

ORIGINAL ARTICLE

Comparison of Day Case Laparoscopic Cholecystectomy Versus Conventional Laparoscopic Cholecystectomy

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ABSTRACT

Objective: To compare the day case Laparoscopic cholecystectomy with conventional Laparoscopic cholecystectomy in terms of early return to activities and intensity of postoperative pain.

Study Design: Randomized control trial (Parallel).

Place and Duration of Study: Department of Surgery Pakistan Institute of Medical Sciences/ Shaheed Zulfiqar Ali Bhutto Medical University Islamabad. Study was conducted from 1st Nov 2014 to 30th April 2015.

Materials and Methods: After approval of hospital ethical committee, patients who were fulfilling the inclusion criteria were included in study after taking informed and written consent. Sample size was calculated using WHO sample size calculator, which turned out to be 42 for each group. Patients were divided into two groups, group A and group B by lottery method. Patients in group A had undergone Day case Laparoscopic cholecystectomy and patients in group B had undergone Conventional Laparoscopic cholecystectomy. Data was collected and recorded on purposively designed Performa. Data was analyzed using SPSS 17; paired t test was used to calculate p-value.

Results: In group A, among 42 patients 13(31%) were on VAS 4, 13(31%), on VAS 5, 8(19%), in VAS 3, 6(14.3%), in VAS 2 and 2(4.8%), in VAS 6. The minimum and maximum "number of days to return to activities" was 3 and 7 days respectively. Among 42 patients, 20(47.6%) patients had returned to their home activities in 3 days, 13(31%) in 4 days, 5(11.9%) in 5 days, 2(4.8%) in 6 days and 2(4.8%) in 7 days. In group B the minimum and maximum intensity of pain on Visual Analogue Scale was 2 and 6 respectively. Among 42 patients 15(35.7%) were on VAS 5, 14(33.3%) were on VAS 3, 8(19%), in VAS 4, 4(9.5%), in VAS 6 and 1(2.4%), in VAS 2. The minimum and maximum "number of days to return to activities" was 6 and 10 days respectively. Out of 42 patients 17(40.5%) had returned to their home activities in 9 days, 17(40.5%) in 8 days, 4(9.5%) in 7 days, 3(7.1%) in 10 days and 1(2.4%) in 6 days.

Conclusion: Patients undergoing day case LC do return to their routine activities earlier than those who undergo conventional LC, but there is no difference in terms of intensity of post-operative pain as measured on Visual analogue scale.

Key Words: *Cholelithiasis, Day Case Surgery, Laparoscopic, Day Case Laparoscopic Cholecystectomy, Laparoscopic Cholecystectomy.*

Introduction

Cholecystectomy is the commonest surgical intervention in hepatobiliary system.¹ Stal Pert Von

Der Weil was the first surgeon who found gall stone during surgery while operating upon a patient with peritonitis in 1687.¹ Ever since the operative management of gall stones is in process of continuous evolution. It was Carl Johann Langenbuch, who performed the first ever open cholecystectomy in Germany.² Later open cholecystectomy became the gold standard treatment for the management of symptomatic gall stone disease.³

Surgeons around the globe were trying to make the procedure as less invasive as possible. The technique of SILS was introduced in which a single umbilical incision was used to insert three small ports. Recently NOTES (Natural Orifices Transluminal Endo Surgery) has been introduced⁴, in which natural

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orifices are used to gain access to the cavity. First NOTES was performed on a 43 years female with symptomatic gall stones in 2007.⁵

Evolution in surgery has led to the concept of day case surgery, which means patient is discharged on same day after surgery. Day surgery is also called outpatient surgery or ambulatory surgery.⁶ Invention of laparoscopic surgery has made it possible to do number of procedure on day case basis, because of the small incision and less pain postoperatively. Now a day's number of conventional procedures like laparoscopic hernia repair and laparoscopic cholecystectomy are being performed on day case basis worldwide. With the passage of time acceptability of day case surgery has increased among clinicians, patients, families and also insurance agencies.⁷ Shortage of medical services in most part of world and financial problems has made space for day case surgery, because of lowering the treatment cost to less than 50%.⁸ Study in Pakistan showed reduction in treatment cost of PKR 6200 to 22800 in day case laparoscopic cholecystectomy (LC).⁹ That is why day case surgery has gained worldwide acceptance.

Day case laparoscopic cholecystectomy is being extensively performed in developed countries⁵, but its scope in developing countries is still less. Laparoscopic cholecystectomy has progressively shortened the hospital stay from 2 to 4 days to 6-8 hours.^{9,10} Studies have also shown early return to home activities in Day Case LC was 22 days.¹¹ Safety profile and technique of LC is making it an "ideal" for day case surgery.^{12,13} Recent literature review has shown Laparoscopic cholecystectomy as safe as conventional laparoscopic cholecystectomy.¹⁰ Up to 70% of patients with symptomatic disease are ideal for day case LC.¹⁴ While there is reasonable volume of data is available from developed world on safety and feasibility of day case LC, Pakistan is lacking behind on this subject and more and more research work is required to establish the safety and feasibility of this procedure in our country. In developing countries like Pakistan Day case LC is still in eggshell. One of the most important reasons for this is inadequate published data on safety and feasibility of procedure. It is the need of hour to collect and publish data on safety and feasibility of day case surgery in our part of world. Surgeons are very reluctant to offer day case

LC to their patients in our part of world. Quality local research data will give surgeons confidence in decision making for day case laparoscopic cholecystectomy.

A study was planned to compare the day case LC with conventional LC in terms of mean of number of days of early return to activities and means of intensity of postoperative pain on VAS.

Materials and Methods

Study design was Randomized Controlled Trial (Parallel) with allocation ration of 1:1. Study was conducted at department of General Surgery, PIMS, Shaheed Zulfiqar Ali Bhutto Medical University (SZABMU) Islamabad from 1st Nov 2014 to 30th April 2015. Sample size was calculated using WHO sample size calculator. Taking 18(2-52) days as population mean+/-SD and 14(2-32) days as test value of population mean+/- SD for early return to activities from previous literature.¹⁵ Level of significance was taken 5%. From given values 42 sample size was calculated for each group. Consecutive sampling was done as per inclusion and exclusion criteria. Operating surgeons were blinded and sampling was done by on floor post graduate trainee. Permission was taken from hospital ethical review board after detailed discussion and defense before the ethical committee.

Inclusion criteria was to include all patients with uncomplicated Cholelithiasis undergoing Laparoscopic cholecystectomy in study from 14 years to 60 years of age, both female and male patients and patients in ASA grade 1 and 2. Patients with known complications of Cholelithiasis like acute cholecystitis and acute pancreatitis, patients with known IHD, uncontrolled DM and uncontrolled HTN, any bleeding disorder and patients who are unfit for GA, or in ASA grade 3 and 4 were excluded from study.

Day case LC was defined as discharge from hospital within 12 hours of admission while conventional LC was defined as discharge from hospital after 24 hours of admission. Return to home activities was calculated in days, from the time of admission to the time of return to routine home activities. Patient was allowed to return to home activities if he was not having any surgical complications, able to move independently for eating, drinking and toilet, has no drain placed, was pain free and tolerating oral diet.

Intensity Postoperative pain was assessed after 6 hours using Visual Analogue scale (VAS).

Study population was all patients, who were booked for Laparoscopic cholecystectomy during the period of study at Surgical Unit 3 of PIMS, SZABMU. Patients who were fulfilling the inclusion criteria were included in study after taking informed and written consent. Patients were divided into two groups, group A and group B by lottery method. Randomization was done by assigned on floor post graduate trainee. Operating surgeons were blinded about group allocation of participants. Patients in group A had undergone Day case laparoscopic cholecystectomy and patients in group B had undergone Conventional Laparoscopic cholecystectomy. Pain was measured by VAS (Visual analogue score) at 6 hours postoperatively and number of days to return to home activities was asked to patient on follow up. For follow up contact numbers and addresses were recorded.

Data was collected and recorded on purposively designed Performa. SPSS 17 was used for data entry and analysis. Mean and standard deviation was calculated for numerical data (parametric) like age, number of days of return to activities and intensity of postoperative pain and frequencies were calculated for categorical data like sex. Unpaired T test was used for numerical data like mean of no of days to return to home activities and mean of postoperative pain. P value <0.05 was considered significant.

Results

Total of 84 patients were included in study. In Group A there were 42 patients who underwent Day Case Laparoscopic Cholecystectomy and in Group B there were 42 patients who underwent conventional Laparoscopic Cholecystectomy. In group A, total number of female patients was 32(76.2%) and male were 10(23.8%). Mean age was 38.95 years with SD of ±9.798. All the patients in group A underwent successful laparoscopic cholecystectomy without any major complications. Out of 42 patients 40(95%) were discharged successfully on same day of admission, fulfilling the Day case Laparoscopic Cholecystectomy Criteria. Rest of the two patients was discharged on second day of surgery. The reason for failure to discharge on same day of surgery was pain and nausea in both patients. The minimum and maximum intensity of pain on Visual Analogue Scale

was 2 and 6 respectively with mean of 3.93 and SD of ±1.135. Among 42 patients 13(31%) were on VAS 4, 13(31%) were on VAS 5, 8(19%) were in VAS 3, 6(14.3%) were in VAS 2 and 2(4.8%) were in VAS 6. The minimum and maximum “number of days to return to activities” was 3 and 7 days respectively, with mean of 3.88 and SD of ±1.109. Out of 42 patients 20(47.6%) had returned to their home activities in 3 days, 13(31%) in 4 days, 5(11.9%) in 5 days, 2(4.8%) in 6 days and 2(4.8%) in 7 days.

In group B, total number of female patients was 32(76.2%) and male were 10(23.8%). Mean age was 44.83 years with SD of ±14.553. All the patients in group B underwent successful laparoscopic cholecystectomy without any major complication. All patients were discharged successfully on second day of admission. The minimum and maximum intensity of pain on Visual Analogue Scale was 2 and 6 respectively with mean of 4.17 and SD of ±1.080. Among 42 patients 15(35.7%) were on VAS 5, 14(33.3%) were on VAS 3, 8(19%) were in VAS 4, 4(9.5%) were in VAS 6 and 1(2.4%) were in VAS 2. The minimum and maximum “number of days to return to activities” was 6 and 10 days respectively, with mean of 8.4 and SD of ±0.857. Out of 42 patients 17(40.5%) had returned to their home activities in 9 days, 17(40.5%) in 8 days, 4(9.5%) in 7 days, 3(7.1%) in 10 days and 1(2.4%) in 6 days.

There was no statistically significant difference between the two groups in terms of intensity of pain on VAS, as P value was greater than 0.05 (P-value:

Table I: No of Days to Return to Activities

Group A			Group B		
No of Days	No of Patients	Percentage (%)	No of Days	No of Patients	Percentage (%)
3	20	47.6	6	1	2.4
4	13	31.0	7	4	9.5
5	5	11.9	8	17	40.5
6	2	4.8	9	17	40.5
7	2	4.8	10	2	7.1
Total	42	100	Total	42	100

Table II: Intensity of Post-Operative Pain in Both Groups on VAS

Group A			Group B		
Intensity of Pain on VAS	No of Patients	Percentage (%)	Intensity of Pain on VAS	No of Patients	Percentage (%)
2	6	14.3	6	1	2.4
3	8	19.0	7	4	9.5
4	13	31.0	8	17	40.5
5	13	31.0	9	17	40.5
6	2	4.8	10	3	7.1
Total	42	100	Total	42	100

0.359 using paired t-test), while there was statistically significance difference in two groups in terms of no of days to return to routine activity as p value was less than 0.05 (P-value: 0.000 using paired t-test)

Discussion

Our study has demonstrated success rate of 92.5%, which is fairly consistent with the international reported figures, which is 95% as reported by Hamad et al.¹⁶ Success rate is quite lower if proper patient selection is not done. Careful patient selection base on the inclusion and exclusion criteria should significantly reduce the number of failed day case surgeries, as patient unfit for day case surgery was identified as leading cause of day case surgery failure in literature.¹⁷ In Our study, which has demonstrated success rate almost comparable to international literature, careful patient selection was done using preset inclusion and exclusion criteria.

In our study we studied the two factors, one is postoperative pain and other one is the early return to home activities. Postoperative pain is one of the most important reasons for failure to discharge patient on same day of surgery. Literature has reported that postoperative pain and nausea is the reason for failure to discharge and even readmission majority of patients undergoing day case surgery.¹⁸ As in our study, minimal post-operative pain has been included in criteria for discharge along with other parameters in almost all of the reported literature on day case surgery.¹⁹ In our study failure to discharge rate after day case surgery was 5%. In all 5% of patients, reasons for delayed discharge was nausea and vomiting, which is again consistent with reported literature.¹⁸ In our study Visual analogue scale (VAS) was used to assess the intensity of post-operative pain. VAS is easy to record and easy to understand scale, which is being used by most of the researcher around the globe.²⁰ Requirement for analgesics in both groups could have been a good variable to record, which our study lacks. Our study also did not find any significant difference between the two groups in term of postoperative pain intensity as P value was more than 0.05, which translates into the fact that patients who are being discharged home on same day will not need extra care for pain management as compared to other group.

Early return to routine activities is quite an important factor in comparing the two groups. The more the patient stays in hospital; the delayed will be his return to normal life. Our study has found significant difference between the two groups in term of early return to routine activities as the P value is less than 0.05. Average of 10 days have been reported in literature for no of days to return to routine activities after conventional laparoscopic cholecystectomy.²¹ Our study has demonstrated 9 mean days for return to routine activities after conventional LC, while 3.88 mean days for day case LC, which was found to be statistically significant. This single variable shows that number of sick leaves days can be reduced by adopting day case surgery, where feasible, but more studies are warranted to validate and strengthen this claim.

As it is evident from the above literature and from our study, that the LC can be performed with success and with safety on day case basis; as shorter hospital stay did not affect the outcomes and rate of complications after surgery. On the other hand day case surgeries have shortens the waiting list for surgeries and have reduced the total cost of surgery because of shorter hospital stay.²² Certain principles should be met for the success of day case surgery. Careful selection of patients after setting inclusion and exclusion criteria and vigilant management of postoperative pain are the parameters for the success of day case surgery.

Conclusion

Patients undergoing day case LC do return to their routine activities earlier than those who undergo conventional LC, but there is no difference in terms of intensity of post-operative pain as measured on Visual analogue scale.

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