ORIGINAL ARTICLE

A Prospective Cohort Study in Pediatric Care Rawalpindi to Compare the Orchidopexy with and without Sac Ligation in Terms of Post-Operative Hernia Formation

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ABSTRACT

Objective: To compare the frequency of hernia formation following orchidopexy of clinically palpable undescended testes, regardless of whether the sac was ligated during the procedure.

Study Design: Prospective-cohort.

Place and Duration of Study: This research was conducted at the Department of Pediatric Surgery, Pak Emirates Military Hospital (PEMH), Rawalpindi, Pakistan from June 2022 to May 2023.

Methods: Eighty-six children were recruited for this study from the OPD using a non-probability consecutive sampling technique. Half of them underwent orchidopexy in which the sac was ligated using the conventional technique (Group A). In the other half, orchidopexy was done in which the sac was separated from the testicular vessels and the vas deferens, but it was not ligated and only divided at the deep ring (Group B). Follow-up was done 02, 06, 12 weeks, and 6 months after discharge, and patients were examined for post-operative hernia formation in either group.

Results: This research showed that the mean age of children included in the study was 5.12 ±3.35 years. The results revealed that 39 (45.3%) children had right palpable undescended testes (UDT), 33 (38.4%) had left undescended testes whereas 14 (16.3%) had bilateral disease. The mean operative time in this study was found to be 33.31±12.26 minutes. The mean operative time in non-ligation group (27.65 ± 7.60 minutes) was significantly reduced as compared to children in ligation group (38.97±13.44 minutes) with *P*-value of less than 0.001. Incidence of hernia formation was comparable in these two groups, and during the follow-up period, no patient in either group developed hernia.

Conclusion: According to this research, it is safe to forego sac ligation during orchidopexy without increasing the risk of post-operative hernia while also shortening the operative time.

Keywords: *Cryptorchidism, Inguinal Hernia, Ligation, Operative Time, Orchiopexy.*

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Introduction

Cryptorchidism or Undescended testis (UDT) is a condition in which testis do not reach scrotum from their original intra-abdominal location.[1] If the migration of testis from posterior abdominal wall to scrotum is arrested along the normal pathway of descent, it will result in true undescended testis whereas a deviation from usual path of descent will result in ectopic testis.[2] UDT is the most common congenital anomaly affecting male infants. In full-term male infants, its incidence is 4.5%; in preterm male infants, it is 45%.[3] Up until the age of four to six months, the testes frequently descend spontaneously during the postnatal period; after that, the likelihood of spontaneous descent decreases significantly. As a result, the testis of 1% to 2% of newborns older than six months have not descended into the scrotum.[4] Bilateral UDTs account for about 10% of cases and many other congenital

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anomalies like abdominal wall and neural defects may be associated with this condition, sometimes as a part of complex syndromes.[5]The mechanism of normal testicular descent is not fully established yet and possibly involves multiple factors. The transabdominal phase of descent is controlled by Insulin-like peptide 3 (Insl3) secreted by the Leydig cells and it is followed by an inguinoscrotal phase which is regulated by androgens that control the migration of the gubernaculum indirectly via genitofemoral nerve and its neurotransmitter Calcitonin-gene-related peptide (CGRP).[6] Descent of testis into scrotum is important for normal spermatogenesis. If left untreated, there is a risk of infertility, testicular tumor, and torsion .[4]In order to reduce the likelihood of these problems, early surgery is advised. The timing of orchidopexy is considered optimal if it is done between six and eighteen months of age.[7] Almost 20% of UDT are clinically impalpable, for which laparoscopic exploration is most commonly used for diagnosis and treatment with single or two-stage orchidopexy.[8]

Standard procedure for palpable undescended testis is orchidopexy through inguinal approach. In conventional orchidopexypatent processus vaginalis (PPV) is separated from the vas deferens and spermatic cord vessels and then ligated at deep ring. It was first described by Max Schuller in 1881.[9] Since then, there have been numerous modifications and innovations to this procedure, including the creation of a subdartos pouch, using anchoring sutures to hold the testis in position, division of spermatic vessels, trans scrotal approach, and laparoscopic exploration. The ligation of PPV has remained a crucial step in conventional orchidopexy despite numerous modifications to its original method, as it is thought to be vital to prevent the formation of post-operative hernias. However, experience with laparoscopic surgery has challenged this concept. Some studies have suggested that closure of the peritoneum over the deep inguinal ring during laparoscopic orchidopexy is not required and does not raise the risk of post-operative hernia formation.[10]Furthermore, it has been suggested that peritoneal closure is not required for any surgical procedure.[11]

Ligation of the sac during orchidopexy requires more operative time and consequently more risk of anaesthesia-related complications. In addition, due to the close proximity of the PPV sac with vessels and vas deferens, extensive dissection and ligation of the sac leads to a greater risk of injury to these structures, which results in testicular atrophy and infertility in the long term. The rationale of this study was to assess whether orchidopexy without sac ligation can replace the conventional method of orchidopexy with sac ligation, without significantly increasing the risk of postoperative hernia formation. The objective of this study is to compare the frequency of post-operative hernia formation in children after orchidopexy for clinically palpable testis, regardless of whether the sac was ligated during the procedure.

Methods

This prospective-cohort study was carried out at Department of Paediatric Surgery, Pak Emirates Military Hospital (PEMH), Rawalpindi, Pakistan. The duration of this study was one year from June 2022 to May 2023. This study was carried out after approval by the Ethical Review Board bearing letter no: A/28/ERC/625/23, dated: 26th May 2022. The study comprised children aged 1 to 12 years who were having orchidopexy for palpable UDT. The study excluded patients with non-palpable, ectopic testis, those with clinically evident inguinal hernia or having risk factors for developing hernia, like connective tissue disorder or Increased intra-abdominal pressure for any reason (peritoneal dialysis, ascites, ventriculo-peritoneal shunt, etc.), and patients undergoing redo orchidopexy. The sample size for this study was calculated using the WHO sample size calculator, based on an estimated difference in postoperative hernia rates between the two groups, with a confidence level of 95% and a power of 80%. Using non-probability consecutive sampling, all children who were satisfied with the inclusion criteria were included in the study.

A total of 86 children with palpable undescended testis were recruited from the outpatient department. Preoperative investigations included complete blood count and a hepatitis profile. General anesthesia fitness was obtained. Participants were divided into two groups (Group A and Group B) at random. The lottery method was

used for this purpose. Group A underwent standard orchidopexy with ligation of the sac, while in group B, orchidopexy without ligation of the sac was carried out. Parents were counseled in detail, and informed consent was obtained after explaining the risks and complications of the procedure. All procedures were done under general anesthesia. Prophylactic antibiotic was given as a single dose of injection Cefuroxime (50 mg/kg) before induction. The landmark for incision was the inguinal skin crease, starting from above the level of the pubic tubercle and then extending the incision laterally. After skin incision, Camper's fascia and Scarpa's fascia are dissected, and the external oblique aponeurosis is divided along the line of incision above the inguinal ligament. The spermatic cord was lifted and the sac separated from the vas deferens and testicular vessels up to the deep inguinal ring. In group A, transfixation and ligation of the PPV sac were done at the deep inguinal ring. In group B, the sac was not meticulously dissected, but the vas deferens and testicular vessels were de-epithelialized, and the sac was divided without ligation at the deep inguinal ring. Once the mobilization of the cord was enough to bring the testis to the scrotum without tension, a subdartos pouch was made in the scrotum, and the testis was brought down and secured in the subdartos pouch. Postoperatively, oral feeding was allowed when the child was awake and recovered from anesthesia. The children were given Syp ibuprofen 5-10mg/kg/dose for pain relief. They were discharged on the following day if post-operative recovery was smooth. Patients were primarily followed up through outpatient department (OPD) visits at 2 weeks, 6 weeks, 12 weeks, and 6 months post-surgery to see post-operative hernia formation in both groups. Although six patients missed their initial post-operative visits, they were successfully contacted via phone . Subsequently, they attended their 6-month follow-up, ensuring complete long-term outcome data for all participants. The primary researcher, a practicing surgeon, was responsible for all follow-up assessments to ensure consistency in clinical evaluation and data collection. This approach minimized interobserver variability and enhanced the reliability of the outcome assessment. The patients were followed up at the intervals of 2, 6, 12 weeks, and 6 months to see post-operative hernia formation in both groups. A specially designed form was used to record all the data, which included patient particulars such as name, age, address, contact number, and hospital reference number. Clinical details included the diagnosis of undescended testis (UDT), laterality (right or left), and whether the testis was clinically palpable or impalpable. Relevant ultrasound (USG) findings were also documented. Follow-up assessments included wound status, presence of swelling, and testicular size at each visit. Statistical Package for the Social Sciences version 22 was used for data analysis. The variables in our study included quantitative data like age, operative time, and categorical data like hernia formation. Quantitative variables were presented as mean and standard deviation. Number and percentages was used for analysis of the categorical variable, that is, post-operative hernia formation, which was the primary outcome measure in this study. The secondary outcome measure in this study was Mean operative time and compared between two groups by using t test. A p-value ≤0.05 was considered to be significant.

Results

In all, 86 patients were included in this research. All children who participated in this study had a mean age of 5.12 ± 3.35 years. The mean age of patients in groups A and B was 5.29 + 3.48 and 4.95 + 3.25 years, respectively as illustrated in table-1.

The study results table-2 revealed that palpable UDT in 39 (45.3%) children were noted on the right side; in 33 (38.4%) children on the left, and in 14 (16.3 %)

Table-1: Age distribution

Age (in years)	Group-A (n=43)	Group-B (n=43)	Total (n=86)
1-6	23 (53.5%)	28 (65.1%)	51 (59.3%)
6-12	20 (46.5%)	15 (34.9%)	35 (40.7%)
Total	43 (100 %)	43 (100 %)	86 (100%)
Mean ± SD	5.29 ± 3.48	4.95 ± 3.25	5.12 ± 3.35

Table-2: Side distribution of UDT among study groups

Side of UDT	Group A	Group B	Total
Right	21 (48.8%)	18 (41.9%)	39 (45.3%)
Left	12 (27.9%)	21 (48.8%)	33 (38.4%)
Bilateral	10 (23.3%)	4 (9.3%)	14 (16.3%)
Total	43 (100%)	43 (100%)	86 (100%)

Table-3: Difference in mean operative time and hernia formation between two study groups

	Group A (n= 43)	Group B (n= 43)	*t*-test value	*P*-value
Operative time (mean ± SD)	38.97±13.44	27.65 ± 7.60	5.75	0.001
Post-operative hernia	Nil	Nil	-	-

children on both sides. These children were randomly divided into two groups. Among 39 children with the right UDT, 21 (48.8%) had sac ligation during orchidopexy (group A) and in 18 (41.9%) children no sac ligation was done (group B). Among 33 children with left UDT, 12 (27.9%) had sac ligation during orchidopexy (group A), and in 21 (48.8%) children, no sac ligation was done (group B). Among 14 children with bilateral UDT, 10 (23.3%) had sac ligation during orchidopexy (group A), and in 4 (9.3%) children, no sac ligation was done (group B).

The findings of this study showed that in group B (no sac ligation) the mean operative time was 27.65 ± 7.60 minutes. This was notably shorter than the mean operation time of 38.97±13.44 minutes recorded for participants in Group A (sac ligation). A t-test was used to calculate the *P* value. With a *P*-value <0.001, the difference between the two groups was statistically significant. After surgery, the follow-up showed that not a single patient from either group had a hernia. These results are shown in table-3.

Discussion

During traditional orchidopexy procedures, the hernia sac is dissected from other cord structures, such as the vas deferens and spermatic vessels, which is followed by division and ligation of the sac at the level of the deep inguinal ring. This step is considered crucial to prevent the development of post-operative hernia.

However, sac ligation carries a danger of harming delicate spermatic cord components, particularly when orchidopexy is done at a younger age. This could result in testicular atrophy and infertility.[12] In addition, it takes a longer operative time and carries a higher risk of problems associated with anesthesia. Our research indicates that there is no increased risk of post-operative hernia formation following orchidopexy performed without sac ligation.

Many researchers who have recommended non-ligation techniques believe that there is rapid peritonealization of the hernia sac opening within 48 hrs. by metamorphosis of the mesodermal cells. Moreover, a protective layer forms within a few hours in the raw area created after cutting the peritoneum.[13]

In prospective research by Maitra SK. et al., that included 217 children between the ages of 6 months and 12 years who had orchidopexy without ligating the processus vaginalis showed no signs of a post-operative hernia following a stringent two- to eight-year follow-up.[14] This study, which has a larger sample size and longer follow-up, supports our findings.

Similarly, Khan. et al. studied Ninety-four children from 6 months to 16 years of age with undescended testis undergoing orchidopexy.[15] This study examined the differences between patients who underwent sac ligation during orchidopexy and those who did not. For these groups, the average operating time was 46.96 ± 1.913 and 36.72 ± 2.208 minutes, respectively. After one, four-, and eight-weeks following surgery, study participants were followed up, and results revealed no discernible difference in post-operative complications or post-operative hernia between the two groups. Correspondingly, in our study, the mean operative time was significantly reduced in patients undergoing orchidopexy without sac ligation.

A prospective comparison study was conducted by Napar NB et al. on 100 children aged 2 to 7 years. [16] According to this study, patients who did not

undergo sac ligation had a considerably shorter mean operation time (21.25±0.90 minutes) than patients who did (33.10±1.10 minutes) (*P*-value 0.001). Following surgery, patients were examined at one, four, eight, and twelve weeks. None of the patients in either group experienced a post-operative hernia. These results are comparable to our results.

Some researchers have studied non-ligation of the sac in patients with indirect inguinal hernia repair with mixed results. In a prospective study, Faud et al. recruited 140 patients with an age range from four months to six years with the diagnosis of indirect inguinal hernias (90 patients, all males) and undescended testis (50 patients) undergoing surgical treatment.[17] Hernia sac was not ligated in both groups. Post-operative follow-up was done for two years. Among the patients who underwent orchidopexy without sac ligation for UDT, no patient developed inguinal hernia postoperatively. However, hernia recurrence was noticed in 2 patients (2.22%) who underwent repair of indirect inguinal hernia without sac ligation. These results suggest that nonligation of the sac may be acceptable in patients with UDT without clinical evidence of associated inguinal hernia, as in our study.

A retrospective study was carried out by Ceccanti et al. to examine the impact of not ligating the sac during orchidopexy.[18] The study had 123 patients with a median age of 3 years, ranging from 1 to 11 years. These patients, some of whom had bilateral undescended testicles, had undergone 147 orchidopexies. In 122 orchidopexies, the hernia sac was only cut at the deep inguinal ring without ligation, whereas 25 orchidopexies were done using standard division and ligation of the hernia sac. On post-operative follow-up, none of the patients had post-operative development of hernia or hydrocele, including those who had associated ipsilateral hydrocele pre-operatively.

In a retrospective study, Shirazi. et al., compared conventional orchidopexy with a modified technique involving processus vaginalis sac tightening, in which a thin layer of the sac was deliberately left attached to the spermatic cord and the opening was tightened as much as possible.[19] In their analysis of 821 orchidopexy cases, they found that the sac tightening technique was associated with significantly fewer postoperative complications compared to conventional orchidopexy. This supports the potential benefit of approaches that avoid complete sac excision, aligning with the rationale of the present study to reduce cord structure injury while maintaining favorable surgical outcomes.

On the other hand, some studies have revealed contradictory findings. According to a retrospective study by Sonmez K. et al., closure of the PPV sac was required to avoid the formation of hernias in 55 children after inguinal orchidopexy.[20] These results contradict those of our study; the explanation for this could be that Sonmez K. et al. evaluated patients whose testicles were not palpable, whereas the individuals in our study had palpable inguinal undescended testicles.[20] Moreover, patients with clinical evidence of hernia or positive silk sign were not excluded from the study, which could be the reason for the different results.

Conclusion

In conclusion, orchidopexy without sac ligation is a simpler and quicker procedure, which may be preferred in cases where the risk of hernia formation is low and in patients with no clinically evident hernia associated with an undescended testis. It is crucial to remember that more research, such as randomized controlled trials, larger sample sizes, and long-term follow-up studies, may be required to draw a firmer conclusion about how well these two strategies compare in terms of preventing the development of post-operative hernias.

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Author Contributions

MHR: Manuscript writing for methodology design and investigation
AA: Conception and design of the work
RA: Data acquisition, curation, and statistical analysis
SJ: Validation of data, interpretation, and write-up of results
HR: Revising, editing, and supervising for intellectual content
MSJ: Writing the original draft, proofreading, and approval for final submission