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Research Article





Retrospective Analysis of Nutritional Outcomes and Long-term Weight loss Outcomes; Single Anastomosis Duodeno-Ileostomy with Sleeve (SADI-S) vs Sleeve Duodeno-Jejunal Bypass (SDJB) vs Sleeve Gastrectomy (SG) alone

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Abstract

The Single Anastomosis Duodenojejunostomy With Sleeve (SDJB) is a novel procedure which like other hypo-malabsorptive procedures may be burdened with long-term nutritional deficits. There is minimal data in the literature on nutritional outcomes of the SDJB and none comparing SDJB to the Single Anastomosis Duodeno-Ileostomy With Sleeve (SADI-S).

Objectives: We aimed to review the 12-month nutritional outcomes of patients undergoing SDJB, SADI-S and SG as a primary procedure. The secondary aim is to ensure longevity regarding excess weight loss of SDJB compared to SADI-S.

Methods: A 6-year retrospective cohort study was performed at a single surgeon institute. 78 SADI, 57 SDJB patients, and a BMI-matched cohort of 135 SG patients were identified. Inclusions: BMI 35-70, operation December 2015 – December 2021. Exclusions: revisional or ring procedures. Data was collected pre- and post-operative. Outcomes were EWL% at 6 years and Biochemistry at 12 months.

Results: The median Preoperative BMI was 50kg/M². SDJB was not significantly different to SADI regarding EWL% at 6 years (p=0.137). SADI and SDJB were superior to SG alone at 3 and 4 years (p=<0.001 and p=0.033). SDJB had significantly improved levels of selenium, corrected calcium, cholesterol and B12 stores compared to SADI (p=0.041, p=0.001, p=<0.001). Conclusion: SDJB proved equal to SADI regarding EWL% over 6 years. SDJB could be considered a safe procedure in regards to nutritional status.

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Keywords: Bypass surgery; Malabsorption; Nutritional deficiency; SADI-S; SDJB

Introduction

Bariatric surgery is an evolving field of surgery with increasing recognition as a highly effective treatment for obesity, especially in the context of the ever-growing western obesity epidemic. Bariatric surgery is now the most effective therapy for patients with morbid obesity with new surgical techniques growing worldwide. [1] The basics of weight loss surgery rely on three techniques caloric restriction, malabsorption, or a combination of the two. Malabsorption procedures simply comes down to, the greater amount of small bowel bypassed the greater the weight loss. There have been numerous developments over the years and discussions as to what is the ultimate length of bowel to bypass to maintain long term weight loss and minimise complications. This remains in conjecture within modern literature. This study aims to review the outcomes of an adaptation of a modern bariatric procedure in comparison with the original procedure to determine if patient outcomes are improved.

Obesity is a worldwide epidemic that has been growing in magnitude over the past decades. Common measures to manage overweight and obese patients are focused on lifestyle intervention inclusive of diet and exercise with behaviour modifications. Studies have shown high rates of Weight Regain (WR) with lifestyle measures alone, thus this is not an effective measure in isolation. [2] Pharmaceutical adjuncts have been trialled alongside lifestyle modification with some improvement in time until WR, however, usually WR is seen upon medication withdrawal. Bariatric surgery is now considered the therapy of choice for patients failing lifestyle management with a Body Mass Index (BMI) > 35kg/m2. In Australia, the most common bariatric procedures performed are the Roux-en-Y gastric bypass (RYGB) and the sleeve gastrectomy. These procedures have high rates of prolonged weight loss, however, the RYGB has been fraught with long-term micronutrient deficiencies requiring long-term monitoring and replacement. [3] The most recognised micronutrient complications of RYGB include Iron deficiency with associated anaemia as well as vitamin D with secondary hyperparathyroidism. Other notable micronutrient deficiencies that occur less commonly include vitamin B12, folate, calcium, and albumin. [4,5] Small intestine bypass procedures are the gold standard for prolonged weight loss however, there remains a balance regarding weight loss and malabsorption complications. More recently, the single anastomosis duodeno-ileostomy bypass with sleeve gastrectomy (SADI-S) has been developed, first reported in 2007 by Sanchez-Pernaute as a simplification of the Duodenal Switch (DS). [6,7] SADI-S aimed to reduce malabsorption and complications of more complex surgeries, however, there are still reports of complications

from this novel procedure including long-term malabsorptive issues [1].

More recently in 2018, Ser reported a modification of the SADI-S whereby the biliopancreatic limb was measured and fixed to 150cm, thus theoretically elongating the common channel. [8] There is little to no known evidence to the author's' knowledge of outcomes regarding shortening the biliopancreatic limb and elongating the common channel to perform a duodenojejunostomy as a single anastomosis procedure nor is there comparative data to the SADI-S. The authors hypothesise that shortening the BP limb and counting proximally from the duodenojejunal flexure, thus theoretically elongating the common channel, may lead to a reduction in complications such as loose bowels and malnutrition whilst maintaining optimum weight loss. This was the rationale behind our study and the development of the SDJB. This novel surgical technique has been employed to maximise the benefits of both sleeve gastrectomy (restrictive weight loss) and small bowel bypass (metabolic foregut theory) and simplify the operative steps. Recently Lee et al published a retrospective study comparing outcomes of sleeve gastrectomy alone vs SDJB. They found the SDJB was superior to SG in T2DM remission, triglyceride improvement and excess weight loss at one year [9-11]. Our Research aims to improve on this body of knowledge and compare nutritional outcomes between SADI-S, SDJB and SG.

Aim

The aim is to compare SADI-S, SDJB and SG groups regarding biochemical markers of malnutrition at 12 months. It is to determine if a fixed measurement of a biliopancreatic limb (BP) to 150cm, as a novel operative technique, maintains long term weight loss outcomes for patients whilst maintaining similar or equal biochemical outcomes.

Materials and Methods

This was a retrospective single-centre observational cohort study. All patients underwent operative intervention by a single highly experienced bariatric surgeon from 2015- 2022. Patients were identified by either having undergone a single anastomosis duodeno-ileostomy (SADI-S) or sleeve duodeno-jejunal bypass (SDJB). Patient surgical allocation was not randomised but individualised according to BMI, comorbidities, patient preference and education.

Inclusion criteria: 1) BMI of 35-72 with operative selection being determined in pre-consults by their preoperative BMI, comorbidities, and patient preference; 2) age between 18 and 65 years; 3) planned single step surgery; 4) no contraindication to malabsorptive surgical component was identified including liver cirrhosis, coeliacs disease, inflammatory bowel diseases, organ transplantation candidate or prior recipient. Patients were excluded

from the study if they had undergone prior bariatric surgery inclusive of minimiser rings. 78 SADI-S patients, 57 SDJB patients and a BMI matched cohort of 135 sleeve gastrectomy patients were included. Patients were informed about all surgical options and thoroughly advised on the risks and potential benefits of surgical intervention. All patients signed specific informed consent for their respective procedures. Ethics approval was sought and granted by the Ramsay Health HREC committee (ethics number: 2022/ETH/0109).

Surgical Procedures and Follow-Up

Patients undergoing bariatric surgery received comprehensive preoperative education, dietetics input, and psychology services if patient willing. Before surgery, all patients followed a very lowcalorie diet for three weeks. The standard surgical technique for sleeve gastrectomy involved a 5-port laparoscopic approach, with the mobilisation of the greater curvature from the greater omentum and the creation of the gastric sleeve using an EndoGIA liner stapler with black and purple reloads over a 36 French bougie. In this study, the two bypass-modified procedures were compared to the control SG group. The SADI-S patients underwent a three-step procedure that included sleeve gastrectomy, division of the first portion of the duodenum, and anastomosis to the small bowel 300-350 cm from the ileocecal valve. The SDJB patients underwent a similar three-step procedure but with a key difference: the anastomosis was made 150 cm down from the duodeno-jejunal flexure, creating a shorter biliopancreatic limb and lengthening the common channel. The entire length of small bowel was not measured in every case and thus exact CC length cannot be commented on. The mesenteric defect was routinely closed.

All patients received postoperative instructions, dietary upgrades, and a generic multivitamin. Follow-up occurred at regular intervals post-surgery at three, six and twelve months, and dietetic support was provided accordingly. Open contact was available to patients if needed during the follow-up period.

Outcomes and Variables

Data was retrospectively obtained from a single surgeon database. Demographic data was collected from all patients including age, gender, occupation, and marital status. Pre- and post-operative data collection is as follows: Biometrics (height, weight, BMI), Bowel motions per day and consistency, Biochemistry inclusive of full blood count, urea electrolytes and creatinine, calcium phosphate and magnesium. Trace elements, liver function tests, B12 and folate. Metabolic disease, bowel habits and surgical complications were also recorded and presented in a separate manuscript. Primary endpoint: assessment of nutritional outcomes at 12 months and comparison of outcomes in patients who had undergone primary SADI-S, SDJB and SG.

Statistical Analysis

Continuous variables were expressed as mean ± Standard Deviation (SD) or median (interquartile range) as determined by normality calculations. Categorical data was expressed as frequency and percentage. Differences between groups were evaluated utilising parametric tests, for continuous variables ANOVA and ANCOVA. Post-analysis was performed accounting for age and gender, all assumptions were met before calculation. Binary measures were analysed with Binary logistic regression tests with all assumptions met and tested. Multinominal logistic regression analysis was performed for categorical variables with testing deemed appropriate via goodness of fit tests. For longitudinal variables, repeated measures ANOVA calculations were utilised and once again assumptions were met post hoc analysis was undertaken with Bonferroni calculations. All statistics were analysed utilising IBM-SPSS statistics version 29 computer software.

Results

A total of 270 patients were included in the study comprising 78 SADI-S, 57 SDJB and a BMI-matched cohort of 135 gastric sleeve patients. Metabolic and biochemical data was analysed postoperatively between 12-24 months. The average follow-up timeframe was 12.6 months (range 7-21 months) with average biochemical resulting data at 10.5 months. Patients' pre-operative demographics are displayed in Table 1. There was no statistical difference between age, gender, BMI, or weight preoperatively.

Efficacy and Weight Loss Outcomes

Pre-operatively and at 6 months postoperative, there was no significant difference between the three groups, refer to Table 2. There was a significant difference between groups regarding BMI upon follow-up at years 1,2,3 and 4 (p=0.020, p=0.007, p= 0.002 and p=0.012 respectively). The difference was found to be at one year between the SADI-S and SG group (p=0.017), at 2 years between both SADI-S, SDJB group and SG (p=0.014 and p=0.045), year 3 between SADI-S and SG (p=0.002) and year four between SADI-S and SG (p=0.018). Of note, SDJB sustained similar if not improved BMI results over SADI-S. Regarding excessive weight low (%EWL), both SADI-S and SDJB were significantly higher than the SG group in years 3 and 4 p=<0.001 (SADI-S versus SG, p= <0.001; SDJB versus SG, p=0.017); p=0.004 (SADI-S versus SG, p= 0.009; SDJB versus SG, p=0.017) respectively. SADI-S had significantly improved EWL over SG at the year one and two follow-ups (p=0.002 and p=0.008). Overall, SDJB had the highest EWL over years 4 and 5 and sustained the highest EWL of all three groups; see Table 2. Due to SDJB being performed in more recent years of the study, there is no 6-year data yet available.

SADI-S (n=78) SADJB (n=5)	7) SG (n=135)	p-value				
	M (SD) / N(%)	M (SD) / N(%)	M (SD) / N(%)			
Age	40 (10.1)	39 (11.5)	40 (10.6)	p=0.723		
Gender						
Male	18 (23%)	21 (36%)	47 (35%)	p=0.139		
Female	60 (77%)	36 (64%)	88 (65%)			
Weight Kg pre op	145.5 (19.2)	147.9 (23.2)	143.9 (26.5)	p= 0.565		
BMI pre op	51 (5.0)	50 (7.2)	50 (6.7)	p=0.565		
Kg= kilogram, pre-op = preoperative, BMI = body mass index. Normal BMI range 18-24overweight = 25-29.9, obese >30						

Table 1: Demographics of cohort.

	SADI-S		SDJB		SG			p-value			
	BMI M (SD)	EWL %	n=78	BMI M (SD)	EWL %	n=57	BMI M (SD)	EWL %	n=135	BMI	EWL
6 months	36.6 (5.8)	54%	61	34.2 (9.2)	61%	46	36.4 (7.9)	55%	92	p = 0.360	p=0.218
1 year	29.1 (4.9)	0.85	50	30.8 (5.0)	0.77	32	32.9 (6.5)	0.71	80	p=0.020	p=0.002
										SADI-S vs SG p=0.017	SADI-S vs SG p=0.001
	28.9 (4.4)	86%	42	27.8 (10.0)	78%	28	33.1 (7.3)	72%	72	p = 0.007	p=0.008
2 years				(-2.2)						SADI-S vs. SG	SADI-S vs. SG p=0.006
										p=0.014	
										SDJB vs. SG p=0.045	
	26.4 (9.5)	85%	20	28.9 (4.8)	84%	18	34.6 (5.1)	62%	69	p=0.002	p=<0.001
3 years										SADI-S vs. SG p=0.002	SADI-S vs. SG p= <0.001 SDJB v SG p=0.017
	29.5 (3.6)	82%	18	29.2 (2.5)	85%	12	34.2 (5.8)	63%	46	p=0.012	p=0.004
4 years										SADI-S vs. SG p=0.018	SADI-S vs. SG p= 0.009 SDJB vs. SG p= 0.017
5 years	33.9 (6.2)	64%	15	33.3 (4.4)	69%	12	35.7 (13.2	49%	20	p=0.872	p=0.197
6 years	36.6 (6.2)	59%	5	-	-	-	41.1 (5.5)	47%	11		

EWL% = excess weight loss expressed as a percentage; M = mean; SD =standard deviation; Note: due to operative dates of SDJB, no 6-year follow-up data is available currently.

Table 2: Results of efficacy and weight loss over 6-year follow-up.

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Biochemical Outcomes

Biochemical outcomes are listed in Table 3. There was no preoperative significance between groups when adjusted for age and gender. There was no significance in mean corpuscular volume, albumin, uric acid, ferritin, vitamin E, vitamin A or zinc between groups postoperatively. Postoperatively, SDJB had a significantly higher haemoglobin level than the SADI-S group (p=0.023), there was a gender difference (p=0.001) with adjustment. Levels of corrected calcium were significantly higher in SDJB and SG compared to SADI-S (p=0.002, p=0.021 respectively) with SDJB and SG having higher corrected calcium values than SADI-S however all levels were within the accepted normal range. The age difference was noted (p=0.035 with adjustment). Both SDJB and SADI-S had significantly lower serum cholesterol compared to the SG group with SADI-S having significantly lower cholesterol

than SDJB p=<0.001, once again gender difference was noted p=<0.001. Triglycerides demonstrated significance between groups with SADI having significantly lower triglycerides than SG p=0.032.

Both B12 and folate had significant differences between groups p=<0.001 and p=<0.001 respectively. SDJB group had significantly higher serum B12 levels compared to the SG group p=<0.001 and both SADI-S and SDJB group had higher folate levels than SG group (p=0.002 and p=0.001). Notably, SADI-S had significantly lower vitamin D levels post-operative compared to both SDJB and SG groups (p=0.009). Selenium, an important trace metal, had significant differences across groups postoperatively, with SADI having a significantly lower level than SDJB (p=0.041).

		SADI-S	SDJB	SG	Sig
		Pre op n= 77	Pre op n= 38	Pre op n= 114	
		Post op n = 70	post op n=30	post op n= 90	
		M(SD)			
Hb	Pre op	138.5 (10.6)	141.1 (14.1)	140.7 (14.7)	
	Post op	132 (13.1)	139 (12.9)	138 (14.4)	p=0.023
					SADI-S vs SDJB
					p=0.049
MCV	Pre Op	87.2 (4.9)	87.4 (4.5)	87.5 (5.4)	
	Post op	89.1 (5.6)	90.4 (4.3)	89.7 (5.3)	p= 0.263
Albumin	Pre Op	40.1 (5.2)	41.0 (3.7)	40.25 (3.5)	
	Post op	38.8 (4.6)	40.3 (3.0)	39.6 (3.8)	p=0.418
Corrected Ca	Pre Op	2.3 (.09)	2.3 (.08)	2.3 (.20)	
	Post op	2.2 (.08)	2.5 (.08)	2.5 (.08)	p=0.002
					SADI-S vs SDJB $p=0.021$
					SADI-S v SG $p=0.002$
Uric acid	Pre Op	.38 (.09)	.40 (.09)	.39 (.10)	
	Post op	.31 (.07)	.30 (.07)	.33 (.09)	p=0.130
Cholesterol	Pre Op	4.9 (1.0)	4.8 (1.0)	5.1(.99)	
	Post op	4.0 (.83)	4.2 (.69)	5.1 (.98)	p=<0.001
					SADI-S vs SDJB $p = 0.045$
					SDJB vs SG $p=0.002$
Triglycerides	Pre Op	1.9 (1.4)	1.7 (1.0)	1.8 (1.0)	
	Post op	1.0 (.39)	1.1 (.39)	1.3 (.67)	p=0.001
					SADI-S vs SG $p=<0.001$
HbA1c	Pre Op	6.1 (1.8)	5.9 (1.2)	5.6 (1.0)	
	Post op	5.0 (.48)	5.0 (.52)	5.3 (.55)	p=0.032
					SADI-S vs SG p=0.030

Volume 08; Issue 16

J Surg, an open access journal

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HbA1c >6.5 (n/%)	Pre Op	13 (19%)	7 (21%)	10 (9.8%)	
	Post op	1 (1%)	1.1 (.39)	1.3 (.67)	p=0.032
					SADI-S vs SG p=0.030
Ferritin	Pre Op	12.0 (4.9)	12.3 (4.2)	12.9 (4.8)	
	Post op	124.8 (184.5)	116.7 (96.4)	134.9 (134.9)	p=0.410
B12	Pre Op	330.4 (126.4)	366.7 (162.9)	336.3 (152.1)	
	Post op	357.9 (206.6)	455.5 (173.3)	291.2 (173.7)	p=<0.001
					SDJB vs SG p=<0.001
Folate	Pre Op	27.2 (11.2)	26.0 (10.5)	26.2 (10.4)	
	Post op	15.1 (9.6)	24.5 (12.0)	22.8 (13.7)	p=<0.001
					SADI-S vs SG p=0.002
					SDJB vs SG p=<0.001
Vit D	Pre Op	55 (19.5)	53.9 (19.6)	52.0 (18.2)	
	Post op	57. 0 (22.5)	70.0 (20.8)	65.3 (22.0)	p=0.009
					SADI-S v SDJB $p=0.019$
					SADI-S v SG $p=0.042$
Vit E	Pre Op	30.0 (11.8)	34.9 (9.8)	31.4 (9.3)	
	Post op	22.5 (6.6)	27.8 (4.1)	30.0 (8.3)	p=0.100
Vit A	Pre Op	1.7 (.57)	1.7 (.46)	1.5 (.45)	
	Post op	1.2 (.44)	1.6 (.71)	1.6 (.50)	p=0.212
Zinc	Pre Op	11.9 (2.3)	11.1 (2.0)	11.0 (2.3)	
	Post op	10.14 (0.30)	11.20(0.4)	10.73 (0.31)	p=0.130
Magnesium	Pre Op	0.81 (0.8)	0.80 (0.08)	0.79 (0.06)	
	Post op	0.81 (0.10)	0.84 (0.07)	0.81 (0.06)	P=0.345
Selenium	Pre Op	1.3 (0.2)	1.3 (0.1)	1.3 (0.2)	
	Post op	1.1 (0.24)	1.41 (0.37)	1.32 (0.21)	p=0.041
					SADI-S v SG $p=0.046$

Table 3: Biochemical results over 12-24 months.

Discussion

This is the first comparative report on long-term outcomes of SADI-S vs SDJB in the literature. A total of 270 patients were recruited who had undergone either 1) primary SADI-S 2) primary SDJB or 3) primary SG. The average age across the three groups was 40, 39 and 40 respectively with no significance between the groups. There was no significance of gender between the groups all three groups having a predominant male contribution. The average weight before procedure was 143.9 kg - 145.5 kg with again, no significance across the groups. Notably, our study had a higher preoperative weight and BMI when comparing data in the literature with pre- op BMI of 50kg/m². We attempted to account for all confounders where possible. Preoperative BMI was matched across all cohorts.

The SADI-S procedure was initially performed to be a simplification of the traditional Duodenal Switch (DS).[10] The idea was to reduce malabsorptive complications, whilst this is true in the fact that it improves malabsorptive outcomes, it does not entirely remove them from the bariatric picture [1]. The SDJB is a further refinement of the SADI-S with hopes to further reduce complications associated with malabsorption. The degree of malabsorption and biochemical deficiency is typically associated with common channel length. Whilst there is no consensus within the literature on the best limb length, it is widely accepted that a CC ≤250cm is associated with higher rates of fat-soluble vitamin and trace element deficiencies [11-13]. A systematic review of the efficacy and safety of SADI-S reported selenium, zinc and iron as the most common deficiencies post-op (up to 50% of reported cases) and Vit A deficiency in up to 53% of reported cases [14].

Calcium homeostasis also appears to be affected within the SADI-S population with PTH, corrected calcium and vitamin D levels being commonly affected. The SADI-S has been reported to have a significant increase in nutritional deficiencies from baseline however, Spinos stated that many papers do not include baseline preoperative blood for comparison and thus make the interpretation of values cloudy [15]. In contrast to other malabsorptive procedures such as the RYGB and DS, SADI-S does not tend to have large alterations in values of albumin, iron, or ferritin.

Our data reflects the literature in regard to SADI-S with significant differences in corrected calcium, yet notably, the SDJB group had significantly higher corrected calcium than their SADI-S cohort, this may be due to the longer length of ileum available for calcium absorption. There was no significant anaemia across all groups with SDJB having the highest Haemoglobin levels which is consistent with current data. [8,10] Overall, there were no significant micronutrient deficiencies and good nutritional status was maintained at 12 months post-procedure. Whilst postop folate levels remained sufficient, all three surgical cohorts demonstrated a decrease in total folate levels, the greatest among the SADI-S cohort, and the difference between cohorts was statistically significant. Despite this, folate levels in this study were higher post-operatively compared to alternate studies [16-18]. Results from this study demonstrate an overall increase in total ferritin levels among all three surgical groups. This is not consistent with comparable deficiency rates of 15-45% SG vs 30-40% SADI-S [13,17]. When compared to nutritional outcomes of alternate studies, mean post-operative ferritin levels in this study were slightly lower (124.8 \pm 184.5 vs 159.5 \pm 195.8ng/mL) [1]. Given the bypassing of duodenal and proximal jejunal absorption sites of iron, it is expected that SADI-S and SDJB would demonstrate lower overall ferritin levels and greater prevalence of deficiency post-operatively than SG which is the case in this study and is in line with previous investigations into nutritional status post SG and conversion to SADI-S. Possible reasons for the lack of deficiency are good supplementation compliance rates, and enhanced absorption rates/capacity of recommended iron supplements. Selenium levels were noted in our study to remain stable post SDJB with the SADI-S cohort being the only cohort with a deficiency post operatively. This is in conjecture with the literature with comparative rates of deficiency being up to 50% [16].

Overall, our cohort did not demonstrate any significant biochemical deficiencies to mark malnutrition, in stark contrast to comparative literature. We were able to demonstrate the SDJB group could maintain serum B12 levels and notably no patient had serum HbA1c over 6.5%. These results may be attributed to good adherence with post operative supplement regimes or due to pathology collection timeframes varying between 12-18 months.

It is noted that some deficiency's take some years to manifest post operatively [5]. The only other comparative research for SDJB published by Lee et al corroborated our data indicating SDJB maintains nutritional levels at 12 months post operative.

Concerning weight loss, the efficacy of SADI-S has already been established and we were able to demonstrate that the SDJB is aligned with SADI-S in long term weight loss maintenance. [19,20] The study's limitations should be considered, including its retrospective nature and drop off in long-term follow-up, especially at 4, 5 and 6 years as expected in this cohort, this may affect the long-term analysis. Also, the variation in pathology collection at 12-24 months may miss some nutritional deficiencies and prolonged measures of biochemistry may yield different results. Nevertheless, the study's strengths include being the first to compare SADI-S versus SDJB over long-term outcomes. Patient group matching for accurate comparison and consideration of confounders for reliable relationship analysis of results.

Conclusions

This study indicates the SDJB has equal efficacy or significantly better efficacy than both the SG and SADI-S procedure in maintaining long-term weight loss and promising results for the maintenance of a balanced nutritional status. It demonstrates that SDJB may be considered as an alternative to the SADI-S and another bariatric technique to add to the surgeon's armoury. Overall, our study demonstrates that fixing the BP limb length to 150cm (counting proximally) and thus theoretically elongating the common channel, maintains good long-term weight loss and has comparative biochemical markers of malabsorption when compared to the SADI-S procedure. This has the potential to change operative techniques and improve patient outcomes over the long term. However, further studies with longer follow-up data are needed to draw definite conclusions.

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