

DISCLOSURE

THE AUTHORS DECLARE
NO CONFLICTS OF INTEREST

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MID-TERM RESULTS OF A RANDOMIZED CLINICAL TRIAL - SINGLE ANASTOMOSIS DUODENO-ILEAL BYPASS VERSUS BILIOPANCREATIC DIVERSION WITH DUODENAL SWITCH



BACKGROUND



- BPD/DS - EFFECTIVE IN WEIGHT MANAGEMENT AND TREATMENT OF METABOLIC DISORDERS
- SMALL FRACTION OF GLOBAL BARIATRIC SURGERIES OWING TO ITS COMPLEXITY, LONG DURATION, AND POTENTIAL SIDE EFFECTS
- SADI SIMPLIFIES SOME OF THE COMPLEXITIES ASSOCIATED WITH BPD/DS, SHORTENING SURGICAL DURATION, LOWERING POSTOPERATIVE COMPLICATIONS, ALL WHILE PRESERVING ITS THERAPEUTIC EFFICACY

OBJECTIVE



COMPARISON OF CLINICAL OUTCOMES: SADI vs. BPD/DS

- WEIGHT LOSS
- EFFECTS ON ASSOCIATED MEDICAL DISEASES
- MALNUTRITION

METHOD



RANDOMIZED CLINICAL TRIAL

APPROVAL BY THE REGIONAL ETHICS COMMITTEE

REGISTRATION NUMBER: NCT03938571 - WWW.CLINICALTRIALS.GOV



SUPERIORITY TRIAL

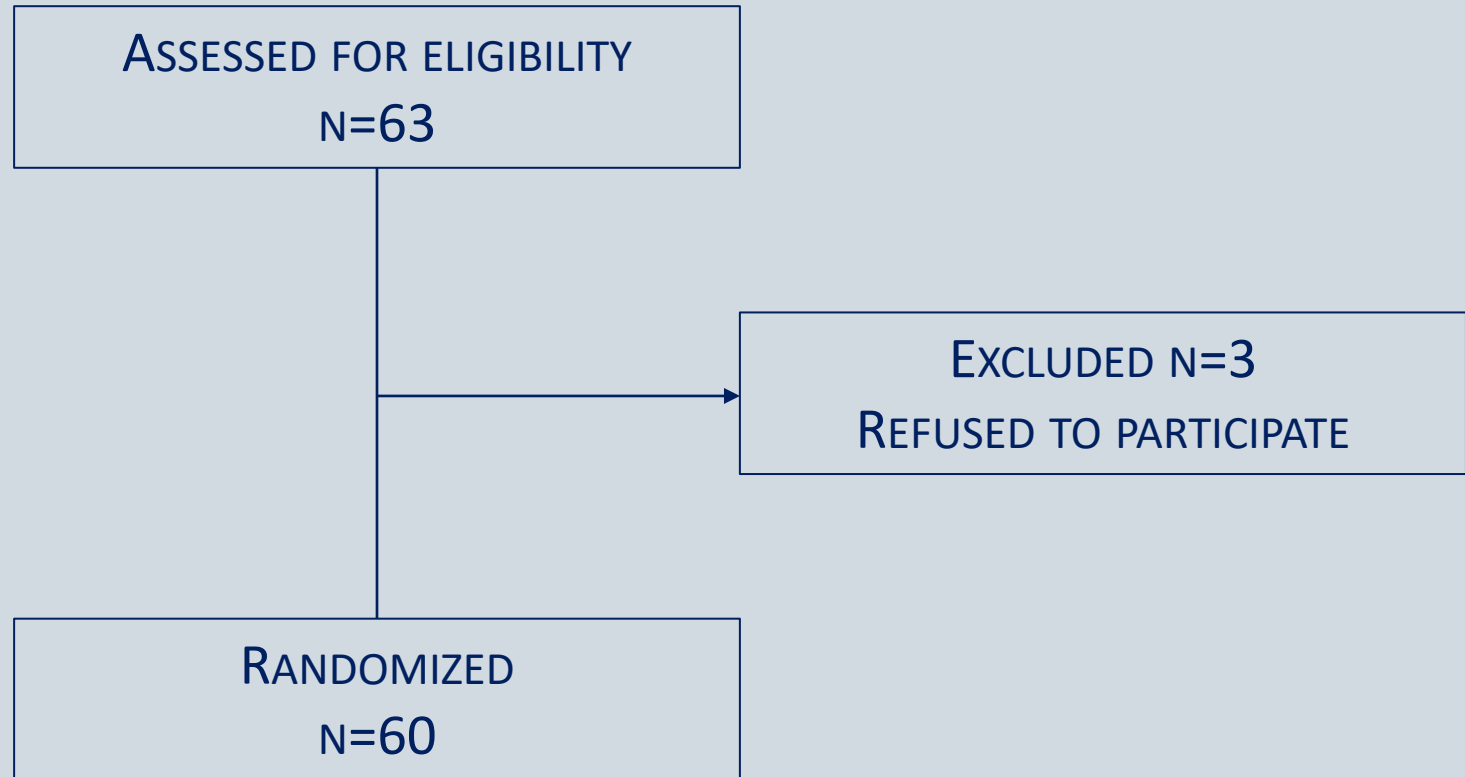
56 PATIENTS - STATISTICAL POWER EXCEEDING 90%

BLOCK RANDOMIZATION

RESULTS



ENROLLMENT AND RANDOMIZATION





ALLOCATION AND INTERVENTION

ALLOCATED TO SADI N=30

RECEIVED THE INTERVENTION N=29

DID NOT RECEIVE THE INTERVENTION N=1

(DUE TO ANATOMICAL CONSTRAINTS)

ALLOCATED TO BPD/DS N=30

RECEIVED THE INTERVENTION N=27

DID NOT RECEIVE THE INTERVENTION N=3

(DUE TO ANATOMICAL CONSTRAINTS)



FOLLOW-UP

LOST TO FOLLOW-UP AFTER SADI N=0
DISCONTINUED THE INTERVENTION N=2
CONVERSION TO GBP N=2

LOST TO FOLLOW-UP AFTER BPD/DS N=1
DISCONTINUED THE INTERVENTION N=3
CONVERSION TO GBP N=1
PROXIMALIZATION OF THE EA N=2

ANALYSIS

ANALYZED AFTER 3 YEARS
N=29

ANALYZED AFTER 3 YEARS
N=26

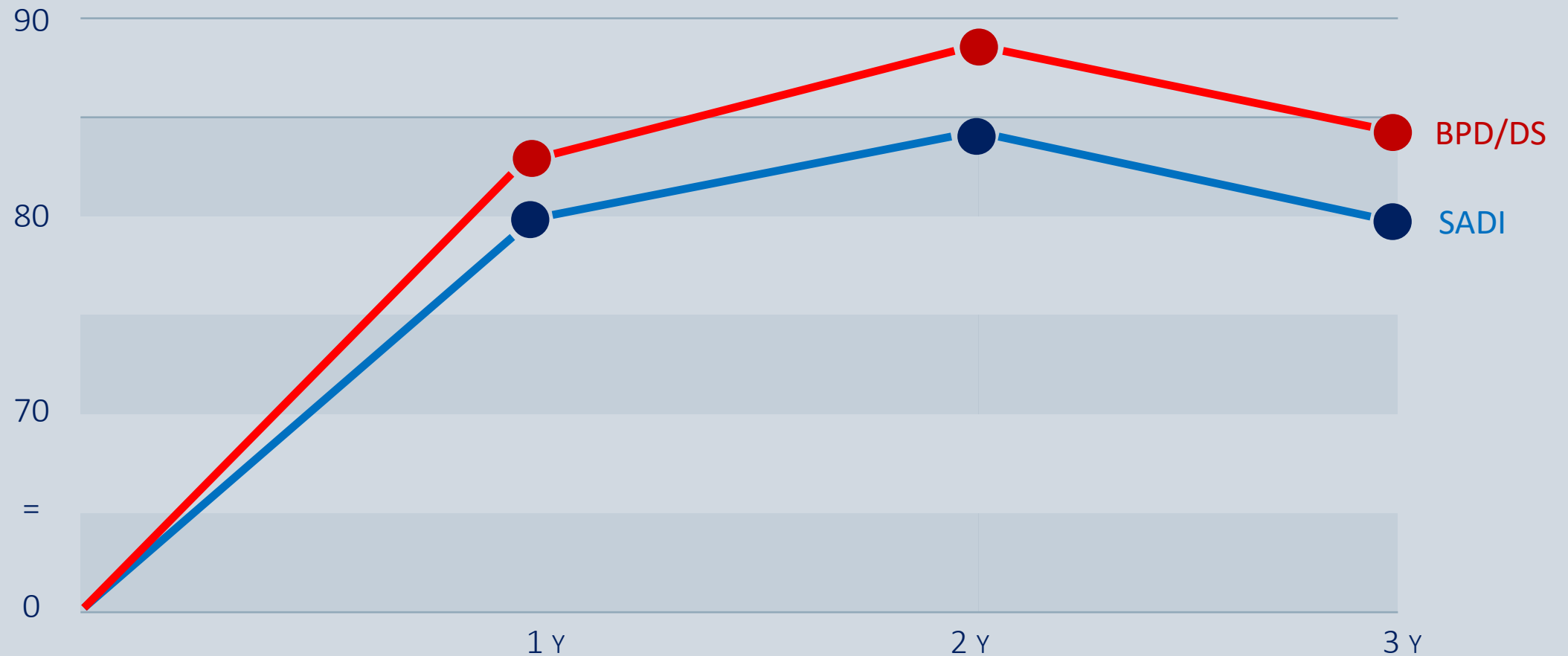


DEMOGRAPHICS AND ANTHROPOMETRICS

| | SADI N=29 | BPD/DS N=27 |
|--------------------------|------------------|--------------------|
| AGE (YEARS) | 41.5 ± 10.5 | 37.8 ± 11.2 |
| FEMALE (%) | 44.8 | 55.6 |
| BMI (KG/M ²) | 46.7 ± 3.8 | 47.6 ± 6.8 |
| T2D (%) | 10.3 | 22.2 |
| HYPERTENSION (%) | 27.6 | 25.9 |
| OSA (%) | 20.7 | 14.8 |
| HYPERLIPIDEMIA (%) | 13.8 | 11.1 |

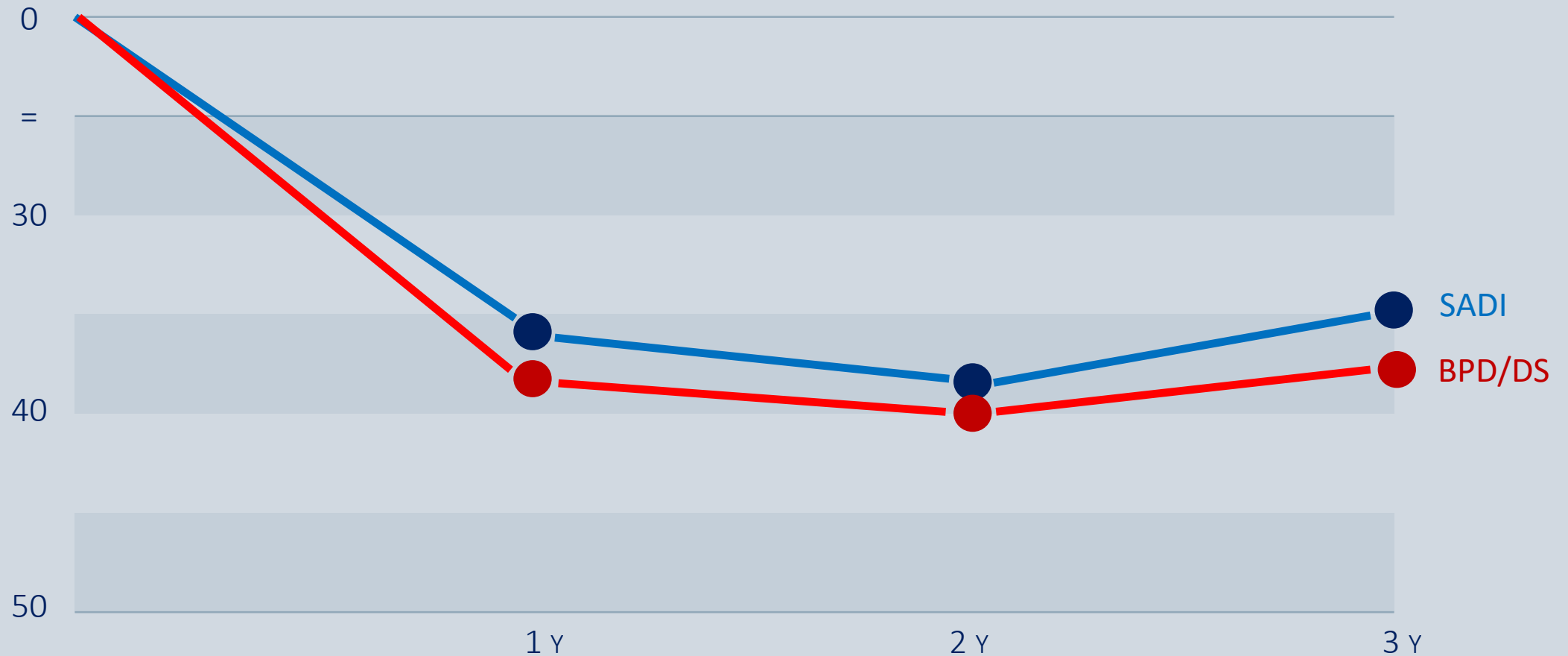


3-YEARS FOLLOW UP - %EWL





3-YEARS FOLLOW UP - %TWL





3-YEARS FOLLOW UP

| | SADI N=29/29 | BPD/DS N=26/27 |
|--------------------------|---------------------|-----------------------|
| BMI (KG/M ²) | 29.9 ± 5.7 | 29.0 ± 4.0 |
| EWL (%) | 78.5 ± 23.6 | 84.0 ± 13.1 |
| TWL (%) | 35.9 ± 10.8 | 38.9 ± 6.2 |



3-YEARS FOLLOW UP

| | SADI N=29/29 | BPD/DS N=26/27 |
|--------------------------|---------------------|-----------------------|
| BMI (KG/M ²) | 29.9 ± 5.7 | 29.0 ± 4.0 |
| EWL (%) | 78.5 ± 23.6 | 84.0 ± 13.1 |
| TWL (%) | 35.9 ± 10.8 | 38.9 ± 6.2 |
| T2D REMISSION | 2/2 | 6/6 |
| HYPERTENSION REMISSION | 5/8 | 4/7 |
| OSA REMISSION | 6/6 | 1/2 |
| HYPERLIPIDEMIA REMISSION | 2/3 | 2/3 |

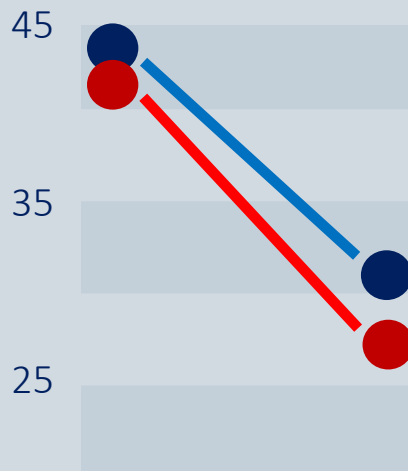


3-YEARS FOLLOW UP

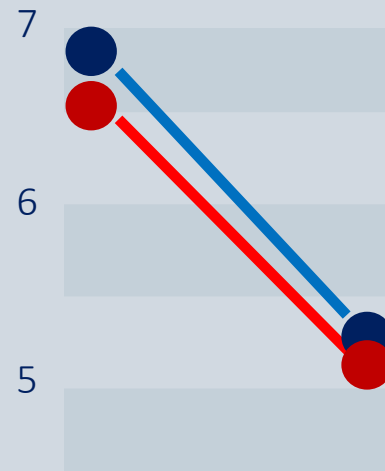
| | SADI N=29/29 | BPD/DS N=26/27 |
|--------------------------|---------------------|-----------------------|
| BMI (KG/M ²) | 29.9 ± 5.7 | 29.0 ± 4.0 |
| EWL (%) | 78.5 ± 23.6 | 84.0 ± 13.1 |
| TWL (%) | 35.9 ± 10.8 | 38.9 ± 6.2 |
| T2D REMISSION | 100% | 100% |
| HYPERTENSION REMISSION | 62.5% | 57.1% |
| OSA REMISSION | 100% | 50% |
| HYPERLIPIDEMIA REMISSION | 33.3% | 33.3% |



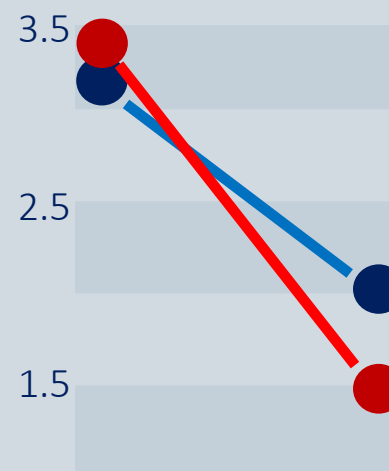
3-YEARS METABOLIC VARIABLES



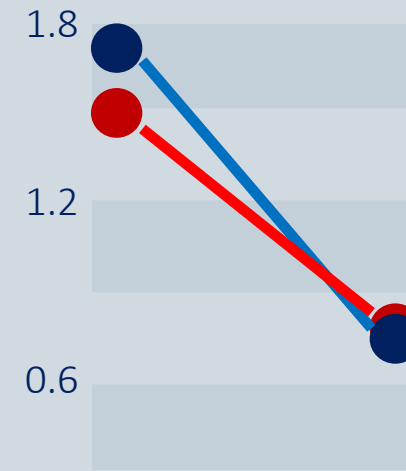
HBA1C



F-GLUCOSE



RATIO LDL/HDL



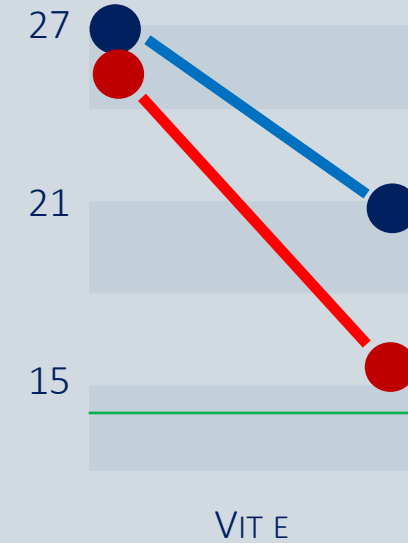
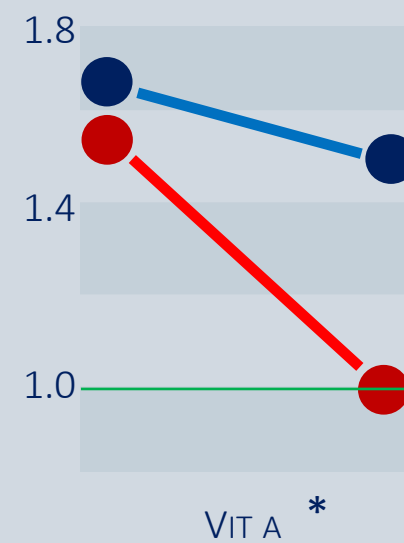
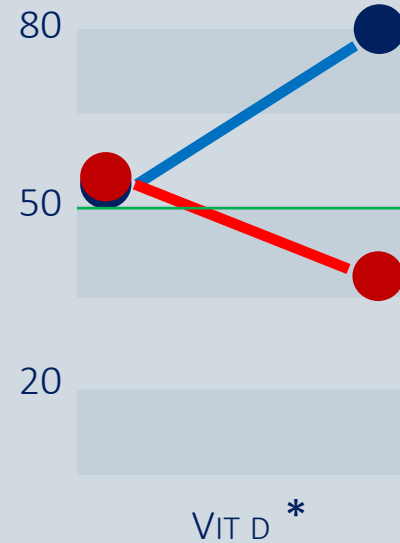
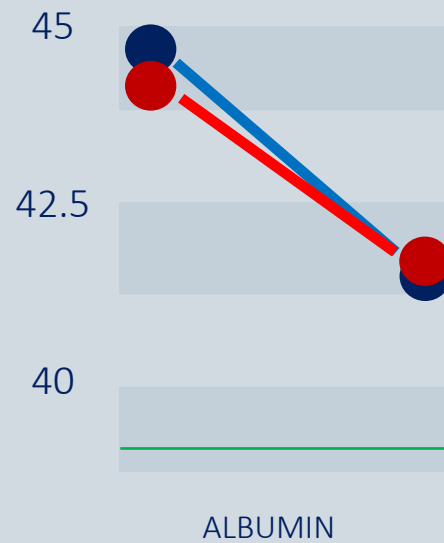
TRIGLYCERIDES

SADI

BPD/DS



3-YEARS NUTRITIONAL STATUS



SADI

BPD/DS

* < 0.003



3-YEARS NUTRITIONAL STATUS

| | SADI N=27/29 | BPD/DS N=26/27 |
|--------------|---------------------|-----------------------|
| ALBUMIN < 36 | 7.4% | 0% |

N.S.



3-YEARS NUTRITIONAL STATUS

| | SADI N=22/29 | BPD/DS N=21/27 | |
|-----------------|---------------------|-----------------------|----------|
| ALBUMIN < 36 | 7.4% | 0% | N.S. |
| VITAMIN A < 1.0 | 13.6% | 47.6% | P = 0.02 |



3-YEARS NUTRITIONAL STATUS

| | SADI N=22/29 | BPD/DS N=21/27 | |
|-----------------|---------------------|-----------------------|----------|
| ALBUMIN < 36 | 7.4% | 0% | N.S. |
| VITAMIN A < 1.0 | 13.6% | 47.6% | P = 0.02 |
| VITAMIN E < 14 | 9.1% | 38.1% | P = 0.02 |



3-YEARS NUTRITIONAL STATUS

| | SADI N=24/29 | BPD/DS N=26/27 | |
|-----------------|---------------------|-----------------------|-----------|
| ALBUMIN < 36 | 7.4% | 0% | N.S. |
| VITAMIN A < 1.0 | 13.6% | 47.6% | P = 0.02 |
| VITAMIN E < 14 | 9.1% | 38.1% | P = 0.02 |
| VITAMIN D < 50 | 20.8% | 73.1% | P < 0.001 |

CONCLUSION



COMPARISON OF CLINICAL OUTCOMES: SADI vs. BPD/DS

- EQUAL WEIGHT LOSS RESULTS
- SIMILAR EFFECTS ON ASSOCIATED MEDICAL DISEASES
- MALABSORPTION/HYPOABSORPTION OF BOTH MICRO- AND MACRONUTRIENTS MORE FREQUENT AFTER BPD/DS

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Thank you - tack så mycket