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ORIGINAL ARTICLE

Is a bridge (rod) necessary for loop ileostomy? A phase II randomized control trial

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Abstract

Background The value of a bridge in loop ileostomies is debated. We aimed to evaluate whether using a bridge when creating a loop ileostomy can reduce morbidity following an ileostomy.

Methods Patients who had a loop ileostomy after elective colorectal surgery from January 2016 to July 2022 were randomized in this multicenter phase 2 randomized superiority trial. The primary endpoint was the absence of postoperative stomal complications at 2 months and was assessed in a blinded fashion by a stoma therapist. Secondary endpoints were morbidity at 1 month and the STOMA-QOL score at 2 months.

Results During the study period, 67 patients were randomized to the bridge group and 63 to the no-bridge group. Epidemiological and perioperative data did not differ between the two groups. The stomal complication-free rate was 76% in the bridge group and 67% in the no-bridge group ($p=0.3$). There was no difference in the distribution of complications at 1 month according to the Clavien–Dindo score ($p=0.2$) or the STOMA-QOL score at 2 months ($p=0.4$) between the two groups.

Conclusion The bridge does not reduce the rate of stomatal complications, nor does it appear to reduce patients' quality of life.

Trial registration number NCT02756273 (May 10, 2016).

Keywords Stoma · Bridge · Quality of life · Divertion

Introduction

In elective colorectal surgery, a diverting stoma (DS) is almost always performed in cases of coloanal anastomosis and selectively in cases of high colorectal anastomosis [1, 2]. The main purpose of a DS is to decrease severity and possibly the risk of anastomotic leak [2]. However, DSs have their own complications that can sometimes be challenging [3, 4].

The first ileostomies were performed in the late nineteenth century and associated with a high morbidity rate, as they were at the level of the skin, without a suture between the stoma and the skin [5]. During the early twentieth century, several improvements decreased the risk of complications, including the use of a stoma bag, suturing and eversion of the stoma, and the use of a bridge. However, the true impact of the use of a bridge on complications is still unclear. Some argue that it could decrease the risk of retraction, whereas others note that it could create a hole between the skin and the stoma, leading to local inflammation or a surgical site infection. It may also increase the risk of section

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of the stoma. Bridges are decreasingly used, in particular in enhanced recovery programs, given the absence of robust clinical data to support their use. Their impact on stoma closure and the associated complications are also unknown [6, 7]. To date, several randomized control trials have been published about the use of a bridge for ileostomies. However these trials have limitations. In 2005, in the trial by Speirs, the authors did not define any clear primary endpoint or sample size. In 2017, Uchino et al. reported a study in a very narrow population (J pounch anastomosis in Japan with a mean BMI of 19 kg/m^2). A 2017 trial by Zindel did not enough power to draw firm conclusions. Thus doing another trial to address these limitation was of interest [8–10].

We aimed to determine whether doing a loop ileostomy without a bridge can reduce the risk of stomal complications.

Patients and methods

Study design

This was a multicenter open-label randomized superiority trial, with a phase 2 Fleming single-stage design, to compare the outcomes of patients who underwent a loop DS after an elective colorectal resection that included a bridge (bridge group) and those who underwent the same procedure that did not include a bridge (no-bridge group). It was a one-sided superiority trial with the hypothesis that doing a loop ilestomy without a bridge could reduce the risk of stomal complications. The trial was conducted in two university hospitals and one non-university hospital in France and was sponsored by a local grant from the CHU Amiens-Picardie. The work has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) [11]. The study received authorization from the Comité national informations et libertés (CNIL PI2015_843_0008), from the Agence National de Sécurité du Médicament (ANSM 2015-A00620-49), and has been registered at ClinicalTrials.gov (NCT02756273).

Participants

We recruited patients 18 years of age or older who had an elective colorectal resection for any reason (cancer, inflammatory bowel disease, diverticulitis) and a loop DS created at the index surgery for any reason. All patients gave their written consent preoperatively and received a full explanation of the protocol. The exclusion criteria were the decision to perform early stoma closure (during the 15 days following the index surgery), receiving corticotherapy or immunotherapy, a body mass index (BMI) > 50 kg/m^2, or a history of stoma at the same site.

Interventions

Randomization was performed intraoperatively after completion of the colorectal resection and anastomosis, regardless of the reason for the stoma (scheduled or due to an intraoperative event), before creating the cutaneous hole for the stoma. The stoma site was systematically marked preoperatively by a stoma nurse. In the bridge group, a bridge was inserted, before opening of the bowel, in the window between the mesentery and the bowel at the top of the stoma. The type of bridge was standardized in the study (90-mm loop ostomy rod; ConvTec, ref. 022356), it was not stitched to the skin, and it was removed at postoperative day 5. The decision to remove the device at postoperative day 5 was taken a priori to ensure a homogenous management. In the no-bridge group, the stoma was created using the same procedure but without the insertion of a bridge and without creating a window between the mesentery and the bowel. In both groups, the stoma was sutured to the skin and not to the subcutaneous tissue. The stoma was not systematically everted. Patients were managed postoperatively from postoperative day 1 by a stoma nurse; the same nurse also managed the patient at 2 months for evaluation of the primary endpoint. The presence of a bridge was not collected in the nurse notes for the study.

Randomization

Randomization was performed during the operation when it was decided to perform a stoma. Participants were randomly assigned using a computer-generated randomization code and minimization, with a ratio of 1:1 between the two arms. The randomization procedure was stratified by BMI.

Objectives of the study

The primary objective of the study was to determine whether the use of a bridge in a loop ileostomy can reduce the risk of complications.

Endpoints

Primary endpoint

The primary endpoint was the rate of the absence of stomal complications identified at 2 months postoperatively by a stoma nurse in a blinded fashion. The 2 months period was chosen to get all the complications from randomization but before stoma closure.

Secondary endpoints

The secondary endpoints were:

- Perioperative outcomes for the index surgery: operative time, stomal activity at 3 days, morbidity rate according to the Clavien–Dindo classification [12], and length of stay.
- Long-term outcomes: death rate at 2 months, quality of life according to the Stoma QOL questionnaire [13] at 2 and 6 months (when the stoma is not closed), and the number of reoperations at 12 months.
- Stoma closure outcomes.

Definitions

Primary endpoint

The primary endpoint was a composite endpoint. The endpoint was considered to be negative for the patient if any complications were present. The entire period from the index surgery to the stoma nurse visit at 2 months postoperatively was considered. Complications included in the primary endpoint were surgical site infection at the stoma site (superficial, deep, or organ/space) [14], peristomal irritation, with a superficial score of at least 3 and a severity score of at least 2 for at least one domain of the discoloration (D), erosion (E), and tissue overgrowth (T) score (DET score) [15], stoma necrosis, defined as localized or extended necrosis at the stoma site, a peristomal hernia, stenosis of the stoma, retraction of the stoma, prolapse of the stoma, and disinsertion of the stoma.

Statistical analysis

The sample size was determined according to the Fleming single-stage design (Fleming, Biometrics, 1982). For the primary endpoint, 67 patients were needed in the no-bridge group to have a power of 90% and a one-sided α risk of 0.10 and a loss of follow-up of 5%, to test the null hypothesis that the proportion of patients achieving no complications at 2 months in the no-bridge group would be > 75% versus < 60% in the bridge group [16]. Randomization was performed with a control group of patients with a bridge (bridge group) to validate the hypothesis of < 60% of no complications at 2 months. Thus, a total of 134 patients had to be included (67 in each group). No interim analysis was performed.

Quantitative data are reported as means (standard deviations) or medians (interquartile ranges) and categorical data are reported as absolute numbers and percentages. Normally distributed quantitative data were analyzed using Student's *t* test or Mann–Whitney tests as appropriate. Qualitative data were compared using Pearson's χ^2 test or the Fisher's exact test, as appropriate. Statistical analyses were performed using R software version 3.4.0 (R Foundation for Statistical Computing, Vienna, Austria; www.r-projet.org) through the RStudio interface Version 1.0.143 and SAS® software (version 9.4, SAS Institute Inc., Cary, NC).

Results

Patients

From January 2016 to April 2023, a total of 63 patients in the no-bridge group and 67 in the bridge group were included in the study (Fig. 1). The demographic and surgical characteristics of the patients are presented in Table 1. The median follow-up was 18 months, and the trial database was locked in August 2023.

Endpoints

Primary endpoint

The rate of no complications at 2 months was 67% (42/63) in the no-bridge group and 76% (51/67) in the bridge group ($p = 0.3$) (Table 2).

Secondary endpoints

- Perioperative outcomes for the index surgery: There was no significant difference in the median operative time between the no-bridge and bridge groups (220.0 min (180.0, 300.0) vs 240.0 min (190.0, 320.0), respectively, $p = 0.06$). The stomal activity at 3 days was not significantly different between the two groups ($p = 0.3$), nor the morbidity rate according to the Clavien–Dindo classification at 30 days ($p = 0.2$) or 60 days ($p = 0.2$). The mean length of stay was also not significantly different between the two groups (10.0 days (7.3, 15.0) vs 10.0 days (8.0, 16.0), respectively, $p = 0.8$).
- Long-term outcomes: At 2 months, the rate of death was nil for both groups. The Stoma QOL score was not significantly different between the no-bridge and bridge groups at 2 months (58.5 (50.0, 65.8) vs 55.0 (46.0, 63.5), respectively, $p = 0.3$), or 6 months (58.0 (50.5, 62.0) vs 47.0 (38.0, 54.0), respectively $p = 0.12$). At 12 months, the median number of reoperations was significantly lower in the no-bridge group (0.0 (0.0, 0.0) vs 0.0 (0.0, 0.8), $p = 0.037$).
- Stoma closure outcomes: There was no difference in the mean operative time between groups (60.0 (48.0, 89.5) vs 60.0 (49.3, 70.0), $p = 0.5$), nor the morbidity rate according to the Clavien–Dindo classification after stoma clo-

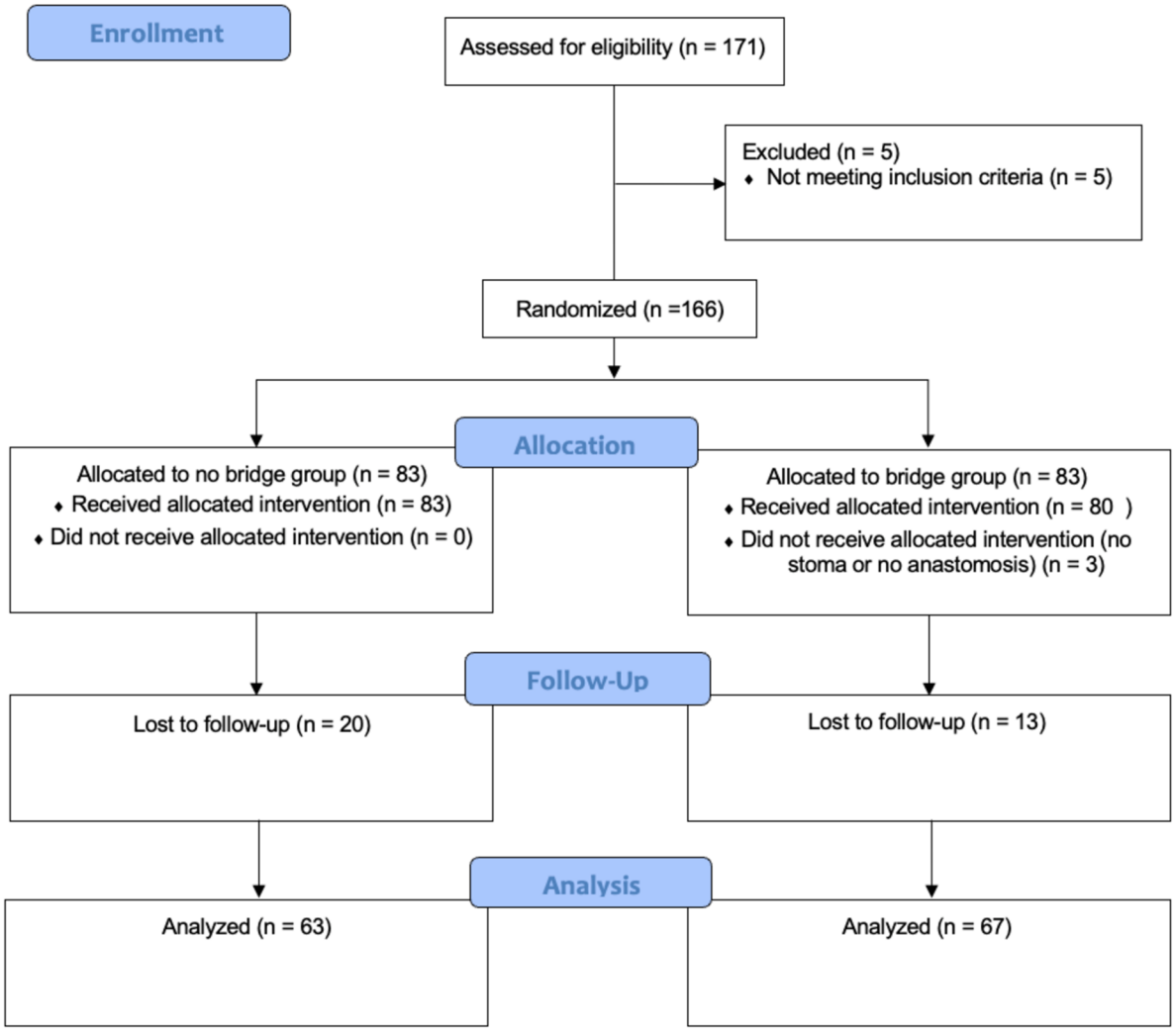

Fig. 1 Flowchart of the study

sure ($p = 0.6$). The number of fistulas was nil for both groups.

Discussion

Despite their frequent use, little is known about the impact of bridges on stomal complications. The IBIP trial was designed to evaluate several factors that could be modified by the use of a bridge during the creation of a stoma, with the hypothesis that creating a stoma without a bridge might decrease the risk of complications. The composite primary endpoint was negative and the trial failed to show superiority of a stoma without a bridge over a stoma with a bridge. The first step of this phase 2 randomized control trial was to validate the hypothesis of the primary endpoint in the control group before a possible phase 3 trial. The hypothesis was, finally, not validated, with a higher rate of patients who did not have any complications in the bridge group (76% vs the expected 60%). This higher proportion may, of course, have had an impact on the negative result of the trial, but it is not the only explanation. To validate the hypothesis, we expected a 15% decrease in the risk of complications. The hypothesis was not validated, as the proportion of patients who had no complications in the no-bridge group was even lower than that in the bridge group (67%).

The use of a bridge has been evaluated in three randomized control trials. In 2005, Speirs et al. conduced the first randomized control trial. In that study, there was no clear primary endpoint or sample size and a total of 57 patients were included. The bridge was left for 7 days. The authors found no differences in stoma activity at 3 days (90% vs 83%) or stomal retraction (6.8% vs 7.1%) and finally concluded that stomal retraction was uncommon and the routine use of a bridge is unnecessary [8]. In 2017, Uchino et al. reported a randomized control trial on the use of a

Table 1 Characteristics of the population

Characteristics	No bridge group ($n=63$)	Bridge group ($n=67$)	p
Age, years	63 (13)	62 (10)	0.5
Women	24 (38%)	26 (39%)	> 0.9
BMI, kg/m^2	26.1 (4.1)	26.0 (4.4)	0.8
ASA score			0.8
I	2 (3.2%)	4 (6.0%)	
II	31 (49%)	34 (51%)	
III	30 (48%)	29 (43%)	
Indication of surgery			0.8
Cancer	49 (78%)	49 (73%)	
Diverticulitis	5 (7.9%)	6 (9.0%)	
Crohn disease	1 (1.6%)	0 (0%)	
Ulcerative colitis	1 (1.6%)	3 (4.5%)	
Other	7 (11%)	9 (13%)	
Type of surgery			0.6
Left colectomy	31 (49%)	35 (53)	
Anterior resection	30 (48%)	29 (43)	
Total colectomy	1 (1.5%)	0 (0)	
J pounch anastomosis	1 (1.5%)	3 (4)	
History of abdominal surgery			0.6
No	25 (40%)	24 (36%)	
Yes	38 (60%)	43 (64%)	
Albuminemia, g/dl	39.0 (6.3)	41.2 (3.8)	0.082
Cardiovascular disease			0.5
No	31 (49%)	37 (55%)	
Yes	32 (51%)	30 (45%)	
Pulmonary disease			0.4
No	51 (81%)	50 (75%)	
Yes	12 (19%)	17 (25%)	
Kidney disease			0.3
No	60 (95%)	60 (90%)	
Yes	3 (4.8%)	7 (10%)	
Neurological disease			0.5
No	56 (89%)	57 (85%)	
Yes	7 (11%)	10 (15%)	
Diabetes			0.073
No	57 (90%)	53 (79%)	
Yes	6 (9.5%)	14 (21%)	
COPD			0.7
No	57 (90%)	60 (90%)	
Yes	5 (7.9%)	7 (10%)	
NA	1 (1.6%)	0 (0%)	
Tobacco			0.3
Active	11 (17%)	14 (21%)	
Former	15 (24%)	23 (34%)	
No	37 (59%)	30 (45%)	

Data are presented as n (%) or mean (standard deviation), *NA* not applicable

Table 2 Primary endpoint and details of the endpoint

Characteristics	No-bridge group ($n=63$)	Bridge group ($n=67$)	p
No complications at 2 months	42 (67)	51 (76)	0.3
Surgical site infection	7 (11)	4 (6)	0.3
Peristomal irritation	5 (7.9)	5 (7.5)	0.9
Stomal necrosis	0 (0)	0 (0)	1
Peristomal hernia	8 (13)	4 (6)	0.2
Stenosis of the stoma	3 (4.8)	2 (3)	0.7
Retraction of the stoma	5 (7.9)	3 (4.5)	0.5
Prolapse of the stoma	4 (6.3)	2 (3)	0.4
Disinsertion of the stoma	1 (1.6)	0 (0)	0.5

Data are presented as n (%)

bridge in the specific situation of loop ileostomy defunctioning in a J pouch anastomosis in Japan. The population was thus highly selected, with a mean BMI in the two groups of 19.7 kg/m^2 vs 19.8 kg/m^2. This is probably one of the main limitations of that study, as the primary objective of the study was to evaluate the risk of stomal retraction. As expected, the rate of retraction was low in both groups (1.9% vs 1.9%). The authors also evaluated the risk of peristomal dermatitis, which was higher in the bridge group (54.1% vs 28.1%, $p<0.01$) [9], validating the hypothesis that a bridge might have a negative impact on the quality of life. In 2017, Zindel et al. reported a randomized control trial that aimed to evaluate the impact of a bridge on local complications. In that trial, the authors also used a composite score to evaluate edema, bleeding, necrosis, skin irritation, abscesses, stenosis, retraction, fistulas, prolapses, parastomal hernias, and incomplete diversion. In total, 180 patients were intended to be included in the trial but only 44 patients were included in the bridge group and 34 in the no-bridge group. Thus, the study was underpowered to address the research question. Moreover, there was a dropout rate of 36% [10]. Despite such methodological concerns, the authors found a higher risk of stomal necrosis and severe necrosis in the bridge group. However, there was no difference in the overall stoma-specific morbidity score between the two groups. The authors also evaluated the quality of life using the Stomal Quality of Life Scale questionnaire before surgery and at 2 weeks and 3 months postoperatively. They found no differences between the groups. Finally, the only observed difference in this trial was the risk of necrosis. However, the bridge was left in place until removal of the stitches, without a clear indication of the time until bridge removal. This could have a considerable impact of the risk of necrosis [10].

Another option could be the use of a subcutaneous bridge instead of a traditional bridge. In 2021, Ye et al. reported a retrospective cohort study comparing the two strategies. The subcutaneous bridge was associated with lower evaluated

pain and a better DET score [17]. This strategy is yet to be evaluated in a randomized control trial.

The strength of our study was its design, as it was a randomized control trial that was able to include the expected number of patients. However, as for any phase II trial, the aim was to validate a hypothesis, ensure the safety of the strategy, and determine whether to advance to a phase III trial. The outcomes of this study showed no difference between the two groups and we believe that they do not support the need for a phase III trial. It would probably require a non-inferiority design and, with a 5% margin, a total of 2292 patients would be necessary. Doing such a trial would require a national level grant for a significant amount of money which is probably offset by the low clinical impact of such a trial. The limitation is the loss of follow-up that required a higher proportion of patients than expected to have enough patients to be analyzed for the primary endpoint. Moreover, the analysis of the primary endpoint was performed at 2 months and for the analysis of postoperative morbidity at 1 month, if the analysis was before 0.5 postoperative months or after 1.5 postoperative months, the data were not considered for the analysis at 1 month and considered as loss of follow-up for this endpoint. Furthermore, the ways in which the ileostomy was made were not collected. Some might be very important, such as the eversion of the stoma, the diameter of the skin resection, and the incision/excision of the subcutaneous fatty tissue.

In conclusion, for patients with a BMI < 50 kg/m^2 the bridge does not reduce the rate of stoma complications including retraction and desinsertion, nor does it appear to have an impact on patients' quality of life.

Author contributions All authors whose names appear on the submission made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; drafted the work or revised it critically for important intellectual content; approved the version to be published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Data availability No datasets were generated or analyzed during the current study.

Declarations

Conflict of interest None of the authors has any conflict of interest about the subject of the paper.

Ethical approval No statement.

Informed consent All patients gave their written consent preoperatively and received a full explanation of the protocol.

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