ORIGINAL ARTICLE

Intraperitoneal Onlay Mesh (IPOM) vs IPOM-plus in Ventral Hernia Repair: A Randomized Controlled Trial

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Abstract

Introduction: Hernias are one of the most common surgical problems faced by a surgeon in the outpatient department. Ventra hernia repair is linked with complications like bleeding, infection, and visceral injury. However, the commonest complication is seroma formation. This study was thus aimed to study the effect of fascial defect closure in ventral hernia repair done laparoscopically on seroma formation.

Patients and methods: This single-blinded randomized controlled trial was done in the Department of Surgery ABVIMS and Dr Ram Manohar Lohia Hospital, Delhi, from January 2021 to May 2022. A total of 50 patients more than 18 years of age with primary anterior abdominal wall hernia having a defect size <7 cm in the largest dimension were included in the study. Patients having complicated/recurrent hernias were excluded from the study.

Results: At 1 week of follow-up, two patients from the intraperitoneal onlay mesh (IPOM)-plus group and four from the IPOM group had seroma formation. This data was statistically insignificant (p-value = 0.667). At 1-month follow-up, two patients from group A and seven patients from group B had seroma formation. This data was also found to be statistically insignificant (p-value = 0.667). The mean pain score of patients from the IPOM-plus group was 3.64, and in the IPOM group, it was 5.08 at 24 hours after surgery. This data was found to be statistically significant with p-value of < 0.001. However, no statistically significant difference in pain scores was observed between both groups at the time of discharge, at 1 week and at 1 month after surgery. Moreover, none of the patients in both groups suffered recurrence of hernia at 1-month postsurgery.

Conclusion: Intraperitoneal onlay mesh-plus has shown better outcomes compared to IPOM in terms of seroma formation and postoperative pain scores.

Keywords: Better outcomes, Complications, Fascial defect closure, Seroma, Surgical.

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Introduction

Hernias are one of the most common surgical problems faced by a surgeon in the outpatient department. Ventral hernia and inguinal hernia are among the commonly encountered entities. Hernias do not heal or go away on their own, and therefore, they must be surgically treated. Hernias that go untreated can become difficult to heal and have disastrous results, such as strangulation. The treatment of ventral hernia has changed dramatically over the years. A primary open repair without mesh was the earliest approach and is currently indicated only for fascial defects less than 2 cm in size.[1] Primary repair, when done for larger defect sizes, has an unacceptably high recurrence rate. With the advent of open mesh repair, this recurrence rate has dropped from 63 to 32.6%.[2] Laparoscopic ventral hernia repair (LVHR) was initially introduced in 1993 by Leblanc K, and since then, it has grown in popularity both among surgeons and patients.[3] Laparoscopic ventral hernia repair, like any other surgery, is associated with complications like bleeding, infection, and visceral injury. However, seroma formation as a complication is still a menace.[4] Laparoscopic ventral hernia repair can also be done by two methods. Firstly, a simple intraperitoneal mesh can be placed over the fascial defect without its closure, known as intraperitoneal onlay mesh (IPOM) repair. Alternatively, the defect could be closed before placing an intraperitoneal mesh, which is known as IPOM-plus.[5] Previous studies on these procedures have reported an incidence rate of seroma ranging from 0.5 to 35%. Researchers have been advocating IPOM-plus to have decreased seroma rates than IPOM. It has been hypothesized that the lower incidence of seroma following defect closure is because of decreased dead space in the residual sac. This, if scientifically proven, can be an important result as it will change the outlook toward ventral hernia surgery. Some studies done in the past, however, had contradictory results when IPOM and IPOM-Plus were compared. Clapp et al. and Zeichen et al. reported a higher incidence of seroma formation in IPOM-plus when compared to IPOM.[6,7]

Therefore, it can be inferred that there are significant lacunae in present knowledge about postoperative seroma formation in laparoscopic midline anterior abdominal wall hernia (LMAAWH) repair. Also, there are very few studies comparing IPOM and

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IPOM-plus in terms of postoperative seroma formation, and that too, with conflicting outcomes. Additionally, there is a paucity of literature on this topic, especially from the Indian subcontinent.

This study is therefore aimed to compare IPOM and IPOM-plus with respect to postoperative seroma formation in LMAAWH repair.

Patients and Methods

This single-blinded randomized controlled trial was done in the Department of Surgery at Atal Bihari Vajpayee Institute of Medical Sciences and Dr. Ram Manohar Lohia Hospital, Delhi, from January 2021 to May 2022.

Institutional ethical committee clearance was taken with ethical clearance number – TP (MD/MS) (166/2020)/IEC/ABVIMS/RMLH/433. This study was registered in Clinical Trial Registry – India (CTRI) with registration number CTRI/2021/05/033370.

A total of 50 patients were enrolled in this study. Randomization was done using a computer-generated random number table, and allotment was done using sequentially numbered opaque sealed envelopes (Fig. 1).

Sample size was calculated according to the study by Suwa et al., who observed that seroma formation in IPOM was 33%, and in IPOM-plus, it was 21%.[8] Taking these values as reference, the minimum required sample size with 80% power of the study, and 5% level of significance is 211 patients in each study group. For a finite sample size, taking the population as 50, the total sample size calculated came to 45, and to reduce the margin of error, the total sample size of 50 was taken (25 per group).

Formula used:

$$n \geq ((pc * (1-pc) + pe * (1-pe)) * (Z\alpha + Z\beta)^2)/(pc-pe)^2$$

with

pc = seroma formation in IPOM

pe = seroma formation in IPOM-plus

$SS \geq n/(1 + [(n - 1)/Pop])$

Where pop is population

Where Zα is the value of Z at a two-sided alpha error of 5% and Zβ is the value of Z at a power of 80%.

Calculations:

$$n \geq ((0.33 * (1-0.33) + 0.21 * (1-0.21)) * (1.96 + 0.84)^2)/(0.33-0.21)^2$$
$$\geq 210.7 = 211 \text{ (approx.)}$$

So *n* for two groups – 2 * 211 = 422

Finite population correction factor:

$$SS \geq 422/(1+(422-1)/50) = 44.80 = 45 \text{ (approx.)}$$

All patients more than 18 years of age with primary anterior abdominal wall hernia having a defect size <7 cm in the largest dimension were included in the study. Patients having complications such as irreducible/obstructed/strangulated/recurrent hernias and those who refused to give consent for laparoscopic surgery were excluded from the study. The size of the defect was detected clinically and by sonography, which was recorded on a patient proforma. Written informed consent was taken from all the patients. Patients were randomized into two groups using a sealed opaque envelope method – group I (IPOM-plus) and group II (IPOM). All patients were subjected to surgery according to the allotted group. In IPOM-plus, mesh was placed after closing the hernia defect, while in IPOM, mesh was placed without closing the hernia defect. All patients were operated on by the same team of one senior surgeon and two assistant surgeons. All patients were given a single shot of antibiotic prophylaxis at the time of induction (Inj. Amoxycillin-Clavulanic Acid 625 mg i.v.), and it was continued in the postoperative period for 3 days.

Postoperatively, resumption of oral feeds was made according to the discretion of the surgeon based on the reappearance of bowel sounds or passage of flatus. Seroma formation in the

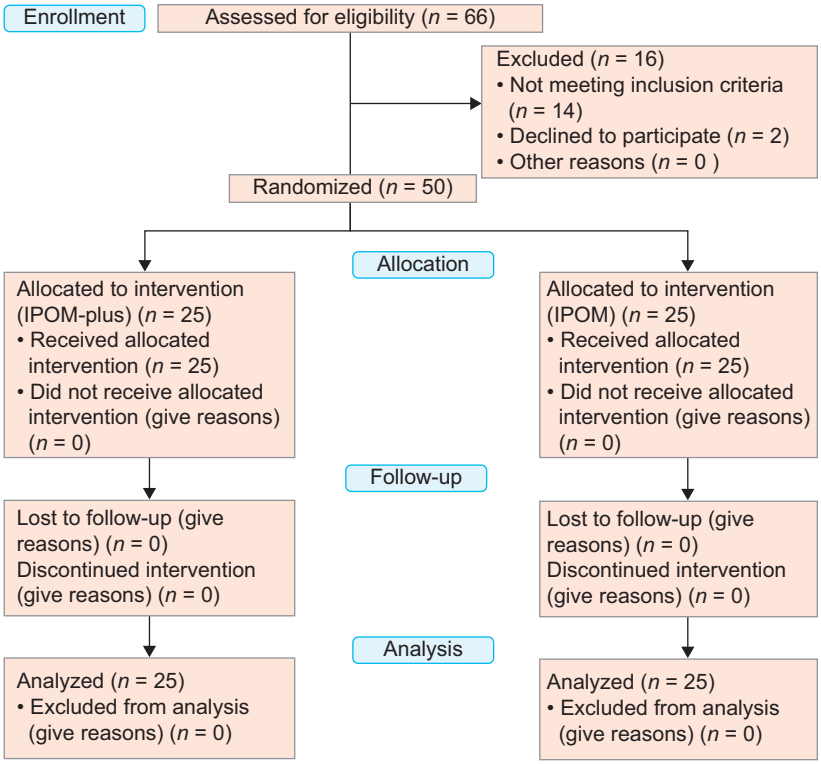

Fig. 1: Consort flow diagram

postoperative period was recorded (at 24 hours, at the time of discharge, 1 week and 1 month) following surgery, assessed using physical examination ± ultrasound. The pain was recorded using the visual analog scale (verbal score from 1 to 10), and the patient was given a painkiller on an SOS basis. During the same duration, early recurrence, if any (within 1 month follow-up), was also assessed.

Statistical Analysis

Continuous variables were presented as mean ± SD, and median and categorical variables were presented in number and percentage (%). The Kolmogorov–Smirnov test was used to test for normality of data. Non-parametric test was used if the normality was rejected.

Statistical tests applied were as follows:

- Unpaired *t*-test/Mann–Whitney test was used to assess quantitative variables (when the data sets were not normally distributed) between the two groups.
- Chi-square test/Fisher's exact test was used to assess qualitative variables.
- A *p*-value of < 0.05 was considered statistically significant.
- The data was analyzed using Statistical Package for Social Sciences (SPSS) version 21.0.

Observation and Results

A total of 50 patients were recruited in the study, with ages ranging from 21 to 60 years. The average age in group A was 37.28 ± 8.81, and in group B, it was 38.56 ± 8.49. A total of 19 patients were males (10 in group A and 9 in group B).

Postoperative Seroma Formation

None of the patients from both groups developed seroma at 24 hours after surgery and at the time of discharge. However, at 1 week of follow-up, two patients from group A and four from group B had seroma formation. This data was found to be statistically insignificant (*p*-value = 0.667). At 1-month follow-up, two patients from group A and seven patients from group B had seroma formation. This data was also found to be statistically insignificant (*p*-value = 0.667) (Table 1).

Postoperative Pain

Mean pain score of patients from group A was 3.64, and in group B, it was 5.08 at 24 hours after surgery. This data was found to be statistically significant with *p*-value of < 0.001. However, no statistically significant difference in pain scores was observed between both groups at the time of discharge, at 1 week and at 1 month after surgery (Table 2).

Recurrence

None of the patients in both groups suffered recurrence of hernia at 1-month postsurgery (Table 3).

Discussion

Most of the study participants who underwent LVHR belonged to the age-group of 31–40 years (37.5%), and their mean age was 37.92 ± 8.58. Sixty-two percent of them were females, and 38% were males. A similar demography was also seen in a study conducted by AhmedAlenazi et al., which showed that hernias were more prevalent in females than in males (63.4 vs 36.6%).[9] Jaykar et al. and Bhamre and Pingale. also concluded that ventral hernias were more prevalent in females.[10,11]

Table 2: Postoperative pain

	Group		Wilcoxon–Mann–Whitney U test	
	IPOM-plus	*IPOM*	*W*	*p-value*
Pain score (24 hours)				
Mean (SD)	3.64 (1.15)	5.08 (1.22)	128.000	<0.001
Median (IQR)	4 (3–4)	5 (4–6)		
Range	1–6	3–8		
Pain score (discharge)				
Mean (SD)	1.12 (0.33)	1.12 (0.33)	312.500	1.000
Median (IQR)	1 (1–1)	1 (1–1)		
Range	1–2	1–2		
Pain score (1 week)				
Mean (SD)	1.00 (0.00)	1.00 (0.00)	312.500	–
Median (IQR)	1 (1–1)	1 (1–1)		
Range	1–1	1–1		
Pain score (1 month)				
Mean (SD)	1.00 (0.00)	1.00 (0.00)	312.500	–
Median (IQR)	1 (1–1)	1 (1–1)		
Range	1–1	1–1		

Table 3: Recurrence rates

	Group			Chi-squared test	
Recurrence	*IPOM-plus*	*IPOM*	*Total*	χ^2	*p-value*
No	25 (100.0%)	25 (100.0%)	50 (100.0%)	–	–
Total	25 (100.0%)	25 (100.0%)	50 (100.0%)		

Table 1: Postoperative seroma formation

	Group			Fisher's exact test	
	IPOM-plus	*IPOM*	*Total*	χ^2	*p-value*
Seroma (1 week)					
Yes	2 (8.0%)	4 (16.0%)	6 (12.0%)	0.758	0.667
No	23 (92.0%)	21 (84.0%)	44 (88.0%)		
Total	25 (100.0%)	25 (100.0%)	50 (100.0%)		
Seroma (1 month)					
Yes	2 (8.0%)	7 (28.0%)	9 (18.0%)	3.388	0.138
No	23 (92.0%)	18 (72.0%)	41 (82.0%)		
Total	25 (100.0%)	25 (100.0%)	50 (100.0%)		

In this study, we found that seroma formation was not seen in either group in the post-op period at 24 hours or at the time of discharge. However, two patients at 1 week and two patients at 1 month in the IPOM-plus group and four patients at 1 week and seven patients at 1 month in the IPOM group had seroma, which was not statistically significant. Numerically, the incidence of seroma formation was lower in IPOM-plus as compared to IPOM over the follow-up period of 1 month. The most common complication after LVHR is seroma formation, which causes pain, discomfort, and sometimes infection at the surgical site and also shatters the esthetic outcome for the patient. Previously reported data on IPOM have shown the incidence of clinical seroma to be around 0.5–78%.[12] The development in imaging modalities can be responsible for this wide range. These newer modalities can also detect small asymptomatic seromas.[13]

Table 4 shows the comparison of studies done in the past which have compared the effect of IPOM-plus and IPOM on seroma formation. Studies by Clapp M et al., Tandon A et al., and Taşdelen HA showed that seroma formation was statistically low in the IPOM-plus group, while studies by Zeichen M et al. and Suwa K et al. showed that there was no statistically significant difference in seroma formation in both groups.[6–8,14,15]

Postoperative pain has always been an issue of capital importance. In this study, pain in the postoperative period was assessed using a visual analog scale. Postoperatively, the scores at 6 hours, 24 hours, at the time of discharge, at 1 week, and at 1 month for IPOM-plus and IPOM groups were 3.64 ± 1.15 and 5.08 ± 1.22, 1.12 ± 0.33 and 1.12 ± 0.33, 1.00 ± 0.00 and 1.00 ± 0.00, 1.00 ± 0.00 and 1.00 ± 0.00, respectively. Pain was significantly lower in the IPOM-plus group as compared to IPOM at 24 hours after surgery. Thereafter, pain starts to settle and becomes statistically insignificant for both groups at the end of the 1-month follow-up period. Clapp et al. analyzed the incidence of chronic pain in IPOM vs IPOM-plus and reported that the incidence was statistically non-significant between the two groups (18.2 and 18.2 %, respectively).[6] Suwa K et al. also found similar results with the incidence of chronic pain in only two patients of IPOM-plus.[8]

Our study did not have any recurrence of hernia in both groups. However, three studies by Clapp ML et al., Zeichen MS et al., and Banerjee A et al. found that IPOM-plus was linked to a lower recurrence rate than IPOM (0 and 16.7, 3.0 and 4.8, and 5.7 and 15.1% recurrence rates, respectively).[6,7,16] However, according to two studies by Gonzales AM et al. and Strey CW IPOM-plus did not help to lower the recurrence rate.[17,18] Zeichen et al. compared non-closure with closure in mesh repair over an average of 26 months of follow-up.[7] The authors found a higher rate of recurrence (19.18%) in the non-closure group than in the closure group (6.25%); however, this difference was not statistically significant. Basukala S et al. in their study on 130 patients found that hernia recurrence within six months was higher in the IPOM group (15.1%) than IPOM-plus group (3.5%) (p-value = −0.029).[19] Suwa K et al. in the contrary found that only one case of recurrence in the IPOM group, which was statistically insignificant.[8]

Table 4: Studies comparing seroma formation in IPOM and IPOM-plus

Study	Number of patients	Results of post-op seroma formation		
		IPOM-plus	IPOM	p-value
Clapp M et al.[6]	176	5.6%	27.8%	0.02
Zeichen M et al.[7]	128	11.4%	4.3%	>0.05
Tandon A et al.[14]	3,638	2.5%	12.2%	<0.05
Taşdelen HA[15]	82	8.6%	22.2%	0.477
Suwa K et al.[8]	49	21%	33%	0.6652

Conclusion

Although the recurrence rates are statistically similar, IPOM-plus has shown better outcomes compared to IPOM in terms of seroma formation and postoperative pain scores. However, we recommend a longer follow-up and a large sample size to assess the long-term impact and comparison of LVHR with or without defect closure.

Limitation of Study

Factors like variations in patient body mass index (BMI), hernial orifice size, and follow-up times have an impact on recurrence rates. Therefore, a short follow-up period and non-consideration of other confounding factors are limitations of this study.

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