

Early vs. Standard Loop Ileostomy Closure: An Unmatched Case-Control Study

Cierre Temprano vs Estándar de Ileostomía en Asa.
Estudio de Casos y Controles no Emparejado

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MANTEROLA, C. & CLAROS, N. Early vs. standard loop ileostomy closure: An unmatched case-control study. *Int. J. Morphol.*, 41(6):1863-1869, 2023.

SUMMARY: Early closure of a loop ileostomy (ECI) is a relatively new practice, for which there is insufficient evidence regarding its effectiveness in relation to closure at conventional times. The aim of this study was to report postoperative complications (POC) and hospital mortality in patients with loop ileostomy (LI) who underwent ECI, compared with patients with LI who underwent late closure. Unmatched case-control study. Patients with LI who underwent surgery at Clínica RedSalud Mayor Temuco (2010-2022) were included. Cases were defined as patients with LI who underwent early closure and controls as subjects who underwent closure at the usual times. No matching was performed, but a 1:1 relationship between cases and controls was considered. Outcome variables were postoperative complications and hospital mortality. Other variables of interest were surgical time and hospital stay. Descriptive statistics were applied with calculation of proportions and measures of central tendency. Subsequently, t-test and Pearson Chi2 for comparison of averages and proportions was applied, and odds ratios and their respective 95 % CI were calculated. In this study 39 patients with AI were operated on (18 cases and 21 controls). Age and BMI average of the studied subjects was 71.3±7.1 years and 27.3±19.8 kg/m² respectively. Mean LI closure time, surgical time, and hospitalization were: 10.0±0.7 months; 62.5±10.6min; 3.8±0.1 days respectively. POC were only surgical site infections. Three in cases (16.7 %) and 3 in controls (14.3 %). No anastomotic dehiscence or hospital mortality was observed in either cases or controls. There were no differences in comorbidities or surgical site infection between cases and controls (OR of 0.6 and 1.2 respectively) In this experience, the results of performing the CTI were similar to the late closing in relation to the variables studied.

KEY WORDS: "Ostomy"[Mesh]; "Surgical Stomas"[Mesh]; "Ileostomy"[Mesh]; Loop ileostomy; "Postoperative Complications"[Mesh]; "Hospital Mortality"[Mesh]; "Case-Control."

INTRODUCTION

An ostomy is a surgically created opening in the anterior abdominal wall, with the purpose of diverting intestinal fluid and feces from the distal intestinal loops to alleviate obstruction or safeguard a distal anastomosis. These ostomies can be colostomies or ileostomies, either temporary or permanent, and can be performed in a loop configuration (Pandiaraja *et al.*, 2021).

The creation of an ostomy is pursued for a variety of conditions, ranging from benign diseases such as complex intestinal fistulas to malignant conditions like colorectal cancer. Particularly, a loop ileostomy (LI, Fig.

1) is employed in cases of intestinal obstruction due to both benign and malignant diseases, for the protection of colorectal sutures, in instances of abdominal trauma, diverticulitis, peritonitis with intestinal perforation, ulcerative colitis, Crohn's disease, and mesenteric ischemia (Vilz *et al.*, 2020). In fact, previous evidence indicates that an ileostomy diminishes symptomatic anastomotic leakage subsequent to low anterior resection for cancer (Matthiessen *et al.*, 2007). Despite the potentially life-saving nature of a LI, complications are not uncommon, the majority of which are minor and amenable to conservative interventions (Vilz *et al.*, 2020).

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FUNDING. Partially financed by project DIUFRO DI23-0020.

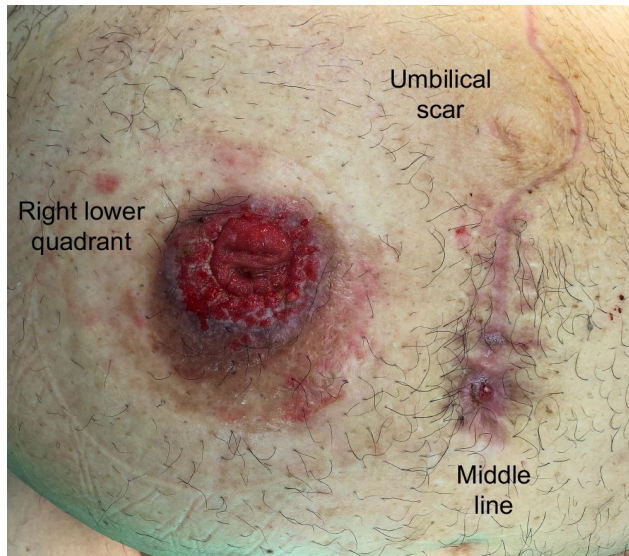


Fig. 1. Image of loop ileostomy, located in the right iliac fossa. The scar from a midline supra- and infraumbilical laparotomy is visible.

Early ileostomy closure (ECI), ≤ 2 weeks from creation, is a relatively new practice, with the first reports dating back to 2012 and 2016 (Omundsen *et al.*, 2012; Lasithiotakis *et al.*, 2016). Multiple studies have shown that this approach is safe, feasible, and cost-effective; however, despite the proven benefits, it is not a routine practice (Caminsky *et al.*, 2023). Indeed, in a recent clinical trial, involving patients scheduled for curative intent low anterior resection for rectal cancer, a comparison was made between an early closure group (8 to 12 days) and a late closure group (> 3 months). Significant differences were not observed in patient-reported quality of life or overall complication rates. However, anastomotic leaks were more prevalent in the late closure group (Ellebæk *et al.*, 2023). Nevertheless, in a systematic review encompassing 4 clinical trials, which included a total of 324 rectal cancer patients, a higher frequency of wound complications was observed in association with early closure (within 2 months), along with more leaks outside the pouch and skin irritation in the late closure group. However, no discernible disparities were evident between the two options in terms of the development of severe complications (Wang *et al.*, 2021). Moreover, a cohort study revealed that delayed closure was associated with a heightened risk of encountering various complications (RR: 1.06 per 30 days with stoma; $p < 0.001$), including ileus (OR: 1.06; 95 % CI: 1.00; 1.11; $p = 0.024$) (Turner *et al.*, 2022).

The aim of this study was to verify differences in the rate of postoperative complications (POC) and hospital mortality in patients with LI who underwent ECI, compared with patients with LI who underwent late closure. The hypothesis of this study is that ECI is associated with similar rates of POC and hospital mortality to late LI closure.

MATERIAL AND METHOD

The report of the results of this study was made following the STROBE proposal (Strengthening the Reporting of Observational Studies in Epidemiology [Vandenbroucke *et al.*, 2007]).

Study design: Unmatched case control study.

Setting: The study was conducted between January 2010 and December 2022 (13 years), with patients undergoing surgery at Clínica RedSalud Mayor Temuco, with a minimum follow-up for all patients, of 6 months at the time of recruitment.

Participants: All patients with AI who underwent surgery consecutively, by the first author, in the aforementioned period, were included. No exclusion criteria were considered. Cases were defined as patients with LI who underwent early closure and controls as subjects who underwent closure at the usual times. No matching was performed, but a 1:1 relationship between cases and controls was considered.

Variables: Outcome variables were POC (dichotomized as yes/no; and, according to the Clavien & Dindo proposal [Clavien *et al.*, 2009]) and hospital mortality. Other variables of interest were surgical time and hospital stay. Clinical variables such as age, body mass index, LI time before closure, existence of comorbidities, and type of surgery performed were also considered. ECI was defined as that performed between two and three months after the AI was realized.

Study size: We worked with all the patients with AI who underwent surgery during the study period by the first author, at the indicated institution; therefore, no matching or sample size estimation was performed.

Statistical methods: Using the statistical package Stata 11.0, an exploratory analysis of the data was performed. Then, descriptive statistics were applied with calculation of proportions and measures of central tendency. Subsequently, t-test and Pearson χ^2 for comparison of averages and proportions was applied. Finally, odds ratios and their respective 95 % CI were calculated.

Surgical technique: The surgery performed in both, cases and controls consisted in the resection of the stoma, including the last few centimeters of both ends (Fig. 2). An ileo-ileal end-to-end anastomosis with a continuous suture of polyglecaprone 25-000 and closure of the

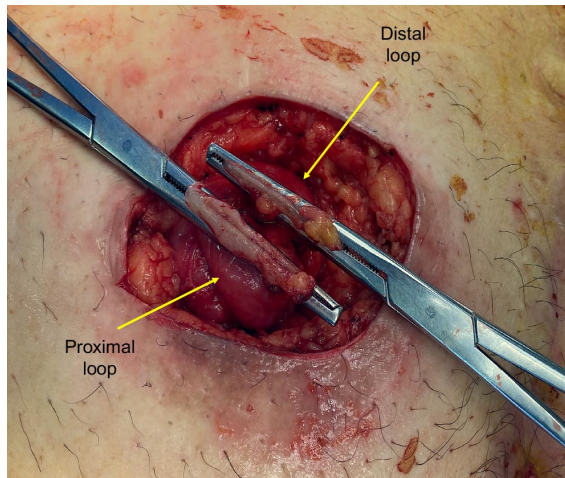


Fig. 2. Following ileostomy resection, the proximal and distal ends are identified between Kocher clamps.

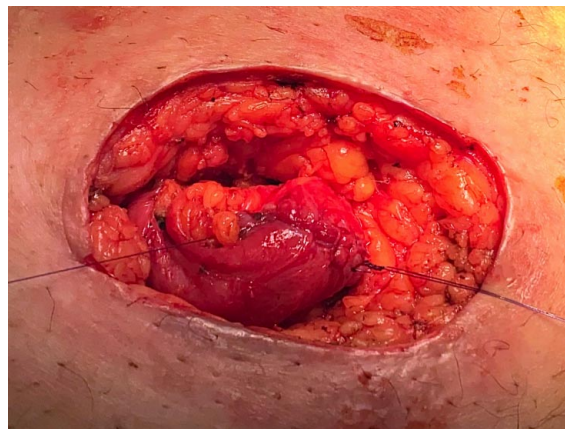


Fig. 3. Ileo-ileal anastomosis performed with continuous Polyglytone 25 (Monocryl-000™) suture.

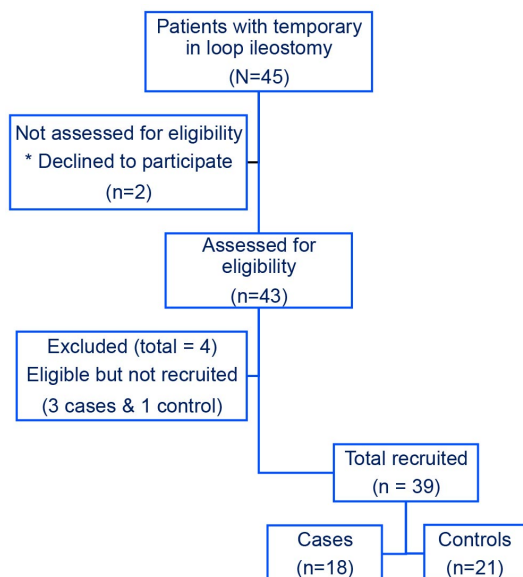


Fig. 4. Participant flowchart.

mesenteric defect with the same material (Fig. 3). Reinsertion of the reconstituted intestine into the peritoneal cavity and closure of the abdominal wall in layers (polyglactin 910-0 to the peritoneum; polydioxanone 1 to the aponeurosis; polyglactin 910-00 to the subcutaneous tissue; and staples to the skin).

Ethics: Identities of all the patients were kept hidden after each one of them was coded. Ethical standards for medical research in humans of the World Medical Association of the Declaration of Helsinki were observed (World Medical Association, 2013).

RESULTS

Participants: In the period studied, 45 patients with AI underwent surgery, but only 39 of them were included in the study (Fig. 4).

Descriptive data: Age and BMI average of the studied subjects was 71.3 ± 7.1 years and 27.3 ± 19.8 kg/m² respectively. Mean AI closure time, surgical time, and hospitalization were: 10.0 ± 0.7 months; 62.5 ± 10.6 min; 3.8 ± 0.1 days respectively.

Outcome data: When comparing the distribution of these variables between cases and controls, statistically significant differences were found in age (controls with an average age 12 years older than cases); BMI (cases with an average of 4 points higher than controls); time to closure of the LI (controls with an average of 15 months longer than cases); and follow-up (controls with an average of 16 months longer than cases) (Table I). In 9 cases, the development of a peristomal hernia was verified (all of them controls).

Main results: POC were only surgical site infections. Three in cases (16.7 %) and 3 in controls (14.3 %), what can be seen in Table II. All of them were treated only with dressings and oral antibiotics; that is, they corresponded to type II of Clavien & Dindo. No anastomotic dehiscence or hospital mortality was observed in either cases or controls. There were no differences in comorbidities or surgical site infection between cases and controls (OR of 0.6 and 1.2 respectively) (Table II).

Table I. Distribution of clinical variables among the study participants.

Variable	Cases (n= 18)	Controls (n=21)	P
Age (years)	65.2±7.1	77.3±2.8	0.0315
BMI (kg/m ²)	29.3±19.8	25.3±0.7	0.0413
Time from ileostomy to closure (months)	2.3±0.1	17.7±1.4	< 0.001
Surgical time (min)	62.5±10.6	62.5±3.5	0.9213
Hospital stance (days)	3.3±0.1	3.8±0.7	0.7531

BMI: Body mass index

Table II. Distribution of clinical variables among the study participants.

Variable	Cases (n= 18)	Controls (n=21)	OR (95 % CI)	p
Comorbidities (%)			1.7 (0.4; 7.3)	0.4445
AHT	8	9		
T2DM	4	3		
AHT + T2DM	3	2		
Obesity	2	2		
T2DM+ Obesity	4	0		
Peristomal hernia (%)				
Yes	0	42.9	0.6 (0.3; 1.2)	0.0635
No	100	57.1		
Surgical wound infection (%)				
Yes	16.7	14.3	1.2 (0.2; 6.8)	0.8374
No	83.3	85.7		

T2DM: Type 2 diabetes mellitus. AHT: Arterial hypertension. OR: Odds ratio. 95 % CI: 95 % confidence interval

DISCUSSION

Generalities: The primary objective behind the implementation of a temporary ileostomy within the surgical context for a substantial cohort of patients diagnosed with rectal cancer and other benign diseases requiring intricate high-risk colorectal or ileorectal anastomoses is to effectively mitigate the potential for anastomotic leakage (Wang *et al.*, 2021). In contrast, a body of empirical evidence substantiates a conspicuous upsurge in complications associated with the stoma, manifesting an escalation from an initial 5 % to an exceeding 30 % within the timeframe spanning from the second week post-operation to the third month of follow-up (Robertson *et al.*, 2005; Lasithiotakis *et al.*, 2016). These ensuing complications encompass an array of significant concerns, including peristomal dermatitis, dehydration, perturbations in hydro-electrolytic equilibrium, parastomal herniation, stoma hemorrhage, prolapse, stoma retraction, stenosis, and instances of intestinal obstruction. It is pertinent to note that these circumstances, in addition to imperiling the patients' overall well-being, concurrently disrupt or postpone potential adjunctive therapeutic interventions. In addition to these challenges are issues detrimentally influencing the patients' quality of life, including feelings of diminished attractiveness, impediments pertaining to clothing adaptation, diminished sexual vitality, among others. These factors are intrinsically linked to the complications arising from stoma bag leakages and challenges associated with maintaining privacy during bag evacuation and related activities (Neuman *et al.*, 2011; Lasithiotakis *et al.*, 2016; Vilz *et al.*, 2020). Henceforth, the proposition of an early stoma closure has emerged. In fact, substantiated by evidence derived from 8 SR, it is indicated that early closure,

specifically within the timeframe of 2 to 6 weeks post-stoma creation, does not exhibit a heightened incidence of complications in comparison to delayed closure. Moreover, early closure is correlated with improved restoration of intestinal motility (Farag *et al.*, 2017; Menahem *et al.*, 2018; Ng *et al.*, 2020; Clausen *et al.*, 2021; Vogel *et al.*, 2021; Wang *et al.*, 2021; O'Sullivan *et al.*, 2022; Podda *et al.*, 2022). There is also evidence that some factors are associated with a longer time to ileostomy closure, including being overweight (BMI ≥ 25 kg/m²

[OR: 4.552; IC95 %: 1.369, 15.136; p=0.013]), and the history of abdominal surgery (OR: 4.377; IC95 %: 1.394; 13.739; p=0.011) (Yu *et al.*, 2022).

Key results: The novelty of our proposal is that it is a regional casuistry, with comparable results with international series (Chow *et al.*, 2009; Man *et al.*, 2016). The existing evidence regarding the incidence of POC, reveals a range for this variable, spanning from 16.4 % to 17.3 %. While complications commonly entail straightforward treatment measures such as urinary retention, prolonged ileus, and surgical wound infections, instances of intestinal obstruction can occasionally transpire. Notably, advanced age, specifically surpassing 80 years, has been identified as an independent risk factor for the onset of POC. Hospital mortality rates typically fall within the range of 0 % to 0.4 % (Chow *et al.*, 2009; Man *et al.*, 2016). This aligns with our own clinical observations and findings.

On the other hand, we have elected to routinely employ manual closure utilizing continuous Monocryl-000 sutures. In this regard, the extant body of evidence, drawing from cohort studies and systematic reviews, indicates that no statistically significant disparities are discernible concerning the deployment of mechanical suture (Madani *et al.*, 2019; Lord *et al.*, 2020).

In a cross-sectional study involving patients who underwent restorative proctectomy with loop ileostomy for rectal cancer and underwent ECI, participants identified enhanced quality of life and a swifter return to normal functioning as the primary advantages associated with ECI. Conversely, insights garnered from interviews with surgeons affirmed that ECI offers benefits and represents a viable

option. However, it was underscored that there exist logistical barriers and impediments to its effective implementation (Caminsky *et al.*, 2023). Nonetheless, findings stemming from a CT involving 104 patients with rectal cancer did not yield statistically significant differences between ECI and conventional closure with respect to quality of life ($p=0.555$). The conclusion drawn from this analysis was that there is no discernible superiority between the two alternative approaches (Ahmadi-Amoli *et al.*, 2023).

There exist several endeavors towards achieving an even earlier closure of ileostomies. In this regard, a CT was conducted involving patients afflicted with ulcerative colitis, who had undergone ileoanal reservoir anastomosis along with diversion ileostomy. The study juxtaposed the closure of ileostomy within a span of 7 to 12 days against closure after an interval of 8 weeks. However, the study was prematurely concluded due to the elevated rate of POC observed in the early closure group (14.8 % compared to 0 %; $p=0.02$). Thirty percent of the complications documented were categorized as severe, with one instance necessitating re-intervention (Vogel *et al.*, 2023). In another CT, focusing on patients who underwent low anterior resection due to rectal neoplasia. One group underwent ileostomy closure at the conclusion of the second postoperative week, while the other group underwent closure after a twelve-week interval. The trial was prematurely halted due to the emergence of clinically significant occurrences of POC within the two-week closure cohort. Notably, the incidence of anastomotic leakage was recorded at a rate of 24 % in contrast to an absence of such cases in the twelve-week closure cohort ($p=0.002$). Furthermore, a reintervention rate of 16 % was observed in the two-week closure group vs. 0 % in the twelve-week group (0.026) (Elsner *et al.*, 2021). Furthermore, deferred closure has been associated with an increased risk of *Clostridium difficile* infection (Richards *et al.*, 2021).

On the other hand, in a SR comprising 6 studies encompassing a cohort of 570 patients (252 for ECI and 318 in late closure), no statistically significant differences were observed in the POC rate (OR: 0.63; 95 % CI: 0.22; 1.78; $p=0.38$) or anastomotic leakage (OR: 0.63; 95 % CI: 0.22; 1.78; $p=0.38$). However, complications associated with the stoma and rates of small bowel obstruction were significantly lower in the ECI group (OR: 0.46; $p=0.02$ and OR: 0.11; $p<0.00001$, respectively) (Menahem *et al.*, 2018). And, in other SR comprising 9 studies (667 patients), wherein ECI (closure ≤ 14 days from the index operation) was compared to late closure (≥ 8 weeks from the index operation), no statistically significant differences were observed in POC, anastomotic leakage, small bowel obstruction, bleeding, and ileus between ECI and late closure.

However, the rate of wound infection was significantly higher after ECI than after late closure; relative difference 0.10 (95 % CI: 0.00-0.19; $p=0.047$); and the rate of stoma-related complications was significantly higher after late closure than after ECI; relative difference -0.28 (95 % CI: -0.45; -0.11, $p=0.001$) (Ng *et al.*, 2020).

Limitations: Within the limitations of this study, it should be noted that it is a small, retrospective experience in which all patients were operated by the same surgeon; and, in which the latest cases still have a short follow-up time. All these are facts that can generate information and interpretation bias. On the other hand, the most significant limitation of case-control studies is their high susceptibility to the introduction of biases, both in the selection of groups and in the information obtained regarding risk factors. In this instance, we also identify the potential for a Neyman bias or selective survival bias, given that the cases under consideration might not be representative of all cases. Additionally, there exists a risk of confounding bias, exacerbated by the lack of matching (Manterola & Otzen, 2015).

Interpretation: Given the limitations of the study, the results should be viewed with caution. Studies with a longer follow-up time and of a prospective nature are necessary to collect the data correctly and in detail.

Generalizability: The observed results represent a trend, which may be generalizable only to similar populations.

CONCLUSION

In this experience, the results of performing the CTI were similar to the late closing in relation to the variables studied.

ACKNOWLEDGMENTS. ANID – MILENIO – NCS2021-013.

MANTEROLA, C. & CLAROS, N. Cierre temprano vs estándar de ileostomía en asa. Estudio de casos y controles no emparejado. *Int. J. Morphol.*, 41(6):1863-1869, 2023.

RESUMEN: El cierre temprano de una ileostomía en asa (IA), es una práctica relativamente nueva, sobre la que no hay suficiente evidencia respecto de su efectividad en relación con el cierre en tiempos convencionales. El objetivo de este estudio fue verificar diferencias en la tasa de complicaciones postoperatorias (CPO) y de mortalidad hospitalaria en pacientes con IA sometidos a cierre temprano comparados con pacientes con IA sometidos a

cierre tardío. Estudio de casos y controles sin emparejamiento. Se incluyeron pacientes con IA que fueron sometidos a cirugía en la Clínica RedSalud Mayor Temuco (2010-2022). Los casos se definieron como pacientes con IA sometidos a cierre temprano y los controles como sujetos con IA sometidos a cierre en tiempos habituales. No se realizó emparejamiento. Se consideró una relación 1:1 entre casos y controles. Las variables de resultado fueron CPO y mortalidad hospitalaria. Otras variables de interés fueron: tiempo quirúrgico y hospitalización. Se aplicó estadísticas descriptivas (cálculo de proporciones y medidas de tendencia central). Posteriormente, se aplicó prueba t-test y Chi2 para comparación de promedios y proporciones; y se calcularon odds ratios e intervalos de confianza del 95 %. Se operaron 39 pacientes con IA (18 casos y 21 controles). El promedio de edad e IMC fue 71,3±7,1 años y 27,3±19,8 kg/m², respectivamente. El tiempo promedio de cierre de IA, tiempo quirúrgico y hospitalización fueron: 10,0±0,7 meses; 62,5±10,6 minutos; 3,8±0,1 días, respectivamente. Las CPO fueron infecciones del sitio quirúrgico (3 casos; 16,7 % y 3 controles; 14,3 %). No se observó dehiscencia anastomótica ni mortalidad hospitalaria en casos ni controles. No hubo diferencias en comorbilidades ni en infecciones del sitio quirúrgico entre casos y controles (OR de 0,6 y 1,2, respectivamente). No se evidenciaron diferencias entre realizar cierre temprano o tardío de IA, respecto de las variables CPO y de mortalidad hospitalaria.

PALABRAS CLAVE: Ostomía; Estomas quirúrgicos; Ileostomía; Ileostomía en asa; Complicaciones postoperatorias; Mortalidad hospitalaria; Estudio de casos y controles.

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