Feasibility and safety of day care laparoscopic cholecystectomy in a developing country

S Bal, L G S Reddy, R Parshad, R Guleria, L Kashyap

Background: Although day care laparoscopic cholecystectomy (DCLC) has been shown to be safe in centres with adequate infrastructure for day care surgery, its feasibility and safety in developing countries has never been studied. Because of differences in the quality of health care delivery, western guidelines for day care surgery cannot be universally applied to developing countries.

Patients and methods: Patients less than 65 years who were graded I and II on the American Society of Anesthesiologists physical status score, irrespective of their educational status, living within 20 km, and willing to make their own arrangements for a return to hospital in case of problems were selected for DCLC. Follow up was done by patients calling the hospital the morning after surgery.

Results: 50% of the eligibility criteria were new; 313/383 patients were suitable for DCLC. The commonest cause for rejection was that the patient lived out of the defined area (50%). Altogether 92% were discharged within eight hours of surgery. The reasons for failure to discharge were the presence of abdominal drains in four (2%), nausea and vomiting in nine (3%), and conversion to open surgery in five (2%). Ten patients (3%) were readmitted; of these only two (<1%) had complications needing re-exploration. Analysis of results showed that the inclusion and discharge criteria were valid and that the readmission and complication rates as well as the ease and accuracy of follow up were comparable to published data. DCLC reduced waiting times and increased patient turnover and may have a positive impact on resident training.

Conclusions: DCLC is safe, feasible, and has potential benefits for health care delivery in developing countries. Each surgical service needs to develop their own guidelines based on local patient demography.

Patients and methods:

Since we had no previous experience of DCLC as an outpatient procedure, a patient selection protocol suitable for our practice conditions was evolved. DCLC was offered to all patients with symptomatic ultrasound proved gallstone disease who:

1. Were less than 65 years, in sound mental health, and had a American Society of Anesthesiologists (ASA) physical status score’ grade I and II (patients with good control of their diabetes, chronic bronchitis, and hypertension were included).
2. Lived within 20 km of the hospital.
3. Had access to a telephone at all times and knew how to use it (it was not necessary that they had a rented line at home).
4. Were living with a responsible adult and were capable of reaching the hospital on their own without depending on ambulance services, which are poorly developed in our region.
5. Were thought to be able to understand instructions (this necessarily included the post-surgery primary care giver). No account was taken of the educational status in the selection of patients but the educational status was recorded.
6. Agreed to the procedure as offered.

Patients with suspected bile duct stones on the basis of discriminant analysis of age, history, biochemistry, and radiology had preoperative endoscopic retrograde cholangiopancreatography'. There was no other exclusion criteria.

No effort was made to avoid or exclude difficult gall bladders or patients with acute cholecystitis. Consultant

Abbreviations: ASA, American Society of Anesthesiologists; DCLC, day care laparoscopic cholecystectomy

See end of article for authors’ affiliations

Correspondence to: Associate Professor Sabyasachi Bal, AIIMS, Ansari Nagar, New Delhi 110029, India; drsbal@yahoo.com

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R ecent publications have reported an increasing trend of traditional inpatient surgical procedures being performed as day care surgery, a development driven mainly by a desire to reduce health care expenditure without compromising the quality of care. Several published studies have testified to the safety and feasibility of day care laparoscopic cholecystectomy (DCLC). These reports, however, emanate from developed countries with well established norms for day care surgery with rigorously monitored outcomes. The reported safety of laparoscopic cholecystectomy cannot therefore be universally extrapolated to surgical practice everywhere.

Health authorities, quality assurance agencies, and surgeons in developing countries have traditionally been reluctant to advocate day care surgery because of major resource variations and inequity in quality of health care delivery. Consequently, there has been little or no attempt either to study the feasibility and safety of DCLC in these countries or to define viable recruitment criteria and determinants of acceptable outcomes of day care surgery.

Surgical groups in developing countries planning major day care surgery are thus severely constrained by the absence of published and validated models which can prospectively determine the safety of early discharge. Most centres have had to define their own methodology, using clinical trials. This is unsatisfactory because outcomes in clinical trials cannot always be predicted and may not be rigorously monitored.

This study describes the process of developing DCLC in a tertiary health care hospital of a developing country without a free standing facility or department for day care surgery and its successful integration into the regular surgical services of the hospital.
surgeons took informed consent and a departmental ethical clearance was obtained.

Premedication and anaesthetic management
A consultant anaesthetist saw all patients in the four weeks before surgery and assigned the ASA physical status score grade. Patients were given an information booklet outlining the procedure, potential problems, and details of perioperative care. Any change in status since the earlier evaluation was noted on the day of surgery using a predetermined proforma. The patients were admitted at 08.00 hours on the day of surgery and were initially (first 50 patients) done as first patients on the list; later, the order in the list was variable provided the surgery was over by 3 pm. This allowed a clear five hours for observation before discharge. Although we have a designated recovery area, there are no nursing staff after 8 pm. All monitoring after this time has to be done by surgical residents; this was thought to be impractical for the purposes of this study.

No premedication was used. Intramuscular diclofenac 50 mg and metoclopramide (for the first 12 patients) or ondansetron tablets to be used on a regular basis were given intravenously at induction. Parenteral diclofenac, metoclopramide, or ondansetron were used whenever indicated. Patients were assessed every 30 minutes by a member of the surgical team for pain, nausea, and vomiting. They were encouraged to sit up, drink as soon as possible, and to go to the toilet under supervision. An assessment chart, based on previously published literature, was used to assess the patient.

Patients were discharged if they were stable, fully conscious and if:
(1) The surgeon did not anticipate any problem from the operation.
(2) There was minimal nausea or vomiting.
(3) Pain was controlled or minimal.
(4) Patients were able to go to the toilet without much difficulty (located about 25 metres from the recovery room).
(5) Patients were able to dress themselves.
(6) Patients were confident about going home.

Patients not satisfying any of the above criteria were admitted. Before discharge, all patients were given 50 mg diclofenac intramuscularly and were prescribed diclofenac and metoclopramide or ondansetron tablets to be used on a regular basis for three days and then used only if required. Telephone numbers of the ward, the resident on call, and the consultant were provided. It was mandatory for the patient (or their care provider at home) to ring the consultant at home the next morning at a predetermined time to give a status report. A bed was kept vacant in the ward till patients phoned in (for the first 25 cases); the practice was later discontinued as experience and confidence improved. Waiting times for all patients undergoing outpatient cholecystectomy was calculated from the date of their first outpatient attendance. Simultaneously as an audit process, the waiting time for 126 patients undergoing DCLC between January 1996 to June 1997 was obtained.

Patients were reviewed at seven days. A published classification system was used to define complications. In the absence of any problems, patients were discharged from follow up. A patient satisfaction questionnaire was filled for all patients. The two tailed t test for independent observations was used for analysis of data relating to waiting periods; p<0.05 was taken as significant.

RESULTS
A total of 383 patients were evaluated for DCLC during the study period; 313 were found suitable (table 2). The mean waiting times for patients undergoing DCLC and inpatient procedure was 39 days (SD 9.6, range 9–63 days) and 136 days (SD 14.7, range 42–216 days) respectively (F test for equality of variance = 2.3447 (125, 312) df, F:0.0000; T for equal variances: −81.3872 p≤0.0000; T for unequal variances: −68.4280 p≤0.0000).

One hundred and twelve patients (36%) did not have personal telephones. In 126 patients (40%), the primary care provider had schooling only until primary level.

Of the 313 patients, 290 patients (92%) were discharged within 2–8 hours of the operation (median 4 hours). The

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<th>Table 1 Patient details</th>
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<tr>
<td>Total patients operated (June 1997 to June 2000)</td>
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<td>Selected for outpatient surgery</td>
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<td>ASA grade I</td>
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<td>ASA grade II</td>
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<td>ASA grade III (controlled hypertension/diabetes)</td>
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<td>Age range</td>
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<td>Sex (M:F)</td>
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<th>Table 2 Reasons for unsuitability for DCLC</th>
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<tr>
<td>Unsuitable ASA grade</td>
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<td>Cancellation</td>
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<td>Age greater than 65</td>
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<td>Unsuitable social conditions</td>
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<td>Lived out of defined area</td>
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<td>Suspected CBD stones</td>
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<td>Patient preference</td>
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*Three patients initially cleared during first evaluation were found to have uncontrolled hypertension; one also had arthritias. CBD, common bile duct.
reasons for failure to discharge are shown in table 3. Six of the 10 (60%) patients with drains were discharged with drains in situ. These were removed after 48 hours in the ward. The remaining four with drains were admitted for observation (table 3). Three were discharged the next morning; one patient, complaining of unexplained pain and tachycardia, was discharged after three days. Five patients (2%) were converted and an open cholecystectomy was performed. They were discharged between three to five days after surgery. Nine patients (3%) could not be discharged due to severe nausea or vomiting; they were discharged next morning.

Eight patients (3%) were readmitted three to five days later with pain and abdominal distension. Six of these eight (75%) recovered on conservative management and were discharged 18–72 hours after readmission. Two patients (2%) were converted and an open cholecystectomy was performed. They were discharged after eight days.

A major problem has been the absence of safe guidelines. There was little published experience of day care surgery from developing countries until recently. Existing experience relates to practice in private health care centres where facilities are in accordance with published western guidelines. A centre without previous experience, and without infrastructure to support major day care surgery, needs to evolve well reasoned guidelines with a rigid and honest appraisal of outcomes to identify deficiencies and potential pitfalls. The absence of malpractice litigation in our surgical practice puts an even greater responsibility on those advocating major day care surgery. Table 5 summarises our results and compares them with the experience reported in the literature.

The viability of our inclusion criteria and the feasibility of day care surgery in our practice was analysed using successful discharge, readmission and complication rates, ease and accuracy of follow up, impact on resident training, and the potential benefit to our surgical service from day care surgery based on DCLC as a model was examined.

Eighty two percent of patients met the criteria for eligibility. Of those found unsuitable, 50% (36/70) were rejected only because they lived out of the defined area. This is common in centres with better infrastructure, resources, and "reputation" referral territories and where patients often have to travel to centres with better infrastructure, resources, and "reputation".

Ninety two percent of patients were successfully discharged thus superficially validating our recruitment criteria. Three of our entry criteria (criteria 2, 3, and 4) are new and have not been reported previously.

The choice of a 20 km radius as the outer limit for entry to our study was arbitrary. This is obviously a variable that depends on economic resources, existing transport services, and the geography of the terrain and our criterion is merely illustrative and intended to serve only as a guideline and methodology tool. Though the onus of reaching the hospital.
for perioperative problems was on the patient, our results sug-
ggest a satisfactory outcome if patients and relatives under-
stand the issues related to day care surgery and the response
expected from them. It also appears that domiciliary
perioperative care, even in our set-up, is feasible and reliable.
Perioperative care needs clearly defined and under-
stood, similar results can probably be achieved in most situa-
tions. In this context, our selection criteria appear to be both
valid and practical.

Our study can be criticised on the grounds that patients
were exposed to unwarranted risks by use of criteria that had
not been validated. This criticism is valid and we concede that
there should be better ways of undertaking feasibility studies.
Unfortunately when we began the study, there were no objec-
tive methods or models available to determine the safety of
early discharge. A recent public publication has illustrated the use of
a simulation model to study transition of care.3 This model has
now been validated and in future, it might be more appropri-
ate to use the model before adopting day care surgery as rou-
tine, especially where experience is small. It must be pointed
out, however, that even minimally literate patients respond
satisfactorily to the demands and responsibilities of day care
surgery and should not be eliminated for this reason alone.

Cancellation on the day of surgery is an indirect indicator of
the quality of day care services. Besides causing inconvenience
to patients, it adversely affects surgical schedules (thereby
annulling the benefits of day care surgery). In addition, a high
cancellation rate suggests deficient initial preanaesthetic
evaluation, which is potentially dangerous. Fewer than 1% of
patients had their operation cancelled on the day of surgery.
A few cancellations are acceptable because new clinical situa-
tions may arise after the earlier evaluation, especially if there is
a significant time between evaluation and surgery; this
happened in three of our patients. Since such changes in clini-
cal status jeopardise patient safety, a close watch needs to be
kept for comorbid conditions that are known to change (for
example, hypertension) over short periods. Further, alteration
of social conditions in the waiting period must also be looked
into. These issues have not been adequately addressed in pub-
lished literature; also, the optimal interval between preopera-
tive anaesthetic evaluation and surgery is uncertain. It has
been recently suggested that this could be up to 30 days for
low risk patients and this is supported by our own experience.
For high risk patients being considered for day care surgery,
the evaluation probably needs to be done as close to surgery as
feasible. There are no studies which have examined this issue
and definite recommendations do not exist. While successful
day care surgery has been reported in high risk patients,1 the
degree of selection exercised in these studies is uncertain.
In most cases, and certainly in conditions like ours, it is probably
better to limit day care surgery to ASA grade I and II patients.

Unplanned admission after day care surgery is an indicator
of quality assurance:3; 3% of our patients needed readmis-
sion. However, only 2/290 patients (<1%) required further
surgery. Both these patients developed complications five days
after discharge and were unlikely to have been examples of
missed diagnosis during initial discharge. Similar experience
has been reported in the literature and is not a specific prob-
lem of day care surgery. Our criteria for discharge are
therefore, satisfactory; the discharge parameters, based on
published criteria, also appear to be reliable.1

Follow up by telephone is the commonest and most cost
effective method after day care surgery. If published guidelines
were to be rigidly followed, countries with poor telecommuni-
cation infrastructure would necessarily have to restrict the
ambit of day care surgery, negating its impact on health care
infrastructure would necessarily have to restrict the
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There is now carefully reviewed evidence that resident training is satisfactory in a well defined training programme where laparoscopic cholecystectomy and day care surgery have been well integrated into training objectives. Planning of services and resource management are going to be the dominant issues of the future and an efficient day care surgery programme will provide invaluable training in the planning of guidelines, assessment of patients, and use of alternative methods of follow up. This will lead to better surgical decision making and acquisition of management skills in scenarios different from traditional inpatient environment.

Authors’ affiliations
S Bal, L G S Reddy, R Parshad, R Guleria, L Kashyap, All India Institute of Medical Sciences, New Delhi, India

REFERENCES