



The IMIGASTRIC Study: Robotic and Laparoscopic Gastrectomy for Cancer Compared with Open Surgery

Analysis of Surgical and Clinical Outcomes, Assessment of Complications

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OBJECTIVES

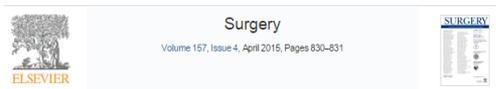
- ❑ **Develop** a multi-institutional database on gastric cancer
- ❑ **Analyze** surgical, clinical and oncological outcomes of Minimally Invasive Surgery
- ❑ **Compare** Laparoscopic and Robotic approach with open surgery

TYPE OF STUDY

Observational Retrospective Cohort Study

ClinicalTrials.gov PRS
Protocol Registration and Results System NCT02325453

- Three treatments arms
- Patients treated with curative intent
- Data from medical records and existing institutional databases



Letter to the Editor

Establishing a multi-institutional registry to compare the outcomes of robotic, laparoscopic, and open surgery for gastric cancer

Amilcare Parisi, MD, Jacopo Desiderio, MD 

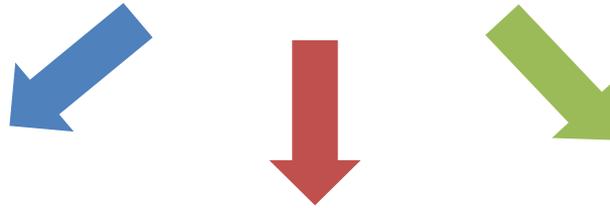
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Open Access Protocol

BMJ Open Robotic, laparoscopic and open surgery for gastric cancer compared on surgical, clinical and oncological outcomes: a multi-institutional chart review. A study protocol of the International study group on Minimally Invasive surgery for GASTRIC Cancer – IMIGASTRIC

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GROUPS



ROBOTIC SURGERY

Da Vinci robotic surgical system

LAPAROSCOPY

Traditional laparoscopic devices

OPEN SURGERY

Conventional surgical approach

DATA COLLECTION

- Patient demographics
- Surgical procedure details
- Tumor characteristics
- Post-operative clinical findings
- Post-operative complications
- Follow-up details



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IMIGASTRIC.LOGIX-SOFTWARE.IT

FIRST INTERIM DATA ANALYSIS

Raw data entered during the first eight months of work were analyzed

Overview of the registry

- total number of entered patients
- age
- sex
- BMI
- ASA
- smoker
- concomitant illness
- previous abdominal surgery
- neo-adjuvant chemotherapy
- neo-adjuvant radiotherapy
- tumor location
- stage
- type of gastrectomy
- extend of gastrectomy
- extend of lymphadenectomy
- type of surgical approach

Patient characteristics by group

- age
- sex
- BMI
- ASA
- smoker
- concomitant illness
- neo-adjuvant chemotherapy

Surgical procedure details

- type of gastric resection
- type of reconstruction
- anastomosis performance
- anastomosis approach
- type of lymphadenectomy
- operative time
- EBL
- number of retrieved lymph nodes
- length of incision
- robotic docking time
- conversion to open surgery
- site of minilaparotomy
- intraoperative complications
- intraoperative death
- margin status
- residual tumor
- intraoperative blood transfusion
- placement of intra-abdominal drain

Tumor characteristics

- tumor location
- stage
- T classification
- N classification
- histology

Post-operative clinical findings

- enhanced recovery after surgery (ERAS) protocols adopted
- length of postoperative hospital stays
- patient mobilization (POD no.)
- liquid diet (POD no.)
- soft solid diet (POD no.)
- resumption of peristalsis (POD no.)
- first flatus (POD no.)
- drain removal (POD no.)
- length of intravenous antibiotic use
- length of intravenous analgesic use
- postoperative blood transfusion
- postoperative complications
- complications after discharge
- death for complication after discharge

Follow-up details

- adjuvant chemotherapy
- adjuvant radiotherapy
- survival analysis
- overall survival
- survival trend up to 60 months
- survival rate at 1, 3, 5 years

STATISTICS

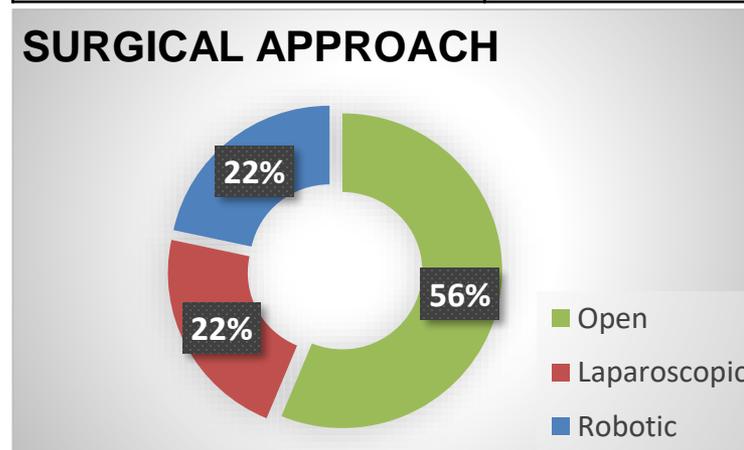
- ❑ IBM SPSS Statistics V.23
- ❑ Dichotomous variables: numbers and percentages
- ❑ Continuous variables: mean and SD, median and IQR
- ❑ Comparison: ANOVA, Pearson's χ^2 test, Fisher's exact test
- ❑ Survival: Kaplan–Meier curves
- ❑ $P < 0.05$ statistically significant

OVERVIEW OF THE REGISTRY

AGE	67.14 ± 12.68
SEX	
F	410 (40%)
M	616 (60%)
BMI	24.11 ± 4.32
ASA	
I	193 (18.8%)
II	556 (54.2%)
III	277 (27%)
COMORBIDITIES	411 (40.1%)

STAGE	
0	39 (3.8%)
IA	213 (20.8%)
IB	138 (13.5%)
IIA	140 (13.6%)
IIB	114 (11.1%)
IIIA	110 (10.7%)
IIIB	128 (12.5%)
IIIC	102 (9.9%)

TYPE OF GASTRECTOMY	
DISTAL	564 (55%)
TOTAL	433 (42.2%)
OTHER	29 (2.8%)
LYMPHADENECTOMY	
D1	53 (5.2%)
D1+	67 (6.5%)
D2	906 (88.3%)



OPEN	577 (56%)
LAPAROSCOPY	227 (22%)
ROBOTIC	222 (22%)

PATIENTS CHARACTERISTICS

AGE (years)	P=0.1
SEX	P=0.13
BMI (kg/m²)	P<0.01
ASA	P=0.05
COMORBIDITIES	P=0.6
SMOKING STATUS	P=0.5
NEOADJUVANT CHEMOTHERAPY	P=0.06



ROBOTIC	LAPAROSCOPY	OPEN
68.76 ± 12.57	66.49 ± 14.13	66.81 ± 12.11
24.58 ± 3.23	23.32 ± 2.52	24.24 ± 3.36

PATHOLOGY

	ROBOTIC	LAPAROSCOPY	OPEN	
0	4 (1.8%)	30 (13.2%)	5 (1.1%)	P<0.05
Ia	56 (25.2%)	62 (27.3%)	103 (18.1%)	
Ib	37 (16.7%)	29 (12.8%)	77 (13.4%)	P>0.05
IIa	39 (17.6%)	23 (10.1%)	86 (15%)	
IIb	23 (10.4%)	20 (8.8%)	76 (13.4%)	
IIIa	31 (14%)	17 (7.5%)	69 (12.1%)	
IIIb	20 (9%)	27 (11.9%)	82 (14.3%)	P<0.05
IIIC	12 (5.4%)	19 (8.4%)	72 (12.6%)	

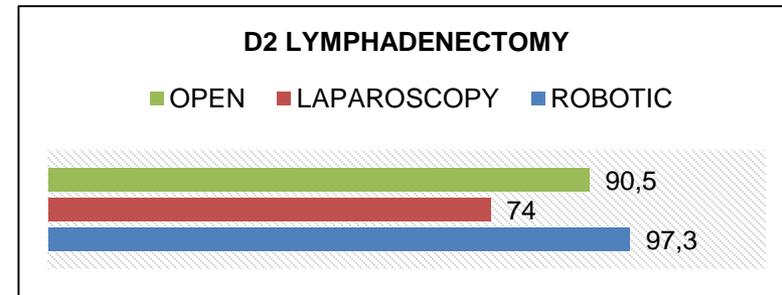
DIFFERENTIATED	70 (45.2%)	97 (52.4%)	179 (43%)	P=0.1
UNDIFFERENTIATED	85 (54.8%)	88 (47.6%)	237 (57%)	

SURGICAL OUTCOMES

OPERATIVE TIME (min)	P<0.001	→
EBL (mL)	P<0.001	→
RETRIEVED LNS (no.)	P<0.001	→

ROBOTIC	LAPAROSCOPY	OPEN
348.73 ± 95.76	207.01 ± 87.42	204.48 ± 67.63
137.93 ± 77.3	95.95 ± 113.72	203.92 ± 158.2
27.47 ± 12.72	24.39 ± 13.05	29.59 ± 14.44

INTRAOP. COMPLICATIONS	P=0.93
INTRAOP. TRANSFUSIONS	P=0.12
INTRAOP. DEATH	P=0.84
RESIDUAL TUMOR (R)	P=0.53



CONVERSION TO OPEN SURGERY		
ROBOTIC	LAPAROSCOPY	P=0.48
11 (5%)	10 (4.4%)	

CLINICAL OUTCOMES

HOSPITAL STAY	P<0.001	→
MOBILIZATION	P=0.001	→
LIQUID DIET	P=0.001	→
SOLID DIET	P=0.001	→
DRAIN REMOVAL	P=0.01	
ANALGESIC USE	P=0.009	

ROBOTIC	LAPAROSCOPY	OPEN
8.74 ± 4.84	8.29 ± 8.12	13.19 ± 9.20
1.20 ± 1	1.25 ± 1.60	1.58 ± 1.53
3.12 ± 2.24	3.53 ± 2.66	3.94 ± 3.18
4.18 ± 2.01	5.46 ± 4.88	6.04 ± 6.51

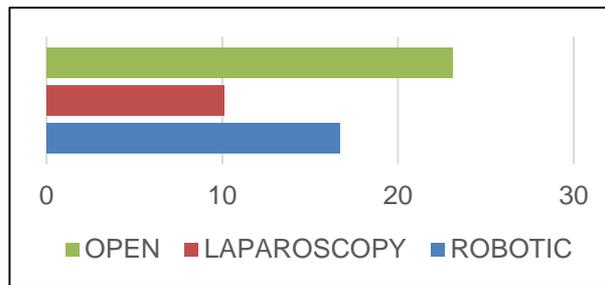
FIRST FLATUS	P=0.08
ANTIBIOTIC USE	P=0.8
TRANSFUSION	P=0.8

COMPLICATIONS

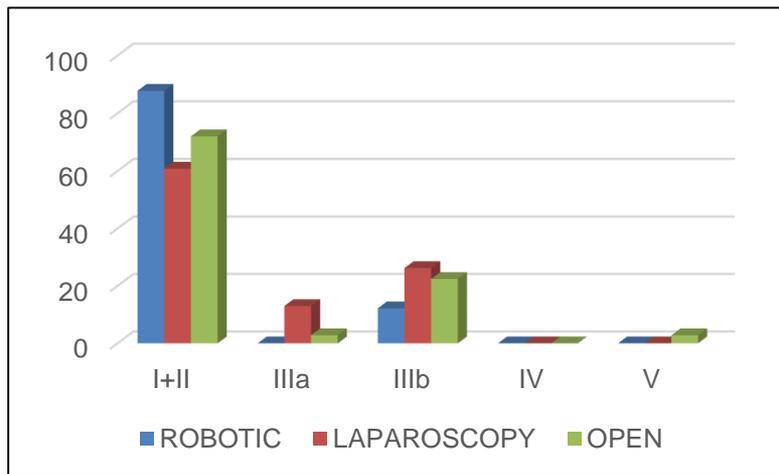
PTs WITH COMPLICATIONS (no.)	P<0.001
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ROBOTIC	LAPAROSCOPY	OPEN
37 (16.7%)	23 (10.1%)	133 (23.1%)

TYPE	P=0.39
SURGICAL	P=0.94
NON-SURGICAL	P=0.17
CLAVIEN-DINDO GRADE	P=0.08
REOPERATION	P=0.27
READMISSION	P=0.09



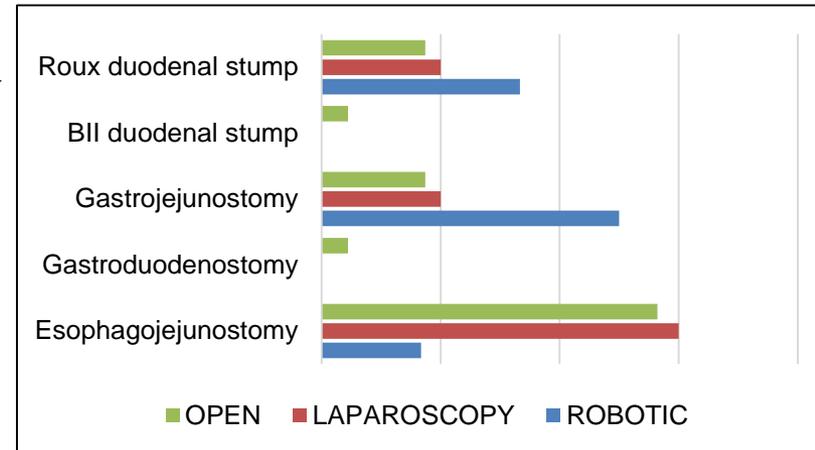
	ROBOTIC	LAPAROSCOPY	OPEN
I+II	36 (87.8%)	14 (60.8%)	129 (72%)
IIIa	0 (0%)	3 (13%)	5 (2.8%)
IIIb	5 (12.2%)	6 (26.2%)	40 (22.4%)
IV	0 (0%)	0 (0%)	0 (0%)
V	0 (0%)	0 (0%)	5 (2.8%)



COMPLICATIONS

Analysis of leakage

SITE OF LEAK	P=0.63
LEAK-RELATED REOPERATION	P=0.1
LEAK-RELATED DEATH	P=0.54



	ROBOTIC	LAPAROSCOPY	OPEN
Esophagojejunostomy	1 (16,7%)	3 (60%)	13 (56,4%)
Gastroduodenostomy	0 (0%)	0 (0%)	1 (4,4%)
Gastrojejunostomy	3 (50%)	1 (20%)	4 (17,4%)
BII duodenal stump	0 (0%)	0 (0%)	1 (4,4%)
Roux duodenal stump	2 (33,3%)	1 (20%)	4 (17,4%)

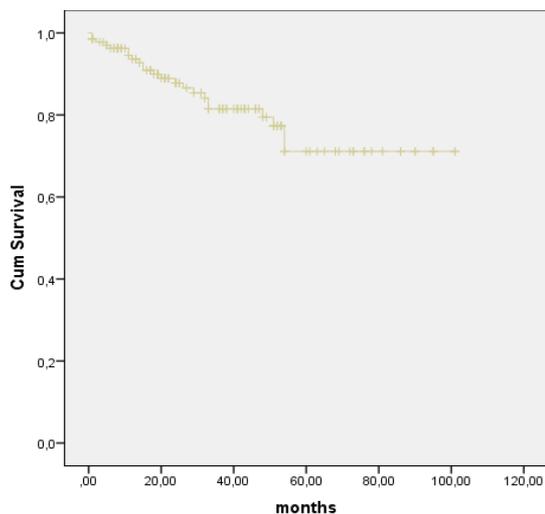
FOLLOW-UP

NO. VALID	516
ROBOTIC	136
LAPAROSCOPY	62
OPEN	318
MEAN FU (MOS.)	40,01 ± 48,89
5-YEAR OVERALL SURVIVAL	P=0.34

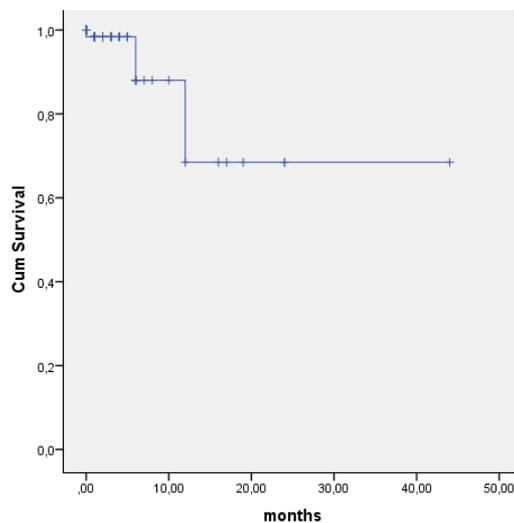
- No case-matched analysis
- Analysis made on the available raw data only to show the statistical survival trend

SURVIVAL TREND

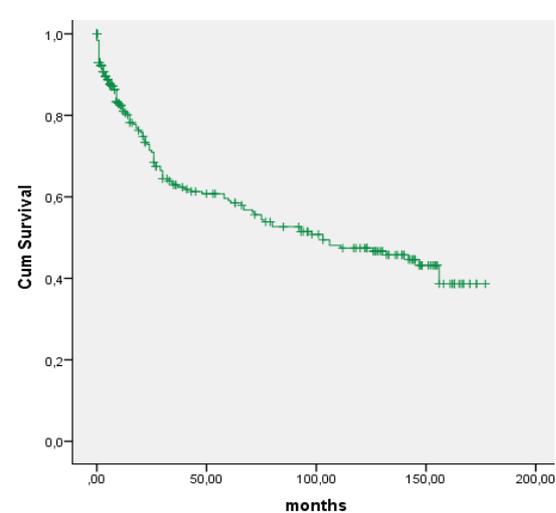
ROBOTIC



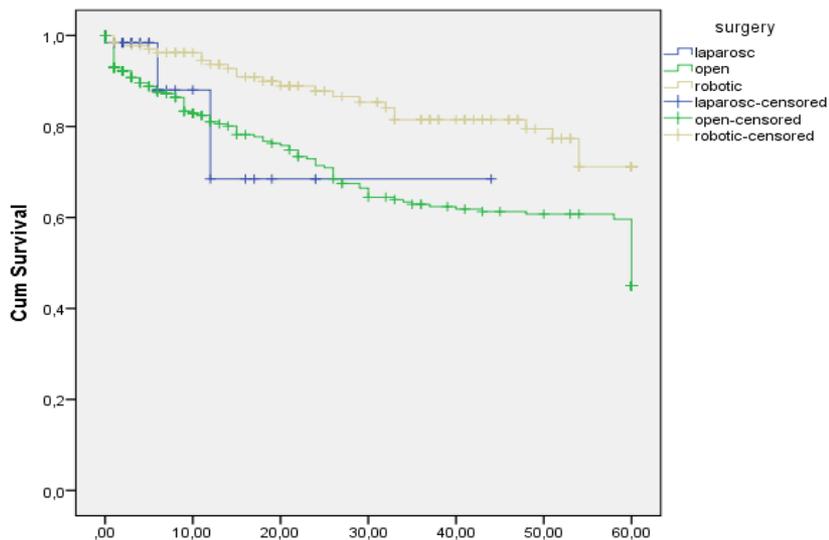
LAPAROSCOPY



OPEN



Survival trend at 60 months follow-up



- ❑ This is the first interim data analysis to monitor the IMIGASTRIC registry
- ❑ MIS shows safety in ensuring oncological radicality
- ❑ MIS leads to shorter hospital stays and the faster resumption of regular diet
- ❑ Trend toward decrease of complications and a lower readmission rate is seen

- ❑ The IMIGASTRIC registry has the potential to become a large database on MIS for gastric cancer
- ❑ Several subgroup analyses are possible
- ❑ The survival analysis is deserving of a targeted analysis but looks promising in this study

- Implementation of data analysis
- Subgroup analysis by specific subjects of interest
- IMIGASTRIC software implementation
- Other interesting fields of investigation
- New studies to overcome the limitations of the present database

PROSPECTIVE TRIAL



- The Promoting Center has already received approval
- Other Centers are joining the study
- Trial registration number: NCT02325453
- Newly identified subjects with gastric cancer
- Enrollment is now opened
- Expected recruitment period of 3 years
- Oncological follow-up will be 5 years

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