

# Comparison of quality of life between pre- and post-operative standard laparoscopic cholecystectomy using Short Form-36



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## ABSTRACT

**Background:** Gallstone disease (cholelithiasis) is a wide spectrum of conditions, ranging from asymptomatic cholelithiasis, biliary colic, empyema gallbladder, and gangrene to perforation and peritonitis. **Aims and Objectives:** The aim of this study was to assess the quality of life before and after a standard laparoscopic cholecystectomy (LC) using the Short Form-36 (SF-36). **Materials and Methods:** In the study cohort of 100 patients using SF-36 in patients of pre-operative and post-operative standard LC are compared in eight domains of health quality index in Maharani Laxmi Bai Medical College, Jhansi between January 2021 and June 2022. **Results:** There is finding of significant change in seven domains in mean  $\pm$  1 month, (1) Physical functioning – pre-operative and post-operative, that is,  $33.00 \pm 31.812$  and  $88.68 \pm 22.40$ , respectively, (2) Role limitations due to physical health – pre-operative and post-operative, that is,  $3.5 \pm 18.401$  and  $98.75 \pm 10.546$ , respectively, (3) Role limitations due to emotional problems – pre-operative and post-operative, that is,  $4.67 \pm 21.128$  and  $98.67 \pm 11.489$ , respectively, (4) Energy/fatigue- pre-operative and post-operative, that is,  $34.94 \pm 16.638$  and  $83.11 \pm 12.456$ , respectively, (5) Social pre-operative functioning – pre-operative and post-operative, that is,  $39.38 \pm 20.428$  and  $98.88 \pm 5.196$  respectively, (6) Pain – pre-operative and post-operative, that is,  $34.73 \pm 18.340$  and  $97.30 \pm 15.489$ , respectively, (7) General health – pre-operative and post-operative, that is,  $35.85 \pm 35.897$  and  $67.00 \pm 35.511$ , respectively, and minimal change in one domain (8) Emotional well-being – pre-operative and post-operative, that is,  $34.16 \pm 15.491$  and  $39.08 \pm 18.694$ . **Conclusion:** The pre-operative and post-operative parameters of the SF-36 questionnaire show a significant change in their mean  $\pm$  standard deviation at 1-month postoperatively following standard LC. The maximum significant change occurred in parameters of physical functioning, role emotion, role physical, energy, social functioning, pain, and general health.

**Key words:** Gallstone disease; Laparoscopic cholecystectomy; Quality of life

## INTRODUCTION

Gallstone disease (cholelithiasis) is a wide spectrum of conditions, ranging from asymptomatic cholelithiasis, biliary colic, empyema gallbladder, and gangrene to perforation and peritonitis.<sup>1</sup> In other words, it can be categorized as lithogenic state, asymptomatic gallstones, symptomatic gallstones, and complicated gallstones.<sup>2</sup> Cholelithiasis

affects 5–22% of the Western population.<sup>3</sup> The Asian and African populations show a lower prevalence in the United States, 6.5% of males and 10.5% of females have gallstones. This gender difference is attributable to estrogen, which increases biliary cholesterol secretion. The incidence of gallstone formation increases with age. Symptoms occur in only 10–30% of the patients,<sup>3</sup> and 1–4% of patients per year are at risk of developing complications.

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Cholecystectomy is one of the most common surgical procedures performed worldwide, with >750,000 cases in the United States reported annually.<sup>4</sup> With the advent of laparoscopic surgery, approximately 90% of elective and 10% of emergency cholecystectomies are performed laparoscopically. Since the first laparoscopic cholecystectomy (LC) performed by Mouret in France in 1987,<sup>5</sup> it has gained acceptance as the gold standard for the management of uncomplicated symptomatic cholelithiasis. It has now become the second most common general surgical procedure post-appendectomy.<sup>6</sup>

Health-related quality of life (HRQoL), a rather unknown aspect two decades ago, is now a vital component of medical research.<sup>7</sup> Despite its acknowledged worth, a conceptual definition of this term is lacking.<sup>8</sup>

Broadly, it entails the physical, emotional, and social functioning status of the human body. Post-operative recovery and quality of life (QoL) are essential components that predict a patient's hospital stay, return to physical strength, emotional status, and routine activities, as well as define the financial burden on the patient and health-care facility.<sup>9</sup> The core purpose is to determine the patient's satisfaction level pre and postoperatively and, repeatedly thereafter, accurately assess the effectiveness of an intervention in terms of long-term well-being. Hence, patient-reported outcomes, such as pain and QoL, are essential considerations from a surgeon's perspective in opting for a surgical procedure. QoL assessment allows further research and modification of a specific surgical procedure.<sup>10</sup>

### Aims and objectives

The aim of this study was to assess the QoL before and after a standard laparoscopic cholecystectomy (LC) using the SF-36.

## MATERIALS AND METHODS

### Ethical

Ethical committee approval was duly taken. Data were collected from the department of general surgery using the bed side tickets of the patients after taking a short history and informed consent from the patients.

### Source of data

The study was conducted on 100 cases of LC in Maharani Laxmi Bai Medical College, Jhansi between January 2021 and June 2022.

### Inclusion criteria

The following criteria were included in the study:

- Age between 20 and 65 years.
- Being elective candidates for cholecystectomy.

- All patient who will be underwent LC.
- Informed consent will be obtained from all the subjects enrolled in the study after explaining to them in detail about the study in their own language.

### Exclusion criteria

The following criteria were excluded from the study:

- Patients over 65 years old.
- Patients with mental retardation.
- Patients not giving consent for standard LC.
- Patients who underwent conversion from laparoscopic method operation to open method.
- Procedure done other than standard LC.
- Patients with biliary calculosis complications meaning acute inflammation.
- Choledocholithiasis.
- Biliary pancreatitis, stenosis papillitis.
- Cholecystoentric fistula.

### Study design

- This was a prospective study.

### SF-36 health survey

The basis of this study is the QoL analysis of the operated patients, using Short Form questionnaire (SF-36) developed from the RAND corporation medical outcomes study (RAND Health, Santa Monica, CA, USA) which were translated to Hindi language without changing the meaning of the questions.

The SF-36 questionnaire is a standardized procedure for the assessment of HRQoL which analyzes eight domains of QoL:

1. Physical functioning
2. Role limitations due to physical problems
3. Social functioning
4. Bodily pain
5. General mental health
6. Role limitations due to emotional problems
7. Vitality
8. General health perceptions.

The answers were categorized in the form of scores in the way recommended from RAND, transforming them into linear analogue scale where the score of 100 indicated the optimal health. After that, they were grouped into the domains. The questionnaire was sent by mail to the addresses of the patients with the accompanying letter, where we explained the kind of research we were conducting and asked the patients to focus on the LC procedure or, in other words, to connect the questions to LC procedure.

### Statistical analysis

The data were summarized as mean values with standard deviations (SD). The statistical analysis was performed

using t-test. The SPSS 20.0 for Windows computer software (SPSS Inc., Chicago, IL) was used for statistical analysis.  $P < 0.05$  was considered significant.

## RESULTS

There is finding of significant change in seven domains in mean  $\pm 1$  month, (1) Physical functioning – pre-operative and post-operative, that is,  $33.00 \pm 31.812$  and  $88.68 \pm 22.40$ , respectively, (2) role limitations due to physical health – pre-operative and post-operative, that is,  $3.5 \pm 18.401$  and  $98.75 \pm 10.546$ , respectively, (3) role limitations due to emotional problems – pre-operative and post-operative, that is,  $4.67 \pm 21.128$  and  $98.67 \pm 11.489$ , respectively, (4) energy/fatigue – pre-operative and post-operative, that is,  $34.94 \pm 16.638$  and  $83.11 \pm 12.456$ , respectively, (5) social pre-operative functioning – pre-operative and post-operative, that is,  $39.38 \pm 20.428$  and  $98.88 \pm 5.196$ , respectively, (6) pain – pre-operative and post-operative, that is,  $34.73 \pm 18.340$  and  $97.30 \pm 15.489$ , respectively, (7) general health – pre-operative and post-operative, that is,  $35.85 \pm 35.897$  and  $67.00 \pm 35.511$ , respectively, and minimal change in one domain, and (8) emotional well-being – pre-operative and post-operative, that is,  $34.16 \pm 15.491$  and  $39.08 \pm 18.694$  (Table 1).

## DISCUSSION

LC is a minimally invasive surgical procedure for the removal of a diseased gallbladder. This technique has essentially replaced the open technique for routine cholecystectomies since the early 1990s.<sup>11</sup>

Cholelithiasis is one of the most common diseases in developed countries. It affects about 10–15% of the population. About 80% of the patients present no symptoms of the disease. Standard treatment is LC. The main indications for that procedure are the clinical symptoms of the disease or its complications. It is believed that asymptomatic patients should not be treated surgically, but there are still many patients who undergo the surgery even though they present no symptoms.

Standard LC, due to its plethora of benefits, soon became the gold standard for cholecystitis and cholelithiasis since its inception. The major benefits included a shorter hospital stay, less pain, higher postoperative mobility, lower morbidity, and less bleeding. Although it has no major downsides, it is still considered to have a considerable learning curve for beginners and is not preferred in certain conditions, like when we are dealing with intra-hepatic gall bladders or severe adhesions.

For evaluating the HRQoL, we have used the SF-36 health survey, which incorporates 36 questions for evaluating eight parameters that include physical functioning, role physical, role emotional, social functioning, bodily pain, vitality, mental health, and general health. We then converted each subscale to a scale of 0–100, where higher scores translated into better HRQoL.

### Demographics

Our study was limited to the Bundelkhand region. The study cohort had its maximum number of patients in the age group of 41–50 years, and out of 100 patients, 72 (72%) were females. This correlates with the age-old phrase that cholelithiasis is a disease of a “fat, fertile, female of forty.” Apart from this, 28% were males. About 21% of patients belonged to the 51–60 year cohort while 4% of patients were above 60 years. (Tables 2 and 3) This is significant because as age increases, the postoperative recovery in QoL scores also gets directly impacted, and hence caution has to be followed when interpreting scores for such age groups. 43% of patients were from the <40 years old cohort. Most of them (55%) were asymptomatic, incidentally diagnosed cases.

Our results hold a significant correlation with already published indexed studies. Atif et al.,<sup>3</sup> in their study, also reported 80% (n=56) patients aged between 31 and 60 years, similar to other reported studies including Lien et al.,<sup>12</sup> Quintana et al.<sup>13</sup> and Shi et al.<sup>9</sup>

### Physical functioning

Physical functioning refers to the extent to which health interferes with a variety of activities such as sports, carrying

**Table 1: QoL**

Domains of QoL, n=8	Mean+SD		P
	Preop. Lap. Chole.	Postop. Lap. Chole.	
1. Physical functioning	33.00±31.812	88.68±22.40	0.0001
2. Role limitations due to physical health	3.5±18.401	98.75±10.546	0.0001
3. Role limitations due to emotional problems	4.67±21.128	98.67±11.489	0.0001
4. Energy/fatigue	34.94±16.638	83.11±12.456	0.0001
5. Emotional well-being	34.16±15.491	39.08±18.694	0.04
6. Social functioning	39.38±20.428	98.88±5.196	0.0001
7. Pain	34.73±18.340	97.30±15.489	0.0001
8. General health	35.85±35.897	67.00±35.511	0.0001

**Table 2: Age (in years) distribution**

Age (in years)	No. of patients	Percentage
20–30 years	20	20.00
31–40 years	23	23.00
41–50 years	32	32.00
51–60 years	21	21.00
>60 years	04	04.00
Total	100	100

**Table 3: Sex distribution**

Sex	No. of patients	Percentage
Male	28	28.00
Female	72	72.00
Total	100	100

groceries, climbing stairs, and walking; higher scores indicate that the patient is able to perform all types of vigorous activities without limitations to health, and lower scores denote that the patient is limited in performing all physical activities, including bathing or dressing. In our study out of 100 patients, for physical functioning, pre-operative LC mean±SD score was 33.00±31.812 and post-operative LC mean±SD score was 88.68±22.40. Then, applying the Student's t-test for P-value, the P-value was 0.0001 (significant), which meant that patients who underwent standard LC had, in general, an improvement in their physical functioning at 1-month postoperatively.

#### Role limitations due to physical health

Role limitations due to physical health in the SF-36 questionnaire are defined as the extent to which health interferes with usual daily activities, such as work, housework, or school; higher scores denoting that there are no problems with work or daily activities as a result of physical health, and lower scores denoting problems with work or other daily activities as a result of physical health. In our study, out of 100 patients, for role limitations due to physical health, the pre-operative LC mean±SD score was 3.5±18.401 and the post-operative LC mean±SD was 98.75±10.546. Then, applying the Student's t-test for P-value, the P-value was 0.01 (significant), which meant patients who underwent standard LC had better improvement in role limitations due to physical health at 1-month postoperatively.

#### Role limitations due to emotional problems

Role limitations due to emotional problems are defined in the SF-36 questionnaire as the extent to which health interferes with usual daily social activities, for example, achieving less than one would like; higher scores denoting no problems with work or other daily activities as a result of emotional problems; and lower scores denoting problems with work or other daily activities as a result of emotional problems. In our study, out of 100 patients,

for role limitations due to physical health parameters, the pre-operative LC mean±SD score was 4.67±21.128 and the post-operative LC mean±SD score was 98.67±11.489. Then, applying the Student's t-test for P-value, the P-value was 0.0001 (significant), which means patients who underwent standard LC had significant benefits from role limitations due to physical health at 1-month, postoperatively.

#### Vitality

Vitality, in the SF-36 questionnaire, is defined as energy or fatigue, with higher scores denoting the patient feeling full of pep and energy all the time and lower scores denoting that the patient feels tired and worn out all the time. In our study, out of 100 patients, the vitality, pre-operative LC mean±SD score was 34.94±16.638 and the post-operative LC mean±SD score was 83.11±12.456. Then, applying the Student's t-test for P-value, the P-value was 0.0001 (significant), which meant that patients who underwent standard LC had a significant improvement in vitality at 1-month postoperatively.

#### General mental health

General mental health, in the SF-36 questionnaire, is defined as a general mood of affect, including depression, anxiety, and psychological well-being during the past week, with higher scores meaning that the patient feels peaceful, happy, and calm all of the time, and lower scores denoting that the patient has feelings of nervousness and depression all of the time. In our study, out of 100 patients, the general mental health parameter for pre-operative LC mean±SD score was 34.16±15.491 and the post-operative LC mean±SD score was 39.08±18.694. Then, applying the Student's t-test for P-value, the P-value was 0.04 (significant), which meant that patients who underwent standard LC had a significant improvement in general mental health at 1-month postoperatively.

#### Social functioning

Social functioning, in the SF-36 questionnaire, is defined as the extent to which health interferes with normal social activities, such as visiting with friends during the past week; with higher scores denoting that the patient performs normal social activities without interference due to physical or emotional problems and lower scores denoting that the patient has extreme and frequent interference with normal social activities due to physical and emotional problems. In our study out of 100 patients, for social functioning parameter, pre-operative LC mean±SD scores was 39.38±20.428 and post-operative LC mean±SD score was 98.88±5.196. Then, applying the Student's t-test for P-value, the P-value was 0.0001 (significant), which meant that the patient who underwent standard LC had a significant improvement in social functioning.

### Bodily pain

Bodily pain, in the SF-36 questionnaire, is defined as the extent of bodily pain in the past week, with higher scores denoting no pain or limitations due to pain and lower scores denoting very severe and extremely limiting pain. In our study, out of 100 patients, the bodily pain parameter's pre-operative LC mean $\pm$ SD score was 34.73 $\pm$ 18.340 and the post-operative LC mean $\pm$ SD score was 97.30 $\pm$ 15.489. Then, applying the Student's t-test for P-value, the P-value was 0.0001 (significant), which meant that patients who underwent standard LC had significant improvement in bodily pain at 1-month postoperatively.

### General health

General health in the SF-36 questionnaire has been defined as the overall rating of current health by the patient in general, with higher scores meaning that the patient evaluates his personal health as excellent and lower scores meaning that the patient evaluates his personal health as poor and believes that it is likely to get worse. In our study out of 100 patients, for general health as a parameter, pre-operative LC mean $\pm$ SD score was 35.85 $\pm$ 35.897 and post-operative LC mean $\pm$ SD score was 67.00 $\pm$ 35.511. Then, applying the Student's t-test for P-value, the P-value was 0.0001, which meant that patients who underwent standard LC had a significant improvement in general health at 1-month postoperatively.

### QoL improvement

Atif et al.,<sup>3</sup> conducted a similar study in a tertiary centre in Pakistan with a similar demographic cohort. However, they used the gastrointestinal QoL index, which had 94.64 $\pm$ 2.24 for pre-treatment and 106.09 $\pm$ 2.40 for post-treatment as scores, with the mean change calculated as 11.44 $\pm$ 3.29 (P=0.001), showing a significant difference in QoL at 3-month postoperatively. Our study results corroborate with the results published in their study at 1-month postoperatively.

Lien et al.,<sup>15</sup> in their study concluded that "all eight SF-36 subscale scores from pre-operative gallstone patients were significantly lower than those from Taiwanese population norms (t test, P<0.0001). Compared with pre-operative quality-of-life status, three out of eight SF subscale domains showed significant improvement (paired t test): Role physical 20.9% (P=0.003), bodily pain 27.8% (P<0.0001), and role emotional 17.7% (P=0.0069). Even after operation, gallstone patients still performed inferiorly to matched general population in seven out of eight SF-36 health dimensions except for role emotional". The results hold true for our study denoting that standard LC has significant improvement in the QoL at 1-month postoperatively.

Quintana et al.,<sup>16</sup> in their study, concluded that "surprisingly, the generic SF-36 showed improvements in more domains

than the GIQLI: The bodily pain, vitality, and social functioning domains." Their study also compared "whether asymptomatic patients had lower HRQoL improvements than symptomatic patients" and concluded that "the bodily pain domain of the SF-36 showed a significantly greater improvement for symptomatic patients, as well as the health transition item, while the GIQLI showed significant improvements in the physical impairment and symptomatology domains." "In addition, the level of satisfaction after the intervention was significantly higher for symptomatic patients." Their findings also correlate with our results in terms of showing that standard LC translates into better QoL improvement in most aspects of the SF-36 questionnaire over the long-term and in all aspects of the SF-36 questionnaire in the short-term of 1 month.

Hsueh et al.,<sup>17</sup> in their study, compared both open cholecystectomy and standard LC in terms of their SF-36 scores at 3-month and 6-month postoperatively and found out that "by 3-month post-surgery, the open cholecystectomy patients had significantly (P<0.05) improved in GIQLI social score; and, by 6-month post-surgery, they had significantly (P<0.05) improved in other dimensions as well." The LC patients, however, exhibited significant improvement in all dimensions at both 3-month and 6-month post-surgery (P<0.05) with effect sizes ranging from 7.41 (physical function) to 17.75 (psychological function) at 3 months, and also from 1.90 (psychological function) to 8.98 (physical function) at 6 months. The HRQoL changes in LC patients were uniformly positive at both 3-month and 6-month post-surgery, with effect sizes ranging from 5.96 (general health) to 24.81 (bodily pain) and from 1.07 (vitality) to 6.48 (bodily pain), respectively. The findings correlate with our study in most of the aspects of the SF-36 questionnaire. Therefore, it can be safely concluded that standard LC translates into better improvement in post-operative parameters of the SF-36 questionnaire and improved patient morbidity.

### Limitations of the study

This was a single-centered study.

## CONCLUSION

The SF-36 is a standardized, widely accepted and useful questionnaire that can be used to quantify and analyze the pre-operative and post-operative parameters to describe the morbidities of standard LC. Having analyzed the same on a cohort of 100 patients, it can be safely concluded that –

1. Standard LC has been widely accepted as the gold standard procedure for both symptomatic and asymptomatic gall stone disease.

2. Gall stone disease was common in the cohort of female patients of 41–50 years.
3. The pre-operative and post-operative parameters of the SF-36 questionnaire show a significant change in their mean±SD at 1-month postoperatively following standard LC.
4. The maximum significant change occurred in parameters of physical functioning, role emotion, role physical, energy, social functioning, pain, and general health.
5. The minimum significant change occurred in emotional well-being.

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NN, NKB, PS, NK, JC, and SG- Concept and design of the study, prepared first draft of manuscript; Interpreted the results; reviewed the literature and manuscript preparation; concept, coordination, preparation of manuscript, and revision of the manuscript.

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