

ORIGINAL ARTICLE

## Postoperative Pain After Gallbladder Retrieval From Umbilical and Epigastric Ports In Laparoscopic Cholecystectomy: A Randomized Controlled Trial

Muhammad Danish Muneeb<sup>1</sup>, Mirza Agha Naushad Baig<sup>2</sup>

1. Assistant Professor Surgery, Baqai University Hospital Karachi, Pakistan.

2. Consultant General and Laparoscopic surgeon, Zubaida Medical Centre Karachi, Pakistan.

**Correspondence to:** Dr. Muhammad Danish Muneeb, Email: [danishmuneeb@yahoo.com](mailto:danishmuneeb@yahoo.com), ORCID: [0000-0003-3414-6473](https://orcid.org/0000-0003-3414-6473)

### ABSTRACT

**Objective:** To compare the postoperative pain after gallbladder removal from umbilical port site versus epigastric port site, after four ports laparoscopic cholecystectomy.

**Methods:** A randomized controlled trial was performed during 1-year period from January 2017 till January 2018, at a private hospital setup. Both male and female patients, with age group 18 years and above were considered, who were planned for four ports laparoscopic cholecystectomy after typical cholelithiasis. Those with polyps, mucocele or empyema in gallbladder or perforated gallbladder requiring emergency surgery were excluded from the study. Patients were equally assigned into two groups based on the removal region, with 65 in group A (umbilical region) and 65 in group B (epigastric region). Postoperative pain was measured using Numerical Analogue Scale (NAS) at 3 points of the study: (1) Day one, (2) at the time of discharge (3) At the time of follow up after 1 month.

**Results:** From 130 patients, group A showed median pain (IQR) of 5 (4-5.5), 4 (3-4) and 2 (2-3) when compared with group B median pain (IQR) of 4 (3-4), 2 (2-3) and 1 (0.5-1) one day after the procedure (p-value=0.001), at the time of release from the hospital (p-value<0.001) and one month post-surgery (p-value<0.001) respectively.

**Conclusion:** Epigastric port site removal of gallbladder produced less postoperative pain after removal of gallbladder as compared to the umbilical port site. Therefore, it is suggested to perform gallbladder removal surgery using epigastric port site.

**Keywords:** Epigastric port Gallbladder retrieval, Laparoscopic cholecystectomy, Numerical Analogue Scale, Postoperative pain, Umbilical port

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### INTRODUCTION

Laparoscopic surgery proved a miracle for the patients suffering from gallstone disease<sup>1</sup>, and has become a gold standard since its invention in 1987.<sup>2</sup> Laparoscopic technique for cholecystectomy as compared to the open technique, proved to be a tool providing less postoperative pain, decreased chances of incisional hernia and superficial skin infections.<sup>3</sup> The advantages of early recovery, short hospital stays, and cost effectiveness are some important benefits of this technique.<sup>4</sup>

Pain is the nuisance for the patients causing them to stay longer in hospital.<sup>5</sup> It has been remarked that the sensations of incisional pain are more pronounced than the visceral pain, in the early recovery period after surgery.<sup>6</sup> Port site complications, like hematoma formation, infection, incisional hernia after laparoscopic cholecystectomy are seen in 21/100,000 patients, which proportionally increases with increase

in the incision length.<sup>7</sup> Postoperative pain can be produced by sudden distension of the peritoneum, traumatic stretching of the nerves at port site due to trocar insertion as well as gallbladder removal.<sup>8,9</sup> Several surgeons have found the use of intraperitoneal or incisional infiltration of local anesthetic agent, use of non-steroidal anti-inflammatory agents, or low pressure nitrous oxide gas use as beneficial in causing reduced postoperative pain, however none of such has become standard of care.<sup>10</sup>

Removal of gallbladder is such a fundamental stage in laparoscopic cholecystectomy, that it effects patient's behavior with regards to postoperative pain at that site. Umbilical and epigastric region are the two commonly recommended ports for gallbladder removal from the body, and are decided as per surgeon's choice.<sup>11</sup> The bias still prevails regarding which gallbladder removal site is a favorable option. This trial has been performed as a tool to know which port site for gallbladder removal is associated with more pain after laparoscopic

cholecystectomy, either umbilical or epigastric, and therefore to continue future surgeries with less pain effected region.

## METHODS

This study was a randomized clinical trial, with 130 patients, 65 in each group. The study period was 1-year from January 2017 till January 2018. All patients either male or female aged between 18-70 years, With a planned four ports laparoscopic cholecystectomy, were included. Whereas patients with high risk of intubation under anesthesia (ASA IV), liver disease, suspicion of cancer, history of obstructive jaundice or elevated alkaline phosphatase levels, and those requiring emergency setting operations for gallbladder disease, were omitted from the study.

A complete history with detailed examination was documented as part of the medical record of all the study participants. Patients were randomly assigned in two groups, A and B, one control and the other study group respectively. The random allotment of groups was done using allocation software version 1.0.0. Verbal and signed consent was obtained from each participants. Ethical approval was sought from Baqai University Hospital prior conducting of the study [IRB #: RF.PF.BUH.20(63)2016].

All patients were given intravenous second-generation cephalosporin 1 gm after the test dose, at the time of start of anesthesia. All operations were conducted by consultant surgeon considering four ports technique in both the groups. A 10mm port was inserted at the infra umbilical site with Direct Trocar insertion technique, and pneumoperitoneum created. Epigastric region then received another 10 mm port using closed technique. When the gallbladder was separated out from its bed, it was extracted either from umbilical or epigastric port site, using a latex bag, self-made with the gloves. In case where gallbladder was removed from umbilical site, camera telescope was moved to the epigastric port, to keep the retrieval under vision. In both cases, if difficulty was found in retrieving the gallbladder completely, it was cut open, where at first the bile was suctioned, and then the stones were removed. Local anesthetic agent was inserted at all the four ports wound margins. The operating surgeon also graded the difficulty in retrieving the gallbladder on Numerical Analogue Scale from 0-10 (0 being easy and 10 being difficult).<sup>12</sup>

Postoperative pain at the port site of gallbladder removal was assessed with Numerical Analogue scale whose range was considered from 0 – 10. All patients

were trained to mark this scale.

Ketorolac 0.3 mg/kg body weight dose was standardized one in 24 hours, to maintain the pain at or below level of 3 on Numerical Analogue Scale, while the requirement was increased from 12 to 8 hours if pain score was found to be 7 on Numerical Analogue Scale was observed.

Postoperative pain was the main outcome variable, it was recorded at three points (I) after one day of surgery, (II) at discharge and (III) one month after surgery. It was undertaken by a trained resident who was blinded to the study.

Sample size was calculated for comparison between two groups, taking significance level 5% and power 80%, and a sample of 60 patients in each group, with reference to a study.<sup>13</sup> A sample of 65 patients was selected after around 10% expansion.

Data analysis was performed using Statistical Package for Social Sciences (SPSS) software 20. Median and inter-quartile ranges were reported for quantitative variables pain after checking normality by Shapiro-Wilk test. For categorical variables like gender, percentages and frequency were noted. Chi-square test was applied to explore the association between gallbladder removal groups. Mann-Whitney test and Friedman test were applied to compare the median postoperative pain scores between the two groups and within the groups respectively. Statistical significance was considered at p-value  $\leq 0.05$ .

## RESULTS

All 130 patients who were selected for the study were operated. The ages of the patients were from 18 years to 66 years having median age of 38 (IQR 31-46) years. In group A, 54 (53.5%) of the patients and in group B, 47 (46.5%) of the patients were females. The ketorolac injection was repeated 8 hourly in 24 hours in 20 patients of group A while no patients in group B (p-value=0.001) (See Table 1).

The umbilical port retrieval group A showed median (IQR) pain scores of 5 (4-5.5), 4 (3-4) and 2 (2-3), while the epigastric port retrieval group B had median (IQR) pain scores of 4 (3-4), 2 (2-3) and 1 (0.5-1) on first day of surgery, at the time of release from hospital and at follow-up one month post-surgery, respectively. Postoperative pain scores on day 1 (p value=0.001), at release from hospital (p-value<0.001) and after a month post-surgery (p-value<0.001) between the groups were found statistically significant. (See Table 2)

A statistically significant regression of the pain scores were noted in both groups from the day 1 of surgery till

**Table 1: Distribution of patients by gender, analgesia and time duration of surgery in group A and B**

|                                 | Group A         | Group B         | p-value* |
|---------------------------------|-----------------|-----------------|----------|
|                                 | n = 65<br>n (%) | n = 65<br>n (%) |          |
| <b>Gender</b>                   |                 |                 |          |
| Female                          | 54 (53.5)       | 47 (46.5)       | 0.140    |
| Male                            | 11 (37.9)       | 18 (62.1)       |          |
| <b>Ketorolac injections</b>     |                 |                 |          |
| 1 in 24 hours                   | 20 (35.7)       | 36 (64.3)       | 0.000    |
| 2 in 24 hours                   | 31 (51.7)       | 29 (48.3)       |          |
| 3 in 24 hours                   | 14 (100)        | 0 (0)           |          |
| <b>Time duration of surgery</b> |                 |                 |          |
| 60-70 min                       | 20 (31.7)       | 43 (68.3)       | <0.001   |
| 70-80 min                       | 43 (66.2)       | 22 (33.8)       |          |
| 80-90 min                       | 2 (100)         | 0 (0)           |          |

\*p-values has been calculated using Chi-square test of association

**Table 2: Postoperative pain score comparison between group A and group B (n = 130)**

| Time          | Group A                | Group B                | p-value* |
|---------------|------------------------|------------------------|----------|
|               | n = 65<br>Median (IQR) | n = 65<br>Median (IQR) |          |
| At 24 hours   | 5 (5.5-4)              | 4 (4-3)                | <0.001   |
| At discharge  | 4 (4-3)                | 2 (3-2)                | <0.001   |
| After 1 month | 2 (3-2)                | 1 (1-0.5)              | <0.001   |

\*p-values has been calculated using Mann-whitney test

**Table 3: Postoperative pain score comparison within group A and group B (n = 130)**

|                | At 24 hours  | At discharge | After 1 month | p-value* |
|----------------|--------------|--------------|---------------|----------|
|                | Median (IQR) | Median (IQR) | Median (IQR)  |          |
| <b>Group A</b> | 5 (5.5-4)    | 4 (4-3)      | 2 (2-1)       | <0.001   |
| <b>Group B</b> | 4 (4-3)      | 2 (2-1)      | 1 (1-0.5)     | <0.001   |

\*p-values has been calculated using Friedman test

**Table 4: Distribution of patients by length of hospital stay and difficulty in retrieval of gallbladder in group A and B**

|   | Group A   | Group B   | p-value* |
|---|-----------|-----------|----------|
|   | n (%)     | n (%)     |          |
| <b>Length of hospital stay</b>  |           |           |          |
| 1 day   | 24 (34.3) | 46 (65.7) | <0.001   |
| 2 days  | 41 (68.3) | 19 (31.7) |          |
| <b>Difficulty in gallbladder retrieval Numerical Analogue Scale (NAS)</b> |           |           |          |
| 3   | 45 (53.6) | 39 (46.4) | 0.271    |
| 4   | 20 (43.5) | 26 (56.5) |          |

\*p-value has been calculated using chi square test

a month at follow-up ( $p$ -values $<0.001$ ), but a greater in pain scores in group B was observed, when compared to group A. (See Table 3)

Distribution of length of hospital stay of patients in days and retrieval difficulty of gallbladder by the surgeons noted on numerical analogue scale, in group A and B are also reported. (Table 4)

## DISCUSSION

The findings of this randomized controlled trial showed the significance of epigastric port site in achieving less pain after gallbladder removal as compared to the umbilical port site. It is reported that pain has its highest intensity during the first 12 hours of surgery, which continues but declines in its severity during the next 3-4 days.<sup>14</sup> Maneuvers like sneezing, coughing and straining can exaggerate the pain, and that's why some patients can experience a rather difficult early postoperative period.<sup>15</sup> The different characteristics of pain doesn't differ significantly but have an impact on patient's morbidity which includes visceral and parietal sensations and shoulder tip pain. These are more important in first 2-3 days of surgery.<sup>16</sup> Therefore, pain at the incision site over the abdominal wall plays the most significant part (50 – 70%) followed by pain caused by stretching of peritoneum and diaphragm due to pneumoperitoneum (20-30%) and lastly but not the least the pain at the gallbladder removal site on liver bed, the post-cholecystectomy wound ( 10 – 20%).<sup>17</sup> Several techniques have been adopted to curtail this agony of pain, and of them the established technique is infiltration of local anesthetic agent around the operative incision site, which we applied to rectify the bias, and also helped the patient to dictate the perceptions of pain well at the required time frames.<sup>18</sup> Pain has psychological and emotional elements and being a subjective sensation, its interpretation is difficult.<sup>19</sup> Different factor including the acute conditions of gallbladder, use of steroidal and inflammatory medicines, and patients' factors including sex, age and duration of surgery, may affect the intensity and variations of pain.<sup>20</sup> The difference of pain scores between the two groups were significant at the three mentioned times, however we also mentioned the procedural part, and that is difficulty perceived by the surgeons in retrieving the gallbladder out from the port site, as this is one of the important procedural step in this surgery, also dictating towards the pain perceived by the patients. In a literature, the mean difficulty in removing of gallbladder observed by the surgeons was  $3.6 \pm 3.0$ .<sup>21</sup> Our study observed the

surgeon's difficulty level in retrieving gallbladder from either port sites between 3 and 4, on NAS with  $p$  value 0.271. This difference is dictated by the site and length of incision, the method of removing gallbladder and the way the surgeon presents the difficulty level. We observed a system of short hospital span in those patients with gallbladder removal from epigastric port. Moreover, the need for the ketorolac injection in epigastric port group was less in 24 hours postoperatively. As per Turkish literature report, they considered epigastric port better for gallbladder removal for short and long term.<sup>22</sup> A national study also commented on less severe and controllable complications as compared those when gallbladder is removed from the umbilical port site.<sup>23</sup> The results of our study parallels with that of the above mentioned literatures, and observes a less morbid procedure if gallbladder is extracted from the epigastric port site in four ports laparoscopic cholecystectomy. The study findings have some limitation that it needs a longer period and a larger sample size to have a more enhanced results of postoperative pain.

## CONCLUSION

Epigastric port site is a respectable option for gallbladder retrieval after laparoscopic cholecystectomy. Since retrieval of gallbladder from the port site is a separate art, and the site of retrieval determines the fate of postoperative pain, we recommend the epigastric region as a favorable option for the removal of gallbladder.

**AUTHORS' CONTRIBUTION:** MDM substantially contributed to the conception and design of the study. MDM and MANB worked in the acquisition, analysis and interpretation of the data. MDM drafted the manuscript and revised it critically for intellectual content and gave final approval.

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