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First RAND-36-Item Health Survey in Three-dimensional Laparoscopy Cholecystectomy: A Prospective Randomized Study

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Abstract. *Background/Aim: National healthcare organizers require feedback from patients to improve medical treatment methods. Three-dimensional laparoscopy cholecystectomy (3D-LC) is a modern technique in surgery. However, there are no studies with patient feedback from validated questionnaires assessing the postoperative treatment results in 3D-LC. Patients and Methods: Initially 200 patients with symptomatic cholelithiasis were randomized into 3D-LC or mini-laparotomy cholecystectomy (MC) groups. RAND-36-Item Health Survey was performed preoperatively and 4 weeks following surgery relating the survey scores between the 3D-LC and MC groups. Results: Similar postoperative RAND-36 scores were reported for both groups preoperatively and at 4 weeks following surgery, and no significant differences in RAND-36 domains were shown. When the patients in both study groups were combined, Mental Health (p<0.001), Bodily Pain (p=0.01) and General Health (p=0.016) domain scores were significantly higher, indicating a significantly positive change in quality of life 4 weeks postoperatively, while those for the Role–Physical domain were significantly lower, indicating reduced physical activity during the 4 weeks following surgery. In comparison to the Finnish reference RAND-36 scores, scores at 4 weeks were significantly higher for the Mental Health domain (MC group, p<0.001 and 3D-LC group, p=0.001) whilst scores were significantly lower in four other domains: Physical Functioning, Social Functioning, Bodily Pain and Role–Physical. Conclusion: This study shows, for the first time using the RAND-36-Item Health Survey, relatively similar short-term outcomes in patients 4 weeks following cholecystectomy by 3D-LC and MC. Although scores for three RAND-36 domains were significantly higher postoperatively, indicating a significantly positive change in quality of life, a longer follow-up after cholecystectomy is needed for final conclusions to be drawn.*

Investigation of short-term outcome following surgery includes assessment of perioperative course, early complications, morbidity and mortality. However, national healthcare organizers require feedback from patients to improve outcome and compare various treatment methods. Patient-reported outcome measures (PROMs) are important questionnaires for assessing the quality of operations from a patient perspective, wherein physical, mental and social elements are assessed as patient-reported variables with activities of daily living. The Short Form Health Survey (SF-36) allow various disease states and surgical methods to be evaluated (1-13), including cholecystectomy. Several studies have evaluated the SF-36 in benign disease and in patients with cancer following surgery (1-13). The RAND-36-Item Health Survey (RAND-36) includes the same set of eight domains as the SF-36, namely General Health (GH), Physical Functioning (PF), Mental Health (MH), Social Functioning (SF), Vitality, Bodily Pain (BP), Role–Physical (RP) and Role–Emotional, however, the scoring of GH and BP scales differs slightly in RAND-36 (14-17). To our knowledge, RAND-36 is rarely evaluated in surgical patients and has not been assessed patients after in 3D-laparoscopic

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Table I. *Baseline demographic characteristics and surgical data for the mini-cholecystectomy (MC) and three-dimensional laparoscopy cholecystectomy (3D-LC) study groups.*

Variable		MC (n=88)	3D-LC (n=112)	*p*-Value
Age, years	Mean±SD	54±16	52±13	0.374
	Median (range)	56 (21-88)	53 (23-88)	
Height, cm	Mean±SD	164±6	168±9	<0.001
	Median (range)	164 (149-185)	166 (146-193)	
Weight, kg	Mean±SD	77±16	81±15	0.114
	Median (range)	75 (48-130)	80 (52-152)	
BMI, kg/m2	Mean±SD	28.9±5.4	28.7±4.8	0.780
	Median (range)	27.6 (19.0-46.6)	28.0 (20.6-42.3)	
Sex, n (%)	Female	81 (92.0)	86 (76.8)	0.001
	Male	7 (8.0)	26 (23.2)	
ASA, n (%)	1	26 (21.5)	49 (43.8)	0.096
	2	48 (54.5)	55 (49.1)	
	3	11 (12.5)	8 (7.1)	
	4	1 (1.1)	0	
Operative time, min	Mean±SD	69±23	78±24	0.011
	Median (range)	64 (34-137)	76 (39-208)	
Time at the operating theatre, min	Mean±SD	121±25	133±27	0.003
	Median (range)	116±76-204)	128 (81-271)	
Bleeding, ml	Mean±SD	41±62	25±31	
	Median (range)	20 (4-350)	20 (0-200)	0.036
Length of the skin incision, cm	Mean±SD	64±18	104±25	<0.001
	Median (range)	60 (45-135)	101 (55-275)	

ASA: American Society of Anesthesiologists physical status score not available in two MC patients; BMI: body mass index; SD: standard deviation. *t*-Test, chi-square test and Fisher's exact test were used.

cholecystectomy (3D-LC) *versus* mini-laparotomy cholecystectomy (MC). Therefore, our study design was to investigate RAND-36 items preoperatively and 4 weeks following cholecystectomy in patients after 3D-LC and MC.

Patients and Methods

The study was approved by the Ethics Committee of Kuopio University Hospital District, Kuopio, Finland (DNRO 27/02/2013), was registered in the ClinicalTrials.gov database (ClinicalTrials.gov Identifier: NCT01723540) and was conducted in accordance with the Declaration of Helsinki. The study included 200 patients with cholelithiasis in 3D-LC (n=112) or MC (n=88) groups. The surgical techniques used were standardized for both groups. An Olympus LTF-S300-10-3D laparoscopic HD device with flexible Endoeye flex videoscopes were used for the 3D-LC procedures (18). The MC technique protocol was fully described by Harju *et al*. (19).

RAND-36 was assessed preoperatively and 4 weeks postoperatively using the validated Finnish version of the questionnaire (17). The scores for the eight health domains were calculated from the 36 questions as detailed in a previous report by Aspinen *et al*. (16).

Baseline demographic characteristics are presented in Table I as means with standard deviations and with interquartile range or frequencies. The baseline group comparisons were executed by independent samples *t*-test and chi-square test or Fishers exact test. Scores for RAND-36 domains are expressed as means and standard deviations. A linear mixed-effect model (LME) was used to test group differences at time points and overall group x time effect and results. RAND-36 domain scores were also tested by one-sample *t*-test against Finnish reference RAND-36 scores separately for the 3D-LC and MC study groups. Data were analyzed by IBM SPSS statistical software (IBM SPSS Statistics for Windows, version 26.0; IBM Corporation, Armonk, NY, USA).

Results

In the present study, 84 patients (84/88=95.4%) in the MC group and 106 (106/112=94.6%) patients in the 3D-LC group were contacted for the preoperative RAND-36 questionnaire. Overall, 62 (62/84=73.8%) of the MC patients and 80 (80/106=75.5%) of the 3D-LC patients returned the RAND-36 questionnaire 4 weeks following surgery. The consort figure of the study and the perioperative surgical data are shown in Figure 1 and in Table I, respectively.

The LME model was used to test group differences during the 4-week follow-period. No significant differences were found in any of the eight domains of RAND-36 preoperatively or at 4 weeks following surgery (Table II).

Considering the MC and 3D-LC groups combined (Table III), the mean RAND-36 scores increased significantly at 4 weeks postoperatively compared with preoperatively for MH (76.4 *vs*. 83.1, $p<0.001$), BP (54.8 *vs*. 61.3, $p=0.010$), GH (63.3 *vs*. 66.2, $p=0.016$), while that for the RP domain was

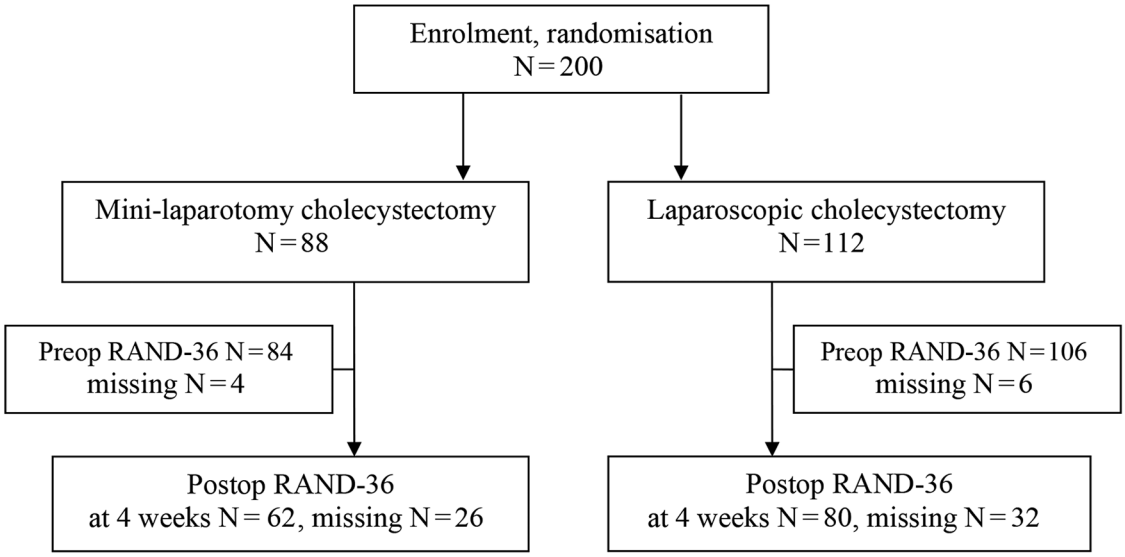

Figure 1. *The flowchart of the study design*.

Table II. *The RAND-36 scores for mini-laparotomy cholecystectomy (MC) and 3D laparoscopic cholecystectomy (LC) groups*.

RAND-36 domain	Time point	MC group	LC group	*p*-Value
Physical functioning				**0.395**
	Preoperative	78.3±24.3	82.2±21.6	0.234
	4 Weeks post surgery	81.7±21.0	82.7±21.3	0.666
Social functioning				**0.781**
	Preoperative	77.3±23.7	78.5±24.4	0.743
	4 Weeks post surgery	77.1±23.9	77.6±22.9	0.981
Vitality				**0.564**
	Preoperative	63.6±21.0	65.0±18.7	0.608
	4 Weeks post surgery	66.9±20.0	67.0±21.2	0.887
Mental health				**0.646**
	Preoperative	74.9±19.5	77.6±15.7	0.280
	4 Weeks post surgery	82.0±15.8	84.1±27.6	0.801
Role–physical				**0.258**
	Preoperative	62.1±42.4	66.3±40.4	0.479
	4 Weeks post surgery	41.0±40.9	54.1±40.7	0.047
Role–emotional				**0.537**
	Preoperative	72.7±39.0	78.6±37.4	0.282
	4 Weeks post surgery	76.0±38.2	76.4±38.7	0.793
Bodily pain				**0.314**
	Preoperative	55.3±27.6	54.4±24.9	0.830
	4 Weeks post surgery	58.8±25.0	63.4±19.8	0.271
General health				**0.568**
	Preoperative	62.6±19.3	63.8±20.0	0.724
	4 Weeks post surgery	65.1±20.7	67.1±22.8	0.464

Values are mean±standard deviation. Bold text: Overall *p*-value using linear mixed-effect model showing the effects of different time and group interactions.

significantly lower (64.4 *vs*. 48.3, $p<0.001$), indicating reduced physical activity during the 4 weeks following surgery (Table III).

The 4-week postoperative scores for the eight RAND-36 domains in MC and 3D-LC groups *versus* the Finnish reference RAND-36 scores were analysed and the results are

Table III. *The RAND-36 scores for mini-laparotomy cholecystectomy (MC) and 3D laparoscopic cholecystectomy (LC) groups combined.*

RAND-36	Time point	MC and LC combined	*p*-Value
Physical functioning	Preoperative	80.5±22.9	
	4 Weeks post surgery	82.3±21.1	0.066
Social functioning	Preoperative	78.0±24.1	
	4 Weeks post surgery	77.4±23.2	0.771
Vitality	Preoperative	64.4±19.7	
	4 Weeks post surgery	67.0±20.6	0.126
Mental health	Preoperative	76.4±17.5	
	4 Weeks post surgery	83.1±23.1	<0.001
Role–physical	Preoperative	64.4±41.2	
	4 Weeks post surgery	48.3±41.1	<0.001
Role–emotional	Preoperative	76.0±38.1	
	4 Weeks post surgery	76.3±38.3	0.890
Bodily pain	Preoperative	54.8±26.0	
	4 Weeks post surgery	61.3±22.3	0.010
General health	Preoperative	63.3±19.6	
	4 Weeks post surgery	66.2±21.8	0.016

Values are mean±standard deviation. *p*-Values shown are for 4-week *versus* preoperative score.

shown in Figure 2. In comparison to the Finnish reference scores, the RAND-36 scores at 4 weeks were significantly higher in the MC and 3D-LC groups for the MH domain ($p<0.001$ and $p=0.001$, respectively) (Figure 2), whilst the RAND-36 scores at 4 weeks were significantly lower for PF, SF, BP, and RP.

Discussion

PROMs are important for assessing quality of treatment from a patient perspective (1-16). Most earlier reports of quality of treatment relate to the length of hospital stay and perioperative follow-up, often with surgical focus and lack of information on the patient's own experience. Understanding the importance of PROMs following surgery is key in the delivery of high-level healthcare. The European Association for Endoscopic Surgery recommend the use of the SF-36 for assessing quality of treatment following LC, because it considers the SF-36 questionnaire valid for investigating functional recovery after cholecystectomy (20). The SF-36 and RAND-36 PROMs are validated, free to use, quality of life measures and have the advantage of being available in different languages, and RAND guidelines for translating the survey into another language also exist (21). Interestingly, the time taken to complete the SF-36 questionnaire was reported in only two studies (22, 23). In these two studies, the time was approximately 15-20 min per patient to complete the SF-36, while it took 5 min per patient to complete the RP and BP subscales (22, 23). This is a limitation of this scoring system because some patients may consider the time too long and the questionnaire may also be laborious for the investigator as it is only available on paper.

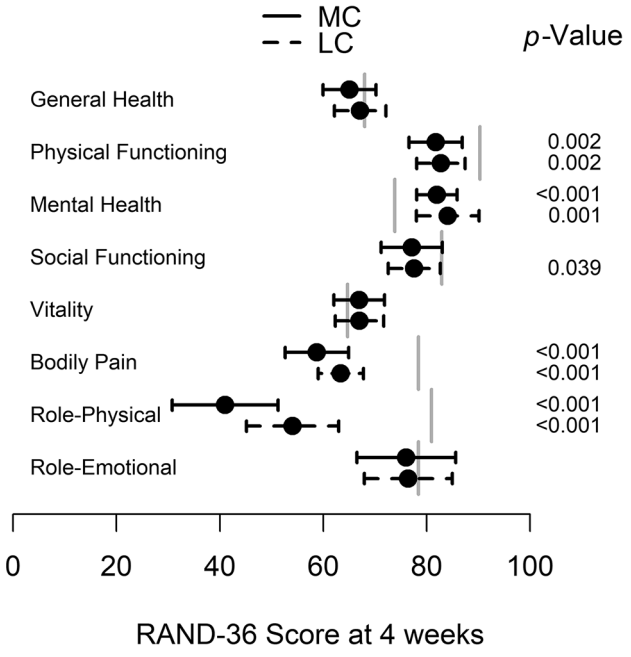

Figure 2. *The mean (95% confidence interval) scores for the eight RAND-36 domains at 4 weeks postoperatively for the mini-laparotomy cholecystectomy (MC) versus 3D laparoscopic cholecystectomy (3D-LC) groups compared to age- and sex-adjusted Finnish reference scores (grey line) (17). The p-values are shown for comparison between groups and Finnish reference scores.*

RAND-36 and SF-36 are essentially the same instrument as they contain the same set of questions; however, the scoring scales differ slightly in the domains of GH and BP. Amini *et*

al. (24) investigated barriers for implementing PROMs in clinical use at an academic centre and concluded that the time required to use RAND-36 may be a barrier to its implementation, along with the lack of availability of a web-based platform. However, Melly *et al*. (25) reviewed PROMs after LC and none of the 21 studies in that review showed that they had used a digital platform. The SF-12 is a shortened version of the SF-36 (21, 26) and it has the same shortcomings in use as the SF-36, but the time needed to complete it is less; however, the SF-12 lacks some specific questions needed for patients with cholelithiasis.

We chose RAND-36 because it was translated into our language and was investigated and reported earlier for reliability, construct validity and reference values in the Finnish general population (17). Interestingly, in their review, Melly *et al*. (25) provide the reason for the authors' choice of PROM method in each study. Four out of the 21 chose a PROM tool because it was validated in their own language, seven selected a PROM because it had been validated previously, and three studies chose the tool because it had been validated previously in cholecystectomy patients (27-29). Unfortunately, it is unclear, whether the PROMS in the review of Melly *et al*. (25) were able to find resolution of symptoms, onset of new symptoms, or persistence of symptoms following LC, because only two out of the six SF-36 studies used a preoperative SF-36 questionnaire (23, 28).

In the present study, RAND-36 questionnaires were correctly filled in over 95% of the study patients preoperatively and 75% of cholecystectomy patients (75%) at 4 weeks following surgery. Therefore, it was possible to elaborate the results understanding how cholecystectomy affected the patients' quality of life and the health status in short-term follow-up. The present study differs from the results of the RAND-36 survey in radical prostatectomy patients following surgery, where fewer than 10% of the patients completed the RAND-36 questionnaire and therefore it was not possible to correctly assess quality of life following radical prostatectomy (14).

The strengths of the present study are: i) A high number of study patients, ii) a study cohort which is comparable to the Finnish reference population (17), and iii) both RAND-36 questionnaire results preoperatively and 4 weeks postoperatively. The PF, BP and RP scores in both study groups were lower compared to the Finnish reference population scores at 4 weeks, indicating health change post-surgery. When the patients in both study groups were combined, the RAND-36 scores increased significantly following surgery for the MH ($p<0.001$), BP ($p=0.010$) and GH ($p=0.016$) domains.

In conclusion, PROMs are very rarely investigated for modern 3D-LC techniques and there are no prospective studies assessing the postoperative health status by RAND-36-Item Health Survey in 3D-LC patients. This study shows the results of the RAND-36-Item Health Survey used for the first time for patients 4 weeks following 3D-LC and MC. Although scores for three RAND-36 domains were significantly higher, indicating a significantly positive change in quality of life postoperatively, a longer follow-up after cholecystectomy is needed to be able to assess the resolution of perioperative symptoms and the possible onset of new symptoms following cholecystectomy.

Conflicts of Interest

The Authors report no conflicts of interest or financial ties to disclose.

Authors' Contributions

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

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