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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?
Karol Rawicz-Pruszyński, krpruszynski@gmail.com

## Contact information

### Type(s)
Scientific


### Contact name
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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

## 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.

### Study design
Observational cross-sectional study

### Primary study design
Observational

### Secondary study design
Cross sectional study

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

### 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 measure
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

### Secondary outcome measures
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

### Overall study start date
01/01/2013

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
90 Years

### Sex
Both

### Target number of participants
13885

### 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

**Sponsor details**
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**Sponsor type**
University/education

**Website**
https://www.umlub.pl

**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

### Publication and dissemination plan
Submission to the International Journal of Surgery

### Intention to publish date
01/09/2023

### 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 |