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Cohort Study

Comparison of outcomes of laparoscopic hernioplasty with and without fascial repair (IPOM-Plus vs IPOM) for ventral hernia: A retrospective cohort study

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ABSTRACT

Background: Intra-peritoneal onlay mesh (IPOM) repair, a type of Laparoscopic Ventral Hernia Repair (LVHR), comprises bridging the defect from the peritoneal side with a composite mesh. Recently, IPOM-Plus has become the recommended type of LVHR in which the defect in the fascia is sutured before placing the mesh.

Materials and methods: This study is a retrospective cohort study conducted at Shree Birendra Hospital (SBH), Nepal. Patients who had undergone IPOM-Plus or IPOM during the past five years (Aug 2016 to Aug 2021) were selected. Data regarding demographics, intraoperative and post-operative outcomes were collected from individual case sheets. Recurrence of hernia was checked at six-month follow-up. Data analysis was performed using SPSS version 25 taking a p-value of <0.05 as statistically significant.

Results: A total of 130 patients were included in this study, out of which 73 patients had undergone IPOM (Group I) and 57 patients underwent IPOM-Plus (Group II). In both the groups, there were no statistical difference in age, sex and Body Mass Index (BMI) of the patients. Hernia defect size among Group I and II varied significantly (p-value < 0.001). The mean operative time for Group II (111.05 ± 28.14 min) was significantly higher than Group I (80.00 ± 27.96 min) (p-value < 0.001). Hernia recurrence within six months was higher in Group I (15.1%) than Group II (3.5%) (p-value $= 0.029$). The adjusted odds ratio (AOR) for six-month recurrence after IPOM repair was 14.86 (95% CI: 2.51–87.85, p-value $= 0.003$) times higher than that after IPOM-Plus repair.

Conclusions: Although the operative time and length of hospital stay is longer, IPOM-Plus repair has shown better outcomes regarding six-month recurrence compared to IPOM repair.

1. Introduction

Ventral abdominal wall hernia surgery is a common procedure in the armamentarium of surgeons. The commonest of these surgical procedures in adults are repair of incisional hernias and paraumbilical hernia. Incisional hernias have been reported to occur following 11%–20% of abdominal surgeries [1–3]. The overall incidence of primary ventral hernia is estimated to be between 4 and 5% in the literature, whereas ventral incisional hernia rates vary from 35 to 60% within 5 years after laparotomy [4,5]. About one in six patients undergoing hernia repair require reoperation within 10 years [6]. Ventral hernia and it's recurrences are a huge burden to the health system and the nation's economy [7,8].

Since it was introduced by Karl Leblanc [9] in 1993, LVHR has gained increasing acceptance due to better postoperative outcomes compared to open ventral hernia repair (OVHR) [10–13] but there is considerable controversy regarding the optimal approach. Several issues related to LVHR are yet to be resolved, such as seroma formation, and high recurrence rate of hernias among extremely obese patients and those with large fascial defects [14].

The laparoscopic repair of ventral hernias consisting of bridging the defect from the peritoneal side with a composite mesh, known as the intra-peritoneal onlay mesh (IPOM) repair was considered as a standard technique. However, such repair is associated with a significant

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incidence of post-operative bulging or eventration of mesh, seromas, recurrences, and non-restoration of abdominal muscle function [15]. To circumvent these problems, sutured closure of the defect in the fascia with intra-peritoneal mesh reinforcement has been described, termed as IPOM-Plus repair [16]. This repair is now the recommended procedure in the guideline of International Endohernia Society (IEHS) [17].

This study aims to compare the outcomes among patients who had undergone laparoscopic onlay mesh repair with and without fascial defect closure (IPOM-Plus vs IPOM).

2. Materials and methods

2.1. Registration

This study has been registered on Research Registry on March 19, 2022 and the unique identifying number is researchregistry7751. The manuscript has been reported in line with the STROCSS criteria [18].

2.2. Ethical approval

The institutional review committee of Nepalese Army Institute of Health Sciences (NAIHS) approved the study with registration number 490.

2.3. Participants and study design

This study is a retrospective cohort study conducted at a 750-bed tertiary care center, Shree Birendra Hospital (SBH), Nepal. Retrospective analysis of patients who had undergone IPOM-Plus or IPOM during the study period of past five years (Aug 2016 to Aug 2021) was done. The inclusion criteria were: (1) patient's age above 18 years; (2) symptomatic patients with primary or incisional ventral hernias; (3) defect size ranging from 2 cm to 6 cm; (4) patients who had completed all follow-up visits up to six months post-operatively. And the exclusion criteria were: (1) patient younger than 18 years; (2) strangulated ventral hernia; (3) patients unfit for laparoscopic surgeries under general anesthesia; (4) defect size <2 cm and >6 cm with loss of domain; (5) those who needed abdominal wall reconstruction; (6) Body Mass Index (BMI) > 35.0 kg/m^2 and (7) patients with HIV/immuno-compromised state.

2.4. Study procedure

During the study period, there were 142 patients admitted with the clinical diagnosis of ventral hernia who underwent LVHR (IPOM or IPOM-Plus). A total of 130 patients who had complete data were selected based on the inclusion and exclusion criteria. Preoperative baseline characteristics, including age, sex, BMI, site and size of primary or incisional hernia, and comorbidities were collected from the individual case sheets of hospital records and analyzed. Intraoperative parameters including operative time, and intraoperative complications were extracted from OT notes and compared. Postoperative details like seroma, surgical site infection (SSI), postoperative pain, total hospital stay after surgery, and recurrence at six months follow-up were reviewed from the patients records and compared.

2.3.1. Surgical technique

The surgical technique for IPOM and IPOM-Plus, as practiced in our institution for the study participants is as below:

Preoperatively, a prophylactic third generation cephalosporin was

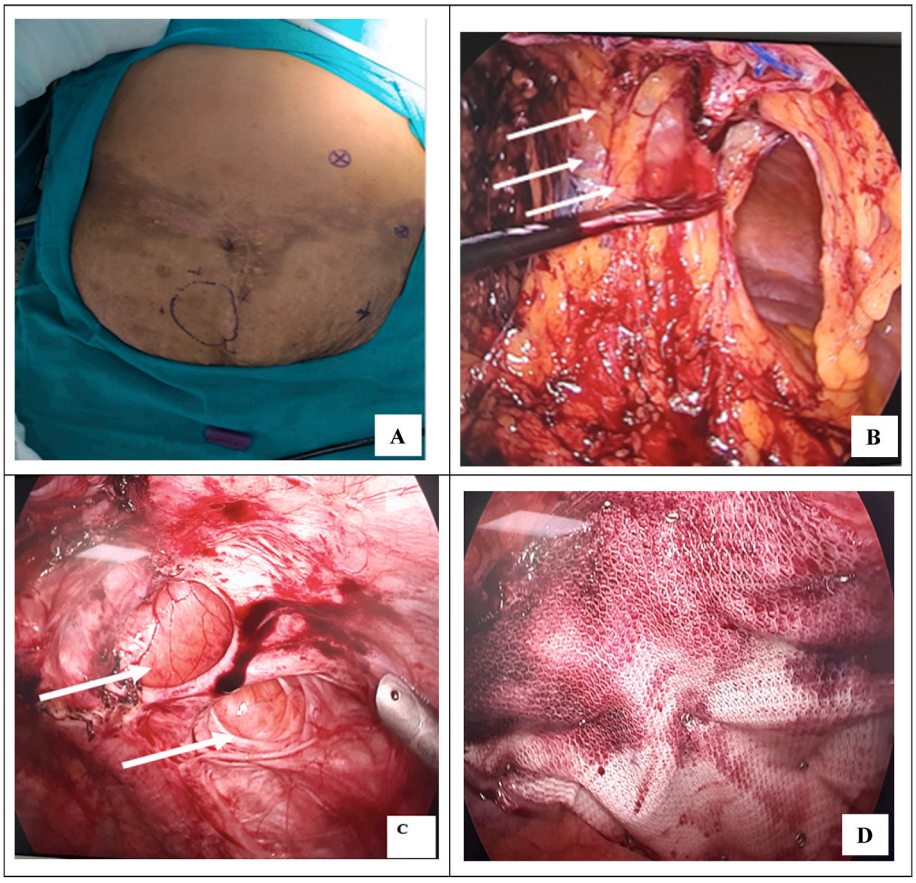

Fig. 1. Laparoscopic images of IPOM repair of ventral hernia: (A). Infraumbilical incisional hernia with marking of defect. (B). Adhesion of omentum in the anterior abdominal wall (white arrows). (C). Defect in the anterior abdominal wall seen after adhesiolysis (white arrows). (D). Defect covered by composite mesh.

given and surgical skin was prepared and marked to identify the defect (Fig. 1A). General anesthesia was induced, and the patient was placed in a supine position with the ipsilateral arm placed over the patient's head. Pneumoperitoneum (12–14 mmHg) was created using a closed needle technique, inserted at palmer's point. In the majority of the cases, 2 ports were used (a 10-mm port at the palmer's point and another 5-mm port in the left lumbar region) and an additional third port (5-mm) was used when required. The port positions varied for a few cases depending on the area of the defect while adhering to the principle of triangulation. Diagnostic laparoscopy and reduction of contents (with or without adhesiolysis) were done, and the defect was defined (Fig. 1B and C). A 30° optic was used for the procedure. The borders of the defect were illuminated and outlined. If extensive adhesions were found in the abdominal cavity, they were taken down laparoscopically in both groups.

For IPOM, the hernia defect was measured, and an appropriately sized prosthetic mesh was tailored to overlap all margins of the defect in each direction by at least 3 cm or up to 5 cm, if possible. Intraperitoneal synthetic composite meshes were used for reinforcement. Points of reference on the mesh and corresponding points on the abdominal wall were marked to aid in orienting the mesh after its introduction into the abdomen. The mesh was rolled up and pushed into the abdomen through the 12-mm trocar. The mesh was then fixed using tackers (covidien and bard; Fig. 1D).

For IPOM-Plus, the defects were closed by an extracorporeal interrupted suture technique with non-absorbable monofilament sutures for additional intraperitoneal onlay mesh reinforcement (Fig. 2). Mesh size selection was based on the original fascial defect, and the mesh overlap was at least 3 cm or up to 5 cm, if possible, in each direction. Fixation of the mesh was performed in the same fashion as IPOM. Then, pneumoperitoneum was reduced and ports were retrieved under vision. Pressure dressing was placed.

2.3.2. Follow-up

Regular follow-up evaluations and physical examinations was done in the surgical out-patient department (SOPD) visits. Skin sutures and the pressure dressings were removed on the first follow-up period (7–10 days). Postoperatively, patients had also been advised to avoid lifting heavy weights for three months, use abdominal binders for a period of 2–3 months and follow a strict balanced diet to prevent obesity and hence, prevent future recurrence. Follow-ups was done in regular intervals of two weeks, three months and six months after the discharge.

2.6. Statistical analysis

After retrospective data collection, the data was cleaned, classified and coded. The coded data was entered and tabulated using Statistical Package for Social Science (SPSS) version 25. Descriptive statistics included mean, median, standard deviation (SD) and Inter-Quartile Range (IQR) for quantitative variable; number and percentage for categorical data. Inferential statistics were performed using Pearson's Chi-square test for categorical data and Mann Whitney *U* test for continuous data, as our data was not normally distributed. Logistic regression analysis was performed to compare the six-month recurrence rate between the two surgical techniques. A p-value of <0.05 was considered to be statistically significant.

3. Results

3.1. Demographic profile

A total of 130 patients were included in this study, out of which 73

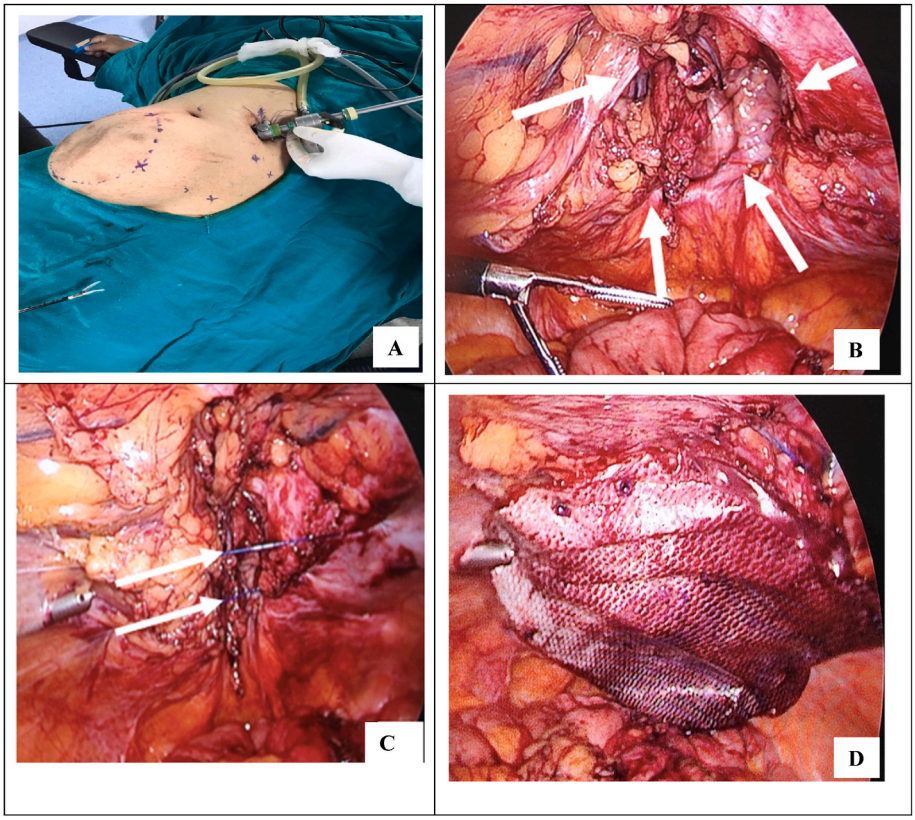

Fig. 2. Laparoscopic images of defect closure with IPOM-Plus: (A). Infraumbilical incisional hernia with working port in palmer's point. (B). Defect in the anterior abdominal wall after reducing the contents (white arrows). (C). Primary defect closed with non-absorbable transfascial suture (IPOM-Plus) (white arrows). (D). Defect covered by composite mesh, secured with transfascial sutures and tackers.

patients had undergone IPOM (Group I) and rest 57 had undergone IPOM-Plus. Among them, there were 25 (34.2%) males and 48 (65.8%) females in Group I while 21 (36.8%) were male and 36 (63.2%) were female in Group II. In both the groups, there were no statistical difference in age, sex and BMI of the patients (Table 1).

3.2. Intraoperative findings

Most of the hernias were M3 and M4, as per European Hernia Society (EHS) classification. Patients undergoing IPOM surgery had significantly different size of hernia defect as compared to those undergoing IPOM-Plus type of repair ($\chi^2 = 35.92$, $p < 0.001$) (Table 2). Since IPOM-Plus involves additional procedures, the mean operative time of Group II patients (111.05 ± 28.14) was significantly higher than Group I patients (80.00 ± 27.96) (Mann Whitney $U = 965.5$, $p < 0.001$).

3.3. Early postoperative outcome

Length of hospital stay was significantly longer in Group II patients as compared to Group I (1.72 ± 0.86 vs 1.51 ± 1.12 days) (Mann Whitney U test = 1492.00, $p = 0.002$). Other early postoperative complications are presented in Table 3.

3.4. Late postoperative complications

Only 13 (10%) patients had recurrence within six months, out of which 11 were from Group I and 2 were from Group II. This observed difference between two surgical procedures regarding the recurrence is significant ($\chi^2 = 4.75$, $p = 0.029$) (Table 4). Similarly, significant difference in recurrence was found among different groups of fascial defect size ($\chi^2 = 9.39$, $p = 0.09$) and status of mesh bulging after the repair ($\chi^2 = 11.18$, $p = 0.013$) (Table 5). Differences in recurrence between the two techniques were found regarding different parameters like BMI, history of previous repair, intraoperative bowel/bladder injury, and development of surgical site infection; but they were not statistically significant. A binomial logistic regression analysis was performed after adjusting the possible confounders like size of defect and mesh bulging, which showed odds of six-month recurrence after IPOM procedure was 14.86 (95% CI: 2.51–87.85, $p = 0.003$) times higher than that after IPOM-Plus type of repair (Table 5).

Table 1
Patient demographics and Hernia Characteristics.

S. No.	Particulars	Group I (IPOM) N (%)	Group II (IPOM-Plus) N (%)	P-value
1.	Sex			
	• Male	25 (34.2)	21 (36.8)	0.759
	• Female	48 (65.8)	36 (63.2)	
2.	Age (years)			
	• Mean ± SD	52.33 ± 13.72	50.81 ± 13.519	0.637
	• Median (IQR)	51.00 (24)	49.00 (22)	1.00
3.	BMI (kg/m^2)			
	• Mean ± SD	29.57 ± 2.81	29.42 ± 2.76	0.923
	• Median (IQR)	29.10 (4.55)	29.10 (3.80)	0.896
	• Overweight	38 (52.1)	29 (50.9)	
	• Obese	28 (38.4)	24 (42.1)	
4.	Type of hernia			
	• Primary ventral hernia	5 (6.8)	12 (21.1)	**0.017**
	• Incisional hernia	68 (93.2)	45 (78.9)	
5.	ASA grading			
	• Grade I	37 (50.7)	40 (70.2)	
	• Grade II	32 (43.8)	15 (26.3)	**0.028**
	• Grade III	4 (5.5)	2 (3.5)	

SD: Standard Deviation; IQR: Interquartile range; BMI: Body Mass Index; ASA: American Society of Anesthesiologists.

Table 2
Intraoperative complications among study patients.

S. no	Particulars	Group I (IPOM) N (%)	Group II (IPOM-Plus) N (%)	P-value
1.	EHS grading of hernia			
	• M1	5 (6.8)	0	
	• M2	7 (9.6)	6 (10.5)	0.109
	• M3	21 (28.8)	16 (28.1)	
	• M4	40 (54.8)	35 (61.4)	
	• M5	–	–	
2.	Defect size			
	• Less than 2 cm	24 (32.9)	1 (1.8)	
	• 2–4 cm	33 (45.2)	16 (28.1)	**<0.001**
	• 4–6 cm	16 (21.9)	40 (70.2)	
3.	Vascular injury			
	• Yes	None	None	
	• No			–
4.	Injury to the bowel or bladder			
	• Yes	3 (4.1)	1 (1.8)	0.631
	• No	70 (95.9)	56 (98.2)	
5.	Operative time			
	• Mean ± SD	80.00 ± 27.96	111.05 ± 28.14	**<0.001**
	•Median (IQR)	90.00 (40)	110.00 (48)	**<0.001**

EHS: European Hernia Society; SD: Standard Deviation; IQR: Interquartile Range.

Table 3
Early Postoperative complications.

S. no	Particulars	Group I (IPOM) N (%)	Group II (IPOM-Plus) N (%)	P-value
1.	Seroma			
	• Yes	4 (5.5)	2 (3.5)	0.695
	• No	69 (94.5)	55 (96.5)	
2.	Hematoma			
	• Yes	3 (4.1)	5 (8.8)	0.297
	• No	70 (95.9)	52 (91.2)	
3.	Wound infection			
	• Yes	2 (2.7)	2 (3.5)	1.000
	• No	71 (97.3)	55 (96.5)	
4.	Length of hospital stay (days)			
	• Mean ± SD	1.51 ± 1.12	1.72 ± 0.86	**0.002**
	• Median (IQR)	1 (1)	2 (1)	**0.001**

SD: Standard Deviation; IQR: Interquartile Range.

Table 4
Late post-operative complications.

S. No.	Particulars	Group I (IPOM) N (%)	Group II (IPOM-Plus) N (%)	P-value
1.	Hernia recurrence within six months			
	• Yes	11 (15.1)	2 (3.5)	**0.029**
	• No	62 (84.9)	55 (96.5)	
2.	Mesh bulging			
	• Yes	6 (8.2)	None	**0.035**
	• No	67 (91.8)	57 (100)	

4. Discussion

The average age of patients in Group I and Group II was 52.33 ± 13.72 and 50.81 ± 13.52 years, respectively. Older adults are at increased risk of developing ventral hernia owing to weak anterior abdominal wall and impaired tissue repair mechanisms. Furthermore, comorbidities occurring in old age such as Chronic Obstructive Pulmonary Disease (COPD) with chronic coughing, constipation, benign prostatic hyperplasia and ascites increase the intraabdominal pressure,

Table 5
Association of different variables with six-month recurrence.

S no.	Variables	Recurrence N (%)	No recurrence N (%)	P-value	Odds Ratio (OR) (95% CI)	Adjusted Odds Ratio (AOR) (95% CI)
1.	Type of surgery				4.88 (1.04–22.98) ref (p-value = 0.045)	14.86 (2.51–87.85)[a] ref (p-value = 0.003)
	• IPOM	11 (84.6)	62 (53.0)	0.029		
	• IPOM-Plus	2 (15.4)	55 (47.0)			
2.	Size of defect					
	• Less than 2 cm	0	25 (21.4)	0.009	–	–
	• 2–4 cm	3 (23.1)	46 (39.3)			
	• 4–6 cm	10 (76.9)	46 (39.3)			
3.	Mesh bulging					
	• Present	3 (23.1)	3 (2.6)	0.013	–	–
	• Absent	10 (76.9)	114 (97.4)			

[a] = Odds ratio (OR) adjusted for size of defect and mesh bulging with IPOM-Plus group as reference.

which can increase the risk of incisional hernias [19–21]. Similarly, there were 25 (34.2%) males and 48 (65.8%) females in Group I while there were 21 (36.8%) males and 36 (63.2%) females in Group II. Prior studies have demonstrated that female patients have higher post-operative rates of surgical site infection, readmission, immediate and chronic postoperative pain, and worse postoperative quality of life [22,23]. Furthermore, systematic review by Parker et al. [24] showed men had significantly lower odds of ventral hernia recurrence (OR 0.77 (0.61–0.97)). However, sex factor should not be taken in isolation while associating it with hernia recurrences because female hernia patients are usually more comorbid, with higher body mass index, thicker subcutaneous fat volume and a higher ratio of hernia volume to intra-abdominal fat volume [25].

In our study, 38 (52.1%) patients were overweight and 28 (38.4%) were obese in Group I while 29 (50.9%) were overweight and 24 (42.1%) were obese in Group II. A clear association between obesity and the rate of primary ventral, inguinal, and incisional hernia formation has already been established. Regner et al. [26] reviewed the National Surgical Quality Improvement Program (NSQIP) data, finding that approximately 60% of 106,968 patients undergoing elective ventral hernia repair (VHR) were obese. Similarly, Goodenough et al. [27] identified a BMI greater than or equal to 25 kg/m^2 as an independent predictor of incisional hernia. Progressively increasing risk of ventral hernia formation with each BMI stratum above 25 kg/m^2 has also been identified [28].

Bowel and bladder injury are the frequent and major intraoperative complications of LVHR surgery; the other post-operative complications being hemorrhage, mesh infection and recurrence [29]. Our study showed a total incidence of 3.1% of intraoperative bowel and bladder injury which was higher than that of the previously conducted studies. A literature review by LeBlanc et al. reported the incidence of bowel injury among 1.78% patients of the 3925 patients undergoing LIVHR [30]. Incisional hernias are associated with greater risk of adhesions requiring adhesiolysis, making bowel and bladder susceptible to injury. Out of four patients who faced intraoperative bowel/bladder injury, none of them developed surgical site infection. This finding is consistent with that of Heniford B T et al., which also showed zero cases of surgical site infection after such complications [31]. It has been suggested that careful dissection and judicious use of energy sources are important measures to reduce the occurrences of bowel and bladder injuries in such procedures [32].

The most common complication after LVHR is seroma formation, which causes discomfort, pain, infections and destroys the aesthetic outcome for patients [33]. Review by Suwa et al. [34] reported the overall incidence of seroma in IPOM-Plus to be 0–11.43%. In our study, seroma was observed in four IPOM patients (5.5%) and in two IPOM-Plus patients (3.5%) (p = 0.695**)**; which is similar to other studies [35]. However, comparison of incidence of seroma formation between IPOM and IPOM-Plus yields varying results in the literature [36–38]. A metanalysis including 16 studies concluded significantly higher rates of seroma formation after IPOM as compared to IPOM-Plus (12.2% versus 2.5%) with a combined relative risk of 0.37 (95% CI:0.23 to 0.57; P < 0.001) [39]. In the current study, the incidence of hematoma formation in IPOM and IPOM-Plus groups was not significantly different (4.1% vs 8.8%; P = 0.297). Hematoma formation is not reported by most of the studies. Wound infection occurred in two patients in each group. In contrast to our findings, Ali et al. reported surgical site infection higher in IPOM group (3/21, 14%), compared to IPOM-Plus (3/94, 3%) [38]. In the current study, length of hospital stay was significantly longer among patients of IPOM-Plus group than IPOM group (1.72 ± 0.86 versus 1.51 ± 1.12) (P = 0.002) which is contradictory to previous studies [16,38,41,42]. Similarly, Suwa et al. [35] reported postoperative hospital stay after IPOM for large incisional hernia was significantly longer than that after IPOM-Plus.

A review by Suwa et al. [34] reported the overall recurrence rate of IPOM-Plus was 0–7.7% with a median follow-up period of 10.5–50.4 months. In our study, the recurrence of hernia within six months was found to be significantly lower in the IPOM-Plus group (2 (3.5%)) compared to the IPOM group (11 (15.1%)). In accordance to this, few studies have indicated that IPOM-Plus was associated with a lower recurrence rate compared with that of IPOM [16,38,40,43]. However, two studies [42,44] reported that IPOM-Plus did not contribute to a reduction in the recurrence rate. A recent study by Christoffersen et al. reported the incidence of recurrence was nearly three times lower in the IPOM-Plus group compared to the IPOM [44].

Mesh bulging or mesh eventration is a recently reported complication of VIHR [12,45,46]. Regarding the mechanism underlying mesh bulging, the central nonfunctioning portion of the abdominal wall will protrude into the hernia sac due to the intraabdominal pressure by Laplace's law, and the patient feels this "bulging". In a review by Clapp et al. [36], the incidence of mesh bulging after IPOM was significantly higher than that after IPOM-Plus (69.4 versus 8.3%) and concluded that IPOM-Plus could control mesh bulging as well as recurrence. On the other hand, a reviewed RCT [47] described that the incidence of mesh bulging after IPOM-Plus and IPOM was similar. In accordance with our study, Suwa et al. [35] reported IPOM-Plus significantly reduced the incidence of mesh bulging as compared to IPOM for large ventral hernias.

The study institution is a military hospital providing free healthcare to military personnel and their families. Hence, very few patients were lost to follow-up and excluded from study. However, some limitations are acknowledged. Since the study is retrospective, follow-up data on recurrence was available only till six-month post-operative period. Data on visual analog scores for acute and chronic pain, quality of life, abdominal muscle function, and return to normal activity were not available. Prospective studies assessing long-term outcomes of IPOM and IPOM-Plus can provide a more comprehensive understanding.

5. Conclusion

Although the operative time and length of hospital stay is longer, IPOM-Plus repair has shown better outcomes compared to IPOM repair.

Our study showed no associations of complications like bowel and bladder injury, surgical site infection, seroma and hematoma with either type of LVHR. However, mesh bulging and recurrence within six months were significantly fewer after IPOM-Plus than after IPOM repair. Hence, IPOM-Plus repair can be the preferred option of LVHR.

Ethical approval

Approved by the Institutional Review Board from Nepalese Army Institute of Health Sciences (NAIHS) (IRC NAIHS/Reg. No. 490).

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None.

Author contribution

Sunil Basukala (SB) and Sushil Bahadur Rawal (SBR): Conceptualization, Supervision. SB, Srijan Malla (SM): Investigation, Data Curation. Subodh Dhakal (SD), Ayush Tamang (AT): Formal Analysis. SB, AT, Ujwal Bhusal (UB), Shriya Sharma (SS) = Visualization, Writing - Original Draft. SB, AT, UB, SS, SD, SBR, SM = Writing - Review and Editing. All the authors read and approved the final manuscript.

Research Registration unique identifying number (UIN)

1. Name of the registry: Research Registry (http://www.researchregistry.com).
2. Unique Identifying number or registration ID: researchregistry7751
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://www.researchregistry.com/browse-the-registry#home/registrationdetails/623612f66a89e2001f710e0e/

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Data statement

The database used in the current study is made publicly available through Mendeley data. It can be accessed at the following https://doi.org/10.17632/m2yyj3vt63.1.

(Note: The dataset was submitted to Mendely Data on May 1, 2022 and is currently in moderation. When accepted, it will be publicly accessible through the above doi link. Currently, the spss file is submitted as a supplementary file.)

Provenance and peer review

Not commissioned, externally peer-reviewed.

Declaration of competing interest

The authors declare that there are no conflicts of interest in this study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2022.104297.

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