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Please accept the same.

S.No	Name of Candidate	Thesis
1	Dr Darshan Patel	Assessment of quality of life after ventral hernia repair – A prospective observational study at AIIMS Jodhpur

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Thanking you

Your Sincerely,

Dr. Ashok Puranik Professor & Head Department of General Surgery AIIMS, Jodhpur

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ASSESSMENT OF QUALITY OF LIFE AFTER VENTRAL HERNIA REPAIR – A PROSPECTIVE OBSERVATIONAL STUDY AT TERTIARY CARE CENTRE



Thesis

Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfillment of the requirement for the degree of

MASTER OF SURGERY (MS) GENERAL SURGERY

JUNE, 2022 AIIMS, JODHPUR **DR. DARSHAN PATEL**



All India Institute of Medical Sciences, Jodhpur

DECLARATION

I hereby declare that this thesis entitled "Assessment of quality of life after ventral hernia repair – A prospective observational study at tertiary care centre" is a bonafide and original research work carried out in partial fulfillment of the requirement for the degree of Master of Surgery in General Surgery under supervision and guidance, in the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur.

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Date: 11/02/2022



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CERTIFICATE

This is to certify that the thesis titled "Assessment of quality of life after ventral hernia repair - A prospective observational study at tertiary care centre" is the bonafide work of Dr. Darshan Patel, carried out under our guidance and supervision, in the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur.

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This is to certify that **Dr. Darshan Patel** has satisfactorily completed her thesis entitled "Assessment of quality of life after ventral hernia repair – A prospective observational study at tertiary care centre" in partial fulfillment of the requirement for the degree of Masters of Surgery in General Surgery. She has done the research work under my supervision and guidance. She has fulfilled all the requisites under the regulations laid by the All India Institute of Medical Sciences, Jodhpur and no part of the thesis has been submitted to any other university.

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Date: 11 / 02 / 2022

ACKNOWLEDGEMENT

At the outset of my post-graduate entrance preparation, little did I imagine that I would be a part of this prestigious institute, expanding my horizons as a budding surgeon. It is solely due to the never-ending motivation of my mentors, family, and colleagues that I could pursue this thirst for surgical knowledge and also complete my thesis work with a sense of pride and satisfaction.

First of all, I am obliged to my guide Dr. Mahendra Lodha, Associate Professor, Department of General Surgery, All India Institute of Medical Sciences, Jodhpur, who has been a constant impetus from the inception to the completion of this thesis. His valuable inputs and level-headed advice have helped me in fine-tuning this research work.

Next, I would like to express my earnest gratitude to my co-guide Professor Col. (Dr.) Ashok Kumar Puranik, Head of the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur, who has never failed to galvanize all of us, with his simplified yet innovative style of teaching, guidance in academic research, distinctive surgical techniques, and congenial nature.

I would also like to thank my co-guide Dr. Mayank Badkur, Assistant Professor, Department of General Surgery, All India Institute of Medical Sciences, Jodhpur, for his constant guidance and help in writing each page of this whole thesis. Without him, this thesis would not be possible at all.

I am highly indebted to my co-guides Dr. Mahaveer Singh Rodha, Additional Professor, Department of General Surgery, All India Institute of Medical Sciences, Jodhpur, for their consistent boost to acquire maximal knowledge and surgical skills; and their contribution in this thesis execution.

I am deeply grateful to Dr. Naveen Sharma, Professor, Department of General Surgery, All India Institute of Medical Sciences, Jodhpur, for his insightful comments and constructive critiquing, which has helped me produce this thesis with near-total perfection.

I extend my sincere gratitude to Dr. Ramkaran Chaudhary, Additional Professor, Dr. Satyaprakash Meena, Assistant Professor, Dr. Indra Singh Chaudhary, Assistant

Professor, Department of General Surgery, All India Institute of Medical Sciences, Jodhpur, for their incessant support and motivation to excel in research work.

I would like to thank Mr. Toufique for his help in statistical analysis.

It would be incomplete if I fail to thank Dr. Ravi Ranjan Kumar, Dr. Satheesh, Dr. Althea Cardoz, and Dr. Krashankant Premi, Dr. Vinod for their support. A special mention must be made for my batchmates and friends Dr. Anupam, Dr. Charan, Dr. Netrananda, for their faith in my capabilities, which has been an eye-opener during my tough times. I would like to thank my beloved juniors Dr. Dheerain, Dr. Piyush, Dr. Sumit, and many more, who have helped me with data collection.

If not for my father Jashvantbhai Patel, mother Mrs. Surekhaben Patel, my dream to become a surgeon would not have been realised and I am deeply indebted to them for being my strongest pillar of support in times of need. Not only this thesis, but any of my life's major tasks in the last 5 years were not possible without the constant inspiration, help, and support of my dearest financeè Dr. Anjali Patel. Thank you would be the least I can say to her!

Last but not the least, I am grateful to all the patients who participated in this study with complete trust in our proceedings, which helped in concluding this thesis successfully. Ultimately, all things are possible through God who strengthens us.

Dr. Darshan Patel

Dedicated to my parents, fiancée

and my patients

TABLE OF CONTENTS

S No.	PARTICULARS	PAGE NO.
1	List of Abbreviations	i
2	List of Graphs	i
3	List of Tables	ii
4	List of Figures	iii
5	List of Annexures	iv
6	Summary of the Project	V
7	Introduction	1
8	Review of literature	2
9	Aims and Objectives	30
10	Materials and methods	31
11	Results	34
12	Discussion	40
13	Conclusion	45
14	Bibliography	46
15	Annexures	58

LIST OF ABBREVIATIONS

QOL	Quality Of Life
IPOM	Intraperitoneal Onlay Mesh Hernioplasty
TAR	Transverse abdominis release
SVC	Superior Vena Cava
IVC	Inferior Vena Cava
СТ	Computed Tomography
COPD	Chronic obstructive pulmonary disease
VAS	Visual analogue scale

LIST OF GRAPHS

Serial No.	Name of Graph	Page No.
1	Pie chart showing various types of hernias in the patients studied	35
2	Bar chart showing types of ventral hernia repairs done in the patients studied	36

LIST OF TABLES

Serial No.	Name of Table	Page No.
1	Distribution of different variables in the study	34
2	Numbers of laparoscopic repairs converted to open repairs and reasons for that.	36
3	Comparison of quality of life (QOL) at 1 st month between open and laparoscopic ventral hernia repairs.	37
4	Comparison of outcome between open vs laparoscopic ventral hernia repairs.	37
5	Comparison of satisfaction between open vs laparoscopic ventral hernia repairs.	38
6	Comparison of postoperative pain and analgesic usage between open vs laparoscopic ventral hernia repairs.	38
7	Comparison of incidence of complications between open vs laparoscopic ventral hernia repairs.	39
8	Comparison of quality of life (QOL) at 1 st month between large and small ventral hernia repairs.	39

LIST OF FIGURES

Serial No.	Name of figure	Page No.
1	Layers of the anterior abdominal wall	
2	Muscles of the anterior abdominal wall	6
3	Formation of rectus sheath above the umbilicus	8
4	Formation of rectus sheath below the umbilicus	8
5	Neurovascular supply of the anterior abdominal wall	9
6	Various types of incisions over the anterior abdominal wall	10
7	Various types of hernias over the abdominal wall	11
8	Clinical image of an irreducible umbilical hernia	13
9	Clinical image of a reducible lower midline incisional hernia with a defect size of $4x5$ cm	13
10	Clinical image of a reducible incisional hernia with a defect size of 5x5 cm	14
11	Clinical image of a small umbilical hernia with a defect size of 0.5x0.5 cm	14
12	Clinical image of a small umbilical hernia	16
13	Intraoperative image: hernia sac dissected and omentum was identified as a content	16
14	Intraoperative image: content reduced and defect size of 0.5x0.5 cm identified, which was closed primarily.	16
15	Dissection planes for anterior and posterior component separation technique	17
16	Structure of the heavy mesh vs light mesh	19
17	Different mesh locations for ventral hernia repair	21
18	Intraoperative image: port placement for laparoscopic IPOM repair	24

19	Intraoperative image: visualization of the defect after reducing the content	24
20	Intraoperative image: primary closure of the defect	24
21	Intraoperative image: mesh reinforcement over the closed defect	24

LIST OF ANNEXURES

Serial No.	Name of Table	Page No.
Ι	Informed consent form (English)	58
II	Informed consent form (Hindi)	59
III	Patient information sheet (English)	60
IV	Patient information sheet (Hindi)	61
V	Patient proforma	62
VI	Ethical clearance certificate	65
VII	Key to master chart	66
VIII	Master chart	-

SUMMARY OF THE PROJECT

Background: Ventral hernias are usually repaired by an open or laparoscopic approach. Quality of life after ventral hernia repair is a very important but often underestimated parameter. This prospective observational study was conducted to assess the quality of life and other related parameters after all types of ventral hernia repair, mainly between open and laparoscopic repairs.

Objectives: This study aimed to determine the quality of life after ventral hernia repairs. We also analysed and compared various parameters such as outcomes and satisfaction, postoperative pain, and complications between laparoscopic and open ventral hernia repair.

Methods: This was a hospital-based prospective observational study conducted from January 2020 to December 2021, which included a total of 70 patients with ventral hernias. 39 patients underwent open repair and 31 patients underwent laparoscopic repair. Demographic data and other data such as postoperative hospital stay, return to activity, post-operative pain, complications, and quality of life were collected and analyzed using SPSS version 28.

Results: The distribution of different types of hernias observed in our study included 34% incisional hernias, 33% umbilical and paraumbilical hernias, and 33% epigastric hernias. The incidence of complications was significantly less in laparoscopic repair compared to open repair. Also, satisfaction at 1 month was significantly more in the laparoscopic group compared to the open group. However, there is no significant difference in the postoperative pain, postoperative hospital stay, return to activity, satisfaction at discharge, and quality of life at 1 month in both the laparoscopic and open repairs.

Conclusion: Laparoscopic ventral hernia repairs are associated with lesser complications and higher satisfaction. The use of tackers and trans-fascial sutures can significantly increase postoperative pain in laparoscopic repair and is the major factor affecting the short-term quality of life in laparoscopic repairs. As there is no difference in postoperative pain, hospital stay, and return to activity, laparoscopic repairs should be preferred wherever possible in view of fewer complications and high satisfaction.

INTRODUCTION

Ventral hernia of the abdomen is defined as a protrusion of the abdominal viscera through a non-hiatal, non-inguinal defect in the fascia of the abdominal wall. (1) They are commonly seen in clinical practice. Patients usually present with swelling or bulge over the abdomen, which is usually reducible on lying down. Sometimes it may be associated with dull aching pain. (2)

Ventral hernias include umbilical, epigastric, spigelian, lumbar, and incisional hernia. (1) According to the European Hernia Society, ventral hernias are classified as primary ventral hernia and incisional hernia. A primary ventral hernia occurs over the previously normal skin while an incisional hernia occurs over the incision of a previously operated site. They are further divided based upon the length and width of the defect size. (3)

Microscopic tissue tears secondary to repetitive stresses are responsible for the pathogenesis of ventral hernia. The main factors responsible for it are chronic cough, urinary straining, constipation, pregnancy, and obesity amongst many others. (4)

Ventral hernias are usually repaired by an open or laparoscopic approach. Recently many surgeons prefer a hybrid approach, mainly for incisional hernia repair. (5) Laparoscopic hernia repairs are usually associated with less postoperative pain, wound infections, and significantly improved quality of life in the long term. (6)

Numerous research has already been done comparing the long-term quality of life before and after individual umbilical, incisional, and other subtypes of ventral hernias. (7–15)

However, there is very minimal research material available comparing the short-term quality of life after all types of ventral hernia repairs. Also, there is very little data available for short-term quality of life after ventral hernia repair in India.

Hence, this prospective observational study is conducted to assess the quality of life after all types of ventral hernia repair, be it open or laparoscopic, small or large, repaired primarily or with mesh hernioplasty.

1

REVIEW OF LITERATURE

HISTORY:

The first described treatment of ventral hernia was heat application to the hernia, to imprison the illness in the belly of the patient, back in the 16th century. (16) Abdomen closure by layers was first described by Celsus 100AD. Pierre Nicholas Gerdy documented the first-ever surgery for incisional hernia which included inversion of hernial sac into the abdominal cavity with ammonia injection in the sac to form adhesions followed by defect closure.

With evolution, different surgeons proposed different approaches. In the 18th and 19th centuries, Maydl and Quenu popularized simple suturing of the edges of the hernia defect. (17) Mass closure of the wall by placing a figure of 8 sutures was suggested by Frappier. In 1899, Mayo suggested overlapping transverse closure of the aponeurotic layer for umbilical hernia repair. But none of these surgeries resulted in satisfying clinical outcomes.

Loewe used skin grafts to repair an incisional hernia (1913) followed by rectus muscle transplantation by Nutall in 1926. Other graft options including periosteum, cartilage, dura, fascia lata, and decalcified bone have also been used. (18,19) However, problems arose due to donor site defects along with vascular and denervation compromise, which was associated with higher recurrence rates.

Higher failure rates of suturing and grafts prompted surgeons to invent other new methods. Many materials were introduced including silver, gold, titanium, and brass. But recurrence rate was still high. (20) Polypropylene was discovered by Giulio Natta and Karl Ziegler in 1961 and was first used by Francis Usher for hernia repair in 1963. Since then polypropylene has become the standard material for developing mesh.

A lot of research has been done regarding the association of pain with pore size and weight of the mesh. The ideal mesh should have the strength of heavyweight mesh and flexibility of lightweight mesh along with very fewer rates of infection and complications. However, there is no ideal mesh available to date. Prosthetic mesh is associated with less recurrence rates compared to simple suturing. (21)

Another problem faced by the surgeons was to find the ideal plane for mesh placement amongst onlay, inlay, and sublay. Mesh is positioned over the sutured anterior fascia in onlay, between the medial edges of a defect in inlay, and in the retromuscular or preperitoneal spaces in sublay, respectively. Sublay placement of the mesh is associated with the lowest risk of infections and recurrences.

Anterior component separation technique for large hernias was described by Ramirez et al. It involves creating a space between subcutaneous fat and anterior rectus sheath followed by incision of external oblique 2 cm lateral to rectus, giving up to 8-10 cm gain for medialization of the rectus muscle. However, this technique is associated with high recurrence and complications rates as high as 50%. (22,23) Carbonell et al. reported a posterior component separation technique with the placement of large mesh in the retro-muscular space. (24) This technique has a low recurrence and complications rate (15%) compared to anterior component separation.

Pauli et al. reported transversus abdominis release technique (TAR) for complicated hernias with loss of domain. (25) Dissection is done between transversus abdominis and transversalis fascia or the peritoneum. This technique gives even wider space than component separation techniques. It is associated with 3% recurrence and 45% complications rates. (25,26)

Up to 1993, open repair was very popular for ventral hernia repair. However, minimally invasive laparoscopic techniques have gained popularity after that and nowadays, around 20 to 27% of ventral hernia repairs are performed laparoscopically. (27) It usually includes entering into the peritoneum, insufflation, adhesiolysis around the sac, content reduction with or without defect closure followed by mesh placement. (28)

Hans Christian Jacobeus first described the term 'laparoscopy' in 1929. Heinz Kalk, who is known as the 'father of modern laparoscopy' invented the first forward

viewing laparoscope. (29) LeBlanc and Booth performed the first laparoscopic ventral hernia repair in 1993. (30)

Initially, polypropylene and polyester meshes were in use. However, due to the formation of extensive bowel to mesh adhesions, the concept of coated mesh became prevalent. (31) Composite mesh is developed for Intraperitoneal onlay mesh hernioplasty (IPOM). It has the strength of synthetic mesh along with a protective antiadhesive coating on one side. (31) Recently absorbable meshes are also being developed for contaminated fields. However, the disadvantage is the decreased strength due to absorption.

Over the years, there have been many updates regarding the number of sutures, number of tacks along with the material of tacks and sutures used for fixation. (32) Fibrin sealant is the new alternative to tackers and sutures, which is less invasive and less painful. (33) However, it is associated with high recurrence rates and is not used routinely.

A tension-free mesh repair is traditionally considered the gold standard for ventral hernia repair. However, defect closure before mesh placement is an evolving technique. It reduces postoperative bulging and gives more strength to the abdominal wall, resulting in less recurrence. However, it is associated with more pain and tension. Rosen et al introduced the laparoscopic component separation technique. (34) It is associated with less recurrence and wound complications (35,36)

Robotic ventral hernia repair has recently been popularized due to seven degrees of freedom of instruments with superior maneuverability along with a three-dimensional high-definition view. (37)

Secondary to the development of new techniques and materials, recurrence rates have decreased significantly, leading to improved long-term quality of life. However, immediate postoperative quality of life is significantly disturbed due to pain and functional limitations secondary to the increasing trend of applying tackers and sutures. This study aims to compare the immediate postoperative quality of life after all types of ventral hernia repairs.

ANATOMY OF ANTERIOR ABDOMINAL WALL:

The abdominal cavity is surrounded by the abdominal wall, which protects many important organs. (38,39)

Structure and Function: The main function of the abdominal wall is to protect the abdominal viscera along with giving a durable covering to prevent the viscera from leaving the abdominal cavity. It also maintains the anatomical position of the abdominal organs. It also assists respiration, mainly expiration by pushing the diaphragm upwards by raising intra-abdominal pressure. Similarly, by increasing intra-abdominal pressure, it also assists in coughing and vomiting.

Layers of the anterior abdominal wall:

- Skin,
- Subcutaneous tissue it forms the thin, single layer above the umbilicus while below the umbilicus, it is divided into two layers (1) Camper's fascia superficial fatty layer (2) Scarpa's fascia deep fascial layer. Between these 2 layers, blood vessels and nerves travel.
- Abdominal wall muscles External oblique, internal oblique, transversus abdominis
- Fascia transversalis,
- Preperitoneal fat
- Parietal peritoneum.



Figure 1: Layers of the anterior abdominal wall (40)

Embryology: The embryo starts to fold in both axis at around the second week of intrauterine life. During this stage, abdominal wall formation starts. Various growth factors help in this process by cellular migration, multiplication, differentiation, and deposition of cells at different sites. At 6 to 10 weeks, proper abdominal wall development starts and congenital defects of the anterior abdominal wall usually occur at this stage.

The ectoderm forms the skin of the abdominal wall while the mesoblast helps in the formation of basic abdominal wall structures. The embryo folds more and more in all four directions: caudal, cranial, and laterally on each side. The cranial fold makes thoracic and epigastric components. The caudal fold forms hypogastrium including hindgut and bladder, and the lateral folds lead to the formation of the midgut and lateral abdominal walls.

Rotation of the midgut usually returns back to the abdomen by 10 to 12 weeks. If it does not return, it will lead to the herniation of abdominal contents known as omphalocele (if covered by membranes) or gastroschisis (if not covered by membranes).

Muscles of the abdominal wall:

They are total of five in number: three flat muscles and two vertical muscles. Flat muscles flex and rotate the trunk, and also prevent herniation.



Figure 2: Muscles of the anterior abdominal wall (40)

Flat Muscles:

- External Oblique It is the largest and most superficial muscle of the abdomen. The fibers are directed in an infero-medial direction, form an aponeurosis and meet at linea alba in the midline. It is extended from the xiphoid process to the pubic symphysis.
- 2. Internal Oblique It is much thinner and smaller compared to the external oblique and located deep to it. It also forms aponeurosis and merges at the linea alba.
- **3.** Transversus abdominis It is the deepest flat muscle and runs transversely. It also merges in the midline at the linea alba. The transversalis fascia is just beneath this muscle.

Vertical Muscles:

- 4. Rectus Abdominis A paired muscle located on both sides of the midline. The lateral border of the muscle is known as linea semilunaris. It is intersected by fibrous intersections at several locations, which is known to give the appearance of "six-packs". It protects and prevents herniation of the abdominal viscera.
- **5.** Pyramidalis vertical triangular muscle located superficial to the rectus abdominis and at the base of the pubic bone. The apex is attached to the linea alba.

Rectus Sheath: It is an aponeurosis contributed by the five muscles of the abdomen and located on both the anterior and posterior walls of the rectus muscle for most of its length. The anterior wall is formed by external oblique aponeurosis and anterior half of the internal oblique. While the posterior half of the internal oblique and transversus abdominis form the posterior wall. The midpoint of the umbilicus and public symphysis is known as arcuate line and inferior to it, only anterior sheath is present and posterior sheath is absent. At this point, rectus muscle is in direct contact with the transversalis fascia.

Blood Supply and Lymphatics: Arterial supply:

- Superior epigastric artery a branch of internal mammary artery
- Inferior epigastric artery a branch of external iliac artery
- Deep circumflex iliac artery
- Superficial epigastric artery
- Superficial circumflex iliac artery
- Six most inferior intercostal arteries



Figure 3: Formation of rectus sheath above the umbilicus (41)



Figure 4: Formation of rectus sheath below the umbilicus (41)

Venous drainage:

• It runs parallel to the arteries. Blood above the umbilicus drains into SVC and below the umbilicus drains into IVC.

Lymphatic drainage:

• Lymphatic drains run parallel to venous drains. Lymphatics above the umbilicus drain into the axillary lymph node basin and below the umbilicus drain into the inguinal lymph node basin.



Figure 5: Neurovascular supply of the anterior abdominal wall (40)

Nerves:

- Lower 6 intercostal nerves
- Ilioinguinal nerve
- Iliohypogastric nerve

Surgical Considerations:

Surgeons must need to understand the abdominal wall anatomy so that the correct incision is made and future hernia and other complications can be prevented. (42)

Types of incisions:

- A midline incision is made through the linea alba with a slight curve at the umbilicus. The blood loss is minimal because of the poor vascularity of linea alba. Also, nerves are not excised. Perhaps this is the most versatile incision for approaching abdominal organs.
- A paramedian is an incision made just lateral to the linea alba. It is better for getting access to the spleen, adrenal, and kidney. However, it is rarely used today as it requires ligation of blood vessels and cutting of nerves.
- A transverse incision is usually made below the umbilicus. But because of its poor healing, it is rarely used today.



Figure 6: Various types of incisions over the anterior abdominal wall (43) **A.** Clockwise from the upper right quadrant are subcostal (Kocher), thoracoabdominal, left lower quadrant, vertical midline, and Rockey-Davis (transverse)/McBurney (oblique). **B.** From superior to inferior are bilateral subcostal with vertical T extension, supraumbilical transverse, infraumbilical transverse, left paramedian, and pfannenstiel incision

- Pfannenstiel or suprapubic transverse incision is made just few centimeters above the pubis. The bladder must be emptied before making the incision, to prevent injury.
- A subcostal incision is made just below the rib cage and allows access to the gallbladder or spleen. It has a limited exposure.
- McBurney's incision is located at one-third distance from the anterior superior iliac spine on the spino-umbilical line. It is consisting of splitting the muscle fibers instead of cutting them. It is commonly used in open appendectomy.

Clinical Significance: The major pathology of the anterior abdominal wall are hernias that include the following:

- Femoral hernias
- Inguinal hernias
- Epigastric hernias
- Umbilical hernias
- Incisional hernias
- Spigelian hernias
- Lumbar hernias

Except for femoral and inguinal hernias, rest of the above hernias come under the 'umbrella' of ventral hernias.



Figure 7: Various types of hernias over the abdominal wall (40)

ETIOPATHOGENESIS OF INTESTINAL OBSTRUCTION:

Risk Factors: A rise in the intra-abdominal pressure may lead to the development of ventral hernia and any condition contributing to an increase in the intra-abdominal pressure is a risk factor for ventral hernia. Some of the common risk factors include (44):

- Chronic cough and COPD
- Straining during defecation or urination
- Constipation
- Heavy weight lifting
- Ascites
- Ventriculoperitoneal shunt
- Family history of hernias

Demographics: As high as 10% of the world population develop some type of hernia during their lifetime. Out of which nearly 75% are the inguinal hernias with a male to female ratio of 7:1. (45) However, the second most common type of hernias are ventral hernias accounting for 24% with a female to male ratio of 2:1, amongst which 14% are umbilical and 10% are incisional hernias. (46) Rest of the hernias include femoral, interparietal, and lumbar.

Males are more prone for developing epigastric hernias with a ratio of 3:1 while umbilical hernias are more common in females with a ratio of 3:1. Similarly, incisional hernias are also more common in females with a ratio of 2:1. (44) Incident data from developing countries is limited but current literature suggests it is similar to more developed countries.

CLINICAL FEATURES OF VENTRAL HERNIAS:

It varies according to hernia size and location. It can be asymptomatic if small or may present with intermittent pain and discomfort. The most common complaint is localized swelling or bulge in the abdominal wall. Coughing or straining aggravates the symptoms. If the hernia is large, overlying skin may be erythematous or ulcerated. Ventral hernias can also present with complications secondary to the incarceration of bowel in the defect. Severe pain, vomiting, and abdominal distension are the predominant features in this situation.



Figure 8: An irreducible umbilical hernia with a defect size of 3x3 cm



Figure 9: A reducible lower midline incisional hernia with a defect size of 4x5 cm



Figure 10: A reducible incisional hernia with a defect size of 5x5 cm



Figure 11: A small umbilical hernia with a defect size of 0.5x0.5 cm

The examination should be done in both standing and supine positions. The cardinal signs of the hernia are cough impulse and reducibility. Supine position allows to check for reducibility. For non-obese patients, edges of the defect can be palpable. Sometimes, more than one defect can be palpated in large hernias.

INVESTIGATIONS:

A hernia is a clinical diagnosis and majority of the hernias can be diagnosed with proper history and clinical examination. However, hernias in obese patients and very small hernias require imaging to diagnose. It helps in patients with abdominal pain without a palpable hernia, or in obese patients for defect size measurements when planning the surgical approach. (47,48) CT is the best investigation for confirmation of diagnosis along with content, numbers, and size of the defect. (49)

MANAGEMENT OF VENTRAL HERNIAS:

Management differs according to the type and size of the hernia. Surgeon preference is also an important factor affecting the treatment plan. Primary ventral hernias occur without previous incision or surgeries and include umbilical, epigastric, spigelian, and lumbar hernias. Incisional hernias occur at the site of a previous incision or surgery.

The recurrence rate of primary and incisional hernia is 5-10% and 25-40% respectively.

Small ventral hernia (defect size <1 cm):

These hernias can be repaired primarily with sutures and with or without mesh placement. (47,50) They can be repaired typically by open technique. Laparoscopic repair in such small hernias is often more invasive but may be considered for obese patients or patients with an increased risk of wound infections. Open suture repair also known as open herniorrhaphy is a simple straightforward option for these small primary hernias.

The procedure includes identification of the defect and making the incision over it. The sac should be identified and dissected from the surrounding tissue. The contents reduced and fascial defect should be closed with mass closure technique. The closing technique and suture material are determined by the surgeon's preference but nonabsorbable continuous sutures are preferred (47). Mesh repairs are usually preferred only when there is a thinned-out linea abla (51,52). Mesh can also be placed with minimally invasive techniques. Small Incisional hernias usually occur at the previous port site of laparoscopic surgery. They should be repaired with mesh reinforcement because simple suture repairing usually results in recurrence.



Clockwise, Figure 12: A small umbilical hernia

Figure 13: Hernia sac dissected and omentum was identified as a content Figure 14: Content reduced and defect size of 0.5x0.5 cm identified, which was closed primarily.

Medium size ventral hernia (defect size 1-10 cm):

It includes majority of the ventral hernias in clinical practice. These hernias usually require mesh reinforcement. They are also divided into two groups:

- **1.** Defect size 1-4 cm: Open repair is usually preferred. Minimally invasive repair can be done in obese patients or in patients with risk factors of developing wound infections.
- Defect size 4-10 cm: Minimally invasive repair is usually preferred.
 (53)

Large ventral hernias (defect size >10 cm) or complex hernias:

These hernias are usually difficult to repair. (54) Complex hernias are mostly associated with loss of domain with half of the abdominal contents outside the abdominal cavity.

They can be treated with a component separation technique or open inlay technique.



Figure 15: Dissection planes for anterior and posterior component separation technique (43)

Minimally invasive underlay is also an option. Laparoscopic repairs are associated with lower infection rates, less pain, and shorter recovery period. Large ventral hernias with loss of domain require anterior or posterior component separation technique, invented by Ramirez (55), in which fascia is approximated first and defect is closed primarily followed by mesh reinforcement. This technique can lead to a gain

of as much as 10 cm on both the sides of the defect and allows primary closure of a large defect. It also restores the abdominal wall function. (56) Transverse abdominis release (TAR) can also be used to facilitate posterior sheath closure, which is useful in defects less than 10 cm.

SELECTION OF SURGICAL APPROACH:

Simple primary repair of the defect can be done with an open approach while mesh reinforcement and component separation can be done via laparoscopic, open, or robotic approach. The general practice is the open repair for very small (<1 cm) and very large hernias (>10 cm), while any of the three approaches for hernias with size 110 cm. Laparoscopic intraperitoneal onlay mesh (IPOM) and IPOM PLUS (IPOM along with laparoscopic primary closure of the defect) have shown very favorable results in terms of wound infection and quality of life (57). Intraperitoneal mesh placement is usually associated with adhesions and related complications which can be minimized by using composite mesh. (58–62) Also, to prevent these adhesions in open repairs, mesh is usually placed in the retro-rectus but extraperitoneal position (Rives-Stoppa repair).

Robotic technique can be similar to any of the laparoscopic IPOM or open RivesStoppa repair. When robotic surgery is not available, laparoscopic repair should be preferred over the open repair for hernias of 1-10 cm defect size as laparoscopic repair is associated with less pain, lower mesh, and surgical site infections, and faster recovery. (63–66) There is no difference in bleeding, hematoma, seroma, and recurrence. Laparoscopic approach is considered for obese patients, patients with comorbidities and smokers, and those who have a high risk of wound infections. Also, it is good for hernias <10 cm in size and off-midline hernias. Open approach is preferred for low-risk patients and small midline hernias. It is also preferred for complex hernias with loss of domain or contamination or large defects.

If robotic surgery is available, then selection between laparoscopic and robotic is dependent on the surgeon's expertise, confidence, and preference. Two trials comparing hernias of <4 cm showed that robotic approach has similar outcomes but is associated with higher cost and longer operative time. (67,68)

Non-mesh vs mesh repair:

Mesh repair should be done in all ventral hernias with a defect size of >1 cm with a clean field. (50) Mesh placement is associated with decreased recurrence. (60,69–71) However, wound complications are more common in mesh repair compared to nonmesh repair. (58,59,62,71) Intraperitoneal mesh can also lead to the formation of adhesions and related complications. (58,62) A meta-analysis conducted in 2017 has shown that mesh placement increases the risk of surgical site infection but decreases the risk of hernia recurrence. (72) **Mesh material:**

Mesh can be biologic, synthetic, or bio-synthetic.

1. Synthetic - It can be made up of Polypropylene/polyester or ePTFE (expanded polytetrafluoroethylene). For elective ventral hernia repairs, lightweight meshes should be avoided because of the increased risk of recurrence, although associated with less pain. (71) Medium to heavyweight meshes should be preferred therefore and there is no difference in outcome between medium and heavyweight mesh.



Figure 16: Structure of the heavy mesh vs light mesh (73)

2. Biologic – It may be derived from animals (bovine, porcine, equine) or human tissues (74). Biologic tissue undergoes a washing process to remove cellular components and so only connective tissue scaffold is left. This will lead to nonimmunogenic property of the mesh. (74) Biological mesh can be used in the infected or contaminated fields and also in patients with a high risk of surgical site infections. (75) However, this area is controversial because most studies are retrospective, small, and with selection bias. It is suggested to use

biological mesh only as a reinforcing layer, not as a fascial replacement. (76) Biological meshes resorb over time and so are associated with high recurrence. (77) According to the LAPSIS trial, biologic mesh is associated with more complications after both open and laparoscopic repair.

3. Biosynthetic – These meshes get resorb between 6 to 36 months. This will lead to more native collagen deposition, more wound strength, and durability without the risk of infection that is associated with synthetic mesh. There is very little data available for these meshes and are not used commonly.

Mesh selection:

Hernia mesh selection primarily depends on the type of wound:

- For clean wounds synthetic mesh is preferred
- For clean-contaminated or contaminated wounds biologic or bio-synthetic mesh should be preferred. (78)
- For dirty infected wounds simple primary closure and delayed staged repair should be the choice of approach. (79) It is not a wise decision to put any mesh in dirty wounds.

Location of the mesh:

It can be onlay (above the fascia), sublay (between the rectus and posterior rectus sheath), underlay (below peritoneum), or inlay (between fascial edges). The inlay technique is used only when the defect is too large to be closed. Sublay mesh repair is usually preferred for open repair, compared to onlay. Underlay mesh is usually preferred for laparoscopic repair. For robotic repair, the mesh can be placed in underlay or sublay. Sublay and underlay mesh placements are associated with less recurrence and complications compared to onlay and inlay techniques. (71,72)

- Onlay Chevrel developed this technique. The defect is closed primarily and a mesh is placed anterior to the fascia. This method is easier to perform but associated with higher complications. (72)
- Sublay Rives, and Stoppa first described this technique via an open approach. The plane of dissection is between the rectus muscle and the

posterior rectus sheath. Mesh is placed anterior to posterior rectus sheath after suturing the defect.

• Underlay - Here, mesh is placed intraperitoneally and fixed with posterior rectus sheath or peritoneum. It can be performed with an open or laparoscopic approach.



Figure 17: Different mesh locations for ventral hernia repair (40)

Mesh size for open repair:

- For defect <1 cm minimum 2 cm overlap around the defect circumferentially.
- For defect >3 cm minimum 3 cm overlap around the defect circumferentially.
- For defect >5 cm or Incisional hernias Minimum 5 cm overlap circumferentially

SPECIAL CIRCUMSTANCES:

Recurrent hernia - It is again a clinical diagnosis. The underlying cause may be multifactorial or may be due to defective mesh placement, pulled mesh, subsequent surgery, or obesity. The rate of recurrence increases with each additional repair performed. (80) Repeated repairs lead to formation the of vicious cycle of complications that includes recurrence followed by reoperation followed by another recurrence due to complications. (80) Due to high recurrence with repeated repairs, these hernias should be repaired with mesh implantation or component separation. Type of the mesh used in the repair is not associated with recurrence.

LAPAROSCOPIC REPAIR:

Most of the ventral hernias can be repaired laparoscopically. The decision depends mainly on expertise, training, and preference. Any condition that is contraindicated for laparoscopy is also a contraindication for laparoscopic ventral hernia repair, which includes the inability to tolerate pneumoperitoneum, hostile abdomen with a history of multiple abdominal surgeries, severe injuries to abdomen or enterocutaneous fistula. (81) Relative contraindications include large ventral hernias with >8 to 10 cm defect size or loss of domain or having intestinal obstruction. These hernias should be repaired via an open approach.

Position of the patient: Patient is in a supine position with arms by the side. Foley's catheter insertion should be done if any history of urinary retention or expected duration of more than 2 hours or lower midline hernias. Ryle's tube placement may be required if peritoneal cavity entry is to be done via Palmer's point (left hypochondrium).

Entry and port placement: The entry should be done at the point where the surgeon is most experienced with (48) as there is no evidence of any single point superiority. (82) Most common point for the entry is Palmer's point (left subcostal area, lateral to midclavicular line). Blunt tip trocars should be preferred. Two to three 5 mm working ports should be placed along the lateral abdominal wall. 10 mm port should be avoided in the lateral abdominal wall due to the risk of port-site hernia.
Adhesiolysis: It is important for reduction of content, mesh placement, and fixation. Bowel injury should be avoided. (48) For hernias near the falciform ligament, it should be taken down to completely visualize the fascial defect.

Fascial closure: Fascial defects should be closed vertically with sutures placed 1 cm apart. (83,84) Mesh reinforcement should be done in all ventral hernia repairs done laparoscopically. Mesh should overlap at least 5 cm circumferential to the defect or the radius of the mesh should be four times more than the radius of the fascial defect. (48,85) Before insertion, four 0 polydioxanone sutures to be placed on the mesh for trans-fascial fixation. Hybrid IPOM is an alternate approach where a small incision is given over the hernia, sac opened, content reduced, mesh introduced inside the peritoneal cavity, and defect closed primarily followed by laparoscopic mesh fixation. It is useful in patients with irreducible and difficult hernias.

Minimally invasive component separation is better to open component separation, in terms of complications. However, there is no strong evidence to support it. Also, minimal surgeries are technically difficult and have higher learning curve. New approaches such as e-TEP (enhanced view totally extraperitoneal) are in the experimental phase and no strong evidence exist. (86)

Mesh can be fixed with trans-fascial sutures and one or two rows of tackers (single crown or double crown technique). (28)

Closure: After ensuring hemostasis and excluding any visceral injury, the peritoneal cavity is de-sufflated, trocars removed and skin closure done.



Clockwise, Figure 18: Port placement for laparoscopic IPOM repair

Figure 19: Visualization of the defect after reducing the content

Figure 20: Primary closure of the defect

Figure 21: Mesh reinforcement over the closed defect

Postoperative period: patients can be discharged on the same or the next day under enhanced recovery protocols. However, there is evidence of increasing pain with more numbers of tackers and it can directly affect the immediate quality of life postoperatively. Generally, meshes should be fixed to bone or ligaments such as cooper's ligaments, ribs, or pubic symphysis which are stronger than anterior abdominal wall muscles. For superior hernias, a part of the mesh should be left overhanged over the diaphragm without fixation.

LeBlanc was the pioneer of the intraperitoneal mesh placement technique (87). Although there is a very low chance of postoperative complications, intraperitoneal placement is superior to other placement locations in terms of surgical site infections. (72) Recently TAPP (transabdominal preperitoneal) and TEP (total extraperitoneal) approaches are also being introduced for ventral hernia repair because of the low cost of mesh and wide area of mesh placement by posterior component separation. (86) However, more research is needed before implementing these techniques into routine use.

Complications: Around 15% of patients undergoing ventral hernia repair, develop complications in the postoperative period. Most common are wound complications (51%) followed by medical complications (42%) followed by surgical complications (29%). (88)

Some of the common complications include:

- Pain postoperative pain is common and often impairs immediate quality of life if severe. It can be due to nerve entrapment by tackers or sutures and can be managed by anti-inflammatory drugs, steroids, nerve block, or excision of sutures or tacks (85).
- Wound complications However, the incidence is less compared to open hernia, 2-4% of patients develop abdominal wall cellulitis surrounding the ports and can be treated with antibiotics (85). Mesh infection is very less (<1%). It should be treated with antibiotics, drainage of any collection, and/or debridement. However, excision is required if all attempts fail to salvage the mesh.
- Seromas they are commonly seen in the postoperative period and mostly resolve in 2-3 weeks. They can be aspirated under sterile conditions. If recurring, surgical drainage may be necessary (85). They can be prevented by intraoperative cauterization of the sac, primary closure of the fascial defect, and applying pressure dressings.
- Iatrogenic bowel injury It occurs in 0-14% of the patients during laparoscopic repair (89). It is in fact, the most common intraoperative complication during laparoscopic ventral hernia repair. (48) It should be included in the preoperative consent. Enterotomy should be repaired or resected. The procedure can be converted to open with mesh placement in the sublay position. 18% of the intraoperative bowel injuries are often missed.

They should be managed with reexploration and repair or resection and mesh removal in most cases. Delayed enterotomies are the most dreaded complications with 100% morbidity and 40% mortality (90). Intraoperative extra care must be taken if any suspicion of bowel injury happens.

- Prolonged ileus The incidence is less than open repair but some patients develop ileus for as long as 5-10 days. Treatment involves nil per oral, Ryle's tube aspiration, minimum narcotic use, and iv fluids.
- Recurrence it is very less (2.7%) as all laparoscopic hernias are repaired with mesh.
- Bulging of the mesh In some cases, the mesh can protrude through hernial defect if the defect was not closed intraoperatively. It would be difficult to differentiate between recurrence and bulging of mesh. For that reason, primary defect closure should be done if possible (91). If the patient is asymptomatic, watchful waiting can be done. If symptomatic, reapproximation of the fascia can be done with or without new mesh repair.

Quality of life: It is defined as a subjective evaluation of the health. It has mainly 3 components: physical health, psychological health, and social functioning. Although complications have been decreased after the invention of newer techniques, hernia surgery still exposes the patient to a major operation leading to some impairment in the quality of life. Quality of life outcomes such as pain, cosmesis, satisfaction, physical and psychological well-being are less often and less well reported. Proper care must be taken at each stage of the patient management, to improve the quality of life as much as possible.

There are many tools available to evaluate the quality of life. Despite the increasing need of QOL assessment, no tool has proven to be effective in this field. (92) Some of the commonly used tools are:

Carolina Comfort Scale (CCS): It is a hernia specific tool. It assesses QOL based on movement, daily functioning, mesh sensation, and pain across a 6point scale. It has been shown to be more sensitive than generic tools. (93–95)

- 2. Hernia-related QOL Survey (HerQLes): This is also an abdominal wall hernia specific tool. (96) It has 12 questions which allows patients to score their emotional and physical well-being. Each question is given a score of 1 to 6. Although used in very few studies, it is the most commonly used tool for measuring the quality of life after hernia repair.
- **3.** Modified Activities assessment scale (AAS): It is also a disease-specific tool for hernia. It assesses patient functioning and QOL by asking questions related to mood, physical activity, and lifestyle. It has not been used widely for QOL measurements after hernia surgery.
- **4. SF-36:** It is a non-specific generic tool used for assessing QOL in a wide range of health problems and it is the most widely used tool for that matter. It is often used with hernia specific tools. SF-12 is a truncated version of SF-36 shown to give comparable results. (97)
- 5. EQ-5D: It is a standard tool for the measurement of health related QOL. It consists of a questionnaire and a visual acuity scale EQ-VAS. QOL scores of EQ-5D are comparable to hernia specific QOL tool CCS (98). Few studies have used this tool for the assessment of QOL after ventral hernia repair.
- 6. WHOQOL-BREF: It is a generic short-form QOL assessment tool for physical, social, and psychological health. Although used widely for different health conditions, very few studies used this tool for the assessment of QOL after hernia repair.

Generic tools give an idea about general QOL perceived by the patient, whereas hernia specific QOL tools give an idea about the change in health and QOL as the result of a specific condition and/or focused treatment received for that. Generic tools are still the most commonly used tools for assessing QOL after ventral hernia repair. Disease specific tools are still not highly validated. Some studies have used generic, independently devised QOL tools. (92)

In this study, we used a self-made 12 questionnaire proforma to assess the QOL after ventral hernia repair. The questions were related to the physical, emotional, and social well-being of the patient. Each question was given a score of 1 to 5. The total score

of all questions was calculated. The mean QOL score was calculated and compared for laparoscopic and open ventral hernia repair.

Ecker et al (98): They performed a retrospective data analysis of all the patients who underwent ventral hernia repairs between 2007 to 2011. The data was collected from two large statewide databases from New York and California states. The primary objective was to compare the quality of life and longitudinal outcomes along with the cost between laparoscopic and open ventral hernia repairs. Any patient who underwent elective ventral hernia repair using mesh was included in the study. Patients <18 years of age, emergency repairs, or repairs with bowel resection were excluded from the study. The primary outcomes were readmission and re-surgery. Secondary outcomes were complications during index surgery, length of hospital stay, and total cost. After analysis of total 13567 patients who underwent elective ventral hernia repair, they found that open ventral hernia repair is associated with a significantly higher incidence of readmissions and re-surgeries. Also, it is associated with more postoperative complications, prolonged length of stay, and higher cost amounting to bad quality of life compared to laparoscopic ventral hernia repair.

Pruneda et al. (14): In this retrospective cohort study, conducted between 2013 to 2019, using data from American hernia society quality collaboration (AHSQC), they compared the postoperative quality of life between open vs robotic retro-muscular ventral hernia repair. The tool used was HerQLes at baseline and 1 year postoperatively. Secondary outcomes were wound complications, morbidity, and recurrence. Out of 236 total patients, 194 underwent open repair and 42 underwent robotic hernia repair. The quality of life at 1 year is comparable in both open and robotic repair. However, robotic repairs are associated with shorter hospital stay and comparable wound complications and recurrence at 1 year. An open approach should be preferred for larger defects.

Philipp et al. (9): In this retrospective observational study conducted at University medical center Rostock between 2012 to 2016, quality of life was compared between laparoscopic and open large ventral hernia repairs using component separation technique. The QOL score used was EQ-5D. The mean follow-up period was 19.5

months postoperatively. Out of 35 patients, 25 underwent open component separation technique and 10 underwent laparoscopic component separation technique. After analysis, they found that patients with open repair have longer hospital stay along with higher risk of major and minor complications. They observed faster recovery and overall higher quality of life in laparoscopic component separation compared to the open component separation technique. However, in long term, this effect diminishes and both show equal quality of life.

Malibary et al. (99): They performed a cross-sectional study of 45 patients who underwent umbilical hernia repair between January 2019 to December 2020 at King Abdul-Aziz University Hospital (KAUH), Jeddah, Saudi Arabia. The primary objective was to compare the quality of life after umbilical hernia repair with mesh and without mesh. The questionnaire used was the 'Carolina Comfort Scale' (CCS) which has 23 questions about 3 main parameters – the sensation of mesh, grade of pain, and limitation of movement in different situations. The total score was calculated for each patient and mean scores were compared between mesh and non-mesh groups. Of 45 patients, 29 patients underwent mesh repair with mean CCS of 4.57 and 14 patients underwent nonmesh repair with mean CCS of 3.00 (p 0.720). They found that the difference in the quality of life between mesh vs non-mesh repair is not statistically significant. However, males of the mesh group had significantly better CCS compared to the males of the nonmesh group. Although in this study, laparoscopic repair is associated with more complications and hospital stay, there is no statistically significant difference between laparoscopic and open hernia repair.

Kumar et al. (100): This was a prospective observational study performed between June 2015 to June 2017 at St. Isabel hospital, Chennai. The primary objective was to compare the quality of life preoperatively and postoperatively in all patients undergoing ventral hernia repair. Patients <18 years, lumbar and parastomal hernias, and complicated ventral hernias were excluded from the study. They used two scores to measure the quality of life. 1) HerQLes 2) CCS. The mean scores were calculated for different variables including age, sex, comorbidities, defect size, and mesh placement. The scores were compared and the difference was evaluated. After studying 90 patients, it was found that there is a significant improvement in QOL after ventral hernia repairs compared to preoperatively. They also found that QOL is better after small hernia repairs (<3 cm) compared to large hernia repairs (>3 cm). Both HERQLES and CCS are equally acceptable to Indian patients and can be used for measuring the quality of life.

AIM AND OBJECTIVES

AIM

To assess the quality of life at 1 month postoperatively after ventral hernia repair.

OBJECTIVES

- 1. To compare outcome and satisfaction among the patients who are treated by open vs laparoscopic ventral hernia repair.
- 2. To measure and compare the quality of life by QOL assessment scale at 1 month postoperatively in patients operated with open and laparoscopic ventral hernia repair.
- 3. To assess and compare postoperative pain in patients operated with open and laparoscopic ventral hernia repair.
- To assess and compare postoperative complications like wound infections, seroma, hematoma, mesh infection in patients operated with open and laparoscopic ventral hernia repair.
- 5. To assess and compare the quality of life at 1 month after large (>7 cm) and small (<7 cm) ventral hernia repair.

MATERIAL AND METHODS

Study setting

This study was conducted in patients operated for ventral hernia in AIIMS Jodhpur, a tertiary care hospital in Rajasthan, India.

Study design

Hospital based prospective observational study

Study duration

After approval of the Institutional Ethics Committee, the study was conducted from January 2020 to December 2021.

Sampling

Time-bound study which included cases from January 2020 to December 2021 after applying inclusion and exclusion criteria. We were expecting a sample size of 100 over the period of 2 years, but due to the shut-down of elective operations in the COVID-19 Pandemic, we could not complete the sample size. Total of 70 patients met the inclusion criteria and were included in this study.

Study participants

Inclusion Criteria:

• Patients (>18 years of age) presented with ventral hernias who were operated electively in our hospital, were included after obtaining written consent.

Exclusion Criteria:

- Patients who presented to acute surgical care unit in view of surgical emergencies like acute intestinal obstruction.
- Lumbar hernias.
- Mentally disabled patients.

Data collection:

This was a single-center prospective observational study conducted at AIIMS Jodhpur. Patients presented with ventral hernias between 1 January 2020 to 31st December 2021, who met the inclusion criteria, were included. The study was approved by the Ethical Committee of AIIMS Jodhpur, Rajasthan, India. All procedures followed were in accordance with the ethical standards of the responsible committee on human experiments (institutional and national). Informed consent was obtained from all patients for being included in the study.

For the proper record, a proforma is prepared for the study. All patients involved in the study underwent a detailed clinical examination and a detailed history according to the designed proforma. The demographic data of the patient, risk factors, comorbidities, previous surgical history, investigations, type, and size of the hernia, defect size, content of the hernia were collected pre-operatively. All patients were explained about surgical options available and were given the freedom to choose the surgery they want to undergo. Patients then underwent surgery by laparoscopic or open technique. Intraoperative data such as findings, procedure performed, drain placement, complications, and need for conversion, were also noted.

Post-operative data such as pain on day 1 and on discharge, wound complications, other systemic complications, drain removal day, postoperative ICU care requirement, postoperative hospital stay, and condition at discharge were also collected for each patient.

Postoperative pain is a significant factor affecting the immediate quality of life after ventral hernia repair. For postoperative pain score measurement, we used the VAS scale. Patient was asked to quantify the pain on a scale of 1 to 10. The more the number, the severe is the pain. We took 3 serial VAS scores at the intervals of 12 hours each and calculated the average pain score from them. We also calculated number of analgesic dosage required for each patient in postoperative period.

For determining the outcome, we measured two parameters: Average hospital stay (in days) and average time to return to activity (in days). Return to activity was considered when patient was completely ambulated and performing routine activities without any pain. Both of these variables were compared between laparoscopic and open ventral hernia repairs.

For measuring satisfaction, we asked the patient to quantify the feeling of satisfaction after the surgery, on a scale of 1 to 10, where 1 is 'very unsatisfied' and 10 is 'highly satisfied'. Mean satisfaction scores at discharge and at 1 month were calculated and compared between laparoscopic and open groups.

We also assessed the patients for postoperative complications within 1 month of the surgery. The wound was assessed for any seroma, hematoma, or infection. Also, complications like continuous pain at 1 month, postoperative ileus, and need for the relaparoscopy were assessed. The incidence of complications was calculated and compared between laparoscopic and open surgeries. Drain was removed when the collection was less than 30 ml per day. Patients were discharged with stable vitals.

After discharge, patients were assessed for quality of life at 30 days postoperatively by the self-made quality of life assessment questionnaire, consisting of 12 questions. The questions were related to the physical, emotional, and social well-being of the patient.

Each question was given a score of 1 to 5, 1 being the 'strongly disagree' and 5 being the 'strongly agree'. The total score of all questions was calculated. The lower the score, the better the quality of life. The mean QOL score at 1st month was calculated and compared for laparoscopic and open ventral hernia repair. The mean QOL score of large and small ventral hernias was also calculated and compared between these two groups.

All data were entered in a patient proforma by the resident in the ward and finally compiled in Microsoft Excel sheet.

Statistical analysis:

Data was entered and analyzed using SPSS version 28. Nominal data were described using frequency or percentages and compared using chi-square test or Fischer exact test. Ordinal data were described using median and interquartile range (IQR) and compared using the Mann-Whitney U test. Continuous data were described using mean +/- SD and compared using unpaired t-test. P value of <0.05 was considered statistically significant.

Ethical consideration:

Ethical clearance was obtained from the Institutional Ethical Committee (IEC). Patients were enrolled after taking informed consent. Patient details were kept confidential. No compromise in patient care was done.

RESULTS

Total 70 patients were included in this study. 39 patients underwent open ventral hernia repair and 31 patients underwent laparoscopic ventral hernia repair. Quality of life was compared in both the groups along with other outcomes including postoperative pain, analgesic usage, postoperative hospital stay, return to activity, postoperative complications, and satisfaction. We also compared the quality of life between large and small ventral hernia repairs.

Demographic data:

Variables		No. of patients
	Male: 52.08 +/- 13.88	35
Age (years)	Female: 50.2 +/- 11.00	35
	Male	35
Gender	Female	35
	Hypertension	15
~	Diabetes	10
Comorbidities	Ischemic heart disease	3
	Asthma	4

Table 1: Distribution of different variables in the study

	Small (<7)	63
Defect size	Large (≥7)	7
	Open	39
Choice of treatment	Laparoscopic	31
	With drain	15
Drain placement	Without drain	55

The mean age of the male patients was 52.08 +/- 13.88 and of the female patients was 50.2 +/- 11.00. Total 35 male patients and 35 female patients participated in the study. The gender distribution in the study was found to be comparable. The co-morbidities associated with these patients included diabetes mellitus, hypertension, coronary artery disease, and asthma and they were not distributed evenly. 55 patients had no major risk factor for a hernia. However, 8 patients had constipation, 4 patients had chronic cough and 4 patients had difficulty in micturition. Out of 70 patients, 63 patients had small hernias and 7 patients had large hernias. Number of patients with large ventral hernias were very less compared to small hernia patients. 39 patients underwent open ventral hernia repair and 31 patients underwent laparoscopic ventral hernia repair. Out of 70, 15 patients required abdominal drain while 55 patients did not require any drain.



Graph 1: Various types of hernias in the patients studied.

Out of 70, 23 patients had epigastric hernia, 23 patients had umbilical & paraumbilical hernias, and 24 patients had incisional hernias. The distribution of different types of hernias was comparable.



Graph 2: Types of ventral hernia repairs done in the patients studied

The most common repair done was open primary repair in 18 patients (for small ventral hernias with defect <2 cm), followed by IPOM in 15 patients, followed by IPOM Plus in 11 patients, open retro-rectus mesh hernioplasty in 10 patients, and open preperitoneal mesh hernioplasty in 8 patients, TAR in 4 patients, open onlay mesh hernioplasty in 3 patients, and e-TEP in 1 patient.

Table 2: Numbers of	f laparoscopic	repairs	converted	to o	pen	repairs	and	reasons	for
that.									

Conversion to open	No. of pat	ients	Reason for conversion
X 7	~	4	Dense adhesions
Yes	5	1	Irreducible content
No	31		

Out of 36 patients who started as laparoscopic repairs, 5 procedures were converted to open repairs. Major reason for conversion was presence of dense adhesions in 4 patients and because of irreducible content in 1 patient.

Table 3: Comparison of quality of life (QOL) at 1st month between open and laparoscopic ventral hernia repairs.

Va	riables	No. of patients	Mean QOL score	SD	t value	p value
Choice of treatment	Open	39	23.8	11.9	1.332	0.187
ti cutiliciti	Laparoscopic	31	20.7	7.33		

p value calculated using independent t test

According to the above data, it is observed that there is no significant difference in the quality of life at 1^{st} month between open ventral hernia repair (QOL 23.8 +/-11.9) and laparoscopic ventral hernia repair (QOL 20.7 +/-7.33) with p value of 0.187.

Table 4: Comparison of outcome between open vs laparoscopic ventral hernia repairs. We have analyzed the outcome by considering two parameters: average hospital stay (in days) and return to activity (in days).

Variables	Open (Mean±SD)	Laparoscopic (Mean±SD)	p value	
Hospital stay	4.12±6.38	2.54±1.31	0.18	
Return to activity	3.07±1.89	3.09±1.68	0.963	

p value calculated using Mann Whitney u test

According to the above data, it is observed that there is no significant difference in the average postoperative hospital stay between open (4.12 +/- 6.38 days) and laparoscopic (2.54 +/- 1.31 days) ventral hernia repair with p value of 0.18. Also, there is no significant difference in return to activity between open (3.07 +/- 1.89 days) and laparoscopic (3.09 +/- 1.68) with p value of 0.963.

Variables	Open (Mean±SD)	Laparoscopic (Mean±SD)	p value	
Satisfaction score at discharge	8.25±1.27	8.45±0.96	0.685	
Satisfaction score at 1 st month	7.18±2.20	8.80±1.40	0.007	

Table 5: Comparison of satisfaction between open vs laparoscopic ventral hernia repairs.

p value calculated using Mann Whitney u test

There is no significant difference in the satisfaction score at discharge between open (8.25 ± 1.27) and laparoscopic (8.45 ± 0.96) ventral hernia repair with p value of 0.685. However, there is a significant difference in the satisfaction score at 1st month between open (7.18 ± 2.20) and laparoscopic (8.80 ± 1.40) ventral hernia repair with p value of 0.007. Laparoscopic hernia repairs are associated with more satisfaction compared to open hernia repairs.

Table 6: Comparison of postoperative pain (VAS score) and analgesic usage (average number of doses) between open vs laparoscopic ventral hernia repairs.

Variables	Open (Mean±SD)	Laparoscopic (Mean±SD)	p value
Average pain score	5.49±2.24	6.03±1.99	0.292
Analgesic usage	2.15±2.97	6.06±3.07	0.216

p value calculated using Mann Whitney u test

There is no significant difference in the postoperative pain between open (5.49 +/-2.24) and laparoscopic ventral hernia repair (6.03 +/-1.99) with p value of 0.292. Also, there is no significant difference in the average analgesic dose usage between open (2.15 +/-2.97) and laparoscopic ventral hernia repair (6.06 +/-3.07) with p value of 0.216. However, laparoscopic repairs are associated with higher number of analgesic doses requirement compared to open repairs.

	Choice of	p value	
Complications	Open	Laparoscopic	
Yes	17	3	0.001
No	22	28	

Table 7: Comparison of incidence of complications between open vs laparoscopic ventral hernia repairs.

Out of 39 patients who underwent open repairs, 17 patients developed any of the defined complications. Whereas out of 31 patients who underwent laparoscopic repairs, only 3 patients developed any of the defined complications. According to the above data, it is observed that there is a significant difference in the incidence of complications between open and laparoscopic ventral hernia repair with p value of 0.001.

Table 8: Comparison of quality of life (QOL) at 1st month between large and small ventral hernia repairs.

Variables		No. of patients	Mean QOL score	SD	t value	p value
	Small (<7)	63	21.1	9.12	2.006	0.005
Defect size	Large (≥7)	7	34.6	11.9	2.906	0.027

p value calculated using independent t test

There is a significant difference in the quality of life at 1^{st} month between large (QOL 34.6 +/- 11.9) and small ventral hernia repair (QOL 21.1 +/- 9.12) with p value of 0.027. Small ventral hernia repairs are associated with a better quality of life compared to large ventral hernia repairs.

DISCUSSION

Any surgery over the abdomen can have serious consequences on the physical, social and mental well-being of the patient and can hamper the quality of life, at least for the first few weeks after the surgery. Our primary aim was to assess and compare the quality of life in ventral hernia repairs. We also compared other outcomes like postoperative pain, complications, average hospital stay, and time to return to activity. Alongside we have also assessed various types of ventral hernias encountered, types of various procedures performed, common risk factors, and comorbidities.

Quality of life is different from the health status of the patient. Quality of life focuses on the subjective appraisal of a patient's wellbeing whereas health status is an objective measure. We have used 12 questionnaire proforma which has questions covering 3 major aspects affecting the patient's wellbeing, including physical health, mental health, and social health. The physical health domain includes items on mobility, daily activities, energy, and pain. The mental health domain includes selfimage, mental status, and tension. The social domain includes social support, outdoor activity, work performance, sexual life, and personal relationships. Pruneda et al. conducted a retrospective cohort study for comparison of quality of life between open and robotic ventral hernia repair. They used HerQLes for QOL measurement, which also has similar 3 domains as of our study. (14)

This prospective observational study conducted in the Department of General Surgery, All India Institute of Medical Sciences, Jodhpur, included a total of 70 patients. Out of which, 39 patients underwent open ventral hernia repair and 31 patients underwent laparoscopic ventral hernia repair. Quality of life and other outcomes were compared in both groups. We also compared the quality of life between large and small ventral hernia repairs.

Total of 35 male patients and 35 female patients participated in the study. The gender distribution in the study was found to be comparable. The mean age of the male patients was 52.08 +/- 13.88 and of the female patients was 50.2 +/- 11.00. The

comorbidities associated with these patients included diabetes mellitus, hypertension, coronary artery disease, and asthma and they were not distributed evenly. 55 patients had no major risk factor for a hernia. However, 8 patients had constipation, 4 patients had chronic cough and 4 patients had difficulty in micturition. Out of 70 patients, 63 patients had small hernias and 7 patients had large hernias. The number of patients with large ventral hernias was very less compared to small hernia patients. Out of 70, 15 patients required abdominal drain while 55 patients did not require any drain.

The common types of ventral hernias encountered in our study were epigastric (33%), umbilical and paraumbilical (33%), and incisional (34%). These 3 common types of hernias were almost equal in this study. This finding is comparable to the study done by Rutkow et al. where they observed the similar demographic distribution. In their study, one-third of the patients had incisional hernias and two-thirds of the patients had primary ventral hernias. (101)

There are number of procedures available for ventral hernia repairs. In our study, the most common repair done was open primary repair in 18 patients (for small ventral hernias with defects <2 cm). Open primary repair was the most common procedure because the majority of the epigastric hernias were <2 cm in size and open primary repair is the treatment of choice for hernias <2 cm in size. IPOM and IPOM Plus were second and third common repairs performed, respectively. Because the majority of the hernias had defect size of 2-7 cm and laparoscopic repair is the treatment of choice for medium size hernias. Also, it was preferred by the majority of the patients, compared to long incisions over the abdomen. 4 patients underwent TAR because of large defect sizes (>7 cm). e-TEP is still in the experimental phase and so only 1 patient underwent that particular procedure. This was a non-randomized observational study, so patients were explained about the different surgical options available and were given the freedom to choose the treatment after considering all pros and cons.

Out of 36 patients who started as laparoscopic repairs, 5 procedures were converted to open repairs. Presence of dense adhesions was the major reason for conversion (in 4 patients). 1 patient required conversion because of the irreducible content and risk

of bowel injury. LeBlanc et al. had observed a conversion rate of 3.6% and the major reason was secondary to enterotomies in 1.8%. This finding is not comparable to our study as we had zero incidence of intraoperative enterotomy. This may be because of the very small sample size in our study. (102) However, the overall conversion rate (13.9%) was higher compared to the above study. We kept our threshold low for conversion in case of dense intra-peritoneal adhesions.

We have observed that there is no significant difference in the average postoperative hospital stay between open and laparoscopic ventral hernia repair with p value of 0.18. Because majority of the small and medium size hernia patients who underwent open repairs had some sort of pain secondary to long abdominal incisions. In contrast, laparoscopic hernia repairs had no major incisions over the abdomen still because of the usage of tackers and trans-fascial sutures intraoperatively, patients experienced moderate to severe pain in the postoperative period and that leads to an overall same hospital stay as like open repairs. A randomized control trial by Shankaran et al. was also suggestive of higher postoperative pain with the use of intraoperative tackers. (103) Chalabi et al. also found that there is no significant difference in the length of postoperative hospital stay between laparoscopic vs open ventral hernia repairs. (67) Although not significant, there is some difference in postoperative hospital stay between laparoscopic and open repairs. Laparoscopic repairs have ~1.5 days early discharge compared to open repairs. This can be attributed to the higher postoperative complications associated with open repairs, leading to increased hospital stay compared to laparoscopic repair. Akinci et al. also proven that postoperative complications are associated with a significantly higher postoperative hospital stay. (104)

There is no significant difference in return to activity between open and laparoscopic repairs. The average duration for return to activity in both groups was 3 days. Although, patients were encouraged to ambulate from postoperative day 1, because of the associated pain in both laparoscopic and open repairs, return to activity took almost 3 days in both the groups. A study done by Forbes et al. was also comparable to the above finding. They have also observed that postoperative pain is associated

with a significantly more time to return to activity, leading to decreased short-term quality of life. (105)

Patient satisfaction is often underestimated component of patient care. But, it is the major factor affecting the overall patient perception. In our study, it was found that there is no significant difference in the satisfaction score at discharge between open and laparoscopic ventral hernia repairs. Because at the time of discharge, cosmetic benefit of the laparoscopic surgery was outweighed by pain secondary to tackers and that affected the satisfaction score significantly at the time of discharge. A study by Eriksen et al. was also suggestive of very high dissatisfaction after laparoscopic ventral hernia repairs secondary to higher pain associated with it. (106) However, there is a significant difference in the satisfaction score at 1st month between open and laparoscopic ventral hernia repair. Laparoscopic hernia repairs are associated with more satisfaction compared to open hernia repairs. Because at 1 month, pain in both the groups was minimal but laparoscopic repairs have the advantage of better cosmesis and that could be the main reason for increased patient satisfaction at 1 month. Chronic pain and complications are major predictors of long-term satisfaction after laparoscopic ventral hernia repairs according to Langbach et al. (107). In our study, because of very less incidence of continuous pain at 1 month, satisfaction scores were improved significantly at 1 month compared to open repairs.

Postoperative pain is the significant determinant of the overall immediate quality of life. In our study, there is no significant difference in the postoperative pain between open and laparoscopic ventral hernia repair. However, there is a non-significantly higher pain in laparoscopic repair. We attributed this finding to the use of tackers and trans-fascial sutures in laparoscopic repairs. A randomized control trial by Shankaran et al. was also suggestive of higher postoperative pain with the use of intraoperative tackers. (103) Also, there is no significant difference in the average analgesic dose usage between open and laparoscopic ventral hernia repair. However again, laparoscopic repairs are associated with 3 times higher number of analgesic doses requirement compared to open repairs.

While assessing and comparing complications, it was found that out of 39 patients who underwent open repairs, 17 patients developed any of the defined complications. Whereas out of 31 patients who underwent laparoscopic repairs, only 3 patients developed any of the defined complications. According to the above data, it is observed that there is a significant difference in the incidence of complications between open and laparoscopic ventral hernia repair with p value of 0.001. This finding is similar to the study by Davies et al. in which laparoscopic repairs were associated with significantly lower complications compared to open repairs. (108)

There is a significant difference in the quality of life at 1st month between large and small ventral hernia repair. Small ventral hernia repairs are associated with a better quality of life compared to large ventral hernia repairs. Large hernia repairs were done by open approach in majority of the patients and were usually associated with extensive dissection in the abdominal wall. This leads to significantly higher pain, more complications, and bad cosmesis, leading to poor QOL in large hernia repairs compared to small hernia repairs.

When the quality of life at 1st month was compared between open and laparoscopic repairs, it was observed that there is no statistically significant difference between the two groups. Based on the above discussion, it is evident that open repairs were associated with significantly more complications, more postoperative hospital stay, and decreased satisfaction at 1 month, leading to the decreased overall quality of life of these patients. We believe that the quality of life of patients with laparoscopic repair was also negatively affected by the pain due to the usage of tackers, leading to overall similar quality of life compared to open repairs. Our findings are similar to a meta-analysis conducted by Chalabi et al. which was suggestive of comparable quality of life and outcomes between laparoscopic vs open ventral hernia repairs. (67) A study by Colavita et al. was also suggestive of comparable long-term quality of life between open and laparoscopic ventral hernia repairs. However, short-term quality of life at 1 month was lower in laparoscopic repairs than open repairs secondary to the more pain. (93) In our study, because of minimal pain at 1st month in majority of

the laparoscopic repair patients, short-term quality of life is comparable to open repairs.

The strength of our study is that there are very few previous publications which have studied and compared the short-term quality of life along with all the associated parameters like postoperative pain, hospital stay, return to activity, complications, and satisfaction between laparoscopic and open repairs.

The limitations of our study include small sample size, non-random nature of the study, use of self-made QOL tool, and subjective variation in terms of individual patient's perception. A multi-centre, randomized trial with larger sample size, with the use of a properly validated QOL tool would help to overcome these shortcomings.

This study was carried out during the times of the COVID-19 pandemic. Despite the odds and difficulties of elective operations, we could operate and gather the data for maximum number of ventral hernia cases.

CONCLUSION

Laparoscopic ventral hernia repairs are associated with lesser complications and higher satisfaction. The use of tackers and trans-fascial sutures can significantly increase postoperative pain in laparoscopic repair and is the major factor affecting the short-term quality of life in laparoscopic repairs. As there is no difference in postoperative pain, hospital stay, and return to activity, laparoscopic repairs should be preferred wherever possible in view of fewer complications and high satisfaction.

RECOMMENDATIONS

Emphasis should be given to maintain physical as well as mental and socioeconomic well-being during the postoperative phase. Special care should be given for controlling the post-operative pain to maximize the quality of life.

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Annexure - I All India Institute of Medical Sciences Jodhpur, Rajasthan

Informed Consent Form

Title of thesis/dissertation: Assessment of quality of life after ventral hernia repair - A prospective observational study at tertiary care centre.

Name of PG Student : Dr. Darshan Patel Tel. No. 7818013459 Patient/Volunteer Identification No. :

I, ______S/o or D/o ______ R/o ______give my full, free, voluntary consent to be a part of the study "A prospective observational study to compare quality of life after open vs laparoscopic ventral hernia repair", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and I am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from ______ (Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____

Signature/Left thumb impression

Place:

This to certify that the above consent has been obtained in my presence.

Date: _____

Place: _____

1. Witness 1

Signature

Name: _____

Address: _____

Signature of PG Student

2. Witness 2

Signature

Name: _____

Address : _____

Annexure - II

अ खल भारतीय आय ुव ाान संथान, जोधपरु स ूचत ल खत सहम त Title of Thesis/Dissertation: "उदर हनया कमर मत के बाद जीवन क गणवुता का आकलन - ततीयकृ देखभाल कम एक संभावत अवलोकन अययन।" Name of PG Student: डॉदशन पटेल Tel. No. 7818013459

Patient/Volunteer Identification No.:

तार खः _____

जगहः _____ ह ता र / बाएं अंगठ्रे का छाप यह मा णत करने के लए क मेर उपप थ त म उपरो त सहम त ा त क गई है

तार खः _____

जगह: _____

पीजी छा ह ता र

1. गवाह 1 2. गवाह 2

61

हता र		हतार	
नाम:	नाम	:	_
पताः		पता	:

Annexure III

ALL INDIA INSTITUTE OF MEDICAL SCIENCES JODHPUR, RAJASTHAN DEPARTMENT OF GENERAL SURGERY

PATIENT INFORMATION SHEET

TITLE: "Assessment of quality of life after ventral hernia repair - A prospective observational study at tertiary care centre."

You have been asked to volunteer for this research study because you have ventral hernia and will be operated by open/laparoscopic ventral hernia repair. This study aims to assess and compare quality of life after ventral hernia repair in a prospective manner. It will help us to know about various aspects of ventral hernia repair. As this is an observational study there is no risk and discomfort to the patients. All the records will be kept confidential to protect your privacy. You are free to withdraw your consent at any point of time without asking any reason, with no penalty or loss of benefits to which you would otherwise entitled. Your signature means you understand the information given to you about the study and agree to join the study.

Contact Person: for further queries-

DR. DARSHAN PATEL
Post Graduate student,
Department of General Surgery, AIIMS,
Jodhpur.
Mobile No: 7818013459
Email ID: darshanjp41195@gmail.com

अ खल भारतीय आयु व ाान सं थान, जोधपरु रोगी सचना**ू** प

शीषक: " उदर ह नया क मर मत के बाद जीवन क गणवु ता का आकलन - ततीयकृ देखभाल क म एक संभा वत अवलोकन अ ययन।"

आपको इस शोध अ ययन को वे छा से करने के लए कहा गया है य क आपको उदर ह नया है और खलेु/ ले ो को पक उदर ह नया क मर मत वारा संचा लत कया जाएगा। इस अ ययन का उ े य भावी तर के से उदर ह नया क मर मत के बाद जीवन क गणवु ता का आकलन और तलनाु करना है। यह हम उदर ह नया क मर मत के व भ न पहलआंु के बारे म जानने म मदद करेगा। जैसा क यह एक अवलोकन अ ययन है, रो गय को कोई जो खम और अस ु वधा नह ं है। आपक गोपनीयता क र ा के लए सभी रकॉड गोपनीय रखे जाएंगे। आप कसी भी कारण का आकलन कए बना कसी भी समय, कसी भी दंड या लाभ के नकसानु के बना अपनी सहम त वापस लेने के लए वतं ह, ि जसके लए आप अ यथा हकदार ह गे। आपके ह ता र का मतलब है क आप अ ययन के बारे म द गई जानकार को समझते ह और अ ययन म शा मल होने के लए सहमत ह।

संपक यय त: आगे के न के लए- डॉ. दशन पटेल नातको तर छा , जनरल सजर वभाग, ए स, जोधपरु मोबाइल नंबर: - 7818013459 ईमेल आईडी: <u>darshanjp41195@gmail.com</u>

PATIENT PROFORMA

"Assessment of quality of life after ventral hernia repair - A prospective observational study at tertiary care centre."

Name:	Patient Identification Number:							
Age / Sex:	Address:	Contact No:						
Date:								
DOA:	DOS:	DOD:						
1. Type of ventral hernia	:							
4. Co-morbidities: DM								
HTN	ſ							
IHD								
Asth	ma							
5. Risk factors: Chronic	cough/ COPD							
Consti	pation							
Difficu	lty in micturition							
Smoki	ng							
6. Previous Surgery nam	ne:							
7. Type of previous surg	gery:							
8. Site of previous surge	8. Site of previous surgery incision:							
9. Hernia site:								

10. Defect number and size:

11. Content:

- 12. Any other USG findings:
- 13. Treatment choice: Open / Laparoscopic
- 14. Intraoperative complications:

- 15. Drain required: Yes/No
- 16. Drain removed on: POD
- 17. Requirement of ICU postoperatively:
- 18. Postoperative hospital stay:
- 19. Pain on discharge: VAS scale
- 20. Condition at discharge:
- 21. Satisfaction at discharge

POST DISCHARGE DATA: (1 month follow up after operation)

- Return to normal activity (days) –
- Satisfaction score at 1 month
- Complications after discharge Wound related: Any discharge

Seroma / Abscess

Mesh infection

Flap necrosis

Hematoma

Wound infection

Wound dehiscence

Any swelling on/around the wound

Not wound related: Ileus

Pneumonia

Deep vein thrombosis

Recurrence

Reoperation/ re-laparotomy

Neuralgia / chronic pain

Any other

QUESTIONNAIRE

Please select the number that is most appropriate for you:

- 1: Strongly disagree
- 2: Moderately disagree
- 3: Neutral
- 4: Moderately agree
- 5: Strongly agree

I feel physical pain after operation	1	2	3	4	5
I feel interference when I walk or climb stairs	1	2	3	4	5
I feel interference when I do moderate activities like bending, running	1	2	3	4	5
I feel interference when I do strenuous activities like swimming	1	2	3	4	5
This operation has a huge impact on my health	1	2	3	4	5
My abdominal wall interferes when I take shower or cook	1	2	3	4	5
My abdominal wall interferes with my sexual activity	1	2	3	4	5
My abdominal wall affects how I feel everyday	1	2	3	4	5
I often stay home after my operation day	1	2	3	4	5
I accomplish less at home after my operation day	1	2	3	4	5
I accomplish less at work after my operation day	1	2	3	4	5
I often feel tensed because of my abdominal wall	1	2	3	4	5

Annexure – VI ETHICAL CLEARANCE CERTIFICATE



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur संस्थागत नैतिकता समिति Institutional Ethics Committee

No. AIIMS/IEC/2020/2075

Date: 01/01/2020

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: AIIMS/IEC/2019-20/1002

Project title: "Assessment of quality of life after ventral hernia repair: A prospective observational study at tertiary care centre"

Nature of Project:	Research Project
Submitted as:	M.S. Dissertation
Student Name:	Dr.Darshan Patel
Guide:	Dr.Mahendra Lodha
Co-Guide:	Dr.Ashok Puranik, Dr.Mahaveer Singh Rodha & Dr.Mayank Badkur

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on 23-12-2019 and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- · Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- · Any unethical principle or practices are revealed or suspected
- · Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

arma Membe ecretar na! Ethics Commit! AIIMS, Jodhpur

Enclose:

1. Annexure 1

Annexure VIII KEY TO MASTER CHART

Sex	1=M	2=F														
Comorbidity	1=Hy	pertension	2=Dia	ibetes	3=Ischemic heart disease		4=Asthma									
Risk factors	1=Co	nstipation	2=Cough	3=Difficult micturitic	y in n		7 in n									
Type of hernia	1=E	pigastric	2=Umb Paraun	ilical & abilical	3=Incisional		3=Inc		3=Incisional		3=Incisional		3=Incisional			
Choice of treatment	1=Open	2=Lapa	roscopic													
Type of repair	1=Open primary repair	2=Open retrorectus mesh hernioplasty	3=Open preperitoneal mesh hernioplasty	4=Open onlay mesh hernioplasty	5=IPOM		5=IPOM		5=IPOM		6=IPOM Plus	7=Etep	8=TAR			
Conversion to open	1=Yes	2=No														
Reason for conversion	1= intra adhe	Dense peritoneal sions	2=Irreducil	ble content												
Drain required	1=Yes	2=No														
Return to normal activity	0=Same day	1=POD 1	2=POD 2	3=POD 3	4=PC 4	DD	5=POD 5	6= POD 6	7=At 2 months							
Postoperative complications	1=Cont	inuous pain	2=Postoper	=Postoperative ileus		perfi infe	cial wound ctions	4=Relap	aroscopy							
Complications at 1 month	1=Contin 1	nuous pain at month	2=Superfi infec	2=Superficial wound infections												