Preliminary results of Polish national multicenter study on colostomy reversal — LICO (Liquidation of Colostomy) study

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Abstract

Introduction: Creation of colostomy is still a commonly performed procedure in emergency settings, when intestinal anastomosis cannot be performed safely. Reversing a stoma has been linked with high rates of morbidity and also mortality.

Aim: The primary goal of the study was to identify the risk of postoperative complications in patients undergoing colostomy liquidation. The secondary goal was to assess perioperative care parameters.

Material and methods: The Liquidation of COlostomy (LICO) study is an open multicenter prospective cohort study that began in October 2022 and will continue until December 2023. Data from 20 Polish surgical departments were collected. Overall 45 patients were reported over the initial 3 months; based on that group we performed a preliminary analysis.

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Results: Mean operative time was 163 min. Patients were operated on by specialists in 93.3% of cases. Complications occurred in 15 (33.3%) patients. Wound infection was the most common complication (17.8%). In 3 (6.7%) cases anastomotic leakage was diagnosed, and in 2 of those cases reoperation was required. The overall mortality rate was 2.2%. The mean length of hospital stay was 10.1 days. Preoperative fasting was used in 53.3% of patients, and the mechanical bowel preparation rate was 75.6%. Only in 8.9% of cases was laparoscopic access used for stoma reversal, and only in 1 out of 45 cases was mesh used for incisional peristomal hernia prophylactics. The stoma site was closed by single sutures in 73.3%, and negative pressure assisted closure was performed in 6.7% of patients. Conclusions: Colostomy liquidation is associated with significant morbidity and minor mortality in the Polish population. Standardized perioperative care should be established for stoma reversal surgery.

Key words: postoperative complications, colostomy, colostomy reversal, liquidation of colostomy.

Introduction

Creation of colostomy during the Hartman procedure is commonly performed in emergency settings, when there is a mechanical obstruction or a perforation of the left part of the colon. This procedure is associated with a delayed second step operation - stoma closure - to restore the continuity of the gastrointestinal tract. Unfortunately, stoma closure is performed only in a fraction of the patients. It is estimated that up to 54% of patients with colostomy never undergo stoma reversal [1, 2]. An alternative to the Hartman procedure is segmental resection of the large bowel with a primary anastomosis, with or without creation of the protection loop ileostomy. Despite the scientific evidence confirming the safety of alternative operations in a selected group of patients, the Hartman procedure is still the most common solution in emergency patients [3, 4]. Other indications for colostomy creation are much less frequent, and thus there is scarce scientific evidence on the further therapeutic pathways of those patients.

Stoma reversal has been associated with surprisingly high morbidity and mortality [5, 6]. There is no standardized perioperative care in this group of patients. Timing of surgery and different surgical techniques also vary from center to center [7, 8]. To date, there has been no prospective multicenter analysis on the perioperative care and therapeutic results in patients undergoing colostomy liquidation or reversal.

Aim

The LICO (Liquidation of COlostomy) study was conducted to combine many Polish surgical centers in an effort to analyze numerous perioperative parameters, especially in the context of postoperative complication rate. The primary goal of the study was to iden-

tify the risk of postoperative complications in patients undergoing colostomy liquidation. The secondary goal was to assess perioperative care parameters. Obtaining results on a greater number of patients can help to establish risk factors for postoperative complications in future studies and to optimize postoperative care in patients undergoing colostomy liquidation.

Material and methods

The LICO study is an open multicenter prospective cohort study that began in October 2022 and will continue until December 2023. From 27 surgical centers in Poland that initially declared collaboration in the framework of the LICO study, we received responses from 20 centers; all the participating centers prospectively collected data during the initial 3 months. Overall, 45 patients were reported over the initial 3 months; based on that group we performed preliminary analysis of the available data.

The Bioethical Committee at Andrzej Frycz Modrzewski Krakow University approved the LICO study protocol (KBKA/55/O/2022).

The preliminary analysis focused on the assessment of multiple perioperative care parameters, surgical technique of colostomy reversal, length of hospital stay after surgery, number and severity of postoperative complications and reoperations, and postoperative mortality during 30 days after surgery.

The demographic and clinical parameters of the LICO study population are presented in Table I. Colostomy data are shown in Table II.

An interesting observation was that amongst patients who had complicated diverticulitis as an indication for colostomy creation, 8 patients (42.0% from that subgroup) had a local form of diverticulitis (Hinchey 2) and the remaining eleven patients had purulent or fecal peritonitis (Hinchey 3 or 4).

Table I. Demographic and clinical data of LICO study preliminary group

Parameter	Value
Male/female, n (%)	22/23 (49.0%/51.0%)
Median age (Q1–Q3) [years]	61 (49–69) (min. 18, max. 81)
Median BMI (Q1–Q3) [kg/m²]	26.2 (24.4–30.0) (min. 18.3, max. 44)
ASA class, n (%)	
I	7 (15.6)
II	24 (53.3)
III	14 (31.1)
Active smokers	8 (17.8)

Results

Preoperative care

Antithrombotic prophylaxis was administered in 41 (91.1%) patients. Preoperative antibiotic prophylaxis was given intravenously in 38 (84.4%) cases, and in 7 cases an antibiotic was administered both intravenously and *per os* (15.6%). Mechanical bowel preparation was used in 34 (75.6%) patients.

Preoperative fasting was used in 24 (53.3%) patients. Patients were allowed to drink fluids until the day of surgery in 8 (17.8%) cases, and food was also allowed until the day of surgery in 13 (28.9%) cases. This data are presented in Table III.

Surgical techniques

In 41 (91.1%) patients the classical open approach was used (laparotomy), and in 4 cases the laparoscopic technique was used (8.9%). Other surgical parameters are given in Table IV. Interestingly, mesh was used only in 1 out of 45 cases for incisional peristomal hernia prophylactics.

During the postoperative course 40 (88.9%) patients had urinary catheters kept after surgery for a mean of 1.85 days. The nasogastric tube, if not removed directly after surgery, was used in 7 patients postoperatively, for a mean of 2.14 days (minimum 1 day, maximum 5 days). Abdominal drains were used in 34 (75.6%) patients, and the mean time for drain removal was 3.03 days. The length of stay after colostomy removal was 10.1 days (minimum 3, maximum 42 days). The longest postoperative stay was observed in the patient with anastomosis leakage,

Table II. Colostomy data

Variable	Value	
End colostomy/loop colostomy	34/11 (75.6%/24.4%)	
Location of colostomy, n (%)		
Sigmoid colon	20 (44.4)	
Transverse colon	13 (28.9)	
Descending colon	12 (26.7)	
Indications for colostomy, n (%)		
Colorectal cancer	16 (35.6)	
Diverticulitis	19 (42.3)	
latrogenic perforation	6 (13.3)	
Colovesical fistula	1 (2.2)	
Ischemia	1 (2.2)	
Anastomotic leakage	1 (2.2)	
Fournier gangrene	1 (2.2)	
Initial surgery performed by specialist/resident, <i>n</i> (%)	43/2 (95.6/4.4)	
Initial surgery uncomplicated/complicated, n (%)	35/8 (77.8/17.8)	
Parastomal hernia, n (%)	16 (35.6)	
Median number of months between initial surgery and stoma reversal (Q1–Q3)	12 (7–17) (min. 3, max. 94)	

Table III. Preoperative care parameters

Parameter	Value
Antithrombotic prophylaxis, n (%)	41 (91.1)
Antibiotics intravenously, n (%)	38 (84.4)
Antibiotics intravenously and orally, n (%)	7 (15.6)
Mechanical bowel preparation, n (%)	34 (75.6)
Preoperative fasting, n (%)	24 (53.3)

reoperation and in-hospital pneumonia with acute respiratory distress. Postoperative care parameters are presented in Table V.

The mortality rate in the group was 2.2% and refers mainly to the patient with severe comorbidities, including liver cirrhosis, who developed urinary tract infection with acute kidney insufficiency in the postoperative course.

Complications occurred in 15 (33.3%) patients. Wound infections were noted in 8 (17.8%) patients. In 3 cases wound infection treatment required negative pressure wound therapy, and in all these cases the length of stay (LOS) was longer than the mean

Table IV. Operative outcomes

Variable	Value	
Laparotomy/laparoscopy, n (%)	41/4 (91.1/8.9)	
Operated by specialist/resident, n (%)	42/3 (93.3/6.7)	
Median operative time (Q1–Q3) [min]	145 (105–210) (min. 45, max. 465)	
Median operative time of end colostomy (Q1–Q3) [min]	167.5 (120–215)	Mann-Whitney test
Median operative time of loop colostomy (Q1–Q3) [min]	105 (75–110)	<i>p</i> -value = 0.004
Handsewn anastomosis/Circular stapled anastomosis, n (%)	18/27 (40.0/60.0)	
Single layer/double layer handsewn anastomosis, n (%)	2/16 (11.1/88.9)	
Leakage test performed	28 (62.2%)	
Median blood loss (Q1–Q3) [ml]	100 (100–200) (min. 10, max. 400)	
Type of stoma closure, n (%)		
Single sutures stoma	33 (73.3)	
Purse-string suture stoma	9 (20.0)	
Immediate negative pressure therapy	3 (6.7)	

Table V. Postoperative care parameters

Parameter	Value
Urinary catheter placement, n (%)	40 (88.9)
Median length of urinary catheterization (Q1–Q3) [days]	2 (1–2)
Nasogastric tube, placement, n (%)	7 (15.6)
Median length of nasogastric tube (Q1–Q3) [days]	1 (1–2)
Postoperative drainage, n (%)	34 (75.6)
Median length of drainage (Q1–Q3) [days]	3 (2–4)
Median length of hospital stay (Q1–Q3) [days]	8 (6–9) (min. 3 – max. 42)
Postoperative morbidity, n (%)	15 (33.3)
Clavien-Dindo class, n (%)	
Ī	4 (8.9)
II	5 (11.1)
IIIA	1 (2.2)
IIIB	3 (6.7)
IV	1 (2.2)
V	1 (2.2)

LOS. In 3 cases anastomotic leakage was diagnosed (6.7%), and in 2 of those cases reoperation was required. One case was treated conservatively by antibiotics and total parenteral nutrition. Among serious complications there were also cases of perihepatic abscess and enterocutaneous fistula formation (2.2% each). The analysis of complications according to the Clavien-Dindo classification is represented below. Two out of 45 patients had failure of colosto-

my reversal due to postoperative complications, and ended up with a permanent colostomy.

Discussion

Colostomy liquidation or reversal is an elective surgical procedure that in certain cases can be associated with higher perioperative risk than the initial emergency surgery when the colostomy was created [9]. In our study we analyzed various factors that could have an impact on the postoperative course. In the preoperative period the rate of proper of antibiotic prophylaxis and antithrombotic prophylaxis was high, as in other types of elective colorectal surgery. Nearly all patients received some form of prophylaxis [10, 11].

The issue of mechanical bowel preparation (MBP) is still not standardized – in our material up to 75% of patients had MBP prior to colostomy reversal. According to the updated Cochrane Database Library meta-analysis, when MBP is used together with oral antibiotics the incidence of surgical site infections (SSI) could be reduced by 44% and the risk of anastomotic leakage could be reduced by 40% [12]. Unfortunately, while the majority of patients in our group received intravenous antibiotics, only 15.6% of patients received oral antibiotics. This might in part contribute to the infections observed in our group. An additional risk factor for poorer treatment outcomes is fasting before surgery [13-16]. The prevalence of preoperative fasting among patients in the LICO study group was as high as 53%; this reflects the traditional approach to surgical patients and - as shown by our study - is still widely used in Poland despite current recommendations to the contrary.

When analyzing surgical technique, laparotomy was found to be the dominant surgical access in the study group. Minimally invasive techniques are widely used in the majority of colorectal elective procedures, but laparoscopic colostomy reversal still is performed only in selected surgical centers [17–20]. General acceptance of the laparoscopic approach to elective colorectal procedures in many Polish surgical centers was very poor [21, 22]. The situation is currently improving, due to for instance the LapCo Poland program, but the lack of standardization of the colostomy reversal procedure is a clear obstacle for the laparoscopic approach in this kind of procedure.

Most of the anastomoses in the study were completed with a circular stapler. In Schineis *et al.*'s study no difference between stapled and handsewn anastomoses was observed in the context of the anastomotic leakage, total length of hospital stay or 30-day readmission rate. However, stapled anastomoses took less time and were more economically efficient [23]. When the anastomosis was handsewn in the study group, mostly double layered anastomo-

ses were performed. Interestingly, a recent study by Warsinggih *et al.* showed that anastomosis strength and leakage rate did not differ significantly between single layer extramucosal stitch and double layer full thickness anastomoses [24].

Assessing colostomy wound closure methods, the most common choice was traditional single suture closure. It is the fastest way, but is also known for a higher rate of SSI [25, 26]. Medical professionals' insufficient comprehension of the level of SSI in patients undergoing colostomy reversal could be responsible for still choosing the single suture technique. Purse-string closure and negative wound pressure therapy are gradually becoming more popular methods with a lower SSI rate, better quality of life and reduced wound pain [27, 28]. However, we found that both alternative methods were used less frequently (26% in total).

Postoperatively abdominal drainage was as common as 75.6% in the study population. Even though some authors report that local drainage can sometimes be advantageous, in general the anastomotic leakage rate is not decreased by abdominal drainage, and instead novel techniques, such as fluorescence guided surgery, should be widely used to prevent leakage [29, 30]. In any case, it might be speculated that drains have been left for postoperative hemostasis control and reduction of intraabdominal hematoma incidence, as the mean time to drain removal was 3 days.

The postoperative complication rate in the group was 33.3%, and the mortality rate was 2.2%. This level of postoperative morbidity is comparable to that seen in the literature [31, 32]. Slightly over 13% of complications were classified as serious according to the Clavien-Dindo classification, but the vast majority of complications in the study group were class I or II. Nevertheless, complications, although not severe, may also have an important and negative impact on the patients' quality of life [33]. Taking into consideration that colostomy is an elective procedure, more effort should be made to reduce the complication rate. We would recommend, especially in the context of the mean time to colostomy reversal that was around 15 months from colostomy creation, introduction of prehabilitation and optimization of patients' status prior to surgery [34-36]. Wider acceptance of oral antibiotics and abandoning preoperative fasting might also contribute to better overall outcomes of stoma

reversal. Various other aspects that can possibly influence the morbidity and mortality in this group of patients, such as timing of stoma liquidation or experience of the surgical team, will be addressed further in LICO group study. There were some limitations of our study. Lack of homogeneous groups of patients from different Polish surgical departments could have led to selection bias. Among other limitations of our study are the heterogeneity and the sample size of the study group in this preliminary report. Interim multivariate statistical analysis was conducted by the authors, but the findings did not demonstrate statistical significance due to the low patient number in this preliminary phase of the LICO study. However, analysis of the complete dataset from the ongoing LICO study will provide larger patient groups and may help to establish better clinical pathways for patients undergoing colostomy liquidation.

Conclusions

Colostomy liquidation is associated with significant morbidity (but in the majority of cases, less severe) and minimal mortality in the Polish population. Despite the preliminary nature of this study and limited number of patients in this dataset, some negative factors for complications can be easily identified already, such as preoperative fasting and lack of oral antibiotics. The LICO study is ongoing, and a larger dataset will be analyzed upon completion of the study.

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Ethical approval

The Bioethical Committee at Andrzej Frycz Modrzewski Krakow University approved the LICO study protocol (KBKA/55/O/2022).

Conflict of interest

The authors declare no conflict of interest.

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