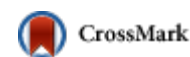


## Article

Surgical Endoscopy

pp 1-7



First online: 22 December 2015

# A matched cohort analysis of single anastomosis loop duodenal switch versus Roux-en-Y gastric bypass with 18-month follow-up

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10.1007/s00464-015-4707-7

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## Abstract

### Background

The Roux-en-Y gastric bypass (GBP) has been considered the gold standard for many years. The loop duodenal switch (LDS) is a relatively new procedure that simplifies the complexity of the duodenal switch (BPDDS) by making it a single anastomosis procedure while at the same time giving it more intestinal absorption to reduce the rates of malnutrition associated with traditional BPDDS. This paper seeks to compare the 18-month weight loss outcomes and complications of the more standard GBP with the newer LDS in a single US center.

### Methods

A retrospective matched cohort was analyzed on 108 patients who had either GBP (54 patients) or LDS (54 patients). Regression analysis was used to compare weight loss outcomes as measured by BMI and weight loss percentages. Complications gathered included bleeds, reoperations, diagnostic or therapeutic endoscopy (EGD), ulcers and chronic nausea.

### Results

GBP and LDS have statistically similar weight loss at 18 months (39.6 vs 41 % weight loss, respectively). However, there were significantly more nausea complaints (26 vs 5), diagnostic endoscopies (EGD) (21 vs 3) and ulcers (6 vs 0) with the GBP than the LDS.

### Conclusion

LDS has comparable weight loss results to GBP. However, LDS has fewer 30-day and 18-month complications and patients suffer from less nausea postoperatively.

## Keywords

Roux-en-Y gastric bypass – Loop duodenal switch – Endoscopies – Nausea – Match cohort

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## Background

The Roux-en-Y gastric bypass (GBP) has been widely regarded as the gold standard almost since its inception since it bridges the divide between complications, weight loss and durability. However, with the arrival of the sleeve gastrectomy (SG) many studies have recognized that it promises weight loss similar to a GBP with far fewer complications. Unfortunately, the SG has poor results in patients with BMI over 50 and has large standard deviations [1], meaning that many patients do well with the sleeve but just as many do not.

In 2011, Torres in Spain started performing the loop duodenal switch (LDS). The main reason was to simplify the duodenal switch (BPDDS). However, they postulated that it would have less weight loss than the BPDDS and be more comparable to the GBP. His first four papers showed great weight loss results and low complication rates [2–5].

In the USA, we began doing the LDS in 2013 after having done regular biliopancreatic diversions with BPDDS since 2011. We were satisfied with the weight loss of the BPDDS but unsatisfied with the frequency of diarrhea, smelly stools, flatulence and vitamin deficiencies of copper and zinc seen in our practice when compared to our gastric bypass patients. The LDS we believed allowed us to keep the weight loss we had seen with the BPDDS while eliminating most of the EGDs, strictures and ulcers we had seen with the GBP. We believed the weight loss would be similar or better than the GBP at 18 months. This retrospective matched cohort analysis at 18-month comparison of LDS vs GBP will test that hypothesis.

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## Methods

All patients in this study had either the loop duodenal switch (LDS) or the gastric bypass (GBP) at a single institution from 2011 to 2014. All LDS and GBP surgeries were performed by one of three surgeons at the same institution. All revisional cases of any type were excluded from this study. The surgical committee at our hospital did not feel like our modification of the BPDDS constituted experimental surgery; therefore, no IRB protocol was obtained.

The surgical technique used for GBP has been published previously [6, 7]. Briefly, we create a 5-cm pouch using a linear stapler and attach a 150-cm Roux limb using a 25-mm EEA technique and an Orvil device (Medtronic). Our biliopancreatic limb is 30 cm long. The surgical technique for LDS has significant variations from the LDS as published by Torres [2–5]. Briefly, although the anastomosis is the same, our common channel is 300 cm rather than 250 cm. The SG is over a 40-French bougie rather than a 56. This makes a smaller SG for greater restriction and a longer common channel for less chance of malabsorption. Torres had a 1 % malnutrition rate at 250 cm, and we hypothesized that it would be near zero at 300 cm [5]. Suture lines on the GBP and SG are not over sewn or buttressed.

Data were gathered retrospectively from a prospectively recorded database. This study is a matched cohort based upon BMI and gender. Criteria for inclusion were same gender with BMI within one point. If a patient did not have a match, they were excluded from this study; 108 patients met the inclusion criteria of this study (54 for each procedure). All patients included had at least three follow-up points after surgery.

Patients were selected for each surgery based on when they came in and the surgeon they chose. One surgeon in our

practice still actively performs GBP the same way our group has for 8 years. All patients of this surgeon had GBP. The two other surgeons in our practice began informing patients of the LDS option in 2013. Patients chose LDS based on an extensive preoperative educational experience and signed a specific informed consent detailing the LDS procedure that included a diagram of the proposed operation. Most who chose this option did so to mitigate internal hernia formation, ulcers, or wanted the ability to take NSAIDs postoperatively.

%WL and BMI were the data points measured for in this study. Demographic data from both procedures were compared using t tests. Comorbidities included in this study were sleep apnea, diabetes, GERD and hypertension. Differences in comorbidities were compared using Chi-squared tests.

All weight loss data were compiled and described through a nonlinear regression analysis. The regression was used to find the mean follow-up points for %WL and BMI at 3, 6, 9, 12, 15 and 18 months.

Complications gathered included, bleeds, reoperations, diagnostic or therapeutic endoscopy (EGD), ulcers, and chronic nausea. Chi-squared tests were then run to compare the comorbidities and gender ratios between the two procedures. Chi-squared tests and z tests were also used to compare complication rates.

All statistical analysis was run through SigmaPlot statistical software.

## Results

Demographically, the groups were not significantly different for weight and comorbid conditions with exception of diabetes, GERD and age (Table 1). Weight loss results between the procedures were statistically significantly similar for BMI and total body weight loss percentage (%WL) for every variable studied (Tables 2, 3; Figs. 1, 2).

**Table 1**

Demographic preoperative data for gender, weights, ages and BMI make up expressed as median  $\pm$  SD

	GBP	LDS	<i>P</i> value
<i>N</i>	54	54	
Male/female	16/38	16/38	1
Weight	301.5 $\pm$ 65.4	292.7 $\pm$ 59.9	.47
Age	46.7 $\pm$ 13.6	51.9 $\pm$ 13	.045
BMI	47.6 $\pm$ 8.8	47.6 $\pm$ 8.8	.99
Sleep apnea	23/54 (42 %)	31/54 (57 %)	.178
Diabetes	15/54 (28 %)	31/54 (57 %)	.004
GERD	19/54 (35 %)	34/54 (63 %)	.007

Hypertension	24/54 (44 %)	34/54 (63 %)	.082
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All comorbidities are expressed as percentage of patients with the comorbidity. Weight here is expressed in lbs., and BMI is expressed as kg/m<sup>2</sup>

**Table 2**

Patients' %WL is found for both procedures at 3, 6, 9, 12, 15 and 18 months

%WL	<i>R</i>	3 months	6 months	9 months	12 months	15 months	18 mo
LDS	.94	19.2	26.8	32.3	36.3	39.1	41
CI		(18.3, 20.1)	(25.7, 27.9)	(31.3, 33.4)	(35.4, 37.3)	(37.9, 40.3)	(39.3, 41.2)
GBP	.9	19.5	27.5	32.7	36.1	38.3	39.6
CI		(18.5, 20.5)	(26.3, 28.8)	(31.5, 33.8)	(34.6, 37.7)	(36, 40.6)	(36.6, 40.2)
<i>P</i> value		>.05	>.05	>.05	>.05	>.05	>.05

**Table 3**

Patients' data for mean BMI at 3, 6, 9, 12, 15 and 18 months between the two procedures are found in this table

BMI	<i>R</i>	3 months	6 months	9 months	12 months	15 months	18 months
LDS	.67	38.4	34.6	32.2	30.2	28.4	26.8
CI		(36.8, 40)	(32.9, 36.4)	(30.4, 34)	(28.7, 31.7)	(26.4, 30.3)	(24, 29.1)
GBP	.63	38.7	34.5	32	30.5	29.8	29.5
CI		(37.5, 39.9)	(33.2, 35.8)	(30.7, 33.3)	(28.8, 32.3)	(27.6, 31.9)	(27.2, 30.2)
<i>P</i> value		>.05	>.05	>.05	>.05	>.05	>.05

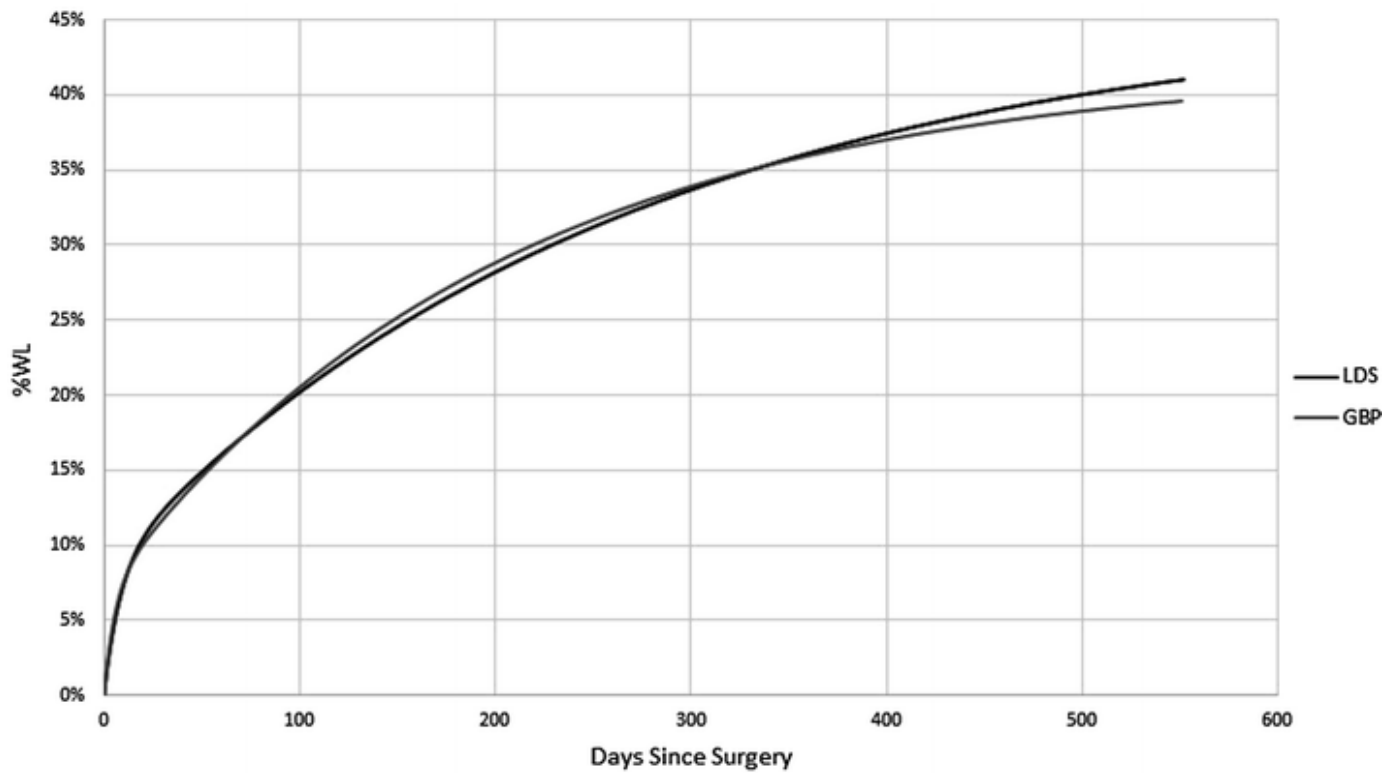


Fig. 1

Differences between the GBP and the LDS for %WL over the course of 18 months

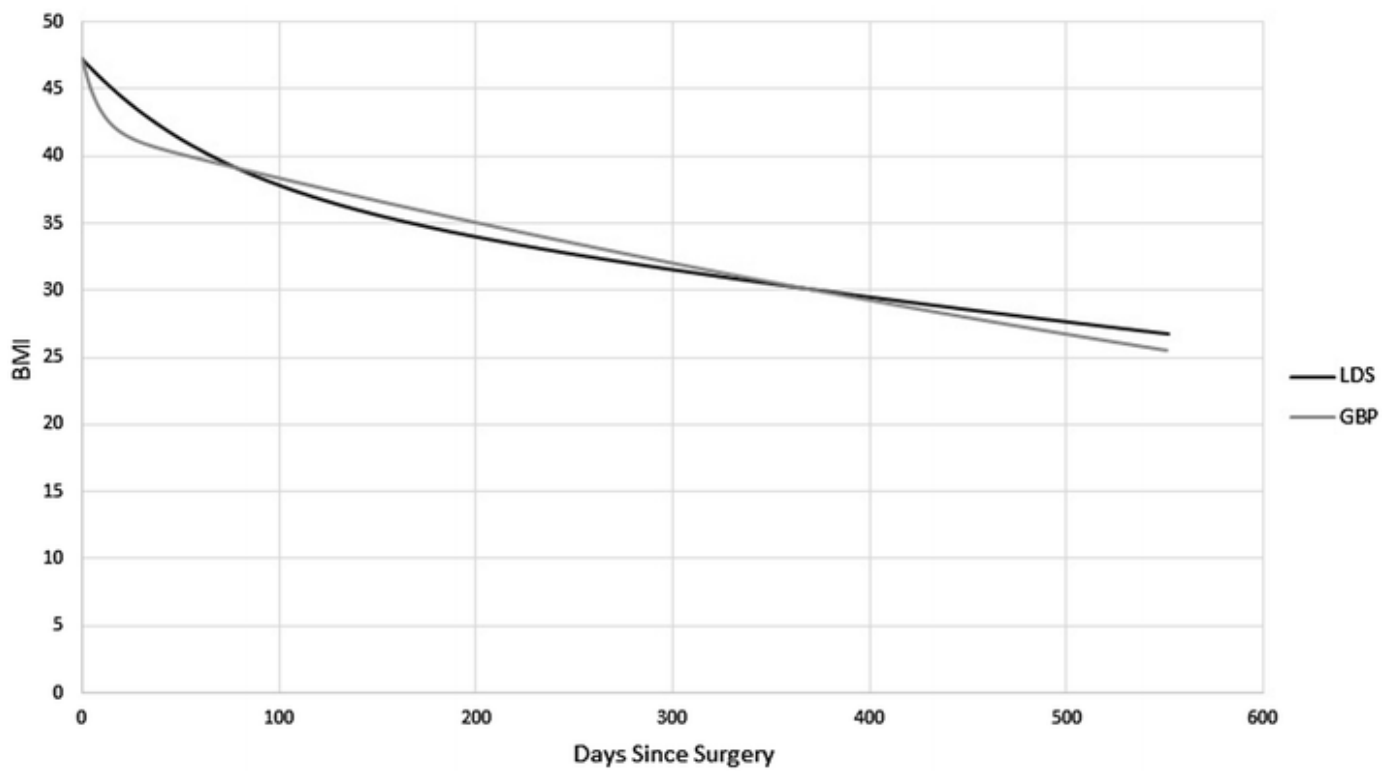


Fig. 2

BMI lost over the course of 18 months for LDS and GBP

GBP patients did not lose a significant additional amount of weight after 12 months ( $P = .123$ ). LDS patients did not

lose significant additional amount of weight after 15 months ( $P = .076$ ).

GBP had a higher occurrence of complications, and it was statistically significantly different from LDS (Tables 4, 5).

GBP had higher nausea rates, and they were significantly different short term ( $P = .02$ ) and long term ( $P = .007$ ). GBP also had a higher ulcer rates at the gastrojejunostomy, and it was significantly different ( $P = .036$ ).

**Table 4**

Complication rates are found between the GBP and the LDS

GBP		LDS	
Short term	Long term	Short term	Long term
Nausea-9	Nausea-17	Nausea-1	Nausea-4
Abdominal pain-4	Ulcers-6	Abdominal Wall Spasms-1	Sleeve Strictures-1
Diarrhea-1	Stricture-1		Dilated Fundus Requiring Reoperation-1
Incisional hernia-1	Adhesions causing small bowel obstruction-3		GERD-1
Diaphoresis-1	Perforation-1		Diarrhea-1
	Intra-abdominal hemorrhaging-1		Miscounted Small Bowel Requiring Reoperation-1
	Low pre-albumin-2		
	GERD-2		
	Renal failure-1		

Short term is <30 days since surgery. Long term is >30

**Table 5**

Comparison of reoperation rates broken down into EGDs and other more invasive procedures is found in this table

	GBP	LDS	<i>P</i> value
EGD	39 % (21/54)	6 % (3/54)	<.001

EGD with dilation	13 % (7/54)	2 % (1/54)	.066
Reoperations <sup>a,b</sup>	19 % (10/54)	4 % (2/54)	.032

<sup>a</sup>In the GBP group, four patients had abdominal pain that led to the patients getting an exploratory laparoscopy which are all negative except for minor adhesiolysis. One patient had abdominal pain that led to laparoscopy to remove adhesions. Another ate fibrous vegetable matter 5 days out from surgery that obstructed the jejunojunostomy (this is contrary to our clinic's teaching). One patient had a non-healing marginal ulcer that is fixed with a gastric bypass reversal to a sleeve gastrectomy. One patient had a bowel obstruction from adhesions that led to reoperation. One patient had a perforation of a marginal ulcer that led to a gastric bypass reversal

<sup>b</sup>In the LDS group, one patient had persistent diarrhea leading to reoperation. During it was found during the initial operation only 160 cm common channel was present. This is increased to 450 cm which alleviated the problem. The other patient had a dilated fundus which required a partial gastrectomy

## Discussion

There are several methods to determine the effectiveness of a procedure. The matched cohort is among the most efficacious. We were able to perform this cohort analysis as all three surgeons perform gastric bypass in our practice. This gave us ample opportunity to match each LDS patient with a GBP patient. It also means that both groups had the same pre-op and postoperative teaching and follow-up recommendations. This eliminates practice variability as a cause of differences between the groups.

In the matching of gender, many studies have shown variable results [8–11]. Our design of a matched cohort helps us eliminate this factor as we have the same ratio of females to males. The most consistent predictor of postoperative weight loss outcomes is preoperative BMI [9, 10, 12–14]. In matching this in the two groups, we eliminated the most common likely variable to effect postoperative weight loss. [6, 15]

While our groups were matched for sex and BMI, they were not matched for T2DM. The LDS group had a higher percentage of T2DM patients. While this was not intentional, it may reflect the bias of two of the three surgeons participating in the study that LDS is a better operation of T2DM than GBP. We must admit that there is little literature to support this bias.

The higher percentage of T2DM in the LDS we thought it would have made the LDS patients more metabolically challenged at 18 months and thus lose less weight than the GBP patients. The literature is mixed on whether T2DM affects weight loss [6, 14, 16–18]. The LDS patients in our study were able to lose as much weight as the GBP even with more diabetic patients. We also believed that age would have made a difference in the study as it has been shown to be a preoperative predictor in many studies [9, 10, 13, 15, 16, 18] and our LDS patients were significantly older than our GBP patients, yet the weight loss outcomes are the same.

The gastric bypass has been described in many circles as the ultimate procedure for GERD since it separates the acid-producing cells from the esophagus. Both groups had high rates of GERD pre-op, and both groups had remarkably low rates of GERD post-op with one LDS patient being on acid-reducing medication at 1 year. This may reflect our aggressive nature in the diagnosis hiatal hernia preoperatively and its treatment intra-operatively. This is counterintuitive and many surgeons will not even perform a SG in the setting of severe reflux. We must acknowledge that this study only looked at acid-reducing medication use pre- and postoperatively and not Ph studies or GERD scores but having 34 patients taking acid-reducing medications preoperatively and one at 1 year really speaks to the effectiveness of aggressive hiatal hernia repair.

Interestingly, we also had two patients on acid-reducing medications in the GBP group. This means that LDS patients

have similar rates of postoperative acid-reducing medication usage. Further analysis beyond this is impossible as this study was not designed to look at GERD and weight loss surgery.

Most surgeons who perform GBP choose not to do BPDDS due to fear of a high rate of malnutrition. This has been studied extensively. This study was not set up to look at that and trying to do so retrospectively in our practice proved impossible. This is a limitation of the study. However, the LDS with its 300-cm common channel empirically should be expected to have less malnutrition and malabsorption than the BPDDS with its shorter common channel and Roux limbs.

One way to demonstrate that there is less malabsorption is the percentage of patients complaining of diarrhea and oily stools. In the LDS group, the only patient to complain of diarrhea had a miscounted common channel of 160 cm which is similar to the total intestinal length of many patients who have a BPDDS traditionally. When that patient was converted to a 450-cm common channel, the diarrhea stopped.

Comparisons of LDS with GBP in terms of total intestinal length are impossible since no study addressing bowel habits and GBP has counted total intestinal length. Hence, no GBP patient or study can ever say with certainty what the level of malabsorption is. With this paper, we can definitively say that LDS and a 300-cm common channel do not routinely cause patients to experience oily stools, diarrhea or smelly gas complaints. If patients do complain of these issues, then laparoscopic exploration for miscounting of Roux limb should be entertained after other causes of diarrhea have been ruled out.

Our study used nonlinear regressions to make the best possible comparison between the two groups' weight loss. The use of nonlinear regression allowed our line of best fit to have a higher correlation coefficient when compared with a linear regression. Regression analysis allowed us to include all patients' data and have the highest accuracy possible.

The results of the gastric bypass weight loss at 1 year fell within established ranges for weight loss [19, 20]. This adds validity to our small sample size since our weight loss results are indicative of GBP patient populations in the published literature.

The only statistical significant difference between the groups related to complications [21–24]. Two of the most vexing problems when dealing with the GBP are nausea and ulcers. Even with our small cohort size, the complaints of nausea between the groups were far greater for GBP than for LDS (Table 4). This is reflected in our rate of EGD's postoperatively between the groups which is also significant (Table 5). Indeed, based on our data, the GBP with its high ulcer, stricture and nausea rate postoperatively would end up being a more expensive malabsorptive operation than a LDS since the cost to place patients on nausea medications and perform all the EGDs postoperatively would drive total cost on the GBP much higher.

Our ulcer rate in our LDS was statistically significantly different than the GBP. We have never seen an ulcer in an LDS patient in well over 200 cases, and neither has Dr. Torres in over 400 (personal communication). We expect larger analysis to continue to prove this correct as well since bile neutralizes the acid from the stomach at the point it enters the small bowel, this is a unique benefit of the loop configuration over the Roux limb which causes ulcers at the gastrojejunostomy in patients years after surgery many times when not smoking or taking NSAIDs. Overall, our ulcer rate was within norms reported in other series [24, 25]

The largest weakness in this study was our high negative EGD rate which led the differences between the two to be very large and higher than reported elsewhere in the literature [7, 25, 26]. There would have been a statistically significant difference in endoscopy rates between the two procedures even excluding negative EGDs in our GBP group.

Another study weakness was sample size. This limitation can be greatly overcome with matched cohort analysis. As our population of LDS grows, we are sure to provide 3-year follow-up, but due to the paucity of published data on the LDS, we elected to perform this analysis as soon as we could get accurate 18-month data. Statistically, all of the weight loss experienced by GBP was done at 12 months and LDS at 15 months. Therefore, our study captures the peak of the weight loss curves of both procedures, and at least in our practice weight loss means are similar between the two groups.



Another interesting, but we feel nonsignificant, limitation is the fact that three surgeons performed the procedures in the study. Each surgeon feels strongly about the benefits of all the procedures that they offer. Each surgeon may offer GBP or LDS to slightly different patients; however, the matched cohort was an attempt to compensate for that. Additionally, this paper is not meant to be the last word in comparing the GBP to the LDS. As such, many more papers and long-term results will be needed to reaffirm the finding of this study.

Another weakness of the study is the lack of vitamin and mineral level analysis. This variable would have enabled a comprehensive look into fat malabsorption. While this would have strengthened the comparisons between the two procedures, since this was a retrospective study it was not designed to look at this. The only intended goal of this study was to look at weight loss and complications and compare their rates between the GBP and LDS.

What is not similar is the confidence intervals between the two groups at 18 months. The LDS has tighter confidence intervals, while the GBP has larger ones reflecting the fact that some GBP patients have already started to regain weight. This outcome was anticipated and most of the success seen by the BPDDS, and we believe the LDS as well, occurs when there is less weight regain when compared to other procedure after 3 years. Durability results will likely require long-term registry data.

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## Conclusion

LDS produces similar weight loss results to the GBP. However, the LDS has longer sustained weight loss and reduced variability as demonstrated by smaller confidence intervals. It also has fewer complaints of nausea, no ulcers and a lower rate of postoperative endoscopies when compared the GBP.

### Compliance with ethical standards

#### *Disclosures*

Austin Cottam, Daniel Cottam, Walter Medlin, Christina Richards, Samuel Cottam, Hinali Zaveri and Amit Surve have no conflicts of interest or financial ties to disclose.

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