Randomised Controlled Trial of Day-Case Laparoscopic Cholecystectomy vs Routine Laparoscopic Cholecystectomy

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Abstract Many randomised controlled trials conducted worldwide favours for day-case laparoscopic cholecystectomy, but questions have been raised regarding its application in developing country like ours. Hence, considering it a high time to review current practices, we conducted this trial to report our experience with day-case laparoscopic cholecystectomy and to assess its feasibility and safety in our set-up. Data from 65 patients with symptomatic gallstone were randomised to perform laparoscopic cholecystectomy either as day-case procedure or as routine (conventional) procedure. Complication, quality of life, satisfaction, post-operative nausea and vomiting and pain were assessed. Ninety-seven per cent (31/32) of day-case laparoscopic cholecystectomy patients were successfully discharged with mean duration of 8.9 ± 4.54 h, which was 3.33 ± 1.45 days (72.92 ± 34.8 h) in routine (conventional) laparoscopic cholecystectomy group. There was no significant difference in complication, quality of life, satisfaction, post-operative nausea and vomiting and pain between the two groups. Day-case laparoscopic cholecystectomy is a safe, feasible and beneficial procedure in our set-up. Patient acceptance in terms of quality of life and satisfaction was similar to that of routine laparoscopic cholecystectomy.

Keywords Day case · Gallbladder · Laparoscopic cholecystectomy · Post operative nausea and vomiting

Introduction

Since the introduction of laparoscopic cholecystectomy about two decades ago, it has become the treatment of choice for symptomatic gall stone disease. Further studies and better skill has led to the popularity of day-case laparoscopic cholecystectomy (DCLC), which has been recently investigated as a safe and feasible procedure. It is associated with less post-operative pain, shorter hospitalisation and earlier returns to work as compared to routine laparoscopic cholecystectomy. This fact merits special point of importance in our developing society where manpower is the base of economy. The aim of this study is to report our experience with day-case laparoscopic cholecystectomy and to assess its feasibility and safety in our set-up.

Materials and Methods

A randomised control trial was conducted at Swaroop Rani Nehru Medical College and its associated hospital, Allahabad Uttar Pradesh, which is a tertiary referral centre. Patients selected from those who were enrolled for elective laparoscopic cholecystectomy in outpatient department (OPD) with either biliary colic, acute cholecystitis or chronic cholecystitis. A total 65 patients, 32 in DCLC group and 33 in routine cholecystectomy group, were included in the study. Indications for surgery were the presence of symptomatic gallstones, confirmed on ultrasonography. The study was approved by the ethics committee, and informed consent was obtained from all participants.

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Inclusion Criteria

The study included all symptomatic patients with ultrasound proved gallstone disease who

1. Were <60 years and had American Society of Anaesthesiologists (ASA) physical status score grades I and II
2. Lived within 30 min of travelling distance from the hospital with adequate motivational level
3. Were living with at least one responsible adult family member at home to take care of patient post-operatively
4. Given informed consent for study.

The following patients were excluded:

1. Patients with extreme obesity and co-morbid conditions like poorly controlled diabetes, hypertension, coronary artery disease or ischaemic heart disease
2. Patients with clinical suspicion of common bile duct stone or complicated stone
3. Other intervention required during operation.

Randomisation

Randomisation was done according to even and odd number of bed head ticket. Patients selected as per inclusion criteria were randomised in two groups: DCLC who were discharged the same day of surgery (<23 h, preferably 6–8 h post-operatively) and routine (conventional) cholecystectomy group, as control.

Anaesthetic Technique

All the cases were conducted under a uniform standard general anaesthetic technique. Intramuscular diclofenac 50 mg and ondansetron 8 mg were given intravenously before the start of anaesthesia as prophylaxis against post-operative pain, nausea and vomiting. A single-dose (1 g) ceftriaxone prophylaxis was given intravenously at induction.

Operative Technique

All the cases of DCLC were performed by consultant surgeons having more than 5 years of experience in laparoscopic cholecystectomy. The patients in routine laparoscopic cholecystectomy group were operated by other consultants of our surgery department with three or more years of experience in laparoscopic surgery.

All patients underwent laparoscopic cholecystectomy under general anaesthesia using the standard four-port technique. In DCLC, 10 ml 0.25 % bupivacaine infiltrated at port sites prior to incision and 10 ml 0.5 % bupivacaine was instilled over gallbladder fossa prior to

port site closure. A closed suction drain was used when indicated. Insertion of a drain was not a contraindication for discharge provided other discharge criteria were met. Operating surgeons were required to record their assessment of the procedure, whether they anticipated any problem in the post-operative period.

Post-operative Evaluation

Patients were shifted to the ward after surgery and maintained on intravenous fluid for 4–6 h post-surgery. They were encouraged to sit up, drink as soon as possible and to go to the toilet. In the evening, the operating surgeon evaluated patients for pain, nausea, vomiting, consciousness level and vitals.

Patients were discharged if they were stable, fully conscious and if:

1. There was minimal nausea or vomiting.
2. Pain was controlled or minimal.
3. Patients were tolerating liquid or semisolid diet per orally.
4. Patients were able to go to the toilet without much difficulty and had passed urine.
5. Patients were willing and confident about going home.
6. The surgeon did not anticipate any problem from the operation.

To ensure safety and early detection of any complications, all DCLC patients were given an information leaflet providing advice on expected recovery pattern, pain control, diet and recognition of complication with our emergency contact number. Their general well being/pain/discomfort/side effects attributable to surgery or anaesthesia were assessed the next morning through a telephonic conversation. They were further followed up at first and fourth week in surgery OPD or early based on individual case basis.

Pain score assessment was done in both DCLC and routine laparoscopic cholecystectomy patients as per visual analogue score, 6–8 h post-operatively.

To compare post-operative nausea and vomiting in both groups, post-operative nausea and vomiting (PONV) score was determined at 6–8 h post-operatively, according to following system.

- 1=no symptom
- 2=symptoms not requiring pharmacological treatment
- 3=symptoms relieved by pharmacological treatment
- 4=symptoms not relieved by pharmacological treatment.

Patient's satisfaction level in both groups were compared at the time of discharge using pre-set questionnaires enquiring about their satisfaction level:

- 0=least satisfied
- 10=most satisfied.

Comparisons of quality of life between two groups were made at the time of follow-up at first and fourth week using pre-set questionnaires in surgery OPD. It included mobility, self-care, usual activity, pain/discomfort, anxiety/depression parameters in three degrees and patient placed in respective degrees as per their answers (Table 1).

Statistical analysis was done using Student's *t* test and chi-square test.

Results

A total of 65 patients were included in the study: 32 patients in the DCLC group and 33 in routine laparoscopic cholecystectomy group.

Mean age of patients in DCLC group was 35.94 ± 12.39 years, (range, 18–58 years) with male and female ratio is being 1:4, while in routine laparoscopic cholecystectomy group, mean age was 42.72 ± 11.89 with male and female ratio of 1:10.

All patients underwent successful laparoscopic cholecystectomy, and none needed conversion to open. In ten patients in the DCLC group, operating surgeons recorded procedure being difficult, anticipated post-operative slow recovery, increase oozing from liver bed and drain were placed. Five of these ten patients show good post-operative recovery, met discharge criteria's and were discharge in the evening after

Table 1 Questionnaires for assessment of quality of life

	At first week	At fourth week
Mobility		
No problem with walking about		
Some problems with walking about		
Confined to bed		
Self-care		
No problem with self-care		
Some problems with washing/dressing		
Unable to wash or dress self		
Usual activity		
No problem with usual activity		
Some problem with usual activity		
Unable to perform usual activity		
Pain/discomfort		
No pain or discomfort		
Moderate pain or discomfort		
Extreme pain or discomfort		
Anxiety/depression		
Not anxious or depressed		
Moderately anxious or depressed		
Extremely anxious or depressed

Fig. 1 Comparison of pain score

removal of drains, which were draining minimal serous fluid. Four of the above patients were kept for observation in the ward and were discharge in the morning the next day after removal of their drains. One patient was discharged with drain in situ showing minimal output of bilious fluid. His drain was removed on day 5 after evaluation by operating surgeon in the ward.

In DCLC group, 22 patients were discharged in <8 h, while nine patients of this group were discharged between 8 and 23 h. Reasons for failure to discharge are nausea and vomiting in two patients, drain (not removed in evening) in five patients and on patient's request in two patients, respectively. Mean post-operative duration of discharge was 8.90 ± 4.54 h in DCLC, while 72.92 ± 34.8 h in routine laparoscopic cholecystectomy group. Successful discharge rate in day-case laparoscopic cholecystectomy group was 97 %. Mean duration of discharge of DCLC and routine cholecystectomy cases was compared using Student's *t* test. *p* value was found to be 0.0001. By conventional criteria, this difference was considered to be statistically significant. Ninety-five per cent confidence interval was -83.53–58.72.

No significant difference in pain score between two groups ($p=0.12$) was observed (Fig. 1). PONV scores were not significantly different in two groups ($p=0.22$; Fig. 2). Reasons for which patients of DCLC called back within a

Fig. 2 Comparison of PONV score

Table 2 Comparison of quality of life between day-case cholecystectomy (DCLC) and routine laparoscopic cholecystectomy

	At first week			At fourth week		
	Day-case LC (n=32)	Routine LC (n=33)	p value	Day-case LC (n=32)	Routine LC (n=33)	p value
Mobility			0.96			0.98
No problem with walking about	19	15		32	32	
Some problems with walking about	12	18		0	1	
Confined to bed	1	0		0	0	
Self-care			0.98			0.98
No problem with self-care	28	29		32	33	
Some problems with washing/dressing	4	4		0	0	
Unable to wash or dress self	0	0		0	0	
Usual activity			0.95			0.98
No problem with usual activity	7	6		28	31	
Some problem with usual activity	18	19		4	2	
Unable to perform usual activity	7	8		0	0	
Pain/discomfort			0.96			0.97
No pain or discomfort	10	9		28	28	
Moderate pain or discomfort	21	22		4	5	
Extreme pain or discomfort	1	2				
Anxiety/depression			0.97			0.80
Not anxious or depressed	28	23		31	28	
Moderately anxious or depressed	4	10		1	5	
Extremely anxious or depressed	0	0		0	0	

week of discharge were nausea and vomiting (12 calls), analgesia requirement (7 calls), return to normal activity (5 calls) and diet (3 calls).

Satisfaction score assessed at the time of discharge was not significantly different in two groups ($p=0.93$). Quality of life assessed at first and fourth week post-operatively under five sub-headings—mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. The difference between two groups was not statistically significant ($p>0.05$) (Table 2). There was no significant difference in surgery-related morbidity between the two groups. Re-admission was nil in each group. No mortality was recorded in either group (Table 3). The lower complication rate DCLC group can be attributed probably to the fact that the operations were performed by the consultant having more than 5 year of experience in laparoscopic cholecystectomy.

Discussion

Laparoscopic cholecystectomy is now widely accepted as treatment of choice for symptomatic gallstone disease. With advancement and availability safer surgical and anaesthetic techniques, many procedures are nowadays performed on day-case basis, and laparoscopic cholecystectomy is one of them. The feasibility, safety and benefits of this procedure at our centre was analysed in our study.

A total of 65 patients of laparoscopic cholecystectomy were included in the study; 32 were offered DCLC. The discharge rate was 97 %. This discharge rate is comparable with the published literature where it varies from 55 to 100 % [2, 4, 8].

Table 3 Outcome analysis of day-case cholecystectomy (DCLC) and routine laparoscopic cholecystectomy

	DCLC (n=32)	Routine LC (n=33)
Mortality	0	0
Surgery-related morbidity		
Bile duct injury	0	1
Intra-abdominal collection	1	1
Wound infection	0	0
Haematoma	1	1
Surgery-related morbidity diagnosed after discharge		
Intra-abdominal collection	1	0
Wound infection	1	2
Haematoma	0	1
Post-operative pancreatitis	0	0
Retained CBD stone	0	1
Re-admission	0	0
Recommendation to others	27	28

Mean age of patients in day-case laparoscopic cholecystectomy was 35.94 ± 12.39 (range, 18–58) years, with male and female ratio being 1:4. Leeder et al., in 2004, observed a similar ratio of 1:4. Chang and Tan, in 2008, found mean age of 48 (range, 28–78) years. The mean age in our study is less because of we selected the patients <60 years only [5, 9].

In our study, only ASA grade I and II patients were considered appropriate candidates like most of the other studies [4]. However Mjaland et al. [10] have shown that some ASA grade 3 patients can be included successfully in day-case laparoscopic cholecystectomy.

No significant difference of pain score ($p=0.121$) between the day-case and routine laparoscopic cholecystectomy group was found, indicating that adequate pain control is possible even at home after laparoscopic cholecystectomy using the protocol that we had adopted. An effective non-parenteral protocol for control of pain is to be essential component in day-case laparoscopic cholecystectomy to achieve the same. Similar results were previously found by Keulemans et al. in 1998 and Calland et al. in 2001 [1, 3].

Calland et al. [3], in 2001, observed no significant difference between post-operative nausea and vomiting between day-case and routine laparoscopic cholecystectomy group. Our study also reveals the similar finding ($p=0.22$).

Our study demonstrated no significant difference ($p=0.93$) in patient satisfaction score between day-case and routine laparoscopic cholecystectomy group. This fact is also evident in studies of Keulemans et al. and Chok et al. [1, 6].

Higher level of anxiety can be expected in a patient offered day-case laparoscopic cholecystectomy owing to the fear of suffering complication and pain at home, but we found no significant difference between the two groups regarding the same, which was included under comparison of quality of life. No significant difference ($p>0.05$) was found between any of the parameters. This is comparable to previous studies by Keulemans et al., Dirksen et al., and Johansson et al. [1, 7, 11].

There was no difference in proportion of the patients who would recommend the form of treatment that they experienced. Thus, the two treatment options seem similar in most regard from a patient prospective.

Although our study has not compared the cost of day-case vis-à-vis routine laparoscopic cholecystectomy, it stands to reason that the former is cheaper due to cut in hospital stay costs. The number of surgical beds in any hospital like ours is relatively constant and non-flexible. Since our region has a high prevalence of gall stones, a large number of beds are used for cholecystectomy. This causes delay in the care of patients with more serious medical problems. Even then, it can reduce waiting time for patient by virtue of early discharge. This has also been the experience of studies like Bal et al. in 2003, Chauhan et al. in 2006 [4, 8]. The present study demonstrated that laparoscopic cholecystectomy can be performed as a day-case procedure without jeopardising the safety of the patient.

Conclusion

A public health centre in a developing country receives a large patient load, which has grown in tandem with the population growth in general. These are the very country that could benefit most from day-case laparoscopic cholecystectomy. Hence, there is need to advocate day-case laparoscopic cholecystectomy. In addition, those centres in developed countries can reduce the medical bill by cutting the hospital stay of patients through day-case surgery.

Considering discharge rate, re-admission rate, complication, ease and accuracy of follow-up, we concluded that day-case laparoscopic cholecystectomy is a safe, feasible and beneficial procedure in our set-up and is at par with routine laparoscopic cholecystectomy. However, each centre needs to develop their own guidelines for patient's selection based on available resources.

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