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Study Summary

Assessment of a circular powered stapler for creation of anastomosis in left-sided colorectal surgery: A prospective cohort study

Herzig DO, Ogilvie JW, Chudzinski A. Int J Surg. 2020;84:140–146.

Conclusion

The ECHELON CIRCULAR™ Powered Stapler has a favourable safety profile and is an effective device for left-sided colon anastomoses, with high surgeon satisfaction for ease of use compared to mechanical circular staplers and few clinically relevant performance issues

Study Aim

To assess the intraoperative performance, safety, and ease of use of the ECHELON CIRCULAR™ Powered Stapler (ECP) for left-sided colon anastomoses.

Methods

- Prospective, single-arm, open-label study of 168 consecutive patients ≥18 years old who underwent elective colectomy with left-sided anastomoses performed using ECP (Ethicon Endo-Surgery Inc., Cincinnati, USA)
- Procedures were performed by 38 surgeons and took place between November 2017 and January 2020 across 12 sites in the USA and Europe; procedural approach (laparoscopy, robotic or open) was based on the surgeon's preference
- Patients were followed up for 28 ± 14 days post-surgery

Primary Endpoint:

- Rate of ECP performance issues

Secondary Analyses:

- Surgeon grip strength and satisfaction with ECP (determined by a questionnaire), intraoperative and postoperative adverse events (AEs)

Performance issues (failure of ECP to perform per its instructions for use) included:

- Incomplete/thin donuts
- Staple line defects/unformed staples
- Difficulty placing/removing ECP
- Misfire/incomplete firing of ECP
- Detached components
- Positive intraoperative air leak
- Tissue damage

Results

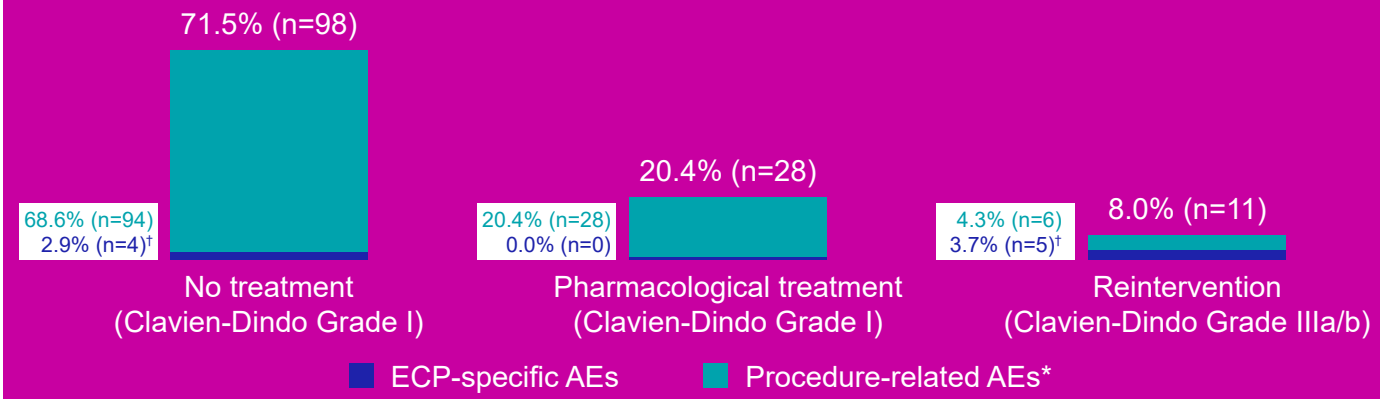
Performance Issues

A total of 22 performance issues occurred across 20/168 (11.9%) procedures (95% CI: 7.4%, 17.8%)

- Incomplete/thin anastomotic donuts were the most common performance issues (14/22)
- Only 1/22 performance issues were related to an AE; this was reported as an instance of incomplete/thin donut that required creation of a new anastomoses and an unplanned diverting ileostomy
- All intraoperative air leak tests were negative compared to a 5.4% positive leak test rate with mechanical circular staplers (MCS) reported in the literature[1]

Safety Profile

Overall, there were 137 AEs in 37 patients (22%); of these, only 9/137 AEs (6.6%) were ECP-specific in 6 patients (3.6%). The treatment required for AEs (n=137) was as follows:



*Excluding ECP-specific AEs; †Postoperative anastomotic leak accounted for 2/4 ECP-specific AEs not requiring treatment and 1/5 ECP-specific AEs requiring reintervention.

- The most frequent AEs were abdominal pain (7.1% patients), nausea/vomiting (4.8% patients) and procedural pain (3.0% patients)

Surgeon Experience

Surgeons completed a satisfaction questionnaire after each procedure and reported that ECP compared to MCS:

was easier to use in	had less movement during firing in	had reduced force to fire in
85.7% of procedures	**88.9%** of procedures	**94.6%** of procedures

Surgeon responses for ease of use and movement during firing were similar between males and females, indicating grip strength is not a factor for effective use of ECP, given that females had a lower grip strength (30.7 kg vs. 44.6 kg; p<0.0001).

References: 1. Offodile AC, Feingold DL, Nasar A, et al. Journal of the American College of Surgeons. 2010;210(3):331–335.

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