



XXIX IFSO World Congress

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Updates in hypoabsorptive surgical strategies

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The Future of Obesity Management:
From Weight Loss to Health Gain



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Disclosure

Advisory Board: Novo-Nordisk, Eli Lilly, Bausch, GI-Windows

Research support: Johnson and Johnson, Medtronic, Bausch, GI-Windows

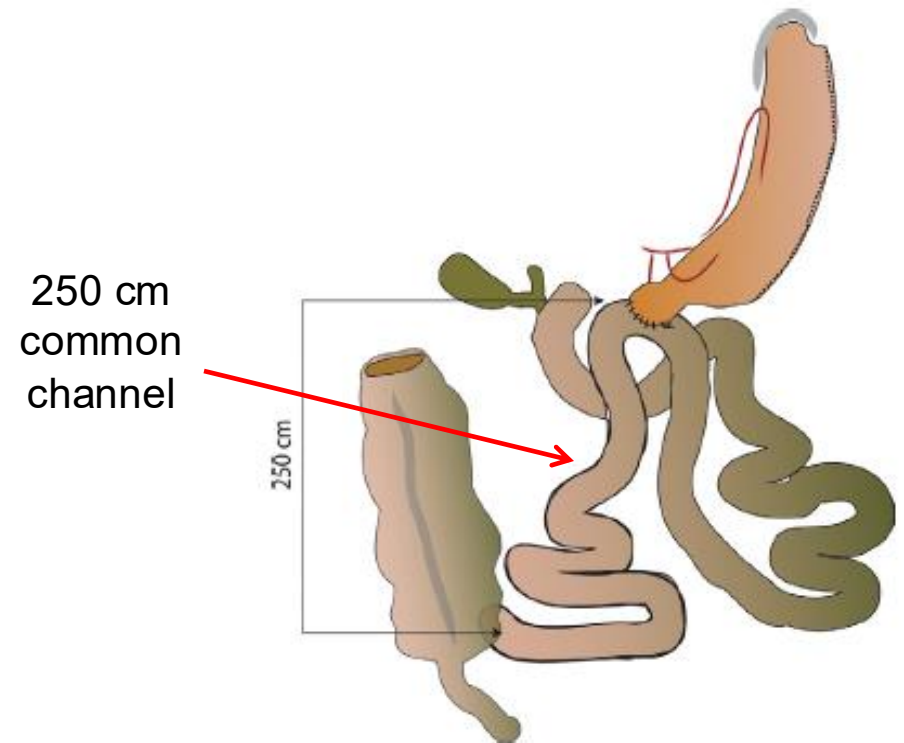
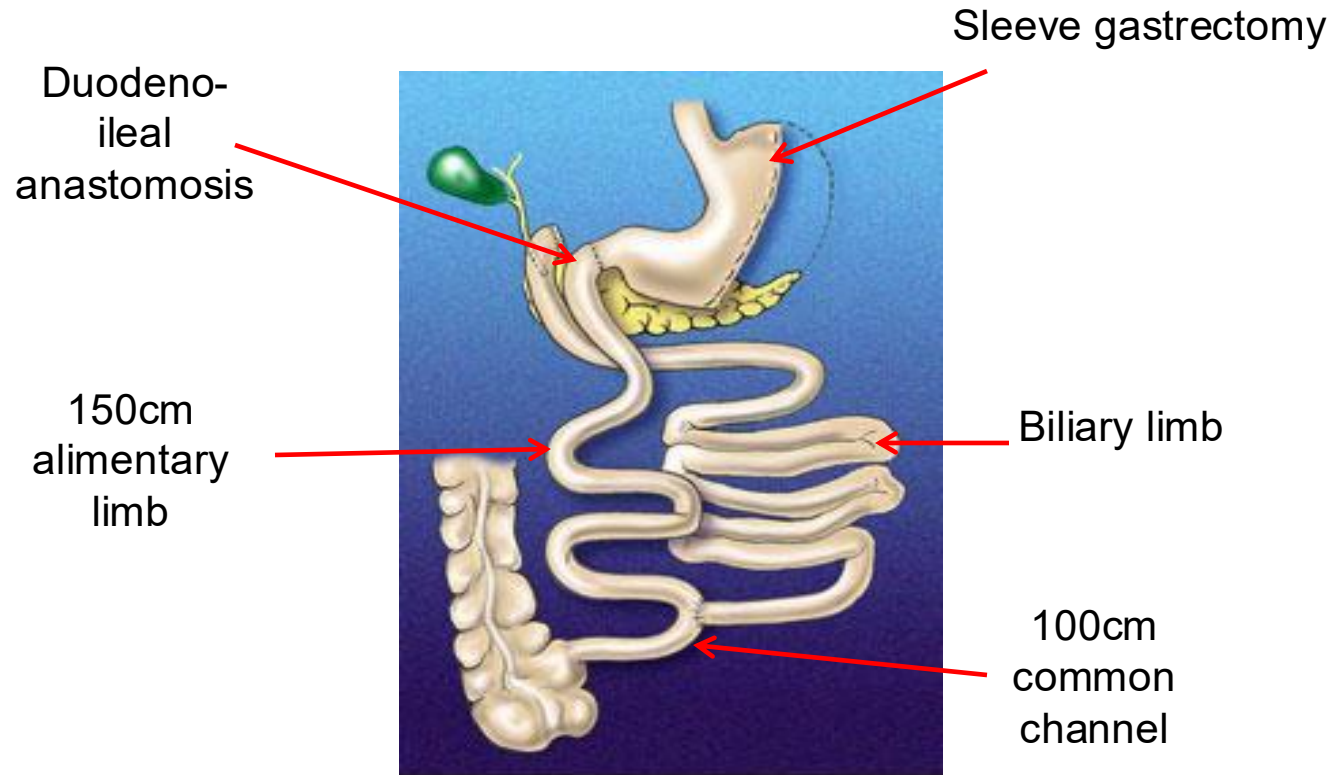


Plan

- Introduction
- 5-year data of One-stage DS Vs SADI-S
- 2-year interim results of Second-stage DS Vs SADI-S
- Conclusion

DS versus SADI-S

Single-Anastomosis Duodeno-Ileal bypass



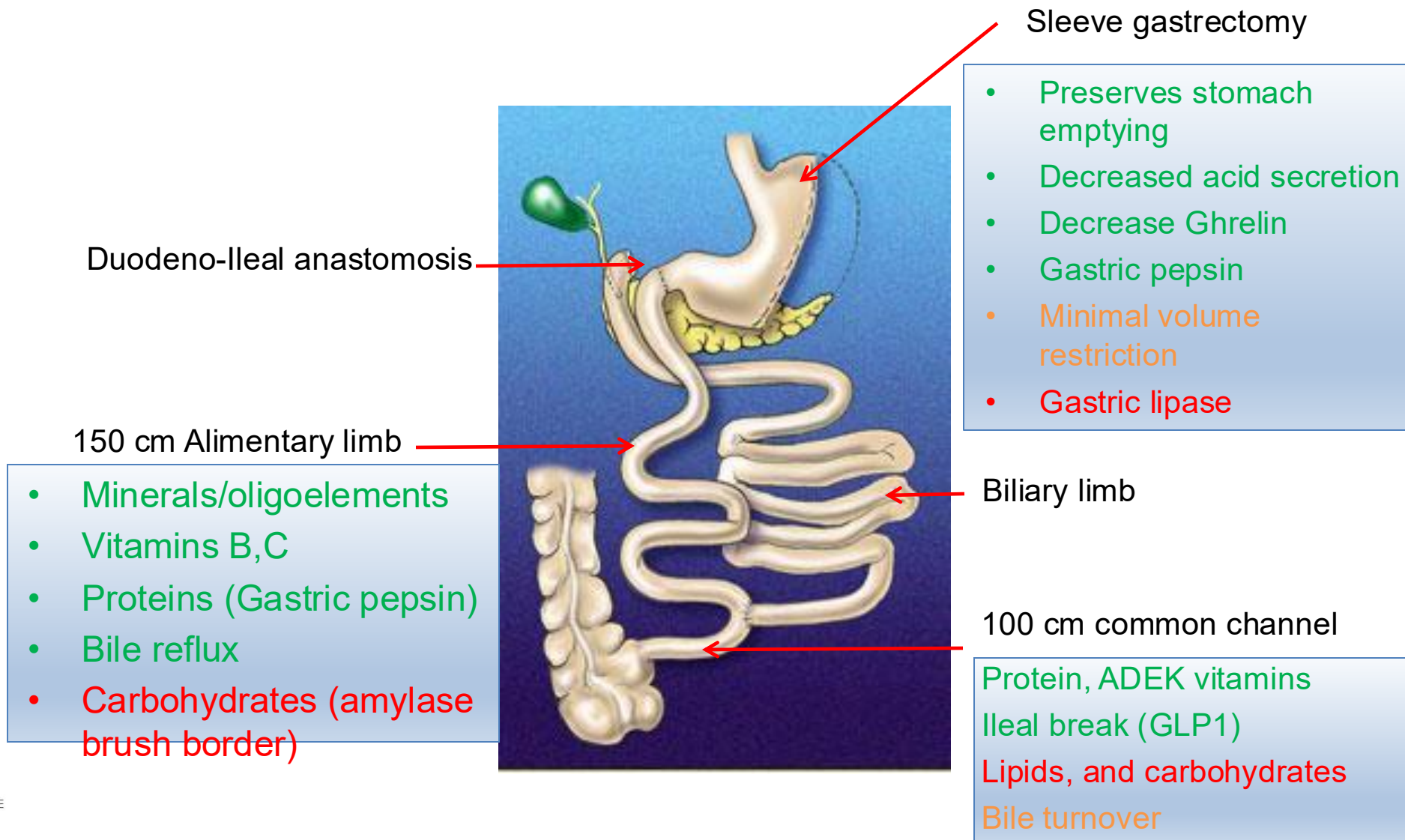
Obes Surg. 2007 Dec;17(12):1614-8. Epub 2007 Nov 27.

Proximal duodenal-ileal end-to-side bypass with sleeve gastrectomy: proposed technique.

Sánchez-Pernaute A¹, Rubio Herrera MA, Pérez-Aquirre E, García Pérez JC, Cabrerizo L, Díez Valladares L, Fernández C, Talavera P, Torres A.

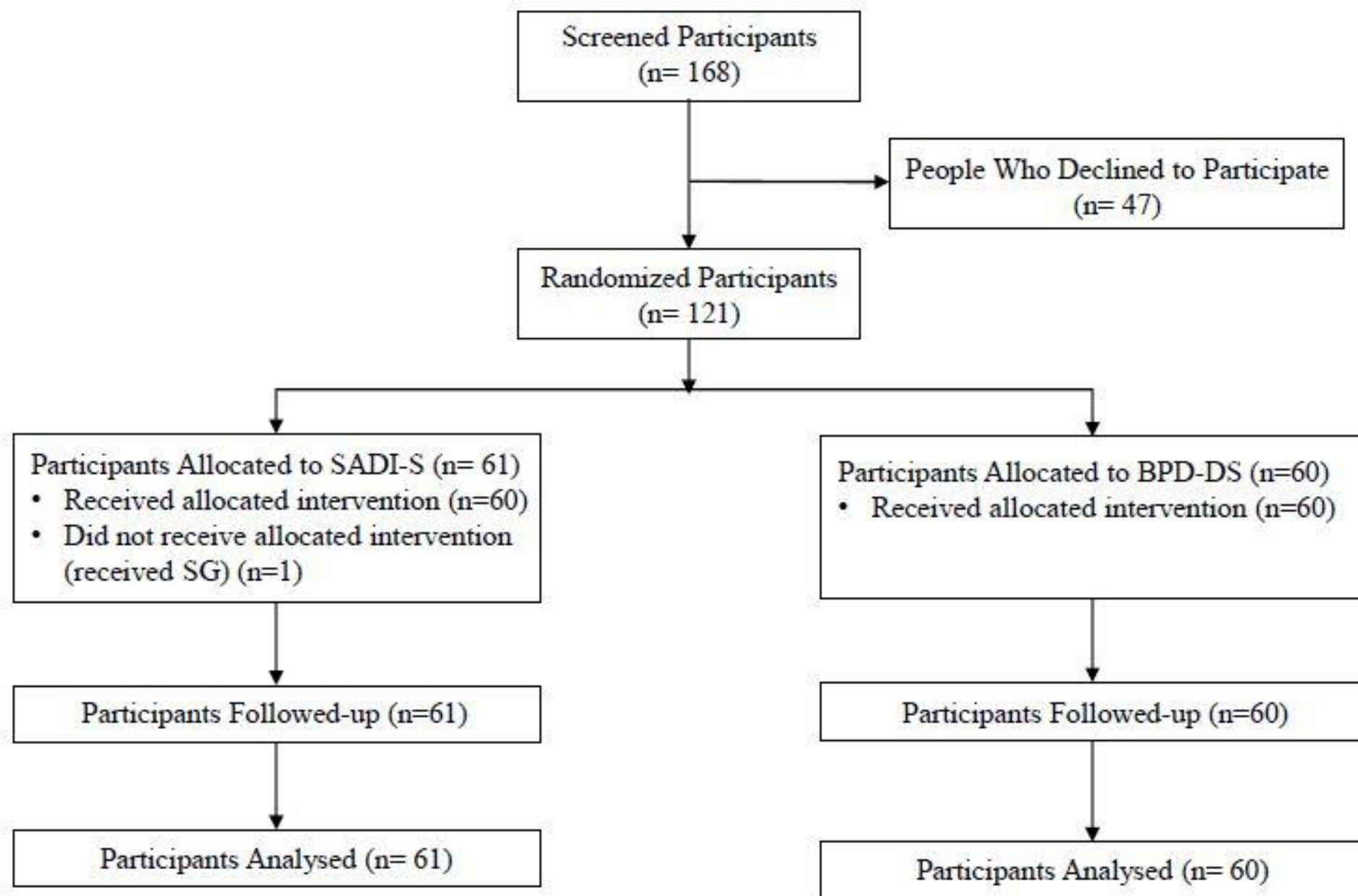
Sanchez-Pernaute et al, Obes Surg 2007

DS Vs SADI-S



**Prospective randomized double-blinded clinical trial
comparing the Single Anastomosis Duodeno-Ileal Bypass (SADI)
to Bilio-Pancreatic Diversion with Duodenal Switch.**

- Randomized 1:1 – One-Stage SADI Vs Standard DS
- Double-blinded (patient-evaluator)
- Standard NIH criteria
- N=120 (60 patients in each group)
 - Powered to detect a 5% difference in EWL
 - Non inferiority trial
 - Primary objective: EWL at 2 and 5 Yrs
- F/U for 5 years



DS Vs SADI 250cm RCT

Preliminary 5 years results

	BPD-DS				SADI				
	Mean	Range			Mean	Range			
n	60				61				
Sex (M :F)	9:51				14:47				NS
Age (y)	42	20	-	60	42	26	-	60	NS
Weight (kg)	132.6	96.2	-	196.4	133.1	90	-	196.4	NS
Height (cm)	164	150	-	180	165	149	-	186	NS
BMI (kg/m ²)	48.8	39.9	-	61.0	48.7	38.9	-	59.8	NS

103/121 patients available for follow-up at 5 years (86%)

Peri-operative data

N	BPD-DS 60	SADI 61	p
Hospital Stay	2.9±2.3	2.9±1.5	0.4
Blood loss	25±26	24±23	0.9
Operative time	166±26	152±27	0.004

Complications ≤ 24m

Clavien-Dindo	DS	SADI	p
1	31	35	NS
2	59	52	NS
3 – requiring surgical, endoscopic or radiological intervention			
3a	2	2	NS
3b	4	6	NS
4a	0	0	
4b	0	0	
5	0	0	
Total	96	95	NS
Related to surgery	51	41	NS
Reoperation	2 (3%)	2 (3%)	NS

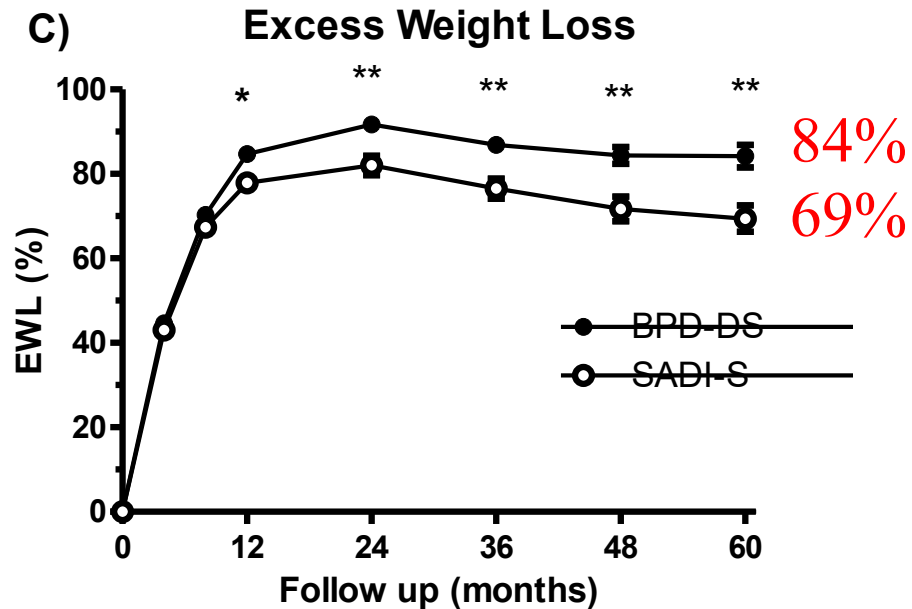
10% vs 13%

SBO (1) leak (1)

Leak (1) Abcess (1)

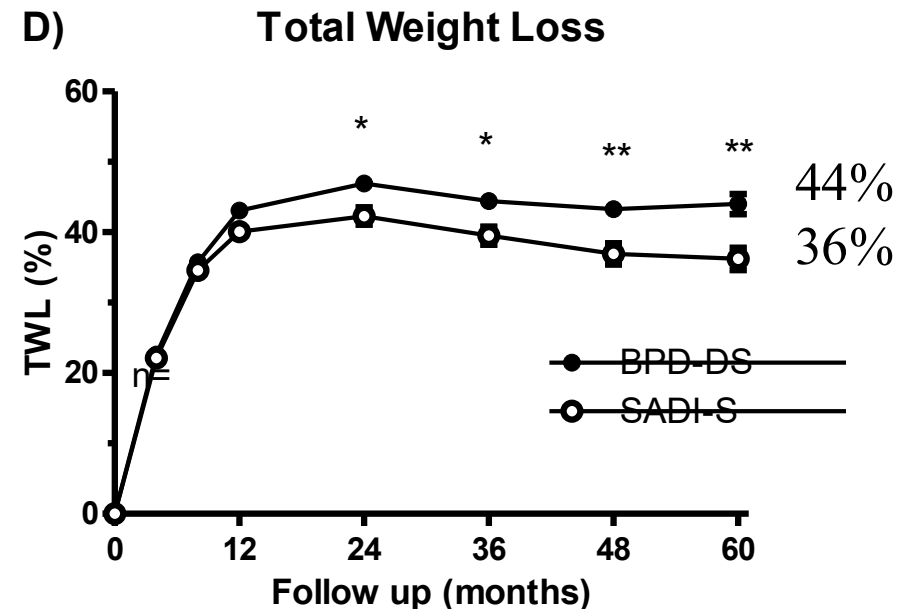
Weight loss

84% versus 69% EWL at 5 years



Repeated measures analysis of variance
time: $p < 0.0001$
surgery: $p = 0.0002$
time*surgery: $p = 0.0438$

* least square means contrast p value < 0.05 after Bonferonni correction
**least square means contrast p value < 0.01 after Bonferonni correction



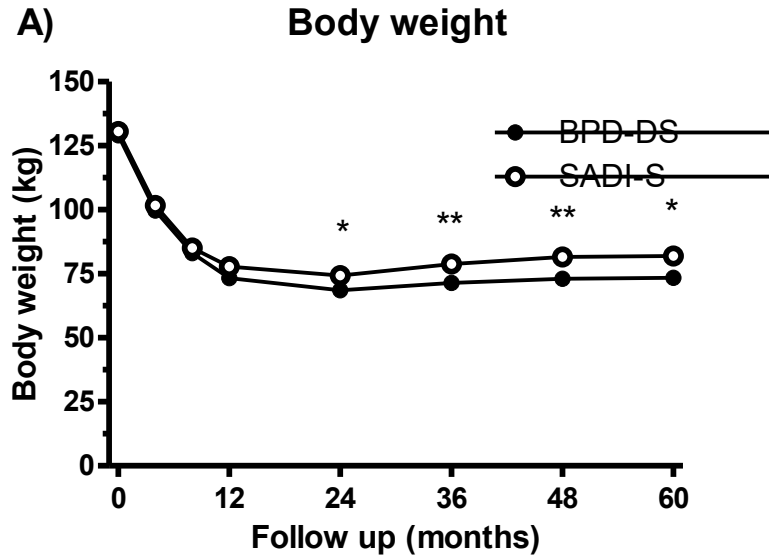
Repeated measures analysis of variance
time: $p < 0.0001$
surgery: $p = 0.0004$
time*surgery: $p = 0.0682$

* least square means contrast p value < 0.05 after Bonferonni correction
**least square means contrast p value < 0.01 after Bonferonni correction

At 5 Years

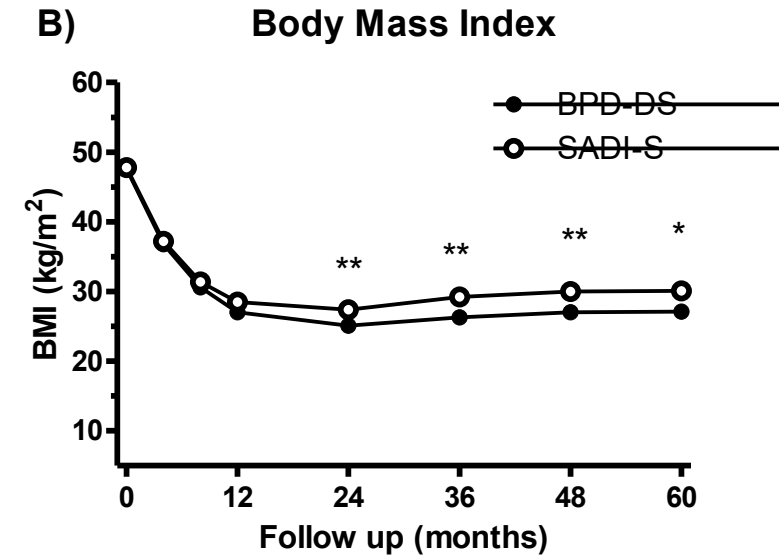
DS: 131 ± 20 to 73 ± 12 kg (-58kg)

SADI: 134 ± 18 to 82 ± 16 kg ADI (-52kg)



Repeated measures analysis of variance
time: $p < 0.0001$
surgery: $p = 0.0071$
time*surgery: $p = 0.1850$

* least square means contrast p value < 0.05
after Bonferonni correction
**least square means contrast p value < 0.01
after Bonferonni correction



Repeated measures analysis of variance
time: $p < 0.0001$
surgery: $p = 0.0055$
time*surgery: $p = 0.0864$

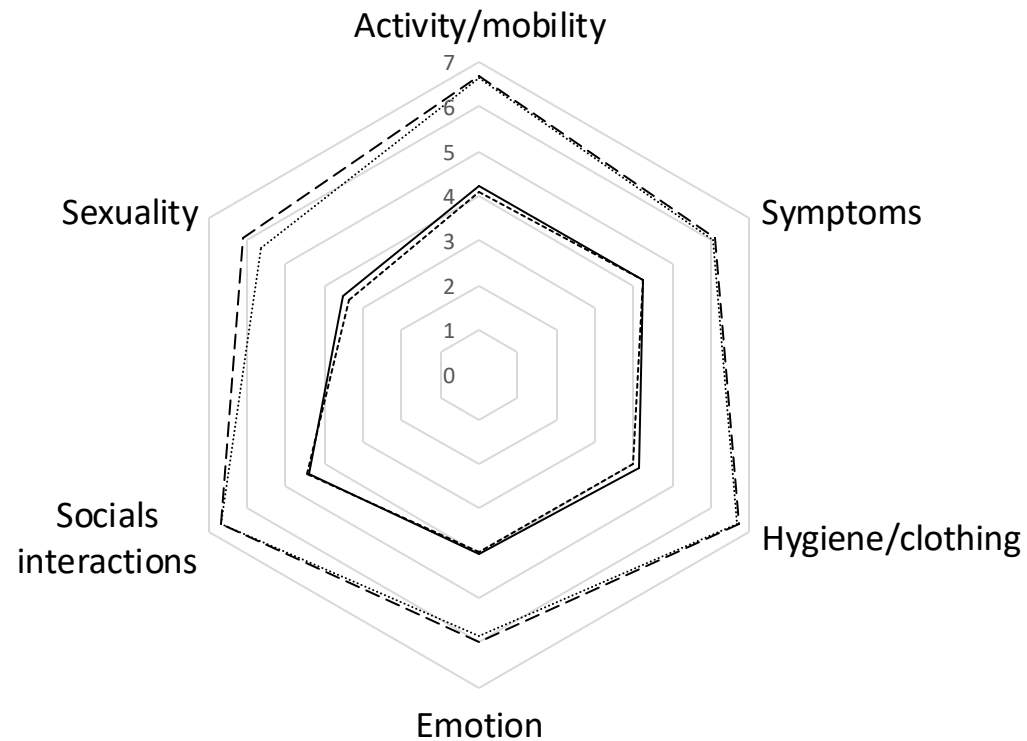
* least square means contrast p value < 0.05 after
Bonferonni correction
**least square means contrast p value < 0.01 after
Bonferonni correction

Quality of life and side-effects

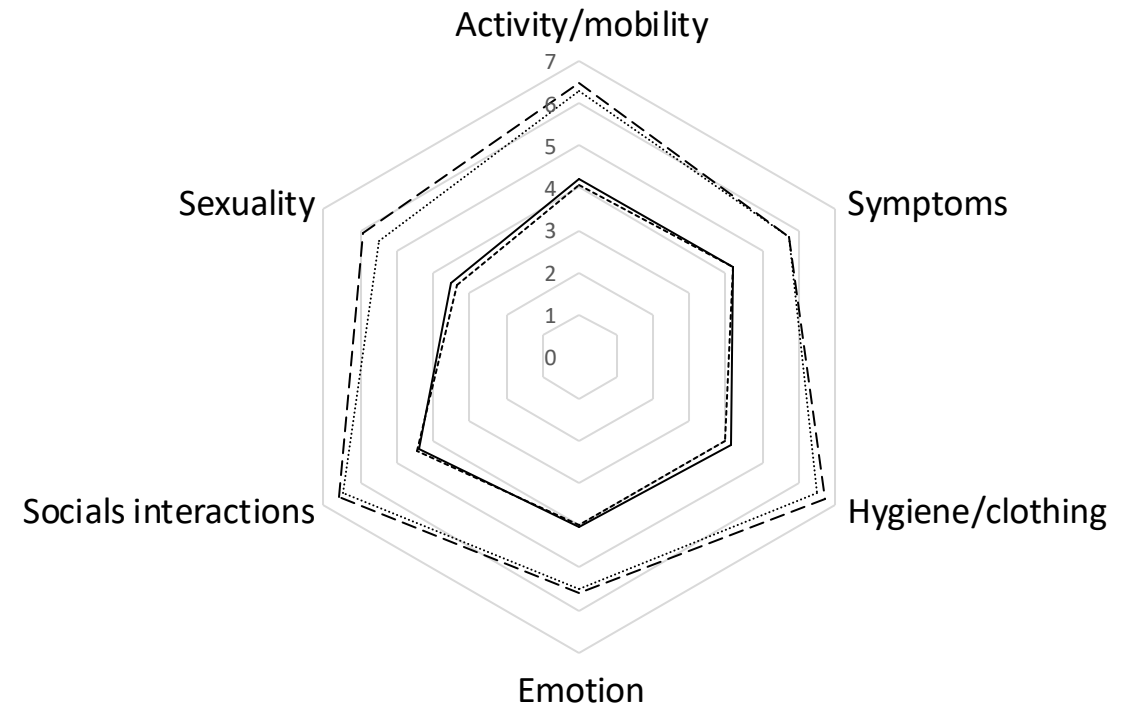
Quality of Life

Laval Questionnaire 44 items, 7-points Likert scale

QoL at 0 and **24 months** for BPD-DS and SADI-S



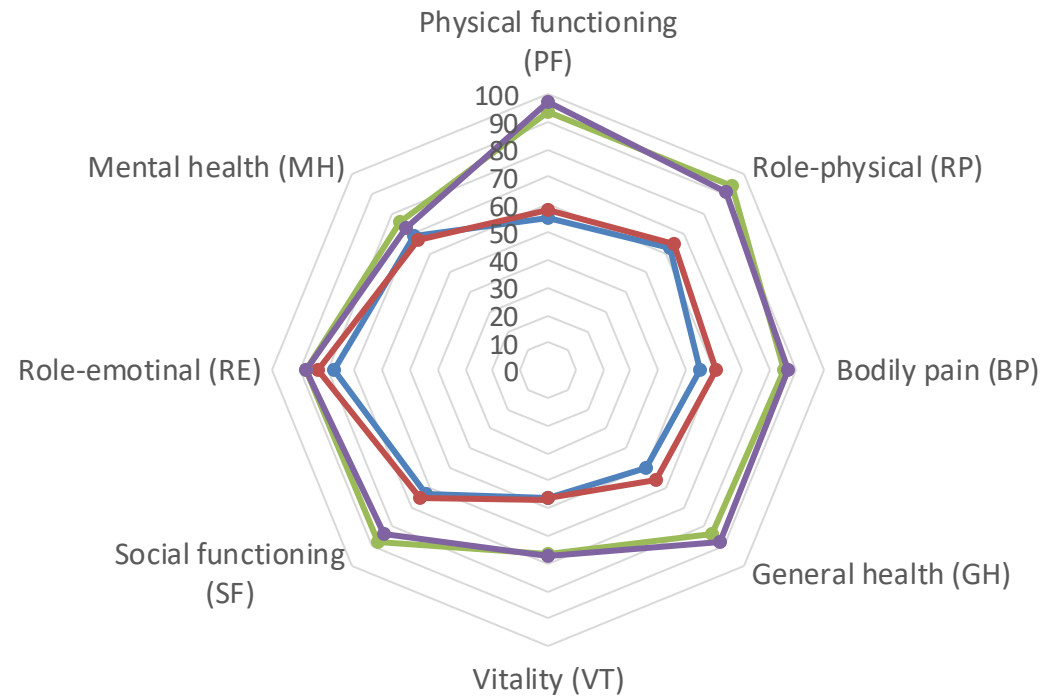
QoL at 0 and **60 months** for BPD-DS and SADI-S



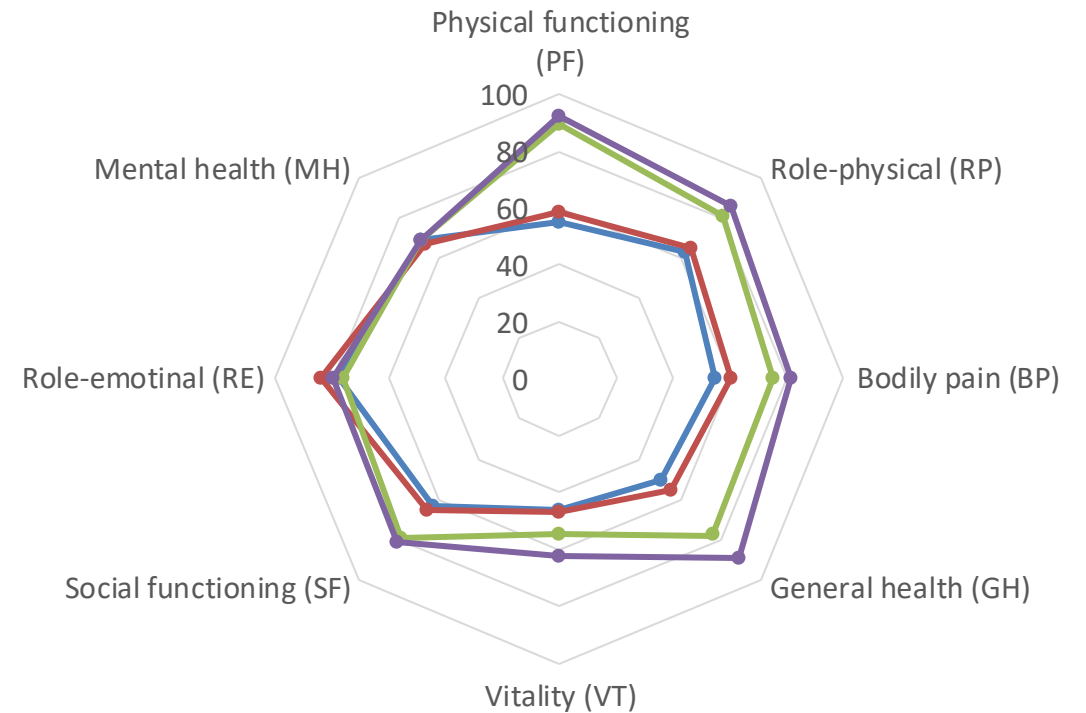
Quality of Life

No difference between surgeries

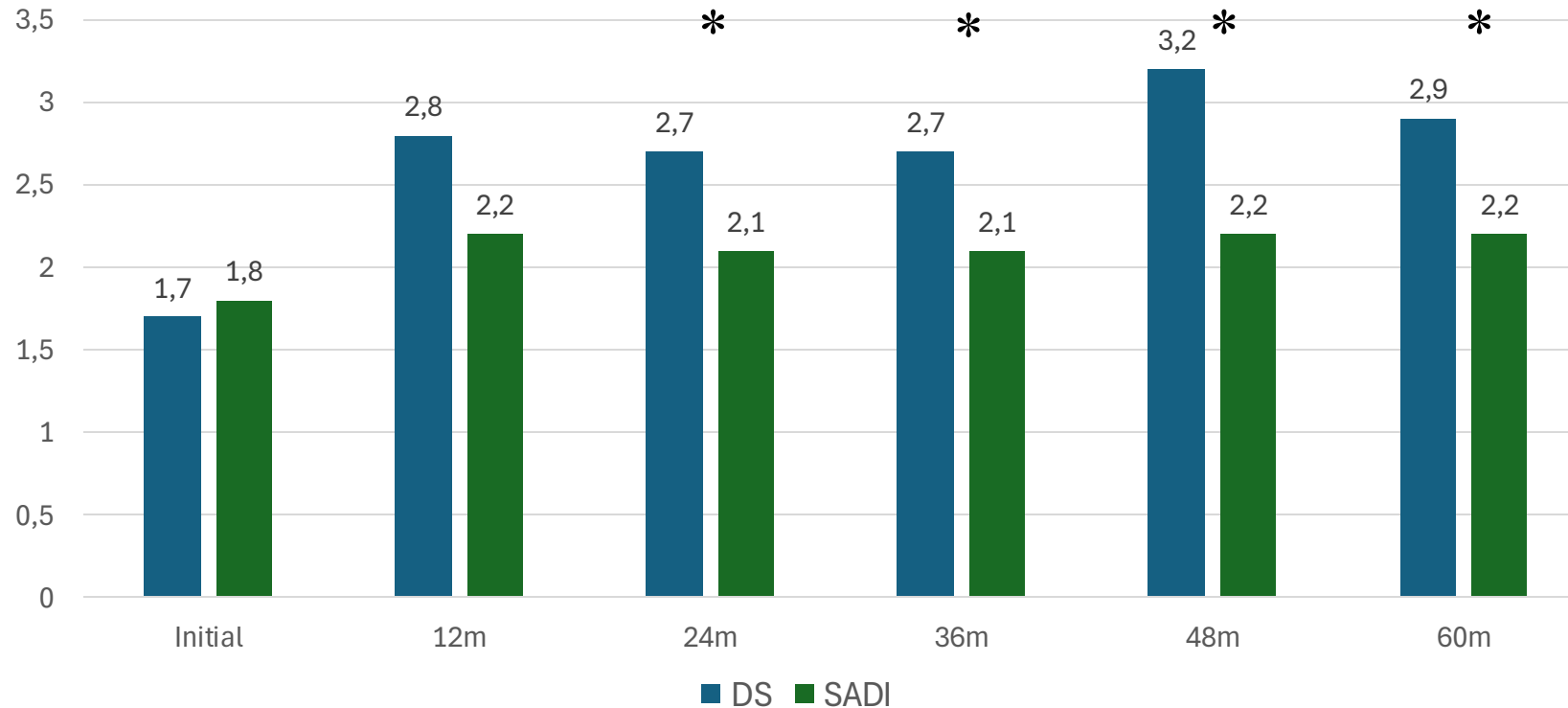
SF-36 at 0 and **24 months** for BPD-DS and SADI-S



SF-36 at 0 and **60 months** for BPD-DS and SADI-S



Number of daily bowel movements

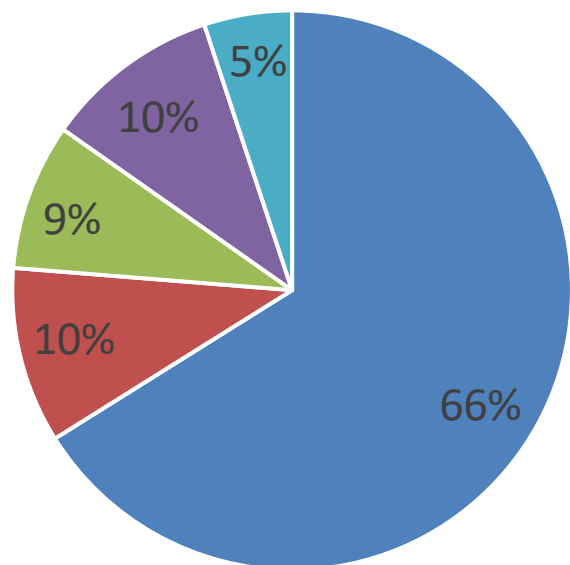


Significant increase from baseline, in both groups

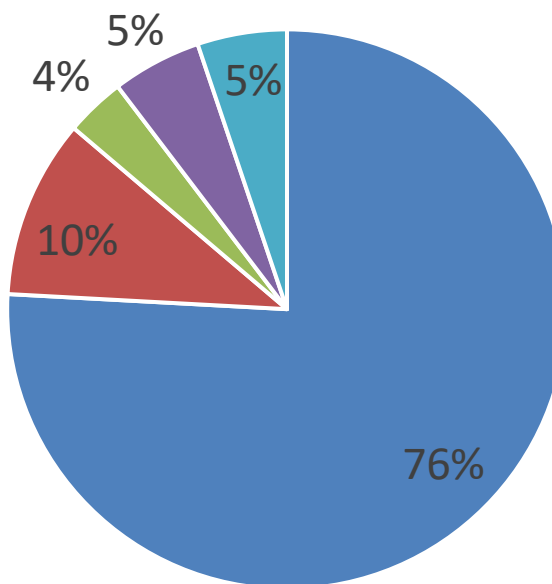
* Significant difference between groups - $P < 0.05$

GERD symptoms – BPD-DS

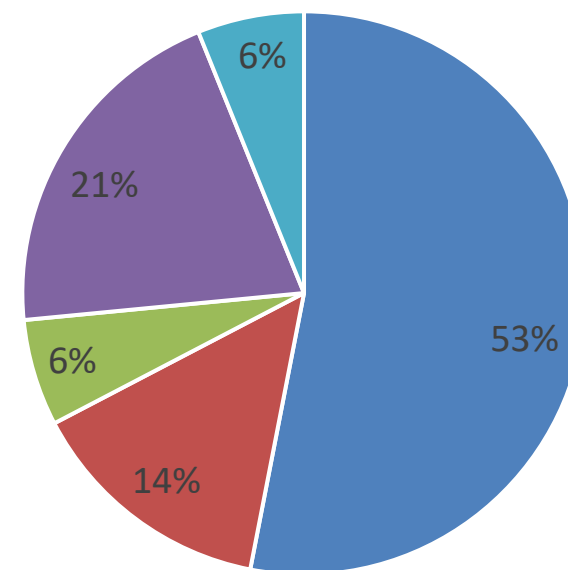
Baseline



24 months*



60 months



Remission (Symptoms ≤ 1 /month)

- Significant increase at 2 Yrs ($p=0.02$)

- No difference at 5 Yrs

■ - Almost never

■ - Once a week

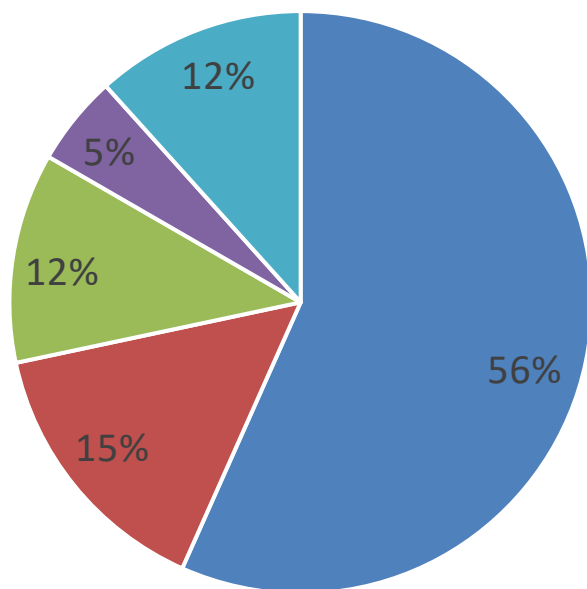
■ - Daily

■ - Once a month

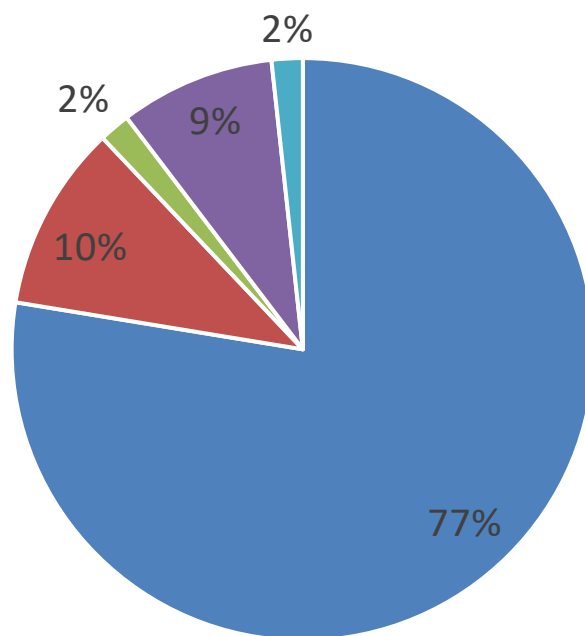
■ - More than once a week

GERD symptoms – SADI-S

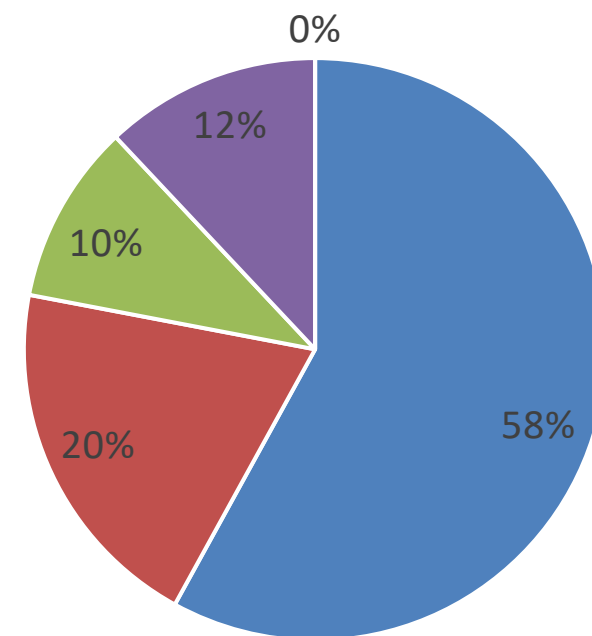
Baseline



24 months *



60 months



Remission (Symptoms ≤ 1 /month)

- Significant increase at 2 Yrs ($p=0.02$)

- No change at 5 Yrs ($p=0.3$)

■ - Almost never

■ - Once a week

■ - Daily

■ - Once a month

■ - More than once a week

Deficiencies at 2 and 5 Years

	DS	SADI	p
Hemoglobin <120			
Baseline	8%	3%	0,2
2 Yrs	32%	10%	0,05
5 Yrs	36%	8%	0,0007
Ferritin <30			
Baseline	22%	18%	0,6
2 Yrs	15%	23%	0,4
5 Yrs	27%	22%	0,7
Vitamin A<1,4			
Baseline	18%	20%	0,8
2 Yrs	38%	25%	0,2
5Yrs	12%	10%	0,8
Vitamin D <50			
Baseline	54%	48%	0,6
2 Yrs	12%	3%	0,2
5 Yrs	8%	4%	0,7

Nutritional supplements

	BPD-DS	SADI	p
Vitamin D	26,000± 25,000	19,000±21,000	0,01
Vitamin A	42,000± 17,000	39,000±17,800	NS
Iron	340±160	345±217	NS
IV Iron	3/56	0/61	NS
Calcium	1100±400	1000±400	NS
Multivitamin	1,5±0,5	1,4±0,6	NS
Pancreatic enzymes	13/46 (22%)	8/53 (13%)	NS
Proteines	3/56 (5%)	1/60 (2%)	NS

DS Versus SADI-S as a second-stage surgery

RCT - 2 years Interim results

Second-Stage DS Vs SADI 250cm RCT

2 years Interim results

- Randomized 1:1 – Second-Stage SADI Vs Standard DS
- Double-blinded (patient-evaluator)
- Standard NIH criteria
- N=62 (30 patients in each group)
- 2 years Data
- 5 year follow-up

Demographic data

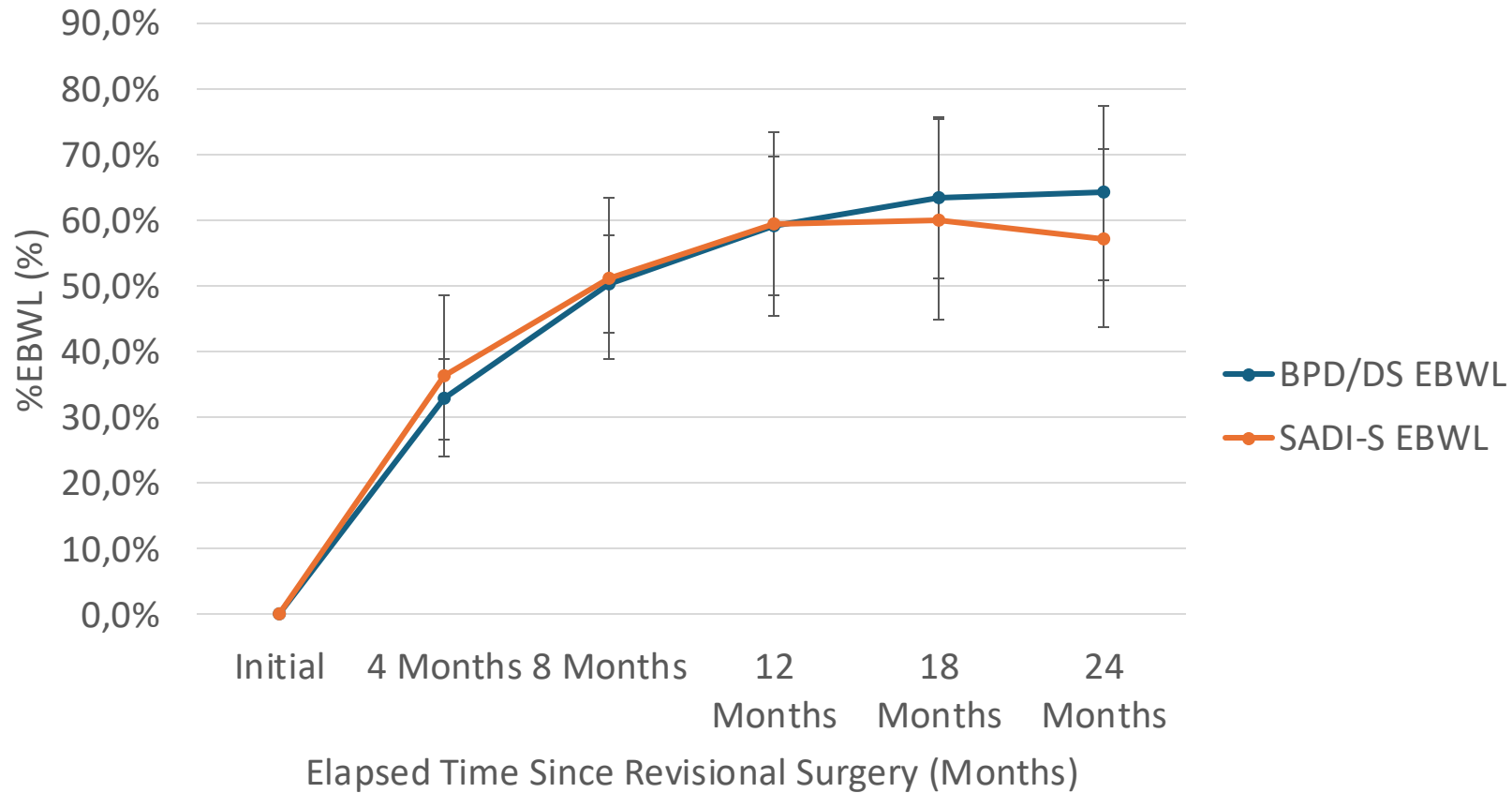
Variable	BPD-DS (n=31)	SADI-S (n=32)	p-value
Age (years)	45,2 ± 9,4	47,7 ± 9,9	0,312
Gender (Male, %)	5 (16,1%)	8 (25,0%)	0,384
BMI prior to SG (kg/m2)	50,4 ± 7,3	49,7 ± 9,40	0,748
BMI prior to revision (kg/m2)	41,2 ± 4,6	40,4 ± 5,9	0,573
Hypertension (%)	12 (38,7%)	14 (43,8%)	0,685
Dyslipidemia (%)	8 (25,8%)	10 (31,2%)	0,633
Obstructive sleep apnea (%)	11 (35,5%)	14 (43,8%)	0,503
GERD (%)	25 (80,6%)	26 (81,3%)	0,951

Peri-operative data

Variable	BPD-DS (n=31)	SADI-S (n=32)	p-value
Operative time (minutes)	133,6 ± 23,0	116,5 ± 27,8	0,010
Length of stay in hospital (days)	2,0 ± 1,9	1,9 ± 0,7	0,802
Minor complication (%)	7 (22,6%)	6 (18,8%)	0,707
Major complication (%)	1 (3,2%)	0 (0%)	0,306

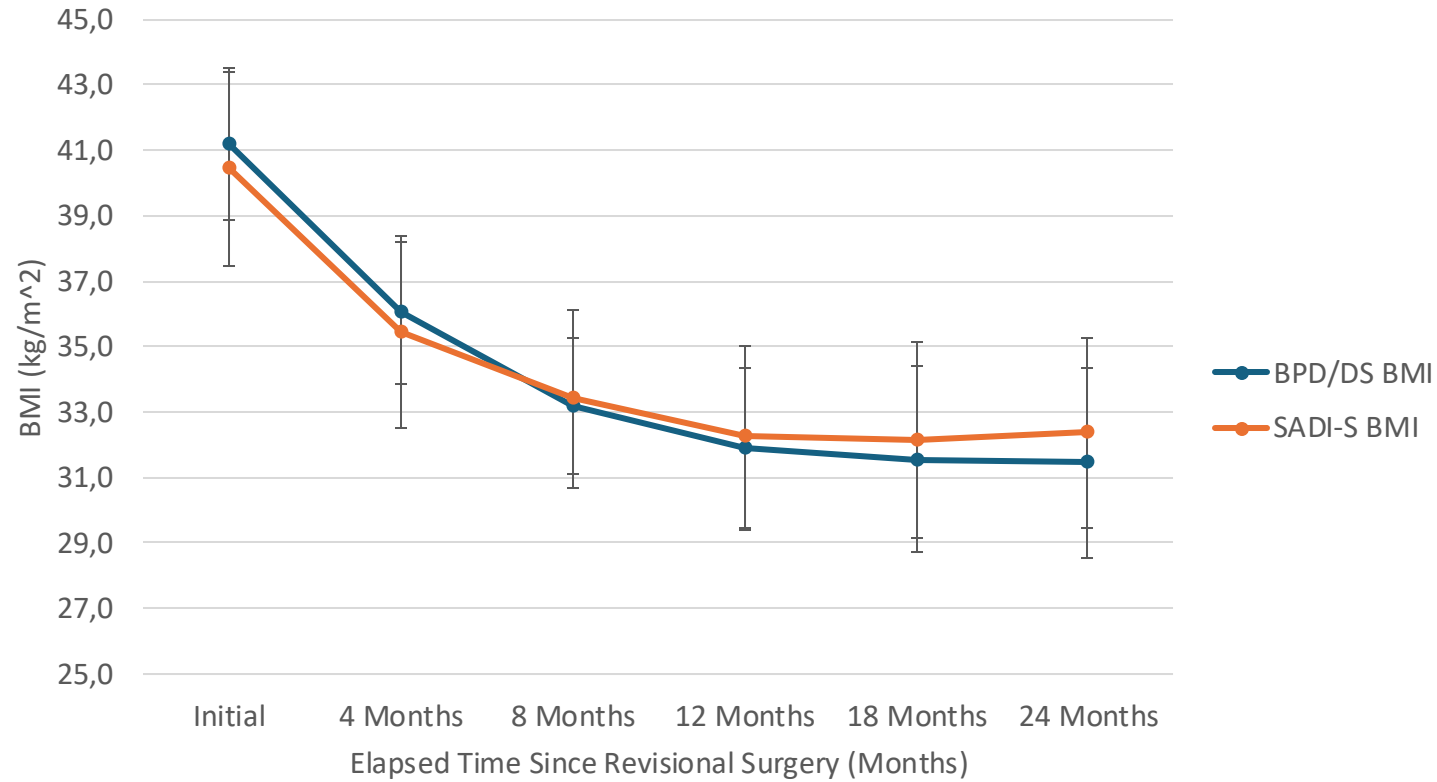
EWL over time

64.3 ± 26 vs $57,3 \pm 27,3$ at 2 year (p=0.3)



BMI reduction over time

BMI of 32.4 Vs 31.5kg/m² at 2 years



Outcomes

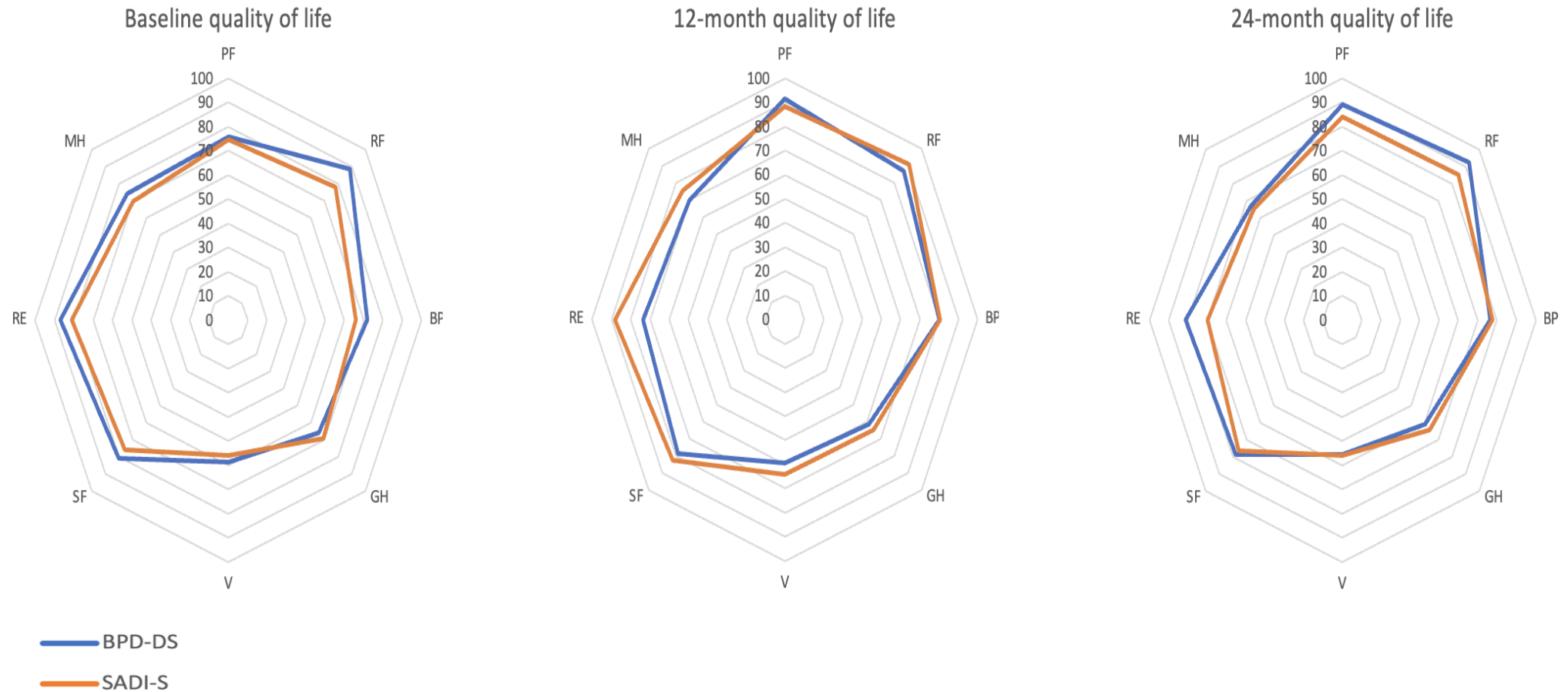
Variable	BPD-DS (n=31)	SADI-S (n=32)	p-value
BMI at 24 months (kg/m ²)	31,5 ± 5,8	32,4 ± 5,8	0,5338
Serum albumin at 24 months (g/l)	37,8 ± 4,3	38,4 ± 4,1	0,5841
BM/day at 24 months	3,3 ± 2,1	2,3 ± 1,20	0,0389
Resolution of hypertension (%)	8 (66,7%)	8 (57,1%)	0,9414
Resolution of diabetes (%)	5 (100%)	2 (50%)	0,2123
Resolution of GERD (%)	8 (32,0%)	6 (23,1%)	0,5083

Complications at 2 years

Complication	BPD-DS (n=31)	SADI-S (n=32)	p-value
Malnutrition (readmission)	1	3	0,6
Worsened GERD	2	1	0,6
Internal hernia	1	0	0,5
Nephrolithiasis	4	2	0,4
Cholelithiasis with biliary colic	1	0	0,5
Sigmoid volvulus	1	0	0,5
Auto-immune hepatitis	0	1	-
Persistent increased liver enzymes	0	1	-
Generalized Anxiety Disorder	0	1	-
TOTAL	10	9	0,6

Quality of life - SF-36

Significant improvement in Physical functioning, role physical and bodily pain



Conclusion

- SADI/DS are the some of the most effective metabolic procedures in terms of weight loss and resolution of obesity-related diseases
- They should be part of the bariatric algorithm
- > It requires more commitment/energy in term of preparation, compliance with vitamin supplementation, follow-up and continuous lifestyle changes

Conclusion - Single-stage SADI Vs DS

- SADI-S and DS offer sustained excess weight loss at 5 years:
84% (DS) vs. 69% (SADI)
- Comparable improvements in metabolic outcomes and Quality of life
- Increased bowel movements and rate of anemia after DS
- Both procedures involve significant intestinal bypass and carry some risks of deficiencies

Conclusion - Second-stage SADI Vs DS

- Staged approach for SADI/DS seems to offer similar benefits to single-stage procedures
- **Additional EWL of 64% Vs 57%** (DS VS SADI) at 2 Yrs (10 points of BMI)
- Similar improvement of obesity-associated diseases
 - Favor SG rather than RYGB if DS/SADI is envisioned
 - Place of DS Vs SADI in high BMI / severe comorbidities or complete weight regain still debated

Conclusion

- Single Anastomosis DS will likely continue to grow
 - Technically easier
 - Reassuring data as a second-stage surgery
 - Potential for fewer GI side effects and reduced long-term nutritional deficiencies

Difficulty to balance the risk of side effects with the risk of long-term weight regain

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24-27 August 2027

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