

LAPAROSCOPIC AND OPEN MESH REPAIR OF VENTRAL HERNIAS: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objective: To compare the operative time and post-operative pain in laparoscopic and open mesh repair of ventral hernias.

Methodology: From October, 2010 to February, 2011 in surgery department, Holy Family hospital, Rawalpindi. In this Randomized Clinical Trial a total of 160 patients were included after taking approval from hospital ethical committee and informed written consent from each patient. The admitted patients for elective surgical repair of ventral hernia were randomly allocated to Group A (laparoscopy) and B (open repair). Information regarding operative time and pain scores after 12, 24 and 72 hours of surgery was recorded.

Results: In group A, the mean age was 41.10 ± 8.98 years and in group B 41.23 ± 9.18 years. There were 36 (22.25%) male patients. There were 18 (11.3%) patients of Incisional, 107 (66.9%) patients of umbilical/paraumbilical and 35(21.9%) patients of Epigastric hernia in this study. In group A, the mean operative time was significantly (p -value= 0.000) less (66.56 ± 16.14 minutes vs. 71.21 ± 12.91 minutes) as compared to group B. There was no difference in mean pain score at 12th hour (p -value= 0.797). At 24th hour and 72nd hour the mean pain score in Laparoscopic group was significantly (p -value = 0.000) lower.

Conclusion: Laparoscopic management of ventral hernia resulted in short operative time, less pain at 24th and 72th hours. So it should be considered as the procedure of choice for ventral hernia repair.

Key Words: Ventral hernia, Laparoscopy, Operative time, Pain score

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INTRODUCTION

Ventral hernias are hernias of the anterior abdominal wall which represent defects in the parietal abdominal wall fascia or muscle through which intra-abdominal or pre-peritoneal contents can protrude. Ventral hernias include incisional hernias, epigastric hernias and umbilical/paraumbilical hernias¹. Ventral hernias generally enlarge over the course of time and treatment is indicated in all symptomatic cases. Diagnosis is by clinical examination. Ultrasound examination may also be useful in diagnosis. Treatment is usually a mesh repair which can be done by either an open technique or by laparoscopy. Studies have shown that laparoscopic repair has less operative time than open mesh repair (92.7 ± 27.2 minutes vs. 102.8 ± 24.1 minutes)² and although the postoperative pain scores are similar in the first 24 hours, at 72 hours, patients undergoing laparoscopic

repair report less pain as compared to patients undergoing open repair³.

Recurrence of the hernia is an important problem following the repair of ventral hernias and studies have reported that following open repair with mesh up to 24% patients in three years of follow up and only 3.4% followed up for 2 years after laparoscopic mesh repair developed recurrence^{4,5}.

There are encouraging results being reported in comparative studies regarding the cost analysis of laparoscopic versus open repair of ventral hernias. In a recent series, laparoscopic ventral hernia repair using a dual-layer polypropylene mesh and transfascial sutures significantly reduced surgical site infections, length of hospital stay and costs as compared to open mesh repair. This study has also shown decreased overall hospital costs for laparoscopic hernia repair despite high-

er operative costs.⁶ However, types of mesh used and fixation device can make sizeable differences in cost calculations. The long-term benefits in terms of early return to work and decreased recurrence rates with laparoscopic repair should also be taken into consideration when deciding on the cost-benefit ratio of laparoscopic versus open repair of ventral hernias. Operative costs may be optimized with judicious selection of mesh and optimal use of transabdominal sutures and fixation device.⁷

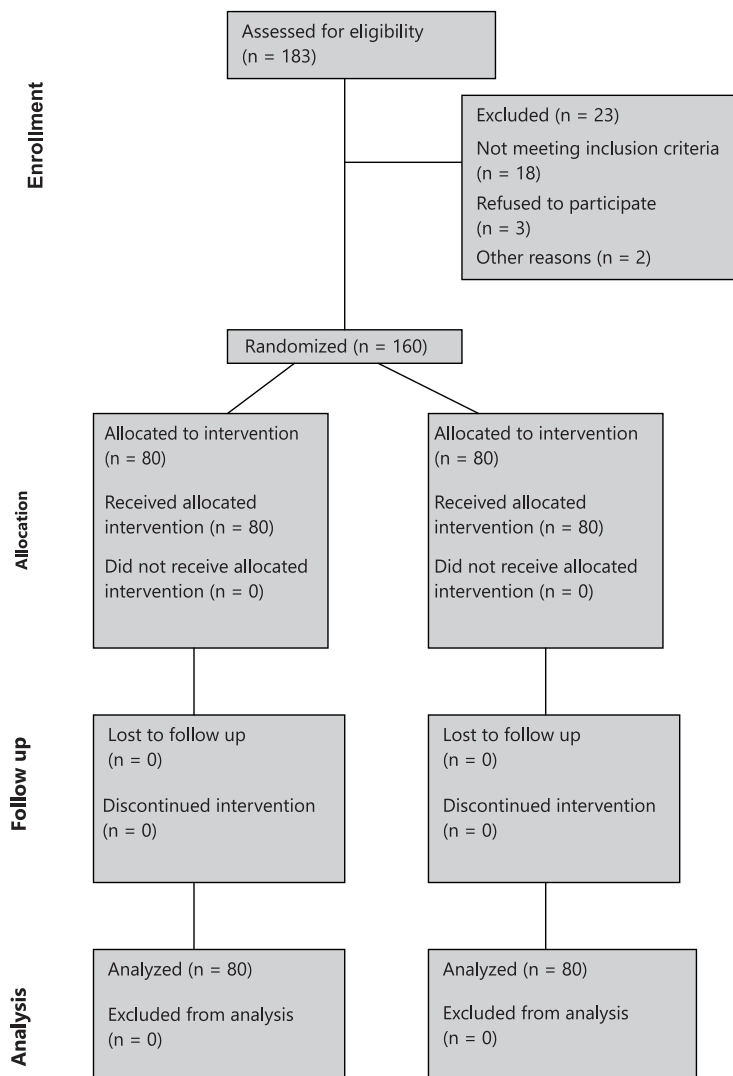
Laparoscopic repair of ventral hernias is, although an attractive option for patients, literature from Pakistan mostly discusses open mesh repair of ventral hernias^{8,9} and local experience in the use of laparoscopic ventral hernia repair is limited. Therefore the present study was planned to compare the operative time and postoperative pain following either open mesh repair or laparo-

scopic mesh repair of ventral hernias in our set up. The findings of this study can provide surgeons with better knowledge as to which is the treatment of choice for the patients presenting with ventral hernias. If the results of this study are in line with the literature search, this would speed up the turnover of the patients in our set up with maximum number of patients benefitting in minimum amount of time.

METHODOLOGY

In this randomized control study a total of 160 patients were selected from department of Surgery, Holy Family hospital, Rawalpindi. Approval of the study was taken from hospital ethical committee and informed written consent was taken from each patient prior to inclusion in the study. The patients were selected from admitted patients in the surgical wards for elective surgical repair of ventral hernia. These patients were select-

Figure: Consort diagram showing the flow of participants through each stage



ed by non-probability, consecutive sampling method and were allocated to two groups randomly by lottery method. Forty slips of each group were made and one slip was selected for each patient and that patient was placed in the group indicated by the slip. The patients of age more than 18 years and of either gender with a clinical and ultrasonographic diagnosis of having incisional, umbilical/paraumbilical or epigastric hernia were include in the study. The patients who had previous history of operation repair of ventral hernias, presence of any amount of intra-abdominal free fluid/ascites on abdominal examination, uncontrolled diabetes and/ or hypertension and pregnant patients were excluded from the study.

Patients were randomly allocated to Group A (laparoscopy) and B (open repair). Both groups had allocated procedure under general anesthesia with same drugs and their dosages on the next elective surgical list. All the procedures were performed by consultant surgeons, well experienced in the procedures, to avoid bias. The operative time for each case was calculated by the investigator using a standard stop watch. Post operatively, All patients were kept Nil per os, (NPO) for at least 8 hours and were given injection Augmentin 1.2 gram I/V TDS and injection Diclofenic Sodium 75 mg I/M immediately after surgery and then after every 12 hours. Postoperative Pain of the all the patients was measured by visual analog scale (VAS) score, having 10 points from 0 to 10, where 0 represents no pain at all and 10 worst pain. These pain scores were recorded on the basis of patient's pain experience and would be asked by the doctor. Pain scores were measured at 12, 24 and 72 hours after surgery. All the findings were noted down on a predesigned pro-forma.

The data was analyzed by using SPSS v. 16. Categorical variables were expressed as frequencies with percentages. Quantitative data was expressed as mean \pm standard deviation. The independent samples t-test was used to compare operative time and pain scores

between groups A and B. P value <0.05 was considered statistically significant.

RESULTS

In this study the mean age of the patients was 41.16 ± 9.05 years with age range of 24-70 years. In group A the mean age was 41.10 ± 8.98 years and in group B the mean age was 41.23 ± 9.18 years. There were 36 (22.25%) males and 124 (77.5%) females in this study. According to the type of ventral hernia, 18 (11.3%) patients had Incisional, 107 (66.9%) patients had umbilical/paraumbilical hernia and 35(21.9%) patients had epigastric hernia as given in Figure 1.

In group A, the mean size of hernia was 5.29 ± 2.41 cm and in group B the mean size of hernia was 5.24 ± 2.49 cm. In both study groups the minimum and maximum sizes of the hernia were 3 cm and 10 cm respectively. In group A, the mean operative time was significantly (p -value= 0.000) less (66.56 ± 16.14 minutes) as compared to group B in which the mean operative time was (71.21 ± 12.91 minutes).

There was no significant difference in mean pain score at 12th hour after surgery in group A (Laparoscopic) (6.38 ± 1.34 vs. 6.70 ± 1.02 , P -value = 0.086) as compared to group B of open surgical technique. At 24th hour the mean pain score was 2.76 ± 0.80 in group A and 4.38 ± 1.21 in group B. In group A and B the minimum pain score was 3 and maximum pain score was 6 and 8 respectively in both groups. The results show that the mean pain score in Laparoscopic group was significantly (p -value = 0.000) lower as compare to Open surgical group. Moreover, the mean pain score at 72nd hour was 2.76 ± 1.60 and 4.38 ± 1.21 in group A and group B respectively. The mean pain score at 72th hour was also significantly (p -value = 0.000) less in group A (Laparoscopic) as compare to group B (Open surgical) as given in detail in table 1.

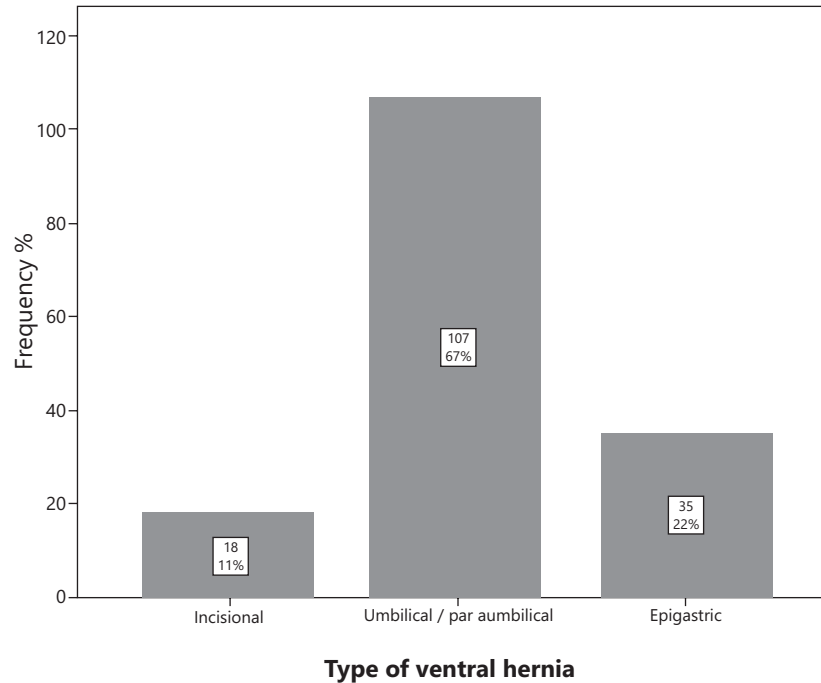
All the patients in laparoscopic group were adminis-

Table 1: Comparison of Operative time and Post operative pain at 12th, 24th and 72nd hour between Laparoscopic and Open surgical group

Parameter	Group	N	Mean	Std. Deviation	P-value
Operative time	Laparoscopic	80	66.56	16.14	0.046 *
	Open Surgical	80	71.21	12.91	
Post Operative pain at 12 hours	Laparoscopic	80	6.38	1.34	0.086 **
	Open Surgical	80	6.70	1.02	
Post Operative pain at 24 hours	Laparoscopic	80	3.95	1.58	0.000 *
	Open Surgical	80	5.49	1.60	
Post Operative pain at 72 hours	Laparoscopic	80	2.76	0.80	0.000 *
	Open Surgical	80	4.38	1.21	

* Difference is significant at 5% level of significance

** Difference is not significant at 5% level of significance

Figure 1: Distribution of Type of ventral hernia

tered oral routine analgesia with parenteral opioids on demand only and the results showed that there was no requirement of additional analgesic dose in laparoscopic group and only 10 patients required routine analgesia for more than 48 hours. But in the open mesh repair group injection analgesia was administered and it was noted that in 72 hours average doses required were 3.77 ± 1.23 in addition to routine analgesia.

DISCUSSION

Laparoscopic repair of ventral hernia is being done at a time when laparoscopic appendectomy and cholecystectomy has shown definite benefit over open procedures. There are many controversies but laparoscopic surgery continues to evolve with regard to laparoscopic repair of ventral hernia and there is more data available compared to the past due to increased popularity of this procedure. Long term studies assessing hernia recurrence rates will be required to help determine the optimal approach to ventral hernia repair¹⁰.

In this study the mean age of the patients was 41.16 ± 9.05 years. Other studies have also reported mean ages of 55.25 years and 56 years^{11,12}.

There were 36 (22.25%) males and 124 (77.5%) females in this study which means the females were dominant in the current study which is also reported by another study.¹³

In this study, according to the type of ventral hernia,

18 (11.3%) patients had Incisional, 107 (66.9%) patients had umbilical/paraumbilical hernia and 35 (21.9%) patients had epigastric hernia. Other study also published the similar findings of Incisional, umbilical/paraumbilical and epigastric hernia^{12,13}.

Internationally Laparoscopic ventral hernia repair is a safe and effective alternative to conventional open ventral hernia repair. The main advantage of this minimally invasive approach is a decrease in the rate of major wound complications and early return to works¹⁴.

In a meta analysis, Studies were selected on the basis of study design (comparison of laparoscopic and open ventral hernia repair), no statistically significant difference in operative times was noted between laparoscopic and open repair (99 vs. 96 minutes; $p=0.38$). Laparoscopic ventral hernia repair offers lower complication rates and shorter length of stay than open repair¹⁵.

In this present study the mean operative time in Laparoscopic group was 66 ± 16.31 minutes with range of 45 to 95 minutes. In group B (Open surgical group) the mean operative time was 75.88 ± 13.98 minutes with range of 44 to 95 minutes. Statistically the mean operative time in group A was less as compare to group B with significant p -value= 0.000. The operating time in another study ranged between 35 min to 120minutes in difficult cases due to adhesions and obesity. Others have reported mean operating time as 90.6 and 117 min, whereas in one series average time taken was 65.6 min (range 28 – 130 min)^{16,17} Open mesh repair also re-

quired longer operating time and associated with greater blood loss than simple repair^{18,19}.

Operating time, hospital stay and postoperative complications were significantly greater in the open group. At a mean follow-up of 27 months there were two recurrences in the open group and one reoperation for intestinal obstruction, and two meshes required removal for chronic infection. In contrast, no hernia relapses or late complications occurred in the laparoscopic group²⁰.

A more recent prospective cohort study of 136 ventral hernia repairs (65 laparoscopic and 71 open) also found that operating time was longer for laparoscopic repair; however, hospital stay was similar (1.1 versus 1.5 days) and hospital costs were 33% greater for the laparoscopic group. Although minor complications were more frequent in the open group, one patient in the laparoscopic group had an unrecognized intestinal perforation and two required mesh removal²¹.

In our study, there was no significant difference in mean pain score at 12th hour after surgery in group A (Laparoscopic) (6.38 ± 1.34 vs. 6.70 ± 1.02 , P -value = 0.086) as compared to group B of open surgical technique. At 24th hour the mean pain score was 2.76 ± 0.80 in group A and 4.38 ± 1.21 in group B. In group A and B the minimum pain score was 3 and maximum pain score was 6 and 8 respectively in both groups. The results show that the mean pain score in Laparoscopic group was significantly (p -value = 0.000) lower as compare to Open surgical group. Moreover, the mean pain score at 72nd hour was 2.76 ± 1.60 and 4.38 ± 1.21 in group A and group B respectively. The mean pain score at 72th hour was also significantly (p -value = 0.000) less in group A (Laparoscopic) as compare to group B (Open surgical). These results are in agreement with other studies at 12 hours and 72 hours, in a study it was noted that the pain scores were similar in the two groups at 24 and 48 hours, but significantly less at 72 hours in the laparoscopic group (mean visual analog scale score, 2.9412 vs 4.1702; $p = 0.001$)²².

Previous researches show that laparoscopic ventral hernia repair using a dual-layer polypropylene mesh and transfascial sutures significantly reduced surgical site infections, length of hospital stay and costs as compared to open mesh repair. This study has also shown decreased overall hospital costs for laparoscopic hernia repair despite higher operative costs.⁶ However, types of mesh used and fixation device can make sizeable differences in cost calculations. The long-term benefits in terms of early return to work and decreased recurrence rates with laparoscopic repair should also be taken into consideration when deciding on the cost-benefit ratio of laparoscopic versus open repair of ventral hernias. Operative costs may be optimized with judicious selec-

tion of mesh and optimal use of transabdominal sutures and fixation device.⁷

Laparoscopic incisional hernia repair can be performed safely with no increased morbidity or mortality, but the ultimate outcome in assessing the success of any hernia repair must be the rate of recurrence. The literature suggests that the laparoscopic approach, regardless of where the mesh is placed, has a midterm recurrence rate that is at least as good as that seen after the open operation. However, long-term assessment from large, well-controlled, prospective studies is needed to confirm the expected advantages of the laparoscopic approach.

Several large studies on laparoscopic ventral hernia repair have been reported". This technique has proven to be a safe and feasible alternative to open mesh repair. Although many are retrospective series and a few comparative studies, only two completed randomized trials comparing open versus laparoscopic mesh repair have been published. Based on these studies, LVHR has been found to have shorter operating time depending on the surgeon's experience, shorter hospital stay, lower complication rates especially wound and mesh infections and lower recurrence rate during the follow up period²³⁻²⁸.

CONCLUSION

According to our experience laparoscopic management of ventral hernia is safe and resulted in short operative time, less pain at 24th and 72nd hours of operation. So, it should be considered as the procedure of choice for ventral hernia repair.

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CONTRIBUTORS

MAK conceived the idea, planned and wrote the manuscript of the study. ZR helped in the planning of the study. MA helped in data analysis and write up of the manuscript. All the authors contributed significantly to the research that resulted in the submitted manuscript.