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Measuring quality in colorectal cancer surgery in Low- and Middle-Income Countries: The Clavien-Dindo Classification in a Sri Lankan cohort

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STUDY SUMMARY

Title	Measuring quality in colorectal cancer surgery in Low- and Middle-Income Countries: The Clavien-Dindo Classification in a Sri Lankan cohort.
Methodology	Retrospective, medical record study, cohort
Study Duration	Data collection from February to March 2020.
Study Center(s)	Single center (Colombo South Teaching Hospital, CSTH, Sri Lanka).
Objectives	<p><u>Primary Objective:</u> To test the applicability of the Clavien-Dindo Classification in a Low- and Middle-Income Country.</p> <p><u>Secondary Objectives:</u> To compare the prevalence and severity of complications between patients <60 and ≥60 years of age. To determine length of hospital stay (LOS).</p>
Number of subjects	88 patients.
Diagnosis and Main Inclusion Criteria	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> - Male and female patients in any age - Patients who undergone colorectal cancer resection - Operation performed at Colombo South Teaching Hospital - Surgery performed at any date <p>Exclusion criteria:</p> <ul style="list-style-type: none"> - Reason for resection other than colorectal cancer.
Study Product, Dose, Route, Regimen	No intervention.
Statistical Methodology	<p><u>Primary Endpoint:</u> Clavien-Dindo Classification calculated with descriptive analyzes.</p> <p><u>Secondary Endpoints:</u> Chi-squared test.</p>

Purpose:

The aim of this study is to investigate short-term outcome after colorectal cancer surgery in a Sri Lankan facility using the Clavien-Dindo Classification to evaluate it as an applicable instrument for measuring surgical quality at medical institutions in Low- and Middle-Income Countries.

Background:

Colorectal cancer is increasing in Low- and Middle-Income Countries as a part of the on-going epidemiological transition. Surgery is the main treatment and global health is now putting focus on improving the safety and quality of surgical care in low-resource settings. The current systems for measuring surgical quality are mainly customized for high-income countries.

December 1, 2021

Goals of the study:

1. To investigate short-term outcome after colorectal cancer surgery in a Sri Lankan facility using the Clavien-Dindo Classification to evaluate it as an applicable instrument for measuring surgical quality at medical institutions in Low- and Middle-Income Countries.
2. To determine length of hospital stay (LOS) as an indicator of process quality.
3. To compare prevalence and severity of overall complications between patients <60 and ≥60 years of age.

Duration of the Study:

Data collection February to March 2020. Statistical analyzes April to May 2020.

Potential Benefits and Risks to Patients:

There is no benefits or risks for the patients since the study is retrospective and based on medical records.

Methods:

- Study Design

This is a retrospective single centre cohort study based on medical records of patients who have undergone resection for colorectal cancer at Colombo South Teaching Hospital (CSTH) from 2017 to the time for data collection. STROCSS guidelines will be used in the reporting of the research. The medical records will be reviewed retrospectively for postoperative complications and the severity will be graded using the Clavien-Dindo Classification.

- Study population and selection criteria

No consent forms are needed since the study is retrospective and based on medical records. Patients included in the study will have undergone colorectal cancer resection at Colombo South Teaching Hospital. Both male and female patients in any age will be included. Patients will be excluded from the study if reason for resection is other than colorectal cancer.

- Recruitment methods

Patients will be collected from the medical records at the surgical department at Colombo South Teaching Hospital.

- Data collection and reporting

Demographic, clinical and pathological characteristics of patients and details of surgeries and postoperative outcome will be obtained from the medical records and documented in Excel. Length of hospital stay (LOS) will be calculated. The medical record will be reviewed for postoperative complications and the treatment required. The severity of complications will be graded according to the Clavien-Dindo Classification. Patients will be anonymized using unique study identification numbers.

Participant Withdrawal or Termination:

None since it is a retrospective study based on medical records.

RANDOMIZATION

None, since no intervention is planned.

STATISTICAL ANALYSIS PLAN

- Primary Endpoint: Distribution of the Clavien-Dindo Classification will be determined by using descriptive analyzes in Statistical Package for the Social Sciences (SPSS) version 26.

December 1, 2021

- Secondary Endpoints: To test if there is any difference in the prevalence and severity of complications between patients <60 and ≥60 years of age the Chi-squared test will be used. P<0.05 is considered statistically significant.

ASSESSMENT OF SAFETY

No risk of adverse events since the study is retrospective and based on medical records.

DATA MONITORING

The Principal Investigators will be responsible to ensure that the study is conducted in accordance with the protocol. Also, that the reported data are accurate, complete and valid.

DATA HANDLING AND RECORD KEEPING

Only the Principal Investigators will handle personal patient information and no unneeded sensitive information is being collected. The data will be kept in a personal computer locked in. All data will be anonymized using unique study identification numbers in an Excel file, which will be used for the rest of the study time.

INSTITUTIONAL REVIEW BOARD

Ethical approval was received from the Ethics Review Committee of the Colombo South Teaching Hospital, January 13th 2020 (reference number MO/PLEC/2020:822).

CONSENT PROCESS

No informed consent form is needed since this is a retrospective, medical record study.

LAWS AND REGULATIONS

This study will align to the principles of the Helsinki Declaration. It will be reported according to the STROCSS guidelines. No national laws or regulations will be crossed. The trial will be registered on www.clintrials.gov.

PUBLICATION AND DATA SHARING POLICY

Data is owned by the participating institutions. Manuscript is written by participating institutions, data sharing upon reasonable request.

STUDY PERSONNEL AND ROLES

Stina Lindholm, MD	Principal Investigator	Conceptualization, methodology, formal analysis, investigation, writing, project administration.
Sofia Lindsbogen, MD	Principal Investigator	Conceptualization, methodology, investigation, visualization, writing, project administration.
David Ljungmang, MD PhD	Co-Investigator, Project Manager	Supervision, validation, writing (review & editing).
Göran Kurlberg, Assoc Prof	Co-Investigator, Project Manager	Supervision, validation, writing (review & editing).

December 1, 2021

Bawantha Gamage, MD	Project Manager	Supervision, validation, writing (review & editing).
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CONFLICTS OF INTEREST

No conflicts of interest have been reported.