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REVIEW ARTICLE

Minimal-invasive gastrectomy: what the west can learn from the east?

Felix Berlth[1,2,3] · **Han-Kwang Yang**[1,2]

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Abstract
Minimal-invasive gastrectomy has been established as commonly used method for the early gastric cancer in Korea and Japan. From the first laparoscopic cancer gastrectomy in 1992 in Japan, numerous prospective randomized trials from these two countries have gained the evidence for non-inferiority or even specific benefits compared to open surgery. In Korea, the "Korean Laparoscopic Gastrointestinal Surgical Study Group" (KLASS group) founded, in 2004, successfully gained evidence not only in regards of oncological safety of laparoscopic gastrectomy, but also for the impact of different reconstruction methods and alternative extents of luminal resection on postoperative outcome and quality of life. Awaited results of latest studies from Korea, Japan, and China may suggest laparoscopic approaches as an option even in advanced gastric cancers. These studies could potentially be the starting point to find the role of laparoscopic gastrectomy in the west, where the incidence of gastric cancer is rather lower; the cancers are mostly diagnosed in advanced stages, and often, a perioperative chemotherapy is applied. Robotic (-assisted) gastrectomy was not shown to be superior to laparoscopic resection in Korea, but new technological developments should continuously be evaluated in clinical trials regarding a potentially favorable learning curve, which might play a key role in regards of the limited case load per center of gastric cancer in the west. This review summarizes the history of laparoscopic cancer gastrectomy in Asia and points out the important steps of establishing a nation-wide scientific network to support the surgical routine by the necessary evidence with a focus on Korea.

Keywords Minimal-invasive surgery · Gastric cancer · KLASS · Laparoscopic gastrectomy · Robotic gastrectomy

Introduction

Gastric cancer is responsible for one of the largest tumor burden worldwide; approximately 600,000–700,000 cases are diagnosed each year [1]. The incidence of gastric cancer in fact dramatically varies among different continents and regions. Korea and Japan show the highest incidence of gastric cancer, while, in Europe and the United States, statistics show a stable decrease of newly diagnosed gastric cancers since the middle of twentieth century [2]. In contrary to a lower incidence, a much higher proportion of advanced gastric cancer is diagnosed in western countries, whereas, in Japan and Korea due to general awareness and government supported screening programs, most gastric cancers are diagnosed and treated in an early stage (about 70%), resulting in a favorable survival outcome [3].

Minimal-invasive operation techniques and technologies have been developed to improve operation methods and reduce the patient trauma during surgery. In 1992, Seigo Kitano was the first surgeon to perform a laparoscopic resection for gastric cancer and from this time on based on multiple studies the laparoscopic approach has become more and more established in gastric cancer surgery, especially for the early gastric cancer [4]. In Japan, the "Japanese Clinical Oncology Study Group" (JCOG) is the platform to launch prospective randomized trials to evaluate the effects of gastric cancer in general and of minimal-invasive gastric cancer surgery; specifically, in Korea, the "Korean Laparoscopic Gastrointestinal Surgical Study Group" (KLASS), founded in 2004 rapidly developed a nation-wide system to launch surgical trials dealing with the latest issues in gastric cancer

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✉ Han-Kwang Yang
hkyang@snu.ac.kr

[1] Division of Gastrointestinal Surgery, Department of Surgery, Seoul National University Hospital, Daehak-ro 101, Jongno-gu, Seoul 03080, Korea

[2] Cancer Research Institute, Seoul National University, Seoul, Korea

[3] Department of General, Visceral and Cancer Surgery, University Hospital of Cologne, Cologne, Germany

treatment and guarantee a certain quality of care and standardized treatment as a challenging aspect for prospective surgical trials. The evidence of laparoscopic gastrectomy is carefully discussed in the latest "Gastric cancer treatment guidelines" of the Japanese gastric cancer association and it is believed that laparoscopic gastrectomy is recommended as the standard treatment in the following editions [5]. However, in the same time, robotic and robotic-assisted surgery is a technology more and more challenging the laparoscopic approach as a second option to perform minimal-invasive gastrectomy. In respect of the timeline between the first laparoscopic gastrectomy and the successful performance of randomized--controlled trials for laparoscopic gastrectomy, it seems most important that the robotic approach is embedded into a scientific environment to carefully evaluate the chances and benefits on one hand and the risks and disadvantages on the other. So far, the fact that the robotic approach is the most cost-intensive one and that the device is mostly launched by a single company creates a certain difficulty for scientific evaluation. However, due to the caseload and scientific infrastructure in gastric cancer surgery, Asia should play a prominent role in evaluating new technologies and new surgical treatment options to be suggested to be beneficial. Western countries can learn in different ways from those efforts of Japan, Korea, and recently China. Obviously, the gained evidence in minimal-invasive gastrectomy can be confirmed in western patients, where some difficulties as more advanced disease and more obese patients are expected. Second, the scientific infrastructure in these Asian countries towards gastric cancer surgery can be an example how to effectively create evidence and monitor a highly standardized surgical treatment at the same time.

The following article reviews the achievements of the Asian study groups evaluating minimal-invasive gastrectomy for gastric cancer, with a special focus on the Korean situation and the studies launched by the "Korean Laparoscopic Gastrointestinal Surgical Study Group".

Korean Laparoscopic Gastrointestinal Surgical Study Group: KLASS

KLASS was founded in 2004 not only to share the experience and techniques of laparoscopic approach but also to bring scientific evidence to the laparoscopic gastric cancer surgery. The idea of the study group was to find the most effective way to create highly standardized scientific evidence on laparoscopic gastric cancer surgery. In that sense, a very transparent system of scientific incentives for the participants and a strict surgical quality control system were established.

For successful collaboration, a system was created that gives any participating surgeon the chance to be in charge of future studies. After launching the first trial, KLASS-01, each of the following trials was supposed to be guided by an investigator with substantial contribution to the previous study. Besides this important position as principle investigator (PI), other participants are able to present the study in scientific meetings or write the manuscript as author. The idea was to balance the responsibility but also the scientific benefits for each member of KLASS to promote a stable recruitment in the studies and keep updated with new study proposals. There are usually two KLASS meetings per year, where the running trials and upcoming studies are openly discussed.

Surgical quality assessment plays a prominent role in the KLASS trials. For example, before launching KLASS-02, a quality assessment of the laparoscopic gastric cancer surgery of all surgeons that applied was performed [6]. The number of laparoscopic and open distal gastrectomy cases per surgeon was asked to be more than 50 cases and the number of those at the institution was asked to exceed 80 cases per year. The surgeons were visited in their institutions by two experienced surgeons. In addition, and in tight collaboration with the experienced international investigators, videos of the resections by each surgeon were assessed. As every surgeon was asked to submit six videos (three open and three laparoscopic) and in every video case, 22 items were evaluated by five domestic and international investigators, so a total number of 660 items were evaluated for each surgeon who applied for KLASS study participation. This application process guaranteed a highly standardized quality of surgical care during the trial. In this moment, the study committee was taking advantage of the fact that laparoscopic surgery can be easily recorded and reviewed as many times as desired from the surgeon`s perspective. Regarding this point, any camera-guided surgery is able to bring a new standard of care into the controlled trials, which contributes to the scientific output in the end.

So far, seven KLASS trials has been launched and more study proposals are under discussion, so it seems obvious that the establishment of a nation-wide study group has already supported the scientific exchange among surgeons, has set a new bar for the standard surgical care, and concludes in well-recognized scientific output as the publications of KLASS-01 [7].

Oncological safety of laparoscopic gastrectomy KLASS-01/KLASS-02 and KLASS-06

The first major topic of the KLASS trials was the oncological safety of laparoscopic gastric cancer surgery compared to open surgery. For that reason, KLASS-01 compared laparoscopy-assisted distal gastrectomy with open surgery for

early gastric cancer (cT1N0) with 5-year overall survival as primary endpoint. Secondary endpoint was the 30-day postoperative morbidity. The study started in 2006 as a phase 3, multicenter (13 University Hospitals, 15 surgeons), open-label, non-inferiority prospective randomized-controlled trial. The recruitment of overall 1416 patients who were randomly assigned to either open distal gastrectomy (ODG) or laparoscopy-assisted distal gastrectomy (LADG) was finished in 2010 [7]. The reconstruction was a matter of choice of the surgeon either Billroth-I, Billroth-II, or Roux-en-Y. The results dealing with the secondary endpoint were published in 2016, showing that LADG were resulting in a significantly lower overall postoperative complication rate compared to ODG in both analyses modified intention-to-treat (LADG $n=686$; ODG $n=696$, $p=0.009$) and per-protocol analysis (LADG $n=644$; ODG $n=612$; $p=0.001$). Dividing postoperative complications into categories significantly lower rate of wound complication was found for the LADG group. Results dealing with the primary endpoint were presented at the ASCO meeting 2016 and overall 5-year survival rates were similar in both groups in the intention-to-treat analysis (LADG 95.8%; ODG 95.9%, $p=0.774$), concluding that LADG is non-inferior to ODG in regards of long-term survival and represents an acceptable alternative in Stage I gastric cancer [8]. A comparable Japanese phase 3 trial (JCOG0912) for the early gastric cancer was recruiting between 2010 and 2013 and short-term outcomes were published in 2017 were also indicating that LADG is safe in terms of short-term clinical outcomes [9]. As, based on these results, laparoscopic approaches became more and more the standard treatment in the clinical routine of early gastric cancer in Korea and Japan, a similar study (KLASS-02) was launched by the KLASS group dealing with the oncological safety for laparoscopy-assisted D2 distal gastrectomy advanced gastric cancer (cT2–cT4a) and recruited between 2011 and 2015 with a 3-year relapse-free survival as primary endpoint. Short-term postoperative results of a Japanese phase II trial (JLLSSG0901) were indicating acceptable postoperative complication rates for LADG with D2 lymph-node dissection in advanced cancer [10]. Short-term postoperative results of KLASS-02 presented in 2016 for 1011 randomized patients in an intention-to treat analysis indicate that the overall complication rate was significantly lower for the LADG groups (16.4% vs. 24.3%; $p=0.002$) [11]. Results dealing with the primary endpoint are expected to be available in 2018 and could, in case of non-inferiority, change the paradigm of open surgery for advanced gastric cancer at least in Korea. These first results dealing with oncological safety for LADG in the early and advanced gastric cancer were encouraging enough to conduct a similar trial design to evaluate laparoscopic total gastrectomy for clinically advanced gastric cancer. This study, KLASS-06, is expected 2018 to be kicked off and is designed to recruit 772 patients for randomization. These trials are able to be the underlying evidence for the use of laparoscopy (-assisted) resection of any type of surgically relevant gastric cancer with the exception of multivisceral combined resections and in respect of the surgeon's preference to perform an adequate resection in any patient.

Reduced laparoscopic surgery for the early cancer: SENORITA Trial

In addition to the important studies being conducted by the KLASS group, the Korean SENORITA phase III trial is evaluating the oncological safety of sentinel node-guided reduced laparoscopic stomach preserving surgery for the early gastric cancer < 3 cm in diameter compared the standard laparoscopic approach [12]. This approach is based on the results of the quality control phase 2 trial in which in 100 out of 112 recruited patients which a sentinel basin could be resected after injecting a dual tracer submucosal. Ten patients of those showed of lymph-node metastases in final pathology after standardized resection and in all ten cases were detected by the sentinel biopsy [13]. The underlying idea is to provide (more) stomach preserving and less aggressive surgery for node negative early gastric cancer patients to reduce morbidity and improve postoperative quality of life. As the oncological safety of sentinel lymph-node-based surgery in gastric cancer is under constant discussion, the SENORITA trial at first focused on this aspect. The study is designed to recruit a sample size of 580 patients using 3-year disease-free survival as a primary endpoint. Data maturation has to be awaited to evaluated the role of this approach, as a first interim analysis after 462 included patients failed to evaluate non-inferiority due to lack of data maturation. Recruitment was stopped to await those results [14]. Difficulty in studying sentinel node is that a large number of the early stage disease are necessary to get enough significance in the safety of this procedure in the node positive patients. Theoretically, we can have only about 20 patients LN positive, even though we have recruited 100 early gastric cancer patients. Therefore, for the validation of sentinel node navigation surgery, we need quite high number of patients (1000 patients' enrollment and then 200 LN positive patients).

Short-term and functional outcomes in laparoscopic gastrectomy KLASS-03-05 and KLASS-07

After dealing with the most important questions regarding the oncological non-inferiority of laparoscopic gastric cancer surgery, other aspects like postoperative morbidity and

functional outcomes became another focus of the KLASS group. In this means, KLASS-03 was conducted to evaluate the postoperative morbidity/mortality after laparoscopy total gastrectomy for upper cT1N0, cT1N1, or cT2N0 gastric cancer patients. 168 were prospectively assigned between 2012 and 2013, and were not only to show a short-term safety for the laparoscopic total gastrectomy as underlying basis for KLASS-06 trial but also to compare different reconstruction methods preferred by different surgeons. The results were presented in 2017 KINGCA meeting and are confirming acceptable safety of laparoscopic total gastrectomy.

The KLASS-04 trial was conducted to evaluate the functional outcome of pylorus-preserving gastrectomy compared to distal gastrectomy. As the oncological safety of the pylorus-preserving surgery was proven by several Japanese and Korean trials before and this principle is already part of the Japanese treatment guidelines for the early gastric cancer with a distal tumor border of at least 4 cm to pylorus, this trial focuses on the prevalence of postoperative Dumping-syndromes [5, 15]. 256 patients meeting the criteria were randomly assigned to laparoscopy-assisted pylorus-preserving gastrectomy (LAPPG) or LADG between 2015 and 2017. Short-term postoperative outcomes are expected to be presented in 2018. KLASS-05 again contributed to the evaluation of stomach preserving resection methods and is aimed to compare laparoscopic total gastrectomy (LTG) with laparoscopic proximal gastrectomy and double tract reconstruction (LPG+DT) for upper third clinically early gastric cancer in terms of postoperative hemoglobin-level development and cumulative Vitamin B12 supplement in the first 2 years after operation [15]. It is an important step towards standardization of stomach preserving surgery as still for even early upper third lesions; total gastrectomy is the standard resection. The study started in 2017 and is expected to finish recruitment of 138 patients in 2018. KLASS-04 and KLASS-05 were designed to evaluate the role of alternative luminal resection methods followed by different reconstruction methods for either more distal cancer (LAPPG vs. LADG; KLASS-04) or proximal cancer (LTG vs. LPG; KLASS-05). However, short-term and functional outcomes are not only supposed to depend on the extend of luminal resection and type of reconstruction but potentially also on the use of laparoscopy-assisted or totally laparoscopic approaches. As it is also a matter of learning curve to provide a certain surgical routine in the sometimes technical challenging intracorporeal anastomotic techniques, a trial comparing laparoscopy-assisted distal gastrectomy and totally laparoscopic distal gastrectomy (KLASS-07) was proposed at the KINGCA meeting 2016 and is anticipated to start recruitment in the first half of 2018. Total 442 are aimed to include and postoperative morbidity is used as a primary endpoint. Quality-of-life measurement is included in this study as secondary endpoint. Another special feature about KLASS-07 is the fact that it is designed as a Korean–Chinese collaboration study. In reference to the KLASS group China has successfully established a similar national institution to produce scientific evidence for laparoscopic surgery, the "Chinese Laparoscopic Gastrointestinal Surgery Study Group" (CLASS group), which has already successfully published data on laparoscopic gastrectomy in advanced gastric cancer [16].

Outcomes of robotic (-assisted) gastrectomy in comparison to laparoscopic approaches

Lately, not only laparoscopic surgery is supposed to provide the benefits of minimal-invasive surgery for gastric cancer patients. The robotic (-assisted) surgery has become a second and quite different approach to perform camera-guided surgery. However, interestingly the scientific evidence for this technology regarding gastric cancer surgery has not reached the level of the laparoscopic approach. Actually, it is not surprising to consider this so-called robot surgery which is a simply laparoscopic surgery using remote-controlled laparoscopic instrument which has advantage of articulating devices.

Several retrospective trials especially from Korea were indicating that the robotic approach was not inferior to the laparoscopic techniques [17]. The robotic technology as for now is much more cost-intensive, and for that reason, superiority should be expected to justify it as a standard method. In addition, the fact that so far mainly one company is dominating the market is a general matter of concern when dealing with robotic surgery in general surgery/surgical oncology. To make the best possible scientific contribution to this upcoming technology, in Korea, a prospective comparative phase 2 trial comparing laparoscopy-assisted gastrectomy with robotic-assisted gastrectomy for cT1–cT3 gastric cancer was conducted in 2011. Within less than 2 years, 434 patients were enrolled and it was shown that, regarding the primary endpoint (postoperative morbidity), both approaches were similar (overall complication rate robotic 11.9% vs. laparoscopic 10.3%). Differences in operation time and costs of surgery were seen in favor of laparoscopic gastrectomy. The authors concluded that robotic gastrectomy is not superior compared to laparoscopic gastrectomy [17]. As this study included a relatively wide spectrum of patients, a subgroup analysis was performed to stratify for resection type, BMI, and type of lymph-node dissection. The authors of this study concluded that robotic surgery can be beneficial in terms of lower blood loss for patients undergoing D2 lymph-node dissection [18]. Probably, the main reason why robot-assisted gastrectomy versus conventional laparoscopic gastrectomy did not show any significant clinical outcome would be because ultrasonic shears are usually used in both

robotic and conventional laparoscopic gastrectomy in Korea. Ultrasonic energy devise cannot be articulate and loose the advantage of robotic approach. Recently, in Japan, a phase II study of robot-assisted gastrectomy demonstrated less pancreatic fistula compared to historic data. In this study, Japanese surgeons use bipolar forceps as energy device which is rather pinpoint application with ease of articulation. However, this result should be confirmed by prospective trials. However, for clinical trials, funding is essential, and like any new chemotherapeutic agent, medical industry's role for funding is necessary.

We are expecting more companies to plan launch more robotic systems, and then, we will have more active research on robot-assisted surgery.

Discussion

In the last decade, certainly minimal-invasive approaches for gastric cancer did not only become more popular in clinical routine but were supported by strong evidence from prospective trials. Besides the JCOG trials and the Japanese evidence, Korea and mostly the KLASS group were successfully conducting the most important trials. For western countries with both, a lower incidence of gastric cancer in general and a higher proportion of advanced cancer at time of diagnosis, not all studies seem to be most relevant at first. For instance, pylorus-preserving gastrectomy is not published to be performed in western countries most likely due to the lack of early cancers and lower level of centralization. However, even KLASS-04 trial might potentially provide benefits for western clinical practice as the KLASS trials in general are a very good example, how the boundaries of surgery can carefully be pushed to a new level if supported by scientific evidence. While KLASS-01 was dealing with the early gastric cancer, KLASS-02 and KLASS-06 are evaluating the role of laparoscopic oncological accuracy for advanced gastric cancer, where a D2 lymph-node dissection is needed. These studies could only be launched in support of the previous studies dealing with the safety of laparoscopic surgery in general and long-term-outcome for early gastric cancer. If KLASS-06 is able to show a non-inferiority for laparoscopic total gastrectomy in clinically advanced gastric cancer, it is potentially one of the most important results to influence the use of minimal-invasive techniques and in gastrectomy in western countries. However, not only the outcome results of the KLASS and JCOG trials and other Korean and Japanese groups could help to standardize the use of minimal-invasive techniques in gastrectomy in western countries. The rapid and successful development of the KLASS group since 2004 itself can be a good example, how surgeons can cooperate nation-wide and provide the necessary evidence for the clinical routine. It seems mandatory, that western countries produce their own evidence in gastric cancer surgery as most countries are dealing with a very different situation compared to Japan and Korea. The fact that the case load per center might be significantly lower in the west even emphasizes the importance of nation-wide or even international collaboration. As the KLASS group started with similar purposes in 2004, in the era of high-definition camera-guided surgery, it becomes rather easy to find a platform to share each center experience and standardize the procedures before starting the actual trials. This way, the outcomes are strong for a certain way which the surgery is carried out, which is crucial in times in which more individualized treatment strategies are desired to be established. Potential study purposes might also arise from the epidemiology and medical infrastructure in the west. As, for now, two different technical and technological approaches exist to perform gastric cancer surgery (laparoscopic and robotic), the influence on the learning curve and the impact on results in lower incident environments could be investigated. Some centers already prefer the robotic approach over the laparoscopic, because a lower number of cases are assumed to overcome the learning curve. However, evidence is needed for these assumptions; otherwise, the best oncological and short-term outcome cannot be guaranteed for the patients. From the past, we have learned that there is a certain time period appearing most appropriate to evaluate the benefits and risks of certain surgical techniques in randomized trials. After the one way or the other is established as the widely accepted standard treatment, it becomes very difficult or even impossible to compare two surgical approaches in randomized trials. Japan and Korea tried to answer the most important questions regarding laparoscopic gastrectomy after the procedures became safe enough and were able to be carried out by several surgeons in a standardized way. Motivated by this experience, the east can only encourage the west to act likewise and accompany the establishment of minimal-invasive techniques in gastric cancer surgical routine by the necessary scientific evidence that can only be gained from randomized-controlled trials (Table 1).

Table 1 Korean multicenter prospective trials for minimal-invasive gastric cancer surgery

Trial	Study arms	Primary endpoint	Secondary endpoints	Recruitment	Results
KLASS-01 (Phase III) NCT00452751	LADG versus ODG in cEGC	Overall 5-year survival	Disease-free survival, morbidity and mortality, quality of life, inflammatory and immune response, and cost-effectiveness	2006–2010 (1416 patients)	LADG non-inferior, LADG lower overall complication rate
KLASS-02 (Phase III) NCT01456598	LADG versus ODG inr cAGC	Overall 3-year relapse-free survival	3-year overall survival, morbidity and mortality, postoperative recovery index, and quality of life	2011–2015 (1050 patients)	LADG lower overall complication rate
KLASS-03 (Phase II) NCT01584336	LTG	Morbidity/mortality	Surgical outcomes according to several methods of reconstruction and the postoperative course	2012–2013 (168 patients)	To be published
KLASS-04 (Phase III) NCT02595086	LAPPG versus LADG in cEGC	Postoperative dumping-syndrome	3-year relapse-free survival and overall survival, morbidity and mortality, body weight change, fat volume change on abdominal CT scan, change of protein and albumin, quality of life, incidence of gallstone, and gross and microscopic changes measured by gastroscopy	2015–2017 (256 patients)	Waiting for data maturation
KLASS-05 (Phase III) NCT02892643	LPD+DT versus LTG in cEGC	Hb development and VitB12 supplement 2 years after surgery	Morbidity/mortality, QoL, 3-year relapse-free survival, overall survival, reflux esophagitis	2017-ongoing (138 patients)	–
KLASS-06 (PhaseIII) NCT03385018	LTG versus OTG in cAGC	3-year relapse-free survival	Morbidity/mortality, 5-year relapse-free survival, 3-year overall survival	Not yet started (772 patients)	–
KLASS-07 (Phase III) NCT03393182	LADG versus TLDG	Morbidity/mortality	QoL	Not yet started (442 patients)	–
Robotic (Phase II) NCT01309256	RAG versus LG	Morbidity/mortality	Operative time, blood loss, rate of open conversion, recovery of bowel function, length of hospital stay, and financial costs	2011–2012 (434 patients)	Robotic gastrectomy is not superior to laparoscopic gastrectomy
SENORITA (Phase III) NCT01804998	Sentinel lymph-node biopsy-guided laparoscopic stomach preserving resection versus standard laparoscopic gastrectomy	3-year disease-free survival	Morbidity/mortality, QoL	2013–2016 (462 patients) recruitment stopped to await data maturation	New interim analysis after further data maturation

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Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interests.

Research involving human participants and/or animals This article does not contain any studies with human participants or animals performed by any of the authors.

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