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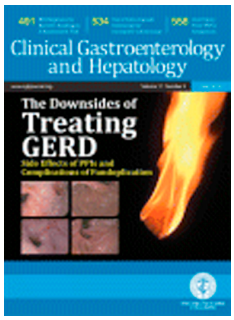

Adverse Events after Implantation of a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux

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Letter to the Editor

Adverse Events after Implantation of a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux.

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Conflict of Interest: As the sole author of this letter, I do not have any conflict of interest to declare.

Ganz et al. provided an overall positive assessment in their report of results 5 years after implantation of the LINX device for symptomatic reflux [1]. While the authors emphasized the safety, they listed 7 surgeries for device removal in the cohort of 100 patients. Similarly positive results were initially reported for the Angelchic prosthesis, an elastic silicon ring for the augmentation of the gastroesophageal junction [2], and the laparoscopically implanted adjustable gastric band for the treatment of morbid obesity [3]. However, complications with intraluminal erosions surfaced with increasing time and popularity of these surgeries [4, 5]. Not seeing erosions of the LINX device into the esophageal lumen is certainly encouraging. However, case reports of such events have been published [6]. A review of post-marketing surveillance tool of the Federal Drug Administration suggest that such cases may not be isolated. The Manufacturer's and User's Device Experience function as data repository (MAUDE) for device-related adverse event. Manufacturers are required to report problems. In addition, physicians, patients and others can submit information about potential complications due to medical devices. Using the publically available search function of MAUDE (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) with the search term LINX and manufacturer's name Torax, a total of 133 case forms listed the device. All but 3 reports were submitted by company representatives and all described device removal. There were 11 cases of endoscopically confirmed device erosion (Figure). The incidence of adverse events cannot be calculated 0as the total number of devices sold or implanted is unknown. Beyond theoretical concerns about potential parallels between LINX and prior experiences with devices implanted in the gastroesophageal junction, data collected in the MAUDE repository should caution us about a more widespread use of surgery in a disorder that – based on study inclusion criteria – was not severe and had not led to significant complications prior to the operative treatment.

Figure