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ORIGINAL RESEARCH

Analysis of Laparoscopic Port Site Complications: An Observational Study

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ABSTRACT

Introduction: Laparoscopic surgery is the gold standard of therapy for many surgeries. Complications occur as number and complexity of laparoscopic surgeries increase. Many of these complications can be directly linked to abdominal access with laparoscopic trocars. **Aim and objectives:** To determine the complications associated with port insertion during laparoscopic surgery and to identify the risk factors associated with it. **Material and methods:** Total 172 patients who were undergoing laparoscopy were taken in study. Their sociodemographic profile was noted. Types of port site complications and clinical profile of patients were compared. Basal metabolic rate (BMI) and other comorbities were noted in patients. **Observations and results:** Incidence of port-site complications was 6.9%. Out of these 7.0 percent had discharge (58.3% patients had purulent discharge and 41.7% had serous discharge), 2.3 percent had port site infection and 1.2 percent had bleeding, failed entry & leaking port. Port-site infection was seen in early follow ups and port-site hernia in later follow-ups There was no statistically significant mean difference in leukocyte levels, Platelet levels, neutrophils and lymphocyte counts across group with port- site complications and the group with no port-site complications ($p > 0.05$). There was no statistically significant association of age, sex, socioeconomic status, education and religion. Odds of having port-site infection in those with higher BMI (i.e. >30 kg/m^2) was 2.2 higher than than those with BMI<30 kg/m^2 (p- 0.003). The participants who were suffering from Diabetes had 16.2 times more odds of having port site complications as compared to non diabetics ($p<0.001$)

Keyword: Laparoscopic surgery, port site complications, port site infections, obesity and laparoscopy

INTRODUCTION

For many surgical and gynecological diseases, laparoscopic surgery is the gold standard of therapy because of its exceptional results and well-established benefits.[1] Less discomfort and scarring, quicker recovery, and shorter hospital stays are the primary reasons why laparoscopic procedures are preferred over abdominal surgery. As medical knowledge advances, more and more procedures are being carried out laparoscopically.[2] However, complications have followed a rapid increase in the number and complexity of laparoscopic surgeries. Many of these complications, such as vascular injuries, visceral injuries, air embolism, subcutaneous emphysema, port site infections, port site incisional hernias, and metastases, can be directly linked to abdominal access with laparoscopic trocars.[3]

The frequency of problems at the port site after laparoscopic surgery is estimated to be approximately 21 per 100,000 instances, and it has demonstrated a commensurate increase with the size of the trocar and port site incision.[4, 5]

It has been demonstrated that in the majority of patients, more than half of the problems occurred during implantation. [6] During the procedure, bleeding and vascular and visceral damage are possible outcomes. Regarding the postoperative outcomes, throughout the follow-up phase, the port site may have wound infection, hematoma, and hernia

The port site infection (PSI) is one such consequence that can be avoided. The benefits of laparoscopic surgery are quickly undermined by port site infection, as patients lose faith in the operating surgeon and get anxious about the persistent infection. There is a noticeable rise in hospital stays, morbidity, and patient financial loss. The entire goal of minimal access surgery—achieving the highest level of cosmesis—is transformed into an unattractive wound, significantly impairing patients'quality of life. [7] It has increased proportionately as the size of the trocar and port site

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incision has grown. [5,8] Other less common side effects include hernia formation, pyoderma gangrenosum[9], and metastases at the port site after laparoscopic oncosurgery.[10, 11]

The type, location, and size of the ports that are generated, as well as the materials used to create them, all affect the occurrence and frequency of these difficulties, which vary greatly in many series.[9,12]

Obesity, the number of port sites, the size of the incision at the port, and umbilical ports are associated with complications. This study's goals were to ascertain the morbidity linked to ports at the location of their insertion during laparoscopic surgery, as well as to pinpoint risk factors for issues and how to handle them.

AIM AND OBJECTIVES

- To determine the incidence of complications associated with port insertion during laparoscopic surgery.
- To identify the risk factors associated with port site complications during alaparoscopic surgery.

MATERIALS AND METHODS

Study Design – Observational Study

Study Area- Department of General Surgery, National Institute of Medical Sciences and Research, Jaipur

Study Population- Patients Undergoing Laparoscopic Surgeries in the Department ofGeneral Surgery.

Sample size – $* 2 = 1.962 * 0.175 * (1-0.175)0.062$ = 154 + 10% dropout = 154 + 16 = 170

- Minimum sample size will be 170
- Z: Inverse normal probability at 95% confidence interval
- P: proportion rate of Laparoscopic surgery at NIMS hospital
- d: Margin of error (6% considered)

Selection of patients

a) Inclusion criteria:

- All patients between the age of 18-60yrs of either sex undergoing various laparoscopic surgeries.

b) Exclusion criteria:

- Patients with immuno-compromised status, co-morbid factors like cardiac /respiratory diseases, organ failure {e.g severe COPD, cardiac anomalies}
- Those cases which will be converted to open procedures

Sample technique

Purposive sampling technique.

Data Analysis

Data was entered in Microsoft excel sheet. Confidentiality of each study participant was maintained throughout the study. The data was analysed using SPSS version 26.0. Descriptive summary using frequencies, percentages, mean, and standard deviation was used to present study results. Probability (p) was calculated to test statistical significance at the 5% level of significance. Categorical variable was analysed using chi square test. Continuous variable was calculated using independent t test. Regression analysis was done to establish association between independent and dependent variables

OBSERVATION AND RESULTS

Following observations were made

Majority (42.4%) of participants were in the age group of 46 to 60 years, 36.0 percent were in the age group of 31 to 45 years while 21.5 percent belongs to age group of 18 to 30 years.

Among all the participants 41.9 percent were males and 58.1 percent were females. A majority (80.8%) of the participants were Hindu and 19.2 percent of the participants belonged to the Muslim religion (Table 1)

Out of the total participants, only 2.9 percent belonged to upper class, 67.4 percent belonged to the lower class and 29.7 percent of the participants belonged to the middle socioeconomic class (SEC)

Out of the total participants, 26.2 percent were literate. About 50.6 percent and 20.3 percent of the participants studied up to high school and intermediate respectively.

Table 2 shows that, out of total complications reported 7.0 percent were discharge, 2.3 percent were port site infection and 1.2 percent were bleeding, failed entry & leaking port.

Amongst the 12(7%) participants which showed discharge as port-site complications, 7 (58.3%) patients had purulent discharge and 5 (41.7%) had serous discharge.

Table 3 shows overall BMI, mean haemoglobin (Hb), Mean TLC (Total leukpcyte count), Mean neutrophil count, mean platelet count among study participants. Thistable also compare these variable in patients with and without port site complications.

Table 4 shows Socio Demographic Profile of the Study Participants Affecting Port Site Complications. It was observed that age, gender, religion, Socioeconomic Class(SEC) and education level had no statistically significant effect.

Table 5 shows that 9.1 percent of the study participants who were having BMI >30 had port site complications while 90.9 percent of the study participants who were having BMI<30 had port site complications. This difference was statistically significant (p- 0.047).

Among the study participants who were suffering from Diabetes 42.1 percent had port site complications, study participants who were suffering from hypertension 13.6 percent had port site complications, and only 9.1 percent who were suffering from hypothyroidism had port site

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complications while who were not suffering from any other co-morbidities 40.9 percent had port site complications and this difference was statistically significant (p<0.001).

Table 6 is showing follow up of study participants for one,two, three and four weeks and complications in that period.

Table 7 shows that two variable i.e. BMI and presence of co-morbidity were identified as significantly (p<0.05) associated with port site complications in univariate analysis as well as multivariate analysis.

Age, gender and type of procedure were statistically insignificant.

Odds of having port-site infection in those with higher BMI (i.e. >30 kg/m2) was 2.2 higher than (AOR= 2.2, 95% CI=1.1-3.9) than those with BMI<30 kg/m2. This was statistically significant (p-0.03).

The participants who were suffering from Diabetes had 16.2 times more odds (AOR=16.2,95% CI=3.8,68.3) of having port site complications as compared to participants who were not suffering from any comorbidities. This was statistically significant (p<0.001).

Table 1: Socio Demographic Profile of the Study Participants

Variable				p-value
		Frequency	Percent	
Age	18- 30 yrs	37	21.5	0.98
	31 to 45 yrs	62	36.0	
	46- 60 yrs	73	42.4	
Gender	Male	72	41.9	0.30
	Female	100	58.1	
Religion	Hindu	139	80.8	0.65
	Muslim	33	19.2	
SEC	Lower	116	67.4	0.64
	Middle	51	29.7	
	Upper	5	2.9	
Education	Illiterate	45	26.2	0.89
	High school	87	50.6	
	Intermediate	35	20.3	
	Graduate	3	1.7	
	Professional	2	1.2	

Table 2: Types of Port-site Complications

Variable	Frequency	Percent
Discharge	12	7.0
Bleeding	2	1.2
Port site infection	4	2.3
Failed entry	2	1.2
Leaking port	2	1.2

Table 3: Clinical Profile of the Study Participants

Variable	Port site complications	Total	95% Confidence Interval of the Difference	p- value		
	Yes	No		Lower	Upper	
BMI (Mean±SD)	26.70±2.65	24.48±2.52	25.51±2.53	-.92332	1.36817	0.032
Hb (Mean±SD)	11.15±1.48	11.80±1.39	11.72±1.41	-1.28036	-.01346	0.045
TLC (Mean±SD)	7757.27±1390.10	7921.80±1315.67	7900.76±1322.36	1.33866	.04484	0.066
Neutrophils (Mean±SD)	63.36±6.14	62.99±7.05	63.03±6.93	-2.755	3.509	0.587
Lymphocytes (Mean±SD)	33.64±6.14	33.79±6.84	33.77±6.74	-3.199	2.899	0.812
Platelets (Mean±SD)	1.90±0.86	1.91±0.75	1.91±0.76	-.35248	.33716	0.923

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Table 4: Socio Demographic Profile of the Study Participants Affecting Port SiteComplications

Variable		Port-site Complications		p-value
		Yes	No	
Age	0 to 20 yrs	4.5%	6.7%	0.72
	20 to 40 yrs	50.0%	41.3%	
	> 40 yrs	45.5%	52.0%	
Gender	Male	31.8%	43.3%	0.30
	Female	68.2%	56.7%	
Religion	Hindu	77.3%	81.3%	0.65
	Muslim	22.7%	18.7%	
SEC	Lower	72.7%	66.7%	0.64
	Middle	27.3%	30.0%	
	Upper	0.0%	3.3%	
Education	Illiterate	31.8%	25.3%	0.89
	High school	50.0%	50.7%	
	Intermediate	18.2%	20.7%	
	Graduate	0.0%	2.0%	
	Professional	0.0%	1.3%	

Table 5: Personal History of the Study Participants Affecting Port Site Complications

Variable		Port-site Complications		p-value
		Yes	No	
BMI >30	No	90.9%	98.0%	0.047
	Yes	9.1%	2.0%	
Comorbidity	None	40.9%	72.7%	0.001
	Diabetes	36.4%	7.3%	
	HTN	13.6%	11.3%	
	Hypothyroidism	9.1%	8.7%	

Table 6: Port Site Complications After Follow Up Period

Variable	Follow up			
	Week 1	Week 2	Week 3	Week 4
None	162(94.2)	170(98.8)	170(98.8)	168(97.7)
Infection/Discharge	10(5.8)	2(1.2)	0	0
Hernia	0(0)	0	2(1.2)	4(2.3)

Table 7: Predictors of Port Site Complications

Variables		Univariate Analysis			Multivariate Analysis		
		OR	95% CI	P value	OR	95% CI	P value
Age (In years)	18 to 30	1.1	0.34,3.5	0.86	2.8	0.66,12.2	0.16
	31 to 45	1.05	0.38,2.9	0.92	2.5	0.67,9.5	0.17
	46 to 60	Reference					
Gender	Female	1.6	0.63,4.2	0.31	1.8	0.54,6.1	0.33
	Male	Reference					
BMI >30 (kg/m^2)	Yes	1.1	0.6-2.2	0.03	2.2	1.1-3.9	0.03
	No	References					
Procedure	Diagnostic laparoscopy	0.73	0.08,6.2	0.77	0.27	0.02,3.4	0.31
	Laparoscopic appendicectomy	0.56	0.17,1.7	0.32	0.61	0.05,6.5	0.68
	Laparoscopic cholecystectomy	Reference					

DISCUSSION

Laparoscopic techniques have revolutionized the field of surgery. Laparoscopic Surgery involve the use of reusable metallic or disposable plastic trocars inserted through small skin incisions or ports made on the skin away from the site of surgery. It has gained popularity due to better aesthesis, lesser pain, early ambulation and discharge from the hospital with early return to work, minimizing the financial burdento the patient. [13]

Benefits of Minimal Access Surgery include decreased postoperative pain, quicker return to normal activity, and less postoperative complications. Laparoscopic Surgery, however, has its package of unique complications. Inadvertent bowel injury or major vascular injury are uncommon but potentially

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life-threatening complications, usually occurring during initial access. [14,15]

In our study the majority (42.4%) of participants were in the age group of 46 to 60 years, 36.0 percent were in the age group of 31 to 45 years while 21.5 percent belongs to age group of 18 to 30 years, which correlates with incidence and detection of gall stone in that age group with patients undergoing laparoscopic surgery which is commonly performed surgery in this study. As patients delay their treatment after getting diagnosed and being asymptomatic after treating the acute pain. Accordingto the study done by Karthik S et al., [16] the mean age of in their study was 35.2 years. Similar to our study Rehman UA et al., [17] also had a slightly higher mean age than the other studies. The mean age in their study was 42.80 ±11.54 years. Similar age group preponderance was seen in some other studies as well. [18,19,20]

Among all the participants 41.9 percent were males and 58.1 percent were females. Amongst those who developed port-site complications in our study, 68.2% were females and 31.8% were males. In the study conducted by Karthik S et al., [16] the percentage of male & female was 53.8 % and 46.2 % respectively, out of which 7.2 % of males and 10.3 % of females developed port site complications. Similarly, according to study conducted by Mudgal MM et al., [21] the percentage of male & female was 22.67 % and 73.33 % respectively out of which 12.3 % male and 27.3 % female population developed port site complications.

Female preponderance in our study is attributed to higher incidence of gallstone in female population and those undergoing laparoscopic surgery for gall stones. India being a developing country, where female population neglects their health and don't take rest after surgery which attributes to higher incidence of complications in them.

In our study, 6.9% study participants had port-site complications in the post-operative period. Out of total complications reported 54.5% were discharge, 9.1% were port site infection and 18.1% were bleeding, failed entry & leaking port. Most of laparoscopic surgeries require three port access and four port access thereby increasing chance of complications. In our study majority of the study participants (77.3%) who were undergone laparoscopic cholecystectomy had port site complications as compared to percent who were undergone laparoscopic appendicectomy and 4.5 percent of who were undergone diagnostic laparoscopy.

Maharaul HH et al., [7] reported 16.67% complications in their study populations, with 75% patients having port-site infection as the most common complication followed by port-site bleeding in 20%.

Similar to our study, the incidence of port-site bleeding was observed in 2 patients (1 each at epigastric site and RIF site) Bleeding points can be identified intraoperatively and managed with electrocautery.

In our study, port site hernia was seen as a long term complication in 6 patients (3.5%)whereas, Majhi H et al., [20] had only 1 patient (0.8 %) with hernia at umblical port site. This was similar to as observed by Chiu et al., [22] (0.33 %). Other such studies showed an overall incidence between 0.02 - 1.6 percent. [23, 24, 25] Fascial closure is recommended for ports ≥ 10 mm. The fascia is closed with sutures to reduce the risk of developing a port site hernia. [20]

Higher BMI was found to be significantly associated with port site complications. India being developing country we have more number of patients in having low BMI. Like every coin has 2 sides India also has patient having BMI > 30 Kg/m2 due unhealthy eating habits and sedentary lifestyle. [26] In Mudgal MM et al., [21] study patients with BMI >25 Kg/m2 (15.3% and 12.7%) had complications compared to BMI 25 Kg/m2 compared to 2% and 2.6% in patients with BMI < 25 Kg/m2. Patients with high BMI have higher chances of complications during entry and closing abdominal wall due to difficulty in accessing abdominal cavity and also during removal of trocar there are higher chances of omental as well as bowel entrapment. There are higher chances of port site infection as well as port site hernia in obese patient. [27]

In a study by Majhi H et al., [20] mean BMI was higher in the patient with complications compared to patients without complications but it was not statistically significant. Patients with high BMI have higher chances of complications during entry and closure of abdominal wall due to difficulty in accessing abdominal cavity and also, during removal of trocar there are higher chances of omental as well as bowel entrapment. There are higher chances of port site infection as well as port site hernia in obese patients. [28] We also found that the patients with higher BMI had 2.2 times higher odds of suffering with port-site infection than those with BMI < 30 kg/m2.

Presence of co-morbidities like Diabetes etc. was significantly associated with presence of port-site complication. Among the study participants who were suffering from Diabetes 42.1 percent had port site complications, study participants who were suffering from hypertension 13.6 percent had port site complications, and only 9.1 percent who were suffering from hypothyroidism had port site complications while who were not suffering from any other co-morbidities 40.9 percent had port site complications and this difference was statistically significant ($p<0.001$). Diabetes has been associated with a significantly increased rate of wound infection following open surgical procedures. It is also thought to be one of the risk factors of conversion to open laparoscopic procedure and believed to be associated with increased morbidity as compared to non-diabetic patients undergoing the same procedure. [30] Diabetes

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is one of the factors that increases a surgical patient's risk for postoperative infection. [30]

The co-morbidities such as hypertension, DM and HCV enhance the risk of port site infection. A study by Rehman UA et al., [17] revealed that among those who developed port-site complications 20% patients had hypertension and 11.7% hypertension & DM while 5.0% patients had hepatitis-C. The findings of a similar study performed by Taj MN et al., [31] which indicated that majority of the patients (44%) had DM, followed by hypothyroidism (14%), obesity (14%), liver cirrhosis (11.1%), bronchial asthma (7.4%) and hypertension (3.7%).

Port site problems are rare after laparoscopic procedures. Even fewer occur even in the case of elective procedures. The incidence of these complications may be further reduced by appropriate patient selection, meticulous surgical technique during entry and exit at all port sites, strict adherence to the instructions for cleaning and sterilising the laparoscopic instruments with the appropriate cleaning agent, pre-operative antibiotic prophylaxis, and ample post-operative care and follow-up.

CONCLUSION

- Incidence of port-site complications is very less. O u r study had the incidence of 6.9% in post-operative period.
- Out of total complications reported 7.0 percent were discharge (58.3% patients had purulent discharge and 41.7% had serous discharge), 2.3 percent were port site infection and 1.2 percent were bleeding, failed entry & leaking port.
- Port-site infection was the most-common seen complications on early follow ups (upto 2 weeks post-operative period) , Port-site hernia was most-commonly observed in later follow-ups (3-4 weeks post operatively)
- There was a statistically significant mean difference in hemoglobin levels across group with port-site complications and the group with no port- site complications (p-0.045)
- There was no statistically significant mean difference in TLC levels, Platelet levels, neutrophils and lymphocyte counts across group with port- site complications and the group with no port-site complications. (p>0.05)
- There was no statistically significant association of age, sex, SES, education and religion across group with port-site complications and the group with no port-site complications. (p >0.05)
- Study participants who were having BMI > 30 (9.1%) had port site complications while 90.9 percent of the study participants who were having BMI<30 had port site complications. This d ifference was statistically significant (p- 0.047). Odds of having port-site infection in those with higher BMI (i.e. >30 kg/m^2) was 2.2 higher than than those with BMI<30 kg/m^2. This was significant statically (p- 0.003)
- The participants who were suffering from Diabetes had 16.2 times moreodds of having port site complications as compared to participants who were not suffering from any comorbidities. This was statisticallysignificant (p<0.001)

Conflict of Interest/Disclosure Statement- All authors declare that they have noconflict of interest

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