Effect of closure of the mesenteric defect during laparoscopic gastric bypass and prevention of internal hernia

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ABSTRACT

INTRODUCTION: The aim of this study is to evaluate the benefits and disadvantages of closing the mesenteric defects during gastric bypass to avoid internal herniation.

METHODS: The study is performed as a single-centre, randomised, controlled, blinded trial. Patients are randomly assigned to either conventional laparoscopic Roux-en-Y gastric bypass (LRYGB) without closing the mesenteric defects (n = 250) or RYGB with closing of the defects with hernia clips (n = 250). Follow-up is conducted at six months, one year, two years and five years after RYGB. The primary endpoint is the incidence of internal herniation (IH).

CONCLUSION: This study will be the first Danish, randomised, controlled study comparing conventional LRYGB with and without closure of the mesenteric defects. The results will contribute to evidence-based recommendations for the prevention of IH.

FUNDING: not relevant.

TRIAL REGISTRATION: The study was registered with the Danish Data Protection Agency (SN-10-2012) and The Central Denmark Regional Committees on Biomedical Research Ethics (1-01-83-0209-12, SJ-284). The study is registered with clinicaltrials.gov: NCT01595230.

Severe obesity is increasing in Denmark as probably 33% of the population has a body mass index (BMI) over 30 kg/m^2 and 13% a BMI over 40 kg/m^2 [1]. Laparoscopic Roux-en-Y gastric bypass (LRYGB) has been documented to have long-term beneficial effects on morbid obesity and co-morbidities [2-4]. Apart from inducing a long-lasting weight loss of over 30% [5], LRYGB is associated with a reduction of morbidities such as hypertension, type 2 diabetes, sleep apnoea, certain cancers, polycystic ovary syndrome, and with an improved quality of life and an overall reduction in mortality of about 30% [2-4, 6, 7].

Since 2005, more than 13,500 gastric bypass operations have been performed in Denmark [8].

Complications

Complications after LRYGB can be classified as early (first 30 days after LRYGB) and delayed (more than 30 days after LRYGB).

Early complications include anastomotic leaks, bleeding, stenosis with possible "blow-out" of the bypassed stomach (gastric rupture), infection, pneumonia and acute venous thromboembolism.

Late complications include stomal ulceration, stenosis, stricture of the gastrojejunal anastomosis, intestinal obstruction due to internal hernia (IH) and intermittent internal herniation (IIH), adhesions and intussusception [9, 10].

IH is a major cause of late complications [11]. The incidence of IH after LRYGB ranges from 0.5 to 11% and seems to increase with longer observation time [10-12]. To date, there are no official recommendations in Denmark concerning primary closure of the mesenteric defects or the preferred method of closure. IH occurs as a result of the changed anatomy after gastric bypass where the alimentary limb is brought up to the gastric pouch, thereby creating a mesenteric defect called Petersen's space between the mesentery of the alimentary limb and the mesocolon through which the small intestine may become interposed. Another mesenteric space is created between the biliary limb and the common limb at the entero-enteroanastomosis (EEA) (**Figure 1**) [9, 10, 12].

IH may cause episodes of postprandial abdominal pain. In cases of intestinal and mesenteric torsion, persistent abdominal pain can develop [9].

Computed tomography (CT) with intravenous and enteral contrast is sometimes helpful in diagnosing IH, but can be inconclusive or falsely negative [9]. Typical signs of IH in CT are mesenteric swirl and dilated small bowel loops [13]. However, laparoscopy may finally verify the diagnosis [9].

Some studies recommend closure of the mesenteric defects at the time of the primary LRYGB procedure [9], but there is no consensus regarding the preferred closure method [14, 15].

Aghajani et al included 1,630 patients in a study in which the mesenteric defects were closed with hernia clips. Results from a 12-month follow-up showed that the IH rate had dropped from 5% to 0.6% [11]. However, no long-term results have been reported.

PROTOCOL ARTICLE

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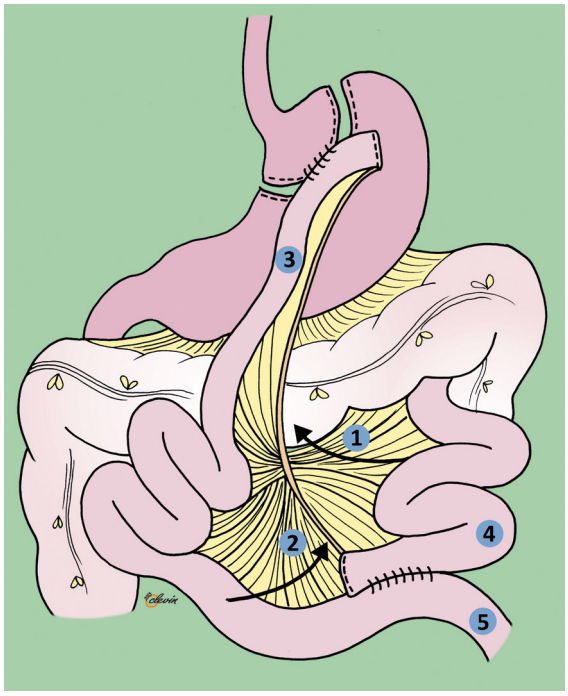
FIGURE 1

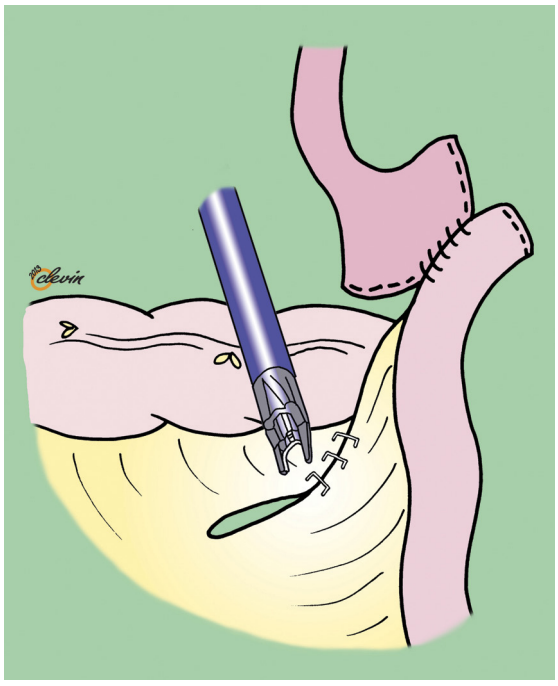
Gastric bypass anatomy.



1) Petersen's space; 2) the mesojejunal space; 3) alimentary limb; 4) biliary limb; 5) common limb.

FIGURE 2

Closure of Petersen's space.



Closure of mesenteric defects during the LRYGB procedure has been criticised for prolonging the procedure and thereby increasing the operative risks [14, 16]; moreover, risks associated with closing the defect may be underreported. Closure of the internal hernia may create kinking near the EEA which will lead to dilatation of the alimentary limb or the biliopancreatic limb with the subsequent increased risk of "blowout" of the bypassed stomach (gastric rupture) [2, 11].

To date, no randomised, controlled trials have been published concerning immediate closure of the mesenteric spaces during the gastric bypass procedure, but an ongoing Swedish study (clinical.trials.gov NCT01137201) compares closure of the mesenteric defects with running, non-absorbable suture with no closure.

METHODS

Study design

The study is a single-centre, randomised, controlled, blinded trial with a five-year follow-up.

Patients are allocated to one of two interventions, either conventional LRYGB without closure of the mesenteric defects (n = 250) or LRYGB with hernia-clip closure of the defects (n = 250).

Participants

All patients from Region Zealand, Denmark, who are eligible for LRYGB according to Danish indication criteria [17] are invited to participate in the study after written and oral information.

Inclusion criteria:

– Current Danish criteria for LRYGB according to reference [17].

Exclusion criteria:

– Open surgery
– Patients in whom a laparoscopic gastric bypass cannot be accomplished.

Surgical procedure

LRYGB is carried out as a standardised procedure with the creation of a small 15–30 ml proximal gastric pouch. The jejunum is transsected 60-80 cm distally to the ligament of Treiz. The transsected distal alimentary limb is anastomosed to the gastric pouch via an antecolic route with a linear stapler technique. The biliopancreatic limb is then anastomosed to the alimentary limb 120–150 cm below the gastrojejunostomy to create a common channel [9, 13].

Mesenteric defect closure is done according to the technique described by Aghajani et al [11] using an Endo

Universal 65 or Universal Hernia stapler 12 mm-4.8 mm (Auto Suture) (**Figure 2** and **Figure 3**)

Anaesthesia

All patients will receive standard anaesthesia based on a propofol-ultiva anaesthesia. The perioperative antibiotics used intravenously are cefuroxime (Zinacef) 1.5 g and metronidazole 1 g.

Data collection

Patients are followed for five years after surgery (**Figure 4**) and will be seen in the outpatient clinic after six months, one year and two years. A telephone interview is planned after five years.

The Department of Surgery, Koege Hospital, serves as the regional centre for surgical treatment of severe obesity for Region Zealand, which allows follow-up to be virtually complete. The patients enrolled in the study will be asked for permission to collect data from their electronic journals. The data collection will run five years from the time of enrolment. Each patient enrolled will have cross-registration of their national electronic journal (e-journal) at six months, one year, two years and five years after the RYGB to ensure a complete follow-up. All data are entered into an SPSS database for further analyses.

Patients will be included from 1 July 2012 through 1 January 2015; follow-up is planned to conclude by 1 January 2021.

Outcome parameters

Primary endpoint

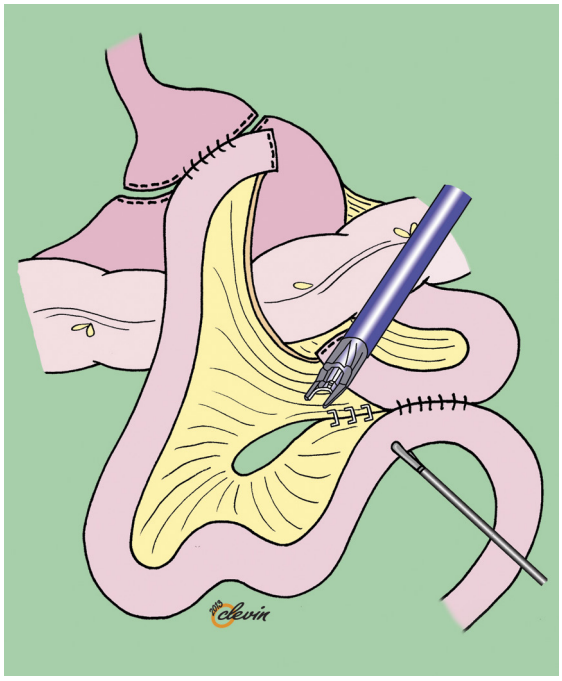
– Incidence of IH and IIH at six months, one year, two years and five years after RYGB.

Secondary endpoints

– Operative time consumption, number of clips, trocar and sutures used
– Post-operative pain score (VAS), at three, six, 12 and 24 months after the LRYGB [18].

FIGURE 3

Closure of mesojejunal space.



Tertiary endpoints

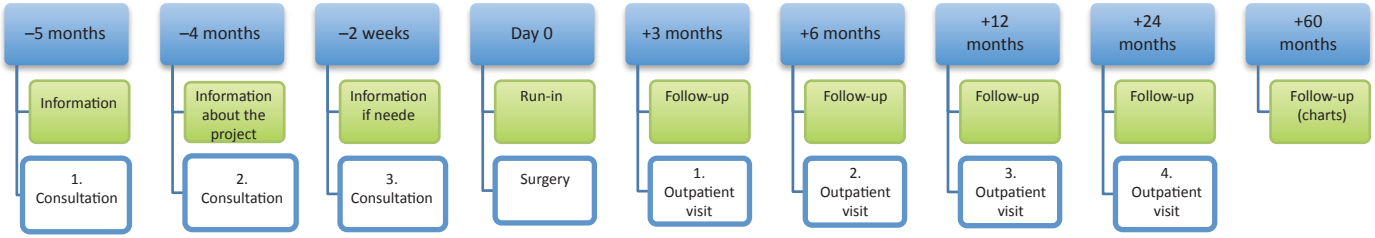
30-day complications:

– Anastomotic leak
– Bleeding (haemoglobin (Hb), mmol/l), blood transfusions.
– Ileus due to kinking, blowout of the bypassed stomach
– Intraperitoneal abscesses.

IH and IIH will be the only late complication considered in this study.

FIGURE 4

Patient & project flow chart.



Blue: time. Green: study intervention. White: preoperative and post-operative care for patients.

Definitions and investigations

Primary endpoint

Patients with symptoms of IH such as intermittent abdominal pain or acute abdominal pain associated with nausea, vomiting and ileus typical of a small bowel obstruction [9, 12]. Patients will undergo a CT or go directly to a diagnostic laparoscopy. If the CT shows IH [9, 13], surgery will be done by a bariatric surgeon or another surgeon trained in operative treatment of IH.

Operative findings and procedures are registered. It will be possible to report three different situations:

1) Internal herniation (IH), defined as herniation of the small bowel through one or both of the mesenteric defects, shown by CT scan and/or laparoscopy and requiring reduction of the herniation and closure of the mesenteric defects.
2) Intermittent internal herniation (IIH), defined as postprandial pain and signs of internal herniation on a CT. At laparoscopy the herniation may not be present, suggesting spontaneous reduction. If the postprandial pain disappears after closure of the mesenteric defects, the diagnosis is considered to have been confirmed.
3) Open spaces are not considered to be conclusive of internal herniation in itself.

Secondary endpoints

– Reporting of the number of clips used to close the defects as well as any additional use of trocars or sutures.
– Reporting of the operation time, i.e. the time used from the first knife cut to the last suture in the skin.
– Pain: At the first meeting with the surgeon before the operation, which is the second overall consultation (Figure 4), the patient will be asked to assess any abdominal pain using a visual analogue scale (VAS) [18]. VAS will be used again on the day of surgery - one hour before the operation is initiated. Control VAS will subsequently be used three months, six months and one year after the operation (Figure 4). VAS will also be used if the patient is admitted to hospital due to any abdominal complication.

Tertiary endpoints (complications after 30 days)

– Anastomotic leak: Symptoms of a leak may occur early – within the first 48 hours – and can be pain, tachypnoea or tachycardia greater than 120 per minute. These symptoms will result in a diagnostic laparoscopy. Late leaks can present as intra-abdominal abscess. CT and gastroscopy will be done [9, 11, 12].
– Bleeding: It is standard to measure the Hb (mmol/l) up to three weeks before the LRYGB operation and the day after the operation. Intraoperative bleeding and post-operative reduction in Hb will be measured and reported. Perioperative and post-operative blood transfusions will be registered. During the anaesthesia, the patient will get one litre of sodium chloride. If the patient is prescribed more fluid, this will be reported.
– Kinking of the alimentary limb near the EEA: Symptoms of kinking may be pain, related to eating and drinking, nausea and vomiting. Some patients may develop symptoms of small-bowel obstruction. The diagnosis can be achieved by CT upper gastrointestinal X-ray series with a water-soluble contrast, or diagnostic laparoscopy [9].
– Blowout of the bypassed stomach (gastric rupture): Typical symptoms are nausea with epigastric pain radiating to scapula and tachycardia. A CT will demonstrate a dilated stomach with air and fluids [9].
– Intraperitoneal abscesses: Can develop up to 30 days after the LRYGB. Symptoms are abdominal pain, fever, tachycardia and nausea. The diagnosis will be verified by CT or ultrasound [9, 13].

Sample size estimation

When calculating the sample size (stat.ubc.ca/~rollin/stats/ssize/) we assumed that the overall risk of IH and IHH in our control group would be about 6% and that it will be reduced to less than 1% in the intervention group. Therefore, with a two-sided alpha (risk of type 1 error) of 5% and a power of 80%, 422 patients will be needed. Additionally, by incorporating a dropout rate of 10%, a total inclusion of 464 (500) patients is required [16, 19].

Randomisation procedure

The schedule for randomisation was generated by block randomisation using four-patient blocks. Following informed written consent, the randomisation envelopes will be opened by a surgical nurse in the operating room when the patient is asleep. The randomisation number will be written in the patient's journal. Two and a half years after the LRYGB, patients will be informed about their randomisation.

Data analyses

Data will be analysed using SPSS version 20. Median and range will be used and clinical, categorical data will be compared by the χ^2-test and continuous data with the Mann-Whitney test. Survival statistics (Kaplan-Meier plots and the log-rank test) will be used for analysing IH in the two groups. The significance level will be set at 5%.

Ethics and trial registration

This study does not involve the testing of new biomaterials or medicines that are not already commercially available. Patients are not expected to be exposed to an increased overall risk of complications; it is hoped that complications will be reduced with the new procedure.

Approval has been obtained from the Danish Data Protection Agency (SN-10-2012) and from The Regional Research Ethics Committee of Region Zealand (RVK Zealand) (1-01-83-0209-12, SJ-284). The study was registered with clinicaltrials.gov: NCT01595230. The results will be published irrespective of their nature.

Trial registration: The study was registered with the Danish Data Protection Agency (SN-10-2012) and The Central Denmark Regional Committees on Biomedical Research Ethics (1-01-83-0209-12, SJ-284). The study is registered with clinicaltrials.gov: NCT01595230.

DISCUSSION

This study will be the first Danish study comparing primary closure of the mesenteric defects using clips with no closure of the mesenteric defects in LRYGB surgery. The relevance of the study is rooted in earlier studies reports that primary closure of the mesenteric defects will reduce the rate of IH and IIH from 6% to 1%. If this reduction can be confirmed, many patients can avoid reoperation for internal herniation provided that primary closure of the mesenteric defects does not cause other serious side effects that exclude primary closure of the mesenteric defect during the primary operation. Suturing the mesentery may lead to bleeding and haematomas, causing circulation impairment to the intestine [19]. Still, Aghajani et al reported no mesenteric haematomas in their 1,630 patients [11]. Case reports show that closure of the mesenteric defects can result in obstruction at the EEA caused by adhesions [20] or rotation of the anastomosis (kinking) [11], but the precise rate of these types of complication remains unknown. Therefore, it is our hope that the present study may elucidate the possible benefits as well as disadvantages in primary closure of the mesenteric defects in LRYGB surgery.

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LITERATURE

1. Forebyggelsespakke – overvægt www.sst.dk/Udgivelser/2013/Forebyggelsespakke%20Overvaegt.aspx (26 Mar 2014).
2. Sjöström CD. Surgery as an intervention for obesity. Results from the Swedish obese subjects study. Growth Horm IGF Res 2003;13(Suppl A):S22-S26.
3. Karlsson J, Taft C, Rydén A et al. Ten-year trends in health-related quality of life after surgical and conventional treatment for severe obesity: the SOS intervention study. Int J Obes (Lond) 2007;31:1248-61.
4. Den danske fedmeepidemi. www.sst.dk/Udgivelser/2003/Den%20danske%20fedmeepidemi%20-%20Oplaeg%20til%20en%20forebyggelsesindsats.aspx (26 Mar 2014).
5. Sjöström L, Narbro K, Sjöström CD et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med 2007;357:741-52.
6. Jamal M, Gunay Y, Capper A et al. Roux-en-Y gastric bypass ameliorates polycystic ovary syndrome and dramatically improves conception rates: a 9-year analysis. Surg Obes Relat Dis 2012;8:440-4.
7. Fredheim JM, Rollheim J, Sandbu R et al. Obstructive sleep apnea after weight loss: a clinical trial comparing gastric bypass and intensive lifestyle intervention. J Clin Sleep Med 2013;9:427-32.
8. Fedmeoperationer – Statens Serum Institut. www.ssi.dk/Sundhedsdataogit/Dataformidling/Sundhedsdata/Saropgorelser/Fedmeoperationer.aspx (26 Mar 2014).
9. Marmuse J-P, Parenti LR. Gastric bypass. Principles, complications, and results. J Visc Surg 2010;147:e31-e37.
10. Higa K, Ho T, Tercero F et al. Laparoscopic Roux-en-Y gastric bypass: 10-year follow-up. Surg Obesity Rel Dis 2011;7:516-25.
11. Aghajani E, Jacobsen HJ, Nergaard BJ et al. Internal hernia after gastric bypass: a new and simplified technique for laparoscopic primary closure of the mesenteric defects. J Gastrointest Surg 2012;16:641-5.
12. O'Rourke RW. Management strategies for internal hernia after gastric bypass. J Gastrointest Surg 2011;15:1049-54.
13. Sunnapwar A, Sandrasegaran K, Menias CO et al. Taxonomy and imaging spectrum of small bowel obstruction after Roux-en-Y gastric bypass surgery. Am J Roentgenol 2010;194:120-8.
14. Cho M, Pinto D, Carrodeguas L et al. Frequency and management of internal hernias after laparoscopic antecolic antegastric Roux-en-Y gastric bypass without division of the small bowel mesentery or closure of mesenteric defects: review of 1400 consecutive cases. Surg Obes Relat Dis 2006;2:87-91.
15. Madan AK, Menzo Lo E, Dhawan N et al. Internal hernias and nonclosure of mesenteric defects during laparoscopic Roux-en-Y gastric bypass. Obes Surg 2009;19:549-52.
16. Bauman RW, Pirrello JR. Internal hernia at Petersen's space after laparoscopic Roux-en-Y gastric bypass: 6.2% incidence without closure – a single surgeon series of 1047 cases. Surg Obes Relat Dis 2009;5:565-70.
17. https://sundhedsstyrelsen.dk/da/sundhed/planlaegning-og-beredskab/specialeplanlaegning/specialeplan-2010/kirurgi/~/media/89A116FF5FD64486BA6EC46BCA15CF6E.ashx?m=.pdf (26 Mar 2014).
18. Rauh KH, Andersen RS, Rosenberg J. Visual analogue scale for measuring post-operative pain. Ugeskr Læger 2013;175:1712-6.
19. Iannelli A, Buratti MS, Novellas S et al. Internal hernia as a complication of laparoscopic Roux-en-Y gastric bypass. Obes Surg 2007;17:1283-6.
20. Gumbs AA, Duffy AJ, Chandwani R et al. Jejunojejunal anastomotic obstruction following laparoscopic Roux-en-Y gastric bypass due to non-absorbable suture: a report of seven cases. Obes Surg 2006;16:12-5.