



RUTGERS

HOSPITALIZATION OUTCOMES OF PATIENTS UNDERGOING LAPAROSCOPIC SLEEVE GASTRECTOMY

By

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the
Degree of Doctor of Philosophy in Biomedical Informatics

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Hospitalization Outcomes of Patients
Undergoing Laparoscopic Sleeve Gastrectomy

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DEDICATION

I dedicate my dissertation to my family. I feel especially grateful to my loving parents, Norah Almudlej and Mohammed Allabun whose words of encouragement and push for tenacity ring in my ears. My sisters Mona, Jamelah, Rana, Amjaad and Raneem never left my side, and our very special brothers, Abdul Mohsen and Wael, always encouraged me.

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TABLE OF CONTENTS

ABSTRACT	ix
LIST OF FIGURES	xi
LIST OF TABLES	xiii
LIST OF ABBREVIATIONS.....	xv
CHAPTER I INTRODUCTION.....	1
Background.....	1
Overweight and Obesity Overview Worldwide	1
The percentage of the Obesity in Eastern Mediterranean Region	4
Management of overweight and obesity	8
Thyroid Gland Role in Obesity	12
Statement of the Problem.....	14
Goals and Objectives.....	14
Research Purpose and Hypotheses.....	15
Significance of Study	18
Relevance to Biomedical Informatics	19
CHAPTER II LITERATUR REVIEW.....	20
CHAPTER III METHODOLOGY	37
First Phase of the Study.....	37
Nationwide Inpatient Sample Data	37
Research Design & Method	41
Research Hypothesis of the first phase	44
Second phase of the study.....	45

Research Design & Method	45
Population and Sample criteria	46
Data collection procedures.....	46
Data analysis.....	47
Ethical considerations.....	47
Research Hypothesis of the Second Phase.....	48
CHAPTER IV RESULTS OF DATA ANALYSIS.....	50
Results from NIH about US Patients	50
The Results of Hospitalization Outcomes of Patients undergoing LSG	67
The results from Saudi Arabian Patients.....	78
Hemoglobin.....	78
Vitamin B ₁₂	80
Vitamin D.....	83
Thyroid Function.....	85
CHAPTER V DISCUSSION AND STUDY LIMITATION	90
CHAPTER VI SUMMARY, SUGGESTIONS FOR FUTURE RESEARCH..	100
REFERENCES	101

ABSTRACT

The increase in the prevalence of obesity in a growing number of populations worldwide presents a rising health threat in this millennium. Overall, about 13% of the world adult population (11% of men and 15% of women) fell into the obese category in 2014.

Management of overweight and obesity used to be through non-surgical methods including diet, exercise, medication, and changing life styles. However, commitment to all these methods is very hard. Hence, surgical intervention has been used on a wide scale. Many types of bariatric surgical procedures were applied, mostly restrictive types such as Laparoscopic Sleeve Gastrectomy, Laparoscopic Adjustable Gastric Banding, or Roux-en-Y Gastric Bypass.

The overall goal of this research is to identify the factors and costs associated with patients undergoing different types of gastrectomy, in terms of length of stay in the hospital and the operations' costs in different types of clinical settings across the United States. Accordingly in the second phase of the project, a prospective study was conducted to evaluate some variables in the LSG candidates, such as hemoglobin level, vitamin levels (B₁₂ and D), and thyroid hormone levels before and after the operation. Moreover, similar study and data sources were made use of from King Khalid University Hospital, Riyadh, Kingdom of Saudi Arabia.

Most patients who underwent the LSG had different kinds of comorbidity, for example; among 2012 candidates in the US, there were 34.22% who had hypertension, complicated or uncomplicated; 15.26% had uncomplicated diabetes; and 12.35% complained of depression.

According to this study's results, a statistically significant association was found between length of stay in the hospitals, and consequently the total cost, and the following comorbidities: obesity ($b=1.119$, $p<0.001$), hypertension ($b=0.076$, $p=0.022$), and deficiency anemia ($b=0.506$, $p<0.001$). No statistically significant evidence of association between length of stay or total cost and hypothyroidism ($p=0.12$) or uncomplicated diabetes ($p=0.385$) was found.

Regarding Saudi patients who received LSG between 2014 and 2015, no statistically significant difference between level of Hb or Vitamin B₁₂ was found in patients before and after the LSG, while there was a statistically significant difference in the level of vitamin D before and after the operations.

Although Sleeve Gastrectomy is popular currently as a solution for obesity, research into the procedure's long-term effects is scarce. More research is required to improve outcomes and to maximize the benefits of those procedures.

LIST OF FIGURES

Figure 1: Global WHO estimates of obese and overweight percentage in 2014	3
Figure 2: Distribution of obesity worldwide in 2013.....	4
Figure 3: Distribution of obesity in Eastern Mediterranean regions.....	5
Figure 4: Percentage change in distribution of body mass index (BMI) categories from 2005 through 2013	8
Figure 5: Gastric bypass procedure.....	9
Figure 6: Sleeve gastrectomy.....	11
Figure 7: Conceptual model for identifying the factors determining total discharge, length of stay and costs.....	42
Figure 8: Compression chart of outcomes of patients who had lap vertical gastrectomy in the US From 2011 till 2013	51
Figure 9: The length of stay by days in the hospitals after laparoscopic sleeve gastrectomy from 2011 till 2013	52
Figure 10: Charges of Laproscopic S.G. in dollars from 2011 to 2013	52
Figure 11: The other measured outcomes after laparoscopic sleeve gastrectomy operation from 2011 to 2013.....	54
Figure 12: The number of patients who had the LSG (laparoscopic sleeve gastrectomy) and the first listed diagnosis (DX1)	57
Figure 13: The number of patients depending on their sex from 2011 till 2013	58
Figure 14: Total number discharged from lap vertical gastrectomy shown by sex in 2012	59

Figure 15: Distributions of the discharge patients who had lap vertical sleeve gastrectomy shown by age in 2012	60
Figure 16: The percentage of payer for patients who underwent laparoscopic sleeve gastrectomy in 2012	61
Figure 17: The percentage of different kind of hospitals picked by the patients who underwent laparoscopic sleeve gastrectomy in 2012.....	62
Figure 18: The percent of patient's picks depending on the bed sizes of the hospitals to undergo the laparoscopic sleeve gastrectomy in 2012.....	64
Figure19: The number of patients according to AHRQ comorbidity measures in 2012 ..	66
Figure 20: The percentage of obesity in USA and Saudi Arabia (KSA) from 2012 until 2014.....	92
Figure 21: The total discharge patients who had three different bariatric surgeries in the US From 2011 till 2013	94
Figure 22: The length of stay by days in the hospitals after three different bariatric surgeries in the USA from 2011 till 2013	95
Figure 23: Charges of three different bariatric surgeries in dollars from 2011 to 2013 in USA.....	96
Figure 24: Comparison of three bariatric surgeries between USA and France in 2011 ...	98

LIST OF TABLES

Table 1: The classification of weight category by BMI	2
Table 2: Comparison between sleeve gastrectomy (SG) and gastric bypass (GBP)	22
Table 3: Comparison of bariatric surgery outcomes.....	23
Table 4: January 2006 - September 2009: comparison of 811 patients those who had SG with 786 patients who had RYGB	25
Table 5: Twenty three non-diabetic obese patient they randomly distributed 12 of them undergo LRYGB and 11 undergo GS.....	26
Table 6: Comparison of two groups of 36 patients underwent RYGB and 36 patients who underwent GS.....	28
Table 7. Retrospective chart review performed for patients who underwent laparoscopic RYGB or LSG between 2007 and 2009 at an HMO hospital.....	29
Table 8: Comparison of 117 patients from January 2008 to December 2008	30
Table 9: Two- and 10-year diabetes incidence and remission rates from the Swedish obese subjects' study.....	31
Table 10: Result of diabetic control after bariatric surgery in different studies	31
Table 11: Data variables used for analysis	38
Table 12: Study hypotheses and corresponding statistical tests	39
Table 13: The national statistics of the lap vertical sleeve gastrectomy procedure outcomes from 2011 till 2013	50
Table 14: The number of patient's who had the LSG (laparoscopic sleeve gastrectomy) and their first listed diagnosis (DX1).....	55

Table 15: The distribution of patients depending of sex in 2012	58
Table 16: The age group of patients who underwent laparoscopic sleeve gastrectomy operation in 2012	60
Table 17: The insurance payer to patients who underwent lap sleeve gastrectomy in 2012	61
Table 18: The number of patients who picked different kind of hospitals to undergo the laparoscopic sleeve gastrectomy in 2012.....	62
Table 19: The number of patients pick different kind of hospitals depending in the bed size to underwent the laparoscopic sleeve gastrectomy in 2012.....	63
Table 20: Number of patients according AHRQ comorbidity measures in 2012.....	65
Table 21: Iron result from Saudi Arabian Patients Data before and after Sleeve Gastrectomy in King Khalid University Hospital.....	79
Table 22: Vitamin B ₁₂ result from Saudi Arabian patients' data before and after sleeve gastrectomy in King Khalid University Hospital.....	81
Table 23: Vitamin D result from Saudi Arabian patients' data before and after sleeve gastrectomy in King Khalid University Hospital.....	83
Table 24: Comparison of three bariatric surgeries between US and France in 2011	86
Table 25: TSH result from Saudi Arabian Patients, data before and after sleeve gastrectomy in King Khalid University Hospital.....	88

LIST OF ABBREVIATIONS

WHO	World Health Organization
LSG OR SG	Laparoscopic Sleeve Gastrectomy
RYGB OR GBP	Laparoscopic Roux-en-Y Gastric By Pass
T ₄	Thyroxin
Hb	Hemoglobin
TSH	Thyroid-stimulating hormone
GERD	Gastro-esophageal reflux disease
BPD OR LBPD	Laparoscopic Bilio Pancreatic Diversion
LAGB	Laparoscopic Adjustable Gastric Band
NIH	National Institutes Of Health
IRB	Institutional Review Board
KKUH	King Khalid University Hospital
H.CUP net	Health Care Cost and Utilization Project

CHAPTER I: INTRODUCTION

1.1 Background

The increase in the prevalence of obesity in a growing number of populations worldwide presents a rising health threat in this millennium. The proliferation of fast food, the lack of exercise, and difficulty committing to a healthy diet combine to create an unhealthy environment. This has led to an increasing percentage of overweight and obese individuals worldwide, leading to cardiovascular disease, diabetes, and other serious medical conditions.

1.1.1 Overweight and obesity overview worldwide

Overweight and obesity are defined as “abnormal or excessive fat accumulation that may impair health.” The World Health Organization (WHO) refines this definition in this manner: Body mass index (BMI) greater than or equal to 25 is overweight, and body mass index (BMI) greater than or equal to 30 is obese.

Simply put, BMI is an index of weight-for-height commonly used to classify overweight and obesity in adults. BMI is calculated as a person's weight in kilograms divided by their height in meters square (kg/m^2). BMI is expressed metrically as kg/m^2 , thus, $\text{BMI} = (\text{Weight in Pounds}) \times 703 / (\text{Height in Inches}^2)$.

Many BMI calculators can be found online, such as the one provided by the National Institute of Health: <http://www.nhlbisupport.com/bmi>. Another good calculator, which

allows for metric or US English input and provides an explanation of the result and risk factors, is available online at <http://www.smartbmiccalculator.com>.⁶³

BMI provides the most useful population-level measure of overweight and obesity because the calculation and scale is the same for both sexes and all ages of adults. It should, however, be considered a rough guide, as it may not correspond with the same degree of obesity in different individuals.⁵⁰

Overweight and obesity are effective risk factors for cardiovascular disease and type 2 diabetes, and they are the main contributor to premature death. The classification of risk by weight category and BMI cut-off points is shown in Table 1.⁵⁰

Table 1: The classification of weight category by BMI

Classification of Population According to BMI	Principal Cut-Off Points BMI (kg/m ²)
Normal range	18.5–24.9
Pre-obese	25.0–29.9
Obese class I	30.0–34.9
Obese class II	35.0–39.9
Obese class III	≥ 40.0

We address eligibility and prioritization for bariatric surgery within the colored zones above.³¹ Source: Adapted from the World Health Organization (WHO) 2015.⁵⁰

Figure 1 illustrates recent estimates from the WHO as to the actual number of people globally who fall into the categories of obesity shown in Table 1.

In 2014, more than 1.9 billion adults globally, 18 years old and older, were overweight. More than 600 million suffer from obesity. Overall, about 13% of the world adult population (11% of men and 15% of women) fell into the obese category in 2014. Similarly, 39% of adults aged 18 years and above (38% of men and 40% of women) were overweight. Worldwide, obesity more than doubled between 1980 and 2014.⁵⁰

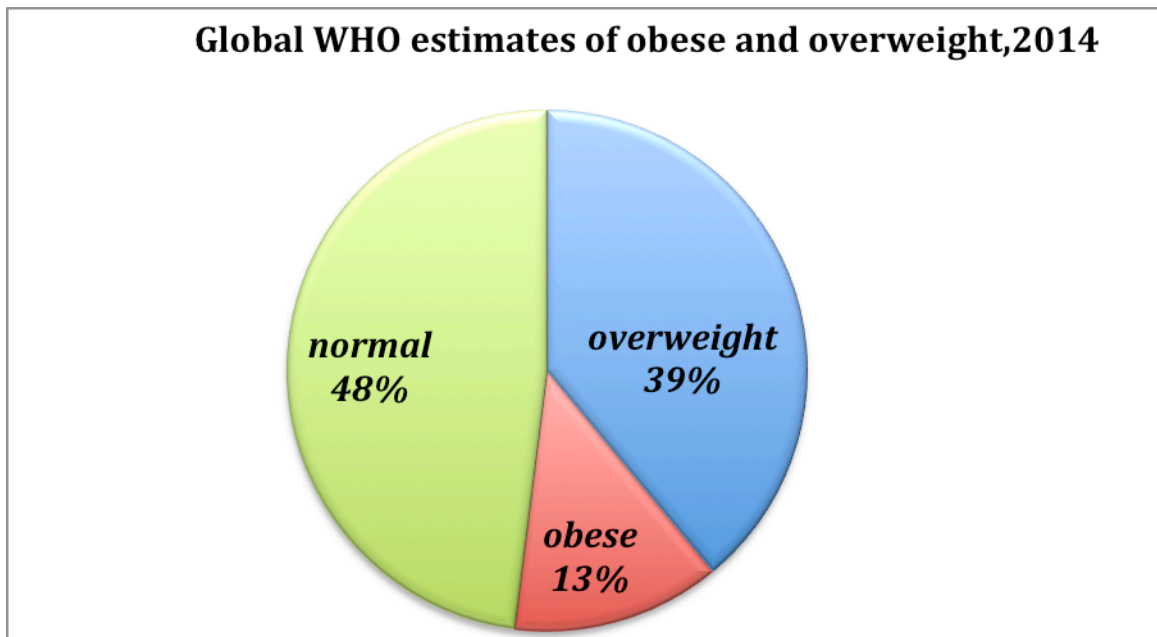


Figure 1: Global WHO estimates of obese and overweight percentage in 2014.⁵⁰

In 2013, 42 million children under the age of 5 years were overweight or obese. Having traditionally been considered the problem of high-income countries, overweight and obesity are now on the rise in low- and middle-income countries, particularly in urban areas. It has been in the emerging economies of developing countries (as defined by the World Bank classification of low- and middle-income countries) that the rate of increase in childhood obesity and overweight has risen more than 30% than that in developed countries.⁵⁰ Figure 2.

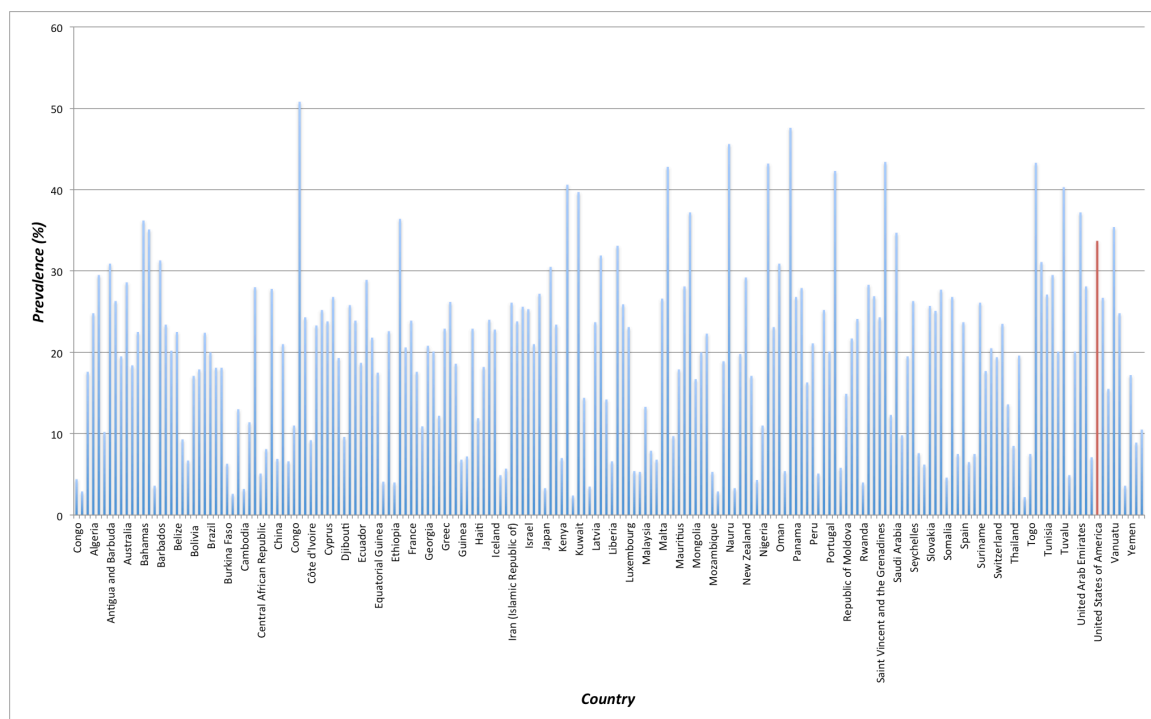


Figure 2: Distribution of obesity worldwide in 2013.⁵⁰

In fact, more people die of diseases linked to obesity than die of diseases linked to malnutrition or low body weight. The death rate due to overweight and obesity does not differentiate between populations with high income or middle-income.⁵⁰

1.1.2 The percentage of the obesity in Eastern Mediterranean region

As shown in Figure 3, a significant percentage of the adult population in the Eastern Mediterranean Region falls into the obese and overweight categories. Data collected from adults aged 15 years and older from 16 countries in the region showed that the highest levels of overweight and obesity were in Egypt, Bahrain, Jordan, Kuwait, Saudi Arabia and the United Arab Emirates. The prevalence of overweight and obesity in these countries ranged from 74% to 86% among women, and 69% to 77% in men. This data indicates that obesity rates are unacceptably high among adult

women, while weight gain has been more pronounced among adult men. It has also been found that there are rising levels of overweight and obese individuals among children and adolescents, which is of particular concern in view of recent evidence of links between the child and the chubby teenager, which may lead to an increased risk of obesity and related diseases in adulthood.⁵¹

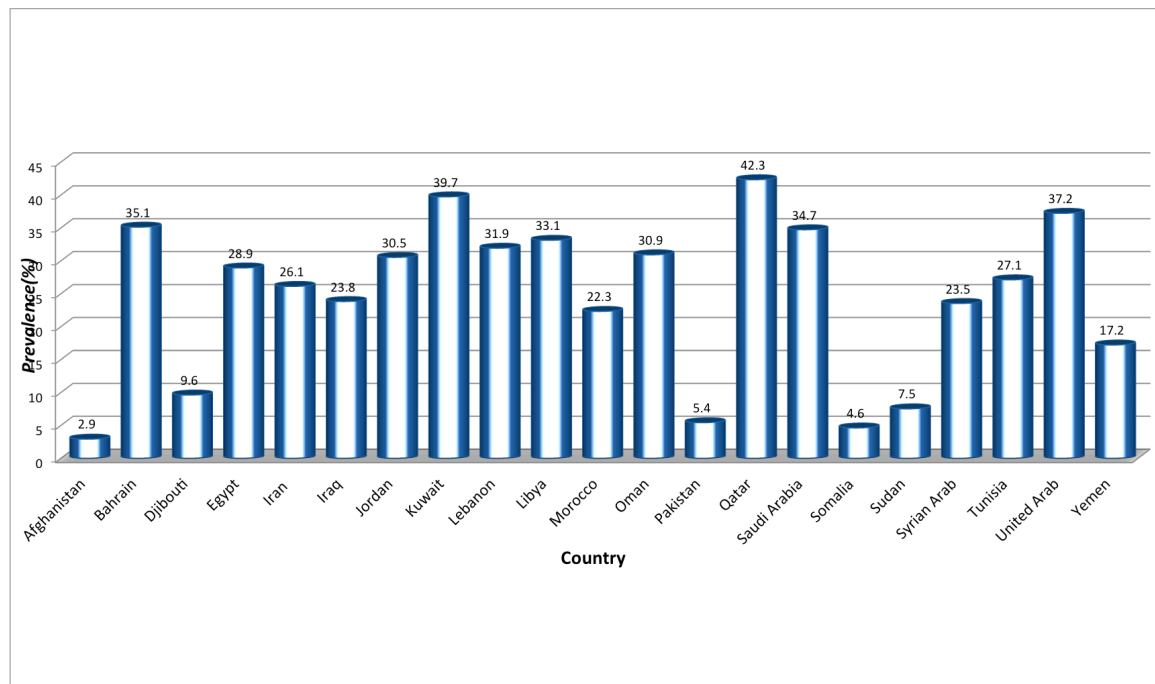


Figure 3: Distribution of obesity in Eastern Mediterranean regions in 2013.⁵⁰

In light of these findings, on March 9, 2014, the Ministry of Health of Saudi Arabia, in collaboration with the Institute for Health Metrics and Evaluation (IHME) from the University of Washington, conducted a study of obesity and overweight in Saudi Arabia.⁵¹

The study pointed out that based on the WHO classification of weight category Table 1. The prevalence of obesity was 28.7% for the entire population (3.6 million people). This study of the Saudi population found that the female ratio recorded the highest rate, 33.5%, compared with 24.1% for males. The findings also determined that, as the age of the population sample increased, obesity reached the highest levels; in the 55-64 age group, 48.0% fell into this category. Furthermore, the study showed that 2.5% of males and 4.7% of females were categorized as morbidly obese, with a devastatingly high BMI of 40.⁴⁹

As far as exercise is concerned, the study found that more than half of Saudi women do not exercise at all, while 29% of them engage in light physical activity. With regard to males, the percentage of them that do not engage in any physical activity at all reached 33%, and the same percentage applies to those who engage in light physical activity.⁴⁹

A correlate to the high percentage of overweight and obesity in the study is the low rate of consumption of vegetables and fruits; the percentage of those who consume more than five servings of fruits and vegetables a day only amounted to 7.6%. Although the incidence of chronic diseases, as well as the high rate of smoking has increased, the survey also pointed out that 75% of the members of Saudi society do not engage in routine medical examination.⁴⁹

Figure 4, derived from the results of 2013 Saudi study, illustrates that obesity levels were lower than those reported in 2005 and those estimated for 2010. When constructing the survey for the purposes of this study, a comparable sample was utilized and a survey method was developed that was similar to the framework used in 2005.⁴⁹

When comparing their survey data with the 2005 survey, the analysis was restricted to the same age categories. Utilizing this data, it was observed that obesity fell by 4.4% for men and 10.7% for women between 2005 and 2013. During the same time period, the survey data reflects an increase in the normal weight category of 7.8% for men and 9.0% for women. Shifts have occurred from obesity to overweight and from overweight to normal weight or obese to normal weight categories. On the contrary, the change in the prevalence of obesity rate differed significantly between age groups for both sexes. This study found that, in 2013, fewer men under the age of 35 were obese than there were in 2005, while men older than 35, as a group, displayed a higher prevalence of obesity.

The 2013 survey results also shows that the prevalence of obesity for women of all age groups has declined since 2005, with the exception of women between 55 and 64 years of age, where the prevalence of obesity increased by almost 10%. This overall decline in the prevalence of the obesity rate is good news for the health of Saudis, where public health interventions are just beginning to show concrete results. This is especially relevant in light of the success stories in reducing obesity levels in other countries as a result of health interventions and environmental changes and policy.⁵⁴

Over the past decade, the Saudi Ministry of Health has issued a mandate to implement many public health programs to reduce obesity. Most of these programs have focused on awareness and behavioral changes. However, it is too early to determine whether the decline seen in this study is due to chance, and therefore not necessarily sustainable, or is related to the implementation of the public health programs.⁵⁴

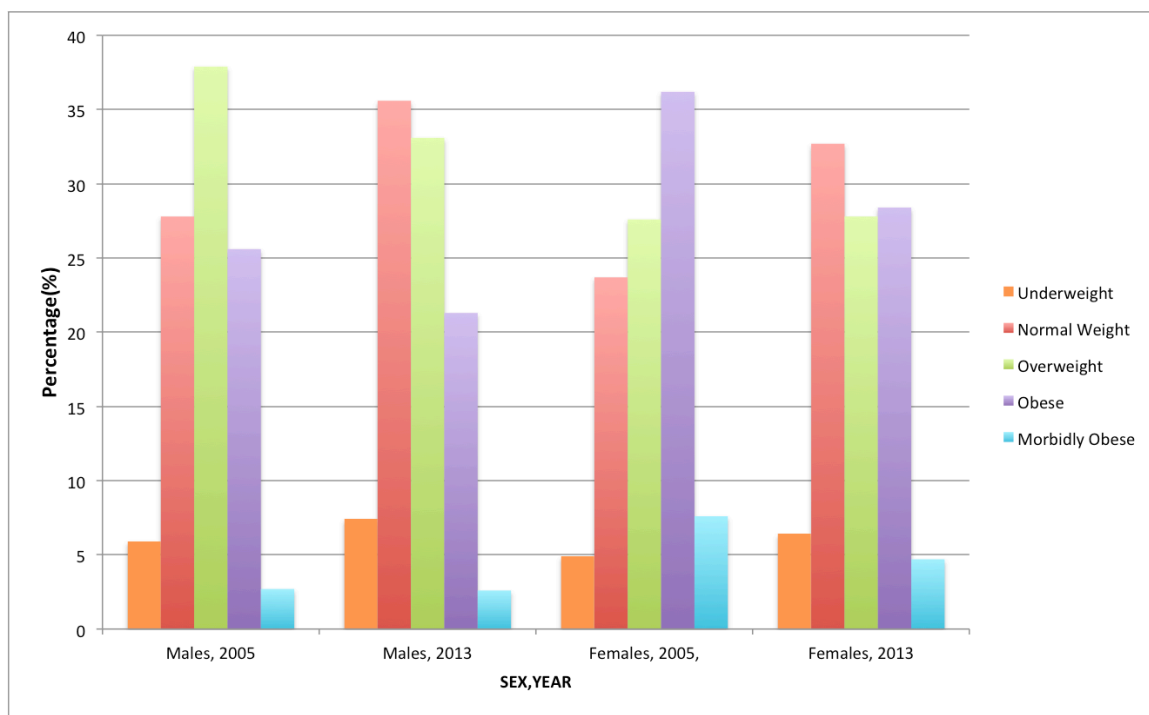


Figure 4: Percentage change in distribution of BMI categories from 2005 through 2013, for men and women, Kingdom of Saudi Arabia. Categories are underweight (BMI <18.5), normal weight (BMI 18.5–24.9), overweight (BMI 25.0–29.9), obese (BMI 30.0–39.9), or morbidly obese (BMI ≥ 40).⁵⁴

1.1.3 Management of overweight and obesity

1. General Overview

A. Non-surgical

- Diet and exercise
- Medication for losing weight
- Change eating habits
- Change of life style

B. Surgical intervention

Bariatric Surgical Procedures can be classified into three main categories:

1) Malabsorptive

- Biliopancreatic Diversion and Duodenal Switch

2) Restrictive

- Laparoscopic Sleeve Gastrectomy, Laparoscopic Adjustable Gastric Banding

3) Combination of Restrictive and Malabsorptive

- Roux-en-Y Gastric Bypass.²⁹

2. BARIATRIC PROCEDURES OVERVIEW

Bariatric surgery is a medical procedure resulting in weight loss by either reducing the absorption of calories or reducing the stomach's absorption capability.²⁹ The goal of Bariatric surgery is for the patient to lose more than half of his or her excess weight, so as to help reduce or prevent obesity-related health problems.²⁹

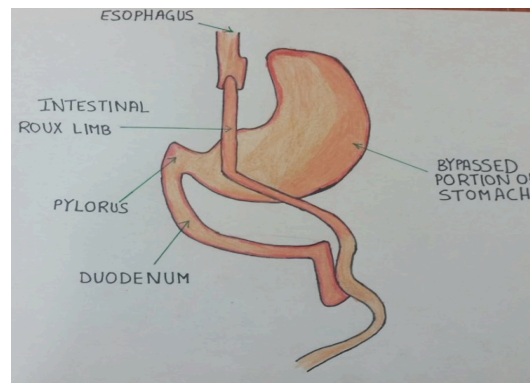


Figure 5: Gastric bypass procedure.³²

Brief description of surgeries:

Biliopancreatic diversion and duodenal switch

In biliopancreatic diversion with duodenal switch, part of the stomach is removed, but the pylorus remains intact. The pylorus controls the passage of food from the stomach to the small intestine. Canvassers connect the pylorus to the bottom of the small intestine, causing the food to bypass a large part of the small intestine. This results in a reduction in the number of calories absorbed, leading to weight loss.⁵²

Laparoscopic roux-en-y gastric bypass

In this procedure, the surgeon creates a small stomach pouch and attaches a section of the small intestine directly to the pouch. This allows food to bypass a portion of the small intestine.

Gastric bypass, Roux en-y (proximal)

This variant is the most commonly employed gastric bypass technique, and is by far the most commonly performed bariatric procedure in the United States.

The small intestine is divided approximately 45 cm (18 in) below the lower stomach outlet and is re-arranged into a Y-configuration, enabling outflow of food from the small upper stomach pouch via a "Roux limb."³²

Gastric bypass, roux en-y (distal)

The small intestine is normally 6–10 m (20–33 ft.) in length. As the Y-connection is moved further down the gastrointestinal tract, the amount available to fully absorb nutrients is progressively reduced, traded for greater effectiveness of the operation. The Y-connection is formed much closer to the lower (distal) end of the small intestine, usually 100–150 cm (39–59 in) from the lower end, causing reduced absorption (mal-absorption) of food, primarily of fats and starches, but also of various minerals and the fat-soluble vitamins.³²

Laparoscopic sleeve gastrectomy

The Laparoscopic Sleeve Gastrectomy is a bariatric procedure in which the surgeon removes approximately 85% of the stomach, shaping the remaining stomach into a tube or “sleeve.” It can be used as a first stage operation prior to a gastric bypass or as a definite procedure.³² During the sleeve gastrectomy procedure, a thin vertical sleeve of stomach is created using a stapling device. The sleeve is about the size of a banana. The rest of the stomach is removed.³²

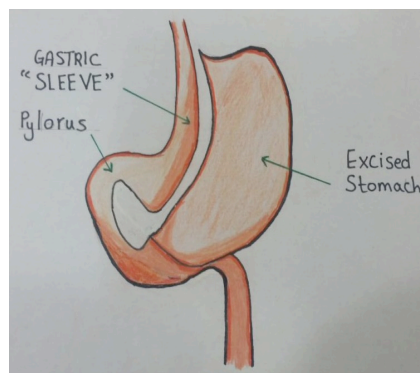


Figure (6): Sleeve gastrectomy.³²

Common health problem of overweight and obesity

Increased risk for the following conditions:

- Liver and gallbladder disease
- Type 2 Diabetes
- Dyslipidemia
- Hypertension
- Gynecological problems
- Coronary heart disease
- Respiratory problems
 - Hypothyroidism
- Osteoarthritis
- Stroke
- Cancers²⁹

1.1.4 Thyroid gland role in obesity

One of the problems that may contribute to obesity is hypothyroidism. It is important to examine how thyroid hormones influence metabolism and whether Bariatric Surgery, and especially Sleeve Gastrectomy, effect thyroid hormone activity.

Function of the thyroid gland

The function of the thyroid gland is to produce the thyroid hormones thyroxine (T4) and triiodothyronine (T3). Both T3 and T4 are made in the thyroid gland. To make thyroid hormones, thyroid cells incorporate stored iodine onto tyrosine amino acids on the protein thyroglobulin; three iodine molecules to make T3 and four to make T4. The thyroid gland is the principle physiologic storage site of iodine, and most dietary iodine is sequestered in this gland. The mature T3 and T4 are released from thyroglobulin and secreted by the thyroid gland, where they function systemically to control metabolism (conversion of oxygen and calories into energy).

A number of different conditions may cause the thyroid gland to become overactive, resulting in hyperthyroidism, or underactive, resulting in hypothyroidism. In hypothyroidism, there is a reduction in body energy, dry skin, joint pain, weight gain, and depression, while hyperthyroidism can lead to increases in heart rate, sleep disorders, and weight loss. Therefore, it is imperative that, thyroid hormone levels are checked prior to weight loss surgery, along with the levels of thyroid stimulating hormone (TSH), to determine the basal level of thyroid activity.^{55, 56}

1.2 Statement of the problem

1.2.1 Goals and objectives

The overall goal of the project is to identify the factors and costs associated with patients undergoing all types of Gastrectomy in terms of length of stay in the hospital and different types of clinical settings across the United States. Specifically the objectives are to determine:

- 1) What clinical factors (such as number and types of comorbidities and procedures) influence the costs and length of stay.
- 2) Whether costs and length of stay differ with race, age, or gender.
- 3) Whether there are differences in the costs and length of stay across the various regions of the US.
- 4) Whether there are differences in the costs and length of stay amongst the different types of hospital settings, rural/urban/hospital with and without teaching.

In the second phase of this project, I will conduct a prospective study to evaluate the following research questions:

1. Are there any changes in the patient's hemoglobin and Vitamins levels: B₁₂ and D?
2. Is there any change in thyroid hormone levels after the operation?

A similar study and data source will be available in Saudi Arabia, through King Khalid University Hospital, after receiving the Ethical Approval of IRB there.

1.2 Research purposes and hypotheses

Phase I Retrospective study of patients undergoing Sleeve Gastrectomy in the United States

A - Null Hypothesis 1 (H01): There are no statistically significant associations between the number and types of comorbidities and total discharge costs and length of stay for patients undergoing sleeve Gastrectomy procedures.

Alternative Hypothesis 1 (HA1): There are statistically significant associations between the number and types of comorbidities and total discharge costs and length of stay for patients undergoing sleeve Gastrectomy procedures.

B- Null Hypothesis 2 (H02): There are no statistically significant differences in costs, total discharge, and length of stay for Gastrectomy procedure patients with race, age, or gender.

Alternative Hypothesis 2 (HA2): There are statistically significant differences in costs, total discharge, and length of stay for Gastrectomy procedure patients with race, age, or gender.

C - Null Hypothesis 3 (H03): There are no statistically significant differences in the costs and length of stay for Gastrectomy procedure patients across the various regions of the US.

Alternative Hypothesis 3 (HA3): There are statistically significant differences in the costs, total discharge and length of stay for Sleeve Gastrectomy procedure patients across the various regions of the US.

D - Null Hypothesis 4 (H04): There are no statistically significant differences in the costs, total discharge, and length of stay for Sleeve Gastrectomy procedure patients amongst the different types of hospital settings.

Alternative Hypothesis 4 (HA4): There are statistically significant differences in the costs, total discharge, and length of stay for Sleeve Gastrectomy procedure patients amongst the different types of hospital settings.

Phase 2 Prospective study of patients undergoing Sleeve Gastrectomy in Saudi Arabia

2A. Null Hypothesis 1 (2H01): There is no statistically significant relationship between hemoglobin levels before Sleeve Gastrectomy and the **change in hemoglobin levels** after Sleeve Gastrectomy.

Alternative Hypothesis 1 (2HA1): There is a statistically significant relationship between hemoglobin levels before Sleeve Gastrectomy and the **change occurred in hemoglobin levels** after Sleeve Gastrectomy.

2B. Null Hypothesis 2 (2H02): There is no statistically significant relationship between vitamin B₁₂ level before Sleeve Gastrectomy and the **change occurred in vitamin B₁₂ level** after Sleeve Gastrectomy.

Alternative Hypothesis 2 (2HA2): There is a statistically significant relationship between vitamin B₁₂ levels before Sleeve Gastrectomy and the **change occurred in vitamin B₁₂ levels** after Sleeve Gastrectomy.

2C. Null Hypothesis 3 (2H03): There is no statistically significant relationship between vitamin D levels before Sleeve Gastrectomy and the **change occurred in vitamin D levels** after Sleeve Gastrectomy.

Alternative Hypothesis 3 (2HA3): There is a statistically significant relationship between vitamin D levels before Sleeve Gastrectomy and the **change occurred in vitamin D levels** after Sleeve Gastrectomy.

2D. Null Hypothesis 4 (2H04): There is no statistically significant relationship between thyroid hormone levels before Sleeve Gastrectomy and the **change occurred in thyroid hormones levels** after Sleeve Gastrectomy.

Alternative Hypothesis 4 (2HA4): There is statistically significant relationship between thyroid hormone levels before Sleeve Gastrectomy and a **change occurred in thyroid hormones levels** after Sleeve Gastrectomy.

1.4 Significance of study

This study is essential and important for a variety of reasons. Preeminent among these is the finding that most Sleeve Gastrectomy patients suffered from malnutrition after the operation, possibly leading to significant changes in hemoglobin levels and vitamin levels, such as vitamins B₁₂ and D.

There are many recent studies about Sleeve Gastrectomy. However, there is yet no study looking comprehensively at the cofactors and comorbidities that might influence the outcomes of the Sleeve Gastrectomy procedure. Further, in Saudi Arabia (already mentioned) there is no data collection on a large scale, which is made available for research purposes. Also it is not yet known how the nature of care as determined by hospitals (and their types), insurance availability, and types of insurances effect the outcomes. Thus, this research project proposes to evaluate the effects of demographics, hospital characteristics, and comorbidities (smoking, alcohol USge, diabetes and the like) on three outcomes: the length of stay, mortality, and total charges for the procedures. The methodology chapter will provide details on the data source employed for this research as well as the various analytical procedures to be used.

1.4.1 Relevance to Biomedical Informatics

This study is important to the field of Biomedical Informatics in that it specifically examines patient outcomes and health care delivery. The study will provide data on the variables that impact hospital resources with regard to quality, costs, and results; thereby, providing direction for future research. On a broader application, the study will help policymakers be better informed in their decisions on health policy in the future, and allow them to more accurately project budgets for the expenses of health care for high-risk populations. One of the reasons that most Sleeve Gastrectomy patients had malnutrition after the operation was because of significant change in hemoglobin level and vitamin levels for example in B₁₂ and D.

Many studies discuss the change in thyroid hormones levels after Sleeve Gastrectomy surgery. These studies deserve further follow up due to how thyroid hormones regulate metabolism, and thus may play a role in post-surgical deficiencies.

CHAPTER II: LITERATURE REVIEW

Sleeve Gastrectomy is currently popular as a “solution” for obesity, but research into the procedure’s long-term effects is scarce. A summary of some of those studies follows.

There was a cohort study involving 68 patients who had the Sleeve Gastrectomy (SG) surgery between August 2004 and December 2007. The findings indicated that, 5.9 years post-surgery, the procedure was effective, with 60% of patients experiencing excessive BMI loss.³⁶

There has also been development of a body of data with regard to patients who had SG between November 2004 and February 2012 from a population of 600 patients in small medical centers and a meta-analysis of other studies.³⁶

The data derived from these 600 patients revealed that, among other things, the mean operation time was 84 minutes, the rate of gastric leak was 2.5%, and the hospital stay time decreased from 4.9 days in 2004 to 4.3 in 2012. The rate of gastrointestinal hemorrhage decreased from 6.4% to 5.5%, and gastric fistula decreased from 4.6% to 1.9%.³⁶

Another study focused on whether there were any chronic leaks following surgery. Eight patients were studied for 16 months. These patients’ mean time from diagnosis to treatment was 14.4 months. The patients in the study underwent different procedures for part of the surgery: four patients underwent endoprosthesis, sealing glue was used in two patients, and two others were treated with a combination of the previous procedures. The mean healing time was 32 days.³⁵

Other researchers evaluated the incidence of gastroesophageal reflux (GERD) and hiatal hernia (HH) following the SG procedure in 378 patients; 25.6% of them preformed both SG and HH repair surgery. Of these, 15.8% had GERD and 11.1% had HH. Eighteen months post-surgery, a follow-up study of these patients found remission of GERD in 73.3%, while the remaining patients were able to minimize the effects of GERD by taking anti-reflux medications. GERD developed again in 22.9% of patients who underwent SG alone, compared to 0% of the patients who underwent SG and HH procedures together.³⁷ There are many studies comparing Laparoscopic Sleeve Gastrectomy and laparoscopic Roux-en-Y gastric bypass for treatment of obesity, as illustrated in Table 2.⁷⁰ Another comparison of the different outcomes in these two types of surgery is shown in Table 3.⁹

Table 2: Researcher comparison between sleeve gastrectomy (SG) and gastric bypass (GBP).⁷⁰

Procedure Names	<ul style="list-style-type: none"> ▪ Vertical Sleeve Gastrectomy (VSG) ▪ Laparoscopic Sleeve Gastrectomy: LSG ▪ Gastric Sleeve 	<ul style="list-style-type: none"> ▪ Gastric Bypass (GBP) ▪ Laparoscopic Roux-en-Y gastric bypass RYGBP ▪ Proximal gastric bypass ▪ Short limb gastric bypass
Procedure Type	▪ Restrictive	▪ Combination
Availability in the Hospitals	Broadly available	Broadly available
Mechanism of action	Limits amount of food that can enter stomach. Reduces ghrelin hormone level.	Decreases size of stomach. Alters flow of nutrients, which causes early satiety. Reduces ghrelin level.
Typical % of Excess Weight Loss at 5 Years	50-60% Limited long term data available	55-70%
Relief of Comorbid Conditions	Good to very good	Very good, better than LAGB, VSG for diabetes
Advantages of the Procedures	No alteration in metabolism of ingested foods. Low operative risk.	Very good balance of weight loss, metabolic side effects, and surgical risk
Ease of Reversibility	90% of stomach removed. Cannot be reversed. Can be converted to gastric bypass.	Moderate to difficult, but can be reversed to normal anatomy and function
Surgical Risk	Low to moderate	Moderate
Disadvantages of the Procedures	May not provide adequate weight loss, especially for people who persist in snacking and/or eating sweets. Sleeve may dilate and lose restrictive effect. Reflux may develop later.	Effectiveness limited if patient snacks. Decreased iron and potential decreased B ₁₂ and calcium absorption. Dumping syndrome.
Supplements after the Operation	Multivitamins, Iron, B ₁₂	Multivitamins, Iron, calcium, B ₁₂

Table 3: Comparison of two bariatric surgery outcomes.⁹

	LVSG	LRYGB	LAGB	LBDP
	Vertical Laparoscopic Sleeve Gastrectomy	Laparoscopic Roux-en-Y Gastric Bypass	Laparoscopic Adjustable Gastric Band	Laparoscopic Bilio Pancreatic Diversion
Mortality (%)	0.4	0.5	0.1	1.1
Complications Early/Late (%)	7 / 24	7 / 15	2/60	
Excess Weight Loss (%)	47	62	47	70
Diabetes Resolved (%)	66	83	47	99
Hypertension Resolved (%)	-	67	43	83
Cholesterol Improved (%)	-	95	78	87
Obstructive Sleep Apnea Resolved (%)	-	80	95	92
Long-term Failure (< 50% Excess Weight Loss)	30	15	> 50	<5

A case-control study design was used to gather data in a 2011 study conducted by the Department of Minimally Invasive and Digestive Surgery, Centre Hospitalier Intercommunal, Poesy-Saint-Germaine, Poissy, France. The outcome of this study described Laparoscopic Sleeve Gastrectomy (LSG) as the operation of choice for the treatment of morbid obesity or obesity in Type II Diabetes Mellitus (DM).¹

This retrospective study was based on comparing the weight loss, resolution of co-morbidities, and complications of both SG and Roux-en-Y Gastric by Pass (RYGB) using a case-control study design. The study group consisted of 200 patients who had undergone SG or RYGB from January 2005 to March 2008. The patients were matched in age, gender, and body mass index. Patient evaluations at 6, 12, and 18 months postoperatively found the same mortality rates in both groups, but morbidity was greater in the RYGB group (20.5%) than in the SG group (6.5%). On the other hand, the resolution of Type 2 Diabetes was better in the RYGB group. The percentages of weight loss at 6, 12, and 18 months, as well as the resolution of non-diabetes co-morbidities were comparable in both groups. The study also found a greater short-term morbidity rate and better diabetes control within the RYGB population.¹ While this study presents interesting and useful data, additional research needs to be conducted.

In 2012, another case-control study was conducted, this time at the Department of Digestive Surgery, Hospital Clínico, Pontificia Universidad Católica de Chile, Santiago, Chile. Comparisons were made of data from 811 LSG patients and 786 Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) patients, from data derived at the beginning of the study, January 2006, and during a three year follow-up of 811 patients in September 2009. These patients were matched by age, body mass index, and gender. Complication

rate, mortality, and percentage of weight loss were analyzed after 1, 2, and 3 years. The findings agreed with the 2011 Poissy, France outcome; these researchers considered SG to be the primary bariatric procedure for obesity. ³ Table (4).

Table 4: January 2006 - September 2009: comparison of 811 patients those who had SG with 786 patients who had RYGB.³

	<i>LRYGB</i> Roux-en-Y Gastric Bypass	<i>GS</i> Sleeve Gastrectomy
Mean age	37.0 ± 10.3 Years	36.4 ± 11.7 years
Gender	76.6%female	76.2% female
Mean operative time	106.2 ± 33.2 minutes	76.6 ± 28.0 min
<i>Preoperative BMI</i>	38.0 ± 3.2 kg/m	37.9 ± 4.6 kg/m
<i>Median length of hospital stay</i>	3.4 ± 4.4 days.	2.8 ± .8 days
<i>Early complication rate</i>	7.1%	2.9%
<i>Weight loss after 12 months</i>	97.2% ± 24.3%	86.4% ± 26.4%
<i>Weight loss after 24 months</i>	94.6% ± 30.2%	84.1% ± 28.3%
<i>Weight loss after 36months</i>	93.1% ± 25.0%	86.8% ± 27.1%
Total cholesterol level at 1 year	169.0 ± 32.9mg/dl	193.6 ± 38.7 mg/dl.
Rate of diabetes remission	86.6%	90.9%

Table 5: 23 non-diabetic obese patients, 12 of who were randomly assigned to undergo LRYGB, and 11 were randomly assigned to undergo GS.⁴

	<i>LRYGB</i> Laparoscopic Roux-en-Y Gastric Bypass	<i>GS</i> Sleeve Gastrectomy
Number of Patients	12	11
Lipid Profiles	Normal	Normal
<i>Weight loss after 2 months</i>	16.4% ± 1.3%,	13.1% ± 1.1%
<i>Weight loss after 6 months</i>	24.8% ± 1.7%	20.7% ± 1.5%
<i>Weight loss after 12 months</i>	34.5% ± 2.7%	27.9% ± 2.6%
Concentrations of Circulating Leptin Levels (from 1 week until 12 months postoperatively)	50%	50%
Fibroblast Growth Factor-21 levels	No change	No change
Adiponectin	Increased progressively	Increased progressively
<i>Net result between LRYGB and LSG groups</i>	No difference	No difference

A 2011 study investigated the two surgical procedures, to determine the effect, if any, on the adipokines and metabolic parameters after weight loss. This was a prospective randomized trial with 1-year follow-up. The study compared the 1-year follow-up results of LRYGB and LSG with regard to weight loss, metabolic control, and fasting adipokines levels. This study proved that there was a rapid improvement in insulin sensitivity even before weight loss. ⁴

Twenty-three non-diabetic obese patients were selected to participate. The researchers randomly distributed 12 of them to undergo LRYGB, and 11 to undergo GS. The patients were supervised before and at 2, 6, and 12 months after surgery. At each stage, measurements were taken of the fasting levels of glucose, insulin, lipids, and adipokines (leptin, adiponectin, and fibroblast growth factor-21).⁴ Table 5.

The two surgical procedures produced similar results with respect to the measured factors. However, it was observed that serum leptin levels decreased and adiponectin increased with weight loss; there was also significant improvement in insulin sensitivity.⁴

Another study was conducted at the Department of General Transplant and Liver Surgery, Medical University of Warsaw, IN. It was a prospective randomized clinical trial in the Polish population as shown in Table 6.¹¹ It is considered the first prospective randomized trial comparing LSG and RYGB in the Polish population. Its results demonstrated the safety and effectiveness procedures accompanying both operations, LSG and RYGB. They compare two groups that of 36 patients who underwent RYGB and 36 patients who underwent GS who were similar in age, gender, body mass index (BMI) and comorbidities. They analyzed the two groups prior to the procedures, and after 6 and 12 months. They measured the percentage of weight loss, and decreases in BMI, morbidity, mortality, reoperations, comorbidities and nutritional deficiencies.¹¹

Table 6: comparison of two groups of 36 patients who underwent RYGB and 36 patients who underwent GS.¹¹

	<i>RYGB</i> Roux-en-Y Gastric Bypass	<i>LSG</i> Laparoscopic Sleeve Gastrectomy
Weight loss	Significant	Significant
Mortality	0%	8.3%
Reoperations	0	2
Comorbidities	No difference	No difference
Nutritional deficiencies	No difference	No difference
Minor complication	16.6%	10.1%
% EWL in 12 months	64.2%	67.6%

They concluded no difference in weight loss for both groups at 6 and 12 months after surgery. They found the two surgeries were safe techniques with no significant difference in minor and major complication rates at 6 and 12 months .¹¹

Research done by Department of Surgery, Kaiser Permanente South Bay Medical Center, Harbor City, California, US and published in 2012.¹² This research compared the outcomes of 192 patients who had SG and 345 patient who had RYGB in-patient procedures between 2007 and 2009.

That study was a retrospective chart review performed for patients who underwent LRYGB or LSG between 2007 and 2009 at an HMO hospital. Data points collected are included in the Table 7. Outcomes measured include excess weight loss, resolution of comorbidities, postoperative complications, and mortality. After one year, Sleeve Gastrectomy showed slightly greater weight loss than RYGB, but no difference in safety.¹²

Table 7: Retrospective chart review performed for patients who underwent laparoscopic RYGB or LSG between 2007 and 2009 at an HMO hospital.¹²

	<i>RYGB</i> Roux-en-Y Gastric Bypass	<i>LSG</i> Laparoscopic Sleeve Gastrectomy
Age	46 Years	48 Years
Completion of a Preoperative Weight Loss Program	93%	90%
BMI	47	43
Presence of Diabetes Mellitus	32% of patients	22% of patients
Median Length of Hospital Stay	3 days.	
Complication Rate	9 per cent.	
Incidence of Gastric Leak	1 %	
Cases of Mortality	1	0
Postoperative Resolution of HTN	48%	34%
Gastro Esophageal Reflux Disease	73%	34%
Weight Loss after 12 Months	61%	72%

Research conducted by the Department of Surgery, Faculty of Medicine, Hospital Universitario de Caracas, Universidad Central de Venezuela and Caracas, Venezuela in 2011 was a prospective study comparing the outcomes after LSG or RYGB for one year in

117 patients from January 2008 to December 2008. Seventy five patients underwent RYGB and 42 underwent SG.¹³

This study prospectively compared both techniques in order to establish whether there is any superiority of one over the other based on morbidity and effectiveness. It found that both techniques are comparable regarding safety and effectiveness, so not one procedure is clearly superior to the other.¹³

Table 8: comparison of 117 patients from January 2008 to December 2008.¹³

	<i>RYGB Roux-en-Y Gastric Bypass</i>	<i>LSG Laparoscopic Sleeve Gastrectomy</i>
Number of Patients	75	42
Mean Operative Time	98 min	82 min
Average Excess Weight Loss	86%	78.8%

They conclude that the weight loss was 86% in RYGB and 78.8% in SG. So, these two operations had the same safety and effectiveness, as shown in Table 8.¹³

Most of the research did not find any difference between the two operations in weight loss, safety, and mortality. The two operations give a high percentage in weight loss that is dependent on the patients' situations. Both operations show remission in glucose rates after two to ten years. Table 9. The RYGB seemed to be more suitable for diabetic patients (Table 10), while SG fitted more with HTN and cardiac patients. More studies need to be done, and followed up on, for at least 10 years to notice the quality of life that patients are experiencing after operation.

Table 9: Two- and 10-year diabetes incidence and remission* rates from the Swedish Obese Subjects Study.³¹

	Surgical	Control
2-year Incident	1%	8%
10-year Incident	8%	24%
2-year Remission	72%	21%
10-year Remission	36%	13%

*Remission based on fasting plasma glucose < 7.0 mmol/l and not on hypoglycemic therapy.³¹

Table 10: Result of diabetic control after bariatric surgery in different studies.¹⁴

Authors	Year	No. of Patients	Procedure(s)	Follow-up (Years)	Outcome Resolution of Diabetes, %
Pories et al.	1995	121	RYGB	14	83
Buchwald et al.	2004	205,989,288	LAGB,RYGB,BPD	13	48,84,98
Sarson et al.	1981	191	RYGB	20	83
Sjostrom et al.	2004	342	RYGB, LAGB	2	72
Torquati et al.	2005	117	RYGB	30	74
Sugerman et al.	1989	1025	RYGB	2	83
Scopinaro et al.	2008	443	BPD	20	91
Dixon O'Brien et al.	2002	50	LAGB	2	64
Ponce et al.	2004	53	LAGB	2	80
Cottam et al.	2006	126	SG	1	81
Silecchia et al.	2006	44	SG	1.9	76
Buchwald et al.	2009	135,246	LAGB,RYGB,BPD	2	57,80,95

Procedures: LAGB (Laparoscopic Adjustable Gastric Band), BPD (Laparoscopic Biliopancreatic Diversion), RYGB (Roux-en-Y gastric bypass), SG (Sleeve Gastrectomy).

Some of the researchers focused on the side effects of the SG operation in half and long term. They followed up on the information of 53 patients in 3 to 6 years post operation from November 2001 and October 2002. Eleven patients received duodenal switches and two patients re-sleeved again after the 3rd year because they regained their weight. Forty one patients had 50% weight loss after the 6th year, and 21% suffered from esophageal reflux.³⁹

A group of researchers tried to find out if there is an improvement of levothyroxine (LT4) absorption after bariatric surgery. They measured blood samples before and at 35 days after surgery for 32 patients with non-hypothyroid; 10 patients underwent SG, 7 patients underwent Roux-en-Y Gastric Bypass, and 15 patients underwent Biliopancreatic Diversion (BPD). They discovered that LT4 absorption after SG and BPD are improved, so they concluded that the stomach and the duodenum were not the primary site of absorption for LT4 because they are bypassed in those operations.⁴⁰

Alagna et al studied the relationship between Leptin level, which is increased in obese patients, and thyroid function (TSH, LT4 and LT3) in 38 patients before the operation and again after 12 months. They concluded that there was no change in TSH and LT4, but found a decrease in LT3 and Leptin level, though they found no relevant relation between thyroid functions and leptin level.⁴¹

Other complications studied after bariatric surgeries were Dumping Syndrome, vitamin deficiencies, and Gastro-esophageal reflux disease (GERD). All patients who underwent SG and RYGB had Dumping Syndrome after procedures, but in GERD it increased after SG and improved after RYGB.⁴⁶

The patients in these studies were saved from malabsorption and vitamin deficiencies.⁴⁶ To measure the vitamin B absorption after bariatric surgery, researchers studied 22 women; 11 of them underwent SG and the other 11 underwent RYGB. They measured the vitamin B concentration after operation and after 3 months of vitamin B intake. They concluded that the amount of energy dropped 64%. Providing vitamin B supplements for 3 months resulted in an increase of 48% of vitamin B₁₂ in the blood, a modest increase of folic acid, and no reduction of blood concentrations of thiamine. Further investigation is required to justify long-term effects of the rapid rise in B₁₂ levels due to the high percentage of supplements.⁴⁵

Researchers also examined possible causes of malnutrition after SG procedures. The stomach, through mechanical and chemical processes, has a unique role in the food processing and bioavailability. Anemia was associated with gastrectomy. The reduction of the secretions of hydrochloric acid is an essential factor leading to decreased iron absorption so it is believed that this also caused the B₁₂ decrease. Weight loss and anemia can be the results of malnutrition in protein and energy often found in these patients who have severe malnutrition depending on the type of surgery, and the length of post-operative care and food received, accordingly, the supervision of nutritional care was strongly recommended.⁴³

Researchers measured the iron, vitamin B₁₂, folate and calcium levels annually for 26 patients who underwent SG. They found that 44% showed normal results, but that 17.5% showed abnormalities. They proposed a policy for annual follow-up.⁴²

Researchers found, by studying 42 patients, that their mean BMI decreased after 9-15 months post-operation. All patients were cured from diabetes mellitus and hypertension, except one patient. Five patients were cured from sleep apnea and asthma. But 5 of 6 thyroid patients showed imbalance e. The found that SG patients showed different improvements in weight loss, DM, hypertension and thyroid functions .⁴⁷

In 2010, a group of researchers at the Louisiana State University School of Medicine led by Ashish Nath studied the first 100 patients that underwent SG. Their data was collected from 3 months to 6 months after operation. They found that the percent of weight loss increased from 34.2% in 3 months to 49.1% in 6 months. The patients with hypertension had a cure rate of 38%, hyperlipidemia patients had a 19% cure rate, and those with diabetes were cured by 46%. They found some complications which included bleeding, acute renal failure, and bleeding at a gastric fistula; though these complications were very limited in number. The net result of the study indicated that SG is safe with few complications.⁷

The Intercontinental Society of Natural Orifice, Endoscopic and Laparoscopic Surgery (I-NOELS) published a research comparison of Gastric Bypass and Sleeve Gastrectomy as solutions to obesity and Type 2 DM. A retrospective study was done for 200 patients from January 2005 through March 2008. They compared both groups at 6 months, 1 year and 18 months. The complications were greater in RYGB (20.5%) than SG (6.5%), but the remission of diabetes was better in the RYGB group.⁶ Finally, the morbidity rate for SG was lower, but better when in diabetic's control for RYGB.⁶

A meta-analysis showed the differences in LRYGB and LSG in resolving Diabetes Mellitus. The study included 2758 patients, calculated their excessive weight loss, and the resolution of hypertension and diabetes mellitus noted over 12 months. The conclusion was that LRYGB had better resolution of diabetic mellitus and hypertension, but more studies will be needed.¹⁵

Other research compared Sleeve Gastrectomy and Roux-en-Y Gastric Bypass with regard to late complications; hypoglycemia occurred in 72% of patients who underwent RYGB, but was rarer in SG patients.¹⁷

A study by Scott and Batterham compared the improvement of Type2 Diabetes (T2D) after the two operations. However, weight loss and resolution of T2D after surgery is heterogeneous and specific to the type of procedure performed by obesity. Traditional mechanisms, such as malabsorption in the intestines and stomach restriction, do not completely explain this. Strong changes in appetite, as a result of re-organization and anatomical neural hormone changes, are the cause of promise. .¹⁹

Benaiges et al studied both surgeries and the resolution of morbidity diseases in cardiovascular risk (CVR) in Spanish populations. They didn't find any difference between RYGB and LSG in the resolution of T2D and hypertension except in hypercholesterolemia resolution. The LSG gave lower effect, but there was still no difference between the two operations in CVR after 1 year follow up.²⁰ Another researcher compared 12 patients who underwent RYGB and 10 patients who underwent LSG. In this study, patients undergoing RYGBP were limited, but gained much lower BMIs, and improved lipid profiles. In addition, low-grade inflammation and metabolic syndrome decreased with LSG in one year follow-ups.²¹

A lot of studies talked about the remission of T2D after RYGB, but there were no significant results after LSG.

de Gordejuela and others decided to compare the remission of T2D after those two operations. They performed a retrospective study in 90 patients (30 SG and 60 RYGB). The result showed no significant changes between the two operations in weight loss or with T2D remission after 2 years of follow up.²²

CHAPTER III: METHODOLOGY

This chapter will present the methodology used for the study. It will include the following: study design, sample size and data analysis methods.

3.1. First phases of study

3.1.1 Nationwide inpatient sample data

The sample data consist of inpatient hospital stay files from the HCUP (Healthcare Cost and Utilization Project), Nationwide Inpatient Sample (NIS). Research and policymakers use NIS data to identify, track and analyze trends in health care utilization, access, charges, quality and outcome. The NIS is nationally representative of all community hospitals (i.e. short-term, non-federal, non-rehabilitation hospitals). The NIS is a sample of hospitals and includes all patients from each hospital, regardless of payer—including the uninsured. It is drawn from a sampling frame that contains hospitals comprising about 95 percent of all discharges in the United States. The NIS includes more than 100 clinical and nonclinical data elements for each hospital stay.

Table 11: Data Variables Used for Analysis.

Study Variables	Original Variable Name in the NIS Data Set	Variable Description
AGE	AGE	Age in years, Numerical Variable
GENDER	FEMALE	Gender of patient FEMALE = 1 is Male; FEMALE=0 is female, Categorical (binary) Variable
TOTAL CHARGE	TOTCHG	Total charges , Numerical Variable
RACE	RACE	1 = White, 2 = Black, 3 = Hispanic, 4 = Asian/Pacific, 5 = Native Am., 6 = Other, Categorical Variable
INSURANCE TYPE	PAY1	1=Medicare, 2=Medicaid, 3=Private insurance, 4=Self-pay, 5=No charge, 6=Other, Categorical Variable
NUMBER OF PROCEDURES	NPR	The number of procedures performed while patient was hospitalized, Numerical Variable
TOTAL HOSPITAL CHARGES	TOTAL_DISC	5(n) Total hospital discharges, Numerical Variable
COMORBIDITIES	CM_ANEMDEF, CM_HYPOTHY, CM_OBESE, CM_DM, CM_HTN	Comorbidities (Anemia, obesity, Hypothyroidism, diabetes, hypertension), Categorical (binary) Variables
LENGTH OF STAY	LOS	The number of days patient was hospitalized, Numerical Variable
NUMBER OF DIAGNOSES	NDX	The number of diagnoses on the patient record, Numerical Variable
HOSPITAL REGION	HOSP_REGION	Four regions are included Northeast = 1, Midwest =2, South = 3, west =4 , Categorical Variable
LOCATION/TEACHING STATUS OF HOSPITAL	HOSP_LOCTEACH	1=Rural, 2=Urban nonteaching, 3=Urban teaching, Categorical Variable

Table 12: Study Hypotheses and Corresponding Statistical Tests

Research Question	Hypothesis	Independent Variables	Outcome Variables	Inferential Analyses	Descriptive Analyses & Predictive Models
Do Types of Comorbidities & Number of Procedures Significantly Affect LOS, TOTCHG & TOTAL_DISC?	Hypothesis 1	CM_ANEMDEF, CM_HYPOTHY, CM_OBESE, CM_DM, CM_HTN	LOS, TOTCHG, TOTAL_DISC	ANOVA (LOS vs CM_DM, vs CM_HTN, vs CM_OBESE, vs CM_ANEMDEF, vs CM_HYPOTHY) ANOVA (TOTCHG vs CM_DM, vs CM_HTN, vs CM_OBESE vs CM_ANEMDEF, vs CM_HYPOTHY) CHI-SQ (TOTAL_DISC vs CM_DM, vs CM_HTN, vs CM_OBESE, vs CM_ANEMDEF, vs CM_HYPOTHY)	Means & SDs for LOS, TOTCHG and TOTAL DISC

Research Question	Hypothesis	Independent Variables	Outcome Variables	Inferential Analyses	Descriptive Analyses & Predictive Models
Do Race, Age & Gender Significantly Affect LOS, TOTCHG & TOTAL_DISC?	Hypothesis2	RACE, GENDER, AGE	LOS, TOTCHG, TOTAL_DISC	ANOVA (LOS vs RACE, LOS vs AGE, LOS vs GENDER) ANOVA (TOTCHG vs RACE, TOTCHG vs AGE, TOTCHG vs GENDER) CHI-SQ (TOTAL_DISC vs RACE, DIED vs GENDER, TOTAL_DISC vs AGE)	Frequency Distributions for TOTAL_DISC
Do LOS, TOTCHG & TOTAL_DISC Significantly Differ with the Geographical Regions?	Hypothesis3	REGION	LOS, TOTCHG, TOTAL_DISC	ANOVA (LOS vs REGION) ANOVA (TOTCHG vs REGION) CHI_SQ (TOTAL_DISC vs REGION)	Multiple Linear Regression for LOS, TOTAL_DISC and TOTCHG with respect to the Independent Variables
Do LOS, TOTCHG & TOTAL_DISC Significantly Differ with the Type of Hospital?	Hypothesis4	HOSPTYPE	LOS, TOTCHG, TOTAL_DISC	ANOVA (LOS vs HOSPTYPE) ANOVA (TOTCHG vs HOSPTYPE) CHI_SQ (TOTAL_DISC vs HOSPTYPE)	Logistic Regression for TOTAL_DISC with respect to the Independent Variables

3.1.2 Research Design & Method

In this project I plan to utilize the datasets obtained from the Nationwide Inpatient Sample (NIS) database towards the analyses of Laparoscopic Sleeve Gastrectomy patients. The NIS is the largest all-payer inpatient care database in the United States containing data from 2011 to 2013. It contains data from approximately 8 million hospital stays each year accruing from all discharge data from 1,050 hospitals located in 44 States, approximating a 20-percent stratified sample of U.S. community hospitals. The sampling frame for the 2012 NIS is a sample of hospitals that comprises approximately 95 percent of all hospital discharges in the United States. The NIS includes more than 100 clinical and nonclinical data elements for each hospital stay. These include:

- Primary and secondary diagnoses
- Primary and secondary procedures
- Admission and discharge status
- Patient demographics (e.g., gender, age, race)
- Expected payment source
- Total charges
- Length of stay
- Hospital characteristics (e.g., ownership, size, teaching status).

Furthermore, the NIS is the only national hospital database containing charge information on all patients, regardless of payer, including persons covered by Medicare, Medicaid, private insurance, and the uninsured.

I plan to acquire all NIS data for 2011 to 2013, and the Statistical Package for the Social Sciences, SPSS 22, will be employed to extract the datasets and perform the analyses. The figure below illustrates the conceptual model employed in this research project.

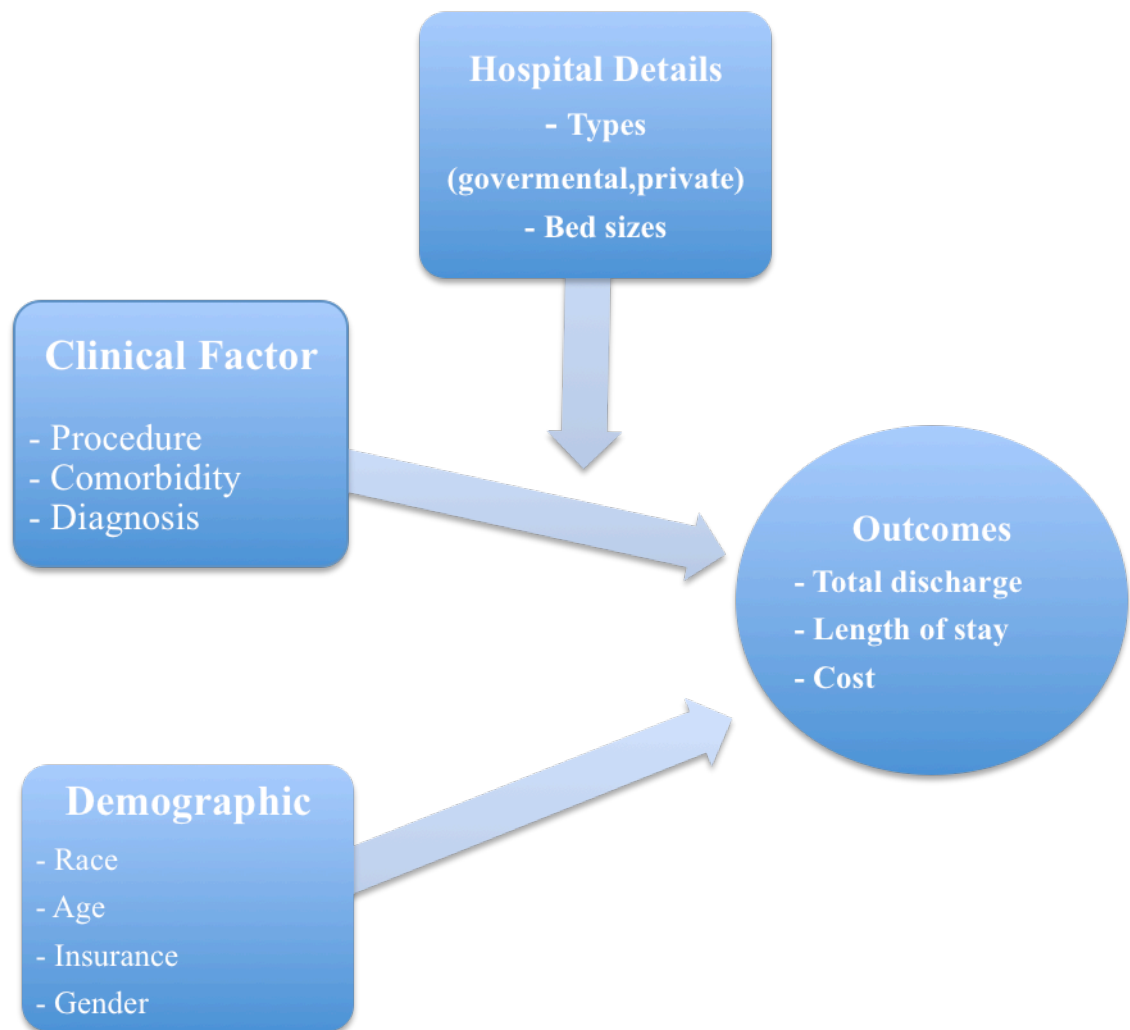


Figure 7: Conceptual model for identifying the factors determining total discharge, Length of Stay and Costs.

Essentially, Figure 7 shows the factors that are hypothesized to affect the research outcomes; the total discharge, length of stay, and the hospitalization costs for the Laparoscopic Sleeve Gastrectomy. These factors are categorized as being clinical: the type of diagnoses, the number and type of comorbidities, and the number of procedures; demographics: race and age of the patient; the type of insurance (Private, Medicare and the like); or hospital details: type of the hospital (teaching/non-teaching), its location in the US, and whether it is rural, metro or urban.

The outcomes of interest, as identified in this proposal, are the length of stay, and the costs involved. Using the datasets obtained from the NIS database, appropriate descriptive and inferential statistics (such as frequency distributions, chi-square analysis, and ANOVAs) will be effective. To relate the factors associated with the research outcome, a multiple linear regression model will be setup and validated. Predictive models such as logistic regression will be employed to determine the risks and ratios for the various factors influencing length of stay (LOS), total discharge cost, demographics, number and types of procedures, hospital types, regions and comorbidities.

3.1.3 Research Hypotheses of the first phase

A - Null Hypothesis 1 (H01): There are no statistically significant associations between the number and types of comorbidities and total discharge and costs and length of stay of patients undergoing sleeve Gastrectomy procedures.

Alternative Hypothesis 1 (HA1): There are statistically significant associations between the number and types of comorbidities and total discharge and costs and length of stay of patients undergoing sleeve Gastrectomy procedures.

B- Null Hypothesis 2 (H02): There are no statistically significant differences in costs, total discharge and length of stay of Gastrectomy procedures patients with race, age, or gender.

Alternative Hypothesis 2 (HA2): There are statistically significant differences in costs, total discharge and length of stay of Gastrectomy procedures patients with race, age, or gender.

C - Null Hypothesis 3 (H03): There are no statistically significant differences in the costs and length of stay of Gastrectomy procedures patients across the various regions of the US.

Alternative Hypothesis 3 (HA3): There are statistically significant differences in the costs, total discharge and length of stay of Sleeve Gastrectomy procedures patients across the various regions of the US.

D - Null Hypothesis 4 (H04): There are no statistically significant differences in the costs, total discharge and length of stay of sleeve Gastrectomy procedure patients amongst the different types of hospital settings.

Alternative Hypothesis 4 (HA4): There are statistically significant differences in the costs; total discharge and length of stay of sleeve Gastrectomy procedure patients amongst the different types of hospital settings.

3.2 Second phase of the study

3.2.1 Research design & methods

This phase of the study will follow a prospective, quantitative, correlational design. Prospective study is the study of a group of cases with similar independent factors concerning some other (dependent) factors, to judge whether these factors are affected or not. A quantitative correlational design is a systematic scientific investigation of data and their relationships.⁷⁹

For this study, the operations were made and the outcomes of interest occurred in 2014 or 2015.

Quantitative research indicates the relationships between variables.⁶² Using this study design will allow the researcher to find the relationship between variables in two different situations, namely, before the operation and after the operation, e.g. High Blood Pressure (HB), vitamin D, vitamin B₁₂, and Thyroid hormones.

3.2.2 Population and sample criteria

The focus of this study will be patients who underwent Sleeve Gastrectomy from 2014 till 2015, ages between 17 and 60, from King Khalid University Hospital, Riyadh, Saudi Arabia.

3.2.3 Data collection procedures

Inclusion criteria

- Age: 17-60
- Sex: both male and female
- BMI: ≥ 35 (class II and class III obese)
 - Clinical Recorded Data: **BMI** is determined for every case.
 - Preoperative Laboratory tests: To be done routinely for every case include:-
 - Hb. – Vitamin D. – Vitamin B₁₂. – Serum Iron level
 - TSH. – T₄.
 - Postoperative follow up: patients are asked to do some Laboratory tests six months after the operation
 - Hb. – Vitamin D. – Vitamin B₁₂.
 - TSH. – T₄.

3.2.4 Data analysis

All statistical analysis will be performed using the Statistical Package for Social Sciences SPSS 22. All inferential tests will be paired by t- test and will utilize a 95% significance level. By hypothesis testing, descriptive statistics for the study will be included.

I used paired t-test to determine if the patients' data before and after the SG were significantly different regarding four measures i.e. Serum Hb, Serum Vitamin D, Serum Vitamin B₁₂, TSH and T4.

When the patients exceeded a BMI of 35, he/she was scheduled for bariatric surgery, using either LSG or RYGB. The doctor discussed with each patient which operation would be done.

Before the operation, CBC had been done including Hemoglobin (Hb). Selected patients for SG sampled for serum vitamin D, B₁₂, T4 and TSH.

Six months later, patients are followed up by doing the following checking their Hb, Vitamin D, Vitamin B₁₂, T4 and TSH.

3.2.5 Ethical considerations

The Data Use Agreement in King Khalid University Hospital (KKUH) assured ethical considerations for the use of this data.

3.2.6 Research hypotheses/the second phase

This study is essential and important for a variety of reasons. Preeminent among these is the finding that most Sleeve Gastrectomy patients suffered from malnutrition after the operation, possibly leading to significant changes in hemoglobin levels and vitamin levels, such as vitamins B₁₂ and D.

A. Null Hypothesis 1 (H01): There is no statistically significant relationship between hemoglobin levels before Sleeve Gastrectomy and the **change in hemoglobin levels** after Sleeve Gastrectomy.

Alternative Hypothesis 1 (HA1): There is a statistically significant relationship between hemoglobin levels before Sleeve Gastrectomy and the **change occurred in hemoglobin levels** after Sleeve Gastrectomy.

B. Null Hypothesis 2 (H02): There is no statistically significant relationship between vitamin B₁₂ level before Sleeve Gastrectomy and the **change occurred in vitamin B₁₂ level** after Sleeve Gastrectomy.

Alternative Hypothesis 2 (HA2): There is statistically significant relationship between vitamin B₁₂ levels before Sleeve Gastrectomy and the **change occurred in vitamin B₁₂ levels** after Sleeve Gastrectomy.

C. Null Hypothesis 3 (H03): There is no statistically significant relationship between vitamin D levels before Sleeve Gastrectomy and the **change occurred in vitamin D levels** after Sleeve Gastrectomy.

Alternative Hypothesis 3 (HA3): There is statistically significant relationship between vitamin D levels before Sleeve Gastrectomy and the **change occurred in vitamin D levels** after Sleeve Gastrectomy.

D. Null Hypothesis 4 (H04): There is no statistically significant relationship between thyroid hormone levels before Sleeve Gastrectomy and the **change occurred in thyroid hormones levels** after Sleeve Gastrectomy.

Alternative Hypothesis 4 (HA4): There is statistically significant relationship between thyroid hormone levels before Sleeve Gastrectomy and a **change occurred in thyroid hormones levels** after Sleeve Gastrectomy.

CHAPTER IV: RESULTS AND DATA ANALYSIS

4.1 The result from NIH about US patients

The data from NIH from 2011 to 2013 regarding the different variables showed the following results: total number of discharges, rate of discharges per 100,000 persons, LOS in days, charges, routine discharge, discharge to another institution (nursing home, rehab) and home health care. All the previous aspects are shown in Table 13. All variables showed increases over the years, except for two, charges and LOS, which showed slight decreases between 2012 and 2013. The changes noted in the chart demonstrate the differences and similarities.

Table 13: the National Statistics of the lap vertical Sleeve Gastrectomy procedure outcomes from 2011 till 2013.

Sleeve gastrectomy procedure outcomes	2011	2012	2013
Total number of discharges	8070	45595	73105
LOS (length of stay), days (mean)	1.922	1.948	1.870
Charges, \$ (mean)	4175 8	43841	43433
Routine discharge	7898	44370	71345
Another institution (nursing home, rehab)	*	110	165
Home health care	*	1045	1540

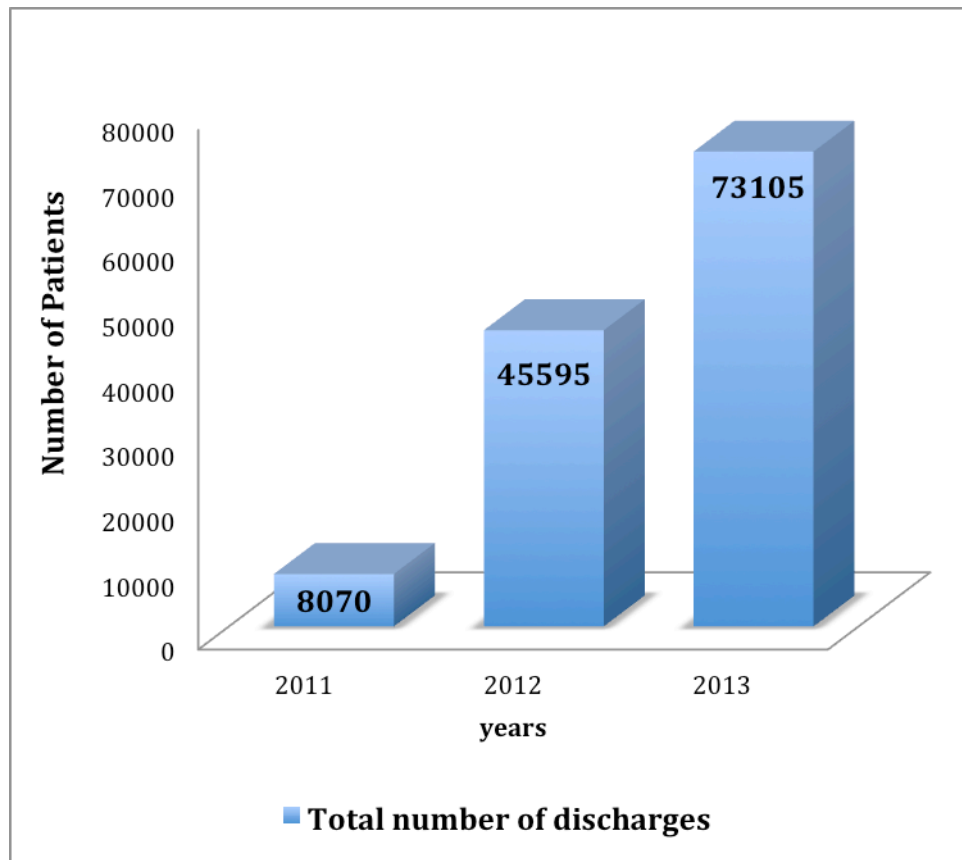


Figure 8: The total discharge patients who had lap vertical gastrectomy in the US From 2011 till 2013.

Figure 8 shows the comparison from 2011 to 2013, which determined that the total number of discharged patients over the years was increased from 8070 to 73105. This increase was parallel with an increase in the obesity percentage in the US which is shown in Figure 2.

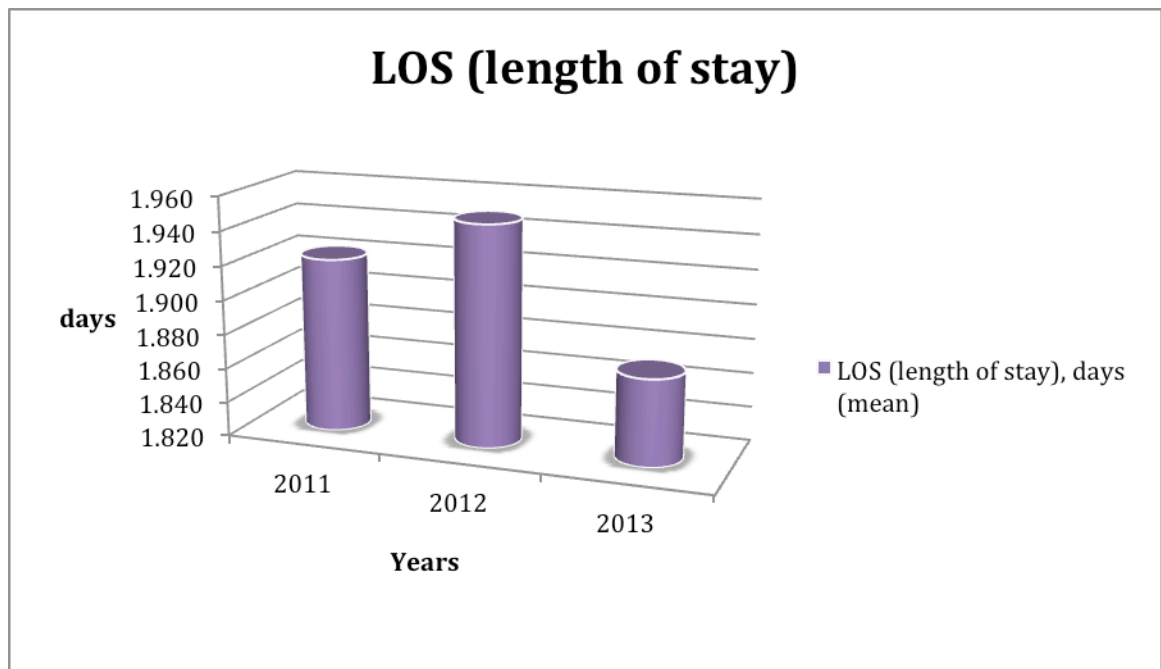


Figure 9: The length of stay by days in the hospitals after laparoscopic sleeve gastrectomy from 2011 till 2013.

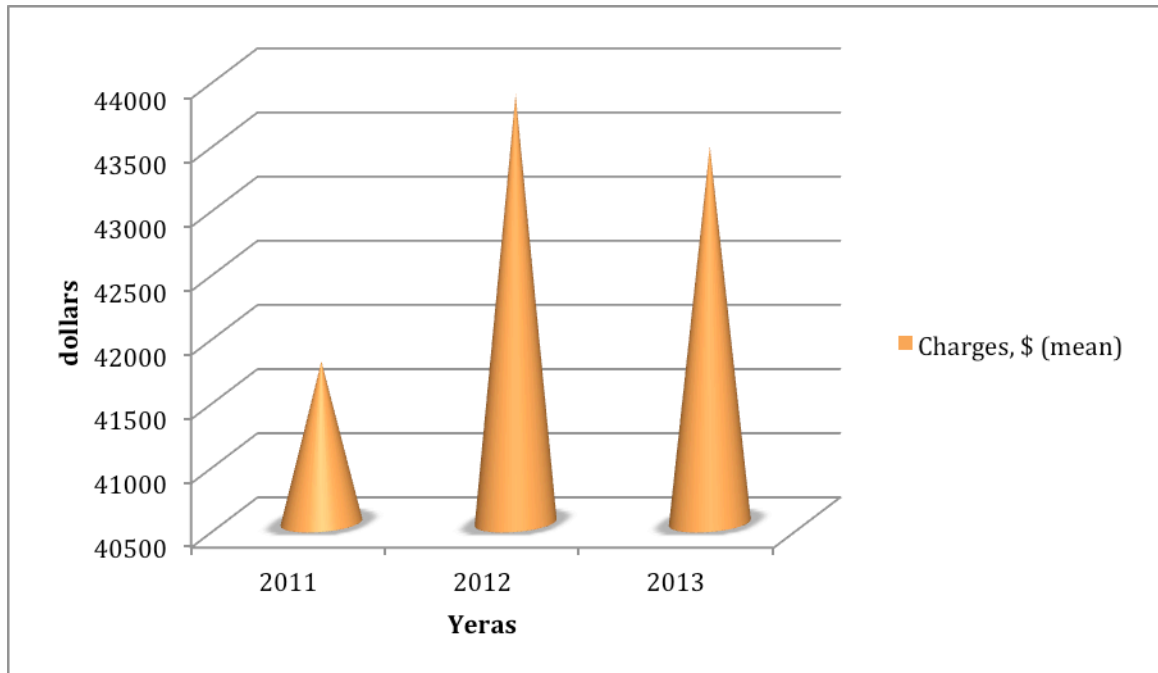


Figure 10:Charges of laproscopic sleeve gastrectomy in dollars from 2011 to 2013.

There was standard length of stay in the hospitals postoperatively, which was between 1 and 3 days. Figure 9 demonstrates the change of the length of stay in days from 2011 to 2013. There was a slight difference between 2011 and 2012, but there were notable changes in 2013 that decreased the mean LOS to 1.87 days (Table 13). The most probable and reasonable cause to explain this change in the LOS after the operation - rather than the increase of LSG candidates - was the change in the doctors having more experience and the presence of new techniques to the Laparoscopic procedure.

The cost of the operations varied from 2011 to 2013, from \$41,758 USD to \$43,841 USD, then the price dropped slightly by \$408 USD to \$43,433 USD. This may have been due to the hospitals' customized the expenses, length of stay, the patients' conditions, and the hospitals rating patients' health care quality as shown in Figure 10.

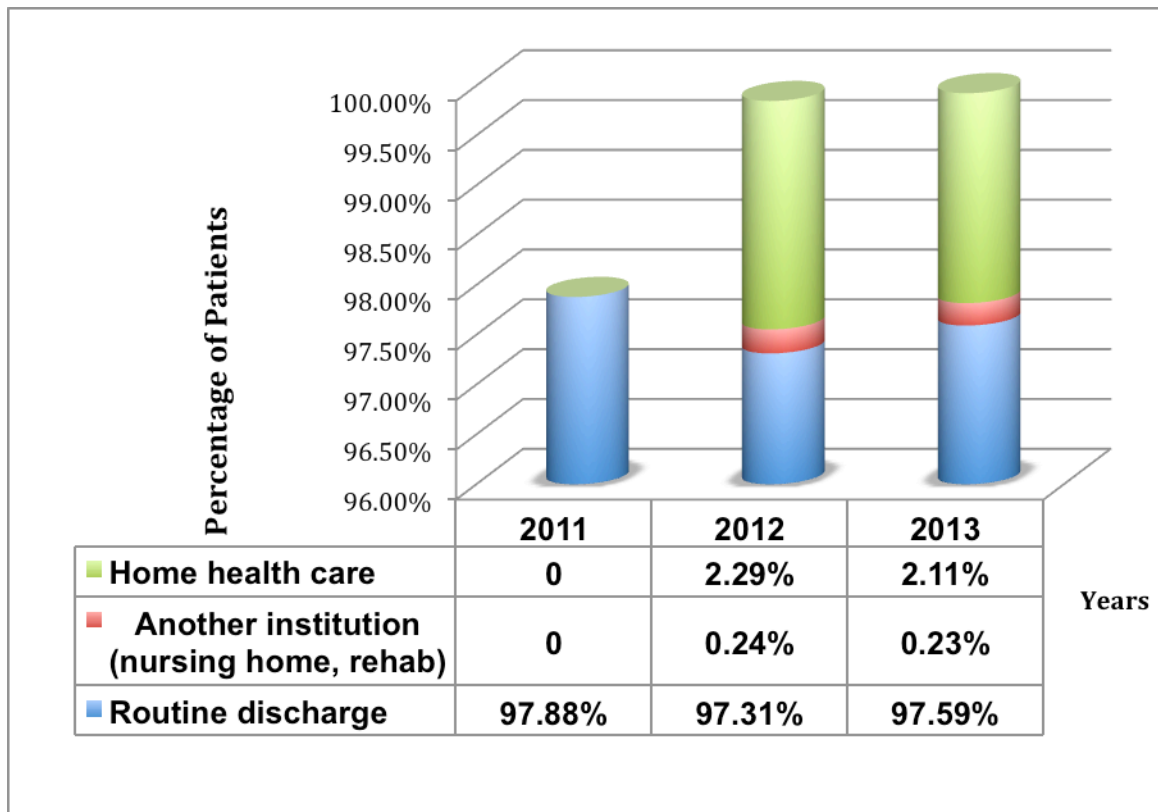


Figure 11: The other measured outcomes after laproscopic sleeve gastrectomy operation from 2011 to 2013.

The other measured outcomes that related to post LSG were if the patients needed or got home health care and were referred to other institutions like nursing homes and rehab centers. Figure 11 illustrates the difference from 2011 to 2013; home health care and other institutions weren't available in 2011 and appear in 2012 in low percentages (2.29% and 0.24%, respectively). In 2013, home health care decreases to 2.11%. With regard to routine discharge, it is noticed that the fluctuation in 2011 was high (97.88%) because there weren't any other health care systems available. It decreased after the appearance of the health care systems in 2012 by 0.57%, and increased again in 2013 by 0.28%.

TABLE 14: The number of patients who had the LSG and their first listed diagnosis (DX1).

ICD-9 CODE DESCRIPTION	ICD-9 CODE	NUMBER OF PATIENTS
MORBID OBESITY	278.01	8826
OTHER COMPLICATIONS OF GASTRIC BAND PROCEDURE	539.09	116
OBESITY UNSPECIFIED	278.00	67
DIAPHRAGMATIC HERNIA WITHOUT OBSTRUCTION OR GANGRENE	553.3	11
OTHER COMPLICATIONS OF OTHER BARIATRIC PROCEDURE	539.89	10
NEOPLASM OF UNCERTAIN BEHAVIOR OF CONNECTIVE AND OTHER SOFT TISSUE	238.1	8
DYSMETABOLIC SYNDROME X	277.7	6
MECHANICAL COMPLICATION OF OTHER IMPLANT AND INTERNAL DEVICE NOT ELSEWHERE CLASSIFIED	996.59	6
MALIGNANT NEOPLASM OF STOMACH UNSPECIFIED SITE	151.9	5
ESOPHAGEAL REFLUX	530.81	5
OTHER SPECIFIED DISORDERS OF STOMACH AND DUODENUM	537.89	5
OTHER DIGESTIVE SYSTEM COMPLICATIONS	997.49	5
MALIGNANT NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE OF ABDOMEN	171.5	4
CONDUCTIVE HEARING LOSS UNSPECIFIED	389	2
NEOPLASM OF UNSPECIFIED NATURE OF DIGESTIVE SYSTEM	239.0	2
DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED	250.00	2
OBESITY HYPOVENTILATION SYNDROME	278.03	2
ACQUIRED HYPERTROPHIC PYLORIC STENOSIS	537.0	2
INFECTION DUE TO GASTRIC BAND PROCEDURE	539.01	2
DYSPHAGIA, UNSPECIFIED	787.20	2
MALIGNANT NEOPLASM OF LOWER THIRD OF ESOPHAGUS	150.5	1
MALIGNANT NEOPLASM OF PYLORIC ANTRUM	151.2	1
MALIGNANT NEOPLASM OF GREATER CURVATURE OF STOMACH UNSPECIFIED	151.6	1
MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF STOMACH.	151.8	1
MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE DIGESTIVE ORGANS AND PERITONEUM	159.9	1
SECONDARY MALIGNANT NEOPLASM OF OTHER DIGESTIVE ORGANS AND SPLEEN	197.8	1
MALIGNANT CARCINOID TUMOR OF THE STOMACH	209.23	1

ICD-9 CODE DESCRIPTION	ICD-9 CODE	NUMBER OF PATIENTS
BENIGN NEOPLASM OF STOMACH	211.1	1
NEOPLASM OF UNCERTAIN BEHAVIOR OF STOMACH INTESTINES AND RECTUM	235.2	1
DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED	250.02	1
DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED	250.62	1
DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED	250.63	1
DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED	250.80	1
LOCALIZED ADIPOSITY	278.1	1
OBSTRUCTIVE SLEEP APNEA (ADULT) (PEDIATRIC)	327.23	1
OTHER ACUTE POSTOPERATIVE PAIN	338.18	1
OTHER SPECIFIED CARDIAC DYSRHYTHMIAS	427.89	1
REFLUX ESOPHAGITIS	530.11	1
PERFORATION OF ESOPHAGUS	530.4	1
DYSPEPSIA AND OTHER SPECIFIED DISORDERS OF FUNCTION OF STOMACH	536.8	1
FISTULA OF STOMACH OR DUODENUM	537.4	1
UMBILICAL HERNIA WITH OBSTRUCTION	552.1	1
INCISIONAL HERNIA WITHOUT OBSTRUCTION OR GANGRENE	553.21	1
PERITONEAL ADHESIONS (POSTOPERATIVE) (POSTINFECTION)	568.0	1
CALCULUS OF GALLBLADDER WITHOUT CHOLECYSTITIS WITHOUT OBSTRUCTION	574.20	1
OTHER AND UNSPECIFIED POSTSURGICAL NONABSORPTION	579.3	1
OTHER CHEST PAIN	786.59	1
NAUSEA WITH VOMITING	787.01	1
HEMATOMA COMPLICATING A PROCEDURE	998.12	1

Table 14 shows that there were 8893 patients who had the lap vertical sleeve gastrectomy primarily because of obesity. There were 126 patients who had the operation because they suffered from complications of other bariatric procedures.

Figure 12 shows that there were high percentage of patients (96.6%) who had the operation because of morbid obesity, and the rest (3.37%) were divided into different reasons, where morbid obesity was not the first choice.

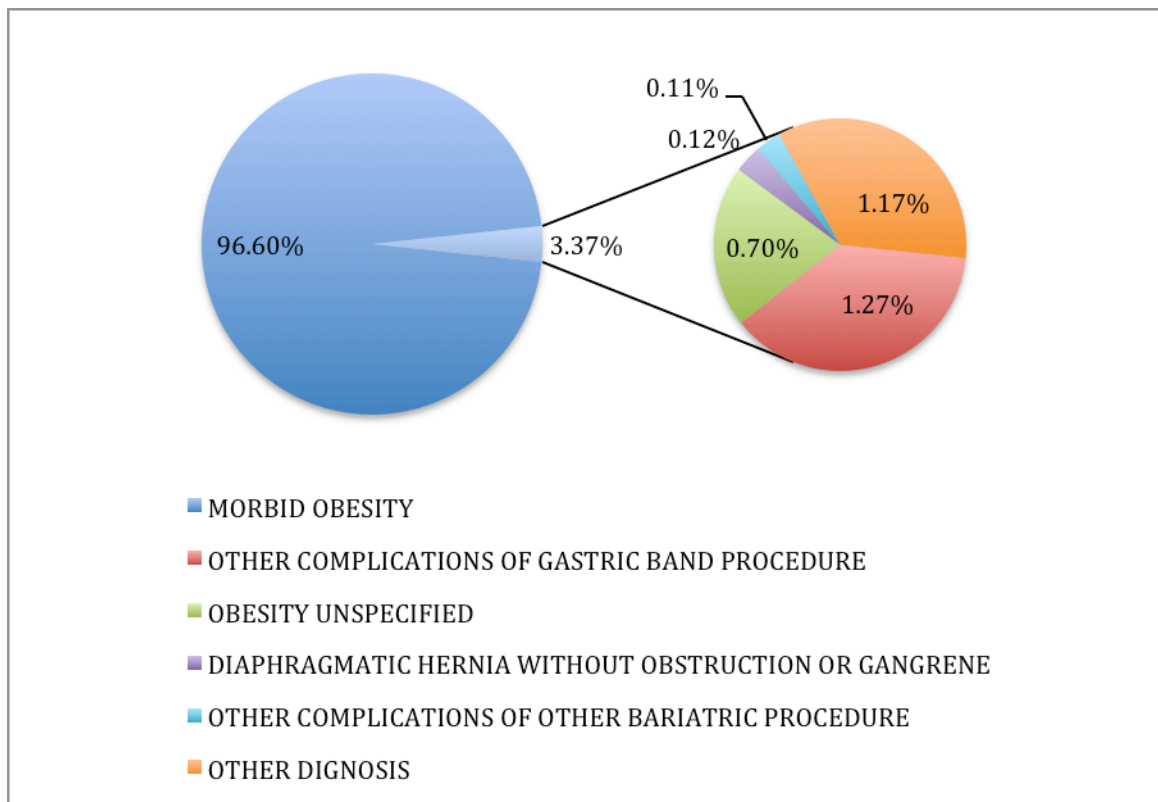


Figure 12: The number of patients who had the LSG (and the first listed diagnosis (DX1)).

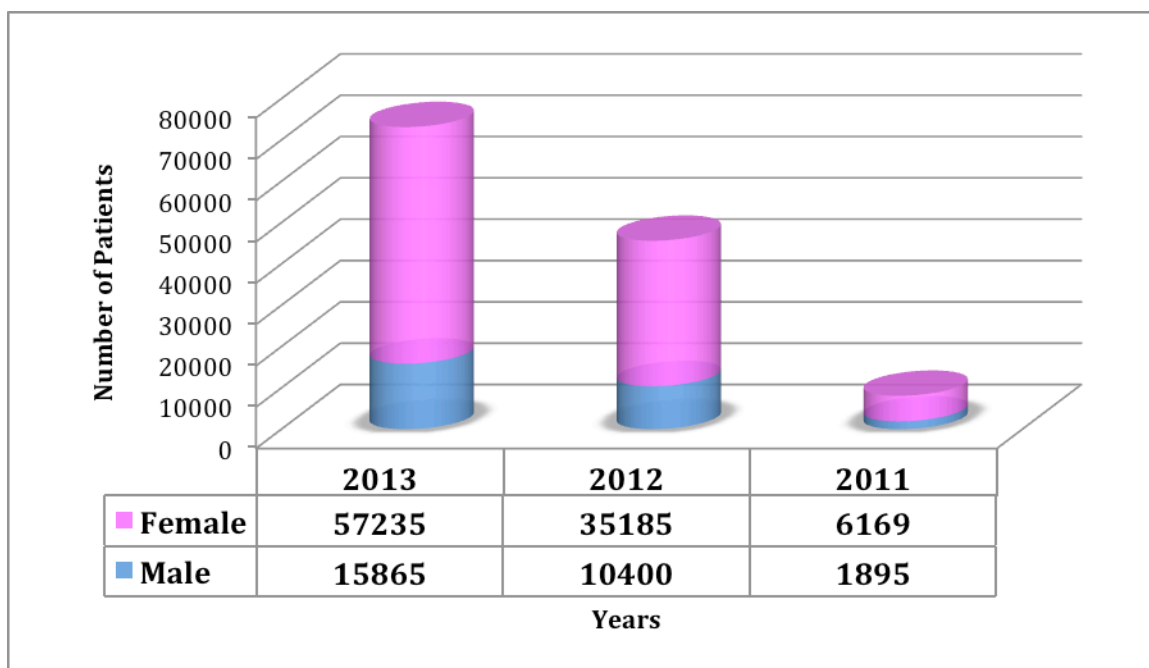


Figure 13: The number of patients depending on their sex from 2011 till 2013.

Table 15: Total Number of Discharged from Laparoscopic Vertical Gastrectomy shown by their sex in 2012.

		Total Number of Discharges
All Discharges		45595
Sex	Male	10400
	Female	35185

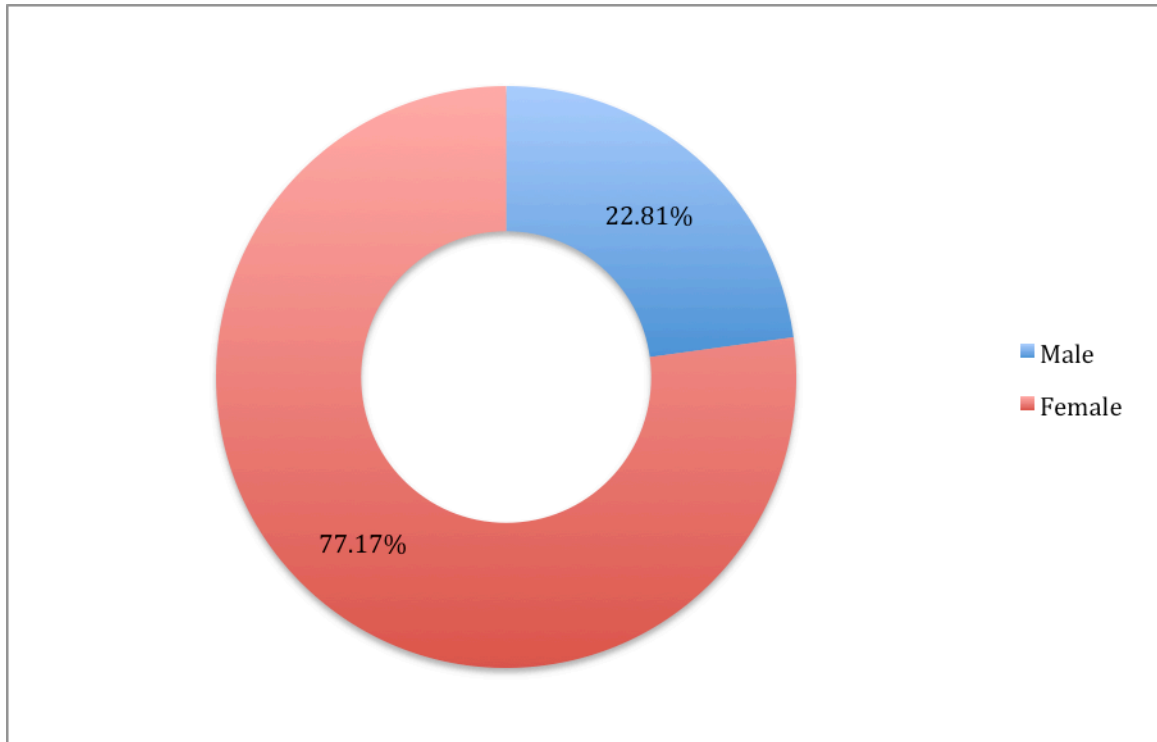


Figure 14: Total Number of discharged from lap vertical gastrectomy shown by their sex in 2012.

A larger number of females had Laparoscopic Sleeve Gastrectomy from 2011 till 2013, as mentioned in Figure 13. It is well noted that both female and male number of patients increased over the years.

In 2012, the number of females and males who elected to have the operation was 35,185 and 10,400; as shown in the Table 15. Women comprised 77.17% of the discharged patients and the men made up 22.81%. Figure 14.

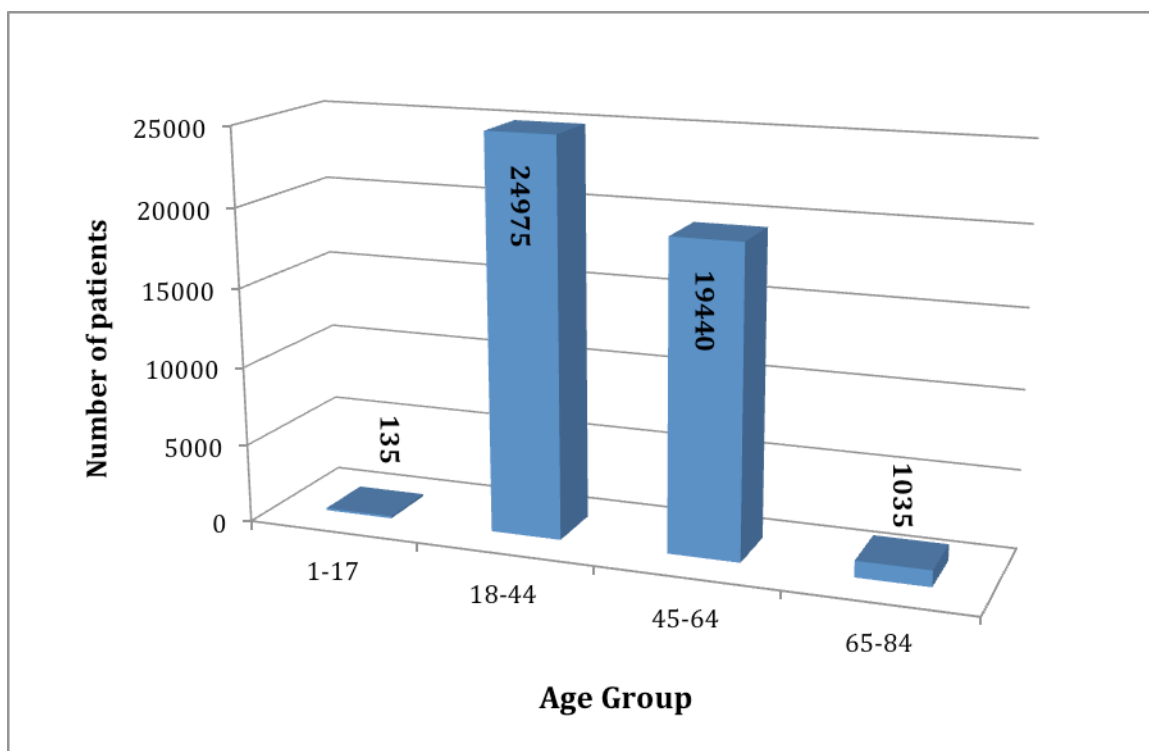


Figure 15: Distributions of the discharge patients who had lap vertical sleeve gastrectomy shown by age in 2012.

There was a difference in the age groups who underwent the lap Sleeve Gastrectomy operation. The highest percentage, as shown in Table (16), was 18-44 years old, at 54.78%. The 45-64 years old, made up 42.64% of the group, the 65-84 years old made up 2.27%, , and the 1-17 years old made up 0.30% of the group. Figure 15 shows the difference in the number of patients and their age groups.

Table 16: The age group of patients who underwent laparoscopic sleeve gastrectomy operation in 2012.

		Total Percentage of Discharges
Age Group	1-17	0.30%
	18-44	54.78%
	45-64	42.64%
	65-84	2.27%

Table 17: The insurance payer to patients who underwent lap sleeve gastrectomy in 2012.

		Total Number of Discharges
Payer	Medicare	1790
	Medicaid	3560
	Private Insurance	35575
	Uninsured	3050
	Other	630

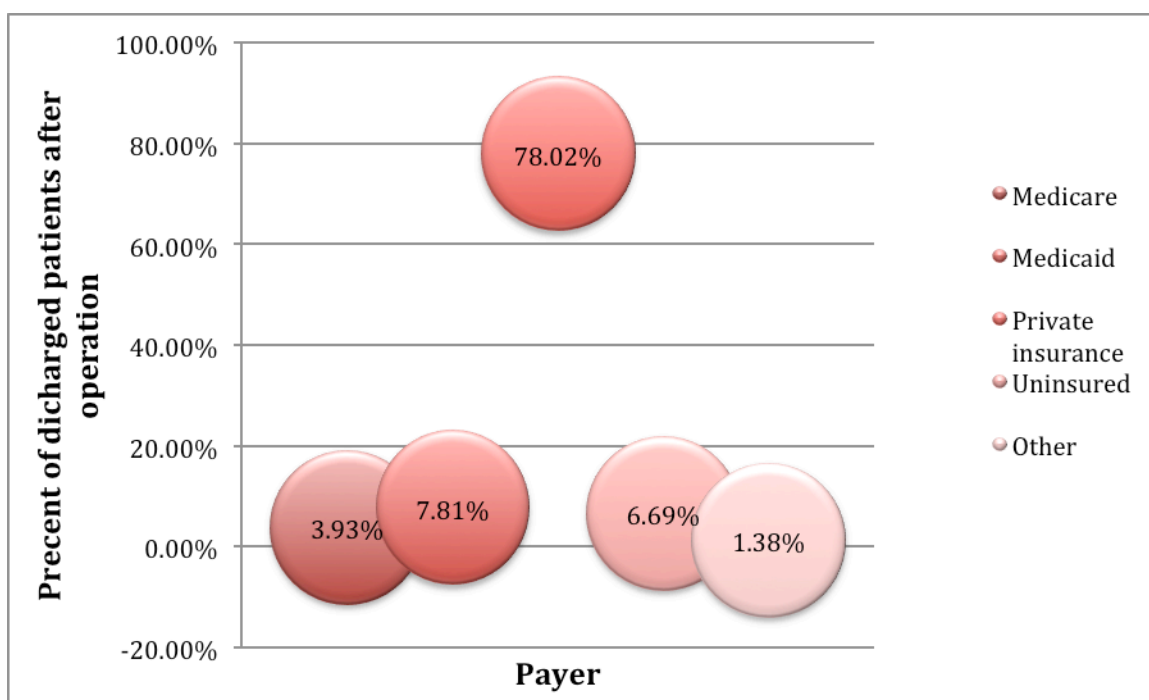


Figure 16: The percentage of payer for patients who underwent laparoscopic sleeve gastrectomy in 2012.

Some insurance companies, like Medicare and Medicaid for senior patients, pay for the operation, but as shown in Table 17 the highest number of patients were covered by private insurance companies, while the lowest percentage were either uninsured (6.96%) or had other sources (1.38%) as presented in Figure 16. Insurance companies covered the operation because most of health problems stem from the obesity. They rallied around the root cause: “elimination of the obesity will cure most of the health problems.”⁵¹

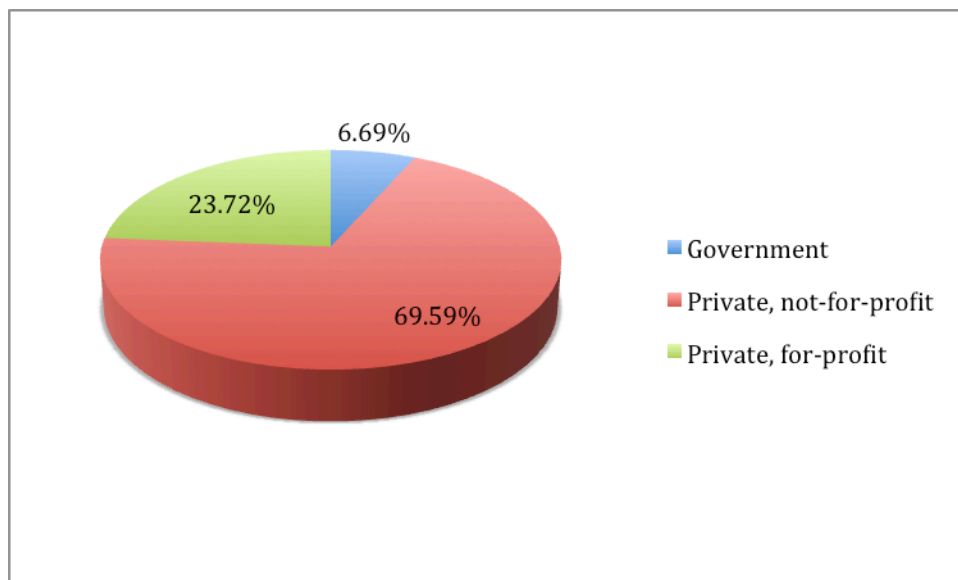


Figure (17): The percentage of different kind of hospitals picked by the patients who underwent laparoscopic sleeve gastrectomy in 2012.

Table 18: The number of patients who picked different kind of hospitals to undergo the laparoscopic sleeve gastrectomy in 2012.

		Total Number of Discharges
All Discharges		45595
Owner	Government	3050
	Private, not-for-profit	31730
	Private, for-profit	10815

The different categories of hospitals are shown in Figure 17: private not for profit; private for profit; and governments' hospitals, which are mentioned in the Table 18, along with the number of discharged patients who were admitted for this operation. The highest percentage of patients went to nonprofit private hospitals, which had higher health care costs than the governmental hospitals, yet were cheaper than the for profit private hospitals.

This selection of hospitals effected even the hospitals' bed sizes. The numbers and percentages in Table 19 and Figure 18 show that 52.09% of the patients received the larger bed sizes.

Table 19: The numbers of patients pick different kind of hospitals depending on the bed size to undergo the laparoscopic sleeve gastrectomy in 2012.

		Total Number of Discharges
All Discharges		45595
Bed size	Small	8470
	Medium	13375
	Large	23750

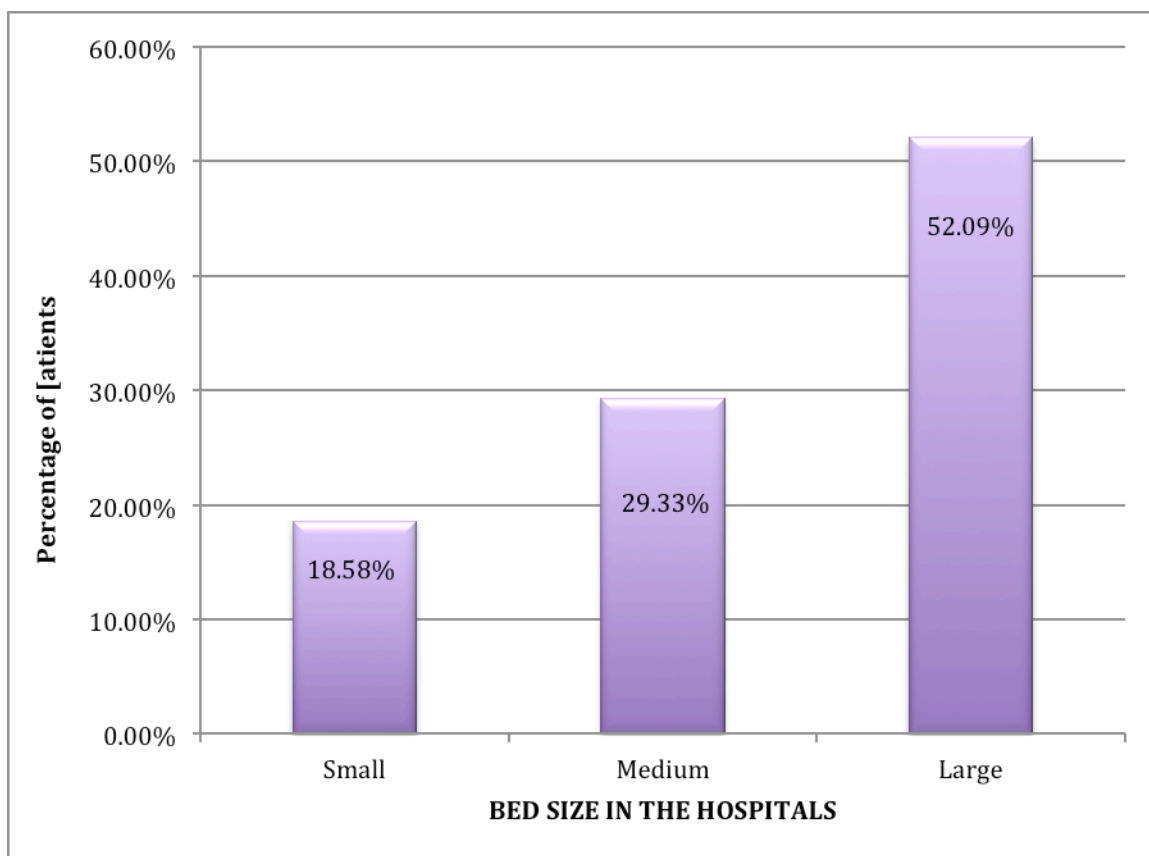


Figure 18: The percent of patient's picks depending on the bed sizes of the hospitals to undergo the laparoscopic sleeve gastrectomy in 2012.

Table 20: Number of patients according AHRQ comorbidity measures in 2012.

AHRQ Comorbidity Measures	Number of Patients
Hypertension (combine uncomplicated and complicated)	4795
Diabetes, uncomplicated	2138
Depression	1731
Chronic pulmonary disease	1482
Hypothyroidism	1007
Liver disease	905
Deficiency anemia	400
Fluid and electrolyte disorders	264
Psychoses	187
Obesity	173
Other neurological disorders	141
Rheumatoid arthritis/collagen vascular diseases	140
Diabetes with chronic complications	123
Congestive heart failure	111
Renal failure	108
Valvular disease	75
Pulmonary circulation disorders	41
Coagulopathy	38
Peripheral vascular disorders	37
Alcohol abuse	26
Drug abuse	25
Chronic blood loss anemia	16
Weight loss	14
Lymphoma	10
Solid tumor without metastasis	9
Acquired immune deficiency syndrome	6
Paralysis	5
Peptic ulcer disease excluding bleeding	3
Metastatic cancer	2

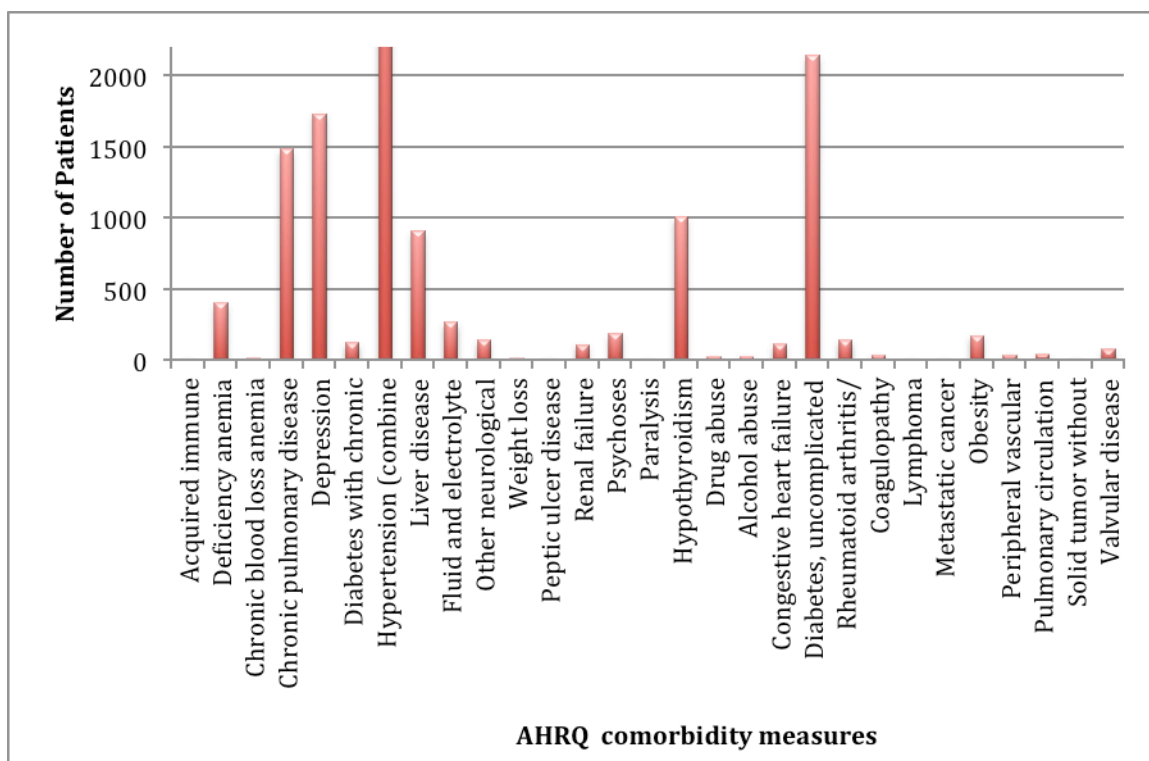


Figure 19: The number of patients according to AHRQ comorbidity measures in 2012.

Most of the Laparoscopic Sleeve Gastrectomy patients had different kinds of comorbidity as shown in Table 20. It was found that most patients (4795) who underwent the operation in 2012 had hypertension, complicated or uncomplicated, as noticed in Figure 19. The second comorbidity was uncomplicated diabetes (2138) which mostly cured after the operation. From third place to eighth place, were depression, chronic pulmonary disease, hypothyroidism, liver disease, deficiency anemia, and fluid and electrolyte disorders. That will be discussed later in the current study on Saudi patients.

4.2 The results of hospitalization outcomes of patients undergo LSG from SPSS software

Multi linear regression with length of stay (LOS):

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.176 ^a	.031	.030	1.413

a. Predictors: (Constant), Location/teaching status of hospital (STRATA), AHRQ comorbidity measure: Deficiency anemias, AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated), AHRQ comorbidity measure: Obesity, AHRQ comorbidity measure: Hypothyroidism, Race (uniform), Indicator of sex, Region of hospital, AHRQ comorbidity measure: Diabetes, uncomplicated, Age in years at admission

ANOVA^a

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	560.470	10	56.047	28.091	.000 ^b
	Residual	17449.770	8746	1.995		
	Total	18010.240	8756			

a. Dependent Variable: Length of stay (cleaned)

b. Predictors: (Constant), Location/teaching status of hospital (STRATA), AHRQ comorbidity measure: Deficiency anemias, AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated), AHRQ comorbidity measure: Obesity, AHRQ comorbidity measure: Hypothyroidism, Race (uniform), Indicator of sex, Region of hospital, AHRQ comorbidity measure: Diabetes, uncomplicated, Age in years at admission

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	1.487	.115		12.979	.000
	AHRQ comorbidity measure: Obesity	1.119	.110	.107	10.194	.000
	AHRQ comorbidity measure: Hypothyroidism	.076	.049	.017	1.555	.120
	AHRQ comorbidity measure: Diabetes, uncomplicated	-.033	.037	-.010	-.870	.385
	AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated)	.076	.033	.026	2.295	.022
	AHRQ comorbidity measure: Deficiency anemias	.506	.075	.071	6.754	.000
	Age in years at admission	.007	.001	.055	4.813	.000
	Race (uniform)	.036	.012	.031	2.956	.003
	Indicator of sex	-.026	.037	-.008	-.706	.480
	Region of hospital	-.101	.015	-.073	-6.685	.000
	Location/teaching status of hospital (STRATA)	.110	.028	.042	3.885	.000

a. Dependent Variable: Length of stay (cleaned)

Multi linear regression with total charge (TOTCHG):

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.218 ^a	.047	.046	24712.218

- a. Predictors: (Constant), Location/teaching status of hospital (STRATA), AHRQ comorbidity measure: Deficiency anemias, AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated), AHRQ comorbidity measure: Obesity, AHRQ comorbidity measure: Hypothyroidism, Race (uniform), Indicator of sex, Region of hospital, AHRQ comorbidity measure: Diabetes, uncomplicated, Age in years at admission

ANOVA^a

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	2.564E+11	10	2.564E+10	41.980	.000 ^b
	Residual	5.155E+12	8442	610693700		
	Total	5.412E+12	8452			

- a. Dependent Variable: Total charges (cleaned)
- b. Predictors: (Constant), Location/teaching status of hospital (STRATA), AHRQ comorbidity measure: Deficiency anemias, AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated), AHRQ comorbidity measure: Obesity, AHRQ comorbidity measure: Hypothyroidism, Race (uniform), Indicator of sex, Region of hospital, AHRQ comorbidity measure: Diabetes, uncomplicated, Age in years at admission

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	40688.672	2061.484		19.738	.000
	AHRQ comorbidity measure: Obesity	18775.390	1922.068	.104	9.768	.000
	AHRQ comorbidity measure: Hypothyroidism	127.061	862.116	.002	.147	.883
	AHRQ comorbidity measure: Diabetes, uncomplicated	100.577	663.773	.002	.152	.880
	AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated)	1148.902	585.760	.023	1.961	.050
	AHRQ comorbidity measure: Deficiency anemias	4582.124	1336.643	.037	3.428	.001
	Age in years at admission	73.246	25.969	.033	2.821	.005
	Race (uniform)	2019.958	218.296	.099	9.253	.000
	Indicator of sex	-2604.096	655.532	-.043	-3.972	.000
	Region of hospital	2675.765	276.149	.107	9.690	.000
	Location/teaching status of hospital (STRATA)	-3519.143	510.119	-.076	-6.899	.000

a. Dependent Variable: Total charges (cleaned)

Multi linear regression with total discharges (TOTAL_DISC):

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.493 ^a	.243	.242	2468.149

a. Predictors: (Constant), Location/teaching status of hospital (STRATA), AHRQ comorbidity measure: Deficiency anemias, AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated), AHRQ comorbidity measure: Obesity, AHRQ comorbidity measure: Hypothyroidism, Race (uniform), Indicator of sex, Region of hospital, AHRQ comorbidity measure: Diabetes, uncomplicated, Age in years at admission

ANOVA^a

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	1.708E+10	10	1.708E+9	280.325	.000 ^b
	Residual	5.328E+10	8746	6091759.73		
	Total	7.036E+10	8756			

a. Dependent Variable: Total number of discharges from this hospital in the NIS

b. Predictors: (Constant), Location/teaching status of hospital (STRATA), AHRQ comorbidity measure: Deficiency anemias, AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated), AHRQ comorbidity measure: Obesity, AHRQ comorbidity measure: Hypothyroidism, Race (uniform), Indicator of sex, Region of hospital, AHRQ comorbidity measure: Diabetes, uncomplicated, Age in years at admission

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	-1618.309	200.158		-8.085	.000
	AHRQ comorbidity measure: Obesity	-58.624	191.880	-.003	-.306	.760
	AHRQ comorbidity measure: Hypothyroidism	29.262	84.964	.003	.344	.731
	AHRQ comorbidity measure: Diabetes, uncomplicated	127.755	65.505	.019	1.950	.051
	AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated)	27.515	57.508	.005	.478	.632
	AHRQ comorbidity measure: Deficiency anemias	64.134	130.967	.005	.490	.624
	Age in years at admission	1.605	2.549	.006	.630	.529
	Race (uniform)	-91.492	21.462	-.040	-4.263	.000
	Indicator of sex	42.592	64.397	.006	.661	.508
	Region of hospital	-169.708	26.505	-.062	-6.403	.000
	Location/teaching status of hospital (STRATA)	2428.084	49.472	.471	49.080	.000

a. Dependent Variable: Total number of discharges from this hospital in the NIS

A - Null Hypothesis 1 (H01): There are no statistically significant associations between the number and types of comorbidities and each of the following variables: a) total discharge, (b) costs, and (c) length of stay of patients undergoing Sleeve Gastrectomy procedures.

Alternative Hypothesis 1 (HA1): There is statistically significant association between the number and types of comorbidities and each of the following variables: a) total discharge, (b) costs, and (c) length of stay of patients undergoing Sleeve Gastrectomy procedures.

According to the results obtained from linear regression analysis, there is statistically significant association between length of stay of patients and the following comorbidities: obesity ($b=1.119$, $p<0.001$), hypertension ($b=0.076$, $p=0.022$) and deficiency anemia ($b=0.506$, $p<0.001$). There is no statistically significant evidence of association between length of stay and hypothyroidism ($p=0.12$) or uncomplicated diabetes ($p=0.385$).

In addition, there is statistically significant evidence of association between total cost and obesity ($b=18775.390$, $p<0.001$), hypertension ($b=1148.902$, $p=0.05$) and deficiency anemia ($b=4582.124$, $p=0.001$). There is no statistically significant evidence of association between total cost and hypothyroidism ($p=0.883$) or uncomplicated diabetes ($p=0.88$).

Finally, there is a marginal statistical significance between total discharge and uncomplicated diabetes comorbidity ($b=127.755$, $p=0.051$). However, there is no evidence of association between total discharge and other types of comorbidities: obesity ($p=0.76$), hypothyroidism ($p=0.731$), hypertension ($p=0.632$) and deficiency anemia ($p=0.624$).

B - Null Hypothesis 2 (H02): There is no statistically significant difference in **costs**, length of stay procedures and total discharge patients with race, age, or gender.

Alternative Hypothesis 2 (HA2): There are statistically significant differences in costs, length of stay of procedures and total discharge patients with race, age, or gender.

My study found a statistically significant association between race and length of stay ($b=0.036$, $p=0.003$), costs ($b=2019.958$, $p<0.001$) and total discharge ($b=-91.492$, $p<0.001$).

In addition, there is a statistically significant association between patient's age and length of stay ($b=0.007$, $p<0.001$) and costs ($b=73.246$, $p=0.005$). There is a statistically significant difference between gender and total costs ($b=-2604.096$, $p<0.001$).

However, there are no statistically significant differences with gender in length of stay ($p=0.480$) or in total discharge ($p=0.508$). Finally, there is no evidence of association between total discharge and age ($p=0.529$).

We use Post Hoc Tukey Test for Total Discharges with Age to know which age group most affected.

Total number of discharges from this hospital in the NIS

Tukey HSD^{a,b}

Age Group	N
1 to 20	119
21 to 40	3623
41 to 60	4775
61 to 80	598
81 to 100	2

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 9.793.

b. The group sizes are unequal. The harmonic mean of the group sizes is used. Type I error levels are not guaranteed.

We use Post Hoc Tukey Test for Length of Stay with Age to know which age group most affected.

Length of stay (cleaned)

Tukey HSD^{a,b}

Age Group	N	LOS
21 to 40	3623	1.88
41 to 60	4775	1.97
1 to 20	119	1.99
61 to 80	598	2.16
81 to 100	2	3.50
Sig.	0.102	

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 9.793.

b. The group sizes are unequal. The harmonic mean of the group sizes is used. Type I error levels are not guaranteed.

C - Null Hypothesis 3 (H03): There is no statistically significant differences in the costs, length of stay of procedures and total discharge in patients across various regions of the US.

Alternative Hypothesis 3 (HA3): There is a statistically significant difference in the costs, length of stay of procedures and total discharge in patients across various regions of the US.

There are statistically significant differences across the various regions of the US in length of stay ($b=-0.101$, $p<0.001$), costs ($b=2675.765$, $p<0.001$) and total discharge ($b=-169.708$, $p<0.001$).

D - Null Hypothesis 4 (H04): There is no statistically significant association between the costs, length of stay of procedure patients and total discharge amongst the different types of hospital settings.

Alternative Hypothesis 4 (HA4): There is a statistically significant difference in each of the costs, length of stay of procedure and total discharge in patients amongst the different types of hospital settings.

There are statistically significant relationship between the types of hospital settings and the length of stay ($b=0.110$, $p<0.001$), costs ($b=-3519.143$, $p<0.001$) and total discharge ($b=2428.084$, $p<0.001$).

Overall Model significance

Overall, all three regression models are statistically significant since the p-values associated with the F-test are lower than 0.001 for each one of them. This means that we can reject the null hypothesis (H_0 : all of the model coefficients are 0) for all models. Hence, we can conclude that the explanatory variables (comorbidities, race, age, gender, region and STRATA of the hospital) can explain a significant proportion of the observed variability in length of stay, total cost and total discharge. In particular, comorbidities, race, age, gender, region and STRATA of the hospital can explain the 17.6% of the observed variability in the length of stay, the 21.8% of the observed variability in total charges, and the 49.3% of the observed variability in total discharge.

4.2 The result from Saudi Arabian patients

4.2.1- Hemoglobin

(A) Null Hypothesis 1 (H01): There is not a statistically significant relationship between hemoglobin level before Sleeve Gastrectomy and change in hemoglobin level after Sleeve Gastrectomy.

Alternative Hypothesis 1 (HA1): There is a statistically significant relationship between hemoglobin level before Sleeve Gastrectomy and change in hemoglobin level after Sleeve Gastrectomy.

Table 21: Iron result from Saudi Arabian patients' data before and after sleeve gastrectomy in King Khalid University Hospital.

Hb before the sleeve gastrectomy operation	Hb after sleeve gastrectomy operation
12.3	13.7
11.0	12.3
11.1	13.1
14.9	14.3
12.5	13.2
14.4	12.4
12.1	13.2
13.6	12.4
14.1	12.0
10.9	11.4
12.9	13.2
12.4	13.4
12.3	13.7
11.0	12.3
11.1	13.1
14.9	14.3
12.5	13.2
14.4	12.4
12.1	13.2
13.6	12.4

One must apply the paired t- test to test for any significant difference in the mean of Iron before and after Sleeve Gastrectomy. The output obtained from SPSS inbuilt function is shown below.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Iron before	12.705	20	1.3461	.3010
	Iron After month	12.960	20	.7500	.1677

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Iron before & Iron After month	20	.270	.249

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Iron before – Iron After month	-.2550	1.3524	.3024	-.8879	.3779	-.843	19	.410

The reported results indicate that P-value = 0.410, $P = 0.410 > 0.05$ since p-value is greater than alpha (0.05). I accept the Null Hypothesis H_0 at 5% level of significance and conclude that there is no statistically significant difference between hemoglobin levels before and after Sleeve Gastrectomy.

4.2 - Vitamin B₁₂

(B) Null Hypothesis 2 (H₀₂): There is no statistically significant relationship between vitamin B₁₂ level before Sleeve Gastrectomy and change in vitamin B₁₂ level after Sleeve Gastrectomy.

Alternative Hypothesis 2 (H_{A2}): There is a statistically significant relationship between vitamin B₁₂ level before Sleeve Gastrectomy and change in vitamin B₁₂ level after Sleeve Gastrectomy.

Table 22: Vitamin B₁₂ result from Saudi Arabian patients' data before and after sleeve gastrectomy in King Khalid University Hospital.

Vitamin B₁₂ before sleeve gastrectomy operation	Vitamin B₁₂ after sleeve gastrectomy operation
335.5	356.2
335.5	356.2
145.6	289.4
352.8	252.8
366.0	266.0
145.6	289.4
249.6	230.0
215.5	198.8
467.4	382.8
280.1	261.4
145.6	114.4
215.5	198.8
467.4	382.8
280.1	261.4
467.4	382.8
280.1	261.4
145.6	114.4
467.4	382.8
280.1	261.4
145.6	114.4
335.5	356.2

One must apply the paired t- test to test if there is any significant difference in the mean of vitamin B₁₂ before and after Sleeve Gastrectomy. The output obtained from SPSS inbuilt function is shown below.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	B12 before	289.420	20	116.3294	26.0120
	B12 After	267.880	20	89.2659	19.9605

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	B12 before & B12 After	20	.815	.000

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 B12 before – B12 After	21.5400	67.5995	15.1157	-10.0975	53.1775	1.425	19	.170

The reported results indicate that P-value = 0.170, $P = 0.170 > 0.05$ since p-value is less than alpha (0.05), I accept H02 at 5% level of significance and conclude that there is no statistically significant difference between vitamin B₁₂ levels before and after Sleeve Gastrectomy.

4.3-Vitamin D

Null Hypothesis 3 (H03): There is no statistically significant relationship between vitamin D level before Sleeve Gastrectomy and change in vitamin D level after Sleeve Gastrectomy.

Alternative Hypothesis 3 (HA3): There is a statistically significant relationship between vitamin D level before Sleeve Gastrectomy and change in vitamin D level after Sleeve Gastrectomy.

Table 23: Vitamin D result from Saudi Arabian patients' data before and after sleeve gastrectomy in King Khalid University Hospital.

Vitamin D before sleeve gastrectomy operation	Vitamin D after sleeve gastrectomy operation
35.38	31.54
63.70	51.87
20.90	19.90
19.17	38.30
35.70	126.80
43.38	114.40
50.20	95.70
23.33	103.30
66.70	130.30
39.97	101.40
25.05	71.38
22.90	17.33
22.90	17.33
23.21	29.25
23.21	29.25
21.11	112.70
43.38	5.79
21.11	112.70
43.38	5.79
25.05	71.38

Again, one must apply the paired t- test to test if there is any significant difference in the mean of Vitamin D before and after Sleeve Gastrectomy. The output obtained from SPSS inbuilt function is shown below.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	vit.D before	33.4865	20	14.49156	3.24041
	vit.D After	64.3205	20	44.14825	9.87185

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	vit.D before & vit. D After	20	.241	.306

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	vit.D before – vit. D After	-30.83400	43.02109	9.61981	-50.96849	-10.69951	-3.205	19	.005

The reported results indicate that P-value = 0.005, $P = 0.005 < 0.05$ since p-value is greater than alpha (0.05), I reject the Null Hypothesis (H_0) at 5% level of significance and conclude that there is statistically significant difference between vitamin D levels before and after Sleeve Gastrectomy.

4.4 – Thyroid Function

4.4.1 - T₄

Null Hypothesis 4 (H04): There is no statistically significant relationship between thyroid hormone level before Sleeve Gastrectomy and change in thyroid hormones level after Sleeve Gastrectomy.

Alternative Hypothesis 4 (HA4): There is a statistically significant relationship between thyroid hormone level before Sleeve Gastrectomy and change in thyroid hormones level after Sleeve Gastrectomy.

Table 24: T₄ result from Saudi Arabian patients' data before and after sleeve gastrectomy in King Khalid University Hospital.

T₄ level before sleeve gastrectomy operation	T₄ level after sleeve gastrectomy operation
14.90	13.50
16.00	28.59
17.40	20.28
14.97	14.37
11.99	26.90
11.54	26.50
17.10	15.38
19.66	16.34
20.13	17.34
16.54	15.54
15.23	14.75
15.56	14.17
15.56	14.17
16.81	17.90
16.81	17.90
15.80	16.90
17.40	20.28
14.97	14.37
11.99	26.90
14.90	13.50

I applied the paired t- test to determine if there was any significant difference in the mean of T₄ before and after Sleeve Gastrectomy. The output obtained from SPSS inbuilt function is shown below.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	T4 before	15.7630	20	2.22044	.49651
	T4 After	18.2790	20	5.00394	1.11892

Paired Samples Correlations

	N	Correlation	Sig.
Pair 1 T4 before & T4 After	20	-.432	.057

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 T4 before - T4 After	-2.51600	6.29116	1.40675	-5.46035	.42835	-1.789	19	.090

The reported results indicate that P-value = 0.090, $P = 0.090 > 0.05$ since p-value is greater than alpha (0.05). I accept the Null Hypothesis (H₀) at 5% level of significance and conclude that there is no statistically significant difference between T₄ levels before and after Sleeve Gastrectomy.

4.4.2 -TSH

Null Hypothesis 4 (H04): There is no statistically significant relationship between thyroid hormone level before Sleeve Gastrectomy and change in thyroid hormones level after Sleeve Gastrectomy.

Alternative Hypothesis 4 (HA4): There is a statistically significant relationship between thyroid hormone level before Sleeve Gastrectomy and change in thyroid hormones level after Sleeve Gastrectomy.

Table 25: TSH result from Saudi Arabian patients' data before and after sleeve gastrectomy in King Khalid University Hospital.

TSH level before Sleeve Gastrectomy operation	TSH level After Sleeve Gastrectomy operation
2.23	3.310
6.87	0.012
1.74	2.400
1.78	5.220
1.61	0.033
5.79	3.120
0.10	0.116
2.18	3.530
1.50	2.070
2.05	0.800
2.11	1.830
1.55	1.320
2.12	1.828
2.04	1.350
5.17	4.120
3.40	2.340
11.54	11.000
2.23	3.310
6.87	0.012
1.74	2.400

I applied the paired t- test to assess whether there was any significant difference in the mean of TSH before and after Sleeve Gastrectomy. The output obtained from SPSS inbuilt function is shown below.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TSH before	3.2310	20	2.70553	.60498
	TSH After	2.50605	20	2.469981	.552304

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	TSH before & TSH After	20	.551	.012

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	TSH before - TSH After	.724950	2.461570	.550424	-.427100	1.877000	1.317	19	.203

The reported results indicate that P-value = 0.203, $P = 0.203 > 0.05$ since p-value is less than alpha (0.05). I accept the Null Hypothesis (H_0) at 5% level of significance and conclude that there is no statistically significant difference between TSH levels before and after Sleeve Gastrectomy.

CHAPTER V: DISCUSSION AND STUDY LIMITATION

This study pointed to whether there is a relationship between different co-morbidities like: diabetes, hypertension, hypothyroidism, obesity and deficiency anemia with total patient discharge, length of stay after the operation, and total charge of the operation. It showed that there is a relation between the HTN with LOS and total charge of operation because controlling HTN in patients needs time and health care, which increases the total charge. In diabetes, the only relationship found with total patient discharge related to obese patients who had diabetes as a second purpose for their operation, which improved their diabetes. In cases of obesity, their relationship with LOS and total charge depended on the percent of the patient's obesity, which drove the long length of stay in the hospital. Deficiency anemia also influenced LOS and total charge, because of the level of health care and supervision required by the patients.

The current study shows that race effected LOS, total charge, and the total discharge, and may indicate genetic reasons, which need further study. Age affected LOS and total charge for the same reason, because the patients needed more care, which increased the cost. It is specially increased from age 61 to 80 years old, which show that they need more care because of presence of other illness like DM and HTN. In the case of gender, the only relationship was with cost. Most of the patients were female, who may have needed more, or other, surgeries that could be done with the operation.

Different regions in the US were impacted by the total number of patients who underwent SG. That impact depended on the percentage of obesity in the area, the number of hospitals, and how the surgeons do their operations. The LOS was followed by an increase in the cost. Even the varieties and types of hospitals effected LOS, cost and total patient discharge for the same reason in different regions in US.

The second part of this study pointed out that, according to the body mass index of 30 kg/m^2 , the prevalence of obesity was 28.7% rate (3.6 millions) in Saudi Arabia. The female ratio recorded the highest rate of 33.5%, compared to 24.1% in males. As BMI increases with age, obesity reached the highest level in the 55-64 age group, a percentage of 48.0%. The study conducted by the Ministry of Health in the Kingdom of Saudi Arabia showed a morbid obesity rate of 40 kg/m^2 . BMIs reached up to 2.5% in males and 4.7% in females in 2013. According to the WHO in 2014, the percentage of obesity in males was 29.9% and in females it reached 41.4%, with BMIs $22.9\text{-}37.7 \text{ kg/m}^2$ and $33.8\text{-}49.1 \text{ kg/m}^2$, respectively. When compared to 2013, an increase in males by 5.8% and female by 7.9% was noted. From those numbers, I conclude that one of the reasons women exceeded the number of men who underwent LSG is that the women want to be in their best shape.

In contrast, in the US, it was found that the percentage of obesity in 2014 was 32.6%, with BMIs between $26.7\text{-}38.7 \text{ kg/m}^2$ in males, and for females, there was a 34.7% BMI between $28.9\text{-}40.7 \text{ kg/m}^2$ with an increase from 2010 by 2.8% in men and 2.2% in women, as shown in Figure (20).

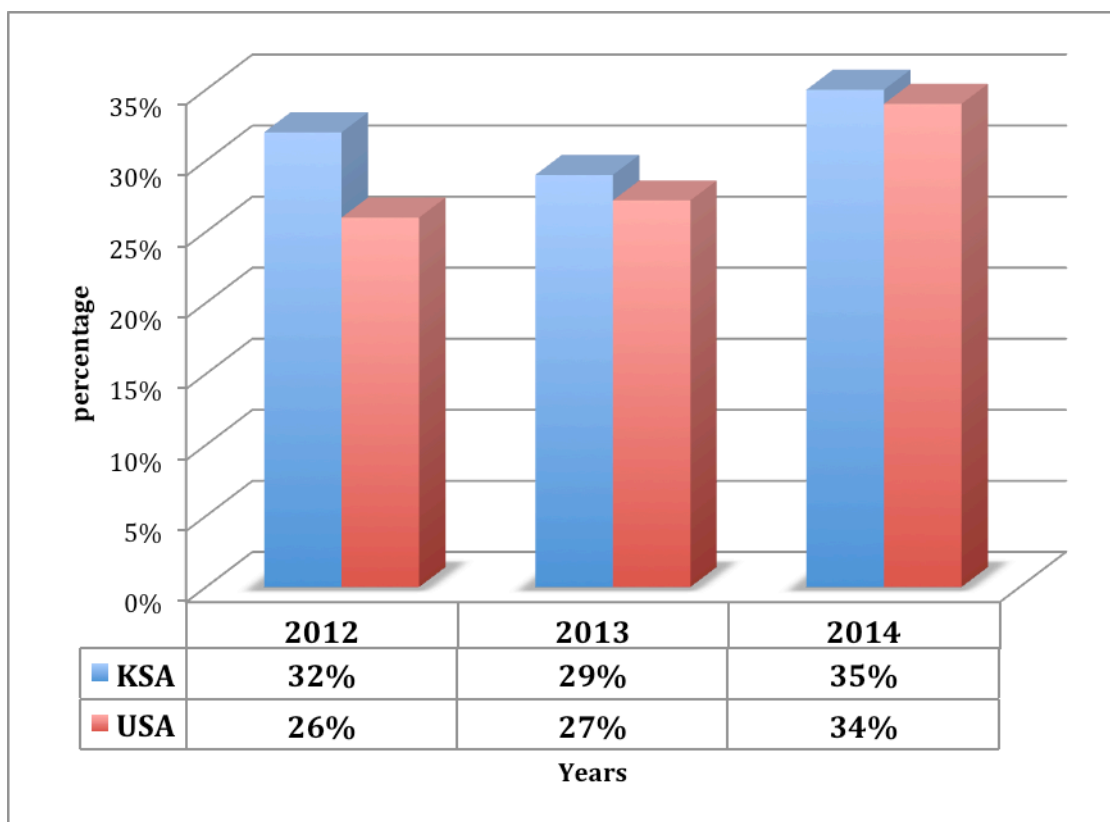


Figure 20: The percentage of obesity in USA and Saudi Arabia (KSA) from 2012 until 2014.

Before operations, CBCs are routinely done, and include Hb. Selected patients for SG are asked to take serum vitamin D, B₁₂, T₄ and TSH. Six months after surgery the following tests are done again: Hb, Vitamin D, Vitamin B₁₂, T₄ and TSH.

The current study showed that vitamin D significantly changes after a Laparoscopic Sleeve Gastrectomy operation. A similar result has been obtained by Wolf E, et al, who had done a double blinded trial with 79 patients whose Vitamin D levels increased after 12 weeks following a laparoscopic sleeve gastrectomy procedure.⁸⁰

Research done by Jadhav, et al, who found 6 patients with changes in their thyroid hormones while studying differences between bariatric surgeries.⁴⁷

Gkotsina et al confirmed that T4 dose is not affected after SG. They tried to find out if there was an improvement of levothyroxine (LT₄) absorption after bariatric surgery. They discovered that LT₄ absorption after SG is improved, so they concluded that the stomach was not the primary site of absorption of LT₄ because the stomach is bypassed in these operations.⁴⁰

Moore, et al measured the vitamin B₁₂ absorption after SG surgery, the vitamin B₁₂ concentration after operation, and after 3 months of vitamin B₁₂ intake. They concluded that the absorption of B₁₂ decreased unless they gave patients high percentage supplements of B₁₂. Further investigation was required to justify long-term effects of the rapid rise in B₁₂ levels in the blood due to the high percentage of supplements.⁴⁵

This study shows no relation between iron before and after SG. Table 20 shows American patients from NIH data that underwent SG in 2012 who also had deficiency anemia. Papini-Berto, et al had different result than this current study with regard to iron and B₁₂. They examined possible causes of malnutrition after the SG procedure. Anemia was associated with gastrectomy, which consequently reduced the secretion of both hydrochloric acid, and was an essential factor leading to decreased iron absorption. Thus, vitamin B₁₂ decreased, as a result, with a net of body weight loss. Anemia was often found in these patients as a result of malnutrition in protein and energy. Severe and lasting malnutrition occurred depending on the type of surgery, and the length of post-operative care and food received. Accordingly, close supervision of nutritional care was strongly recommended.⁴³

Barley, et al proved that some patients were impacted by the SG and some were not, by including 26 patients who underwent SG blood test of iron, vitamin B₁₂, folate and calcium done annually. They found that 44% of those patients had normal results, but 17.5% showed abnormality. They proposed a policy for annual follow-up.⁴²

There are many studies concerned with the effect of bariatric operations on different vitamin levels, but a high number have not yet focused on of Sleeve Gastrectomy patients, especially those from Saudi Arabia. Many studies are needed to compare the before and after of SGs, and patients need to have dietitian consultations and proper follow up to ensure proper supplement intake.

As mentioned earlier there are 3 categories of bariatric surgery: Malabsorptive, Restrictive, and a combination of Restrictive and Malabsorptive.²⁹

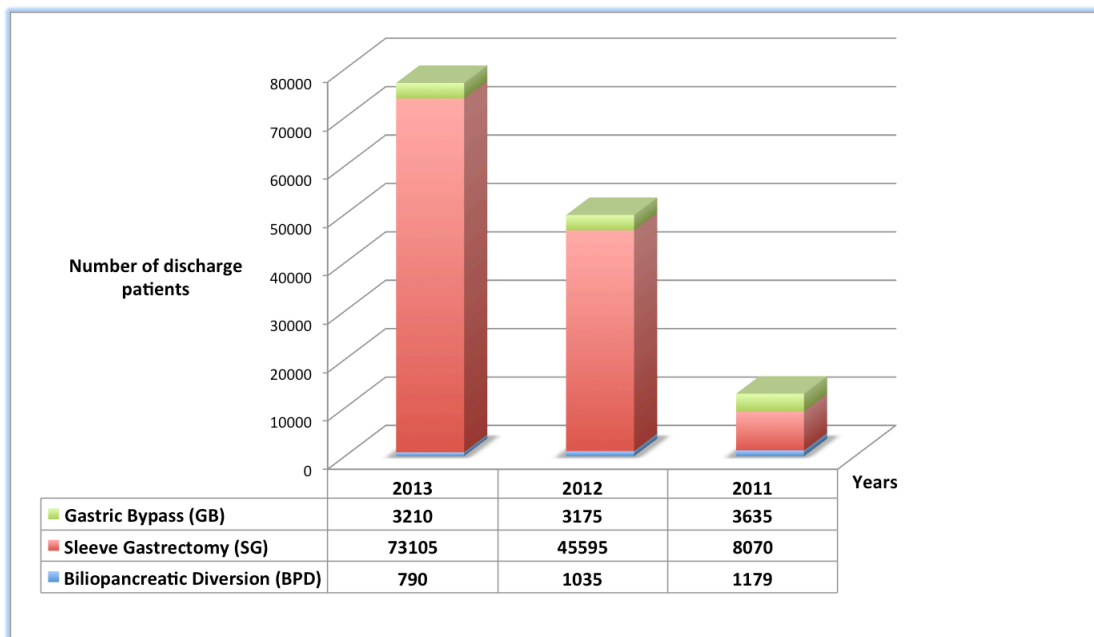


Figure 21: The total discharge patients who had three different bariatric surgeries in the US From 2011 till 2013.

Figure 21 shows the comparison between the total numbers of discharges in three different bariatric surgeries (Gastric Bypass, Sleeve Gastrectomy, and Biliopancreatic Diversion) in the US. Between 2011 till 2013, a drop occurred in BPD operations, due to a lower number of patients who underwent this kind of operations over those years. However, the decrease in the number of patients slightly decreased or different reasons that will be discussed later. It's also important to notice the sharp increase in SG operations over the three years.

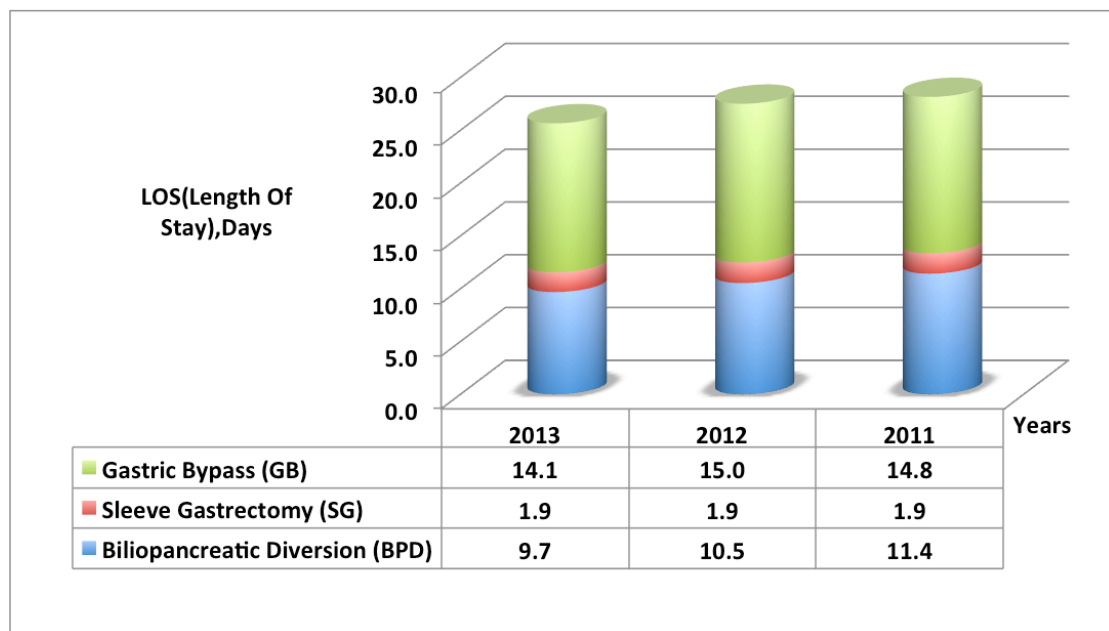


Figure 22: The length of stay by days in the hospitals after three different bariatric surgeries in the US from 2011 till 2013.

Figure 22 shows the length of stay in the hospitals after the operations. In GB and BPD, there was a fluctuation in the length of stay by ± 1 day, but in SG, it didn't change over the years.

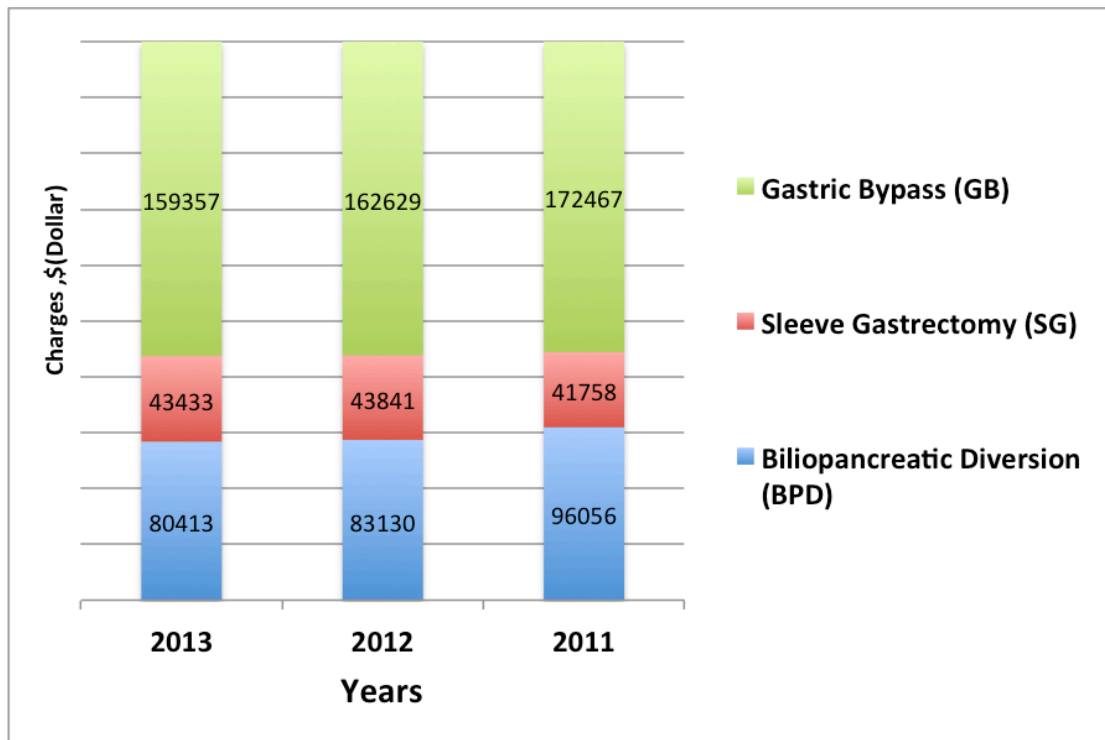


Figure 23: Charges for three different bariatric surgeries in dollars from 2011 to 2013 in US.

Figure 23 illustrates the charge for the operations. Notice that BPD and GB charges decreased from 2011 to 2013 because of the unpopularity of the operation resulting in fewer discharged patients. The SG charge slightly increased over the three years.

In the ranking the total discharged patients for all kinds of operations in the US in 2013, Sleeve Gastrectomy was number 55 of 100, but in 2012, the ranking went to 88 of 100. In regard to the charge for operations in 2013, gastric bypass ranked 52 of 100. For patients who died after gastric bypass in 2013, the ranking was in 91 of 100, but in 2012, the ranking changed to 80. That data indicated that gastric bypass was unsafe and one of highest costing operation in 2013. The data for 2012 and 2013 also shows that SG was one of the most commonly performed bariatric procedures in the United States.

There is much research comparing the three operations and different aspects of those operations, like mortality, morbidity, nutritional deficiency, improved HDL outcomes, cures for diabetics, bleeding during or after surgery, greater percentage of fat loss, weight loss, and which were the safest operations. Abu-Jaish et al's 2010 research found that LSG is a popular surgery as a primary stage operation with regard to its proven safety and mid-term and short-term efficacy. When compared to procedures like RYGBP and BPD, they found that LSG was safer, with less morbidity in the short and long term. But they concluded that there is still limited outcome data.³²

In 2012, Madura, et al said that Laparoscopic Roux-en-Y Gastric Bypass and the Laparoscopic Biliopancreatic Diversion, cause significant micronutrient deficiencies. Laparoscopic Biliopancreatic Diversion is chosen by doctors for the super-obese patient (BMI > 50 kg/m²). They found, too, that BPD had higher rates of complications, weight loss, mortality, diabetic resolve, hypertension resolve, and sleep apnea resolve. On the other hand, RYGBP had higher rates in cholesterol improvement, and SG had a high percentage of long term failure for regaining weight and a lower percentage in mortality.⁹

Thibault, et al discovered in 2016 that all three procedures cause nutritional deficiencies and malnutrition if patients are not assisted before and taken care of with suitable supplements. They suggest further study on these procedures.⁷¹

In 2015, Aminian, et al showed the impact of RYGB, SG and BPD on high density lipoprotein HDL. After the RYGB and SG surgeries, which had a small intestine, they showed an increase in HDL. On the other hand, BPD showed a slight increase in HDL.⁷²

A systemic review made in France by Lazzati, et al collected data from 2005 to 2011. They found a sharp increase in SG and GBP, and that BPD remained the same. Most of their procedures were done in low volume and private hospitals.⁷³ The number of patients who underwent SC, GBP, and BPD in the US and France in 2011 is illustrated in Figure 24.

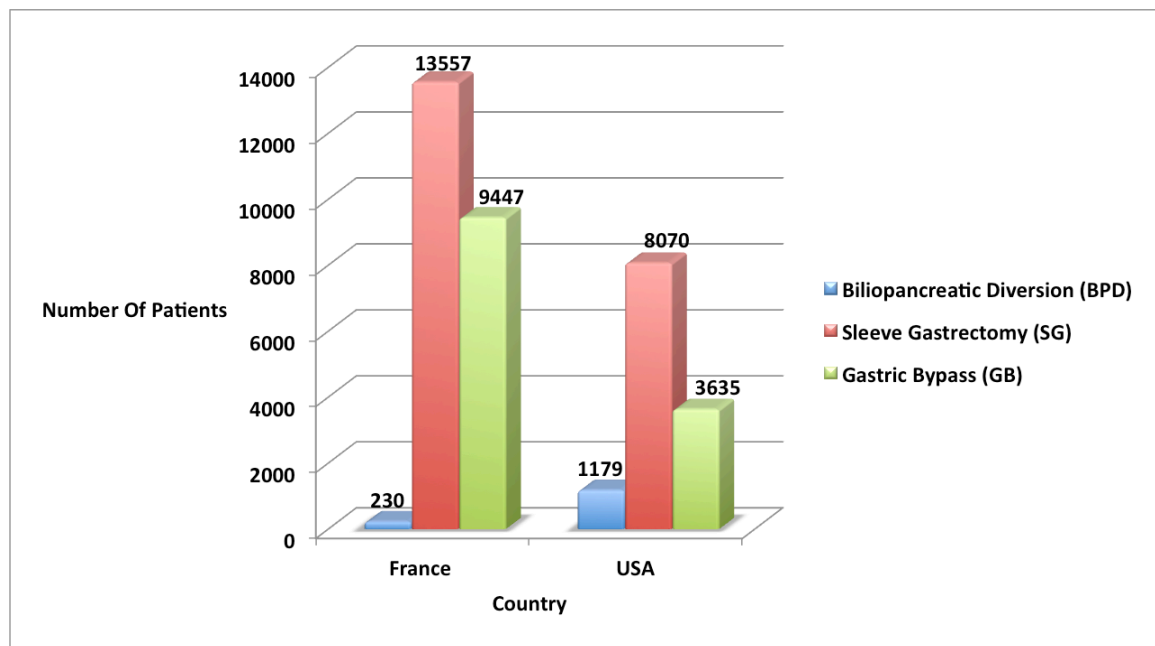


Figure 24: Comparison of three bariatric surgeries between USA and France in 2011.

Other research done by Sarkhosh, et al discusses the improvement of obstructive sleep apnea (OSA) which occurs with the obesity after the bariatric surgery. The result was an improvement in OSA of over 75% of patients that had the bariatric surgery. Patients showed 99% improvement or resolution from OSA in patients with BPD, 85.7% improvement after LSG, and 79.2% improvement after RYGB.⁷⁴

Maglione, et al conducted research, such as AHQR comparative effectiveness reviews, and found that their evidence of efficacy for treating obese patients with BMIs between 30 to 34.9 kg/m². They found diabetes improvement in RYGB and SG patients in short term (up to 2 years). In cases of BPD the evidence is low because of fewer studies founded.⁷⁵

Topart P, et al compared the three bariatric surgeries in early outcomes, and concluded that after SG no fatal outcomes occur. They found more co-morbidity in BPD and SG. In contrast the complication rate increased in BDP, but they found no difference between RYGB and SG. Finally, they concluded that SG had a greater bleeding rate than RYGB, and thus, the RYGB would be a safer operation than the others due to the high risk of postoperative complications with BPD.⁷⁶

Spyropoulos, et al found that a high rate of developing leakage after the operation was respectively high in BPD, SG and RYGB. They concluded that it can be managed with non-operative methods.⁷⁷

Strain, et al in 2009, compared the percentage of weight loss, which was 84%, 70%, and 49% for the BPD, GB and SG groups, respectively. They also measured the fat percentage after the SG, which was 37.7%, BPD was 32.7%, and GB was 25.7%.⁷⁸

CHAPTER VI: SUMMARY, SUGESSTIONS FOR FUTURE RESEARCH

The Laparoscopic Sleeve Gastrectomy shows incredible results in losing excess weight. A large number of obese patients chose this operation in different countries. It is affordable in price in comparison to other bariatric surgeries. As mentioned previously, SG is effective and had less co-morbidity than other operations. The problems appearing during and after the operation include: bleeding, gastric leak, and GERD. Development of technique process can overcome the leak problems, and GERD can be solves via of healthier eating and medication.

The vitamin deficiencies were the most well-known problem after LSG procedures. These need more study to overcome the problem. After operations, patients need long term follow up with a dietitian to know which kinds of food and portions they need. Whether or not they need supplements also needs to be checked. Referrals can be made to other doctors if they need psychiatric or behavioral modification. Depression for American patients in 2012 is reported in Table 20.

Future researches must work on modifying SG long-term outcomes, especially in Saudi Arabia. They must also compare different bariatric surgeries and categorize them by the application.

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