

## **CRC Project Proposal**

**Name:** Lisa Ditchek, MD

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**Project Title:** The Effect of Sleeve Gastrectomy on Adolescents at NYP-Columbia

**Principal Investigator:** Ilene Fennoy, MD

### **A. Study purpose and rationale:**

#### **Background:**

Bariatric surgery is a well-established treatment to combat obesity and obesity-related comorbidities which is now being recognized as a tool not only for adults, but for obese adolescents. There has been hesitation to utilize this tool in the adolescent community and historically, a push for lifestyle changes and medication management. The dire need to address pediatric and adolescent obesity is made clear by the severe consequences of untreated disease. It has been recognized that obesity in adolescence increases risk for cardiovascular disease<sup>7</sup>, cardiovascular morbidity, and mortality<sup>9</sup>. Children with obesity have been found to have higher systolic and diastolic blood pressure and greater evidence of metabolic diseases<sup>2</sup>. One study found that 70% of obese children have at least one cardiovascular risk factor, and 39% have two or more<sup>2</sup>. The negative consequences of undertreated obesity in the pediatric and adolescent population support the need for effective interventions in this age group, including bariatric surgery. This general attitude of limiting treatment to lifestyle changes has shifted as we have seen studies showing the multitude of benefits of these procedures, not only limited to weight loss but also resolution of dyslipidemia, diabetes, kidney disease, and hypertension. While studies have suggested the positive impact of bariatric surgery, the generalizability of these studies has been limited to white and privately insured populations due to a multitude of reasons likely motivated by inequity in the healthcare system.

There have been many promising studies documenting the positive effects of bariatric surgery in the adolescent community. One longitudinal study looked at 30- year risk of cardiovascular disease in adolescents with severe obesity who underwent surgery compared to patients with severe obesity who did not. This study found that adolescents who underwent surgery had reduced risk of cardiovascular events. One retrospective study of 544 adolescents, predominantly female (79%) and white (66%), who underwent bariatric surgery showed significant reduction in BMI at 1- and 3- year follow up appointments<sup>3</sup>. Another study in 108 obese children (ages 5-21 years) who underwent laparoscopic sleeve gastrectomy showed resolution of dyslipidemia, hypertension, prehypertension, OSA, diabetes, and prediabetes<sup>1</sup>. One multicenter, prospective study of bariatric surgery in adolescents found significant improvements in weight, cardiometabolic health, and weight-related quality of life at 3 years after the procedure, with normalization in blood pressure in 74% of participants<sup>4</sup>. Of note, in this study, 75% of the participants were female, and 72% were white<sup>4</sup>. With these many studies suggesting the benefits of bariatric surgery to the adolescent population, as also seen in the adult literature, the generalizability of these studies is limited due to the lack of diversity. As shown by these promising studies, bariatric surgery is an effective tool to combat obesity and related comorbidities, but there is limited data regarding outcomes in non-white populations.

While the data are promising regarding benefits of having bariatric surgery, complicated issues of access, discriminatory practices, and long-standing (understandable) fear of the medical system contribute to lack of diversity in the studies mentioned. There is overrepresentation of high-income Caucasians than people of low income, low education level, and nonwhite people. This is a multifaceted issue with many root causes, including nonwhite people being offered this treatment less than the Caucasian group for fear of increased complication rate and fear of non-adherence<sup>5</sup>, based in racist ideology. Lack of insurance or public insurance is another contributor regarding the overrepresentation of Caucasians being offered this treatment<sup>5</sup>. For this reason, the data that exists regarding the consequences of bariatric surgery have gaps.

This gap is significant due to studies suggesting varying obesity-related comorbidities among different ethnic and/or racial groups, and varying data in resolution of comorbidities and effects of these surgeries.

Interestingly, there is conflict between studies, presenting varying data on comorbidities in certain populations and the varying remission of comorbidities on bariatric surgery among these different populations. For example, one retrospective analysis of 1,539 adolescent who underwent bariatric surgery found baseline characteristics differing between racial/ ethnic groups: Black patients had higher pre-operative BMI, more hypertension and asthma than white and Hispanic patients. White patients had higher rates of depression and GERD. This study did not find differences in weight loss and comorbidity remission between racial groups<sup>6</sup>. One study looking at associations of race with perioperative and postoperative outcomes suggested difference in comorbidity resolution, showing higher remission rates of sleep apnea and GERD in Black patients, with hypertension resolution rates lower in Black patients compared to white patients<sup>8</sup>. Because of the aforementioned overrepresentation of Caucasian patients in these studies and conflicting existing data on resolution of comorbidities in non-white populations, this study aims to bridge the gap by providing insight into the effects of bariatric surgery on majority non-white patients and their resolution of comorbidities, especially hypertension. Due to the known high prevalence of hypertension in our patient population and the existing adult data on white and nonwhite patients, it is speculated that bariatric surgery in non-white, mainly Hispanic patients will provide resolution of obesity-related comorbidities, especially hypertension.

### **Aims:**

1. Investigate the effects of sleeve gastrectomy in a cohort of patients of diverse SES and ethnicity, specifically assessing effects on weight loss and blood pressure.

### **B. Methodology:**

For this study, the database of adolescents who underwent sleeve gastrectomy at New-York Presbyterian/ Morgan Stanley Children's Hospital, Columbia University Irving Medical Center (CUIMC) from 2011-2019, will be accessed. Evaluation of patients included measurement of weight, glucose tolerance testing, and blood pressure measurement at time 0, 6, and 12 months post-procedure. To better understand the study participants, demographic variables including type of insurance and ethnicity were assessed through analysis of patient charts on EPIC.

### **C. Analysis:**

There will be a table 1 of patient characteristics including ethnicity, insurance type, gender, age, and baseline HOMA index to describe the patient population involved in the study. Patients in this cohort will be subdivided into groups- those with private insurance and those with public insurance, those who identify as hispanic and those who identify as non-hispanic. Insurance will be used as a marker of socioeconomic status to understand potential differences between these two groups. Two-way ANOVA will be done to understand if there is an interaction between the SES and ethnicity on weight loss and change in blood pressure.

Power analysis will be conducted. We will assume a p value of <0.05 for statistical significance and 80% power. Thus far, we have a known N of 175, but it is unclear the proportion of which are non-privately insured and identify as hispanic.

In a similar study (9), it was found that at 6 month follow up, with mean weight loss of 48.1% with IQR (33.7-61.4) that a difference of 12% could be detected with a power of 80% assuming a p value of <0.5.

**D. Study drugs and alternatives:**

Not Applicable

**E. Medical Devices:**

Not Applicable

**F. Potential conflict of interest:**

No conflict of interest to declare.

**G. Potential risks:**

This retrospective study does not involve risk to a patients' health or well-being.

**H. Potential benefits:**

This study has benefit for future patients in further exploring if there are certain populations who would benefit from sleeve gastrectomy who are underrepresented in the current literature.

**I. Limitations:**

The limitations of this study include its retrospective nature. Additionally, while this study aims to look at populations of varying SES, we are using insurance (private vs. non-private) as a measure of SES. This may not be completely representative.

**J. Future considerations:**

Due to the gap in the literature examining non-white and lower SES patients, it would be valuable to track blood pressure and weight loss at 3 and 5 year post-procedure to understand the long-term outcomes of sleeve gastrectomy in our unique population.

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