

## TEXT OF THE FULL PRESENTATION

First, I would like to thank all the Investigators and Institutions involved in the IMIGASTRIC project. All of them have made great efforts for the opening of the study, just two weeks ago.

The poster, that I am presenting, summarizes all the challenging work that has been done for the conception, design and development of the Imigastric project up to the official opening of this international registry and future perspectives.

Gastric cancer is a major worldwide challenge, resulting rampant in some regions and overall representing the fourth most common cancer.

It needs a multidisciplinary context and dedicated institutes, where surgery plays the main role.

Many are the current areas of research in order to identify the best treatment strategies. Among these, is steadily emerging interest in minimally invasive surgery thanks to the continuous technological development.

Since Kitano who performed in 1994 the first laparoscopic assisted gastrectomy and then Hashizume that in 2003 first used the robotic approach, we arrive until today where many experiences from different Centers have been published.

Particularly, several meta-analyses have been made with the goal of defining the role of minimally invasive approaches for gastric cancer. However the current evidences are far from be able to consider these procedures in common surgical practice. In the current guidelines, laparoscopy has been described as a possible alternative to open surgery for EGC, while robotic surgery has intrinsic technological advantages but they have not been verified by studies with an appropriate level of evidence.

Research in the field of minimally invasive surgery aims to assess the impacts on perioperative outcomes and so quality of life of the patient, while respecting oncological principles. The increasing attention to these approaches in gastric surgery unfortunately comes up against the limited data available to date, that don't allow the scientific community the achievement of specific guidelines.

In the current studies, few questions have been answered and few indications have arisen, while many issues have become subject of debate.

Our project started from an accurate analysis of the scientific literature, aimed at a deeper study of the problem.

Our review highlighted significant limitations of the examined studies:

- Small samples of patients, mostly comparative studies of low quality
- Selection bias in the comparison groups (stage, extent of lymphadenectomy)

- Absence of subgroup analysis in significant research fields
- Lack of information on the surgical techniques adopted
- Significant differences in the postoperative management of patients

What kind of study can be helpful in this context?

- A large sample of patients is considered necessary by all studies already performed
- The collection of multiple variables permits to generate a comprehensive statistical report
- The standardization of the methodology to be adopted increases the accuracy
- Bringing together the experience of East and West and finding shared points could allow the development of future guidelines and get directions for future studies.

A large multicenter registry could therefore be the best way to clarify the actual role of minimally invasive surgery.

So, we restart from the previously performed analysis of literature to identify centers potential interested to be involved in this kind of project. An invitation letter has been sent to the corresponding authors of the identified articles and so we proceeded according to a pre-established scheme, as highlighted in the graphic. At the end of the screening period, 18 centers sent a positive feedback and resulted potentially interested in participating in the development of a shared project.

Over the following months it has reached an agreement on the principles of the study, objectives, type of data to be collected and instruments to be adopted in order to really make a valuable contribution to scientific research on surgery for gastric cancer. On this basis, a study protocol was subsequently developed.

The overall objective of the study is to develop and maintain a multi-institutional database comprising information about the surgical, clinical and oncological features of patients undergoing gastrectomy with robotic, laparoscopic or open approach.

The project includes an initial retrospective phase, during which will be included data arising from the review of medical records. Then, from the experience accumulated in this phase is planned to start a prospective trial.

The specific aims include to compare different surgeries in terms of intraoperative outcomes, assessment of the recovery of gastrointestinal functions, postoperative stay and short and long term complications. At the same time verifying the respect of oncological principles, overall survival and disease-free survival.

Patients will be considered for the registry, based on inclusion and exclusion criteria, as shown in the graphic.

For data collection, 6 categories were identified: patient characteristics, details of the surgical procedure, tumor characteristics.

Data concerning the postoperative period and any complications, surgical complications after discharge, details of oncological follow-up.

From the collected data will be calculated and compared seven outcomes. Three primary outcomes, concerning safety and feasibility, respect of oncological principles, surgical effectiveness

Four secondary outcomes, regarding the postoperative recovery of the patient, the severity of complications, the role of intracorporeal procedures, the surgical stress.

The study will consider data of patients treated from January 1, 2000 to the official opening of the register. The 18 initial sites are already accredited for entering data, but the registry is open to other interested Institutions.

All investigators act in compliance with the guidelines of Good Clinical Practice.

Each investigator must follow the rules of his institute regarding the collection of data.

The great innovation introduced in this type of study, concerns the adopted tools. It was created an IT instrument thanks to a close cooperation with experts in software development. Combining medical and engineering expertises it has been developed a unique and tailored instrument. This makes possible to facilitate and standardize data collection, speed up the creation of a shared database and ensure the security of sensitive data. All this accessible at each moment from anywhere in the world.

The creation of a multi-institutional registry involves many problems.

The investigators are in different parts of the world, then there is a high risk of transmission errors generated during the various steps of collecting and sending data. So, the main purpose was to make very friendly and fast data entry and sharing.

The software has some principles characteristics, such as: different levels of user profiles, each center has its own independent management, all the data are collected in a global registry, you can get statistics about your center or overall level.

Moreover:

- 1.Data entry of patients complies with most stringent privacy regulations, sensitive data are not recorded in a server, but the software generates a reference code.
2. For each patient an IT folder is generated by the system containing six specific areas to fill.
- 3.The software is designed to guide the user in data entry, thus avoiding generating errors.
- 4.The different fields are filled in by selecting the various options from "drop-down" menus made available for each parameter. all the characteristics to be entered have been previously standardized, without the need to write or specify anything else during the filling in. Any considered variable derives from an analysis of all the data reported in the studies found in the literature and in accordance with guidelines.

5. Also, the software uses predefined control instruments and automatic calculation.

6. The phase of evaluation and testing of the software was carried out between March and May, through the access to a demo version. There were subsequently all digital certifications were gained and the definitive server for storing data purchased. From the 15 of May, accredited centers officially started data entry.

The project won a grant as a non-profit research, provided by CARIT foundation, which will allow keeping open the registry for this first phase, until the end of 2017.

You can obtain further information by visiting the study website: [www.imigastric.com](http://www.imigastric.com), where a form to contact the organizing secretariat and the coordinating staff is available.

You can also use social networks to follow the news and the daily updates on the project and to interact with investigators. Interested researchers are invited to join us.