A Comparison of technical failures and patient-related adverse events associated with three widely used mechanical lithotripters for ERCP: Insights from the FDA Manufacturer and User Facility Device Experience (MAUDE) Database

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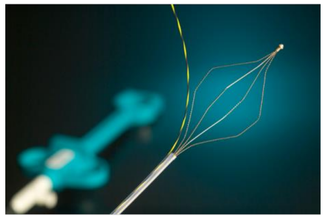
BACKGROUND

Mechanical lithotripsy is an effective method for fragmenting large or complex biliary or pancreatic duct stones, facilitating subsequent removal from the ducts. Mechanical lithotripsy was first introduced in 1982 and has since increased the success rate of difficult bile duct stone removal. Despite their widespread and long-standing use, there is little published data on mechanical lithotripter technical failures and patient-related adverse events.

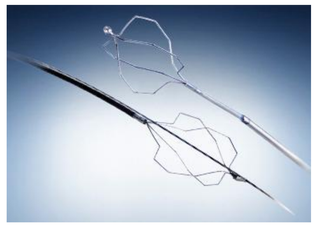
The aim is to review the medical device reports (MDRs), compiled in the MAUDE database in order to provide an overview of reported device failures and patient-related adverse events related to mechanical lithotripter use.

METHODS

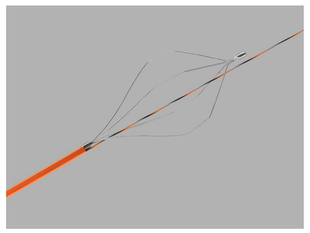
- Queried the FDA MAUDE database from January 1, 2010 through October 31, 2021
- Analyzed MDRs of three widely-used ERCP mechanical lithotripters:
  - Trapezoid RX (Boston Scientific)
  - LithoCrush (Olympus Endoscopy)
  - Fusion Lithotripsy Extraction Basket (Cook Endo)
- Individual reports were carefully analyzed for device failures and patient adverse events.
- MAUDE reports and case narratives were then individually reviewed and subclassified by type of device failures and type of patient adverse event.



Trapezoid RX



LithoCrush



Fusion Lithotripsy Extraction Basket

RESULTS

Total of 1128 MDRs
- 838 for Trapezoid RX
- 274 for LithoCrush
- 16 for Fusion Lithotripsy Extraction Basket

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Device issues reported according to mechanical lithotripter brand

Device problem	Trapezoid RX	LithoCrushV	Fusion
Guidewire port/sheath failure	345	31	3
Basket tip separation failure	262	52	1
Handle failure	246	16	3
Entrapment of basket	224	129	4
Basket failed to crush stone	174	58	1
Nonbasket wire fracture	142	115	3
Basket unable to open/close	114	8	1
Basket wire fracture	75	94	3
Other/miscellaneous	21	4	0

Adverse events reports according to mechanical lithotripter

Adverse event	Trapezoid RX	LithocrushV	Fusion
Additional procedure to remove basket	93	72	5
Bleeding	9	6	0
Bowel perforation	3	2	0
Cholangitis	2	0	0
Pancreatitis	2	0	0
Bile duct perforation	1	1	1
Mucosal injury	1	0	1
Retroperitonitis	1	0	0
Retropneumoperitoneum	1	0	0
Pancreatic duct perforation	0	0	0
Death *	4	0	0

LIMITATIONS

- MAUDE database reporting is inconsistent because it relies on mandatory and voluntary reporters to submit adverse events; adverse events may be under-reported
- Variability in specificity of details included in MAUDE database, making it difficult to establish exact cause of all reported events
- Incidence of adverse events cannot be calculated because total number of devices used during data timeframe is unavailable
- MAUDE database does not report the total number of ERCPs that used mechanical lithotripters

CONCLUSIONS

- Mechanical lithotripters have been used by gastroenterologists for decades, but their use is not without risks.
- Understanding device malfunctions and patient-related adverse events related to the use of ERCP mechanical lithotripters is crucial to their safe operation.
- By reviewing the MAUDE database, we hope to raise awareness of potential risks to reduce patient harm.
- This is the largest report on the safety of mechanical lithotripters in real-life clinical practice

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