Clinical Trial Protocol

Study Title (English): Transection versus reduction of hernia sac in open pediatric inguinal hernia repair: A randomized controlled trial study

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Sponsor or planned sponsor, grant, scholarship <if applicable>:

- None -

Conflict of Interest:

- None -

Study sites (list all as planned):

- Faculty of Medicine, Ramathibodi Hospital, Mahidol University

Trial registration: *< Trial identifier and registry name. If not yet registered, name of intended registry>*

- The trial will be registered in the Clinical Trials Registry after obtaining approval from the Research Ethics Committee

Background and Significance:

An inguinal hernia is a common condition in children where abdominal contents push through a weak spot in the abdominal wall into the groin area. Normally, when the testicles move from the abdomen into the scrotum, the peritoneal lining is pulled downward with them through the inguinal canal. The testicles are fully descended into the scrotum at about eighth months of gestation. Afterward, the opening created by this pouch closes and dissolves. The persistence of this inguinal canal, which should have closed spontaneously, is a common cause of hernias in children, with an incidence of 3.5-5% and it increases up to 44-55% in premature

infants.1 Inguinal hernias often require surgical repair due to the risk of complications like bowel obstruction, which occurs in a significant percentage of cases (with an incidence of 3-16%).(2) Open surgery remains the most common method for inguinal hernias. A study by Chukwubuike KE et al. found that pediatric inguinal hernia repair had a postoperative complication rate of 9.9%. The most common complications were scrotal edema, scrotal hematoma, wound infection, hernia recurrence, testicular atrophy และ sensory disturbance in the groin region.(3)

Laparoscopic hernia surgery has become more widely used since the first operation in 1993. In this procedure, the hernia sac is cut open and the patent processus vaginalis is used to tighten the internal inguinal ring to prevent future hernias.[4] The purse-string technique is used to close the opening of the internal ring without removing the hernia sac. Laparoscopic surgery offers faster recovery[5] and less risk of spermatic cord injury, with similar operative times and shorter hospital stays compared to open surgery.[6] However, it requires a higher initial cost and the expertise of a surgeon experienced in the procedure.

In a study by Kelly Dreuning, Laparoscopic versus open pediatric inguinal hernia repair: state of the art comparison and future perspectives from a meta-analysis, laparoscopic and open hernia repairs were performed in 375 and 358 patients, respectively. There was no difference in recurrence between the two groups.[7]

Open hernia repair is still used for pediatric patients at Ramathibodi Hospital in order to remove the hernia sac from the spermatic cord. It is a complicated procedure, especially when dealing with big hernias. A hernia sac removal procedure is necessary because it can be challenging to remove the entire hernia sac in certain people. In a study by Roberto Cirocchi et al., Comparison of hernia sac transection and full sac reduction for the treatment of inguinal hernia: A systematic review and meta-analysis of clinical trials, 1,824 patients were included in the systematic review and meta-analysis of clinical trials which comprised 12 randomized controlled trials (RCTs) and 3 controlled clinical trials (CCTs). Nine hundred and thirty-five of these 1,824 patients had hernia sac transection, and nine hundred and sixty-six had hernia sac reduction. The study found that the two techniques were similar in terms of primary and secondary outcomes, even though hernia sac reduction might lead to a lower, albeit not statistically significant, recurrence rate.[8]

The study by Mohamed Ali Chaouch et al., A systematic review and meta-analysis of hernia sac management in laparoscopic groin hernia mesh repair: reduction or transection, is a systematic review and meta-analysis (PRISMA) study which included 6 studies with a total of 2,941 patients: 821 in the transection group and 2,120 in the reduction group. It was found that the transection group had a significantly lower rate of postoperative seroma than the reduction group (OR = 1.71; 95% CI [1.22, 2.39], p = 0.002). However, there was no significant difference between the two groups in operative time (MD = -4.39; 95%CI [-13.62, 4.84], p = 0.35) and recurrence rate (OR = 2.70; 95%CI [0.50,14.50], p = 0.25)[9]

The aforementioned information indicates that research has been done on the rates of complications following hernia surgery involving the excision of the hernia sac by reduction and transection. However, as of now, there are no conclusive findings about laparoscopic surgery. Thus, this study aimed to assess the rates of complications in pediatric patients who underwent open hernia surgery using reduction and transection techniques.

Objectives:

Primary Objective:

To study the rates of complications including reactive hydrocele, scrotal hematoma, hernia recurrence, and testicular atrophy, in pediatric patients who had open inguinal hernia surgery using reduction and transection techniques at Ramathibodi Hospital.

Secondary Objectives (if any):

To study the amount of pain medication use associated with open inguinal hernia surgery using reduction and transection techniques in pediatric patients at Ramathibodi Hospital.

Study design/methodology:

This study was a randomized controlled trial comparing the complication rate associated with open inguinal hernia surgery using reduction and transection techniques. The study was conducted at the Faculty of Medicine, Ramathibodi Hospital, Mahidol University. The data was collected from May 2025 or upon approval until June 30, 2027.

Data collection details: As per the form annexed hereto

Study Population:

Inclusion Criteria:

1) Male pediatric patients under 18 years of age.

2) Patients who underwent open inguinal hernia surgery on the affected side by a pediatric surgeon.

3) Patients who had in-person follow-up in-person after inguinal hernia surgery at Ramathibodi Hospital or phone follow-up (Telemed) for 6 months.

4) Patients who agree to participate in the study by signing an informed consent form

Exclusion criteria

1) Preterm infants

2) Inguinal hernia patients with intestinal ischemia

3) Patients with non-communicating hydrocele

4) Patients who had follow-up at another hospital after inguinal hernia surgery

5) Patients who refused to participate in the study or withdrawn

Study drug /Interventions <if applicable>:

Group 1: Patients who underwent open inguinal hernia surgery using reduction technique.

Comparator/Control <if applicable>:

Group 2: Patients who underwent open inguinal hernia surgery using transection technique.

Treatment Allocation and concealment:

The study was conducted in patients who underwent open inguinal hernia surgery on the affected side from May 2025 or upon approval until December 31, 2027. A block randomization with a block size of a and a 1:1 allocation ratio was performed using a computer. The patients were divided into 2 groups as follows:

Group 1: Patients who underwent open inguinal hernia surgery using reduction technique.

Group 2: Patients who underwent open inguinal hernia surgery using transection technique.

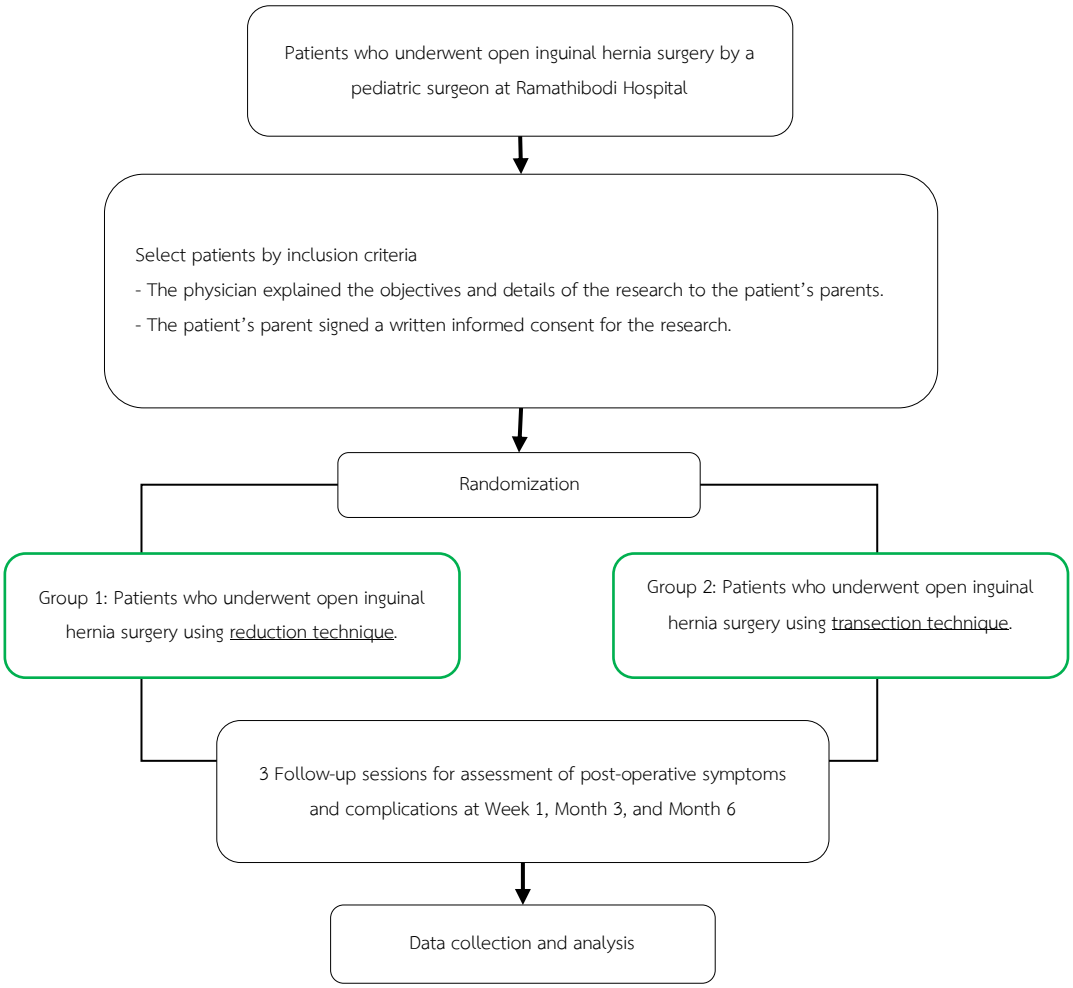
Blinding (masking):

- None

Participant timeline and Procedures:

Starting the research project	Pediatric patients who underwent open inguinal hernia surgery
Providing patients with research objectives and procedures at the surgical outpatient unit	The patient's parent signed a written consent to participate in the research.
Assessment of post-operative symptoms and complications	3 post-operative follow-up sessions as follows: 1st Follow-up (Week 1) - Reactive hydrocele, - Scrotal hematoma, - Course of pain killer requirement 2nd Follow-up (Month 3) - Reactive hydrocele, - Scrotal hematoma, - Hernia recurrence, - Testicular atrophy 3rd Follow-up (Month 6) - Reactive hydrocele, - Scrotal hematoma, - Hernia recurrence, - Testicular atrophy

Flow chart:



Outcomes/endpoints:

Primary Outcome:

1) Reactive hydrocele: diagnosed through a physical examination that includes a transillumination test, where a soft, fluid-filled mass in the scrotum will glow with a soft, transparent light.

2) Scrotal hematoma: diagnosed through a physical examination showing a hard lump, bruising, abnormal skin color, and subcutaneous hemorrhage, sometimes with shallow rugae in the scrotum.

3) Hernia recurrence: diagnosed through a physical examination showing intermittent bulge in the groin. However, if the bulge is non-palpable, imaging tests are useful to confirm the diagnosis while a transillumination test is not a primary tool because it lacks the necessary transparency for a definitive diagnosis.

4) Testicular atrophy: If the testicular volume is reduced by 20% from pre- to post-operation after measuring the width, length and height of the testicles in centimeters, it is considered testicular atrophy.

Secondary Outcome:

1) Course of painkiller requirement: Measures the amount of painkiller medication used for less than or equal to 1 day or more than 1 day.

Discontinuation/withdrawal criteria:

Potential Risks or Discomforts to Research Participants:

Patients who underwent open inguinal hernia surgery using reduction or transection techniques may experiencing the following symptoms:

1) Hydrocele or testicular hematoma which can be observed and they are more likely to disappear on its own without the need for surgery.

2) Recurrent inguinal hernias often require further surgery for correction.

3) Testicular atrophy is not reversible with surgery, but the chance of it occurring as a complication of a hernia repair is not as low as 0.2%.

Adverse Event Reporting:

-None-

Statistical Analysis Plan:

1) Basic data is presented using descriptive statistics, including frequency, percent, mean, standard deviation, median, and inter-quartile range/range.

2) Comparative surgical data between the two groups.

- For continuous data, use t-test or Wilcoxon Mann-Whitney test.
- For group data, use Chi-square or Fisher's exact test.

Sample size determination:

The sample size was determined based on a systematic review[9] of laparoscopic surgery (the most relevant study, but this study used an open surgery method). The study only documented the recurrence following laparoscopic surgery; it did not include time-to-event data. The odds of recurrence in the reduction group were increased 2.79 (OR = 2.79) times compared to the transection group, and the recurrence probability was 7.9% (p0 = 0.079). From this data, the sample size can be determined using the STATA program as follows:

```
. power mcc 0.079, oratio(2.79)

Performing iteration ...

Estimated sample size for a matched case-control study
Asymptotic z test, 1:1 matched design
Ho: OR = 1  versus  Ha: OR != 1

Study parameters:

        alpha =    0.0500
        power =    0.8000
        delta =    2.7900
           p0 =    0.0790
      oratio =    2.7900
        corr =    0.0000
           M =         1

Estimated sample size:

      N cases =       136
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Where Ratio = 1:1, Alpha = 0.05, p_0 = 0.079, power = 80%

According to a review of retrospective patient data from Ramathibodi Hospital, the number of patients who underwent the procedure code 530: unilateral repair of inguinal hernia in the Department of Pediatric

Surgery at Ramathibodi Hospital from January 1, 2019, to December 31, 2024, is shown in the table. In this study, the data on recurrence was collected and presented as a time-to-event analysis.

Since the researcher is a pediatric surgery resident with a 4-year study period, it is anticipated that data from about 40 cases, including 20 patients who underwent open inguinal hernia surgery using reduction technique and 20 patients who underwent open inguinal hernia surgery using transection technique, should be gathered.

Year	Number of Patients
2019	6
2020	12
2021	6
2022	8
2023	19
2024	18

Source: (ICD-9 Code 530) Power BI, Data Service Unit, Faculty of Medicine, Ramathibodi Hospital, Date 09/7/2025

Recruitment procedure:

- None (This study was conducted in pediatric patients who meet the inclusion criteria. The parents were asked for consent to participate in the study according to the informed consent process.

Informed Consent Process:

1) For patients who meet the inclusion criteria, the physician of this study scheduled a time for the patient's parents to be informed on the study's details at the patient's bedside in the surgical outpatient unit after explaining the study's goal, research procedures, and possible side effects of treatment. The patient's parents would be required to sign a written informed consent form if they consented to take part in the study.

Additionally, parents of both groups of patients were informed that post-operative phone follow-up would be conducted in the event that the patients were unable to attend their hospital appointments.

2) The patients were randomly divided into two groups. If the parents of the patients do not wish to be randomized, they can voluntarily refuse to participate in the research project without any impact on the standard treatment they should receive.

Group 1: Patients who underwent open inguinal hernia surgery using reduction technique.

Group 2: Patients who underwent open inguinal hernia surgery using transection technique.

3) An anesthesiologist administered general anesthesia before the procedure was performed.

4) After administering anesthesia, a standard open inguinal hernia surgery typically was performed by the surgeon.

5) Other practices for the patient were as per standard care, including examination, diagnosis, treatment and follow-up of the patient's condition at Week 1, Month 3, and Month 6 for assessment of post-operative symptoms and complications.

If there were any side effects or adverse events during the research, the patient's parents could directly inform the researcher, Piyanuch Lormuangthong, MD., Tel. 087-3063838 or contact the Department of Surgery, Building 1, 5th Floor.

Privacy and confidentiality (Data Management Plan) :

1) The data collected in this study were stored separately from the hospital's medical record system. Only a summary of the research findings was shared using a study identification number (ID), and the data were kept confidential. The study's findings could not be connected to any specific person, and no first names, last names, or other information that may be used to identify particular people was used. As a result, that data was solely accessible to the research team.

2) Patient consent forms were kept by the principal investigator.

Ethical consideration:

- Risks to participants and how to minimize the risks:

- In contrast to traditional inguinal hernia surgery, the surgical technique used in this study was modified from laparoscopic inguinal hernia surgery, which carries no risk to the patient.
- The basic surgical procedures for hernia sac reduction and transection are the same, however transection eliminates the need to dissect the hernia sac from the surrounding tissue, which lowers the possibility of damaging blood vessels and nerves during the dissection process.

- Direct Benefits to Participants

Surgery was performed on the patients in accordance with accepted practices that have been examined for safety in worldwide studies.

- Scientific or social value

Effective treatment planning for pediatric patients was made possible by the study's findings, which showed the complication rates of open hernia surgery performed using removal or transection techniques.

- Justification if enrolling potentially vulnerable subjects

None.

- Travel compensation and compensation for injury

None. Patients will receive treatment in compliance with Ramathibodi Hospital's guidelines if they experience complications following open inguinal hernia surgery.

- Plan of board consent

The patient recruitment was planned after obtaining approval from the Human Research Ethics Committee.

Study Timeline:

Activity	October 2024 – May 2025	June 2025 – May 2027	June 2027
1. Proposal writing and EC approval			
2. EC approval			
3. Data collection			
4. Data cleaning and analysis			

5. Manuscript preparation			
6. Research presentation			

Budget:

-None-

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