

Nutrition Health interventions and Quality of life following Mini Gastric Bypass surgery- a randomized control trial

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Abstract

Background Laparoscopic mini gastric bypass (LMGB) bariatric surgery, characterized by a single ante colic gastro-jejunostomy (GJ) anastomosis procedure, requires specialized post-surgery care.

Objective The aim of the study is to evaluate the impact of personalized counseling using nutrition health education (NHE) material, developed based on the Bariatric Analysis and Reporting Outcome System (BAROS), as compared to standard hospital care, on post-operative patient's quality of life (QoL).

Methodology A prospective randomized control trial was conducted, wherein 120 patients registered for the LMGB surgery were enrolled and followed up over 3 months after surgery. Based on alternate allocation randomization, odd number patients were allocated to the experimental group (Group E $n = 60$) receiving the personalized NHE material, and even number patients were allocated to the control group (Group C $n = 60$) receiving the standard hospital care. QoL and health outcomes data were analyzed pre- and post-surgery using SPSS-23 software.

Results Post-operative findings indicated better weight loss and improved quality of life scores in group E patients. The mean %excess weight loss at 3 months post-surgery of group E patients was 18% more compared to group C patients. Notably, the BAROS scores for group E patients were within the good category (4.80 ± 1.63) versus group C patients' scores being in the fair category (3.00 ± 1.64), representing a statistically significant difference ($p < 0.001$).

Conclusion Based on the type of bariatric surgery (be it restrictive, mal-absorptive, or combined procedure), a focused bariatric surgery-specific nutrition and education leads to better weight loss, resolution of comorbidity, improved quality of life, prevention of weight regains, and minimal post-surgical complications as compared to general counseling.

Keywords Laparoscopic mini gastric bypass · Bariatric surgery · Nutrition health education · Bariatric nutrition · Quality of life · BAROS

Introduction

Overweight and obesity, characterized by abnormal or excessive fat accumulation resulting from a positive energy balance, is emerging as a colossal health epidemic worldwide. As per the World Health Organization (WHO) in 2016, non-communicable diseases (NCDs) accounted for approximately 63% of deaths, with obesity being a significant contributor. Furthermore, obesity has an adverse impact on the quality of life, indicating psychological dysfunction and poor social

interaction [1]. In response to the escalating burden of NCDs, The National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) (Ministry of Health & Family Welfare, Government of India) was launched by the government of India.

Pertaining to the strategies to fight overweight and obesity, people try conventional weight-loss therapies and fail to achieve the desired results. Recognizing this, the National Institute of Health has identified bariatric surgery as a last resort for effective long-term treatment of severe obesity [2]. Clinically induced long-term weight loss and reduction in obesity-related comorbidities are the primary targeted outcomes of a “Bariatric Surgery” [3].

Robert Rutledge introduced the mini gastric bypass surgery and the laparoscopic mini gastric bypass (LMGB) surgery with latero-lateral anastomosis. This technique being

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straightforward and more refined by having one anastomosis, it offers multiple benefits like easy revision and reversal if needed, along with considerable weight loss and remission of comorbidities [4]. Weight loss in LMGB surgery is achieved by both restriction and malabsorption of food due to the reduced stomach capacity along with reduced calorie absorption in the intestines.

Few studies have shown the pivotal relationship between weight loss surgery and the improvement in patient's quality of life (QoL). A study by Rutledge et al. (2005) and Carbajo et al. (2005) noted enhancements in QoL post-surgery, but comprehensive assessments were lacking [5, 6]. A long-term study by Bruzzi et al. (2015) further affirmed the QoL improvements, illustrating elevated scores in social, psychological, and physical domains [7]. Notably, QoL improvements were also observed in patients with improved obstructive sleep apnea syndrome (OSAS) after the LMGB surgery [8]. Several studies have reported a positive outcome of LMGB surgery [6, 9, 10]. However, the data on the quality of life by the Bariatric Analysis and Reporting Outcome System (BAROS) post-LMGB surgery in India is limited. The technical success of bariatric surgery has overshadowed the subsequent impact on patient's QoL. In order to address the gaps, the present study reviews the pivotal role of QoL in the context of LMGB surgery. To further delve deeper into the relationship between post-surgery interventions and its implications on patients' overall well-being, the current study aimed to evaluate weight loss and QoL of individuals who underwent LMGB surgery. The assessment was conducted in the context of receiving personalized nutrition health education (NHE) material in contrast to standard hospital care.

Methodology

Study design

A prospective randomized controlled trial was conducted to assess the impact of personalized NHE material on QoL and weight loss in patients who underwent LMGB surgery.

Location

The study was conducted at the Asian Bariatrics Hospital located in Ahmedabad, Gujarat, India.

Sample size and sampling method

In total, 120 patients who were admitted for LMGB surgery were enrolled in the study. For sample selection, an alternate

allocation approach of randomization was adopted. Based on the registration, patients were assigned unique identification numbers. Odd number of patients were assigned to the experimental group (group E), and an even number of patients were assigned to the control group (group C). Each group contained 60 patients. This method was chosen to distribute patients equally in each group.

Data collection and data analysis

Baseline data, including demographic information, body composition (Inbody 370 Body Composition Analyzer), medical history, and preoperative QoL score using the Bariatric Analysis and Reporting Outcome System (BAROS), was collected before surgery. Post LMGB surgery, similar data was collected and reported comorbidities and minor complications, if any. Weight loss, %excess weight loss, medical condition, and QoL data were tracked using the BAROS tool. Follow-up was taken after 3 months of the surgery. Data was analyzed using SPSS-23 software.

Intervention

Group E patients received personalized NHE material, and group C patients received general counseling as per standard hospital care practice. The NHE material, prepared using the American Society for Metabolic and Bariatric Surgery (ASMBS) 2016 guidelines, covered information about the after-LMGB surgery care in terms of weight loss/maintenance, nutrition therapy, potential complications post-surgery and their appropriate mitigation strategies through appropriate diet, customization of meal plans with food substitution lists, explanation of issues like weight loss reaching its plateau, post-LMGB surgery supplement use, and a regular follow-up regime. The NHE material was delivered to group E patients using a variety of channels encompassing e-mail and WhatsApp, along with traditional offline platforms, including in-person counseling and PowerPoint presentations. The counseling was delivered 24 × 7 through WhatsApp if needed by group E patients for 3 months.

Results

Pre-operative characteristics

A total of 120 patients were enrolled in the study, comprising 50 males and 70 females. The age range of the cohort ranged from 19 to 77 years, representing a diverse age group. Notably, 76% of the patients were from Gujarat, with an additional 9.2% from Maharashtra.

According to the World Health Organization's 2016 classifications, 33.3% of group E patients and 36.7% of group C patients suffered from Grade III obesity. The body fat content was 3-fold higher, and the body fat percentage was 30 times higher in both groups compared to the normal range (Inbody370 Body Composition Analyzer). The pre-operative health statistics also reported significant comorbidities in both groups: 73% in group E patients and 75% in group C patients with conditions such as diabetes mellitus, hypertension, dyslipidemia, thyroid, and cardiac issues. Anthropometrically, the group E patients had a mean body weight of 113.38 ± 21.92 kg, in contrast to group C patients' mean weight of 125.8 ± 27.20 kg. The baseline data revealed significant differences between both groups. The mean BMI was elevated in both groups, with group E patients at 42.85 ± 6.15 kg/m² and group C patients at 46.98 ± 10.18 kg/m² (Table 1).

Weight loss post surgery

Body weight reduction

A very high significant ($p < 0.001$) impact on the body weight loss was observed in group E patients as compared to group C patients (24 kg vs. 17 kg, respectively) 3 months post LMGB surgery. Weight loss in group E patients exceeded group C patients by approximately 7 kg, highlighting the positive impact of personalized NHE material. Consequently, the reduction in excess body weight (26.26 ± 14.74 kg) and body mass index (33.58 ± 5.66 kg/m²) of group E patients was reduced significantly ($p < 0.001$ for each). Remarkably, group E patients exhibited less difference between ideal body weight and their weight at 3 months post-surgery than group C patients (26.24 kg vs. 44.7 kg) (Table 2).

Table 1 Demographic details of patients who underwent laparoscopic mini gastric bypass surgery

	Group E (mean \pm SD)	Group C (mean \pm SD)
Age (yrs)	44.9 ± 11.7 yrs	48.4 ± 12.7 yrs
Sex ratio (M/F)	21/39	29/31
Weight (kg)	113.38 ± 21.92 kg	125.8 ± 27.20 kg
Height (cm)	162.52 ± 10.06 cm	163.60 ± 11.86 cm
Body mass index (kg/m ²)	42.85 ± 6.15 kg/m ²	46.98 ± 10.18 kg/m ²
Body fat mass (kg)	56.74 ± 12.42 (36–113)	60.97 ± 18.47
% body fat	50.65 ± 5.80	50.32 ± 8.14
Waist/hip	0.97 ± 0.16	0.96 ± 0.18

Table 2 Post-operative anthropometric data comparison between group E patients and group C patients

Parameter	Group E Mean \pm SD	Group C Mean \pm SD	T value
Weight (kg)	88.74 ± 17.34	108.38 ± 27.32	4.61***
Excess body weight (kg)	26.26 ± 14.74	44.52 ± 25.24	4.75***
Body mass index (kg/m ²)	33.58 ± 5.66	40.42 ± 9.71	4.62***

$p < 0.05^*$; $p < 0.01^{**}$; $p < 0.001^{***}$

Reduction in obesity grades and body mass index

In terms of the obesity grades, a significant difference ($p < 0.004$) was noted in group E patients as compared to group C patients. Over 3 months post-surgery, the reduction in Grade III obesity was notably higher in group E patients than group C patients, about 25.4% and 15.5%, respectively. A noteworthy outcome emerged from the reduction of BMI, where 1.8% of group E patients attained normal BMI values. Additionally, the gender-based analysis revealed that grade III obesity was notably elevated in group C females than the group E females (13.1% vs. 5.2%) (Table 3).

Percentage of Excess Weight Loss (%EWL)

The excess weight loss percentage in group E patients was significantly higher (50.82 ± 19.09) than in group C patients (33.23 ± 20.09) (Table 4). An 18% higher %EWL was observed in group E patients, satisfying the enhanced effectiveness of the personalized NHE material. Notably, in group E patients, a significant portion of patients achieved intermediate %EWL; 44.1% and 37.3% of patients achieved 25–49% and 50–74% of %EWL, respectively. Conversely, higher portions of patients, approximately 80% of patients from group C, achieved a lower %EWL ranging from 0 to 49%. These distribution patterns suggest more promising %EWL outcomes amongst group E patients compared to group C patients. A higher %EWL between 75 and 100% was observed in 13.6% and 5.5% of patients in groups E and C, respectively.

Table 3 Post-operative obesity grade distribution comparison between group E patients and group C patients

Obesity grades	Group E (%)	Group C (%)	Pearson chi-square value
Normal	1.8	0	15.1**
Overweight	14	5.3	
Grade I	15.8	11.4	
Grade II	12.3	9.6	
Grade III	7.9	21.9	

$p < 0.05^*$; $p < 0.01^{**}$; $p < 0.001^{***}$

Table 4 Post-operative % excess weight loss comparison between group E patients and group C patients

Parameter	Group E Mean \pm SD	Group C Mean \pm SD	T value
%EWL	50.82 \pm 19.09	33.23 \pm 20.09	4.79***

p < 0.05*; p < 0.01**; p < 0.001***

Comorbidity and minor complications resolution

Following a 3-month interval post-LMGB surgery, both patient groups exhibited notable reductions in comorbidities. Group E patients demonstrated a 66% decline compared to group C patient's 62% reduction. This trend was evident across several comorbidities, including diabetes mellitus, hypertension, dyslipidemia, thyroid, cardiac, and pulmonary issues. Considering the outcomes, group E saw 71% of improvement in patients' comorbid conditions, with an additional 22% experiencing resolution in their comorbid condition. In contrast, group C patients marked a 67% in improvement rate and 20% in resolution rate of the comorbid conditions (Fig. 1). The results indicate the efficacy of the LMGB surgery, particularly when personalized post-operative care is complemented. Enhancement in health conditions was measured based on the improvement in the mean values of all biochemical parameters like cholesterol, triglycerides, low-density lipoprotein (LDL), HbA1c, serum glutamic pyruvic transaminase (SGPT), creatinine, and total proteins. However, there was no change in the hemoglobin and RBC count post-surgery. Interestingly, both the group patients saw an improvement in their gastrointestinal conditions like acidity, gas, diarrhea, constipation, and vomiting.

Quality of life (QoL) as per the Bariatric Analysis and Reporting Outcome System (BAROS)

The Bariatric Analysis and Reporting Outcome System's (BAROS) mean score was 4.8 ± 1.63 (good) for group E patients and 3.0 ± 1.64 (fair) for group C patients. The overall BAROS score outcome was very statistically significant

($p < 0.001$) in group E patients compared to group C patients.

In evaluating QoL, parameters encompassing daily activities, self-esteem, physical activity, social engagement, work activity, and sexual activity are considered. Post LMGB surgery, along with the receiver of the NHE material, the efficiency of doing daily activities notably improved by 22.8% in group E patients versus 10.5% improvement was seen in group C patients after receipt of standard hospital care. Similar trends were seen in enhancement of social activities (27.2% for group E versus 10.5% for group C) and in eagerness to perform any physical activity (23.7% for group E versus 14.9% for group C) (Table 5). Furthermore, a statistically significant upliftment in the self-esteem metric was recorded in group E patients, with nearly a third of patients (29.8%) expressing high satisfaction post-LMGB surgery.

Post-operative dietary practices

Group C patient's standard care: On the second postoperative day of surgery, group C patients received a clear liquid diet, and continued for 3 days if devoid of any complications. Subsequently, patients transitioned to a full liquid diet for an additional 3 days, followed by a pureed diet for the next 5 days. A gradual shift to a soft diet was planned for the next 15 days. At the time of discharge, patients were handed a booklet explaining all the dietary phases and a prescription for essential multivitamins and protein supplementation to support their recovery.

Group E patient's personalized NHE material and dietary advice: Similar to group C, patients in group E also adhered to a structured dietary routine received from the hospital. Beyond this, they also received a personalized NHE material kit specific to LMGB surgery. This education material encompassed diverse topics to enhance post-operative care and well-being. It covered details about LMGB surgery, medical nutrition therapy guidelines, post-LMGB surgery possible complications, and their resolution using adequate diet and nutrients. It also included topics on dietary diversity based on traditional meal choices, food exchange lists, and early and late gastrointestinal complications arising

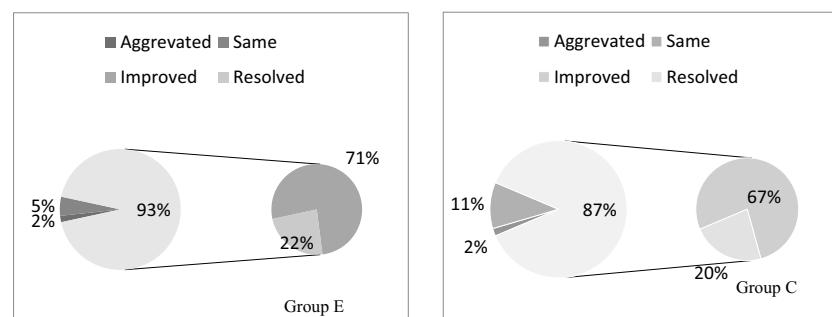
Fig. 1 Post-operative comorbidity resolution in group E patients and group C patients

Table 5 The Bariatric and Reporting Outcome System (BAROS) outcome post-surgery

BAROS outcome categories	Group E (%)	Group C (%)	Pearson chi-square value
Failure	0.9	4.4	23.8**
Fair	10.5	26.3	
Good	23.7	13.2	
Very good	14.9	2.6	
Excellent	1.8	1.8	

The outcome categories are measured based on the following scores: Failure 1 point or less, fair >1 to 3 points, good >3 to 5 points, very good >5 to 7 points, and excellent >7 to 9 points

$p < 0.001***$

post-LMGB surgery. Furthermore, information on weight loss plateau and the use of supplements was also addressed in the education material. Notably, patients in group E benefited from the continuous support through 24 × 7 WhatsApp-based counseling, if needed.

Regarding dietary diversity, greater quantities of legumes (25.3% vs. 8.7%), dairy products (10.7% vs. 9.7%), and vegetables (9.7% vs. 3.9%) were consumed by patients in group E compared to those in group C.

Discussion

The present study explored the multifaceted impact of personalized NHE material on the QoL of individuals undergoing LMGB surgery. Our findings underscore a substantial connection between post-operative weight loss and improved QoL, aligning with a growing body of research that recognizes the profound influence of LMGB surgery on patients' overall well-being. Guided by the Bariatric Analysis and Reporting Outcome System (BAROS), the present study evaluated the outcomes encompassing %excess weight loss, comorbidity/medical condition resolution, and QoL post-surgery along with recording the changes in the dietary diversity based on the personalized NHE material. The following discussion section delves into the comprehensive assessment of postoperative outcomes and addresses the complexities and challenges introduced by post-surgical factors.

To date, only one randomized control trial is available between Roux-en-Y Gastric Bypass (RYGB) and Mini Gastric Bypass (MGB), revealing MGB's favorable performance [11]. Following surgery, the outcome assessment should not only be based on weight loss but should include parameters like improvement in medical conditions and change in the patient's QoL [12]. Additionally, bariatric nutrition is also one of the evolving domains to manage the nutrition requirements of post-surgery patients [13].

The study observed a significant pre-operative mean weight of 113.38 ± 21.92 kg and mean BMI of 42.85 ± 6.15 kg/m² in group E patients, showcasing a noteworthy mean %EWL of 51% post-3 months of surgery compared to 33% in group C. Regarding weight post-surgery, group C's mean weight was 19% higher than group E with remarkably significant values. These findings were along the lines of past studies. For instance, a study reported 30 kg weight loss in 3 months, resulting in mean 75% EWL after 1 year [5]. Significantly, current findings align with literature illustrating 75% of excess weight loss after 1 year [14]. Additionally, the first study from India on mini gastric bypass surgery reported 63% excess weight loss at 1 year of LMGB surgery, which was higher than the %EWL after sleeve gastrectomy surgery [15]. In a series of 1163 mini gastric bypass surgery patients, results reported 72.9% EWL at the end of 5 years of follow-up [11].

Notably, the current study's NHE intervention exhibited favorable outcomes enhancing % excessive weight loss, resolution of comorbidities, reduction of minor comorbidities, and QoL in group E patients. Though after surgery weight loss tends to happen to a certain extent, it is a challenging job for a nutritionist to deliver proper knowledge regarding dietary practices and a regular follow-up regime to maintain the excess weight loss and avoid weight regain. Chances of weight regain are high if patients do not follow the regime properly.

Furthermore, pre-LMGB surgery, comorbidity prevalence was reported to be more than 70% in both the groups. Following the surgical procedures, rates of resolution and improvement were higher in group E patients (93% to 22%) compared to group C patients (87% to 20%). Our outcomes align with the results of Wang et al. (2005), Rutledge et al. (2005), and Noun et al. (2012), further supporting the positive impact of LMGB on comorbidities [9, 10, 13]. Kular et al. (2014) reported 92% remission rates of diabetes in LMGB patients, which was highly significant ($p < 0.05$) compared to laparoscopic sleeve gastrectomy (LSG) patients [16]. In particular, group E patients experienced improvements in the biochemical results, particularly in cholesterol, LDL, SGPT, and HbA1c levels. This trend resonates with Milone et al.'s (2015) findings of improved cholesterol and triglyceride levels in mini gastric bypass surgery patients as compared to LSG patients [17]. Additionally, it is crucial to note that concerns related to bile reflux are common post-LMGB surgery but cannot be solely attributed to anatomical alterations. Factors such as smoking, use of NSAIDs, late night eating, consumption of fried foods, and alcohol intake can be one of many reasons for bile reflux complications post-surgery. This observation is in accordance with the insights of Rutledge, Kular et al. (2016), highlighting the multifaceted nature of post-surgical complications related to bile reflux [18]. Consequently, LMGB is claimed to be the

preferred surgical option as its results have proven less incidence of complications, which is acceptable after comparing it with other surgeries for morbid obesity [19].

Also, it is important to note that the length of the bypassed limb is a variable factor in this procedure, and which significantly influences factors like weight loss, comorbidity resolution, and nutrition absorption. In the present study, 150–200 cm of the limb was bypassed, which was also similar to the study by Piazza et al. (2011). Surgeons generally use a fixed limb length of 200 cm [20].

Moreover, patients' QoL is impacted during the management of obesity. In the current study, enhancements in QoL were observed in group E patients in comparison to group C patients, particularly concerning daily activities, social engagement, physical activity, and self-esteem status following a 3-month period post-LMGB surgery. The BAROS scale was used to analyze the QOL of the patient's post 3 months of surgery. Within the experimental group, noteworthy proportions of patients (23.7% and 14.9%) achieved good and very good BAROS scores for LMGB outcomes, respectively, in contrast to the control group, where such scores were less prevalent. The overall outcome of BAROS will tend to be in good categories if the dietitian is well-trained to carry out proper follow-up sessions. The rarity of studies regarding QOL based on BAROS in the current study underscores the novelty of our Indian investigation in this context.

It is to be noted that the findings of the present study revealed significant differences in QoL outcomes between group E patients and group C patients. It is important to consider the role of personalized NHE material education, which was exclusively given to group E patients. The continuous 24 × 7 counseling offered through WhatsApp exhibited considerable improvements in QoL. This contrasted with group C patients, who only received standard hospital care without benefiting the constant counseling. Offering personalized counseling on demand, 24 × 7 played a pivotal role in addressing concerns, clarifying doubts, and providing support.

Additionally, research based on dietary aspects following LMGB surgery has not yet been reported. Information regarding 4 phases of diet post-surgery is available in which ideally, the first phase starts with a clear liquid diet (1–2 days) followed by a full liquid diet (10–14 days), pureed diet (10–14 days), and soft diet (> 14 days) and then continued with regular diet [2]. The current study's personalized NHE material focused specifically on protein and multivitamin supplementation, given the decreased dietary intake, and compromised nutrient absorption due to bypassed intestines. Nutrition knowledge reinforcement after surgery is very important to avoid any nutritional complications. A knowledgeable bariatric nutritionist can

help in resolving any post-surgical complications related to health and nutrition. Though vitamin B12 deficiency is common after bariatric surgery, our patients reported an acceptable range which was due to good compliance with supplements. The mean iron values were less than the pre values, yet in the normal range. Iron deficiency anemia was the common nutrition deficiency seen in 5% of patients after mini gastric bypass surgery after 1 year of LMGB surgery [13].

LMGB surgery is believed to be more malabsorptive than RYGB surgery, reporting malnutrition in 31/2410 patients of one study and 4/1000 patients of another study [9, 13, 21]. The general guidelines which recommend starting multivitamin chewable tablets after the 3rd day of surgery, followed by protein supplements from the 7th day of the surgery, were followed by the patients of the present study. Bariatric surgery requires super specialty care. In the same way, super special nutritionists/dietitians are required. Best counseling methods help in treating and caring for the patient post-surgery. It is a tool, not a cure, hence patient participation to resolve the morbid condition and their continuous follow-up and interaction with the dietitian is necessary. Therefore, the current study's NHE material focused on motivational counseling (psychological and social). This approach presented notable efficacy in attaining a significant %EWL and positive overall well-being in group E patients. The counseling also encouraged and motivated patients to follow a post-surgery nutrition regime along with taking long-term follow-ups. Thus, it is important that obesity management guidelines [22, 23] are drafted keeping in mind all surgical procedures of bariatric surgery for providing a better quality of life to the patients.

Limitations

One potential limitation of the current study is the relatively short follow-up period of only 3 months post-surgery. While this timeframe may be sufficient to evaluate the short-term outcomes of the intervention, a longer-term follow-up would be needed to assess the sustainability of the weight loss and other outcomes.

Another potential limitation is the lack of blinding of the study participants and the researchers to the intervention, which could introduce bias into the results. Additionally, the study only included patients from a single center, which may limit the generalizability of the findings to other settings. In terms of the results, the study suggests that personalized nutrition health education focused on LMGB leads to better weight loss, comorbidity resolution, and quality of life scores as compared to general counseling.

Conclusion

In conclusion, the present study reports the effectiveness of personalized nutrition health education (NHE) intervention post laparoscopic mini gastric bypass (LMGB) surgery. The findings highlighted the potential benefits of NHE in facilitating weight loss, improving QoL, and resolving comorbidities among patients. The tailored approach utilized in NHE not only addressed dietary aspects but also encompassed psychological and social aspects, contributing to more favorable outcomes. The comparison between group E patients and group C patients revealed better results in terms of %EWL, comorbidity resolution, and QoL for group E patients, justifying the pivotal role of personalized NHE material in managing obesity. Remarkably, both groups suffered from low rates of minor complications post-LMGB surgery. The nutritional deficiencies were also low pertaining to a regular adherence to the prescribed dietary regime and supplementations, as needed.

Thousands of LMGB procedures have been performed, but one with a nutrition interventional plan in Indian settings is hardly available. Specific counselling and patient education programs should be recommended after the bariatric surgeries to bring about long-lasting positive outcomes. Considering our research as a pilot study, further studies can be carried out.

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Declarations

Ethical clearance The study commenced following clearance from the department research committee and institutional ethical clearance from the academic institute (The Department of Foods and Nutrition) and place of the study (Asian Bariatrics, Ahmedabad), with written consent obtained from all patients.

Conflict of interest The authors declare no conflict of interest.

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