XVI ème Congrès National de la SMED

Endoscopie bariatrique et métabolique

Prof Guido Costamagna

DIGESTIVE ENDOSCOPY UNIT - Foundation Policlinico A. Gemelli - Rome

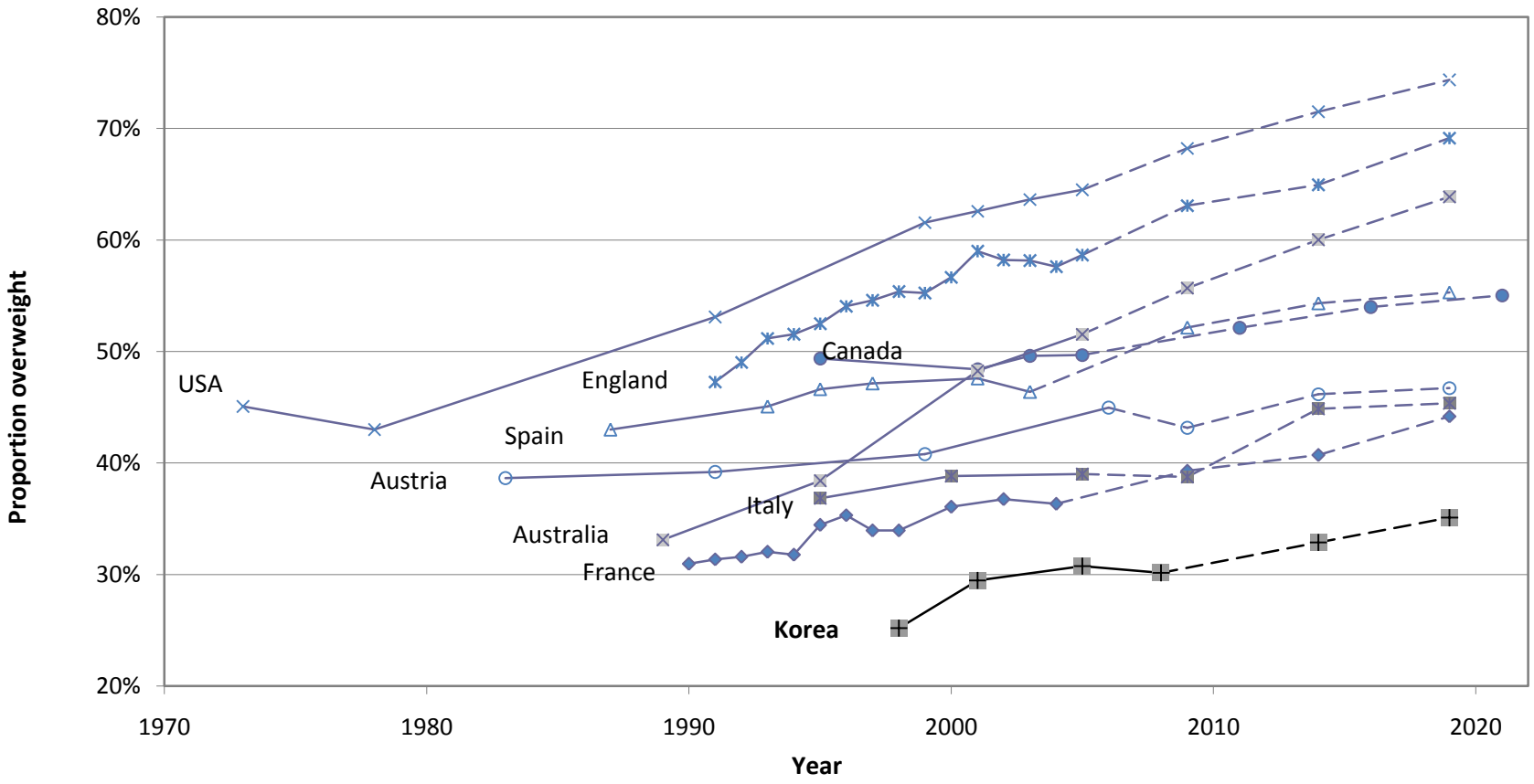
European Endoscopy Training Centre - Rome

Institut de Chirurgie Guidée par l'Image de Strasbourg

Faculté de Médecine et de Pharmacie de Fès

les 22 et 23 Juin 2018

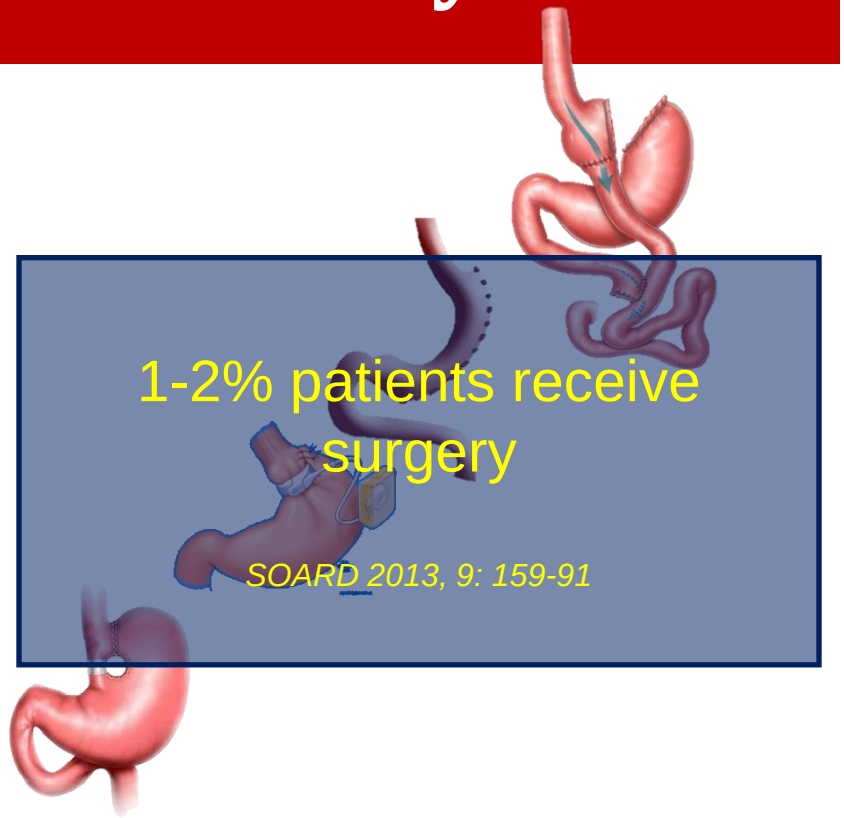
The growing Challenge of Diabesity



BETTER POLICIES FOR BETTER LIVES

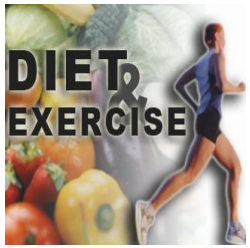
Treatments for obesity

EFFICACY



1-2% patients receive surgery

SOARD 2013, 9: 159-91

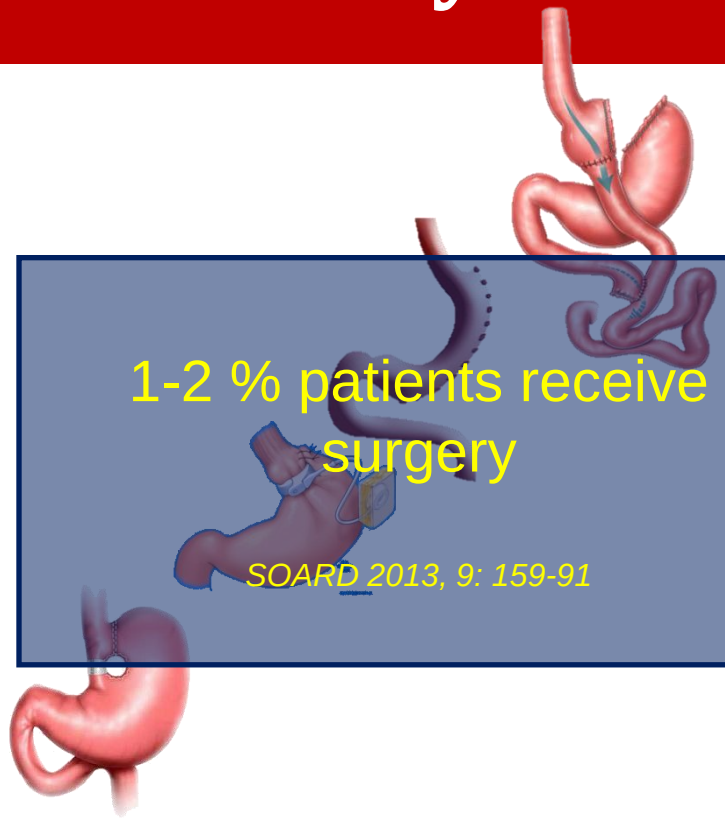


Risk

Treatments for obesity

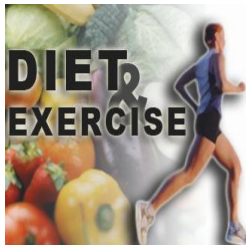
EFFICACY

Treatment Gap



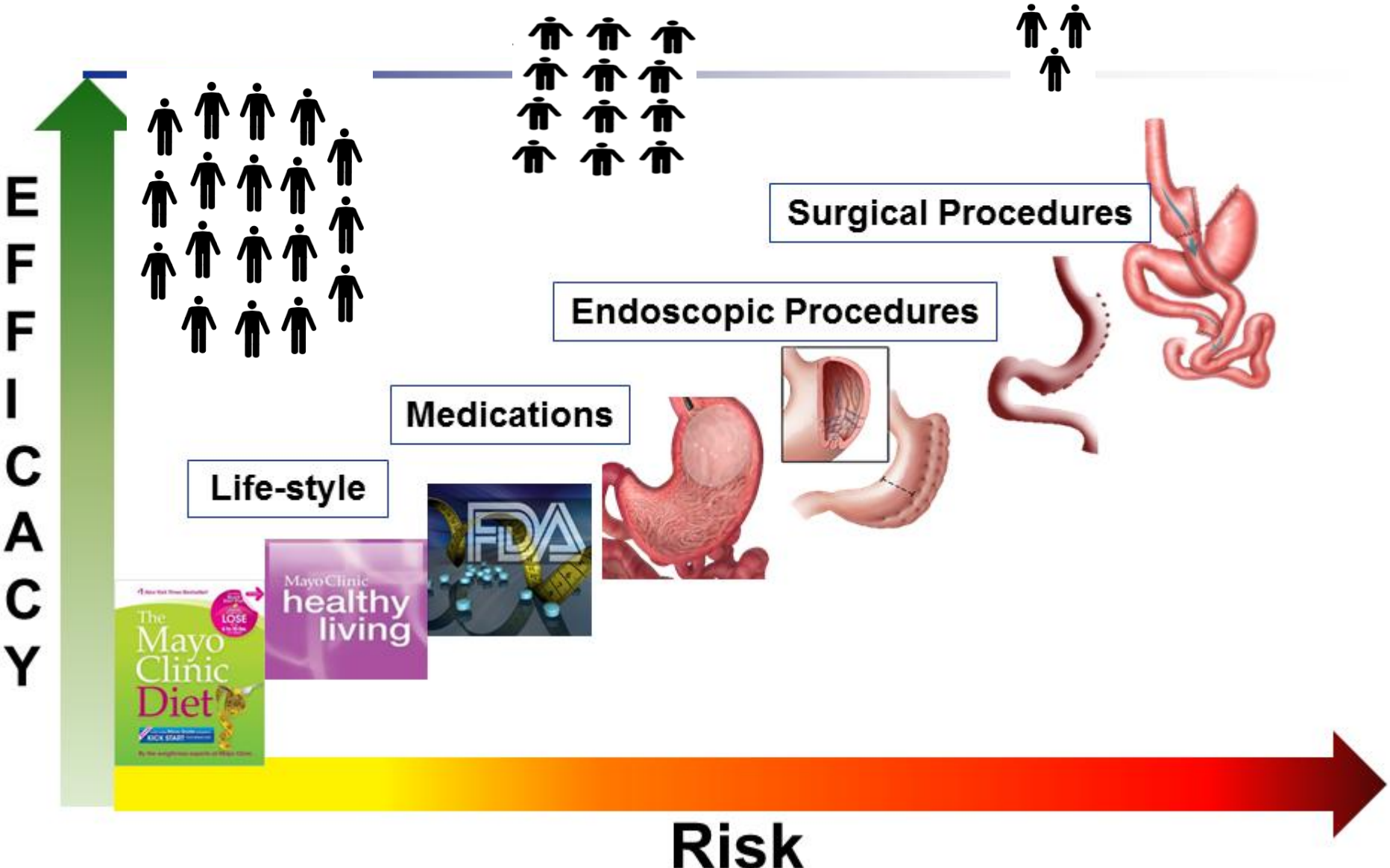
1-2 % patients receive surgery

SOARD 2013, 9: 159-91

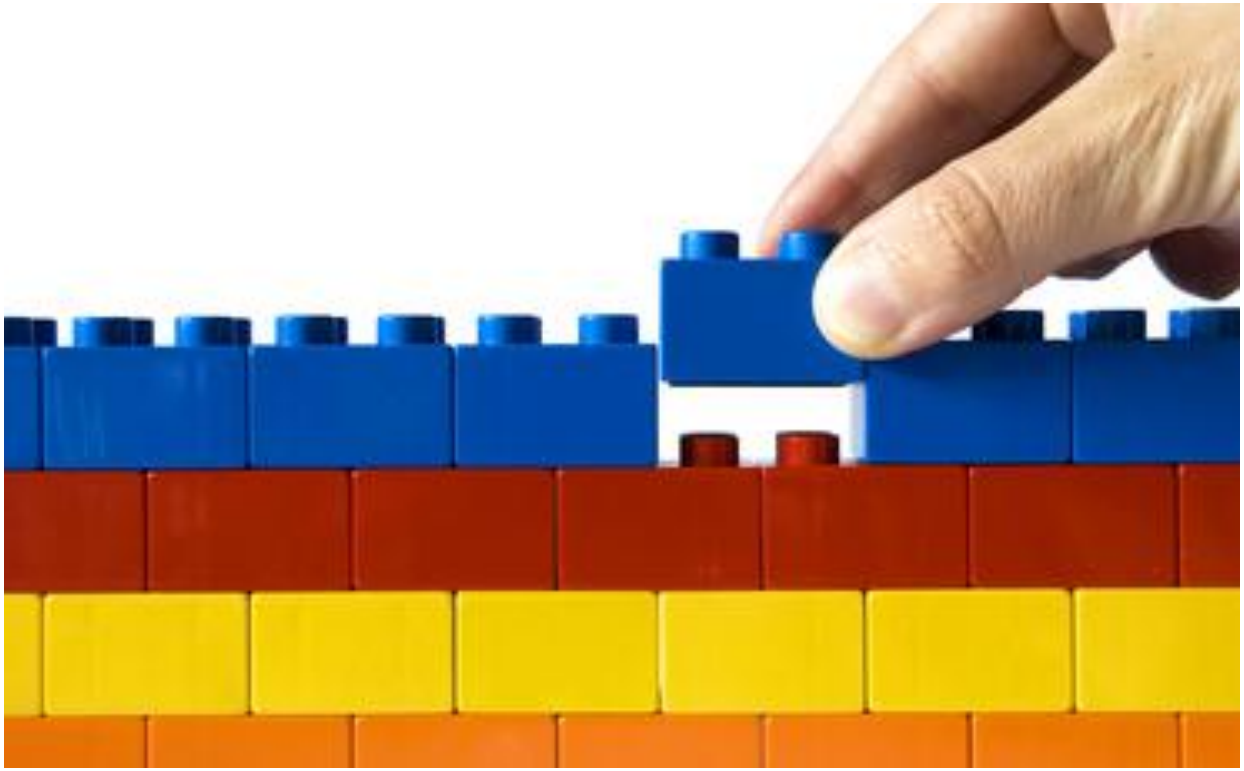


Risk

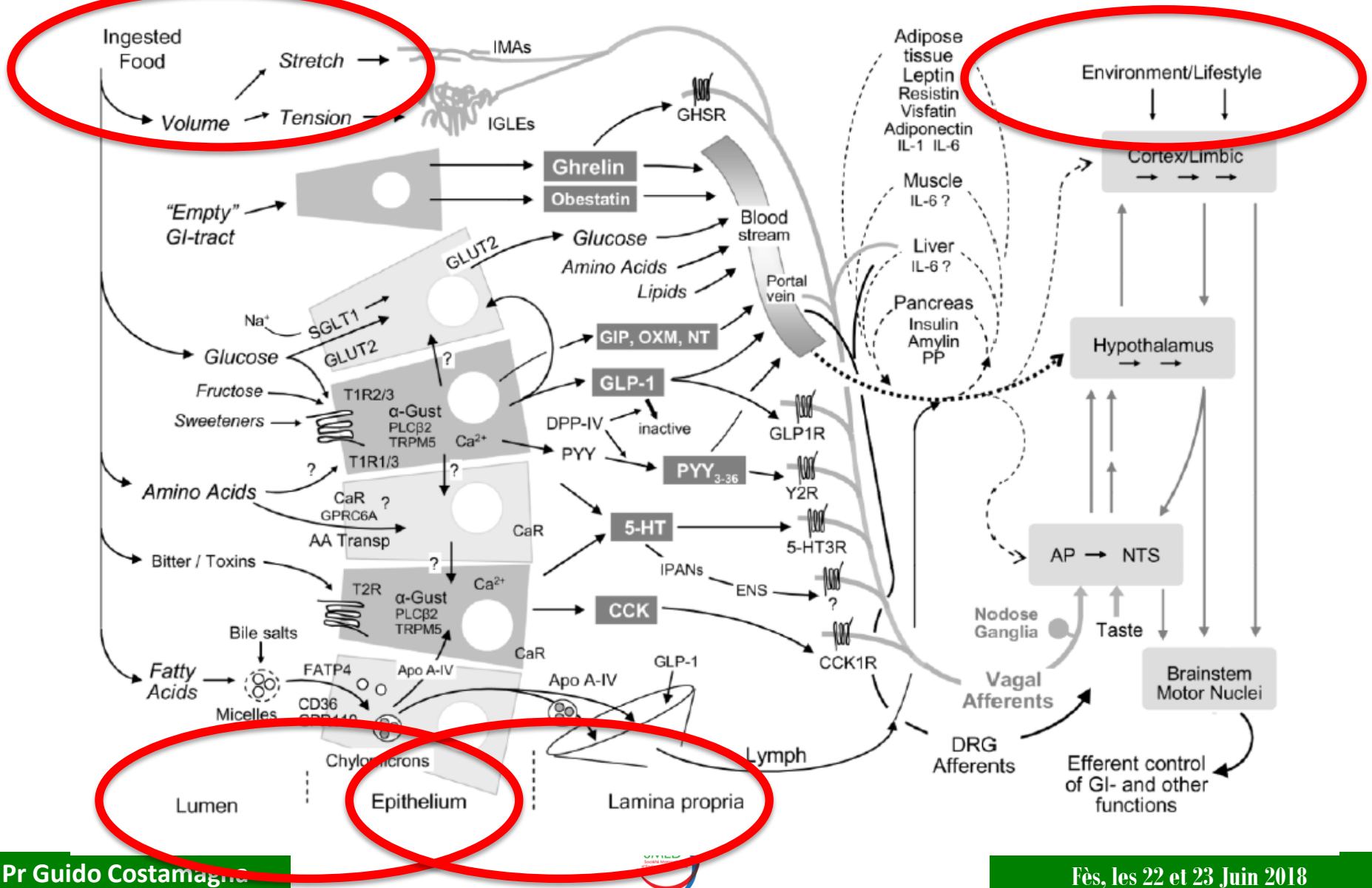
Obesity Continuum



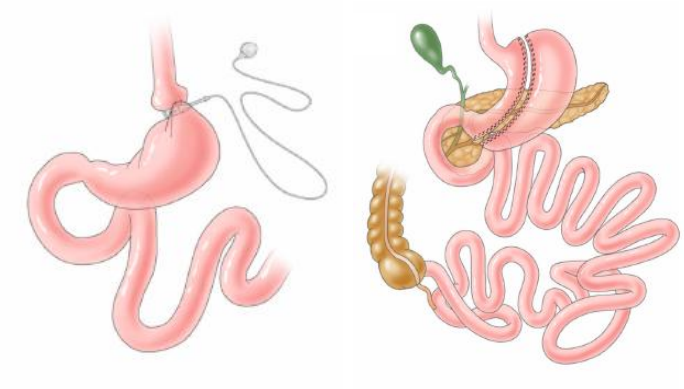
EBTs that fill the gap



Satiation, Satiety, and the Gut-Brain Axis



The Surgical Portfolio

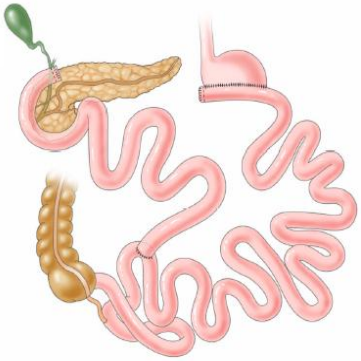


Restrictive Bariatric Surgery

Reduces amount of oral intake and produces early satiety.

Low risk of metabolic or nutritional complications as alimentary canal is left intact.

Examples: gastric banding, sleeve gastrectomy

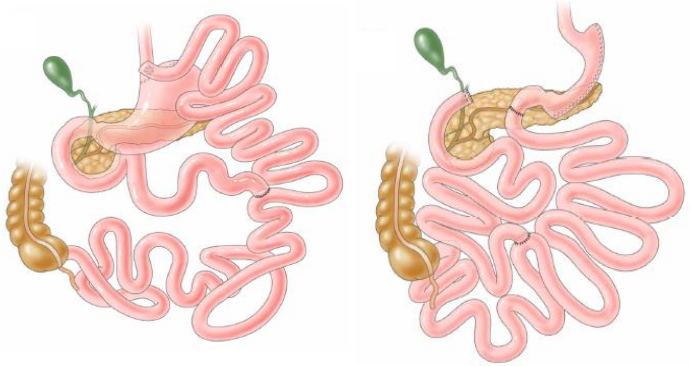


Malabsorptive Bariatric Surgery

Bypasses major portions of stomach and proximal intestine, causing malabsorption

Increased chance of nutritional and metabolic complications

Examples: biliopancreatic diversion, jejunoileal bypass

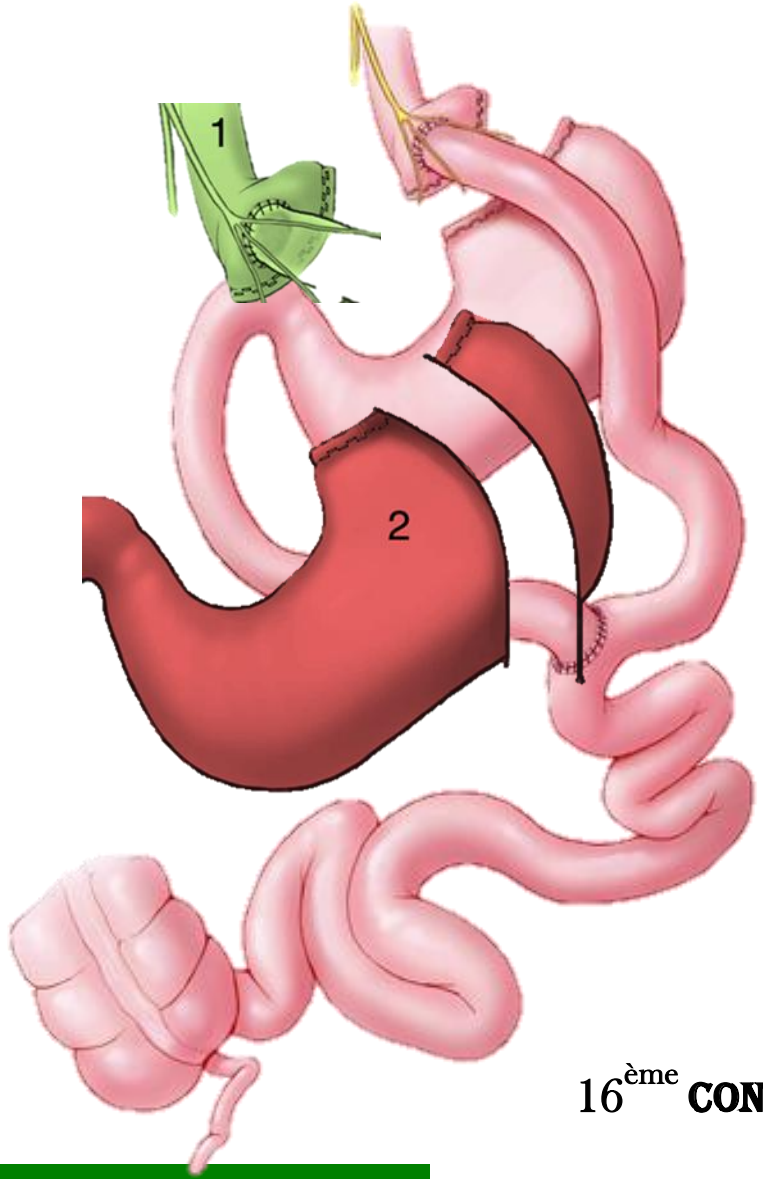


Mixed Bariatric Surgery

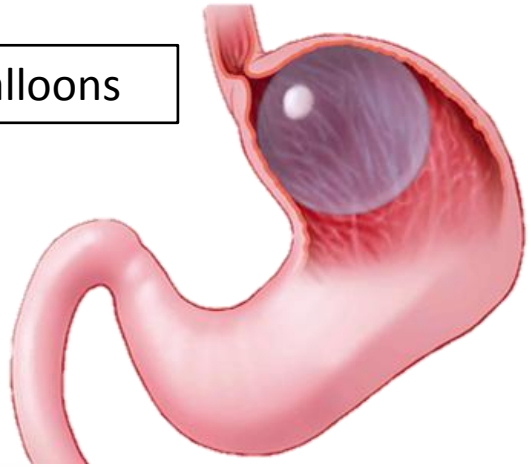
Applies both techniques of restriction and malabsorption

Examples: roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch

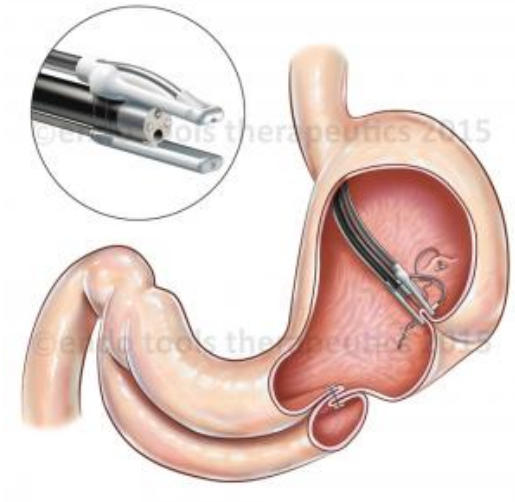
Gastric EBTs



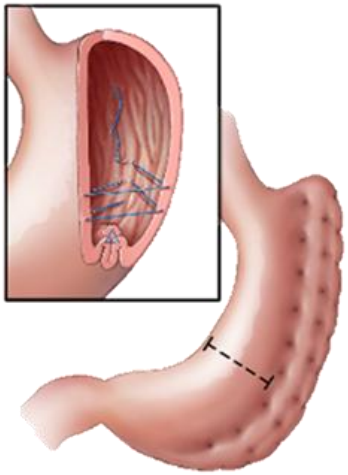
Balloons



Endomina



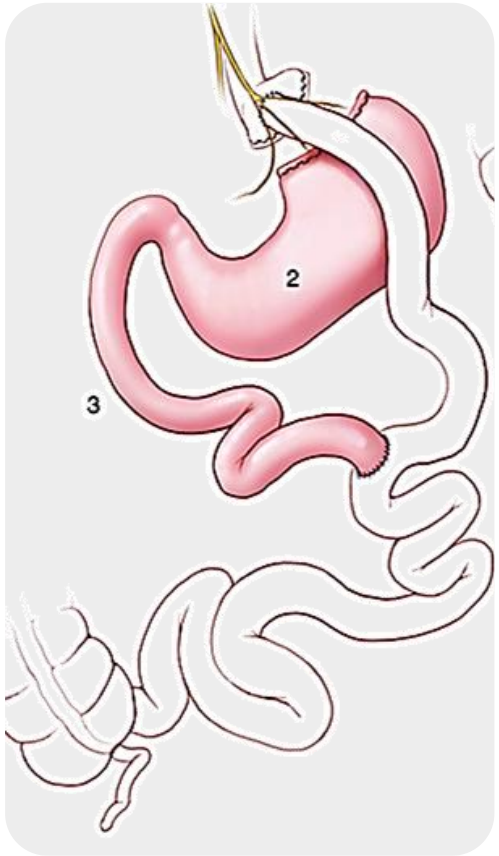
ESG



Others

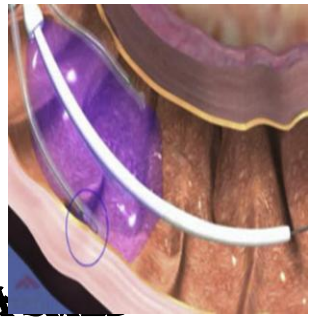
Small Bowel EBTs

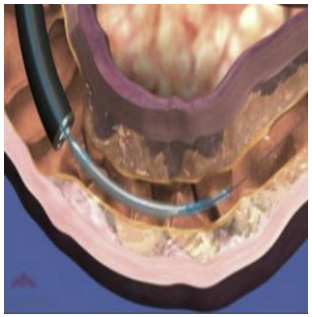
Duodenal Sleeves



Gastroduodenojejunal Sleeves

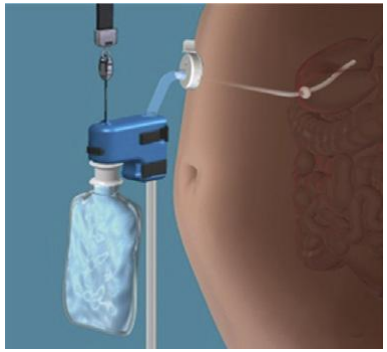
Duodenal Mucosal Resurfacing

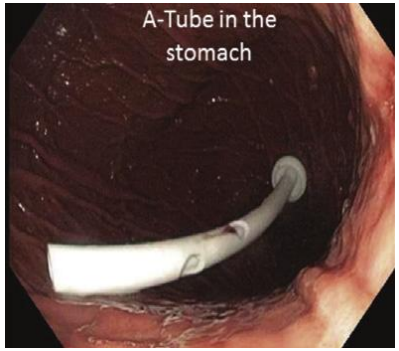




Other EBTs

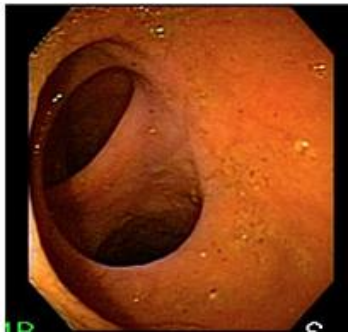
Aspiration Therapy

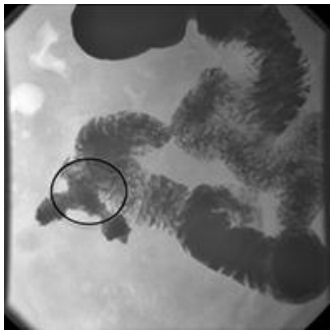




Full Sense Device

Self-assembling Magnets for Endoscopy

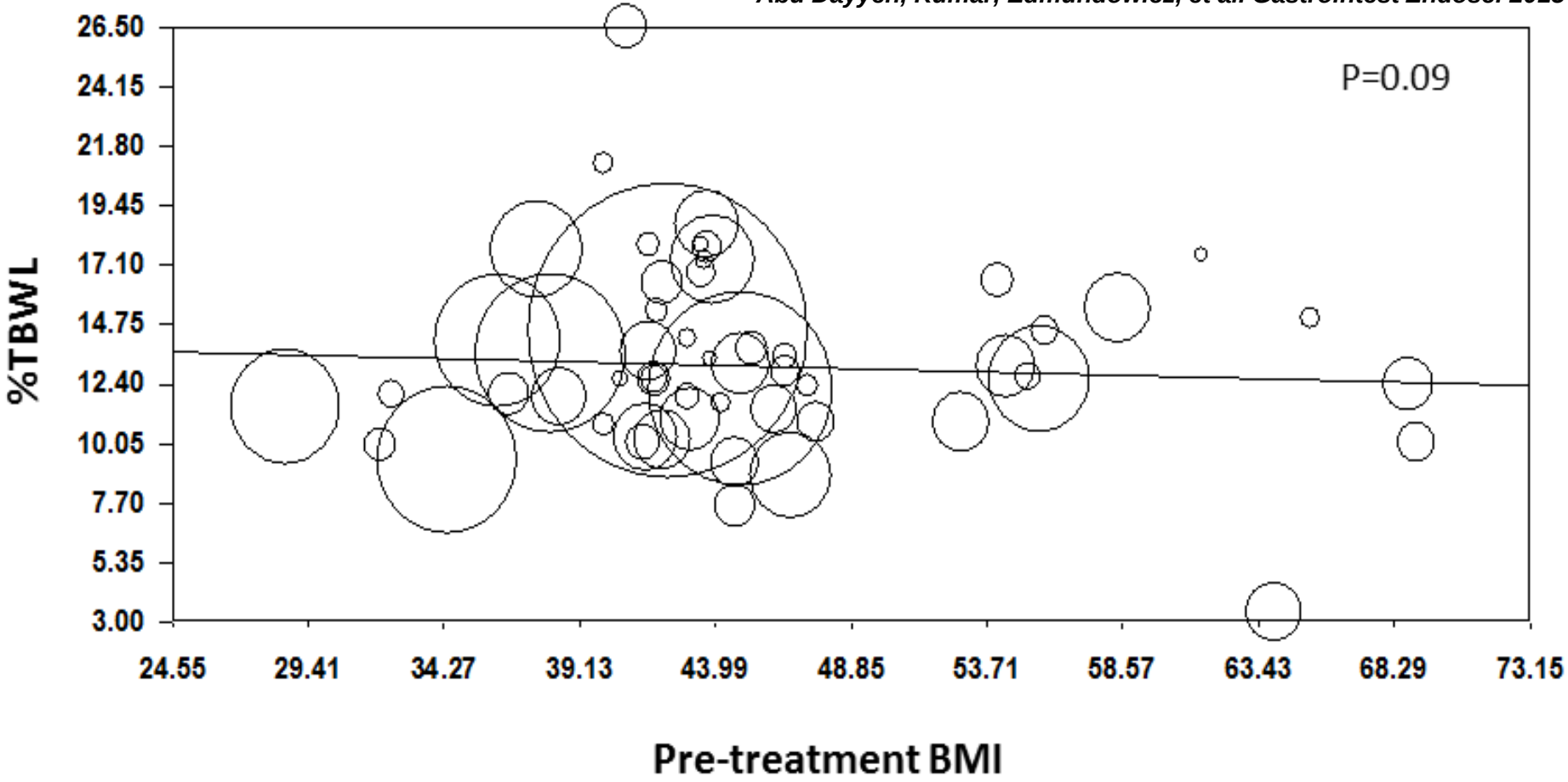




Intragastric Balloons

%TBWL with the Orbera IGB: Published International Experience N=6845

Abu Dayyeh, Kumar, Edmundowicz, et al. Gastrointest Endosc. 2015



OBES SURG (2008) 18:841–846
DOI 10.1007/s11695-007-9331-8

RESEARCH ARTICLE

Safety and Effectiveness of the Intragastric Balloon for Obesity. A Meta-Analysis

Iñaki Imaz · Carmen Martínez-Cervell · Elvira Elena García-Álvarez · Juan Manuel Sendra-Gutiérrez · Jesús González-Enríquez

Table 5 Effectiveness of BIB® to loss weight at the end of treatment

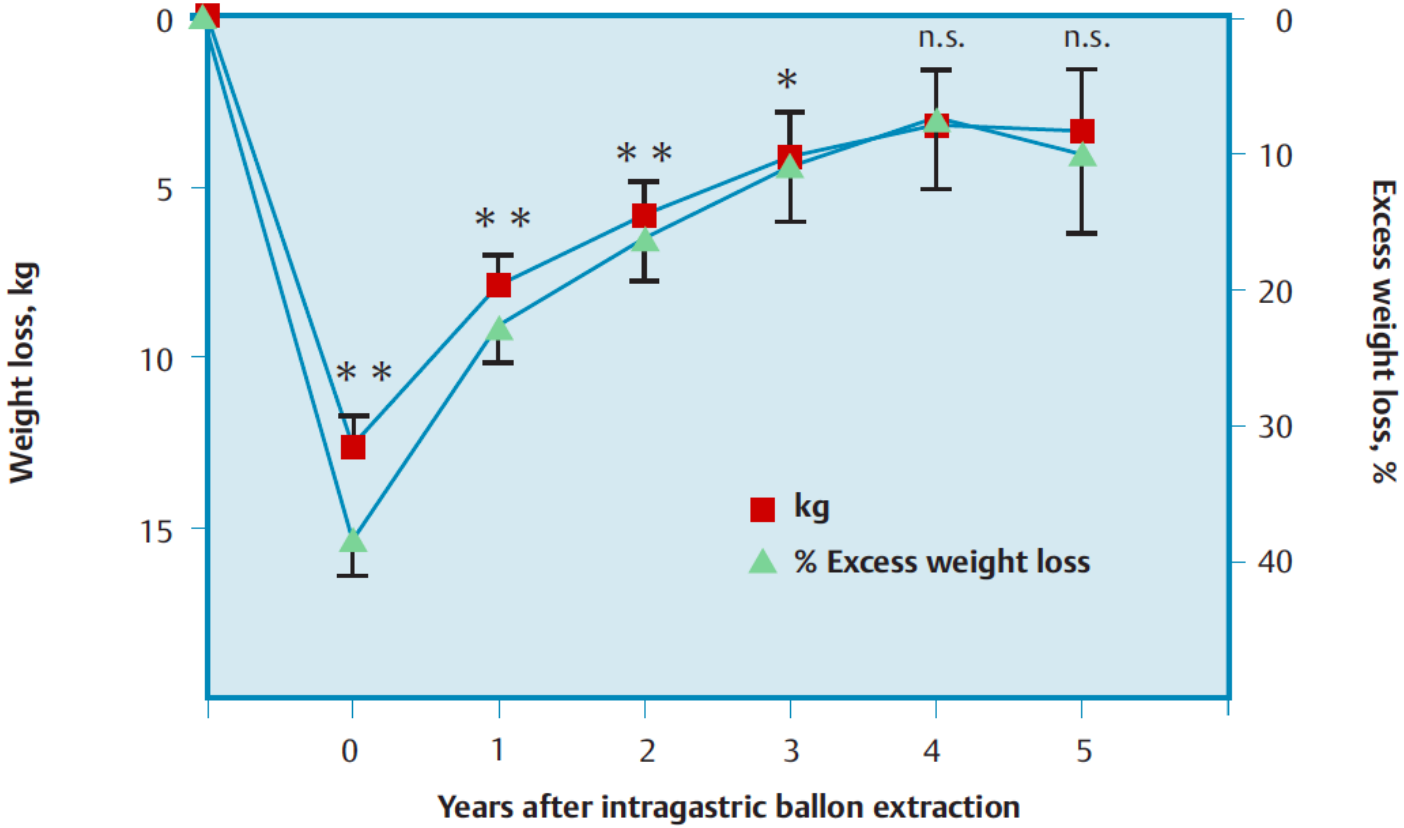
	Studies/Groups/Patients	Mean (95% CI)
Kg	15/18/3,608	14.7 (12.4–17)
Pkg	11/13/3,358	12.2 (10–14.3)
BMI	9/11/3,200	5.7 (4.4–6.9)
PEW	11/13/3,513	32.1 (26.9–37.4)

BMI=Body Mass Index lost, CI=Confidence Interval, Kg=Kilograms lost, PEW=Percentage of excess weight lost, Pkg=Percentage of kilograms lost

Conclusion The use of the BIB®, within a multidisciplinary weight management program, is a short-term effective treatment to lose weight, but it is not yet possible to verify its capacity to maintain the weight lost over a long period of time.

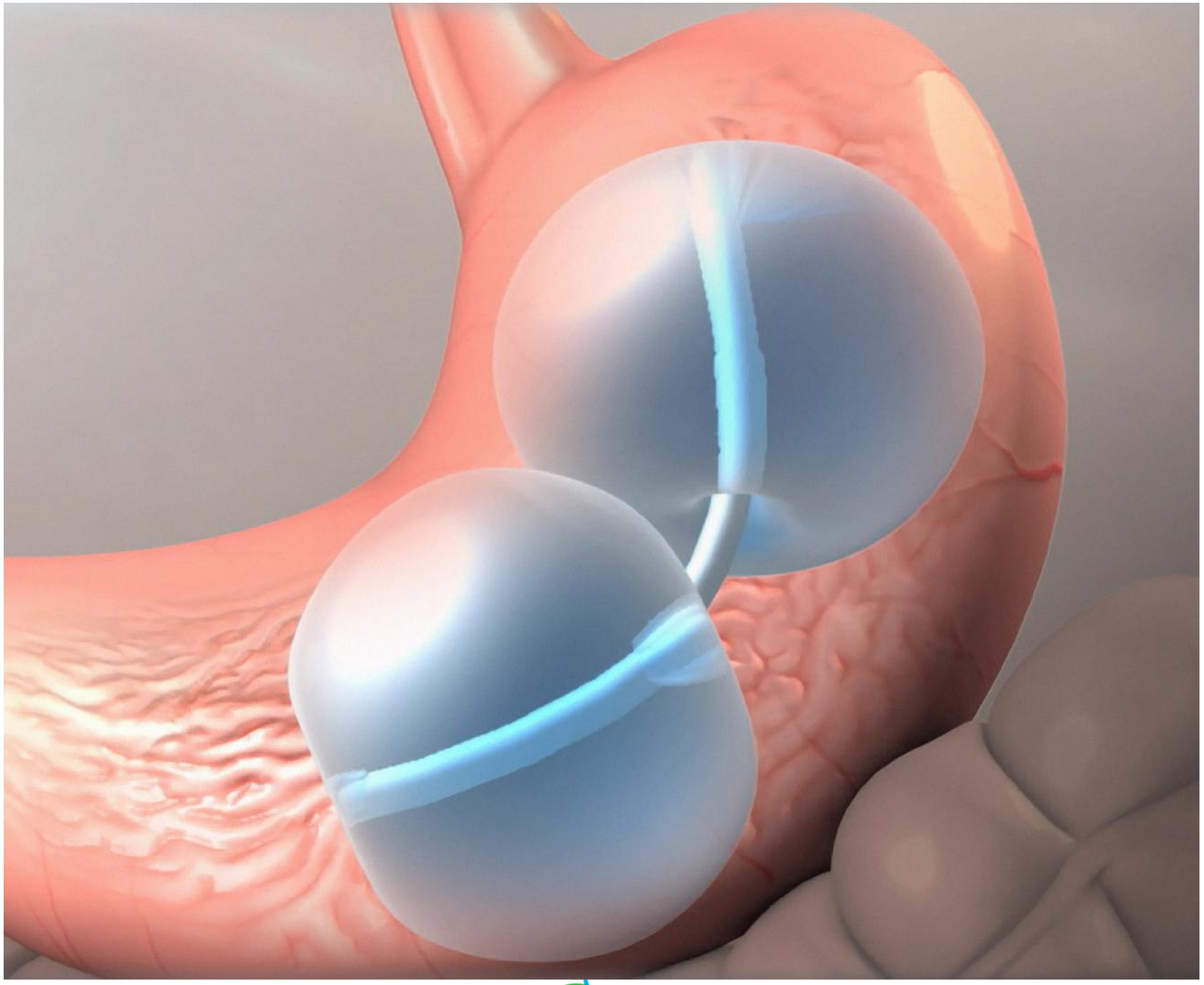
Balloons and weight loss: long term

Negrin Dastis et al. Endosc 2009



Number of patients	100	100	100	80	57	43

The Reshape DUO balloon



Weight changes after DUO balloon

		Total weight loss (kg) (mean±SD)	% of weight loss (%)	% of excess weight loss (%)
	Total (n=60)	16.60±9.33	15.45±7.95	47.1±4 26.72
Obesity grade	BMI<40 kg/m^2 (n=39)	14.49±8.07*	14.90±7.71	52.27±28.72*
	BMI≥40 kg/m^2 (n=21)	20.52±10.39*	16.46±8.47	37.48±19.72*
Gender	Male (n=11)	15.79±9.66	12.09±7.63	30.92±21.03*
	Female (n=49)	16.78±9.34	16.20±7.89	50.73±26.68*
Age	≤40 years (n=34)	16.94 ± 9.75	15.56±8.01	48.49±26.72
	>40 years (n=26)	16.15±8.90	15.31±8.02	45.28±27.13

Comparisons of absolute means between groups were with T of Student: *$p<0.05$

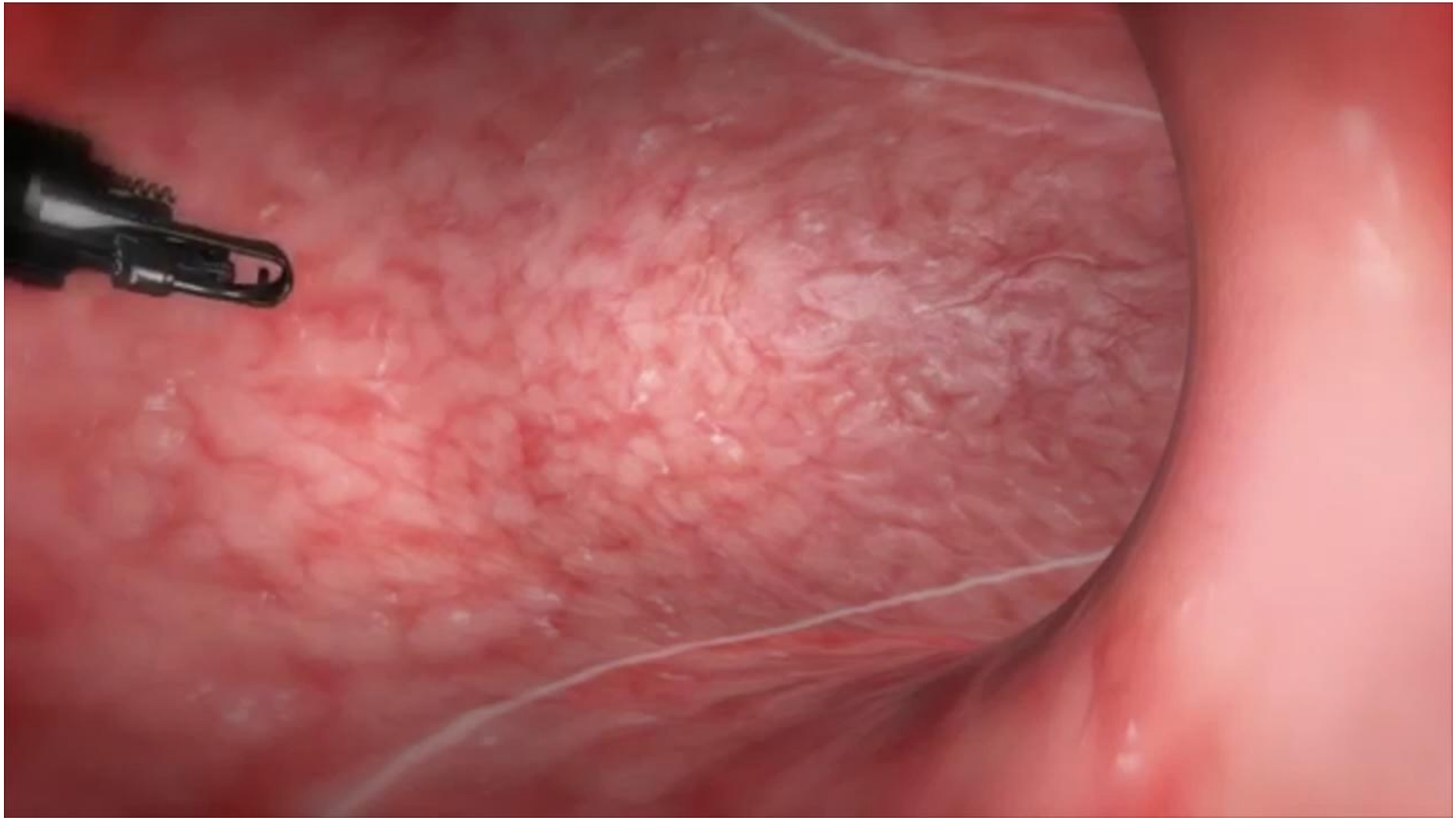
Lopez-Nava et al. Obes Surg 2015

Endoscopic Gastroplasty Techniques

The OverStitch Endoscopic Suturing System – Apollo Endosurgery

16ème CONGRÈS NATIONAL DE LA SMED

Endoscopic Sleeve Gastroplasty



Endoscopic Sleeve Gastroplasty

Study	Patients N	Mean BMI	6 Mo TWL	12 Mo TWL	24 Mo TWL
Sharaiha RZ, 2015	25	38,5 ± 4,6	NA	18,7 ± 10,7	NA
Kumar N, 2015	126	36,2	NA	20 ± 3,8	NA
Lopez-Nava G, 2016	25	35,5	17.8 ± 7.5	18.7 ± 10.7	NA
Abu Dayyeh BK, 2017	10	45,2	33	NA	NA
Lopez-Nava G, 2017	248	37.8 ± 5.6	15.2	NA	18.6
Sartoretto A, 2018	112	37,9 ± 6,7	16.4 ± 10.7	NA	NA

Reported complications 2%

ESG at Foundation Policlinico Gemelli

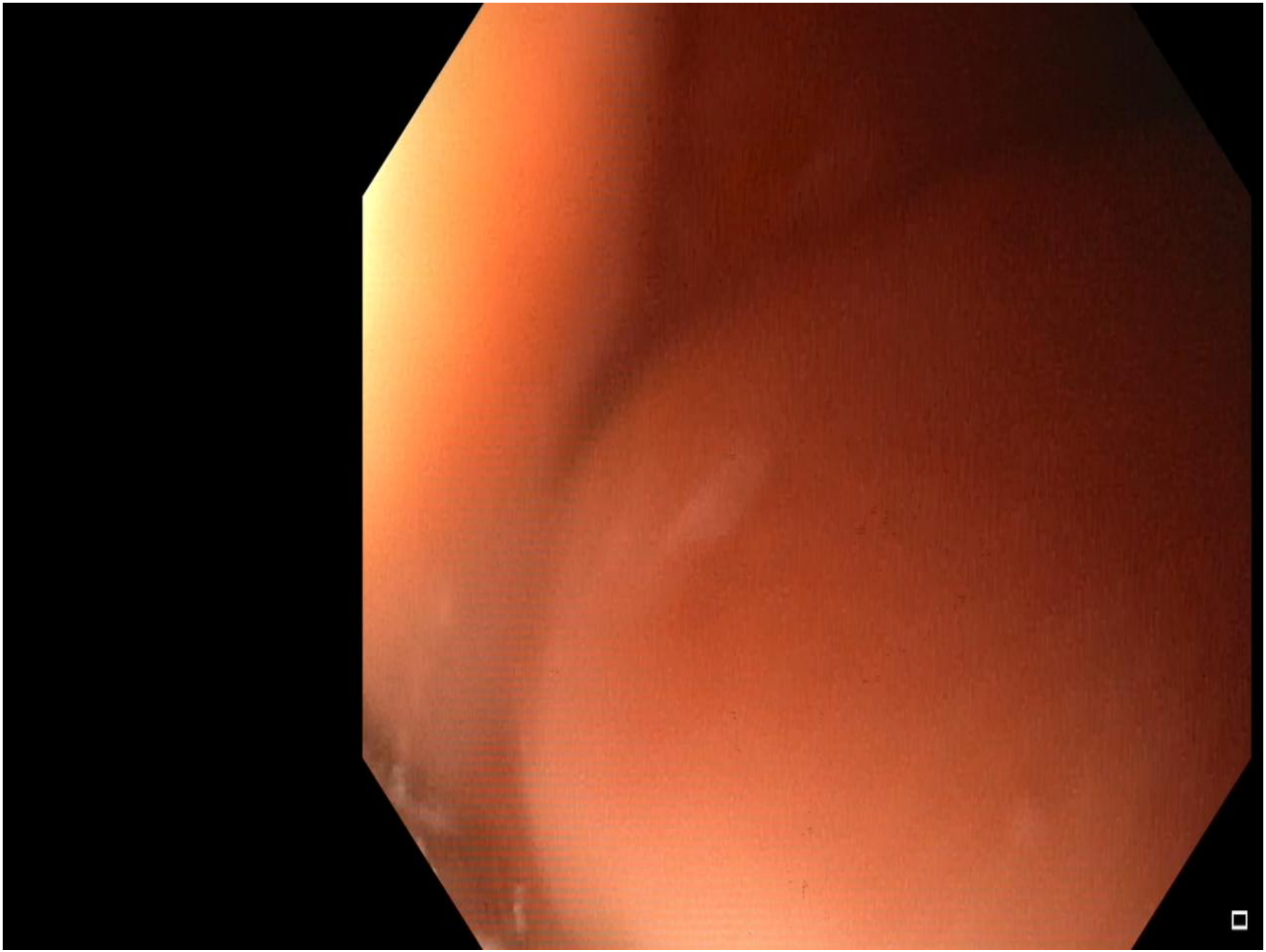
- **Inclusion criteria:** same as for bariatric surgery
- **Pre-procedure evaluation:**

  endocrinologist, dietitian, psychiatrist
- **Follow-up:** endocrinologist, dietitian, psychiatrist

ESG at Policlinico Gemelli Foundation

- 28 pts
- Follow-up available for 12 pts (8 female, mean age 49.6) from May 2016 to August 2017
- Baseline mean BMI was 41.5 (range 35-45.7)
- Mean weight 117 kg (range 95-149)

Boskoski et al. Endoscopy 2018; Abstract



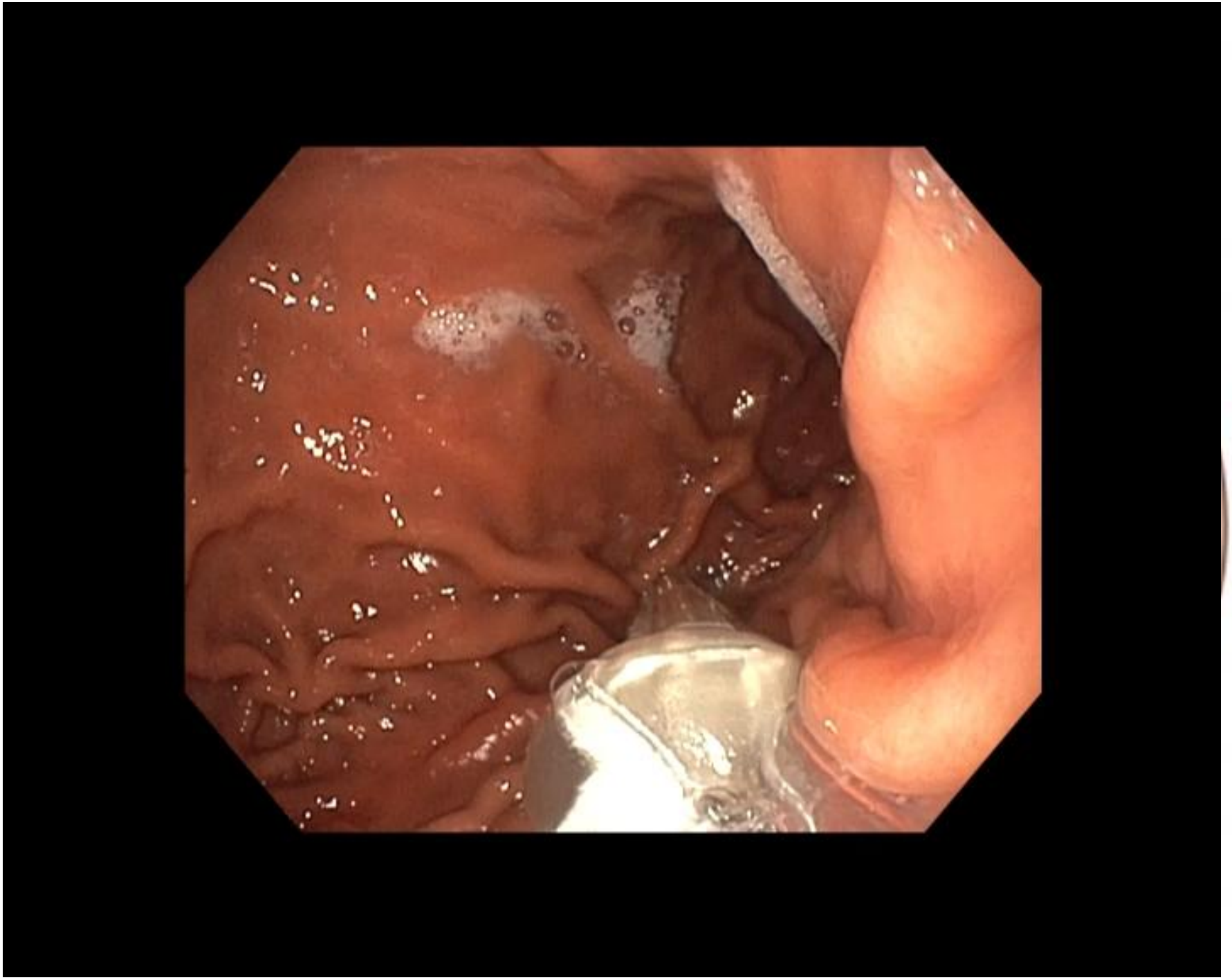
Trainees involved!

- Mean procedure time: ***61 minutes*** (range 30-92)
- Mean number stitches ***5.4/patient*** (range 3-8)
- After suturing the patency of the gastric outlet was tested with standard gastroscope
- ***No complications***

Boskoski et al. Endoscopy 2018; Abstract

- ***Telephonic follow-up*** done at 1, 3, 6 and 12 months
- ***Mean weight loss*** at 1 month follow-up was ***5.7 kg (BMI 39.4)***, at 3 months was ***12.1 kg (BMI 36.6),*** at 6 months was ***14.0 kg (BMI 35.3)*** while at 12 months was ***14.3 kg (BMI 34.6). EWL 49,5%.***
- Only one patient regained weight compared to baseline during the follow up.
- ***100% satiety*** after 1 month, 72.3% after 6 months, 66% after 12 months.
- ***73%*** improvement of quality of life

Boskoski et al. Endoscopy 2018; Abstract



Safety and feasibility of an endoluminal-suturing device for endoscopic gastric reduction (with video)

Vincent Huberty, MD,[1] Mostafa Ibrahim, MD,[1] Martin Hiernaux, Mig,[2] Alexandre Chau, Mig, PhD,[2] Sonia Dugardeyn, RN,[1] Jacques Devière, MD, PhD[1]

Brussels, Gosselies, Belgium

Transoral endoscopic gastroplasty using Endomina appears to be safe and effective at mid-term follow-up.

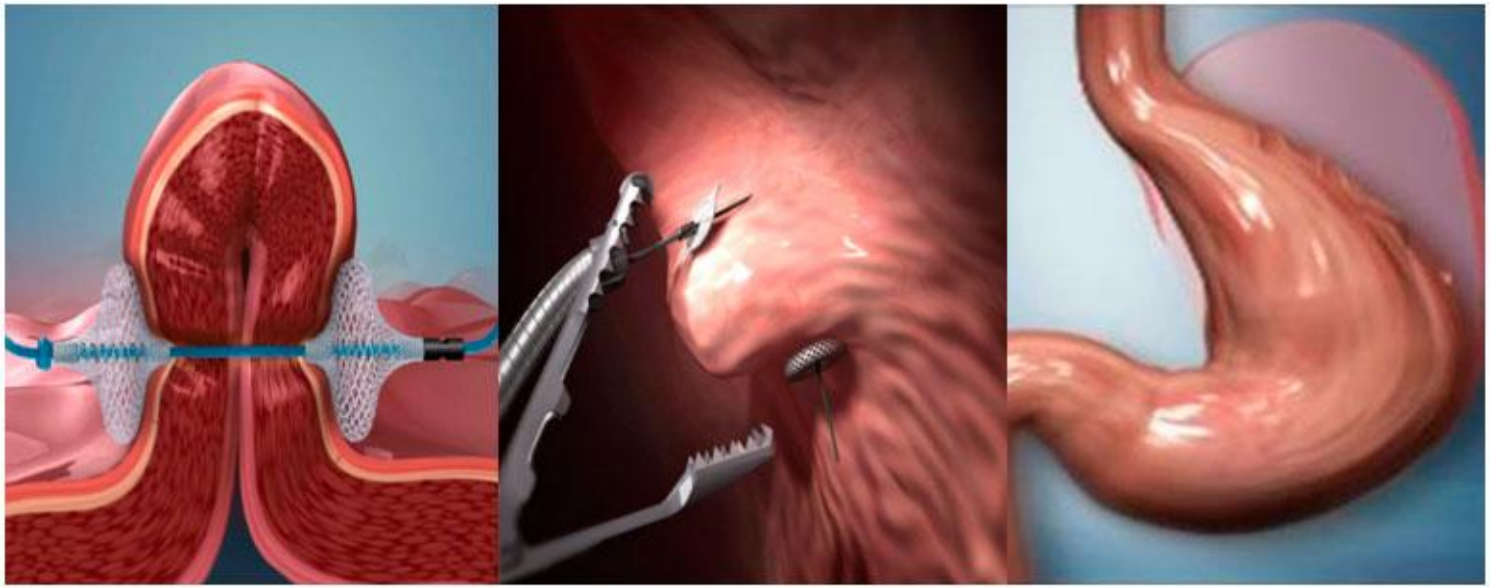
TABLE 1. Summary of BMI and weight loss results

Parameter	Baseline (n = 11)	1-Month follow-up (n = 11)	3-Month follow-up (n = 10)	6-Month follow-up (n = 10)
BMI	34.6 (2.1)	32.5 (1.8)	31.5 (2.4)	30.7 (3.1)
Weight loss, kg		5.8 (2.7)	8.8 (4.9)	10.9 (7.3)
Excess weight loss, %		21 (9)	33 (22)	41 (33)
Total body weight loss, %		6 (3)	9 (5)	11 (8)

Values are means with standard deviations in parentheses. Excess weight loss is defined as the difference between BMI-25 weight and actual patient's weight as defined by the American Society for Gastrointestinal Endoscopy.[19]

BMI, Body mass index.

P.O.S.E. Procedure



THE POSE METHOD

INCISIONLESS
WEIGHT LOSS
PROCEDURE

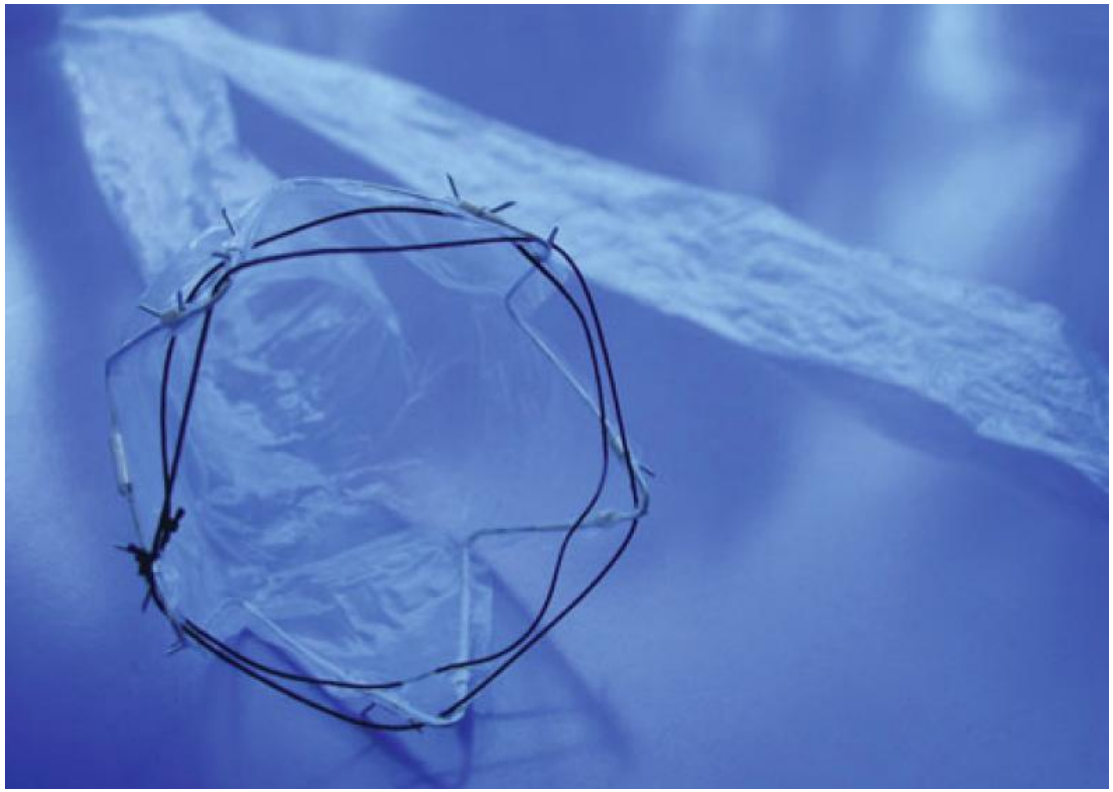
P.O.S.E. Procedure

- 147 POSE procedures & 1 y f-up
- Baseline BMI was 38.0 ± 4.8 kg/m
- At 1 y, 116 patients had a mean TWL of 16.6 ± 9.7 kg,

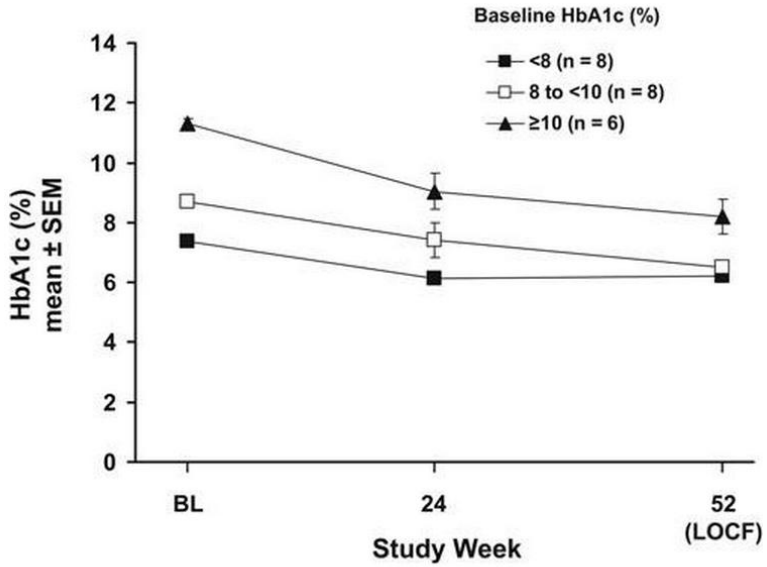
Lopez-Nava G et al. Surg Obes Relat Dis. 2015

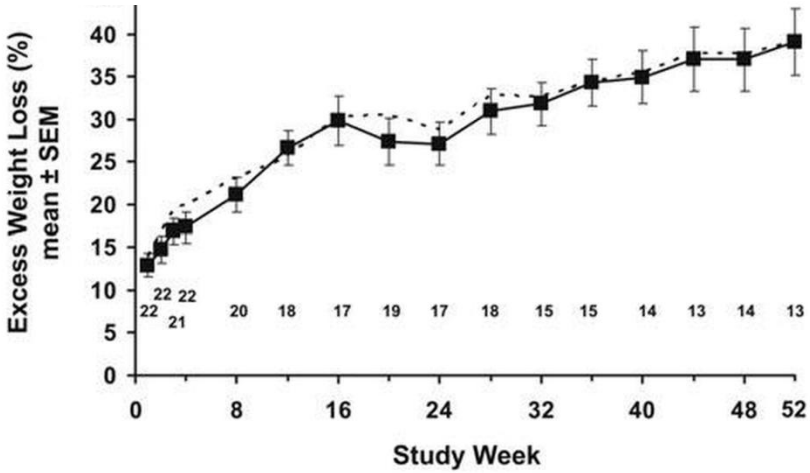
Duodenal sleeves

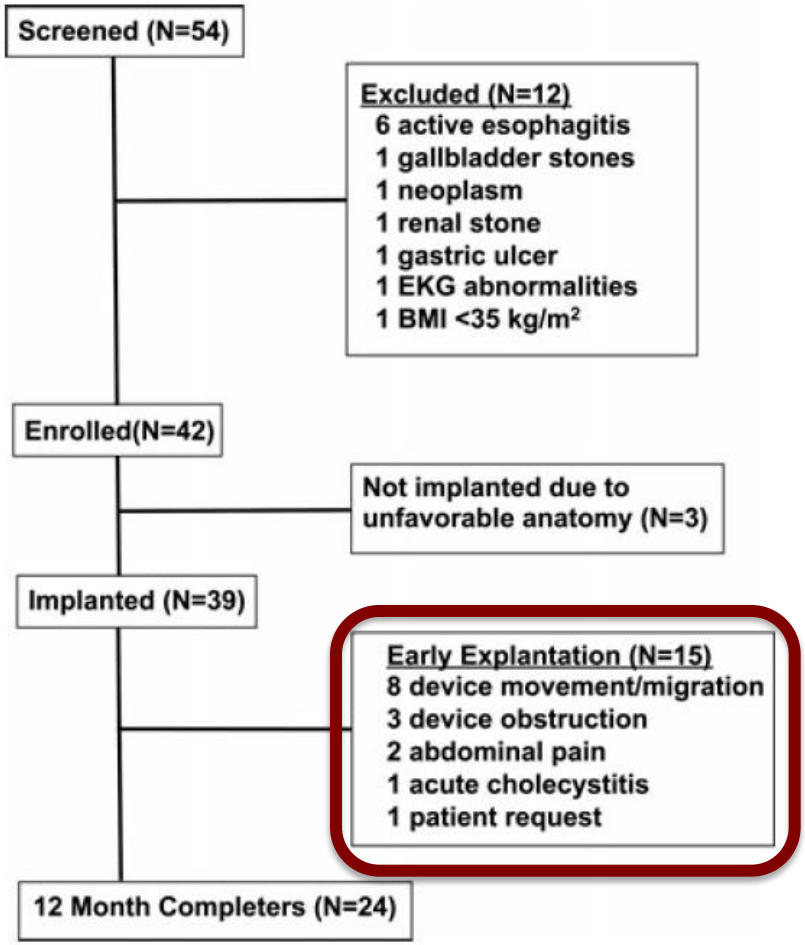
Duodenal-jejunal bypass liner EndoBarrier



Outcomes of DJBL in obese type 2 DM







NATIONAL DE LA SMED

Escalona et al. Ann Surg 2012

de Moura et al. Diab Tech Ther 2012

Complications rate is the major issue
Systematic review of Endobarrier trials

- 10 trials, 342 patients
- Short term EWL in morbidly obese patient
- Effect on diabetes possible but never compared with optimal pharmacotherapy
- Complications (mostly minor) in 64-100% compared to 0-27% in control groups and incidence of GI bleeding (4%) preclude recommending DJS in routine
- FDA multicentric trial stopped in 2015 for major complications

Zechmeister-Loss et al Obes Surg 2014

Endobarrier: Effect on Diabetes

- 28 patients: BMI 44.8±7.4 kg/m
- 13 patients completed the 52-week study (Migration , Bleeding , Pain)
- Reduction
- In fasting blood glucose (-30.3±10.2 mg/dL)
- In fasting insulin (-7.3±2.6 µU/mL)
- In HbA1c (-2.1±0.3%)

Benefit maintained 6 months after removal

De Moura EG. Diabetes Technol Ther. 2012

GI Dynamics Press Release - March 05, 2015

< Back to Press Releases

ENDO Trial Placed on Enrollment Hold

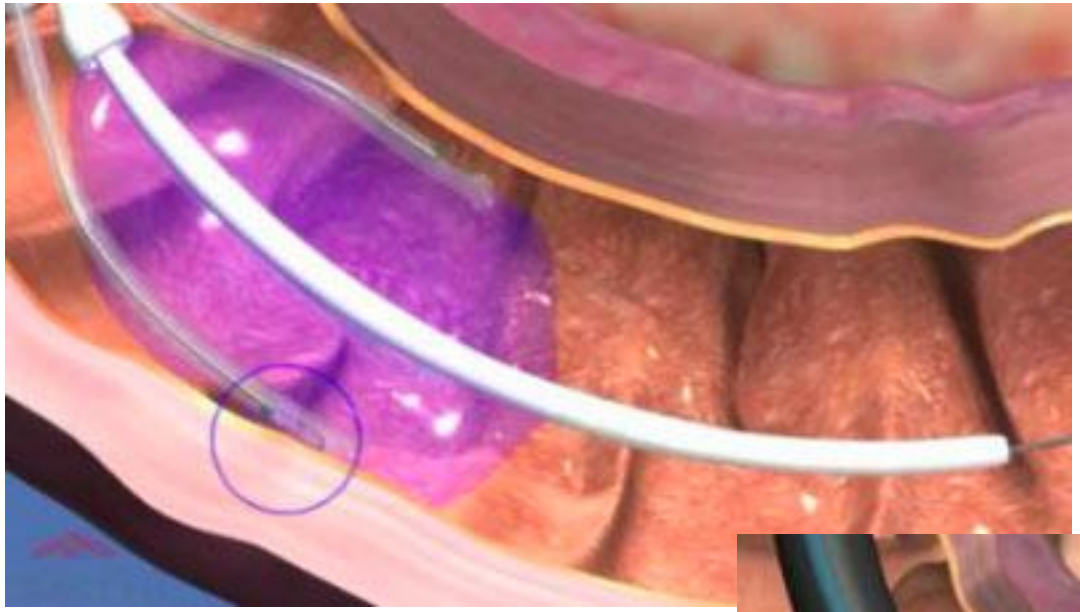
LEXINGTON, Mass & SYDNEY--(BUSINESS WIRE)--GI Dynamics, Inc. (**ASX: GID**) (**GI Dynamics** or the **Company**), a medical device company developing innovative treatments for type 2 diabetes and obesity, announced today that the U.S. Food and Drug Administration (**FDA**) has placed a hold on enrollment in the Company's ongoing pivotal clinical trial of EndoBarrier® Therapy (the **ENDO Trial**) in the U.S. Monitoring and data collection involving patients currently enrolled in the ENDO Trial will continue.

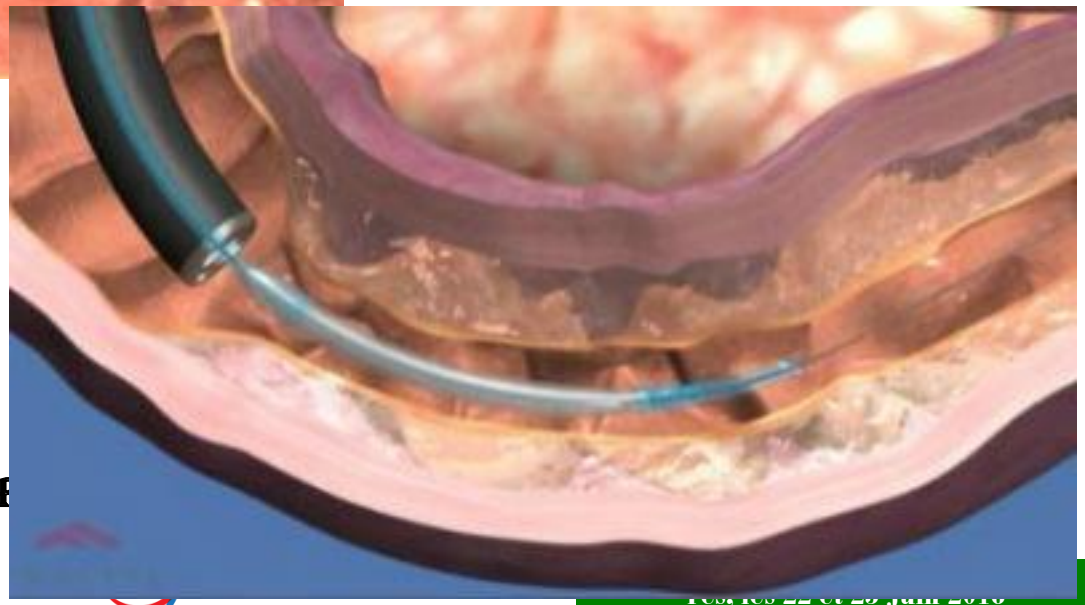
The decision to hold further enrollment results from 4 cases of a bacterial infection of the liver, known as hepatic abscess, among the 325 subjects currently enrolled in the ENDO Trial. Hepatic abscess is a known event related to the use of EndoBarrier but has recently presented at a higher than anticipated rate in the ENDO Trial. The FDA has therefore requested additional information to further assess the risk:benefit profile of the EndoBarrier in the ENDO Trial.

Duodenal Mucosal Rejuvenation

Pr Guido Costamagna

REVITA Duodenal mucosal resurfacing



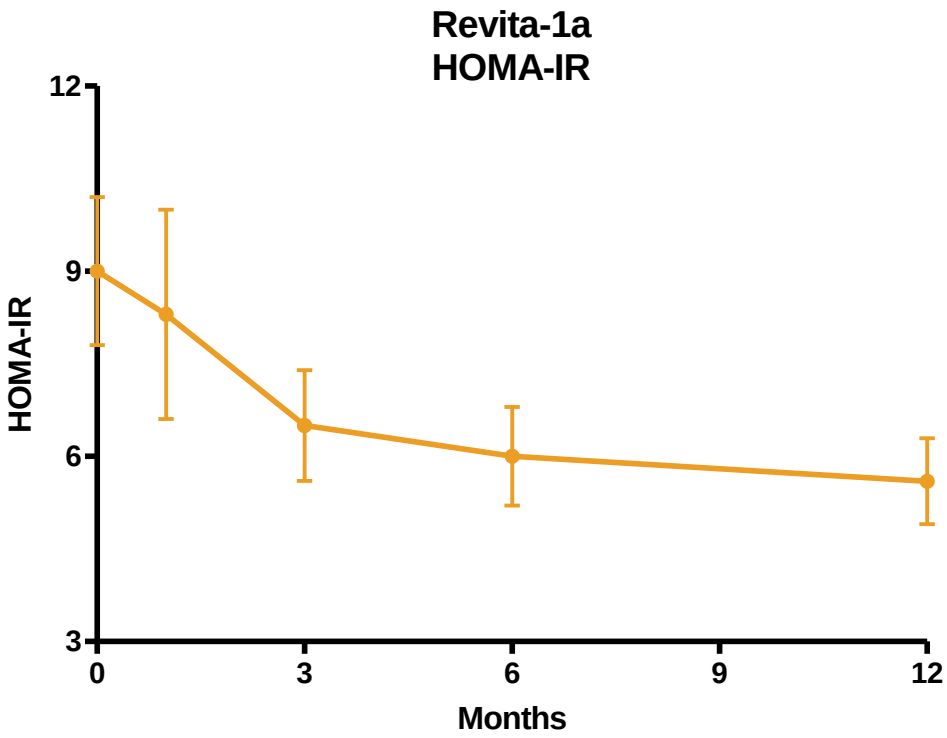


Duodenal mucosal resurfacing

DMR Safety and Tolerability

- Total ~100 cases in early First-in-Human ("FIH") and ongoing
- multicenter Revita-1 study
- Post-procedure: favorable tolerability profile with minimal GI symptoms
- Three duodenal stenoses in early FIH experience → each successfully treated with single non-emergent balloon dilation and no later sequelae
- One small bowel perforation SAE in recent use
- No other device/procedure related SAEs No apparent hypoglycemic risk
- No evidence of malabsorption
- No late adverse events observed (60+ patients >12 months)

Revita-1 Trial Key Finding: Durable Lowering of HOMA-IR

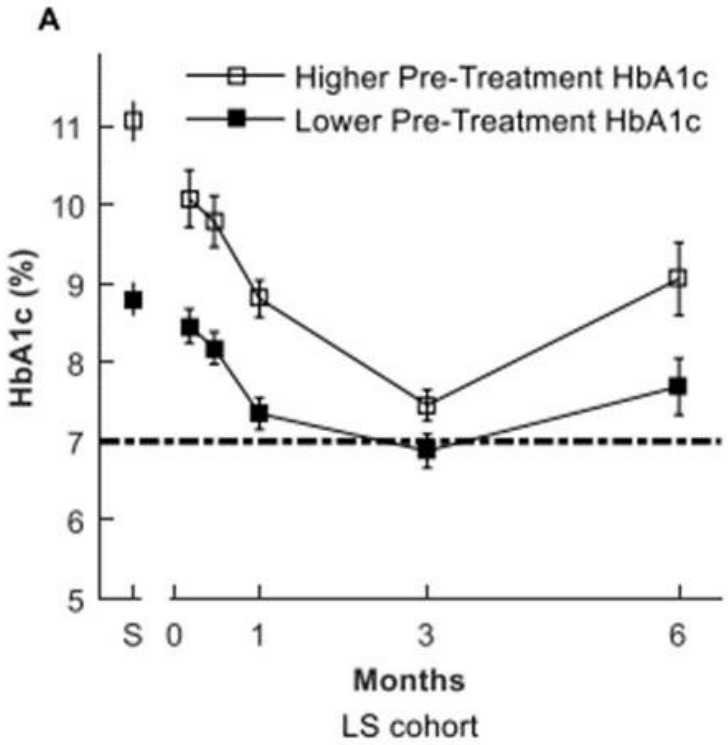


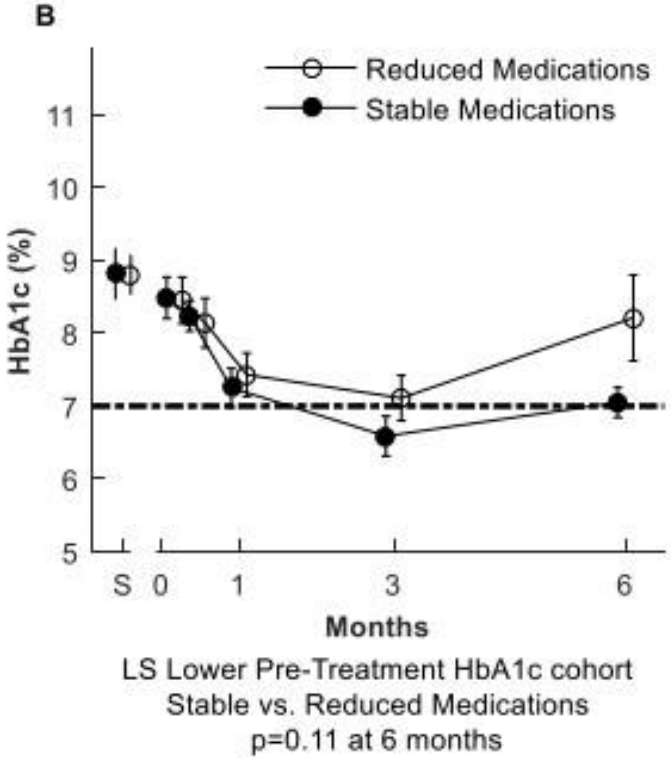
- Durable reductions in insulin
- resistance (HOMA-IR) - highlights our mechanism of action
- Reductions seen in both glucose levels and insulin levels
- Weight loss independent of
- metabolic improvement
- No lifestyle intervention in the
- study
- Consistent with observations from duodenal bypass surgery
- 27 patients at study entry & 23
- patients at 12 month follow up

DMR Lowered A1C (0-6 Month Data)

A1C change in LS-DMR subjects with higher (>10%) and lower (<10%) entry A1C

A1C change in LS-DMR subjects with lower entry A1C (<10%) where background OAD was either stable or reduced





Feinglos et al. Diabetes Care, 2016

SINGLE CATHETER FOR DUODENAL MUCOSAL RESURFACING DEMONSTRATES SIMILAR SAFETY PROFILE WITH IMPROVED PROCEDURE TIME WHEN COMPARED TO ORIGINAL DUAL CATHETER: MULTICENTER STUDY OF SUBJECTS WITH TYPE 2 DIABETES

Annieke van Baar, Jacques Deviere, Guido Costamagna, Manoel Galvao Neto, Caroline O'Hara, Shweta Mani, Leonardo Antonio Rodriguez, Rehan Haidry, Jacques Bergman

Mo1934 DDW 2017

	Dual-catheter n (%)	Single-catheter n (%)
N[b]	28	23
Overall AEs	24 (85.7)	18 (78.2)
Overall SAEs	0 (0.0)	1 (4.3)
Severe AE	0 (0.0)	1 (4.3)
Overall procedure related AEs[c]	16 (57.1)	12 (52.1)
- Possibly procedure related	9 (32.1)	4 (17.4)
- Probably procedure related	7 (25)	5 (21.7)
- Definitely procedure related	7 (25)	3 (13.0)
Device/procedure related SAEs[d]	0 (0.0)	0 (0.0)
Device/procedure related UADEs	0 (0.0)	0 (0.0)
Overall hypoglycemia[e]	2 (7.1)	0 (0.0)
Most frequent AEs by System Organ Class, n (%)[f]		
Gastrointestinal disorders[g]	17 (60.7)	13 (56.5)
Musculoskeletal and connective tissue disorders	8 (28.6)	3 (13.0)
Respiratory, thoracic and mediastinal disorders	6 (21.4)	0 (0.0)
General disorders and administration site conditions	5 (17.9)	3 (13.0)
Metabolic and nutrition disorders	4 (14.3)	2 (8.7)
Infections and infestations	4 (14.3)	2 (8.7)
Injury, poisoning and procedural complications	3 (10.7)	1 (4.3)

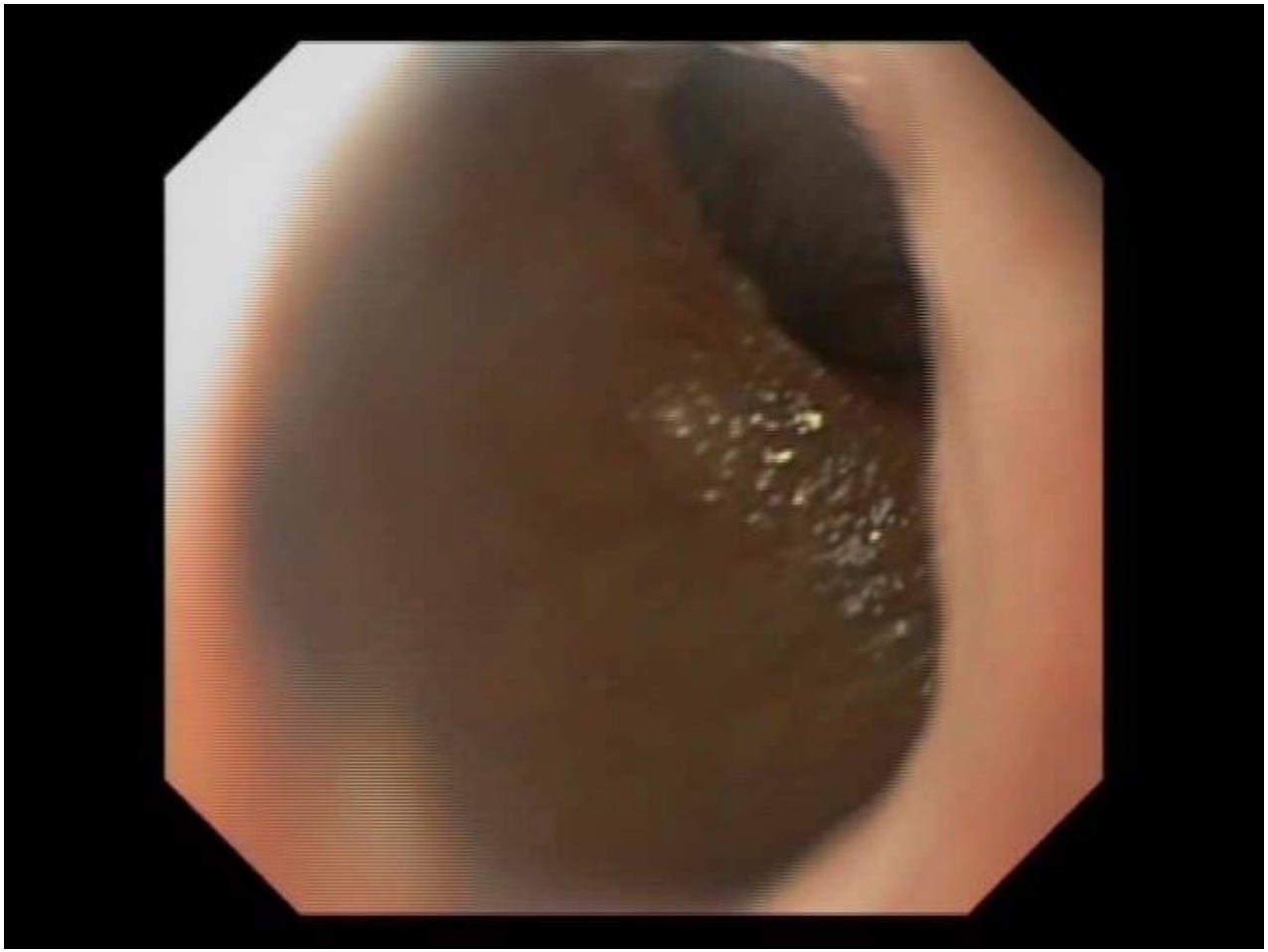
- Equal procedure success between the dual- and single-catheters;
- Reduction in procedure time and AEs with single-catheter.

Re-do techniques for RYGP

Indications:

- Weight regain (>50% and after 2 yrs)
- Dumping syndrome

TORe procedure



ORIGINAL ARTICLE

Transoral outlet reduction for weight regain after gastric bypass: long-term follow-up

Nitin Kumar, MD,[1] Christopher C. Thompson, MD[2]

Boston, Massachusetts, USA

150 patients who had regained 49.9% ± 3.6%

	3 months	6 months	12 months	24 months	36 months
No. (no. lost to follow-up)	146 (4)	144 (2)	109 (2)	63 (1)	40 (3)
Weight loss, kg	9.6 ± 0.6	10.6 ± 0.7	10.5 ± 1.2	9.0 ± 1.7	9.5 ± 2.1
BMI loss, kg/m^2	3.5 ± 0.2	3.8 ± 0.2	3.8 ± 0.4	3.3 ± 0.6	3.4 ± 0.8
EWL, %	25.0 ± 1.9	28.8 ± 2.7	24.9 ± 2.6	20.0 ± 6.4	19.2 ± 4.6
TWL, %	8.7 ± 0.5	9.6 ± 0.6	9.5 ± 0.9	8.1 ± 1.4	8.6 ± 1.5

TORe at Policlinico Gemelli Foundation

- 41 consecutive post-RYGB patients (35 female, mean age 43.7) with weight regain (BMI>30) and enlarged gastrojejunal anastomosis aperture (>15 mm) from January 2015 to August 2017
- Baseline mean BMI was 37.9 (range 31-50)
- Mean weight 107.9 kg (range 77-132)
- Before suturing the outlet rims were cauterized with pulsed Argon Plasma on 40 Watts in all patients

Bove et al. Endoscopy 2018; Abstract

TORe at Policlinico Gemelli Foundation

Trainees involved!

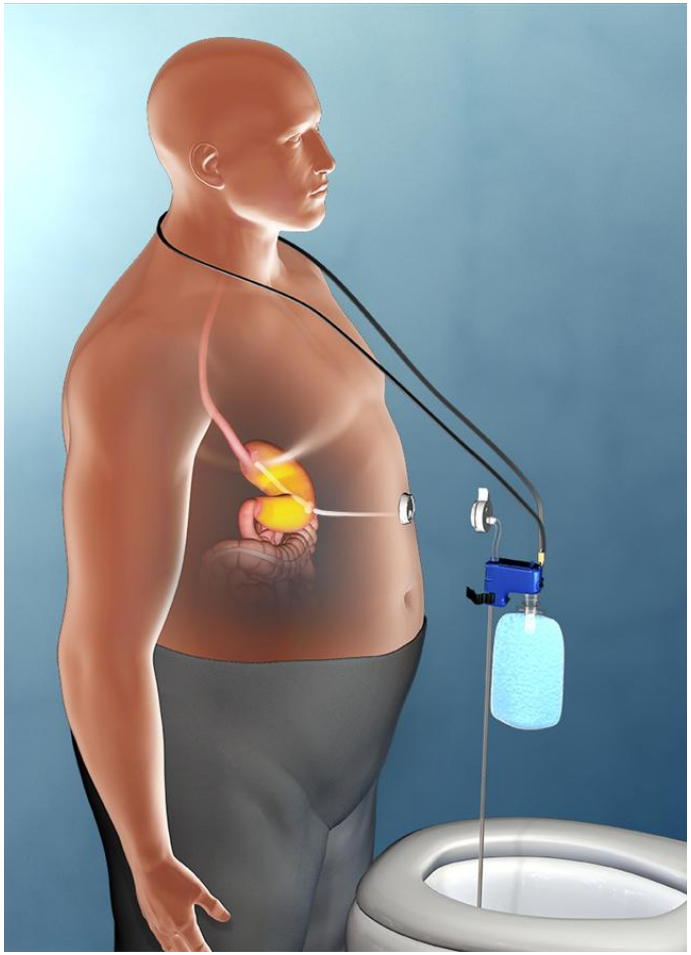
- Mean procedure time ***34 minutes*** (range 15-60)
- Mean number stitches ***2.3/patient*** (range 2-4)
- After suturing the patency of the new redone outlet was tested with standard gastroscope
- ***Complications:*** one patient developed fever due to small retrogastric collection treated with antibiotics; one **gastric perforation** that required urgent surgery
- ***Mean hospital stay 2.4 days*** (range 1-10)

Bove et al. Endoscopy 2018; Abstract

- ***Telephonic follow-up*** done at 1, 3, 6 and 12 months
- ***Mean weight loss*** at 1 month follow-up was ***10.7 kg (BMI 34.1)***, at 3 months was ***15.3 kg (BMI 32.5),*** at 6 months was ***18.5 kg (BMI 31.4)*** while at 12 months was ***19 kg (BMI 31.2).***
- Only one patient regained weight compared to baseline during the 6 months follow up.
- ***100% satiety*** after 1 month, 56.1% after 6 months, 40% after 12 months.
- ***Over 50%*** improvement of quality of life

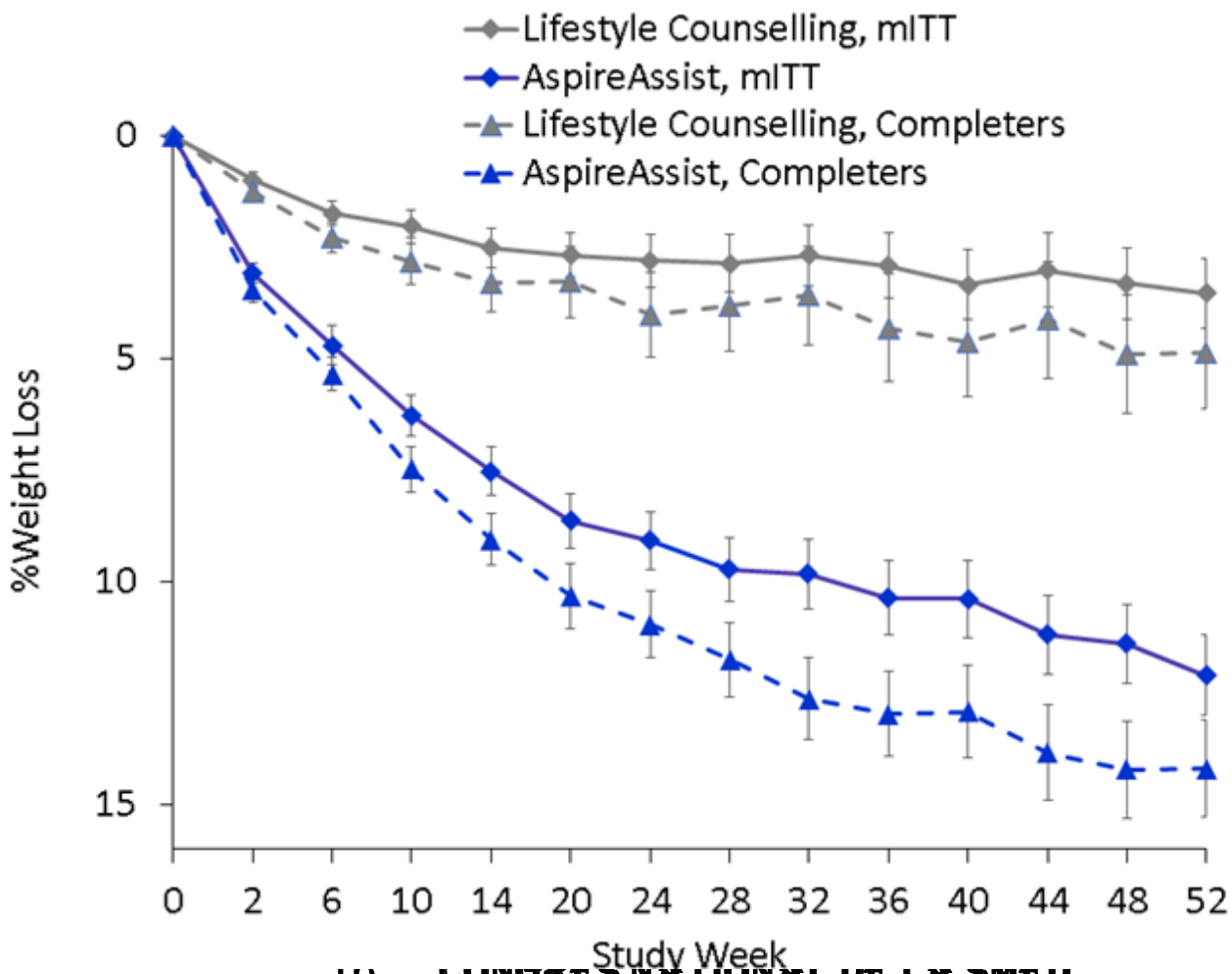
Bove et al. Endoscopy 2018; Abstract

Aspiration Therapy



16ème CONGRÈS NATIONAL DE LA SMED

Aspiration Therapy: US Pivotal Trial Results N=207



Thompson, Abu Dayyeh, Kushner, et al. DDW 2016

Norén and Forssell *BMC Obesity* (2016) 3:56
DOI 10.1186/s40608-016-0134-0

BMC Obesity

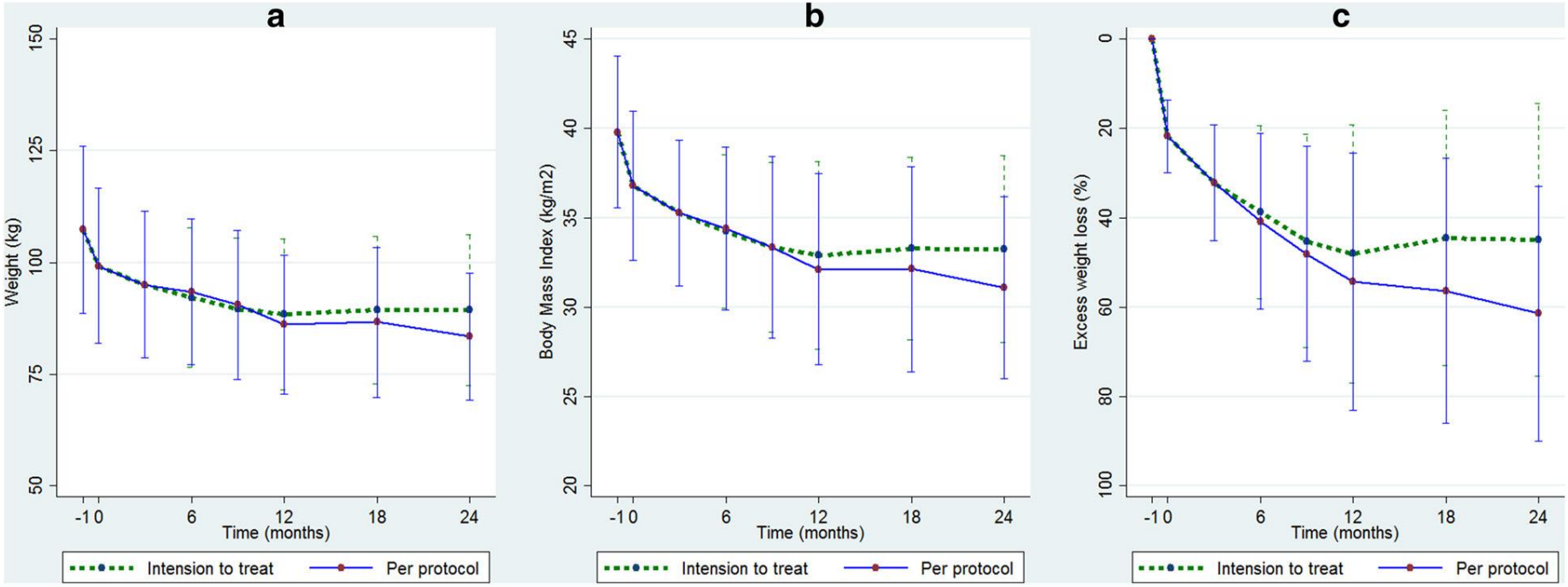
RESEARCH ARTICLE Open Access

Aspiration therapy for obesity; a safe and effective treatment

Erik Norén[1*] and Henrik Forssell[1,2]

prospective observational study with 25 pts

Mean T0 BMI was **39.8** ; after 1 y mean BMI was **32**



The ideal endoscopic treatment

- It should follow a physiological mechanism of action and preserve normal anatomy.
- It should allow the patient to eat normally and maintain normal absorption, with the intention of only reducing caloric intake.
- It should have no adverse side effects and should not burn bridges to other possible therapies.
- If the treatment is not tolerated or ineffective, the device should be removable.
- Removability may also be desired if the treatment has achieved its therapeutic goal, in which case repeatability should be an option.
- The hallmark of a successful endoscopic device is simplicity of Design.