

# COMPARISON OF OUTCOME OF SAC LIGATION VERSUS NO SAC LIGATION IN PEDIATRIC PATIENTS UNDERGOING INGUINAL ORCHIDOPEXY FOR INCOMPLETELY DESCENDED PALPABLE TESTES: A RANDOMIZED CONTROLLED TRIAL

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## Abstract

**Background and Objective:** The case of undescended Testis (UDT) is one of the most common condition presented to a pediatric surgeon. The standard procedure to rectify UDT is known as Orchidopexy. The main objective of this study is to examine and compare the results of orchidopexy surgeries conducted with or without sac ligation in palpable undescended testis of pediatric patients.

**Methods:** This randomized controlled trial was done over a period of 12 months (July 2018 to July 2019) at the Department of Pediatric Surgery, Children's Hospital & Institute of Child Health, Lahore. The selection of cases was made dependent upon fulfillment of departmental criteria and approval by ethical review committee. Consequently, 280 cases divided into two equal groups i.e. Group-A and Group-B (140 cases in each group) were shortlisted for the study after detailed scrutiny. The allotment of patient to above mentioned groups was randomized by lottery method. The patients in Group-A underwent orchidopexy with ligation of sac while the patients of Group-B were operated without sac ligated. The surgeries were performed under general anesthesia by consultant surgeons of same caliber and competence. Moreover, in order to quantify and analyze the results of surgeries parameters such as Mean Operative Time, Postoperative Manifestations and recurrence of UDT were recorded on proforma. Subsequently, SPSS version 25 statistical software was utilized for calculating the mean and standard deviation of numerical variables such as age and operative time. Additionally, the frequency and percentage of variables such as recurrent UDT were also calculated. Chi-square test was applied to recurrent UDT and development of inguinal hernia. It is highlighted that P-value  $\leq 0.05$  was taken as significant.

**Results:** Among 140 patients of sac ligation group, 40.7% were 1-4 years old and among 140 patients of no sac ligation group, 42.9% were 1-4 years old. In sac ligation group, 60.0% patients had right undescended testis while in no sac ligation group, 67.1% patients had right undescended testis. In sac ligation group, the mean operative time was  $37.81 \pm 8.82$  minutes while in non-sac ligation group; the mean operative time was  $24.34 \pm 4.12$  minutes. In sac ligation group, no patient had post-operative hernia while in non-sac ligation group, 1.4% patients had post-operative hernia ( $p=0.15$ ). In sac ligation group, 1.4% patients had recurrent UDT while in non-sac ligation group, 2.1% patients had recurrence. ( $p=0.65$ )

**Conclusion:** Study concluded that non-sac ligation technique is more effective than sac ligation technique in terms of operative time and should be preferred for patients by surgeons.

**Keywords:** Orchidopexy, undescended testes, testicular atrophy, inguinal hernia, recurrence.

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The Undescended Testis (UDT) or Cryptorchidism has been identified as the most common congenital urological diseases<sup>1</sup> and common endocrine disorder among boys. It is a condition where one or both testes are unable to descend to the base. The incidence of UDTs ranges between 2-5% in the normal male population, however in the premature boys it is approxi-

mately 30%.<sup>2</sup>

On physical examination undescended testes may be palpable or non-palpable. Approximately 20% of undescended testes are non-palpable.<sup>3</sup> The non-palpable testis can be absent, atrophic, or have failed to descend into inguinal canal or scrotum and can be found in intra-abdominal cavity. During fetal life, descent of testis takes place in two phases: a transabdominal phase that occurs during the first trimester and an inguinoscrotal phase that occurs between 25 to 30 weeks of gestation.<sup>4</sup> Occasionally UDTs can naturally descend as well during the first six months of life, under the effect of pituitary gonadotrophin. During the 3rd month of life, there is a sudden rise in secretion of testosterone hormone, which is also called as mini puberty, which may help in spontaneous descent of the testes. It observed to be quite rare for testis to descend after 6 months of life therefore it is not reasonable to wait for spontaneous testicular descent after this period.<sup>5</sup> Hence every boy who is born with either unilateral or bilateral empty scrotum should be kept under surveillance and should be followed after 3 months of life. If it is observed that the testis are undescended till 3<sup>rd</sup> month then the diagnosis of UDT is established and the child is advised to undergo orchidopexy at around 6<sup>th</sup> month of life. However, in case the testis descends spontaneously during the first 12 weeks of life, then such child must be kept under regular follow-up for next few years to ensure that they do not ascend back into inguinal canal known as acquired undescended testis. Patients who have UDT are at risk of multiple complications like infertility, testicular torsion, malignancy, trauma, inguinal hernia/hydrocele and psychiatric disorders.<sup>6</sup>

Although there is possibility of spontaneous descent of testis, however if they fail to descend, then it requires a definitive surgical repair. The most acceptable and successful therapeutic approach for UDT is inguinal orchidopexy. First description on how to perform orchidopexy was presented by Schuller in 1881 and over past 100 years considerable innovations and modi-

fications have been made to the original surgical procedure. But recently there is a lot of discussion regarding ligation of the sac in hernia as well as processes vaginalis in orchidopexy.<sup>7</sup>

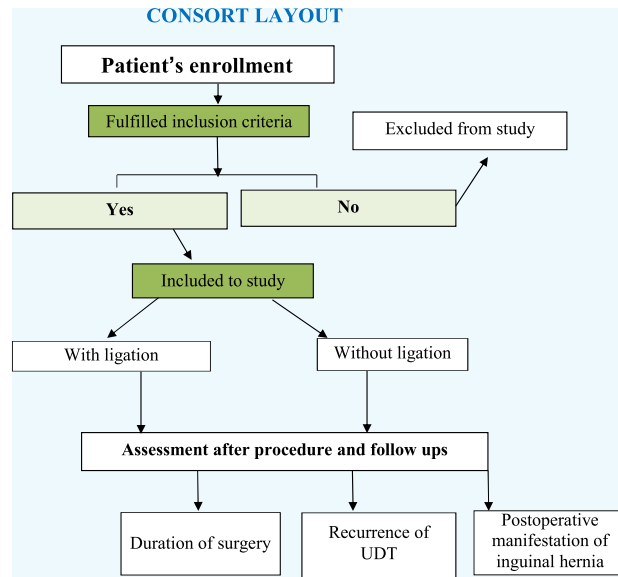
Thus rationale of this study was to compare orchido-pxy with and without sac ligation. As no consensus has been made yet and surgeons routinely use the technique of sac ligation through inguinal approach during orchidopexy which is more time consuming and is associated with more surgical complications, through this study we want to provide evidence that orchidopexy can be done successfully without sac ligation in a relatively lesser time. The main objective of this study is to examine and compare the results of orchidopexy surgeries conducted with or without sac ligation in palpable undescended testis of pediatric patients

## METHODS

This Randomized controlled trial study was carried out during 12 months (July, 2018 till July, 2019) in the Pediatric Surgery ward of the Children Hospital and The university of Child Health Lahore, duly approved by Ethical Review Committee Vide No. 34835-5 dated 07/07/2018. Recruitments were done by Consecutive (non-probability) sampling. According to operational definitions, patients aged 1-12 years, with palpable UDT (assessed through clinical examination and USG) who were planned to undergo single stage orchidopexy, were included in study. Patients with history of orchidopexy, impalpable testes, or high abdominal testes, preoperative hernia associated with UDTs (on clinical examination), ambiguous genitalia (on clinical examination) and comorbidities (neural tube defects, storage disorders etc on USG) were excluded from study.

Sample size of 280 cases; 140 cases in each group (where 1 case was considered as 1 testes undergoing orchidopexy) is calculated with 95% confidence level, 80% power of test and taking percentage of testicular atrophy in ligation and non-ligation group as 4.3% and 0% respective.<sup>8</sup> After taking approval from ethical

review committee, 280 cases (140 cases in each group) were made part of the study after fulfilling the inclusion criteria. Parents/ guardians of patients were informed and written consent from them was taken. After enrollment, their demographic information (name, age, gender, and contact number) was obtained. The patients were randomly assigned into two groups by lottery method. One group was called Group-A and other was called Group-B. In Group A, the sac was ligated



while in Group B the sac was not ligated.

### Fig 2: Participant Inclusion and Follow-up.

Consultant surgeons of the same caliber performed the surgeries under general anesthesia. A lower skin crease incision was given on lower abdomen over the external ring. After skin, scarpa's fascia and is opened, after scarpa's fascia the external oblique aponeurosis was opened in its plane of fibers with scalpel and is further extended with ilioinguinal nerve carefully preserved. Then, the spermatic cord was exposed, testis identified and delivered out of the wound with traction on them after opening and tunica vaginalis. The gubernaculum distal attachments were identified and divided. With traction on testis the cremastaric fibers were stripped off. The vas and vessels were separated from the hernia sac and protected by a small retractor. In group A, the sac edges were identified, dissected and ligated with absorbable suture. Whereas, in group B the sac was stripped off from the cord and vessel up till the deep inguinal ring. In case when the length of vessel was inadequate, extra length was achieved by

freeing up the lateral side of the gonadal vessels in the retroperitoneal space when adequate length was achieved, an incision was given on the scrotal skin and subdartos space, a subcutaneous pouch was created in the scrotum by undermining the surgical cut with scissors. After that, path was created from the inguinal incision to the scrotum by blunt dissection. Artery forceps, guided by the retreating finger, is passed through the inguinoscrotal fascia. The forceps grasps the testes, and pull down the testes carefully not to twist the cord structures to the scrotal incision into subdartos pouch. Mean operative time, postoperative manifestation of inguinal hernia, testicular atrophy and recurrence of UDT were recorded (as per operational definition). All this information was recorded on proforma (attached). Cases were followed up till 6 months. The outcome variables were operative time, occurrence of post-operative inguinal hernia and recurrence of UDT. Operative time was measured as the time taken in orchidopexy from skin incision to skin closure in minutes. Post-operative Inguinal Hernia was labeled when there is inguino-scrotal swelling with intra-abdominal contents in it within 6 months of surgery. Recurrence of UDT labeled if cases were seen with one or both testes not present in scrotum and were present elsewhere in inguinal canal after 6 months of surgery.

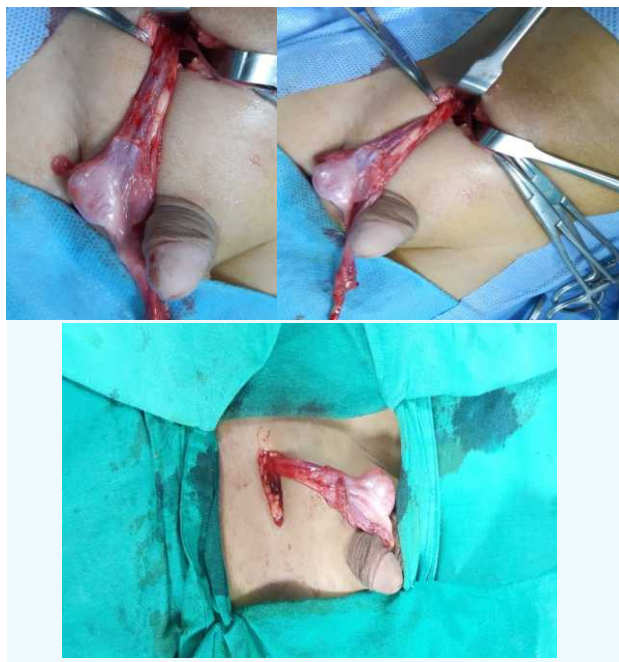
The data analysis was carried out using a statistical software i.e. SPSS (version 25). Descriptive and quantitative statistics were used to compute mean and standard deviation (SD) for numerical variables like age and operating time. Qualitative analysis of variables like recurrent UDT were made for calculating Percentage (%) and frequency. Independent samples t-test was used to compare operative time in two groups. Further, Chi-square test was applied to recurrent UDT. P-value  $\leq 0.05$  was taken as significant. On completion of 25% of the cases, an interim analysis was done and no adverse outcome was noted.

## RESULTS

Study was conducted at The Children's Hospital Lahore to compare the outcome of sac ligation versus no sac ligation in pediatric patients undergoing inguinal orchidopexy for incompletely descended palpable testes. A total of 280 patients took part in the study and were divided into two groups ; Group-A and Group-B. In

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Group A, sac was ligated while in Group B the sac was not ligated.



**Source:** Picture taken at the operation theatre of The Children's Hospital & Institute of Child Health Lahore (2019)

Among 140 patients of sac ligation group, 57 (40.7%) were 1-4 years old and 54 (38.6%) were 5-8 years old while 29 (20.7%) patients were aged 9-12 years. The patients' mean age was  $5.80 \pm 3.33$  years. Likewise, among 140 patients of non-sac ligation group, 60 patients (42.9%) were 1-4 years old and 30 (21.4%) were 5-8 years old while 50 (35.7%) patients were 9-12 years old (Mean age:  $6.57 \pm 4.10$  years).

Regarding site of undescended Testes among 140 patients of sac ligation group, 84 (60.0%) had right undescended testis while 56 (40.0%) patients had left undescended testis. Among 140 patients of non-sac ligation group, 94 (67.1%) had right undescended testis and 46 (32.9%) patients had left undescended testis.

Regarding Operative time among 140 patients of sac ligation group (Group A), the mean operative time was  $37.81 \pm 8.82$  minutes. While among 140 patients of non-sac ligation group (Group B), the mean operative time was  $24.34 \pm 4.12$  minutes. The result was found statistically significant as the p-value was  $<0.001$  after applying independent sample t test. (Table 1)

Regarding post-operative hernia among 140 patients of sac ligation group, no patient had post-operative hernia (100%). Among 140 patients of non-sac ligation group, 2 (1.4%) had post-operative hernia and 138 (98.6%) had no post-operative hernia. The result was found statistically insignificant as the p-value was 0.15. (Table 2) Regarding recurrent UDT among 140 patients of sac ligation group, 2 (1.4%) had recurrent UDT and 138 (98.6%) had no recurrent UDT. Out of 140 patients of no sac ligation group, 3 (2.1%) had recurrent UDT and 137 (97.9%) had no recurrent UDT. The result was found statistically insignificant as the

**Table 1:** Frequency Distribution of Patients According to Operative Time

Study groups	Operative Time (minutes)	P value
	Mean $\pm$ SD	
Sac ligation (n=140)	$37.81 \pm 8.82$	$<0.00$
Non sac ligation (n=140)	$24.34 \pm 4.12$	

**Table 2:** Frequency Distribution of Patients According to Post Operative Outcomes

Post-operative Outcomes	Sac ligation (n=140)		No sac ligation (n=140)		P value
	Frequency	Percentage	Frequency	Percentage	
Post operative inguinal hernia					
Yes	0	0	2	1.4	0.15
No	140	100.0	138	98.6	
Recurrent UDT					
Yes	2	1.4	3	2.1	0.65
No	138	98.6	137	97.9	

p-value was 0.65 after applying chi square test.

### DISCUSSION

Most common urological disease among children is undescended testis. In the last hundred years, several innovations and alterations have been proposed for original surgical treatment. In spite of all alterations, sac ligation was considered obligatory till past decade during orchidopexy. But now there is great debate regarding sac ligation among pediatric patients undergoing inguinal orchidopexy. Experts suggest that there is no need to ligate hernial sac. Current study was carried out at Department of Pediatric Surgery, The

Children's Hospital and The Institute of Child Health Lahore to compare outcomes of orchidopexy with and without sac ligation in pediatric patients of undescended testes in terms of operative time, postoperative inguinal hernia, recurrence of UDT. To acquire appropriate outcomes, 280 patients were made part of the study and divided into two groups namely Group-A and Group-B. In Group A, the sac was ligated while in Group B the sac was not ligated.

It was found during study that the mean age of group A patients was  $5.80 \pm 3.33$  years. Likewise, in group B, the mean age of patients was  $6.57 \pm 4.10$  years. The findings of a similar study carried out by Amanollahi and Kashanian (2017) are comparable with our study results who reported that among patients who underwent orchidopexy (with/without sac ligation), majority (83.6%) was 1-4 years old while 10.9% and 5.5% were 5-8 years old and 9-12 years old, respectively<sup>9</sup>. Another study demonstrated that 4.36 years was the mean age of the patients<sup>10</sup> while study done by Noor-ul-Ferdous and colleagues (2018) indicated  $2.8 \pm 2.3$  years as the mean age of patients.<sup>11</sup>

As far as site is concerned, study revealed that in both groups majority of the patients had right undescended testis. In sac ligation group, 60.0% and in no sac ligation group, 67.1% patients had right undescended testis while remaining proportion in both groups had left undescended testis. This corresponds to the findings of a study performed by Gajbhiye and coworkers<sup>12</sup> who asserted that 60.0% cases were right sided. But Tiwari and associates demonstrated in their study that most of the cases (58.9%) were left sided.<sup>13</sup>

When the operative time between both groups was assessed, study highlighted that no sac ligation technique is better and required less time than the sac ligation technique because in sac ligation group the mean operative time was  $37.81 \pm 8.82$  and in no sac ligation group the mean operative time was  $24.34 \pm 4.12$  (P-value 0.001). The results of a study conducted by Salimi and teammates exhibited that sac ligation group consumes more time than non-sac ligation in which sac ligation group consumes mean operative time of  $18.4 \pm 3.7$  minutes whereas in no sac

ligation group the mean operative time was  $11 \pm 2.1$  (P-value 0.03),<sup>14</sup> however it was less than the time we observed in our study.

Regarding post-operative hernia, the literature supports the fact that development of post-operative hernia by either technique is extremely rare. In our study we found that no patient developed post-operative hernia in sac ligation group while 1.4% patients developed inguinal hernia in non-sac ligation group ( $p=0.15$ ), we observed that in order to prevent occurrence of post-operative hernia the hernial sac should be stripped off till the level of deep inguinal ring but further studies on larger scale are needed to confirm these findings. The finding of our study is comparable to Al-Mandil and colleagues who stated that post-operative inguinal hernia developed in 3.2% of patients undergoing sac ligation orchidopexy.<sup>15</sup> Mallikarjuna and coworkers reported an incidence of 13.4% of post-operative hernia in all types of orchidopexies.<sup>16</sup> Jain and collaborators confirmed in their study that hernial sac does not need to be ligated and it is a needless step.<sup>17</sup>

Study showed that 1.4% patients in sac ligation group while 2.1% patients in non-sac ligation group had recurrence of undescended testis ( $p=0.65$ ), our results are comparable to study performed by Ceccanti and fellows who reported recurrence in 4.3% patients noted in sac ligation group and 1.7% patients in non-sac ligation group ( $p=0.42$ ).<sup>18</sup> In another study by Ziylan and colleagues reported an overall incidence is 7.5-13 % of recurrence in UDT, they concluded that inadequate repair of hernial sac or patent process vaginalis is considered as major cause in 62.5% of cases after primary orchidopexy.<sup>19</sup>

Regarding Limitations of Study, it is a single center study with small sample size so the results cannot be generalized to larger population.

## CONCLUSION

Undescended testis is a most common inherited urological disease. Present study compared the outcome of sac ligation versus no sac ligation in pediatric patients undergoing inguinal orchidopexy for incompletely

descended palpable testes. Study concluded that non-sac ligation technique is more effective than sac ligation technique in terms of operative time and testicular atrophy where p value is significant therefore it should be preferred for patients by surgeons to save the time and to reduce heavy load of patients at tertiary care hospitals. Further studies are needed on larger scale to compare the outcome of sac ligation versus no sac ligation in pediatric patients undergoing inguinal orchidopexy for incompletely descended palpable testes.

### Ethical Approval

The ethical Approval was obtained from Institute of Child Health, Lahore. (Reference No. 34835-5).

**Conflict of Interests:** *None*

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