

Original article

# The incidence of complications associated with loop duodeno-ileostomy after single-anastomosis duodenal switch procedures among 1328 patients: a multicenter experience

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## Abstract

**Background:** The single-anastomosis duodenal switch procedure is a type of duodenal switch that involves a loop anastomosis rather than traditional Roux-en-Y reconstruction. To date, there have been no multicenter studies looking at the complications associated with post-pyloric loop reconstruction.

**Objectives:** The aim of the study was to report the incidence of complications associated with loop duodeno-ileostomy (DI) following single-anastomosis duodenal switch (SADS) procedures.

**Setting:** Mixed of private and teaching facilities.

**Methods:** The medical records of 1328 patients who underwent primary SADS procedure (single-anastomosis duodeno-ileal bypass with sleeve gastrectomy or stomach intestinal pylorus-sparing surgery) by 17 surgeons from 3 countries (United States, Spain, and Australia) at 9 centers over a 6-year period were retrospectively reviewed, and their results were compared with articles in the literature.

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**Results:** Mean preoperative body mass index was 51.6 kg/m<sup>2</sup>. Of 1328 patients, 123 patients received a linear stapled duodeno-ileostomy (DI) and 1205 patients a hand-sewn DI. In the overall series, the anastomotic leak, ulcer, and bile reflux occurred in .6% (9/1328), .1% (2/1328), and .1% (2/1328), respectively. None of our patients experienced volvulus at the DI or an internal hernia. Overall, 5 patients (.3%) (3/123 [2.4%] with linear stapled DI versus 2/1205 [.1%] with hand-sewn DI [ $P < .05$ ]) experienced stricture at the DI in this series.

**Conclusions:** The overall incidence of complications associated with loop DI was lower than the reported incidence of anastomotic complications after Roux-en-Y gastric bypass and biliopancreatic diversion with duodenal switch. SADS procedures may cause much fewer anastomotic complications compared with Roux-en-Y gastric bypass and biliopancreatic diversion with duodenal switch. (*Surg Obes Relat Dis* 2018;14:594–602.) © 2018 American Society for Metabolic and Bariatric Surgery. All rights reserved.

**Keywords:** Incidence; Duodeno-ileostomy; Gastrojejunostomy; Single-anastomosis duodenal switch; Roux-en-Y gastric bypass; Biliopancreatic diversion with duodenal switch

Historically, the 4 most common types of bariatric surgical techniques include Roux-en-Y gastric bypass (RYGB), adjustable gastric banding, sleeve gastrectomy (SG), and biliopancreatic diversion with duodenal switch (BPD-DS). Recently, a variant of the BPD-DS, called the single-anastomosis duodenal switch (SADS), has been popularized around the world, but the numbers of published reports have been small in comparison with other bariatric surgical procedures [1]. The SADS procedure is a type of duodenal switch (DS) that involves a loop anastomosis rather than traditional Roux-en-Y reconstruction [2]. This modification simplifies the procedure, decreases the potential complication rate, and combines the physiologic advantages of a post-pyloric reconstruction with the technical advantages of a loop reconstruction.

The SADS procedure has gone by many names and can be categorized into 2 categories, depending on the position of the anastomosis. Procedures like loop duodeno-jejunosomy bypass with SG and single-anastomosis duodeno-jejunal bypass with SG use duodenum and jejunum, whereas single-anastomosis duodeno-ileal bypass with SG (SADI-S) and stomach intestinal pylorus-sparing (SIPS) use duodenum and ileum to create the anastomosis [3–6].

In this report, surgeons from different centers have performed either SADI-S or SIPS. The SIPS was introduced in the United States in 2013. The SIPS surgery is also a modification of DS [6,7]. It is similar to SADI-S but differs in that a smaller bougie is used and the intestinal length is 50 cm longer [8]. However, in both procedures the technique to create the duodeno-ileostomy (DI) is same. Currently, numerous reports address the incidence of anastomotic complications after RYGB [9–13]. This is the first article in the literature that reports the incidence of complications associated with loop DI after SADS procedures (SADI-S and SIPS).

## Methods

The medical records of 1328 patients who had undergone primary SADS procedure by 17 surgeons at 9 centers over a

6-year period were retrospectively reviewed from each institution's prospectively collected database. The centers are as follows: center 1—Bariatric Medicine Institute in the United States, performed by DC; center 2—Hospital Clínico San Carlos in Spain, performed by ASP and A. Torres; center 3—Roller Weight Loss & Advanced Surgery in the United States, performed by JR, YK, and JM; center 4—Panhandle Weight Loss Center in the United States, performed by BS and BN; center 5—Bariatric Specialists of North Carolina in the United States, performed by PE, MT, JB, and SB; center 6—NS-LIJ-Lenox Hill Hospital and Northern Westchester Hospital in New York in the United States, performed by MR; center 7—Orlando Regional Medical Center in the United States, performed by MJ and A. Teixeira; center 8—Center For Weight Loss Surgery in the United States, performed by MS; and center 9—Pindara Private Hospital in Australia, performed by JF. The data collection was standardized across the 9 institutions. Each database retrospectively searched for anastomotic complications unique to the creation of the DI. These were then placed into the studies database. This database was unique; however, 25% of the patients in the database have been included in previously published articles by the authors.

Each center had an informed consent process in place before the study; the process included a consent detailing the procedure, risks, and potential benefit. Each patient was given an examination before surgery to verify understanding of the procedure. Demographic data were collected for all patients, including age, weight, and body mass index. All patients were advised to have monthly postoperative follow-up visits. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Because this is a retrospective study, formal consent was not required.

The inclusion criterion was primary SADS procedure. Descriptive statistics were used to analyze preoperative characteristics, such as weight and body mass index.

Table 1  
Demographic characteristics of patients who had undergone primary single-anastomosis duodenal switch procedure

Center	Total number of patients	M/F	Mean preoperative BMI, kg/m <sup>2</sup>	Mean preoperative weight, kg
1	341	123/218	49.6	143.4
2	260	100/160	56	144.9
3	150	44/106	48.6	140.4
4	135	31/104	52.9	150.3
5	125	28/97	49.3	140.6
6	116	37/79	47.3	132.9
7	102	33/69	58.2	167.3
8	72	22/50	51.6	149
9	27	7/20	51.3	150.4
Total/mean	1328*	425/903*	51.6†	146.5†

M = male; F = female; BMI = body mass index.

\*Values expressed as total.

†Values expressed as mean.

### Operative technique

**SADS.** For the retrograde tracing and tacking, the terminal ileum was located, and the small bowel was traced retrograde to 250 (SADI-S) or 300 cm (SIPS) from the ileocecal valve. In SADI-S, the sleeve was created over 54-Fr bougie; in SIPS, it was created over 34- to 44-Fr bougie. Once the sleeve was completed, the gastroepiploic vessels were taken down from the end of the sleeve staple line past the pylorus to where the perforating vessels from the pancreas enter the duodenum. This was nearly 2 to 3 cm beyond the pylorus.

The DI can be created using a hand-sewn approach or a stapled approach. For the hand-sewn technique, the antimesenteric border of the loop limb was approximated to the proximal duodenal stump with a running suture. Enterotomies of approximately 3 cm were made at the proximal duodenal stump and in the loop limb. These were then closed posteriorly and anteriorly with a running suture. A leak test was performed intraoperatively as routine with all patients.

For the linear stapling technique, the proximal duodenal stump was approximated to the antimesenteric border of the loop limb using continuous 2–0 nonabsorbable suture. Then an enterotomy was made in the proximal duodenal stump and the loop limb. A linear stapler was inserted approximately 20 mm into each opening and fired. The enteroenterostomy was closed with absorbable sutures starting at each corner. A leak test was performed intraoperatively as routine with all patients.

### Results

For analysis, 1328 patients were identified from 2010 to 2017. This equated to 2064 patient-years. The mean preoperative body mass index and weight were 51.6 kg/m<sup>2</sup>

and 146.5 kg, respectively. The preoperative characteristics can be seen in Table 1. Anastomotic leak, ulcer, stricture at the DI, and bile reflux occurred in .6%, .1%, .3%, and .1% patients, respectively. None of our patients experienced volvulus at the DI or internal hernia (Table 2). The comparison of the incidence rate of anastomotic complication after SADS with the reported incidence of anastomotic complication after RYGB and BPD-DS can be seen in Table 3. Most complications were class II to III on the Clavien-Dindo classification (Table 4). In total, 18 anastomotic complications occurred. Of the 18 complications, (.8%) were grade IIIb, 5 (.3%) were grade IIIa, and 2 (.1%) were grade II. There were no mortalities related to anastomotic complications.

### Discussion

The single-anastomosis techniques have flourished in many places around the world over the past decade [14]. There are certain advantages and disadvantages of SADS over RYGB [6]. The benefits of post-pyloric reconstruction in SADS procedures over prepyloric reconstruction in RYGB include a reduction in marginal ulcers, dumping syndrome, strictures, and internal hernias [15,16]. In this study, we have reported the incidence of complications associated with loop DI after SADS and have also compared this with the reported incidence of anastomotic complications after RYGB and BPD-DS. The incidence rate of anastomotic complication after SADS is low compared with the reported incidence rate of anastomotic complication after RYGB and BPD-DS. However, because this is a retrospective chart review, percent follow-up and percent lost to follow-up are inherently less accurate than prospective studies. A weakness of our study design is that we do not know if the patients received medical care for possible complications at any other institutions. Additionally, because leaks and ulcers occur early, we have essentially 100% follow-up for the period (6 weeks) concerned. However, complications of bile reflux and internal hernia/volvulus can occur months to years after the surgery. Essentially, although we have 1328 patients and 2000 patient-years, we cannot provide the exact percentage of patients who have this complication, but we can say that the authors of this paper have rarely seen it. This article does not say that the actual incidence is not higher; it just is not significantly higher than we are showing because patients with long-term complications do not always present to the surgeon or practice that performed the surgery.

### Anastomotic leaks

Anastomotic leaks are one of the most serious complications after bariatric surgery [17]. Anastomotic leaks after RYGB procedure can occur at the gastrojejunostomy (GJ)

Table 2

Demonstrates the incidence of complications associated with the duodeno-ileostomy after single-anastomosis duodenal switch surgery

Center	Total number of patients	Yr	Number of patients	Bile reflux, n	Stricture at the DI, n	Ulcer, n	Internal hernia, n	Volvulus at the DI, n	Anastomosis leak, n
1	341	1	341	1	0	0	0	0	0
		2	231	0	0	0	0	0	0
		3	76	0	0	0	0	0	0
		4	8	0	0	0	0	0	0
2	260	1	260	0	0	0	0	0	3
		2	230	0	0	0	0	0	0
		3	200	0	0	0	0	0	0
		4	170	0	0	0	0	0	0
		5	140	0	0	0	0	0	0
3	150	1	150	0	1	0	0	0	0
		2	76	0	0	0	0	0	0
4	135	1	135	0	3	0	0	0	5
		2	83	0	0	0	0	0	0
		3	19	0	0	0	0	0	0
5	125	1	125	0	1	0	0	0	0
		2	45	0	0	0	0	0	0
6	116	1	116	1	0	0	0	0	1
		2	81	0	0	0	0	0	0
		3	48	0	0	0	0	0	0
		4	18	0	0	0	0	0	0
7	102	1	102	0	0	1	0	0	0
		2	4	0	0	0	0	0	0
8	72	1	72	0	0	0	0	0	0
9	27	1	27	0	0	1	0	0	0
		2	1	0	0	0	0	0	0
Total	1328	-	-	2	5	2	0	0	9

DI = duodeno-ileostomy.

The anastomotic leak, ulcer, stricture at the DI, and bile reflux, occurred in .6% (9/1,328), .1% (2/1,328), .3% (5/1,328), and .1% (2/1,328) patients, respectively. None of our patients experienced volvulus at the DI or internal hernia.

and jejuno-jejunostomy (JJ). The most commonly reported location for an anastomotic leak after RYGB is at the GJ (68%), although some have reported a greater mortality

from JJ leaks [18]. This complication carries with it a reported mortality ranging from 1% to 6% [19–22]. A study of 3000 patients undergoing RYGB found that anastomotic leaks are one of the strongest independent risk factors for postoperative death [21]. The reported incidence of leakage varies from .1% to 5.6% [22].

Table 3

Demonstrates the comparison of incidence rate of anastomotic complication after SADS with the reported incidence rate of anastomotic complication after RYGB and BPD-DS

Anastomotic complication, range (% of patients)	Procedure		
	RYGB	BPD-DS	SADS
Leak	.1–5.6	.5–6	.6
Volvulus	2–17	-	0
Internal hernia	.5–16	.4–18	0
Ulcer	.6–20	.2–1.9	.1
Stricture	.4–23	1.9–2.3	.3*
Bile reflux	.9	-	.1

RYGB = Roux-en-Y gastric bypass; BPD-DS = biliopancreatic diversion with duodenal switch; SADS = single-anastomosis duodenal switch.

\*Of 123 patients who received linear stapled DI, 3 patients (2.4%) experienced stricture at the DI. Of 1205 patients who received hand-sewn DI, only 2 patients (.1%) experienced stricture at the DI. Overall, 5 patients (.3%) experienced stricture at the DI in this series. The incidence rate of anastomotic complication after SADS is low compared with the reported incidence rate of anastomotic complication after RYGB and BPD-DS.

Another advantage of SADS procedures is that it has 1 anastomosis compared with 2 in RYGB and BPD-DS. The reported incidence of anastomotic leak after BPD-DS varies from .5% to 6% [23–28]. In our experience, the class III anastomotic leaks after SADS occurred in .6% (9/1328) of anastomoses over 6 years (range, 1–6 yr).

### Internal hernia/obstruction

One of the complications after RYGB and biliopancreatic limb is bowel obstruction secondary to internal herniation; however, obstructions may occur due to a number of other causes, such as adhesions, strictures, volvulus, or other complications at the JJ or Peterson’s space [29–33]. In 1900, Petersen was the first surgeon to report an internal hernia after GJ [34]. The reported incidence of internal hernias after RYGB varies from .5% to 16% [35–38]. The possible locations for internal hernias include the opening

Table 4  
Specific anastomotic complication distribution by Clavien-Dindo grade

Anastomotic complication	I	II	IIIa	IIIb	IVa	IVb
Bile reflux, n	-	-	-	2	-	-
Stricture at the DI, n	-	-	5	-	-	-
Ulcer, n	-	2	-	-	-	-
Internal hernia, n	-	-	-	-	-	-
Volvulus at the DI, n	-	-	-	-	-	-
Anastomotic leak, n	-	-	-	9	-	-
Total, n	0	2	5	11	0	0

DI = duodeno-ileostomy.

In total, 18 anastomotic complications occurred. Of the 18 complications, 11 complications (.8%) were grade IIIb, 5 complications (.3%) were grade IIIa, and 2 complications (.1%) were grade II.

of the transverse mesocolon, through which the Roux limb is brought to become connected to the gastric pouch (67%); the small bowel mesenteric defect at the JJ (21%); and the space between the transverse mesocolon and Roux limb mesentery (7.5%) [37].

Obeid et al. [38] reported long-term outcomes after RYGB with 10 to 13 years of data. The incidence of internal hernia postRYGB was 12.8% at an average of 3.7 years [38]. The reported incidence of internal hernias after BPD-DS varies from .4% to 18% [26,39–41]. In both procedures, articles with long-term follow-up indicate that the internal hernias per year were >1%, regardless of the method used to close the internal hernia.

To date, there has been no primary incidence of internal herniation after SADS. This is not to say that there could not be a hernia/volvulus at the DI, just that it is rare and the total incidence should be much less than the Roux-en-Y reconstruction.

### Ulcers

Anastomotic site ulceration (marginal ulcer) is a well-known complication after GJ, with an incidence of approximately .6% to 20%, and the etiology remains obscure [11,42–46]. The possible contributing factors include local ischemia, anastomotic tension, increased gastric acidity, tobacco use, nonsteroidal anti-inflammatory drug use, and chronic irritation caused by the suture materials at the anastomosis [44,47–49]. Ulcer formation is a consistent finding whenever a Roux limb is created to the stomach. It can be said that the creation of the Roux limb is ulcerogenic, and this is just an accepted outcome of the technique. The reported incidence of anastomotic ulcer after BPD-DS varies from .2% to 1.9% [39,50,51].

The loop configuration in the SADS procedure maintains contact between pancreatic enzymes, bile salts, and food, eliminating the ulcers and strictures associated with both the RYGB and BPD-DS. We experienced .1% incidence of class II to III ulcers at the DI after SADS. Thus, this technique does not eliminate ulcers but reduces their incidence from commonplace after RYGB to rare with

SADS. In none of the patients in the series was tobacco or nonsteroidal anti-inflammatory drug use a contributing factor. Also, none of the surgeons who participated in this survey routinely use proton-pump inhibitor therapy postoperatively to stop ulcers for this procedure. Due to the location of the DI on the ileum, preoperative endoscopy would not have helped reduce the incidence of postoperative ulcers.

### Stricture at the DI

The reported incidence of anastomotic stricture after RYGB was as high as 23% and varies from 1.9% to 2.3% after BPD-DS [35,50,52–57]. Many published studies have shown that the rate of anastomotic stricture is relatively higher with the circular stapling technique than with the hand-sewn technique, while the linear stapled technique falls in between [58–60].

All methods have technical advantages and disadvantages, especially with respect to developing strictures at the DI. As with any other small bowel anastomosis, the approach to this anastomosis can be hand sewn, robotic assisted, or stapled. A retrospective review of our experience suggests that the linear stapler technique for creating the DI is associated with an increased incidence of anastomotic stricture compared with the hand-sewn technique. Of 1328 patients, 123 received linear stapled DI, and 1205 received hand-sewn DI. Of 123 patients who received linear stapled DI, 3 (2.4%) experienced stricture at the DI. Of 1205 patients who received hand-sewn DI, only 2 (0.1%) experienced stricture at the DI. Overall, 5 patients (0.3%) experienced a class III stricture at the DI in this series. The difference in stricture rates between hand-sewn and linear stapled anastomosis was statistically significant ( $P < .05$ ). These strictures all responded to pneumatic balloon dilation.

### Bile reflux

Another theoretic concern is bile reflux. Bile reflux is a potential late complication of RYGB and SADS. The Roux-en-Y configuration of the traditional DS does not allow bile to reflux into the stomach causing the complication of bile reflux gastritis. Bile reflux after RYGB that refluxes into the gastric pouch or proximal Roux limb should not occur unless the Roux limb is inappropriately short [61]. The reported incidence of bile reflux after RYGB was .9% [61].

Most concerns about bile reflux have been generated by the single anastomosis gastric bypass. This configuration as it is currently practiced around the world has a 1% incidence of bile reflux causing reintervention. In our series, 2 patients (.1%) had class II clinically significant bile reflux after SADS. We attribute the much lower incidence of bile reflux due to the post-pyloric reconstruction of our single anastomosis DI. It is also possible because both of the



patients with bile reflux were from a single site that it could be technique related.

Apart from the aforementioned known complications, we have encountered an unusual complication of retrograde filling of the afferent limb, causing symptoms like partial bowel obstruction in 2 of our patients [62]. This was due to adhesions around the DI and scar tissue from the gallbladder fossa after cholecystectomy to the efferent limb. To circumvent this unusual complication after SIPS procedure, an antiobstruction stitch was placed, where the afferent limb was tacked up to the antrum of the stomach. After adopting this practice, to date, we have not encountered any patients with this unusual complication.

### Weight loss

With many studies published on the outcomes from this procedure. The SADS-type procedures have been proven to have clinically significant weight loss. At 1 year, excess weight loss ranges from 61.7% to 87%; at 2 years, excess weight loss ranges from 83.7% to 93.9% [1,3–5,7,8,63–66].

This study was retrospective, which limited the ability capture all complications and track them as a prospective study would. Second, the surgeons used different techniques to create the DI. This may lead to differing amounts of anastomotic complications. Third, these cases were all part of the learning curves of all the surgeons involved, and we might have fewer leaks in the future. Lastly, as nice as these data appear, most of our conclusions are based on data that are <3 years old, and the possibility exists that some of the complications such as bile reflux might only manifest beyond 3 years.

### Conclusions

The overall incidence of complications associated with loop DI was lower than the reported incidence of anastomotic complications after RYGB and BPD-DS. This paper suggests that practitioners who perform SADS may experience fewer small bowel complications than those who use Roux techniques.

Additionally, in our limited experience, using a linear stapled technique has resulted in differing rates of DI stricture. This is not to say that intuitions might develop expertise in the stapled approach that might have low complication rates (we know of such institutions doing standard DS). Indeed, the linear stapled experience was all in the learning curve of those surgeons and might not be applicable with more experience.

### Disclosures

*DC is the corresponding author reports personal fees and other from Medtronic, outside the submitted work. PE reports personal fees and other from Medtronic and Intuitive. JB reports personal fees and other from J&J*

*and Endo 360. MR reports personal fees and others from Medtronic and J & J. All other authors have no conflicts of interest to declare.*

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### Editorial comment

## Comment on: the incidence of complications associated with loop duodeno-ileostomy after single-anastomosis duodenal switch procedures among 1328 patients: a multicenter experience

Over the last 20 years, introducing a new surgical procedure has become a more complicated process. As the field of bariatric surgery has matured, attention has been focused on protecting patients and surgeons from procedures that have a greater risk than value. No longer can bariatric surgeons expect a procedure to be accepted by patients, insurance companies, or surgical societies unless the procedure is studied in a meaningful manner and the results published in peer-review journals. Investigators must show that the procedure is at least as safe as established procedures and that patient outcomes are equal or better. This can be a long, arduous process, especially because most third-party reimbursement is withheld until this process is complete. As many have said, this is a “catch 22.” The authors of this paper, however, have managed to collect retrospective data over a 6-year period from 9 centers, including 7 in the United States. Although 25% of the patients reported in this study were previously reported, the total number of patients (1328) and the detail of reporting goes a long way in supporting the argument that a single anastomosis duodenal switch (DS) is at least as safe as currently practiced bariatric procedures. The only major drawbacks to the study, as the authors admit, were that the study was retrospective, done by very experienced bariatric surgeons, and that some unreported complications may have occurred well past the time limits of the study. The question of whether the single-anastomosis DS is as safe as other well-established bariatric procedures in the hands of experts is well demonstrated in this study, but whether it is superior will only be answered in a randomized investigation or when the procedure is adopted by many more bariatric surgeons.

In the introduction of the paper, the authors do an excellent job of describing the different DS procedures.

As a reader who does not normally perform any of these procedures, the authors make their differences and similarities easily understandable. The nomenclature used by various surgeons can be confusing, and I found this paper goes a long way in correcting the problem. The highlight of the paper is that it looked at several short-term serious complications that occur after other well-established bariatric procedures, including leak, ulcer, and stricture formation. Their reported incidence of leak (.6%) is comparable to what we should expect from sleeve gastrectomy or Roux-en-Y gastric bypass in the hands of very experienced surgeons. One must be careful, however, not to compare this incidence with higher numbers reported from studies, which include a much larger population of surgeons. Many, including myself, have worried that a leak after a single-anastomosis procedure that allows for the contamination of bile would have a much more serious consequence than a leak after a Roux-en-Y reconstruction. This study appears to lay this concern to rest, although the number of leaks seen in the study was very limited. The lack of anastomotic strictures reported by the authors is admirable, but again maybe related to their expertise. More importantly, the study establishes that anastomotic ulcers after single-anastomosis DS are extremely rare (.1%). This is not an unexpected benefit because placement of the anastomosis distal to the pylorus allows for mixture of bile and acid. The advantage of a postpyloric anastomosis must surely be taken into consideration when deciding the overall safety of the procedure. A more long-term complication, bile reflux, may however be increased by the same post pyloric single anastomotic configuration. Although the study only reports a .1% incidence of bile reflux, the true number may be confounded by the length of follow-up of individual patients and the number lost to follow-up. Only