

Laparoscopic Cholecystectomy: Closure versus Non-Closure of the Fascial Sheath Opening of the Sub-Umbilical Port Site “10mm.”

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ABSTRACT

Aims Rate of complications such as obstructed port site hernia is low depending on size and site of the port incision, type of used trocar, patient’s condition, and surgeon’s experience. This study was aimed to compare closure versus non-closure of the fascial sheath opening of the sub-umbilical port site “10mm”.

Materials & Methods This prospective study was performed on 50 patients in AL-Karama Teaching Hospital from September 2017 to January 2018. They were alternatively divided to Group A: sub-umbilical port site fascial defect of 10mm in diameter was closed with Zero Nylon in addition to skin closure with Zero Silk, and Group B: sub-umbilical port site fascial defect of 10mm in diameter was left without closure, only skin was closed with Zero Silk. A sharp trocar 10mm was introduced through the linea alba into the abdominal cavity at the sub-umbilical site for laparoscopic access.

Findings The two groups had incidence rates of port site hernia, infection, and bleeding of zero, and there was no complication (hernia, bleeding, and infection) related to sub-umbilical port sites in both groups during 4-16 weeks follow-up.

Conclusion The closure of the laparoscopic port fascial defects is time-consuming; using suture material increases the procedure’s financial cost. It is not free of complications such as inadvertent omentum or bowel loop injury.

Keywords Laparoscopic Cholecystectomy; Trocar; Fascial Sheath; Complications

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Introduction

The laparoscopic techniques have many benefits, including reduced postoperative pain, quick return to normal activity, and fewer postoperative complications; thus, they revolutionized the field of surgery. Laparoscopic surgery is a minimal access surgery (MAS) where operations are performed with specialized instruments designed to be inserted through small incisions. Performance of minimal access surgery needs the creation of pneumoperitoneum. The pneumoperitoneum is essential for improving visualization by moving the abdominal wall away from the viscera. This initial step in establishing pneumoperitoneum is done blindly with a Veress needle to prepare for the trocar entrance into the peritoneal cavity or directly by the trocar. The initial trocar insertion is the most critical step in minimally invasive surgery. Understanding the composition of the abdominal wall and its relationship with the viscera and vessels below it is crucial for the safe placement of trocars. The umbilicus is the best site for the Veress needle or primary trocar because the skin is attached to the fascia and anterior peritoneum with minimal intervening muscle or fat. The abdominal midline is an avascular area. When getting away from the midline, the superior and inferior epigastric arteries can be injured where they course just beneath the rectus abdominis muscles. These arteries are anatomically located in the mid-portion of the rectus sheath, running longitudinally^[1].

Numerous small vessels can be injured when trocars are inserted through the abdominal wall. By transilluminating the abdominal wall, many of these vessels can be seen and avoided. The relation of the intra-abdominal viscera, including the retroperitoneal vasculature, to the insertion site, must also be considered. This is particularly most important in the very thin and very obese. The normal relationships between the abdominal wall and the vasculature are widely variable; in thin people, the distance between the abdominal wall and the retroperitoneal vessels may be less than 2 cm. Also, the distal aorta and right common iliac artery are particularly vulnerable to injury since the junction of these two vessels is directly below the umbilicus, according to Anaise^[2].

Adhesions between the intra-abdominal contents and the abdominal wall must be considered during insertion of Veress needle or direct first trocar insertion. According to Vilos *et al.*^[3], the incidence rates of adhesions between the abdominal wall and intra-abdominal viscera range 0%-60%, varying according to patient's history in those without any previous abdominal surgery and those with a previous midline laparotomy. Passage of a Veress needle or trocar near or through adhesions may result in injury. However, laparoscopic techniques are associated with certain port site incisions/entrance complications and the

cholecystectomy procedure itself. Complications related to laparoscopic cholecystectomy are bile duct injury, bile leakages, bleeding, and bowel injury resulting in part from patient selection, surgical inexperience, and technical constraints inherent to the minimally invasive approach^[4-7].

A major cause of biliary ductal injury is diathermic burns, which may go unnoticed and usually involve the right or common hepatic ducts. Also, the intrinsic sequelae of biliary tract diseases such as inflammation and scarring have led to the "Stop Rules" concept for surgeons performing this operation. In essence, if a safe dissection cannot be laparoscopically ensured, early conversion to an open approach should be readily accepted as the proper course^[8].

Inadvertent bowel or major vascular injury is uncommon, but they are potentially life-threatening complications during initial laparoscopic access^[9].

The first publication of the port site hernia (PSH) following laparoscopic cholecystectomy (LC) was in 1991 by Maio *et al.*^[10].

Port site complications accompanying laparoscopic access to the abdominal cavity by laparoscopic instruments were 21 per 100,000 laparoscopic cholecystectomies. They show a proportional rise with the increase in the port site incision and the type of trocar used^[11-13].

Port site hernia is a rare complication forming approximately 1% of all laparoscopic cholecystectomy complications. With sharp trocars, some surgeons have argued that all port sites do not require fascial closure. Several cases of PSH, however, have been reported recently with the use of sharp trocars. The incidence of PSH varies between 0.18-2.8%. The diameter of the trocar, Body Mass Index (BMI), and patient's age play a fundamental role when deciding close or not to close the port site fascia defect. Closure of the port site fascial defect is the most important factor to prevent PSH^[14].

The incidence rate of major vascular injury during initial laparoscopic entry ranges between 0.05-0.5%. Vascular injuries may involve retroperitoneal, intraperitoneal, or port site vessels^[15].

The port site infection (PSI) soon erodes the advantages of (LS) when the patient becomes worried about the lazy and nagging infection and loses confidence in the operating surgeon. This leads to a significant increase in morbidity, hospital stay, and financial loss to the patient. The whole purpose of (MAS) to achieve the utmost cosmetic is turned into an unsightly wound, and the patient's quality of life is seriously affected. There is an emphasis on managing PSI due to the emerging rapidly growing atypical mycobacteria that do not respond to the standard anti-tubercular drugs. No surgical wound is completely immune to infections. Despite the advances in antimicrobial agents, sterilization techniques, surgical techniques, and operating room

ventilation, PSIs still prevail. Incidence of PSI after elective laparoscopic cholecystectomy is less than that after open elective cholecystectomy due to short diameters of the laparoscopic incision [16].

Francis *et al.* [17] reported the factors predicting 30 days readmission after laparoscopic colorectal cancer surgery. Out of 268 patients who underwent laparoscopic colorectal surgery in their study, 48 (18%) were readmitted with surgical site infection (SSI). The umbilical PSI rate in LS has been reported to be 8%, 89% of them occur after laparoscopic cholecystectomy, whereas 11% of them occur after laparoscopic appendectomy [18]. The direct primary trocar entry technique to the peritoneum does not differ in umbilical PSI in patients undergoing laparoscopic cholecystectomy [19].

Several other authors have found that the SSI incidence rate is much higher in conventional surgical procedures than in MAS [20]. The immune functions are less affected in LS as compared to open surgery [21]. Many techniques, devices, and measurements (e.g., use of blunt trocar, prophylactic antibiotics, and detection of coagulopathies and control them) have been used through practice to minimize the risk of port-site complications [22].

PSH occurrence in laparoscopic surgery depends on the trocar diameter, the trocar design, pre-existing fascial defects, and the direction of the trocar insertion. The risk of PSH is greater in obese patients because of large pre-peritoneal space and elevated intra-abdominal pressure. Some authors advise closure of any port site fascial defects more than 5mm in diameter.

The various methods for port site fascial defect closure after laparoscopic surgery are:

- 1- Standard closure (via skin wound);
- 2- Laparoscopic direct visualization fascial defect closure;
- 3- Usage of a spring-loaded needle and suture passer needle [23].

Port site infection is a type of surgical site infection that can occur at the trocar site in laparoscopic surgery. The most common complication of the laparoscopic port site is the incisional port site hernia [24].

This study was aimed to compare closure versus non-closure of the fascial sheath opening of the sub-umbilical port site "10mm".

Materials and Methods

This prospective study was observational with a simple randomized sample and conducted in the surgery department, Al-Karama Teaching Hospital, Iraq, from September 2017 to January 2018. A total of 50 patients with symptomatic cholecystitis (with/without gallstones) were referred to the Al-Karama Teaching Hospital during the study period and underwent laparoscopic cholecystectomies performed by different specialized laparoscopic surgeons. The diagnosis of the type of cholecystitis

(acute calculus cholecystitis, chronic calculous cholecystitis, acute acalculous cholecystitis, and chronic acalculous cholecystitis) was clinically, and it was confirmed by ultrasonography. The individuals were selected randomly and alternatively to close the sub-umbilical port site fascial defects at the level of the fascial sheath to be categorized as group A (N=25), and others weren't sutured to be categorized as group B (N=25). Patients with a previous history of upper laparotomy, large umbilical/para-umbilical hernias, acute pancreatitis, choledocholithiasis, skin infections, and those unfit for laparoscopic surgery were excluded from this study.

This study started after approval of the Ethics Committee of Medical College of Wasit University in Iraq on the study proposal on 13-9-2017. A signed and informed consent was obtained from every patient or his/her guardian. A full history, physical examination, and investigations were completed for each patient. The investigations included complete blood count, fasting blood sugar, blood urea, serum creatinine, liver function test, hepatitis viral screening, coagulopathy tests, Chest-X-ray, ECG, and abdominal ultrasonography ACUSON X300 (Siemens device; Germany). All patients were subjected to calculate the body mass index (BMI) by measuring the weight (kg) using a weighing scale (BOMANN) and height (m) using a meter as in the following equation ($\text{weight}/\text{height}^2$) to be categorized according to the classification of WHO for BMI and as follow: [25].

- Under-weight (BMI is less than 18.5);
- Normal weight (BMI is 18.5-24.9);
- Overweight (BMI is 25-29.9);
- Obese (BMI is more than 30).

The patients were given prophylactic third-generation cephalosporin (Ceftriaxone) 1gm per 12 hours (three doses), and the first dose was routinely given at the time of induction of anesthesia.

The Operative technique: All patients were operated on under general anesthesia. After skin scrubbing with povidone-iodine solution 10% (from the nipple line to the mid-thigh) and draping, a 10mm horizontal incision was made at the inferior aspect of the umbilicus then deepened through the subcutaneous fat to the anterior rectus sheath. A Veress needle (KARL STORZ; Germany) was used for laparoscopic access and creation of carbon dioxide pneumoperitoneum, followed by a sharp trocar entrance into the abdominal cavity. The laparoscope (KARL STORZ; Germany) was introduced into the abdominal cavity. A 10mm horizontal incision was made three fingerbreadths below the costal margin to the right of the midline and deepened into the subcutaneous fat to be followed by a sharp trocar entrance into the abdominal cavity. Two other horizontal incisions of 5mm were made: one at the mid-clavicular line and the other at the right anterior-axillary line below the costal margin. After

completing the laparoscopic cholecystectomy procedure, all instruments were carefully removed under direct vision; carbon Dioxide was evacuated out through valves of 10mm cannulae. The primary port sheath (sub-umbilical one) was the last one to be removed. The sub-umbilical port site fascial was closed at the level of the fascial sheath with number zero nylon suture (Dyneck Pty Ltd, Australia). All port sites were closed at the skin level with zero silk sutures (DemeTECH, USA). We used the closure method via skin wound to close the fascial sheath using Alice's artery forceps to separate the skin and display the fascial sheath to distinct it from the fat for suturing the sheath by vertical mattress single suture. To assess the incidence rates of the complications: PSH, PSB, and PSI, the patients were followed up (4-16 weeks) after their operation. All patients were clinically and ultrasonographically assessed for a diagnosis of the complications above. Data were statistically analyzed using SPSS 20 software to find the correlations between variables.

Findings

This study included 50 laparoscopically cholecystectomies patients whose ages ranged from 20-67 years. The mean±SD of their ages was 40.18±11.65 years.

The patients were distributed into five age groups according to sex (with more frequency at the age group of 30-39 years for male), cholecystitis status (with more frequency at the age group of 40-49 years and less frequency at the age group of 60-69 years), BMI with the highest frequency in overweight and obese at the age group of 40-49 years (Table 1).

Table 1) distribution of the patients' age based on sex, cholecystitis status, and BMI

Variables	Age (Year)					Total
	<29	30-39	40-49	50-59	60-69	
Sex						
Male	1	4	3	2	1	11
Female	9	6	14	8	2	39
Total	10	10	17	10	3	50
Cholecystitis status						
Acute calculous cholecystitis	3	2	3	1	0	9
Chronic acalculous cholecystitis	2	1	2	2	0	7
Chronic calculous cholecystitis	5	7	12	7	3	34
Total	10	10	17	10	3	50
BMI						
<18.5	2	0	0	0	0	2
18.5-24.9	2	1	0	3	0	6
25-29.9	5	7	11	2	1	26
>30	1	2	6	5	2	16
Total	10	10	17	10	3	50

The incidence rates of port site hernia, infection, and bleeding for Groups A and B were zero through the follow-up period. The researchers observed no complications related to the laparoscopic cholecystectomy procedure during the follow-up.

Discussion

This study included 50 laparoscopically cholecystectomies patients aged from 20 to 67 years with Mean±SD of 40.18±11.65.

The results of the study were analyzed, reviewed, and discussed. The main variables were the port site complications, including Port Site Hernia, Port Site Bleeding and Port Site Infection of both study groups: Group A (the closure of the fascial sheath defect at the sub-umbilical port site incision) and Group B (non-closure of the fascial sheath at the sub-umbilical port site incision).

The results of each one of the complications (Port Site Hernia, Port Site Bleeding, and Port Site Infection) were compared between both groups A and B. Then results of each complication (Port Site Hernia, Port Site Bleeding, and Port Site Infection) of both these study groups were compared with results of similar related international studies.

Regarding the incidence rate of laparoscopic port site hernia (PSH), this study had an incidence rate of 0.00% for either group during the period of follow-up that ranged from 4-16 weeks.

Hussain *et al.* [26] and Jamil *et al.* [27] reported incidence rates of PSH of 0.1 and 1.1 respectively in closure groups of their studies.

Hussain *et al.* [26], in 2009 with 5541 patients as a sample of their study, used the closure method to close the Port Site fascial defect and supposed that the laparoscopic port site closure using the classical method was associated with an acceptable incidence of Port-Site Hernia (0.1%). Modification of the current methods of laparoscopic port site fascial defect closure may lead to a new technique to prevent or reduce the incidence of port-site incisional hernias, this suggestion supported by Aziz [28] in 2013, who suggested that the closure of the fascial sheath should remain simple, easy, cost-effective, and quick to apply. It should also be safe and without any complications.

According to Yi *et al.* [29], in 2012 with 400 patients as a sample of their study with the incidence of Port-Site Hernia (0.5%), where they used the non-closure method to deal with the port site fascial defect, and they supposed that the good surgical teams and experience, seem to prevent dangerous complications. For this cause, the surgical teams had performed the laparoscopic cholecystectomies of patients of this study. They were well trained and expert; thus, they had no Port Site Hernia as complications of laparoscopic cholecystectomy.

Soroush *et al.*'s [30] study in 2013 that included 220 patients reported an incidence rate of Port-Site Hernia of 2.3%. They reported that such PSH occurred in 10mm port sites more in the fascial non-closure method than fascial closure. Consequently, suturing the fascia is recommended until further studies can be carried out

Jamil *et al.* [27] in 2016 reported that their study included 450 patients PSH with an incidence rate of

1.10% using the closure method for the fascial sheath defect.

Also, Singal *et al.* [31] in 2016 reported that 200 patients were divided into two groups. The blunt trocar was introduced into the abdomen to be safe, without visceral injury, and no bleeding was seen in both groups. Also, they had not encountered any patient PSH during their follow-up that ranged from 6 - 8 months where they used blunt trocar to split the muscle fibers at the site of entrance of trocar instead of cutting them by sharp trocar was used through our study.

Al-Dhahiry *et al.* [32], in the study in 2017, included 570 patients. They used the non-closure method for the fascial sheath defect. Their study had PSH with an incidence rate of 0.35%, eliciting that the closure of 5 and 10mm laparoscopic port site fasciae was not essential because non-closure was associated with a very low incidence of PSH. Also, closure of the laparoscopic port site fascia prolongs the time of surgery and unnecessary use of suture material that should economically increase the cost of surgery.

In this study, the incidence rate of PSB was 0.00% for both study groups A and B during the follow-up period that ranged 1 -4 months. Veagens *et al.* [33], in their study in 2006 that included 220 patients, used the non-closure method to deal with the port site fascial defect. Their study reported an incidence rate of PSB of 1.55%. They suggested that the bleeding occurred at the laparoscopic port site. Although the bleeding was not significant in its amount, its origin could not be revealed, and conversion to open technique was inevitable. Though bleeding is a potentially catastrophic complication inherent to the laparoscopic technique, it is the most preventable complication because it is largely related to operator technique.

According to Marakis *et al.* [34] study in 2007 included 1225 patients. Their study's incidence rate of PSB was 1.22%; they used the non-closure method to deal with the port site fascial defect. They supposed that good surgical teams and experience could prevent dangerous complications early recognized and treated.

Tuveri *et al.*'s [35] study in 2007 included 1878 patients. They used the closure method to close port site fascial defect; the incidence rate of PSB in their study was 0.63%. They noticed that branches of the iliac arteries, especially those of the right iliac artery, lie just below the umbilicus; thus, they are at risk of injury during forceful insertion of the trocar.

Khan. *et al.*'s [36] study in 2010 included 4957 patients. They used the non-closure method to deal with the port site's fascial defect. Their study reported an incidence rate of PSB of 0.04%. They reported that good surgical technique, awareness, and early recognition and treatment of PSB were keys to success when dealing with this complication. Yi *et al.* [29] study in 2012 had included 400 patients with symptomatic cholelithiasis. They

laparoscopically cholecystectomies their patients. They used the non-closure method to deal with port site fascial defects. The incidence rate of PSB in their study was 4.50%. They concluded that a good surgical team and experience in laparoscopic procedures could prevent dangerous complications. Karthik *et al.*'s study [21] in 2013 had included 579 patients with different forms of cholecystitis. They had cholecystectomies laparoscopically for their patients. They had closed the port site for fascial defects. The incidence rate of PSB in their study was 0.70%. They reported that laparoscopic surgery is associated with minimal port-site complications. They concluded that complications are related to the increased number of ports; umbilical port involvement is common. Most complications are manageable with minimal morbidity and can be further minimized with meticulous surgical technique during the entry and exit of the laparoscopic ports. Regarding Port Site Infection (PSI), our study's incidence rate of PSI was 0.00%, including both groups A and B during the follow-up period that ranged 1 -4 months.

Taj *et al.* [37] study in 2012 had included 492 patients with various forms of cholecystitis. They had allocated their patients into two groups, one with closure method and the second with the non-closure method to deal with sub-umbilical port site fascial defect. Their study reported an incidence rate of PSI of 5.48%. They had concluded that using the surgical glove to extract the gallbladder was safe, cheap, simple, and potentially reduced significant morbidity. They reported that its routine use at laparoscopic cholecystectomy is mandatory in laparoscopic cholecystectomy.

Yi *et al.* [29] study in 2012 had included 400 patients with cholecystitis. They had used the non-closure method to deal with port site fascial defects. In their study, the incidence rate of PSI was 2.75%; a good surgical team and experience in laparoscopic procedure seem to prevent dangerous complications.

Karthik *et al.*'s [21] study in 2013 included 570 patients with various forms of cholecystitis. They had cholecystectomies laparoscopically for their patients. They had used the non-closure method to deal with port site fascial defects. Their study had an incidence rate of PSI of 1.8%. They had concluded that despite this a valuable percentage, PSI was less than that occurring in conventional open surgery.

Mir *et al.*'s [38] study in 2013 had included 675 patients. In their study, they had used the non-closure method to deal with port site fascial defects. The incidence rate of PSI in their study was 6.7%. They had reported that the commonest organism isolated by the culture which was responsible for PSI was *Pseudomonas*. Also, they reported that most *Pseudomonas* strains were resistant to commonly used antibiotics in their hospital. *Pseudomonas* was 100% resistant to the combination of Ampicillin +

Sulbactam and Ceftriaxone, and it was sensitive to Imipenem, Amikacin, and Vancomycin in different percentages. Their study will help choose effective empirical prophylactic antibiotic therapy for patients prepared for elective laparoscopic cholecystectomies. This will have a great impact on morbidity and mortality caused by PSI.

Yanni *et al.* [39] study in 2013 had included 100 patients. They had used the non-closure method to deal with port site fascial defects. In their study, the incidence rate of PSI was 4%. They had concluded that restricting antibiotic prophylaxis to high-risk patients has no detrimental effects in increasing the rate of infections in those with no risk factors. Also, they had concluded that non-description of prophylactic antibiotics for low-risk patients would reduce the financial costs. It would also reduce the risk of drug resistance and clostridial infections. The lack of difference between the two types of surgical methods may be because of the study sample size, the short follow-up period; the excellent experience of the laparoscopic study surgeons; The high standard of surgical theater sterilization and antiseptic measures.

We recommend increasing the sample of the future studies and increasing the postoperative follow-up period with regular clinical and ultrasonic examinations of the patients.

Conclusion

The closure of the laparoscopic port fascial defects is time-consuming; using suture material increases the procedure's financial cost. It is not free of complications such as inadvertent omentum or bowel loop injury.

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Conflicts of Interests: -

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