HCor Research Institute

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THE GATEWAY RANDOMIZED TRIAL

Effects of Bariatric Surgery in Patients with Hypertension: 3-Year Outcomes

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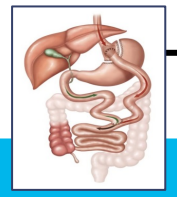
DISCLOSURES

Speaker: Johnson & Johnson Brasil

Research Grant: Ethicon Inc.

Single center, open-label, randomized clinical trial to evaluate the efficacy of Gastric Bypass in reducing the prescription of antihypertensive drugs and its effect on hypertension and other cardiovascular risk factors.



Concealed Randomization 1:1

Gastric Bypass Plus Medical Therapy

Medical Therapy
(Lifestyle intervention with visits to cardiologist, nutritionist and psychologist)

m I T T

6 PATIENTS LOST TO FOLLOW-UP

44 PATIENTS WERE INCLUDED

9 PATIENTS LOST TO FOLLOW-UP
1 PATIENT WITHDREW CONSENT

m I T T

40 PATIENTS WERE INCLUDED

Schiavon et al. BMJ Open. *2014;4:e005702.*

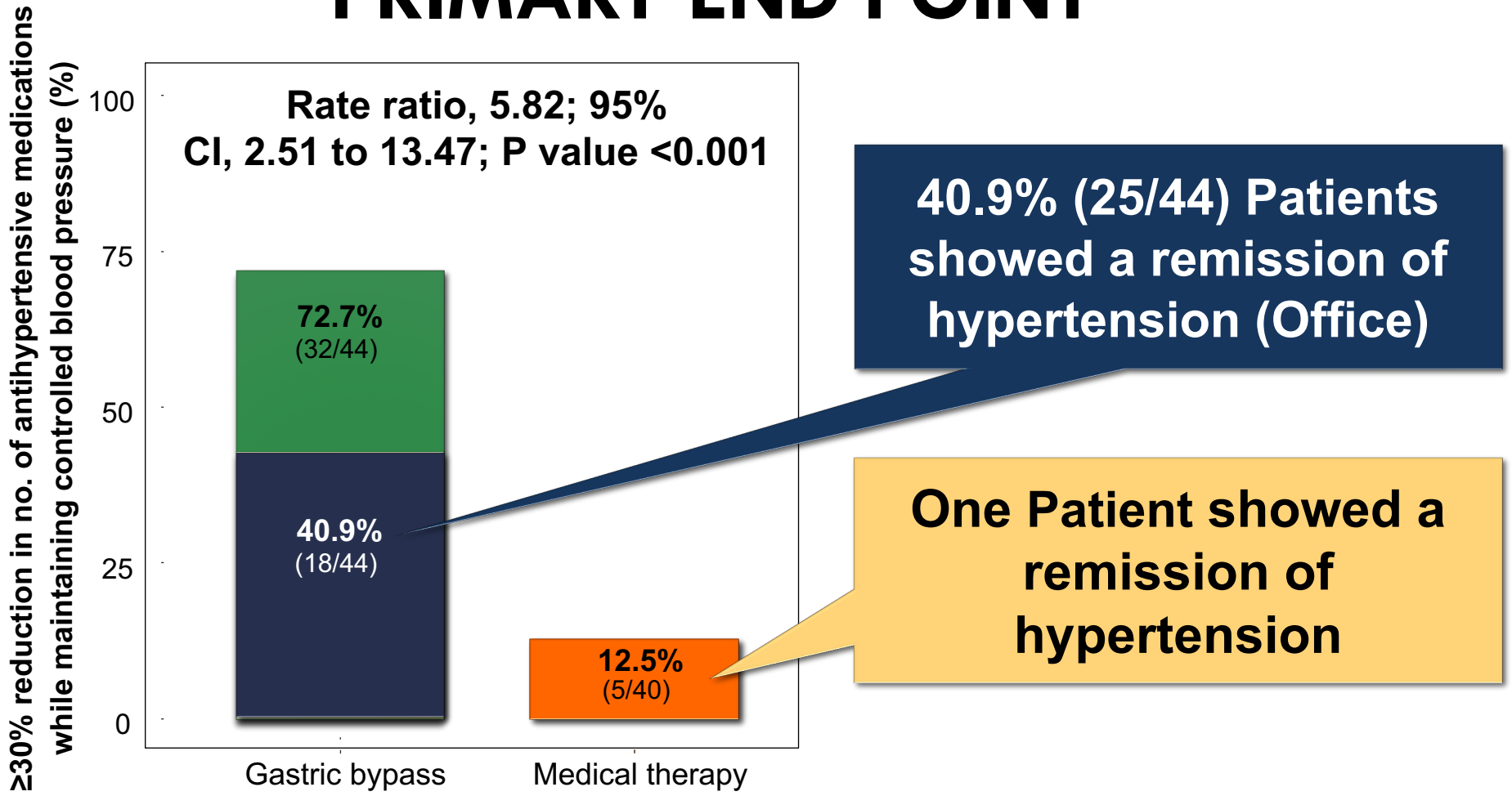
ClinicalTrials.gov (NCT1784848)

Schiavon et al. Circulation. 2018;137(11):1132-42.

BASELINE

Characteristics	Gastric Bypass (n=50)	Medical Therapy (n=50)
Age - years	43.1 ± 9.2	44.6 ± 9.2
Female – no.(%)	36 (72)	34 (68)
Race, Caucasian – no.(%)	31 (62)	34 (68)
Afro-Brazilian – no.(%)	19 (38)	16 (32)
BMI – Kg/m^2	**37.4 ± 2.4**	**36.4 ± 2.9**
Dyslipidemia – no.(%)	20 (40)	16 (32)
Diabetes – no.(%)	4 (8)	4 (8)
Framingham – median (IQR)	4.5 (2.9 to 7.3)	5 (2.8 to 7.1)
Creatinine – mg/dL	0.7 ± 0.1	0.8 ± 0.2
Office SBP – mm Hg	123.0 ± 11.6	122.8 ± 12.9
Office DBP – mm Hg	77.6 ± 7.0	78.0 ± 9.3
Number of antihypertensive drugs Median (IQR)	**3 (2 to 3)**	**3 (3 to 3)**
Number of antihypertensive drugs	**2.8 ± 0.6**	**3.1 ± 0.7**

PRIMARY END POINT



Consistent with these sensitivity analyses: complete-case analysis; per-protocol analysis, as-treated analysis, worst-case scenario, and multiple imputation analysis.

Secondary End Points	Gastric Bypass	Medical Therapy	Between-Groups Difference (GB-MT), Mean (95% CI)	P Value
Body Mass Index, Kg/m²	**26.8 ± 3.7 (n=37)**	**36.3 ± 4.2 (n=35)**	**-9.5 (-10.9 to -8.0)**	**<0.001**
Body weight, Kg	73.1 ± 13 (n=37)	99 ± 15.1 (n=35)	-26.2 (-31.9 to -20.4)	<0.001
Waist circumference – cm	86.1 ± 9.9 (n=32)	111 ± 11.1 (n=24)	-24.5 (-28.7 to -20.2)	<0.001
Fasting Plasma Glucose - mg/dl	86.1 ± 7.3 (n=41)	99.1 ± 12.7 (n=37)	-15.6 (-22.7 to -8.6)	<0.001
Glycated hemoglobin - %	**5.2 ± 0.4 (n=40)**	**5.7 ± 0.6 (n=37)**	**-0.6 (-0.8 to -0.3)**	**<0.001**
Insulin - mU/L	5.8 ± 3 (n=39)	19.3 ± 7.7 (n=36)	-12.9 (-16.7 to -9.0)	<0.001
HOMA-IR Index	1.2 ± 0.7 (n=39)	4.7 ± 1.9 (n=36)	-3.4 (-4.3 to -2.4)	<0.001
Low-density lipoprotein cholesterol - mg/dL	**85.2 ± 27.1 (n=40)**	**129.3 ± 41.1 (n=37)**	**-43.39 (-57.6 to -29.2)**	**<0.001**
High-density lipoprotein cholesterol - mg/dL	64.4 ± 17.3 (n=40)	52.5 ± 15.7 (n=37)	11.0 (4.8 to 17.3)	<0.001
Triglycerides - mg/dL	**85.5 ± 38.4 (n=40)**	**148.7 ± 69.6 (n=37)**	**-63.2 (-91.8 to -34.5)**	**<0.001**
High-sensitive C-reactive protein - mg/L	**1.0 ± 1.1 (n=40)**	**7.6 ± 9.4 (n=37)**	**-6.0 (-9.9 to -2.1)**	**0.003**
10-year Framingham risk score - %	3.4 ± 2.4 (n=37)	5.0 ± 3.5 (n=35)	-1.6 (-3.0 to -0.2)	0.024

SECONDARY END POINTS

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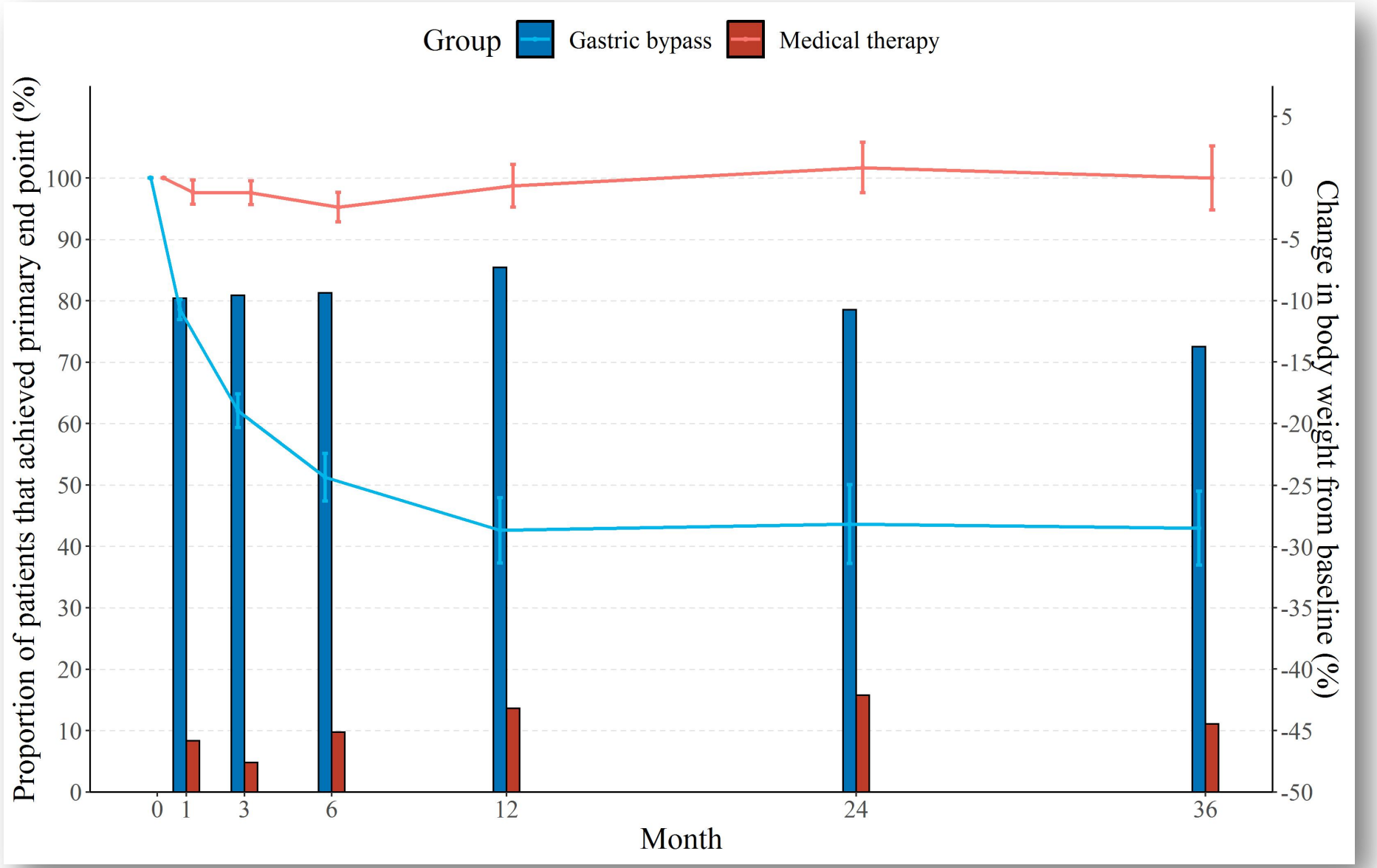
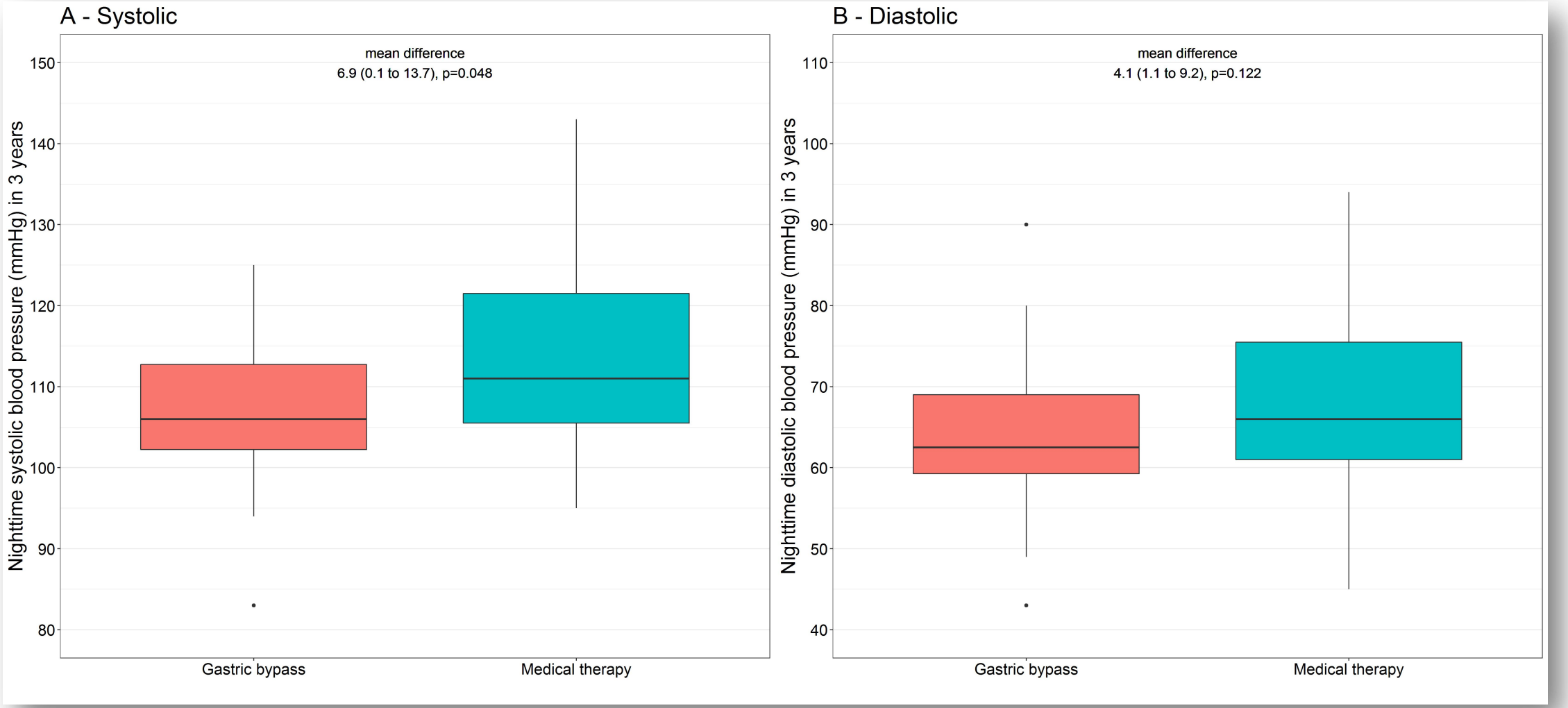
	Gastric Bypass	Medical Therapy	P
Number of antihypertensive drugs Median (IQR)	**1 (0 to 2) (n=44)**	**3 (2.8 to 4) (n=40)**	**<0.001**
Number of antihypertensive drugs	**1.0 ± 1.1**	**3.1 ± 1.1**	**<0.001**
SBP - mmHg	122.3±16.1 (n=40)	124.8±16.0 (n=36)	0.382
DBP - mmHg	77.2±10.9 (n=40)	78.9±10.8 (n=36)	0.54
Statins	5/46 (10.9%)	21/40 (52.5%)	
Glucose-lowering drugs	2/46 (4.3%)	13/40 (32.5%)	

Primary End Point x Weight Loss



Nighttime Blood Pressure



CONCLUSIONS

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In hypertensive patients with grade 1 and 2 obesity, Bariatric Surgery represents an effective and durable strategy for:

- reduce anti-hypertensive drugs, maintaining controlled office and 24-h BP levels;
- improve metabolic and inflammatory profiles, and;
- minimize non-adherence to medical therapy.