

Late intestinal complications in minimally invasive total gastrectomy for gastric cancer

Submission date 28/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/09/2024	Condition category Surgery	<input type="checkbox"/> 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

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Susumu Shibasaki

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Prevention, Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

20 years

Upper age limit

91 years

Sex

All

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

ROR

<https://ror.org/046f6cx68>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes