WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES

SJIF Impact Factor 7.421

Volume 7, Issue 10, 1-37

Research Article

ISSN 2278 - 4357

a

COMPARISON BETWEEN MESH VERSUS NON-MESH REPAIR OF INGUINAL HERNIA

*Hayder Salim Shaker Al-Mindylawi

M.B.CH.B.M.S., AL-Kidney Collage of Medicine Baghdad University / Iraq.

Article Received on 23 July 2018,

Revised on 13 August 2018, Accepted on 03 Sept. 2018

DOI: 10.20959/wjpps201810-12391

*Corresponding Author
Dr. Hayder Salim Shaker
Al-Mindylawi
M.B.CH.B.M.S., AL-Kidney
Collage of Medicine
Baghdad University / Iraq.

ABSTRACT

Background: Hernias are abnormal protrusions of aviscus (part of it) through a normal or abnormal opening in a cavity (usually the abdomen). They are most commonly seen in the groin; a minority are para-umbilical or incisional. In the groin, inguinal hernias are more common than femoral hernias. Inguinal hernias occur in about 15% of the adult population, and inguinal hernia repair is one of the most commonly performed surgical procedures in the world. Approximately 800,000 mesh hernioplasties are performed each year in the United States, 100,000 in France, and 80,000 in the United Kingdom. **Aims of Study:** The present study was the first study that done at Baqubah

Teaching Hospital\Diyala\Iraq. The present study aims to comparing mesh with non-mesh repair of inguinal hernias regarding:

- 1. Duration of surgery
- 2. Development of early post-operative complications such as wound infection, hematoma and seroma formation.
- 3. Development of late post-operative complications such as persistent pain, testicular atrophy and recurrence of inguinal hernia.

Materials and Methods: This is a prospective study for 200 patients underwent surgeries for inguinal hernias at Baqubah Teaching Hospital. There were 192 (96%) male patients and 8 (4%) female patients. The surgeries were done over a period of 2 months (October–November 2013) in the department of general surgery at Baqubah Teaching Hospital and followed for 10 months. The patients are categorized into two groups: group 1 composed of 100 patients named the mesh group (the male patients were 96 and female patients were 4) as they included (Lichtenstein mesh repair) for their hernias and group 2 which also composed of 100 patients, named the non- mesh group (also the male patients were 96 and female

patients were 4) in which their hernias are repaired using the (modified Bassini's repair) or (Darn repair). The age range of the patients was (16-63 year) for group 1 and (16-70 years) for group 2. The surgeries were randomly performed by senior surgeons. The two groups were compared regarding development of early post-operative complications such as(wound infection, hematoma and seroma formation) and development of late post-operative complications such as (persistent pain, testicular atrophy and recurrence of inguinal hernia). They are also compared regarding the duration of surgery. In the Lichtenstein mesh repair a (7.5×15cm) piece of polypropylene mesh is commonly used for a Lichtenstein hernioplasty. The non-mesh repair involve either (modified Bassini's repair) or (Darn repair). Results: Regarding the development of early post-operative complications, the results were not significantly different. Regarding the development of late post-operative complications especially the persistent pain and recurrence of inguinal hernias, the results were significant. There were more cases in the non-mesh group; the P-value was (0.030). Conclusion: The mesh repair is superior to the non-mesh repair of inguinal hernias especially in terms of postoperative persistent pain and recurrence of inguinal hernias; however, continuous clinical trials have to be undertaken to find out the optimum surgical treatment of hernias.

KEYWORDS: Inguinal hernia, mesh hernioplasty, non-mesh repair of inguinal hernias.

INTRODUCTION

Hernias are abnormal protrusions of aviscus (part of it) through a normal or abnormal opening in a cavity (usually the abdomen). They are most commonly seen in the groin; a minority are Para umbilical or incisional (A.E.Kirk. et al, 1995).

In the groin, inguinal hernias are more common than femoral hernias. Inguinal hernias occur in about 15% of the adult population, and inguinal hernia repair is one of the most commonly performed surgical procedures in the world (Akyol C. et al, 2013).

Approximately 800,000 mesh hernioplasties are performed each year in the United States, 100,000 in France, and 80,000 in the United Kingdom (Albo D. et al, 2006).

The word "hernia" is derived from a Latin term meaning a "rupture". The earliest reports of abdominal wall hernias date back to 1500 BC. During this early era, abdominal wall hernias were treated with trusses or bandage dressings (Amid PK. et al, 1994).

The first evidence of operative repair of a groin hernia dates to the first century AD. The original hernia repairs involved wide operative exposures through scrotal incisions requiring orchidectomy on the involved side. Centuries later, around 700AD, principles of operative hernia repair evolved to emphasize mass ligation and en bloc excision of the hernia sac, cord, and testis distal to the external ring (Awad SS. et al, 2002).

The modern surgical era began with Bassini, who in 1887 developed the first modern anatomically based hernia treatment, this procedure spread worldwide, but was often executed poorly, and hernia repair fell into a state of second hand surgery (Amid PK. et al, 2007).

The first true Cooper's ligament repair, which affixes the pectineal ligament to Poupart's ligament and thereby repairs both inguinal and femoral hernia defects, was introduced by Lotheissen in 1898(Butters M. et al, 2007).

Darn repairs were first introduced in the early 20th century to reduce wound tension by using either autologous tissue or synthetic suture to bridge the gap between fascial tissues. In 1918; Handley introduced the first use of silk as a prosthetic darn and nylon followed several years later. However, it was found that heavy prosthetic material increased the risk of wound infection, and the silk suture ultimately lost its strength over time (Bisgaard T. et al, 2007).

The use of autologous or synthetic patches was also attempted in order to reduce wound tension and improve rates of recurrence. The first patches, beginning in the early 20th century, consisted of silver wire filigree sheets that were placed along the inguinal canal. Over time, the sheets suffered from metal fatigue leading to hernia recurrence (Bay-Nielsen M. et al, 2004).

In the late 1940, Canadian surgeon E.Shouldice developed a hernioplasty similar to the Bassini's operation. This procedure became extremely popular as well as the standard of the classic pure tissue hernioplasties; its only problem was that it was difficult to reproduce the great results that Shouldice achieved with this repair (Butters M. et al, 2007).

In 1956 American surgeon Chester McVay and anatomist Barry Anson clarified the anatomy of the groin and popularized the Cooper's ligament Hernioplasty (Bringman S. et al, 2006).

In 1984 Lichtenstein and colleagues published their results in repairing primary hernias using a prosthetic mesh in a tension free manner, since then this repair has been accepted world wide as the gold standard repair, this was based on the definite reduction in recurrence rates as well as post-operative pain (Chastan P. et al, 2009).

Given the evidence that the use of mesh lowers the recurrence rate as well as the availability of various prosthetic meshes for the reinforcement of the posterior wall of the inguinal canal, most surgeons now prefer to perform tension-free mesh repair. Lichtenstein tension-free hernioplasty is one of the most popular techniques used for inguinal hernia repair (Chung L. et al., 2007).

AIMS OF STUDY

The hernia is a common problem and in Baqubah Teaching Hospital, the inguinal hernias cases were common. So, there were a daily operative lists in the theatre including inguinal hernias. The present study was the first study that done at Baqubah Teaching Hospital. I would found that many surgeons in this hospital still use the non-mesh repair technique of inguinal hernia repair.

The policy of many surgeons was the routine use of non- mesh repair of inguinal hernia whereas the mesh repair technique done after taking the agreement of the patients before the surgical operation. Therefore, the present study aims at comparing mesh with non-mesh repair of inguinal hernias regarding:

- 1. Duration of surgery.
- 2. Development of early post-operative complications such as wound infection, hematoma and seroma formation.
- 3. Development of late post-operative complications such as persistent pain, testicular atrophy and recurrence of inguinal hernia.

Anatomic consideration

A useful learning tool for gaining a working knowledge of the inguinal region is to visualize the region as it is surgically approached in the open technique of hernia repair (Chung RS. et al, 1999).

The inguinal region is part of the anterolateral abdominal wall, which is made up of the following nine layers, from superficial to deep: skin, Camper's fascia, Scarpa's fascia,

external oblique aponeurosis, internal oblique muscle, transversus abdominis muscle, transversalis fascia, preperitoneal fat and the peritoneum (DeBord JR. et al, -2007).

The first layers encountered in the inguinal region upon dissection through the subcutaneous tissues are the Camper's and Scarpa's fasciae. Contained in this space are the superficial branches of the femoral vessels, namely, the superficial circumflex and the epigastric and external pudendal arteries, which can be safely ligated and divided when encountered (Delikoukos S. et al, 2008).

The inguinal canal can be visualized as a tunnel traveling from lateral to medial in an oblique fashion. It has a roof facing anteriorly, a floor facing posteriorly, a superior (cranial) wall, and an inferior (caudal) wall. The canal contents (in men, cord structures; in women, the round ligament) are the traffic that traverses the tunnel (Earle DB. et al, 2008).

Anatomy of the inguinal canal

The external oblique aponeurosis serves as the roof of the inguinal canal and opens just lateral to and above the pubic tubercle. This is the external or superficial inguinal ring, which allows the cord structures egress from the inguinal canal to the scrotum (Ferzli GS. et al, 2008).

The floor of the inguinal canal is composed of the transversus abdominis muscle and the transversalis fascia. The entrance to the inguinal canal is through these layers, and this entrance constitutes the internal or deep inguinal ring (Earle DB. et al, 2008).

The inferior wall of the inguinal canal is the inguinal (Poupart) ligament. This ligament is formed by the lower edge of the external oblique aponeurosis and extends from the anterior superior iliac spine to its attachments at the pubic tubercle and fans out to form the lacunar (Gimbernat) ligament. The inguinal ligament folds over itself to form the shelving edge. This folded-over sling of external oblique aponeurosis is the true lower wall of the inguinal canal (Fingerhut A. et al, 2006).

The superior wall of the inguinal canal consists of a union of the internal oblique muscle and transversus abdominis aponeurosis, which arches from its attachment at the lateral segment of the inguinal ligament over the internal inguinal ring, ending medially at the rectus sheath and coming together inferomedially to insert on the pubic tubercle, thus forming the conjoined tendon (Fitzgibbons RJ Jr. et al, 2006).

In males, the contents of the inguinal canal include the obliterated processus vaginalis (which, when patent, forms the sac of the indirect inguinal hernia), the spermatic cord, and the ilio-inguinal nerve (which comes out of the superficial inguinal ring along with the spermatic cord).

In females, the inguinal canal contains the ilio-inguinal nerve and the round ligament of the uterus (Earle DB. et al, 2008).

The coverings of the spermatic cord include the following: internal spermatic fascia, derived from the transversalis fascia at the deep inguinal ring. Cremaster muscle, derived from the internal oblique muscle at the deep inguinal ring. External spermatic fascia, derived from the external oblique aponeurosis at the superficial inguinal ring (Fingerhut A. et al, 2006).

The contents of the spermatic cord include the following: vas deferens, testicular artery, and artery of the ductus deferens, Cremasteric artery, pampiniform plexus, and genital branch of the genito-femoral nerve, para-sympathetic and sympathetic nerves and lymphatic vessels (Fitzgibbons RJ. et al, 2005).

The key nerves in the inguinal region are as follows: iliohypo- gastric nerve, ilio-inguinal nerve and genital branch of the genito-femoral nerve (Franklin ME Jr. et al, 2004).

Anatomy of nerves of groin

The ilio-inguinal nerve runs medially through the inguinal canal along with the cord structures traveling from the internal ring to the external ring. It innervates the upper and medial parts of the thigh, the anterior scrotum, and the base of the penis (Franklin ME Jr. et al, 2002).

The iliohypogastric nerve runs below the external oblique aponeurosis but cranial to the spermatic cord, then perforates the external oblique aponeurosis cranial to the superficial ring. It innervates the skin above the pubis (Franneby U. et al, 2006).

The genital branch of the genito-femoral nerve lies within the spermatic cord and travels with the Cremasteric vessels through the inguinal canal. It innervates the cremaster muscle and provides sensory innervation to the scrotum. Some variations in the anatomic distribution of these nerves may be observed, for instance, the occasional absence of an ilioinguinal nerve (Gianetta E. et al, 2000).

The Hesselbach triangle is bounded by the inguinal ligament below, the lateral border of the rectus abdominis medially, and the inferior epigastric vessels laterally. The sac of a direct hernia lies in this triangle, whereas the neck of an indirect hernia sac lies outside the triangle (lateral to the inferior epigastric vessels) (Grosz CR. et al, 2000).

Types of inguinal hernias

An indirect hernia is defined as a hernia protruding through the internal or deep inguinal ring, whereas a direct hernia is a hernia protruding through the posterior wall of the inguinal canal. To put it in a more anatomic way, an indirect hernia is lateral to the inferior epigastric artery and vein, whereas a direct hernia is medial to these vessels (Franneby U. et al, 2006).

The Hesselbach triangle is the zone of the inguinal floor through which direct hernias protrude, and its boundaries are the epigastric vessels laterally, the rectus sheath medially, and the inguinal ligament inferiorly (Gianetta E. et al, 2000).

An incomplete hernia is confined to the inguinal canal, while a complete hernia comes out of the inguinal canal through the external or superficial ring into the scrotum. Direct hernias are always incomplete, while indirect hernias can be complete (Haapaniemi S. et al, 2004).

A sliding inguinal hernia is one in which a portion of the wall of the hernia sac is made up of an intra-abdominal organ. As the peritoneum is stretched and pushed through the hernia defect and becomes the hernia sac, retroperitoneal structures such as the colon or bladder are dragged along with it and thus come to make up one of its walls (Hair A. et al, 2000).

Bilateral pediatric hernias are most commonly indirect hernias and arise because of the patency of the processus vaginalis. Simple ligation of the hernia sac (herniotomy) alone is enough (Haapaniemi S. et al, 2004).

Surgical treatment of indirect hernias in adults, unlike that in children, requires more than simple ligation of the hernia sac. This is because the patent processus is only part of the story. With time, the internal ring dilates, leaving an adult with what can be a sizable defect in the floor of the inguinal canal; this must be closed in addition to division or reduction of the indirect hernia sac (Hair A. et al, 2000).

Types of inguinal hernia repair

Inguinal hernia repairs may be divided into the following 3 general types: The first type is *Herniotomy* (removal of the hernial sac only): This is adequate for an indirect inguinal hernia in children in whom the abdominal wall muscles are normal; formal repair of the posterior wall of the inguinal canal is not required (Hakeem A. et al, 2011).

The second type is *Herniorrhaphy* (herniotomy plus repair of the posterior wall of the inguinal canal): This may be suitable for a small hernia in a young adult with good abdominal wall musculature; the Bassini's and Shouldice repairs are examples of herniorrhaphy (Hosgor M. et al, 2004).

The third type is *Hernioplasty* (herniotomy plus reinforcement of the posterior wall of the inguinal canal with a synthetic mesh): This is required for large hernias and hernias in middle aged and elderly patients with poor abdominal wall musculature; the Lichtenstein tension-free mesh repair is an example of hernioplasty (Hair A. et al, 2000).

Indications of inguinal hernia repair

Classically, the existence of an inguinal hernia, in itself, has been considered a reason enough for operative intervention. However, some studies have shown that the presence of a reducible hernia is not, in itself, an indication for surgery and that the risk of incarceration is less than 1% (Junge K. et al, 2001).

Symptomatic patients (with pain or discomfort) should undergo repair; however, as many as one third of patients with inguinal hernias are asymptomatic. The question of observation versus surgical intervention in this asymptomatic or minimally symptomatic population was addressed in two randomized clinical trials. The two trials yielded similar results: After long-term follow-up, no significant difference in hernia-related symptoms was noted, and watchful waiting did not increase the complication rate (Kark AE. et al, 1995).

In one study, the substantial patient crossover from the observation group to the surgery arm led the authors to conclude that observation may delay but not prevent surgery. This reasoning holds particularly true in the younger patient population. Thus, even an asymptomatic patient, if medically fit, should be offered surgical repair (Kristin Masukawa. et al, 2010).

A long-term follow-up study determined that most patients with a painless inguinal hernia will develop symptoms over time and concluded that surgery is recommended for medically fit patients (Junge K. et al, 2001).

Koch et al found that recurrence rates were higher in women and that recurrence was 10 times more likely to be of the femoral variety in women than it was in men. Such findings have led some to the conclusion that procedures providing coverage of the femoral space (e.g. laparoscopic repair) at the time of initial operation are better suited for women as primary repairs (Kark AE. et al, 1995).

Contraindications of inguinal hernia repair

Inguinal hernia repair has no absolute contraindications. Just as in any other elective surgical procedure, the patient must be medically optimized (Koch A. et al, 2005).

Any medical issues (e.g. Upper respiratory tract or skin infection, poorly controlled diabetes mellitus, chronic constipation, urinary obstruction, persisting cough, obstruction or strangulation, or allergy to local anesthesia or prosthetic devices) should be fully addressed and the operation delayed accordingly (Liem M.S. et al, 2003).

Patients with elevated American Society of Anesthesiologists (ASA) scores and high operative risk should undergo a full preoperative workup and determination of the risk to benefit ratio (Kark AE.et al, 1995).

Use of mesh for inguinal hernia repair

Emphasizing the Halstead principle of no tension, the Lichtenstein group advocated routine use of mesh in 1984. The prosthesis used to reinforce the weakened posterior wall of the inguinal canal is placed between the transversalis fascia and the external oblique aponeurosis and extends well beyond the Hesselbach triangle (Lichtenstein IL. et al, 1988).

Mesh implants do not actively shrink, but they are passively compressed by the natural process of wound healing. Mesh shrinkage occurs only to the extent to which the tissue contracts. A mesh with a small pore size is likely to shrink more (McCormack K. et al, 2003).

Shrinkage of the different types of mesh in vivo is in the range of (20-40%), thus, it is important for the surgeon to ensure that the mesh adequately overlaps the defect on all sides. It is advisable to use a large (e.g. 7.5×15cm) sheet of mesh extending approximately (2cm)

medial to the pubic tubercle,(3-4cm)above the Hesselbach triangle, and (5-6cm) lateral to the internal ring so as to allow for mesh shrinkage (Lichtenstein IL. et al, 1988).

Although the use of traditional microporous or heavyweight polypropylene meshes over the past 2 decades has reduced the recurrence rate after hernia surgery to less than 1%, a major concern has been the formation of a rigid scar plate that causes patient discomfort and chronic pain, impairing quality of life (Kark AE. et al, 1995).

More than 50% of patients with large mesh prosthesis in the abdominal wall complain of paresthesia, palpable stiff edges of the mesh, or physical restriction of abdominal wall mobility (Lichtenstein IL. et al, 1990).

It was assumed that the flexibility of the abdominal wall is restricted by implantation of excessive foreign material and by excessive scar tissue formation (McCormack K. et al, 2003).

A better knowledge of the biomechanics of the abdominal wall and the influence of mesh on those mechanics has led to the current understanding that "less is more". In other words, a less dense, lighter-weight mesh with larger pores, though still stronger than the abdominal wall and thus usable for the purposes of repair, will result in less inflammation, better incorporation, better abdominal wall compliance, greater abdominal wall flexibility, less pain, and possibly less scar contraction, therefore, its use will lead to a better clinical outcome (Liem MS. et al, 1997).

Lightweight composite mesh was developed in the conviction that the ideal mesh should be just strong enough to handle the pressure of the abdominal wall while remaining as low in mass and as thin as possible.

The advantage of increasing the mesh pore size is that it makes it easier for tissue to grow through the pores and thereby create a thinner, better-integrated scar (Malangoni MA. et al, 2007).

The newer lightweight composite meshes offer a combination of thinner filament size, larger pore size, reduced mass, and increased percentage of absorbable material. Thus, less foreign material is implanted, the scar tissue has greater flexibility (with almost physiologic

abdominal wall mobility), there are fewer patient complaints, and the patient's quality of life is better (Liem MS. et al, 1997).

The use of lightweight mesh for Lichtenstein hernia repair has not been shown to affect recurrence rates, but it has been found to improve some aspects of pain and discomfort 3 years after surgery. According to data from randomized, controlled trials and retrospective studies, light meshes seem to have some advantages with respect to post-operative pain and foreign body sensation (Milic DJ. et al, 2003).

Many manufacturers have now shifted toward lighter, more porous constructions that maintain the strength of the repair but putatively reduce the inflammatory response. These meshes may decrease long-term discomfort, but possibly at the cost of increased recurrence rates (e.g. from inadequate fixation or overlap) (Nordin P. et al, 2002).

The question of absorbable versus permanent sutures to secure the mesh is based on surgeon preference; to date, there has been no evidence conclusively favoring one type over the other. Sutures made of polyglactin (Vicryl) or polypropylene are commonly used, with undyed polyglactin often preferred for subcutaneous tissue. Theoretical advantage of absorbable suture is that if nerve impingement is inadvertently caused, the suture material disappears with time (Milic DJ. et al, 2003).

Intra-operative planning

For better hemostasis, sharp dissection is preferred to blunt dissection. This is one operation in which every red blood cell must be caught. If a lipoma is present in the spermatic cord, it should be excised to reduce the bulk of the cord (Nordin P. et al, 2002).

Some surgeons excise the cremaster muscle fibers in the cord; others prefer not to. With a direct hernia, the sac is not dissected and opened, as is done with an indirect inguinal hernia. Rather, it is inverted (pushed back) into the extraperitoneal space, sometimes with plication of the transversalis fascia (Malangoni MA. et al, 2007).

Bilateral hernias can be repaired in a single procedure, especially with a Lichtenstein tension-free mesh hernioplasty. Some surgeons, however, prefer to repair only one hernia at a time, deferring repair of the other for about (4-6 weeks); this avoids the risk of bilateral infection and the higher risk of penile and scrotal edema after bilateral inguinal hernia repair (Sanabria A. et al, 2007).

If the inguinal hernia is irreducible or obstructed, the sac should be opened first at its fundus, before it is dissected up to its neck, to allow evacuation of toxic fluid and inspection of the bowel for ischemia. If the conventional technique, in which the sac is first completely dissected up to its neck, is followed, the ischemic bowel may slip back into the peritoneal cavity before the sac is opened at its fundus and may then be difficult to retrieve for inspection (Taylor EW. et al, 2004).

Ischemic bowel is blue-black and thick-walled, lacks luster, feels firm to the touch, and has no peristalsis. The bowel must be wrapped in moist warm packs, and 100% oxygen should be delivered for a few minutes. The bowel is then reassessed for viability. Any non-viable bowel will have to be resected (Akyol C. et al, 2013).

Equipments

Standard operating room anesthesia equipment, outfitted for possible conversion to general anesthesia and endotracheal intubation, is required. Inguinal hernia repair can be achieved under local infiltration or field block and regional block spinal or epidural anesthesia (Terzi C. et al, 2006).

Instruments and materials on hand may include the following: syringe, 25-Gauge needle, surgical knife with blade, Mosquito forceps, dissecting scissors, polypropylene (Prolene) or polyester mesh, Langenbeck retractors, Adson thumb forceps, needle holder, sutures (absorbable or non- absorbable), Penrose drain or umbilical tape and non-crushing intestinal clamps (in case bowel resection is required, in a strangulated hernia) (Bay-Nielsen M, et al, 2004).

The umbilical tape or Penrose drain may be used to retract the mobilized spermatic cord, but a hernia ring forceps can also be used. If the neck of the hernia sac is particularly tight, the use of a grooved probe or dissector may help minimize injury to the contents (Albo D. et al, 2006).

Monitoring and Follow-up

With the routine use of mesh for hernia surgery, the recurrence rate has fallen to less than 1%. Although some recurrences occur early, cases may be reported many years later. Thorough clinical evaluation, a high degree of suspicion, and appropriate follow-up are advised for keeping track of recurrences. A follow-up visit is routinely scheduled for 1 week

after the procedure. Thereafter, follow-up is scheduled on an as-needed basis (Amid PK. et al, 2007).

Although the post-operative course is generally uncomplicated, patients must be routinely instructed to recognize certain signs and symptoms that can alert them to potential complications. Patients with chronic groin pain, post-operative neuralgia, paresthesia, neurapraxia, or hypoesthesia for more than six months after surgery should be referred for further evaluation, surgical exploration, and, if required, excision of the involved nerve (Albo D. et al, 2006).

A multidisciplinary approach at a pain clinic is an option for the treatment of chronic post-herniorrhaphy pain. Surgical means of treating specific causes of such pain include the following: resection of entrapped nerves, mesh removal (in mesh-related pain), removal of fixating sutures and burying the nerve endings in the internal oblique muscle (Franklin ME Jr. et al, 2002).

Large-scale studies examining the convalescence period after elective inguinal hernia repair convincingly demonstrated that the median length of absence from work was seven days when patients were advised by their surgeons to limit the recuperation period and to resume normal activities within one day after the procedure. Moreover, these studies confirmed that the risk of recurrence was not increased by early resumption of activities. Thus, with adequate analgesia, patients can safely return to their daily duties (Bringman S. et al, 2006).

Approach considerations

Open inguinal hernia repairs other than Lichtenstein hernioplasty are not merely of historical interest. Surgeons must know and understand these repairs so that they can be carried out when they are appropriate. Specifically, cases that involve a contaminated field (eg, necrotic or perforated bowel secondary to hernia strangulation) are not amenable to prosthetic repair. In such cases, either a primary tissue repair or a biologic implant repair is necessary (Albo D. et al, 2006).

Lichtenstein tension-free mesh repair

Incision

The incision is placed about 1 cm above and parallel to the inguinal ligament, beginning from the pubic tubercle and extending (5-6cm) laterally up to the mid-inguinal point. The

subcutaneous fat is then opened along the length of the incision, and careful hemostasis is achieved by ligating superficial pudendal and superficial epigastric vessels (Hakeem A. et al, 2011).

The Scarpa's fascia is similarly opened along the length of the incision, down to the external oblique aponeurosis, and the external inguinal ring and the lower border of the inguinal ligament are visualized. Although the risk is very low, routine exploration of the femoral canal is advised in the absence of an inguinal hernia and in women. The external oblique aponeurosis is then opened along the line of incision, starting from the external ring and extending laterally for up to (5cm). The ilio-inguinal nerve, lying underneath the aponeurosis, is safeguarded during this procedure (Chastan P. et al, 2009).

The superior and inferior flaps of the external oblique aponeurosis are gently freed from the underlying contents of the inguinal canal and overturned and separated to expose the cremaster with the cord structures, the ilioinguinal and iliohypogastric nerves, the uppermost aponeurotic portion of the internal oblique muscle and conjoined tendon, and the free lower border of the inguinal ligament. Wide separation of the two flaps provides ample space for placement and fixation of mesh under vision while protecting the nerves (Hakeem A. et al, 2011).

Dissection of the spermatic cord

The spermatic cord, along with the cremaster, is then lifted up and separated from the pubic bone for about (2cm) beyond the pubic tubercle to create space for extending the mesh well beyond the pubic tubercle. When lifting the cord, the surgeon must be sure to include the ilioinguinal nerve, the genito-femoral nerve, and the spermatic vessels along with it. All of these structures may then be encircled in a tape for ease of handling (Liem MS. et al, 1997).

The anatomic plane between the cremaster and the aponeurotic tissue attached to the pubic bone is avascular, and cord structures encircled in the tape can be separated from the floor of the inguinal canal up to the internal ring (Chastan P. et al, 2009).

A visible landmark for safeguarding the genito-femoral nerve is the external spermatic vein, usually referred to as the "blue line". If the blue line is kept with the spermatic cord, the surgeon can be sure that the genital branch of the genito-femoral nerve, which is always adjacent to this vein, is well protected (Nathan JD. et al, 2003).

Identification and management of the hernial sac

The cord structures and all of the nerves of the inguinal canal having been visualized, the next step is to identify and isolate the hernia sac. The patient is asked to cough (if the procedure undertaken under local or regional anesthesia), and the groin region is examined for the presence of an indirect hernia, a direct hernia, a femoral hernia, a combined hernia, or a spigelian hernia (McCormack K. et al, 2003).

A hernia sac can be managed by means of inversion, division, resection, or ligation. Resection and ligation of a small hernia sac should not be performed unnecessarily, because it causes post-operative pain. However, the hernia sac must be well separated from the internal ring before it is invaginated (Chastan P. et al, 2009).

The risk of recurrence is not increased when a small or medium-sized indirect hernia sac is not ligated. Excision of an indirect inguinal hernia sac is associated with a lower risk of hernia recurrence than is division or invagination (Hair A. et al, 2000).

When the hernia sac is excised or divided, the proximal sac should never be left open; doing so may lead to recurrence (McCormack K. et al, 2003).

The proximal sac is dissected free of cord structures well above the internal ring, and a high ligation of the neck of the sac should be performed. The indirect hernia sac lies anterolateral to the cord structures and is visualized by dividing the cremaster muscle longitudinally. The cremaster muscle should not be divided transversely or excised, because doing so may result in low-lying testes and dysejaculation (Hakeem A. et al, 2011).

The neck of a large hernia sac is transected at the midpoint of the inguinal canal, and the proximal part is suture ligated. A high ligation of the proximal sac is recommended, and the stump is reduced deep underneath the internal ring. The distal sac is left in place; however, the anterior wall of the distal sac is incised to prevent post-operative hydrocele formation (Nathan JD. et al, 2003).

A direct inguinal hernia lies posteromedial to the cord structures. The direct hernia sac is isolated and dissected free. Its contents are reduced, and the peritoneal sac is inverted and maintained in position with a purse-string suture. If a femoral hernia is suspected, the femoral ring should be evaluated by incising the medial part of the iliopubic tract. If a sac is seen entering the femoral ring, it is reduced and dealt with by inverting or ligating the neck of the

sac. Sliding hernia is simply dissected free and inverted in the preperitoneal space (Vale L.et al, 2004).

Placement and fixation of the mesh

A (7.5×15cm) piece of polypropylene mesh is commonly used for a Lichtenstein hernioplasty. On the medial side, the sharp corners of the mesh are trimmed to conform to the patient's anatomy. For a femoral hernia, the mesh is tailored so that it has a triangular extension from its lower edge on its medial side (Milic DJ. et al, 2003).

To compensate for future shrinkage, the mesh should be wide enough to extend (3-4cm) beyond the boundary of the inguinal triangle. To compensate for increased intra-abdominal pressure when the patient stands up, the mesh should be placed lax in the posterior wall of the inguinal canal in such a way that it acquires a domelike wrinkle. The first medial most stitch fixes the mesh (2cm) medial to the pubic tubercle, where the anterior rectus sheath inserts into the pubic bone (Nathan JD. et al, 2003).

Care should be taken not to pass the needle through the periosteum of the bone or through the pubic tubercle; this is one of the most common causes of chronic postoperative pain. The same suture is then used as a continuous suture to fix the lower edge of the mesh to the free lower border of inguinal ligament up to a point just lateral to the internal ring. Next, a slit is made in the lateral end of the mesh to create a narrower lower tail (the lower one third) and a wider upper tail (the upper two thirds). The slit extends up to a point just medial to the internal inguinal ring. Lower edge of mesh sutured to inguinal ligament up to internal inguinal ring (Milic DJ. et al, 2003).

To accommodate cord structures, lateral end of mesh is divided into wider upper (two thirds) tail and narrower lower (one third) tail. The upper tail is then passed underneath the cord in such a way as to position the mesh posterior to the cord in the inguinal canal, and the spermatic cord is placed between the two tails of the mesh. The upper tail is then crossed over the lower one, and the two tails are held in an artery forceps. With the mesh kept lax, its upper edge is then fixed to the rectus sheath and the internal oblique aponeurosis with 2 or 3 interrupted non-absorbable sutures (Nilsson H. et al, 2007).

On occasion, the iliohypogastric nerve is found to be in the way of upper edge of the mesh. In such cases, the mesh may be split to accommodate the nerve. The two tails are then tucked

together and fixed to the inguinal ligament just lateral to the internal ring, thus creating a new internal ring made of mesh. The tails are trimmed (5cm) beyond the internal ring and placed underneath the external oblique aponeurosis (Nordin P. et al, 2003).

Suturing the mesh beyond the internal ring is unnecessary; doing so may cause injury to the femoral nerve. Similarly, fixation of the tails of the mesh to the internal oblique muscle, lateral to the internal ring, may cause entrapment of the ilio-inguinal nerve. Trying to suture the two tails without crossing them or trimming the tails shorter than (5-6cm) beyond the internal ring may result in recurrence at the deep inguinal ring (Nathan JD. et al, 2003).

If any of the inguinal nerves is injured or of doubtful integrity, it can be resected and its proximal end ligated and buried within the fibers of the internal oblique muscle to keep the stump of the nerve away from scarring. In male patients, the testes should always be gently pulled back down to their normal scrotal position after fixation of the mesh (Nilsson H. et al, 2007).

Closure

Hemostasis is ensured in the inguinal canal, which is then closed by suturing the two flaps of the external oblique aponeurosis, with care taken not to injure the underlying ilioinguinal nerve (Nordin P. et al, 2003).

Suturing is started laterally and continued medially, where an adequate opening is left at the newly created superficial inguinal ring so as not to occlude the emerging spermatic cord. Subcutaneous tissue is approximated with interrupted sutures to obliterate any dead space, and the skin is approximated with sutures, clips, or adhesive strips (Norrie J. et al, 2010).

A subcuticular continuous stitch with (3-0) absorbable sutures obviates any need for stitch or clip removal and provides better cosmetic results. The operative site is cleaned and a sterile dressing applied. Local infiltration of a long-acting anesthetic agent (e.g. bupivacaine or ropivacaine) into the subcutaneous tissue around the incision provides good immediate postoperative pain relief (O'Dwyer PJ. et al, 2005).

Plug-and-patch repair

The plug-and-patch repair adds a polypropylene plug shaped as a cone, which can be deployed into the internal ring after reduction of an indirect sac. The plug then acts as a toggle bolt to reinforce the defect (Milic DJ. et al., 2003).

McVay repair

In the McVay repair the conjoined tendon is sutured to the inguinal ligament with interrupted non-absorbable sutures (Nordin P. et al, 2002).

Bassini's repair

The Bassini's technique for inguinal hernia repair involves suturing the transversalis fascia and the conjoined (transversus abdominis and internal oblique) tendon to the inguinal ligament behind the spermatic cord with monofilament non-absorbable suture. It also involves the so-called Tanner slide, which is a vertical relaxing incision in the anterior rectus sheath intended to prevent tension (O'Dwyer PJ. et al, 2006).

Shouldice repair

The Shouldice technique is a 4-layer inguinal hernia repair performed with the patient under local anesthesia. The transversalis fascia is incised from the internal ring laterally to the pubic tubercle medially, and upper and lower flaps are created. These flaps are then overlapped (double-breasted) with two layers of sutures. The conjoined tendon is then sutured to the inguinal ligament, again in two overlapping layers. This reinforces the posterior wall and narrows the deep inguinal ring. The Shouldice repair is classically done with a continuous suture of (32-34 gauge) stainless steel wire, but synthetic monofilaments (e.g. polypropylene) can also be used. The external oblique aponeurosis is then closed in a double-breasted fashion in front of the spermatic cord (Parviz K. et al, 2003).

Darn repair

A pure-tissue tensionless technique that is performed by placing a continuous suture in zigzag way between the conjoined tendon and the inguinal ligament without approximating the two structures (Paajanen H. et al, 2010).

Post-operative Care

Early mobilization is the key to rapid convalescence. Patients can safely ambulate on the evening of the operation. If general or regional anesthesia is used, the patient may be hospitalized for a few days. There is some pain in the post-operative period, and suitable analgesics should be prescribed. The dressing is removed on post-operative day 5, and stitches are removed on post-operative day 7 (Scott NW. et al, 2002).

Patients should be advised to avoid strenuous activities for a few weeks. Typically, light work can be resumed after one week, heavier jobs after six weeks. Male patients should be monitored for testicular atrophy, which may occur as a result of venous or arterial injury or obstruction in the spermatic cord (Parviz K. et al, 2003).

All patients should be monitored for the development of nerve pain from nerve entrapment in suture material. Finally, patients should be monitored for recurrence, which may arise as a consequence of inadequate repair, wound infection and chronic straining (e.g. From coughing, constipation, or urination) (Sanders DL. et al, 2013).

Complications of inguinal hernia

Intra-operative complications

1. Vascular injuries

Superficial epigastric vessels in the incision may bleed. These vessels not only should be identified when the incision is being made but also should be ligated and divided. Inferior epigastric vessels may be injured during dissection of the spermatic cord in the inguinal canal, dissection of an indirect inguinal hernia sac within the spermatic cord, plication of the transversalis fascia, or transfixion of the hernial sac. These vessels should be identified at an early stage and protected (Shamberger RC.et al, 1984).

External iliac or femoral vessels, especially veins, may be injured during fixation of the mesh to the inguinal ligament in its lateral part. The tissue bites in the inguinal ligament should not be very deep. Although less common than other intraoperative complications, vascular injuries are potentially disastrous. They can be avoided by respecting the proximity of the femoral vessels, particularly when suturing the mesh to the inguinal ligament (Shankar VG. et al, 2010).

Hematoma formation can result from injury of the inferior epigastric vessels or pampiniform plexus veins or from failure to ligate the superficial subcutaneous veins (Sanabria A. et al, 2007).

2. Injuries to abdomino-pelvic structures

Cord structures (e.g. testicular artery, pampiniform plexus of veins, and vas deferens) may be injured during opening of the coverings of the spermatic cord or dissection of the indirect

hernial sac within the spermatic cord. In particular, the surgeon should always be aware of the vas deferens and should protect it from injury (Scott NW. et al, 2002).

Injury to the urinary bladder may occur during plication of the transversalis fascia. In addition, injury to the urinary bladder, cecum, or sigmoid colon may occur during transfixion of the hernial sac in a sliding indirect inguinal hernia (where these viscera are not contained in the hernial sac but form a part of the wall of the sac) (Sanchez-Manuel FJ. et al, 2007).

A sliding hernia should be recognized early; if it is present, the entire hernial sac should not be excised. Injury to the bowel may occur during transfixion of the neck of an indirect hernial sac. The head end of the operating table can be lowered to ensure complete reduction of contents of the sac, the sac can be twisted to push the contents into the peritoneal cavity, and a tissue bite can be taken and the suture tied under vision (Simons MP. et al, 2009).

3. Nerve injuries

The ilio-hypogastric nerve, because it lies on the conjoined tendon outside the inguinal canal, may be injured during dissection of the upper flap of the external oblique aponeurosis or fixation of the mesh to the conjoined tendon. It may also become trapped in sutures during closure of the external oblique aponeurosis (Starling JR.et al, 1989).

The ilioinguinal nerve, because it lies in the inguinal canal along with the spermatic cord, may be injured during dissection of the cord. The genital branch of the genito-femoral nerve, because it lies within the spermatic cord, may be injured during dissection of the hernia sac (Milic DJ. et al, 2003).

Post-operative complications

1. Wound infection

Deep and persistent infection may necessitate removal of the mesh. Wound infection can also weaken the repair and may be responsible for recurrence of the inguinal hernia (Stylianidis G. et al, 2010).

2. Pain

Post-operative chronic pain is more frequent than was previously understood and has become one of the most important primary endpoints in hernia surgery. In published reports, the incidence of postherniorrhaphy pain has ranged from 0% to more than 30% (Taylor EW. et al, 2004).

Chronic inguinodynia is defined as pain persisting more than 3 months post herniorrhaphy, after the process of wound healing is complete. On-fixation or inadequate mesh fixation results in folding and rolling of the mesh, which can cause chronic pain and recurrence of the inguinal hernia (Terzi C, et al, 2006).

Chronic pain after mesh hernioplasty also results from neuroma formation after accidental division of the nerves. The ilio-inguinal, ilio-hypogastric, and genito-femoral nerves are visualized and protected throughout the operation. They should not be dissected free from their natural bed; doing so can lead to perineural fibrosis and chronic pain postoperatively (Vale L. et al, 2004).

Deliberate sectioning of the nerves intra-operatively to prevent chronic groin pain has been described but is still controversial. Current recommendations consist of nerve identification, minimal handling, and preservation. Prevention of nerve injury is very important because treatment of chronic neuralgias may not be successful. Entrapment of a nerve by suture or mesh appears to be an important cause of postoperative pain. The groin nerves should be identified and protected (Van Veen RN. et al, 2008).

Fibrin or biologic glues may be used instead of sutures to secure the mesh. It appears that cyanoacrylate glue may be a viable alternative to sutures, and it is anticipated that the use of fewer sutures may be associated with less inguinodynia. Another cause of significant post-herniorrhaphy pain is the placement of a stitch into the periosteum at the pubic tubercle for fixation of the mesh medially. This is often the point of maximal tenderness post-operatively. Therefore, one should avoid taking a deep bite through the periosteum of the pubic tubercle; tough, fibrous tissue in that region should instead be used for fixing the mesh (Stylianidis G. et al, 2010).

The use of a low-density macroporous mesh with semi-resorbable, self-fixing properties during tension-free repair may be a satisfactory solution to the clinical problems of pain and recurrence after inguinal herniorrhaphy (Van Veen RN. et al, 2007).

3. Recurrence

The recurrence rate for Lichtenstein hernioplasty at specialist clinics in the United States is consistently less than 1%. In an audit of Lichtenstein hernioplasty performed with local

anesthesia by surgical residents, the recurrence rate was 2.1% over a ten years follow-up period (Weyhe D. et al, 2007).

Recurrence in Lichtenstein hernioplasty may be due to inaccurate execution of the technique (inadequate size or improper fixation of the mesh) or to an overlooked hernia at the primary operation. To avoid the latter, the patient should be asked to cough, and the region should be carefully examined for an indirect hernia, a direct hernia, a femoral hernia, or a combined hernia (Wiese M. et al, 2010).

Recurrence may be more frequent in the presence of comorbid conditions such as chronic obstructive pulmonary disease, obesity and the use of steroids. Other contributing factors may be the use of too small pieces of mesh placed flat under tension, failure to achieve adequate overlap [medially,(2cm) beyond the pubic tubercle; laterally,(5-6cm) beyond the internal ring], or failure to cross the tails of the mesh (Wijsmuller AR. et al, 2007).

A thorough clinical evaluation, a high degree of suspicion, and diligent follow-up are advised to keep track of recurrences. Women, because of the higher frequency of femoral hernias, are at greater risk for recurrence (inguinal or femoral) after an open inguinal hernia operation than men are. In female patients, the existence of a femoral hernia should always be excluded by exposing the femoral canal (Liem MS. et al, 1997).

4. Seroma and Hematoma

Most seromas disappear spontaneously within (6-8weeks). If a seroma persists, it may be aspirated. A small hematoma may be treated conservatively. For larger hematomas, which are asymptomatic, evacuation under anesthesia should be considered. Meticulous dissection with adequate hemostasis will reduce the incidence of seroma and hematoma formation (Woods B. et al, 2008).

5. Ischemic orchitis and thrombosis

Ischemic orchitis leading to testicular atrophy is a rare but well-known complication of inguinal hernia surgery. The patient may complain of pain and testicular swelling post-operatively. Symptoms may last for 2-3 months, and testicular atrophy may occur. The rarity of this complication notwithstanding, the surgeon should maintain a high index of suspicion. Testicular ultrasonography and Doppler studies may facilitate early diagnosis and help avoid orchiectomy (Zhao G. et al, 2009).

Ischemic orchitis is thought to be secondary to venous thrombosis rather than arterial injury. Thrombosis is caused by surgical trauma to the delicate veins of the pampiniform plexus and disruption of the collateral blood supply to the testes during an attempt at complete removal of a large hernia sac. It is also more likely in operations for recurrent hernia. It is thus advisable not to attempt complete dissection and excision of a large hernia sac. The neck of the hernia sac is transected at the midpoint of the inguinal canal, and the distal sac is left in place; however, the anterior wall of the distal sac is incised to prevent post-operative hydrocele (Scott NW. et al, 2002).

MATERIALS AND METHODS

This is a prospective study for **200** patients underwent surgeries for inguinal hernias at Baqubah Teaching Hospital. There were 192 (96%) male patients and 8 (4%) female patients. The surgeries were done over a period of 2 months (October–November 2013) in the department of general surgery at Baqubah Teaching Hospital and followed for 10 months in outpatient clinic and by personal communications (by phoning them) during period of follow up.

The patients are categorized into two groups according to policy of the surgeons: **group 1** composed of **100** patients named the mesh group (the male patients were 96 and female patients were 4) as they included (Lichtenstein mesh repair) for their hernias and **group 2** which also composed of **100** patients, named the non-mesh group (also the male patients were 96 and female patients were 4) in which their hernias are repaired using the (modified Bassini's repair) or (Darn repair).

The age range of the patients was (16-63 years) for group 1 and (16-70 years) for group 2. The surgeries were randomly performed by senior surgeons. The policy of many surgeons was routine use of non- mesh repair of inguinal hernia whereas the mesh repair technique done after taking the agreement of the patients before the surgical operation.

The two groups were compared regarding development of many post-operative complications: Early post-operative complications such as (wound infection, hematoma and seroma formation) and late post-operative complications such as (persistent pain, testicular atrophy and recurrence of inguinal hernia) as shown in (Figure-2) and (Table-2). They are also compared regarding the duration of surgery (Figure-3) and (Table-3).

The following patients are excluded from our study:

- 1. Patients under age of sixteen years old.
- 2. Patients who refuse the mesh repair.
- 3. Patients with contraindication to mesh repair such as strangulated inguinal hernia due to higher risk of infection.

In the **Lichtenstein mesh repair** a (7.5×15cm) piece of poly- propylene mesh is commonly used for a Lichtenstein hernioplasty. On the medial side, the sharp corners of the mesh are trimmed to conform to the patient's anatomy. To compensate for future shrinkage, the mesh kept wide enough to extend (3-4cm) beyond the boundary of the inguinal triangle.

The first medial most stitch fixes the mesh (2cm) medial to the pubic tubercle, where the anterior rectus sheath inserts into the pubic bone. The same suture is then used as a continuous suture to fix the lower edge of the mesh to the free lower border of inguinal ligament up to a point just lateral to the internal ring. Next, a slit is made in the lateral end of the mesh to create a narrower lower tail (the lower one third) and a wider upper tail (the upper two thirds). The slit extends up to a point just medial to the internal inguinal ring. Lower edge of mesh sutured to inguinal ligament up to internal inguinal ring.

To accommodate cord structures, lateral end of mesh is divided into wider upper (two thirds) tail and narrower lower (one third) tail. The upper tail is then passed underneath the cord in such a way as to position the mesh posterior to the cord in the inguinal canal, and the spermatic cord is placed between the two tails of the mesh.

The upper tail is then crossed over the lower one, and the two tails are held in an artery forceps. With the mesh kept lax, its upper edge is then fixed to the rectus sheath and the internal oblique aponeurosis (conjoint tendon) with 2 or 3 interrupted non-absorbable sutures. On occasion, the iliohypogastric nerve is found to be in the way of upper edge of the mesh. In such cases, the mesh may be split to accommodate the nerves. The two tails are then tucked together and fixed to the inguinal ligament just lateral to the internal ring, thus creating a new internal ring made of mesh. The tails are trimmed (5cm) beyond the internal ring and placed underneath the external oblique aponeurosis.

The **non-mesh repair** involve either (modified Bassini's repair) or (Darn repair). The *Bassini's technique* for inguinal hernia repair involves suturing the transversalis fascia and the

conjoined (transversus abdominis and internal oblique) tendon to the inguinal ligament behind the spermatic cord with monofilament nonabsorbable suture. It also involves the so-called Tanner slide, which is a vertical relaxing incision in the anterior rectus sheath intended to prevent tension. *Darn technique* for inguinal hernia repair performed by placing a continuous suture in zigzag way between the conjoined tendon and the inguinal ligament without approximating the two structures.

Statistical Methodology

Statistical data analysis was done using a computer, EP16 info, adopted by WHO and SPSS 7.5 (statistical analysis packages for social sciences version 7). The results were presented in single measures for frequency, percentage, mean and standard deviation. Chi-square test is used to test the significant difference between the proportions. P-value of equal or less than (0.05) was considered as the level of significance.

RESULTS

In this study (200) patients were evaluated, the age range was (16-63 years) for group 1 and (16-70 years) for group 2 as shown in (table-1). There were 192 (96%) male patients and 8 (4%) female patients and different types of inguinal hernias were operated as shown in (figure-1). The P-value is considered significant if it is less than (0.05) and non-significant if it is larger than (0.05). I would like to emphasis that the study needs more time of follow up regarding the development of post-operative persistent pain and recurrence of inguinal hernias.

Early post-operative complications

1. Wound infection

Three patients (3%) in group 1 developed postoperative superficial wound infection in form of minor redness of skin edge and clear serous discharge that treated conservatively by antibiotics and two patients (2%) in group 2 as shown in (table-2) and (Figure-2) developed post-operative deep wound infection in form of pus discharge and partially opened wound treated by daily dressing and antibiotics.

2. Wound hematoma

Two (2%) patients in group 1 and one (1%) patient in group 2 as shown in (table-2) and (Figure-2) developed post-operative wound hematoma and treated conservatively by analgesics and antibiotics.

3. Wound seroma

One (1%) patient from each group developed post-operative wound seroma as shown in (table-2) and (Figure-2) and also treated conservatively by follow up only.

Late post-operative complications

1. Persistent of pain

Two (2%) patients in group 1 developed post-operative persistent pain in comparison to five (5%) patients in group 2 developed this complication as shown in (table-2) and (Figure-2).

2. Recurrence of inguinal hernia

Two (2%) patients in group 1 developed post-operative recurrence of inguinal hernia in comparison to five (5%) patients in group 2 developed this complication as shown in (table-2) and (Figure-2).

3. Testicular atrophy

There were no reported cases in both groups of patients regarding this post-operative complication in this study as shown in (table-2) and (Figure-2).

Therefore, regarding the development of early post-operative complications, the results were not significantly different-value (>0.05) which is statistically insignificant, whereas regarding the development of late post-operative complications especially the persistent pain and recurrence of inguinal hernias, the results were significant. P-value (<0.05) which is statistically significant. There were more cases in the non-mesh group, the P-value was (0.030) (table-2).

Operative time

They are also compared regarding the duration of surgery: as shown in (Table-3) and (figure-3), the mean operative time was 30.4 minute in group 1 in comparison to 50.4 minute in group 2. The operative time was calculated from the moment of the first incision to the end of the last suture. So, the operative time in group 2 is longer than the operative time in group 1. P-value (>0.05) and so the difference is statistically insignificant.

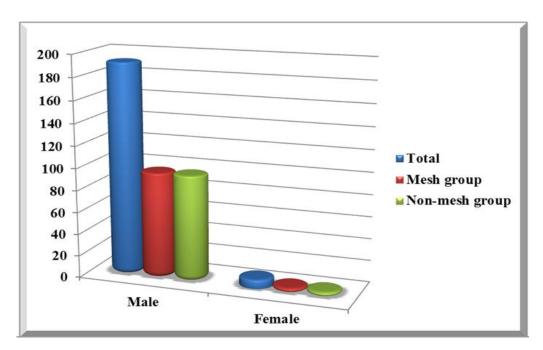


Figure 1: Shows the sex in both groups of the patients. The total number of male patients was (192) and (8) were female patients (blue columns). In each group, the male were 96 and the female were 4 patients (red and green columns).

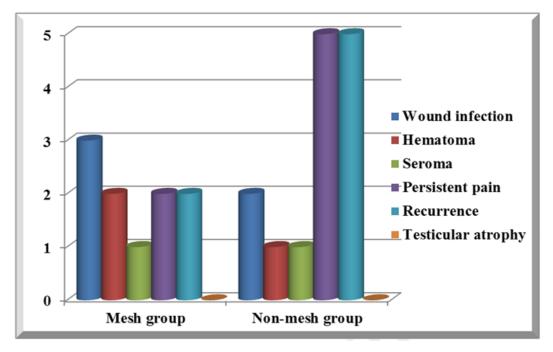


Figure 2: Shows the comparison of the post-operative complications (early and late) in both groups of the patients (mesh and non-mesh repair of inguinal hernia).

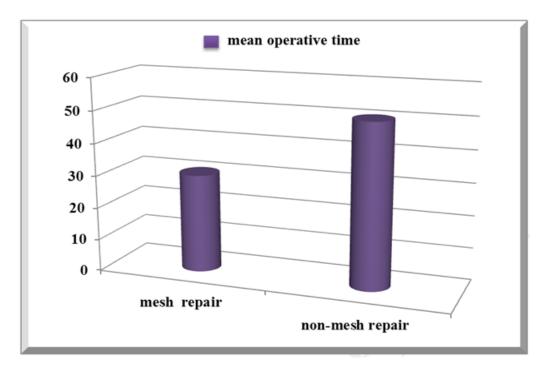


Figure 3: Shows the comparison of the mean operative time (minute) in two groups of patients (mesh and non-mesh repair of inguinal hernia).

Table 1: Shows the distribution of variables.

Variable		Group 1 (mesh group)	Group 2 (non-mesh group)
Number of patients (n)		100	100
Age range		16 -63 years	16-70 years
Gender n (%)	Male	96 (96%)	96 (96%)
	Female	4 (4%)	4 (4%)
Type of inguinal hernia	Indirect	66 (66%)	63 (63%)
n (%)	Direct	34 (34%)	37 (37%)

Table 2: Comparison of postoperative complications in two groups of patients (n=number of patient).

Early postoperative Complications:	Group I (Lichtenstein's Mesh Repair) n =100, n (%)	Group II (Modified Bassini's Suture Repair) n =100, n (%)	P-value
Wound Infection	3 (3%)	2 (2%)	0.067
Hematoma	2 (2%)	1 (1%)	0.073
Seroma	1 (1%)	1 (1%)	1
Late postoperative complications:			
Persistent pain	2 (2%)	5 (5%)	0.030
Testicular Atrophy	0	0	-
Recurrence of hernia	2 (2%)	5 (5%)	0.030

Table 3: The Mean Operative Time in both groups of patients (mesh and non-mesh repair of inguinal hernia).

Variable	Group 1 (Mesh Repair)	Group 2 (Non-mesh Repair)	P-value
Mean operative time (minute)	30.4	50.4	> 0.05

DISCUSSION

Tissue based suture repair by different techniques (Bassini's, Shouldice etc.) has remained conventional surgical treatment of inguinal hernia. These techniques shared many things in common such as excessive tension on the suture line as well as the neighboring tissues, a lot of dissection, trauma and undue operative time. These factors were found to be responsible for a number of recurrences, persistent pain after surgery and morbidity leading to an undue economical burden on the patient. This led to the introduction of mesh repair in the late's 1980 with the concept of tension free repair of hernias. Since then a number of studies have claimed improved results with mesh repair in terms of recurrence of hernia (Amid PK. et al, 2002).

This study compares and demonstrates the efficacy of non-mesh (Bassini's) and mesh (Lichtenstein) repair. The two groups were compared regarding the duration of surgery, development of early post-operative complications such as (wound infection, hematoma and seroma formation) and development of late post-operative complications such as (persistent pain, testicular atrophy and recurrence of inguinal hernia).

Our study demonstrated that the tension-free mesh repair of inguinal hernia offer a significant benefit over non mesh repair especially regarding post-operative persistent pain and recurrence of inguinal hernia, P-value was (<0.05).

In our study, the gender distribution in the two groups of patients was 192(96%) male patients and 8(4%) female patients. There were (96) male and (4) female in each group of patients. These finding are agree with Arkan A. Al-Ogaili et al. (2009). In this study also the male patients were found in majority which clarifies that the inguinal hernias are common in males.

Another study done by Malik AM. Et al. (2007), also found an increase incidence of male patients in the inguinal hernias.

About characteristic of hernia, there were 66 patient indirect inguinal hernia in group 1 and 63 patient in group 2 whereas 34 patient direct inguinal hernia in group 1 and 37 patient in group 2. These finding are agree with Parviz K. Amid (2003). In this study, also the indirect inguinal hernias are more common than direct inguinal hernia in both groups of patients.

Regarding post-operative wound infection, our study resulted in three patients (3%) in group I and two patients (2%) in group II. P-value (> 0.05) which is statistically insignificant. This is agreeing with the results of the study done by Grant Am. (2005).

Also these results are agreed with study done by Scott et. al, (2002). This study was showed that the rate of infection is more with mesh repair group of the patients which is similar to our study.

Regarding post-operative wound seroma, there were one (1%) patient from each group developed this complication. P-value (> 0.05) which is statistically insignificant. This result is in agreement with Arkan A. Al-Ogaili et al. (2009).

Regarding post-operative wound hematoma, there were two (2%) patients in group I and one (1%) patient in group II developed this complication. P-value (> 0.05) which is statistically insignificant. Also this result is agreed with Arkan A. Al-Ogaili et al. (2009).

As shown from our result in (figure-2) and (table-2) that two (2%) patients in group I developed post-operative persistent pain in comparison to five (5%) patients in group II developed this complication-value was (<0.05) which is statistically significant. This result is agreed with A.E. Kirk et al. (1995). A study done by Kristin and Masukawa et al. (2010) also shows a similar result.

Recurrence is a major problem encountered by the surgeons. Tension is a cardinal factor in the failure of a hernia repair. Tissue sutured under tension will tend to pull apart and the suture creates an area of ischemic necrosis. (Liem M.S. et al. 2003).

In our study, two (2%) patients in group I developed post-operative recurrence in comparison to five (5%) patients in group II developed this complication. P-value was (<0.05) which is statistically significant. This result is agreed with study done by Malik AM. et al. (2007). Another study done by W.W. Vrijland et al. (2002) also shows the same result.

Bisgaar T *et al* and Butters (2007) mention a similar recurrence rate and found that the mesh repair (Lichtenstein) was superior to suture repair of inguinal hernia.

Other complication which is not seen in our study is ischemic orchitis (testicular atrophy) occur especially in recurrent inguinal hernia and this due to excessive dissection of the cord lead to thrombosis of veins draining the testicle. This result is agreed with study done by Wants GE. (1997).

Regarding the duration of surgical procedure, the overall operative time differs significantly in two techniques and the mean operative time in mesh repair group (30.4 minute) is much less than the mean operative time in non- mesh repair group (50.4 minute). P-value (>0.05) which is statistically insignificant. This result is in agreement with Parviz K. Amid (2003).

Another study done by Malik AM. Et al. (2007), also found that the mean operative time in the non-mesh group is longer than the mean operative time in the mesh group.

CONCLUSION

- 1. It was found that the use of traditional inguinal hernia repair (tissue repair or non-mesh repair) is associated with considerable post-operative pain and more chance of recurrence than mesh repair.
- 2. The mesh repair (tension-free repair) is superior to the non-mesh repair of inguinal hernias especially in terms of post-operative recurrence and persistent pain.
- 3. Mesh repair technique of inguinal hernias takes shorter operative time than non-mesh repair of inguinal hernias.

ACKNOWLEDGEMENTS

I would like to express my gratitude to everybody who has helped me during the long time I have worked with this thesis. In particular I would like to thank *Dr. Muqdad Fouad Abdul Kareem* (FICMS in General Surgery) for his support and help.

My deep gratitude to Assistant Professor *Dr. Mustafa Khalil Hameed Khalaf* (FICMS in General Surgery) and all teaching staff in College of Medicine \ Diyala University for encouraging my scientific work.

My full respect and appreciation to *Dr. Hussain Alwan Khalaf* (FICMS in General Surgery) for revising the scientific assessment of this thesis.

Finally I would like to thank *Diyala Health Directorate* for their aids and the medical staff members in surgical department in Baqubah Teaching Hospital and all the patients who participated in my study and made it possible for the study to be completed.

REFERENCES

- 1. A.E.Kirk, M. Kurzer, K.J. Waiters. British hernia center tension free mesh hernia repair, Journal Royal College of Surgery, 1995; 77(54): 299-304.
- 2. Akyol C, Kocaay F, Orozakunov E, Genc V, Kepenekci Bayram I, Cakmak A, et al. Outcome of the patients with chronic mesh infection following open inguinal hernia repair. *J Korean Surg Soc.*, May 2013; 84(5): 287-91.
- 3. Albo D, Awad SS, Berger DH, Bellows CF. Decellularized human cadaveric dermis provides a safe alternative for primary inguinal hernia repair in contaminated surgical fields. *Am J Surg.*, Nov. 2006; 192(5): e12-7.
- 4. Amid PK, Shulman AG, Lichtenstein IL. Local anesthesia for inguinal hernia repair step-by-step procedure. *Ann Surg.*, Dec. 1994; 220(6): 735-7.
- 5. Arkan A. Al-Ogaili et al. Open Mesh versus Non-Mesh Repair of Inguinal Hernia. A prospective randomized trial at AI-Yarmouk Teaching Hospital and Al-Mussayb General Hospital in a period between, April 2005–October 2009.
- 6. Awad SS, Fagan SP. Current approaches to inguinal hernia repair. *Am J Surg.*, Dec. 2004; 188(6A Suppl): 9S-16S.
- 7. Amid PK. How to avoid recurrence in Lichtenstein tension-free hernioplasty. *Am J Surg.*, Sep. 2002; 184(3): 259-60.
- 8. Amid PK. Lichtenstein tension-free hernioplasty. In: Fischer JE. *Mastery of Surgery*. 2.5th. Lippincott Williams & Wilkins, 2007: 1933-9.
- 9. Butters M, Redecke J, Koninger J. Long term results of randomized clinical trial of Shouldice, Lichtenstein and transabdominal preperitoneal hernia repairs. Br J Surg, 2007; 94(5): 562–569.
- 10. Bisgaard T, Bay-Nielson M, Christensen IJ, Kehlet H. Risk of recurrence 5 years or more after primary Lichtenstein mesh and sutured inguinal hernia repair. Br J Surg, 2007; 94: 1038–40.
- 11. Bay-Nielsen M, Thomsen H, Andersen FH, et al. Convalescence after inguinal herniorrhaphy. *Br J Surg.*, Mar. 2004; 91(3): 362-7.

- 12. Bringman S, Wollert S, Osterberg J, Smedberg S, Granlund H, Heikkinen TJ. Three-year results of a randomized clinical trial of lightweight or standard polypropylene mesh in Lichtenstein repair of primary inguinal hernia. *Br J Surg.*, Sep. 2006; 93(9): 1056-9.
- 13. Chastan P. Tension-free open hernia repair using an innovative self-gripping semi-resorbable mesh. *Hernia*., Apr. 2009; 13(2): 137-42.
- 14. Chung L, O'Dwyer PJ. Treatment of asymptomatic inguinal hernias. *Surgeon.*, Apr. 2007; 5(2): 95-100.
- 15. Chung RS. Meta-analysis of randomized controlled trials of laparoscopic versus conventional inguinal hernia repair. *Surg Endosc.*, 1999; 7: 68-94.
- 16. DeBord JR, Whitty LA. Biomaterials in hernia repair. In: Fischer JE. *Mastery of Surgery*. 2.5th. Lippincott Williams & Wilkins, 2007: 1965-8.
- 17. Delikoukos S, Fafoulakis F, Christodoulidis G, Theodoropoulos T, Hatzitheofilou C. Reoperation due to severe late-onset persisting groin pain following anterior inguinal hernia repair with mesh. *Hernia*., Dec. 2008; 12(6): 593-5.
- 18. Fingerhut A, Millet B, Veyrie N, et al. Inguinal hernia repair, update 2006. In: Edmund AM, Neugebauer S, Fingerhut A, et al. *EAES Guidelines for Endoscopic Surgery*. 1. Springer; 2006: 294-307.
- 19. Earle DB, Mark LA. Prosthetic material in inguinal hernia repair: how do I choose? *Surg Clin North Am.*, Feb. 2008; 88(1): 179-201.
- 20. Fitzgibbons RJ Jr, Giobbie-Hurder A, Gibbs JO, et al. Watchful waiting vs repair of inguinal hernia in minimally symptomatic men: a randomized clinical trial. *JAMA*., Jan 18, 2006; 295(3): 285-92.
- 21. Fitzgibbons RJ, Filippi CJ, Quinn TH. Inguinal hernias. In: Brunicardi FC, Andersen DK, Billiar TR, Dunn DL, Hunter JG, Pollock RE (Editors). *Schwartz's Principles of Surgery*. 8th Edition. New York, NY: McGraw-Hill, 2005.
- 22. Franklin ME Jr, Gonzalez JJ Jr, Glass JL. Use of porcine small intestinal submucosa as a prosthetic device for laparoscopic repair of hernias in contaminated fields: 2-year follow-up. *Hernia*., Aug. 2004; 8(3): 186-9.
- 23. Franklin ME Jr, Gonzalez JJ Jr, Michaelson RP, Glass JL, Chock DA. Preliminary experience with new bioactive prosthetic material for repair of hernias in infected fields. *Hernia*., Dec. 2002; 6(4): 171-4.
- 24. Franneby U, Sandblom G, Nordin P, Nyren O, Gunnarsson U. Risk factors for long-term pain after hernia surgery. *Ann Surg.*, Aug. 2006; 244(2): 212-9.

- 25. Gianetta E, Cuneo S, Vitale B, Camerini G, Marini P, Stella M. Anterior tension-free repair of recurrent inguinal hernia under local anesthesia: a 7-year experience in a teaching hospital. *Ann Surg.*, Jan. 2000; 231(1): 132-6.
- 26. Grosz CR. Iliohypogastric nerve injury. Am J Surg., Nov. 1991; 142(5): 628.
- 27. Hair A, Duffy K, McLean J, Talor S, Smith H, Walker A *et al.* Groin hernia repair in Scotland. BJS, 2000; 87: 1722–6.
- 28. Haapaniemi S, Nordin P, van der Linden W, Nilsson E. Choice of anesthesia and risk of reoperation for recurrence in groin hernia repair. *Ann Surg.*, Jul. 2004; 240(1): 187-92.
- 29. Hair A, Duffy K, McLean J, et al. Groin hernia repair in Scotland. *Br J Surg.*, Dec. 2000; 87(12): 1722-6.
- 30. Hakeem A, Shanmugam V. Inguinodynia following Lichtenstein tension-free hernia repair: a review. *World J Gastroenterol*, Apr. 14, 2011; 17(14): 1791-6.
- 31. Hosgor M, Karaca I, Ozer E, Suzek D, Ulukus C, Ozdamar A. Do alterations in collagen synthesis play an etiologic role in childhood inguino-scrotal pathologies: an immunohistochemical study. *J Pediatr Surg.*, Jul. 2004; 39(7): 1024-9.
- 32. Junge K, Klinge U, Prescher A, Giboni P, Niewiera M, Schumpelick V. Elasticity of the anterior abdominal wall and impact for reparation of incisional hernias using mesh implants. *Hernia.*, Sep. 2001; 5(3): 113-8.
- 33. Kark AE, Kurzer M, Waters KJ. Tension-free mesh hernia repair: review of 1098 cases using local anesthesia in a day unit. *Ann R Coll Surg Engl.*, Jul. 1995; 77(4): 299-304.
- 34. Kristin Masukawa, B. A, Samuel E. Wilson, Complication of mesh hernia repair USA, 2010.
- 35. Koch A, Edwards A, Haapaniemi S, Nordin P, Kald A. Prospective evaluation of 6895 groin hernia repairs in women. *Br. J. Surg.*, Dec. 2005; 92(12): 1553-8.
- 36. Liem M.S. van Duyn E. B. van der Graaf Y. et al. A randomized comparison recurrence after conventional laparoscopic inguinal hernia repair. American Journal of surgery, 2003; 237(1): 136-41.
- 37. Lichtenstein IL, Shulman AG, Amid PK, Montllor MM. Cause and prevention of postherniorrhaphy neuralgia: a proposed protocol for treatment. *Am J Surg.*, Jun. 1988; 155(6): 786-90.
- 38. Lichtenstein IL, Shulman AG, Amid PK, Montllor MM. The tension-free hernioplasty. *Am J Surg.*, Feb. 1990; 157(2): 188-93.
- 39. McCormack K, Scott NW, Go PM, Ross S, Grant AM, EU Hernia Trialist Collaboration. Cochrane Database Syst Rev., 2003; (1): CD 001785.

- 40. Liem MS, Halsema JA, van der Graaf Y, Schrijvers AJ, van Vroonhoven TJ. Costeffectiveness of extraperitoneal laparoscopic inguinal hernia repair: a randomized comparison with conventional herniorrhaphy. Coala trial group. Ann Surg, 1997; 226: 668–76.
- 41. Malik AM. et al. Acomparative analysis between non-mesh (Bassini's) and mesh (Lichtenstein) repair of primary inguinal hernia. A retrospective comparative analytical study 2000 to December 2007 Liaquat University of Medical and Health Sciences, Hyderabad/ Jamshoro, Pakistan.
- 42. Malangoni MA, Rosen RJ. Hernias. In: Townsend CM, Beauchamp RD, Evers BM, and Mattox KL (Editors). *Sabiston Textbook of Surgery*. 18th edition. Philadelphia, PA: Elsevier, 2007.
- 43. Milic DJ, Pejic MA. Tension free procedures in the surgical treatment of groin hernias. Spr Arh Cleok Lek, 2003; 131(1-2): 82–91.
- 44. Nordin P, Bartelmess P.Jansson C, Svensson C, EdlundG. Randomized trial of Lichtenstein versus Shouldice hernia repair in general surgical practice. Br J Surg, 2002; 89: 45–9.
- 45. Nathan JD, Pappas TN. Inguinal hernias: an old condition with new solutions. Ann Surg., 2003; 238(6 suppl): S148–57.
- 46. Nilsson H, Stylianidis G, Haapamaki M, Nilsson E, Nordin P. Mortality after groin hernia surgery. *Ann Surg.*, Apr. 2007; 245(4): 656-60.
- 47. O'Dwyer PJ, Alani A, McConnachie A. Groin hernia repair: postherniorrhaphy pain. *World J Surg.*, Aug. 2005; 29(8): 1062-5.
- 48. Nordin P, Zetterstrom H, Gunnarsson U, Nilsson E. Local, regional, or general anesthesia in groin hernia repair: multicenter randomized trial. *Lancet.*, Sep. 13, 2003; 362(9387): 853-8.
- 49. Norrie J, Chung L, O'Dwyer PJ. Long-term follow-up of patients with a painless inguinal hernia from a randomized clinical trial. *Br J Surg.*, Nov. 30, 2010; 5: 143-156.
- 50. O'Dwyer PJ, Norrie J, Alani A, Walker A, Duffy F, Horgan P. Observation or operation for patients with an asymptomatic inguinal hernia: a randomized clinical trial. *Ann Surg.*, Aug. 2006; 244(2): 167-73.
- 51. Parviz K.Amid: Lichtenstein tension—free hernioplasty for repair of primary and recurrent inguinal hernias. Nyhus and Condon's, PIONEERS IN HERNIA SURGERY. Lichtenstein tension-free hernioplasty, March 2003.

- 52. Paajanen H, Varjo R. Ten-year audit of Lichtenstein hernioplasty under local anesthesia performed by surgical residents. *BMC Surg.*, Aug. 2010; 10: 24.
- 53. Scott NW, McCormac K, Graham P, Go PM, Ross SJ, Grant AM. Open mesh versus non-mesh for repair of femoral and inguinal hernia. Cochrane Database Syst Rev., 2002; (2): CD002197.
- 54. Sanders DL, Waydia S. Asystematic review of randomized control trials assessing mesh fixation in open inguinal hernia repair. *Hernia*., May 7, 2013; 98(5): 279-89.
- 55. Scott N, Go PM.N.Y.H, Graham P, McCormack K, Ross SJ, Grant AM, Open mesh versus non-mesh repair of groin hernia: meta-analysis of randomized trials in 20 countries, 2002.
- 56. Shamberger RC, Ottinger LW, Malt RA. Arterial injuries during inguinal herniorrhaphy. *Ann Surg.*, Jul. 1984; 200(1): 83-5.
- 57. Shankar VG, Srinivasan K, Sistla SC, Jagdish S. Prophylactic antibiotics in open mesh repair of inguinal hernia a randomized controlled trial. *Int J Surg.*, 2010; 8(6): 444-7.
- 58. Sanabria A, Dominguez LC, Valdivieso E, Gomez G. Prophylactic antibiotics for mesh inguinal hernioplasty: a meta-analysis. *Ann Surg.*, Mar. 2007; 245(3): 392-6.
- 59. Sanchez-Manuel FJ, Lozano-García J, Seco-Gil JL. Antibiotic prophylaxis for hernia repair. *Cochrane Database Syst Rev.*, Jul. 18, 2007; CD003769.
- 60. Simons MP, Aufenacker T, Bay-Nielsen M, Bouillot JL, Campanelli G, Conze J, et al. European Hernia Society guidelines on the treatment of inguinal hernia in adult patients. *Hernia*., Aug. 2009; 13(4): 343-403.
- 61. Starling JR, Harms BA. Diagnosis and treatment of genitofemoral and ilioinguinal neuralgia. *World J Surg.*, Sep-Oct. 1989; 13(5): 586-91.
- 62. Scott NW, McCormack K, Graham P, Go PM, Ross SJ, Grant AM. Open mesh versus non-mesh for repair of femoral and inguinal hernia. *Cochrane Database Syst Rev.*, 2002; CD002197.
- 63. Stylianidis G, Haapamäki MM, Sund M, Nilsson E, Nordin P. Management of the hernial sac in inguinal hernia repair. *Br J Surg.*, Mar. 2010; 97(3): 415-9.
- 64. Taylor EW, Duffy K, Lee K, et al. Surgical site infection after groin hernia repairs. *Br J Surg.*, Jan. 2004; 91(1): 105-11.
- 65. Terzi C. Antimicrobial prophylaxis in clean surgery with special focus on inguinal hernia repair with mesh. *J Hosp Infect.*, Apr. 2006; 62(4): 427-36.

- 66. Vale L, Grant A, Mc Cormac, Scott NW, EU Hernia Trialist collaboration. Cost effectiveness of alternative methods of surgical repair of inguinal hernia. Int J Technol Assess Health Care, 2004; 20(2): 192–200.
- 67. Van Veen RN, Mahabier C, Dawson I, et al. Spinal or local anesthesia in Lichtenstein hernia repair: a randomized controlled trial. *Ann Surg.*, Mar. 2008; 247(3): 428-33.
- 68. Van Veen RN, Wijsmuller AR, Vrijland WW, Hop WC, Lange JF, Jeekel J. Long term follow up of a randomized clinical trial of non-mesh versus mesh repair of primary inguinal hernia. Br J Surg, 2007; 94: 506–10.
- 69. W.W. Vrijland, M. P van den Tol, R. W Luijendijk, W.C. J Hop, J.J. V Busschbach, D.C.D de Lange, D van Geldere, A.B. Randomized clinical trial of non-mesh versus mesh repair of primary inguinal hernia, 293-297.
- 70. Wants GE. My experience without tension, primary inguinal hernia in man, Journal international of surgery, 1997; 71(46): 111-6.
- 71. Wantz GE. Complications of inguinal hernial repair. *Surg Clin North Am.*, Apr. 1984; 64(2): 287-98.
- 72. Weyhe D, Belyaev O, Müller C, Meurer K, Bauer KH, Papapostolou G, et al. Improving outcomes in hernia repair by the use of light meshes--a comparison of different implant constructions based on a critical appraisal of the literature. *World J Surg.*, Jan. 2007; 31(1): 234-44.
- 73. Wiese M, Kaufmann T, Metzger J, et al. Learning curve for Lichtenstein hernioplasty. *Open Access Surgery.*, Jul. 2, 2010; 3: 43-6.
- 74. Wijsmuller AR, Lange JF, Kleinrensink GJ, et al. Nerve-identifying inguinal hernia repair: a surgical anatomical study. *World J Surg.*, Feb. 2007; 31(2): 414-20; discussion 421-2.
- 75. Woods B, Neumayer L. Open repair of inguinal hernia: an evidence-based review. *Surg Clin North Am.*, Feb. 2008; 88(1): 139-55, ix-x.
- 76. Zhao G, Gao P, Ma B, Tian J, Yang K. Open mesh techniques for inguinal hernia repair: a meta-analysis of randomized controlled trials. *Ann Surg.*, Jul. 2009; 250(1): 35-42.