INTRODUCTION

Laparoscopic cholecystectomy (LC) since its initiation in 1989 has turned into the gold standard procedure for the treatment of symptomatic gall stone disease. It offers a lot of benefits over the open procedure in terms of less invasiveness, early recovery, shortened hospital stay, improved cosmesis, and earlier return to work and daily activities. The technique of performing LC has undergone many changes and variations. The standard technique of performing LC is to use four ports; using two 10-mm and two 5-mm trocars. However, in view of making the surgery more minimally invasive and to inflict lesser post-operative surgical site pain and better cosmesis, many surgeons have modified their operations either by reducing the port size, that is, from 10 mm to 5 mm or from 5 mm to 3 or 2 mm or by reducing the number of ports. Few studies have also shown that the use of smaller sized port was associated with more satisfactory cosmetic outcome, less post-surgical pain, and local wound damage. Conventionally, 10-mm 30° telescope is used in LC. However, it can also be done with a 5-mm 30° telescope in case of using a 5-mm sized umbilical port.
Aims and objectives
The objective of our present study is to compare the outcomes of conventional LC with modified LC (using 5-mm umbilical port, 10 mm epigastric port, and two 5-mm right hypochondrium and right lumbar ports), in terms of operating time, average hospital stay, post-operative complications, and cosmesis, with the ultimate aim of improving the quality of life of patients.

Few similar studies were available worldwide, but no such studies were conducted in Eastern India. Therefore, our intention for this study was to find out the comparative outcomes of both methods in a medical college of Eastern India.

MATERIALS AND METHODS
This prospective, comparative, and randomized study was conducted in ESIC-PGIMSR, Joka, Kolkata from June 2017 to December 2018. One hundred and fifty patients of symptomatic gall stone disease diagnosed clinically and radiologically, were included in this study, after obtaining written informed consent from all of them. The study was approved by the Institutional Ethical Committee (ESIC/32/IEC/JOKA dated 12.03.2017).

One hundred and fifty patients were randomly allocated into two groups. Randomization was done by toss a coin method. Group-I included 75 patients who underwent LC by conventional way (port size 10-10-5-5), whereas, Group-II consisted of 75 patients who underwent LC with modified method, using 5-mm umbilical port instead of 10 mm (port size 5-10-5-5). The sample size was calculated by appropriate statistical tests based on our study design. All 150 patients were operated according to an elective schedule, by a single surgical team, all of whom had experience of laparoscopy for a minimum of 3 years. Certain exclusion criteria were set beforehand.

Exclusion criteria
The following criteria were excluded in the study:
- Age <16 years and ≥75 years
- Past h/o upper abdominal surgery
- Symptomatic gall stone disease with deranged LFT
- Patients having comorbidities such as cirrhosis of liver and coagulation disorder
- Anesthesia fitness with ASA grading 3 or above.

Preoperatively, all patients were administered a single dose of injection Ceftriaxone (1 g) intravenously, after sensitivity test, during induction. All surgeries were performed under general anesthesia. In all patients, pneumoperitoneum was established using carbon dioxide gas and 10-mm epigastric port, 5-mm right hypochondrium and right lumbar ports were positioned. The body position of the patient was then changed to reverse Trendelenburg position. Dissection of the cystic duct and artery was performed by and electro-dissector through the epigastric port. After exposing both the duct and artery, double 10-mm clips were introduced to ligate both and divide those using endoscissors. Gallbladder was dissected from the liver bed using a hook dissector. After achieving hemostasis, the gallbladder was removed through the subxiphoid port under direct vision of laparoscope, using a specimen retrieval bag. In Group-I patients, umbilical port sheath was closed with (1-0) absorbable polyglactin 910 suture and subsequently skin was closed with the same suture, whereas, in Group-II patients, no suture was applied at umbilical port sheath and skin. However, in all 150 patients, skin of other three ports was opposed with absorbable (3-0) polyglactin 910 rapide suture. After completion of surgery, all incision wounds were covered with sterile water proof dressing. Not a single patient in either group required conversion to open cholecystectomy.

Standard post-operative care was given to all patients including analgesics, wound care, and initiation of solid food as soon as the patients were able to tolerate it. Post-operative pain over the umbilical wound was measured at 24 h and 72 h after surgery, using a visual analog scale (VAS), representing an intensity of pain from 0 (no pain) to 10 (worst imaginable pain) (Figure 1).

After discharge, all patients were followed up at 6 weeks, 6 months, and 1 year after surgery. During follow-up at 6 months and 1 year, we enquired each patient about their perception of aesthetic acceptability of their umbilical wound. We formulated a scoring system ranging from 1 to 5 (1 indicating hypertrophied umbilical scar, 2 indicating moderately thickened scar, 3-mildly thickened scar, 4-umbilical scar with minimal thickness, and 5-negligible

Figure 1: Visual analog scale
scar). All patients were asked to score as per their perception and those were documented. During clinical follow-up, any suspected port site hernia was evaluated radiologically.

Both groups were compared based on demographic data, data regarding operating time, hospital stay, umbilical port site pain score, post-operative complications such as port-site bleeding, intraperitoneal trocar injury while inserting, bleeding from cystic artery, biliary spillage, umbilical port-site wound infection, trocar site hernia (TSH), and cosmetic outcome of umbilical wound.

RESULTS

Data analysis were carried out using Microsoft Excel 2010 spreadsheet and SPSS version 20.0 software. Descriptive statistics were expressed in terms of absolute number, percentage, and mean along with standard deviation (SD). Inferential statistical procedures such as Chi-square test and Student-t test, and non-parametric tests such as Mann–Whitney U-test were also applied using confidence interval to be 95% and P<0.05 as statistically significant.

Age distribution

Table 1 shows maximum number of patients were in age group 46-55 years in both groups.

From Figure 2, it is obvious that female patients are more common in both groups.

Body mass index (BMI) in both groups of patients

BMI comparison doesn't show any statistical significance as shown in Table 2. The combined demographic data are presented in Table 3.

Pain score over umbilical wound

The mean pain score over umbilical wound for the 10-mm LC group was found to be much higher in comparison to the 5-mm LC group, both 24 h and 72 h postoperatively. Both were found to be statistically significant (24 h; P=0.02, 72 h; P=0.03) (Table 4).

Operating time and average hospital stay

The mean duration of surgery for Group-I and Group-II patients was 49.6 (20.7) min and 47.3 (20.8) min, respectively. The difference was found to be statistically significant (P=0.03). The mean length of hospital stay after surgery was 3.2 (2.4) days and 3.1 (2.1) days, respectively, for 10-mm LC and 5-mm LC group. However, considering P-value, no statistically significant difference was found (P=0.16) (Table 5). The post operative complications were not statistically significant in any cases (Table 6).

Table 1: Age distribution and mean age of patients in Group-I and Group-II.

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Group-I (n=75) (%)</th>
<th>Group-II (n=75) (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(16–25)</td>
<td>12 (16)</td>
<td>10 (13.33)</td>
<td>22 (14.67)</td>
</tr>
<tr>
<td>(26–35)</td>
<td>15 (20)</td>
<td>14 (18.67)</td>
<td>29 (19.33)</td>
</tr>
<tr>
<td>(36–45)</td>
<td>17 (22.67)</td>
<td>18 (24)</td>
<td>35 (23.33)</td>
</tr>
<tr>
<td>(46–55)</td>
<td>19 (25.33)</td>
<td>21 (28)</td>
<td>40 (26.67)</td>
</tr>
<tr>
<td>(56–65)</td>
<td>10 (13.33)</td>
<td>9 (12)</td>
<td>19 (12.67)</td>
</tr>
<tr>
<td>(66–75)</td>
<td>2 (2.67)</td>
<td>3 (4)</td>
<td>5 (3.33)</td>
</tr>
<tr>
<td>Mean age (±SD)</td>
<td>48.2±14.7</td>
<td>48.8±15.2</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: BMI (calculated by weight in kilograms divided by the square of height in meters) in both group of patients with calculated P-value (calculated by student-t-test).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group-I</th>
<th>Group-II</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Range</td>
</tr>
<tr>
<td>Group-I</td>
<td>24.4</td>
<td>4.8</td>
<td>19-32.2</td>
</tr>
<tr>
<td>Group-II</td>
<td>24.2</td>
<td>4.3</td>
<td>18.8-31.4</td>
</tr>
</tbody>
</table>

BMI: Body mass index

Table 3: Combined demographic data and BMI of patients in our study population

<table>
<thead>
<tr>
<th>Variables</th>
<th>All patients (%)</th>
<th>Group-I (%)</th>
<th>Group-II (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numbers</td>
<td>150</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>Age (years)</td>
<td>Mean=48.5</td>
<td>Mean=48.2</td>
<td>Mean=48.8</td>
</tr>
<tr>
<td>Male</td>
<td>60 (40)</td>
<td>31 (51.67)</td>
<td>29 (48.33)</td>
</tr>
<tr>
<td>Female</td>
<td>90 (60)</td>
<td>44 (48.89)</td>
<td>46 (51.11)</td>
</tr>
<tr>
<td>BMI [mean (SD)]</td>
<td>24.6 (4.4)</td>
<td>24.4 (4.8)</td>
<td>24.2 (4.3)</td>
</tr>
</tbody>
</table>

BMI: Body mass index

Table 4: Post-operative pain score assessment over umbilical wound with P-value (Mann–Whitney U-test applied)

<table>
<thead>
<tr>
<th>Time since operation</th>
<th>Group-I</th>
<th>Group-II</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 h</td>
<td>7.4 (2.3)</td>
<td>5.2 (2.1)</td>
<td>0.02</td>
</tr>
<tr>
<td>72 h</td>
<td>6.4 (3.1)</td>
<td>3.9 (1.7)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

BMI: Body mass index
Post-surgical complications in both groups
Post operative complications like bleeding from port – site, trocar injury, cystic artery bleeding, biliary spillage, wound infection and trocar site hernia were assessed in both groups and the statistical analysis was shown in Table 6.

Cosmetic outcome of umbilical port-site wound
Cosmetic results were evaluated during follow-up at 6 months and 1 year after surgery and the results were analyzed. Statistically significant differences were not detected in both occasions (P<0.05) (Table 7).

DISCUSSION
Nowaday, LC is the most common laparoscopic surgery performed worldwide. Although 5-mm 30\(^\circ\) laparoscope was used for diagnostic purposes initially in 1980,\(^6\) it was not widely considered by surgeons due to poor image resolution and narrow visual field. In present era, there is lot of advancement of fiber optic materials and 5-mm laparoscopes are now available with image quality equivalent to 10-mm conventional laparoscopes. The cost of 5-mm 30\(^\circ\) laparoscope is also comparable with 10-mm 30\(^\circ\) laparoscope, for most of the renowned brands available in the market. Hence, many surgeons are now in favor of using that through 5-mm umbilical port, in an attempt to reduce the operating time and post-surgical wound pain, shorten the hospital stay and to improve the overall cosmetic appearance of surgical site.\(^7\)

In our study, majority of the patients were within the age group (46–55) years, in both study groups, with the mean age of 48.2 years and 48.8 years in Group-I and Group-II, respectively. This is in accordance to the study done by Bailey et al.,\(^8\) (47 years) and Radunovic et al.,\(^9\) (51 years).

In the present study, statistically significant differences were observed while assessing mean VAS score over umbilical port wound, both 24 h and 72 h after operation. Similarly, studies done by Bisgaard et al.,\(^10\) and Sarli et al.,\(^1\) also demonstrated that reducing port size in LC had the advantage of eliciting significantly less wound pain.

In our study, while comparing mean surgical duration time, we found statistically significant difference within both study groups. This outcome goes similar to the study done by Atasoy et al.,\(^11\) and Ros et al.\(^12\)

In the current study, we did not find any statistically significant difference between two groups, in view of average hospital stay and post-surgical complications such as port-site bleeding, intraperitoneal trocar injury, cystic artery bleeding, biliary spillage, umbilical port-site wound infection, and TSH. These results are very much promising and support the safety and feasibility of LC using 5-mm 30\(^\circ\) laparoscope through 5-mm umbilical port. Study done by Crist et al.,\(^13\) showed that the use of 10-mm port may rarely cause a TSH. Although 10-mm umbilical port sheath is always closed with absorbable suture, it becomes very difficult in obese patients to close the facial layer and may also be time consuming. In our study, we detected only one case of TSH through umbilical port site during follow-up and that the patient had BMI of 31. It clearly indicates that chances of TSH are more in obese patients with 10-mm umbilical port.\(^13\)

Several studies have concluded that small-sized incisions result in minimal scarring and better cosmesis.\(^14,15\) However, in the present study, we were unable to establish any satisfactory significant difference between the groups regarding cosmetic outcome of the umbilical port site wound. It may have happened due to absence of any reliable objective scale and variations in patients’ perspective regarding wound cosmesis.

There is no uniform nomenclature for different techniques of LC. Haribhakti and Mistry,\(^7\) proposed that if only one 10-mm port and rest all 5-mm ports are used, it should be named as mini LC (MLC). If one 10-mm port, one 5 mm, and rest 2–3 mm ports are being used, then also it should be called MLC.

Table 7 shows that our study results are at par with most other international studies.
Table 8: Results of prospective randomized trials comparing MLC and LC

<table>
<thead>
<tr>
<th>Source</th>
<th>Type of procedure</th>
<th>No of cases</th>
<th>Operating time</th>
<th>Pain score</th>
<th>Hospital stay</th>
<th>Cosmesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reardon et al.</td>
<td>MLC</td>
<td>15</td>
<td>Not prolonged</td>
<td>Decreased</td>
<td>Shortened</td>
<td>Superior</td>
</tr>
<tr>
<td></td>
<td>LC</td>
<td>50</td>
<td>88.7 (5.9)*</td>
<td>Decreased</td>
<td>1.5 (0.2)*</td>
<td>Superior</td>
</tr>
<tr>
<td>Bisgaard et al.</td>
<td>MLC</td>
<td>13</td>
<td>85</td>
<td>Lower</td>
<td>Decreased</td>
<td>Superior</td>
</tr>
<tr>
<td></td>
<td>LC</td>
<td>13</td>
<td>85</td>
<td>Lower</td>
<td>1.2 (0.5)*</td>
<td>Better</td>
</tr>
<tr>
<td>Sarli and Costi</td>
<td>MLC</td>
<td>30</td>
<td>50.6 (12.3)*</td>
<td>Lower</td>
<td>1.1 (0.4)*</td>
<td>Better</td>
</tr>
<tr>
<td></td>
<td>LC</td>
<td>30</td>
<td>45.8 (10.7)*</td>
<td>Higher</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Huang et al.</td>
<td>MLC</td>
<td>19</td>
<td>Increased</td>
<td>Decreased</td>
<td>No difference</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>LC</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NE: Not evaluated. *Data are given as mean (SD). MLC: Mini laparoscopic cholecystectomy, LC: Laparoscopic cholecystectomy

Limitations of the study
Our study had few limitations such as small sample size and follow-up period of 1 year which is considered short for detecting TSH. Therefore, large, multicentric, and longer follow-up studies are needed to confirm the results of our study.

CONCLUSION
From our study, we can conclude that performing LC using 5-mm 30° telescope through 5-mm umbilical port instead of a 10-mm 30 laparoscope is a safe and feasible option in terms of shorter operating time and reduced post-surgical umbilical wound pain. The chance of development of umbilical port-site hernia is also less due to shorter sheath incision length. However, regarding umbilical wound cosmesis, we could not demonstrate any significant statistical difference. Hence, surgeons can use 5-mm 30° laparoscope for LC without any compromise from surgical point of view.

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REFERENCES


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SS- Concept and design of the study, preparation of manuscript, revision of manuscript; BB- Review of literature, preparation of first draft of manuscript; BP- Concept, coordination, statistical analysis, and interpretation.

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