

Interventional Endoscopy: Bariatrics

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Disclosures

- Embarcadero stock ownership
- MicroTech Endoscopy research grant
- Past consultant, Obalon
- Past Research Support, Spatz, Apollo Endosurgery

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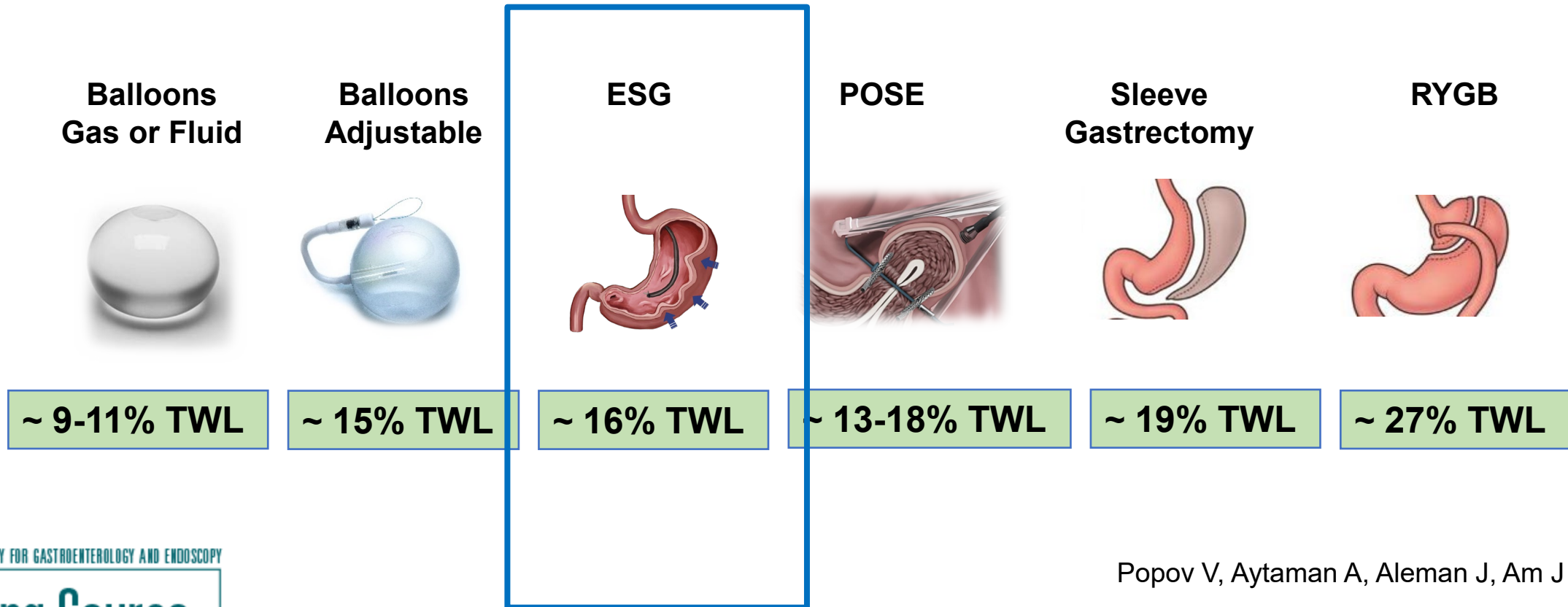
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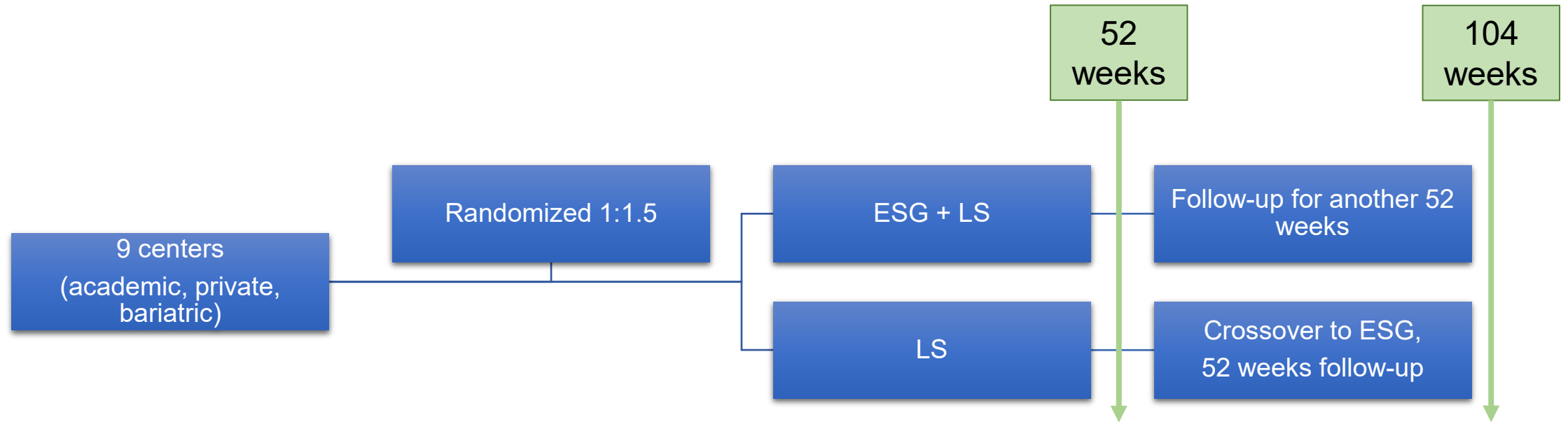
Endobariatric and Bariatric Procedures



Popov V, Aytaman A, Aleman J, Am J Gastro 2022

ENDOSCOPIC SLEEVE GASTROPLASTY (ESG) IMPACT ON OBESITY AND COMORBIDITIES (MERIT)

Abu Dayyeh B, Vargas E, Chapman C, Sharaiha R, Thompson C, et al.



Primary Objective: ASMBS/ASGE (1 year) 25% EWL, 15% Delta to LS, <5% SAE

Secondary Objectives: Durability at 2 years
Impact on Co-morbidities(HTN, DMI II, Metabolic syndrome, GERD)

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NYSGE

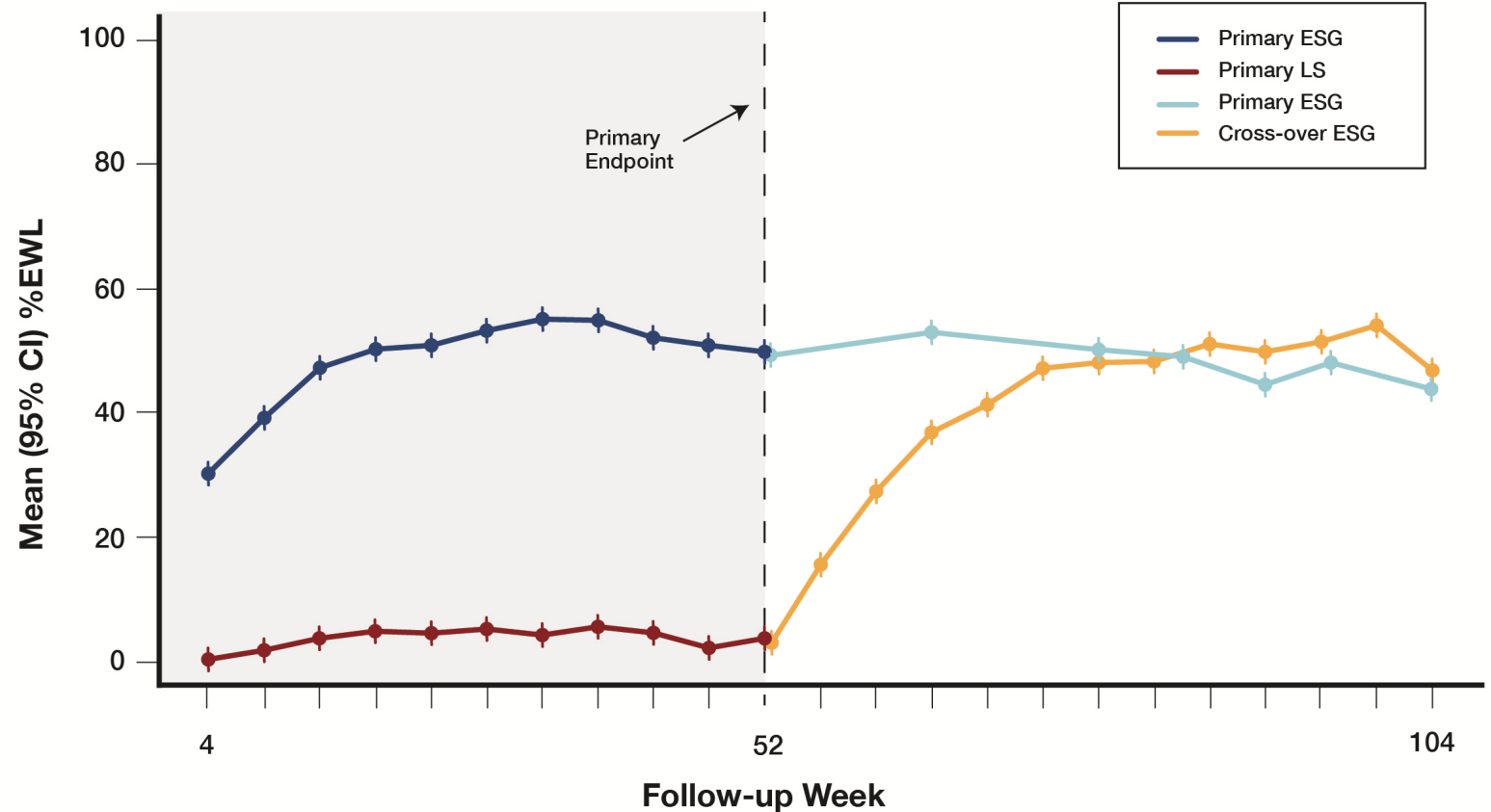
New York Society
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MERIT Results

Primary Objective

YEAR 1

- **49.2% EWL** (target 25%)
- **45% difference vs LS**, (target 15%)
- **77% responder rate** \geq 25% EWL
- **16.3 \pm 7% % TBWL** amongst responders



MERIT Results

Metabolic Comorbidities

| Comorbidity | Standard Medical Care | ESG | Difference | Standard Error of Difference | 95% CI | p-value |
|--------------------|-----------------------|---------------|------------|------------------------------|-------------|---------|
| Type II Diabetes | 8/29 (27.7%) | 11/20 (70.0%) | 42.2 | 12.0 | 65.0, 15.1 | 0.002 |
| Hypertension | 22/59 (37.3%) | 27/42 (64.3%) | -27.0 | 9.7 | -44.6, -7.2 | 0.007 |
| Multiple Sclerosis | 10/20 (50.0%) | 9/20 (45.0%) | 4.9 | 11.0 | 97.0, 88.0 | 0.994 |

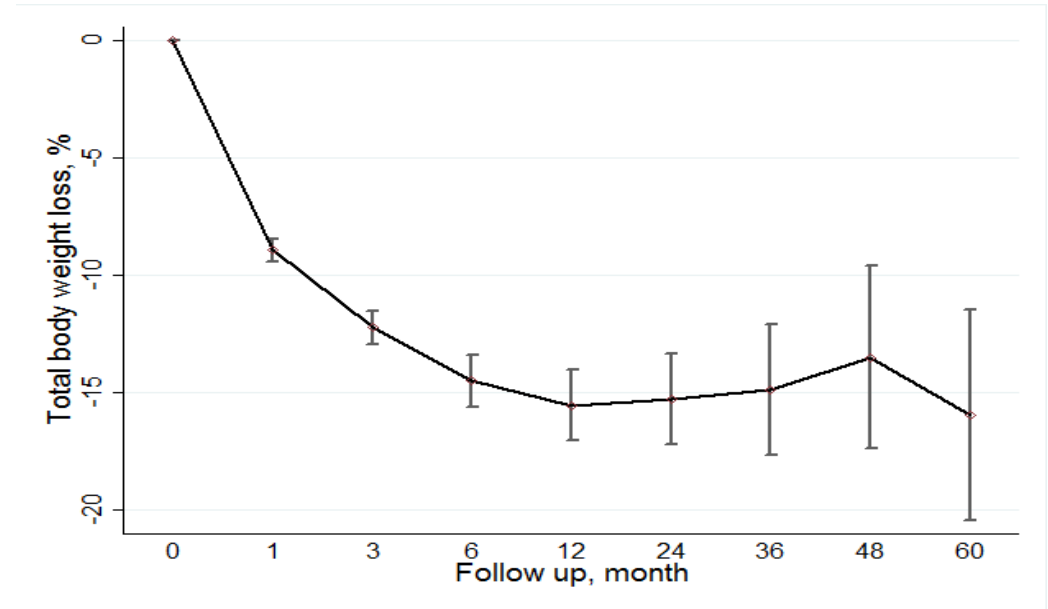
MERIT Results

Safety

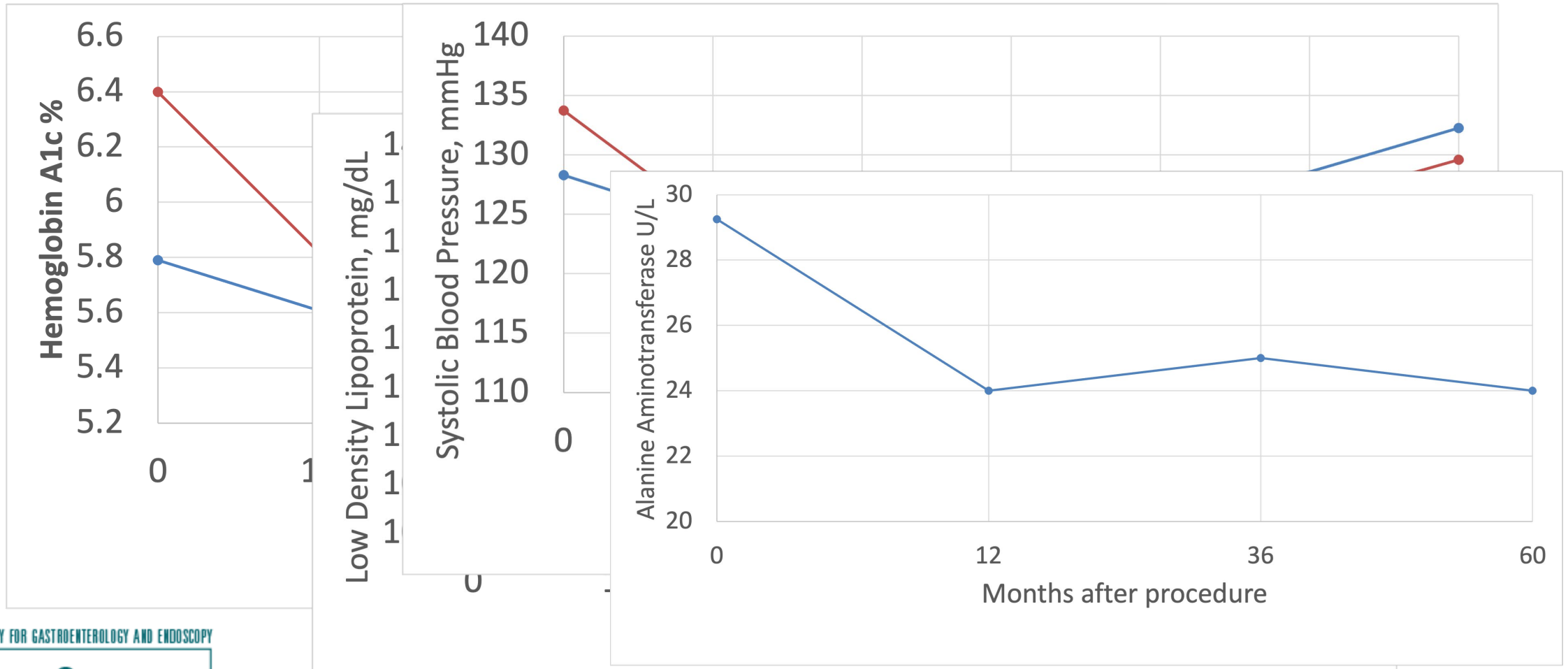
- 3 SAE grade III Clavien-Dindo (2%)
 - 1 peri-gastric abscess
 - Endoscopy
 - Abx
 - Upper GI bleed
 - Endoscopy
 - No transfusion
 - Malnutrition
 - Endoscopy reversal

ESG: Durability Of Endoscopic Suturing

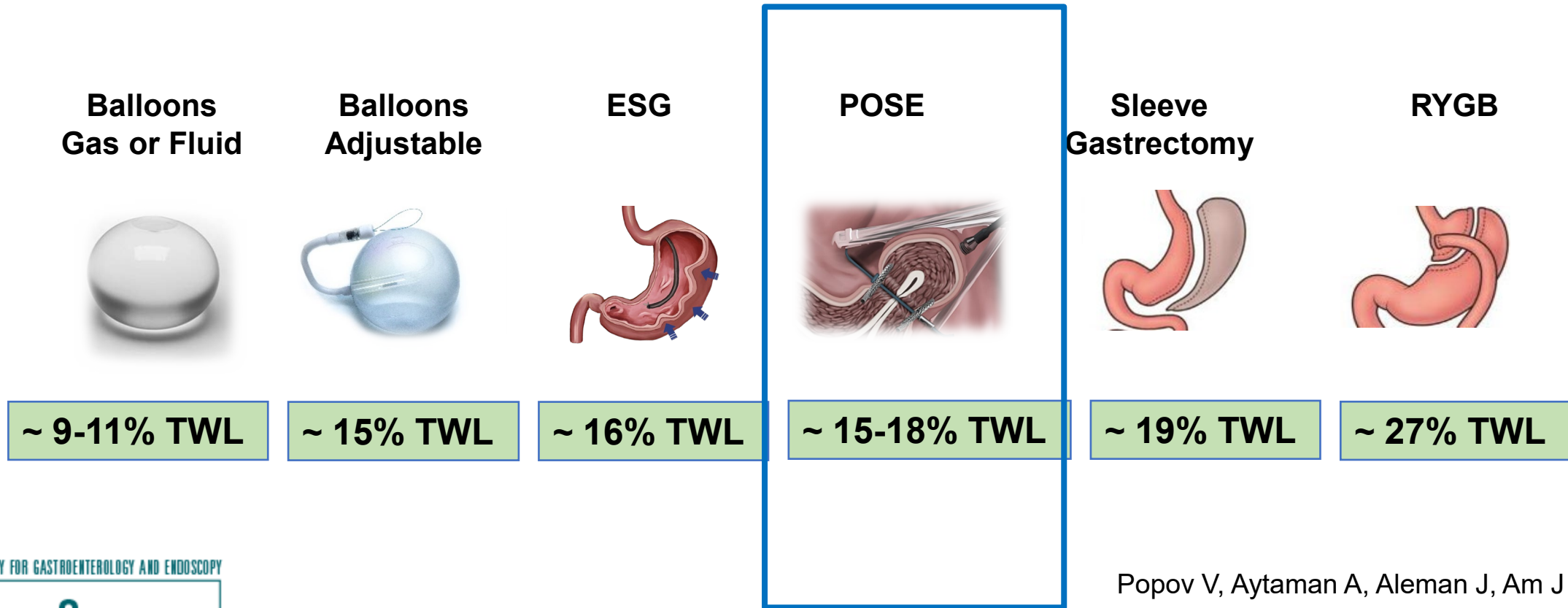
| Follow up, month | TBWL% (95%CI) | pvalue | TBWL≥10%, n(%) |
|------------------------------|------------------|---------|----------------|
| 12 | 15.6 (14.1-17.1) | <0.0001 | (77) |
| 24 | 15.3 (13.4-17.2) | <0.0001 | (72) |
| 36 | 14.9 (12.1-17.7) | <0.0001 | (63) |
| 48 | 13.5 (9.6-17.4) | <0.0001 | (67) |
| 60 | 15.9 (11.7-20.5) | <0.0001 | (61) |
| Weight loss% at nadir weight | 16.7 (15.6-17.7) | <0.0001 | (80) |



ESG: 5-Year Improvement in Comorbidities



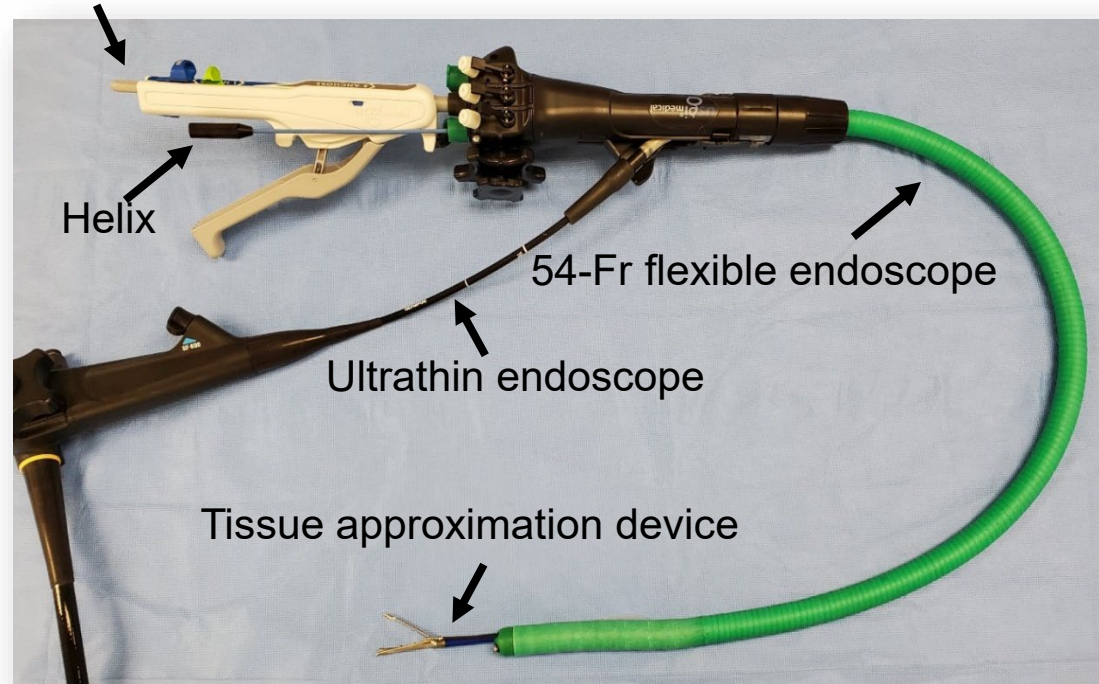
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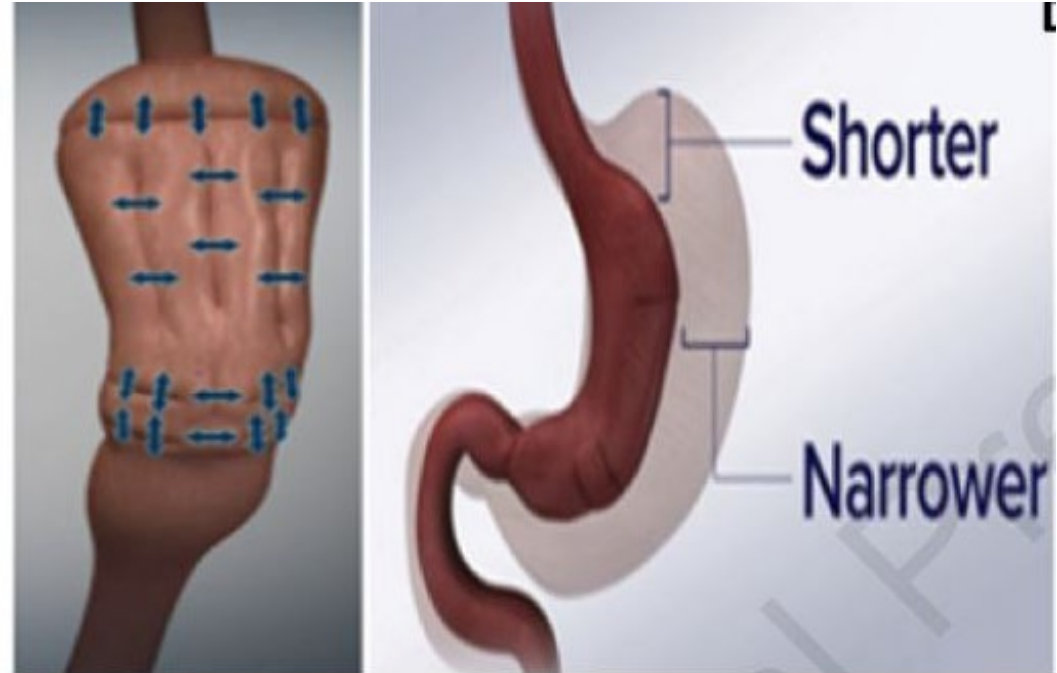
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Primary Obesity Surgery Endoluminal 2 (POSE 2) Procedure

Needle/tissue anchors



Cleared by the FDA for tissue apposition



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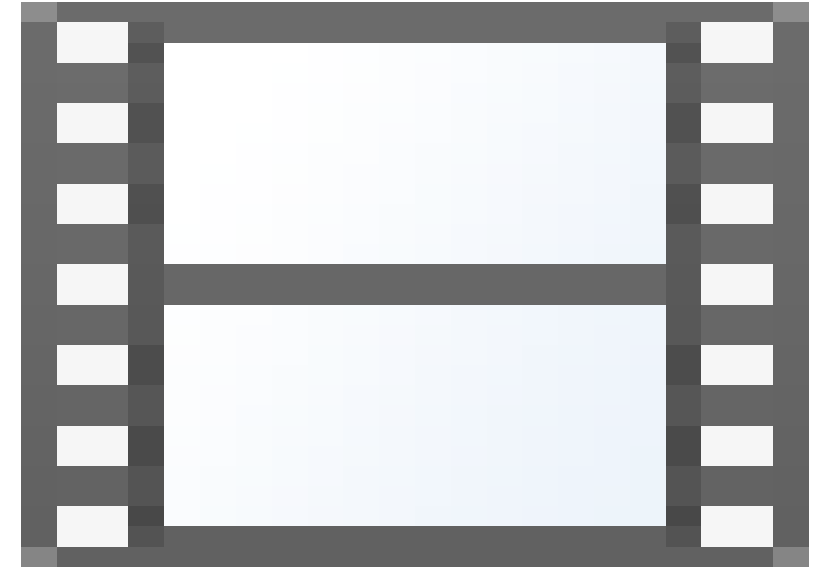
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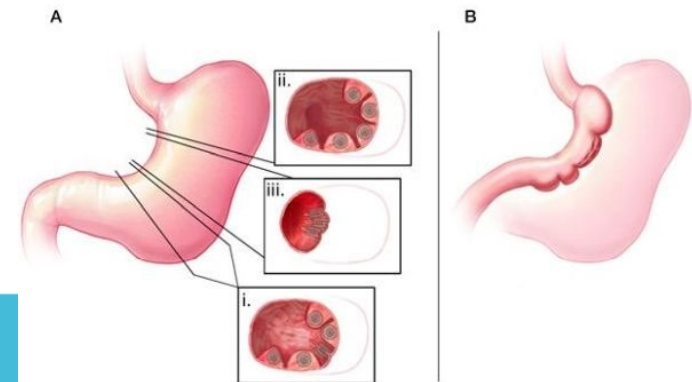
POSE 2: An International Multicenter Prospective Trial

Multicenter study (44 patients)

- TBWL 15.7% \pm 6.6% at 12 months.
- 86% lost \geq 10% TBWL at 12 months.
- ALT (n=36) improved from a baseline of 33.4 mg/dL to 19.1 mg/dL at 6 months (p=0.0074)
- CAP (n=15) of 299 dB/m to 220 dB/m at 6 months (p=0.00024).
- **No SAE**



Jirapinyo P, Thompson C GIE 2020



Lopez Nava et al . DDW 2022, CGH 2022

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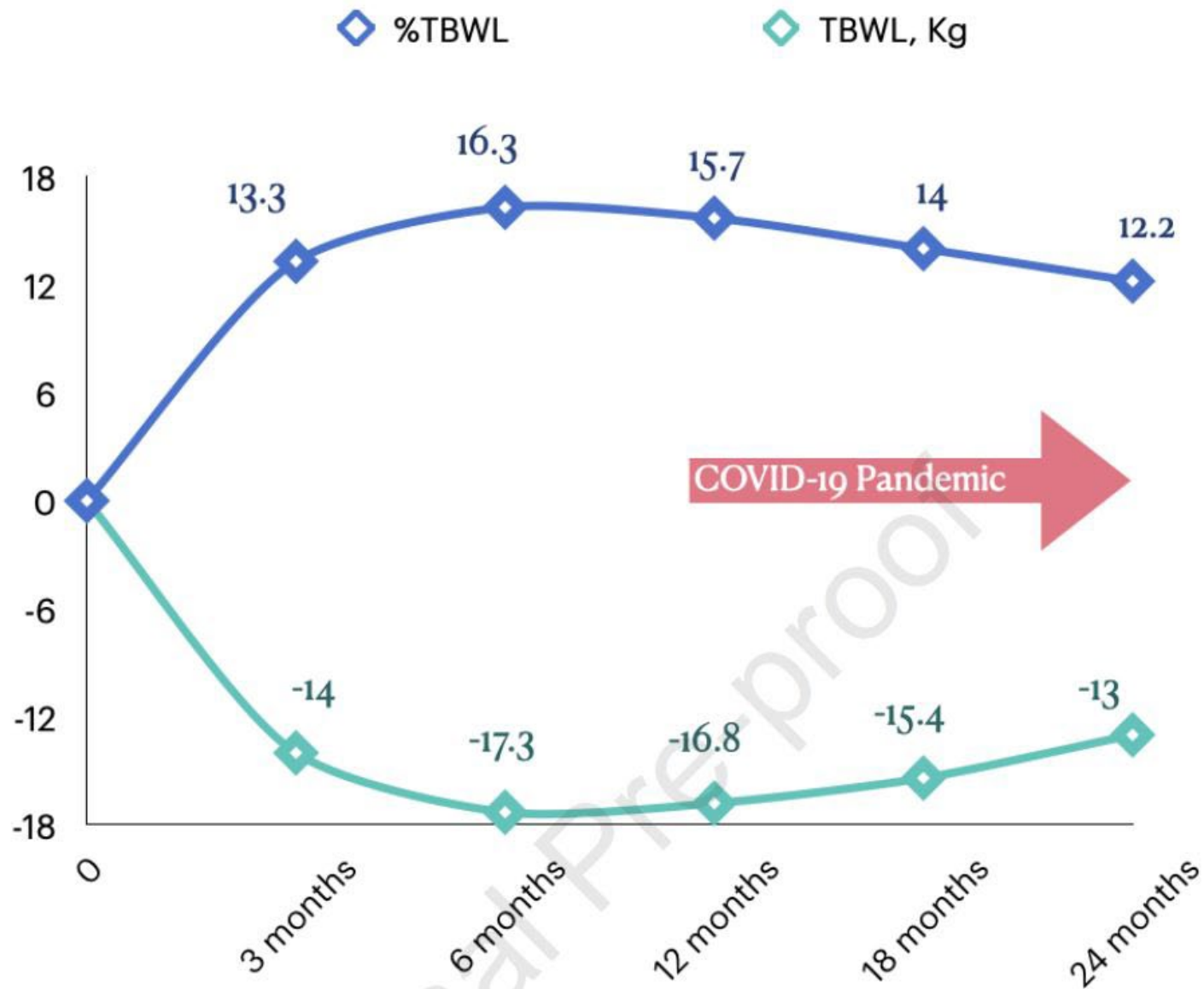
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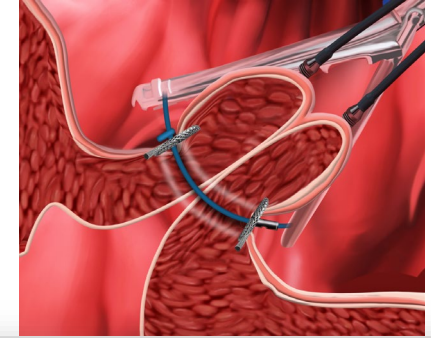
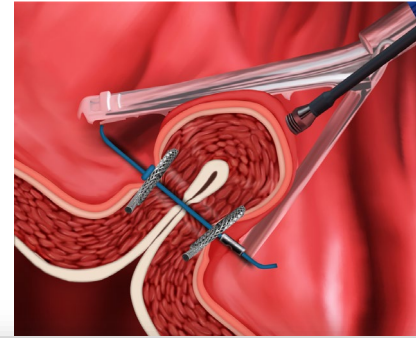


POSE 2: An International Multicenter Prospective Trial

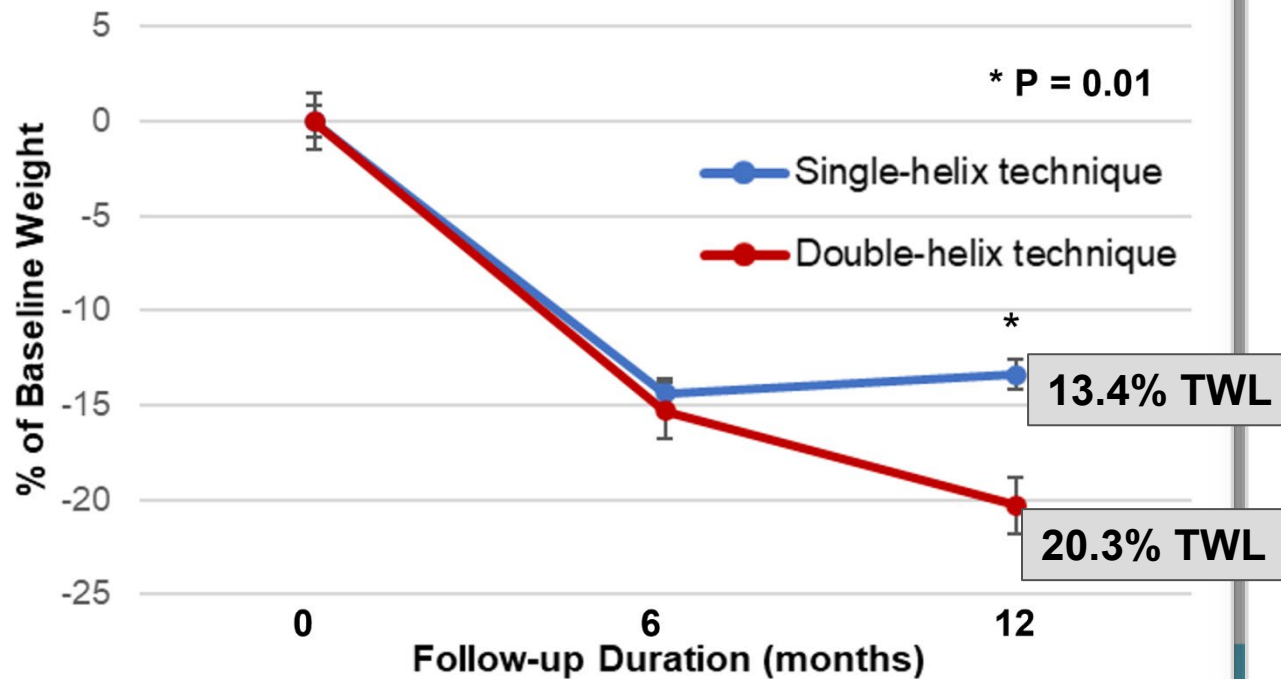


A Comparison of Distal POSE Techniques for the Treatment of Obesity

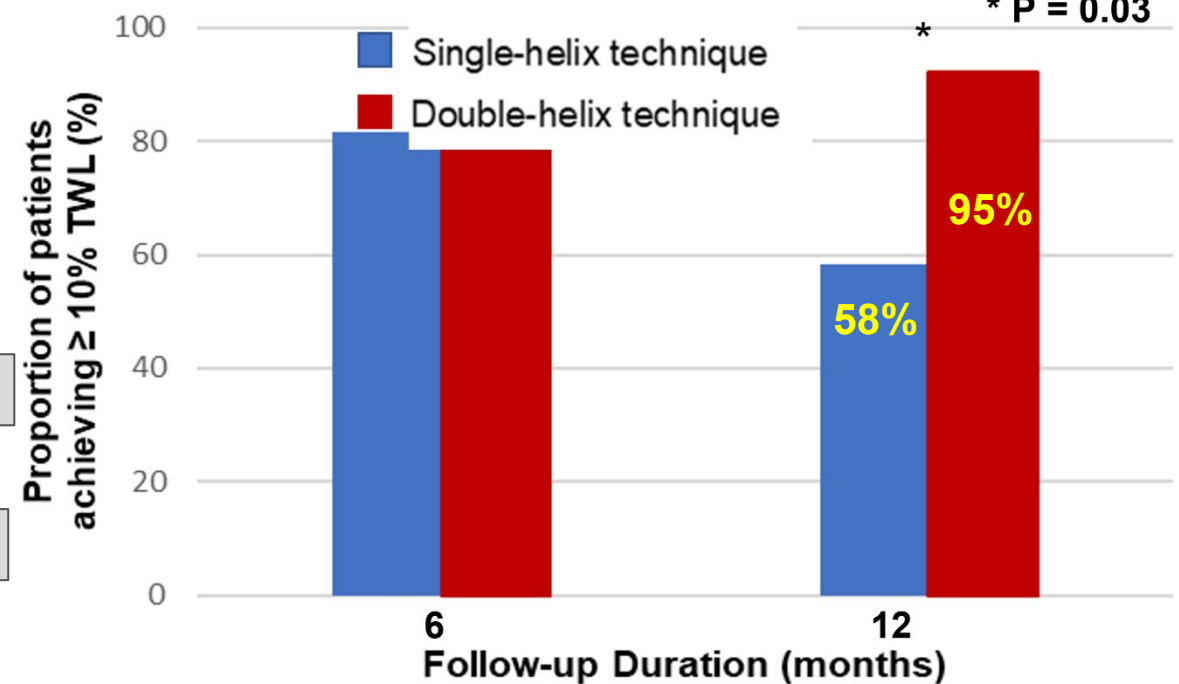
Jirapinyo P , Thompson CC, DDW 2022, GIE 2022



Weight Trend Following Distal POSE

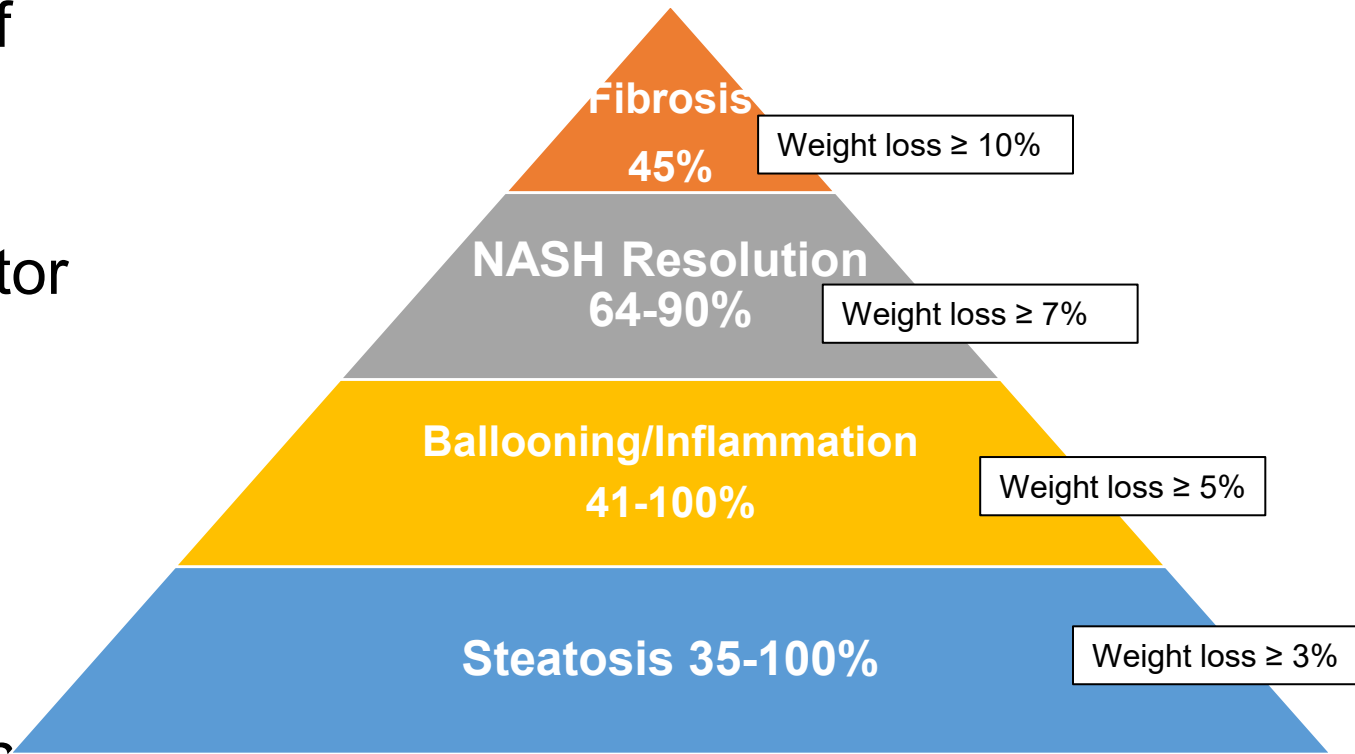


Response Rate Following Distal POSE



Nonalcoholic Fatty Liver Disease (NAFLD)

- NAFLD is the most common cause of chronic liver disease
- Fibrosis stage is the strongest predictor of disease progression
- There is no approved therapy that specifically targets fibrosis
- Weight loss of 10% is associated with fibrosis regression

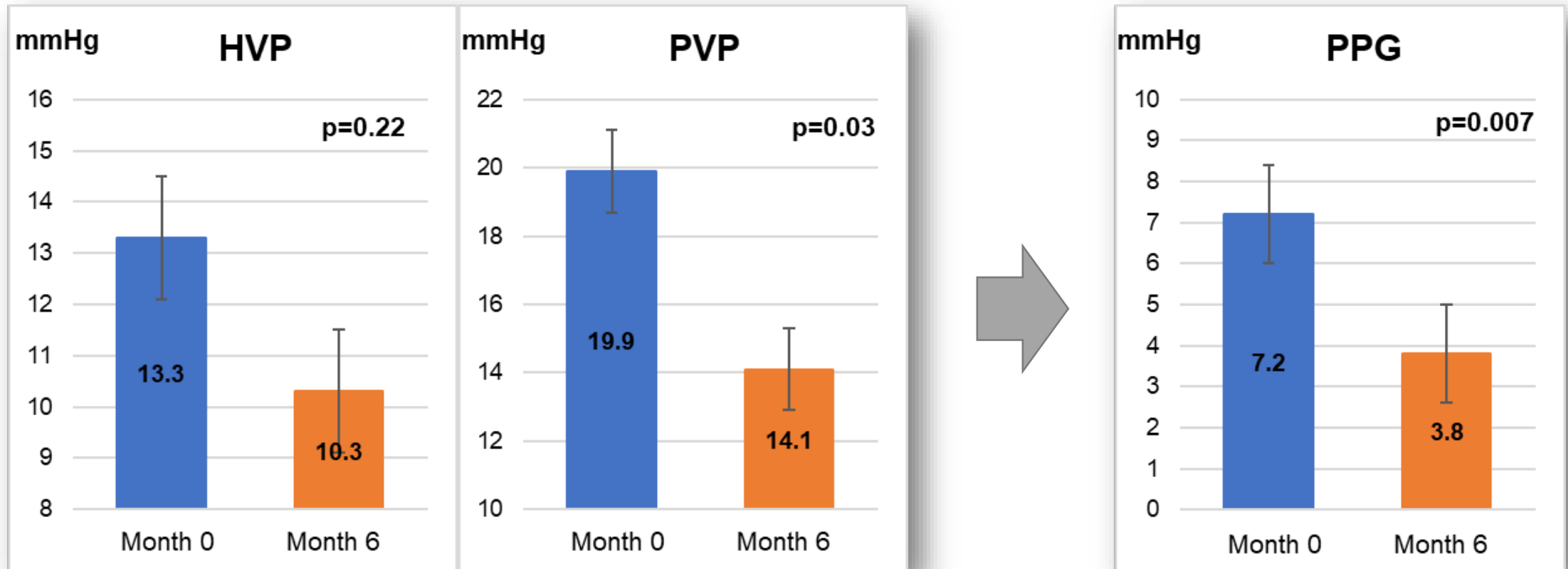


The Effect of POSE2 On Liver Fibrosis in Patients with Nonalcoholic Steatohepatitis

- 30 patients with obesity and NAFLD/NASH with advanced fibrosis underwent EUS-guided PPG measurement as part of the bariatric endoscopic work-up

| Characteristics | N = 30 |
|--|------------|
| Age (years) | 53 ± 12 |
| Sex (female, %) | 22 (73) |
| BMI (kg/m ²) | 41.2 ± 7.4 |
| Vibration-Controlled Transient Elastography | |
| Controlled Attenuation Parameter (CAP) (dB/m) | 343 ± 54 |
| Liver stiffness measurement (LSM) (kPa) | 16.4 ± 8.0 |
| Fibrosis Stage | |
| - F3 (n, %) | 12 (40) |
| - F4/cirrhosis (n, %) | 18 (60) |

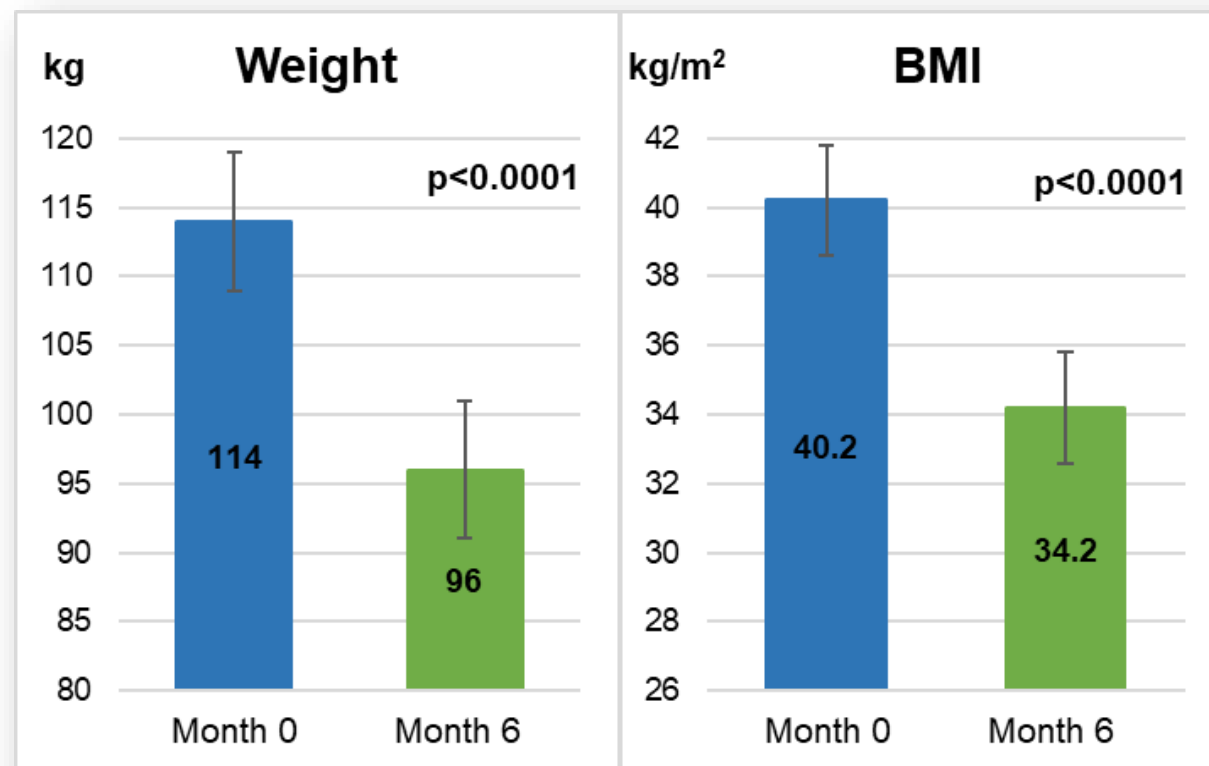
Primary Outcome: Change in Portal Pressure Gradient



PPG decreased from 7.2 ± 5.0 mmHg to 3.8 ± 4.9 mmHg ($p=0.007$)

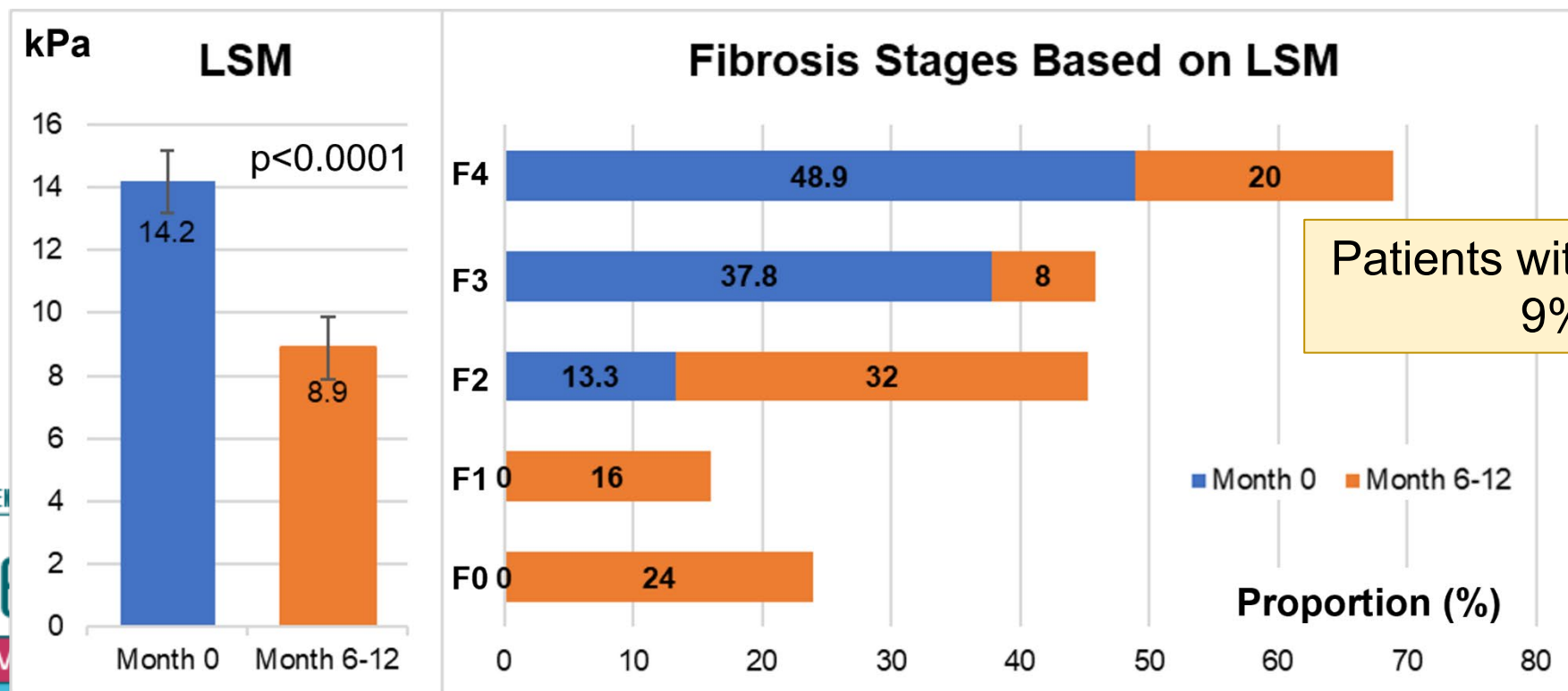
Secondary Outcome: Weight Loss

- **Weight loss at 6 months**
 - $13.6 \pm 5.7\%$ TWL
 - 88% achieved at least 7% TWL (threshold for NASH histologic improvement)
 - 69% achieved at least 10% TWL (threshold for fibrosis regression)

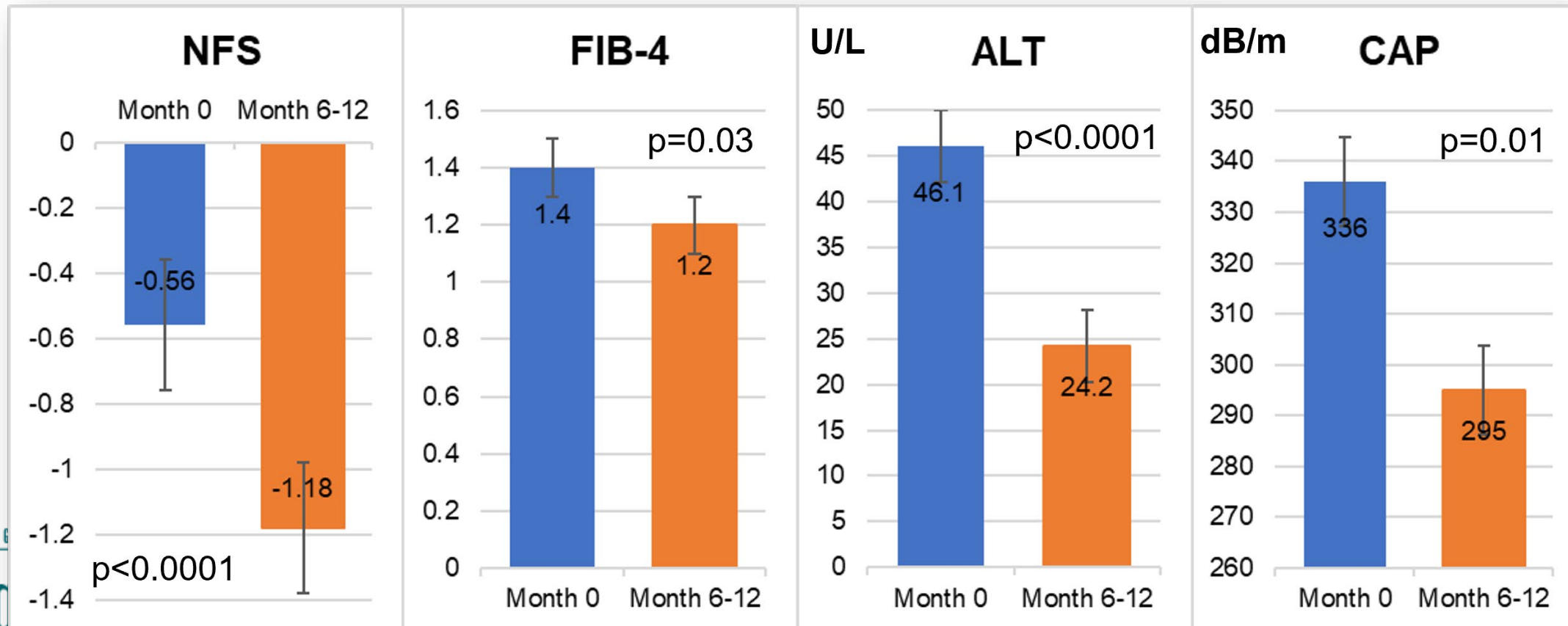


Effect on Liver Stiffness

- At 6-12 months (82% follow-up rate for liver-related outcomes):
 - 68% experienced regression of fibrosis by at least 1 stage
 - 96% experienced no worsening in fibrosis stage



Other Liver Fibrosis- Related Outcomes



Thank You!



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