Pediatric Surgery Stapler Malfunction – A MAUDE Analysis

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Introductions

With advancements in medical technology, the use of surgical devices in pediatric surgery has increased, necessitating these tools to be safe for children. However, there is a paucity of research on mechanical malfunctions in clinical settings specific to pediatric surgery. This study aims to elucidate the frequency and types of surgical stapler malfunctions reported to the Food and Drug Administration (FDA).

Methods

We conducted a retrospective review of the Manufacturer and User Facility Device Experience (**MAUDE**) database for reports involving **surgical staplers** [1,2]. Reports from **2018 to 2023** were extracted and analyzed for data on adverse effects and malfunctions. Reports involving patients aged **18 years or younger** were included. Duplicates were removed by matching the patient's age, incident date, and incident narrative.

Results

Of 441 reports, 31 (7.01%) pediatric reports were identified. After removing duplicates, 31 reports were analyzed. Of these, 26 (83.9%) reports pertaining to the JustRight 5mm Stapler. No deaths were reported (Figure 1). Ten out of 31 incidents (32.3%) did not result in patient harm, and four reports (12.9%) lacked sufficient information regarding patient conditions. Types of patient injuries are shown in Figure 2.

Malfunction Types

- Failure to form staples (n=6)
- Firing problems (n=6)
- Failure to fire (n=3)
- Physical resistance/sticking (n=3)

Case Categories

- Thoracic Surgeries (n=11)
- Laparoscopic Appendectomy (n=9)
- Case types unknown (n=7)
- Other GI Cases (n=3)

Figure 1: Case Reports

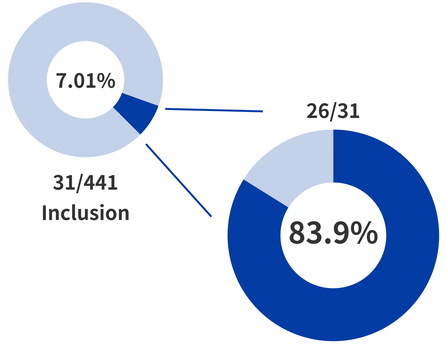
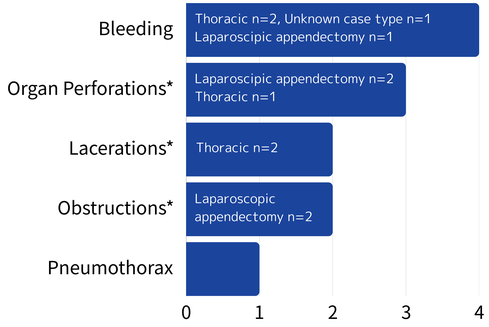


Figure 2: Patient Injuries



*Details of the injuries unknown
All injuries were associated with **JustRigh 5mm Stapler

Discussion: MAUDE System

Under-reporting → Mandatory reporting by operating room staffers in ALL malfunctions

Disparities in report contents → Make basic demographic info (e.g., ages and genders) and surgery type mandatory

Lack of third-party investigation → Malfunctions resulting in mortality or morbidities should be investigated by third-party.

Conclusions

Despite rigorous safety mechanisms, malfunctions still occur in pediatric surgeries. Further investigations into malfunctions are warranted.

References

[1] Manufacturer and User Facility Device Experience (MAUDE) Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (accessed November 21, 2024).
[2] GURTCHEFF SE. Introduction to the MAUDE Database. Clin Obstet Gynecol 2008; 51: 120–123.