

# MULTICENTRIC INTERNATIONAL STUDY TO EVALUATE PERFORMANCE AND SAFETY OF LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING (HELIOGAST)

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# Introduction

- Many surgical techniques are routinely used in patients with severe obesity (BMI > 35). Laparoscopic adjustable gastric banding (LAGB) is the unique truly reversible surgical option effective on morbid obesity
- The objective of this multicenter retrospective study is to measure LAGB efficacy and tolerance in current practice
- Primary objective: to measure the effectiveness of LAGB (Heliogast®) at 12 and 24 months by excess weight loss (EWL) measurement
- Secondary objective: safety of the device by measuring early and late complications observed on the band and the implantable chamber, as well as the rate of reintervention

## Methods

- **Patients enrolled** (01/2018 – 12/2022) 1079
  - **M/F ratio** 113/966
  - **Mean age (range)** 41.8 yrs (14-67)
  - **Mean BMI (range)** 38.1 (31-56)
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- Heliogast® was proposed to any patient respecting the indications for treatment by adjustable gastric banding
  - Patients were included in accordance with the usual practice of the investigating centers

**LAGB placement**



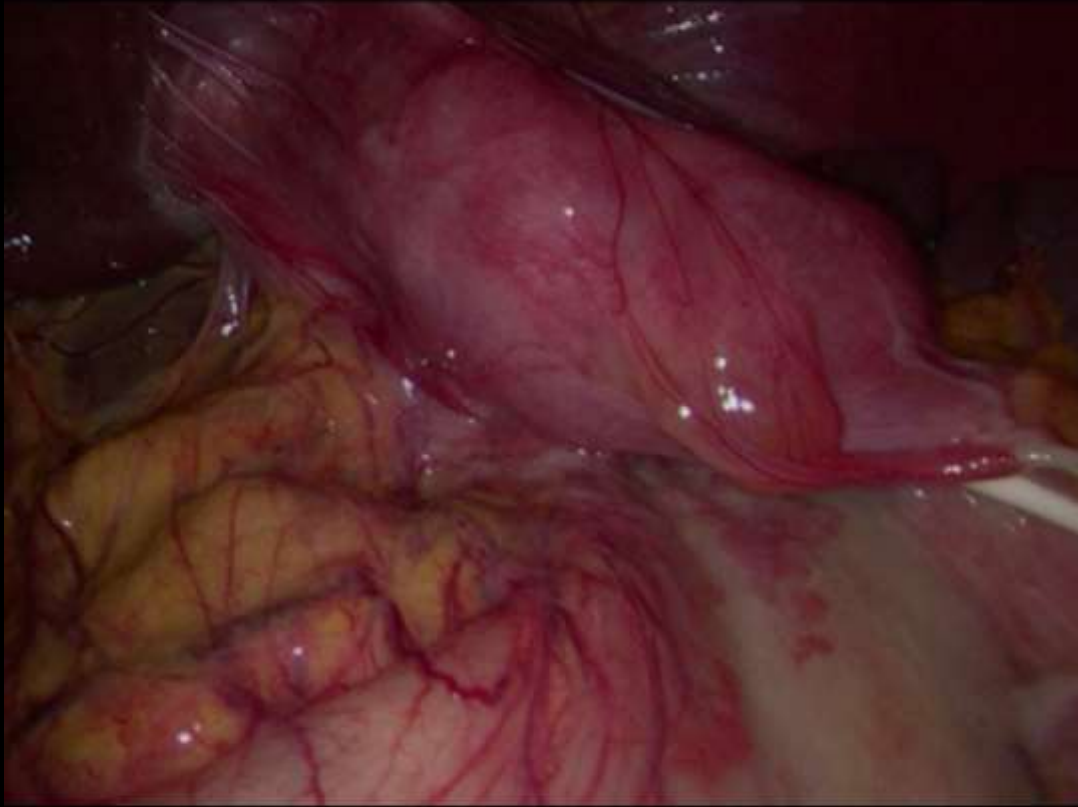
# Results (per protocol)

- **Follow-up**
  - ✓ 12 months 805 (74%)
  - ✓ 24 months 527 (49%)
- **Mean EWL (range)**
  - ✓ 12 months 69% (19-316)
  - ✓ 24 months 54% (-6-188)
- **Mean BMI (range)**
  - ✓ 12 months 29 (21-37)
  - ✓ 24 months 31 (22-48)

# Complications

|   |           |
|---|-----------|
| • <b>Mortality</b>  | 0         |
| • <b>Band slippage</b>  | 64 (6%)   |
| ✓ Repositioning   | 3         |
| ✓ Removal   | 63        |
| • <b>Port infection</b> (removal, medical treatment, re-implantation) | 11 (1%)   |
| • <b>Band erosion/intraluminal migration</b>                          | 4 (0.4%)  |
| • <b>Port twisting</b> → repositioning                                | 19 (1.7%) |
| • <b>Band intolerance</b> (vomiting, GERD) → removal                  | 32 (3%)   |
| • <b>Transient port pain</b>  | 12 (1%)   |

# LAGB removal



# Endoscopic removal





# Conclusions

- Efficacy was in line with literature data on adjustable gastric banding
- More than 90% of patients kept their band implanted with satisfaction up to 24 months, with mild and transient side effects
- Fast and easy procedure for implantation of the band and the implantable port
- Gastric band easily unlocked and retrieved when removal is necessary
- Double-balloon of the HAGA allows a low pressure on the stomach wall (low intraluminal migration rate)
- Low rate of complications and no unknown adverse effects