

## Research Article

### Size Does Matter: A Randomized Trial Comparing Postoperative Pain Using 10mm Vs 5mm Umbilical Ports in Laparoscopic Cholecystectomy

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#### Abstract

**Objective:** To accomplish the comparison of postoperative pain in laparoscopic cholecystectomy, using 10mm vs 5mm umbilical ports.

**Methodology:** Randomized controlled trial was performed from August 2014 till July 2015, with selection of patients of either gender above 18 years of age, undergoing laparoscopic cholecystectomy for symptomatic gallstones. Patients requiring cholecystectomy for gallbladder polyps or carcinoma, emergency surgery for acute cholecystitis, empyema, mucocele or perforated gallbladder and also patients having relative contraindications for laparoscopic cholecystectomy were excluded. They were randomly assigned, 50 patients into 10mm umbilical port group (group A) and 50 patients in which 5mm umbilical port was used (group B). Postoperative pain was assessed after 24 hours, at discharge and a month after surgery, using Numerical Analogue Scale (NAS).

**Results:** There were a total of 100 patients. Group A patients had median (IQR) pain scores of 4.5 (1), 3 (2) and 2 (1) as compared to group B pain scores of 4 (2), 2 (1) and 0 (1) at 24 hours of surgery (p-value=0.009), at discharge (p-value<0.001) and after 1 month of surgery (p-value<0.001), respectively. A comparatively higher decline in the postoperative pain scores was evaluated in group B from the first day of operation till one month post-surgery follow up. (p-value<0.001).

**Conclusion:** The use of 5mm umbilical port, supersedes 10mm umbilical port in having decreased frequency of postoperative pain after laparoscopic cholecystectomy.

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#### Introduction

Laparoscopic surgery revolutionized the treatment of gallstones in 1987,<sup>1</sup> and became the gold standard in 1992. Laparoscopic technique for cholecystectomy has an effect of reduced postoperative pain in the surgical management of gallbladder disease.<sup>2</sup> Step down pattern for the trocar use from 10mm, 5mm and 3-2mm has been an eye catching for

the technical advances in laparoscopic cholecystectomy.

Pain is the reason for prolonged hospital stay.<sup>3</sup> It has been reported that the sensitivity of incisional pain is more than the visceral pain recorded in early postoperative hours.<sup>4</sup> Port site complications after laparoscopic cholecystectomy, like hematoma formation, infection, incisional hernia are found in

21/100,000 patients, which proportionally increases with increase in size of trocar and incision length.<sup>5</sup>

In a study, reducing the port size from 10mm to 5mm, a marked decline in the early post-operative period pain, with less consumption of analgesia was seen.<sup>6</sup> On the contrary, some studies provide the evidence that by decreasing the trocar and incision size, there is decrease in postoperative pain but to a minimal extent<sup>7</sup>. Even some says there is no difference in the postoperative pain scores observed after decreasing the calibre of instruments.<sup>8</sup>

Producing smaller surgical wounds at the ports site, causes less tissue damage and enhance both the postoperative recovery by decreasing the pain and improving cosmetic outcome.<sup>9</sup>

The use of fine caliber instruments is a surgical art, providing favorable options for patients, producing comfort and less pain. A definitive achievement is still required in this particular field of minimal invasive surgery. The use of 5mm instruments have been introduced in our setup, and therefore we aimed at comparing postoperative pain scores with 10mm vs 5mm ports at the umbilical site in laparoscopic cholecystectomy, using numerical analogue scoring system. The use of fine caliber instruments in our study will be a guide in achieving a decreased morbidity of postoperative pain after laparoscopic cholecystectomy.

## Methodology

This study was a randomized clinical trial, with 100 patients selected on the basis of 5% prevalence and bound error 5% with 95% confidence interval. All patients of either gender with age above 18 years, undergoing laparoscopic cholecystectomy for symptomatic cholelithiasis, were included. Patients having high risk to undergo intubation under anesthesia (ASA IV), diseases of liver, suspicion of cancer, history of obstructive jaundice or elevated alkaline phosphatase levels, and those requiring emergency surgery for acute cholecystitis, empyema, mucocele, perforated gallbladder were excluded from the study.

Detailed history and examination were performed in each patient. Patients were randomly allocated in two equal groups, A (control group) and B (study group), by random allocation software version 1.0.0. Infor-

med consent was taken from every patient. Ethical approval was sought from the Institutional Review Board of Dow University of Health Sciences.

All patients were given intravenous injection of Ceftriaxone 1gm after test dose, at the time of induction of anesthesia. All operations were performed by consultants using four ports technique in both the groups. A 10 mm umbilical port in group A and a 5 mm umbilical port in group B were used for the insertion of camera telescope. Other three ports were epigastric port used for removal of gall bladder, one port in mid clavicular line and another in anterior axillary line were used. All operations were done with a 0-degree camera telescope.

In both groups, the sub umbilical trocar was inserted through Direct Trocar Insertion technique, using blunt trocar. A 13 mm Hg pressure pneumoperitoneum was created, connecting sub umbilical trocar with CO<sub>2</sub> insufflator tube.

Retraction of the gallbladder and liver were performed with the help of two instruments which were placed on right lateral aspect of abdomen while dissections and applications of clips for both the cystic artery and duct was done via the instrument through epigastric port. The gallbladder was removed from the abdomen through the epigastric port and the fascial defect was repaired with Vicryl 0 sutures. Suturing of the fascial defect was not required for the two 5mm retraction ports. It was also not required for the 5mm sub umbilical port in Group B, however, suturing of the sheath was done in Group A patients with 10mm port. There was no need for the transfusion of blood products due to the minimal blood loss per operatively. At the end of surgery, before the removal of trocars, their valves were kept open until complete evacuation of the residual gas. Patients were counselled to mobilize out of the bed, and also to start liquid diet, 8 hours after the procedure.

Operating time was registered. Need to convert to open procedure was not required in either groups. The degree of postoperative pain was determined using a numerical analogue pain scale at 24hrs, at discharge, and 1 month after surgery. All patients were prescribed intravenous Ketorolac 12 hourly as postoperative analgesia which was increased to 8 hourly on

patients demand. They were shifted to oral analgesia after 24 hours of surgery. The number of injections administered during the first 24 hours were recorded. The time for passing stools was also defined.

The variable of interest in our study was the postoperative pain score after one month of surgery, so its value was used to predict the mean postoperative pain scores of both groups for significance.

The numeric in the scale ranged from 0 - 10. The '0' in the scale defines "no pain", and '10' gives "severe pain". The patients were asked to mark a number on the pain scale according to the severity of perceived pain.

To eliminate bias, same senior resident who was blinded, evaluated the postoperative pain scores of the patients.

Data was analyzed by using Statistical Package for Social Sciences (SPSS) software version 17.0. Mean and standard deviation were reported for quantitative variable like age. Median and inter-quartile range were reported for postoperative pain scores after checking normality of these quantitative variables by Shapiro-Wilk test, whereas frequency and percentages were reported for categorical variables like gender etc. Chi-square test was used to check the association between the trocar groups and other categorical independent variables. Mann-Whitney test was employed to compare the median postoperative pain scores between two groups. Friedman test was run to compare the median postoperative pain scores within groups at different postoperative weeks. Statistical significance was taken at  $p$ -value  $< 0.05$ .

## Results

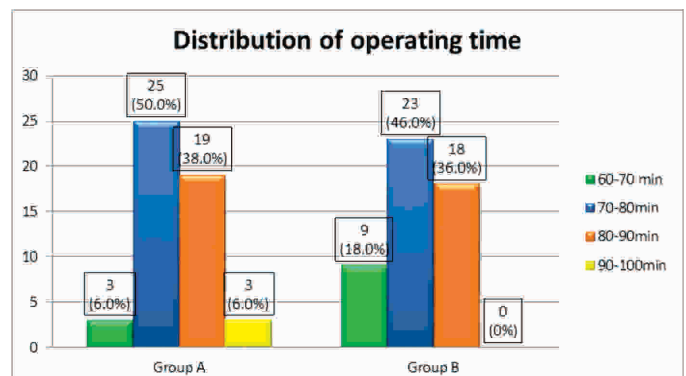
A total of 100 patients were operated, 50 from each group. The ages of the patients were from 18 years to 71 years with a mean age of 39.67 years and SD  $\pm 11.56$  years. In group A, 78% ( $n=39$ ) of the patients and in group B, 80% ( $n=40$ ) of the patients were females. In group A, 36% ( $n=18$ ) of the patients received 3 ketorolac injections whereas only 14% ( $n=7$ ) of the patients of group B, received 2 ketorolac injections in 24 hours. In group A, 20% ( $n=10$ ) of the patients were able to tolerate orally after 8 hours whereas in group B, this number of patients was

double (48%,  $n=24$ ). It was found that the number of analgesic doses ( $p$ -value=0.011) and tolerate orally ( $p$ -value  $< 0.001$ ) was showing significant association with the port groups (See Table 1). Distribution of operating time in minutes and time of passing stools in hours in group A and B are also reported in Graph 1 and Graph 2, respectively.

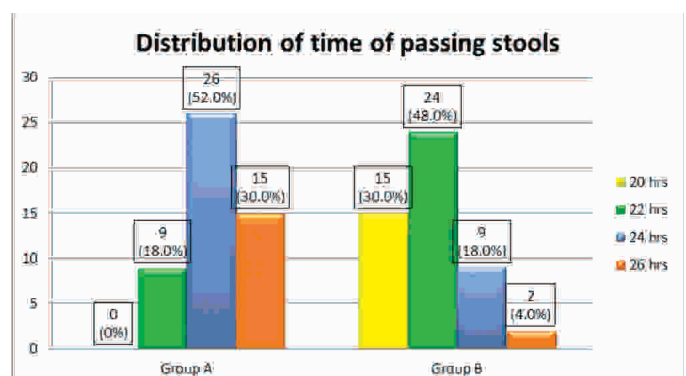
Gallstones from gallbladder were identified as multiple stones in 79 percent of the patients ( $n=79$ ) while single stone in 21 percent of the patients ( $n=21$ ), considering both groups.

In group A (10mm port group), median (IQR) pain scores were 4.5 (1), 3 (2) and 2 (1), while comparing group B (5mm port group), median pain scores were 4 (2), 2 (1) and 0 (1) on day 1, at discharge and after 1 month of surgery, respectively. Postoperative pain comparison on day 1 ( $p$ -value=0.009), at discharge ( $p$ -value $<0.001$ ) and after 1 month of surgery ( $p$ -value $<0.001$ ) was found statistically significantly different. (See Table 2)

A statistically significant decline in the pain scores were observed in both groups from the 1st day of surgery till one month afterwards ( $p$ -values $<0.001$ ), but a comparatively higher decline was observed in pain scores in group B. (See Table 3)



Graph 1



Graph 2

**Table 1:** Distribution of Patients by Gender, Analgesia and Tolerate Orally in Group A and Group B

|                             | Group A         | Group B         | p-value* |
|-----------------------------|-----------------|-----------------|----------|
|                             | n = 50<br>n (%) | n = 50<br>n (%) |          |
| <b>Gender</b>               |                 |                 |          |
| Female                      | 39 (78.0)       | 40 (80.0)       | 0.806    |
| Male                        | 11 (22.0)       | 10 (20.0)       |          |
| <b>Ketorolac injections</b> |                 |                 |          |
| 2 in 24 hours               | 32 (64.0)       | 43 (86.0)       | 0.011    |
| 3 in 24 hours               | 18 (36.0)       | 7 (14.0)        |          |
| <b>Tolerate orally</b>      |                 |                 |          |
| 8 hours                     | 10 (20.0)       | 24 (48.0)       | < 0.001  |
| 10 hours                    | 20 (40.0)       | 24 (48.0)       |          |
| 12 hours                    | 20 (40.0)       | 2 (4.0)         |          |

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

**Table 2:** Postoperative Pain Score Comparison between Group A and Group B (n = 100)

| Time          | Group A      | Group B      | p-value* |
|---------------|--------------|--------------|----------|
|               | n = 50       | n = 50       |          |
|               | Median (IQR) | Median (IQR) |          |
| At 24 hours   | 4.5 (1)      | 4 (2)        | 0.009    |
| At discharge  | 3 (2)        | 2 (1)        | < 0.001  |
| After 1 month | 2 (1)        | 0 (1)        | < 0.001  |

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

**Table 3:** Postoperative Pain Score Comparison within Group A and Group B (n = 100)

|         | At 24 hours  | At discharge | After 1 month | p-value* |
|---------|--------------|--------------|---------------|----------|
|         | Median (IQR) | Median (IQR) | Median (IQR)  |          |
| Group A | 4.5 (1)      | 3 (2)        | 2 (1)         | < 0.001  |
| Group B | 4 (2)        | 2 (1)        | 0 (1)         | < 0.001  |

\*p-values has been calculated using Friedman test

## Discussion

Results of this study showed a significant decline in the mean pain scores at discharge and one month after laparoscopic cholecystectomy, in patients with 5mm sub umbilical port, as compared to the 10mm port. Reduced postoperative pain and good cosmetic outcome has been observed by using small diameter laparoscopic instruments as compared to the conventional ones.<sup>10,11</sup>

After laparoscopic cholecystectomy, postoperative pain can be caused by sudden distension of the peritoneum, traumatic stretching of the nerves at port site due to trocar insertion as well as gallbladder removal.<sup>12,13</sup>

Studies performed in Asia and Europe with level I evidence, also emphasized the need to explore the

significance of using small caliber instruments, as its been shown to be helpful in several aspects.<sup>14</sup>

The established advantages of laparoscopic surgery are reduced postoperative pain, better cosmesis and enhanced recovery after surgery. However, this is still not sure whether these pros are from less dissections and decreased need for retractions, or small incisions of access,<sup>15</sup> Fine caliber instruments are now increasingly used in our setups, which has introduced several benefits in surgical outcome, one being defined in this study.

A study using mini laparoscopic techniques with small caliber ports and instruments was associated with less pain and better cosmesis as compared to standard instruments.<sup>16</sup>

Laparoscopic cholecystectomy possible through 3mm ports caused less post-operative pain and better cosmetic results.<sup>17</sup> Surgery through 3mm ports was associated with reduced pain and decreased port site hernias because fascial closure was usually not required for ports less than 10mm in size.<sup>18</sup>

Several researchers,<sup>19</sup> also proved that making smaller incisions caused decreased postoperative pain. In a randomized trial of seventy-five patients using small caliber instruments, showed significantly decreased postoperative pain and reduced analgesic dosage after laparoscopic cholecystectomy.<sup>20</sup> It's been a matter of importance that a significant proportion of patients in the smaller sized incision and trocar group were almost free of incisional pain 1 month after surgery.<sup>21</sup>

Our study shows, a significant reduction in the pain intensity of the patients in Group B (5mm port group) as compared to the Group A (10mm port group). Also the use of analgesia in group B patients and their capability to tolerate orally was also enhanced, which also defines a positive aspect of reduced postoperative pain.

In this study there is significant decrease in postoperative pain (p-value<0.001) starting from the day 1 till 1 month after surgery, in Group B (5mm trocar group) as compared to Group A (10mm trocar).

## Conclusion

The trend towards using small caliber instruments is now being on demand in our surgeons society. Less trauma and decreased stretching of rectus sheath bypassing the need to suture it, and hence rarely seen complications like hematoma and suture reactions, are well defined benefits from the use of fine caliber instruments. Therefore, we conclude by providing confidence to the surgeons, that the use of 5mm port at the umbilical site is associated with less post-operative pain as compared to the 10mm port, after

laparoscopic cholecystectomy.

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