

Maternal and Neonatal Outcome After Laparoscopic Adjustable Gastric Banding: a Systematic Review

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Abstract The number of women of reproductive age undergoing bariatric surgery, including laparoscopic adjustable gastric banding (LAGB), has increased in recent years. The objective of this study was to list both maternal and neonatal outcomes in pregnancies in obese women ($BMI \geq 30 \text{ kg/m}^2$) after LAGB and compare them with pregnancies in obese or normal weight women without LAGB. Studies showed a lower incidence of gestational diabetes, pregnancy-induced hypertension (PIH), pre-eclampsia, caesarean section (CS), macrosomia, and low birth weight babies in post-LAGB pregnancies compared to pregnancies in obese women

without LAGB. Gestational weight gain was also lower in post-LAGB pregnancies. However, the incidence of PIH, pre-eclampsia, CS, preterm birth, large for gestational age, spontaneous abortion, and NICU admission was higher in post-LAGB pregnancies than in normal weight pregnancies. In conclusion, LAGB seems to improve pregnancy outcomes in obese women, even when obesity is still present at the onset of pregnancy. However, further research is needed and pregnant women with a gastric band should always be closely monitored by a multidisciplinary team.

Keywords Pregnancy · Pregnancy outcome · Obesity · Bariatric surgery · Laparoscopic adjustable gastric banding

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Introduction

Obesity, defined as a body mass index ($BMI > 30 \text{ kg/m}^2$), is recognized as a major global health problem [1, 2]. The prevalence of obesity has increased dramatically in recent years and this pandemic is becoming one of the most important causes of death [2–4]. Consequently, there is a rise in the number of women at reproductive age who are overweight or obese which leads to an increase in adverse maternal and neonatal outcome rates [1, 4–6]. Maternal problems include gestational diabetes (GD), pregnancy-induced hypertension (PIH), and/or pre-eclampsia, infectious morbidity, miscarriage, primary postpartum hemorrhage, instrumental delivery, caesarean section (CS), and excessive gestational weight gain (GWG) [1, 4, 5, 7, 8]. Infants of obese women are more likely to develop congenital malformations, fetal growth abnormalities, and neonatal macrosomia. Stillbirth is also more common in this group [4, 5, 7, 8].

Maternal pre-pregnancy weight is an important element in pregnancy outcome because a higher weight at this stage increases the risk of several of these adverse pregnancy outcomes [9, 10]. Weight loss before pregnancy may

decrease the number of adverse pregnancy outcomes in obese women and improve fertility [4, 5]. Lifestyle changes (decreasing energy intake and increasing physical activity) and pharmacotherapy often fail to successfully achieve long-term weight loss. For this reason, the number of women of reproductive age undergoing bariatric surgery increased over the last years [11, 12]. In (morbidly) obese women, bariatric surgery has proven to be highly effective in terms of controlled and permanent weight reduction and consequently in reducing co-morbidities associated with obesity [4, 13–15]. Consequently, rates of adverse maternal and neonatal outcomes may be decreased in women who become pregnant after bariatric surgery [11]. Despite positive outcomes, concerns arise with regard to the potential negative impact on pregnancy. Broad summaries of possible complications for mother and fetus after bariatric surgery lack in present literature. In patients with laparoscopic adjustable gastric banding (LAGB) unique complications can occur. Pouch enlargement, band slip, band erosion, port-site infections, and port breakage are the most common complications associated with LAGB. These must be recognized and managed properly to achieve and maintain good outcomes [16]. Pregnancy may have an additional impact on possible complications after LAGB. Because severe vomiting in early postoperative period can provoke band complications and because nausea and vomiting are frequent in the first trimester of pregnancy, pregnancy can compromise the outcome of the gastric band and can cause band migration, and even balloon leakage in some cases [17].

There is a paucity of data describing adverse outcomes of pregnancies in women with a gastric band. The objective of this systematic review is to list both maternal and neonatal outcomes in pregnancy following LAGB in obese women and to compare different findings in literature regarding safety of the gastric band during pregnancy.

Methods

Search Strategy

Identification of relevant studies was performed in two steps. A thorough search in databases Medline, DARE, and NGC was conducted. Medline was searched for MeSH terms “pregnancy”, “laparoscopic adjustable gastric banding”, “bariatric surgery”, “obesity”, and “pregnancy outcome”. A second search was conducted by screening the reference list of each relevant publication for other relevant references.

Inclusion and Exclusion Criteria

Studies concerning women with a BMI greater than 30 kg/m² and who had undergone laparoscopic adjustable gastric

banding were included. There were no restrictions on publication date. Only articles published in English, Dutch, or French language were included. Case reports were excluded for data extraction but were not ignored as background information.

Data Extraction

Study results were abstracted and presented in data tables. Maternal and neonatal outcomes were presented in separate tables. A distinction between results of observational studies with or without control group was made to guard overview and relevance for comparing the results.

Results

Selected Studies

Different keyword searches identified 36 studies. Minimal criteria for the studies to be included were presenting both maternal and neonatal outcomes and only using LAGB as bariatric procedure. Eleven studies matched our criteria; four observational studies with and seven without a control group [1, 4–6, 17–23]. Some studies used two comparison groups [5, 20]. The selected studies resulted in 728 LAGB pregnancies in 638 women.

Outcomes

Both maternal and neonatal outcomes were described in the studies investigating pregnancies following a LAGB procedure. Four studies compared the pregnancy outcomes of women with a history of LAGB (with a mean pre-pregnancy BMI >30 kg/m²) with the pregnancy outcomes in obese or normal weight women who did not get the procedure (the control or comparison group). The most commonly reported maternal outcomes in these studies were band-related complications or adjustments, mean GWG, GD, PIH, pre-eclampsia, and caesarean delivery rate. Neonatal outcomes included pre-term delivery (<37th gestational week), low birth weight (<2,500 g), high birth weight (macrosomia, >4,000 g), large for gestational age (LGA), small for gestational age (SGA), spontaneous abortion, congenital abnormalities, and admission on neonatal intensive care unit (NICU).

Lapolla et al. compared the maternal and neonatal outcomes of 83 post-LAGB pregnancies to outcomes of 120 pregnancies in morbidly obese women without LAGB and to outcomes of 858 pregnancies in normal weight women without GD. The study also compared the outcomes of 27 post-LAGB pregnancies with the outcomes of 27 pre-LAGB pregnancies in the same women. Additionally, the study compared the pregnancy outcomes in the 83 post-LAGB

pregnancies according to pre-pregnancy BMI (still morbidly obese patients with a BMI > 35 kg/m² vs. no longer morbidly obese patients with a BMI < 35 kg/m²). The pregnancies in the still morbidly obese group occurred significantly earlier (2.5 ± 1.4 years) than in the no longer morbidly obese group (3.5 ± 2.5 years) [5]. The study of Skull et al. consisted of an observational part in which the hospital database provided information and a case–control study in which 44 women participated, resulting in 80 pregnancies [20]. The first group consisted of all the post-LAGB pregnancies in obese women. The control group was a historical control, i.e., the pre-LAGB pregnancies of the same women. This means that a multiparous woman could contribute to both of the groups and that a primiparous woman would only contribute to the first group of the study. The study of Dixon et al. [4] compared the outcomes of the first post-LAGB pregnancies (*n*=79) of women with a BMI greater than 35 kg/m² with the outcomes of the last pre-LAGB pregnancies of these same women (*n*=40) and with the obstetric histories of matched severely obese women (*n*=79), taken from a larger group of women presenting for LAGB surgery. Additionally, these outcomes were compared to community outcomes published for the state of Victoria. Ducarme et al. performed a retrospective case–control study with 13 obese women who had undergone LAGB and 414 unoperated obese women [1]. Weiss et al. observed seven unexpected pregnancies (within 2 years after surgery) in 215 obese women of reproductive age who agreed to remain on reliable contraceptives for 2 years after LAGB surgery. These women had reported to use unreliable methods of birth control, like coitus interruptus and periodic abstinence. Among women using oral contraceptives, no pregnancies occurred. Only one woman reached a normal pre-pregnancy BMI of 24.8 kg/m², while all other women were still obese. The study of Carelli et al. described the outcomes of 121 post-LAGB pregnancies in 92 women [22]. Bar-Zohar et al. observed 81 singleton post-LAGB pregnancies in 74 women [6]. The study of Martin et al. observed the outcomes of 23 pregnancies in 20 women [22]. The mean pre-pregnancy BMI, however, was not reported. Dixon et al. studied the outcomes of 22 pregnancies in women after a Lap-Band® placement [19]. The study of Sheiner et al. compared pregnancy outcome between different types of surgery, including 202 pregnancies following LAGB in women [21]. The French study of Jasaitis et al. described pregnancy outcomes of 21 pregnancies in 18 women [23].

Maternal Outcomes

Maternal outcomes in the selected observational studies with a control group are listed in Table 1 and those without a control group are listed in Table 2.

Band Related Complications or Adjustments

In the study of Lapolla et al., 14 of the 83 women (16.9 %) had their band deflated percutaneously during their pregnancy because nutrient requirements were not met by dietary intake and/or in case of frequent vomiting [5]. In the study of Skull et al., two of the 49 LAGB pregnancies presented band-related complications [20]. Both women had acute gastric prolapse through the band and the band had to be removed laparoscopically. After this surgery, both pregnancies proceeded without events. Both prolapses occurred in women with a Lap-Band® which was placed using the original perigastric approach, before the introduction of the pars flaccida technique. Of all 49 women, eight women (18 %) had their band adjusted during their pregnancy; two of them had their band emptied (2 ml was removed), four had 1 ml removed, one had 0.25 ml removed. One patient had fluid (0.5 ml) added. Dixon et al. do not report an exact incidence of band-related complications or adjustments [4]. However, one woman developed symptomatic gallstones and had an episode of acute pancreatitis, one woman had persistent vomiting despite removal of all fluid from the band, and two complained about tenderness over the reservoir site during late pregnancy [22]. In the study of Carelli et al., band adjustments were made in 71 % of the pregnant patients, with an average of 1.07 adjustments per pregnancy (range, 0–5). More women had their band loosened than filled; with an average amount of 1.28 ml fluid extracted (range, 0.2–0.4). More adjustments were made during the first trimester than during the second and third trimester. Nineteen women had their band completely deflated at some point in their pregnancy. An important note made by the authors was the fact that many women in their first trimester requested to loosen the gastric band due to fear of inadequate intake to sustain fetal development, and not based on symptoms. The number of band adjustments during pregnancy was not influenced by the time between surgery and pregnancy. Band slips occurred in three women (3.2 %) during pregnancy. Eight women (8.7 %) suffered from band slips within the first 6 months postpartum. In four patients (4.3 %) port leaks occurred; two intrapartum and two within the first 6 months postpartum [22]. In the study of Bar-Zohar et al., band slips occurred in two pregnancies (2.4 %) at the end of the second trimester, leading to vomiting, severe dehydration, and electrolyte disturbance. They underwent laparoscopic removal of the gastric band and had no further complications [6]. In the study of Martin et al., six women had band adjustments. Three women had to have fluid removed from the band due to nausea and vomiting. One other asymptomatic woman requested to have all fluid removed from the band and lost 17.6 kg during her pregnancy. One woman requested to have her band emptied when pregnancy was diagnosed; she gained the most

Table 1 (continued)

Study	Maternal outcome				Pre-eclampsia %				CS %	
	GD (%)		PIH %		LAGB		Control		LAGB	Control
	LAGB	Control	LAGB	Control	LAGB	Control	LAGB	Control	LAGB	Control
Lapolla et al. (2010) [5]	6.0	50.0***	9.6	23.5*	12.0	20.8*	45.9	65.8**		
	7.4	–	14.8	2.4***	7.4	2.3***	54.2	28.2***		
	11.8	7.4	29.4	33.0	14.7	14.8	51.6	36.0		
	8	2.2	8.1	8.9*	0	11.1	28.5	42.9		
Skull et al. (2004) [20]		27*		22.5		6.4		16		

The interval operation to conception or birth (τ) is formulated in months, unless stated differently

NR not reported, IQR interquartile range

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.0001$ (compared with LAGB) and * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$ (obese vs normal weight) <

^a BMI expressed as mean \pm SD or mean (range) (kg/m²)

weight. One other woman had fluid removed by the surgeon to prevent band-related vomiting [18]. Ducarme et al. reported a rate of 60 % of band adjustments necessary to prevent nausea and vomiting in the first trimester [1]. However, the performed adjustments were not specified. In the study of Weiss et al., all women had their band deflated due to nausea and vomiting [17]. This occurred after the diagnosis of pregnancy and was found not to be band related. In two women a nasogastric tube was placed for a few days because of uncontrollable vomiting; this to minimize gastric filling and to prevent possible damage to the band site. In one patient, intragastric band migration occurred after 16 months. Since the band remained deflated and there were no signs of surgical or infectious complications, severe vomiting was assumed to be the cause of band migration. The migrated band was removed endoscopically. Another patient suffered from band leakage which was detected after a successful delivery. In the study of Dixon et al., one woman developed hyperemesis and another woman developed symptomatic gallstones and both required removal of all fluid from the band [19]. In the study of Sheiner et al., 5 % of post-LAGB pregnant women showed bariatric complications, although these were not specified [21]. In the study of Jasaitis et al., the gastric band was deflated systematically in three asymptomatic women (14 %). In four other women (19 %) the band was deflated due to epigastralgia caused by a band rotation in two women, band migration in one woman, and band disconnection in another woman [23]. This study compared the pregnancy outcomes between women who had their band deflated during pregnancy and those who had not. Women who had their band deflated gained significantly more weight during pregnancy. They concluded that gastric bands are generally well-tolerated during pregnancy and should only be deflated in symptomatic women because of the risk of less well controlling GWG [23]. It is important to note that in most studies the reason for deflation or other adjustments to the band was not mentioned and thus it was not clear whether this happened in symptomatic or asymptomatic women.

Gestational Weight Gain

In the study of Lapolla et al., the LAGB group had a median weight change of 7.0 kg during pregnancy (range, –28.0–+32.0 kg). Seventeen patients (20.5 %) lost weight, 42 (50.6 %) had a moderate gain of weight (0 to 10 kg), and 24 women (28.9 %) gained more than 10 kg [5]. The average GWG was significantly lower in the post-LAGB obese group than in the normal weight group. The average GWG was significantly lower in the 27 post-LAGB pregnancies than in the 27 pre-LAGB pregnancies in the same women [5]. In the case–control study of Skull et al., GWG in LAGB pregnancies was significantly lower than in the

Table 2 Overview of observational studies without a control group: results in maternal outcome in pregnancy after laparoscopic adjustable gastric banding (LAGB)

Study	Sample (pre-pregnancy BMI ^a)	Interval operation to conception or birth (τ)	Maternal outcome									
			Band adjustments					Mean GWG (kg)	GD (%)	PIH (%)	Pre-eclampsia (%)	CS (%)
			Total (%)	Fluid removed (%)		Fluid added	Balloon management					
Emptied	Partially											
Bar-Zohar et al. (2006) [6]	81 pregnancies (30.3±3.0)	27±3 (τ)	2.4	NR	NR	NR	Removal of the band	10.6±2.1 (range, 7–18)	16	7.4	NR	20
Carelli et al. (2011) [22]	121 pregnancies (32.9±7.53, range, 21.4–52.3)	NR	71	15.7	NR	NR	Deflation of the band to avoid excessive nausea and vomiting	11.5	4	5	5	45
Dixon et al. (2001) [19]	22 pregnancies (35±7, range, 26–49)	16.6±11 (range, 1–43)	81.8	81.8	NR	27.3	Active band management	8.3±7	4.5	4.5	NR	13.6
Jasaitis et al. (2007) [23]	21 pregnancies (36±8, range, 23–58)	48±37 (range, 6–132)	33	33	NR	NR	Deflation of band by principle or symptomatic	12±7	4	0	0	38
Martin et al. (2000) [18]	23 pregnancies (NR)	NR	33.3	11.1	22.22	0	Adjustment of band to relieve nausea and vomiting when they become medical concerns	NR	0	0	0	22.2
Sheiner et al. (2009) [21]	202 pregnancies (31.9±6.2)	22.8±16.0	NR	NR	NR	NR	NR	13.1±9.6	6.0	6.9	NR	30.7
Weiss et al. (2001) [17]	7 (unexpected) pregnancies (34.8 (24.8–42.0))	12 (range, 1–22)	100	NR	NR	0	Systematic deflation of the band in attempt to relieve nausea and vomiting	15.62	0	0	0	29

GWG gestational weight gain, NR not reported, GD gestational diabetes, PIH pregnancy induced hypertension, CS caesarean section
The interval operation to conception or birth (τ) is formulated in months, unless stated differently

^a BMI expressed as mean ± SD or mean (range) (kg/m²)

previous non-LAGB pregnancies in the same women [20]. In the study of Dixon et al., the mean GWG in the LAGB group was significantly lower than those of the pre-LAGB pregnancies in matched women and the matched severely obese controls [4]. The mean GWG in the study of Ducarme et al. was significantly lower in the LAGB group than in the non-LAGB group [1]. In the study of Weiss et al., five women carried their pregnancy to full-term after LAGB [17]. Four of them continued to gain weight after band decompression (2, 20.3, 25, and 38.5 kg). The fifth woman lost 7.7 kg [17]. Carelli et al. saw an average GWG of 11.5±3.6 kg (range, -13.6 to +38.6) in patients after LAGB [22]. Martin et al. do not report details of GWG, but do report that subjects gained approximately twice the weight that is recommended for women of normal weight (31 and 39 kg) [18]. One woman who was carrying twins gained 27 kg. The women with the most excessive weight gain had no fluid in their bands. One woman, the one who gained the most weight, requested her band to be emptied when she found out that she was pregnant. One other woman requested to

remove all fluid out of her band, although she did not have symptoms like vomiting and nausea, and lost 17.6 kg during her pregnancy. Of the 12 other women who kept the diameter of their gastric bands constant, three subjects lost weight (1.8–7.6 kg) and nine gained weight (1.4–25 kg) during their pregnancies. In the studies of Bar-Zohar et al., Dixon et al., Jasaitis et al., and Sheiner et al., the mean GWG ranged from 8.3 to 13.1 kg [6, 19, 21, 23]. In conclusion: GWG seems to be lower in pregnancies after LAGB than in non-LAGB pregnancies in obese or normal weight women [1, 5, 19, 20].

Gestational Diabetes

All included studies described the incidence of GD. In the study of Lapolla et al. the rate of GD was significantly lower in the LAGB group than in the obese control group [5]. The rate of GD did, however, not differ between the pre- and post-LAGB pregnancies in the same women. GD was not observed in the normal weight group. Patients who were still

morbidly obese after LAGB had a higher rate of GD in comparison with no longer morbidly obese patients after LAGB, although this was not statistically significant [5]. In the study of Skull et al., the incidence of GD was significantly lower in the LAGB group than in the non-LAGB group [20]. The incidence of GD in the study of Dixon et al. was lower in the pre-LAGB pregnancies than in the matched obese cohort [4]. Ducarme et al. also found a significant lower incidence of GD in their LAGB group than in the control group [1]. The studies of Carelli et al., Jasaitis et al., Bar-Zohar et al., Dixon et al., and Sheiner et al. reported a GD incidence ranging from 4 to 16 % [6, 19, 21–23]. In the other studies none of the subjects developed GD [17, 18]. In conclusion: the incidence of GD is lower in LAGB pregnancies than in non-LAGB pregnancies in obese women [5, 19, 20].

Gestational Hypertension

Gestational or pregnancy-induced hypertension (PIH) was described in all selected studies. Lapolla et al. found a lower incidence rate of PIH in women who had a gastric band than in obese women without a gastric band. They also found a lower incidence in the normal weight group than in the LAGB group [5]. The post-LAGB pregnancies were characterized by a lower frequency of PIH compared with the pre-LAGB pregnancies, although this was not statistically significant. Patients who were still morbidly obese after LAGB had a significantly higher rate of PIH in comparison with no longer morbidly obese patients [5]. In the study of Skull et al., the PIH rate was lower in the LAGB group than in the non-LAGB group, although not statistically significant [20]. Ducarme et al. also observed a lower incidence of PIH in the LAGB group than in the control group, although this was again not statistically significant [1]. In the study of Dixon et al., the incidence of PIH was lower in the LAGB group than in the pre-LAGB and the matched obese group [4]. In the studies of Weiss et al., Martin et al., and Jasaitis et al., none of the subjects developed PIH [17, 18]. In the studies of Carelli et al., Bar-Zohar et al., Dixon et al., and Sheiner et al., the incidence rate of PIH ranged from 4.5 to 7.4 % [6, 19, 21, 22]. In conclusion: the incidence of PIH is lower in LAGB pregnancies than in non-LAGB pregnancies in obese women, but higher than in non-LAGB normal weight women [4, 5].

Pre-eclampsia

Pre-eclampsia or eclampsia was described in seven of ten studies. In the study of Lapolla et al., significantly less pregnant women in the post-LAGB group developed pre-eclampsia than in the obese control group, but more women than in the normal weight group. There was no significant difference in the incidence of pre-eclampsia between the women with LAGB-pregnancies and pre-LAGB pregnancies

[5]. In the study of Skull et al., 0 % of the women in the LAGB group versus 6.4 % in the non-LAGB group developed pre-eclampsia, although this was not statistically significant. In each group, one pregnant woman developed the next eclampsia stage (2 vs 3.2 %) [20]. The incidence of pre-eclampsia in the study of Dixon et al. was significantly lower in the LAGB group than in the non-LAGB pregnancies and the obese cohort [4]. In the study of Ducarme et al., no subjects in the LAGB group developed pre-eclampsia while in the control group 3.1 % developed pre-eclampsia ($p < 0.05$) [1]. Carelli et al. saw pre-eclampsia in five women (5 %) during the pregnancy [22]. In the study of Weiss et al., Martin et al., and Jasaitis et al., none of the subjects developed this complication [17, 18]. In conclusion: the incidence of pre-eclampsia is lower in LAGB pregnancies than in non-LAGB pregnancies in obese women, but higher than in normal weight women without LAGB [1, 4, 5, 20].

Caesarean Section

The CS rate was discussed in all studies. In the study of Lapolla et al., post-LAGB women had statistically significant more CSs than normal weight women, but statistically significant less CSs than unoperated obese women. In the 27 pregnancies carried out before LAGB the incidence of CS was lower than in the 27 pregnancies after LAGB in the same women, although this was not statistically significant [5]. In the study of Skull et al., the incidence of CS was higher in the LAGB group than in the non-LAGB group, but again not statistically significant [20]. In the study of Dixon et al., no statistically significant difference in the number of CSs between the study groups was found [4]. Ducarme et al. did however find a significant lower rate of CS in the LAGB group than in the control group [1]. In the studies of Bar-Zohar et al., Weiss et al., Carelli et al., Sheiner et al., Martin et al., Dixon et al., and Jasaitis et al. the incidence of CS ranged from 13.6 to 45 % [6, 17–19, 21–23]. In conclusion: the incidence rate of CS is lower in LAGB pregnancies than in non-LAGB pregnancies in obese women, but higher than in normal weight women without LAGB [1, 5].

Neonatal Outcomes

Neonatal outcomes in the selected observational studies with control group are listed in Table 3 and without control group are listed in Table 4.

Preterm Birth

Preterm delivery was discussed in seven studies and defined as a delivery before the 37th week of gestation. In Lapolla et al., the rate of preterm delivery was significantly higher in

the LAGB group and in the obese non-LAGB group than in the normal weight group [5]. The rate of preterm-born neonates in the study of Ducarme et al. was also higher in the LAGB group than in the control group, however not statistically significant [1]. In the study of Dixon et al., contrary to previous results, the rate of preterm-born neonates was lower in the LAGB group than in the obese control group, however again not statistically significant [4]. In the LAGB study group of Carelli et al., 6 % of the neonates were born preterm [22]. In the study of Sheiner et al., 9.9 % had a preterm delivery [21]. The study of Bar-Zohar et al. mentioned a range of 36–41 weeks regarding weeks of gestation, but the specific number of preterm deliveries is unclear. In all other studies all pregnancies were full term [17–19]. In the study of Jasaitis et al., there were no preterm deliveries, but six women (28 %) had a gestational duration longer than 41 weeks [23]. In conclusion: the rate of preterm deliveries was higher in the LAGB group than in the normal weight group without LAGB [5].

Birth Weight in Relation to Gestational Age

Lapolla et al. report findings regarding neonates large for gestational age, defined as a birth weight >90th percentile, or small for gestational age, defined as a birth weight <10th percentile, based on standard growth and development tables for the Italian population [5]. There were less SGA babies in the LAGB group than in the obese group and the normal weight group, however the observed difference was not statistically significant. There were no SGA babies in the 27 LAGB pregnancies versus a rate of 8.0 % SGA babies in the 27 pre-LAGB pregnancies in these same women (NS). In these same subjects, there were no significant differences in the rate of LGA babies between the pre- and post-LAGB group. In the French study of Jasaitis et al., three babies (13 %) had a birth weight below the 10th percentile and eight babies (36 %) had a birth weight higher than the 90th percentile [23].

Low Birth Weight (<2,500 g) and Macrosomia (>4,000 g)

In the study of Lapolla et al., there were no statistically significant differences in the rate of macrosomia between the LAGB, the obese, and normal weight group [5]. There was also no statistically significant difference in the rate of macrosomia between the 27 pre-LAGB pregnancies and the 27 post-LAGB pregnancies. In the post-LAGB group in the study of Dixon et al., less babies were born with a low birth weight than in the obese group, however not statistically significant. One of these low birth weights may have been band related: the mother, a 41-year-old primigravida, had episodic vomiting throughout pregnancy, despite having all fluid removed from her balloon. In the post-LAGB group,

less babies were born with a high birth weight than in the obese group, however also not statistically significant. In the study of Ducarme et al., the rates for low birth weights was significantly lower in the LAGB group than in the control group [1]. The incidence of macrosomia was also significantly lower in the LAGB group than in the control group. In the study of Carelli et al., 8 % of the neonates had a low birth weight and 7 % of the neonates had a high birth weight [22]. In the study of Dixon et al., four infants (22.7 %) with a birth weight over 4,000 g were reported [19]. In the study of Sheiner et al., 9.4 % had a low birth weight, while 4.5 % had a high birth weight [21]. In other studies no babies with birth weights outside the normal range were reported [17, 18, 20]. In conclusion: the incidence of macrosomia or low birth weight is lower in LAGB pregnancies than in non-LAGB pregnancies in obese women [1].

Spontaneous Abortions

The rate of spontaneous abortions and an explanation on the possible causes were not reported in all included studies. In Lapolla et al., more spontaneous and voluntary abortions occurred in the LAGB group than in the obese group and normal weight group [5]. The abortion rate in the normal weight group was also lower than in the obese group. There was no statistically significant difference in the rate of spontaneous abortions between the 27 post-LAGB pregnancies and the 27 pre-LAGB pregnancies. In the study of Weiss et al., two pregnancies after LAGB ended in spontaneous abortions (29 %) [17]. In the study of Martin et al., two women (8.7 %) had a spontaneous abortion during the first trimester and two women (8.7 %) had elective abortions. One woman with a spontaneous abortion required removal of fluid from the band for nausea and vomiting [18]. Carelli et al. report a number of 20 miscarriages in their study (17 %) [22]. In the study of Dixon et al., one woman had a spontaneous first trimester abortion and was therefore excluded from their study [19]. In the study of Jasaitis et al., one woman suffering from chronic hypertension had a spontaneous abortion at 26 weeks of pregnancy [23]. In conclusion: the rate of spontaneous abortions is higher in LAGB pregnancies than in non-LAGB pregnancies in obese or normal weight women [5].

Apgar Score

Apgar score (at 5 min) was assessed in three studies. In the study of Ducarme et al., 15.4 % of the newborns had an Apgar score lower than 7 (versus 13.4 % in the control group) [1]. This difference was however not statically significant. In the study of Sheiner et al., only 1.5 % of the newborns had an Apgar score below 7 [21]. In the study of Carelli et al., an Apgar score below 7 at 5 min was not seen

Table 3 Overview of observational studies with a control group: results in neonatal outcome in pregnancy after laparoscopic adjustable gastric banding (LAGB)

Study	Sample (pre-pregnancy BMI ^a)	Neonatal outcome											
		Preterm birth (%)				LGA (%)				Macrosomia (>4,000 g) (%)		Low birth weight (<2,500 g) (%)	
		LAGB	Control	LAGB	Control	LAGB	Control	LAGB	Control	LAGB	Control	LAGB	Control
Lapolla et al. (2010) [5]	83 pregnancies (35.0±7.3)	17.6	13.7	17.6	26.5	8.1	9.4	NR	NR				
	120 pregnancies in non-LAGB morbidly obese women (39.4±3.8)												
	858 pregnancies in non-LAGB normal weight women (without GD) (22.2±1.4)												
Dixon et al. (2005) [4]	27 pregnancies (36.1±5.8)	8.3	8.0	20.8	20.0	4.2	16.0	NR	NR				
	34 pregnancies morbidly obese (41.7±5.5)	16.1	19.0	25.8	11.9	NR	NR	NR	NR				
	79 first pregnancies (NR)	6.3	12.7	NR	NR	11.4	17.7	6.3	8.9				
	79 pregnancies in non-LAGB matched obese cohort (43.7±6.3)												
Ducarme et al. (2007) [1]	13 pregnancies (34.8±3.2)	7.7	7.1	NR	NR	7.7	14.6 [*]	7.7	10.6 [*]				
	414 pregnancies in non-LAGB obese women (35.0±4.0)												
	Victorian community (n=61,000) (NR)												
Study	SGA (%)	Spontaneous abortion (%)				Congenital anomalies (%)				NICU admission (%)			
		LAGB		Control		LAGB		Control		LAGB		Control	
		LAGB	Control	LAGB	Control	LAGB	Control	LAGB	Control	LAGB	Control	LAGB	Control
Lapolla et al. (2010) [5]	1.4	4.3	10.8	2.5 [*]	0.0	0.0	20.3	10.3 [*]					
	0.0	2.3	11.1	0.3 ^{***} *	0.0	0.0	12.5	9.0 ^{**} *					
	0.0	8.0	8.8	7.4	0.0	0.0	16.1	12.0					
Dixon et al. (2005) [4]	NR	2.4	NR	6.7	0.0	0.0	NR	23.8					
	NR	NR	NR	NR	1.26	NR	NR	NR	NR				
Ducarme et al. (2007) [1]	NR	NR	NR	NR	NR	NR	NR	NR	NR				
	NR	NR	NR	NR	NR	NR	NR	NR	NR				

LAGB large for gestational age, SGA small for gestational age, NICU neonatal intensive care unit, NR not reported

^aBMI expressed as mean ± SD or mean (range) (kg/m²)

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$; **** $p < 0.0001$ (compared to LAGB) and * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$ (obese vs normal weight)

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Table 4 Overview of observational studies without a control group: results in neonatal outcome in pregnancy after laparoscopic adjustable gastric banding (LAGB)

Study	Sample (pre-pregnancy BMI ^a)	Neonatal outcome						
		Preterm birth (%)	SGA (%)	Low birth weight (<2,500 g) (%)	Macrosomia (>4,000 g) (%)	LGA (%)	Spontaneous abortion (%)	Congenital anomalies (%)
Bar-Zohar et al. (2006) [6]	81 pregnancies (30.3±3.0)	NR	NR	NR	NR	NR	NR	0
Carelli et al. (2011) [22]	121 pregnancies (32.9±7.53, range, 21.4–52.3)	6	NR	8	7	NR	17	NR
Dixon et al. (2001) [19]	22 pregnancies (35±7, range, 26–49)	0	NR	0	18.2	NR	4.3	0
Jasaitis et al. (2007) [23]	21 pregnancies (36±8, range, 23–58)	0	13	NR	NR	36	4	NR
Martin et al. (2000) [18]	23 pregnancies (NR)	0	NR	NR	NR	NR	8.7	0
Sheiner et al. (2009) [21]	202 pregnancies (31.9±6.2)	9.9	NR	9.4	4.5	NR	NR	NR
Weiss et al. (2001) [17]	7 (unexpected) pregnancies (34.8 (24.8–42.0))	NR	NR	1	0	NR	29	0

NR not reported, SGA small for gestational age (birth weight below the 10th percentile), LGA large for gestational age (birth weight >90th percentile)

^aBMI expressed as mean ± SD or mean (range) (kg/m²)

[22]. The average Apgar score was 9.17 (±0.45) with a range of 8–10.

Abnormalities

It is interesting to look at the number of abnormalities in infants of women who underwent LAGB surgery because of the paucity in data and contradictions in the available literature. A clear distinction has to be made between congenital abnormalities (present at birth) and postnatal complications. In none of the selected studies, however, this difference was made [22, 24]. In the study of Dixon et al., there was one stillbirth of a 3,200 g infant delivered at 41 weeks and one congenital abnormality (1.26 %), a case of duodenal atresia [4]. In the study of Skull et al., a low ‘neonatal complication’ rate was reported, without significant difference between the LAGB group (4 %) and the non-LAGB group (3 %) [20]. However, it was not clear whether these complications could be attributed to congenital abnormalities. In the study of Carelli et al., six sets of twins were born [22]. While two of these babies were healthy, the other babies suffered from various medical problems ranging from simple jaundice to pulmonary insufficiency and bradycardia. In the singleton newborns the most common health complication was jaundice (10 %). Three babies suffered from neurological problems (3 %), two with infectious complications (2 %) including meningitis, two (2 %) with gastrointestinal problems including necrotizing enterocolitis; and one each

with pulmonary insufficiency, multicystic kidneys, two-vessel cord, hemophilia, meconium aspiration, and oligohydramnios. Seventy-eight of the hundred singleton babies did not have health complications. Bar-Zohar et al. only reported two babies in need of phototherapy because of hyperbilirubinemia, caused by ABO incompatibility [6]. Jasaitis et al. reported three cases of intra-uterine growth-restriction, of which two cases happened in patients with chronic hypertension [23]. In all other studies no major abnormalities occurred [5, 6, 17–19].

NICU Admission

Only one study discussed the admission on neonatal intensive care unit [5]. A significant higher rate of NICU admissions was observed in babies born in the LAGB group than in the obese group and the normal weight group. A significant difference in NICU admission rate was also seen between the normal weight and obese group. There was no significant difference in the rate of NICU admission between the post-LAGB and pre-LAGB group [5].

Discussion

Today an increasing number of (morbidly) obese women of reproductive age are undergoing LAGB surgery in search of a long-term solution for their weight problem. Because of

the increased fertility after the surgery-induced weight loss, (unexpected) pregnancies are frequent in this population. Consequently, concerns arise concerning the potential impact of LAGB on future pregnancy.

The observational studies with a control group showed a lower incidence of GD, PIH, pre-eclampsia, CS, macrosomia, and low birth weight babies in post-LAGB pregnancies than in non-LAGB pregnancies in obese women. All four studies consistently saw a statistically significant lower GWG in post-LAGB pregnancies. However, the rate of spontaneous abortion and NICU admission was higher in post-LAGB pregnancies than pregnancies in non-LAGB obese women [5]. When comparing the pregnancy outcomes of a post-LAGB pregnancy to the outcomes of pregnancies in normal weight women, the GWG post-LAGB was still statistically significantly lower. However, the rate of adverse maternal and neonatal outcomes (PIH, pre-eclampsia, CS, preterm birth, LGA, spontaneous abortion, and NICU admission) was higher in this group, compared to normal weight women. In contradiction with Granström's [24] findings of intra-uterine growth-restriction in women with a gastric band, no statistically significant difference was seen in major congenital abnormalities. Nevertheless, some of the selected studies reported a few abnormalities.

Despite a possible restriction of calorie intake and, according to most studies, a significant reduction in GWG after LAGB, most studies showed no negative impact on birth weight. In fact, the study of Ducarme et al. showed a statistically significant lower rate of high and low birth weights [1]. Adjustment of the gastric band, which was performed in most studies, could possibly have had a positive effect on dietary intake and consequently on neonatal birth weight.

In all of the included studies the post-LAGB women still had a mean pre-pregnancy BMI higher than 30 kg/m². This means that weight loss after surgery was not enough to prevent all women from being obese at the beginning of pregnancy. In a few studies, in which pre-pregnancy BMI was presented as a range value, all of the women after LAGB were still obese [20] or overweight [19] at the onset of their pregnancy. In the study of Carelli et al. and Jasaitis et al., the range of pre-pregnancy BMI indicated that at least one woman reached a normal BMI (<25.0 kg/m²) [22] and in the study of Weiss et al. one woman reached a normal BMI of 24.8 kg/m². An advantage of having the same mean pre-pregnancy BMI in the post-LAGB group versus the non-LAGB group is to investigate the independent effect of LAGB on pregnancy outcomes. A possible explanation that the study of Ducarme et al. gave for the better pregnancy outcomes in obese women who become pregnant after LAGB in comparison with obese women without LAGB was the significant weight loss associated with better blood glucose levels and the alteration in the women's metabolism

which may have improved oxidative stress and lipid metabolism and decreased insulin resistance. Apparently, some weight loss after LAGB suffices to improve pregnancy outcomes and a BMI above 30 kg/m² obtained after weight loss provides better outcomes than a similar BMI without previous weight loss. The study of Lapolla et al. compared maternal and fetal outcomes in post-LAGB pregnancies between patients who were still morbidly obese and patients who were no longer morbidly obese and only saw a significant lower incidence of gestational hypertension in the no longer morbidly obese group [5].

LAGB seems generally well-tolerated during pregnancy [20]. Band-related complications are possible, but not common. With active management of the gastric band, thus with anticipating to complaints, problems can be avoided. Gastric bands should however not be deflated systematically during pregnancy because of the risk of less well controlling the GWG and related obstetrical complications [23]. The change to the pars flaccida technique has made the overall incidence of band complications, such as gastric prolapse, to decrease dramatically [19].

Important to note is the apparent lack of robust evidence. Because randomized controlled trials are not feasible for assessing pregnancy outcomes in these women, observational studies (case control and cohort studies) are the best available evidence. Furthermore, literature regarding long-term outcomes in children born to women with a gastric band or other bariatric surgery is not available. Further and larger research may introduce a more standardized protocol for data collection when women with a gastric band appear to be pregnant, expected or unexpected [17].

Our review is limited by the methodological quality of the original studies. Some studies are made in retrospect, which can compromise the quality of the given data. A limited sample size, a large heterogeneity in sample, the comparison of primigravidae to multigravidae can all act as a confounding factor in the outcome assessment. Additionally, case-control studies may provide more valuable information than mere observational studies. However, in the comparison of the outcomes of case-control studies, it has to be taken into account that these studies often used different control groups. These limitations prevent us from drawing strong conclusions. On the other hand, the strength of this review lies in presenting a clear overview of both maternal and neonatal outcomes. This systematic review was restricted to the investigation of pregnancy outcomes of one specific type of bariatric surgery (LAGB) and not comparing these outcomes with other types of bariatric surgery. The included comparison between penultimate pre-LAGB pregnancies and post-LAGB pregnancies in the same women give the opportunity to have a clear look on how a gastric band can affect a pregnancy.

Conclusion

In conclusion, LAGB seems to be relatively safe during pregnancy and can have a positive effect on possible adverse neonatal and maternal outcomes observed in obese women, even when weight loss is not enough to obtain a BMI below 30 kg/m². Therefore, LAGB seems to be a useful and applicable way for improving pregnancy outcomes in (morbidly) obese women of reproductive age. Although LAGB seems to be reasonably safe, larger-scale studies and further research is needed to better understand the extent to which LAGB can improve pregnancy outcomes. Several studies, however, have reported the occurrence of band complications. Women with a gastric band who become pregnant should therefore be closely monitored by a multidisciplinary team of surgeons, gynecologists, primary care physicians, obstetricians, and nutritionists to ensure a successful pregnancy.

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