

Pregnancy After Bariatric Surgery: Implications for Mother and Newborn

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Abstract

Background The present study aimed to identify the implications for the mother and the newborn in pregnancies occurring after the bariatric surgery.

Methods The present retrospective, exploratory cohort study was conducted to analyze the implications for the mother and the newborn in women of childbearing age (10 to 49 years) who became pregnant after undergoing bariatric surgery in Maringá, Paraná, Brazil, during the period from 1999 through 2008.

Results The study identified 32 women with the following characteristics: the majority of the women were Caucasian, slightly more than half were living with a partner, had some higher education, and most of them were without surgical complications. In addition, the mean weight loss post-surgery was 44.09 lbs, with an average interval of 40 months between the surgery and the pregnancy, with improvement of various comorbidities post-surgery. Conversely, they presented more neuropsychiatric disorders,

post-surgery anemia, and higher prevalence of cesarean delivery. The majority of children were born at term with normal birth weight and no history of anemia. Hospitalization was required for 36.58% of the post-surgery pregnant women, while 17.07% of such cases required blood transfusion due to anemia. Lastly, there were fewer pregnancy-related hypertension cases than before the surgery.

Conclusions Pregnancy after bariatric surgery has proven to be safe for both the mother and the newborn. The newborn birth weight was not compromised even though some of the pregnant women were anemic.

Keywords Obesity · Morbid obesity · Bariatric surgery · Pregnancy · Pregnancy outcome · Birth weight

Introduction

Worldwide, obesity has reached epidemic proportions [1]. Data from the World Health Organization (WHO) estimate that in 2015 approximately 2.3 billion adults would be overweight, while another 700 million would be obese [2].

The prevalence of obesity is particularly high in American women. About 30% of them are obese and many of them are in their reproductive age. Thus, they are at a specific risk for reproductive and obstetric complications related to obesity [1, 3].

The pregnant obese women have significant risk of complications such as fertility problems, gestational diabetes, gestational hypertension, preeclampsia, macrosomia, higher rate of cesarean section, and its related complications such as hemorrhage, wound infection, and anesthetic complications [4, 5]. The American College of Obstetrics and Gynecology advocates weight loss before conception to reduce the risk of complications during pregnancy [4].

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Treatment of obesity by behavioral changes (diet and exercise) and medications have proved to be ineffective in maintaining weight loss [6]. Further, the results are even more disappointing in the case of morbid obesity [7].

Bariatric surgery is an important form of treatment for morbid obesity, resulting in long-term weight loss greater than 60% with weight stabilization around 2 years after the surgery [8], and often with complete resolution of several comorbidities [9]. Currently, 84% of the patients who undergo gastroplasty are women. Many of them are of childbearing age [10] and show significant improvement in the reproductive function, increased sexual activity, and improved fertility [11]. One of the consequences of the worldwide increase of bariatric surgery in women of childbearing age is the increased number of pregnancies after the surgery. However, on the other hand, they experience malnutrition resulting from the surgery. Few studies have focused on pregnancies after bariatric surgery and have reported only a small number of cases.

Materials and Methods

The present retrospective, exploratory cohort study was conducted to analyze the implications for the mother and the newborn in women of childbearing age (10 to 49 years) who became pregnant after they had undergone bariatric surgery in Maringá, south of Brazil, during the period from 1999 through 2008. The sample was drawn from the medical records of patients from four hospitals in Maringá that perform this procedure: a university hospital, a philanthropic/private hospital, and two other private hospitals and included 1,951 patients. Of these, 586 women fit the inclusion criteria and 445 women were included considering a margin of error of 3% plus 10% for losses. Of this group, 356 (80%) did not become pregnant, 35 (7.87%) became pregnant postoperatively, 3 (0.67%) of them were pregnant and the expected delivery date was after the end of the trial, 1 (0.22%) died, and 50 (11.23%) could not be located.

Of the 35 women contacted by telephone, 32 women agreed to participate in the study. During home visits, the investigator collected data from the participants using a three-part form. The form consisted of a social and demographic profile, followed by the characterization of the treatment and the obstetrical and newborn results.

Nonparametric tools and statistical tests (chi-square homogeneity, Fisher's exact test, and chi-square Pearson's, and McNemar test, and chi-square of independence) were used to test the association between the variables. The data on body mass index (BMI) were obtained using the weight and height listed in the hospital records, calculated by the formula $BMI = \text{weight (kg)} / \text{height}^2 (\text{m}^2)$. The current weight and height were reported by the study participants. The

BMI classification followed the recommendation of the WHO [12]. The sole criterion for the definition of comorbidities was the in-service medical records and/or the participant's reports. The ideal weight was calculated by the Devine formula (1974), which creates a mean BMI of 23.0 kg/m² for males and 20.8 kg/m² for females [13]. During the evaluation of pre-pregnancy BMI, the subjects were classified as underweight (<19.8 kg/m²), eutrophic (19.8–26 kg/m²), or obese (26–29 kg/m²) according to the recommendations of the Institute of Medicine of the USA [14]. Newborns with low birth weight are those weighing less than 2,500 g and insufficient weight newborn ranging from 2,500 to 2,999 g, according to the WHO [15].

The newborns were classified by birth weight and gestational age according to the curves of the fetal growth at different gestational ages. The percentiles criteria were: adequate for gestational age (AIG)—between the 10th and 90th percentiles, small for gestational age (SGA)—below the 10th percentile, and large for gestational age (LGA)—above the 90th percentile [16]. The study was approved by the Research Ethics Committee of the State University of Maringá.

Results

According to the conducted interviews, it was observed that obesity began in childhood in 40.63% ($n=13$), adolescence in 28.13% ($n=9$), and adulthood in 31.25% ($n=10$) of the subjects. No surgical complications were reported, and only 2 (6.25%) women required postoperative care in the intensive care unit (ICU). The only late complications observed were incisional hernia (3.13%), vomiting (3.13%), and diarrhea (3.13%). There were no late complications in 93.74% of the cases. All the women were referred for surgery because of morbid obesity. In one case, a cholecystectomy was also performed in addition to the bariatric surgery. Demographic characteristics, body mass index classification, comorbidities, obstetric history and post-bariatric surgery data are shown in Tables 1, 2, 3, 4, 5, 6, and 7.

It was observed that of all the women who became pregnant, 19 (59.38%) became pregnant more than 2 years after the bariatric surgery, 11 (34.38%) of them became pregnant after 1 to 2 years, and 2 (6.25%) became pregnant within 1 year post-surgery. Of the respondents of the study, 84.38% ($n=27$) reported daily use of vitamins, while 15.63% ($n=5$) did not take vitamins regularly. During pregnancy, this rate increased to 93.75% ($n=30$). However, two women did not take any vitamins (6.25%).

Fisher's exact test at a confidence level of 95% was used for tests carried out for the first child after the surgery. However, no association was found between the gestational age and the time between the surgery and the pregnancy.

Table 1 Social and demographic characteristics and body mass index classification in the pregnancy of women who became pregnant after the bariatric surgery: Maringá, Brazil 2009

Variables	Number (%)
Race	
Caucasian	30 (93.75)
Not known	2 (6.25)
Marital status	
With partner	17 (53.12)
Without partner	15 (46.88)
Education level	
Completed elementary school	1 (3.12)
Completed high school	9 (28.13)
Did not complete high school	1 (3.12)
Completed tertiary education	15 (46.88)
Did not complete tertiary education	6 (18.75)
Age at pregnancy	
20 to 34 years	23 (71.87)
35 years or more	9 (28.13)
Early pregnancy BMI classification	
Normal weight	19 (59.38)
Overweight	7 (21.87)
Obesity grade 1	4 (12.50)
Ignored	2 (6.25)
Gestational BMI classification	
Eutrophic	22 (68.75)
Obesity	08 (25.00)
Ignored	02 (6.25)

No statistical association was found between the birth weight and the BMI of the mother (chi-square, $p=0.21$ and Fisher's, $p=0.23$ tests), the birth weight and the type of delivery (chi-square, $p=0.85$ and Fisher's, $p=1.00$ tests), the birth weight and the time between the surgery and the pregnancy (chi-square, $p=0.08$ and Fisher's, $p=0.11$ tests), the BMI of the mother and anemia during pregnancy (chi-square, $p=0.62$ and Fisher's, $p=0.67$ tests), or the gestational age and a low birth weight (chi-square, $p=0.29$ and Fisher's, $p=0.28$).

Table 2 Body mass index classification, age, and time interval between the surgery and the pregnancy of women who became pregnant after the bariatric surgery: Maringá, Brazil 2009

Variables	Number	Mean/standard deviation
Current BMI (kg/m ²)	32	27.23±4.49 (21.26–39.35) ^a
Current age (years)	32	32.50±5.63 (20–45)
BMI in early pregnancy	30	25.12±3.52 (20.20–33.30)
Age at pregnancy	32	29.68±5.31 (20–37)
Excessive weight (kg)	28	60.56±15.87 (42.23–96.02)
Weight loss (kg)	28	44.09±16.04 (15–85)
Percentage weight loss (%)	28	0.73±0.20 (0.25–1.00)
Time between surgery and pregnancy (months)	32	40.78±27.16 (3–96)

^a Minimum and maximum are given in parentheses

The education level did not appear to be a risk factor for low birth weight. No statistical association was found between the low birth weight and a low education level (chi-square, $p=0.112$ and Fisher's, $p=0.1631$: first child after the bariatric surgery; chi-square, $p=0.1111$ and Fisher's, $p=0.0611$: second child after the bariatric surgery).

The Pearson's chi-square ($p=0.5286$) and the Fisher's exact tests ($p=0.4239$) indicated no significant difference in the birth weight of newborns in women who had children before or after the bariatric surgery procedure. Of all the women who became pregnant, 11 had children prior to bariatric surgery, and 3 of them had a second child, thereby totaling 14 children. The McNemar test ($p=0.2482$), at a 5% significance level, showed that the probability of low birth weight infants before or after the mother underwent bariatric surgery was equal.

Discussion

This study differs from others by its comparative data of pregnant women before and after bariatric surgery. It was observed that of all the 32 women who became pregnant after the bariatric surgery, 11 had one or more children before the surgery, whereby this previous pregnancy served as its own control. The main finding of this study was that there was no difference in newborn outcomes when comparing pregnancies before and after the performance of bariatric surgery. The prevalence of white women in this study is in agreement with the predominance of this race in the last Brazilian national census [17].

It was observed that morbid obesity in Brazil is more common among separated couples (4.5%). In southern Brazil, morbid obesity affects 18% of the population living without partners [18]. The absence of stable partners is cited by some authors as a risk factor for low birth weight. In this context, one study found a risk 1.22 times greater in comparison to pregnant women with a partner [19].

Morbid obesity is more common in functional illiterates and in people with higher levels of education (4% in each of these levels of schooling). In southern Brazil, morbid

Table 3 Comorbidities of women who became pregnant after the bariatric surgery: Maringá, Brazil 2009

Comorbidities	Before surgery				After surgery			
	No	%	Yes	%	No	%	Yes	%
Diabetes mellitus	31	96.77	1	3.23	32	100.00	–	–
Hypertension	23	71.88	9	28.13	31	96.88	1	3.13
Osteoarticular diseases	27	84.38	5	15.63	31	96.88	1	3.13
Hypercholesterolemia	31	96.88	1	3.13	32	100.00	–	–
Anemia	29	90.63	3	9.38	12	37.50	20	62.50
Neuropsychiatric diseases	32	100.00	–	–	30	93.75	2	6.25
Hypothyroidism	30	93.75	2	6.25	30	93.75	2	6.25

obesity is found in 23% of the population who have completed tertiary education [18].

Another study described higher rates of comorbidities in obese pregnant women such as dyspnea (65% of the patients), arthropathy (47%), hypertension (29%), diabetes (16%), sleep apnea (10%), and varicose veins in the lower extremities (9.5%) [20]. The lower rate of comorbidities in the present study (21.88%) probably can be attributed to the younger age of the patients. There were no complications after the bariatric surgery in the women studied, as also found elsewhere [21].

There is controversy in the literature about the need for ICU admission in the immediate postoperative period after the bariatric surgery. The decision depends on factors such as medical staff judgment, patients' previous comorbidities, and/or complications during the surgery. About 6% to 24% of patients subjected to surgical procedures need care in the ICU for more than 24 h [22].

Table 4 Obstetric histories of women who became pregnant after the bariatric surgery: Maringá, Brazil 2009

Variables	Number (%)
Abortion/number	
No	26 (81.25)
Before bariatric surgery	3 (9.38)
After bariatric surgery	3 (9.38)
Guidance on the type of delivery	
Cesarean section	26 (81.25)
Normal delivery	2 (6.25)
Not oriented	4 (12.50)
Indication for cesarian section	
Breech presentation	5 (15.62)
Previous cesarean section	3 (9.37)
Patient choice ^a	9 (28.13)
Not applicable	1 (3.13)
Determined by the obstetrician	14 (43.75)

^a In two cases, the choice was due to tubal ligation, and in five cases, it was attributed to the fear of disruption of surgical staples

The average age of women in the present study (29.68 ± 5.31 years) was similar to other women who underwent restrictive and malabsorptive surgeries in Roux-en-Y, France, who were aged 31.3 ± 4.6 years [23] and 31.8 ± 6.5 years [24]. Conversely, the mean BMI (27.23 ± 4.49) found in the present study was lower in comparison to another study (average pre-pregnancy BMI of 30.6 ± 6.3 kg/m²) [23]. The BMI of these women before the surgery showed 22 cases (68.75%) of obesity grade III, 8 cases (25%) of obesity grade II, 1 (3.12%) obesity grade I, and 1 unknown (data not provided).

The American College of Obstetricians and Gynecologists recommends weight loss before conception to reduce the risk of complications during pregnancy. In this respect, bariatric surgery is considered as a promising treatment for weight loss [4].

When women became pregnant after the bariatric surgery, 22 of them (68.75%) had normal weight, 8 (25.00%) were obese, and 2 (6.25%) were unknown. Underweight patients were not reported in any pregnancy. These findings show the effectiveness of the surgical procedure regarding weight loss in this sample. The average weight gain during pregnancy of the women studied was 9.28 ± 7.26 kg, lower when compared to another study that found an average gain of 11.6 ± 9.6 kg [23].

On evaluating the gestational weight gain of the studied women according to the recommendations of the Institute of Medicine of the USA [14], the nutritional status measurement, assessed by gestational BMI, found 22 cases (56.41%) of suboptimal gestational weight gain, 8 cases (20.51%) of gain above the ideal, 5 women (12.82%) with weight gain within the normal range, 2 cases (5.12%) of weight loss during pregnancy, and 2 cases (5.12%) with unknown values (data not provided). The underweight pregnant women are required to comply with a total weight gain of 12.5 to 18 kg, and the eutrophic and overweight pregnant woman are allowed to gain 11.5 to 16 and 7.0 to 9.1 kg, respectively [14].

Bariatric bypass surgery in Roux-en-Y resulted in a weight loss of about 65% of excess body weight in severely obese patients [8]. In the present study, a higher average

Table 5 Birth weights of children born during the pre-and postoperative period to women who became pregnant after the bariatric surgery: Maringá, Brazil 2009

Weight	Before surgery		After surgery	
	Underweight, <i>N</i> (%)	Normal weight <i>N</i> (%)	Underweight, <i>N</i> (%)	Normal weight, <i>N</i> (%)
First child	1 (9.09)	10 (90.91)	6 (18.75)	26 (81.25)
Second child	–	3 (100.0)	2 (22.22)	7 (77.78)
Third child	–	–	–	1 (100.0)

loss (73% of excess weight) was observed. It has been recommended that women wait at least 12 to 18 months to become pregnant after the bariatric surgery to avoid nutritional complications as well as achieve success in weight loss [25].

The average time between the execution of the bariatric surgery and pregnancy was more than 3 years (40.78 ± 27.16 months). The shortest interval observed was 3 months, while the longest was 96 months.

A study included 2,432 patients who have undergone bariatric surgery, of which 34 became pregnant in the first year after the surgery and 13 became pregnant after 1 year of the surgery. They observed that all full-term babies were healthy and no congenital malformations were found [5].

The substantial weight loss that occurs in the few months after bariatric surgery is considered alarming by some authors. The risk of specific nutritional deficiencies in the mother rises on concerns that bariatric surgery may cause some fetal complications such as premature birth, low birth weight, neonatal hypocalcemia, rickets, osteomalacia, mental retardation, and neural tube defects [26]. For this reason,

other authors recommend close monitoring and nutritional supplementation of childbearing age women before conception and during the pregnancy [11]. The favorable results obtained in the present study may result from the nutritional supplements taken by the majority (93.75%) of the women during pregnancy.

In the present study, there was a complete resolution of the comorbidities such as diabetes and hypercholesterolemia. Significant improvement was observed in comorbid hypertension and osteoarticular diseases after the bariatric surgery. Heart disease was absent pre- and postoperatively.

Other studies suggest that bariatric surgery reduced the pregnancy complications related to obesity in comparison to pregnancies in the same patients before the surgery. A study was conducted to compare 36 pregnancies postoperatively to 17 preoperatively (control group). The obtained results showed decreased rates of gestational diabetes, hypertensive disorders, and fetal macrosomia in the postoperative group [25].

No differences were found between abortion rates in women studied before and after the surgery. The acceptable

Table 6 Weight and height of the children and the mother's weight gain during pregnancy, for women who became pregnant after the bariatric surgery: Maringá, Brazil 2009

Variables	Number	Mean/standard deviation
Children before surgery		
First child		
Birth weight (kg)	11	$3,462.73 \pm 846.54$ (1,000–4,050) ^a
Birth height (cm)	11	49.45 ± 3.75 (39–53)
Weight gain during pregnancy (kg)	9	27.00 ± 26.90 (6–90)
Second child		
Birth weight (kg)	3	$3,870.00 \pm 461.84$ (3,480–4,380)
Birth height (cm)	3	51.00 ± 1.73 (49–52)
Weight gain during pregnancy (kg)	2	17.50 ± 7.78 (12–23)
Children after surgery		
First child		
Birth weight (kg)	32	$3,011.25 \pm 512.97$ (1,900–3,880)
Birth height (cm)	31	48.37 ± 3.83 (39–58)
Weight gain during pregnancy (kg)	32	10.38 ± 7.18 (2–34)
Second child		
Birth weight (kg)	9	$2,850.56 \pm 626.36$ (2,000–3,850)
Birth height (cm)	8	45.38 ± 4.87 (38–51)
Weight gain during pregnancy (kg)	9	6.6 ± 5.98 (5–15)

^a Minimum and maximum are given in parentheses

Table 7 Distribution of women who became pregnant after the bariatric surgery according to child characterization and inter-currences: Maringá, Brazil, 2009

Variable	Child before surgery ^a , <i>n</i> =14 <i>n</i> (%)	Child after surgery, <i>n</i> =41 <i>n</i> (%)
Gender		
Female	7 (50.00)	15 (36.58)
Male	7 (50.00)	26 (63.42)
Gestational age		
<37 weeks	1 (7.14)	2 (4.88)
≥37 weeks	13 (92.86)	39 (95.12)
Color/race		
Caucasian	11 (78.57)	35 (85.36)
Black	3 (21.43)	6 (14.64)
Birth weight		
Underweight	1 (7.14)	8 (19.51)
Normal weight	13 (92.86)	33 (80.49)
Type of delivery		
Cesarean	14 (100.00)	36 (87.80)
Normal	–	5 (12.20)
Mother with anemia		
No	14 (100.00)	30 (73.17)
Yes	–	11 (26.83)
Mother with vomiting		
No	14 (100.00)	31 (73.16)
Yes	–	10 (24.40)
Mother hospitalization		
No	12 (85.72)	26 (63.42)
Yes	02 (14.28)	15 (36.58)
Mother blood transfusion		
No	14 (100.00)	34 (82.93)
Yes	–	7 (17.07)
Mother hypertension		
No	7 (50.00)	39 (95.12)
Yes	7 (50.00)	2 (4.88)

^a Eleven women had one child before the bariatric surgery and three of them had a second child

indexes of cesarean delivery for industrialized countries should lie between 6% and 16.5%. The main indications for cesarean section include dystocia, fetal disproportion, prematurity, multiple pregnancy, intrauterine growth retardation, very low weight, and high birth weight [27]. The occurrence of cesarean delivery in women who became pregnant after the bariatric surgery is higher (25.2%) in comparison with the general population (12.2%) [23]. Therefore, bariatric surgery appears to be a risk factor for cesarean section ($p<0.001$) [28]. A significantly higher frequency (81.25%) of cesarean sections in post-bariatric surgery pregnant women living in Maringá was observed in comparison to normal deliveries (6.25%). This is a much higher rate than found elsewhere [23].

The majority of children born after bariatric surgery (80.49%) had normal birth weight ($n=32$), while only 19.51% ($n=8$) had low birth weight in the present study. This number, however, is higher than that recommended by

the WHO (up to 15% of low birth weight) [12]. A lower rate of low birth weight after restrictive and malabsorptive surgeries has been described by other authors, who found 7.3% of newborns weighing less than 2,500 g at birth [23].

In the city of Campinas, Brazil, 25.6% of infants had insufficient weight and 9.1% had low birth weight. Analysis of the certificates of live births revealed the following risk factors for the underweight at birth (between 2,500 and 2,999 g): female newborns, children of primiparae, inadequate prenatal care, and vaginal delivery [29]. In the present study, according to this classification, there were 18 AIG (56.2%), 11 (34.4%) LGA, and 3 (9.4%) SGA infants (detailed data not provided).

In 21 pregnancies that occurred within 1 year post-surgery, the average weight of the baby was 2,868 g (1,786 to 3,940 g), and low birth weights were found for only one set of twins (2,325 and 1,786 g). In pregnancies that occurred more than 1 year after the surgery (13 cases out of

34), the average weight of infants was 2,727 g (1,616 to 3,895 g), and all pregnancies were full-term [5].

The average weight gain of women during the pregnancies before the bariatric surgery was 27 kg for the first child and 17.5 kg for the second child. This weight gain was higher in comparison to the average gain after surgery, which was 10.38 kg for the first child and 6.61 kg for the second child. In another study, the average weight gain in pregnancies before surgery was lower (20.4 kg), and women who became pregnant after surgery gained more weight (12.7 kg) [25]. Preterm births (gestational age <37 weeks) were observed in 3.6% of the pregnancies after the bypass procedures for weight loss [23], rates lower than those found in the present study.

In an analysis of 14 women who underwent bariatric surgery, the gestational age at birth was lower than those found in the present study, with an average of 35.6 ± 3.3 weeks [24]. In another study with 34 pregnant women after bariatric surgery, 33 of the pregnancies were full-term, and only one twin pregnancy was preterm (35 weeks of gestation). There were no congenital anomalies and the babies were born healthy. Twenty-one pregnancies (61%) occurred less than 1 year after the surgery, with five miscarriages, one ectopic pregnancy, and one set of twins [5].

Of the 32 mothers surveyed in the present study, no one presented anemia during the pregnancy prior to the bariatric surgery. However, this rate increased to 24.4% ($n=10$) in pregnancies after the surgery. Lower rates were described by other authors, where only 1 patient out of the 34 studied showed iron deficiency during pregnancy [5].

In this research, the women showed higher rates of vomiting during pregnancy in comparison to mothers in general. This should be considered in prenatal care as a result of the risks caused by this complication to the mother and the fetus. Hypertensive disease has been reported in 7.3% of pregnant women undergoing surgery to reduce weight (restrictive and malabsorptive) [23]. A lower proportion has been described in this study (4.88%).

Great emphasis should be given to possible complications in the post-bariatric surgery population. Vomiting and anemia, for example, are described as major side effects of laparoscopic restrictive and malabsorptive surgeries and may cause fetal malnutrition [30].

It is imperative to observe the importance of prenatal care of women undergoing bariatric surgery in Maringá (an average of six medical appointments). Further, it was also important to examine the motivation for the care during pregnancy by both the obstetrician and the surgeon, as a high concern in a post-bariatric surgery period. In general, pregnancies after bariatric surgery had fewer complications than pregnancies of the same women when they were obese. Similar findings were observed by other authors [31].

Factors, such as the age and the BMI of the mother, the type of delivery, and the time between the surgery and the pregnancy showed no statistically significant association with low birth weight. The degree of education of the mother is not a risk factor for low birth weight in pregnancies after bariatric surgery.

Conclusion

If provided with appropriate monitoring, nutritional control, and efficient prenatal care, pregnancy during the post-bariatric surgery period has proven to be effective and safe for both the mother and the newborn. Although a few post-surgery pregnant women presented anemia and significant weight loss, their pregnancies involved no serious complications.

Further studies are needed regarding the indication of cesarean section in the post-bariatric surgery population, since the rates of surgical deliveries were far above the levels currently recommended for the general population. In addition, the growth and development of children born after bariatric surgeries need to be closely followed to certify if its course is normal or not. The small sample of the present study, despite the prolonged period of research (10 years), represents a limitation on the interpretation of the results.

Conflicts of Interest None.

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