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General Surgery

OUTCOMES OF LAPAROSCOPIC VERSUS OPEN VENTRAL HERNIA REPAIR

Dr K. Karthik MBBS MS Fmas DNB Surgical Oncology

M Shravan Kumar* MBBS DNB General Surgery*Corresponding Author

ABSTRACT The study is a prospective cohort study conducted in the department of surgery at Lisie Hospital and was performed in a restricted period of time (one year) comprising 25 patients with laparoscopic repair and 25 patients with open mesh repair, selected randomly. Laparoscopic ventral hernia mesh repair was done for the LVHR group and onlay mesh repair was done for the OVHR group. The study was divided into two groups (LVHR and OVHR).The patient distribution in the LVHR group consisted of 72% Umbilical hernias(UH), 20% Incisional hernia(IH), 4% Epigastric hernia(EH), 4% Infra Umbilical Hernia(IUH) while the OVHR group included 64% Umbilical Hernia(UH),16% Incisional hernia(IH), 12% Para Umbilical hernia(PUH), 4% Epigastric hernia(EH), 4% Supra Umbilical hernia(SUH). There was no mortality in either group. Recurrence rate of 0% was seen for both the groups due to less period of follow up. The Complication rate was 4% for the LVHR group and 24% for the OVHR group. The only complication in the laparoscopic group was seroma. The recovery period is faster for a laparoscopic hernia repair with a mean postoperative hospital stay of 2.160days as compared to 4.84 days for open mesh repair. The postoperative pain for laparoscopic hernia repair was of a lower score when compared to open mesh repair by visual analog scale measurement. Laparoscopic hernia repair is associated with a faster return to normal activities (avg 13.76 days) when compared to open mesh repair(avg 21 days).

KEYWORDS : Open hernia repair, Laparoscopic hernia repair, Complication rate, return to normal activities

AIMS AND OBJECTIVES

- To study the advantages and disadvantages of laparoscopic and open methods for repair of Ventral hernias.
- To study the Outcomes and complications of laparoscopic and open methods for repair of Ventral hernias

METHODOLOGY

SOURCE OF DATA AND STUDY POPULATION: patients belonging to age 18-80 years admitted in surgical wards of Lisie Hospital, Ernakulam are to be included in the study

DESIGN OF THE STUDY: prospective study

PERIOD OF STUDY:

A prospective study is to be done from Jan 2013 to Dec 2013(one year) in Lisie Hospital Ernakulam. The cases included will be those that were admitted after Jan 2013 the study outcomes via records and subsequent follow-ups, as well as studying those cases admitted during the study period. A minimum follow-up period of 6 months for the cases is to be considered.

SAMPLE SIZE:50

SAMPLING METHOD: Random sampling

SAMPLE SIZES AND DETERMINATION:

Medical records were traced to find out number of patients attending surgery OPD lisie hospital in the period of Jan 2012 to Dec 2012 in regions of Ernakulam .Total 74 patients attended surgery OPD for that period being diagnosed as suffering from Ventral hernias, during a period of one year. After applying selection criteria (Inclusion and Exclusion criteria) 60 patients were eligible for study of which 50 patients were came for follow up.

A similar pattern of patient selection is to be followed during the study period from 1st Jan 2013 to 31st Dec 2013. Using the said method of determination, a sample size of 50 is to be considered.

The sample size for any study depends upon: the acceptable level of significance, the power of the study, expected effect size, underlying event rate in the population and the standard deviation of the population.

After a detailed review of literature and studies conducted comparing the outcomes of laparoscopic and open techniques the mentioned variables were defined and the sample size calculated using the formula[37]

$$ss = \frac{Z^2 \times p \times (1-p)}{C^2}$$

Where, ss = Sample size

Z = This represents the probability that the sample will fall within a certain distribution

p = percentage of population picking a choice, expressed as a decimal.

C = confidence interval, expressed as a decimal

Z values for confidence levels (obtained from the Cumulative Normal Probability Table)

1.645 = 90 percent confidence level

1.96 = 95 percent confidence level

2.576 = 99 percent confidence level

To determine the sample size ,this formula was used ; n= Z2 pq/d2 where ,

n= desired sample size

Z=standard normal deviate, usually set at 1.96

t 5%level,which correspondence to 95% confidence interval

p=proportion of population q=1-p

d=degree of accuracy level considered as 10% which assumes 0.1

The incidence of Ventral hernias is approximately 3-13%.As per theory nearest 50% should be taken as p". so p=13%.If p=13% is the percentage of incidence in population ,q = 1-p =87% with 95% confidence and error of estimation as 10% the minimum sample size worked out for the study according to formula $n> Z^2 pq/d^2$ is 43.43 , expecting some non cooperation the sample size is fixed as 50

CASE SELECTION:

Inclusion criteria:

Patients aged 18-80 years older of both genders, Incisional Hernia,Swiss cheese type

- hernia, are to be included in the study.

Exclusion criteria:

- History of malignancy within the past 5 yrs.
- Several co morbid conditions likely to limit survival to less than 2 yrs
- Cirrhosis with or without ascitis
- presence of bowel obstruction
- presence of local and systemic infection.

METHOD OF COLLECTION OF DATA

All patients fulfilling inclusion and exclusion criteria ,belonging to age 18-80 years will be included in this study after taking informed

consent. A detailed history and clinical examination will be done. All patients will be evaluated with the list of laboratory investigations included in case sheet proforma. Ultrasonogram ,CT scan will be done based on the needs of individual patient. Similar postoperative blood and imaging investigations will be employed based on the needs of individual patients. All patients will be discharged only after they are completely stabilised.

FOLLOW UP: Patients will be followed up for a maximum period of 6 months

ETHICAL CONSIDERATION :
All the patients/ legal guardians were given an explanation of the study and operative procedures to be performed along with their merits and demerits, expected results and possible complications. If they agreed, then the case was selected for this study. The study does not involve any additional investigation or any significant risk. It does not cause an economic burden to the patients. The study was approved by the institutional review board prior to commencement of data collection. Informed consent was taken from each patient/guardian.

METHOD OF CLINICAL SURVEY:
All the patients selected for the study will be evaluated on the basis of a specialized format. The patients will be offered a choice of repair (Laparoscopic or open), after explaining the merits as well as demerits of both the procedures. The patients are then assigned to their respective groups and further management will be carried out. The patients will be followed throughout their course in the hospital with emphasis on postoperative pain, mobilization and hospital stay. After discharge the patients were followed-up at regular intervals with emphasis on return to work, local complications like seroma and surgical site infection and recurrence.

The data regarding the type of surgery, postoperative pain, mobilization and return to work was gathered from the hospital archives and the respective hospital records marked, for future reference.

A total of 50 cases(25 each for LVHR and OVHR) will be selected.

The operative techniques used will be Lap ventral hernia repair with mesh for the LVHR group and the Overlay mesh repair for the OVHR group. The outcome variables will be analyzed using statistical methods and the results, compared to ones achieved in the large scale randomized trials to arrive at a conclusion.

VARIABLES TO BE STUDIED:
The successful outcomes of a hernia operation must be balanced against the potential adverse events of that procedure when choosing the most appropriate approach. Success can be measured by examining recurrence rates, level of postoperative pain, and return to normal activities. Outcomes of laparoscopic inguinal hernia repair can be compared against conventional open techniques using these outcome measures.[38]

- Duration of surgery
- Postoperative pain
- Mobilization
- Postoperative complications
- Duration of hospital stay
- Duration of return to normal work
- Recurrence

DATA ANALYSIS
Statistical tests used: two independent sample t-test(also known as two sample t-test)for continuous variables and Pearson's Chi square test for categorical variables

PLAN OF ACTION:
- Patients with primary Ventral hernias satisfying the inclusion criteria will be included into study.
- A detailed clinical examination will be carried out for all the patients.
- Each case will be thoroughly investigated and taken up for surgery.
- Written informed consent will be obtained from patients preoperatively.

OBSERVATION AND RESULTS

Our study included 25 patients diagnosed with ventral hernia who underwent a laparoscopic ventral hernia repair(LVHR group- the study group). They were compared with 50 patients diagnosed with ventral hernia who underwent a Open ventral hernia repair with mesh(OVHR group- the control group)

Postoperative pain :
The assessment of the pain was on the basis of the VAS(visual analog scale). The VAS is a unidimensional measure of pain intensity. It is a continuous and a single item scale

Score	LVHR	OVHR
1-2	22	5
>2	3	20

Results: Pearson's Chi-square test revealed that there is a statistically significant difference in the post-operative pain when comparing the type of surgical procedure [$\chi 2$ (1, N = 50) = 23.26892, p = 0.0000 < 0.05]. conclusion :Reject the null hypothesis.

Duration of surgery:
An independent sample t-test was run on the data as well as 95% confidence intervals (CI) for the mean difference. It was found that the duration of surgery in the Laproscopic group (76.4(±11.5) minutes) were significantly higher than the open group (41.60(±4.50)) (t(50) = 14.09, p = 0.000 < 0.05).

Two-Sample T-Test and CI: DURATION, Group
Two-sample T for DURATION

Group	N	Mean	StDev	SE Mean
LAPAROSCOPIC REPAIR	25	76.4	11.5	2.3
OPEN VENTRAL HERNIA REPAIR	25	41.60	4.50	0.90

Difference = mu (LAPAROSCOPIC REPAIR) - mu (OPEN VENTRAL HERNIA REPAIR)
Estimate for difference: 34.80
95% CI for difference: (29.83, 39.77) T-Test of difference = 0 (vs not =): T-Value = 14.09

P-Value = 0.000 < 0.05 means it is
significant DF = 48
Both use Pooled StDev = 8.7345

Postoperative course in the hospital:
The postoperative course takes into account the mobilization and the total duration of stay of the patient.

Chi-Square test

Mobilization	LVHR	OVHR
Day 1	12	2
Day 2	13	23

$1xc^2$ = 9.920635, P Value = 0.001634

Results:
Postoperative mobilization: Post-operative mobilization (measured in days) is normally distributed for both groups.Pearson's Chi-square test revealed that there is a statistically significant difference in the post-operative mobilization when comparing the type of surgical procedure [$\chi 2$ (1, N = 50) =9.920635, P Value = 0.001634 < 0.05].

Postoperative hospital stay
Duration of hospital stay (measured in days) is normally distributed for both groups. An independent sample t-test was run on the data as well as 95% confidence intervals (CI) for the mean difference. It was found that the post-operative duration of hospital stay in the Laproscopic group (2.160 ± 0.374 days) were significantly lower than the open group (4.840 ± 0.554days) (t(50) = -20.05, p< 0.000)

Two-Sample T-Test and CI: HOSPITAL STAY, Group
Two-sample T for HOSPITAL STAY

Group	N	Mean	StDev	SE Mean
LAPAROSCOPIC REPAIR	25	2.160	0.374	0.075
OPEN VENTRAL HERNIA REPAIR	25	4.840	0.554	0.11

Difference = mu (LAPAROSCOPIC REPAIR) - mu (OPEN VENTRAL HERNIA REPAIR)

Estimate for difference: -2.680

95% CI for difference: (-2.949, - 2.411) T-Test of difference = 0 (vs not =):
T-Value = -20.05
P-Value = 0.000
DF = 48
Both use Pooled StDev = 0.4726

Return to work

Studies indicate that factors other than operative technique, including patient expectations, are strongly associated with return to work after ventral hernia repair.

Result

An independent sample t-test was run on the data as well as 95% confidence intervals (CI) for the mean difference. It was found that the time of return to work in the Laproscopic group (13.76 ± 0.66 days) were significantly lower than the ventral group (21.00 ± 2.04 days)($t(50) = -16.87, p < 0.000$).

Two-sample T for RETURN TO WORK:

Group	N	Mean	StDev	SE Mean
LAPAROSCOPIC REPAIR	25	13.760	0.663	0.13
OPEN VENTRAL HERNIA REPAIR	25	21.00	2.04	0.41

Difference = mu (LAPAROSCOPIC REPAIR) - mu (OPEN VENTRAL HERNIA REPAIR)

Estimate for difference: -7.240
95% CI for difference: (-8.103, -6.377)
T-Test of difference = 0 (vs not =): T-Value = -16.87
P-Value = 0.000
DF = 48
Both use Pooled StDev = 1.5177

Postoperative complications:

Complication	LVHR	OVHR
Hematoma	0	4
Seroma	1	1
Wound gape	0	1

Results: The Chi-square test for the post-operative complications revealed that there is a statistically significant difference in the complication rate when comparing the type of surgical procedure [$\chi 2 (1, N = 50) = 4.152824, p = = 0.041565 < 0.05$].

Complications :

Complications	LVHR	OVHR
NO	24	19
YES	1	6

x2= 4.152824, P Value = 0.041565

Conclusion : Reject the null hypothesis.

Recurrence:

Recurrence	LVHR group	OVHR group
Present	0	O
Absent	50	50

Results of statistical analysis to test difference:

Variable	t- statistic	p-value	95% confidence limits Lower	95% confidence limits Upper
Duration Of surgery	14.09	0.000	29.83	39.77
Hospital stay	-20.05	<0.000	-2.949	-2.411
Return to work	-16.87	<0.000	-8.103	-6.377

The analysis of our sample using the independent sample t-tests for the continuous variables [duration of surgery (mins), hospital stay (days), and days to return to work] indicates that there are statistically significant differences between these variables among LVHR and OVHR groups.

Categorial variables:

Variable	Chi-sq statistic	p-value
Postoperative pain	23.26892	0.0000
mobilization	9.920635	0.001634
Complications	4.152824	0.041565

The analysis of our sample using chi-square test for categoria varaibles [post operative pain,mobilization in days, and complications indicate that there are statically significant difference between these variables among LVHR and OVHR

CONCLUSION

Laparoscopic Ventral hernia repair offers a minimal access approach to open hernia repair. In the hands of an experienced surgeon, a laparoscopic repair is considerably safe with less acceptable morbidity. It can be recommended as the procedure of choice who are anxious to return to their daily activities rapidly. Thus the laparoscopic approach gives a much better understanding of the anatomy of ventral hernia and can be recommended in patients with a recurrence after a previous open repair in whom the anatomy is likely to be distorted.

Though the learning phase is long and there is a trend towards increased complications and recurrence during the learning phase, these are within acceptable limits and the post-operative results and recovery are better than open mesh repair once the art of surgery is mastered.

Thus we conclude that Laparoscopic Ventral hernia repair should be an option given to a patient, considering its safety, efficacy, acceptable morbidity, fast postoperative recovery, lesser postoperative pain and hospital stay. Also, considering the long learning curve and better results in the hands of an experienced surgeon, laparoscopic hernia training should be incorporated in all centers associated with surgical training.

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