





# Can laparoscopic cholecystectomy be a same-day procedure?<sup>1</sup>

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### Abstract

Gall bladder surgery by video-laparoscopy (VL) can now successfully fulfill the same goals as traditional surgery and is associated with comparable, if not better, results both in terms of positive surgical outcome and patient satisfaction. With public health spending under growing social and administrative pressures, and continuous efforts being focused on enhancing the efficiency of both surgical instruments and operating procedures, it is a most attractive, albeit initially challenging, prospect to regard video-laparoscopic surgery as day-care surgery. In the period January 1994 to December 1996, 1334 patients underwent VL cholecystectomy (898 were women and 436 men). A total of 1034 laparoscopies used gas and 300 were gas-less. Of the 1334 patients, 72 (5.4%) were treated on an outpatient basis. The authors assess this option, in light of recent technical developments and of the relevant major organisational and professional implications, and consider the feasibility of a day-care surgery project which might be implemented. © 1997 Elsevier Science B.V.

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## 1. Introduction

Historically, surgeons have classed day case procedures as minor surgery. In recent years, an increasing number of surgeons have focused their attention on the new notion of 'major day case surgery', which involves greater commitment, and an in-depth understanding of the relevant clinical, surgical and organisational aspects. This has occurred because surgeons have been forced to modify their attitude and behaviour for reasons that are both scientific and financial.

There is no doubt that this type of surgery demands a great deal of experience as well as adequate technical skills. Video-laparoscopic (VL) surgery also requires the surgeon to acquire an in-depth understanding of the specific instruments, and to develop very keen eyesight.

These fundamental objectives must necessarily be fulfilled if the surgeon is to avert risks and complications which may, at times, be very serious.

The financial pressures that have driven the demand for new treatment approaches and clinical evaluation methods are essentially the following: in-patient beds are being eliminated in many wards, and consequently it is difficult for patients to be hospitalised for anything less critical than cancer or acute emergencies, therefore ward waiting lists are growing steadily; hospital administrators are keen to cut spending as a result of the skyrocketing costs associated with hospital care; and payments now tend to be made in respect of individual treatments, rather than ward stays. Hence the need to carefully review which operations are best suited to day-surgery.

Same-day surgery should ideally be adopted when the procedures are of minimal to moderate difficulty, the duration of the procedure is limited and the incidence of serious complications decisively low. Furthermore, the post-operative period should be virtually pain-free for the patient.

The onset of interventional radiology, surgical endoscopy, hernia repair and minimally invasive vein surgery, in addition to the latest anaesthetic techniques, have greatly increased the indications for day-care surgery. It must be emphasised, however, that none of these procedures involves opening the peritoneal cavity.

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Since the dawning of the laparoscopic era in the 1960s, research has permitted awesome progress to be made, and with video technology dramatically enhancing the surgeon's view of the surgical field, diagnostic and surgical indications that seemed farfetched even a few years ago have now become routine.

As far as VL cholecystectomy is concerned, it is quite feasible that the development of so-called 'pharmacological' treatments for gallstones may have discouraged some surgeons from endeavouring to improve their operating technique. Later disappointments surrounding attempts to dissolve or shatter stones have led to cholecystectomy being appreciated as the definitive gallstone procedure, driving research efforts toward minimising problems associated with scarring, post-operative paralytic ileus, and pain, and thus shortening the duration of ward care.

Cholecystectomy is one of the most common procedures performed in Italian hospitals. In the US an estimated 500 000 operations are carried out every year. with a mean ward stay until a few years ago, of 3-5 days. With the advent of minimally invasive laparoscopic cholecystectomy many patients are out of bed hours after surgery. Post-operative pain is minimal; scarring at the stab wound site is as a rule only mildly tender; abdominal discomfort is generally restricted to the first 24 h post-operatively; occasionally there may be some tenderness in the scapular region associated with pneumoperitoneum, which however subsides very quickly. Painful meteorism is avoided thanks to the absence of paralytic ileus and the almost immediate return to normality of the digestive system, so that the patient can take oral fluids within hours of surgery, and the diet can virtually return to normal on the following day. There is a rapid return to work and to a normal social life, with obvious benefits for the patient, the family and society as a whole [1-11].

Therefore it is quite reasonable to assume that using this technique which minimises patient discomfort and adverse post-operative effects cholecystectomy might be considered feasible as a day case.

# 2. Materials and methods

We retrospectively assessed the case studies of three surgical centres located in Lombardy: the Institute of General and Thoracic Surgery of the Ospedale Maggiore Policlinico in Milan; the General and Minimally Invasive Surgery Department of the Policlinico San Marco in Zingonia-Osio Sotto (Bergamo); and the General Surgery Division (7th floor) of the Ospedale San Carlo in Milan.

In the period January 1994 to December 1996, 1,334 patients underwent VL cholecystectomies (898 were women and 436 men). Of these 1034 laparoscopies used gas and 300 were gas-less.

The average age of the patients was 51 years (range 11–87). Of the total number of patients 1177 (88.2%) presented with simple gallstones (including 60 with associated conditions), 78 (5.9%) presented with acute cholecystitis (two with associated conditions), 59 (4.4%) with chronic cholecystitis (one also had a leiomyosarcoma of the small intestine) and 20 patients (1.5%) had other assorted diseases.

Of 1334 patients 896 (67.2%) belonged to ASA class I, 387 (29%) to ASA class II, and 51 (3.8%) to ASA class III

All the VL cholecystectomies using gas were carried out under general anaesthesia, while 15 of the 300 gas-less procedures were carried out under epidural anaesthesia following injection of an anaesthetic mixture at the level of L2-L3/L3-L4/L4-L5. Of these 15 cases, 11 were classed as ASA I, three were ASA II and one was ASA III; the anaesthetic assessment contra-indicated general anaesthesia due to the presence of associated diseases such as BPCO, hypertension, diabetes mellitus and dilated congestive cardiomyopathy.

The average hospital stay for all patients was 3 days (range: 24 h-5 days). Of the patients who had the conventional procedure using gas, 12 (1.2%) were discharged within 1 day of surgery, 14 (1.4%) within 2 days, 687 (66.5%) within 3 days, 213 (20.6%) within 4 days and 107 (10.3%) within 5 days.

As regards the patients who were subjected to a gas-less cholecystectomy procedure, the average ward stay was 24 h for 60 patients (20%), 2 days for 180 (60%) and 4 days for 60 patients (20%).

Out of the total 1334 patients who underwent VL cholecystectomy with or without gas, 72 patients (5.4%) were treated on an outpatient basis.

Eighty percent of the patients discharged beyond day 4 post-operatively were kept on the ward for primarily logistic reasons: e.g. they lived too far away from the hospital, or were living alone; in some cases there was a suspicion that adequate care might not be provided by family members; and several patients were elderly and not satisfactorily cooperative.

The naso-gastric tube was removed from 1248 patients (93.6%) within the first 24 h; it was removed immediately upon leaving the operating theatre in 998 patients (80%), about 5 h following surgery in a further 150 (12%), and over 6 h later in the remaining 100 (8%).

Of the total 1334 patients 1170 (87.7%) were able to take oral fluids within the first 24 h, 1110 (94.9%) only 4 h after the operation, 42 (3.6%) after 6 h and 18 (1.5%) after 8 h.

Normal bowel movements resumed on the first day in 1213 patients (90.3%).

Of the patients who underwent the VL cholecystectomy using gas, only three (0.3%) required a bladder drain, which was removed during the first day. All 300

patients who had the gas-less procedure were routinely fitted with a catheter, which was removed within the first 24 h. Episodes of urinary retention occurred in only three (0.2%) of the total 1334 patients.

The presence of low-grade benign prostatic hypertrophy is not a contraindication to a same-day procedure. In our series, we encountered 10 cases of known BPH, of which seven were stage 1 and 2, and three were above stage 3. Of the BPH stage 1 and 2 patients, none developed urinary retention, while all three patients with grade 3 or above disease did develop one episode of urinary retention. Of the total number of patients 923 (89.3%) treated laparoscopically with gas and 291 (97%) of those given the gas-less procedure—totalling 1214 (91%)—were back on their feet within 24 h. Ninety five percent of these were walking normally within 3 h of surgery.

Revision surgery was required for only one patient (0.1%) out of the 1334 cases treated. This patient was returned to the operating theatre on day 2, following the formation of a sub-hepatic haematoma.

Drains were placed in 319 (23.9) patients, of whom 19 (1.8%) had the conventional cholecystectomy procedure using gas. This latter group included two patients (0.2%) with acute cholecystitis, five (0.4%) with chronic cholecystitis, 11 (0.8%) patients with gallstones associated with cirrhosis of the liver, and one (0.1%) with choledochocholecystic lithiasis.

Generally speaking, the patients with uncomplicated gallstones treated laparoscopically with gas insufflation never required a drain, which was positioned only in patients at increased haemo-coagulative risk. This approach was possible thanks to the characteristic laparoscopic view of the surgical field, which is highly magnified and therefore affords very accurate haemostasis.

In the group treated with the gas-less procedure, the drain was positioned routinely regardless of specific patient conditions. However, the drain was removed within 24 h in 99% of the patients.

Intra-operative complications appeared in 0.3% of the patients, but were never serious enough to warrant conversion to an open procedure.

Eleven patients (0.9%) developed post-operative complications: two pseudo-obstructions on day 3; one case of persistent post-operative pain on day 1; one Transient Ischemic Attack on day 1; two cases of vomiting that did not respond adequately to antinausea treatment; two cases of arrhythmia: one atrial fibrillation and one tachyarrhythmia on day 5, both controlled by specific therapy; one admission to intensive care due to the onset of-pulmonary oedema on day 3; one case of haematoma in the vicinity of the umbilical stab wound; and one case of slight biliary leakage (at the drainage site) which did not require the procedure to be repeated.

## 3. Discussion

Since 1987, laparoscopic cholecystectomy has virtually replaced open cholecystectomy for the treatment of gallstones [21]. This is due to the excellent view that the surgeon has of the surgical field, combined with the negligible discomfort experienced by the patient. Keimbeck carried out a study on 19 patients who underwent laparoscopic cholecystectomy, and none of them reported nausea or vomiting or required medication of any kind. The patients were allowed to go home on the same day as the procedure, and were checked on every 6 h. All stated that they resumed eating light meals about 6 h after surgery, and at the 1 week follow-up, 18 (94.7%) reported that they went back to work after 2 days [12].

Several authors have stressed that patients operated on laparoscopically require less analgesics than those submitted to the open procedure [13–15].

Delaunay evaluated nine ASA class 1 patients who underwent laparoscopic cholecystectomy. They were seen on the same day as the operation, on day 3 and again on day 10 post-operatively. The author checked patient discomfort, heart rate, arterial  $pO_2$ ,  $O_2$  and  $CO_2$  consumption, and observed that the post-operative values were not significantly different to the pre-operative values. This confirms diminished muscular and cardiorepiratory impairment after laparoscopic cholecystectomy [16].

In economic terms, Fullarton observed that out of 100 laparoscopic cholcystectomies carried out between 1990 and 1992, the costs associated with the first 50 cases were only slightly lower than the cost of open cholecystectomy. In the next 50 cases, the difference was more markedly in favour of the laparoscopic procedure. Obviously the experience of the surgeon contributes not only to improving the technical outcome, but to better controlling complications and post-operative sequelae, which are the principal causes of longer hospital stays and higher costs [17].

In a study involving 55 surgeons who had performed 8839 laparoscopic cholecystectomies between 1989 and 1993, Moore stressed that, depending on the surgeon's technical skill, the likelihood of causing a VBP lesion in the course of the surgeon's first case was 1.7%, but dropped to only 0.17% during the 50th case [18].

The parameter measured by Peters was the average duration of the procedure. He reported that over a period of 6 months, after 100 VL cholecystectomies, this parameter dropped from 122 + 45.4 to 78.5 + 30 min [19].

Traverso estimated that 60% of the costs associated with a VL cholecystectomy pertain to the operating theatre: i.e. the use and maintenance of the surgical instruments account for 17% of the costs for the entire in-patient stay, and 28% of the costs pertaining to

theatre maintenance. Operating theatre personnel account for 24% of the total cost of the patient's hospital stay, and 41% of operating theatre costs. Accordingly, in order to contain the cost of the operation, surgeons should try to shorten the duration of the procedure, a factor depending largely on their experience and technical competence [20].

As already underlined, the average hospital stay of a patient undergoing a VL cholecystectomy in most centres, is 2-3 days [21]. However, in view of the low postoperative complication rate and the speed of recovery (immediate removal of the nasogastric tube, absence or early removal of urinary catheter, absence or early removal of drain, absence of significant pain, nausea and vomiting, early mobility, early normalisation of bowel movements and fast return to a normal diet), some centres have proposed performing laparoscopic cholecystectomy as a day-surgery procedure [22].

The greatest hurdles in successfully managing laparoscopic cholecystectomy as a day-surgery procedure are on the one hand represented by the patient's diffidence—many patients fear that they will be given inadequate post-operative care—on the other hand, some surgeons feel that since the procedure is intra-abdominal, albeit far less traumatic than the traditional technique, better direct post-operative care is needed than a same-day procedure can afford.

Already in 1989, several Anglo-Saxon authors spoke in favour of same-day patient discharges and soon thereafter began reporting their results. Between 1989 and 1991, Arregui performed 622 VL cholecystectomies, 106 of which were on a day-surgery basis. None of the patients required post-operative admission, and only one patient was sent home with medication to counteract vomiting [23].

Various authors have proven the feasibility of carrying out the procedure and managing it post-operatively on a day-surgery basis, including Prasad and Foley. who studied 103 patients undergoing VL cholecystectomy. Of the total 103 patients 42 were selected to have the operation as a day case. The patients were under 60 years of age, belonged to ASA class I or II, had explicitly asked for the procedure to be carried out on an outpatient basis, had no history of jaundice or drug intolerance and lived close to the hospital. The average duration of the anaesthesia was 70 min (ranging from 60 to 95 min), and the average duration of the procedure was 43 min (range: 20-65 min). At the end of the operation, after spending 2-3 h under observation on the ward, the patients were invited to mobilise, take oral fluids and pass urine. At the conclusion of the observation period, it was decided whether the patient could be discharged. The authors reported no significant post-operative complications in the group [24].

What pre-, intra- and post-operative parameters can be used to guarantee that discharging the patient is 'safe', and what compulsory procedures must be implemented and subsequently evaluated for this purpose?

The pre-operative evaluation is a critical step toward ensuring a correct indication and avoiding disagreeable surprises (ASA class, associated illnesses, clinical history, location of patient's home, psychological status, physical conditions, physical examination).

The patients booked in for a cholecystectomy on a day-surgery basis must necessarily be studied with the utmost attention. They should be put on a separate waiting list than the normal ward list, to facilitate an accurate pre-operative work-up.

The patients should begin with a day-hospital schedule including all the various routine pre-operative blood chemistry and instrumental examinations, with special attention being focused on the cardio-vascular system. The purpose of the work-up is to rule out any conditions, pathological or not, which may contraindicate the day-surgery procedure. The inclusion criteria shown in Table 1, are namely: patient motivation; age < 70 years; ASA class I or II; body mass index < 35; clinical history of biliary colict; absence of anxiety; no history of jaundice; no suspected bile duct stones; total anaesthesia not contraindicated; and the assurance of someone at home prepared to provide help, if necessary.

Any associated medical disorders need to be carefully evaluated. Jaundice or a suspicion of stones in the main bile duct should be ruled out by endoscopic retrograde cholangiopancreatography (ERCP) followed, if necessary, by papillotomy to remove the stones, or, alternatively, an interoperative cholangiography can be performed during the laparoscopic procedure, followed by choledochoscopy and removal of the stones through the cystic duct.

During the pre-operative examination, the patient must always be informed of the possibility that the laparoscopic procedure might need to be converted to an open procedure (the conversion rate reported in the literature is around 3.7%).

Table 1 Inclusion criteria

Outpatients	Inpatients
Age < 70 years	Age < 70 years
ASA I, II	ASA III, IV
Body mass index <35	Body mass index >35
Biliary colic	Acute or chronic cholecystitis
No history of jaundice	Clinical history of jaundice
No suspected main bile duct calculi	Anxious personality
Motivated	Previous attempts at day-surgery
	failed
	Living alone
	Home far from hospital or without telephone

The operation must be carried out in a suitable environment and operating theatre. The surgical and anaesthetic team must be well qualified to perform this type of procedure and, above all, trained to follow up the patient after being discharged and sent home. The patient may be given mild premedication, in the literature, several authors claim that none is necessary; I.V. and I.M. antiemetics and pain medication should be available during the post-operative period.

The intra-operative evaluation focuses on how easily the procedure is performed, and whether there is any suspicion of immediate complications such as vascular, biliary or visceral lesions. Further parameters include the normal induction of and awakening from anaesthesia, together with the total absence of suspected complications associated with pneumoperitoneum. At the conclusion of the procedure, great attention must be devoted to eliminating virtually all the gas insuffflated into the abdomen, so as to reduce the risk discomfort due to scapular pain [25].

The post-operative evaluation must make reference to the rapid removal of the nave-gastric tube; the patient's ability to take oral fluids without nausea and/or vomiting; removal of the bladder catheter, if used; rapid recovery of normal diuresis; early mobility and when used early removal of the drain. Furthermore, the patient must feel little pain, be able to walk unaided and be alert and conscious.

It is essential for all vital signs to be within the normal range. The decision to discharge the patient must be taken jointly by the surgeon and the anaesthetist. On discharge, patients are given only oral analgesics, and are accompanied home. Within 24–48 h the surgeon checks up on them by telephone.

Our experience with 1334 consecutive cases confirm the findings reported in the literature. When well defined protocols and indications are complied with the patients make a speedy and uneventful recovery and the rate of clinically signficant complications is relatively low. In our series, the total incidence of conversions, repeat procedures and intra- and post-operative complications warranting admission to an in-patient ward, amounted to 1.8%.

Of the total number of patients 93.5% reported normal gastro-intestinal functions within 24 h; 90.2% of the patients were able to take oral fluids on the same day as the operation and had bowel movements within the first day post-operatively.

Recovery of diuresis was rapid and no bladder catheter was required in most of the cases where gas was used (99.7%); in the rest, the catheter was removed in 93.6% of cases within the first 24 h, and only 0.3% of the patients reported episodes of urinary retention.

Obesity was not found to be an absolute contraindication to day-surgery. In our series we treated nine obese patients and none presented unusual post-operative sequelae compared to the non-obese patients.

Even patients of advanced years (i.e. aged over 65-70) can be treated on an out-patient basis. Of course their general health must be good and there must be a low anaesthetic risk. In such cases the use of selective spinal anaesthesia—which we opted for in the gas-less procedures—proved beneficial and effective.

No post-operative infections were reported.

The literature mentions the unfavourable effects of pneumoperitoneum on cardiorespiratory functions and the acid-base balance in patients with cardiac or bronchopulmonary disorders [26,27]. In our series of procedures using gas, we noted the appearance of arrhythmia or metabolic acidosis in only 0.2%. Of course, it was intended that gas-less laparoscopy and epidural anaesthesia should exclude the risk of complications associated with pneumoperitoneum, in cases considered to be at risk from this procedure.

We observed post-operative complications serious enough to advise against a rapid discharge in less than 1% of the cases that underwent conventional laparoscopy, and 0.2% of the cases treated with the gas-less procedure [28-31].

## 4. Conclusion

Most American and Anglo-Saxon, and now even European centres are well equipped to treat uncomplicated gallstones in a day-surgery environment. The studies published in the literature justify and confirm the feasibility of the procedure.

Several reports in the literature, already mentioned in this paper, have presented encouraging results in terms of the parameters for carrying out VL cholecystectomy in total safety and the subsequent protected discharge of the patients. In selected case studies, the authors report very accurate data on the removal of the navegastric tube and bladder catheter, and the time it took patients to resume oral fluids and normal diuresis; conversely, there are no convincing protocols or indications regarding the placement and removal of drains. This aspect is probably more strongly influenced than other parameters by the experience and individual preferences of the surgeon.

Based on experience acquired both in the principal European and American centres and in our own hospitals, we may safely conclude that when correct protocols and indications are followed, VL cholecystectomy with or without gas can definitely be carried out as a day case procedure, in patients selected on the basis of an accurate preoperative evaluation, a successful intra-operative assessment and an uneventful immediate post-operative period. However, the procedure can only be performed in centres featuring a strong positive attitude towards 'day-surgery'. Staff must be suitably trained for shorter, but closer patient contact, schedules

must be well-planned, follow up at the patient's home must be carried out routinely, and it must be possible (i.e. both administratively and in terms of personnel availability) and feasible to re-admit patients to the ward if required. These are just a few of the factors on which the success of such a project depends.

Nor should we forget the mentality and sensitivity of the patient, who must not be distressed by behaviour that could conceivably be interpreted as indifferent or negligent, for this might result in dire medico-legal consequences.

Lastly, the medico-legal aspect itself. Clear communications with the patients and their family members, an accurate informed consent questionnaire, an efficient technical and organisational approach are naturally indispensable. However, the law, the judges and the medico-legal experts must also learn to reconcile entrenched beliefs and procedures with the evolution of scientific knowledge, so that from their point of view, laparoscopic procedures such as day-surgery VL cholecystectomy, can be and are legally safeguarded.

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