

# Is the ligation of hernial sac necessary in herniotomy for children? A randomized controlled trial of evaluating surgical complications and duration

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## Abstract

**Background:** Herniotomy is a common operation done by pediatric surgeons. Recent studies have shown that high ligation in herniation in adult is not necessary, but this method was not fully evaluated in children. We compared non-ligation with high-ligation sac in herniotomy in terms of surgical complications and duration.

**Materials and Methods:** This randomized controlled trial study was done on 104 children with inguinal hernia at Al-Zahra Hospital, Isfahan, Iran, between 2011 and 2013. Patients were equally randomized to undergo herniotomy with ligation of sac at the internal ring level or to undergo herniotomy without sac ligation. Patients were followed up just after the operation, and in the 1<sup>st</sup>, 6<sup>th</sup>, and 12<sup>th</sup> weeks postoperation to discover early (scrotal hematoma, edema, wound infection, and postoperation fever) and late (adhesion and recurrence) complications. Also, duration of operation was recorded for each group.

**Results:** The incidence of early complications (nine cases in high-ligation and eight cases in non-ligation group) was the same in both groups ( $P = 0.402$ ). No late complication was observed in any group. The mean duration of operation in high-ligation group ( $18.84 \pm 5.47$  min) was significantly shorter than non-ligation group ( $21.46 \pm 9.03$  min) ( $P < 0.001$ ).

**Conclusion:** Complications are the same in herniotomy with or without ligation of the sac, but the duration of the non-ligation procedure is shorter than that of high-ligation. We suggest that herniotomy without sac ligation in children be the procedure of choice to save time and also to prevent any other possible complications such as nerve damage, spermatic cord injury, or peritoneal tearing.

**Key Words:** Child, herniorrhaphy, herniotomy, inguinal hernia, ligation

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## INTRODUCTION

Indirect inguinal hernia is a prevalent surgical problem in both adults and children. It is more common in males. Approximately 1-4% of children have inguinal hernia. So far, herniotomy has been the best treatment for inguinal hernia and is the most common operation still done by pediatric surgeons.<sup>[1]</sup> It is not new to surgeons, but it continues to evolve. The standard procedure is high ligation of the

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peritoneal sac during herniotomy with monofilament absorbable sutures. It seems that sac ligation is mandatory.<sup>[2]</sup> This procedure has some early and late complications. Some conditions are expected to be associated with inguinal hernia recurrences. The most common cause is increased intra-abdominal pressure as due to ventriculo-peritoneal (VP) shunt, ascites, posterior urethral valve, weight lifting, and pulmonary diseases causing chronic cough. Others include growth failure, prematurity (less than 31 weeks), malnutrition, connective tissue disorders, bladder exstrophy, cryptorchidism, and seizure disorders with spasticity. In traditional procedures, in order to prevent recurrence, high ligation of sac and the avoidance of injury to the canal floor were considered to be useful and important.<sup>[3]</sup> In contrast, non-ligation of sac was expected to be better than high ligation. Recent studies have shown that high ligation in indirect inguinal hernia in adults is not necessary and that the non-ligation procedure led to fewer complications.<sup>[4]</sup> But this method is not fully evaluated in pediatric groups.

A few studies have investigated the necessity of high ligation in children. In one study, it was reported that there was no need to ligate the peritoneal sac before division, and this seemed to be a strategy that could save time and also prevent unnecessary destruction of spermatic cord structures.<sup>[5]</sup> Another study explained the advantage of non-ligation of sac in terms of time-saving, safety, and the prevention of peritoneal tearing in patients with extremely thin peritoneum.<sup>[6]</sup> According to the lack of randomized clinical trials, in this study we aimed to compare complications and operation duration of herniotomy with sac ligation and herniotomy without sac ligation in children.

## MATERIALS AND METHODS

### Patients and setting

This randomized controlled trial study was conducted at Al-Zahra Hospital, Isfahan, Iran between 2011 and 2013. One hundred and four children under the age of 12 years (with a range of 1 month to 12 years) and in 1 and 2 American Society of Anesthesiologists (ASA) classification with inguinal hernia were selected. Exclusion criteria were cases with strangulated inguinal hernia or incarcerated inguinal hernia. The study was approved by the Ethics Committee of the Isfahan University of Medical Sciences (research project number: 392194), and informed consent was obtained from all patients in the study.

### Intervention

Patients were randomly divided into two groups: Herniotomy without sac ligation and herniotomy with

high-ligation, by random allocation software.<sup>[7]</sup> Both groups were anesthetized with general anesthesia and caudal block for pain relief. Then an incision was made in the groin of each patient in both groups. Both groups underwent cutting of the Camper and Scarpa fasciae. The external oblique aponeurosis, the cremasteric muscle, and the sac along with spermatic cord structures were separated. Next, the sac was dissected from the spermatic cord structures. The first group underwent high ligation of the peritoneal sac after division with 4-0 delayed absorbable sutures (high ligation group), and in the other group the sac remained open at the level of the internal ring (non-ligation group). All of these procedures were done by one surgeon.

### Assessments

Patients were followed up just after the operation, and in the 1<sup>st</sup>, 6<sup>th</sup>, and 12<sup>th</sup> weeks postoperation, when early (scrotal hematoma, edema, wound infection, and postoperation fever) and late (adhesion and recurrence) complications were discovered. The early and late complications were evaluated by a pediatric surgery fellow. Also, duration of operation was recorded for each group. The duration was calculated as the duration from the onset of general anesthesia to the time when the skin incision was sutured.

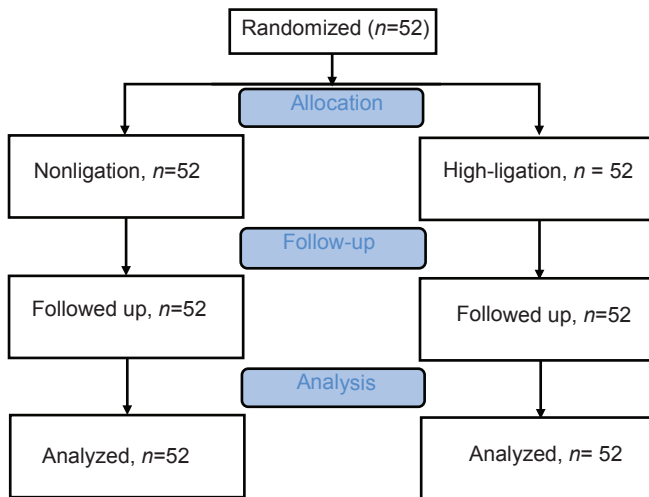
### Data analyses

Data were analyzed by the SPSS software version 16.0 (SPSS Inc., Chicago IL., USA). Quantitative and qualitative data are expressed as mean  $\pm$  standard deviation (SD) or number (%) and were compared between the two groups using the independent *t*-test and the Chi-square test, respectively. A *P* value of less than 0.05 was considered as significant.

## RESULTS

A total of 104 patients with inguinal hernia were evaluated as eligible for our study. There were 93 male and 11 female patients, all between the ages of 1 month and 8 years. Inguinal hernia was at right, left, and bilateral sides in 62 (59.6%), 21 (20.2%), and 21 (20.2%) of the patients, respectively. The two groups were not different regarding gender ( $P = 0.263$ ), age ( $P = 0.215$ ), or the side of inguinal hernia ( $P = 0.085$ ). All of the patients completed the study [Figure 1, patients' flow diagram].

The incidence of early complications is reported in Table 1. There was no significant difference in the incidence of fever, scrotal hematoma, scrotal edema, and surgical site infection between the two groups ( $P = 0.402$ ). None of the patients in any group experienced recurrence or adhesions. No association



**Figure 1:** Patients' flow diagram

**Table 1: Incidence of early complications in each group**

Early complication	Group (n=52)		Total
	High-ligation	Non-ligation	
No complication	43	44	87
Fever	3	3	6
Scrotal hematoma	2	3	5
Scrotal edema	3	2	5
Infection	1	0	1

was found between occurrence of complications, and age ( $P = 0.985$ ), gender ( $P = 0.356$ ), or side of inguinal hernia ( $P = 0.457$ ).

Mean duration of operation in the high-ligation group ( $18.84 \pm 5.47$  min) was significantly shorter than in the non-ligation group ( $21.46 \pm 9.03$  min) ( $P < 0.001$ ).

## DISCUSSION

Herniotomy is the standard procedure used to treat inguinal hernia in children. It was conventionally done by ligation of sac after division. The ligation was expected to be mandatory in this procedure to prevent postoperative recurrence, but it turned out to be unnecessary. Inguinal hernia in children is not due to muscular weaknesses. It is caused by nonclosure of the processus vaginalis. Direct inguinal hernia is rare in this age group. Therefore, the cause of inguinal hernia in children is an open sac.<sup>[8]</sup> It is important to consider that a patent processus vaginalis may increase the chance of contralateral inguinal hernia and disturb the results.<sup>[9]</sup>

In this study, 104 children with inguinal hernia were randomly divided into two groups (high ligation group and non-ligation group). The results indicated that herniotomy with or without sac ligation did not change the incidence of early or late complications, but that

the operation duration in the non-ligation group was significantly shorter than in the high ligation group. The results suggested that performing the non-ligation procedure could save more time compared to the other procedure.

The evidence in early studies on adults indicated a high recurrence rate of 10-15%.<sup>[10-13]</sup> Some studies reported that non-ligation of sac in indirect hernia was harmless. In a study by Shulman *et al.* on 6321 adult patients, non-ligation of peritoneal sac decreased postoperative pain.<sup>[4]</sup> In adults, it is fully understood that the peritoneal sac need not be closed after cutting. Contrary to the belief in the advantages of non-ligation herniotomy in adults, some articles showed that in certain cases high ligation of peritoneal sac was still the choice. However, the ligation of peritoneal sac is associated with a higher incidence of postoperative complications, thus it should be performed with caution.<sup>[14]</sup> Generally, it may decrease the likelihood of recurrence, and the rate of recurrence is further decreased when mesh repair is performed in primary inguinal hernia.<sup>[15]</sup>

A few studies have explained the need for ligation of peritoneal sac in children. For example, Mohta *et al.* reported that ligation of hernia sac during herniotomy was not necessary in children and that the incidence of complications in the two groups was the same, but they only investigated the relationship in 55 patients, so the results could not be generalized.<sup>[6]</sup> The result of a study on 50 cases done by Kumari *et al.* indicated that any peritoneal defect would be closed within a day after surgery by metamorphosis of *in situ* mesodermal cells, thus rendering hernia sac ligation unnecessary in inguinal herniotomy. Non-ligation of sac is a time-saving procedure and prevents accidental injury to the spermatic cord structures.<sup>[5]</sup> Sundeeep *et al.* opined that high division with simple excision is better than conventional herniotomy and reminded that it is reasonable to further evaluate this procedure.<sup>[16]</sup> Recurrence as a late complication of herniotomy should be considered. The rate of recurrence in children is reported variously by previous studies. Harvey *et al.* estimated a 2.5% incidence of recurrence.<sup>[17]</sup> Rowe *et al.* reported that the recurrence rate may vary depending on the operating conditions, the kind of procedure, and the specific patient's condition.<sup>[9]</sup> The patient's condition may vary from simple hernia to incarcerated hernia, with lower and higher recurrence. Some conditions increase the rate of recurrence where the most important is increased intra-abdominal pressure in such situations as VP shunt, ascites, posterior urethral valve, weight lifting, and pulmonary diseases causing chronic cough.<sup>[3]</sup> Other causes include growth failure, prematurity, malnutrition, connective

tissue disorders, bladder exstrophy, cryptorchidism, and seizure disorders with spasticity. Most of these disorders were excluded in the study. Such technical details as minimal mobilization of spermatic cord structures and posterior floor of inguinal canal were considered important. Grasfeld *et al.* suggested that certain potentially predisposing factors played a role in the recurrences. The first factor was improper ligation of sac at the internal ring and the second one was the presence of a large internal inguinal ring.<sup>[3]</sup>

The results indicated that ligation or non-ligation of peritoneal sac did not change the recurrence rate or other complications in children. This may be due to the small sampling size or differences in the target population. Another reason may be due to the exclusion of patients with such predisposing factors as increased intra-abdominal pressure. The results of studies by Mohta *et al.* and Kumari *et al.* were consistent with the results of this study.<sup>[5,6]</sup> The other factors that Grasfeld *et al.* studied that proved important in recurrence were inheritance weakness or fragility of tissues in patients with connective tissue disorders or conditions associated with increased intra-abdominal pressure.<sup>[3]</sup>

It is also important not to overlook bilateral inguinal hernia. Rothenberg *et al.* reported that 100% of infants and 65.8% of children had patent processus vaginalis, which was confirmed by a large number of other studies.<sup>[18-21]</sup> However, the opinion of whether contralateral inguinal hernia is significant or not is controversial.<sup>[9]</sup>

To summarize the advantages of herniotomy without sac ligation the following can be listed:

1. Time saving. As indicated in the study, the mean operation duration in herniotomy without sac ligation is smaller than that for high ligation
2. Safety. Non-ligation of sac prevents accidental injury to the spermatic cord structures
3. Simplicity
4. Prevention of formation of a peritoneal scar.

One postoperative complication is pain. Although severe chronic pain is uncommon, it is potentially disturbing. The optimal method to reduce pain after surgery in children is almost unknown. Splinter *et al.* indicated that intravenous ketorolac as a local anesthetic supplement was more effective than caudal analgesia.<sup>[22]</sup> Bower *et al.* revealed that there was a way to relieve postoperation pain, comparing preoperative identification of involved nerves and the performance of high ligation and division of sac. Obviously, it is important to note individual anatomical variations to prevent consequent complications.<sup>[23]</sup> The pain relief and nerve damage after these two techniques were

not completely evaluated and it could be investigated in future.

## CONCLUSION

In conclusion, complications are the same in herniotomy with or without ligation of the sac, but duration of non-ligation procedure is shorter than with high-ligation. It is safe for pediatric surgeons to leave the peritoneal sac open after division in herniotomy, there are no adverse effects. We suggest that herniotomy without sac ligation in children be the procedure of choice to save time and also to prevent any other possible complications such as nerve damage, spermatic cord injury, or peritoneal tearing.

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