

ORIGINAL RESEARCH

A Randomised Controlled Trial Compared the Pain Felt at the Surgical Port Site Following Gall Bladder Retrieval via an Epigastric Port versus an Umbilical Port during Laparoscopic Cholecystectomy

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ABSTRACT

Background: In adult patients undergoing four-port elective laparoscopic cholecystectomy at a tertiary care hospital, the purpose of this study is to determine whether or not the removal of the gall bladder (GB) through the umbilical port is associated with more pain at the port site when compared to the removal of the GB through the epigastric port.

Materials and Methods: Patients over the age of 18 who were scheduled to undergo elective laparoscopic cholecystectomy at our facility in 2021 and who were randomly assigned to either group 1 or group 2 were evaluated for the purpose of this study. A VAS was used to evaluate the patient's level of pain at 1, 6, 12, 24, and 36 hours following surgery by a registered nurse.

Results: At 1, 6, 12, 24, and 36 hours following surgery, the VAS for pain measured at the umbilical port was lower than the VAS for pain measured at the epigastric port, and this difference was statistically significant (p-value 0.001). After correcting for age, sex, duration of surgery, and supplementary analgesic use, multiple linear regressions were done for port site pain after 24 hours. The results showed that the VAS at the umbilical port was lower than the epigastric port, with a difference in VAS of 0.9.

Conclusion: When patients are undergoing elective laparoscopic cholecystectomy, retrieving the gall bladder through the umbilical port is related with less pain at the port site than retrieving the gall bladder through the epigastric port. For the removal of the gall bladder, we recommend using the umbilical port.

Keywords: Randomized controlled trial, pain felt, surgical port, gall bladder retrieval, epigastric port, umbilical port during laparoscopic cholecystectomy.

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INTRODUCTION

The 1987 invention of laparoscopic cholecystectomy has now become the technique of choice. By lowering postoperative discomfort, the danger of surgical site infection, and the chance of an incisional hernia, laparoscopic cholecystectomy has transformed the surgical

management of gall bladder (GB) illnesses.^[1,2] Due to a shorter hospital stay, earlier return to work, and overall lower cost, laparoscopic cholecystectomy is said to be superior than open cholecystectomy. The most common reason for hospital overnight stays the day of surgery and the most common complaint following laparoscopic cholecystectomy is pain. Numerous factors contribute to pain after laparoscopic cholecystectomy, including blood vessel rupture brought on by rapid peritoneal distension, traumatising traction on the nerves, and injury to the abdominal wall during port insertion and GB retrieval, and pneumoperitoneum produced by the use of CO₂ to maintain high abdominal pressure. According to reports, incisional pain predominates in the first 48 hours following laparoscopic cholecystectomy and is more severe than visceral discomfort. In addition, each person responds differently to various pain-relieving techniques.^[3-7] Numerous studies have evaluated various pain management techniques following laparoscopic cholecystectomy, including the use of non-steroidal anti-inflammatory drugs, pre-emptive analgesia (incisional or intraperitoneal infiltration of local anaesthetic agent), intraperitoneal saline, a gas drain, heated gas, low-pressure gas, and nitrous oxide pneumoperitoneum. Although several of these techniques have been shown to be effective, none of them have received standard of care recommendations. One of the documented factors affecting postoperative port site discomfort is the reported recovery of GB, which is a significant terminal event of laparoscopic cholecystectomy.^[8,9] GB is frequently removed from the umbilical or epigastric ports. Both ports have been suggested for the laparoscopic cholecystectomy GB retrieval procedure and are always chosen based on the surgeon's preference. There is currently no proof that one port is better than another for GB extraction when taking into account the pain at the postoperative port location. This study is being conducted to see if adult patients undergoing four port elective laparoscopic cholecystectomy at a tertiary care hospital experience more discomfort at the port site when the gall bladder (GB) is removed from the umbilical port as opposed to the epigastric port. We predicted that discomfort upon GB extraction from an umbilical port would be worse than from an epigastric port based on the findings of Poon et al.^[10-14]

MATERIALS AND METHODS

In 2021, we carried out this randomised controlled experiment over the course of six months in a tertiary care facility. We took into account patients between the ages of 20 and 70 who were having an elective laparoscopic cholecystectomy for benign GB disorders (symptomatic gallstones, GB polyps), as well as those in whom informed consent could be acquired. Acute cholecystitis, empyema, mucocele, suspected or proved GB cancer, patients whose laparoscopic cholecystectomy had to be changed to an open operation, chronic steroid and painkiller use, and patients with acute cholecystitis were the exclusion criteria. Before the procedure, each participant gave their informed consent in a language the patient could understand. Sociodemographic, clinical, and outcome characteristics were all included in the data that was entered onto the Proforma. Under general anaesthesia and the four ports approach, surgery was performed by a consultant general surgeon or the chief resident (Resident year V). At the infraumbilical (open technique) and epigastric areas, 10 mm ports were placed (closed technique). After the dissection was finished, the GB was removed in a bag that was self-made from a latex glove, either through the umbilical or epigastric port. In order to make GB extraction easier, the epigastric port was dilated with a metallic dilator if it was intended to be used for GB retrieval. On the other hand, if GB was to be recovered through an umbilical wound, the telescope was moved to an epigastric port to make this possible. In both groups, the GB was opened at the time of retrieval and bile was suctioned (and/or stone was extracted) under supervision if it was discovered to be distended or to contain a large stone. If GB could still not be recovered, a metallic groove dilator was placed over the sheath. Without applying local anaesthesia to the wound borders, the facial sheath of the umbilical wound was stitched shut with absorbable sutures (Vicryl) and the skin with

non-absorbable sutures (Prolene). Operative surgeon, who rated the difficulty on VAS, scored the difficulty of GB retrieval. In both groups, postoperative analgesia was uniform. Only during the first 24 hours following surgery did intramuscular pethidine (0.5 mg/kg body weight every 6 hours) take effect. Once the diet was started postoperatively, oral analgesics (paracetamol in dose of 1000 mg every 6 h or diclofenac, 50 mg every 12 h) were given. Despite receiving standard analgesia, patients with significant pain (defined as VAS of 7 or more, as determined by a registered nurse caring for the patient who was not involved in the study) required additional analgesia (intravenous pethidine at a dose of 0.5 mg/kg body weight or intravenous ketorolac at a dose of 0.3 mg/kg every 8 hours) to reduce pain to an acceptable level, defined as VAS of 3 or less.^[15-17] Postoperative port site pain was measured using a Visual Analog Scale (VAS), which ranges from 0 to 10. Prior to surgery, patients received education about using VAS (either in clinic or in ward before surgery). A trained nurse who was unaware of the intervention evaluated pain in each patient at both port sites at 1, 6, 12, 24, and 36 h after surgery. Despite a thorough review of the literature, neither a local nor an international study that analysed the differences in port site pain between two groups was found. We used the mean postoperative port site pain at umbilical and epigastric ports, respectively, following laparoscopic cholecystectomy from a study by C.M. Poon et al. to estimate the sample size. A sample of 60 people with inflation of 10% was chosen. Age, the length of the procedure, the pain score, and the amount of postoperative analgesia used are all continuous variables that are examined as Means. Sex and the location of the GB retrieval were categorical variables that were proportionally examined. If the assumptions were met, the outcome, or port site discomfort, was compared between the two groups using the student's T-test; if not, the Mann Whitney U test was applied. Age, sex, the need for additional analgesics, the length of the procedure, and the difficulty in retrieving the GB were confounding and effect modifying variables that were examined by multiple linear regression for pain at 24 hours.

RESULTS

200 patients were assessed during the study period in order to choose 99 patients who met the inclusion criteria, and 101 patients were eliminated due to the aforementioned exclusion criteria. Fig. 1 depicts the process flow for enrolling, allocating, monitoring, and analyzing patients. In terms of the baseline data [as listed in Table 1], both groups were comparable, with mean SD ages in groups A and B of 42.5 10.7 and 40.6 12.6 years, respectively. There were no dropouts during the 36-hour pain evaluation period during which all patients were monitored. At 1, 6, 12, 24, and 36 hours following surgery, the VAS for pain at the umbilical site was lower than the epigastric port, and the difference was statistically significant [Table 3].

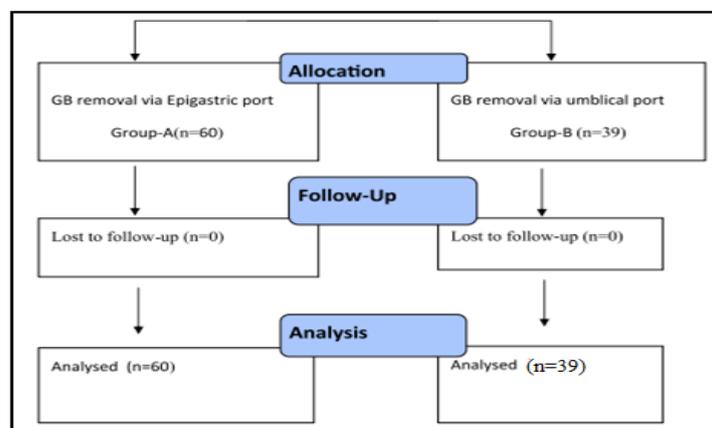


Figure 1: Flow diagram of participants

After correcting for age, sex, the length of the procedure, retrieval difficulty, and the use of additional analgesics, multiple linear regression was performed for port site pain at 24 hours, and the VAS at the umbilical port was lower than that at the epigastric port by a factor of 0.9. The difference in operative time, the difficulty of gall bladder retrieval as reported by the operating surgeons, and the need for additional analgesics was statistically insignificant [Table 1, 2].

Table 1: Showing comparison of different variables between the groups as per age and sex.

Variable	Group 1	Group 2	p-value
Age (years)	20-60 years	20-60 years	
Sex	42.5±10.7	40.6±12.6	0.38
Male	25	19	0.41
Female	35	20	

Table 2: Showing comparison of different variables between the groups as other indications.

Variable	Group 1	Group 2	p-value
Symptomatic gallstones	47	27	
Gall bladder polyp	13	12	
Duration of surgery in minutes	52.5±12.1	56.7±13.8	0.0078
Retrieval difficulty	4.4±1.2	4.2±1.1	0.393
Number of patients required	19	27	0.42
Additional Analgesia			
Pethidine requirement in mg	10±16.7	8±15.4	0.49
Ketorolac requirement in mg	6.5±14.7	3.7±9.8	0.23

Table 3: Showing comparison of VAS for pain at specified port site at different post-operative periods between the groups.

Pain Score	Group 1 Epigastric port	Group 2 Umbilical port	p-value
1hr	5.9±1.1	4.1±1.5	<0.01
6hr	4.6±0.94	3.5±1.05	<0.01
12hr	3.9±0.85	2.4±0.79	<0.01
24hr	3.05±0.87	2.15±0.87	<0.01
36hr	1.9±0.8	1.2±0.49	<0.01

DISCUSSION

The findings of this RCT showed that GB retrieval through an umbilical port was less painful than an epigastric port, however we were unable to reject the null hypothesis. The pain score between two ports utilised for gall bladder retrieval is being compared in this study's first randomised trial. A registered nurse who was not aware of the location of the retrieval or the study hypothesis evaluated the pain, eliminating any possibility of information bias. The use of a metallic dilator, which causes the skin to be torn apart occasionally and the sheath and muscles to be severely stretched in order to deliver the gall bladder, may be the cause of the epigastric group's more intense pain. In contrast to epigastric ports, umbilical ports were placed using an open approach, requiring a 5 mm stab wound in the sheath to allow for port entry. This may have made the port site broader, allowing for the delivery of the gall bladder with little to no stretching. Within the first few hours after LC, pain peaks; however, it then

gradually lessens over the following two to three days.^[18] Early post-operative pain can be particularly severe for certain patients, and dynamic circumstances like coughing and movement can make it worse. Visceral and parietal pain are the most significant during the first 24–48 hours following surgery. Three forms of pain, including shoulder tip, parietal, and visceral pain, have been proposed, each with a different severity and time course. The primary sources of pain include incision sites within the abdominal wall, the pneumoperitoneum in connection with both local and systemic changes (including peritoneal and diaphragmatic stretching, acidosis, and ischemia), and the "postcholecystectomy wound" within the liver (visceral pain). Pneumoperitoneum (20–30%), incisional sites (50–70%), and "cholecystectomy wound" (10–20%) make up the majority of the component. Numerous strategies have been used or researched to lessen the pain caused by one or more of the processes mentioned above. Pre-emptive local anaesthetic at port sites is a common measure that has virtually become standard of care; we chose not to use it in order to assess the actual pain at port sites following gall bladder resection. Additionally, we must keep in mind that measuring pain is challenging because it is a subjective experience. Pain involves motivational and affective components in addition to sensory stimuli, which may be tied to cultural and prior painful experiences. Pain perception is influenced by a variety of things. During the subject selection phase, a number of conditions were disqualified, including empyema, mucocele, acute cholecystitis, tumours, and long-term steroid or analgesic use. Multivariate linear regression was used to control additional variables, such as sex, age, the length of the surgery, and supplemental analgesics, during the analysis phase.^[19-21]

Regardless of whether the difference of 0.9 is clinically meaningful or not, this data needs to be considered in the clinical context even though the difference in pain score was statistically significant. In order to respond to this, we must also take into account the procedure's other features, such as the difficulty of removing the GB from both ports, the comfort of educating the residents, and the ergonomics and safety of the tools. In a laparoscopic cholecystectomy, the difficulty of removing the gall bladder from the port site has a significant role in determining postoperative pain. According to the surgeon's evaluation of our study groups, the mean difficulty level for gall bladder retrieval was 4.25 for group 1 and 4.43 for group 2, respectively. Gall bladder retrieval had a mean difficulty rating of 3.6–3.0 in a research by Poon CM et al. Our study's higher difficulty in retrieving the gallbladder may be explained by differences in the incision's length, the technique used to retrieve it, and the surgeons' perceptions of its difficulty. Although every patient included in our study received the same conventional analgesic regimen, patients in both groups did need supplemental analgesics.

CONCLUSION

In individuals undergoing elective laparoscopic cholecystectomy, gall bladder retrieval using an umbilical port is associated with less discomfort than retrieval from an epigastric port. For the removal of the gall bladder, we advise an umbilical port. We were unable to reject the null hypothesis, although the results of this RCT did demonstrate that GB retrieval through an umbilical port was less painful than an epigastric port. The first randomised trial of this investigation compares the pain score between two ports used for gall bladder removal. The pain was assessed by a registered nurse who was unaware to the site of the retrieval or the study hypothesis, so removing any chance of information bias. The more severe pain in the epigastric group may be due to the use of a metallic dilator, which occasionally tears the skin apart and aggressively stretches the muscles and sheath to deliver the gall bladder.

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