Review
of
Literature
EVOLUTION OF HERNIA SURGERY

In the earlier part of first century AD, Celcus described the operation in vogue at that time in the Greco-Roman area\textsuperscript{10}, Through an incision in the neck of the scrotum, the hernial sac was dissected off the spermatic cord and transected at the external inguinal ring. The testis usually was excised as well. The incision was generally left open. Guy de Chauliac, in 1363, differentiated between inguinal and femoral hernia and described the technique or reduction for strangulation\textsuperscript{11}. In 1556, Franco illustrated the use of a grooved director to cut the strangulated neck of the hernia while avoiding the bowel\textsuperscript{12}.

Evolution of Herniorrhaphy

Marcy an American surgeon was the first to introduce antiseptic technique in the repair of hernia. He was also the first to recognize the importance of the transversalis fascia and of closing the internal ring. In 1871, he published the report of two patients operated on in the previous year in whom he used carbolized catgut to suture the ring\textsuperscript{13}.

The greatest contribution to hernia surgery was that of Italian surgeon Edoardo Bassini\textsuperscript{14-18}. He realized the importance of repairing the transversalis fascia and of reinforcing the posterior wall of the canal. Using interrupted sutures of silk, he sutured the internal oblique and the transversalis abdominis muscles as well as the upper left of the transversalis fascia in one layer to the lower leaf of the transversalis
fascia and the inguinal ligament. Bassini first performed this operation in 1884. During the next 100 years most inguinal hernias were repaired by the Bassini method or variations of it.

Notable among the improvements in this technique was the multilayered repair described by Shouldice in 1953\textsuperscript{19}. This method has become popular in the past -20 years and is probably the most successful of the pure tissue methods, suturing only the local tissues without the addition of any prosthetic material. However, this method is rather complicated and in some cases, calls for extensive dissection and suturing under tension. Also the technique is difficult and the results are not reproducible by other hernia clinics, leading to a very high recurrence rate outside Shouldice clinic.

**Introduction of Mesh in Hernia Surgery**

A hernia repair very result of some inherent weakness of the tissues but recurrent Hernia are usually because of ischaemic necrosis of the tissues caused by pressure of sutures under tension. To overcome rather complicated and some cases, calls for these problems, operators have sought the ideal tension less or tension -free repair.

There has already been general agreement that the first step, after dealing with the sac, is to repair the weakened or torn posterior wall of the inguinal canal, the transversalis fascia, and to tighten the stretched internal ring around the cord. This means doing a Marcy type of repair\textsuperscript{20}. Some surgeons have been satisfied with this procedure alone, but others have sought a means of reinforcing the posterior wall
with either natural tissue or biological or synthetic in the form of a tension free darn between the conjoint tendon and the inguinal ligament. The earlier of these Darners was Mc Arthur, who in 1901, reported using pedicied strips of the external. Oblique aponeurosis woven between the conjoint tendon and the inguinal ligament\textsuperscript{21}.

Later on Moloney introduced the forerunner of modern nylon darn technique in 1948\textsuperscript{22} with a recurrence rate of less than 1\%\textsuperscript{[23-24]}. This is a tensionless technique in which after dealing with the sac, the posterior wall of the canal is repaired by approximating the rectus sheath and conjoint tendon to the inguinal ligament with a continuous monofilament nylon suture.

Later on surgeons sought sheets of natural tissues as sheets of fascia as free sheets of skin, as reported by Mair, in 1945\textsuperscript{25}, to be sutured to the edges of the posterior wall of the inguinal canal. These methods proved uniformly disappointing with no real progress was made until the development of modern synthetic polymer plastics in the form of sheets of woven or knitted mesh of polyamide and the newer Polypropylene. These were popularized by Usher in 1958\textsuperscript{26}. The threads are monofilament, extensively smooth, and inert and thus elicit less tissue reaction. These synthetic mesh usually were used to strengthen the repair of transversalis fascia to create a strong and tensionless repair.
Modern herniologists such as Lichtenstein and Gilbert have simply laid a swatch of the synthetic mesh, without sutures, deep to or in front of the repaired fascia transversalis\textsuperscript{27-28}.

CLASSIFICATION SYSTEM AND GROIN HERNIA'S

*GILBERT CLASSIFICATION WITH ADDITION BY RUTKOW AND ROBBINS\textsuperscript{45}*

In 1988, Gilbert described a detailed classification system based on anatomic and functional defects established intra operatively, namely the presence or absence of hernia sac, the size and competency of the internal ring, and the integrity of the transversalis fascia -transversus abdominis aponeurosis layer (posterior wall) within Hesselbach's triangle. Incorporating these three components, Gilbert categorized Groin hernias into five classes: Type I' 2, and 3 were indirect, whereas type 4 and 5 were direct.

In 1993, Rutkow and Robbins expanded on Gilbert's classification scheme. A type 6 was added to encompass those Groin hernias consisting of both direct and indirect components (Pantaloons hernias).
TYPE 1

Are indirect inguinal hernias in which the internal abdominal ring is of normal size, configuration, and structure. The hernial sac can extend from just distal to the internal ring to the middle of the inguinal canal but the area of Hesselbach’s triangle remains normal.

TYPE 2

These are indirect inguinal hernias in which the internal sac does not reach the scrotum but may occupy the entire inguinal canal. Nyhus recommends that for type 1, no fascial repair is necessary high ligation of the sac should suffice. Even Nyhus (type 2) in which the internal ring is somewhat dilated, a high ligation is completed, and the ring is simply closed 9i.e. strengthened with a few interrupted sutures.

TYPE 3

Hernias consist of three subtypes (direct, indirect and formal) and always represent loss of posterior wall integrity.

Type 3A are direct inguinal hernias in which the protrusion represents a weakened transversalis fascia (i.e., area constituting Hesselbach’s triangle) bulging outward in front of the hernia with the mass. Every direct hernia, regardless of size or shape of the defect, constitutes a type 3A.

Type 3B are indirect inguinal hernias with a large, dilated ring that has expended medially and encroaches on the inguinal floor. The hernial sac frequently reaches to the scrotum. Occasionally, the caecum on the
right of the sigmoid colon on the left makes up a "slinging" portion of the wall of the sac. Such sliding hernias always destroy a portion of the inguinal floor. In addition, the internal ring may be attenuated with or without displacement of the inferior epigastric vessels.

Occasionally, direct and indirect components of the hernial sac may straddle these vessels to create a pantoloon hernia. Nyhus recommends that for types 3A and 3B, repair be accomplished via either an anterior (e.g. Shouldice (1953)31, McVay Cooper (1942)32 ligament, or Condon (1960)33 (iliopubic tract) or posterior preperitoneal approach. The posterior technique and Condon’s iliopubic tract method should include an inlay buttress of mesh to support the anatomic repair.

**TYPE 4**

Hernias are recurrent defects. They can be direct (type 4A), indirect (type 4B), femoral (type 4C), or a combination of these types (type 4D). They incorporate intricate management problems and carry a higher morbidity than do other hernias. Nyhus recommendation for management of all type 4 hernias is a posterior preperitoneal approach entirely avoids the risk for ilioinguinal or genitofemoral neuralgia reported to occur with anterior approaches.

**BENDAVID CLASSIFICATION**

In 1993, Bendavid proposed the type, staging, and dimension (TSD) classification scheme. Five types of Groin hernias are described: (1) type-1, or anterolateral (formerly, indirect); (2) type-2, or anteromedial (formerly, direct); (3) type-3, or posteromedial (formerly,
femoral), (4) type-4, or posterolateral (formerly, prevascular); and (5) type-5, or anteroposterior (formerly, inguinofemoral). Further, he classified each type in three stages that denote the extent of herniation anatomically.

**STOPPA CLASSIFICATION**

This is partially derived from NYHUS classification, with special attention to so-called 'aggravating factors'.

**Type-1** is an indirect hernia, with a normal internal ring, measuring less than 2 cm and is most commonly noted in young patients. The inguinal floor is solid.

**Type-2** hernias are also indirect, but with the internal ring greater than 2 cm in diameter, although the inguinal floor remains solid.

**Type-3** are all indirect and direct inguinal and femoral hernias associated with a weakened inguinal floor, or type-2 hernias are complicated by an aggravating factor.

**Type-4** are all recurrent hernias of any type-3s complicated with aggravating factor.

Of the four classification systems presented, in the Nyhus classification the result are easily reproducible.

**THE LAPAROSCOPIC HERNIA REPAIR**

The history of surgery, demonstrates that the procedures which are less traumatic, even if more complex tends to supersede those which involve more pain and trauma, and we believe laparoscopic
Laparoscopic groin hernia repair will prove such an advance. Laparoscopic groin hernia repair has advantage over open hernia repair as small puncture wounds, minimal dissection, less chance of injury to the spermatic cord and decreased incidence of ischaemic orchitis, decreased incidence of bladder injury, no ilioinguinal postoperative neuralgia, procedure, ability to achieve a very high closure of the peritoneal sac and minimal postoperative discomfort.

The laparoscopic inguinal herniorrhaphy can be divided into three approaches.

1. **Transabdominal Pre-peritoneal repair (TAPP).**

2. **Extra abdominal Preperitoneal repair or (TEP) Total Extraperitoneal Repair**

3. **Intra abdominal peritoneal on-lay patch repair which has now more or less been given up.**

In the 1980s, Lichtenstein and Shulman developed tension-free hernioplasty using a polypropylene mesh implanted anteriorly not only for recurrent hernias, but also for the repair of primary hernias. Using a similar technique, Krischner had used homologous fascia lata to repair recurrent inguinal hernias as long ago as 1910. The spread of laparoscopic surgery after the establishment of laparoscopic cholecystectomy at the end of the 1880s finally led, in 1990, to the development of transabdominal preperitoneal hernia repair (TAPP), as described by Shultz et al. and Corbitt preperitoneal approach with its advantage of bilateral evaluation and treatment of all existing and
potential inguinal hernial orifice, avoidance of the trauma associated with the transinguinal approach, and safeguarding of healthy tissue structures. The underlying final surgical goal of posterior, open (Stoppa, Wantz, Nyhus) and laparoscopic hernia is the preperitoneal space with reinforcement of the posterior inguinal floor using an alloplastic mesh. Against this background, the establishment of totally extraperitoneal hernioplasty (TEP) by Dulueq [g] in 1991 in Europe and by Mckernan and Laws and Philips et al [45]. In the United States may be considered a logical further development of TAPP or anterior preperitoneal repair.

The TEP procedure combines the advantages of tension-free mesh reinforcement of the grain with those of laparoscopic surgery, with its low postoperative pain and curtailed recovery time while obviating the need for a transabdominal approach.

Among these TEP approach is preferred as no pneumopertitoneum is required. This has the benefit that the initial insufflation is performed without the need for the blind insertion of a Veress needle. This can be a dangerous stage in laparoscopy with the risks of major visceral injury. As the peritoneum is not entered, therefore the dangers of possible intraperitoneal trauma are minimized.

In 1982, under laparoscopic guidance, Ger and colleagues [34] used a Michel staple applied with a ocher Clamp to close the peritoneal opening of a hernial sac. These authors saw several potential advantages of laparoscopic hernioplasty, including reduced post-
operative pain, earlier return to activity, and others as described earlier.

The laparoscopic hernia repair can be divided into three approaches.

**Transabdominal Pre-peritoneal repair (TAPP)**

This is the form of laparoscopic inguinal hernia repair which is routinely performed under general anaesthesia/spinal anaesthesia. After creating a pneumoperitoneum, three ports are introduced, one infraumbilically and two at the level of umbilicus over the stearing the surgery.

A horizontal incision is made in the peritoneum over the cephalad aspect of the hernia, followed by dissection of the preperitoneal space, reduction or incision of the sac neck if large, placement of a periperitoneal mesh prosthesis and approximation of the peritoneum with staples.

Lastly inject a long – acting local anesthetic such as bupivacaine into the preperitoneal space before closure, if desired to decrease postoperative pain. Bilateral hernias can be repaired using one long transverse peritoneal incision extending from one anterior superior iliac spine to the other and using a large single piece of mesh.

**Intraperitoneal onlay Mesh repair**

Advocated by Fitzgibbons and colleagues\(^{36}\) and Franklin\(^{37}\) and later on abandoned by Fitzgibbons because of complications related to possible mesh erosion into bowel.
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To avoid these complications associated with incision of the peritoneum or intraperitoneal placement of mesh, the surgeons began performing the Stoppa preperitoneal prosthetic mesh repair laparoscopically in 199038. Here the polypropylene mesh is placed between the underside of the abdominal wall and the peritoneum, fixing the mesh to cooper’s ligament and the aponeurotic sling. This type of repair is more technically difficult but is associated with fewer complications and recurrences.
This technique has been most extensively used by McKernan and Laws\textsuperscript{45}, they began the procedure with an incision at umbilicus, identical to that which would be used for open laparoscopy. The fascia at the umbilicus is opened, but the peritoneum is left intact. An open laparoscopic cannula is placed in the incision and an operating laparoscope is used to create a working space between the peritoneum and fascia transversalis.

Philips\textsuperscript{45} from Los Angeles is also a proponent of the totally extraperitoneal procedure. He prefers an initial diagnostic laparoscopy, however, so that he can carefully inspect both sides of the groin to assess the hernias from an intra abdominal viewpoint. He then introduces a Veress needle into the preperitoneal space and under direct vision creates the “pneumoeextraperitoneum”. A trocar is then placed directly into the preperitoneal space and the pneumoperitoneum is released. The procedure is then similar to Mckernan and laws.

Aregui\textsuperscript{45}, one of the pioneers of the TAPP procedure, is now performing almost exclusively totally extraperitoneal laparoscopic hernia repairs.

McKernan and Laws (1993)\textsuperscript{46} extensively used the technique of laparoscopically guided repair of a hernia effect without entering the peritoneal cavity (Totally extraperitoneal). He performed 155 of these repair on 106 patients (69 direct hernias, 85 indirect hernias including 2 sliding), and 1 femoral hernia. The total number of recurrent hernias were 32, and 49 of the hernias were bilateral. They had seen no
recurrences on short-term follow-up. Complications included one case of postoperative orchitis, several cases of seromas in the preperitoneal space that responded to aspiration or observation only, five transient testicular swellings, four genitofemoral and four lateral femoral cutaneous neuralgias, one hematoma, one wound infection, and two cases of urinary retention. This procedure had to be converted to TAPP repair, two of them because of the creation of a small hole in the peritoneum and one in a patient who had a previous radical prostatectomy with radiation therapy, which obliterated the pre-peritoneal space. The average time reported for the operation was 55 minutes.

In a prospective, randomized studies performed by Payne and colleagues (1994)\textsuperscript{47}. Lichtenstein type tension free repair were compared with TEP and TAPP repairs. Patients were subjected to carefully designed physical tests and evaluated according to type of hernia, job requirements, and insurance coverage. Post-operative discharge times were similar for all groups. Return to work was significantly earlier in laparoscopic groups. There was one recurrence in each laparoscopic group. Complications were more common following open repair.

Liem MS and Vander Graaf Y et. Al.\textsuperscript{48}. Department of surgery Netherland in 1997 compared the conventional anterior surgery and laparoscopic surgery for inguinal hernia repair. Study was performed on 57 patients who were treated by conventional anterior repair and 487
Follow-up of the patients was done after one and six weeks, six months, one and two years. They concluded that patients with inguinal hernias who underwent laparoscopic repair, recover more radical prostatectomy with radiation therapy, which obliterated the pre-peritoneal space. The average time reported for the operation was 55 minutes.

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Liem MS and Vander Graaf Y et. Al, 48. Department of Surgery Netherland in 1997 compared the conventional anterior surgery and laparoscopic surgery for inguinal hernia repair. Study was performed on 507 patients who were treated by conventional anterior repair and 487 patients who were treated by extraperitoneal laparoscopic repair. Follow-up of the patents was done after one and six weeks, six months, one and two years. They concluded that patients with inguinal hernias whop underwent laparoscopic repair, recover more rapidly and had fewer recurrences than those underwent open surgical repair.
Kozol and colleagues (1997) performed a randomized, prospective blind comparison of TEP repair and open mesh repair with regards to post-operative pain and the cumulative dosage of analgesia during 48 hrs. In these 62 patients, all of whom had general anaesthesia, postoperative pain was significantly less in those having laparoscopic repairs.

In a prospective, randomized study by Heikkinen and colleagues (1997) both repairs were performed under general anaesthesia and then compared in relation to operative time and costs, hospital stay, post-operative pain, return to work and patient satisfaction. Differences that reached significance between the two repairs were as follows: Laparoscopic repair had higher costs, resulted in less post-operative pain and analgesic consumption, allowed patients to return to work earlier, and had lower complications.

Sudhir kumar et. Al (1999), Department of General Surgery, Western General Hospital NHS Trust, Edinburgh, U.K. presented a paper on 15th May 1998 in which they conducted a prospective study of 50 patients who had laparoscopic TEP repair (n=25) or Lichtenstein repair (n=25) for recurrent inguinal hernia. They concluded that Laparoscopic repair was associated with fewer complications and a significantly shorter duration of post-operative analgesia than Lichtenstein repair of recurrent inguinal hernia.

W. R. Fleming and T. B. Elliot et. Al., 52 (Department of Surgery Melbourne Australia) in 2001 did a randomized clinical trial on 200
patient to compare the totally extraperitoneal inguinal hernia repair with the Shouldice technique. Out of 200 patients 117 patients had TEP repair and 115 patient had Shouldice repair. Comparison showed that median operative time was longer for TEP repair but patients were discharged earlier and had a quick return to work and normal life style. Conclusion of the study was that TEP repair results in fewer complications and an earlier return to work and normal life style.

Randomized clinical trial performed on 134 patient by Colak T, and Akca T in 2003\textsuperscript{53} for the comparision of laparoscopic totally extraperitoneal approach with open mesh repair in inguinal hernia showed that mean operative time, visual analogescale score, hospital stay, and duration of recovery was significantly les for TEP repair in comparision was approximately equal in each group.

A Randomized controlled study was conducted by the Lal P, kajla R. K. et. Al., 54 on the laparoscopic total extraperitoneal and open lichenstein inguinal hernia repair in the department of surgery Maulana Azad Medical College, New Delhi, India in 2003. In a prospective randomized study open hernia repair was performed in one group and TEP repair using a large mesh was performed in another group. The intraoperative and postoperative complications and results were compared. Result of the study showed that mean operative time in TEP group was significantly longer than the open group. The mean pain score in TEP groups was lower than open group. The mean postoperative analgesic dose was lower in the open group. The return to
work time was significantly lower in TEP group in comparison to open group. No recurrence was seen in either of two groups. This study concluded that TEP repair is significantly less painful in the early post-operative period, TEP results in significantly earlier return to work and better cosmetic results.

Brigman S, and Ramel S. et. Al, 56 from center for surgical sciences, Stockholm, Sweden in 2003 compared the TEP method of inguinal hernia repair with two open tension free hernia repairs (Meshplug and Lichtenstein). In this randomized study hundred Ninety-nine men 30 to 75 years old were observed who underwent TEP repair method and open operation. They concluded that most of the patients were discharged within 24 hrs. Post-operative pain was lower in the patients who had a TEP repair. The median time to full recovery was significantly shorter in the TEP group compared to other groups. There were no major complications and equal number of recurrences were found in both groups.

C. Tamme and H. Scheidback et. al., (2003)56 from the department of surgery and center for Minimally Invasive Surgery. Hanover hospital, Germany, presented a report after performed TEP as the method of choice in more than 92% of all the patients presenting with inguinal hernia, including those with incarcerated, strangulated, or inguinoscrotal hernias. After reduction of the hernial sac and appropriate dissection of the preperitoneal space, they placed a slit-free 10 x 15 cm polypropylene mesh without the use of the staple fixation.
They observed 29 recurrent hernias, which occurred during the first 2 years. During subsequent years, the recurrence rate settled to approximately 0.3%. In the intra-operative complications, eight injuries to the bladder and no bowel injuries or damage to iliac vessels observed. Post operatively single case of mesh infection and bowel obstruction was noticed due to inadequate closure of a peritoneal lesion. They concluded, totally extraperitoneal endoscopic inguinal hernia repair to be a procedure that carried an acceptably low complication rate combining the advantage of minor access surgery and mesh reinforcement of the groin, early post operative return to usual activities and very low recurrence rate.

Bodil Anderson and magnus Hallen et. al., (2003) 57 from the department of surgery. Lund University hospital, Lund Sweden, in a prospective randomized controlled trial designed a study to compare the Laparoscopic extraperitoneal inguinal hernia repair (TEP) with open mesh repair. In this study one hundred sixty-eight men aged 30 to 65 years with primary or recurrent inguinal hernia were randomized to TEP or open mesh technique. 8 patients were randomized to TEP and 87 to open repair for 1 patient in each group, the operation was converted to a different type of repair follow-up was done after 1 week.

Result of the study showed that there was no significant difference seen in overall complications between two groups. However, 1 patient in the TEP group underwent operation for small bowel obstruction after surgery. A higher frequency of post-operative
Hematomas were seen in the open group. Patients in the TEP group consumed less analgesic after surgery, returned to work earlier and had a shorter time in full recovery. Two recurrences occurred in the TEP group 1 year after surgery. From the result they concluded that there was less post-operative pain in TEP technique, shorter time to full recovery and an earlier return to work in comparison to open mesh repair.

Haidenberg J, and endrick ML et. al., 58 from the department of surgery. Rochester, U.S.A. in (2003) emphasized on totally extraperitoneal approach for inguinal hernia as they analysed 264 consecutive patient undergoing TEP for inguinal hernia repair. They concluded that totally extraperitoneal approach is a safe and effective method of inguinal hernia repair. They noticed less post operative complications in TEP method for inguinal hernia repair.

H. Scheuerlein, and A. Schiller et. al., (2003)59 performed a prospective single center study on totally extraperitoneal repair recurrent inguinal hernia using data obtained from 179 consecutive patients with recurrent inguinal hernia. Average age of the patients was 56 years and follow-up period of the patients was 2-3 years. Result of the study showed that average operating time was 57 minutes in 68
table (104) of the patients, adhesions, adherent epigastric vessels or cicatrical changes were found, which resulted in the inadvertent opening of the peritoneum in 26.3% of the patients. Intra-operative complications were developed in patients (one injury to the bladder and three cases of
bleeding from side branches of the epigastric vessels). The conversion rate was 0%.

The post-operative complications requiring treatment were hematomas in 7 patients, in 2 patient re-operation became necessary. In both cases haemorrhage was due to pre-operative undiagnosed coagulation disorder was found. No cases of wound or patch infection were observed. From this result they conducted that although for its definitive management, recurrent hernia requires a reliable operative technique but in a representative patient population with recurrent hernia, TEP method to repair recurred inguinal hernia achieves very good results in term of re-recurrence rate (0%), intraoperative and post-operative complications and rehabilitation.

H. Lau and M. G. Patil (2003) 60 evaluated the prevalence and severity of chronic groin pain after endoscopic totally extraperitoneal inguinal hernioplasty. Study was performed on 313 consecutive patients who underwent TEP method for inguinal hernia repair. They resulted that the prevalence of chronic groin pain was 9.2. In more than half of the patients, the groin pain occurred less often than once a month and its duration did not exceed 1 minute. Only one patient reported an impairment of functional activities as a resulting pain. Conclusion of the study renowned that the prevalence of chronic groin pain in patient after TEP was low. The pain was mostly mild and transient without associated sensory symptoms.
department of surgery and institute fro Minimally Invasive Surgery, Washington university school of medicine, USA in 2004 collected the data of patients undergoing TEP repair since 1997 (total number of patient – 147) and open mesh repair since 1999 (total number of patient 198) for the study of perioperative outcomes and complications of open and laparoscopic extraperitoneal inguinal hernia repair. Their dates showed that operative times were significantly shorter in the TEP group for both unilateral and bilateral repairs. Patient undergoing TEP repair were more likely to develop urinary retention but were less likely to have skin numbness or prolonged groin discomfort. TEP repairs can be performed efficiently and without major complications.

G. Ferzli K. Shapiro et. al., (2004)62 emphasized on Laparoscopic extraperitoneal approach for acutely incarcerated inguinal hernia repair. Study was done on 16 patients out of which 5 cases were done using a conventional anterior repair and 11 cases had TEP approach. Follow-up of the patients was done for the period of 9 to 69 patients. They concluded that the mean operative time for TEP repair was 50 minutes, and the length of hospital stay was 4-5 days. During a follow-up period, there was no recurrence and the two complications were found.

M. Ghoghesali, H. R. Langeveld, R. Veld Kamp (2005)63, Nethereland emphasies an laparoscopic hernia repair and concludes that over all cost society for Laparoscopic hernia repair (TEP) is not
higher and in fact may be lower due to lower indirect cost. There is also less likely hood of chronic inguinal pain after endoscopically repaired hernia than open hernia repair. The TEP (endoscopic) approach clearly benefits quality of life, making it a preferred technique from patient perspective.