The effect of gastric plication on obesity and diabetes mellitus type 2: a systematic review and meta-analysis

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2. Summary

Author: Hauke Heinrich Georg Meyer
Title: The effect of gastric plication on obesity and diabetes mellitus type 2: a systematic review and meta-analysis

Aim: To compare and summarize the current data in the literature in regards to the effect of gastric plication on obesity and diabetes mellitus type 2.

Objectives:
1. To estimate the short term and long term weight loss in patients, who underwent gastric plication procedure.
2. To evaluate the changes in HbA1c and necessity of antidiabetic drugs and/or insulin therapy after gastric plication procedure.
3. To investigate the possible improvement of comorbidities.

Methodology: The systematic review was performed according to the PRISMA guidelines and registered at PROSPERO under the registration number: CRD42018114314. The literature was searched and reviewed systematically using the MEDLINE (PubMed) and BJS databases for studies published in the last 10 years (from 2010 to 2018). Older studies were excluded. Various text words and medical subject headings (MeSH) terms were selected. Statistical analysis was performed using RevMan version 5.3.

Study participants: No patients were included in this study.

Results:
Mean preoperative BMI ranged from 34.42 to 46.3 kg/m^2. Most of the patients were female. The operation time was in a range from 50 to 192.23 minutes. Mean follow up was from one month till 12 years, with most studies having a follow up of less than 2 years. The postoperative BMI ranged from 28.59 -38, with reported excess weight loss (EWL%) ranging from 20-70%.
HbA1c values decreased to up to 5.1% after surgery, ranging from 5.1 -7.5%.

Conclusion:
While it is reassuring to note short-term effectiveness of LGCP, the quality of most of the studies was low, with a general lack of control data, many data gaps including follow-up of patients, follow up time, and even the measures of variance and standard deviation were absent in multiple studies. There is a big need for a higher level of evidence regarding the effect of LGCP, especially in the long term. In the present meta-analysis it was shown that, in the short term, gastric plication is an effective measure for weight loss, while the effect on diabetes mellitus type 2 is statistically not significant.
3. Conflicts of Interest

The author reports no conflicts of interest.

4. Ethics Committee Clearance

No ethics committee clearance was needed for the conduction of this study, as no patients were involved.
5. Abbreviation list

LGCP – Laparoscopic greater curvature plication.
BJS – British journal of surgery
DM T2 – diabetes mellitus type 2
BMI – body mass index
EBMIL – excess body mass index loss
TWL – total weight loss
EWL – excess weight loss
LSG – laparoscopic sleeve gastrectomy
AGB – adjustable gastric banding
BPD – biliopancreatic diversion
RYGB- Roux-en-Y gastric bypass
mo – months
p – the level of significance (probability value)
6. Terms

Bariatric surgery - weight loss surgery.
Biliopancreatic diversion with duodenal switch – malabsorptive surgical weight loss procedure for morbid obesity.
Forrest plot - graphical display of estimated results from a number of scientific studies addressing the same question.
Gastric plication - restrictive procedure for morbid obesity that shrinks the size of the stomach by making large folds.
Laparoscopy – a type of minimally invasive surgery inside the abdomen or pelvis using small incisions with the aid of a camera.
Morbid obesity – body mass index over 40kg/m² or >35kg/m² with obesity-related health conditions
PRISMA guidelines – the evidence-based minimum set of items that help authors to report a wide array of systematic reviews and meta-analyses.
PROSPERO – a database of systematic review protocols of reviews currently being undertaken.
Random effect model – statistical model with random variables as parameters.
Sleeve gastrectomy – a type of restrictive weight loss surgery for morbid obesity.
Vertical banded gastroplasty – a type of weight loss surgery for morbid obesity.
7. Introduction

Overweight and obesity is a growing problem worldwide. Since 1975 obesity has almost tripled [1]. In 2016 1.9 billion adults (>18 years old) were overweight, with 650 million being obese (BMI \( \geq 30 \)). Overall, that makes 13\% of the population of the world being obese in 2016 [2]. Alongside obesity, diabetes type 2 is also increasing in prevalence, with an estimated 422 million adults suffering from diabetes in 2014, which is around 8\% of the world's adult population. Studies estimate a further increase in diabetes until 2030 [1].

Overweight and diabetes are managed with multiple conservative as well as surgical procedures, where surgical procedures showed a clearly better result in terms of reduction of body fat and a decrease in comorbidities [3], [4], [5].

As of now, bariatric surgery is the only solution for sustained weight loss and decreasing comorbidities in the morbidly obese [6]. All the bariatric surgeries evolved greatly over the past decades, ranging from jejunoileal bypass related procedures over Roux – en – Y bypass to restrictive procedures like sleeve gastrectomy. A rather new approach in bariatric surgery is the laparoscopic greater curvature plication (LGCP)[7]. Gastric plication was first described by Tretbar et al. [8] in 1976 as surgery for the treatment of obesity and was initially done in an open way. The laparoscopic approach was proposed by Talebpour et al. [9] and is gaining growing interest as an alternative to other bariatric surgeries.

New studies have shown, that LGCP has low postoperative complications, improves comorbidities of the patients and has the advantage of not resecting part of the stomach and thus being less invasive and potentially reversible [10].

The aim of this study was to compare and summarize the current literature in regards to the outcomes of gastric plication in obesity and diabetes mellitus type 2.
8. Aim and objectives of the Thesis

Aim:
To compare and summarize the current data in the literature in regards to the effect of gastric plication on obesity and diabetes mellitus type 2.

Objectives:

1. To estimate the short term and long term weight loss in patients, who underwent gastric plication procedure.
2. To evaluate the changes in the necessity of antidiabetic drugs and/or insulin therapy after the gastric plication procedure.
3. To investigate the possible improvement of comorbidities.
9. Literature review

Bariatric surgery is an effective measure to decrease body weight and treat obesity-related comorbidities, such as diabetes mellitus type 2. Aside from the benefits for physical health improvement, it also causes improvement in a person's functional and psychological health. [11] Respectively, bariatric surgery evolved to not only treating obesity but also for improvement in glycemic control, inducing DM T2 remission or improvement. [12],[13] Current guidelines state, that bariatric surgery is indicated for obese patients with a BMI over 35kg/m² with obesity-related comorbidities, or patients with a BMI of over 40kg/m² without associated comorbidities. [5]

The way of action of bariatric surgery is to reduce weight by either restriction of intake of food, malabsorption of food, or a combination of both.

Mostly the success or failure of those bariatric procedures is expressed as weight loss or changes in comorbidities. [14]

Many different surgeries exist to fulfill those purposes. As of today, frequently used procedures in the world are gastric bypass, sleeve gastrectomy, biliopancreatic diversion with duodenal switch and gastric banding. [15] All of these procedures are mostly performed laparoscopically. [16]

Laparoscopic surgery has the advantage to be less invasive, which leads to a shorter hospital stay, faster recovery time and fewer complications. [17]

Adjustable gastric banding is one of the restrictive bariatric surgeries, in a way that it restricting the food intake per meal. In this procedure, the stomach itself stays intact, with the adjustable band being introduced below the gastro – esophageal junction and held in place by gastro – gastro sutures. [18] The Roux-en-Y gastric bypass is one of the most common gastric bypass procedures. It is a combined procedure, with a restrictive as well as malabsorptive technique, since it creates a smaller gastric pouch as well as a bypass, preventing full absorption of food. The Roux-en-Y procedure leaves a part of the upper stomach using surgical staples to make a small pouch and a small exit to the intestine. [19]

Complications of gastric bypass include staple line or anastomotic leak, postoperative hemorrhage and bowel obstruction. [20]

Biliopancreatic diversion with duodenal switch is a malabsorptive type of bariatric surgery, which is proven to be very effective for extremely obese patients. In this procedure, a partial gastrectomy is combined with transsection of the duodenum, a gastroenterostomy creating an alimentary limb which is anastomosed with a biliopancreatic limb is performed. This combination results in the highest weight loss, but is also associated with more postoperative complications and is mainly recommended as a second stage procedure. [21]
Sleeve gastrectomy is a primarily restrictive procedure, which was first planned to be a first stage operation, being followed by either gastric bypass or duodenal switch. Later on, it was noticed to be effective enough as a stand-alone procedure for weight loss. The idea behind sleeve gastrectomy is to divide the stomach to decrease its size, while leaving the pyloric valve intact, allowing a normal stomach function and digestion. [22]

A long term meta-analysis from 2018 found that bariatric surgery is an effective tool for durable weight loss, with BPD with or without DS having the highest weight loss, followed by RYGB and LAGB. However, this study had little data on sleeve gastrectomy and none on LGCP. [23]

Laparoscopic greater curvature plication is a newer bariatric procedure which also reduces the stomach volume, but without any resection of the stomach. [24]

The greater curvature of the stomach is folded into itself and fixed with one or multiple rows of stitches, resulting in a restrictive effect as seen in the sleeve gastrectomy, although the weight loss is inferior for LGCP. [25]

For now, there is no standardized technique for LGCP, however, there are 2 main steps for the operation. Firstly the greater curvature of the stomach has to be mobilized, being followed by a plication (suturing) of the gastric fold. [26], [27], [28], [29], [30]

Fried et al., and Gudaityte [29], [31] found no significant differences between single-row plications compared to two-row plications for the effectiveness and safety of the procedure.

The literature is still controversial as for which type of suture is better, with some studies reporting two rows of running sutures [26], others two rows of interrupted sutures [28], [27], [32] and some reporting a combination of both running and interrupted sutures. [30]
10. Research methodology and methods

Methods:
The systematic review was performed according to the PRISMA [33],[34] guidelines and registered at PROSPERO [35] under the registration number: CRD42018114314.

Systematic search strategy
The literature was searched and reviewed systematically using the MEDLINE (PubMed) and BJS databases for studies published in the last 10 years (from 2010 to 2018).
Various text words and medical subject headings (MeSH) terms were selected (Table 1).

Table 1. Search terms

<table>
<thead>
<tr>
<th>Terms</th>
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<td>&quot;Gastric plication&quot;, &quot;Gastric plicature&quot;, &quot;Great curvature plication&quot;, &quot;Gastric vertical plication&quot;, &quot;Laparoscopic gastric greater curvature plication&quot;, &quot;Laparoscopic gastric plication&quot;, &quot;diabetes Mellitus“, &quot;diabetes“, &quot;diabetes surgical treatment“, „obesity“, „surgical treatment for obesity““, „type 2 diabetes mellitus“, „bariatric surgery““, „morbid obesity“</td>
</tr>
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</table>

Eligibility:
Studies, which reported the long or short- term effect of gastric plication surgery on objectively measured weight loss, were included; changes in the pharmaceutical treatment of diabetes mellitus after gastric plication, changes in Insulin secretion and need of additional insulin therapy after gastric plication were investigated.
Studies published earlier than 10 years ago, studies focusing on other bariatric surgeries and animal studies were excluded. Abstracts, unpublished studies, guidelines, newspaper articles, small case reports and studies where the full text was unavailable were also excluded.

Study selection
From November 2017 till December 2018, the databases were searched using the keywords mentioned in Table 1. Terms were combined using the words „and“ and „or“.
The author screened the titles for eligibility. First, the abstracts were screened for relevance; seemingly relevant abstracts were screened in the full text. Disagreements were solved by consensus and discussion.
In the case of duplicated publications, the most complete and recent studies were selected.
The primary and secondary outcomes were extracted from the full texts.
Methodological quality
The author assessed the bias risk and quality of included studies, by considering the following characteristics: completeness of outcome data, specificity of studied intervention, missing patient characteristics and other sources of bias.

Outcome measures
The primary outcomes, objective weight loss and changes in the therapy of diabetes mellitus type 2 (DM T2), were extracted from the included articles. Data on the number of patients who underwent gastric plication and follow up weight loss as well as changes in the treatment of diabetes were obtained.
Secondary outcomes were the time frame of effect, complications after surgery.

Quality appraisal
The selected studies were appraised according to the PRISMA statement. Controlled were incomparable groups, information bias because of incomplete or inadequate outcome measures and selection bias by incomplete follow-up.
The final decision regarding the inclusion of the articles was reached in a meeting; discrepancies were solved in a consensus manner.

Statistical analysis
A random effect model was used to pool the different outcomes of the studies in order to show an overall outcome of weight loss and change in diabetes treatment.
To estimate heterogeneity between the included studies, tau values in the Forrest plots were used.
All statistical analysis was performed using RevMan version 5.3.
11. Results

Included studies

Using the above-named search terms, 338 publications were found. After exclusion of 321 articles, the remaining 17 articles were chosen for further reading. 3 articles did not match the criteria for critical appraisal. The remaining 14 articles were read in full text and extracted for data.

Study characteristics

The 14 studies included 2071 patients. Most articles varied strongly in sample sizes, ranging from 13 – 800 patients. Most of the studies included women and men, while one study included women only [36]. All of the remaining 13 studies had a majority of female patients. 5 studies only investigated the effect of gastric plication on weight loss and only 1 study reported only outcomes on diabetes mellitus type 2.

Fig. 1

PRISMA diagram showing the selection of articles for review
Only one study was conducted in Lithuania, with the majority of studies published in the Czech Republic.

All studies had participants with a mean preoperative body mass index (BMI) of >35, with only one study from China reporting a mean preoperative BMI of 34.42. The highest preoperative BMI was in Lithuania with 46.3. [31]

Seven studies had a follow up of one year or less, two studies reported a follow up to 2 years and five studies presented data of a follow-up period of over 2 years. Only 2 studies reported a follow up of over 5 years.

Time of surgery varied over the studies, from around 50 minutes [28] to 192.23 minutes [32].

The outcome measurement differed among the included studies, some using preoperative and postoperative BMI, others excess body mass index loss (EBMIL), total weight loss (TWL) or others for weight loss and HbA1c changes, withdrawal or decrease in oral antidiabetic drugs and/or insulin for diabetes mellitus type 2 respectively.

Seven studies reported the weight loss using pre and postoperative BMI measurements, 5 reported weight loss in percent, either as EBMIL or excess weight loss (EWL), one study reported weight loss as the amount of kilograms lost. Only one study did not report the outcomes of weight loss.

Five studies did not investigate the outcome of gastric plication on diabetes mellitus type 2.

Six studies reported the effect by means of pre and postoperative HbA1c values.

The remaining 3 studies reported the outcome as the percentage of patients achieving either remission or improvement of diabetes mellitus type 2 by means of reduced or withdrawn medications.

Only 4 studies compared the BMI pre- and postoperative, indicating the standard deviation and only 4 mentioned the standard deviations in regards to HbA1c values. Other studies did not report standard deviations, used different units to display the weight loss and effect on diabetes mellitus type 2, or did not report one of the outcomes.

In this review, the mean preoperative BMI was ranging from 34.42 to 46.3.

The preoperative BMI was in the lower range, with only one study having a BMI >45 kg/m2. Of importance is, that there might be a correlation between the higher preoperative BMI and weight loss, with one study pointing out, that the total EWL was higher in a group with a preoperative BMI of <45 when compared to a group who had a BMI of >45kg/m2. [27]

In a recent study from Lithuania, Gudaityte et al. [31] investigated the intermediate results of LGCP in 61 patients with a mean preoperative BMI of 46.4. In their 3 years follow up, they concluded, that LGCP has only a moderate effect on weight loss, with an EBMIL% of 47.25%, 44.8%, 41.9% at 1,2 and 3 years, respectively. They also stated, that of the 19 patients having diabetes preoperative, the HbA1c values decreased from 7.8 to 6.8 after 3 years (p=0.001). In this sample size, 72.3% of the preoperative diabetics achieved either remission or improvement after the surgery, with 27% of
patients undergoing the procedure achieving DM T2 remission. Other comorbidities also improved after the surgery, with 38.3% achieving remission and 29.8% reaching improvement in hypertension. Other studies showed an improvement of other comorbidities after gastric plication, showing improvement or remission in hypertension, hypercholesterolemia, gastroesophageal reflux and other. A research by Ospanov et al. [37] published in 2016 assessed the connection between gastric greater curvature plication combined with Nissen fundoplication effect on obesity and other comorbidities such as diabetes mellitus, hypercholesterolemia, and gastroesophageal reflux. Apart of the clear effect on weight loss, a significant amount of patients showed remission and/or improvement of type 2 diabetes mellitus (p=0.03), hypercholesterolemia (p=0.0001) and gastroesophageal reflux (GERD) subjective symptoms, caused by esophagitis (p=0.0001).

While most studies prove LGCP as safe and feasible in the short term treatment of obese people with and without DM type 2 [31], [37], [27], [38], [26], [39], [29], [28], [40], [30], [36], other studies point out the risks of weight regain threatening the procedure to be unsustainable and inferior in longer term. [28], [26], [40] The main risk factor for weight regain is dependent on the patients' lifestyle post operation [26].

Most studies only had a short term follow up period of 1 – 18 months [28], [29], [30], [32], [36], [37], [39], [41], [42] which showed an effective decrease in weight and improvement or remission in diabetes mellitus over that time. Only 5 studies studied the outcomes after gastric plication for a longer period of time, 4 of which for an intermediate term follow up of up to 5 years, and only one study with a follow up of 10 years.

The long term study from Talebpour [26] showed acceptable results as a method to treat morbid obesity, however, pointed out that there is a tendency of weight regain after 4 and 5 years after the surgery. Complication rates are low [31], [38], [26], [29], [28] while the costs are significantly less for LGCP than for other types of bariatric surgery [27], [26] All studies determined that the side effects were mostly nausea and vomiting, with the complications and failure of the procedure being related to the preoperative BMI (p=0.063) [27].

Dolezalova et al. [38] had the longest follow up of the studies from the Czech Republic, with a follow-up time of 5 years. With a significant BMI decrease for the first 2 years (p<0.001), it proved LGCP to be effective in short-term. A plateau from 3-4 years and an increase (p<0.01) in BMI at 5 years postoperatively, however, showed a less successful outcome in medium and longer term (p<0.001). Along with other studies focusing on the effect on diabetes mellitus type 2 from the same country, the authors indicated LGCP to be feasible and effective in the treatment of diabetes mellitus type 2, with an improvement rate of 65.5% at 5 years in the 57 patients who had diabetes mellitus type 2 before the surgery. Short-term effect on diabetes mellitus type 2 was shown in a reduction in oral hypoglycemic agents and/or insulin intake. Buzga et al. [42] found a 90% decrease in the use of oral hypoglycemic
agents, which proved LGCP to be superior to other bariatric surgeries, however, pointed out that the sample size of patients was insufficient to make a definitive statement about the effectiveness of LGCP. However, another study by Taha et al. [28] reported the HbA1c levels of 7.5% postoperatively compared to 7.9% preoperatively, in 55 patients at 12 months, with no patients withdrawing their hypoglycemic medications.

Two small studies [36], [41], focusing on the effect on diabetes mellitus type 2 after LGCP, estimated an improvement in 6 months follow up not only in DM type 2 but also in the metabolic profile of the patients. In both studies, GIP levels increased after the plication, with Vrbikova [41] reporting a decrease of C peptide as a marker of DM T2 after LGCP and Bradnova [36] finding a statistically significant decrease in HbA1c (p<0.0001) and improvement of hyperglycemia (p<0.05).

DM T2 was resolved in 4/20 (20%) patients and improved in 12/20 (60%) after 6 months in the plication group. Total insulin secretion did not change significantly for the plication group (p<0.001). While both showed an effective weight loss after the procedure, Vrbikova et al. [41] found a less markedly decrease in BMI and waist circumference when compared to BPD (p<0.001).

One study [38] tried to determine the difference of effects by determining cluster groups according to age and BMI preoperatively. The most successful weight loss was in a cluster of young females (<50 years old), with a mean BMI of 38.5. The study estimated the probability of success after surgery to be higher the lower the preoperative body fat percentage is, with a person with 50% body fat percentage preOP had a chance of success of 90%, a person with 60% had only a 50% chance of success after LGCP (p<0.001).

A longer follow up study with 12 months follow up on DM T2, showed LGCP to be effective for DM T2 improvement, with 33% of patients discontinuing oral hypoglycemic medication and insulin and 88% reaching a target HbA1c of <4.8%. [42]

The biggest study from the Czech Republic [29] with 244 patients, but a shorter follow up with only up to 18 months described LGCP to be feasible for weight loss and improvement of DM T2, with HbA1c reducing to 5.1 (p<0.001) and EBMIL of 31-4% (p<0.001). At 6months, the BMI decreased to 36.1 from preoperatively 41.4. Also, 96.9% of patients that had DM T2 achieved remission or improvement by 6 months after surgery. The authors found a correlation with higher preoperative BMI leading to less weight loss, however by 9 months follow up there seemed to be no statistically significant difference in their sample size.

Critical appraisal showed a lack of information especially on long and intermediate term follow up and a high risk of bias, due to different follow-up times, sample sizes and outcome reporting methods.
There are many limitations to this study. Especially a lack of long term follow up makes it difficult to predict the true effect of gastric plication. Also in the current literature, there is a lack of high-quality data concerning long, but also short-term outcomes of gastric plication.

The majority of the included studies have a low number of patients included. Although this study includes 2071 patients, only 5 studies had over 100 patients. Furthermore, there is a high need for medium- and long- term follow-ups regarding LGCP, with only 2 studies reporting a follow up of over 3 years.

Therefore, to make valid estimations, medium, and long term follow up studies with larger sample sizes and a standardized method of outcome reporting is needed.

This meta-analysis is trying to give an overview of the current literature of this novel procedure.

Meta-analyses
The Meta-analysis was performed for those studies where the standard deviations were reported and comparable outcome data was provided and where more than two studies were available for the time outcome.

The outcomes of weight loss and improvement or remission of diabetes mellitus type 2 are presented in forest plots. The lowest postoperative weight loss was a loss of 2.9 BMI after 1 month follow up [36] The highest weight loss was 9.93 kg/m² loss of BMI postoperative (95%CI).

An overall test for heterogeneity between the included studies was performed in each forest plot and gave consistently significant results (I² values in Figures 2-8).

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Pre - surgery Mean</th>
<th>Pre - surgery SD</th>
<th>Post - surgery Mean</th>
<th>Post - surgery SD</th>
<th>Std. Mean Difference IV, Random, 95% CI Year</th>
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<td>29.62</td>
<td>4.94 135 25.1% 1.77 [1.48, 2.05] 2011</td>
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<td>244</td>
<td>35.6</td>
<td>4.7 244 26.9% 1.13 [0.94, 1.32] 2012</td>
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<td>3.1 212 26.9% 1.98 [1.65, 2.11] 2017</td>
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<td>Li 2018</td>
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<td>5.02</td>
<td>53</td>
<td>28.53</td>
<td>3.52 53 21.8% 1.35 [0.93, 1.77] 2018</td>
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<td>46.3</td>
<td>61</td>
<td>0</td>
<td>61</td>
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**Figure 2: Influence of LGCP on BMI**

Random effect forest plot illustrating the total effect of LGCP on weight loss. Weight is put in values as BMI preoperative and postoperative where available. Only four studies illustrated the pre and postoperative BMI values with standard deviations. The other studies are listed, but not included in the statistical analysis. The I² value shows a high heterogeneity between the studies.
Figure 3: 6 months outcomes of LGCP on BMI
Random effect forest plot indicating the effectiveness of LGCP in terms of BMI change after the surgery at 6 months. Only two studies illustrated the 6-month outcome on weight loss reporting BMI values with standard deviation. Other studies were not included to reduce heterogeneity.

Figure 4: 12 months outcomes of LGCP on BMI
Random effect forest plot representing the effectiveness of weight loss after LGCP at 12 months postoperatively. One additional study reported the BMI with standard deviations after surgery. Heterogeneity between the three included study is high ($I^2 = 92\%$).

Figure 5: Influence of LGCP on diabetes mellitus
Random effect forest plot showing the effect of LGCP on HbA1c values after surgery. Only the studies representing data with their standard deviation were included in the statistical analysis. $I^2$ value shows a high heterogeneity between the studies.
Figure 6: 3 months outcome of LGCP on HbA1c
Random effect forest plot summarizing the effect of LGCP on HbA1c at 3 months post surgery. There is a very high heterogeneity between the studies ($I^2 = 99\%$). These results are also not statistically significant, as the 95% CI involves the null value.

Figure 7: 6 months outcome of LGCP on HbA1c
Random effect forest plot summarizing the effect of LGCP on HbA1c at 6 months post surgery. There is a very high heterogeneity between the studies ($I^2 = 99\%$). These results are also not statistically significant, as the 95% CI involves the null value.

Figure 8: 12 months outcome of LGCP on HbA1c
Random effect forest plot summarizing the effect of LGCP on HbA1c at 12 months post surgery. There is a very high heterogeneity between the studies ($I^2 = 99\%$). These results are also not statistically significant, as the 95% CI involves the null value.
12. Discussion

The current data show that LGCP has a promising short-term result for weight loss and that there might be certain advantages of gastric plication over other existing bariatric surgeries such as sleeve gastrectomy, gastric banding, and gastric bypass. Possible advantages are the possibility for reversibility, lack of resection, lower invasiveness and lower cost.

It should be noted, that despite those advantages LGCP cannot eliminate the risks of complications completely.

Another advantage of LGCP is, that there is no problem of second stage operation in cases of insufficient weight loss.

Although the risk and number of complications are low, evidence shows that LGCP is inferior and less sustainable than other bariatric surgeries, mainly LSG and AGB. [28]

Weight regain started at 6-12 month [28] and was most evident at 4-5 years postoperative. [26]

Longer term effect of gastric plication on weight loss is not depended mostly on the type of bariatric surgery but on the ability of the patient to follow and keep the lifestyle changes. [26]

Intermediate follow up results showed only a modest weight loss, increased hunger being the main risk factor for unsatisfactory weight loss. [31]

The remission of diabetes in most studies was based on the HbA1c value decreasing postoperatively (>0.5 decrease), which showed a mean decrease in HbA1c of 1.625 over the 6 studies[29], [31], [32], [39], [41], [28]. Other studies determined DM T2 remission by either withdrawal of medication and/or insulin.

Skredas et al. [27] followed the weight loss after LGCP for 2 years, showing a marked decrease of EWL, with a loss of 51.7% at 6 months and 67.1% at 12 months respectively. Ramos et al. [30] found a similar effect in the short term, reaching an EWL up to 62% at 18months. However, the decrease became less marked in longer follow up (65.1% at 24 months). This is in accordance with other long-term studies [26], [38]. They also found that the higher the preoperative BMI, the inadequate weight loss was doubled when compared to a control group with a BMI under 45 (p=<0.001). The effectiveness of the procedure was not affected by a single (21.4% insufficient weight loss) or multiple plications (21.5% insufficient weight loss).

The study from China [32] showed a less prominent effect on a weight loss (with a lower BMI and EWL, p<0.001), with LGCP having a less marked decrease in EWL at 12 months, compared to LSG.(p=0.010). Initial weight loss, at 1 month follow up, was similar for both procedures, but later the effect LGCP declined with LSG having a greater EWL at 3 (p=0.008), 6 (p=0.032) and 12 (p=0.010) months, respectively. Li et al. found no significant difference in HbA1c and other blood sugar profiles pre and postoperatively after LGCP (p <0.05) [32].
Studies from the Czech Republic in contrast to the one from Asia found LGCP to be effective in the short term in regards of weight loss and showed a clear improvement of diabetes mellitus type 2 and other comorbidities after undergoing the surgery.

Talebpour, who introduced the laparoscopic gastric plication, published multiple studies to this procedure [26], [39]. In his 2012 [26] study, the biggest one up to date, he found LGCP to be effective in short-term treatment of obesity. He achieved an EWL loss of 70% after 2 years, 55% after 5 years. This tendency already proved a weight regain after LGCP in the longer term, with 5.5% of patients experiencing an increase in weight after 4 years, and a whole 31% after 12 years. In conclusion, they found LGCP to be comparable to other restrictive procedures in terms of EWL. It is safe (1.6% complication) and cheap. The advantages are that it is reversible and can be combined with other additional malabsorptive methods in case of insufficient weight loss.

What has to be pointed out, that this data is not the most accurate, due to a high drop out of patients in the long-term follow-up.

In a later, short term follow up study [39], LGCP was not only found effective in the short term for obesity, with a weight loss of 57kg after 6months but also for other comorbidities. All of the 60 included patients suffering from DM T2 achieved either remission (92%) or improvement (8%). There was a marked decrease in Blood pressure (p=0.001), HbA1c (p=0.002), weight (p=0.001), total cholesterol (p=0.001) and triglycerides (p=0.001).

A similar study design from Egypt [28], determined an EWL of 35% after 12 months, with BMI decreasing to 38 from preoperative 43.5. However the trend of insufficient weight loss and weight regain after intermediate and long term follow up was found here already after 6 months, with 23% of patients stopping to lose weight at 6 months, and 11% regaining weight after 9months. For DM T2 they found LGCP to be an inferior restrictive procedure, with no patients stopping their oral hypoglycemic medications.
13. Conclusion

While it is reassuring to note short-term effectiveness of LGCP, the quality of most of the studies was low, with a general lack of control data, many data gaps including follow-up of patients, follow-up time, and even the measures of variance and standard deviation were absent in multiple studies. There is a big need for higher levels of evidence regarding the effect of LGCP, especially in the long term. The effectiveness of LGCP should also be evaluated in an economical way, since, although cheap, the good results are only in short term.

In the present meta-analysis it was shown that, in the short term, gastric plication is an effective measure for weight loss, while the effect on diabetes mellitus type 2 is statistically not significant. LGCP decreases comorbidities related to obesity.
14. References


## 15. Annexes

### Annex 1: Table summarizing the included studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>N</th>
<th>Mean preoperative BMI (kg/m²)</th>
<th>Weight loss (follow up in months)</th>
<th>Diabetes mellitus</th>
<th>Dynamic</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 m.</td>
<td>3 m.</td>
<td>6 m.</td>
</tr>
<tr>
<td>M. Fried et al., Czech Republic</td>
<td>244</td>
<td>41.4</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>R. Gudaityte et al., Lithuania</td>
<td>61</td>
<td>46.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Yu-Hsien Li et al., China</td>
<td>53</td>
<td>34.42</td>
<td>31.22 (-3.2)</td>
<td>29.88 (-4.54)</td>
<td>28.67 (-5.75)</td>
</tr>
<tr>
<td>M. Talebpour et al., Iran</td>
<td>60</td>
<td>42.4</td>
<td>-</td>
<td>-42kg</td>
<td>-57.21kg</td>
</tr>
<tr>
<td>J. Vrbikova et al., Czech republic</td>
<td>20</td>
<td>42.4</td>
<td>39.5 (-2.9)</td>
<td>37.7 (-4.7)</td>
<td>-</td>
</tr>
<tr>
<td>O. Taha, Egypt</td>
<td>55</td>
<td>43.5</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>K. Dolezalova-Kormanova Et al., Czech republic</td>
<td>212</td>
<td>41.4</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>M. Bužga et al., Czech Republic</td>
<td>74</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>O. Ospanov et al., Kazakhstan</td>
<td>56</td>
<td>36.6</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>G. Skrekas et al., Greece</td>
<td>135</td>
<td>39.55</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>O. Bradnova et al., Czech Republic</td>
<td>13</td>
<td>40.1</td>
<td>36.1 (-4)</td>
<td>34.9 (-5.2)</td>
<td>-</td>
</tr>
<tr>
<td>M. Talebpour et al., Iran</td>
<td>800</td>
<td>41.2</td>
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<td>-45% of EW</td>
<td>-60% of EW</td>
</tr>
<tr>
<td>Ramos et al., Brazil</td>
<td>42</td>
<td>41</td>
<td>-20% of EW</td>
<td>-32% of EW</td>
<td>-48% of EW</td>
</tr>
<tr>
<td>Total</td>
<td>1831</td>
<td>Mean BMI 40.86</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
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