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 Desideri1, Daniel Reim2, Alexander Novotny1, Ninh T Nguyen1, Feng Qi1, Tong Liu1, Zhi-Wei JIANG3, Shu ZHANG1, Yanbing ZHUO1, Shougen CAO1, Changming HUANG1, Jian-xian LIN1, Lu ZANG1, Junjun MA1, Pei-wu YU1, Ben ZHANG2, Felice Berghi1, Alessandra Marano1, Fabio Cianchi1, Giusto Arcuri1, Liang-Chun Zhang1, Zhen Shuai1, Orhan Altunoglu1, Tunc Erim3, Francesco Bazzocchi2, Andrea Avanzolini1, Johan Gagnevere4, Deniz Pekiz5, Simone D’Imperiozaro3, Graziano Pernazza3, Andrea Coratti3, Mario Amicone6, Juan-Santiago Azagra8, Martine Goergen7, Olivier Facy7, Natalie G. Coburn9, Steven T. Brover10, Alessandro Gemin11, Stefano Trastulli12, Amicale Paris11

1Department of Digestive Surgery, St. Mary’s Hospital, University of Perugia. Terni, Italy; 2Chirurgische Klinik und Poliklinik, Klinikum Rechts der Isar der Technischen Universität München, München, Germany; 3Department of Surgery, Division of Gastrointestinal Surgery, University of California, Irvine Medical Center, Orange CA, USA; 4Gastrointestinal Surgery, Tianjin Medical University General Hospital, Tianjin, P.R. China; 5Department of General Surgery, Jining Hospital, Medical School, Nanjing University, Nanjing; 6Department of Surgery, The Affiliated Hospital of Ditan Medical University Union Hospital, Beijing; 7Department of Surgery, Beijing Hospital, Beijing, P.R. China; 8Department of General Surgery, Third Military Medical University Southwest Hospital, Chongqing, P.R. China; 9Department of General Surgery, A.O. San Giovanni di DioCarega, Como, Italy; 10Department of General Surgery, A.O. San Giovanni di DioCarega, Como, Italy; 11Department of Oncologic Minimally Invasive Surgery, University Hospitals, Santusg, Dijon, France; 12Department of General Surgery, University of Vermont, College of Medicine, Burlington, VT, USA; 13Department of Gastrointestinal Surgery, Istanbul Medipol University, Istanbul, Turkey; 14Department of General Surgery, Division of General, Gastroenterologic and Minimally Invasive Surgery, O.B. Margaret Hospital, Raub, Malaysia; 15Department of General Surgery, Tianjin Medical University General Hospital, Tianjin, P.R. China; 16Department of General Surgery, Istanbul Medipol University, Istanbul, Turkey; 17Department of General Surgery, Division of Oncological and Robotic Surgery, Department of Oncology, Charité University Hospital, Berlin, Germany; 18Minimally Invasive and Endoscopic (UMADE), Centre Hopitalier de Luxembourg, Luxembourg; 19Service de chirurgie digestive et cœléoprotologue CHU Bocage, Dijon, France; 20Division of General Surgery, Sunnybrook Health Sciences Centre, Toronto, Canada; 21Department of Surgical Oncology and MBS 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 describing 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)