GOODBYE HARTMANN- AFTER 100 YEARS HARTMANN'S PROCEDURE IS GOING TO BE ABANDONED?

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Study Title	GOODBYE HARTMANN – AFTER 100 YEARS HARTMANN'S PROCEDURE IS GOING TO BE ABANDONED?
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1. SUMMARY

Rationale: Hartmann's procedure was described for the first time in 1921 as an alternative to abdominoperineal resection for the treatment of upper rectal tumours. Although Hartmann's procedure fell out of favour for rectal cancer after the introduction of restorative procedures, it remained the most common procedure in emergency setting for many years. Nowadays Hartmann's procedure is a useful procedure in selected cases e.g. severely ill patients with a high risk of anastomotic failure;
However, restoring intestinal continuity for Hartmann patients is often associated with high morbidity, and about 70% will live with a permanent colostomy.
Hartmann procedure' is a rapid and simple surgical technique intended to decrease perioperative morbidity and mortality. This technique is often performed by young surgeons Indeed, end-colostomy may be necessary in situations where restoration of continuity is risky, either because of unfavourable local conditions (Hinchey IV peritonitis) or because a more definitive resection must be aborted due to hemodynamic instability.
In the last decade the Hartmann's procedure has been revalued in many studies.
In diverticular disease the results of DIVA arm of the LADIES trial showed that more patients in the primary anastomosis group were stoma free compared with patients in the Hartmann's procedure group.

Other studies have observed no differences in major postoperative complications or postoperative mortality between patients undergoing primary anastomosis versus Hartmann's procedure. Hartmann's procedure reversals were associated with a higher risk of serious postoperative complications than were stoma reversals after primary anastomosis with ileostomy.
The management of colorectal cancer emergencies is challenging. WSES guidelines recommend in case of perforation resection with anastomosis, with or without ileostomy. Hartmann's procedure should be preferred to simple colostomy, since colostomy appears to be associated with longer overall hospital stay and need for multiple operations, without a reduction in perioperative morbidity in patients with colorectal cancer obstruction. Resection with primary anastomosis

should be preferred for uncomplicated malignant left-sided large bowel obstruction in absence of other risk factors. Patients with high surgical risk are better managed with Hartmann's procedure

Despite the growing evidence in favour of primary anastomosis and its inclusion as a valid treatment option for perforated diverticulitis or perforated sigmoid colon in recent clinical practice guidelines, some surgeons have been hesitant to undertake anastomosis in the setting of purulent or faecal contamination and continue to choose Hartmann's procedure to eliminate concerns about anastomotic leakage.

Primary study objective:

1. To evaluate the role of Hartmann's procedure in emergency setting for left-sided colonic acute surgical disease (perforated diverticulitis with purulent or fecal peritonitis; colon cancer perforation-occlusion; ischemic colitis; abdominal trauma) and the type of surgery commonly performed in different level of care hospitals.
2. To investigate which factors contribute in the choice of Hartmann's procedure instead of colon resection with primary anastomosis (Hospital characteristics, surgeon experience, time of surgery, age of patients, comorbidities, etc)

Study design: International multicenter prospective cohort study.

Study population: Adult patients with left-sided colonic acute surgical disease who need surgery in an emergency setting (perforated diverticulitis with purulent or fecal peritonitis; colon cancer perforation-occlusion; ischemic colitis; abdominal trauma).

Primary outcome: Hartmann's procedure vs colonic resection with primary anastomosis performed in a 3-months interval in an emergency setting for left-sided acute surgical colonic diseases.

Secondary outcomes: risk factors for Hartmann procedure **(**Hospital characteristics (secondary, tertiary level, trauma center), surgeon experience, time of surgery (day of surgery- weekend; day or night), patient's age, comorbidities, clinical status etc.

Sample size calculation: The data will be used to investigate the specific characteristics to choose Hartmann's procedure versus primary anastomosis for left-sided acute surgical colonic diseases. Based on literature findings it has been estimated that, on average, three patients will undergo urgent left-sided colonic diseases resection per month at each participating centre. Applying a

root mean square percentage error (rMSPE) of 15%, 400 patients treated with left colon resection with or without primary anastomosis should be included.
Inclusion of 400 patients will be sufficient to analyze primary study objective 1 and primary study objective 2. Therefore, the aim is to include at least 500 patients.

2.INTRODUCTION AND RATIONALE

Left-sided surgical acute colonic diseases (perforated diverticulitis with generalized peritonitis, colon perforation, large bowel obstruction, colon cancer perforation or obstruction, ischemic colitis, abdominal trauma) are still a life-threatening condition requiring urgent surgical intervention.
Despite several published randomized trials, showing that primary anastomosis with or without protective ileostomy is feasible and randomized trials for laparoscopic lavage with conflicting results, the Hartmann's procedure, described for the first time in 1921 as
an alternative to abdominoperineal resection for the treatment of upper rectal tumours,
is still performed in many hospitals worldwide. It remained the most common procedure for acute diverticulitis and colonic perforation in emergency setting for many years. Hartmann's procedure is safe for severely ill patients; however, restoring intestinal continuity for such patients is often associated with high morbidity leaving a great percentage of patients with (up to 50%) with a permanent stoma. [1]
Hartmann procedure' is a rapid and simple surgical technique intended to decrease perioperative morbidity and mortality. This technique is often performed by young surgeons Indeed, end-colostomy may be necessary in situations where restoration of continuity
is risky, either because of unfavourable local conditions (Hinchey IV peritonitis) or because
a more definitive resection must be aborted due to hemodynamic instability. Although anastomosis at the time of surgery is an alternative approach to Hartmann's procedure, there have been concerns about the safety of this approach.
In the last decade the Hartmann's procedure has been revalued and the results of different studies [DIVA arm of the LADIES trial (the fourth and largest randomized clinical trial to date to compare Hartmann's procedure with primary resection and anastomosis in patients with

perforated diverticulitis with purulent or and fecal peritonitis); DIVERTI study; Halim et Al] showed that more patients in the primary anastomosis group were stoma free compared with patients in the Hartmann's procedure group. [2,3,4]

Several studies have observed no differences in major postoperative complications or postoperative mortality between patients undergoing primary anastomosis versus Hartmann's procedure. Hartmann's procedure reversals were associated with a higher risk of serious postoperative complications than were stoma reversals after protected primary anastomosis. [2-7]

The management of colorectal cancer emergencies is challenging. WSES guidelines recommend in case of perforation resection with anastomosis, with or without ileostomy. Hartmann's procedure should be preferred to simple colostomy, since colostomy appears to be associated with longer overall hospital stay and need for multiple operations, without a reduction in perioperative morbidity in patients with colorectal cancer obstruction. Resection with primary anastomosis should be preferred for uncomplicated malignant left-sided large bowel obstruction in absence of other risk factors. Patients with high surgical risk are better managed with Hartmann's procedure

Despite the growing evidence in favour of primary anastomosis and its inclusion as a valid treatment option for perforated diverticulitis or perforated sigmoid colon cancer in recent clinical practice guidelines, surgeons have been reluctant to perform anastomosis. Moreover, the postoperative course of the septic patient is unpredictable and it very hard to estimate it intraoperatively.

In the setting of purulent or fecal contamination most surgeons choose Hartmann's procedure to eliminate also legal concerns about anastomotic leakage. It's important to note that most of these procedures are performed off normal working hours when maybe best colorectal expertise is lacking for decision making regarding anastomosis. [8-10]

3. STUDY OBJECTIVES

- To evaluate the role of Hartmann's procedure in emergency setting for left-sided acute surgical colonic disease (perforated diverticulitis with purulent or fecal peritonitis; colon cancer perforation-obstruction; ischemic colitis; abdominal trauma).
- To investigate which risk factors contribute in the choice of Hartmann's procedure instead of primary anastomosis (Hospital characteristics, surgeon experience, time of surgery, age of patients, comorbidities).

- To evaluate postoperative course and complications rate (Length of stay, complication, reoperation) of different surgical procedures.

4. STUDY DESIGN

4.1 *STUDY TYPE*

International multicenter prospective cohort study.

4.2 *DURATION OF THE STUDY*

Data from 3 months cohort of patients who underwent urgent or emergency Hartmann's procedure, resection with primary anastomosis for left-sided colonic disease from March 1st 2021 until May 31st 2021 will be recorded with one-year follow-up from surgery until May 2022. The total study duration will be from January 2021 until December 2022(24 months).

4.3 STUDY TIMELINE

- November 1st – November 30th 2020: Database building and approval of the first version of the protocol.

- December 2020: Invitation of surgeons by sending first version of protocol and CRF.

- January 2021: study document preparation. Protocol and CRF refinement based on comments of pilot study results.

- February 2021:: Final protocol and CRF is sent to participating centers. All participating surgeons receive a REDCap database login.

- March 2021 – May 2021: Data collection.

-March 2022 – May 2022: Follow-up

- June 2022 – December 2022: Analysis and manuscript writing.

4.4 STUDY SETTING

This study will be performed in a multicenter and international setting. A large proportion of the group of hospitals that comprises Emergency Surgery Unit is expected to participate.

5. STUDY POPULATION

5.1 POPULATION

All consecutive adult patients with left-sided colonic disease who have been operated in urgent-emergency setting between March -May 2021 will be prospectively analyzed and evaluated time of surgery, patient's characteristic, hospital's characteristics. All patients who have been operated in urgent-emergency setting for left-sided colonic disease are suitable for inclusion.

5.2 INCLUSION CRITERIA

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Aged 18 years or older;
- Patients admitted in Emergency setting for left-sided colonic disease (perforated diverticulitis with purulent or fecal peritonitis; large bowel perforation-obstruction; colon cancer perforation-obstruction; ischemic colitis; abdominal trauma).
- Patients who underwent urgent or emergency surgery for left-sided colonic disease (perforated diverticulitis with purulent or fecal peritonitis; large bowel perforation-obstruction; colon cancer perforation-obstruction; ischemic colitis; abdominal trauma).

5.3 EXLUSION CRITERIA

- Aged 17 or younger.
- Elective surgery.
- Non-surgical treatment.
- Patients with personal history of colorectal cancer treated surgically.
- Patients with stoma.
- Unstable patients who benefited of damage control procedures.

5.4 SAMPLE SIZE CALCULATION

This is an explorative study and data will be used to investigate the specific characteristics behind the choice between Hartmann's procedure and primary anastomosis in left-sided urgent and emergency surgery.

METHODS

5.5 PRIMARY OUTCOME PARAMETER

- Number of Hartmann's procedure vs colic resection with primary anastomosis performed in 2-months in urgent or emergency setting for left-sided acute colonic diseases.

5.6 SECONDARY OUTCOME PARAMETERS

- Patient characteristics
- Etiology
- Hospital characteristics
- Treatment
- Surgeon experience
- Time of surgery
- Follow-up

5.7 LIST OF STUDY PARAMETERS

- Etiology: perforated diverticulitis; perforated colonic cancer; large bowel perforation-obstruction; colon cancer perforation-obstruction; colon ischemia; abdominal trauma.
- Hospital Characteristics: hospital type (academic, non-academic teaching, categorical, secondary hospital, tertiary hospital, level 4- trauma center); annual volume of

emergency surgical procedures; annual volume of left-sided colonic disease; types of diagnostic and treatment modalities that are available in the hospital.

- Treatment: Hartmann's procedure, colonic resection with primary anastomosis with or without diverting stoma, stoma without colic resection.
- Surgeon experience (surgeon in training: less than 50 colorectal resections performed; less than 5 resections per year in the last 5 years;
  Trained surgeon: more than 50 colorectal resections performed; more than 10 resections per year in the last 5 years)
- Time of surgery: weekdays, weekend, bank holidays, night shift (day: 8am- 8pm; night: 8pm-8am)
- Postoperative course: Clavien-Dindo Classification; reoperation

5.8 PATIENT CHARACTERISTICS

- Age
- Sex
- Weight
- Previous abdominal surgery
- Charlson comorbidity index
- ASA classification
- Clinical status: stable patient; unstable patient; sepsis (qSOFA score)

6. **ANALYSIS**

6.1 ANALYSIS STRATEGY

The first study objective is to investigate what factors contribute in the choice of Hartmann's procedure instead of colonic resection with primary anastomosis and what type of surgery is commonly performed in different level of care hospitals
Univariate analysis is performed on relevant parameters that are described in chapter 5.7-*list of study parameters* and 5.8-*patient characteristics.* Factors that are considered to be clinically relevant based on literature and/or expert opinion are selected for multivariate analysis. Backwards selection is used to exclude values of $p>0.05$ from the model.

The results obtained by the described analyses will also be performed in subgroups of patients who underwent Hartmann's procedure or primary anastomosis with or without diverting ileostomy. By performing this sensitivity analysis, we will investigate the factors behind the choice to perform Hartmann's procedure or colic resection with primary anastomosis.

7. ETHICS STATEMENT AND REGULATORY APPROVAL

This study will be conducted in compliance with the principles of the declaration of Helsinki. The study protocol and relevant documents have been approved by the medical ethical committee of the Parma University Hospital. All participating centers are provided with the study protocol and relevant documents in March 2021, so that participating centers can ask their local ethical committees for approval if needed according to local ethical protocols.

8. DATA HANDLING

8.1 DATABASE SYSTEM

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. A designated collaborator at each participating site will be provided with REDCap project server login details, allowing them to securely submit data on to the REDCap system. REDCap has previously been successfully used for a range of other international cohort studies led by the central unit.

8.2 CASE REPORT FORM (CRF)

A detailed CRF is created from REDCap database and provided to the invited centers (see also appendix 1). The CRF includes info points with definitions and guidelines that aid in adequate scoring of the listed parameters.

8.3 DATA COLLECTION AND DATA ENTERING

All patient data will be entered anonymously by or under supervision of the treating physician(s). Only anonymised data will be uploaded to the database. No patient identifiable data will be collected. Data collected will be on comorbidities, treatment/operation. No dates (e.g. date of surgery) will be collected. The study will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out in the Helsinki Declaration (64th Assembly Fortaleza, Brazil, in October 2013), and according to current legislation.

8.4 DATA PRIVACY STATEMENT

All anonymous study data will be available to the GOODBYE HARTMANN study team. The data of a center will be available to that specific center only through the REDCAP database system website. The data will not contain identifiable patient parameters (e.g. no date of birth etc.) in compliance with the General Data Protection Regulation (GDPR - EU 2016/679). Each patient will be coded with a unique patient number so that patients in the study are untraceable from the study database. Surgeons that participate in the GOODBYE HARTMANN study are asked to keep a password coded file that can identify individual patients locked away in their practice.

9. **PUBBLICATIONS**

The GOODBYE HARTMANN study embraces corporate authorship and all collaborators that contribute to this study will form the GOODBYE HARTMANN collaborative group. This group will co-author all publications in which GOODBYE HARTMANN study data is used.

The protocol writing committee is fully involved in conducting this study and will be included as authors in both main publications in which the GOODBYE HARTMANN study data is used. If the manuscript is submitted to a journal that does not allow the full number of authors, a number of authors will join the collaborative group instead, based on scientific input during the study, manuscript writing and revising.

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12. APPENDIX 1 – PRINTED CASE REPORT FORM (CRF)

1. Patient selection – Inclusion criteria (YES/NO)

1.1 Was the patient aged 18 years or older at time of operation?

1.2 Did the participant have a diagnosis of urgent or emergency left-sided colonic disease?

1.3 Did the patient undergo surgery?

1.4 *Did the patient undergo previous colorectal surgery?*

2. Baseline Characteristics - Patient Characteristics - General

2.1 Age

2.2 Sex

2.3 Weight

2.4 Height

2.5 BMI

3. Baseline Characteristics - Patient Characteristics – Comorbidities

3.1 ASA Classification.

3.2 Has the participant had previous abdominal surgery? (YES/NO)

3.3 *Does the patient have any of the following comorbidities?*

- Myocardial infarction
- Congestive heart failure
- Peripheral vascular disease

- TIA or CVA with mild/no residual weakness
- Hemiplegia
- Dementia
- Chronic pulmonary disease
- Connective tissue disease
- Peptic ulcer disease
- Moderate or severe renal disease
- Diabetes without end-organ damage
- Diabetes without end-organ damage
- Moderate or severe liver disease
- None of the above
- Unknown

4. **Baseline Characteristics - Patient Characteristics- Clinical Status**

4.1 Fever?

4.2 Systolic blood pressure?

4.3 Respiratory rate?

4.4 Altered mental status, GCS <15?

4.5 CRP

5. Baseline Characteristics - Disease Characteristics (YES/NO)

5.1 Complicated acute diverticulitis? If yes describe the presence of purulent or fecal peritonitis and disease stage according to WSES 2015 CT driven classification of left colon acute diverticulitis. [10]

5.2 Large bowel perforation? Cause of perforation? Perforated colon cancer? If yes describe the presence of local or generalized peritonitis, purulent or fecal peritonitis

5.3 Large bowel obstruction? Colon cancer obstruction? Other cause? Which colic segment was involved?

5.4 Colonic ischemia?

5.5 Abdominal trauma? Blunt or penetrating trauma?

6. Operation

6.1 Time from admission to surgery?

- *Less than 1 hour*
- *Between 1 and 6 hours*
- *From 6 hours to 12 hours*
- *From 12 hours to 24 hours*
- *After 24 hours?*

6.2 In which day surgery was performed?
- *Weekday*
- *Weekend*
- *Public holyday*

6.3 At what time surgery was started?
- *Day: 7am- 8pm;*
- *Early night: 8pm-11pm*
- *Late night: 11 pm- 7am*

6.4 Abdominal approach?
- *Laparoscopy*
- *Laparotomy*
- *Robotic*

6.5 If 'Abdominal approach' is not equal to 'Laparotomy' answer this question: Abdominal conversion? YES/NO

6.6 What type of intervention was performed?
- *Hartmann's procedure*
- *Sigmoidectomy with primary anastomosis without ileostomy (Low tie of inferior mesenteric artery ligation)*
- *Sigmoidectomy with primary anastomosis with ileostomy (Low tie of inferior mesenteric artery ligation)*
- *Left colectomy with primary anastomosis without ileostomy (High tie of inferior mesenteric artery ligation)*
- *Left colectomy with primary anastomosis with ileostomy (High tie of inferior mesenteric artery ligation)*
- *Loop ileostomy*
- *Loop colostomy (Sigmodostomy- transverse colostomy)*
- *End ileostomy*
- *End colostomy (Sigmodostomy- transverse colostomy)*

6.7 If case of cancer an oncological resection was performed? YES/NO

6.8 Complication during surgery? YES/NO

6.9 Abdominal organ lesions?
- *Urether lesion*
- *Bladder*

- *Vagina*
- *Prostate*
- *Uterus*
- *Other*
- *Unknown*

7. Postoperative course

7.1 Length of stay?

7.2 Complications? YES/NO

7.3 Clavien-Dindo Classification

Grade I *Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.*
Grade II *Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusionsand total parenteral nutritionare also included.*
Grade III *Requiring surgical, endoscopic or radiological intervention*
- IIIa *Intervention not under general anesthesia*
- IIIb *Intervention under general anesthesia*
Grade IV *Life-threatening complication (including CNS complications)* requiring IC/ICU-management*
*- **Iva** single organ dysfunction (including dialysis)*
*- **IVb** multiorgandysfunction*
Grade V *Death of a patient*

7.4 Anastomotic leakage? (In case of primary anastomosis) YES/NO

7.5 Surgical Reintervention? YES/NO

7.6 Percutaneous drainage? YES/NO

7.7 Was necessary a surgical reintervention for anastomotic leakage? YES/NO

7.8 If surgery was performed for anastomotic leakage what kind of surgery was made?

- *Resection with loop ileostomy?*
- *Resection with loop colostomy?*
- *Hartmann's procedure?*
- *Percutaneous abdominal drainage?*

8. **Hospital Characteristics**

8.1 Hospital type?

- *Academic*
- *Non-academic teaching*
- *Categorical*
- *Secondary hospital*
- *Tertiary hospital*
- *Level 4- trauma center*

8.2 Annual volume of emergency surgical procedures?

- *Less than 500 per year*
- *Between 500 and 1000 per year*
- *More than 1000*

8.3 Annual volume of elective colorectal resections?

- *Less than 50 per year*
- *Between 50 and 100 per year*
- *More than 100*

8.4 Abdominal approach performed for elective colorectal surgery?

- *Laparoscopy*
- *Robotic*
- *Laparotomy*

8.5 Presence of Intensive Care Unit (ICU)? YES/NO

9. **Surgeon experience**

9.1 Has the surgeon performed more than 50 colorectal resections? YES/ NO

9.2 Has the surgeon performed more than 10 resections per year in the last 5 years? YES/NO

10. **Follow-up**

10.1 Permanent stoma? YES/NO

10.2 *Surgery for ostomy reversal?* YES/NO

10.3 *Complication during reversal surgery?* YES/NO

10.4 *Late anastomotic leakage?* YES/NO