Afbeelding met tekening

Automatisch gegenereerde beschrijving

Data Collection Form

for the study of

SURGICAL COMPLICATIONS OF BARIATRIC SURGERY IN PREGNANCY IN BELGIUM

Hash code

BACKGROUND INFORMATION

The obesity epidemic is a growing concern for our global health. 45% of Belgian inhabitants is either overweight or obese (1). As the prevalence increases, so does the prevalence of associated health consequences. In terms of reproductive health, obese women are at risk for impaired fertility. If lifestyle adaptations and pharmacotherapy have failed, bariatric surgery (BS) can be considered as a treatment. Good candidates for bariatric surgery (BS) have a BMI ≥ 40 kg/m2 or BMI ≥ 35-40 kg/m2 with at least one comorbidity that can be improved by weight loss (2, 3). The incidence of BS procedures is currently > 10000/y in Belgium (1, 4). Most of the patients are women, of whom 50% is of reproductive age. This results in an increased pregnancy rate after BS.

Pregnancy after BS does not go without any concern. Surgical complications of BS are claimed to happen more often during gestation. Beside invaginations, intussusceptions and gastric band related problems, the most frequent and important complication is an internal herniation (IH) of the small bowel loops. Patients with a history of Roux-en-Y Gastric Bypass (RYGB) are prone to develop an IH because of the anatomical changes made during surgery. During pregnancy, the risk is further increased and estimated at 3%-10% after RYGB (5-8). It occurs typically during second and third trimester, when the uterus has reached a considerable size to uplift the bowels, resulting in an increase of intra-abdominal pressure. An IH is a medical urgency that is potentially life-threating for mother and infant. Outcomes are highly dependent from early recognition and time-to-intervention (8).

This study is set up to monitor maternal morbidity caused by BS. Our aim is to investigate the epidemiology and risk factors, in order to create more awareness about the complications of BS during pregnancy.

1. *KCE. Bariatric surgery: an HTA report on the efficacy, safety and cost-effectiveness. 2019.* [*https://kce.fgov.be/sites/default/files/atoms/files/KCE\_316\_Bariatric\_surgery\_Report.pdf*](https://kce.fgov.be/sites/default/files/atoms/files/KCE_316_Bariatric_surgery_Report.pdf)*.*
2. *Heymsfield SB, Wadden TA. Mechanisms, Pathophysiology, and Management of Obesity. The New England journal of medicine. 2017;376(15):1492.*
3. *Busetto L, Dicker D, Azran C, Batterham RL, Farpour-Lambert N, Fried M, et al. Practical Recommendations of the Obesity Management Task Force of the European Association for the Study of Obesity for the Post-Bariatric Surgery Medical Management. Obesity facts. 2017;10(6):597-632.*
4. *IFSO. Third IFSO global registry report. 2017 [Available from: https://www.ifso.com/pdf/final-3rd-ifso- report-21st-august-2017.pdf. ]*
5. Stenberg E, Chen R, Hildén K, Fall K. Pregnancy As a Risk Factor for Small Bowel Obstruction After Laparoscopic Gastric Bypass Surgery. Annals of Surgery. 2020;272(1):125-9.
6. Petersen L, Lauenborg J, Svare J, Nilas L. The Impact of Upper Abdominal Pain During Pregnancy Following a Gastric Bypass. Obesity surgery. 2017;27(3):688-93.
7. *Devlieger R, Jans G, Matthys C. Outcomes of pregnancy after bariatric surgery. The New England journal of medicine. 2015;372(23):2266.*
8. *Vannevel V, Jans G, Bialecka M, Lannoo M, Devlieger R, Van Mieghem T. Internal Herniation in Pregnancy After Gastric Bypass: A Systematic Review. Obstetrics and gynecology. 2016;127(6):1013-20.*

CASE DEFINITION

Every pregnant woman identified with bariatric surgery prior to conception presenting with a surgical complication diagnosed as

* Bowel obstruction
  + Internal herniation
  + Intussusception
  + Volvulus
* Anastomotic stricture
* Anastomotic or gastric ulcer
* Ventral incisional hernia
* Gastric band erosion
* Gastric band slippage

### Tables

### Table 1: Bariatric procedures

|  |  |
| --- | --- |
| Roux-en-Y Gastric Bypass (RYGB) | Procedure in which the stomach is split in a small pouch and a bypassed part. The jejunum is cut in two, of which the distal end (Roux limb) is anastomosed to the pouch (gastrojejunal). A jejunojejunal anastomosis is made between the proximal end and the jejunum distal from the Roux limb. Food bypasses 95% of the stomach, the duodenum and part of the jejunum, which limits absorption. |
| Mini gastric bypass (MGB) | = single anastomosis Gastric Bypass. Comparable to a RYGB, but without splitting the jejunum. The pouch is anastomosed to a loop of jejunum as an antecolic and antegastric loop gastrojejunostomy. |
| Gastric Sleeve Gastrectomy | Removal of approximately 70% of the stomach. The greater curvature of the stomach is taken down from the antrum to the Angle of His. The remaining section is formed into a tube-like structure with maintenance of the pylorus. |
| Biliopancreatic diversion (BPD) + duodenal switch (DS) | = Sleeve procedure + gastroileostomy. Part of the stomach is resected as in a sleeve procedure and an alimentary tract is created of the most distal 200cm of the ileum. The ileum is anastomosed to the stomach (right after the pylorus). The biliopancreatic limb is anastomosed to the alimentary tract 100cm proximal to the ileocecal valve. |
| Scopinaro technique (BPD) | Comparable to a BPD + DS, but with a partial distal gastrectomy (resection of the pylorus) instead of a sleeve resection. The common channel is only 50cm. This procedure is no longer carried out today. |
| Laparoscopic adjustable banding | The placement of an inflatable silicone band around the upper part of the stomach. A gastric pouch is created which restricts the amount of food that can be received. |

*KCE Report 316: Bariatric surgery: an HTA report on the efficacy, safety and cost-effectiveness.*

### Table 2: surgical complications

|  |  |
| --- | --- |
| Internal herniation | Protrusion of abdominal viscera, most often small bowel loops, through a defect (congenital or acquired) of the peritoneum or mesentery into a compartment of the abdominal cavity. |
| Intussusception | Invagination of a proximal segment of the intestine into the lumen of the distal segment in a telescope-like fashion. |
| Volvulus | Mesoaxial twisting or torsion of a segment of the gastrointestinal tract. |
| Anastomotic stricture | Anastomotic stenosis. |
| Anastomotic or gastric ulcer | An open sore on the lining of the digestive tract. |
| Ventral incisional hernia | Hernia due to loss of mechanical integrity of the abdominal wall muscles and tendons, caused by an incompletely healed surgical wound. |
| Gastric band erosion | Gastric wall injury caused by migration of the band into the gastric lumen. |
| Gastric band slippage | Prolapse of part of the stomach trough the band, with varying degrees of gastric obstruction. |

*Monkhouse SJW, Morgan JDT, Norton SA. Complications of bariatric surgery: Presentation and emergency management - A review. Ann R Coll Surg Engl. 2009;91:280–6. doi: 10.1308/003588409X392072*

### Section 1: Woman’s details

* 1. Year of birth:      (YYYY)
  2. Country of birth:
  3. Current nationality (max. 2):

Belgian (Belge ou titre de séjour de minimum 5 ans / Belg of verblijfsvergunning voor minimum 5 jaar)

Other:

* + Please specify
  + Please specify (double nationality):

Not known

* 1. What is the highest degree of the patient?

No formal schooling  
 Primary school *(lagere school, école primaire)*  
 Lower secondary school *(1e-3e middelbaar, collège)*   
 Higher secondary school *(4e-6e middelbaar, lycée)*  
 College *(hogeschool, grande école)*   
 University school *(Universiteit, Université)*  
 PhD  
 Not known

* 1. Marital status:

Single

Married or cohabiting

Not known

* 1. Did the patient or her partner had a steady income during pregnancy (excl. social security)?

Yes

No

Not known

* 1. What was the gestational age at first prenatal visit?   w  d
  2. What was the maternal pregestational weight (kg):
  3. What was the maternal weight at first prenatal visit (kg):
  4. What was the maternal height (cm):
  5. Did the woman smoke during pregnancy? (answer yes, even if she stopped during pregnancy)

Yes

No

Not known

### Section 2: Previous Obstetric History

* 1. Gravidity (Number of pregnancies including current one): G =
  2. Number of completed (both life- and stillbirths) pregnancies ≥ 22 weeks:
* How many of these pregnancies were completed before bariatric surgery took place?
  1. Did the woman experience pregnancy problems in previous pregnancies? (≥ 1 possible)

Yes

Partus immaturus (16-24 weeks)

Partus prematurus (24-37 weeks)

Miscarriage (< 22 weeks)

* + Please specify how many:

Stillbirth (≥ 22 weeks)

Neonatal death

Gestational diabetes

Preeclampsia

PPROM

Placenta praevia

Placental abruption

Postpartum haemorrhage

Hyperemesis requiring admission

Severe infection e.g. pyelonephritis

* Please specify:

Surgical procedure in pregnancy

* + Please specify:

Complication of bariatric surgery

* + Please specify:

Other

* + Please specify:

No

Not known

### Section 3. Previous medical history

* 1. Date of bariatric surgery:   /  /   (DD/MM/YYYY)
  2. In which country was the bariatric surgery performed?

Belgium

Abroad

* Please specify

Not known

* 1. Patient’s weight was known prior to surgery:

Yes

* Please specify       kg

No

* 1. What type of procedure was performed? (≥ 1 possible)

Roux-en-Y gastric bypass

Mini gastric bypass

Gastric Sleeve gastrectomy

Biliopancreatic diversion (BPD) + duodenal switch (DS)

Scopinaro technique (BPD)

Laparoscopic adjustable banding

Not known

* 1. Did the woman undergo a reintervention in the first 3 months following bariatric surgery?

Yes

What was the reason for reintervention?

What were the performed acts during reintervention?

No

Not known

* 1. Did the woman undergo other abdominal surgical procedures?

Yes

Please specify which ones:

No

Not known

* 1. Did the woman have other pre-existing medical problems? (≥ 1 possible)

Yes

Cardiac disease

Please specify:

Diabetes mellitus

Please specify:

Thyroid disorders

Please specify:

Respiratory disease

Please specify:

Renal disease

Please specify:

Essential hypertension

Inflammatory bowel disease

Please specify *(e.g. Crohn, Colitis Ulcerosa)*:

Hematological disorders

Please specify:

Myeloproliferative disorders

Please specify:

Systemic lupus erythematosus

I.V. drug use

HIV

Neoplasia

Please specify:

Psychiatric disorder

Please specify:

Other

Please specify:

No

Not known

### Section 4: This pregnancy

### Section 4.1: General

* + 1. Estimated Date of Delivery\* (EDD):   /  /   (DD/MM/YYYY)

\*(due date / verwachte verlosdatum / date prevue d’accouchement)

* + 1. Number of fetuses in current pregnancy:
    2. Conceiving method:

Spontaneous

Ovulation induction and/or intrauterine insemination

IVF/ICSI

Not known

* + 1. Were there any pregnancy problems so far? (≥ 1 possible)

Yes

Please specify:

For example: gestational diabetes, hyperemesis/dehydration requiring admission, (pre)eclampsia, severe infection e.g. pyelonephritis, antepartum haemorrhage, placenta praevia, placental abruption, premature rupture of membranes, preterm labour, etc.

No

Not known

### Section 4.2: Surgical complications

* + 1. Which of following complications occurred during pregnancy? (≥ 1 possible)

Bowel obstruction

Internal herniation

Intussusception

Volvulus

Anastomotic stricture

Anastomotic or gastric ulcer

Ventral incisional hernia

Gastric band erosion

Gastric band slippage

Other

* Please specify
  + 1. Date and time of hospital admission:   /  /         am/pm
    2. Approximate time interval between symptom onset and admission:      hours
    3. Did the patient already consult a health worker in the context of these symptoms before admission?

Yes

Gynecologist

Family doctor

Emergency doctor

Midwife

Other

No

Not known

* + 1. Present symptoms at admission (≥ 1 possible):

General

Nausea

Vomiting

Anorexia

Fever

Abdominal pain

Abdominal cramps

Obstipation of new onset

Diarrhea

Black stools (melaena)

Red blood per anum

Haematemesis

Haemodynamic shock

Other

* Please specify

Obstetric

Rupture of membranes

Uterine contractions

Vaginal bleeding

Reduced fetal movements

* + 1. Complete following table OR **upload** the lab results (on https://forms.b-oss.be/data\_form/bariatrics\_data\_form) from the blood sample taken at admission.

|  |  |
| --- | --- |
|  | **Value at admission** |
| CRP (mg/L) |  |
| White blood cell count (10E3/µL) |  |
| Hemoglobin (g/dL) |  |
| Lactate (mmol/L) |  |
| LDH (U/L) |  |
| CK (U/L) |  |

* + 1. What imaging techniques were performed during admission (incl. pregnancy ultrasound)? What were the findings?

|  |  |  |
| --- | --- | --- |
| **Investigation** | **Date** | **Findings** |
|  | /  / |  |
|  | /  / |  |
|  | /  / |  |
|  | /  / |  |

* + 1. How was the surgical complication treated? (≥ 1 possible)

Fasting (*nil per os*)

Nasogastric tube

IV Fluids

Total parenteral nutrition (TPN)

Pain killers

Antibiotics

If known, which Antibiotic was used?

Intervention

Laparoscopy

* + - Date and time of the intervention:   /  /         am/pm
    - Please copy paste the operation report. If not available, resume per-operative findings and actions:

Laparotomy

* + - Date and time of the intervention:   /  /         am/pm
    - Please copy paste the operation report. If not available, resume per-operative findings and actions:

Endoscopy

* + - Date and time of the intervention:   /  /         am/pm
    - Please copy paste the operation report. If not available, resume per-operative findings and actions:

Other

* Please specify:

### Section 5: Delivery

* + - 1. Is the patient still pregnant?

Yes

* Will she be receiving the rest of her antenatal care from your hospital?

Yes

No

Please name the hospital that will provide future care:

* Please go to section 6.2 and fulfill the data of section 5 and 6.1 once patient has delivered.

No

* What was the pregnancy outcome?

Delivery

Miscarriage (<22 weeks)

Please specify date:   /  /   (DD/MM/YYYY)

What was the cause of miscarriage?

Move on to section 6.2

Ectopic pregnancy

How was this treated?

Move on to section 6.2

Termination of pregnancy

Please specify date:   /  /   (DD/MM/YYYY)

Reason for termination:

Move on to section 6.2

* + - 1. What was the planned mode of delivery?

Vaginal

Caesarean section

* Indication:
  + - 1. Was delivery induced?

Yes

* Please specify the reason for induction:

No

* + - 1. Did the woman labour?

Yes

No

* + - 1. What type of fetal monitoring was performed?

CTG

STAN monitoring

None

* + - 1. Were CTG abnormalities/STAN events recorded?

Yes

* Please describe:

No

Not applicable

* + - 1. Mode of delivery 1st neonate:

Spontaneous cephalic

Breech

Instrumental vaginal delivery

Elective caesarean section

* + Please specify the reason for caesarian section

Maternal

Please specify:

Fetal

Please specify:

Urgent caesarean section

* + Please specify the reason for caesarian section

Maternal

Please specify:

Fetal

Please specify:

* + Grade of urgency

Afbeelding met schermafbeelding

Automatisch gegenereerde beschrijvingCategory I

Category II

Category III

Category IV

* + - 1. Type of analgesia

General

Loco-regional (e.g. epidural)

None

Not known

### Section 6: Outcomes

### Section 6.1: Infant outcomes

*Please complete one section for each infant. See appendix 1.*

* + 1. Date and time of birth:   /  /         am/pm
    2. Birth weight:       grams
    3. Percentile:       %
    4. Was the infant stillborn (≥ 22 weeks)?

Yes

* Date of diagnosis:   /  /   (DD/MM/YYYY)
* Primary cause of death as stated on the death certificate:
* Findings of the autopsy if performed:
* Move on to section 6.2

No

* + 1. 5 min Apgar score:
    2. Complete the umbilical cord blood gas analysis if known:

|  |  |  |
| --- | --- | --- |
|  | **Umbilical Artery** | **Umbilical Vene** |
| *pH* |  |  |
| *Base deficit (mmol/L)* |  |  |

* + 1. Was the infant admitted to a neonatal ward (NICU or N\*)?

Yes

* Indication for admission:
* Amount of days:       days

*tick if the infant is still in NICU/N\*:*

Not known

* + 1. Did any major neonatal complication occur?

Yes

Respiratory distress syndrome

Necrotising enterocolitis

Intraventricular haemorrhage

Severe infection (e.g. septicaemia, meningitis)

* Please specify:

Neonatal encephalopathy

Other

* Please specify:

No

Not known

* + 1. Did the infant die?

Yes

Primary cause of death as stated on the death certificate:

Findings of the autopsy if performed:

No

### Section 6.2: Maternal outcomes

* + - 1. Duration of stay in the hospital:       days
      2. Was the woman admitted to an Intensive Care Unit?

Yes

Specify date of admission:   /  /   (DD/MM/YYYY)

Duration of stay:       days

*tick if the woman is still in ICU:*

Reason for admission:

No

Not known

* + - 1. Did any major complication occur? (≥ 1 possible)

Yes

Bowel ischaemia

Peritonitis

Septicaemia

Adult respiratory distress syndrome (ARDS)

Pneumonia/pneumonitis

Pulmonary Embolism

Cardiac arrest

Acute renal failure

Acute liver failure

Disseminated intravascular coagulopathy

Postpartum haemorrhage

Other haemorrhages

Please specify:

Cerebrovascular accident

Other

Please specify:

No

Not known

* + - 1. Did the mother die?

Yes

* Date and time of death:   /  /         am/pm
* Primary cause of death as stated on the death certificate:
* Findings of the autopsy if performed:

No

### Section 7: additional information

Today’s date:   /  /

### Please use this space to enter any other information you feel may be important:

### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Finished

### Appendix 1: lists:

List 1: Previous pregnancy problems

1. Partus immaturus (16-24 weeks)
2. Partus prematurus (24-37 weeks)
3. Stillbirth (≥ 22 weeks)
4. Neonatal death
5. Gestational diabetes
6. Preeclampsia (hypertension + proteinuria)
7. PPROM
8. Placenta praevia
9. Placental abruption
10. Postpartum haemorrhage
11. Hyperemesis requiring admission
12. Severe infection e.g. pyelonephritis
13. Surgical procedure in pregnancy (please specify)
14. Complication of bariatric surgery (please specify)
15. Other, please specify

List 2: Previous or pre-existing maternal medical problems, including

1. Cardiac disease (please specify)
2. Diabetes mellitus (please specify type)
3. Thyroid disorders (please specify)
4. Respiratory disease (please specify)
5. Renal disease (please specify)
6. Essential hypertension
7. Inflammatory bowel disease (Crohn, Colitis Ulcerosa)
8. Hematological disorders (please specify)
9. Myeloproliferative disorders (please specify)
10. Systemic lupus erythematosus
11. I.V. drug use
12. HIV
13. Neoplasia (please specify)
14. Psychiatric disorder (please specify)
15. Other (please specify)

List 3: current pregnancy problems

1. Gestational diabetes
2. Hyperemesis/dehydration requiring admission
3. Preeclampsia
4. Severe infection (please specify)
5. Antepartum haemorrhage
6. Placenta praevia
7. Placental abruption
8. Premature rupture of membranes
9. Preterm labour
10. Other, please specify

List 4: Major maternal medical complications

1. Bowel ischaemia
2. Peritonitis
3. Septicaemia
4. Adult respiratory distress syndrome (ARDS)
5. Pneumonia/pneumonitis
6. Pulmonary embolism
7. Cardiac arrest
8. Acute renal failure
9. Acute liver failure
10. Disseminated intravascular coagulopathy
11. Postpartum haemorrhage
12. Other haemorrhage (please specify)
13. Cerebrovascular accident
14. Other (please specify)

### Appendix 2

### Section 6.1: Infant outcomes

*Please complete one section for each infant.*

* + 1. Date and time of birth:   /  /         am/pm
    2. Birth weight:       grams
    3. Percentile:       %
    4. Was the infant stillborn (≥ 22 weeks)?

Yes

* Date of diagnosis:   /  /   (DD/MM/YYYY)
* Primary cause of death as stated on the death certificate:
* Findings of the autopsy if performed:
* Move on to section 6.2

No

* + 1. 5 min Apgar score:
    2. Complete the umbilical cord blood gas analysis if known:

|  |  |  |
| --- | --- | --- |
|  | **Umbilical Artery** | **Umbilical Vene** |
| *pH* |  |  |
| *Base deficit (mmol/L)* |  |  |

* + 1. Was the infant admitted to a neonatal ward (NICU or N\*)?

Yes

* Indication for admission:
* Amount of days:       days

*tick if the infant is still in NICU/N\*:*

Not known

* + 1. Did any major neonatal complication occur?

Yes

Respiratory distress syndrome

Necrotising enterocolitis

Intraventricular haemorrhage

Severe infection (e.g. septicaemia, meningitis)

* Please specify:

Neonatal encephalopathy

Other

* Please specify:

No

Not known

* + 1. Did the infant die?

Yes

Primary cause of death as stated on the death certificate:

Findings of the autopsy if performed:

No