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Traditional lateral ileostomy versus percutaneous ileostomy by exclusion probe for the protection of extraperitoneal colo-rectal anastomosis: The ALPPI (Anastomotic Leak Prevention by Probe Ileostomy) trial. A randomized controlled trial

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Abstract

Background: Low colo-rectal anastomoses have a relevant risk of leakage. The protective stomas (ileostomy or colostomy) have always been utilized to reduce the complications due to anastomotic leakage. The stoma not only causes relevant morbidity but also needs a second operation to be closed, with an added risk of complications.

Purpose: For this reason we planed and carried out a temporary percutaneous ileostomy by a jejunal probe introduced in the distal ileum, that can be removed without a surgical procedure and with negligible complications.

Methods: The ALPPI trial is a randomized controlled, open, parallel, equivalence multicenter study. Patients undergoing elective laparoscopic or laparotomic surgery for rectal cancer with extraperitoneal anastomosis, will be randomly allocated to undergo either lateral ileostomy or percutaneous ileostomy by exclusion probe.

Results: The primary endpoint is the protection of the extraperitoneal colo-rectal anastomosis in terms of incidence of symptomatic and asymptomatic anastomotic leakages. The secondary endpoints are the evaluation of complications due to the placement and the removal of the exclusion probe for percutaneous ileostomy.

Conclusions: The ALPPI trial is designed to provide the surgical community with an evidence based new technique in the protection of low colo-rectal anastomosis, alternative to the conventional stomas.

Trial registration: The ALPPI trial was approved by the Ethical Committee of Regional Public Health System of Umbria, Italy, (Protocol Number 28657/11/AV, study code RO-MA 01) and it is registered in the International Standard Randomised Controlled Trial Number (ISRCTN) Register with identification number ISRCTN99356919.

Keywords: Extraperitoneal colo-rectal anastomoses; Leakage; Percutaneous ileostomy; Rectal cancer; Anterior rectal resection; Randomized trial

Introduction

Anastomotic leakage is one of the most dreaded complications after colo-rectal surgery. It is associated with increased morbidity and peri-operative mortality (from 2% up to 24% in the presence of an anastomotic dehiscence).[1] Moreover, a leakage can increase the risk of stenosis of the anastomosis, and the local recurrence reducing the overall survival.[2–4]

The protective stomas have always been utilized to reduce the complications due to anastomotic leakage, and therefore the rate of leak-related re-intervention.[2,5–11] Retrospective studies reported anastomotic leakage rates range 4.9%–8.2% when the protective stoma was performed, and 16–17% in patients without protective

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Abbreviations

RCT	randomized controlled trial
TME	total mesorectal excision
CT	computed tomography
ASA	American Society Anesthesiologists
ANOVA	analysis of variance

stoma.[5,10] The RCT by Matthiessen reported a symptomatic leakage rate of 10.3% in patients with defunctioning stoma and 28.0% in those without stoma, while the need for urgent abdominal re-operation was 8.6% versus 25.4% respectively.[9] The meta-analyses by Montedori, Tan and Huser reported that a defunctioning stoma decreases clinical anastomotic leakage (with odds ratios of 0.33, 0.39 and 0.32 respectively) and re-operation rates (odds ratios of 0.23, 0.29 and 0.27 respectively).[1,8,11] Therefore many Authors recommend performing a defunctioning stoma in low anterior resection for rectal cancer.[1,2,8–11]

Several studies have sought to evidence which type of temporary stoma (ileostomy or colostomy) is the most effective in protecting either colo-rectal or colo-anal anastomosis.[12–19] They showed that loop ileostomies have fewer constructive complications[19] and they are less bulky, less prone to prolapse, less odorous and better sited for patients.[20]

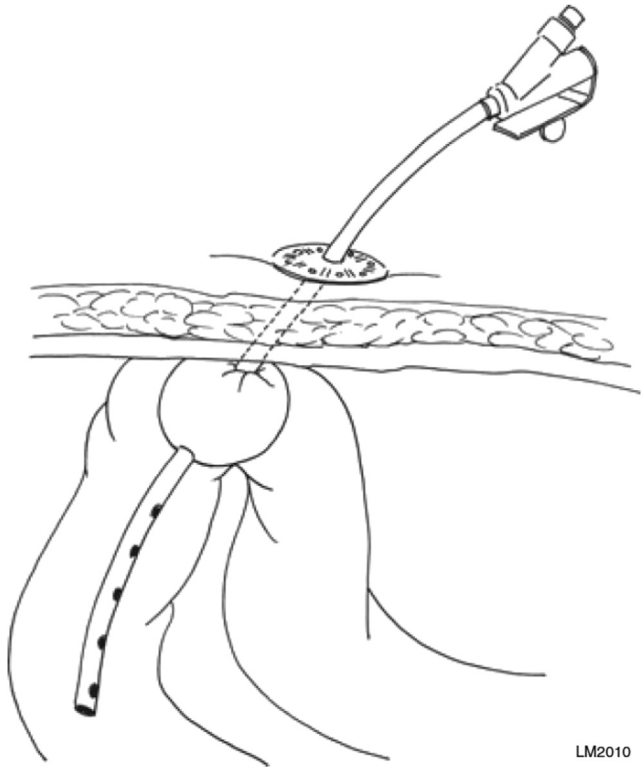

Figure 1. Percutaneous ileostomy by exclusion probe placement.

Besides causing relevant morbidity (discomfort, peristomal inflammation, and dehydration resulting from high output) a stoma needs a second operation to be closed, with an added risk of complications: small bowel obstruction (0–15%), wound infections (0–18.3%), anastomotic leakage (0–8%), entero-cutaneous fistulae (0.5–7%), and site hernias in up to 12% of patients.[21] About loop ileostomies' closure literature shows an overall morbidity of 17.3% and a mortality ranging 0.4–3.7%, with an elevated possibility (19%) that a defunctioning stoma remains a permanent stoma.[20,21]

The possibility to realize a faecal derivation able to protect the extraperitoneal anastomosis without requiring a second surgical procedure to remove itself, could be a very important advantage for the patient. For this reason we planed and carried out a temporary percutaneous ileostomy by a modified jejunal probe introduced in the distal ileum (Fig. 1). Our preliminary experience[22] and retrospective study[23] showed that this technique is safe and efficacy, it ensures an optimal faecal diversion and effectively protects the colo-rectal anastomosis from the stool transit, not increasing the anastomotic leak, when compared with the conventional lateral ileostomy. Moreover percutaneous ileostomy ensures less patient discomfort and it can be removed without a surgical procedure and with negligible complications.

A randomized controlled trial is essential in order to asses the efficacy of percutaneous ileostomy by exclusion probe (versus a conventional lateral ileostomy) in protecting extraperitoneal colo-rectal anastomosis avoiding symptomatic and asymptomatic leakages.

With these medical and technical considerations we created the trial protocol according to this described design.

Material and methods

Design

The ALPPI trial is a randomized controlled, open, parallel, equivalence multicenter study.

Patients undergoing elective laparoscopic or laparotomic surgery for rectal cancer with extraperitoneal anastomosis, will be randomly allocated to undergo either lateral ileostomy or percutaneous ileostomy by exclusion probe.

The aim of the study is to test the hypothesis that the percutaneous ileostomy by exclusion probe protects the extraperitoneal colo-rectal anastomosis avoiding leakages as the conventional lateral ileostomy does.

Primary endpoint

The primary endpoint of the study is the protection of the extraperitoneal colo-rectal anastomosis in terms of incidence of symptomatic and asymptomatic anastomotic leakages.