“Open anatomical repair v/s laparoscopic repair of umbilical hernia using no. 1 Polydioxanone suture (PDS), Randomized Control Trial”

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ACCEPTANCE LETTER

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LIST OF ABBREVIATIONS USED

UH	**:**	Umbilical hernia
PDS	**:**	Polydioxanone suture
SNOSE	**:**	Serially Numbered Opaque Sealed Envelope
POSAS	**:**	The Patient and Observer Scar Assessment Scale
RCT	**:**	Randomized Control Trial
Lap	**:**	Laparoscopic

ABSTRACT

INTRODUCTION:

Umbilical hernia can be described as an abnormal protrusion of a viscus, or part of a viscus through a congenital or acquired defect via umbilical cicatrix. Almost, 90% of umbilical hernia in adults are acquired. Only about 10% of adult umbilical hernia are found since childhood. Umbilical hernia has an incidence of 2% in adult population. The observed male: female ratio is 1:3. Development of umbilical hernia occurs as a result of possible weakness either through exit site of umbilical vessels or weakened umbilical fascia (Richet's fascia). Contents of umbilical hernia could be preperitoneal pad of fat, omentum, and intestine (small or large). Treatment options range from observation to surgery. Surgery may be performed open or laparoscopically. Narrow neck in umbilical hernia as compared to inguinal hernia sac explains pathogenesis of strangulation and incarceration. Hence, surgical repair even for small hernias is advisable. Use of mesh prophylactically in these small hernia's may be an overtreatment and may not be cost effective. Few studies are available comparing the open versus laparoscopic suture umbilical repair (mostly retrospective). Present study is a prospective randomised control trial comparing Open anatomical repair v/s Laparoscopic suture repair of umbilical hernia.

OBJECTIVE:

To find out effectiveness of open anatomical repair v/s laparoscopic suture repair of umbilical hernia with no.1 PDS on following points:

1) Intra operative time

2) Duration of hospital stay, post-operative pain, cosmesis, Complications –seroma, infection, recurrence (short term-6months).

RESULTS:

A total sixty patients with umbilical hernia size less than 2cms were included in the study. Thirty patients underwent laparoscopic anatomical repair and thirty patients underwent open anatomical repair with No. 1 PDS. The two groups were almost similar with respect to age and sex distribution. There was significant reduction in intra-operative time and post-operative pain in the patients who underwent laparoscopic repair. There was also significant better cosmetic outcome in laparoscopic group as compare to open. There was lower incidence of postoperative complications (seroma, wound infection and recurrence) in laparoscopic group as compared to open but this was not statistically significant.

CONCLUSION:

Laparoscopic suture repair of umbilical hernia <2cm is technically feasible . It provides clear advantages over open repair such as reduced postoperative pain, better cosmetic outcome and shorter operating time when compared to open repair.

Key words:

Laparoscopic, Minimal access, Umbilical hernia, Anatomical repair

CONTENTS

S.NO	TOPIC	PAGE NO
1	INTRODUCTION	1-5
2	OBJECTIVES	6
3	REVIEW OF LITERATURE	7-15
4	MATERIALS AND METHODS	16-32
5	RESULTS	33-41
6	DISCUSSION	42-44
7	CONCLUSION	45
8	SUMMARY	46
9	BIBLIOGRAPHY	47-49
10	ANNEXURES	
	ANNEXURE I ETHICAL CLEARANCE CERTIFICATE	50
	ANNEXURES I: CONSENT FORM	51-56
	ANNEXURES II: PROFORMA	57-62
	ANNEXURES III: KEY TO MASTER CHART	63
	ANNEXURES IV: MASTER CHART	64-65

LIST OF FIGURES

S.NO	DESCRIPTION	PAGE NO
1	Umbilicus (a: in the foetus, b: view from within peritoneal cavity)	9
2	Regions of abdomen	10
3	Position of the patient (open anatomical repair)	18
4	Preoperative picture showing umbilical hernia.	18
5	Incision in open anatomical repair.	19
6	Operative pictures of open anatomical repair.	20
7	Flap necrosis after open umbilical hernia repair.	23
8	Position for laparoscopic hernia repair	24
9	Laparoscopic setup	25

LIST OF FIGURES

S.NO	DESCRIPTION	PAGE NO
10	Veress needle	26
11	Insertion of verees.	26
12	Telescopes	27
13	5mm port	27
14	Light source	28
15	Camera	28
16	Recorder	28
17	Laparoscopic port placement	29
18	Operative steps in laparoscopic surgery	30
19	Operative steps in laparoscopic surgery	31

LIST OF GRAPHS

S.NO	DESCRIPTION	PAGE NO
1	Pie chart showing sex distribution of patients	33
2	Pie chart showing distribution of patients according to BMI	34
3	Graph showing recurrence statistics according to BMI	35
4	Graph showing pain statistics at different intervals in both groups	36

LIST OF TABLES

S.NO	DESCRIPTION	PAGE NO
1	Sex distribution of cases	33
2	Recurrence as per sex distribution	33
3	Distribution of cases according to BMI	34
4	Recurrence statistics according to BMI	35
5	Intraoperative time	36
6	Postoperative pain	36
7	Duration of stay in hospital	37
8	Postoperative complications	37
9	Postoperative complications according to BMI	37
10	Postoperative cosmesis (using POSAS scale: observer and patient score)	39
11	Statistical analysis	41

INTRODUCTION

Umbilical hernia is one of the common hernia seen in surgical OPD. With every passing year surgical interventions are on the rise[1][2]. Umbilical hernia can be described as an abnormal protrusion of a viscus, or part of a viscus through a congenital or acquired defect via umbilical cicatrix.

AETIOLOGY: Almost, 90% of umbilical hernia in adults are acquired [3].Only about 10% of adult umbilical hernia are found since childhood. Umbilical hernia is predominant in females. Population affected have high intra-abdominal pressure as in ascites, obesity, during pregnancy or chronic distention.

EPIDEMIOLOGY: Umbilical hernia has an incidence of 2% in adult population; more common in obese multiparous females. As much as 20% of patients with ascites cirrhotic condition developed umbilical hernia[4]. The observed male: female ratio is 1:3[5][6][7].

PATHOPHYSIOLOGY: Development of umbilical herniaoccurs as a result of possible weakness either through exit site of umbilical vessels or weakened umbilical fascia (Richet's fascia) [8]. The common causes include conditions leading to increased intra-abdominal pressure such as during pregnancy, ascites, overstretching of muscle fibresand connective tissue weakness of anterior abdominal wall [5][9].

In cirrhotic patients, umbilical hernia develops mainly as a result of ascites which causes raised abdominal pressure, umbilical vein dilatation or weakness of tissue due to poor nutrition[10]. Contents of umbilical hernia could be preperitonealpad of fat, omentum, and intestine (small or large). Narrow neck in umbilical hernia as compared to inguinal hernia sac explains pathogenesis of

strangulation and incarceration.[11]. Hence, surgical repair even for small hernias is advisable.

HISTORY AND EXAMINATION: Most common presentation is protrusion or bulge from the umbilicus[12]. Possible symptoms include gastrointestinal discomfort and pain. Small hernias are often asymptomatic, large may become tender and complicated with time.

One of the common complications is strangulation which creates *umbilical bulge with tenderness and change in skin colour*. These signs can be seen when the sac contains a loop of intestine[13]. The probability of incarceration ranges from 2.8% - 4.8% at 3 months and 2 years, respectively. This might be possibly due to weakened abdominal wall and decreased pressure on the sac and its contents[14].

EVALUATION: Physical examination can diagnose an umbilical hernia. Examination can reveal the content of the hernia and the defect size. In some cases, ultrasonography or/and Computed tomography may be needed to confirm the content and to look for bowel viability respectively. This can also be used in obese patients where clinical diagnosis is difficult[15].

TREATMENT AND MANAGEMENT: Treatment may not be needed for asymptomatic cases, especially for small hernias. In case they enlarge, surgery may be required at a later stage. Such surgery can be performed either by open methods or laparoscopically[16].

Treatment options range from observation to surgery. Surgery may be performed open or laparoscopically.

i. Open primary anatomical repair

ii. Open repair with mesh repair

iii. Laparoscopic anatomical closure

iv. Laparoscopic mesh repair

Open primary anatomical repair:Can be done by many techniques like mayo's repair, simple interrupted or continuous suture with non-absorbable or delayed absorbable suture.

Advantages: Less infection as compared to mesh repair

Disadvantages: Recurrence, cosmesis. Overall complication rate: 6.8% [17].

Open repair with mesh:This technique is suitable for defects >2 cms, some of the surgeons also prefer to put mesh for smaller defects prophylactically.

Advantages: Low recurrence

Disadvantages: Prosthetic materials are known to have a high chance of wound and mesh complications. Hence, there is continuous research going on to identify optimal treatment for umbilical hernia. Also, patients demand for less morbidity has led surgeons to adopt laparoscopic approach. Overall complication rate: 26.9% [17].

Laparoscopic primary repair:

For defects of <2cms suture repair is still accepted. It can be done by intra-corporeal or suture passer technique either interrupted or continuous.

Advantages:Less postoperative pain, cosmetically better scar, less hospital stay, less chances of infection.

Disadvantages: Recurrence rate is dependent on surgeon's skill. Complication rate: 11% [17]

Laparoscopic mesh repair:Suitable for hernias >2cms, recurrent hernias.

Advantages: This technique is superior to open mesh in terms of infection rates, operative complications and postoperative pain.

Disadvantages: Laparoscopic mesh repair is costly procedure. Cost constraint limit the use of dual mesh repair in laparoscopy. Hence laparoscopic suturing can be considered for small hernias (size <2cm).

REFRENCE TO EARLIER WORK: A recently concluded meta-analysis of randomised controlled trials indicated significant decrease in wound complication risks (such as seroma, hematoma, infection etc.) with laparoscopic repair. Such repair is not only technically feasible, but also safer and effective with good prognosis in comparison to open repairs. Laparoscopic repairs are related with decreased postoperative pain and complications, infection rate and analgesic need with early return to normal activities[4].

NEED FOR STUDY: An umbilical hernia tends to be related with high morbidity and mortality as well as higher risk of strangulation and incarceration and that need an emergency procedure.

Usually smaller umbilical hernias (<2cms) have been managed by open anatomical closure such as Mayo repair. Open repair for small umbilical hernias is still accepted however advancement in suturing techniques is required.

Technical aspect of proper suturing like the ‘rule of one’ has been described in laparotomy wound closure which decrease the incidence of hernia. It is postulated that applying similar principals for open and laparoscopic closure of <2cm umbilical hernia may decrease the recurrence rates, traditionally seen in open suture repairs. Use of mesh prophylactically in these small hernia’s may be an overtreatment and may not be cost effective. Few studiesare available comparing the open versus laparoscopic suture umbilical repair (mostly retrospective)[8][9][10]. Present study is a prospective randomised control trial comparing Open anatomical repair v/sLaparoscopic suture repair of umbilical hernia

OBJECTIVES

To find out effectiveness of open anatomical repair v/s laparoscopic suture repair of umbilical hernia with no.1 PDS on following points:

1) Intra operative time

2) Duration of hospital stay, post-operative pain, cosmesis, Complications –seroma, infection, recurrence (short term - 6months).

REVIEW OF LITERATURE

HISTORICAL REVIEW:

Arroyo et al., In a randomized controlled trial compared the outcomes of open mesh and suture repair of umbilical hernia. It was identified that rate of recurrences was significantly higher after suture repair compared to open mesh repair (11% vs. 1%; P = 0.0015). The incidences of complications such as haematoma, seroma and wound infection were similar in both groups[18].

Polat et al. compared the results of open mesh and suture repair of umbilical hernia in a randomized clinical trial and found no recurrence following mesh repair. The suture repairs reported 11% recurrences. The incidence of complications like wound infection, seroma and haematoma were identical inboth groups[19].

Carbajo et alcompared Lap ventral hernia repair and open repair through a prospective randomized study. They provided proof for significant advantages of laparoscopic over open repair. The study randomly assigned 60 patients for either laparoscopic repair or open surgery. These groups were similar for age, gender distribution, incisional hernia type or defect size. The study found significant shorterhospital stays and operating times with lap group. It also reported minimal complications and low recurrence rates in a mean follow-up period of 27 months[20].

Chari et al reported cases of open and laparoscopic repair (14 for each procedure). The study reported lower mean operating time for laparoscopic repair (124 minutes) compared to open repair (78 minutes). However, the postoperative infection rate was 7% with laparoscopic repair compared to 0% in open repair. Additionally, hospital stay was same in both groups[21].

De Maria et al reported 21 cases of laparoscopic procedures and 18 cases of open procedures. The study reported shorter hospital stay and less painful recovery with laparoscopic repair. The post-operative complications rate was found to be 57% in laparoscopic procedure compared to 72% in open procedure. Similarly, post-operative infection rate was more in open as compared to laparoscopic (33% vs 10%). Seroma rate was high in open repair compared to laparoscopic repair (50% vs19%). However, recurrence rate was 6% with laparoscopic repair at 24 months follow up[22].

Many published studiescomparing open with laparoscopic mesh repair (as described above) are available in public domain. Most of the studies are retrospective. A study to compare open with laparoscopic anatomical repair for small umbilical hernia's is not done before. Ours is a prospectiveRCTconducted to compare the open anatomical repair with laparoscopic suture repair of umbilical hernia.

EMBRYOLOGY OF UMBILICUS:

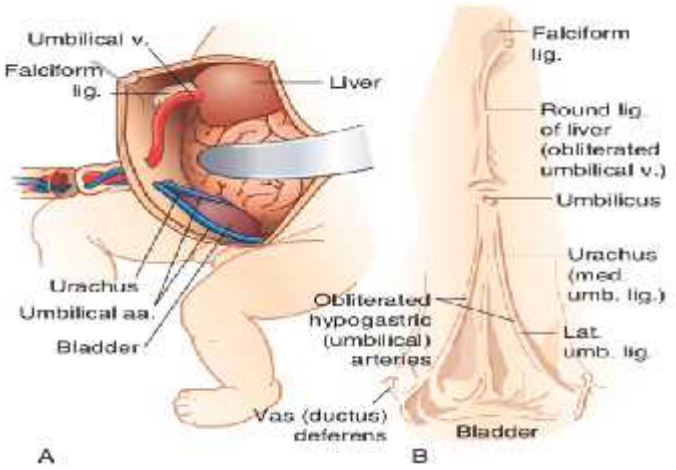
In the very early stages of foetal development the abdominal wall begins to form. It happens embryonic differentiation from the lateral plate of the embryonic mesoderm. During this phase, the embryo consists of 03 layers—*ectoderm; endoderm;* and *mesoderm.*

The mesoderm is divided into splanchnic and somatic layers. Of these, the splanchnic layer contributes in formation of the viscera. The somatic layer participates in abdominal wall development. By the 3rd week of foetal life, the fascial margins of the umbilical defect are formed, when 4 folds of the somatopleurae tend to fold inward.

Umbilical cord forms as a tubular structure. It consists of allantois, foetal blood vessels and omphalomesenteric duct. Body wall closes by the end of the 3rd month of gestation, excluding umbilical ring. As the alimentary tract quickly increases in length compared to coelomic cavity volume increase, lot of the gut projects through the umbilical ring to rest in the umbilical cord. The coelomic cavity expands by 10th week and the intestine returns to the peritoneal cavity. Thus,omphalomesenteric duct, allantoisand foetal blood vessels remain in shrunken umbilical ring. (fig no. 1). Umbilical malformations can occur, in case any of these processes are defective.

At birth, the umbilical blood vessels have obliterated, and the omphalomesenteric duct gradually reduced to ligaments which no longer communicates to intestine. This fibrous cord is attached to the umbilical ring on the inferior border with 02 obliterated umbilical arteries and remnants of the urachus. The ligament protects against herniation by covering the umbilical ring. However, any congenital disorders at umbilicus can cause potential weakness and herniation.

The umbilical ring is further supported by Richet's fascia. In case it is absent or partially covering the ring, causing weakness of the area.



<u>Figure no.1</u>. (a), in the foetus. (b) umbilicus view from within the peritoneal cavity

ANATOMY OF UMBILICUS:

The umbilicus indicates the site of entry of the umbilical cord in the foetus. In adults, it is located at the midpoint of anterior abdominal wall. The fibrous tissues make the umbilicus floor. The umbilicus also is a weak point in the abdominal wall that is susceptible to protrusion of viscus due to increased intraabdominal pressure[23][24][25].

REGIONS OF THE ABDOMEN:

For clinical purposes the abdomen is divided into nine quadrants by 2 sets of imaginary lines which are two vertical and two horizontal lines. Vertical lines are the midclavicular lines (right and left) and horizontal lines are upper transpyloric and lower intratubercular lines. Using these four lines, three central regions are defined from above downwards: epigastric, umbilical, and suprapubic or hypogastric regions. Similarly, there are three lateral regions on each side of the umbilicus: hypochondrial, lumbar and iliac regions [26] (fig no. 2).

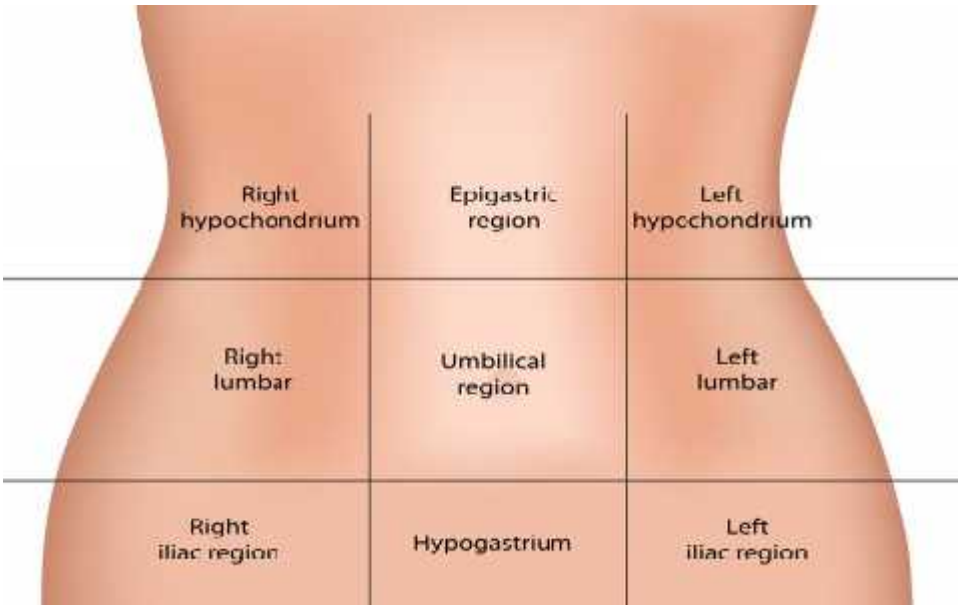


Figure no. 2: regions of the abdomen.

Umbilical malformations and hernias: Umbilical hernias are categorized into 03 forms: acquired umbilical hernia, infantile umbilical hernia and; omphalocele and gastroschisis.

Acquired Umbilical Hernia - Upper margin of the umbilicus is common site of herniation. Weakness of umbilical cicatrix causes closure of umbilical ring. This can be result of excessive abdominal wall stretching, in situations like vigorous labour, pregnancy or ascites. Acquired umbilical hernias generally do not resolve spontaneously rather increases in size gradually. Strangulation of herniated intestine or omentum can happen due to thick fibrous ring at the neck of hernia.

Infantile umbilical hernia –Sloughing of the stump of umbilical cord resultsinto this type of umbilical hernia. The infantile umbilical hernia is covered by skin. This hernia occurs as a result of weakness in adhesion between umbilical ring and umbilical cord's scarred remnants. Generally, this hernia appears at the upper margin of umbilical ring and are usually reducible.

Mostly within first 2 years of life, such hernias resolve, and any complications are very rare. Operative procedures are required for children still having hernia beyond 3 or 4 years of age.

Omphalocele - It is described as a funnel-shaped defect in the centre of abdomen.Visceral protrusion happens at umbilical cord base. This results from failure of the abdominal wall muscles to unite in the midline during foetal development. Umbilical vessels are pushed to one side. In some larger defects, the spleen and liver may remain within the cord, along with a portion of the intestine. These defects are not covered by skin. In 50-60% of infants born with an omphalocele, concurrent congenital anomalies of other organs are also seen.

Gastroschisis - It is a congenital defect of the abdominal wall where the umbilical membrane ruptures in utero. Here intestines herniate outside the abdominal cavity. Almost always, this defect is to the right side of the umbilical cord. Additionally, in gastroschisis, the intestine is not covered with amnion or skin. Concurrent congenital anomalies are seen in about 10% of cases.

PATHOGENESIS

Infantile Umbilical Hernia - Intestines herniate into the omphaloceleby 6^{th} week of intrauterine life, as the growth of intestines being very rapid compared to the foetus growth and the abdominal cavity. Leaving behind small space for umbilical artery and vein, rest of the umbilical ring closes by birth. With the ligation of the cord, the vessels undergo thrombosis and cause closure of ring by scar tissues. In case of larger ring or abnormal scar formation, protrusion of intraabdominal content can happen through the defect. Thus, increased umbilical hernia incidences are encountered in premature babies[27][28][29].

Umbilical Hernia in Adults - Anatomically, it occurs through a potential weakness in the lineaalba. Although, the precise aetiology is unclear, Mayo has provided a convincing hypothesis. The midlinestretches laterally with obesity as a result of a higher intra-abdominal volume. Midline is pulled downwards by subcutaneous fat. Thus, with midline being pulled downwards and laterally, the centre becomes weak causing umbilical hernia. Aponeurosis of all the oblique muscles decussate and forms the midline above the umbilics. While aponeurosis of all the oblique muscle fibres is in single planebelow the umbilicus. Triple decussation being stronger compared to single decussation, hernia tends to develop in weak single decussation. The hernia

may contain omentum, fat tissues and small intestine. As the neck is narrow, complications like strangulation and incarceration many become common[30].

CLINICAL FEATURES: These are most common abdominal wall defects noted in infants and children. There is swelling of umbilicus when the child cries, which is diagnostic of umbilical hernia. Most common presentation is flange or bulge from the umbilicus[12]. Gastrointestinal discomfort and pain are other symptoms that may possibly occur. Small hernias are often asymptomatic, large may become tender and irreducible. Strangulation is one of the frequent and common complication. This represents irreducible and tender umbilical bulge with changes in skin colour along with possible signs of intestinal obstruction[13].

DIAGNOSIS: Physical examination can diagnose an umbilical hernia. The size of the detect and content can be ascertained by clinical examination. USG can confirm if content is omentum or intestines. Computed tomography may be needed to evaluate viability of bowel. This can also be used in obese patients where clinical diagnosis is difficult[15].

MANAGEMENT:

Infantile Umbilical Hernia - Usually umbilical hernias of infancy and childhood slowly regresses as the child grows. The result of strapping, mere waiting for operative treatment are all the same. The recent concept in treatment is to wait and watch. Complications are rare. Surgery is reserved for hernias not involuted by six years with complications. Surgical correction consists of excision of hernia sac and correction of fascial defect by Mayo's repair with or without preserving the umbilical cicatrix.

Adult Umbilical Hernia - Treatment may not be needed for asymptotic cases, especially for small hernias. In case they enlarge, surgery may be required at a later stage. Such surgery can be performed as an open procedure or laparoscopically[16].

Treatment options being as follows:

i. Open primary anatomical repair (e.g. Mayo's repair)

ii. Open repair with mesh repair

iii. Laparoscopic anatomical closure

iv. Laparoscopic mesh repair

Open primary anatomical repair: can be done by many techniques like mayo's repair, simple interrupted or continuous suture with suture with non-absorbable or delayed absorbable suture.

Advantages: Less infection as compared to mesh repair

Disadvantages: Recurrence, cosmesis. Overall complication rate: 6.8%[17]

Open repair with mesh: this technique is suitable for defects >2 cms, some of the surgeons also prefer to put mesh for smaller defects prophylactically.

Advantages: Low recurrence

Disadvantages: Prosthetic materials are known to have a raised chance of wound infection and mesh complications. Hence, there is continuous research going on to identify optimal treatment for umbilical hernia. Also, patients demand for less

morbidity has led surgeons to adopt laparoscopic approach. Overall complication rate: 26.9% [17]

Laparoscopic primary repair:

<2cms suture repair is still accepted. It can be done by intra-corporeal or suture passer technique either interrupted or continuous.

Advantages: less postoperative pain, cosmetically better scar, less hospital stay, less chances of infection.

Disadvantages: Recurrence, surgeon's skill dependent. Complication rate: 11%.[17]

Laparoscopic mesh repair: suitable for hernias >3cms, recurrent hernias.

Advantages: This technique is superior to open mesh in terms of infection rates, operative complications and postoperative pain.

Disadvantages: Laparoscopic mesh repair is costly procedure. Cost constraint limit the use of Mesh repair in Laparoscopy. Hence laparoscopic suturing can be considered for small hernias (size <2cm).

METHODOLOGY

This study is a prospective comparative study conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, between January to December 2019 on 60 patients undergoing umbilical hernia repair.

Study design

It was a prospective double blinded RCT.

Study period and duration

The present study was carried out for a period of 01 year from January to December 2019.

Place

This study was done under the Department of General Surgery of a tertiary care teaching hospital attached to KAHER's Jawaharlal Nehru Medical College, Belagavi.

Source of Data

Patients with umbilical hernia undergoing repair were included in the study.

Sample size

The study sample was comprised of 60 patients.

Formula:

$n = 4pq/d^2$

where,

p= incidence of difficult laparoscopy in patients with high CRP

q= (100-p),

d= permissible error

Statistical analysis: Pearson's Chi Square test

Sampling procedure

Systematic Random Sampling

SELECTION CRITERIA

Inclusion criteria

- Written informed consent
- Patients aged 18 years and above.
- Umbilical hernia with defect size of <2cm (by ultrasonography)

Exclusion criteria

- Patients with obstructed or strangulated umbilical hernia
- Patients with recurrent umbilical hernia.

Ethical clearance

The Ethical clearance was obtained from the Institutional Ethics Committee, Jawaharlal Nehru Medical College, Belagavi prior to the commencement.

Informed Consent

Those patients who fulfilled selection criteria were briefed about the nature of study and a written informed consent regarding the study, investigations sent and procedure involved was obtained (Annexure I) prior to the enrolment.

Method of collection of data

Patients meeting the selection criteria were interviewed.Data were collected on age, gender and presenting complaints. The selected patients were clinically examined and the findings were noted on a pretested and predesigned proforma (Annexure II). The participants were randomly allocated to both groups using a random number sequence generated through computer.Allocation concealment was done by Serially Numbered Opaque Sealed Envelope (SNOSE) method.

PROCEDURE OF OPEN ANATOMICAL REPAIR:

Position: The patient was placed in the supine position with the left arm tucked alongside as shown. (fig no 3) A prophylactic antibiotic (first-generation cephalosporin) is administered intravenously.

Fig no. 3: Position of patient

Anaesthesia and draping: General endotracheal anaesthesia given, the abdominal skin was painted and draped. Ryle's tube and Foley's catheter inserted.

Incision: A curvilinear infraumbilical incision taken and deepened, umbilical hernia sac identified. (fig no. 5)

Fig no 4: preoperative picture showing umbilical hernia.

Fig no 5: Incision in open anatomical repair.

Procedure: Surrounding tissue dissected to make the sac free. Attachments to umbilicus separated, defect localised, adhesions of sac to defect separated, sac reduced. Surrounding tissue around the defect cleared of fat. Number 1 PDS used to take continuous sutures to close the defect by adopting the rule of 1 as in laparotomy closure. Umbilicus anchored from inside to the sheath. Subcutaneous tissue approximated and skin closed. (fig no 6)

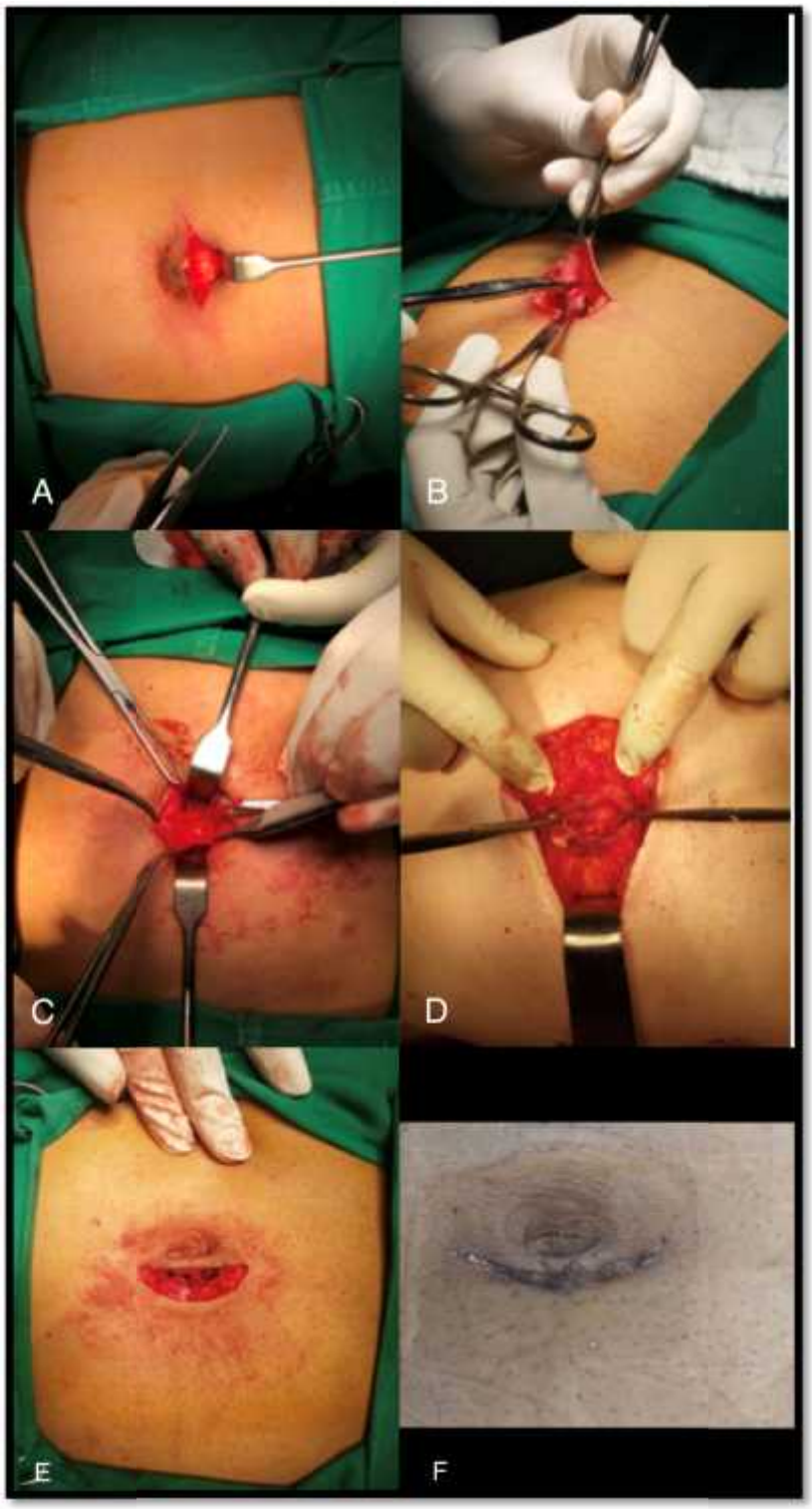


Fig no. 6: Operative pictures of open anatomical repair. (A) Incision deepened to expose the hernial sac. (B, C) Surrounding tissue dissected to make sac free. (D) Sac reduces. (E) Defect closed using no. 1 PDS. (F)Subcutaneous tissue approximated and skin closed.

Complications related to primary hernia repair

In some cases, hernia repairs can be associated with complications. This can range from infection, bleeding, and ileus. Some of the specific complications related with ventral hernia repair, include recurrence and pulmonary complications.

1. Haematoma

Bleeding complications are expected to happen during ventral hernia repair as it requires extensive dissections compared to standard midline incision. This complication requires proactive haemostatis as main prevention strategy. Commonly, subcutaneous drains allow identification of any problem very quickly.

White et al. have shown that the subcutaneous drains can increase the infection rate at wound site; thus, other measures should be explored. A careful history taking specifically focusing on any bleeding disorders in patient or family and any signs of bleeding in the past should be considered. Discontinuation of anticoagulants such as heparin or aspirin should be done.

2. Seromas

Seromas are serous fluid-filled space in the subcutaneous plane. The excessive dissection is a predisposing factor for seromas. White et al indicated thatthe rate of seroma formation is not decreased with use of subcutaneous drains. However, use of closed suction drains for shorter periods (2 to 4 days) is still advised by surgeons. As a preventive measure, obliteration of dead space with subcutaneous sutures and compressive dressings should be considered. In case seroma persists, aspiration could be considered as an option. If it is performed, it should be done under strict aseptic conditions. Seromas or hematomas can give rise of other complications such as wound infection, which could be major cause of recurrent ventral hernia.

3. Wound infection

Although in the modern era prophylactic antibiotics are used, occurrence of infection is still a leading complication of hernia repairs. Features of infection include erythema, warmth, induration and discharge at a later point. Such infections can increase the risk of repair failure; but probability can be reduced by meticulous aseptic surgical technique. Additionally, sharp dissection, gentle tissue handling, avoiding tissue dehydration and small tissue bits during ligatures can significantly reduce occurrence of necrosis and infection.

4. Recurrence

Hernia recurrence is usually reported as a later complication of surgery. Many factors can play a role in hernia recurrence. It is usually seen due to infection or excessive tension at surgical site. Obesity is also seen as a risk factor for recurrence. Incisions in the overweight patients can result in more trauma to tissue causing wound infection, along with excessive tension at suture lines. Some of the measures that can help reduce the occurrence changes are – smoking cessation, gastric decompression, pre-operative pulmonary toilet and proper anaesthetic technique. Generally, hernias with less than 04 cm do not recur. A proper surgical technique with minimal wound tension, seroma or hematoma controls and would infection can limit the possibility of recurrence of hernia.

5. Flap necrosis

To avoid any occurrence of flap necrosis, the surgeon should possess a good knowledge on anatomy and blood supply of abdominal wall. The aim should be to preserve the abdominal wall blood supply as much as possible. A periumbilical perforator sparing technique has showed promising results in reducing skin necrosis

by preserving the blood supply to the skin flap[23]. This technique involves tunnelling around the periumbilical pedicle of perforator vessels. (fig no 7)

Fig no. 7: Flap necrosis after open umbilical hernia repair.

LAPAROSCOPIC REPAIR OF UMBILICAL HERNIA:

Main types of laparoscopic surgery of umbilical hernias include - anatomical closure and closure with prosthesis reinforcement (in the intraperitoneal or extraperitoneal plane). We have discussed about laparoscopic anatomical repair of umbilical hernia.

Indications:

All umbilical hernia patients less than 2 cm size.

Contraindications:

Absolute Contraindications:

Peritoneal dialysis

Infection

Peritonitis

Strangulation

Relative contraindications:

Extensive adhesions

Pulmonary diseases

Morbid obesity.

Cardiac diseases.

Portal hypertension.

Position: The patient is placed in the supine position with the left arm tucked alongside the patient. (fig no. 8). Monitor placed on right side of patient. A first-generation cephalosporin is administered intravenously.

Fig no. 8: Position for laparoscopic hernia repair

Anaesthesia: Patient induced using general anaesthesia. After induction parts are painted with povidone iodine and spirit and draped. Ryle's tube is kept in place as to avoid gastric trauma while veress insertion, Foley's catheter is inserted.

Whole laparoscopy unit checked before starting the procedure.

Fig no. 9: Laparoscopic setup

Abdominal access: is gained by veress needle approach (fig no 10)

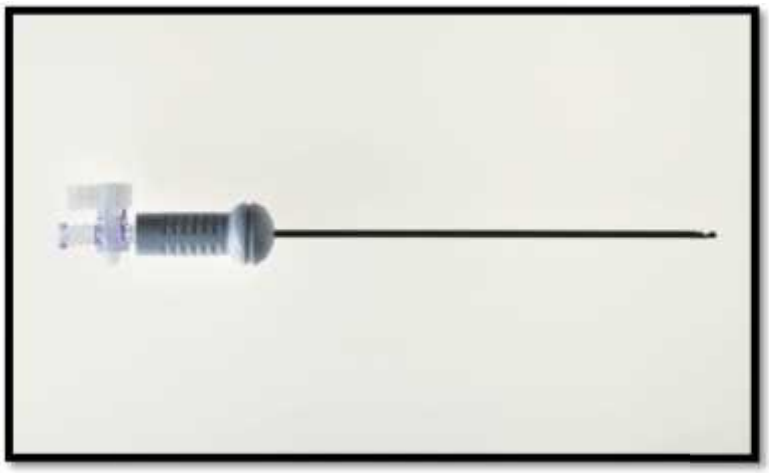


Fig no. 10: Veress needle

Veress needle is inserted at palmers point. Pneumoperitoneum is created with CO_2 with flow rate of 2.5 litres/min upto 14mm of Hg. A 5-mm port is then placed percutaneously at palmers point. (fig no 11)

Fig no 11: Insertion of verees.

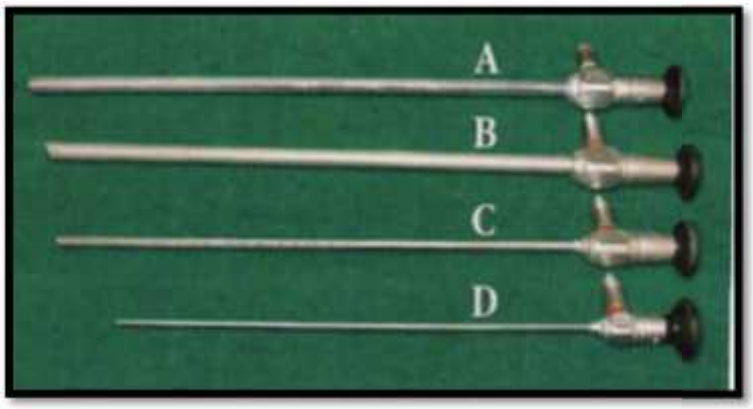


Fig no 12: Telescopes. (A): 0î, 10mm. (B): 30î, 10mm. (C): 30î, 5mm. (D): 30î, 3mm.

A 10mm, 0° and 30° telescopes are routinely used.(fig no 12) A 30° scope provide excellent view of anterior abdominal wall. We have used all 5mm ports. (fig no 13)

Fig no. 13: 5mm port

A 30° 5mm laparoscope is placed through the 5mm port. Camera is attached to the port. (fig no 15)

A good camera with a good light source is must as it prevents any inadvertent enterotomies during adhesiolysis. (fig no 14). Latest digital camera with xenon light source is used. (fig no 15). Cases recorded using a recorder (fig no 16).

Fig no 14: light source

Fig no 15: Camera

Fig no 16: Recorder

Two additional 5mm ports inserted on left side of abdomen under direct vision as shown. (fig no 17)

Fig no 17: Laparoscopic port placement.

Procedure: Complete examination of abdomen is done to rule out any abnormalities. Adhesiolysis is performed with scissors and tissue holding forceps while applying counter pressure on the umbilicus with other hand (fig no 18 A). The incarcerated contents if any are reduced. No attempt is made to remove the hernia sac. A 2mm stab incision with 11mm blade is made just 1 cm lateral to hernia site. No.1 PDS suture with needle introduced transcutaneously just 1cm away from hernia on right side. (fig no 18 B, C) . The needle then used to take continuous sutured with 1 cm bites on either side of sac. (fig no 18 D). Similar bites are taken in reverse towards point of needle insertion. The needle is then brought out to the skin via a separate site near the initial entry site (fig no 19 A). At least three sutures are placed across the fascial defect and are tied after reducing pneumoperitoneum (fig no 18 D, 19-B, C, D)

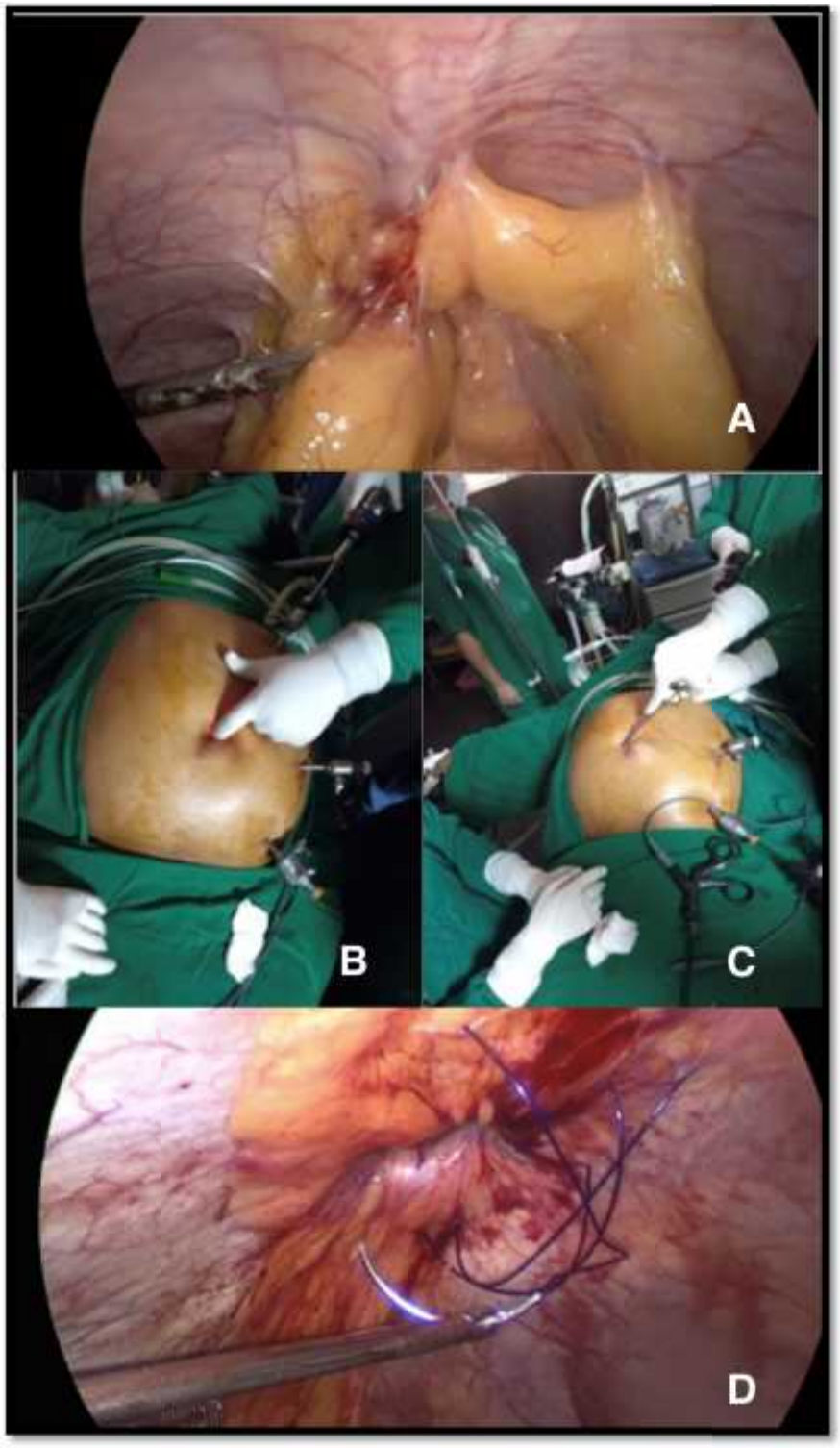


Fig no 18: Operatives steps in laparoscopic surgery

Fig no 19: Operative steps in laparoscopy

Complications expected in laparoscopic repair:

- Seromas
- Recurrence
- Small haematomas
- Ecchymoses

- Wound infection
- Trocar cellulitis
- Nerve entrapment
- Subcutaneous emphysema
- Intestinal injury
- Trocar site hernia

ANALYSIS OF OUTCOMES

Demographics

Patients' age, sex, BMI were assessed.

Assessment: The patients from both the groups were assessed for:

1) Intraoperative time (in minutes).

2) Postoperative pain (by using Visual Analogue Scale**)** grading done in the range of 0-10.

3)Cosmesis (by using POSAS scale- The Patient and Observer Scar Assessment Scale)

Patient was followed up for 6 months and the follow up visits were at 72 hours, 1 week, 6 week, 6 months by OPD visits or telephonic conversations.

Statistical analysis

All the relevant data was tabulated in Microsoft excel and calculated using SPSS version 20. Intraoperative time was calculated, postoperative pain was calculated by using Visual Analogue Scale, cosmetic outcome assessed by using POSAS scale.

RESULTS

In our study, we selected 60 patients; 30 of them underwent open anatomical repair while other 30 patients underwent laparoscopic repair.

OBSERVATIONS:

1. Sex distribution of cases:

Out of total 60 patients in our study total of 19 were females and 41 males

SEX	NO. OF PATIENTS	PERCENTAGE
FEMALES	19	31.67
MALES	41	68.33
TOTAL	**60**	**100.00**

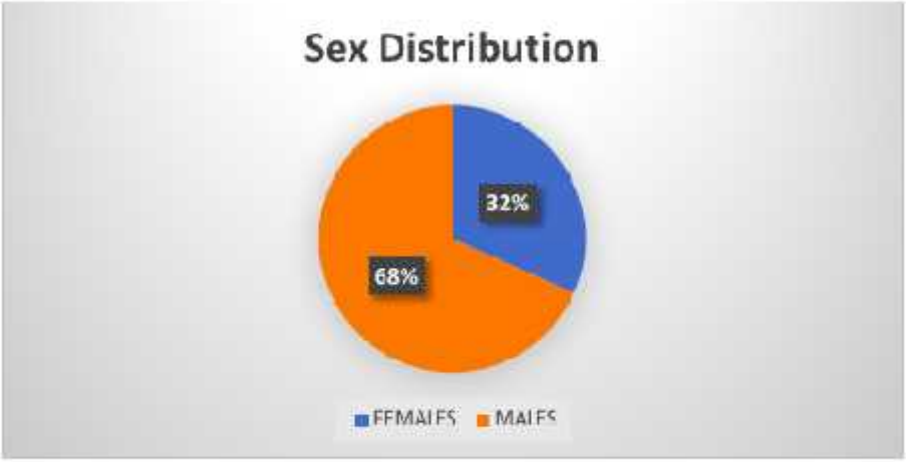


Fig no. 20: Pie chart showing sex distribution of patients

2. Recurrence as per sex distribution:

RECURRENCE	NO	YES	TOTAL
FEMALES	19	0	19
MALES	37	4	41
TOTAL	**56**	4	**60**

3. Distribution of cases according to BMI:

BMI CATEGORY	NO. OF PATIENTS	PERCENTAGE
UNDERWEIGHT (< 18.5)	2	3.33
NORMAL (18.5 – 24.9)	52	86.67
OVERWEIGHT (25 – 29.9)	2	3.33
OBESE (≥ 30)	4	6.67
TOTAL	**60**	**100.00**

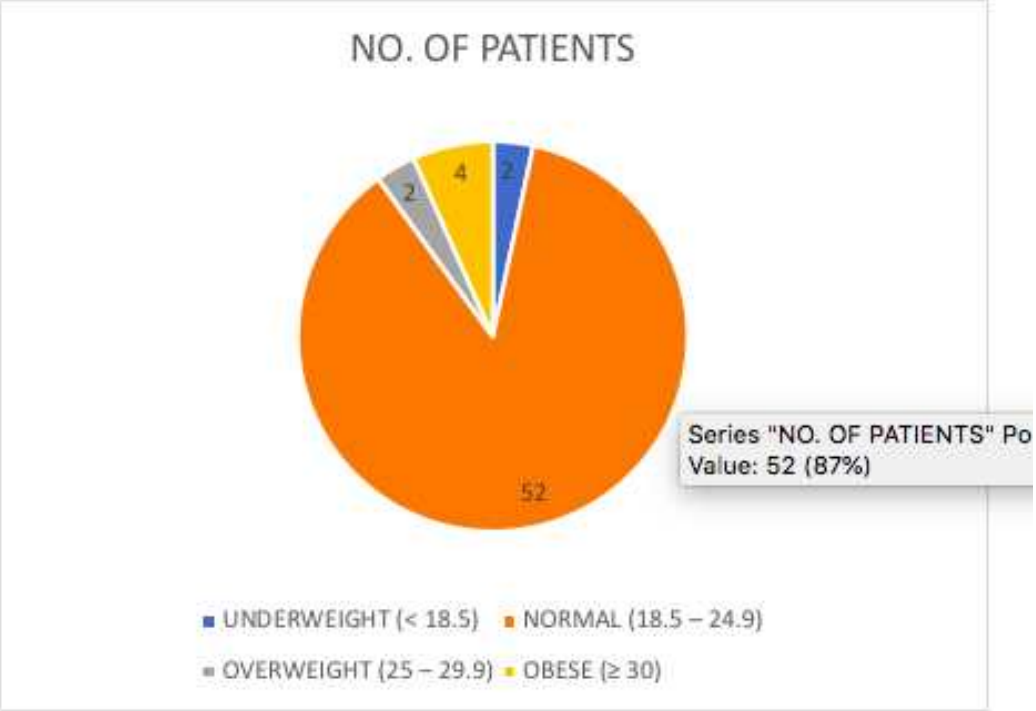


Fig no. 21: pie chart showing distribution of patients according to BMI

4. Recurrence statistics according to BMI:

RECURRENCE ACCORDING TO BMI	NO	YES	GRAND TOTAL
UNDERWEIGHT (< 18.5)	2 (3.33%)	0(0%)	2(3.33%)
NORMAL (18.5 – 24.9)	52(86.67%)	0(0%)	52(86.67%)
OVERWEIGHT(25 – 29.9)	0(0%)	2(3.33%)	2(3.33%)
OBESE (≥ 30)	2(3.33%)	2(3.33%)	4(6.67%)
GRAND TOTAL	**56(93.33%)**	**4(6.67%)**	**60(100%)**

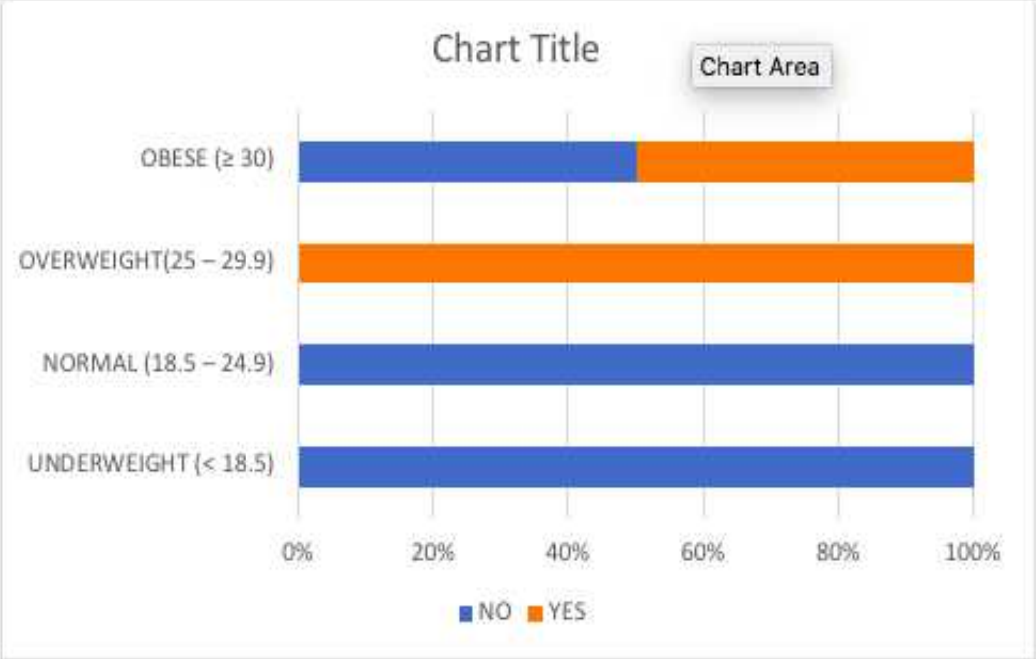


Fig no. 22: Graph showing recurrence statistics according to BMI

5. Intraoperative time was calculated in minutes:

(Calculated from the time of induction of patient till skin closure)

INTRAOPERATIVE TIME (MINS)	MEAN ± SD
OPEN	66.93 ± 16.84
LAPAROSCOPIC	52.00 ± 14.98

6. Postoperative pain was calculated for both groups at following intervals:

	LAPAROSCOPY			OPEN		
	NO	YES	TOTAL	NO	YES	TOTAL
PAIN AT 72 HRS.	26	4	30	13	17	30
PAIN AT 1 WEEK	28	2	30	19	11	30
PAIN AT 6TH WEEK	29	1	30	21	9	30
PAIN AT 6 MONTHS	30	0	30	26	4	30

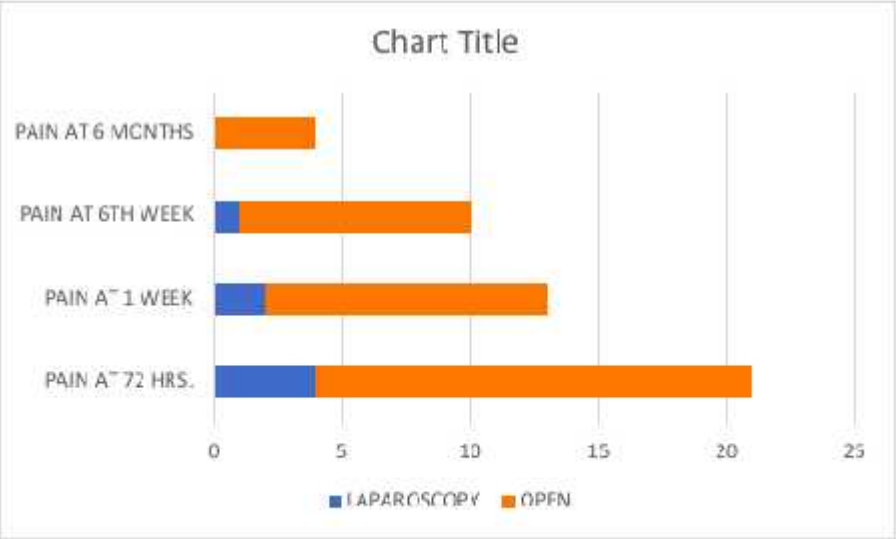


Fig no 23: Graph showing pain statistics at different intervals in both groups

7. Duration of stay in hospital for each group was calculated:

(from the day of admission till discharge)

DURATION OF STAY (IN DAYS)	MEAN ± SD
OPEN	5.43 ± 2.51
LAPAROSCOPIC	4.17 ± 1.05

8. Postoperative complications for both the groups were calculated:

(short term recurrence for 6 months was observed)

	LAPAROSCOPY			OPEN		
	NO	YES	TOTAL	NO	YES	TOTAL
SKIN NECROSIS	30	0	30	29	1	30
SEROMA	30	0	30	28	2	30
INFECTION	30	0	30	29	1	30
RECURRENCE	29	1	30	27	3	30

9. Postoperative complications according to BMI were also calculated

	SKIN NECROSIS		SEROMA		INFECTION		RECURRENCE	
	NO	YES	NO	YES	NO	YES	NO	YES
UNDERWEIGHT	2	0	2	0	2	0	2	0
NORMAL	52	0	52	0	52	0	52	0
OVERWEIGHT	1	1	2	0	2	0	2	2
OBESE	4	0	2	2	3	1	0	2
TOTAL	59	1	58	2	59	1	56	4

10. Postoperative cosmesis was assessed using POSAS score:

Patients with laparoscopic repair had better scores and were cosmetically more satisfied. It has 2 major components patient score marked by the patients and observer score marked by the surgeon as shown.

3) Cosmesis (by using POSAS scale- The Patient and Observer Scar Assessment Scale)

Observer Scar Assessment Scale

	normal skin 1	2	3	4	5	6	7	8	9	10 *worst scar imaginable*
Vascularization	●	○	○	○	○	○	○	○	○	○
Pigmentation	●	○	○	○	○	○	○	○	○	○ Hypo ☐ Mix ☐ Hyper ☐
Thickness	○	●	○	○	○	○	○	○	○	○
Relief	○	○	●	○	○	○	○	○	○	○
Pliability	○	●	○	○	○	○	○	○	○	○

Total score Observer Scar Scale: 9

Patient Scar Assessment Scale

No, no complaints 1	2	3	4	5	6	7	8	9	10 *Yes, worst imaginable*
Is the scar painful ?	●	○	○	○	○	○	○	○	○	○
Is the scar itching?	●	○	○	○	○	○	○	○	○	○

No, as normal skin 1	2	3	4	5	6	7	8	9	10 *Yes, very different*
Is the color of the scar different?	○	●	○	○	○	○	○	○	○	○
Is the scar more stiff ?	○	○	●	○	○	○	○	○	○	○
Is the thickness of the scar different?	○	●	○	○	○	○	○	○	○	○
Is the scar irregular?	●	○	○	○	○	○	○	○	○	○

Total score Patient Scar Scale: 10

Results were as below:

OBSERVER SCORE	LAPAROSCOPY	OPEN	TOTAL
BEST	30	28	58
WORST		2	2
TOTAL	**30**	**30**	**60**

PATIENTS SCORE	LAPAROSCOPY	OPEN	GRAND TOTAL
BEST	30	27	57
WORST	00	03	03
TOTAL	**30**	**30**	**60**

27 out of 30 patients were cosmetically satisfied in case of open repair.All 30 were cosmetically satisfied in case of laparoscopic repair.

Statistical analysis of data was done using various test as shown in the table below:

Variables	Laparoscopic Group	Open Group	P - value
Age (yrs.)	43.57 ± 11.94	47.43 ± 12.95	0.234
Hernia size	1.29 ± 0.414	1.31 ± 0.398	0.811
Sex M / F	18 / 12	23 / 7	0.165
Hospital Stay	4.17 ± 1.053	5.43 ± 6.32	0.11
Operating time	52 ± 14.97	66.93 ± 16.83	0.001*
Patients Observers Score	9.93 ± 7.5	7.30 ± 0.53	0.056
Patients Score	12.3 ± 10.9	8.33 ± 1.093	0.069

	Laparoscopic Group	Open Group	Fishers test	Pearson's Chi-Square
Skin Necrosis	0	1	1.00	0.313
Seroma	0	2	0.49	0.150
Infection	0	1	1.00	0.313
Recurrence	1	3	0.612	0.301
Pain at 72 minutes	04	17	0.001*	0.0000*
Pain at 1st week	02	11	0.01*	0.005*
Pain at 6th week	01	09	0.012*	0.006*
Pain at 6 months	00	04	0.112	0.038*
Observer score	30	28	0.492	0.150
Patients score	30	27	0.237	0.076
Cosmetically Satisfied	30	24	0.024*	0.01*
Presence(M/F)	13 / 7	11 / 9	0.748	0.519

DISCUSSION

The laparoscopic procedure to umbilical hernia has shown to be effective as well as safe. Some of the key benefits of laparoscopy includes:

i. Shorter intraoperative time (maximum within 40-60 mins). In our study P-value for intraoperative time was 0.001, which was statistically significant.

ii. Reduced postoperative pain - No patients reported pain compared to 6 patients in open repair at the end of 6months. In our study Pearson's Chi-Square test was done which reported to be 0.038 that is statistically significant.

iii. Duration of stay 4.17 ± 1.05 in laparoscopic as compared to 5.43 ± 2.51 in open repair.

iv. Hospital stay of 4 days in laparoscopic as compared to 9 days in open in patients with complications.

v. Seroma formation in no patient compared to 2 patients in open repair.

vi. No Wound infection in laparoscopy group compared to 1 patient in open repair.

vii. Improved recurrence rates 3.3% as compared to 10% in the open procedures.

viii. The cosmetic outcome is satisfactory (All 30 in case of laparoscopic repair whereas 27 in case of open repair). Pearson's Chi-Square test reported to be significant.

Rule of one is used in closure of laparotomy wounds, where we take a bite 1cm from each side of the defect to attain a good tissue approximation. We apply the

same principle for closure of hernia defect in our study. It provides good tissue approximation and less chances of recurrence.

The suture bite is parallel to long axis of rectus abdominis muscle. It should help in avoiding tension over the suture while muscle contraction. It ultimately helps in better tissue approximation.

Laparoscopic repair is favourable as compared to open repair in many aspects. It offers better postoperative outcomes, reduced painpostoperatively, shorter hospital stay, low complications of infection and seromaformation ; when compared to open repair.

In open repair the incision is longer and present in contaminated area. Traditionally the camera port is a 10mm port. With advancement in technology (high definition camera system) even a 5mm laparoscope provides images comparable to a 10mm laparoscope. This has allowed us to use all 5mm trocar for performing this surgery making it more minimally invasive. The widely spaced 5mm trocars may explain the less postop pain, early discharge, reduced complications. The cosmetic benefit of 5mm are also evident in this study.

PDS suture is used for anatomical repair. It has various advantages such as configuration of the needle is such that it allows us to directly pass needle without any use of suture passer. It is a delayed absorbable suture and takes 183-238 days for its complete absorption. By that time hernia defect approximates and closes with minimal chances of recurrence. Thus, for defects smaller than 2cm laparoscopic anatomical repair provides good results.

Mesh placement in defects less than 2cm is not required and considered as over treatment as there is more tissue handling, risk of foreign body reaction and increased cost. Increased recurrence was seen with raised BMI. Different studies postulate different hypothesis relating obesity with wound complications. Poor vascular supply and anatomical variations are important factors for complications .Reduced oxygen supply results in disturbed collagen synthesis. It ultimately leads to decreased fighting capacity for infections.

CONCLUSION

Laparoscopic suture repair of umbilical hernia <2cm is technically feasible . It provides clear advantages over open repair such as reduced postoperative pain, better cosmetic outcome and shorter operating time when compared to open repair. However, more studies with longer follow up periods are required to comment on recurrence.

SUMMARY

This study was conducted at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi between January 2019 and December 2019.

A total sixty patients with umbilical hernia size less than 2cms were included in the study. Thirty patients underwent laparoscopic anatomical repair and thirty patients underwent open anatomical repair with No. 1 PDS.

The two groups were almost similar with respect to age and sex distribution.

There was significant reduction in intra-operative time and post-operative pain in the patients who underwent laparoscopic repair. There was also significant better cosmetic outcome in laparoscopic group as compare to open. There was lower incidence of postoperative complications (seroma, wound infection and recurrence) in laparoscopic group as compared to open but this was not statistically significant.

To comment on recurrence long term follow up is required. Hence, there is a need for further studies with larger sample size and longer follow up period, to come to conclusion regarding the superiority of a particular treatment method for small umbilical hernias.

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ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed - to-be-University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (Govt.)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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\Ref: MDC/DOME/ \O

Date: 24/11/2018

REG NO.B H 0 1 1 8 0 0 8

PG student in Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled " **OPEN ANATOMICAL REPAIR V/S LAPAROSCOPIC REPAIR OF UMBILICAL HERNIA USING NO. 1 POLYDIOXANONE SUTURE (PDS), RANDOMIZED CONTROL TRIAL ",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE II

CONSENT STATEMENT

INFORMATION SHEET

Mr./Mrs./Miss. _____ we are requesting you to enroll you in study titled **"Open anatomical repair v/s laparoscopic repair of umbilical hernia using no. 1 PDS suture, a Randomized Control Trial**"conducted by **REG NO. BH0118008**, Post Graduate in M.D. General surgery under the guidance of Dr._____ ,Associate Professor, Department of General Surgery, J.N. Medical College, Belagavi under KAHER, Belagavi.

Respected Sir/Madam We request you to kindly enrol in this study. During the study, you will be asked some questions regarding your present complaint and you are supposed to answer to the best of your knowledge.

Your participation in this research is voluntary. Your decision whether or not to participate in the study will not affect your relationship with J.N. Medical College. If you decide not to participate you are free to withdraw at any time.

Purpose of the study:

I will ask you your present and past medical history. You will be clinically examined in detail and routine investigations like CBC, Platelet Count, ECG, Chest XRAY, etc. Will be done accordingly. You will be allotted into one of the two groups randomly using a simple randomization technique.

Risks:

Hernia repair is generally a very safe operation with few risks, but rarely complications can occur. Therefore, in the period following your operation you should seek medical advice if you notice any of the following problems:

1. Increasing pain, redness, swelling or discharge
2. Recurrence
3. Severe bleeding
4. Difficulty in passing urine
5. High temperature over 38˚or chills
6. Nausea or vomiting

Possible complications of laparoscopy include:

1. Need for umbilical excision might occur.
2. Injury to the bowel, bladder, ureters (tubes coming from the kidneys to the bladder), blood vessels in the abdominal wall and pelvis
3. Injury to surrounding vital structures
4. Infection
5. Bleeding with the possibility of a blood transfusion and the attendant risks of hepatitis / AIDS
6. Death is extremely rare
7. If a serious injury should occur, it is possible that a laparotomy (opening the abdomen) would be necessary to repair the injury or stop the bleeding
8. Recurrence – recurrence of a hernia after surgery can happen in up to 10% of patients. It is more likely if you are overweight.
9. Chronic pain – you may experience significant pain after the operation particularly if it is performed laparoscopically. You will be given painkilling medications, and most pain settles down by six weeks. If you experience pain lasting for longer than this, please contact the team for a review

Possible complications of open repair:

1. Need for umbilical excision
2. Bleeding
3. Pain
4. Infection
5. Injury to surrounding vital structures
6. Wound haematoma - bleeding under the skin can produce a firm swelling of blood clot (haematoma). This may simply disappear gradually or leak out through the wound.

Anaesthesia risks:

In addition, there are risks associated with anaesthesia such as:

1. Allergic reactions
2. Heart rate irregularity
3. Blood pressure changes
4. Pneumonia
5. Body may lose ability to control body temperature (malignant hyperthermia)
6. Cardiac arrest
7. Risk of death very rare

Feeling sick and vomiting after surgery

1. Sore throat
2. Dizziness, blurred vision
3. Headache
4. Bladder problems
5. Damage to lips or tongue (usually minor)
6. Itching

7. Aches, pains and backache
8. Pain during injection of drugs
9. Bruising and soreness
10. Confusion or memory loss

These complications are not all-inclusive but represent those most commonly associated with laparoscopy and general anaesthesia. Fortunately, these are quite rare.

Voluntary Participation/Withdrawal:

Taking part in the study is voluntary. You may choose not to enroll in this study. Your decision will not change present or future health care services offered to you at K.L.E. hospital.

Alternatives:

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and Confidentiality:

Utmost privacy will be maintained and all the personal information will be kept confidential.

CONSENT FORM

Study title: **A ONE YEAR RCT TO COMPARE OPEN ANATOMICAL REPAIR AND LPROSCOPIC SUTURE REPAIR WITH N0.1 PDS LOOP OF UMBILICAL HERNIA"**

Subject's name: _____

I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. ☐

(i) I understood that my participation in the study is voluntary and that I am free to withdraw at anytime, without giving any reason, without my medical care or legal rights being affected. ☐

(ii) I understood that doctor of the clinical trial, others working on the doctor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understood that my identity will not be revealed in any information released to third parties or published. ☐

(iii) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

(iv) I agree to take part in the above study. ☐

Subject name: _____

Signature (or thumb impression) of the subject: _____

Date (dd-mm-yyyy): ☐☐ - ☐☐ ☐☐☐☐

Name of the person obtaining informed consent: _____

Signature of the person obtaining informed consent: _____

If a patient has limited ability to read and write, In these instances the patient his/her thumb impression in the place of the signature.

Patient's Legally Acceptable Representative's Statement: ☐

I, as the patient's legally acceptable representative, was present during the consenting procedure and understand the preceding information describing this study. All of the questions regarding the study and the patient's participation in it have been answered to my satisfaction and that of the patient. I state that all aspects of the study were clearly presented during the consent procedure. The patient is willing to participate in the study and I sign below on his/her behalf testifying to this effect.

Name of the patient: _____

Name of the Legally Acceptable Representative: _____

Relationship to the patient: _____

Signature of the Legally Acceptable Representative: _____

Date (dd-mm-yyyy) : ☐☐ ☐☐ ☐☐☐☐

ANNEXURES III: PROFORMA

SCREENING FORM

1. Patient's UHID no.: ☐☐☐☐☐☐☐

2. Age (in years) ☐☐

3. Gender: 1. Male 2. Female ☐

4. Height (in cms): ☐☐☐

5. Weight (in kg): ☐☐

6. BMI (kg/m^2): ☐☐☐

7. History : Swelling present (no. of days) ☐

   Nature of swelling:1. Reducible 2. Non reducible ☐

   Signs of obstruction: 1. Yes 2. No ☐

8. On Examination: On palpation size of swelling ☐☐ (in cm)

   Nature: 1.Reducible ☐
2. Nonreducible

   Pain/tenderness: 1. Yes ☐
2. No

Investigations: USG (defect size in cms) ☐

DOA (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

10.DOD (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

11.Date of interview (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

12. Address: 1. Belagavi
2. Outside Belagavi ☐

13.Phone: ☐☐☐☐☐☐☐☐☐☐

14.Occupation: 1-Unemployed ☐
2-Unskilled
3-Semi-skilled
4-Skilled
5-Professional

15.Education: 1-Illiterate ☐
2-Primary (1st-7th std)
3-High school (8th-10th std)
4-Intermediate
5-Degree and above

16.Socio-economic status :1-Low ☐
2-Middle
3-High

17.Applicant is willing to give consent: 1-Yes ☐
2-No

18.Final result1-Inelgible ☐
2-Elgible but refused
3-Elgible and participating

PROFORMA

1. Patient UHID no. ☐☐☐☐☐☐☐

2. Age (in years) ☐☐

3. Gender: 1. Male 2. Female ☐

4. Height (in cms): ☐☐☐

5. Weight (in kg): ☐☐

6. BMI (kg/m^2): ☐☐

7. DOA (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

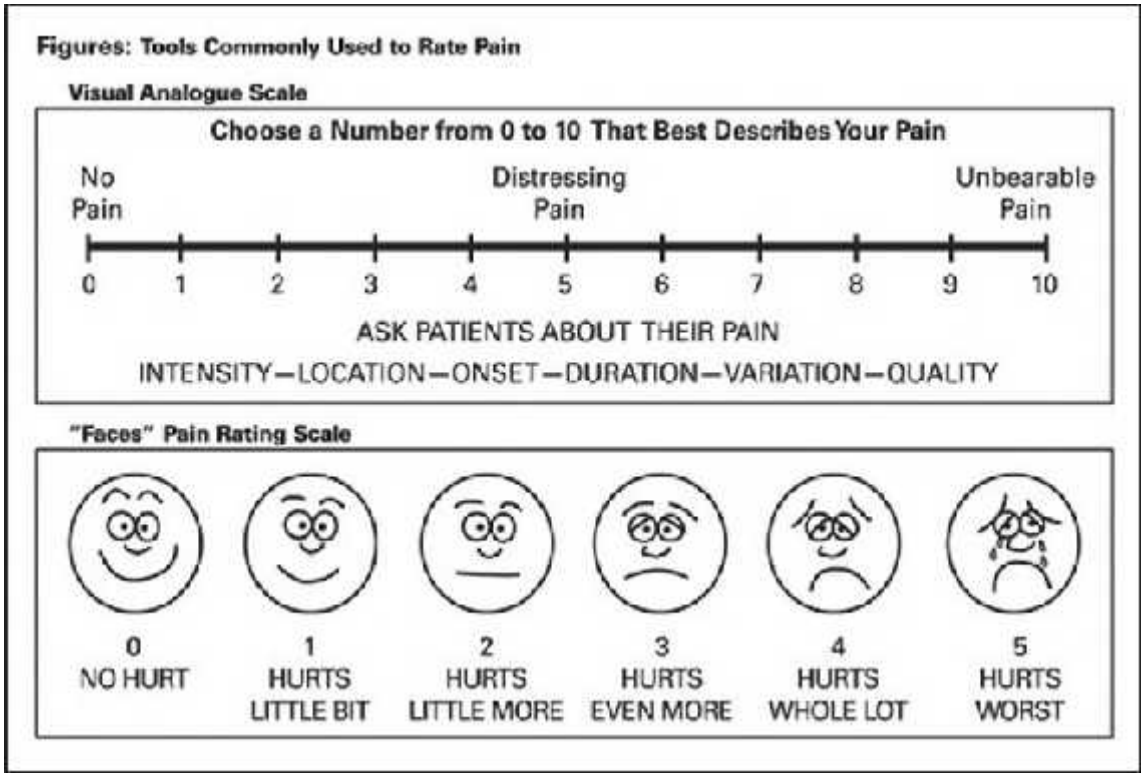
8. DOD (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

9. Date of interview (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

ANALYSIS

1) Postoperative hospital stay:Number of Days ☐☐

2) Postoperative pain: by using Visual Analogue Scale ☐



3) Cosmesis (by using POSAS scale- The Patient and Observer Scar Assessment Scale)

Observer Scar Assessment Scale

	normal skin	1	2	3	4	5	6	7	8	9	10	*worst scar imaginable*
Vascularization		○	○	○	○	○	○	○	○	○	○	
Pigmentation		○	○	○	○	○	○	○	○	○	○	Hypo ☐ Mix ☐ Hyper ☐
Thickness		○	○	○	○	○	○	○	○	○	○	
Relief		○	○	○	○	○	○	○	○	○	○	
Pliability		○	○	○	○	○	○	○	○	○	○	

Total score Observer Scar Scale:

Patient Scar Assessment Scale

	No, no complaints	1	2	3	4	5	6	7	8	9	10	*Yes, worst imaginable*
Is the scar painful ?		○	○	○	○	○	○	○	○	○	○	
Is the scar itching?		○	○	○	○	○	○	○	○	○	○	

	No, as normal skin	1	2	3	4	5	6	7	8	9	10	*Yes, very different*
Is the color of the scar different?		○	○	○	○	○	○	○	○	○	○	
Is the scar more stiff ?		○	○	○	○	○	○	○	○	○	○	
Is the thickness of the scar different?		○	○	○	○	○	○	○	○	○	○	
Is the scar irregular?		○	○	○	○	○	○	○	○	○	○	

Total score Patient Scar Scale:

4) Seroma formation: a. 72hours ☐

b. After 1 week ☐

c. After 6 weeks ☐

d. After 6 months ☐

(1. Yes 2. No) ☐

5) Recurrence (short term): a. 72 hours

b. After 1 week ☐

c. After 6 weeks ☐

d. After 6 ☐ months(1. Yes 2. No)

ANNEXURES IV

KEY TO MASTERCHART

1. Age- In years
2. Sex-
    - Male- M
    - Female- F
3. hsCRP- High sensitivity C reactive protein (mg/L)
4. 'Difficult?': Difficult laparoscopy (Also applicable for subtotal and conversion)
    - Y: Yes
    - N: No
5. Other findings:
    - Y: Present
    - N: Absent

ANNEXURES V: MASTER CHART

IP no.	Age	Sex	BMI	Hernia size	Procedure	Intra-op time	Hospital stay	Pain at 72 hrs	Pain at 1week	Pain at 6 weeks	Pain at 6 months	Skin necrosis	Seroma	Infection	Recurrence	POSAS (observer score)	POSAS (patient score)	Cosmetically satisfied
946392	38	M	22.9	0.9	O	68	9	Y	Y	Y	N	N	N	N	N	7	8	Y
947649	42	M	23.9	1.6	O	70	4	Y	Y	Y	N	N	N	N	N	7	8	Y
946487	50	F	20.0	0.7	O	75	3	N	N	N	N	N	N	N	N	7	15	Y
953169	59	F	21.0	0.8	O	72	4	N	N	N	N	N	N	N	N	10	12	Y
954818	36	M	20.9	1.9	O	62	4	N	N	N	N	N	N	N	N	8	10	Y
954943	67	M	25.6	1.8	O	64	4	N	N	N	N	N	N	N	N	7	9	Y
956355	31	M	21.3	1.2	O	70	4	N	N	N	N	N	N	N	N	8	8	N
957760	39	M	29.0	1.1	O	68	9	Y	Y	Y	Y	N	Y	Y	Y	31	42	N
958364	79	M	24.8	1.8	O	71	4	N	N	N	N	N	N	N	N	8	10	Y
953528	42	M	19.5	1.2	O	63	4	Y	N	N	N	N	N	N	N	8	8	Y
921265	35	F	18.0	1.1	O	92	4	Y	N	N	N	N	N	N	N	8	10	Y
941667	65	M	23.8	1.2	O	98	11	Y	Y	Y	Y	N	N	N	N	7	8	N
943026	56	M	28.9	1.8	O	91	9	Y	Y	Y	Y	N	Y	N	Y	22	28	N
943682	46	M	24.4	1.3	O	56	9	Y	Y	N	N	N	N	N	N	7	8	Y
944801	19	M	18.3	1.0	O	94	4	N	N	N	N	N	N	N	N	10	16	N
956695	49	M	24.3	1.2	O	100	9	Y	Y	Y	Y	N	N	N	N	6	8	Y
921440	40	M	22.1	1.0	O	42	4	Y	N	N	N	N	N	N	N	8	8	Y
923535	65	F	25.0	1.9	O	40	4	Y	N	N	N	N	N	N	N	7	8	Y
930637	50	M	21.1	1.9	O	70	4	Y	N	N	N	N	N	N	N	7	8	Y
943196	48	M	20.6	1.5	O	75	5	Y	Y	N	N	N	N	N	N	7	9	Y
947275	37	M	19.3	0.8	O	62	3	N	N	N	N	N	N	N	N	7	6	Y
924162	30	F	19.9	1.4	O	48	3	N	N	N	N	N	N	N	N	7	7	Y
925373	55	F	23.9	1.2	O	44	4	Y	N	N	N	N	N	N	N	7	7	Y
926829	40	M	19.9	1.4	O	72	6	N	N	N	N	N	N	N	N	8	9	Y
936376	58	M	23.6	1.8	O	77	9	Y	Y	Y	N	N	N	N	N	7	8	Y
939940	46	F	21.6	1.2	O	70	4	N	N	N	N	N	N	N	N	8	9	Y
940539	57	M	23.8	1.1	O	52	10	Y	Y	Y	N	N	N	N	N	9	10	Y
943281	48	M	20.9	0.8	O	50	4	N	N	N	N	N	N	N	N	8	10	Y
943922	55	M	30.0	2.0	O	52	5	Y	Y	Y	N	Y	N	N	Y	40	56	N
944121	38	M	22.2	0.8	O	40	3	N	N	N	N	N	N	N	N	7	8	Y
928188	40	F	22.8	0.6	L	30	4	N	N	N	N	N	N	N	N	7	8	Y
928011	61	M	24.8	2.0	L	35	4	N	N	N	N	N	N	N	N	7	8	Y
933476	29	F	19.0	0.8	L	42	5	N	N	N	N	N	N	N	N	7	8	Y
933399	52	F	22.7	1.8	L	44	5	N	N	N	N	N	N	N	N	7	8	Y
943558	38	M	20.1	1.2	L	46	3	N	N	N	N	N	N	N	N	8	9	Y
948515	50	F	23.9	1.2	L	48	4	N	N	N	N	N	N	N	N	7	8	Y
951882	30	F	19.9	1.1	L	43	3	N	N	N	N	N	N	N	N	7	8	Y
959331	38	M	20.2	1.2	L	64	4	N	N	N	N	N	N	N	N	7	7	Y
921312	30	M	21.2	1.3	L	48	4	N	N	N	N	N	N	N	N	7	7	Y
923714	30	M	19.5	0.8	L	68	4	N	N	N	N	N	N	N	N	7	7	Y
923703	35	M	22.6	1.8	L	70	3	N	N	N	N	N	N	N	N	7	7	Y
942065	39	M	23.1	0.9	L	50	4	N	N	N	N	N	N	N	N	7	7	Y
945602	30	F	21.1	1.1	L	44	5	N	N	N	N	N	N	N	N	7	7	Y
945627	36	M	21.8	1.0	L	72	4	N	N	N	N	N	N	N	N	7	8	Y
945619	39	M	23.9	1.6	L	41	4	N	N	N	N	N	N	N	N	7	7	Y
951481	40	M	24.0	0.8	L	45	4	N	N	N	N	N	N	N	N	7	8	Y
952612	42	M	24.3	1.1	L	40	4	N	N	N	N	N	N	N	N	7	9	Y
962333	51	M	24.9	1.2	L	41	4	N	N	N	N	N	N	N	N	8	8	Y
936708	70	M	32.0	2.0	L	104	9	Y	Y	Y	N	N	N	N	Y	9	10	Y
938556	38	M	23.3	1.8	L	44	4	N	N	N	N	N	N	N	N	8	10	Y
935602	46	M	21.1	1.2	L	43	4	N	N	N	N	N	N	N	N	8	9	Y
924231	58	F	23.6	1.1	L	66	4	N	N	N	N	N	N	N	N	8	10	Y
965714	25	F	19.5	0.8	L	40	3	N	N	N	N	N	N	N	N	8	8	Y
922940	54	F	22.7	1.9	L	68	4	Y	N	N	N	N	N	N	N	7	10	Y
924839	50	F	21.8	0.8	L	50	4	N	N	N	N	N	N	N	N	7	10	Y
925776	60	F	24.3	1.3	L	70	5	Y	Y	N	N	N	N	N	N	7	10	Y
928430	32	F	20.1	1.8	L	52	4	N	N	N	N	N	N	N	N	8	10	Y

IP no.	Age	Sex	BMI	Hernia size	Procedure	Intra-op time	Hospital stay	Pain at 72 hrs	Pain at 1 week	Pain at 6 weeks	Pain at 6 months	Skin necrosis	Seroma	Infection	Recurrence	POSAS (observer score)	POSAS (patient score)	Cosmetically satisfied
932617	62	M	22.1	1.8	L	51	4	N	N	N	N	N	N	N	N	7	8	Y
932441	42	M	20.8	1.2	L	48	4	N	N	N	N	N	N	N	N	7	8	Y
942627	60	M	24.1	1.6	L	53	4	Y	N	N	N	N	N	N	N	7	8	Y