EnteroPlug: a novel journey to complex enteric fistula control in a tertiary Ecuadorian hospital

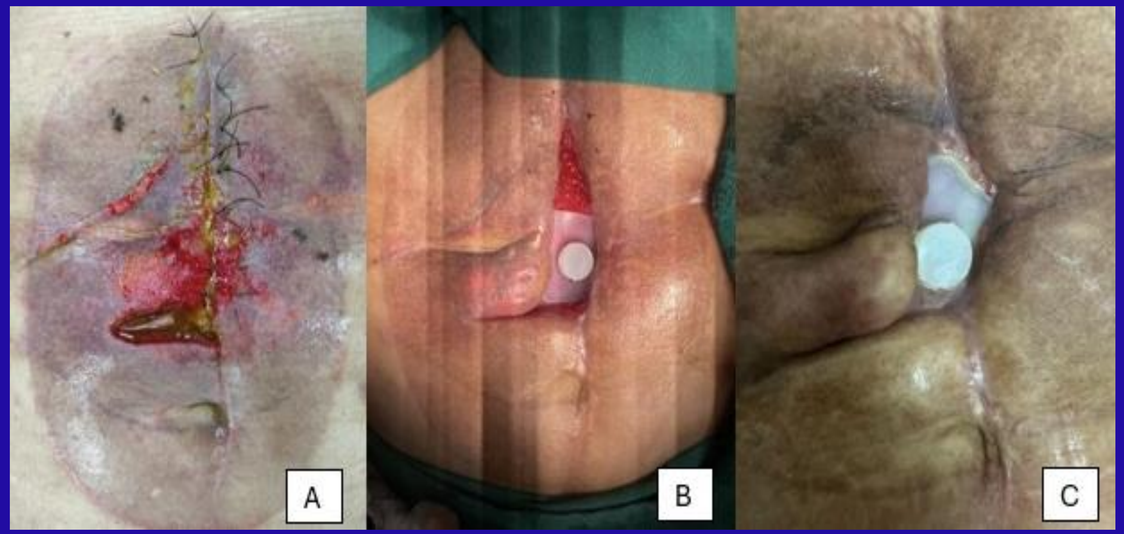
Andrea Villarreal-Juris1; Cristian Arias-Llerena1; Winston Jaramillo- Cañas1
1 Alfredo Paulson's Hospital, Guayaquil-Ecuador

INTRODUCTION

For the management of enterocutaneous and enteroatmospheric fistulae, the application of a minimally invasive silicone device to occlude the fistula tract hasn't been proven over the years. The aim of this study: describe the short-term outcomes of adult patients with complex enteric fistulae (enterocutaneous and enteroatmospheric) treated with EnteroPlug, a three-piece silicone novel device, from November 2023-to-April 2024 at Alfredo Paulson's Hospital in Ecuador.

METHODS AND PROCEDURES

Observational, prospective, and analytical study. Data was obtained from electronic medical records and analyzed using SPSS 27.0. Schein's classification was used for fistulae. Management: surgical cleaning and the use of a silicone device to occlude the fistula tract. Main outcomes—fistula characteristics and output, hospital stay, type of nutrition, weight at 15, 30 and 90 days, %of total weight gain, blood albumin and transferrin.



RESULTS

Nine patients were included: 44.44% female, 55.56% male; mean age: 61.33 years (53 – 71 years). All were type IV fistulae **(A);** 66.67% postoperative, 33.33% posttraumatic.

BEFORE EnteroPlug	AFTER EnteroPlug	
Descriptives	**Descriptives**	**Inferential analysis**
Mean total **hospital stay**: 57.56 days (26 – 83 days)	Mean total hospital stay after EnteroPlug: 8.56 days (7 – 11 days)	Non-significative impact on mean total hospital stay
All patients received total parenteral **nutrition**	All were fed enterally	-
Mean 24h **output**: 922.22ml [600 – 1500ml] (high output)	Fistula output ceased completely **(B)**	-
Mean seric **albumin**: 2.7g/dL (2.5 – 2.9g/dL)	Mean seric albumin at 90 days: 4.18 g/dL (4.1 – 4.3 g/dL)	Average significant albumin increase: 1.48 g/dL (t = 23.88; p < 0.001)
Mean initial **weight**: 62 kg (50 – 71 kg)	Mean weight at 90-days: 68.44 kg (61 – 74 kg)	Average significant **weight gain**: 3.67kg at 15 days, 5.2kg at 30 days, and 8.78kg at 90 days (t = 2.43, p = 0.041; t = 3.72, p = 0.006; t = 7.61, p < 0.001; respectively)
		% of total weight gain: 15.14% (7.35 – 25.86%)
		Gained significantly les weight: patients with diabetes (t = 2.98; p = 0.020) and chronic kidney disease (t = 2.153; p = 0.068
Mean initial **BMI**: 20.77 kg/m2 (18.82 – 23.53 kg/m2)	Mean BMI at 90-days: 23.84 kg/m2 (21.88 – 25.26 kg/m2)	Average significant BMI increase: 3.07kg/m2 (t = 7.62; p <0.001
Mean initial **fistula diameter**: 3.06cm (2 – 5cm)	Mean fistula diameter at 90-days: 1.84cm (1 – 3.10cm)	Significant reduction of Fistula diameter (t = -5.48; p <0.001) **(C)**
Mean initial **CRP**: 199.44 mg/dl (12 – 401 mg/dl)	Mean CRP at 90-days: 7.34 mg/dl (2.25 – 12.20 mg/dl	Significant reduction of CRP level [by an average of 192.10 mg/dl (t = 3.26; p = 0.011)]
Mean initial **transferrin**: 162.67 ug/dL (109 – 182 ug/dL)	Mean transferrin at 90-days: 186.67 ug/dL (170 – 227 ug/dL)	Transferrin at 90-days: 86.67 ug/dL (170 – 227ug/dL)

CONCLUSION

EnteroPlug is a novel silicone three-piece, easy-to-place, minimally-invasive device, that allows weight gain, restart of enteral feeding, and BMI and albumin increase in patients with enteric fistulae, thus, improving patient's clinical condition and enabling a temporary closure of the fistula, to later opt for secondary intention healing or surgical resection.