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Deflation versus maintained inflation of gastric band in pregnancy: a national cohort study

Short Title: Gastric band management in pregnancy

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Declarations: As specified and agreed in the UKOSS letter of understanding, the views expressed do not necessarily represent those of the UKOSS Steering Committee. This work would not have been possible without the contribution of the clinicians reporting to UKOSS who have supplied information.

Abstract

Background: With no evidence to guide management of the gastric band in pregnancy, we aim to compare outcomes according to band management.

Methods: Data were collected on all women pregnant (November 2011-October 2012) following Gastric Banding, using the UKOSS surveillance system. We compared outcomes between band management groups and with national data.

Results: Band management was variable; deflation 43.4%, inflation maintained 56.6%. The deflation group had lower risk of small for gestational age infants (no cases vs 11.3%; risk ratio 0·14, p=0·05). There was greater gestational weight gain (deflation 15·4kg, inflation 7·6kg; adjusted p=0·05), and perhaps higher risk of gestational hypertension (deflation 10·5%, inflation no cases; p=0·08) in the deflation group. Other maternal outcomes were similar between management groups but overall worse than national data.

Conclusions: Deflation is associated with better outcomes for babies but worse outcomes for mothers than maintained inflation.

Introduction

Obesity affects in excess of 20% of women of reproductive age (1) and its prevalence is expected to increase. (2) Obesity is associated with adverse pregnancy outcomes, including gestational diabetes,(3) pre-eclampsia,(3) venous thromboembolism,(4) post-partum haemorrhage,(3) maternal mortality,(5) and stillbirth.(6) Risks increase with BMI(3, 6, 7) whereas weight loss before pregnancy and limitation of weight gain during pregnancy are associated with better outcomes.(8)

Bariatric surgery is more effective (9) in achieving weight loss than non-surgical methods; Laparoscopic Adjustable Gastric Banding (LAGB) accounts for 30% of bariatric procedures.(10) LAGB involves laparoscopic placement of an inflatable band around the upper portion of the stomach, reducing nutritional intake. The degree of band inflation and nutritional intake can be adjusted with the addition or removal of fluid via a subdermal port. Pregnancy after bariatric surgery, including LAGB, has been associated with improved maternal outcomes compared with obese controls, and compared with pregnancies in the same women before bariatric surgery.(11) However, concerns exist over perinatal outcomes, with some studies reporting increased rates of small for gestational age infants and intrauterine growth restriction in pregnancies following bariatric surgery.(11) A recent study has also suggested that there may be increased rates of perinatal mortality in pregnancies following bariatric surgery. (12)

There is no guidance on how to manage the gastric band in pregnancy. One option may be to deflate the band routinely to allow sufficient nutritional intake,(11) but it might result in excessive gestational weight gain and its associated complications.(13) Another option might be to maintain band inflation to limit nutritional intake, but low gestational weight gain has been associated with intrauterine growth restriction(14) and preterm birth.(15) Whereas there have been large observational studies and systematic reviews of pregnant women with previous bariatric surgery,(11, 16, 17) few have exclusively studied gastric banding,(18-20) and no study has compared outcomes according to band management (deflation, maintained inflation).(21)

In this national cohort study the aim was to estimate the prevalence of pregnancy after LAGB in the UK, determine how the gastric band was managed, and compare maternal and perinatal outcomes according to band management.

Methods

This was a national cohort study of women with confirmed pregnancy following gastric band surgery, and booking at a maternity unit within the UKOSS (UK Obstetric

Surveillance System)(22) network between November 2011 and October 2012. A nominated clinician in each unit identified the presence of LAGB. Duplicate cases, and women pregnant after procedures other than LAGB (as identified from the data collection form), were excluded.

We collected data across the UK using the UKOSS data collection system.(22) Nominated clinicians reported demographic, clinical, and outcome data for each case anonymously after birth, using a standardized UKOSS form. We excluded cases with absent outcome data and duplicates from comparative analyses. We divided cases into a deflation (band deflated for some or all of pregnancy), and an inflation (band inflation maintained throughout pregnancy) group. Data collection was completed in March 2013.

Primary maternal outcomes included gestational weight gain (Kg), and BMI change (kg/m^2) derived from the difference between first (booking) and late third trimester measurements; gestational hypertension, and pre-eclampsia, as defined by the reporting hospital; gestational diabetes; and mode of birth (vaginal or Caesarean).

Secondary maternal outcomes included anaemia (as defined by the reporting hospital), induced labour, and thromboembolic disease.

Primary perinatal outcomes included birth weight (grams), low birth weight (defined as birth weight <2.5kg), macrosomia (defined as birth weight >4kg), gestational age at birth (completed weeks), and preterm birth (<37 completed weeks). Estimated date of delivery was based on a best estimate with either scan or last menstrual period. We did not standardise birth weight on national averages (z scores) as information on gender was not available, but adjusted all birth weight analyses for length of gestation. Additionally we calculated birthweight percentile for gestation using calculators proposed by Hadlock et al (23). Small for gestational age (SGA) was defined as birthweight <10th percentile for gestational age, whereas large for gestational age (LGA) was defined as birthweight >90th percentile for gestational age. Secondary perinatal outcomes included neonatal unit admission, low Apgar score (<7 at 5 minutes), and congenital abnormalities (as defined by the reporting unit). Other variables of interest for multivariable (adjusted) analyses included age, parity, ethnicity, BMI at booking (first trimester), employment status, and smoking (yes, no).

We consulted a maternity patient panel to define not only clinically important outcomes but also those that were deemed important to patients. Outcomes relevant to perinatal wellbeing were consistently perceived as at least as / more important than maternal health, by the members of the lay panel. This information was used to design the data collection forms, ensuring evaluation of outcomes that were both clinically relevant and important to patients.

We did not use inferential measures or statistical tests to compare descriptive data in compliance with STROBE guidelines.(24) We calculated the prevalence of LAGB in pregnancy using the UK national maternity rate(25) as the denominator. Multiple pregnancies were counted as one maternity.

We compared maternal and perinatal outcomes according to band management (deflation or maintained inflation). Women where band management was unknown were excluded from this analysis. We excluded from comparative analyses women with multiple (multi-fetal) pregnancies and cases with completely missing obstetric outcome data.

Furthermore, we compared outcomes for women with LAGB to national data to allow findings to be contextualized.

We used linear or modified Poisson multivariable regression analysis to adjust for confounding factors; including age, parity, smoking, and BMI at booking. Unadjusted exact logistic regression was used when the number of patients and cases was small. Analyses were performed with Stata 13·1.

To test the robustness of comparisons (sensitivity analysis) we re-analyzed gestational weight gain and BMI change using multiple imputations (50 sets using chained equations under a missing at random framework and the different variables presented in tables 1-3), and Rubin's combination rules.(26) We also considered two not missing at random scenarios by imputing weight gain for participants with missing information with the largest weight lost and then with the largest gain observed between the first and third trimester measurements. We considered women with missing information for outcomes other than gestational weight gain and BMI change and babies with missing perinatal outcomes alternatively as cases and non-cases.

Institutional review board approval for this study was obtained from the UK Southwest research Ethics Committee (NRES 11/SW/0227).

Results

After exclusion of two duplicate cases, 127 pregnant women met inclusion criteria. There were 703,630 UK maternities in 2012,(25) suggesting a UK prevalence rate of pregnant women with LAGB of approximately 18·0 per 100,000 maternities (95% CI 15·0 to 21·5).

Sixteen women with missing outcome data and 12 women in whom band management was unknown were excluded. A further 3 women with multiple pregnancy were also excluded leaving 96 cases for comparative analysis. Of these, 54 (56·3%) had band inflation maintained throughout pregnancy and 42 (43.8%) underwent band deflation before or during pregnancy (nine before pregnancy, sixteen in the first trimester, five in the second trimester, two in the third trimester, ten at unknown timing).

Descriptive Data *(Table 1):*

Women in the LAGB inflation and deflation groups had comparable clinical and socio-demographic characteristics: age, prevalence of nulliparity, ethnicity, median weight at booking (first trimester), and BMI at booking. There were more women unemployed, smoking at booking, with pre-existing diabetes or hypertension in the inflation group.

Comparison of outcomes according to band management

Maternal outcomes (Table 2)

There was evidence of greater weight gain in the group who had band deflation before or during pregnancy compared with those who had band inflation maintained throughout (weight gain 15·4kg, 95% CI 10·8 to 20·0, and 7·6kg, 95% CI 3·7 to 11·5, p=0·05; BMI change 5·6kg/m^2, 95% CI 4·0 to 7·1, and 2·4kg/m2, 95% CI 1·1 to 3·7, p=0·01). The strength of evidence varied between the different sensitivity analyses, i.e. by strategies to handle missing data, but the strength of larger differences persisted (Table S1).

Rates of gestational hypertension was greater in the band deflation group (10·5%) compared with the inflation group (no cases), but this difference was not statistically significant (p=0·08). Other maternal outcomes did not differ by band management group.

Perinatal outcomes (Table 3)

There was evidence of higher birth weight in the deflation compared with the inflation group by 332 grams (p=0·002). Infants in the band deflation group had a lower risk of being small for gestational age (birthweight <10th percentile for gestational age) compared to the band inflation group (deflation 0%, inflation 11.3% RR 0.14 p=0.05). There was weak evidence of an increased incidence of large for gestational age infants (birthweight >90th percentile for gestational age) in the band deflation group compared to inflation (deflation 26.2%, inflation 9.4% RR 2.49, p 0.06). There was no difference in risk of preterm birth between the two LAGB groups (deflation 9·5%, and inflation 13·2%, p=0·44). Other adverse perinatal outcomes had low levels of risk and did not differ significantly between LAGB groups. The strength of evidence varied with different scenarios in the sensitivity analyses, but the (numerically large) difference persisted. (Table S2).

Comparison of LAGB groups with national data

Maternal outcomes (Figure 1 a)

Women who underwent band deflation had a higher risk of gestational hypertension compared with national data (10·5% and 2·2%; unadjusted risk ratio 4·74, 95% CI 1·88 to 11·98, p=0·001). This difference was not seen in the band inflation group. Rates of gestational diabetes were high but not significantly different between LAGB groups (deflation 7·7%, inflation 8·0%) and national data (3.8%) (inflation vs national p=0.12, deflation vs national p=0.20).

There was higher risk of birth by Caesarean section in both LAGB groups (inflation 41.1%, deflation 48.8%) compared with national data (24·5%, both comparisons p<0·001). There was also evidence of higher risk of induction of labour for women in the banded groups (inflation 43.4%, deflation 31%) compared with national data (19·8%; p<0·001 (inflation vs national), 0.05 (deflation vs national)).

Perinatal outcomes (Figure 1 b)

There was evidence of higher risk of low birth weight in the inflation group compared with national data (13·2% and 6·5%, unadjusted p=0·04), and a higher risk of macrosomia for infants of women in the deflation group compared with national data (11·7%, p=0·01). Other measured perinatal outcomes were similar between LAGB groups and national data.

Discussion

Main findings:

Pregnancies after gastric banding appeared to be managed variably, particularly with regards to band inflation or deflation. Maintaining band inflation throughout pregnancy was associated with lower gestational weight gain and lower risk of gestational hypertension compared to deflation. When considering perinatal outcomes a different picture was seen. Maintained band inflation was associated with higher risk of small for gestational age infants. It was not possible to identify from the collected data whether this was the result of obstetric intervention (early delivery) because of concerns over maternal or fetal wellbeing. It did not appear to translate into strong evidence of increased short-term neonatal morbidity (using as markers a low Apgar score or neonatal unit admission). Preterm birth, however, including late preterm birth (34 to 36 completed weeks), has been associated with long-term morbidity, childhood hospital admissions, respiratory disease, childhood illness, behavioural and learning difficulties.(27) Therefore, it is possible that maintaining band inflation may be associated with longer-term morbidity. Band deflation, however, was associated with a higher risk of large for gestational age infants, in turn associated with short and long term morbidity (28, 29).

Strengths and limitations:

This national cohort study is the first to assess maternal and perinatal outcomes following LAGB separately from other types of bariatric surgery, and the first to compare them according to band management (deflation, maintained inflation). Data were collected in a single year and were not susceptible to changes in healthcare practice over time, unlike previous studies. This study also benefited from a sensitivity analysis to test the robustness of conclusions, and adjustment for confounding factors.

We combined all band deflations into one group for the purposes of analysis. Most deflations occurred before or in early pregnancy, making the group reasonably homogenous. Whilst we recognise that knowledge of the volume of fluid in the individual bands would have added to our study, band inflation restricts the passage of food therefore limiting nutritional intake whereas band deflation removes this restriction. Therefore it is not unreasonable to treat them as two distinct groups in terms of the impact on nutritional intake. We acknowledge that numbers in the band management comparison groups were relatively small thereby limiting the power of our study for some outcomes. However, no previous publications have assessed outcomes according to band management. This study is the first to provide any comparative data and guidance regarding band management. We also acknowledge that ideally the controls would have been BMI matched with adjusting for confounders as with the banded group. Unfortunately this data was not available. However, as the primary focus of the study was to compare band management strategies the control group in the instance served to contexualise findings rather than draw direct comparisons.

Interpretation (in the light of other evidence):

Before this study, the majority of the literature (11, 12, 30, 31) had studied all types of bariatric surgery combined, with various controls, and not always adjusting for important confounding factors. A registry-based retrospective study of women with previous bariatric surgery(17) found similar rates of adverse maternal outcomes, but increased rates of preterm birth and small for gestational age, compared with BMI-matched controls. The majority of women in that study, however, had had gastric bypass and only 57 women (16.6%) had had gastric banding surgery. There was no subgroup analysis. Another study(16) comparing perinatal outcomes in women following any bariatric surgery with BMI-matched controls, found higher rates of preterm birth (iatrogenic and spontaneous) and small for gestational age infants after bariatric surgery, with no effect modification by procedure type (gastric banding, bypass, or vertical banding gastroplasty). However, that study included data collected over 18 years and did not differentiate between band management strategies. In contrast, a recent retrospective case-control study (32) suggested no increase in small for gestational age infants in those who had undergone restrictive bariatric surgery compared to controls matched for pre-surgery BMI. However, unlike our study, LAGB was not considered separately from sleeve gastrectomy, and numbers in the LAGB group were relatively small (n=72). Moreover, band management was not taken into consideration. One systematic review (29) studied specifically maternal and perinatal outcomes following gastric banding and demonstrated improved maternal and perinatal outcomes in the banded groups compared to obese controls. They also described band management in each of the included studies, which was variable. However, none of the included studies compared outcomes according to band management.

This study moves knowledge one step forward, by helping understand the outcomes of two different band management options (deflation, maintained inflation). The results reveal a fine balance between maternal and perinatal outcomes that should be addressed by clinical judgment, taking into account patient preference. The results suggest that band deflation for at least part of pregnancy may be the safest course - achieving a balance between reducing gestational weight gain and allowing adequate nutritional intake for fetal growth. Whilst in an ideal world the next step would be to conduct a randomised control trial to define more clearly the best timing of band deflation, as pregnancies following LAGB are still relatively uncommon it is unlikely that a study sufficiently powered for important and not just statistically convenient outcomes would ever be feasible.

Conclusion

In conclusion, this is the first study using an established national surveillance system to compare maternal and perinatal outcomes by gastric band management in pregnancy within a distinct and narrow time period, with adjustment for important confounding factors. The findings suggest that it is important to find a balance between deflation and inflation, taking patient preference and experience into account. Perhaps the gastric band should be deflated in the first half of pregnancy but re-inflated afterwards, with careful monitoring of both maternal and fetal condition thereafter. However, this strategy would have to be tried in practice, or within the context of a large and prolonged international trial.

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Disclosure of Interests

The Authors declare that there is no conflict of interest.

Contribution to Authorship

Amanda Jefferys obtained ethics approval, assisted in the analysis and wrote the manuscript.

Erik Lenguerrand conducted the analysis and co-wrote the manuscript.

Katie Cornthwaite co-wrote the manuscript.

Andrew Johnson conceived the idea, arranged funding, and edited the manuscript.

Judith Hyde conceived the idea, co-prepared the protocol, and edited the manuscript.

Mary Lynch edited the manuscript.

Tim Draycott conceived the idea and edited the manuscript.

Dimitrios Siassakos obtained ethics approval, supervised the analysis, co-wrote and edited the manuscript, and is data guarantor.

All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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