

Is the double-ligation method safe and effective in laparoscopic paediatric inguinal hernia repair? A retrospective cohort study

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Abstract

Introduction: Laparoscopic paediatric hernia repair has since been performed more frequently. Recently, a double-ligation method was introduced to prevent recurrence in laparoscopic surgery. The objective of our study was to compare the postoperative outcomes of patients who underwent double and single ligations.

Patients and Methods: We performed a retrospective review of patients with inguinal hernia who underwent laparoscopic paediatric inguinal hernia repair from 2014 to 2018 at our institution. Patients were divided into two groups and underwent single ligation and double ligation.

Results: Three hundred and six patients (single-ligation group: 142 and double-ligation group: 164) were included. Four patients experienced recurrence, and the recurrence rate was 1.29%. The recurrence rate was significantly higher in the single-ligation group. There were no statistically significant differences in the postoperative complications between the two groups.

Conclusion: Double-ligation method in laparoscopic paediatric hernia repair was relatively safe and helpful.

Keywords: Double ligation, laparoscopic surgery, paediatric hernia, recurrence

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INTRODUCTION

Inguinal hernia repair is one of the paediatric patients' most commonly performed surgeries. Inguinal hernias occur in 0.8%–4.4% of term babies and up to 30% of preterm babies.^[1,2]

Laparoscopic paediatric hernia repair was introduced as a new modality over two decades ago and has since been performed more frequently in Korea. In a recent study that

used nationwide inpatient data in Korea from 2011 to 2015, the proportion of laparoscopic surgeries for paediatric inguinal hernia increased from 1.8% to 29.8%. The ratio of laparoscopic surgeries for paediatric inguinal hernias has been continuously growing.^[3]

The basic concept of laparoscopic paediatric hernia repair is the suturing and closing of a hernia orifice. In laparoscopic repair, the orifice of the hernia sac is closed with circuit suturing around the internal ring with a nonabsorbable

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suture. There are two main laparoscopic paediatric hernia repair techniques: the intracorporeal and extracorporeal techniques.^[4] Many variations have been described in the literature. Extracorporeal techniques use various instruments, such as a spinal needle, to suture the hernia orifice percutaneously.^[5,6] Compared with intracorporeal techniques, extracorporeal techniques are generally more straightforward because of less abdomen handling.^[7]

Recurrence is the most critical problem in patients with inguinal hernia. A recurrence may occur when the knot is loosened or the suture is incomplete. Recently, a double-ligation method was introduced to prevent recurrence.^[8,9] The objective of our study was to compare the postoperative outcomes of patients who underwent double and single ligations.

PATIENTS AND METHODS

Patients

We retrospectively reviewed the medical records of patients with inguinal hernia who underwent laparoscopic paediatric inguinal hernia repair at our institution between January 2014 and December 2018. The diagnosis was based on clinical presentation, physical examination and ultrasonography. If the guardian consented, preoperative ultrasonography was performed to evaluate the contralateral patent processus vaginalis (CPPV) and other abnormalities, such as undescended testis.

Data collection and follow-up

The collected data included the demographics, operative time, recurrence rate, incidence of metachronous contralateral hernia and complications. Patients were followed up in the hospital at 1 and 4 weeks. We conducted a survey using a Google Forms questionnaire and telephone to check whether recurrence or metachronous contralateral inguinal hernia (MCIH) occurred.

Surgical techniques

We performed extracorporeal techniques, also known as laparoscopic percutaneous extraperitoneal closure (LPEC). One 3 mm size bladeless trocar was placed through the umbilicus for the insertion of a 3 mm camera. We closely observed both sides of the internal inguinal ring in the laparoscopic view. The repair was performed if a patent processus vaginalis was followed in the operative field. A 2.8 mm BERCI fascial closure instrument (Karl Storz, Tuttlingen, Germany) was inserted 1 cm lateral to the internal ring on the opposite side of the lesion and was identified by applying pressure using a finger. This insertion site was used again to insert a 21-gauge spinal needle for CPPV or inguinal hernia repair. We inserted the fascial

closure instrument before the 21-gauge spinal needle to manipulate the tip of the needle and suture materials. A 21-gauge spinal needle with non-absorbable sutures (2-0 Prolene) was inserted approximately 1 cm lateral to the hernia orifice [Figure 1]. For the single-ligation method, we used a general way to suture half of the hernia orifice and ligate it extracorporeally. The first half of the internal ring was sutured using a spinal needle with Prolene in the form of a loop. The other half of the internal ring was sutured using a spinal needle with a second Prolene thread and passed through the Prolene loop. The Prolene loop was carefully pulled out, and the second Prolene thread made a loop around the internal ring [Video 1]. The double-ligation method in this study was performed by suturing two separate circuits around the hernia orifice and ligating them individually. The first circuit was fabricated in the same manner as in the single-ligation method. The second circuit was slightly outside the first circuit [Figure 2].

Statistical analyses

Statistical analyses were performed using Rex (version 3.0.3, RexSoft Inc., Seoul, Korea). The results were expressed as mean values $\pm$ standard deviations or median values with interquartile ranges. *P*-values were derived from the independent *t*-test, the Mann–Whitney U-test for continuous variables and the Chi-squared test or Fisher's exact test for categorical variables as appropriate. Statistical significance was set at *P* < 0.05.

RESULTS

A total of 306 patients who underwent LPEC at our institution during the 5-year period were included. Among this group, 142 patients underwent single ligation from January 2014 to May 2016 and 164 patients underwent double ligation between June 2016 and December 2018.

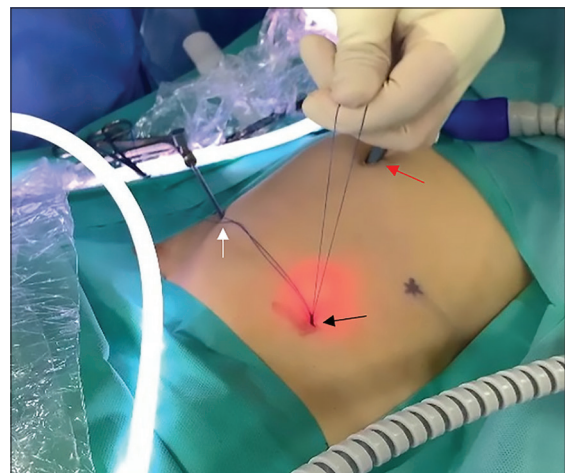


Figure 1: Trocar placement. (White arrow: Fascia closure, red arrow: Camera port, black arrow: Insertion site for spinal needle)

The demographics of the LPEC population are presented in Table 1. The mean age of the patients at surgery was 45 ± 29.5 months (range, 1 month to 15 years). Fifty-two premature infants born before the estimated gestational age of 37 weeks were included in this study, accounting for 16.99% of the study population. A total of 192 patients were male, and 114 patients were female. The male-to-female ratio was 1.7:1. Six of the total patients had twin brothers, and three of six patients had hernias in other

siblings as well. A total of 30 patients were classified as American Society of Anesthesiologists classification (ASA) Class II (9.8%) and the rest as ASA class I. Patients' baseline characteristics are listed in Table 1.

The preoperative diagnosis was made based on the clinical presentation and preoperative ultrasonography. Preoperative ultrasonography was performed only with parental consent, and in the non-consent group, the

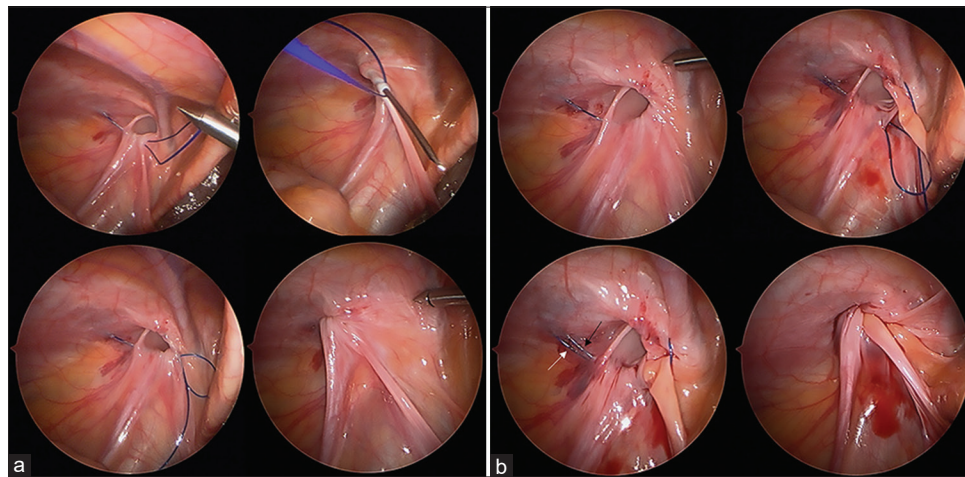


Figure 2: (a) Single-ligation method, (b) Double-ligation method

Table 1: Baseline characteristics

Variable	Single ligation (n=142)	Double ligation (n=164)	Total (n=306)	P
Sex				
Male	96 (67.61)	96 (58.54)	192 (62.75)	0.535
Female	46 (32.39)	68 (41.46)	114 (37.25)	
Age* (months)	45 (1–186)	29.5 (1–161)	37.5 (1–16)	0.071
Body weight* (kg)	15.05 (3.80–65.00)	13 (4.30–50.00)	14.2 (3.80–65.00)	0.0639
Pre-term				
Yes	18 (12.68)	34 (20.73)	52 (16.99)	0.2137
No	112 (78.87)	125 (76.22)	237 (77.45)	
Not applicable	12 (8.45)	5 (3.05)	17 (5.56)	
ASA class				
1	129 (90.85)	147 (89.63)	276 (90.20)	0.9204
2	13 (9.15)	17 (10.37)	30 (9.80)	
Family history of hernia				
Yes	0	3 (1.83)	3 (0.98)	0.0807
No	142 (100.00)	161 (98.17)	303 (99.02)	
Pre-operative diagnosis				
Right	78 (54.93)	76 (46.34)	154 (50.33)	>0.05
Left	56 (39.44)	75 (45.73)	131 (42.81)	
Bilateral	8 (5.63)	13 (7.93)	21 (6.86)	
Pre-operative ultrasonography				
USG	123 (86.62)	159 (96.95)	282 (92.16)	
None	19 (13.38)	5 (3.05)	24 (7.84)	
Repair site at first procedure				
Right	63 (44.37)	47 (28.66)	110 (35.95)	
Left	45 (31.69)	38 (23.17)	83 (27.12)	
Bilateral	34 (23.94)	79 (48.17)	113 (36.93)	
CPPV				
Yes	26 (18.31)	67 (42.07)	93 (30.39)	
No	116 (81.69)	97 (57.93)	213 (69.91)	

*Data was presented as median (minimum–maximum) for non-normal distributed variables and frequency (percentage) for categorical variables.

ASA: American Society of Anesthesiologists, USG: Ultrasonography, CPPV: Contralateral patent processus vaginalis. P-value for Pre-operative USG, Repair site at first procedure, CPPV: >0.05

preoperative diagnosis was made based on only the clinical presentation. In the single-ligation group, 134 of the 142 patients (right: 78 and left: 56) were diagnosed with unilateral inguinal hernia and 8 of the 142 patients were diagnosed with bilateral inguinal hernia preoperatively. In the double-ligation group, 151 of the 164 patients were diagnosed with unilateral inguinal hernia (right: 76 and left: 75) and 13 of the 164 patients were diagnosed with bilateral inguinal hernia preoperatively.

Preoperative ultrasonography was performed in 282 of the total 306 patients (92.15%). Of the 306 patients, 21 were diagnosed with bilateral inguinal hernia during the preoperative period. Only 4 of the 21 patients were diagnosed with bilateral inguinal hernia by clinical presentation, and all of them were premature. Seventeen of the 21 patients were diagnosed with unilateral hernia by clinical presentation, and the diagnosis was changed to bilateral inguinal hernia after ultrasonography. One patient had a preoperative diagnosis of bilateral inguinal hernia on ultrasonography, but only a unilateral inguinal hernia was found in the operative field.

In the single-ligation group, 108 of the 142 patients underwent unilateral internal inguinal ring repair, and 34 of the 142 patients underwent bilateral internal inguinal ring repair. In the double-ligation group, 85 of the 164 patients underwent unilateral internal inguinal ring repair, and 79 of the 164 patients underwent bilateral internal inguinal ring repair. Of the total 306 patients, 93 (30.39%) had CPPV; 90 of the 93 patients had undergone preoperative ultrasonography during the preoperative period, but CPPV had not been detected.

In April 2021, a survey using Google Forms was conducted to investigate whether recurrence and MCIH occurred, and if there was no response, a wired survey was conducted. A total of 97 cases responded to the survey using Google Forms, and 209 cases took part in the wired survey. There were no newly discovered recurrences in the surveys, but there was one new case of MCIH. The median follow-up period was 74 months in the single-ligation group and 42.5 months in the double-ligation group ($P < 0.05$).

The incidence of MCIH was 2.31% (7/302, preoperatively asymptomatic). Four patients had left inguinal hernia and three patients had right inguinal hernia at the time of the first operation. There was no statistically significant difference in the incidence of MCIH by hernia site at the time of the first operation ($P = 0.4578$). The incidence of MCIH was significantly higher in the single-ligation group,

with MCIH occurring in six cases compared to one case in the double-ligation group ($P = 0.0446$) [Table 2].

Four of the total 306 patients experienced recurrence and the recurrence rate was 1.29% (4/310, preoperative symptomatic sides). The recurrence rate was significantly higher in the single-ligation group, with recurrence occurring in four cases compared to none in the double-ligation group ($P < 0.05$) [Table 2]. Three of the four recurrences were caused by loosening of the knot, and one case was caused by incomplete suturing of the internal inguinal ring [Figure 3]. If the knot of the circuit suture was maintained firmly without the suture loosening, the operative finding in Figure 4 was observed. Characteristics of patients with recurrence are listed in Table 3.

There were nine patients with minor postoperative complications: six patients in the single-ligation group and three in the double-ligation group (wound infection, 3; suture granuloma, 4 and postoperative hydrocele, 2). There were no statistically significant differences in the postoperative complications between the two groups ($P = 0.2277$).

There were no statistically significant differences in the mean operative time between the two groups ($P = 0.5118$). For unilateral inguinal hernia repair during the first operation, the mean operative time was not statistically significant between the double-ligation group (17.64 ± 5.04 min) and the single-ligation group (18.00 ± 4.32 min) ($P = 0.5930$). For bilateral inguinal hernia repair during the first operation, the mean operative time was not statistically significant between double-ligation group (21.37 ± 6.05 min) and single-ligation group (22.80 ± 3.84 min) ($P = 0.1650$) [Figure 5].

DISCUSSION

Inguinal hernia is one of the most common abnormalities in the paediatric population. It has traditionally been treated with open repair with high ligation of the hernia sac. Laparoscopic inguinal hernia repair was introduced in the late 1990s and recently gained popularity. Many studies have demonstrated the advantages, safety, and efficacy of

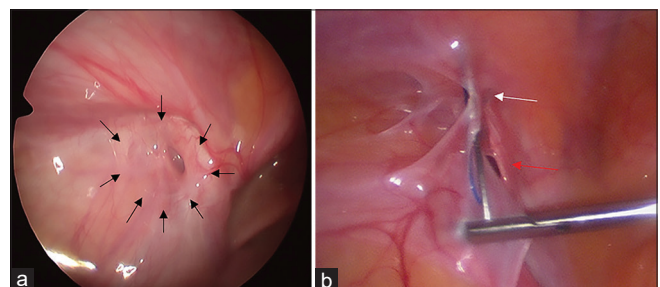


Figure 3: (a) Loosening of the knot, (b) Incomplete suturing

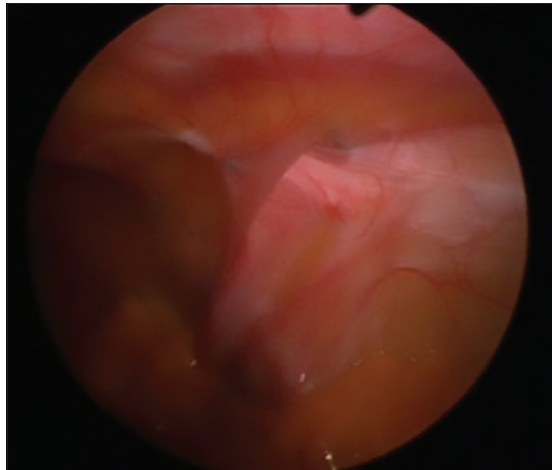
Table 2: Post-operative outcomes

Variable	Single ligation, n (%)	Double ligation, n (%)	Total, n (%)	P
MCIH*	n=141	n=161	n=302	
Yes	6 (4.25)	1 (0.62)	7 (2.31)	0.0446
No	135 (95.75)	160 (99.38)	295 (97.69)	
Recurrence	n=143	n=167	n=310	
Yes	4 (2.80)	0	4 (1.29)	0.0296
No	139 (97.20)	167 (100)	306 (98.71)	
Post-operative complications	n=142	n=164	n=306	
Yes	6 (4.23)	3 (1.83)	9 (2.94)	0.2277
Wound infection	2	1	3	
Post-operative hydrocele	0	1	1	
Suture granuloma	3	1	4	
Fluid collection	1	0	1	
No	136 (95.77)	161 (98.17)	297 (97.06)	

*MCIH was calculated based on the pre-operative asymptomatic side, and the recurrence rate was calculated based on the pre-operative symptomatic side. P-values were derived two-sample proportion test for categorical variables. MCIH: Metachronous contralateral inguinal hernia

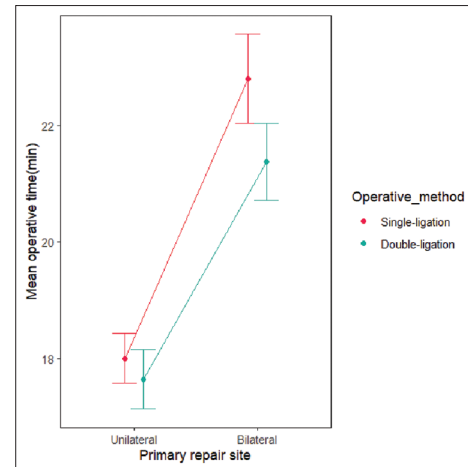
Table 3: Characteristics of patients with recurrence

Sex	Age (months)	Pre-term	Incarceration at the first operation	Recurrent side	Time to recurrence (months)	Cause of recurrence
Female	181	No	No	Right	16	Incomplete suturing
Male	133	No	No	Right	9	Suture loosening
Male	80	No	No	Left	6	Suture loosening
Male	4	Yes (25+1 weeks)	Yes (small bowel)	Right	52	Suture loosening

**Figure 4: Complete closure after internal inguinal ring repair**

laparoscopic inguinal hernia repair. The advantages of laparoscopy include excellent visual exposure, visualization of the contralateral processus vaginalis, and improved cosmetic results.^[1,10,11] Although the follow-up period has not been long enough, comparable recurrence and complication rates have been reported.^[1,2,11]

Within the laparoscopic approaches, the methods for repairs vary significantly, mainly categorised into intracorporeal and extracorporeal approaches.^[4] Although studies comparing these techniques found no differences in recurrence rates, the extracorporeal technique generally had shorter operative times.^[12,13] In Intracorporeal techniques, there are sac dissection method and the purse-string technique.^[14] Sac dissection involves dissecting

**Figure 5: Mean operative time by operative method**

the hernia sac. The purse-string technique entails making an incision around the internal ring and then using an absorbable or nonabsorbable suture to create a purse-string stitch that approximates the crural arch and conjoined tendon. Interrupted stitches may be added for larger hernias. Extracorporeal method involves passing a suture through a small incision and guiding it around the internal ring under laparoscopic vision. The suture is then passed around the medial and lateral halves of the ring, creating a loop. The suture is tied extracorporeally. Surgeon preference determines the specific devices used for forming the loop and closing the internal ring, such as hollow bore needles or specialised needles with wire loops. Care is taken to prevent damage to the vas deferens and testicular vessels.^[5,6]

In the conventional LPEC procedure, as described by Takehara *et al.*, two skin incisions are needed, including an umbilical incision for the camera port and another incision for grasping forceps on the left side of the umbilicus.^[6] We modified the incision site to grasp the forceps on the opposite side of the hernia repair site. If CPPV was present or bilateral inguinal hernia was diagnosed preoperatively, a spinal needle for repairing the internal inguinal ring at the opposite side was inserted through the incision to insert the grasping forceps. Both internal inguinal rings could be repaired without an additional incision by inserting a spinal needle through the incision to insert the grasping forceps.

In the LPEC procedure, the hernia orifice is sutured percutaneously and ligated extraperitoneally. There is a concern about recurrence in case of loosening the knot or incomplete suturing of the orifice. To reduce recurrence, a double-ligation method was introduced.^[8,9]

In the double-ligation method, techniques of ligating twice without an additional puncture have been reported.^[5,8] The first half of the hernia orifice is sutured using a spinal needle with a loop of a non-absorbable suture. The other half of the hernia orifice is sutured using a spinal needle with two threads of a non-absorbable suture or a loop of a non-absorbable suture. The second loop or two threads of non-absorbable sutures are passed through the first loop, and the first loop is carefully pulled out. Some modified methods using special equipment to perform this process have been described in the literature.^[5] Techniques that do not require an additional puncture are relatively simple and less likely to damage the vas deferens or spermatic vessels. However, there are concerns about double-ligation methods without additional punctures. In this double-ligation method that does not require an additional puncture, only one circuit is made, as in the single-ligation method.^[5,8] As a result, two threads are placed into only one circuit and ligated to each other in the same circuit. Therefore, if the internal inguinal ring is incompletely sutured initially, both ligations can be performed in the incomplete circuit.

In the literature, the incidence of recurrence following laparoscopic paediatric hernia repair has been reported to range from 0.8% to 4.3%.^[2] We encountered four cases of recurrence (1.29%). In all these cases, the operative findings were captured laparoscopically. Three of the four cases were caused by the loosening of the knot, and incomplete closure of the internal ring was observed in one case. We introduced a double-ligation method to reduce recurrence. In addition, as we experienced a case of incomplete closure of the internal ring, we thought it was necessary to form a second circuit that was totally independent of the first one.

We used the conventional technique to make a first-circuit suture for the internal inguinal ring. We then sutured the internal inguinal ring slightly lateral to the first circuit to create an independent second circuit. To suture the second circuit securely, we pulled the thread of the first circuit with enough tension to slightly close the internal inguinal ring. By applying this technique, we prevented damage to the ductus deferens and the spermatic vessels.

In the literature, the average time to recurrence after open repair has been reported to be between one and 2 years.^[15] The average time to recurrence following laparoscopic repair is often within the first 6 months, which is shorter than that following open repair.^[16] In this study, the average time to recurrence was 20.75 months (range, 6–52 months). Of the four recurrences, three were among males, and three were on the right side. One patient was a premature infant at 25 weeks and 1 day of gestation, 4 months old at the time of surgery and recurrence happened 52 months after surgery. He had a large internal inguinal ring defect and small bowel incarceration at the time of the first operation.

The incidence of MCIH in the paediatric population has been reported to be 3.0%–14.7%,^[17] and the rate of CPPV found during laparoscopic paediatric inguinal hernia repair in the recent literature was 38.5%.^[18] In our study, the CPPV rate was 30.39% (93 of 306 patients). Whether CPPV should be repaired remains controversial. CPPV is accepted as a cause of MCIH, but not all CPPVs progress into MCIH.^[18,19] There are no conclusions regarding the relationship between CPPV and MCIH or proper indications for the repair of CPPV. Therefore, there is a view that routine repair of CPPV may lead to overtreatment.^[20] On the other hand, repair of the CPPV is a simple and safe procedure in laparoscopic surgery and has the advantage of avoiding a second surgery. According to a recent systematic review of CPPV repair, prophylactic closure results in a 5.7% reduction in the risk of developing future contralateral inguinal hernias.^[18] We performed the repair in all cases in which CPPV was found on laparoscopy. In our study, the incidence of MCIH was 2.31%, which was relatively low compared to that reported in other studies. In a Taiwanese nationwide study, the rate of MCIH was 12.3%^[21] and a previous meta-analysis calculated the pooled estimate of 7.3%.^[20] Second surgery due to MCIH might be a major concern for patients and their parents. Repair of CPPV may be considered as a treatment option to reduce the incidence of MCIH, and more studies are needed to evaluate the efficacy and safety of CPPV repair.

The extracorporeal technique has been reported to have a shorter operative time than the intracorporeal

technique.^[22,23] Moreover, the operative time for bilateral repair has been reported to be similar to that for unilateral repair.^[24] In our study, the mean operative time for unilateral repair was 19.40 ± 6.24 min, and the mean operative time for bilateral repair was 23.18 ± 7.10 min. Although there was a statistically significant difference in operative time between the unilateral and bilateral repair groups, it was not a significant difference. Interestingly, the operative time in this study was significantly shorter in the double-ligation group than in the single-ligation group ($P < 0.05$) [Figure 5]. These results were probably due to the surgeon's proficiency and experience in surgical techniques. According to a recent study related to the learning curve of LPEC, it took 48.2 repairs for the operation time to become less than 25 min and 125.2 repairs for the operation time to become less than 20 min.^[7] This suggests that the surgical techniques of LPEC are relatively easy but difficult to become proficient at. Our results regarding operation time may also be related to these aspects. We demonstrated excellent operative times using the double-ligation technique. This suggests that if the surgeon is proficient, it does not require much operative time, even if double ligation is performed.

Cosmetic satisfaction is a crucial advantage of the laparoscopic method.^[25,26] In our study, skin repairs were performed using cyanoacrylate tissue adhesive at all incision sites. The 3 mm stab incision site for grasping forceps and the spinal needle insertion site were closed using only cyanoacrylate tissue adhesive. Cyanoacrylate tissue adhesive was applied to the umbilical incision site after fascia closure. In our experience, the cosmetic result was quite good, and all incisions were virtually invisible at follow-up. We encountered three cases of suture granuloma at the spinal needle insertion site using a Prolene knot. The cyanoacrylate tissue adhesive must be applied when maintaining the state where the knot is entirely buried beneath the skin layer using forceps.

This retrospective study had limitations with regard to the follow-up period (mean = 74 months in the single-ligation group, 42.5 months in the double-ligation group). Long-term follow-up was generally not performed in benign diseases like inguinal hernias. Therefore, evaluating long-term postoperative complications, such as recurrence or MCIH, is challenging. We conducted a survey to address this point. Another limitation of the follow-up period was the significant difference between the two groups. In our study, the incidence of MCIH was significantly higher in the single-ligation group than the double-ligation group (6 vs. 1, $P = 0.0446$), and it is probably related to the difference between the two groups. It is necessary to

implement long-term follow-up. Long-term complications, such as infertility, should be evaluated over a more extended follow-up period. One limitation of this study is that the enhanced results might be influenced by the increased proficiency of the surgeon or centre. While this observation underscores the potential impact of experience, it should be noted that variations in skill level were not directly addressed in this research. Further investigation into the role of surgeon or centre proficiency and its potential effects on outcomes could provide additional insights.

Since the introduction of laparoscopic paediatric inguinal hernia repair in 1993 and 1994, many results related to surgical outcomes have been reported compared to open hernia repair. Laparoscopic repair has shown comparable postoperative outcomes, and there are additional advantages, such as better cosmetic results and observation of the contralateral side.^[1,2,10,25] However, there are various methods for laparoscopic paediatric inguinal hernia repair, and comparative studies related to these variations are very rare. This is a retrospective comparative study to evaluate the postoperative outcomes of the double-ligation method first conducted in Korea. We believe that the double-ligation method with two independent circuits is a very effective and safe method for minimally invasive inguinal hernia repair in paediatric patients.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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