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Outcomes of pregnancy after Bariatric Surgery: Results of a French matched cohort study.

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Outcomes of pregnancy after Bariatric Surgery: Results of a French matched cohort study.

5 ABSTRACT

Background: While the benefits of bariatric surgery (BS) on pregnancy outcomes have been demonstrated for women when compared to matched controls on pre-surgery body mass index (pB-BMI), data are lacking and those benefits are uncertain when compared to matched
10 controls on pre-pregnancy BMI (pP-BMI).

Objectives: Our study aimed to evaluate outcomes (Obstretical and neo-natal) of single pregnancy in women previously exposed to BS compared to women unexposed to BS matched on pB-BMI and pP-BMI.

Settings: Retrospective matched cohort study from two observational studies of pregnant
15 women conducted in a French administrative county (Finistère).

Methods: From April, 1st 2015 and January, 31st 2019, pregnant women with previous BS (n=52) were included and compared to two different control groups: group A (n=104) matched for pB-BMI, age and parity and group B (n=104) matched for pP-BMI, age and parity.

20 **Results:** In women exposed to BS, mean age was 27.1 (± 4.9) years and pB-BMI was 46.0 (± 4.6) kg/m². Operated women differed significantly from group A but not from group B for pP-BMI (29.4 ± 6.1 vs. 45.3 ± 4.5 group A vs. 28.6 ± 6.6 group B) and gestational diabetes mellitus (GDM) (12.0% vs. 44.0% group A vs. 17.0% group B), respectively. In the group of women exposed to BS, birth weight (gr) was significantly lower (2960 \pm 545 vs. 3381 \pm 735

25 group A vs. 3310 ± 645 group B) and large-for-gestational-age infants less frequent (0% vs. 13% group A vs. 8% group B).

Conclusion: Bariatric surgery reduced risks of excessive fetal growth and GDM with a trend for a higher risk of small-for-gestational-age, despite matching on pP-BMI suggesting a risk associated to BS and solely to previous surgery induced weight loss.

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Key Words: Bariatric surgery; pregnancy; obstetric complications; neo-natal complications; follow-up

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Introduction

Obesity is a chronic disease and a major global public health problem. In France, the national ESTEBAN survey in 2015 identified that 49.0% of French people over the age of 18 were at least overweight and 17.2% were obese (17.4% for women affected by obesity) [1].

55 Furthermore, the majority of patients undergoing bariatric surgery (BS) worldwide and in France are women of childbearing age [2,3], thus raising question of a possible impact of such a surgical procedure on subsequent pregnancies and newborns.

Numerous studies demonstrated the superiority of BS compared to medical management on long-term mortality [3] and a reduction in cardiovascular risk factors, in particular type 2
60 diabetes (T2D) in operated patients compared to a control group [4]. After surgery, the greatest weight loss occurs in the first year, explaining that within the framework of a pregnancy project, the recommended period of conception is 12 to 18 months after the surgical procedure[5,6].

Female obesity has specific issues related to reproductive life and pregnancy. Pregnancy in
65 women affected by obesity is considered at risk for the mother and the newborn. In case of maternal obesity, the risks of miscarriages, gestational diabetes mellitus (GDM), macrosomia, pre-eclampsia, prematurity and neonatal morbidity are increased [7,8]. Many studies confirmed the contribution of surgery-induced weight loss in this population, in particular on obstetric complications reduction, when compared to non-operated women
70 affected by obesity[9–11]. Pregnancies after BS are associated with a reduced risk of GDM and macrosomia, with an increased risk of small-for-gestational-age (SGA) [11].

Two study designs stand out in the literature according to the type of matched control group. A pre-bariatric surgery body mass index (pB-BMI) matching highlights the effect of surgery

but also the effect of induced massive weight loss. On the other hand, a pre-pregnancy BMI
75 (pP-BMI) matching highlights the impact of surgical procedure alone.

Our aim was to compare obstetric and neonatal complications between a group of
women who underwent BS (exposed women) and two groups of control women (unexposed
women) matched on pB-BMI and pP-BMI, using data from two multicenter prospective
observational studies.

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Methods

1. Design and settings

85 Our retrospective matched cohort study was carried out using the databases of two
prospective observational studies: HEMOTHEPP (Haemorrhage and venous
thromboembolism in the postpartum - NCT 02443610) and HPP IPF (Study of biological
determinants of postpartum haemorrhage - NCT 02884804) conducted in five obstetrical units
of a French administrative county (Finistère). All pregnant women aged 16 and over admitted
90 in one of these units to give birth were eligible to participate. The non-opposition form was
collected during a pregnancy follow-up visit by a gynecologist or a midwife, or during
admission to the delivery room. Data related to medical and surgical history (including the
history of BS), obstetrical history, treatments taken during pregnancy, course of pregnancy,
occurrence of obstetric and neonatal complications, childbirth and post-partum period were
95 systematically recorded. These two prospective studies were approved by the local ethics
committee, so our retrospective study did not require a new agreement from the ethics
committee.

2. Population

All pregnancies occurring after a previous BS in Finistère between April 3, 2015 and January 31, 2019 were identified from the HEMOTHEPP and HPP IPF databases. The exclusion criteria were twin pregnancies, pregnancies after removal of a gastric band, pregnancies that occurred before BS, refusal to participate, no available control during the matching process (Figure 1).

The surgical indication for BS was made according to ongoing French recommendations [3]. The different BS procedures performed in the included women were Roux-Y gastric bypass (malabsorptive and restrictive procedure), sleeve gastrectomy (restrictive procedure) and adjustable gastric banding (restrictive procedure). Reported age has been recorded at the time of delivery. Weights were recorded by nurses/physicians. The pB-BMI was calculated from the weight before BS according to the formula $[\text{weight (in kg)} / (\text{height (in m)}^2)]$. The pP-BMI was calculated according to the same formula using the weight early in pregnancy (first visit of pregnancy monitoring).

3. Matching process

We created a matched control cohort composed of women without a history of BS selected from HEMOTHEPP cohort. Each woman exposed to BS was matched twice, with:

- two controls on pB-BMI ($\pm 5\text{kg} / \text{m}^2$), age (± 5 years) and parity (primiparous or multiparous): control group A
- two controls on pP-BMI ($\pm 5\text{kg} / \text{m}^2$), age (± 5 years) and parity (primiparous or multiparous): control group B

4. Outcomes

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4.1. Pre conceptional maternal characteristics and obstetric outcomes

Weight gain during pregnancy corresponds to the difference between the weight at the last visit (33 and 36 weeks of gestation (WG)) and that at the beginning of pregnancy (first visit at 8 or 12 WG).

130 Infertility is defined by the WHO as the impossibility of a couple to carry a pregnancy to term after a year or more of regular sexual intercourse in the absence of contraception.

Dyslipidemia was defined as the presence of at least one of the following criteria: a total cholesterol concentration above 5.7 mmol/l (220mg/dl), a serum HDL-c (High Density Lipoprotein-cholesterol) concentration below 1.0 mmol/L (38.7mg/dl), a triglyceride
135 concentration above 1.7 mmol/l (15.0mg/dl) or the use of lipid-lowering medication.

Patients were considered to have obstructive sleep apnea syndrome if they were already being treated by nocturnal continuous positive-airway pressure therapy.

Gestational diabetes mellitus was defined as first trimester fasting blood glucose level above 0.92 g / L or a positive oral glucose-tolerance test between 24 and 28 WG[12]. Gestational

140 hypertension was defined by systolic blood pressure greater than 140 mmHg and / or diastolic blood pressure greater than 90 mmHg at 20 WG or after. Pre-eclampsia was defined as pregnancy-induced hypertension associated with protein/creatinine ratio greater than 0.30 mg / mmol[13]. Post partum hemorrhage is defined as the loss of ≥ 500 ml of blood through the genital tract within 24 hours. Stillbirth is defined as fetal death after 20 WG. Neonatal death
145 is defined as a death that occurs before 28 days of life.

The threat of preterm delivery was the combination of uterine contractions and changes in cervical length with a measurement less than 25 mm on ultrasound, before 37 WG [14]. Early miscarriage was a miscarriage that occurs in the first trimester of pregnancy [16].

4.2. Neonatal outcomes

Large-for-gestational-age infants were defined as those with a birth weight greater than the 90th percentile for sex and gestational age, and small-for-gestational-age infants as those with a birth weight less than the 10th percentile. Preterm birth was defined as delivery before 37 completed WG [15]. Neonatal morbidity was assessed by an APGAR score of less than 7 at 5 min, an arterial pH at the cord less than 7.15 and by admission to neonatology intensive care unit [16].

5. Statistical analysis

Data collection was carried out with Ennov Clinical version 7.5 software. Statistical analysis and matching of cases and controls was done with SAS software version 7.1 (Statistical Analysis Software). Quantitative data were described using mean and standard deviation or median and interquartile range as appropriate. Qualitative data were presented in terms of frequency and percentage. The difference between the groups were investigated by the Student's T-test for quantitative data and by a Chi2 test or a Fisher test appropriately for quantitative data.

Multivariate linear regression analysis (cases and group B) were used to investigate variables associated with birth weight. In our final model, multivariate analysis was adjusted on gestational diabetes mellitus, maternal age and BMI.

A p-value less than 0.05 was considered significant.

Results

1. Population

Between April 3, 2015 and January 31, 2019, 22,854 pregnancies were included in the HEMOTHEPP and HPP-IPF databases. Of these, 67 pregnancies occurred after BS. After excluding those with exclusion criteria, 52 women were selected for the present analysis and matched twice with two controls as previously described (Figure 1):

- Control group A included 104 women matched to exposed women on pB-BMI, age and parity

- Control group B included 104 women matched to exposed women on pP-BMI, age and parity

Characteristics of women exposed to BS are given in Table 1. The mean age at the time of surgery was 27.1 ± 4.9 years. Sleeve gastrectomy was the intervention mainly performed (58.0%). Presurgical BMI was 46.0 ± 4.6 kg/m². The mean of minimum BMI after surgery was 26.7 ± 5.2 kg/m². The percentage of maximum weight loss after surgery was $36.1 \pm 11.5\%$. The median time between BS and conception was 3.0 ± 3.0 years, with 18 pregnancies (35%) occurring in the year following BS. The mean weight loss between surgery and the start of pregnancy was 45.1 ± 14.4 kg.

Women exposed to BS were similar to controls from group A and B for age (31.1 ± 5.0 years). Characteristics of the two control groups are given in Table 2. Pre-pregnancy BMI was 29.4 ± 6.1 kg/m² for women exposed to BS compared to 45.3 ± 4.5 kg / m² in the group A ($p < 0.001$) and 28.6 ± 6.6 kg/m² in the group B ($p = 0.54$).

2. Obstetric outcomes

Among women exposed to BS, six (12%) GDM were diagnosed compared to 46 (44%) in controls from group A ($p < 0.001$) and 18 (17%) in controls from group B ($p = 0.35$) (table 3). Preeclampsia was less frequent than in control group A (2% vs 13%; $p = 0.036$). There was

no significant difference as regards gestational hypertension between exposed and non-exposed women (2% vs 5% in group A ; $p = 0.38$; 2% vs 5% in the group B; $p = 0.38$). Threat of preterm delivery was significantly more frequent in exposed women than in controls from group A (8% vs 0; $p = 0.0042$). Weight gain during pregnancy was 9.3 ± 5.5 kg for operated women compared to 5.3 ± 4.8 kg for controls from group A ($p < 0.001$) and 9.7 ± 5.7 kg for controls from group B ($p = 0.67$). There was no significant difference between exposed women and controls for prematurity (15% vs. 18% in group A; $p = 0.65$; 15% vs. 7% in group B; $p = 0.084$). Caesarean section rate was increased in operated women compared to controls from group B (40% vs 17%; $p < 0.001$).

3. Neonatal outcomes

Birth weights (g) (2960 ± 545) were significantly ($p < 0.001$) lower in operated women group compared to group A (3381 ± 735) and B (3310 ± 645). There were no large-for-gestational-age infants in exposed women group (0% vs 13% (group A); $p < 0.001$; 0% vs 8% (group B); $p < 0.001$). As regards neonatal morbidity, 17% of newborns from operated women were transferred to the neonatal unit compared to 6% of newborns in group A ($p = 0.02$) and 8% in group B ($p = 0.065$).

4. Multivariate analysis

In multivariate linear regression (for exposed women and group B), only the history of BS was negatively associated with birth weight ($t = 7.13$; $p < 0.001$).

Discussion

1. Main results

225 In our multicenter cohort study, 52 pregnancies in women with previous BS were compared
to pregnancies in women without surgery matched on pB-BMI and pP-BMI. Bariatric surgery
was associated with a significant decrease of GDM, preeclampsia, birth weight and large-for-
gestational-age infants, compared to the control group matched on pB-BMI. Regardless of
230 matching, bariatric surgery was associated with a lower birth weight than in the two control
groups.

2. Obstetric outcomes

Our results are consistent with those of previous studies, such as those of Johansson *et al* who
235 found a reduced risk of GDM in operated women (1.9% vs 6.8%; $p < 0.001$) [9]. In another
study, the occurrence of GDM was reduced in the BS group but the hypertensive disorders
were not significantly different between the two groups [17]. Preeclampsia and gestational
hypertension are often grouped under one item in studies. As their consequences on
pregnancy outcomes are different, it seems important to distinguish between these two
240 entities. Our results were also concordant with those of Rottenstreich *et al* that included a
population comparable to ours in terms of pP-BMI [18].

The matching on pP-BMI did not suggest in our study a decrease of GDM, preeclampsia and
gestational hypertension in women operated with BS. These data were in agreement with
those of Kwong *et al* [11]. They highlight that history of BS has an impact on maternal
245 complications mainly through the induced massive weight loss [19].

We found that women undergoing BS have similar weight gain during pregnancy but neonatal
birth weights were significantly lower. We can hypothesize that weight gain distribution

varies between groups however no body composition assessment was available in our database[20].

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3. Neonatal outcomes

The birth weight in the group of women exposed to BS was always lower than in the control group regardless of matching, and only history of BS was negatively associated with birth weight in our multivariate analysis. However, in contrast to previous data [20], we did not find any significant difference with regard to small-for-gestational-age infants. This may be explained by the small size of our population. In the literature, occurrence of small-for-gestational-age infants did not differ according to the matched control group. Kwong's meta-analysis showed an increase in small-for-gestational-age infants with an OR of 2.16 with a matching according to pB-BMI and an OR of 2.23 according to pP-BMI [11]. Those results and ours seemed to indicate the intrinsic role of BS regardless of the weight loss previously achieved.

Large for gestational age infants was reduced in the group of women exposed to BS. This benefit was already described by Johansson et al (OR = 0.33) [9]. This is an important issue since it contributes to decrease maternal and perinatal morbidity associated with fetal macrosomia [23].

As regards prematurity, available data were discordant. We did not find any significant difference between groups of exposed and non-exposed women. Kwong et al. found a significant increase in preterm deliveries after BS, regardless of matching [11]. In the study by Lesko et al, prematurity was increased with matching according to pre-surgical BMI (OR = 3.64; $p < 0.01$) [24]. This was not confirmed in the cohort of Johansson et al [9].

4. Time between bariatric surgery and pregnancy

275 According to international guidelines, optimal time between BS and conception is 12 to 18 months [25]. In our study, this time was less than 12 months in 35% of cases with a median of 3.0 years. This raises question about monitoring and follow-up of women of childbearing age after BS. The problem of poor follow-up was identified recently in France in a national cohort of operated patients [26]. Experts believe that most patients will have achieved weight
280 stability after at least 12 months [27]. In the first year after surgery, significant weight loss results in improved fertility [28]. The time to conception is therefore a determining factor, but the data in the literature were very discordant. Yau et al and Sheiner et al. did not show any significant association between obstetric complications and time from BS to conception [29]. In contrast, Parent et al showed that time to conception of less than two years after surgery
285 had an impact on neonatal complications with an increased risk of prematurity (RR = 1.48) and transfer to neonatal intensive care unit (RR = 1.54) [22].

5. Strengths and limits

290 One of the strengths of our study was the multicenter recruitment. Indeed, our study having included women coming from all the maternities of the department of different levels of perinatal care, the recruitment was exhaustive and not selected, allowing a good representativeness of women giving birth with or without previous BS. Another strength was
295 the prospective collection which reduced the lost of pregnancy and childbirth data.

The originality of the present report was to compare a single group of women exposed to BS to two different control groups with matching on pB-BMI (group A) and pP-BMI (group B).

To our knowledge, there is only one monocentre retrospective study in the literature that carried out a double matching on pP-BMI and pB-BMI, for similar size cohort of operated patients [24].

Among limits of our study, the small sample size did not permit comparison between different bariatric surgical procedures on pregnancy outcomes. Because HEMOTHEPP and HPP-IPF were not specifically designed to test the impact of BS on pregnancy outcomes, we were not able to collect information on variables relative to nutrition or lifestyle even though the risk of nutritional deficiency is known to be increased after any type of bariatric procedure, and could affect pregnancy outcomes [3]. This is important to be known since women affected by obesity are at risk of vitamin deficiencies[30]. At last the features of our prospective database could underestimate miscarriage rate among women affected by obesity. Further studies would be required to develop this specific issue.

Conclusion

Bariatric surgery is justified in women affected by morbid obesity of childbearing age, because of its beneficial effects such as the reduction of certain obstetric (GDM, preeclampsia) and neonatal (macrosomia) complications. We did not find a significative difference regarding small for gestational age, probably because of the small sample size. Nevertheless, since the birth weight of infants in the group of women exposed to BS was always lower than in the control groups, we can suppose a trend for a higher risk of small-for-gestational-age as a direct consequence of the surgery itself".. It is necessary to make health professionals aware of the specifics of pregnancies carried out after BS and to recall the importance of multidisciplinary follow-up in these women.

Figure 1 : Flow chart

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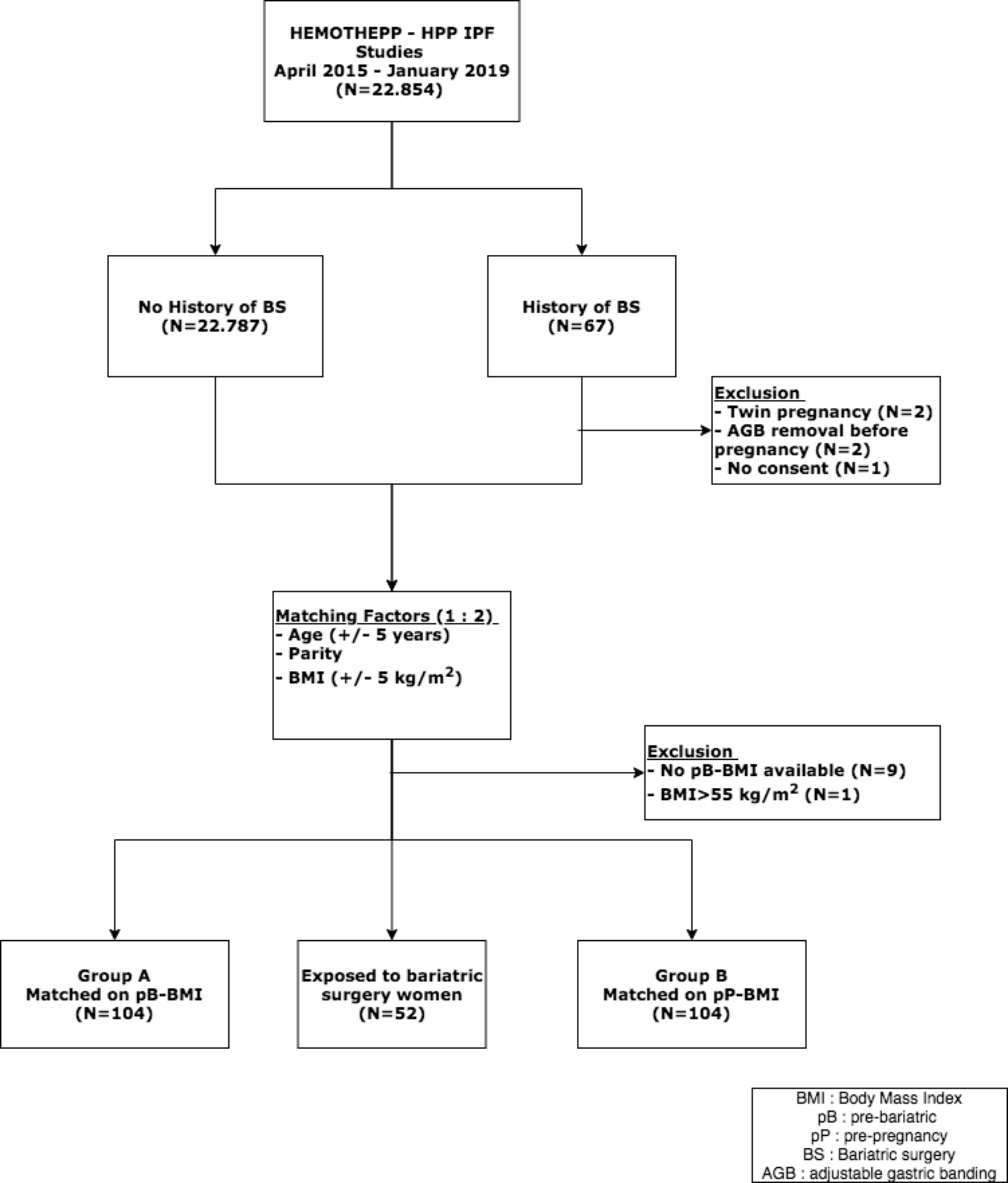


Table 1 Characteristics of pregnant women exposed to bariatric surgery (n=52)

| | Pregnancy after bariatric surgery (N=52) |
|---|---|
| Age at time of bariatric surgery (years) | 27.1 ±4.9 |
| Type of procedure : GBP SG AGB | 19 (37%) 30 (58%) 3 (5%) |
| Presurgical BMI (kg/m ²) | 46.0 ±4.6 |
| % maximal weight loss after bariatric surgery | 36.1±11.5 |
| Follow-up with nutritionist during pregnancy | 39 (76%) |
| Vitamin supplementation during pregnancy | 33 (65%) |
| <u>Co-existing conditions</u> None Type 2 diabetes Obstructive sleep apnea Hypertension Dyslipidaemia | 44 (85%) 2 (4%) 4 (8%) 3 (6%) 1 (2%) |
| Time between bariatric surgery and conception (years) | 3.3 ±3.2 |
| Rate of patients with time between bariatric surgery and conception < one year | 18 (35%) |
| Loss of weight between bariatric surgery and conception (kg) | 45.1 ±14.4 |
| Infertility before bariatric surgery | 12 (24%) |
| Infertility after bariatric surgery | 11 (21%) |
| Miscarriage before bariatric surgery | 15 (29%) |
| Miscarriage after bariatric surgery | 12 (24%) |
| Values are expressed by means and standard deviation, or number (%) BMI : Body Mass Index ; GBP : Gastric Bypass ; SG :Sleeve Gastrectomy ; AGB : adjustable gastric banding | |

Table 2 : Characteristics of women exposed to bariatric surgery, of control women non exposed to bariatric surgery matched on presurgical body mass index (group A) and on pre-pregnancy body mass index (group B)

| Characteristics | Exposed women (N=52) | Group A (N=104) | Group B (N=104) | p-Value* |
|---|----------------------|-----------------|-----------------|-------------|
| Age (years) | 31.1 ±5.0 | 30.9 ±4.7 | 31.2 ±5.0 | 0.83/0.99 |
| Pre-pregnancy BMI (kg/m ²) | 29.4 ±6.1 | 45.3 ±4.5 | 28.6 ± 6.6 | <0.001/0.54 |
| History of smoking | 18 (35%) | 34 (33%) | 20 (19%) | 0.20/0.11 |
| <u>Co-existing conditions</u> | | | | |
| None | 44 (85%) | 92 (88%) | 101 (97%) | 0.50/0.004 |
| Hypertension | 3 (6%) | 2 (2%) | 1 (1%) | 0.20/0.07 |
| Type 2 diabetes | 2 (4%) | 7 (7%) | 2 (2%) | 0.47/0.47 |
| Obstructive sleep apnea | 4 (8%) | 6 (6%) | 0 | 0.64/0.004 |
| Dyslipidaemia | 1 (2%) | 0 | 0 | 0.16/0.16 |
| <u>Parity</u> | | | | |
| Multiparous | 35 (67%) | 72 (70%) | 70 (67%) | 0.74/0.99 |
| Primiparous | 17 (33%) | 31 (30%) | 34 (33%) | |
| Values are expressed by means ±Standard Deviation or number (%) | | | | |
| BMI : body mass index | | | | |
| Pre-pregnancy BMI : BMI at time of conception | | | | |
| * Exposed women vs Group A / Exposed women vs Group B | | | | |

Table 3 : Obstetrical and neonatal outcomes of women exposed to bariatric surgery, of control women non exposed to bariatric surgery matched on presurgical body mass index (group A) and on pre-pregnancy body mass index (group B)

| | Women exposed to bariatric surgery (N=52) | Group A Matched on pre-surgical BMI (N=104) | Group B Matched on pre-pregnancy BMI (N=104) | p-Value * |
|---|--|--|---|------------------|
| Gestational diabetes mellitus | 6 (12%) | 46 (44%) | 18 (17%) | <0.001/0.35 |
| Pre-eclampsia | 1 (2%) | 13 (13%) | 0 | 0.036/0.16 |
| Gestational hypertension | 1 (2%) | 5 (5%) | 5 (5%) | 0.38/0.38 |
| Threat of preterm delivery | 4 (8%) | 0 | 8 (8%) | 0.004/0.99 |
| Weight gain (kg) | 9.3 ±5.5 | 5.3 ±4.8 | 9.7 ±5.7 | <0.001/0.67 |
| <u>Labor :</u> Spontaneous Induced | 28 (54%) 15 (29%) | 37 (36%) 39 (37%) | 63 (61%) 34 (33%) | 0.087/0.12 |
| Emergent caesarean | 9 (17%) | 28 (27%) | 7 (7%) | |
| Caesarean section | 21 (40%) | 58 (56%) | 18 (17%) | 0.070/<0.001 |
| Term (days) | 270 ±18 | 269 ±25 | 275 ±23 | 0.93/0.12 |
| Prematurity <37WG | 8 (15%) | 19 (18%) | 7 (7%) | 0.65/0.084 |
| Postpartum hemorrhage | 4 (8%) | 13 (13%) | 9 (9%) | 0.43/0.84 |
| Birth weight (grams) | 2960 ±545 | 3381 ±735 | 3310 ±645 | <0.001/<0.001 |
| Small-for-gestational age infants | 9 (17%) | 8 (8%) | 8 (8%) | 0.069/0.069 |
| Large-for-gestational-age infants | 0 | 13 (13%) | 9 (8%) | <0.001/0.029 |
| Birth weight > 4000 grams | 1 (2%) | 23 (22%) | 6 (6%) | <0.001/0.27 |
| Early spontaneous miscarriage | 15 (29%) | 33 (32%) | 23 (22%) | 0.35/0.19 |
| Stillbirth or neonatal death | 1 (2%) | 2 (2%) | 2 (2%) | 0.99/0.99 |
| Admission in neonatal intensive care unit | 9 (17%) | 6 (6%) | 8 (8%) | 0.021/0.065 |
| Values expressed by means ± Standard deviation or number (%) * Exposed women vs Group A / Exposed women vs Group B, except for labor (trend test for the 3 items) BMI: body mass index; WG: week of gestation | | | | |