

Bariatric Surgery vs. Intensive Medical Therapy in Obese Diabetic Patients

Results of the STAMPEDE Trial

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Disclosures

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Background

- < 50% of patients w/ moderate to severe T2DM achieve adequate glycemic control on current pharmacotherapy.
- Observational studies demonstrate improvement in glycemic control of T2DM following bariatric surgery.
- Cardiovascular risk factors often improve following bariatric surgery.
- However, limited RCT data are available comparing optimal medical therapy vs. bariatric surgery for management of hyperglycemia in obese T2DM patients.

Objective

Compare the ability of intensive medical therapy vs. bariatric surgery to achieve biochemical resolution of diabetes in overweight or obese patients

Endpoints

Primary

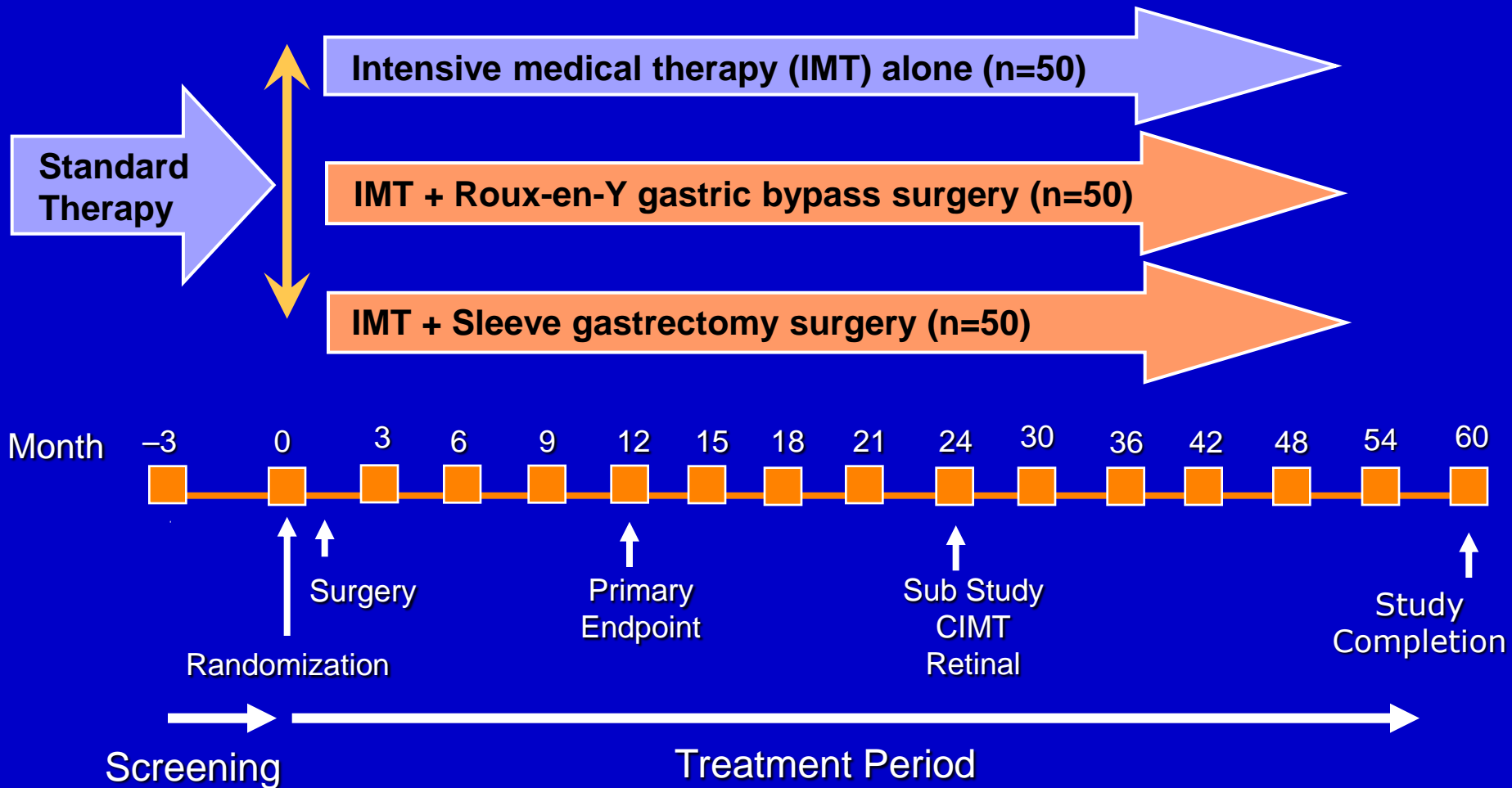
Success rate of achieving $\text{HbA1c} \leq 6\%$

Secondary

- Change in fasting plasma glucose (FPG)
- Change in BMI
- Change in lipids, blood pressure, hs-CRP
- Change in medications
- Safety and adverse events

Study Design

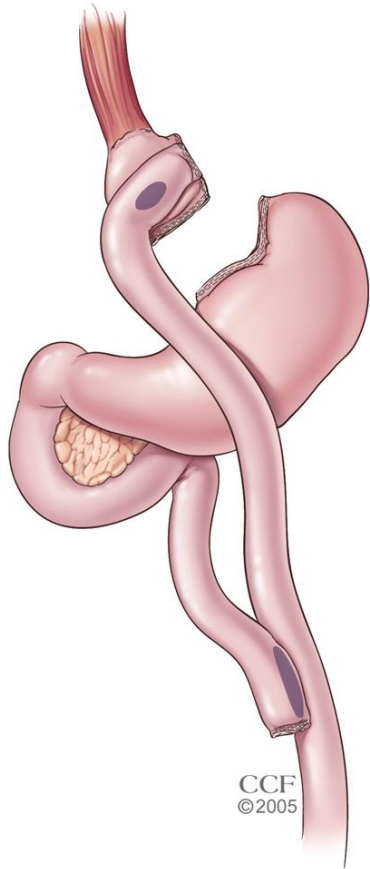
150 T2DM patients (HbA1c >7.0%, BMI 27- 43 kg/m²
age 20-60 years)



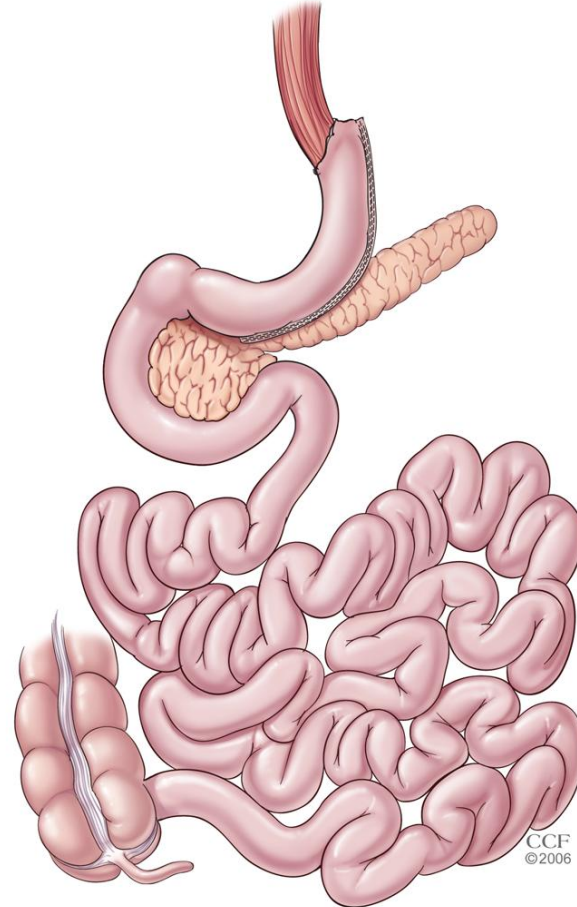
Intensive Medical Therapy

- Weight management with diet and lifestyle counseling per ADA clinical care guidelines*
- Insulin sensitizers, GLP-1 agonists, sulfonylureas and multiple insulin injections utilized to target HbA1c $\leq 6\%$
- Scheduled visits with nutrition, psychology and endocrinology per protocol
- Frequent home glucose monitoring and titration of medications for all patients

Bariatric Surgery



Roux-en-Y Gastric Bypass



Sleeve Gastrectomy

STAMPEDE Trial: Flow of Patients

218 patients screened

150 randomized

50

Intensive medical
therapy alone

50

Medical therapy
plus
gastric bypass

50

Medical therapy
plus
sleeve gastrectomy

7 withdrew consent
2 missed 9 and 12
month visits

1 withdrew consent
prior to surgery

Population for Primary Analysis

41

50

49

Baseline Characteristics

Parameter	Medical Therapy (n=41)	Bypass (n=50)	Sleeve (n=49)
Mean age (yrs)	50.7	48.3	47.8
Females	65%	58%	78%
Duration of diabetes (yrs)	8.6	8.2	8.3
HbA1c (%)	8.9	9.3	9.5
Mean Body Mass Index (kg/m ²)	36.8	37.0	36.2
Concomitant medications			
≥ 3 diabetes medications	61%	52%	46.9%
Insulin	51.2%	46%	44.9%
Lipid lowering agents	82.9%	86%	77.6%
Antihypertensive agents	75.6%	78%	67.3%

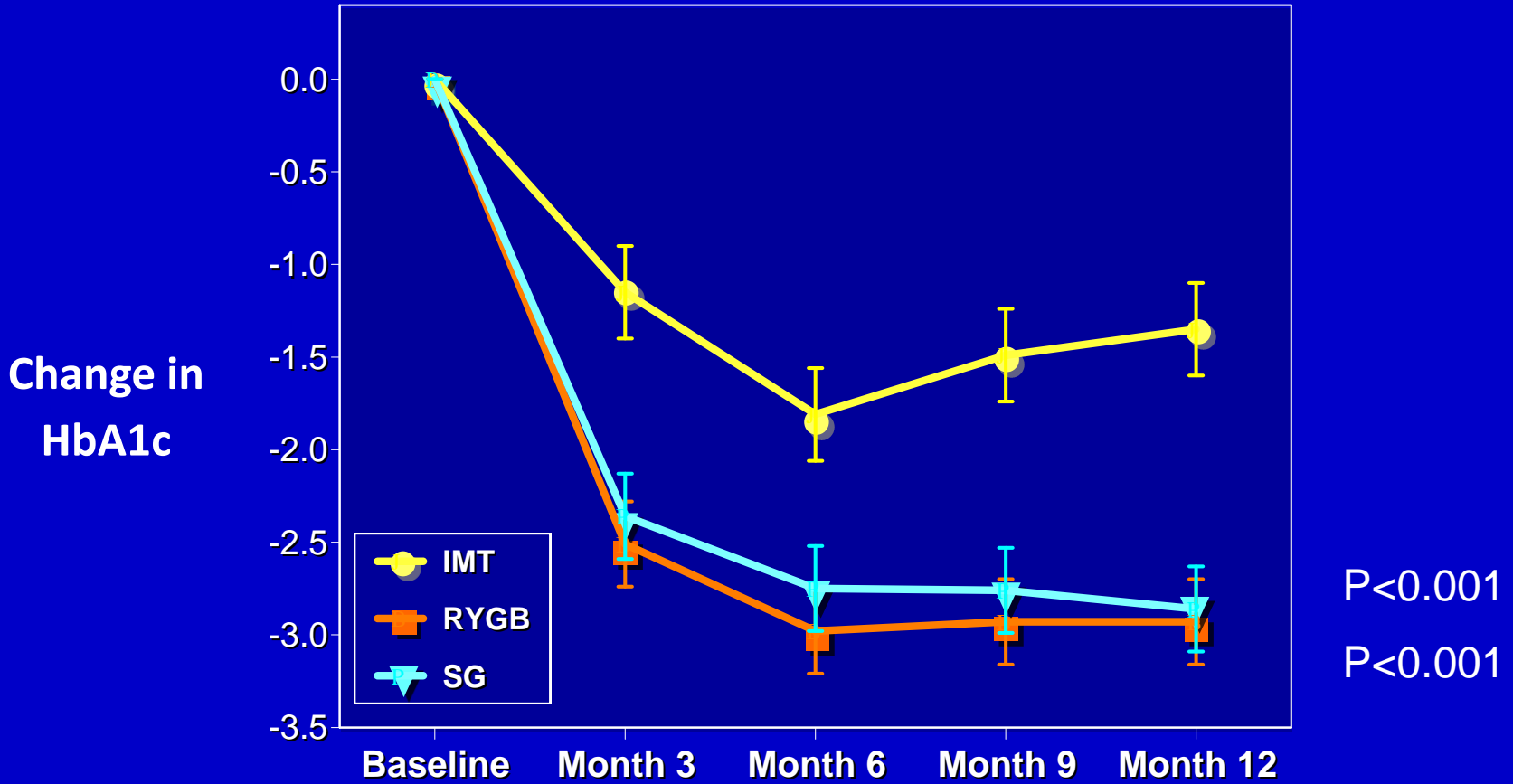
Note: Based on analyzed population

Primary and Secondary Efficacy Endpoints

Parameter	Medical Therapy (n=41)	Bypass (n=50)	Sleeve (n=49)	P Value ¹	P Value ²
HbA1c ≤ 6%	12.2%	42%	36.7%	0.002	0.008
HbA1c ≤ 6% (without DM meds)	0%	42%	26.5%	<0.001	0.003
Change in FPG (mg/dL)	-28	-87	-63	0.004	0.003
Change in BMI	-1.9	-10.2	-9.0	<0.001	<0.001
% change in HDL	11.3	28.5	28.4	0.001	0.001
% change in Trigs	-14	-44	-42	0.002	0.08
% change in hsCRP	-33	-85	-80	<0.001	<0.001

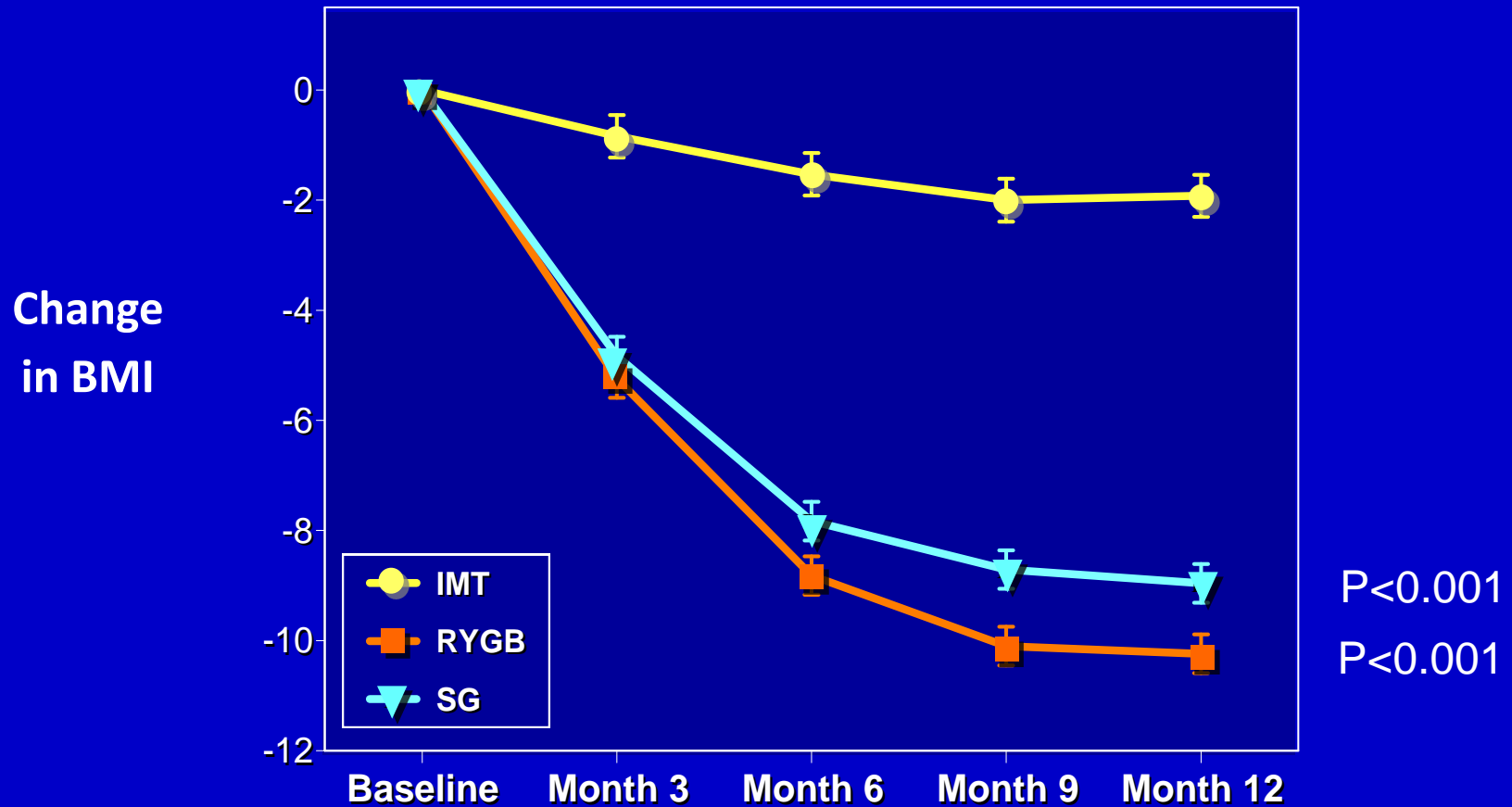
¹ Gastric Bypass vs Medical Therapy; ² Sleeve vs Medical Therapy

Change in HbA1c



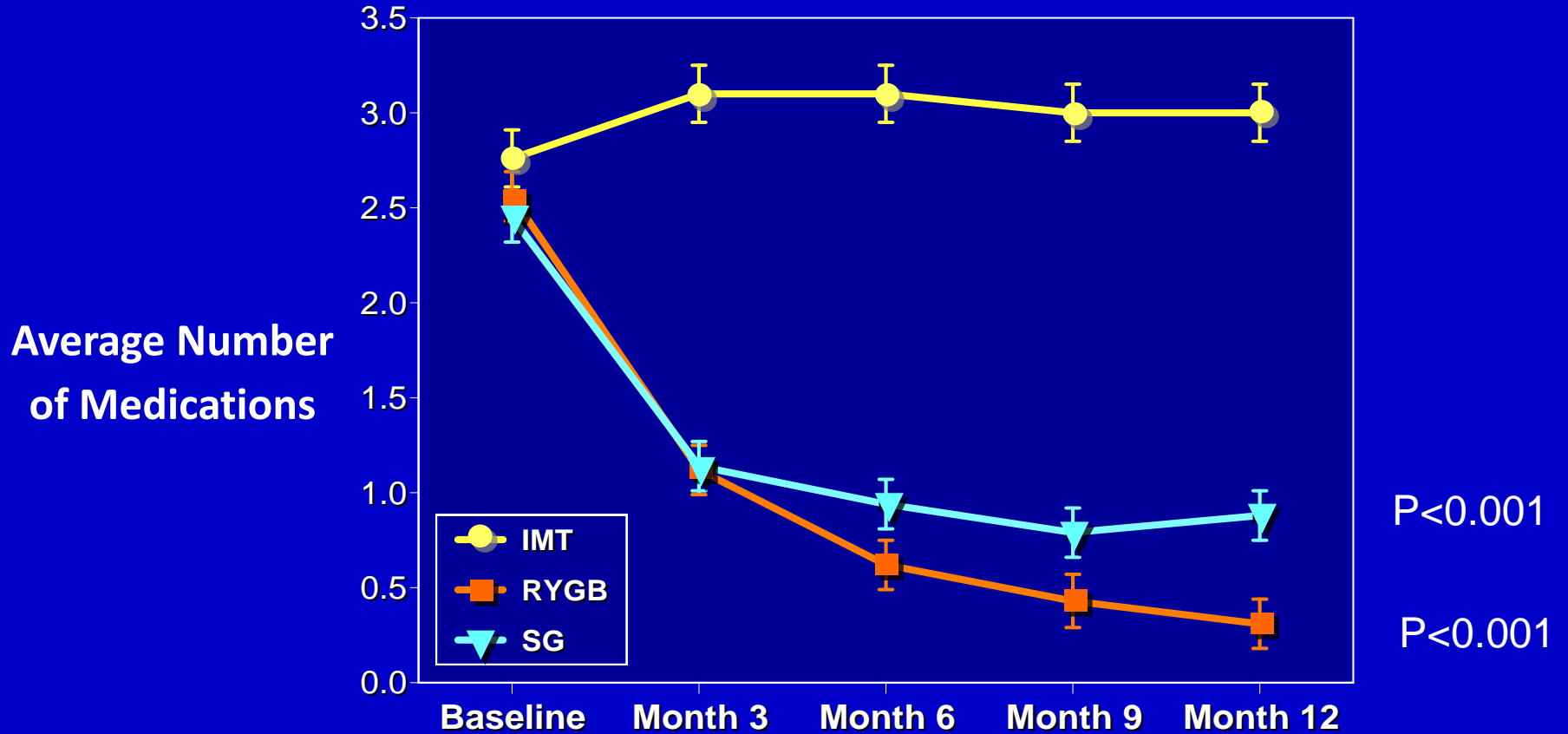
IMT	8.9	7.7	7.1	7.4	7.5
RYGB	9.3	6.8	6.3	6.4	6.4
SG	9.5	7.1	6.7	6.7	6.6

Change in Body Mass Index



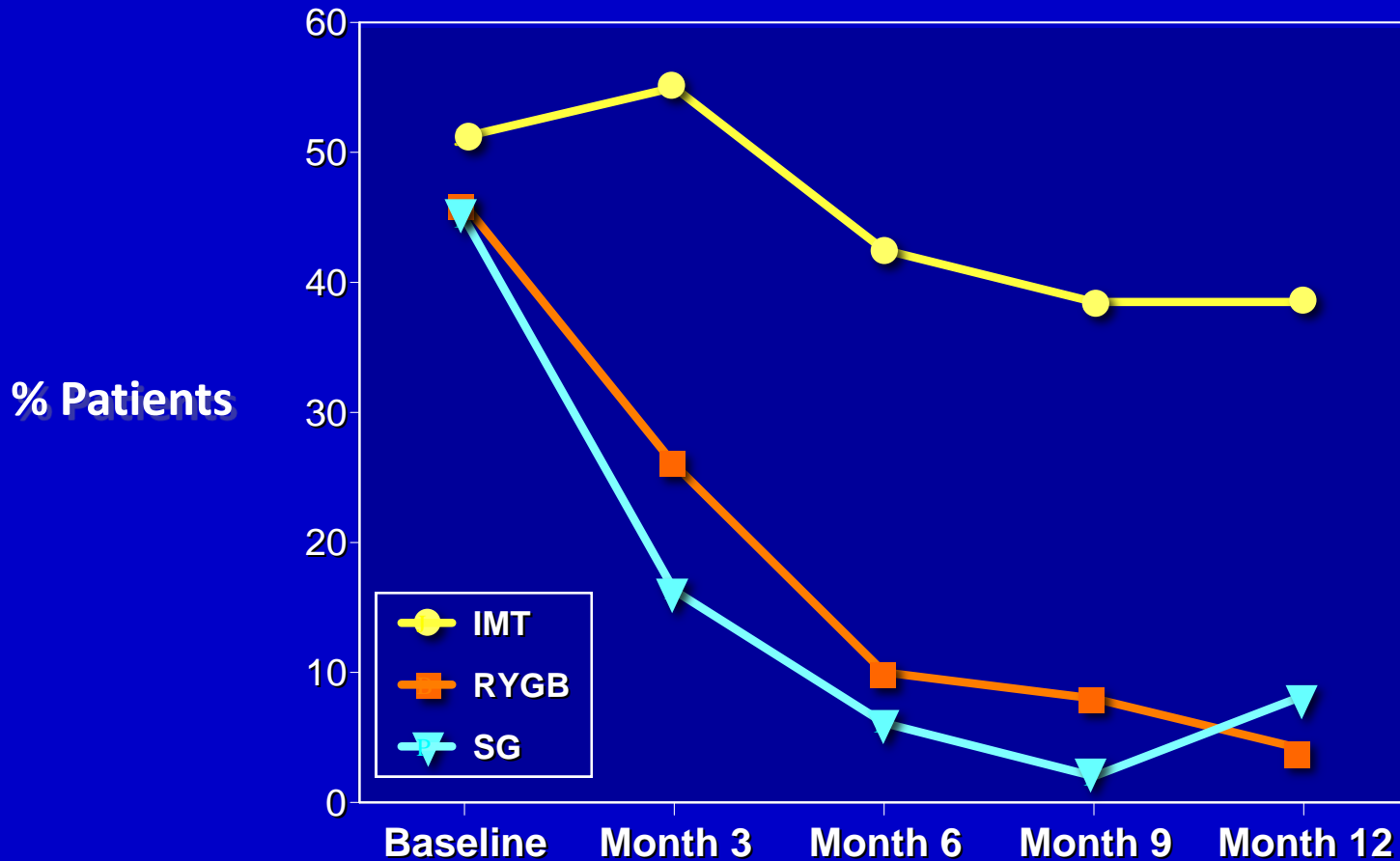
IMT	36.8	35.4	34.8	34.5	34.4
RYGB	37.0	31.8	28.2	26.9	26.8
SG	36.2	31.3	28.3	27.3	27.2

Average Number of Diabetes Medications



IMT	2.8	3.1	3.1	3.0	3.0
RYGB	2.6	1.1	0.6	0.4	0.3
SG	2.4	1.1	0.9	0.8	0.9

Percentage of Patients on Insulin



IMT	52.2	00.0	00.0	00.0	38.5
RYGB	46.0	00.0	00.0	00.0	4.1
SG	44.9	00.0	00.0	00.0	8.2

CV Medications at Baseline and Month 12

CV medications – number (%)	Medical Therapy (n=41)	Bypass (n=50)	Sleeve (n=49)
Baseline			
None	0 (0)	3 (6.0)	2 (4.1)
1	7 (17.1)	5 (10.0)	12 (24.5)
2	15 (36.6)	12 (24.0)	16 (32.7)
≥ 3	19 (46.3)	30 (60.0)	19 (38.8)
Month 12			
None	0 (0)	24 (49.0) *	20 (40.8) *
1	3 (7.7)	13 (26.5)	17 (34.7)
2	13 (33.3)	10 (20.4)	5 (10.2)
≥ 3	23 (59.0)	2 (4.1)	7 (14.3)

* P value <0.001 with Medical Therapy group as comparator

Note: Based on analyzed population

Adverse Events

Parameter	Medical Therapy (n=50)	Gastric Bypass (n=50)	Sleeve Gastrectomy (n=50)
IV treatment for dehydration	0	4 (8.0)	2 (4.0)
Re-operation	0	3 (6.0)	1 (2.0)
Gastrointestinal Leak	0	0	1 (2.0)
Transfusion	0	1 (2.0)	1 (2.0)
Anastomotic ulcer	0	4 (8.0)	0
Hypoglycemic episode (self-reported)	35 (70.0)	28 (56.0)	39 (78.0)
Hypokalemia	1 (2.0)	2 (4.0)	2 (4.0)
Anemia	3 (6.0)	6 (12.0)	7 (14.0)

Limitations

- Some adverse effects of bariatric surgery were noted, but were modest in severity
- Short duration of follow-up, but 4-year extension is ongoing to assess durability of the results
- Single-center trial – multicenter studies needed to determine if results can be generalized
- Larger studies will need to determine potential benefit on cardiovascular events

Conclusions

- In overweight/obese patients with T2DM, medical therapy plus bariatric surgery achieved glycemic control in significantly more patients than medical therapy alone at 12 months
- Many patients in the surgical treatment group achieved glycemic control without use of any diabetic medications
- Secondary endpoints (FPG, cardiovascular risk factors, medication use) showed more favorable results in the surgical treatment groups
- Bariatric surgery (gastric bypass or sleeve gastrectomy) may be considered as a treatment option for patients with obesity and poorly controlled T2DM

Publication Available On-line

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