NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of laparoscopic gastric plication for the treatment of severe obesity

Treating severe obesity by stitching folds in the stomach to make it smaller using keyhole surgery

Laparoscopic gastric plication reduces the size of the stomach to limit food intake. It is carried out using keyhole surgery through several (usually 5 or 6) small cuts in the abdomen (belly). It involves folding the stomach in on itself and stitching it together to reduce its volume by about 70%. None of the stomach is removed and the procedure is potentially reversible.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2012.

Procedure name

- Laparoscopic gastric plication
- Laparoscopic total gastric vertical plication
- Laparoscopic gastric greater curvature plication
- Laparoscopic anterior surface plication
- Laparoscopic gastric imbrication

Specialty societies

- Association of Laparoscopic Surgeons of Great Britain and Ireland
- Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland
- British Obesity and Metabolic Surgery Society

Description

Indications and current treatment

Severe obesity is defined as a body mass index (BMI) of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 in association with significant comorbidities such as hypertension, diabetes, arthritis, back pain, shortness of breath, hyperlipidaemia and impaired ability to move about. Weight loss reduces the risk of comorbidities worsening and improves long-term survival.

Severe obesity is managed by advice on diet, exercise, lifestyle changes and medication. Bariatric surgery is considered as a treatment option in selected patients who have not lost enough weight using these measures.

Surgical procedures for severe obesity aim to reduce weight and to maintain weight loss by restricting the size of the stomach or by decreasing food absorption, or both. Most of procedures can be carried out laparoscopically. Procedures that reduce the size of the stomach (gastric volume) restrict food intake by producing a feeling of satiety. They include laparoscopic gastric banding and sleeve gastrectomy. Procedures aimed at decreasing absorption of food include biliopancreatic diversion and duodenal switch. Patients are also advised to modify their eating behaviour by adhering to an explicit postoperative diet.

What the procedure involves

Laparoscopic gastric plication aims to promote weight loss by reducing the size of the stomach and is usually done by plicating the greater curve of the stomach. Because none of the stomach is removed, it is potentially a reversible procedure, in contrast to gastric resection.

The procedure is done with the patient under general anaesthesia, using several (usually 5 or 6) small incisions in the abdomen for the placement of a camera and ports for instruments. Greater curvature plication involves freeing the greater curve of the stomach by dissecting it from the greater omentum and short gastric vessels. Plication is done by folding the gastric wall inward along the greater curvature and securing this fold using rows of running sutures. Modifications of the technique may include a double or triple plication of the greater curve, and this may need extra rows of sutures. Anterior plication has also been reported.

Patients are placed on a postoperative diet that typically involves progression from fluids to semi-solid foods, avoiding intake of solid foods for approximately 6 weeks.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic gastric plication for the treatment of severe obesity. Searches were conducted of the following databases, covering the period from their commencement to 25 January 2012: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with severe obesity.
Intervention/test	Laparoscopic gastric plication.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on approximately 412 patients from 5 case series[1–5].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on laparoscopic gastric plication for the treatment of severe obesity

Abbreviations used: ASP, anterior surface plication; BMI, body mass index; EWL, excess weight loss; GI, gastrointestinal; GCP, greater curvature plication; IWQOL, impact of weight on quality of life; LGCP, laparoscopic gastric curvature plication; LOS, length of stay; LTGVP, laparoscopic total gastric vertical plication; MDT, multidisciplinary team; NIH, National Institute of Health; NR, not reported; NS, not significant; PPI, proton-pump inhibitors; QOL, quality of life; SD, standard deviation; TWL, total weight loss; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Skrekas G 2011[1]

Prospective case series

Greece

Recruitment period: 2008–2009
Study population: obese patients with at least 1 comorbidity

n=135

Age: mean 36 years
Sex: 77% (104/135) females

Patient selection criteria:
Older than 18 years
BMI > 40 kg/m^2 or BMI >35 kg/m^2 with at least 1 comorbidity. Patients with BMI >50 kg/m^2 were not encouraged to participate in the study.

Technique: laparoscopic gastric GCP
Single plication GCP technique: a 5 trocar port technique was used and</td>
<td>Number of patients analysed: 135
93 single plication technique
42 multiple plication technique

Mean hospital LOS:
1.9 days (range 1–6 days)
BMI:
Mean preoperative BMI: 39.6 ± 6.2 kg/m^2
Mean postoperative BMI: 29.6± 4.9 kg/m^2

% EWL
<table>
<tr><th>Follow-up</th><th>Mean % EWL ± SD
n=135</th></tr>
<tr><td>3 months</td><td>34.3 ±12.2</td></tr>
<tr><td>6 months</td><td>51.7 ±18.5</td></tr>
<tr><td>12 months</td><td>67.1 ± 24.7</td></tr>
<tr><td>23 months</td><td>65.2 ± 23.5</td></tr>
</table>
(Actual numbers followed up not reported)

Inadequate weight loss (defined as % EWL < 50): 21.48% (29/135) (mean follow-up 23 months)
Failure of procedure (defined as % EWL < 30): 5.9% (8/135) (mean follow-up 23 months)

Subgroup analysis by BMI</td>
<td>Overall complication rate 8.8% (12/135)

Postoperative complications by technique
Overall complication:
Single plication (n=93): 10/93
Multiple plication (n=42): 2/42
The difference in overall complication was significant (p < 0.001).

Nausea and vomiting:
Single plication (n=93): ‘most patients’ had prolonged nausea and vomiting for 2–20 days (attributed to mucosal oedema caused by venous stasis; actual numbers not reported).
Multiple plication (n=42):nausea and vomiting for ‘a few hours’.

Readmissions for complications : 5.9% (8/135)
<table>
<tr><th>Complication</th><th>Timing/treated</th><th>Patients</th></tr>
<tr><td>Prolonged nausea and vomiting</td><td>Timing of readmission not stated. Treated with intravenous anti-emetics and hydration</td><td>4</td></tr>
<tr><td>Gastrointestinal bleeding</td><td>5th and 30th postoperative day. Treated conservatively; further details not reported</td><td>2</td></tr>
<tr><td>Abdominal pain because of micro</td><td>Readmission on 7th</td><td>2</td></tr>
</table>
</td>
<td>Follow-up issues:
• No loss to follow-up reported.

Study design issues:
• Simple study design.
• Large case series to evaluate the effectiveness and also assess early and late complications.
• Used 2 different techniques (original and modification techniques). First period of the study used original technique (Apr 2008–Apr 2009).
• Second period of the study</td>
</tr>
</table>

Abbreviations used: ASP, anterior surface plication; BMI, body mass index; EWL, excess weight loss; GI, gastrointestinal; GCP, greater curvature plication; IWQOL, impact of weight on quality of life; LGCP, laparoscopic gastric curvature plication; LOS, length of stay; LTGVP, laparoscopic total gastric vertical plication; MDT, multidisciplinary team; NIH, National Institute of Health; NR, not reported; NS, not significant; PPI, proton-pump inhibitors; QOL, quality of life; SD, standard deviation; TWL, total weight loss; VAS, visual analogue scale

following dissection of the greater gastric curvature, single plication of the gastric curvature was performed.

Multiple plication GCP Technique

Modification of the above technique included creating a double or triple plication (multiple gastric plications) of the apposed gastric walls with the first row of stitches.

Follow-up: mean **23 months**

Conflict of interest/source of funding: none reported

	Group 1 (BMI < 45) (n=110)	**Group 2 (BMI > 45) (n=25)**	**p value**
Preoperative BMI (kg/m^2)	38.3 ± 4.0	49.8 ± 3.5	NR
Mean postoperative BMI (kg/m^2)	28.4 ± 3.9	35.5 ± 5.2	NR
Overall % EWL	69.9% ± 23.7	55.5% ± 19.3	0.006
% of patients with inadequate weight loss (% EWL < 50%)	18.2% (20/110)	36% (9/25)	< 0.001
Failure (% EWL < 30%)	5.45% (6/110)	8% (2/25)	0.063 (NS)

Results reported as mean ± SD unless otherwise noted.

Subgroup analysis by technique

	Single plication (n=93)	**Multiple plication (n=42)**	**p value**
Preoperative BMI (kg/m^2)	39.5 ± 6.2	39.6 ± 6.3	NS (p value not reported)
Mean postoperative BMI (kg/m^2)	29.2 ± 4.7	30.4 ± 5.4	NS (p value not reported)

leak from suture line	postoperative day. Treated conservatively; further details not reported.	

Reoperations for complications: 3.0% (4/135)

Complication	**Timing/type of reoperation**	**Patients**
Partial jejunal necrosis (because of portomesenteric thrombosis)	Timing of assessment: 24th postoperative day. Treated by small bowel resection	1
Acute gastric obstruction because of partial prolapse of gastric fundus between 2 distal fasteners of the suture line	14 months. Surgical reduction of the herniated fundus and reinforcement of the suture line was performed laparoscopically	1
Acute gastric obstruction caused by accumulation of serous fluid within the cavity formed by the plicated gastric wall	3 months. Initially treated conservatively but reversion of plication undertaken because of refractory obstructive symptoms. Successfully treated.	2

(May 2009–Dec 2009) used modified technique.

- Excess weight defined as amount of weight above the patient's ideal body weight, based on Metropolitan Life Insurance Company BMI tables (1983).

Other issues:

- Patients discharged as soon as they were able to tolerate liquid diet, advised to progress to soft diet after 15 days and solid diet after 30 days.
- Apart from 4 patients in the single plication group who had nausea and vomiting needing readmission, it

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Overall % EWL	68.2% ± 23.1	64.7%±23.6	NS (p value not reported)
% of patients with inadequate weight loss (EWL < 50%)	21.5% (20/93)	21.4% (9/42)	NS (p value not reported)
Length of hospital stay (days)	2.1	1.4	< 0.001

Postoperative complications according to BMI

Group 1 (BMI < 45) (n=110): 10/110

Group 2 (BMI > 45) (n=25): 2/25

NS (p value not reported)

was not clear for which technique all the readmissions and reoperations occurred.

- Quoted figures for overall % EWL are the same as those for operative time, which seems unlikely.

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Talebpour M (2007)[2]

Prospective case series

Iran

Recruitment period: 2004–2007

Study population: patients with BMI over 40 kg/m^2 or over 35 kg/m^2 with comorbidity

n=**100**

Age: mean 32 years

Sex: 76% (76/100) females

Patient selection criteria:

Patients with BMI over 40 kg/m^2 or over 35 kg/m^2 with comorbidity were included. Comorbidity in 38 patients (diabetes, low back pain, hypertension, complete lower limb paralyses, sleep apnoea).

Technique:

Laparoscopic total gastric vertical plication (LTGVP):

Patients were placed in supine position with a 30-degree Trendelenburg position. Trocars

Number of patients analysed: **100**

Mean hospital LOS: 1.3 days (range 1–4 days)

% EWL

Follow-up	Mean % EWL
1 month (n=100)	21%
6 months (n=72)	54%
12 months(n=56)	61%
24 months (n=50)	60%
36 months (n=11)	57%

4 patients had weight gain comparable to their maximum weight loss, but EWL over 50% at 3 years. Mean BMI: 47 kg/m^2 (range 36–58 kg/m^2); postoperative BMI not reported.

Improvement in comorbidities

Comorbidity at 6-month follow-up	Patients (n=38)
Diabetes	61.5% (8/13)
Hypertension (considered corrected if pressure was below 15/9 kPa)	66.6% (6/9)
Low back pain	71.4% (15/21)
Sleep apnoea	100% (3/3)

Postoperative complications

Complication	Timing of assessment	Rate
Nausea (due to gastric fullness) and vomiting	4 hours to 24 days; average: 3.1 days; nausea 'which by adaptation was corrected during a short time'	100%
Epigastric pain (because of manipulation, transient ischemia and oedema of the gastric wall)	Timing of assessment unclear; resolved in 48 hours with 'milk of magnesium' and ranitidine	25% (25/100)
Hypocalcaemia	NR	1% (1/100)
Non obstructive jaundice	2 weeks after procedure; complication 'disappeared spontaneously'	2% (2/100)
'Permanent' vomiting and discomfort (because of adhesion between fundus and liver)	8 months after procedure. Resolved by release of adhesion at reoperation	1% (1/100)
Intracapsular liver haematoma with abscess	6-month follow-up Resolved by drainage of the abscess using a laparoscopic approach.	1% (1/100)

Follow-up issues:

- 89% patients lost to follow-up at 36 months. Reasons not reported.

Study design issues:

- Patient selection criteria not clearly reported.
- QOL was reported for 70 patients but the methodology for its assessment and reporting of outcomes was unclear and not presented.

Other issues:

- Procedure was done by only 1 surgeon in private hospitals in Iran for 3 years.
- Liquid diet was advised for the first 3 weeks after the procedure and

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were inserted based on ergonomic assessment (three 5 mm and 1 10 mm). After releasing the greater curvature, bleeding was controlled by ligature and continuous sutures were used with 00 nylon from the fundus to 3 cm of the pylorus. A vertical plication was performed in 1 or 2 layers. Follow-up: mean **18 months** Conflict of interest/source of funding: not reported		<table><tr><td></td><td></td><td></td></tr><tr><td>Acute gastric perforation in the prepyloric area</td><td>3 days after procedure. Repaired by laparotomy without any change to plication.</td><td>1% (1/100)</td></tr><tr><td>Gastric leak at the suture line</td><td>2 days after procedure. Repaired by suturing.</td><td>1%(1/100)</td></tr><tr><td>Total complications needing reoperation</td><td></td><td>4% (4/100)</td></tr></table>No blood transfusions were needed. **Restriction to intake** In all patients intake of liquid exceeding 50 cc resulted in painful conditions (stomach volume was 100 cc) immediately after the operation (time to resolution not described and no further details given).	volume of liquid intake was 2.5 litres by oral or intravascular infusion. All of the patients were on a diet and were ordered to exercise. • In patients with unacceptable EWL, a second operation (e.g. biliopancreatic diversion) was advised after 6 months.

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Brethauer SA (2011)[3]

Case series

USA

Recruitment period: not reported

Study population: Patients from outpatient population who expressed an interest in the procedure and met the inclusion criteria.

n=**15** (9 ASP and 6 GCP)

Age: mean 42 years

Sex: 80% (12/15) females

Patient selection criteria: Included: Patients 21–60 years old, with a BMI of > 35 kg/m^2 but < 50 kg/m^2 or a BMI of 35–40 kg/m^2 with ≥ 1 significant medical conditions related to obesity (met NIH criteria for bariatric surgery).

Exclusion criteria: Pregnancy or lactation, history of drug or alcohol abuse within 2 years, previous malabsorptive or restrictive procedures, participation in any device or drug study within 12

Number of patients analysed:**15**

Mean hospital LOS: 37 hours

First 2 patients in GCP technique (2/6) needed longer LOS (77 hours) because of nausea

Mean % change in BMI

(Mean preoperative BMI: 43.3 kg/m^2 [36.9–49.0 kg/m^2])

ASP (n=9) 10.7% kg/m^2 (the change in BMI was not statistically significant ; p-value not reported)

GCP (n=6) 24.4% kg/m^2 (the change in BMI in the GCP group was significant at 1 year; p < 0.0001)

The percentage of change in BMI compared with the ASP group was statistically significant across all visits (p < 0.0001)

% EWL

Follow-up	ASP*	GCP*	p value
1 month	17.8% ± 5.3	23.3% ± 4.9	NR
3 months	23.4% ± 6.2	38.5% ± 7.9	NR
6 months	28.4% ± 10.7 (n=6)	49.9% ±12.1	NR
12 months	23.3% ± 24.9 (n=5)	53.4% ± 22.7	0.065 (NS)

*Results reported for 9 patients and 6 patients in the ASP and GCP groups, respectively, unless otherwise stated. Results reported as mean ± SD.

No bleeding or infectious complications.

No complications associated with using full thickness monofilament sutures.

One patient in GCP group (1/6) needed reoperation and plication reduction because of gastric obstruction by the intraluminal fold (2 days after procedure). The gastric obstruction was attributed to the considerable amount of oedema and venous congestion in the fold postoperatively.

Acute cholecystitis was reported in 1 patient treated by GCP (at 11 months; treated by laparoscopic cholecystectomy).

Severe nausea (2 patients) and mild to moderate nausea in patients (all resolved within 2 weeks).

No new onset or worsening of gastroesophageal reflux during follow-up period.

Postoperative pain

ASP (n=9): 2.0; GCP (n=6) 2.4; p=0.8

Follow-up issues:

- Four patients in the ASP procedure were lost to follow-up (authors attributed this to poor weight loss in the ASP group).

Study design issues:

- Single centre in USA.
- Pain assessed after procedure and before discharge using VAS scale (further details on scale not reported).
- The IWQOL-Lite is used to assess effects of obesity on QOL of those seeking weight loss treatments. Scores range from 0 to 100, with higher scores indicating

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weeks of enrolment, conditions that would preclude compliance with the study (inflammatory disease of GI tract within previous 10 years, congenital or acquired anomalies of GI tract, severe cardiopulmonary disease, uncontrolled or portal hypertension, chronic or acute upper GI bleeding conditions), cirrhosis, congenital or acquire intestinal telangiectasia, oesophageal or gastric disorders, treatment with > 50 units per day of insulin, hiatal hernia, previous surgery of the foregut, pancreatitis, immunocompromised status, autoimmune connective tissue disease, use of prescription or over the counter weight reduction medications within 30 days of screening visit.

Technique: 2 different procedures were used to laparoscopically reduce gastric volume.

ASP: the anterior gastric wall was infolded from the fundus to the antrum using 2 rows of running suture. The greater and lesser curvatures were approximated to create an intraluminal fold of the stomach.

GCP: the short gastric vessels were divided and the greater curvature was folded inward, with 2 suture lines to create a large intraluminal gastric fold.

Endoscopic evaluation (to assess plication durability)

Follow-up	ASP (n=9)	GCP (n=6)
3 months	A partially disrupted distal fold in 1 patient	NR
6 months	NR	Durable intraluminal folds
12 months	Additional fold disruption noted in the same patient (n=5)	A partial disruption of intraluminal fold at the distal end due to a broken suture in 1 patient

QOL

	Follow-up	ASP (n=9)	GCP (n=6)
Overall (total) IWQOL score	12 months	Improvement not statistically significant (scores not reported; p=0.38)	Overall score had improved significantly (scores not reported; p=0.009)
SF-12 scores	12 months	No significant change compared with baseline scores	Significant improvement (p < 0.001) for the physical component

better QOL).

- They were considered to show meaningful improvement if the score had increased 7–12 points, depending on the baseline severity compared with normative mean.
- SF-12 (range 0–100; higher scores indicates better health) assessed at baseline and approximately 4 weeks postoperatively.

Other issues:

- Progression from liquid to solid diet over 4 weeks after the procedure.

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Intraoperative endoscopy was done to confirm size and shape and full thickness bites during creation of the plications. Follow-up: **12 months** Conflict of interest/source of funding: Three authors are consultants and speakers for Ethicon Endo-Surgery. One author is an engineer at the same company and contributed to protocol, technique and data analysis. The study was funded by Ethicon Endo-Surgery.			(scores not reported; p value not reported)	scores; mean scores for mental component had returned to the baseline values (scores not reported) **Sutures needed to complete procedure** ASP (n=9): 7 patients needed 2 rows, 2 patients needed 3 rows GCP (n=6): 5 patients needed 2 rows, 1 patient needed 3 rows	

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Andraos Y (2011)[4]

Case series

Lebanon

Recruitment period: 2010–2011

Study population: patients who met the inclusion criteria for bariatric surgery.

Mean preoperative BMI: 40.4 kg/m^2 (range 30–63 kg/m^2)

n=**120**

Age: mean 36 years

Sex: 67% (80/120) females

Patient selection criteria: patients who met NIH criteria for bariatric surgery: BMI of 40kg/m^2 or more, or a BMI of over 30 kg/m^2 with at least 1 comorbidity; FDA approval of adjustable gastric band performed with the Lap-Band in patients with BMI of 40kg/m^2 or more, or a BMI of 30kg/m^2 or more and 1 or more obesity related comorbid conditions.

Technique: Laparoscopic greater curvature plication

General anaesthesia and 4–5 trocars were used. After releasing the greater curvature, gastric plication was done by invagination of the greater curvature over a 32 French tube. Leak and patent lumen

Number of patients analysed: **120**

Procedural outcomes

Mean hospital LOS	36 hours
Discharge after 24 hours	93.3% (112/120)

%EWL

Follow-up	% EWL
1 month	30.2%
3 months	43.9%
6 months	48.5%

%TWL

Follow-up	Mean % TWL
1 month	11.2%
3 months	16%
6 months	23%

Intraoperative complications

Bleeding was the major complication during the procedure. All the bleeding cases were related to laparoscopy and not specific to LGCP.

Complication	Treatment	Rate
Bleeding related to mesenteric trocar lesion	Hemoperitoneum was aspirated, mesentery sutured and plication achieved by laparotomy.	0.8% (1/120)
Massive trocar port bleeding	Controlled by reverdin needle suturing.	2.4% (3/120)
Moderate mesocolic bleeding	Controlled by laparoscopy	0.8% (1/120)
Gastrosplenic vessel bleeding	Haemostasis achieved by clips and catheterisation.	1.6% (2/120)
Left hepatic subcapsular hematoma	Managed conservatively with complete resorption 1 month after the procedure.	1.6% (2/120)
Intramural gastric parietal hematoma	Managed by extrinsic compression.	2.4% (3/120)
Severe subcutaneous emphysema related to pneumomediastinum occurred during hiatal hernia repair.	Operation achieved at low intra-abdominal pressure.	0.8% (1/120)

Early postoperative complications (within 30 days)

Complication	Timing of assessment/treatment	Rate
Gastric leak causing peritonitis (gastric fistula 3 cm below the gastrooesphageal	3 days after procedure; treated laparoscopically by suturing the leak hole, performing looser plication and cleaning the	0.8% (1/120)

Follow-up issues:

- Follow-up scheduled for 24 months but only first 6 months results reported.
- All complications during the procedure, up to 30 days and 6 months were monitored and recorded.

Study design issues:

- Single centre in Lebanon.
- Case series to evaluate early complication.
- Study received ethical approval of the local ethics committee.
- Patients evaluated by MDT.
- Patients had blood and barium meal tests before the

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tests were performed with 50–100 ml of diluted methylene blue. 6 hours after the procedure patients were asked to walk. At day 1, gastrografin meal was given and if there were no leaks or obstruction, liquid was given immediately at the rate of 1 tea spoon each 20 minutes and as tolerated. Patients were discharged with proton pump inhibitor, single dose for 2 months, antispasmodic and antiemetic suppositories and multivitamins. Postoperatively, dieticians advised clear liquids for the first week, semi-liquids as tolerated for 3 weeks, solid foods after 4 weeks. Follow-up: **6 months** Conflict of interest/source of funding: authors report no conflicts of interest.		junction of the stomach with peritonitis).	peritoneum cavity. Antibiotics were given for 3 weeks.		• procedure. • All patients monitored postoperatively by anaesthesiologist and committee of morbidity at the hospital. **Study population issues**: • It is not clear how many adjustable gastric band and vertical banded gastroplasty patients were included in the study. • Authors report 4 reoperation cases (2 following band removal and 2 following vertical banding gastrectomy). The gastric tissue was thicker and additional stitches were
		Gastric obstruction and leak due to rupture of stitches and herniation of fold between stitches	Timing and treatment not reported.	0.8% (1/120)	
		Complete gastric obstruction of residual gastric pouch (due to gastric fold oedema).	In 5 cases fold oedema noted on post-operative day 1; resolved spontaneously in 3–7 days. Moderate hypocalcaemia was treated by IV calcium gluconate. In 1 patient, 3 days after the procedure; obstruction resolved by looser plication at reoperation.	5% (6/120)	
		Perisplenic abscess (in a patient with reoperation for gastric obstruction)	3 days after the procedure, treated with intravenous antibiotics for 3 weeks.	0.8% (1/120)	
		Obstruction in the intraoesophageal fold invagination when the fundus plication was not fixed.	Timing and treatment not reported.	0.8% (1/120)	
		Pneumonia	Resolved after 5 days of intravenous antibiotics.	0.8% (1/120)	
		Food intolerance with no evidence of obstruction.	10 days after the procedure; resolved immediately after gastroscopy.	1.6% (2/120)	
		Transitory brachial paralysis	Regressed within 72 hours.	0.8% (1/120)	
		Minor hematemesis	At post-operative week 1; disappeared spontaneously within 4–5 days At postoperative month 1, managed conservatively with	15% (18/120) 5.6%	

Abbreviations used: ASP, anterior surface plication; BMI, body mass index; EWL, excess weight loss; GI, gastrointestinal; GCP, greater curvature plication; IWQOL, impact of weight on quality of life; LGCP, laparoscopic gastric curvature plication; LOS, length of stay; LTGVP, laparoscopic total gastric vertical plication; MDT, multidisciplinary team; NIH, National Institute of Health; NR, not reported; NS, not significant; PPI, proton-pump inhibitors; QOL, quality of life; SD, standard deviation; TWL, total weight loss; VAS, visual analogue scale

	proton pump inhibitors at high doses.	(7/120)
Melena	Managed conservatively with proton pump inhibitors at high doses.	1.6% (2/120)
Nausea	At post-operative week 1; disappeared spontaneously within 4–5 days	40% (48/120)
Vomiting	At post-operative week 1; disappeared spontaneously within 4–5 days	25% (30/120)
Sialorrhoea	At post-operative week 1; disappeared spontaneously within 4–5 days	22% (27/120)
Conversion to plication	2 after band removal and 2 after vertical banding gastrectomy.	3% (4/120)

Endoscopic and radiological evaluation:

Mild to moderate esophagitis reported at 1 and 4 months in only 4 patients due to reflux symptoms. This was treated by long-term proton pump inhibitors and antacids.

Late complications (up to 6 months): 1.6% (2/120)

Complication	Timing of assessment/ treatment	Rate
Spontaneous hemoperitoneum (due to corpus luteum rupture)	1, 6 weeks after the procedure; treated conservatively by 2 units of blood transfusion. Spontaneous resorption achieved within 15 days.	0.8% (1/120)
Upper gastric bleeding (due to fold ulceration)	1, 2 months after the procedure; treated by gastroscopy and adrenaline injection with 2 units of blood transfusion.	0.8% (1/120)

used in these cases.

Abbreviations used: ASP, anterior surface plication; BMI, body mass index; EWL, excess weight loss; GI, gastrointestinal; GCP, greater curvature plication; IWQOL, impact of weight on quality of life; LGCP, laparoscopic gastric curvature plication; LOS, length of stay; LTGVP, laparoscopic total gastric vertical plication; MDT, multidisciplinary team; NIH, National Institute of Health; NR, not reported; NS, not significant; PPI, proton-pump inhibitors; QOL, quality of life; SD, standard deviation; TWL, total weight loss; VAS, visual analogue scale

Ramos A 2010[5]

Prospective case series

Brazil

Recruitment period: 2007–2009

Study population: morbidly obese patients with BMI > 40 kg/m^2 or BMI > 35 kg/m^2 with at least 1 comorbidity.

n=**42**

Age: Mean 33 years

Sex: 71% (30/42) females

Patient selection criteria: BMI > 40 kg/m^2 or BMI > 35 kg/m^2 with ≥1 comorbidity (USA NIH criteria for bariatric surgery). Mean BMI 41 kg/m^2; exclusion criteria: BMI > 50 kg/m^2

Technique: LGCP through a 5 port approach. The greater curvature was invaginated using multiple rows of non-absorbable sutures performed over a 32-Fr bougie to ensure a patent lumen. Leak test performed with methylene blue.

Patients discharged as soon as they accepted a liquid diet without vomiting and received a prescription of a daily PPI (single dose) for 60 days. Ondasteron and hyoscine (anti-spasmodic) prescribed for 7 days.

Follow-up: **18 months** with endoscopic evaluation at 1, 6, and

Number of patients analysed: **42**

Conversion to open surgery: none

Weight regain

Weight regain was not observed in any of the patients.

% EWL

Follow-up	Mean % EWL
1 month (n=42)	20%
3 months (n=33)	32%
6 months (n=20)	48%
12 months (n=15)	60%
18 months (n=9)	62%

% TWL

Follow-up	Mean % TWL
1 month (n=42)	10%
3 months (n=33)	15%
6 months (n=20)	22%
12 months(n=15)	28%
18 months (n=9)	30%

Mean LOS: 36 hours (range 24–96 hours)

Return to normal activities: 7 days (range 4–13 days)

There were no intra-operative or major complications.

Minor postoperative complications (n=42)

Nausea 20%; vomiting 16%; sialorrhea (hypersalivation) 35% (assessed in the 1st postoperative week; resolved within 2 weeks; actual numbers not reported)

Potential reasons for adverse events were the severity of the restriction induced by the invagination of the greater curvature and/or oedema caused by venous stasis.

Mild oesophagitis (grade A of Los Angeles classification) was reported in 3/12 patients at 1 month. These patients were symptomatic (nausea, vomiting, sialorrhea) and were kept on PPI as per protocol.

Postoperative and/or follow-up endoscopic and radiological findings: greater curvature fold was smaller at 6 months when compared with fold at 1 month (12 patients) and appeared unchanged at 12 months (7 patients).

Follow-up issues:

- 79% lost to follow-up. Reasons not reported.
- Follow-up scheduled at 24 months but not completed. Reasons not reported.

Study design issues:

- Changes to and impact on comorbidities not measured.

Other issues:

- Postoperative diet: customised liquid diet for 2 weeks, then a progressive return to solid foods. Dietary restrictions removed at 4–6 weeks, depending on patient acceptance.

Abbreviations used: ASP, anterior surface plication; BMI, body mass index; EWL, excess weight loss; GI, gastrointestinal; GCP, greater curvature plication; IWQOL, impact of weight on quality of life; LGCP, laparoscopic gastric curvature plication; LOS, length of stay; LTGVP, laparoscopic total gastric vertical plication; MDT, multidisciplinary team; NIH, National Institute of Health; NR, not reported; NS, not significant; PPI, proton-pump inhibitors; QOL, quality of life; SD, standard deviation; TWL, total weight loss; VAS, visual analogue scale			
12 months Conflict of interest/source of funding: 2 authors are consultants for Ethicon EndoSurgery Inc. No direct funding was allocated to this study or paper.			

Efficacy

Weight loss

Total weight loss

The case series of 135 patients reported a reduction in BMI from 39.6 to 29.6 kg/m^2 (mean 23-month follow-up). Subgroup analysis by technique (single plication [mean BMI 29.2 kg/m^2] compared with multiple plication [mean BMI 30.4 kg/m^2]) showed no significant difference in the mean BMI (mean 23-month follow-up; p value not reported)[1].

A case series of 42 patients with a mean BMI of 41 kg/m^2 treated by laparoscopic gastric curvature plication reported mean total weight loss of 30% in 9 patients at 18-month follow-up[5].

The case series of 120 patients with a mean BMI of 40 kg/m^2 reported mean total weight loss of 23% at 6 months follow-up[4].

Overall excess weight loss

A case series of 15 patients comparing 9 patients treated by anterior surface plication and 6 patients treated by greater curvature plication with a mean BMI of 43.3 kg/m^2 reported mean excess weight loss of 23% in 5 patients in the anterior surface plication group and 53% in the greater curvature plication group at a mean follow-up of 1 year (p=0.065)[3].

A case series of 135 patients reported mean excess weight loss of 65% at a mean follow-up of 23 months (number of patients followed up not reported). The study reported a significantly higher mean excess weight loss for patients with a BMI of < 45 kg/m^2 (110/135) than patients with a BMI of > 45kg/m^2 (25/135) (70% compared with 56% respectively, p=0.006)[1].

A case series of 100 patients with a mean BMI of 47 kg/m^2 treated by the procedure reported mean excess weight loss of 21% (n=100) at 1-month follow-up, 54% (n=72) at 6-month follow-up, 61% (n=56) at 12-month follow-up and 60% (n=50) at 24-month follow-up[2].

The case series of 120 patients reported mean excess weight loss of 49% at 6 months follow-up[4].

Inadequate excess weight loss

The case series of 135 patients reported inadequate weight loss (defined as excess weight loss < 50%) in 21% (29/135) of patients at a mean follow-up of 23 months. The study also reported inadequate weight loss in more patients with a BMI of > 45 kg/m^2 than patients with a BMI of < 45 kg/m^2 (36% [9/25] and 18% [20/110] respectively; p < 0.001). A non-significant difference between the single

and multiple plication groups was reported for the number of patients with inadequate weight loss (22% [20/93] and 21% [9/42] respectively at mean 23-month follow-up [p value not reported])[1].

Weight re-gain

Weight re-gain was not reported in any patients in the case series of 42 patients at 18-month follow-up[5].

Failure of procedure

In the case series of 135 patients failure of procedure (excess weight loss < 30%) was reported in 6% (8/135) of patients. The study also reported that failure rates were not associated with patients' BMI[1].

Disruption of plication

In the case series of 15 patients, of the patients available for endoscopic evaluation, 1 patient in the anterior surface plication group (n=5) had a partial disruption of the distal fold and 1 patient in the greater curvature plication group (n=6) had a partial disruption of the intraluminal fold at 12-month endoscopic follow-up[3].

Improvement in comorbidities

In the case series of 100 patients, 38 patients had comorbidities such as hypertension, diabetes, sleep apnoea and low back pain. Improvements were reported for 71% of patients with low back pain (15/21), 61% of patients with diabetes (8/13), 67% of patients with hypertension (6/9), and 100% of patients with sleep apnoea (3/3) 6 months after the operation[2].

Quality of life

The case series of 15 patients reported the overall quality of life score (IWQOL [Impact of Weight on Quality Of Life]-Lite; range 0–100, higher score indicating better quality of life). The improvement was significant (p=0.009) in the greater curvature plication group (n=6) and was non-significant (p=0.38) in the anterior surface plication group (n=9) at 12-month follow-up (numerical scores not reported).

Quality of life scores measured on the physical and mental health component of the SF-12 (range 0–100; higher score indicating better function) were significantly improved ($p < 0.001$) for the physical component score at 12-month follow-up in the greater curvature plication group (scores not reported) but there was no significant change compared with baseline in the anterior surface plication group at 4-week follow-up (scores and p value not reported)[3].

Safety

Gastric perforation and suture leakage

Gastric perforation in the prepyloric area was reported in 1 patient in the case series of 100 patients 3 days after the procedure. This was repaired at laparotomy without any change to plication[2].

Micro leak at the suture line was reported in 2 patients in the case series of 135 patients (timing not stated)[1]. Both patients were readmitted 7 days after the procedure and were treated conservatively (no further details reported). Gastric leak at suture line with pain secondary to forceful vomiting was reported in 1 patient in the case series of 100 patients 2 days after the procedure. This was treated by repairing the suture line[2].

Gastric leak causing peritonitis 3 days after the procedure was reported in 1 patient in the case series of 120 patients. This was treated laparoscopically by suturing the leak hole, performing looser plication, cleaning the whole peritoneum cavity and antibiotic treatment for 3 weeks. Gastric obstruction and leak by rupture of stitches and herniation of fold between stitches was reported in 1 patient (timing and treatment not reported)[4].

Gastric obstruction

Complete gastric obstruction of residual gastric pouch due to gastric fold oedema (1 day after the procedure in 5 patients after contrast meal and 3 days after the procedure in 1 patient) was reported in 5% (6/120) of patients in the case series of 120 patients. This resolved spontaneously in 3 to 7 days in 5 patients and by looser plication at reoperation in 1 patient. Obstruction in the intraoesophageal fold invagination when the fundus plication was not fixed was reported in 1 patient (timing and treatment not reported)[4].

Gastric obstruction due to herniation of the ‘gastric fundus between 2 distal fasteners of the suture line’ was reported in 1 patient in the case series of 135 patients 14 months after the procedure. This was treated by surgical reduction of the herniated fundus and reinforcement of the suture line using a laparoscopic approach. Intragastric seroma that resulted in gastric obstruction was reported in 2 patients in the case series of 135 patients 3 months after the procedure. This was treated by revision of plication[1].

Moderate hypocalcaemia was also reported in 5 patients who had complete gastric obstruction 1 day after the procedure in the case series of 120 patients. This was treated by intravenous calcium gluconate[4].

Partial jejunal necrosis

Partial jejunal necrosis due to portomesenteric thrombosis was reported in 1 patient in the case series of 135 patients on the 24th day after the procedure. This was treated by small bowel resection at laparotomy[1].

Bleeding

Upper gastric bleeding due to fold ulceration 2 months after the procedure was reported in 1 patient in a case series of 120 patients. This was treated by gastroscopy and adrenaline injection with 2 units of blood transfusion[4].

Gastrointestinal bleeding was reported in 2 patients in the case series of 135 patients. The patients were readmitted 5 and 30 days after the procedure and were treated conservatively (no further details reported)[1].

Intracapsular liver haematoma

Intracapsular liver haematoma with abscess was reported in 1 patient in the case series of 100 patients 6 months after the procedure. This was treated by drainage of the abscess using a laparoscopic approach[2].

Perisplenic abscess

Perisplenic abscess with no evidence of gastric fistula 3 days after the procedure was reported in 1 patient in the case series of 120 patients. This was treated by intravenous antibiotics for 3 weeks with no need of percutaneous drainage[4].

Nausea and vomiting

Prolonged nausea and vomiting (attributed to mucosal oedema caused by venous stasis) for 2–20 days were reported in 'most' of 93 patients (patient number not reported) treated by single plication, but only for a 'few hours' in 42 patients treated by multiple plication (exact figures not reported) in the case series of 135 patients who had laparoscopic greater curvature plication. Eight patients with prolonged vomiting were readmitted and treated with intravenous antiemetics and hydration (timing of readmission not stated)[1].

Nausea and vomiting were reported in all patients for an average of 3 days (range 4 hours to 24 days) in the case series of 100 patients and 'permanent' vomiting and discomfort due to adhesions between liver and stomach were reported in 1 patient (this was resolved by release of adhesion at reoperation 8 months after procedure)[2].

Nausea (40% [48/120]), vomiting (25% [30/120]), sialorrhoea (22% [27/120]), and minor haematemesis (15% [18/120]) were reported in the case series of 120 patients in the first week after the procedure. Symptoms disappeared spontaneously within 4 to 5 days and patients returned to normal activities 5–7 days after the procedure[4].

Non-obstructive jaundice

Non-obstructive jaundice was reported in 2 patients in the case series of 100 patients for more than 2 weeks after the procedure; it 'disappeared spontaneously'. Hypocalcaemia was reported in 1 patient in the case series of 100 patients (no further details reported)[2].

Pneumonia

Pneumonia within 30 days was reported in 1 patient in the case series of 120 patients (resolved after 5 days of intravenous antibiotics)[4].

Validity and generalisability of the studies

- Development of the techniques used for this procedure was described in the included papers.
- Most of the patients were women.
- Follow-up ranged from 1 month to 36 months.
- A small number of case series (4 studies in fewer than 300 patients) has been published on this procedure.
- Postoperative rehabilitation (including guidance on water or food intake and exercise) varied between the studies.

Existing assessments of this procedure

The American Society for Metabolic and Bariatric Surgery published a policy statement on laparoscopic gastric plication in October 2011[5]. The statement concluded that the quality and quantity of evidence regarding safety and efficacy of this procedure is insufficient to draw any definitive conclusions. The statement recommends that the procedure should be considered investigational and performed under a study protocol with third party oversight to ensure evaluation of patient safety and review adverse events and outcomes. It also recommends reporting short and long term safety and efficacy outcomes to a research database.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Clinical guidelines

- Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. NICE clinical guideline 43 (2006). Available from www.nice.org.uk/guidance/CG43

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Ashish Desai, Mr James C Halstead, Mr Haris Khwaja, Mr Abeezar Sarela, Mr Muhammed Shafiq, Mr Richard Welbourn (Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland); Mr Michael Rhodes (British Obesity & Metabolic Surgery Society)

- One Specialist Adviser had performed this procedure before and 6 Specialist Advisers had never performed this procedure before.
- Six Specialist Advisers considered the procedure to be novel and of uncertain safety and efficacy and 1 Specialist Adviser considered this a minor variation on an existing procedure
- All Specialist Advisers listed the relevant comparator as laparoscopic sleeve gastrectomy and 1 Specialist Adviser also listed adjustable gastric banding as a relevant comparator.
- Five Specialist Advisers stated that the procedure is likely to be performed by less than 10% of specialists, 1 Specialist Adviser stated that it may be performed by 10–50% of specialists and 1 stated that an estimate could not be given.
- The Specialist Advisers stated that key efficacy outcomes were excess weight loss at 1, 2, 6, 18 months and 1, 3, 5 and 10 years, incidence of weight regain, durability of plication as assessed by endoscopic evaluation or contrast swallow at 12 months, quality of life and resolution of the comorbidities of severe obesity.
- One Specialist Adviser stated that the main uncertainties relate to the technique, in terms of tightness of plication and length of plication of a long greater curvature, and long-term rates of suture line breakdown and weight regain have not been published. One Specialist Adviser noted that there was uncertainty about the extent and durability of weight loss by this procedure and another Specialist Adviser noted there was uncertainty about durability. One Specialist Adviser noted that current results were still early and long-term results needed to be gathered. Another Specialist Adviser noted there were no published large studies looking at efficacy parameters in the long-term.
- The Specialist Advisers stated that adverse events reported in the literature were nausea, vomiting, obstruction, abdominal compartment syndrome, lack of permanence, gastric necrosis, gastric leak, leak from plication suture line,

disruption of plication due to broken suture, gastric obstruction due to too tight plication, early vomiting prolonged nausea and vomiting, intracapsular liver haematoma, hypocalcaemia, hepatitis, portomesenteric thrombosis and complete occlusion of the 'sleeve'.

- One Specialist Adviser stated anectodal adverse events included disruption of plication due to 'broken suture causing weight regain'.
- Specialist Advisers listed theoretical adverse events as injuries from laparoscopic access to the abdomen (common to all laparoscopic operations), bleeding during dissection of omentum from the greater curvature of the stomach, damage to the stomach during dissection with subsequent leakage and peritonitis, injury to spleen, ischaemia or infarction of the plicated stomach, dysphagia, weight gain because of dilation of the 'sleeve' or failure of the plication sutures, gastric ischaemia, bleeding, deep vein thrombosis, pulmonary embolism, risks of general anaesthesia and infection.
- One Specialist Adviser stated that it was not clear whether the procedure is used as a primary weight loss surgery or whether it is used as a salvage procedure for failed gastric bands or gastric sleeves.
- Training: 1 Specialist Adviser stated that standard laparoscopic training is needed because the procedure is less technically demanding than laparoscopic gastric bypass. One Specialist Adviser noted that bariatric surgeons who currently perform gastric bypass and sleeve gastrectomy operations will have the necessary technical skills to do laparoscopic gastric plication. One Specialist Adviser stated that advanced laparoscopic technique as well as training in bariatric surgery were essential.
- In terms of patient numbers and use of resources, 2 Specialist Advisers noted that this procedure could have a major impact on the NHS. One Specialist Adviser noted that, because the procedure does not need staples, bands or special equipment, the procedure was likely to be less expensive than current popular bariatric practices. Two Specialist Advisers stated that the impact on the NHS would be moderate and 2 Specialist Advisers stated that it would be minor and 1 stated the procedure could have both a major and moderate impact.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- Only papers describing laparoscopic gastric plication as a primary weight loss procedure were included.
- Articles with combined techniques describing laparoscopic gastric plication surgery combined with gastric band placement were excluded because they discuss gastric plication as an adjunct to gastric banding.
- There was a lack of long-term follow-up in the included studies.

- Future trials:
  - NCT01293877: location: Israel; type: non-randomised comparative study, comparing laparoscopic gastric plication and laparoscopic sleeve gastrectomy for treatment of morbid obesity; estimated enrolment: 200; estimated primary completion date: March 2012
  - NCT01512940: location: USA; type: single-arm; estimated enrolment: 50; estimated primary completion date: October 2012
  - NCT01077193: location: USA, Czech Republic; type: single-arm; estimated enrolment: 45; estimated primary completion date: December 2013
  - NCT01207609: location: USA; type: single-arm; estimated enrolment: 50; estimated primary completion date: December 2013
  - NCT01393886: location: USA; type: single-arm; estimated enrolment: 10; estimated primary completion date: December 2015

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1. Skrekas G, Antiochos K and Stafyla VK (2011). Laparoscopic gastric greater curvature plication: results and complications in a series of 135 patients. Obesity Surgery 21(11): 1657–63

2. Talebpour M and Amoli BS (2007). Laparoscopic total gastric vertical plication in morbid obesity. Journal of Laparoendoscopic & Advanced Surgical Techniques (6): 793–8

3. Brethauer SA, Harris JL, Kroh M et al. (2011). Laparoscopic gastric plication for treatment of severe obesity. Surgery for Obesity and Related Diseases 7(1) 15–22

4. Andraos Y, Ziade D, Achcouty R et al. (2011) Early complications of 120 laparoscopic greater curvature plication procedures. Bariatric Times 8(9): 10–15.

5. Ramos A, Galvao, NM, Galvao M, Evangelista, LF et al. (2010) Laparoscopic greater curvature plication: initial results of an alternative restrictive bariatric procedure. Obesity Surgery 20 (7): 913–8

6. ASMBS Policy Statement on Gastric Plication (2011) American Society for Metabolic and Bariatric Surgery. Available from http://asmbs.org/guidelines-statements [accessed 16 February 2012]

Appendix A: Additional papers on laparoscopic gastric plication for the treatment of severe obesity

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Huang CK, Lo CH, Shabbir A and Tai CM (2012). Novel bariatric technology: laparoscopic adjustable gastric banded plication: technique and preliminary results. Surgery for obesity and related diseases 8 (1): 41–5	N=26 Follow-up: mean 8 months	Two complications developed: gastrogastric intussusception and tube kinking at the subcutaneous layer. Both cases were corrected by reoperation. No mortality was observed. Laparoscopic adjustable gastric banded plication provides both restrictive and reductive effects and is reversible. The technique is safe, feasible, and reproducible and can be used as an alternative bariatric procedure.	The technique described involved an adjustable gastric band, therefore the procedure is different from the focus of the guidance. In addition it is not possible to identify from the abstract what the timing of the complication was.
Huang CK, Asim S and Lo CH (2011) Augmenting weight loss after laparoscopic adjustable gastric banding by laparoscopic gastric plication. Surgery for Obesity and Related Diseases 7 (2): 235–6	No details	No abstract	
Hussain A, Mahmood H and El-Hasani S (2010). Gastric plication can reduce slippage rate after laparoscopic gastric banding. Journal of the Society of Laparoendoscopic Surgeons 14 (2): 221–7	N=464 Follow up: mean 26 months	Laparoscopic gastric plication adds greater security and provides optimum gastric band placement. It is an effective method to reduce slippage after gastric band insertion.	Reports on gastric plication after laparoscopic gastric banding.
Zagzag J, Schwack BF, Youn H et al. (2012) Does adding a lesser-curvature gastrogastric plication suture reduce the need for revision after laparoscopic adjustable gastric band placement? Surgical Endoscopy 26 (2): 514–7	N=1365 laparoscopic adjustable gastric band patients Follow-up: mean 22 months	Adding gastrogastric plication sutures offers no benefit of reducing the rate of revision after laparoscopic adjustable gastric band surgery.	Reports on improving technique of laparoscopic adjustable gastric band using gastric plication.

Hii MW, Clarke NE et al. (2012) Gastrogastric herniation: an unusual complication following greater curve plication for the treatment of morbid obesity. Annals of Royal College of Surgery England 94:e76-e78.	Study design=case report n=1 Study population= patient with failed weight loss after gastric banding. Technique= laparoscopic gastric curve plication. Follow-up = post-operative up to 5 days.	Severe nausea and vomiting occurred due to excessively tighter greater curve plication. Two gastrogastric hernias developed through the plication suture. Stitch was removed and a re-imbrication performed. Patient symptoms settled and discharged after 72 hours tolerating a liquid diet.	Larger studies included in table 2 (complication already reported in table 2).
Watkins BM (2011) Gastric compartment syndrome: an unusual complication of gastric plication surgery. Surgery Obesity Related Disorders Sep 10.	No details		No abstract, Unavailable due to copy right restrictions.
Tsang A, Jain V. (2011) Pitfalls of bariatric tourism: a complication of gastric plication. Surgery for obesity and related diseases: official journal of the American society for bariatric surgery.	No details		No abstract, Unavailable due to copy right restrictions.

Appendix B: Related NICE guidance for laparoscopic gastric plication for the treatment of severe obesity

Guidance	Recommendations
Clinical guidelines	**Obesity: Guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. NICE clinical guideline 43 (2006)** **1.2.6 Surgical interventions** **Adults and children** 1.2.6.1 Bariatric surgery is recommended as a treatment option for people with obesity if all of the following criteria are fulfilled: • they have a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight • all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months • the person has been receiving or will receive intensive management in a specialist obesity service • the person is generally fit for anaesthesia and surgery • the person commits to the need for long-term follow-up. See recommendations 1.2.6.12 and 1.2.6.13 for additional criteria to use when assessing children, and recommendation 1.2.6.7 for additional criteria for adults. 1.2.6.2 Severely obese people who are considering surgery to aid weight reduction (and their families as appropriate) should discuss in detail with the clinician responsible for their treatment (that is, the hospital specialist and/or bariatric surgeon) the potential benefits and longer-term implications of surgery, as well as the associated risks, including complications and perioperative mortality. 1.2.6.3 The choice of surgical intervention should be made jointly by the person and the clinician, and taking into account: • the degree of obesity • comorbidities • the best available evidence on effectiveness and long-term effects • the facilities and equipment available • the experience of the surgeon who would perform the operation. 1.2.6.4 Regular, specialist postoperative dietetic monitoring should be provided, and should include: • information on the appropriate diet for the bariatric procedure • monitoring of the person's micronutrient status • information on patient support groups • individualised nutritional supplementation, support and

	guidance to achieve long-term weight loss and weight maintenance. 1.2.6.5 Arrangements for prospective audit should be made, so that the outcomes and complications of different procedures, the impact on quality of life and nutritional status, and the effect on comorbidities can be monitored in both the short and the long term. 1.2.6.6 The surgeon in the multidisciplinary team should: • have undertaken a relevant supervised training programme • have specialist experience in bariatric surgery • be willing to submit data for a national clinical audit scheme.

Appendix C: Literature search for laparoscopic gastric plication for treatment of severe obesity

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	19/04/2012	Issue 3 of 12, Mar 2012	1
Database of Abstracts of Reviews of Effects – DARE (CRD website)	17/04/2012	-	0
HTA database (CRD website)	17/04/2012	-	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	19/04/2012	Issue 4 of 12, Apr 2012	22
MEDLINE (Ovid)	17/04/2012	1946 to April Week 1 2012	56
MEDLINE In-Process (Ovid)	17/04/2012	April 16, 2012	61
EMBASE (Ovid)	17/04/2012	1980 to 2012 Week 15	63
CINAHL (NLH Search 2.0 or EBSCOhost)	17/04/2012	-	24

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

MEDLINE search strategy

1 plication*.tw.

2 (GCP or LTVGP or LGCP).tw.

3 (gastr* adj1 (sleeve* or imbrication* or pleat*)).tw.

4 1 or 2 or 3

5 Laparoscopy/

6 Laparoscopes/

7 Surgical procedures, Minimally Invasive/

8 (laparoscop* or peritoneoscop* or celioscop*).tw.

9 5 or 6 or 7 or 8

10 Bariatric Surgery/mt [Methods]

11 ((bariatric* or restrictive) adj3 (surger* or procedur*)).tw.

12 10 or 11

13 exp Obesity/

14 (obes* or ((over adj2 weight) or over-weight or overweight)).tw.

15 (overeat* or over eat* or over-eat*).tw.

16 Weight Gain/

17 ((weight adj2 gain*) or (weight adj2 los*)).tw.

18 weight chang*.tw.

19 ((bmi or body mass index) adj2 (gain* or los* or chang*)).tw.

20 13 or 14 or 15 or 16 or 17 or 18 or 19

21 4 and 9

22 4 and 12

23 21 or 22

24 23 and 20

25 animals/ not humans/

26 24 not 25

27 limit 26 to ed=20120124-20120430