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JGS Journal of Gastric Surgery

Designed for practictioners involved in oncology, obesity, metabolic and other abdominal diseases

IN THIS ISSUE

- Prof. Vito D'Andrea in the editorial introduces aims and scope of this new journal.
- Prof. Amilcare Parisi and Prof. Chang-Ming Huang highlight a new concept of scientific cooperation and the establishment of an International Gastric Cancer Unit (IGCU).
- Dr. Jacopo Desiderio shows the rationale of an innovative study on lymphadenectomy assisted by the fluorescence imaging technology during robotic gastrectomy. This study aims to validate the concept of Navigation Surgery.
- The International Study Group on Minimally Invasive Surgery for Gastric cancer (IMIGASTRIC Research Group) publishes a protocol for a prospective data collection with high methodological quality on minimally invasive and open gastrectomies.
- Among the other contents there are an update on the use of new technologies in gastric surgery and a technical note on reconstruction after laparoscopic gastrectomy.

INTERNATIONAL GASTRIC CANCER UNIT IGCU

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EDITORIAL
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Aims and scope of a new journal on gastric diseases and surgical practice

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Dear Authors,
the Journal of Gastric Surgery (J Gastr Surg, JGS) is a peer-reviewed journal published and managed by the International Gastric Cancer Unit established between the Department of Surgical Sciences (Sapienza University), Department of Gastric Surgery (Fujian Medical University), Department of Digestive Surgery (St. Mary's Hospital of Terni).
J Gastr Surg publishes original articles, reviews, editorials and letters to the Editor.
Gastric Surgeons all over the world are kindly invited to contribute to the growth of the Journal of Gastric Surgery.
When I was a child, my mother died from inoperable gastric cancer and I decided to dedicate my entire life to surgical research, as I consider that one of the most relevant field in health sciences.
I am the Director of the Department of Surgical Sciences and of the Ph.D. Programme in "Advanced Surgical Technologies" at Sapienza University of Rome.
I decided to found the Journal of Gastric Surgery, together with my Collegues Prof.Amilcare Parisi and Prof.Chang-Ming Huang, in order to publish the advancements in gastric surgery worldwide.
Gastric Cancer is the fourth most common cancer type and the second leading cause of cancer mortality in the world.
Most patients with gastric cancer have advanced stage (III or IV) disease at the time of diagnosis.
Gastrectomy with lymph node dissection still remains the only curative treatment for patients with gastric cancer.
Laparoscopic, open and robotic surgical studies are welcome for publication in the journal.
Gastric Surgery is popular as well in obese patients, since weight loss, diabetes remission, improvement in cardiovascular risk factors and other comorbidities are better achieved with bariatric surgery than medical therapy.
Laparoscopic sleeve gastrectomy and roux-en-y gastric by-pass are the most common procedures.
The metabolic diseases that are most affected by gastric surgery are type 2 diabetes mellitus and the metabolic syndrome. Hypertension and cardiovascular diseases are also improved by gastric surgery through weight loss effects.
The metabolic syndrome is represented by obesity, glucose intolerance, dyslipidemia and hypertension. The metabolic manifestations of the metabolic syndrome respond to surgical therapy.
I'm glad to read your welcome manuscripts,
Yours Sincerely,

Prof. Vito D'Andrea

UE Cancer Mission Board Member
Full Professor of General Surgery
Director of the Department of Surgical Sciences
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A protocol for cooperation to establish an International Gastric Cancer Unit (IGCU)

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ABSTRACT
The following text shows the terms of a protocol for cooperation recently signed between The Department of Digestive Surgery - St. Mary's Hospital (Terni, Italy; hereinafter "SMH"), the Department of Surgical Sciences - "La Sapienza" University (Rome, Italy; hereinafter "SUR") and the Department of Gastric Surgery - Fujian Medical University Union Hospital (Fuzhou, Fujian Province, PRC; hereinafter "FMU").

Background:

The SMH, the SUR, and the FMU (hereinafter the "Parties"),

- Whereas SMH works with national and international partners to develop and promote cancer treatment and research programs,
- Whereas SMH is the founding member of the IMIGASTRIC group[1, 2], which has the objective of collecting and providing large sets of multi-institutional data on gastric cancer[3, 4],
- Whereas SUR is one of the largest European universities and is one of the world's oldest, having been founded in 1303,
- Whereas FMU is a globally recognized leading gastric cancer center and a key center for surgical treatments, education, and scientific research,
- Recognizing that cooperation between the Parties has progressively developed, as manifested by their successful cooperation in the field of gastric cancer research, the Parties express a strong willingness to deepen this cooperation,
- Believing that the extension of cooperation is in the interest of all Parties within the frameworks of their respective mandates and in view of each organization's strengths and comparative advantages,
- Desirous of further developing and institutionalizing their cooperation, the Parties agree to the following sections.

General Provisions:

The purpose of this Protocol for Cooperation is to promote cooperation between the Parties and establish a framework for intensifying and expanding this cooperation.

Areas of Cooperation:

Cooperation between SMH, SUR, and FMU will focus on the following areas of work:

- Data collection and research
- Networking and common events
- Communication and awareness-raising activities
- Capacity development
- Where appropriate cooperation in these areas could, inter alia, take the form of the following:
- Coordination of data collection and analysis;
- Participation in relevant expert meetings;
- Collaboration in research project surveys or forthcoming publications;
- Coordination of respective research methodologies with which to enhance the comparability of project results,
- Joint efforts to identify common stakeholders;
- Exchange of information on respective stakeholder interaction;
- Cooperation in implementing networking activities;
- Joint organization of events;
- Dissemination of information on relevant subjects to their respective stakeholders and partners;
- Joint efforts to build a pool of experts in gastric cancer research (International Gastric Cancer Unit, *Figure 1*).

Figure 1: Official Logo of the International Gastric Cancer Unit

Implementation

In order to implement specific activities under this Protocol for Cooperation, the Parties, if required, shall conclude supplementary agreements for individual projects or programs in accordance with SMH, SUR, and FMU internal regulations, rules, policies, and procedures.

Consultation and Exchange of Information

The Parties shall, on a regular basis, keep one another informed of and consult one another on matters of common interest that in their opinion are likely to lead to mutual collaboration.

A meeting between senior members of all three organizations shall take place in the first half of each year with the aim of discussing possible opportunities for joint activities, challenges to be faced, and ways of further developing the Parties' partnership for their mutual benefit.

Consultation and exchange of information and documents under this Article shall be without prejudice to arrangements that may be required to safeguard the confidential and restricted character of certain information and documents.

The Parties shall invite one another to send observers to meetings or conferences convened by them or under their auspices in which, in the opinion of any Party, the others may have an interest. Invitations shall be subject to the procedures applicable to such meetings or conferences.

Exchange of Research Personnel

The Parties shall endeavor to cooperate in education and research in areas of mutual interest.

The Parties shall consult with one another about the possibility of exchanging teaching and research personnel. Particular areas of interest for possible exchange include research projects and graduate and PhD education.

The host Party shall provide study and research privileges for guest faculty/researchers that are comparable to those available to resident faculty and research staff.

Exchange faculty/researchers are expected to study and work according to their plan for professional involvement, teaching, and research as endorsed by the host Party.

Specific agreement for the use of any special facilities or resources shall be arrived at by the Parties in advance of the exchange.

The duration of these exchanges shall be agreed upon in advance of any exchange and limited to the specific

research/academic programs agreed to by the Parties.
All Parties agree to develop more specific protocols regarding exchange and collaboration.
Exchange personnel must abide by the laws of the host country and the rules and regulations of the host Party.

Contact Points
Each Party shall appoint points of contact with a view to facilitating effective cooperation among the Parties.

Name/Logo
None of the Parties shall use the name or logo of the other Parties or any abbreviation thereof in connection with its activities or otherwise without the express prior written approval of the other Parties in each activity.

Settlement of Disputes
Nothing in this agreement shall be construed as creating any legal or financial relationships between the parties.
All disputes that may emerge in relation with the interpretation or application of the present Protocol for Cooperation shall be settled by means of consultations among representatives of the Parties.

Amendments and Supplements
This Protocol for Cooperation may be subject to amendments with the mutual consent of all Parties through the adoption of supplements.
Each Party may request consultations with the intention of amending this Cooperation Agreement.

Entry in Force and Termination
Each Party may terminate this Protocol for Cooperation by providing written notification to that effect. Such termination enters into force after a period of 60 days that shall starts with the first day of the month following the month in which the other Parties received the written notification of termination.
This Protocol for Cooperation enters into force on the day of its signature.

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Not applicable

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AP, CMH, JXL, ST, SB, VDA and JD were involved in conception and designing of this protocol.

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Competing interests
No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

Availability of data and materials
Further information are available from the corresponding author on reasonable request.

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Not applicable

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Fluorescence image-guided lymphadenectomy using indocyanine green and near infrared technology in robotic gastrectomy

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ABSTRACT

Background:
Gastric cancer is a worldwide challenge due to its spread, even epidemic in some areas, and the high mortality rates. Lymphadenectomy is considered the fundamental step during radical gastrectomy. In recent years, some researchers have tried to find a way to improve the surgical identification of the lymphatic drainage routes and lymph node stations. This new surgical frontier is the so called "navigation surgery". Among the different reported solutions, lately, the indocyanine green (ICG) has drawn attention. It is a fluorescence dye, that can be detected in the near infrared spectral band (NIR). The development of specific fluorescence imaging devices has allowed surgeons to visualize tumors, vascular and lymphatic structures. The Da Vinci Xi robotic system has an integrated imaging technology that has been used in colo-rectal and hepato-biliary surgery. However, up to date, the combined use of fluorescence imaging and robotic technology has not been evaluated during lymphadenectomy in gastric cancer.

Methods:
General design: to evaluate the role of fluorescence imaging during robotic lymphadenectomy for gastric cancer.
Type of study: interventional prospective pilot study.
Duration: 18 months.
Experimental group: patients undergoing dissection assisted by ICG.
Control group: patients undergoing the same surgery without the injection of ICG.
Primary outcomes: Fluorescent lymph nodes (FLNs) identification rate, accuracy of the procedure, comparison with the control group on the total number of lymph nodes retrieved.
Sample size: 20 patients in the experimental group, 20 patients in the control group.

Ethics:
This study is conducted in compliance with ethical principles originating from the Helsinki Declaration, within the guidelines of Good Clinical Practice and relevant laws/regulations.

Trial registration number:
NCT03931044

Background:

Gastric cancer is the fourth most widespread cancer in the world and is characterized by high mortality rates [1, 2]. A multidisciplinary context, in which surgery plays the main role, is essential to offer the best therapeutic strategy. Lymph node involvement in gastric cancer is present in 2-18% when the depth of the tumor invasion is limited to the mucosal or submucosal layer, but rises to 50% when the tumor involves the subserosa [3]. Lymphadenectomy is a fundamental surgical phase that must guarantee the oncological radicality and allow an appropriate tumor staging. Although it is among the most relevant factors influencing long-term survival, its extension and standardization is still the subject of much debate. The two latest editions of the JGCA guidelines [4] recommend a dissection on different levels (D1, D1 +, D2) depending on the type of gastrectomy and the clinical stage of the tumor. In recent years, some researchers have tried to apply the concept of "sentinel lymph node" to gastric cancer [5-6]. Although some do not consider that terminology the appropriate one in the context of gastric cancer, because of the multidirectional gastric lymphatic flows, several studies have highlighted interesting aspects, such as: limiting an extensive lymphatic dissection when not necessary, identifying the drainage routes outside the standard anatomical planes, possible assistance in minimally invasive procedures [7]. Most of the experiences in lymph nodes mapping were performed with a radio-isotope (Tc99m) associated or not with the intraoperative use of vital dyes (Blue dye). More recently, the properties of the indocyanine green (ICG) have been studied. This is a fluorescence dye, that can be detected in the near infrared spectral band (NIR) [8, 9]. The development of imaging tools using "Near-Infrared / Indocyanine Green (NIR / ICG)" technology is therefore an innovative approach for visualizing tumors, vascular structures, lymphatic channels, and lymph nodes [10]. Some advantages of the ICG are: reduced toxicity, absence of radioactivity, low cost, safe administration both intravenously and endoscopically through the submucosa or subserosa, protein binding without changing molecular structures, macrophages interaction at the lymph node level. Devices for fluorescence imaging are currently available in both open and minimally invasive surgery. In this field, robotic surgery has been becoming of great interest thanks to the manufacturing of new instruments which, compared to laparoscopy, allow to improve manual skills and gentleness in challenging movements [11]. The Da Vinci Xi robotic system has also produced an innovative imaging technology for ICG visualization made up with a laser source integrated in the robotic camera (Firefly). The surgeon at the console has therefore a 3-D vision that can switch to the fluorescence mode without the need to change the camera. Few clinical experiences have been reported to date [11]. Published articles refer to assistance in colo-rectal and hepato-biliary surgery for vessels or biliary structures visualization, while its use during lymph node dissection for gastric cancer has not yet been the subject of study protocols.

Hypothesis

Fluorescence imaging during lymphadenectomy in gastric cancer can significantly improve the quality of the dissection through a better visualization of anatomical planes and allow tailored dissections. Moreover, the tumor status in the fluorescent nodes could predict the nodes status in the overall specimen with high accuracy rate.

Methods

General study design:

the overall objective is verifying the feasibility and the role of a lymphadenectomy assisted by fluorescence imaging during robotic gastrectomy. Two levels of investigation are planned:

- to detect the possible advantages of a fluorescence-guided surgery ("Navigation Surgery");
- to evaluate the possibility of considering the lymph nodes labeled by the ICG as predictive of the state of tumor diffusion ("Targeted Surgery")

Type of study:

pilot study, interventional prospective study.

Specific aims:

1- To verify the ability of the procedure to highlight the main tumor lymphatic drainage pathways.
2- To validate the concept of Navigation Surgery in gastric surgery by comparing the group of the experimental procedure with a control group undergoing the same type of surgery but not assisted by fluorescence.
3- To find a correlation between the nodes marked by the ICG and the remaining nodes removed during the procedure.
4- To identify the characteristics of those patients in whom the ICG can effectively discriminate the type of lymphadenectomy to be performed.

Eligibility:

- Inclusion criteria: diagnosis of gastric cancer proved through the endoscopic biopsy, cT1 - cT3 and cN0 - N+ at the preoperative staging.
- Exclusion criteria: history of allergies related to iodine, pregnancy, distant metastases, synchronous malignant tumors in other organs, ASA score ≥ 4

Description of the experimental procedure:

the day before surgery, the ICG will be injected endoscopically into the submucosa around the tumor (0.83mg / mL, 0.3mL x 4-6). Each patient will undergo a modified total D2 gastrectomy that includes the following lymph node stations: 1 - 7 + 8a, 9, 11p, 11d, 12a. The lymph node dissection will be performed using the Da Vinci Xi robotic system and the assistance of the near infrared technology to detect ICG fluorescence. Even the resulting fluorescent lymph nodes outside the standard dissection plane will be retrieved. The lymph node stations will be sent to the pathologist in different containers and further subdivided according to fluorescence.

Control group:
data from patients undergoing the same surgery without the ICG imaging procedure will be collected during the same study period.

Data collection:
the following information will be collected for each patient.
- General variables: demographic, histopathological, intra and post-operative features, complications. - Specific variables: total number of lymph nodes retrieved (LNs), Fluorescent lymph nodes (FLNs), metastatic LNs, LNs by station, FLNs outside the standard dissection plane, FLNs status (positive or negative for tumor), non-fluorescent LNs status

Analysis of the experimental procedure:
- FLNs identification rate: patients in which the procedure detects FLNs (%).
- Accuracy: degree of deviation between the FLNs tumor status and the status found in the other LNs analyzed.

Comparison with the control group
- Usefulness of the Navigation Surgery: comparison between the two groups on the total number of LNs retrieved (mean ± SD)
- Impact on the D2 lymph node dissection: comparison between the two groups on the number of LNs removed in the D2 anatomical plane (stations 8a, 9, 11p, 12a) (mean ± SD).

Duration of the project:
18 months.

Institution involved:
Department of Digestive Surgery and Department of Gastroenterology and Endoscopy. St. Mary's Hospital. Terni, Italy.

Sample size:
considering the volume of patients included in published studies available in the literature on the use of fluorescence imaging and adding that the present project is the first to describe the use of robotic technology with fluorescence assistance in gastric cancer, a total of 20 patients will be enrolled for the experimental procedure. An additional sample including 20 patients will be the control group, based on the same eligibility criteria. The total sample of patients planned for the present study is therefore of 40 subjects.

Statistical analysis:
SPSS v23 will be used to perform data analysis. The dichotomous variables will be expressed as numbers and percentages, while the continuous variables as mean and standard deviation, or median and IQR (minimum and maximum values). For the comparison with the control group, the continuous variables will be analyzed with the T test for independent samples and a value of $P < 0.05$ will be considered statistically significant.

Impact on clinical practice and healthcare system
This project can pave the way for a new concept of lymphadenectomy in gastric cancer involving minimally invasive surgery. Patients could benefit from a more tailored approach to their disease.

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Not applicable.

Contributors
JD was involved in conception of the study, JD, AM, ST, AP, VDA were involved in designing the study, analyzing the literature, references searching, drafting the rationale and description of the study methods.

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval
The study was approved by the ethics Committee of CER Umbria (Prot. No. 15928/19/AV dated 21/03/2019).
This study is conducted in compliance with ethical principles originating from the Helsinki Declaration, within the guidelines of Good Clinical Practice and relevant laws/regulations.

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Prospective, observational, multicenter study on minimally invasive gastrectomy for gastric cancer: robotic, laparoscopic and open surgery compared on operative and follow-up outcomes - IMIGASTRIC II study protocol

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ABSTRACT
Background:
Several meta-analyses have tried to define the role of minimally invasive approaches. However, further evidence to get a wider spread of these methods is necessary. Current studies describe minimally invasive surgery as a possible alternative to open surgery but deserving further clarification. However, despite the increasing interest, the difficulty of planning prospective studies of adequate size accounts for the low level of evidence, which is mostly based on retrospective experiences.
A multi-institutional prospective study allows the collection of an impressive amount

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of data to investigate various aspects of minimally invasive procedures with the opportunity of developing several subgroup analyses.

A prospective data collection with high methodological quality on minimally invasive and open gastrectomies can clarify the role of different procedures with the aim to develop specific guidelines.

Methods and analysis:

a multi-institutional prospective database will be established including information on surgical, clinical and oncological features of patients treated for gastric cancer with robotic, laparoscopic or open approaches and subsequent follow-up.

The study has been shared by the members of the International study group on Minimally Invasive surgery for GASTRIc Cancer (IMIGASTRIC)

The database is designed to be an international electronic submission system and a HIPPA protected real time data repository from high volume gastric cancer centers.

Ethics:

This study is conducted in compliance with ethical principles originating from the Helsinki Declaration, within the guidelines of Good Clinical Practice and relevant laws/regulations.

Trial registration number:

NCT02751086

Background

Oncologic gastric surgery represents a major field of interest and development for minimally invasive surgery. Several institutions have continuously published reports regarding their experiences and progress, which has allowed authors of systematic reviews and meta-analysis to try to define the role of minimally invasive surgery (laparoscopy, robotic) by comparing it with the open approach[1-3].

However, the current level of evidence has not yet allowed for defining and sharing rules for the application of minimally invasive approaches in common surgical practice.

Guidelines describe laparoscopy as a possible alternative to open surgery for early gastric cancer[4]; meanwhile, robotic surgery possesses intrinsic technological advantages. However, researchers have not yet verified these advantages through studies with an appropriate level of evidence[5]. Research in this field aims to assess the effects on perioperative outcomes and the patient's quality of life while still respecting oncological principles. The increasing attention that researchers have paid to these approaches are unfortunately limited by the incomplete data currently available[5].

Robotic systems have revolutionized the way we perform minimally invasive surgery and have facilitated the evolution of traditional laparoscopy. Surgeons can overcome the limits of traditional laparoscopy through three-dimensional vision, articulated instruments, and the absence of tremors, thus creating greater dexterity and precision in dissection and suturing movements. These are key elements when performing an extended lymphadenectomy for gastric cancer, and complex and gentle reconstruction to restore digestive continuity.

Despite the technological advances, several issues are currently subject to debate. The most important issue is ensuring proper oncological surgery by performing an adequate lymphadenectomy with minimally invasive approaches. Researchers still regard nodal clearance as an important factor influencing long-term survival[6-13]. In randomized trials[3], laparoscopy demonstrated the removal of at least 15 lymph nodes, as required by international guidelines[14]; however, a significant difference in favor of open surgery resulted in the total number of lymph nodes harvested.

Robotic surgery can facilitate better D2 dissection. This advanced technology clearly possesses intrinsic advantages for this surgical step, but researchers have not yet proven and verified them through appropriate trials: only four studies[15-18] have compared robotic surgery with the open approach, and only one study shows a statistically significant difference versus laparoscopy[19].

Among the intraoperative outcomes, most of the available studies found that blood loss was in favor of minimally invasive surgery. This finding has achieved high statistical significance for laparoscopy in Vinuela's meta-analysis of RCTs[3]. Meanwhile, with regard to robotic surgery, a general consensus among different studies seems to have detected some advantages over laparoscopy and open surgery in reducing operative bleeding[19, 20]. However, several studies have also reported conflicting results[21, 22].

Regarding the post-operative period, the largest RCT[23], which was performed by the Korean Laparoscopic Gastrointestinal Surgery Study Group, found no significant difference between laparoscopy and open surgery in overall complications. Other studies[3] have shown a significant reduction in medical and minor surgical complications when using laparoscopy. Researchers have obtained inconsistent findings in studies on robotic surgery in terms of demonstrating differences compared to laparoscopy in the analysis of complications[22, 24, 25].

Overall, minimally invasive surgery has demonstrated relevant advantages over open surgery with regard to postoperative hospital stays[1, 26-28], despite the extreme heterogeneity among studies. Some evidence[18, 29] has indicated that patients who underwent robotic gastrectomy could be discharged at an earlier date than patients who underwent open or laparoscopic gastrectomy. However, the low number of studies in this field and the high heterogeneity weaken this conclusion.

Manually handling organs during surgery is an important contributor to the inflammatory response after surgery[27, 28, 30]. Theoretically, smaller robotic instruments may cause less inflammation than the instruments used in other approaches. Therefore, postoperative bowel recovery in the robotic group may occur sooner, but this hypothesis still must be proven.

New research must contribute to the current literature in order to define the role of different surgical approaches, and researchers still have to explore many aspects of minimally invasive surgery for gastric cancer[5, 31, 32]. We have a long way to go. Currently, the scientific community is wondering what strategies should be adopted in future studies.

Rationale

A review of the scientific literature[5], which was recently published by the IMIGASTRIC study group, aimed to perform a more complete analysis of the current situation regarding performing minimally invasive surgery for gastric cancer. Significant limitations were found in the analyzed studies, including:

- Small samples of patients, mostly low-quality comparative studies
- Selection bias in the comparison groups (e.g. stage, extent of lymphadenectomy)
- Absence of subgroup analysis in significant research fields
- Lack of information on the surgical techniques adopted

A large prospective multicenter registry could thus be the optimal way to clarify the role of minimally invasive surgery for gastric cancer and permit the evaluation of its short and long-term effects. A working basis for analyzing outcomes of interest and obtaining directions for guidelines and future study developments can also be created. The following would be the main advantages of a large prospective multicenter registry:

-Achieving a large sample of patients

-Collecting multiple variables, allowing for the making of a comprehensive statistical report

-Standardizing the methodology to be adopted, thus

increasing accuracy
-Bringing together the experiences of both East and West to discover shared points
A prospective registry can become a powerful tool that can guide research in this field to new developments and pave the way for other investigational opportunities.

Preliminary data
A research group was first established in 2014 and after sharing a specific study protocol, data collection officially started at the end of 2015 through a retrospective chart review (IMIGASTRIC)[5, 32, 33].
More than 4200 cases have been entered in the registry to date.
60% of entered cases are from Asia, but over 1600 cases were collected by western institutions. About 2600 patients underwent a MIS approach.
A first comparison including a matching analysis regarding operative results, postoperative recovery, and complications was published[34].
The operative time was significantly longer in the Robotic group than the other two groups. A statistical difference in favor of the open group was also observed when compared with the laparoscopic group. A reduction in blood loss resulted in favor of both minimally invasive approaches vs the open group and particularly slightly in favor of the laparoscopic group when compared with the robotic group. Regarding the number of retrieved lymph nodes, MIS confirmed to guarantee an adequate number of nodes for pathological assessment with no significant difference with the open approach. No differences were found regarding intraoperative complications or the residual tumor status. The conversion rate was 5.3% in the LG and 4.6% in the RG with no significant difference. A significantly shorter hospital stay was found in both MIS group vs the OG, without differences between the LG and RG.
All steps in the patients' recovery status happened faster in both minimally invasive approaches than the open surgery. A small benefit was found to be significant in the minimally invasive groups vs the OG in intravenous analgesic discontinuation. The other outcomes showed a slight advantage in favor of minimally invasive surgery.
A decrease in the number of patients experiencing postoperative complications was shown in both the robotic and laparoscopic group versus the open group, however this difference was not statistically significant. No differences were shown in surgical and non-surgical complications, as well as regarding the type of complication. Leakage, bleeding, and pancreatic fistula were the most observed surgical complications. Pneumonia and urinary were the most common medical complications. Majority of cases were low grade complications based on the Clavien Dindo classification (76.9%, overall). The number of patients requiring reoperation did not differ among the three groups.
Anastomotic leakage was the most relevant surgical complication. Therefore, further analysis is reported. No differences in the overall leakage rate was shown between groups, as well as the distribution by different sites. The leak-related reoperation rate did not differ among the three groups.
Laparoscopic and robotic surgery, in this report, showed safety in ensuring oncological radicality with short hospitalization, benefits in all patients' functional recovery steps and a lower trend in complications rates.

Methods and analysis

General study design:
The overall purpose is to develop and maintain a multi-institutional database comprising of information regarding surgical, clinical and oncological features of patients that will be treated for gastric cancer with robotic, laparoscopic or open approaches and subsequent follow-up.
The main objective is to compare the three surgical arms on surgical and clinical outcomes, as well as on the oncological follow-up.

Specific aims:
AIM 1: To compare robotic and laparoscopic surgery to the open approach in terms of safety and feasibility based on the intraoperative outcomes.
AIM 2: To verify the respect of oncological principles through minimally invasive approaches by comparing histopathological findings to open surgery.
AIM 3: To compare the three treatment arms regarding the postoperative course.
AIM 4: To compare the incidence, types and severity of in-hospital and long-term complications after gastrectomy by the three approaches according to the Clavien-Dindo classification system[35]
AIM 5: To verify whether minimally invasive approaches ensure the same effectiveness as open surgery in terms of overall survival and disease-free survival at the scheduled endpoints.

Eligibility
Every patient is required to meet all the inclusion criteria and none of the exclusion criteria.
Inclusion criteria
- Histologically proven gastric cancer
- Preoperative staging work-up performed by upper endoscopy and/or endoscopic ultrasound, and CT scan and in accordance to international guidelines[14]
- Early Gastric Cancer
- Advanced Gastric Cancer
- Patients treated with curative intent in accordance to international guidelines[14]

Exclusion criteria
- Distant metastases: peritoneal carcinomatosis, liver metastases, distant lymph node metastases, Krukenberg tumors, involvement of other organs
- Patients with high operative risk as defined by the American Society of Anesthesiologists (ASA) score > 4
- History of previous abdominal surgery for gastric cancer
- Synchronous malignancy in other organs
- Palliative surgery

Data collection (main variables)

Patient Demographics

- Year of birth
- Sex
- BMI
- Surgical risk (ASA score)
- Concomitant illness
- Previous surgery
- Staging laparoscopy
- Neoadjuvant chemo/radio-therapy
- Pre-operative blood samples

Surgery

- Operation date
- Type of surgical approach (Open, Laparoscopy, Robotic)
- Type of gastric resection (Total gastrectomy, Distal gastrectomy, Pylorus-preserving gastrectomy, Proximal gastrectomy)
- Type of recostruction
- Anastomosis approach (intracorporeal, extracorporeal)
- Anastomosis performance (linear stapler, circular stapler, hand-sewn)
- Site and lenght of mini-laparotomy
- Placement of intra abdominal drain
- Placement of nasogastric tube
- Total operative time
- Estimated blood loss
- Conversion to open surgery
- Intraoperative complications
- Extent of lymphadenectomy
- Resection margins
- Surgical radicality (R)
- Number of retrieved lymph nodes

Tumor

- Location and diameter
- Depth of invasion (T classification)
- Number of metastatic lymph nodes
- Lymph node status (N classification)
- AJCC pathological stage
- Histological type

Post-operative clinical findings

- ERAS protocols adopted
- Length of postoperative hospital stays
- Patient mobilization (POD no.)
- Liquid diet (POD no.)
- Soft solid diet (POD no.)
- First flatus (POD no.)

In-hospital post-operative complications

- Type of complication
- Reoperation for complication
- Clavien - Dindo grade[35]

Early and late complications after discharge

- Date of occurrence
- Type of complication
- Death related to the complication
- Need of surgery

Follow-up

- Adjuvant chemo/radio-therapy
- Date of follow up visits
- Patient status at follow-up visits (alive, dead, lost to follow-up assessment)
- Disease-free or not during follow-up

Primary outcome measures

- Safety and feasibility of procedures: rate of intraoperative complications, rate of intraoperative death, rate of conversion to open surgery, average of estimated blood loss during surgery.
- Respect of oncological principles: average of retrieved lymph nodes, rate of patients achieving R0 resection, rate of patients achieving specimen margins free of disease, at the histopathological analysis.
- Effectiveness of surgery: overall survival and disease–free survival achieved at 1, 2, 3, 4, 5 years from surgery.

Secondary outcome measures

- Recovery after surgery: rate of post-operative blood transfusion, average of time to patient mobilization, average of time to resumption of peristalsis, average of time to starting oral intake, average of time to first flatus, average of length of intravenous antibiotic use, average of length of intravenous analgesic use, average of hospitalization after surgery until discharge.
- Early and long-term complications after surgery: rate of total complications, rate of specific surgical complications, severity of complications scored on the Clavien-Dindo classification system[35].

Statistical analysis

Based on the data of the registry every investigator can perform all the statistical analysis he needs for his researchers' purposes, while a basic analysis for monitoring the study will be performed as follows. SPSS version 23 will be used to carry out the interim data analyses.

The dichotomous variables will be expressed as numbers and percentages, while continuous variables as mean and SD, or median and IQR (minimum and maximum values). Continuous variables will be compared using one-way ANOVA analysis of variance with post hoc multiple comparison by Tukey's procedure.

Pearson's $\chi 2$ test or Fisher's exact test, as appropriate, will be used for analysis of categorical data.

The Z test with the Bonferroni correction will be used to evaluate statistical significance among the surgical approaches: Robotic, Laparoscopy, Open.

For each of these tests a value of $\alpha<0.05$ will be considered statistically significant.

Subgroup analysis will be done to evaluate the overall survival, by considering patients with follow-up details at the data extraction time.

Overall survival will be computed from the day of surgery to the day of death or to the last reported follow-up visit. Overall survival analysis will be performed using Kaplan–Meier curves. Comparison between different groups will be carried out using the log rank test.

Sample size

It is estimated from the IMIGASTRIC I study that the rate of procedures performed with minimally invasive surgery at referral institutes for gastric cancer, considering patients who follow inclusion and exclusion

criteria of this protocol, is of 65%.
According to the number and volume of the participating centers and to reach a sample of 1000 subjects treated with laparoscopic or robotic surgery, is estimated that data of at least 1500 patients need to be collected.

Study period and sites
The database will remain open for data collection (including the participation of other interested Institution) for at least 10 years, considering current available funds from the promoting institution (St. Mary's Hospital of Terni).
It is estimated that the sample size will be reached in 5 years. The maximum length of each patient for the oncological follow-up is 5 years. Subsequent amendments will extend the follow-up period based on the progress of the project.
The study has been shared by the members of the International study group on Minimally Invasive surgery for GASTRIc Cancer (IMIGASTRIC)[32]. The group involves some of the most important researchers and institutes around the world for the treatment of gastric cancer and began working in 2014.

Ethics and dissemination

Ethical aspects
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.
Investigators shall undertake to act according to the rules of the Institutional Review Board (IRB) and Ethics Committee (EC) regarding the prospective collection of data.

Potential risks and safety management
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.
Confidentiality and data security will be ensured by:
1) removing direct participant identifiers;
2) limiting access to information using the assignment of codes;
3) limiting access to information to center investigators.
Risks are minimized using appropriate tailor-made systems.
Data will be collected and recorded by all institutions through a specific online software (https://imigastric.logix-software.it/).
The system provides the following safeguards:
1. Data entry of patient information complies with the most stringent privacy regulations; sensitive data are not recorded on a server, but the software generates a reference code.
2. For each patient, the system generates an IT folder containing six specific areas to complete.
3. The software is designed to guide the user in data entry, thus avoiding the generation of errors.
4. The different fields are filled in by selecting the various options from drop-down menus available for each parameter. All characteristics to be entered have been previously standardized, without the need to write anything else when filling in the fields. Any considered variable derives from an analysis of all the data reported in previous studies found in the literature and in accordance with accepted guidelines[14].
5. The software uses predefined control instruments.
The data and safety monitoring plan for the research registry will involve routine monitoring by the organizing committee of any conditions that may negatively impact the confidentiality of information contained within the research registry.
In addition, any unauthorized access to medical record information contained within the research registry or to the database linking the registry information to participant direct identifiers will be reported to a data and safety monitoring board.

Study's website
A Study's website is available at: www.imigastric.com to obtain information and follow the news of the project. Contact information for the organizing secretariat and the coordinating staff is available there. Interested centers can join this prospective registry.

Publications
Each participating center, with equal right, will be able to access the data of the registry, perform statistical analysis, discuss the results, and freely write scientific manuscripts. However, each study that is generated based on the registry must be known by all Centers before final publication.

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Contributors
AP, JD were involved in conception of the study. JXL, EN, FB, AM, FC, BB, FQ, TL, DR, AN, AC, FG, NTN, OA, IAO, SB, FB, AA, LS, OI, CC, LL, AI, MC, GP, JSA, MG, YZ, SC, JG, DP, SDI, OSM, RS, LZ, NGC, CK, GA, ST, CHZ, AP, CMH and JD were involved in designing the study, analyzing the literature, references searching and in drafting the rationale. JXL, ST, CHZ, AP, CMH and JD were involved in description of the study methods.

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Competing interests
No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

Availability of data and materials
The datasets used and/or analyzed during the current study are available
from the corresponding author on reasonable request.

Ethics approval
The study was approved by the ethics Committee of CEAS Umbria (Prot. No. 7649/16/ON dated 18/02/2016).
This study is conducted in compliance with ethical

principles originating from the Helsinki Declaration, within the guidelines of Good Clinical Practice and relevant laws/regulations.

Provenance and peer review
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REVIEW

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Robotic surgery for gastric cancer: expert opinion from a western perspective

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ABSTRACT
Gastric surgery is one of the most relevant fields of development for minimally invasive technologies. Laparoscopy is now widespread, and several studies have demonstrated its feasibility and safety even in some advanced oncological procedures. Robotic surgery has several intrinsic advantages that theoretically can improve an extensive lymphadenectomy or the reconstruction phase.
Much remains to be addressed in this field and further studies are necessary to offer the patient the best possible approach based on his characteristics and the stage of his disease.
The present report offers an overview on robotics and its role in gastric surgery.

Background

Robotic technology has spread throughout the world in the last decades and Italy has been one of the first countries introducing robotic systems in Europe.

In recent years the number of procedures has dramatically increased.

Over 86 robotic systems are currently active, and the number of procedures is now over 13,000 operations per year. Therefore, nowadays, Italy together with France is the first country in Europe for the total number of robotic surgical procedures performed per year.

Robotic technology has revolutionized our approach to minimally invasive surgery.

In this context, many fields of interest are currently under development: new devices and platforms, imaging integrated technology, teaching opportunities, new techniques.

The Xi robot represents the 4th generation of the Da Vinci systems and the evolution of the previous Si version. Moreover, new devices have been produced with instruments even more advanced. For example, the endowristed robotic stapler that allows the surgeon to sectioning by a correct angle of vision from the console. The vessel sealer uses advanced radiofrequency energy and could be particularly useful for liver parenchyma transection.

Then, the single site surgery could open the possibility for new applications even for gastric surgery.

Today the Xi system offers the possibility of combining images from different sources. For example, it's possible to perform an intraoperative ultrasound or follow a gastroscopy, from the robotic console, together with the 3D view of the operative field. These developments are improving and changing the way we perform oncological surgical procedures and new concepts of surgery are now emerging: the navigation surgery and the targeted surgery[1].

Robotic technology represents also a huge opportunity for education. Young surgeons can perform different surgical steps of complex procedures through mentoring. Robotic simulators are also available.

So, training in robotic surgery can start at the simulator and then go through the execution of different surgical steps from the easier to the challenging ones, and finally approach the entire operation.

Robotic gastric surgery

Certainly, oncologic gastric surgery is one of the areas of greatest interest and development in the field of minimally invasive and robotic surgery[2-4].

Many centers have published their own experiences[5] and comparative studies, giving authors of systematic reviews and meta-analysis the opportunity to try to define the role of robotic surgery by comparing it with traditional laparoscopy or open surgery. However, the current level of evidence is far from being able to consider these procedures in common surgical practice. Current guidelines describe laparoscopy as a possible alternative to open surgery for early gastric cancer, while robotic surgery is recognized to have some advantages, but this approach is not mentioned in gastric cancer guidelines[6].

The main discussed limitations are the proper execution of an extended lymphadenectomy, when required, and a safe approach for reconstruction. The latter is still the object of controversy and most surgeons are concerned about the possibility to perform a totally intracorporeal procedure.

Face the reconstruction with new approaches: the Parisi's Technique

The technique we have developed for reconstruction after total gastrectomy is called "double loop method"[7-9] in which a first loop of bowel is measured and shifted up antecolic to directly perform the esophago-jejunal anastomosis. The jejunal loop is secured to the posterior wall of the esophagus with seromuscular interrupted stitches (second posterior layer of the anastomosis). The row of metallic stitches at the esophagus margin is removed and a 3 cm incision is made at the jejunum side. A double continuous suturing is performed with PDS 3/0. The anastomosis is completed with a second anterior layer performed with interrupted stitches.

The second loop (alimentary limb) is measured up to 40 cm starting from the esophago-jejunostomy and is fixed to the biliary limb close to the previous anastomosis on its left side.

A jejuno-jejunal anastomosis is now performed as usual. Finally, the two anastomoses are interrupted by firing the linear stapler.

Preliminary results of this approach were previously reported[7, 9].The double loop method increases the feasibility of a full hand-sewn intracorporeal reconstruction.

Robotic Gastrectomy in Italy: IMIGASTRIC data

We have looked to the data collected in the IMIGASTRIC database[10-13] and we extracted those patients who underwent robotic surgery in Italian Institutions to show their characteristics and outcomes.

Overall data of 222 patients were found. The average age was 68yo, BMI around 25, 50% of patients had comorbidities. At the pathology examination 56% of cases were Advanced Gastric Cancer, most with undifferentiated histology. Majority of patients, 74%, underwent a distal gastrectomy.

Among the intraoperative outcomes, mean EBL was 137ml, a low rate of intraoperative complications occurred, there were no major intraoperative complications or death.

Overall, during the postoperative course, patients underwent mobilization on the 1 postoperative day, the liquid diet was administered at the 3 POD and a soft solid diet on the 4 POD. Intravenous analgesics were used for an average of 3 days. Mean hospital stay resulted 8 days. 16% of patients experienced medical or surgical related postoperative complications. The majority were low-grade complications (CD I+II), while only 5 patients (2%) had major complications requiring a reoperation. 4% of patients were readmitted after discharge. No death occurred. Among surgical complications, 6 patients had leakages (leakage rate 2,7%) but only one underwent reoperation.

Conclusion

Despite the potential benefits of robotic surgery, there is still a lot of research to be done in this field and the scientific community is asking what strategies need to be adopted in future studies to develop and standardize minimally invasive surgery.

That's why, 3 years ago, we have established a multi-institutional cooperation with a project aimed to collect eastern and western data in a large registry, called IMIGASTRIC. A network is today needed to bring together different experiences and institutions with the aim of improving medical and surgical care in gastric cancer patients.

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TECHNICAL NOTE
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Reconstruction methods during laparoscopic gastrectomy

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ABSTRACT
Laparoscopic surgery has been progressively developed in gastric cancer surgery.
Although the feasibility of laparoscopic procedures has been demonstrated, there are many issues being debated, including the feasibility of intracorporeal anastomoses.
The anastomosis execution method has a major impact on perioperative outcomes.
Few articles in the literature described a full laparoscopic execution of the reconstructive phase and others do not explained how this phase is run or mixed procedures were reported.
This article offers the reader detailed description of the most popular laparoscopic methods and how they are performed.

Background

Minimally invasive gastrectomy is gaining popularity worldwide as it is associated with earlier recovery of patients when compared with traditional open surgery[1-3].

Surgical outcomes related to emerging techniques for reconstruction deserve attention.

Laparoscopic gastrectomy has conventionally been followed by reconstruction through a mini-laparotomy.

Recently, investigators have described numerous techniques for totally intracorporeal procedures to improve surgical efficiency and invasiveness.

Some investigators have shown quicker recovery of bowel function when compared with extracorporeal reconstructions[4].

Probably, this allows for less manipulation of the bowel and is useful particularly in obese patients where access through a minilaparotomy can be limited.

In this technical note we'll focus on the most interesting and newest strategies for reconstruction proposed for the laparoscopic approach.

Laparoscopic Techniques

"Laparoscopy-assisted gastrectomy" requires a minilaparotomy for specimen removal and extracorporeal anastomoses. This approach is still widely performed and applied in most clinical trials.

Intracorporeal anastomosis, which made this procedure the so called "totally laparoscopic surgery," enables more sophisticated reconstruction methods.

It can decrease the length of the mini-laparotomy and shift the incision for specimen retrieval in more convenient positions (below the umbilicus, McBurney incision), which results in reduced incision-related pain.

After intracorporeal Billroth I was safely performed with delta-shaped anastomosis, totally laparoscopic distal subtotal gastrectomy gained popularity.

Many efforts have also been made to perform the intracorporeal esophago-jejunal anastomosis during total gastrectomy. While hand-sewn anastomosis is not an attractive choice in the laparoscopic approach, it is gaining attention by robotic surgeons[5].

Reconstruction after distal gastrectomy

Numerous procedures and technical solutions have been proposed for reconstruction during laparoscopic distal gastrectomy.

Gastro-duodenostomy is one of the most common types of reconstruction.

In literature[6], extracorporeal procedures are performed with the modified double stapling method or the posterior wall method, while the modified delta shaped method is the most attractive technique for the intracorporeal approach.

For the two extracorporeal methods, usually a 5 cm length of transverse mini-laparotomy is made on the right upper quadrant of the abdomen.

The Modified Delta-Shaped Method, as developed by Prof. Huang[7], is performed with the following described steps.

The stomach is resected from the greater curvature to the lesser curvature. Small incisions are created on the greater curvature of the remnant stomach and the anti-mesenteric side of the jejunum located 12–15 cm distal to the Treitz ligament. After the 60mm endoscopic linear stapler is opened, one stapler limb is first inserted into the jejunum incision towards the direction of the jejunal proximal end. The jejunum is pulled out forward, and the other limb of stapler is inserted into the incision on the remnant stomach greater curvature. The stapler is fired to complete a side-to-side gastrojejunostomy with a common stab incision.

The common stab incision is closed using the 60mm linear stapler. At the end we can clearly see the inverted "T" shaped appearance of the Modified Delta-Shaped Method anastomosis.

Other possible reconstruction is through a gastrojejunostomy.

Surgeons have described the Billroth II method or the Roux-en-Y method, both performed with the extracorporeal or the intracorporeal approach.

The Billroth II method is very fast and convenient. Small incisions are created on the greater curvature of the remnant stomach and the anti-mesenteric side of the jejunum. After the 60mm endoscopic linear stapler is opened, one stapler limb is first inserted into the jejunum, while the other limb into the incision on the remnant stomach greater curvature. The stapler is fired to complete a side-to-side gastro-jejunostomy with a common stab incision. The latter is closed using the linear stapler.

In case of a Roux-en-Y extracorporeal reconstruction an upper midline or a left subcostal transverse skin incision is necessary[8].

A totally Roux-en-Y intracorporeal reconstruction [9] can be performed with the following described steps. A small opening is made at the end of the stapling line on the greater curvature side of the stomach and at the jejunum, 20 cm away from the Treitz ligament. Then the linear stapler is inserted and fired. The common entry hole is closed by the linear stapler. Next, in the same manner, the side to side jejuno-jejunostomy is performed at 25 cm below the gastro-jejunostomy using the linear stapler. Finally, a 45mm knifeless linear stapler (uncut procedure) is applied to the afferent loop between the gastro-jejunostomy and jejuno-jejunostomy for preventing bile reflux.

Reconstruction after total gastrectomy

Laparoscopic esophago-jejunostomy is the most critical and technically challenging step during laparoscopic total gastrectomy. Various methods for esophago-jejunostomy have been introduced, but no standard protocol exists.

Extracorporeal and intracorporeal anastomosis are described, and further classified into side-to-side anastomosis using linear staplers and end-to-side anastomosis when using circular staplers.

Usually, procedures involving the circular stapler need at least a 5 cm vertical mini-laparotomy in the epigastrium. It is possible to use a laparoscopic purse-string suture instrument, while other surgeons prefer the use of an anvil delivery device (OrVil) that is designed to insert the anvil trans-orally into the esophagus. The side-to-side jejunojejunostomy is usually performed extracorporeally using a linear stapler.

The Intracorporeal Isoperistaltic Jejunum-Later-Cut Overlap method performed by Prof. Huang[6, 7] can be performed with the following steps.

The esophagus is transected applying a linear stapler. Small incisions are made on the left side of the esophagectomy margin and on the boundary of the mesenteric membrane of the jejunum about 20 cm from the Treitz ligament. After each incision is inserted into one of the limbs of the stapler, the fork of the stapler is closed and fired to perform a side-to-side esophagojejunostomy.

Confirmation of no injury or bleeding is made via the common stab incision, which is then manually sutured.

Finally, the lateral-lateral jejunojejunostomy is created at about 40-45 cm from the esophageal-jejunum anastomosis.

Conclusion

laparoscopy is a constantly evolving surgery and nowadays the development of new instruments and better viewing images allows the surgeon to safely deal with demanding operation steps, such as reconstruction after gastrectomy.

A completely intracorporeal approach appears to offer the patient significant benefits in the postoperative period and should be the approach of choice in minimally invasive surgery.

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