

Pregnancy after Lap-Band® Surgery: Management of the Band to Achieve Healthy Weight Outcomes

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Background: Severely obese women have higher obstetric risks and poorer neonatal outcomes. Weight loss reduces obstetric risk. The introduction of a laparoscopically-placed adjustable gastric band, a safe and effective method of weight loss, has given us the ability and responsibility to adjust the band in relation to pregnancy.

Objective: Our aim was to devise a safe management plan to achieve healthy maternal weight gain (Institute of Medicine 1990) during pregnancy.

Methods: In a cohort group of 650 patients to have a Lap-Band® placement for severe obesity, we have reviewed the management of the band and pregnancy outcomes of all women (n=20) to complete a pregnancy (n=22) with a band in-situ.

Results: All 22 pregnancies were singleton, with no primary caesarean sections (3 for recurring indications). The mean maternal weight gain was 8.3 kg compared with 15.2 kg for the 15 previous pregnancies of women in this group (p<0.05). There was no difference in birth weights. Obstetric complications were minimal, and there were no premature or low birth weight infants. 11 of 15 subjects with active management of the band achieved a maternal weight gain within the advised range compared with only 2 of 7 prior to this.

Conclusion: The ability to adjust gastric restriction allows optimal control of maternal weight change in pregnancy and should help avoid the risks of excessive weight change.

Key words: Morbid obesity, gastric banding, laparoscopy, pregnancy, obstetric management

Introduction

Pregnancy in severely obese women is associated with increased risks and costs. These women suffer an increased incidence of complications during pregnancy including hypertension, preeclampsia, late fetal death and gestational diabetes.¹⁻⁵ There is a higher risk of induction of labor, primary caesarian section and perioperative morbidity.⁶⁻⁸ Their infants are more likely to have fetal growth abnormalities, macrosomia and intrauterine growth retardation, and are more likely to require admission to a neonatal intensive care unit.² They may also be at greater risk of developmental abnormalities including neural tube defects.⁹⁻¹¹ Duration of hospital stay and overall cost is strongly related to maternal weight.⁸

Weight loss has been shown to lead to improved fertility and lower obstetric complications.^{5,12} Effective and durable weight loss is rarely achieved by medical programs alone, and in the reports cited, the weight loss was achieved by gastric stapling or bypass surgery. These forms of bariatric surgery generate a fixed restriction to food and/or malabsorption, which continues through the pregnancy and thus must be seen to carry risks as well as benefits. Specific nutritional deficiencies may cause fetal abnormalities,¹³ and weight-loss or inadequate weight gain during pregnancy may lead to low birth weight with its associated risks.¹⁴⁻¹⁷

The introduction of a laparoscopically-placed adjustable gastric band for the surgical management of morbid obesity provides an opportunity for achieving weight loss prior to the pregnancy and

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then modifying the degree of restriction of food intake during the pregnancy to ensure optimal outcome for the mother and the baby. The gastric band is placed 2 cm below the gastroesophageal junction and functions by producing gastric restriction and a sense of early satiety. There is no malabsorption. The band has an internal balloon into which saline can be instilled or removed to adjust the degree of gastric restriction. The balloon is connected via tubing to a Portacath reservoir attached to the anterior rectus sheath and adjusted percutaneously. Further description and outcomes have been published elsewhere.¹⁸

Optimal weight gain for pregnancy requires a balance between allowing sufficient weight gain to allow for normal fetal growth and development, and yet avoiding excess weight gain with its obstetric risks, macrosomia and post-pregnancy weight retention. The Institute of Medicine (IOM) in 1990, issued total gestational weight gain recommendations based on pre-pregnancy BMI.¹⁹ These guidelines may not apply to severely obese women where recommendations for a minimum weight gain may be unnecessary.^{20,21} We have found no reference recommending a net weight loss during pregnancy.

From a group of 650 patients who have had placement of the Lap-Band system[®] (BioEnterics Corporation, Carpinteria, CA), a laparoscopically-placed silicone adjustable gastric band, we have followed all women having a pregnancy. We present the results of these pregnancies and our current approach to the management of the Lap-Band[®] system during pregnancy. In addition, obstetric histories have been taken from severely obese women presenting for Lap-Band[®] surgery, and their incidence of obstetric complications is compared with the group who have completed pregnancy after Lap-Band[®] placement.

Methods

Patients with a body mass index (BMI) greater than 35 kg/m², suffering significant medical, physical or psychosocial disabilities and who have attempted weight reduction by other means for at least 5 years were considered for entry into the Lap-Band[®] pro-

gram. Preoperative assessment included as part of the medical assessment a questionnaire that enquired about infertility, parity and obstetric history. Details of this history were then obtained at preoperative interview or at post-operative review visits. The history was dependent on the mother's recall of obstetric events. A history of gestational hypertension was difficult in many cases to further classify; consequently this category contains all women diagnosed with hypertension in pregnancy who had no pre-gestational hypertension.

All patients were followed regularly at a central multidisciplinary bariatric clinic and urged to inform us of any intention to become pregnant or of pregnancy, as soon as possible. Patients are advised to delay pregnancy for at least 1 year after Lap-Band[®] placement, but this recommendation is not always followed, as obesity-related infertility often resolves with early weight loss.

During the period of study an active approach for the management of the Lap-Band[®] during pregnancy evolved. The key elements of this were:

- 1) Close co-operation was established with the obstetrician.
- 2) As early as possible during pregnancy, all fluid was removed from the band to minimize band restriction, thereby allowing optimal nutrition during embryogenesis and minimizing the effect of the band on hyperemesis during the first trimester.
- 3) Optimal weight gain for the pregnancy was discussed with all women, and fluid was added after 14 weeks gestation or later if weight gain is excessive. The adjustment was aimed to limit excessive weight gain rather than to assist with weight loss.
- 4) All fluid was again removed from the band at 36 weeks gestation to minimize its impact on delivery and the establishment of lactation. Once lactation was established, the band was adjusted to near pre-pregnancy level, to allow for continued weight-loss or weight maintenance as appropriate. Feeling the band reservoir through the skin allows us to make band adjustments, and we have not required ultrasound to locate the site in any pregnant women to date.
- 5) Optimal weight gain for pregnancy was based on the IOM recommendations for weight gain at varying BMI levels. In addition, we did not set a minimum weight gain for those with a BMI >35 kg/m² at the commencement of pregnancy.

Data Analysis

Descriptive statistics include mean and standard deviation for continuous variables. The chi-squared test was used for binary variables to assess the significance of proportions. Unpaired t-test was used to assess pregnancy weight outcomes before and after weight loss. A p-value of 0.05 or less was considered statistically significant.

Results

We obtained obstetric histories from 264 parous women prior to Lap-Band® surgery; 88 (30%) of the 264 parous women had had at least one caesarean section, with 168 (31%) of 621 babies born by caesarean section. This is significantly above the Australian caesarean section rate of 20% ($p < 0.01$).²² Gestational hypertension complicated pregnancies in 98 women (37%). It was a factor in 35% of 264 primigravids, 34% of 217 second, 39% of 101 third and 38% of 39 fourth or subsequent pregnancies, all significantly higher than the expected community incidence of 10-13% ($p < 0.001$).²³ Gestational diabetes had been diagnosed in 9.4% of women compared with a community incidence of 5.5% ($p < 0.05$)²⁴ with universal screening.

Twenty women have completed 22 pregnancies with a Lap-Band® in-situ. One woman (not included in this study) had a spontaneous first trimester abortion. The details of the mothers' demographics, weight gain and pregnancy outcomes are shown in Table 1. All were singleton pregnancies. Nineteen of 22 had vaginal deliveries, with two primigravids requiring low forceps assistance. Three had elective caesarean section for recurring indications: two for previous obstructed labors and one for previous pelvic fracture. There were no primary caesarean sections.

Eight of these 20 women suffered infertility prior to weight loss. Four had primary and four had secondary infertility. In seven, infertility appeared to be related to anovulation associated with severe obesity and resolved spontaneously with weight loss. The remaining woman achieved a pregnancy

Table 1. Pregnancy (N=22) details for 20 women with Lap-Band in situ during pregnancy

	Mean (SD)	Range
Maternal age (years)	28.8 (4.4)	22-40
Parity	1.85 (0.8)	1-4
Pre Lap-Band, weight (kg)	129 (18)	105-172
Pre Lap-Band, BMI (kg/m ²)	46.4 (6.0)	37-60
Time from L/B placement to conception (months)	16.6 (11)	1-43
% EWL at start of pregnancy (%)	45 (17)	17-80
Pre-pregnancy BMI (kg/m ²)	35 (7)	26-49
Pre-pregnancy weight (kg)	99 (19)	72-145
Pre-delivery weight (kg)	107.3 (17)	82-139
Pregnancy weight gain (kg)	8.3 (7)	-8-26
Gestation (weeks)	39.3 (1.3)	37-42
Birth weight (gm)	3495 (485)	2735-4540
Infants Male : Female	14:8	

following *in vitro*-fertilization.

Ten women had a past history of 15 previous deliveries, with average maternal weight gain for pregnancy of 15.3 (SD 8) kg and a mean infant birth weight of 3,415 (SD 520) gm. The mean maternal weight gain in the patients with a band in-situ was significantly less 8.3 (SD 7) kg ($p < 0.05$), but this was not at a cost of lower birth-weight (mean 3,495 SD 485 gm).

There were few pregnancy complications. One primigravid woman developed mild uncomplicated gestational hypertension in late pregnancy. A diabetic woman developed mild hyperglycemia late in her second pregnancy. She had previously developed gestational diabetes in her first pregnancy, and 2 years later type 2 diabetes was diagnosed and controlled with diet. Before Lap-Band® placement, fasting blood glucose was 9.6 mmol/l and HbA1c 7.8%. With weight loss after surgery and prior to pregnancy she was normoglycemic with fasting glucose 4.5 mmol/l and HbA1c 5.4%. Fluid was added to the band during pregnancy to limit weight gain. She re-developed mild diabetes late in pregnancy. Her macrosomic infant (4,540 gm) was delivered normally and required management of hypoglycemia in the early neonatal period. There were no long-term effects.

In this small group of 22 pregnancies, there was a lower incidence of gestational hypertension ($p < 0.05$) and primary caesarean ($p < 0.05$) than the severely obese comparison group.

There were only two other maternal complications, both possibly indirectly related to weight

loss surgery. One woman managed at a distant center without liaison developed hyperemesis in late pregnancy, having a net weight loss of 2 kg for the pregnancy. The band had not been adjusted for the pregnancy and she had not attended for follow-up. She was induced for hyperemesis but continued to vomit post-natally and required urgent post-natal removal of all fluid to control vomiting. Another woman developed symptomatic gallstones with frequent attacks of biliary colic and an episode of pancreatitis during the last trimester. Fluid was removed from the band on diagnosis of the biliary colic but despite this she had a net weight loss of 7 kg for the pregnancy. She had an uncomplicated delivery of a 3,560 gm healthy male after induction at 38 weeks gestation. An uneventful laparoscopic cholecystectomy was performed 6 weeks post-partum.

There were no premature deliveries, low birth weight infants (< 2,500 gm), congenital abnormalities or major neonatal problems. There were 5 infants with weight less than 3,000 gm and 4 over 4,000 gm with one macrosomic infant (> 4,500 gm).

Maternal weight gains for pregnancy with pre-pregnancy BMI levels are plotted in Figure 1, with

IOM recommended gains indicated and a possible adjustment for maternal BMI > 35 kg/m² also indicated (Table 2). Two of three who had all fluid removed for the pregnancy and were not reviewed until after the pregnancy had excessive weight gain. Three of four who had fluid in the band and had no adjustments at all during pregnancy had a net weight loss. Of 15 with planned active management, all had the fluid removed from the band early in pregnancy and were given advice regarding nutrition and optimal weight gain. Only 6 required the addition of fluid during pregnancy. Eleven of 15 patients with active band management had weight gain within the advised range. Only two of seven treated prior to establishing the active management plan achieved weight gain within this range.

Discussion

The obstetric histories of severely obese women presenting for Lap-Band[®] gastric restrictive surgery are consistent with known increased risks of hypertension during pregnancy, gestational dia-

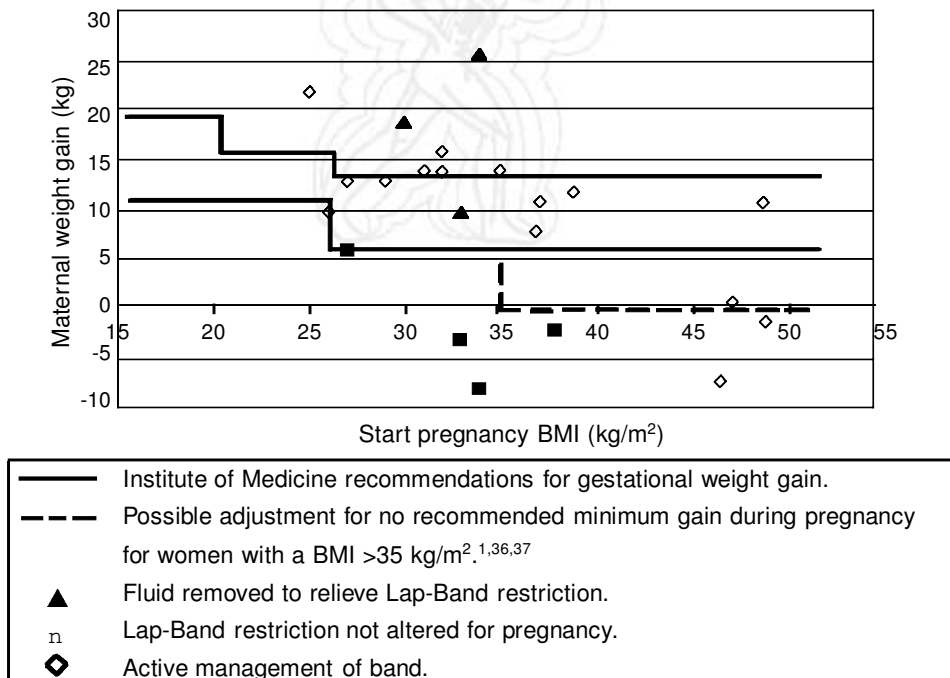


Figure 1. Weight gain for pregnancy vs pre-pregnancy BMI (N=22).

Table 2. Recommended weight gain in pregnancy

BMI Range	Lower wt gain kg (lbs)	Upper wt gain kg (lbs)
BMI < 20*	11.5 (25)	18 (39)
BMI 19-26*	11.5 (25)	15.5 (34)
BMI 26-29*	7 (15)	13 (24)
BMI 29+*	7 (15)	13 (24)
BMI 35+**	0	13 (24)

*Institute of Medicine 1990 recommendations for weight gain in pregnancy.

** Minimum weight gain in pregnancy for severely obese women in pregnancy may be inappropriate.^{1,37,38}

betes and high caesarean section rate in these women. In our series of 22 pregnancies, these obstetric complications were lower than the comparison group and consistent with reports from other groups reporting pregnancy outcomes after bariatric surgery and for a non-obese population.^{5,12,23,24} Neonatal outcomes were also excellent, with a mean birth weight of 3,495 gm consistent with community birth weight, and not different from the mean birth weight of infants born to these women prior to weight loss surgery.²⁵ A low mean birth weight has been reported following other non-adjustable forms of weight loss surgery.^{14,15,26}

Obese women are extremely concerned at the possibility of gaining excessive weight during pregnancy and there is some justification for this concern. Obese women tend to gain less weight during pregnancy than women of normal weight do.²⁷ However, they have greater weight retention after pregnancy and tend to gain more weight between pregnancies.²⁸ For this reason, women are reluctant to have their gastric restriction relieved for pregnancy. A policy of removing the fluid may lead to excessive weight gain. Because of this fear, women may delay informing us of the pregnancy in an attempt to continue weight loss. However, not relieving the gastric restriction may put the fetus at risk of nutritional deficit and low birth weight, both preventable risks, which may have long-term consequences. Fetal malnutrition in infants born into an affluent society may have increased risk of the metabolic syndrome as proposed by Barker.^{17,29} These children have, of course, a family history of severe obesity. Active management of the adjustable band permitted women to choose a

healthy weight gain for their child with the knowledge that, if necessary, restriction could be added during the pregnancy to prevent excessive weight gain. Only six of our patients required some added restriction during pregnancy. With the presence of adjustability, they are also reassured that increase of the level of gastric restriction when lactation is established will minimize weight retention and allow continued weight loss.

Nutritional considerations are also important during pregnancy. It is vital that women of child-bearing age have adequate folic acid prior to pregnancy to minimize the risk of neural tube defects. An oral supplement of 400 mcg /day is recommended for all women who could become pregnant.³⁰ We have recently found that patients losing weight after Lap-Band® surgery require higher plasma levels of folate and vitamin B12 to maintain normal homocysteine levels.³¹ Multivitamin supplements containing folate, vitamin B6 and vitamin B12 help minimize this effect. Recent weight loss by the mother may put the child at increased risk of neural tube defects. Robert et al³² found an association between weight loss in the month after conception and neural tube defect. While selective multivitamin supplements during pregnancy may be appropriate, care should be taken to avoid risk. Supplement of vitamin A more than 5000 IU/day should be avoided.³³

Iron deficiency is not associated with gastric restrictive Lap-Band® surgery, and routine supplementation during pregnancy is of no proven value and unnecessary.³⁴ Iron tablets can be locally erosive³⁵ in association with delayed gastric emptying, a necessary feature of gastric restrictive surgery. Monitoring hemoglobin and iron status prior to and during pregnancy would be more appropriate, with liquid oral or parenteral iron therapy given if necessary. A calcium intake of 1200-1500 mg is recommended throughout pregnancy and lactation, and dietary advice to achieve this intake is necessary.³⁶

Severely obese women are at high risk for obstetric complications. The introduction of a laparoscopically-placed, adjustable and effective method of weight loss gives us the opportunity to use this system in severely obese women planning future pregnancies, to reduce obstetric risks in addition to the other advantages of losing weight. While it is

ideal for women to lose most of their excess weight prior to pregnancy, it is reassuring that the system can be used with the knowledge that band restriction can be decreased during pregnancy.

Conclusion

In our experience, an active management which utilizes the adjustability of the Lap-Band® and planned and careful monitoring of pregnant women with a Lap-Band® in situ, has achieved optimal weight control and appears to be associated with reduction of the risks and complications of pregnancy for the mother and infant.

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