# Three-year results of comparison between Ringed versus non-ringed Roux-en-Y gastric bypass A Randomized Control Trial

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# Background

**Roux-en-Y gastric bypass (RYGB)** one of the cornerstones of MBS (2013-2014-2023)

**Most common revisional procedure**

**Weight loss failure (WLF)** is terms of weight recurrence (WR) or insufficient WL is not uncommon after laparoscopic RYGB, **reported WLF rates ranges from 20–35%**

**Several factors:** patient's related – anatomical factors.

It may also be attributed to **dilatation** of the gastric pouch and gastrojejunostomy.

Resizing the pouch/gastrojejunostomy +/- ring application has been reported.

Many reports (mid-term and long-term) showed better weight loss with ringed-RYGB

# Objective

Compare outcomes at **6 months** and **3 years**

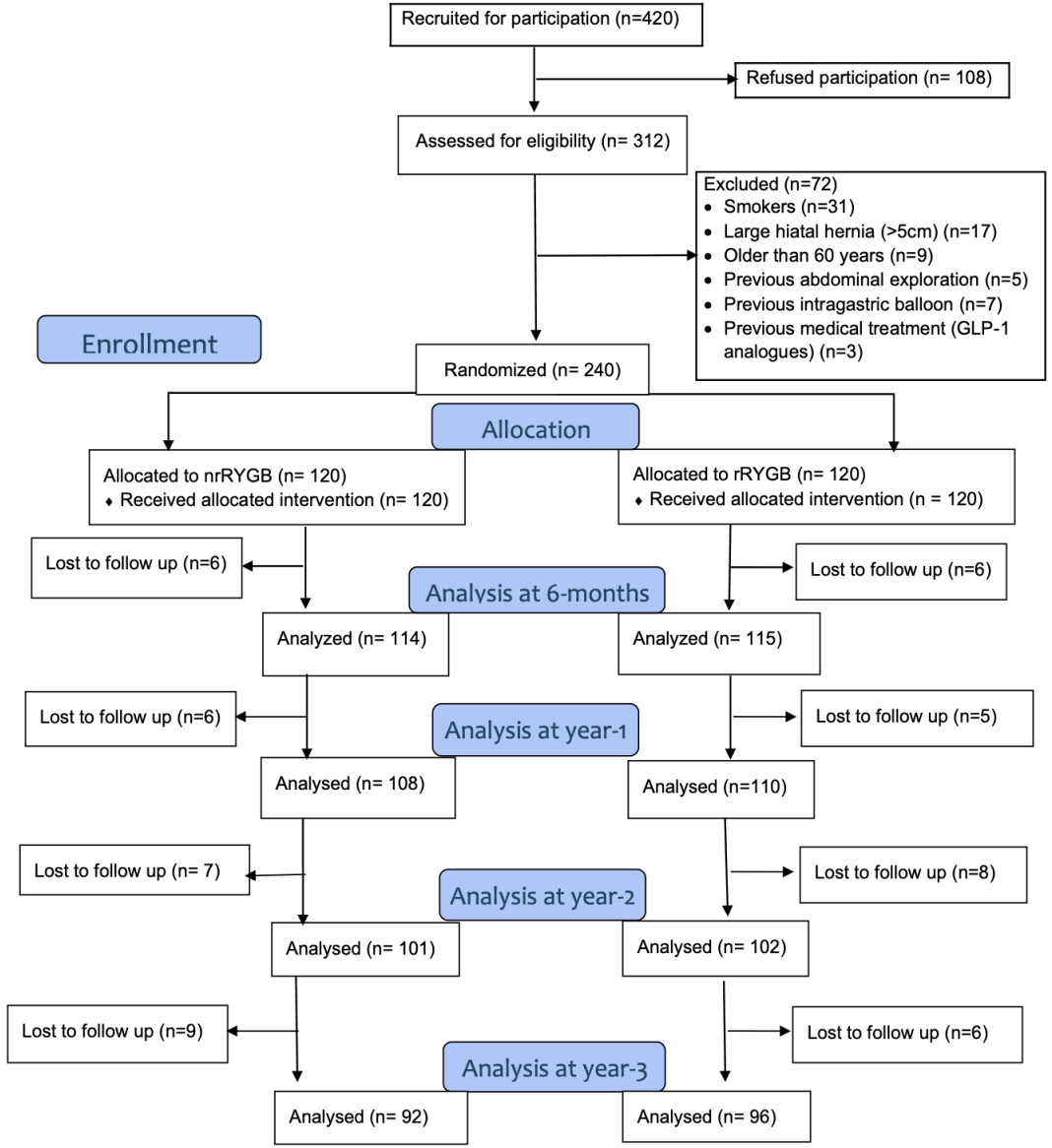
**Non-ringed RYGB (nrRYGB)**

**vs.**

**Ringed RYGB (rRYGB)**

*Several studies are available; however, no studies has a assessed a wide variety of outcomes.*

# Flowchart


Recruited for participation (n=420)
Refused participation (n= 108)
Assessed for eligibility (n= 312)
Excluded (n=72)
• Smokers (n=31)
• Large hiatal hernia (>5cm) (n=17)
• Older than 60 years (n=9)
• Previous abdominal exploration (n=5)
• Previous intragastric balloon (n=7)
• Previous medical treatment (GLP-1 analogues) (n=3)
Enrollment
Randomized (n= 240)
Allocation
Allocated to nrRYGB (n= 120)
♦ Received allocated intervention (n= 120)
Allocated to rRYGB (n= 120)
♦ Received allocated intervention (n = 120)
Lost to follow up (n=6)
Lost to follow up (n=6)
Analysis at 6-months
Analyzed (n= 114)
Analyzed (n= 115)
Lost to follow up (n=6)
Lost to follow up (n=5)
Analysis at year-1
Analysed (n= 108)
Analysed (n=110)
Lost to follow up (n= 7)
Lost to follow up (n=8)
Analysis at year-2
Analysed (n= 101)
Analysed (n= 102)
Lost to follow up (n=9)
Lost to follow up (n=6)
Analysis at year-3
Analysed (n= 92)
Analysed (n= 96)

# Methods

A single-blinded randomized controlled study (Two centers)

- Weight loss in %TWL and %EWL
- Weight recurrence
- Volumetric changes in the gastric pouch and gastro-jejunostomy anastomosis
- Complications
- RAND 36 QoL
- Food tolerance (FT) & dumping score
- Endoscopy

# Baseline characteristics of the sample cohort

| *Baseline characteristics* | nrRYGB (n = 120) | rRYGB (n = 120) | p |
|---|---|---|---|
| Age, mean±SD | 46.4 ± 6.8 | 45.9 ± 7.7 | 0.601 |
| Sex (female), n (%) | 97 (80.8) | 101 (84.2) | 0.610 |
| Anthropometrics | | | |
| Height (m), mean±SD | 1.6 ± 0.1 | 1.6 ± 0.1 | 0.920 |
| Weight (kg), mean±SD | 118.3 ± 11.3 | 118.1 ± 9.6 | 0.873 |
| Ideal body weight (kg), mean±SD | 65.8 ± 5.5 | 65.8 ± 6.0 | 0.944 |
| Excess weight (kg), mean±SD | 52.5 ± 9.3 | 52.3 ± 8.1 | 0.884 |
| BMI, mean±SD | 45.0 ± 3.7 | 45.1 ± 3.7 | 0.937 |
| *Imaging* | | | |
| Hiatal hernia, n (%) | 27 (22.5) | 25 (20.8) | 0.876 |
| Calcular cholecystitis, n (%) | 5 (4.2) | 7 (5.8) | 0.769 |
| *Endoscopy* | | | |
| Hiatal hernia, n (%) | 27 (22.5) | 25 (20.8) | 0.876 |
| GERD grade A, n (%) | 10 (8.33) | 11 (9.17) | 1.000 |
| GERD grade B, n (%) | 2 (1.7) | 1 (0.8) | 1.000 |
| *Associated medical problems* | | | |
| Osteoarthritis, n (%) | 18 (15.0) | 21 (17.5) | 0.726 |
| Dyslipidemia, n (%) | 17 (14.2) | 18 (15.0) | 1.000 |
| Diabetes mellitus, n (%) | 14 (11.7) | 14 (11.7) | 1.000 |
| Hypertension, n (%) | 11 (9.2) | 12 (10.0) | 1.000 |
| Sleep apnea, n (%) | 12 (10.0) | 13 (10.8) | 1.000 |
| Cardiac ischemia, n (%) | 2 (1.7) | 3 (2.5) | 1.000 |

# Methods

- Key features Surgical techniques **rRYGB and nrRYGB**

- **Expanded Pouch**

| | |
|---|---|
| **Bougie size** | **40 fr** |
| **Width of pouch** | 2-2.5 cm |
| **First stapler fire (Lower pouch limit)** | Above the level of incisura angularis (10cm below angle of His) |
| **Last stapler fire** | 1–1.5 cm lateral to esophago-gastric junction |
| **His angle dissection** | Yes |
| **Length of pouch** | 8-10 cm above the gastro-jejunostomy |
| **Capacity of pouch** | 35-40 ml |
| **Counting the whole bowel length** | yes |
| **Limb lengths** | Alimentary limb 100cm<br>Biliopancreatic limb 100cm<br>Always keeping a common limb length of at least 300cm. |
| **Width of gastroenterostomy** | 2-2.5 cm |
| **Reinforcement** | Oversewing invaginating sero-muscular sutures |
| **Hiatal hernia repair** | Yes, if pre-operatively diagnosed |
| **Methylene blue test** | yes |

# Methods

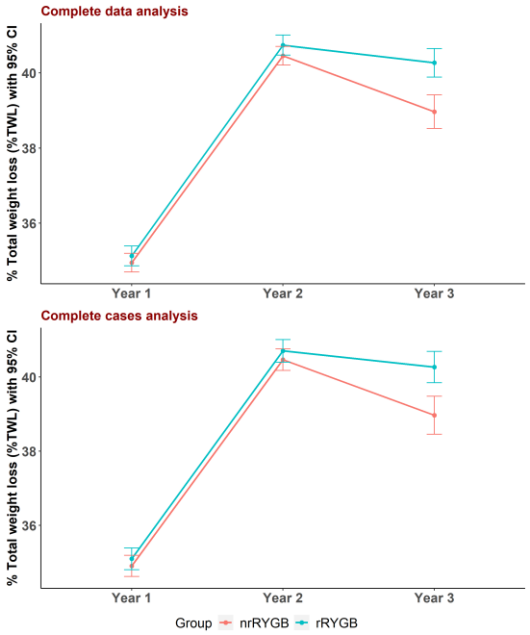
Extra info **rRYGB**:

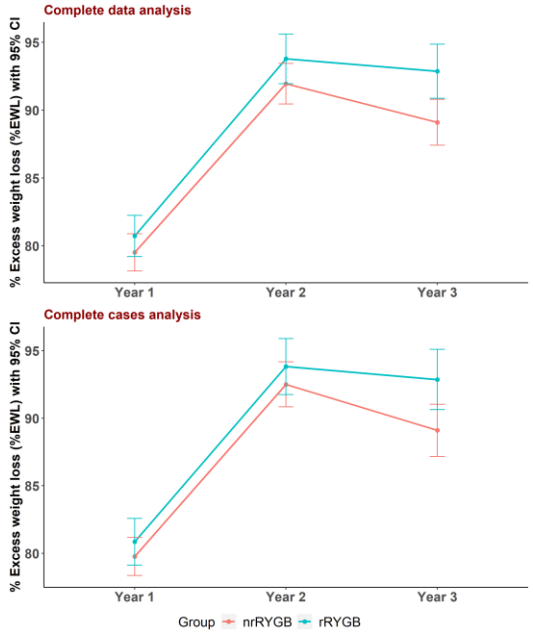
- MiniMizer Gastric Ring was used
- 3 cm above the gastro-jejunostomy
- Ring was loosely placed around the pouch
- Fixed in place by two non-absorbable sutures

# Results

**Weight loss @3years:**

| | nrRYGB | rRYGB | Mean difference: rRYGB – nrRYGB (95% CI) | p |
|---|---|---|---|---|
| %TWL | 39.0 ± 2.5 | 40.3 ± 2.1 | 1.3 (0.6, 2.0) | < 0.001* |
| %EWL | 89.1 ± 9.5 | 92.9 ± 11.2 | 3.8 (0.8, 6.7) | 0.012* |




Weight recurrence was **significantly lower** in rRYGB

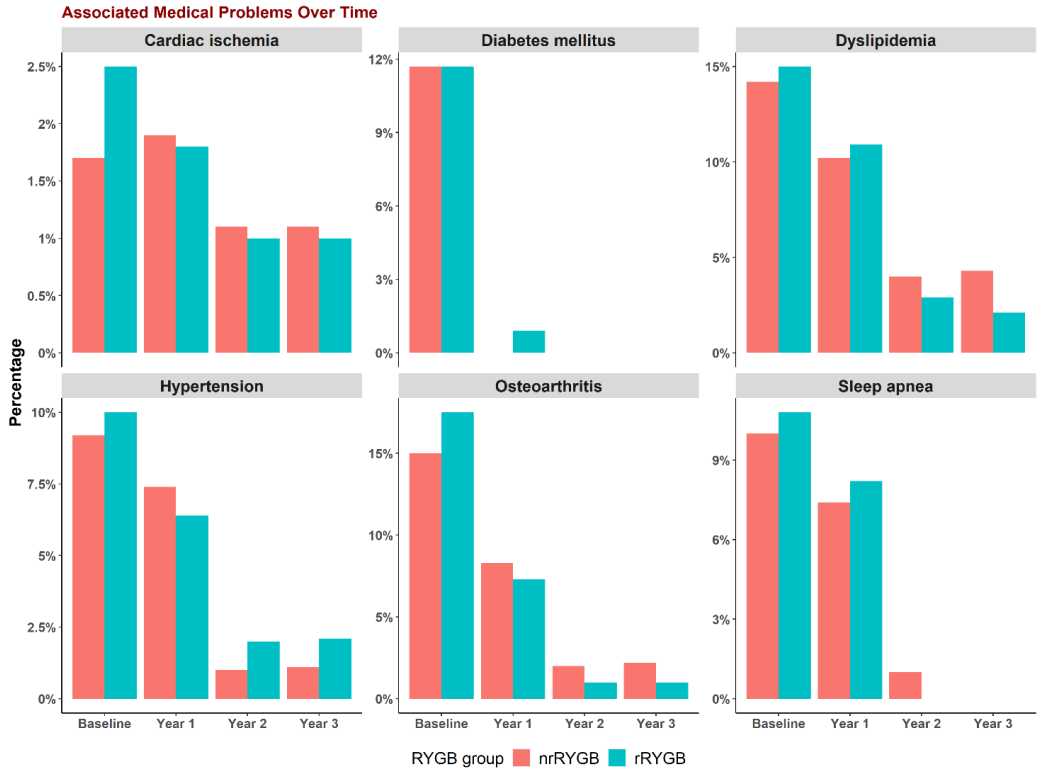
# Results

- **No significant** differeces in **complications, readmissions, reoperations**

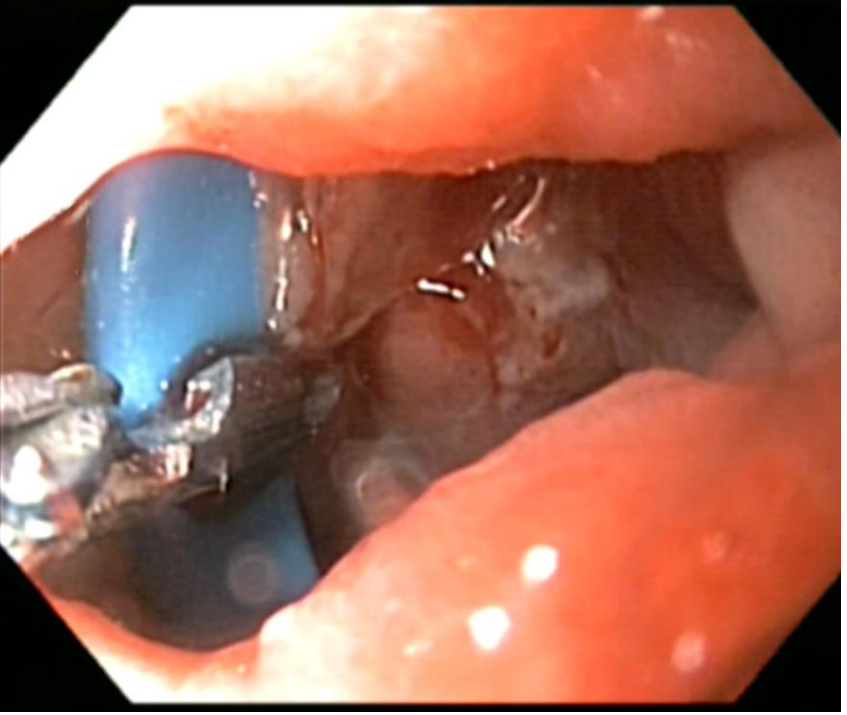
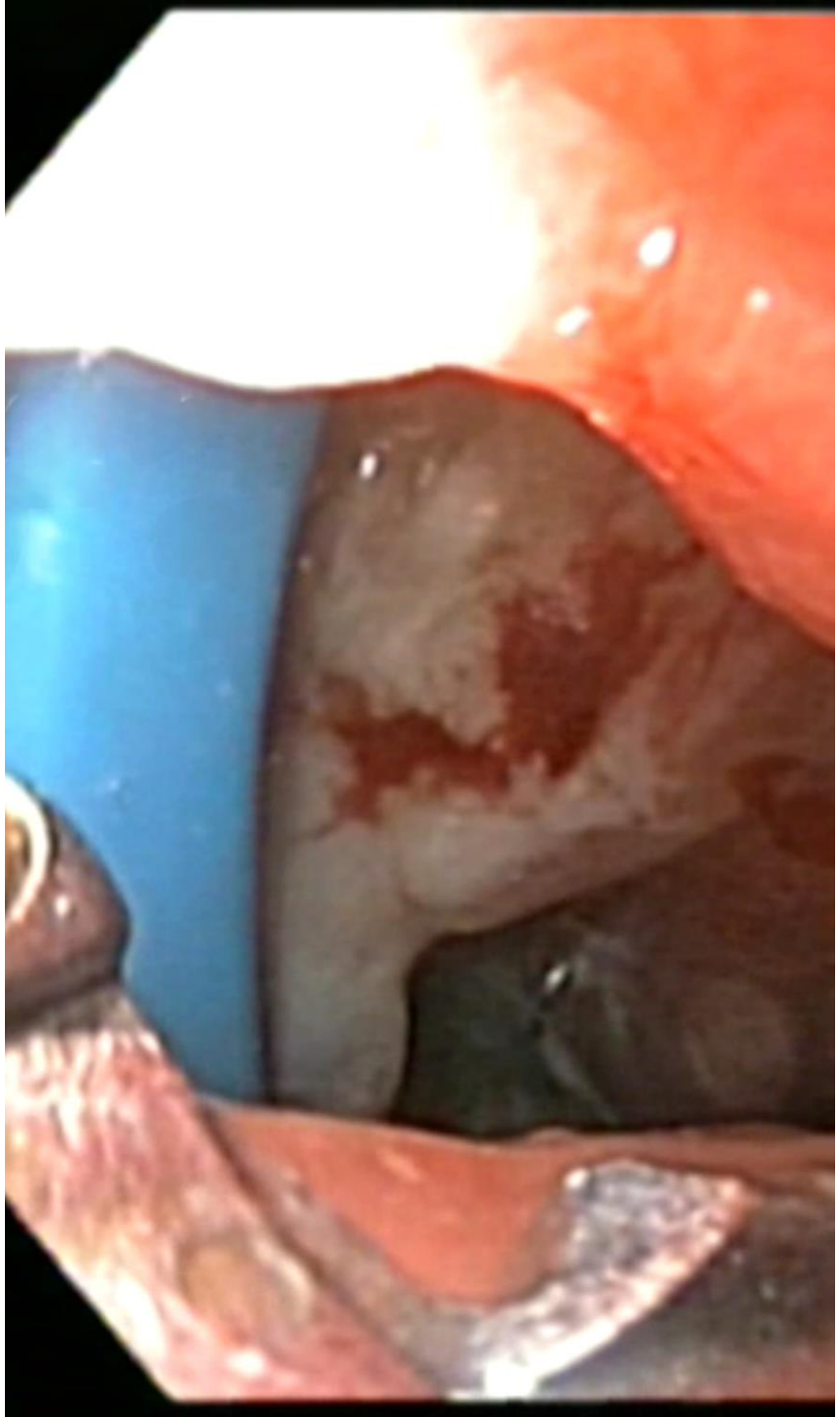
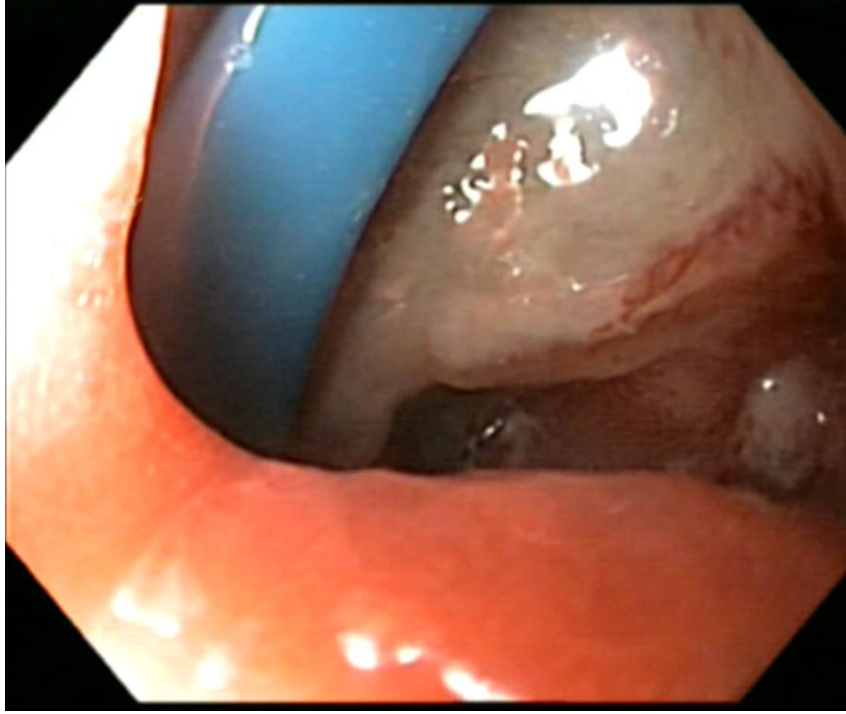
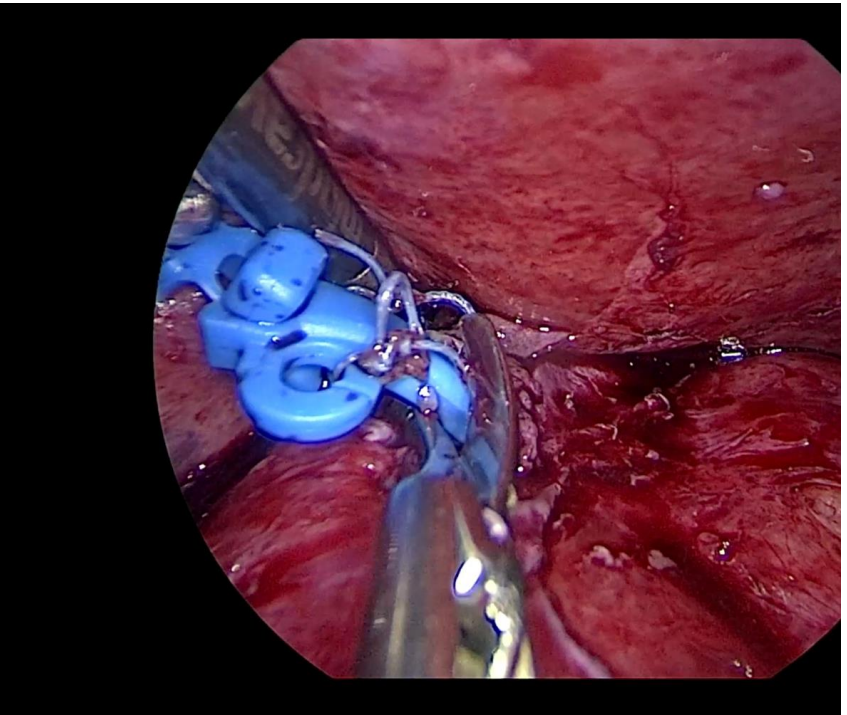
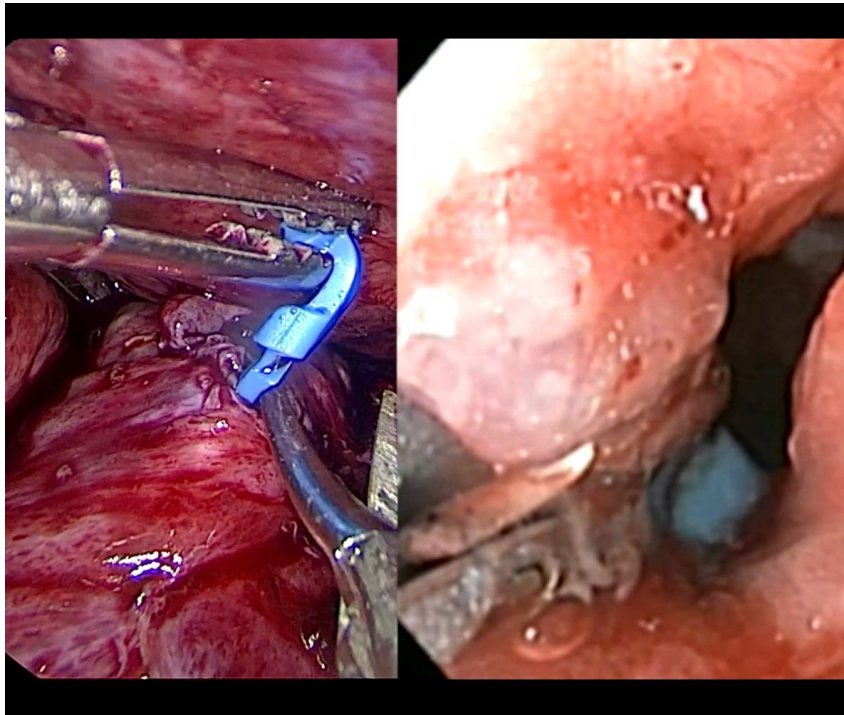
- **No significant differences** between groups for RANDSF36
  But **a significant improvement** in both groups pre vs. 3 years

- Both groups had **comparable significant improvement**

in **associated medical problems** at 3-years compared to baseline.



| | | | |
|---|---|---|---|
| Overall complications | 36 (30.0) | 38 (31.7) | 0.889 |
| Early complications | 7 (5.8) | 8 (6.7) | 1.000 |
| Hemorrhage | 1 (0.8) | 2 (1.7) | 1.000 |
| Melena | 2 (1.7) | 1 (0.8) | 1.000 |
| Vomiting | 4 (3.3) | 5 (4.2) | 1.000 |
| Late complications | 29 (24.2) | 31 (25.8) | 0.882 |
| Hiatal hernia | 10 (10.8) | 11 (11.5) | 1.000 |
| Marginal ulcer | 4 (3.3) | 3 (2.5) | 1.000 |
| Internal hernia | 0 (0.0) | 1 (0.8) | 1.000 |
| Port-site hernia | 1 (0.8) | 1 (0.8) | 1.000 |
| Anemia | 3 (2.5) | 5 (4.2) | 0.722 |
| Denovo GERD | 2 (1.7) | 2 (1.7) | 1.000 |
| Perforation | 0 (0.0) | 1 (0.8) | 1.000 |
| Dysphagia | 0 (0.0) | 1 (0.8) | 1.000 |
| Calcular cholecystitis | 15 (12.5%) | 14 (11.7) | 1.000 |
| Clavien-Dindo classification | | | |
| I | 4 (3.3) | 5 (4.2) | 1.000 |
| II | 2 (1.7) | 1 (0.8) | 1.000 |
| III-b | 1 (0.8) | 2 (1.7) | 1.000 |
| Readmission | 10 (8.3) | 11 (9.2) | 1.000 |
| Reoperation | 2 (1.7) | 4 (3.3) | 0.684 |
| Reoperation cause | | | |
| Exploration for early complications | 1 (0.8) | 2 (1.7) | 1.000 |
| Exploration for internal hernia | 0 (0.0) | 1 (0.8) | 1.000 |
| Port-site hernia repair | 1 (0.8) | 1 (0.8) | 1.000 |
| Endoscopy year 1 | | | |
| Denovo hiatal hernia | 2 (1.9) | 1 (0.9) | 0.620 |
| Denovo GERD A | 2 (1.9) | 1 (0.9) | 0.620 |
| Marginal ulcer | 1 (0.9) | 0 (0.0) | 0.495 |
| H pylori | 3 (2.8) | 4 (3.6) | 1.000 |
| Endoscopy year 3 | | | |
| Denovo hiatal hernia | 10 (10.8) | 11 (11.5) | 1.000 |
| Denovo GERD A | 2 (2.2) | 2 (2.1) | 1.000 |
| Marginal ulcer | 4 (4.3) | 3 (3.1) | 0.716 |
| H pylori | 4 (4.3) | 5 (5.2) | 1.000 |

# Results

- **Leptin** and **ghrelin** levels were **significantly higher** in the **rRYGB** group

| **Baseline characteristics** | **nrRYGB (n = 120)** | **rRYGB (n = 120)** | **p** |
|---|---|---|---|
| Leptin, fasting (ng/ml), mean±SD | 30.7 ± 1.4 | 30.5 ± 1.4 | 0.319 |
| Ghrelin, fasting (pg/ml), mean±SD | 327.6 ± 41.1 | 321.2 ± 43.7 | 0.241 |

| **Post-op Lab investigations** | **nrRYGB N = 92** | **rRYGB N = 96** | **p** |
|---|---|---|---|
| Leptin, fasting (ng/ml), mean±SD | 14.3 ± 1.5 | **14.8 ± 1.4** | 0.020* |
| Ghrelin, fasting (pg/ml), mean±SD | 228.4 ± 42.5 | **243.8 ± 42.3** | 0.014* |

# Results

**Volumetry@3 years:**

- rRYGB had **significantly lower**
  - Total gastric pouch volume,
  - Gastrojejunostomy dimeter
  - Alimentary limb diameter

| Volumes | nrRYGB | rRYGB | *p* |
|---|---|---|---|
| Total pouch Volume (ml) | 72.4 ± 6.1 | **55.7 ± 6.9** | < 0.001* |
| Anastomosis size (cm) | 3.2 ± 0.5 | **1.8 ± 0.5** | < 0.001* |
| ITM, n (%) | 37 (30.8%) | 45 (37.5%) | 0.341 |
| Migration distance of ITM (cm) | 1.2 ± 0.5 | 1.2 ± 0.5 | 0.522 |
| Diameter of alimentary limb (cm) | 3.3 ± 0.6 | **2.1 ± 0.5** | < 0.001* |

# Results

**Volumetry**

**Specific in rRYGB:**

| Volumes | 6 months | 3 years | *p* |
|---|---|---|---|
| Volume of the pouch above the ring (ml) | 25.7 ± 3.9 | 41.9 ± 5.5 | < 0.001* |
| Volume of the pouch below the ring (ml) | 16.9 ± 3.1 | 14.3 ± 3.3 | < 0.001* |
| Distance between the band and the anastomosis (cm) | 2.4 ± 0.5 | 1.5 ± 0.5 | < 0.001* |

# Results

# Results

**Food Tolerance (up to 27, higher indicate excellent eating quality**

**Dumping (>7 Sigstad score was considered positive for dumping syndrome)**

| | nrRYGB | rRYGB | *p* |
|---|---|---|---|
| **At 3-years of follow-up** | **N = 92** | **N = 96** | |
| Patients with Sigstad score ≥ 7, n (%) | 51 (55.4) | 38 (39.6) | 0.042* |
| FT score at 3 years, mean±SD | 24.0 ± 1.4 | 22.5 ± 2.5 | < 0.001* |

# Conclusion

**The ringed RYGB @ 3 years**

Better WL in terms of higher %EWL and %TWL
Less Weight recurrence
Maintained smaller volumes of the pouch
Lower incidence of dumping

**Nevertheless,**
**Worse** food tolerance score
**Higher** leptin and ghrelin levels

# Thank you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