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## Original Research Article

## Obstetric outcome following bariatric surgery in kingdom of Bahrain

Amala Sunder<sup>1\*</sup>, Bessy Varghese<sup>1</sup>, Haya Albuainain<sup>1</sup>, Noora Bahzad<sup>1</sup>,  
Reem Talal Almehzab<sup>1</sup>, Basma Darwish<sup>1</sup>, Nawal Dayoub<sup>2</sup><sup>1</sup>Bahrain Defense Force Hospital, Riffa, Bahrain<sup>2</sup>Assisted Reproductive and Gynecology Center, London, England

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## ABSTRACT

**Background:** Obesity has complications in relation to health as well as pregnancy. Bariatric surgeries gain interest among obese women to reduce the adverse obstetric outcomes. However, pregnancy post bariatric surgeries have benefits as well as risks. The study analyzed the effects of bariatric surgery on pregnancy, delivery, and postpartum period.

**Materials and Methods:** This is a retrospective study conducted in Bahrain Defense Force Hospital from September 2019 till August 2020. The study included women in the reproductive age who had bariatric surgery before planning pregnancy and a control group of women who did not undergo the bariatric surgeries. Comparison of obstetric outcome was done between both groups. Data included demographic characteristics, method conceived, antenatal pathway, delivery process and postpartum period. Results were presented as odds-ratios (OR) with 95% confidence interval (CI) and P-values. P values of less than 0.05 were considered statistically significant.

**Result:** This analysis includes 2972 patients. 47 patients of them had undergone previous bariatric procedure. Patients with previous bariatric surgery were older 32.8vs 29.9 and interestingly heavier with BMI 34.5 vs 31.1. Patients with previous bariatric surgery had more antenatal complications 36% vs 18.5% (p=0.002). The most evident complication is gestational diabetes with 21.3% of patients who had bariatric surgery developed Gestational Diabetes Mellitus(GDM) during pregnancy compared to 8.9% of patients without the surgery (P=0.004). Both groups had similar start of labor, 1<sup>st</sup> stage of labor, 2<sup>nd</sup> stage of labor, 3<sup>rd</sup> stage of labor and prolonged 2<sup>nd</sup> stage of labor. Caesarean section rate was similar at 42.6% vs 35.4% (p=0.31). After adjusting confounding factors, previous bariatric surgery increased length of stay in hospital more than 3 days with OR 2.3 95%CI (1.2-4.4) P=0.01.

**Conclusion:** Our study concluded the antenatal complications, Gestational diabetes as well as postpartum length of stay are significantly increased in post bariatric pregnant women. However, labor process and fetal outcome did not show significant difference.

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## 1. Introduction

Obesity global prevalence almost tripled between 1975 and 2016.<sup>1</sup> Obesity increases the risk of non-communicable morbidities such as cardiovascular, diabetic,

musculoskeletal and cancers,<sup>2</sup> as well as maternal and fetal adverse outcomes.<sup>3</sup> Obesity and the potential complications are correctable mostly upon individual interest of lifestyles.<sup>2</sup> However Bariatric surgeries are recommended upon individual assessment for the effective management of obesity. Generally, Bariatric surgeries are advocated for the individual with Body Mass

\* Corresponding author.

E-mail address: [sunderamala1@yahoo.co.in](mailto:sunderamala1@yahoo.co.in) (A. Sunder).

Index (BMI) more than 40 kg/m<sup>2</sup> or BMI more than 35 kg/m<sup>2</sup> with associated comorbidities.<sup>4,5</sup> However the study by Eisenberg D and et al., supported Metabolic and bariatric surgery (MBS) with a body mass index (BMI)  $\geq$ 35 kg/m<sup>2</sup>, not in relation with comorbidities and BMI of 30-34.9 kg/m<sup>2</sup> with associated comorbidities.<sup>6</sup> The recommendations of the surgical practice to be specified according to individual assessment as well as requirement and follow up to reduce the adverse effects of the surgeries.<sup>6</sup>

The rate of bariatric surgeries slowly increased almost six-fold from 1998 to 2005 and rapidly increased in the past ten years. Approximately 50% of bariatric surgeries are done for the women in reproductive age.<sup>7</sup> Bariatric surgeries reduce the complications related to obesity during pregnancy such as gestational diabetes and pregnancy induced Hypertension reduced to the rate of 2.5% from 13% as well miscarriage rate reduced to 7.85 from 33.3% in obese individuals without bariatric surgeries.<sup>8–10</sup> However, the adverse effects of surgeries could include low birth weight babies, fetal growth restriction, maternal nutritional deficiencies, and maternal anemia.<sup>11</sup> Analyzing the effect of bariatric surgeries on antenatal, labor, and postnatal period is essential to provide adequate care for the women undergoing these surgeries in reproductive age as well as to optimize care during pregnancy.

## 2. Materials and Methods

This is a retrospective observational study of pregnant women who delivered in our maternity unit at Bahrain Defense Force Hospital, West Riffa, Bahrain, from September 2019 till August 2020. The study was approved by the Royal Bahrain Defense Force Hospital Ethical Committee. Data were collected from the electronic records of women from our maternity unit and data were anonymized as well as data protection policy was followed. The population undergone bariatric surgeries before the pregnancy were selected for the study and control group was the women not had bariatric surgeries.

### 2.1. Inclusion criteria

Pregnant women who undergone bariatric surgeries before the pregnancy were included for the study. Also, the same population who delivered at gestational age more than 24 weeks were included in the study. The pregnant women delivered at gestational age more than 24 weeks with no history of bariatric surgery were included as control group.

### 2.2. Exclusion criteria

Pregnant women with gestational age of less than 24 weeks were excluded from the study. Pregnant women who were infected with coronavirus disease 2019 (COVID-19) during pregnancy or around delivery were excluded from the study upon the confirmation by nasopharyngeal samples

using the polymerase chain reaction (PCR) or SARS-CoV-2 GeneXpert during the study period as well as patients with incomplete records.

The clinical variables we included were age, BMI, method conceived, parity, current and past obstetric details, and maternal co morbidities such as hypertension, gestational hypertension, eclampsia, preeclampsia, diabetes, GDM and obstetric cholestasis. Antenatal course, such as development of anaemia, GDM, Gestational hypertension, preeclampsia. Our departmental clinical protocols are based on Royal College of Obstetricians and Gynecologists (RCOG)<sup>12</sup> as well as American College of Obstetricians and Gynecologists (ACOG)<sup>13</sup> guideline recommendations. Preeclampsia is defined when the systolic blood pressure is 140 mm Hg or more or diastolic blood pressure is 90 mm Hg or more on two occasions at least four hours apart after 20 weeks of gestation in a woman with a previously normal blood pressure along with proteinuria, which is defined when 300 mg or more per 24-hour urine collection or protein/creatinine ratio of 0.3 mg/dl or more or dipstick reading of 1 and more, or in the absence of proteinuria, new-onset hypertension along with deranged hematological tests, impaired liver function tests/renal function tests. In the absence of proteinuria, high blood pressure is categorized as gestational hypertension. Eclampsia is any new onset of convulsions in the absence of disorders such as epilepsy and cerebral pathology. To identify GDM, we do Glucose tolerance test at 24-28 weeks of gestation for all pregnant women and if a woman has a previous history of GDM, we do the screening test at the booking visit. We categorize antepartum hemorrhage as any obstetric hemorrhage after 22 weeks of gestation. In our study we defined oligohydramnios when Amniotic fluid calculation of Deep Vertical Pocket (DVP) < 2cm or AFI < 5- 6 cm and polyhydramnios when Amniotic fluid calculation of Deep Vertical Pocket (DVP) more than 8cm or AFI more than 20 cm during third trimester scan. The delivery process such as stages of delivery, mode of delivery, gestational age at delivery, stages of labor, perineal tears, shoulder dystocia, and postpartum course, which includes estimated blood loss, postpartum hemorrhage, postpartum sepsis, wound infections, and length of stay in days were analysed. Patients staying in hospital more than 3 days were considered to have prolonged hospital stay post-delivery. Additionally, we studied Gestational age at delivery, growth profile of the fetus, birth weight of the babies, Apgar scores, stillborn, fetal anomalies, and neonatal unit admission. In our study we calculated death of a live birth neonates during the first seven days of life as early neonatal death.<sup>14</sup> We studied preterm deliveries before 37 weeks of gestation and late term deliveries, the women delivered between 41 weeks to 41+6 weeks.<sup>15</sup> Low Apgar score considered when Apgar score at 5 minutes post-delivery was 0- 3. Birth centiles were calculated based on the World Health Organization (WHO)

gestational age and birth weight calculator.<sup>16</sup>

### 2.3. Statistical analysis

Statistical analysis was done using Statdirect software (Version 3.3.5 22/03/2021). The first assessment was done on the data to explore differences between the groups with regards to basic characteristics such as age, BMI, parity, previous obstetric history, and any comorbidities. Furthermore, labor outcome, maternal/neonatal complications and post-partum complications were also compared between the groups. Two-sided Unpaired t test was used for normally distributed continuous variables, two sided Mann-Whitney test was used for nonparametric variables and Chi square/ fisher test were used for categorical variables. Multiple logistic regression analyses were performed to identify the effect of having previous Bariatric surgery on the risk of maternal morbidity, delivery complications, fetal complications, and post-partum morbidities after adjusting results for covariates. Results were presented as odds-ratios (OR) with 95% confidence interval (CI) and P-values. P values of less than 0.05 were considered statistically significant.

### 3. Results

This analysis includes 2972 patients. 47 of them had undergone previous bariatric procedure. Patients with previous bariatric surgery were older 32.8 vs 29.9 years ( $P=0.0002$ ), and interestingly heavier with BMI of 34.5 vs 31.1 ( $P=0.005$ ). Patients with previous bariatric surgery also had more coexisting morbidity 38.3% vs 18.5%. Patients in the bariatric surgery group had a history of previous caesarean more than the other group 38.3% vs 17.4%. There was no difference in parity and IVF conception. Both groups have a similar percentage of smokers (Table 1).

Patients with previous bariatric surgery had more antenatal complications 36% vs 18.5% ( $p=0.002$ ). The most evident complication is gestational diabetes with 21.3% of patients who had bariatric surgery developed GDM during pregnancy compared to 8.9% of patients without the surgery ( $P=0.004$ ). There was no difference in bleeding, hypertension, pre-eclampsia, obstetric cholestasis, and poly/oligo hydramnios (Table 2).

Both groups had similar start of labor, 1<sup>st</sup> stage of labor duration, 2<sup>nd</sup> stage of labor duration, 3<sup>rd</sup> stage of labor duration and prolonged 2<sup>nd</sup> stage of labor rate. Caesarean section rate was similar at 42.6% vs 35.4% ( $p=0.31$ ). Both groups delivered around 38 gestational weeks with similar fetal weight at delivery 3.1vs 3.2 kg ( $P=0.57$ ). Both groups had similar birth weight centile and poor Apgar score. Furthermore, post-delivery complications were comparable. (Tables 3 and 4)

Assessment of the groups post-partum revealed a higher percentage of patients staying in hospital more than 3 days

in the bariatric group 34% vs 15.7% ( $P=0.0007$ ). All factors leading to prolonged stay were assessed and surprisingly no difference was noted between the groups with regards to wound problems, infections, UTI, estimated blood loss/ blood transfusion, Postpartum haemorrhage. (Table 5)

Logistic regression analysis was done to assess risk of bariatric surgery on maternal morbidities, antenatal complications, GDM, artificial start of labor, caesarean delivery, delivery complications, postpartum complications, fetal complications, and prolonged hospital stay of more than 3 days. After adjusting confounding factors, previous bariatric surgery increased length of stay in hospital more than 3 days with OR2.3 95% CI (1.2-4.4)  $P=0.01$ . (Table 6)

### 4. Discussion

Obese individuals in reproductive age, who have been battling infertility resort to bariatric surgery once the lifestyle modifications failed. The aim of bariatric surgery is to improve chances of pregnancy and to reduce the complications of obesity during pregnancy as well as to optimize pregnancy outcome. Between 2006 -2009, Menke MN and colleagues conducted a multi-center cohort study including 650 women from 10 United States hospitals found that women with history of infertility, had a higher conception rate following bariatric surgery.<sup>17</sup> Self-esteem enhancement and body image improvement are key factors in sexual functioning in women after bariatric surgery. These findings were concluded by Nilsson-Condori E et al. after a thematic analysis of questionnaire data followed by a qualitative study.<sup>18</sup> A cohort study involving 216 very obese premenopausal women with polycystic ovaries who underwent bariatric surgery was done to assess fertility and gestational outcomes by Benito E et al. It was estimated that pregnancy and fertility were higher without many maternal and neonatal complications.<sup>19</sup> Our analysis did not look at preconception fertility issues but found no difference in IVF conception between the groups.

In this study we noted older patients in the post bariatric surgery group. Similar findings were reported by Sesilia K and colleagues.<sup>20</sup> This was also noticed by Youssef Zadeh group after a large retrospective cohort study including a population of 14,648,135 patients out of whom 53,950 had bariatric surgery.<sup>21</sup> In cases of both laparoscopic and open bariatric surgery smoking was considered a modifiable risk factor which increases the post-operative morbidity concluded Haskins IN et al.<sup>22</sup> In our observation we found that both the bariatric surgery group and the non- bariatric surgery group had similar percentage of smokers.

A retrospective study was conducted in Brazil by Balestrin B et al to assess the influence of bariatric surgery on gestational outcomes. Women with BMI more than or equal to 30kg/m<sup>2</sup> (205 women) and those who had undergone bariatric surgery (93 women) were interviewed. An evaluation of their medical records and antenatal

**Table 1:** Basic patients characteristics

	<b>Surgery N= 47</b>	<b>No surgery N=2925</b>	<b>P value</b>
Age mean $\pm$ SD	32.8 $\pm$ 4.6	29.9 $\pm$ 5.8	0.0002
Body Mass Index median (range)	34.5 (23.3-55)	31.1 (16-66)	0.005
Parity median (range)	2.7 (0-11)	2.2 (0-11)	0.35
Any comorbidity	18 (38.3)	541 (18.5)	0.0006
Smoking	0 (0)	13 (0.4)	>0.99
Previous Caesarean Section	18 (38.3)	510 (17.4)	0.0002
In vitro Fertilization	2 (4.3)	86 (2.9)	0.65

**Table 2:** Pregnancy characteristics

	<b>Surgery N= 47</b>	<b>No surgery N=2925</b>	<b>P value</b>
Antenatal complications	17 (36.2)	540 (18.5)	0.002
Gestational Diabetes Mellitus	10 (21.3)	263 (8.9)	0.004
Hypertension	1 (2.1)	37 (1.3)	0.46
Gestational Hypertension/Preeclampsia	2 (4.3)	72 (2.5)	0.33
Threatened /Antepartum Haemorrhage	2 (4.3)	29 (1)	0.09
Obstetric cholestasis	1 (2.1)	17 (0.6)	0.25
Oligo hydramnios	0 (0)	75 (2.6)	0.63
Polyhydramnios	1 (2.1)	35 (1.2)	0.44

**Table 3:** Labor characteristics

	<b>Surgery N=47</b>	<b>No surgery N=2925</b>	<b>P value</b>
Artificial start of labor	33 (70.2)	1664 (56.9)	0.07
1 <sup>st</sup> stage of labor mean $\pm$ SD	148.1 $\pm$ 167.2	204.8 $\pm$ 202.4	0.06
2 <sup>nd</sup> stage of labor $\pm$ SD	7.6 $\pm$ 16.8	8.3 $\pm$ 16.2	0.75
3 <sup>rd</sup> stage of labor mean (range)	4.7 (0-14)	5.9 (0-140)	0.27
Prolonged 2 <sup>nd</sup> stage	1 (2.1)	44 (1.5)	0.51
Mode of Delivery	20 (42.6)	1035 (35.4)	0.31
Post-delivery perineal trauma	21 (44.7)	1216 (41.6)	0.67

**Table 4:** Baby information

	<b>Surgery N=47</b>	<b>No surgery N=2925</b>	<b>P value</b>
Gestational age mean $\pm$ SD	38.4 $\pm$ 1.8	38.3 $\pm$ 2.1	0.57
Fetal weight mean $\pm$ SD	3.1 $\pm$ 0.5	3.2 $\pm$ 0.6	0.57
Birth weight centile mean $\pm$ SD	57.8 $\pm$ 29.8	61.9 $\pm$ 28.8	0.33
Birth weight <10 <sup>th</sup> centile	4 (8.5)	182 (6.2)	0.55
Birth weight >90 <sup>th</sup> centile	8 (17)	694 (23.7)	0.28
Good Apgar score	46 (97.9)	2882 (98.5)	0.51
Delivery complication total	5 (10.6)	468 (16)	0.32
Stillborn	0 (0)	19 (0.7)	>0.99
Early neonatal death	0 (0)	11 (0.4)	>0.99
Preterm	4 (8.5)	390 (13.3)	0.51
Post date	0 (0)	81 (2.8)	0.64
Neonatal Intensive Care Unit	3 (6.4)	174 (6)	0.76
Congenital anomalies	3 (6.4)	201 (6.9)	>0.99
Multiple Pregnancy	0 (0)	79 (2.7)	0.64

**Table 5:** Post-partum

	Surgery N=47	No surgery N=2925	P value
Postpartum complications	2 (4.3)	164 (5.6)	>0.99
Wound problems	1 (2.1)	37 (1.3)	0.46
Infection related problems	0 (0)	63 (2.2)	0.63
Urinary tract infection	0 (0)	51 (1.7)	>0.99
Estimated blood loss mean $\pm$ SD	362.8 $\pm$ 241.3	368.2 $\pm$ 244.4	0.88
Postpartum Haemorrhage	0 (0)	54 (1.9)	>0.99
HB levels mean $\pm$ SD	11.8 $\pm$ 1.22	11.5 $\pm$ 1.4	0.23
Blood products	0 (0)	58 (2)	>0.99
Length of hospital stay >3 days	16 (34)	460 (15.7)	0.0007

**Table 6:** Risk of complications in patients with history of bariatric surgery

	OR	95% CI	Z value	Coefficient	Standard error	P
Maternal morbidity	0.9	0.12-6.8	-0.09	-0.09	1.02	0.93
Antenatal complications	1.7	0.8-3.4	1.4	0.51	0.37	0.17
Gestational Diabetes Mellitus	1.3	0.5-3.4	0.55	0.27	0.49	0.58
Artificial start of labor	1.3	0.7-2.6	0.8	0.28	0.35	0.42
Caesarean	1.5	0.8-2.8	1.42	0.43	0.3	0.16
Delivery complications	0.6	0.2-1.4	-1.21	-0.58	0.48	0.23
Post partum complications	0.7	0.17-3.02	-0.47	-0.35	0.74	0.64
Fetal complications	0.8	0.34-1.76	-0.61	-0.25	0.42	0.54
Birth weight >90 <sup>th</sup> centile	0.7	0.3-1.4	-1.08	-0.42	0.39	0.28
Birth weight <10 <sup>th</sup> centile	1.4	0.5-3.9	0.64	0.34	0.53	0.52
Length of hospital stay >3 days	2.3	1.2-4.4	2.6	0.84	0.33	0.01

information was done. Hypertensive disorders of pregnancy were found to have a lower occurrence in women who had bariatric surgery (14%) when compared to pregnant obese women (56.6%).<sup>23</sup> Surprisingly, we did not find any difference in the incidence of hypertension and pre-eclampsia. Balestrin study investigated diabetes as well and found less occurrence in women who had bariatric surgery (16.1%) in comparison to 30.2% in the obese group.<sup>23</sup> Another retrospective study of 23,594 women who underwent bariatric surgery between 2002 -2006, showed that the incidence of gestational diabetes was lower in individuals who underwent bariatric surgery.<sup>24</sup> Similarly, another study found the likelihood for developing gestational diabetes was lower in the bariatric group (19.67% vs 37.7%).<sup>25</sup> Contrary to this finding, we deduced from our study that gestational diabetes mellitus was found to be 21.3% in women who underwent bariatric surgery in comparison to 8.9% of women who did not have the surgery. (p=0.004). In our study, the surgery may have reduced the initial weight, but patients, post-surgery, were still heavier than the control group. After controlling all potential confounding factors including weight, our analysis found no effect of bariatric surgery on diabetes occurrence. Alike our initial findings, Sesilia K et al.<sup>20</sup> concluded in an observational study in Finland that there was an increased risk of gestational diabetes mellitus in the bariatric group. This study included 314 pregnant women with a history of

bariatric surgery and 750,019 women in the non -bariatric group during 2004-2016.<sup>20</sup>

Burke AE group also investigated cesarean section rate and concluded that there was a decrease in cesarean section after bariatric surgery.[24] On the contrary, Różańska-Wałędziak A et al. opined that the number of cesarean sections were higher in the bariatric group (57.38% vs 40.98%). Scheduled caesarean section, fetal distress indication and other urgent indications were all increased in the bariatric group.<sup>25</sup> In our study we concluded that the caesarean section rate was similar between post bariatric surgery and the non- operated group (42.6% vs 35.4%). Assessment of the course of pregnancy, maternal and neonatal outcomes of 77 patients who underwent bariatric surgery were compared to 345 patients who matched the BMI and delivered at a tertiary perinatal center by Różańska-Wałędziak A et al.<sup>25</sup> They observed that women who underwent bariatric surgeries had longer pregnancies of 39 weeks when compared to 37 weeks for those in the control group. Preterm deliveries were lesser in the bariatric surgery group (13.11% vs. 37.7%).<sup>23</sup> Our study found similar gestational delivery in both groups around 38 weeks.

Women with bariatric surgery had smaller for gestational age babies.<sup>23</sup> An exploratory retrospective multicenter cohort study by Grzegorzycyk-Martin V et al. assessed IVF outcomes after bariatric surgery in France. They found

that there was no significance in cumulative live birth rate between the operated and non-operated groups. However, in obese individuals who did not go through Bariatric surgery with a mean BMI of 37.7kg/m<sup>2</sup>, the live birth rate was significantly lower (9.3%) when compared to the other groups namely the non-operated group with mean BMI-28.8kg/m<sup>2</sup> (20%) and the group of women with history of bariatric surgery with mean BMI=28.9kg/m<sup>2</sup> (18%).<sup>26</sup> In the operated group there was a significant increase in small for gestational age.<sup>26</sup> Similarly, Rozanska group found small for gestational age was more likely in the bariatric group (18.03% vs 13.11%).<sup>25</sup> This was also the finding in Sesilia K et al observational study. We noted that the fetal weight at delivery was similar in the operated as well as the non-operated group in our analysis 3.1 vs 3.2(p=0.57).<sup>20</sup>

This analysis evaluated the possible labor complications between the groups. Interestingly there was no difference noted. One potential cause to this finding is the fact that post bariatric patients have higher BMI than the non-operated group. However, logistic regression analysis confirmed no difference between the groups after adjusting for all confounding factors including BMI.

Rózańska-Wałędziak group investigated the Apgar score at 5 minutes which was higher in the bariatric group.<sup>25</sup> We found the Apgar scores in both groups to be much the same. Similarly, our analysis identified no difference in the post-partum course between the groups. The only significant finding noted in our patients who underwent previous bariatric surgery is a longer hospital stay of more than 3 days post-partum with OR 2.3 95% CI (1.2-4.4) p=0.01 after adjusting for all other contributing factors such as age, BMI, and maternal morbidities. It is possible that most patients who had previous bariatric surgery were significantly morbidly obese and even after bariatric surgery they still have significant risk factors and associated morbidities as well as possibly poor mobilization post operatively.

## 5. Why is this Study Conducted?

Obesity increases the complications during pregnancy, delivery and affects birth outcome. The study is important to add knowledge in maternal as well as fetal outcome for the women who underwent bariatric surgeries before their pregnancies to understand the benefits and risks of the bariatric surgeries as it is major surgery and needs long term follow up and optimization of health.

## 6. What did the Study Add?

Our analysis did not show differences in most of the obstetric outcomes between study groups. However, we found the median BMI of both groups was still under the category of obesity and the women undergone bariatric surgery did not reach the optimal weight before embarking

on pregnancy. Regardless of BMI, bariatric surgeries significantly increased postpartum length of stay in hospital more than 3 days.

## 7. Strength of the Study

This study analyzed a significant and wide range of antenatal complications, intra partum process, and postpartum complications of pregnancies post bariatric surgeries. Some of the factors investigated were not reported by any previous studies. The study findings can be used in pre surgery counselling to optimize maternal outcome.

## 8. Limitations

The study sample size is small. Types of bariatric surgeries as well as the interval between the surgeries and the pregnancy were not studied, which could add to the correlation in obstetric outcome. Also, maternal nutritional deficiencies occurring after these procedures were not determined. The range of weight loss after the surgery was not studied, which might be very relevant when assessing the outcome.

## 9. Conclusion

Bariatric surgery has brought about a revolution in the management of obese women desiring pregnancy. Though pre-pregnancy bariatric surgeries reduced the complications of obesity during pregnancy, our study concluded bariatric surgeries significantly increased postpartum length of stay in the hospital. Also, our study did not prove many benefits in obstetric outcome after bariatric surgeries. Informed decision making with multi-disciplinary approach as well as long term follow-up programs before planning pregnancy is important for the optimal weight loss. Additionally, assessment of nutritional deficiencies and pregnancy care could help in achieving a successful pregnancy outcome in these high-risk individuals. Further, studies involving a larger number of patients, types of bariatric surgeries, weight loss as well as the interval between the surgeries and conception of pregnancy are required to highlight the impact of bariatric procedures on pregnancy.

## 10. Ethical Declaration and Consent to Participate

The study was performed according to the standard of our Institute, Bahrain Defense Force Hospital. The study was conducted after the approval of the ethical committee, the Crown Prince Centre for Training and Medical Research, Ref: RMS-BDF/P&PEC/2023-772.

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Not Applicable.

## 12. Competing Interest

None.

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## Author biography

**Amala Sunder**, Chief Resident (OBG)

**Bessy Varghese**, Senior Resident (OBG)

**Haya Albuainain**, Senior Resident (OBG)

**Noora Bahzad**, Senior Resident (OBG)

**Reem Talal Almezhaa**, Senior Resident (OBG)

**Basma Darwish**, Consultant (OBG)

**Nawal Dayoub**, Fertility Consultant

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