Bariatric Surgical Procedures Clinical Outcomes at Maternal and Fetal levels

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Abstract

**Background:** Maternal obesity a cornerstone challenging issue that raised concerns all over the world, improvements in bariatric surgery procedures made pregnancy after bariatric surgery a common clinical case scenario. However, researchers have increased concerns about clinical outcomes around the impact of bariatric surgery management interventions on maternal and fetal outcomes.

**Aim** to assess and evaluate the clinical outcomes of bariatric surgical procedure on maternal and fetal levels

**Methodology:** A prospective research study conducted from April 2013 till December 2018 on 180 study subjects that were recruited and categorized in two research study groups group I involved 45 cases that have undergone bariatric surgery and research group II involved 135 cases that are obese and didn’t undergo bariatric surgeries.

**Results:** There was a statistically significantly lower frequency of Gestational diabetes (GDM) and Large for gestational age (LGA) in women of research group I (post bariatric surgery) (p value=0.028, 0.025, consecutively). The rates of macrosomia was lower in research group I, but not to a statistically significant level (p value=0.208). The rates of Small for gestational age (SGA) and Low birth weight (LBW) were statistically significantly higher among women of research group I (Pvalues =0.027, and 0.048, consecutively). The rates of preterm labor were higher, but not to a statistical significant level, among women of research group I (p value=0.762. The rates of Still birth (SB) and neonatal mortality were comparable in both research groups (Pvalues=0.999).

**Conclusions:** There is positive impact of bariatric surgery on Gestational DM and Large for gestational age rates in obese cases, however preterm labor concerns in the current research requires future research efforts on multicentric fashion and larger sample sizes.

Introduction

Around 300 million females all over the globe are classified as obese. That has raised concerns about the impact of obesity on maternal and fetal health, with the appearance and advances in bariatric surgery practice all over the world. Many cases at child bearing age got pregnant after bariatric surgical interventions due to metabolic and hormonal improvements. However still there are health concerns about the impact of various types of bariatric surgical interventions on maternal and fetal health [1-3].

Although bariatric surgeries are considered the most effective long-term management in obese and morbidly obese cases reducing and causing remission of associated comorbidities such as type 2 DM and hypertensive disorders. Malabsorptive issues of micronutrients and its impact on fetal intrauterine development is a major issue of concern. Research teams of investigators all over the globe interested in maternal and fetal health have growing interest in investigating the impact of different bariatric surgical procedures on maternal and fetal clinical statuses [4-6].

On the other hand, maternal obesity has different and numerous hazardous clinical cases scenarios such as still birth, macrosomia and preeclampsia making bariatric surgery in females looking forward to conceiving a demanding and lifesaving surgical intervention particularly in cases suffering morbid obesity and have associated medical comorbidities [7-9].

Various prior research groups of investigators have revealed and displayed that on long-term and short term that obese and morbidly obese cases managed with bariatric surgeries have shown remission from type 2 DM that improved their fertility potential and their obstetric clinical outcomes. The impact ofpregestational
bariatric surgical interventions however was investigated in an inadequate number of research studies that didn’t take into account the prepregnancy BMI. On the other hand, the research systematic reviews that have shown reduced rates of neonatal complications are based on small sample size research studies [10-12].

Methodology
This research study was carried out in Saudi Arabia, in Jeddah at a private hospital (Bugshan Hospital), and was conducted in a prospective manner from April 2013 till December 2018 on 180 study subjects that were recruited and categorized in two research study groups group I involved 45 cases that have undergone bariatric surgery and research group II involved 135 cases that are obese and didn’t undergo bariatric surgeries. All patients included in the study were provided with an informed consent after receiving a full explanation of the nature and protocol of the study.

For all cases, the age, BMI before and after surgery, early pregnancy parity and associated comorbidities were obtained and statistically analyzed. Fetal and maternal clinical outcomes were observed such as development gestational DM, macrosomia, still birth and various other clinical outcomes in order to compare and contrast between both research groups recruited. The interval of time between bariatric surgical procedure performance and the occurrence of pregnancy was determined. Cases that refused participation and those whom developed complications from bariatric surgical procedures were excluded from the research study.

Statistical analysis
Inferential analyses were done for quantitative variables using independent t-test in cases of two independent groups, ANOVA test for more than two independent groups with post hoc Tuky’s test. In qualitative data, inferential analyses for independent variables were done using Chi square test for differences between proportions and Fisher’s Exact test for variables with small expected numbers. Logistic regression was done for factors affecting clinical and completed first trimester pregnancy among the studied cases. The level of significance was taken at P value < 0.050 is significant, otherwise is non-significant.

Results
A total of 45 pregnant women who had undergone bariatric surgery were included as group I, along with 135 control pregnant obese women who had never undergone bariatric surgery as group II.

Table 1: Initial Characteristics of Included Women

|                  | Group I [Post-Bariatric Surgery Group] (n=45) | Group II [Control Group] (n=135) | MD/OR (95% CI) | P     |
|------------------|---------------------------------------------|----------------------------------|----------------|-------|
| Age (years)      | 26.13 ± 4.83                               | 25.94 ± 4.75                     | 0.19 (-1.43 to 1.81) | 0.8171 |
| BMI before Surgery (kg/m²) | 46.51 ± 6.77                               | --                               | --             | --    |
| Interval between Surgery and Pregnancy | 2.11 ± 1.08                               | --                               | --             | --    |
| BMI in Early Pregnancy (kg/m²) | 30.22 ± 2.98                               | 40.09 ± 5.81                     | -9.87 (-11.65 to -8.01) | <0.0011 |
| Nulliparous      | 11 (24.4%)                                 | 43 (31.9%)                       | 0.69 (0.32 to 1.50) | 0.3482 |
| Parous           | 34 (75.6%)                                 | 92 (68.1%)                       |                 |       |

Comorbidities
- Diabetes mellitus
  - Group I: 2 (4.4%)
  - Group II: 3 (2.2%)
  - MD/OR (95% CI): 2.05 (0.33 to 12.66) (P = 0.7932)
- Hypertension
  - Group I: 1 (2.2%)
  - Group II: 1 (1.5%)
  - MD/OR (95% CI): 1.51 (0.13 to 17.07) (P = 0.7372)
- Sleep apnea
  - Group I: 4 (8.9%)
  - Group II: 6 (4.4%)
  - MD/OR (95% CI): 2.10 (0.56 to 7.80) (P = 0.5422)

Data presented as mean ± standard deviation; or frequency (percentage)
BMI body mass index
MD (95% CI) mean difference and its 95% confidence interval
OR (95% CI) odds ratio and its 95% confidence interval
1 Analysis using independent student’s t-test
2 Analysis using Yates’ corrected chi-squared test

Table-1 shows initial characteristics in both groups. There were no statistical significant differences as regards the age, parity and incidence of comorbidities (DM, hypertension, sleep apnea) (P values=0.817,0.348, 0.793, 0.737, 0.542, consecutively). The mean BMI in early pregnancy was statistically significantly lower in women of research group I (post bariatric surgery) (p value=0.001) (table-1).
| Group I [Post-Bariatric Surgery Group] (n=45) | Group II [Control Group] (n=135) | OR (95% CI) | p* |
|---------------------------------------------|----------------------------------|-------------|----|
| Gestational Diabetes                        |                                  | 0.22 (0.05 to 0.95) | 0.028 |
| LGA                                         |                                  | 0.3 (0.10 to 0.91)  | 0.025 |
| Macrosomia                                  |                                  | 0.32 (0.07 to 1.46) | 0.208 |
| SGA                                         |                                  | 3.03 (1.09 to 8.4)  | 0.027 |
| LBW                                         |                                  | 4.0 (1.16 to 13.82) | 0.048 |
| Preterm Birth                               |                                  | 1.41 (0.46 to 4.3)  | 0.762 |
| SB                                          |                                  | 3.05 (0.19 to 49.7) | 0.999 |
| Neonatal Mortality                          |                                  | 3.05 (0.19 to 49.7) | 0.999 |

Data presented as frequency (percentage)
LGA large for gestational age - SGA small for gestational age
LBW low birth weight - SB stillbirth
OR (95% CI) odds ratio and its 95% confidence interval
1 Analysis using Yates’ corrected chi-squared test

There was a statistically significantly lower frequency of GDM and LGA in women of research group I (post bariatric surgery) (p value=0.028, 0.025, consecutively). The rates of macrosomia was lower in research group I, but not to a statistically significant level (p value=0.208). The rates of SGA and LBW were statistically significantly higher among women of research group I (P values =0.027, and 0.048, consecutively). The rates of preterm labor were higher, but not to a statistical significant level, among women of research group I (p value=0.762. The rates of SB and neonatal mortality were comparable in both researchgroups (Pvalues=0.999) (table-2).

| Group I [Post-Bariatric Surgery Group] (n=45) | Group II [Control Group] (n=135) | OR (95% CI) | p 1 |
|---------------------------------------------|----------------------------------|-------------|----|
| Gestational Diabetes                        |                                  | 0.23 (0.03 to 1.81) | 0.233 |
| Interval < 2 years                          | 1/21 (4.8%)                     | 24 (17.8%)  | 0.023 |
| Interval ≥ 2 years                          | 1/24 (4.2%)                     | 24 (17.8%)  | 0.166 |
| Reduction < 12 kg/m²                         | 1/28 (3.6%)                     | 24 (17.8%)  | 0.107 |
| Reduction ≥ 12 kg/m²                         | 1/17 (5.9%)                     | 24 (17.8%)  | 0.368 |
| LGA                                         |                                  | 0.33 (0.07 to 1.47) | 0.214 |
| Interval < 2 years                          | 2/21 (9.5%)                     | 33 (24.4%)  | 0.214 |
| Interval ≥ 2 years                          | 2/24 (8.3%)                     | 33 (24.4%)  | 0.137 |
| Reduction < 12 kg/m²                         | 1/28 (3.6%)                     | 33 (24.4%)  | 0.027 |
| Reduction ≥ 12 kg/m²                         | 3/17 (10.7%)                    | 33 (24.4%)  | 0.155 |
| SGA                                         |                                  | 5.6 (1.75 to 17.9) | 0.006 |
| Interval < 2 years                          | 6/21 (28.6%)                    | 9 (6.7%)    | 0.006 |
| Interval ≥ 2 years                          | 2/24 (8.3%)                     | 9 (6.7%)    | 0.006 |
| Reduction < 12 kg/m²                         | 3/28 (10.7%)                    | 9 (6.7%)    | 0.727 |
| Reduction ≥ 12 kg/m²                         | 5/17 (29.4%)                    | 9 (6.7%)    | 0.009 |
| LBW                                         |                                  | 6.12 (1.5 to 25.02) | 0.021 |
| Interval < 2 years                          | 4/21 (19%)                      | 5 (3.7%)    | 0.021 |
| Interval ≥ 2 years                          | 2/24 (8.3%)                     | 5 (3.7%)    | 0.632 |
| Reduction < 12 kg/m²                         | 1/28 (3.6%)                     | 5 (3.7%)    | 0.630 |
| Reduction ≥ 12 kg/m²                         | 5/17 (29.4%)                    | 5 (3.7%)    | 0.005 |

Data presented as frequency (percentage)
LGA large for gestational age - SGA small for gestational age
LBW low birth weight - SB stillbirth
OR (95% CI) odds ratio and its 95% confidence interval

As regards Gestational DM interval between surgery and pregnancy (<2 years and ≥ 2 years) and to the reduction in BMI (<12 kg/m² and ≥ 12 kg/m²) (p values=0.233, 0.166, 0.107, 0.368, consecutively).

As regards LGA...... (P values=0.214, 0.137, 0.027, 0.155, consecutively)
As regards SGA...... (P values=0.006, 0.889, 0.727, 0.009, consecutively)
As regards LBW...... (P values =0.021, 0.632, 0.630, 0.005, consecutively)

Statistically significantly different outcomes were re-analyzed after categorization according to the interval between surgery and pregnancy (<2 years and ≥ 2 years) and to the reduction in BMI (<12 kg/m² and ≥ 12 kg/m²) (table-3). This categorization showed that women who had an interval less than 2 years between surgery and pregnancy and those who had ≥ 12 kg/m² loss in their BMI were at higher risk of having SGA and LBW (table-3).

Discussion

Bariatric surgery the most efficient management protocol for obesity particularly morbidly obese cases withlong lasting valuable clinical impact as regards weight loss and metabolic disorders. Even though surgical induced weight loss has a positive effect on clinical pregnancy outcome, the surgical procedures couldbe associated with adverse clinical outcomes e.g. micronutrient deficiencies, iron or B12 deficiency anemia, dumping syndrome, surgical complications such as internal hernias, and small for gestational age offspring, probably due to maternal under nutrition [13-15].

This research study involved a total of 45 pregnant study subjects who had undergone bariatric surgery were included as research group I, along with 135 control pregnant obese study subjects who had never undergone bariatric surgery as research group II. There was a statistically significantly lower frequency of GDM and LGA in women of research group I (post bariatric surgery) (p value=0.028, 0.025, consecutively). The rates of macrosomia were lower in research group I, but not to a statistically significant level (p value=0.208). The rates of SGA and LBW were statistically significantly higher among women of research group I(P values =0.027, and 0.048, consecutively). The rates of preterm labor were higher, but not to a statistically significant level, among women of research group I(p value=0.762. The rates of SB and neonatal mortality were comparable in both research groups (P values=0.999).

Statistically Significantly different outcomes were re-analyzed after categorization according to the interval between surgery and pregnancy (<2 years and ≥ 2 years) and to the reduction in BMI (<12 kg/m² and ≥ 12 kg/m²) (table-3). This categorization showed that women who had an interval less than 2 years between surgery and pregnancy and those who had ≥ 12 kg/m² loss in their BMI were at higher risk of having SGA and LBW.

A prior prospective cohort research study similar to the current research study in methodology and approach have revealed and displayed that cases with a prior history of bariatric surgical interventions had a lower clinical risk of developing gestational DM and large-for-gestational- age infants and a raised clinical risk for development of SGA infants and a briefer gestational period cases that didn’t perform bariatric surgeries implemented as control research group after matching both research groups regarding the pre-pregnancy BMI [16-18].

On the other hand prior research studies have revealed and displayed debatable and conflicting research study findings as regards the impact of bariatric surgeries on the pathological development of gestational DM those conflicting results could be justified by the fact that there was small sample sizes and differences and variabilities in research study methodologies [19].

In a previous research study similar to the current study there were no cases of gestational DM among 70 study subjects recruited having a past history of performing bariatric surgical interventions however another research study have revealed that there was gestational DM diagnosis in around 1.9% cases recruited and investigated that have previously undergone bariatric Surgical procedures and in 6.8% of matched research controls. Furthermore it was revealed and observed among the findings that perinatal mortality was 5.7% within gestations having a history of bariatric procedures and 0.7% within the research control gestations. All previous findings show great harmony and similarity to the current research study findings [1, 3, 5, 7].

On the other hand another research team of investigators performed a research study similar to the current research have revealed and displayed as regards fetal outcomes that there was A greater clinical risk of stillbirth or neonatal death in cases having past history of bariatric surgical procedures that raises the concerns of bariatric surgical procedures safety on fetal health and development however those findings could be justified by the small sample size present in that study besides the differences between the study and control groups wasn’t statistically significant interestingly it was observed previously in similar studies to the current one that cases having bariatric surgical interventions before pregnancy had reduced clinical risk of giving birth to large-for-gestational-age neonates but on the other hand had but a greater risk of giving birth to risk of delivering small-for-gestational-age infants[2,4,6].

A prior research meta-analysis, performed on females that have undergone bariatric surgery have revealed and displayed that there is a reduced risk of gestational DM, hypertensive diseases, and macrosomic fetuses in comparison to obese females with no previous history of performing bariatric surgical interventions, on the other hand, there was raised clinical risk of small for gestational age neonates, no statistical significant differences have been observed for preterm labor [8,10].

Gestational DM and hypertensive diseases are two crucial obstetric clinical scenarios. It was shown that pregnant cases after bariatric interventional procedures have at minimum 50% lower odds of developing gestational DM and hypertensive diseases in comparison to obese Cases without a past history of a bariatric surgical interventions. Interestingly a prior research group of investigators have revealed and displayed that there was a raised risk of Gestational DM and reduced weight loss among cases becoming pregnant within the first 2 years after weight losing surgery in comparison to cases getting pregnant after 2 years those research findings could be justified by the fact that it takes time for metabolic remission and stabilization in obese cases that could be disrupted by occurrence of pregnancy before 2 years since pregnancy.
is considered a diabetogenic state challenging the physiologic and metabolic profile of the cases so early. Another research team of investigators did not mention any statistically significant differences concerning maternal or feta clinical outcomes as regards timing of pregnancy after bariatric surgery [11, 13].

Nutritional challenges after bariatric surgical procedures could intensify during gestation and could have an impact on maternal and fetal levels. They investigated the impact of nutritional clinical counseling and displayed that, a personalized nutritional follow-up during post-bariatric gestation could contribute to improved micronutrient intake and diet quality; this could explain the higher birth weight[15,18].

Furthermore, prior research studies similar in approach and methodology to the current research have shown that there was no statistically significant higher clinical risk of preterm labor between obese cases without bariatric surgery performance and cases that have a past history of bariatric surgery. On the other hand, it was revealed that the risk of preterm labor subgroup analyses suggested that this risk could be raised among cases with a better reduction in BMI between surgery and early gestation [11,16,19].

**Conclusions and recommendations**

From this research study there is a positive impact of bariatric surgery on gestational DM and large for gestational age rates in obese cases; however, preterm labor concerns in the current research requires future research efforts on multicentric fashion and larger sample sizes. Furthermore, the future research efforts should put in consideration racial and ethnic differences among cases that could impact the clinical outcomes after bariatric surgical procedures.

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