A3417

12th International Gastric Cancer Congress
20-23 APRIL, 2017 | BEIJING·CHINA

PROSPECTIVE, OBSERVATIONAL, MULTICENTER STUDY ON MINIMALLY INVASIVE GASTRECTOMY FOR GASTRIC CANCER: ROBOTIC, LAPAROSCOPIC AND OPEN SURGERY COMPARING SURGICAL AND FOLLOW-UP OUTCOMES.

IMIGASTRIC II STUDY

Jacopo Desiderio[1], Daniel Reim[2], Alexander Novotny[2], Ninh T Nguyen[3], Feng QI[4], Tong LIU[4], Zhi-Wei JIANG[5], Shu ZHANG[5], Yanbing ZHOU[6], Shougen CAO[6], Changming HUANG[7], Jian-xian LIN[7], Lu ZANG[8], Junjun MA[8], Pei-Wu YU[9], Ben ZHANG[9], Felice Borghi[10], Alessandra Marano[10], Fabio Cianchi[11], Benedetta Badii[11], Maurizio Cesari[12], Giacomo Arcuri[12], Orhan Alimoglu[13], Tunc Eren[13], Francesca Bazzocchi[14], Andrea Avanzolini[14], Johan Gagniere[15], Denis Pezet[15] Simone D'Imporzano[16], Graziano Pernazza[17], Andrea Coratti[18], Mario Annecchiarico[18], Juan-Santiago Azagra[19], Martine Goergen[19], Olivier Facy[20], Natalie G. Coburn[21], Steven T. Brower[22], Alessandro Gemini[1], Stefano Trastulli[1], Amilcare Parisi[1]

[1]Department of Digestive Surgery, St. Mary's Hospital, University of Perugia. Terni, Italy; [2]Chirurgische Klinik und Poliklinik, Klinikum Rechts der Isar der Technischen Universität München. München, Germany; [3]Department of Surgery, Division of Gastrointestinal Surgery, University of California, Irvine Medical Center. Orange CA, USA; [4]Gastrointestinal Surgery, Tianjin Medical University General Hospital. Tianjin, P.R. China; [5]Department of General Surgery, Jinling Hospital, Medical School, Nanjing University. Nanjing, P.R. China; [6]Department of General Surgery, The Affiliated Hospital of Qingdao University. Qingdao, P.R. China; [7]Department of Gastric Surgery, Fujian Medical University Union Hospital, Fuzhou, P.R. China; [8]Department of Surgery, Ruijin Hospital, Shanghai Jiaotong University, School of Medicine. Shanghai, P.R. China; [9]Department of General Surgery, Third Military Medical University Southwest Hospital. Chongqing, P.R. China; [10]Department of General Surgery, A.S.O. Santa Croce e Carle. Cuneo, Italy; [11]Unit of minimally invasive and endocrine surgery, Center of oncologic minimally invasive surgery (COMIS), Careggi University hospital. Florence, Italy; [12]Department of General Surgery, Hospital of Città di Castello, USL1 Umbria. Città di Castello, Italy; [13]Department of General Surgery, School of Medicine, Istanbul Medeniyet University. Istanbul, Turkey; [14]Department of General Surgery, Division of General, Gastroenterologic and Minimally Invasive Surgery, G.B.Morgagni Hospital. Forlì. Italy; [15]Digestive and Hepatobiliary Surgery Department. University of Auvergne, University Hospital Estaing. Clermont-Ferrand, France; [16]Esophageal Surgery Unit, Tuscany Regional Referral Center for the Diagnosis and Treatment of Esophageal Disease, Medical University of Pisa. Pisa, Italy; [17]Minimally Invasive and Robotic Surgery Unit, San Giovanni Addolorata Hospital. Rome, Italy; [18]Division of Oncological and Robotic Surgery, Department of Oncology, Careggi University Hospital. Florence, Italy; [19]Unité des Maladies de l'Appareil Digestif et Endocrine (UMADE), Centre Hospitalier de Luxembourg. Luxembourg; [20]Service de chirurgie digestive et cancérologique CHU Bocage, Dijon, France; [21]Division of General Surgery, Sunnybrook Health Sciences Centre. Toronto, Canada; [22]Department of Surgical Oncology and HPB Surgery, Englewood Hospital and Medical Center. Englewood NJ, USA.

BACKGROUND

Several meta-analyses have attempted to define the role of minimally invasive approaches for surgical management of gastric cancer. However, further evidence to get a wider adoption of these approaches are needed. Current studies describe minimally invasive surgery as an alternative to open surgery but deserving further detail analysis, and in this context robotic surgery has some potential technological advantages. Despite the increasing interest, it is difficult to plan prospective studies with adequate sample size. Therefore, most studies to date are low level of evidence and retrospective experiences.

A multi-institutional prospective study allows collection of a large amount of data to perform detail analysis of the various aspects of minimally invasive procedures.

The Imigastric project is a multi-center study including an initial retrospective phase and, in this phase, the development of a prospective trial.

Collect prospective data with high methodological quality on minimally invasive and open gastrectomies can clarify the role of different procedures and develop specific guidelines.

GENERAL STUDY DESIGN

To develop and maintain a multi-institutional database comprising of information regarding surgical, clinical and oncological features of patients undergoing treatment for gastric cancer with robotic, laparoscopic or open approaches and its subsequent follow-up.

SPECIFIC AIMS

AIM 1 (safety and feasibility): To compare MIS versus open surgery on intraoperative findings and complications.

AIM 2 (oncological effectiveness): To determine the appropriateness of procedures analyzing histopathological findings.

AIM 3 (postoperative recovery): To compare the three arms on the clinical postoperative course.

AIM 4 (survival): To determine effectiveness of MIS compared to open surgery in overall survival and disease-free survival at scheduled endpoints.

ELIGIBILITY

Inclusion criteria:

- Preoperative biopsy proven gastric cancer
- Early Gastric Cancer
- Locally Advanced Gastric Cancer
- Surgery planned for curative intent

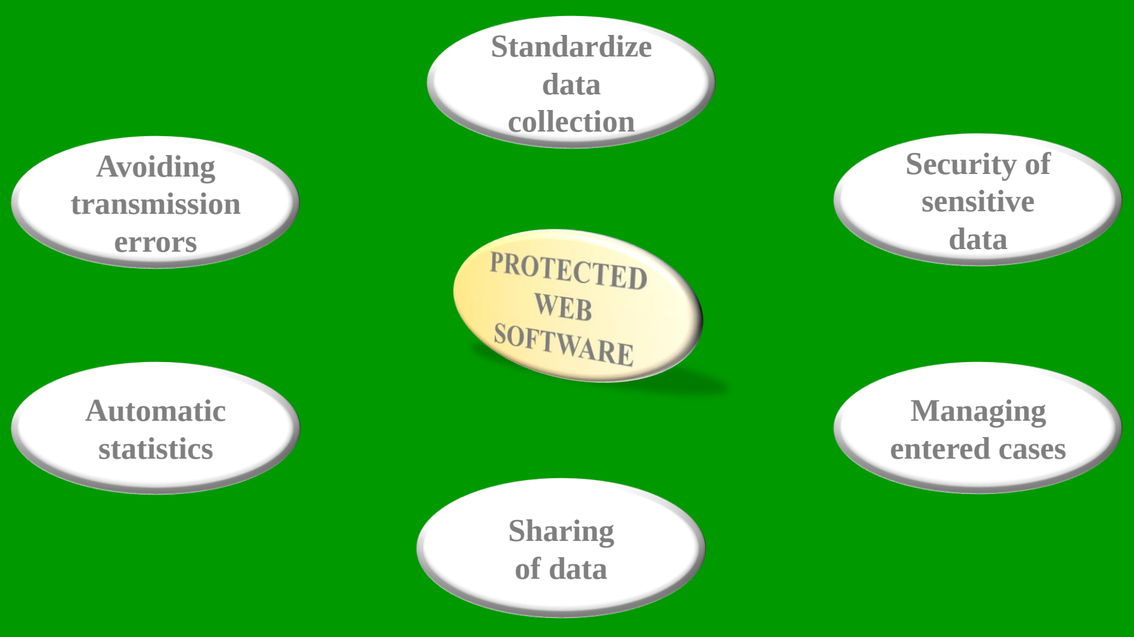
Exclusion criteria:

- Evidence of metastatic disease
- Remnant gastric cancer
- Synchronous malignancy
- Surgery planned for palliative purposes
- High operative risk (ASA score > 4)

DATA COLLECTION

- Demographics
- Surgical procedure details
- Pathology
- Post-operative (in-hospital) clinical findings
- Complications after discharge
- Follow-up at scheduled endpoints (1, 3, 6 months; 1, 2, 3, 4, 5 years)

TOOLS FOR DATA COLLECTION
THE IMIGASTRIC SOFTWARE



JOIN THE STUDY

www.imigastric.com

ACKNOWLEDGEMENTS

IT solutions: Logix software

No profit cooperation

Web manager: Edoardo Desiderio

Graphic designer: Valentina Betti