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Obstetrical and neonatal outcomes in women following gastric bypass: a Danish national cohort study

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Conflict of interest
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Abstract

Objective. To assess obstetrical and neonatal outcomes in women following gastric bypass, compared with adipose women without surgery and with a normal weight control population. *Design.* Historical controlled cohort study. *Setting.* Denmark. *Population.* All women undergoing gastric bypass during the period 1996–2011, and subsequently giving birth. *Methods and main outcome measures.* Obstetrical and neonatal outcomes in women without gastric bypass matched on age, parity, plurality, year, and body mass index, and normal weight women. *Results.* In 415 women giving birth after gastric bypass we found significantly more women with hypertension in pregnancy; relative risk (RR) 2.5 (95% confidence interval 1.3–5.0), gestational diabetes; RR = 6.9 (3.5–13.5), and acute abdominal pain during pregnancy; RR = 4.7 (2.9–7.8) compared with normal weight controls. Compared with women with similar body mass index, they had a lower incidence of preeclampsia and emergency cesarean sections, and their children a lower incidence of asphyxia; RR = 0.4 (0.2–0.8). Their children were on average 212 g smaller than newborn of normal weight mothers, and 319 g smaller than newborn of adipose controls, and had significantly more admissions to neonatal intensive care unit compared with newborn of normal weight mothers; RR = 1.5 (1.1–2.0). *Conclusions.* Gastric bypass may reduce the risk of preeclampsia, emergency cesarean section, and perinatal asphyxia, compared with adipose women without surgery. Compared with normal weight controls women who had had a gastric bypass had a higher risk of hypertension, gestational diabetes, and acute abdominal pain during pregnancy and their children a lower birthweight and higher incidence of admittance to neonatal intensive care.

Abbreviations: BMI, body mass index, kg/m^2; ICD, International Classification of Diseases; RR, relative risk; RYGB, Roux-en-Y gastric-bypass.

Introduction

Obesity has increased epidemically all over the world during the last three decades. In Denmark, 46.8% of the population over 18 years are overweight [body mass index (BMI) ≥25] and 13.4% are obese (BMI ≥30) (1).

Many interventions have been done to prevent and treat obesity, including bariatric surgery. Surgery was primarily intended to have a restrictive function (gastric banding), but weight loss proved to be more efficient and

Key Message

Gastric bypass may reduce the risk of preeclampsia, emergency cesarean section, and perinatal asphyxia, compared with adipose women without surgery but increases the risk of acute abdominal pain, low birthweight, and admission to neonatal intensive care unit.

persistent if combined with an intended malabsorption, now defined as Roux-en-Y gastric bypass (RYGB) (2). Since 2006, the dominating weight-reducing surgery in Denmark has been RYGB, accounting in 2010 for 98.2% of all reported procedures. The annual number of RYGB surgeries increased from one in 2004–2695 in 2010 (3).

Many of these patients are women of fertile age, and the full consequences of this surgical procedure on pregnancy, birth and neonatal outcome remain to be clarified. Several studies have evaluated obstetrical outcomes (4–22). The studies are, however, limited by the number of patients enrolled, lack of comparison groups, and the length of follow-up. For some of these studies stratification according to type of surgery has not been performed despite a potential negative effect of malabsorption on pregnancy and fetus with the RYGB procedure. A recently published Danish study included 286 delivering women having undergone RYGB, but the outcomes were not compared with those in delivering women with a normal BMI (21).

We aimed to assess pregnancy morbidity, and obstetrical and neonatal outcomes in children of mothers after RYGB, and to establish two control populations of (i) adipose women without gastric bypass and (ii) normal weight women.

Material and methods

The study was designed as a controlled historical cohort study. First, we identified all women 15–49 years old who had bariatric surgery between January 1996 and June 2011. The women were identified in the National Health Registry, which by law has collected discharge diagnoses from public and private hospitals since 1977 according to the WHO International Classification of Diseases (ICD 10) and surgical codes according to a Scandinavian NOMESCO classification (23). Bariatric surgery included RYGB (surgical codes KJDF10 and 11) and gastric banding (KJDF00, 01, 20 and 21). If a woman had undergone first a gastric banding and subsequently RYGB surgery, she was categorized as a woman with RYGB from the date of this surgery. This study was thus focused only on women having had RYGB surgery.

The National Birth Registry provided information on children born to these women, and data regarding these deliveries. The National Health Registry provided information on all pregnancy outcomes; ectopic pregnancies (O.000-009), hydatidiform mole (O.010-O019 and O.020B/C), miscarriages (O.021 and O.030-O.039), induced abortion (O.040-O.059), and deliveries (O.600-O.849), with record linkage between the two registers. Ethical approval was not required according to Danish legislation as the study only involved register data. The Danish Data Protection Agency approved the study (J.no 2011-41-6818).

All women with a singleton delivery were identified and prior RYGB surgery constituted the 'exposed' cohort of women. The BMI in the Birth Register is the BMI just before pregnancy. It was not possible to obtain information on the women's BMI before surgery. Two control groups were established for this exposed cohort. Both were matched on age (born same year), parity, plurality, and year of delivery. The first control cohort was additionally matched on their exact pre-gestational BMI (adipose controls). The other had normal pre-gestational BMI (20–24). Besides these matching criteria, these controls were selected 1:2 at random from the Birth Registry. All eligible controls were given a number, and then the SAS program was randomly selected two of these eligible controls.

After matching, the exposed group, the adipose control group and the normal weight control group had a mean age of 31.2, 31.1, and 31.2 years, respectively. The percentages of primiparous were 42.5, 42.7 and 42.2% in the same groups.

The close matching on these obstetrical variables was an alternative to a logistic regression analysis with adjustment for these variables. Relevant obstetrical, puerperal and neonatal outcomes were assessed in the exposed cohort as well as in the two control cohorts, and the frequency of these complications was compared mutually between the three cohorts (Tables 1 and 2). Differences in frequency of outcomes were tested for significance by the chi-squared test with a significance level set at 5%. Relative risks were calculated with 95% confidence limits.

Definitions of certain outcomes were as follows. Hypertension in pregnancy or gestational hypertension: blood pressure higher than 140/90 diagnosed after 20 weeks of gestation. Preeclampsia: gestational hypertension with proteinuria. Abdominal pain: only included if this diagnosis was the main discharge diagnosis for a pregnant woman. Perinatal asphyxia: sign of asphyxia during delivery (judged from the cardiotocography pattern or pH in fetal scalp blood below 7.2). Asphyxia of the newborn: ICD10: P210: Asphyxia defined as pH <7.05 in the umbilical cord blood. Illness in the neonatal period: Illness during the first 28 days of life leading to hospital admission to neonatal intensive care unit.

Results

We identified 7145 women who had undergone bariatric surgery during the study period. Of these, 6563 had RYGB surgery. Of those who had undergone RYGB surgery, 404 women had accomplished 431 deliveries during the follow-up period, of which 16 were twin deliveries. Among 849 matched adipose controls, all of whom had

Table 1. Obstetrical complications in women with gastric bypass, and in two control populations, one of adipose women without gastric bypass and the other of normal weight women.

		Gastric bypass		Adipose controls		Normal weight controls	
Obstetrical condition	ICD-10	*n*	%	*n*	%	*n*	%
Deliveries (singletons)		415	100	826	100	829	100
Liveborn child		413	99.5	823	99.6	827	99.8
Stillborn child		2	0.5	3	0.4	2	0.2
Pregnancy complications							
Hypertension in pregnancy	O.100-19, 139	19	4.6**	52	6.3***	15	1.8
Edema in pregnancy	O.120	0	0.0	3	0.4	3	0.4
Proteinuria in pregnancy	O.121-22	0	0.0	6	0.7*	0	0.0
Preeclampsia mild	O.140	11	2.7	37	4.5***	10	1.6
Preeclampsia severe	O141	4	1.0	6	0.7	7	0.8
HELLP syndrome	O.142	0	0.0	2	0.2	3	0.4
Preeclampsia all types	O.140-42	16	3.9	46	5.6***	18	2.2
Hyperemesis	O.210-12	15	3.6	20	2.4	21	2.5
Venous thrombosis confirmed	From database	1	0.2	2	0.2	0	0.0
Urinary tract infection	O.230-4	23	5.5	24	2.9*	31	3.7
Diabetes before pregnancy	O.240-43	12	2.9***	12	1.5*	3	0.4
Gestational diabetes	O.244-49	38	9.2***	67	8.1***	11	1.3
Placental abruption	O.350-59	2	0.5	8	1.0	11	1.3
PPROM	O.420-29	26	6.3	60	7.3	73	8.8
Placenta previa	O.440-49	2	0.5	5	0.6	7	0.8
Perinatal asphyxia	O.680-89	52	12.5	149	18.0*	128	15.4
Ileus	K.566-67	3	0.7	1	0.1	0	0.0
Surgery for ileus or adhesions	KJFK96-97	3	0.7	0	0.0	0	0.0
Acute abdominal pain	R.10	52	12.5***	16	1.9***	22	2.7
Delivery complications							
Postpartum hemorrhage	O.720-23	29	7.0	80	9.7	85	10.3
Vacuum extraction	O.814	14	3.4*	45	5.5	55	6.6
Planned cesarean section	O.820	67	16.1***	115	13.9***	67	8.1
Emergency cesarean section	O.821	57	13.7	130	15.7**	93	11.2
Anemia in postpartum period	O.990	21	5.1	24	2.9	35	4.2
Surgical evacuation of uterus	KMBA00-03	3	0.7*	3	0.4	0	0.0
Manual removal of the placenta	KMBA10-96	6	1.5*	18	2.2	29	3.5
Suture of the perineum	KMBC00-30	1	0.2	0	0.0	2	0.2
Suture of sphincter ani	KMBC33	6	1.5	21	2.5	23	2.8
Revision of hematoma	KMBC40	1	0.2	2	0.2	2	0.2

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

The significance asterisks in the gastric bypass column are compared with normal controls.

The significance asterisks in the adipose women column are on left side compared with gastric bypass women and on the right side compared with normal controls.

delivered, 22 had twin deliveries. Among the 858 normal weight delivering control women, 29 had twin deliveries. The frequency of twin pregnancies did not differ significantly between the three cohorts. The twin deliveries were excluded for simplicity and transparency. The average BMI in the three singleton cohorts was 31.6, 31.2 and 22.0, respectively.

The RYGB cohort gave birth to 415 singletons. The corresponding numbers were 827 in the adipose control cohort and 829 in the normal weight control cohort (Table 1). We found two (0.5%), four (0.5%) and two (0.2%) stillborns in the same three cohorts (ns).

While delivery was a matching criterion, other pregnancy outcomes were assessed during the follow-up periods,which were identical in length. We found no significant differences in the frequency of first trimester miscarriages ($n = 36/51/61$), second trimester miscarriages ($n = 5/14/11$), induced abortions ($n = 25/37/47$), or ectopic pregnancies ($n = 1/8/8$).

Hypertension in pregnancy was twice and three times more frequent in the RYGB and adipose control group, respectively, compared with the normal weight control group (Table 1). The frequency of all types of preeclampsia was not significantly increased in the RYGB group

Table 2. Neonatal outcomes in children born by women after gastric bypass surgery, and among adipose controls and normal weight controls.

Neonatal data	Gastric bypass	Adipose controls	Normal weight controls
Number of children born	415	827	829
Gestational age (days)	275	278	278
Birthweight (g)	3,258	3,577	3,470
Weight difference (g)	−212***	***107***	Reference
Apgar score at 5 min	9.8	9.7	9.8
	n (%)	*n* (%)	*n* (%)
Liveborn	413	823	827
Stillborn	2	4	2
Admittance NICU	83 (20.1)**	137 (16.6)	112 (13.5)
Illness in neonatal period	137 (33.1)*	274 (33.2)**	217 (26.2)
Congenital malformations	30 (7.3)	52 (6.3)	44 (5.3)
Asphyxia in newborn	10 (2.4)	**48 (5.8)	33 (4.0)

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.
The significance asterisks in the gastric bypass column are compared with normal controls.
The significance asterisks in the adipose women column are on left side compared with gastric bypass women and on the right side compared with normal controls.

(3.9%) but was significantly higher in the adipose control group (5.6%) when compared with the normal weight control women [2.2%, RR = 1.8 (95% CI 1.1–3.0)]. A significantly higher proportion of the RYGB women and adipose control women had diabetes before pregnancy compared with the normal weight controls (Table 1). The corresponding frequencies of gestational diabetes in the three cohorts were 9.2% [RR = 6.9 (3.5–13.5)], 8.1% [RR = 6.0 (3.2–11.6)] and 1.3% (reference group), respectively.

Women with RYGB surgery had significantly more admissions with acute abdominal pain during pregnancy (12.5%) compared with the adipose controls [1.9%; RR = 6.4 (3.7–11.3)] or normal weight controls (2.7%; RR = 4.7 (2.9–7.8)]. Three RYGB women were recorded with an ileus diagnosis and two had open surgery for this complication. One woman had surgery for adhesions without an ileus diagnosis. In the adipose control group, one woman had a diagnosis of ileus but could be treated without surgery. None of the normal weight control group was recorded with ileus or abdominal surgery. Urinary tract infections were significantly more frequent in the RYGB cohort (5.5%) than in the adipose control group (2.9%; $p < 0.05$), but not different from the normal weight controls (3.7%). We found no difference between the three cohorts regarding the frequency of hyperemesis, venous thrombosis, preterm primary rupture of membranes, placenta previa, placental abruption, postpartum hemorrhage, retention of placenta, or postpartum anemia.

Planned cesarean section was more common in women after RYGB [16.1%; RR = 2.0 (1.4–2.8)] and in the adipose control women [13.9%; RR = 1.7 (1.3–2.3)] than in normal weight control women, 8.1% (Table 1). Emergency cesarean section was not more frequent in women after RYGB surgery or in the adipose group compared with normal weight women. Vacuum extraction was carried out in 3.4% of women and manual removal of the placenta 1.5% in the RYGB group and significantly less frequent than in normal weight controls, 6.6% and 3.5%, respectively.

The mean gestational age (defined by ultrasound) was very similar in the three cohorts (Table 2) but the birthweight was on average 212 g less in the RYGB cohort and 107 g higher in the adipose control group compared with the normal weight control cohort. The Apgar scores after five minutes were similar in the three cohorts, despite a lower rate of neonatal asphyxia in the RYGB cohort (2.4%) compared with adipose control women [5.8%; RR = 0.4 (0.2–0.8)]. Admittance to neonatal intensive care unit was seen in 20.1% of the babies born to RYGB mothers, a significantly higher proportion than in the normal weight cohort [RR = 1.5 (1.1–2.0)]. We found an overall significantly higher frequency of having an illness within the first 28 days of life leading to hospital admissions in both the RYGB cohort [33.1%, RR = 1.3 (1.0–1.6)] and in the adipose control cohort [33.2%, RR = 1.3 (1.1–1.5)] compared with the normal weight controls. There was no difference in congenital malformations between the three cohorts (Table 2).

Discussion

We found a significantly increased risk of hypertension in pregnancy, gestational diabetes and acute abdominal pain

among women who had undergone an RYGB procedure as compared with women with a normal BMI. Children born to women after RYGB surgery had a lower birthweight than the normal weight control group and a significantly increased risk of being admitted to neonatal intensive care unit, when compared with babies born to normal weight mothers. The higher frequency of hypertension in the two adipose cohorts as compared with the normal weight cohort was expected. Bennett et al. (14) compared women before and after bariatric surgery with regard to hypertension and found a significantly lower number of women with hypertension after surgery, suggesting that the weight loss was responsible for this effect. Josefsson et al. (17) found no difference in frequency of hypertension between adipose women with and without surgery. Santulli et al. (12) conducted a smaller study, and did not find any difference in frequency of hypertension among 24 patients pregnant after bypass surgery. In conclusion, weight loss caused by gastric bypass surgery seems to reduce the risk of hypertension during pregnancy even among women still adipose after surgery. The RYGB group did not have a significantly higher incidence of preeclampsia compared with the normal weight women, while the adipose controls had. Another study found the same lowered risk of preeclampsia after bariatric surgery compared with before surgery (14) but did not provide information on BMI, suggesting a protective effect of weight loss even with persistent obesity. Women undergoing gastric banding procedures have also been reported to have a reduced risk of preeclampsia (24,25).

Although most patients undergoing bariatric surgery are cured of their type 2 diabetes after surgery (26), this benefit does not prevent the increased risk of gestational diabetes.

It is well known that RYGB may lead to internal herniation in pregnant women as well as other women (27). The diagnosis is often delayed, and treatment is difficult. In our study, women having had RYGB had a significantly higher risk of admission for acute abdominal pain than both control groups, and three women in our RYGB group were diagnosed with ileus most likely due to internal herniation. The difficulty in diagnosing these women suggests that after RYGB, pregnant women should be followed up at centralized departments.

A significantly higher proportion of babies born to mothers after RYGB were admitted to neonatal intensive care unit compared with both control groups. This finding conflicts with the study by Kjaer et al. (21) who did not find any difference. Another French study compared the outcome of 94 newborn stratified by the mother's type of bariatric surgery and did not find any difference either (20). More studies concerning the reasons for admission to neonatal intensive care unit are needed to clarify the background for these results.

The lower birthweight in children born to RYGB mothers is in agreement with most other studies (8,12,17,21), which leads to speculation on malnourished fetuses (12). So far, no study, including the present study, found more malformations in the RYGB-exposed children. To clarify this, more larger or merged studies with several years of follow-up are needed.

The RYGB cohort had a higher incidence of planned but not of emergency cesarean section, while the adipose control group had more emergency sections compared with the normal weight controls. This is consistent with results of Santulli et al. (12). In addition, the RYGB cohort in our study had a lower incidence of vacuum extraction. The smaller babies in the RYGB group and the lower incidence of newborns who were large for gestational age compared with newborns of adipose mothers shown in the study by Patel (10) and Kjaer (21) are both factors reducing the risk of dystocia. The lower incidence of vacuum extraction and emergency cesarean sections in the RYGB cohort could be a result of this.

The main strength of this study was the inclusion of all Danish women undergoing gastric bypass and who subsequently became pregnant. To our knowledge, this is the largest study published so far looking both at early pregnancy and obstetrical outcomes. In addition we had almost a complete follow-up in the Birth Register. The register approach permitted us to establish two large closely matched control cohorts to compare the outcomes with.

One limitation of this study is that the validity of some diagnoses of obstetrical complication is not 100%. The inclusion of some non-valid diagnoses generally tends to underestimate risk differences in outcomes. Another limitation is that we had no information about smoking. Obesity and smoking have a strong association with socioeconomic status. Thus, comparing the RYGB cohort with an adipose control cohort with the same BMI might have captured some confounding influences from smoking.

Matching the women on their pre-surgical BMI would have been optimal to show the benefit of surgery. It would also have removed any bias concerning their metabolic abnormalities and any difference in socioeconomic and genetic profile that might have affected the results. Women who have gone through RYGB and gone from severe to moderate obesity could have a different risk profile than primarily moderately obese women.

It would also make the results stronger if we had had matched according to artificial reproductive technology, which in itself slightly increases the risk of obstetrical

complications (28). However, any potential confounding influence from artificial reproductive technologies is expected to be small.

The time between surgery and pregnancy has been a concern due to suspected malnutrition of the fetus in the catabolic state just after surgery. However, two studies did not find any difference in outcomes according to timing of pregnancy after surgery (4,29).

In summary, women having undergone RYGB before pregnancy have comparable outcomes compared with a BMI-matched group for hypertension and gestational diabetes. There might be a protective effect of the surgery and the following weight loss on the risk of preeclampsia, emergency cesarean section, vacuum extraction, and perinatal asphyxia as well as asphyxia in newborns, as compared with adipose women not undergoing surgery. However, these possible benefits are counterbalanced by a higher frequency of acute abdominal pain during pregnancy, lower birthweight, more newborns admitted to neonatal intensive care units, and illness in the neonatal period. Thus, dealing with pregnancy, delivery and newborns of mothers who have gone through RYGB remains a specialized and multidisciplinary challenge.

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