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# **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**

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#### 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.

### **TOOLS FOR DATA COLLECTION** THE IMIGASTRIC SOFTWARE



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	0.0	14.0	10.0	4.0	0.5	190.0	6.0	4.0	85.0	0.8
			3	0.0	12.0	10.0	4.0	0.7	200.0	7.0	4.0	90.0	0.9
Tumor location *	Upper third V		5	14.0	9.0	5.0	20	0.5	100.0	6.0	^ 3.0	89.0	1.0
Long diameter of tumor (cm) *	4	4					Bleeding Anostomosis leakage Anastomotic stenosis Marginal ulcer (without active bleeding) Dumping syndrome Delayed gastric emptying Remnant stomach necrosis Omental infarction Prolonged postoperative ileus Adhesive lieus (postoperative adhesions formation)					U	Jpdate
Depth of invasion (T classification) *			In-hospital post-operative complications In-hospital post-operative complications Hospital post-operative complications								1.		
Number of metastatic limph nodes *	Tis T1a ⊳ T1b T2										n) Save	е	
Lymph node status (N classification) * N0 No regional lymph node metastasis N1 Metastasis in 1 to 2 regional lymph nodes N2 Metastasis in 3 to 6 regional lymph nodes	T3 T4a T4b			omplication *			Other intestin Small bowel Colon perfora Small bowel	nal obstruction perforation ation infarction					
N3 Metastasis in 7 or more regional lymph nodes			Reoperation for complication *			Colon infarction Unexplained postoperative fever							
Histological type *	~ ·		Clavien - Dindo grade *				Fluid collection / Intra-abdominal abscess Wound infection Wound seroma						
Lauren classification *	×		Insert			Abdominal wall haematoma Incisional hernia Enterocutaneous leak							
Proximal resection margin (cm)							Acute Pancre	eatitis					
							Pancreatic fis						
							Cholecystitis					F	Finish
Distal resection margin (cm)							Gallbladder e Common bile						
								- and injury					

omplications after discharge							
Early and late surgery-related cor	nplications after discharge						
Complications after discha	arge						
Death related to the comp	Grade I Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infection						
Add one or more complications	opened at the bedside Grade II Requiring pharmacological treatment with drugs other than such allowed for grad						
Date of occurence * (yyyy/mm/dd)	complications Blood transfusions and total parenteral nutrition are also included Grade III Requiring surgical, endoscopic or radiological intervention Grade IIIb Intervention not under general anesthesia Grade IIIb Intervention under general anesthesia						
Type of complication*	Grade IV Life-threatening complication (including CNS complications)* requiring IC/ICU management						
Surgical intervention *	Grade IVa Single organ dysfunction (including dialysis) Grade IVb Multiorgan dysfunction Grade V Death of a patient						
Clavien - Dindo grade *							
Death related to the comp	lication *						

M

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Automatic statistics are available

							Inser
Follow up 2 years							
Visit: 2 years							
Date of visit: 2014-0	-01						
Patient status: alive							
Disease-free or not d	urina follow-	up: Yes					
Karnofsky scale: 100							
Weight loss last 3-6 r							
Hemoglobin level White blood cell c Neutrophil to lymp Total bilirubin: 0.1. Platelet: 170.0 K/u Protein: 7.0 g/dL Albumin: 4.0 g/dL Glucose: 95.0 mg/ Creatinine: 0.9 mg	ount (WBC): bhocytes ratio <sup>7</sup> mg/dL L		cells/L				
						U	pdate

#### JOIN THE STUDY





No profit cooperation

Web manager Graphic designer

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