Comparative safety study to assess the risk of anastomotic leakage of two-row versus three-row manual circular staplers in colorectal anastomosis

First published: 16/01/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS50570

Study ID

50692

DARWIN EU® study

No

Study countries

United States

Study description

The retrospective cohort study is designed to estimate the risk of anastomotic leak among patients who underwent a left-sided colorectal surgery with use of a 2-row manual circular stapler (Ethicon Manual Circular Staplers or Medtronic EEA™ Circular Stapler with DST™ technology) relative to use of a 3-row manual circular stapler (i.e. Medtronic EEA™ Circular Stapler with Tri-Staple™ technology). This study will include two head-to-head comparisons: Ethicon Manual Circular Stapler versus Medtronic EEA™ Circular Stapler with Tri-Staple™ Technology, and Medtronic EEA™ Circular Stapler with DST™ Technology versus Medtronic EEA™ Circular Stapler with Tri-Staple™ Technology. The index procedure will be defined as the initial procedure in which the device of interest was used. The index admission will include the time from admission to discharge. Propensity score weighting (PSW) will be used for confounding adjustment, followed by log-binomial regression for risk estimation. All eligible patients identified from the Premier Healthcare Database between Jan 2019 and Jun 2022 will be included in the analysis.

Study status

Finalised

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

Study institution contact

Tongtong Wang TWang124@its.jnj.com

Study contact

TWang124@its.jnj.com

Primary lead investigator

Tongtong Wang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/01/2023

Actual: 12/01/2023

Study start date

Planned: 23/01/2023

Actual: 30/01/2023

Data analysis start date

Planned: 28/02/2023

Actual: 27/02/2023

Date of final study report

Planned: 30/09/2023

Actual: 18/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Johnson & Johnson

Study protocol

RWE23-SAF-001 -Manual Circular Staplers_v1_Redacted.pdf (8.05 MB)

RWE23-SAF-001 -Manual Circular staplers_V2_Redacted.pdf (3.98 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To estimate the risk and relative risk (RR) of anastomotic leak (AL) among patients who underwent a left-sided colorectal surgery with use of a 2-row manual circular stapler relative to use of a 3-row manual circular stapler.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Additional medical condition(s)

left-sided colorectal surgery

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

12.000

Study design details

Outcomes

To estimate the risk and RR of AL within 30 days post-index procedure among patients who underwent a left-sided colorectal surgery with use of a 2-row manual circular stapler (Ethicon Manual Circular Staplers or Medtronic EEA™ Circular Stapler with DST™ technology) relative to use of a 3-row manual circular stapler (i.e. Medtronic EEA™ Circular Stapler with Tri-Staple™ technology). To estimate the RR of AL among patients who underwent a left-sided colorectal surgery with use of a 2-row manual circular stapler relative to use of a 3-row manual circular stapler, stratified by diverting stoma prior to or on the same day as a left-sided colorectal surgery during the index admission.

Data analysis plan

1) Descriptive analyses will be first performed for demographic, clinical, and procedural characteristics of patients at the time of the index procedure where a study device was used. Cumulative incidences of AL and 95% confidence interval (CIs) will calculated for all device cohorts, and also stratified by key characteristics. 2) In the primary analyses, a propensity score weighting (PSW) method will be used to control for potential confounders, followed by log-binomial regression for risk estimation. 3) In the secondary analyses, all primary analyses will be repeated separately in those with and without a diverting stoma procedure prior to or on the same day as the index procedure (i.e. left-sided colorectal surgery) during the index admission. 4) A sensitivity analysis will be conducted by repeating the primary analysis among patients from hospitals with at least 30 days continuous enrollment in PHD after the patients' index procedure.

Documents

Study results

IJCD online publication.pdf (633.49 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Premier Healthcare Database United States

Data sources (types)

Other

Data sources (types), other

This study will use hospital billing records contained in the Premier Healthcare Database (PHD). The PHD contains complete clinical coding, hospital cost, and patient billing data from more than 1041 hospitals throughout the United States.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No