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Anastomotic Leak in Barcelona Technique and Staple Height: Experimental Randomized Trial in Pigs

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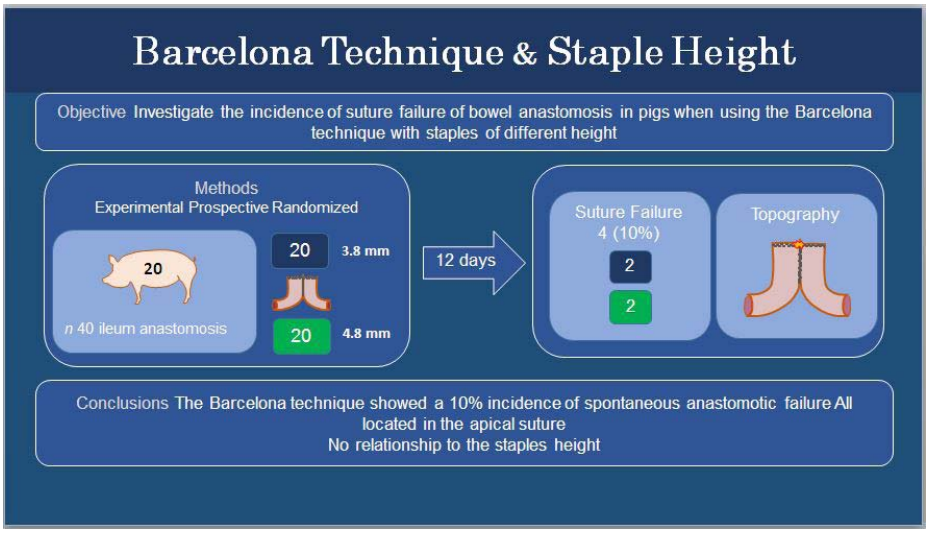
Abstract



Keywords: Barcelona technique; Bowel anastomosis; Anastomotic leak

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Abbreviations

SF: Suture Failure; BT: Barcelona Technique

Introduction

Suture failure (SF) in intestinal surgery remains a major problem that carries a high rate of morbidity and mortality. Although mechanical suture allows for standardization of some technical steps in the preparation of gastrointestinal anastomoses, its superiority over manual suture continues to be controversial [1,2].

The stapled side-to-side intestinal anastomosis described by Ravitch, also known as the Barcelona Technique (BT), is widely used for right colectomy reconstruction and ileostomy reversal [3,4]. However, a recent European collaborative study of unselected cases reported a concerningly high rate of SF of 8.2% [5]. Historically, experimental research in relation to technical aspects of SF has focused on impaired wound healing models and dehiscence models [6-8], as well as on stapler brand and type (linear or cutting) [1]. The possible influence of staple height has been less frequently evaluated [9].

The aim of this experimental study was to evaluate, under standardized technical conditions, the incidence of SF when using the BT with staples of different heights.

Methods

The research method used in this study was approved by the Ethics Committee for Animal Experimentation of Faculty of Medicine, University of the Republic. There was full compliance with the ARRIVE guidelines in accordance with the UK Animals Act, and associated guidelines of the National Institutes of Health (NIH) for the care and use of laboratory animals were followed.

A prospective, randomized, blinded and paired experimental study was designed.

Twenty young female pigs (Sus Scrofa, Pampa Rocha strain) weighing 20 kg to 30 kg were used in this work.

Animals were fasted for 8 h before all surgical procedures, and intravenous Ampicillin/Sulbactam (1000/500 mg) was given as prophylactic antibiotic. General anesthesia was done with intramuscular pharmacological combination of Ketamin (20 mg/kg) and Xylazine (2 mg/kg), applied in the back with a 21G needle using a 20 ml syringe. Next, a venous line was placed in the ear with a 22G catheter. Analgesia was administered by intravenous application of Ketoprofen (3 mg/kg diluted in 100 ml saline solution). Subsequently, animals were intubated with 6.0 orotracheal tubes.

All surgical procedures were performed under strict sterile conditions. All operations were performed by the same surgeon as a way to minimize experimental error, and an analogous procedure was carried out for both types of staples in each animal. A 2% iodine-alcohol solution was used for abdominal asepsis and a medium infraumbilical incision was done (approximately 8 cm). After exposure of the middle and distal sections of the ileum, two intestinal sutures were made in each animal (40 sutures in total), the first at 20 cm and the second at 60 cm from the ileocecal valve, by side-to-side mechanical anastomosis using the BT. Surgical linear cutting stapler's size 80 mm were used. The staples height used for the distal anastomosis was randomly selected (3.8 mm, blue; or 4.8 mm, green), and the proximal anastomosis was performed with the other load color. After random selection of the distal anastomosis staples, the sutures were divided into two groups:

Group 1 (n=20): Blue load anastomosis

Group 2 (n=20): Green load anastomosis

The surgical staplers and loads used for mechanical suture were the entire same brand (Covidien) (Figures 1-3).

The green and blue loads were all discarded after a single use. The surgical staples were reloaded a total of 8 times, the upper limit recommended by the fabricants, after which they were also discarded.

The laparotomy was closed at the fascial plane with continuous sutures using polyglactin 910-1. Skin was closed with continuous sutures using nylon 2-0.

Figures 1: Ileal loop vascularization.

Figure 2 and 3: Anastomosis using the Barcelona technique.

In the postoperative period, the animals were clinically monitored for bowel movements, urination, and wound condition. Analgesia was given by intramuscular administration of Ketoprofen (3 mg/kg).

Food and water were withheld for the first 24 h and afterwards the pigs were fed ad libidum with a liquid diet formulated for laboratory animals based on corn, sorghum, rice and/or wheat bran, pumpkin, soybean flour, mineral salt and cassava flour.

Twelve days into the postoperative period the pigs were reoperated under anesthesia and the anastomoses were macroscopically evaluated in situ and ex situ (also by their mucous side, everting the anastomoses). This procedure was carried out by other surgeon, who was blinded to the assignment of groups. Animals were sacrificed with an intravenous sodium pentobarbital overdose (200 mg/kg).

Our findings regarding the quality of the anastomoses were classified according to the grading scale of the International Study Group of Rectal Cancer (ISREC) [10,11]. For this work, the classification was adapted as follows:

A- Suture in good condition

B- Anastomotic abscess formation

C- Purulent or fecal peritonitis

Categories B and C were deemed as SF. We kept record of the topography of all failures for the anastomoses performed in this study, as well as written, photographic and filmic records of the procedures and the results obtained in each animal.

Results

There was no record of any incident or accident in any of the procedures that could have modified the results obtained.

The 20 pigs survived the postoperative period, and were sacrificed and necropsied at day 12 as planned. All animals kept mobility, tolerated food and water, and their urinary and digestive function did not evidence any surgical complications.

Macroscopically, edema and erythema were observed in all suture lines. In all of them, fecalith deposition was observed in the terminal portion of the line ("cul de sac"). In the sectors where the failure was found, ischemic changes were observed (transmural intestinal sector with defined necrotic borders, without surrounding inflammatory process).

Regarding the quality of the anastomosis:

- No major SF with purulent or fecal peritonitis (C) was observed.

- Four different sutures (10%) showed abscess formation on the suture line (B), less than 1.5 cm for all of them.

Group 1: 2 pigs

Group 2: 2 pigs

Failures were detected on 4 different pigs. In the 4 cases in which a perianastomotic abscess was found (B), the other suture of different height was healthy (A).

The remaining 36 sutures were classified as A (Table 1).

There were no differences with respect to the height of the loads

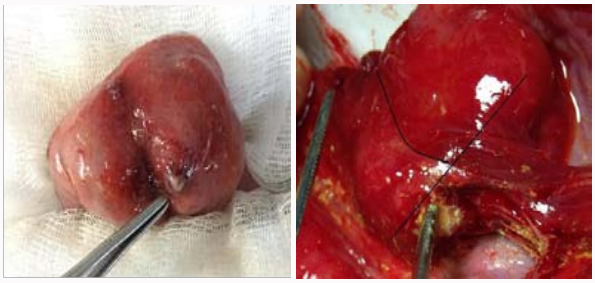
Table 1: Categories of suture and its classification.

Categories	Classification	N° of animals
A	Suture in good conditions	36
B	Anastomotic abscess formation	4
C	Purulent or fecal peritonits	0

Table 2: Load used in each suture, and it´s relationship with the suture.

N° of animal	Proximal Suture	Distal Suture	Leak
1	Green	Blue	No
2	Blue	Green	No
3	Green	Blue	No
4	Green	Blue	No
5	Blue	Green	No
6	Blue*	Green	Yes
7	Green*	Blue	Yes
8	Blue	Green	No
9	Blue	Green	No
10	Green	Blue	No
11	Blue	Green	No
12	Green	Blue	No
13	Green	Blue	No
14	Green	Blue	No
15	Blue	Green	No
16	Blue*	Green	Yes
17	Green	Blue	No
18	Green*	Blue	Yes
19	Blue	Green	No
20	Blue	Green	No

*Color of de failed suture



Figures 4 and 5: Topography of the suture failure.

used and the SF, since 2 were in the anastomoses with 3.8 mm staples (blue) and 2 in the anastomoses with 4.8 mm staples (green) (Table 2).

Regarding the anastomosis failure topography:

All abscesses on the suture line were located in the terminal sector of the anastomosis, on the intersection of the lateral and terminal sutures. SF was blocked by visceral adhesions (Figures 4-6).

Discussion

SF continues to be a major problem in colorectal surgery with devastating consequences for the patient, in addition to increasing healthcare costs. Despite the technological advances over the past 25 years, there has been no significant reduction in SF, with rates ranging from 1.5% to 23% [12].

Figure 6: Reverse of the anastomosis, with mucosa, staples and failure site.

The cause of SF is multifactorial which makes it difficult to prevent. The surgical technique plays a critical role within the so-called alterable risk factors, and the physiopathological mechanisms responsible are not completely understood.

This study focused on the BT because it is a technical variant frequently used in the reconstruction of the right colectomy (and ileostomy reversal), which continues to report high rates of SF [5]. Concerning the primary objective of this study, there was no relationship between the staples height (blue *vs.* green) and the incidence of SF in stapled anastomosis using the BT, other relevant findings were also observed.

In the first place, we found a 10% incidence of spontaneous SF (4 in 40 anastomoses performed in 20 animals) in stapled anastomoses carried out by the same surgeon under technically ideal conditions. The 4 anastomotic leaks presented as suture line abscesses; they were observed in different animals all of which were asymptomatic (or subclinical), which was related to blockage due to visceral adhesions. Although the porcine model has been proposed as the most appropriate for the investigation of intestinal anastomosis [13], SF in technically proper sutures is considered a rare event [14]. This apparent resistance and healing capacity of intestinal anastomosis in pigs has been an obstacle for their use in reproduction of anastomotic insufficiency models observed in clinical practice in humans [8,15]. Our findings demonstrate that SF occurs in technically suitable bowel anastomosis performed in pigs. The seemingly height rate of SF observed in this study could be connected with the timing of necropsy, and with the method used for assessment of the anastomosis. It is possible that the anastomotic abscesses were observed because necropsy was performed at 12 days, before they could spontaneously resolve. The examination of the anastomosis from its luminal face by eversion, allowed to clearly and completely identifying the suture lines, evidencing failures blocked by adhesions without peritonitis.

Another relevant finding was that abscesses were consistently located in the apical or transversal suture, close to the staple crossing. Such location has been reported as the site with the highest failure or dehiscence risk in dogs [16], alleging mechanisms such as closing by eversion (longer inflammatory response), tissue thickness, and decreased blood supply. Experimental studies report the apical suture, and, to a lesser degree, the crotch, as the locations with higher risk for dehiscence [16]. There are no clinical reports specifying the most frequent locations of failure for the BT in humans; even the need to reinforce the anastomosis is a controversial technical aspect. Recent reports from retrospective clinical trials have not demonstrated a

significant reduction in SF by oversewing [5] observed no significant differences: 7.9% *vs.* 9.7% without reinforcement, P=0.43), nor a connection to the type of stapler used (cutting or linear) [1]. Contrary to these reports, other studies have emphatically pointed out the protective effect of reinforcing the entire anastomosis by continuous or interrupted seromuscular suturing, which would lead to less severe failures and a lower rate of reinterventions [17,18,19]. Most surgeons (57% to 70%) add a total or partial reinforcement to the BT anastomoses [1,12], despite the lack of strong evidence to support this, denoting a particular concern on the matter.

Finally, we want to highlight the consistent finding of fecalith deposition in the anastomotic cul de sac, which has not been reported in previous studies. This observation could point to a mechanical factor of endoluminal hypertension associated with secondary infection, which could explain the protective role of oversewing.

Within the limitations of this research it should be noted that the number of animals in the experiment did not match the sample size calculated for chi-square under the assumption of an event frequency of 5% to 10%. This bias may result in a type II error and detract from the results, but the sample size averages the animal number range used in similar studies with pigs. Moreover, the experimental procedure can be easily reproduced and additional results should be easily comparable to the ones reported in this study.

While we cannot possibly establish the relevance of these findings in humans, SF incidence rates as well as their location seemed to be comparable, providing new information on likely mechanisms involved in SF.

Conclusion

The BT performed in the small intestine of a porcine model had an incidence of 10% of spontaneous anastomotic leakage presented as small abscesses in necropsy studies performed 12 days after surgery. SF was consistently located in the apical BT suture, and we did not observe a connection with the height of staples used.

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