A Capstone Project

entitled

Bariatric Surgery and Obesity: The Ejection Fraction Story Both Pre- and Post-Operation

by

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Abstract

The prevalence of obesity has impacted society by decreasing the overall quality of life in many individuals. This study was designed to improve the knowledge between cardiovascular functionality, individually measured by ejection fraction (EF), and bariatric surgery to see if any changes occur to the subject's EF 1 year post-operation.

In this retrospective cohort study, subjects were separated based on their bariatric procedure: the bariatric sleeve, gastric bypass, or lap-band procedure. Subjects utilized in this study were patients of a private bariatric practice based in Atlanta, GA, during 2016-2019. Preoperative EF measurements were compared to post-operative EF measurements 1 year after bariatric surgery, and variables such as race, BMI, and gender were examined for correlation. From 2016-2019, there were 1,560 total bariatric procedures; however, there were 85 subjects (37 sleeves, 36 bypasses, 13 lap bands) who qualified for this study who were diagnosed with CVD, specifically low EF, before bariatric surgery. The study utilized a retrospective cohort study using a 3x2 factorial mixed subjects' design. A power analysis was not available to decide on the desired sample size due to a lack of public research on this topic. Thus, all available subjects who met the inclusion criteria were utilized to complete this study as recommended.

Results: The data yielded no overall significance in EF changes post-op when comparing them to pre-op measurements. However, EF measurements were significant when comparing the lap-band procedure to the other procedures based on the bariatric procedure. Data also yielded no significant relationship between race, gender, BMI, or comorbidities, and changes in ejection fraction measurements 1 year postoperative, considering all procedure types.

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The global pandemic of obesity has increased public health concerns because of its association with multiple comorbidities, including cardiovascular disease (Gurka et al., 2018). Some healthcare providers recommend bariatric surgery to combat the risks of developing a cardiovascular disease related to obesity. Obesity and its association with reduced life expectancy are well-established, with cardiovascular disease being one of the significant causes of fatality (Benotti et al., 2017). For example, a total of 2,065 cardiovascular disease deaths in obese individuals were reported out of 86,000 in a study (Jiang et al., 2013) and has increased as the years progress. Besides, years of life lost are associated with excess weight ranging from 6.5 years for subjects with a BMI between 40 and 44.9 to 13.7 years for those with a BMI between 55 and 59.9 (Printz, 2014). Consequently, healthcare providers are focused on overcoming the adverse effects of cardiovascular disease associated with obesity.

Among many approaches to treat severe obesity, studies have demonstrated that bariatric surgery is the most effective and cost-effective treatment (Kuno et al., 2019). More importantly, previous studies have shown that bariatric surgery reduces the overall mortality and the incidence of myocardial infarction and stroke (Kuno et al., 2019). While there have been numerous efforts designed to understand better the impact bariatric surgery has on the physiology of the heart, there are limited studies that focus on ejection fraction. The specific exploration of ejection fraction changes before and after bariatric surgery may help emphasize the benefits of bariatric surgery in cardiovascular disease subjects and combat the global impact obesity has on society.

Background

Even though obesity has been identified as a problem, the epidemic continues to increase nationally. Obesity impacts each segment of the population, increasing the probability of additional chronic illnesses in those affected by the disease. In 2015-2016, the prevalence of obesity was 39.8% and affected about 93.3 million adults in the United States (U.S.) (Centers for Disease Control and Prevention [CDC], 2018). A more recent study by Maffetone and Laursen (2017) indicated that approximately 70.7% of adults aged ≥ 20 years are obese in the United States. Possibly even more startling is the increasing obesity rate in children both nationally and globally. According to statistical forecasts, by 2030, 51% of the entire U.S. population will be diagnosed with obesity (Hruby & Hu, 2015).

This obesity epidemic has been linked to a host of health-related problems such as hypertension, cancer, and type II diabetes, with cardiovascular disease (CVD) being the most prevalent (Antonelli et al., 2014). The CDC (2018) indicated that CVD is one of the leading causes of morbidity and mortality in obese individuals. CVD is responsible for one in every four deaths, killing over a million people nationally a year (CDC, 2018). Also, the quality of life and life expectancy for obese individuals suffering from CVD is compromised due to reduced cardiac output (the amount of blood being pumped throughout the body) caused by decreased left ventricular contractility (Crisan et al., 2018). To measure the cardiac output in obese individuals, ejection fraction (EF) is the primary measuring tool to see how well the heart functions under stress stemming from an individual’s weight. The American Heart Association recognizes EF(s) as quality indicators in the overall management of CVD patients (Kunig et al., 2014).

Moreover, CVD has been found to have additional comorbidities, including respiratory complications and infections (Crisan et al., 2018). According to a systematic review by Tune et al. (2017), there is a linkage between CVD and individuals who suffer metabolism issues associated with obesity. Obese individuals who suffer from CVD experience fatigue, shortness of breath, abnormal heart rhythms, and edema (swelling) alongside other medical problems. These issues are the concurrence of mutually associated cardiovascular risk factors, including abdominal obesity, impaired glucose tolerance, hypertriglyceridemia, decreased HDL cholesterol, and hypertension (Tune et al., 2017). As a result, obese individuals who suffer from CVD may be referred to a bariatric surgeon to induce weight loss and improve their physiological limitations fueled by their obesity (Lavie et al., 2013; Pirlet et al., 2020). This information could be very influential in the fight to overcome heart disease stimulated by obesity.

Problem Statement

It is well known that high levels of body fat mass worsen most CVD risk factors, such as plasma lipids, blood pressure, glucose/insulin resistance, and inflammation (Ortega et al., 2016). Considerable data from experimental, epidemiological, and clinical studies support the notion that obesity has independent adverse effects on hemodynamics and cardiovascular structure and function through adipose tissue dysfunction and abnormal inflammatory pathways (Kim et al., 2016). However, it is less known by the general population that high levels of fat-free mass might also have some detrimental effects on cardiovascular health (Ortega et al., 2016). It has been previously reported that higher fat-free mass largely explains the higher circulating blood volume that has been observed in obese individuals (Ortega et al., 2016). In return, the left ventricle’s (LV) stroke volume increases, as measured by EF, and increases cardiac output. Such changes place an extra heavy burden on the heart, resulting in ventricular (both left and right) alterations that ultimately lead to ventricular (both left and right) hypertrophy and enlargement, predisposing to heart failure (HF) (Ortega et al., 2016).

Purpose of the Research

The purpose of this project was to increase the understanding between bariatric surgery and cardiovascular functionality, as measured by EF, explicitly focusing on any changes that occur in EF measurements postoperative. With conflicting conclusions on the benefits of bariatric surgery in previous literature, whether positive or negative, it was pivotal to evaluate current research to combat CVD and obesity globally. Existing literature correlating EF and bariatric surgery has been limited, and the findings have been conflicting. However, this study can add a more concise understanding to the existing literature on how the heart is impacted by obesity and what methods could be used as an intervention in individuals who suffer from CVD with low EFs.

Significance of this Research

The importance of this study was to evaluate changes in EF 1 year after bariatric surgery based on the specific procedure: gastric bypass, gastric sleeve, or lap band. Although there is data on cardiovascular functionality improvements after surgically induced weight loss, there is minimal data comparing the changes per bariatric procedure. This experience could identify if subjects who underwent a specific bariatric procedure experienced significant changes in their EF measurement compared to those who underwent a different approach. Moreover, this study will help combat obesity and CVD mortality by increasing how bariatric surgery interventions impact them. As a result, bariatric interventions could be utilized more often to increase the overall quality of life in obese individuals and improve physiological limitations.

Research Questions

The research questions for this study and associated hypotheses are the following:

Primary:

RQ1: Do subjects diagnosed with low ejection fraction before bariatric surgery experience any changes in ejection fraction measurements 1 year postoperative?

H1: There is a significant increase in the bariatric patient's ejection fraction measurements 1 year postoperative.

Secondary:

RQ2: If there is a change in EF postoperatively, what type of bariatric procedure displays the most significant change in ejection fraction when comparing before and after surgery measurements?

H2: There are significant differences in EF measurements before and 1 year post-operation between bariatric procedures.

H2.1: Subjects who undergo the sleeve will display changes in ejection fraction measurements significantly different from those who do not.

H2.2: Subjects who undergo the gastric bypass procedure will have the most significant increase in ejection fraction measurement than gastric sleeve and lap-band techniques.

H2.3: Subjects who undergo the lap-band procedure will have the least amount of change in their ejection fraction measurement than gastric sleeve and bypass procedures.

RQ3: What are the relationships between ejection fraction and race, gender, body mass index (BMI), and comorbidities, both pre- and post-operation?

H3.1: There is a significant relationship between race and changes in ejection fraction measurements 1 year postoperative.

H3.2: Men will have a more significant change in their ejection fraction measurements 1 year postoperative when compared to women.

H3.3: There will be a significant relationship between BMI and changes in ejection fraction 1 year post-op.

H3.4: There will be a significant relationship between comorbidities and ejection fraction at 1 year post-op.

Research Design

This research followed a correlational research design in which a retrospective analysis was utilized on a factorial varied subjects group design. The factorial mixed ANOVA design was chosen to assess the statistical relationship between bariatric surgery and EF changes. During this examination, variables such as the procedure (sleeve, bypass, or lap band), race, and gender were compared to understand their relationship with EF changes if they occur. This design is pivotal to understanding how surgically induced weight loss affects cardiovascular functionality, measured explicitly by EF. This design could also provide data that one procedure has more of an impact when compared to the postoperative EF results of other operations.

Summary

To conclude, the obesity pandemic has been identified and continues to be an increasing problem in society. There is evidence of a decrease in the quality of life stimulated by obesity due to its relationship with other cardiovascular diseases. Such results in low EF due to the left ventricle having to overexert itself to support the physiological demands of the obese individual. This research will help improve the understanding between cardiovascular function and bariatric surgery by comparing preoperative and postoperative EF measurements to determine a correlation between them. In return, this research can help fight against obesity and cardiovascular disease by recognizing bariatric surgery as an intervention for both disorders.

Chapter 2: Literature Review

Introduction

This section presents a current literature review focusing on understanding obesity and its impact on cardiovascular functionality. This chapter begins with a brief overview of obesity in the United States and how it affects different populations. Because of obesity's prevalence in society, a discussion of literature will focus on the adult population and what factors contribute to the diagnosis. One of the most critical factors that will be discussed is the impact that obesity has on the cardiovascular system, how they are connected through adverse events, and measuring functionality to assess the cardiovascular state of the individual. In return, this chapter will conclude with literature expanding on the left ventricle, how ejection fraction is measured, the cardiovascular benefits of weight loss, and bariatric surgery.

Numerous methods were used from August 2018 through March 2020 to prepare literature for this review. The research reviewed in this chapter primarily spans over the past 8 years; although, some dated literature will be included to support the foundation of this study. A few online databases, such as MedlinePlus, PubMed, EMBASE, and Cochrane Library, accessed from WellStar Medical Library or JCHS, were searched for relevant literature on obesity, bariatric surgery, lap-band procedures, gastric sleeve outcomes, bariatric outcome comparison, obesity impacts on society, ejection fraction, left ventricular ejection fraction measurements, cardiovascular functionality, obesity impacting the cardiovascular functionality, benefits of bariatric surgery, weight loss impact on the heart, improving cardiovascular disease limitations, and life after bariatric surgery in CVD patients. Searches utilizing Google Scholar were used to locate articles about bariatric surgery procedure types. Moreover, websites such as the World Health Organization (WHO), CDC, and the National Institutes of Health (NIH), were searched for current literature on CVD and obesity.

Obesity Epidemic

The obesity epidemic in the United States is a health crisis that warrants considerable intervention through public policy and medical treatment. Organizations such as the CDC (2017) link a higher or disproportionate Body Mass Index (BMI) of an individual to the potential of suffering from obesity. The CDC (2017) defines BMI as a person's weight (in kilograms) divided by the square of height (in meters). There is an abundance of literature that recognizes the comorbid conditions that define the prevalence of obesity among various population groups in the United States. For instance, Arterburn and Courcoulas (2014) described obesity as a highly prevalent chronic disease that leads to substantial morbidity, premature mortality, impaired quality of life, and excess healthcare expenditures. The scholars highlighted obesity as a case involving a BMI of 35 (or higher) in the presence of comorbid health conditions (hypertension, diabetes, osteoarthritis, and sleep apnea) or a BMI of 40 (or higher) in the absence of comorbidities. Apovian (2016) further posited that all the comorbid conditions associated with obesity can alter how the body functions and stores adipose. Based on the observations of Arterburn and Courcoulas (2014), Ghouri et al. (2018) and Boudina (2019) pointed out that the pervasiveness of obesity in the United States has led researchers to label obesity as an epidemic. Antonelli et al. (2014) clarified the findings of Ghouri et al. (2018) and Engin (2017) by arguing that obesity has compromised the health of many Americans because it connects to a host of health-related problems, one of which is cardiovascular disease (CVD). Along with other bodies of literature on obesity, the findings of the outlined studies will enhance a comprehensive understanding of the epidemic and the need for evidence-based practice to combat its prevalence among U.S. citizens.

Obesity in the United States

In the United States, various organizations, particularly the NIH, have expended more than $1,055 million thus far to eradicate the disease of obesity (NIH, 2019). However, Kim and Basu (2016) argued that such financial expenditures have done little to reduce the pervasiveness and rate of obesity and its associated health consequences. Recent assessments performed by the CDC (2019) demonstrated that the dominance of obesity was about 39.8%, with the related health conditions affecting around 93.3 million adults in the United States between 2015 and 2016. Between 2015 and 2016, obesity prevalence among U.S. adults aged 20 and over indicates that more women than men had obesity, with the crude estimates being 41.5% and 38%, respectively (CDC, 2017). The National Health and Nutrition Examination Survey reported that the age-adjusted occurrence of obesity among U.S. adults, race, and sex, also proved a higher prevalence of obesity among White, Black, Asian, and Hispanic women than men between 2015 and 2016 (CDC, 2017). Generally, the prevalence among adults aged 40–59 (42.8%) was more inflated than among adults aged 20–39 (35.7%). However, there was no significant difference in prevalence among adults aged 60 and over (41.0%) and younger age groups (CDC, 2017). Specifically, African American and Hispanic women are disproportionately affected by obesity, defined as a BMI of 30 or higher. The data findings reported by CDC (2017) were confirmed by the study performed by Hales et al. (2017), which revealed that the prevalence of obesity was 38.0% in non-Hispanic White, 54.8% in non-Hispanic Black, 14.8% in non-Hispanic Asian, and 50.6% in Hispanic women.

Various kinds of literature have addressed the implications of obesity on the affected individuals. In the study done by Knox-Kazimierczuk et al. (2018), obesity is a health condition that affects all aspects of life, including adversely influencing the physical, mental, and financial health of affected persons. CDC (2017) proved Knox-Kazimierczuk et al.'s (2018) suggestions by highlighting the correlation between weight, diabetes, and cardiovascular functionality. The CDC (2017) data defined the relationship by indicating that more than 85.2% of obese persons also have type II diabetes. This strong correlation between obesity, diabetes, and CVD is particularly evident among African Americans. The National Health and Nutrition Examination Survey performed by CDC (2017) found that 46.8% of African Americans 18 years and older are overweight or obese.

Obesity in Adults and Contributing Factors

Various studies have discussed the principal factors influencing obesity prevalence among diverse population groups in the United States. Knox-Kazimierczuk et al. (2018), for instance, contended that a host of factors affects several cases of obesity, with the most common risk factors being inactivity, dietary consumption, socioeconomic status, and the environment. Similarly, the study conducted by Tan et al. (2017) found that the other factors pertinent to the development and persistence of obesity include the environment, access to food, and the availability of entities that promote healthy living, such as gym facilities and weight-loss management programs. However, Bandera et al. (2016) added that an individual's exposure to an unhealthy lifestyle, work-life balance, and lack of physical exercise are critical factors fostering a person's potential to become obese. Although the emerging factors identified by Knox-Kazimierczuk et al. (2018) and Tan et al. (2017) play a crucial role in obesity development, these variables will not be measured individually in this study.

Regarding the U.S. adult population group, obesity has become one of the most challenging issues to address due to the complexity of the disease. As identified by the CDC (2018), obesity is a serious concern because it is associated with adverse mental health issues, quality of life outcomes, and death in the United States and worldwide. On a similar framework, Johnson (2018) identified that the prevalence of obesity nationwide begins with its roots in childhood obesity. Based on the national data provided by CDC (2018), Johnson (2018) contended that about 40% of overweight children (under the age of 18) endure weight problems through adolescence, and 75% to 80% of obese adolescents often become obese adults.

Borgeraas et al. (2018) confirmed the arguments published by CDC (2018) that countless factors influence obesity in adults, including genetics, eating habits, physical activity, and mental health status. McDonald and Bendern (2019) did a study that claimed that the principal contributing factor being examined to understand obesity better is genetics. As stated by the CDC (2018), genes provide the body with directions on responding to the environment's changes. Navarro et al. (2017), however, posited that obesity cannot be considered a genetic disease "per se" because it has a genetic component, with specific associated alleles and alterations. Lotta et al. (2016) confirmed the suggestions of Navarro et al. (2017) that the genetic makeup of obesity controls the storage of fat and stable conditions within the blood flow; hence, it can be traced to specific changes in the expression of genetic regulators. According to Lotta et al. (2016), some variation occurs in individuals' body size and shape within a particular environment. Part of this variation results from genetic factors. Overall, the familial studies conducted by Navarro et al. (2017), Lotta et al. (2016), and Ruderman (2019) proved that BMI is highly correlated with parental obesity.

Numerous other studies highlight the negative implications of obesity on an individual's health condition. Eaton and Eaton (2017) demonstrated that obesity negatively affects a person's activity level by arguing that their predisposition to obesity correlates with their physical activity level and BMI. Pandey et al. (2018) also highlighted that as physical activity increases, fat mass decreases because of increased insulin secretion by the pancreas. In contrast to Eaton and Eaton (2017) and Pandey et al. (2018), Knox-Kasimierczuk et al. (2017) contended that technological advances have mechanized much of the workforce and thus prevented the physical labor that once dominated many jobs, thus limiting the duration spent daily in physical activity, therefore increasing opportunities for snacking on unhealthy foods.

Dietary habits also correlate with obesity in adulthood, mostly when the wrong foods are consumed. A study conducted by Huang et al. (2009) revealed data that suggest poverty in the United States is associated with higher obesity rates. In contrast, in many developing countries, higher rates of obesity are found in higher-income groups due to economic growth and improved living standards. As highlighted by the CDC (2017), obesity prevalence was lower (29.7%) in the highest income populations than in the lowest (45.2%) and middle (42.9%) income groups. The prevalence pattern among women was identified among Hispanic, non-Hispanic Asian, and non-Hispanic White women. Ogden et al. (2017) posited that one explanation for these observations is that high-income groups in the United States can afford or have greater access to energy-dense and nutrient-rich foods. According to Solon-Biet et al. (2014), such foods have increased proportions of sugar, dietary fats, and refined grains, for which the cost has steadily decreased. Huang et al. (2009) noted that the supply of such food items has steadily increased over the last 40 years. According to Hsu et al. (2009), diets with increased nutrient levels have much higher calorie costs. In this regard, poor eating choices are often due to the number of resources available (Huang et al., 2009).

Finally, it is vital to examine the individual's psychological wellness to understand how their behavior can affect weight. Isasi et al. (2015) pointed out that a person's level of psychosocial stress relates to the potential of suffering from obesity through biological and behavioral pathways. Palta et al. (2015) opined that the physiological responses to stress include the activation of neuroendocrine and inflammatory pathways that directly increase fat accumulation, promote visceral adiposity, and release appetite hormones that increase food consumption, leading to a positive energy balance. Like the findings of Isasi et al. (2015), da Costa Louzada et al. (2015) concluded that the body's response to these psychological issues is simply a coping mechanism in which the individual finds comfort in foods. Furthermore, when under stress, as the brain reward system is activated, individuals may prefer more palatable foods richer in sugars and fats, contributing to excess calories (Isasi et al., 2015).

Cardiac-related Effects of Obesity

It is important to note that the connotations for the term CVD apply to many disorders, including congestive heart failure, hypertension, coronary artery disease, and other pathologies. Persons diagnosed with obesity are at increased risk for CVD, which is the leading cause of death worldwide (WHO, 2018). Annually, an estimated 17.9 million people die from CVD, representing 31% of all global deaths, of which 85% of CVD-related deaths are associated with heart attacks or stroke (WHO, 2019). McDowell et al. (2018) observed that the cases of congestive heart failure emanate when a damaged heart muscle cannot maintain enough blood supply throughout the body, leading to various adverse health consequences.

As demonstrated by Nagarajan et al. (2016), obesity-induced hemodynamic and physical deviations on the heart range from an abnormally increased circulatory volume to overt systolic dysfunction. The authors opined that in obesity, excessive adipose accumulation, and fat-free mass result in increased left ventricular (LV) stroke volume, leading to increased systemic blood volume, hyperdynamic circulation, stress on LV walls, and ultimately LV enlargement. In the assessment of Payne et al. (2015), when the LV increases in size (hypertrophy), the heart's movement becomes isokinetic due to the muscle wall of the heart thickening. In this regard, rapid isokinetic behavior is dangerous. It often leads to a heart attack because the body is not receiving the oxygen needed through proper blood flow due to the heart muscle being overworked (Nagarajan et al., 2015). Aronow (2017) clarified that heart attacks could happen in which the tissue begins to die due to a lack of oxygen created by a coronary blockage.

Both obesity and congestive heart failure diminish a person's quality of life. Francis and Tang (2019) found that during obesity and heart failure, various body systems start to overexert themselves in compensation to meet functional demands, leading to congestive heart failure. Similarly, Nieminen et al. (2015) concluded that congestive heart failure is typically chronic and frequently progressive; exacerbated by obesity, heart failure often creates other issues that cause body systems to shut down. Francis and Tang (2019) and Aronow (2017) agreed that acute heart failure is characterized by poor quality of life and frequent hospitalizations. In clinical practice, Nieminen et al. (2015) suggested that the efficacy of treatments for advanced heart failure is often assessed by parameters including clinical status, hemodynamics, neurohormonal status, and echocardiographic and magnetic resonance imaging (MRI) indices. However, Tham et al. (2015) posited that a patient's perspective of his or her life-quality tends to focus on his or her daily functionality, ability to exercise, mental status, and duration and frequency of hospitalization, and these parameters are essential contributors to overall treatment efficacy in advanced heart failure. According to Di Lullo et al. (2015), the effects of various interventions on these quality-of-life parameters are underrepresented in clinical therapeutic trials of advanced heart failure data and are overall scarce.

Obesity and its Connection with Adverse Cardiac Events

In their survey of clinical experts and patients in a U.S. healthcare context, Nystoriak and Bhatnagar (2018) found that the pervasiveness of obesity and its association with cardiac events are primarily due to risk factors associated with metabolic syndrome—dyslipidemia, hypertension, glucose intolerance, and sleep disorders. The assessment of metabolic syndrome by Iyer et al. (2018) had similar findings with Nystoriak and Bhatnagar (2018) that the condition is associated with the type of obesity that affects the abdominal or central areas of the body; such fat is disproportionately distributed to the abdominal viscera. According to the study done by Mozaffarian (2016), the disproportionate distribution of fat caused the development of a large belly. As a result, Nystoriak and Bhatnagar (2018) suggested that measuring the waist circumference and waist to hip ratio are convenient ways of assessing the fat distribution, and when these values are increased, the subject is at increased cardiovascular risk.

At the other end of the spectrum, Mnafgui et al. (2015) suggested that obesity has a cardioprotective effect, in that obese adults with heart failure may have a similar or even lower risk of mortality due to adverse cardiac events than do their normal-weight counterparts. In their study, Brown and Kuk (2015) found that heart failure is a chronic disease state characterized by the inability of the heart to pump blood efficiently. Consequently, some obese adults are better equipped to handle cardiovascular issues as they arise. Besides, Canning et al. (2015) pronounced that obese persons who undergo coronary revascularization have lower risks of in-hospital mortality and adverse cardiac events compared with healthy patients, which reflects the findings of Brown and Kuk (2015) and Canning et al. (2015). Although obesity is a significant risk factor for developing fatal conditions, once the disease is present, obesity may increase survival (Brown & Kuk, 2015).

Lavie et al. (2016) proposed that obesity is a significant risk factor for most CVDs, including hypertension and coronary heart disease, two of the leading contributors to the development of heart failure. Comparatively, Alpert et al. (2016) suggested that obesity directly exacerbates the pathogenesis of heart failure through adverse effects on LV morphology and function. Therefore, according to Lavie et al. (2016), it is unsurprising that the incidence and severity of heart failure are dramatically increased in the setting of obesity. Furthermore, Nystoriak and Bhatnagar (2018) clarified that medical professionals who treat obese patients have difficulty diagnosing CVD because of obesity-associated constraints in performing physical examinations, electrocardiography, imaging studies, and cardiac catheterization. Depending on the amount of fat that a signal must cross, a person’s weight can significantly affect the clarity and thus utility of various imaging studies (Lavie et al., 2016; Myers et al., 2015; Ortega et al., 2016;). About the diagnostic resources available in a medical facility, obtaining an accurate diagnosis regarding CVD can be particularly challenging in obese patients. Gupta et al. (2015) confirmed the conclusions drawn by Nystoriak and Bhatnagar (2018) and Lavie et al. (2016) by arguing that as many as 49% of patients with CVD are obese, and the mortality of obese subjects diagnosed with CVD increases gradually.

Measurement of Ejection Fraction to Assess Cardiovascular Function

Obesity is strongly associated with diastolic dysfunction due to improper filling of the ventricles and abnormalities in the EF parameter (Lee et al., 2016). The American Heart

Association identifies EFs as a valuable gauge in the overall management of CVD patients (Koenig et al., 2014). The amount of the ventricular blood volume that departs the heart each time it contracts measures the effectiveness with which the heart pumps are classified as EF (Kunig et al., 2014). Also, EFs are the most commonly used measure of heart function in patients with cardiovascular-related issues, including chest pain, fluid retention, shortness of breath, and obesity (Sharma & Kass, 2014). Because of its role in pumping oxygenated blood to the body, the LV is the typical site for measuring EFs. A left ventricle ejection fraction (LVEF) of 55% or higher is considered normal; LVEFs of 50% or lower are considered abnormal (Frühbeck, 2015), and obese persons who are candidates for bariatric surgery commonly have LVEFs that are lower than 40% (Clark et al., 2014).

Sepehri et al. (2014) noted that some instruments for measuring cardiovascular functionality are limited in their utility because of how the measurements are susceptible to inaccurate results and thus diagnoses. According to Xu et al. (2014), the most common examples include the existing cuff-based devices for obtaining blood pressure measurements during EF testing procedures. With these devices, Jee et al. (2018) pointed out that blood pressure measurements are obtained by constricting an artery until blood flow is blocked entirely and then slowly releasing the constriction. In other words, the pressure of the pulse alongside the individual’s anatomy can be affected due to arterial restriction. Along with the study conducted by Jee et al. (2018), Kang et al. (2018) mentioned that the diastolic pressure is derived from measurements obtained when the transmural arterial pressure is close to zero, thus implying that those measurements are made under non-physiologic conditions. As a result, the correct analysis of cardiac functionality is essential to ensure accurate results.

The research performed by Ryder et al. (2016) found that EFs can be measured by using several imagining techniques, including echocardiography, cardiac catheterization, nuclear medicine scans, MRI, and computerized tomography. Similarly, Balaji et al. (2015) observed that using sound waves to reveal cardiac wall motion, echocardiography could facilitate the diagnosis of various cardiac abnormalities, including damage or disease of the heart muscle or valves. Echocardiography helps measure and analyze EFs. There are four types of echocardiography: transthoracic, transesophageal, Doppler, and stress (Balaji et al., 2015). Transthoracic echocardiography requires the sonographer to press the transducer firmly against the skin of the chest; the transducer records soundwave echoes from the subject’s heart, and the computer converts the echoes into moving images on a monitor (Balaji et al., 2015; Basha et al., 2018; Ryder et al., 2016). Ryder et al. (2016) and Basha et al. (2018) suggested that transesophageal echocardiography is a test that produces pictures of the heart by measuring the frequency of sound waves that create detailed images of the heart and arteries by passing a transducer through the esophagus. The Doppler echocardiography procedure provides valuable information into cardiac structure and function, mainly supporting the precise evaluation of hemodynamics; Doppler echocardiography can be used to quantify and assess both systolic and diastolic function (Ryder et al., 2016). Stress echocardiography is a procedure for investigating how well the heart and blood vessels function under loaded conditions. In most cases, stress echocardiography does not apply to patients who lack mobility, have cardiovascular issues such as coronary artery disease, or are morbidly obese (Balaji et al., 2015).

Clinical Factors that Could Impact EF

One of the primary variables that has an impact on EF is the subject’s age. In elderly patients, HF is the leading cause of hospitalization and is associated with high morbidity and mortality, resulting in an enormous burden on hospital resources (Veenis et al., 2019). Due to the high prevalence of comorbidities in elderly patients, optimizing HF management remains even more challenging (Veenis et al., 2019). A study identifying heart failure trends identified annual incidence rates per 10,000 person-years declined among older individuals (rates in 1995 versus 2012: 164 versus 115 in individuals >74 years, 63 versus 35 in individuals 65–74 years, and 20 versus 17 in individuals 55–64 years; $P < 0.0001$ for all), but increased among the younger (0.4 versus 0.7 in individuals 18–34 years, 1.3 versus 2.0 in individuals 35–44 years, and 5.0 versus 6.4 in individuals 45–54 years; $P < 0.0001$ for all). The proportion of patients with incident heart failure ≤50 years of age doubled from 3% in 1995 to 6% in 2012 ($P < 0.0001$) (Christiansen et al., 2017). Due to the increase in incidence, it is shown that low EF has a significant impact on all age populations and not primarily the elderly population as it did a couple of decades ago.

Another variable that could impact EF is the gender of the subject. However, there is a limited amount of studies investigating gender comparison amongst low EF patients. Heart failure with preserved ejection fraction (HFpEF) affects more women than men, suggesting gender plays a significant role in disease evolution. Of the 260 HFpEF patients, 181 (69.6%) were female, and 79 (30.4%) were male. The median age of female study participants was 73.0 years (IQR: 67.5–77.0) and 72.0 years (IQR: 66.0–77.0) in men ($p = 0.237$) (Duca et al., 2018). Another study revealed that risk factors act differently in female subjects than males, such as diabetes mellitus confers a 3-fold higher risk of developing HF in women than a 2-fold risk in men (Marra et al., 2018). Obesity is a more common comorbidity, and systemic hypertension is more prevalent in women with HF than men.

On the other hand, the most common cause of HF in men is ischemic cardiomyopathy (Marra et al., 2018). Furthermore, hormones act differently on the cardiovascular system of men and women, ultimately leading to a different structural phenotype of the LV (Marra et al., 2018). While females tend to present with reduced volumes, higher contractility, and concentric remodeling, typically male HF patients are characterized by eccentric remodeling with higher volumes and reduced ejection fraction (Marra et al., 2018).

Lastly, another factor to consider having an impact on EF is the race of the diagnosed individual. Low EF has been known to affect minorities based on current literature, but some studies conflict with this belief. According to a study by Lewis et al. (2018), Black patients with HFpEF, heart failure (HF) with preserved ejection fraction have a higher HF hospitalization risk than non-Black patients. Black HFpEF patients (n = 302) were younger and were more likely to have diabetes mellitus and hypertension than non-Black patients but had similar HFpEF severity (Lewis et al., 2018). Contrarily, a multi-ethnic study of atherosclerosis (MESA) included 6,781 participants (White, Black, Chinese, and Hispanic men and women 45–84 years of age, free of baseline cardiovascular disease) with the primary endpoint was time to the diagnosis of HFpEF (left ventricular ejection fraction ≥ 45%) (Silverman et al., 2016). Over a median follow-up of 11.2 years (10.6 – 11.7), 111 individuals developed HFpEF (cumulative incidence 1.7%), while incidence rates were similar across all races/ethnicities (Silverman et al., 2016). In a race-stratified analysis, the lifetime risk for overall HF was higher in non-Blacks than Blacks (25.9% versus 22.4%) (Pandey et al., 2018). Among HF subtypes, preserved ejection fraction, and reduced ejection fraction, the lifetime risk for preserved EF was higher in non-Blacks than Blacks (11.2% versus 7.7%), whereas that for reduced EF was similar across the two groups (Pandey et al., 2018).

Overview of Bariatric Surgery

According to Hood et al. (2016), bariatric surgery denotes a procedure in which the stomach or intestines are altered to induce weight loss. Aveyard et al. (2016) also contended that bariatric surgery is the most effective approach to achieving significant, long-term weight loss and resolving or reducing comorbid medical conditions. However, Hood et al. (2016) held that bariatric surgery's long-term success is predicated on many problematic behaviors, including regular attendance at follow-up appointments and complying with stringent dietary, exercise, and vitamin recommendations. According to NHLBI (2018), the first line of defense against obesity is a lifestyle change, which is considered the achievement of weight loss through behavioral means. For people who cannot effectively integrate lifestyle changes, the most effective treatment for significant weight loss and weight loss maintenance is bariatric surgery (NHLBI, 2018). In their examination, Arterburn and Courcoulas (2014) outlined the argument that Mason and Ito introduced the gastric bypass surgical procedure in 1969. It was later modified into a Roux-en-Y gastric bypass configuration for drainage of the proximal gastric pouch to avoid bile reflux. Over time, the Roux-en-Y gastric bypass has been refined into its current laparoscopic form, which includes a small proximal gastric bag of 15-20 mL, a regular and smaller gastric-to-intestinal stoma size, and a complete staple line transection to avoid staple line separation or failure (Arterburn & Courcoulas, 2014).

Buchwald (2014) outlined that the following major bariatric procedure introduced in the early 90s was the adjustable form of gastric banding, modified for laparoscopic placement and creates a small superior gastric pouch with a flexible outlet. The elastic gastric band is a silicone belt with an inflatable balloon in the lining that is buckled into a closed ring around the upper stomach (Arterburn & Courcoulas, 2014). The most recent major bariatric procedure to be introduced in 2005 is the vertical sleeve gastrectomy, and it is rapidly increasing in popularity (Buchwald, 2014). This technique consists of a 70% vertical gastric resection, which creates a long and narrow tubular gastric reservoir with no intestinal bypass component (Arterburn & Courcoulas, 2014). The benefits of bariatric surgery are reducing the severity of weight-related diseases and long-term maintenance of average weight loss (Hood et al., 2016).

Ashrafian et al. (2013) proposed that bariatric surgery has become a viable option in obese and morbidly obese persons for whom traditional weight-loss treatments include diet, lifestyle changes, and behavioral therapy. Comprising the bariatric sleeve, the gastric bypass, and gastric lap-band procedures, the scholars argue that bariatric operations were developed to achieve weight reduction and treat obesity and its comorbidities. According to Yousseif et al. (2014), the type of bariatric surgery performed depends on the surgeon's recommendation and reflects the patient's comorbidities present and preference. Makaronidis et al. (2016) advanced the findings of Ashrafian et al. (2013) by proposing that bariatric surgeries are classified as restrictive, malabsorption, or combination procedures. The most commonly used bariatric procedures, lap-band surgeries, are conditional operations that entail a synthetic gastric band's insertion that reduces the size of the stomach (Ashrafian et al., 2013; Makaronidis et al., 2016; Yousseif et al., 2014). Makaronidis et al. (2016) further outlined that malabsorption operations consist of bypassing a portion of the small intestine to limit the body's number of nutrients.

Among the surgical procedures, the smallest treatment effect in weight loss was observed in the lap band, while conflicting results were seen between gastric bypass and gastric sleeve (Kang et al., 2017). In a retrospective review conducted by Barr et al. (2019), various studies and reports identify bariatric surgery as aiding in the success of 40%–71% excess weight loss post-surgery. Within each ANOVA and ANCOVA model in this study, gastric sleeve patients typically had less percent excess weight loss than gastric bypass patients (Barr et al., 2019). Of nine trials (n=765) that reported BMI as one of their outcomes at a year, six trials compared the bypass and sleeve procedure, two trials examined between bypass and lap band, and one trial compared bypass with the sleeve (Kang et al., 2017). The highest BMI reduction was observed in the gastric sleeve, followed by the gastric bypass and lap-band procedure (Kang et al., 2017). The mean BMI reduction was 13.5kg/m2 for RYGB (n=355), 14.4kg/m2 for SG (n=257), and 10.6kg/m2 for LAGB (n=153) (Kang et al., 2017). On the other hand, some studies show that there is not much difference in the procedures after time passes. A two-group randomized trial by Peterli et al. (2018) revealed excess BMI loss was not significantly different at 5 years: for sleeve gastrectomy, 61.1%, in comparison to Roux-en-Y gastric bypass, 68.3% (absolute difference, −7.18%; 95% CI, −14.30% to −0.06%; P = .22 after adjustment for multiple comparisons) (Peterli et al., 2018).

Bariatric Surgery and the Potential to Improve Cardiac Function

Obesity is associated with cardiac dysfunction and increased cardiovascular risk. In their findings, Nakamura et al. (2014) and Aggarwal et al. (2016) concurred that the people who manifest the harmful effects of obesity are more susceptible to heart failure and diminished quality of life. Findings from the Framingham Heart Study suggest an association, 38%, between obesity and heart failure, reporting that obese patients have a higher risk of developing heart failure than subjects with a healthy BMI (Carbone et al., 2017). Heart failure with preserved ejection fraction is more prevalent in women, and it is more characteristically associated with obesity; up to 85% of patients with preserved EF are obese, while in patients with reduced EF, obesity prevalence is usually lower than 50% (Carbone et al., 2017). Along with the findings outlined by Ashrafian et al. (2013) and Aggarwal et al. (2016), bariatric surgery has the potential to improve cardiac structure and functionality in obese persons.

The results of the study conducted by Schauer et al. (2014) highlighted that the three types of bariatric surgery had yielded encouraging results, evident through rapid weight loss, decreased overall morbidity, and improved life expectancy. Besides, long-term follow-up of bariatric patients revealed reductions in long-term healthcare expenses and reduced mortality due to CVD and diabetes (Kwok et al., 2014). Chang et al. (2014) determined that bariatric surgical operations decreased cardiovascular risk in asymptomatic obese patients and reduced cardiac mortality and morbidity in obese patients with established cardiac pathology. Correctly, Benraoune and Litwin (2011) concluded that the degree of weight loss with bariatric surgery relies on the technique applied. Purely restrictive methods, including gastric banding, often generate around 50 pounds of weight loss (47% excess body weight). The scholar further indicated that the Roux-en-Y method is usually linked with about 100 pounds of weight loss (62% of excess body weight). In the research conducted by Kaiser et al. (2014), a population of 52 consecutive patients who underwent laparoscopic sleeve, gastrectomy, or gastric bypass surgery was examined through conventional 2D and 3D echocardiography before and at 6 months after the procedure. Hübner et al. (2015) also found that the postsurgical imaging revealed substantial, beneficial remodeling of the volumes and masses of both ventricles.

The propositions of De La Garza et al. (2017) outlined the existence of a robust correlation between obesity bariatric surgery and changes in ventricular function/structure. Compared with the study performed by De La Garza et al. (2017), Vest et al. (2016) found that the left ventricular systolic dysfunction (LVSD), meaning an EF less than 40%, group (about 2,588 respondents) had an increased prevalence of obesity comorbidities in the baseline as well as a slight excess of early myocardial infarction and postoperative heart failure. Vest et al. (2016) found that clients with LVSD attained commendable weight loss, with a decrease in mean of about 22.6% and a lack of evidence of mortality in a 1-year duration. De La Garza et al. (2017) conducted a study in which 57 patients diagnosed with morbid obesity underwent echocardiography before and after bariatric surgery. Within 3.6 years, LV mass and the LV mass index had decreased in patients who had undergone weight loss from bariatric surgery (De La Garza et al., 2017). In other words, the LV had been reduced in size, thus decreasing the likelihood of mortality due to the heart overworking to compensate for wall thinning. Conversely, Vest et al. (2016) recommended that patients who had not undergone bariatric surgery showed increased LV size according to these same two metrics. Apart from De La Garza et al. (2017), almost all the findings in this research concluded that although patients who had undergone bariatric surgery did not demonstrate significant changes in EF, their weight loss influenced beneficial changes in LV structure independent of those in obesity-related comorbidities.

Labbe et al. (2014) conducted a study to determine whether weight loss achieved through diet and exercise would decrease glucose intolerance and cardiovascular functional abnormalities over 3 years. Considering the various frequencies of diagnosis between the control and treatment groups, the period to the onset of diabetic cases over 160 weeks in all randomized trials was 2.7-fold longer with liraglutide than with placebo (Le Roux et al., 2017). Specifically, the confidence interval (95%) was 1.9 to 3.9, with a p-value being <0.0001. According to Le Roux et al. (2014), the data corresponds with a 0.21 hazard ratio (confidence interval of 95%). In Labbe et al. (2014), whereas LV end-diastolic volume did not differ, LV end-systolic volume (that is, the residual amount in the ventricle after valve closure) decreased significantly lifestyle intervention leading to increases in LV stroke volume, cardiac output, and cardiac index.

Furthermore, blood flow and oxidative metabolic indexes from acetate kinetics decreased significantly during follow-up, indicating improved oxygenation efficiency throughout the body (Labbé et al., 2014). According to Serhiyenko and Serhiyenko (2018), however, heart rate, systolic and diastolic blood pressure, and the rate pressure product remained unchanged. Labbe et al. (2014) demonstrated that modest reductions in weight and waist circumference induced through lifestyle changes were associated with marked improvements in cardiac function and metabolism in subjects with impaired glucose tolerance. According to the identified shreds of research, these remarkable changes were associated with a significant reduction in myocardial partitioning of dietary fatty acids, decreasing the overflow of metabolized triglycerides around the heart.

Saur et al. (2014) highlighted the benefits of bariatric surgery on cardiovascular risk factors, such as LV hypertrophy. In bariatric patients, the postoperative resolution of diabetes, hypertension, and hyperlipidemia resulted in an overall 10-year reduction in coronary heart disease (Saur et al., 2014). In particular, Saur et al. (2014) contended that the non-surgery control group experienced 234 adverse cardiac events and 49 cardiovascular deaths compared with 199 incidents and 28 deaths in the surgery group. Svane et al. (2016) examined how bariatric surgery affected cardiovascular functionality in people with diabetes by linking the procedure to reducing fatal myocardial infarctions. Insulin resistance at baseline rather than BMI predicted the beneficial effects of bariatric surgery (Saur et al., 2014).

Furthermore, bariatric surgery reduced cardiovascular events at 13 years postoperatively in patients with type 2 diabetes compared with the control group (Svane et al., 2014). In this regard, the highlighted studies reiterate the benefits of bariatric surgery after weight loss. Surgically induced weight loss increases the individual’s quality of life postoperative by minimizing the complications of obesity, such as diabetes and decreased cardiovascular functionality.

LVEF after Bariatric Surgery

Due to a lack of compliance from patients who undergo bariatric surgery, little data regarding postsurgical effects of LVEF are available. Lee et al. (2016) posited that patients miss follow-up appointments after reaching the desired weight loss or when weight loss reaches the lowest level. Whereas normal EFs range between 55% and 70%, those before bariatric surgery typically fall around 35% or less, indicating moderately to severely diminished pumping ability of the heart (Lee et al., 2016). In the study performed by Lee and Cha (2016), obese persons with abnormal LVEFs tended to experience shortness of breath, the inability to exercise, swelling of the feet and lower legs, fatigue, weakness, irregular heartbeat, abdominal discomfort, and mental confusion. The current study aimed to measure EF before and at 1 year after bariatric surgery and evaluated the significance of the difference in these values. Following the research findings of Wang et al. (2016), bariatric surgery might be considered a treatment for chronic heart failure in obese patients if beneficial changes occur. However, bariatric surgery is not widely popular as a therapeutic option among physicians because many view it as only a “quick fix” for obesity without realizing the physiologic benefits of bariatric procedures (Lee et al., 2016).

The systematic review conducted by Aggarwal et al. (2016) revealed a modest yet significant increase in LVEF after bariatric surgery, with high heterogeneity between studies. Zevin et al. (2012) also contended that the intentional weight reduction in obese patients led to decreased total and circulating blood volume, LV stroke volume, cardiac output, LV stroke work, and LV work. Intentional weight loss was often accompanied by a decrease in mean arterial pressure in hypertensive obese patients, but effects of intentional weight loss on systemic vascular resistance and pulmonary hemodynamics were variable (Lavie et al., 2014).

Leung et al. (2016) evaluated the gastric sleeve procedure to determine whether the subjects, who were obese and diabetic, showed improved LV function. The findings of Leung et al. (2016) indicated the average weight loss was about 28(±16)kg, with BMI reducing to 35(±6)kg/m2 from 44(±9)kg. The significance of the study was demonstrated by the p-value of 0.001. Overall, the study revealed that postoperative improvement in LV systolic function was independent of the postoperative decrease in HbA1c levels but paralleled the degree of weight loss. The higher the reductions in weight and HbA1c levels were, the more significant the improvements in LV diastolic function during follow-up were (Leung et al., 2016). Furthermore, the decrease in final HbA1c concentration and weight loss had equivalent effects on decreasing the LV filling pressure. In summary, when combined with diet and lifestyle changes, sleeve gastrectomy resulted in substantial weight loss, supported proportional improvements in both LV systolic and diastolic function, and promoted a decrease in LV filling pressure (Leung et al., 2016).

Literature Review Summary

In summary, the literature review highlights the impact that obesity has on society from a national level. The analysis explained factors contributing to the prevalence of obesity in adults and affect their quality of life. One of the main aspects impacted is their cardiovascular functionality due to CVD. As a result, the literature review expands on bariatric surgery as an intervention in obese subjects and the impact that weight loss has on the workload of the cardiovascular system. Overall, a collection of the research submitted in the literature review section suggests that cardiac structure and function are consistently impacted after bariatric surgery.

One study in particular provided evidence of bariatric surgery being associated with significant improvements in the weighted incidence of several cardiac indices, including a decrease in the left ventricular mass index (11.2%, 95% confidence intervals [CI] 8.2–14.1%), left ventricular end-diastolic volume (13.28 ml, 95% CI 5.22–21.34 ml), and went atrium diameter (1.967 mm, 95% CI 0.980–2.954) (Aggarwal et al., 2016). There were beneficial increases in left ventricular ejection fraction (1.198%, 95% CI −0.050–2.347) (Aggarwal et al., 2016). These broadly beneficial effects include statistically significant changes in cardiac geometry, diastolic function, and systolic function that emerge after substantial weight loss and that are apparent through diverse cardiac imaging modalities, including echocardiography and MRI (Aggarwal et al., 2016). In the context that weight loss contributes to improving cardiovascular functionality over time, the proposed study assesses the effect of weight loss explicitly due to bariatric surgery on EF. This research will mainly determine the relationship between the type of bariatric procedure performed and EF 1 year after surgery. It will evaluate the extent to which cardiac effects parallel weight loss. The proposed study’s findings will promote understanding of EF changes, if any, postoperative bariatric surgery.

Chapter 3: Methodology

This chapter provides an overview of the methods and procedures used in this study and includes a description of the research design, population, instruments, data collection procedures, and data analysis strategy.

Research Design

The study followed a retrospective cohort study using a 3x2 factorial mixed subjects' design. This design was chosen to separate subjects' ability by comparing ejection fraction pre- and postoperative to the three procedure types. This group design aimed to examine if the bariatric interventions (bariatric sleeve, bypass, or lap band) affect ejection fraction induced by weight loss 1 year postoperative. The pretest data from the cohort included the EF measurements of each study participant before bariatric surgery, while the posttest cohort consisted of all EF measurements 1 year postoperative. The primary purpose of this study was to compare preoperative ejection fraction measurements to the posttest to identify any differences that may have occurred after bariatric surgery. The significance of the differences was also compared across different participants' conditions such as gender, number of comorbidities, and type of surgical procedure.

The study utilized data gathered from the EClinicalWorks (ECW), an electronic medical record system used by private practice. Three years of data, January 2016-2019, were examined to gather data for the pre- and postoperative EF measurements. There were approximately 1,560 total bariatric surgeries (not just cardiovascular patients) that the surgeons within the practice performed during this review period. Out of 1,560, there were only 85 subjects who met the inclusion criteria required for this study. Nine possible subjects failed to meet the inclusion criteria because they had CHF with a normal EF. Also, 27 subjects met the inclusion criteria but received an open-heart procedure during the bariatric process. There were 33 patients who never completed their post-op stress test or were noncompliant with the bariatric follow-up program after their 6-month follow-up.

Target Population

The retrospective analysis utilized data from a private bariatric practice in which the researcher served as a cardiovascular specialist. The practice is in Atlanta, Georgia, and has served the bariatric community for over 20 years. Given the researcher's professional connection to the organization and the data accessibility, private practice patients represent a sample.

The bariatric practice's sample population consists of a mixture of male and female subjects between the ages of 16 to 70 with and without comorbidities. The sample methodology included dividing the entire low ejection fraction bariatric population (18+ years of age) into subgroups (based on the surgical procedure received). Therefore, subjects who met the inclusion criteria were utilized for this study. The inclusion and exclusion criteria are discussed in more detail later in the Sample Size section.

Sampling

The private practice's bariatric population was determined based on parameters set by the researcher, as follows:

Inclusion Criteria. The selected subjects were a minimum of 18 years of age and had received their bariatric procedure laparoscopically within the past 3 years (2016-2019). Due to data accessibility, 3 years of data were utilized due to the practice's transition to a stand-alone electronic medical record (EMR) system in 2016 because they were no longer affiliated with a local hospital. This transition assisted with having accessibility to data without going through the hospital's IRB process, which can be very time-consuming. Subjects who qualified for the study had to have a body mass index (BMI) greater than 35, which guaranteed the patient had been diagnosed with morbid obesity before bariatric surgery. The National Institute of Health advocates a BMI of 35 with comorbid conditions for gastric bypass procedures (NIH, 2018). Furthermore, patients were deemed eligible for the study if they had echocardiograms within 60 days of their surgical operation and up to 30 days postoperative for their final EF measurement as required by their insurance for cardiovascular clearance. All inclusion criteria are summarized in Table 1.

Furthermore, subjects were excluded if they received any type of cardiovascular intervention during their bariatric treatment process. Subjects diagnosed with CHF but exhibited a normal EF were also excluded from this study. Lastly, subjects who were non-compliant with their follow-ups post-op were excluded from this study due to the lack of required data.

Table 1

Inclusion Criteria and Justification

Inclusion criteria	Justification
Over the age of 18	-Minimum age required at the practice to receive bariatric surgery. -Bariatric surgery is often seen as the treatment of last resort for adolescence (<18) (Santos et al., 2019)
Received laparoscopically bariatric surgery within the 3 past years	A 3-year range is due to the private practice's implementation of the custom electronic health record system.
Subjects diagnosed with heart failure with a low ejection fraction before the surgery	The patient must be cleared from a cardiology standpoint to ensure that they will tolerate the surgery and recovery.
Subjects with a BMI higher than 35	Standard-based off insurance criteria and Considered Class I Obesity (Aminian et al., 2018).
Subjects who have had echocardiograms within 60 days of their operation	Insurance requirement
Subjects without diastolic HF	Heart failure without an impacted ejection fraction impact will not be beneficial for this study

Sample Size

Due to a lack of literature on EF changes pre- and postoperative bariatric surgery, it was determined that a power analysis was not available to decide on the desired sample size. As a result, the researcher benefited from a sample of general subjects, using as many as possible to analyze the inclusion criteria. There was no difference in cost to include all of the patients compared to some of the patients. Thus, it was better to have as much data as possible with an unknown effect size to ensure that even minor effects can be detected.

Ethical Protocol for Subject Acquisition (IRB)

Data accessibility was approved and granted by the surgeons and bariatrician who serve as the clinical review personnel. The HIPPA Privacy Officer authorized access to the data and patient information, and permission was granted through consent forms signed by the participating subjects before testing, lucidly stating that results may be used for research purposes. All patient data was de-identified by the researcher and the HIPPA Privacy Officer before the study to ensure that patient confidentiality was respected.

Data Collection

Identification of subjects was gathered through EclinicalWorks (ECW), the electronic medical record system that can isolate patients based on desired criteria and place information into a spreadsheet. By adjusting the subject parameters in ECW with the assistance of an ECW computer engineering representative, the template isolated patients into a spreadsheet who had been diagnosed with heart failure (HF) before their surgery date. However, not all patients with HF have low EF measurements, so it is essential to ensure that only subjects with an EF of less than 50% (considered low EF) are used for sampling. HF with preserved ejection fraction, also referred to as diastolic HF, causes almost one-half of the 5 million cases of HF in the United States (Gazewood & Turner, 2017). It is more common among older patients and women and results from abnormalities of active ventricular relaxation and passive ventricular compliance, leading to a decline in stroke volume and cardiac output (Gazewood & Turner, 2017). Each chart was reviewed individually by the researcher and ECW representative to ensure patients' EF measurements were considered low by the usual standards established by the American Heart Association of <50% before the bariatric procedure. This list was then referenced for inclusion criteria, and those who met those standards had their data extracted and placed into an excel document from ECW.

Table 1.2

Subject Extraction Process

1. ECW (the EMR system) will be utilized to gather all bariatric patients from 2016-2019.
2. Subjects from that list will be isolated using ECW by implementing inclusion criteria, which will create an entirely new list.
3. ECW will then generate this patient population into an excel file based on variables selected by the researcher (procedure type, gender, BMI, comorbidities race, EF measurements pre- and post).
4. The Excel file will be converted to SPSS for the analysis.

Although specifics vary depending on local coverage mandates, many insurance carriers require significant preoperative measures such as supervised diets, specialist evaluations, and laboratory testing before patients undergo bariatric surgery (Love et al., 2017). The preoperative EF measurements for this study were gathered no more than 60 days before the patient's bariatric procedure, primarily because insurance only allows a 2-month expiration on cardiac clearances before surgery. Subjects would have had to get retested if they did not utilize the cardiac consent from the exam within the 60 days of receiving the preoperative procedure measuring LV function to determine EF. On the other hand, the postoperative EF measurement was gathered within 30 days of the subject's 1-year postoperative appointment. A 30-day window was applied to ensure that the data was within the years' time frame, which is that patients typically lose the most weight within their first year post-surgery. Subjects utilized in this study had undergone a chart review by the surgeon, cardiologist, and fellow before bariatric surgery to identify any interventions and procedures that could affect their EF that may have occurred during the pre- and postoperative measurements. This exclusion was vital because if a subject has had a heart transplant or other types of interventions, this will likely change the physiology of their heart, leading to a difference in EF percentages. For exclusion purposes, comorbidities and any additional cardiovascular procedures were analyzed during the chart review to ensure that the patient had not had any invasive cardiovascular procedures such as a bypass or transplant, which could contaminate the data results.

The echocardiogram results were gathered from the list of subjects with CHF who qualified for the study. To accurately collect this data, the pre- and postoperative echo results were based on sex (male or female), age (compared between subjects within ±10 years age difference), and obesity (BMI ≥35 kg/ m^2) with a low preoperative measuring EF (<50%). The echocardiograms were individually measured and monitored by a cardiologist during preoperative and postoperative appointments to calculate the ejection fraction. The entire data set was analyzed in SPSS v 24 and coded for data extraction, as displayed in Table 2.

Table 2

Codebook for Bariatric Data Extraction

Value	Label
Gender	
1	Male
2	Female
Age	The number will be based on the age of the subject during the pre-op measurement.
BMI (Pre-/Post)	
Exact BMI#	The number will vary per subject.
Race- Black compared to other races.	
1	White
2	Black
3	Asian
4	Hispanic or Latino or Spanish Origin
5	Two or More Races
CMOR (Comorbidities)	
1	One comorbidity
2	Two or more comorbidities
EFPRE (Pre-operative EF Measurement)	
EFPOST (Post-operative EF Measurement)	The number will individually be based on ejection fraction measurement of each subject before and after
Direct ejection fraction measurement	
BARIPT (Bariatric Procedure Type)	
1	Bariatric sleeve
2	Gastric Bypass
3	Lap band

The instrument variable and coding in Table 3 illustrate how bariatric subjects with low ejection fractions are represented in Excel from ECW, the electronic medical record system used by the practice. The table categorizes data based on the subject, BMI, race, and pre- and post-EF.

Table 3

Instrument Variable and Coding

Field name	Data Type	Field Size	Data Format	Description	Example
PatientID	Text	5	LLNNN	Unique record of each patient	GS001
Age	Number	2	NN	Age of during research	24
Gender	Text	1	L	Gender of the subject	M
CMOR	Number	1	N	Number of comorbidities the subject is diagnosed with before surgery	1
BMI	Number	2	N	Body mass index of Pt	42
Race	Number	1	N	Ethnicity of Subject	2
EFPRE	Number	2	N	Pre-op EF measurement	34
EFPOST	Number	2	N	Post-op EF Measurement	42
BARIPT (Procedure type)	Number	1	N	Procedure type represented by a number (1 = sleeve, 2 = gastric bypass, 3 = band)	1

Data Analysis Strategy

First, the data were examined for outliers, data that varies notably from other observations, and missing data issues were appropriately handled. An imputation procedure was used if more than 5% of the cases were absent in one or more variables. With 5% or fewer cases, missing data can just be disregarded (Tabachnick & Fidell, 2007). The sample used in the study was also assessed for sociodemographic aspects such as gender and age. Descriptive statistics (mean, standard deviation, etc.) were evaluated in these cases.

After these initial analyses, the hypotheses of the study were assessed. A 3x2 ANOVA was used to evaluate the primary theory in which procedure type (3) signifies a between-subject variable while time represents the within-subjects variable (2). Therefore, time was the main effect being tested in Hypothesis 1 to determine if there was a change in EF from pretest to posttest (H1). The Procedure X Time interaction was used to test for Hypothesis 2.1 and 2.2.

Regarding H3.1, the subject's race was added to the two-way design to examine its effects on data, resulting in a layout following Procedure X Time X Race design. Subjects were evaluated based on being Black in comparison to other races. The same strategy was applied to gender in H3.2, adding gender to the two-way design and examining its effects following a Procedure X Time X Gender design. The exact process was also applied to gender in H3.3, adding BMI to the two-way design and examining its effects following a Procedure X Time X BMI design. Lastly, this strategy was used in H3.4, adding comorbidities to the two-way design and studying its impact following a Procedure X Time X comorbidities design. If needed, the single df test or Tukey b test was implemented to examine interactions and effects in greater detail. The assumptions of ANOVA were tested before conducting the tests, which were homogeneity of variances, normality, multicollinearity of dependent variables, and outliers. Violations of any assumption were appropriately handled (Hair et al., 2014).

In summary, the statistical techniques applied to the test of the different hypotheses are summarized in Table 4.

Table 4

Data Analysis Strategy

Hypotheses	Statistical method	Dependent variable(s)	Independent variable (s)
H1: There is a significant difference in EF measurements before and 1 year post-op.	ANOVA	EFPRE EFPOST	EFPRE vs. EFPOST (Time)
H2.1: Subjects who undergo the sleeve will display changes in ejection fraction measurements compared to those who do not.	Mixed between-within subjects' ANOVA	EFPRE EFPOST	EFPRE vs. EFPOST X BARIPT (Type of bariatric procedure and time)
H2.2: Subjects who undergo the gastric bypass procedure will have the most increase in ejection fraction measurement than gastric sleeve and lap-band techniques.	Mixed between-within subjects' ANOVA	EFPRE EFPOST	EFPRE vs. EFPOST X BARIPT (Type of bariatric procedure and time)
H3.1: There is a significant relationship between being Black and changes in ejection fraction measurements 1 year postoperative.	Mixed between-within subjects' ANOVA	EFPRE EFPOST	EFPRE vs. EFPOST X BARIPT X Race (Time X Race interaction)
H3.2: Men will display more change in their EF measurements due to more weight being 1 year loss post-op than women.	Mixed between-within subjects' ANOVA	EFPRE EFPOST	EFPRE vs. EFPOST X BARIPT X Gender (Time X Gender Interaction)
H3.3: There will be a significant relationship between BMI and changes in ejection fraction 1 year post-op.	Mixed between-within subjects' ANOVA	EFPRE EFPOST	EFPRE vs. EFPOST X BARIPT X BMI (Time X BMI Interaction)
H3.4. There will be a significant relationship between comorbidities and	Mixed between-within	EFPRE EFPOST	EFPRE vs. EFPOST X BARIPT X COMORBIDITIES

ejection fraction at 1 year post-op.	subjects' ANOVA		(Time X Comorbidities Interaction)

The techniques presented in the table above are all parametric (i.e., the dependent variable should be normally distributed). If the distribution of EF ends up being non-normal, the non-parametric alternatives were used instead (Friedman's test instead of ANOVA).

Chapter 4: Results

In total, 85 bariatric subjects were utilized for the overall data analysis to complete this study. All of these patients were diagnosed with CVD with a low EF before their bariatric procedure. This section will reveal whether the data is significant or insignificant based on the given hypothesis. Each hypothesis was tested for normality, and a post-hoc test was executed when acceptable. A p-value (represented by Sig in Figure 1.2) larger than 0.05 indicated non-significance.

An Overview of the Sampled Population

Using the office-based computer software and a thorough chart review of the researcher and HIPPA privacy officer, a sample population for this study was gathered (N = 85). For the analysis of the data, subjects were separated based on procedure type in which the gastric sleeve procedure recipients were composed of the most available subjects amongst the group (n = 37), followed by the gastric bypass (n = 36) and lap-band (n = 13) procedure recipients. From a gender perspective, male subjects (57%) trumped their female counterparts (43%).

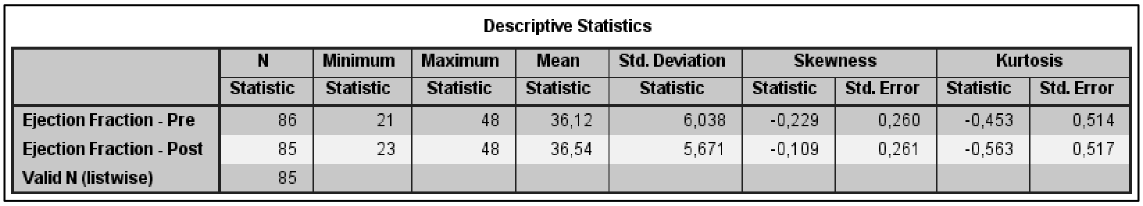
The overwhelming majority of subjects (44%) were Black, followed by White (35%), Asian (14%), Hispanic (4%), and Biracial (3%) participants. In reference to the number of comorbidities the subject was diagnosed with before their bariatric procedures, subjects with two or more diagnoses led the group (49%), followed by those with one comorbidity (44%) and concluded with those with no comorbidities (7%). Lastly, subjects were categorized based on their age range, in which subjects between the ages of 18-29 (n = 27) accounted for most subjects. Following this age group were subjects between the ages of 40-49 (n = 22), ages 30-39 (n = 19), ages 50-59 (n = 13) and concluded with subjects ages 60-69 (n = 5).

Normality Check

One of the assumptions that mixed ANOVA models have is that variables' scores follow a normal distribution. However, it should be noted that ANOVA is relatively robust when the assumption of normality is violated (Skidmore & Thompson, 2013). One of the methods to assess normality is to look at values of skewness and kurtosis. Both values should remain between -1 and 1 to indicate normality. As shown in Figure 1 below, no values surpass this threshold, which means no significant deviation from a normal distribution.

Figure 1

Testing for Normality



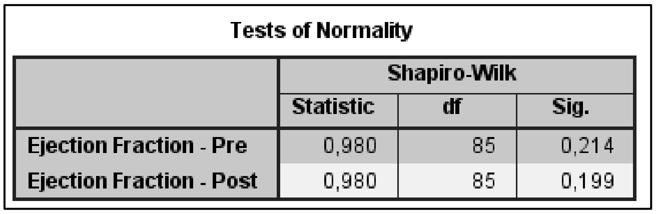
Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation	Skewness		Kurtosis	
	Statistic	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Std. Error
Ejection Fraction - Pre	86	21	48	36,12	6,038	-0,229	0,260	-0,453	0,514
Ejection Fraction - Post	85	23	48	36,54	5,671	-0,109	0,261	-0,563	0,517
Valid N (listwise)	85								

A Shapiro-Wilk test showed a non-significant depart from normality for pre, W(85) = 0.980, p = 0.214, and post scores, W(85) = 0.980, p = 0.199 (see Figure 1.2).

Figure 1.2

Testing for Normality- SW



Tests of Normality

	Shapiro-Wilk		
	Statistic	df	Sig.
Ejection Fraction - Pre	0,980	85	0,214
Ejection Fraction - Post	0,980	85	0,199

The following two histograms, Figure 1.3 and Figure 1.3.1, were plotted to allow a broader visualization of the distribution of ejection fraction scores. The bars show the frequency of individuals that fall under certain intervals of values.

Figure 1.3

Normality Distribution

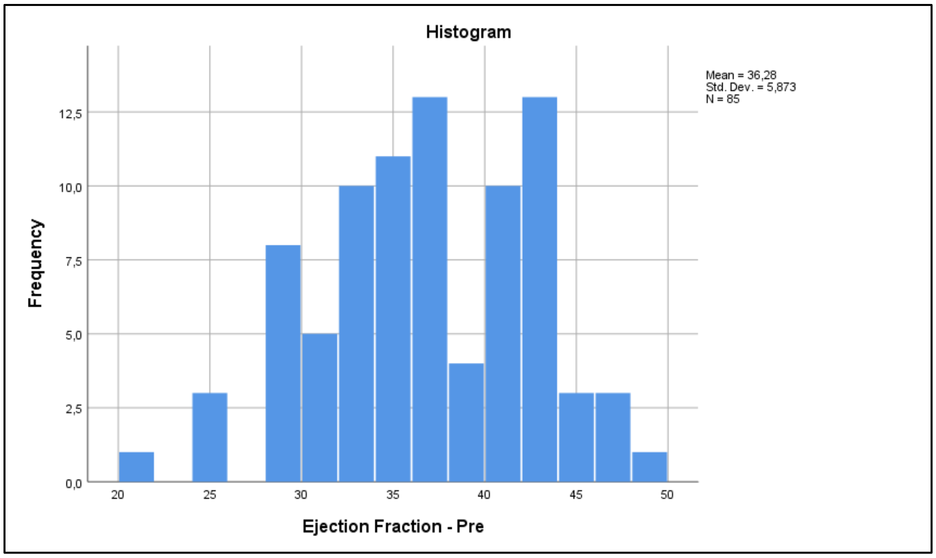
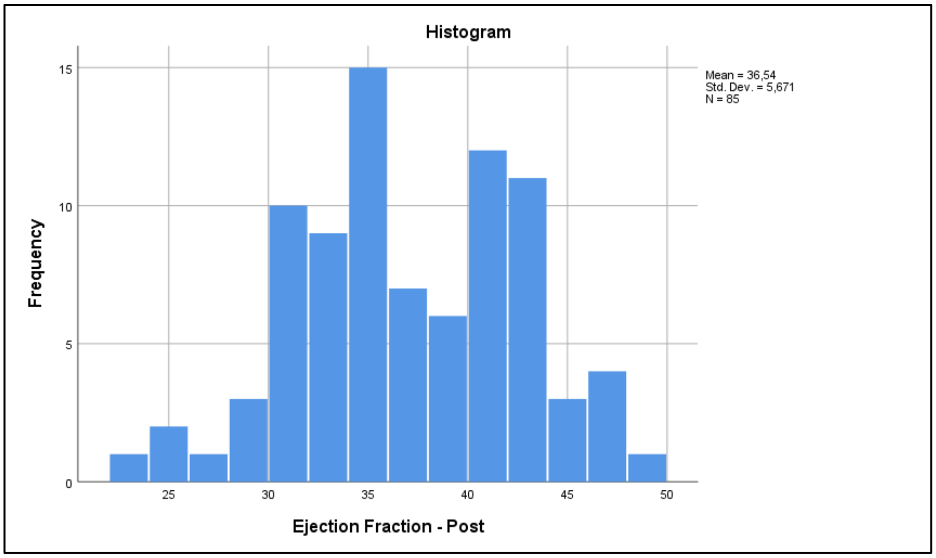


Figure 1.3.1

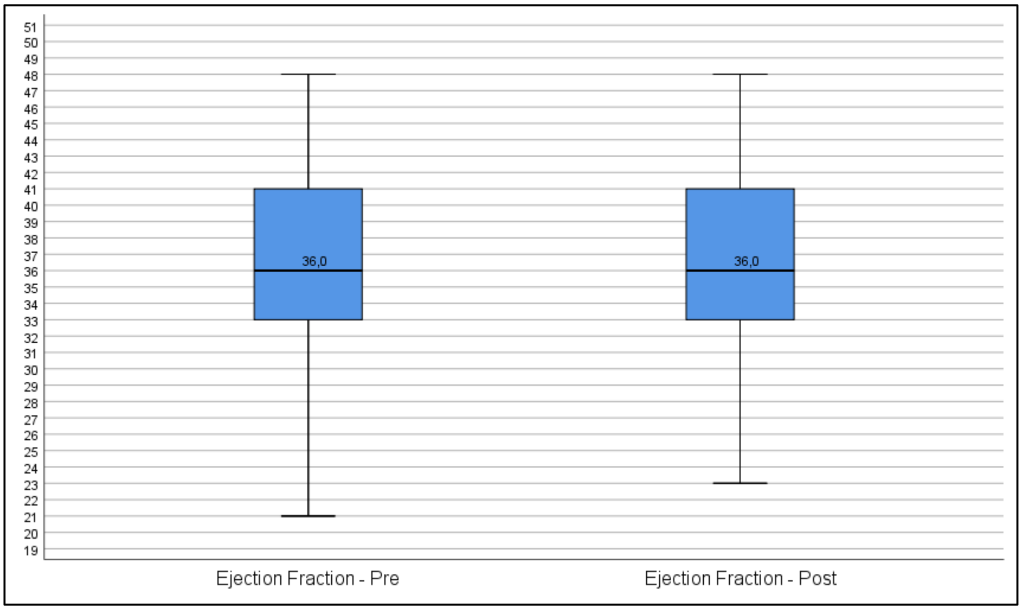
Normality Distribution



The second type of data distribution visualization used was a box plot, as shown in Figure 1.4. No outliers are present for both variables, and values are distributed between around 20 to around 48 in both scales. The median (36.0) is the same in both cases.

Figure 1.4

Normality Box Plot



By confirming normal distribution by testing for normality, the hypothesis testing was the next step of the analysis process. The following section will examine each theory, test for normality, and utilize graphs and figures to visualize the tested hypothesis. If necessary, a post-hoc test was also implemented for the given theory.

Hypotheses Testing

H1: There is a significant difference in EF measurements before and 1 year post-operation.

The results from the pre-operation (*M* = 36.12, *SD* = 6.038) and post-operation (*M* = 36.54, *SD* = 5.671) ejection fractions indicate that the ejection fraction does not change significantly from the pre-op measurement to the post-op measurement, as shown in Figure 1 and Figure 1.2.

H2: There are significant differences in EF measurements before and 1 year post-operation between bariatric procedures.

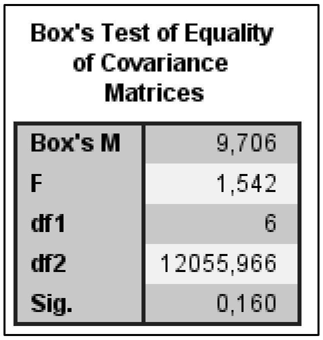
In addition to normality, two additional assumptions are present in the mixed ANOVA method: homogeneity of intercorrelations and equality of variances.

For all levels of the between-subjects factor (in this case, the different bariatric procedures), variances and intercorrelations of the pre-and post-operation scores must be homogeneous. Homogeneity of intercorrelations is tested using Box M's test (see Table H2), of which results should not be significant under the 1% significance level (Pallant, 2010).

The execution of the test indicated the assumption was not violated, Box's M (6) = 9.706, p =.160. Homogeneity of variances, in its turn, is tested with Levene's test (see Table H2-1) (Levene, 1961), and the results should not be significant as well. Results were non-significant for pre-ejection fractions, F = .003, p = .997, as well as post-op, F = .587, p = .558 (see Table H2-1).

Table H2

Box M Test

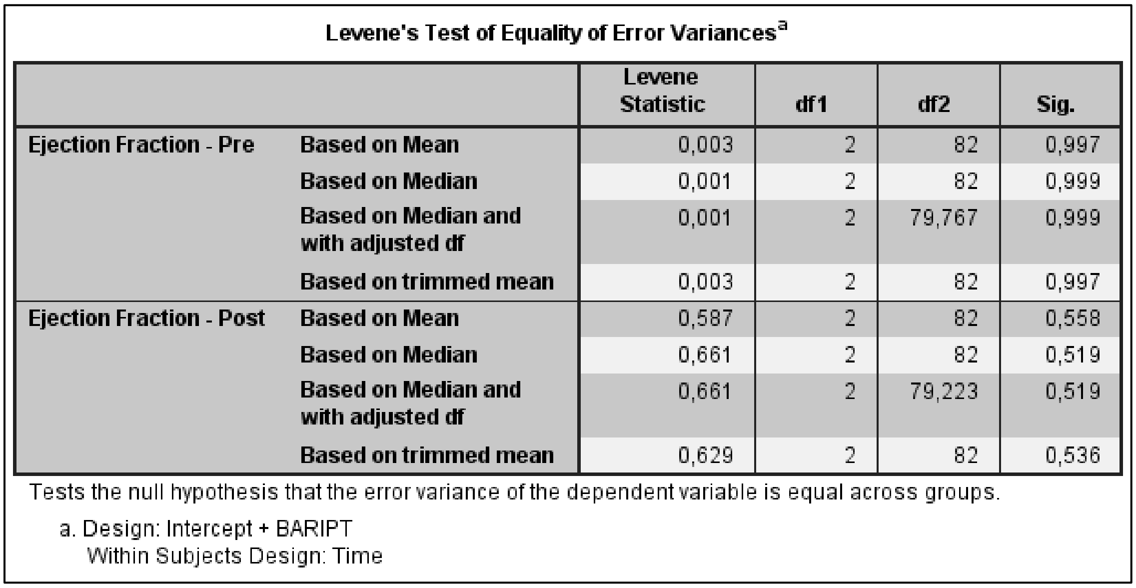


Box's Test of Equality of Covariance Matrices

Box's M	9,706
F	1,542
df1	6
df2	12055,966
Sig.	0,160

Table H2-1

Levene's Test



Levene's Test of Equality of Error Variances[a]

		Levene Statistic	df1	df2	Sig.
Ejection Fraction - Pre	Based on Mean	0,003	2	82	0,997
	Based on Median	0,001	2	82	0,999
	Based on Median and with adjusted df	0,001	2	79,767	0,999
	Based on trimmed mean	0,003	2	82	0,997
Ejection Fraction - Post	Based on Mean	0,587	2	82	0,558
	Based on Median	0,661	2	82	0,519
	Based on Median and with adjusted df	0,661	2	79,223	0,519
	Based on trimmed mean	0,629	2	82	0,536

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + BARIPT
Within Subjects Design: Time

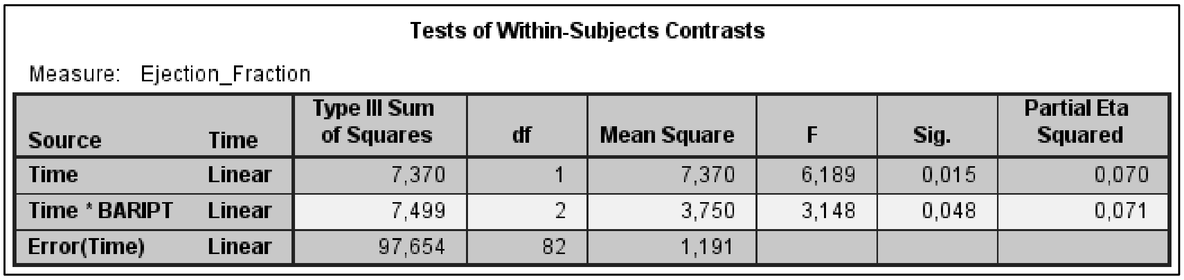
With regards to the results of the between-within-subjects ANOVA, there was a significant interaction between time and bariatric procedures, F (2, 82) = 3.148, p = .048, η_p^2 = .071 (first figure below). The effect size (partial eta squared - η_p^2) has the following thresholds (Cohen, 1988):

- 0.01: small effect.
- 0.06: medium effect.
- 0.138: large effect.

The interaction effect size can be considered slightly higher than the medium. A significant interaction means that the differences in EF measurements between pre- and post-operation are significantly different between distinct types of procedures overall. The main effect of Time (without considering type of procedure) was also significant (see Table: H2-2), F (1, 82) = 6.189, p = .015, η_p^2 = .070.

Table H2-2

EF Within-Subjects Contrast



Tests of Within-Subjects Contrasts

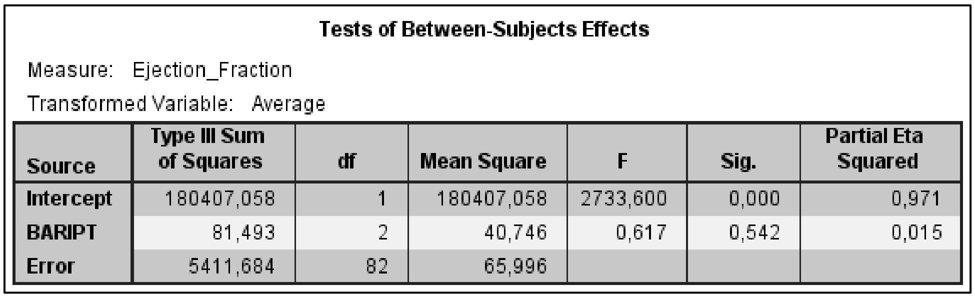
Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Linear	7,370	1	7,370	6,189	0,015	0,070
Time * BARIPT	Linear	7,499	2	3,750	3,148	0,048	0,071
Error(Time)	Linear	97,654	82	1,191			

The main effect of bariatric procedure on EF measurements (without considering time) was not significant, F (2, 82) = 0.617, p = .542, η_p^2 = .015 (see Table H2-3).

Table H2-3

EF Between-Subjects Effects



Tests of Between-Subjects Effects

Measure: Ejection_Fraction

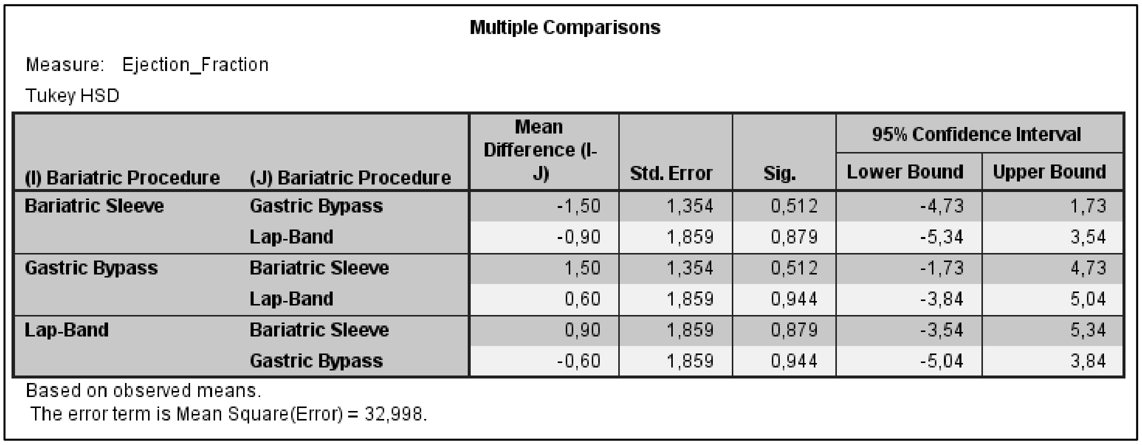
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	180407,058	1	180407,058	2733,600	0,000	0,971
BARIPT	81,493	2	40,746	0,617	0,542	0,015
Error	5411,684	82	65,996			

The figure below (see Table H2-4) is a post-hoc test to evaluate whether there are differences in the effect of time on EF measurements between pairs of bariatric procedures. Essentially this is aimed at understanding where the differences are demonstrated. The figure shows no significant differences between operations teams, meaning that statistical significance was revealed only when comparing the global effect or the three procedures together.

Table H2-4

Post-Hoc Test



Multiple Comparisons

Measure: Ejection_Fraction
Tukey HSD

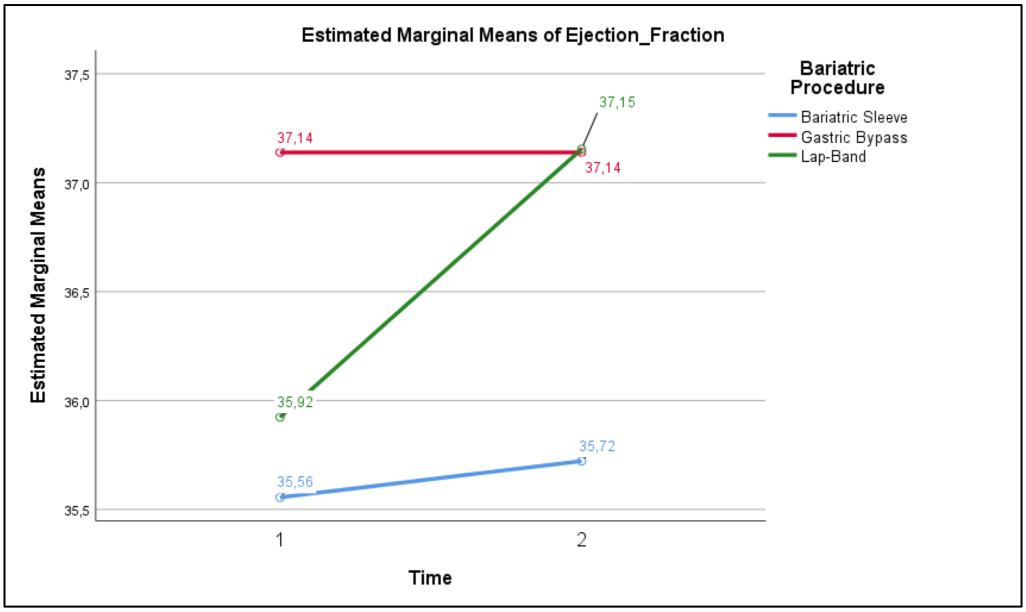
(I) Bariatric Procedure	(J) Bariatric Procedure	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Bariatric Sleeve	**Gastric Bypass**	-1,50	1,354	0,512	-4,73	1,73
	Lap-Band	-0,90	1,859	0,879	-5,34	3,54
Gastric Bypass	**Bariatric Sleeve**	1,50	1,354	0,512	-1,73	4,73
	Lap-Band	0,60	1,859	0,944	-3,84	5,04
Lap-Band	**Bariatric Sleeve**	0,90	1,859	0,879	-3,54	5,34
	Gastric Bypass	-0,60	1,859	0,944	-5,04	3,84

Based on observed means.
The error term is Mean Square(Error) = 32,998.

The following graph was plotted to visualize better where the differences are present (see Table H2-5). The figure shows that while the gastric bypass procedure shows no difference in ejection fraction between time 1 (pre) and time 2 (post), the sleeve shows a slight increase, and the lap band shows a relatively higher growth than the other procedures.

Table H2-5

Post-Hoc Test

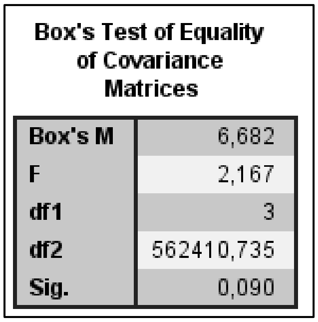


H2.1: Subjects who undergo the sleeve will display changes in ejection fraction measurements significantly different from those who did not.

For this hypothesis, no assumption was violated as well, as the p-values (column “Sig.”) were above the 1% significance level for all tests (p > 0.001) (see Tables H2.1, H2.1*1).

Table H2.1

Gastric Sleeve Box M Plot

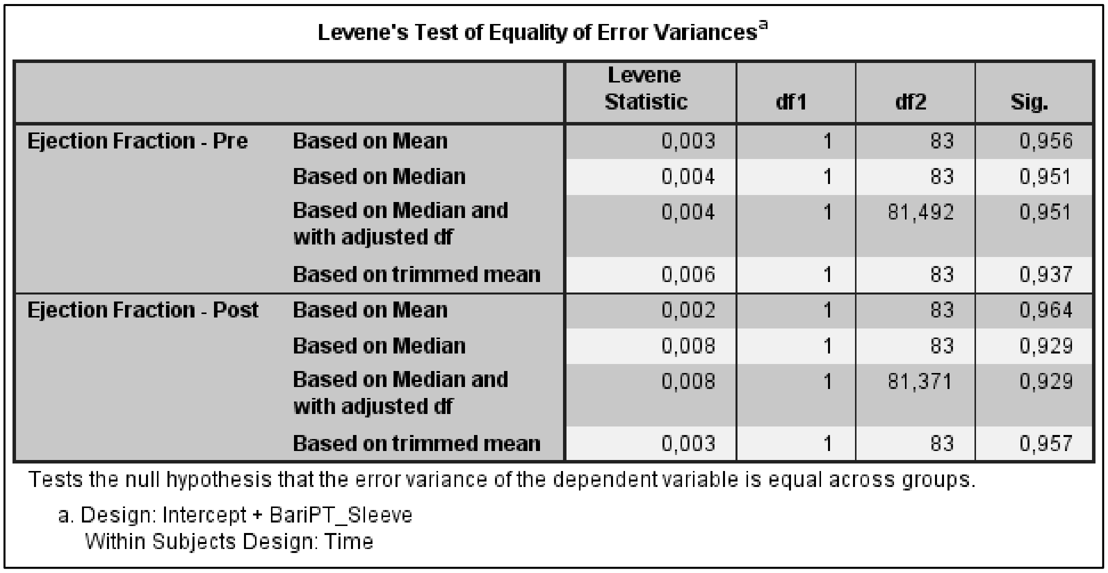


Box's Test of Equality of Covariance Matrices

Box's M	6,682
F	2,167
df1	3
df2	562410,735
Sig.	0,090

Table H2.1*1

Gastric Sleeve Levene’s Test



Levene's Test of Equality of Error Variances[a]

		Levene Statistic	df1	df2	Sig.
Ejection Fraction - Pre	**Based on Mean**	0,003	1	83	0,956
	Based on Median	0,004	1	83	0,951
	Based on Median and with adjusted df	0,004	1	81,492	0,951
	Based on trimmed mean	0,006	1	83	0,937
Ejection Fraction - Post	**Based on Mean**	0,002	1	83	0,964
	Based on Median	0,008	1	83	0,929
	Based on Median and with adjusted df	0,008	1	81,371	0,929
	Based on trimmed mean	0,003	1	83	0,957

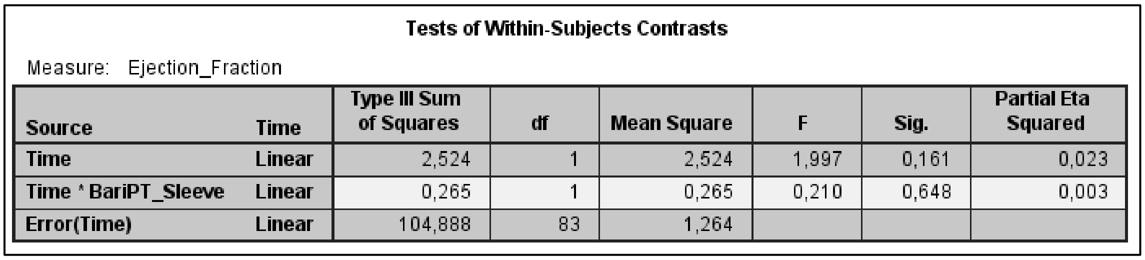
Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + BariPT_Sleeve
Within Subjects Design: Time

Looking at the sleeve procedure only (see Table H2.1*2), no significant interaction effect was present between time and being operated with the sleeve (in comparison with the other two procedures), F (1,83) = .210, p = .648, η_p^2 = .003. No main effects were also observed, neither for time, F (1,83) = 1.997, p = .161, ηp2 = .023, nor for procedure type, F (1,83) = 1.143, p = .288, ηp2 = .014. The tables below illustrate the results outlined above, followed by the same graph illustrated for the previous hypothesis, but this time comparing those who were operated by sleeve compared to those who were not. The following graph was utilized to better visualize where the differences are present (see Table H2.1*4).

Table H2.1*2

Gastric Sleeve Within Subjects Contrast



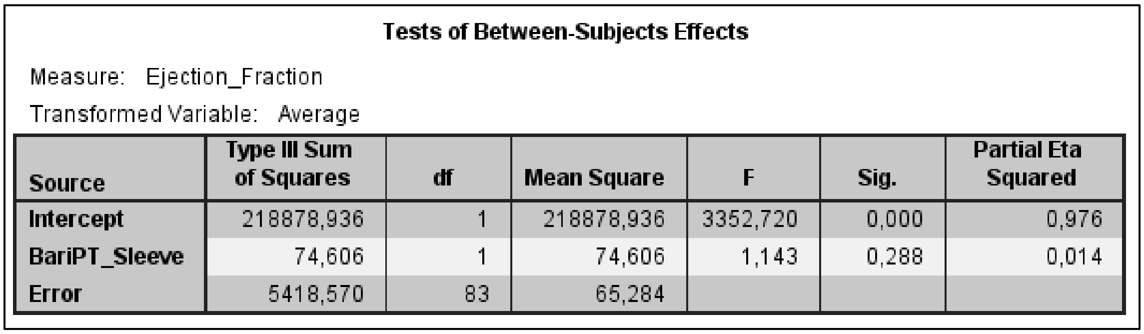
Tests of Within-Subjects Contrasts

Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Linear	2,524	1	2,524	1,997	0,161	0,023
Time * BariPT_Sleeve	Linear	0,265	1	0,265	0,210	0,648	0,003
Error(Time)	Linear	104,888	83	1,264			

Table H2.1*3

Bariatric Sleeve Between Subjects Effects



Tests of Between-Subjects Effects

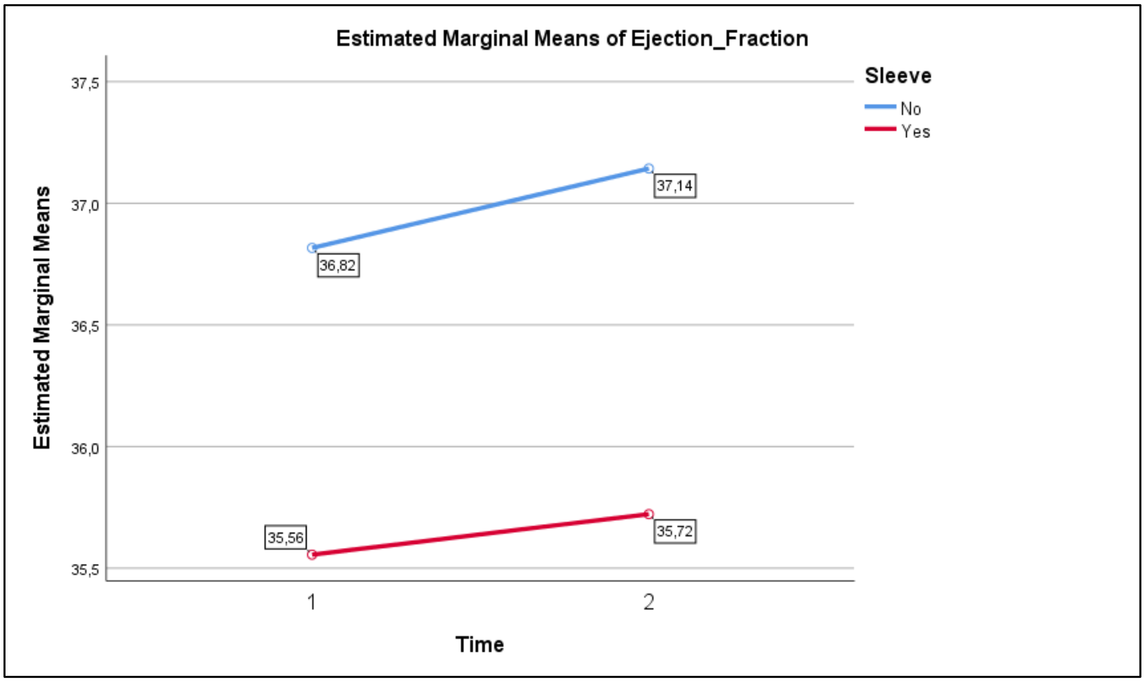
Measure: Ejection_Fraction

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	218878,936	1	218878,936	3352,720	0,000	0,976
BariPT_Sleeve	74,606	1	74,606	1,143	0,288	0,014
Error	5418,570	83	65,284			

Table H2.1*4

Post-Hoc Test

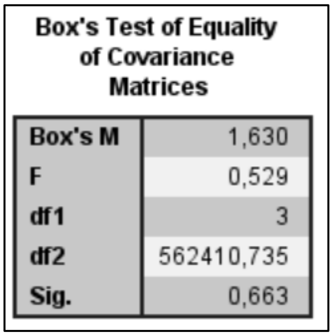


H2.2: Subjects who undergo the bariatric bypass will display changes in ejection fraction measurements significantly different from those who do not.

Assumptions were not violated for this hypothesis as well (tables below).

Table H2.2

Gastric Bypass Box M Plot

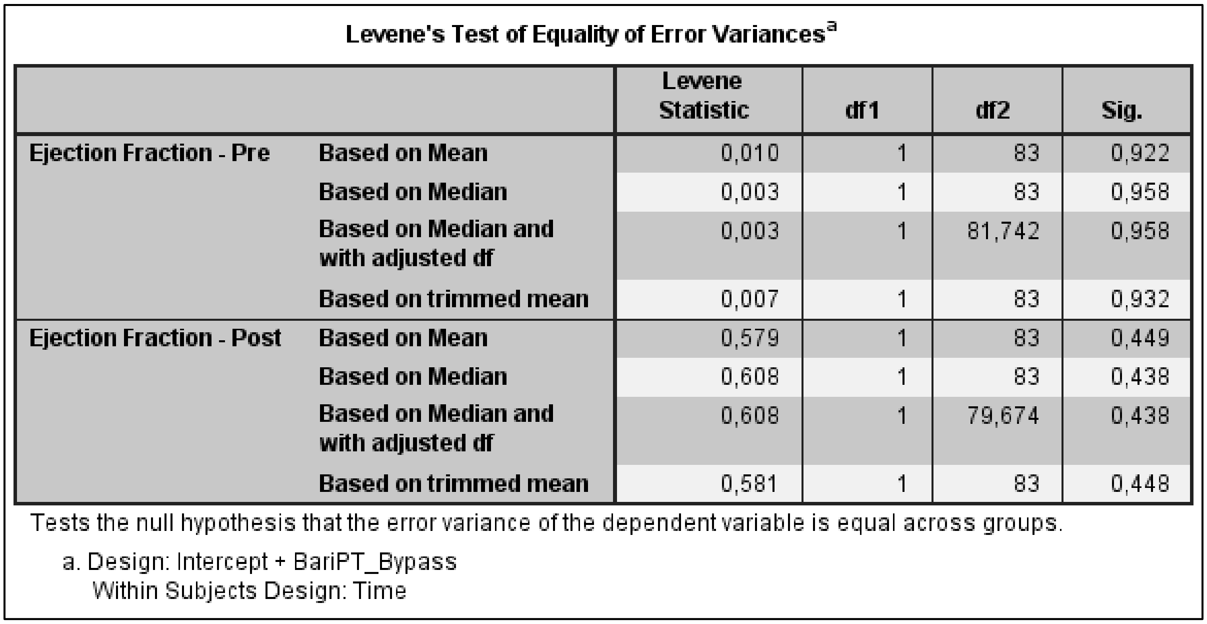


Box's Test of Equality of Covariance Matrices

Box's M	1,630
F	0,529
df1	3
df2	562410,735
Sig.	0,663

Table H2.2*1

Gastric Bypass Levene's Test



Levene's Test of Equality of Error Variances[a]

		Levene Statistic	df1	df2	Sig.
Ejection Fraction - Pre	**Based on Mean**	0,010	1	83	0,922
	Based on Median	0,003	1	83	0,958
	Based on Median and with adjusted df	0,003	1	81,742	0,958
	Based on trimmed mean	0,007	1	83	0,932
Ejection Fraction - Post	**Based on Mean**	0,579	1	83	0,449
	Based on Median	0,608	1	83	0,438
	Based on Median and with adjusted df	0,608	1	79,674	0,438
	Based on trimmed mean	0,581	1	83	0,448

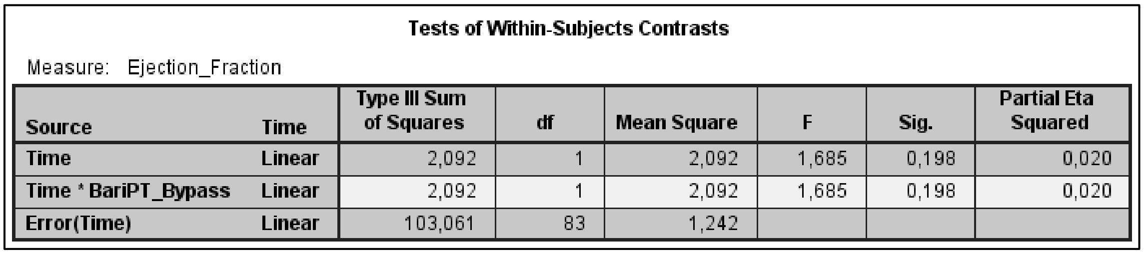
Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + BariPT_Bypass
Within Subjects Design: Time

With regards to the bypass, no significant interaction effect was present between time and being operated with this technique as well, F (1,83) = 1.685, p = .198, ηp2 = .020. No main effects were also observed, neither for time, F (1,83) = 1.685, p = .198, ηp2 = .020, nor for procedure type, F (1,83) = 1.010, p = .318, ηp2 = .012.

Table H2.2*2

Gastric Bypass Within Subjects Contrast



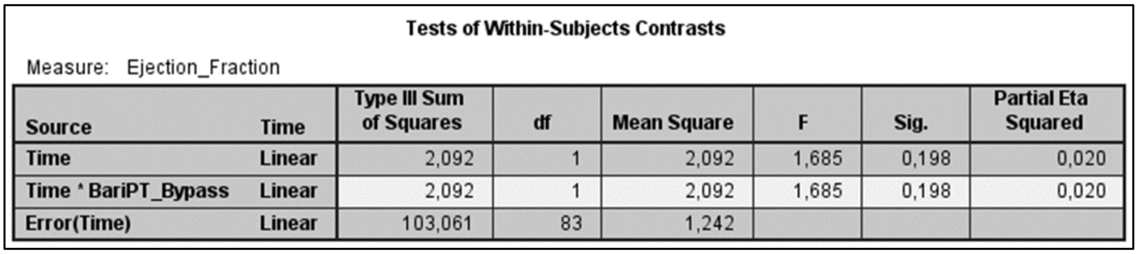
Tests of Within-Subjects Contrasts

Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Linear	2,092	1	2,092	1,685	0,198	0,020
Time * BariPT_Bypass	Linear	2,092	1	2,092	1,685	0,198	0,020
Error(Time)	Linear	103,061	83	1,242			

Table H2.2*3

Gastric Bypass Between Subjects Effects



Tests of Within-Subjects Contrasts

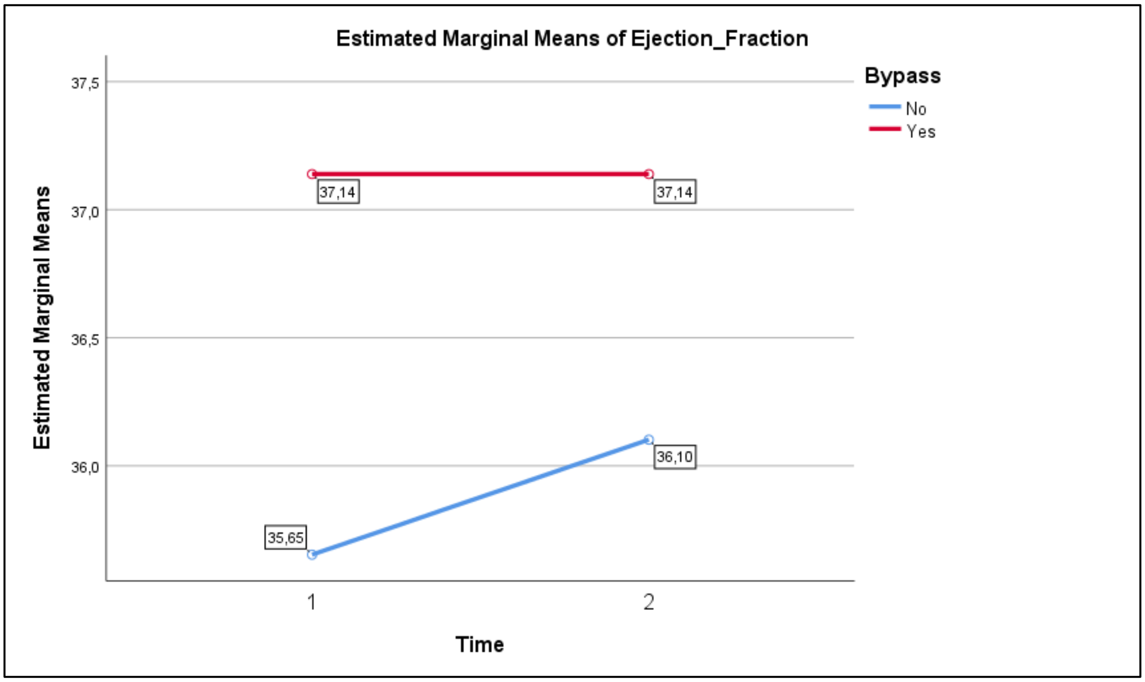
Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Linear	2,092	1	2,092	1,685	0,198	0,020
Time * BariPT_Bypass	Linear	2,092	1	2,092	1,685	0,198	0,020
Error(Time)	Linear	103,061	83	1,242			

The ejection fraction measurements for those who underwent this procedure were the same pre- and post-op (see Table H2.2*4).

Table H2.2*4

Gastric Bypass Post-Hoc

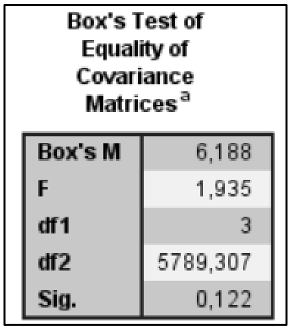


H2.3: Subjects who undergo the lap band will display changes in ejection fraction measurements significantly different from those who do not.

Similarly, no violation of the method assumptions occurred here (see Tables H2.3, H2.3*1).

Table H2.3

Lap Band Box M Plot

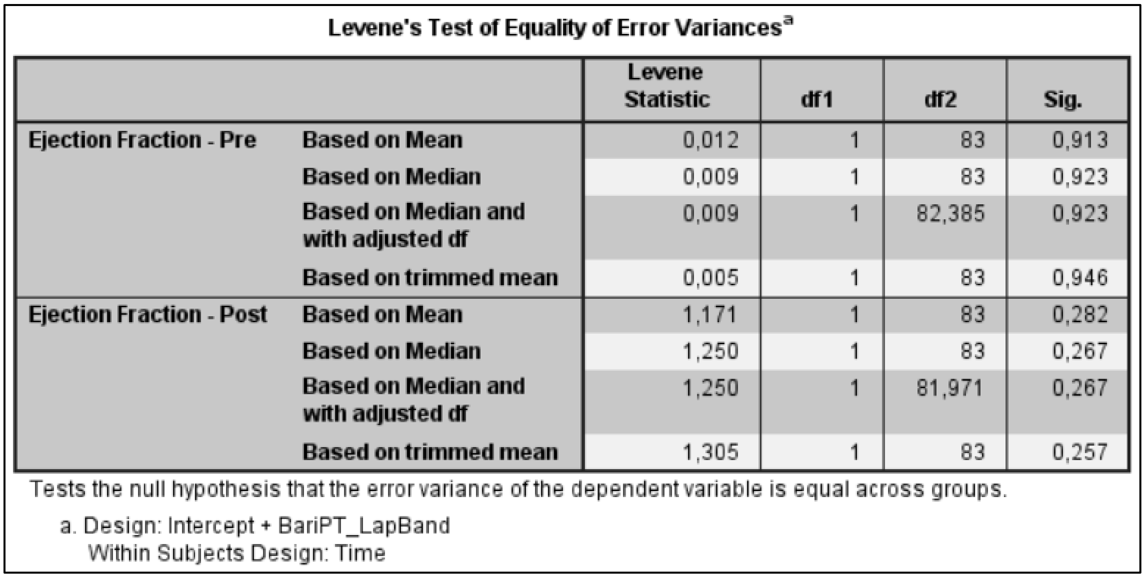


Box's Test of Equality of Covariance Matrices[a]

Box's M	6,188
F	1,935
df1	3
df2	5789,307
Sig.	0,122

Table H2.3*1

Lap Band Levene's Test



Levene's Test of Equality of Error Variances[a]

		Levene Statistic	df1	df2	Sig.
Ejection Fraction - Pre	Based on Mean	0,012	1	83	0,913
	Based on Median	0,009	1	83	0,923
	Based on Median and with adjusted df	0,009	1	82,385	0,923
	Based on trimmed mean	0,005	1	83	0,946
Ejection Fraction - Post	Based on Mean	1,171	1	83	0,282
	Based on Median	1,250	1	83	0,267
	Based on Median and with adjusted df	1,250	1	81,971	0,267
	Based on trimmed mean	1,305	1	83	0,257

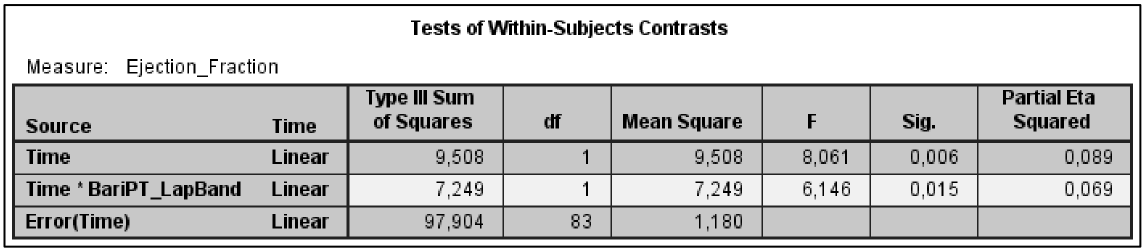
Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + BariPT_LapBand
Within Subjects Design: Time

Contrastively to the two earlier hypotheses, a significant interaction effect was present between time and being operated with the lap band, F (1,83) = 6.146, p = .015, ηp2 = .069. A main effect was observed for time, F (1,83) = 8.061, p = .006, ηp2 = .089, but not for the procedure type (which is expected, since the differences between procedures are only expected to appear when looking over time), F (1,83) = 0.007, p = .931, ηp2 = .000. See Tables H2.3*2 and H2.3*3.

Table H2.3*2

Lap Band Within Subjects Contrast



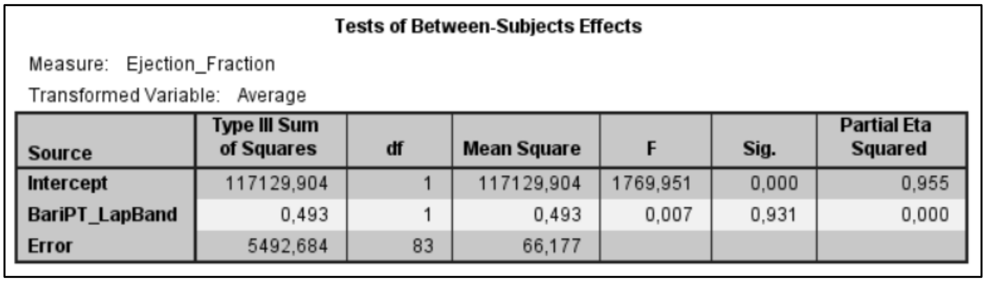
Tests of Within-Subjects Contrasts

Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Linear	9,508	1	9,508	8,061	0,006	0,089
Time * BariPT_LapBand	Linear	7,249	1	7,249	6,146	0,015	0,069
Error(Time)	Linear	97,904	83	1,180			

Table H2.3*3

Lap Band Between Subjects Effects



Tests of Between-Subjects Effects

Measure: Ejection_Fraction

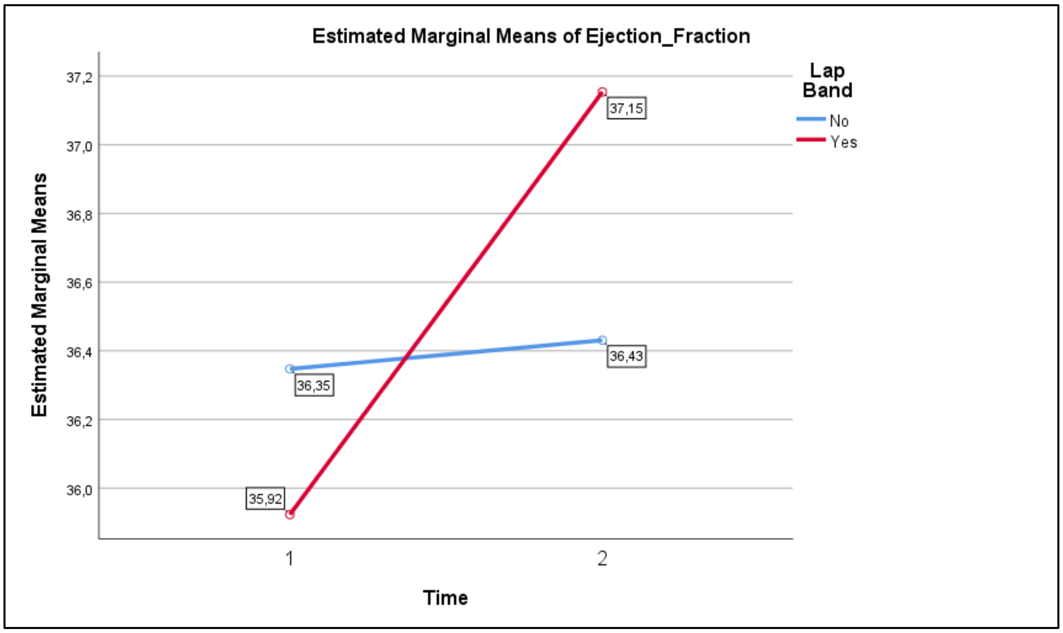
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	117129,904	1	117129,904	1769,951	0,000	0,955
BariPT_LapBand	0,493	1	0,493	0,007	0,931	0,000
Error	5492,684	83	66,177			

The graph in Table H2.3*4 shows the substantial difference between those who received the lap band and those who did not. Ejection fractions increase considerably for the first case while stable over time for those who received the other two procedures.

Table H2.3*4

Lap Band Post-Hoc

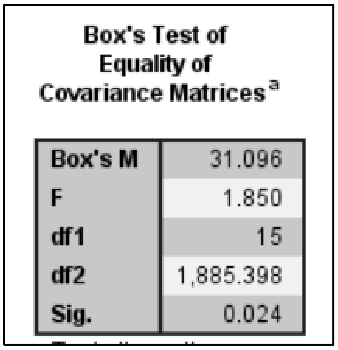


H3: There is a significant relationship between the Black race and changes in ejection fraction measurements 1 year postoperative for different procedure types.

The same test was conducted to evaluate a significant interaction between race, procedure type, and time when examining ejection fractions. Assumptions tests are shown in Tables H3 and H3.1. No violations were reported (p > 0.001).

Table H3

Box M Plot for Black Subjects

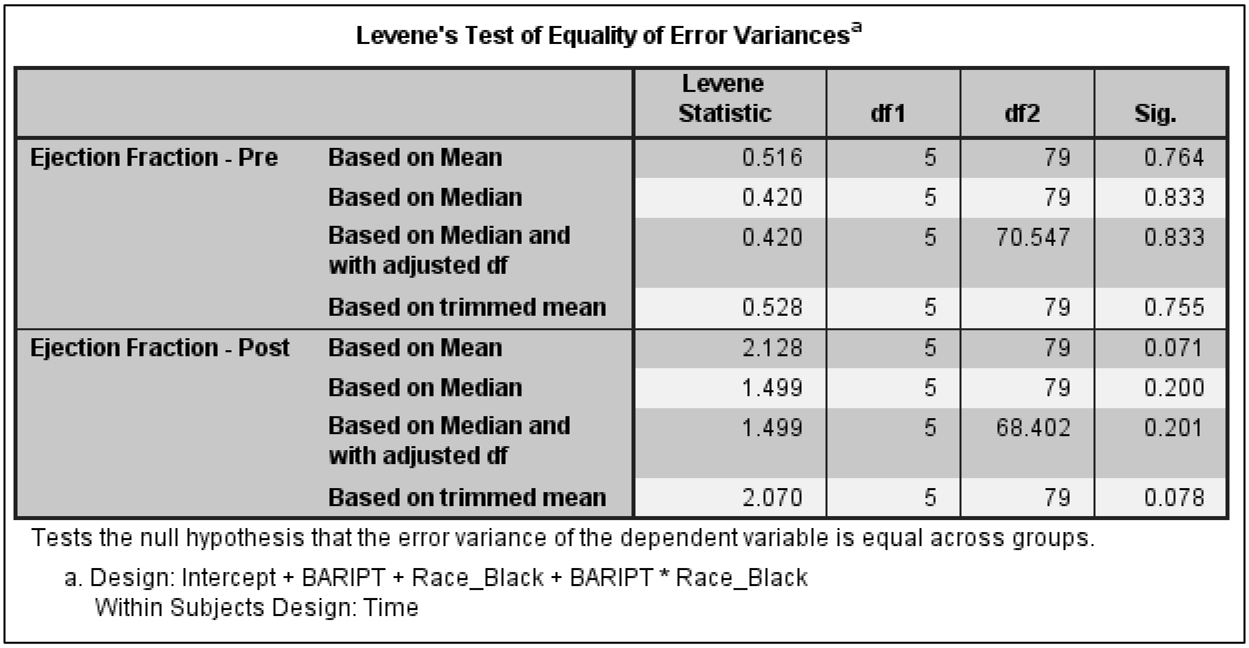


Box's Test of Equality of Covariance Matrices[a]

Box's M	31.096
F	1.850
df1	15
df2	1,885.398
Sig.	0.024

Table H3.1

Levene's Test for Black Subjects



Levene's Test of Equality of Error Variances[a]

		Levene Statistic	df1	df2	Sig.
Ejection Fraction - Pre	**Based on Mean**	0.516	5	79	0.764
	Based on Median	0.420	5	79	0.833
	Based on Median and with adjusted df	0.420	5	70.547	0.833
	Based on trimmed mean	0.528	5	79	0.755
Ejection Fraction - Post	**Based on Mean**	2.128	5	79	0.071
	Based on Median	1.499	5	79	0.200
	Based on Median and with adjusted df	1.499	5	68.402	0.201
	Based on trimmed mean	2.070	5	79	0.078

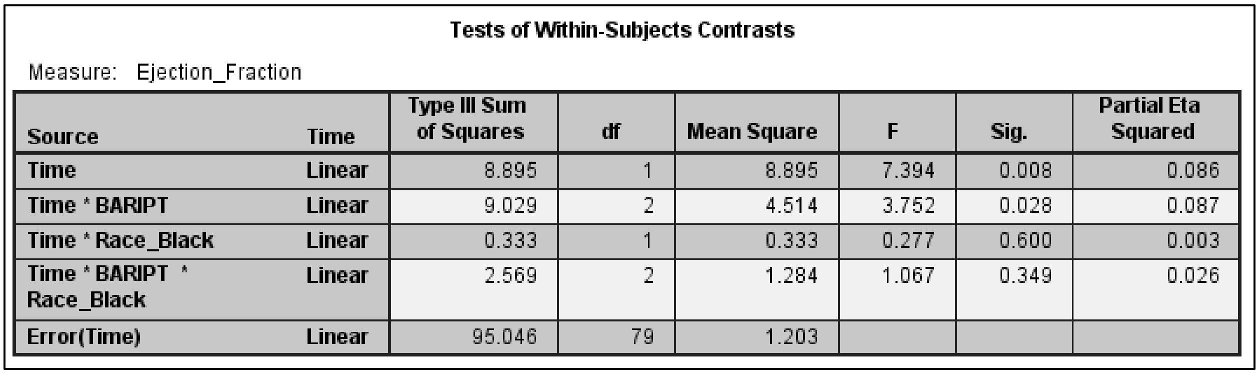
Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + BARIPT + Race_Black + BARIPT * Race_Black
Within Subjects Design: Time

The race variable was recoded into being Black and being other races. No significant interaction effect was present between time and being Black, F (1,83) = 0.277, p = .600, η_p^2 = .003. This means that the differences in ejection fractions are not different between those who are Black and those who are not. A significant main effect was observed for time, F (1,83) = 7.394, p = .008, η_p^2 = .086. Race, alone, has no significant effect on ejection fractions, F (1,83) = 0.118, p = .732, η_p^2 = .001. A significant interaction was observed between Time and Procedure, F (1,83) = 3.752, p = .028, η_p^2 = .087. See Tables H3.3 and H3.4.

Table H3.3

Within-Subjects Contrast in Black Subjects



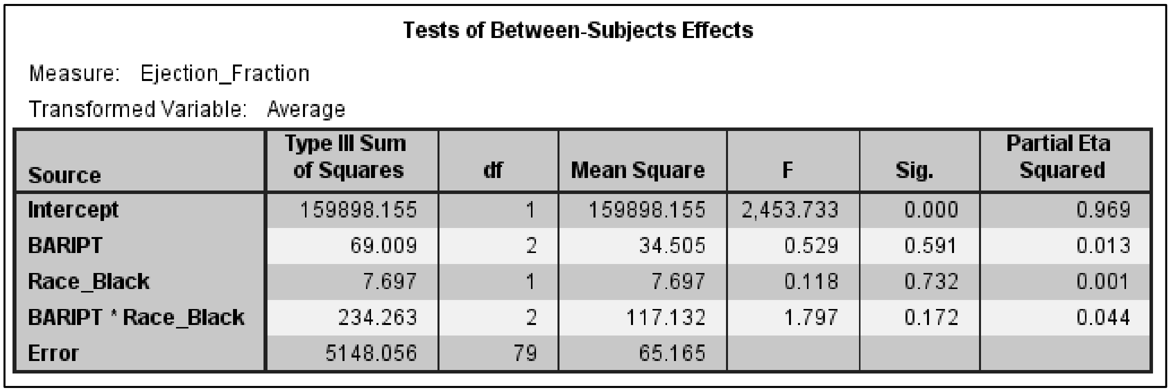
Tests of Within-Subjects Contrasts

Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Linear	8.895	1	8.895	7.394	0.008	0.086
Time * BARIPT	Linear	9.029	2	4.514	3.752	0.028	0.087
Time * Race_Black	Linear	0.333	1	0.333	0.277	0.600	0.003
Time * BARIPT * Race_Black	Linear	2.569	2	1.284	1.067	0.349	0.026
Error(Time)	Linear	95.046	79	1.203			

Table H3.4

Between-Subjects Effects in Black Subjects



Tests of Between-Subjects Effects

Measure: Ejection_Fraction

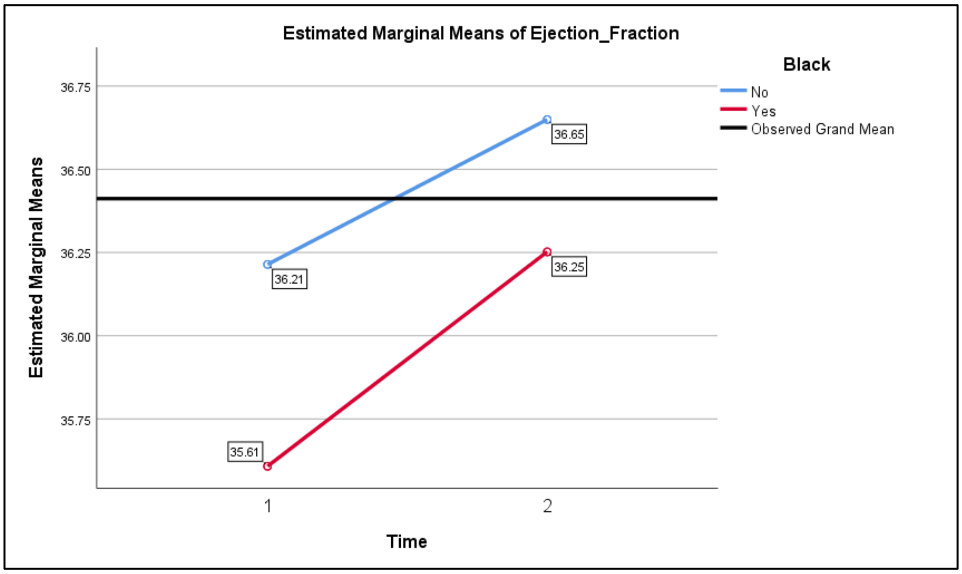
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	159898.155	1	159898.155	2,453.733	0.000	0.969
BARIPT	69.009	2	34.505	0.529	0.591	0.013
Race_Black	7.697	1	7.697	0.118	0.732	0.001
BARIPT * Race_Black	234.263	2	117.132	1.797	0.172	0.044
Error	5148.056	79	65.165			

The graph in Table H3.5 illustrates the estimated marginal means for Black subjects and non-Black Subjects. Although Black subjects show a higher increase in ejection fractions over time than those, who are not, this is not statistically significant.

Table H3.5

Post Hoc of Black Subjects in Comparison to Other Races Adjusted for Procedure Types

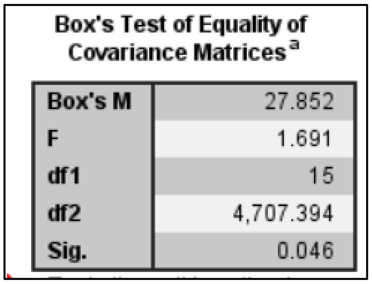


H4: There is a significant relationship between gender and changes in ejection fraction measurements 1 year postoperative for different procedure types.

No violations were reported here as well (see Tables H4, H4.1).

Table H4

Box M Plot for Male Subjects

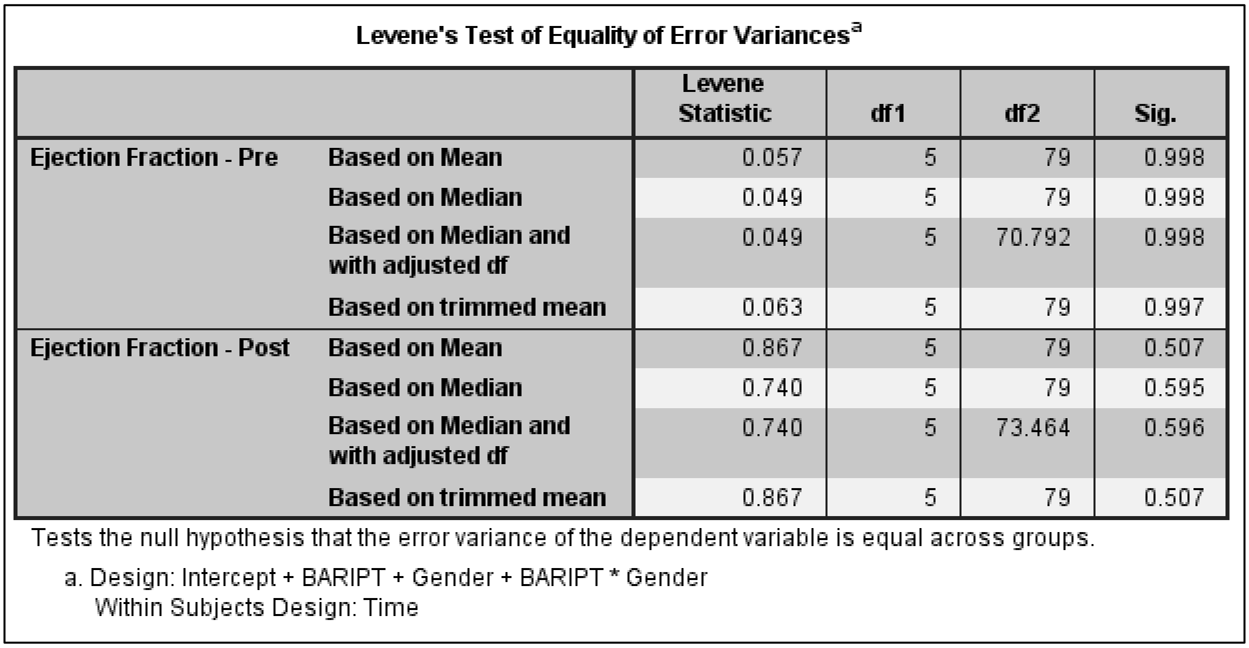


Box's Test of Equality of Covariance Matrices[a]

Box's M	27.852
F	1.691
df1	15
df2	4,707.394
Sig.	0.046

Table H4.1

Levene's for Male Subjects



Levene's Test of Equality of Error Variances[a]

		Levene Statistic	df1	df2	Sig.
Ejection Fraction - Pre	**Based on Mean**	0.057	5	79	0.998
	Based on Median	0.049	5	79	0.998
	Based on Median and with adjusted df	0.049	5	70.792	0.998
	Based on trimmed mean	0.063	5	79	0.997
Ejection Fraction - Post	**Based on Mean**	0.867	5	79	0.507
	Based on Median	0.740	5	79	0.595
	Based on Median and with adjusted df	0.740	5	73.464	0.596
	Based on trimmed mean	0.867	5	79	0.507

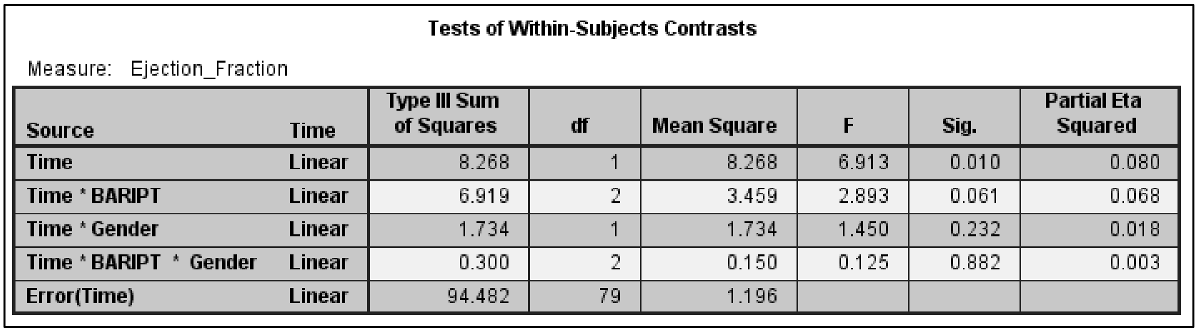
Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + BARIPT + Gender + BARIPT * Gender
Within Subjects Design: Time

Similarly to what was observed for race, no significant interaction effect was present between time and gender, F (1,83) = 1.450, p = .232, η_p^2 = .018. Different genders do not display differences on their variation on ejection fractions. A significant main effect was observed for time, F (1,83) = 6.913, p = .010, η_p^2 = .080, but not for gender, F (1,83) = 1.068, p = .340, η_p^2 = .013 (see Tables H4.2, H4.3). The three-way interaction is also not significant.

Table H4.2

Within-Subjects Contrast for Male Subjects



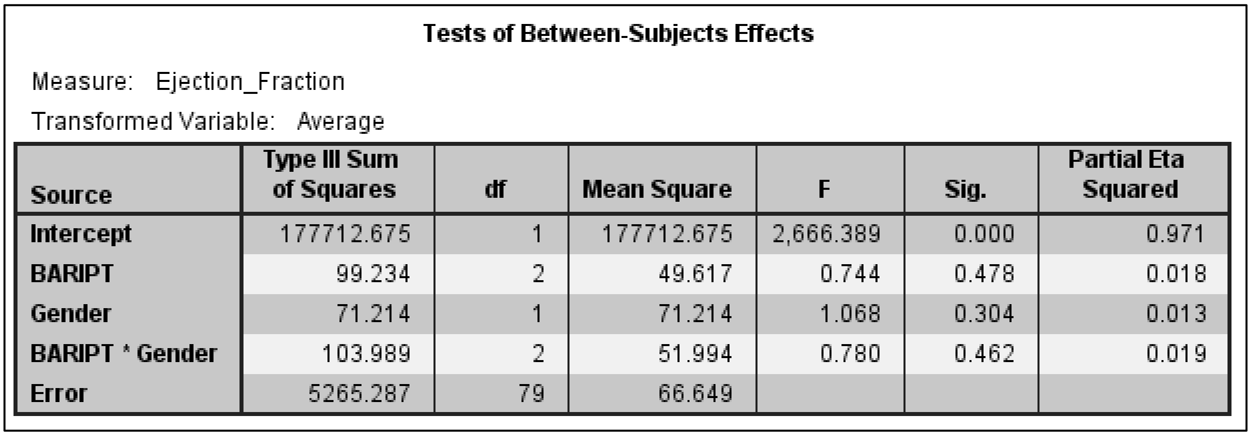
Tests of Within-Subjects Contrasts

Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	**Linear**	8.268	1	8.268	6.913	0.010	0.080
Time * BARIPT	**Linear**	6.919	2	3.459	2.893	0.061	0.068
Time * Gender	**Linear**	1.734	1	1.734	1.450	0.232	0.018
Time * BARIPT * Gender	**Linear**	0.300	2	0.150	0.125	0.882	0.003
Error(Time)	**Linear**	94.482	79	1.196			

Table H4.3

Between-Subjects Effects for Male Subjects



Tests of Between-Subjects Effects

Measure: Ejection_Fraction

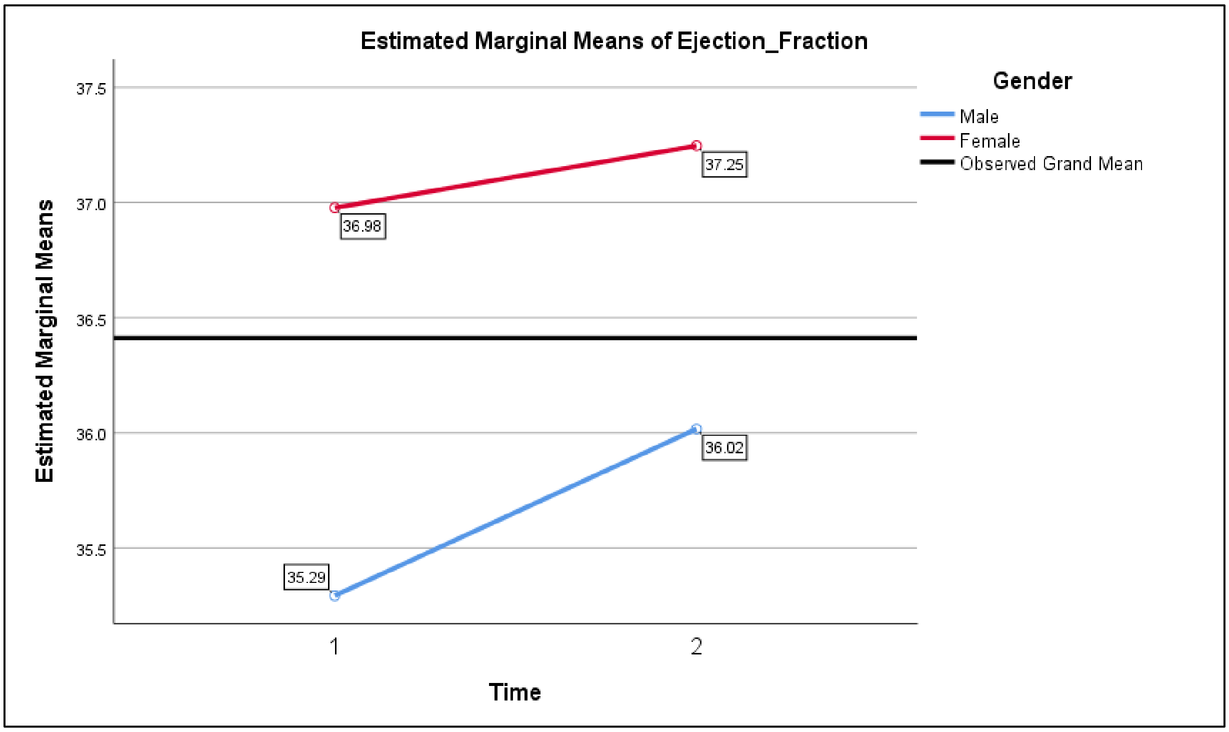
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	177712.675	1	177712.675	2,666.389	0.000	0.971
BARIPT	99.234	2	49.617	0.744	0.478	0.018
Gender	71.214	1	71.214	1.068	0.304	0.013
BARIPT * Gender	103.989	2	51.994	0.780	0.462	0.019
Error	5265.287	79	66.649			

From a nominal perspective, there is a higher increase for men (see Table H4.4). Nevertheless, as shown above, this is not statistically significant.

Table H4.4

Post-Hoc for Gender

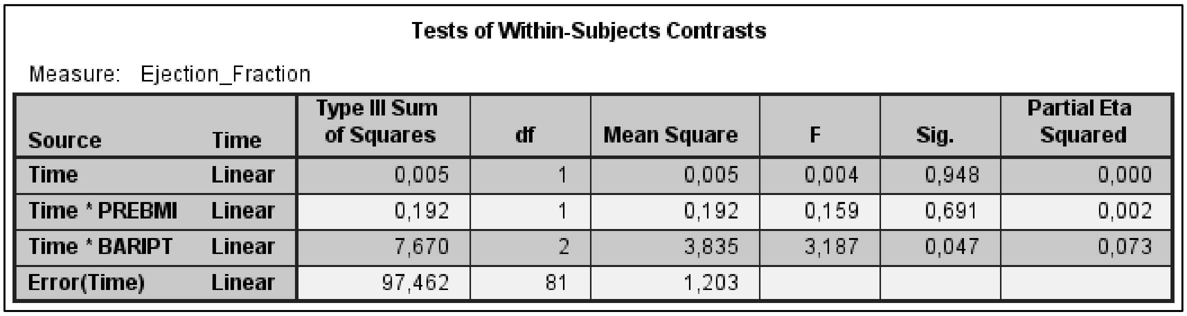


H5: There is a significant relationship between pre-op BMI and changes in ejection fraction measurements 1 year postoperative.

This hypothesis was tested by including the BMI measure pre-operation as a covariate in the general linear model. The assumptions of homogeneity of intercorrelations and equality of variances are not applicable here as BMI is a continuous variable and not a grouping variable. The homogeneity test for the different procedures was reported in H2. There was no significant interaction effect between pre-measurements of BMI and time, F (1,83) = 0.159, p = .691, η_p^2 = .002. There was also no significant main effect of BMI on ejection fractions, F (1,83) = 0.158, p = .692, η_p^2 = .002. The interaction between Time and Procedure was also significant here, F (1,83) = 3.187, p = .047, η_p^2 = .073. See Tables H5 and H5.1.

Table H5

Within-Subjects Contrast for BMI



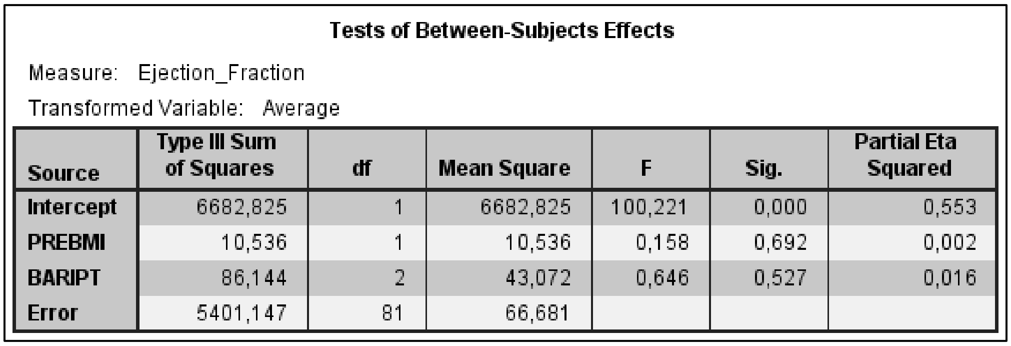
Tests of Within-Subjects Contrasts

Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Linear	0,005	1	0,005	0,004	0,948	0,000
Time * PREBMI	Linear	0,192	1	0,192	0,159	0,691	0,002
Time * BARIPT	Linear	7,670	2	3,835	3,187	0,047	0,073
Error(Time)	Linear	97,462	81	1,203			

Table H5.1

Between-Subjects Effects for BMI



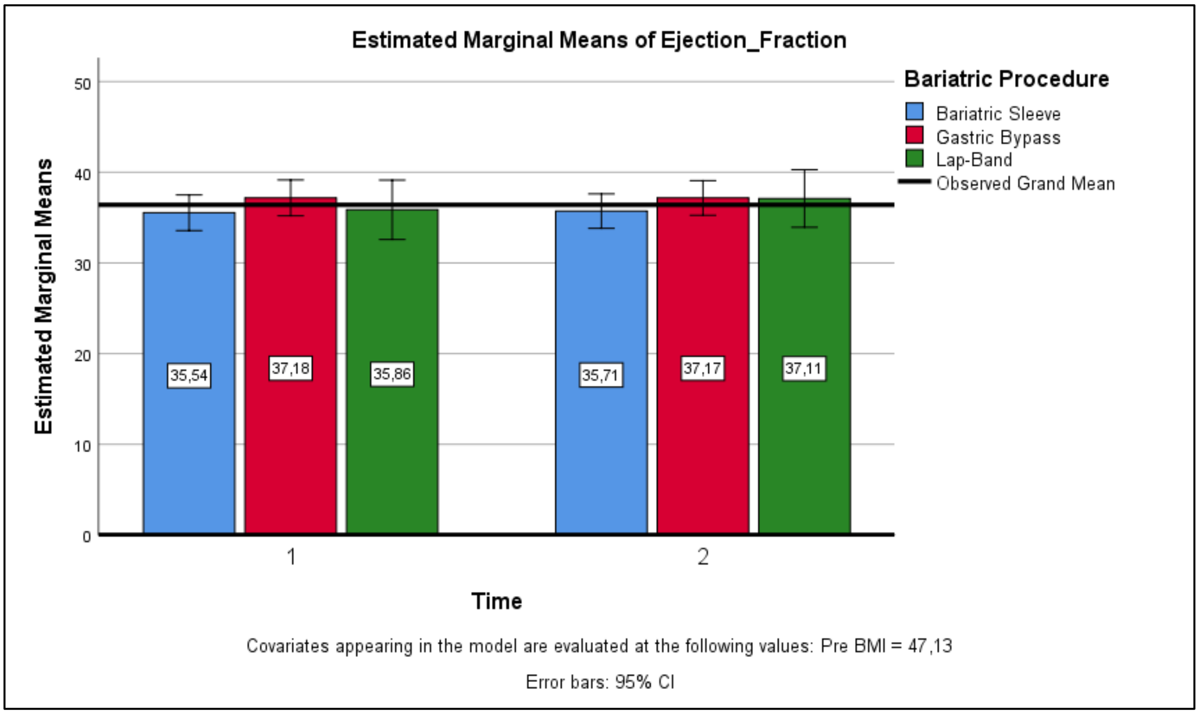
Tests of Between-Subjects Effects

Measure: Ejection_Fraction

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	6682,825	1	6682,825	100,221	0,000	0,553
PREBMI	10,536	1	10,536	0,158	0,692	0,002
BARIPT	86,144	2	43,072	0,646	0,527	0,016
Error	5401,147	81	66,681			

The graph below shows the estimated means for ejection fractions for the different procedures (adjusted for Pre-BMI) and standard error bars (95% confidence level). Ejection fractions for lap band increase considerably (35.68 to 37.11).

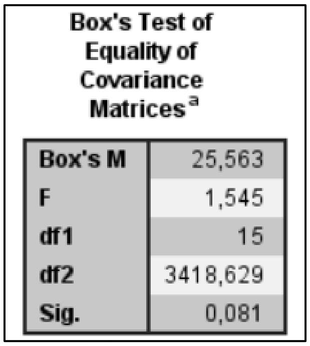


H6: There is a significant relationship between having two or more comorbidities and changes in ejection fraction measurements 1 year postoperative.

The groups compared for this test were patients who had two or more comorbidities (N = 42) versus those who had one or none (N = 43). The results of the assumptions are see in Tables H6 and H6.1, which were also non-significant.

Table H6

Box M Plot for Comorbidities

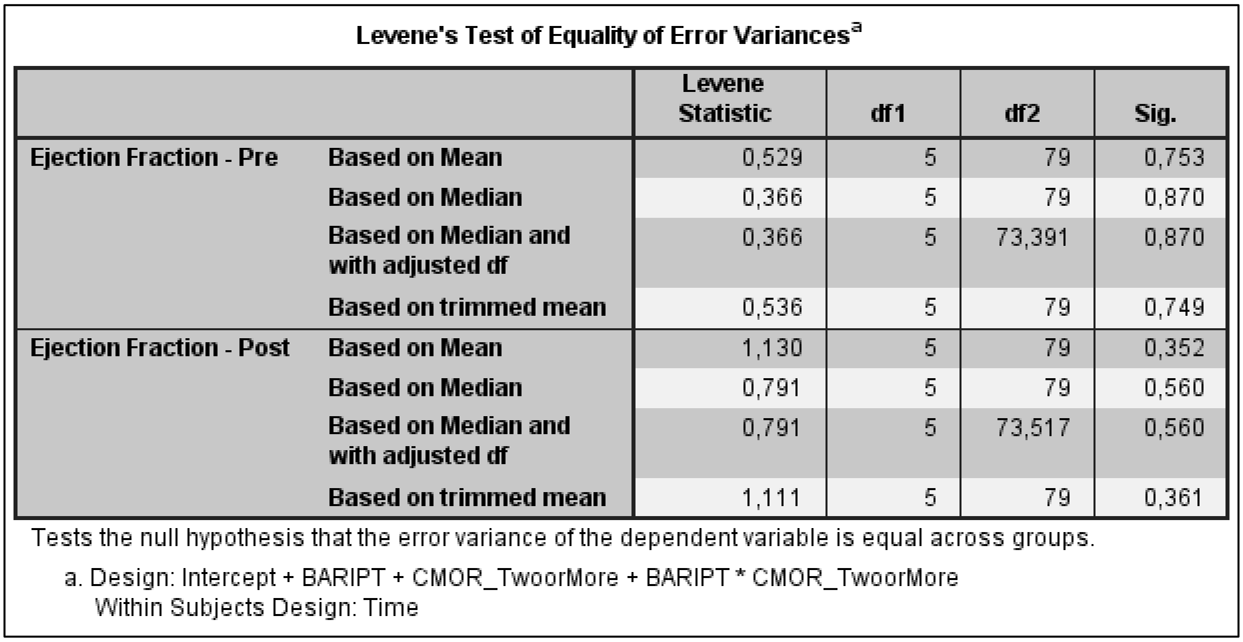


Box's Test of Equality of Covariance Matrices[a]

Box's M	25,563
F	1,545
df1	15
df2	3418,629
Sig.	0,081

Table H6.1

Levene's Test for Comorbidities



Levene's Test of Equality of Error Variances[a]

		Levene Statistic	df1	df2	Sig.
Ejection Fraction - Pre	Based on Mean	0,529	5	79	0,753
	Based on Median	0,366	5	79	0,870
	Based on Median and with adjusted df	0,366	5	73,391	0,870
	Based on trimmed mean	0,536	5	79	0,749
Ejection Fraction - Post	Based on Mean	1,130	5	79	0,352
	Based on Median	0,791	5	79	0,560
	Based on Median and with adjusted df	0,791	5	73,517	0,560
	Based on trimmed mean	1,111	5	79	0,361

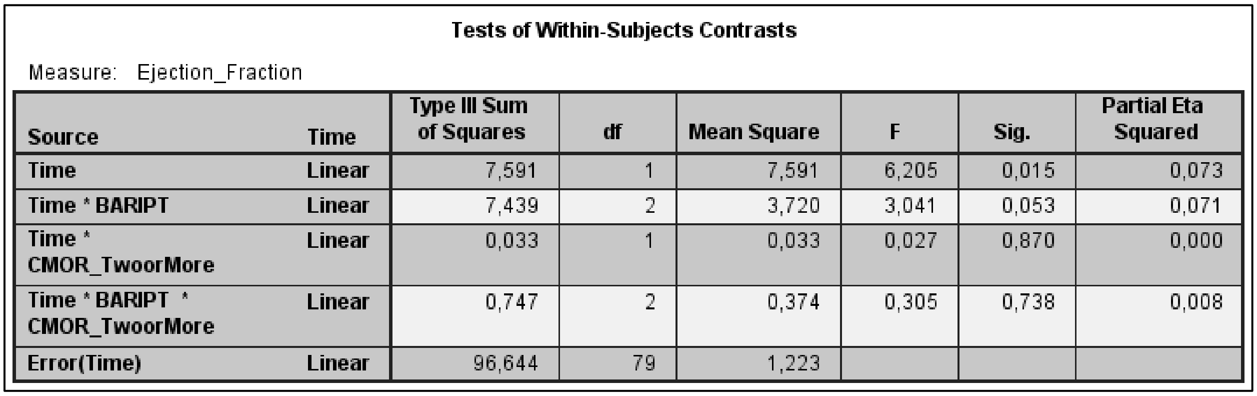
Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + BARIPT + CMOR_TwoorMore + BARIPT * CMOR_TwoorMore
Within Subjects Design: Time

Similarly to other cases, no significant interaction effect was demonstrated between time and having two or more comorbidities, F (1,83) = 0.027, p = .870, $\eta_p^2 < 0.001$. The main effect of having two or more comorbidities was also not significant, F (1,83) = 0.620, p = .783, ηp2 = .008. See Tables H6.2 and H6.3.

Table H6.2

Within Subjects Contrast for Comorbidities



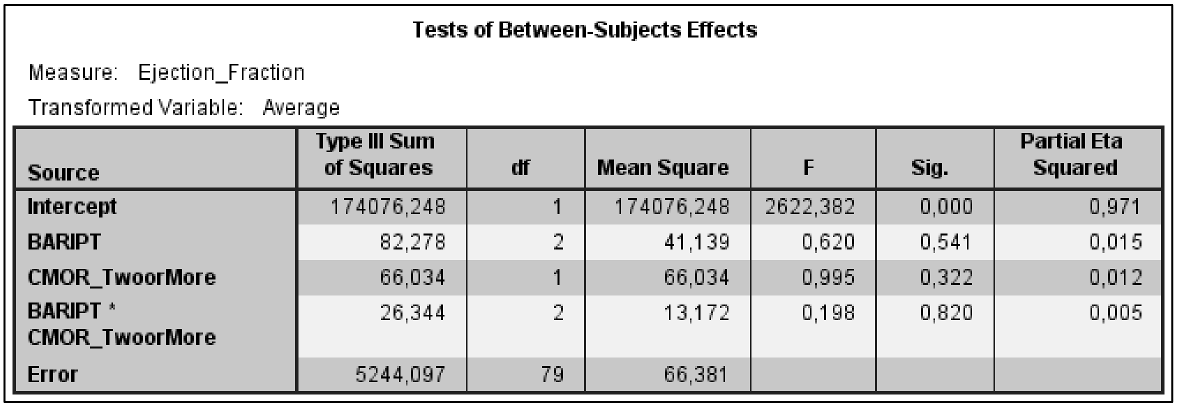
Tests of Within-Subjects Contrasts

Measure: Ejection_Fraction

Source	Time	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	Linear	7,591	1	7,591	6,205	0,015	0,073
Time * BARIPT	Linear	7,439	2	3,720	3,041	0,053	0,071
Time * CMOR_TwoorMore	Linear	0,033	1	0,033	0,027	0,870	0,000
Time * BARIPT * CMOR_TwoorMore	Linear	0,747	2	0,374	0,305	0,738	0,008
Error(Time)	Linear	96,644	79	1,223			

Table H6.3

Between-Subjects Effects for Comorbidities



Tests of Between-Subjects Effects

Measure: Ejection_Fraction

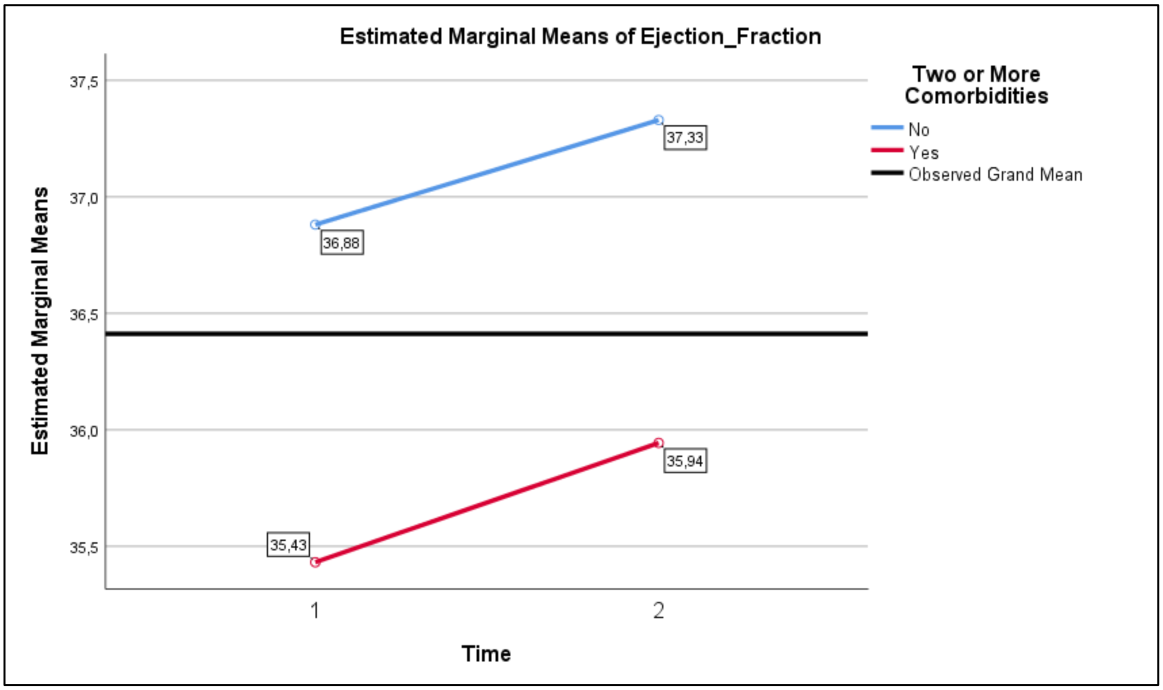
Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	174076,248	1	174076,248	2622,382	0,000	0,971
BARIPT	82,278	2	41,139	0,620	0,541	0,015
CMOR_TwoorMore	66,034	1	66,034	0,995	0,322	0,012
BARIPT * CMOR_TwoorMore	26,344	2	13,172	0,198	0,820	0,005
Error	5244,097	79	66,381			

The graph in Table H6.4 illustrates the differences. Both groups show slight increases in ejection fraction over time.

Table H6.4

Post-Hoc for Comorbidities



Summary of the tests of hypotheses

Table 7 summarizes the results of the study hypotheses. There was no significant difference in EF measurements at the one-year post-op overall. However, there was some significance in the data at 1-year post-op based on the bariatric procedures. The individuals who underwent gastric sleeve and gastric bypass procedures did not display more importance than their lap-band counterparts. Furthermore, the data did not show any significance in race, gender, nor BMI when comparing pre-op EF to the one-year post-op measurement. Lastly, the data did not display any significance in having two or more comorbidities to those who had one or less.

Table 7

Overall Hypotheses Results

Hypothesis	Outcomes
H1: There is a significant difference in EF measurements before and 1 year post-operation.	Not confirmed
H2: There are significant differences in EF measurements before and 1 year post-operation between bariatric procedures.	Confirmed
H2.1: Subjects who undergo the sleeve will display changes in ejection fraction measurements significantly different from those who do not.	Not confirmed
H2.2: Subjects who undergo the bariatric bypass will display changes in ejection fraction measurements significantly different from those who do not.	Not confirmed
H2.3: Subjects who undergo the lap band will display changes in ejection fraction measurements significantly different from those who do not.	Confirmed
H3: There is a significant relationship between the Black race and changes in ejection fraction measurements 1 year postoperative, considering all procedure types.	Not confirmed
H4: There is a significant relationship between being male and changes in ejection fraction measurements 1 year postoperative, considering all procedure types.	Not confirmed
H5: There is a significant relationship between pre-op BMI and changes in ejection fraction measurements 1 year postoperative, considering all procedure types.	Not confirmed
H6: There is a significant relationship between having two or more comorbidities and changes in ejection fraction measurements 1 year postoperative, considering all procedure types.	Not confirmed

Chapter 5: Discussions, Conclusions, Recommendations

Restatement of the Problem

With obesity being one of the most prevalent diseases in society with a negative impact on the overall quality of life, it is essential to understand the disease process. Obesity affects mobility and serves to introduce other comorbidities, including heart disease, hypertension, and diabetes. Therefore, bariatric interventions have been utilized over the last 60 years to combat the prevalence of the disease. This study, in particular, looked at cardiovascular functionality by way of ejection fraction to see how such bariatric interventions assisted with improving cardiovascular conditions after a year of surgically induced weight loss.

Many studies have looked at obesity, its impacts on cardiovascular adverse events, and bariatric interventions. Both obesity and congestive heart failure reduce a person's quality of life. Francis and Tang (2019) stated that during obesity and heart failure, various body systems start to overexert themselves in compensation to meet functional requirements, leading to congestive heart failure. Also, Nieminen et al. (2015) indicated that congestive heart failure is usually chronic and often progressive; intensified by obesity, heart failure often generates other issues that cause body systems to shut down. Studies have also shown how EF can be used in obese patients to assess their cardiovascular functionality regarding this study. According to Lee et al. (2016), obesity is significantly associated with diastolic dysfunction due to inadequate filling of the ventricles, leading to abnormalities in the EF parameter.

Lastly, there is also evidence of bariatric interventions assisting with overall improvements in cardiac conditions. For example, Chang et al. (2014) revealed that bariatric surgical procedures decreased cardiovascular risk in asymptomatic obese patients and decreased cardiac mortality and morbidity in obese patients with established cardiac pathology. However, at the time of this study, no studies currently looked at bariatric surgery and its impact on EF based on the bariatric procedure. Thus, this study attempted to understand the relationship between bariatric surgery and ejection fraction at the 1-year post-op mark to determine if there is a significant relationship between the intervention and the possible EF changes.

Discussions of the Findings

During this study, the researcher wanted to examine the significant relationship between the received bariatric procedure: gastric sleeve, gastric bypass, lap-band procedure, and the EF measurement of obese patients diagnosed with CHF before their bariatric procedure. Moreover, the researcher wanted to compare the pre-operative EF measurements to the post-operative EF measurement to determine any changes at the 1-year mark.

First, the ability to reject the null hypothesis involves a change in EF when comparing the overall EF measurements taken pre-operatively to those taken post-operatively. As shown in Figure 1 and Figure 1.2, there was no significant difference in the post-op EF measurements following the intervention. This rejection supports the study that revealed that normal EFs range between 55% and 70%, and those before bariatric surgery typically fall around 35% or less, indicating moderately to severely diminished pumping ability of the heart (Lee et al., 2016). Perhaps the ability to reject the null hypothesis at the 1-year post-op may be related to diminished pumping ability before the bariatric procedure, stemming from obesity. Therefore, the impact of obesity can broadly affect the data post-operatively.

Second, the inability to reject the null hypothesis involves regarding the difference in EF measurements pre- and post-operatively between the bariatric procedures. As shown in Table H2, this hypothesis was tested for normality, and no issues were presented. However, concerning ANOVA, the post-hoc test revealed only significance statistically when comparing the three procedures together instead of individually. The sleeve and the lap band displayed an increase in EF while the gastric bypass subjects experienced no change. This data supports the idea of bariatric surgery being related to significant progress in the weighted prevalence of several cardiac indices, containing a decrease in the left ventricular mass index (11.2%, 95% confidence intervals [CI] 8.2–14.1%), left ventricular end-diastolic volume (13.28 ml, 95% CI 5.22–21.34 ml), and went atrium diameter (1.967 mm, 95% CI 0.980–2.954) (Aggarwal et al., 2016). Furthermore, previous research does support the idea that bariatric surgery can be valuable in improving the overall cardiovascular system.

Thirdly, the ability to reject the null hypothesis regarding those who underwent the gastric sleeve displays more changes in EF measurements significantly different from those who did not. After following the assumptions of normality, the data revealed no significant interaction between time and the sleeve procedure. Thus, the sleeve procedure did not display better results than those that received either sleeve or the bypass, as illustrated in the Post-hoc test (Table H2.1*4). The same ability to reject the null hypothesis regarding those who underwent gastric bypass displayed significantly different EF measurements from those who received the other procedure. No assumptions were violated, as shown in Table H2.2 and Table H2.2*1. However, there was no significance between time and the procedure type. A possible reason could be the amount of weight that had to be lost by the subjects who received the gastric sleeve or gastric bypass. Those procedures are more evasive than the lap band; these individuals are usually more prominent and may have a more significant body fat percentage.

On the other hand, when it came to displaying changes in EF at the 1-year post-op measurement, the researcher failed to reject the null hypothesis when examining the lap band recipients. Such is because the researcher believes that those who underwent the lap-band procedure would experience the least amount of, if any, change to the post-op EF measurement. The lap band is less demanding than the other procedures, so subjects typically do not lose as much weight as those who undergo the gastric sleeve or bypass procedure. As stated in an article by Kang et al. (2017), between the surgical procedures, the lowest treatment impact in terms of weight loss was observed in subjects who received the lap band.

Next, the researcher rejected the null hypothesis regarding being Black and EF changes compared to those not Black to see if race affected EF post-op. Data displayed that race alone had no effect on EF, nor did time impact EF measurements in Black subjects than other races.

The researcher believed that Blacks would experience more of a significant change in EF than other races due to low EF being more prevalent in minorities. However, as stated previously in the literature review, there are studies that conflict with this belief. For instance, in a race-stratified analysis, the lifetime probability for overall HF was greater in non-Blacks than Blacks (25.9% instead of 22.4%) (Pandey et al., 2018). Furthermore, the researcher was able to reject the null hypothesis regarding males experiencing a significant change in EF compared to their female counterpoints. Such was believed because men typically do better with weight loss post-op when compared to women, but there is limited data that EF has on gender comparisons.

Lastly, there was a rejection in the null hypothesis regarding BMI significantly impacting EF changes at the 1-year post-op measurements. The results also reject the null hypothesis that significant EF changes in subjects with two or more comorbidities pre-operatively. The data revealed that BMI had no significant effect on EF when comparing pre-and post. Furthermore, the data also told that out of 85 subjects, 42 of them had two or more comorbidities. The remaining 43 subjects with one morbidity or less yielded the same results at the 1-year post-op. Initially, the researcher believed that subjects with a greater BMI and those with two or more comorbidities would experience more significant changes in their EF post-op because they would most likely be recipients of the more invasive procedures, gastric sleeve or gastric bypass.

Limitations

The surprising results of this study identifying the lap-band procedure as yielding significantly higher increases in ejection fractions than other surgical procedures was one of curiosity. One of the prime limitations was the amount of time between the pre-op measurement and the post-op measurement. For example, instead of looking at EF at the 1-year post-op appointment, could the data be more significant at 3 or 5 years post-op measurement? Although subjects lose most of their weight within the first year with bariatric surgery, sometimes it takes time for the body to adjust to the weight loss from a physiological standpoint. Thus, coming back to look at EF after about 3 to 5 years could yield different results in bariatric subjects, especially if they could keep the weight off during that time. Another limitation was the number of individuals used in this study. Unfortunately, the number of available individuals for this study was limited to 85 bariatric surgery recipients. There is a possibility that a larger patient population could add some distinction to the data results.

Strengths

The primary strength of this research is that it establishes a foundation for future research. There is limited literature available that looks explicitly at EF after bariatric surgery. Thus, having evidence that a bariatric procedure could impact an individual's EF suffering from CVD is a significant finding. If the minor invasive lap-band procedure can display some significance at the 1-year post-op measurement, the gastric bypass and gastric sleeve may likely display changes in EF after more drastic weight loss. Furthermore, there is also evidence that overall, there are changes in EF post-op after bariatric surgery. Such is a sign that bariatric surgery may be an option to assist with overcoming low EF in bariatric patients suffering from CVD.

Future Research

For future research purposes, the researcher would recommend comparing this data among multiple surgeons to see if different patient populations yield different results after their post-op period. By comparing subjects who may have to pay out of pocket, researchers would see if their self-enforced compliance produces better results than patients who may have their procedure funded by the government. This information is valuable because subjects who have their procedure paid for by the government do not have weight requirements post-op, so they are strictly motivated by willpower. Usually, subjects that pay out are inspired because they are paying for the surgery and each post-op appointment. Another aspect to look at with multiple surgeons is their surgical technique. Doing so would examine the technique to see if surgeons who are more aggressive with their bariatric procedures, such as the sleeve, yield better results than surgeons who create a less restrictive sleeve from a size perspective. This difference can also affect weight loss as time progresses to see if patients experience more weight loss, impacting their EF. Lastly, increasing the amount of post-op time for the EF measurement may be evidence of all three bariatric procedures impacting EF changes. At a minimum, a possible consideration is to remeasure each subject’s EF at the 3-year surgical anniversary to see if the time impacts EF based on each bariatric procedure.

Conclusion

The obesity epidemic in America is the leading cause of adverse cardiac events. The purpose of this capstone is to expand the understanding between bariatric surgery and cardiovascular functionality, as measured by EF, by explicitly focusing on any changes that occur in EF measurements postoperative. This study aimed to provide information regarding the possible relationship between bariatric surgery and EF 1 year postoperative to understand better. EF may be considered an adequate tool in assessing the impact of bariatric surgery on the heart, specifically the after-weight loss. EF determines how much blood the left ventricle pumps out with each contraction. An EF below 40% represents a sign that heart failure or cardiomyopathy exists, and this percent is typically observed in obese patients.

This capstone intended to provide research to improve the understanding of measurements before and after bariatric surgery and any potential relationships between the type of bariatric procedure performed and EF. As the data yields, there is a significant difference in EF at 1-year post-op based on the bariatric procedure, with the lap-band surgery showing the most significance. This study has implications for the field of medicine by advancing the education and awareness of overcoming CVD, specifically low EF, by possibly improving cardiovascular functionality influenced by weight loss after bariatric surgery.

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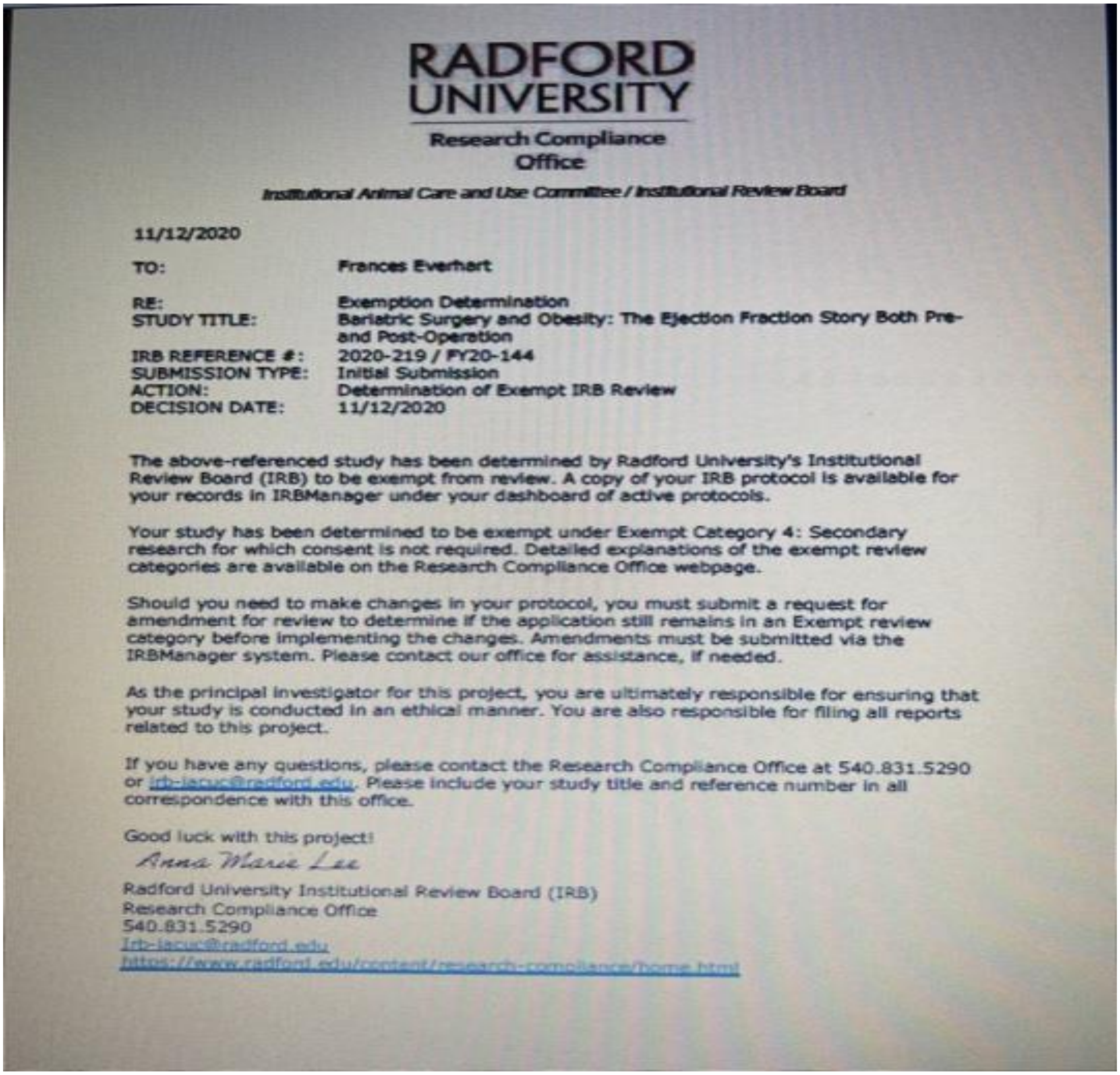
Appendix A



RADFORD
UNIVERSITY
Research Compliance
Office
Institutional Animal Care and Use Committee / Institutional Review Board

11/12/2020

TO: **Frances Everhart**

RE: **Exemption Determination**
STUDY TITLE: **Bariatric Surgery and Obesity: The Ejection Fraction Story Both Pre- and Post-Operation**
IRB REFERENCE #: **2020-219 / FY20-144**
SUBMISSION TYPE: **Initial Submission**
ACTION: **Determination of Exempt IRB Review**
DECISION DATE: **11/12/2020**

The above-referenced study has been determined by Radford University's Institutional Review Board (IRB) to be exempt from review. A copy of your IRB protocol is available for your records in IRBManager under your dashboard of active protocols.

Your study has been determined to be exempt under Exempt Category 4: Secondary research for which consent is not required. Detailed explanations of the exempt review categories are available on the Research Compliance Office webpage.

Should you need to make changes in your protocol, you must submit a request for amendment for review to determine if the application still remains in an Exempt review category before implementing the changes. Amendments must be submitted via the IRBManager system. Please contact our office for assistance, if needed.

As the principal investigator for this project, you are ultimately responsible for ensuring that your study is conducted in an ethical manner. You are also responsible for filing all reports related to this project.

If you have any questions, please contact the Research Compliance Office at 540.831.5290 or irb-iacuc@radford.edu. Please include your study title and reference number in all correspondence with this office.

Good luck with this project!

Anna Marie Lee

Radford University Institutional Review Board (IRB)
Research Compliance Office
540.831.5290
irb-iacuc@radford.edu
https://www.radford.edu/content/research-compliance/home.html