

## Synopsis of the study

<b>Title</b>	<b>Robotic, Laparoscopic and Open Surgery for Gastric Cancer Compared on Surgical, Clinical and Oncological Outcomes: Establishing a Multi-Institutional Registry</b>
<b>Code</b>	<b>IMIGASTRIC</b>
<b>Background</b>	<p>Gastric cancer represents a great challenge for health care providers and requires a multidisciplinary context in which surgery plays a main role.</p> <p>Minimally invasive surgery has been progressively developed, first with the advent of laparoscopy and more recently with the spread of robotic systems, but a number of issues are currently being debated, including the limitations in performing effective extended lymph node dissections and, in this context, the real advantages of using the robotic systems, the possible role for the Advanced Gastric Cancer, the reproducibility of completely intracorporeal techniques and the oncological results achievable during follow-up.</p> <p>A multicenter study with a large number of patients is now needed to further investigate the safety and efficacy as well as long-term outcomes of robotic surgery, traditional laparoscopy and the open approach.</p>
<b>Overall purpose</b>	<p>The Overall purpose is to develop a multi-institutional database comprising information regarding surgical, clinical and oncological features of patients undergoing surgery for gastric cancer with robotic, laparoscopic or open approaches and subsequent follow-up at participating centers.</p>
<b>General study design</b>	<p>The registry will be established by retrospectively identifying subjects with gastric cancer treated at the participating centers.</p> <p>Information gathered will be obtained from existing data and records, diagnostic tests and surgical interventions.</p> <p>Information will be collected and recorded by all institutes through a specific online shared system.</p>
<b>Main objectives</b>	<ul style="list-style-type: none"><li>-To determine the surgical, clinical, and oncological outcomes in both the short and long term</li><li>-To compare results according to the type of intervention, device used and manner of execution of different surgical phases</li></ul>

	<p>-To relate results of different surgeries with baseline characteristics of patients and stage of disease</p>
<p><b>Clinical relevance</b></p>	<p>Studies that reported results of minimally invasive surgery for gastric cancer and recent meta-analysis emphasize the need for large trials.</p> <p>A further consideration in this field regards the need of numerous patients to reach a statistical significance on surgical, clinical and oncological outcomes, in order to fully assess the effectiveness and the differences between the different surgical approaches.</p> <p>At present, a multicenter registry may represent the best research tool to assess the role of minimally invasive approaches by comparing the methods with traditional open surgery.</p> <p>Therefore, for this project, a large registry will be created by collecting data from the different participating centers to create a working basis for analyzing outcomes of interest and obtaining directions for further investigation.</p> <p>The data collected will clarify the role of laparoscopic and robotic surgery versus the open approach regarding in terms of:</p> <ul style="list-style-type: none"> <li>-safety and feasibility based on the intraoperative outcomes.</li> <li>-respect of oncological principles in relation to the stage and location of the tumor</li> <li>-recovery of gastrointestinal function considering the outcomes measured during the postoperative hospital stay</li> <li>-incidence, types and severity of postoperative complications</li> <li>-overall survival and disease-free survival</li> </ul>
<p><b>Inclusion criteria</b></p>	<ul style="list-style-type: none"> <li>- Histologically proven gastric cancer</li> <li>- Preoperative staging work-up performed by upper endoscopy and/or endoscopic ultrasound, and CT scan</li> <li>- Early Gastric Cancer</li> <li>- Advanced Gastric Cancer</li> <li>- Patients treated with curative intent in accordance to international guidelines</li> </ul>
<p><b>Exclusion criteria</b></p>	<ul style="list-style-type: none"> <li>- Distant metastases: peritoneal carcinomatosis, liver metastases, distant lymph node metastases, Krukenberg tumors, involvement of other organs</li> <li>- Patients with high operative risk as defined by the American Society of Anesthesiologists (ASA) score &gt;4</li> </ul>

	<ul style="list-style-type: none"> <li>- History of previous abdominal surgery for gastric cancer</li> <li>- Palliative surgery cases</li> </ul>
<b>Study period under review</b>	The chart review for the registry takes into account all available data of patients treated at the participating Centers between the 1st January 2000 and the official opening of the registry.
<b>Type of data collection</b>	<p>In the present study, the following information will be collected:</p> <ul style="list-style-type: none"> <li>-Patient Demographics</li> <li>-Surgical Procedure details</li> <li>-Tumor characteristics</li> <li>-Operative findings</li> <li>-Post-operative clinical findings</li> <li>-Post-operative complications</li> <li>-Follow-up details</li> </ul>
<b>Statistical analysis</b>	<p>Based on the data of the registry every investigator can perform all the statistical analysis he needs for his researches purposes, while a basic analysis for monitoring the study will be performed as follows.</p> <p>The dichotomous variables will be expressed as numbers and percentages, while continuous variables will be expressed as mean and standard deviation (SD) or median and interquartile range (minimum and maximum values).</p> <p>Continuous variables, will be compared using one-way ANOVA with post hoc multiple comparison by Tukey's procedure. Pearson's <math>\chi^2</math> test or Fisher's exact test, as appropriate, will be used for analysis of categorical data. For each of these tests a value of alpha (<math>\alpha</math>) &lt; 0.05 will be considered statistically significant.</p>
<b>Potential risks and safety management</b>	<p>Participation in the research registry involves the potential risks of a breach of confidentiality of the medical record information and associated privacy of the participants.</p> <p>Such risks will be minimized by the use and the establishment of appropriate information technology services.</p>
<b>Ethical consideration</b>	<p>All Investigators agree the study is conducted in compliance with ethical principles originating from the Helsinki Declaration, with the guidelines of Good Clinical Practice (GCP) and with applicable laws.</p> <p>Investigators shall undertake to act according to the rules of their Institutional Review Board (IRB) and Ethics Committee (EC) regarding the retrospective collection of data.</p>

<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• Vinuela EF, Gonen M, Brennan MF, Coit DG, Strong VE. Laparoscopic versus open distal gastrectomy for gastric cancer: a meta-analysis of randomized controlled trials and high-quality nonrandomized studies. <i>Ann Surg.</i> 2012;255:446-56.</li> <li>• Alimoglu O, Atak I, Eren T. Robot-assisted laparoscopic (RAL) surgery for gastric cancer. <i>The International Journal of Medical Robotics and Computer Assisted Surgery.</i> 2014;10:257-62.</li> <li>• Shen WS, Xi HQ, Chen L, Wei B. A meta-analysis of robotic versus laparoscopic gastrectomy for gastric cancer. <i>Surg Endosc.</i> 2014.</li> <li>• Marano A, Choi YY, Hyung WJ, Kim YM, Kim J, Noh SH. Robotic versus Laparoscopic versus Open Gastrectomy: A Meta-Analysis. <i>J Gastric Cancer.</i> 2013;13:136-48.</li> <li>• Liao G, Chen J, Ren C, Li R, Du S, Xie G, et al. Robotic versus open gastrectomy for gastric cancer: a meta-analysis. <i>PLoS One.</i> 2013;8:e81946.</li> <li>• Hyun MH, Lee CH, Kim HJ, Tong Y, Park SS. Systematic review and meta-analysis of robotic surgery compared with conventional laparoscopic and open resections for gastric carcinoma. <i>Br J Surg.</i> 2013;100:1566-78.</li> <li>• Xiong B, Ma L, Zhang C. Robotic versus laparoscopic gastrectomy for gastric cancer: a meta-analysis of short outcomes. <i>Surg Oncol.</i> 2012;21:274-80.</li> </ul>
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