Safeheal Colovac Colorectal Anastomosis Protection Device Evaluation (SAFE-2) Pivotal Study: A Multicentre Clinical Trial

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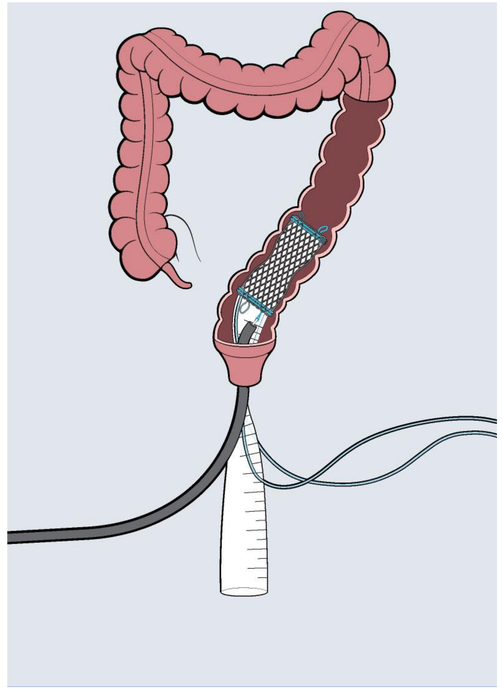
OBJECTIVES

- Proximal faecal diversion is the standard of care to protect high-risk colorectal anastomoses from the septic sequelae of anastomotic leakage (AL).
- The Colovac device (CD) is an intraluminal bypass device intended to avoid stoma creation in patients undergoing low anterior resection (LAR).
- A preliminary study (SAFE-1) demonstrated 100% protection of colorectal anastomoses in 15 patients. We present the preliminary results of SAFE-2, a phase III clinical trial.

METHODS

- SAFE-2 is an international multicentre, prospective, open-label, randomized, controlled trial. Trial NCT05010850
- After a run-in period, patients undergoing LAR for rectal cancer were randomized 1:1 ratio to CD or diverting loop ileostomy (control).
- The co-primary endpoints included the rate of major postoperative complications within 12 months of surgery and the stoma creation rate.

Randomized Patients n = 18	Colovac n = 10	Ostomy n = 8
Age (years, SD)	67.1 (10.9)	60.9 (11.4)
Gender (%)		
Male	4 (40.0)	5 (62.5)
Female	6 (60.0)	3 (37.5)
BMI (kg/m^2, SD)	24.8 (5.5)	25.7 (4.8)
Tumour distance from anal origin (cm)	7.3 (3.8)	6.3 (3.7)
Stage (%)		
T1/T2	2 (20.0)	2 (25.0)
T3/T4	8 (80.0)	6 (75.0)
Neoadjuvant chemotherapy (%)	8 (80.0)	6 (75.0)
Neoadjuvant radiotherapy (%)	7 (70.0)	5 (62.5)
Clavien-Dindo Grade (%)		
II	0 (0.0)	2 (25.0)
III	3 (30.0)	1 (12.5)
IV+	0 (0.0)	1 (12.5)
Anastomotic leak (%)	1 (10.0)	2 (25.0)
Stoma avoidance (%)	7 (70.0)	0 (0.0)



RESULTS

- Enrollment was conducted across 7 US and 5 European centres between January 2022 and January 2023.
- 35 patients were enrolled including 17 in the run-in (non-randomized) period and 18 randomized to CD (10) and control (8). 8 CD and 6 control patients completed the 12-month follow-up.
- There were no significant differences with respect to age, gender, BMI, stage, distance from the anal margin, or neoadjuvant treatment.
- Rate of Clavien-Dindo Grade (CDG) III+ complications was 30% (3/10) in the CD arm vs 25% (2/8) in controls, which included AL, incisional hernia, colonic intussusception, and malnutrition.
- Clinically significant ALs were detected in 10% (1/10) of CD patients, and 25% (2/8) of control patients, with one death in the control group.
- Two patients in the CD arm had CT detected, clinically non-significant AL, and were diverted. Thus, 70% of patients avoided a stoma.
- In the run-in period, 52.9% (9/17) avoided the creation of a stoma, and the rate of clinically significant ALs was 17.6% (3/17), which is comparable to the randomized CD and control arms.
- No deaths were recorded, and 5/17 (29.4%) of patients had CDG III complications.
- The study was voluntarily suspended and closed due to a higher-than-expected rate of device migration, which occurred in 37% (10/27) of all CD patients, 3/10 were clinically significant in the CD arm.

CONCLUSIONS

While the SAFE-2 trial was closed to allow for the design of a next generation vacuum system, the Colovac device is a safe alternative to an ostomy in the protection of high-risk colorectal anastomoses. With a stoma avoidance rate of 70%, a CD may potentially omit the need for ostomy, subsequent reversal, and drastically improve the patients' quality of life.

Disclosures: JHL: Consultant for SafeHeal, Intuitive, SWL: Founder of Guard Medical, consultant for Olympus, Boston Scientific, Fujifilm, Noah Medical, Endoquest Robotics and Applied Medical, KZ: Consultant for Takeda, speaker for Natera, DS: Consultant for SafeHeal, Vioptix, Moon Surgical, has an ownership in Brainchild Surgical, JM: Consultant for Covidien, PR: Proctor for Intuitive, ZL: Consultant for Stryker, Coloplast, lecturer from Intuitive, Pfizer, Takeda, PS: Consultant for SafeHeal, Medtronic, Ethicon, RedDress, Stryker and Heron Medical