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Randomized Clinical Trial

Randomized clinical trial on closure *versus* non-closure of mesenteric defects during laparoscopic gastric bypass surgery

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Abstract

Background: Internal herniation is a well known and potentially life-threatening complication of laparoscopic Roux-en-Y gastric bypass (LRYGB). The aim of this study was to evaluate the benefit and harm of closing the mesenteric defects with clips during LRYGB to prevent internal herniation.

Methods: This was a single-centre, single-blinded RCT. Patients eligible for LRYGB were randomized to surgery with or without closure of mesenteric defects with clips. The primary endpoint was the incidence of (intermittent) internal herniation after LRYGB with a minimum follow-up of 24 months. Secondary outcomes were duration of surgery, number of clips used, trocars and sutures used, postoperative pain measured by a visual analogue scale (VAS), and postoperative complications.

Results: Between 13 August 2012 and 18 May 2017, 401 patients were randomized to closure (201) or non-closure (200) of mesenteric defects. Median follow-up for both groups was 59 months (range 8–67 and 16–67 months in non-closure and closure groups respectively). The cumulated risk of internal herniation after 2 years was 8.0 per cent in the non-closure group compared with 4.5 per cent in the closure group (hazard ratio (HR) 1.81, 95 per cent c.i. 0.80 to 4.12; $P = 0.231$). At 5 years, rates were 15.5 and 6.5 per cent respectively (HR 2.52, 1.32 to 4.81; $P = 0.005$). Closure of mesenteric defects increased operating time by a median of 4 min (95 per cent c.i. 52 to 56 min for the non-closure group and 56 to 60 min for the closure group; $P = 0.002$). There was no difference in postoperative blood transfusion rates and VAS scores between the groups.

Conclusion: Routine closure of the mesenteric defects in LRYGB with clips is associated with a lower rate of internal herniation. Registration number: NCT01595230 (http://www.clinicaltrials.gov).

Introduction

Laparoscopic Roux-en-Y gastric bypass (LRYGB) is a common and effective procedure for the treatment of severe obesity[1]. An antecolic, antegastric LRYGB creates a mesenteric defect between the mesentery of the alimentary limb and the mesocolon (Petersen's space), and between the biliopancreatic limb and the common limb at the enteroenteroanastomosis (mesojejunal defect)[2,3] (*Fig. 1a*). These mesenteric defects are prone to internal herniation of small bowel, a potentially life-threatening complication after LRYGB[2–4]. Internal herniation is associated with acute onset of abdominal pain, and the herniated and obstructed bowel may incarcerate[5]. Some patients suffer from intermittent internal herniation with episodes of postprandial abdominal pain. The reported incidence of (intermittent) internal herniation in patients without closure of the mesenteric defects is 4–17 per cent[6–9]. Closure of the mesenteric defects with sutures reduces this risk, but is associated with an increased risk of early postoperative complications[10], including torsion of the small bowel near the jejunojejunostomy resulting in (partial) obstruction of the alimentary or the biliopancreatic limb[11,12]. Sutured closure of mesenteric defects has also been criticized for prolonging the surgical procedure[13,14]. Closure of the mesenteric defects with clips has been reported to be quicker and to have a lower risk of postoperative complications than use of sutures[13,14], but this has not been tested in an RCT. The aim of this randomized trial was to evaluate the benefit and harm of closing the mesenteric defects with clips during LRYGB.

Methods

This single-centre, single-blinded RCT was performed at Zealand University Hospital in Denmark. Approval was obtained from the Danish Data Protection Agency (SN-10-2012) and from the Regional Committee on Health Research Ethics in Region Zealand (1-01-83-0209-12, SJ-284). The study was conducted in accordance with the ethical standards of the Helsinki Declaration (6th revision). The study was reported according to the Consolidated Standards for Reporting Trials (CONSORT). It was registered with ClinicalTrials.gov (NCT01595230) and the complete study protocol is available online (*Appendix S1*)[15].

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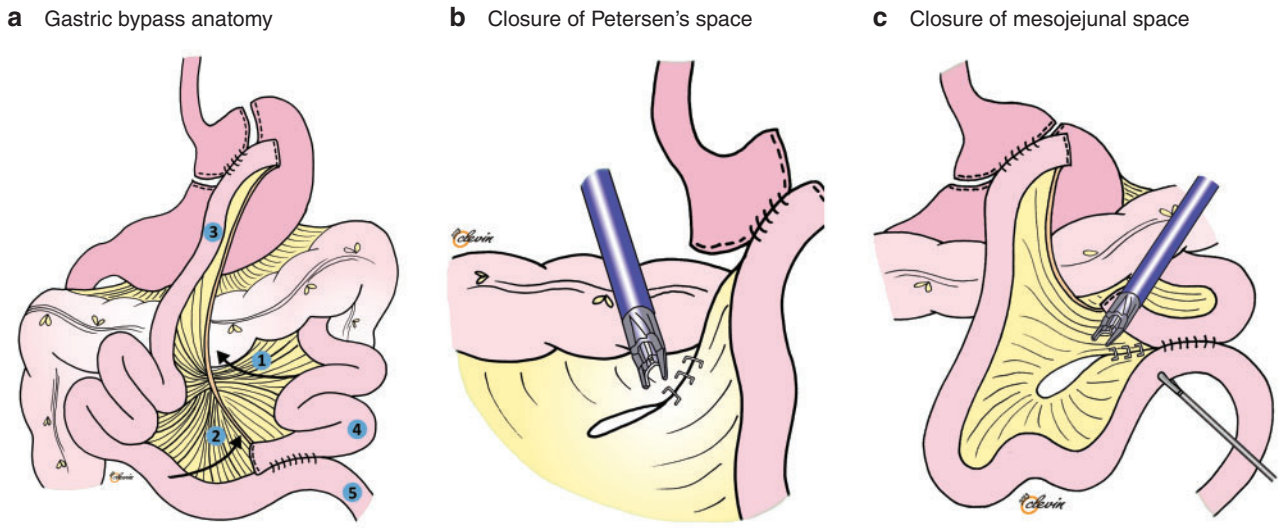

Fig. 1 Roux-en-Y gastric bypass

a Gastric bypass anatomy showing Petersen's space (1), mesojejunal space (2), alimentary limb (3), biliary limb (4), and common limb (5); **b** closure of Petersen's space; and **c** closure of mesojejunal space.

Eligibility for LRYGB was assessed according to Danish national guidelines, which until 2014 required either a BMI of over 40 kg/m^2, or BMI more than 35 kg/m^2 combined with obesity-related co-morbidity, such as type 2 diabetes, hypertension, polycystic ovarian syndrome, obstructive sleep apnoea, or arthrosis[16]. Between 2014 and 2017, the BMI required for patients without co-morbidity was temporarily raised to over 50 kg/m^2. All eligible patients were informed about the study and offered enrolment at the time of preliminary assessment. Written and oral consents were obtained from all participants before enrolment.

Sample size

The sample size was calculated based on studies that showed an incidence of internal herniation of between 0.5 and 11 per cent after LRYGB, increasing with longer observation time[8,12,17]. The overall risk of internal herniation and intermittent internal herniation was expected to be reduced from 6 per cent in the non-closure group to 1 per cent in the closure group. With a two-sided significance level of 5 per cent and a power of 80 per cent, 422 patients would be needed. By incorporating a dropout rate of 10 per cent, a total of 464 patients were required.

In 2014, the Danish eligibility criteria for bariatric surgery were changed, which resulted in a dramatic decrease in the number of LRYGB procedures performed and led to a considerably longer inclusion period than expected[18]. During this time, an RCT[10] showed that the benefits from closing the mesenteric defects with sutures were much greater than expected. Therefore, the author group found it unethical to continue, and decided to terminate the inclusion of patients before reaching the calculated sample size (1 June 2017).

Randomization and blinding

The schedule for randomization was generated in a 1 : 1 ratio by randomization in blocks of four patients (http://www.randomization.com) and was overseen by the principal investigator. When a LRYGB was possible during laparoscopic inspection, a concealed envelope was opened and the patient underwent LRYGB either without closure of the mesenteric defects, with or closure of the defects using clips. The randomization number was written in the operative report. Patients were informed about their randomization after the 24-month follow-up, or if they underwent surgery for internal herniation. All healthcare providers, besides surgeons and other personnel in the operating theatre, were blinded to the allocated treatment.

Procedures

LRYGB was carried out as a standardized procedure with creation of a small gastric pouch (approximately 30 ml). The jejunum was transected 75 cm distal to the ligament of Treitz. An anastomosis was created between the alimentary limb and the gastric pouch with a linear stapler via an antecolic route. The biliopancreatic limb was then connected to the alimentary limb 120 cm below the gastrojejunostomy using a linear stapler[5] (*Fig. 1a*). Closure of the mesenteric defects was performed according to the technique described by Aghajani and colleagues[12] using an Endo Universal™ (Covidien, US) 65 or a Universal Hernia Stapler 12–4.8 mm® (AutoSuture, Johnson & Johnson, US) in a single layer (*Fig. 1b,c*). Both the LRYGB and closure of the mesenteric defects were performed by five surgeons who were trained in LRYGB in similar manner.

Follow-up

All demographic data were collected before operation, and follow-up data were collected 3, 6, 12, and 24 months after surgery in the regional outpatient clinic. Follow-up was cross-checked and continued by using electronic nationwide medical records up to 5 years after operation to ensure complete follow-up regarding operations for internal herniation or intermittent internal herniation.

Outcomes

According to the published protocol[15], the primary endpoints were the incidence of internal herniation and intermittent internal herniation after LRYGB. Internal herniation was defined as herniation of the small bowel through one or both of the mesenteric defects as diagnosed by CT and/or laparoscopy, and requiring surgical correction and closure of the mesenteric defect[15]. Intermittent internal herniation was defined by recurrent postprandial pain and laparoscopy, when at least one of the mesenteric defects was open and herniation was not present,

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suggesting spontaneous reduction. If the postprandial pain disappeared within 3 months after closure of the mesenteric defects, the diagnosis was confirmed[15]. The presence of open defects alone when performing laparoscopy for other causes was not considered conclusive of intermittent internal herniation[15].

Secondary endpoints were: duration of surgery, number of clips used, trocars and sutures used, postoperative pain measured by the visual analogue scale (VAS)[19] 3, 6, 12, and 24 months after LRYGB[15]; and postoperative complications. Postoperative complications were graded according to the Clavien–Dindo classification[20]; Clavien–Dindo grades IIIb–V were classified as severe complications.

Statistical analysis

Categorial variables, presented as number of patients and percentage with 95 per cent confidence interval, were analysed using the χ^2 test. Normally distributed variables, presented as median with either i.q.r. or range, were analysed using the Mann–Whitney *U* test. The Kaplan–Meier estimator was used to investigate the incidence of internal herniation and intermittent internal herniation. The interval included in the survival statistics was from the day of LRYGB until the end of follow-up (19 May 2019), or until the first operation for internal herniation or intermittent internal herniation. Patients were censored if they either died or emigrated. Results are presented as hazard ratios (HRs) with 95 per cent confidence intervals, and two-sided $P < 0.050$ was considered significant. Patients with missing data were not included in the analyses. Statistical analyses were performed using RStudio® version 1.1.463 (RStudio, Boston, Massachusetts, USA).

Results

Between 13 August 2012 and 18 May 2017, 401 patients were included in the study. Some 201 patients were randomized to closure and 200 to non-closure of the mesenteric defects (*Fig. 2*). All patients were available for follow-up 30 days after surgery. After 12 and 24 months, 400 (99.8 per cent) and 398 (99.3 per cent) had follow-up respectively. One patient in the non-closure group emigrated after 8 months, one died from cancer in the gastric remnant after 21 months, and one patient died from lung cancer after 22 months. Were the two patients who died from the closure group (see *Fig. 1*). Some 127 of 401 patients (31.7 per cent) were included in the 5-year follow-up. Median follow-up was 59 (i.q.r. 54–63) months. Patient characteristics are shown in *Table 1*.

Primary outcomes

Internal herniation

Within the first 2 years, 16 of 200 included patients had surgery for internal herniation in the non-closure group and 9 of 201 in the closure group. The cumulated risk of internal herniation in the non-closure and closures group after 2 years was 8.0 and 4.4 per cent respectively (HR 1.81, 95 per cent c.i. 0.80 to 4.12; $P = 0.231$). In the non-closure group, seven patients had an internal hernia at Petersen's space, four at the mesojejunal defect, and five at both Petersen's space and the mesojejunal defect. In the closure group, five hernias were located at Petersen's space, three at the mesojejunal defect, and one at both Petersen's space and the mesojejunal defect.

The incidence of internal herniation increased with duration of follow-up (*Table S1*, *Fig. 3*). After 3 years, the cumulative difference in internal herniation was significantly higher in the non-closure group.

After 5 years, 31 patients in the non-closure group had internal herniation. Of these, 13 hernia were located at Petersen's space, seven at the mesojejunal defect, and 11 at both Petersen's space and the mesojejunal defect. In the closure group, 13 of 92 patients had internal herniation. Of these, five were located at Petersen's space, five at the mesojejunal defect, and three at both Petersen's space and the mesojejunal defect. The cumulated risk of internal herniation in the non-closure and closure group after 5 years was 15.5 and 6.5 per cent respectively (HR 2.52, 1.32 to 4.81; $P = 0.005$) (*Table S1*).

Intermittent internal herniation

After 2 years, 6 of 200 patients in the non-closure group had intermittent internal herniation, and 9 of 201 in the closure group. The cumulated risk of intermittent internal herniation in the non-closure and closure groups after 2 years was 3.0 and 4.5 per cent (HR 0.66, 95 per cent c.i. 0.24 to 1.86; $P = 0.436$) respectively.

As for internal herniation, the risk of intermittent internal herniation increased during follow up, but with no significant difference between the groups. After 5 years of follow-up, 13 of 104 patients in the non-closure group were diagnosed with intermittent internal herniation compared with 10 of 92 in the closure group. The cumulated risk of intermittent internal herniation in the non-closure and closure groups after 5 years was 6.5 and 5.0 per cent respectively (HR 1.23, 0.57 to 2.96; $P = 0.535$) (*Table S1*).

Surgical data and postoperative outcomes

Closure of the mesenteric defects was associated with an increased median operating time of 4 min (no closure 54 min (range 30–112) min *versus* closure 58 (30–157) min; $P = 0.002$) (*Table 2*). A median of 20 (range 10–60, 95 per cent c.i. 1.9 to 2.1) clips was used for closure were. No procedures were converted to open surgery. An extra trocar was needed to perform the gastric bypass in one patient in the non-closure group, and two in the closure group. On the first postoperative day, the change in haemoglobin level from the preoperative value was lower in the closure group than in the non-closure group: median 0.7 (range –0.5 to 4.1) and 0.55 (–1.1 to 3.8) mmol/l respectively ($P = 0.013$). There was no difference in preoperative haemoglobin level between the groups, or in blood transfusion rates, or preoperative or postoperative VAS scores. There was no difference in abdominal pain before or after surgery in the closure group compared with the non-closure group (*Table 2*).

Ten patients in the closure group and five in the non-closure group had severe complications (Clavien–Dindo grades IIIb–V). This difference was not statistically significant (*Table 2*). In the non-closure group, five patients underwent laparoscopic reoperation within 30 days, four because of iatrogenic bowel perforation. In the closure group, nine patients underwent a laparoscopic reoperation within 30 days. One was a diagnostic laparoscopy, three procedures were for bleeding and one because of iatrogenic bowel perforation, three patients had bowel obstruction because of torsion of the jejunojejunostomy, and one patient had internal herniation through Petersen's defect. Five patients had iatrogenic perforation of the small bowel needing reoperation (1 in closure group and 4 in non-closure group). One patient in the closure group with small bowel obstruction was treated in ICU for 5 days. No patient died within 30 days (*Table 2*).

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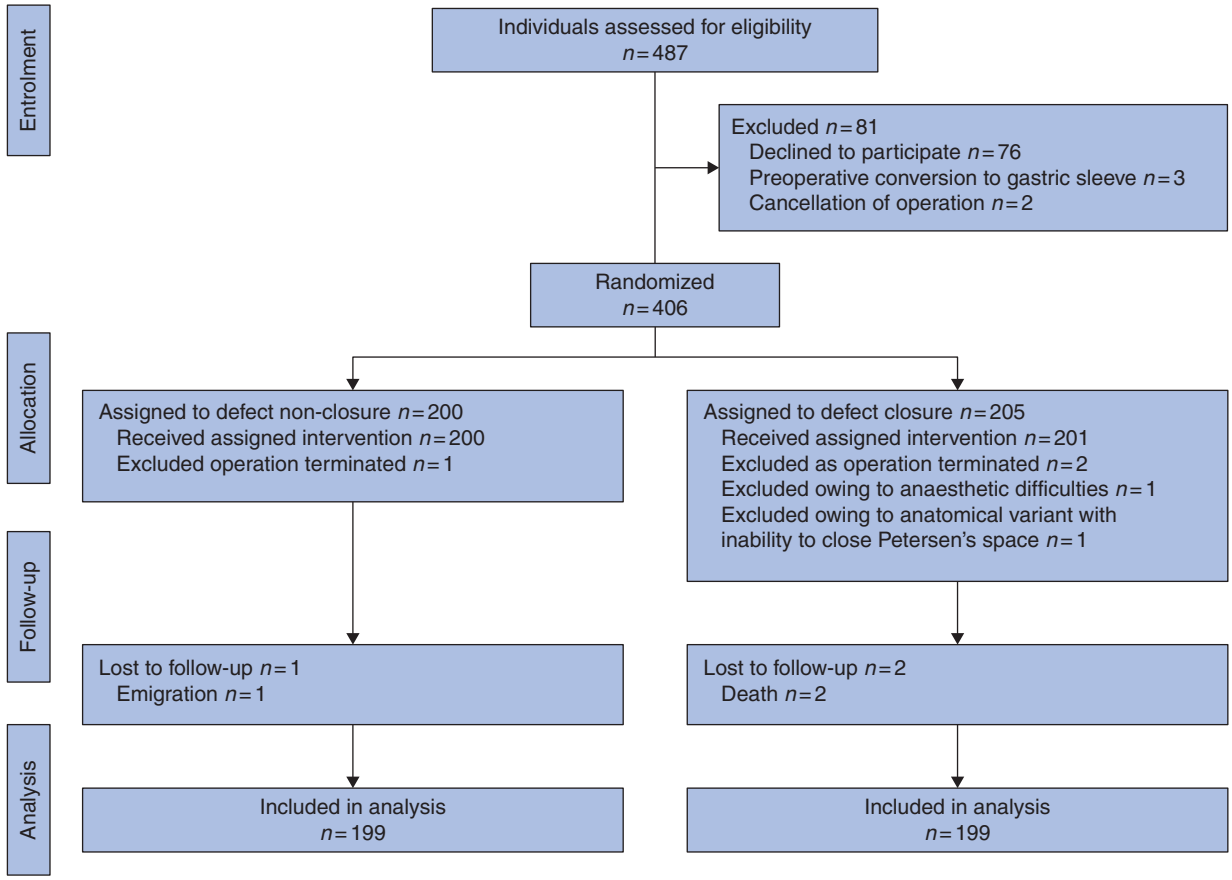

Fig. 2 CONSORT diagram for trial

Table 1 Baseline characteristics

	Non-closure of defects (*n* = 200)	Closure of defects (*n* = 201)
Age (years)*	40.5 (33–48)	43 (35–48)
Sex ratio (F : M)	159 : 41	158:43
Preoperative BMI (kg/m^2)*	44.3 (40.8–49.6)	44.6 (40.3 – 48.2)
Obesity-related co-morbidities		
Hypertension	56 (28.0)	61 (30.3)
Type 2 diabetes	46 (23.0)	48 (23.9)
Obstructive sleep apnoea	23 (11.5)	22 (10.9)
Polycystic ovarian syndrome	24 (12.0)	24 (11.9)
Arthrosis	50 (25.0)	54 (26.9)
Smoking	45 (22.5)	36 (17.9)
Alcohol consumption (units/week)‡		
0–5	188 (95.9)	186 (94.4)
6–15	8 (4.1)	11 (5.6)
Preoperative haemoglobin (mmol/l)†	8.9 (7.3–11.0)	8.8 (6.9–12.1)
Preoperative pain score (VAS) 0–3	200 (100)	201 (100)

Values in parentheses are percentages unless indicated otherwise; values are *median (i.q.r.) and †median (range). ‡Data missing for eight patients. VAS, visual analogue scale.

Discussion

This RCT showed that closure of the mesenteric defects with clips during LRYGB reduces the rate of internal herniation compared with non-closure. There was no difference in the incidence of intermittent internal herniation between the two groups. Postoperative complications were more frequent after closure of the defects, mostly owing to torsion of small bowel at the jejunojejunostomy. Closure of the mesenteric defects was associated with a clinically non-relevant prolonged operating time and lower haemoglobin level on the first postoperative day.

Stenberg and colleagues[10] reported a significantly lower incidence of small bowel obstruction 3 years after LRYGB with closure of mesenteric defects using non-absorbable suture compared with non-closure. They also reported a possible increased risk of early small bowel obstruction caused by torsion of the jejunojejunostomy after closure of the mesenteric defects[10]. In a large multicentre cohort study by Aghajani and co-workers[9], the incidence of internal herniation after 5 years was significantly lower in the closure group in which a stapler was used than in the non-closure group (2.5 *versus* 11.7 per cent). They also found an increase (0.2 per cent) in early complications caused by torsion of the jejunojejunostomy in the closure group[12]. However, after changing surgical technique, torsion was no longer reported in the historical follow-up[9]. The incidence of internal herniation in the present study was similar to that reported by Stenberg *et al.*[10], but higher than the rate documented by Aghajani and co-workers[9]. Thus, it could be speculated that adoption of the Aghajani technique in present study could have reduced the incidence of internal herniation. Stenberg and colleagues[10] did not include patients with intermittent internal herniation, whereas Aghajani *et al.*[9] described a risk of intermittent internal herniation similar to that in the present study.

In this trial, the rate of early complications CD grade IIIb (*Table 2*) was almost twice as high after closure of the mesenteric defects (4.5 *versus* 2.5 per cent). Although this was not

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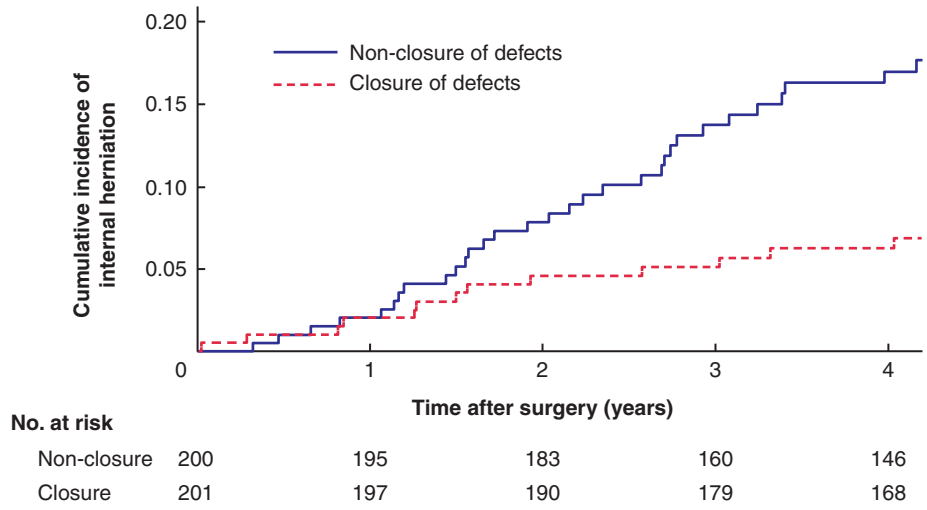

Fig. 3 Kaplan–Meier estimates of incidence of internal herniation in groups with and without closure of mesenteric defects
$P = 0.004$ (log rank test).

Table 2 Surgical data and postoperative outcomes

	Non-closure of defects ($n = 200$)	Closure of defects ($n = 201$)	P[¶]
Duration of operation (min)[*]	54 (30–112; 52, 56)	58 (30–157; 56, 60)	0.002[#]
Bleeding			
Intraoperative bleeding	2 (1.0; 0.1, 3.6)	4 (2.0; 0.5, 5.0)	
Change in Hb from preoperative value[§] (mmol/l)[*]	0.55 (–1.1 to 3.8; 0.5, 0.6)	0.7 (–0.5 to 4.1; 0.6, 0.8)	0.013[#]
Postoperative treatment with PRBCs	4 (2.0; 0.5, 5.0)	6 (3.0; 1.1, 6.4)	
Postoperative complications (Clavien–Dindo grade)			
I: no need for treatment	1 (0.5; 0.0, 2.8)	4 (2.0; 0.5, 5.0)	
II: needing pharmacological treatment	3 (1.5; 0.3, 4.3)	6 (3.0; 1.1, 6.4)	
IIIa: needing surgical treatment without general anaesthesia	0 (0)	0 (0)	
IIIb: needing surgical treatment under general anaesthesia[†]	5 (2.5; 0.8, 5.7)	9 (4.5; 0.2, 0.8)	0.416
IV: needing ICU treatment	0 (0)	1 (0.5; 0.1, 2.7)[‡]	
V: death	0 (0)	0 (0)	
Duration of hospital stay (days)[*]	2 (1–12; 2, 2)	2 (1–37; 2, 2)	0.085[#]
Follow-up (months)[*]	59 (8–67; 58, 60)	59 (16–67; 58, 60)	0.782[#]
Postoperative pain score			
3 months after operation ($n = 390$)	$n = 195$	$n = 195$	0.312
VAS 0–3	189 (96.9; 93.4, 98.9)	192 (98.5; 95.6, 99.7)	
VAS 4–10	6 (3.1; 1.1, 6.6)	3 (1.5; 0.3, 4.4)	
6 months after operation ($n = 375$)	$n = 184$	$n = 191$	0.344
VAS 0–3	178 (96.7; 93.0, 98.8)	181 (94.8; 90.6, 97.5)	
VAS 4–10	6 (3.3; 1.2, 7.0)	10 (5.2; 2.5, 9.4)	
1 year after operation ($n = 374$)	$n = 187$	n = 187	0.261
VAS 0–3	179 (95.7; 91.7, 98.1)	174 (93.0; 88.4, 96.2)	
VAS 4–10	8 (4.3; 1.9, 8.3)	13 (7.0; 3.8, 11.6)	
2 years after operation ($n = 336$)	$n = 165$	$n = 171$	0.684
VAS 0–3	157 (95.2; 90.7, 97.9)	161 (94.2; 89.5, 97.2)	
VAS 4–10	8 (4.8; 2.1, 9.3)	10 (5.8; 2.8, 10.5)	

Values in parentheses are percentages, with 95 per cent confidence interval, unless indicated otherwise; [*] values are median (range; 95 per cent c.i.). [†] Owing to internal herniation, torsion at the enteroenterostomy, or stenosis of the anastomosis. [‡] ICU treatment for aspiration pneumonia; this patient also had surgical treatment for ileus due to stenosis of the anastomosis. [§] Data were missing for seven patients. Hb, haemoglobin; PRBCs, packed red blood cells; VAS, visual analogue scale. [¶] χ^2 test, except [#] Mann–Whitney U test.

statistically significant, it could still represent a clinically relevant difference.

The haemoglobin count on the first postoperative day was significantly lower in the closure group. Although this does not seem clinically relevant, and the significant result could be due to a statistical error, more patients in the closure group had blood transfusions and needed surgery for intra-abdominal bleeding. However, the possible increased risk of early complications should be considered small compared with the long-term benefits of closing mesenteric defects with clips.

The operating time was approximately 4 min longer in the closure group, similar to the finding of Aghajani and colleagues[9]. Stenberg *et al.*[10] reported that the operation was prolonged by a median of 13 min when defect closure was achieved with running non-absorbable sutures. Thus, closing with clips seems less-time consuming than use of sutures. Closure times with clips and sutures were compared in a register-based cohort study[21] in which closure with clips was found to be faster and an easier technique to master. Closing the mesenteric defects with clips was, however, more expensive. Furthermore, the suture

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technique was slightly more effective in decreasing the risk of internal herniation after 5 years (7.3 and 6.9 per cent in groups closed with clips and sutures respectively).

In the present study, there were no differences between the closure and non-closure groups in VAS pain score before or 2 years after operation. Stenberg and colleagues[22] described a significant increase in bodily pain measured by the Short Form 36 scale among patients with defects closed using clips compared with sutures. However, more studies are needed to confirm whether there is a clinically relevant difference in pain between closure with sutures and clips.

The main limitation of this study was its early termination after publication of the two studies in 2016[10] and 2017[9]. Both studies showed a lower risk of internal herniation among patients with closed mesenteric defects. Therefore, it was deemed unethical to continue this trial. However, the incidence of internal herniation of 15.5 per cent in the non-closure group and 6.5 per cent in the closure group in the present study was considerably higher than expected. A *post hoc* power calculation with a significance level of 5 per cent and a power of 80 per cent showed that a total of 378 patients would be needed to reveal a possible difference in the risk of internal herniation between the two groups.

In 2014, the eligibility criteria for bariatric surgery were a BMI exceeding 50 kg/m^2, or over 35 kg/m^2 combined with a serious obesity-related co-morbidity. In 2017, the criteria changed to a BMI above 35 kg/m^2 combined with an obesity-related co-morbidity or a significant risk of the development of such. This change in eligibility criteria could have led to a different risk of internal herniation.

There was a risk of systematic bias owing to health-seeking behavioural traits[23], as some patients with abdominal pain might have omitted to seek medical help, whereas other patients might have sought medical help without abdominal pain being a primary problem. Considering the severity of the condition, this was not considered likely for patients with internal herniation.

Another limitation may be a placebo effect in the group with intermittent internal herniation. For some of these patients, closure of the mesenteric defects may have reduced pain for 1–2 months, given that they were informed that the mesenteric defects had been closed, resulting in overestimation of the treatment effect in this group.

Finally, the trial was conducted as a single-centre study, but the present results are comparable with outcomes from larger register-based studies[10].

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Disclosure. The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

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