



A significant difference between two randomized controlled trials to compare laparoscopic and open distal gastrectomy for early gastric cancer

Chang Min Lee, Sungsoo Park

Department of Surgery, Korea University College of Medicine, Seoul, 02841, Korea

Correspondence to: Dr. Sungsoo Park, MD, PhD. Department of Surgery, Korea University College of Medicine, 73, Incheon-ro, Seongbuk-gu, Seoul, 02841, Korea. Email: kugspss@korea.ac.kr.

Comment on: Katai H, Mizusawa J, Katayama H, *et al.* Survival outcomes after laparoscopy-assisted distal gastrectomy versus open distal gastrectomy with nodal dissection for clinical stage IA or IB gastric cancer (JCOG0912): a multicentre, non-inferiority, phase 3 randomised controlled trial. *Lancet Gastroenterol Hepatol* 2020;5:142-51.

Received: 15 April 2020; Accepted: 14 May 2020; Published: 30 December 2020.

doi: 10.21037/dmr-20-47

View this article at: <http://dx.doi.org/10.21037/dmr-20-47>

Since Kitano *et al.* first reported laparoscopy-assisted distal gastrectomy (LADG) in 1994 (1), laparoscopic approach has been widely accepted as an option for early gastric cancer. Recently, Korean Laparoscopic gAstrointestinal Surgery Study group (KLASS) issued the results of a multicenter study (KLASS-01) showed that laparoscopic gastrectomy is comparable to open gastrectomy with respect to long-term oncologic outcomes in gastric cancer (2). About 4-year later, as JCOG0912 study, a randomised controlled trial (RCT) performed by Japan Clinical Oncology Group (JCOG), also showed the similar results (3), laparoscopic surgery can be further strongly supported in terms of the long-term oncologic efficacy for the treatment of stage I gastric cancer.

Although JCOG0912 study showed the similar information regarding the long-term survival to KLASS-01, it has a significant discriminating feature with regard to interpretation of the final results.

Most of all, the clinical outcomes of JCOG0912 added the more emphasized universality than those of KLASS-01. This feature is correlated with the current status of each country in which RCT was performed. In Korea, even before the rise of LADG, gastric cancer surgeries had been concentrated in the university hospitals. Thus, the newly introduced procedure, laparoscopic surgery for gastric cancer, should be mainly tried in the university hospital. Moreover, for quality control, the surgeons who want to participated in KLASS-01 trial must satisfy the following conditions; (I) the surgeons who had performed at least 50

cases each of LADG and open distal gastrectomy (ODG), (II) the surgeons who perform more than 80 cases of either LADG and ODG per year, and (III) the surgeon who passed the validation process through reviewing their unedited video performing LADG. In Korea, at the time of initiating KLASS-01 study, the surgeons who met these requirements were limited in the university-associated centers (4). This process is apparently necessary to eliminate the confounding variables regarding the surgeon factors in the surgery-associated study. Conclusively, due to this quality control program, KLASS-01 trial has been processed in the similar level of the university hospitals, and therefore this study reflected the procedures performed in the high-volume centers at that time when LADG rose in Korea.

However, a considerable number of local institutes have participated in JCOG0912 trial, whereas only the university-associated centers had participated in KLASS-01 study. Although JCOG also accomplished the quality control before the actual enrollment of JCOG0912, some systemic differences exist between two trials. At first, JCOG0912 trial did not indicate the number of surgeries per year (3), and therefore the participating institutes were not limited by the patient-volume. In addition, the requirements were different between the ODG and LADG groups in JCOG0912; while 60 or more open gastrectomies were accredited in the ODG group, the surgeons who allocated in the LADG group should be accredited for 30 or more ODG and LADG procedures as well as

certification by the JSES (Japan Society for Endoscopic Surgery). Even though we ignore the numeric differences of each requirement in KLASS-01 and JCOG0912, it is remarkable that the existence of the certification system could make an important difference between two studies. At the time of initiating the multicenter RCT, whereas KLASS emphasized the number of procedures per year to compensate the absence of the certifying system for LADG, JCOG just required the certification by the JSES. Therefore, regardless of the patient-volume, any accredited institutes (including the local hospitals) could participate in JCOG0912. This difference might be the reason why KLASS-01 reported the shorter operation time and smaller blood loss than JCOG0912. Nevertheless, since the number of harvested lymph nodes in KLASS-01 and JCOG0912 were equivalent, we never deny the oncologic accuracy of JCOG0912.

Acknowledgments

Funding: None.

Footnote:

Provenance and Peer Review: This article was commissioned by the editorial office, *Digestive Medicine Research*. The article did not undergo external peer review.

Conflicts of Interest: Both authors have completed the ICMJE uniform disclosure from (available at <http://dx.doi.org/10.21037/dmr-20-47>). SP serves as an unpaid editorial board member of *Digestive Medicine Research* from Oct 2019 to Sep 2021. The authors have no other conflicts of interests to declare.

doi: 10.21037/dmr-20-47

Cite this article as: Lee CM, Park S. A significant difference between two randomized controlled trials to compare laparoscopic and open distal gastrectomy for early gastric cancer. *Dig Med Res* 2020;3:99.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Open Access Statement: This is an Open Access article distributed in accordance with the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 International License (CC BY-NC-ND 4.0), which permits the non-commercial replication and distribution of the article with the strict proviso that no changes or edits are made and the original work is properly cited (including links to both the formal publication through the relevant DOI and the license). See: <https://creativecommons.org/licenses/by-nc-nd/4.0/>.

References

1. Kitano S, Iso Y, Moriyama M, et al. Laparoscopy-assisted Billroth I gastrectomy. *Surg Laparosc Endosc* 1994;4:146-8.
2. Kim HH, Han SU, Kim MC, et al. Long-term results of laparoscopic gastrectomy for gastric cancer: a large-scale case-control and case-matched Korean multicenter study. *J Clin Oncol* 2014;32:627-33.
3. Katai H, Mizusawa J, Katayama H, et al. Survival outcomes after laparoscopy-assisted distal gastrectomy versus open distal gastrectomy with nodal dissection for clinical stage IA or IB gastric cancer (JCOG0912): a multicentre, non-inferiority, phase 3 randomised controlled trial. *Lancet Gastroenterol Hepatol* 2020;5:142-51.
4. Kim HH, Han SU, Kim MC, et al. Prospective randomized controlled trial (phase III) to comparing laparoscopic distal gastrectomy with open distal gastrectomy for gastric adenocarcinoma (KLASS 01). *J Korean Surg Soc* 2013;84:123-30.