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PALERMO, 13 - 14 MARZO 2025

**IL TRATTAMENTO
INTEGRATO DELL'OBESITÀ
CHIRURGIA, ENDOSCOPIA E FARMACI
UNA SINERGIA VINCENTE**

Weight regain o insufficient weight loss: Ruolo dell'endoscopia

AMATA MICHELE

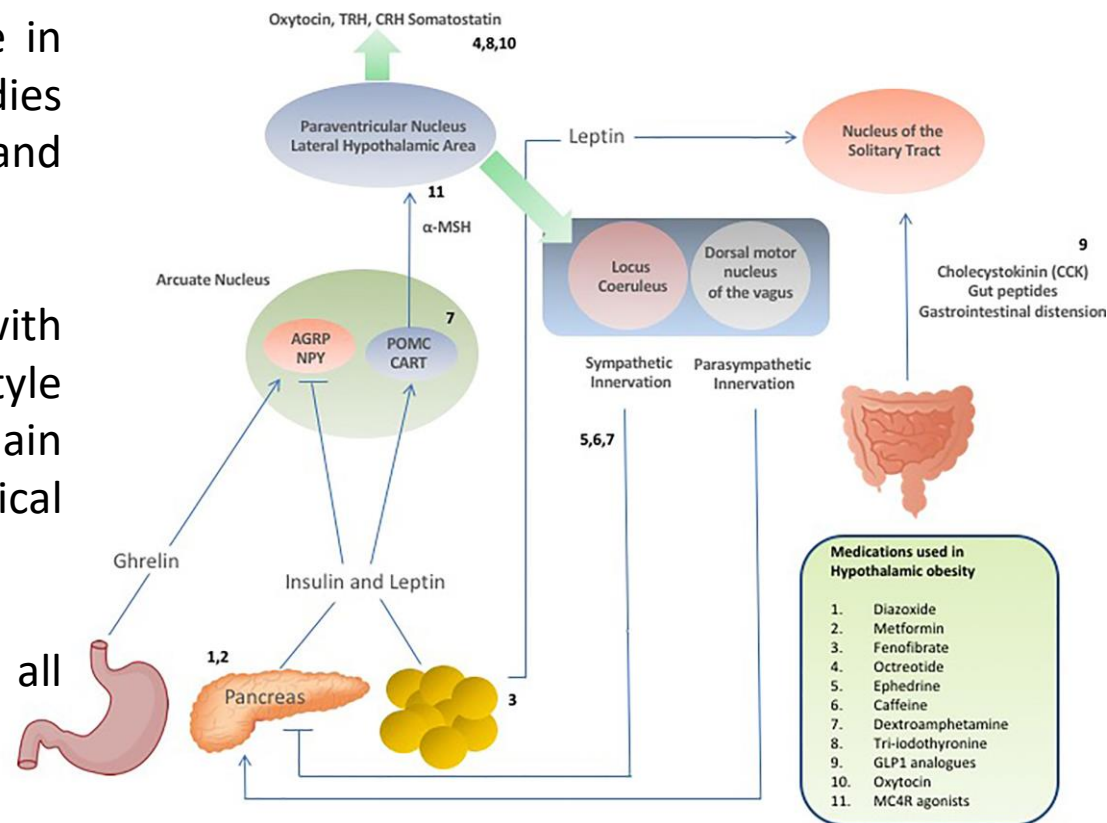
GASTROENTEROLOGY AND DIGESTIVE ENDOSCOPY UNIT
AZIENDA DI RILIEVO NAZIONALE ED ALTA SPECIALIZZAZIONE
" OSPEDALI " ARNAS CIVICO DI CRISTINA BENFRATELLI
PALERMO, ITALY

INTRODUCTION

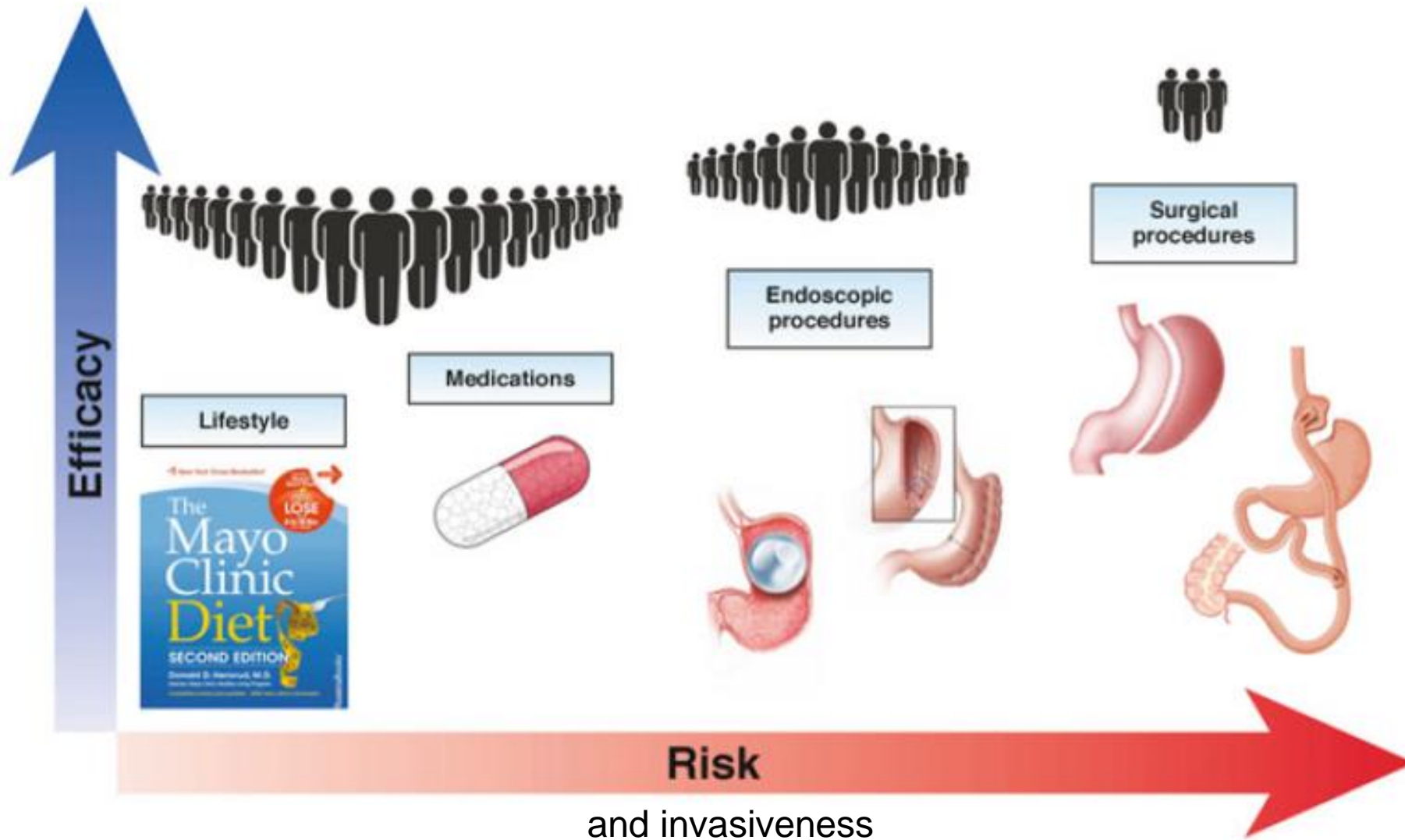
The phenomenon of weight regain (WR) is a frequent issue in bariatric surgery and has been reported in many studies analyzing obesity recurrence, its related comorbidities and worsening of health-related quality of life

The background of WR remains unknown and associated with high initial body mass index (BMI), insufficient lifestyle modification (rarely change their eating habits and remain sedentary) and lack of patient adherence to psychological support.

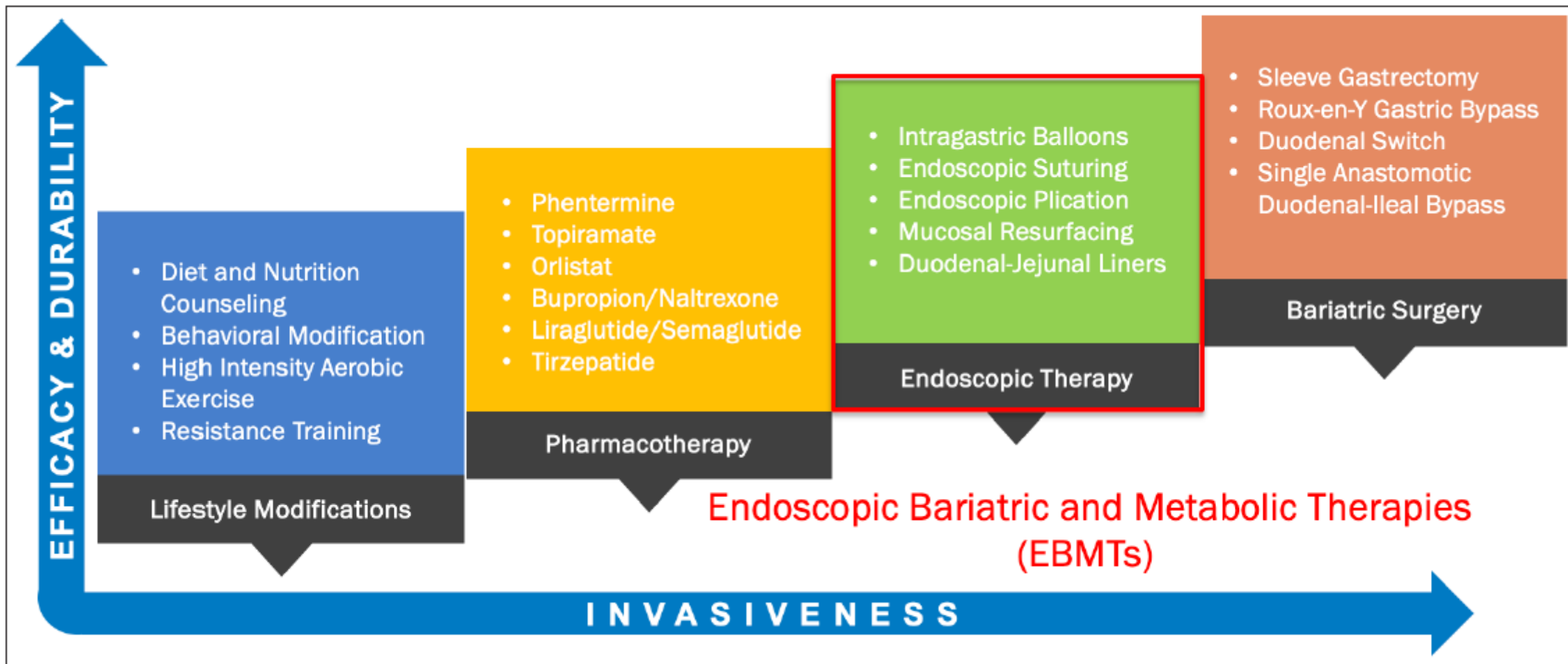
Revision bariatric surgery in the USA accounts for 15.4% of all bariatric interventions in 2018 (6% in 2011).



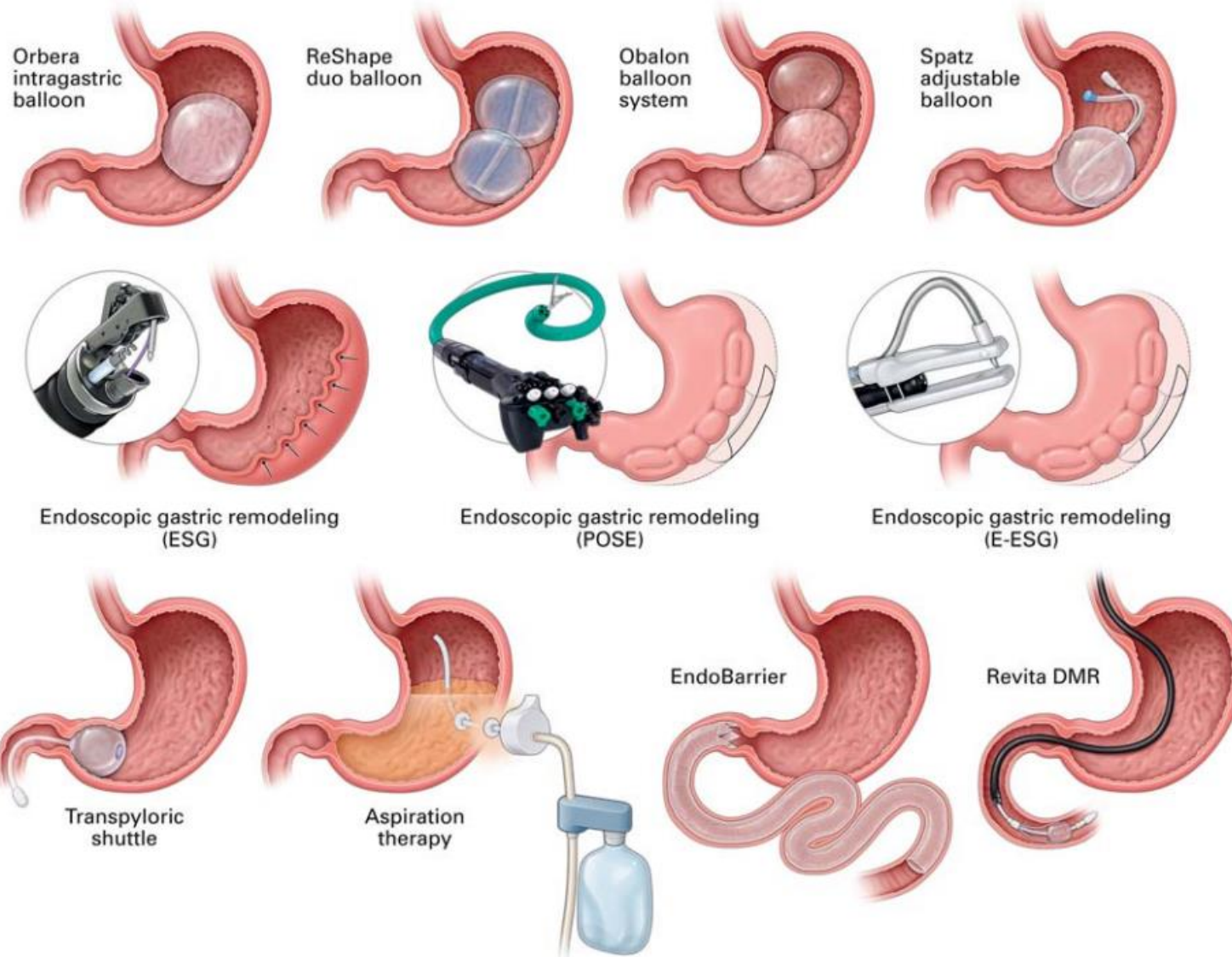
INTRODUCTION



INTRODUCTION



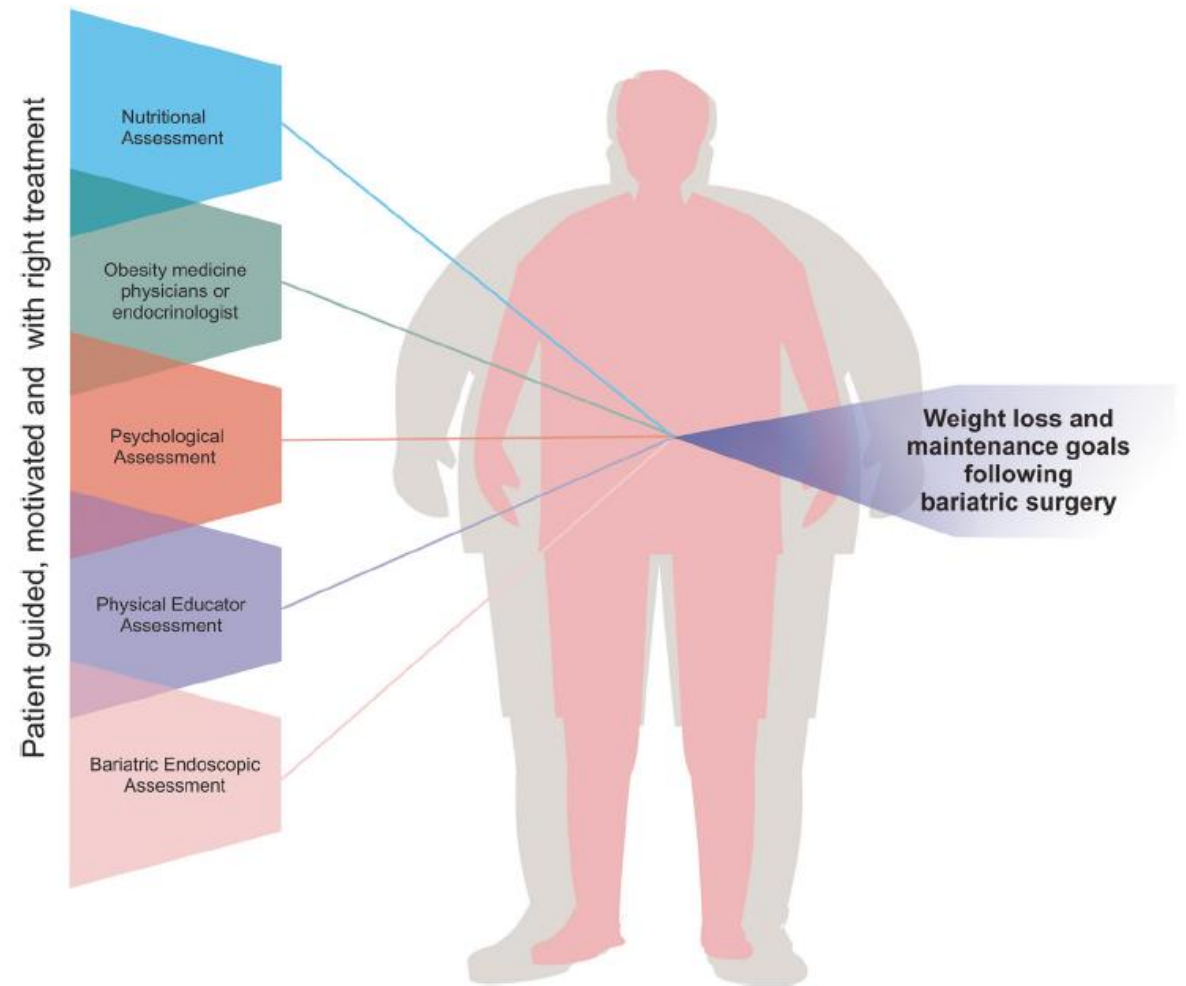
BARIATRIC ENDOSCOPIC TREATMENT



DEFINITIONS

When to think about INSUFFICIENT WEIGHT LOSS?

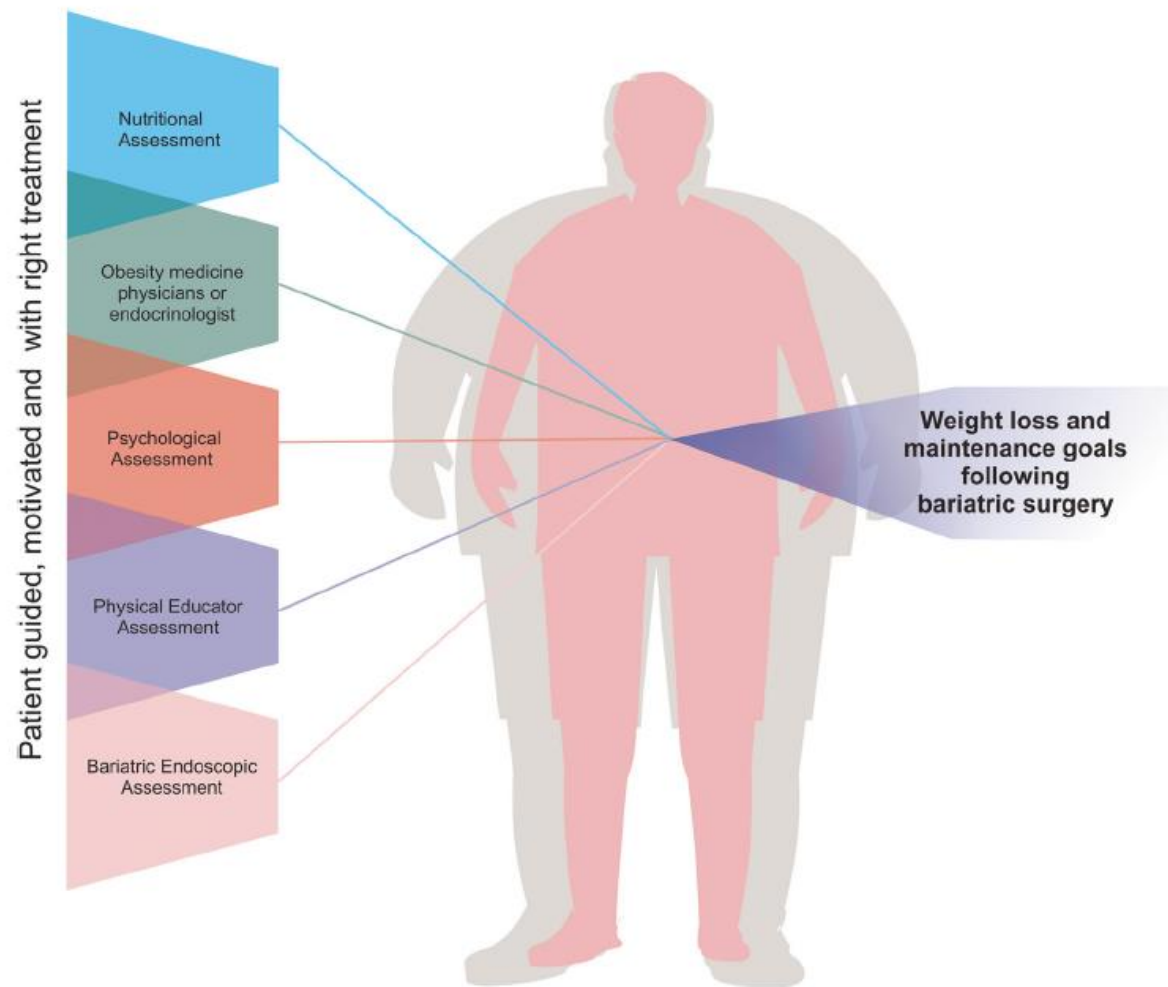
- % EWL is less than 50%
- BMI is more than 35
- * According to the Reinhold criteria



DEFINITIONS

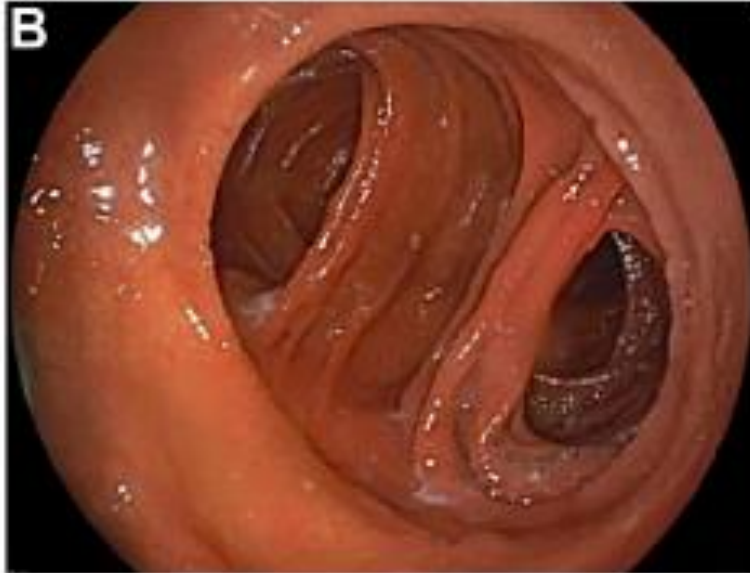
When to think about WEIGHT REGAIN?

- BMI > 35 kg/m² after adequate weight loss
- EWL increase more than 25% from nadir
- Increase > 10 Kg from nadir
- Impossibility to maintain >20% of TBWL after surgery



DEFINITIONS

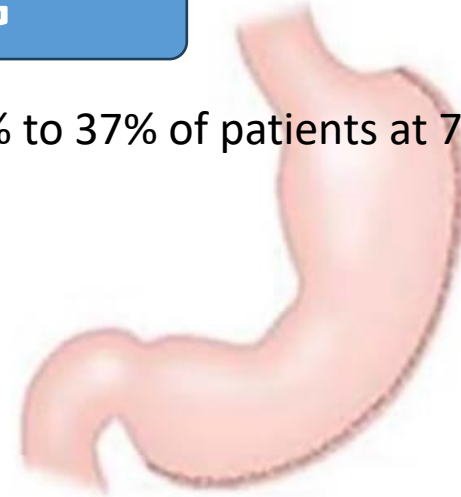
RYGB



20-30% of the weight at ten years after RYGB

LSG

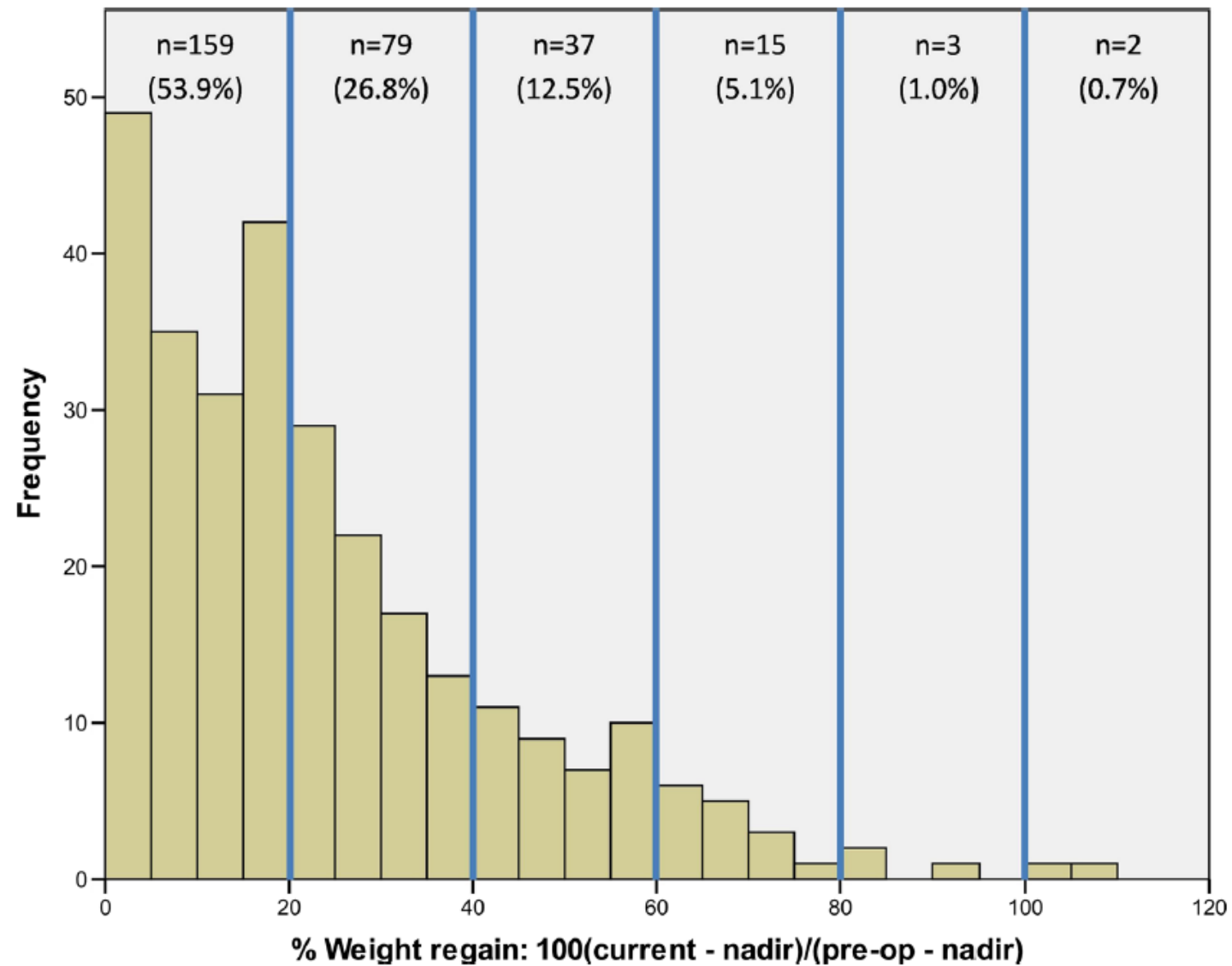
14% to 37% of patients at 7 years of follow-up



Civico Di Cristina Benfratelli
Azienda di Rilievo Nazionale ad Alta Specializzazione

INTRODUCTION

Fig. 2 Frequency distribution of percent weight regain from nadir weight. Mean (SD) weight regain for all patients was 23.4 %±20.4. Patients are further subcategorized into six cohorts



INTRODUCTION

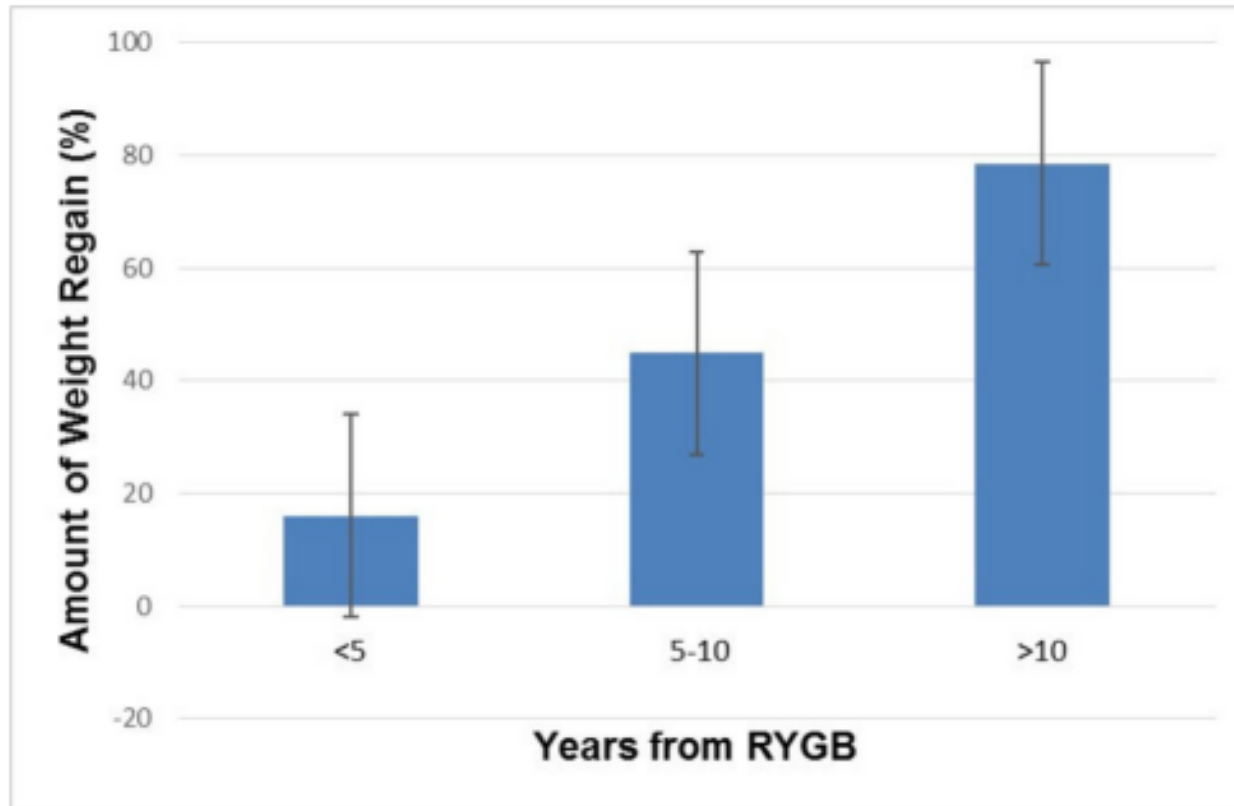


Figure 3 Amount of weight regain in patients who were <5, 5–10 and >10 years post-RYGB. RYGB, Roux-en-Y gastric bypass.

What are the new findings?

- ▶ Patients who experience weight regain following RYGB have worse QoL than those whose weights remain stable after surgery.
- ▶ Patients who experience weight regain following RYGB have similar QoL as those who have not undergone RYGB despite lower body mass index (BMI).
- ▶ Weight regain is a significant negative predictor of QoL after bariatric surgery after controlling for age, BMI and years from RYGB.

FACTORS

Table 1. Consistent correlations with weight loss failure [15]

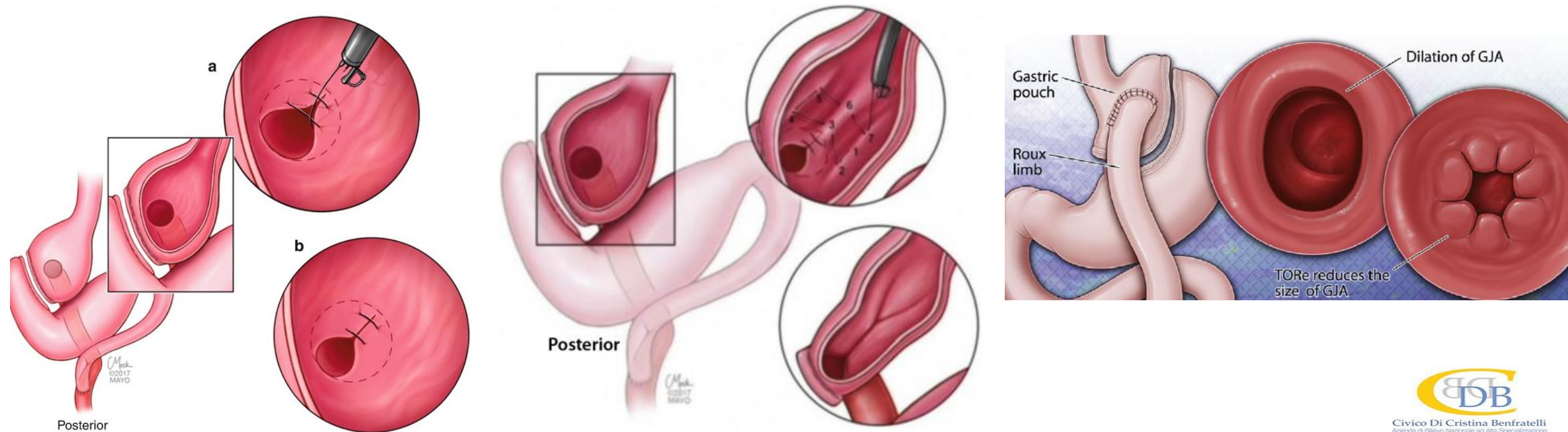
Consistent correlation	Factors
Positive	Gastro-jejunal stoma diameter, gastric volume following sleeve, anxiety, time after surgery, eating behaviors (sweets consumption, emotional eating, portion size, binge eating, loss of control/disinhibition when eating), genetics.
Negative	Postprandial serum GLP-1 level, eagerness to change physical activity habits, self-esteem, social support, fruit consumption

Transoral Outlet Reduction (TORe)

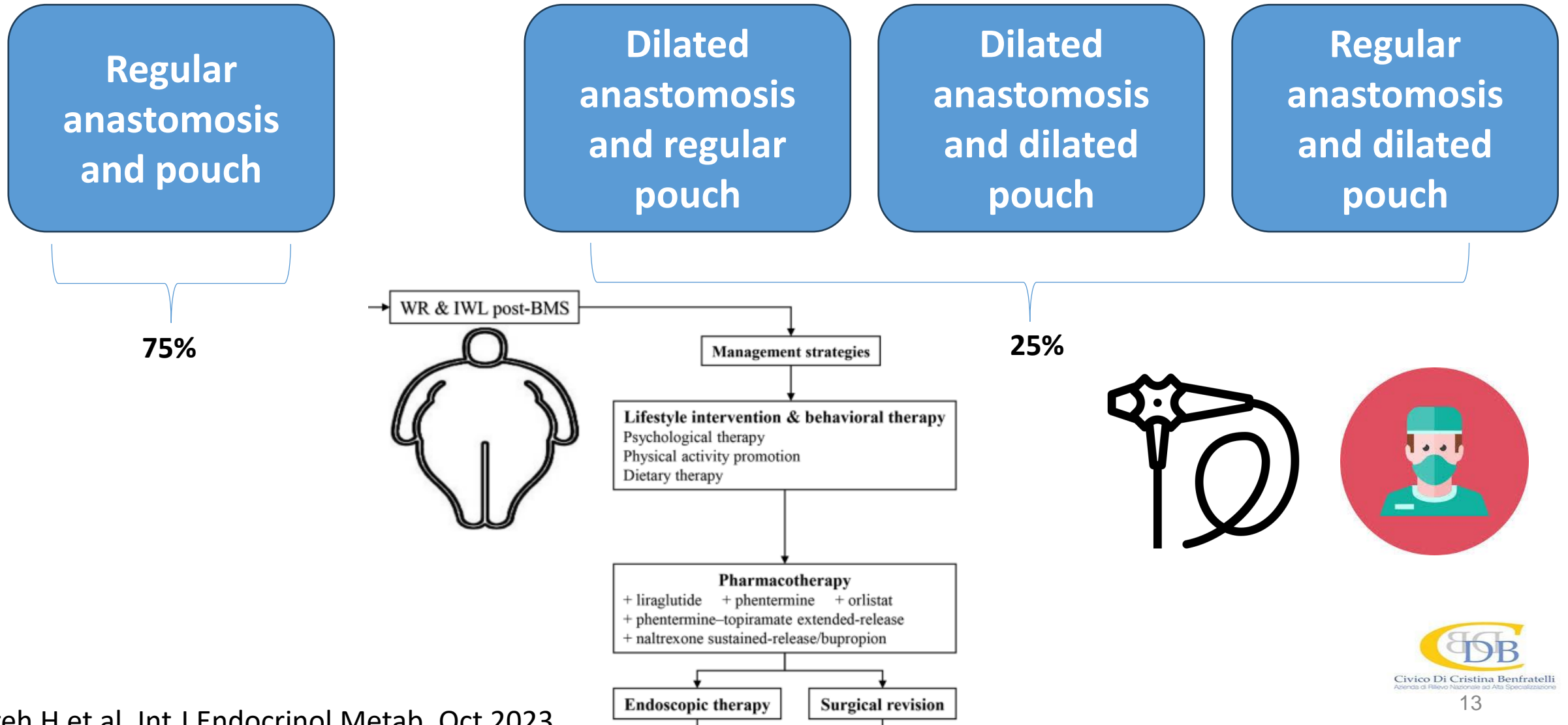
Roux-en-Y gastric bypass (RYGB), is one of the most common bariatric surgical procedures. Weight regain → 20-30% of the weight at ten years after RYGB.

FACTORS:

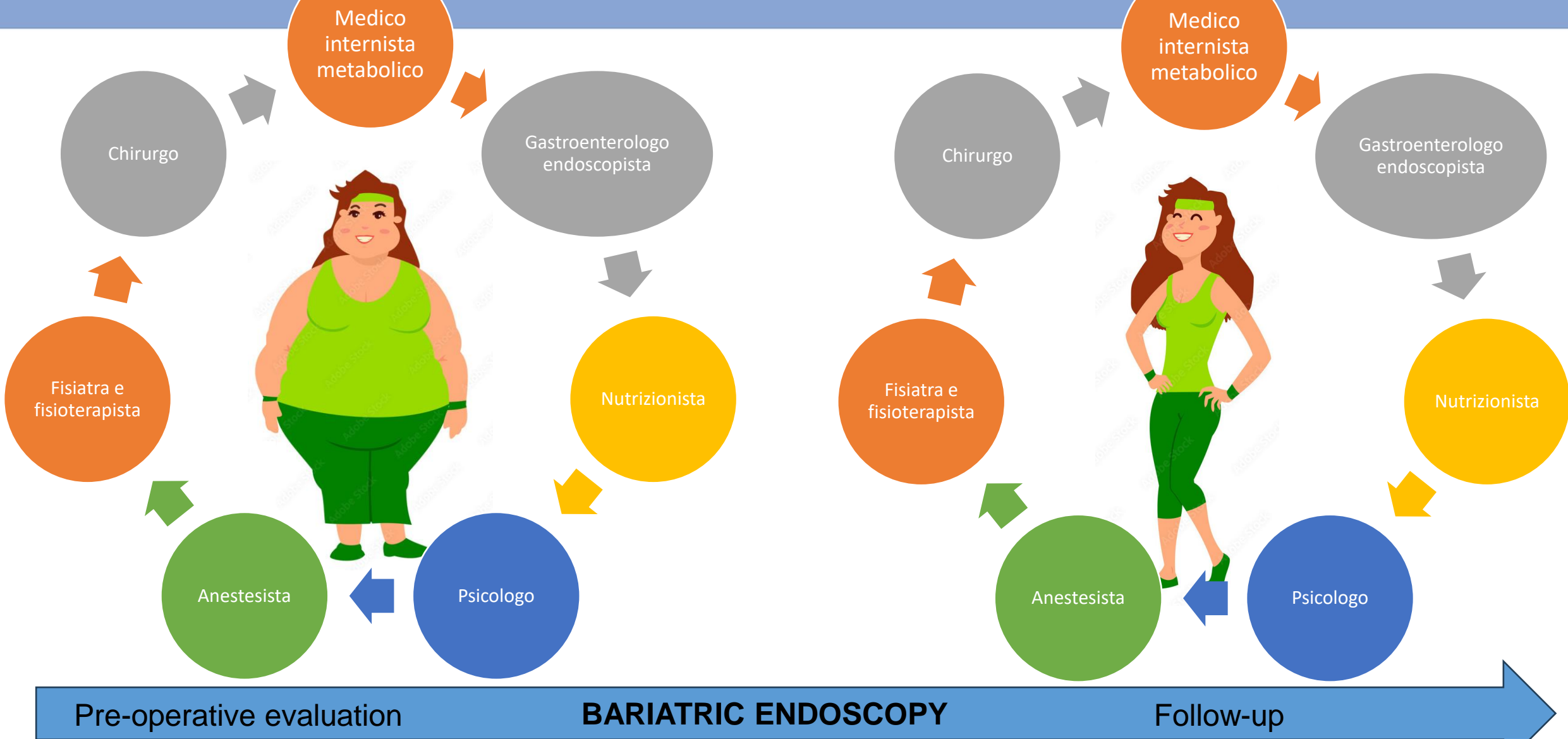
- **LIFESTYLE** → Diet – Sport - Behavior
- **ANATOMICAL** → GJ dilated > 20 mm



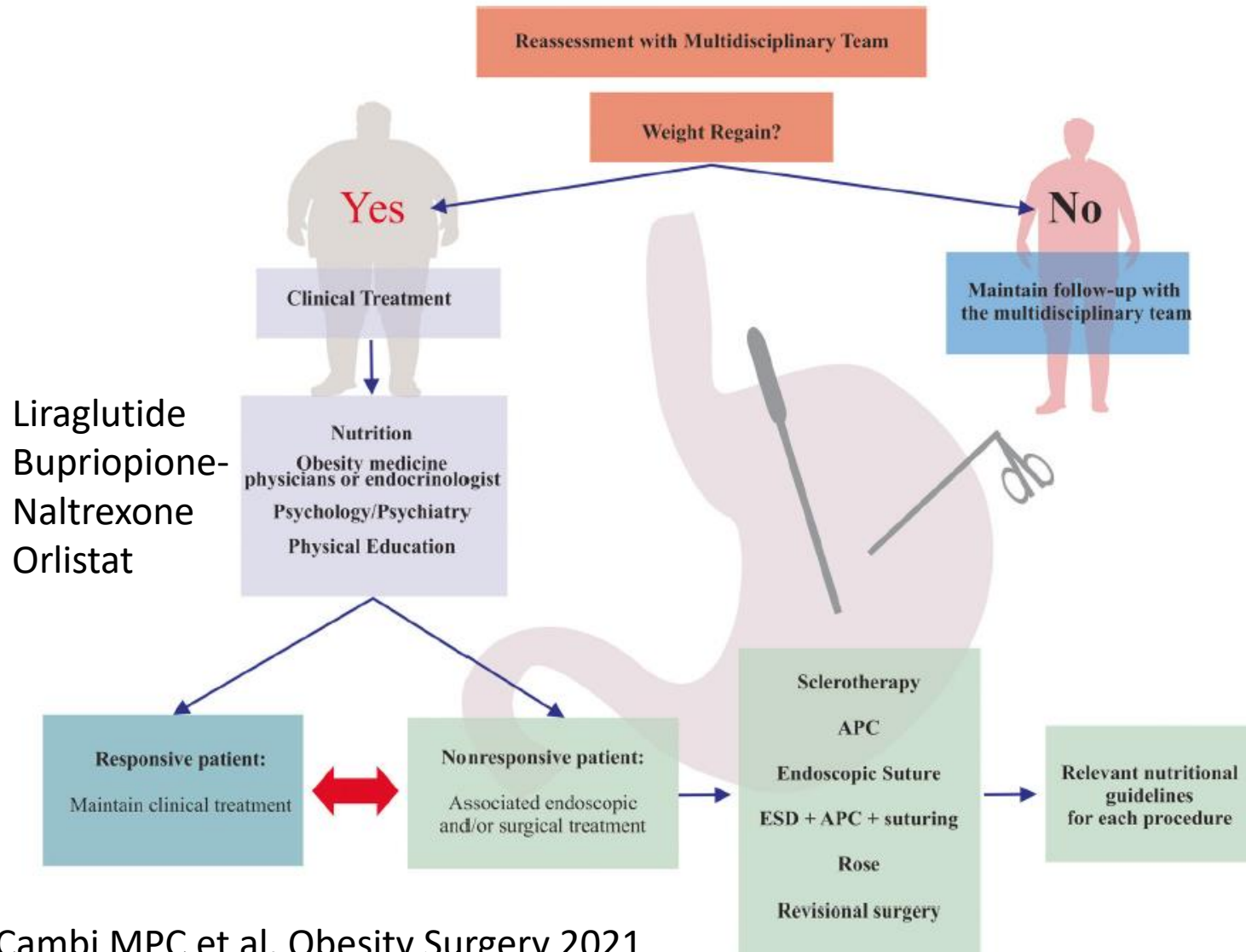
Targeting the patients



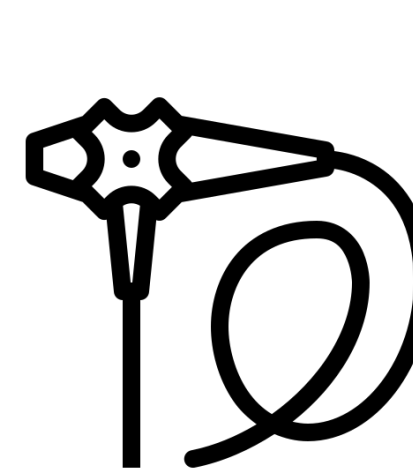
MULTIDISCIPLINARY EVALUATION



Transoral Outlet Reduction (TORe)



Morbidity and AEs 15-50%
Mortality > 2 times if compared to the primary surgery



ENDOSCOPIC TREATMENT: WHY?

ATTRACTIVE:

Minimally invasive (compared to surgery)
Outpatient procedure
Reversible
Repetable

LIMITATION:

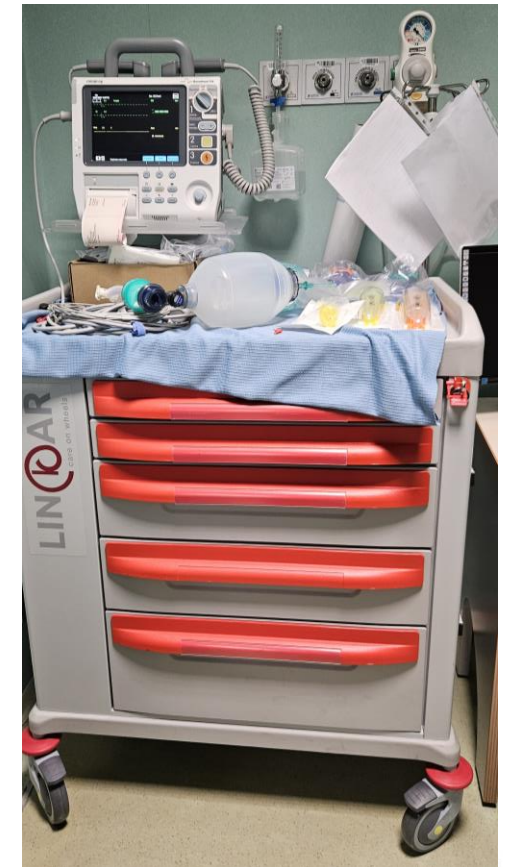
Cost?
Durable?

ENDOSCOPIA: equipment



ENDOSCOPIA: equipment

Device per anestesia e assistenza al paziente



ENDOSCOPIA: equipment

Disposizione della sala endoscopica

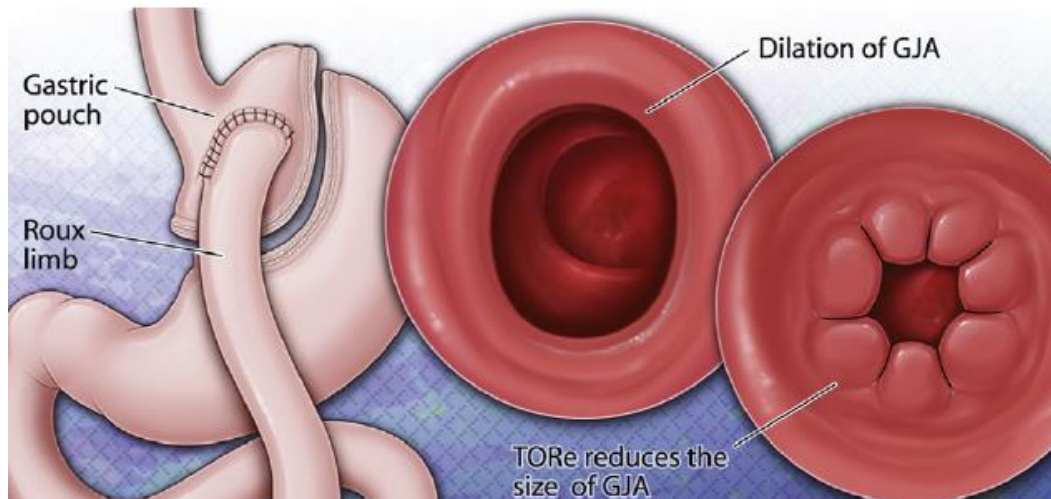
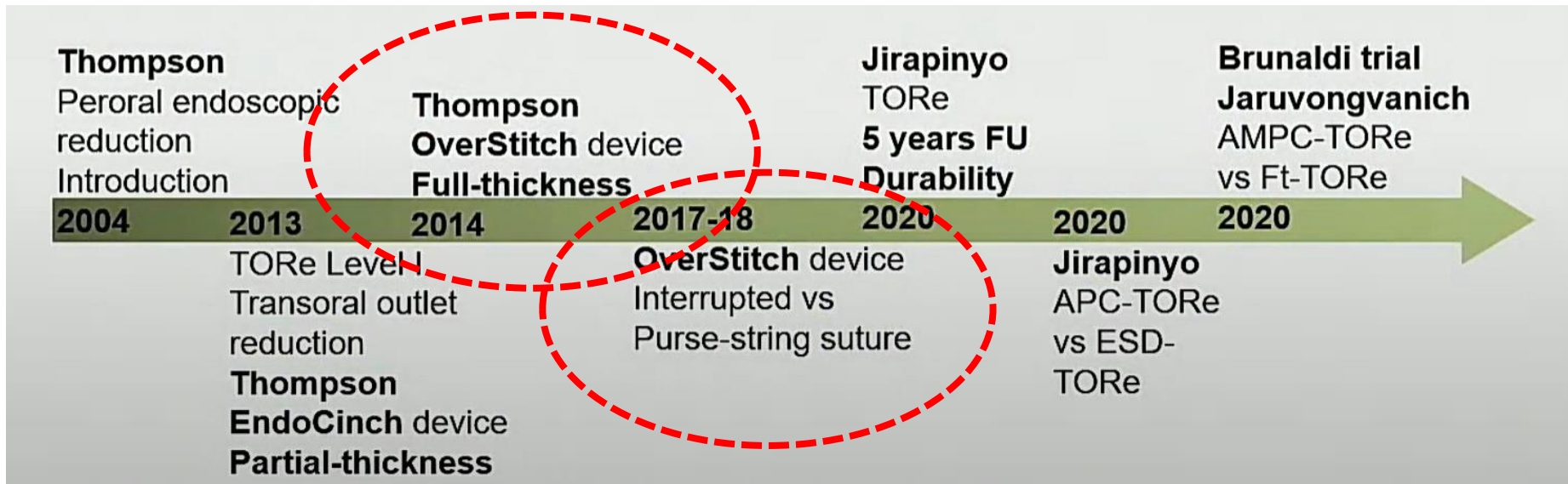




ENDOSCOPIA: equipment



Transoral Outlet Reduction (TORe)

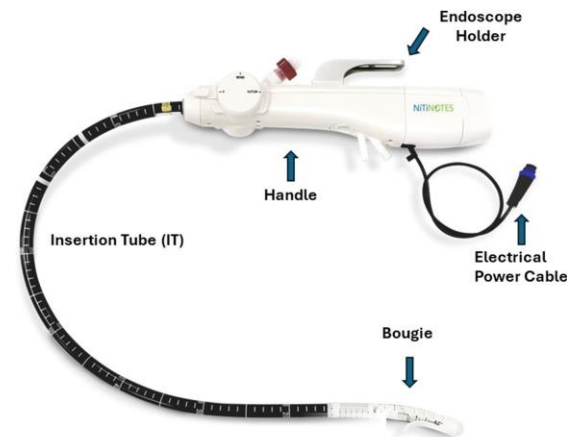


Endoscopic suturing devices

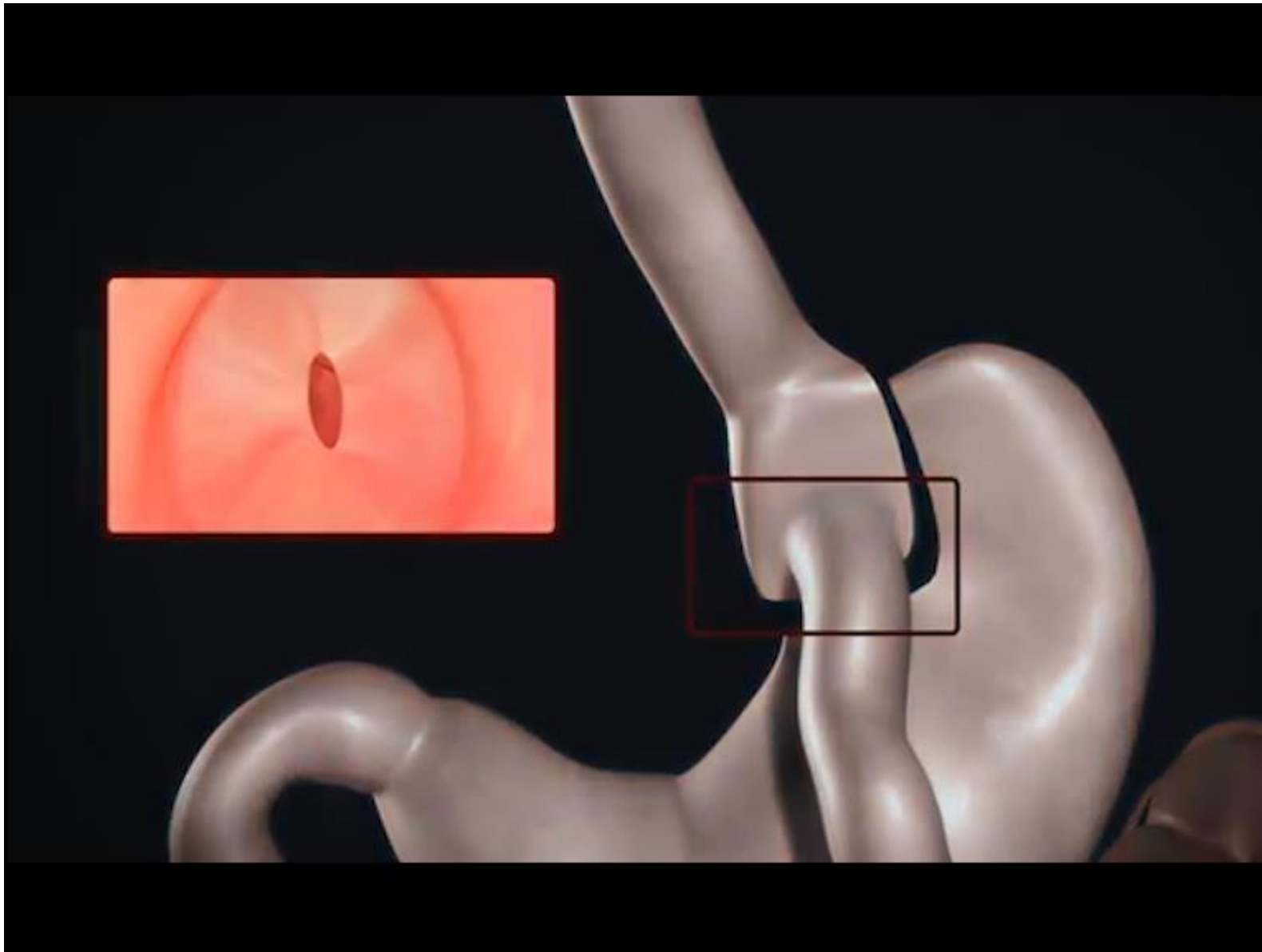
- The advent and widespread availability of a commercially available Endoscopic Ssuturing Systems has led to the creation of novel endoscopic procedures, increasing the field of the interventional endoscopy

Devices

- 1) Apollo Overstitch (Apollo Endosurgery)
- 2) Endomina (Endo Tools)
- 3) Pose 2
- 4) Endozip



Transoral Outlet Reduction (TORe)



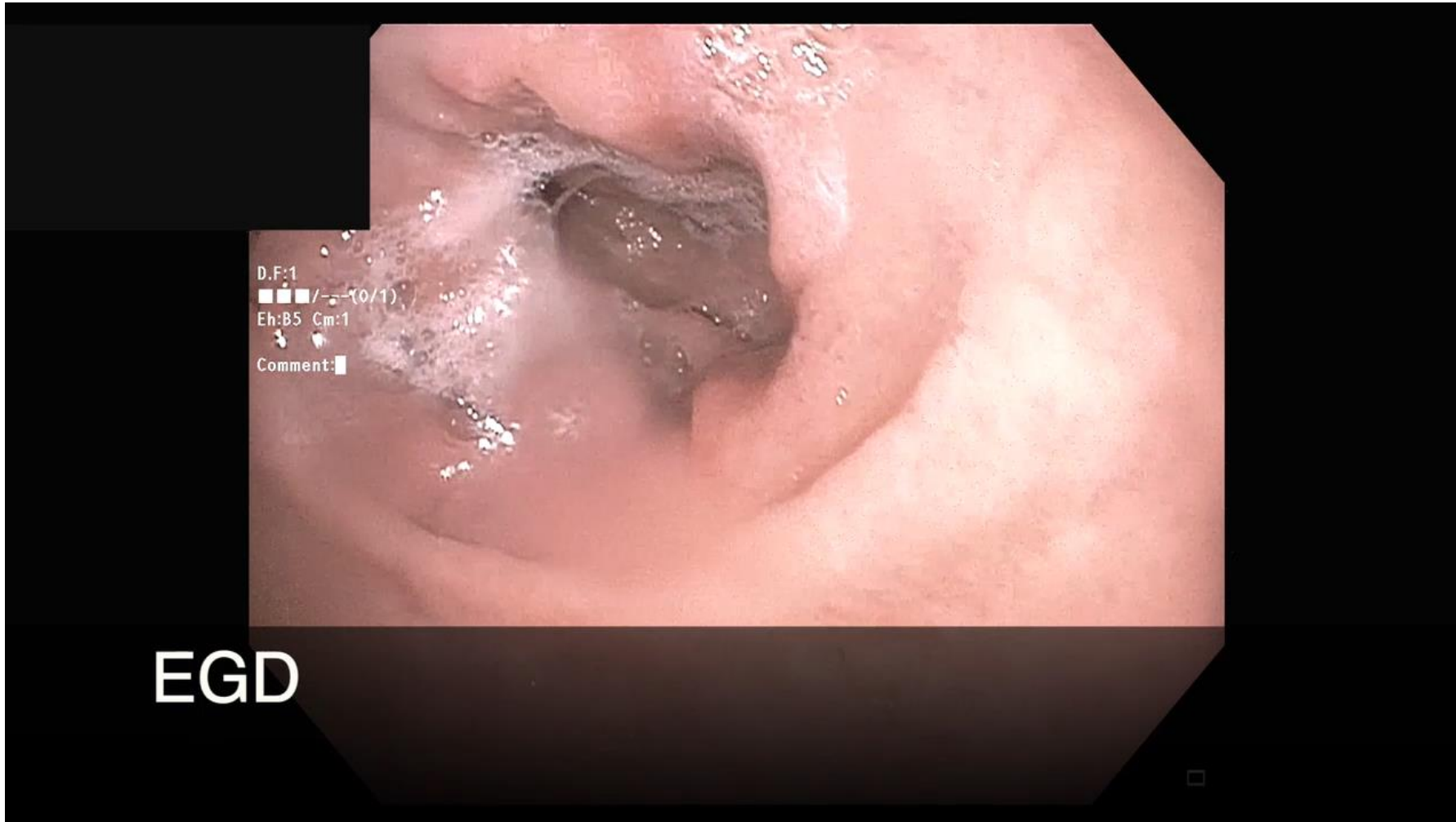
FR-TORe

Full-thickness stitches using endoscopic suturing device (Overstitch, Apollo Endosurgery)

Adverse Events are typically mild/moderate and include:

- Abdominal Pain
- Mucosal Lacerations
- Bleeding

Transoral Outlet Reduction (TORe)

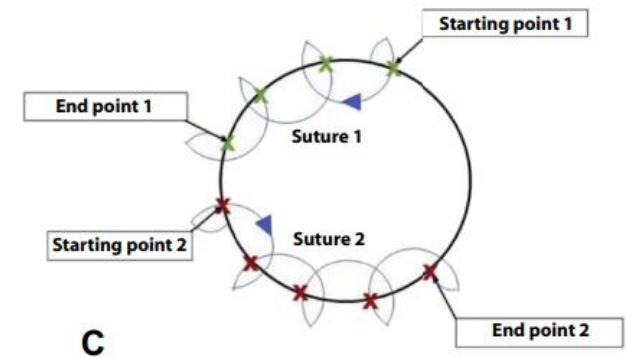


FT-TORe

OverStitch Sx

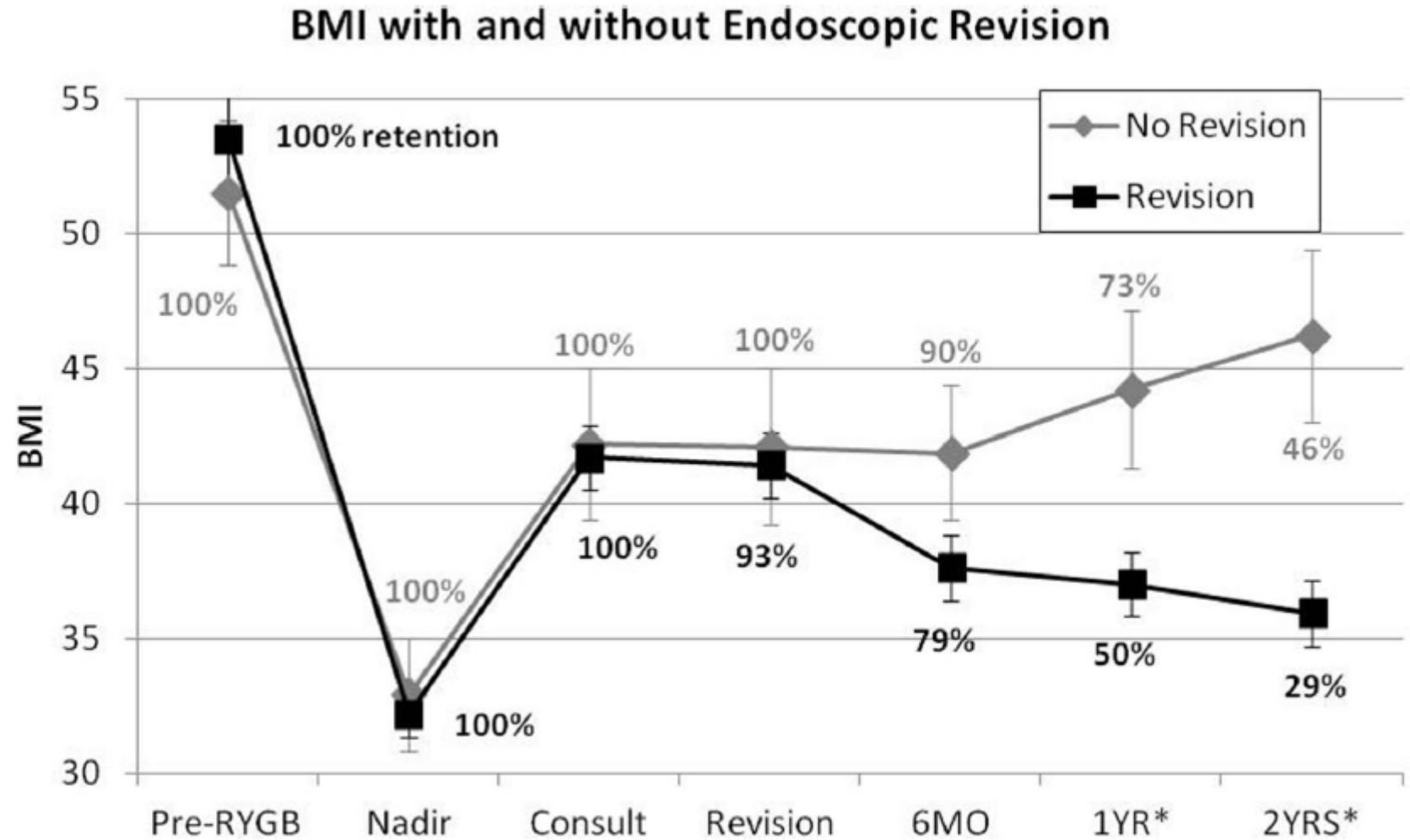
Therapeutic gastroscopie

2 running sutures

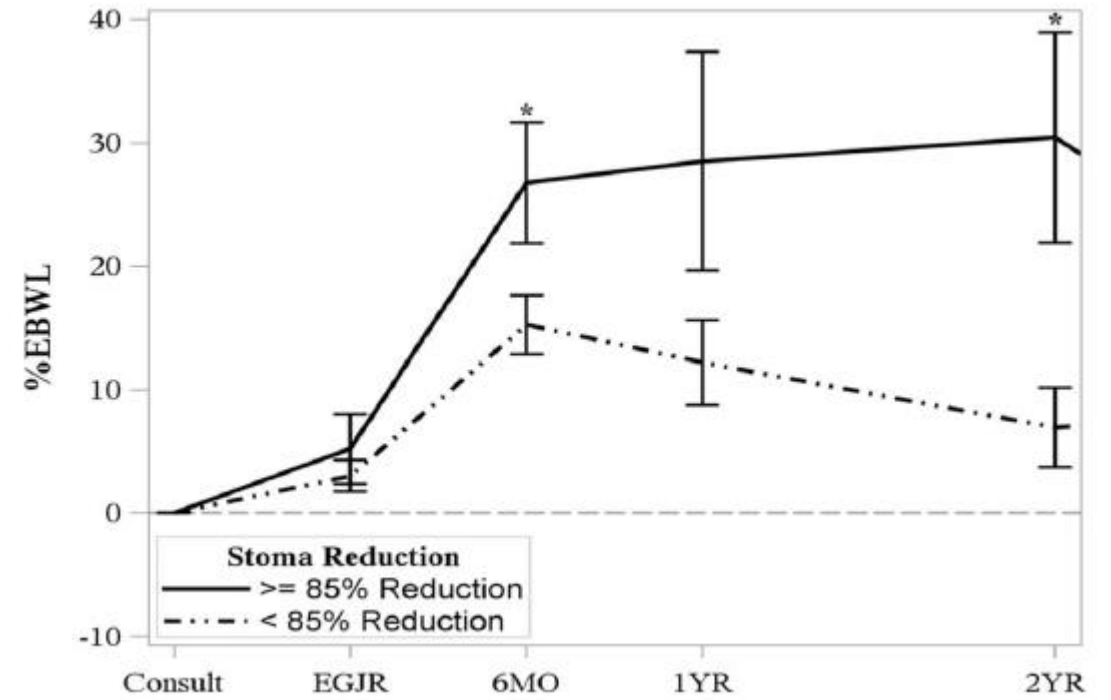
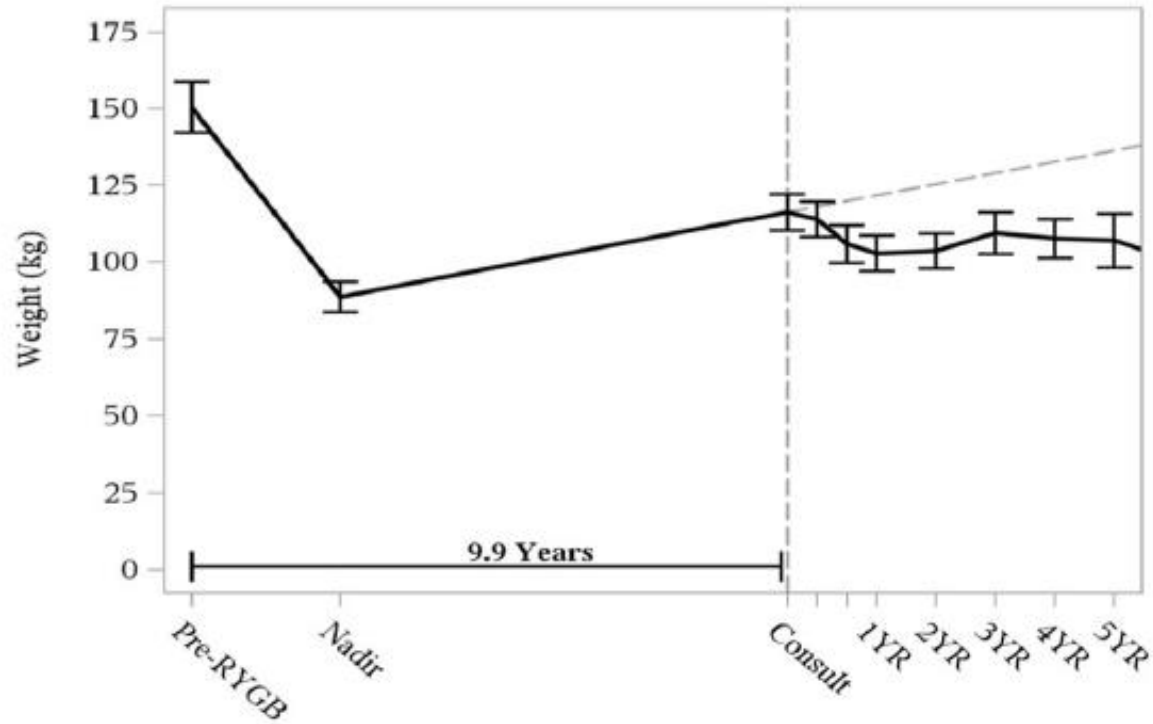


Transoral Outlet Reduction (TORe)

Fig. 2 Means and standard errors of BMI over time;
* $p < 0.05$. Percentages next to data points indicate percentage of patients retained in follow-up



Transoral Outlet Reduction (TORe)



Transoral Outlet Reduction (TORe)

Kumar N et al, 2014 → 59 pt with superficial suture (EndoCinch) vs 59 pt with Apollo OverStitch

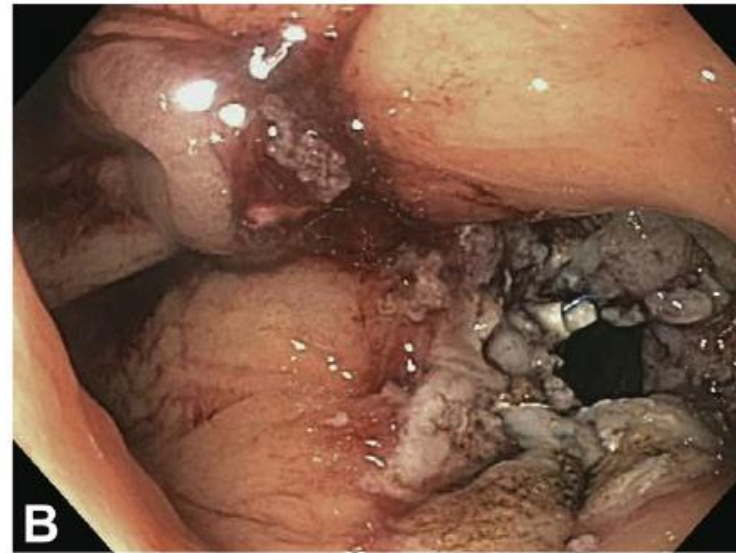
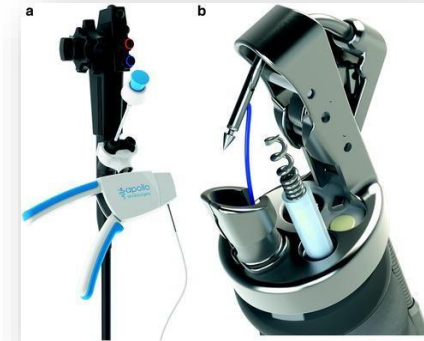
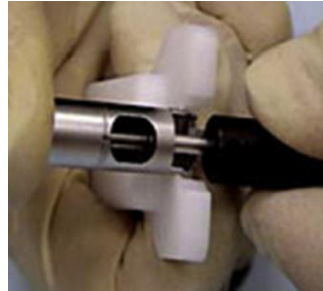


Figure 1. A, Dilated gastrojejunal anastomosis (GJA). B, GJA after transoral outlet reduction (TORe) with a full-thickness suturing device. C, GJA 6 months after full-thickness TORe.

Transoral Outlet Reduction (TORe)

TABLE 1. Baseline characteristics (matched cohort)

	Superficial (n = 59)	Full-thickness (n = 59)	P value
Sex,* no.	3 M/56 F	15 M/44 F	< .01
Age, y	48.8 ± 1.1†	49.9 ± 1.3	.52
Diabetes mellitus, %	17.2	23.7	.49
Lost weight regained, %	32.5 ± 3.0	40.9 ± 3.2	.06
Weight regained, kg	18.7 ± 1.8	18.6 ± 1.5	.97
Before TORe BMI	40.4 ± 1.0	41.1 ± 1.3	.67
Before TORe GJA, mm	24.3 ± 0.8	24.8 ± 0.9	.68
Before TORe pouch, mm	51.8 ± 1.5	49.7 ± 2.4	.46

M, Male; F, female; TORe, transoral outlet reduction; BMI, body mass index; GJA, gastrojejunal anastomosis.

*Statistical significance.

†(Mean ± SEM)

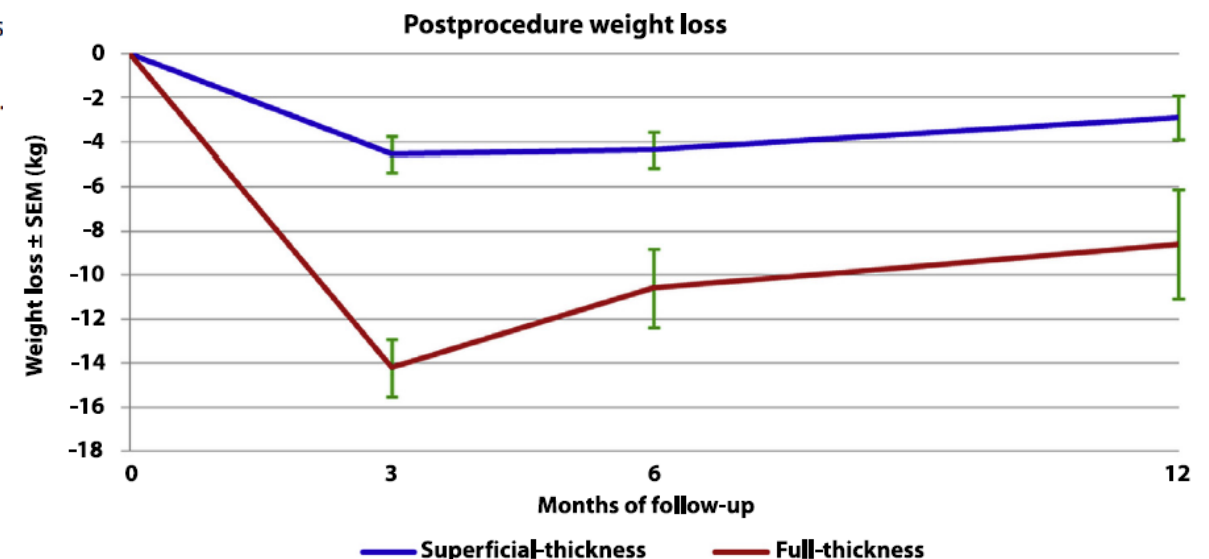
TABLE 3. Procedure characteristics

	Superficial (n = 59)	Full-thickness (n = 59)	P value
Total stitches	3.5 ± 0.1*	3.8 ± 0.2	.18
Stitches, GJA†	3.3 ± 0.1	2.5 ± 0.2	< .01
Stitches, pouch†	0.3 ± 0.1	1.2 ± 0.2	< .01
After-TORe GJA, mm	6.9 ± 0.2	7.1 ± 0.3	.58
After-TORe pouch, mm	48.6 ± 2.0	46.4 ± 2.1	.45

GJA, Gastrojejunal anas

*(Mean ± SEM)

†Statistical significance.



Transoral Outlet Reduction (TORe)

Kumar N et al, 2016 → n: 150 patients , found that the mean TBWL was:

- At 1 year: 10.5 ± 1.2 Kg;
- At 2 year: 9.0 ± 1.7 Kg;
- At 3 year: 9.5 ± 2.1 Kg

Jirapinyo P et al, 2020 → 331 patients with baseline BMI of 40 ± 9 kg/m²

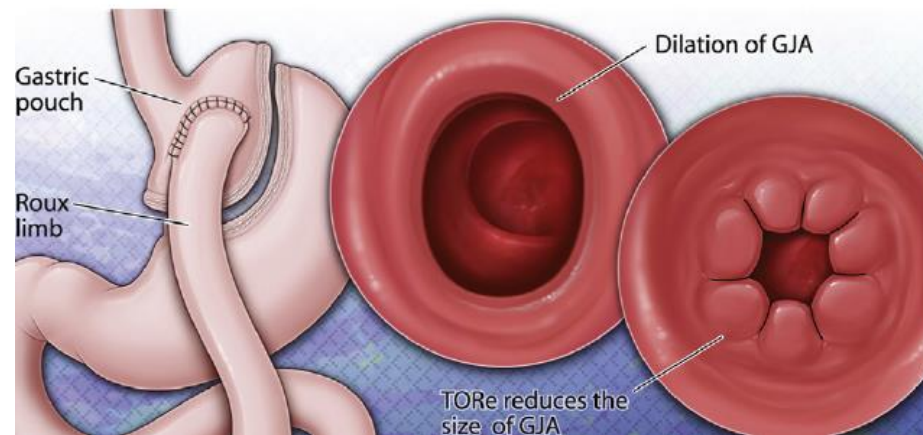
- Efficacy at 5 years: 8.8% TBWL (62% maintained 5% TWL)
- TORe successful at preventing weight gain in 77% of cohort



Figure 2. Weight loss trend. TORe, transoral outlet reduction.

TABLE 2. Total weight loss with and without pouch reduction

	No pouch reduction	Pouch reduction	P value
12 mo	6.7 ± 1.5	9.9 ± 1.2	.10
24 mo	9.6 ± 2.4	6.5 ± 1.7	.28
36 mo	7.5 ± 2.3	7.2 ± 2.1	.94



Ft-TORe with APC: outcomes

Meta-analysis with 26 studies and 1148 patients:

- 320 patients ft-TORe + APC
- 828 patients ft-TORe alone

FT-Tore + APC vs FT-Tore
24.2% vs 11.7% EWL, P<.001

Fig. 3 Mean absolute weight loss after full-thickness endoscopic suturing to treat weight regain

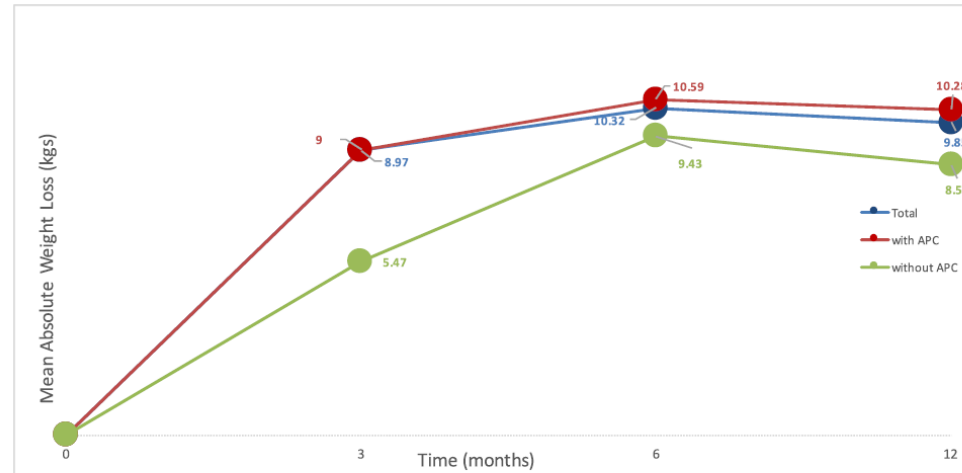
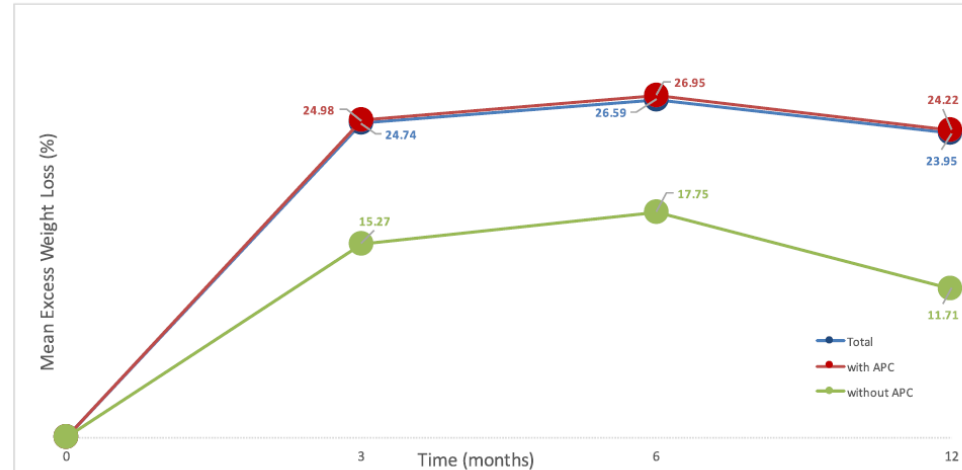
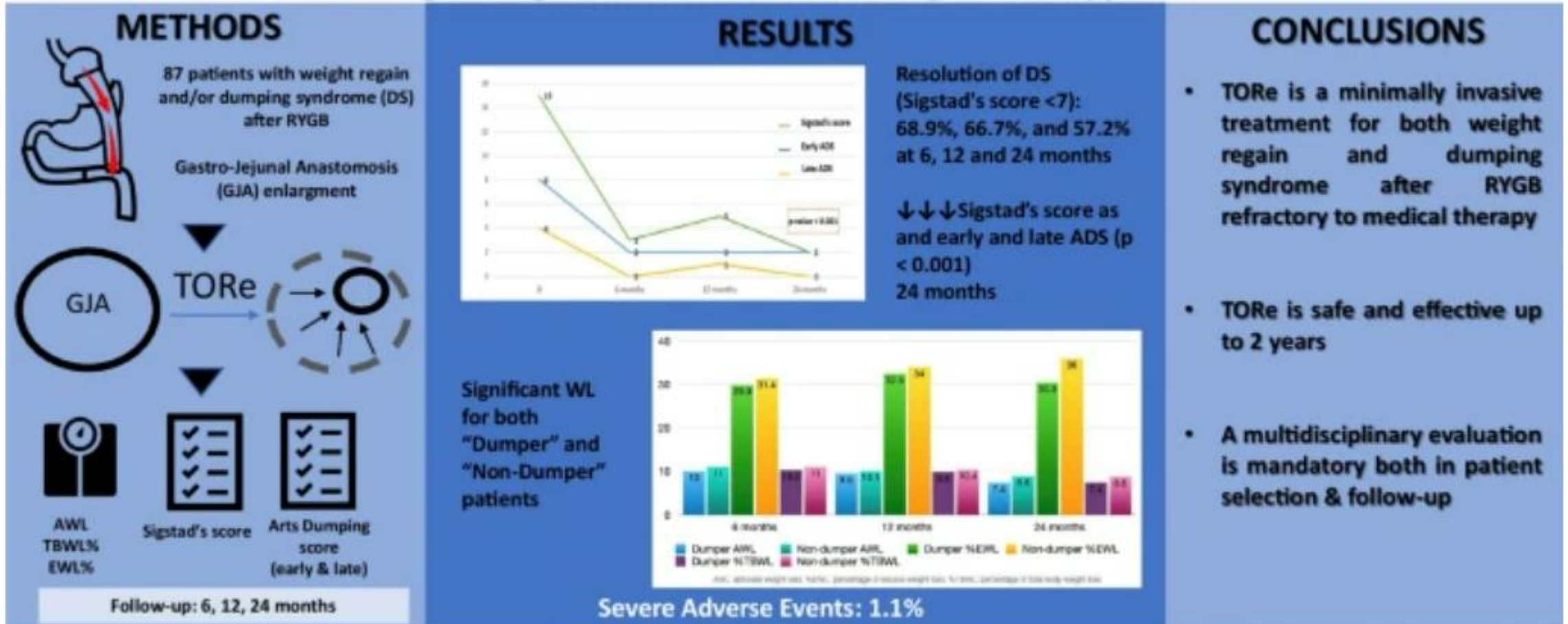


Fig. 4 Mean excess weight loss after full-thickness endoscopic suturing to treat weight regain



Ft-TORe with APC: outcomes

Long-term outcomes of Transoral Outlet Reduction for dumping syndrome and weight regain after Roux-en-Y gastric bypass.



Ft-TORe with APC: outcomes

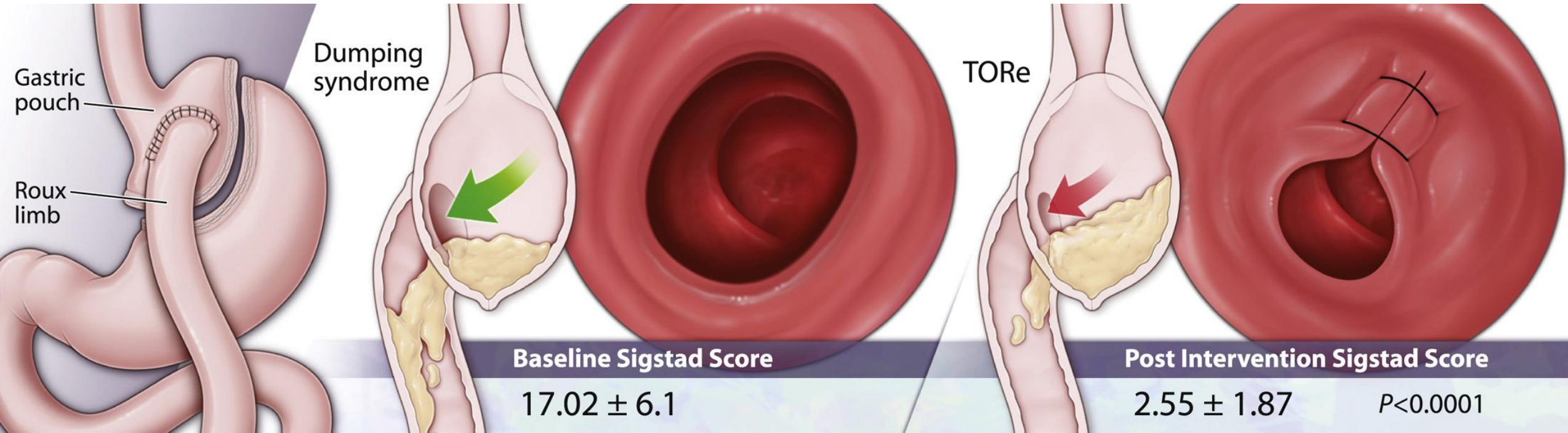


TABLE 3. Postintervention results

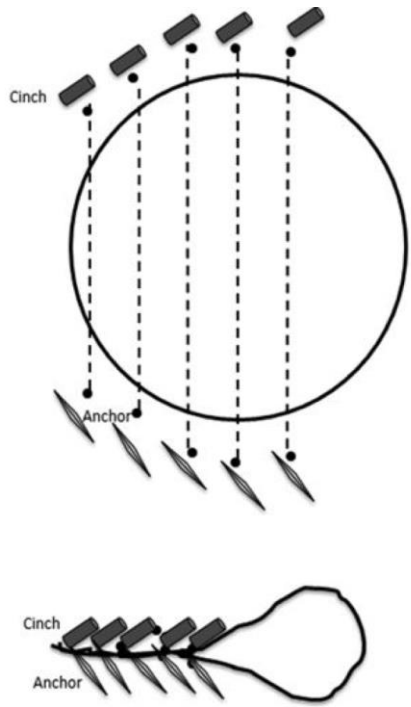
Variable	At 3 months	Mean difference	P value
Sigstad score	2.55 ± 1.87	-14.5 ± 5.5	<.0001
Weight, kg	89.4 ± 1.96	-9.3 ± 3.8	<.0001

Values are mean ± standard deviation.

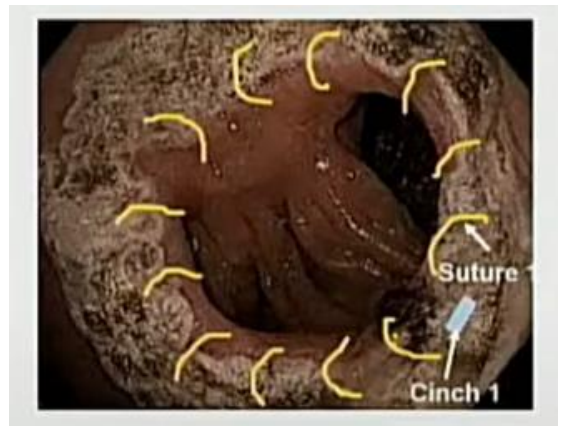
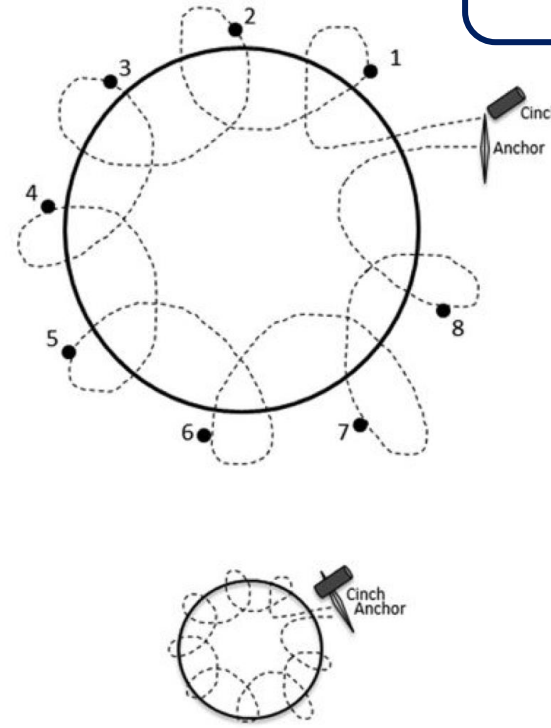
Suture patten in TORe

Interrupted stitch vs Purse-string

Improvement at 12 months
EWL 11.7% vs 19.8% (p<0.001)
TBWL 6.4% vs 8.6% (p0.02)



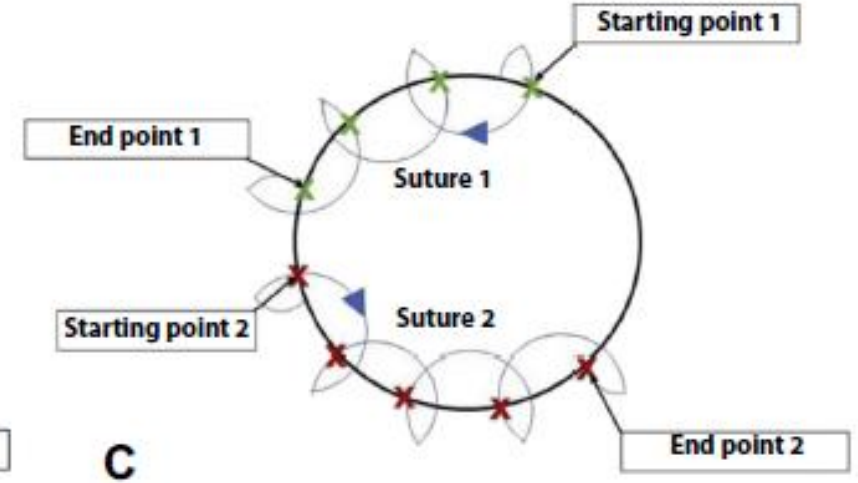
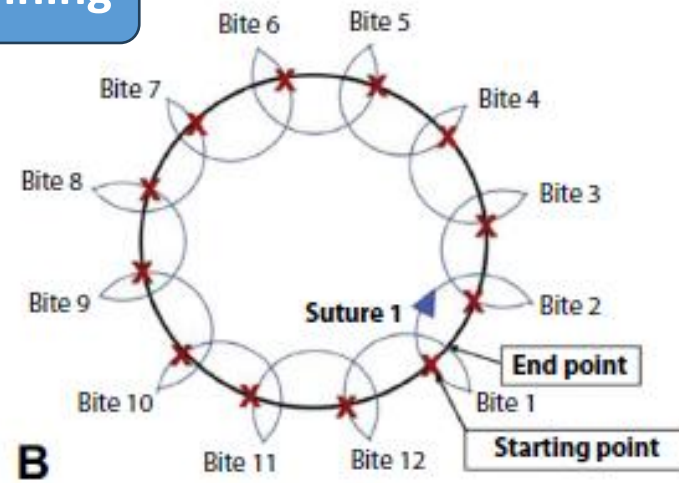
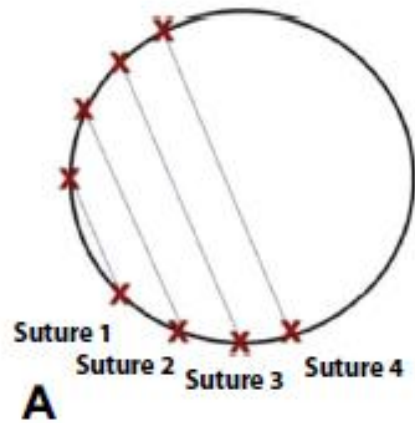
Interrupted stitches until size ≤ 12 mm



Single purse-string suture from 3 o'clock, counterclockwise
Hydrostatic ballon to 8-12 mm \rightarrow Suture tightened

Suture patten in TORe

Interrupted stitch, Purse-string and running



Single purse-string suture from 3 o'clock, counterclockwise
Hydrostatic ballon to 8-12 mm → Suture tightened

Transoral Outlet Reduction (TORe)

TORe purse-string versus interrupted stitch technique

Schulman et al



Figure 4. Transoral outlet reduction following an interrupted suture pattern (A) or purse-string pattern which requires suture tightening and cinching over a balloon (B) followed by balloon withdrawal (C).

Suture patten in TORe

TABLE 2. Procedure characteristics and outcome differences between patients undergoing interrupted versus purse-string suturing patterns

	Interrupted group (n = 48 at 3 mo, n = 44 at 12 mo)	Purse-string group (n = 164 at 3 mo, n = 131 at 12 mo)	P value
Stitches, GJA	9.7 ± 5.6	8.7 ± 2.8	.70
Percent total weight loss			
3 mo	8.0 [6.5, 9.4]†	8.6 [6.8, 9.4]	.41
12 mo	6.4 [4.7, 8.1]	8.6 [7.3, 9.4]	.02*
Percent excess weight loss			
3 mo	16.7 [11.0, 21.3]	20.5 [18.0, 23.0]	.39
12 mo	11.7 [5.8, 20.0]	19.8 [16.4, 23.0]	<.001*
Total weight loss, kg			
3 mo	11.3 [6.7, 17.7]	9.5 [8.6, 10.5]	.32
12 mo	7.8 [5.5, 9.3]	9.5 [7.7, 11.2]	.04*
Percent regained weight lost			
3 mo	33.3 [23.5, 56.0]	44.7 [24.5, 65.1]	.56
12 mo	27.8 [11.4, 60.0]	40.2 [31.9, 48.5]	.02*

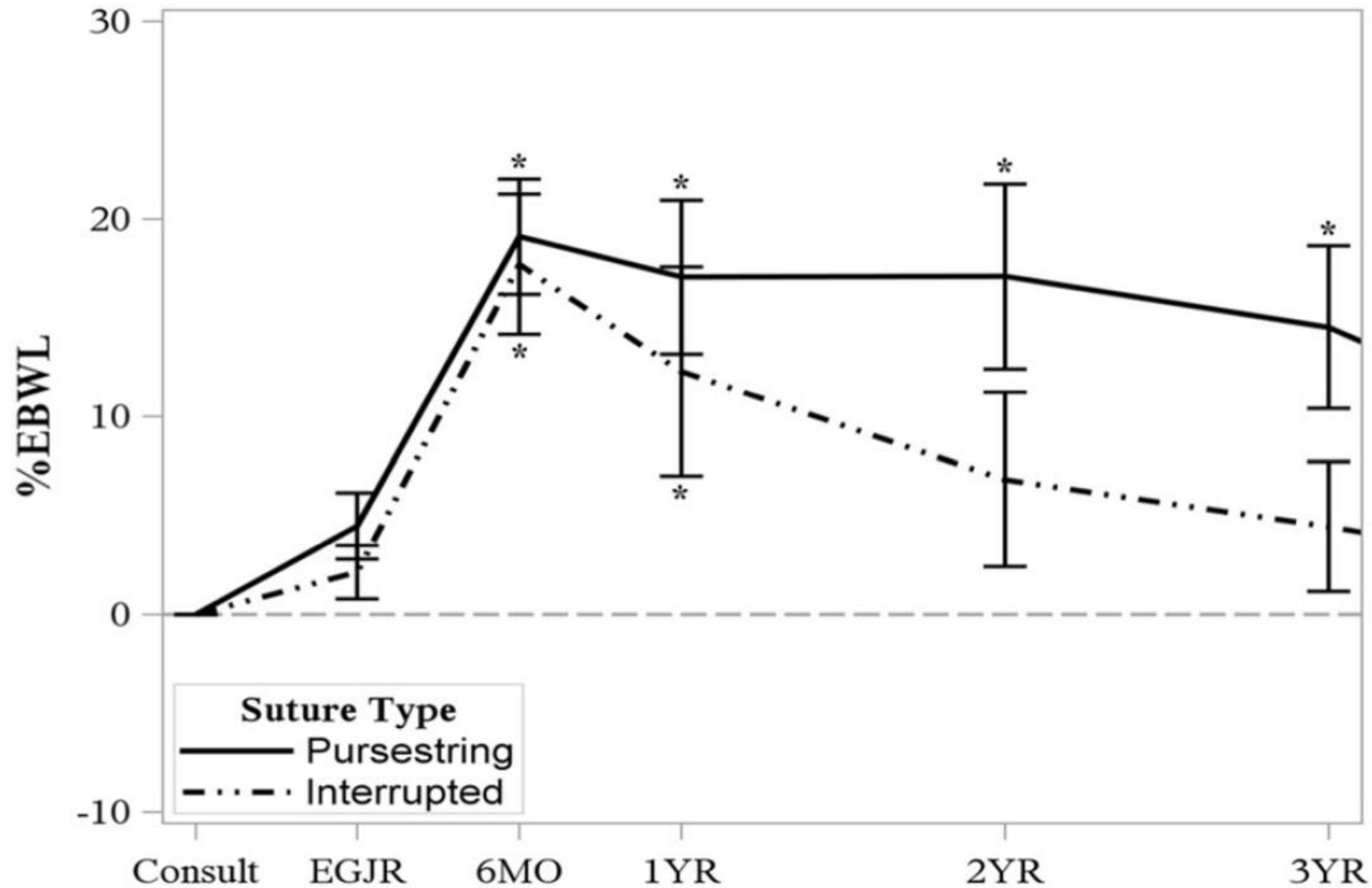
GJA, Gastrojejunal anastomosis.

*Denotes $P < .05$.

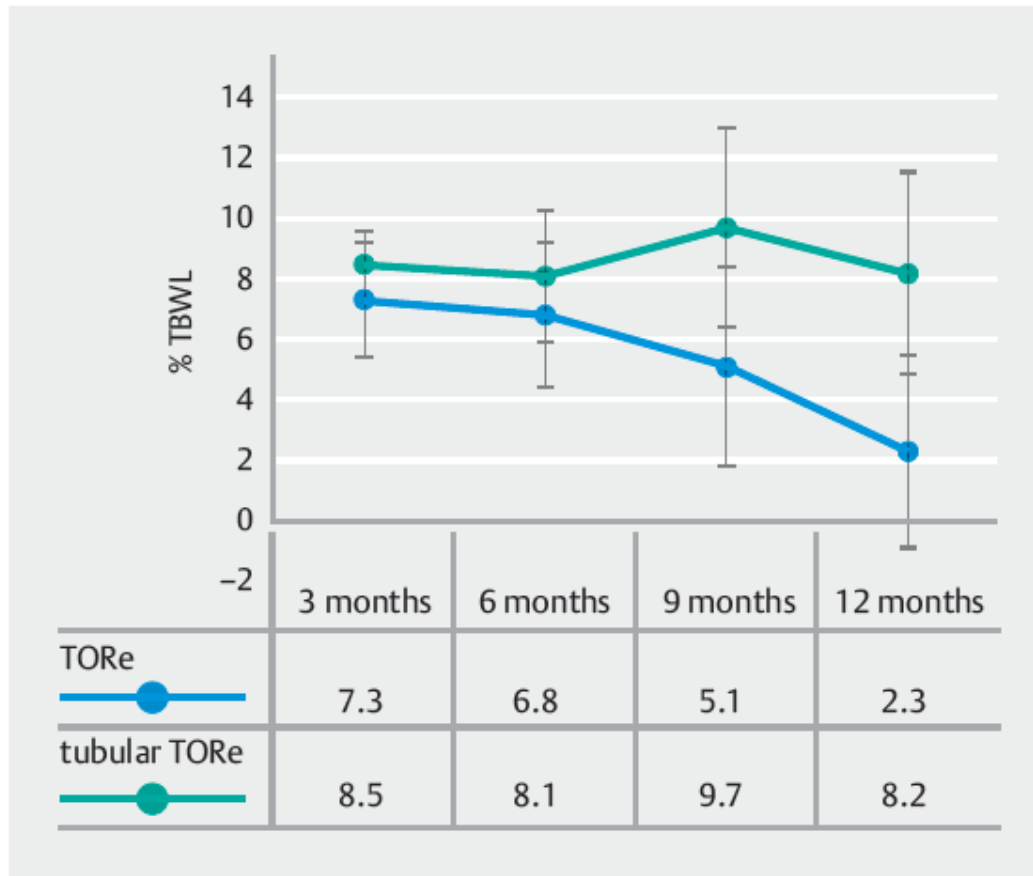
†Median ± [25th, 75th interquartile range]

- Patients n → 241
- Superiority of purse-string (vs interrupted) in terms of weight loss.
- No statistical differences at 3 months, but after 1 y (more durable approach?)
- Purse-string TORe technique was superior to the original interrupted TORe suture pattern with the efficacy of 8.6% versus 6.4% TWL at 12 months, respectively (P .02).

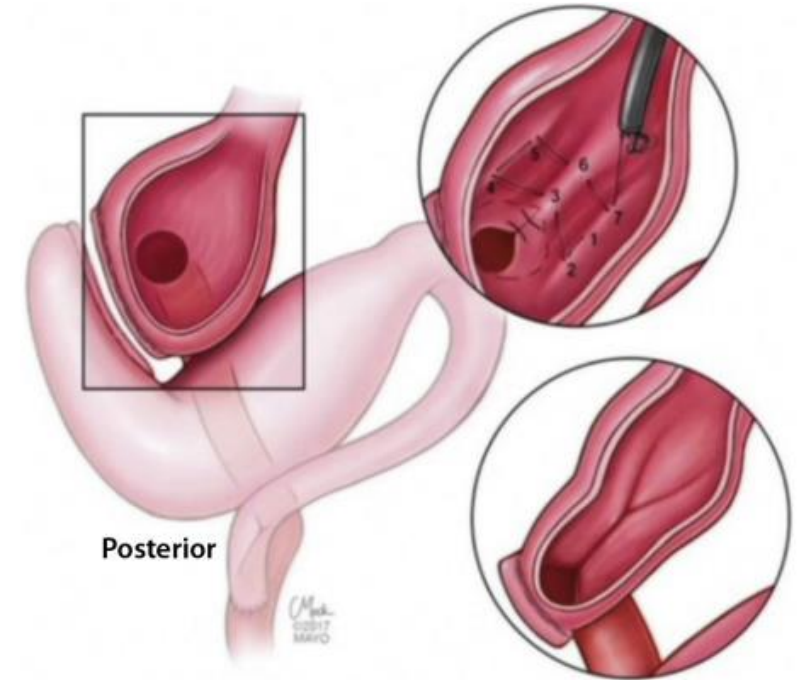
Suture patten in TORe



Tubular transoral outlet reduction (tTORe)



► **Fig. 1** Comparison of % TBWL trend between tTORe and TORe over a 1-year period. At 12 months, $P = 0.01$. P value was non-significant at 3, 6, and 9 months.



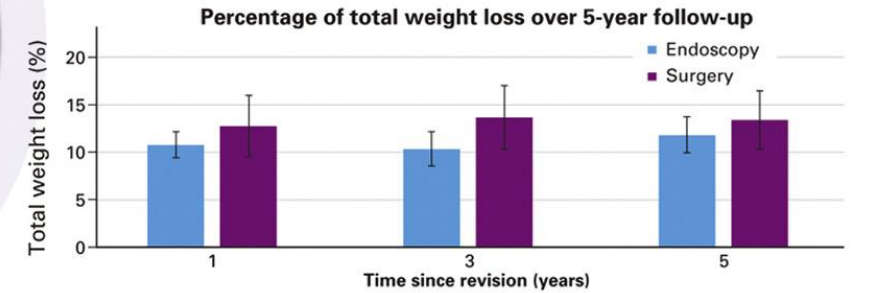
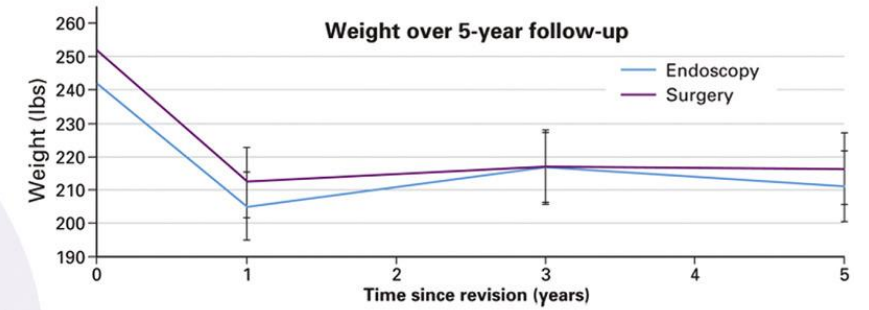
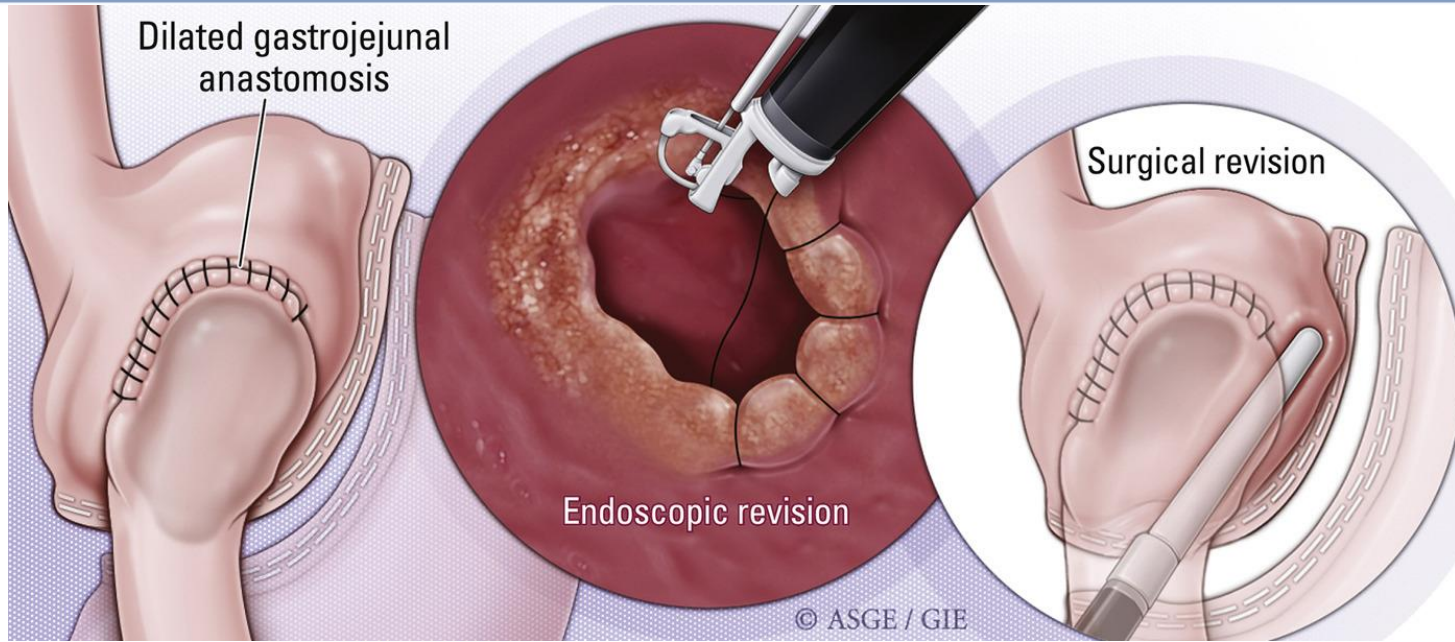
Retrospective analysis of a prospectively database

128 patients (tTORe = 85, TORe = 43)

At 12 months: %TBWL was significantly higher in the tubularization group (8.2 ± 10.8 vs. $2.3 \pm 7.3\%$, $P = 0.01$).

Procedural time: 60.5 vs. 53.4 minutes, $P = 0.03$

TORe vs Surgical Revision



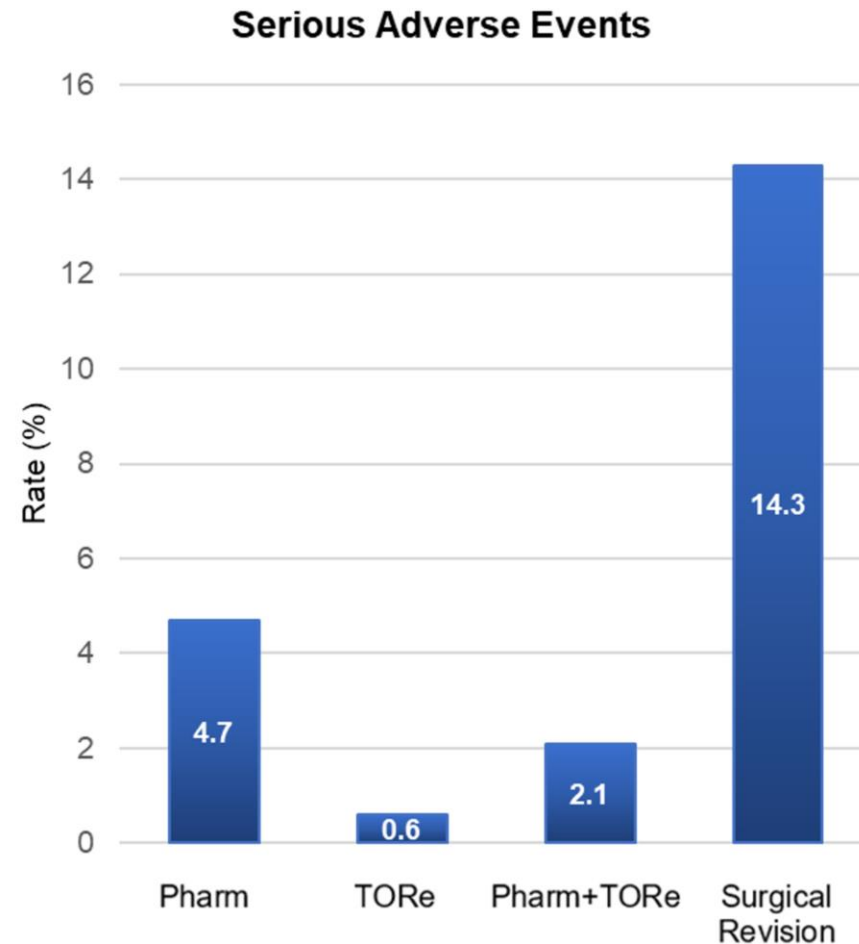
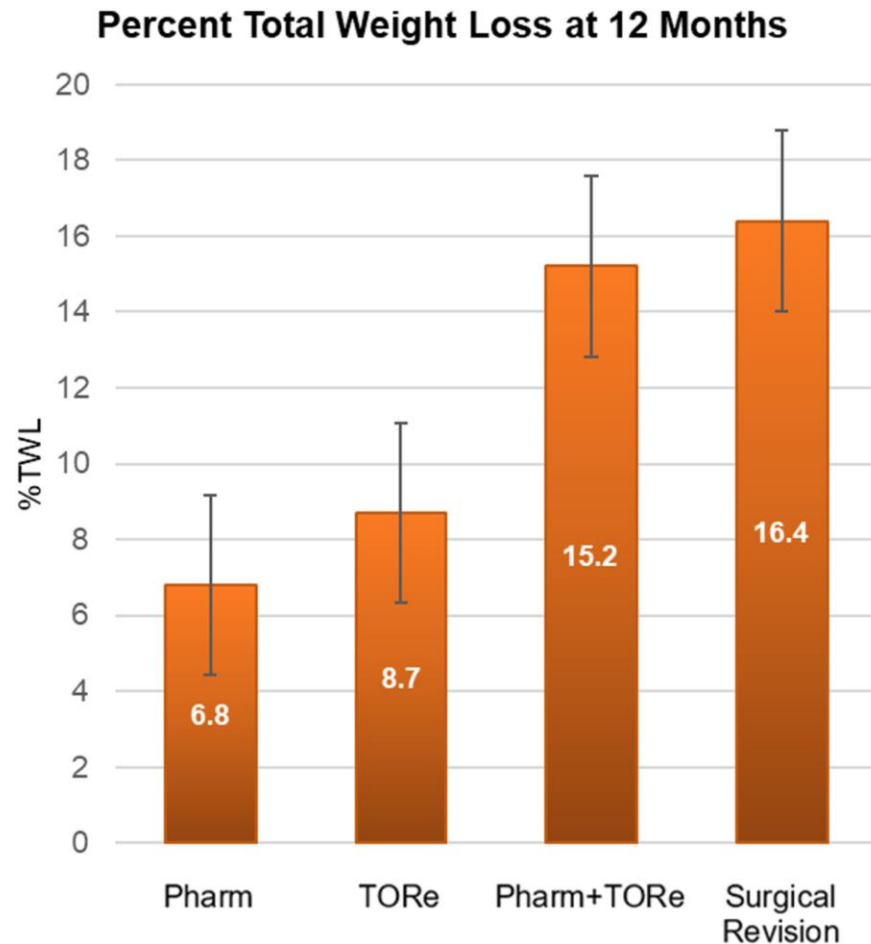
The 5-year efficacy of TORe has been demonstrated to be similar to surgical RYGB revision (11.5% [TORe] vs 13.1% [surgical] TWL; P .67), but with significantly fewer adverse events (AEs; 6.5% vs 29%; P .043).

	ENDO	SURGICAL	p
Efficacy at 5 years	11.5% TBWL	13.1% TBWL	0.67
Adverse events	6.5%	29.0%	0.04
Safety profile	0% SAE rate	19.4% SAE rate	0.024

TABLE 2. Adverse event rate comparison

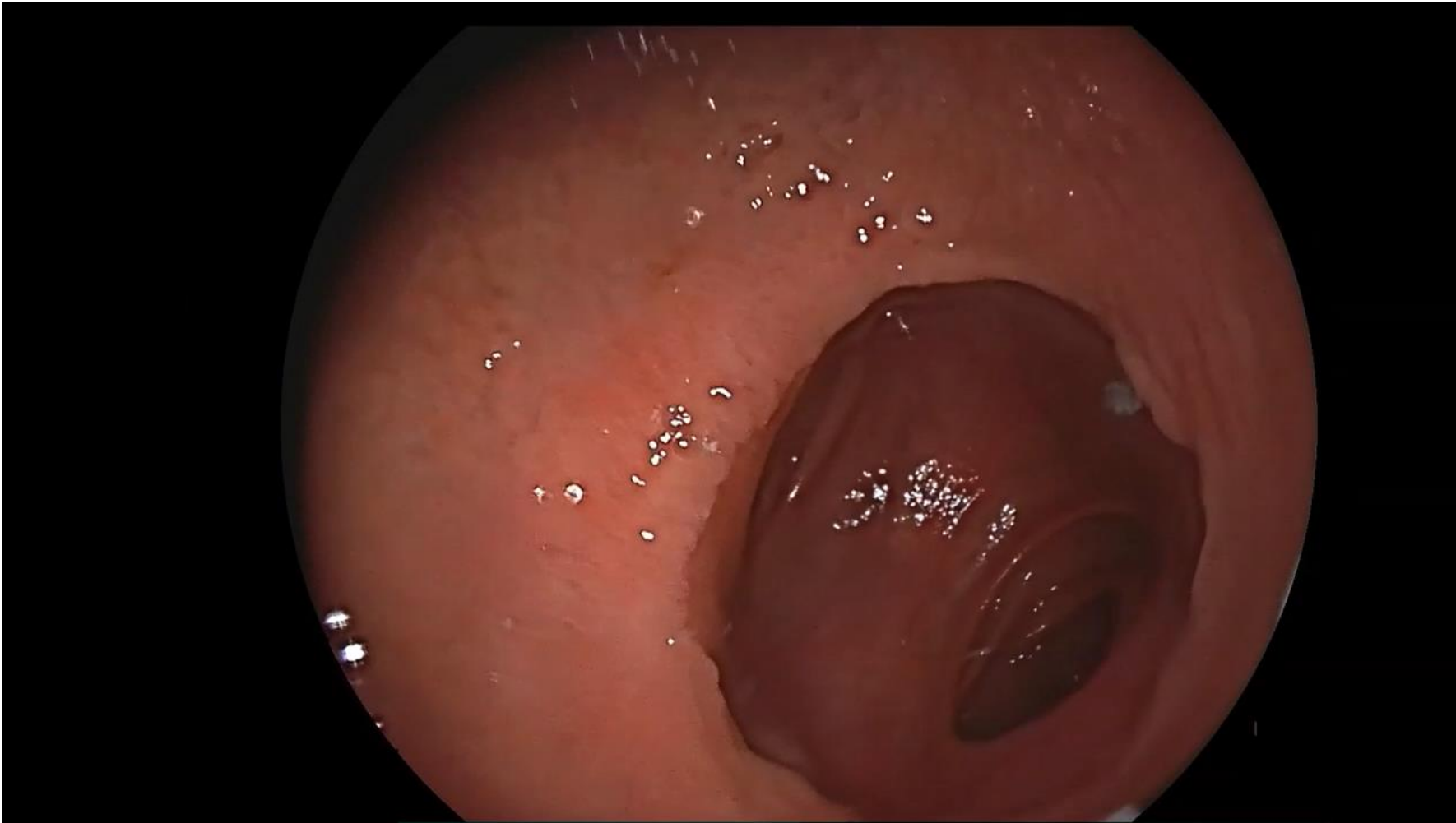
Outcome	Endoscopy (n = 31)	Surgical (n = 31)	P value
Adverse event	2 (6.5)	9 (29)	.043
GI leak/perforation	0	3 (9.7)	
Ulcer	0	1 (3.2)	
Gastrojejunal anastomosis stenosis	1 (3.2)	2 (6.5)	
GI bleeding	1 (3.2)	1 (3.2)	
Small-bowel obstruction	0	1 (3.2)	
Incarcerated incisional hernia	0	1 (3.2)	
Serious adverse events	0	6 (19.4)	.024
Early adverse events	1 (3.2)	7 (22.3)	.53

Endoscopic revision vs medical management



Combination therapy was associated with 15.2% versus 6.8% TWL for AOMs alone ($P < .0001$) and 8.7% for TORe alone ($P < .0001$) at 12 months. SAE rates were similar for combination therapy (2.1%), AOM alone (4.7%), and TORe alone (0.6%) ($P > .05$).

Modified ESD-TORe

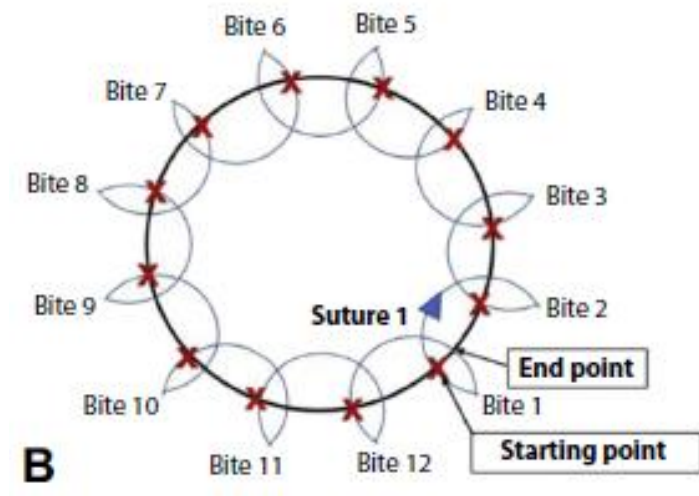


ESD-TORe

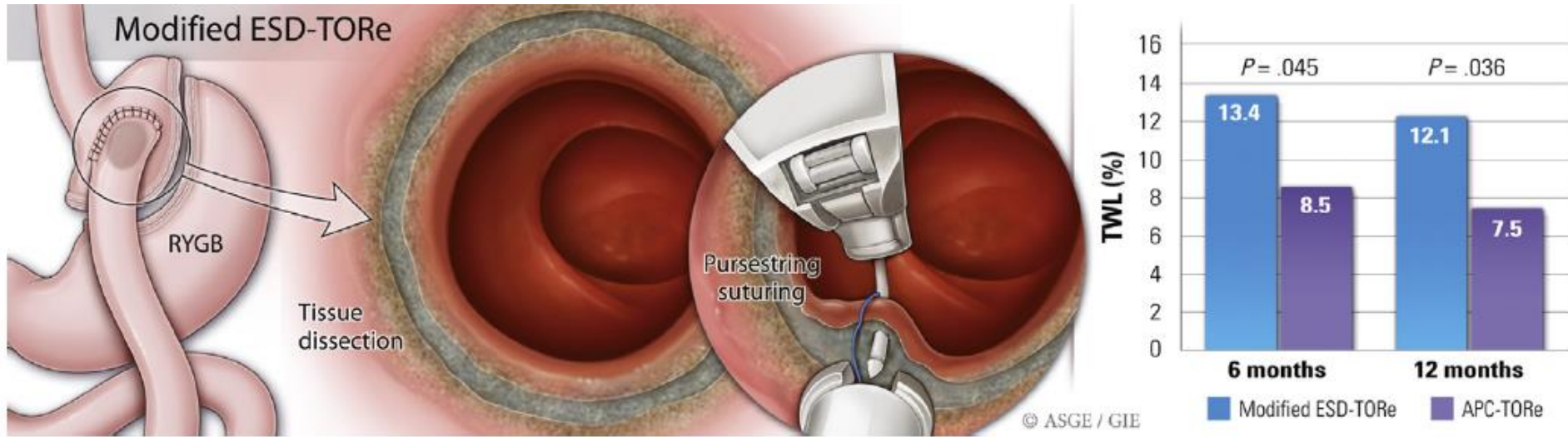
Apollo OverStitch

Double channel endoscope

Purse-string sutures



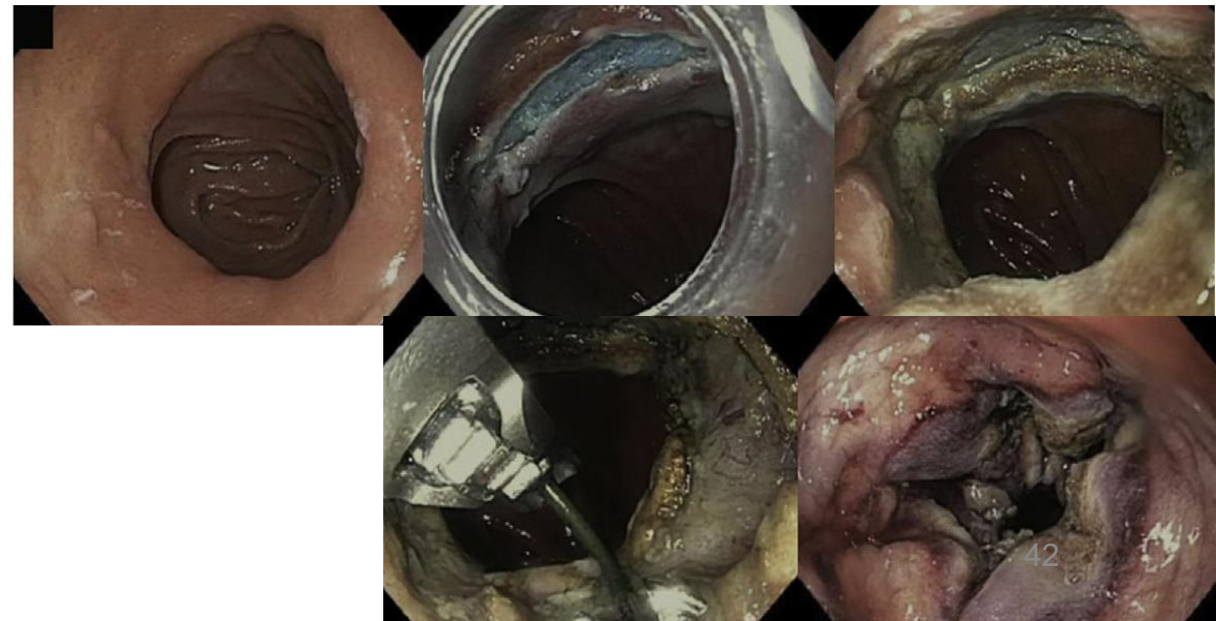
Modified ESD-TORe



15 patients with ESD-TORe were matched 1:3 to 45 patients with APC-TORe based on baseline GJA and pouch sizes.

- 1) Injection into the submucosa layer
- 2) Circunferential submucosa incision
- 3) Trimming of submucosal space
- 4) APC on margins
- 5) Purse-string suture pattern

Complications: esophageal erosions



Ft-TORe and APMC-TORe

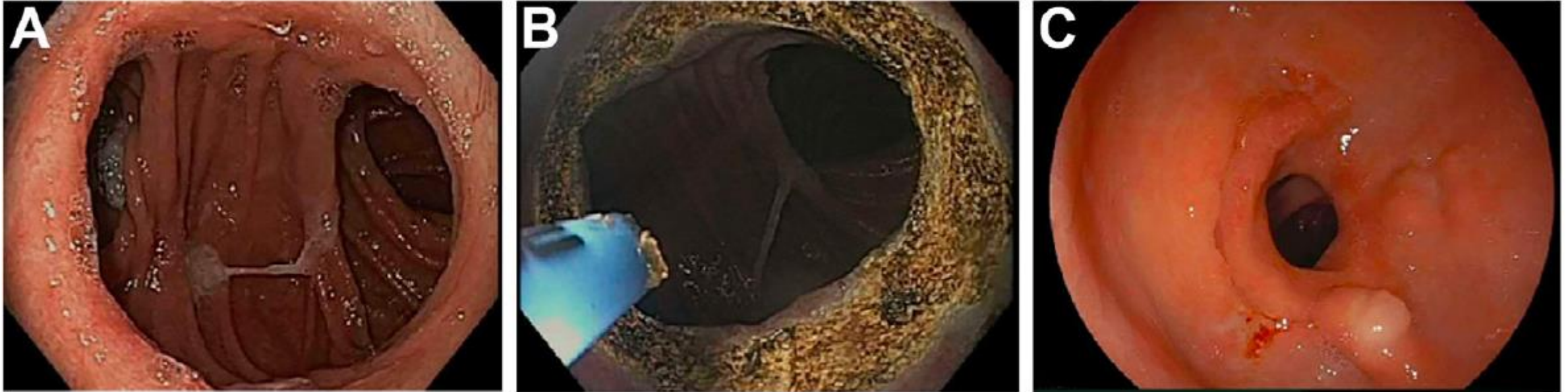
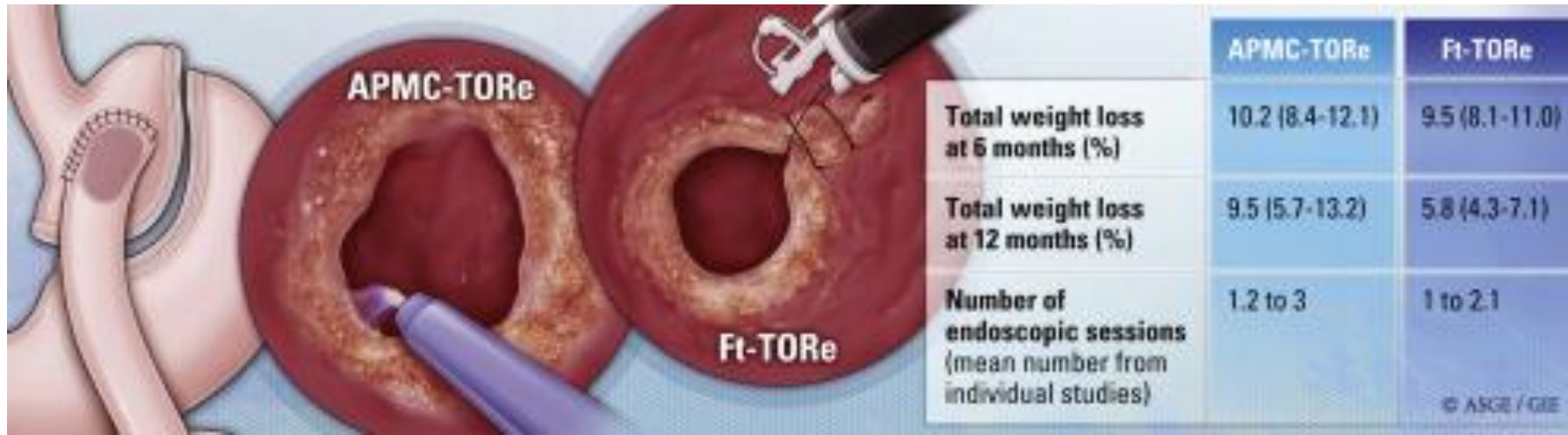


Fig. 7. (A) Dilated GJA, (B) GJA after first APC session, and (C) GJA after 3 APC sessions.

Ft-TORe and APMC-TORe



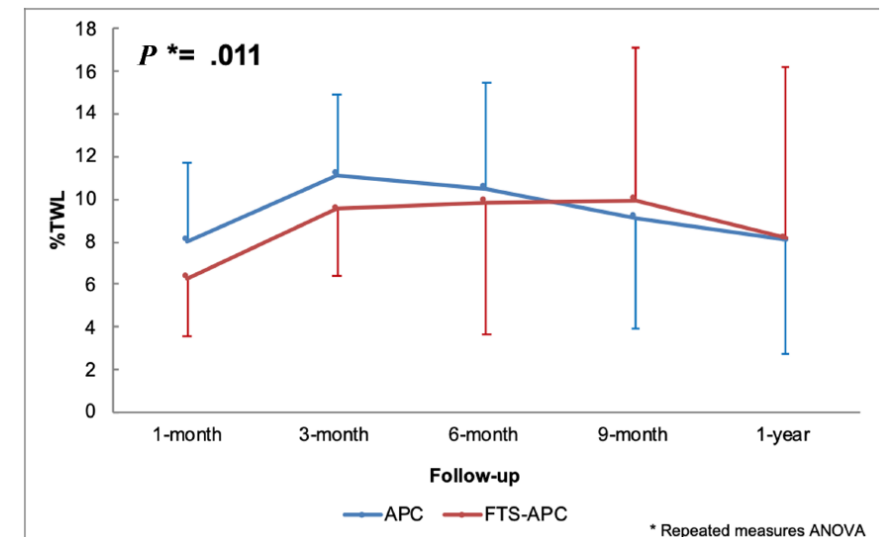
APMC-TORe - APC Mucosal ALONE (n=888 patients)

→ Series of sessions (4) (*but more straightforward and widely available*)

ft-TORe (n=737 patients)

→ Single session

Smaller aperture of the post-TORe GJA and greater change in the GJA diameter correlated with greater weight loss in APMC-TORe and numerical trends in ft-TORe.



APMC-TORe

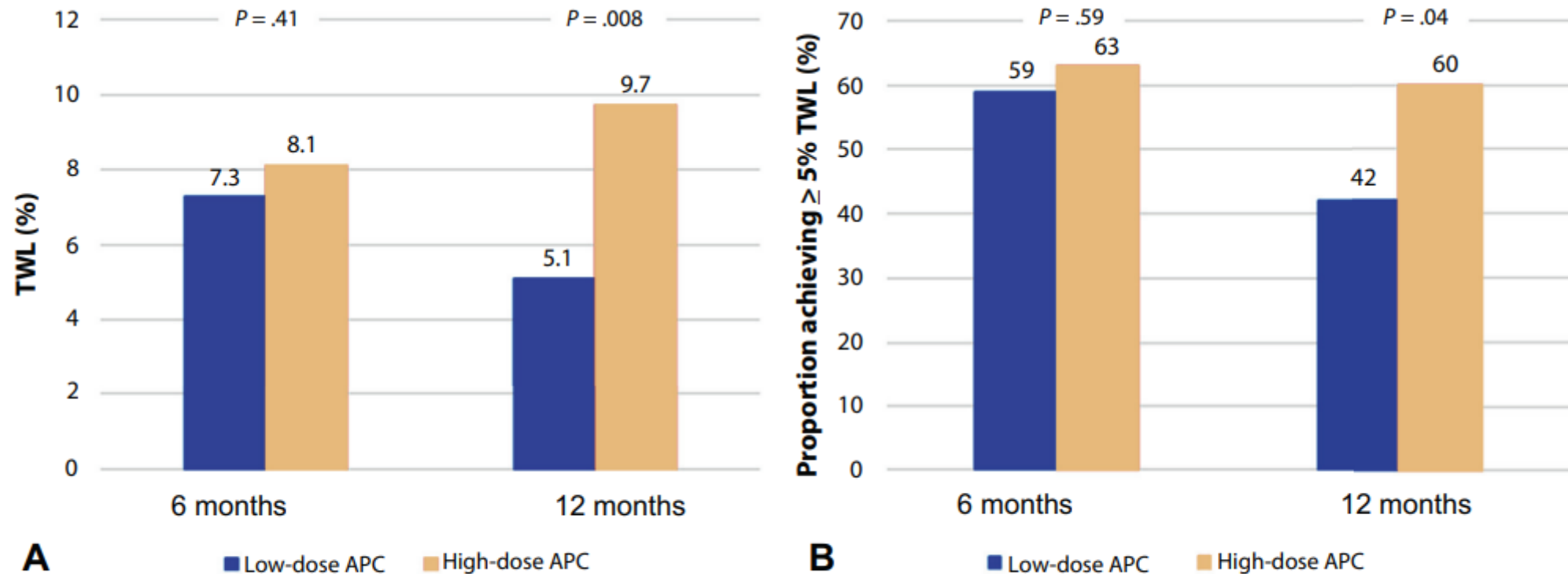
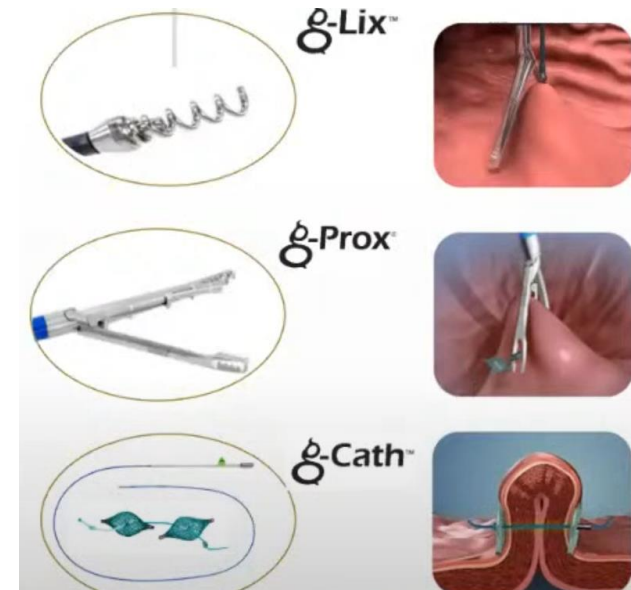
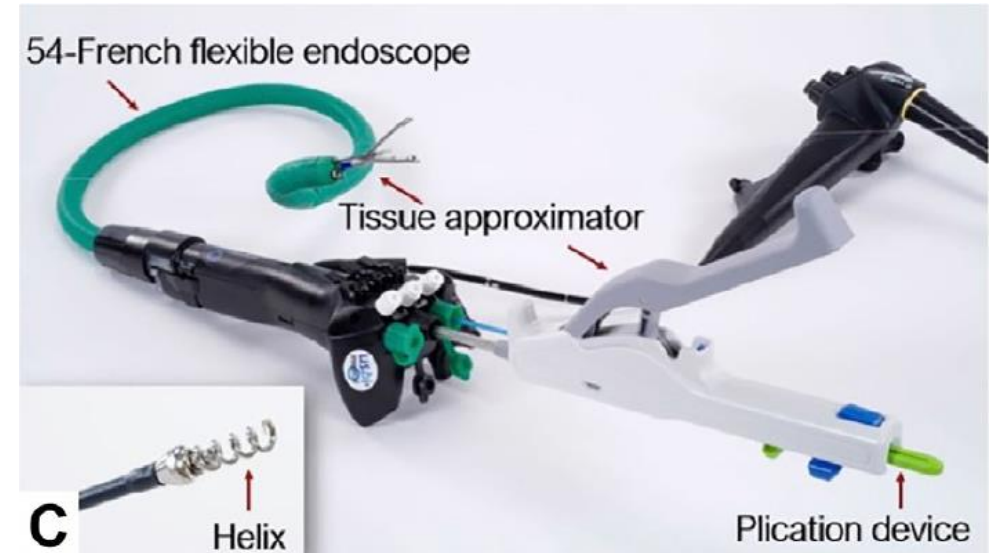
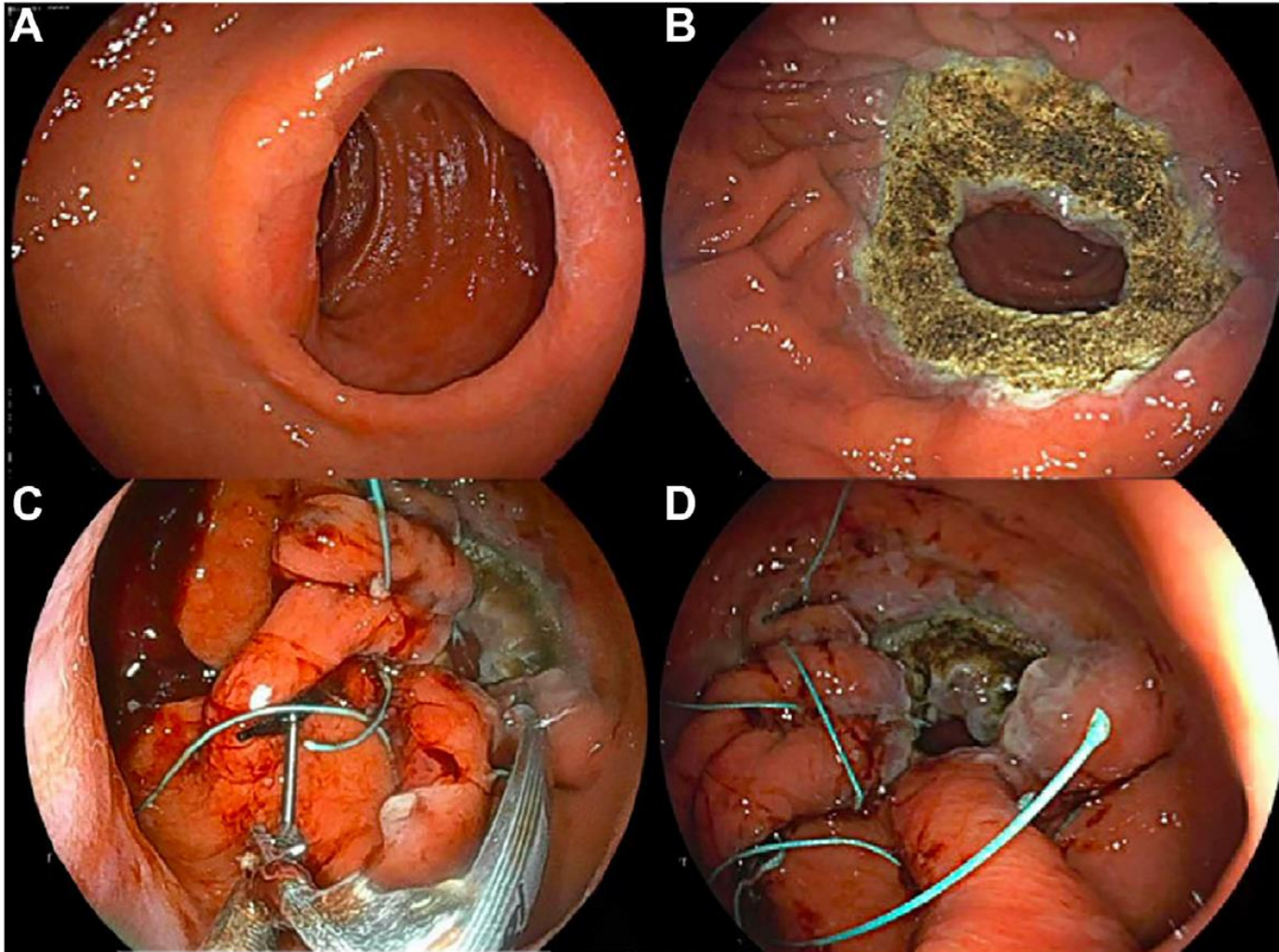


Figure 2. Efficacy of low- and high-dose argon plasma coagulation (APC) for the treatment of weight regain after Roux-en-Y gastric bypass. **A**, Percent total weight loss (TWL) at 6 and 12 months. **B**, Proportion of patients who achieved at least 5% TWL at 6 and 12 months.

- High-dose (70–80 W) APC was superior to low-dose (45–55 W) APC for the treatment of weight regain.
- A single-center study including 217 patients who underwent 411 APC sessions showed that the 12-month TWL was 9.7% in the high-dose APC group versus 5.1% in the low-dose APC group (P = .008), with no significant difference in the GJA stenosis rate

Plication-TORe (P-TORe)

Incisionless Operating Platform (IOP)
plication device



Plication-TORe (P-TORe)

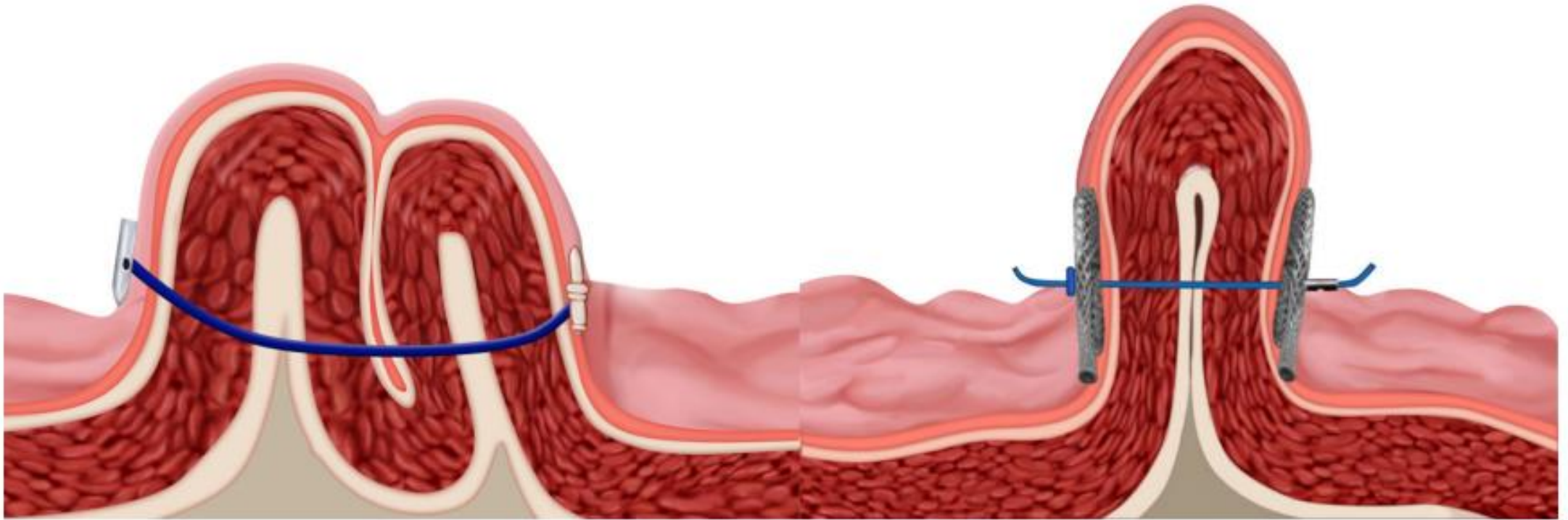
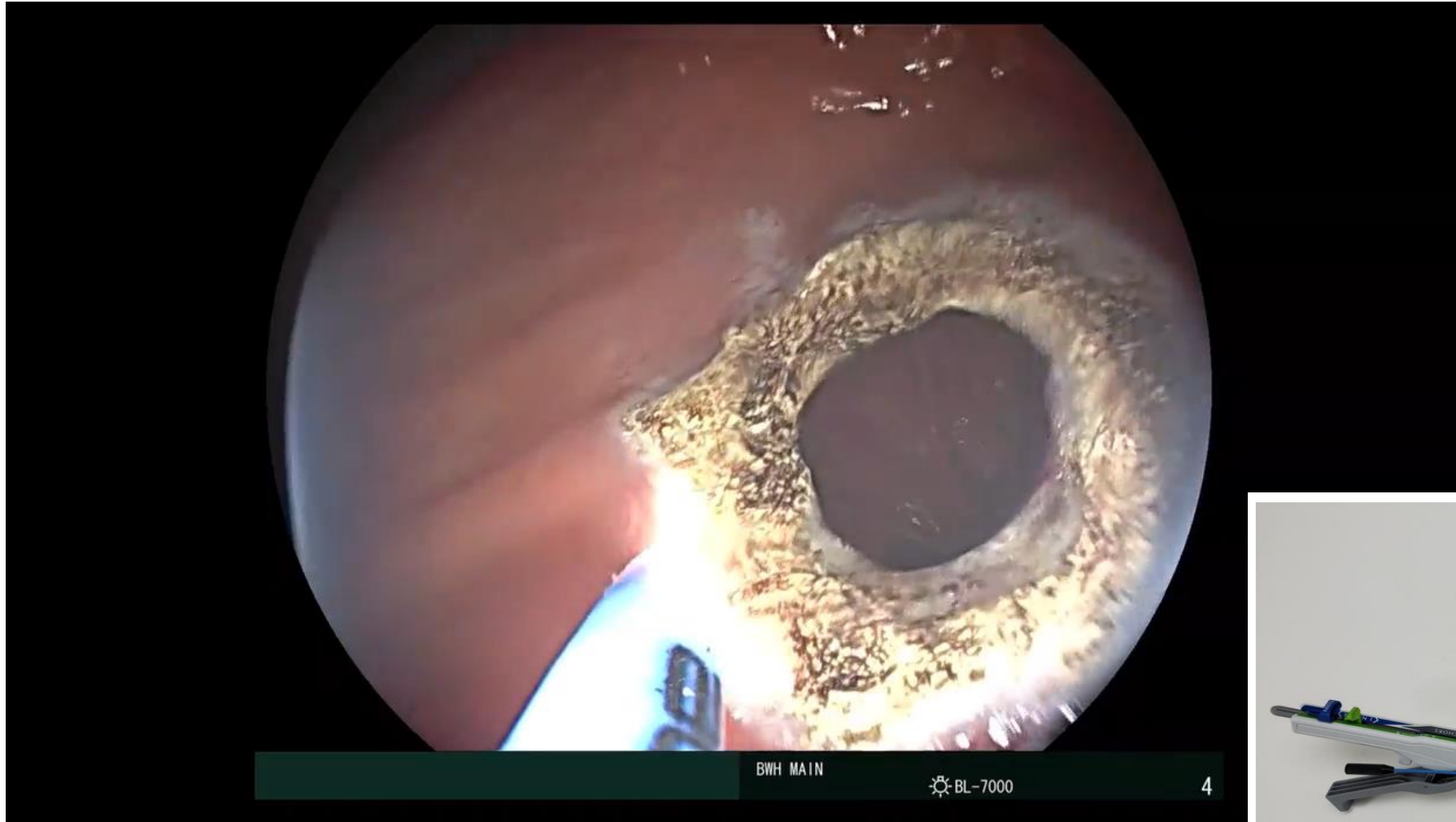


Figure 1.

(A) Endoscopic suturing with mucosa-to-mucosa tissue apposition (B) Endoscopic plication with serosa-to-serosa tissue apposition.

Plication-TORe (P-TORe)



P-TORe

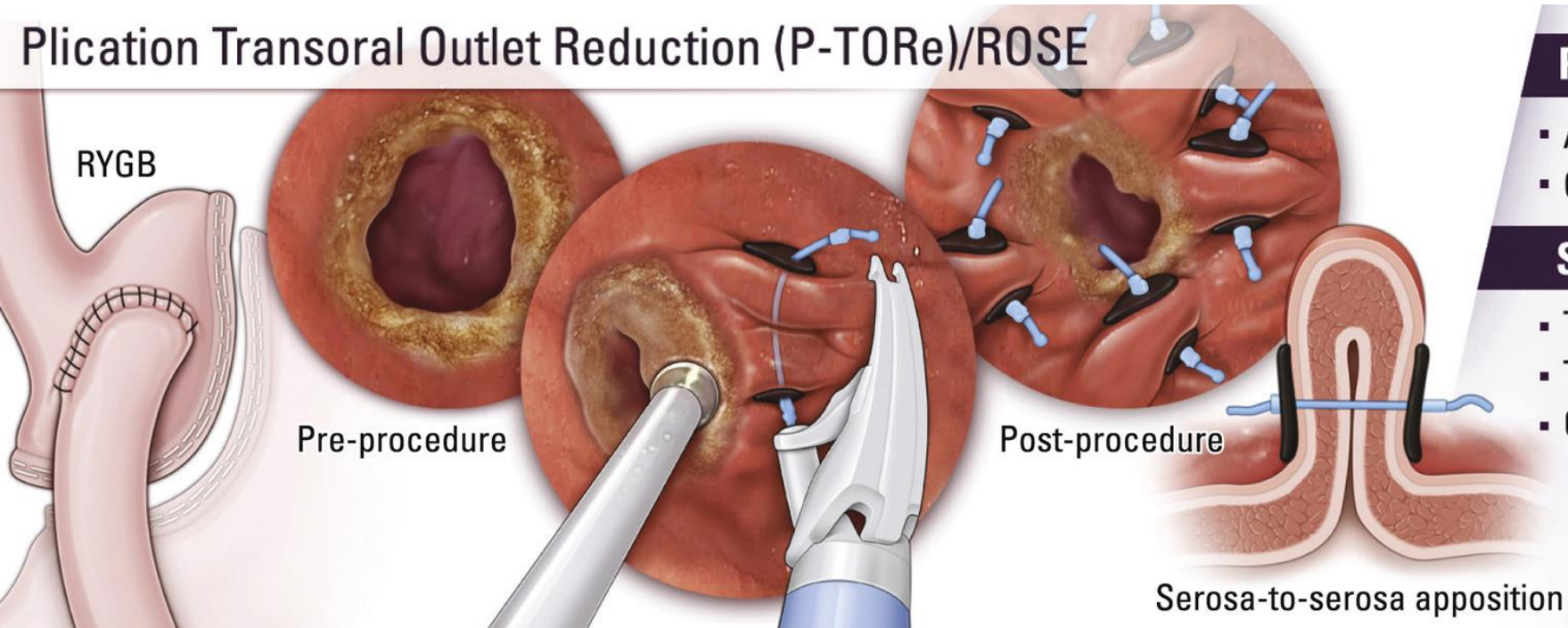
POSE-2 system

Ultraslim endoscope

Single sutures



Plication-TORe (P-TORe)



Primary Outcome

- At 12 months, patients experienced $9.5 \pm 8.5\%$ TWL
- Clinical success rate was 73%

Secondary Outcomes

- Technical success rate was 100%
- Total number of plications per case was 7 ± 3
- Overall AE rate was 12.6%
 - GJA stenosis (9.9%)
 - Melena due to marginal ulceration (1.8%)
 - Deep vein thrombosis (0.9%)

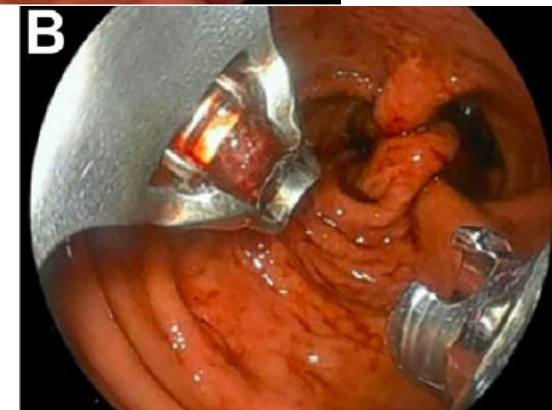
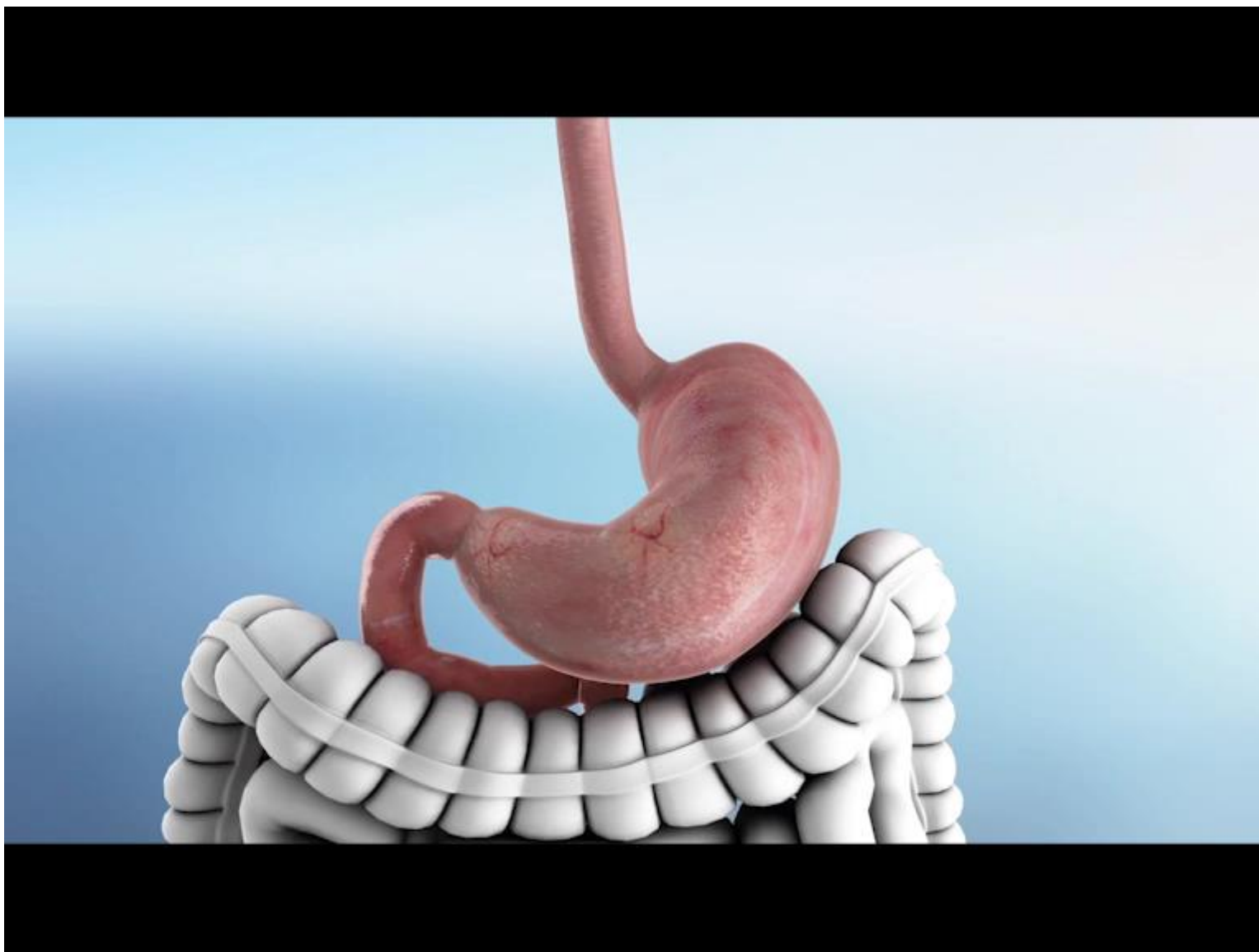
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Jirapinyo et al, showed that P-TORe with APC around the GJA prior to plication resulted in 9.5% TWL at 12 months.

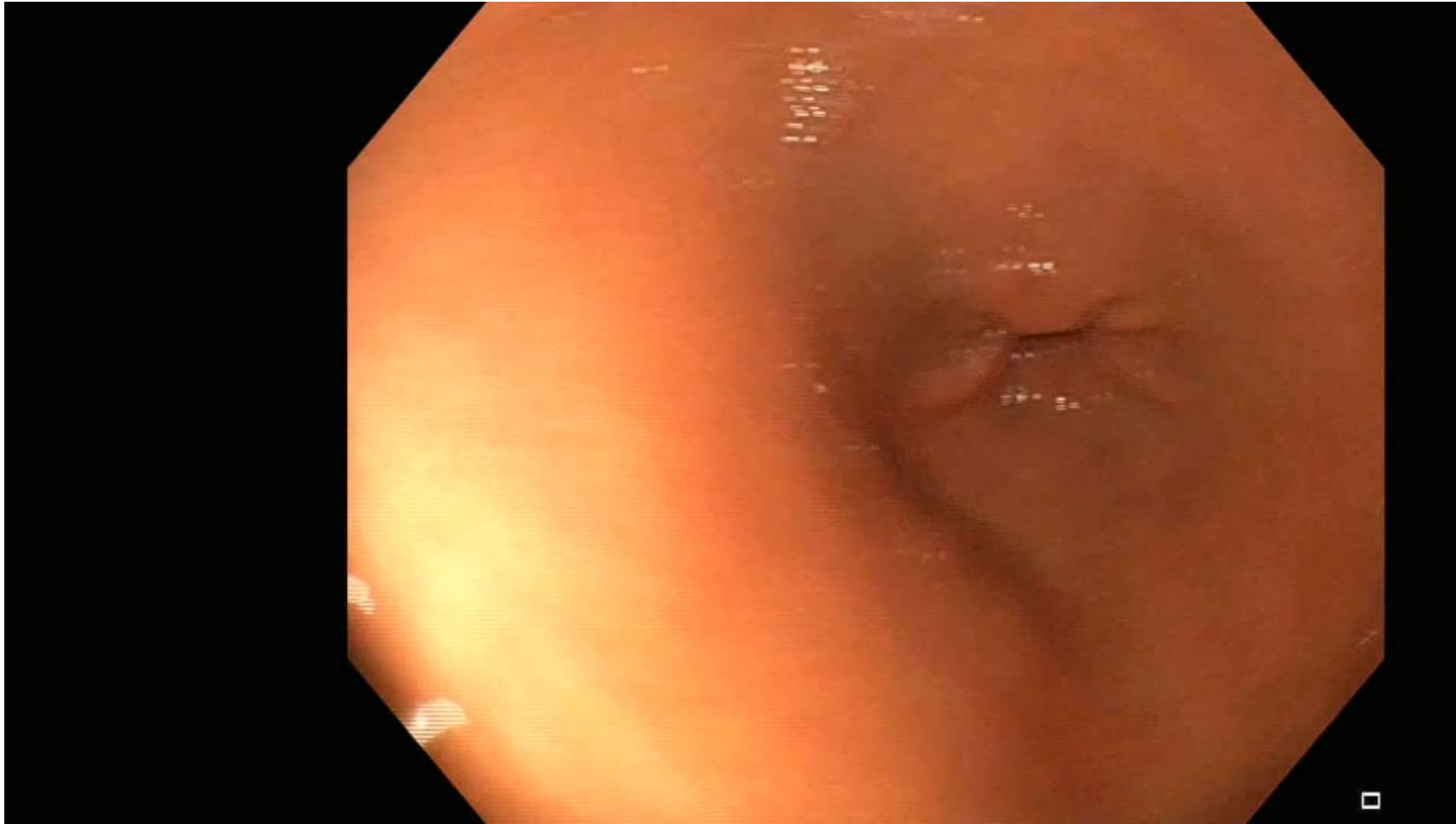
There were no reported SAEs.

The GJA stenotic rate was 9.9%, all of which were treated endoscopically

Revisional endoscopic sleeve gastroplasty (R-ESG)



Revisional endoscopic sleeve gastroplasty (R-ESG)



R-ESG

Previous ESG with POSE-2

Apollo OverStitch

Double channel endoscope



Civico Di Cristina Benfratelli
Azienda di Rilievo Nazionale ad Alta Specializzazione

Revisional endoscopic sleeve gastroplasty (R-ESG)

Revisional Endoscopic Sleeve Gastroplasty Of Laparoscopic Sleeve Gastrectomy

82 patients across 9 international centers

Median of 4 sutures

BMI at endoscopic revision (kg/m²), mean SD 37.2±5.7

TABLE 1. Demographic and procedural information

Patient and procedural characteristics	Distribution (n = 82)
Sex (% female)	92.7
Weight at time of LSG (kg), mean ± SD	159.5 ± 75.0
Lowest weight after LSG (kg), mean ± SD	104.1 ± 46.1
Weight regain after LSG (kg), mean ± SD	27.9 ± 20.7
Time from LSG to revision (years), median (IQR)	5 (4-7)
Weight at R-ESG (kg), mean ± SD	128.2 ± 57.5
Age at R-ESG (years), mean ± SD	42.8 ± 10.4
BMI at endoscopic revision (kg/m ²), mean ± SD	37.2 ± 5.7
No. of patients with dilated surgical sleeve noted at time of R-ESG (%)	36 (44)
Procedure duration (minutes), mean ± SD	48.3 ± 20.5
No. of sutures used, median (IQR)	4 (3-4)

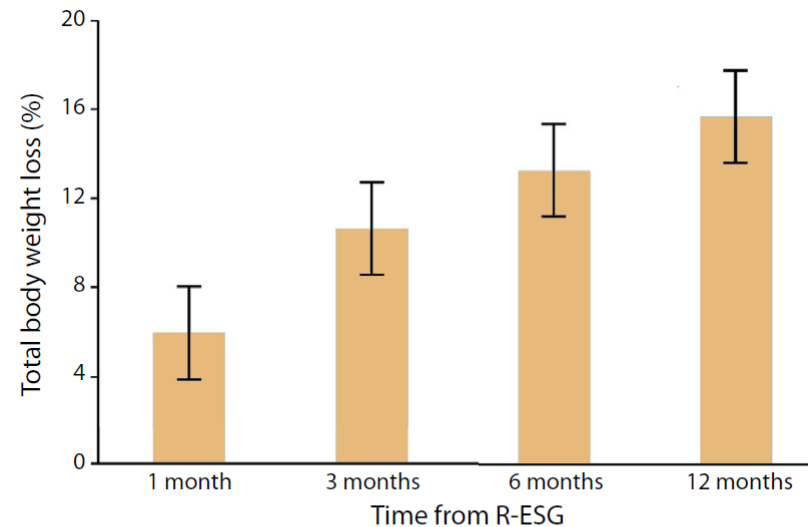
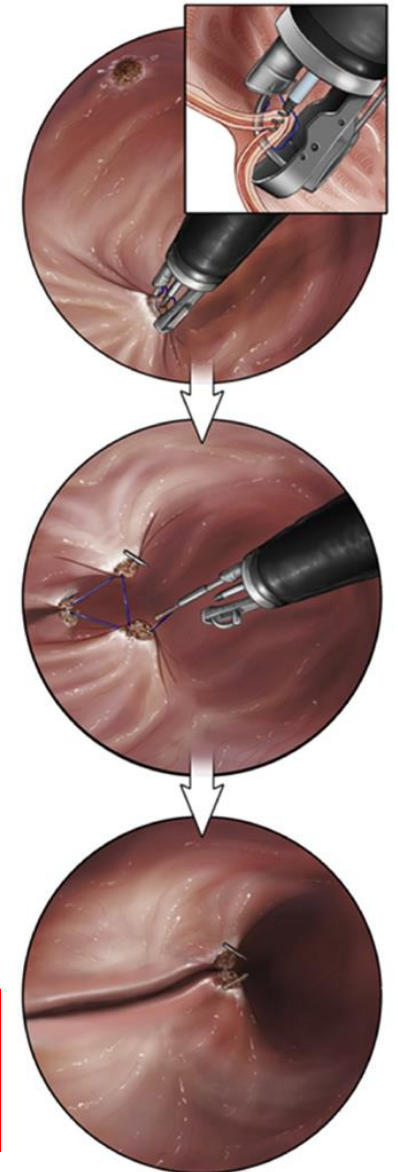


Figure 4. Total body weight loss (TBWL) after revisional endoscopic sleeve gastroplasty (R-ESG). TBWL (follow-up %) was 6.6% ± 3.2% at 1 month (81.7%), 10.6% ± 4.4% at 3 months (74.4%), 13.2% ± 10.1% at 6 months (63.4%), and 15.7% ± 7.6% at 12 months (51.2%).



Revisional endoscopic sleeve gastroplasty (R-ESG)

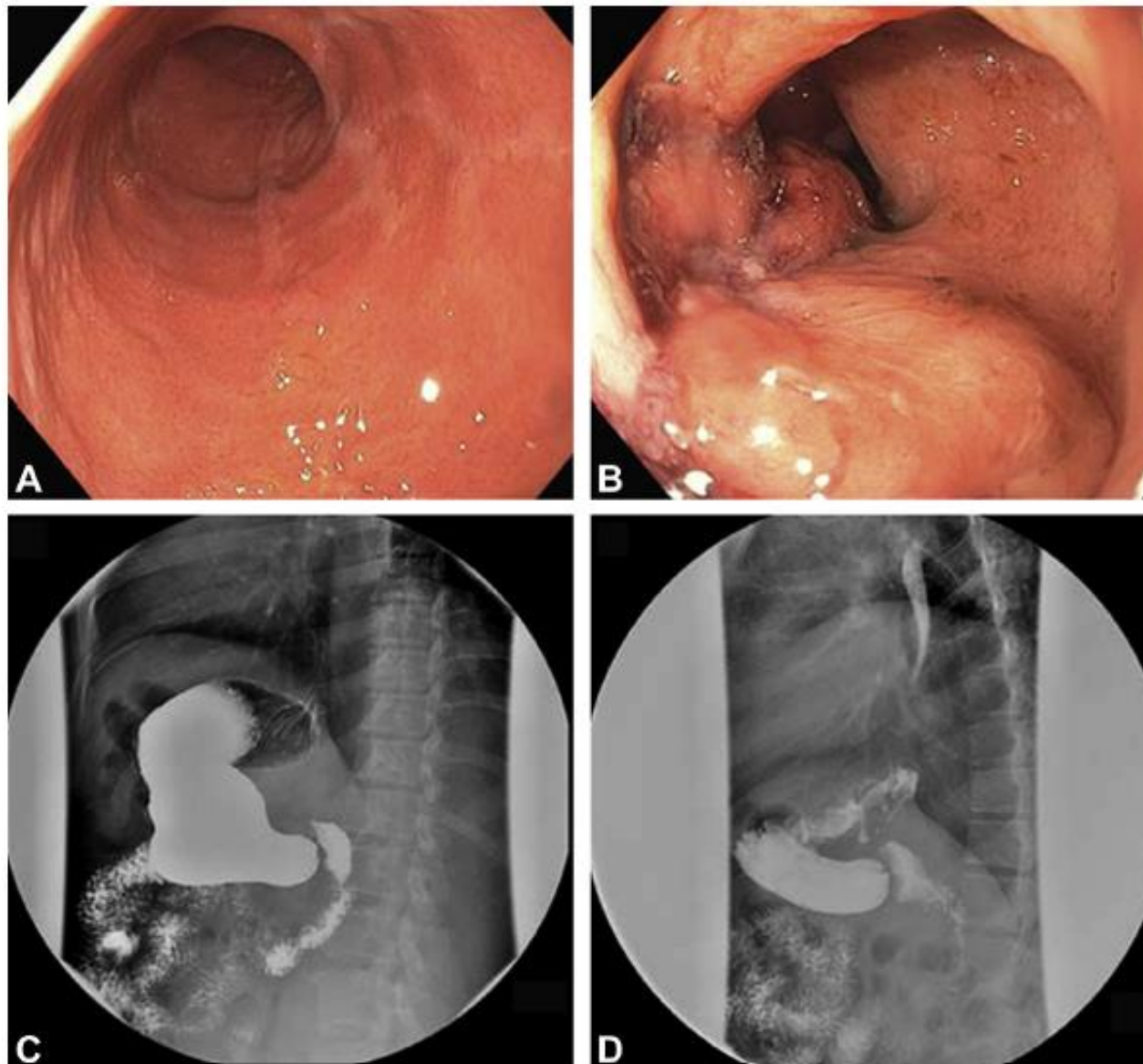
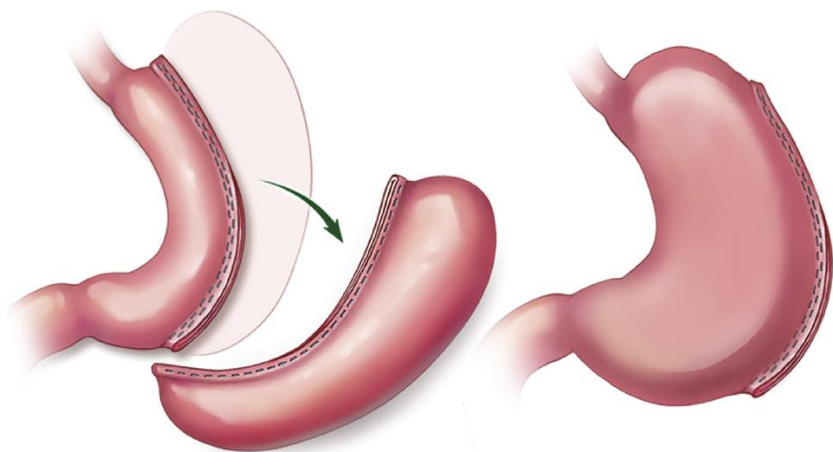


Figure 1. Laparoscopic sleeve gastrectomy (left) with postsurgical sleeve dilation (right).

OverStitch Sleeve Revision (R-EndoSleeve)

Adverse event	Proportion of subjects observed with AE (%)	Severity grading	Attribution	Therapy provided
Dehydration requiring IVF fluids	4/82 (4.9%)	Mild	Definite	IV fluids
New GERD symptoms	4/67 (9.0%)	Mild	Probable	Oral proton pump inhibitor therapy
Vomiting, narrowed gastroesophageal junction on UGI series	1/82 (1.2%)	Moderate	Definite	Single endoscopic dilation, 2 day hospitalization

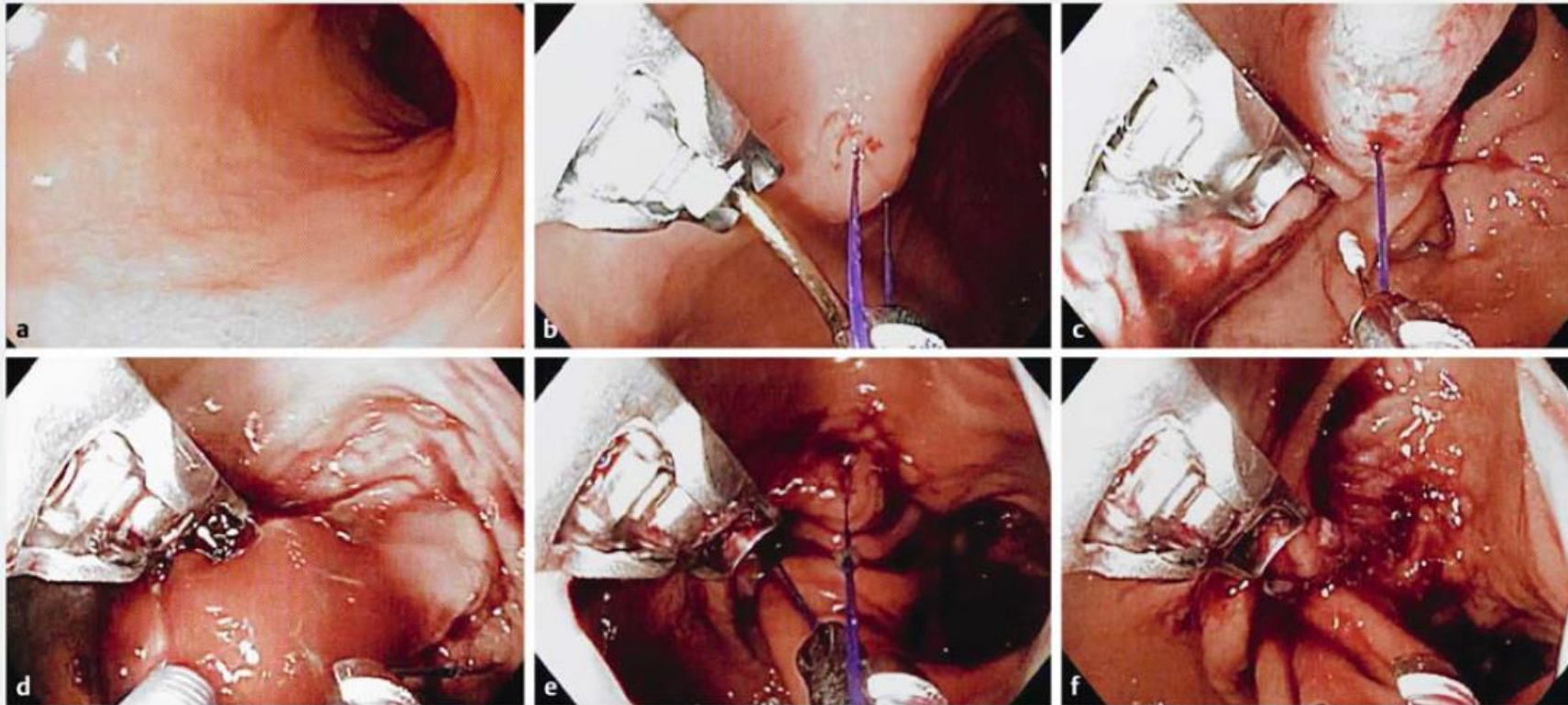
No SAES

%TBWL → 15.7% ± 7,6% at 12m

At 12m → 81%pt >10%TBWL

At 12m → 52,4%pt > 15%TBWL

OverStitch Sleeve Revision (R-EndoSleeve)

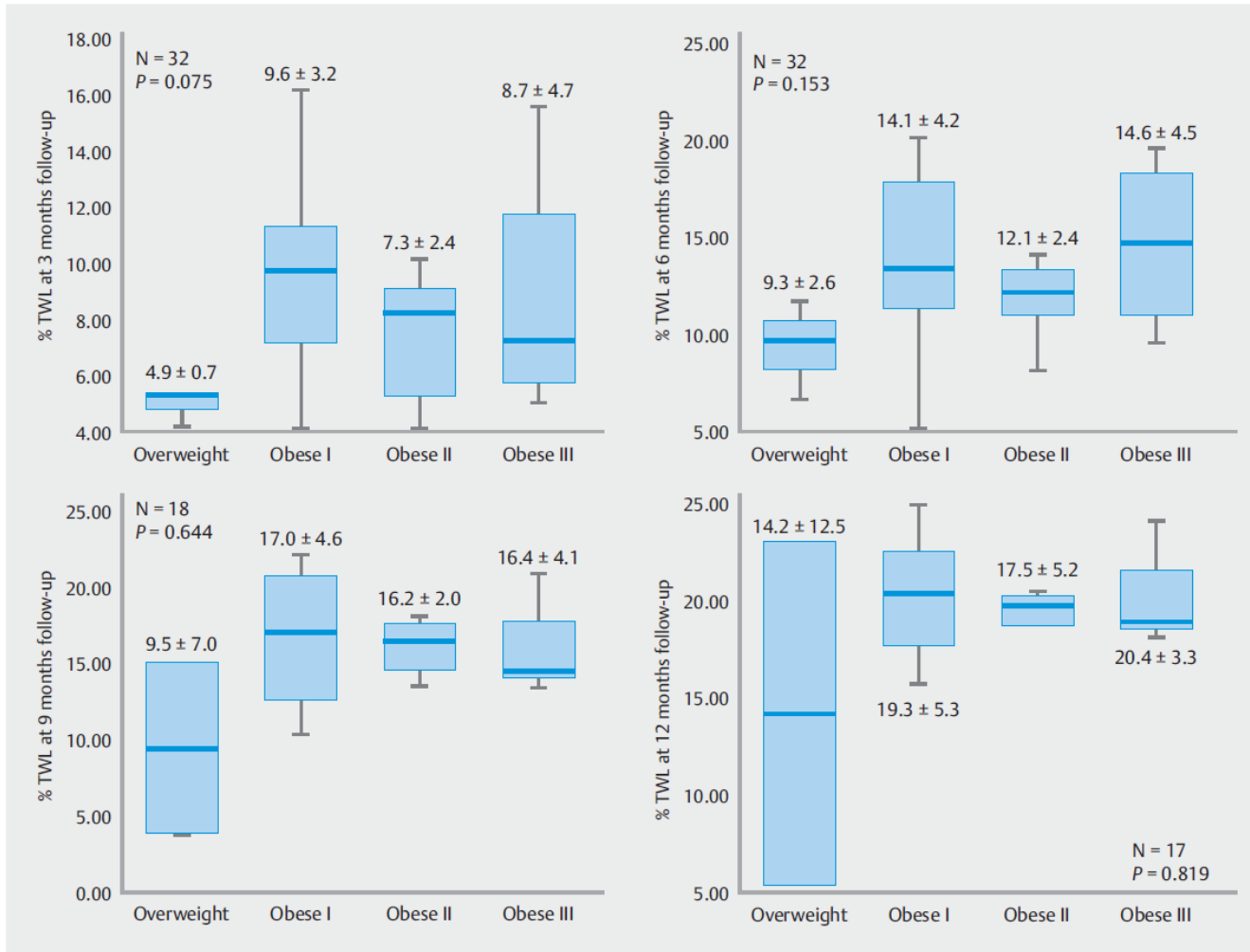


Revisional Endoscopic Sleeve Gastroplasty Of Laparoscopic Sleeve Gastrectomy

34 patients across 12
international bariatric centers
(Brazil)

3-5 sutures
At 1 year, 82.4% and 100% of
patients achieved $\geq 10\%$ TWL and
 $\geq 25\%$ EWL,
respectively.

OverStitch Sleeve Revision (R-EndoSleeve)



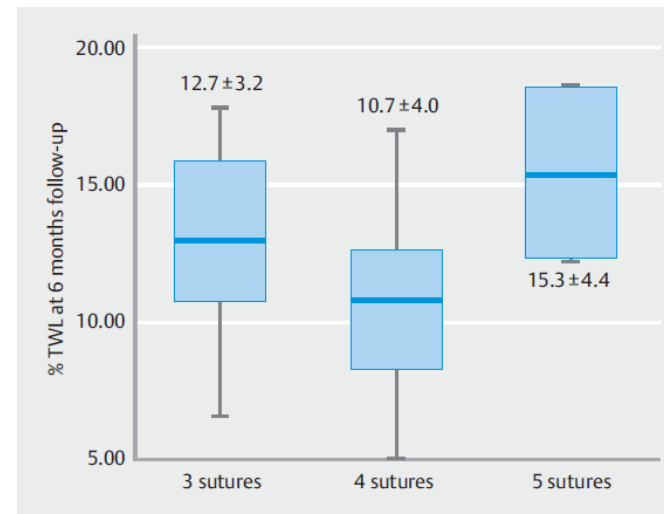
► Fig. 3 Comparison between percent total weight loss (%TWL) at 3, 6, 9, and 12 months after endoscopic sleeve gastroplasty in all body mass index subgroups.

Revisional Endoscopic Sleeve Gastroplasty Of Laparoscopic Sleeve Gastrectomy

34 patients across 12 international bariatric centers (Brazil)

3-5 sutures

At 1 year, 82.4% and 100% of patients achieved $\geq 10\%$ TWL and $\geq 25\%$ EWL, respectively.



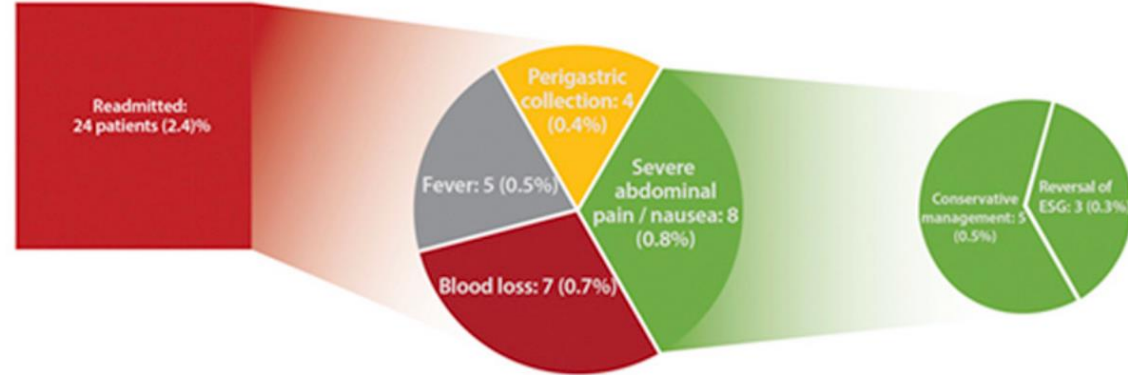
OverStitch Sleeve Revision (R-EndoSleeve)

Single-Surgeon Registry



N=1,000
 BMI=33.3 ± 4.5kg/m²
 Age=34.4 ± 9.5 years

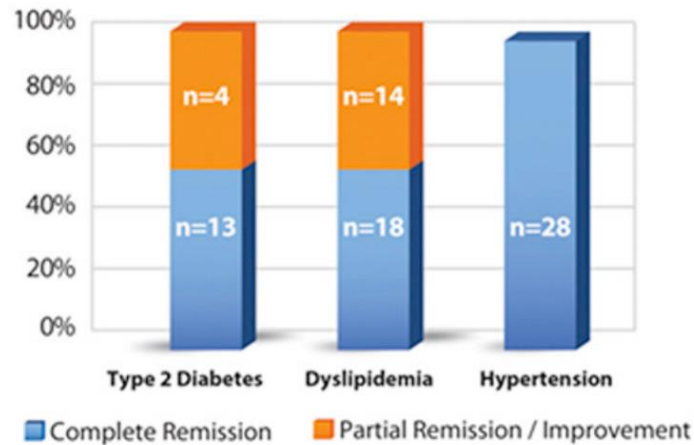
Readmissions after ESG



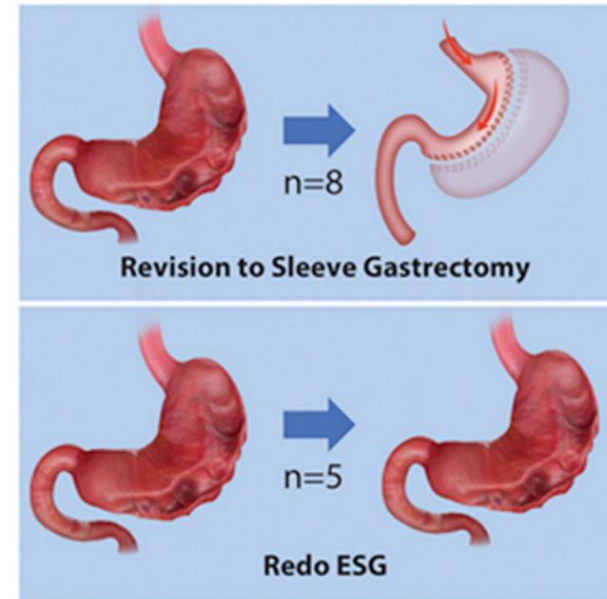
% Excess Weight Loss after ESG



Change in Co-morbidities after ESG



Revision/Redo



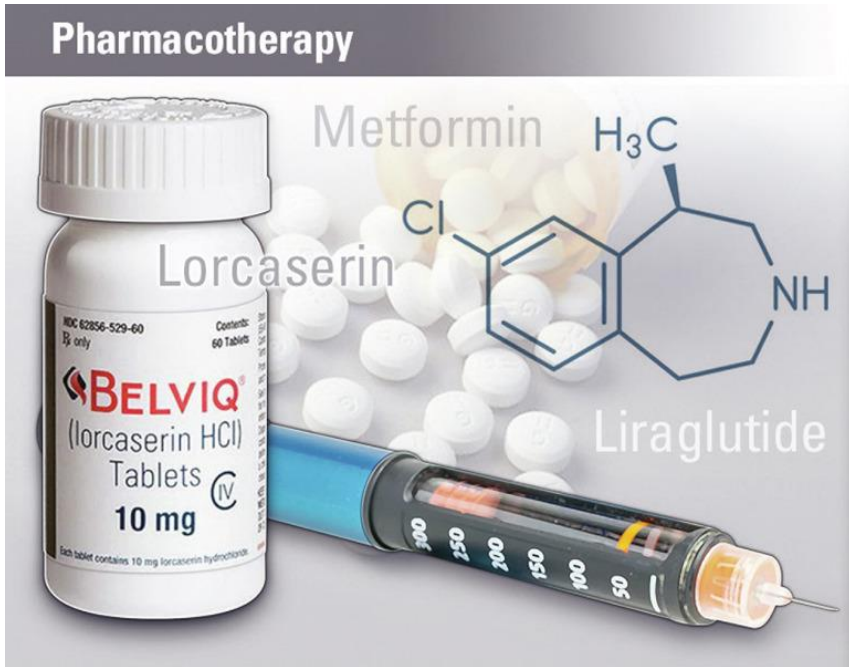
OverStitch Sleeve Revision (R-EndoSleeve)

TABLE 4. Revision rates after primary ESG in the first 1000 patients who underwent the procedure at our center

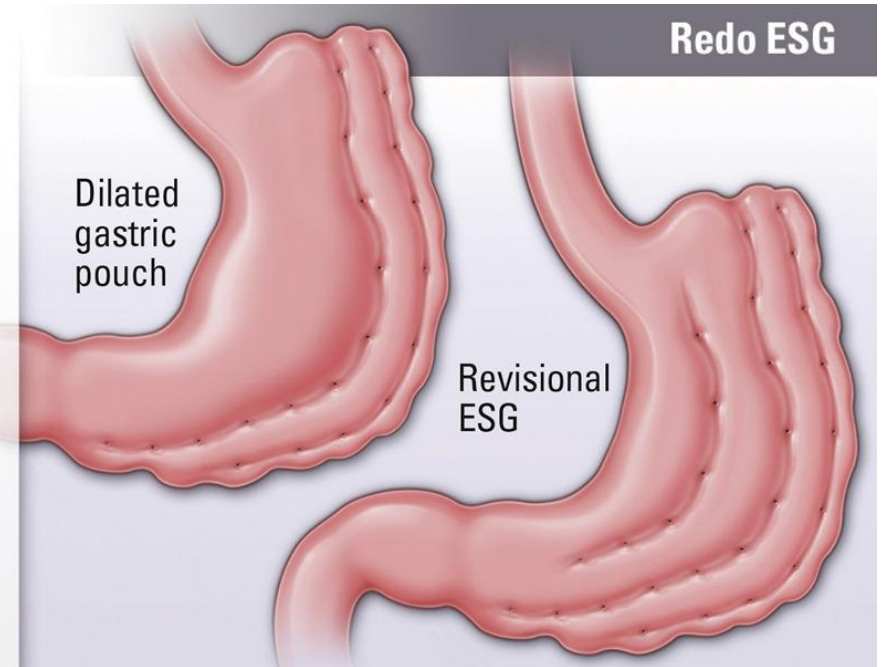
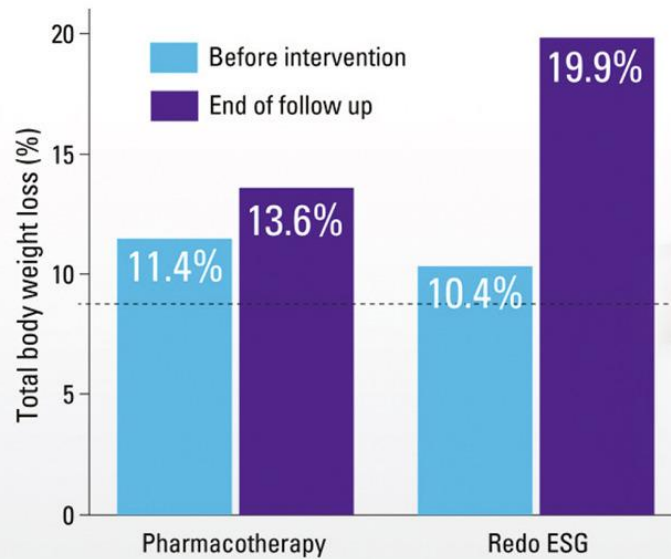
Procedure	No. of patients (%)
Endoscopic–laparoscopic revision to sleeve gastrectomy	8 (.8)
Redo-ESG	5 (.5)
Reoperation	0 (.0)

ESG, Endoscopic sleeve gastropasty.

R-EndoSleeve vs Pharmacotherapy




Improvement in total body weight loss



- Fifty-five patients were started on AOM and 24 patients underwent R-ESG
- The additional TBWL after R-ESG was significantly (both clinically and statistically) better than after initiation of AOM ($9.5\% \pm 7.2\%$ vs $2.1\% \pm 8.6\%$, respectively; $P = .001$).
- Final TBWL clearly favored R-ESG over AOM for treatment of weight recidivism ($19.9\% \pm 10.4\%$ vs $13.6\% \pm 9.2\%$, $P = .028$).

Curriculum for bariatric endoscopy and endoscopic treatment of the complications of bariatric surgery: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement



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CONCLUSION

Weight regain following Metabolic and bariatric surgery is a complex and multifactorial condition that necessitates a multidisciplinary and personalized approach to management.

Lifestyle and behavioral modifications should be encouraged, and psychological and social support should be offered to all patients.

Understanding the anatomic changes and postoperative complications that may contribute to weight regain is essential for tailoring the most effective endoscopic revision approach.

Endoscopic revision of Metabolic and bariatric surgery is being increasingly performed for the treatment of weight regain given its safety, efficacy and mini-invasiveness (especially in high-risk or inoperable patients).

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2025



Director Roberto Di Mitri | Co-director Alessandro Repici

Palermo | March 19-21, 2025

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**Grazie
Thank you
Kamsa
Hamnida**

