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The Influence of Sleeve Gastrectomy on Appetite, Body Composition and Energy Expenditure: A Study Protocol

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ABSTRACT

Sleeve gastrectomy has become one of the most common medical therapies for patients who complain of obesity and comorbidities associated with it. However, numerous reports have shown an increase in body weight after sleeve gastrectomy; therefore, this area requires further investigation. Evidence has shown that there are changes in appetite hormones post sleeve gastrectomy including leptin, ghrelin, cholecystokinin, glucagon-like-peptide 1, peptide tyrosine-tyrosine, and insulin. The main objectives of the current study are 1) to assess the changes in appetite before and after meal consumption at baseline, 3 months, 6 months, and 12 months after sleeve gastrectomy, 2) to assess the interrelationship between dietary intake, body composition, energy expenditure, and physical activity prior and post sleeve gastrectomy. Patients (n=150) will be recruited from King Abdullah bin Abdulaziz University Hospital, Saudi Arabia. A general physical activity assessment, basal measurements including body height, weight, waist circumference, resting metabolic rate measurement, body composition assessment using bioelectrical impedance, dual-energy X-ray absorptiometry, and 24 h food records will be conducted during all the sessions. Blood samples and a visual analog scale will be obtained to measure appetite at four time points prior and an hour following meal consumption. The results of this study will elucidate the reason underlying the regain of body weight in patients one year after sleeve gastrectomy.

Keywords: Sleeve gastrectomy, appetite, appetite hormones, resting metabolic rate, body composition

INTRODUCTION

Obesity is a serious emerging public health condition that has become an epidemic disease worldwide[1]. The first line of medical interventions for obesity is the implementation of lifestyle changes such as increasing physical activity and improving dietary intake. Another strategy for obesity treatment is bariatric surgery[2]. Sleeve gastrectomy is the most common bariatric surgery for weight reduction[3]. According to the 1991 National Institutes of Health Consensus guidelines, patients with body mass index (BMI) 35-40 kg/m² and other health comorbidities or those with BMI above 40 kg/m² are eligible for bariatric surgery[4]. Sleeve gastrectomy procedures are successful in reducing excess body weight by 50%[5]. Although sleeve gastrectomy can be a faster therapy for weight loss in patients with morbid obesity, many patients may return to their original weight 3–4 years after sleeve gastrectomy surgery due to several factors such as increased appetite and food intake[2,6-9].

Appetite can be defined as a process that covers the entire field of

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food intake, selection, motivation, and preference[10]. The regulation of appetite is influenced by numerous hormonal and neural signals in response to stimuli, such as depression and pain. It is also influenced by diet, exercise, gastric motility, body size, and temperature[11-13]. Other factors that may influence appetite include sensory and environmental stimulation, such as the palatability of food, social habits, taste, and smell of food[10,12,13]. Researchers can assess appetite subjectively or objectively[10,14,15]. Subjective appetite can be assessed by palatability, which comprises the property of foods, an individual's reaction to food under standardized conditions, or the impact of foods on ingestion[10,15-17]. Contrarily, objective appetite can be measured through appetite-related hormones such as cholecystokinin (CCK), glucagon-like-peptide 1 (GLP1), glucagon-like-peptide 1 (GLP1), peptide tyrosine-tyrosine (PYY), insulin, leptin, and ghrelin[10,11]. The main role of these anorexigenic gastrointestinal hormones is to decrease food intake by controlling satiety and delaying meal termination by inhibiting pancreatic secretion and gallbladder motility [10, 15]. These hormones remain low during periods of fasting and increase in response to dietary intake [10]. In contrast to anorexigenic hormones, orexigenic ghrelin in the acylated form is an appetite-stimulating hormone. The level of acylated ghrelin remains high during fasting before decreasing in response to dietary intake.

A positive energy balance, which occurs when dietary intake exceeds energy expenditure, can result in obesity. Total energy expenditure (TEE) incorporates three components: resting energy expenditure (REE), activity-related expenditure, and the thermic effects of foods. The difference between energy intake and TEE results in an energy balance. The resting metabolic rate (RMR), one of the components of energy expenditure, involves an assessment of the energy required to maintain vital organ functions in the resting state. Because RMR constitutes approximately 60–70% of TEE in most individuals, researchers utilize this metric for the estimation of energy requirements in various populations[18].

Physical activity has a major influence on body weight in two ways:1) burning the energy consumption from diet and 2) regulating appetite regulation hormones (PYY, GLP-1, insulin, leptin, and ghrelin). The impact of physical activity on appetite and energy intake has been reported in athlete[19]. After bariatric surgery, patients need to increase their physical activity to control appetite and maintain healthy body weight. However, most patients do not increase their physical activity to the recommended levels[20]. Furthermore, a growing body of literature indicate that these patients engage in high levels of sedentary behavior prior to bariatric surgery, with little to no improvement post surgery[21,22]. Improvement in sedentary behavior after surgery might be associated with healthier body composition[23]. Thus, it is important to measure physical activity and sedentary behavior as covariate outcomes in this study.

The objective of the current study is to assess the variables that influence body weight in patients after sleeve gastrectomy. The specific aims of the current study are: 1) to assess the changes in appetite before and after meal consumption at baseline, 3 months, 6 months, and 12 months after sleeve gastrectomy via assessing the hormones associated with appetite and satiety sensations and via visual analog scale , and 2) to assess the interrelationships between dietary intake, body composition, energy expenditure, and physical activity after sleeve gastrectomy in patients.

METHODS

Population and Study Design: This study will apply a repeated measures study design. Data collection will be conducted at the Lifestyle and Health Research Center of the Health Sciences Research Center at Princess Nourah bint Abdulrahman University (PNU), Saudi Arabia. The inclusion criteria of the study will comprise patients 18–50 years old with BMI 35-40 kg/m² and other health comorbidities (such as hypertension, diabetes, and/or dyslipidemia) or BMI above 40 kg/m² who are being followed up in the pre-bariatric clinic at King Abdullah bin Abdulaziz University Hospital (KAAUH) and living in Riyadh City. The exclusion criteria for the study will include the following: patients who have had a previous bariatric surgery, pregnant women, or any participants who report acute or chronic diseases that may affect appetite and/or energy expenditure, such as irritable bowel syndrome, celiac disease, Crohn's disease, ulcerative colitis, hypothyroidism, and eating disorders. All eligible obese patients will be recruited from the pre-bariatric clinic at KAAUH. The study will be performed at four time points. The first visit (baseline) will include all eligible patients who agree to participate in the study. The follow-up visits will be at 3 months, 6 months, and 1 year after sleeve gastrectomy (Figure 1). Informed consent will be obtained from all participants before the start of the study protocol (Figure 2). Ethical approval for this study has been obtained from the institutional review board (IRB) of Princess Nourah bint Abdulrahman University (20-0122).

Sample Size: The sample size calculation indicated that we need a sample size of 150 patients to test our aims. Sample size was calculated based on the mean of ghrelin of 1.08 pg/mL and mean of 0.97±0.49 pg/mL (population) with beta 0.2 with power 80%, and alpha 0.05[24]. This calculation accounts for a possible dropout rate of up to 25%.

Anthropometric Measurements: A trained researcher will perform anthropometric measurements according to written standardized procedures. Specifically, the researcher will measure weight to the nearest 50 g and height to the nearest 0.1 cm using calibrated medical scales (Seca 274, Germany). The participants will be measured while wearing minimal clothing and without shoes. BMI will be calculated as the weight in kilograms divided by the height in m². Waist circumference (WC) will be measured to the nearest 0.5 cm, using a non-stretching measuring tape (Seca 201, Germany) at the midpoint between the bottom of the rib cage and above the top of the iliac crest while the participants stand and follow normal expiration. The measurement will be taken twice and the average of both values will be used. Finally, the waist (cm) to height (cm) ratio will be calculated.

Body Composition Measurements: Body composition measurement will be performed using two techniques: Dual-energy X-ray absorptiometry (DXA; Lunar iDXA, GE Healthcare, USA) and bioelectrical impedance analysis (BIA; mBCA 515, Seca, Germany). DXA contains minimal radiation and can measure both whole and segmental body composition, in addition to bone mineral density, using the enCORE software platform. Body composition parameters from the DXA output include fat mass (FM), fat-free mass (FFM), lean soft tissue (LST) mass, and bone mineral content. A single trained technician will perform whole-body DXA body composition scan according to the manufacturer's instructions (GE Healthcare, USA), for all the participants in the fasting state. Participants will be requested to remove all metal accessories and then lie in the middle of the table bed in a natural position; all the body parts must be included in the scanning spectrum. For participants who are wider than the DXA table, the mirroring technique will be performed as described previously[25-27].

Moreover, bioelectrical impedance analysis (BIA) will be applied to measure FM, FFM, and appendicular skeletal muscle mass. Participants will be asked to remove shoes and metals, ensure they have dry hands and feet, and then stand in the middle of the weighting platform with feet on marked circles and hold the handles of the machine appropriate to their height (with upper extremity not touching the body).

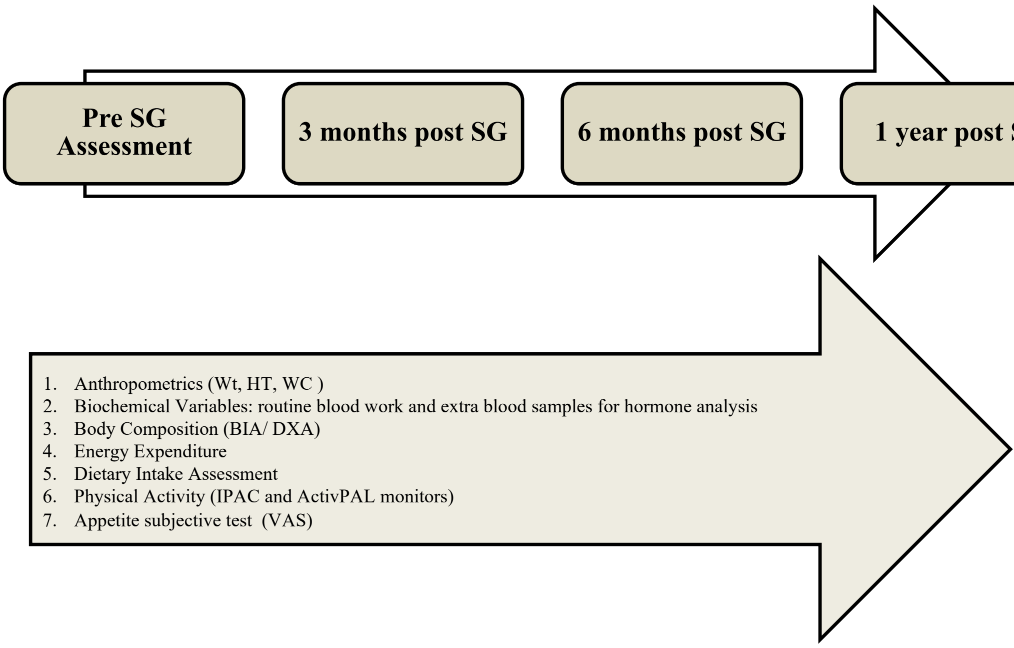


Figure 1: Study design. Abbreviations: Bioelectrical impedance analysis (BIA); Dual-energy X-ray absorptiometry (DXA), Height (ht); International Physical Activity Questionnaire (IPAC), Resting metabolic rate (RMR), Visual analog scale (VAS); Weight (wt); Waist Circumference (WC)

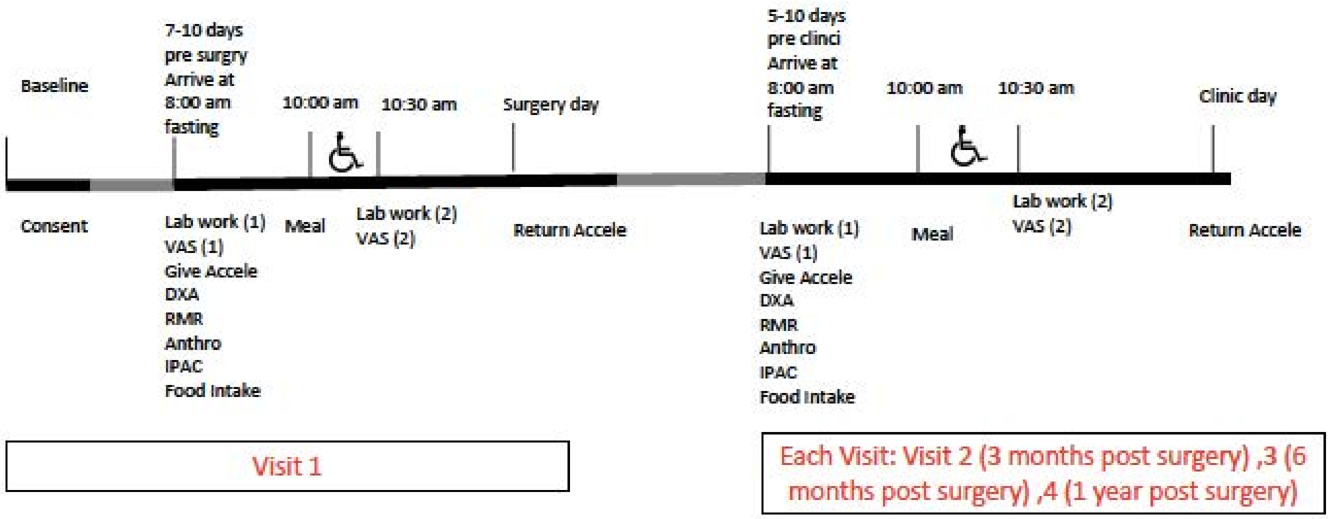


Figure 2: Study Assessment. Abbreviations: Bioelectrical impedance analysis (BIA); Dual-energy X-ray absorptiometry (DXA), International Physical Activity Questionnaire (IPAC), Resting metabolic rate (RMR), Visual analog scale (VAS)

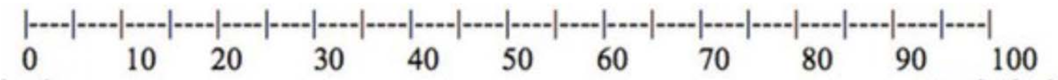
Additional calculations will be assessed as follows: fat mass index (FMI) (FM/height in m^2), fat-free mass index (FFMI) (FFM/height in meter ^{2}) and lean soft tissue index (LSTI) (LST/height in m^2). The appendicular skeletal muscle (ASM) will be calculated as the sum of LST from the arms and legs. The appendicular skeletal muscle index (ASMI) (ASM/height in m^2) and ASM/weight will be further computed.

Resting Metabolic Rate (RMR): The researchers will measure the RMR using indirect calorimetry, with a canopy placed over each participant's head. The gas exchange variable will be measured continually using a Metamax analyzer (Cortex, Germany), while the participant is lying supine on a medical bed for at least 20 min. Prior to this test, researchers will inform participants to obtain 7–8 h of sleep and fast for 12 h before arriving at the laboratory the following morning. In addition, participants will receive instructions to abstain from caffeine for 24 h and avoid strenuous exercise for at least 48 h before the day of the laboratory tests.

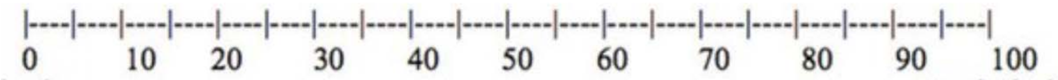
Blood Sample Collection and Biochemical Analysis: Participants will be asked to fast for routine blood test at baseline and after sleeve gastrectomy (3, 6 months and 1 year), including liver enzymes (alanine aminotransferase (ALT), aspartate aminotransferase (AST), and γ-glutamyltransferase (γGT)), fasting glucose, insulin, lipid profile (triglyceride (TG), total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL)), and C-reactive protein (CRP). Results of the routine blood test will be obtained from the hospital medical records. Participants will also provide extra blood samples of 10 ml for the analysis of appetite-regulating hormones, including CCK, GLP1, PYY, insulin, leptin, and ghrelin[28]. Another blood post prandial draw (2 hours after breakfast buffet) will be taken from all participants.

On a scale from 0 (not at all) to 100 (extremely), select your answer to each of the following questions:

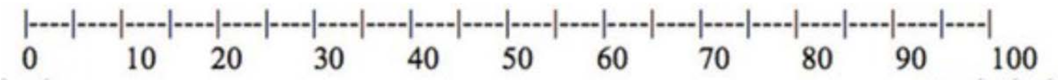
How hunger do you feel?



How full do you feel?



How Satisfied do you feel?



How much do you think you can eat now?

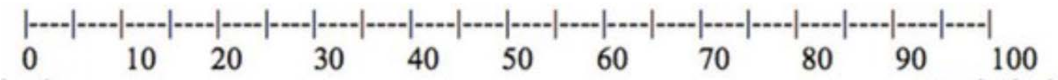


Figure 3: Appetite Test-Visual Analog Scale (VAS)

Table 1: Food buffet items

Food Type	Amount	Energy (Kcal)	Carbohydrate (g)	Protein (g)	Fat (g)	GI
Bread white	4 slices (232 g)	308	57.32	10.28	3.88	70
Bread brown	4 slices (232 g)	316	55.16	12.4	5.24	72
Bun Small	4 white buns	456	80	16	7.2	72
Boiled egg	2 L egg	156	1.2	12.6	10.6	0
Cheese Cheddar	2 slices (40g)	124	1.6	7.2	10	0
Cream cheese	40 gm	134	0.8	2.8	13.2	0
jam	28gm	124	31.62	0	0	91
Honey	2 tablespoon = 10-12 gm	36	10	0.04	0	87
Cucumber	10 slices = 28.0 g	6	1.2	0.4	0.08	0
Tomato	0.5 tomato = 40.0 g	15	2.74	0.14	0.03	0
Apple Gala	2 medium (182g)	104	27.48	0	0.72	40
banana	2 medium =117 gm	210	53.9	2.58	0.78	62
Apple juice	Two juice box= 200 ml	180	47.4	0	0	44
Orange juice	Two juice box= 200 ml	184	44	3.4	0	53
Low-fat milk	Two milk box= 200 ml	216	20	13.4	8.32	34
Dates	10 pieces	38	10.6	0.6	0	55
Arabic Coffee		0	0	0	0	0
Nescafe/ Tea		0	0	0	0	0
Sugar	3 packet= 15 gm= 3tsp	57	15	0	0	84
Stevia	2 packet	0	1	0	0	0
Water		0	0	0	0	0

To monitor hormone levels in patients after sleeve gastrectomy, blood samples will be collected in pre-chilled ethylenediaminetetraacetic acid (EDTA)-containing tubes during fasting and after ad libitum breakfast. All the samples will be centrifuged at 3,000 rpm and 4 °C for 15 min. Plasma samples will be aliquoted and stored at −80 °C until processing. Upon completion of the study, samples from each patient will be assayed and analyzed on the same plate. Total ghrelin (intra-assay coefficient of variation (CV), <8%), leptin (intra-assay CV, <8%; Bioassay Technology Laboratory, Shanghai, China), CCK (intra-assay CV, <8%; MyBioSource, San Diego, USA), GLP1 (intra-assay CV, <8%; MyBioSource, San Diego, USA), and PYY (intra-assay CV, <8%; MyBioSource, San Diego, USA) assays will be assessed according to the manufacturer's guidelines using a VarioskanTM LUX multimode microplate reader (Thermo Scientific, Waltham, MA, USA).

Subjective Appetite: Upon arrival, baseline appetite will be measured using the visual analog scale (VAS), which typically comprises a

100 mm horizontal line anchored at both ends by extreme subjective feelings of fullness or hunger (Figure 3)[29]. Participants can place a mark on this horizontal line, which represents a continuum, to reflect the intensity of a subjective sensation at a particular time[14]. VAS can be used to ask a variety of questions regarding subjective appetite and includes four basic scales: hunger, fullness, prospective food consumption, and desire to eat[10,30,31]. Specifically, participants can use the tool after consuming meals to assess the effect of palatability on food intake, thereby measuring objective appetite and changes in appetite within meals. In this situation, the measurement of food intake in grams usually accompanies VAS 10. In addition, VAS will be also taken after breakfast buffet.

Breakfast : After completing the session, an ad libitum breakfast buffet will be provided (**Table 1**). The breakfast buffet will be chosen based on the commonly available foods in Saudi Arabia[32]. Participants can have breakfast for a maximum of 30 min. After breakfast, the amount of food consumed from the buffet will be calculated. Blood draw and VAS will be obtained during fasting and within 2 h after meal consumption.

Dietary Intake : Dietary intake will be assessed using three days' food recored (one weekend and two weekdays) using the multiphase technique[33,34]. Nutritics software will be applied to analyze macro and micronutrient intake (Nutritics LTD, Ireland). The glycemic index (GI) and glycemic load (GL) of each food item will be calculated using GI tables, as reported by Foster-Powell, Holt, & Brand-Miller (2002) and Atkinson, Foster-Powell, &Brand-Miller (2008)[35-37]. The calculation and cutoff points for high GI and GL values will be as described previously[35-38].

Physical Activity and Sedentary Behavior: Physical activity and sedentary behavior will be measured using both subjective and objective measures. The International Physical Activity Questionnaire (IPAQ), which is a validated tool, will be used to assess physical activity[39,40]. The scores will be calculated as median and interquartile ranges for walking, moderate-intensity activities, vigorous-intensity activities, and the sum of physical activity scores. All continuous scores shall be expressed in metabolic equivalent task (MET)-min/week, as described previously[39].

To objectively monitor physical activity and sedentary behavior, we will use thigh-worn activPAL monitors (PAL Technologies Ltd., UK), which contain both accelerometers and inclinometers. ActivPAL monitors are valid methods to assess the number of steps and intensity of activity, which can be used to estimate the energy expenditure due to physical activity. Furthermore, activPAL can discriminate between sitting and standing positions by detecting static acceleration in relation to thigh orientation in space; thus, it can uniquely measure sedentary behavior patterns and duration[41,42]. Participants will be asked to wear the activPAL monitor continuously for 7 days at each study assessment point and instructed to take the monitor off only when fully submerged underwater. While wearing the monitor, participants shall be given a sleep and monitor diary to record when they went to sleep and when they woke up along with any time point they removed the monitor and attached it back. Sleep duration will be calculated using both activPAL and sleep diary data.

Statistical Analysis : Data analysis will be performed using Statistical Analysis Software (SPSS; IBM® SPSS® Statistics 29), with significance set at $p \leq 0.05$. Continuous variables will be reported as mean ± standard deviation (SD) and categorical variables will be measured as n numbers and (percentages). Analysis of variance will be performed to assess significant differences in hormone levels over the study period. Regression analysis will be conducted to assess the relationship between hormone levels (CCK, GLP1, PYY, insulin, leptin, and ghrelin) and VAS scores. Multivariate logistic regression will be used to measure the association between appetite (hormones and/or VAS) and other factors (RMR and body composition). Missing data shall be treated using the appropriate statistical techniques.

DISCUSSION

Research has extensively identified obesity as a serious public health condition worldwide[43]. Sleeve gastrectomy is one of the available treatments for obesity. However, an increase in body weight one year after sleeve gastrectomy has been reported[2,6-9]. Changes in appetite regulation hormones may be one of the main reasons underlying this observation. Therefore, the current study aims to assess numerous variables, including appetite that causes a positive energy balance and increases body weight in patients, after sleeve gastrectomy.

Despite the objective of maintaining a consistent energy balance, several physiological and pathological factors may alter an individual's energy balance[44]. The sex of the individual can influence metabolic activities within cells. Compared to women, men generally experience higher metabolic rates, which may result from their higher muscle mass[44,45]; however, pregnant or lactating women also experience a rise in metabolic activity[46]. Furthermore, metabolic activity is affected by age, increasing in infancy and childhood because of extensive metabolic processes required for growth, but decreasing in elderly individuals[44]. Additionally, physically active individuals display higher metabolic rates than their sedentary counterparts[47,48].

Sleep parameters, such as duration or quality, are additional factors that can influence RMR[49,50]. Other demographic factors can influence REE and metabolic rate, including body composition, body size, and ethnicity, as well as various environmental and genetic factors[48,51].

Several studies have reported improvements in one or more parameters of physical behavior (physical activity, sedentary behavior, and sleep) post bariatric surgery[21,52,53]. These mixed results of no change or small changes indicate that other factors might mediate the relationship between bariatric surgery and physical behavior. One factor might be the heterogeneity in assessing physical behavior observed in published studies. Thus, in our study, we assessed physical activity and sedentary behavior both objectively and subjectively, using highly accurate instruments. Another factor might be the interrelationship between physical behaviors and appetite regulation. In fact, a study by Bond et al. indicated an association between appetite and physical activity and sedentary behavior in people who underwent bariatric surgery[54]. These promising results will be explored further in our study to assess appetite pre/post meals along with blood analysis of appetite hormones.

Due to limited resources, we only chose physical activity and sedentary behavior from all possible lifestyle covariates that might influence the primary outcomes. Although sleep data will be collected, it will not be used in the main analysis. Sleep data will be used as an exploratory factor in subsequent analysis.

Standard clinical practice uses BMI to measure obesity. BMI is derived from the measurement of the body mass (kg) divided by the square of the body height (m^2). This tool defines four categories: underweight, normal, overweight, and obese (defined as BMI ≥ 30 kg/m^2). Despite its standardized use, reliance on BMI has drawbacks. This tool, used in isolation, fails to accurately measure adipose tissue. In addition, elevated BMI can result from increased muscle mass or edema. Consequently, researchers should combine the BMI results with more precise methods such as BIA and DXA, to provide a more accurate assessment of obesity. Accordingly, the investigator will measure the participants' height and body weight during each visit to calculate BMI. DXA and BIA, which are available at the Lifestyle and Health Research Center laboratory, will be used to measure the body composition of the participants, including fat and lean tissues.

CONCLUSION

It has been reported that patients post sleeve gastrectomy may experience regain body weight[2,6-9]. The current protocol study aims to assess different factors influencing body weight in patients post sleeve gastrectomy. These factors including appetite which will be measured objectively through blood hormones and subjectively using visual analog scale. Other factors affecting body weight include dietary intake, body composition, resting metabolic rate, and physical activity will be assessed as well. Assessing all the above variables in patients undergoing bariatric surgery will help to understand the underlying factors that may alter body weight in patient post sleeve gastrectomy.

Authorship Contribution: All authors share equal effort contribution towards (1) substantial contributions to conception and design, acquisition, analysis and interpretation of data; (2) drafting the article and revising it critically for important intellectual content; and (3) final approval of the manuscript version to be published. Yes.

Potential Conflict of Interest: None

Competing Interest: None

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Informed Consent: Ethical approval for this study has been obtained from the institutional review board (IRB) of Princess Nourah bint Abdulrahman University (20-0122). Informed consent will be obtained from all participants before the start of the study protocol.

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