A Randomized Control Study to Compare the Clipless Laparoscopic Cholecystectomy (CLLC) and Conventional Laparoscopic Cholecystectomy (CLC)

**Abstract:** Background: Present study was undertaken to compare the advantages of Clipless Laparoscopic Cholecystectomy (CLLC) over conventional laparoscopic cholecystectomy (CLC). Material & methods: This prospective randomized study was conducted in the Department of Surgery IGMC, Shimla over a period of 1 year starting from 1st July 2019 to 30th June 2020. In this study 100 consecutive patients of symptomatic cholelithiasis confirmed by USG reporting were participated and randomized into 2 groups of 50 each. Group 1 patients underwent CLC and Group 2 patients underwent CLLC. Outcomes were measured in terms of operative time, intra operative stone spillage, intra operative blood loss, amount of CO₂ used, post operative pain, conversion into open cholecystectomy and post operative complications. Results: In the present study among 100 patients, 19 were males and 81 were females. Among them, 5 males and 45 females underwent CLC using electrocautery while 14 males and 36 females underwent CLLC. Mean age of males were 47.60 ± 3.36 years and females were 45.20 ± 15.82 years in CLC group and mean age of males were 53.07 ± 18.96 and females were 44.44 ± 15.41 in CLLC group. Present study showed that there was significant less Operative Time, Less Mean CO₂ used, less Approx. Blood Loss, less Average pain score at 6 & 24 hours, less Average Length of hospital stay, less Intra Op. Stone spillage and less Use of Drain in CLLC as compared to CLC but there was no significant difference in Conversion to Open Cholecystectomy and Post op. Complications in both groups. Conclusion: Study concluded that CLLC had significant advantage over CLC in terms of operative time, intraoperative stone spillage, intraoperative blood loss, amount of CO₂ used, postoperative pain & use of Drain.

Keywords: Comparison, Clipless Laparoscopic Cholecystectomy (CLLC), Conventional Laparoscopic Cholecystectomy (CLC)

**INTRODUCTION**

Conventionally 6 titanium clips are used for laparoscopic cholecystectomy, 3 for cystic duct and 3 for cystic artery before division. Advanced energy source, harmonic scalpel, provide the advantage of shorter operating time by reducing smoke, bloodless dissection in calot’s triangle, lower risk of bleeding from cystic artery due to secure vessel sealing and reducing use of large number of titanium clips. 1,4

Total Clipless laparoscopic cholecystectomy by means of Harmonic shears have also been used for closure and division of cystic artery and cystic duct but division of cystic duct with only harmonic shears is controversial. The fear that this is not enough to withstand the pressure and carry out a postoperative bile leakage could be a limiting factor for its widespread use, especially in large cystic duct (greater than 5mm). Therefore by using absorbable suture we reduce the chances of biliary leakage. 1,5

Theoretical benefits for use of Clipless Laparoscopic Cholecystectomy (CLLC) technique using Absorbable suture material and harmonic scalpel are Less operative time, Less bleeding, Early post operative recovery, Cost factor (using 1 clips instead of 6), Less spillage of stones, Less chances of converting into open cholecystectomy, Less pain post operatively and Less amount of CO₂ used. 1,5,6
There is paucity of studies conducted for Comparison of Clipless Laparoscopic Cholecystectomy (CLLC) between Vs Conventional Laparoscopic cholecystectomy (CLC). Thus, a study has undertaken to compare the advantages Clipless Laparoscopic Cholecystectomy (CLLC) over conventional laparoscopic cholecystectomy (CLC).

Aims and Objectives
To compare advantages of Clipless Laparoscopic Cholecystectomy (CLLC) over Conventional Laparoscopic cholecystectomy

Material And Methods
Study Settings- A tertiary care hospital based study in the Department of General Surgery, IGMC Shimla.
Study Period- w.e.f. 1st July 2019 – 30th June 2020.
Study Design- Prospective Randomised Study in a tertiary care center.
Study Population and Sample Size - All consecutive patients of symptomatic cholelithiasis confirmed by USG reporting and all patients were operated by same team of surgeons in a study period mentioned above. Sample size was 100 patients.

Approval of Ethical Committee of IGMC-After approval of ethical committee of IGMC Shimla data collection was started.

Inclusion criteria for our study were patients between age between 21 and 80, ASA score of <3 and Symptomatic Gall stones.

Patient with BMI >40, Patient with cholelithiasis with cholelithiasis, Previous upper abdominal surgery, Patient with bleeding disorder, Acute cholecystitis and Patient on warfarin were considered as high risk patients and were not included in the study.

All eligible patients were randomised into these two groups of 50 each using sealed opaque envelopes which will contain a computer-generated random number. Group 1 included patients undergoing dissection of gall bladder by harmonic scalpel with application of absorbable PDS suture on cystic duct and Group 2 included patients undergoing gall bladder dissection by conventional method.

Before the surgery, all patients were undergo basic investigations such as routine haematological and biochemical investigations, electrocardiogram, Ultrasonography of the abdomen and radiologic imaging such as chest radiograph. All operations were performed by same group of surgeons.

The following parameters were recorded in each group-
A. Intraoperative Parameters
1. Operative findings including status of gall bladder, presence of adhesions, any intraoperative stone spillage.
2. Operative time calculated (in minutes) for all cases from skin incision to skin closure
3. Bleeding – Assessed through gauge visual analogue method
4. Quantity of CO2 used
5. Use of drain
6. Conversion to Open Cholecystectomy

B. Postoperative Parameters
1. Postoperative pain at 6h and 24h after surgery using visual analogue scale (VAS) used and the requirement of post operative analgesics was noted.
2. Length of Hospital stay (in days)
3. Any postoperative complications

Data Compilation
At the end of study data was compiled and outcome parameters were studied as Duration of surgery, Quantity of CO2 used, Intra operative stone spillage, Intra operative blood loss, Post operative pain at 6 hour and 24 hour after the surgery, Duration of hospital stay and Any postoperative complications.

Statistical Methods:
Data collected, cleaned and entered into excel spread sheet. Expressions of discrete variables were as percentages or proportions. Chi-Square test was used to study difference in distribution of discrete variables. Expression of continuous variables were as Mean + SD or median + Interquartile range. Significance of difference in continuous variables were analysed using Student T test or Wilcoxon Signed Rank Test depending on distribution of variables. For all statistical analysis two tailed tests were used. Data was analysed using Epi – info version 7.2.2. P value <0.05 was considered as statistically significant.

Results & Observations
Out of 100 patients, 19 were males and 81 were females. Among them, 5 males and 45 females underwent conventional laparoscopic cholecystectomy (CLC) using electrocautery while 14 males and 36 females underwent Clipless Laparoscopic Cholecystectomy (CLLC)

In between two groups, mean age of males were 47.60 ± 3.36 years and females were 45.20 ± 15.82 years in CLC group and mean age of males were 53.07 ± 18.96 and females were 44.44 ± 15.41 in clipless laparoscopic cholecystectomy group.
Table-1: Age and Gender Distribution

<table>
<thead>
<tr>
<th>Groups</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>CLC</td>
<td>5</td>
<td>10</td>
<td>45</td>
</tr>
<tr>
<td>CLLC</td>
<td>14</td>
<td>28</td>
<td>36</td>
</tr>
</tbody>
</table>

In between the two groups ,Mean operative time (min) of CLC was 43.10 ± 9.68 and CLLC was 37.30 ± 8.22 with mean difference of 5.80 min with P value of <0.002. Mean CO₂ used CLC was 31.52 ± 9.28 litres and CLLC was 24.90 ± 4.26 litres with mean difference of 6.62 litres and P value of <0.001. Approx. blood loss in CLC was 28.90 ± 11.71 ml and CLLC was 8.40 ± 3.70 ml with mean difference of 20.50 ml and P value of <0.001.

Average pain score at 6 hours in CLC was 6.44 ± 1.16 and CLLC was 5.96 ± 0.49 with mean difference of 0.48 and P value of 0.008. Average pain score at 24 hours in CLC was 2.68 ± 1.25 and CLLC was 2.04 ± 0.28 with mean difference of 0.64 and P value of 0.001. Average stay in CLC was 1.98 ± 1.97 and CLLC was 1.10 ± 0.46 with mean difference of 0.88 and P value is 0.003.

Table 2: Inter-group comparison of various quantitative variables

<table>
<thead>
<tr>
<th></th>
<th>CLC</th>
<th>CLLC</th>
<th>Mean difference</th>
<th>t value</th>
<th>P value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative Time (min)</td>
<td>43.10± 9.68</td>
<td>37.30 ± 8.22</td>
<td>5.80</td>
<td>3.22</td>
<td>0.002</td>
<td>Significant</td>
</tr>
<tr>
<td>Mean CO₂ used(litres)</td>
<td>31.52±9.28</td>
<td>24.90 ± 4.26</td>
<td>6.62</td>
<td>4.58</td>
<td>&lt;0.001</td>
<td>Significant</td>
</tr>
<tr>
<td>Approx. Blood Loss (ml)</td>
<td>28.90±11.71</td>
<td>8.40 ± 3.70</td>
<td>20.50</td>
<td>11.80</td>
<td>&lt;0.001</td>
<td>Significant</td>
</tr>
<tr>
<td>Average pain score at 6 hours</td>
<td>6.44±1.16</td>
<td>5.96 ± 0.49</td>
<td>0.48</td>
<td>2.68</td>
<td>0.008</td>
<td>Significant</td>
</tr>
<tr>
<td>Average pain score at 24 hours</td>
<td>2.68 ± 1.25</td>
<td>2.04 ± 0.28</td>
<td>0.64</td>
<td>3.52</td>
<td>0.001</td>
<td>Significant</td>
</tr>
<tr>
<td>Average Length of hospital stay (Days)</td>
<td>1.98 ± 1.97</td>
<td>1.10 ± 0.46</td>
<td>0.88</td>
<td>3.06</td>
<td>0.003</td>
<td>Significant</td>
</tr>
</tbody>
</table>

Statistical Analysis: Independent sample t test. Statistically significant if P<0.05

In terms of stone spillage, 14 patients of CLC group and 4 patients of CLLC group had intraoperative stone spillage with P value of 0.009. In this study, among 16 patients of CLC group and 4 patients of CLLC group, intra operatively drain was used with P value of 0.003.

In terms of conversion, 2 patients of CLC group and 1 patient of CLLC group converted to open cholecystectomy with P value of 0.558. In the present study, 4 patients of CLC group and 1 patient of CLLC group had postoperative complication with P value of 0.169.

Table 3: Inter-group comparison of various qualitative variables

<table>
<thead>
<tr>
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<th>CLC [n=50]</th>
<th>CLLC [n=50]</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N %</td>
<td>N %</td>
<td></td>
</tr>
<tr>
<td>Intra Op. Stone spillage</td>
<td>Yes</td>
<td>14</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>36</td>
<td>72</td>
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<tr>
<td>Use of Drain</td>
<td>Yes</td>
<td>16</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>34</td>
<td>68</td>
</tr>
<tr>
<td>Conversion to Open Cholecystectomy</td>
<td>Yes</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>48</td>
<td>96</td>
</tr>
<tr>
<td>Post op. Complications</td>
<td>Yes</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>46</td>
<td>92</td>
</tr>
</tbody>
</table>

Statistical Analysis: Chi-square test. Statistically significant if P<0.05.
DISCUSSION

In conventional laparoscopic cholecystectomy (CLC) mean operative time (min) was 43.10 ± 9.68 and in clipless laparoscopic cholecystectomy (CLLC) was 37.30 ± 8.22 with mean difference of 5.80 min and P value of <0.002 respectively. 2 patients of CLC group and 1 patient of CLLC group converted to open cholecystectomy due to frozen calots triangle. So the mean operative time markedly increased due to above mentioned three cases. Operating time was significantly less in the harmonic ace assisted LC group in the study conducted by Jain et al.,² and Kadil et al.,⁷ Rajnish et al.,¹ suggested that there was no significant difference in operating time.

Intra operative blood loss is measured with the help of gauge visual analogue method and in terms of approximate blood loss, blood loss in CLC was 28.90 ± 11.71 ml and in CLLC was 8.40 ± 3.70 ml with mean difference of 20.50 ml and P value is <0.001. Husher et al.,³ and Bessa et al.,⁹ suggest a significant reduction in blood loss in four port laparoscopic cholecystectomy, Rajnish et al.,¹ and Guanqun et al.,¹⁰ suggested that there was no significant difference in blood loss.

In our study, in terms of stones spillage, 14 patients of CLC group had intraoperative stone spillage and 4 patients of CLLC group had intraoperative stone spillage, P value is 0.009. Kandil et al.,⁷ in their study, showed that the risk of GB perforation was significantly higher in the traditional group than in the harmonic group (18.6% vs. 7.1%, respectively; p = 0.04). Risk of GB perforation was not found significant in the study conducted by Mukesh et al.,¹¹ Janssen and colleagues¹² reported that the gallbladder perforation with stone spillage was 6 times higher in the electrocautery group than the ultrasonic dissection group. Guanqun et al.,¹⁰ reported no statistical significance between two groups in terms of gallbladder perforation.

In our study mean CO₂ used in CLC was 31.52 ± 9.28 litres and in CLLC was 24.90 ± 4.26 litres with mean difference of 6.62 litres and P value is <0.001. Amount of CO₂ used depends directly on operating time. No study to our knowledge has compared amount of CO₂ used. But various studies had compared mean operative time which reflect indirectly amount of CO₂ used. Blood loss, intraoperative stone spillage require use of suction intra operatively which also indirectly reflect amount of CO₂ used.

In our study average pain score at 6 hours in CLC was 6.44 ± 1.16 and in CLLC was 5.96 ± 0.49 with mean difference of 0.48 and P value is 0.008. Average pain score at 24 hours in CLC was 2.68 ± 1.25 and in CLLC was 2.04 ± 0.28 with mean difference of 0.64 and P value is 0.001. Jain et al.,² noted that postoperative pain was significantly less in the harmonic shear group. This is due to less release of inflammatory mediators, as there is less lateral tissue and nerve damage. Also, the duration of peritoneal distension is less due to the shorter surgery duration, thereby directly affecting the duration and degree of traction to vessels and nerve. Mahabaleshwar et al.,³ also concluded that the postoperative pain is less in the harmonic scalpel group. Post-operative pain scores after 24 hours were found to be significantly better in harmonic ace assisted LC by Kandil et al.,⁷ as well (4.48 ± 1.89 vs. 3.12 ± 1.84; p = 0.000)²⁴ Guanqun et al.,¹⁰ and Rajnish et al.,¹ report there is no significant pain reduction in post operative pain and analgesic requirement in both groups.

In terms of conversion to OC, 2 patients of CLC group and 1 patient of CLLC group converted to open cholecystectomy, P value is 0.558. Reason for conversion was frozen calots triangle along with intraoperative stone spillage and intraoperative bleed. Kandil et al.,⁷ suggest less conversion rate in HA group but that was not statistically significant. Bessa et al.,⁹ Guanqun et al.,¹⁰ and Rajnish et al.,¹ report no statistically significant difference between two groups.

In our study average stay in CLC was 1.98 ± 1.97 and in CLLC was 1.10 ± 0.46 with mean difference of 0.88 and P value is 0.003. Guanqun et al.,¹⁰ shows mean stay in hospital after surgery as 3.0 ± 0.4 in Harmonic ace group and 2.9± 0.4 in Electrocautery group with P value of 0.315. Gelmini et al.,¹³ shows mean post operative hospital stay in both group as 2 days and P value is 0.799.

In our study 4 patients of CLC group and 1 patient of CLLC group had postoperative complication with P value of 0.169 which is not significant. These complications in the form of bile leak were managed with ERCP stenting and surgical site infection were managed with daily aseptic dressings and secondary suturing. In Rajnish et al.,¹ study post operative complications in term of surgical site infection and intra abdominal collection there was no statistically significant difference in between two groups. Guanqun et al.,¹⁰ showed no significant post operative complications in two groups.

CONCLUSION

This study concluded that CLLC had significant advantages over CLC in terms of operative time, intra operative stone spillage, intra operative blood loss, amount of CO₂ used, post operative pain, hospital stay and Use of Drain making CLLC a feasible procedure in Himalayan terrain patients where patients have to travel long distance to health care facilities. Further multicenter randomized trials with large sample size are required to substantiate a clear advantage of CLLC over CLC.
REFERENCES


