

# Developing a New Tool for Determining the Difficulty of Laparoscopic Bariatric Surgery

**Ali Kabir**

Iran University of Medical Sciences

**Syed Imran Abbas**

Dubai Hospital

**Marziyeh Moradi**

Iran University of Medical Sciences

**Abdolreza Pazouki** (✉ [apazouki@yahoo.com](mailto:apazouki@yahoo.com))

Iran University of Medical Sciences

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## Research

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# Abstract

**Background:** Recommendations for candidates of bariatric surgery are available but they seldom give guidance to help a specific patient. The purpose of this study is to develop a new tool for determining the difficulty of laparoscopic bariatric surgery before surgery.

**Methods:** This was a mixed method study. After a comprehensive search, semi structure interview and focus group discussions (FGD) with surgeons, and operating room personnel and department, initial draft of the questionnaire was prepared. We used Delphi method to achieve a group consensus of national and international surgeons. Finally, after several times of review and modification of the designed questions, a final questionnaire was prepared. Content and face validity, reliability and internal consistency (using Cronbach's alpha) were determined.

**Results:** Final questionnaire has 31 questions consist of I. Factors related to surgeon: experience(four questions), and exposure(one question), II. Factors related to patient: anatomy(eleven questions), and comorbidities(two questions), patient's position(one question), and others(one question), III. Factors related to instruments and operation room, quantity(two questions), and quality(one question), IV. Factors related to other personnel: anesthesia team(six questions), and other personnel(two questions). Cronbach's alpha was 0.98 for the whole questionnaire and between 0.86 and 0.97 for the four subscales.

**Conclusions:** The psychometrics analysis indicated that it is valid and reliable for determining the difficulty of laparoscopic bariatric surgery. We recommend using this questionnaire for different settings either need to know difficulty of a bariatric surgery before a surgery or as an independent variable in various research projects.

## 1. Background

Bariatric surgery is more effective than conventional treatments of obesity with a 30% reduction in total mortality in obese patients who underwent surgery (1, 2). There are several types of bariatric surgery, which the most common are Roux-en-Y Gastric Bypass (RYGB), Sleeve-Gastrectomy (SG) and one anastomosis gastric bypass (OAGB)(3). The advantages of bariatric surgery for the patient are already well known. On the other hand, the disadvantages for the surgeon and the operating team also are becoming increasingly known (4).

Obesity patients who are candidates for surgery should be evaluated before the procedure by a team of specialist physicians, including physicians, nutritionists, and psychologists (5). Reducing the risk of complications during and after surgery requires several clinical evaluations of the patient before surgery (6). National Institute of Clinical Excellence (NICE) and National Institute of Health (NIH) recommend that obesity surgery should be offered to patients with a BMI of 35-40 kg/m<sup>2</sup> who have obesity-related illnesses, such as diabetes or sleep apnea, or in those with a BMI above 40 kg/m<sup>2</sup> without regard to comorbidities (7, 8). In the guidelines, recommendations for referring candidates for bariatric surgery are available but there is rarely any guidance to help patients with specific conditions (9, 10).

Before surgery, the surgeon should evaluate the positive and negative side effects of bariatric surgery based on evidence (11). There are many criteria for selecting patients for bariatric surgery, such as body mass index (BMI), the presence of co-morbidities, and a history of prior weight loss. If someone is candidate for surgery, an assessment team evaluates the patient before surgery. This is an individualized assessment of each patient (12-14). Some reports have shown, despite the above assessments, the surgical team needs a series of more detailed evaluations of the patient's condition (5, 15). Treatment failure after obesity surgery and some complications after surgery are due to weakness in the team's knowledge of the patient's condition (5). On the other hand, all patients should be given the correct and realistic information about their condition to the surgical assessment team to select the best procedure for the patient. These individual assessments for each patient is a critical part of preoperative assessments (13).

One of the most fundamental deficiencies in surgical procedures for the surgeon is the lack of a checklist for evaluating the patient and his preoperative conditions. Therefore, surgeons select a type of procedure for patients based on an empirical approach. This choice can be based on the patient's clinical phenotype, treatment goal, and potential risks (11). According to patient characteristics, surgery can be difficult or impossible. For example, laparoscopic surgery in patients with large abdominal hernia, severe intra-abdominal adhesions, and large liver, high BMI with central obesity or physiological intolerance can make it difficult or impossible to operate (12, 16-18). Although there is a need for a specialized team to evaluate the patient before surgery, the equipment and facilities of the operating room for surgery can also influence the process of surgery. Even the hospital environment, patient clothing, beds, and chairs that fit into the condition of patients, especially those with severe obesity, affect the surgery process (15, 19). Based on discussions with specialists in the field of obesity surgery we found that surgeon and surgical team members, and even the operating room staff will need a tool to measure the difficulty of the surgical operation and the progression of the operation based on the patient's condition, especially for patients with specific conditions. Before the surgery, they can provide the appropriate equipment and facilities to fit into the patient's circumstances and the surgeon can make the best decision about the type of operation, the time of operation (for example, difficult or more complicated surgeries in the early morning and easier surgeries afterwards), the number of surgeon or operating room personnel, and the equipment according to the patient's conditions and reducing the complications during and after the operation. This study aimed to develop a new tool for determining the difficulty of laparoscopic bariatric surgery to identify the problems and difficulties of surgical operations before the operation, which will help them to be ready before surgery.

## **2. Material And Methods**

The mixed-method used to develop the difficulty of laparoscopic bariatric surgery questionnaire. This study has been reported in line with the STROCSS criteria (20). After a comprehensive search for the determinants of the difficulty of laparoscopic bariatric surgery, semi-structured interviews with surgeons, and operating room personnel and department, then, Delphi method, face and content validity was used.

In a flow chart, we have shown the processes used to develop the difficulty of laparoscopic bariatric surgery questionnaire (Figure 1).

## **1. A comprehensive search and semi-structured interviews**

A comprehensive search of relevant literature on the determinants of the difficulty of obesity surgery was used. To identify relevant studies, the electronic databases of PubMed, Scopus, and Web of knowledge were used. Searches showed no instructions or tools to determine the difficulty of obesity surgery. Therefore, to achieve a new tool agreed by surgeons, semi-structured interviews were planned with surgeons and operating room and department personnel.

In interviews, surgeons who had performed more than 200 obesity surgery as well as operating room personnel were invited to participate in the study. Semi-structured interviews began with questions consist of "In your opinion, which factors related to patient can make obesity surgery more difficult?", "which factors related to surgeon can make obesity surgery more difficult?", "which factors related to other personnel can make obesity surgery more difficult?", and "which factors related to instruments and operation room can make obesity surgery more convenience?". The information was recorded during the interviews. Interviews usually lasted between 30 and 40 minutes. After each interview, the text of the interview was heard and typed and rechecked with the interviewee. Then, the codes were extracted from the interviews. A focus group discussion (FGD) was designed with an expert panel. Seven surgeons participated in FGD for one hour. Surgeons discussed the most important factors related to determination of the difficulty of obesity surgery. Also, five films of obesity surgery were shown to five surgeons and we asked them to identify the related factors with difficulty of obesity surgery. When the interviews were completed, initial draft of the questionnaire designed. The initial questionnaire was returned to the surgeons for approval. Finally, after several times of review and modification of the designed questions, a questionnaire with 64 items was prepared for use in the first round of the Delphi method.

## **2. Delphi Method**

The second part of study included Delphi method. The inclusion criteria for this part of study were also having more than 200 obesity surgeries. In the pilot phase, the questionnaire with a request form for participation in the study was sent by E-mail to 10 national surgeons and anesthesiologists and international surgeons. The duration of the pilot phase was two weeks. After the implementation of this phase, eight surgeons returned the questionnaire.

The questionnaire was modified according to the views of surgeons in the pilot phase and was prepared for the first round. In this round, fifty-five national and international surgeons were identified from around the world, their scientific background was examined, and finally, 55 surgeons entered this part of study (40 surgeons from Iran, 15 surgeons from other countries). The questionnaire was sent to all of them. The duration of this round was two weeks. Finally, the first round was completed with 39 Surgeons (32 surgeons from Iran, 7 surgeons from other countries). The Expert panel reviewed the surgeons' opinions for the modification of the questionnaire.

After summarizing the views of surgeons and expert panels, the main themes of the second questionnaire were extracted. In the second round, the questionnaire was sent to 39 surgeons, and we asked them to rank the factors determining the difficulty of laparoscopic bariatric surgery.

After completing the questionnaires and receiving the opinion of surgeons, prioritization of the determinants of the difficulty of laparoscopic bariatric surgery was examined and analyzed.

### **3. Validity**

#### **1. Content validity**

To assess the content validity, 14 experts including surgeons and anesthesiologist rated the necessity of each item through a 3-point descriptive scale. Clarity, relatedness, simplicity and consistency of each item were assessed through a 4-point Likert scale (1=not relevant, 2=somewhat relevant, 3=relevant, 4=very relevant). Then the Content Validity Ratio (CVR) and Content Validity Index (CVI) were computed.

#### **2. Face validity**

Face validity demonstrates the questionnaire appears to be appropriate to the study aim. It evaluates the appearance of the questionnaire in terms of feasibility, readability, consistency of style and formatting, and the clarity of the language used. Seven surgeons were invited to participate in this section. According to the opinion of the surgeons, some questions were removed, merged, modified, or added to the questionnaire. Finally, a new tool for determining the difficulty of laparoscopic bariatric surgery designed.

### **3. Reliability**

Once the validity procedures were completed, the final version of the questionnaire was examined to assess its reliability. Internal consistency reliability was used to examine the reliability of the questionnaire.

#### **1. Internal Consistency Reliability**

Internal consistency indicates how well the items fit together conceptually and examines the inter-item correlations within a tool (21). In addition, a total score of all the items is computed to estimate the consistency of the whole questionnaire. Cronbach's alpha was computed to examine the internal consistency of the questionnaire. If an instrument contains two or more subscales, Cronbach's alpha should be computed for each subscale as well as the entire scale. Therefore, in this study, Cronbach's alpha was computed for each subscale.

## **3. Results**

The final questionnaire consisted of four domains with 31 questions:

- I. Factors related to surgeon: experience (four questions), and exposure (one question)
- II. Factors related to patient: anatomy (eleven questions), and comorbidities (two questions), patient's position (one question), and others (one question)
- III. Factors related to instruments and operation room, quantity (two questions), and quality (one question)
- IV. Factors related to other personnel: anesthesia team (six questions), and other personnel (two questions).

### **3.1. Semi-structured interviews:**

A total of 14 surgeons and 9 operating room personnel and department, participated in interviews. Four general themes were extracted from the interviews. Each one of these themes had one or more subscales (Figure 2).

Based on semi-structured interviews and two focused group discussions, the initial draft of the determining the difficulty of laparoscopic bariatricsurgery questionnaire consisted of 64 items in four domains prepared.

### **3.2. Delphi methods**

After a pilot phase and two rounds, 39 out of 55 selected surgeons who the questionnaire was sent to them by E-mail, completed and returned it. (Response rate: 70.91%)

After two rounds, the 64-items questionnaire was reduced to 31-items questionnaires.

In the second round of the Delphi method, we asked the surgeons to give a score from 0 to 100 to each item for determining the relative importance of the indicators (table 1).

All of the determinants of the difficulty of obesity surgery had relative importance above 60%, and only two questions had relative importance under 60%.

### **3.3. Content validity**

For checking the content validity, 14 surgeon and anesthesiologist rated the necessity of the items by using a 3-point scale (necessary, useful, and not necessary). According to Lawshe's table, when the number of panelists is 14, the minimum reasonable CVR is 0.51.

The minimum reasonable CVR was set as 51.78% for items. All 31 items showed CVR scores higher than 51%. CVI of the total score of the questionnaire was 85.71% (Table 2).

### **3.4. Face validity**

Seven surgeons from Iran completed the face validity form. In Face validity, we identified some words or phrases which were hard to understand for the subjects and the modifications were made.

### **3.5. Internal Consistency Reliability**

Cronbach's alpha was computed for the final questionnaire with 31 questions. Various reports have reported acceptable values of alpha, between 0.70 to 0.95. The Cronbach's alpha computed for each of the four subscales. All subscales had a Cronbach's alpha above 0.86 (Table 3).

## **4. Discussion**

The present study provided a new tool for determining the difficulty of laparoscopic bariatric surgery to identify the problems and difficulties of surgical operations before the surgery.

The results of this study showed that the questionnaire of determining the difficulty of laparoscopic bariatric surgery in obese patients has acceptable indices of a standard questionnaire. About CVR and S-CVI, all percentages are higher than 51% and 80% respectively, which can be considered as the minimum acceptable for a new tool (22). Therefore, most of them are acceptable and such a questionnaire can be used in similar settings.

The present study showed that factors related to patients, surgeon, instruments/ operating room, and to other personnel are effective in determining the difficulty or convenience of obesity surgery. However, some studies have also shown that the bariatric surgeon must be able to manage, and have coverage to manage, the postoperative patient and any problems and complications that may occur. Expert anesthesiology, knowledgeable in the specific problems of the bariatric patient, is necessary and the operating room equipment and facilities have a significant impact on the process of obesity surgery (5, 15). Wauben and colleagues showed the importance of the conditions and position of obese people in the process of surgery for obesity (19). The results of these studies are in line with the factors found in our study.

The internal consistency of the questionnaire by Cronbach's alpha value was very high (0.98), and for all subscales ranged between 0.86 and 0.97. Although the reliability of this questionnaire was evaluated by Cronbach's alpha and maximum levels of Cronbach's alpha were reported in this scale (0.97) which shows high internal consistency of the items, however, other indicators of reliability need to be investigated in future works.

Based on the Lawshe table, when a content evaluation panel is composed of fourteen members a minimum content validity ratio of 0.51 is required (22). Considering that in this study fourteen surgeons participated, this questionnaire has acceptable content validity.

## **5. Conclusions**

In conclusion, this study demonstrates that the 31-item questionnaire has good and acceptable psychometric properties (including content validity ratio, content validity index, face validity and Cronbach's alpha coefficient) to be used for determining the difficulty of laparoscopic bariatric surgery. It can be considered as a reliable tool for use by obesity surgeons before surgery.

## Declarations

### Conflict of Interests

The authors declare that they have no conflict of interests.

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## Tables

**Table 1:Relative Importance of Laparoscopic Obesity Surgery**

	<b>Questions*</b>	<b>Score (On the basis of importance) from 100 points</b>
<b>I</b>	<b>Factor related to surgeon</b>	
<b>IA</b>	<b>Related to experience</b>	
IA1	Active Surgeon (50 bariatric surgeries per year)	85.33
IA2	Experienced Surgeon(125 bariatric surgeries for lifetime and annually 50 bariatric surgeries per year)	85.67
IA3	Tiredness of Surgeon(First operation early in the morning till last operation at the end of the day)	68.33
IA4	Port site selection(If port site was not suitable bariatric surgery will be difficult)	82.69
<b>IB</b>	<b>Related to exposure</b>	
IB5	Suitable exposure by surgeon left hand and by assistant	82.14
<b>II</b>	<b>Factors related to patient</b>	
<b>IIA</b>	<b>Anatomy</b>	
IIA6	Previous Abdominoplasty	61.67
IIA7	Previous banding and mesh gastroplasty (Redo)	76
IIA8	Hepatomegaly and fatty liver	66.33
IIA9	Thick mesentery of small intestine	65
IIA10	Chest diameter	64.64
IIA11	Central obesity	65.67
IIA12	Male Gender	61.67
IIA13	Thick omentum	70
IIA14	Short neck and difficult intubation	68.21
IIA15	Multipara Female	64.23
IIA16	Thickness of Abdominal Wall	57.69
<b>IIB</b>	<b>Comorbidities</b>	
IIB17	Diabetes, Asthma, Sleep Apnea	54.33
IIB18	Previous chronic use of Steroids	65.33
<b>IIC</b>	<b>Patient's position</b>	
IIC19	The Patient must be fixed with operation bed with a belt and	75.67

	must be at a suitable place of the bed.	
<b>IID</b>	<b>Others</b>	
IID20	Consultations before operation with related specialties	70.67
<b>III</b>	<b>Factors related to instruments and operation room</b>	
<b>IIIA</b>	<b>Quantity</b>	
IIIA21	Suitable Ergonomics and setup and instruments	83
IIIA22	Suitable, sufficient and accurate device	83.67
<b>IIIB</b>	<b>Quality</b>	
IIIB23	Trocar type	72.33
<b>IV</b>	<b>Factors related to other personnel</b>	
<b>IVA</b>	<b>Anesthesia team</b>	
IVA24	Active and experienced Anesthesiologist about laparoscopic bariatric surgery (Lifetime more than 125 cases and 50 cases/year)	78.67
IVA 25	Active and Experienced anesthesia assistant for bariatric surgery	71.33
IVA 26	Tiredness of Anesthesiologist and other anesthesia personnel (Fresh and end of the shift)	62.5
IVA 27	Understanding of surgical and Anesthesia Team	74.87
IVA 28	OGT** must be inserted carefully	65
IVA 29	Patient abdomen must be maintained relax with the help of the Anesthesia team	75.36
<b>IVB</b>	<b>Other personnel</b>	
IVB30	Suitable gas pressure must be controlled.	79.33
IVB31	Active and Experienced Scrub Nurse	77.14

\*These items should be assessed based on the physicians' (surgeon and/or anaesthesiologist) experience before surgery.

\*\*OGT: oral gastric tubes

**Table 2: Scale Level Content Validity Index (S-CVI) for the 31-item questionnaire**

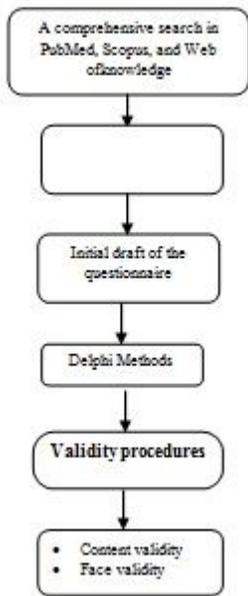
S-CVI %	Number of surgeons answering the question	Total number of question	No.of surgeons with relevant and very relevant answers	No.of surgeons with not relevant and somewhat relevant answers
85.71	14	31	12	2

No.: number, S-CVI:Scale Level Content Validity Index

**Table 3. Internal consistency of the questionnaire according to related factors with difficulty of laparoscopic bariatric surgery**

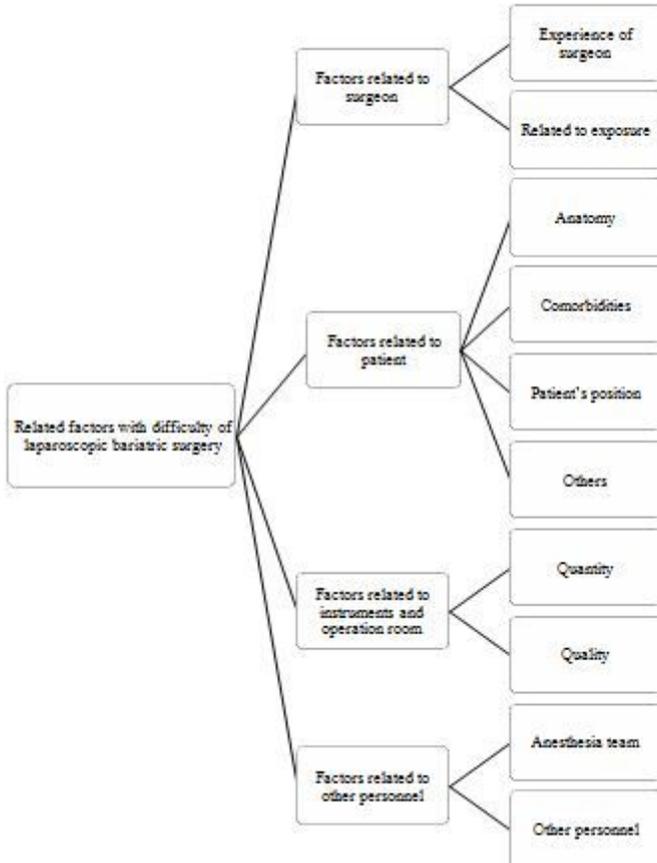
Domains	Cronbach's alphacoefficient
Factors related to surgeon	0.90
Factors related to patient	0.97
Factors related to other personnel	0.86
Factors related to instruments and operation room	0.90
Total	0.98

## Figures



**Figure 1**

A flow chart depicting the process used to develop the difficulty of laparoscopic bariatric surgery questionnaire



## Figure 2

A flow chart depicting themes are extracted from semi-structured interviews