



Universitat de Girona
Facultat d'Infermeria
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PERCUTANEOUS INTERNAL RING
SUTURING, A SIMPLE MINIMAL
INVASIVE TECHNIQUE, VERSUS
OPEN REPAIR IN INGUINAL HERNIA
IN CHILDREN

Final degree project

Hospital Universitari Doctor Josep Trueta de Girona

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Do it with passion or not at all- Unknown.

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ABBREVIATIONS

IH: inguinal hernia

IIH: indirect inguinal hernia

MCH: metachronous contralateral hernia

OH: open herniotomy (open hernia repair)

LH: laparoscopic herniotomy (laparoscopic hernia repair)

PV: processus vaginalis

PPV: patent processus vaginalis

IIR: inguinal internal ring

DX: diagnosis

IHR: inguinal hernia repair

PIRS: percutaneous internal ring suturing

LPEC: laparoscopic percutaneous extraperitoneal closure

SILPEC: single- incision laparoscopic percutaneous extraperitoneal

SEAL: subcutaneous endoscopically assisted ligation

LIHIL: laparoscopic inguinal hernia inversion and ligation

ABSTRACT

Background: indirect inguinal hernia is a common pathology in children. Its treatment is surgical with the aim of healing to avoid possible complications arising. Over the past few years, different minimally invasive techniques have been developed in order to displace the classic open herniotomy. However, the bibliography is very heterogeneous, and more studies are needed to come to a consistent conclusion.

Objective: Determine which surgical technique, open surgery versus PIRS, has lower recurrence rate in paediatric patients with indirect inguinal hernia.

Design: It is a longitudinal, prospective, analytical, randomized, parallel and single-blind study carried out in a single center (University Hospital Dr. Josep Trueta de Girona) for 5 years.

Participants: Children of paediatric age, up to 14 years old, who have been referred, by their pediatrician, to the pediatric surgery office of the University Hospital Dr. Josep Trueta de Girona with suspicion of primary indirect inguinal hernia.

Methods: from December 2020 to December 2025 all children, whose families have signed informed consent, will have IIH operated on and monitored by the pediatric surgery team until the first year after surgery and will then continue with annual visits to the pediatrician for the registration of post-surgical recurrences and complications, among others.

Keywords: pediatric, inguinal hernia, laparoscopic inguinal hernia repair, PIRS, open surgery, recurrence, post-operative complications.

INTRODUCTION

PEDIATRIC INGUINAL HERNIA

DEFINITION AND CLASSIFICATION

We define hernia as the abnormal protrusion of an organ or tissue of the anatomical structure that contains it (1). They can be classified according to lateralization:

- **Unilateral hernia:** it is the most frequent form of presentation and represents 85% of all inguinal hernias in the paediatric population (2)(3). 60% (4) are located on the right side because the descent and, therefore, the involution of processus vaginalis occurs first on the left and then on the right side (5)(6).

- **Bilateral hernia :** bilateral hernias are more frequent in younger patients (if the age of the patient is <1 year, they will be present in 50%; therefore, when the patient is older the incidence rate decrease, being 45% in babies <2 years and of 37% in <5 years) (3).

They can also be classified according to their pathophysiology:

- **Direct inguinal hernias:** due to muscle weakness of the abdominal wall, being very rare in pediatric age (7).

- **Indirect inguinal hernias:** derived from the maintenance of the permeability of the processus vaginalis. In this document we will focus basically on these ones.

Additionally, we have to talk about the **contralateral metachronous hernias** which are defined as those that, once intervened with that of a flank, the contralateral is developed and diagnosed requiring its treatment. Its incidence is around 7.3% (8), although the interval is very wide, 5-20% (9).

EPIDEMIOLOGY

The repair of inguinal hernia in patients under 18 years is one of the most common non - emergency procedures performed by pediatric surgeons (2,6,10–16). The incidence varies from 0,8- 1% (3,15) up to 5% (6). However, when it comes to premature infants, the incidence rises up to 30% (11).

However, when we talk about bilateral hernias, the data vary a bit. They are more frequent at a younger age. We find them in 50% of patients under one year (9).

The presence of hernias is higher in male and premature children. They are usually associated with pathologies that occur with increased abdominal pressure and connective tissue diseases (6).

ETIOLOGY AND PHYSIOPATHOLOGY

The development of IH in the paediatric population is due to the persistence of the vaginalis processus (17) which, under normal conditions, closes between 36 and 40 weeks of gestation (4).

The testicular descent consists of a consecutive intra-abdominal and extra-abdominal stages:

- In the **intra-abdominal phase**, it is necessary to differentiate boys from girls. In the case of boys, the testes are attached to the diaphragm by the cranial suspensory ligament, which returns between the eighth and fifteenth postpartum week, causing the trans-abdominal migration of these. At the same time, the thickening of the gubernaculum causes the union of the testes with the scrotum through the external and IIR. In the case of girls, there is no regression of the cranial suspensory ligament, the ovaries are located retroperitoneally in the abdomen, and, in contrast to boys, there is no thickening of the gubernaculum, but it remains as round ovarian ligament.

- In the **extra-abdominal phase** (between the gestational age of 25 and 35 weeks), the testes, located retroperitoneally, descend intra-abdominally through the inguinal canal. Simultaneously, a peritoneal lining, known as the vaginal processus, is extended. Under normal conditions, the PV regresses and closes causing an absence of communication between the abdominal cavity and the extra-abdominal inguinal canal and the scrotum (5) except for the vaginal tunica, it remains (4).

Therefore, incomplete regression of the PV leads to PPV and thus the maintenance of communication between the intra-abdominal cavity and the extra-abdominal inguinal canal. Thus, if this communication is wide, the abdominal viscera can protrude, giving rise to indirect inguinal hernias. However, not all cases of PPV will develop an IIH although their risk is, between 25% and 50%, higher (5). Therefore, having a PPV is a necessary condition for the development of an IIH, but not sufficient (4).

A certain genetic risk of the development of IIH has been found in the case of siblings with this pathology (4).

SIGNS AND SYMPTOMS

Patients explain the appearance of an intermittent localized lump in the groin (17). This anomaly becomes apparent with weeping, coughing or, for example, with constipation (4).

In cases of incarcerated hernia, the possible presence of intestinal obstruction will state in the form of vomit and abdominal distention and on the physical examination we feel a prominent mass. In the girls, it can be an ovary (9).

DIAGNOSIS

The diagnosis is made by the clinical history and confirmed with the physical examination. To confirm dx, the most commonly used methods to increase intra-abdominal pressure are the following:

- Cause the baby to cry.
- Cause the patient to laugh, for example with tickling.
- Asking the patient to cough.
- Ask the patient to inflate a balloon.
- "Silk purse" or "silk glove": the presence of this positive sign suggests the presence of IIH. It will be positive if when rotating the structures of the cord through the pubic tubercle, the health worker notices movement in the sac.

However, complementary tests can be used to reach a more precise diagnosis. For example, an ultrasound can be used to differentiate between a PPV and an IIH (4).

TREATMENT

The treatment is the surgical repair of the hernia, that is herniotomy. This surgical procedure consists in the complete high ligation of the PPV at the level of the IIR (11,18) either through the traditional open technique or minimally invasive techniques. It is carried out in order to reduce the risk of complications, such as ischemia of the intestine or atrophy or infarction of the gonads, if the patient does not undergo to the intervention (5).

If the patient has an incarcerated hernia it is necessary to try to perform a manual reduction under analgesia/ sedation. The professional presses with his fingers the neck of the hernia exercising constant pression until it is reduced. Subsequently, you will have the defining treatment. The incidence of incarcerated hernia in children is estimated to be between 6 and 18%, however, this percentage increases, up to 30%, in younger patients (9).

HERNIOTOMY

To carry out the herniotomy, we basically differentiate between two types of approach: open and laparoscopic.

OPEN REPAIR

OH has been a long time the surgical approach of choice (2). However, various new techniques have been developed, all of them derived from the description by *Pott et al* (7) which aimed to achieve a simple high ligation and, as far as possible, to extract the hernial sac. It consists of making a single transverse incision in the abdominal skin of the suprapubic region of the patient. Next, the external

oblique is opened, parallel to its fibers, and its lower part is retracted at the same time that the fibers of the cremasteric are separated, allowing recognition of the sac (characteristically greyish in colour). The interior of the sac is then inspected to determine the presence and, if necessary, release the intestine, omentum, ovary or tubes. Finally, the sac will be rotated, and its neck sutured, the external oblique, superficial fascia, subcutaneous tissue, and lastly the skin will be closed.

OPEN REPAIR ADVANTAGES

This technique offers the following advantages:

- Allows the possibility of performing it under regional anesthesia (15)
- Low morbidity
- Good aesthetic results (16).

OPEN REPAIR DISADVANTAGES

Some risks are related with this technique:

- Vascular injury
- Wound hematoma
- Infection
- Recurrence (2,19)
- Deference vas injury
- Spermatic cord injury (20)
- Iatrogenic cryptorchidism (9)

One of its most relevant drawbacks is the impossibility of, in the same surgical act, exploring the opposite side (21).

LAPAROSCOPIC REPAIR

We define laparoscopy as that surgical approach which allows the visualization of the peritoneal cavity thanks to the introduction, through the abdominal wall, of an endoscope. It is used both for the diagnosis and treatment of pathologies.

LAPAROSCOPIC TECHNIQUES

In the 1990s, a successful herniotomy was performed using the laparoscopic approach was published for the first time. Since then, different laparoscopic techniques have been published for this purpose (2).

We can differentiate the diverse laparoscopic techniques according to (22):

- **The approach to the IIR:** which can be intraperitoneal or extraperitoneal.
- **Suture technique:** intracorporeal or extracorporeal (consists of a suture in the contour of the IIR which passes through the abdominal wall in the preperitoneal plane using percutaneous techniques) (9,23)
- **The number of ports used:** a single or multiple.
- **Material used**
- **Safety, feasibility and reproducibility.**

		Suture technique		Others
		Intracorporeal suture	Extracorporeal suture	
Number of ports	Single		<ul style="list-style-type: none"> - PIRS - SILPEC - SEAL - Modified SEAL technique with dual encircle - Hooked injection method - Single port laparoscopic assisted technique with hook-shaped needle 	
	Multiple	<ul style="list-style-type: none"> - Intracorporeal suturing and knotting technique - Inversion with ligation - Resection with ligation - Three port technique - Flip- flap technique 	<ul style="list-style-type: none"> - LPEC 	<ul style="list-style-type: none"> - Resection and no ligation

Table 1: Summary of laparoscopic techniques explained below

Some of the most widely used laparoscopic techniques are briefly described below:

- **Intracorporeal suturing and knotting technique:** this technique employs three ports and non- absorbable suture with the aim to perform an intraperitoneal knotting to close the IIR. It has a high recurrence rate and is more difficult as the extraperitoneal sutures because the surgeon needs good skills to do the intracorporeal knotting. For this reason, the surgical time and recurrence rate is higher than extraperitoneal (2,22).

- **Inversion and ligation technique:** more used in girls, is derived from the technique explained above (it uses three ports and non-absorbable suture) so it also has the same drawbacks. It consists of the isolation of the sack, its investment and subsequent ligation. It was described with the objective to reduce the recurrence rate from the second one (22). It also has the ability to identify and treat CPPV and diagnose dysgenetic syndromes (24).
- **Resection and ligation technique:** derived from the second one, it is based on the resection and closure of the sack. It was described with the objective to reduce the recurrence rate from the second one (22).
- **Resection and non-ligation technique:** is characterized by using three ports and not using suture to allow spontaneous closure after resection of the sac at the level of the inner inguinal ring (22). It is based on the pathology of IIH, as it is not secondary to an aponeurotic defect. It has demonstrated low recurrence rate, comparable to other procedures, and maintain the same general advantages of laparoscopy (25).
- **Three port technique:** it is characterized by the use of an umbilical port through which the endoscope is inserted and two additional side ports to get place to operate with the instrument necessary for the realization of the intracorporeal suture of the IIR. This technique may be useful in cases of patients with low abdominal subcutaneous tissue and wide IIR (26,27).
- **Percutaneous internal ring suturing (PIRS):** with the patient in supine decubitus, a transverse incision is made at the lower part of umbilicus to generate the pneumoperitoneum. When inspecting the abdominal cavity, the hernias are reduced by movements from outside the body always under camera control. The position of the inner inguinal ring is then evaluated from the outside to determine the location of the needle puncture through which it will pass and the thread to knot the IIR. So, you only need one port and one puncture point for the needle (19,28). This technique gets the same results as the intracorporeal suturing, but easier and faster to perform because avoids the difficult to manipulate the instruments inside the abdominal cavity. One of the advantages is the unique scar, but there is an important point to see: the possibility to injury the iliac vessels with the puncture during the procedure (iliac vessels are near to the iliac vessels) (19).
- **Laparoscopic percutaneous extraperitoneal closure (LPEC):** with the patient in supine decubital, two incisions are made. The laparoscope will be placed through the umbilical one and on the left side of the umbilicus, the grasping forceps. Then, after exploration bilateral internal rings, in the midpoint of inguinal line, the LPEC, with non- absorbable suture material, is inserted to allow to sew a suture circuit around the inner inguinal ring extraperitoneally (18,29–32). This technique is characterized by its easy doing (does not need great skills), feasible, safe and reproducible. There are some advantages related with this technique: the cosmetic result is good and it has also a lower rate of spermatic duct and vessels injury (30) and it has small recurrence rate (29). However, the material used is special (LPEC) (22). Some

studies published the operating time of LPEC is comparable (there aren't significant differences) to OH (30,32).

- **Extraperitoneal laparoscopic percutaneous single incision (SILPEC):** is the technique derived from the one explained above that has better aesthetic results and less invasion. It consists, unlike the previous one, of a single transumbilical vertical incision where the laparoscope will be placed with the grasping forceps but thought different input. This technique is safe and feasible and is comparable to OH in recurrence and complications rates (29,33).
- **Subcutaneous endoscopically assisted ligation (SEAL):** With the patient in supine decubitus, this technique uses a single umbilical port through which the endoscope passes that will monitor the procedure at all times. To reach the IIR we will use a needle with suture material which will externalize the tip against laterally, allowing it to be picked up by a needle holder, working on the extraperitoneal plane. When the material is attached and blocked, it will be removed and proceed with the IIR ligation. However, there are variations of how to pass the suture around the IIR and how to insert and remove the instrument. For example: **the modified SEAL technique with dual encircle** described in order to avoid recurrences (11). Although it presents some disadvantages intrinsic to laparoscopic technique, such as instrumentation or abdominal insufflation, potential recurrences, by the fact of only performing a ligation, to perform properly it is necessary that the curvature of the needle matches with IIR and is not applicable in large defects (28); it also has certain advantages to consider. The patient will not have an incision in the groin, does not require side ports, there is less risk of vascular lesions thanks to its direct visualization, offers ease of access to the contralateral side if necessary and, finally, is fast and easy. However, its superiority to traditional approach has not been studied exhaustively (34,35).
- **Hooked injection method:** a technique developed from SEAL and PIRS characterized by the injection of isotonic saline solution, through a needle, in the preperitoneal space with the aim of preperitoneum dissection; being, only, necessary an umbilical trocar and puncture. It should be noted that this modification provides greater safety in the technique already allows the separation of the peritoneum and vascular structures (28).
- **Single port laparoscopic assisted technique with hook-pin needle:** with the patient in supine position, an umbilical trocar is inserted through which the endoscope will pass. The herniary defect is then sought thanks to the laparoscopic light. Once found, a hooked needle with suture thread needle is inserted and, through the preperitoneal space where isotonic saline is injected, intraabdominal space is reached. The suture is then separated from the pin, which is removed, leaving the end of the suture in the abdominal cavity. Then, through the same hole, the needle is reintroduced on the side of the herniary defect in order to catch and externalize the thread through the abdominal skin. Finally, it closes extraperitoneally. This technique shares the advantages of the one explained before others that it closes the IIR

without defects, reducing the risk of recurrence, or interposition of other tissues. However, it is not recommended in cases of brazen hernias or with the concomitance of hydroceles as more material is needed for good resolution (36,37).

- **Flip-flap technique:** is characterized by the use of a flip-flap to close the defect in the IIR. It employs three ports and absorbable suture (22).
- **Use of tissue adhesives** (22).

OUR TECHNIQUE: PIRS

In 2006, Patkowski(28) published the technique called PIRS, whose acronym corresponds to percutaneous internal ring suturing, which consists of the percutaneous closure of the IIR under endoscopic control located in the navel.

This procedure is performed with the supine decubital patient under general anesthesia with endotracheal intubation. Throughout the intervention, the heart rate, blood pressure and pulse oximetry of the patient will be monitored. The screen is placed at the patient's feet and the first surgeon next ipsilateral to IIR. It consists of the following points:

1. First, it is necessary to prepare the surgical field and sterilize it.
2. Next, make an umbilical transverse incision through which a 5mm trocar is inserted. *Figure 1.*
3. Sand inflates the abdomen to create a pneumoperitoneum between 8 and 10mmHg depending on the patient's age.
4. The 5mm-30-degree endoscope is inserted through this same hole. *Figure 2.*
5. The peritoneal cavity is inspected. In this step we can determine the presence of a patent contralateral vaginal process. *Figure 4 and 5.*
6. To determine the location of the needle puncture, it is necessary to press from the outside manually. The ideal place is one where you allow the needle to enter perpendicular to the hole.
7. Once located, under digital control, a needle with a 2-zero non-absorbable monofilament is inserted into the abdominal wall by taking half of the IIR tissue with adjacent tissue and ligament creating a loop with the thread inside the abdomen. *Figure 6 and 7.*
8. The needle is removed so that the ends of the monophilate are externalized.
9. Then another needle with one end of a 2-zero non-absorbable braided suture thread is reintroduced through the same anterior hole surrounding the other half of the IIR with part of the round ligament. During the whole procedure we try to avoid the injury of vas deferens and testicular vessels. *Figure 8.*

10. The end of the braided suture is inserted into the loop created with the other thread and removed together, leaving the two ends hanging from the abdominal wall at the same point.
Figure 9, 10 and 11.
11. The suture is knotted to close the IIR and placed under the skin.
12. If a contralateral PPV is located, it would proceed to close it with the same steps explained above, but on the opposite side. It will close as long as the conduit is permeable.
13. Valsalva's maneuver is performed on the patient to reduce the pneumoperitoneum.
14. The umbilical incision is closed with quick absorption suture and covered with synthetic glue. The needle puncture area is not sutured or covered.

Surgical complications, ipsilateral recurrences and the conversion rate of the PIRS technique are dependent on experience, so, to reach the minimum values of these variables it is necessary to perform 35 or more surgeries of this type. However, the rate of post-surgery complications is independent of the surgeon's technique and experience. As with the implementation of this technique which is easy to implement (38).



Figure 1: umbilical transverse incision

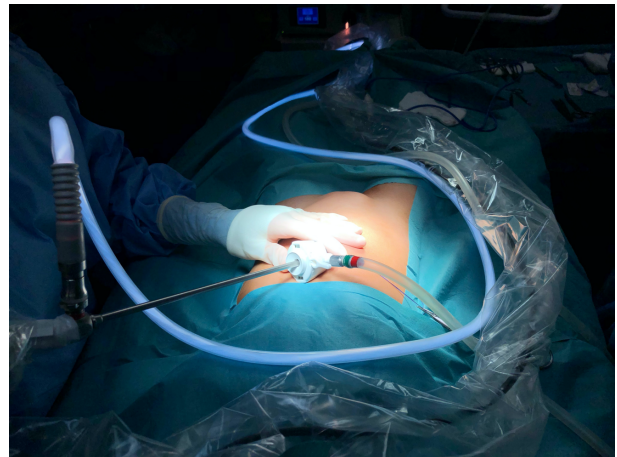


Figure 2: the 5mm- 30degreee endoscope is inserted through the umbilical incision.

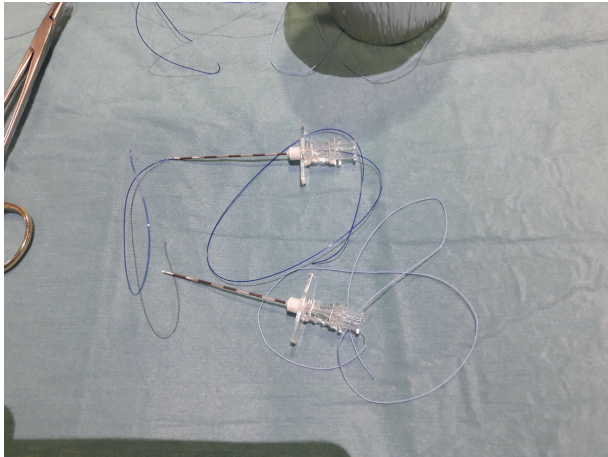


Figure 3: a needle with a 2-zero non-absorbable monofilament and a needle with a 2-zero non-absorbable braided suture

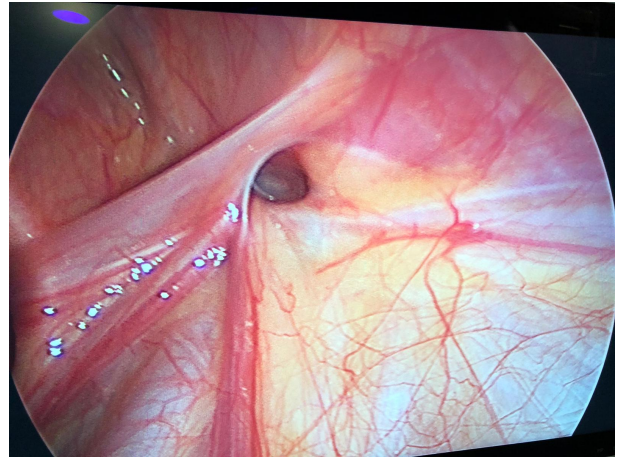


Figure 4: presence of a patent contralateral vaginal process

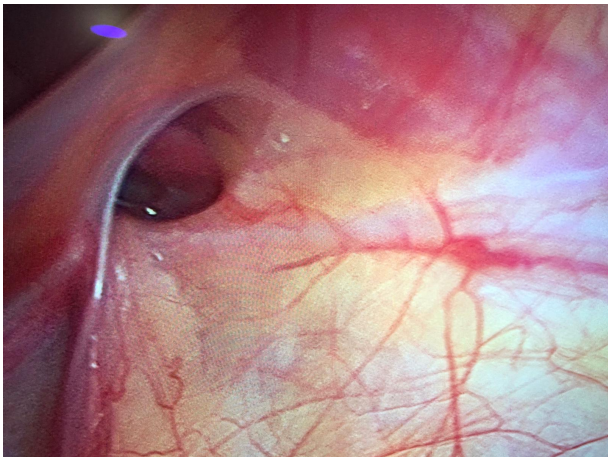


Figure 5: presence of a patent contralateral vaginal process



Figure 6: a needle with a 2-zero non-absorbable monofilament is inserted into the abdominal wall

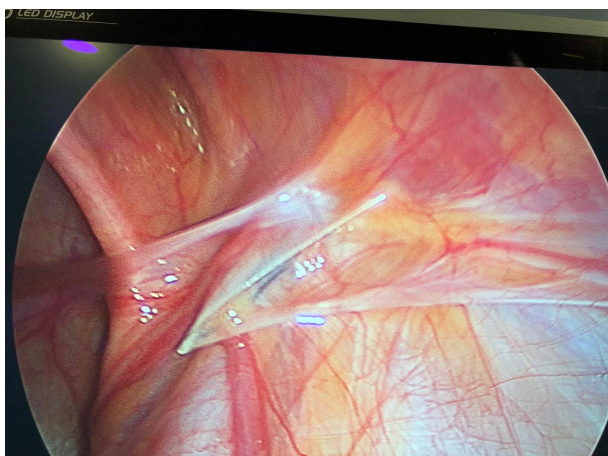


Figure 7: a needle with a 2-zero non-absorbable braided suture is inserted into the abdominal wall

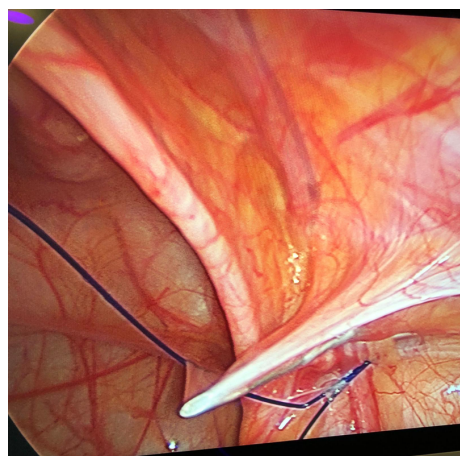


Figure 8: taking half of the IIR tissue with adjacent tissue and ligament.

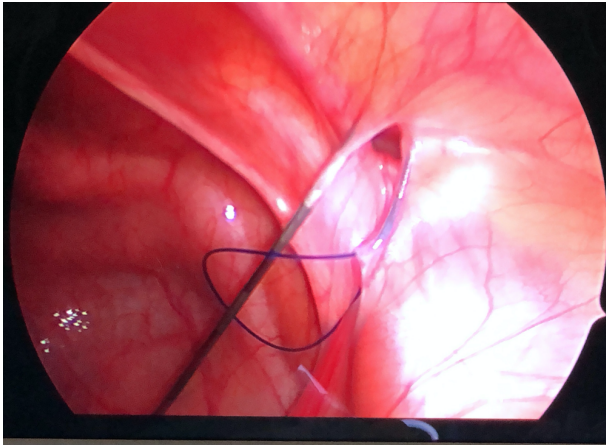


Figure 9: the end of the braided suture is inserted into the loop created with the other thread

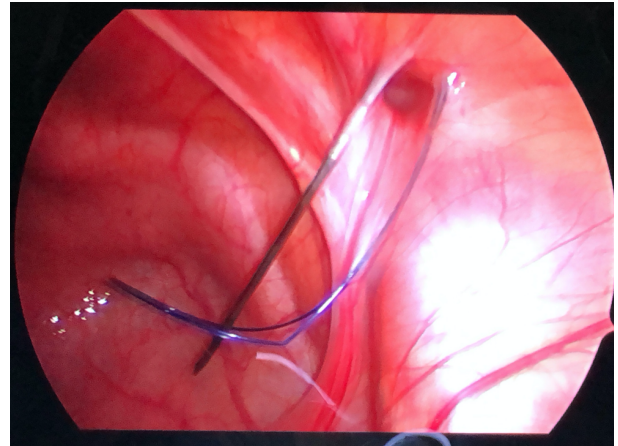


Figure 10: the end of the braided suture is inserted into the loop created with the other thread

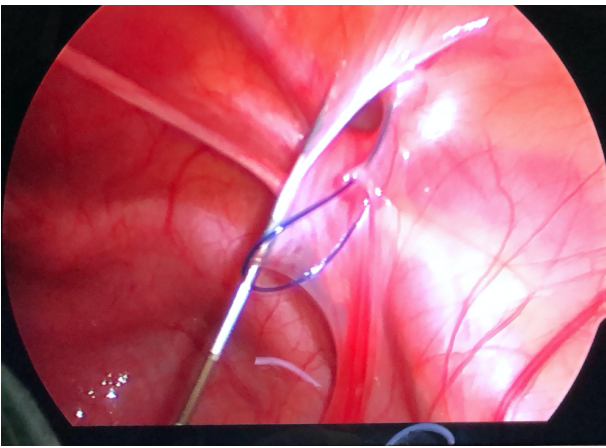


Figure 11: finally, removed together

LAPAROSCOPIC ADVANTAGES

Laparoscopic approach is characterized by being simple, safe and feasible. In addition, certain advantages have been determined including (9,20,22,23):

- Less pain after surgery due to less manipulation and dissection.
- Less surgical time in bilateral hernia repairs.
- Fewer lesions on groin duct structures.
- Wide field of view allowing the identification of asymptomatic contralateral IH. The incidence of PPV is 38.5% and it has been determined that to prevent one metachronous contralateral hernia it is necessary to close 18 PPV (39).
- Diagnose, in other atypical locations, of previously unknown hernias; for example, those of femoral location or shutters, can be treated in the same surgical act. It also makes it possible to diagnose other pathologies and therefore their treatment on site.
- Better aesthetic results.

- Shorter hospital stay time and therefore return to normal activities earlier.
- Recurrence rate comparable to traditional approach.
- This approach is safer, cheaper, with better aesthetic results and lower hospital stay in patients with brazen HD (40).

LAPAROSCOPIC DISADVANTAGES

As any surgical technique has also been collected disadvantage:

- It is characterized by being an expensive technique.
- Potentially higher recurrence rate.
- Possible iatrogenic injury of testicular vessels and, consequently, increased risk of atrophy.
- Possible iatrogenic lesions of intra-abdominal structures.
- Steep and long learning curve (23) although at the same time, in greater experience, surgical time is reduced (20) becomes better or comparable to OH (40).
- Techniques employing multiple ports will leave a greater number of scars.
- Special skills, such as intracorporeal suture, are required to carry out the intervention (19).
- Intracorporeal sutures consume longer surgical time than extracorporeal sutures (20).

JUSTIFICATION

Once we read the preamble, we can extract some important ideas.

On the one hand, we know that IIH in paediatric patients is a very common pathology that represents a large part of the care burden of pediatric surgeons. This is not only due to its incidence, but also the possible complications arising from the abstention of its surgical treatment which, unlike its simple causing pathology, can trigger more severe consequences.

Since 1950, when *Pott et al* described the open herniotomy, different methods have been developed for the approach of this pathology. And as could not be otherwise, the extension and popularization of minimally invasive techniques came to this discipline causing the generation of new laparoscopic techniques, each of the times was intended to surpass the previous one. The objective of the treatment remained and remains the same, but we currently have many more resources to achieve it.

On the other hand, today, there is no common consensus that this new generation of procedures replaces the traditional gold standard. Various meta-analysis has been developed with the aim of determining the superiority between the two currents (3,9,15,16,21,41–43). However, the conclusion is unclear. All converge that current literature is scarce and heterogeneous and therefore more well-designed studies are needed in order to reach a firm resolution (3,9,13,15,16,21,23,41,43). While the advantages of laparoscopy are widely known, the main one being the ability to visualize an asymptomatic contralateral PPV, it is not entirely clear whether its recurrence rate (main parameter for determining the effectiveness of a surgical technique) is less than or equal to open conventional surgery.

So, is the classic procedure still the gold standard? Or will it be replaced by minimally invasive techniques?

HYPOTHESIS

The PIRS laparoscopic technique has a lower or equal rate of recurrences than open surgery in the treatment of indirect inguinal hernia in paediatric patients.

OBJECTIVES

MAIN OBJECTIVE

Determine which surgical technique, open surgery versus PIRS, has lower recurrence rate in paediatric patients with indirect inguinal hernia.

SECONDARY OBJECTIVES

- Learn which surgical technique, open surgery versus PIRS, has lower rate of postoperative complications in paediatric patients with indirect inguinal hernia.
- Discover which surgical technique, open surgery versus PIRS, has lower rate of intraoperative complications in paediatric patients with indirect inguinal hernia.
- Detect which surgical technique, open surgery versus PIRS, has less surgical time in paediatric patients with indirect inguinal hernia.
- Find out which surgical technique, open surgery versus PIRS, has less anesthesia time in paediatric patients with indirect inguinal hernia.
- Determine which surgical technique, open surgery versus PIRS, has less hospital stay time in paediatric patients with indirect inguinal hernia.
- Ascertain which surgical technique, open surgery versus PIRS, has less recovery time in paediatric patients with indirect inguinal hernia.
- Learn which surgical technique, open surgery versus PIRS, has lower requirement of post-surgery analgesia in paediatric patients with indirect inguinal hernia.
- Describe which surgical technique, open surgery versus PIRS, has better post-surgery aesthetic results in paediatric patients with indirect inguinal hernia.

SUBJECTS AND METHODS

STUDI DESIGN

It is a longitudinal, prospective, analytical, randomized, parallel and single-blind study carried out in a single center (University Hospital Doctor Josep Trueta of Girona) for 5 years.

STUDY POPULATION

Children of paediatric age, up to 14 years old, diagnosed with unilateral or bilateral primary indirect inguinal hernia.

SUBJECTS SELECTION

The members of the study will be all those children, with the informed consent signed by the parents or legal guardians, who have been referred, by their pediatrician, to the pediatric surgery office of the University Hospital Dr. Josep Trueta de Girona with suspicion of primary inguinal hernia whose treatment is surgery.

INCLUSION CRITERIA

Patients under the age of fourteen diagnosed, by physical examination by the pediatric surgeon, of a single or bilateral primary IIH

EXCLUSION CRITERIA

- Patients who in the same surgical act will receive more than one operation. For example: circumcision or orchiopexy.
- Patients who in the same hospitalization will receive other unrelated surgeries
- Concomitant intra-abdominal procedure
- Expected long hospitalization time for concomitant pathology
- IIH cases with prior recurrences
- Patients with prior herniation repair stories
- Presence of femoral or umbilical hernia
- Patients with ascended testicles
- Liver disease
- History of low abdominal surgery
- Contraindications of medication used

SAMPLING

SAMPLE SIZE

In a bilateral contrast, accepting an alpha risk of 0.05 and a beta risk less than 0.2, 3780 subjects in the first group (PIRS) and 3780 in the second (OH) are required to detect as statistically significant the difference between the recurrence rates, which for the PIRS group is expected to be 0.015 and in the OH group of 0.024. A follow-up loss rate of 0% has been estimated because we treat pediatric patients. The ARCSINUS approximation has been used.

SAMPLE COLLECTION

The sample will be integrated for children who are derived from primary care centers by pediatricians for consultation with pediatric surgeons at the University Hospital Dr. Josep Trueta de Girona for the assessment of a suspected inguinal hernia.

Once the diagnosis is confirmed, parents will be given the opportunity to participate in the study. The objective of this and the employed methodology, as well as the monitoring and collection of data, will be reported. They will be explained that both interventions consist on, the risks and possible complications arising from both. In the event that they agree to participate, they sign the informed consent where, in detail, in writing the same information will be recorded.

RANDOMIZATION AND MASKING

Once the parents or legal guardians of the children have signed the informed consent and have therefore agreed to participate in the study, they will be added to the waiting list for surgery.

On the same day of the intervention, in the waiting room of the operating rooms, the parents, just before the beginning of the intervention, will choose one of the two equal sealed envelopes which will contain the name of the technique to be performed. The surgical material will be ready for both, so that neither the nursing team nor the surgeon will know firsthand which procedure they will have to perform.

After the operation is complete, dressings will be placed to cover the wounds. Regardless of the technique used, all children will wear three dressings: one umbilical (to cover the laparoscopic trocar wound), one located in the needle puncture area in the PIRS technique, and one inguinal (to cover the wound of open surgery). This way, neither the resuscitation room team nor the parents will know the choice.

Parents will be aware of the chosen procedure and findings on the first postoperative visit at two weeks. Postoperative visits will be made by a different pediatric surgeon to avoid subjective impressions. This is feasible as the pediatric surgery team at this hospital consists of four members.

VARIABLES

INDEPENDENT VARIABLE

Procedure: a herniotomy will be performed by classical open approach or by the laparoscopic PIRS technique according to the contents of the sealed envelope chosen by the parents at random. So, we will get two study groups which we will divide into **OH** (open herniotomy) and **LH** (laparoscopic herniotomy). *(For more details of the procedure see the introduction)*. Nominal dichotomous qualitative variable. Both techniques will be performed by the same pediatric surgeon always assisted by another pediatric surgeon and assisted by the same nursing team throughout the study.

Pre-surgery protocol refers to all those procedures prior to surgery. Regardless of the technique used, it consists of:

1. Time to enter hours before surgery
2. No medication needed
3. Disinfection of the surgical area with iodate solution
4. No catheterize is necessary, emptying will be performed if the child has urinated.

Anesthesia protocol: general anesthesia with endotracheal intubation

Medication to discharge: after surgery and the patient is discharged should not take any medication other than analgesia (ibuprofen or paracetamol in pediatric doses) if necessary.

Follow-up: after surgery, the following control visits will be made which will be supervised by a pediatric surgeon other than the one who performed the procedure:

- First visit at two months
- Second visit three months after the operation
- Third visit six months after the operation
- Fourth visit a year after the operation. In this control the patient will be discharged by the pediatric surgery team, however, he must continue with annual checks with his pediatrician which must be re-referred to the pediatric surgery team if he finds any complications secondary to the intervention. It is important because in 50% of recurrences occurs at 6

months, 76% at 2 years and 96% at 5 years (44) In this way, post-intervention tracking will be extensive, and data will not be lost.

To avoid biases, the follow-up time or exclusion of the follow-up time will not be changed, even if the patient does not present complications.

DEPENDENT VARIABLE

Recurrence: nominal dichotomous qualitative variable. He'll express with **yes** or **not**. We define it as the clinical manifestation of ipsilateral inguinal hernia to surgical intervention, so, the recurrence of symptomatology after definitive treatment. In case of recurrence, the elapsed time of the operation until its intervention will be specified.

Post-surgery complications: nominal dichotomous qualitative variable. He'll express with **yes** or **not**. Refers to difficulties during the intervention. In case of complications, the etiology will be specified. These may include:

- Contralateral metachronous inguinal hernia
- Surgical site edema
- Scrotal oedema
- Hematoma at the surgical site
- Postoperative bleeding
- Surgical wound infection
- Disruption of the wound
- Postoperative pain
- Postoperative vomiting and nausea
- Accidental puncture
- Iatrogenic hydrocele
- Iatrogenic cryptorchism
- Iatrogenic testicular atrophy
- Ascent of the testicles

COVARIABLES

Age: discrete quantitative variable. It will be expressed in **years**.

Prematurity: nominal dichotomous qualitative variable. It will be divided into **premature** and **not premature**.

Sex: nominal dichotomous qualitative variable. It will be divided into **female** and **male sex**.

Weight: continuous quantitative variable. It shall be expressed in **grams** and recorded on the day of the intervention.

Size: continuous quantitative variable. It shall be expressed in **centimeters** and measured on the day of the intervention.

Clinical laterality: nominal non-dichotomous qualitative variable. It will be expressed on **right, left** or **bilateral**. The first day of hearing will be determined with the pediatric surgeons' team and reviewed prior to surgery.

Surgical time: continuous quantitative variable. It will be expressed in **minutes**. We will establish as surgical time from the moment the umbilical incision starts, in the case of PIRS, or inguinal, in the case of open surgery, until the complete suture of the lesions. It shall be specified whether the closure of an asymptomatic contralateral PPV has been performed in the same surgical act.

Surgical conversion: nominal dichotomous qualitative variable. He'll express with **yes** or **not**. It refers to the need to change techniques during intervention regardless of the cause. In case of conversion requirement, the cause shall be specified:

- Uncontrollable bleeding
- Impossibility of the PIRS technique

Intraoperative complications: nominal dichotomous qualitative variable. He'll express with **yes** or **not**. Refers to difficulties during the intervention. In case of complications, the etiology will be specified. They can be:

- Bleeding
- Injury to the elements of the sperm cord
- Injury of herniated organs (bladder, ovary, tube...)

Anesthesia time: continuous quantitative variable. It will be expressed in **minutes**. Refers to the time from the start of induction until the patient's awakening.

Hospital stay time: continuous quantitative variable. It will be expressed in **minutes**. Refers to the time from arrival at the resuscitation unit until discharge when the patient is hemodynamically stable, with no residual effects of anesthesia, tolerates the oral diet, pain is under analgesic control and surgical wound has no complications. It's outpatient surgery unless it's complicated. When

discharged, parents or legal guardians will be explained that in the presence of warning signs, before the first follow-up check, they have to reconsult in the emergency room.

Recovery time: continuous quantitative variable. It will be expressed in **days**. It is defined as the number of days it takes the patient to recover their quotidian activities from their everyday life.

Post-intervention analgesia requirements: continuous quantitative variable. It will be expressed in **days** (days when the patient required analgesia).

Post-surgery aesthetics: ordinal qualitative variable. It will be valued by the parents and the surgeon who follows up.

- **Visibility of the wound.** It will be expressed in **null, slight** or **marked** visibility.
- **Umbilical deformity/protrusion.** It shall be expressed in **null, slight** or **marked**.

DATA COLLECTION

Depending on the type of information, it will be collect at different stages of the study (*see Annex 1*):

Pre-surgical stage: the basic data prior to the intervention will be recorded and where it has to consist of the age, prematurity, sex, weight and size and clinical laterality.

Perioperative stage: recording of data during the procedure and where the praying, surgical time, surgical conversion, intraoperative complications and time of anesthesia must be recorded.

Post-surgery stage: registration of data after immediate postoperative intervention until end of follow-up by the head pediatrician. It must be hospital time, recurrence, recovery time, postintervention analgesia requirements, postsurgery aesthetics and complications.

STATISTICAL ANALYSIS

UNIVARIANT STATISTIC

For the analytical description of the sample and groups, qualitative variables shall be expressed in **percentages** with a **confidence interval of 95%** and quantitative variables shall be expressed by **arithmetic** or **median mean** (if the presence of extreme values), as a central trend measure, with the **standard deviation** or **interquartile ranges** (if extreme values are present), as dispersion measures.

All results will be classified by each of the two techniques separately.

BIVARIANT STATISTICS

To compare the proportions between the type of surgery chosen (nominal dichotomous qualitative variable) and the recurrence (nominal dichotomous qualitative variable) we will use the **χ^2 test**, as well when we compare the independent variable with the other qualitative variables.

However, to compare the proportions between the type of surgical intervention chosen and the quantitative variables we will use the **T-student test**.

We accept a P value <0.05 statistically significant, assuming that the probability of chance is really low.

MULTIVARIATE STATISTICS

In order to relate more than two variables to the surgical technique used (nominal dichotomous qualitative variable) we will use the multivariate study of **logistic regression**. In this way we will be able to determine the probability of recurrence based on the invasive procedure and any other variable studied.

ETHICAL AND LEGALS ASPECTS

This study complies with the basic ethical principles *compiled in the Declaration of Helsinki of Ethical Principles for Medical Research Involving Human Subjects* signed by the World Health Association in October 2013:

- **Principle of autonomy** preserves the patient's freedom through the patient information sheet, informed consent and the document for the revocation of informed consent (*see annex number 2, 3 and 4*). All parents or legal guardians of the minors who participate, after listening to the professional's explanations, ask their questions and/or hesitations and read the informed consent, will sign it. It's an indispensable requirement. The patient is guaranteed confidentiality and privacy in accordance with *Regulation (EU) 2016/679 of parliament and the European Council, April 27, 2016, concerning the protection of natural persons with regard to the processing of personal data and the "ley Orgánica 3/ 2018, de 5 de diciembre, de Protección de Datos Personales y Garantía de los Derechos Digitales (LOPD-GDD)"*.
- **Principle of beneficence:** treatment for IIH is surgical; in such a way that the patient and the parents or legal guardians of the same treatment are offered regardless of the study since both techniques are accepted and are used for the cure of this pathology. In addition, the study is justified (*see justification section*) and the design is appropriate (*see subjects and methods section*).
- **Non-maleficence:** the patient and parents are offered two surgical techniques for the treatment of IIH whose treatment is the same accept or not participate in the study.
- **Justice:** all children derived by their pediatrician with diagnostic suspicion of primary indirect inguinal hernia and whose diagnosis is confirmed by the pediatric surgery team of the University Hospital Dr. Josep Trueta de Girona will be presented with the possibility of participating in this research.

The study will also be recorded, and the results published in accordance with Helsinki declaration.

However, this project has to be evaluated and approved by the Ethics Research Committee (CIS) of the University Hospital Dr. Josep Trueta de Girona. In addition, it has to be accepted by the direction of this.

Because such a protocol is a research project with invasive procedure we must comply with the "Ley 14/2007", the "Ley 14/2007" and the "Real Decreto 1716/2011" for research on biological samples and the "Real Decreto 1090/2015" for clinical research with sanitary products.

STUDY LIMITATIONS

We must take into account a limitation referred to in this protocol:

STUDY DESIGN

It is a study carried out in a single hospital which allows us to develop the procedures in a well-defined and uniform way avoiding the surgeon's bias. Likewise, we ensure the presence of extensive experience prior to the laparoscopic technique avoiding possible complications arising from a lesser knowledge of it. In return, according to the design of the study, the surgeon is not randomized as he would always take care of the same operations.

INCLUSION/ EXCLUSION CRITERIA

This protocol has no selection bias as all patients in the province of Gerona of paediatric age with suspected primary IIH are referred to the reference hospital. However, by applying the exclusion criteria we are ruling out recurrent multipathological and herniated patients as they may condition the outcome of operations for other extrinsic reasons on the technique.

SAMPLE SIZE

One of the limitations we can find is that the sample size is small as this study only covers the children in Girona and the incidence is low when it comes to full-term births. It may also influence that the proposed 5-year duration is really short time. Therefore, it could be amplified with a multicenter study.

RANDOMIZATION AND MASKING

As these are surgical operations, masking is complicated. However, we have developed techniques to be able to do a single-blind trying to avoid possible biases:

- Knowing the technique moments before the operation with all the material already prepared for both by the surgeon and nurses, allows us to avoid possible personal predispositions.
- Hiding the technique from parents or legal guardians and the monitoring surgeon allows us to dodge personal impressions.

PROCEDURE

One of the limitations lies in the same procedure since contralateral PPV inspection is only performed by laparoscopic approach and therefore there is a greater likelihood of developing a contralateral mechatronic hernia in the open technique.

EVALUATION OF THE VARIABLES

It is possible, although attempted to minimize, subjective impressions when it comes to the assessment of some variables such as the aesthetics of the surgical wound, the analgesic requirements after the intervention or the recovery time by the parents.

Another limitation in follow-up should be noted. It will stop with the study; so that we will have patients with five years of follow-up compared to others with little time. The assessment of some variables such as recurrence and postoperative complications will be more influenced by the results obtained in the first patients of the research than the recent patients because their data will not be complete or registered.

WORK PLAN AND CHRONOGRAM

RESEARCH TEAM PERSONNEL

The research team will be composed of the head of the pediatric surgery service of the University Hospital Dr. Josep Trueta of Girona who works together with two more surgeons of the team (one will take care of the follow-up while the other will assist in the surgery). Finally, the person who closes the group will be a statistical analyst whose function will be to carry out the analytical study of the results obtained from the evaluation of the variables.

STUDY STAGES

STAGE 0: STUDY DESIGN

From September 2020 to November 2020:

- Choosing the subject of study
- Bibliographic research
- Protocol elaboration

STAGE 1: ETHICAL EVALUATION OF THE PROTOCOL

November 2020:

- Presentation of the protocol to the Ethical Research Committee (CIE) of the University Hospital Dr. Josep Trueta de Girona.
- Presentation of the protocol to the hospital management for approval.

STAGE 2: SAMPLE COLLECTION AND STUDY CONDUCT, DATA COLLECTION AND FOLLOW- UP

From December 2020 to December 2025:

- All patients referred to the pediatric surgery service of the University Hospital Dr. Josep Trueta de Girona derived from their pediatrician with suspected IIH and whose diagnosis is confirmed, will be offered the possibility of participating in the study taking into account the criteria of inclusion and exclusion.
- Signing of informed consent by all collaborating families.
- Performing surgical interventions by the head of the pediatric surgery service and other surgeon.
- For each child involved, the data registration documents (*see Annex 1*) shall be filled in due course respectively. The results will be recorded in an electronic database, even if the sheets of paper will also be saved.

- The established follow-up will be carried out and, once discharged by the pediatric surgery team, the monitorization will be followed with the reference pediatrician. The follow-up period will end along with the study.

STAGE 3: DATA ANALYSIS, INTERPRETATION AND DISCUSSION OF THE RESULTS

From December 2025 to April 2026:

- The statistical analyst will perform the analysis of the results.
- Pediatric surgeons will interpret and discuss the results obtained

STAGE 4: REDACTION AND PUBLICATION OF RESULTS

From April 2026 to June 2026:

- The results and interpretation of the results will be drafted, as well as their discussion and conclusion of the investigation.
- Once the text is finished, the study will be published.

CHRONOGRAM

STEPS	2020				2021	2022	2023	2024	2025	2026						
	S	O	N	D						J	F	M	A	M	J	
STAGE 0: STUDY DESIGN																
Choosing the subject of study																
Bibliographic research																
Protocol elaboration																
STAGE 1: ETHICAL EVALUATION OF THE PROTOCOL																
Protocol approbation by CEI																
Presentation of the protocol to the hospital management																
STAGE 2: SAMPLE COLLECTION AND STUDY CONDUCT, DATA COLLECTION AND FOLLOW- UP																
Sample collection																
Surgery intervention																
Data collection and registration																
Follow up																
STAGE 3: DATA ANALYSIS, INTERPRETATION AND DISCUSSION OF THE RESULTS																
Statistical analysis																
Interpretation and discussion of the results																
STAGE 4: REDACTION AND PUBLICATION OF RESULTS																
Elaboration the report																
Publication the repost																

BUDGET

The budget for this study will not be very high for the following reasons:

- The bibliographic search was carried out through Pubmed for free.
- This research will be carried out at the University hospital Dr. Josep Trueta de Girona offering the same treatment for this pathology regardless of the application of this protocol. The hospital's resources will be used as we are offering a procedure that is already performed in a way indicated for the healing of IIH in paediatric patients. No supplementary material, learning courses of the techniques used or training by professionals is needed. No additional infrastructure is required.
- Even surgeons who will develop it will not charge.
- Participating families will not receive an economic refund for accepting.

However, the following expenses should be taken into account:

- Computer expert: responsible for designing the database. It is estimated that 5 hours of work will be needed that will be paid at 30 €/h, amounting the total expenditure to 150 euros.
- Data manager: the person in charge of filling in the database with the results obtained in the different stages of collection of these. We believe that you will work for three years and need half an hour to record all the data of each patient. If you will be paid 10 euros/h, we calculate a total of 37.800 €.
- Statistical analyst: we estimate that we will need about 60 hours of work, for 2 months, which will charge 50 euros/h. Therefore, we calculate a total of 3.000 euros
- Article publication: refers to the costs of review, editing, graphic design... We estimate it's going to cost about 2.000€.
- Presentation of the study at a national congress: registration, travel expenses and diets add up to an expense of 1.500€.
- Presentation of the study at an international conference: registration, travel expenses and diets amount to 2.500€.

Type of cost	Cost	TOTAL
Computer expert	5h x 30 €/h	150€
Data manager	10 euros/h	37.800 €
Statistical analyst	60h x 50€/h	3.000€
Article publication		2.000€
National congress		1.500€
International congress		2.500€
TOTAL		46.950€

Table 2: Study expenses

FEASIBILITY

This protocol offers the possibility of conducting a study in a viable and feasible way, although it has some limitations (*see section of limitations of the study*) for the following reasons:

- Its application will not alter the agenda of the pediatric surgery team of the university hospital Dr. Josep Trueta of Girona. That is, all scheduled operations will continue to be carried out in the same way until now since the procedure is identical, regardless of the application of this protocol, for the treatment of IIHs.
- A null loss of follow-up is estimated to be a sample composed of paediatric patients.
- The estimated budget is not very high as no additional means are needed than those available for daily practice.
- The planning and schedule, well defined above, follow adequate tempos so that all the necessary tasks and activities can be developed.

IMPACT

Indirect inguinal hernia is a prevalent pathology in the paediatric population whose physiopathology conditions their specific surgical treatment. It is necessary to repair it due to the possible complications that it can develop and whose severity is greater than the pathology by itself.

Basically, we can distinguish two types of surgery, open and minimally invasive, whose objective is the same: to close the PPV at the IIR level. The classic open approach has been established as the gold standard with recurrence rates from 0 to 6%. However, in recent years minimally invasive techniques have been developed with recurrence rates from 0 to 5,5% (9)(9). With this data, a competition has been established to determine which technique is best for the treatment of this anomaly.

For this reason, it is necessary to develop well-defined studies. This protocol aims to bring a little bright to this issue by comparing the PIRS, laparoscopic technique, adopted at the University Hospital Dr. Josep Trueta in Girona. Depending on the results obtained, treatment of IIH may change. We might encounter two situations:

- That the results obtained are very different between the two techniques and, therefore, we could determine which is better of both
- That the results obtained are very similar and, therefore, the choice of the technique used is taking into account which the surgeon feels most comfortable or taking advantage of the over-added advantages of laparoscopy (visualization of the presence of a contralateral PPV, hernias in other locations or other undiagnosed pathologies).

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ANNEXES

ANNEX 1: DATA RECORD TEMPLATES

REGISTRO DATOS PRE QUIRÚRGICOS PACIENTES CON HERNIA INGUINAL INDIRECTA

CÓDIGO DEL PACIENTE: _____

FECHA: ____ / ____ / ____

EDAD:

<1año: _____ meses

>1año: _____ años

PREMATURIDAD:

Prematuro

NO prematuro

SEXO:

Masculino

Femenino

PESO: _____ gramos

TALLA: _____ centímetros

LATERALIDAD CLÍNICA:

Derecha

Izquierda

Bilateral

REGISTRO DATOS PERI QUIRÚRGICOS PACIENTES CON HERNIA INGUINAL
INDIRECTA

CÓDIGO DEL PACIENTE: _____

FECHA: ____ / ____ / ____

PROCEDIMIENTO:

- PIRS
- OH

TIEMPO QUIRÚRGICO: _____ minutos

- Cierre contralateral de un PPV asintomático

CONVERSIÓN QUIRÚRGICA:

- NO
- SÍ → ¿por qué?
 - Sangrado incontrolable
 - Imposibilidad de la técnica

COMPLICACIONES INTRAOPERATORIAS:

- NO
- SÍ → ¿cuales?
 - Sangrado
 - Lesión de los elementos del cordón espermático
 - Lesión de los órganos herniados (vejiga, ovario, trompa...)

TIEMPO DE ANESTÉSIA: _____ minutos

REGISTRO DATOS POST QUIRÚRGICOS PACIENTES CON HERNIA INGUINAL INDIRECTA

CÓDIGO DEL PACIENTE: _____

TIEMPO DE ESTADA HOSPITALARIA: _____ minutos

REQUERIMIENTOS DE ANALGÉSIA POST INTERVENCIÓN: _____ días

TIEMPO DE RECUPERACIÓN: _____ días

SEGUIMIENTO:

2 semanas → fecha: ____ / ____ / ____

Sin complicaciones

Recurrencia: SÍ NO

Estética (cirujano y padres o tutores legales)

Visibilidad de la herida: nula leve marcada

Visibilidad de la herida: nula leve marcada

Deformidad/ protrusión umbilical: nula leve marcada

Deformidad/ protrusión umbilical: nula leve marcada

Complicaciones post IQ → ¿cuales?

Recurrencia _____ SÍ NO

Contralateral metachronous inguinal hernia _____ SÍ NO

Edema del sitio quirúrgico _____ SÍ NO

Edema escrotal _____ SÍ NO

Hematoma en el sitio quirúrgico _____ SÍ NO

Hemorragia postoperatoria _____ SÍ NO

Infección de la herida quirúrgica _____ SÍ NO

Interrupción de la herida _____ SÍ NO

Dolor post operatorio _____ SÍ NO

Vómitos y náuseas post operatorios _____ SÍ NO

Punción accidental _____ SÍ NO

Presencia de un cuerpo extraño _____ SÍ NO

Hidrocele iatrogénica _____ SÍ NO

Criptorquismo iatrogénico _____ SÍ NO

Atrofia testicular iatrogénica _____ SÍ NO

Ascenso de los testículos _____ SÍ NO

3 meses → fecha: ____ / ____ / ____

Sin complicaciones

Recurrencia: SÍ NO

Estética (cirujano y padres o tutores legales)

Visibilidad de la herida: nula leve marcada

Visibilidad de la herida: nula leve marcada

Deformidad/ protrusión umbilical: nula leve marcada

Deformidad/ protrusión umbilical: nula leve marcada

Complicaciones post IQ → ¿cuales?

Recurrencia _____ SÍ NO

Contralateral metachronous inguinal hernia SÍ NO

Edema del sitio quirúrgico _____ SÍ NO

Edema escrotal _____ SÍ NO

Hematoma en el sitio quirúrgico _____ SÍ NO

Hemorragia postoperatoria _____ SÍ NO

Infección de la herida quirúrgica _____ SÍ NO

Interrupción de la herida _____ SÍ NO

Dolor post operatorio _____ SÍ NO

Vómitos y náuseas post operatorios _____ SÍ NO

Punción accidental _____ SÍ NO

Presencia de un cuerpo extraño _____ SÍ NO

Hidrocele iatrogénica _____ SÍ NO

Criptorquismo iatrogénico _____ SÍ NO

Atrofia testicular iatrogénica _____ SÍ NO

Ascenso de los testículos _____ SÍ NO

6 meses → fecha: ____ / ____ / ____

Sin complicaciones

Recurrencia: SÍ NO

Estética (cirujano y padres o tutores legales)

Visibilidad de la herida: nula leve marcada

Visibilidad de la herida: nula leve marcada

Deformidad/ protrusión umbilical: nula leve marcada

Deformidad/ protrusión umbilical: nula leve marcada

Complicaciones post IQ → ¿cuales?

- | | | |
|--|-----------------------------|-----------------------------|
| Recurrencia_____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Contralateral metachronous inguinal hernia | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Edema del sitio quirúrgico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Edema escrotal _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hematoma en el sitio quirúrgico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hemorragia postoperatoria _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Infección de la herida quirúrgica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Interrupción de la herida _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Dolor post operatorio _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Vómitos y náuseas post operatorios _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Punción accidental _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Presencia de un cuerpo extraño _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hidrocele iatrogénica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Criptorquismo iatrogénico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Atrofia testicular iatrogénica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Ascenso de los testículos _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |

1año→ fecha: ____ / ____ / ____

Sin complicaciones

Recurrencia: SÍ NO

Estética (cirujano y padres o tutores legales)

Visibilidad de la herida: nula leve marcada

Visibilidad de la herida: nula leve marcada

Deformidad/ protrusión umbilical: nula leve marcada

Deformidad/ protrusión umbilical: nula leve marcada

Complicaciones post IQ → ¿cuales?

- | | | |
|--|-----------------------------|-----------------------------|
| Recurrencia_____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Contralateral metachronous inguinal hernia | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Edema del sitio quirúrgico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Edema escrotal _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hematoma en el sitio quirúrgico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hemorragia postoperatoria _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Infección de la herida quirúrgica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |

- | | | |
|--|-----------------------------|-----------------------------|
| Interrupción de la herida _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Dolor post operatorio _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Vómitos y náuseas post operatorios _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Punción accidental _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Presencia de un cuerpo extraño _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hidrocele iatrogénica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Criptorquismo iatrogénico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Atrofia testicular iatrogénica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Ascenso de los testículos _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |

DERIVACIÓN → fecha: ____ / ____ / ____ ¿Motivo?

Recurrencia: SÍ NO

Complicaciones post IQ → ¿cuales?

- | | | |
|--|-----------------------------|-----------------------------|
| Recurrencia _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Contralateral metachronous inguinal hernia | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Edema del sitio quirúrgico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Edema escrotal _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hematoma en el sitio quirúrgico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hemorragia postoperatoria _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Infección de la herida quirúrgica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Interrupción de la herida _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Dolor post operatorio _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Vómitos y náuseas post operatorios _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Punción accidental _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Presencia de un cuerpo extraño _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Hidrocele iatrogénica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Criptorquismo iatrogénico _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Atrofia testicular iatrogénica _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |
| Ascenso de los testículos _____ | <input type="checkbox"/> SÍ | <input type="checkbox"/> NO |

ANNEX 2: PATIENT INFORMATION SHEET

HOJA DE INFORMACIÓN A LOS PADRES O TUTORES LEGALES DEL PACIENTE

Buenos días/ tardes,

Nos dirigimos a ustedes para informarle que actualmente se está realizando un estudio y nos gustaría solicitar la participación de su hijo/hija. Dicho estudio ha superado todos los análisis éticos a los cuales ha sido sometido y se realiza en el hospital universitario doctor Josep Trueta de Girona.

Nuestro objetivo es determinar que técnica quirúrgica, cirugía abierta o la técnica laparoscópica PIRS, tiene menor tasa de recurrencia en el tratamiento de hernia inguinales en pacientes en edad pediátrica. Y, por tanto, determinar cual sería la de elección en un futuro.

Para su desarrollo necesitamos pacientes, como su hijo/hija, derivados des de su pediatra de cabecera con un diagnostico de sospecha de hernia inguinal el cual ha sido confirmado por los cirujanos pediátricos y en esta consulta se ha determinado la necesidad de su tratamiento quirúrgico.

Para su realización, es imprescindible que ustedes desconozcan que técnica se empleará hasta el primer control a consultas externas a las dos semanas después de la cirugía. No obstante, antes de la intervención, escogerán uno de los dos sobres que se les proporcionará. Cada uno de los los cuales contendrá un papel con el nombre de cada una de las técnicas, de esta forma, elegirán de forma indirecta. Los cirujanos y todo el equipo conocerán la decisión minutos antes de iniciarse. El seguimiento lo llevará a cabo un cirujano distinto al que operó a su hijo/hija. Durante el proceso se recogerán una serie de datos, recopilados en formularios, necesarios para llegar a una conclusión.

Para ello solicitamos su permiso para poder realizar la intervención a su hijo/hija de forma enmascarada y la recopilación de los datos necesarios de forma totalmente confidencial para la realización del estudio de acuerdo con la normativa vigente. Cabe destacar que en ningún formulario constará el nombre ni datos identificativos del paciente. A si mismo, en el caso de la publicación de los resultados estos serían de forma global.

La participación de su hijo/hija es exclusivamente voluntaria. En caso de negación no tendrá consecuencias en el seguimiento y tratamiento de su patología por el equipo de cirugía pediátrica del hospital universitario doctor Josep Trueta de Girona.

Los riesgos que pueda ocasionar dicho proyecto no son más que los propios de las técnicas quirúrgicas empleadas. Es decir, el hecho de que sea de forma enmascarada no aporta mayor peligro

adicional ya que el tratamiento para la patología de su hijo/hija será el mismo. Las posibles complicaciones específicas de dicho procedimiento son las siguientes:

- Recurrencia
- Edema del sitio quirúrgico
- Edema escrotal
- Hematoma en el sitio quirúrgico
- Hemorragia postoperatoria
- Infección de la herida quirúrgica
- Interrupción de la herida
- Dolor post operatorio
- Vómitos y náuseas post operatorios
- Punción accidental
- Presencia de un cuerpo extraño
- Hidrocele iatrogénico
- Criptorquismo iatrogénico
- Atrofia testicular iatrogénica
- Ascenso de los testículos

Igualmente, también forman parte los generales derivados de una intervención quirúrgica y la anestesia.

El final de la investigación irá juntamente con la finalización del seguimiento por parte de los pediatras. Es decir, el análisis de los datos de su hijo/hija se seguirán hasta el día que sea mayor de 14 años. No obstante, recibirá el alta por parte del equipo de cirugía pediátrica después de hacer un seguimiento a corto plazo post intervención.

Muchas gracias por su atención, ante cualquier duda restamos a su disposición.

Equipo de cirugía pediátrica del hospital universitario doctor Josep Trueta de Girona

ANNEX 3: INFORMED CONSENT

CONSENTIMIENTO INFORMADO

Girona, _____ de _____ del _____

DATOS DE LOS PADRES O TUTORES LEGALES

Sr/ Sra:

DNI:

Teléfono:

DATOS DEL PACIENTE

Nombre y apellidos:

DNI:

CÓDIGO DEL PACIENTE:

MANIFIESTA

He recibido toda la información, de forma clara y comprensible, sobre los dos tipos de cirugía y los riesgos que ambas conllevan.

He entendido que no hay tratamientos alternativos.

He comprendido las posibles complicaciones derivadas de las intervenciones.

Se me han aclarado todas las dudas que me han surgido.

Se me ha notificado la posibilidad de revocar, en cualquier momento, el consentimiento que ahora estoy autorizando.

He recibido una copia de la hoja de información a los padres o tutores legales del paciente.

DATOS DEL FACULTATIVO QUE INFORMA

Nombre y apellidos:

Número de colegiado:

Firma del médico:

Firma del padre o tutor legal:

ANNEX 4: REVOCATION DOCUMENT OF INFORMED CONSENT

REVOCACIÓN DEL CONSENTIMIENTO OTORGADO

Girona, _____ de _____ del _____

DATOS DE LOS PADRES O TUTORES LEGALES

Sr/ Sra:

DNI:

Teléfono:

DATOS DEL PACIENTE

Nombre y apellidos:

DNI:

CÓDIGO DEL PACIENTE:

MANIFIESTA

La voluntad de denegar el consentimiento otorgado para la inclusión de su hijo/hija en el estudio.

Firma del padre o tutor legal: