

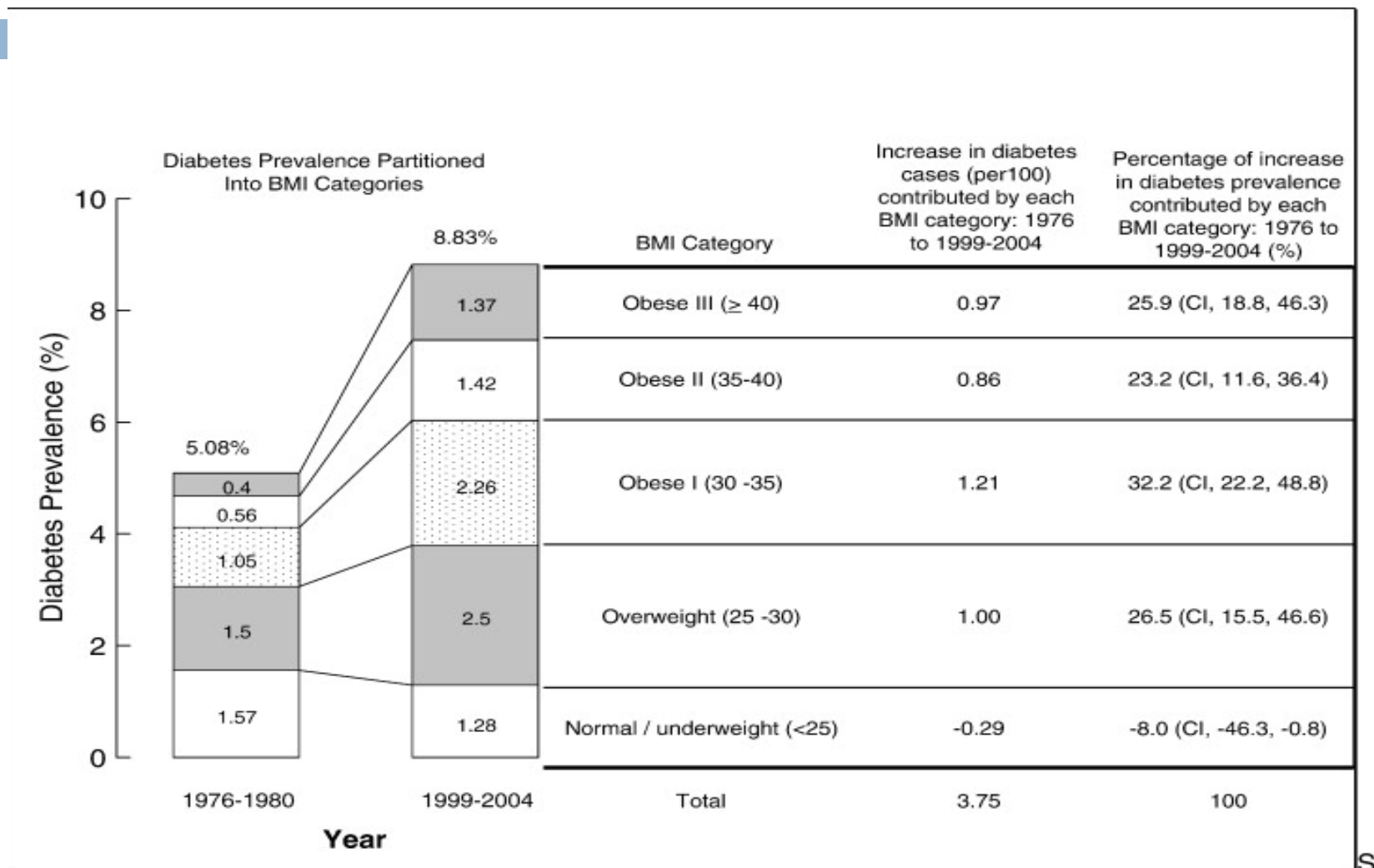
**III WORKSHOP CONGIUNTO SICOB – SID – SIO**

**CONFRONTO TRA LE DIVERSE  
TECNICHE NEL TRATTAMENTO  
CHIRURGICO DEL DIABETE TIPO 2**

**Luigi Angrisani**

***Direttore* – UOC di Chirurgia Generale ed Endoscopica  
Ospedale “S.Giovanni Bosco” ASL Napoli 1 Centro  
*Presidente*-Federazione Mondiale per la Chirurgia  
Bariatrica e Metabolica (IFSO)**

# Where is the increase in diabetes occurring?



## **American Diabetes Association Clinical Practice Recommendations 2010.**

**In overweight and obese insulin-resistant individuals, modest weight loss has been shown to reduce insulin resistance. Thus, weight loss is recommended for all overweight or obese individuals who have or are at risk for diabetes.**

*Diabetes Care 2010;33:S4.*

# ANTI-OBESITY PROCEDURES

N=1956

Jan 1996- Dec 2013

LAP-BAND

BYPASS

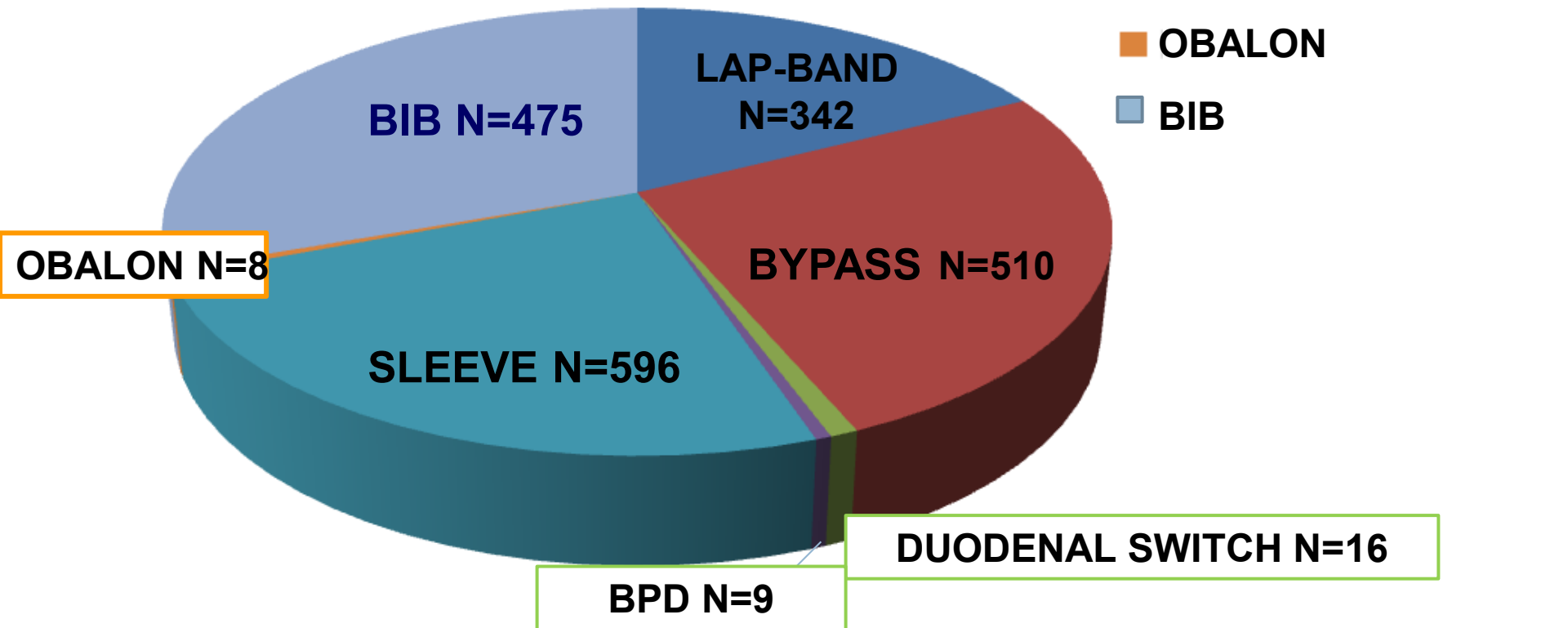
DUODENAL SWITCH

BPD

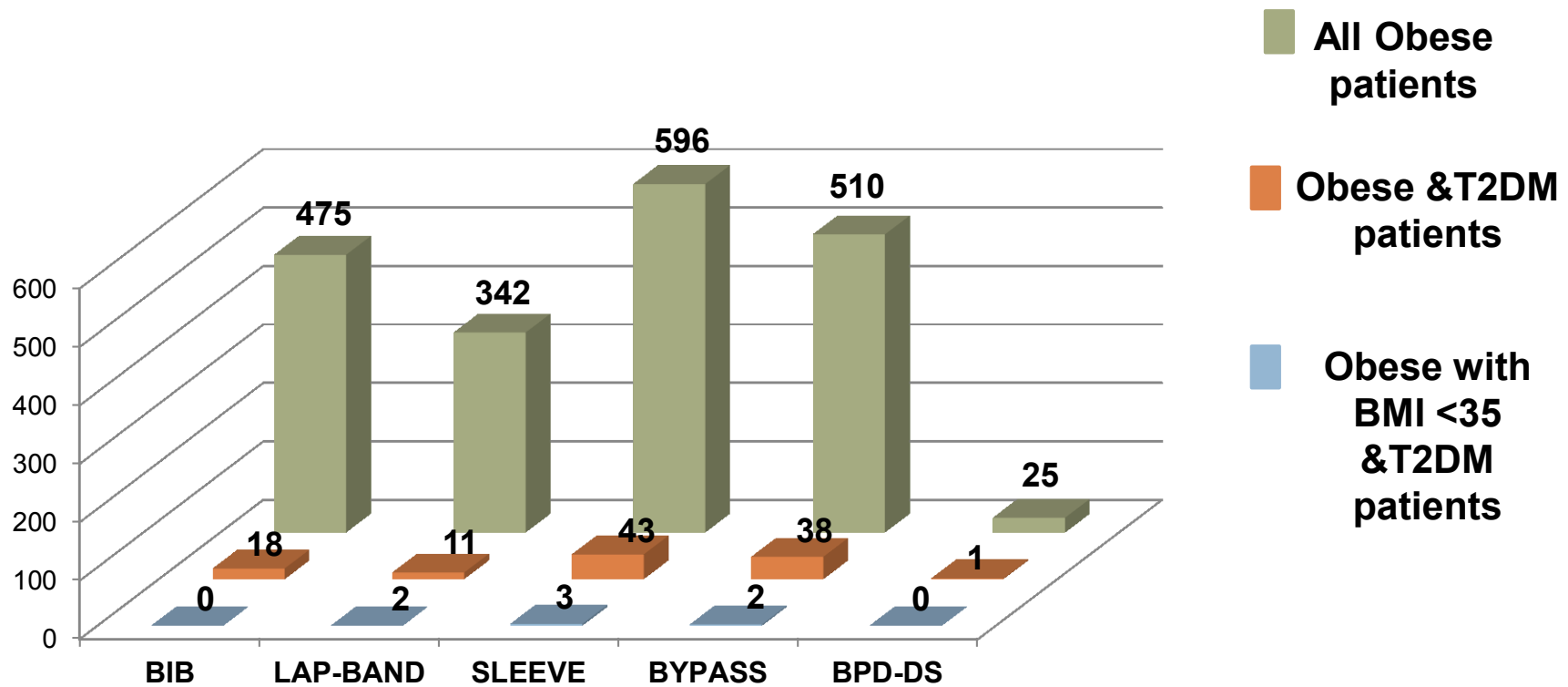
SLEEVE GASTRECTOMY

OBALON

BIB

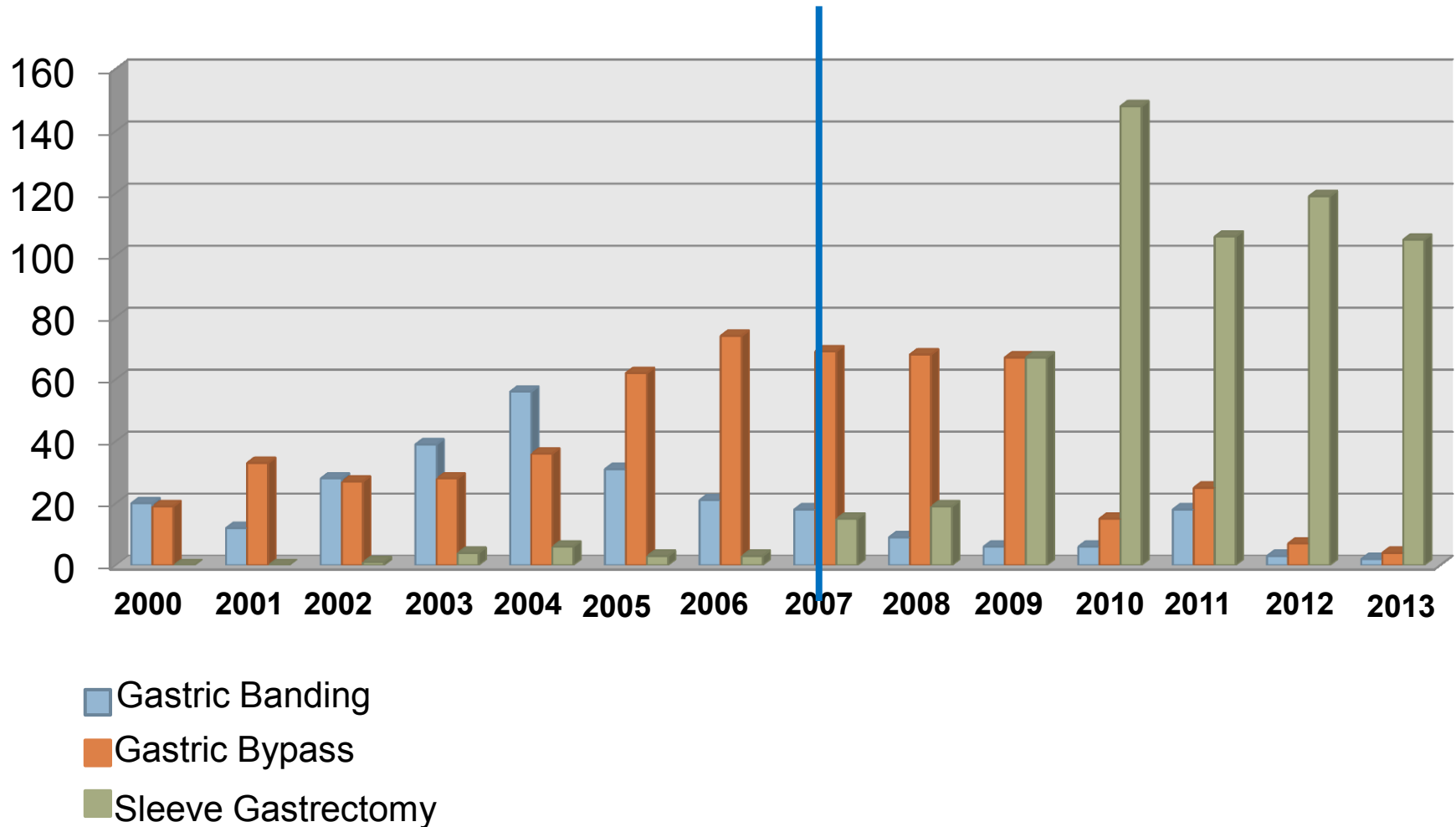


# N= 111 BARIATRIC PROCEDURES IN N=95 OBESE TYPE II DIABETIC PATIENTS Jan 1996- Dec 2013



# “S. GIOVANNI BOSCO” EXPERIENCE

N=1399 Pts



# CHIRURGIA BARIATRICA E DIABETE MELLITO

- **Tutte le tecniche chirurgiche e  
parachirurgiche in grado di procurare calo  
ponderale comportano la remissione  
parziale o completa del Diabete Mellito di  
tipo 2.**

# CHIRURGIA BARIATRICA E DIABETE MELLITO

- **La percentuale di successo (remissione/cura) del Diabete Tipo II nei pazienti obesi è direttamente proporzionale al BMI di partenza: ottimale negli Obesi Patologici e Super Obesi**



# CHIRURGIA BARIATRICA E DIABETE MELLITO

- **Il recupero del peso perso nei Diabetici Obesi sottoposti con successo a Chirurgia Bariatrica comporta la ripresa della malattia**

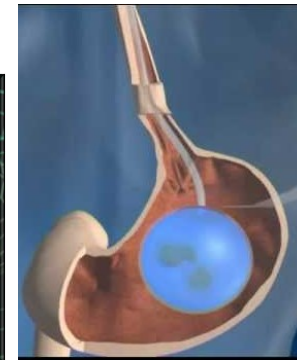
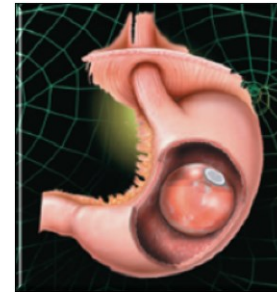
# GERARCHIA DELLA CHIRURGIA DELL'OBESITA'



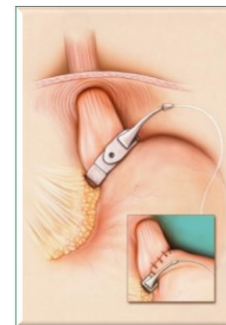
**PALLONE AD  
ARIA**



**PALLONE AD  
ACQUA**



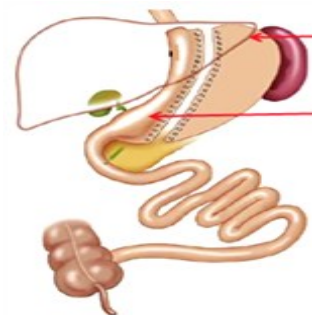
**BENDAGGIO  
GASTRICO**



# GERARCHIA DELLA CHIRURGIA DELL'OBESITA'

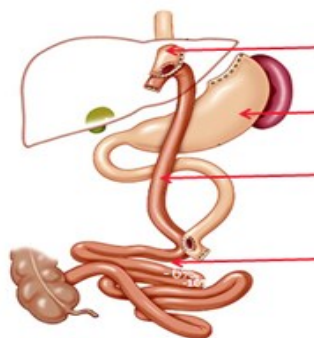
**CHIRURGICHE  
(II LIVELLO)**

**GASTRECTOMIA  
VERTICALE**



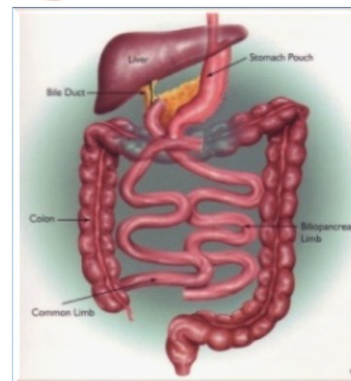
**CHIRURGICHE  
(III LIVELLO)**

**BYPASS  
GASTRICO**



**CHIRURGICHE  
(IV LIVELLO)**

**DIVERSIONE  
BILIOPANCREATICA /  
DUODENAL SWITCH**

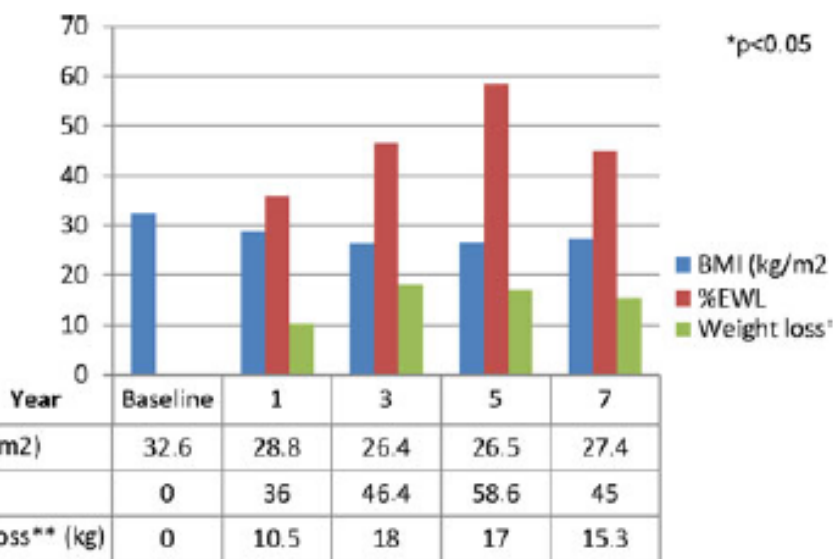




CLINICAL RESEARCH

# Long-Term Outcomes of Laparoscopic Adjustable Silicone Gastric Banding (LAGB) in Moderately Obese Patients With and Without Co-morbidities

Luigi Angrisani • Pier Paolo Cutolo •  
 Giampaolo Formisano • Gabriella Nosso •  
 Antonella Santonicola • Giuliana Vitolo



Preoperative co-morbidities	n (%)
Hiatal hernia and/or GERD	8 (23.5)
Arterial hypertension	7 (20.6)
Dyslipidaemia	4 (11.7)
Obstructive sleep apnoea	4 (11.7)
<u>T2DM</u>	<u>2 (5.8)</u>
Degenerative lumbar disc disease	2 (5.8)

Co-morbidities were diagnosed in 17/34 (50 %) patients at baseline and underwent remission or improvement in all cases after 1 year.

*Conclusions* LAGB in a safe and effective procedure in patients with a BMI <35 kg/m<sup>2</sup>.

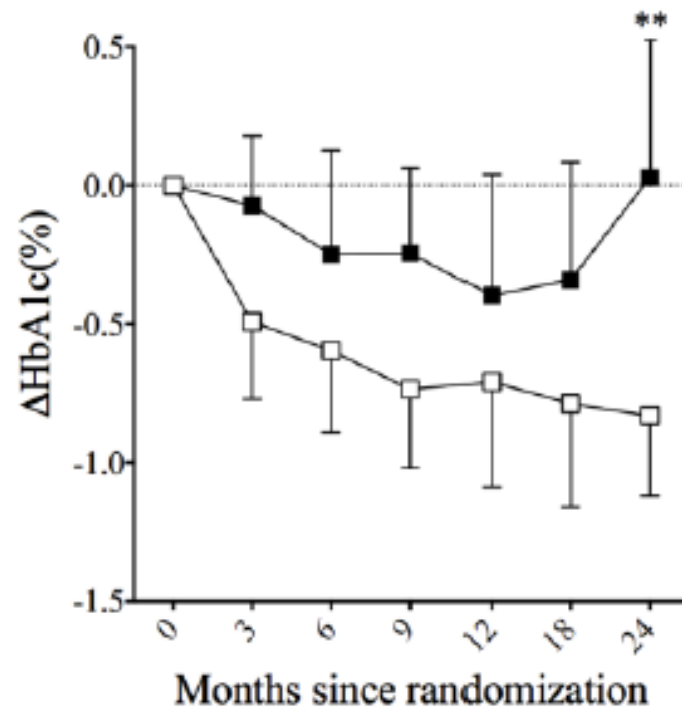
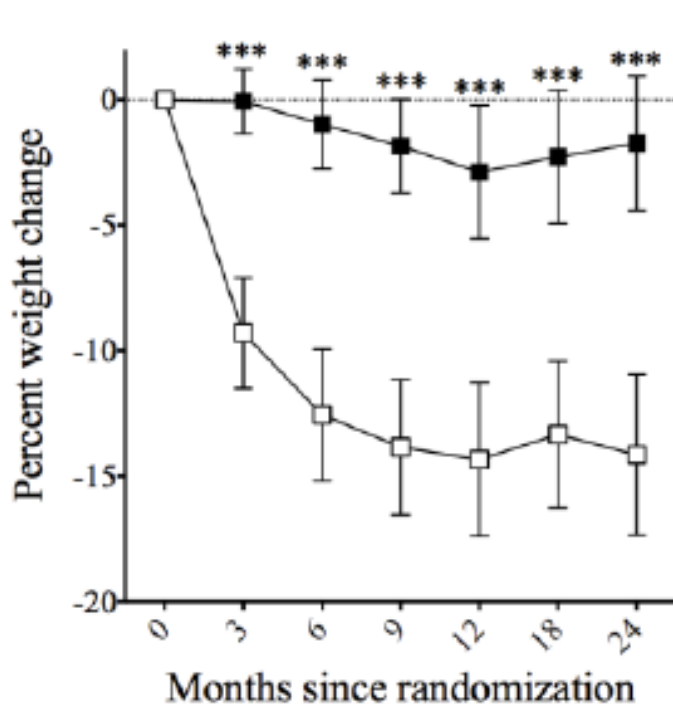
**A Randomized Controlled Trial of Multidisciplinary Diabetes Care with and without Bariatric Surgery in Overweight People (BMI 25-30kg/m<sup>2</sup>).**

John M Wentworth <sup>1,2</sup>, Julie Playfair <sup>1</sup>, Cheryl Laurie <sup>1</sup>, Matthew E Ritchie <sup>2</sup>, Wendy A Brown<sup>1</sup>, Paul Burton <sup>1</sup>, Jonathan E Shaw <sup>3</sup>, Paul E O'Brien <sup>1</sup>.

	<b>LAGB Group (n=25)</b>	<b>MDC Group (n=26)</b>
Age (years)	53±6 (36-64)	53±7 (34-62)
M/F (n)	6/19	9/17
Weight (kg)	81±10 (64-103)	83±12 (62-108)
Height (m)	1.67±0.10 (1.50-1.87)	1.69±0.12 (1.48-1.90)
BMI (kg/m <sup>2</sup> )	29±1 (26-30)	29±1 (26-30)
Systolic blood pressure (mmHg)	130±18 (90-160)	131±11 (112-152)
Diastolic blood pressure (mmHg)	83±10 (65-114)	84±9 (67-105)
Diabetes duration (months)	18 [8-48]	30 [12-60]
Prior smoker (n)	7	11
Current smoker (n)	4	5
Fasting glucose (mg/dL)	134±38 (79-247)	148±41 (88-236)
HbA1c (%)	6.9±1.2 (4.3-10.5)	7.2±1.1 (5.6-9.4)
HbA1c (mmol/mol)	52±13 (23-91)	56±12 (38-79)

## A Randomized Controlled Trial of Multidisciplinary Diabetes Care with and without Bariatric Surgery in Overweight People (BMI 25-30kg/m<sup>2</sup>).

John M Wentworth <sup>1,2</sup>, Julie Playfair <sup>1</sup>, Cheryl Laurie <sup>1</sup>, Matthew E Ritchie <sup>2</sup>, Wendy A Brown<sup>1</sup>, Paul Burton <sup>1</sup>, Jonathan E Shaw <sup>3</sup>, Paul E O'Brien <sup>1</sup>.



*The Lancet Diabetes & Endocrinology in press*

**A Randomized Controlled Trial of Multidisciplinary Diabetes Care with and without Bariatric Surgery in Overweight People (BMI 25-30kg/m<sup>2</sup>).**

John M Wentworth <sup>1,2</sup>, Julie Playfair <sup>1</sup>, Cheryl Laurie <sup>1</sup>, Matthew E Ritchie <sup>2</sup>, Wendy A Brown<sup>1</sup>, Paul Burton <sup>1</sup>, Jonathan E Shaw <sup>3</sup>, Paul E O'Brien <sup>1</sup>.

We conclude that LAGB combined with MDC for overweight people with T2D is more effective at controlling blood glucose levels than MDC alone. The favourable safety profile and widespread acceptance of LAGB <sup>12, 24</sup> argue for a more prominent place for this surgery in managing T2D in overweight people.

# Clinical Efficacy of Laparoscopic Sleeve Gastrectomy vs Laparoscopic Gastric Bypass in Obese Type 2 Diabetic Patients: a Retrospective Comparison

P. P. Cutolo • G. Nosso • G. Vitolo • V. Brancato •  
B. Capaldo • L. Angrisani

OBES SURG 2012

	LSG (n=15)	LRYGB (n=16)	p
Sex (M/F)	7/8	7/9	ns
Age (years)	45±7	45±8	ns
BMI (kg/m <sup>2</sup> )	51±8	48±4	ns
EW (%)	129±46	110±24	ns
Blood glucose (mg/dl)	129±38	171±76	ns
HbA1c (%)	7.9±2	8.6±1	ns
Duration of diabetes (years)	3±2	3±2	ns
Hypoglycaemic therapy (n)			
Diet	0	1	
Metformin	13	13	
Metformin+insulin	2	2	
Antihypertensive drugs (n)	9	9	
Lipid-lowering agents (n)	5	2	

*Conclusions* LSG and LRYGB are equally effective in terms of weight loss and remission of obesity-related comorbidities. Controlled long-term comparisons are needed to establish the optimal procedure in relation to patients' characteristics.

Table 3 Number of patients who discontinued the pharmacological treatment

	6 months		12 months		18–24 months	
	LSG, n (%)	LRYGB, n (%)	LSG, n (%)	LRYGB, n (%)	LSG, n (%)	LRYGB, n (%)
Hypoglycaemic drugs	12 (80)	15 (100)	13 (87)	14 (93)	13 (87)	14 (93)
Antihypertensive drugs	4 (44)	7 (78)	5 (56)	7 (78)	5 (56)	8 (89)
Lipid-lowering agents	3 (60)	1 (50)	3 (60)	1 (50)	3 (60)	1 (50)



# Long-term remission of type 2 diabetes in morbidly obese patients after sleeve gastrectomy

Francesca Abbatini, M.D.<sup>a</sup>, Danila Capoccia, M.D.<sup>b</sup>, Giovanni Casella, M.D.<sup>a</sup>, Emanuele Soricelli, M.D.<sup>a</sup>, Frida Leonetti, M.D., Ph.D.<sup>b</sup>, Nicola Basso, M.D.<sup>a,\*</sup>

<sup>a</sup>*Surgical-Medical Department for Digestive Diseases, Policlinico "Umberto I," University of Rome "Sapienza," Italy*

<sup>b</sup>*Department of Clinical Sciences, Policlinico "Umberto I," University of Rome "Sapienza," Italy*

	Preoperative	3 months	12 months	36 months	60 months
Patients (n)	33	33	33	26	13
BMI (kg/m <sup>2</sup> )	52.1 ± 8.5	42.8 ± 5.3*	34.3 ± 6.7*	32.4 ± 4.7*	36.7 ± 2.2*
FPG (%)	143.2 ± 47.9	104.5 ± 22.1*	93.8 ± 40.3*	88.4 ± 14.1*	101.6 ± 15.3*
HbA <sub>1c</sub> (%)	7.3 ± 1.4	5.5 ± 1.9*	5.6 ± 2.6*	5.5 ± 2.3*	5.9 ± 2.1*
Hypertension (n)	18	17	6	5	5
Hypertriglyceridemia (n)	6	6	3	3	3
Hypercholesterolemia (n)	7	7	3	3	3
<u>T2DM remission (n)</u>		29/33	29/33	22/26	10/13
T2DM retinopathy(n)	1	1	1	1	1

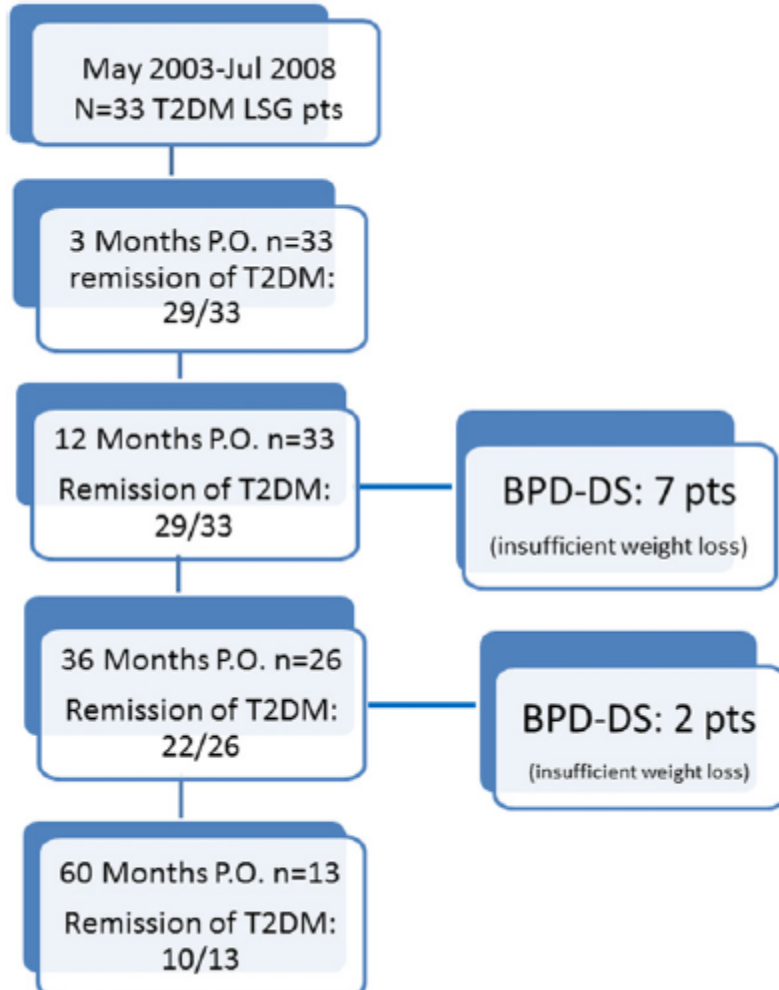
BMI = body mass index; FPG = fasting plasma glucose; HbA<sub>1c</sub> = glycosylated hemoglobin; T2DM = type 2 diabetes.

\**P* < .05.

**Conclusions:** This study confirms the efficacy of LSG in the treatment of T2DM and indicates that, at both 36- and 60-month follow-ups, LSG can provide a significant percentage of treated patients with a prolonged remission of T2DM, with diminished cardiac risk factors and no development of diabetic retinopathy.

# Long-term remission of type 2 diabetes in morbidly obese patients after sleeve gastrectomy

Francesca Abbatini, M.D.<sup>a</sup>, Danila Capoccia, M.D.<sup>b</sup>, Giovanni Casella, M.D.<sup>a</sup>, Emanuele Soricelli, M.D.<sup>a</sup>, Frida Leonetti, M.D., Ph.D.<sup>b</sup>, Nicola Basso, M.D.<sup>a,\*</sup>



- 33 morbidly obese T2DM patients underwent LSG
- Of the super obese patients, 7 underwent biliopancreatic diversion 1 year after LSG and 2 others did after 36 months because of insufficient weight loss irrespective of T2DM remission
- 11 patients did not achieve 5 years follow-up.

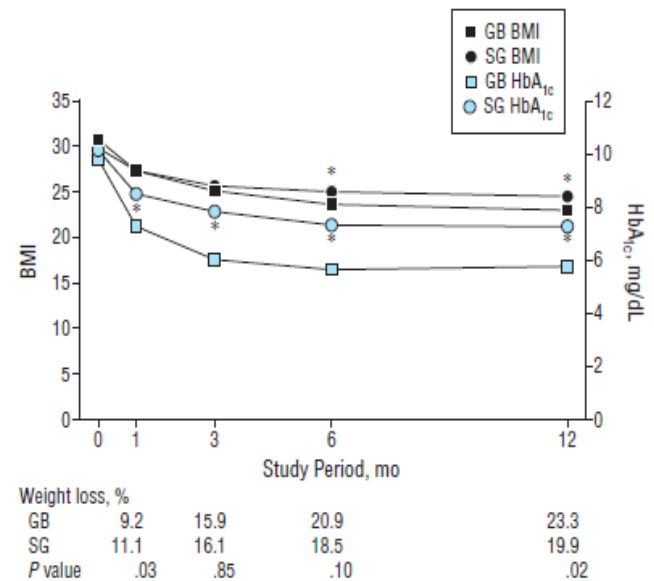
# Gastric Bypass vs Sleeve Gastrectomy for Type 2 Diabetes Mellitus

## A Randomized Controlled Trial

Wei-Jei Lee, MD, PhD; Keong Chong, MD; Kong-Han Ser, MD; Yi-Chih Lee, PhD;  
Shu-Chun Chen, RN; Jung-Chien Chen, MD; Ming-Han Tsai, MD; Lee-Ming Chuang, MD

**Patients:** We studied 60 moderately obese patients (body mass index >25 and <35) aged >30 to <60 years who had poorly controlled type 2 diabetes mellitus (T2DM) (hemoglobin A<sub>1c</sub> [HbA<sub>1c</sub>] >7.5%) after conventional treatment (>6 months) from September 1, 2007, through June 30, 2008. Patients and observers were masked during the follow-up, which ended in 2009, 1 year after final enrollment.

**Conclusions:** Participants randomized to gastric bypass were more likely to achieve remission of T2DM. Duodenum exclusion plays a role in T2DM treatment and should be assessed.



## Can Diabetes Be Surgically Cured?

### *Long-Term Metabolic Effects of Bariatric Surgery in Obese Patients with Type 2 Diabetes Mellitus*

*Stacy A. Brethauer, MD,\* Ali Aminian, MD,\* Héctor Romero-Talamás, MD,\* Esam Batayyah, MD,\* Jennifer Mackey, RN,\* Laurence Kennedy, MD,† Sangeeta R. Kashyap, MD,† John P. Kirwan, PhD,† Tomasz Rogula, MD,\* Matthew Kroh, MD,\* Bipan Chand, MD,‡ and Philip R. Schauer, MD\**

**TABLE 2.** Baseline Characteristics of Patients

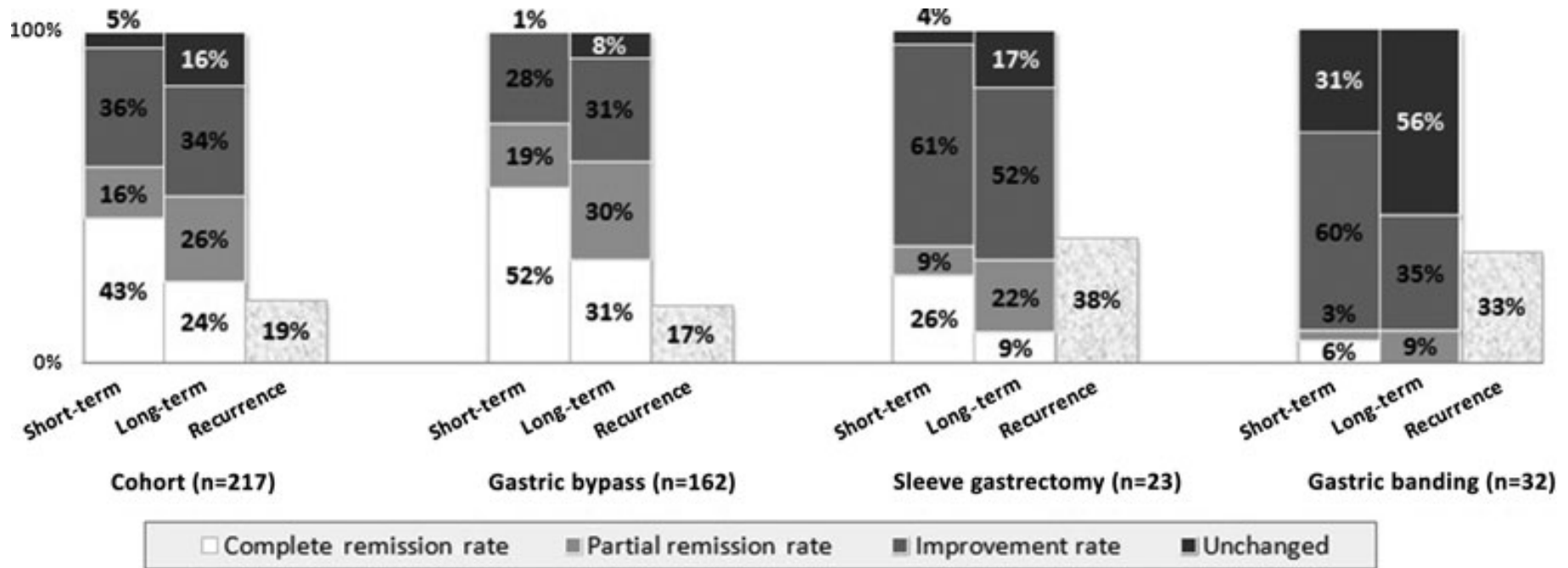
	Whole Cohort (n = 217)	Gastric Bypass (n = 162)	Sleeve Gastrectomy (n = 23)	Gastric Banding (n = 32)	P
Female, n (%)	159 (73)	120 (74)	17 (74)	22 (69)	0.82
Age, mean ± SD, y	51.4 ± 10.2	49.4 ± 9.5	57.7 ± 10.2	57.3 ± 10.0	<0.001
BMI, mean ± SD, kg/m <sup>2</sup>	48.8 ± 7.8	48.8 ± 7.6	50.7 ± 10.6	47.5 ± 7.5	0.35
Duration of diabetes, median (IQR), y	6 (3–12)	5 (2–10)	10.5 (5–15)	8 (4–16)	0.004
Diabetes pharmacotherapy, n (%)	207 (95)	154 (95)	22 (96)	31 (97)	0.90
Use of insulin, n (%)	71 (33)	47 (29)	11 (48)	13 (41)	0.12
No. diabetes medications, median (IQR)	2 (1–2)	2 (1–2)	2 (1–3)	1.5 (1–3)	0.12
A1C, mean ± SD, %	7.5 ± 1.5	7.6 ± 1.6	7.8 ± 1.6	7.3 ± 1.3	0.61
FBG, median (IQR), mg/dL	137 (113–188)	139 (114–194)	137 (106–172)	136 (99–188)	0.56
Hypertension, n/total (%)	165/218 (76)	122/162 (75)	17/23 (74)	26/32 (81)	0.75
Dyslipidemia,* n/total (%)	175/186 (94)	128/137 (93)	21/23 (91)	26/26 (100)	0.36

\*Presence of LDL >100 mg/dL, HDL in men <40 mg/dL, HDL in women <50 mg/dL, or triglycerides >150 mg/dL.  
IQR indicates interquartile range.

# Can Diabetes Be Surgically Cured?

## Long-Term Metabolic Effects of Bariatric Surgery in Obese Patients with Type 2 Diabetes Mellitus

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Among the surgical procedures, the glycemic outcomes were significantly better after RYGB.

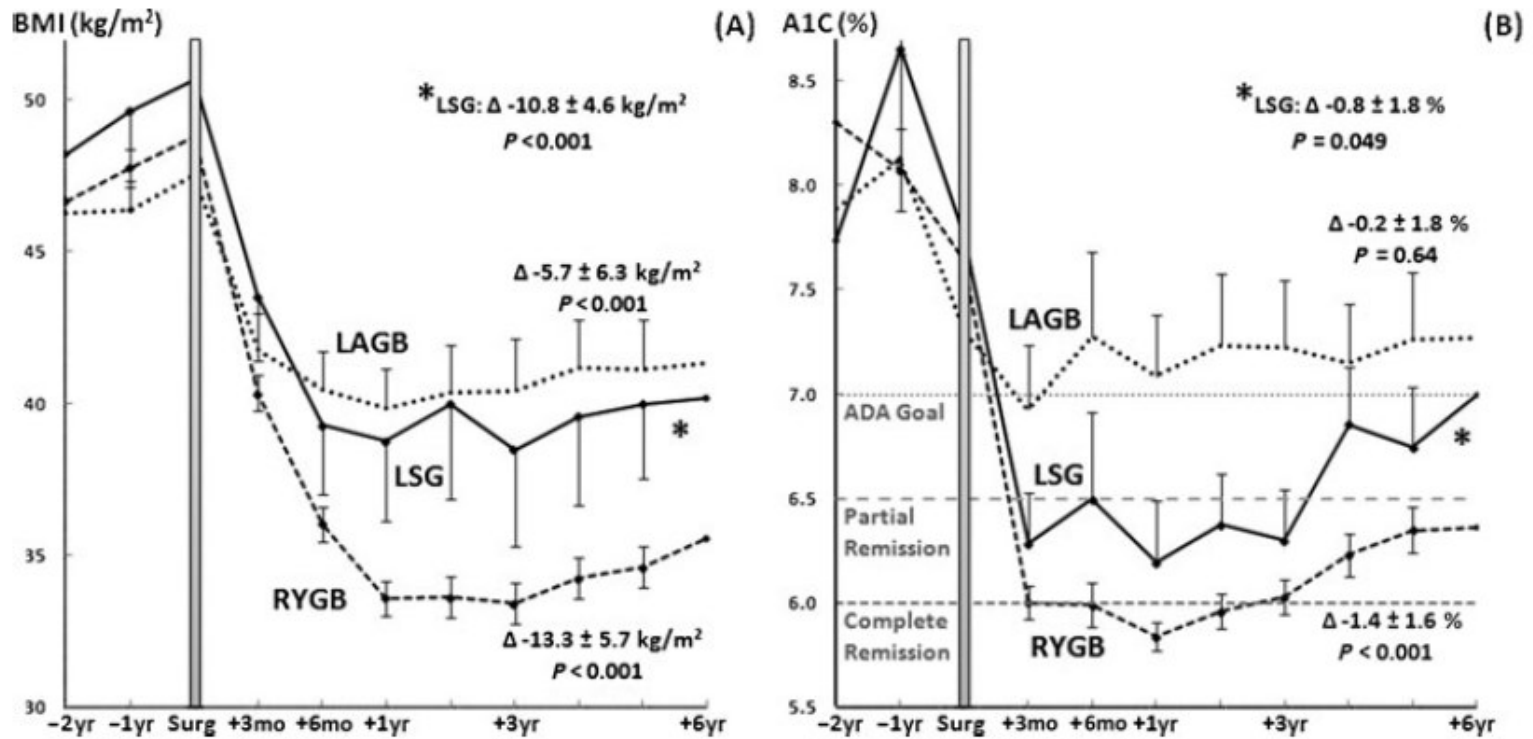
Remission rate of T2DM after RYGB vs LSG ( $P = 0.006$ ), RYGB vs LAGB ( $P < 0.001$ ), and LSG vs LAGB ( $P = 0.04$ ).



# Can Diabetes Be Surgically Cured?

## Long-Term Metabolic Effects of Bariatric Surgery in Obese Patients with Type 2 Diabetes Mellitus

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## Can Diabetes Be Surgically Cured?

### *Long-Term Metabolic Effects of Bariatric Surgery in Obese Patients with Type 2 Diabetes Mellitus*

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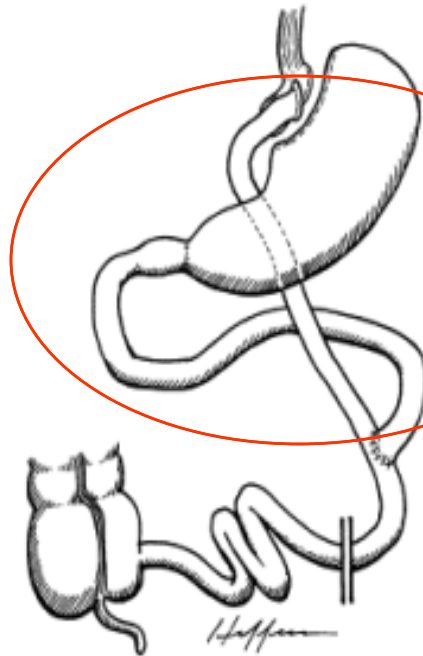
- **Our study reports durable weight loss in type 2 diabetic patients with an overall T2DM remission rate (complete and partial) of 50% with a median follow-up period of 6 years after bariatric surgery.**
- **Although the term “cure” with respect to T2DM is still controversial, our study demonstrated that 24% of all patients and 31% of gastric bypass patients achieved long-term complete remission with an A1C less than 6.0% and that 27% of the gastric bypass patients sustained that level of glycemic control off medication continuously for more than 5 years.**

# Rates of Remission of Diabetes



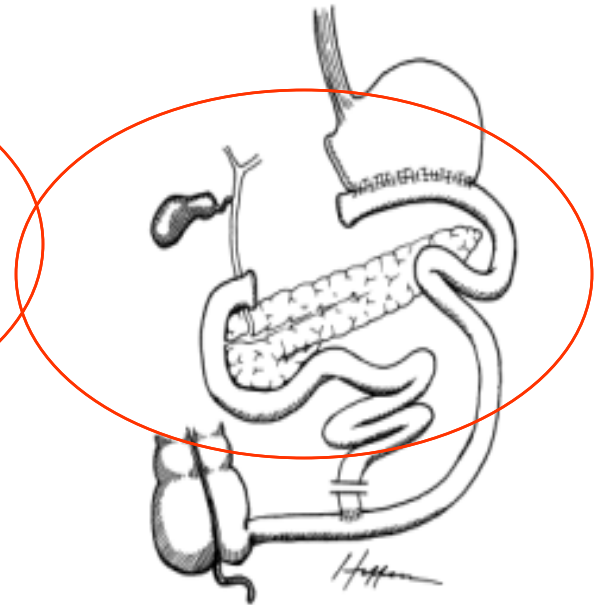
**Adjustable  
Gastric Banding**

**48%**  
**(Slow)**



**Roux-en-Y  
Gastric Bypass**

**84%**  
**(Immediate)**

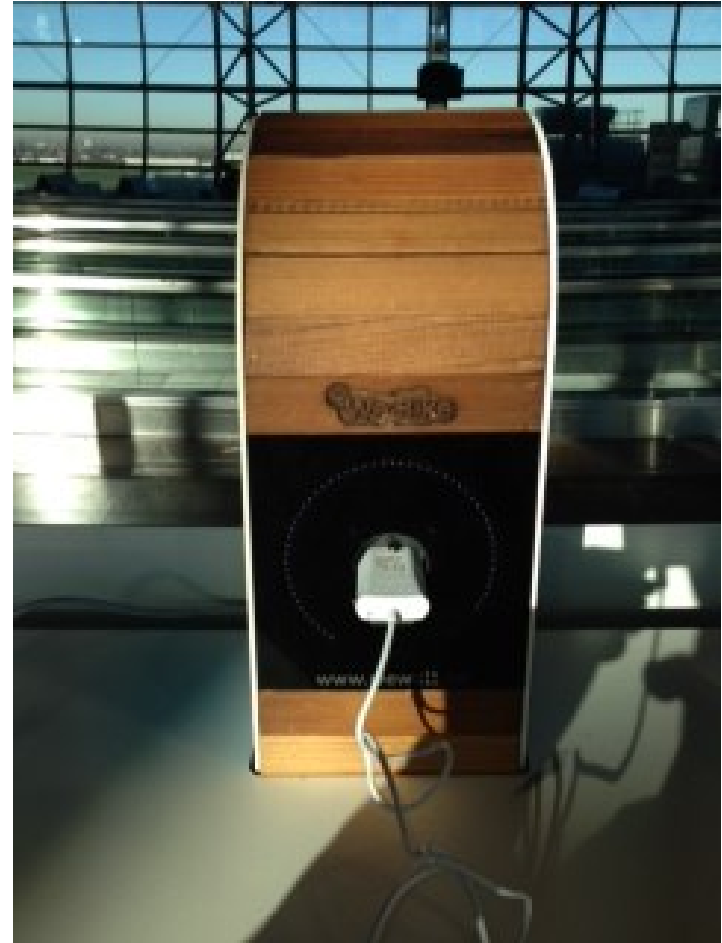
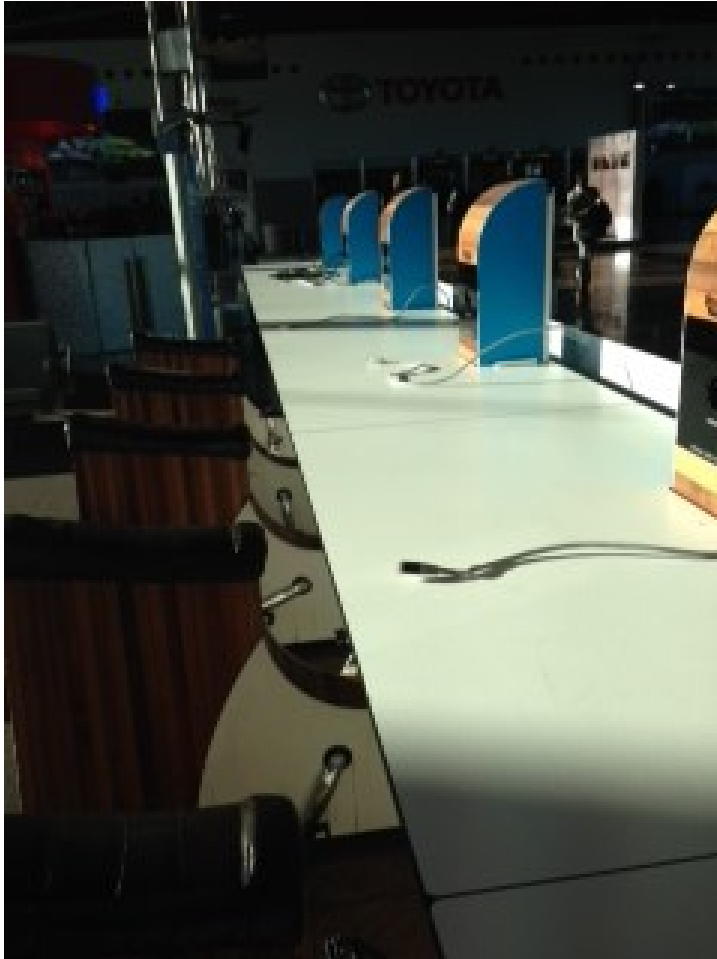


**Biliopancreatic  
Diversion**

**>95%**  
**(Immediate)**



# CONCLUSIONI



# Can Diabetes Be Surgically Cured?

## Long-Term Metabolic Effects of Bariatric Surgery in Obese Patients with Type 2 Diabetes Mellitus

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*Annals of Surgery* October 2013

**TABLE 6.** Long-term Bariatric Surgery Studies Reporting Biochemical Evidence of Type 2 Diabetes (T2DM) Remission

Author	Study Design	N Procedure	Follow-up Time (yr) and Rate (%)	A1C Definition of Complete Remission	Remission Rates
Adams et al <sup>21</sup>	P	418 RYGB (93 T2DM) 417 nonsurgical obese control (106 T2DM) 321 population-based control (92 T2DM)	6 (93%) 6 (73%) 6 (97%)	<6.5%	62% complete 8% complete 6% complete
Sjostrom et al <sup>34</sup>	P	641 band, VBG, RYGB 627 matched controls	10 (75%) 10 (74%)	NR	36% 13%
Arterburn et al <sup>30</sup>	R	4434 RYGB	5 (68%)	<6.0%	68% complete 9% partial
Cohen et al <sup>11</sup>	P	66 RYGB	6 (100%)	<6.5%	88% complete 11% partial
Lakdawala et al <sup>22</sup>	P	52 RYGB	5 (100%)	<7.0%	58% complete 38% partial
Heneghan et al <sup>36</sup>	R	52 RYGB, LSG, LAGB	5 (NR)	<6.5%	44% complete 33% partial
Sultan et al <sup>28</sup>	R	95 LAGB	5 (85%)	<6.0%	40% complete 40% partial
Scopinaro et al <sup>23</sup>	R	312 BPD	10 (85%)	NR	97%
Pontiroli et al <sup>24</sup>	R	23 BPD 78 LAGB 37 Control	5.5 (NR)	NR	100% 66% None
Marceau et al <sup>25</sup>	R	1356 DS (377 T2DM)	7 (97%)	NR	92%
Brethauer et al (current study)	R	217 RYGB, LSG, LAGB	6 (79%)	<6.0%	24% complete 26% partial

BPD indicates biliopancreatic diversion; DS, duodenal switch; NR, not reported; P, prospective; R, retrospective; VBG, vertical banded gastroplasty.



## Bariatric surgery 4



# Beyond BMI: the need for new guidelines governing the use of bariatric and metabolic surgery

*David E Cummings, Ricardo V Cohen*

Bariatric surgery use is largely governed worldwide by a 1991 National Institutes of Health consensus statement that advocates BMI as the primary operative criterion and restricts surgery to severely obese patients. These guidelines have been enormously valuable in standardising practice, thereby facilitating accumulation of a copious database of information regarding long-term surgical benefits and risks, from vast clinical experience and research. However, the National Institutes of Health recommendations had important limitations from the outset and are now gravely outdated. They do not account for remarkable advances in minimally invasive surgical techniques or the development of entirely new procedures. In the two decades since they were crafted, we have gained far greater understanding of the dramatic, weight-independent benefits of some operations on metabolic diseases, especially type 2 diabetes, and of the inadequacy of BMI as a primary criterion for surgical selection. Furthermore, there is now a substantial and rapidly burgeoning body of level-1 evidence from randomised trials comparing surgical versus non-surgical approaches to obesity, type 2 diabetes, and other metabolic diseases, including among only mildly obese or merely overweight patients. Herein, we present arguments to impel the development of new guidelines for the use of bariatric and so-called metabolic surgery to inform clinical practice and insurance compensation.

# Bariatric surgery 4



## Beyond BMI: the need for new guidelines governing the use of bariatric and metabolic surgery

David E Cummings, Ricardo V Cohen

### Randomised trials of surgical versus medical or lifestyle interventions, or both, for type 2 diabetes and obesity

	Interventions compared	Number of participants	Baseline BMI (kg/m <sup>2</sup> )	Follow-up length	Main findings*
Ikramuddin et al <sup>27</sup>	RYGB vs intensive medical and lifestyle care	120 adults with type 2 diabetes	30-40	1 year	Achieved composite goal† for type 2 diabetes, hypertension, and dyslipidaemia: RYGB 49%, medical and lifestyle care 19% (OR 4.8, 95% CI 1.9-11.7)
Schauer et al <sup>24</sup> and Kashyap et al <sup>21</sup>	RYGB vs VSG vs intensive medical care	150 adults with type 2 diabetes	27-43	1 year	HbA <sub>1c</sub> <6.0% (42 mmol/mol): RYGB 42%, VSG 37%‡, medical care 12%
Mingrone et al <sup>23</sup>	RYGB vs BPD vs conventional medical care	60 adults with type 2 diabetes	≥35	2 years	HbA <sub>1c</sub> <6.5% (48 mmol/mol) without diabetes drugs: RYGB 75% (OR 7.5, 95% CI 2.0-28.6, vs medical care), BPD 95% (OR 9.5, 95% CI 2.5-35.5, vs medical care), medical care 0%
Dixon et al <sup>25</sup>	LAGB vs conventional medical care	60 adults with type 2 diabetes	30-40	2 years	HbA <sub>1c</sub> <6.2% (44 mmol/mol) without diabetes drugs: LAGB 73%, medical care 13% (OR 5.5, 95% CI 2.2-14.0)§
O'Brien et al <sup>26</sup>	LAGB vs supervised lifestyle intervention	50 adolescents without type 2 diabetes	>35	2 years	>50% excess bodyweight loss: LAGB 84%, lifestyle intervention 12%

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## Bariatric surgery 4



# Beyond BMI: the need for new guidelines governing the use of bariatric and metabolic surgery

David E Cummings, Ricardo V Cohen

- **The Diabetes Surgery Summit recommends surgery for patients with class 1 obesity (BMI 30–35 kg/m<sup>2</sup>) only in cases where all medical and lifestyle interventions for type 2 diabetes have failed.**
- **The International Diabetes Federation deems surgery reasonable for patients with class 1 obesity and type 2 diabetes who have failed to respond adequately to just lifestyle changes and two oral antidiabetic drugs, placing surgery on the same algorithmic level as thiazolidinediones, dipeptidyl peptidase-4 inhibitors, acarbose, and basal insulin.**



## Metabolic Surgery for Type 2 Diabetes in Patients with a BMI of $<35 \text{ kg/m}^2$ : A Surgeon's Perspective

Ricardo Cohen • Pedro Paulo Caravatto • Tarissa Petry

- Several communications have reported that regardless of BMI complete or partial remission of type 2 diabetes mellitus (T2DM) is possible.
- These results mostly occur before weight loss, positioning metabolic surgery as a good tool for controlling the current T2DM epidemic.
- Medical treatment is evolving, but is expensive and not risk-free.
- Surgery aimed mainly at diseases such as diabetes and not weight loss are referred to as “metabolic surgery.”
- Metabolic surgery has been proven to be safe and effective and can effectively treat T2DM in individuals with any BMI, including that below  $35 \text{ kg/m}^2$ .



## Metabolic Surgery for Type 2 Diabetes in Patients with a BMI of $<35 \text{ kg/m}^2$ : A Surgeon's Perspective

OBES SURG 201

Ricardo Cohen • Pedro Paulo Caravatto • Tarissa Petry

### *RYGB Versus SG in Patients with a BMI Below 35*

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Two randomized controlled trials (RCTs) compared RYGB versus SG in patients with lower BMIs. Schauer et al. [55], although in a study not powered for lower BMIs and without specific details, showed better glycemic control in surgical than medical treatment. In this study, which included patients with a BMI of 27 and above, RYGB had similar results on glycemic control to those of SG, with a potential trend toward better outcomes in the RYGB group. In another RCT, Lee et al. [39] compared RYGB versus SG in patients with BMIs of  $>25$  and  $<35$ . Of the 60 patients enrolled, all completed the 12-month follow-up. Remission of T2DM was achieved by 28 (93.3 %) patients in the RYGB group and 14 (46.7 %) patients in the SG group ( $P < 0.05$ ). In this RCT, RYGB was significantly superior to SG in terms of T2DM remission.



# Adjustable Gastric Banding and Conventional Therapy for Type 2 Diabetes

## A Randomized Controlled Trial

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John B. Dixon, MBBS, PhD

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Paul E. O'Brien, MD

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Julie Playfair, RN

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Leon Chapman, MBBS

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Linda M. Schachter, MBBS, PhD

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Stewart Skinner, MBBS, PhD

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Joseph Proietto, MBBS, PhD

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Michael Bailey, PhD, MSc(stats)

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Margaret Anderson, BHealthMan

**Context** Observational studies suggest that surgically induced loss of weight may be effective therapy for type 2 diabetes.

**Objective** To determine if surgically induced weight loss results in better glycemic control and less need for diabetes medications than conventional approaches to weight loss and diabetes control.

**Design, Setting, and Participants** Unblinded randomized controlled trial conducted from December 2002 through December 2006 at the University Obesity Research Center in Australia, with general community recruitment to established treatment programs. Participants were 60 obese patients (BMI >30 and <40) with recently diagnosed (<2 years) type 2 diabetes.

**Interventions** Conventional diabetes therapy with a focus on weight loss by lifestyle change vs laparoscopic adjustable gastric banding with conventional diabetes care.

**Main Outcome Measures** Remission of type 2 diabetes (fasting glucose level <126 mg/dL [7.0 mmol/L] and glycated hemoglobin [HbA<sub>1c</sub>] value <6.2% while taking no glycemic therapy). Secondary measures included weight and components of the metabolic syndrome. Analysis was by intention-to-treat.

**Results** Of the 60 patients enrolled, 55 (92%) completed the 2-year follow-up. Remission of type 2 diabetes was achieved by 22 (73%) in the surgical group and 4 (13%) in the conventional-therapy group. Relative risk of remission for the surgical group was 5.5 (95% confidence interval, 2.2-14.0). Surgical and conventional-therapy groups lost a mean (SD) of 20.7% (8.6%) and 1.7% (5.2%) of weight, respectively, at 2 years ( $P < .001$ ). Remission of type 2 diabetes was related to weight loss ( $R^2 = 0.46$ ,  $P < .001$ ) and lower baseline HbA<sub>1c</sub> levels (combined  $R^2 = 0.52$ ,  $P < .001$ ). There were no serious complications in either group.

**Conclusions** Participants randomized to surgical therapy were more likely to achieve remission of type 2 diabetes through greater weight loss. These results need to be confirmed in a larger, more diverse population and have long-term efficacy assessed.

## Metabolic Surgery for Type 2 Diabetes in Patients with a BMI of $<35 \text{ kg/m}^2$ : A Surgeon's Perspective

OBES SURG 201

Ricardo Cohen • Pedro Paulo Caravatto • Tarissa Petry

- What is the proper timing for surgery? The sooner the better, while there is still reasonable  $\beta$ -cell function?
- How do we select patients? The 1991 NIH guidelines need to be revised because BMI centric surgical indications are prone to deny treatment for a large number of patients. What should be the other criteria along with BMI to revise the surgical indications?
- Can we provide “hard data” regarding benefits of surgery over medical treatment, e.g., microvascular disease resolution?
- Do we need to geographically individualize parameters for surgical indications?

There is no longer any doubt that metabolic surgery has several advantages and is reasonably safe and effective. Its time has come in the treatment of T2DM.

# META-ANALYSIS

original article

*Diabetes, Obesity and Metabolism* 14: 262–270, 2012.  
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## Metabolic effects of bariatric surgery in type 2 diabetic patients with body mass index < 35 kg/m<sup>2</sup>

Q. Li<sup>1,\*</sup>, L. Chen<sup>1,\*</sup>, Z. Yang<sup>2</sup>, Z. Ye<sup>1</sup>, Y. Huang<sup>1</sup>, M. He<sup>1</sup>, S. Zhang<sup>1</sup>, X. Feng<sup>1</sup>, W. Gong<sup>1</sup>, Z. Zhang<sup>1</sup>, W. Zhao<sup>1</sup>, C. Liu<sup>3</sup>, S. Qu<sup>2</sup> & R. Hu<sup>1</sup>

- **13 studies selected**
- **357 patients evaluated.**
- **Bariatric procedures performed**
  - **Laparoscopic Roux-en-Y gastric bypass (4 studies)**
  - **Duodenal-jejunal bypass (3 studies)**
  - **Bilio-pancreatic diversion (3 studies)**
  - **Laparoscopic mini-gastric bypass (2 studies)**
  - **Laparoscopic ileal interposition with diverted sleeve gastrectomy (1 study)**

## Metabolic effects of bariatric surgery in type 2 diabetic patients with body mass index < 35 kg/m<sup>2</sup>

Q. Li<sup>1,\*</sup>, L. Chen<sup>1,\*</sup>, Z. Yang<sup>2</sup>, Z. Ye<sup>1</sup>, Y. Huang<sup>1</sup>, M. He<sup>1</sup>, S. Zhang<sup>1</sup>, X. Feng<sup>1</sup>, W. Gong<sup>1</sup>, Z. Zhang<sup>1</sup>, W. Zhao<sup>1</sup>, C. Liu<sup>3</sup>, S. Qu<sup>2</sup> & R. Hu<sup>1</sup>

- Total weight loss 17.23 kg (p<0.00001).
- Mean BMI reduction 5.18 kg/m<sup>2</sup> (p<0.00001).
- 80% patients reached a HbA1c value <7% and these patients were off T2DM medications.
- Mean reduction in fasting plasma glucose levels was -4.4mmol/L (p<0.00001)
- mean reduction of HbA1c was 2.59% (p<0.00001) in 11 studies.
- These important effects on glucose metabolism were accompanied by a significant reduction in LDL cholesterol and triglycerides levels

**Conclusions:** Bariatric surgery is effectual and safe in the treatment of non-severely obese (BMI < 35 kg/m<sup>2</sup>) T2DM patients. Moreover, the metabolic benefits acquired from the procedures can be long sustained after the surgery.

## Italian Group for Lap-Band System®: Results of Multicenter Study on Patients with BMI $\leq 35$ kg/m<sup>2</sup>

L. Angrisani; F. Favretti; F. Furbetta; A. Iuppa; S. B. Doldi; M. Paganelli; N. Basso; M. Lucchese; M. Zappa; G. Lesti; F. D. Capizzi; C. Giardiello; N. Di Lorenzo; A. Paganini; L. Di Cosmo; A. Veneziani; S. Lacitignola; G. Silecchia; M. Alkilani; P. Forestieri; F. Puglisi; A. Gardinazzi; M. Toppino; F. Campanile; B. Marzano; P. Bernante; G. Perrotta; V. Borrelli; M. Lorenzo

**Table 2.** Co-morbidities in patients with initial BMI  $\leq 35$  kg/m<sup>2</sup>. Follow-up after 1 year.

	Preoperatively n	Postoperatively n (%)	Success n (%)
Anxiety and depression	47	2 (4.2)	45 (95.8)
Osteoarthropathy§	43	4 (9.2)	39 (90.8)
Hypertension	9	1 (11.1)	8 (88.9)
GERD†	5	0	5 (100)
Diabetes*	4	0	4 (100)
Respiratory disorders	1	1 (100)	0

§=including 2 patients with rheumatoid arthritis and 1 patient with poliomyelitis

†=Gastro-Esophageal Reflux Disease

\*=non-insulin dependent

**Table 1.** Intra- and postoperative complications and their treatment

	Number (%)	Treatment
Gastric pouch dilation	11/210 (5.2%)	Band deflation = 5 Band repositioning = 2* Band removal = 4
Tube-port leak	4/210 (1.9%)	Tube-port reconnection = 2 Port replacement = 2
Intragastric migration	2/210 (0.9%)	Band removal = 2

\* = 'slipping band'

# BARIATRIC SURGERY IN CLASS I OBESITY.

## A Position Statement from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)

**Luigi Angrisani**

*Director General and Endoscopic  
Surgery Unit*

*S. Giovanni Bosco Hospital, Naples, Italy*

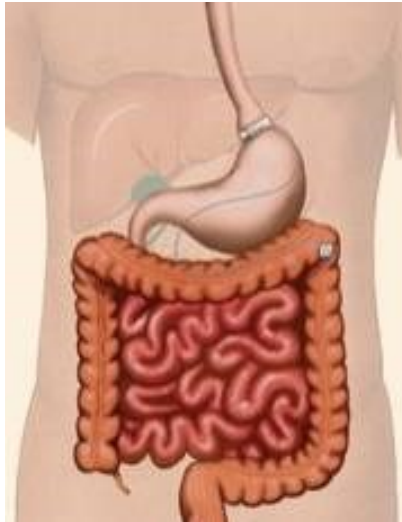
*Incoming President IFSO*



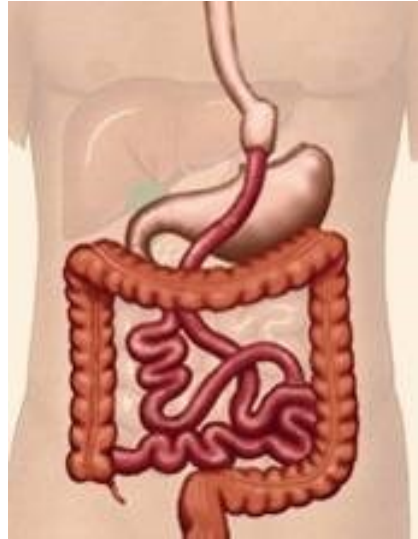
*International Federation for the  
Surgery of Obesity and Metabolic  
Disorders (IFSO)*  
[www.ifso.com](http://www.ifso.com)



# BMI > or < 35 & Type 2 Diabetes



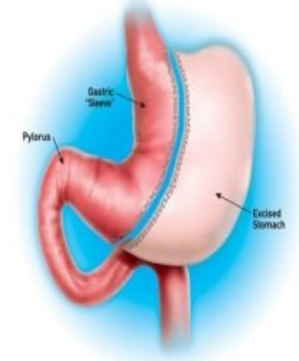
Laparoscopic Adjustable Gastric Band (LAGB)



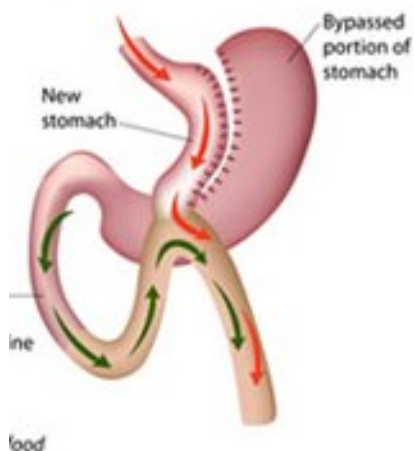
Roux-en-Y Gastric Bypass (RYGB)



Biliopancreatic Diversion (BPD)

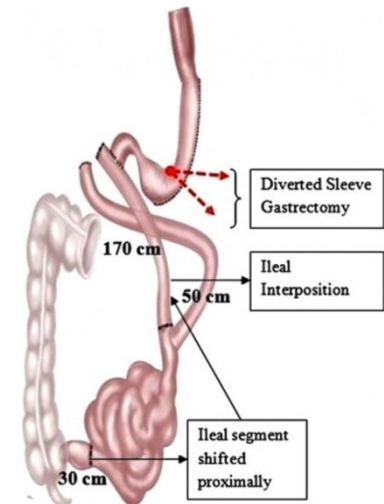


Vertical Sleeve Gastrectomy (VSG)



Mini Gastric Bypass

**GO FOR IT!**



Ileal interposition

# Is T2DM a Surgical Disease?



*“My daddy is a doctor and he treats diabetes.”*

*“My daddy is a surgeon and he cures it.”*



# DM TIPO 2:PREVALENZA IN ITALIA

