

# Comparative Study between Intraperitoneal Onlay Mesh Repair (IPOM) vs Intraperitoneal Onlay Mesh Repair with Closure of Fascial Defect (IPOM PLUS) for Ventral Hernias

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## Abstract

## Original Research Article

**Introduction:** In the recent times, minimal access surgery for ventral hernias is becoming popular. However several issues like postoperative pain, recurrence, seroma formation arising due to the procedure are yet to be resolved. To find a solution to the above mentioned issues, closing the defect in the fascia laparoscopically along with reinforcement by mesh has been tried. **About The Study:** It was a prospective randomized study done at KEMPEGOWDA INSTITUTE OF MEDICAL SCIENCES BENGALURU from October 2018 to March 2020. **Aims and Objectives:** To compare between intra peritoneal onlay mesh repair (IPOM) V/S intra peritoneal onlay mesh repair with closure of fascial defect (IPOM PLUS) for ventral abdominal wall hernias. To study: 1) Postoperative bulge (pseudo hernia). 2) Seroma formation. 3) Pain in the postoperative period. 4) Recurrence. 5) Early return to normal activity especially forward bending. **Materials and Methods:** The study was conducted on 40 patients. All of them underwent surgery on an elective basis...A pneumoperitoneum of 12-15mmhg was built up by inflating through veress needle at the palmer's point. A camera port and two working ports were inserted. The sac of the hernia was excised after cutting the adhesions. The defect was closed from within with self sustaining continuous /interrupted non absorbable sutures. A composite mesh was oriented with transfascial sutures. Additional tackers applied if required. Patients are divided into two groups of 20 each namely the closure and the non closure groups respectively. Each patient was assessed for pain, seroma, forward bending and pseudo bulge on postop day 1,3 and day of discharge. Patient is called for follow up after, 1 month and 6 months. **Conclusion:** Patients who underwent IPOM PLUS had a decreased incidence of seroma formation, recurrence, postoperative bulge and a early return to normal activity when compared to those who underwent IPOM.

**Keywords:** Computerized tomography, Expanded polytetrafluoroethylene, Intra peritoneal onlay mesh repair, Lower segment caesarian section, Randomized control trial, Ultra sonogram. Urinary tract infection, date of discharge, Pseudo bulging, Forward bending.

**ABBREVIATIONS:** CT - Computerized tomography, ePTFE - Expanded polytetrafluoroethylene, IPOM - Intra peritoneal onlay mesh repair, LSCS - Lower segment caesarian section, RCT - Randomized control trial, USG - Ultra sonogram, UTI - Urinary tract infection, DOD- date of discharge, PB- Pseudo bulging, FB-Forward bending.

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## INTRODUCTION

In the recent times, minimal access surgery for ventral hernias is becoming popular. However several issues like postoperative pain, recurrence, seroma formation arising due to the procedure are yet to be resolved. To find a solution to the above mentioned issues, closing the defect in the fascia laparoscopically along with reinforcement by mesh has been tried.

## MATERIALS AND METHODS

### STUDY DESIGN

This study was undertaken at KIMS (Kempegowda Institute of Medical Sciences) Bangalore from October 2018 to February 2020. A Prospective time bound randomized study was planned.

40 patients undergoing laparoscopic ventral hernia repair by all the surgeons at the KIMS hospital, Bengaluru were included in the study. The patients

were divided into two groups by computer based randomization.

- Group-1: patients undergoing intra peritoneal onlay mesh IPOM procedure
- Group-2: patients undergoing IPOM PLUS procedure.

Ethical committee clearance was taken and a written informed consent was obtained from all the patients before the study.

#### Inclusion Criteria

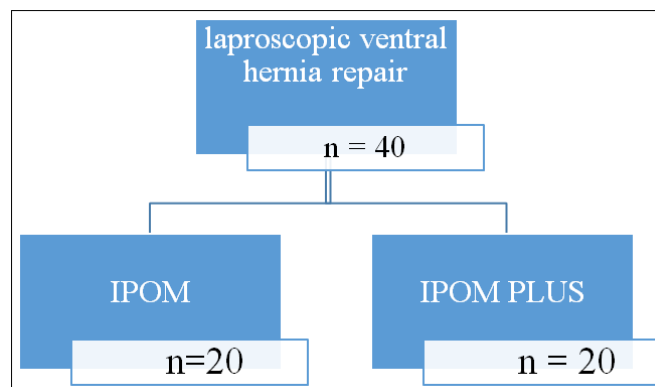
- Those who are willing to give written consent
- Patients with ventral hernias greater than 18 years
- Size of the defect between 2- 5cm

- Patients who are fit for general anesthesia

#### Exclusion Criteria

- Patients not willing for the surgery
- Patients less than 18 years
- Obstructed, strangulated or incarcerated hernias
- Patients with a defect size of more than 5 cm
- Patients not fit for general anesthesia
- Densely scarred abdomen
- Complete loss of abdominal domain due to hernia

The Study period was from October 2018 to February 2020.



#### SURGICAL TECHNIQUE

The patients were admitted to surgical floor after a clinical diagnosis of ventral hernia. Routine pre-operative investigation in the form of CBC, BT/ CT, RFT, RBS, Serology, Urine analysis, ECG, X ray chest was done. Ultrasound of abdomen and pelvis was done for all patients to rule out ascites and also to identify the size of the hernial defect. No other special investigations were required for any of the patients.

Patients were evaluated for Cardiac, Pulmonary and Physician fitness. Also a Pre-anesthetic evaluation was done for all the patients.

The procedure and its probable complications including conversion to open hernioplasty was explained to all the patients and consent was taken for the same. The technique of surgery was same in both the groups except for the technique of mesh fixation.

3<sup>rd</sup> generation cephalosporin was given to all patients prophylactically before anesthesia and it was continued in the post operative period for 24 hours.

Surgery was performed with the patient placed in supine position. The surgeon and the assistant are on the side of the patient which is opposite to the ventral hernia. If the hernia is in the midline, the surgeons stood on the left side. The trocars were inserted as lateral as possible from the hernial defect. Open technique was used to introduce 10mm trocar at the level of the

umbilicus to create artificial pneumoperitoneum with insertion of 30 degrees scope. Then, two 5 mm trocars were inserted under vision cephalic and caudal to the first trocar.

Scissors were used to cut the adhesions and diathermy was avoided to prevent thermal injury.

We used Composite mesh (LOTUS,) which has polyester on one side and the other side contains absorbable collagen to prevent adhesions to the visceral structures. The mesh is oriented and fixed with the help of 2 prolene sutures which are already attached to it. 10mm trocar is used to introduce the mesh after rolling it up. The non adherent side having collagen is faced towards the viscera. Edges of the defect are overlapped by 5 cm on all directions.

#### GROUP-1 (IPOM)

In this group, the mesh was fixed at the periphery with trans-fascial sutures every 5 cm. Around 6 to 8 small incisions are made in the abdominal wall and the suture passer was passed through these incisions to take the prolene sutures fixed to the mesh and pull them out through the abdominal wall. These sutures were fixed over the abdominal wall. The ports were removed and the sheath at the site of 10-mm port was closed under vision. Pressure dressing was applied at the site of the hernia to reduce the incidence of seroma formation.

**GROUP-2 (IPOM PLUS)**

In this group The fascial defect is closed intracorporeally with self sustaining continuous /interrupted non absorbable prolene sutures.

A composite mesh is oriented with transfascial sutures as described above. Additional tackers applied if required.

In the postoperative period, patients from both the groups were kept on paracetamol 1gm intra-venous every 8 hours and started oral intake once the bowel sounds became audible. The patients were discharged once they tolerated full oral intake, no fever, mild or moderate pain which can be controlled by oral analgesics. Patients were reviewed postoperatively on 1<sup>st</sup> week, 2<sup>nd</sup> week and 6 months on out patient basis.

The various postoperative data collected were

1. Post-operative pain as VAS score on day 1, day 3, day of discharge, 1<sup>st</sup> week, 2<sup>nd</sup> week and 6 months
2. Seroma formation on 1<sup>st</sup> day, 3<sup>rd</sup> day, day of discharge, 1<sup>st</sup> week, 2<sup>nd</sup> week and 6 months
3. Forward bending on day 1, day 3, day of discharge, 1<sup>st</sup> week, 2<sup>nd</sup> week and 6 months
4. Pseudo bulge on day 1, day 3, day of discharge, 1<sup>st</sup> week, 2<sup>nd</sup> week and 6 months
5. Recurrence
6. Length of hospital stay.

**STATISTICAL METHODS**

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean  $\pm$  SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven's test for homogeneity of variance has been performed to assess the homogeneity of variance. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small.

**Significant figures**

+ Suggestive significance (P value: 0.05<P<0.10)

\* Moderately significant ( P value:0.01<P  $\leq$  0.05)

\*\* Strongly significant (P value : P $\leq$ 0.01)

**Statistical software**

The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

**RESULTS**

**Table 1: Diagnosis of Ventral Abdominal Hernia and Procedures (IPOM and IPOM Plus)**

DIAGNOSIS		PROCEDURE		Total
		IPOM	IPOM Plus	
epigastric hernia	Frequency	3	2	5
	%	15.0%	10.0%	12.5%
para umbilical hernia	Frequency	2	0	2
	%	10.0%	0.0%	5.0%
Para umbilical hernia	Frequency	0	1	1
	%	0.0%	5.0%	2.5%
umbilical hernia	Frequency	15	17	32
	%	75.0%	85.0%	80.0%
Total	Frequency	20	20	40
	%	100.0%	100.0%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	3.325	3	.344

Umbilical hernia attributed to 80% within procedure than other ventral abdominal hernia [epigastric hernia (12.5%), Paraumbilical hernia (5%)].

There was no significant association in diagnosis of ventral abdominal hernia.

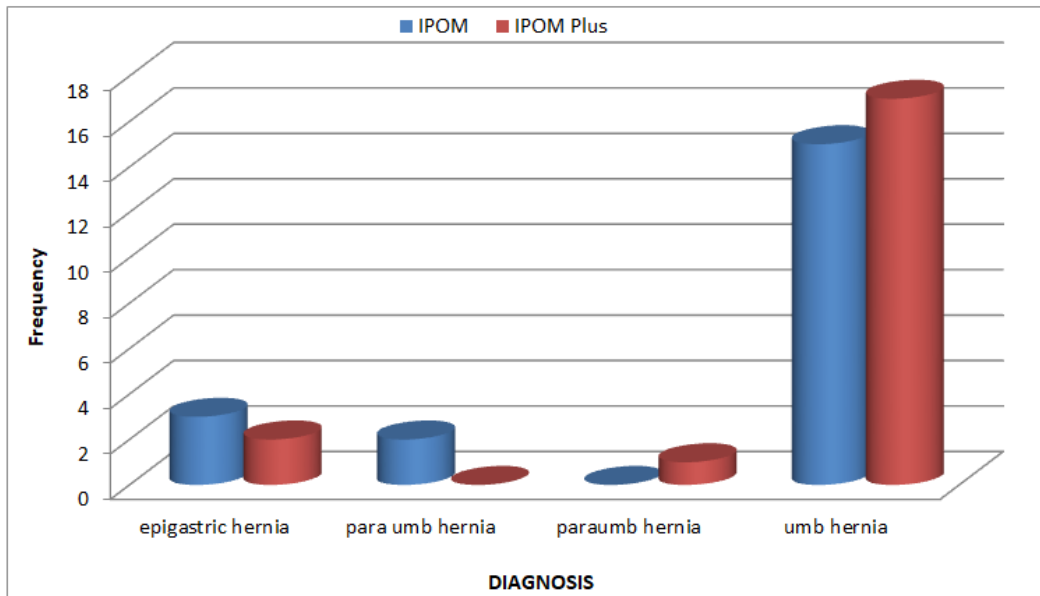


Figure 1: Comparison between IPOM and IPOM plus procedure in ventral abdominal hernia

Table 2: Intra OP complications with procedure

INTRA_OP_COMP		PROCEDURE		Total
		IPOM	IPOM Plus	
Nil	Frequency	20	20	40
	%	100.0%	100.0%	100.0%
Total	Frequency	20	20	40
	%	100.0%	100.0%	100.0%

No complications were noted in the intra operative period in both the groups.

Table 3: Threshold of mean pain score over the period with Procedures

Sessions	PROCEDURE	Mean	Std. Deviation	F	P value
PAIN_D1	IPOM	6.55	0.60	10.705	.001
	IPOM Plus	6.65	0.59		
	Total	6.60	0.59		
PAIN_D2	IPOM	4.35	1.04		
	IPOM Plus	3.15	0.99		
	Total	3.75	1.17		
PAIN_DOD	IPOM	2.35	0.99		
	IPOM Plus	1.45	0.51		
	Total	1.90	0.90		
PAIN_1WEEK	IPOM	1.50	1.10		
	IPOM Plus	0.50	0.51		
	Total	1.00	0.99		
PAIN_2WEEKS	IPOM	0.65	0.93		
	IPOM Plus	0.00	0.00		
	Total	0.33	0.73		
PAIN_6MONTHS	IPOM	0.05	0.22		
	IPOM Plus	0.00	0.00		
	Total	0.03	0.16		

A sustainable decrease in pain was noticed from day 1 (Mean: 6.65) to week 2 (Mean: .00) in case of IPOM Plus procedure while from day 1 (Mean: 6.55)

to 6 months (Mean: .05) in IPOM. A significant association (F=10.705; p= .001) was seen between the groups emphasizing IPOM plus superior over IPOM

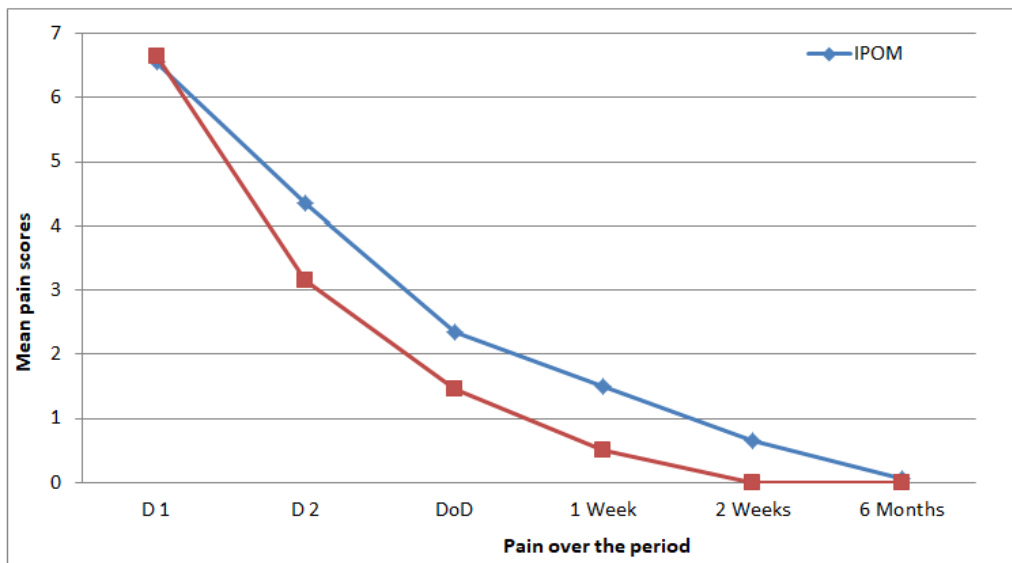


Figure 3: Mean threshold of pain associated over the period depending on IPOM and IPOM Plus

A slow decrease in the threshold of pain was noticed from day 1 and with no pain by 2 weeks in

IPOM Plus in comparison IPOM a decline was achieved by 6 months.

Table 4: Independent Sample test on duration of surgery, age, defect size and hospital size

	PROCEDURE	N	Mean	Std. Deviation	Std. Error Mean
DURATION_OF_SURGERY	IPOM	20	57.50	4.73	1.05755
	IPOM Plus	20	77.25	7.52	1.68097
AGE	IPOM	20	48.25	13.64	3.05035
	IPOM Plus	20	46.30	7.88	1.76233
DEFECT_SIZE	IPOM	20	2.68	0.25	.05614
	IPOM Plus	20	2.99	0.33	.07395
Hospital stay	IPOM	20	8.60	1.82	.40653
	IPOM Plus	20	6.35	0.59	.13129

A significant difference was present between groups in duration of stay ( $p = .001$ ), defect size ( $p = .002$ ), hospital stay ( $p = .001$ ) whereas there was no

statistical significance observed in mean age of samples between the groups, in other words the two group samples are matched with respect to age.

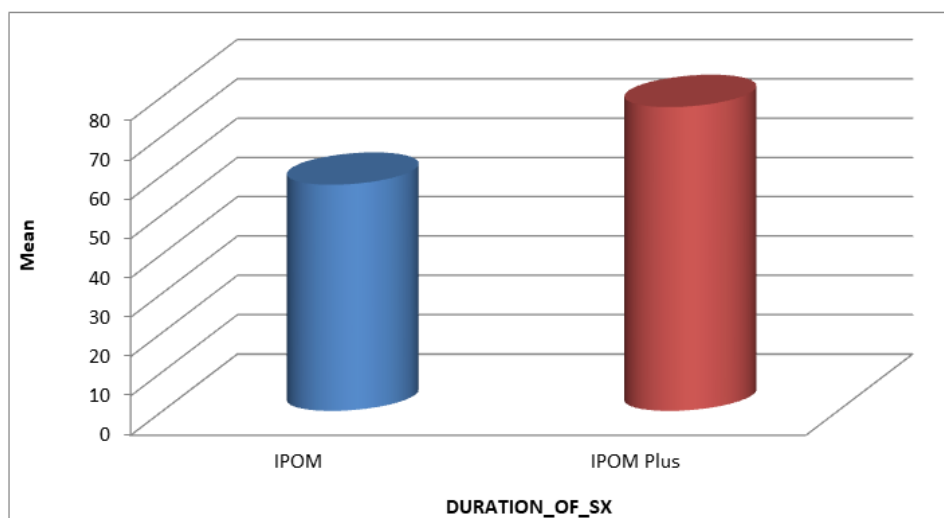


Figure 4: Mean Duration of surgery associated with PROM and PROM Plus

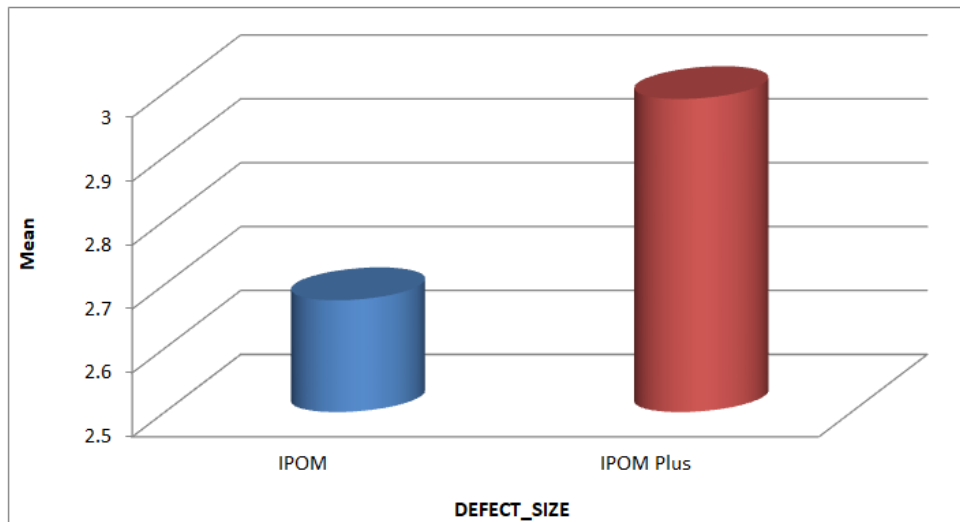


Figure 5: Closure of Defect size based on the PROM and PROM plus procedure

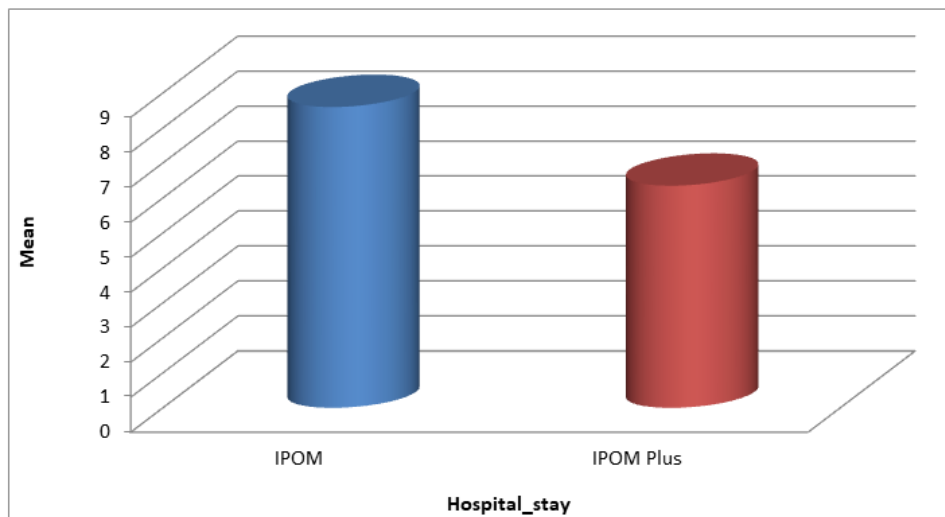


Figure 6: Effects on duration of hospital stay depending on the Procedures.

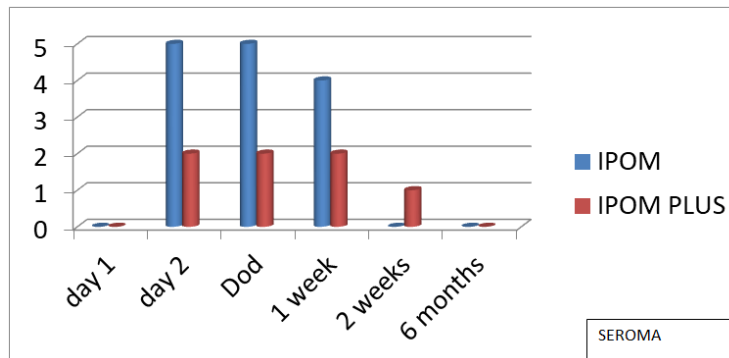
Table 5: SEROMA formation involving IPOM and IPOM Plus procedures

Groups	SEROMA		Sessions						Total
			D1	D2	DOD	1wk	2wk	6mnts	
IPOM	Yes	F	0	5	5	4	0	0	14
		%	0.0%	25.0%	25.0%	20.0%	0.0%	0.0%	11.7%
	No	F	20	15	15	16	20	20	106
		%	100%	75.0%	75.0%	80.0%	100%	100%	88.3%
	Total	F	20	20	20	20	20	20	120
		%	100%	100%	100%	100%	100%	100%	100%
IPOM Plus	Yes	F	0	1	1	1	1	0	4
		%	0.0%	5.0%	5.0%	5.0%	5.0%	0.0%	3.3%
	No	F	20	19	19	19	19	20	116
		%	100%	95.0%	95.0%	95.0%	95.0%	100.0%	96.7%
	Total	F	20	20	20	20	20	20	120
		%	10%	100%	100%	100%	100%	100%	100%

Groups		Value	df	P value
IPOM	Pearson Chi-Square	16.173	5	.006
IPOM Plus	Pearson Chi-Square	2.069	5	.840

In case of IPOM, a significant association ( $X^2=16.173$ ;  $p=.006$ ) between duration and presence/absence of Seroma. We find a significant reduction in SEROMA cases from D2 to 6 months which ended up in nil patients.

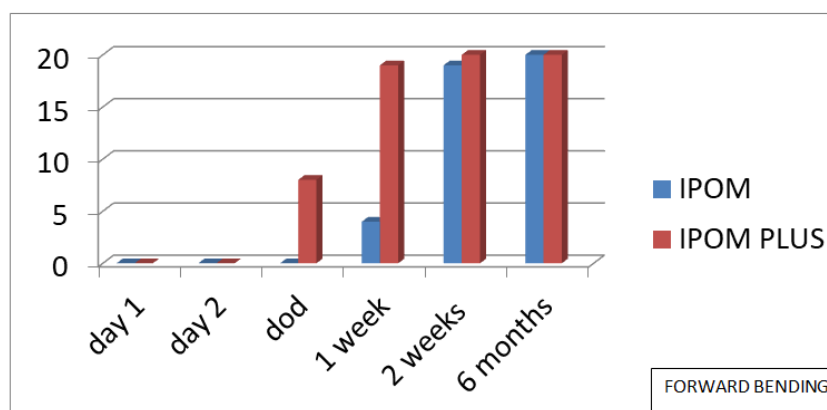
However, in the case of IPOM Plus group, a non-significant association ( $X^2=2.069$ ;  $p=.840$ ) was noticed with hardly any change in the decrease/ increase of number of patients with SEROMA from d1 to 6 months. In other words, IPOM Plus is more effective than IPOM as far as number of cases reported from day 1 to 6 months.



**Table 6: Forward Bending involving IPOM and IPOM Plus**

Grps	FB		Sessions						Total
			D1	D2	DOD	1wk	2wk	6mnts	
IPOM	Yes	F	0	0	0	4	19	20	43
		%	0.0%	0.0%	0.0%	20.0%	95.0%	100.0%	35.8%
	No	F	20	20	20	16	1	0	77
		%	100%	100%	100%	80.0%	5.0%	0.0%	64.2%
IPOM Plus	Yes	F	0	0	8	19	20	20	67
		%	0.0%	0.0%	40.0%	95.0%	100%	100%	55.8%
	No	F	20	20	12	1	0	0	53
		%	100%	100%	60.0%	5.0%	0.0%	0.0%	44.2%

Chi-Square Tests					
Grps		Value	Df	Asymp. Sig. (2-sided)	
IPOM	Pearson Chi-Square	101.951	5	.000	
IPOM Plus	Pearson Chi-Square	96.683	5	.000	



In case of IPOM, forward bending was noticed at week 1 whereas in IPOM Plus a significant performance of forward bending was noticed from

DOD. A total of 35.8% in case of IPOM and 55.8% in case of IPOM Plus was able to return to normal activity/ attain forward bending.

**Table 7: Pseudo-bulging associated with IPOM and IPOM Plus**

Grps	PB		Sessions						Total
			D1	D2	DOD	1wk	2wk	6mnts	
IPOM	Yes	F	1	3	3	3	3	3	16
		%	5.0%	15.0%	15.0%	15.0%	15.0%	15.0%	13.3%
	No	F	19	17	17	17	17	17	104
		%	95.0%	85.0%	85.0%	85.0%	85.0%	85.0%	86.7%
	Total	F	20	20	20	20	20	20	120
		%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
IPOM Plus	Yes	F	-	-	-	-	-	1	1
		%	-	-	-	-	-	-	-
	No	F	20	20	20	20	20	19	19
		%	100.0%	100.0%	100.0%	100.0%	100.0%	95.0%	95.0%
	Total	F	20	20	20	20	20	20	120
		%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Chi-Square Tests				
Grps		Value	df	Asymp. Sig. (2-sided)
IPOM	Pearson Chi-Square	1.442	5	.920
IPOM Plus	Pearson Chi-Square	.		

In IPOM, a detection of pseudo bulging was present from day 1 and a total of 13.3% was noticed whereas there was one pseudo bulging in IPOM Plus.

**Presence/absence of Forward Bending (FB) in IPOM and IPOM Plus**

On Day 1 and day 2, absence of forward bending was noticed in both the groups undergoing IPOM and IPOM Plus surgery. On DOD ( $X^2=10.0$ ;  $p=.003$ ), association between the groups and presence/absence of FB was significant. In IPOM group we find the cases with absence of FB, whereas in IPOM Plus group, there were 40.0% of the cases with FB.

At one week, 20% of cases were able to perform FB who underwent IPOM whereas incase of IPOM plus 90%, which is highly significant ( $X^2=23.0180$ ;  $p=.001$ ).

At 2 weeks, there was no significant association between groups and presence/absence of FB ( $X^2=1.026$ ;  $p=1.00$ ). At 6 months, all the cases were able to do forward bending or able to return to their normal activity.

On Day 1, 5% of cases with PB were present in IPOM, while there was no PB in cases who underwent IPOM Plus.

15% of PB was present in IPOM on day 2, DOD, week 1, week 2 and 6 month respectively in comparison to IPOM Plus which had no cases PB.

**Table 8: Presence/absence of pseudo-bulging with IPOM and IPOM Plus groups**

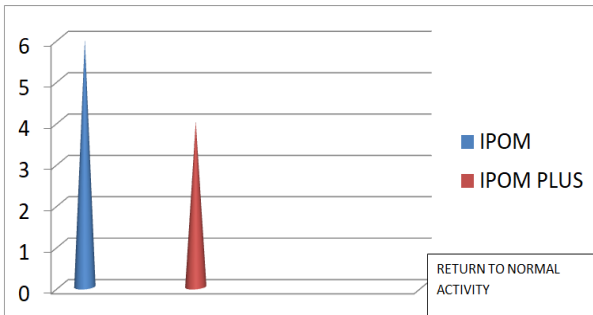
Sessions	SEROMA	Grps		Total	
		IPOM	IPOM Plus		
D1	Yes	F	1	0	1
		%	5.0%	0.0%	2.5%
	No	F	19	20	39
		%	95.0%	100.0%	97.5%
D2	Yes	F	3	0	3
		%	15.0%	0.0%	7.5%
	No	F	17	20	37
		%	85.0%	100.0%	92.5%
DOD	Yes	F	3	0	3
		%	15.0%	0.0%	7.5%
	No	F	17	20	37
		%	85.0%	100.0%	92.5%
1wk	Yes	F	3	0	3
		%	15.0%	0.0%	7.5%
	No	F	17	20	37
		%	85.0%	100.0%	92.5%
2wk	Yes	F	3	0	3
		%	15.0%	0.0%	7.5%
	No	F	17	20	37
		%	85.0%	100.0%	92.5%
6mnts	Yes	F	3	0	3
		%	15.0%	0.0%	7.5%
	No	F	17	20	37
		%	85.0%	100.0%	92.5%

**Table 9: Return to normal activity at the end of 6 months by groups**

PROCEDURE	N	Mean	Std. Deviation	Std. Error Mean
IPOM	20	6.20	.61	.137
IPOM Plus	20	4.05	.60	.135



t-test for Equality of Means			
t	Df	Sig. (2-tailed)	Mean Difference
11.142	38	.001	2.15000



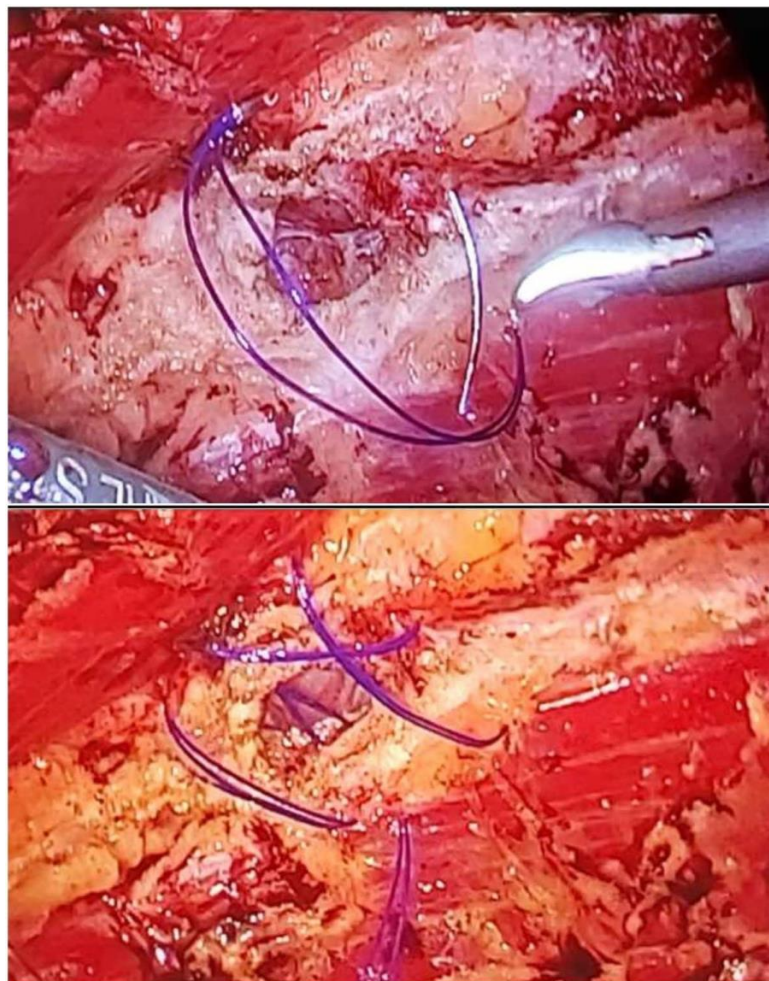
Independent Sample test with respect to return to normal activity showed that a major difference was observed among the two groups ( $p = .001$ ). In other words patients with the IPOM Plus procedure were able to return to normal activity with the less duration (Mean= 4.05 ±.60) compared to IPOM procedure group (Mean= 6.20 ±.61).

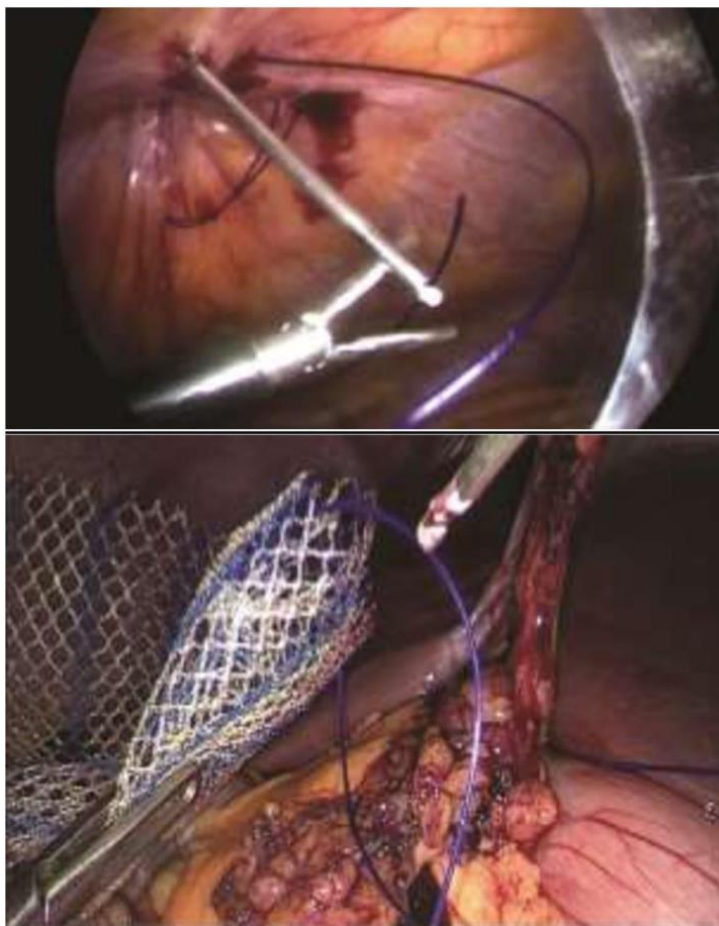
**Table 10: Recurrence at the end of 6 months with groups**

		Grps		Total
		IPOM	IPOM Plus	
Yes	Frequency	2	0	2
	%	10.0%	0.0%	5.0%
No	Frequency	18	20	38
	%	90.0%	100.0%	95.0%
Total	Frequency	20	20	40
	%	100.0%	100.0%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.105 <sup>a</sup>	1	.147

Though there were 10% of recurrence observed in IPOM group when compared with IPOM Plus group at the end of 6 months after procedure.





## DISCUSSION

Treatment for ventral abdominal wall hernias by laparoscopic approach is gaining popularity over the last few years and it is acknowledged by many operating surgeons and hospitals globally [1-3].

Many studies have proven that laparoscopy is as efficacious and safe as open surgery for treating ventral hernias in various aspects like decrease in the length of hospital stay, lesser incidence of post-operative complications, a lower rate of surgical site infection and also recurrence [4].

The methods adopted to close the fascial defect can be continuous, interrupted, intracorporeal or extracorporeal [5]. In extracorporeal technique, puncture wounds are made on each side of the defect and the suture material is passed to take stitches in an interrupted manner [6]. It is more prone to the formation of a stitch granuloma. Even the rate of infection and cosmetic dissatisfaction are higher in this method [7].

In our study we have studied the pain threshold, seroma, forward bending, return to normal activity and recurrence rates between patients undergoing IPOM and IPOM PLUS procedures.

The average pain threshold in patients undergoing IPOM PLUS showed a gradual decrease from day 1 compared to IPOM however it was not statistically significant. This result is supported in a study conducted by Katsuhito Suwa, Tomoyoshi Okamoto and Katsuhiko Yanaga [8] in June 2015.

Average time taken to complete the surgery was 77 minutes for IPOM PLUS and 57 minutes for IPOM respectively as extra time was consumed in suturing the fascial defect/linea alba [9].

The mean duration of hospital stay was six days in patients who underwent IPOM PLUS and 8 days in patients who underwent IPOM procedures respectively which was found to be statistically significant. This observation of ours is supported in 2 other studies [10].

Seroma is the most frequently encountered problem after a laparoscopic ventral hernia repair [11]. Incidence of seroma was significantly less among the patients who underwent IPOM PLUS which was 3.3% and comparatively more with IPOM group with 14.7%. The predictive risk factors for seroma are BMI (obesity), previous surgery, number of previous procedures, previous hernia repair, SSI, size of defect, and excessive use of cauterization [12].

Forward bending without difficulty was noticed in 55.8% of the patients who underwent IPOM PLUS and 35.8% of patients who underwent IPOM respectively which was found to be statistically significant [13].

Pseudo bulging was noted in 13.3% of the patients who underwent IPOM procedure and one of the 20 patients who underwent IPOM PLUS developed pseudo bulging at the end of 6 months which was found to be statistically significant.

Return to normal activity and ability to carry out routine work without difficulty was attained by 4 weeks in patients who underwent IPOM PLUS procedure and the same was attained by 6 weeks in an average in patients who underwent IPOM procedure. This observation was statistically significant and it has been mentioned in many studies [14].

The observations made in our study showed that IPOM PLUS was associated a lesser rate of postoperative complications when compared to IPOM.

## CONCLUSION

Annually 20 million patients are affected by the complications of hernia surgery across the globe. A surgical option not well selected can lead to many complications which will have an impact on the patient's lifestyle, daily routine, mental and physical health. Hence finding a best technique is of prime importance

IPOM plus repair is safe, feasible and with possible advantages over a standard IPOM repair as reported in literature. Therefore we prefer closure of fascial defect while repairing ventral abdominal wall hernias.

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