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Patient-centered outcomes after laparoscopic cholecystectomy

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Abstract
Background Laparoscopic cholecystectomy (LC) is the second most common general surgical operation performed in the United States, yet little has been reported on patient-centered outcomes.
Methods We prospectively followed 100 patients for 2 years as part of an institutional review board–approved study. The Surgical Outcomes Measurement System (SOMS) was used to quantify quality-of-life (QoL) values at various time points postoperatively.
Results Maximum pain was reported at 24 h (5.5 ± 2.2), and decreased to preoperative levels at 7 days (1.2 ± 2.3 vs. 2.0 ± 1.6, $P = 0.096$). Bowel function improved from before the operation to 3 weeks after surgery (10.7 ± 3.8 vs. 12.0 ± 3.2, $P < 0.05$), but then regressed to preoperative levels. Physical function worsened from before surgery (31.7 ± 6.2) to 1 week (27.5 ± 5.9, $P < 0.0001$), but surpassed preoperative levels at 3 weeks (33.5 ± 3.4, $P < 0.01$). Return to the activities of daily living occurred at 6.3 ± 4.7 days and work at 11.1 ± 9.0 days. Fatigue increased from before surgery (15.8 ± 6.2) to week 1 (20.7 ± 6.6, $P < 0.0001$) before improving at week 3 (14.0 ± 5.8, $P < 0.01$). Forty-four patients contacted the health care team 61 times before their 3 weeks appointment, most commonly for wound issues (26.2 %), pain (24.6 %), and gastrointestinal issues (24.6 %). Seventy-two percent reported that the procedure had no negative effect on cosmesis at 6 months. Satisfaction with the procedure was high, averaging 9.52 out of 11.
Conclusions QoL is significantly affected in the 24 h after LC but returns to baseline at week 3. Cosmesis and overall satisfaction are high, and QoL improvements are maintained in the long term except for bowel function, which regresses to preoperative levels of impairment. Analysis of patient-initiated contacts after LC may provide feedback on discharge counseling to increase patient satisfaction.

Keywords Cholecystectomy · Complications · Gallbladder · Pain · Quality of life

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As advances in technology and technique improve procedural outcomes, traditional comparative metrics such as morbidity and mortality often fail to differentiate between procedures. This was the case for open versus laparoscopic cholecystectomy (LC), when quality of life (QoL) measurements provided a means to systematically elucidate benefits of the minimally invasive approach [1, 2]. Today, LC is considered the gold standard for gallbladder removal and indicated for a variety of biliary issues. Despite the ubiquity of the procedure in operating rooms around the world, few studies have assessed QoL during the long-term postoperative course.

QoL instruments are used in surgical research to enhance the understanding of patient outcomes beyond radiographic imaging, laboratory tests, and assessments of symptoms during clinic visits. This study aims to describe QoL during the short- and long-term periods after LC as well as the clinical outcomes, and patient-initiated contact (phone call/hospital Intranet message) with health care providers after surgery. A more detailed understanding of the postoperative course may enhance patient counseling and postoperative management, with the goals of improving efficiency of care and patient satisfaction.

Methods

After receiving institutional review board approval, we prospectively collected data from consenting patients who underwent LC at our institution from August 2009 to December 2012. Exclusion criteria were patients younger than 18 years of age, previous midline surgery, current pregnancy, or porcelain gallbladder. Patients presenting with acute or chronic cholecystitis, choledocholithiasis, gallstone pancreatitis, biliary dyskinesia, or gallbladder polyps that required cholecystectomy were invited to participate in the study.

Three surgeons who complete 100–200 LC per year performed the procedures at three hospitals. Perioperative variables were duration of surgery, estimated blood loss, additional techniques, and intraoperative complications. Postoperative analgesia type was standardized with a multimodal analgesic therapy that included ketorolac tromethamine immediately after surgery and a prescription for ibuprofen and hydrocodone/acetaminophen. Inpatient analgesia administration was abstracted from the electronic medical records, and patients received a pain medication diary in which to record their postdischarge analgesia usage.

QoL was assessed by the Surgical Outcomes Measurement System (SOMS) instrument, which is an extension of the National Institutes of Health–funded Patient-Reported Outcomes Measurement Information System (PROMIS) (http://www.nihpromis.org) [3]. PROMIS uses modern psychometric methods, including item response theory, to "calibrate" and "bank" large sets of items to assess a given symptom or functional area. This provides a flexible platform to derive a precise score with very few questions per patient. This measurement approach improves precision, reduces respondent burden, and makes assessments more feasible in clinical practice. Regardless of the subset of items administered, the score reported is on the same standardized, common metric or scale.

A subset of these were further refined and tested for use as complementary outcomes in surgical recovery trials (SOMS) [4]. SOMS was developed with the PROMIS methodology, using similar Likert-type scoring scales. Item content for SOMS was developed with input from postoperative patients, surgeons, and surgical nurses. When possible, specific items from the NIH PROMIS were incorporated into SOMS to allow for score cross-walks across the initiatives.

SOMS outcomes include physical function, impact of pain on QoL, cosmesis, fatigue, bowel function, and overall satisfaction with results. A dedicated research coordinator administered SOMS questionnaires before surgery and after cholecystectomy at 24 hours, 72 h, and 1 week, as well as during scheduled clinic visits of 3 weeks, 6 months, 1 year, and 2 years. If patients were unable to attend clinic visits, the SOMS questionnaire was mailed to their residence or e-mailed, according to patient preference. In addition, pain intensity was measured with a visual analog scale (VAS) given concurrently with SOMS preoperatively and at multiple postoperative time points (24 h, 72 h, 1 week, 3 weeks).

Follow-up was obtained during postoperative clinic visits with port-site hernia examinations. It is institutional policy that every patient-initiated contact (phone call/hospital Intranet message) is recorded in the patient's electronic medical record. We recorded the number and type (superficial wound, pain, gastrointestinal, work letter, illness, other) of patient contacts between surgical hospital discharge and the 3 week postoperative visit.

Data were summarized using descriptive statistics (e.g., means and standard deviation for continuous variables; count and frequency for categorical variables). QoL data were plotted and summarized at each data collection point. Mixed-effects models with random intercept were used to examine the trajectory of QoL outcomes over time. Mixed models permit data to exhibit correlation and nonconstant variability and are superior for handling unequal time intervals and missing data, enabling us to include all participants in our statistical analysis. Post hoc pairwise analyses adjusted for multiple tests were conducted to compare QoL outcomes between preoperation and multiple postoperative time points. Statistical significance was established at an alpha level of 0.05. All statistical analyses were performed by SAS 9.2 statistical software (SAS, Cary, NC).

Results

The mean age of subjects in our series was 47.7 ± 17.5 years, and 76 % of patients were female. Mean body mass index (BMI) was 29.5 ± 6.4 (kg/m^2), with 43 % of subjects having a BMI of >30.0 kg/m^2 and 22 % of subjects with a BMI of >35.0 kg/m^2 (Table 1).

Table 1 Patient characteristics [a]

Characteristic	Value
Age (years)	47.7 ± 17.5
Body mass index (kg/m^2)	29.5 ± 6.4
Female sex	76 (76 %)
ASA score class	1–3
Indication	
Chronic cholecystitis	76
Acute cholecystitis	16
Gallstone pancreatitis	9
Choledocholithiasis	6
Biliary dyskinesia	2

ASA American Society of Anesthesiologists

[a] Data are presented as mean ± SD; range; or *n* (%)

Perioperative data are displayed in Table 2. All patients received narcotics during inpatient or outpatient periods, with total morphine equivalents ranging from 20 to 347 mg. No bile duct injuries or surgery-related mortalities occurred. There was one instance of morbidity (1 %), a postoperative hemorrhage from an omental vessel requiring transfusion and surgical reintervention. The patient recovered without further sequelae. There were three umbilical hernias identified at a clinical follow-up of 17.7 ± 12.6 months; however, two were preexisting hernias, repaired during initial cholecystectomy by suture closure, that recurred during the postoperative course.

Forty-four patients contacted the health care team a total of 61 times before their 3 weeks appointment, most commonly for dermal/superficial wound issues (26.2 %), pain (24.6 %), and gastrointestinal issues (24.6 %) (Table 3). Thirteen patients contacted the team more than once (range, 2–4 contacts), and eight patients contacted the health care team multiple times for the same issue.

Table 2 Perioperative data [a]

Characteristic	Value
Operative time (min)	53.4 ± 24.6
Estimated blood loss (ml)	16.1 ± 29.1
Intraoperative cholangiogram	9
Common bile duct exploration	3
Length of hospital stay (hours)	22.4 ± 37.5
Complications	1
Port-site hernia	3
Return to activities of daily living (days)	6.3 ± 4.7
Return to work (days)	11.1 ± 9.0
Duration of analgesia usage (days)	3.7 ± 4.5
Inpatient analgesia (total morphine equivalents, mg)	45.2 ± 29.0
Outpatient analgesia (hydrocodone, mg)	43.5 ± 55.2

[a] Data are presented as mean ± SD; or *n*

Mixed-effects models revealed significant second-degree time effects for most of QoL outcomes except for cosmesis and satisfaction. Overall response rates were as follows: preoperative (100 %), 24 h (78 %), 72 h (78 %), 1 week (78 %), 3 weeks (79 %), 1 year (54 %), and 2 years (37 %). There were no differences in demographics, perioperative outcomes, or receipt of pain medication between patients who completed full follow-up and those who dropped out.

VAS pain intensity rose from before the operation (1.2 ± 2.3) to its greatest level 24 h after surgery (5.5 ± 2.2), before declining at 72 h (3.7 ± 1.8), 1 week (2.0 ± 1.6), and 3 weeks (0.90 ± 1.6) after cholecystectomy (Fig. 1). Significant pain intensity was defined as at least a 7 on the VAS, which falls between the descriptions "hurts even more" and "hurts a whole lot." Preoperatively, 7.7 % of patients reported significant pain levels, which increased to 44.7 % at 24 h after cholecystectomy. At 3 and 7 days, 8.3 and 2.7 % of patients had significant pain, respectively, which decreased to zero 3 weeks after the operation.

Greater scores on the pain impact on QoL outcome indicated more impairment; the greatest possible score is 30. The impact of pain on QoL followed a similar trend to pain intensity, rising from before the operation (11.3 ± 7.0) to maximum levels 24 h (19.6 ± 6.8) after surgery and decreasing at 72 h (15.5 ± 5.8), 1 week (11.7 ± 5.4), and 3 weeks (8.1 ± 3.4) after the procedure, when the impact of pain on QoL fell below preoperative levels ($P < 0.001$) (Fig. 2). Pain impact on QoL was considered significant when subjects reported "Quite a bit" or "Very much" on individual SOMS pain impact questions (Table 4). Preoperatively, pain most commonly affected patients' day-to-day (19.2 %) and social activities (16.2 %), as well as their ability to fall asleep (17.2 %) and work (16.2 %). 24 h after cholecystectomy, pain significantly affected more than half of patients in their work (62.8 %), day-to-day (56.4 %), and social activities (61.5 %), as well as over a third in walking (34.6 %), falling asleep (35.9 %), and caring for oneself (37.1 %). However, by 72 h after surgery, only 7.7 % of patients had significantly impaired sleep and 14.1 % had impairment with walking due to pain. At 1 week after surgery, 27.2 % of patients reported significant pain impact on any of the SOMS activity categories, and at 3 weeks, this rate fell to 4.0 %. Overall, 39.7 % of subjects reported difficulty falling asleep as a result of pain at some point in the 3 weeks after LC.

A significant deficit in physical function was defined as an inability to do basic everyday tasks or only being able to complete them "with much difficulty" (Table 5). Preoperatively, 18 % of patients reported at least one significant

Table 3 Patient-initiated contacts (phone calls/hospital Intranet messages) with the health care team before the week 3 appointment

Contact	*n* (%)
Patient-initiated contacts	61
Patients who contacted the team	44 (44 %)
Repeat contacts	13
Repeat contacts for same issue	8
Issues	
Dermal/superficial wound	16 (26.2 %)
Pain	15 (24.6 %)
Gastrointestinal	15 (24.6 %)
Work letter	11 (18.0 %)
Illness	2 (3.3 %)
Other	7 (11.5 %)

deficit in physical functioning. One week after cholecystectomy, 45.4 % of patients reported significant deficits in physical function, and mean scores significantly worsened from preoperative levels (27.5 ± 5.9 vs. 31.7 ± 6.2, $P < 0.0001$) (Fig. 2). Greater scores indicated greater physical function deficits with a maximum score of 35. By 3 weeks after surgery (33.5 ± 3.4), however, physical function improved past preoperative levels, and improvements persisted at 6 months (34.1 ± 4.5), 1 year (34.7 ± 2.7), and 2 years (33.9 ± 5.1) after the procedure (all $P < 0.05$).

Greatest fatigue was indicated by a score of 35. Patients reported feeling more fatigued 1 week after surgery compared to preoperative levels (20.7 ± 6.6 vs. 15.8 ± 6.2, $P < 0.0001$) (Fig. 2). However, fatigue was less than preoperative levels 3 weeks after cholecystectomy (14.0 ± 5.8 vs. 15.8 ± 6.2, $P = 0.0039$) and low at 6 months (12.4 ± 5.3), 1 year (12.4 ± 4.8), and 2 years (13.7 ± 5.9).

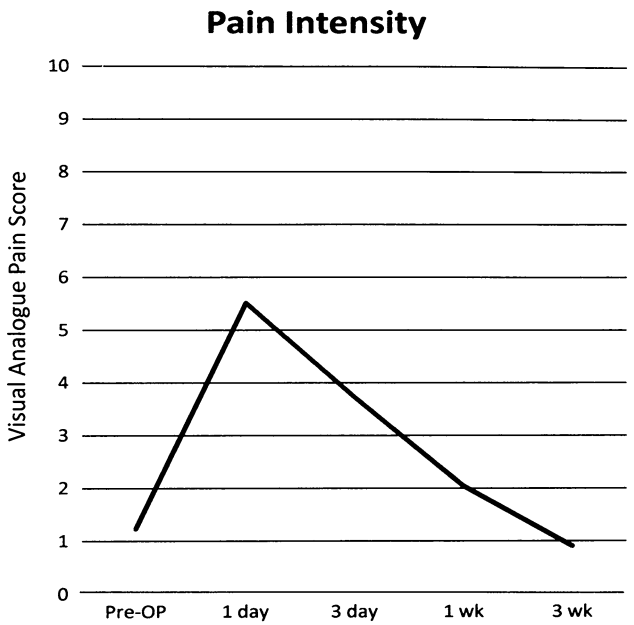

Fig. 1 Pain intensity after LC measured by VAS

The bowel dysfunction score is composed of questions about the frequency of urgent bowel movements (BM), pain during BM, cramping, loose BM, bloating, constipation, and accidental stool leakage during urination. A greater score indicated greater impairment, with a highest score of 35. Bowel dysfunction reached maximum levels 1 week after surgery (12.0 ± 3.2) and convalesced past preoperative impairment at week 3 (10.7 ± 3.8 vs. 9.5 ± 3.1, $P < 0.05$) (Fig. 2). No difference was found between preoperative bowel dysfunction versus levels at 6 months (9.9 ± 3.6), 1 year (9.7 ± 3.4), and 2 years (10.4 ± 3.3) after LC (All $P > 0.05$).

Greater cosmetic satisfaction was indicated by lower scores with an optimal score of 4. Cosmesis was 5.2 ± 1.8 at 3 weeks, 4.7 ± 1.6 at 6 months, 4.3 ± 0.7 at 1 year, and 4.4 ± 1.1 at 2 years (Fig. 2). Seventy-two percent reported that the procedure had no negative effect on cosmesis at 6 months.

Greater satisfaction with the procedure was indicated by higher scores. Satisfaction averaged 9.3 ± 2.3 out of a maximum score of 11 at week 3, 9.6 ± 2.0 at 6 months, 9.7 ± 2.1 at 1 year, and 9.6 ± 2.0 at 2 years after surgery (Fig. 2). In addition, 87.5 % of subjects reported complete satisfaction with the operation 2 years after cholecystectomy. When asked to compare personal expectations of surgery to the results of their operation, most patients reported achieving similar or better results at 3 weeks (93.6 %), 6 months (98.5 %), 1 year (95.7 %), and 2 years (96.9 %) after cholecystectomy. Many patients also found the side effects of LC to be similar to or better than what they expected at 3 weeks (83.3 %), 6 months (93.9 %), 1 year (93.6 %), and 2 years (93.8 %) after surgery.

Discussion

The results from this study describe QoL dynamics over multiple time points during the short- and long-term periods after LC.

Pain intensity after LC

VAS pain assessment indicated that the surgical insult of LC results in substantial pain 24 h after surgery, which significantly decreases in severity by 72 h. These results agree with several reports, including a recent study comparing pain between surgical procedures using over 50,000 day 1 VAS [5–7]. Our VAS reports (5.5) were slightly higher than the mean pain scores in the comparative study (4.76), which indicated that LC patients reported

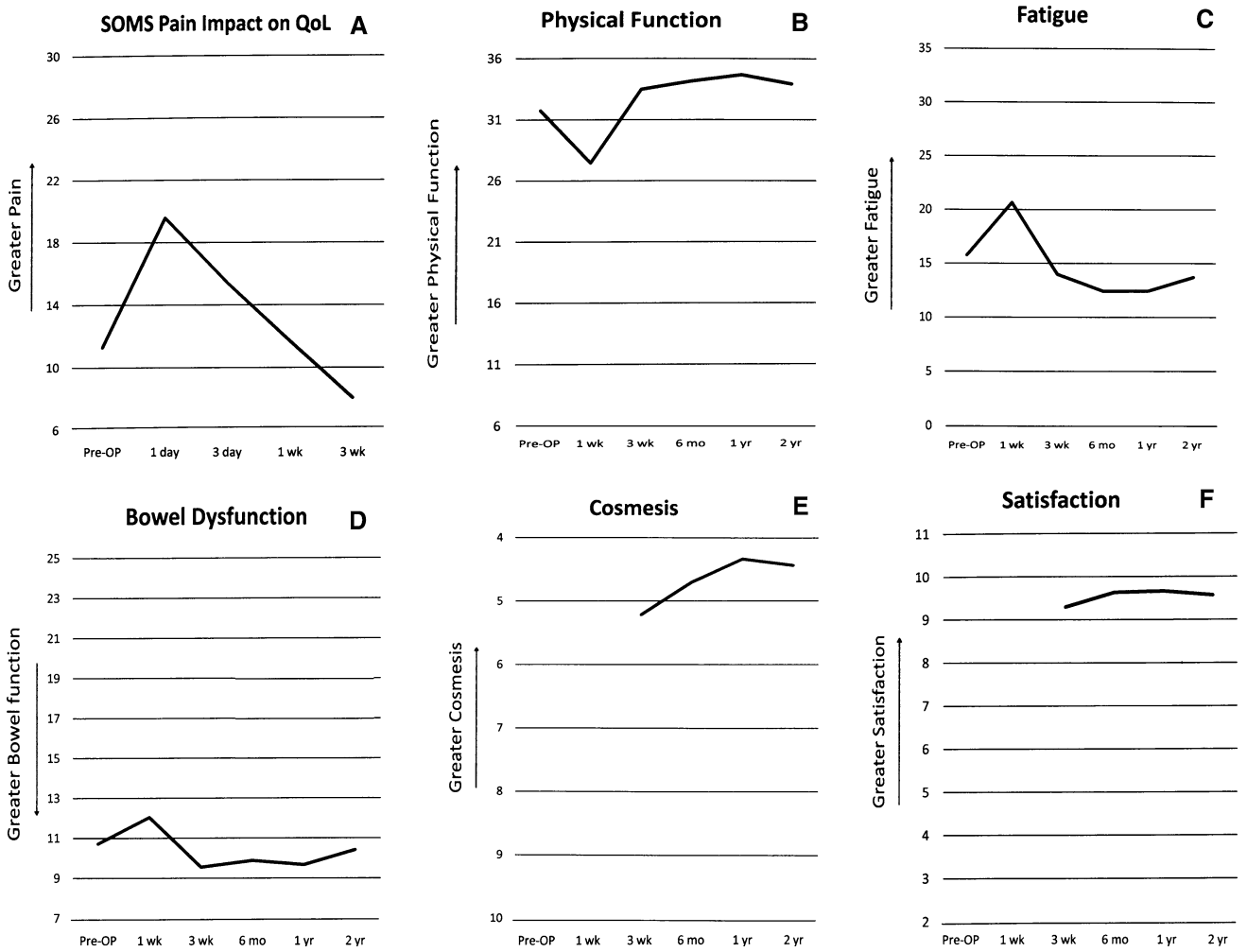

Fig. 2 SOMS QoL outcomes for (**A**) pain impact on QoL, (**B**) physical function, (**C**) fatigue, (**D**) bowel dysfunction, (**E**) cosmesis, and (**F**) satisfaction

Table 4 Percentage of subjects reporting significant impact of pain quality-of-life measures

Time point	Falling asleep	Walking	Day-to-day activities	Social activities	Ability to work	Ability to take care of self
Before surgery	17.2	13.1	19.2	16.2	16.2	10.1
24 hours	35.9	34.6	56.4	61.5	62.8	37.2
72 hours	7.7	14.1	24.4	28.2	33.3	12.8
1 week	10.4	11.7	15.6	13.0	16.9	5.2
3 weeks	1.4	2.7	4.1	1.4	1.4	0

greater pain on postoperative day 1 than total/subtotal gastrectomy or open lung resection [7]. Authors attribute the high pain reports after LC to low levels of opioid consumption. We theorize that cautery use during dissection off the liver bed may also play a role. This intense pain is short-lived; 3 days after surgery, mean pain is described as less than moderate, and by 1 week, pain intensity is similar to preoperative levels.

QoL in the first 3 weeks after LC

Physical function, fatigue, bowel function, and the impact of pain on QoL all demonstrated a similar short-term postoperative course, first declining during the week after surgery before convalescing by week 3. We found that many patients reported difficulties falling asleep because of pain on postoperative day 1 that largely resolved by 72 h,

Table 5 Percentage of subjects reporting significant deficits in physical function

Time point	Get in and out of car	Get in and out of bed	Bend down and pick up clothing from floor	Keeping balance after standing	Limit with moderate activities	Limit climbing stairs	Walk for 15 min
Before surgery	6	5	6	3	14	10	7
1 week	3.9	7.9	17.1	1.3	35.5	10.5	10.5
3 weeks	0	0	0	1.3	6.7	0	2.7
6 months	2.9	2.9	2.9	2.9	2.9	1.5	1.5
1 year	0	0	0	0	2.1	2.1	0
2 years	2.7	2.7	2.7	2.7	5.4	2.7	2.7

which accords with a study by Bisgaard et al. [8] that recorded subjective reports of sleep quality taken each night after LC. 24 h after surgery, self-care and walking were significantly impaired in over a third of patients as a result of pain, and at 1 week, less severe walking deficits persisted, which is corroborated by Feldman et al. [9] with a 6-min treadmill test and by other studies that found 28–32 % of patients walk with some difficulty at this time [9–11]. At postoperative day 7, fatigue, physical function, and bowel function remained impaired, and pain continued to significantly affect some aspect of daily living in more than a fourth of patients. However, by day 21, these outcomes improved beyond preoperative levels, and every patient reported returning to activities of daily living.

Long-term QoL

Our results suggest that QoL improvements in physical functioning and fatigue demonstrated 3 weeks after LC are largely maintained during the 2 year postoperative course. The durability of such improvements has been demonstrated in trials with general QoL instruments and gallstone-specific [12] QoL tools in patients up to 5 years after cholecystectomy [13], in those undergoing short-stay surgery [12], and in patients with chronic, acute [13], and asymptomatic [14] biliary presentations [1, 10, 12–18].

We found that bowel function regressed to preoperative levels 6 months after surgery and remained unchanged at 1 and 2 years. Although other studies using gastrointestinal QoL instruments found improvements after LC, we believe our focus on bowel function allowed us to better detect postcholecystectomy issues [12, 13, 17]. Indeed, several studies [18–20] implicate bowel dysfunction, including the work of Fort et al. [20], which used radiopaque pellet imaging to find decreased colonic transit time 1 month and 4 years after the procedure, which was associated with self-reported loose stools and an increased frequency of BM. Further, a recent large controlled trial concluded that there was no difference in reflux after cholecystectomy [21]. More studies are required to better characterize the gastrointestinal issues after LC and their impact on QoL.

Patient-initiated contact with the health care team

To our knowledge, this study adds to the literature as the first to describe in detail patient-initiated contact with the medical staff after LC. We found that patients most commonly contact the health care team about superficial wound issues, pain, and gastrointestinal problems. Analysis of the concerns and complaints raised during patient-initiated contacts can identify common postdischarge issues with the goal of improving in-hospital service and operative counseling. We found that several patients were concerned about small amounts of bleeding or discharge from the surgical wound. We hope that by addressing such common issues more deliberately during operative counseling, we can prevent unnecessary patient anxiety associated with normal sequelae while concurrently saving the time of the health care team. Further studies are required to assess the efficacy of such an intervention.

Satisfaction

We found high rates of satisfaction with cosmesis and with the overall surgical experience. Overall procedural satisfaction was also high, with 90 % of patients reporting complete satisfaction with the experience of surgery 2 years after cholecystectomy, which agrees with the range found in other studies of 80–92 % at various postoperative time points [22–24]. We found that over 93 % of patients found the results of the operation similar to or better than what they expected, and over 93 % of patients rated the adverse effects of the operation similar to or better than what they expected.

Time after surgery and QoL report

This study describes a dynamic postoperative QoL course after LC with outcomes changing across short- and

long-term time periods. Because cholecystectomy involves both healing of tissue and homeostasis of bile acid metabolism, these outcomes may be expected [25]. Perhaps future studies should place a greater emphasis on describing QoL results in a temporal framework. Further, although comparative studies that utilize a single postoperative QoL assessment are valuable, they are at risk of reporting results more influenced by time than by the outcomes of the procedure. For example, if one group is composed of more short-term evaluations than the other group, the results may represent the factor of time on QoL report more than the experimental manipulation.

Limitations

There are several limitations to our study that may affect the interpretation of the results. Socioeconomic factors have been shown to affect QoL outcomes after surgical procedures [26, 27]. Our hospital system serves several privileged areas, and we believe that physical work demands and socioeconomic determinants of health might cause different QoL outcomes after LC in other populations. Perhaps a study utilizing multiple centers that serve a variety of socioeconomic regions may represent a wider QoL profile. In addition, our QoL instrument, SOMS, is an extension of the NIH-funded PROMIS, which aims to build efficient, flexible, and precise measurements of commonly studied patient-reported outcomes. As an early adopter of SOMS, we have scant reference data from populations or from other surgical patients to compare with our results. Our study was also limited in its ability to detect biliary pain in the long-term course after cholecystectomy. We did not utilize pain QoL measures after 3 weeks because we thought they would be ineffective at capturing sporadic biliary attacks.

Conclusions

QoL is significantly affected in the 24 hours after LC, but pain, physical function, fatigue, and bowel function convalesce beyond preoperative impairment before week 3. Cosmesis and overall satisfaction are high, and QoL improvements are maintained in the long term except for bowel function, which regresses to preoperative levels of impairment. Analysis of patient-initiated contacts after LC may provide feedback on in-hospital service and operative counseling toward the goals of improved efficiency and patient satisfaction.

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Disclosures Drs. Ujiki, Denham, Linn, Barrera, Butt, and Wang as well as Mr. Zapf and Ms. Carbray have no conflicts of interest or financial ties to disclose.

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