



LAPAROSCOPIC TAPP VERSUS OPEN PREPERITONEAL MESH VERSUS CONVENTIONAL OPEN LICHTENSTEIN TENSION FREE MESH HERNIOPLASTY - A RANDOMIZED CONTROLLED TRIAL.

General Surgery

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ABSTRACT

BACKGROUND: Several studies have shown advantages in terms of less pain and faster recovery after laparoscopic hernia repair, whereas others have not and the cost-effectiveness has been questioned. The laparoscopic technique must be thoroughly compared with the open procedures before its true place in hernia surgery can be defined.

AIMS AND OBJECTIVE: To evaluate the influence of the laparoscopic technique in hernia repair regarding time to full recovery and return to work, and their complications, recurrence rate, and economic aspects.

METHODS AND MATERIALS: Six hundred thirteen male patients aged 30 to 60 years were randomized to the conventional procedure (Lichtenstein open subaponeurotic mesh hernioplasty), open preperitoneal mesh hernioplasty (Open Posterior approach), or laparoscopic preperitoneal mesh plasty (TAPP). Follow-up was after 7 days, 3 weeks, 4 weeks, 6 weeks, 6 months and 1 year.

RESULT: Patients who underwent TAPP gained full recovery and was able to perform non-strenuous activities as pre-operatively after 18.4 days, compared with 24.2 days for open preperitoneal (p 0.001) and 26.4 days for the open Lichtenstein procedure (p 0.001). Patients who underwent TAPP returned to work after 20 days, compared with 27 days for open posterior preperitoneal procedure and 30 days for the open Lichtenstein procedure (p 5 0.04). They also had significantly less restriction in physical activities after 7 days. However, complications were relatively more common in the TAPP group.

CONCLUSION: The laparoscopic technique results in both shorter time to full recovery and shorter time to return to work, at the price of considerably increased costs.

KEYWORDS

Laparoscopic Mesh, Preperitoneal Mesh, Inguinal hernia, unilateral.

INTRODUCTION:

The surgical history of inguinal hernias has paralleled the evolution in anatomical understanding and development of the techniques of general surgery. The late nineteenth century (1887), when Edoardo Bassini proposed his first successful reconstruction of the inguinal floor, those surgical techniques started rapidly evolving. Then, in the late twentieth century (1984-88) the tension-free repair, introduced by Irving Lichtenstein, caused a dramatic drop in recurrence rates and became the procedure of choice [1, 2]. No doubt, it was considered the gold standard of hernia repair by the American College of Surgeons. However, the introduction of a laparoscopic technique by Ralf Ger. in the early 1990s sparked a new debate over the best method of inguinal hernia repair [3]. Since then there has been many studies and reviews comparing Laparoscopic procedure and open tension free repairs. But clear consensus has not been arrived as to which procedure is superior. Lichtenstein tension free mesh repair is widely accepted and used even in recurrent cases with very low recurrence rates. However, repair of recurrent inguinal hernia after Lichtenstein hernioplasty is usually a difficult surgery due to the development of dense fibrotic scar tissue around the mesh with the further increased risk of vas deferens and testicular damage and local vascular injuries. However, a preperitoneal (posterior) approach, open or laparoscopic, reduces these problems. Laparoscopic preperitoneal hernia repair (Lap TAPP) has been found to be an excellent choice for inguinal hernia repair in various studies with regard to early post-operative recovery, reduced postoperative pain, hospital stay and recurrence rates, especially under hands of experienced surgeons. The cost and long learning curve are the two major disadvantages of laparoscopic approach.

The open posterior preperitoneal mesh repair described by Nyhus is also a good alternative for recurrent inguinal hernias. Main advantage of preperitoneal approach are mesh placement in the preperitoneal space where the hernia originates and also disadvantage of reoperating through scar tissue can be avoided. However, it is technically more demanding in comparison to the relatively easier straightforward Lichtenstein repair.

AIMS AND OBJECTIVE:

To evaluate the influence of the laparoscopic technique in hernia repair regarding time to full recovery and return to work, post-operative pain, complications, recurrence rate, duration of hospital stay and economic aspects.

MATERIAL AND METHODS:

The study was a randomized, open trial with two three treatment arms: conventional Lichtenstein Mesh plasty, open preperitoneal mesh technique, and laparoscopic preperitoneal mesh placement procedure (TAPP).

Surgical Procedures

Open Lichtenstein Mesh hernioplasty:

- Skin crease incision about half inch above medial part of inguinal ligament.
- Incision through external oblique aponeurosis to open the inguinal canal from superficial ring to laterally past deep ring.
- After evaluation of the cord, and dealing with the sac, a 15 x 7.5 cm polypropylene light mesh was used to reconstruct the posterior wall by suturing its lower edge to pubic crest and reflected edge of inguinal ligament.
- Lateral edge of mesh divided to incorporate cord and resewn together laterally to the inguinal ligament. Rest of the edges of the mesh secured to conjoint tendon with few interrupted sutures.
- External oblique aponeurosis closed over the repair and cord.

Open posterior or preperitoneal mesh hernioplasty:

- Through a lower abdominal transverse incision, the anterior rectus sheath was incised and the muscle retracted medially.
- The preperitoneal space was cleaved with blunt dissection, exposing the myopectineal orifice.
- The cord was explored and the hernias were reduced.
- A 10x15 cm polypropylene mesh with a slit was inserted in the preperitoneal space and fixed with nonabsorbable sutures to pubic tubercle and Cooper's ligament.
- The mesh was passed behind the cord and manipulated to lay flat against the posterior inguinal floor overlapping the entire myopectineal orifice. The mesh was to cover both direct and indirect inguinal and femoral openings and to go well below the ileopubic tract.
- No sutures were allowed below the ilioinguinal tract lateral to Cooper's ligament.
- The wound was closed with interrupted or continuous sutures in the fasciae and interrupted or continuous skin closure.

Laparoscopic Trans abdominal preperitoneal approach:

- A supraumbilical incision is used to access the peritoneal cavity with a 10-12 mm port.

- A 30 degree scope was used to place two 5 mm ports in the midclavicular line at umbilical level bilaterally.
- Hernia was visualized, and the peritoneum overlying it incised sharply 3-4 cm superiorly from the medial umbilical ligament to the anterior superior iliac spine.
- Blunt dissection can be used to peel the peritoneal flaps inferiorly, exposing the inferior epigastric vessels, the pubic symphysis and the Cooper's ligament, and the iliopubic tract.
- A direct hernia should be reduced if seen, and an indirect dissected from the cord structures.
- Femoral and obturator hernias can also be visualized and reduced.
- Care is taken to avoid the "Triangle of Doom" containing the external iliac vessels bordered by the vas deferens medially and the gonadal vessels laterally.
- A mesh ranging from 10 to 15 cm in diameter of polypropylene or polyester is introduced through the supraumbilical trocar and positioned anterior along the pelvic wall with the centre over of the primary hernia defect.
- Mesh was secured to Cooper's ligament with titanium staples (EMS Hernia Stapler, Ethicon). No staples were to be placed below the ilioinguinal tract lateral to Cooper's ligament.
- The peritoneum was closed with a continuous, resorbable suture or metal staples, aiming at complete peritoneal coverage of the mesh.

In all three groups, the wounds were infiltrated with 0.25% bupivacaine (Marcaine, Astra, Sweden) for postoperative pain relief. In the open surgery groups, 15 ml of bupivacaine was infiltrated along the line of incision, 10 ml at the iliac crest at the ilioinguinal and iliohypogastric nerves, and an additional 15 ml under the external oblique aponeurosis. In the laparoscopic group, the incisions were subcutaneously infiltrated with 5 ml of bupivacaine each.

All patients were given Injection Amoxycillin-Clavulanic acid combination 1.2 gm 1 hr. before induction and continued for 3 more dosage 8 hrly in the post-operative period. In case of allergy to Amoxy-Clav, Injection Clindamycin 600 mg was given 1 hr. prior and continued for 3 more dosage in the post-operative period.

Anaesthesia

Open procedures were performed under regional or general anaesthesia in accordance with the patient's preference or depending on anaesthesiologist considerations. The laparoscopic procedure was always performed under general anaesthesia.

Hospital Stay

The procedures were performed as inpatient procedures with emphasis on oral nutrition 6hrs after surgery and ambulation the next day of surgery.

Preoperative and Perioperative Parameters

Before surgery, the following parameters were recorded: age, height, weight, primary or recurrent hernia, history and size of hernia, ASA (American society of Anaesthesiologist) classification, and type of work (desk work, light manual, heavy manual, or no work). Status regarding testes and inguinal innervation were checked. Surgical time skin-to-skin, type of hernia, perioperative complications, type of anaesthesia, and hospital stay were noted.

Postoperative Follow-Up

Mean post-operative discharge time in Lichtenstein group was 50 hours, 48 hours in Open preperitoneal group and 46 hours in Lap TAPP group.

Follow-up was done after 1 week, 3 weeks, 4 weeks, 6 weeks, 6 months and 12 months after surgery. The patients were asked whether they had had any pain at rest in the treated groin and also whether the operated groin caused any restrictions of activity. These subjective variables were graded on a Likert scale (none, mild, moderate, severe, maximal). The testes, nerve status, and wound and the presence of a recurrent hernia were examined. Hernia recurrence was defined as a palpable, reducible lump in the treated groin, with or without symptoms. In patients with persistent discomfort, or if full recovery was not achieved at the 8-week visit, extra visits were performed at intervals of 4 weeks until full recovery was noted. Time to full recovery and to end of sick leave was noted by the patient in a self-administered record form. The time to full recovery was defined as when inguinal discomfort did not interfere with normal daily and athletic activities. In terms of sick leave, the patient received written instructions and was encouraged to

return to his normal work as soon as he found himself capable. After the operation, the patient received an off-work certificate for 2 weeks, if needed.

INCLUSION CRITERIA: Studies with adult patients above 22 years of age of both genders up to 60 years who underwent inguinal hernia repair (direct and indirect) were included in the meta-analysis. Only published studies were used for the analysis.

EXCLUSION CRITERIA: Studies, which included patients with recurrent inguinal hernias, irreducible scrotal hernia, femoral hernia or incarcerated, obstructed, strangulated hernia, requiring an emergency surgery, were excluded. Non-randomized and non-controlled studies were also excluded.

STATISTICAL ANALYSIS:

The variables were analyzed with Fisher's exact test. The software package RevMan 5.1.2 was used for statistical analysis to achieve a combined outcome. The risk ratio (RR) with a 9 per cent confidence interval (CI) was calculated for binary data and the standardized mean difference (SMD) with a 95% CI was calculated for continuous data variables with significance set at $p < 0.05$.

RESULT:

From October 2013 TO September 2020, 613 patients were randomized in to the study, and after surgery, 98.5% were followed for 1 year. Of these, 238 patients underwent Lichtenstein procedure, 185 patients had undergone open preperitoneal mesh repair and 190 patients underwent Lap TAPP procedure. Patients who underwent Lap TAPP gained full recovery after 18.4 days, compared with 24.2 days for patients undergoing open preperitoneal mesh repair ($p < 0.001$) and 26.4 days for the Lichtenstein procedure ($p < 0.001$). Patients who underwent Lap TAPP, returned to work after 14.7 days, compared with 21 days for open preperitoneal mesh ($p < 0.05$) and 24.5 days for the Lichtenstein procedure ($p < 0.04$). They also had significantly less restriction in physical activities after 7 days. The Lap TAPP procedure was more expensive, mainly as a result of longer surgical time and equipment costs, even after compensation for earlier return to work. Complications were more common in the Lap TAPP group, with a varying pattern between the groups. One recurrence in the Lichtenstein (0.42 %), 2 in the open preperitoneal mesh (1.08 %), and 2 in the Lap TAPP group (1.05%) were recorded after 1 year. 4 patients in Lichtenstein group, 1 patient in Open preperitoneal group and 6 patients in Lap TAPP group complained of chronic neuralgia. 2 patients in Lichtenstein group developed persistent Seroma requiring repeated aspiration, zero patient in Open preperitoneal group and 4 patients in Lap TAPP group developed such Seroma.

DISCUSSION:

The ideal method of hernia repair would cause minimal discomfort to the patient, both during the surgical procedure and in the postoperative course. It would be technically simple to perform and easy to learn, would have a low rate of complications and recurrence, and would require only a short period of convalescence. Finally, cost-effectiveness is important. Does laparoscopic hernia repair meet these demands better than open methods? First, it is difficult to know with what we compare. The results from specialized centres are often good. Low recurrence rates have been reported with the Shouldice technique, even, 1% [9, 10]. Other authors have reported higher recurrence rates (approximately 6%) when using the same method, however [13, 14]. Series using various mesh techniques have also shown good results. The tension-free hernioplasty introduced by Lichtenstein was used in 1000 consecutive patients with no recurrence after 1 to 5 years of follow-up. A series of 1011 mesh hernia plug repairs with a recurrence rate of 0.2% was presented by Rutkow and Robbins [15]. Stoppa et al used a large prosthetic mesh introduced through the preperitoneal route, also with favourable recurrence rates. It can be assumed, however, that there exists a publication bias and that the results in the general surgical community are not as good. This is confirmed by results from a Swedish prospective registration in eight hospitals, where 17% of the hernia operations were performed for recurrent hernia [16]. It has been claimed that the Shouldice procedure should be the gold standard when evaluating new herniorrhaphy methods [14]. Against this can be argued that there is a learning curve for this procedure [17]. The present study was designed to mimic clinical reality in general surgery, and the conventional method was therefore not standardized, and no specialized hernia centres participated in the study. Most laparoscopic hernia studies

compare laparoscopic mesh procedures with open procedures without mesh. This might lead to difficulties when analysing to what extent the laparoscopic technique or the prosthetic mesh influences the results. In the present study, the mesh placement was almost the same in the open and laparoscopic procedures with comparison to current practical gold standard of inguinal hernia repair, i.e., Lichtenstein tension free mesh hernioplasty. This design makes it possible to evaluate the role of the minimal access trauma surgery itself for the outcome of the hernia repair. A nonrandomized comparison of TAPP with the open preperitoneal mesh method by Goodwin and Traverso found similar short-term outcomes in the groups but increased cost and complication potential for the TAPP procedure [18]. The results of the present study show a significantly shorter sick-leave period and shorter time to full recovery in the TAPP group than in the open groups. This is in line with earlier published randomized series [19–28]. However, there are also randomized studies that have not shown this favourable shortening of postoperative recovery with the laparoscopic technique [29–32]. A possible bias source is the positive expectations by patients about new techniques, as well as the fact that the study surgeons themselves were responsible for the follow-up. To avoid this, a study with a double-blind design would be needed. The definition of “normal activity” probably varies between different studies, and therefore the time to return to normal activity is difficult to compare from one study to another. The sick-leave period in our study was fairly long in all groups. This might reflect a tradition in Sweden of long (up to 6 to 8 weeks) sick-leave periods after hernia surgery. Although written information with encouragement to return to work as soon as possible was given to every patient, we assume that the patients in the study were well aware of this tradition. Similar results have been found in other studies [21, 22]. Recurrences were more common in the open preperitoneal mesh group, although the difference was not statistically significant. Early recurrences (i.e., within 6 months) might reflect technical errors. In this study, both the patients in the open preperitoneal mesh and lap TAPP groups suffered the drawback of being operated on during the learning curve. The complication pattern varied among the groups. Seroma and hydrocele were more common in the lap TAPP and Lichtenstein mesh repair groups. The chronic pain problems seen in the TAPP group, even after 1 year, were alarming, and this issue needs to be studied further. The total extra cost for TAPP versus the conventional procedure was calculated. Even when performed with reusable ports, the TAPP procedure carries higher perioperative costs. A significant part of the extra cost is attributable to the longer duration of the surgical procedure, apart from the consumable items cost, which can be expected to decrease with increasing experience. Hernia repair is one of the most commonly performed surgical procedures: Approximately 600,000 procedures are performed annually in the United States [15]. In Sweden, 20,376 hernia procedures were registered in 1992 and 16,598 in 1995 [33]. A change in the cost for these procedures, therefore, has a large economic impact on society. Is the additional cost for TAPP outweighed by the shorter sick-leave period? In our study, the laparoscopic technique resulted in shorter time to return to work, but not short enough to compensate for the increased perioperative cost. Different health care and social reimbursement systems, as well as calculations that include reduced production, may produce other results. In this study, a difference of 21 days in time to return to work between TAPP and conventional procedures would be needed to compensate for the extra perioperative cost in the TAPP group compared with those treated with the conventional technique. A main determinant of cost-effectiveness is the recurrence rate. It has been suggested that recurrences after prosthetic mesh repair appear early after surgery, in contrast to conventional repair, where recurrences appear later in the postoperative course [21]. If this is true, an increased recurrence rate for the conventional group might be expected in time. A high rate of recurrence and subsequent need for reoperation will rapidly consume other advantages to the patient and society. In this study, the patients will be followed up to 5 years, and these long-term results will be published subsequently. To summarize, it is of great importance that the laparoscopic technique in hernia surgery be thoroughly evaluated before considering it as one of the standard procedures for hernia surgery. In this study, we found substantial advantages for the laparoscopic approach in terms of both time to return to work and to full recovery. However, the method has clear drawbacks: longer operating time, increased costs, and the need for general anaesthesia, a major deterrent in COPD and ischaemic heart disease patients. The complication potential, not the least of which is long-term pain, is worrying. In the future, individual evaluation will probably become more important to determine the most suitable hernia procedure for each patient.

CONCLUSION:

Inguinal hernia repair is one of the commonly performed general surgical procedures. Currently both open and laparoscopic procedures are being performed for inguinal hernia repairs and they have various advantages and disadvantages. In our study we have come to a conclusion that laparoscopic repair of unilateral inguinal hernia has a considerable short term clinical advantage than open hernia repair.

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