Management of Asymptomatic inguinal hernias

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UNIVERSITY
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I dedicate my work to

My father *who taught me science*

My wife *who taught me sacrifice*

My children *who taught me perseverance*

A. Alani

No disease of the human body, belonging to the province of the surgeon, requires in its treatment a better combination of accurate anatomical knowledge with surgical skill than Hernia in all its varieties. (Sir Astley Paston Cooper, 1804)

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2. Observation or operation for patients with an asymptomatic inguinal hernia: a randomized clinical trial
   O'Dwyer PJ, Norrie J, Alani A, Walker A, Duffy F, Horgan P.
   Ann Surg. 2006 Aug; 244(2):167-73

3. Hernias are the most common cause of strangulation in patients presenting with small bowel obstruction
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SUMMARY

Hernia surgery remains one of the most common operations carried out by general surgeons worldwide with more than 800,000 repairs performed in the USA alone in 2003. Advancement in surgical technique has meant fewer recurrences are now encountered with figures dropping to less than 2% using the laparoscopic approach. Yet despite the progress achieved in securing the repair, post operative pain remains an issue with many authors reporting figures of 30% in patients following groin hernia repair [1,2], 3% of patients report sever pain that limits their daily activities and renders them off work.

Many patients with inguinal hernia have very little in the way of symptoms and even some of them are asymptomatic, having noticed their hernia by accident or by their general practitioner.

In order to clarify two issues (the first being the incidence of acute hernia presentation, its management and subsequent outcome, while the second was the management of patients with an asymptomatic inguinal hernia) 4 studies were carried out: The first study was a prospective observational study looking at all patients presenting to our unit with an acute hernia, the aim of the study was to prospectively assess the presentation and management of acute hernias in light of recent changes in hernia management.

Data on all patients admitted with an acute hernia between 2001 and 2004 was collected prospectively. During the 3 year study period 91 patients were admitted with an acute hernia. 46 had a previous medical assessment either as an acute admission (12) at a surgical clinic (22) or by a General Practitioner (12). Eighteen had been declared unfit for operation at that assessment, 10 were ASA4, 5 ASA3 and 3 ASA2. Eleven patients were on the waiting list for operation 3 of whom had a previous acute hospital admission. For 30 patients this hospital admission was the first indication that they had a hernia while the remainder refused operation or did not seek medical advice. Five patients died, 2 while being assessed for operation and 3 postoperatively, 3 were ASA4 while 2 were ASA3. The number of patients undergoing operation for an acute hernia amounted to 8.4% (80 of 952) of all hernia operations carried-out during the study period.

This study concluded that despite advances in hernia surgery there was still room for improvement, to ensure that all suitable patients presenting with an acute hernia receive an operation during their acute hospital admission.

The second study was a prospective study of all patients presenting with subacute bowel obstruction in one teaching hospital between 2003 and 2004. The aim of the study was to identify the most frequent causes of strangulation in patients presenting with small bowel obstruction.

During the study one hundred and sixty-one patients with symptoms and signs of small bowel obstruction were admitted. Eighty-nine were confirmed with contrast studies. The male: female ratio was 1:1.6. The aetiology of obstruction was hernia in 29 (18%), adhesions in 97 patients (60.2%), and miscellaneous in 35 (21.8%) Operative procedures were performed on 74 patients (46%), 31 of them (42%) with adhesions, 25 (34%) with hernias and 18 (24%) due to other causes. Strangulated bowel occurred in 15 patients (9.3%); 12 had hernias whilst three had adhesions ($P < 0.0001$). Of the strangulated hernias, ten were femoral, one was inguinal and one was paraumbilical.

Our conclusion was that whilst adhesions are the most common cause of small bowel obstruction, femoral and not inguinal hernias remain the most frequent cause of strangulation.

The third and main study was a prospective randomized trial comparing surgery and no intervention for asymptomatic inguinal hernias. The aim of the study was to compare operation with a wait and see policy in patients with an asymptomatic hernia.

160 male patients 55 years or older were randomly assigned to observation or operation. Patients were assessed clinically and sent questionnaires at 6 months and 1 year. The primary endpoint was pain and general health status at 12 months; other outcome measures included costs to the health service and the rate of operation for a new symptom or complication.

At 12 months there were no significant differences between the randomised groups of observation or operation, in visual analogue pain scores at rest, 3.7mm versus 5.2mm (P=0.34), or on moving, 7.6mm versus 5.7mm (P=0.39). Also the number of patients who recorded pain on moving 29 versus 24 (P=0.31), and the number taking regular

analgesia, 9 versus 17, (P=0.14) was similar. At 6 months there were significant improvements in most of the dimensions of the SF-36 for the operation group, while at 12 months although the trend remained the same the differences were only significant for change in health (P=0.039). The rate of crossover from observation to operation was 23 patients at a median follow-up of 574 days, this was higher than predicted. The observation group also suffered 3 serious hernia related adverse events compared to none in the operation group.

Finally a sub study was generated from the non randomised patients within the asymptomatic trial. The aim here was to assess the outcome of patients opting for no surgery in terms of need for surgery and outcome.

There were 72 patients (58 opting for observation and 14 wanting an operation), 13 patients (22.4%) in the observation group became symptomatic and required an operation, 9 patients had died at the time of data analysis, all of which were due to co morbid illnesses.

The final 2 studies concluded that repair of an asymptomatic inguinal hernia did not affect the rate of long-term chronic pain and might be beneficial to patients in improving overall health and reducing potentially serious morbidity.

INTRODUCTION – REVIEW OF THE LITERATURE

1.1 Introduction

Each year approximately 70000 inguinal hernias are repaired in the National Health Service in England (90% elective and 10% emergency), affecting 0.14% of the population and utilizing over 100,000 NHS bed days of hospital resources, with a total cost of £ 56.000000 [3], and this high incidence of the disease makes inguinal hernia repair the most frequent procedure in general surgery, accounting for 10-15% of all operations [4] . These data demonstrate the huge impact of herniorrhaphy on health-care expenditure and working disability, bearing in mind that the average time off work following a groin hernia repair is one month [5]. The significance of these large numbers is that small variations in practice patterns can have huge socioeconomic implications. Operations that might seem unimportant because they account for only a small percentage of herniorrhaphies actually are important in that they account for a large absolute number of procedures. And although Bassini's classic articles on a successful method of repair, based on a pathophysiological understanding of the development of inguinal hernias, were published more than a hundred years ago, opinions still differ about the technique of hernioplasty, the addition of mesh and the introduction of laparoscopic surgery have provoked more discussion about the procedure of choice. And now that recurrence rates are at all time low attention is focused at the increasingly apparent problem of post surgical chronic pain.

1.2 Historical Background [6,7]

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. 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 700 AD, 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. The first report of groin hernia classification based on the anatomy of the defect (i.e., inguinal versus femoral) dates to the 14th century, and the

anatomical descriptions of direct and indirect types of inguinal hernia were first reported in 1559.

The modern surgical era began with Bassini, who in 1887 developed the first modern, anatomically based hernia treatment, this procedure spread world wide, but was often executed poorly, and hernia repair fell into a state of second hand surgery.

In addition to Bassini's contributions, 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.

The advances in groin hernia repair in the century following Bassini shared the primary goal of reducing long-term hernia recurrence rates. To this end, efforts have been directed at developing a repair that imparts the least tension on the tissues that are brought together to repair the hernia defect. 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. Muscle and fascial flaps were attempted without consistent success. 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. 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. Reports of the wire patches eroding into adjacent inguinal structures and even the peritoneal cavity itself caused even more concern with this technique.

In the late 1940s, Canadian surgeon E. Shouldice developed a Hernioplasty similar to the Bassini 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.

In France in 1956, Henri Fruchaud published his wonderful anatomic study of the groin, which became the basis for anatomical teaching in Europe. Two years later, American surgeon Chester McVay and anatomist Barry Anson clarified the anatomy of the groin and popularized the Cooper’s ligament Hernioplasty.

At the same time, convenient modern prosthetic materials were introduced after World War II in France by Aquaviva who used nylon and in the United States, Usher and Koontz using polypropylene. Experience with polyester mesh was reported in France by Rives and Stoppa. All these fabrics have similar good tolerance in clean hernia procedures, as it is the macro porosity that ensures a rapid integration and resistance to infection.

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.

Today, laparoscopic techniques have been validated as safe and effective in the treatment of groin hernias and have become commonplace. The laparoscopic approaches were initially developed in the early 1990s as laparoscopic techniques diffused throughout other specialties of general surgery.

1.3 Epidemiology [8,9]

Hernias are a common health problem. Exactly how prevalent they are is not known, but in an adult male population examined by surgeons, one out of four had a hernia or had been operated on for hernia[10], while the life time risk for requiring an inguinal hernia repair in women was only 3% [11].

The same investigation found that over the age of 75, almost half of the male population had a hernia or had been operated on for hernia. Similar results were found in a Swedish epidemiological study of men aged 54 years (22%) and 62 years (30%) [10].

It is clear that aging increases the incidence of groin hernias, the likelihood of strangulation, and the need for hospitalization.

Approximately 75% of all hernias occur in the inguinal region[11], 54% are right sided, 39.7% left sided and 6.3% are bilateral. This right sided predominance is attributed to a delay in atrophy of the processus vaginalis following the normal slower descent of the right testis to the scrotum during fetal development.

Indirect hernias predominate over direct hernias at a ratio of 2 to 1, regardless of gender.

Direct hernias are very uncommon in women, and indirect hernias are at least 10 times more likely to strangulate than direct ones.

Up to 30% of people with a primary unilateral hernia will subsequently develop a hernia on the other side, and these bilateral hernias are four times more often direct than indirect. In a 38-year follow-up of 1,944 patients, investigators found a contra lateral lesion in 15.8% [12].

Ten percent of women and 50% of men who have a femoral hernia either have or will develop an inguinal hernia.

Strangulation, the most common and serious complication of a groin hernia occurs in 1.3 to 3.0 percent of groin hernias [11], more often in the 7th and eighth decades [13,14], accounts for 25% of cases admitted with intestinal obstruction [15], and has a post operative mortality of 13% [16]. Most strangulated hernias are indirect inguinal hernias as direct hernias are responsible for only 3% of strangulations, but the femoral hernia has the highest rate of strangulation (5-20%) of all hernias.

The probability of a groin hernia presenting acutely varies with location and duration. For an inguinal hernia the probability is 2.8 percent after 3 months from development and increases to 4.5 percent after 2 years; for femoral hernias it is 22 percent at 3 months and 45 percent at 21 months. The probability of strangulation, in both inguinal hernia and femoral hernia, is greatest in the first 3 months, suggesting that patients with a short history of herniation should be referred urgently to a surgeon [16].

The recurrence rate of hernia repairs ranges from 0.2% to 15% [11], with 16% of all repairs being for recurrent hernias [17].

Statistical data from the US National Centre for Health Statistics showed that 94% of patients with an inguinal hernia without obstruction had surgery, with a probability of death of 0.005. However for inguinal hernia with obstruction, 88% underwent surgery with a death rate of 0.05 – a ten fold increased risk of death[18], and the rate of death from hernia with obstruction fell from 5 per 100 000 in 1986 to 3 per 100 000 indicating that elective surgery had contributed to a lower death rate from complicated hernia.

Mortality rate for elective hernia repair is less than 1 death per 10000 operations, for emergency surgery the figure may rise to 5% [11].

1.4 Aetiology of Inguinal hernias[19]

In order to understand the natural history of a hernia and be able to sensibly assess the risk of a patient with an asymptomatic hernia developing pain and producing acutely it is helpful to have a view on the aetiology of such hernias.

Indirect inguinal herniation arises from incomplete obliteration of the patent processus vaginalis. In a large series of patients with hernias occurring in childhood, Rowe et al reported that the patent processus vaginalis closed over a period of time in most cases [20]. In premature babies, both sides were patent. In the neonatal period, the contra lateral side was patent in 60% of cases, but by the age of 2 years, only 40% of the children had a patent processus vaginalis. This 40% rate persists into adult life, but in only 15-20% of these cases does symptomatic hernia develop; the other 20% have a lifelong patent processus that does not produce any symptoms [12,20,21].

Other factors must be present to cause failure of the transversalis fascia to retain the visceral sac in the myopectineal orifice.

The erect stance of human beings, in contrast to that of four-legged animals, promotes herniation by stretching and exposing the groin and, when a hernia is present, permitting the dependent intestines to drop into the hernial sac.

The myopectineal orifice of Fruchaud [22] is an area of transversalis fascia that is not protected by the posterior rectus sheath or by muscle. This is an area of potential weakness through which all groin hernias emerge. Some degree of protection is afforded by the shutter mechanism, whereby with increased intra-abdominal pressure the curved fibers of the internal oblique and the falx inguinalis flatten and move toward the inguinal ligament. Contraction of the transversus abdominis muscle also pulls up and tenses the crura of the internal ring.

Hernias are also caused by a mechanical disparity between visceral pressure and resistance of the abdominal musculature. Causes of increased abdominal pressure include coughing, constipation, prostatism, and unusual exertion (especially lifting heavy weights). Under these circumstances, when a patent processus vaginalis is present or the endoabdominal fascia is attenuated, hernia results. The sudden onset of a painful hernia in a young person after lifting a heavy weight is usually associated with a patent processus vaginalis that expands suddenly like a collapsed balloon. In older persons, the

abdominal muscles and fascia weaken with the aging process, so even moderate effort may be sufficient to produce a hernia.

Inguinal hernias of all types occur equally in sedentary and in physically active men. Vigorous physical activity per se is not a cause of inguinal herniation, although strenuous effort may aggravate predisposing factors and precipitate herniation.

The fascia transversalis, like other fascial tissue, derives its strength from collagen fibers that are continually being produced and reabsorbed. A disturbance of this balance results in attenuation of the fascia. Congenital defects, such as occur in Marfan, Ehlers-Danlos, and Hunter-Hurler syndromes, can predispose to hernia formation. It appears that certain life-styles can lead to defective collagen production, so that collagen that is produced is reduced in tensile strength. An association between cigarette smoking and groin hernias has also been demonstrated. Levels of circulating serum elastolytic activity as well as protease substances have been shown to be significantly greater in patients who smoke, and it is this disturbed protease/ antiprotease balance and the destruction of tissues that leads to herniation [23].

Other factors may also have an effect in some cases, abdominal distention and chronic increase in intra abdominal pressure from ascites and peritoneal dialysis may damage the myopectineal orifice and cause a patent processus vaginalis to dilate. Fracture deformities of the pelvis and denervation of the shutter mechanism following a low cosmetic appendectomy incision are well-known but uncommon causes of inguinal herniation.

Genetic factors are important in the aetiology of inguinal hernia: a study of congenital indirect inguinal hernias in China on 280 families indicated that the mode of transmission was autosomal dominant, with incomplete penetrance and paternal transmission from their father's hernia[24], other evidence has shown the inheritance to be multifactorial and probably not sex linked [24].

1.5 Definition

A hernia (Latin, rupture; Greek, bud) is defined as a protrusion of a viscus through an opening in the wall of the cavity in which it is contained. Clinically the important part of the definition is the protrusion, because without the protruding viscus a diagnosis of hernia is essentially impossible. This definition was used when enrolling patients with an asymptomatic lump into the asymptomatic hernia trial.

1.6 Composition of a hernia [25]

As a rule, a hernia consists of three parts: the sac, the coverings and the contents of the sac.

1) The sac: is a diverticulum of peritoneum consisting of mouth, neck, body and fundus. The neck is usually well defined, but in some direct inguinal hernias there is no actual neck. The diameter of the neck is important because strangulation of bowel is a likely complication where the neck is narrow.

The body of the sac varies greatly in size and is not necessarily occupied. In cases occurring in infancy and childhood the sac is thin. In long-standing cases the wall of the sac may be comparatively thick.

2) The coverings: are derived from the layers of the abdominal wall through which the sac passes. In long-standing cases they become atrophied and amalgamate so that they are indistinguishable from each other.

3) The Contents: These could be any of the following:

• Omentum = omentocele.

• Intestine = enterocele. More commonly small bowel, but may be large intestine or appendix;

• A portion of the circumference of the intestine = Richter's hernia;

• A portion of the bladder (or a diverticulum) may constitute part of or be the sole contents of a direct inguinal, a sliding inguinal or a femoral hernia;

• Ovary with or without the corresponding fallopian tube.

• A Meckel's diverticulum = Littre's hernia;

• Fluid.

1.7 Types of inguinal hernias

Inguinal hernias can be subdivided into direct and indirect hernias:

1. Indirect hernia: occurs as a protrusion of abdominal contents through the internal ring, lateral to the inferior epigastric vessels, into the inguinal canal. Indirect inguinal hernias are situated within the spermatic cord and therefore may extend into the scrotum. In female patients, the hernia follows the round ligament and may present as a swelling in the labium.

2. Direct hernia: is a protrusion through the triangle of Hesselbach medial to the inferior epigastric vessels. These hernias develop through an area where the endoabdominal fascia is not protected by overlying muscle. Direct hernias do not usually involve the cord, as they tend to protrude forward. However, they occasionally track alongside the cord down the entire length of the inguinal canal and even enter the scrotum. For this reason, the only absolute distinction between a direct and an indirect hernia is the relationship to the inferior epigastric vessels.

1.8 Presentation of Inguinal hernias

Patients with a groin hernia could present in a variety of ways, from the asymptomatic hernia (which is seen in about 30% of patients) to a painful lump (which is the commonest presentation accounting for 66% of patients), this pain is mild in about 53.9% and severe in less than 1% of patients [26,27]. Overwhelming or focal pain from a groin hernia is unusual and should raise the suspicion of hernia incarceration or strangulation.

The most common presenting symptomatology for a groin hernia is a dull feeling of discomfort or heaviness in the groin region that is exacerbated by straining the abdominal musculature, lifting heavy objects, or defecating. These maneuvers worsen the feeling of discomfort by increasing the intra-abdominal pressure and forcing the hernia contents through the hernia defect. Pain develops as a tight ring of fascia outlining the hernia defect compresses intra-abdominal structures with a visceral neuronal supply. With a reducible hernia, the feeling of discomfort resolves as the pressure is released when the patient stops straining the abdominal muscles. The pain is often worse at the end of the

day, and patients in physically active professions may experience the pain more often than those who lead a sedentary lifestyle.

The probability of patients presenting with pain increases with time to almost 90% at 10 years. Patients with an indirect inguinal hernia are considerably more likely to have pain when compared with those that have a direct hernia, and 6% of patients have nausea and vomiting on the time of presentation [26].

McEntee et al [14] demonstrated that one third of patients presenting acutely with an inguinal hernia will be aware that their hernia is present but will not report it to their family doctor, an additional one third present within days of noticing their hernias, before elective operation can be contemplated, while the final one-third have been deemed too high risk for elective repair either by their GP or Surgeon.

For those patients presenting with an acute hernia the symptoms vary according to the pathology within the hernia and the presentation could be as follows:

1. Irreducible hernia: Here the contents cannot be returned to the abdomen, but there is no evidence of other complications. It is usually due to adhesions between the sac and its contents or from over crowding within the sac. Irreducibility without other symptoms is almost diagnostic of an omentocele, and any degree of irreducibility predisposes to strangulation.

2. Obstructed hernia: This is an irreducible hernia containing intestine which is obstructed from without or within, but there is no interference to the blood supply to the bowel. The symptoms (colicky abdominal pain and tenderness over the hernia site) are less severe and the onset more gradual than is the case in strangulation, but more often than not the obstruction culminates in strangulation. Usually there is no clear distinction clinically between obstruction and strangulation, and the safe course is to assume that strangulation is imminent and treat accordingly. It may also be difficult to differentiate fat from bowel contents in the hernia sac, and it is important to recognize that incarcerated omental fat alone can produce significant pain and tenderness on physical examination.

Incarcerated hernia, the term ‘incarceration’ is often used loosely as an alternative to obstruction or strangulation, but is correctly employed only when it is considered that the

lumen of that portion of the colon occupying a hernial sac is blocked with faeces. In that event the contents of the bowel should be capable of being indented with the finger.

3. Strangulated hernia: A hernia becomes strangulated when the tight circumferential pressure applied by the hernia defect impedes the venous outflow from the hernia contents, resulting in congestion, edema, and tissue ischemia. Ultimately, the arterial inflow to the hernia contents is compromised as well, resulting in tissue loss and necrosis, termed strangulation of the hernia. Gangrene may occur as early as 5-6 hours after the onset of the first symptoms. Although inguinal hernia may be 10 times more common than femoral hernia, a femoral hernia is more likely to strangulate because of the narrowness of the neck and its rigid surrounds.

Strangulation produces intense pain in the hernia followed quickly by tenderness, and signs and symptoms of sepsis. A strangulated hernia, in contrast to an irreducible hernia, does not enlarge or transmit an impulse when the patient coughs.

Incarceration and strangulation of a groin hernia may present as a bowel obstruction when the tight hernia defect constricts the lumen of the viscus. Hence, all patients presenting with bowel obstruction require a thorough physical examination of the groin region for inguinal and femoral hernias. If there is no bowel in the hernia sac, an incarcerated groin hernia may alternatively present as a hard, painful mass that is tender to palpation. The physical exam differs between an incarcerated and a strangulated hernia. The incarcerated hernia may be mildly tender due to venous congestion from the tight defect. The strangulated hernia will be tender and warm and may have surrounding skin erythema secondary to the inflammatory reaction from the ischemic bowel. The patient with the strangulated hernia may have a fever, hypotension from early bacteremia, and a leukocytosis. The incarcerated hernia requires operation on an urgent basis within 6 to 12 hours of presentation. If the operation is delayed for any reason, serial physical exams are mandated to follow any change in the hernia site indicating the onset of tissue loss. The strangulated hernia clearly requires emergency operation immediately following diagnosis.

1.9 Diagnosis [19,28]

-History and Clinical Examination:

It is important to take a full history because hernias can develop as a result of raised intra-abdominal pressure such as occurs with respiratory, urinary or bowel problems, or during peritoneal dialysis. Often the hernia is noticed during standing or straining; typically the patient is aware that the lump disappears on lying down and is uncomfortable after exertion. Symptoms caused by complications of the hernia, such as abdominal distention and colicky abdominal pain, may be noticed by the patient before they notice the groin lump.

The inguinal region should be examined with the patient in both supine and standing positions. The examiner should visually inspect and palpate the inguinal region, observing for asymmetry, bulges, or a mass. Having the patient cough or perform a Valsalva maneuver can facilitate identification of a hernia. The examiner places a fingertip over the inguinal canal and repeats the examination

A bulge moving lateral to medial in the inguinal canal suggests an indirect hernia. If a bulge progresses from deep to superficial through the inguinal floor, a direct hernia is suspected. This distinction is not critical, because repair is approached the same way regardless of the type of hernia.

If the hernia extends into the scrotum, it must be distinguished from a hydrocele or testicular swelling. An inguinal hernia is reduced through the superficial inguinal ring, which lies above and medial to the pubic tubercle. This distinguishes it from a femoral hernia, in which the neck of the hernia is below and lateral to the pubic tubercle. An indirect hernia can usually be controlled by pressure over the deep ring; a direct one, however, cannot, as it emerges forwards through the posterior wall of the inguinal canal medial to the deep ring. Percussion and auscultation may be performed to determine whether the hernia contains bowel.

A groin bulge described by the patient that is not demonstrated on examination presents a clinical challenge. Having the patient stand or walk for a period of time may allow the undiagnosed hernial mass to become visible or palpable.

-Investigations:

With ultrasound examination in supine and upright positions supported by a Valsalva maneuver, inguinal hernia can be diagnosed with a sensitivity and specificity of more than 90% [29]. The accuracy of distinguishing indirect from direct hernias, even with the aid of Duplex-ultrasonography, is no higher than 73% [29]. When there is a palpable mass, sonographic examination can differentiate between incarcerated hernia and lymph nodes. Duplex-ultrasonography of testicular perfusion can be used to assess pre-existing deficiencies and avoid postoperative litigation, especially in patients with recurrent hernias or testicular changes. In rare cases of inguinal pain without clinical or sonographic findings, computed tomography is indicated to rule out obturator hernias. Herniography is no longer justified due to its invasiveness.

-Differential diagnosis

The differential diagnosis if an inguinal hernia includes the following:

1. Femoral hernia
2. Hydrocele
3. Undesecnded testicle
4. Lymph node
5. Lipoma
6. Femoral artery aneurysm
7. Saphena varix.

1.10 Chronic pain

1.10.1 Definition

The International Association of the Study of pain (IASP) defined chronic pain as pain persisting beyond the normal tissue healing time assumed to be 3 months [30].

Cunningham et al [31] divided such pain into 3 categories:

-Mild pain: an occasional pain or discomfort that did not limit activity, with a return to prehernia lifestyle.

-Moderate pain: pain preventing return to normal preoperative activities (*i.e.,* inability to continue with prehernia activities such as golf, tennis, or other sports, and inability to lift objects, without pain, that patient had been lifting before the hernia occurrence).

-Severe pain: pain that incapacitated the patient at frequent intervals or interfered with activities of daily living (*i.e.,* a pain constantly present or intermittently present but so severe as to impair normal activities, such as walking).

1.10.2 Epidemiology of chronic pain

It is generally recognized that inguinal herniorrhaphy results in greater morbidity than was previously appreciated. Now that modern hernioplasty techniques have reduced recurrence rates to a minimum, chronic postoperative groin pain syndromes have emerged as the major complication facing inguinal hernia surgeons.

In a critical review of inguinal herniorrhaphy studies between 1987 and 2000, the incidence of long-term groin pain after surgery was as high as 53% at 1 year (range 0% - 53%)[32], and the best estimate was that moderate to severe pain occurred in about 10% of patients and some degree of restriction of activity in about 25%. These findings are similar to those made by Bay-Nielsen [1]who found that the incidence of chronic pain one year after hernia repair was 29%, while 11% of patients reported that their pain interfered with daily activities, and 5% stated that it was difficult for them to stand for 30 minutes or more indicating a significant functional impairment.

In a prospective, randomized study it was clear that, postoperative groin pain is often persistent and debilitating. At 1 year after surgery, 62.9% of patients had some degree of groin pain and 11.9% of those patients rated the pain as moderate to severe [31]. At 2 years,

the figures were 53.6% and 10.6%, respectively. In an other study looking at patients 3 years after their surgery the figures were 18% and 5%[33]. But these figures are similar to those recorded by Callesen et al 1 year after surgery (19% and 6% respectively) [34]. and those of Franneby et al, with 30% of the patients reporting some form of pain or discomfort, and close to 6% of all patients reporting inguinal pain of such intensity that it disturbed their concentration in activities of daily life during the week preceding follow-up [2].

Such variations in pain percentages are partly due to differences in the definition, measurement, and timing of assessment of chronic pain.

The impact of chronic groin pain on patients' daily physical or sporting activity is a matter of concern as these patients felt uncomfortable carrying a bag of groceries or playing sports such as golf, about 30% said that the pain was brought up by standing or going up stairs [1], and 60% were unable to enjoy social or leisure activity, and 12% claiming it has effected their sleep[1,35]. This has a large implication on the working force knowing that 97.5% of these patients failed to return to work at 3 months [36].

1.10.3 Aetiology of chronic pain [32,37]

Postsurgical chronic pain is the consequence either of ongoing inflammation or, much more commonly, a manifestation of neuropathic pain, resulting from surgical injury to major peripheral nerves (Figure 1.1).

Therefore postoperative pain can be divided accordingly into the following:

1. Nociceptive (somatic) pain: is the pain that results from activation of high threshold peripheral sensory (nociceptor) neurons by intense mechanical, chemical, or thermal noxious stimuli. This pain is the pain that results, for example, from a scalpel blade cutting through skin. It signals the presence, location, intensity, and duration of a noxious stimulus and fades once the peripheral driving force is removed.

In hernia repair this pain is due to ischemia induced in musculo-fascial tissues by a repair done under tension. In this situation, the sutures slowly cut through the tissues, relieving the pain but setting the stage for recurrence. The other major cause of ischemia-induced pain is tight closure of either the deep or superficial inguinal ring during repair. Most

often, ischemia in the ring is partly due to oedema following operative dissection, and resorption of oedema postoperatively leads to gradual resolution of pain; rarely does testicular atrophy supervene[38]. Cunningham et al. [39] reported the most common type of chronic post-hernia pain syndrome is somatic, which is localized to common ligamentous insertion to the pubic tubercle. Somatic pain may be due to damage to the pubic tubercle during the stapling of mesh prosthesis or from deep muscle layers. Incorporation of the periosteum of the pubic tubercle into the most medial suture was widely advocated during open hernia repair up until reports of chronic pain suggested this technique being implicated and recommended that surgeons no longer incorporate the pubic tubercle in their first stitch.

2. Inflammatory pain: is the heightened pain sensitivity that occurs in response to tissue injury and inflammation. It results from the release of sensitising inflammatory mediators that lead to a reduction in the threshold of nociceptors that innervate the inflamed tissue (peripheral sensitisation). As a consequence of an increase in the excitability of neurons in the central nervous system (central sensitisation), inflammatory pain is also associated with exaggerated responses to normal sensory inputs. These phenomena, although evoked within a matter of minutes, can outlast the precipitating tissue injury for several hours or days. However, the changes are generally reversible and normal sensitivity of the system is eventually restored. Inflammatory pain is the pain that, in the absence of any peripheral nerve damage, drives acute postoperative pain until the surgical wound has healed. If a focus of ongoing inflammation persists, however, so will the pain.

3. Neuropathic pain: is the pain that arises after injury to nerves or to sensory transmitting systems in the spinal cord and brain. A key feature of neuropathic pain is the combination of sensory loss with paradoxical hypersensitivity. Damage to the afferent transmission system causes partial or complete loss of input to the nervous system, leading to negative sensory phenomena, such as loss of touch or temperature or pressure sensations. Nerve injury is the starting point for reactive changes that sweep centrally to produce abnormal neural function. In addition to sensory loss, which is a universal

response to nerve damage, there can in some individuals be development of so-called positive phenomena, including spontaneous pain, dysaesthesia, and hypersensitiviry, including allodynia-in which pain is evoked by innocuous stimuli such as light touch or gentle pressure to deep tissue, hyperalgesia-an exaggerated or amplified response to a noxious stimulus, and hyperpathia-an explosive abnormal pain that outlasts a stimulus. The hypersensitiviry located within and beyond the damaged nerve innervation territory can mask the sensory loss. There is no specific diagnostic method or test to unequivocally show the presence of neuropathic pain.

Neuropathic pain is probably attributable to damage to the ilioinguinal or genitofemoral nerve. Neuropathic pain usually develops in the sensory distribution of an injured nerve. Chronic residual neuralgia occurs as a result of surgical handling of sensory nerves. The nerve trauma can be due to partial or complete division, stretching, contusion, crushing, electrical damage, or sutures compression. Secondary nerve damage can occur due to irritation or compression by an adjacent inflammatory process such as granuloma. Nerves are at risk of adherence to or abrasion against mesh used for hernia repair compared with a simple sutured Marcy repair. The genitofemoral nerve may also be at risk when the prosthetic mesh is secured in a continuous suture along the inguinal ligament or when the external spermatic vessels are divided to skeletonise the cord [40]. Descriptors of neuropathic pain include pulling, tugging, tearing, throbbing, stabbing, shooting, numbing, and dull. The onset of neuropathic pain is often delayed, occurring after a latent period of days to weeks. Pain is often aggravated by ambulation, stooping, or hyperextension of hip and sexual intercourse; and alleviated by recumbent position and flexion of the hip and thigh. In laparoscopic hernia repair there is a risk that, when stapling the mesh, it can penetrate the wall of the inguinal canal entrapping and irritating the sensory nerves. Kinking of the nerves can cause chronic irritation. Tanphiphat et al [41] speculated that thermal injury from intraoperative cautery was the cause of neuralgia rather than nerve entrapment.

There is increasing speculation about the cause of chronic groin pain and why laparoscopic repair appears to be superior to open mesh repair in this context. One possible explanation for neuropathic pain is injury to the ilioinguinal, iliohypogastric or

genitofemoral nerves, either during exposure of the inguinal canal or handling of the cord and dissection of the hernia sac in open surgery.

Accurate diagnosis is important because if the cause of pain is incorporation of a nerve in staples or sutures, effective surgical treatment is available. The nerves usually involved are the ilioinguinal nerve, the iliohypogastric nerve, the genital and femoral branches of the genitofemoral nerve, and the lateral cutaneous nerve of the thigh. The first two nerves are especially likely to be injured during a conventional herniorrhaphy, whereas the latter two are more likely to be damaged during a preperitoneal herniorrhaphy. Neuropathy is generally signaled by pain or paraesthesia in the injured nerve's distribution; however, there is significant overlap in the distributions of these nerves, and as a result, it is frequently difficult to determine exactly which nerve is damaged.

In most affected patients, postsurgical chronic pain closely resembles neuropathic pain. Major nerves trespass the surgical field of most of the surgical procedures associated with chronic pain, and damage to these nerves is probably a prerequisite for the development of postsurgical chronic pain. A continuous inflammatory response, such as after inguinal mesh hernia repair, can contribute to a maintained inflammatory pain.

In the immediate postoperative period, with direct activation of nociceptors, inflammation, and in some cases injury to nerves, the clinical picture is dominated by spontaneous resting and breakthrough pain referred to the site of surgery and the surrounding tissues. Movement or touching of the wound site, breathing, coughing, and gastrointestinal motility can all evoke flares of pain. Stimulus-evoked hypersensitivity is present both in the injured area and the surrounding non-injured tissue. Most patients respond well to opiates and COX inhibitors. If nerves are injured during surgery, a neuropathic component of the pain might develop immediately and then persist in the absence of any peripheral noxious stimulus or ongoing peripheral inflammation. This pain, once established, is likely to be resistant to COX inhibitors.

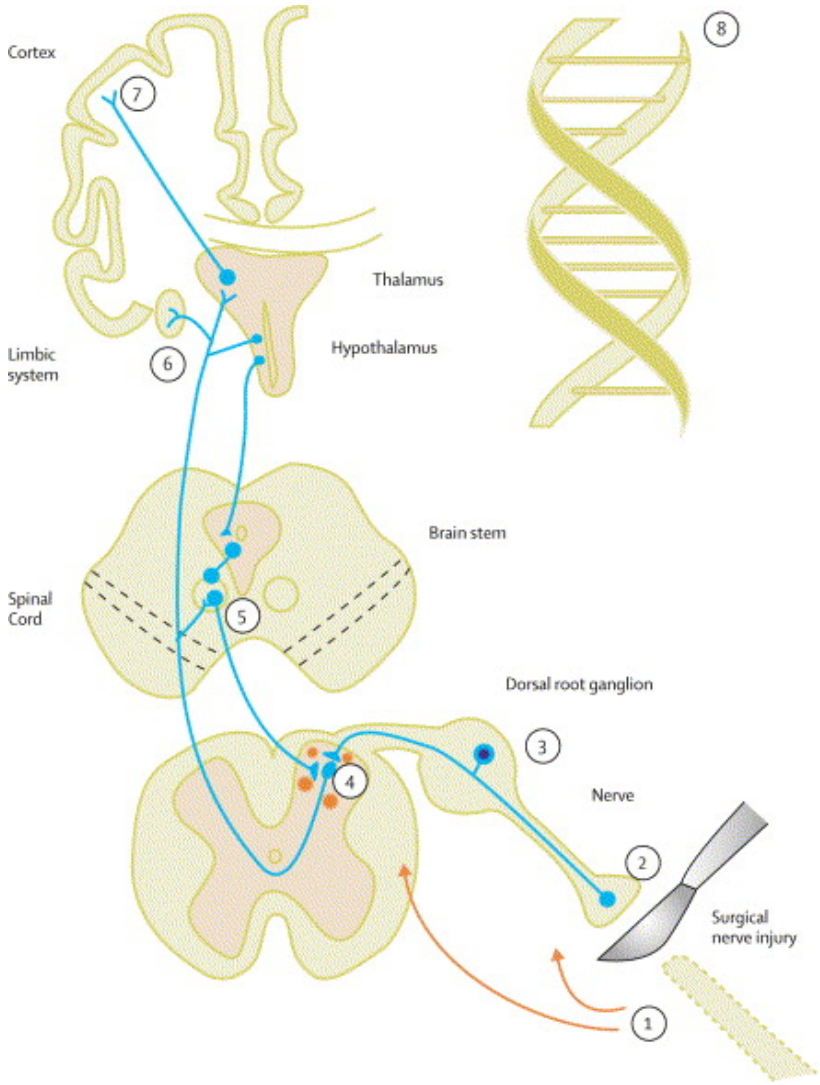


Figure - 1.1

Sites and mechanisms responsible for chronic postsurgical neuropathic pain. *(From Kehlet H, Jensen TS, Woolf CJ. Persistent postsurgical pain: risk factors and prevention. Lancet 2006; **367**: 1618–1625)*

(1) Denervated Schwann cells and infiltrating macrophages distal to nerve injury produce local and systemic chemicals that drive pain signaling. (2) Neuroma at site of injury is source of ectopic spontaneous excitability in sensory fibres. (3) Changes in gene expression in dorsal root ganglion alter excitability, responsiveness, transmission, and survival of sensory neurons. (4) Dorsal horn is site of altered activity and gene expression, producing central sensitisation, loss of inhibitory interneurons, and microglial activation, which together amplify sensory flow. (5) Brainstem descending controls modulate transmission in spinal cord. (6) Limbic system and hypothalamus contribute to altered mood, behaviour, and autonomic reflexes. (7) Sensation of pain generated in cortex (past experiences, cultural inputs, and expectations converge to determine what patient feels). (8) Genomic DNA predispose (or not) patient to chronic pain and affect their reaction to treatment.

Studies have shown that the intensity of acute pain after herniorrhaphy is related to the risk of developing chronic postoperative pain [37], and that preoperative pain response to a nociceptive stimulus correlates with the intensity of early postoperative pain [37]

It would be too simplistic to regard chronic pain as being caused by either one or the other of the above mentioned mechanisms, in truth it is often a combination of two, although usually one plays the predominant role. In addition, acute and chronic pain is expressed against a complex physiological, genetic, and psychosocial background, which contributes not only to the conversion of somatosensory activity into a pain experience, but also to the amplitude of and reaction to the sensation, and to related changes to mood and behaviour.

1.10.4 Factors influencing chronic pain[42]

1. Preoperative pain

Prior to undergoing elective repair of an inguinal hernia, most patients usually report mild to moderate pain at rest and during activity. Only around 1% to 2% have severe pain at rest, and 10% have severe pain on moving [27]. Interestingly, there is an association between those who record pain due to their hernia preoperatively and the subsequent reporting of chronic pain. In a prospective study of more than 300 patients from our unit undergoing inguinal hernia repair, Page et al noted that nearly 80% of patients who reported chronic pain had had pain due to their hernia preoperatively. This figure was compared to the 47% of those who were now pain-free, and the difference was highly significant. Although patients with chronic pain had higher pain scores preoperatively and at 6 and 24 hours postoperatively, these differences were not significant. The only other difference between the groups was the fact that those who had chronic pain were significantly younger than those who reported no pain. Callesen et al. demonstrated similar findings and noted that the risk of chronic moderate or severe pain was increased in patients who had a high pain score 1 week after operation [34]. A further study by Franneby et al [2], demonstrated that a high level of preoperative pain indicated an increased risk of long-term pain, as reported also by Poobalan et al [35] and Courtney et al.[43] This might suggest that the hernia disease was already complicated prior to surgery

in some patients; stretching, entrapment, and/or inflammation of local nerves are conceivable mechanisms, but psychologic susceptibility or increased pain sensitivity may also play a role. Moreover, the pain prior to the operation may also have originated from other conditions than the hernia, and will then persist after the operation. A third possibility is that interindividual variations in the manner of communicating subjective feelings may have affected the observed relationship. A general inclination to report pain and other feelings in an exaggerated way will most likely persist both before and after the operation and so will a propensity for being stoical. However, a cautious interpretation of these results is needed since the answer to the question of preoperative pain is the patient's recollection of the pain level. The complexity of inguinal pain is underlined by the fact that a substantial proportion of patients also reported pain from the non treated contralateral groin.

One reason for an association between preoperative pain and the subsequent reporting of chronic pain may be the fact that repair of a hernia reduces rather than eliminates the pain caused by the hernia[27]. In a prospective study where pain scores (VAS) were measured preoperatively and 1 year postoperatively, the average pain scores at rest and on moving were reduced by approximately 50% at the 1-year time point. Further evidence that this pain is related to the hernia rather than the operation is evidenced by the fact that those who recorded no pain from their hernia preoperatively had minimal pain at rest and no pain on moving 1 year postoperatively.

2. Early post operative pain

Many studies have shown that patients who complain from early post operative pain are more likely to suffer from chronic groin pain[2,31,34-36]. Courtney et al [43] reported that two third of patients who complain from severe or very severe pain at three months will still be having pain at 2-3 years.

3. Primary versus Recurrent hernia

Callesen and coworkers carried out a large-scale consecutive study with a follow-up rate of 93 %, the findings were that patients treated for a recurrent hernia had a fourfold higher rate of moderate or severe pain than those treated for a primary hernia. The rate of

moderate or severe pain was almost three times higher after recurrent hernia repair even when a Lichtenstein mesh repair was used. A sevenfold increase in the frequency of moderate or severe pain after 1 year was reported in patients who had a high pain score 4 weeks after operation compared with those with a low pain score [34].

4. The use of mesh

According to a review study by the EU Hernia Trialist Collaboration[44] reviewing all randomized or quasi-randomized trials comparing open-mesh with non-mesh methods published until 1999, a minority of studies reported a measure of postoperative chronic pain. Of the 15 trials included in the review study, 12 compared a flat mesh to non-mesh repairs. The mean or median duration of follow-up of all 15 of the studies ranged from 6 days to 5 years. There were few reported cases of chronic pain, with reported rates similar for mesh and non-mesh groups. Recently Van Veen et al carried out a 10-year follow-up study comparing both groups and this provided evidence that mesh repair of inguinal hernia is equal to non-mesh repair with respect to long-term chronic pain [45].

5. Lightweight versus Heavyweight Meshes

There is some evidence from a number of small randomized trials that lightweight meshes may cause less long-term pain than their heavyweight counterparts [46,47]. This effect, however, seems to be most evident in patients suffering mild or very mild pain, there was no obvious effect on those with severe or very severe pain. This may reflect the number of patients in the various studies, as none has had the power to show a significant difference in severe or very severe chronic pain. O'Dwyer and coworkers compared a lightweight partially absorbable mesh with a heavyweight prolene mesh and showed significantly fewer patients in the lightweight group had pain at 1 year (39.5% vs. 51.6%) [46].

6. Nerve Division versus Preservation

Some authors routinely divide the genital branch of the genitofemoral nerve, whereas others divide the ilioinguinal nerve if it is at risk of a traction injury or of being incorporated with a non-absorbable suture. There is no evidence that either strategy has any impact on the subsequent development of long-term chronic pain as shown recently

in a well designed randomised controlled study by Picchio et al, who demonstrated that at 1 year 76.5% of those who had had nerve preservation were pain-free compared to 73.0% of those who had had nerve division, also at the 1 and 6 months' follow-up evaluation there were no significant differences in pain between the groups [48].

7. Open versus Laparoscopic Repair

Laparoscopic repair is known to be less painful than open repair in the early post operative period, having the advantage of minimal access and less traumatic dissection to free the sac from the inguinal canal. As reported by several authors who noted significantly less pain after laparoscopic than open repairs[2,46,49,50], the MRC trial quoted lower rates of chronic groin pain following laparoscopic repair (28.7%) compared to open repair (36.7%)[51], this difference was not significant. Moreover, at 5 years 4.3% of patients in the laparoscopy group had attended a hospital pain clinic compared to 3.7% in the open group. And there was no difference regarding the impact of the operation on day-to-day life [51]. The EU Hernia Trialist group had similar findings in their meta-analysis of randomized controlled trials of laparoscopic and open prosthetic mesh repair of groin hernias, where they found that chronic pain is less likely to occur after laparoscopic repair than after open repair[52]. However, they had reservations about this finding because of a lack of uniform definition of chronic pain in these trials.

The nature of this pain differs as well ,as was demonstrated by Wright et al[36], who on following up patients for 5 years, found that patients undergoing laparoscopic repair were more likely to have testicular pain, while those undergoing open repair were more likely to have pain along the inguinal ligament and were maximally tender over the pubic tubercle.

In contrast other authors have found that the type of repair does not influence pain scores in patients having a hernia repair[1,36,53] .

These contradictive results could be explained by the fact that most of these studies lacked any assessment of preoperative risk factors or detailed appraisal of the intensity of pain and consequences of the chronic pain state, including a full assessment of nerve damage, moreover open repair operations were often performed by surgeons in training, whereas the laparoscopic approach was undertaken by experienced surgeons, making

interpretation of results difficult [54]. Consideration must also be given to surgical expertise because many hernia centres claim very low incidences of chronic pain. Interpretation of such claims has so far been hindered by insufficient follow-up and lack of independent observation. Future studies require a complete and detailed follow-up, comparing technically experienced centres of excellence with results from regular general surgical activity[55], as reports from the later have shown no correlation between the type of hernia, grade of the operator or the presence or absence of post operative complications and the subsequent development of chronic pain[35].

7. Miscellaneous

Other factors associated with chronic pain include: The absence of a visible bulge before surgery[31], younger patients[1,35], presence of numbness in the surgical area postoperatively[56], patients who required 4 or more weeks before returning to work[31,34] and patients with other chronic pain conditions [43].

1.10.5 Presentation of chronic pain

Patients suffering from chronic pain present with a variety of symptoms, the descriptors of pain commonly used by this group of patients usually include both neuropathic (nerve injury) and nociceptive (tissue injury) components but may differ among populations (Table 1.1) [1,43]. Courtney [43] had shown that Patients with very mild or mild pain were more likely to describe the pain using a single term that indicated that the character of the pain was either neuropathic or nociceptive. In contrast, patients with severe or very severe pain were more likely to describe the pain using multiple terms which indicated that the character of the pain was both neuropathic and nociceptive. Numbness was present in significantly more patients in the severe or very severe pain group (18 of 22 *versus* 18 of 38; $P < 0.001$). Around 50% report numbness over the groin or thigh, and the point of maximal tenderness is usually at the pubic tubercle. Patients in the severe-very severe group were significantly more likely to suffer from other chronic pain conditions than those in the very mild-mild group (20 of 22 *versus* 23 of 37; $P = 0.016$). The most common illness was chronic back pain in both groups, and significant numbers also suffered from headache and irritable bowel syndrome. Other conditions that caused

chronic pain in these patients included pain from scars elsewhere in the body and peptic ulcer disease.

Scotland		**Denmark**	
Neuropathic pain		*Neuropathic Pain*	
Aching	(45%)	Shooting	(29%)
Stabbing	(23%)	Pricking	(25%)
Shooting	(18%)		
Nociceptive pain		*Nociceptive pain*	
Throbbing	(28%)	Tender	(42%)
Pulling	(23%)		
Tender	(21%)		
Three or more words used	(42%)		

Table - 1.1 Common descriptors of pain used by patients with chronic pain.
(From: Bay-Nielsen M, Perkins FM, Kehlet H. Ann Surg 2001; 233: 1-7 and Courtney: Br J Surg, Volume 89(10).October 2002.1310–1314)

Whatever the mechanism of chronic pain following hernia repair it would seem that the individual's perception of pain may also be important. Patients who go on to suffer chronic pain are more likely to have complained of pain from the hernia before operation than those who have no postoperative pain [36]. In population based studies [57] 27-39 % of patients surveyed indicated that they had had back pain in the previous week or month; the respective figures for patients with very mild-mild or severe-very severe pain were 46 and 77 per cent. An alternative explanation for the high incidence of back pain in the severe pain group may be related to placing excessive strain on the back muscles in an effort to protect the groin. Further studies on the interrelationship between these conditions and the psychological profile of the patients are required.

1.10.7 Investigations

Perhaps the most important single issue in dealing with post herniorrhaphy pain is whether the current pain is the same as or different from the pain that brought the hernia to the attention of the physician in the first place. If the latter is the case, efforts must be made to determine which of the numerous potential causative conditions is responsible. Computed tomography, ultrasonography, laparoscopy, and magnetic resonance imaging all are of diagnostic value in this setting. Of these, MRI has emerged as the most useful because of its ability to differentiate between muscle tears, osteitis pubis, bursitis, and stress fracture. A strain of the adductor muscle complex (comprising the adductor longus, the adductor brevis, the adductor magnus, and the gracilis) is a commonly overlooked cause of pain.

1.10.8 Prevention and Treatment

There is general agreement that chronic pain after hernia repair is an important adverse outcome. However, knowledge of the relative roles of pre, intra and postoperative factors is incomplete. There is also a lack of evidence-based treatment strategies.

Knowledge of the anatomy of cutaneous nerves and their aberrant courses may help avoid nerve injury. Care must be taken to avoid suture insertion at the medial insertion of the inguinal ligament and that undue tightness of the inguinal ligament should be avoided at the pubic tubercle. Lichtenstein et al [58] recommended preserving the nerves in the inguinal canal to minimize the incidence of chronic pain. Sometimes this is difficult as the nerves may hinder the dissection or may lie across the prosthetic mesh on the posterior inguinal wall; in such circumstances some surgeons prefer to divide these nerves. One study demonstrated that dividing the inguinal nerves did not reduce the incidence of chronic pain[59]. In a recent systematic review by Wijsmuller el at, it was clear that inguinal nerves should be identified during surgery, dividing them or preserving them had similar results in terms of post operative pain scores [60].

It has been argued that prosthetic mesh may contribute to the development of chronic groin pain [61]. However, the EU Hernia Trialists' systematic review found that mesh repairs are less likely to cause chronic pain than non-mesh repairs [62], but surgeons must

be aware that factors related to the securing and stapling of mesh are reported to be a main cause of neuralgia. Suggestions to avoid staples or to use tacks and to avoid nerve entrapment while stapling have been made to prevent neuralgia, although there are no randomized data to support these hypotheses. Staples should not be placed below the level of iliopubic tract when stapling lateral to the internal spermatic vessels. Kiruparan et al. [63] suggested that helical titanium tacks should be used, rather than staples, to anchor the mesh. Other authors have suggested that neuralgia can be avoided if mesh is kept in place by intra-abdominal pressure alone and use of staples is avoided. Sensory nerves should be preserved, but this is not always possible, and some very small nerves are invariably divided. Other than avoiding damage to the sensory nerves by sutures or staples, intentional division of sensory nerves in the groin is thought to prevent chronic neuralgia at the expense of an area of anesthesia above the pubis.

Treatment is difficult and often fails entirely. The difficulty is compounded when workers' compensation issues cloud the picture. The first possibility that must be ruled out is a recurrent hernia.

The management of patients with severe pain is largely based on empiric evidence for managing other chronic pain conditions. As a rule, all types of pain are best treated initially with reassurance and conservative treatment (e.g., anti-inflammatory medications and local nerve blocks).Other adjunctive therapy includes analgesics, Tricyclic antidepressants (such as amitriptyline), anticonvulsants (such as gabapentin), anxiolytics, steroid Injections, psychological treatment, acupuncture and transcutaneous electrical stimulation (which is widely used and can undoubtedly be effective in some cases, having the advantage of a few side effects and no long term damage). There is no strong evidence that one form of therapy is any more effective than another. Treatment, however, should be initiated as rapidly as possible, as there is evidence that early treatment can reduce the development of resistant chronic pain.

Frequently, the complaint resolves spontaneously, and the general advice is to avoid re-exploration in the first year after the procedure to allow for the possibility of spontaneous resolution. When groin exploration is required, neurectomy and neuroma excision, adhesiolysis, muscle or tendon repair, and foreign-body removal are all possibilities. The

role of surgery in patients with chronic pain is controversial. Some report excellent results with neurectomy plus or minus mesh removal [61]. This effect, however, is likely to be related to the potent placebo effect of the operation. The surgeon's major role should be to prevent this problem in the first instance. This should include warning the patient of the likelihood of severe chronic pain, careful surgical technique paying particular attention not to incorporate nerves into stitches or staples, and providing adequate postoperative pain control.

It is clear from the above that postoperative complications are a major risk factor for both recurrence [64] and for long-term pain. And therefore a meticulous technique in the dissection probably will decrease the risk of pain as well as of recurrence. When considering other aspects of surgery, such as choice of repair, the risk of long-term pain may have to be weighed against the risk of recurrence [2].

1.10.9 Outcome of chronic pain

Although many patients report chronic pain after groin hernia repair, when assessed by questionnaire only half of those with severe pain seek medical assistance. Fewer still are referred back to their surgeon, and only a small group sees a pain specialist. Over time, the pain disappears in around 30%, becomes mild in 45%, and continues to be severe in the remainder [43].

1.11 Management of asymptomatic hernia: an overview

There is no dispute regarding the need to operate on patients with symptomatic inguinal hernias, however the case with asymptomatic hernias is still open to debate, as different surgeons adopt various strategies in dealing with these hernias with the majority opting to operate on the basis that these hernias if left alone will become symptomatic and may present acutely with incarceration or even strangulation.

Yet several authors have shown this risk to be much less than previously thought. In a study by Gallegos et al [16] looking at strangulation and the duration a hernia was present, he found that the cumulative probability an inguinal hernia presenting acutely was 2.8% at 3 months rising to 4.5% after 2 years. With the need to resect non viable tissue being quite rare occurring in only 1 of 439 patients (0.2%) operated on for an inguinal hernia during the study period. These findings are similar to those of Hair et al who found that only 0.3% of patients presenting with an acute hernia required resection of bowel or omentum [26].

The above is true for the hernia population in general, but data concerning the incidence of strangulation of an asymptomatic inguinal hernia are scarce, because there are few studies of large populations with untreated inguinal hernias. And the commonly held assumption that there is a 4% to 6% lifetime risk for strangulation might be more a matter of speculation than fact.[13,65] Reports summarized by Neuhauser [66] in 1977, have shown that the lifetime risk of strangulation for an 18-year-old man is 0.272% or 1 of 368 patients and for a 72-year-old man it is 0.034% or 1 of 2,941 patients.

Based on the current information we have on strangulation, it may be that repairing all asymptomatic hernias is unlikely to lower the incidence of operation for strangulation. A study by McEntee et al [14] demonstrated that one third of patients presenting acutely with an inguinal hernia present within days of noticing their hernias, before elective operation can be contemplated. An additional one third will be aware that their hernia is present but will not report it to their family doctor, and the final one third will be considered too high-risk for elective operation by their general practitioner or surgeon.

Additional data collected prospectively on 699 patients presenting to three surgeons at two Glasgow Hospitals revealed that 34% of patients were asymptomatic at presentation, while 10% of patients had their hernia for 5 or more years before presentation [26].

In another study from Glasgow Page et al [27] demonstrated that asymptomatic patients who had no pain at rest from their hernia before operation reported significant pain scores from the hernia repair site. These findings are similar to those of Bay Nielsen, who noted that 2.5% of patients undergoing hernia repair stated that their hernia pain was worse after than before surgery [67].

Added to this is the fact that more than one third of these patients will be complaining from chronic groin pain one year after their surgery [1,26,32,34-36,43], such pain can be disabling with considerable impact on daily activities as well as on quality of life [1,43,68] and there is evidence to suggest increased use of health service by patients who have chronic pain [69], the identifiable health service cost is likely to be a considerable underestimate because it fails to include the social cost of time off work and possible reduced over all performance of patients with chronic pain [26,32], as it has been shown that 80% of patients with chronic pain would have failed to return to work at 5 years [36].

The other major drive in repairing asymptomatic hernias has been the high mortality rates reported with emergency hernia repairs, but it has been noted that patients considered too high-risk for an elective operation almost certainly contribute to the high mortality associated with emergency hernia operations. Evidence for this selection process affecting mortality comes from a population-based study in which the 30-day mortality of elective hernia repair for men was significantly less than that of the 30-day mortality in the general population[70]. Mortality for emergency inguinal hernia operations in the same study was just under 3%. When deaths after elective and emergency hernia repair in this study of more than 16,000 men are combined, a total of 44 patients died within 30 days of operation. This compared with an expected mortality from the general population using the standard mortality rate during the same time period of 36, leaving a standardized mortality rate for hernia repair of 1.2 (95% CI 0.77 to 1.94, P = 0.6), indicating that most patients who died after hernia repair did so because of serious co morbid disease and not elective or emergency hernia operations. This is in accordance with the Scottish Audit of Surgical mortality findings; that most of the patients who died

following elective or emergency hernia repair were American Society of Anaesthesiology grade 3 to 5 [71].

Neuhauser[66] examined Medicare discharge data from 1971 to determine the mortality rate from inguinal herniorrhaphy, and confirmed that the mortality rate for obstruction (0.04%) was 10 times higher than that for herniorrhaphy without obstruction (0.005%), but the absolute number of deaths associated with obstruction was much less than 0.1% to 0.2% as reported in the literature. Neuhauser concluded that a 65-year-old has a greater probability of death from herniorrhaphy than death from obstruction, and that watchful waiting under the supervision of a surgeon seems to be a relatively safe management strategy.

Hair et all acknowledged that the weakness in his study looking at the effect of time on patient's hernia symptoms was the lack of information on the natural history of the untreated asymptomatic inguinal hernia [26], and therefore an assumption was made, that patients in his study who presented after 5 years or longer were asymptomatic when they first noticed that they had a hernia. Yet at a median follow up of 9 years, 36 (62%) had pain and in 13 (21%) the hernia had become irreducible. And as already mentioned many patients will choose not to attend a doctor with their hernia, and some that do will not be referred for surgical repair [14,72], these results are likely to overestimate the true incidence of pain or irreducibility associated with an inguinal hernia.

Further debate is being generated by Results from other randomized controlled trials looking at the quality of life of patients up to a year after their hernia repair, these have demonstrated that one third of patients have no improvement in these parameters subsequent to their repair [51]; 5% of patients say that they were made worse by their hernia repair. 5-8% had a wound infection [26,73], 7-15 % developed post operative haematoma [26,51]. Furthermore 10% of patients would require re-operation for a recurrent hernia [51]. And therefore a decision to operate on patients with asymptomatic hernias should only be taken after a thorough discussion with the patients, outlining the associated morbidity in terms of chronic groin pain which is reported in one third of patients a year after their surgery, 6% of which will be severe restricting their daily activities [27,34].

Finally it is clear that the surgical community lacks a general consensus regarding the proper management of asymptomatic inguinal hernias, and this could be attributed to the lack of proper randomized prospective trials looking into the proper management of such hernias.

Prospective clinical trials to establish the role of operations for the asymptomatic inguinal hernia are necessary. And for them to yield meaningful results, these trials require close collaboration among patients, primary care physicians, and surgeons.

1.12 Classification systems of groin hernias

The results of hernia repair are closely related to the location and the size of the fascial defect. For example, risk of recurrence in a large direct hernia is at least five times as high as in a small indirect one. Therefore, all groin hernias should be classified by a precise and uniform terminology to make clinical studies reproducible and comparable. An unequivocal categorisation is the essential basis for a controlled analysis of applied methods and recurrence rates. The classification should clearly describe the localisation and size of the fascial (hernial) orifice and the strength of the posterior inguinal wall. All types of groin hernia should be accommodated but for practical purposes the classification should avoid division into too many groups.

Numerous classification schemes for groin hernias have been devised, usually bearing the name of the responsible investigator or investigators (e.g., Gilbert[74], Bendavid[75], Nyhus[76], Schumpelick[77] and finally the EHS[78]). The variety of classifications in current use indicates that the perfect system has yet to be developed [9]. The main problem in developing a single classification scheme suitable for wide application is that it is impossible to eliminate subjective measurements and thus impossible to ensure consistency from observer to observer.

The Following are some of the commonest classification systems around:

1. Stoppa's classification [79]

Classification	Description
Type I	indirect hernia with a normal int. ring measuring less than 2 cm. Inguinal floor is solid
Type II	Indirect hernia with int. ring > 2cm inguinal floor solid
Type III	Indirect H + direct H. + femoral hernia with a weak inguinal floor
Type IV	Recurrent hernia

Nyhus [76,80] introduced a classification of four different types. The first three types, relating to primary hernias, are grouped according to diameter of the internal ring, displacement of the epigastric vessels, and condition of the posterior wall. The fourth type includes all recurrent groin hernias.

2. Nyhus Classification [76]

Type I	Indirect inguinal hernia—internal inguinal ring normal (e.g., paediatric hernia)
Type II	Indirect inguinal hernia—internal inguinal ring dilated but posterior inguinal wall intact; inferior deep epigastric vessels not displaced
Type III	Posterior wall defect
A	Direct inguinal hernia
B	Indirect inguinal hernia—internal inguinal ring dilated, medially encroaching on or destroying the transversalis fascia of Hesselbach's triangle (e.g., massive scrotal, sliding, or pantaloon hernia)
C	Femoral Hernia
Type IV	Recurrent Hernia
A	Direct
B	Indirect
C	Femoral
D	Combined

3. Aachen Classification [77]

Grade I	Normal diameter of int. ring (up to 1.5cm)	
Grade II	Indirect and direct hernia with an orifice of 1.5 to 3 cm)	
In combined hernia total diameter of two defect is calculated and is added		
L	Lateral (indirect)	
M	Medial (direct)	
F	Femoral	

It is similar to Nyhus classification with an additional measurement incorporating size of the hernial orifice.

4. European Hernia Society (EHS) Classification [78]

EHS groin hernia classification		**Primary**	**Recurrent**		
	0	1	2	3	
L					
M					
F					

The EHS classification largely resembles the Aachen classification. In the Aachen classification, 1.5 cm is used as reference for the size of the hernia orifice. EHS proposed the index finger as the reference in open surgery, since the usual size of the tip of the index finger is mostly around 1.5–2 cm. This dimension is also reported to be identical to the length of the branches of a pair of most laparoscopic graspers, dissectors or scissors, enabling the surgeon to use the same classification during laparoscopic surgery.

As can be seen in the table above, the size of the hernia orifice is registered as 1 (≤1 finger), 2 (1–2 fingers) and 3 (≥3 fingers). Thus a hernia orifice of 2.5 cm is depicted as a size 2 hernia. For the anatomic localisation, the same criteria are used as in the Aachen classification (L = lateral, M = medial, F = femoral). For a combined hernia it was propose to mention the different hernias in the table by ticking the appropriate box instead of using the term Mc as in the Aachen classification.

In addition, the letter P or R can be encircled to depict, respectively, a primary or recurrent hernia.

1.13 Anatomy of the inguinal region[8,28]

The surgeon must have a thorough understanding of the anatomy of the groin to properly select and utilize various options for hernia repair. In addition, the relationships of muscles, aponeurosis, fascia, nerves, blood vessels, and spermatic cord structures in the inguinal region must be mastered to obtain the lowest incidence of recurrence and to avoid complications. These anatomic considerations must be understood from both the anterior and posterior approaches, as both approaches are useful in different situations.

Because most hernias are repaired through an anterior approach, it is essential to understand the anatomy from the skin surface to the preperitoneal space. Beneath the skin

and subcutaneous tissues are the superficial circumflex iliac, superficial epigastric, and external pudendal arteries and accompanying veins. These vessels arise from and drain to the proximal femoral artery and vein, respectively, and are directed superiorly. If encountered during operation, these vessels can be retracted or even divided when necessary.

The skin of the lower anterior abdominal wall is innervated by anterior and lateral cutaneous branches of the ventral rami of the seventh through 12th intercostal nerves and by the ventral rami of the first and second lumbar nerves. These nerves course between the lateral flat muscles of the abdominal wall and enter the skin through the subcutaneous tissue.

The first layers encountered beneath the skin are Camper's and Scarpa's fasciae in the subcutaneous tissue. The only significance of these layers is that when sufficiently developed, they can be re-approximated to provide another layer between a repaired inguinal floor and the outside. The major blood vessels of this superficial fatty layer are the superficial inferior epigastric vessels, and the superficial circumflex iliac vessels (which are branches of the femoral vessels).

- **Inguinal Canal**

The inguinal canal is approximately 4 cm in length and is located 2-4 cm superior to the inguinal ligament. The canal extends between the internal (deep) inguinal and the external (superficial) inguinal rings in an oblique path. The inguinal canal contains the spermatic cord in men and the round ligament of the uterus in women.

The anterior wall consists of the aponeurosis of the external oblique abdominal muscle. The posterior wall is the aponeurosis of the transverse abdominal muscle and the transversalis fascia. Superiorly lies the conjoint tendon while the inferior margin is formed by the inguinal ligament.

The angle of entrance of the deep ring is acute medially and obtuse laterally. The transverse aponeurosis and transversalis fascia comprise the medial border of the deep ring. It is fibrous, definable, and palpable and is the margin surgeons repair during hernioplasty. The lateral border of the deep ring is formed by the transverse abdominal muscle. It is soft, elastic, muscular, and indistinct. The internal oblique abdominal muscle

covers the deep ring and forms the shutter mechanism. This muscle obscures the deep ring from view and prevents its palpation from the anterior approach. The lateral border of the deep ring is so blunt as to be indistinguishable and unrecognizable even from the posterior view.

The spermatic cord is composed of cremasteric muscle fibers, the testicular artery and accompanying veins, the genital branch of the genitor femoral nerve, the vas deferens, the cremasteric vessels, the lymphatics, and the processus vaginalis. The cremaster muscle arises from the lowermost fibers of the internal oblique muscle and encompasses the spermatic cord in the inguinal canal. The cremasteric vessels are branches of the inferior epigastric vessels and pass through the posterior wall of the inguinal canal through their own foramen. These vessels supply the cremaster muscle and can be divided to expose the floor of the inguinal canal during hernia repair without damaging the testis (Figure 1.2).

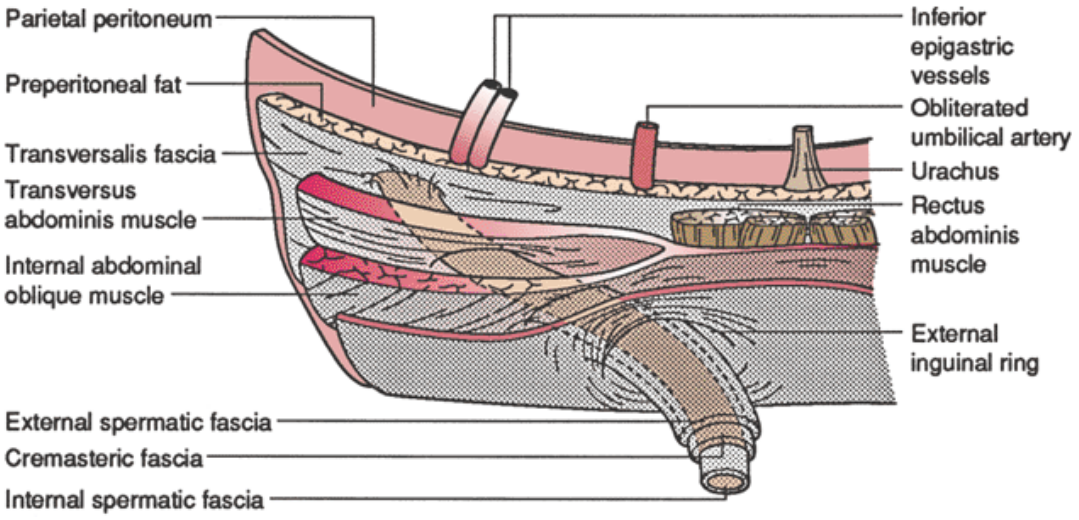


Figure -1.2

Component layer coverings of the spermatic cord

(From Greenfield's Surgery: scientific principles and practice. Lippincott Williams & Wilkins;2006)[81]

The Hesselbach triangle refers to the margins of the floor of the inguinal canal. The inferior epigastric vessels serve as its superolateral border, the rectus sheath as medial

border, and the inguinal ligament as the inferior border. Direct hernias occur within the Hesselbach triangle, whereas indirect inguinal hernias arise lateral to the triangle. It is not uncommon, however, for medium and large indirect inguinal hernias to involve the floor of the inguinal canal as they enlarge.

- **External Oblique Muscle and Aponeurosis**

The external oblique muscle fibers are directed inferiorly and medially and lie deep to the subcutaneous tissues. The aponeurosis of the external oblique muscle is formed by a superficial and deep layer. This aponeurosis, along with the bilaminar aponeurosis of the internal oblique and transversus abdominis, forms the anterior rectus sheath and, finally, the linea Alba by linear decussation (Fig 1.2). The external oblique aponeurosis serves as the superficial boundary of the inguinal canal. The inguinal ligament (Poupart's ligament) is the inferior edge of the external oblique aponeurosis and extends from the anterior superior iliac spine to the pubic tubercle, turning posteriorly to form a shelving edge. The lacunar ligament is formed by the insertion of the inguinal ligament to the pubis. The external (superficial) inguinal ring is an ovoid opening of the external oblique aponeurosis that is positioned superior and slightly medial to the pubic tubercle. The spermatic cord exits the inguinal canal through the external inguinal ring (Figure 1.3).

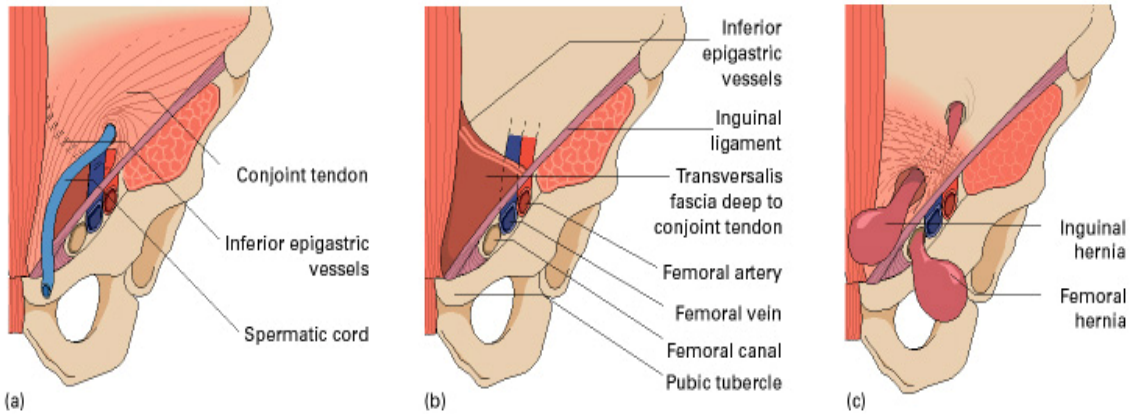


Figure -1.3
The Anatomy of the inguinal region

(From *Cheek C, Kingsnorth A. Inguinal and Femoral hernias. In Morris PJ, Wood WC, eds. Oxford text book of surgery, Oxford University Press, 2000)*[19].

- **Internal Oblique Muscle and Aponeurosis**

The internal oblique muscle fibers are directed superiorly and laterally in the upper abdomen; however, they run in a transverse direction in the inguinal region. The internal oblique muscle serves as the superior border of the inguinal canal. The medial aspect of the internal oblique aponeurosis fuses with fibers from the transversus abdominis aponeurosis to form a conjoined tendon. This structure actually is present in only 5% to 10% of patients and is most evident at the insertion of these muscles on the pubic tubercle. The cremasteric muscle fibers arise from the internal oblique and encompass the spermatic cord.

- **Transversus Abdominis Muscle and Aponeurosis and Transversalis Fascia**

The transversus abdominis muscle layer is oriented transversely throughout most of its area; in the inguinal region these fibers course in a slightly oblique downward direction. The strength and continuity of this muscle and aponeurosis are important for the prevention of inguinal hernia.

The aponeurosis of the transversus abdominis covers both anterior and posterior surfaces. The lower margin of the transversus abdominis arches along with the internal oblique muscle over the internal inguinal ring to form the transversus abdominis aponeurotic arch. The transversalis fascia is the connective tissue layer that underlies the abdominal wall musculature. The transversalis fascia is a component of the inguinal floor. It tends to be denser in this area but still remains relatively thin.

The iliopubic tract is a continuation of the transverse abdominis aponeurosis and fascia at the upper border of the femoral sheath. The iliopubic tract also forms the inferior crus of the deep inguinal ring. The superior crus of the deep ring is formed by the transversus abdominis aponeurotic arch. The iliopubic tract is located posterior to the inguinal ligament, and it crosses over the femoral vessels and inserts on the anterior superior iliac spine and inner lip of the wing of the ilium.

The iliopubic tract is an extremely important structure in the repair of hernias from both the anterior and posterior approaches. It comprises the inferior margin for most anterior repairs. The portion of the iliopubic tract lateral to the internal inguinal ring serves as the inferior border below which staples or tacks should not be placed during a laparoscopic

inguinal hernia repair because the lateral femoral cutaneous and genitor femoral nerves are located inferior to the iliopubic tract.

- **Cooper's Ligament**

Cooper's ligament is formed by the periosteum and fascia along the superior ramus of the pubis. This structure is posterior to the iliopubic tract and forms the posterior border of the femoral canal.

- **Nerves in the groin area**

The iliohypogastric and ilioinguinal nerves and the genital branch of the genitofemoral nerve are the important nerves in the groin area. The iliohypogastric and ilioinguinal nerves provide sensation to the skin of the groin, the base of the penis, and the ipsilateral upper medial thigh. The iliohypogastric and ilioinguinal nerves lie beneath the internal oblique muscle to a point just medially and superior to the anterior superior iliac spine, where they penetrate the internal oblique muscle and lie beneath the external oblique aponeurosis. The main trunk of the iliohypogastric nerve runs on the anterior surface of the internal oblique muscle and aponeurosis medial and superior to the internal ring. The iliohypogastric nerve may provide an inguinal branch that joins the ilioinguinal nerve. The ilioinguinal nerve runs anterior to the spermatic cord in the inguinal canal and branches at the superficial inguinal ring. The genital nerve innervates the cremaster muscle and the skin on the lateral side of the scrotum and labia. This nerve lies on the iliopubic tract and accompanies the cremaster vessels to form a neurovascular bundle (Figure 1.4).

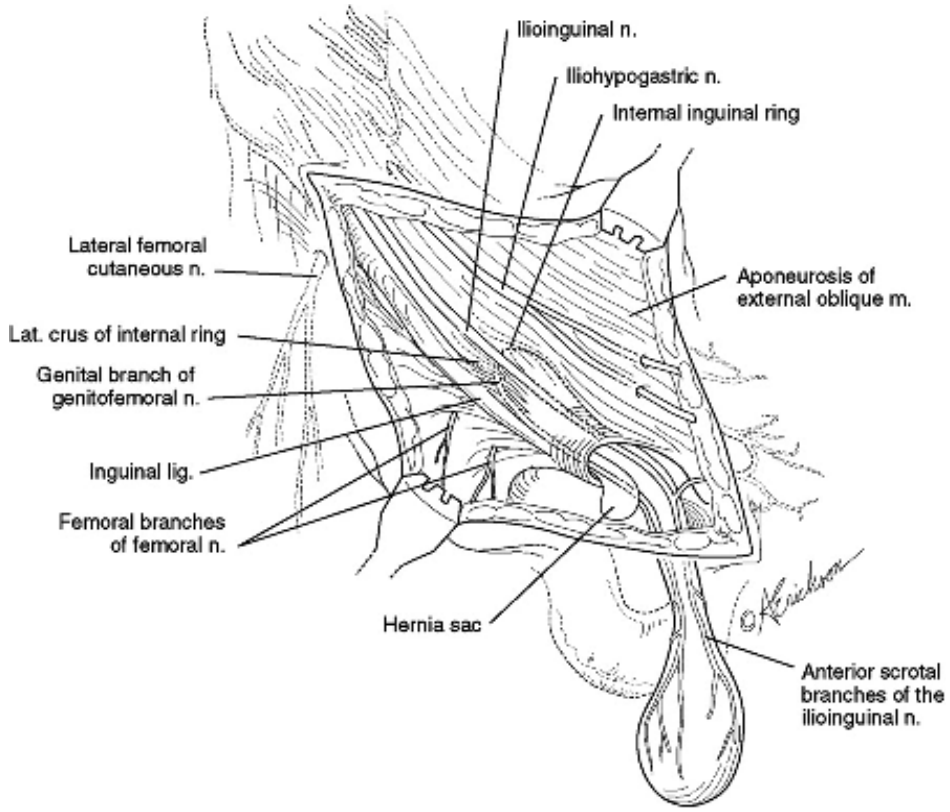


Figure -1.4
Nerves encountered during the anterior inguinal herniorrhaphy approach.
(Courtesy of A. Erickson, Brooklyn, NY. From Ferzli GS., Edwards E., Al-Khoury G. et al. Post herniorrhaphy pain and how to avoid it. Surg Clin. N Am 88 (2008) 203–216.)[82]

- **Femoral Canal**

The boundaries of the femoral canal are the iliopubic tract anteriorly, Cooper's ligament posteriorly, and the femoral vein laterally. The pubic tubercle forms the apex of the femoral canal triangle. A femoral hernia occurs through this space and is medial to the femoral vessels (Figure 1.3).

- **Fruchaud's Myopectineal Orifice**

Traditionally the hernias of the groin have been defined as separate entities, which create confusion. Fruchaud's (1956) concept of the anatomy of hernias of the groin is important. Rather than viewing hernias solely by their varied clinical presentation (i.e., indirect, direct, femoral, prevascular, interstitial), Fruchaud emphasized their common origin by

noting that all the hernias of the groin begin within a single weak area that he called the myopectineal orifice.

The myopectineal orifice is the area in the groin bounded superiorly by the internal oblique muscle and the transverse abdominal muscle, laterally by the iliopsoas muscle, medially by the rectus muscle and sheath, and inferiorly by the pecten pubis. This bony-muscular framework is bridged and bisected by the inguinal ligament, traversed by the spermatic cord and femoral vessels, and sealed like a drum on its inner surface by the transversalis fascia only (Figure 1.5). Therefore the integrity of the myopectineal orifice is dependent on the transversalis fascia. A groin hernia is defined as protrusion of a peritoneal sac through the transversalis fascia spanning the myopectineal orifice. Failure of the transversalis fascia to retain the peritoneum then becomes the fundamental cause of all hernias of the groin.

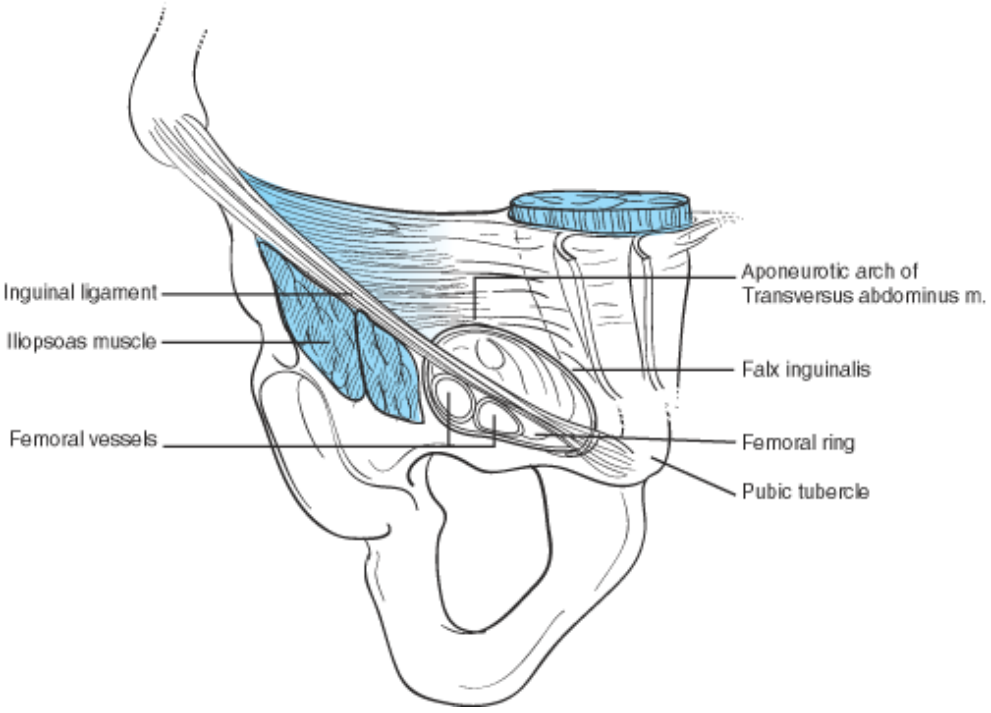


Figure -1.5
The Myopectineal orifice of Fruchaud

(From Fitzgibbons RJ, Filipi CJ, Quinn TH: Inguinal hernias. In Brunicardi FC; Anderson DK; Billiiar TR; et al [eds.]: Schwartz's Principles of Surgery, The MacGrow-Hill companies 2005)[83]

- **Preperitoneal Space**

The preperitoneal space contains adipose tissue, lymphatics, blood vessels, and nerves. The nerves of the preperitoneal space of specific concern to the surgeon include the lateral femoral cutaneous nerve and the genitofemoral nerve (Figure 1.3). The lateral femoral cutaneous nerve originates as a root of L2 and L3 and is occasionally a direct branch of the femoral nerve. This nerve courses along the anterior surface of the iliac muscle beneath the iliac fascia and passes either under or through the lateral attachment of the inguinal ligament at the anterior superior iliac spine. This nerve runs beneath or occasionally through the iliopubic tract lateral to the internal inguinal ring.

The genitofemoral nerve usually arises from the L2 or the L1 and L2 nerve roots. It divides into genital and femoral branches on the anterior surface of the psoas muscle. The genital branch enters the inguinal canal through the deep ring, whereas the femoral branch enters the femoral sheath lateral to the artery.

The inferior epigastric artery and vein are branches of the external iliac vessels and are important landmarks for laparoscopic hernia repair. These vessels course medial to the internal inguinal ring and eventually lie beneath the rectus abdominis muscle immediately beneath the transversalis fascia. The inferior epigastric vessels serve to define the types of inguinal hernia. Indirect inguinal hernias occur lateral to the inferior epigastric vessels, whereas direct hernias occur medial to these vessels (Figure 1.6).

The vas deferens courses through the preperitoneal space from caudad to cephalad and medial to lateral to join the spermatic cord at the deep inguinal ring.

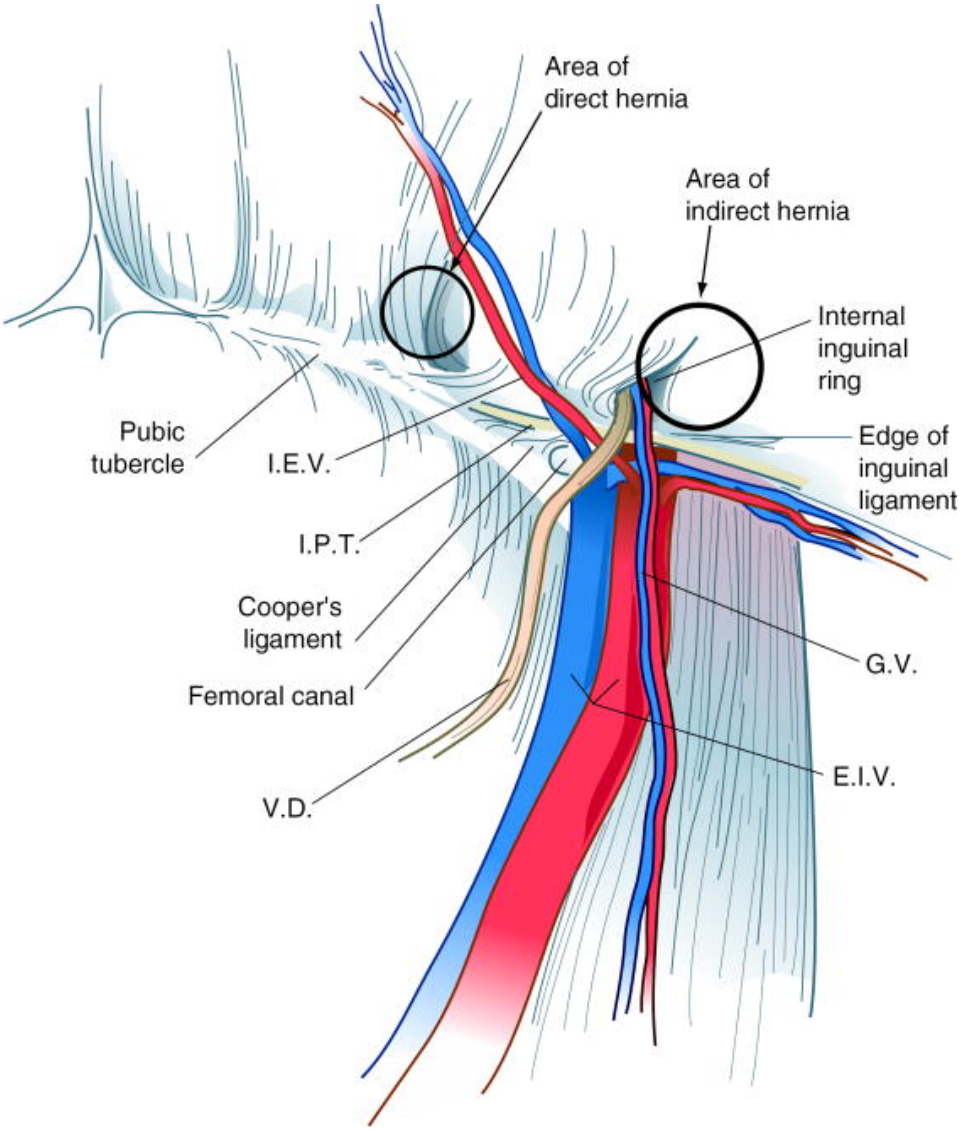


Figure -1.6

Anatomy of the important preperitoneal structures in the right inguinal space

IEV, inferior epigastric vessels; IPT, iliopubic tract; VD, vas deferens; GV, gonadal vessels; EIV, external iliac vessels.

(From Talamini MA, Are C: Laparoscopic hernia repair. In Zuidema GD, Yeo CJ [eds] , 5th ed. Philadelphia, WB Saunders, 2002, vol 5, p 140.)[84].

1.14 Prosthetic Material for Hernioplasty [8,85]

Knowledge of the various prosthetic materials is essential as some of these meshes have been implicated in chronic post surgical pain.

The use of mesh in hernia repair has become the standard repair world wide, this was based on the definite reduction in recurrence rates as well as post operative pain scores in these patients (from 4.9% to 2% and from 10.7% to 5.05% respectively) [52]

Early in the 20th century Billroth stated that ' if an adequate tissue replacement could be found, the problem of hernia would no longer exist' this triggered a search for an ideal tissue replacement, and since then Several materials have emerged as suitable for routine use in hernia surgery, as they fulfill the characteristics of an ideal prosthesis [22] :

1. Not modified physically by tissue fluid
2. Chemically inert
3. Does not cause an inflammatory or foreign body reaction
4. Does not cause carcinogenesis
5. Does not cause allergic or hypersensitivity responses
6. Resistant to mechanical strain
7. Conformable
8. Sterilizable

Non degradable and biologic-tolerant synthetic mesh prostheses are readily available. Those proven useful are Marlex, Prolene, Trelex, Surgipro, Mersilene, and Gore-Tex. Each has its advocates, none is perfect, and in practice the selection of the prosthesis material will be a compromise.

The following are some of the most commonly used meshes:

1. <u>Polypropylene mesh (Marlex, Trelex, and Prolene)</u>: which resemble one another, are composed of knitted monofilament fibers of polypropylene. All are porous, slightly elastic, semi rigid, and relatively heavy, and they contain plastic memory and buckle when bent in two directions at once.

2. <u>Surgipro mesh</u>: is composed of knitted, braided strands of polypropylene. Its physical characteristics closely resemble those of knitted meshes of monofilament polypropylene.

3. Mersilene: is an open-knitted mesh composed of pure, uncoated, braided fibers of the polyester Dacron. It is porous, soft, light, lacelike, supple, elastic, and without plastic memory; it has a grainy texture that prevents slippage and has only a minimal tendency to buckle when bent in two directions at once.

4. Gore-Tex is expanded polytetrafluoroethylene (PTFE, or Teflon). It is a nonporous, smooth, supple, fabric like material containing through-and- through microscopic pores into which fibroblasts grow but through which serosanguineous fluid will not flow.

The prostheses made of polypropylene and polyester trigger a prompt fibroblast response and are rapidly integrated in the body with minimal inflammation.

Gore-Tex is inert and does not incite fibroplasia or inflammation. It is not integrated in the tissues but rather is segregated by encapsulation. The process of encapsulation is slow, taking as long as 30 to 40 days. Perforated Gore-Tex is available, permitting early fixation and immobilization of the prosthesis during the process of encapsulation. The tendency of intestines to adhere to Gore-Tex is minimal. This feature, which the other permanent prostheses lack, may be advantageous for certain circumstances where the mesh would be in direct contact with the intestine.

Polyester and polypropylene permanent prostheses should never contact abdominal viscera directly. They provoke binding and intimate adhesions that are difficult to divide and can cause intestinal obstruction and fistulization. Such adhesions can be prevented by interposing the omentum or an absorbable prosthesis between the permanent prosthesis and the bowel. Absorbable prostheses of knitted or woven polyglactin (Vicryl) and polyglycolic acid (Dexon) are available. These prostheses also incite fibroplasia and can cause adhesions. However, they prevent the viscera from touching the permanent prosthesis during mesothelial integration of the permanent prosthesis and prevent grafting of the prosthesis to the viscera. A membranous sheet of Gore-Tex is also available. It is intended to substitute for absorbable meshes for the prevention of adhesions between viscera and polypropylene or polyester prostheses.

Problems with Synthetic Non absorbable Prostheses

All the synthetic materials can become sequestered, act like a foreign body and aggravate and prolong infections. Hence the risk of infection is balanced by the risk of recurrence. Theoretically, monofilament mesh ought to tolerate infection better than polyfilament mesh because bacteria can settle into and be hard to dislodge from the interstices of the polyfilament fibers. In practice this is not necessarily true, however, perhaps because the fibers are fine and the braid or twist is loose. The braided, knitted Dacron mesh Mersilene tolerates infection as well as, for example; the non-braided, solid- fiber polypropylene meshes. If either is infected, integration rather than infection is the rule, provided suitable treatment is given and the prosthesis is in contact with healthy tissues and is not sequestered.

1.15 Treatment of Inguinal Hernia

The current surgical literature suggests that all inguinal hernias should be repaired unless specific contraindications are present. This recommendation is based on the presumption that complications of incarceration, obstruction, and strangulation are greater threats than are the risks of operation. The operative mortality, especially in the elderly, is increased at least nine fold to 10-fold when obstruction occurs [5,86,87]. The treatment of a groin hernia is surgical unless a serious medical condition precludes repair, and because of the ease with which groin hernias can be repaired under local anesthesia, the number of these conditions has dropped dramatically.

1.15.1 Non operative Management [19,28]

Surgery is the usual treatment for groin hernias, and with the use of local anaesthesia few patients should be refused surgery. Selected patients who do not wish to have surgery or who wish to work whilst awaiting surgery can be offered a truss.

Non-operative treatment is recommended only for asymptomatic, reducible, direct hernias in elderly individuals where an improvement in quality of life is unlikely. Some hernias enlarge and become symptomatic, particularly the indirect, sliding type; in such cases, and particularly in younger patients, surgery should be advised.

There is no evidence to suggest that truss wearing causes increased risk of recurrence after hernia surgery, but it is important to remember that complications can occur despite their use and these include testicular atrophy (1.2-9.6%), hernial incarceration (0-7%), ilioinguinal and femoral neuritis and thrombosis of the iliac vessels [88].

Trusses have been used in the treatment of groin hernias for many years; approx. 40 000 are prescribed per annum in the United Kingdom [89]. Trusses are appliances designed to be worn throughout the day to keep the hernia reduced by compressing the area through which the hernia protrudes. There are two main types: elastic trusses, which need replacing every 6 months, and spring trusses, which need to be renewed every 2 years. It is essential that the truss be correctly measured for and fitted, if it is to benefit the patient. Patients must be fully instructed on how to fit and wear their truss. In a study by Law and Trapnell assessing 250 patients fitted with a truss, it was found that only 31% of patients had part or complete control of the hernia and 64% found the truss to be uncomfortable [90].

It is generally agreed that non operative management should not be used for femoral hernias because of the high incidence of associated complications, particularly strangulation.

1.15.2 Operative Management [9]

-General considerations

The major indication for a surgeon to choose any one inguinal hernia repair over another is personal experience with a particular operation. Thus, in theory, any patient can be considered a candidate for any of these procedures. Some general guidelines are useful, however. The overriding consideration should be the need to tailor the operation to the patient's particular hernia. For example, a simple Marcy repair would be completely adequate for a pediatric patient with a Nyhus type 1 hernia but not for an elderly patient who has an indirect hernia in conjunction with extensive destruction of the inguinal floor. The conventional anterior prosthetic repairs are particularly useful in high-risk patients because they can easily be performed with local anesthesia. On the other hand, giant prosthetic reinforcement of the visceral sac (GPRVS), especially when bilateral, necessitates general or regional anesthesia and thus is best for patients with bilateral

direct or recurrent hernias or, perhaps, for patients with connective tissue disorders that appear to be associated with their hernia. If surgery has previously been done in either the anterior or the preperitoneal space, the surgeon should choose a procedure that uses the undissected space. If local or systemic infection is present, a non prosthetic repair is usually considered preferable, though the newer biologic prosthesis now being evaluated may eventually change this view. Uncorrected coagulopathy is a contraindication to elective repair.

-Antibiotic cover

At present there is insufficient evidence to recommend routine antibiotic prophylaxis for elective inguinal hernia repair. In a multi centre prospective study of 2493 inguinal repairs Gilbert and Felton found a wound infection rate of less than 1% whether antibiotics were used or not [91], this is similar to the findings by Hair et al who looked at 5506 hernia repairs carried out in Scotland and concluded that the use of antibiotics does not change the incidence of wound infection [5].

1. ANTERIOR APPROACH

Anaesthesia[9,92]

Both surgeon and patient play a role in deciding the type of anaesthesia used. Anxious and uncooperative patients will require general anaesthesia, but most patients are suitable for local anaesthesia. Local anaesthesia provides several advantages over general anaesthesia-namely, demonstration of the hernia and testing of repair during the procedure, early mobilisation, reduction of urinary retention, and, in the elderly and in patients with cardiac or pulmonary disease, ease of perioperative management[93]. Additionally, patients benefit from longer pain relief and need less analgesic drug treatment. Furthermore, costs are reduced and patients' turn-round time is accelerated. Surgical clinics specialising in hernia surgery use local anaesthesia in more than 90% of the procedures, with excellent results [93,94]. Local anaesthesia is very popular in the United States, where it is used in 70 % of hernia repairs, but is less commonly used in the United Kingdom (6 % of cases) [5]. Most of the numerous agents available for local anaesthesia are suitable for the hernia procedure. A mixture of short-acting and long-acting

substances provides good pain relief in difficult, lengthy operations and in the first postoperative hours. Furthermore, it lessens the risk of overdose. Additional sedation should be used with caution because some patients develop troublesome respiratory depression; more commonly in elderly patients.

Operative technique [9]

It is important to know what the different techniques of repair entail in order to have a better understanding of the origins of chronic pain following each technique.
The various anterior no prosthetic herniorrhaphies have a number of initial technical steps in common; they differ primarily with respect to the specific details of the actual repair.

Traditionally, the skin is opened by making a small oblique incision in the space between the anterior superior iliac spine and the pubic tubercle. For cosmetic reasons, however, many surgeons now prefer a more horizontal skin incision placed in the natural skin lines. In either case, the incision is deepened through Scarpa's and Camper's fasciae and the subcutaneous tissue to expose the external oblique aponeurosis. The external oblique aponeurosis is then opened through the external inguinal ring.
The superior flap of the external oblique fascia is dissected away from the anterior rectus sheath medially and the internal oblique muscle laterally. The iliohypogastric nerve could be identified at this time; and if so it can be either left in situ or freed from the surrounding tissue and isolated from the operative field by passing a hemostat under the nerve and grasping the upper flap of the external oblique aponeurosis. Routine division of the iliohypogastric nerve along with the ilioinguinal nerve is practiced by some surgeons but is not advised by most. The cord structures are then bluntly dissected away from the inferior flap of the external oblique aponeurosis to expose the shelving edge of the inguinal ligament and the iliopubic tract. The cord structures are lifted en masse with the fingers of one hand at the pubic tubercle so that the index finger can be passed underneath to meet the ipsilateral thumb or the fingers of the other hand. Mobilization of the cord structures is completed by means of blunt dissection, and a Tape or a sling is placed around them so that they can be retracted during the procedure.

Complete division of the cremaster muscle has been common practice, especially with indirect hernias. The purposes of this practice are to facilitate identification of the sac and to lengthen the cord for better visualization of the inguinal floor. Almost always, however, adequate exposure can be obtained by opening the muscle longitudinally, which reduces the chances of damage to the cord and prevents testicular damage. Accordingly, the latter approach should be considered best practice unless there are extenuating circumstances.

High ligation of the sac should be considered equivalent to reduction of the sac into the preperitoneal space without excision. The two methods work equally well and are highly effective. Some surgeons believe that sac inversion results in less pain (because the richly innervated peritoneum is not incised) and may be less likely to cause adhesive complications. To date, however, no randomized trials have been done to determine whether this is so.

It is better to divide an indirect inguinal hernial sac in the mid portion of the inguinal canal once it is clear that the hernia is not sliding and no abdominal contents are present. The distal sac is not removed, but its anterior wall is opened as far distally as is convenient. Contrary to the opinion commonly voiced in the urologic literature, this approach does not result in excessive postoperative hydrocele formation but in fact reduces the incidence of ischaemic orchitis and testicular atrophy.
Closure of the external oblique fascia serves to reconstruct the superficial (external) ring. The external ring must be loose enough to prevent strangulation of the cord structures yet tight enough to ensure that an inexperienced examiner will not confuse a dilated ring with a recurrence. Scarpa's fascia and the skin are closed to complete the operation.

Details of Specific Repairs

1. Marcy repair

The Marcy repair is the simplest non prosthetic repair performed today. Its main indication is for treatment of Nyhus type 1 hernias (i.e., indirect inguinal hernias in which the internal ring is normal). It is appropriate for children and young adults in whom there is concern about the long-term effects of prosthetic material. The essential features of the Marcy repair are high ligation of the sac and narrowing of the internal ring. Displacing the cord structures laterally allows the placement of sutures through the muscular and fascial layers.

2. Bassini repair

Edoardo Bassini (1844-1924) modernized inguinal hernia surgery at the turn of the 20th Century, his technique involved combining high ligation of a hernial sac with reconstruction of the inguinal floor; this operation, known as the radical cure, became the gold standard for inguinal hernia repair for most of the 20th century.

Bassini began the reconstruction of the inguinal floor by opening the transversalis fascia from the internal inguinal ring to the pubic tubercle, thereby exposing the preperitoneal fat, which was bluntly dissected away from the undersurface of the superior flap of the transversalis fascia. This step allowed him to properly prepare the deepest structure in his famous "triple layer" (comprising the transversalis fascia, the transversus abdominis, and the internal oblique muscle).

The first stitch in Bassini's repair includes the triple layer superiorly and the periosteum of the medial side of the pubic tubercle, along with the rectus sheath. In current practice, however, most surgeons try to avoid the periosteum of the pubic tubercle so as to decrease the incidence of osteitis pubis. The repair is then continued laterally, and the triple layer is secured to the reflected inguinal ligament (Poupart's ligament) with non absorbable sutures. The sutures are continued until the internal ring is closed on its medial side (Figure 1.7).

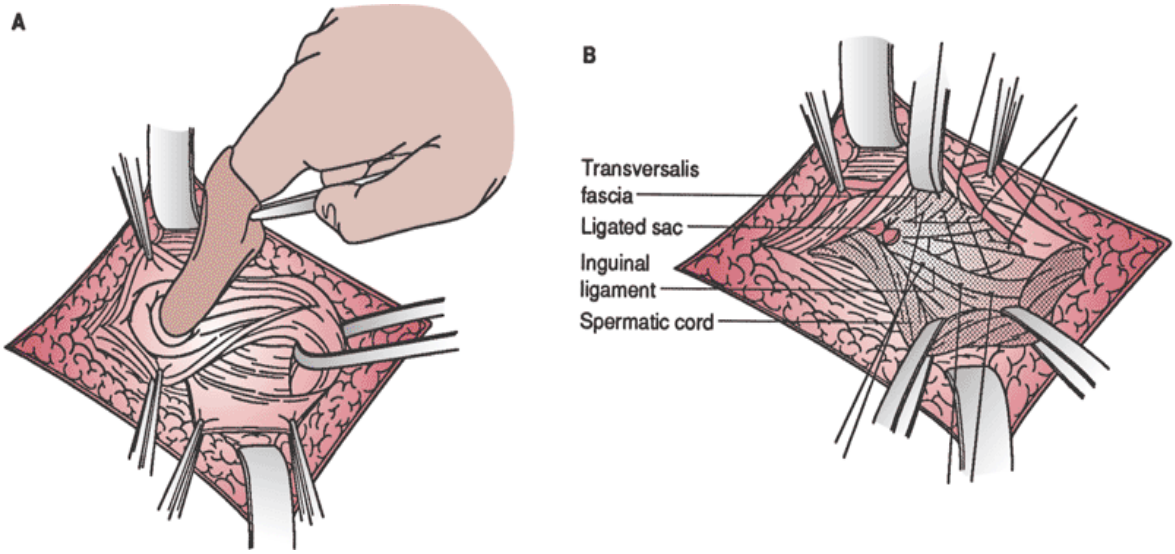


Figure -1.7
Bassini repair

(From Greenfield's Surgery: scientific principles and practice. Lippincott Williams & Wilkins;2006) [81].

3. McVay (Cooper's ligament) repair

A relaxing incision is made in the internal lamina of the anterior rectus sheath in a vertical direction and is extended 1 t 2 cm above the pubis to a level opposite the internal ring (Figure 1.8). The resulting defect in the sheath is protected posteriorly by the body of the rectus muscle, which prevents herniation at the site.

4. Maloney darn

The Maloney darn gets its name from the way in which a long nylon suture is repeatedly passed between the tissues to create a weave that one might consider similar to a mesh. A continuous nylon suture is used to oppose the transversus abdominis, the rectus abdominis, the internal oblique muscle, and the transversalis fascia medially to Poupart's ligament laterally. The suture is continued into the muscle around the cord and is woven in and out to form a reinforcement around the cord. On the lateral side of the cord, it is sutured to the inguinal ligament and tied. The darn is a second layer. The sutures are placed either parallel or in a criss-cross fashion and are plicated well into the inguinal

ligament below. The darn must be carried well over the medial edge of the inguinal canal. Once the darn is complete, the external oblique muscle is closed over the cord structures.

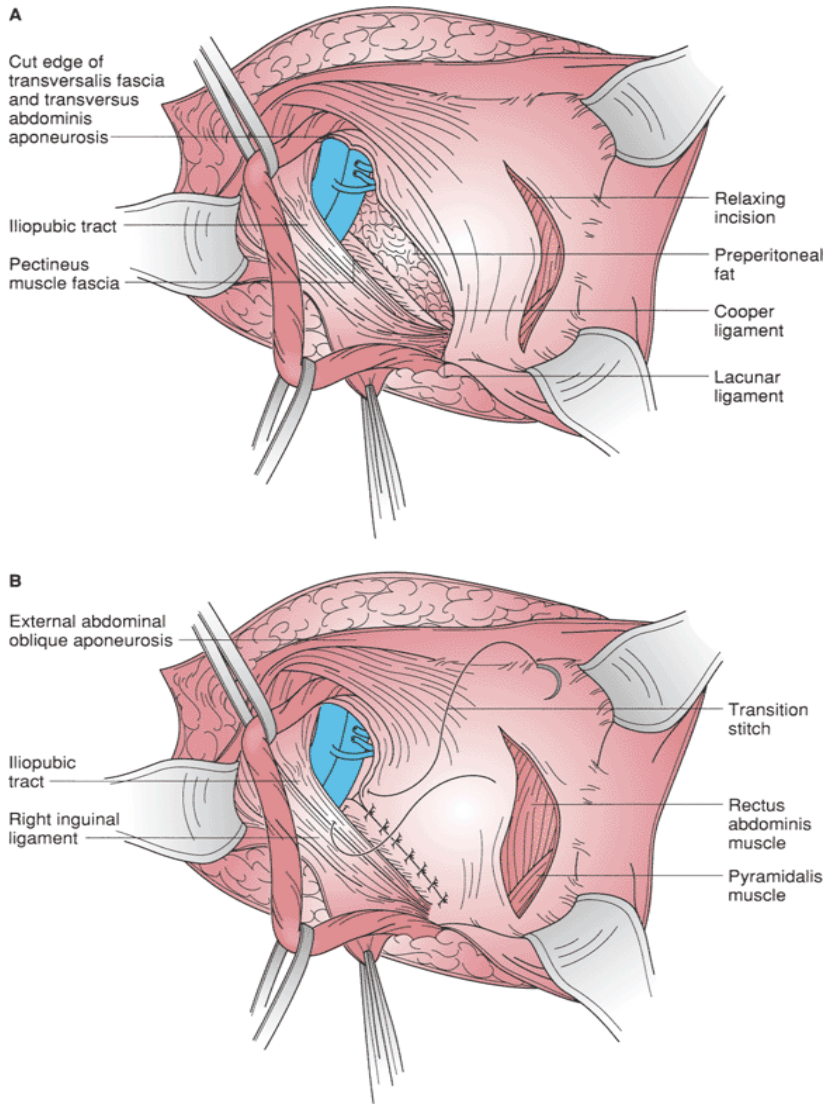


Figure -1.8
McVay (Cooper's ligament) repair

(From Greenfield's Surgery: scientific principles and practice. Lippincott Williams &Wilkins;2006) [81].

5. Shouldice repair

A continuous non absorbable suture (typically of monofilament steel wire) is used to repair the floor. The Shouldice surgeons believe that a continuous suture distributes tension evenly and prevents potential defects between interrupted sutures that could lead to recurrence.

The repair is started at the pubic tubercle by approximating the iliopubic tract laterally to the undersurface of the lateral edge of the rectus abdominis. The suture is continued laterally, approximating the iliopubic tract to the medial flap, which is made up of the transversalis fascia, the internal oblique muscle, and the transversus abdominis. Eventually, four suture lines are developed from the medial flap. The continuous suture is extended to the internal ring, where the lateral stump of the cremaster muscle is picked up to form a new internal ring. Next, the direction of the suture is reversed back toward the pubic tubercle, approximating the medial edges of the internal oblique muscle and the transversus abdominis to Poupart's ligament, and the wire is tied to itself and then to the first knot. Thus, two suture lines are formed by the first suture.

A second wire suture is started near the internal ring, approximating the internal oblique muscle and the transversus abdominis to a band of external oblique aponeurosis superficial and parallel to Poupart's ligament—in effect, creating a second, artificial Poupart's ligament. This third suture line ends at the pubic crest. The suture is then reversed, and a fourth suture line is constructed in a similar manner, superficial to the third line (Figure 1.9). At the Shouldice clinic, the cribriform fascia is always incised in the thigh, parallel to the inguinal ligament, to make the inner side of the lower flap of the external oblique aponeurosis available for these multiple layers. In general practice, however, this step is commonly omitted.

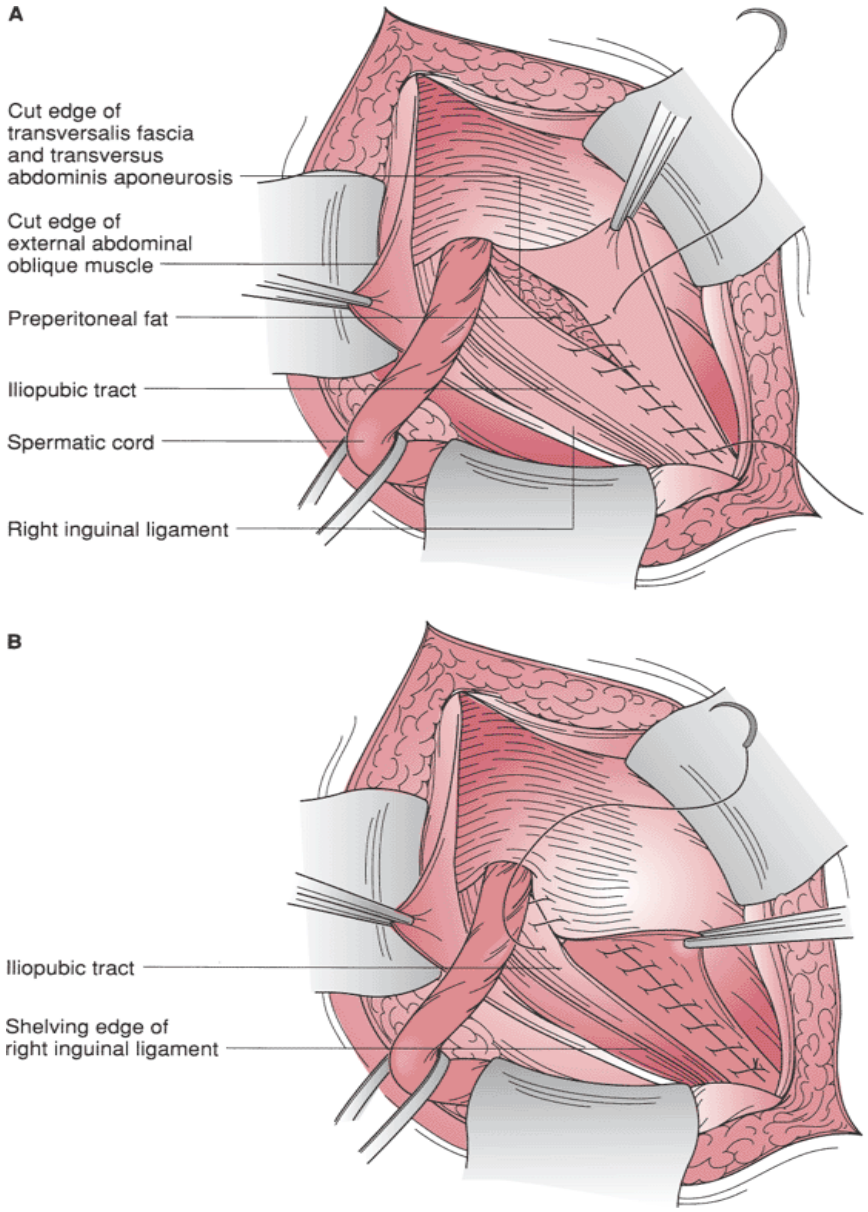


Figure - 1.9
Shouldice repair

(From Greenfield's Surgery: scientific principles and practice. Lippincott Williams &Wilkins;2006) [81].

6. Lichtenstein repair [95]

The tension-free mesh repair was introduced in 1984 by Irvine Lichtenstein and colleagues. The operation is simple, rapid and almost pain free, and allows prompt resumption of unrestricted physical activity, most importantly these results can be reproduced in specialized as well as non specialized units [96].

The initial steps of a Lichtenstein repair are very similar to those of a conventional anterior non prosthetic repair but there are certain technical points that are worthy of emphasis. The external oblique aponeurosis is generously freed from the underlying anterior rectus sheath and internal oblique muscle and aponeurosis in an avascular plane from a point at least 2 cm medial to the pubic tubercle to the anterior superior iliac spine laterally. Blunt dissection is continued in this avascular plane from the area lateral to the internal ring to the pubic tubercle along the shelving edge of the inguinal ligament and the iliopubic tract. As a continuation of this same motion, the cord with its cremaster covering is swept off the pubic tubercle and separated from the inguinal floor. Besides mobilizing the cord, these maneuvers create a large space beneath the external oblique aponeurosis that can eventually be used for prosthesis placement. The ilioinguinal nerve, the external spermatic vessels, and the genital branch of the genitofemoral nerve all remain with the cord structures.

For indirect hernias, the cremaster muscle is incised longitudinally, and the sac is dissected free and reduced into the preperitoneal space.

Direct hernias are separated from the cord and other surrounding structures and reduced back into the preperitoneal space. Dividing the superficial layers of the neck of the sac circumferentially (which in effect, opens the inguinal floor) usually facilitates reduction and helps maintain it while the prosthesis is being placed. This opening in the inguinal floor also allows the surgeon to palpate for a femoral hernia. Sutures can be used to maintain reduction of the sac, but they have no real strength in this setting; their main purpose is to allow the repair to proceed without being hindered by continual extrusion of the sac into the field, especially when the patient strains.

A mesh prosthesis is positioned over the inguinal floor. For an adult, A 6 x 8 cm prosthesis is trimmed to size. The medial end is rounded to correspond to the patient's particular anatomy and secured to the anterior rectus sheath at least 2 cm medial to the pubic tubercle. A continuous suture of non absorbable material should be used. Wide overlap of the pubic tubercle is important to prevent the pubic tubercle recurrences all too commonly seen with other operations. The suture is continued laterally, securing the prosthesis to either side of the pubic tubercle (not into it) and then to the shelving edge of the inguinal ligament. The suture is tied at the internal ring.

A slit is made at the lateral end of the mesh in such a way as to create two tails, a wider one (approximately two thirds of the total width) above and a narrower one below. The tails are positioned around the cord structures and placed beneath the external oblique aponeurosis laterally to about the anterior superior iliac spine, with the upper tail placed on top of the lower. A single interrupted suture is placed to secure the lower edge of the superior tail to the lower edge of the inferior tail, creating a shutter valve. This step is considered crucial for preventing the indirect recurrences occasionally seen when the tails are simply reapproximated. The same suture incorporates the shelving edge of the inguinal ligament so as to create a domelike buckling effect over the direct space, thereby ensuring that there is no tension, especially when the patient assumes an upright position.

Two interrupted absorbable sutures are placed to attach the superior and medial aspects of the prosthesis to the underlying internal oblique muscle and rectus sheath. On occasion, the iliohypogastric nerve, which courses on top of the internal oblique muscle, penetrates the medial flap of the external oblique aponeurosis. In this situation, the prosthesis should be slit to accommodate the nerve, though researchers have shown that cutting the nerve does not make a difference [59].The prosthesis can be trimmed in situ, but care should be taken to maintain enough laxity to allow for the difference between the supine and the upright positions, as well as for possible shrinkage of the mesh.
Closure is accomplished in the same manner as in a conventional anterior non prosthetic repair using a non absorbable suture.

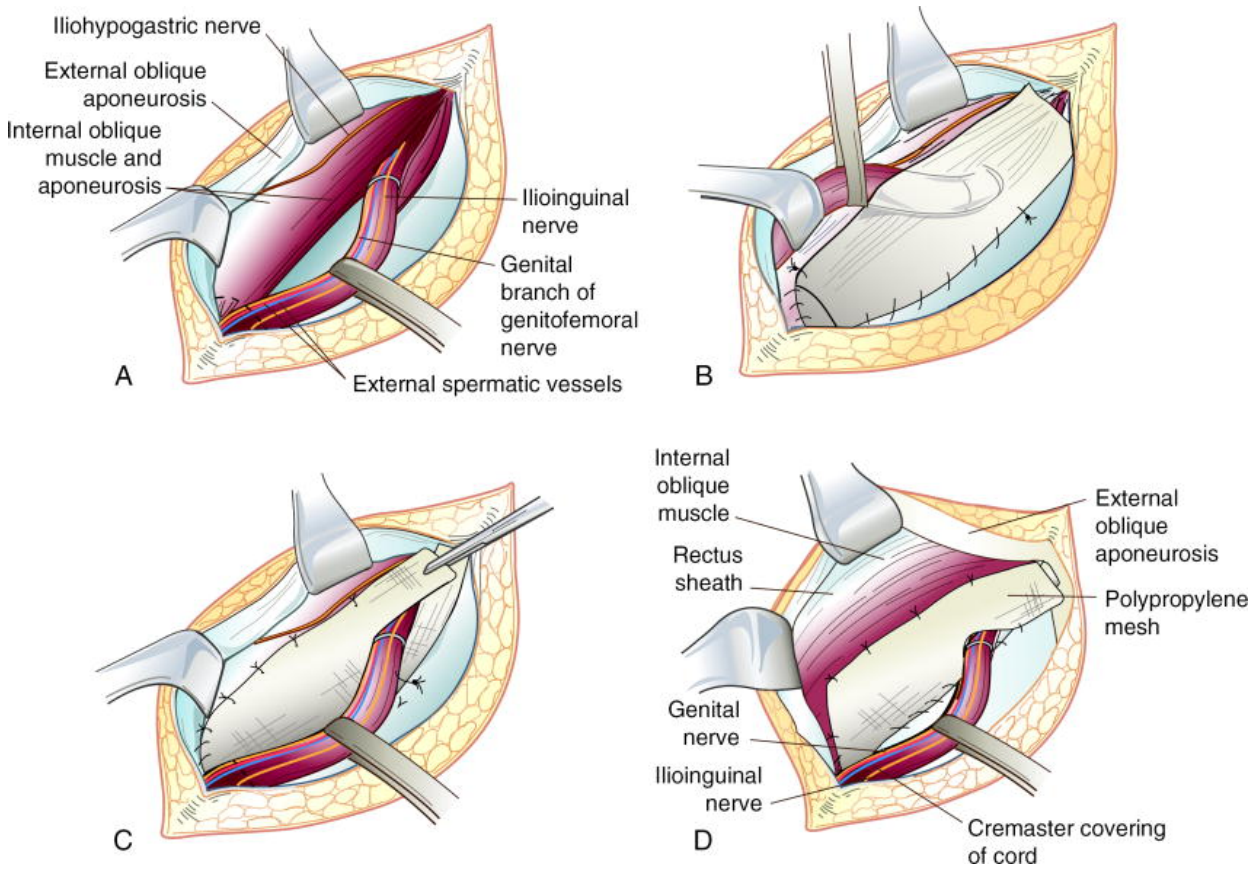


Figure - 1.10
Lichtenstein repair

(From Arregui ME, Nagan RD [eds]: Inguinal Hernia: Advances or Controversies? Oxford, England, Radcliffe Medical, 1994)[97].

If a femoral hernia is present, the posterior surface of the mesh is sutured to Cooper's ligament after the inferior edge has been attached to the inguinal ligament, thereby closing the femoral canal.

In their series of 4,000 patients, Lichtenstein and colleagues [98,99] recorded a recurrence rate of 0.1%, including procedures for recurrent hernias; other complications occurred only rarely. Other authors who used this technique outside the Lichtenstein clinic have reported low recurrence rates, indicating that good results are reproducible outside specialist units [96,100,101].

7. Plug and Patch repair

The mesh plug technique was first developed by Gilbert and subsequently modified by Rutkow and Robbins, Millikan, and others[102]. The groin is entered via a standard anterior approach. The hernial sac is dissected away from surrounding structures and reduced into the preperitoneal space. A flat sheet of polypropylene mesh is rolled up like a cigarette, tied, inserted in the defect, and secured with interrupted sutures to either the internal ring (for an indirect hernia) or the neck of the defect (for a direct hernia).

A prefabricated prosthesis that has the configuration of a flower is commercially available, which is tailored to each patient's particular anatomy by removing some of the "petals" to avoid unnecessary bulk. Many surgeons consider this step important for preventing erosion into surrounding structures (e.g., the bladder); indeed, such complications have been reported, albeit rarely.

The patch portion of the procedure is optional and involves placing a flat piece of polypropylene in the conventional inguinal space so that it widely overlaps the plug, much as in a Lichtenstein repair. The difference with a plug-and-patch repair is that only one or two sutures—or even, perhaps, no sutures—are used to secure the flat prosthesis to the underlying inguinal floor.

This technique is easy to teach, is acclaimed to be as good as the Lichtenstein repair[103], and is said to be faster to perform which has made it popular in both private and academic centers. Two randomized controlled trials compared the plug and patch with the Lichtenstein repair; in the first trial Kingsnorth and colleagues demonstrated that patients undergoing the plug and patch repair had a faster postoperative recovery compared with the Lichtenstein repair (return to normal activity 2.8 vs. 3.6 days and return to work 17 vs. 20.8 days) [104], while Frey and colleagues demonstrated that both repairs were comparable with respect to post operative complications and recurrence rates [105].

2. POSTERIOR APPROACH

Preperitoneal Approach (Stoppa-Rignault-Wantz Repair - Giant Prosthetic Reinforcement of Visceral Sac GPRVS) [9]

GPRVS has its roots in the important contribution that Henri Fruchaud made to herniology. In describing the myopectineal orifice that bears his name, Fruchaud, who was Stoppa's mentor, popularized a different approach to the aetiology of inguinal hernias. Instead of subdividing hernias into direct, indirect, and femoral and then examining their specific causes, he emphasized that the common cause of all inguinal hernias was the failure of the transversalis fascia to retain the peritoneum. This concept led Stoppa to develop GPRVS, which reestablishes the integrity of the peritoneal sac by inserting a large permanent prosthesis that entirely replaces the transversalis fascia over the myopectineal orifice of Fruchaud with wide overlapping of surrounding tissue. With GPRVS, the exact type of hernia present (direct, indirect, or femoral) is unimportant, because the abdominal wall defect is not addressed.

The preperitoneal space is situated between the transversalis fascia and the peritoneum. The transversus abdominis muscle and its aponeurosis and fascial coverings are probably the most important layer in the groin. The aim of hernia repairs should be to return this layer to normal. By strengthening the preperitoneal area, this goal can be achieved [22].

In 1983, the concept of reinforcement of the preperitoneal layer in the lower abdomen by placing a large piece of mesh in this area was developed. This can be done through a transverse lower abdominal incision [106-108]. The peritoneum can be dissected away from the undersurface of the transversalis fascia to expose the defect through which the hernia protrudes. Alternatively, a lateral rectus approach via a transverse incision can be used to expose the defect. A few centimeters above the pubic tubercle, the rectus sheath can be opened and the rectus muscle retracted medially[109].

Access is then gained to the preperitoneal space, through which the repair is performed using a large prosthesis that extends far beyond the margins of the myopectineal orifice and envelops the visceral sac. The mesh is held in place by intra-abdominal pressure, which pushes outward toward the undersurface of the transversalis fascia. Later, as a consequence of connective tissue in-growth, the mesh becomes incorporated in the body tissues, which further strengthens this layer. The mesh also adheres to the peritoneum, so

that the peritoneum cannot protrude through the parietal defect. This technique works by preventing the peritoneum from bulging outward rather than by repairing abdominal wall defects. No sutures are placed in this method of hernia repair, and it is tension-free. Because the incision for a preperitoneal hernia repair is away from the groin area and directly accesses the preperitoneal space, dissection of the inguinal canal, spermatic cord, or sensory nerves of the groin is not performed. The complications involving these structures that occur with other hernia repairs are very rare with the preperitoneal repair. If the hernial sac is large, it is amputated or inverted beneath a purse string suture to smooth the external surface of the visceral sac. The distal peritoneal sac is left in place, undissected and attached to the cord. With a sliding indirect hernia, the sac would have to be dissected away from the cord. The mesh is composed of multifilament fibers of Dacron, which is soft, elastic, supple, and rapidly integrated into tissue. Other meshes are not suitable because they are semi rigid and buckle when bent in two directions.

In a bilateral repair, the chevron-shaped mesh is usually measured to be transversely 2 cm less than the distance between the anterior superior iliac spines and vertically the distance between the umbilicus and the symphysis pubis. The mesh is placed in the preperitoneal space so that it underlies the rectus muscle for a width of about 2 to 3 cm and extends this same distance above the level of the myopectineal orifice in all directions. The preperitoneal or posterior approach for the repair of groin hernias is particularly useful with very large or recurrent hernias [109]. Laparoscopic hernioplasty is an extension of the preperitoneal concept. In many of the laparoscopic repairs, the prosthesis is placed in the preperitoneal space.

3. LAPAROSCOPIC APPROACH

The trans-abdominal preperitoneal (TAPP) and the totally extraperitoneal (TEP) laparoscopic inguinal herniorrhaphies are the most popular approaches. Both are modeled after the conventional preperitoneal operations. The major difference is that the preperitoneal space is entered through three trocar sites rather than through a large conventional incision. The ensuing radical dissection of the preperitoneal space with placement of a large prosthesis is similar to the conventional preperitoneal operation.

A. Transabdominal preperitoneal repair (TAPP)

The procedure is begun with a thorough diagnostic laparoscopy to rule out unrelated pathology and carefully inspect both myopectineal orifices. Two additional cannulae are placed just lateral to the rectus sheath on either side of the umbilicus. For a unilateral hernia, a transverse incision is begun at the lateral side of the medial umbilical ligament and extended to open its lateral leaf to the anterior superior iliac spine. If the medial umbilical ligament appears to compromise exposure, it can be divided. Electrocautery is used to minimize bleeding from the remnants of the embryologic umbilical artery. A radical dissection of the preperitoneal space is then performed with mostly blunt dissection and generous use of electrocautery, as bleeding in this area is particularly troublesome if it interferes with illumination. The ipsilateral and contra-lateral pubic tubercles, the inferior epigastric vessels, Cooper's ligament, and the iliopubic tract are identified (Figure 1.6). The cord structures are mobilized, and the peritoneal flap is dissected several centimeters proximal to the bifurcation of the vas deferens and the internal spermatic vessels. Recurrences have been attributed to inadequate mobilization of the peritoneal flap, which does not allow the prosthesis to lie flat in this area. If small, an indirect sac is mobilized away from the cord structures and reduced. If large, the sac is divided at a convenient point distal to the internal ring and only the proximal portion is mobilized. A direct sac readily reduces during the preperitoneal dissection. An easily visible layer of fatty tissue separates the thinned out transversalis fascia lining the defect and the peritoneum.

A large piece of polypropylene mesh (at least 15 × 10 cm) is stapled in place, beginning at the contra-lateral pubic tubercle medially and extending onto the anterior abdominal wall superiorly at least 2 cm above the hernia defect, to the anterior superior iliac spine laterally, and to Cooper's ligament inferiorly. Most surgeons prefer to fasten the prosthesis with staples or tacks. Some surgeons feel fixation is not necessary at all when a large prosthesis is used that widely overlaps the entire myopectineal orifice. Staples or tacks are never placed below the iliopubic tract when lateral to the internal spermatic vessel because of the danger of damage to the important nerves in this area. Damage to these nerves results in neuralgia, such as was commonly observed in the developmental stages of laparoscopic inguinal herniorrhaphy, before the anatomy of the preperitoneal

space was appreciated from a laparoscopic perspective. To decrease further the incidence of neuralgia, staples are placed horizontally for the superior border of the prosthesis to correspond to the direction of the more superficially located yet vulnerable ilioinguinal and iliohypogastric nerves. Laterally, staples are placed vertically, as this is the direction of the lateral cutaneous nerve of the thigh and the femoral branch of the genitofemoral nerve. The last step is to cover the prosthesis with the inferior peritoneal flap.

For bilateral inguinal hernias, the same peritoneal incision and preperitoneal dissections are used. The symphysis pubis is completely exposed so that both preperitoneal dissections communicate with each other. This exposure allows the placement of one large prosthesis (at least 25 ×7.5 cm) that essentially covers the entire lower pelvis. By not incising the peritoneum between the two medial umbilical ligaments, one avoids the theoretical complication of dividing a patent urachus.

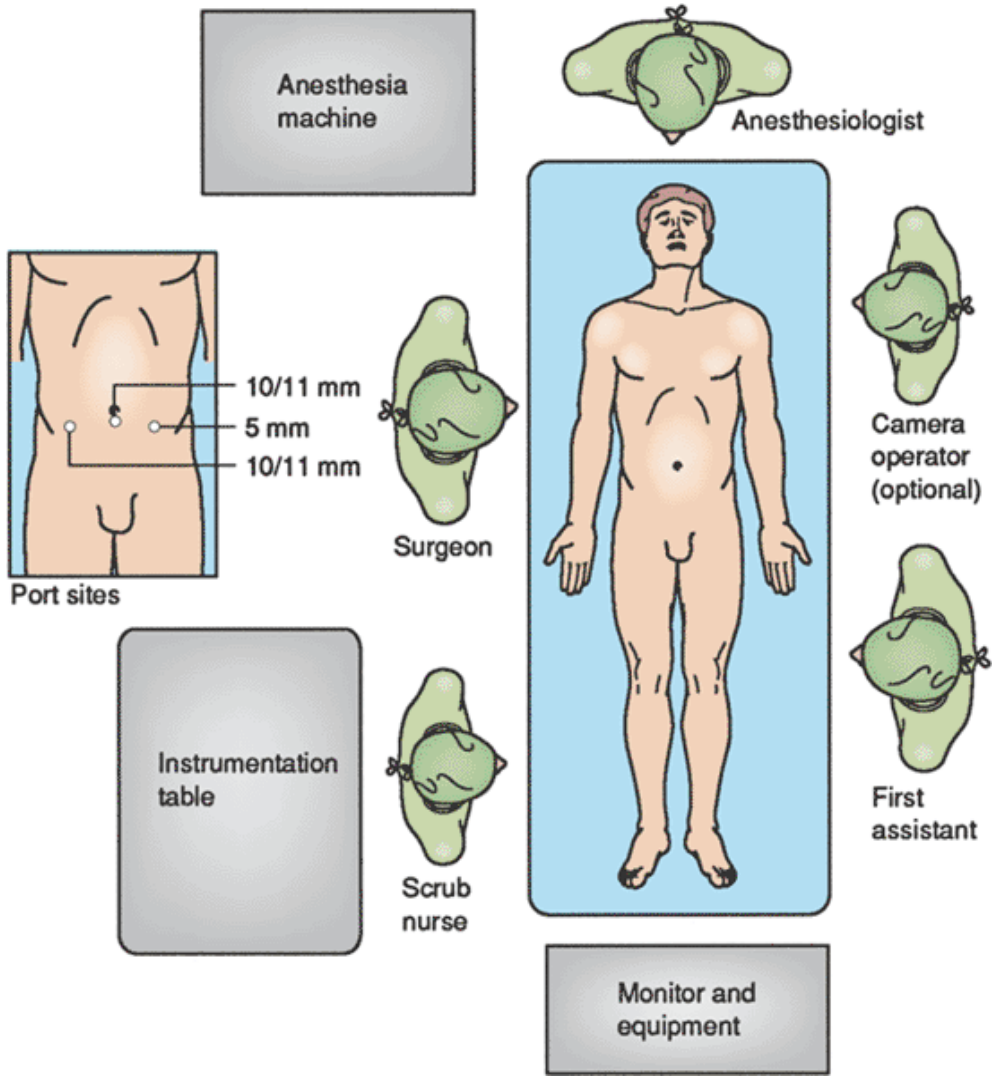


Figure -11
Typical operative setup and cannula site selection for a Transabdominal preperitoneal (TAPP) Laparoscopic inguinal herniorrhaphy.

(From Greenfield's Surgery: scientific principles and practice. Lippincott Williams &Wilkins;2006) [81].

B. Totally extraperitoneal repair (TEP)

With extraperitoneal laparoscopic inguinal hernia repair, the peritoneal cavity is not intentionally violated [110]. An incision is made at the umbilicus, as if one were planning to perform open laparoscopy. The rectus sheath is opened on one side and the rectus muscle is retracted laterally. Blunt dissection is then begun in the space between the rectus muscle and the posterior rectus sheath. The space is enlarged by placing a blunt instrument blindly or an operating laparoscope (a rigid laparoscope with a working channel). Once the space is large enough, two additional cannulae are placed in the midline, one approximately 5 cm above the symphysis pubis and the other midway between the umbilicus and the symphysis pubis. The dissection of the preperitoneal space is completed under direct vision. The rest of the operation is identical to the TAPP procedure, described above. Popular alternatives are to use a water- or air-filled balloon dissector to perform the preperitoneal dissection (Figure 1.12) and to place the two accessory cannulae on either side of the umbilicus, as in the TAPP procedure, instead of in the midline.

The presumed advantages of the TEP procedure are that the inherent complications of entering the peritoneal cavity, such as intra-abdominal organ injury or postoperative bowel obstruction secondary to adhesions or trocar site herniation, are avoided. However, the operative space is limited, and considerable experience is required to become familiar with the anatomy from this perspective.

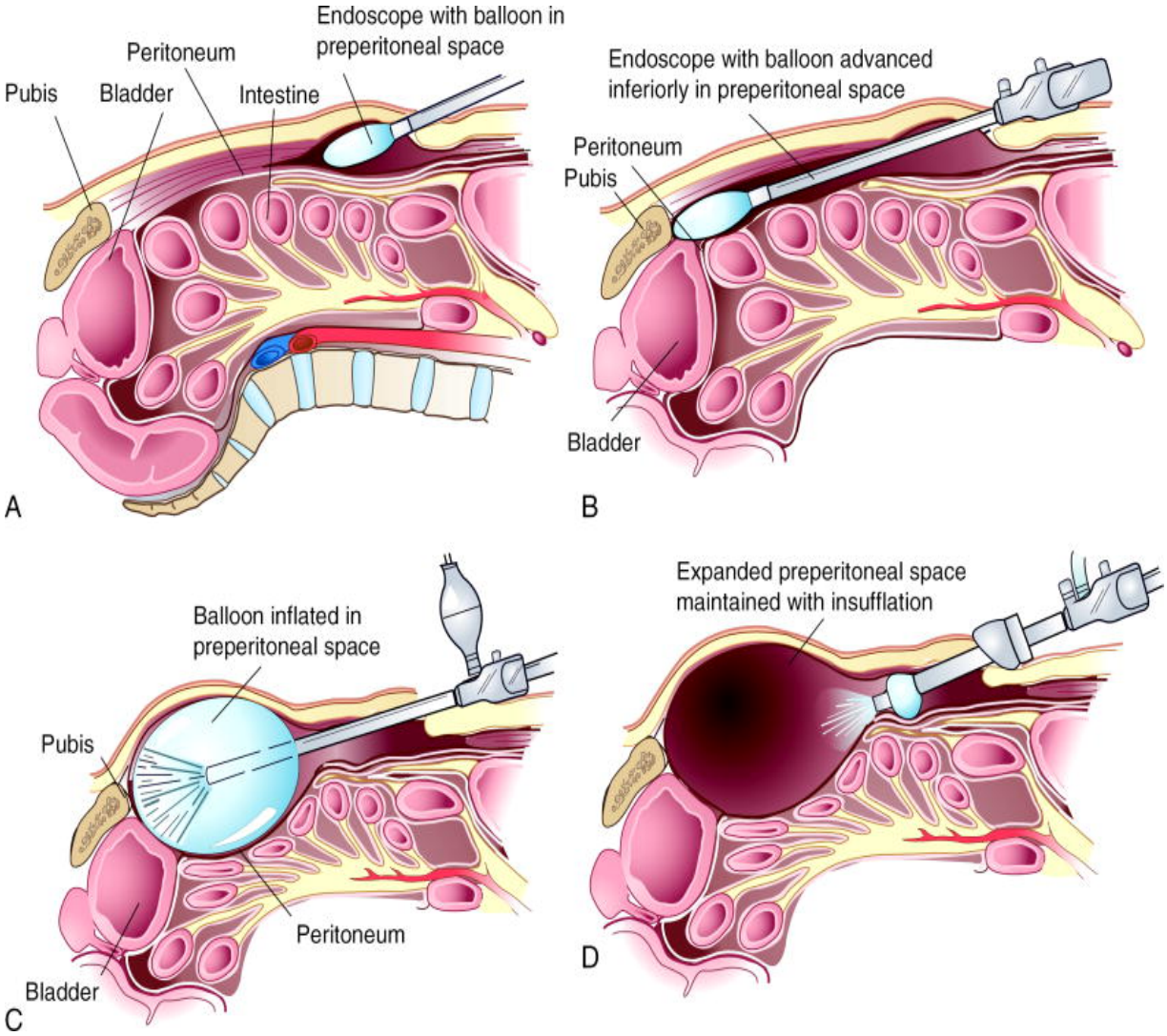


Figure - 1.12
The Total extraperitoneal (TEP) laparoscopic hernia repair

A, The TEP approach for laparoscopic hernia repair is demonstrated. Access to the posterior rectus sheath is gained in the periumbilical region. A balloon dissector is placed on the anterior surface of the posterior rectus sheath. **B,** The balloon dissector is advanced to the posterior surface of the pubis in the preperitoneal space. **C,** The balloon is inflated, thereby creating an optical cavity. **D,** The optical cavity is insufflated by carbon dioxide, and the posterior surface of the inguinal floor is dissected.

(From Shadduck PP, Schwartz LB, Eubanks WS: Laparoscopic inguinal herniorrhaphy. In Pappas TN, Schwartz LB, Eubanks WE [eds]: Atlas of Laparoscopic Surgery. Philadelphia, Current Medicine, 1996)[111].

1.15.3 Recovery

Patients should be discharged within a few hours of operation, if social circumstances allow. Simple analgesics are to be prescribed and they should be told to resume normal activity as soon as the pain permits, as a correctly done open prosthetic mesh repair can withstand any degree of stress immediately[98]. Return to full activity does not increase recurrences and therefore patients should be encouraged to go back to work as soon as possible; on the other hand unnecessary caution will engender anxiety and probably justify the patients decision to remain off work for 6 weeks [112-114].

1.15.4 Complications [8,92]

The importance of the postoperative complications of hernia repair is due not so much to their frequency or severity as to the very large number of these procedures performed every year. Not all complications can be prevented, but knowledge and understanding are the first steps to reduce them, bearing in mind that patients who report high pain levels in the immediate post operative period go on to develop chronic pain later on.

Thromboembolic complications are also very rare (0.3%)[49]. With local anaesthesia and immediate postoperative mobilization, heparin, if needed at all, can be restricted to single-shot low-dose prophylaxis.

Some of the commonest complications are listed below:

1) Chronic pain [9]

The subject of chronic pain was discussed in detail previously.

2) Ejaculatory pain

ejaculatory related pain, is due to dysfunction of periurethral structures involved in ejaculation[31,115]. One possible mechanism is the injury to either somatic sacral or sympathetic nerves, resulting in dyssynergia of the ejaculatory effector muscles[31].

It can also be due to stricture in the spermatic duct from the scar tissue or twisting of the cord. [115]

3) Numbness

Numbness is reported in 9% of patients undergoing open hernia repair [5]. The Medical Research Council trial demonstrated clearly that the incidence of numbness is much higher in patients undergoing open repair in comparison to laparoscopic repair (40% vs. 8% at 1 year and 25% vs. 13% at 5 years respectively) [36,51]

Courtney et al noted a higher prevalence of numbness is patients with severe or very severe pain (81.8%) [43].

4) Ischaemic orchitis and testicular atrophy

A painful swelling of the testis, occasionally accompanied by fever and mild leucocytosis within 2 days of the operation, indicates the onset of an ischaemic orchitis. Remission is spontaneous in about 60% of cases. In all other cases the orchitis progresses to testicular atrophy. This most dreaded complication occurs in 0.03 to 0.5% and 0.8 to 5% of patients after the repair of primary and recurrent hernias, respectively. Testicular atrophy may develop even after a straight forward primary repair done by an experienced surgeon[116,117]. The etiology of ischemic orchitis is thrombosis of the spermatic cord, and the testicular pathology is intense venous congestion. The thrombosis is induced by surgical trauma to the cord especially that associated with the dissection to completely remove a large indirect hernial sac. Dissection of a scrotal indirect hernial sac damages the delicate veins of the pampiniform plexus, initiates the thrombosis, and coincidentally disrupts collateral circulation. However, frequency of orchitis and atrophy is highest with sliding hernias (for which an extended dissection of the sac from the cord is necessary) and after previous or simultaneous surgery on the testis, which may disrupt collateral blood supply. Furthermore, the risk is 2 to 10 times higher after the repair of a recurrence [118].

Reduction of the incidence of ischaemic orchitis can be achieved by careful dissection and preservation of vessels. In indirect hernias, division of the sac at the internal ring, leaving the distal sac undisturbed, prevents this complication [117]. In cases of multiple recurrences, the peritoneal approach avoids further dissection of the inguinal canal and thereby minimises the risk of further injuries to the vessels [118].

Bendavid, in a study on the incidence of testicular atrophy at the Shouldice Hospital, found that this complication occurred in only 19 (0.036%) of 52,583 primary inguinal hernia repairs and 33 (0.46%) of 7,169 recurrent inguinal hernia repairs[119].

5) Wound Complications

-Haematoma

Post herniorrhaphy bleeding; usually the result of delayed bleeding from the cremasteric artery, the internal spermatic artery, or branches of the inferior epigastric vessels, can produce a wound or scrotal haematoma. Injuries to the deep circumflex artery, or the external iliac vessels may result in a large retroperitoneal haematoma.

The incidence of haematoma varies from 2-15.7% [51,120] depending on the surgeon's skill, the use of subcutaneous Heparin[5] and the difficulty of repair rather than on the procedure used, hence the higher incidence of haematoma following a recurrent inguinal hernia repair.

Most haematomas are treated conservatively and would resolve spontaneously and only rarely is surgical intervention required.

-Seroma

Seromas occurs more commonly after mesh repair. Large, un-resolving, symptomatic seromas can be treated by aspiration under aseptic conditions; infected seromas can results in an increased risk of recurrence, and should be treated swiftly with antibiotics and aspiration.

6) Infection

In a study by Hair et al looking at groin hernia repairs carried out in Scotland between April 1998 and March 1999 it was found that 8% of repairs will develop wound infection[5]. Taylor et al reported a 5.3% incidence of surgical site infection from 3046 patients undergoing groin hernia repair[73], while Allan Kark reported a lower 3% incidence of deep wound infection following 3,175 primary hernia repairs [120].

This frequency of infection is irrespective of whether prosthetic meshes or antibiotics are used [91].The prostheses used for inguinal herniorrhaphies, unlike those used for ventral

herniorrhaphies, rarely become infected. The reasons why the groin is apparently a protected area are unclear.

The management of infections in wounds in which there is a synthetic prosthetic mesh is no different from that of other wounds. All that is needed is the application of sound surgical principles. Superficial infections not directly involving the mesh can be expected to heal. Early infections involving the mesh must be treated vigorously and aggressively. The entire prosthesis must be exposed without delay. Failure to expose the entire prosthesis will lead to sinus formation. Local treatment is directed at irrigating purulent material, lysing cellular, fibrous, and fibrinous debris, and destroying the infectious agent. Saline solution, granulated sugar, and topical antimicrobial substances are all useful. Complete incorporation can be expected with meshes of both polypropylene and polyester (but not with expanded polytetrafluoroethylene) in 3 to 4 weeks, providing the mesh firmly contacts tissue and is not floating free. Systemic antibiotics, of course, are essential.

On the other hand if an infection develops in the space containing Gore-Tex, the material has to be removed, because there is no chance that it will become incorporated before bacteria have inhabited the microscopic spaces in the material, as these spaces are too small to allow entrance of phagocytes and antimicrobial substances.

Delayed infections involving the prosthesis occur, and the interval between prosthetic implantation and infection may be months or years. In these cases and in all infected prosthetic wounds that have healed with a sinus, it is rarely possible for the prosthesis to become reintegrated, excision of the sequestered mesh is necessary. Only the sequestered mesh must be removed; the integrated mesh can remain.

The use of prophylactic antibiotics is controversial with some surgeons stating that its use does not alter the rate of wound infection [5,91], while Platt et al advocated its use noting a drop in wound infection rates (from 4.2% to 2.3%) [121].

7) Osteitis Pubis [9]

Osteitis pubis has diminished in frequency since surgeons began to realize the importance of not placing sutures through the periosteum. In laparoscopic repairs, staples are used to attach the mesh to Cooper's ligament, which may cause osteitis in some cases.

8) Prosthesis related complications [9]

Tissue response, which is variable from person to person, can be so intense that the prosthetic material is deformed by contraction. Erosion can result in intestinal obstruction or fistulization, especially if there is physical contact between intestine and prosthesis[122].

9) Complications Related to Laparoscopy

-Vascular Injury

The most serious injuries occur to vessels that reside in the retroperitoneum [123,124]. The risk for injury to vessels that requires operative intervention is 0.05% [125]. The vessels most at risk are the distal aorta, common iliac arteries and veins, and inferior vena cava. Injuries to the renal vessels have also been reported. These vessels are fixed and may be penetrated even if the safety mechanisms of the needle or trocar are working properly. The mesenteric and omental vessels are also at risk, especially in the presence of adhesions. The epigastric arteries may be injured with secondary cannula placement.

-Visceral Injury

Visceral injuries are uncommon, occurring in 0.05% to 0.4% of all laparoscopic procedures, but they have a mortality rate of 5% [22]. The most common means of injury is the insufflation needle. Injuries caused by the needle usually do not require repair. A lateral tear injury to the bowel, especially in the presence of a fixed adhesion, requires correction. Quite often, the injury goes unnoticed at the time of insult; so that visceral injury is the most common cause of late morbidity and mortality associated with laparoscopic access. Patients typically present with peritonitis and sepsis 2 days to 1 week after surgery.

Visceral injury can occur in open hernia repair as well as during laparoscopic repair. It is important that the contents of the hernial sac be inspected before their reduction into the abdomen. The bladder can be at risk during repair of femoral and direct inguinal hernias; large bowel can be injured in repair of sliding hernias.

-Port-site hernias

Small-bowel obstruction occurs in 0.3 % of patients after laparoscopic hernia repair [19], more commonly in the Trans abdominal approach. Occasionally this is due to a port-site hernia, a complication that can be avoided by adequate closure of the fascial defects created by the ports.

10) Recurrence [8]

A recurrence is a weakness in the operating area exacerbated by a valsalva maneuver necessitating further operation or the provision of a truss. Long term follow up has shown that 15-30% of hernia repairs will fail [126], with higher rates of failure following suture repair of recurrent groin hernias.

A comprehensive audit from the national hernia registers in Sweden[127] and Denmark[128] have shown an incidence of recurrence of 16-18% following primary repair using a variety of techniques, while the rates following repair of recurrent hernias went up to 30% due to the technical difficulties associated with such repair[129], but these rates are much lower in the hands of very experienced hernia surgeons using classical repairs with rates in the range of 0-3% being reported, with the lowest rates being obtained using the laparoscopic approach [51,126,130-134]

Recurrences predictably are more common in patients with direct hernias, especially bilateral direct inguinal hernias, direct hernias presenting on both sides of the inferior epigastric vessels, and in direct hernias combined with an indirect hernia. Most recurrences are direct and are usually in the region of the pubic tubercle, where suture line tension is the greatest. Indirect recurrences result from insufficient excision of the proximal end of the sac, insufficient repair of the deep ring, and continued atrophy of the shutter mechanism. In General recurrences could be due to various causes ranging from inadequate dissection, tension on the suture line, defects in collagen metabolism, inadequate hernioplasty and missed hernias following a sutured repair, while recurrence following a mesh repair could be due to mesh lifting (secondary to haematoma formation), insufficient mesh size and overlap, improper fixation and mesh folding. In a study by Obney and Chan who reported on 1057 recurrent inguinal hernias repaired in the Shouldice Hospital, 37% were due to technical errors, 8% were missed femoral hernias,

10% had two or more hernias and 45% had direct hernias that were either overlooked or were inadequately repaired initially [135].

Taking all this into consideration the best results would therefore be obtained when these hernias are repaired by a specialist using either the open (GPRVS) or laparoscopic preperitoneal repair[131,133,134,136,137], this technique circumvents the scar tissues from previous repair [128], provides good visualisation of the groin anatomy and minimizes the risk of neural and spermatic cord injury, and as there is no need for stapling of the mesh post operative groin pain is reported to be less [134].

Yet despite its advantages it is not flawless as re-recurrence could occur if the preperitoneal space is not cleaved widely enough or if the prosthesis is too small, poorly shaped, or incorrectly implanted. Recurrences after GPRVS usually are approached anteriorly and are managed by adding a prosthetic extension to the existing prosthesis. Alternatively, another permanent prosthesis can be implanted Trans abdominally.

Therefore authors are now calling for Individualization in treating these hernias and that each case is treated on its own merits [137,138]

11) Death

Mortality rates following elective repair are usually low, with the Danish hernia data base quoting a 30 day mortality for patients below and above the age of 60 years of 0.02% and 0.48% respectively [139]. Higher mortality rates of 3.8% are noted with emergency repair [140], 10% with strangulation[14] and up to 37% with bowel resection [13], this rise in mortality rate is thought to reflect the selection of medically fit patients for elective repair leaving the high risk patients with complex comorbid illnesses for emergency repair.

AIMS

It is a known fact that acute abdominal wall hernias are associated with a significant morbidity, mortality and prolonged hospital stay [13,14,16,141], and for around 40% of patients, an acute presentation will be the first indication of a hernia [13,14].
In order to asses the incidence and outcome of acute groin hernia including those presenting with intestinal obstruction in our population two studies where carried out; the first study was a prospective observational study looking at all patients presenting to our unit with an acute hernia, while the second study was a prospective study of all patients presenting with sub acute bowel obstruction in one teaching hospital over a years period.

Two further studies were carried out; the main study was a prospective randomized trial comparing surgery and no intervention for asymptomatic inguinal hernias, the Final study was generated from eligible non randomised patients and patients who did not fulfill the recruitment criteria for the previous study but who had an asymptomatic hernia.
The aims of all 4 studies could be summarized as follows:
1. To prospectively assess the presentation, management and outcome of acute hernias in our population.

2. To identify the most frequent causes of strangulation in patients presenting with small bowel obstruction.

3. To compare the outcome of patients with an asymptomatic hernia treated surgically with those treated conservatively (with a wait and see policy).

4. To assess the outcome of the non-randomised asymptomatic hernia patients group who opted for no surgery in terms of need for surgery and mortality rate.

Study -1

Presentation and outcome of patients with an acute Abdominal wall hernia

Methods

Between March 2001 and February 2004 all patients admitted through the Emergency Department of one teaching hospital with an acute hernia had their details entered onto a prospective database (The hospital covers a population of 260,000 and has well established day case and inpatient facilities). Data collected included age, sex, American Society of Anaesthesiology (ASA) status, type of hernia and the length of time the patient was aware they had a hernia.

The presenting symptom and its duration with details of current management whether surgical or conservative, were also recorded. Patients were also asked about previous attendance to their GP, surgical outpatients or previous emergency admissions with their hernia. Finally a check on all elective hernia repairs performed during the study period was obtained from hospital diagnosis and procedure codes.

Results

During the 3-year study period 91 patients were admitted with an acute hernia, of these there were 24 inguinal, 24 femoral, 19 incisional, 16 paraumbilical, 6 epigastric and 2 parastomal hernias. Patient demographics and hernia type are shown in Table 2.1.

Twelve (13%) had a previous hospital admission for an acute hernia while 34 (37.4%) had been assessed by their GP (12) or at a surgical clinic (22). Of those, 18 had been declared unfit for surgery in view of co-morbid illness while 11 were on the waiting list for an operation (Table 2.2). Of the 18 patients declared unfit for operation, ten were ASA 4, five were ASA 3 and three were ASA 2. The median time patients were on the waiting list before acute presentation was 2 months (range 1 week to 1 year). The patient waiting for 1 year had a myocardial infarction soon after been put on the waiting list and was awaiting re-evaluation at the time of his acute presentation.

Age & Sex	
Age (years) [a]	68 (21-93)
Male	41
Female	50
*** ASA Grade**	**Number of patients**
1	15
2	20
3	37
4/5	15
Hernia Type	**Number of patients**
Inguinal	24 (26.4%)
Femoral	24 (26.4%)
Incisional	19 (20.8%)
Paraumbilical	16 (17.6%)
Epigastric	6 (6.6%)
Parastomal	2 (2.2%)

* Not all patients had their ASA grade recorded

[a] Values are mean (range)

Table -2.1
Patient Demographics and hernia type

Outcome	**GP** (Total no. =12)	**Surgeon** (Total no. =22)	**Acute Admission** (Total no.=12)	**Total (46)**
Declared unfit	0	11	7	18
Placed on waiting list	0	8	3	11
Reassured	5	2	0	7
Given a clinic appointment	*7	0	1	8
Declined operation	0	1	1	2

* Six failed to keep their appointment for a surgical clinic.

Table - 2.2
Outcome of patients that had a previous medical assessment
(Values in columns are number of patients)

In 30 (33%) patients this hospital admission was the first indication that they had a hernia. Most were femoral (n=15) although eight had a ventral hernia and seven had an inguinal hernia. Fifteen (16.6%) patients were aware that a hernia was present but had not sought any medical advice concerning it.

Only 55 (60.4%) patients presented within 24 h of the onset of their symptoms.
Pain and incarceration was present in 56 (61.5%), 9 (9.9%) caused obstruction, while 26 (28.6%) were strangulated. Strangulation was most common in femoral hernias (n=14) followed by ventral (n=6) and inguinal (n=4). Both parastomal hernias had strangulated (Table 2.3).

Hernia type	Pain and incarceration	Strangulation	Obstruction
Inguinal	18 (75%)	4 (16.7%)	2 (8.3%)
Femoral	8 (33.3%)	14(58.4%)	2 (8.3%)
Ventral	30 (73.2%)	6 (14.6%)	5 (12.2%)
Parastomal	-	2 (100%)	-
Total	56 (61.5%)	26(28.6%)	9 (9.9%)

Table - 2.3
Presentation of acute hernias
(Values in columns are number of patients)

Eighty patients had an operation while four were placed on the waiting list; one was given an outpatient appointment while six were considered unfit for surgery (Table 2.4). Of the 18 patients that had previously been declared unfit for operation 14 had an operation while 4 were treated conservatively.

	Mesh repair	**Non-mesh repair**	**Bowel/omental resection [a]**	**No operation**
Inguinal	16	6	4 (3 Bowel resections)	2
Femoral	3	20	13(12 Bowel resections)	1
Ventral	6	27	7 (4 Bowel resections)	8
Parastomal	–	2	2 (Both had bowel resections)	–
Total	25	55	26 (21 Bowel resections)	11

[a] All had a non-mesh repair

Table - 2.4
Treatment of acute hernias
(Values in columns are number of patients)

Most inguinal hernias were repaired with mesh while less than one-third of ventral hernias had a mesh repair. No patient with a bowel or omental resection had a mesh repair (Table 2.4). During the study period a total of 952 hernias were repaired electively at the same hospital, 686 were inguinal, 29 were femoral while 237 were ventral. Thus 3.1% of inguinal, 44.2% of femoral and 12.2% of ventral hernias had an acute presentation with a postoperative mortality of 3.8% for those that underwent repair. There was no postoperative morality in any of the patients undergoing elective repair of their hernia within the same time period.

Five patients died; two while being assessed for operation and three with strangulated hernias (two ventral and one femoral) died postoperatively (Table 2.5). One of the patients who died while being assessed had a paraumbilical hernia reduced manually. This patient was ASA 4, had two previous acute admissions and was deemed unfit for surgery by a consultant anaesthetist. The second patient was ASA3 and dehydrated on admission from an obstructing femoral hernia. During rehydration the patient aspirated and subsequently died from aspiration pneumonia. Of the 3 patients who died postoperatively, two had previously been assessed and deemed unfit for surgery because of significant cardiac disease (ASA 4); one had an MI while the other developed cardiopulmonary failure and died. The remaining patient (ASA3) died of acute pulmonary oedema following laparotomy and small bowel resection for a strangulated femoral hernia.

	Inguinal	**Femoral**	**Ventral**	**Parastomal**
Operative	0 (22)	1 (23)	2 (33)	0 (2)
Overall	0 (24)	2 (24)	3 (41)	0 (2)
Total	0	3 [12.5%][a]	5 [12.1%][a]	0

Values in columns are the number of mortalities and values in parenthesis are the number of patients in each group

[a] Represents the percentage of mortality in each group

Table - 2.5
Operative and overall mortality for various acute hernia types

Discussion

Over half of the patients presenting with an acute hernia in this study had been previously assessed by either their general practitioner or surgeon. In approximately one-third, this hospital admission was the first indication that they had a hernia while the remaining refused operation or did not seek medical advice. The most common reasons for patients assessed by medical staff not undergoing elective operation was because they had been declared medically unfit or had been on the waiting list for hernia repair. All patients who died were at high risk, with three of the five previously considered unfit for an elective operation and having a ventral hernia.

The finding of a high percentage of patients with an acute hernia having had a previous medical assessment is in keeping with other studies [14]. In a study by McEntee et al. 29 (37%) of 79 patients with an acute hernia had been seen either by their family doctor, non-surgical medical personnel or surgical personnel. Over half of those assessed by surgical personnel had been declared unfit for surgery. Although most patients declared medically unfit in this study were ASA4, it is clear that some were not and would have benefited from an elective hernia repair.

Three of the 11 patients on the waiting list in this study had a previous acute admission for their hernia while other patients were given an outpatient appointment. This suggests that patients presenting with an acute hernia that is reduced should be offered repair during their acute hospital admission and not be placed on a waiting list or given an appointment for a surgical clinic. Of the remaining patients who had been on the waiting list for a short period of time, four had a ventral hernia, two an inguinal and two a femoral hernia and given the current pressures on inpatient and day case beds it is unlikely their acute admission could have been prevented.

It is becoming increasingly clear that most patients who die from an acute hernia were at high risk and would often have been turned down for surgery in the past [71,142]. This is particularly the case in large incisional or large paraumbilical hernias where a general anaesthetic with muscle paralysis would be required for an optimal repair. It is difficult to understand, however, why a conservative approach to symptomatic inguinal hernias is

still entertained given that most can have a local anaesthetic repair. Similarly, small to moderate sized paraumbilical or epigastric hernias are also amenable to local anaesthetic repair [143].

In this study it is interesting to note that in the era of mesh repair [144] most acute ventral hernias have a non-mesh repair. While there is no logical contraindication to use of mesh, particularly in the onlay or sublay position for such hernias, in this study most surgeons avoided it irrespective of whether there was strangulation or not. This approach is clearly associated with high recurrence rates [145] and should probably be reviewed particularly in cases where there is no overt contamination of tissues.

One of the important differences in this study and other studies examining acute hernias[13,14] is the large number of patients presenting with acute ventral hernias. Excluding the two parastomal hernias nearly one-half of all acute hernias were epigastric, paraumbilical or incisional. This compares to 10–20% of all acute adult hernias from previous studies [13,14]. One reason for this may be a decrease in the number of inguinal hernias repaired as an emergency. In this study only 3.1% of patients with an inguinal hernia had an emergency presentation, compared to 8.7% for the same population in 1993 [146]. The respective figures for femoral hernia have changed little, however, from 50.6% in 1993 to 44.2% in the current study. This decline in emergency inguinal hernia surgery is mirrored by an increase in elective surgery and in certain rural communities where this has not happened; over two-thirds of all incarcerated hernia are inguinal [147].

It is well known that paraumbilical hernias often present acutely and this is likely to be related to the fact that the defect is often small and can easily lead to an irreducible hernia. In this study the number of incisional hernias repaired acutely (13%) was similar to that for paraumbilical hernias. This may be related to reluctance to perform elective repair for such hernias based on poor outcome, 16.6% of all incisional repairs in this study were for recurrence, and the fact that such patients are often elderly and usually recovering from treatment of neoplastic diseases.

It is clear from our study that the rate of acute inguinal hernia presentation remains low (3.1 %) in comparison to femoral hernias, of which almost half (44.2%) present acutely,

the dilemma is differentiating between the two especially when these patients are examined by junior medical staff whether in hospital or in the primary care setting. It is also evident from our study that the 0.44% incidence of bowel strangulation in acute inguinal hernias is slightly higher than the 0.3% noted by Hair and co workers, suggesting that the incidence of strangulation in acute inguinal hernias might be slightly higher than previously thought.

It is a known fact that acute abdominal wall hernias are associated with a significant morbidity, mortality and prolonged hospital stay [13,14,16,141], and although this study would indicate that mortality rates have fallen with acute hernias; there is still room for improvement. High-risk patients need a proper anaesthetic assessment for elective repair of large incisional or paraumbilical hernias. All other hernias should be considered for local anaesthetic repair. Patients presenting acutely should undergo repair during their acute hospital admission while manual reduction should only be considered in those previously declared unfit for elective operation.

Recent advances in hernia surgery such as increasing use of day case surgery and the almost universal adoption of tension-free mesh repair for inguinal hernia[5] should help to make these operations more acceptable to patients. In addition these factors should also encourage earlier referral by family doctors and non-surgical hospital personnel, while improvements in anaesthesia and perioperative care should reduce the numbers declared unfit or too old for surgery.

Study -2

Hernias are a cause of small bowel strangulation

A prospective study of patients admitted with Small bowel obstruction

Methods

Data was collected prospectively on all patients with symptoms and signs of small bowel obstruction who were admitted to one teaching hospital between January 2003 and July 2004. Diagnosis was made from patient's history, physical examination and radiological findings. During surgery, the decision on a strangulated bowel segment was taken by the principal surgeon (consultant or specialist registrar) and confirmation made on pathology. Demographic data, aetiology of obstruction, clinical details, operative findings and outcome were collected for each patient onto standardized forms, and then transferred into a computerized database.

Statistical analysis was performed using Student's *t* test, and $P <= 0.05$ was accepted as statistical significance.

Results

One hundred and sixty-one patients with symptoms and signs of obstruction were admitted over the 18 month period. Patients' demographics are summarized in Table 3.1. There were 96 females and 65 males (male: female ratio of 1:1.6), the values in columns represents the number of patients in each group, while values in parenthesis are percentages.

Age groups	**Hernia**	**Adhesions**	**Miscellaneous**
21–30	1 (3.4)	6 (6.2)	2 (5.7)
31–40	2 (6.9)	10 (10.3)	4 (11.4)
41–50	1 (3.4)	10 (10.3)	7 (20.0)
51–60	2 (6.9)	16 (16.5)	5 (14.3)
61–70	7 (24.1)	20 (20.6)	10 (28.6)
71–80	7 (24.1)	27 (27.8)	3 (8.6)
81–90	7 (24.1)	6 (6.2)	4(11.4)
91–100	2 (6.9)	2 (2.1)	-
Total	29 (18)	97 (60.2)	35 (21.8)
Sex			
Male	11 (38.0)	36 (37.1)	18 (51.5)
Female	18 (62.1)	61 (62.9)	17 (48.5)
Previous surgery	12 (41.4)	91 (93.8)	

Table - 3.1 Demographic data
(Values in columns are number of patients, while those in parentheses are percentages)

The aetiology of obstruction was hernia in 29 (18%), adhesions in 97 (60.2%) and miscellaneous in 35 (21.8%) patients; these included Malignancy, Crohn's disease, Gallstone ileus, Pseudo-obstruction, Appendicular abscess, Radiation stricture, Intra-abdominal collection and the rest were of unknown aetiology.

Of the hernia obstructions 3 were inguinal, 12 femoral, 8 ventral, 1 parastomal, 2 diaphragmatic and 3 internal.

The 71–80 year age group was most affected both in hernia and adhesions (24.1 % and 27.8% respectively).

91 patients (93.8%) in the adhesion group and 12 (41.4%) in the hernia group had a history of previous abdominal procedure.

In 31 patients (31.9%) with adhesive obstruction who underwent surgery, 16 (51.6%) had multiple matted adhesions, whilst 15 (48.4%) were obstructed secondary to a single band.

All the patients had plain abdominal X-ray. No further investigations were done in 72 patients (44.7%), whilst 89 patients (55.3%) had contrast studies (45 CT scans and 44 gastrografin studies). The majority of the patients who had no further investigations were diagnosed with adhesive obstruction, which resolved on conservative management, or hernias, for which an operation was performed.

The causes of strangulation and simple obstruction are shown in Table 3.2. There was a total of 15 strangulations (12 strangulated hernias and 3 adhesion strangulations), it was clear that there was a significant difference in the rate of bowel strangulation between patients presenting with hernias and those presenting with adhesions (41.4% vs. 3.1%, $P < 0.0001$).

Aetiology	**Strangulated obstruction**	**Simple obstruction**
Hernia	12 (7.5%)	17 (10.6%)
Adhesion	3 (1.9%)	94 (58.3%)
Miscellaneous	–	35 (21.7%)
Total	15 (9.4%)	146 (90.6%)

Table - 3.2
Aetiology of strangulated and simple obstruction
(Values in columns are number of patients)

Table 3.3 illustrates patient treatment. 68% of the patients with obstruction due to adhesions were managed conservatively, whilst 86.2% of those with hernias had an operation ($P < 0.0001$). Of the obstructed hernias 12 (41.4%) needed bowel resection due to strangulation, of which only 2 were inguinal and the remainders were femoral.

Aetiology	**Conservative**	**Surgery**	**Bowel resection**
Hernia	4 (13.8%)	25 (86.2%)	12 (41.4%)
Adhesions	66 (68.0%)	31 (32.0%)	2 (2%)
Miscellaneous	17 (48.6%)	18 (51.4%)	-
Total	87 (54.0%)	74 (46.0%)	

Table - 3.3
Treatment

The overall mortality rate was 4.3% (7 patients). Five deaths occurred in patients without strangulation, whilst two occurred in patients with strangulation, both of which were hernia patients (Table 3.4). Of the five deaths in patients without strangulation, three were declared unfit for surgery due to associated co-morbidity, whilst two had advanced cancer.

Type of obstruction	**Number of patients**	**Mortality**
Simple obstruction	146	5 (3.4%)
Strangulated obstruction	15	2 (13.3%)

$P = 0.034$

Table - 3.4
Mortality rate in simple and strangulated obstruction

Discussion

Small bowel obstruction remains one of the main causes of emergency hospital admissions, and is a frequent indication for surgery. The key to successful management is to intervene before development of strangulation or perforation. It is widely believed that small bowel obstruction is seen twice as frequently in males as in females. In this study, the male to female ratio was found to be 1:1.6.

Hernias are a common cause of small bowel obstruction. However, some authors have reported low rates (2%) due to elective repair of groin hernias [148]. Immediate operative management is advised, due to an increased incidence of strangulation and mortality. Reported strangulation and mortality rates range from 6% to 24% and 4.3% to 6.5% respectively [149,150]. In our study hernias accounted for 18% of small bowel obstruction (of which only 1.8% were inguinal), within the hernia group strangulation occurred in 41.4% of obstructed patients, with femoral hernias accounting for the majority of strangulated hernias (10 out of 12). Mortality within this group was 6.9%.

3 patients had an inguinal hernia, and of these 2 required small bowel resection due to strangulation within the hernia, both presented within less than 24 hours and both had their hernia for more than 2 years; one was referred to a surgical clinic for surgical assessment while the other was on the waiting list for repair. Both patients had an uneventful post operative recovery.

Looking with further detail; it was clear that small bowel obstruction due to hernia carries a 20 fold rise in the risk of bowel strangulation necessitating resection when compared with adhesion obstruction (41.4% of all hernia obstructions vs. 2% of adhesion obstructions).

Several published reports have shown adhesions accounting for more than half of the admissions for small bowel obstruction [148,150,151]. The type of adhesion (matted versus single band) influences severity of symptoms and recurrence of obstruction [152]. We noticed an even distribution between single band (48.4%) and multiple matted (51.6%) adhesions, which is similar to that reported by Miller and Boman [152].

In a study carried out by Yilmaz and Gulsen [149] strangulation and mortality rates from adhesive bowel obstruction were 20.3% and 9.6% respectively. Miller and Boman

[152]reported strangulation rates of 18% for patients with a single band, 16% for those with multiple matted adhesions, and an overall strangulation rate of 6%.

In our study 13% of patients with a single band, and 7% with multiple bands, had strangulated bowel. The overall incidence of strangulated bowel and mortality due to adhesive obstruction was 3.1% and 5.1%, respectively. The lower rates in our series may be due to a policy of operating early following unsuccessful conservative management. 68% of patients thought to have partial adhesive obstruction responded to conservative therapy with or without gastrograffin during this period.

Strangulation occurs in 5–42% of all small bowel obstructions [153] It is associated with a 10-fold increase in mortality. Differentiating strangulation from simple obstruction is often difficult. Therefore many surgeons have advocated early surgical intervention in patients presenting with small bowel obstruction, as the classical signs of strangulation are not always present and this threshold should be even lower with patients presenting with an obstructed hernia as the chances of it being strangulated are much higher as seen in our study were 41.1% of patients required bowel resection due to dead bowel.

Finally it is clear from the above that although adhesions are the most common cause of small bowel obstruction, inguinal hernias remain a substantial cause of such obstructions, albeit with a low risk of strangulation (2 of 161 patients, 1.2%); in contrast femoral hernias are a major cause of small bowel strangulation.

Study -3

Management of asymptomatic inguinal hernias: Randomised controlled study

Methods

Informed consent was obtained from suitable patients attending North Glasgow NHS Trust who were 55 years or older with an asymptomatic inguinal hernia to randomize them to repair or observation, randomization commenced in June 2001 and ended in June 2003. This study was performed in close collaboration with General Practitioners in the region, who were informed of the study and spoken to in person, they were asked to send all patients with an asymptomatic inguinal hernia to surgical outpatients for assessment. Patients were also recruited from the wards, which were found on clinical examination to have an asymptomatic inguinal hernia. Patients were informed of the study at outpatient clinic, suitable patients, determined by inclusion criteria, were then randomized to either treatment or no treatment by phone call to a central randomization centre coordinated by the Robertson Centre for Biostatistics.

Inclusion criteria

Patients included in the study fulfilled the following criteria:

1. Male
2. Aged 55 or more.
3. With an asymptomatic inguinal hernia
4. Reducible.
5. Fit for local anaesthetic inguinal hernia repair
6. No pain at hernia site at rest or during activity

Study patients would have completed a 100 mm visual analogue pain scale (VAS) and should have registered no pain at rest or movement for inclusion. Also all participants were asked to complete a questionnaire on general health status (SF-36); this was repeated at 6 months, 1 year later and annually thereafter (Appendix 1).

The SF-36 covers eight health concepts: physical functioning, bodily pain, role limitations owing to physical or emotional problems, general mental health, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health (Appendix 1). The score for

each scale is calculated as the sum of the scores for each item (ranging from 0 to 4 on a five-point Likert scale) and transformed linearly into a range from 0 to 100; a higher score denotes a better level of functioning. We used disability as assessed with the Barthel Index to measure any adverse effects the patients hernia may have on activities of daily living [154].

All hernias were categorised into direct and indirect and the size of the hernia was measured by the degree of protrusion and the diameter of the defect (to estimate potential increase in size over time), this measurement was carried out by the researcher surgeon and verified by the research nurse; the measurements were in centimeters using a tape measure.

The duration the hernia was present was also recorded, as were details on whether it was primary or recurrent.

Patients randomized to treatment had an open tension free mesh repair (Lichtenstein repair) under local or General anaesthetic (as a day case procedure where appropriate).

Patients in the observation arm were given a contact number to telephone should their hernia become symptomatic or complicated, and this was available from 9am-5pm each day with arrangements made to contact the receiving surgical senior house officer at night and weekends should a problem arise (Appendix 1). Patients also had open access to our weekly Hernia clinic if required.

Participants in both groups were examined at six months, 12 months and annually thereafter at a single Research Clinic at the Western Infirmary, Glasgow.

This clinic had the Researcher Surgeon and the Research Nurse, assessment at the hernia clinic was made by the Research Nurse who had access to a senior clinician for any queries he had.

The criteria for which patients in the observation group received advice to undergo operation were as follows:

1) Pain of any duration at the hernia site that the patient reported to the Research Centre or attended the open access clinic.
2) Pain at the hernia site of any duration that affected the patient's work, leisure or sexual activity.
3) An increase in the size of the hernia that affected any of the same parameters.

4) A hernia that became difficult to reduce, irreducible or strangulated.

While the criteria for which Patients in the surgically treated group received advice to undergo a further operation were as follows:

1) A hernia recurrence.
2) Development of a chronic wound sinus or infection.
3) Chronic pain that does not respond to medical treatment at a pain clinic.

The development of a new contralateral inguinal hernia was also considered; only those that were symptomatic would have been treated surgically in the control group while all new contralateral hernias were treated in the surgery group.

A data collection form for recording aspects of Hospital resources was completed by the research nurse who was present at all operations and subsequent follow-up. The subjects covered included time of return to normal activities, the disruption this caused to the life of the patient and their carers and any other costs incurred.

The impact of a shift in policy of not operating on an asymptomatic inguinal hernia was also assessed from an economic perspective. This included hospital and patient costs as well as the cost of any significant complication. Costing was also assessed from a societal perspective in terms of differences in cost and quality of life scores. SF-36 data were converted to utility values using an algorithm supplied by the Health Economics Department School of Health and Related Research, University of Sheffield [155].

The study was powered to address the primary endpoint of pain at 1 year. At the time of the original power calculation, previous studies have shown that a reasonable assumption was for at least one-third of patients to report pain at the hernia repair site one year following open mesh repair [51]. We also calculated that if 15% of asymptomatic patients were to develop pain or a complication that required operation each year then most of the population would end up having their hernia operation delayed rather than not operated on. Therefore, with 125 subjects in each of the randomized groups the study would have an over 80% power at the 5% level of significance to detect an absolute difference in pain at one year of 16% between groups (from 31% to 15%). After 1 year of the study we had not recruited as quickly as we anticipated due to the fact that a high number of patients refused to be randomised because they did not want an operation (Figure 4.1)

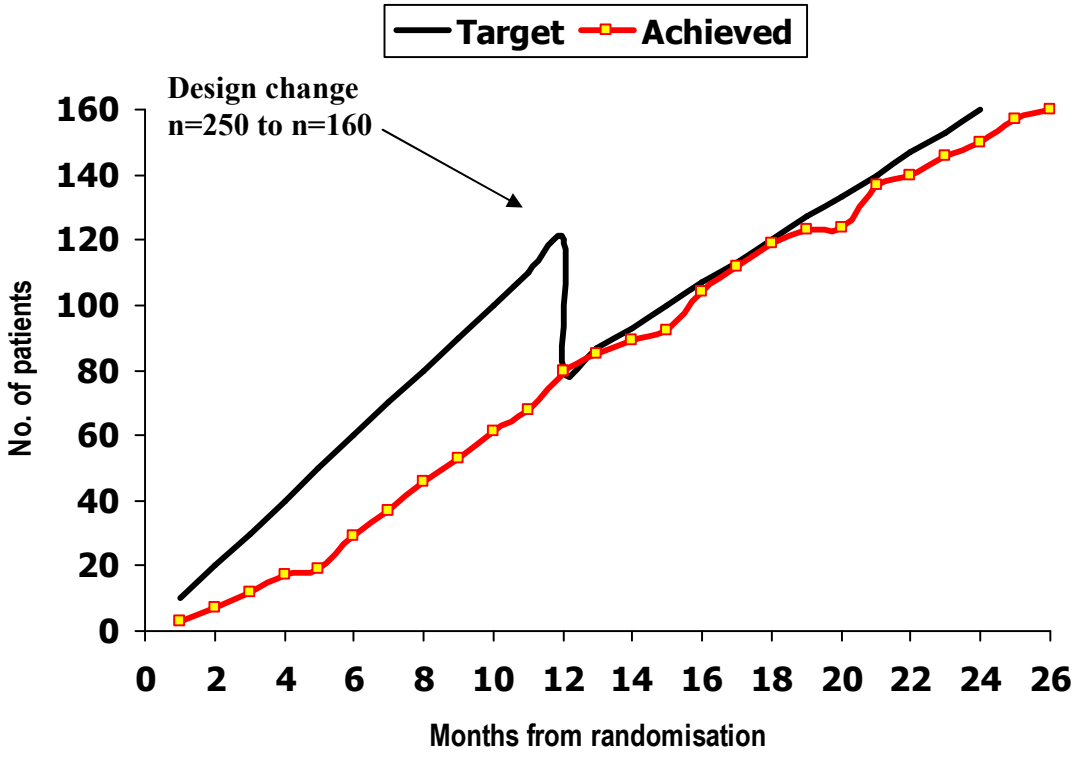


Figure - 4.1

Patient Randomisation

Therefore a revised power calculation indicated that 80 subjects per group would give the study an 83% power to detect a slightly larger difference of 20% (from 35% to 15%), and that we could achieve this number in the scheduled recruitment window given the recruitment rate experienced in the first year. We therefore modified the design of the study to recruit 160 patients in total.

The primary analysis was according to the intention to treat principle. Baseline data were tabulated by randomised treatment groups (observation or operation). Categorical data at 6 and 12 months (such as taking regular analgesia Yes/No, Pain at Rest/At Movement Yes/No) were compared between the two randomised groups by chi-squared tests.

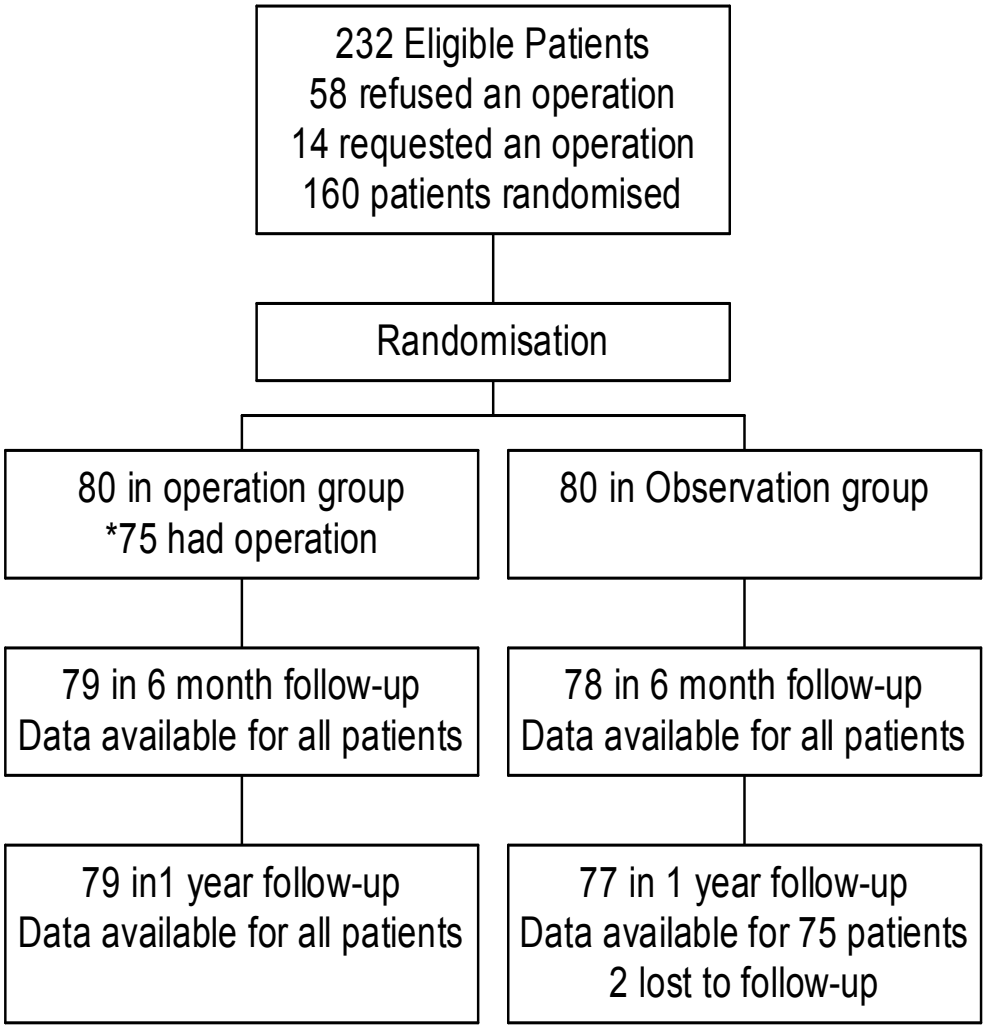
Continuous data (such as the SF-36 Health dimensions, and the VAS Pain at Rest and At Movement scores) at 6 and 12 months were given as mean (standard deviation) and compared using linear models that adjusted for the baseline measure of the outcome under consideration. Additional linear models which further adjusted for other baseline covariates were fitted (age, hernia type, duration, side of hernia, and degree of protrusion). For the pain outcomes, a linear model adjusted for both the baseline and the 6 or 12 month variable measuring whether the participant was taking regular analgesia. In those randomised to observation, a Kaplan Meier time to crossover from observation to surgery curve was plotted, and univariate and multivariate Cox proportional hazards models fitted to investigate the influence of the baseline covariates on the propensity to transition to surgery.

For the SF-36 Change in Health component outcome, and for the pain scores at rest and on moving, secondary supporting analyses to the intention to treat analysis was performed reclassifying the subjects according to what intervention they had actually received (observation or operation) at 6 and then at 12 months regardless of their randomised allocation. For those randomised to observation, we also compared the pain scores (at rest and on moving) for those who transitioned to surgery against those that remained on observation. We compared the most recent pain score before surgery with the 12 month pain scores in those that remained on observation, using a linear model that adjusted for baseline pain score and other baseline covariates, including age.
All analyses were carried out in SAS 9.1 for Windows. No adjustment has been made for multiple comparisons.

Results

There were 232 eligible patients with an asymptomatic hernia during the study period (June 2001- June2003), of whom 160 agreed to randomisation. For those who did not participate in the study, 58 refused an operation, while 14 requested an operation.

The trial profile was therefore as follows:



3 patients had died from non-hernia related causes by 6 months while an additional patient had died at one year.

*1 died while awaiting operation, 1 was cancelled because of myocardial infarct while 3 refused operation.

Figure - 4.2
Trial Profile

All patients in both groups completed baseline data and visual analogue pain scores at rest and on movement. And though none of these patients had pain from their hernias, some patients in both groups recorded a pain score at rest (Figure 4.3) and on moving (Figure 4.4) which they related to chronic back pain secondary to osteoarthritis.

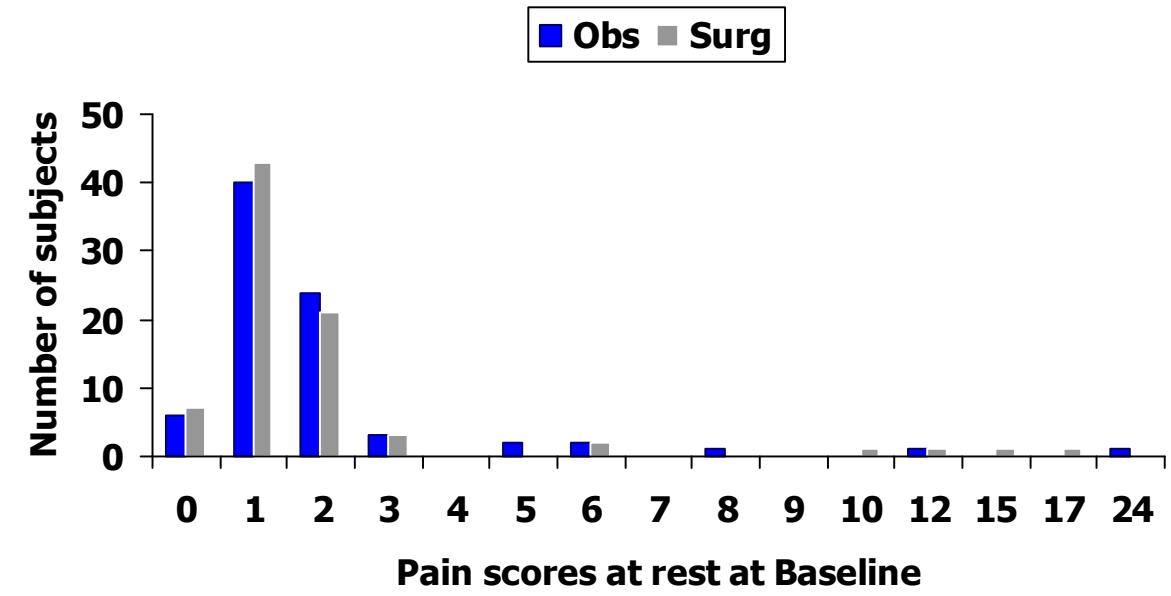
Baseline characteristics of participants in both groups are detailed in Table 4.1

Characteristic	**Measure**	**Observation (N:80)**	**Operation (N:80)**
Mean Age (years)		71.9	70.9
Hernia type	Primary N (%)	79 (99%)	77 (96%)
	Recurrent N (%)	1 (1%)	3 (4%)
	Direct	48 (60%)	51 (64%)
	Indirect	31 (39%)	27 (34%)
	Combined	1 (1%)	2 (2%)
Side	Left	34(43%)	46(58%)
	Right	38(48%)	29(36%)
	Bilateral	8(10%)	5(6%)
Hernia size (cms)		3.23	3.39
Duration of hernia (yrs)		3.04	3.46
Barthel Index	N (% at maximum)	79 (99%)	77 (96%)
International activities of daily living (IADL)	N (% at maximum)	78 (98%)	77 (96%)
SF-36 Mean values	General Health	72	67
	Physical Functioning	79	72
	Physical Role	58	50
	Emotional Role	78	70
	Social Functioning	88	83
	Bodily Pain	80	73
	Vitality	68	64
	Mental Health	81	79
	Change in 12 months*	50	48

* “Compared to 1 year ago, how would you rate your general health now?”

N= Number

Table - 4.1
Baseline Characteristics



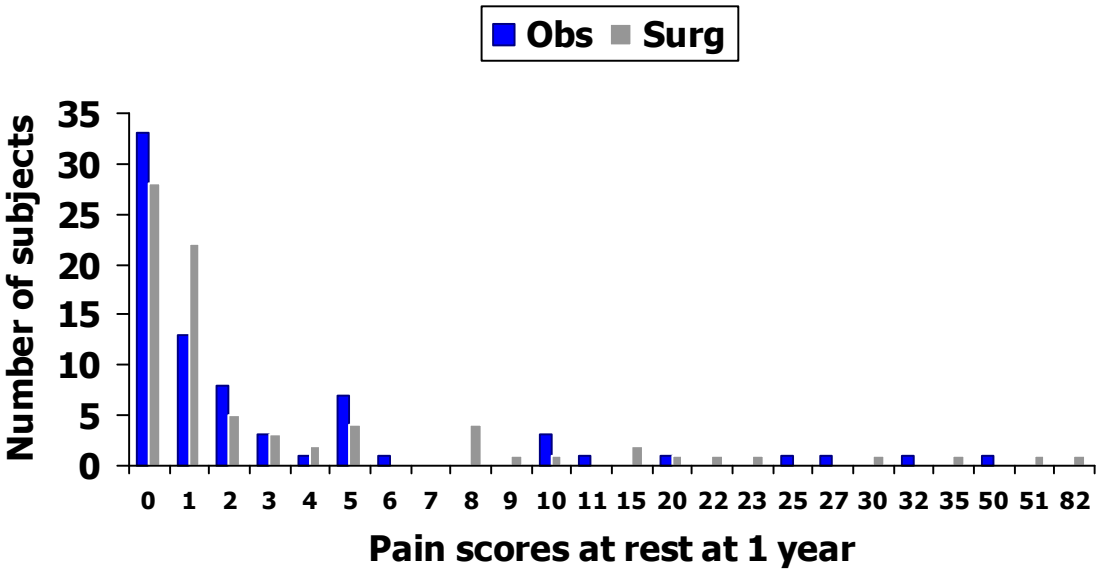


Figure - 4.3
Pain scores at rest at Baseline and at 1 year
(Pain scores at base line were due to back pain and arthritis)

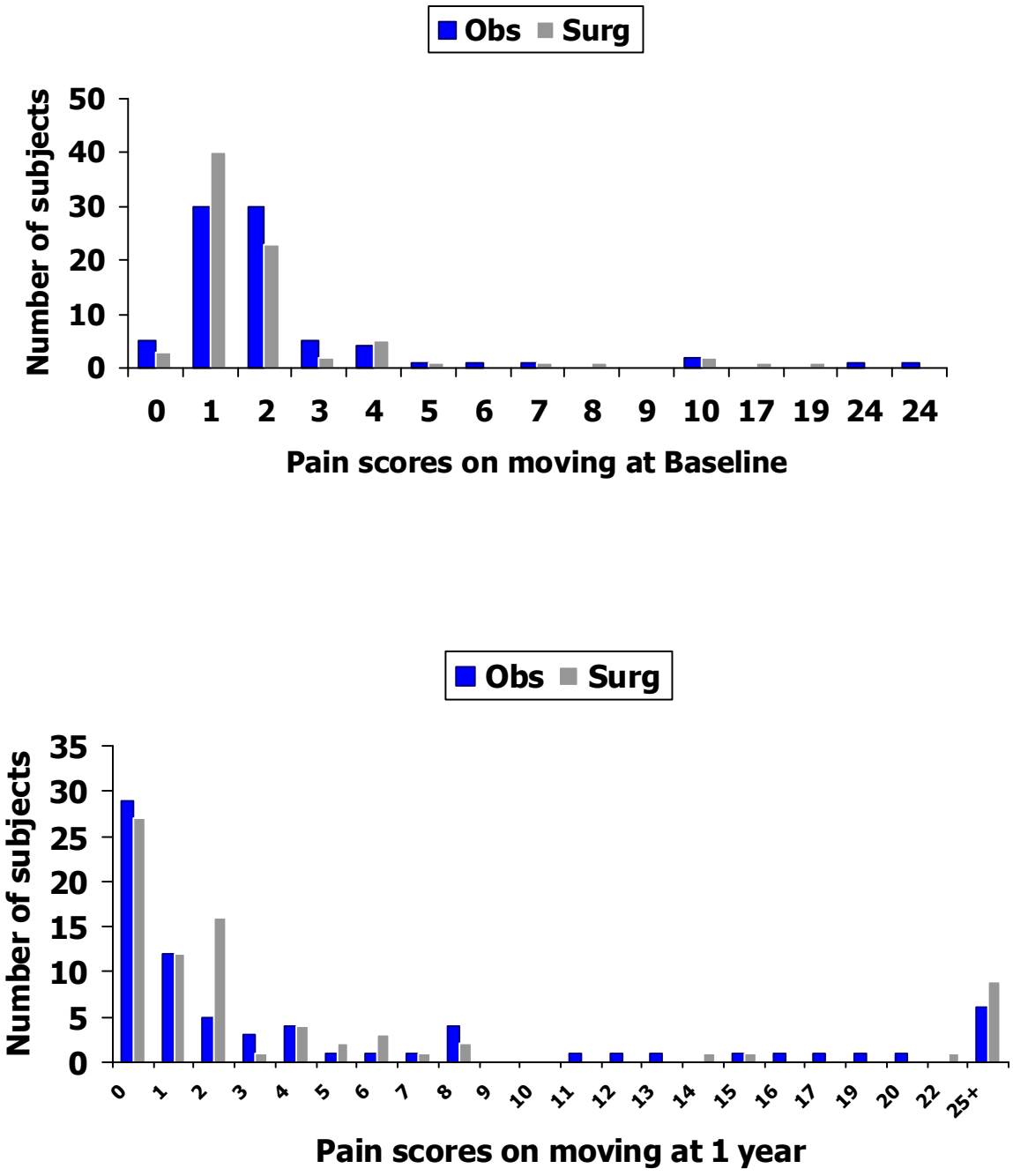
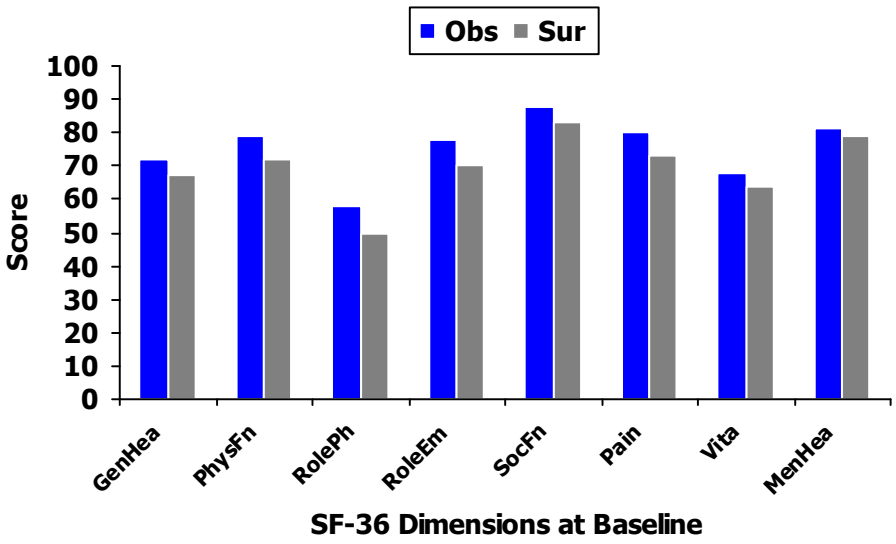


Figure - 4.4
Pain scores on moving at Baseline and at 1 year

There was a tendency for the operation group to have slightly worse SF-36 scores at baseline consistently across all components, with slightly larger hernias which have been endured for slightly longer. This was thought to be due to chance (Figure 4.5).



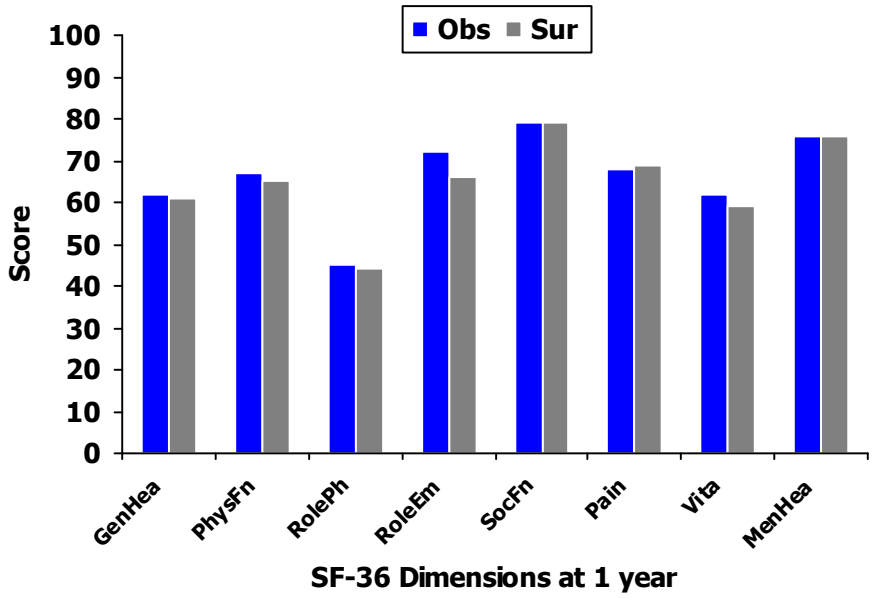


Figure - 4.5
SF-36 Dimensions at Baseline and at 1 year

Of the 80 participants randomised to operation 75 underwent hernia repair. One patient died from cancer while awaiting repair, one had a serious cardiac event and repair was cancelled while three refused multiple admission dates for repair. The mean (standard deviation) time from randomisation to surgery for the 75 of 80 participants in the operation group who proceeded to surgery was 103 (97) days (range 8 to 486 days, median 78 days).

We did not find any statistically significant evidence that either the waiting time for surgery, or the elapsed time since surgery, had an influence on either the SF-36 scores or the pain scores

Pain at 6 and at 12 months

Visual analogue pain scores at rest and on movement were similar in both groups at 6 and 12 months following randomisation (Table 4.2).

Pain measure	Observation		Operation		Model	Mean Difference Operation – observation 95% CI	P-value
	N	Mean(SD)	N	Mean (SD)			
At rest							
Baseline	80	2.0(3.0)	80	2.0(2.9)	-	-	-
6 months	78	8.0(14.0)	79	4.8(10.7)	A	-3.2(-0.7, 7.1)	0.11
					B	-3.3(-0.2,6.8)	0.062
12 months	75	3.7(8.2)	79	5.2(12.3)	A	1.5(-1.6,4.8)	0.34
					B	1.4(-1.7,4.5)	0.38
At Movement							
Baseline	80	2.3(3.0)	80	2.4(3.1)	-	-	-
6 months	78	10.9(16.0)	79	6.1(11.9)	A	-4.8(-9.2,-0.3)	0.036
					B	-5.0(-9.1,-0.9)	0.018
12 months	75	7.6(15.0)	79	5.7(11.5)	A	-1.9(-6.1,2.4)	0.39
					B	-2.4(-6.6,1.7)	0.25

Models:
A – Adjusting for relevant baseline pain measurement
B – Additional adjustment for analgesia and other baseline covariates

Table - 4.2
Pain Scores at Rest and At Movement at Baseline, 6 and 12 months.

At 6 months 34 (44%) in the observation group recorded pain (at least 2mm on the 10 cm Visual Analogue Scale) at the hernia site at rest compared to 29 (37%) in the operation group (difference in proportions, observation – surgery 7% [95% CI –8% to 22%] (P=0.42). The respective numbers for pain on movement were 40 (51%) and 32 (41%) (Difference 10% [95% CI –5% to 26%], P=0.20). At one year the numbers had reduced to 21 (28%) in the observation group and 24 (30%) in the operation group at rest (difference –2% [95% CI –17% to 12%], (P=0.86) while on movement the respective figures were 29 (39%) and 24 (30%) (difference -9% [95% CI –7% to 23%], P=0.31). Only 6 (8%) patients had a VAS >10mm at rest in the observation group at 1 year compared to 9 (11%) in the operation group (difference –3% [95% CI –13% to 6%], P=0.59). The respective numbers for VAS >10mm on moving were 15 (20%) and 11 (14%) (Difference 6% [95% CI –6% to 18%], P=0.39). At baseline 5 (6%) participants in each randomised group were taking regular analgesia, while at six months this was 14 (18%) in the observation group and 13 (16%) in the operation group (difference 2% [95% CI –10% to 14%], (P=0.84); by 12 months the respective numbers were 9 (12%) and 17 (22%) in the operation group (difference -10% [95% CI –21% to 2% (P=0.14).

SF-36 at 6 and 12 months

On an intention to treat analysis there was a consistent trend to improvement of about 5 points in all of the dimensions (except emotional role) in the operation group compared with the observation group at 6 months (Table 4.3 and Figure 4.5). The change in the previous 12 months was significantly increased in the operation group, with a mean difference of 8 (95% CI 2 to 14, P=0.0079). At 12 months similar trends were observed but typically now about 3 units increase rather than 5. Change in health in the previous 12 months remained significantly increased with a mean difference of 7 (95% CI 0 to 14, P=0.039).

6 months				
Dimension	**Observation (n=78)**	**Operation (n=79)**	**Mean Difference (Operation – Observation), 95% CI**	**P-value**
General Health	-10.3 (18.9)	-3.4 (17.6)	5.8(0.1, 11.5)	0.046
Physical functioning	-11.7 (20.4)	-4.7 (22.3)	4.8(-1.7,11.4)	0.15
Physical role	-12.7 (21.9)	-3.3 (22.5)	6.2(-0.5,12.8)	0.069
Emotional role	-8.5 (45.7)	-3.4 (40.2)	0.8(-11.2,12.9)	0.89
Social functioning	-11.4 (23.3)	-4.4 (23.5)	5.4(-1.7,12.5)	0.14
Bodily pain	-10.1 (22.5)	-1.6 (25.2)	5.3(-1.7,12.3)	0.14
Vitality	-9.9 (17.3)	-3.3 (21.0)	5.0(-0.8,10.9)	0.093
Mental Health	-8.5 (15.9)	-2.6 (17.9)	4.9(-0.3,10.0)	0.063
Change in 12 months	-3.5 (22.0)	7.3 (20.5)	9.4(3.6,15.1)*	0.0016
12 months				
Dimension	**Observation (n=75)**	**Operation (n=79)**	**Mean Difference (Operation – Observation), 95% CI**	**P-value**
General Health	-10.1 (18.3)	-5.3 (16.7)	3.7(-1.8,9.2)	0.097
Physical functioning	-12.9 (17.7)	-7.2 (22.5)	4.5(-2.0,11.0)	0.17
Physical role	-12.8 (22.0)	-6.8 (23.3)	3.3(-3.7,10.2)	0.36
Emotional role	-5.8 (45.3)	-4.2 (46.9)	3.3(-9.3,15.9)	0.60
Social functioning	-9.0 (21.4)	-4.2 (21.8)	3.3(-3.3, 9.9)	0.33
Bodily pain	-11.1 (23.8)	-3.0 (24.8)	5.2(-2.1,12.5)	0.16
Vitality	-6.6 (16.4)	-4.7 (18.2)	0.1(-5.1,5.2)	0.98
Mental Health	-5.0 (14.4)	-2.4 (17.2)	1.6(-3.2,6.4)	0.51
Change in 12 months	-0.3 (23.4)	8.5 (25.6)	7.0(0.2,13.7)*	0.045

***** For overall change in health status in the preceding 12 months, from a linear model that adjusts for other baseline covariates, the difference between operation and observation groups was 8.0 (95% confidence interval 2.1 to 13.8, P=0.0079) at 6 months, and 7.3(0.4 to 14.3, P=0.039) at 12 months.

Data shown are mean (SD) for the change over baseline, and the estimated difference between operation and observation, with a 95% confidence interval and associated P-value, from a linear model that adjusts for the baseline level of the relevant SF-36 component.

Table - 4.3
SF-36 values at 6 and 12 months

Treatment Received Supporting Analyses

In practice, some participants randomised to observation had received surgery by 6 or 12 months post randomisation, and some patients who were randomised to surgery became unable to have the surgery or had not yet had the surgery by either 6 or 12 months. In an analysis to complement the intention to treat analyses, we then compared the SF-36 Change in Health question according to whether the subjects had or had not received surgery at 12 months. This involved 8 participants randomised to surgery being reclassified to observation and 15 participants randomised to observation being reclassified to surgery. The difference between the operation and observation groups was then 9.9 (95% CI 4.1 to 15.7, P=0.0010), so confirming the intention to treat results.

The pain score analyses according to intervention received showed very similar results to the intention-to-treat analyses reported in Table 4.2 (data not shown). For those randomised to observation, we also compared the pain scores for the 15 who transitioned to surgery (using their most recent pain score before transition – that is, baseline if the transition occurred within the 1st six months, or the 6 month score if transition took place in the 2nd six months) against the 12 month pain score for the remaining 60 that remained on observation and had data at 12 months. For pain at rest, the mean scores were 13.5 and 3.7 (difference in means, 11.6 [95% CI 5.3 to 17.8, adjusted for baseline pain and age, P=0.0004), and for pain on moving, mean scores were 15.6 vs. 7.1 (adjusted difference 9.9 [95% CI 1.4 to 18.4], P=0.023).

Crossovers from observation to surgery

At a median follow-up of 574 days 23 patients (28.75%) in the observation group have had an operation (Figure 4.6). The reasons for operation were: pain and an increase in hernia size (11), pain (8), increase in size affecting work or leisure activities (3) and acute presentation (1). A Cox proportional hazards regression model (Table 4.4) to study the influence of baseline characteristics on crossover indicated that the degree of protrusion was the only factor that came close to predicting such an event. Hazard Ratio on univariate analysis (95%CI) 1.29 (0.98-1.69 P=0.073), which in a multivariate model adjusting for all the other factors increased to 1.35 (1.00 – 1.83, P=0.053*)*.

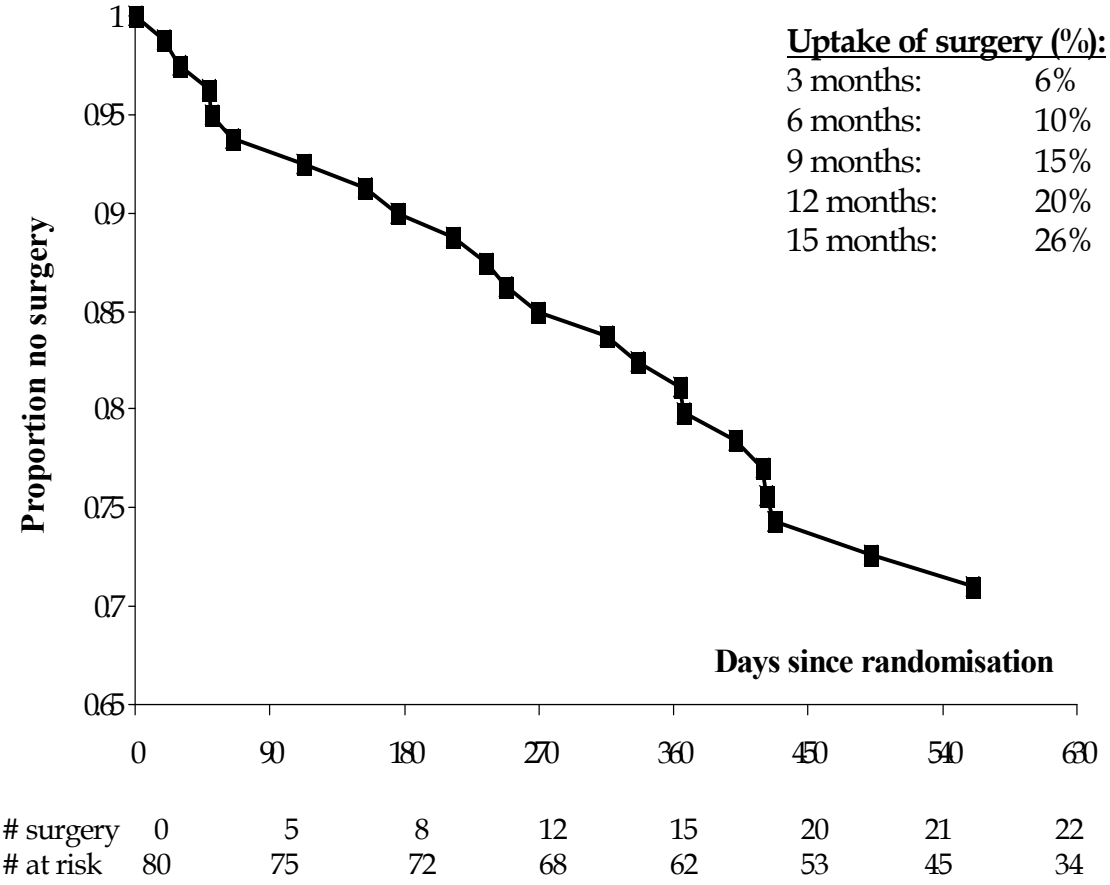


Figure - 4.6
Kaplan Meier plot of time to decision for surgery in those participants randomised to the observation group.

All operations were performed by the same surgical unit that carried out surgery in the operation group. One patient had a postoperative myocardial infarct and died while another had a cerebrovascular accident, both patients were in the observation group. No serious postoperative complications were noted in the operation group. A further 9 patients have died on follow-up, 4 in the observation group and 5 in the operation group. The causes of death has been cardiovascular disease (6) and cancer (3) related.

Baseline covariate	**Univariate**		**Multivariate**	
	HR (95% CI)	**P-value**	**HR (95% CI)**	**P-value**
Direct	1.54(0.63,3.79)	0.34	1.80(0.71,4.60)	0.22
Duration (1 yr)	1.02(0.87,1.19)	0.80	1.05(0.89,1.24)	0.56
Left only	0.80(0.35,1.85)	0.60	0.84(0.35,2.01)	0.69
Protrusion (1 cm)	1.29(0.98,1.69)	0.073	1.35(1.00,1.83)	0.053
Vertical (1 cm)	1.35(0.65,2.80)	0.42	Not fitted*	
Transverse (1 cm)	1.14(0.57,2.29)	0.72	Not fitted*	
Age (10 yrs)	1.03(0.60,1.77)	0.92	0.97(0.55,1.71)	0.91

Data shown are Hazard Ratio (HR) for the given increment (e.g. 1 year of age) with a 95% confidence interval and associated P-value.

* Not fitted in the multivariate model (Spearman correlations: vertical size and protrusion 0.68, transverse and protrusion 0.48, vertical and transverse 0.46).

Table - 4.4
Univariate and Multivariate Cox proportional hazards model for baseline predictors of crossover from observation to surgery

Economics

The cost to the Health Service was £401.9 per patient greater for the operation group at the median follow-up of 574 days. This took into account clinic and operative costs and the cost of complications for both groups [156-158]. Despite improvements in general health there was no significant quality-adjusted life year gain (QALY) for the operation group at 12 months (Table 4.5).

Time	Observation		Operation		Operation – Observation (95% CI)	P-value
	N	Mean (SD)	N	Mean (SD)		
Base	80	0.818 (0.094)	80	0.798 (0.117)	-	-
6m	78	0.775 (0.136)	79	0.778 (0.121)	0.003 (-0.038, 0.44)	0.88
12m	75	0.772 (0.129)	79	0.769 (0.130)	-0.003 (-0.044, 0.038)	0.89
6m-base					0.020 (-0.003, 0.044)	0.15
12m-base					0.017 (-0.019, 0.053)	0.34

Table - 4.5
Utility values derived from SF-36 data

Discussion

This study was set up against the background that operation on an asymptomatic hernia or a hernia that had little effect on the patient's social or daily activities may result in considerable chronic pain and discomfort. Interestingly this was not the case, and on any parameter measured up to 1 year after randomisation, pain scores, the number who reported pain and analgesia consumption there was no difference between those that were observed and those that had an operation. Moreover patients that underwent operation perceived that their general health had improved, as did those who crossed over to have an operation; on the contrary to those that were observed who felt that their health had declined. It was clear from our study that the rate of crossover to operation in the observation group was higher than expected. At a median follow-up of 574 days 23 patients (28.75%) in the observation group have had an operation, with pain and increase in hernia size being the main reason for cross over. Interestingly the only factor to predict crossover from observation to operation was the degree of protrusion of the hernia.

These findings are quite similar to those published by Fitzgibbons et al [159] who reported a 20% cross-over rate to surgery for patients randomised to observation within 2 years of follow-up, and an improvement in SF-36 parameters in these patients.

It could therefore be said that the safe practice would be to operate on these patients given the improvement in their general well being as well as their SF-36 parameters, this view is supported by findings of Franneby [2], Poobalan [35] and Courtney et al[43], who demonstrated that a high level of preoperative pain indicated an increased risk of long-term pain, and given this; operating on these patients earlier would seem to lessen the chances of them developing chronic pain later on. Added to this is the high cross over rate seen in both studies suggesting that observing these patients will just merely delay their operation to a time when they might be unfit for such surgery. This is clearly demonstrated in the three serious adverse events that occurred in the observation group in our trial (one acute hernia, one postoperative stroke and one myocardial infarction that resulted in postoperative mortality). The later 2 patients that had a serious postoperative event, had co-morbid cardiovascular disease which had deteriorated significantly in the period under observation and it is fair to say that if these patients were operated upon

under local anaesthesia on their first presentation with an asymptomatic hernia it might have been possible to prevent these serious morbidities and mortalities, as studies have clearly demonstrated that serious morbidity and mortality are rare after elective hernia repair even for elderly patients[139]. On the contrary, mortality from acute groin hernia surgery remains high, rates of 3.8% are noted with emergency repair [140], going up to 37% with bowel resection [13], this rise in mortality rate is thought to reflect the selection of medically fit patients for elective repair leaving the high risk patients with complex co morbid illnesses for emergency repair, with only a small subset having strangulated bowel[13]. While there are a number of reasons for this, a significant contribution is made by surgeons turning high-risk patients down for elective operation in the first instance[14], and this approach needs to change as most patients will be suitable for elective repair under local anaesthesia irrespective of the nature or severity of any co-existing illness.

Study -4

Management of asymptomatic inguinal hernias: The non-randomised patients

Methods

Data was collected from patients with an asymptomatic hernia who either did not fulfil the recruitment criteria or refused to participate in the asymptomatic hernia trial.

Case notes of all the above patients were reviewed and data was collected and entered onto a separate data base, data collected included age, sex, date of refusing randomisation, number of patients requiring surgery, time to surgery and finally mortality rate.

Results

Of the total 232 eligible patients within the asymptomatic hernia trial, 72 patients refused to participate in the study of which 58 opted for observation and the remaining 14 wanted an operation.

The age range, median and mean age of both groups within the non randomized patient group is shown in Table 5.1.

	Surgery Group	**Observation Group**
No. aged < 55	1	15
No. aged 55-79	7	27
No. aged > 79	6	16
Mean age	72	66
Median age	74	71

Table - 5.1
Age range of non randomised patients

Fourteen patients (age range 20-91) opted for surgery, had their operation and had no further follow-up.

While 58 patients with a median age of 71 years (age range 22-95) refused surgery and wished to be observed. At the time of analysis there were 9 mortalities (15.5%) within the

observation group, none of which had been operated on, and all were unrelated to the hernia and due to co-morbid illnesses. This left 49 patients for final analysis.

13 (22.4%) patients within the observation group required surgery because of pain, the time to surgery ranged from 13 to 1774 days [(median 244 and mean 333 days), (Figure 5.1)]. The age range for those converted was 29-84 (median of 74 and mean of 63.5 years).

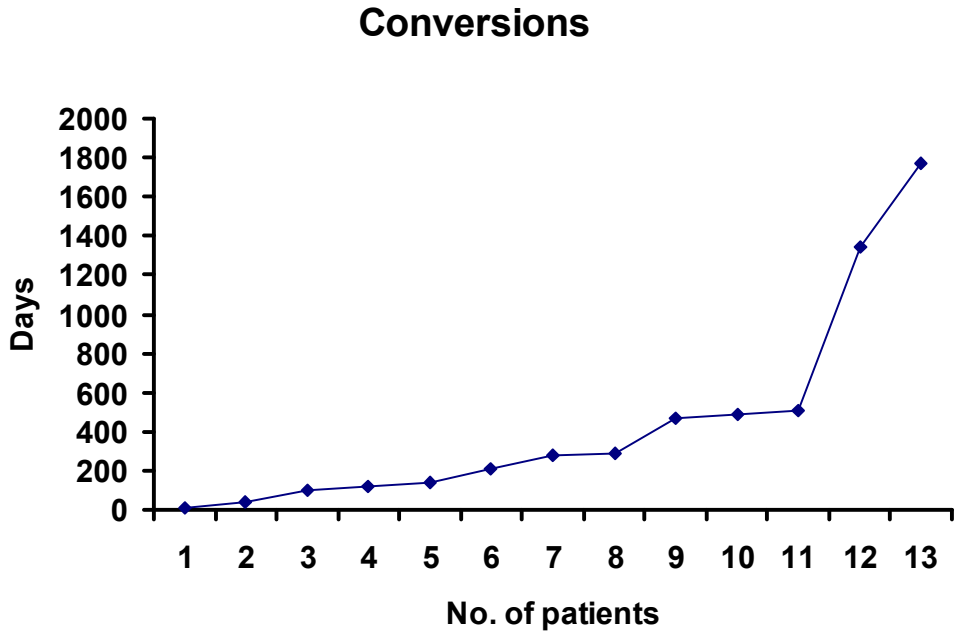


Figure - 5.1

Non-randomised observation patients requiring surgery.

Discussion

22.4% of patients who wished to be observed became symptomatic and required surgery within an average time of less than a year (333 days). These findings from this non randomized group of patients is similar to the findings from our randomized trial discussed previously in which 20% of patients at 1 year became symptomatic and required surgery.

As far as we know this is the first study that looks into a non randomized group of patients with an asymptomatic hernia and follows them up to assess their outcome in terms of need for surgery and mortality. It is unfortunate that this group did not wish to be randomized and hence we could not send them the VAS and the SF-36 to assess their pain scores pre and post surgery. Up to our knowledge and from reviewing their case notes, none of the 13 patients had been referred back to our clinic with chronic pain or been referred to the pain specialist by their general practitioner.

It is therefore safe to conclude that the outcome from this non-randomized group of patients is similar to that of the randomized group and hence final conclusions could be drawn applicable to both groups.

FINAL DISCUSSION

Inguinal hernia repair remains one of the most common operations in general surgery with more than 500.000 repairs carried out every year in the United states [160] , with an estimated average cost of £1000. The costs to society in terms of time off work are harder to estimate [72].

Advancements made in hernia repair reduced recurrence rates to all time low and brought to light a new concept of postoperative pain. Bay- Nielsen et al[1] described the incidence of post operative pain to be 28.7% one year after groin hernia repair in a nationwide study, and of those with pain 69.8% mentioned that the pain interfered with their daily activities. In a second study he noted that after 30 days of hernia repair 6.8% of patients had not resumed employment and 17% had not resumed leisure activity, 60% of these patients quoted pain as the reason for their delay[161].

Findings from our acute hernia study demonstrated that out of the 91 patients admitted with an acute hernia 24 were inguinal, of these only 4 were strangulated (16.6%) necessitating a bowel resection. This translates to 3.1% of hernias presenting acutely when the total of 952 hernias repaired electively during the study period was taken into account, and none of these patient died post operatively.

These findings were similar to those of the Intestinal obstruction study, which demonstrated that From the 161 patients presenting with small bowel obstruction only 1.8% were due to inguinal hernias, and of the total 15 strangulations only 2 were due to inguinal hernias, none of these patients had an adverse outcome from their emergency surgery.

Knowing all the above, we set up a prospective randomised trial aiming to reduce the high rates of post operative pain. We hoped that by adopting an observation policy for patients with an asymptomatic inguinal hernia we would reduce the incidence of pain and functional impairment. To our surprise the results came to prove the opposite, on any parameter measured up to 1 year after randomisation; pain scores, the number who reported pain and analgesia consumption, there were no differences between those that were observed and those that had an operation. More interestingly, patients that underwent operation perceived that their general health had improved, whereas those that

were observed felt that their health had declined in keeping with increasing age in an elderly population.

The rate of crossover to operation in the observation group was higher than expected in this study. This occurred at a steady rate over the period of observation and may indicate that such a tactic would merely delay rather than avoid operation. In our initial calculation based on expected survival for the age group, our estimate was that, if 15% of patients developed pain or a complication that required operation each year, then a non operative policy would not be viable. In the first year of follow-up, almost 20% have required an operation for such an event and a further 6% of the at risk population have been operated on 3 months into the second year of follow-up. Interestingly, the only factor to predict crossover from observation to operation was the degree of protrusion of the hernia. Factors such as the duration the hernia was present, whether the hernia was direct or indirect, the side of the hernia, and age of the patient had no effect. However, these data should be interpreted cautiously as the study was not designed to look at predictors of crossover.

In a larger study from the United States, Fitzgibbons et al enrolled 720 men from 5 North American centers into either watchful waiting (364 men) or surgery (356 men) and followed them to a minimum of 2 years after randomisation[159]. He reported primary outcomes at 2 years for watchful waiting vs. surgical repair: pain limiting activities (5.1% vs. 2.2%); Physical component score of the SF-36(improvement over baseline, 0.29 points vs. 0.13 points), yet none of these differences were statistically significant. He reported a 23% cross over rate to surgery for patients who were assigned to watchful waiting (this rose further to almost a third of patients by 4.5 years time).

The as-treated analysis was not substantially different from the intention-to-treat analysis except for the fact that patients who crossed over reported a much improved Physical Component Score. Multivariate analyses found no relation between the duration until hernia repair and operative time, the incidence of complications, long-term pain, or functional status. Operation was remarkably effective in improving pain and the ability to undertake activities, although both intention-to-treat groups improved somewhat during the course of the study.

The lower crossover rate 23% at 2 years vs. 28.75% at 574 days (in our study) could be explained by the fact that 40% of the patients enrolled in Fitzgibbons study only had a hernia on impulse, and the inclusion of such patients would dilute the results (especially the quoted 1.8 per 1000 risk of incarceration [162]).

With the above results Fitzgibbons concluded that watchful waiting is an acceptable option for men with an asymptomatic hernia, to this we would state that by observing these patient we are only delaying the inevitable (as evident from the high cross over rate), and it would be most appropriate to operate on these patient electively given the improvement in the SF-36 figures these patients gave at 6 and 12 months following their repair in comparison to those that were observed. Patients assigned to watchful waiting who crossed over to receive surgical repair reported significantly larger improvement from baseline in Physical Component Score relative to patients receiving surgical repair as assigned (difference, 2.50; 95% confidence interval, 0.01 to 5.0; $P = .01$).

Also the reduction in perception of pain unpleasantness was significantly greater for patients receiving surgical repair than for those receiving watchful waiting (surgical repair, -6.2 mm vs. watchful waiting, -2.3 mm; difference, 3.9 mm; 95% confidence interval, 0.8 to 7.0 mm; $P = .01$). Patients also reported on their ability to perform a spectrum of everyday activities. In all categories of activities, intent-to-treat analyses indicated that patients receiving surgical repair showed significantly greater improvement than did watchful-waiting patients.

The reason Fitzgibbon's trial failed to demonstrate statistical significance could be the 40% patients having an occult hernia, and this could be the same reason why there were less acute hernias and less morbidity within the observation group in his trial.

The major drive to repair asymptomatic hernia has been the risk of acute presentation, Andrews et al noted that the longer the delay to operate the higher is the risk of a bowel resection with a higher mortality rate (7.3% vs. 37%) [13]. Hair et al had a similar observation that the probability of an inguinal hernia becoming irreducible increased with time from 6.5% at 12 months to 30% at 10 years [26], and the cumulative probability of a patient presenting with pain increased with time to almost 90% at 10 years. And of the 61

patients that had their hernias for 5 years or longer before presentation, 38 (62%) had pain and in 13 (21%) the hernia had become irreducible.

Figures from the acute hernia study from our institution [140], demonstrated that during the 3 year study period 50% (46) of patients presenting acutely with an abdominal wall hernia had a previous medical assessment either as an acute admission (12 patients), at a surgical clinic (22 patients) or by a General Practitioner (12 patients). Eighteen had been declared unfit for operation at that assessment and therefore were not offered surgery, but on acute admission 14 of these patients had an operation while the remainder 4 were treated conservatively, indicating a room for improvement in the management of this group of patients.

In the asymptomatic hernia trial we had three serious adverse events recorded, all in the observation group of our trial: one patient had an acute hernia that needed to be reduced in another hospital, he was then operated upon on an urgent elective list in our hospital, one had a postoperative stroke, and one had a myocardial infarction and died postoperatively, all three had their operations on an urgent elective basis for pain.

In contrast serious morbidity and mortality are rare after elective hernia repair, even for elderly patients. The Danish hernia Data base quoted 0.48% as the 30-day mortality for elective patients over 60 years of age, whereas that for patients over 70 years was 0.32% for the corresponding Swedish Hernia Register[139,141]. More interestingly these figures are lower than the standardized mortality rate for individuals of the same age in the Swedish population as a whole. In this context, it is clear from review of the patients' case records in our study that had a serious postoperative event, both patients had serious cardiovascular comorbid illnesses which had deteriorated significantly in the period under observation and had they been operated on at presentation then the morbidity and subsequent mortality could have been avoided.

Advancements made in anaesthesia, surgical technique and perioperative care have made it safer to operate on high-risk patients, resulting in a lower morbidity and mortality. But despite these advancements surgeons are still reluctant to operate on high-risk patients, resulting in higher mortality rates when these patients turn up with an acute hernia requiring an emergency repair.

In a prospective nationwide study from Denmark, 7% of patients with an acute presentation died within 30 days of operation[139]. This high mortality occurs mostly because of severe comorbid illness with only a small subset having strangulated bowel [71]. And while there are a number of reasons for this, a significant contribution is made by clinicians turning high-risk patients down for elective operation in the first instance[14].
In another study by Gunnarsson et al looking at 146 consecutive hernia repairs in patients over the age of 75 the conclusion was that emergency operations were more common in this age group and this was the single factor that impaired long term survival, the other findings were that elective repair improved the patients quality of life and had a low operative risk, making it a worthwhile option for these patients [163].

Chronic post operative pain has been the main reason for clinicians to advocate a watchful waiting policy in the management of asymptomatic groin hernias. But Franneby et al demonstrated that a high level of preoperative pain indicated an increased risk of long-term pain [2], as reported also by Poobalan et al [35] and Courtney et al[43]. This might suggest that the hernia disease was already complicated prior to surgery in some patients; stretching, entrapment, and/or inflammation of local nerves are conceivable mechanisms, but psychologic susceptibility or increased pain sensitivity may also play a role. Moreover, the pain prior to the operation may also have originated from other conditions than the hernia, and will then persist after the operation. A third possibility is that interindividual variations in the manner of communicating subjective feelings may have affected the observed relationship. A general inclination to report pain and other feelings in an exaggerated way will most likely persist both before and after the operation and so will a propensity for being stoical. However, a cautious interpretation of these results is needed since the answer to the question of preoperative pain is the patient's recollection of the pain level.

The complexity of inguinal pain is underlined by the fact that a substantial proportion of patients also reported pain from the non treated contralateral groin. Randomized intervention studies are required to answer the question whether special preoperative investigations and/or tailored management, for instance specially adapted analgesia and

anesthesia or particularly atraumatic surgical techniques, may diminish the risk of long-term pain among patients with atypically high preoperative pain levels.

Finally one might assume from looking at the cost figures that operating on patients with asymptomatic groin hernias might not appear cost-effective within the follow-up period of this study, but the time trends in the results all suggest that, with longer follow-up, it would become increasingly cost-effective. These include a growing number of patients in the observation group requiring operation, thereby reducing the cost difference and the cost of managing serious complications rising over time. For example, the average health services cost per patient of a stroke as occurred in the observation group in this trial have been calculated to be £15,306 over 5 years[51]. This rises to £29,405 if the costs of informal care are included and £57,235 if these costs are based on home help rates rather than at the minimum wage, also the potential costs of a regular clinic follow up program have not been addressed, for if patients in the observation arm were to continue clinic review, the costs of clinical attendances might outweigh those of a hernia repair as well. The Fitzgibbons trial [159] similarly demonstrated an increased cost of £913.2 for patients with surgery; however, it determined that the cost per quality-adjusted life year gained from assignment to the surgical treatment group was £28.7. This cost is generally considered a reasonable cutoff for a publicly funded medical procedure; hence, both watchful waiting and surgery appear to be equally cost-effective measures from an economic standpoint [164].

CONCLUSION

It is clear from our trial that repairing an asymptomatic inguinal hernia improved long term pain, general well being, and might have helped reduce serious morbidity and unnecessary mortality.

We also acknowledge that a larger trial has concluded that a strategy of watchful waiting is a safe and acceptable option for men with asymptomatic or minimally symptomatic inguinal hernias.

Therefore we conclude that longer follow up of these patients is required in order to clarify whether watchful waiting is a safe approach or is it better to operate on these patients once a hernia is identified.

It is also of the utmost importance that an optimum basis of repair is established when operating on patients with groin hernia in order to minimize the incidence of post operative chronic pain. Furthermore, careful steps to control pain among younger patients and patients with a high level of preoperative pain are important potential fields of improvement and research. One obvious step that is necessary to make improvement possible regarding the endpoint long-term pain is to include evaluation of pain after some years in quality assurance systems for hernia surgery.

The main consideration for future research should include the pathogenesis and treatment of chronic post-herniorrhaphy pain and the role of patient-related factors versus surgery-related factors. Randomized intervention studies are required to answer the question whether special preoperative investigations and/or tailored management, for instance specially adapted analgesia and anesthesia or particularly atraumatic surgical techniques, may diminish the risk of long-term pain among patients with atypically high preoperative pain levels.

Finally the question whether a strategy of operating on patients with an asymptomatic hernia produces sufficient health gain to justify additional health care costs, is one for future trials to answer.

APPENDIX

1. ACUTE HERNIA STUDY PERFORMA
2. INTESTINAL OBSTRUCTION STUDY PERFORMA
3. FORMS AND QUESTIONNAIRE SENT TO PATIENTS IN THE ASYMPTOMATIC HERNIA TRIAL:

- **Consent form**
- **Information sheath**
- **Patient Advice card**
- **Randomization form**
- **Baseline data form**
- **Visual Analogue Score (VAS)**
- **SF-36**
- **BARTEL Index**
- **IADL form**
- **Study withdrawal form**

ACUTE HERNIA STUDY

NAME:

UNIT NO

D.O.B

CONSULTANT: _____

ADMISSION: _____DISCHARGE:_____

PRESENTATION

PAIN ☐

INCARCERATION ☐

STRANGULATION ☐

OTHER ☐

INCIDENTAL ☐

COMORBIDITIES

COAD ☐

MI / ANGINA ☐

HYPERTENSION ☐

DM ☐

ASA ☐

DURATION OF SYMPTOMS_____ PRIMARY/RECURRENT

TYPE OF HERNIA:

INGUINAL ☐

FEMORAL ☐

EPIGASTRIC ☐

PARAUMBILICAL ☐

INCISIONAL ☐

OTHER ☐

DURATION OF HERNIA:_____

PREVIOUS ADMISSION: Y ☐

N ☐

DETAILS PREV ADMISSION:

.....

.....

SIDE OF HERNIA **RIGHT** ☐ **LEFT** ☐

HERNIA SYMPTOMS:

NONE ☐

PAIN ☐

GI UPSET ☐

OBSTRUCT. ☐

STRANG. ☐

HERNIA FOLLOW UP:

PREV UNAWARE ☐

IGNORED ☐

SEEN BY GP ☐

SEEN SOPD ☐ ----------

PREV REPAIR ☐ ----------

OTHER ☐ ----------

TREATMENT THIS ADMISSION:

CONSERVATIVE ☐

OPERATION ☐

OTHER ☐ _____

OPERATION DETAILS:

APPROACH _____

STRAN. BOWEL ☐

STRAN. OMENT ☐

BOWEL RESECT ☐

MESH ☐

OTHER ☐ _____

POST OPERATIVE COMPLICATIONS:

NONE ☐

CHEST INFECTION ☐

WOUND INFECTION ☐

UTI ☐

Acute Intestinal obstruction prospective Study

Demographics

Name

D.O.B

Hospital no.

Sex M ☐ F ☐

Date of admission ☐

Date of discharge ☐

Consultant in charge ☐

Presentation

Pain ☐

N. & V. ☐

Abd. Distension ☐

Constipation ☐

Duration of symptoms ☐

Working Diagnosis

Adhesion obstruction ☐ Hernia obstruction ☐

Malignant obstruction ☐

Miscellaneous ☐

Radiological investigations

Plain abd. Film ☐ Findings ☐

Contrast study ☐ Findings ☐

Previous operation details

Date of Surgery

Type of Surgery

Type of Incision

Post operative complications following the 1st operation

None ☐ Wound infection ☐ Anastomotic leak ☐

Co morbidities

None ☐ DM ☐ Hypertension ☐ COPD ☐

ASA ☐

Management for this admission

Conservative ☐

Drip & suck ☐ Gastrograffin ☐

Surgery ☐

Findings at Surgery

Type of adhesions on Laparotomy

Single band ☐
1-2 Adhesions ☐
Diffuse adhesions ☐

Dead bowel

Yes ☐
No ☐

Final Diagnosis at discharge

FORM OF CONSENT FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Title of Project : Should we operate on patients with an asymptomatic inguinal hernia?
A randomised controlled clinical trial.

By signing this form you give consent to your participation in the project whose title is at the top of this page. You should have been given a complete explanation of the project to your satisfaction and have been given the opportunity to ask questions. You should have been given a copy of the patient information sheet approved by the West Ethics Committee to read and to keep. Even though you have agreed to take part in the research procedures you may withdraw this consent at any time without the need to explain why and without any prejudice to your care.

Consent:

I,.....(PRINT)

of.....

give my consent to the research procedures above, the nature, purpose and possible consequences of which have been described to me

by.....

Patient's signature.....Date.....

Doctor's signature.....

INFORMATION SHEET FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Brief Title of Project

Should we operate on patients with an asymptomatic inguinal hernia? A randomised controlled clinical trial.

Your general practitioner has referred you to this hospital because you have developed an inguinal hernia (rupture). Often the best course of action is to have it repaired, this is certainly true if you have a large painful hernia. Some surgeons believe that an operation on a small, painless and easily reducible hernia (one that 'disappears' when you lie down or gently push it back into place) may be unnecessary. This is supported by the fact that many people with small, painless easily reducible hernias often have them for years without causing any trouble.

We would like to invite you to participate in a study to determine if it is indeed necessary for patients to undergo an operation for a hernia that is not troublesome to them. Your surgeon has examined you and considers you equally suitable for having your hernia repaired or undergoing a period of observation. The most common complication of an operation is a collection of blood underneath your scar while that of no treatment is likely to be pain at the hernia site. Other complications of an operation include the development of a wound infection, difficulty in passing urine or rarely the development of persistent pain at the wound site. The most serious complication of no treatment is likely to be the development of strangulation which occurs in about 1 in every 400 patients with an inguinal hernia.

If you agree to participate in this study you will be allocated to either an observation group or to undergo an operation to repair the hernia. Allocation will be carried out in a random fashion (like the toss of a coin) by a telephone call to the Robertson Centre of Biostatistics at Glasgow University. If you are allocated "an operation" you will undergo a local or general anaesthetic hernia repair as a day case procedure or overnight stay where appropriate. All patients will be seen at a specialist hernia clinic six months after their initial hospital visit and then on an annual basis. You will be given a card detailing symptoms for which you should contact your surgeon and a contact number will be issued that will allow you direct access to a hernia clinic for immediate assessment for any new symptom or complication. **The contact person will be Mr P Duffy, Research Centre, Western Infirmary, (Tel No: 0141 211 2806.)**

In order to determine any effect surgery or observation has we would like you to complete a general health questionnaire, complete a pain scale and to perform braking reaction times on a car simulator.

- The pain scale involves placing a cross on a 10cm line that ranges from no pain to worst pain imaginable to indicate the level of discomfort caused by the hernia upon rest and movement.

- To perform the braking reaction times the patient presses a foot brake when the computer screen changes colour. The hand reaction times are also measured whereby the patient holds down a button located on the steering wheel and then strikes a centrally located horn when the computer screen changes colour.

These tests and general health questionnaires require to be completed at your first hospital consultation and then after 6 months, 1 year and annually thereafter. The size of the hernia will be measured at these time points for patients allocated to the observation group.

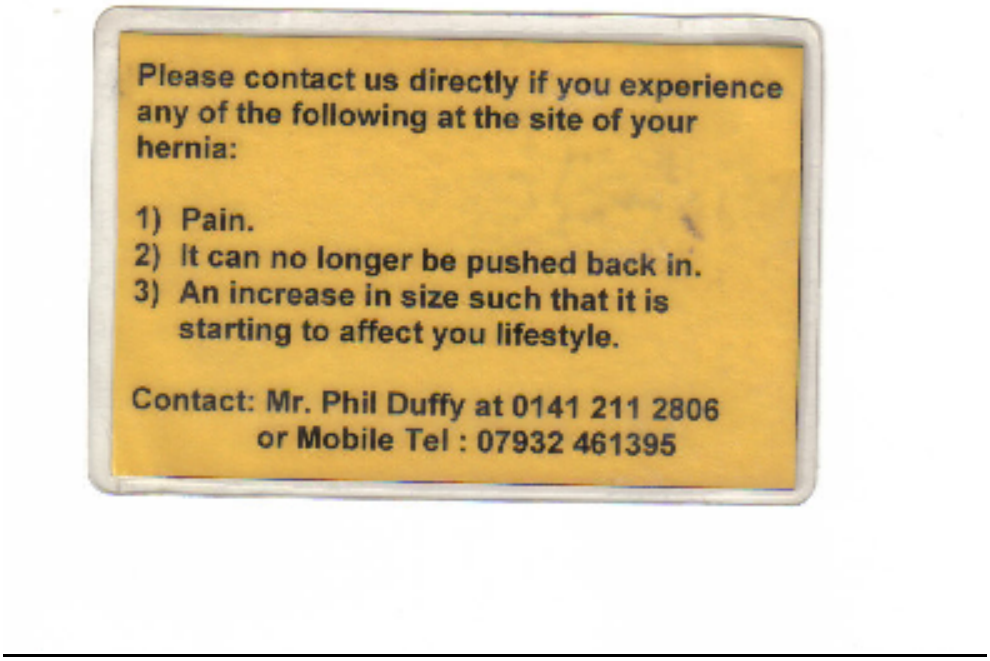
It should be noted that your participation in this study may not be of direct benefit to you, but could help in the development of treatment for the benefit of future patients.

If you do not wish to participate in this study, or wish to withdraw at any time after commencing the trial, your care will in no way be affected.

If you wish to take part in this study, your General Practitioner will be advised of your participation and the clinical management that you will undergo.

If you have any questions concerning the study please contact Mr P Duffy, Research Centre, Western Infirmary. 0141 211 2806.

Card handed to patients participating in the asymptomatic inguinal hernia trial



SCOTTISH OFFICE
ASYMPTOMATIC HERNIA STUDY

FAX Randomisation Form (FRF)

Version 1.0

SECTION A

Investigator Details

Hospital _____

Consultant _____

Your FAX No. for return ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Date of Request ☐☐/☐☐/☐☐☐☐ (D D M M Y Y Y Y)

SECTION B

Patient Details

Patient Date of Birth ☐☐/☐☐/☐☐☐☐ (D D M M Y Y Y Y)

Patient Initials ☐☐☐☐

Requested by: _____ ☐☐/☐☐/☐☐☐☐ (D D M M Y Y Y Y)
Signature

SECTION C

Allocation Details

Study Number Allocated ☐☐☐☐

Intervention Allocated
(Surgery or Observation) _____

_____ ☐☐/☐☐/☐☐☐☐ (D D M M Y Y Y Y)
RCB Randomisation Operator

SECTION D

Intervention received

Signatures

_____ ☐☐/☐☐/☐☐☐☐ (D D M M Y Y Y Y)
Investigator

Please FAX to 0141 357 4694 at the Study Data Centre, Robertson Centre for Biostatistics, Boyd Orr Building, University of Glasgow, Glasgow, G12 8QQ.

SCOTTISH OFFICE

Baseline

ASYMPTOMATIC HERNIA STUDY

Version 1.0

Patient Initials | Centre | Visit No. | Date of Initial Visit (D D / M M / Y Y Y Y)

A. PATIENT DETAILS

1. Hospital Number:
2. Surname: _____
   Forename: _____
3. Date of birth (D D / M M / Y Y Y Y)

B. EXCLUSION CRITERIA

Answer YES or NO to the following:

	Yes	No
1. Medically Unfit	1	2
2. Irreducible hernia	1	2

(Answer must be **NO** to **both** of these for subject to be included.)

C. INCLUSION CRITERIA

Answer YES or NO to the following:

	Yes	No
1. Age ≥60	1	2
2. Spontaneous reduction of hernia on lying down or on minimal applied pressure	1	2
3. Agrees to randomisation	1	2
2. Consent obtained	1	2

(Answer must be **YES** to **ALL** of these questions for subject to be included.)

If patient eligible and has given consent, phone the Central Telephone Randomisation Line to randomise, and write allocated study number below:

Study Number

D. DETAILS OF HERNIA

	Yes	No
1. Is hernia Primary?	1	2
or Recurrent?	1	2

2. Duration of present hernia — Years / Months

3. Side of present hernia? Left 1 | Right 2 | Bilateral 3

4. Size of present hernia - degree of protusion when standing: cms

5. Size of defect:
   Vertical cms
   Transverse cms

6. Is hernia:

	Yes	No
Direct	1	2
Indirect	1	2
Inguinoscrotal	1	2

Investigators Name | Investigators Signature | Date

SCOTTISH OFFICE

ASYMPTOMATIC HERNIA STUDY

Version 1.0

Patient Initials	Centre	Visit No.	Date of Visit
			D D / M M / Y Y Y Y

Thank you for completing this booklet. Please follow the instructions.

Confidentiality: Your name and address do not appear anywhere on this booklet. The information that you give will not be used in any way that could identify you personally.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

GENERAL HEALTH

*For questions 1 and 2, please **circle the number** that best describes **your health**.*

	Excellent	Very good	Good	Fair	Poor
1. In general, would you say your health is:	1	2	3	4	5

	Much better	Somewhat better	About the same	Somewhat worse	Much worse
2. **Compared to one year ago**, how would you rate your health in general **now**?	1	2	3	4	5

HEALTH AND DAILY ACTIVITIES

3. The following questions are about activities you might do in a typical day. Does **your health** limit you in these activities? If so, how much? ***Please circle one number on each line.***

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) **Vigorous activites**, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
b) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	1	2	3
c) Lifting or carrying groceries.	1	2	3
d) Climbing **several** flights of stairs	1	2	3
e) Climbing **one** flight of stairs.	1	2	3
f) Bending, kneeling or stooping.	1	2	3
g) Walking **more than a mile**.	1	2	3
h) Walking **half a mile**.	1	2	3
i) Walking **100 yards**.	1	2	3
j) Bathing or dressing yourself.	1	2	3

4. During the **past 4 weeks**, have you had any of the following problems with your work or other daily activities **as a result of your physical health**?

Please **circle 1** *for* **Yes** *or* **2** *for* **No** *on each line.*	Yes	No
a) Cut down on the **amount of time** you spend on work or other activities	1	2
b) **Accomplished less** than you would have liked.	1	2
c) Were limited in the **kind** of work or other activities.	1	2
d) Had difficulty performing the work or other activities (for example, it took extra effort).	1	2

SCOTTISH OFFICE

PF36, Page 2

ASYMPTOMATIC HERNIA STUDY

Version 1.0

Patient Initials | Centre | Visit No. | Date of Visit (D D M M Y Y Y Y)

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

Please **circle 1** *for* **Yes** *or* **2** *for* **No** *on each line.*

	Yes	No
a) Cut down on the **amount of time** you spend on work or other activities	1	2
b) **Accomplished less** than you would have liked.	1	2
c) Did not do work or other activities as **carefully** as usual.	1	2

For questions 6,7 & 8, please **circle the number** *that* **best** *describes* **you** *and* **your health**.

6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or other groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
1	2	3	4	5

7. How much bodily pain have you had over the **past 4 weeks**?

None	Very Mild	Mild	Moderate	Severe	Very Severe
1	2	3	4	5	6

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
1	2	3	4	5

YOUR FEELINGS

9. The following questions are about how you feel and how things have been with you **during the last month**. For each question, please **circle the number** that **best** describes the way you have been feeling.

Make sure that you circle one number on each line.

How much time during **the past month**:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a) Did you feel full of life?	1	2	3	4	5	6
b) Have you been a very nervous person?	1	2	3	4	5	6
c) Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d) Have you felt calm and peaceful?	1	2	3	4	5	6
e) Did you have a lot of energy?	1	2	3	4	5	6
f) Have you felt downhearted and low?	1	2	3	4	5	6
g) Did you feel worn out?	1	2	3	4	5	6
h) Have you been a happy person?	1	2	3	4	5	6
i) Did you feel tired?	1	2	3	4	5	6
j) Has your health limited your social activities (like visiting friends or close relatives)?	1	2	3	4	5	6

ASYMPTOMATIC HERNIA STUDY

Version 1.0

Patient Initials	Centre	Visit No.	Date of Visit
			D D / M M / Y Y Y Y

HEALTH GENERAL

10. Please choose the answer that **best** describes how **true** or **false** each of the following statements is for you.

*Please **circle one number** on **each** line.*

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
a) I seem to get ill more easily than other people.	1	2	3	4	5
b) I am as healthy as anyone I know.	1	2	3	4	5
c) I expect my health to get worse.	1	2	3	4	5
d) My health is excellent.	1	2	3	4	5

Investigators Name *Investigators Signature* *Date*

SCOTTISH OFFICE

VAS

ASYMPTOMATIC HERNIA STUDY

Version 1.0

Patient Initials	Centre	Visit No.	Date of Visit
			D D / M M / Y Y Y Y

Please put a vertical (straight up and down) line through the scale from 0-100 corresponding to how much pain you have from your hernia TODAY. The scale goes from 0 (no pain) to 100 (worst pain imaginable).

1. On the scale below, please mark the amount of pain you have at ***REST*** today

0 _____ 100

No pain — Worst pain imaginable

For office Use Only

2. On the scale below, please mark the amount of pain you have ***ON MOVING*** today

0 _____ 100

No pain — Worst pain imaginable

For office Use Only

3. Are you taking any medication for pain relief? Yes [1] No [2]

   If Yes, please specify

   Name _____ Dose _____

4. Has your hernia ever given you pain? Yes [1] No [2]

Once you have completed both scales please give this form and the SF36 Questionnaire to a member of staff to put into your study folder.

Thank you for completing this form.

Investigators Name	*Investigators Signature*	*Date*

SCOTTISH OFFICE

ASYMPTOMATIC HERNIA STUDY

Version 1.0

BARTEL

Patient Initials | Centre | Visit No. | Date of Visit (D D / M M / Y Y Y Y)

A. INFORMATION

Information from

- Subject/Client 1
- Relative or carer 2
- Nurse 3
- Therapist 4

B. INDEX

1. Bowels

- Continent 2
- Occasional accidents 1
- Incontinent 0

2. Bladder

- Continent 2
- Occasional accidents 1
- Incontinent 0

3. Feeding

- Independent 2
- Needs some help 1
- Dependent 0

4. Grooming (face/hair/teeth/shaving)

- Independent 1
- Needs some help 0

5. Dressing

- Independent 2
- Can do half 1
- Dependent 0

6. Transfer

- Independent 3
- Minor help 2
- Major help (can sit) 1
- Unable 0

7. Toilet Use

- Independent 2
- Needs some help 1
- Dependent 0

8. Walking

- Independent 3
- Walks with help 2
- Wheelchair independent 1
- Unable 0

9. Stairs

- Independent 2
- Needs help 1
- Unable 0

10. Bathing

- Independent 1
- Dependent 0

TOTAL SCORE ☐☐

Investigators Name | *Investigators Signature* | *Date*

SCOTTISH OFFICE

ASYMPTOMATIC HERNIA STUDY

IADL

Version 1.0

Patient Initials	Centre	Visit No.	Date of Visit
			D D / M M / Y Y Y Y

1. Can you use the telephone?

- Without assistance [2]
- With assistance [1]
- Unable [0]

2. Can you get to places out of walking distance?

- Without assistance [2]
- With assistance [1]
- Unable [0]

3. Can you go shopping (groceries/clothes)?

- Without assistance [2]
- With assistance [1]
- Unable [0]

4. Can you prepare your own meals?

- Without assistance [2]
- With assistance [1]
- Unable [0]

5. Can you do your own housework?

- Without assistance [2]
- With assistance [1]
- Unable [0]

6. Can you take your own medicine?

- Without assistance [2]
- With assistance [1]
- Unable [0]

7. Can you handle your own money?

- Without assistance [2]
- With assistance [1]
- Unable [0]

TOTAL SCORE [ ]

Investigators Name	*Investigators Signature*	*Date*

SCOTTISH OFFICE
ASYMPTOMATIC HERNIA STUDY

Study Withdrawal Form

Version 2.0

Patient Initials	Centre	Visit No.	Date of Visit
[01]	[02]	[03]	D D M M Y Y Y Y [05]

A. REASON FOR WITHDRAWAL

1. Primary reason for permanent withdrawal:

- Non-fatal adverse event [1]
- Subject died [2]
- Protocol violator [3]
  - Specify _____ [09]
- Subject refusal / non-attendance [4]
- End of study [5]
- Other reason [6] [08]
  - Specify _____ [07]

2. Date of last visit attended: D D M M Y Y Y Y [06]

B. WITHDRAWAL DUE TO ADVERSE EVENT

Complete this section only if options 1 or 2 circled in Section A

1. If non-fatal event, who recommended withdrawal?

- General practitioner [1]
- Other medical practitioner [2]
- Patient initiated [3]
- Other [4] [10]
  - Specify _____
  - _____ [11]

C. ADMIN CENTRE SECTION

This section is for Admin Centre use only.

Was withdrawal due to a serious adverse event?

Yes [1] No [2] [11]

If No, state relationship to trial therapy:

- Certain [1]
- Probable [2]
- Possible [3]
- Unrelated [4]
- Unassessable [5] [12]

D. SURGERY FOR HERNIA POST-RANDOMISATION

1. Type of surgery

_____ [13]

2. Date of surgery D D M M Y Y Y Y [14]

Subject ID [15]

Investigators Name	Investigators Signature	Date
_____	_____	_____

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