

MP04-14 Complications of Endovascular Stapling Devices During Minimally Invasive Radical Nephrectomy: An Updated Review of the Food and Drug Administration Database from 2009-2019



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Introduction

- While approximately 2,000 minimally invasive radical nephrectomies are performed in the US yearly¹, precious little is known about complications involving endovascular staplers, which arguably are involved with the aspect of the procedure with the potential for greatest morbidity: ligation of the renal hilum.
- MAUDE (Manufacturer and User Facility Device Experience) database contains reports submitted to the FDA concerning faulty devices with or without manufacturer evaluation.² Previous studies have characterized hemostatic device complications during laparoscopic radical nephrectomy using this database but are over 10 years old.^{3,4}
- The current study sought to provide an updated look at complications of endovascular staplers during laparoscopic and robot assisted radical nephrectomies within the last 10 years.

Methods

- We queried the MAUDE database for faulty endovascular stapler reports submitted between January 1, 2009 and August 1, 2019. Broad search terms such as “stapler robotic nephrectomy” and “stapler laparoscopic nephrectomy” were used.
- Staplers were categorized according to type (Ethicon Inc.TM, GIATM, and TATM). Information on each case concerning type of surgery; reason for surgery; device complication with respect to intraoperative and postoperative course; and manufacturer evaluation of faulty device were collected.
- Descriptive statistics and chi-square analysis were used to characterize differences in complications among the three stapler types. P<0.05 was considered statistically significant.

Results

- 383 cases of complications involving endovascular staplers**
 - 22 deaths (5.7% of total complications) due to staplers** – incomplete staple line on renal artery
 - 98 cases (25.6% of total complications) involved conversion to open
 - Intraoperative significant bleeding occurred in 57 cases (14.6% of total complications)
 - 10 cases (2.6% of total complications) required reoperation due to failure of staple line
- Deaths occurred with GIA (10 cases) and Ethicon staplers (12 cases) but not with TA staplers
- TA staplers were less likely to be associated with conversion to open as compared to Ethicon and GIA staplers
- No reoperations due to failure of staple line occurred with TA staplers

Relative Frequencies of Device Complications by Stapler Type

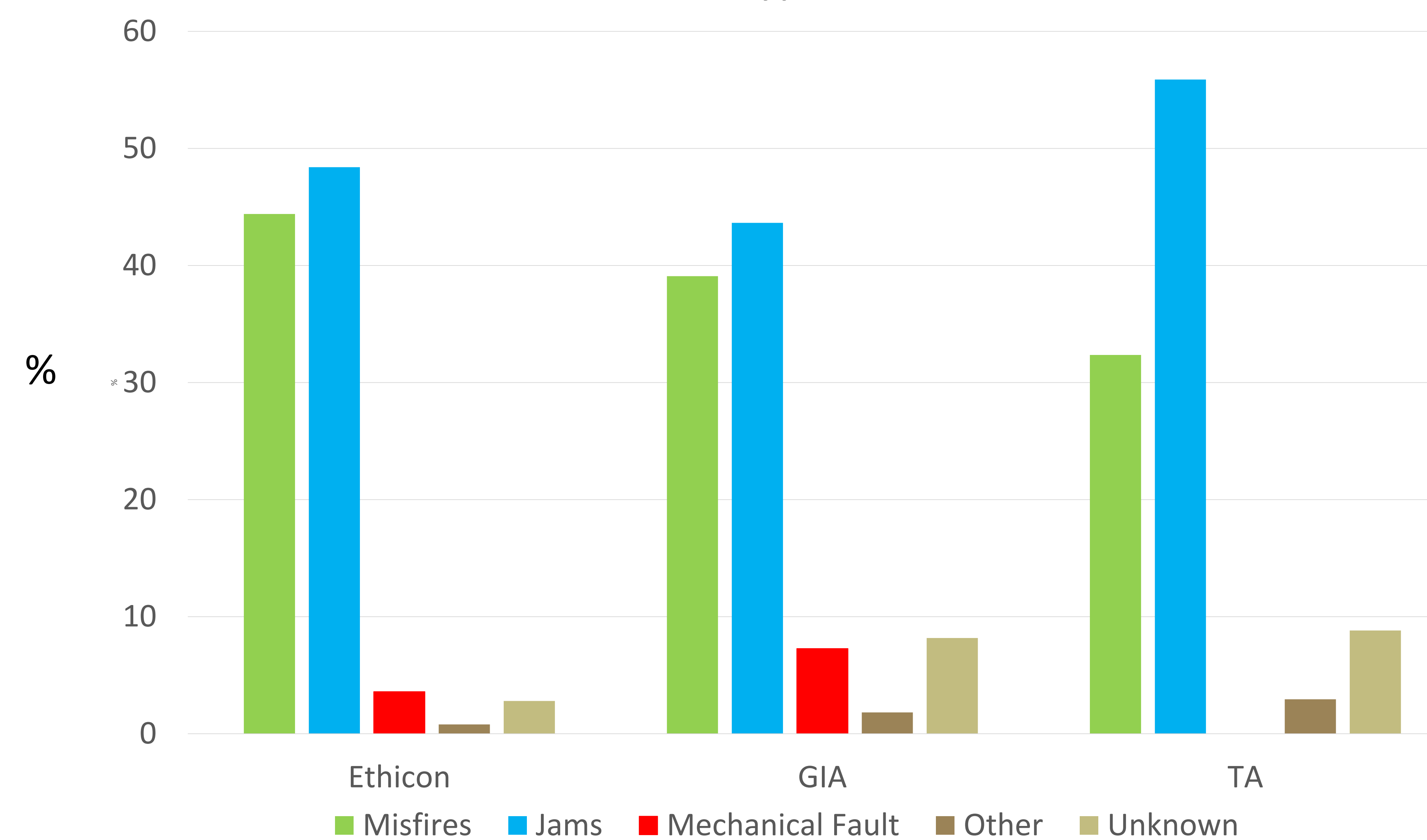


Figure 1. Types of complications for each stapler:

Misfire = Staple line incomplete or absent despite cutting
 Jam = Stapler unable to open or close; surgeon unable to squeeze down handle
 Mechanical Fault = Stapler battery dies; cartridge gets dislodged from stapler

Stapler misfires and jams constituted most of the complications. No statistically significant difference was noted in relative proportion of device complications among the different stapler types.

Relative Frequencies of Etiology of Device Malfunction by Stapler Type

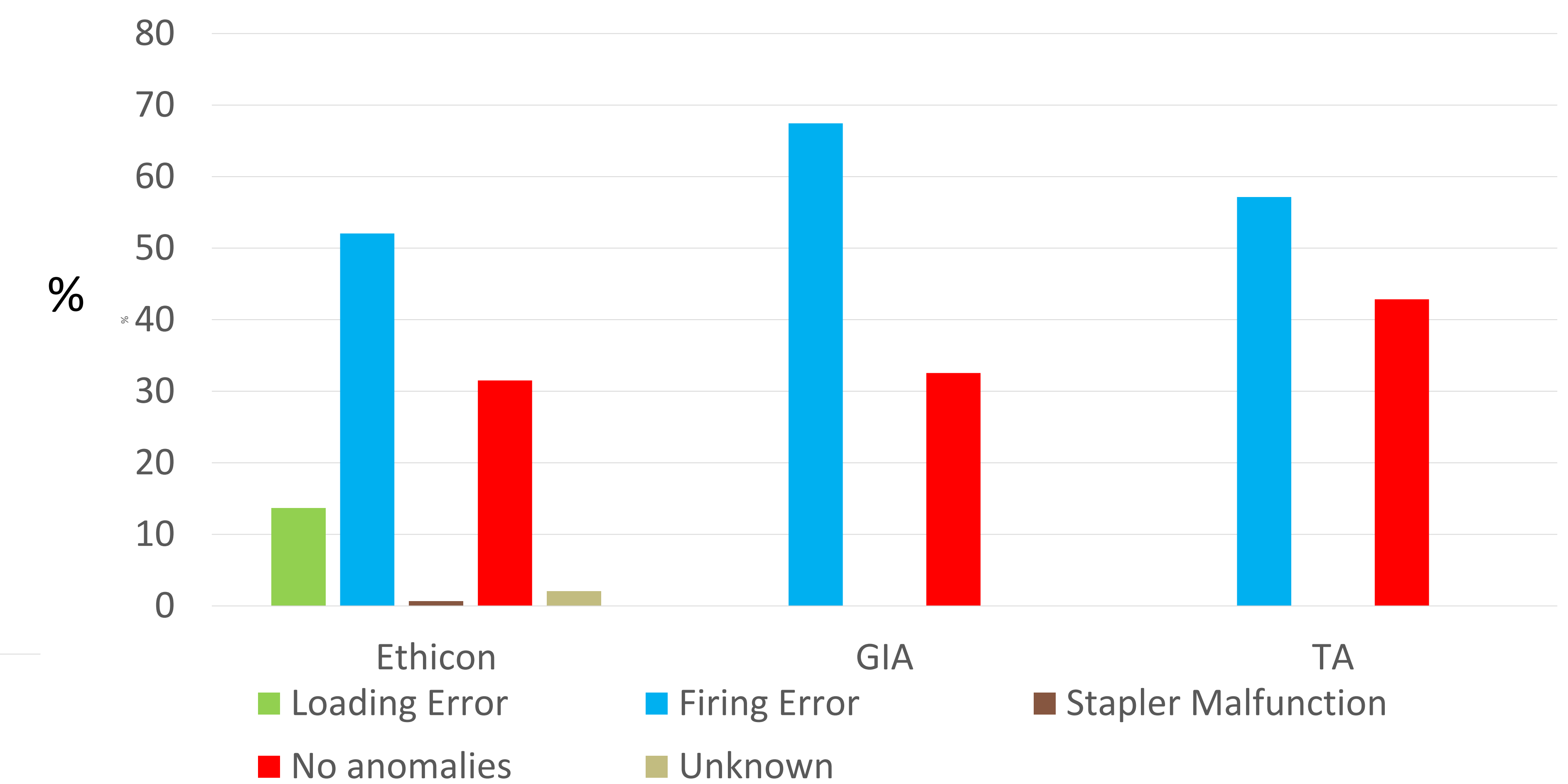


Figure 2. Reasons for faulty devices as determined by manufacturers

Loading Error = Improper cartridge loaded into stapler (i.e., 45 mm reload into a 60 mm stapler)
 Firing Error = Firing stapler on tissue beyond recommended thickness, firing with clip in jaw of stapler, prematurely stopping firing cycle

Apart from loading errors seen only with Ethicon staplers, no other differences in error types were found among stapler groups. **Note that only 1 error was attributed to an intrinsic device problem. The remaining errors were due to human misuse of product: a third of “faulty” devices had no problems when evaluated by manufacturer.**

Conclusion

- Endovascular staplers can cause life-threatening complications
- Reduced incidence of significant complications with TA staplers compared to Ethicon and GIA staplers – May be explained by cutting and stapling being done in separate steps
- Almost all staplers submitted to manufacturer for evaluation were deemed faulty due to human misuse of product – Need for adequate in-service training of OR staff on setting up and using staplers along with troubleshooting complications that may arise

References

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