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Late intestinal complications in minimally invasive total gastrectomy for gastric cancer

Submission date
28/02/2024

Recruitment status
No longer recruiting

Registration date
19/03/2024

Overall study status
Completed

Last Edited
09/09/2024

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Although minimally invasive total gastrectomy for gastric cancer is commonly performed, reports regarding late complications are limited. Since 2009, the study team made several improvements each time severe late complications were experienced. This study aims to evaluate the clinical efficacy of these improved procedures in preventing late complications.

Who can participate?
Patients who underwent laparoscopic or robotic total gastrectomy for gastric cancer between January 2009 and December 2019

What does the study involve?
The patients will be divided into two groups: Period-I (2009–2013, before established standardization of procedure) and Period-II (2014–2019, after established standardization of procedure). The procedure has been standardized through four major steps, typified by the closure of the mesentery and diaphragm crus, and fixation and linearization around the anastomotic site of esophagojejunostomy. The incidence of late complications will be retrospectively compared between the two groups.

What are the possible benefits and risks of participating?
There were no direct benefits for participating, but possibility to contribute to future advances in medical science. There were no risks of participating, due to no interventions required.

Where is the study run from?
Fujita Health University

When is the study starting and how long is it expected to run for?
August 2020 to August 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Susumu Shibasaki, susumushi48@mist.ocn.ne.jp

Study website
https://fujita.bvits.com/esct/publish_document.aspx?ID=3570

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Susumu Shibasaki

ORCID ID
http://orcid.org/0000-0003-2454-5083

Contact details
1-98, Dengakugakubo, Kutsukake
Toyoake
Japan
470-1192
+81562939254
susumushi48@mist.ocn.ne.jp

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The risk factor of late intestinal complications in minimally invasive total gastrectomy for gastric cancer

Study objectives
The standardized procedures will prevent late intestinal complications by comparing two periods: before and after the establishment of standardization of the minimally invasive total gastrectomy procedure.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/08/2020, The Institutional Review Board of Fujita Health University (1-98, Dengakugakubo, Kutsukake, Toyoake, 470-1192, Japan; +81-562-93-2865; f-irb@fujita-hu.ac.jp), ref: HM23-318

Study design
Single-center retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records

Study type(s)
Prevention, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Prevention of late intestinal complications in patients who underwent minimally invasive total gastrectomy for gastric cancer.

Interventions
The procedure comprises four major steps, typified by the closure of the mesentery and diaphragm crus, and fixation and linearization around the anastomotic site of esophagojejunostomy.

Intervention Type
Procedure/Surgery

Primary outcome measure
The incidence of complications within 3 years after surgery measured using data collected from medical records at one time point

Secondary outcome measures
The following secondary outcome variables will be measured using data collected from medical records at one time point:
1. Clinicopathological characteristics

2. Short-term surgical outcomes:
2.1. Operative time
2.2. Surgeon console time

2.3. Estimated blood loss
2.4. Number of dissected lymph nodes
2.5. Rates of local and systemic complications
2.6. Mortality rate
2.7. Length of postoperative hospitalization
2.8. Severity of reflux esophagitis at preoperative year (POY) 1
2.9. Body weight loss rate at POY 1

3. Long-term survival outcomes:
3.1. 3-year overall survival (OS)
3.2. 3-year relapse-free survival (RFS)

Overall study start date
01/01/2020

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. Patients between January 2009 and December 2019.
2. Patients underwent total gastrectomy for gastric cancer at our division.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
20 Years

Upper age limit
91 Years

Sex
Both

Target number of participants
302

Total final enrolment
302

Key exclusion criteria
1. Open gastrectomy
2. Clinical or pathological stage IV
3. Remnant gastric cancer
4. Palliative surgery

5. EGJ cancer
6. Observation period < 90 days
7. Use of circular stapler

Date of first enrolment
01/01/2021

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Japan

Study participating centre
Fujita Health University
Dengakugakubo, Kutsukake
Toyoake
Japan
470-1192

Sponsor information

Organisation
Fujita Health University

Sponsor details
Center for Clinical Trial and Research Support, 1-98, Dengakugakubo, Kutsukake
Toyoake
Japan
Aichi 470-1192
+81-562-93-2884
c-int-rl@fujita-hu.ac.jp

Sponsor type
University/education

Website
https://www.fujita-hu.ac.jp/

ROR
https://ror.org/046f6cx68

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Susumu Shibasaki, susumu.shibasaki@fujita-hu.ac.jp. The data that support the findings of this study will be shared. All data were anonymized so consent from participants was not required or obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/06/2024	09/09/2024	Yes	No