

A Finnish Version of RAND-36-Item Health Survey Versus Structured Interview 8 Years Postoperatively

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Abstract. *Background/Aim:* The aim was to assess the 8-year health status after minicholecystectomy (MC) versus laparoscopic cholecystectomy (LC) for gallstone disease (GS) by using the RAND-36 Health Survey. *Patients and Methods:* Initially, 88 patients with symptomatic GS disease were randomized to undergo either MC (n=44) or LC (n=44). RAND-36 survey was performed 8 years postoperatively. *Results:* In three RAND-36 domains (social functioning, role physical, role emotional) MC procedure was significantly better than LC. In MC patients, the 8-year postoperative scores of social functioning ($p<0.001$), role physical ($p=0.002$) and role emotional ($p<0.001$) were significantly higher than the age- and gender-adjusted Finnish reference scores. *Conclusion:* The Finnish version of the RAND-36 survey can be used as a valid and reliable method for measuring the quality of life and long-term outcome of cholecystectomy patients following surgery.

The core outcome measures following surgery have classically been complications such as morbidity, mortality, requirement of analgesia, number of postoperative analgesic doses and long-term outcome including post-operative symptoms, disease recurrence and long-term complications (1-3). However, several patient-rated outcome measures, such as Beck Depression Inventory (BDI) (4), Montgomery-

Åsberg Depression Rating Scale (5), Spielberger State-Trait Anxiety Inventory (STAI) (6), Numeric Rating Scale (NRS) (7) and Brief Pain Inventory (BPI) (8) have been reported as important patient-rated indicators for evaluating treatment results and quality of life (QoL) after surgery.

One of the most frequently used health-related QoL tools for assessing post-surgical outcomes is the Short Form Health Survey Questionnaire (SF-36) (9-12). The RAND-36 instrument contains the same questions as SF-36, but minor differences exist in scoring general health (GH) and bodily pain (BP) scales. The Finnish version of the RAND-36-Item Health Survey has been validated and provides reference values for Finnish population (9). We have previously reported short-term health related QoL after minicholecystectomy (MC) versus laparoscopic cholecystectomy (LC) using RAND-36 (10, 11). However, the long-term post-cholecystectomy outcome using RAND-36 has not been addressed in MC versus LC patients. Thus, we designed the present study to i) assess long-term health status using RAND-36 in MC versus LC, ii) compare long-term post-cholecystectomy RAND-36 values with reference values in the general Finnish population. Moreover, we performed a telephone-interview to further assess QoL at 8 years after MC versus LC.

Patients and Methods

The study was approved by the Ethics Committee and registered in the ClinicalTrials.gov database (ClinicalTrials.gov Identifier: NCT01723540, Figure 1), and design and surgical techniques used in the study are presented in our earlier paper (12) and Figure 1. The operations were carried out between September 2010 and April 2012 (12).

A telephone interview was conducted between January 2019 and January 2020. A structured questionnaire including assessment of residual symptoms, *de novo* symptoms, QoL and cosmesis was completed. Moreover, health related QoL was assessed postoperatively using the validated Finnish version of the RAND-36 by mail prior the interview (9). The eight health domains were calculated from the 36 questions as instructed by the RAND-36

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Key Words: RAND-36, telephone interview, quality of life, postoperative, cholecystectomy.

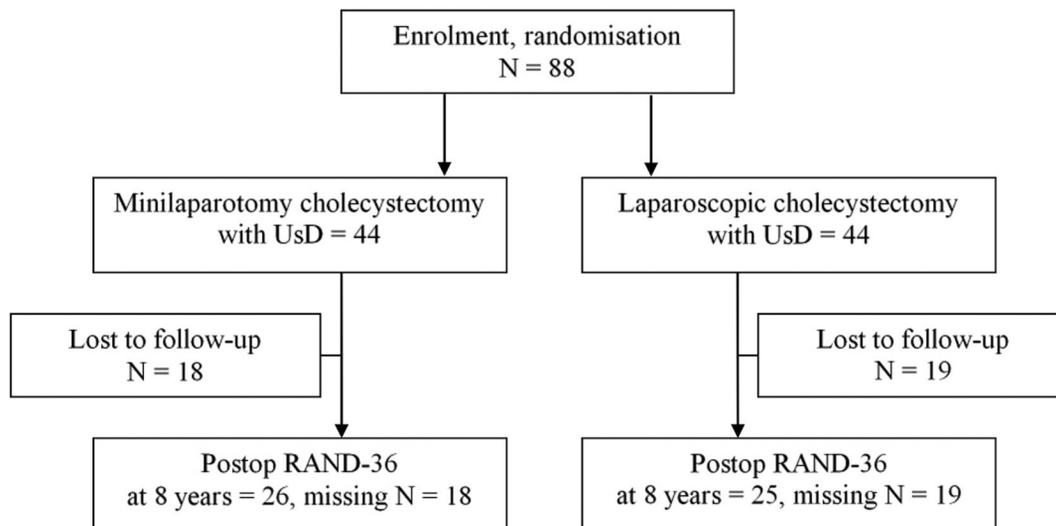


Figure 1. The flowchart. MC: Minicholecystectomy; LC: laparoscopic cholecystectomy; UsD: ultrasonic knife dissection.

item health survey (9). The design of our structured telephone interview performed in this study is presented in our recent paper (11) and in Table I. The data were analyzed with a statistical software program (IBM SPSS Statistics 26.0, 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.

Results

Thirty-eight (38/44=86.4%) in the MC group and thirty-five (35/44=79.5%) patients in the LC group were reached for the structured questionnaire phone interview by phone at 8 years following surgery. Further on, 26 (26/44, 59.1%) of the MC patients and 25 (25/44, 56.8%) of the LC patients returned the Finnish version of RAND-36 questionnaire 8-year following surgery. The consort figure and clinical data of the study are shown in Figure 1 and in Table II.

At the structured interview no statistically significant differences between MC and LC patients were shown; residual abdominal symptoms ($p=0.61$), right upper quadrant pain ($p=0.89$), reflux symptoms ($p=0.16$), diarrhea/loose stools ($p=0.14$), avoid fatty/fried food ($p=0.90$), overall satisfaction with the procedure ($p=0.40$), cosmetic satisfaction ($p=0.52$), recommend the procedure to others ($p=0.12$), quality of life ($p=0.60$) (Table I).

The eight RAND-36 domains with scores in MC versus LC patients 8 years postoperatively are shown in Table III. In three RAND-36 domains; social functioning ($p=0.019$), role physical ($p=0.043$), role emotional ($p=0.008$), the scores were significantly higher in the MC than LC patients. The 8-

year scores of eight RAND-36 domains in the MC and LC groups versus the Finnish reference scores are shown in Figure 2. The 8-year postoperative scores of social functioning ($p<0.001$), role physical ($p=0.002$) and role emotional ($p<0.001$) were significantly higher than the age- and gender –adjusted Finnish reference scores.

Discussion

The present study applied the Finnish version of the RAND-36, which was originally developed to examine health related QoL. The validity and reference values for the Finnish population have been verified for the RAND-36. We have previously studied the short-term outcomes after cholecystectomy, but the current literature lacks long-term health related patient centered outcome data. Moreover, a comparison to a reference population was deemed important and thus RAND-36 was selected to provide a reliable outcome instrument for the task.

In our previous report (10), we found no statistically significant QoL differences when comparing the MC and LC patients except for the higher score in 'health change' subscale at 4 weeks following surgery in the MC group. In addition, when study groups combined, four RAND-36 domains showed statistically significant improvement in health related QoL four weeks following surgery. Moreover, six RAND-36 domains improved 6 months postoperatively compared to the baseline. We also presented mid-term outcomes after MC vs. LC and showed that RAND-36 scores improved in several domains in MC and LC patients with a similar postoperative course (11). The linear mixed effect model was used to test the overall significance of RAND-36

Table I. *The results of the structured telephone interview at 8 years.*

Variable	MC group n=38	LC group n=35	p-Value
Residual abdominal symptoms			
Yes/no/could not say	79.0%/15.6%/5.2%	73.3%/17.1%/8.6%	0.61
Right upper quadrant pain attacks			
Yes/no/could not say	5.2%/84.2%/10.5%	7.9%/81.6%/10.5%	0.89
Reflux symptoms			
Less/not changed/more	31.6%/63.2%/5.2%	26.3%/52.6%/21.1%	0.16
Diarrhea or loose stools			
Less/not changed/more	5.3%/78.9%/15.8%	2.6%/68.4%/29.0%	0.14
Avoid fatty/fried food			
Yes/no/could not say	13.2%/84.2%/2.6%	18.4%/81.6%/-	0.90
Overall satisfaction with the procedure			
Satisfied/dissatisfied/could not say	91.1%/2.6%/5.3%	97.4%/2.6%/-	0.40
Cosmetic satisfaction			
Mean NRS (SD)	8.1 (1.7)	8.4 (1.8)	0.52
Recommend the procedure to others			
Yes/no/could not say	81.6%/15.8%/2.6%	97.4%/-/2.6%	0.12
Quality of life			
Better/not changed/worse	92.1%/7.9%/-	89.5%/10.5%/-	0.60

NRS: Numeric rating scale; SD: standard deviation; MC: minicholecystectomy; LC: laparoscopic cholecystectomy.

Table II. *Baseline clinical data of study patients in the minicholecystectomy (MC) and laparoscopic cholecystectomy (LC) patients. Data are mean (SD) or number of cases.*

Variable	MC group n=44	LC group n=44	p-Value
Age (years)	44 (14)	43 (12)	0.74
Gender (male/female)	8/36	3/41	0.11
Height (cm)	167 (7)	167 (8)	0.95
Weight (kg)	68 (11)	73 (12)	0.07
BMI (kg/m ²)	24.5 (3.3)	26.1 (3.2)	0.034
Operative time (min)	55 (14)	57 (25)	0.21
Time at operative theater (min)	107 (16)	113 (22)	0.15
Perioperative bleed (ml)	25 (34)	29 (37)	0.59
Length of the skin incisions (cm)	4.6 (1.1)	6.6 (2.6)	<0.001
ASA 1/2/3	33/10/1	32/12/0	0.95
Conversions	1	2	

BMI: Body mass index; ASA: American Society of Anaesthesiologists Physical Status Score.

Table III. *The results of RAND-36 at 8 years.*

RAND-36	MC and LC combined	MC group	LC group	p-Value
Physical functioning	89.9 (16.4)	93.1 (9.2)	86.6 (21.2)	0.168
Social functioning	88.7 (18.0)	94.6 (12.0)	82.7 (21.1)	0.019
Vitality	69.0 (21.7)	72.5 (20.4)	65.2 (23.0)	0.240
Mental health	77.0 (17.4)	79.2 (15.5)	74.7 (19.3)	0.360
Role physical	89.9 (16.4)	95.0 (20.4)	76.0 (40.5)	0.043
Role emotional	85.5 (33.2)	98.7 (6.7)	74.7 (41.1)	0.008
Bodily pain	80.0 (23.3)	83.3 (20.1)	76.6 (26.3)	0.312
General health	71.9 (21.7)	74.8 (17.3)	68.8 (25.4)	0.327

MC: Minicholecystectomy; LC: laparoscopic cholecystectomy. Values are means (standard deviation).

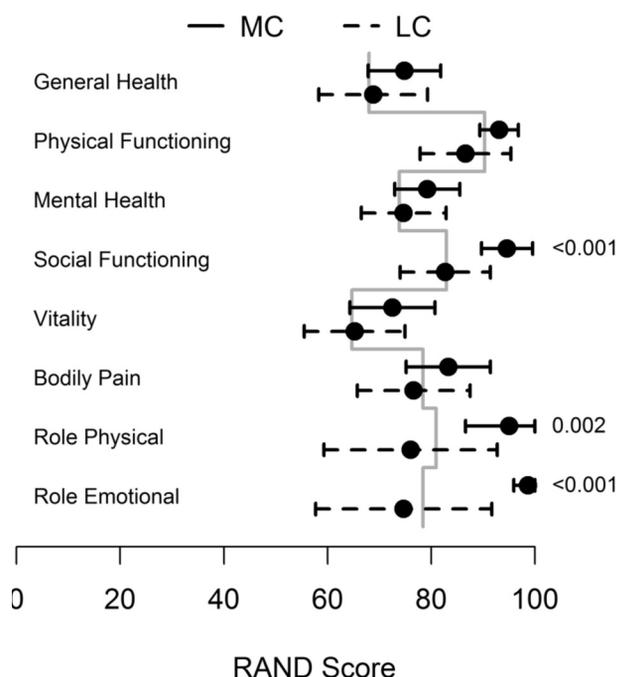


Figure 2. The 8-year postoperative RAND-36 counts in the minicholecystectomy (MC) and laparoscopic cholecystectomy (LC) groups versus the age- and gender –adjusted Finnish reference scores (dashed line) (9).

survey during the 3-year study period and the overall *p*-values were statistically significant in vitality, mental health, role physical and bodily pain domains (11). However, at mid-term, no significant differences in residual symptoms, *de novo* symptoms, QoL or cosmesis measures between MC and LC patients were shown. In the current article, the long-term RAND-36 showed three domains with significantly improved health related QoL scores in MC *versus* LC patients.

While considering the strengths of the present study, we feel that language bias might not exist, since the Finnish version of the RAND-36 includes only a few minor translation modifications, which were made in the translation process and wording of some items to make them more appropriate to the Finnish culture (9). We acknowledge that there are some limitations of this study. Firstly, this study lacks preoperative and earlier follow up RAND-36 interviews in this patient cohort. Secondly, due to lack of previous follow-up data, linear mixed effect model analysis was not possible in this study cohort. It is to be admitted that the small number of patients may have affected our final results, however, this could be taken in consideration when planning future studies.

We have previously applied a structured telephone-interview to assess long-term residual and *de novo* symptoms, QoL and cosmesis between MC and LC patients (10, 11). This structured

interview takes 15 minutes to register 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 QoL. We found no statistically significant health status differences using a structured telephone-interview in comparing the MC and LC groups.

Conclusion

The results of our study support the reliability of the Finnish version of the RAND-36 as a measure of QoL following cholecystectomy.

Conflicts of Interest

The Authors have no conflicts of interest or financial ties to disclose regarding this study.

Authors' Contributions

All Authors contributed to the collection and analysis of data, drafting and revising the manuscript, read and approved the final manuscript.

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