Evaluation of the 2024 Metabolic and Bariatric Surgery Clinical Trial Pipeline

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Background

- **Clinical trials (CTs):** highest level of evidence and helped define **Metabolic & Bariatric Surgery (MBS)** practice
- Surgical CTs historically **lag behind** other areas of medical research
- **Medical weight loss** evolving with recent FDA approval of anti-obesity medications

Objective

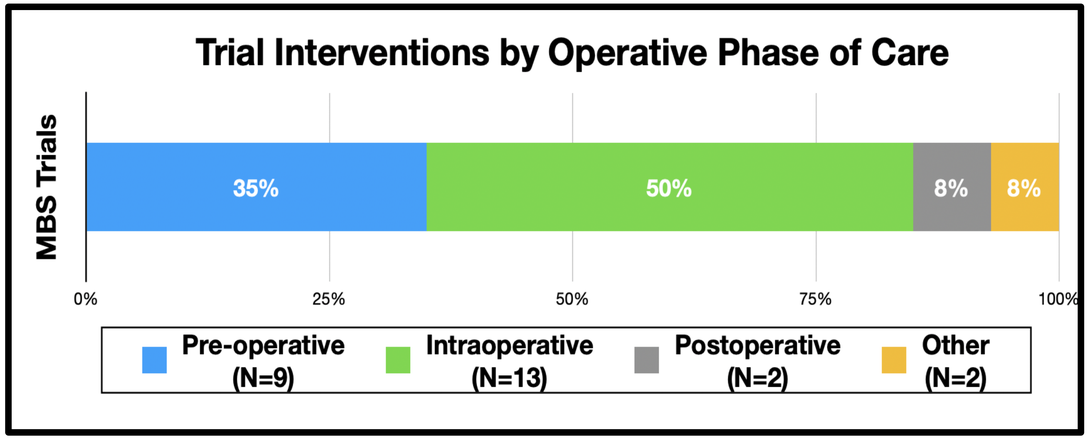
To evaluate the current state of MBS clinical trial activity in the 2024 pipeline

Methods

- Identified MBS trials from ClinicalTrials.gov, a national trial registry overseen by the NIH
- Phase I-IV as of September 1, 2024
- Trial interventions categorized by perioperative timeline: pre-/intra-/post-op

Results

- **26 of 483 MBS trials** from CT.gov (search terms "bariatric" and "obesity"). Excluded completed, non-surgical, duplicate



2024 MBS Trial Characteristics

- 23% trials in early phase (I or II), 77% in late phase (III or IV)
- **CT Outcomes**: 54% focused on minor outcomes (pain, nausea, vomiting); 19% diabetic control; 8% weight loss
- Only one trial focused on operative technique directly
- **Study Sites**: 10 US-based, 16 International

Conclusions

- **MBS trials represent a vast minority** of ongoing obesity-related clinical trial activity, possibly due to recent successes of medical weight loss
- Modern trials tend to focus on **minor clinical events**, possibly due to design challenges related to surgical CTs
- **US-based trials** make up less than half of MBS trials and tend to be conducted at academic referral centers, likely due to high patient volumes and dedicated bariatric programs
- **Further studies** are needed to better elucidate the challenges related to conducting MBS trials