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COMPARISON OF THE OUTCOME OF ORCHIDOPEXY WITH AND WITHOUT SAC LIGATION IN RANDOMIZED PAEDIATRIC POPULATION WITH PALPABLE UNDESCENDED TESTES

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Abstract

Background: Orchiopexy is the standard surgical treatment for palpable undescended testes in children. Routine ligation of the hernia sac during orchiopexy is traditionally performed; however, its necessity and impact on postoperative outcomes remain controversial.

Objective: The study was done to compare the postoperative outcomes of orchiopexy performed with sac ligation versus without sac ligation in children with palpable undescended.

Methodology: This randomized controlled trial included 60 male children ≤ 15 years of age with palpable undescended testes at Children Hospital & Institute of Child Health, Faisalabad, Pakistan. Patients were randomized in to: Group A ($n=30$): Orchiopexy with sac ligation; Group B ($n=30$): Orchiopexy without sac ligation. Demographic data, operative time (minutes), and post-operative complications were recorded during the follow-up done at 1, 4, 8, and 12 weeks for assessment of hernia and other complications. Data were analyzed with SPSS v21, *t*-test and chi-square applied.

Results: A total of 60 patients were included, with comparable baseline characteristics between the two groups in terms of age, laterality of undescended testis, and preoperative findings. Group A (with sac ligation) had a significantly longer mean operative time (30.3 ± 3.0 minutes) than Group B (no sac ligation) at 21.0 ± 2.1 minutes ($p < 0.001$). No postoperative hernias were observed in either group. Postoperative pain scores were significantly lower in Group B, and the duration of hospital stay was shorter compared with Group A. Minor complications such as hematoma and wound infection occurred infrequently with no significant between the groups.

Conclusion: Orchiopexy without sac ligation significantly reduces operative time without increasing risk of post-operative hernia. Based on the study, it appears that routine sac ligation appears unnecessary in pediatric palpable undescended testes.

Keywords: Length of hospital stay, Orchiopexy, Palpable UDT, Sac ligation, Undescended testes

INTRODUCTION

Cryptorchidism, or undescended testis (UDT), is the most common congenital anomaly of the male genitalia, affecting 2–4% of full-term and up to 30% of preterm newborn males. Although many testes descend spontaneously within the first few months of life, 1–2% of boys older than six months require surgical intervention. In South Asia, including Pakistan, the prevalence appears comparable, though precise population-based data are limited due to underreporting and delayed presentation (1).

Normal testicular descent occurs from the intra-abdominal region near the kidney into the scrotum by the last trimester of gestation, guided by androgens and genitofemoral nerve signals. Failure of descent at any stage results in UDT, which may be palpable (inguinal canal or just above the scrotum) or impalpable (intra-abdominal, atrophic, or absent) (2, 3). Palpable testes account for 70–80% of cases and represent the most common indication for orchidopexy in children. UDT is clinically significant due to its association with reduced fertility and a 3–8-fold increased risk of testicular cancer; early orchidopexy reduces, but does not eliminate, these risks. Orchidopexy, the gold-standard surgical treatment, aims to relocate the testis into the scrotum, fix it to prevent re-ascent, and reduce associated complications (4). Traditionally, high ligation of



the PV sac has been performed, following principles of inguinal hernia repair, to prevent postoperative hernia (5). However, the studies suggest that sac ligation may often be unnecessary, with minimal risk of hernia formation when omitted (6, 7).

The proposed compares the outcomes of orchiopexy performed with and without sac ligation in children with palpable undescended testes. The outcomes assessed include postoperative pain, length of hospital stay, and operative time, along with postoperative complications such as inguinal hernia, wound infection, hematoma, and testicular atrophy. The study was designed to determine whether omission of sac ligation provides comparable surgical safety while improving postoperative recovery and operative efficiency.

MATERIALS AND METHODS

STUDY DESIGN AND SETTING

This prospective, parallel-group randomized controlled trial was conducted in the Department of Pediatric Surgery, Children Hospital and Institute of Child Health from August 2024 to February 2025. Ethical approval was obtained from the Ethical Review Committee of the hospital (Ref No. 32/CH&ICH/FSD; dated 16 January 2024) and the College of Physicians and Surgeons Pakistan (CPSP) Karachi (Ref No. CPSP/REU/PSG-2023-290-572; dated 20 August 2024). The study was conducted in accordance with the principles of the Declaration of Helsinki.

PARTICIPANTS

Male children aged >6 months and ≤15 years presenting with palpable undescended testes (UDT) and scheduled for single-staged orchiopexy were included in the study. Patients with impalpable testes, recurrent UDT, previous orchiopexy, preoperative inguinal hernia, ambiguous genitalia, or those requiring staged or laparoscopic procedures were excluded.

SAMPLE SIZE & RANDOMIZATION

The sample size was calculated using the WHO sample size calculator with a 5% level of significance and 80% study power. The anticipated mean operative time in the no sac ligation group was derived from the study by Napar *et al.* (8). Based on these assumptions, a total sample size of 60 patients was calculated. Participants were enrolled through non-probability consecutive sampling and randomly allocated into two equal groups (30 patients each) using the lottery method. Group A underwent orchiopexy with sac ligation, whereas Group B underwent orchiopexy without sac ligation.

DATA COLLECTION

Written informed consent was obtained from the parents or legal guardians of all enrolled children prior to participation in the study. The patients were randomly allocated into two equal groups using the lottery method. Data were collected using a structured proforma. Baseline demographic variables, including age of the patient, side involved, and anatomical location of the undescended testis, were recorded at the time of enrollment. All procedures were performed under general anaesthesia, and postoperative pain was managed using standard weight-based intravenous/parenteral analgesics according to hospital protocol. Operative time was measured intraoperatively, as the duration from skin incision to skin closure, and recorded in minutes. Patients were monitored for post-operative complications, including the occurrence of inguinal hernia, wound infection, hematoma, and testicular atrophy. These outcomes were assessed during scheduled follow-up visits at 4, 8, and 12 weeks after surgery. In our study, blinding was not feasible due to the nature of the surgical intervention, which may have introduced observer bias in postoperative assessment; therefore, the trial was conducted as an open-label study. The length of hospital stay (LOS) was calculated as the number of days from hospital admission for the surgical procedure until discharge. Post-operative pain was evaluated using the Visual Analog Scale (VAS), ranging from 0 (no pain) to 10 (worst imaginable pain). Pain scores were recorded at predefined postoperative intervals (3, 12 and 24, and 48 hours following surgery), and analgesics were administered accordingly. Moreover, the testicular atrophy

was assessed clinically as reduction in testicular size and consistency compared with the contralateral normal testis during follow-up examination.

STATISTICAL ANALYSIS

Data were entered and analysed using SPSS version 21. Depending upon the data distribution, quantitative variables were expressed as mean±standard deviation (SD) or median (interquartile range, IQR), whereas qualitative variables were presented as frequency and percentage. Normality of data was checked using the Shapiro-Wilk test. Independent sample t-test was applied for normally distributed variables, whereas the Mann-Whitney U test was used for non-normally distributed variables. Chi-square test was used for comparison of categorical variables. A p-value ≤0.05 was considered statistically significant.

RESULTS

The baseline demographic characteristics were collected from study participants in both groups. The mean age of patients in Group A was 6.8 ± 2.3 years, while in Group B it was 6.0 ± 2.0 years. Regarding laterality of undescended testes, left-sided involvement was more common in both groups, observed in 60% of patients in Group A and 56% in Group B, whereas right-sided involvement was seen in 40% and 44% of patients in Groups A and B, respectively, as shown in Table I.

Table I. Comparison of the baseline characteristics of patients

Variables	Group A (n=30)	Group B (n=30)
Mean age (years)	6.8 ± 2.3	6.0 ± 2.0
Age range	6 months – 12 years	6 months – 11 years
Laterality (left %)	60%	56%
Laterality (right %)	40%	44%

The mean operative time in Group A (orchiopey with sac ligation) was 30.3 ± 3.0 minutes, with a range of 27–37 minutes, whereas Group B (orchiopey without sac ligation) had a significantly shorter mean operative time of 21.3 ± 1.9 minutes, ranging from 17–25 minutes. The difference in operative time between the two groups was statistically highly significant ($p < 0.001$), indicating that omission of sac ligation was associated with a marked reduction in surgical duration. Table II compares the operative time between the two study groups, whereas the scatter plot showing operative time (minutes) in patients is shown in Figure 1. Postoperative pain scores and duration of hospital stay were compared between the two groups i.e., Group A (with sac ligation) was compared with Group B (orchiopey without sac ligation). Since Shapiro-Wilk testing showed non-normal distribution of these variables, data were expressed as median (IQR) and analyzed using the Mann-Whitney U test. The median postoperative pain score (VAS) was significantly higher in Group A, that is 4.4 (IQR: 3.35–5.5) versus 3.25 (IQR: 2.75–3.8) in Group B ($p < 0.001$). Likewise, the duration of hospital stay was significantly shorter in Group B, with a median stay of 1 day (IQR: 1–2), compared with 2 days (IQR: 2–3) in Group A ($p < 0.001$).

Table II. Comparison of mean post-operative pain scores (VAS) and mean hospital stay (days)

Variables	Group A (with sac ligation) n=30	Group B (without sac ligation) n=30	P-value
Operative time of the surgery#	30.3 ± 3.0 (27–37)	21.3 ± 1.9 (17–25)	<0.001†
Postoperative pain score (VAS)*	4.4 (3.35–5.5)	3.25 (2.75–3.8)	<0.001†
Mean hospital stay*	2 (2–3)	1 (1–2)	<0.001†

VAS pain scores were tested for normality using the Shapiro-Wilk test and found to be non-normally distributed; therefore, data are presented as median (IQR) and analyzed using the Mann-Whitney U test.

Data presented as Mean (Range); * Data presented as Median (Interquartile Range, IQR); † Mann-Whitney U test applied after Shapiro-Wilk test showed non-normal distribution of VAS scores

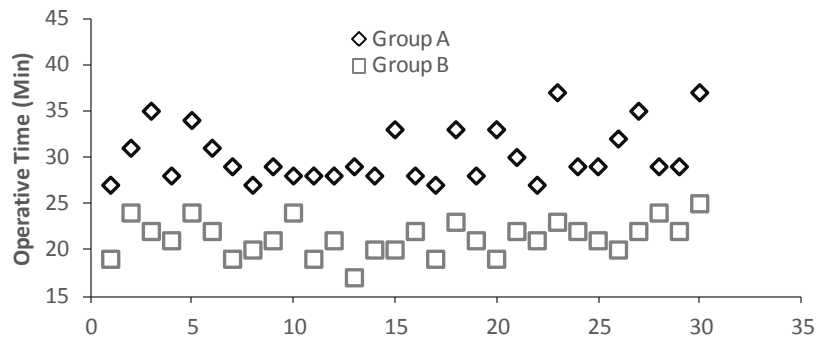


Fig. 1. Scatter plot showing operative time (minutes) in patients undergoing orchiopexy with sac ligation (Group A) and orchiopexy without sac ligation (Group B). Each point represents an individual patient

Table III. Comparison of the post-operative complications

Complication	Group A	Group B	P-value
Post-op hernia	0%	0%	—
Wound infection	3.33%	3.33%	1.00
Hematoma	6.67%	0%	0.155
Testicular atrophy	0%	0%	—

In this study, no cases of post-operative hernia or testicular atrophy were reported in either Group A or Group B. We found that the wound infection occurred in 3.33% of patients in both groups ($p = 1.00$). The orchiopexy is considered a clean surgical procedure with a low reported incidence of wound infection, superficial surgical site infection was observed in one patient in each group in the present study. This relatively higher percentage likely reflects the small sample size, as a single event corresponded to 3.3% of the study population. The hematoma formation was observed in 6.67% of patients in Group A, whereas no cases were reported in Group B; however, this difference did not reach statistical significance ($p = 0.155$). Table III summarizes the post-operative complications observed in both study groups.

DISCUSSION

This randomized controlled trial compared outcomes of orchidopexy with and without sac ligation in pediatric patients with palpable undescended testes. The results clearly demonstrated that omitting sac ligation significantly reduced operative time without increasing the risk of postoperative hernia. Furthermore, patients in the no-ligation group reported lower postoperative pain scores and shorter hospital stays, suggesting recovery advantages.

Sac ligation also prolongs operative time and increases dissection around the spermatic cord, potentially raising the risk of injury and postoperative pain (9). It is noteworthy findings that emerged from our study is the significant differential in the duration of the surgical process. The group that got sac ligation had a longer duration, whereas the group that did not undergo sac ligation had a shorter duration. The reduction in operative time is clinically meaningful, particularly in high-volume paediatric surgery centres where operating room efficiency is essential. Improved operative efficiency may contribute to enhanced patient turnover, reduced surgical waiting times, optimal utilisation of operating room resources, and decreased institutional healthcare costs (10). This is especially true in Pakistan, where tertiary care institutions regularly cope with massive caseloads despite having little resources. Additionally, shorter surgical times may result in a reduction in the quantity of anaesthesia exposure, considering the emerging concerns regarding the neurodevelopmental risks that are linked with prolonged exposure to anaesthesia (11). A similar finding was made by Jan *et al.* (2021), who discovered that minimally invasive orchidopexy treatments led to an increase in postoperative comfort. This demonstrates how important it is to modify surgical procedures in order to lower the risk of morbidity (12).

The current study exhibited significantly lower postoperative pain scores in the non-sac ligation group compared with the conventional sac ligation group. The reduced postoperative pain in Group B may be attributed to less tissue dissection, reduced manipulation of the spermatic cord structures, and avoidance of unnecessary ligation of the processus vaginalis. Similar findings have been reported in previous studies,

where omission of sac ligation was associated with decreased operative trauma and improved postoperative comfort without increasing surgical complications (8, 13). Reduced tissue handling may also minimise local inflammatory response and postoperative oedema, thereby contributing to lower pain perception. Shorter hospital stays also reduce healthcare costs and minimize disruption to family life, an important consideration in pediatric populations where caregiver burden is high (14). Importantly, length of hospital stay in the present study was influenced by local discharge practices; therefore, this parameter may not be directly comparable with international centres where orchiopexy is routinely performed as a day-care procedure.

The findings that substantiate the safety of the no-ligation procedure is that the incidence of complications such as wound infection, haematoma, and testicular atrophy were comparable between the groups. These findings, which are in accordance with the growing body of research call into question the long-held surgical orthodoxy that routine sac ligation is essential during orchidopexy. It was determined by Mohta and colleagues (2003) that orchidopexy without sac ligation did not increase the incidence of hernia in contrast to ligation, which generated a discussion among paediatric surgeons (7). In a study that was conducted more recently, Napar *et al.* (2020) discovered that there was no difference in the frequency of postoperative hernias between the two operations. Furthermore, they observed that the group that did not have ligation had shorter operating times (8). In the past, it was thought that a significant amount of closure of the process vaginalis (PV) was required in order to forestall the development of a hernia or hydrocele in the future. Although there is a lack of meaningful data to establish the necessity of this surgery, sac ligation has historically been included in the surgical protocol for orchidopexy (15, 16).

The primary rationale for sac ligation is the belief that leaving the processus vaginalis open increases the risk of postoperative inguinal hernia. However, our study observed no postoperative hernia in either group during 12 weeks of follow-up. Similar to our study, another retrospective cross-sectional data concluded that orchidopexy without sac ligation is less time taking procedure and is not linked with the danger of developing post-operative hernia (17). Additionally, the intervention without ligation frequently led to spontaneous peritoneal scarring and complete closure of the internal inguinal ring (15). Importantly, orchidopexy without ligation did not increase the risk of testicular atrophy during the prescribed period of followup. This study strengthens the safety of omitting sac ligation, which does not affect testicular vascularity or fixation stability. Eliminating sac ligation streamlines the technique, saves time, reduces anaesthesia exposure, and speeds surgical training. This method may also enable widespread day-care orchidopexy, reducing hospital expenditures⁸. International standards from the European Association of Urology (EAU) and the American Urological Association (AUA) favour orchidopexy before 18 months over technical variations, allowing surgeon's discretion in sac ligation (18, 19). Another recent study demonstrated that without-ligation of sac is not related to any risk of recurrence both in elective as well as emergency arrangements (20). Our findings and the growing body of evidence from other countries justify new sac ligation-focused guidelines. Public health-wise, no-ligation orchidopexy could reduce healthcare costs while maintaining patient outcomes. This is particularly relevant in low- and middle-income countries, where cost-effectiveness is a central consideration in surgical practice (21).

This study had certain limitations. It was conducted at a single tertiary care centre with a relatively small sample size, which may limit the generalizability of the findings. The follow-up duration was short, therefore long-term outcomes such as testicular atrophy, recurrence, fertility potential, and late development of inguinal hernia could not be assessed.

CONCLUSION

This study contributes to the growing evidence that sac ligation during orchidopexy for palpable undescended testes may be unnecessary. These findings suggest that omission of sac ligation during orchidopexy may offer advantages in terms of post-operative comfort and reduced hospitalization, without increasing the risk of hernia or other complications. In resource-constrained environments, adopting such evidence-based simplification could improve surgical efficiency and patient outcomes.

Conflict of interest:

Authors declared no conflict of interest.

Authors' contribution:

RD Study design, data collection/interpretation, manuscript drafting, and final approval; HS Conceptualization, study design, surgical procedures, supervision and final approval; SAM Statistical analysis, interpretation of data, manuscript editing; AM Literature review, data entry/interpretation, and manuscript formatting; TSNB Data interpretation, critical review of the manuscript.

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