Evaluation of the SafeHeal Colovac+ Anastomosis Protection Device as an alternative to protective ileostomy after low anterior resection for rectal cancer: the Safe Anastomosis Feasibility Evaluation (SAFE) 2019 trial

Nicolas De Hous[1], Antonio D'Urso[2], Guy-Bernard Cadière[3], Philippe Rouanet[4], **Niels Komen**[1] and Jérémie Lefevre[5]

[1]Department of Abdominal Surgery, UZA, Antwerp, Belgium; [2]Department of General, Digestive and Endocrine Surgery, CHRU, Strasbourg, France; [3]Department of Digestive Surgery, CHU Saint-Pierre, Brussels, Belgium; [4]Department of Oncological Surgery, ICM, Montpellier, France; [5]Department of Digestive Surgery, Saint-Antoine Hospital, Paris, France

Background

The Colovac device is a unique endoluminal bypass sheath placed in the colon following rectal resection.
Colovac placement postpones the decision to perform diverting stoma until anastomotic healing can be assessed, and selectively reserves the use of diverting stoma for only those patients with evidence of incomplete anastomotic healing.

The objective of this study was to evaluate the preliminary safety and feasibility of the Colovac+, second version of the Colovac Anastomosis Protection Device.

Methods

This prospective, single arm study enrolled patients at 5 European tertiary centers.

After creation of the anastomosis, the Colovac+ was anchored to the colon proximal to the anastomosis.
At postoperative day (POD) 9, anastomosis integrity was examined by CT-scan.
At POD 10, Colovac+ was removed endoscopically. Patients without an anastomosis leakage were discharged home. Those requiring longer anastomosis protection underwent ostomy.

A vacuum loss alert system (VLAS) accessory to detect any vacuum loss was used by the last 17 subjects.

Demographic, surgical, QOL and AE data were collected through POD 90.

Results on the 17 subjects enrolled with the last product accessory evolution are presented below.

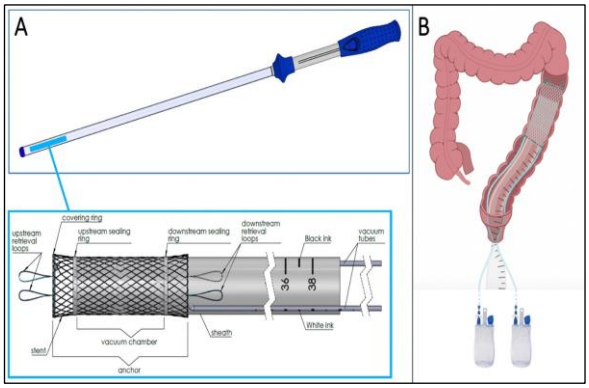

Figure 1. The SafeHeal Colovac+ Anastomosis Protection Device. (A) Detailed structure. (B) Device anchoring in the colon.

Results

Seventeen (17) patients were treated. 2 were excluded because of major protocol deviations.
53% of subjects were men (mean age= 64y).
60% of tumors were stage cT3/T4. Neoadjuvant treatments included chemotherapy (73%) and radiotherapy (67%).

100% of device placements and 80% of endoscopic retrievals were easy or very easy. No major discomfort was reported during implantation.

As part of the selective stoma algorithm, 27% of patients were converted to stoma (1 (7%) anastomosis rupture at POD 2, 3 (20%) incomplete anastomosis healing).

Overall, the Colovac+ allowed avoidance of the protective ileostomy in 73% patients.

Conclusion

Consistent with the SAFE 1 Study, Colovac+ protects the anastomosis during healing, avoids an ostomy in patients without anastomotic complications and allows safe conversion to the ostomy standard of care if longer protection is required.

If these results are confirmed by a larger, RCT, Colovac could become an effective patient management alternative for patients undergoing LAR.

Contact information

Jérémie Lefevre, MD, PhD
Department of Digestive Surgery, Saint-Antoine Hospital, Paris, France
E-mail: jeremie.lefevre@aphp.fr

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