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REVIEW ARTICLE

Closing A Temporary Stoma – The Procedure Tactics

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT: The paper presents the results of clinical trials and meta-analyses regarding the closing time of: ileostomy (protective) after primary colorectal resection with anastomosis and colostomy – after Hartman's surgery. Rectal cancer surgery and ileal pouch-anal anastomosis (IPAA) in inflammatory bowel diseases often involves an ileostomy (temporary protective, preventive), which in a significant proportion of cases is eliminated at different times from the initial surgery. There is a discussion in the literature regarding the selection of the appropriate time of stoma closure, taking into account the experience of many clinical centers. An ileostomy is performed when the entire colon and rectum must be removed, or to protect the colon or ileorectal anastomosis. The creation of a protective stoma reduces the frequency of clinically significant anastomotic leakages and the need for surgical revisions in patients at increased risk of leakage. Also, the time of digestive system reconstruction, i.e., colostomy elimination, after Hartman's surgery depends on many factors, including the stage of disease and indications for adjuvant treatment. Should it be standard practice to close the stoma early? Based on previous studies and meta-analyses, as well as own experience – it is advisable to individualize the procedure, taking into account many factors that determine the clinical and oncological status (selection of the date – early or deferred, but not as a standard [!]).

KEYWORDS: anastomotic leak, anterior rectal resection, closing ileostomy, colostomy

ABBREVIATIONS

CT – computed tomography
DI – obstruction of the small intestine around ileostomy
EC – early closure
FAP – familial adenomatous polyposis
IPAA – ileal pouch-anal anastomosis
LARS – Low Anterior Resection Syndrome
LC – delayed closure
LSC – linear skin closure
PSC – purse-string skin closure
RCT – randomized controlled trials
SHTH – complementary therapy completed
SRO – stoma-related obstruction
SSI – surgical site infection
TME – total mesorectal excision
UC – ulcerative colitis

INTRODUCTION

Stoma connects the lumen of a selected section of the gastrointestinal tract with the skin of the anterior abdominal wall. A stoma can be created virtually anywhere along the gastrointestinal tract in order to change the pathway of digestive passage. The most common stomas include the distal small intestine (ileostomy) and the large intestine (colostomy), but special clinical cases also involve stomas on other parts of the small intestine (jejunostomy), duodenum (duodenostomy), and stomach (gastrostomy). A colostomy, as a type of ostomy surgery within the digestive tract, is performed when it is necessary to bypass or remove the distal part of the colon, rectum or anus, and when simultaneous restoration of the digestive tract is inadvisable or impossible [1, 2].

If the rectum and the anal sphincter are removed, the colostomy is permanent, but if the sphincter and its function are preserved, the stoma can be reversed. Similarly, an ileostomy can be permanent or temporary.

Clinical practice often involves an ileostomy (temporary protective, preventive or permanent), which in a significant proportion of cases is eliminated at different times from the initial surgery. There is a discussion in the medical literature regarding the selection of the appropriate time of stoma closure (removal), taking into account the experience of many clinical centers. An ileostomy is performed when the entire colon and rectum must be removed, or to protect the colon or ileorectal anastomosis. Protective ileostomy is an established method of protecting low colorectal anastomosis following rectal cancer surgery. Numerous studies [2, 3] show that a protective stoma can decrease the clinically significant anastomotic leakage rate and the need for surgical revision in patients with an increased risk of leakage. However, studies are still needed to identify patients with a high risk of anastomotic failure following an anterior rectal resection [2, 3]. The impact of an ileostomy on symptoms of sphincter dysfunction after its closure is assessed differently. In numerous cases, ileostomy closure may contribute to development of Low Anterior Resection Syndrome (LARS) and it has a significant impact on reducing the quality of life [4].

According to the Polish consensus, [1] the following criteria for protective ileostomy were adopted: male sex, age > 60 years, obesity, low anastomosis < 3 cm from the edge of the anus, the need for blood transfusion during surgery, anemia < 8 g/dL, hypoalbuminemia < 3.5 g/dL, neoadjuvant therapy, coexistence of vascular diseases, steroid therapy, immunosuppression, stimulants – cigarettes, alcohol, TME (total mesorectal excision), positive result of anastomotic tightness and/or incomplete stapler rings, duration of procedure > 4 hours, significant intraoperative difficulties (including very narrow pelvis, technical difficulties), malnutrition – BMI < 19, ASA III or IV, center performing less than 20 anterior resections per year/surgeon performing less than 10 anterior resections per year [1].

After the stoma is created and the anastomosis has healed, and thus the desired result has been achieved, patients may experience some stoma-related complications, such as inflammatory skin lesions around the stoma, stoma prolapse, peristomal hernia, and intestinal obstruction. The incidence of these complications is high (21–70%), and they may require aggressive conservative or surgical treatment resulting in extended hospital stay and additional medical costs [5, 6]. Therefore, the ability to make rational choices about treating complications, taking into account their etiology, is essential.

Okita et al. [7] indicated a high risk of ileostomy obstruction (25.8%) in patients undergoing restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) due to ulcerative colitis. A similar frequency (27.3%) of intestinal obstruction was reported by Okada et al. [8] in patients undergoing IPAA for ulcerative colitis (UC) or surgery for rectal cancer.

There are still significant divergences of view considering the time of stoma closure. There are a number of studies on the timing of stoma closure and the restoration of anatomical continuity of the gastrointestinal tract, but the results are inconclusive. The aim of the study by Farag S. et al. [9] was to evaluate the surgical outcomes and feasibility of ileostomy closure within 2 weeks of primary surgery in patients undergoing distal colon resection. Meta-analysis methodology was used.

Four randomized, controlled trials with 446 patients were analyzed to assess the feasibility and outcomes of early (176 patients) or delayed stoma closure (270 patients). The risk of anastomotic leak [hazard ratio 0.37 (CI: 0.10–1.42), p = 0.15], anastomotic stricture [hazard ratio 4.79 (CI: 0.23–98.47), p = 0.31], and postoperative complications [hazard ratio 0.75 (CI: 0.48–1.16), p = 0.19] were similar in both groups. The duration of surgery [standardized mean difference -0.49 (CI: -01.09, -0.12), p = 0.12] and length of hospitalization [standardized mean difference -0.04 (CI: -0.25, -0.18), p = 0.75] did not differ statistically significantly.

The authors concluded the study by stating that early ileostomy closure in patients undergoing distal colon resection is feasible with results comparable to delayed closure.

Alves et al. [10] included 186 patients in the study groups. Early closure was performed on day 8 (EC), and delayed closure (LC) 2 months after primary surgery. There were no deaths within 90 days and the overall incidence rate was similar in the EC and LC groups (31% *vs.* 38%, respectively; p = 0.254); the percentage of surgical complications was similar, but surgical site infections were more frequent after EC (19% *vs.* 5%; p = 0.007). Small intestinal obstruction (3% *vs.* 16%; p = 0.002) and general complications (5% *vs.* 15%; p = 0.021) were more common with LC. The length of hospitalization was shortened at EC [16 (6–59) *vs.* 18 (9–262) days; p = 0.013]. Hence, the study suggests that early stoma closure after proctectomy is possible in selected patients, but it is associated with some advantages and disadvantages, such as shorter hospital stay but a higher rate of surgical site infections that should be considered and discussed with the patient before making a final decision [10].

Early closure (EC; 30 days post-stoma) and standard closure (LC; 90 days post-stoma) of ileostomy were compared in a single-center randomized controlled trial conducted at the National Cancer Institute (Vilnius, Lithuania) [11]. Patients with a transient ileostomy who had undergone rectal cancer surgery and had no anastomotic leakage or other serious complication were randomized to early or standard ileostomy closure groups. The endpoint of the study was morbidity 30 days after closure of the ileostomy. The study was terminated prematurely for safety reasons after 86 patients were randomized to the EC (43 patients) and LC (43 patients) groups.

The total incidence rate 30 days after surgery was significantly higher in the EC group (27.9% *vs.* 7.9%; p = 0.024). In addition, severe complications (Clavien-Dindo ≥ 3) only occurred after early ileostomy closure (EC) in 5 (11.6%) patients. According to these authors, [11] mearly ileostomy closure 30 days after radical rectal resection is not safe and should not be performed.

Wang et al. [12] developed a meta-analysis regarding the choice of stoma closure time.

Complications caused by early (EC) or late (LC) closure included: complete complications, severe complications, and various individual complications before or after closure. Four randomized controlled trials (RCTs) were analyzed, including the EASY trial which included a total of 324 patients. In rectal cancer patients with temporary ileostomy, EC caused more postoperative complications than LC. This difference was mainly related to complications in the wound healing process. LC caused more complications than EC before closure, such as leakage outside the pouch and skin irritation. There was no significant difference in severe postoperative complications or systemic complications. With fewer general and wound-related complications, LC appeared more appropriate than EC for rectal cancer patients with a protective ileostomy. However, choosing the time of a liquidation of ileostomy should also involve the consideration of pre-closure complications, which relate to cases in which the stoma is closed at a later date.

Most clinicians who perform a loop ileostomy usually intend to remove it between eight weeks and three months after the original procedure, when the anastomosis is well healed. Cheng et al. [13] conducted a systematic review in which they identified 6 studies that compared early with delayed ileostomy closure. Early closure was defined as closure within days 8 to 17 of ileostomy formation in five studies and within one month in the sixth study. Late closure was defined as closure from day 57 to day 278 after ileostomy. Compared to late closure, early ileostomy closure was associated with shorter operative time, lower incidence of small bowel obstruction/postoperative obstruction, and higher incidence of SSI. In addition, there was no difference between the two groups in the frequency of reoperations and anastomotic leakage [13]. Thus, the presented results [10–13] indicate that early stoma closure increases the risk of complications in wound healing and surgical site infections compared to deferred closure.

Polish authors presented a different view, which resulted from the conducted research. Kłęk et al. [14] believe that early closure of a protective ileostomy could change the situation and should become part of ERAS. The effectiveness of early stoma closure in ERAS patients was analyzed. A randomized clinical trial was conducted from October 1, 2016 to December 31, 2017. Fifty-eight adult patients (24 females, 34 males, mean age: 55.7 and 56.2) were operated for rectal cancer according to the ERAS protocol, with

an ileostomy. Patients were randomly assigned to the group with late (LC) or early (EC) closure (14 days after discharge). The initiation time of adjuvant chemotherapy, the incidence of complications and the cost of health care were analyzed. There were no significant differences between the groups in terms of the length of procedure (83.2 ± 15.9 *vs.* 87.1 ± 21.7 min in EC and LC, respectively), intraoperative blood loss (15.2 ± 7.5 *vs.* 17.3, respectively). ± 11.1 mL), median hospital stay, time to passing first gases and stool. The difference in the time to start adjuvant treatment (38.7 ± 5.7 *vs.* 33.2 ± 5.8 days, $p < 0.01$) was compensated by a shortened life with a stoma (17.2 *vs.* 299.0 days) and health care costs: (43,68 *vs.* 698,42 USD). The authors believe that [14] early closure is a safe and effective therapeutic approach to improve recovery and should be implemented as part of the ERAS protocol for patients with rectal cancer.

The issues of the improper functioning of the stoma – ileostomy, also necessitate a decision on the removal of the stoma or its new formation. In the studies by Yang et al. [15] on stoma dysfunction, the study group consisted of adult patients who underwent low anterior resection with concomitant dysfunctional loop ileostomy in 2002–2014. The cohort consisted of 4,658 patients who underwent lower anterior resection with concomitant dysfunctional loop ileostomy. The 30-day, 90-day, and 1-year mortality of these patients was 1.2%, 2.2%, and 5.1%, respectively. Reoperation rate was 5.5%, re-admission to hospital 13.4%, serious complications 28.5%, deep/organ-space infection requiring percutaneous intervention 5.2%, acute kidney injury requiring hospitalization 10.4%. In this group, 86% of patients had a closed ileostomy, and 13.2% were left with a permanent stoma.

After ileostomy closure, the 30-day and 90-day mortality was 0.6% and 0.9%, respectively. The rate of serious complications was 10.3%, intestinal obstruction – 7%, abdominal hernias – 10.5%, "deep" infections of the peritoneal cavity – 1.7%, and reoperations – 2.3% [15].

Ileostomy after a two-stage IPAA is often performed in patients with Crohn's disease with an increased risk of postoperative complications. However, data on morbidity after stoma closure are lacking. Iesalnieks et al. [16] analyzed a group of 121 patients. The median interval between ileostomy and ileostomy reversal was 4 months; of the 121 patients with available data, 97 (80%) gained weight between the two operations. Hemoglobin concentration increased between operations in 107 patients (85%), and 15 patients (11.5%) received parenteral fluid replacement or parenteral nutrition between both operations. In the period between the stoma formation and removal, there were 37 readmissions (29%). After ileostomy closure, 14 patients experienced anastomotic complications (11%). Based on multivariate regression analysis, it was found that preoperative steroid intake (hazard ratio 4.5, 95% CI: 1.11–18.0, $p = 0.035$) and re-admission to hospital due to infectious complications (HR 4.5, 95% CI: 1.11–18.0, $p = 0.035$) were statistically significantly associated with an increased risk of postoperative anastomotic complications. There were no postoperative deaths [16].

The postoperative course may also be influenced by the type of stoma closure technique. Sayuen et al. [17] conducted a study that analyzed skin closure (post ileostomy) in the form of purse-string skin closure (PSC) and a linear skin closure (LSC) – performed in 31 and 45 patients, respectively. PSC involved the preservation of a central hole with a diameter of 5 mm, which allowed for the spontaneous drainage of any residual hematoma or exudate. The linear closure group had their intestine managed and next had single subcutaneous absorbable sutures and single nonabsorbable mattress sutures applied to the skin. The sutures were removed within 1–2 weeks after the procedure. Thirty days after surgery, 3 patients in the PSC closure group experienced SSI compared with 14 patients in the linear closure group (9.7 *vs.* 31.1%, $p = 0.028$). Moreover, there was no significant difference in overall postoperative complications. The use of PSC closure to close the stoma led to a significantly lower percentage of SSI compared to LSC, with no difference in the length of hospital stay.

The aim of another study was to determine whether laparoscopic access during primary colon surgery at the time of ileostomy had a beneficial effect on the outcomes of ileostomy closure [18].

A retrospective analysis of the prospective database of patients who underwent ileostomy closure in 2010–2017 was performed. Patient demographic data, operative reports, and the postoperative course were analyzed. A regression analysis was performed for overall complications and length of stay to further evaluate the impact of laparoscopy.

The study group consisted of 795 patients (363 women) who underwent ileostomy reversal. The surgical technique in the primary operation was laparoscopy in 65% of patients. The overall complication rate was lower and the length of hospital stay was shorter in patients who underwent ileostomy closure after primary laparoscopic surgery. Laparoscopy was also associated with a lower incidence of postoperative bowel obstruction and lower estimated blood loss during ileostomy reversal. Multivariate regression analysis showed that laparoscopy has significant benefits over laparotomy in terms of overall complications and length of hospital stay [18].

In the study by Elsner et al. [19] patients were randomized to either early (2 weeks) or late (12 weeks) stoma closure. The integrity of colorectal anastomosis was examined prior to closure. The primary endpoint was quality of life 6 weeks after resection. Secondary endpoints included safety (morbidity) and quality of life 4 months after low anterior resection. The study was terminated for safety reasons after 71 patients were randomized to early closure (37 patients) or late closure (34 patients). The baseline data was [comparable between the groups. There was no difference in quality of life 6 weeks after the primary surgery. Perioperative bleeding tendency (visual analog scale: 35.8 *vs.* 19.3; $p = 0.011$), adhesions (visual analog scale: 61.3 *vs.* 46.2; $p = 0.034$), leakage of colonic anastomosis (19% *vs.* 0%; $p = 0.012$), ileal anastomosis (24% *vs.* 0%; $p = 0.002$) and re-intervention (16% *vs.* 0%; $p = 0.026$) were significantly higher after early closure. The concept of early closure failed in 10 patients, 27% *vs.* 0% in the late closure group. The study was terminated prematurely due to safety concerns. The target group size was not achieved. Early stoma closure does not provide a better quality of life up to 4 months after low anterior resection, but it is significantly more morbid than late closure [19].

Another retrospective cohort study was conducted on 173 patients who underwent ileostomy closure in 2012–2018 [20]. The primary endpoint was intestinal obstruction; secondary endpoints included postoperative complications. The relationship between

duration of liquidation of ileostomy and intestinal obstruction was investigated using several analyses to ensure that time is treated appropriately as a continuous, non-linear variable.

Overall, 20.2% of patients had intestinal obstruction. Multivariate analysis identified no significant association between the independent predictors and intestinal obstruction, although there was a trend towards an increased risk of intestinal obstruction with increasing duration to liquidation of stoma. A duration of > 328 days independently increased the likelihood of intestinal obstruction (OR = 3.25, p = 0.033). The mean time needed for a gastric probe was 3.2 days.

The conclusion from these studies is that a longer duration to removal of the stoma was associated with a trend towards an increased risk of intestinal obstruction; the risk tripled when the ileostomy lasted more than 328 days [20].

Some clinical cases may require early closure of the stoma due to complications with the stoma itself. Stoma-related obstruction (SRO) is defined as an obstruction of the small intestine around the ileostomy (DI). A study by Maemoto et al. [21] aimed to investigate the prevalence, risk factors, and treatment of SRO following laparoscopic colorectal surgery with ileostomy.

This study included 155 patients who underwent laparoscopic colon surgery for ileostomy for rectal cancer (n = 138), ulcerative colitis (UC) (n = 14), and familial adenomatous polyposis (FAP) (n = 3) from 2011 to 2019. The incidence of SRO was 7.7% (n = 12) and was significantly lower (p < 0.01) in patients with inferoanterior or intersphincteric resection (4.3%) than in patients with IPAA (35.2%). Multivariate analysis showed that IPAA was independently associated with SRO (p = 0.001). Eleven of 12 patients (92%) with SRO required stoma tube decompression, and 8 (67%) underwent early stoma closure.

IPAA was an independent risk factor for SRO in laparoscopic colorectal surgery with ileostomy. Early stoma closure was required in most cases of SRO [21].

The results of the presented studies are divergent. However, with careful analysis of groups of respondents, which are not always comparable, and on the other hand, the need to individualize and personalize the procedure tactics, it is the results of these tests that entitle each individual to consider the selection of the date of stoma closure. Bearing in mind patient safety, after presenting all aspects of the case the decision should involve the consideration of numerous factors, such as: postoperative course after primary surgery, wound healing, the need for adjuvant treatment (it is not recommended to waste time [!] on surgical treatment), the patient's mental attitude and stoma tolerance, the general condition of the patient, the patient's age and possibility of the stoma patient receiving support from his relatives, as well as the patient's opinion.

Stoma closure – how to proceed?

1. Reversal of temporary stoma (protective ileostomy, colostomy) – delayed until the patient returns to baseline and inflammation subsides with partial resolution of adhesions, which may last 3–4 months (inflammatory diseases);

2. After Hartman's surgery:

   - in non-oncological patients (complicated diverticular disease) – after obtaining the conditions for closure, i.e., good general condition of the patient, postoperative wound healing, no septic complications – at different times,
   - depending on the primary postoperative course [!];
   - after oncological operations – after completion of adjuvant treatment, follow-up examinations (CT, colonoscopy) – no recurrence – digestive tract reconstruction. It should be remembered! that the operation is often performed in advanced, complicated neoplasm (perforation, obstruction) – the risk of recurrence is high and another stoma may be necessary;

3. Protective ileostomy – healed anastomosis, complementary therapy completed (CHTH), removal of an ileostomy should be considered, similarly in the case of a formed colostomy (protective, decompressive);

4. If adjuvant therapy is necessary – stoma closure must be postponed until its completion, except for patients who have good tolerance for adjuvant chemotherapy (6–8 weeks), and if adjuvant therapy is not necessary – early ileostomy closure is possible, but not earlier than after 3–4 weeks after confirming the integrity of the anastomosis;

5. After Hartman's surgery – after oncological surgeries – prognostic, without a high risk of recurrence and dissemination, without adjuvant treatment – early stoma closure is also justified.

Early stoma closure – should it be standard? Based on previous work and meta-analyses, as well as own experience – it is necessary to individualize the procedure, taking into account many factors that determine the clinical and oncological status (selection of the date – early or deferred, but not as a standard [!]).

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Table of content: https://ppch.pl/resources/html/articlesList?issueId=0 Page of count: 5 Tables: – Figures: – References: 21

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