].

It should be noted that during 24 h after surgery, all patients received cefazolin 20 mg/kg every 12 h.

The checklist for each patient, including age, duration of hospitalization, length of surgery time, and surgical procedure, was also identified by the codes of A and B. At the next follow-up of 1 week, 1 month, and 6 months after operation by a resident of surgery who was not aware of the purpose of the study, the success of the operation and the occurrence of primary and secondary complications such as patent processus vaginalis (PPV), wound infection, testicular atrophy, hernia, hydrocele hematoma, and recurrence were investigated and recorded.

The success of the operation was to place the testes inside the scrotum, which was examined by the physician in 1 week and 6 months after the operation in the two groups. In addition, in children with bilateral UDTs, descending of testes on both sides was considered as a successful treatment.

The testicular back in the inguinal canal and its absence in the scrotum were considered as relapses in 1 week and 6 months after the operation. Furthermore, the hematoma involved the accumulation of blood within the scrotal cavity or the wound site, which was determined by the surgeon's physician until 3 days after the operation. Testicular atrophy was a reduction in the size of the testes proportionate to the opposite side, and hydrocele was the accumulation of fluid around the testes, which was considered by the surgeon's doctor until 6 months after the operation.

Finally, the collected data were entered into SPSS (version 22; SPSS Inc., Chicago, Ill., USA) and analyzed using Fisher's exact test and independent *t*-test. In all analyses, the significance level was considered <0.05.

## Results

In the present study, 50 boys with the mean age of  $10.22 \pm 2.08$  months who underwent trans-scrotal surgery were selected that 72% had unilateral and 28% had bilateral UDT, respectively. In the group undergoing traditional surgery, there were 50 boys with the mean age of  $10.16 \pm 1.72$  months, of whom 88% had unilateral

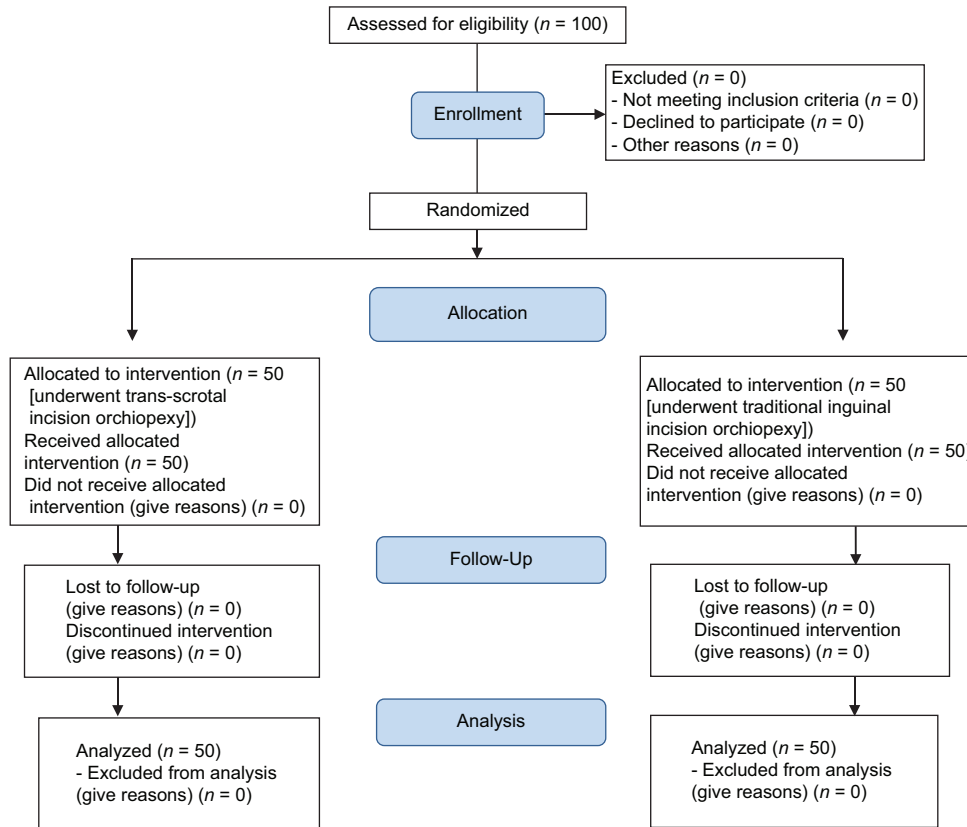


Figure 1: Consort flow diagram

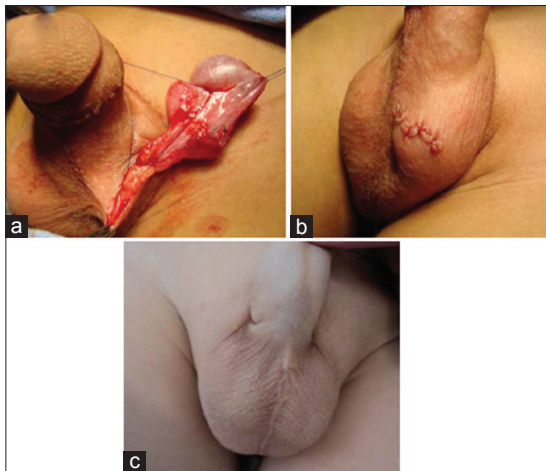


Figure 2: (a) The testis mobilized and delivered through the incision. (b) Final appearance for unilateral undescended testis. (c) Final appearance for bilateral undescended testes

and 12% had bilateral UDT, which were not statistically significant in terms of age and UDT ( $P > 0.05$ ) [Table 1].

In the evaluation of the primary and secondary complications of the surgery, in both traditional and trans-scrotal approaches, it was found that the duration of hospitalization in Group I was  $2.03 \pm 0.88$  days while it lasted for  $2.41 \pm 0.76$  days in trans-scrotal group. This was significantly more than that in Group II ( $P = 0.026$ ). In addition, the duration of surgery in Group I was

significantly lower than Group II ( $P < 0.001$ ). Incidence of PPV was also reported as 24% in Group I and 12% in Group II. Among the secondary side effects of this surgery, complications such as hydrocele, hematoma, and opening of the surgical site were not observed at all. Furthermore, there was no significant difference between the two groups in terms of the incidence of wound infection, testicular atrophy, testicular hypotrophy, and relapse ( $P > 0.05$ ). In addition, the success rates were 98% in Group I and 94% in Group II. There were no significant differences between the two groups in this respect too ( $P > 0.05$ ) [Table 2].

## Discussion

The results of this study showed that trans-scrotal method with a single incision is a useful method in terms of simplicity without significant surgical problems. Furthermore, the rate of success in the trans-scrotal method was 98%; however, in the traditional method, the success rates were reported  $> 90\%$ ; therefore, the two groups did not differ in terms of success rate.

In line with the results of the present study, in many previous studies, the rate of success in these two methods of surgery has been expressed by over 90%. For example, the rate of success in the single scrotal incision orchiopexy in the study by Bianchi and Squire was reported as 95.8%, in the study by Dayanc *et al.* as 97.6%, and in the study by Na *et al.* as 92.5%, and in the traditional method, it was 96.5%.<sup>[10,15,16]</sup>

**Table 1: Comparison of baseline characteristics between two study groups**

Characteristics	Group I (n=50)	Group II (n=50)	P
Age; month	10.22±2.08	10.16±1.72	0.875
Laterality, n (%)			
Unilateral	36 (72)	44 (88)	0.078
Bilateral	14 (28)	6 (12)	

Group I: Underwent trans-scrotal incision orchiopexy, Group II: Underwent traditional inguinal incision orchiopexy

**Table 2: Comparison of surgical outcomes between two study groups**

Variables	Group I (n=50)	Group II (n=50)	P
Primary outcome			
Duration of hospitalization; days	2.03±0.88	2.41±0.76	0.026
Operative time; min	30.24±19.16	70.74±7.42	<0.001
Incidence of patent processus vaginalis, n (%)	12 (24)	6 (12)	0.192
Secondary outcome, n (%)			
Wound infection	2 (4)	1 (2)	0.558
Testicular atrophy	5 (10)	4 (8)	0.727
Testicular hypotrophy	0	1 (2)	0.315
Hernia	1 (2)	2 (4)	0.558
Hydrocele	-	-	-
Hematoma	-	-	-
Relapse	1 (2)	3 (6)	0.617

Group I: Underwent trans-scrotal incision orchiopexy, Group II: Underwent traditional inguinal incision orchiopexy

In fact, traditional inguinal incision orchiopexy mobilization was a mandatory method to obtain adequate mobilization of the spermatic cord but requires two standard skin incisions for direct visualization of the cord structures, and separation and high ligation of commonly associated inguinal hernia are not easy without opening the inguinal canal.<sup>[19]</sup> Furthermore, in the pediatric population, there is good mobility of the skin incision and a relatively short distance from the external to the internal inguinal ring. These points led others to believe that one scrotal incision rather than two may be sufficient for orchiopexy in patients with a palpable and low-lying UDT. The single incision trans-scrotal technique was introduced by Bianchi and Squire in the 1980s.<sup>[16]</sup> Bianchi and Squire proposed that moving the incision by retraction and the short distance from the internal to the external ring made it possible to dissect the hernia sac without opening the canal.<sup>[16]</sup> The suggested that the benefits of using one incision in the scrotal skin fold included decreased pain, improved cosmesis, and a shorter operative time with less incision needed to close the wound window.<sup>[16,19]</sup> A recent study showed that the efficacy of single subcoronal incision as a feasible approach to the anatomic structures for the treatment of hypospadias and concomitant UDT.<sup>[20]</sup>

It should be noted that the rate of surgical success depends on these two methods, which is why the researchers point to surgery with higher success and less risk.

In addition, all previous studies have indicated a significant reduction in the length of the surgery and the duration of hospitalization in trans-scrotal method than the traditional one,<sup>[15-18]</sup> which is consistent with the results obtained in the present study.

Systematic and meta-analysis studies have suggested more patient satisfaction, surgeon satisfaction, more beauty, more success rates, and fewer complications in trans-scrotal compared with the traditional method.<sup>[14,17]</sup> In this regard, in our study, the incidence of complications was very rare and scarce so that complications such as hematoma, hydrocele, and hematoma were not observed at all. In contrast, one of the first complications of this procedure was the incidence of PPV in 24% in Group I and 12% in Group II.

It is necessary to mention that the application of single incision trans-scrotal technique has been limited due to several postoperative complications and failure to ligate the PPV highly. However, it has been confirmed that trans-scrotal orchiopexy offers more advantages regarding smaller dissection with better comfort for the patients compared with conventional two-incision operation. In this regard, the incidence of PPV among the studies showed that in cryptorchidism, the PPV was patent in 20%–73% of cases<sup>[21,22]</sup> and was lower in cases of retractile testes. The incidence of PPV in UDTs is quite variable, varying from 20% to 70% in the literature.<sup>[23]</sup> Dayanc *et al.* reported that the incidence of PPV in their study was 35%.<sup>[10]</sup> In one systematic review and meta-analysis, the incidence of PPV was 46.1%, and there was no statistically significant difference between the two groups.<sup>[14]</sup> Therefore, we can infer that the surgery was indicated for many gliding testis. The lack of surgical reports regarding the presence of this finding may interfere with the result.

In addition, in our study, wound infections were seen in only 2% of Group I and 4% of Group II, which did not differ significantly between the two groups.

In the same vein, wound infection has also been found in many studies,<sup>[18,24-26]</sup> with 1.1% of patients undergoing trans-scrotal surgery and 2.5% in the traditional method suffered from the complication. However, in these studies, no significant difference in the incidence of complication was found between the two surgical methods.

On the other hand, the incidence of testicular atrophy complications in Group I with 10% was higher than that of Group II with 8%, and in contrast, testicular hypotrophy, hernia, and relapse in Group II were 2%, 4%, and 6%, respectively, which were higher than those of Group I with 0%, 2%, and 2%, respectively. There was no significant difference in the incidence of the complications between the two groups ( $P > 0.05$ ).

In line with the present study, Novaes *et al.* found that the incidence of recurrence, testicular atrophy, and testicular hypotrophy was low.<sup>[17]</sup> In a meta-analysis by Feng *et al.*, the occurrence of testicular atrophy had been found there was no significant difference in the two methods in this term.<sup>[14]</sup> In addition, the occurrence of hernia and hydrocele was identified as the rarest complication during the follow-up which may be prevalent with <1%.<sup>[24]</sup>

It should be noted that one of the limitations of the present study was the minor examination of the results with regard to testicular locations. Some researchers have done their study on testes with specific conditions. For example, with the distinction of testicular locations to the testis located within the inguinal canal and the testis located beyond the external inguinal ring, they have reported more accurately the rate of success and complications. They showed that with the division of the testicular location, the success rate and reduction of complications are persistent and may only affect the accuracy of the surgeon in deciding on the choice of type of surgery.<sup>[10]</sup>

Our study had also some other limitations, such as the lack of evaluation of testis volume in follow-up and small sample size; due to the long-term follow-up of patients and the shortage of time, it was not possible to increase the sample size. However, we suggest that further studies in larger sample sizes aimed to evaluate the details of the testicle in terms of size, position, and so on.

## Conclusion

Overall, it can be concluded that both surgical methods have a high success rate and there is no significant difference in the incidence of complications; however, in terms of beauty, satisfaction, and shortening the duration of surgery and the duration of hospitalization, trans-scrotal approach was more successful than the traditional method. Perhaps, more precise and detailed studies can be made in deciding a safe and secure method.

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## Conflicts of interest

There are no conflicts of interest.

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