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ORIGINAL ARTICLE

FOUR ARM RANDOMISED TRIAL COMPARING LAPAROSCOPIC AND OPEN HERNIA REPAIRS

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Aim: *To compare four approaches in primary repair of inguinal hernia as regards operative and postoperative outcome.*
Methods: *One hundred consecutive patients with primary inguinal hernia Nyhus I-III were randomized into four groups. Group I had Open pro-peritoneal repair, group II had Lichtenstein tension-free mesh repair, group III had Transabdominal pro-peritoneal repair (TAPP) while group IV had laparoscopic totally extraperitoneal hernia (TEP) repair.*
Results: *Operative time ranged from 10.71 to 120.61 minutes. Laparoscopic operations were significantly longer than open operations (54.5+13.2, 34.21+23.5 versus 96.12+22.5, 77.4+43.21; t = 3.891, p <0.001). Open pro-peritoneal approach had significantly longer operative time compared to Lichtenstein approach (54.5+13.2 versus 34.21+23.5). Postoperative pain was significantly higher in patients who had open repairs (7.067+1.831, 6.5+3.5 versus 5.8 +1.568, 4.8+2.33; t = 3.424, p = 0.002). There was one case of conversion in each of the two laparoscopic groups. Laparoscopic operations were associated with significantly faster return to normal domestic activities and to work.*
Conclusion: *Laparoscopic hernia repair offers less postoperative pain and rapid recovery on the expense of longer operative time. TEP and TAPP laparoscopic techniques gave similar results.*

Keywords: *Minimally invasive, Inguinal hernia, Pro-peritoneal repair.*

INTRODUCTION

Inguinal hernia repair is the most frequently performed operation in general surgery. The standard method for inguinal hernia repair had changed little over a hundred years until the introduction of synthetic mesh. The next milestone in hernia repair might be the introduction of laparoscopy. Extensive and sound clinical research is, however, required to set a new "gold standard" for hernia repair.[1,2]

Following the evidence base of hernia surgery, we can see the first turn in the practice guidelines when, in the year 2002, Cochrane Database Systemic Review showed that open mesh repair is better than non-mesh for repair of femoral and inguinal hernia as regards recurrence rate. The review found no clear differences between mesh and non-mesh groups as regards complications. Mesh repair offered shorter length of hospital stay and quicker return to usual activities for mesh group in some of the studies. The main outcome, however, was that: the use of open mesh repair is associated with a reduction in the risk of recurrence of between 50% and 75%.[3] One year later, Cochrane Database Systemic Review (2003) compared laparoscopic techniques versus open techniques for inguinal hernia repair. There have been 41 published reports of eligible randomized trials involving 7161 participants. The laparoscopic operation was found to be significantly longer p<0001. Laparoscopic operations were associated with more serious complications including visceral and vascular injuries. There was no difference in recurrence rate comparing laparoscopic methods with open mesh methods of hernia repair. Length of hospital stay did not differ but laparoscopic operation offered earlier return to usual activity p<0.0001 and earlier return to work.[1]

In the year 2005, Cochrane Database Systemic Review tried to look at the different techniques of laparoscopic

hernia repair, namely the Transabdominal pre-peritoneal repair (TAPP) versus totally extraperitoneal repair (TEP) for inguinal hernia repair. They found no statistical difference between TAPP and TEP when considering: duration of operation, hematoma, length of hospital stay, time to return to usual activity and recurrence. TAPP was associated with higher rates of port-site hernias and visceral injuries. TEP was associated with more conversions. The reviewers found that the available data are insufficient to draw conclusions.[4]

Wellwood J, et al published a RCT comparing open versus laparoscopic hernia repair. They looked at pain scoring and patient satisfaction. Pain scores were higher in the open group. For every activity time was significantly shorter for the laparoscopic group.[5]

Sains PS et al analyzed data of 351 patients. Laparoscopy reduced the hospital stay ($P < 0.003$) and wound infections ($P = 0.03$). 6 Kuhry E analyzed the data of 4,231 patients. Laparoscopy had significantly higher hospital costs in spite of shorter hospital stay.[7]

To date, the current evidence does not show clear evidence to support laparoscopy for the routine repair of inguinal hernia.

Among the published studies comparing open and laparoscopic hernia repair, it was noted that only four studies were concerned solely with the repair of primary inguinal hernia.[8-11] The present work aimed at comparing four approaches in primary repair of inguinal hernia: Open properitoneal repair, Lichtenstein tension-free mesh repair, Transabdominal pro-peritoneal repair (TAPP) and totally extraperitoneal repair (TEP) as regards operative time, postoperative pain, postoperative complications, length of hospital stay, time to return to usual domestic activities and time to return to work.

PATIENTS AND METHODS

This prospective trial was conducted on 100 consecutive male patients with primary inguinal hernia Nyhus I-III admitted to the Department of surgery of the Alexandria Main University Hospital. Patients were randomized into four groups by random number allocation, twenty five patients each. Group I had Open pro-peritoneal repair, group II had Lichtenstein tension-free mesh repair, group III had Transabdominal pro-peritoneal repair (TAPP) while group IV had laparoscopic totally extra-peritoneal hernia (TEP) repair. The study was approved by the ethical committee of the Faculty of Medicine, University of Alexandria. An informed consent was obtained from every patient.

The study population was restricted to adult male patients. Exclusion criteria were: Patients with recurrent, irreducible or obstructed hernia; patients with previous lower abdominal operations (other than appendectomy), patients with coagulopathies and those with obstructive airway disease, constipation or obstructive uropathy.

All patients underwent thorough clinical examination and laboratory work up.

The study was single blinded. All operations were performed by the one surgeon. The results of the trial were recorded by a medical officer who was not directly involved in the surgery.

- ***The technique of the pro-peritoneal repair:***

The operation is performed under spinal anaesthesia with the patient supine. The skin incision is placed 2 to 3 cm below the level of the anterior superior iliac spine but above the internal ring; it begins 2 cm lateral to the midline and extends laterally for 6 to 7 cm. The skin and subcutaneous tissue are opened. A vertical curved incision is made following the linea semilunaris at the outer border of the rectus sheath, exposing the transversalis fascia. The fascia overlying the space of Retzius is then opened without violation of the peritoneum. A combination of blunt and sharp dissection is continued laterally posterior to the rectus abdominis and the inferior epigastric vessels. The pro-peritoneal space is completely dissected to a point lateral to the anterior superior iliac spine. The symphysis pubis, Cooper's ligament, and the iliopubic tract are identified. Inferiorly, the peritoneum is generously dissected away from the vas deferens and the internal spermatic vessels up to the level of bifurcation of the iliac vessels. The sac is identified. Small sacs are mobilized from the cord structures and reduced back into the peritoneal cavity. Long sacs are divided, with the distal portion left in situ and the proximal portion dissected away from the cord structures and ligated. Any excessive fatty tissue (lipoma of the cord) is reduced back into the pro-peritoneal space. Then, parietalization of the cord is ensured (dissection of the spermatic cord off the peritoneum to provide sufficient length to permit it to settle on the posterior abdominal wall). A polypropylene mesh 15 x 10 cm is placed centered opposite to the hernial defect. The mesh is fixed to the pubic tubercle, inguinal ligament, and anterior abdominal wall by few 2/0 prolene. The linea semilunaris is re-approximated using continuous 2/0 prolene suture including the anterior border of the mesh. No drain is used.

- ***The laparoscopic transabdominal preperitoneal repair (TAPP):***

General endotracheal anesthesia is used routinely. The patient is placed in the supine position with 15 degrees Trendelenburg tilt. A single video monitor is placed at the foot of the patient. The surgeon stands on the opposite side; the cameraman stands opposite to the surgeon. A 10 mm 30° laparoscope (Karl Storz) is used. Pneumoperitoneum is induced via an umbilical incision using open technique. CO_2 is then insufflated up to a pressure of 12 mm Hg. The laparoscope is introduced. The abdomen is explored including both inguinal areas. Two 5 mm ports are now inserted at the lateral border of

each rectus abdominis muscle at the level of the umbilicus. The four key anatomic landmarks are identified on both sides, namely: the spermatic vessels, the obliterated umbilical artery (medial umbilical ligament), the inferior epigastric vessels (lateral umbilical ligament) and the external iliac vessels. The hernia defect is inspected. A curved scissors is now used to cut the peritoneum transversely, beginning at the medial edge of the anterior superior iliac spine (ASIS) to the root of the epsilateral umbilical ligament. Peritoneal flaps are raised. The properitoneal space is dissected from lateral to medial at the level of the retroinguinal (Bogros') space, with parietalization of the spermatic cord posteriorly and outwards. The dissection is continued medially towards the retropubic (Retzius') space, extending behind the symphysis pubis and iliopubic tract, exposing the pectineal ligament. The peritoneum forming the hernial sac is pulled in, separating it from the cord structures in case of indirect hernia. Large indirect hernial sac is partially reduced then divided leaving the distal part undissected. This allows the lower flap to be dissected further dissected cephalad up to a point where the vas crosses the iliac artery. Now the field is prepared to receive the mesh. The right 5mm trocar is replaced by a 12 mm. trocar (Ethicon). A 15 x 10 cm sheet of polypropylene mesh is introduced into the abdomen through this trocar. The mesh is placed so as to cover the direct space (Hesselbach's triangle), the indirect space, and the femoral ring areas. The mesh is fixed using an endoscopic multifire hernia stapler (Ethicon, Johnson & Johnson), beginning at the pubic tubercle and proceeding laterally. The upper margin is stapled to the rectus muscle and the transversus abdominis fascia and arch, with care taken to avoid the inferior epigastric vessels. All staples are placed superior to the iliopubic tract. The peritoneum is tightly closed using 3/0 running vicryl suture. The trocars are removed under direct vision, and the peritoneum is deflated. The fascia at the two 10/12 mm port site is closed using 2-0 Prolene sutures.

- ***The technique of TEP:***

General endotracheal anesthesia is induced. The patient lies supine with 15 degrees Trendlenberg tilt. The main surgeon stands on the opposite side of the hernia, the cameraman on the other side. A 10mm, 30 degree telescope is used. An infraumblical 2-3 cm horizontal skin incision is done just lateral to the midline. The incision is deepened to reach anterior rectus sheath appears. The anterior rectus sheath is opened transversally and the rectus muscle is retracted laterally. A blunt digital dissection is used to develop a tunnel medial to rectus muscle that leads to the pro-peritoneal space. A ten millimeters cannula is now inserted under vision into the pocket created. CO_2 insufflation is started through that trocar to a pressure of 12 mmHg. The telescope is introduced through the trocar and advanced to find the pubic bone. From there the shaft of the telescope is swept laterally breaking the flimsy areolar tissue till reaching the anterior superior iliac spine. Once the space is cleared, one 5mm trocar is placed in the midline immediately suprapubic. Another trocar is placed in the midline, midway between the other two ports under direct vision. The midline space is further developed by blunt dissection. The curve of the pubic arch is cleared of flimsy attachments well across the midline. This is followed by identification of the key anatomical landmarks namely the pubic tubercle, pubic bone, direct hernia if present, inferior epigastric vessels, deep inguinal ring, spermatic cord and anterior superior iliac spine. The hernial sac is now identified, separated carefully from the inferior epigastric vessels. The sac is dissected off the spermatic vessels and the vas difference. It is either reduced back to the abdomen or transected leaving the distal part open and ligating the proximal stump. Now the peritoneum of the posterior abdominal wall is striped off cephalad till the level where the vas deference crosses the iliac artery. A polypropylene mesh 15x10cm is now introduced into the pro-peritoneal space through the 10mm trocar to cover the floor of the inguinal canal from midline of the pubis to the anterior superior iliac spine laterally. No mesh fixation is done. The CO_2 is deflated and the peritoneum is allowed to relay on the mesh under vision. Great attention is paid to keep the mesh unfolded. The opening of the10mm port is closed using 2/0 polyglactin absorbable sutures.

Operative time was calculated in minutes starting after the induction of anaesethia and including the time required for the setup of the laparoscopy.

Postoperative pain was assessed using the Visual Analog pain scale (VAS) which is a 10 points scale where 0 means feeling no pain while 10 means the worst possible pain. Intensity of pain was recorded twice: six hours postoperatively and mid-day on the second day postoperative.

Postoperative hospital stay was recorded in days.

The period, in days, required for the patient to resume his normal domestic activities namely going to the toilet, showering, self dressing and driving were calculated.

The period, in days, required for the patient to return to work was calculated.

Patients were followed up through outpatient clinic visits arranged at 2, 12 and 24 weeks postoperative.

The data were analyzed using SPSS version 11 software. T or X2 tests were used for significance at a level of error of 5%. Mont Carlo test was used to compare small numbers.

RESULTS

One hundred adult male patients with primary inguinal hernia were recruited for the study. They were randomly divided into four groups. The groups were comparable, with no significant statistical difference, as regards age, body mass index (BMI), risk factors such as smoking and

heavy weight lifting as shown in Table 1.

Operative time ranged from 10.71 to 120.61 minutes. Laparoscopic operations were significantly longer than open operations. There was no significant difference, however, between TEP and TAPP approaches. Open pro-peritoneal approach had significantly longer operative time compared to Lichtenstein approach. Table 2.

Postoperative pain scores recorded 6 hours postoperatively were significantly higher in patients who had open repairs compared to those who had laparoscopic repairs. They did not however differ significantly between the TEP and TAPP repairs or between the two open repairs. This remained the case for pain scores recorded in the second postoperative day as shown in Table 3.

There were no serious visceral complications in any of the four groups of the study. One case had to be converted from TEP to TAPP approach because the peritoneum was inadvertently opened during while developing the pro-peritoneal pocket at the start of the operation. This led to collapse of the working space. Attempts at deflation of the peritoneum using an intra-peritoneal verrus needle failed. So, the operation was converted to the trans-peritoneal approach. Another patient was converted from TAPP to the open pro-peritoneal approach because of technical failure. Two patients had recurrence of the hernia: One patient of the TAPP group had immediate postoperative persistence of his hernia. This was due to incomplete separation of the peritoneum from its attachment to the lateral edge of the internal ring. Another patient of the TEP group had a recurrence two weeks after his operation. Overall, there was no significant difference in the incidence of complications among the studied groups. Table 4.

The majority of the patients in all study groups stayed in the hospital for one day. Two patients stayed for more than two days: One patient in the Lichtenstein group had scrotal hematoma that resolved on conservative treatment and one patient in the TAPP group who developed severe groin pain immediately postoperative. His pain was controlled only by regular administration of parenteral analgesics. The length of hospital stay did not vary significantly among the four approaches as shown in Table 5.

The time lapse from the operation till regaining the normal capacity to perform regular domestic activities was collectively presented in Table 6. Laparoscopic operations were associated with significantly faster return to normal domestic activities compared to open approaches, again with no difference between the two laparoscopic approaches or the two open approaches. The length of the sick leave for the operation followed an identical pattern. Table 6.

Table 1. Demography of the study population.

Character	Pro-peritoneal	Lichtenstein	TAPP	TEP	Test of sig.
-Age (Mean+SD)	35.67+12.965	35.12+10.11	36.73+12.06	34.91+13.0	t = 0.864 p = 0.393
-BMI (Mean+SD)	22.2+1.568	24.34+14.22	22.4+1.242	23.2+5.3	t = 0.555 p = 0.582
Smoking	11	10	11	9	$\chi 2$ = 0.417 p = 0.519
Heavy weight lifting	8	8	9	10	$\chi 2$= 0.102 p= 0.749

Table 2. Operation time.

	Pro-peritoneal	Lichtenstein	TAPP	TEP	Test of sig.
Time	54.5+13.2	34.21+23.5	96.12+22.5	77.4+43.21	t = 3.891* p <0.001

* comparing laparoscopic approaches to open approaches.

Table 3. Pain scores.

	Pro-peritoneal	Lichtenstein	TAPP	TEP	Test of sig.
Day 1	7.067+1.831	6.5+3.5	5.8 +1.568	4.8+2.33	t = 3.424* p = 0.002
Day 2	4.933+ 1.624	4.63+2.22	4.133+1.125	3.98+4.35	t = 2.438* p = 0.020

* Statistically significant.

Table 4. Complications.

	Pro-peritoneal	Lichtenstein	TAPP	TEP	Test of sig.
Scrotal haematoma	1	0	1	0	
Wound infection	1	1	1	0	
Groin pain	0	0	1	0	MCp = 0.425
Conversion	0	0	1	1	
Recurrence	0	0	1	1	

Table 5. Hospital stay (days).

DAYS	Pro-peritoneal	Lichtenstein	TAPP	TEP	Test of sig.
one	22	21	22	24	
two	3	3	2	1	t = 1.009 p = 0.320
more	0	1	1	0	

Table 6. Return to normal domestic activities and work.

Duration(days)	Pro-peritoneal	Lichtenstein	TAPP	TEP	Test of sig.
Domestic	12.27 +3.535	12.11+4.23	9.8 +5.979	7.53+3.65	t = 5.746* p <0.001
Work	16.13+ 3.758	15.25+2.53	14.87+8.774	13.22+7.98	t = 5.774* p <0.001

* comparing laparoscopic approaches to open approaches.

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?[12] Hernia repair is one of the most commonly performed surgical procedures: approximately 600,000 procedures are performed annually in the United States. A change in the cost for these procedures, therefore, has a large economic impact on society.[12] It has been estimated that hernia repair causes the loss of 10 million working days each year, at a cost that has not been defined precisely, but is obviously enormous.[13,14]

The current study has demonstrated significant variation

of the operating time in favor of open repairs. Lichtenstein repair was significantly faster to perform. This reflects the relative simplicity of the latter approach. Yet, it might be well attributed to the familiarity of the surgeon and the team with it. This has been noted by Kurzer who stated that despite these clear benefits and excellent results, opern pro-peritoneal mesh repair has not been widely adopted, in part because of unfamiliarity with this approach.[15] In a survey of surgical practice 85 per cent of repairs for recurrent inguinal hernia were open anterior procedures (76 per cent mesh and 9 per cent non-mesh) and only 15 per cent were preperitoneal (9 per cent laparoscopic and 6 per cent open preperitoneal).[16] Since the setup time was included, the operating time for the laparoscopic approaches became further elongated. Our results are supported by most published reports that consistently state that laparoscopy take longer to perform, again with no difference between TEP and TAPP approaches.[5,17] It is clear that there is a considerable learning curve for laparoscopic repair, estimated by some to be at least 50 repairs.[18-20] The UK Medical Research Council study concluded that laparoscopic hernia repair had a lengthy learning curve and should be performed only by individuals who have considerable experience with the technique.[21] In contrast, the learning curve of the open pro-peritoneal approach is as short as 20 cases.[22,23]

Pain is a difficult parameter to assess. Individual variation, personal expectations and social implications all affect pain perception and expression.[24] This might explain the wide disparity in the published reports. There is, however, significant evidence to support that laparoscopic approaches cause less postoperative pain, at least in the immediate postoperative period.[25]

Hospital stay is an even more illusive parameter when used to compare the efficacy of surgical techniques. It is largely affected by the trend in the medical practice, the local social traditions, the way a given health system is being financed and the patient housing conditions. Hernia operations are currently performed as day surgery, often under local anaesthesia. Introduction of laparoscopy is unlikely to give better result. On the contrary, longer hospital stay and more re-admissions might be expected as laparoscopy prevails. The general anaesthesia and the complicated nature of the laparoscopic operations justify such expectations. To date, however, most of the published data do not support this assumption. Yet, it does not show any advantage of the laparoscopy either.[26,27]

Laparoscopic repairs cost more than open repairs. Much of the extra cost is attributable to the longer duration of the surgical procedure, which can be expected to decrease with increasing experience. This extra cost is to be compensated by reducing the loss of working days.[12] The length of the sick leave after a hernia operation is affected by the type of employment of the patient. Self employed patient tend to return to work earlier. It depends also on the impression given to the patient by his physician, the general attitude towards the operation and other variants. The results of the present study show a significantly shorter sick-leave period after laparoscopy groups than in the open groups. This is in line with earlier published randomized series.[28-37] However, there are also randomized studies that have not shown this favorable shortening with the laparoscopic technique.[38-41]

Regaining the ability to perform certain domestic activities with no undue discomfort might be a more accurate measure of postoperative recovery. Vroonhoven et al studied the performance of abdominal muscular after inguinal hernia repair. Performance was compromised at 1 week after operation but recovered by 6 weeks after surgery. This indicates that patients should be physically able to return to normal activity and work within 6 weeks regardless of operative technique.[42]

In the present study, patients returned to normal domestic activity significantly sooner after laparoscopic repairs. This finding was universal among the reported trials and was confirmed by the analysis by Memon et al. Subgroup analysis which showed significantly earlier return to normal activity after either TAPP or TEP repair compared with open repairs.[43]

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