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Comparison of outcomes of extracorporeal suturing versus intracorporeal suturing of the defect in laparoscopic intraperitoneal on lay mesh repair of ventral hernia: A prospective observational study

[1]Dr. Bhushankumar Thaukur, Associate Professor, Dept of General Surgery, Seth GS Medical College and KEM Hospital.
[2]Dr. Shwetambari Ingawale, Junior Resident, Dept of General Surgery, Seth GS Medical College and KEM Hospital.
Corresponding Author: Dr. Shwetambari Ingawale, Junior Resident, Dept of General Surgery, Seth GS Medical College and KEM Hospital.

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Abstract

An abdominal hernia results from the protrusion of organs or tissues through defects in the abdominal wall. Ventral hernias are very commonly encountered by a general surgeon and it requires consideration of the hernia anatomy in conjunction with patient characteristics for choosing a surgical approach. IPOM – Plus is the vental hernia repair technique in which defect is closed along with the mesh placement. The defect closure can be intracorporeal as well as extracorporeal, both of them having their own benefits and problems.

Hence a study was done with aim to compare outcomes after extracorporeal suturing versus intracorporeal suturing of the ventral hernia defect in laparoscopic IPOM-Plus repair up to end point of 6 months. . In this prospective observational study, 200 patients, who underwent elective laparoscopic IPOM Plus repair for ventral hernia (defect size 2-5cm), were examined to compare surgical outcomes between extracorporeal (n=100) and intracorporeal defect closure (n=100). They were followed up to duration of 6 months and the primary outcome studied was early hernia recurrence (at 6 months). Secondary outcomes studied included demographic data of patients presenting with ventral hernia, comparison of operative time, wound complications between the two techniques.

We have concluded that, extracorporeal suturing is associated with lesser operative time, lesser seroma formation than intracorporeal suturing. Early hernia recurrence between the two groups is comparable (1.5%) and both methods are effective for ventral hernia repair. Both techniques are safe with acceptable post-operative wound complications.

Keywords: Ventral Hernia, Laparoscopic Repair, IPOM Plus, Defect, Intracorporeal Suturing, Extracorporeal Suturing.

Introduction

A hernia is a protrusion of a viscus, or a part of the viscus, through the wall of the cavity in which it is normally contained. An abdominal hernia results from the protrusion of organs or tissues through defects in the abdominal wall.

Abdominal wall hernias are typically classified by location (Ventral Hernia, Groin Hernia, Pelvic Hernia or

Flank Hernia) or etiology (Congenital or Acquired). Ventral hernias occur through defects in the anterior abdominal wall and include primary ventral hernias (epigastric, umbilical, Spigelian) and most incisional hernias (incisional ventral hernias). These may be asymptomatic but often they cause pain and discomfort, and can lead to serious complications, such as bowel incarceration, obstruction or strangulation. Various operative techniques have been described for hernia repair. In 1993, LeBlanc and Booth published an article on laparoscopic ventral hernia repair (LVHR), and ever since, LVHR has gained popularity across the globe(1). It has achieved better surgical outcomes than the conventional open technique with benefits being less pain, shorter hospital stay, less blood loss and low rates of infection(2). Recurrence rates and post-operative pain have been similar between the two techniques (1). In the wake of continuous innovation, many new techniques for laparoscopic ventral hernia repair have evolved such as IPOM (Intra Peritoneal Onlay Mesh) Repair, IPOM-Plus (Intra Peritoneal Onlay Mesh- Plus) Repair, SCOLA (Subcutaneous Onlay Laparoscopic Approach) Repair, ETEP (Extended view Totally Extra Peritoneal) Repair, Endoscopic Component Separation techniques as well as hybrid repairs(4).

The basic laparoscopic technique involves adhesiolysis, reduction of the hernia sac, delineating the hernia defect, and then covering the defect with an Intraperitoneal Onlay mesh (IPOM or s-IPOM)(3). IPOM, that simply bridges the hernia orifice without closure of the defect, is associated with problems such as increased recurrence rate, mesh bulging / eventration, seroma formation, and non-restoration of the abdominal wall function (5). To overcome these problems, fascial closure technique with IPOM reinforcement in LVHR, named “IPOM-Plus” (Defect Closure / Augmentation/ “Plus” Repair), has been introduced and has been included in the Guidelines for the management of ventral abdominal wall hernias. This hernia defect closure in “IPOM- Plus”(3). Repair of Ventral Hernia can be achieved by Extracorporeal suturing or Intracorporeal Suturing, as per surgeon discretion(6)

In IPOM Plus Repair of ventral hernia, the closure of the hernia defect can be achieved by intracorporeal suturing or extracorporeal (transfacial suturing). In Extracorporeal Suturing, small stab wounds are used to introduce and retrieve the sutures from the peritoneal cavity. This may increase the risk of infection, suture granuloma, or cause multiple dimples on the skin (5). Intracorporeal suturing does not entail requirement of stab wounds, and hence may have lesser incidence of skin dimpling and suture granulomas. However, laparoscopic intracorporeal suturing is technically more demanding, and therefore, may result in longer operative time. Extracorporeal suturing includes all layers of the abdominal wall, whereas intracorporeal suturing includes the fascial and inner muscle layers only. This may have important implications of on the strength of the sutured defect, and thereby, on hernia recurrence, as well as, on occurrence of post-operative pain.

Presently, both extracorporeal and intracorporeal suturing methods are used for defect closure. However, there is dearth of literature regarding improved outcomes with use of any one method over the other. Hence this study needs to be carried out to document the difference in outcomes, if any, with extracorporeal versus intracorporeal suturing.

Aims

The aim of this study is to evaluate and compare the outcomes of closure of the ventral hernia defect with Extracorporeal (transfacial) suturing versus intracorporeal suturing in patients undergoing

Intraperitoneal Onlay Mesh – Plus (IPOM Plus) repair with respect to Hernia Recurrence.

Objectives

To study the clinical profile and course of patients undergoing laparoscopic repair of ventral hernias

Inclusion Criteria

• Patients undergoing elective hernia repair with Laparoscopic IPOM Plus in a tertiary care hospital.

• Midline uncomplicated or Irreducible ventral hernia.

• Defect size 2 - 5 cm in diameter.

• Age >18 years and<60 years.

Exclusion Criteria

• Conversion to open surgery.

• Obstructed/ Strangulated Ventral Hernia.

• Recurrent incisional hernia.

• Patients given Regional Blocks/ Local Port Site Infiltration.

• Patient unwilling to take part in study or lost to follow up.

Materials and Methods

Ethics: The study has been initiated after approval from the Institutional Ethics Committee (IEC). Institutional and Departmental records of patients were accessed only after appropriate permission and authorization obtained.

Setting: The study was conducted at a tertiary healthcare centre with availability of advanced laparoscopic setup.

Sample size: The sample size will be of 200 patients.

Sample size calculation: The primary objective of the study is to assess the incidence of recurrence between the two groups. (Extracorporeal versus Intracorporeal Suturing) In a similar study by Lomanto et al, the incidence of recurrence was 10% in one repair group. Assuming that incidence in the other laparoscopic group will be 1%, sample size was calculated as follows: Using formula for sample size calculation for comparing proportions in independent groups, Sample size $n = (Z\ \alpha/2 + Z\ \beta)\ 2 * (p\ 1\ (1-p\ 1) + p\ 2\ (1-p\ 2)) / (p\ 1 - p\ 2)\ 2$,

where $Z\ \alpha/2$ is the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), $Z\ \beta$ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84) and p 1 and p 2 are the expected sample proportions of the two groups. Online sample size calculator available at https://www.stat.ubc.ca/~rollin/stats/ssize/b2.html was used to do further calculations, using p1=0.1 and p2 = 0.01, 80% power and alpha error of 5%. Thus, Sample size = 100 in each group

Method

After application of inclusion and exclusion criteria,

Patients undergoing laparoscopic ventral hernia repair in tertiary health centre included in

Study

↓

Informed consent taken; history and preoperative findings recorded

↓

Cases operated with standardized operative technique as per Institutional protocol are

Included in this study. Patients included are those undergoing Elective IPOM-Plus repair, with placement of composite mesh (Proceed™). The mesh is anchored at four corners by transfacial suturing of pre-placed sutures (Polydiaxone) along with absorbable tacks (Secure Strap™) by double crowning method. The facial defect is closed transfacially (extracorporeally) or intracorporeally with non- absorbable suture material (Prolene).

↓

Intraoperative findings of these cases recorded.

↓

Postoperative parameters recorded on Day 1 and Day 7.

↓

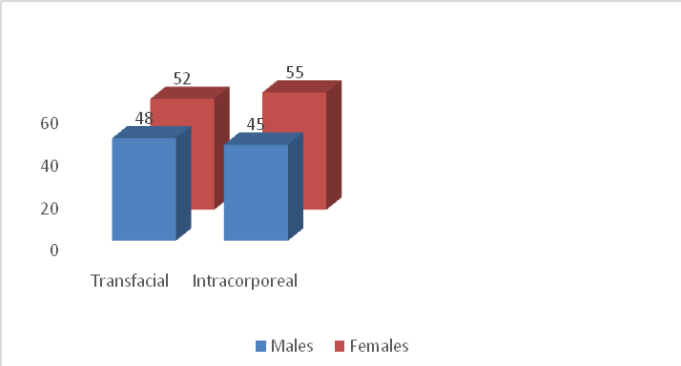
At routine follow up visits at 1 month and at 6 months, postoperative parameters recorded.

↓

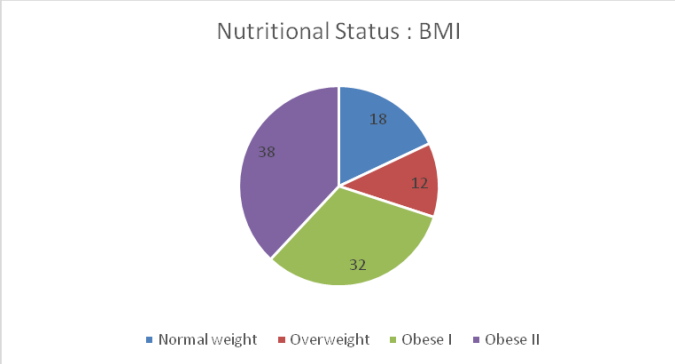
All the data recorded on pre-approved Case Record Forms. Data entry in Excel sheet done and Data analysed to produce results.

Results

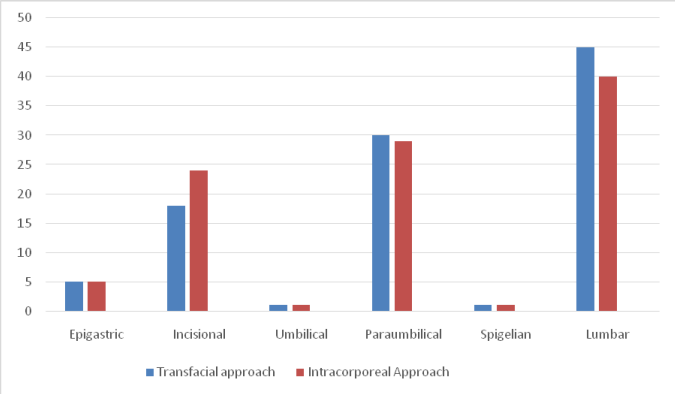
Gender distribution for transfacial and intracorporeal approach



Nutritional status of patients

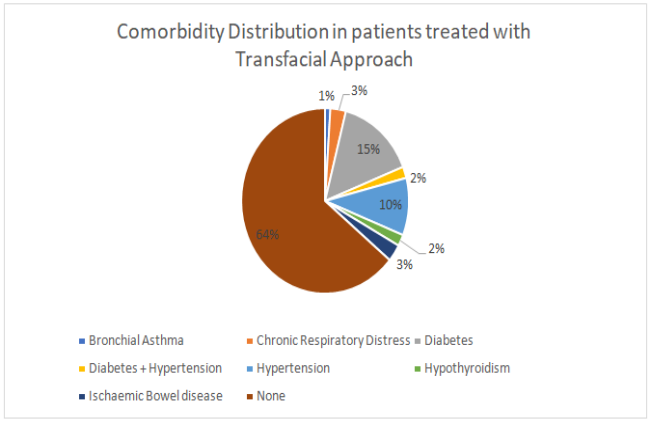


Hernia distribution in Transfacial Vs Intracorporeal Approach

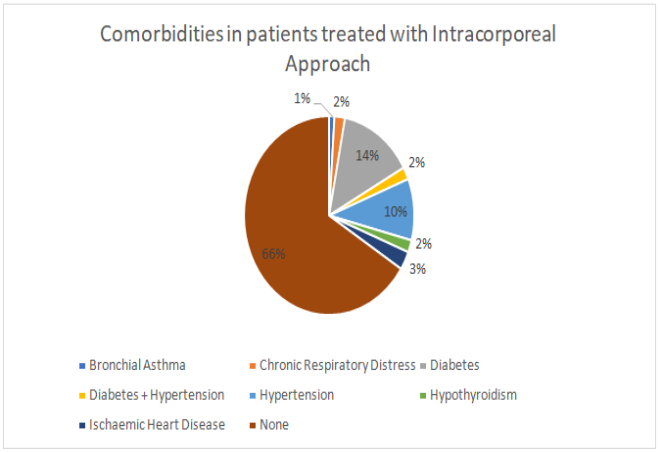


Comorbidity distribution in patients treated with

1) Transfacial Approach



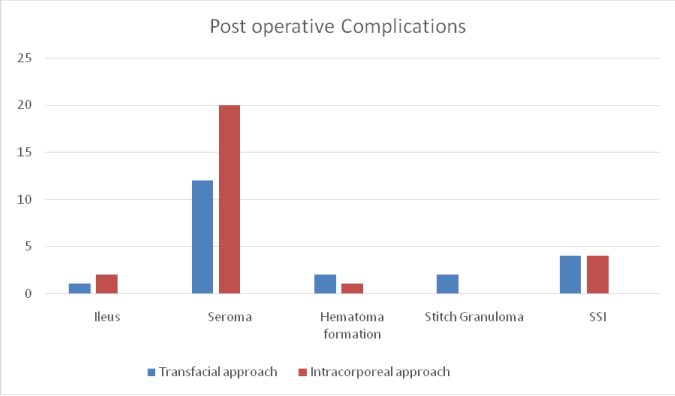
Intracorporeal Approach



Descriptive statistics for Operative time in minutes and Hospital Stay for different closure techniques

	Closure technique		Statistic	Std. Error
Operative time in minutes	Transfacial	Mean	62.39	1.443
		Median	60.00	
		Std. Deviation	14.428	
		Minimum	40	
		Maximum	90	
		Range	50	
	Intracorporeal	Mean	68.40	1.155
		Median	70.00	
		Std. Deviation	11.553	
		Minimum	50	
		Maximum	90	
		Range	40	
Hospital stay in days	Transfacial	Mean	3.895	.0998
		Median	4.000	
		Std. Deviation	.9982	
		Minimum	2.0	
		Maximum	7.0	
		Range	5.0	
	Intracorporeal	Mean	3.895	.1018
		Median	4.000	
		Std. Deviation	1.0183	
		Minimum	2.0	
		Maximum	7.0	
		Range	5.0	

Incidence of Post operative Complications



Incidence of Recurrence of hernia within 6 months of repair.

Closure technique	No. of patients with recurrence
Transfacial approach	1
Intracorporeal approach	2

Discussion

Continuing innovation and technological advancements in the field of hernia repair have led to development of a plethora of techniques for management of ventral hernias. The ideal technique for their management however still remains to be a topic of debate(9). Since its introduction in 1993 by Le Booth, Laparoscopic ventral hernia repair is increasingly being used and has become popular among minimally invasive surgeons and patients (11). It promises better results than open repair, such as shorter length of hospital stay, decreased local morbidity like surgical site infections (11) and better cosmetic results. Though the recurrence rates as compared to open are still debatable, the systematic review of literature shows results favouring LVHR.

Standard IPOM (sIPOM), which involves simple mesh reinforcement of composite intraperitoneal mesh without defect closure has now been superceded by IPOM-Plus, which involves defect closure in addition to mesh placement(12). IPOM plus had advantages of lesser incidence of seroma, less recurrences and less mesh eventeration/bulging as compared to sIPOM. The defect closure in IPOM-Plus can be done in an extracorporeal (transfacial) or intracorporeal fashion. The extracorporeal suturing is generally done by using suture passers to close the defect in a transfacial manner, incorporating all layers of the abdominal wall, and with the knot placed on the external body wall(13). Lai JH, Loo GH, Shuhaili MA, Kosai NR have described novel method of transfacial suturing using intravenous cannula as an alternative to the suture passer. Whatever be the technique, the incorporation of all layers of the

abdominal wall may lead to increased pain postoperatively(14). Similarly, the placement of the non-absorbable suture knots externally may predispose to increased risk of stich granulomas. In the intracorporeal suturing technique, technical difficulty may entail longer operative time (9). Also, the closure of facial defect involving only the inner fascial layers as opposed to inclusion of all layers may lead to important implications on hernia recurrence(15). In the study by Sieda BM and Khalil OH, surgical outcomes were evaluated between sIPOM and IPOM-Plus by transfacial closure and introcorporeal closure (10). In this study, Transfacial suture closure of hernia defect was found to be the simplest method of repair and found to be effective with fewer incidences of seroma and early recurrence as compared with non-fascial repair technique (15).

Results

The aim of this study is to evaluate surgical outcomes of IPOM- Plus repair of ventral hernia with extracorporeal suturing of the defect versus intracorporeal suturing. In this prospective observational study, 200 patients, who underwent elective laparoscopic IPOM Plus repair for ventral hernia (defect size 2-5cm), were examined to compare surgical outcomes between extracorporeal (n=100) and intracorporeal defect closure (n=100). They were followed up to duration of 6 months and the primary outcome studied was early hernia recurrence (at 6 months). Secondary outcomes studied included demographic data of patients presenting with ventral hernia, comparison of operative time, wound complications between the two techniques. AGE: The mean age of patients in our study (n = 200) is 45.09 years (Standard deviation: 10.749). The mean age in the Extracorporeal group (n = 100) is 45.37 years (SD: 10.771) and that in the intracorporeal group (n = 100) is 44.81 years (SD: 10.775). Ventral hernias are morecommonly observed in middle age groups, and similar findings are seen in our study.

Sex: The overall male to female ratio (n = 200) is 0.86. The ratio in the extracorporeal group (n = 100) is 0.92 (52 females, 48 males) and in intracorporeal group (n = 100) is 0.82 (45 males, 55 females). The female preponderance in occurrence of hernia is well known and is seen in our study as well.

BMI: The mean BMI (n = 200) is 28.2287 kg/m2 (SD : 4.16142) with only 18% individuals having BMI in normal range, while 12% are overweight, 32% belong to Obesity Class 1, and 38 % belong to obesity class 2. Ventral hernia occurs commonly in individuals with greater BMI. The mean BMI in extracorporeal group is 28.1547 kg/m2 (SD : 4.09037) and that in intracorporeal group is 28.3028 kg/m2 (SD : 4.25059).

Defect Size: The study included defect sizes between 2cm to 5 cm only. The mean defect size (n = 200) for this range is 3.2695 cm (SD : 0.927).

Type of hernia: The most common hernia type encountered (n = 200) is Umbilical hernia (42 %), followed Paraumbilical hernia (30%), Incisional hernia (21%), Epigastric hernia (5%) , Lumbar hernia (1%) and Spigelian hernia (1%). Many studies report Umbilical and incisional hernias tobe the most commonly encountered ventral hernias. Since Incisional hernias have higher rates of recurrence as compared to primary ventral hernias, their distribution in both groups was checked and found to be equal.

Occurrence of comorbidity: 35% patients (n = 200) had pre-existing comorbid conditions the most common being Type 2 Diabetes Mellitus (14.5 %), Hypertension (10 %), Chronic respiratory disease (3.5%), Ischemic Heart Disease (3%) and Hypothyroidism (2%). Similar Comorbidity profile has been shown in several previous studies outlining demographic data of patients with

ventral hernia. Since presence of comorbid conditions can confound surgical outcomes, their frequency and distribution in both comparison groups was checked, and found to be equal.

Hernia Complications: Since complicated (obstructed/ strangulated)and emergency hernia repairs were excluded from this study, the only pre-operative hernia complication found was Irreducibility, seen in 12% cases in extracorporeal group and 15 % cases in intracorporeal group.

Operative Time Vs Closure Technique: The mean operative time for extracorporeal suturing is 62.39 minutes (SD : 14.428) and for intracorporeal suturing is 68.40 minutes (SD: 11.553). The p value for operative time is0.001 which is highly significant. Hence, operative time with transfacial approach is significantly less as compared with the intracorporeal approach. This may reflect the technical difficulty in intracorporeal suturing of the defect.

Post operative surgical site occurrence vs closure technique: Seroma formation occurred in 12 cases following extracorporeal suturing and 20 cases following intracorporeal suturing. This difference was statistically significant ($p<0.023$) with intracorporeal suturing associated with more seroma formation. Most of these resolved spontaneously, however, persistent seroma at 6 months, causing patient discomfort and requiring percutaneous aspiration was seen in 2 cases following extracorporeal suturing and 3 cases following intracorporeal suturing. Post-operative hematoma was seen in 2 cases following extracorporeal suturing and 1 case of intracorporeal suturing; however, this difference was not found to be statistically significant. Post-operative stitch granuloma was seen in 2 cases following extracorporeal suturing and none after intracorporeal suturing, however, this difference was also not found to be statistically significant. Superficial SSI was seen in 4 cases in extracorporeal and intracorporeal group each, and hence comparable in both groups. There was no case of deep SSI or mesh infection requiring mesh explantation, in either group.

Limitations

1. Literature regarding this topic is scarce and findings have been inconsistent, hence there is need for large scale studies with greater sample size for better interpretation and comparison.
2. Since most hernia recurrence occurs after 6 months, longer follow-up is required to compare true incidence of recurrence following both techniques.
3. Our study includes elective uncomplicated hernia repair of small ventral hernias (defect size 2-5cm). Positive results, including lesser incidence of SSI, hernia recurrence and post-operative seroma need to be interpreted in light of strict selection criteria of patients.

Conclusion

Laparoscopic ventral hernia repair has proven benefits as compared to open ventral hernia repair. The ideal technique for management of ventral hernia, however, remains a topic of debate. In our prospective observational study on comparison of surgical outcomes following extracorporeal versus intracorporeal suturing of the ventral hernia defect in IPOM-Plus, we have concluded that, extracorporeal suturing is associated with lesser operative time, lesser seroma formation than intracorporeal suturing. Early hernia recurrence between the two groups is comparable (1.5%) and both methods are effective for ventral hernia repair. Both techniques are safe with acceptable post-operative wound complications(16 % seroma formation, 4% Superficial SSI, 1.5% wound hematoma, 1% stich granuloma, no case of deep SSI requiring mesh explanatation) and low

rates of hernia recurrence(early hernia recurrence 1.5%)). Although several methods of laparoscopic mesh placement outside of the peritoneal cavity are gaining prominence as potential alternatives to IPOM-Plus, for the general surgeon, IPOM- Plus, thus, is a relatively safe and effective method of repairing ventral hernias, with a low recurrence rate. Proper Patient selection, preoperative optimisation and "individualised" tailored approach for each patient are of paramount importance for the success of ventral hernia repair. Large scale Randomized controlled studies, with longer duration of follow up are necessary to give more credible results which can be generalized to the entire population.

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