ANNALS OF SURGERY
Vol. 228, No. 6, 734–740

Laparoscopic Cholecystectomy: Day-Care *Versus* Clinical Observation

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Objective

To determine the feasibility and desirability of laparoscopic cholecystectomy (LC) in day-care *versus* LC with clinical observation.

Summary Background Data

Laparoscopic cholecystectomy has been performed regularly as outpatient surgery in patients with uncomplicated gallstone disease in the United States, but this has not been generally accepted in Europe. The main objections are the risk of early severe complications (bleeding) or other reasons for readmission, and the argument that patients might feel safer when observed for one night. Quality-of-life differences hitherto have not been investigated.

Methods

Eighty patients (American Society of Anesthesiology [ASA] I/II) with symptomatic gallstones were randomized to receive LC either in day-care or with clinical observation. Complications, (re)admissions, consultations of general practitioners or the day-care center within 4 days after surgery, use of pain medication, quality of life, convalescence period, time off from professional activities, and treatment preference were assessed. The respective costs of day-care and clinical observation were determined.

Results

Of the 37 patients assigned to the day-care group who underwent elective surgery, 92% were discharged successfully after an observation period of 5.7 ± 0.2 hours. The remainder of the patients in this group were admitted to the hospital and clinically observed for 24 hours.

For the 37 patients in the clinical observation group who underwent elective surgery, the observation time after surgery was 31 ± 3 hours.

Three patients in the day-care group and one patient in the clinical observation group had complications after surgery. None of the patients in either group consulted a general practitioner or the hospital during the first week after surgery.

Use of pain medication was comparable in both groups over the first 48 hours after surgery. There were no differences in pain and other quality-of-life indicators between the groups during the 6 weeks of follow-up.

Of the patients in the day-care group, 92% preferred day-care to clinical observation. The same percentage of patients in the clinical observation group preferred at least 24 hours of observation to day-care.

Costs for the day-care patients were substantially lower (approximately $750/patient) than for the clinical observation patients.

Conclusion

Effectiveness was equal in both patient groups, and both groups appeared to be satisfied with their treatment. Because no differences were found with respect to the other outcomes, day-care is the preferred treatment in most ASA I and II patients because it is less expensive.

Laparoscopic cholecystectomy (LC) has become the treatment of choice for most patients with symptomatic cholelithiasis. Introduction of the laparoscopic procedure resulted in a shorter hospital stay, a shorter period of convalescence, and an earlier return to work.[1–8] In the United States, LC is regularly performed as an outpatient procedure in patients with uncomplicated gallstone disease. The results of LC in day-care are promising,[9–12] but performing LC on an outpatient basis is not generally accepted in Europe.[13] In the Netherlands, the mean hospital stay is 4 to

Supported by a grant from the Richtlijnen Commissie AMC (Committee for Development of Clinical Guidelines).
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Accepted for publication July 13, 1998.

5 days, and LC is seldom performed on an outpatient basis (according to data from the SIG Zorginformatie, Landelijke Medische Registratie).

Opponents of performing LC in day-care argue that patients discharged within 24 hours after surgery are at risk for early severe complications, such as bleeding from the cystic artery, and generally may be at risk for readmission.[14] Another argument against day-care is that patients might feel safer when observed in the hospital for at least one night. However, patients may prefer to recover at home, and day-care has the potential advantage of cost savings.

Recently, the feasibility of LC in day-care was demonstrated in a pilot study.[15] Consequently, a prospective randomized trial was conducted to compare complications, readmissions, consultations of general practitioners, convalescence, pain, and quality of life in patients treated in day-care and in patients admitted to the hospital for at least 24 hours after LC. Because the surgical procedures are identical—the only difference is the setting—we focused for sample size calculations on two questions. First, is the quality of life in patients treated in day-care after 1 and 6 weeks reasonably equivalent (within 5 points on the 0-to-100 EuroQol scale) to that in the clinical observation group? Second, is the absolute prevalence of readmission after day-care LC (expected to be 5% to 10%) less than 25%? (We considered that day-care surgery would be too cumbersome after that point.)

PATIENTS AND METHODS

The study design was a randomized controlled trial. Approval was obtained from the hospital ethics committee before the start of the trial.

Patients

Recruitment of patients at the outpatient clinic of the Academic Medical Center started in February 1996 and was completed in December 1997. The indication for LC was symptomatic cholelithiasis (according to the Rome criteria),[16] confirmed by ultrasound. Patients with an American Society of Anesthesiology [ASA] physical fitness classification[17] of III or IV, patients older than 70 years, and patients with extensive previous abdominal surgery, clinical suspicion of common bile duct stones, acute cholecystitis, and calcified gallbladder were not considered eligible for outpatient surgery and were excluded from the study. Patients had to live no more than 50 km from the hospital and were required to have an adult willing to accompany them home and to stay with them for at least 24 hours.

Consecutive patients who fulfilled the inclusion criteria were asked to enter the trial. The nature and purpose of the study were explained to the patients, and informed consent was obtained. Patients were then randomly allocated, by opening a sealed envelope, to either the day-care group or the clinical observation group. Sex, age, ASA score, comorbidity, height and weight, employment status, and nature and duration of biliary symptoms were recorded at the entry of the study. Presurgical investigation included physical examination, laboratory tests (alkaline phosphatase, gamma-glutamyl transferase), and ultrasonography of the gallbladder and bile ducts.

Surgical Procedure and Anesthesia

The LC procedures were performed during the morning by a surgeon-in-training with an experienced surgeon as an assistant. Routine cholangiography was not performed.[18] At the start of the procedure, all patients were given cefuroxime 1.5 g intravenously.

Prophylactic analgesia (paracetamol 1 g) was given as a suppository, and the trocar puncture sites were infiltrated with 0.5% bupivacaine with adrenalin before making the incision. At the time of induction of anesthesia, all patients were given ondansetron 4 mg intravenously to minimize nausea after surgery. Anesthesia was induced with propofol 2 to 2.5 mg/kg and fentanyl or alfentanil, a muscle relaxant, and maintained with either sevoflurane or isoflurane in oxygen/air.

For pain relief after surgery, a single dose of intramuscular morphine (5 to 10 mg) was given on request. All patients received 1 g naproxen as a suppository. Thereafter, the patients controlled the medication intake, and the nursing staff was allowed to provide analgesia if indicated. Paracetamol/codeine 500/20 mg was given up to 6 times per day and naproxen 500 mg up to 3 times per day.

Day-Care Group

Day-care patients were admitted to the day-care center on the day of surgery. On return to the center after surgery, they were encouraged to mobilize and start oral fluids if they were conscious and were not nauseated. Patients were to be admitted to the clinic for the following indications: after conversion to an open procedure; if acute cholecystitis was found during surgery; and if significant bleeding or bile leakage occurred during the procedure. Discharge was allowed if patients required oral pain medication only, tolerated oral fluids, could walk to the lavatory, had passed urine spontaneously, and felt confident that they could manage at home. The decision about discharge was made by both the surgeon and the anesthesiologist before 7 PM. Paracetamol/codeine and naproxen were supplied to the patients at discharge. The morning after discharge, patients were called by the day-care nurse and asked about their well-being, complaints, or complications.

Clinical Observation Group

During this study, a short-stay ward was opened in our hospital. As a consequence, the first 19 patients in the study were admitted to the hospital on the day before the sched-

uled LC for presurgical assessment by the anesthesiologist, and the next 21 patients were admitted to the short-stay ward on the day of surgery. The latter patients were seen by an anesthesiologist at the outpatient clinic. Both total hospital stay and hospital stay after surgery were determined.

After undergoing LC, patients were observed in the recovery room until considered fit enough by the anesthesiologist to return to the surgical ward. Patients stayed in the hospital for at least one night after surgery. If all went well and the patients wanted to go home, they were discharged the following morning. At discharge, patients received a form giving instructions about symptoms for which a general practitioner should be consulted: chills or a temperature of more than 38°C; an increase in abdominal pain; nausea or vomiting for more than 1 day; bleeding from the surgical wounds for more than 2 days; or pain and inflammation around the surgical wounds.

Outcome Assessment

Surgical findings (acute cholecystitis, adhesions, bile spill, and an intrahepatic gallbladder), surgical time, and complications were recorded. Surgical time was defined as the time between skin incision and closure of the last wound.

Administration of anesthesia was recorded from the anesthetist's protocol. At the surgical ward and at the day-care center, medication intake was recorded by the nurses. After discharge, medication intake was recorded by the patient.

All complications were addressed to ascertain the role of setting-specific factors.

Pain was scored by the patient 1, 6, 24, 36, and 48 hours after surgery and once a week for 6 weeks using a visual analog scale. Other quality-of-life indicators were assessed using the EuroQol questionnaire: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. With the scores obtained for each item, an overall health status score was calculated 1 and 6 weeks after surgery using the following formula: 113.99 − (mobility score × 10.22) − (self-care score × 5.77) − (usual activity score × 6.81) − (pain/discomfort score × 7.25) − (anxiety depression score × 6.69), as suggested by Kind.[19] Two additional questions about mood and overall quality of life were added (using a visual analog scale with 0 representing the worst imaginable health and 10 representing the best imaginable health).[20–22]

The length of interruption of professional activity was determined after 6 weeks of follow-up. One and 6 weeks after surgery, patients were asked to express their preference for either day-care or clinical observation.

Costs of the stay at the hospital or day-care center were obtained from the rates as given by the Centraal Orgaan Tarieven Gezondheidszorg. According to these, the cost of the postsurgical stay at the day-care center was $188. The cost of a 1-day stay in the hospital was $488. For the clinical observation group, we determined total hospital stay as well as postsurgical hospital stay. The costs of investigations, interventions, readmissions, and consultations of general practitioners or the hospital or outpatient clinic were to be determined if the number differed for the two groups.

Sample Size and Statistics

Sample size calculations focused on testing whether quality of life was equivalent in the two groups (after 1 week and 6 weeks of follow-up) and whether a readmission rate of 25% was exceeded (α: 0.05, β: 0.20).

For quality of life, an overall EuroQol score (0 to 100) was selected, with an estimated standard deviation of 10 in moderately ill patients. An equivalence sample size in this case implies that the number of patients is sufficient to rule out with α: 0.05 that the average EuroQol score of day-care patients is more than 5 points less than that of clinically observed patients (one-sided testing). A total number of 80 (2 × 40) patients is then sufficient.

For the readmission rate, only the number of patients in the day-care group was relevant. We estimated based on prior experience a probability of 5% to 10%. For logistic and clinical reasons, we decided to reject day-care as a routine option if a rate of 30% or more could not be ruled out. A sample size of 40 patients allows ruling out 25% or more, if the average ratio is 10%; with a lower average rate, the confidence interval is even lower. From this we decided to include 2 × 40 patients.

The Student's t test and the Mann-Whitney test were used to compare the data of the two study groups. Patients' ratings of outcome were analyzed by the chi square test for linear trend. All values are presented as means (SE) if not specified.

Primary results are presented for randomized patients undergoing the assigned surgery protocol. The outcomes of some patients unable to undergo the scheduled surgery (because of acute deterioration, requiring early surgery, or because the patient decided to postpone surgery) are presented separately because the measurement schedule could not be applied in a comparable way.

RESULTS

Patients

From February 1996 to December 1997, 179 consecutive patients with symptomatic gallstones were scheduled for elective LC. Of the total group of patients, 80 (44%) were included in this study. Fifty-seven (32%) of the patients did not fulfill the inclusion criteria for the study.

Forty-two other patients could have been included, but they underwent LC before being asked to participate in the study. Their baseline characteristics, mean surgical time (73 ± 6 minutes), surgical findings, number of conversions (1/42), and complications did not differ from those of the patients who participated in the study. Although clinical

Table 1. DEMOGRAPHIC DATA OF PATIENTS INCLUDED IN THE STUDY (N = 80)

	Day-Care n = 40	Clinical Observation n = 40	p value
Sex ratio M/F	12/28	6/34	0.11
Age (years)	39[20–62]	48[19–65]	0.14
ASA-score 1/2	29/11	24/16	0.24
Body mass index	25 ± 1	26 ± 1	0.25
Paid employment	73%	68%	0.63
Biliary pain			
Duration (months)	17 ± 3	13 ± 3	0.40
Frequency (×/month)	5 ± 2	3 ± 1	0.07
Previous removal of CBD-stones	2	3	0.64
Liver function tests			
Alkaline phosphatase, (>80 IU/l)	12	13	0.81
Gammaglutamyl transpeptidase, (>50 IU/l)	15	9	0.14
Enzymes both increased	8	6	0.56

observation after LC is the standard treatment in our hospital, 13 of these patients underwent LC in day-care. Two of these day-care patients were admitted to the hospital, one because of nausea and one because of acute cholecystitis diagnosed during surgery. The mean total hospital stay (58 ± 3 hours) and postsurgical hospital stay (37 ± 3 hours) of the 29 admitted patients did not differ from the results of the randomized patients in the clinical observation group.

The two study groups were comparable in sex, ASA score, body mass index, and percentage of patients with professional activities outside the home. The duration and frequency of biliary pain were not different for the two groups. Previous removal of common bile duct stones by endoscopic retrograde cholangiopancreaticography and increased levels of serum liver enzymes were evenly distributed in the two groups (Table 1).

Two patients in the day-care group and one patient in the clinical observation group desired to postpone surgery until they became symptomatic. These patients are doing well, without biliary complaints.

One patient in the day-care group and two patients in the clinical observation group were admitted to the hospital before the scheduled LC because of acute cholecystitis (2) or repeated cholangitis resulting from common bile duct stones. These patients underwent urgent LCs, and all procedures were converted to open cholecystectomies. These patients were discharged from the hospital 6 ± 1 days after surgery.

Outcomes

Surgery was uneventful in all patients (n = 74), with no difference between mean surgical time (76 ± 5 *vs.* 81 ± 5 minutes, p = 0.32). Surgical findings—adhesions (n = 17), acute cholecystitis (n = 1), intrahepatic gallbladder (n = 3), and bile spill (n = 28)—were evenly distributed. There were no conversions, and no drains were inserted.

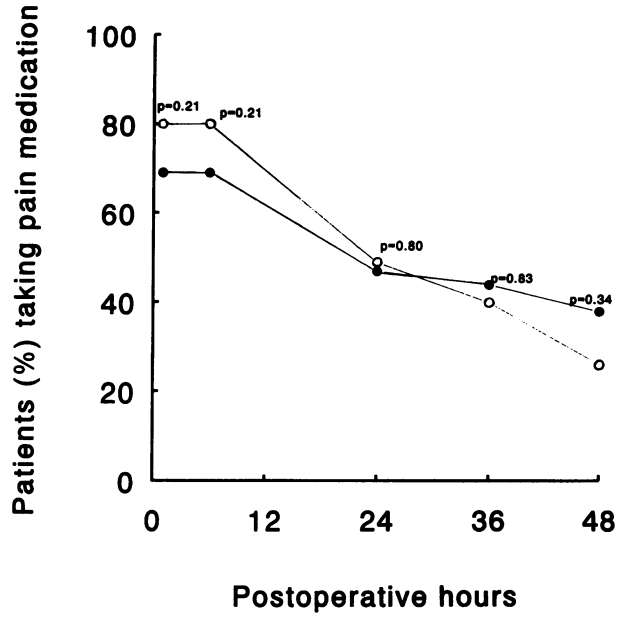

Figure 1. Percentage of electively operated day-care patients (○) and clinically observed patients (●) taking medication (naproxen and/or paracetamol/codeine) during the 48 hours after surgery.

Medication intake during the first 48 hours after surgery and pain scores are summarized in Figures 1 and 2, respectively. Fifty-one percent of the day-care group and 53% of the clinical observation group had stopped pain medication

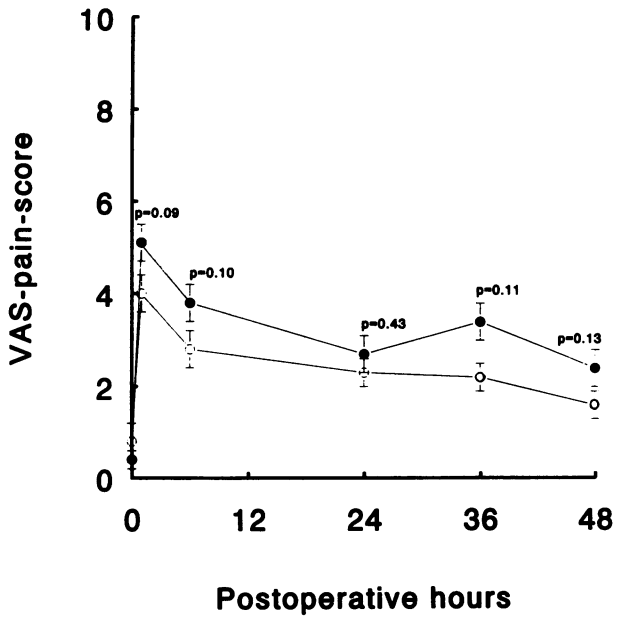

Figure 2. Visual analog scale (10 cm) pain score for day-care patients (○) and clinically observed patients (●) during the 48 hours after surgery. (Mean scores ± SE; n = 2 × 37; 0 = no pain, 10 = unbearable pain).

Table 2. FIVE ASPECTS OF QUALITY OF LIFE AS SCORED WITH THE EUROQOL QUESTIONNAIRE OF PATIENTS WHO UNDERWENT ELECTIVE CHOLECYSTECTOMY IN DAY-CARE OR WITH CLINICAL OBSERVATION. BEST POSSIBLE SCORE: 1, WORST POSSIBLE SCORE: 3. DATA ARE PRESENTED AS THE NUMBER OF PATIENTS IN THE DAY-CARE GROUP (DC) OR CLINICAL OBSERVATION GROUP (CO) THAT SCORED 1, 2 OR 3 PER ASPECT OF QUALITY OF LIFE.

	After 1 Week Follow-Up			After 6 Weeks Follow-Up		
	DC n = 32* n (%)	CO n = 36† n (%)	p value	DC n = 32* n (%)	CO n = 36† n (%)	p value
Mobility						
1 No problems with walking about	19 (60)	16 (44)	p=0.22	32 (100)	35 (97)	p=0.34
2 Some problems with walking about	12 (37)	20 (56)			1 (3)	
3 Confined to bed	1 (3)					
Selfcare						
1 No problems with self-care	28 (87)	31 (86)	p=0.87	32	36 (100)	p=0.99
2 Some problems with washing/ dressing	4 (13)	5 (14)				
3 Unable to wash or dress self						
Usual activity						
1 No problems with usual activity	7 (22)	7 (19)	p=0.94	28 (87)	32 (89)	p=0.86
2 Some problems with usual activity	18 (56)	20 (56)		4 (13)	4 (11)	
3 Unable to perform usual activity	7 (22)	9 (25)				
Pain/discomfort						
1 No pain or discomfort	10 (31)	10 (28)	p=0.65	28 (87)	29 (81)	p=0.44
2 Moderate pain or discomfort	21 (66)	23 (64)		4 (13)	7 (19)	
3 Extreme pain or discomfort	1 (3)	3 (8)				
Anxiety/depression						
1 Not anxious or depressed	28 (87)	25 (69)	p=0.26	31 (97)	31 (86)	p=0.12
2 Moderately anxious or depressed	4 (13)	11 (31)		1 (3)	5 (14)	
3 Extremely anxious or depressed						

* In the day-care group, 32 patients completed the quality of life form, of the remaining 8 patients 1 was acutely operated, 2 postponed surgery, and 5 did not return the quality of life forms.

† In the clinical observation group, 36 patients completed the quality of life form, of the remaining 4 patients 2 were acutely operated, 1 postponed surgery, and 1 did not return the quality of life forms.

intake 24 hours after surgery. The visual analog pain scores during the first 48 hours after surgery showed a similar decreasing profile. Neither medication intake nor pain scores were significantly different.

Postsurgical Complications

There were no contacts with general practitioners or the hospital or outpatient clinic because of complications within the 4 days after surgery. In the day-care group, three patients had minor complications: one patient had a wound infection and two patients had colicky pain. In the clinical observation group, one patient had a complication (wound hematoma). Except for one patient from the day-care group who became symptomatic 14 days after surgery, all complications were reported during the visit to the outpatient clinic 1 week after surgery. These complications were diagnosed after a mean period of 8 days (range 7 to 14).

Quality of Life During Follow-Up

Pain and other quality-of-life indicators (mobility, self-care, usual activity, pain/discomfort, and anxiety/depression) were comparable for the two groups 1 and 6 weeks after surgery (Table 2). Mood, quality of life, and overall health status score were not significantly different for the groups at 1 and 6 weeks of follow-up (Table 3). There was no difference in length of interruption of usual activities

Table 3. MOOD, QUALITY OF LIFE AND HEALTH STATUS SCORE ONE AND SIX WEEKS AFTER SURGERY

	Day-Care n = 37	Clinical Observation n = 37	p value
After 1 week follow up			
1. Mood*	6.1 ± 0.5	6.2 ± 0.5	0.94
2. Quality of life*	6.3 ± 0.5	5.7 ± 0.4	0.23
3. Health status score†	58 ± 2	56 ± 2	0.45
After 6 weeks follow up			
1. Mood*	7.4 ± 0.5	7.4 ± 0.6	0.79
2. Quality of life*	7.4 ± 0.5	7.2 ± 0.5	0.77
3. Health status score†	75 ± 1	73 ± 1	0.52

* Best possible score: 10, worst possible score: 0.
† Best possible score: 80, worst possible score: 3.

between the groups. The percentage of patients who had resumed their usual activities after 2, 4, and 6 weeks was 63%, 81%, and 88% for the day-care group and 65%, 83%, and 89% for the clinical observation group. Patients returned to their jobs after 14 ± 3 days for the day-care group and after 16 ± 3 days for the clinical observation group.

Treatment Preference

During interviews at 1 and 6 weeks after surgery, the percentage of patients who preferred day-care was 92% for the day-care group and 8% for the observed group. The percentage who preferred admission for 24 hours was 8% and 80%, respectively. The percentage who preferred admission for more than 24 hours was 0% and 12%, respectively.

Hospital Stay and Costs

The mean postsurgical hospital stay in the day-care group was 7.2 ± 0.8 hours. The mean postsurgical hospital stay in day-care patients who were actually discharged on the day of surgery was 5.7 ± 0.1 hours. The mean total hospital stay in the clinical observation group was 51 ± 4 hours (postsurgical hospital stay: 31 ± 3 hours). Thirty-four of the 37 patients (92%) in the day-care group who underwent elective surgery could be discharged on the day of surgery; three patients were admitted and discharged the day after surgery.

In the day-care group, no readmissions or consultations of physicians occurred within the first 4 days after surgery. No readmissions occurred in the clinical observation group, and none of the patients consulted a physician in the first 4 days after surgery.

For LC in day-care, the hospital costs were $212 ± 14 per patient. For patients in the clinical observation group, the costs for LC were $1002 ± 76 per patient for the hospital stay alone.

DISCUSSION

This study demonstrates that approximately 70% of patients with symptomatic gallbladder stones are candidates for LC in day-care and were willing to undergo this procedure in day-care. This percentage is in accordance with other studies.[9,12] The mean hospital stay in the Netherlands for LC in 1996 was 4.5 days. In the same year, only 36 patients (0.3%) underwent LC in day-care. Because 11,162 LCs were performed in 1996, the advantage for the health service of early discharge after surgery will be substantial. At least $750 per patient will be saved if the procedure is performed in day-care. If the procedure could be performed in day-care in 70% of the patients, or approximately 7800 patients, this would lead to a savings of $6 million yearly. In fact, the cost savings would probably be substantially greater, because the mean hospital stay in the Netherlands is longer than the hospital stay of patients in the clinical observation group in the present study. The shorter hospital stay was probably partly the result of the fact that the clinically observed patients had been informed that the other patient group left the hospital on the day of surgery.

The morbidity of LC has been reported to be 4% to 20%. Therefore, it has been recommended that patients be observed for at least 24 hours so that intervention can be performed quickly if major complications occur.[14] However, the incidence of a major complication such as arterial bleeding is low (1:2000), and such a complication generally becomes symptomatic within a few hours after surgery.[23,24] Another severe complication is a bile duct injury; the incidence after LC is much higher than hemorrhage (0.5%). Most often bile duct injuries are detected during surgery or become symptomatic several days after LC.[13]

Several studies have demonstrated the safety of LC with discharge on the same day.[9,11,12] In the present study, patients were observed for approximately 6 hours after surgery. Patients had to meet several criteria before discharge was allowed, and it is unlikely that patients with severe complications such as major vascular lesions would meet these criteria. No difference in the number of postsurgical complications was found between the day-care group and the clinical observation group. This was expected, because the surgical procedures were identical; there was only a difference in the setting. More important, none of the complications became manifest during the hospital stay, implying that the hospital stay did not reduce the detection and subsequent consequences of complications. Therefore, 6 hours of observation after LC appears to be sufficient.

Pain was demonstrated to be well controlled with oral pain medication, and medication intake was comparable for the two groups. Four other quality-of-life indicators (mobility, self-care, usual activities, and mood) were also not different for the two groups. Clinical observation did not

have a positive influence on the length of interruption of usual activities or paid employment. Considering all these quality-of-life indicators, it is unlikely that discharge on the day of surgery has important negative effects on quality of life. Moreover, patients who underwent the procedure in day-care were satisfied with the treatment modality they underwent.

Because no benefit of clinical observation after LC could be demonstrated in the present study, the costs that can be saved with treatment in day-care will become important.

CONCLUSIONS

The outcome of patients who underwent LC appeared not to be influenced by clinical observation after surgery. There were no differences in morbidity, number of readmissions, and various aspects of quality of life. The costs of day-care treatment, however, were considerably less than those of LC with clinical observation. Therefore, day-care LC is preferable and could be performed in about 70% of the patients.

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