

Original Research Article

A prospective randomized comparative study of umbilical port site complications following fascial sheath closure versus non-closure in laparoscopic surgeries at a tertiary care centre in central India

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ABSTRACT

Background: The increase in laparoscopic surgeries has been accompanied by concerns over trocar site complications, particularly port site hernia (PSH). Among surgical debates, the necessity of fascial sheath closure for umbilical ports ≥ 10 mm remains unresolved. Objective of the study was to compare the incidence of umbilical port site complications between fascial sheath closure and non-closure in laparoscopic surgeries.

Methods: A prospective, interventional, randomized study was carried out at a tertiary care centre in Central India from July 2020 to December 2022. 100 patients undergoing elective laparoscopic procedures were enrolled and divided into two groups: group A (fascial closure) and group B (non-closure). Patients were assessed for port site hernia, hematoma, and infection through clinical and ultrasonographic evaluation over a mean follow-up period of 14 months.

Results: Port site hernia was observed in 3 patients (3%) overall: 1 patient in the closure group and 2 in the non-closure group ($p=1.0$). Port site infection occurred in 10 patients: 6 in the closure group (12%) and 4 in the non-closure group (8%) ($p=0.688$). A single case of port site hematoma was recorded in the non-closure group. No statistically significant differences were observed in hospital stay or complication rates.

Conclusion: There is no statistically significant difference in the incidence of port site complications between fascial closure and non-closure groups. Routine fascial closure of the umbilical port may not be essential in all cases.

Keywords: Laparoscopy, Port site hernia, Fascial closure, Trocar complications

INTRODUCTION

Minimally invasive surgery has become standard in many surgical fields due to its well-established benefits: reduced postoperative pain, faster recovery, and shorter hospital stay. There are two techniques of port insertion i.e., closed, and open. The closed technique usually involves Veress' needle for insufflation followed by blind trocar insertion, whereas in the open technique (Hasson), the abdominal wall is opened, and the port is inserted under direct vision. However, the technique introduces complications specific to trocar usage, including bleeding, hematoma, infection, and notably, port site hernia (PSH). First described by Fear in 1968, PSH continues to be a concern in laparoscopic

procedures, particularly at the umbilical site which lacks muscular support and is often the site for specimen retrieval.

Port site hernia is a potentially dangerous complication as it can lead to life threatening complications, such as bowel obstruction and strangulation. The predisposing factors associated in development of trocar site hernia are related to patient characteristics and the surgical technique. An important predisposing factor is obesity: as there is a substantially thicker preperitoneal space along with a higher intraabdominal pressure. There is also difficulty in achieving full thickness closure in such patients. Advanced age, gender, renal insufficiency, malignancy etc.

contribute to formation of trocar site hernia. As far as surgical technique is concerned, wide fascial defect, longer procedures with excessive manipulation at port sites, cutting trocars and undetected omentum or bowel entrapment into the intraperitoneal defect after trocar removal etc. Post-operative wound infection is also a known and important factor for development of trocar site hernia.

The debate persists around whether fascial sheath closure is necessary to prevent PSH. While some studies suggest that closure reduces the risk of herniation, others report no significant difference and point to increased operative time, infection risk, and technical difficulty.¹⁻¹⁰ The goal of this study is to clarify whether fascial closure significantly affects the incidence of complications at the umbilical port site.

The aim of the study was to compare incidence of umbilical port site complications in laparoscopic surgeries following closure and non-closure of fascial sheath.

Objectives were to study the complications at umbilical port site in laparoscopic surgeries with non-closure fascial sheath at port site, and to study the complications at port site in laparoscopic surgeries with fascial sheath closure at port site.

Other objectives include to analyze treatment options for umbilical port site complications following fascial sheath closure and non-closure fascial sheath.

METHODS

Study design

It was a prospective randomized comparative study.

Setting

The study was conducted at the Department of General Surgery at Tertiary Care Centre in Central India (Government Medical College and Hospital, Nagpur).

Study period

The study was conducted from July 2020 to December 2022.

Sample size

100 patients (50 in each group), calculated based on an estimated incidence of PSH in closure group with 95% confidence interval and 10% precision.

Randomization method

Block randomization method was used.

Inclusion criteria

Patients aged between 18-60 years, body mass index (BMI) 18.5-27 kg/m² and elective laparoscopic procedures: 10 mm umbilical port, were included in the study.

Exclusion criteria

Patients with diabetes, chronic obstructive pulmonary disease (COPD), immunosuppression, malignancy, steroid use, prior laparotomy, umbilical hernia, and conversion to open surgery, were excluded.

All surgeries used either Veress needle (closed) or Hasson (open) technique with a 10 mm umbilical port. Group A underwent fascial closure; group B had only skin closure. Follow-ups included clinical and ultrasonographic assessments at 48 hours, 7-10 days, and at months.^{1,4,7,11,15,19,23}

After taking informed consent, patients were enrolled in for the study. Detailed history was recorded, and physical examination was carried out and presence of any comorbidity like diabetes, smoking, immunodeficiency disorder was detected. Type of surgery and its indication were noted. Pre-operative factors like age, gender, and BMI were assessed.

Each patient was selected alternatively for umbilical port site fascial sheath closure and non-closure.

For statistical analysis, data were initially entered into a Microsoft Excel (MS Excel) spreadsheet and the analyzed using statistical package for social sciences (SPSS) (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism (version 5). Numerical variables were summarized using means and standard deviations, while data were entered into Excel and analyzed using SPSS and GraphPad Prism. Numerical variables were summarized using mean and standard deviations, while categorical variables were described with counts and percentages. Two-sample t-tests were used to compare independent groups, while paired t-tests accounted for correlations in paired data. Chi-square tests (including Fisher's exact test for small sample sizes) were used for categorical data comparisons. P values ≤ 0.05 were considered statistically significant numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples.

Paired t-tests were a form of blocking and had greater power than unpaired tests. A Chi-squared test (χ^2) was any statistical hypothesis test where in the sampling distribution of the test statistic is a Chi-squared distribution when the null hypothesis is true. Without other qualification, Chi-squared test often was used as short for Pearson's.

Group A

The access to the abdomen in laparoscopic surgery in this group was via Veress needle or open technique followed by insufflation of abdominal cavity with gas (CO₂) and trocar site was closed by absorbable polyglactin suture and skin was closed.

Group B

The access to the abdomen in laparoscopic surgery in this group was via Veress needle or open technique followed by insufflation of abdominal cavity with gas (CO₂) followed by entry of 10 mm trocar for the umbilical port. After surgery the fascia was not closed trocar site and only skin was closed.

Follow up

At 48 hours clinical examination, at 7 to 10 days clinical examination + ultrasonography, at 30 days (1 month). clinical examination + ultrasonography, at 4th month clinical examination ultrasonography, at 7th month clinical examination + ultrasonography, at 11th month clinical examination – ultrasonography and at 15th month clinical examination + ultrasonography.

Then after every 4th month clinical examination + ultrasonography was done.

Complications of laparoscopic surgery

Ponsky in 1991 has described many complications following laparoscopic cholecystectomy such as subcutaneous emphysema, mediastinal emphysema, pneumothorax, gastrointestinal tract perforation, solid visceral injuries, cardiac arrhythmia, hernia and bleeding at the trocar insertion site as potential complications.¹¹ These are associated with abdominal access and creation of pneumoperitoneum.

One of the main complications associated with trocar insertion or injury to solid or hollow viscera and trocar site hernia. Hematoma and wound infections at the insertion site area are also seen which are comparatively more seen but are less serious.

Laparoscopic surgeries are associated with a specific type of incisional hernia through the trocar insertion site which may cause complications such as small bowel obstruction.

RESULTS

Demographics

Age distribution

Mean age was 40.4±10.75 (closure) versus 38.6±10.70 (non-closure), p=0.784.

Maximum number of study subjects belonged to the age group of 31-40 years in both closure group and in non-closure group (Table 1).

Table 1: Age demographics.

Age groups (years)	Total cases	Closure		Non-closure		P
		Num-ber	%	Num-ber	%	
<20	0	0	0	0	0	0.818
21-30	21	9	18	12	24	
31-40	33	16	32	17	34	
41-50	25	13	26	12	24	
51-60	21	12	24	9	18	
Total	100	50	100	50	100	

Gender distribution

The gender distribution is shown in Table 2.

Table 2: Gender distribution.

Sex	Total cases	Closure		Non-closure		P
		Num-ber	%	Num-ber	%	
Male	36	19	38	17	34	0.907
Female	64	33	66	31	62	
Total	100	50	100	50	100	

BMI distribution

Maximum cases in both groups belonged to BMI group (18.0-22.9) (Table 3).

Table 3: BMI distribution.

BMI	Total cases	Closure		Non-closure		P
		Num-ber	%	Num-ber	%	
18.0-22.9	40	19	38	21	42	0.919
23.0-24.9	33	17	34	16	32	
25.0-27.0	27	14	28	13	26	
Total	100	50	100	50	100	

Surgery distribution

Laparoscopic cholecystectomy was most common (73%) (Table 4).

Complications

Complications involved port site hernia, port site infection, and port site hematoma.

Table 4: Surgery distribution.

Surgery	Total cases	Closure		Non-closure		P
		N	%	N	%	
Diagnostic laparoscopy	6	3	6	3	6	0.54*
Laparoscopic append-icectomy	18	8	16	10	20	
Laparoscopy cholecystect-omy	73	34	68	39	78	
Laparoscopy peri-cystectomy	3	2	4	1	2	
Total	100	50	100	50	100	

*P value is insignificant

Port site hernia

Port site hernia was observed in total 3 patients (6%) of which closure group had 1 (2%) patient and non-closure group had 2 (4%) patients, p=1 (Table 5).

Table 5: Post site hernia distribution.

Port site hernia	Total cases	Closure		Non-closure		P
		N	%	N	%	
48 hours	0	0	0	0	0	1*
7-10 days	0	0	0	0	0	
30 days	0	0	0	0	0	
3 rd month	0	0	0	0	0	
7 th month	1	1	0	0	0	
11 th month	2	1	2	1	2	
15 th month	0	0	0	0	0	
19 th month	0	0	0	0	0	
23 rd month	0	0	0	0	0	

*P value is insignificant

Port site infection

Port site infection was observed in total 10 patients of which 6 were in closure group (12%) and 4 were in non-closure group (8%), p=0.688.

Table 6: Post site infection distribution.

Port site infection	Total cases	Closure		Non-closure		P
		N	%	N	%	
48 hours	1	1	2	0	0	0.688
7-10 days	10	6	12	4	8	
30 days	2	1	2	1	2	
3 rd month	0	0	0	0	0	
7 th month	0	0	0	0	0	
11 th month	0	0	0	0	0	
15 th month	0	0	0	0	0	
19 th month	0	0	0	0	0	
23 rd month	0	0	0	0	0	

Port site hematoma

Port site hematoma was observed in 1 case in non-closure group and not observed in closure group (Table 7).

Table 7: Port site hematoma distribution.

Port site hematoma	Total cases	Closure		Non-closure		P
		N	%	N	%	
48 hours	1	0	0	1	2	1*
7-10 days	0	0	0	0	0	
30 days	0	0	0	0	0	
3 rd month	0	0	0	0	0	
7 th month	0	0	0	0	0	
11 th month	0	0	0	0	0	
15 th month	0	0	0	0	0	
19 th month	0	0	0	0	0	
23 rd month	0	0	0	0	0	

*P value is insignificant

Hospital stay

Hospital stay was 2.06 days in (closure) while 2.01 days in (non-closure), p=0.6182 (Table 8).

Table 8: Hospital stay distribution.

Variable	Closure	Non-closure	P value
	Mean±SD	Mean±SD	
Hospital stay	2.06±0.70	2.01±0.10	0.6182*

*P value is insignificant

DISCUSSION

Our study found no statistically significant difference in umbilical port site complications between closure and non-closure groups.

The introduction of laparoscopic approach in 1987 and the unceasing innovation in development of laparoscopic equipment since then, has led to an impetus in the branch of minimally invasive surgery.

Laparoscopy has evolved from being a diagnostic tool to a therapeutic aid in many abdominopelvic and thoracic surgeries. With the advances in laparoscopy search for ideal laparoscopic access system has continued. A prospective randomized comparative study was conducted for 100 patients undergoing Laparoscopic surgeries admitted in Tertiary Care Centre in Central India Government Medical College and Hospital Nagpur.

They were divided into two groups namely fascial closure and fascial non-closure equally. The patients were then followed up postoperatively at defined time intervals and assessed for port site hernia, port site hematoma and port site infection in both the groups.

Age distribution

Study conducted by Uslu et al have found that, patients more than 60 years are more likely to develop trocar site hernia due to weaker fascia in these patients.¹² Older women >60 years often have unrecognized fascial defect which confers higher risk. Here, mean age of the patients as 50.89. Duron et al ha means age of 56 years.¹³ The incidence of port site hernia in preschool children is higher (5.3%) as compared to incidence in adults. The reason for this is due to thinner abdominal wall and weak muscles in children. Study by Chiong et al showed mean age in port site hernia patients 70.7 years.¹⁵ In study by Boike et al showed mean age inpatients who developed hernia to be 50.5 years.¹⁶ In our study the mean age of the patients who developed hernia was also noticed in studies by Azurin et al in 1995 and Hussain, and coworkers in 2009.^{9,14} In our study as per inclusion criteria, patients between age 18-60 years were taken and were randomized. The mean age in closure group was 40.4±10.753 and non-closure group was 38.58±10.701. Then maximum number of study subjects belonged to the age group of 31-40 years in both closure group and in non-closure group.

Sex distribution

In our study, the percentage of females in closure group was 56% and 52% in non-closure group. The percentage of males in closure group was 66% and 62% in non-closure group. The male to female ratio was 1: 1.78, similar to other studies by Tonouchi, Yi et al, and Marakis, however study by Hussain had male predominance.^{2,14,17,18}

Types of surgery

Majority of studies were conducted with only laparoscopic cholecystectomy. Hussain et al studied a variety of lap procedures and incidence trocar site complications similar to our study.¹⁴ Study by Helgstrand included only laparoscopic cholecystectomy same like Marakis, and Yi et al.^{5,17,18}

In our study, different laparoscopic surgeries were conducted at our center namely laparoscopic cholecystectomy, appendicectomy, peri cystectomy for hepatic hydatid cyst and diagnostic laparoscopy. Maximum number of patients underwent laparoscopic cholecystectomy with 73% with gallbladder extraction done from epigastric port. Out of these patients undergoing laparoscopic cholecystectomy, 68% were in closure group and 78% in non-closure group.

BMI distribution

In our study as per the inclusion criteria the patients with a BMI range of 18.5 to 27 included. Maximum patients belong to BMI group of 18-22.9. Mean BMI in closure group was 22.85 and non-closure group was 22.20. Inpatients who developed hernia mean BMI of these patients was 24.30. Obesity has been suggested as a

predisposing factor in some studies.^{2,9,12,14} The majority of studies did not assess the effect of BMI on the incidence of PSH. Hence, BMI >27 was not considered in our study.

Port site hernia

The incidence of port site hernia in various studies is as described, 0.77%; 1.8%; 1.3%; 1.7%; 1.6%; 1.5%; 0.74%; 1.2%; and 2%.^{4,6,9,19-23} However, few studies showed high incidence like 5.4%; 25.9%, and 22%.^{12,24,25} In our study, the hernia patients were symptomatic. The presence of defect with herniation was identified sonologically due to regular follow up which involved clinical as well as sonological examination.

There are many studies which recommend closure of the port sites especially >10 mm ones. Uslu et al in his study did not perform fascial closure at any of the port sites and observed a high incidence 5.2% (40 out of 776 patients).¹² They recommend fascial repair for patients >60 years, BMI 25 and surgery duration >90 minutes. Kadar et al in his retrospective review noted that frequency of port site hernia was higher when the fascia was left open, though all cases involved 11 mm or 12 mm trocar port site and recommends closure of fascia whenever 10 mm or greater size trocars are entered into abdomen.¹ Tonouchi et al identified 22 patients of hernia, fascial defect was closed in 8 and open in 14.² They recommended to close the fascial layers including peritoneum wherever 10 mm or greater trocars were used and even 5 mm ones if active manipulation during prolonged surgery is done. Crist in his review article recommends fascial closure of all 10 mm port sites as a prevention for hernia.³ Bunting in his retrospective study concluded that fascia at umbilical port should always be closed.⁴ The study also suggests that if epigastric port is used for gall bladder extraction, then its fascia should always be closed. Helgstrand in his systematic review noticed the incidence of trocar site hernia after fascial closure to be 0.6% (42 out of 8719) compared to 1.5% (53 out of 3585) in fascial non-closure and recommends closure of 10 mm port sites.⁵

There are many studies which observed closure is not protective for hernia. Coda in 2000 observed in his study that 16 out of 1210 patients developed hernia despite all ports have fascial closure done.⁶ Sanz Lopez in his retrospective study observed that despite fascial an incidence of 1.2%.⁷ Lago et al in his prospective study of 195 patients observed hernia in 4 patients wherein fascia was closed and 1 patient in the group wherein fascia wasn't closed.⁸ The study also concluded that suturing fascia does not prevent PSH and even predisposes to wound site infection. Azurin in his study found 0.77% trocar site herniation and all of them were present at umbilical site.⁹ All herniation occurred despite primary closure of the fascial site. Hussain in his retrospective analysis observed 8 port site incisional hernias wherein closure of fascia was done for all ports >5 mm, though they still suggest new technique of closure to prevent port site hernia.¹⁴ Johnson in his retrospective study in 2006 observed an incidence of

1.2% of hernia.²² All these cases were present at the Hasson's fascial closure site. None noted at radially dilating trocar site.

There are studies showing that despite fascial non-closure there is no development of port site hernia. Liu et al observed 70 patients and total 180 laparoscopic sites had fascial non-closure non-bladed trocars were used. No patient developed ventral hernia in a follow up of 11 months.²⁶

In our study umbilical port site herniation developed in 3 patients: 1 closure and 2 non-closure group. P value was insignificant when compared with both the groups. Thus, our study concludes there is no significant difference in the rates of hernia development whether the fascia is closed or not with a p value of 1.0. The incidence of trocar site hernia in our study is 3% (3 patients out of 100). Similar incidence has been noted in other studies barring few. Tonouchi et al reported the incidence of trocar site hernias was between 0.65% and 2.80%.²

Port site hematoma

In study by Bhojru et al observed hematoma at 24 hours in 20% patient while using conventional cutting trocars and fascial closure was done.²⁷ In our study the maximum incidence of port site hematoma was seen within 48 hours post-surgery with a frequency of 1.0% (1 patient). Case was observed in the fascial non-closure group only.

Port site infection

In a prospective trial by Lago et al they observed 10 wound infections in fascial closure group while 3 in fascial non-closure though difference was not statistically significant.⁸ Mir et al in their study observed PSI incidence of 6.7% in a series of 675 patients who underwent elective laparoscopic cholecystectomy. Yi et al in their study of complications of Laparoscopic Cholecystectomy observed a PSI incidence of 2.75% in a series of 400 patients.¹⁷ In our study, total port site infection incidence as 11%. The maximum incidence of port site infection was seen at 7 to 10 days being 12.0% (6 patients) in the closure group and 8% (4 patients) in non-closure group with a p value of 0.688. At 1-month postoperative (30 days) period, continuation of port site infection from previous follow up was also seen which was 1 in closure and 1 in non-closure group. No fresh port site infection was observed beyond 10 days post-operative period in both the groups. In our study, the average hospital stay in closure group is 2.06 days and non-closure group is 2.01 days. P value was insignificant.

Follow up duration

The follow up duration of different studies were variable. Chiong had follow up 13 months (7- 37 months).¹⁵ Johnson had a follow up period of 24 months.²² Hussain et al had a follow up of 43 months (25-96 months).¹⁴ They all were retrospective studies. Few prospective studies had

similar follow up period. Bhojru et al had a median follow up of 27 months (13-46 months).²⁷ Nassar had a follow up period of 3-6 months.¹⁹ Uslu et al had follow up of 1 month only.¹² Mayol range of 3-51 months with minimum of 3 months follow up, in our study we did a postoperative follow up with the minimum follow up of 3-month maximum follow up at 23 months.²⁸ The complications at the port site were assessed clinically well as sonological. In our study, the mean follow-up month in fascial closure group was 14.27 month and in fascial non-closure group was 14.15 months with p value of 0.9 being insignificant.

Limitations of study

In spite of every sincere effort my study has lacunae. The notable shortcomings of this study are that the sample size was small. Only 100 cases were studied. The study has been done in a single center. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out. Prolong follow up require.

CONCLUSION

In our study, the clinical evidence concludes that there is no significant difference between closure and non-closure of fascia at the site of laparoscopic port insertion in terms of umbilical port site hernias and other complications. Thus suturing of fascial defect does not prevent port site hernia.

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