Risks of Adjustable Gastric Banding

Using MAUDE data to reveal blind spots in the literature

Crosby P, Alsaad R, Ripley-Hager C, Coker A, Adrales GL, The Johns Hopkins University, Division of Minimally Invasive Surgery

Problem / Question

Frequency of laparoscopic adjustable gastric banding complications as reported in the MAUDE database, and how it compares to the current literature. Is there under-reporting in the MAUDE database?

Introduction

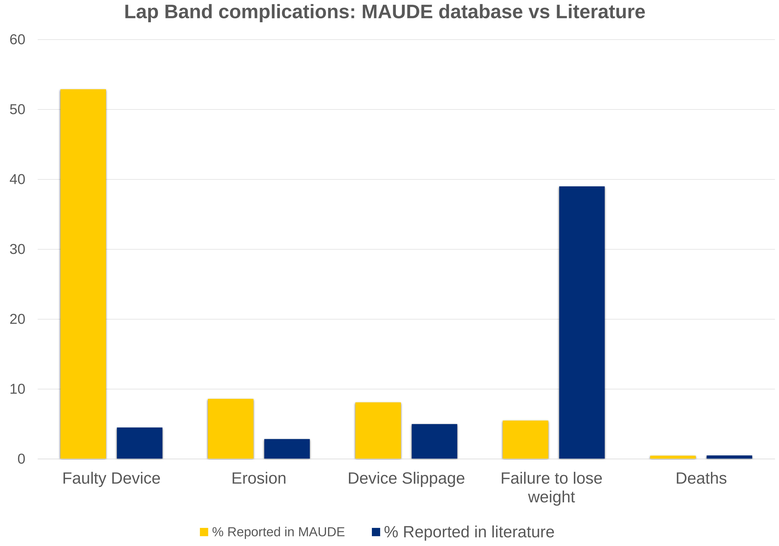
At the turn of the century, there is ample literature to prove the durability of weight loss with bariatric surgery over medical management alone. Since the 1990s, laparoscopic adjustable gastric bands gained popularity due to their early weight loss with low rates of postoperative complications. Initial studies confirmed that LAGB was a safe bariatric procedure; but has been supplanted due to concerns of complications and efficacy. The purpose of this study is to examine the frequency of the different post-operative complications and device malfunction after LAGB leading to re-operation and deficiencies in reporting.

Materials and Methods

We performed a retrospective review of the Manufacturer and User Facility Device Experience (MAUDE) database, searching for all reported post-operative adverse events after LAGB from 2011 to 2021 that lead to re-operation. Our initial search included 3498 reported complications or malfunctions after LAGB. After excluding adverse events that were not clearly explained, we analyzed 3246 entries. We compared our results to other peer reviewed published articles describing the complications after LAGB.

Results

Complication	% of total events reported in MAUDE	% reported in the literature
Faulty device (fluid leak, tubing issues)	52.9 %	2.58 – 6.5%
Erosion	8.6 %	0.9 – 3.9%
Device Slippage	8.1 %	5 %
Failure to lose weight	5.5 %	16 – 62%
Deaths	0.47 %	0.51%



Conclusion

Although LABGs were introduced into the market as a relatively simple and safe intervention, over the last 10 years we found nearly 3500 reported adverse events in the MAUDE database ranging from regurgitation to death. However, when compared to current literature, our data suggests possible underreporting of these complications in the literature when compared to the MAUDE database. This urges us to encourage adverse event reporting to promote device quality control and prevention of adverse events. As more events are reported, future research should move towards establishing guidelines for long term surveillance and possible early removal of the device before severe complications occur.

Works Cited

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