

Bariatric Surgery vs. Intensive Medical Therapy in Obese Diabetic Patients: 3-Year Outcomes

Results of the STAMPEDE Trial

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Disclosures

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Background

- T2DM affects over 25 million individuals in the US, but < 50% of patients achieve adequate glycemic control on current pharmacotherapy.
- Observational studies show improvement in glycemic control and CV risk factors following bariatric surgery.
- Short-term (1-2 yrs.) RCTs, including the 1 year data of the STAMPEDE trial demonstrated remission of T2DM following bariatric surgery*.
- However, no long-term (≥ 3 yrs) RCT data exist to compare the durability of bariatric surgery vs medical therapy for T2DM control.

Objectives

- 1) Compare the durability of bariatric surgery vs medical therapy with respect to:
 - Achieving biochemical resolution of T2DM
- 2) Compare differences between types of surgery

Endpoints

Primary

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

Secondary

- Change in fasting plasma glucose (FPG)
- Change in lipids, blood pressure, BMI
- Change in carotid intimal medial thickness
- Change in medications
- Safety and adverse events
- Quality of Life

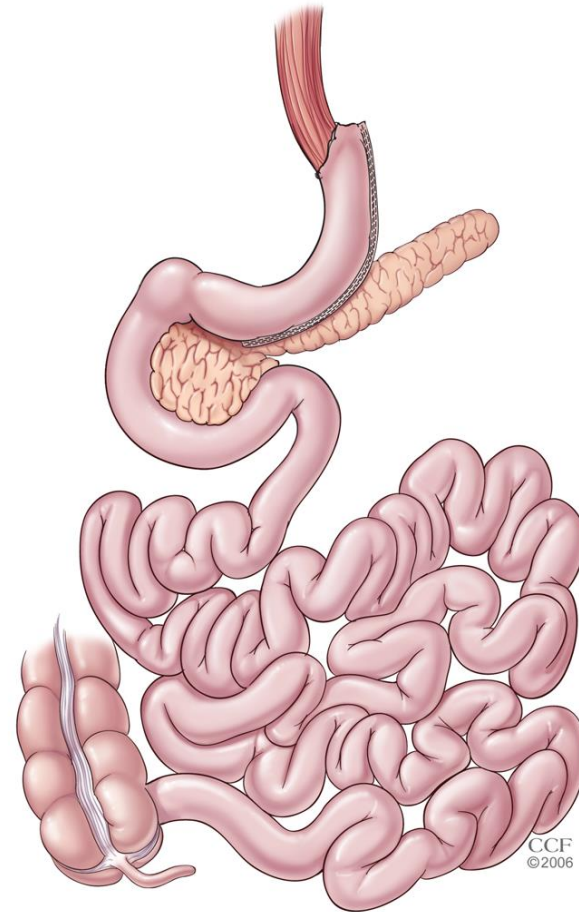
Intensive Medical Therapy

- 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
- Follow-up visits every 3 months through year 2, and every 6 months for remaining follow up

Bariatric Surgery

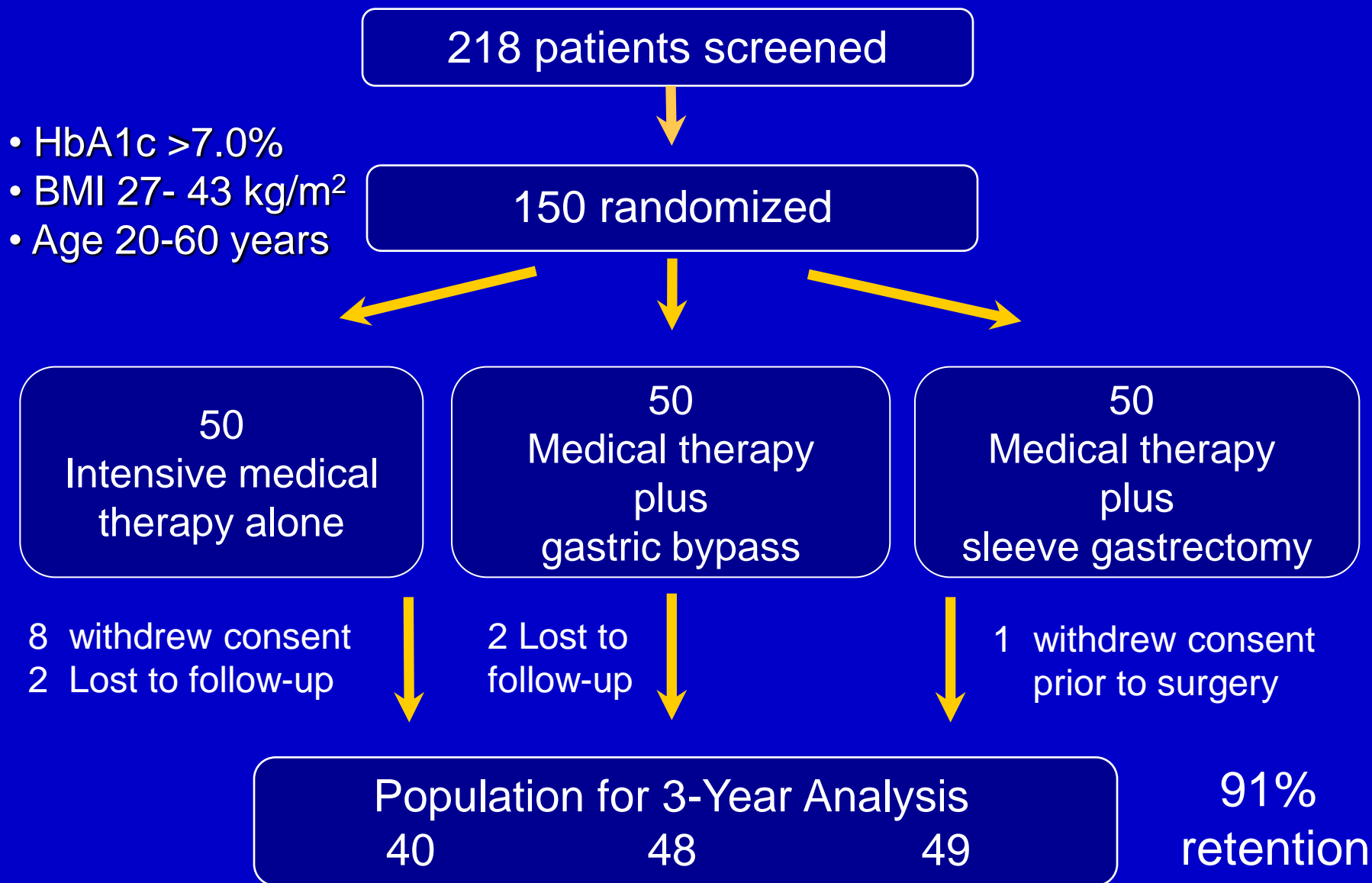


Roux-en-Y Gastric Bypass



Sleeve Gastrectomy

STAMPEDE Trial: Flow of Patients



Baseline Characteristics

Parameter	Medical Therapy (n=40)	Bypass (n=48)	Sleeve (n=49)
Age (yrs)	50.3	48.0	47.8
Females	67%	58%	78%
Duration of diabetes (yrs)	8.8	8.0	8.3
HbA1c (%)	9.0	9.3	9.5
Body Mass Index (kg/m ²)	36.4	37.1	36.1
≥ 3 diabetes medications	61%	52%	46.9%
Insulin use	51.2%	46%	44.9%
Depression	32%	37%	46%
Microvascular complications	20%	42%	29%

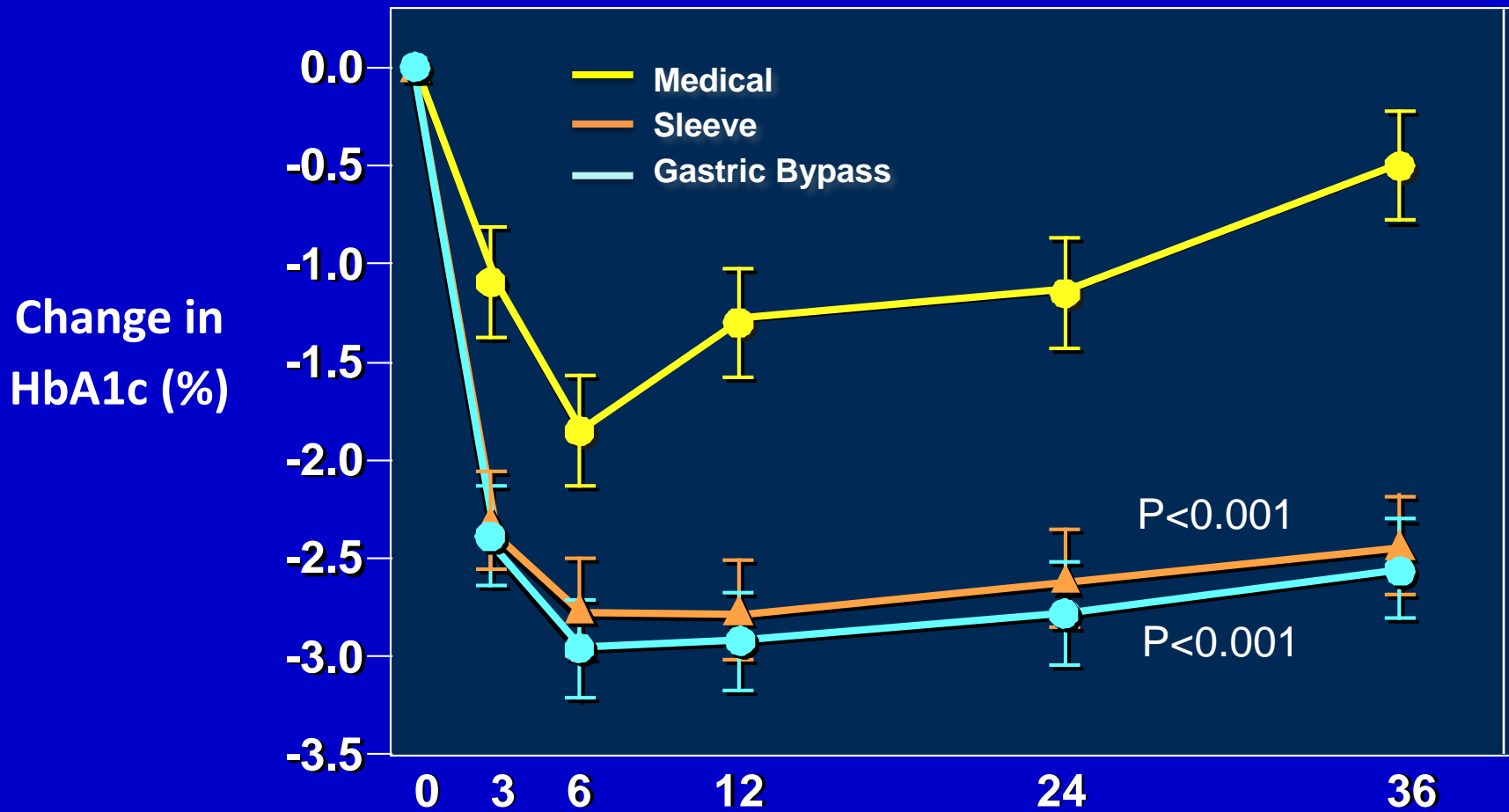
Note: Based on analyzed population

Primary and Secondary Endpoints at 36 Months

Parameter	Medical Therapy (n=40)	Bypass (n=48)	Sleeve (n=49)	P Value ¹	P Value ²
HbA1c ≤ 6%	5%	37.5%	24.5%	<0.001	0.012
HbA1c ≤ 6% (without DM meds)	0%	35.4%	20.4%	<0.001	0.002
HbA1c ≤ 7%	40%	64.6%	65.3%	0.02	0.02
Change in FPG (mg/dL)	-6	-85.5	-46	0.001	0.006
Relapse of glycemic control	80%	23.8%	50%	0.03	0.34
% change in HDL	+4.6	+34.7	+35.0	<0.001	<0.001
% change in TG	-21.5	-45.9	-31.5	0.01	0.01
% change in CIMT	0.048	0.013	0.017	0.36	0.49

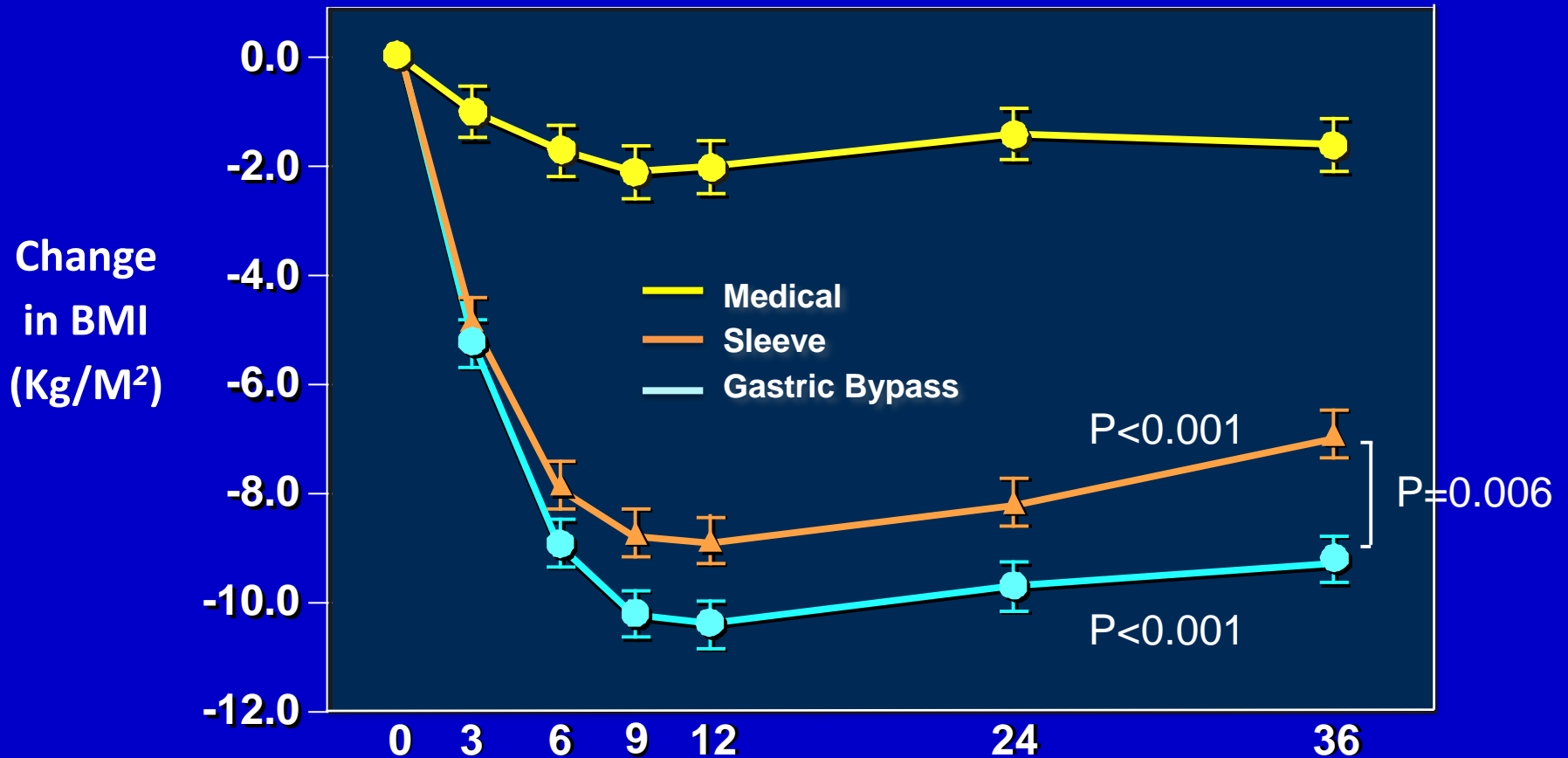
¹ Gastric Bypass vs Medical Therapy; ² Sleeve vs Medical Therapy

Change in HbA1c



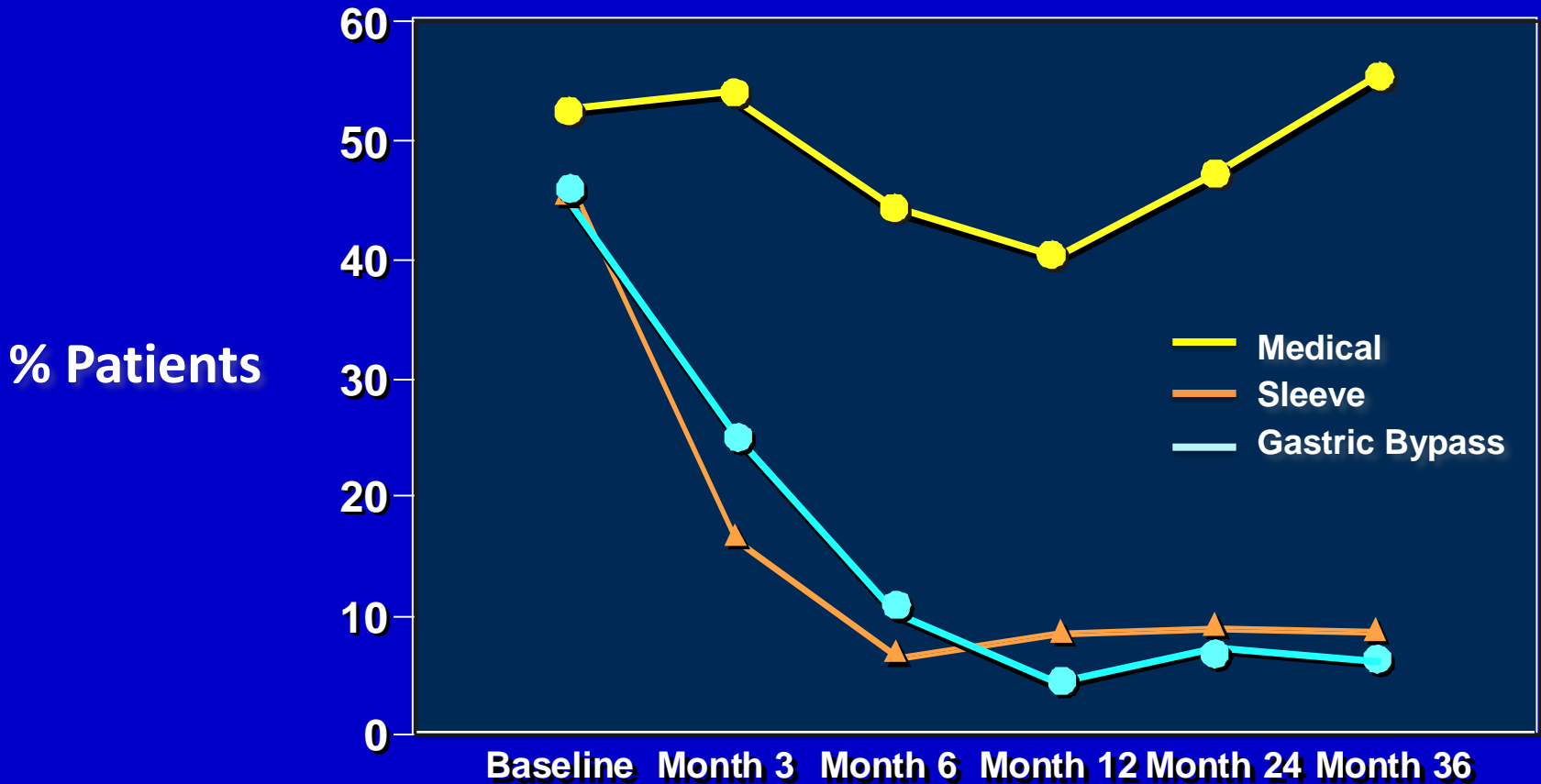
Value at Visit	Baseline	Month 6	Month 12	Month 24	Month 36
Medical	9.0 (8.5)	7.1 (6.8)	7.5 (6.9)	7.7 (7.3)	8.4 (7.6)
Gastric Bypass	9.3 (9.2)	6.3 (6.2)	6.3 (6.1)	6.5 (6.4)	6.7 (6.6)
Sleeve	9.5 (8.9)	6.7 (6.4)	6.6 (6.4)	6.8 (6.8)	7.0 (6.6)

Change in Body Mass Index



Value at Visit	Baseline	Month 6	Month 12	Month 24	Month 36
Medical	36.4	34.6	34.2	35.0	34.8
Gastric Bypass	37.1	28.2	26.7	27.3	27.9
Sleeve	36.1	28.3	27.1	27.9	29.2

Percentage of Patients on Insulin



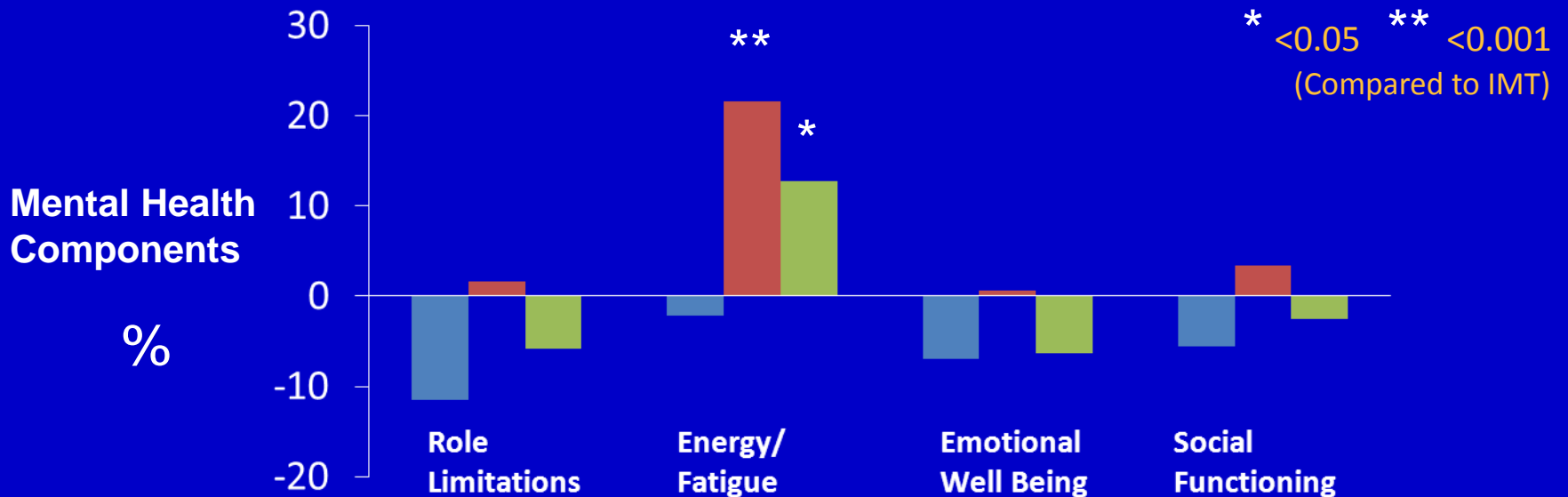
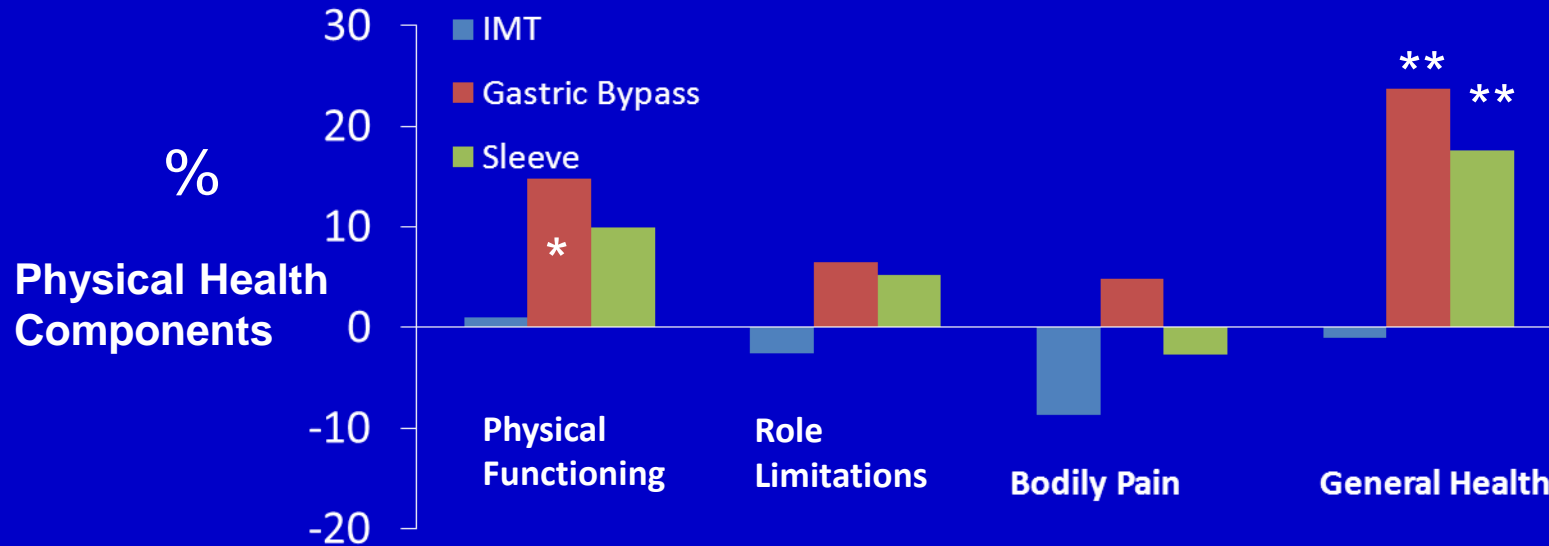
Medical	52	54	44	40	47	55
Gastric Bypass	46	25	10	4	7	6
Sleeve	45	16	6	8	9	8

Cardiovascular Medications at Baseline and Month 36

CV medications – number (%)	Medical Therapy (n=40)	Bypass (n=48)	Sleeve (n=49)
Baseline			
None	0 (0)	3 (6.3)	2 (4.1)
1 - 2	19 (47.5)	17 (35.4)	28 (57.1)
≥ 3	21 (52.5)	28 (58.3)	19 (38.8)
Month 36			
None	1 (2.5)	33 (68.8) *	21 (42.9) *
1 - 2	18 (45)	14 (29.2)	25 (51)
≥ 3	21 (52.5)	1 (2.1)	3 (6.1)

* P value <0.05 with Medical Therapy group as comparator

Quality of Life



Adverse Events through 36 Months

Parameter	Medical Therapy (n=43)	Bypass (n=50)	Sleeve (n=49)
GI complications	2 (5)	13 (26)	5 (4)
Re-op	0	2(4)	2(4)
Stroke	0	0	1 (2)
Retinopathy	0	1 (2)	2 (4)
Nephropathy	4 (9)	7 (14)	5 (10)
Foot ulcers	0	2 (4)	1 (2)
Excessive weight gain	7 (16)	0	0

Limitations

- Single-center trial – multicenter studies needed to determine if results can be generalized.
- Larger studies will need to determine potential benefit on cardiovascular events and diabetes related microvascular complications.

Summary

- Bariatric surgery was more effective than intensive medical therapy in achieving glycemic control (HbA1c \leq 6.0%) with weight loss as the primary determinant of this outcome.
- Many surgical patients achieved glycemic control without use of any diabetic medications (particularly insulin).
- Metabolic syndrome components (HDL, triglycerides, glucose, BMI) showed greater improvement after surgery.
- Marked improvement in quality of life.

Conclusion

Bariatric surgery (gastric bypass or sleeve gastrectomy) should be considered as a treatment option for patients with uncontrolled T2DM and moderate to severe obesity (BMI > 30 Kg/M²) with results durable through 3 years of follow up.

Renal Outcomes through 36 Months

Parameter	Medical Therapy (n=40)	Bypass (n=48)	Sleeve (n=49)
Baseline Albuminuria	4 (10.0)	13 (27)	10(20)
Resolved	1/4 (25)	8/13 (61)	8/10 (80)
Developed	0	1 (2)	2 (4)
Baseline GFR	105	108	109
% Change	-2.5	-4.8	-3.5