

**Original article:**

## **Clinical outcome of primary closure versus non-closure of small hernial defect among patients undergoing laparoscopic hernioplasty for ventral wall hernia**

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### **Abstract**

**Introduction-** Laparoscopic Ventral Hernia Repair (LVHR) is now routinely used over open ventral hernia repair for following cosmetic as well as functional advantages. However, rates of seroma formation, eventration (bulging of mesh or tissue), and recurrence still remain high with standard LVHR and primary repair of defect is being added to the meshplasty.

**Objectives** -To study is the clinical outcomes of LVHR with and without primary closure of the hernia defect with regards to post-operative pain, seroma formation and recurrence.

**Materials and Methods** :This was a prospective comparative study conducted in department of Surgery, NRCH, New Delhi, from April 2015 to June 2018 in patients undergoing LVHR for a ventral hernia where the smaller dimension was not more than 5cms.It compared standard LVHR to LVHR + primary repair of defect. The patients were followed for minimum 1 year in terms of the clinical and technical outcomes.

**Observation and Results:** 120 patients were studied with 60 patients randomized to each group. Incisional hernia had maximum incidence 97 (80.8%). Majority of the patients belonged to 41–60 years of age group (74 patients) with range 35 years to 71 years. The overall incidence was higher in females 68%. The cases undergoing standard LVHR + primary repair had significantly more post operative pain (mean VAS score  $5.53 \pm 1.13$  on POD-0 and  $3.30 \pm 1.38$  on POD-1 )than the cases undergoing standard LVHR (mean VAS score  $3.38 \pm 0.90$  on POD-0 and  $1.30 \pm 0.50$  on POD-1;  $p < 0.001$ ) but had lower incidence of seroma formation postoperatively - 8.3% compared to 21.7% ( $p < 0.041$ ). Recurrence was more in the cases undergoing standard LVHR 3.3% compared to nil in standard LVHR + primary repair group ( $p < 0.248$ ).

**Conclusion** : Standard LVHR with primary repair is advisable as it is better in functional outcomes, though it has slightly more post operative pain.

**Key words** - Ventral Hernia , Laparoscopic Repair, meshplasty

### **INTRODUCTION:**

Ventral hernias, whether naturally occurring (congenital) or the result of previous surgery(acquired), comprise one of the most common problems confronting for general surgeons, with overall incidence between 2 and 13%<sup>[1-4]</sup>. Laparoscopic ventral hernia repair (LVHR) was described on firsts by Leblanc

in 1993 for all types of hernias<sup>[1-5]</sup>. This laparoscopic technique has improved over time and has proven to be an effective treatment option and is now routinely used over open ventral hernia repair for following reasons: small incisions, fewer wound complications, faster functional recovery, shorter hospital stay and improved cosmesis and has become the solution of choice in the treatment of ventral wall hernia<sup>[6,7]</sup>. Despite improved surgical outcomes with standard laparoscopic ventral hernia repair, rates of seroma formation, eventration (bulging of mesh or tissue), and hernia recurrence still remain high<sup>[8]</sup>. Seromas or eventration have been termed pseudo-recurrences because they can present post-operatively as a bulge that appears no different from a hernia recurrence<sup>[9]</sup>.

Standard laparoscopic ventral wall hernia repair is performed by fixating the mesh intra-peritoneal onlay mesh (IPOM) without closing the hernia gap. This is done to create as little tension as possible. Despite the risk of creating increased tension to the tissue, closing the gap is gaining increasing acceptance owing to a possible prevention of mesh protrusion through the gap (bulging), which provides a better cosmetic result, lowers the recurrence rate and improves abdominal wall functions<sup>[10-12]</sup>. The technique may also decrease seroma formation<sup>[28]</sup> and improve overall patient satisfaction<sup>[10,13]</sup>. In this study, we report our experience in the treatment of ventral hernias by laparoscopy in patients with primary closure of the hernial defect before placing mesh in a randomized trial.

#### **OBJECTIVES:**

“To study is the clinical outcomes of laparoscopic hernioplasty for Ventral Hernial repair with and without primary closure of the hernia defect” with regards to:

1. Post-Operative pain
2. Seroma formation
3. Recurrence within 12 months of surgery.

#### **MATERIALS AND METHODS:**

The study was conducted in department of Surgery, Northern Railway Central Hospital, New Delhi, from April 2016 to March 2019, with the last patient being operated in March 2018. Considering the recent development of this procedure, there are very few studies in India which have evaluated the advantages of standard LVHR + primary repair of defect as the treatment modality. The study is intended to critically evaluate the patients undergoing the procedure prospectively on post operative day 0 & 1, after a week, and 12 months in terms of the clinical and technical outcome of the procedure.

The study group consisted of 120 patients, 60 in each group of age group 18-80 years who presented in surgical outpatient Department, investigated and operated at Northern Railway Central Hospital having a ventral hernia where the smaller dimension was not more than 5cms.

**Study Design :** A Prospective Comparative randomised Study.

Sample Size was determined based on the recurrence rates in primary closure versus non closure (Group 1 vs Group 2) of Hernia defect in Laproscopic hernioplasty of small ventral wall hernia. We chose a 20% baseline ratio of recurrence rate based on previous study. The formula for calculated sample size is given below:

$$n = \frac{[Z_{1-\alpha/2} \cdot \sqrt{2P(1-P)} + Z_{1-\beta} \cdot \sqrt{\{P_1(1-P_1) + P_2(1-P_2)\}}]^2}{(P_1 - P_2)^2}$$

Where

$P_1$  = Anticipated proportion of recurrence rate in Group 1

$P_2$  = Anticipated proportion of recurrence rate in Group 2

$P = (P_1 + P_2)$

At 80% power and significant p-value at 0.05, to detect a 15% difference in recurrence rate after surgery between two groups a sample size of 60 was required.

#### **Statistical Methods:**

Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

#### **OBSERVATIONS AND RESULTS:**

The following observations were noted in our study.

##### **Distribution of patients studied in each group:**

Total 120 patients were studied with 60 patients randomized to each group using computer generated table. The outcome of patients after standard laparoscopic ventral hernia repair (LVHR) and standard LVHR with primary closure were observed and compared.

##### **Clinical Types of Ventral Hernia and their sex related incidence:**

Among the 120 cases of ventral hernia 97 (80.8%) were incisional hernia; 18 (15%) were para-umbilical hernia, 4 (3.3%) were umbilical hernia and 1 (0.8%) was epigastric hernia. The overall incidence of ventral hernias was observed to be more in females 68% (82 cases) than in males 32% (38 cases).

##### **Age Incidence among ventral hernias:**

Table shows age wise distribution in the study population. In this study maximum representation was from age groups 41-50 years (33 cases) and 51-60 years (41 cases). In our study, youngest patient was aged 35 years and eldest patient was 71 years. This is statistically significant ( $p < 0.05$ ).

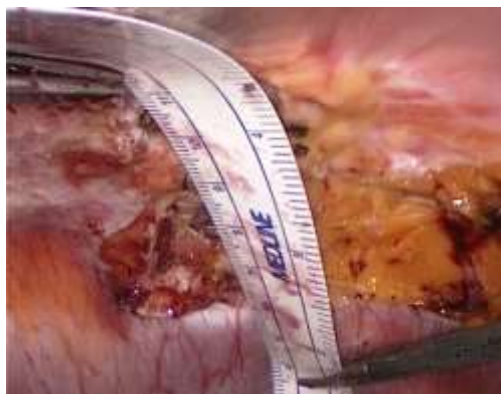
##### **Post-operative pain assessment**

It was observed that cases undergoing standard LVHR + primary repair had more post operative pain than cases undergoing standard LVHR on day 0 as well on day 1. This difference was statistically significant ( $p < 0.001$ ), in both instances.

Out of 120 cases 18 cases leads to seroma formation postoperatively out of which 13 cases (21.7%) belonged to Standard LVHR group, and 5 cases (8.3%) belonged to Standard LVHR+ primary repair group. This is statistically significant ( $p < 0.05$ ).

Out of 120 cases recurrence was observed in 02 cases (3.3%) which belonged to Standard LVHR group. No recurrence was observed in Standard LVHR+ primary repair group. This is statistically insignificant ( $p > 0.05$ ).

## **HERNIAL DEFECT**



**MEASUREMENT OF DEFECT BY FLEXIBLE STERILE RULER**



**PRIMARY CLOSURE OF HERNIAL DEFECT**



**DUAL SURFACE MESH FIXED WITH TACKERS**

**TABLE-1 : TYPES OF VENTRAL HERNIA AND THEIR SEX DISTRIBUTION**

Type of Hernia	Frequency	%	Female		Male	
			Frequency	%	Frequency	%
Incisional Hernia	97	80.8%	65/120	54.2%	32/120	26.7%
Paraumbilical Hernia	18	15.0%	12/120	10.0%	6/120	5.0%
Epigastric Hernia	1	0.8%	1/120	0.8%	0/120	0.0%
Umbilical Hernia	4	3.3%	4/120	3.3%	0/120	0.0%
Total	120	100.0%	82/120	68%	38/120	32%

**TABLE-2 : TYPES OF VENTRAL HERNIA AND THEIR AGE DISTRIBUTION**

Age Groups	Total cases	Type of Hernia				P-Value
		Incisional Hernia	Para-umbilical Hernia	Epigastric Hernia	Umbilical Hernia	
<35 yrs	0					0.009
35 - 40 yrs	14	7 (50%)	4 (28.6%)	1 (7.1%)	2 (14.3%)	
41 - 50 yrs	33	23 (69.7%)	9 (27.3%)		1 (3.0%)	
51 - 60 yrs	41	37 (90.2%)	3 (7.3%)		1 (2.4%)	
61 - 70 yrs	28	27 (96.4%)	1 (3.6%)			
>70 yrs	4	3 (75%)	1 (25%)			
Total	120	97 (80.8%)	18 (15%)	1 (7.1%)	4 (3.3%)	

**TABLE-3 : COMPARISON OF STANDARD LVHR Vs LVHR+ DEFECT CLOSURE**

		Standard LVHR		Standard LVHR + primary repair of defect		P-Value
		Mean ± SD	Min - Max	Mean ± SD	Min - Max	
Pain Assessment	POD-0	3.38 ± 0.90	2 to 6	5.53 ± 1.13	3 to 8	<0.001
	Pod-1	1.30 ± 0.50	1 to 3	3.30 ± 1.38	1 to 6	<0.001
Seroma Formation		Frequency	%	Frequency	%	0.041
	No	47	78.30%	55	91.70%	
	Yes	13	21.70%	5	8.30%	
Recurrence		Frequency	%	Frequency	%	0.248
	No	58	96.70%	60	100.00%	
	Yes	2	3.30%	0	0.00%	

**DISCUSSION:**

In the present study 97 cases of incisional hernia were studied which accounted for 80.8% of total ventral hernia. This study compares well with the S M Bose<sup>(14)</sup> series having 62.86% incisional hernia but is higher than the Mohan Rao series<sup>(15)</sup> having 30.65% .

In several prior studies, average age of presentation of ventral hernia was 35-40 yrs. The lowest age in one study conducted by Bruce Ramshaw *et al.*, was 16 yrs<sup>(15)</sup>. The maximum age in various several studies was 70 yrs. In the study held by Sharma *et al*<sup>(17)</sup>, youngest patient was aged 22 yrs and eldest patient was 78 yrs. In this present study, maximum cases were observed between age 41-60 years, youngest patient was aged 35 years and oldest 71 years. In present study out of 120 patients, 38 (32%) were males and 82 (68%) were females. This is comparable to study conducted by S. M. Bose<sup>(14)</sup> in which out of the 175 patients, 79 (45.14%) were males and 96 (54.86%) were females.

In this present study female predominance in the ratio of 1: 2.03 M:F ratio was noted. This correlates well with the Akman series<sup>(18)</sup> and Siedel series<sup>(19)</sup> which were 1:4.8 and 1:3 respectively. This shows that incisional hernia occurs more commonly in females than in males. In present study, post-operative pain was more in cases undergoing Standard LVHR + primary closure than cases undergoing Standard LVHR alone. Present study is comparable with findings of KirurgiskSektion *et al*<sup>(20)</sup> and M. W. Christoffersen *et al*<sup>(21)</sup>. In their study, KirurgiskSektion *et al* concluded that, the gap closure technique induce more post-operative pain than the non-closure repair, but it may also be superior with regard to other important surgical outcomes<sup>(20)</sup>. In the present study, 21.7% (13/60 cases) in non-closure group (Standard LVHR group) developed seroma postoperatively and 8.3% (5/60 cases) in closure group (Standard LVHR+ primary repair group) developed seroma. The present study is comparable with the studies of Nguyen DH *et al*<sup>(22)</sup>, Clapp ML *et al* (2013)<sup>(10)</sup> and Tandon A *et al*<sup>(23)</sup>.

Nguyen DH et al, in their studies suggested that primary fascial closure (n = 138) compared to non-closure (n = 255) resulted in lower recurrence rates (0-5.7 vs. 4.8-16.7 %) and seroma formation rates (5.6-11.4 vs. 4.3-27.8 %). They concluded that the closure of the central defect during LVHR resulted in less recurrence, bulging, and seroma than non-closure<sup>(22)</sup>.

Clapp ML et al, observed that the LVHR and Trans-cutaneous Closure of Central Defects (TCCD) patients had significantly lower rates of seroma formation (5.6 % versus 27.8 %; p = 0.02), mesh eventration (0.0 % versus 41.4 %; p = 0.0002), tissue eventration (4.0 % versus 37.9 %; p = 0.003), clinical eventration (8.3 % versus 69.4 %; p = 0.0001), and hernia recurrence (0.0 % versus 16.7 %; p = 0.02) when compared to the standard LVHR case control.<sup>(10)</sup> A et al observed that CFD (closure of fascial defect) resulted in a significantly lower rate of seroma (2.5 per cent (39 of 1546) versus 12.2 per cent (47 of 385)). They concluded that CFD during LVHR reduces the rate of seroma formation and adverse hernia-site events.<sup>(23)</sup> In the present study, 3.3% (2/60 cases) in non-closure group (Standard LVHR group) had recurrence while none of the case in closure group (Standard LVHR+ primary repair group) had recurrence. The present study is comparable with the studies of Nguyen DH et al<sup>(22)</sup>, Banerjee A et al<sup>(1)</sup>, Clapp ML et al<sup>(10)</sup> and M. S. Zeichen et al<sup>(13)</sup>.

Nguyen DH et al, in their studies suggested that primary fascial closure (n = 138) compared to non-closure (n = 255) resulted in lower recurrence rates (0-5.7 vs. 4.8-16.7 %).<sup>(22)</sup>

Banerjee A et al (2012), in their retrospective observational study, observed that the rate of recurrence in those treated with PSR + MU was 3% (two of 67 cases) in comparison with 4.8% (six of 126 patients) associated with mesh alone. They concluded that, primary laparoscopic repair along with mesh placement for the management of ventral hernia was found to be effective as evidenced by the low rate of recurrence when compared with conventional laparoscopic repair with mesh alone.<sup>(1)</sup>

Clapp ML et al, observed that the LVHR TCCD patients had significantly lower rates of hernia recurrence (0.0 % versus 16.7 %; p = 0.02) when compared to the standard LVHR case control.<sup>(10)</sup>

M. S. Zeichen et al, in his study, observed that 14 patients (19.18 %) developed recurrent hernias in the non-closure group with an average time to presentation of 23.17 months (range 5.3–75.3). Two patients (6.25 %) developed recurrent hernias in the percutaneous group with an average time to presentation of 12.95 months (range 9.57–16.33).<sup>(13)</sup>

#### **CONCLUSION:**

In the present study, the overall incidence of ventral hernias was observed to be more in females than in males. Out of the total cases of ventral hernia, incisional hernia has maximum incidence with majority of the patients belonged to 41–60 years of age group.

The study had shown that the standard LVHR with primary repair of defect technique induces more post-operative pain than the standard LVHR (non-closure repair), but it is found to be superior with regard to other important surgical outcomes such as decrease incidence of seroma formation post operatively and low rate recurrence rate when compared with conventional laparoscopic ventral hernia repair with mesh alone.

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