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Effectiveness of Efferent Loop Stimulation Prior to Protective Ileostomy Closure Short

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Abstract

***Introduction:** Postoperative ileus after an ileostomy closure is the most frequent complication and involves a significant increase in morbidity, hospital stay and costs. Our aim was to define the effect of stimulation of the efferent loop before the closure of the ileostomy in those terms.*

***Methods:** Prospective and comparative study of a consecutive 45 cases subjected to an ileostomy closure with a previous stimulation of the distal end loop (SEL), compared to a cohort of 40 unstimulated historical controls (NSEL). Time to oral tolerance, reappereance of bowel movements, postoperative ileus and hospital stay were compared. Results: Both groups were homogeneous in age, sex, BMI, ASA, previous surgeries, complications after the first intervention, and interval until the ileostomy closure. The SEL group had an earlier return to oral tolerance (2.8 ± 1.1 vs 6 ± 4.4 days, p <0.001) and passage of flatus (2.17 ± 0.88 vs 3.29 ± 1, 99 days, p = 0.002). Postoperative ileus and hospital stay were lower in SEL (20% vs 41.5%, p = 0.03 and 3.7 ± 0.99 vs 7.7 ± 4 days, p <0.001 respectively). It seems there is a tendency to decrease the postoperative ileus depending on the days of stimulation, though it did not reach statistical significance.*

***Discussion:** Our main limitation is the non-randomized set up, which might impair external validity.*

***Conclusion:** Stimulation of the efferent loop before the ileostomy closure is a safe technique and reduces postoperative ileus and hospital stay, while allowing earlier oral tolerance and restitution of bowel functions.*

Keywords: *Efferent Loop Stimulation, Postoperative ileus.*

Introduction

Protective ileostomy in low colorectal anastomosis reduces the morbidity and mortality associated with dehiscence or anastomotic leak[1,2,3,4,5]. The subsequent closure of this ileostomy is not free of morbidity (8-45%), reoperation (8%) and even mortality (0.5- 5%)[6-7].

Postoperative ileus is the most frequent complication, reaching up to 35% in some series[8]. It involves a delay in the oral tolerance, prolonged serum therapy, the need for nasogastric aspiration, catheter complications, nosocomial infections, discomfort for the patient, longer hospital stay and, ultimately, an excessive consumption of resources[9-11]. A defunctionalized

intestine causes atrophy of the intestinal villi[11,12], decreased absorption capacity[12-13], smooth muscle atrophy and contractile force reduction[12-15]. All this justifies a delay in the restitution of intestinal functionalism after the closure of an ileostomy as it is described in the literature. The stimulation of the efferent loop before it closure could reverse these changes and, consequently, decrease postoperative ileus.

Objective

The aim of this study is to assess the effect of stimulation of the efferent loop before the closure of the ileostomy in terms of incidence of paralytic ileus and length of hospital stay.

Materials and Methods

Descriptive and comparative study from June 2013 to June 2018, which included a consecutive series of 45 patients collected prospectively conforming the intervention group, all of them subjected to ileostomy closure after the stimulation of the efferent loop (SEL) versus 40 historical controls not stimulated (NSEL) collected prospectively from our database within that same period. We deemed randomization was not appropriate due to preliminary results with the stimulation. The inclusion criteria were a previous low anterior rectal resection (LAR) with protection ileostomy. We excluded patients whose aptitude or psychosocial condition did not allow the stimulation. Before the closure of the stoma, it was confirmed the absence of recurrence (CT and CEA) and the rectal anastomosis (colonoscopy and opaque enema with water-soluble contrast) was examined. An informed consent of the procedure was obtained according to the protocol established in our center after the approval of the ethical committee of the Consorci Sanitari Integral hospital.

Demographic data were compared in order to assure homogeneity between the groups. Postoperative ileus, days to oral tolerance, pass stools or gas, need of prokinetics, complications (Clavien-Dindo) and hospital stay were compared.

Efferent Loop Stimulation and Preoperative Preparation

It was provided an educational session for the patients by the stomatotherapist, so that the stimulation was to be performed in an outpatient basis. Subsequently, every 24 hours and during 21 days before the ileostomy closure, the patient instilled in home 500cc of physiological saline mixed with 30g of nutritional thickening agent (Nestle Resource®) through the distal end of the ileostomy by an irrigation system with a 50cc syringe during 20 min (Fig 1). On the other hand, patients were instructed in the rehabilitation of atrophic sphincter muscles by Kegel exercises[14]. Antibiotic prophylaxis (amoxicillin-clavulanic 1g) was administrated 45 min before surgery and the ileostomy area was washed with povidone-iodine.

Surgical Procedure

The surgical interventions were performed by the same surgical team (Coloproctology Unit). In all cases it was performed a resection of approximately 5 cm of small intestine containing the stoma and an end-to-end anastomosis with loose points 3/0 silk. A supraaponeurotic penrose drainage was left during 48-72 hours and removed before discharge.

Postoperative Protocol

The same enhanced recovery protocol (ERP) was followed in both groups. In our center, those pathways include a progressive liquid diet started at 4-6 hours after surgery, and suspension of serum therapy and endovenous medication after 24 hours of tolerance. Ileus was defined as intolerance to enteral nutrition before 72 hours or if it was necessary to introduce a nasogastric tube. Discharge criteria were correct oral tolerance and intestinal transit (emission of gases and /or stools), in the absence of fever or pain.

Statistical Analysis

The gathered data were analyzed by using Stata 13.1 statistical package for Mac. An analysis of the homogeneity between both groups was performed. To compare continuous variables, T-student test or U Mann-Whitney test was applied depending on whether or not they followed a normal distribution. To study the relationship between the categorical variables a Chi square test or Fisher's exact test were conducted. The level of statistical significance was established in 0.05.

Different factors collected between patients who presented paralytic ileus and those who did not were compared. For this analysis, the tests beforehand mentioned were applied. Those variables that differed between patients with and without paralytic ileus in the bivariate analysis ($p = 0.1$) were included in a logistic regression model to identify the independent predictors of the appearance of paralytic ileus, adjusted for the group of intervention.

Results

We report data from 40 patients within the NEDL group vs 45 patients within the EDL group. Both groups were homogeneous in terms of baseline characteristics except in the presence of Diabetes Mellitus (DM), more prevalent inside the EDL group (as shown in Table 1). Patients from the EDL group exhibited an earlier oral tolerance (p<0,001), earlier reappearance of bowel movements and passing of stool (p=0,002 y p=0,02, respectively), lower incidence of postoperative paralytic ileus (p<0,03) lesser need for peristaltogenics (p<0,04) and shorter hospital stay (3,7±0,99 vs 7,7±4 days, p<0,001). There were no differences in terms of frequency or grade (Clavien-Dindo) of complications (as shown in Table 2).

The regression analysis only found one factor related to paralytic ileus and it was the stimulation of the efferent limb previous to the closure (p<0,005). It was also found a tendency to lesser incidence of paralytic ileus in relation to an increasing number of stimulation days, though it did not reach statistical significance (p=0,062).

Table 1. *Baseline characteristics.*

	NSEL (n=40)	ESL (n=45)	Differences
Sex (%, Relationship M/F)	73,2/26,8	77,8/22,2	n.s.
Mean age (years, SD)	68,3 (10,2)	66,9 (13,2)	n.s.
Anesthaesic risk (%)			n.s.
ASA I	0	4,4	
ASA II	87,8	73,33	
ASA III	12,2	22,2	
IMC (SD)	26,3 (5,4)	27,8 (4,7)	n.s.
Tabaquism (%)	51,2	46,7	n.s.
DM (%)	9,8	28,9	p=0,03
Previous Surgeries (%)	63,4	71,1	n.s.
Neadjuvance (%)	95,1	74,4	p=0,0087
Paralitic ileus (1st surgery, %)	28,5	22,2	n.s.
Anastomotic leak (1st surgery, %)	17,8	9,8	n.s.
Suboclusive episodes (%)	14,6	11,1	n.s.
Time until closure (m, SD)	11,9 (5,4)	14 (7,2)	n.s.

Table 2. *Postquirurgic results.*

	NSEL (n=40)	ESL (n=45)	Differences
Intestinal function			
Oral tolerance (days, SD)	6 (4,4)	2,8 (1,1)	p<0,001
TTFF (days, SD)	3,3 (1,9)	2,17 (0,88)	p=0,002
Passage of stool (days, SD)	4 (2,11)	3 (0,98)	p=0,02
***Procinetics need* (%)**	34,2	15,6	p=0,04
Postoperative ileus (%)	41,5	20	p=0,03
Complications (%)	10	13,3	n.s.
Clavien-Dindo I	2	3	
Clavien-Dindo II	1	1	
Clavien-Dindo III	1	2	
Clavien-Dindo IV	0	0	
Hospital stay (days, SD)	7,7 (4)	3,7 (0,99)	p<0,001

Discussion

The making of a protective ileostomy does not directly decrease the risk of dehiscence or anastomotic leak after a LAR, but it sure does minimize its potential impact on morbimortality[4,5,16,18]. In this sense, many would perform this temporary stoma, especially when the patient has received neoadjuvant radiotherapy, when performing a low or very low anastomosis (i.e. coloanal) or even in those cases when the surgeon is unsure about the result[2,4,5]. However, there is still plenty controversy regarding when and how to perform it.

Closure of a temporary stoma is not risk-free, and morbidity might even reach up to 20% in some series[10], even more so when we take under consideration the rates of postoperative ileus. Among its many causes, many authors point to factors related to the first surgery, such as an unadverted anastomotic leak. This might lead to an anastomotic stenosis, and thus a difficulty for the restitution of bowel transit. Moreover, it could also contribute to the formation of peritoneal adhesions to the pelvis, which would also increase the risk of postoperative ileus after stoma closure. Other aspects to be taken under consideration are the time the patient waits for the stoma closure[18-20]. Optimal time for the closure of a protective ileostomy is still extremely controversial. We did not find differences between both groups regarding to this aspect, although it has quite high (13±6,4 months). This could account for the longer hospital stay we report, when comparing our results to the published series. Some authors also point to the administration of neoadjuvancy as a risk factor, and though the regression analysis does not show a relationship between neoadjuvant treatment and postoperative ileus (p=0,311), it was found to be higher within the NSEL.

Intraoperative factors such as type of anastomosis might also have a role in the onset of postoperative ileus, since the defunctionalized end of the stoma usually presents a reduced diameter. According to the current literature, there are no differences between manual or mechanical anastomosis, when closing a stoma[11,22]. Every patient of this study underwent an end-to-end manual anastomosis, which we believe does not offer an impaired caliber, even if the potential discordance between the two ends is supposed to carry a higher risk of mechanical ileus. Even if the hand-sewn technique might account for our slower return of bowel function, the homogeneity within both groups still allows us to compare the effect of the stimulation, which was the sole purpose of the study.

It is accepted that a defunctionalized intestine might lead to a decrease in absorption due to the atrophy of the villi, a decrease in motility and contractibility, and ultimately in a reduction of its caliber[14,18]. All these changes might lead to a functional obstruction when the stoma is closed. When reversing all these phenomena prior to the surgery through the stimulation of the efferent loop it might be possible to achieve a reduction in the incidence of postoperative ileus. There are few studies that demonstrate this effect. Abrisqueta et al[15] previously reported a lower incidence of ileus after the stimulation, but further studies are needed in order to confirm it.

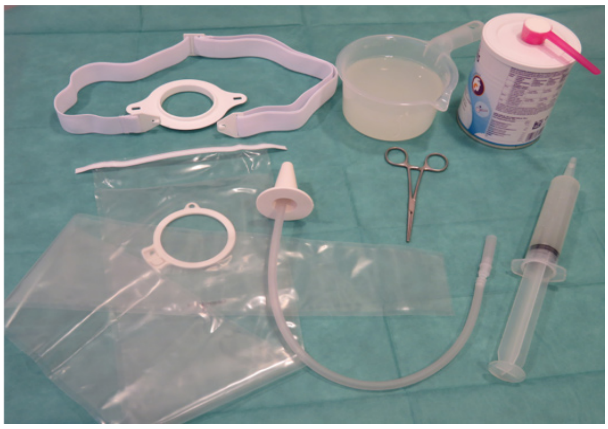
Patients that undergo stimulation report evacuation of the preparation around the 2-3rd session. Moreover, they not only present an earlier oral tolerance but also an early passage of flatus and stool, the latter being described as with more "consistency". This translate into an earlier recuperation of bowel functionality and lower incidence of postoperative ileus. Our results suggest that the stimulation would increase motility, absorption and might, in conclusion, be the reason for the reduction observed regarding ileus and hospital stay, which is to be associated with a lower consumption of resources as well. Although we have not performed an analysis of costs, it all seems like a cost-effective measure.

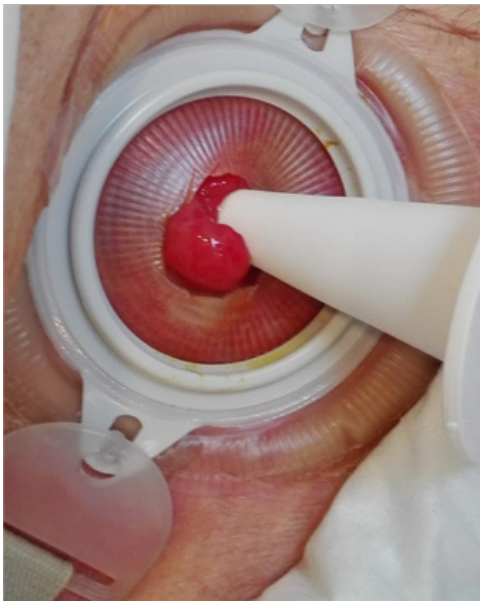
Some studies have shown that the complete restoration of the microscopical changes of the intestinal mucosa is not fully reached until the 6th month after the closure of the stoma[14,23]. Our results show an inverse relationship between the days of stimulation and the occurrence of ileus, which might mean that with a longer protocol we could achieve a greater effect in motility and absorption.

The ideal protocol for stimulation is currently unknown. One of many future fields of study would be to investigate the proper amount of days and modality of stimulation in order to accomplish the ideal outcomes. Fernández F et al[24] recently published a new protocol of stimulation involving the use of short chain fatty acids, with very promising preliminary results, which also accounts for the many opportunities for improvement that we might find when searching for the ideal protocol.

We want to highlight that ours is the first series in the literature reporting the stimulation being followed through by means of an outpatient basis. By changing the traditional Foley catheter to an irrigation device (Fig 1), and by ensuring the proper instruction of the patients through the guidance of the stomatherapist, it is possible to guarantee the daily stimulation during the three weeks prior to the surgery, without patient admission or other additional costs.

Fig 1. *Outpatient basis stimulation of the efferent loop kit (A). Irrigation system close- up (B). Educational session and also supplied to the patient (C).*





We also have to be aware of the limitations of our study, and since the patients were not randomized, the external validity of our analysis is surely to be reduced. Our preliminary results with the stimulation discouraged us from performing a randomized study, due to its potential ethical implications. Even though the stimulation of the efferent loop is a somehow novel concept, and thus the takedown of a loop ileostomy without it should not be considered unethical, the initial experience with the stimulation came with such promising results that it soon became the standard of care in our institution.

We are well aware that ours is the experience of a small single institution, but we believe our results add some value to the existing clinical knowledge. First of all, we report that the technique is safe and feasible in an institution of our characteristics, which even though it has been already reported by Abrisqueta[14-15], and is currently the subject of a formal RCT in Canada[25], might be encouraging to some groups and help the popularization of the technique. Second of all, we report some promising and satisfactory results, but, most importantly, we were able to successfully carry out the stimulation in an outpatient basis, which is something we could not find in the literature to date.

Conclusion

Efferent loop stimulation prior to the closure of a temporary stoma is a safe and easily reproduced technique that lowers that incidence of postoperative ileus and hospital stay. It is a procedure that improves patient's postsurgical return to oral tolerance and early intestinal transit, and offers the possibility to be done under an outpatient basis.

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