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Minimally-invasive versus open surgery for gastric cancer - cross-sectional analysis

Submission date	Recruitment status	[_] Prospectively registered
21/08/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/08/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2024	Cancer	

Plain English summary of protocol
Background and study aims
Since gastric (stomach) cancer is one of the most common cancers worldwide, this study aimed to assess the outcomes of the two most common types of surgery among gastric cancer patients: open surgery versus minimally invasive (laparoscopic, robotic) surgery.

Who can participate?
Patients aged 18 years and over with gastric cancer who underwent curative-intent treatment between 2013-2019

What does the study involve?
The study involves the assessment of the optimal method of surgery (open versus minimally invasive) in gastric cancer patients using data collected from the National Cancer Database (NCDB).

What are the possible benefits and risks of participating?
This is an observational study, however, the results of this retrospective data suggest a need for further prospective trials comparing open versus minimally-invasive surgery for gastric cancer.

Where is the study run from?
Medical University of Lublin (Poland)

When is the study starting and how long is it expected to run for?
January 2013 to December 2019

Who is funding the study?
Medical University of Lublin (Poland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Improved NCCN guideline compliance and textbook oncological outcomes among patients undergoing minimally invasive surgery for locally advanced gastric cancer – cross-sectional analysis of national cancer database

Study objectives
To investigate the rates of National Comprehensive Cancer Network (NCCN) guideline adherence and textbook oncological outcome (TOO) among patients undergoing minimally invasive versus open surgery for gastric cancer

Ethics approval required
Ethics approval not required

Ethics approval(s)
The study was determined to be exempt by the Institutional Review Board of the Ohio State University. The NCDB, a joint quality improvement initiative of the American College of Surgeons Commission on Cancer and the American Cancer Society, is one of the largest cancer registries in the world, comprising over 70% of newly diagnosed cancer cases nationwide. Current NCDB data is available up to 2019 for Higher Education Authorities in the US, including Ohio State University. Since the current study did not change or interfere with available data, there was no need for additional ethics board approval.

Primary study design
Observational

Study design
Observational cross-sectional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gastric cancer

Interventions
In this cross-sectional study patients with stage II/III gastric cancer (cT2-T4N0-3M0) who underwent curative-intent treatment between 2013-2019 were evaluated from National Cancer Database (NCDB). Multivariable analysis was performed to assess the association between surgical approach, NCCN guideline adherence, TOO, and overall survival (OS).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. National Comprehensive Cancer Network (NCCN) guideline adherence, defined as receipt of stage-specific curative intent treatment (yes/no). For systemic treatment, patients were classified as receiving guideline-adherent care if any perioperative adjunctive therapy (single- or multiagent) was administered (yes/no). For surgical treatment, patients were classified as receiving guideline-adherent care if the primary surgical procedure included evaluation of at least 15 lymph nodes (yes/no),
2. Textbook oncological outcome (TOO) The TOO definition consisted of chemotherapy receipt, (yes/no) adequate gastric resection to achieve negative resection margins (R0) (yes/no), examination of at least 15 lymph nodes (yes/no), followed by no prolonged length of hospital stay (yes/no), no 30-day mortality (yes/no), and no 30-day readmission (yes/no)
Data collected from the National Cancer Database (NCDB) for patients with stage II/III gastric cancer (cT2-T4N0-3M0) who underwent curative-intent treatment between 2013-2019

Key secondary outcome(s)
Overall survival, collected from the National Cancer Database (NCDB) for patients with stage II /III gastric cancer (cT2-T4N0-3M0) who underwent curative-intent treatment between 2013-2019

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Patients with stage II/III LAGC (cT2-T4N0-3M0) who underwent curative-intent treatment between 2013 and 2019 evaluated from the National Cancer Database (NCDB)

Participant type(s)
Population

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
13885

Key exclusion criteria
1. Did not undergo resection
2. Metastatic (cM1) or early (cT1) GC
3. Underwent palliative care
4. Did not receive or died before planned multimodal treatment
5. Had missing information

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
United States of America

Study participating centre
The Ohio State University, Wexner Medical Center
395 W. 12th Ave.
Suite 670
Columbus
United States of America
43201

Sponsor information

Organisation
Medical University of Lublin

ROR
https://ror.org/016f61126

Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Medyczny w Lublinie

Alternative Name(s)
Medical University of Lublin, UML, MUL

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/01/2024	14/02/2024	Yes	No