Abstract | Discussion Forum (0)

THE REAL-WORLD BURDEN OF SURGICAL RESCUE IN ENDOSCOPIC SLEEVE GASTROPLASTY: A MAUDE DATABASE ANALYSIS OF MECHANISM AND SEVERITY IN THE POST-AUTHORIZATION ERA

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Background

Endoscopic Sleeve Gastroplasty (ESG) has transitioned from use in expert centers to widespread clinical adoption following FDA De Novo authorization in 2022. While pivotal trials (e.g., MERIT) demonstrated a favorable safety profile, the "denominator effect" of mass adoption may unmask low-frequency, high-severity device failures that require surgical intervention. We analyzed the FDA MAUDE database to characterize the mechanism of failure and the burden of surgical rescue associated with the ESG system in the post-marketing landscape.

Methods:

We queried the FDA MAUDE database for the Endoscopic Tissue Approximation Device (Product Code: OCW) from 2020 to 2025. Reports were rigorously filtered to isolate the Apollo Overstitch system, excluding laparoscopic and gynecological suturing devices. Natural language processing (NLP) categorized narrative reports into hardware failure modes (e.g., suture breakage, needle driver entrapment) and clinical outcomes. Data were stratified into "Pre-FDA" (Expert Phase) and "Post-FDA" (Adoption Phase) eras to evaluate safety signals associated with procedural democratization.

Results:

A total of 264 unique device event reports were analyzed. Suture Malfunction (breakage, failure to cinch, or unraveling) was the predominant hardware failure mode, identified in 158 cases (59.8%). This was followed by Needle/Driver Jams in 67 cases (25.4%), often necessitating device disassembly inside the patient. We identified 79 cases (29.9%) of gastric leak/perforation and 59 cases (22.3%) of major bleeding requiring transfusion or intervention.

Notably, 73 patients (27.6%) required emergent conversion to laparoscopic or open surgery. The primary indication for surgical salvage was full-thickness gastric perforation following suture integrity failure.

Post-market surveillance revealed a >5-fold increase in report volume in the Post-FDA "Adoption Phase" (n=227) compared to the Pre-FDA "Expert Phase" (n=37). Despite increased user experience globally, the proportion of reports involving surgical conversion remained significant.

Discussion

While ESG is an effective minimally invasive therapy, real-world surveillance identifies a persistent signal of suture-related device failure leading to gastric perforation. The absolute burden of 73 surgical rescues highlights that device malfunctions-specifically suture compromise-can precipitate life-threatening complications. As ESG adoption expands, standardized training in endoscopic "bail-out" strategies and surgical rescue protocols is essential to mitigate morbidity.