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A RANDOMIZED CONTROLLED STUDY

Longitudinal Relaxing Incision as a Technique for Recurrence Prevention in Ventral Hernia, Does it Help? : A Randomized Controlled Study

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Abstract

Background: Ventral hernias of the abdomen are defined as a non-inguinal, non-hiatal defect in the fascia of the abdominal wall. The aim of this work was to determine the efficiency of using longitudinal relaxing incision as a technique for recurrence prevention in ventral hernia.

Methods: This randomized controlled study was carried out on 40 patients aged from 18 to 60-years-old, both sexes, diagnosed with primary type of ventral hernia (not incisional) and scheduled for elective open repair. Patients were randomly allocated into two equal groups: Group A who underwent traditional hernial repair as control group, and Group B who had the longitudinal release incision.

Results: The duration of the surgical procedure had a median of 40 minutes in Group A, compared to 45 minutes in Group B, with no significant difference. Additionally, intraoperative blood loss was statistically comparable between the two groups (40 vs. 35 minutes in the same groups, respectively). No intraoperative complications were encountered in the current study. Insignificant differences were detected between both groups regarding hospital stay, time to drain removal, postoperative morbidity [Infection, dehiscence, and seroma], mortality, recurrence at six-month, and changes in quality of life (QOL). Only one patient developed recurrence in Group A.

Conclusions: The application of longitudinal relaxing incision is not associated with a significant decline in the incidence of recurrence on the short term, after open surgical repair of ventral hernias.

Keywords

Longitudinal relaxing incision, Recurrence prevention, Ventral hernia, Quality of life

Introduction

Ventral hernias of the abdomen are defined as a non-inguinal, non-hiatal defect in the fascia of the abdominal wall. Annually, there are about 350,000 ventral hernia operations [1]. The repair of these abdominal wall defects is a common surgery performed by general surgeons. Surgery is typically recommended for individuals with acceptable operative risk, symptomatic hernias, or those at elevated risk of developing complications from a hernia. They can affect an individual's quality of life (QOL) and can lead to hospitalizations and even death in some cases [2-4].

Etiology of a ventral hernia can be broken down into 2 main categories: Acquired or congenital. The vast majority of hernias that general surgeons see and treat are acquired; however, some individuals live with their ventral hernias from birth for prolonged periods of time before having them surgically repaired [5].

Common causes of acquired ventral hernias include previous surgery causing an incisional hernia, trauma, and repetitive stress on naturally weak points of the abdominal wall. These naturally occurring weak points in the abdominal wall include the umbilicus, semilunar line, bilateral inguinal regions, and oesophageal hiatus. Obesity is an important risk factor of hernias as well because it stretches the fascia of the abdomen causing it to weaken. Specifically, the action of repetitive weight gain and loss leads to weakening [6].

The most common treatment of ventral hernias

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is surgery. Asymptomatic hernias are repaired on an elective basis, but those presenting with strangulation require immediate surgery. Incarceration without strangulation is not a surgical emergency; however, the risks and benefits of surgery should be discussed with the patient, and a patient with reasonable operative risk should have their hernia repaired within a sensible time frame [1].

Non-surgical management of abdominal wall hernias with the use of binders, trusses, or corsets is not considered to be effective. However, this may be the only option in a patient who is not a reasonable candidate for surgery [7-9].

Over the years, many types of surgical techniques have been developed to repair hernias. The most important being a tension-free repair, which is composed of the use of a mesh with 3 to 5 cm of overlap, meticulous handling of the mesh, preventing surgical site infections, and using a sublay technique, if possible, with the closure of the fascia. The most basic approach is a primary open repair without mesh, which should typically be reserved for defects in the fascia of less than 2 cm [10].

Hernia recurrence is an extremely important long-term morbidity which challenges surgical efficacy. Several surgical modifications were suggested to decrease recurrence rate after ventral hernia repair including the level of mesh placement whether sublay or inlay or intraperitoneal, and the complex component separation techniques [11].

The aim of this work was to determine the efficiency of using a simple technical modification, namely longitudinal relaxing incision as a technique for recurrence prevention in ventral hernia.

Patients and Methods

This comparative study is a randomized controlled trial. It was carried out on 40 patients aged from 18 to 60-years-old, both sexes, diagnosed with primary type of ventral hernia (not incisional) and scheduled for elective open repair.

An informed written consent was obtained from the patient or relatives of the patients. The study was done after approval from the Institutional Review Board (IRB) of the Faculty of Medicine, Assiut University.

This study took place from December 2022 to February 2024.

Exclusion criteria were recurrent hernia, and complicated hernias (irreducible, strangulated, or obstructed hernias).

Randomization and grouping

After obtaining the patients' consent, they were randomly allocated using computer generated randomization into two equal groups: Group A who underwent traditional hernial repair as control group, and Group B who had the longitudinal release incision.

Pre-operative assessment

All patients were subjected to history taking [Personal history, current complaint, duration of each complaint, review of other GIT symptoms, review of other body systems focusing on respiratory symptoms (chronic cough) and urinary symptoms (related to prostatic enlargement), current medical comorbidities with their commenced medications, and previous surgical history], clinical examination [general examination including patient look, body built, body mass index (BMI), cardiac and chest examination, peripheral limb examination, and assessment of vital signs, and local abdominal examination including inspection, palpation (for the defect and its contents), percussion, and auscultation], laboratory investigations [Complete blood count (CBC), liver function tests, serum creatinine, random blood sugar, glycosylated haemoglobin in patients with diabetes, virological workup including HCVAb, HBsAg, and HIVAb], radiological investigations [pelviabdominal ultrasonography, and abdominal computed tomography], and anesthetic consultation was classified according to the American Society of Anaesthesiologists (ASA).

The surgical procedure

The procedures were performed under general or spinal anesthesia according to the location of the hernial defect and according to the anaesthetist preference. The procedures were performed when the patient was in a supine position. A broad-spectrum antibiotic (IV ceftriaxone 2 gm) was commenced for all cases 10 minutes before the skin incision. After proper sterilization and draping of the abdominal wall, a horizontal incision was done over the hernia defect. We continued dissection through the subcutaneous fatty tissues till reaching the hernial sac. The hernial sac was opened to examine its contents. If any dirty omentum was encountered, it was excised. Other bowel contents were reduced into the abdominal cavity after ensuring its viability. The maximum diameter of the defect was measured in cm using a sterile metallic ruler, and that diameter was recorded. The abdominal wall defect was closed by continuous non-absorbable sutures (Prolene 0 or 1 sutures). A longitudinal relaxing incision was performed bilaterally in group B patients, about 3-4 cm away from the defect related to size of defect and about 2 cm above and below the defect regarding length in anterior rectus sheath layer. That helped in medialization of the recti muscles and easy closure of the defect. That step was omitted in Group A. Over the closed defect, a prolene mesh was placed onlay keeping in mind to extend at least two cm beyond the defect borders. The mesh was secured using non-absorbable

prolene 2/0 sutures. After good wash and proper hemostasis, a suction drain was inserted between the mesh and the overlying skin flaps. The subcutaneous tissue was approximated by vicryl 0 sutures, followed by closure of the skin using subcuticular sutures.

Postoperative care

All patients were transferred to the post-anesthesia care unit (PACU) then to the internal ward, where close monitoring was done. Early mobilization was encouraged. Analgesia was maintained by IV paracetamol (1 gm/8 hours) and IV ketorolac (30 mg/12 hours). If no significant response was achieved, IV morphine 2-3 mg was commenced for pain relief. Oral fluid intake was allowed 6-8 hours after the procedure, unless complications were encountered. Most patients were discharged during the first postoperative day. An oral broad-spectrum antibiotic in addition to oral analgesics were commenced for all cases. The drains were removed if its discharge was less than 30 cc/day for 2 consecutive days [12].

Follow-up

The first follow-up visit was arranged after two weeks for stitch removal. Any postoperative complications, including wound infection, hematoma, and dehiscence, were recorded and managed. Other follow-up visits were arranged at one, three and six months after the operation. The incidence of late complications like seroma or recurrence was also recorded. Assessment of quality of life using the Caroline Comfort Scale (CCS) at the last follow-up visit (six-month visit).

The primary outcome was the incidence of recurrence. The secondary outcomes were operative time, intraoperative blood loss, the duration of hospitalization, the incidence of other complications, and changes in the quality of life.

Statistical analysis

Statistical analysis was done by SPSS v28 (IBM©, Armonk, NY, USA). Shapiro-Wilks test and histograms were used to evaluate the normality of the distribution of data. Quantitative parametric data were presented as mean and standard deviation (SD) and were analysed by unpaired student t-test. Quantitative non-parametric data were presented as the median and interquartile range (IQR) and were analysed by Mann Whitney-test. Qualitative variables were presented as frequency and percentage (%) and analysed using the Chi-square test or Fisher's exact test when appropriate. A two-tailed P value < 0.05 was considered statistically significant.

Results

In this study, 64 patients were assessed for eligibility, 16 patients did not meet the criteria and 8 patients refused to participate in the study. The remaining 40 patients were randomly allocated into two groups (20 patients in each). All allocated patients were followed-up and analysed statistically (Figure 1).

Table 1 showed that there were no significant differences regarding patient-related criteria [Age, gender, BMI, Comorbidities, (Diabetes, hypertension, COPD, and chronic liver disease), smoking (COPD), ASA class (I, and II), patients' presentation [Abdominal pain, and cosmetic disfigurement], duration of manifestations, and hernia characteristics [Hernia type, defect diameter, and content].

The duration of the surgical procedure had a median value of 40 minutes in Group A, compared to 45 minutes in Group B, with no significant difference in the statistical analysis. Additionally, intraoperative blood loss was statistically comparable between the two groups (40 vs. 35 minutes in the same groups, respectively). No intraoperative complications were encountered in the current study (Table 2).

Insignificant differences were detected between both groups regarding hospital stay, time to drain removal, morbidity [Infection, dehiscence, and seroma] and mortality, recurrence at six-month, and changes in QOL assessed using the Carolinas Comfort Scale (CCS). Only one patient developed recurrence in Group A (Table 3).

Discussion

Ventral hernias of the abdomen are non-inguinal, non-hiatal defects in the fascia of the abdominal wall. They are commonly seen in clinical practice. The repair of these abdominal wall defects is a common surgery performed by general surgeons [1].

The mean age of the included cases was 45.25 years in Group A compared to 43.75 years in Group B. A previous Egyptian study reported a mean age comparable to ours with (49.28 ± 11.67 years) [13].

On the other hand, Kroese, et al.'s [14] study reported older patient age, as the mean age of patients with primary ventral hernia was 55.61 (14.69) years. However in Jaykar RD, et al's [15] study the mean age was approximately 41 years.

We noted a significant increased prevalence of male gender in both study groups, as they constituted 65% and 75% of cases in Groups A and B, respectively.

Our findings are in accordance with Jadhav, et al. [16] who reported that epigastric hernias were more common in males (70%), while incisional hernias were more common in females (76%). It was expected to encounter more men in our study as we did not include patients with incisional hernia.

Even we included uncomplicated cases, some of the included cases reported abdominal pain (35% in both study groups). According to the previous literature, uncomplicated ventral hernia can cause abdominal pain in some cases. The severity and location of the pain

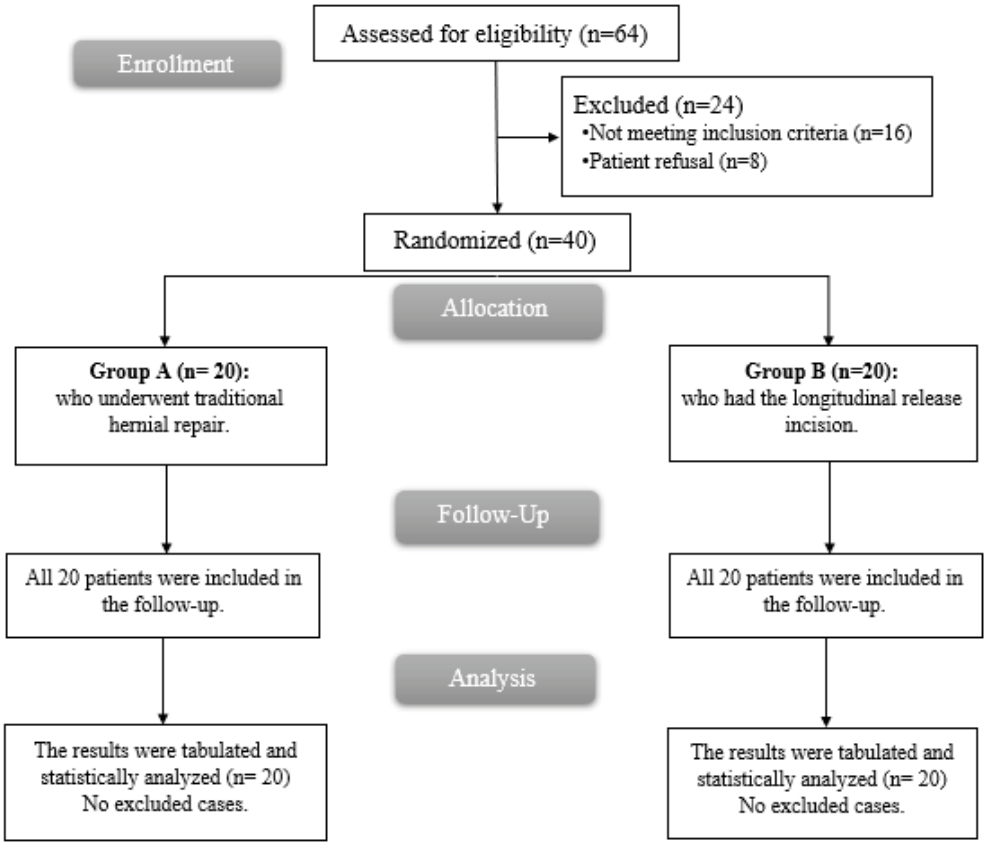

Figure 1: CONSORT flowchart of the studied patients.

Table 1: Patient-related criteria, presentation, and hernia characteristics in the study groups (n = 40).

		Group A (n = 20)	Group B (n = 20)	P-value
Age (years)		45.25 ± 9.67	43.75 ± 9.01	0.615
Sex	**Male**	13 (65%)	15 (75%)	0.490
	Female	7 (35%)	5 (25%)	0.490
BMI (kg/m²)		27.27 ± 2.97	28.12 ± 3.68	0.431
Comorbidities	**Diabetes**	3 (15%)	4 (20%)	0.677
	Hypertension	4 (20%)	4 (20%)	1
	COPD	5 (25%)	4 (20%)	0.705
	Chronic liver disease	1 (5%)	0 (0%)	0.311
Smoking (COPD)		5 (25%)	6 (30%)	0.723
ASA class	**I**	9 (45%)	6 (30%)	0.327
	II	11 (55%)	14 (70%)	
Presentation	**Abdominal lump**	20 (100%)	20 (100%)	-
	Abdominal pain	7 (35%)	9 (35%)	0.519
	Cosmetic disfigurement	14 (70%)	14 (70%)	1
Duration of manifestations (months)		13 (6-24)	12 (6-24)	0.744
Hernia characteristics				
Hernia type	**Umbilical**	10 (50%)	11 (55%)	0.090
	Epigastric	6 (30%)	6 (30%)	
	Paraumbilical	4 (20%)	3 (15%)	
Defect diameter (cm)		2 (1.5-3.5)	2 (1.5-3.5)	0.390
Content	**Omentum**	11 (55%)	12 (60%)	0.885
	Omentum and bowel	3 (15%)	2 (10%)	
	Extraperitoneal fat	6 (30%)	6 (30%)	

Data are presented as mean ± SD, median (range), or frequency (%). BMI: Body Mass Index; COPD: Chronic Obstructive Pulmonary Disease

Table 2: Operative data in the study groups.

	Group A (n = 20)	Group B (n = 20)	P-value
Operative time (min)	40 (30-50)	45 (35-55)	0.069
Blood loss (ml)	40 (20-50)	35 (20-50)	0.223
Intraoperative complications (bowel injury)	0 (0%)	0 (0%)	-

Data are presented as median (range) or frequency (%)

Table 3: Hospital stay, time to drain removal, morbidity and mortality, recurrence at six-month, and changes in QOL in the study groups.

	Group A (n = 20)	Group B (n = 20)	P-value
Hospitalization period (round to the nearest whole number in days)	1 (1-2)	1 (1-2)	0.747
Time to drain removal (round to the nearest whole number in days)	10 (7-14)	9 (7-14)	0.577
Morbidity and mortality			
Infection	1 (5%)	1 (5%)	1
Dehiscence	1 (5%)	0 (0%)	0.311
Hematoma	0 (0%)	0 (0%)	-
Flap necrosis	0 (0%)	0 (0%)	-
Seroma	1 (5%)	1 (5%)	1
Mortality	0 (0%)	0 (0%)	-
Recurrence	1 (5%)	0 (0%)	0.311
Improvement in the quality of life at six-month follow-up	41.85 ± 9.11	39.55 ± 10.44	0.462

Data are presented as mean ± SD, median (range), or frequency (%)

can vary depending on factors such as the size of the hernia, its location, and the presence of any associated complications. The pain may be intermittent or constant and can range from mild discomfort to sharp or stabbing sensations [17,18]. Jadhav, et al. [16] reported that 24% of their ventral hernia patients had abdominal pain.

Our findings showed no significant difference between the two groups regarding operative time (40 vs. 45 minutes in Groups A and B, respectively - p = 0.069). It is reasonable not to encounter significant difference in operative time between the two approaches, as the performance of two superficial release incision would not lead to significant prolongation in operative time.

Likewise, Rabie, et al. [19] reported that the same variable had mean values of 120.4 ± 23.2 and 131.8 ± 25.2 minutes in the conventional and component separation groups respectively with no significant difference (p = 0.083).

In the current study, postoperative wound infection occurred in 5% of cases in both study groups. That lies within the reported range of incidence of the superficial wound infection after open hernial repair (0.4%-14%) [20-23].

In contrast to our findings, other studies reported that component separation is associated with much higher morbidity rates that could reach up to 50% of cases, half of them develop surgical site infection [24,25]. However, our technique is much simpler with no complex dissection as is the case with component separation techniques.

In our study, wound dehiscence occurred in only one patient in the standard repair group, compared to no cases in the other group (p > 0.05).

Another study reported the incidence of the same adverse event in 5.4% of cases in the conventional group, and 10.9% of cases in the component separation group, with no significant difference in the statistical analysis (p = 0.130) [26].

Contrarily, Kilma and his associates reported a significant increase in wound breakdown in the component separation group (10.8% vs. 0.7% in the standard group - p < 0.001) [27].

In our study, the surgical drains were removed after a median duration of 10 days in Group A, and nine days in Group B (p = 0.577).

Another study reported that it took 11.4 ± 4.2 days to remove the drains in the conventional group, compared to 13.7 ± 4.0 days in the component separation group, which was significant in the statistical analysis (p = 0.039) [19].

That could be explained by the increased procedure complexity in the component separation technique used by the authors. More surgical dissection leaves a

wider raw area leading to increased drain discharge and longer time to removal.

No mortality was encountered in the current study. Another study reported no mortality after ventral hernia repair via the standard and component separation approaches [26].

In the current study, only one patient in each group developed seroma (5%) with no significant difference in the statistical analysis (p = 1.0).

Although radiological finding of seroma is reported in up to a 100% of the cases after hernia repair, clinically symptomatic seroma is reported in up to 12.5% of patients following open incisional hernia repair [28-30]. Our incidence of seroma lies within the previous range.

On the other hand, Klima and his colleagues reported a significant rise in the incidence of seroma in association with the component separation approach (14.9% vs. 3.9% in the standard group - p = 0.005) [27].

Only one patient developed recurrence in our study, and it was in Group A. He was the patient who had preoperative compensated liver cirrhosis. Recurrence in this patient could be explained by increased intra-abdominal pressure cause by development of ascites and portal hypertension [31]. Additionally, impaired wound healing due to liver cirrhosis caused by various factors, including reduced synthesis of collagen (a protein essential for wound healing) and altered immune function [32-34].

Our findings revealed a significant improvement in the QOL in both groups compared to the corresponding baseline values. Additionally, the improvement was statistically comparable between the two groups ($p > 0.05$).

One could expect a great improvement in the QOL after hernia repair, and that could be explained by relief of symptoms, restoring the functionality of the abdominal wall, improving the body image and self-esteem, and potentiate psychological well-being [35,36].

Similar to our findings, Klima, et al. [27] reported similar QOL for component separation patients versus those undergoing a standard ventral hernia repair in both short- and long-term follow-ups.

Limitations

The relatively small sample size that was collected from a single surgical center is the main drawback. Our study also lacks intermediate- and long-term follow-up. The upcoming studies should address the previous drawbacks.

Conclusion

The application of longitudinal relaxing incision is not associated with a significant decline in the incidence of recurrence on the short term, after open surgical repair of ventral hernias.

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Nil.

Conflict of Interest

Nil.

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