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
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 8 mg was given intravenously before the start of anesthesia as prophylaxis against postoperative 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:
(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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<td>Total patients operated (June 1997 to June 2000)</td>
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<td>Selected for outpatient surgery</td>
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<tr>
<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>Median</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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*Three patients initially cleared during first evaluation were found to have uncontrolled hypertension; one also had arthritism. CBD, common bile duct.
DISCUSSION

Day care surgery is possibly the clearest and most evident example of economy in any health care system. Evidence supporting safety of major DCS including laparoscopic cholecystectomy is predominantly composed of case series of selected patients. Universal extrapolation of published experience is potentially dangerous because poor and unacceptable outcomes have been reported. The risk may be even more in economically deprived countries where low literacy rates, lack of reliable and efficient transport, absence of organised referral patterns, poorly developed communication systems, underdeveloped primary health care services, and absence of community nursing have prevented the successful introduction of major surgical operations as day care surgery. Unfortunately, these are the very countries that could benefit most from day care surgery by reducing health care expenditure and waiting times.

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, admission 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 developing countries and highlights a major problem in the organisation of day care surgery where there are no defined 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 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.

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for perioperative problems was on the patient, our results sug-
gest 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. Problems of day care surgery were 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 publication has illustrated the use of
a simulation model to study transition of care. 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, 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% 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.

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
delivery. Our data clearly show that follow up can be equally
reliable if patients are asked to telephone the hospital rather
than the traditional method of medical teams contacting
patients.

During the initial part of the study (first 45 patients)
consultants assessed patients after day care surgery using a
structured proforma, but as experience grew residents took
over this job. All patients (n = 17; 6%) who called the hospital
with perceived problems were satisfactorily assessed using a
structured interview. Structured forms have been shown to be
a better assessment tool compared with narrative notes and
they also help in training medical personnel.

The most important benefit of day care surgery is reduction
in health care expenditure but benefits are not necessarily
similar for all countries. The cost of surgery in developing
countries is low \textit{vis a vis} those in developed countries. An
expectation of reduction in costs would be rational but our
data do not permit us to project a categorical benefit. There
may, however, be another definite advantage of day care
surgery that is relevant to surgical practice in developing
countries as described below.

The number of surgical beds in any hospital, including ours,
are relatively constant and non-flexible. Since our region has a
high prevalence of gallstones, a large number of beds are used
for cholecystectomy. This causes delays in the care of patients
with more serious medical problems such as malignancies and
emergencies. Additionally, more than 60% of patients are from
outside the proposed geographical area of our hospital.
Repeated journeys to the hospital for evaluation and therapy
increase cost of health care tremendously. Inpatient evalua-
tion is often the most efficient approach to diagnosis and
therapy in these groups but can often run into problems since
beds may be blocked by patients with benign but widely
prevalent surgical disease. Surgery, however, continues (as shown by the long waiting period for patients undergoing
inpatient cholecystectomy) to favour more serious illnesses
but this may be unfair to patients with benign diseases like
gallstones, because it delays treatment. Benign diseases often
occur in those who are relatively young, who are in the most
productive period of life, and who may have young depend-
ents. Moreover, symptoms and complications of benign
diseases including gallstones can be severe or even life threat-
ening. It is therefore necessary to achieve an optimal balance
without compromising care of groups with more complex dis-
case. Our study has shown reduction in waiting times for patients undergoing day care surgery compared with inpatient
cholecystectomy. The study has also transferred a large
number of patients with gallstones (who would otherwise be
treated as inpatients) to day care surgery thereby leading to
better bed utilisation. This has also been the experience of
other groups.

This outcome is theoretically beneficial but it is not a long
term solution to the complex issue of equitable distribution
of acceptable health care for the two groups and problems are
bound to arise in the future. It is the recognition of this future
problem that makes the result of our study so important. Our
results should encourage additional studies to expand the list
of procedures that can be brought under the umbrella of day
care surgery. It should also provide health authorities with
viable options while planning solutions and act as evidence
based impetus for the development of exclusive day care
facilities. In this way, the management of both simple and
complex health problems can receive equitable attention and
would become more efficient.

The last issue concerns surgical training. Objections have
been raised about several aspects of training where day care
surgery has been used. It is our belief that maintaining the
dual objective of ensuring patient safety while training
residents is feasible and training can proceed unaffected in a
well supervised programme of day care surgery. Sixty one per-
cent of the operations in the study were performed by
residents with similar outcomes to those performed by
consultants. Residents also participated in evaluation, peri-
operative assessment, and follow up of patients. This demon-
strates that training and acquisition of operative experience
need not suffer in active day care programmes and that train-
ing and ensuring patient safety are not mutually exclusive.
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.

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REFERENCES