

# RAND-36-Item Health Survey: A Comprehensive Test for Long-term Outcome and Health Status Following Surgery

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**Abstract.** *Background/Aim:* The aim of this study was to assess the 3-year health status of cholecystectomy patients by the RAND-36 Survey. *Patients and Methods:* Initially, 110 patients with symptomatic gallstone disease were randomized to undergo either minicholecystectomy (MC) (n=58) or laparoscopic cholecystectomy (LC) (n=52). RAND-36 survey was performed preoperatively, 4 weeks, 6 months and 3 years following surgery. *Results:* RAND-36 scores improved in several RAND-36 domains in MC and LC groups with a similar postoperative course over the 3-year study period. In addition, at the 3-year follow-up telephone interview, no significant differences in patient-reported outcome measures between MC and LC patients were shown. The linear mixed effect model was used to test the overall significance of the RAND-36 survey during a 36-month follow-up period and the overall p-values were statistically significant in vitality, mental health (0.03), role physical and bodily pain domains. *Conclusion:* During the three years following cholecystectomy, four RAND-36 domains remained significantly higher, indicating a significant positive change in quality of life. RAND-36-Item Health Survey is a comprehensive test for analyzing long-term outcome and health status after cholecystectomy.

The classical outcome measures evaluated after surgery are usually perioperative course, complications, morbidity,

mortality and long-term outcome (post-operative symptoms, disease recurrence, long-term complications) (1-5). One of the most frequently used quality of life (QoL) assessment tools for patients following surgery is the Short Form Health Survey Questionnaire (SF-36) (2, 6-13). RAND-36, much like SF-36, is a widely used generic, coherent, and comprehensive health survey. It contains a total of eight domains: general health (GH), physical functioning (PF), mental health (MH), social functioning (SF), vitality (VT), bodily pain (BP), role physical (RP) and role emotional (RE). RAND-36 includes the same set of items as SF-36, however, the scoring of GH and BP scales differs slightly (14, 15). Several studies have evaluated SF-36 in benign disease and in cancer patients following surgery (1, 2, 4, 8, 10-12). To our knowledge, RAND-36 is rarely evaluated in surgical patients (3, 16, 17). In addition, RAND-36-Item Health Survey has not been addressed earlier in minilaparotomy cholecystectomy (MC) versus laparoscopic cholecystectomy (LC) patients with ultrasonic dissection. Therefore, our study design was to investigate RAND-36 domains preoperatively and repeatedly following surgery. In addition, a 3-year follow-up structured telephone interview was conducted asking the patients if they had any symptoms or pain following surgery and the pain intensity was reported on an 11-point numerical rating scale (NRS). The end-point of our study was to determine differences in the 3-year health outcome in MC versus LC patient groups.

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## Patients and Methods

The study was approved by the Ethics Committee of Kuopio University Hospital District, Kuopio, Finland (DNRO 27/02/2013), registered in the ClinicalTrials.gov database (ClinicalTrials.gov Identifier: NCT01723540, Consort diagram), and was conducted in accordance with the Declaration of Helsinki. Written consent was collected from participants, after receiving verbal and written information about the study. Operations were carried out in two hospitals in Finland; Helsinki University Central Hospital, Helsinki (n=28) and Kuopio University Hospital, Kuopio (n=82) between

Table I. The clinical data of MC (minicholecystectomy) and LC (laparoscopy) patients. Data are mean (SD) or number of cases.

Variable	MC group n=58	LC group n=52	p-Value
Age	50.1 (13.6)	52.1 (13.4)	0.46
Gender (male/female)	13/45	17/35	0.23
Height (cm)	167.1 (7.3)	168.3 (9.2)	0.16
Weight (kg)	77.4 (14.2)	82.0 (18.0)	0.48
BMI (kg/m <sup>2</sup> )	27.7 (4.5)	28.3 (5.2)	0.25
Operative time (min)	68.6 (26.7)	68.5 (36.0)	0.26
Time at operative theater (min)	118.4 (27.0)	125.2 (35.8)	0.31
Perioperative bleed (ml)	39.3 (59.7)	28.6 (35.8)	0.26
ASA 1/2/3	31/21/6	21/20/11	0.10
Conversions	2 (3.5%)	3 (5.8%)	0.58

March 2013 and May 2015. The design of the study is presented in Figure 1.

The study was a prospective, randomized, multicenter clinical trial with two parallel groups. Altogether, 110 patients with uncomplicated symptomatic cholelithiasis confirmed by ultrasound were randomized to undergo cholecystectomy with LC, 52 patients, or with MC, 58 patients. Sealed envelope method was used for randomization. The operations were carried out by three consultant-level surgeons (JH, PJ, ME), and both techniques were familiar to each operator.

The surgical techniques used were standardized in both groups (18). The LC is a laparoscopic operation and was performed using the four-trocar technique (two 10-mm and two 5-mm trocars), and intra-abdominal pressure was set at 12 mmHg. Ultrasonic scissors (Harmonic ACE®, Ethicon Endo-Surgery, Cincinnati, OH, USA) were used both in the MC and LC procedures.

The MC technique is a minimally invasive open technique with a very short wound. The rectus muscle is not cut, but split in the MC technique. A skin incision length of more than 7.0 cm or cutting of the rectus muscle was considered as a conversion to a conventional open operation. Incisions were infiltrated with local anesthetic (20 ml ropivacaine 7.5 mg/ml) at the end of the operation.

RAND-36 was assessed pre- and postoperatively using the validated Finnish version of the questionnaire (15). Non-responders were interviewed by phone. The eight health domains were calculated from the 36 questions as instructed by the RAND-36 item health survey (15, 16). The RAND-36 questionnaire takes 10-15 min to complete. We have earlier shown instructions for calculation of the eight health domains from the 36 questions of the RAND-36 survey (17).

At the 3-year follow-up, a telephone interview was conducted between January 2018 and May 2018. In the structured interview, the patients were asked whether they have experienced: a) similar abdominal symptoms or right upper quadrant pain, as they had before cholecystectomy, b) whether they have diarrhea or loose stools, and reflux symptoms, c) or if they had to avoid fatty or fried food to escape abdominal symptoms. If any of these symptoms were present, the interview continued with the question whether the patient had been further examined or received any other treatment for the residual symptoms. Pain or other symptoms at the incision

area/port sites were filed, and patients reported the pain intensity on an 11-point numeric rating scale (NRS) when at rest, in physical activity, and lifting heavy objects or coughing. Regarding satisfaction with the surgery, the patients were asked whether the operation had had any impact on their QoL, if they were satisfied with the cosmetic outcome, and the satisfaction with the surgery in general. The patients were asked to answer the question on a five-point Likert-scale. The author (I.S.), who performed all interviews and filed the questionnaires of the study persons, did not participate in the primary operation or treatment of any of the study patients and was blinded to the operative technique used in cholecystectomy.

The data were entered and analyzed with a statistical software program (IBM SPSS Statistics 24.0, IBM, Armonk, NY, USA). Differences in the baseline characteristics between groups were tested by Fisher's exact test and in the case of continuous data the analysis was performed by independent samples *t*-test. Group differences at four time points were tested by the Mann-Whitney *U*-test and the Wilcoxon signed rank test. The linear mixed effect model was used to test overall significance of RAND-36 during the follow-period and the overall *p* value shows the interaction effects of different time and group interactions.

## Results

Fifty-three patients (53/58=91.4 %) in the MC group and 44 (44/52=84.6 %) patients in the LC group underwent a follow-up phone interview at 36 months. Further on, 44 (44/58=75.9 %) of the MC patients and 43 (43/52=82.7%) of the LC patients returned the 3-year RAND-36 questionnaire following surgery (mean±SD, 43.2±7.7 months). The CONSORT diagram of the study and the perioperative surgical data are shown in Figure 1 and Table I, respectively.

Three patients in both groups (MC, 3/58 and LC, 3/53) had an incisional hernia of which two patients in both groups underwent hernia repair. None of the patients have shown signs of recurrent gallstones or surgery associated injuries in the bile ducts.

At the 3-year follow-up, no statistically significant differences in the structured interview domains between MC and LC patients were shown; residual abdominal symptoms (*p*=0.26), right upper quadrant pain (*p*=0.16), reflux symptoms (*p*=0.13), diarrhea/loose stools (*p*=0.27), fatty/fried food (*p*=0.69), overall satisfaction with the procedure (*p*=0.90), cosmetic satisfaction (*p*=0.30), recommend the procedure to others (*p*=0.60), quality of life (*p*=0.34, Table II).

The linear mixed effect model was used to test overall significance between groups during the 3-year follow-period and no significant differences were shown in any of the eight domains of RAND-36 at 4 weeks, 6 months or 36 months after surgery (Table III). The only significant difference between MC and LC groups following surgery was higher BP score in MC patients compared to LC patients at 6 months (*p*=0.04, Table III).

In the MC and LC groups combined (Table IV), the RAND-36 scores increased significantly in the 'VT' (mean

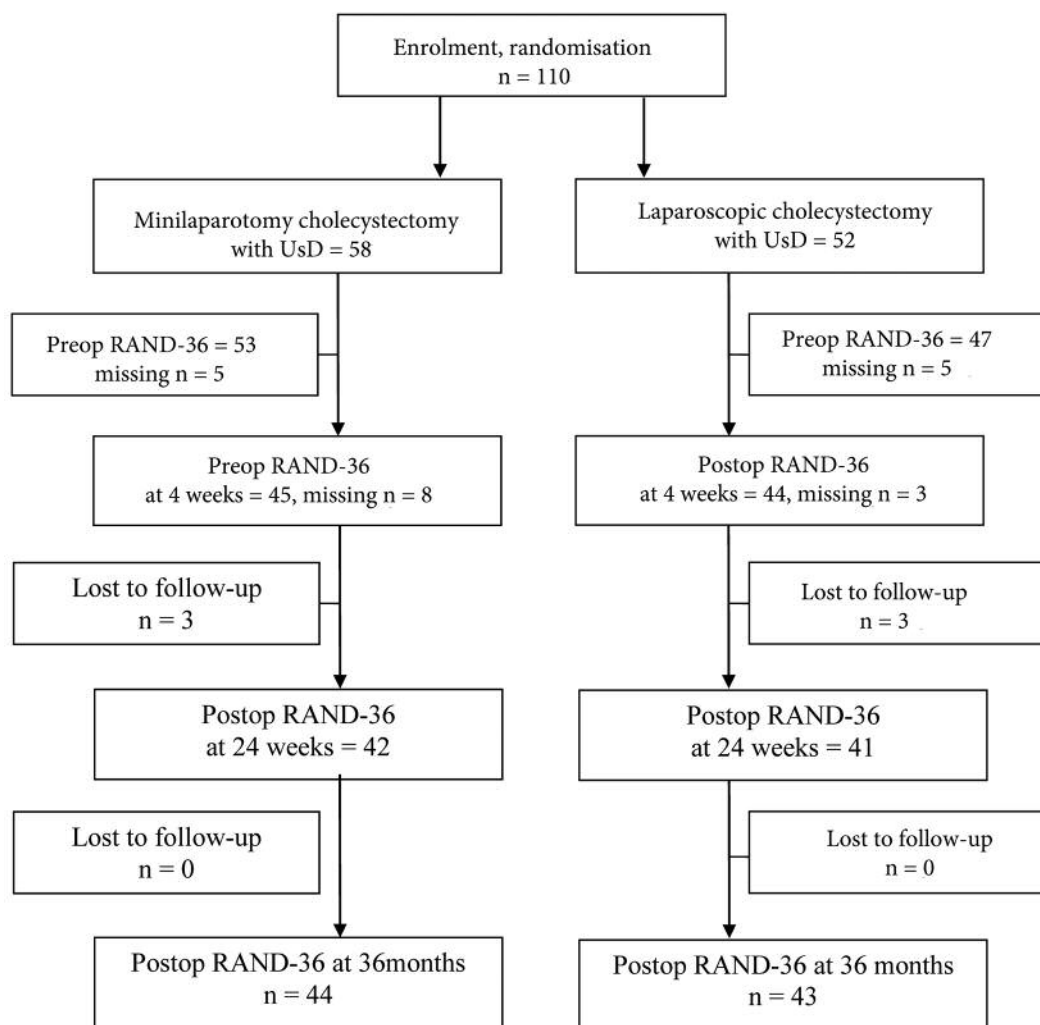


Figure 1. The flowchart of the study design.

preoperative score 65.0 vs. 4-week postoperative score 72.0,  $p=0.03$  vs. 6-month postoperative score 75.7,  $p=0.001$  vs. 36-month postoperative score 72.3,  $p=0.03$ ), 'MH' (mean preoperative score 75.8 vs. 4-week postoperative score 85.2,  $p=0.001$  vs. 6-month postoperative score 82.1,  $p=0.04$ ), 'RP' (preoperative score 69.3 vs. 4-week postoperative score 47.2,  $p=0.008$  vs. 6-month postoperative score 84.4,  $p=0.03$ ), 'BP' (mean preoperative score 57.6 vs. 6-month postoperative score 75.4,  $p=0.0001$  vs. 36-month postoperative score 75.7,  $p=0.0001$ , Table IV). The linear mixed effect model showed overall significance of the RAND-36 during three years following cholecystectomy and the overall statistically significant RAND-36 domains were VT ( $p=0.002$ ), MH ( $p=0.031$ ), RP ( $p<0.001$ ) and BP ( $p<0.001$ , Table IV).

The 3-year postoperative scores of eight RAND-36 domains in MC and LC groups *versus* the Finnish reference scores are shown in Figure 2.

## Discussion

The patient-reported outcome measures (PROMs) are important outcome indicators for evaluating treatment from a patient perspective (1-5, 19). In a review of 103 Swedish healthcare quality registries, authors encouraged to include PROMs in their arsenal of outcome measures and to collect PROM data to ensure highest level of registry classification (19). Evidence-based guidelines of the European Association for Endoscopic Surgery advice the use of the SF-36 for evaluating health status in patients following cholecystectomy, because the SF-36 questionnaire seems to be valid for evaluating patients' functional recovery after cholecystectomy (6). In our earlier preliminary RAND-36 report (16), there was no statistically significant difference between the LC and MC groups in seven RAND-36 domains, but the RE score was slightly higher in the LC group than in the MC group ( $p=0.038$ ).

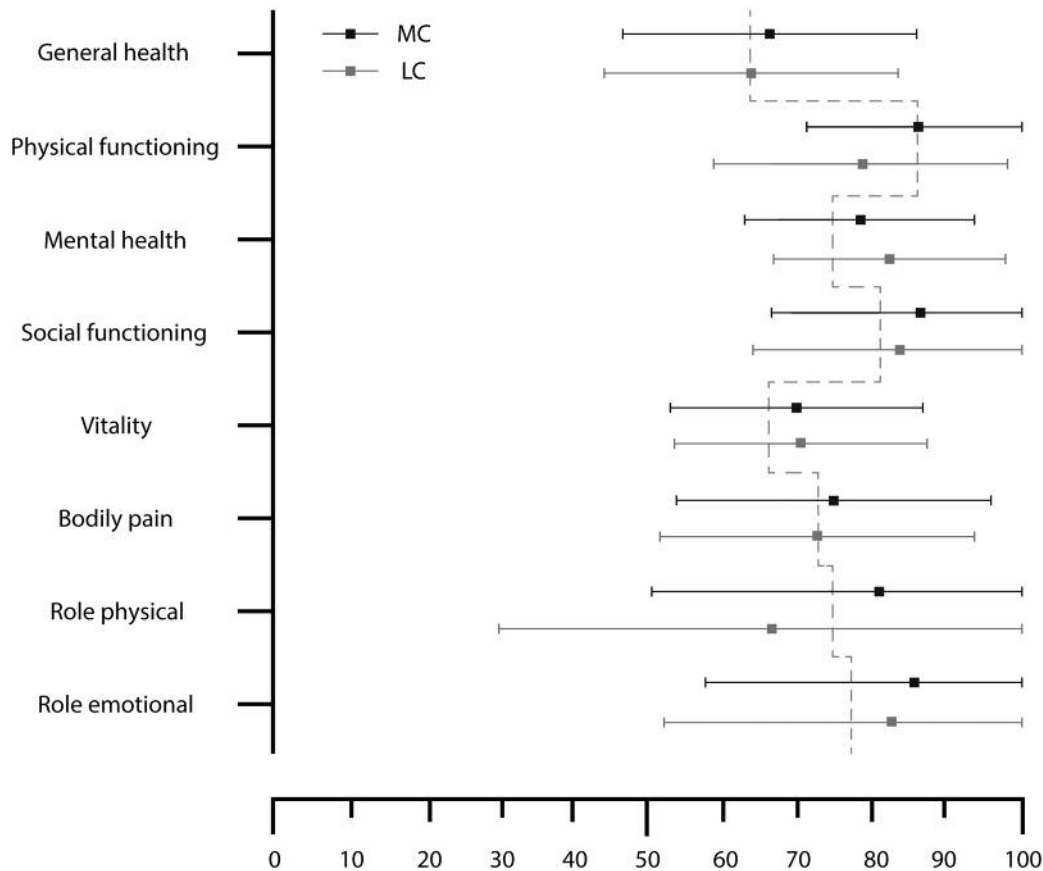


Figure 2. The 3-year postoperative scores of eight RAND-36 domains in MC and LC groups versus the age- and gender -adjusted Finnish reference scores (dashed line) (15).

Table II. The long-term symptomatic outcome and patient satisfaction at the 3-year follow-up structured interview of the MC (minicholecystectomy) and LC (laparoscopy) patients.

Variable	MC group n=53	LC group n=44	p-Value
Residual abdominal symptoms			
Yes/no/could not say	35.9%/56.6%/7.5%	42.9%/42.9%/11.9%	0.26
Right upper quadrant pain attacks			
Yes/no/could not say	5.7%/94.3%/–	4.8%/95.2%/–	0.16
Reflux symptoms			
Less/not changed/more	50.9%/37.7%/11.3%	61.9%/31.0%/7.1%	0.13
Diarrhea or loose stools			
Less/not changed/more	17.0%/67.9%/15.1%	23.8%/61.9%/14.3%	0.27
Avoid fatty/fried food			
Yes/no/could not say	37.7%/60.6%/1.9%	38.1%/54.8%/7.1%	0.69
Overall satisfaction with the procedure			
Satisfied/dissatisfied/could not say	88.7%/7.8%/3.8%	95.2%/4.8%/–	0.90
Cosmetic satisfaction			
Satisfied/dissatisfied/could not say	81.1%/17.0%/1.9%	90.5%/7.2%/2.4%	0.30
Recommend the procedure to others			
Yes/no/could not say	77.4%/7.5%/15.1%	85.7%/7.6%/7.1%	0.60
Quality of life			
Better/not changed/worse	81.1%/17.0%/1.9%	83.3%/11.9%/4.8%	0.34

Table III. The RAND-36 domains and scores in minicholecystectomy (MC) and laparoscopic cholecystectomy (LC) patients. Values are mean (standard deviation).

RAND-36	MC group	LC group	p-Value
Physical functioning			0.233*
Preoperative	81.3 (20.5)	82.7 (23.6)	0.53
4 weeks after surgery	83.3 (19.0)	79.6 (25.4)	0.93
6 months after surgery	87.3 (21.4)	83.9 (21.5)	0.39
36 months after surgery	87.3 (16.3)	79.0 (22.0)	0.06
Social functioning			0.254*
Preoperative	77.9 (21.8)	76.5 (19.3)	0.21
4 weeks after surgery	76.9 (21.1)	77.6 (23.0)	0.76
6 months after surgery	88.0 (20.0)	84.4 (22.0)	0.42
36 months after surgery	87.5 (19.2)	84.3 (19.2)	0.32
Vitality			0.729*
Preoperative	64.0 (18.5)	64.2 (19.9)	0.98
4 weeks after surgery	68.9 (18.3)	66.6 (23.8)	0.97
6 months after surgery	74.2 (17.8)	72.3 (17.5)	0.50
36 months after surgery	70.0 (17.2)	71.0 (18.8)	0.67
Mental health			0.572*
Preoperative	76.6 (15.1)	83.0 (21.1)	0.63
4 weeks after surgery	82.5 (14.5)	80.9 (15.7)	0.74
6 months after surgery	82.2 (15.5)	80.6 (17.0)	0.61
36 months after surgery	79.6 (16.5)	81.3 (13.0)	0.87
Role physical			0.107*
Preoperative	65.3 (38.1)	67.9 (36.4)	0.74
4 weeks after surgery	39.7 (38.2)	48.0 (42.1)	0.36
6 months after surgery	81.5 (33.6)	81.6 (33.8)	0.93
36 months after surgery	81.1 (33.4)	67.7 (41.1)	0.12
Role emotional			0.939*
Preoperative	83.0 (31.5)	80.1 (33.1)	0.63
4 weeks after surgery	80.7 (35.8)	73.3 (37.9)	0.20
6 months after surgery	90.2 (25.0)	83.8 (31.4)	0.20
36 months after surgery	86.2 (31.6)	81.6 (34.4)	0.49
Bodily pain			0.055*
Preoperative	59.1 (24.9)	59.2 (27.7)	0.97
4 weeks after surgery	59.4 (23.1)	63.4 (26.6)	0.40
6 months after surgery	80.4 (21.5)	69.6 (26.6)	0.04
36 months after surgery	75.9 (24.2)	73.0 (26.4)	0.65
General health			0.123*
Preoperative	66.6 (21.7)	64.8 (18.3)	0.57
4 weeks after surgery	67.2 (20.8)	62.7 (19.9)	0.28
6 months after surgery	70.9 (18.1)	63.4 (20.8)	0.10
36 months after surgery	66.0 (20.3)	63.2 (20.4)	0.49

\*The linear mixed model p-value showing the interaction effects of different time and group interactions.

The results of the present study support the validity of the RAND-36 as a survey of health-related quality of life in cholecystectomy patients following surgery. In particular, BP, RP, MH and VT scores improved significantly following cholecystectomy, which indicates that RAND-36-Item Health Survey could be a comprehensive test for long-term outcome and health-status. The present study cohort of patients was comparable to the Finnish reference population (15) in terms of the GH and BP scores 3 years following surgery. However,

Table IV. The RAND-36 domains and scores in minicholecystectomy (MC) and laparoscopic cholecystectomy (LC) groups combined. Values are mean (standard deviation).

RAND-36	MC and LC combined	p-Value
Physical functioning		0.132*
Preoperative	79.8 (25.0)	
4 weeks after surgery	81.3 (23.4)	0.965
6 months after surgery	86.4 (21.6)	0.05
36 months after surgery	85.4 (19.3)	0.175
Social functioning		0.254*
Preoperative	79.4 (22.5)	
4 weeks after surgery	80.8 (21.4)	0.857
6 months after surgery	85.6 (21.1)	0.353
36 months after surgery	87.0 (17.7)	0.137
Vitality		0.002*
Preoperative	65.0 (19.4)	
4 weeks after surgery	72.0 (20.3)	0.03
6 months after surgery	75.7 (16.5)	0.001
36 months after surgery	72.3 (16.9)	0.03
Mental health		0.031*
Preoperative	75.8 (18.2)	
4 weeks after surgery	85.2 (13.1)	0.001
6 months after surgery	82.1 (16.2)	0.042
36 months after surgery	80.9 (15.4)	0.220
Role physical		<0.001*
Preoperative	69.3 (36.9)	
4 weeks after surgery	47.2 (38.5)	0.008
6 months after surgery	84.4 (29.1)	0.030
36 months after surgery	75.5 (37.2)	0.631
Role emotional		0.725*
Preoperative	78.3 (33.9)	
4 weeks after surgery	77.8 (37.4)	0.435
6 months after surgery	77.8 (37.4)	0.446
36 months after surgery	81.5 (35.8)	0.660
Bodily pain		<0.001*
Preoperative	57.6 (27.0)	
4 weeks after surgery	63.1 (24.1)	0.775
6 months after surgery	75.4 (25.4)	0.0001
36 months after surgery	75.7 (23.2)	0.0001
General health		0.425*
Preoperative	64.0 (21.5)	
4 weeks after surgery	66.8 (20.9)	0.922
6 months after surgery	66.9 (21.6)	0.894
36 months after surgery	65.3 (22.0)	0.941

\*The linear mixed model p-value showing the different time effects. A p-value in the preoperative versus 4-week score and in the preoperative versus 6-month score and in the preoperative versus 36-month score.

the MH, SF, VT and RE scores, were higher compared to the reference population, and the bodily pain and the health change scores further increased by 6 months and 36 months following surgery, indicating recovery. Both MC and LC groups significantly improved the MH, SF, VT and RE scores at 36 months following surgery.

At the 3-year follow-up, no statistically significant differences in our structured telephone interview domains between MC and LC patients were shown; residual

abdominal symptoms, right upper quadrant pain, reflux symptoms, diarrhea/loose stools, fatty/fried food, overall satisfaction with the procedure, cosmetic satisfaction, recommend the procedure to others and quality of life.

At the 3-year RAND-36 follow-up, the only statistically significant difference between MC and LC patients was higher BP score in MC group at 6 months following surgery. Moreover, the linear mixed effect model was used to test overall significance between groups during the 3-year follow-period and no significant differences were observed in any of the eight domains of RAND-36 at 4 weeks, 6 months or 36 months after surgery. Although, there are earlier reports available of SF-36 and RAND-36, the long-term outcome and health-status by RAND-36 in MC *versus* LC patients has been rarely reported. Marchiori *et al.* (3) evaluated the pelvic floor rehabilitation programme for continence recovery after radical prostatectomy by RAND-36 –health survey and found that data provided by RAND-36 questionnaire could help to evaluate the costs and benefits of treatment options. Pilger *et al.* (4) studied quality of life and sexuality of patients after treatment for gynaecological malignancies in 55 patients by the SF12 questionnaire and found that patients who reported changes of sexuality were also shown to have lower overall SF12 score. Yonemoto *et al.* (2) evaluated quality of life of long-term survivors of high-grade osteosarcoma by SF-36 and concluded that limb-sparing surgery improved the quality of life of survivors, and the highest SF-36 domains were found to be GH, VT, SF and MH. These results are in line with the results of this study.

In the MC and LC combined analysis, the RAND-36 scores increased significantly following surgery in the ‘PF’ (6 months), ‘VT’ (4 weeks, 6 months and 36 months), ‘MH’ (4 weeks, 6 months), ‘RP’ (4 weeks, 6 months), ‘BP’ (6 months and 6 months) and ‘health change’ (4 weeks, 6/36 months). The linear mixed effect model was used to test overall significance of RAND-36 during the three-year follow-period and showed a statistically significant value of RAND-36 domains in vitality ( $p=0.002$ ), mental health ( $p=0.031$ ), score, role physical ( $p<0.001$ ) and bodily pain ( $p<0.001$ ).

In conclusion, RAND-36 scores improved significantly in several RAND-36 subscales in MC and LC groups with a similar postoperative course over the 3-year study period. At the 3-year follow-up telephone interview, no statistically significant differences in patient-reported outcome measures between MC and LC patients were shown. It also seems that RAND-36-Item Health Survey is a comprehensive test for long-term outcome and health status after cholecystectomy. Health-related QoL is a multidimensional concept considering all aspects of patients’ health and used widely as an outcome measure of treatment (1). Outcome data provided by QoL instruments complement clinical outcomes and may help to evaluate benefits of treatment options and care of patients.

## Conflicts of Interest

The Authors report no conflicts of interest or financial ties to disclose. The Authors alone are responsible for the content and writing of this article.

## Authors’ Contributions

All Authors have met all of the following four criteria: 1. Substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work, 2. Drafting the work or revising it critically for important intellectual content, 3. Final approval of the version to be published, 4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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