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Observational study of influence of obesity on the improvements in quality of life in female patients undergoing laparoscopic cholecystectomy for chronic symptomatic gallstone disease

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Abstract

Background: To objectively compare the quality of life of obese and non-obese female patient's pre and post laparoscopic cholecystectomy using the GIQLI questionnaire.

Method: This is a prospective observational study. Female patients ≥18 years admitted to a tertiary care centre for elective laparoscopic cholecystectomy were divided into 2 groups obese and non-obese based on BMI and evaluated using the GIQLI questionnaire preoperatively and 30 days postoperatively.

Results: A total of 92 patients were included (47 obese, 45 non-obese) with a mean age of 41.6 years. The BMI cut off value was 25 for classification (As per Asian guidelines for BMI) Mean duration of complaints was 4 months. 34.09% of the patients had co-morbidities, diabetes mellitus was the commonest (20.45%). 15 patients had past H/O of acute cholecystitis (17.08%) The patients were evaluated by the GIQLI Score pre-operatively and 30 days post-operatively. A significant improvement in GIQLI score was observed postoperatively, with mean total GIQLI score increasing from 106.7±8.49 (98.21-115.19) to 122.4±7.58 (114.82-129.98) ($p < 0.001$) in non-obese group and 94.43 +9.82(82.63-106.23) to 105.59 + 9.3(96.29-114.89). Significant improvements were also observed in GIQLI

subgroups of gastrointestinal symptoms, physical status, emotional status and social function status in both the groups.

Conclusion: Laparoscopic Cholecystectomy restores quality of life to a significant extent in both obese and non-obese women and BMI should not be a negative determinant in choosing a candidate for elective laparoscopic cholecystectomy.

Keywords: Laparoscopic cholecystectomy, Quality of Life, GIQLI Questionnaire, Female Obesity, Post operative Quality of Life

Introduction

Quality of life (QOL) is a broad concept with multiple dimensions that usually includes a subjective evaluation of both the positive and negative aspects of life.

Every patient has a different perception regarding their quality of life and it isn't easy to quantify and objectively assess this. Any doctor-patient interview remains incomplete without understanding this aspect of the patient's life. 'How does the patient feel?' is of primary concern to every doctor and the answer to that question depends on multiple facets of his everyday life. Today, the newer innovations in laparoscopic and endoscopic surgeries can no longer be evaluated unless this is taken into account.

Gallstones are now prevalent all over the world and about 10-20% of the adult population has gallstones. In India, out of 800 million adult population, approximately 15% (120 million) have gallstones. [1,2] Asymptomatic gallstone disease has a benign natural course; the progression of asymptomatic to symptomatic is relatively low with about 2% becoming symptomatic each year. The manifestation of gall stones varies from no symptoms at all to frequent attacks of intense biliary colic with a profound influence on quality of life and potentially serious complications, such as acute cholecystitis, pancreatitis and cholangitis.

It's no more an unknown fact that the risk of gallstone disease is associated with obesity as the increased HMG-CoA reductase activity causes increased biliary secretion of cholesterol [3]. Across the world, studies are in abundance which have shown high incidence of cholelithiasis in obese patients. An increasing obese population has become a national affliction not only in the Western nations, but also in the Asian subcontinent.

Female patients in India have been known to under report severity of symptoms on verbal history. Obesity has a definite influence on QoL measures in patients with GI diseases.

(Evidence based Guidelines by European association for endoscopic surgery)[4] Obesity is reported as a positive predictor of surgical morbidity. Obese patients undergoing laparoscopic cholecystectomy for chronic gallstone disease may not be deriving equal benefits as some of their symptom complex may be related to other underlying conditions such as subclinical GERD, OSA[1] etc. This has not been quantified in Indian population and needs to be evaluated.

Currently, laparoscopic cholecystectomy is the standard of care for symptomatic cholelithiasis. But, in spite of the huge number of obese patients undergoing laparoscopic cholecystectomy, there hasn't been any quantification to study the improvements in their QoL following surgery. This has prompted us to undertake this study.

The use of GIQLI score (Gastro-Intestinal Quality of Life Index) has helped assess the actual QoL related burden of gallstone disease.[5]

Materials and methods

Study Design and patient Inclusion Criteria

This is a single centre, prospective study. All adult female patients (≥18 years on admission) with Chronic symptomatic cholelithiasis (documented radiologically by either USG/CT scan) admitted in the General Surgery Department at a Tertiary care centre in Mumbai were included. Patients unable to consent due to pre-existing psychiatric illness were excluded. Patients with past history of acute cholecystitis were included in the study. Patients with concomitant common bile duct stones were managed with ERCP and stone retrieval prior to surgery and were included in the study. Patients with complications of gallstones during current admission like acute cholecystitis, acute pancreatitis and cholangitis and also patients undergoing cholecystectomy as part of a more extensive procedure like Whipple's procedure or Bariatric surgery were excluded. Patients who needed conversion to open surgery due to intra-operative complications and patients with post operative bile leaks/ bile duct injuries were excluded from the study.

Data Collection

The study has been initiated after approval from the Institutional Ethics Committee (IEC) of Seth G.S Medical College and KEM Hospital, Mumbai.

Patients were divided into 2 groups based on BMI (25 kg/m2 being the cut off value as per WHO Classification for Asian population) Study doctors collected prospective data and ensured completion of the GIQLI questionnaire. Demographic and clinical data, including

duration of symptoms and co-morbidities were collected. Imaging findings were compiled. We recorded operative details (surgical access, operation duration) length of hospital stay, morbidity and mortality. Length of hospital stay was defined from date of admission to discharge. Mortality was defined as death within 30 days of surgery or during the current admission.

GIQLI[2]

GIQLI is a 36-question survey, with five response levels (Lickert Scale) to each question (0-4, a higher value indicates a better outcome). The questionnaire assesses the health status of a patient over the past two weeks and records the response as "all the time, most of the time, some of the time, a little of the time or never". The data is then subdivided into four subgroups: gastrointestinal symptoms (19 questions, 0-76), physical status (7 questions, 0-28), emotional status (5 questions, 0-20) and social function status (5 questions, 0-20). The overall score can be from 0-144. It is user friendly and easy to calculate. A pre-validated version is available in Hindi. The questionnaire was administered pre-operatively at the time of consent and 30 days post-operatively in both the groups. We follow up our patients routinely at 30-day post-surgery and hence the post-operation questionnaire was administered in the same setting. Further patient contact was not done. Default method of administration was Self- Administration. Inter viewer-assisted administration was done for patients who were illiterate.

Statistical analysis

Data was entered in an Excel Master sheet. It was analysed using Wilcoxon Rank sum test to compare pre-operative and post-operative total GIQLI scores in both groups, as well as subgroup analysis, with a p-value of <0.001 accepted as statistically significant.

Results

A total of 92 (45 in non-obese and 47 in non-obese) patients who met the inclusion criteria were agreeable for participation in our study pre-operatively and completed the pre-operative GIQLI questionnaire. One patient was converted to open surgery due to intra-operative

difficulty was later excluded. One patient had a post operative bile duct Injury was later excluded. Two patients were lost to follow up. The final statistics and results have been derived from a total of 88 patients (44 in each group) The median age in the non-obese group was 40y and in the obese group was 43y. The commonest co-morbidity was diabetes mellitus (20.45%) followed by hypertension (13.7%). Out of the 18 patients with diabetes mellitus, 13(75%) belonged to obese group and 5(25%) belonged to non-obese group. As noted in many earlier studies, there is a positive correlation between increasing obesity and the risk for diabetes mellitus. Mean BMI in non-obese group was 23.01 kg/m^2. Mean BMI in obese group was 27.90 kg/m^2. (Min BMI – 19.56 kg/m^2, Max BMI – 32.27 kg/m^2)

Table 1: Patient Demographics (n=88)

	BMI< 25 kg/m^2	BMI > 25 kg/m^2
Age	40.05(SD 5.76) MIN-22Y MAX-52Y	43.32(SD 5.066) MIN-27 Y MAX-56Y
Mean Duration of Complaints	4.2 m	5.2m
Duration of Hospital stay	3.36 days (0.53)	3.52 days (0.64)
Co-Morbidities Diabetes Mellitus Hypertension Bronchial Asthma IHD Hypothyroidism CVA	 5/44(11.36%) 4/44(9.09%) 1/44(2.27%) - 1/44(2.27%) -	 13/44(29.54%) 9/44(20.45%) 4/44(9.09%) 1/44(2.27%) 2/44(4.5%) 1/44(2.27%)
History of ERCP	5/44(11.36%)	7/44(15.90%)

Table 2: Comparison of pre and post operative group GIQLI Scores for non-obese (<25kg/m^2)

	Preoperative (Mean±2SD, 95%CI)	Postoperative (Mean±2SD, 95%CI)	p-value
Total score	106.73 + 8.49	122.45 + 7.58	<0.001
Gastrointestinal symptoms (19 items, range 0-76)	58.8 + 4.8	67.25 + 4.3	<0.001
Physical condition (7 items, range 0-28)	19.66 + 3.36	22.32 + 3.32	<0.001
Emotional status (5items, range 0-20)	13.86 + 2.46	15.93 + 2.12	<0.001
Social function(5item, range 0-20)	14.41 + 2.452	15.95 + 2.32	<0.001

The p value for the Wilcoxon Signed rank test is 0.0001 which is significant for the global scores as well as all the subscales. Hence, post-operative scores are significantly different from the pre-operative scores for non-obese.

Table 3: Comparison of pre and post operative group GIQLI Scores for non-obese (>25kg/m^2)

	Preoperative (Mean±2SD, 95%CI)	Postoperative (Mean±2SD, 95%CI)	p-value
Total score	94.43 + 9.82	105.59 + 9.30	<0.001
Gastrointestinal symptoms (19 items, range 0-76)	53.66 + 5.48	59.27 + 5.86	<0.001
Physical condition (7 items, range 0-28)	16.82 + 4.26	19.55 + 5.2	<0.001
Emotional status (5 items, range 0-20)	11.89 + 2.82	13.3 + 3.74	<0.001
Social function (5 items, range 0-20)	12.07 + 2.90	13.48 + 2.80	<0.001

The p value for the Wilcoxon Signed rank test is 0.0001 which is significant for the global scores as well as subscales. Hence, post-operative scores are significantly different from the pre-operative scores even in the obese group.

Therefore, both the groups have experienced a significant improvement in all dimensions of Quality of Life. Three Individual questions showed significant improvement in the non-obese group as compared to the obese group.

1) Abdominal pain (symptom score)
2) Loss of stamina (physical score)
3) Felt restricted by treatment (social score)

Hence, pre-operatively, the intensity of abdominal pain was comparable in both the groups. However, post-operatively, the non-obese group (BMI<25kg/m^2) experienced significantly less abdominal pain as compared to the obese group (BMI >25 kg/m^2). Similarly, stamina improved significantly more in the non-obese group. Also, the obese group felt more restriction due to medical treatment than the non-obese group.

Discussion

GIQLI Score was developed to assess the Quality of Life objectively in patients with GI Diseases. In this study, we have evaluated the GIQLI Scores in 2 groups, obese and non-obese women undergoing laparoscopic cholecystectomy for chronic symptomatic gallstone disease. We studied the short-term improvement in quality of life at 1 month. Further, it is highly unlikely that if it was restored at 1 month, it would worsen later unless any complications occur thereafter. In our study, all the complications were revealed within 1 month.

In the Non-Obese group

The mean global score was 106.7 preoperatively and 122.4 post-operatively. Mean improvement in GIQLI for non-obese individuals was 15.7 points.

In the Obese group

The mean global score was 94.4 preoperatively and 104.5 post-operatively. Mean improvement in GIQLI for obese individuals was 10.1 points.

In a similar study done in patients undergoing index admission laparoscopic cholecystectomy for acute cholecytitis by Hongyan Yu et al, Mean improvement in pre-operative to post-operative Global GIQLI score was 13.5 points. [6]

Another study by Li Chen et al showed an increase of 6.4 points at 5 weeks in patients treated with elective LC for cholelithiasis [7] They assessed improvement after laparoscopic v/s open approach and concluded that QoL was restored in the laparoscopic group much faster than

in the open group. They applied the GIQLI Score pre-operatively, at 2, 5, 10 and 16w post-operatively. Thus, the magnitude of improvement of QoL is proportional to its worsening. [8,9,10]

Wen Tsan Chang et al conducted a study in which 627 patients were divided into 3 Groups based on BMI and these patients underwent laparoscopic cholecystectomy for symptomatic cholelithiasis. They found that overweight and obesity were not associated with conversion and complication rates but were related to a trend toward longer operating time. Thus, they concluded that BMI doesn't affect clinical outcomes and that LC is a safe procedure in obese patients with uncomplicated gallstone disease. [11]

Anna et al [12] conducted a study on 166 patients who were analyzed in groups: cholecystectomy - laparoscopic (74) and open (30), appendectomy - laparoscopic (30) and open (32). Each group was divided into subgroups according to BMI and was assessed retrospectively and investigated by the GIQLI Score up to 5 months after Surgery. The findings were Mean hospital stay time was 3.2 and 3.8 days after laparoscopic operations vs 5.4 and 5.4 days after open ones respectively. Quality of life was significantly better after laparoscopic than open cholecystectomy in obese patients (Scores: 128.4 +/- 12.7 vs 120.6 +/- 12.2 respectively)

In our study, the mean duration of hospital stay was 3.25 days for non-obese and 3.52 days for obese women.

QoL is a multi-dimensional measure and is not restricted to presence and severity of clinical symptoms alone. A systematic review of 38 studies and 9,903 patients reported that upper abdominal pain persisted in 33% of patients after cholecystectomy and new onset abdominal pain occurred in 14% of patients. [6,13] Their conclusion was that cholecystectomy is often ineffective with regards to symptoms. But this review likely included low quality studies, 26 studies with a self-administered questionnaire, 15 studies with open cholecystectomy and a variable follow up duration and hence these results must be interpreted with discretion. Morbidity related to the procedure affects short term QoL negatively. In our study, patients with severe co-morbidities were low, patients with post-operative complications were excluded and this was likely the reason for improved QoL outcomes. Furthermore, in patients with symptomatic cholelithiasis, persistent abdominal pain is commonest cause for a negative outcome and in the acute setting, immediate pain relief is achieved by surgery and this has contributed to improved QoL.

Also, the emotional, social and physical scores all showed improvements in both groups. So, the benefits cannot be attributed solely to improvement of abdominal symptoms. Further, this questionnaire has only one item on abdominal pain and hence overall impact of improvement in abdominal pain is unlikely to influence the total GIQLI symptom score.

The strength of our study is that it is a unique prospective study done to quantify QoL improvement in obese v/s non-obese female patients who underwent laparoscopic cholecystectomy for symptomatic cholelithiasis. It has groups of patients with differing BMIs and various co-morbidities. Single centre and a small sample were our limitations.

In our study, the improvement in abdominal pain is seen in both the groups. However, the non-obese group has an improvement of significant magnitude. Similarly, significant improvement in stamina is seen in the non-obese group. Also, the obese group felt restricted by medical treatment to a greater extent than the non-obese group post-operatively. It is well established that obesity

decreases overall fitness and stamina. Illness further worsens this. It remains to be seen if the fitness levels improve later on for this group, requiring a longer duration of follow up. Further follow up was not done in our study.

1 of our patients had a past history of CVA and reported a poor social score and physical score.

Conclusion

In our study, we noted that the baseline functional status and Quality of Life are better in the non-obese group as seen by the mean pre-operative Higher GIQLI Score.

It was seen that individual parameters improved in both the groups post-operatively. Although non-obese individuals showed a greater improvement as compared to obese individuals, this improvement was of statistical significance only for 3 questions (Abdominal pain, Loss of stamina, Restriction due to medical treatment)

However, the difference in overall improvements in the Global GIQLI Score and the subscales of the GIQLI score were not statistically significant in both the groups.

Therefore, we would like to conclude that improvements in Quality of Life are seen in both obese and non-obese after laparoscopic cholecystectomy to a significant extent. Obesity increases the technical difficulty of performing laparoscopic cholecystectomy. It is associated with more co-morbid illnesses. It also increases the mean duration of hospital stay. But, eventually, the Improvement in Quality of life is same as that of a non-obese female patient undergoing the surgery.

Therefore, BMI should not be a factor for choosing suitability for laparoscopic cholecystectomy as this is the current standard of care and is equally beneficial to patients across a wide range of BMI.

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