Metabolic Surgery

BARCELONA MEETING

Hospital Universitari de Bellvitge

Bellvitge Hospital

Institut Català de la Salut

FOUNDER

ICE INTERNATIONAL CENTER OF EXCELLENCE

INTERNATIONAL CENTER OF EXCELLENCE FOR BARIATRIC SURGERY

SURGICAL REVIEW CORPORATION

Metabolic Surgery

INNOVATIONS IN SURGICAL APPROACHES AND DEVICES

Almino Cardoso Ramos

Gastro Obeso Center

Centro Avançado de Gastroenterologia e Cirurgia de Obesidade

www.gastroobesocenter.com.br

International Diabetes Federation

Bariatric Surgical and Procedural Interventions in the Treatment of Obese Patients with Type 2 Diabetes

A position statement from the International Diabetes Federation Taskforce on Epidemiology and Prevention

Table 1: The classification of weight category by BMI

Classification	BMI(kg/m²)	
	Principal cut-off points	Cut-off points for Asians
Normal range	18.5 - 24.9	18.5 - 22.9
		23.0 - 24.9
Pre-obese	25.0 - 29.9	25.0 - 27.4
		27.5 - 29.9
Obese class I	30.0 - 34.9	30.0 - 32.4
		32.5 - 34.9
Obese class II	35.0 - 39.9	35.0 - 37.4
		37.5 - 39.9
Obese class III	≥40.0	≥40.0

Table 9: Eligibility and prioritisation for bariatric surgery based on failed non-surgical weight loss therapy*, BMI, ethnicity** and disease control

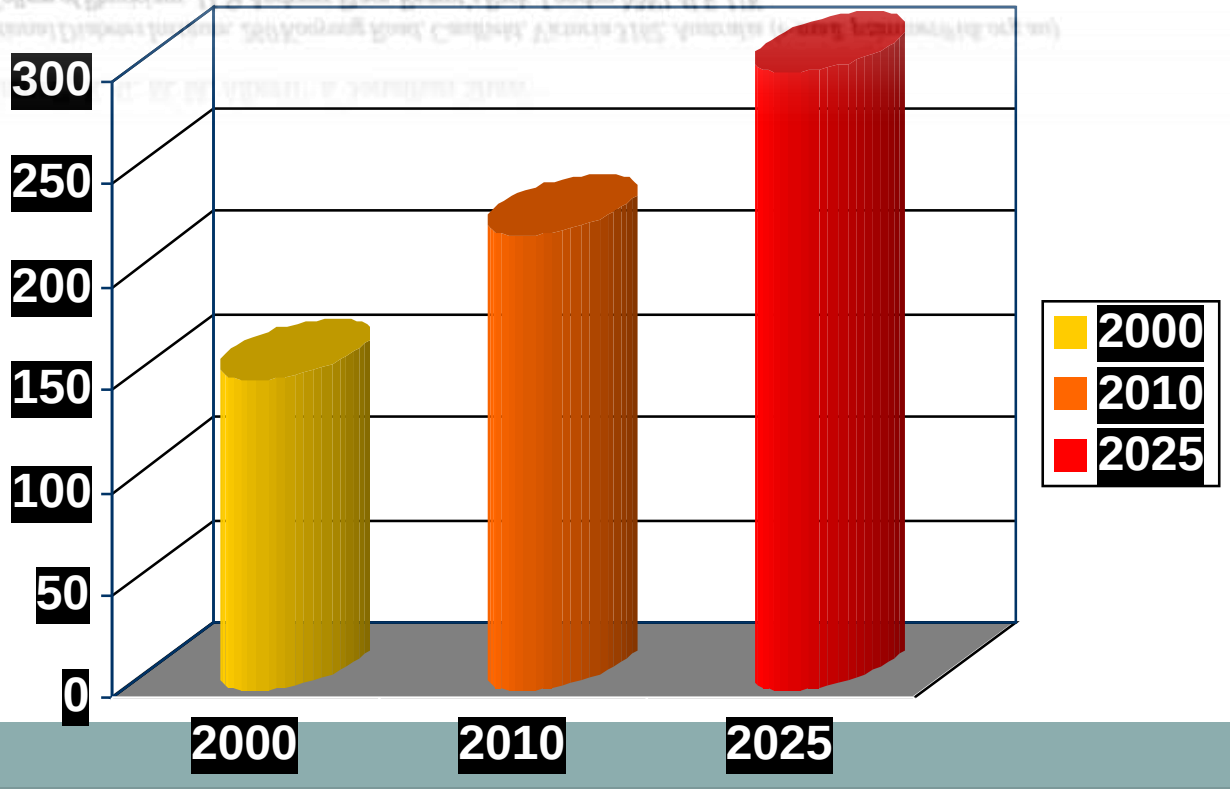
BMI Range	Eligible for surgery	Prioritised for Surgery
<30	No	No
30 -35	YES-Conditional***	No
35-40	YES	YES-Conditional***
>40	YES	YES

insight review articles

Global and societal implications of the diabetes epidemic

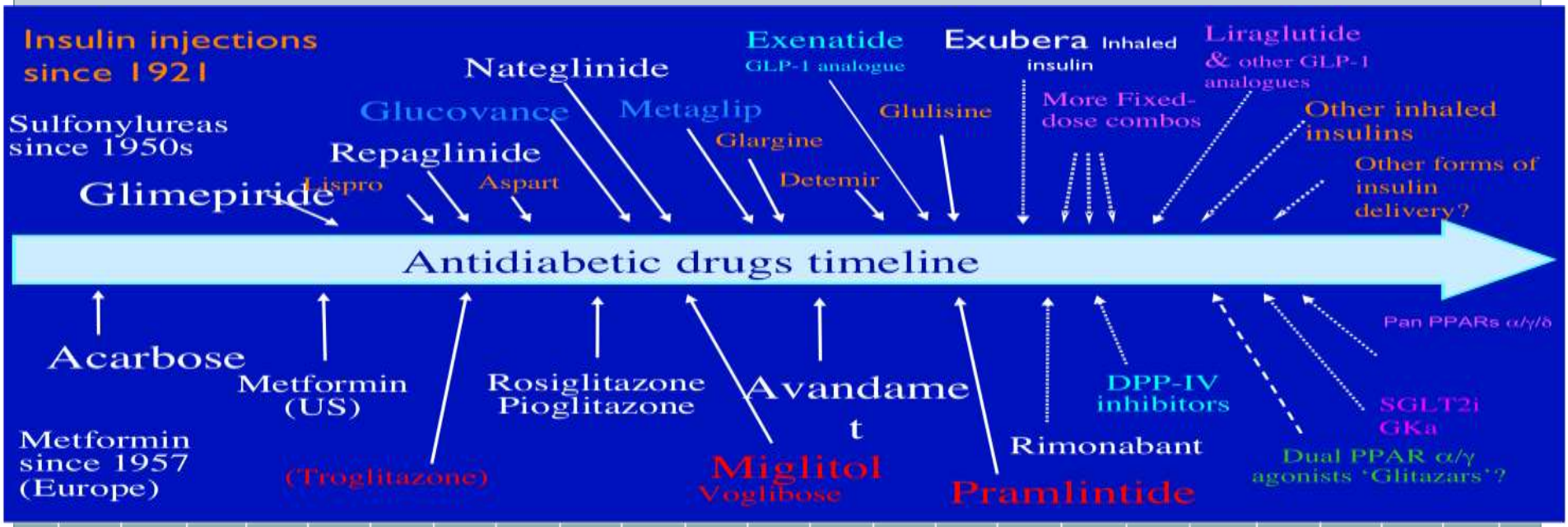
Paul Zimmet*, K. G. M. M. Alberti† & Jonathan Shaw*

*International Diabetes Institute, 260 Kooyong Road, Caulfield, Victoria 3162, Australia (e-mail: pzimmet@idi.org.au)
†Royal College of Physicians, 11 St Andrews Place, Regent's Park, London NW1 4LE, UK

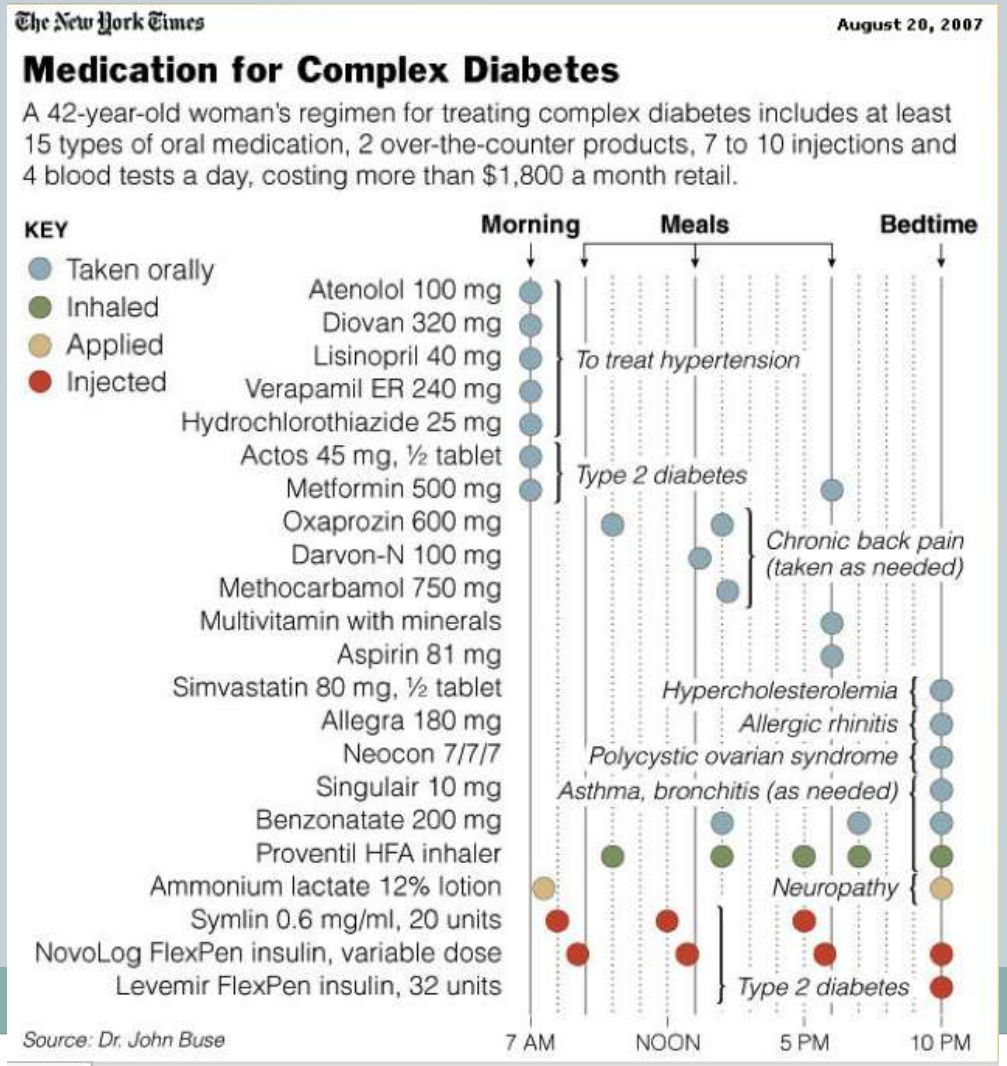


Current Treatment Strategy for T2DM

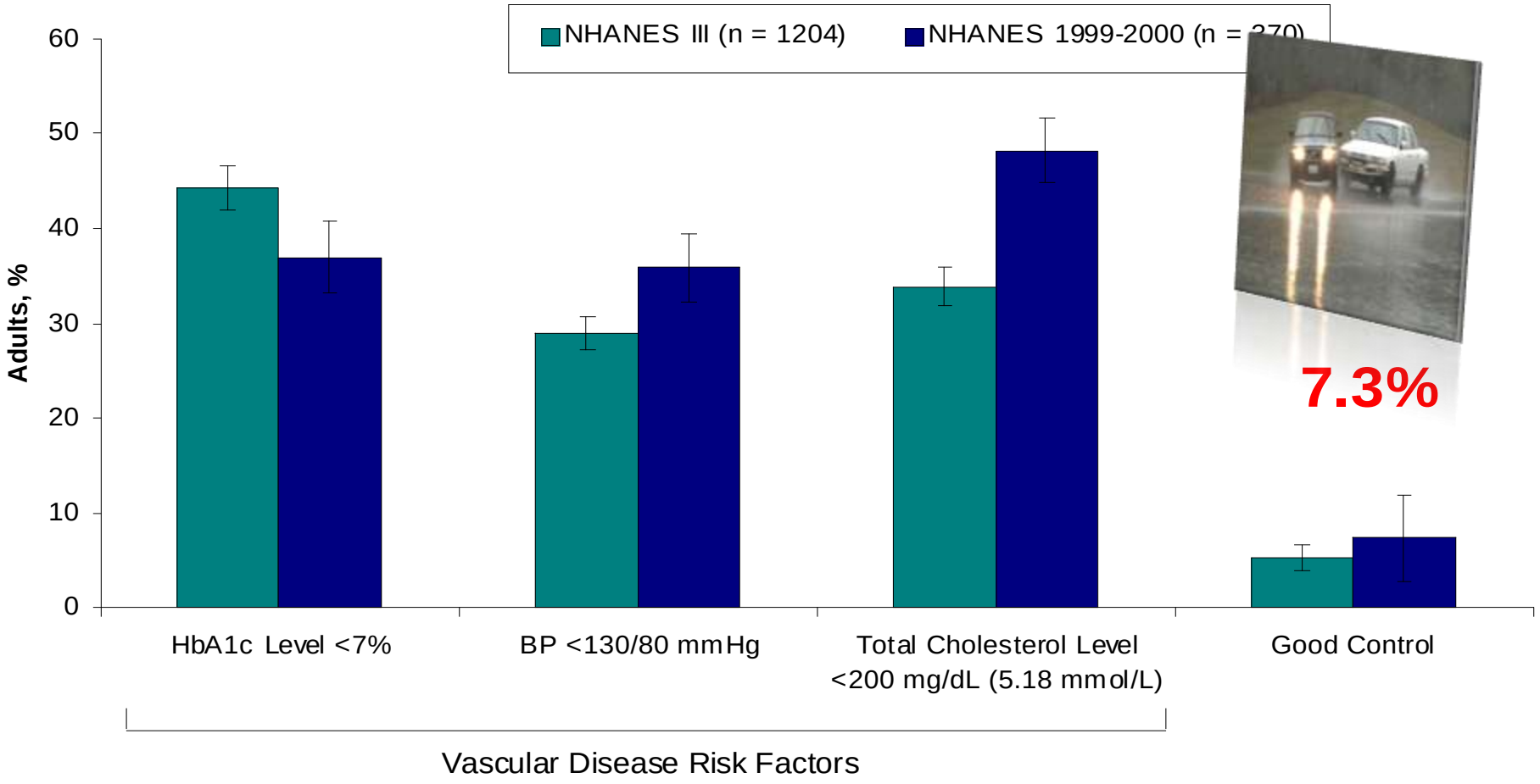
- Diet
- Lifestyle modifications
- Medical therapy



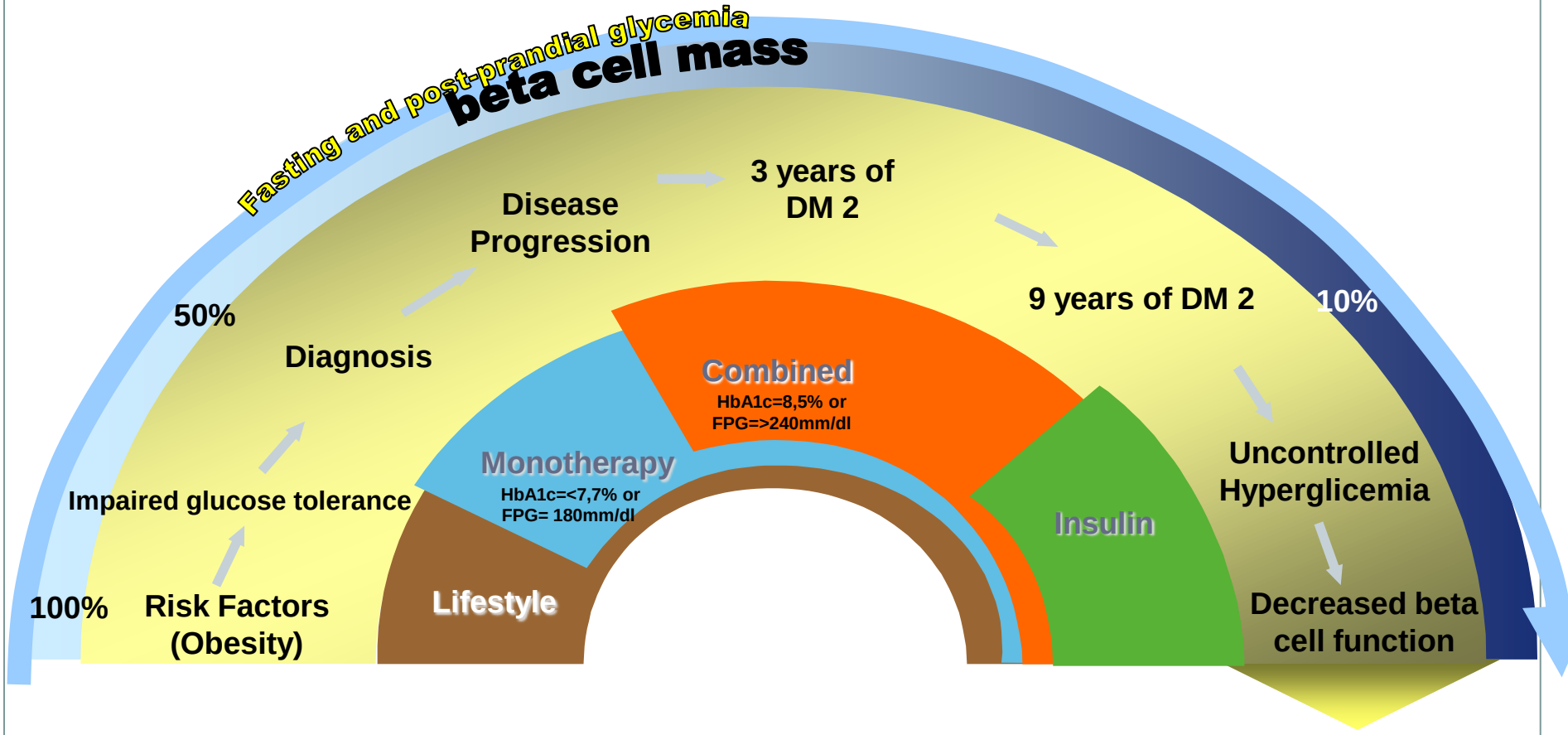
Aggressive Medical Treatment of T2DM "Polypharmacy"



Most of DM patients are not under control !!!



NATURAL HISTORY OF T2DM
CHRONIC & PROGRESSIVE

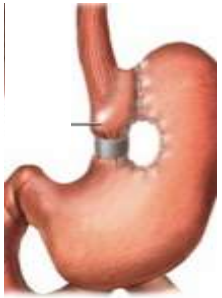
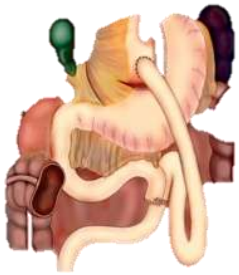


Weight and Type 2 Diabetes after Bariatric Surgery: Systematic Review and Meta-analysis

Henry Buchwald, MD, PhD,[a] Rhonda Estok, RN, BSN,[b] Kyle Fahrbach, PhD,[b] Deirdre Banel, BA,[b]
Michael D. Jensen, MD,[c] Walter J. Pories, MD,[d] John P. Bantle, MD,[e] Isabella Sledge, MD, MPH[b]

The American Journal of Medicine, Vol 122, No 3, March 2009

1990-2006; 19 studies, 4070 diabetic patients

	Total				
% EBWL	55.9				
% Resolved Overall	78.1				
% Resolved <2 yrs	80.3				
% Resolved ≥2 yrs	74.6	58.3	77.5	70.9	95.9

%EBWL = percent excess body weight loss
BPD/DS = biliopancreatic diversion/duodenal switch

Control + Improvement: 95%

BMI < 35 ?

Although weight loss was not the main goal of Rahele Malanca's bariatric surgery, she dropped 55 pounds. She is seen here before her surgery (sitting) and after (right).

RAHELE MALANCA

(Continued from page 1)

The Surgical Treatment of Type Two Diabetes Mellitus

Walter J. Pories, MD[a,b,*], James H. Mehaffey, BS[c], Kyle M. Staton, BS[d]

Surg Clin N Am 91 (2011) 821–836
doi:10.1016/j.suc.2011.04.008
surgical.thedinics.com

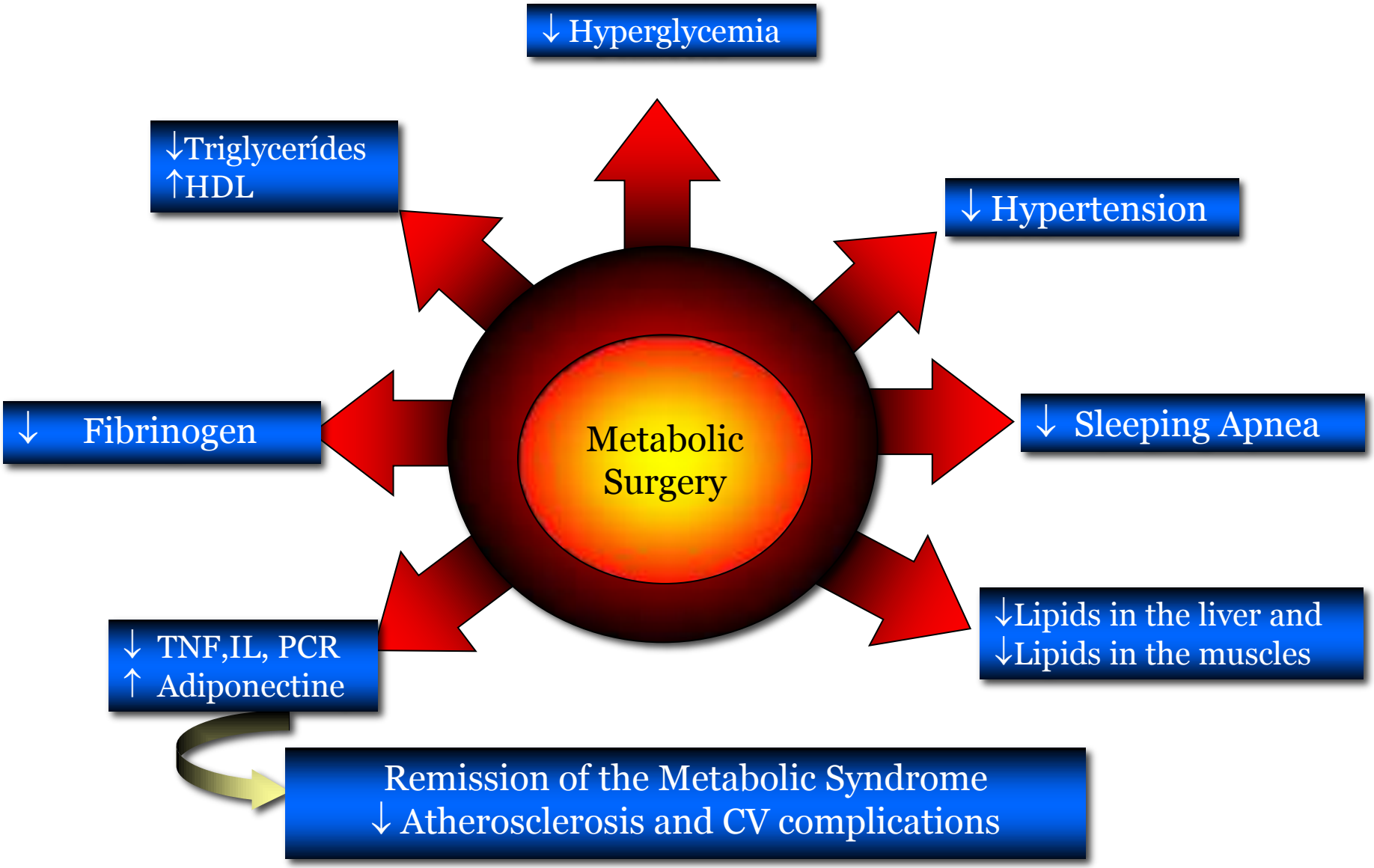
METABOLIC SURGERY

Metabolic Surgery

- Buchald and Varco - 1978: The surgical handling of a normal organ or system to achieve a biological result of health improvement
- Any anatomic change(s) in digestive tract that improves metabolic conditions

- T2DM
- HBP
- Dislipidemia

} Metabolic Syndrome

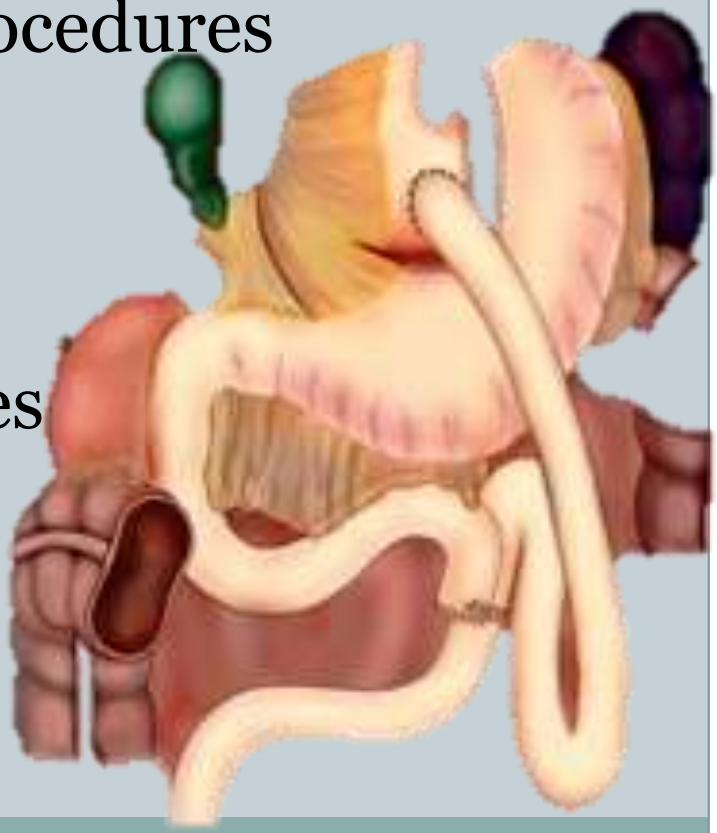

↓ Hyperglycemia
↓Triglycerídes
↑HDL
↓ Hypertension
↓ Fibrinogen
Metabolic Surgery
↓ Sleeping Apnea
↓ TNF,IL, PCR
↑ Adiponectine
↓Lipids in the liver and
↓Lipids in the muscles
Remission of the Metabolic Syndrome
↓ Atherosclerosis and CV complications

How does surgery improve T2DM?

- Diet - Caloric Restriction
- Weight loss
- Reduction of fat cell mass
- Incretin effect
- Bile absortion
- Bioma changes

METABOLIC SURGERY

- ***NEW PROCEDURES…***
  - Gastric volume reduction procedures
  - Duodenal-jejunal exclusion procedures - devices
  - Ileal “stimulation” procedures
  - Electrical stimulation



METABOLIC SURGERY

Metabolic Surgery

- New procedures…
  - Gastric volume reduction procedures

INTRAGASTRIC BALLOON T2DM TREATMENT

- Endoscopic Endolumenal
- Temporary – 6m
- Effective weight loss of 10-15% (TBW)
  - Gastro Obeso Center (non-published)
    - 12pt 30-35 BMI with non controlled T2DM
      - 6 on insulin
        - All had imp

SLEEVE GASTRECTOMY
T2DM TREATMENT

OBES SURG (2008) 18:1077–1082
DOI 10.1007/s11695-008-9547-2

RESEARCH ARTICLE

Type 2 Diabetes Mellitus and the Metabolic Syndrome Following Sleeve Gastrectomy in Severely Obese Subjects

J. Vidal · A. Ibarzabal · F. Romero · S. Delgado · D. Momblán · L. Flores · A. Lacy

- 12m prospective study n 91 severely obese T2DM SG (SG; $n = 39$ / GBP; $n = 52$), matched for DM duration, type of DM treatment, and glycemic
- **Results**
  - Similar weight (%EBL: SG: 63.00 ± 2.89%, BPG: 66.06 ± 2.34%; $p = 0.413$)
  - T2DM resolution of 33 out of 39 (84.6%) for SG
  - T2DM resolution of 44 out of 52 (84.6%) for GBP ($p = 0.618$).

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes

Philip R. Schauer, M.D., Sangeeta R. Kashyap, M.D., Kathy Wolski, M.P.H., Stacy A. Brethauer, M.D., John P. Kirwan, Ph.D., Claire E. Pothier, M.P.H., Susan Thomas, R.N., Beth Abood, R.N., Steven E. Nissen, M.D., and Deepak L. Bhatt, M.D., M.P.H.

This article (10.1056/NEJMoa1200225) was published on March 26, 2012, at NEJM.org.

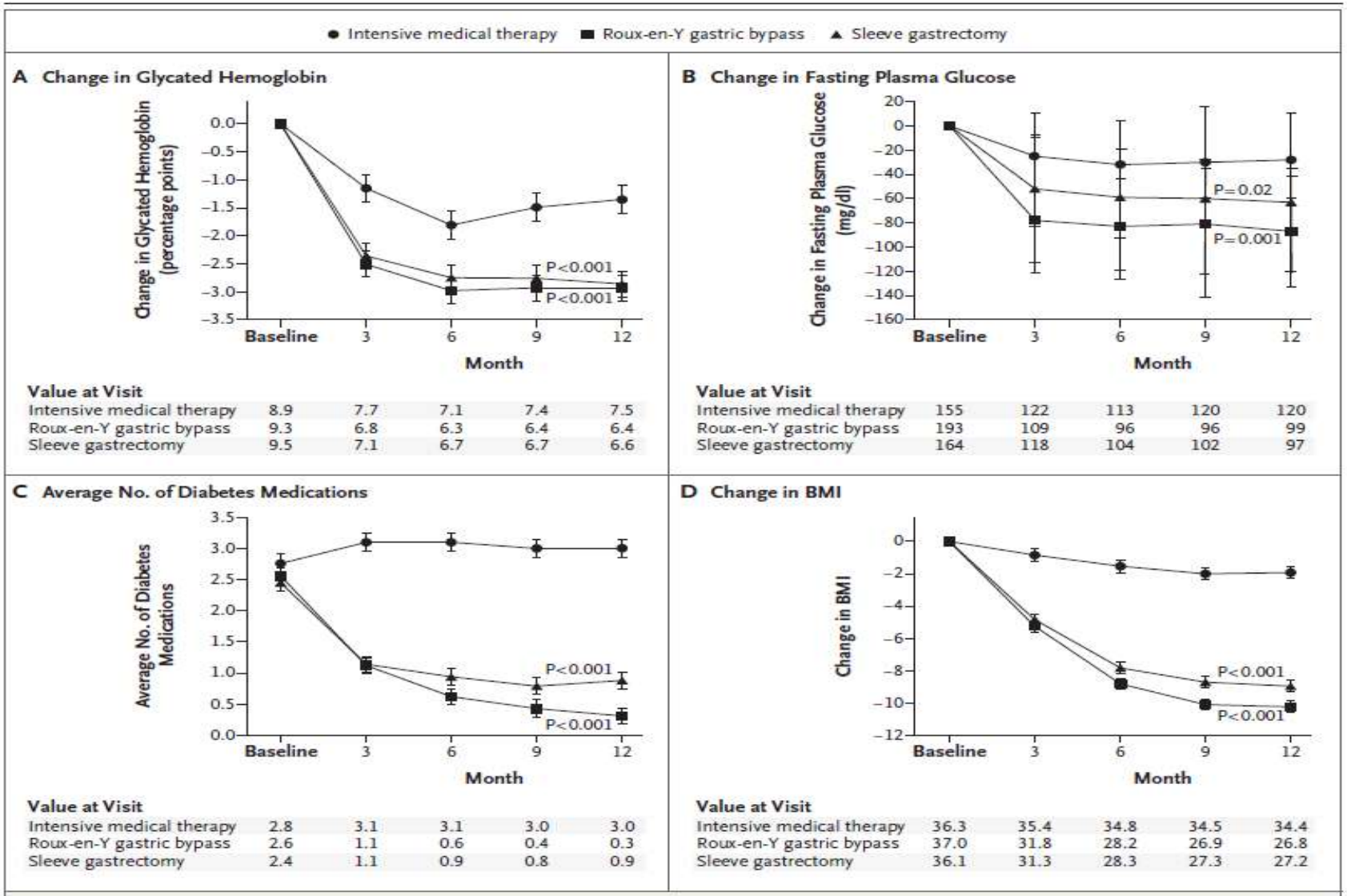
N Engl J Med 2012.

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Medical Therapy (N=50)	Gastric Bypass (N=50)	Sleeve Gastrectomy (N=50)	P Value
Duration of diabetes — yr	8.9±5.8	8.2±5.5	8.5±4.8	0.72
Use of insulin — no. (%)	22 (44)	22 (44)	22 (44)	1.00
Age — yr	49.7±7.4	48.3±8.4	47.9±8.0	0.46
Female sex — no. (%)	31 (62)	29 (58)	39 (78)	0.08
Body-mass index†				
Value	36.8±3.0	37.0±3.3	36.2±3.9	0.42
<35 — no. (%)	19 (38)	14 (28)	18 (36)	0.54
Body weight — kg	106.5±14.7	106.7±14.8	100.8±16.4	0.10
Waist circumference — cm	114.5±9.4	116.4±9.2	114.0±10.4	0.43
Waist-to-hip ratio	0.95±0.09	0.96±0.07	0.96±0.09	0.88
White race — no. (%)‡	37 (74)	37 (74)	36 (72)	0.97
Smoker — no./total no. (%)	15/42 (36)	20/50 (40)	11/50 (22)	0.14
Metabolic syndrome — no. (%)	46 (92)	45 (90)	47 (94)	1.00
History of dyslipidemia — no./total no. (%)	36/43 (84)	44/50 (88)	40/50 (80)	0.55
History of hypertension — no./total no. (%)	26/43 (60)	35/50 (70)	30/50 (60)	0.51

Table 2. Primary and Secondary End Points at 12 Months.*

End Point	Medical Therapy (N=41)	Gastric Bypass (N=50)	Sleeve Gastrectomy (N=49)	P Value		
				Gastric Bypass vs. Medical Therapy	Sleeve Gastrectomy vs. Medical Therapy	Gastric Bypass vs. Sleeve Gastrectomy
Glycated hemoglobin						
≤6% — no. (%)	5 (12)	21 (42)	18 (37)	0.002	0.008	0.59
≤6% with no diabetes medications — no. (%)	0	21 (42)	13 (27)	<0.001	<0.001	0.10
Baseline — %	8.9±1.4	9.3±1.4	9.5±1.7			
Month 12 — %	7.5±1.8	6.4±0.9	6.6±1.0	<0.001	0.003	0.23
Change from baseline — percentage points	−1.4±1.5	−2.9±1.6	−2.9±1.8	<0.001	<0.001	0.85
Body weight — kg						
Baseline	104.4±14.5	106.7±14.8	100.6±16.5			
Month 12	99.0±16.4	77.3±13.0	75.5±12.9	<0.001	<0.001	0.50
Change from baseline	−5.4±8.0	−29.4±8.9	−25.1±8.5	<0.001	<0.001	0.02
High-density lipoprotein cholesterol						
Percent change from baseline	11.3±25.7	28.5±22.7	28.4±21.9	0.001	0.001	0.98
Triglycerides						
Median percent change from baseline (interquartile range)	−14 (−40 to 3)	−44 (−65 to −16)	−42 (−56 to 0)	0.002	0.08	0.17
High-sensitivity C-reactive protein						
Median percent change from baseline (interquartile range)	−33.2 (−71 to 0)	−84 (−91 to −59)	−80 (−90 to −63)	<0.001	<0.001	0.59



A Change in Glycated Hemoglobin					
Value at Visit					
Intensive medical therapy	8.9	7.7	7.1	7.4	7.5
Roux-en-Y gastric bypass	9.3	6.8	6.3	6.4	6.4
Sleeve gastrectomy	9.5	7.1	6.7	6.7	6.6

B Change in Fasting Plasma Glucose					
Value at Visit					
Intensive medical therapy	155	122	113	120	120
Roux-en-Y gastric bypass	193	109	96	96	99
Sleeve gastrectomy	164	118	104	102	97

C Average No. of Diabetes Medications					
Value at Visit					
Intensive medical therapy	2.8	3.1	3.1	3.0	3.0
Roux-en-Y gastric bypass	2.6	1.1	0.6	0.4	0.3
Sleeve gastrectomy	2.4	1.1	0.9	0.8	0.9

D Change in BMI					
Value at Visit					
Intensive medical therapy	36.3	35.4	34.8	34.5	34.4
Roux-en-Y gastric bypass	37.0	31.8	28.2	26.9	26.8
Sleeve gastrectomy	36.1	31.3	28.3	27.3	27.2

Figure 1. Changes in Measures of Diabetes Control from Baseline.

Values for change in glycated hemoglobin (Panel A), change in fasting plasma glucose (Panel B), the average number of diabetes medications (Panel C), and change in body-mass index (BMI) (Panel D) were plotted at 3, 6, 9, and 12 months. Least-square means and standard errors from a repeated measures model are plotted for glycated hemoglobin, average number of medications, and BMI; medians and interquartile ranges are plotted for fasting plasma glucose. P values are for the comparison between each surgical group and the medical-therapy group and were calculated from a repeated-measures model that considers data over time.

Table 4. Adverse Events at 12 Months.*

Adverse Event	Medical Therapy (N=43)	Gastric Bypass (N=50)	Sleeve Gastrectomy (N=49)
		no. of patients (%)	
Serious adverse event			
Requiring hospitalization	4 (9)	11 (22)	4 (8)
Intravenous treatment for dehydration	0	4 (8)	2 (4)
Reoperation	0	3 (6)	1 (2)
Transfusion	0	1 (2)	1 (2)
Hemoglobin decrease ≥5 g/dl	0	1 (2)	0
Gastrointestinal leak	0	0	1 (2)
Transient renal insufficiency	0	1 (2)	0
Cholelithiasis	0	1 (2)	0
Arrhythmia or palpitations	2 (5)	0	1 (2)
Pleural effusion	0	0	1 (2)
Ketoacidosis	0	1 (2)	0
Wound infection	0	1 (2)	0
Cellulitis	1 (2)	0	0
Pneumonia	0	2 (4)	0
Kidney stone	1 (2)	0	0
Hernia	0	1 (2)	0
Other adverse event			
Hypoglycemic episode†	35 (81)	28 (56)	39 (80)
Anemia‡	3 (7)	6 (12)	6 (12)
Hypokalemia	1 (2)	2 (4)	2 (4)
Anastomotic ulcer	0	4 (8)	0
Excessive weight gain§	3 (7)	0	0

Adjustable Gastric Banding and Conventional Therapy for Type 2 Diabetes

A Randomized Controlled Trial

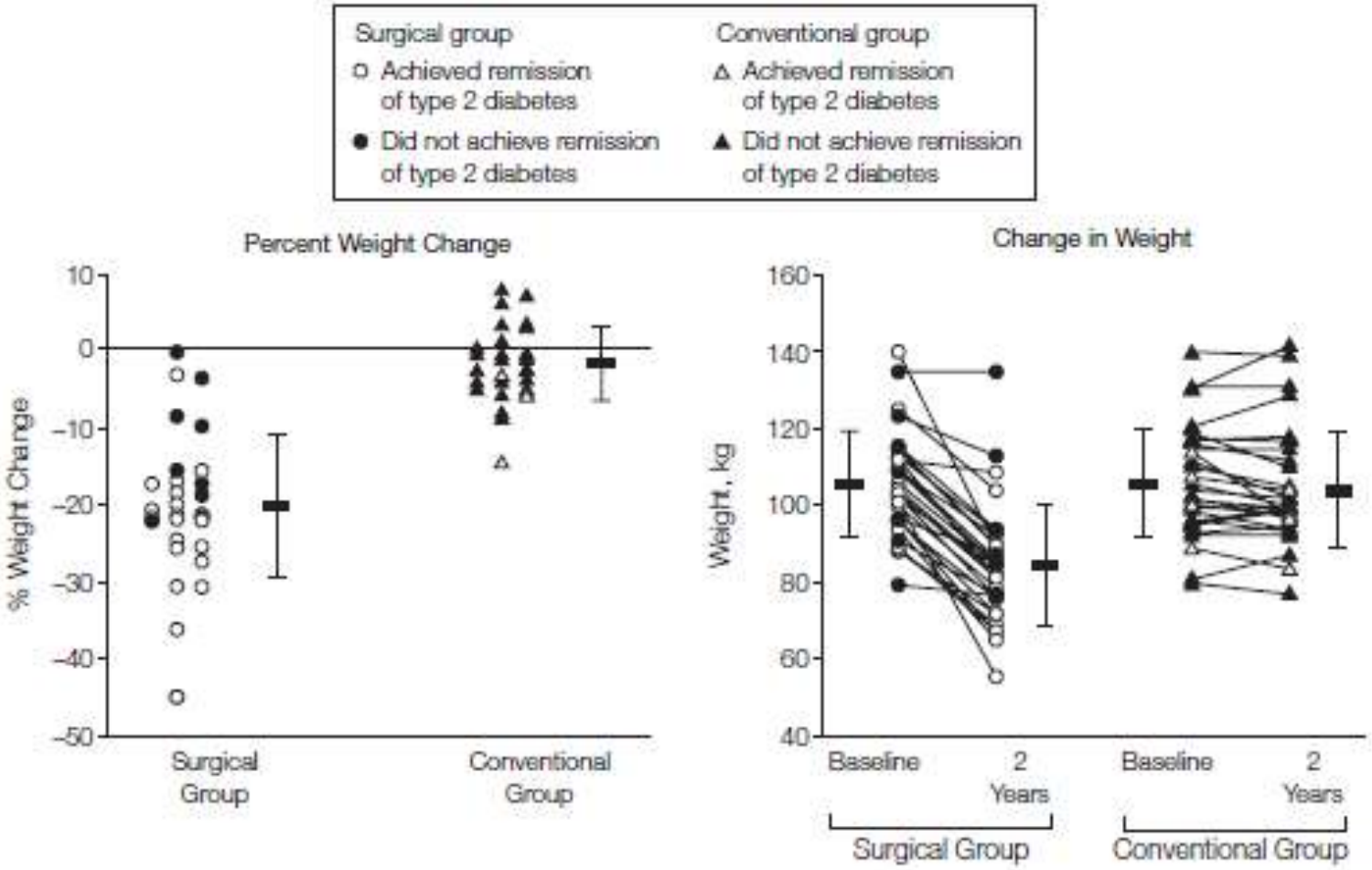
John B. Dixon, MBBS, PhD
Paul E. O'Brien, MD
Julie Playfair, RN
Leon Chapman, MBBS
Linda M. Schachter, MBBS, PhD
Stewart Skinner, MBBS, PhD
Joseph Proietto, MBBS, PhD
Michael Bailey, PhD, MSc(stats)
Margaret Anderson, BHealthMan

JAMA, January 23, 2008—Vol 299, No. 3 (Reprinted)

Table 1. Baseline Characteristics of Participants[a]

Characteristic	Surgery (n = 30)	Conventional Therapy (n = 30)
Age, mean (SD), y	46.6 (7.4)	47.1 (8.7)
Men, No. (%)	15 (50)	13 (43)
Hypertension, No. (%)	28 (93)	27 (90)
Metabolic syndrome, No. (%)	29 (97)	29 (97)
Coronary artery disease, No. (%)	0	1 (3)
BMI, mean (SD)[b]	37.0 (2.7)	37.2 (2.5)
Weight, mean (SD), kg	105.6 (13.8)	105.9 (14.2)
Waist circumference, mean (SD), cm	114.1 (10.2)	116.0 (10.0)
Waist to hip ratio, mean (SD)	0.96 (0.09)	0.96 (0.10)
Neck circumference, mean (SD), cm	41.8 (4.0)	42.4 (4.5)
Blood pressure, mean (SD), mm Hg		
Systolic	136.4 (15.6)	135.3 (14.4)
Diastolic	86.6 (9.4)	84.5 (9.8)
HbA_{1c}, mean (SD), %	7.8 (1.2)	7.6 (1.4)
Plasma glucose, mean (SD), mg/dL	156.7 (38.5)	158.0 (48.7)
Plasma insulin, median (IQR), μIU/mL	19.7 (16.5-27.5)	18.7 (13.7-30.7)
Lipids, mean (SD), mg/dL		
Total cholesterol	201.8 (32.7)	198.2 (56.7)
Triglycerides	190.6 (106.6)	188.7 (111.8)
HDL-C	47.1 (10.1)	48.1 (11.1)
Total cholesterol to HDL-C ratio	4.41 (0.87)	4.23 (1.11)

Figure 2. Percentage of Weight Loss Achieved Over the 2-Year Study Period (n=60) and Individual Weight Measures at Baseline and at 2 Years



Remission indicates those achieving remission of type 2 diabetes (see "Methods") at 2 years. Data markers with error bars indicate mean (SD).

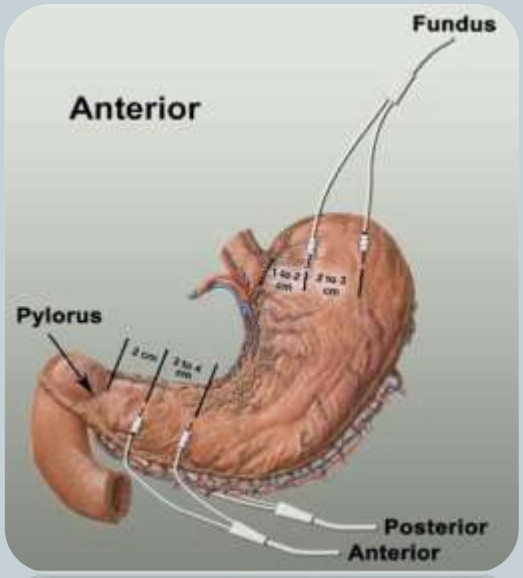
Table 2. Primary and Secondary Outcomes at 2 Years[a]

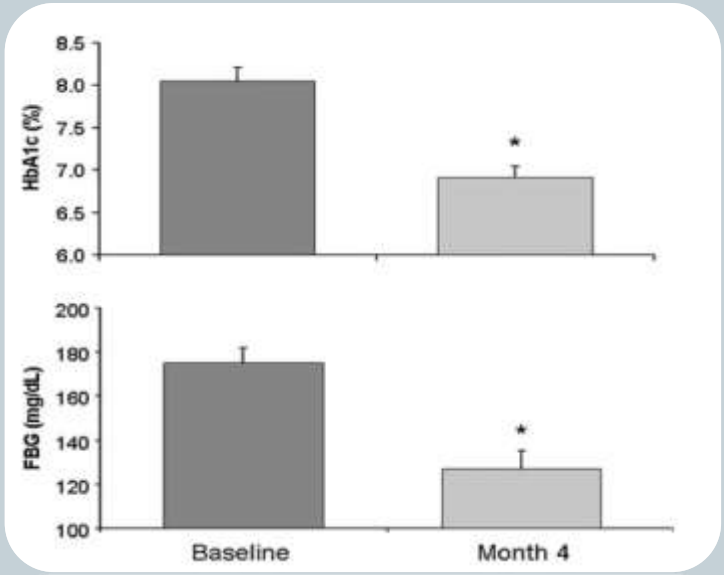
Variable	Mean (SD)		Between-Group Difference, Mean (95% CI)	*P* Value
	Surgery (n = 30)	Conventional Therapy (n = 30)		
Primary Outcome, No. (%)				
Remission of diabetes, No. (%)	22 (73)	4 (13)	RR for surgical remission, 5.5 (2.2 to 14.0)	<.001
Secondary Outcomes				
Weight, kg	84.6 (15.8)	104.8 (15.3)		
Change, kg	−21.1 (10.5)	−1.5 (5.4)	−19.6 (−23.8 to −15.2)	<.001
Waist circumference, cm	95.8 (10.3)	112.7 (10.3)		
Change, cm	−17.9 (10.8)	−4.0 (9.1)	−13.9 (−19.0 to −8.7)	<.001
Waist to hip ratio	0.90 (0.06)	0.95 (0.08)		
Change	−0.06 (0.06)	−0.01 (0.06)	−0.05 (−0.07 to −0.007)	.02
Blood pressure, mm Hg				
Systolic	130.4 (19.0)	132.6 (17.7)		
Change	−6.0 (17.9)	−1.7 (14.2)	−4.3 (−13.6 to 5.1)	.37
Diastolic	85.4 (7.0)	83.1 (8.5)		
Change	−0.7 (11.1)	−0.9 (11.1)	0.2 (−5.4 to 6.0)	.92
HbA_{1c}, %	6.00 (0.82)	7.21 (1.39)		
Change	−1.81 (1.24)	−0.38 (1.26)	−1.43 (−2.1 to −0.80)	<.001
Plasma glucose, mg/dL	105.6 (30.3)	139.6 (38.1)		
Change	−51.2 (37.6)	−18.4 (41.2)	−32.8 (−53.1 to −12.3)	.002
Plasma insulin, μIU/mL	9.8 (4.7)	24.1 (13.6)		
Change	−12.4 (8.4)	1.0 (14.8)	−13.4 (−19.6 to −7.3)	<.001
HOMA IR[b]	1.90 (0.73)	3.50 (0.97)		
Change, %	−45.5 (19.0)	−3.3 (35.4)	−42.2 (−57 to −26.8)[c]	<.001
Total cholesterol, mg/dL	205.4 (46.6)	197.8 (59.3)		
Change	3.6 (51.6)	−0.4 (31.4)	4.0 (−18.8 to 26.0)	.72
Triglycerides, mg/dL	118.9 (79.7)	186.7 (127.2)		
Change	−71.7 (92.9)	−2.1 (120.6)	−69.6 (−125.3 to −13.6)	.02
HDL-C, mg/dL	59.7 (13.6)	50.7 (12.1)		
Change	12.6 (9.8)	2.6 (6.1)	10.0 (5.8 to 14.2)	<.001
Total cholesterol to HDL-C ratio	3.58 (1.00)	4.1 (1.4)		
Change	−0.82 (1.9)	−0.14 (1.04)	−0.68 (−1.24 to −0.14)	.02

GASTRIC ELECTRICAL STIMULATION
T2DM TREATMENT

Improvement in glycemic control by gastric electrical stimulation (TANTALUS^{TM}) in overweight subjects with type 2 diabetes

A. Bohdjalian · B. Ludvik · B. Guerci · L. Bresler · E. Renard · D. Nocca · E. Karnieli · A. Assalia · R. Prager · G. Prager





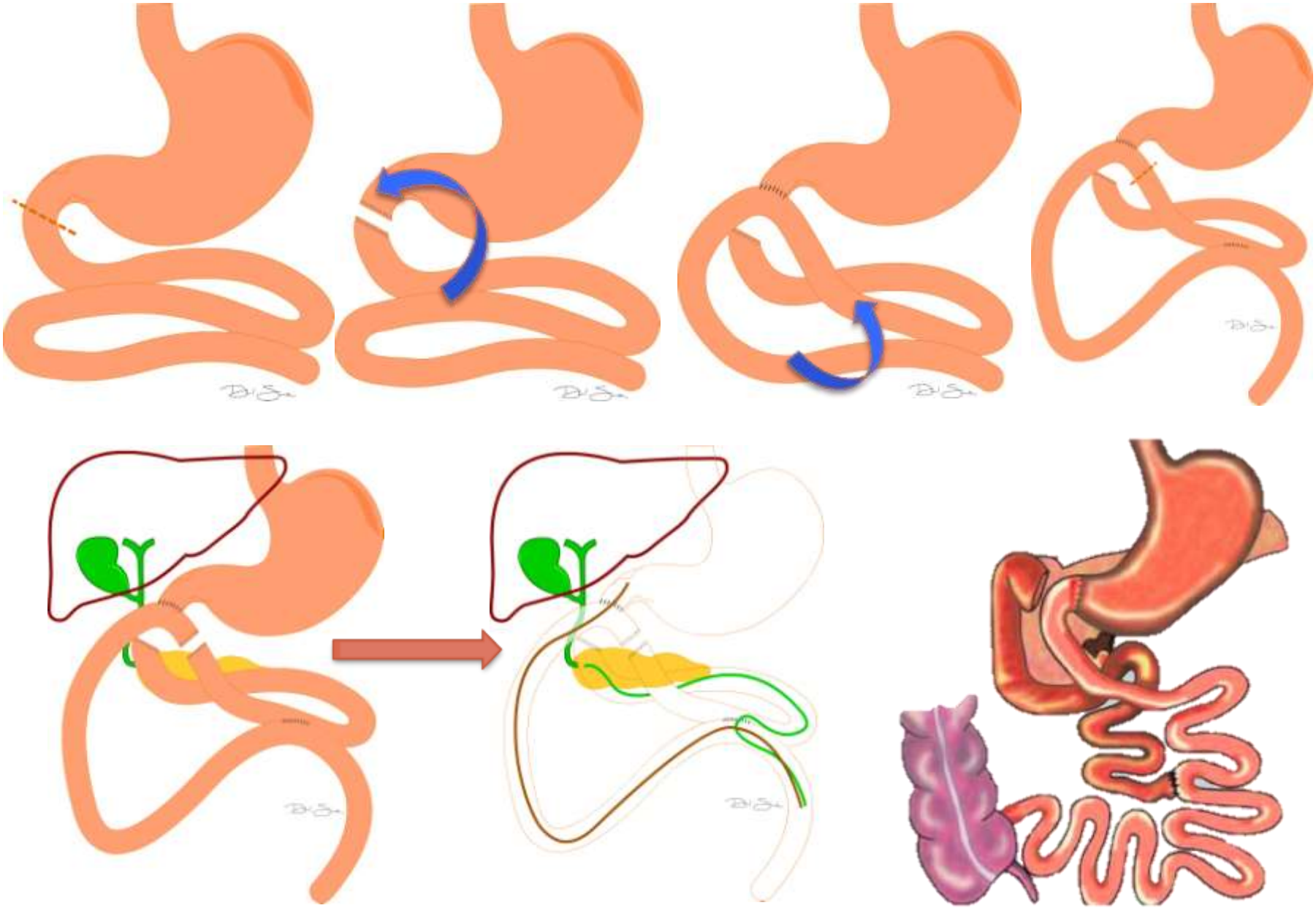
GASTRIC VOLUME REDUCTION
CLINICAL DATA – CRITICAL ANALYSIS

- Sleeve gastrectomy is growing as metabolic surgery
  - No long term follow up
  - Looks an easy procedure – no anastomosis
  - No mal absortion
  - Good safety profile when compared with RYGB
  - Good initial results
- Endoscopic approaches - Balloons
  - Very safety profile when compared with RYGB
  - > 85% T2DM control
  - Temporary – beginning with 1 and 2ys balloons
  - Expensive – Half a price of RYGB
  - Clinical use in LA, EU and Asia
- Electrical Stimulation
  - Very safety profile when compared with RYGB
  - Very expensive – doble in comparison with surgery
  - Experimental procedure
  - Starting studies about ileal electrical stimulation

METABOLIC SURGERY

Metabolic Surgery

- New procedures…
  - Duodenal-jejunal exclusion procedures



DUODENAL-JEJUNAL EXCLUSION CONCEPT –EXPERIMENTAL

Effect of Duodenal–Jejunal Exclusion in a Non-obese Animal Model of Type 2 Diabetes

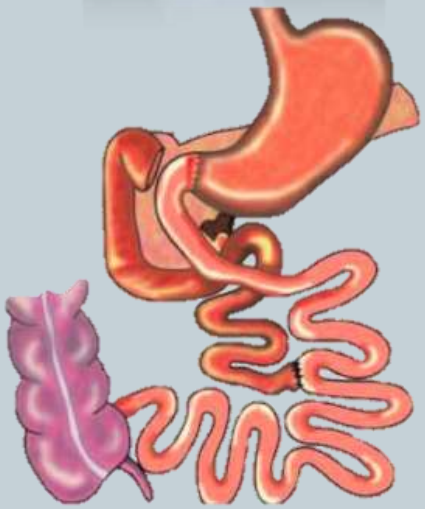
A New Perspective for an Old Disease

Francesco Rubino, MD, and Jacques Marescaux, MD, FRCS

Annals of Surgery • Volume 239, Number 1, January 2004

Mechanisms of action

- Hormonal
  - "Foregut"
    - Duodenal exclusion
    - Proximal bowel bypass

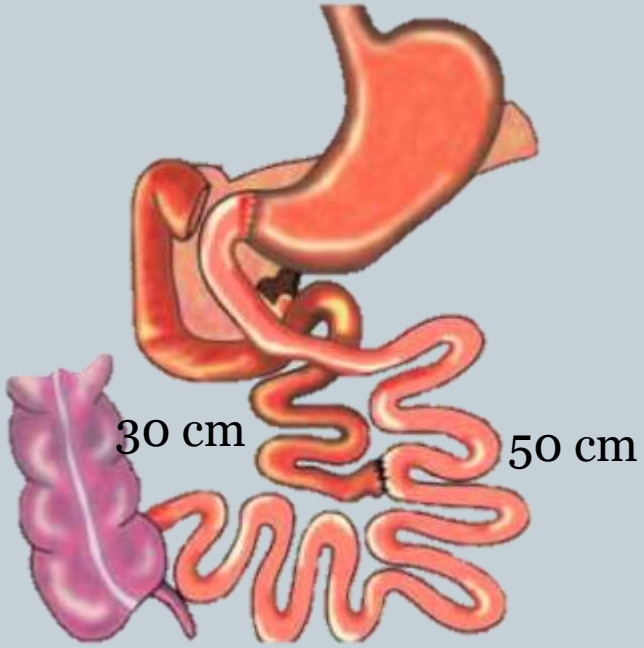


DUODENAL-JEJUNAL EXCLUSION CLINICAL DATA

Duodenal-jejunal bypass for the treatment of type 2 diabetes in patients with body mass index of 22–34 kg/m^2: a report of 2 cases

Ricardo V. Cohen, M.D., F.A.C.S.,[a,*] Carlos A. Schiavon, M.D.,[a] José S. Pinheiro, M.D.,[a] Jose Luiz Correa, M.D.,[a] Francesco Rubino, M.D.[b,c]

2007

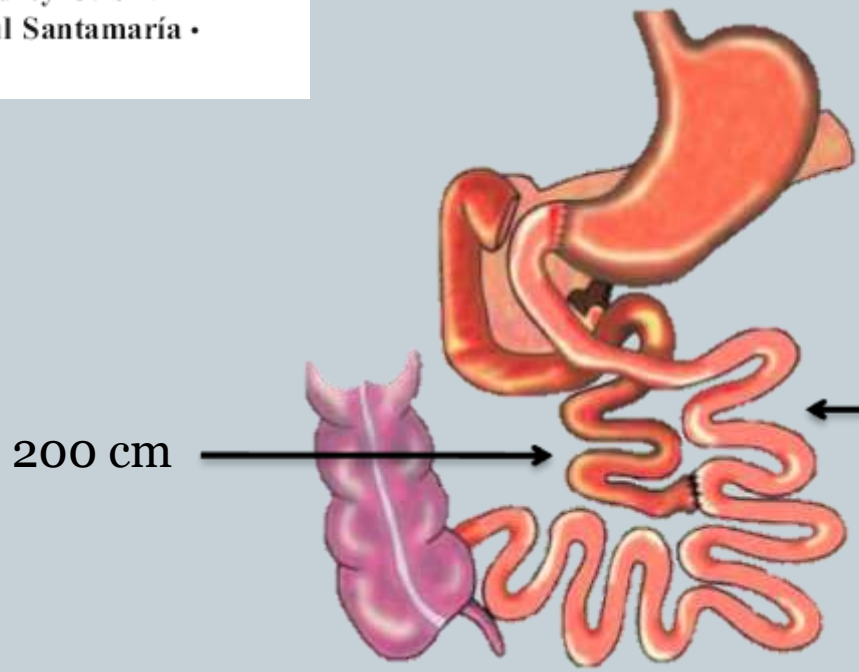


N=27

DUODENAL-JEJUNAL EXCLUSION CLINICAL DATA

Laparoscopic Duodenal–Jejunal Exclusion in the Treatment of Type 2 Diabetes Mellitus in Patients with BMI < 30 kg/m^2 (LBMI)

Almino C. Ramos · Manoel P. Galvão Neto · Yglésio Moyses de Souza · Manoela Galvão · Abel H. Murakami · Andrey C. Silva · Edwin G. Canseco · Raúl Santamaría · Trino A. Zambrano



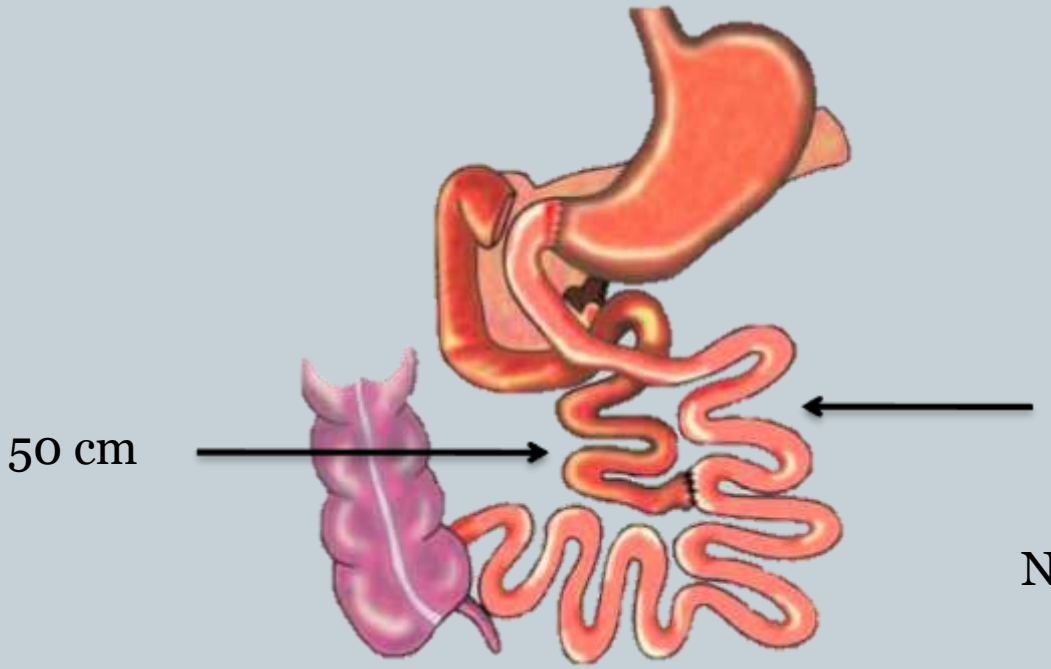
May 2008

N=20

DUODENAL-JEJUNAL EXCLUSION CLINICAL DATA

Surgery for Nonobese Type 2 Diabetic Patients: An Interventional Study with Duodenal–Jejunal Exclusion

Bruno Geloneze · Sylka R. Geloneze · Carla Fiori · Christiane Stabe · Marcos A. Tambascia · Elinton A. Chaim · Brenno D. Astiarraga · Jose Carlos Pareja



May 2008

N=20

DUODENAL-JEJUNAL EXCLUSION AND ILEAL "STIMULATION"

Obesity Surgery, 17, 138-139

Correspondence

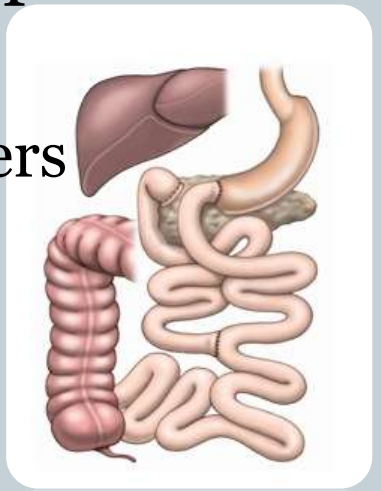
End-to-side Duodeno-jejunostomy with Half-and-Half Biliopancreatic Limb for the Treatment of Type 2 Diabetes: a Proposal for a Simpler Technique

DUODENAL-JEJUNAL EXCLUSION
CLINICAL DATA – CRITICAL ANALYSIS

- Keeps stomach intact
- Good safety profile
  - When compared with RYGB as golden standard
- Very good initial results
  - > 80% T2DM resolution
- Poor results on long term follow-up 6-12 ms
  - > 60% T2DM recidivism
- Actual data
  - Experimental procedure
  - Almost no clinical use
  - Adding a sleeve gastrectomy make the procedure works!

DUODENAL-JEJUNAL EXCLUSION CLINICAL DATA – CRITICAL ANALYSIS

- Sleeve Gastrectomy + Duodenal Jejunal Bypass
  - Cohen – 2010
    - First 50 pts @ 18 mo Follow up (27 insulin users
    - Mean preop BMI = 28.9
    - TBWL 6.8% +- 3.7%
    - 100 % between Control &Resolution
      - 8 (16 %) pts with A1c less than 6



Follow-up	Mean A1c	Insulin	Unchanged	Control,A1c<7 Less meds	Resolution No meds,A1c<7
18 mo	6.2+-0.5*	NONE	0 - NO	32%(16 pts)	68%(34 pts)

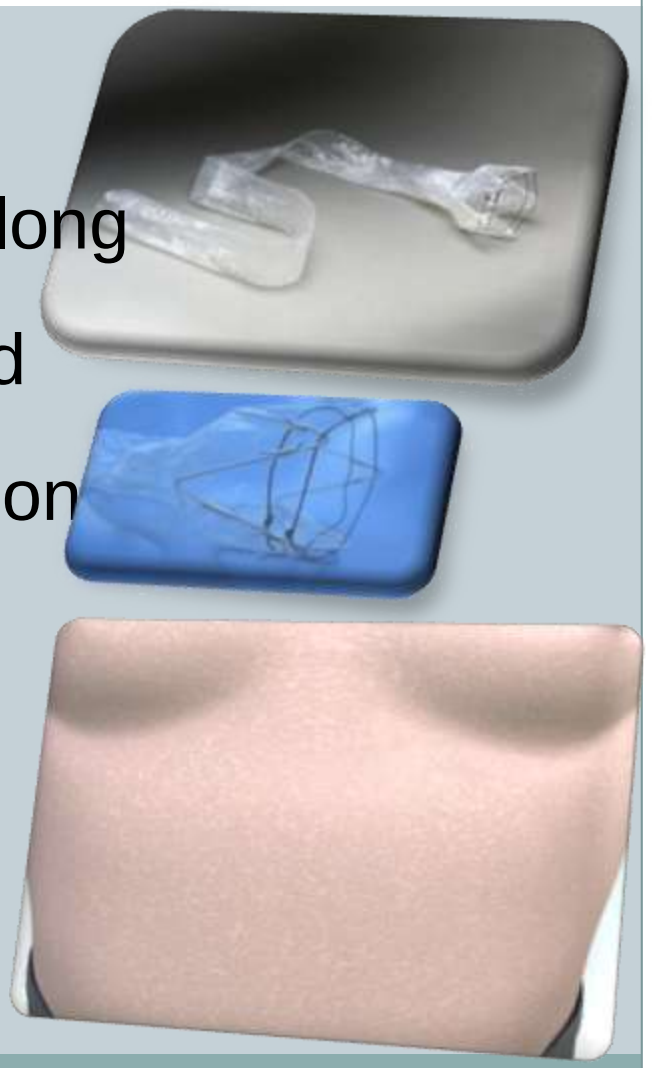
METABOLIC SURGERY

Metabolic Surgery

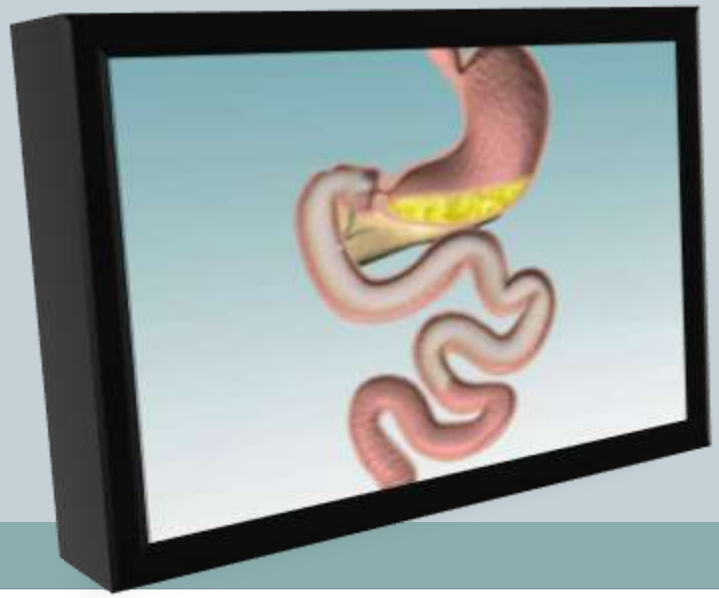
- New procedures…
  - Duodenal-jejunal exclusion device

The EndoBarrier Gastrointestinal Liner

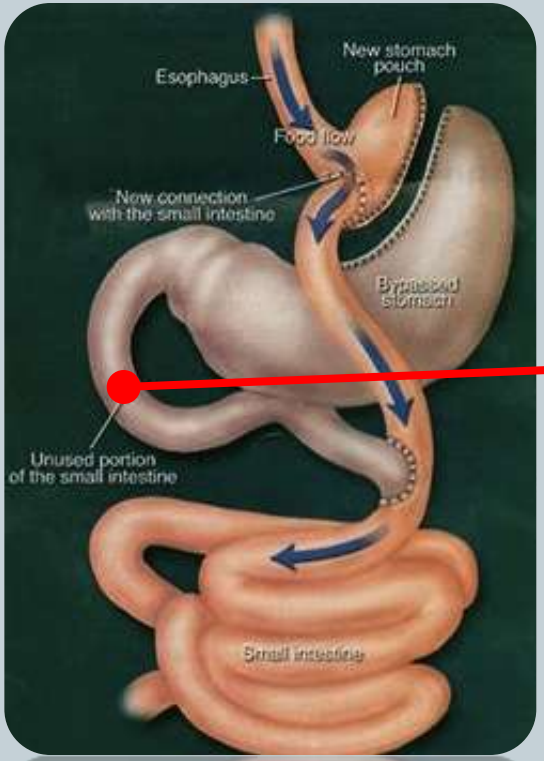
- Impermeable liner
- Anchored in the duodenum, 60 cm long
- Endoscopically placed and removed
- Provides a duodenal-jejunal exclusion
- T2DM and weight loss studied
- Over 500 patients since 2005
- CE mark with clinical use in EU

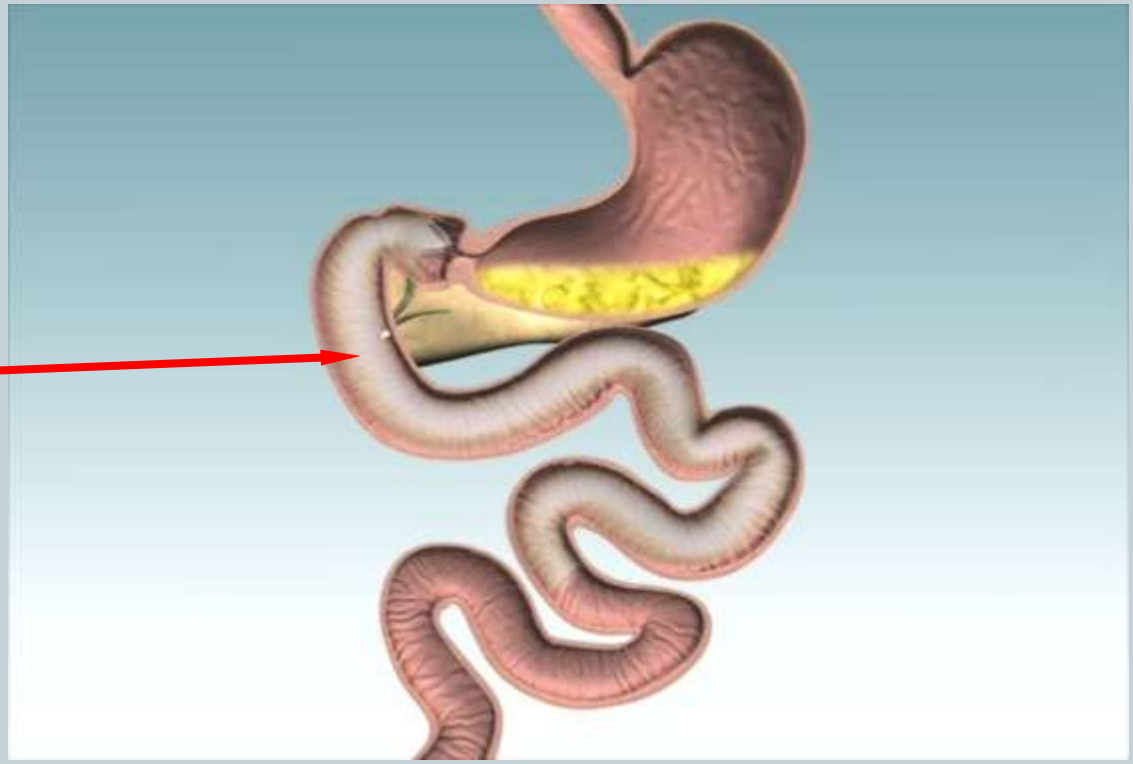


The EndoBarrier Gastrointestinal Liner



The EndoBarrier Gastrointestinal Liner





The EndoBarrier Gastrointestinal Liner

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 11, Number 11, 2009

DOI: 10.1089/dia.2009.0063

Pilot Clinical Study of an Endoscopic, Removable Duodenal-Jejunal Bypass Liner for the Treatment of Type 2 Diabetes

Leonardo Rodriguez, M.D., M.B.S.,[1] Eliana Reyes, M.D.,[1] Pilar Fagalde, M.D.,[1] Maria Soledad Oltra, M.D.,[1] Jorge Saba, M.D.,[1] Carmen Gloria Aylwin, M.D.,[1] Carolina Prieto, M.D.,[1] Almino Ramos, M.D., M.B.S.,[2] Manoel Galvao, M.D., M.B.S.,[2] Keith S. Gersin, M.D.,[3] and Christopher Sorli, M.D.[4]

Rodriguez MD, Ramos A , Galvao Neto M et al.

The EndoBarrier Gastrointestinal Liner

OBES SURG
DOI 10.1007/s11695-011-0387-0

CLINICAL RESEARCH

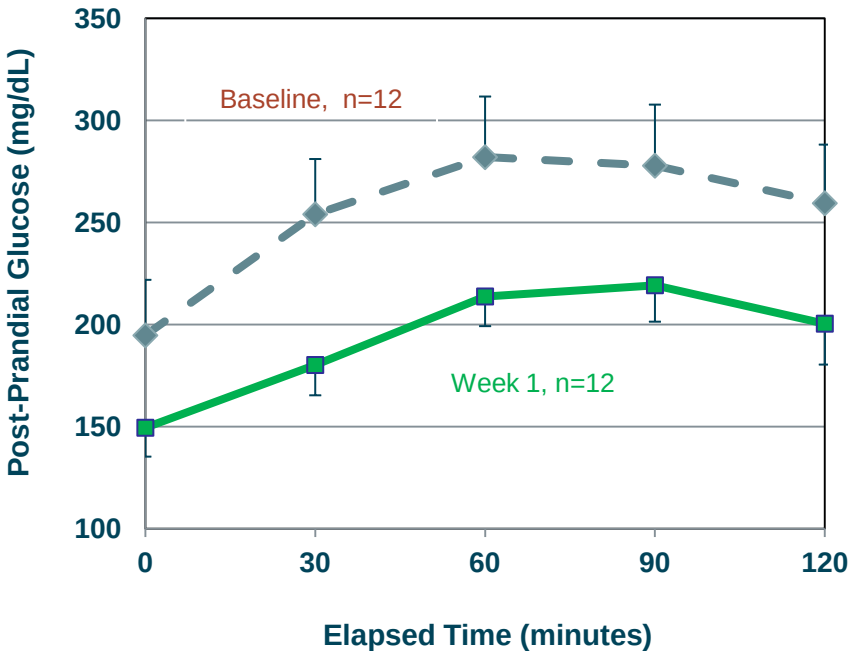
Improvement of Insulin Resistance and Reduction of Cardiovascular Risk Among Obese Patients with Type 2 Diabetes with the Duodenojejunal Bypass Liner

Eduardo Guimarães Hourneaux de Moura · Ivan Roberto Bonotto Orso · Bruno da Costa Martins · Guilherme Sauniti Lopes · Suzana Lopes de Oliveira · Manoel dos Passos Galvão-Neto · Marcio Correa Mancini · Marco Aurélio Santo · Paulo Sakai · Almino Cardoso Ramos · Arthur Belarmino Garrido-Júnior · Alfredo Halpern · Ivan Cecconello

Moura EGH PhD, Ramos A , Galvao Neto M et al.

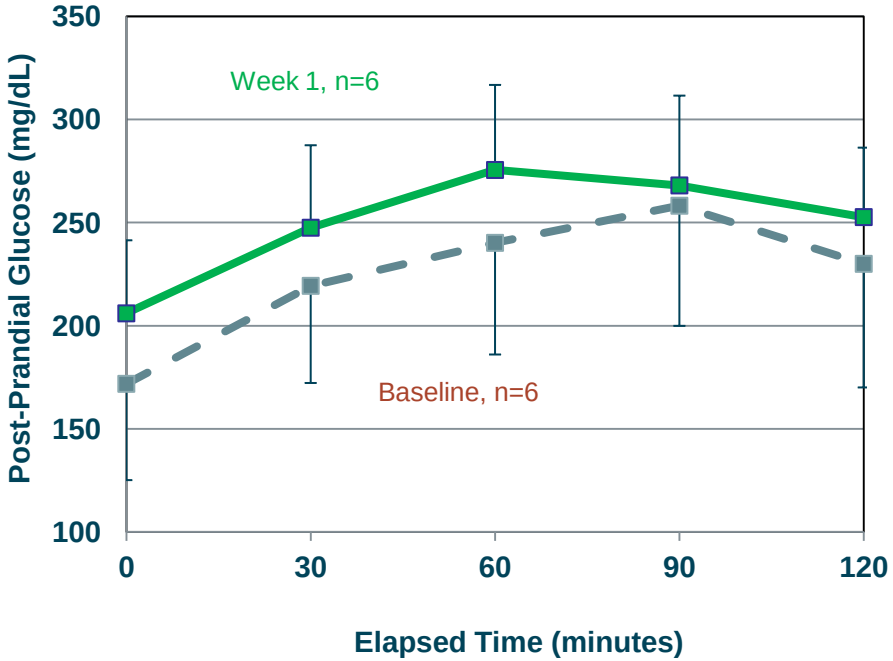
The EndoBarrier Gastrointestinal Liner

EndoBarrier Subjects



AUC *decreased* by 19.1% at Week 1

Sham Subjects



AUC *increased* by 10.8% at Week 1

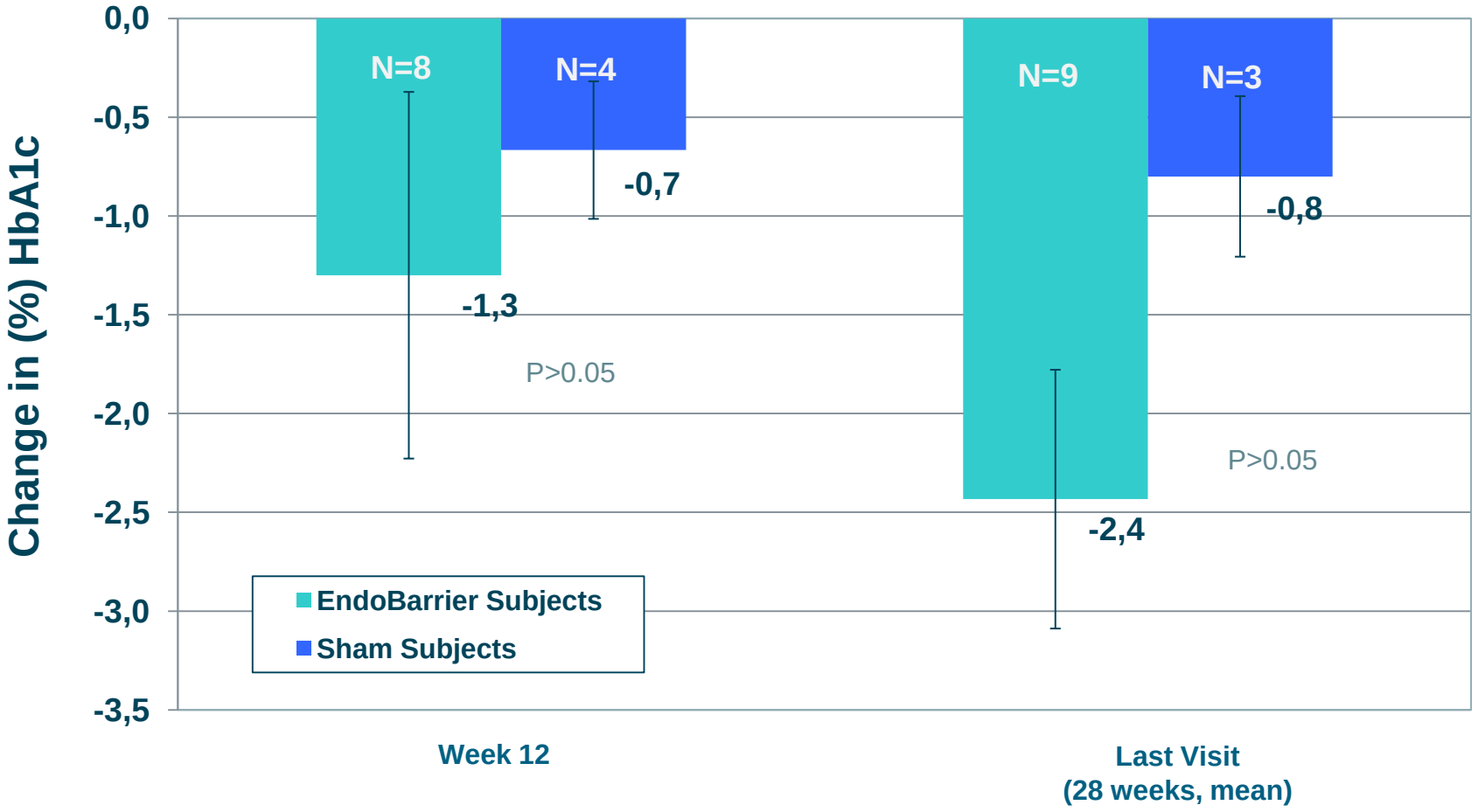
p=0.014

Data Presented at ADA Annual Meeting, June 2008

Rodriguez MD, Ramos A , Galvao Neto M et al.

The EndoBarrier Gastrointestinal Liner

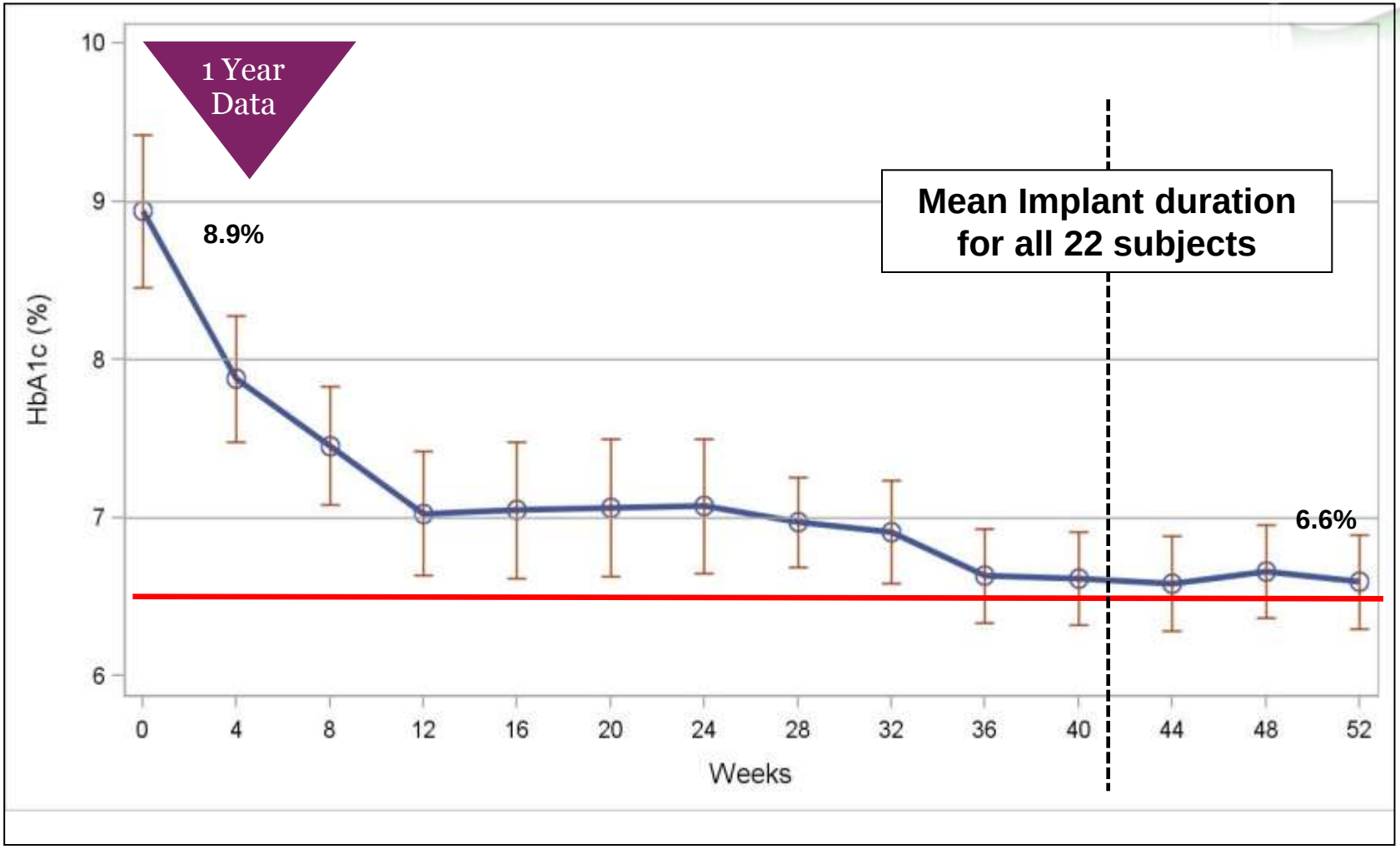
Baseline %HbA1c= 9.2 for EndoBarrier and 9.0 for Sham



Data Presented at ADA Annual Meeting, June 2008

Rodriguez MD, Ramos A , Galvao Neto M et al.

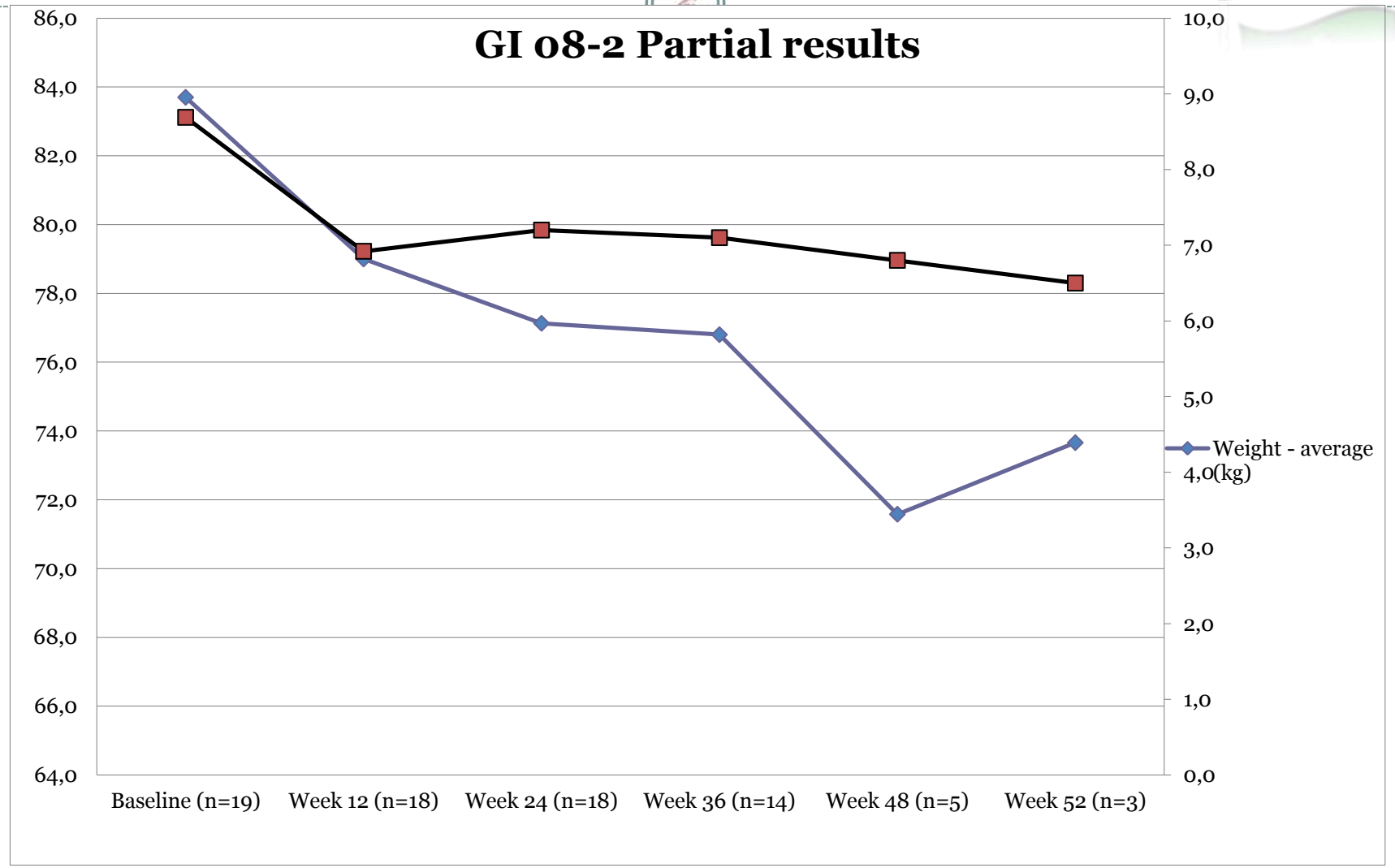
Studied T2DM pts BMI 35 to 70



Moura EGH PhD, Ramos A , Galvao Neto M et al.

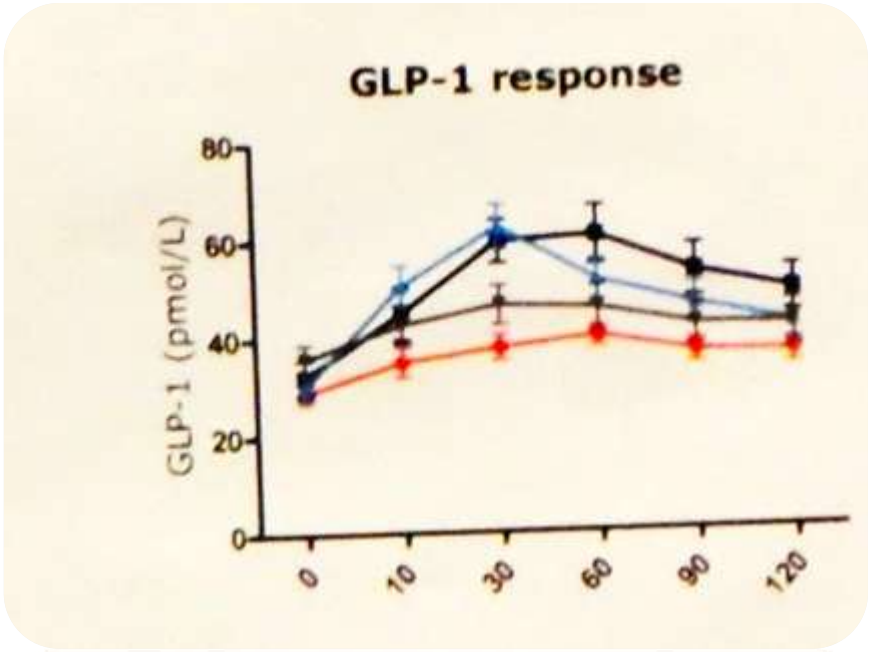
Studied T2DM pts BMI 26 to 34.9

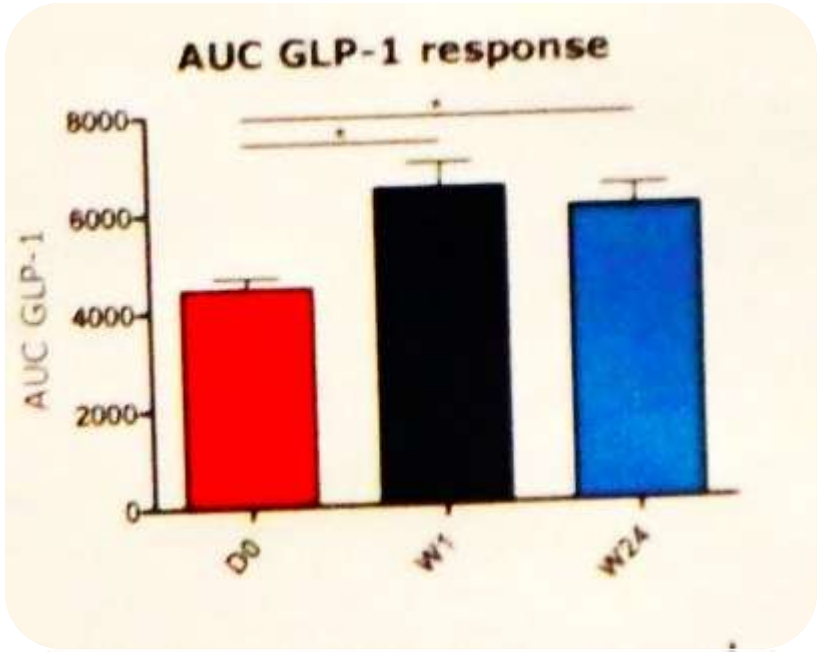
Cohen at all



Cohen R PhD, Galvao Neto M et al.

The EndoBarrier Gastrointestinal Liner





Verban F. J, MD, Greeve J., PhD et al.

DUODENAL-JEJUNAL EXCLUSION DEVICE CLINICAL DATA – CRITICAL ANALYSIS

- Endoscopic - Endolumenal – “simple”
- Temporary – 1y
- Clinical use in LA (Chile) and EU(CE Mark)
- Good safety profile
- Good T2DM control
  - > 85% control or improvement
- Can be repeated (on-going study)
- Patients with difficult control on CM
- May become a “pre-op” test
- Actual data
  - Promising results
  - Initial clinical use
  - Trying to get to 2y

METABOLIC SURGERY

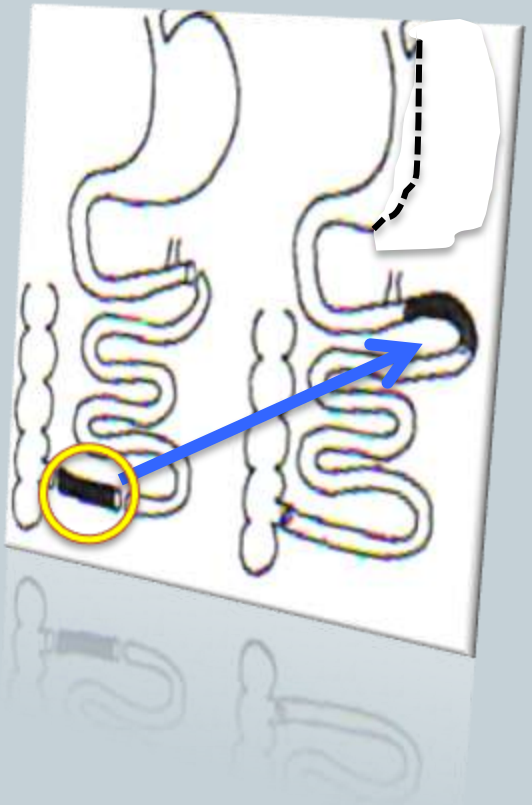
Metabolic Surgery

- New procedures…
  - Ileal “stimulation” procedures

ILEAL "STIMULATION" PROCEDURES

Mechanisms of action

- Hormonal
  - "Hindgut"
    - Early ileal stimulation
    - "Ileal break"



ILEAL "STIMULATION" PROCEDURES
ILEAL INTERPOSITION

Surg Endosc
DOI 10.1007/s00464-007-9472-9

Laparoscopic treatment of type 2 diabetes mellitus for patients with a body mass index less than 35

A. L. DePaula · A. L. V. Macedo · N. Rassi · C. A. Machado · V. Schraibman · L. Q. Silva · A. Halpern

ILEAL "STIMULATION" PROCEDURES DIGESTIVE "BI-PARTITION

ARTIGO ORIGINAL

Comunicação Preliminar

Entero-omentectomia adaptativa: Bases fisiológicas e evolucionárias de uma proposta cirúrgica auxiliar no tratamento de diabetes tipo 2

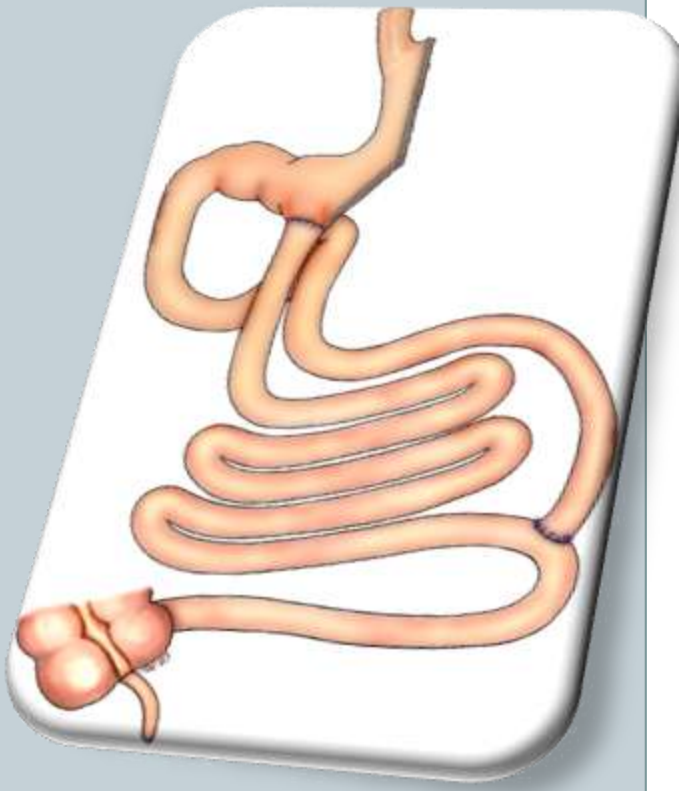
Relato dos dois primeiros casos

Preliminary Report

Adaptive entero-omentectomy: Physiological and evolutionary bases of an auxiliary treatment to type 2 diabetes

A report on the first two cases*

Sérgio Santoro[1], Manoel Carlos Prieto Velhote[2], Carlos Eduardo Malzoni[3], Alexandre Sérgio Garcia Mechenas[4], Sérgio Flávio de Albuquerque Felizola[5]



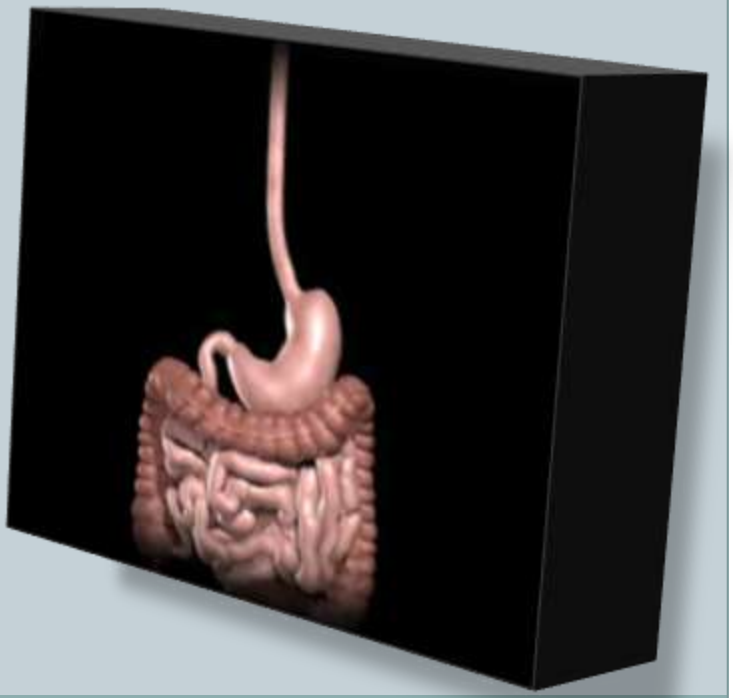
ILEAL "STIMULATION" PROCEDURES CLINICAL DATA – CRITICAL ANALYSIS

- Much more complex and difficult procedures
- Less safety profile
  - When compared with RYGB as golden standard
- Very good initial results
  - > 90% T2DM control
- Good results on mid and long term follow-up
  - > 80% T2DM control
- Actual data
  - Very few clinical use
  - Experimental

METABOLIC BYPASS

Metabolic Surgery

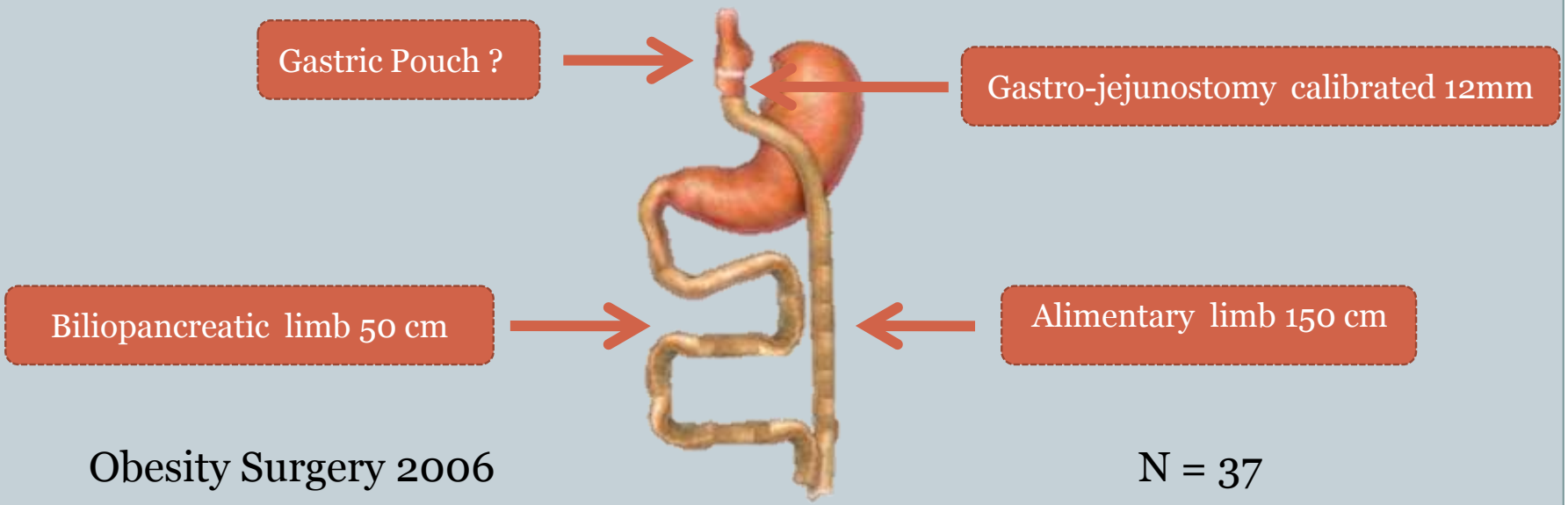
- Roux and Y gastric Bypass – RYGB
  - *Gold standard*
- "Metabolic Bypass"
  - Gastric reduction
  - Duodenal-jejunal bypass
  - Ileal stimulation



METABOLIC BYPASS

Laparoscopic Roux-en-Y gastric bypass for BMI <35 kg/m^2: a tailored approach

Ricardo Cohen, M.D.*, Jose S. Pinheiro, M.D., Jose L. Correa, M.D., Carlos A. Schiavon, M.D.



Obesity Surgery 2006

N = 37

METABOLIC BYPASS

Gastric Bypass in the Treatment of Type 2 Diabetes in Patients with a BMI of 30 to 35 kg/m^2

Vladimir Curvelo Tavares de Sa · Alvaro A. Ferraz ·
Josemberg M. Campos · Almino C. Ramos ·
Jose Guido C. Araujo Jr · Edmundo M. Ferraz

Gastric Pouch 50 cm^3

Gastro-jejunostomy not calibrate?

Biliopancreatic limb 100 cm

Alimentary limb 150 cm

Obesity Surgery 2010

N= 27 { Laparotomy - 17 ; Laparoscopy - 10

METABOLIC BYPASS

Metabolic Bypass , initial experience with Roux-en-Y Gastric Bypass on type II diabetes treatment

Almino C Ramos, Manoel Galvao, Manuela Galvao,
Andrey Carlo, Edwin Canseco, Thales D. Galvão, Luis F Evangelista, Alvaro Ferraz e Josemberg L Campos
São Paulo and Recife - Brasil

Gastric Pouch "double size"

Gastro-ileostomy not calibrate

Biliopancreatic limb 200 cm

Alimentary limb 100 – 200 cm

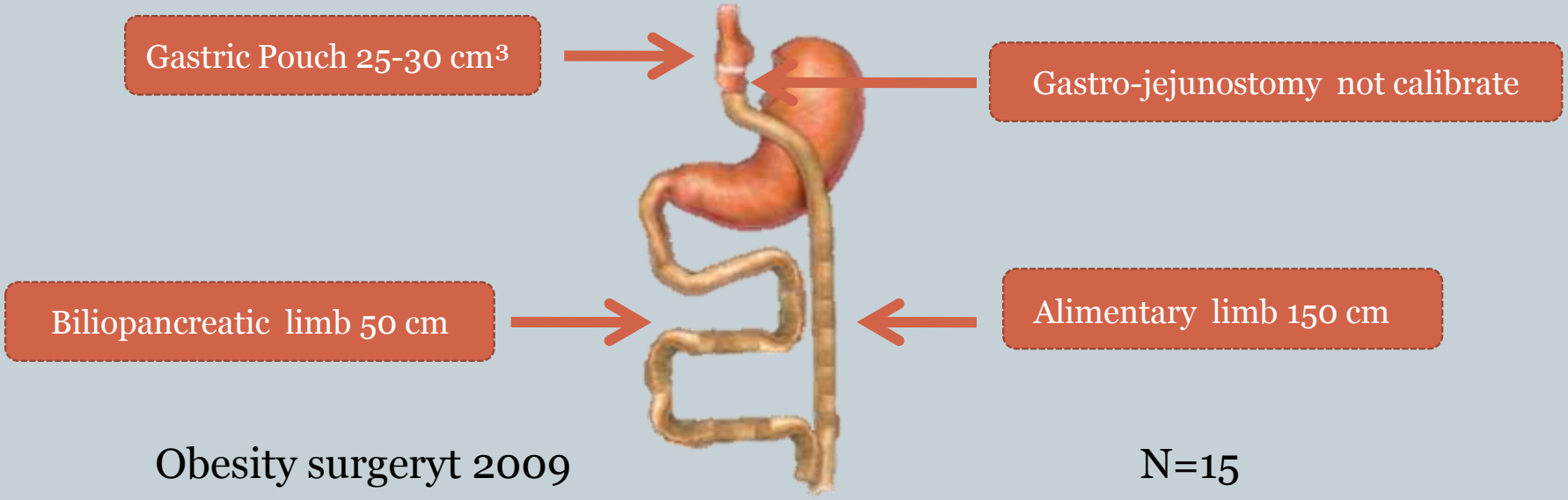
IFSO 2010

IFSO 2010

METABOLIC BYPASS

Diabetes remission and reduced cardiovascular risk after gastric bypass in Asian Indians with body mass index <35 kg/m^2

Shashank S. Shah, M.S.[a], Jayashree S. Todkar, M.S.[a], Poonam S. Shah, M.D.[a], David E. Cummings, M.D.[b,*]



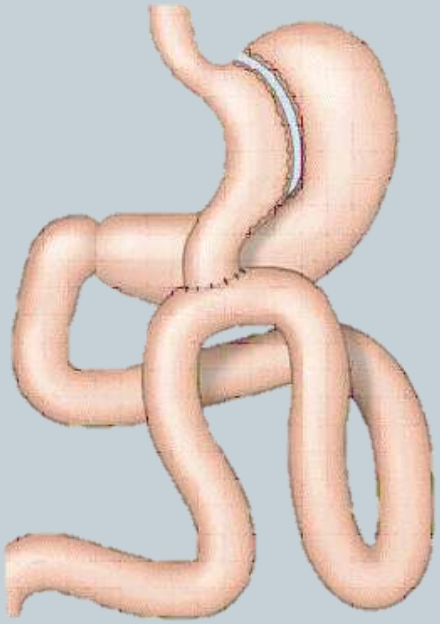
Obesity surgeryt 2009

N=15

METABOLIC BYPASS

Effect of Laparoscopic Mini-Gastric Bypass for Type 2 Diabetes Mellitus: Comparison of BMI >35 and <35 kg/m^2

Wei-Jei Lee · Weu Wang · Yi-Chih Lee · Ming-Te Huang · Kong-Han Ser · Jung-Chien Chen



Obesity Surgery 2007

N=44

METABOLIC BYPASS
CLINICAL DATA – CRITICAL ANALISIS

- Standard bariatric procedure
- Most promisor technique as metabolic surgery
- Safety profile
  - Is the standard to be compared with it
  - Mortality < 0.20%
  - Serious complications < 2.5%
  - MIP - laparoscopic
- Very good results on mid and long term follow up
- Actual data
  - Most used procedure
  - Lot's of studies looking for the changes for use in low BMI

nature publishing group

REVIEWS

METHODS AND TECHNIQUES

Beyond the BMI: The Search for Better Guidelines for Bariatric Surgery

Walter J. Pories[1], Lynis G. Dohm[2] and Christopher J. Mansfield[3]

The application of the BMI of ≥35 as the major prerequisite for access to bariatric surgery is no longer appropriate because the index, now incorporated in the requirements of Medicare, Medicaid and most private carriers, does not reflect the degree or distribution of adiposity, it discriminates unfairly on the basis of gender, race, age, fitness, and body fat composition. Further, with increasing evidence that bariatric surgery can also induce full and durable remission of such comorbidities as type 2 diabetes even in patients with BMIs <30, new guidelines must be pursued.

Obesity (2010) **18,** 865–871. doi:10.1038/oby.2010.8

METABOLIC SURGERY RESULTS

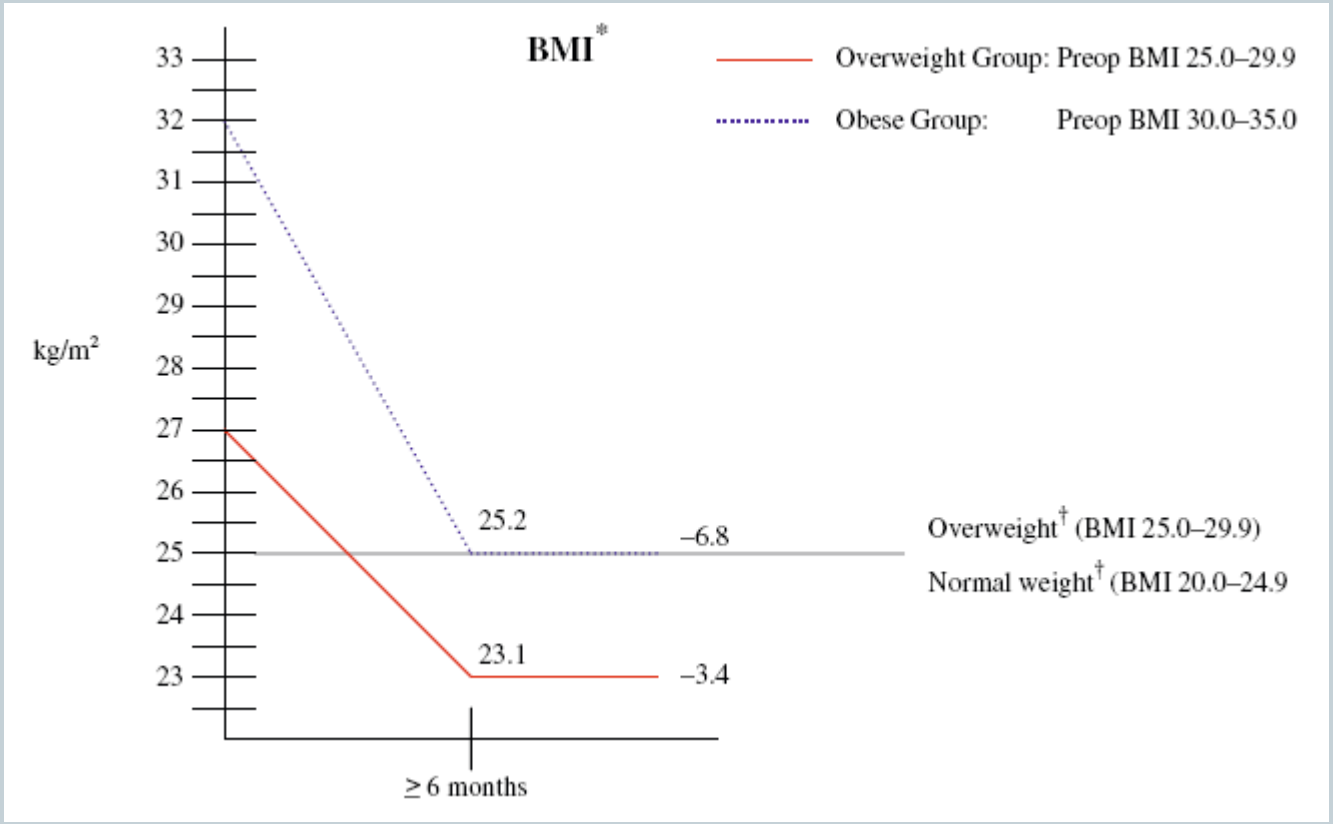
Metabolic Surgery for the Treatment of Type 2 Diabetes in Patients with BMI <35 kg/m^2: An Integrative Review of Early Studies

M. Fried · G. Ribaric · J. N. Buchwald · S. Svacina · K. Dolezalova · N. Scopinaro

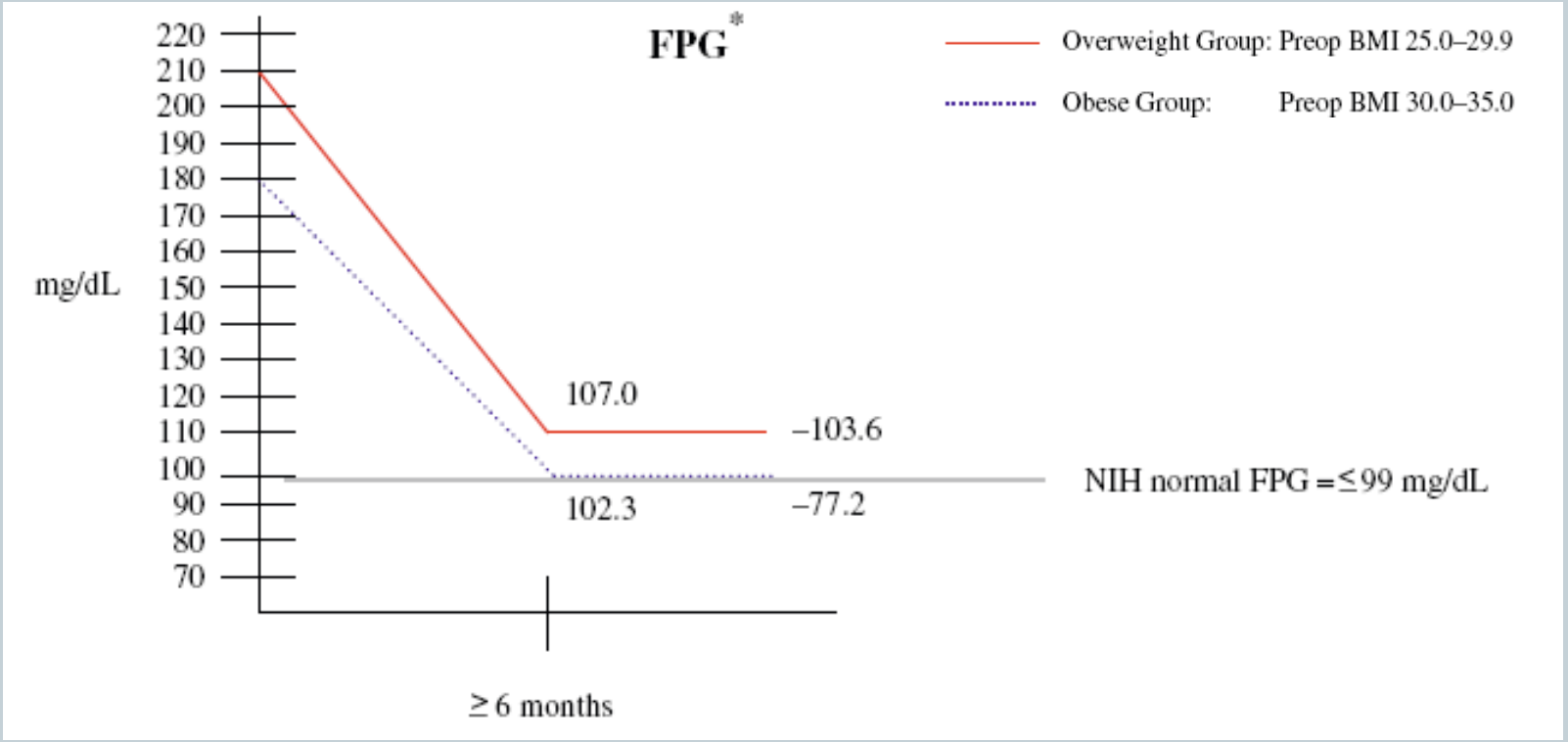
Table 1 Characteristics of studies of T2DM patients with BMI <35 kg/m^2

	Study	Country[a]	Procedure	Design
1.	Noya et al. [79]	Italy	BPD-SPP	Prospective: observational study
2.	Angrisani et al. [71]	Italy	LAGB	Retrospective: multi-center prospectively collected database experience of 27 Italian sites
3.	Parikh et al. [72]	USA with Australian database	LAGB	Retrospective: prospectively collected database study
4.	Cohen et al. [74]	Brazil	RYGB	Prospective: IRB-approved observational study
5.	Scopinaro et al. [81]	Italy	BPD	Retrospective: prospectively collected database study
6.	Cohen et al. [80]	Brazil	DJB	Prospective: preliminary results in two of 50 IRB-approved patients in an observational study
7.	Lee et al. [75]	Republic of China	MGB	Retrospective: prospectively collected database study
8.	Sultan et al. [73]	USA	LAGB	Retrospective: prospectively collected database study; surgery in <35 vs >35 BMI groups
9.	DePaula et al. (a) [76]	Brazil	II-DSG	Prospective: IRB-approved observational study
10.	DePaula et al. (b) [77]	Brazil	II-SG and II-DSG	Prospective: IRB-approved observational study
11.	Ramos et al. [82]	Brazil	DJB	Prospective: IRB-approved observational study
12.	Geloneze et al. [83]	Brazil	DJB	Prospective: IRB-approved study, surgery vs matched control group on standard medical care
13.	Ferzli et al. [84]	USA	DJB	Prospective: IRB-approved observational study
14.	Chiellini et al. [85]	Italy	BPD	Prospective: IRB-approved pilot study, surgery vs matched group on energy-restricted diet
15.	Shah et al. [78]	India	RYGB	Prospective: IRB-approved observational study
16.	Scopinaro et al. [86]	Italy	BPD	Prospective: IRB-approved pilot study, surgery in 25.0–35.0 BMI (with comparison of 25.0–29.9 and 30–35)

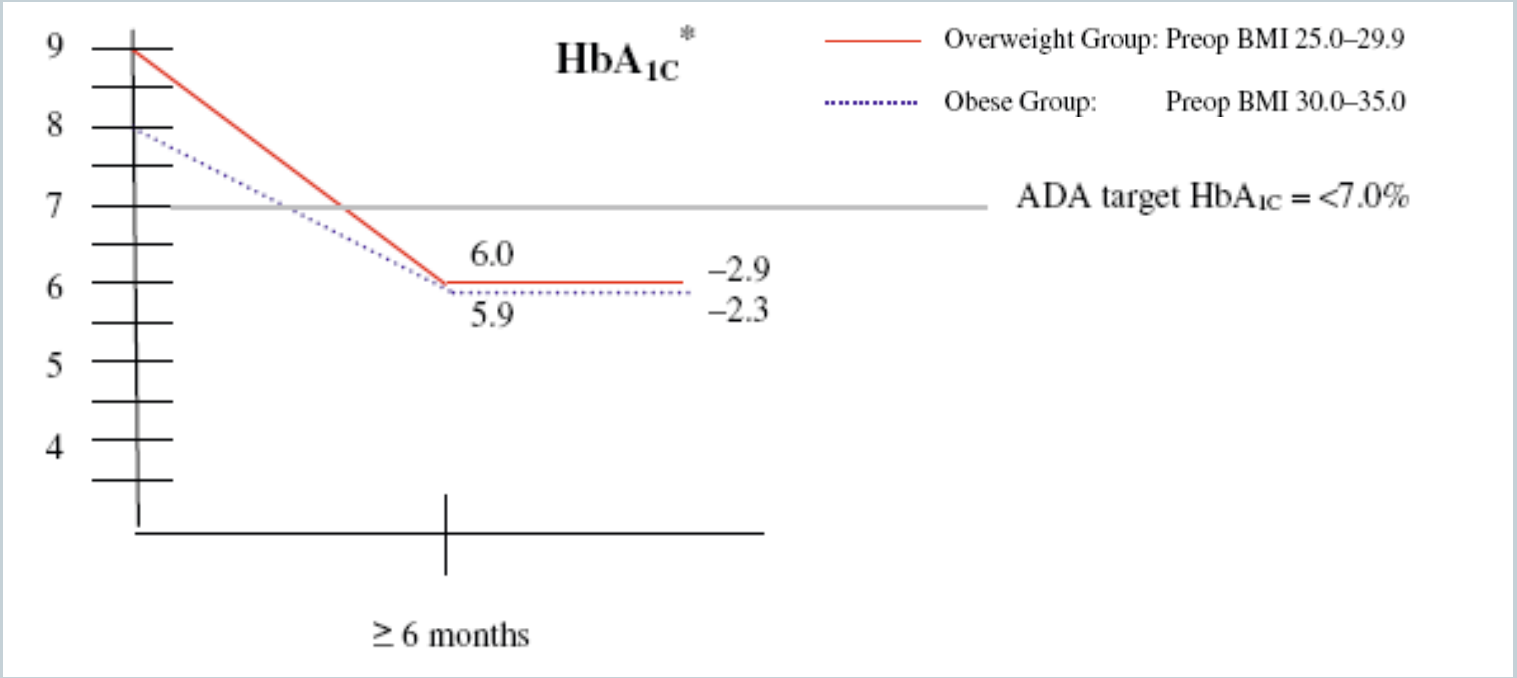
METABOLIC SURGERY RESULTS



METABOLIC SURGERY RESULTS



METABOLIC SURGERY RESULTS



METABOLIC SURGERY

CONCLUSIONS

- The great majority of studies of T2DM patients undergoing metabolic surgery corroborated the results of the animal researches previously reported regarding good postoperative glicemic control
- Metabolic surgery
  - Safe
  - Effective in T2DM
  - Reproducible
  - Low complications
- Metabolic surgery seems to be a therapeutic alternative to low BMI T2DM difficult control patients
- Gastric bypass is actually the preferred procedure
- Increase BP limb and decrease C limb
- Endoscopic procedures are coming
- The number of cases recommended to surgery are increasing
- When recommend MS in low BMI patients

THANKS

GRACIAS

OBRIGADO

Almino Cardoso Ramos

ramos.almino@gmail.com


10
Gastro
Obeso
Center
Centro Avançado de Gastroenterologia
e Cirurgia de Obesidade
years

Thanks - Gracias

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