Postoperative pain and quality of life after single-incision distal gastrectomy versus multiport laparoscopic distal gastrectomy for early gastric cancer – a randomized controlled trial

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Abstract
Background Although it has been more than ten years since its first introduction, single-incision distal gastrectomy (SIDG) still lacks solid evidence and there are also no reports on patient quality of life (QOL). This study evaluates the postoperative outcomes and patient QOL of SIDG compared to multiport laparoscopic distal gastrectomy (MLDG).

Methods This study was designed as a prospective phase II randomized controlled study. Patients diagnosed with early gastric cancer in the distal 2/3rd of the stomach were randomized to either multiport or single-port group. Primary endpoint was pain using the visual analogue scale on postoperative day (POD) 1. Other outcomes include operative data, complications, and patient QOL using the EORTC C30 and STO22 modules.

Results A total of 43 patients in the SIDG group and 40 patients in the MLDG group were enrolled from September 2017 to February 2020. Mean operation time was 154.3 ± 53.3 min in the MLDG group and 148.9 ± 50.1 min in the SIDG group (p = 0.631). There was no difference in POD1 pain scores between the two groups (MLDG = 4.0 ± 1.3, SIDG = 4.3 ± 1.3, p = 0.372). Mean hospital stay was 5.5 (range 4—12) days in the MLDG group and 5 (range 4—17) days in the SIDG group (p = 0.993). There was no statistical significance in postoperative QOL scores.

Conclusion Unlike previous reports, there was no difference in POD1 pain scores between SIDG and MLDG. Nevertheless, SIDG did not increase short-term morbidity compared to MLDG and had similar outcomes in QOL.

Keywords Stomach neoplasm · Laparoscopy · Minimally invasive surgical procedures

With the release of several pivotal trials, such as the KLASS-01 long-term results [1], laparoscopic distal gastrectomy is now accepted as standard treatment for early gastric cancer (EGC) with a 5-year survival of over 94% [1–3]. These high survival rates have led the paradigm to shift from radical resection to more minimal surgery for patients with EGC, trying to preserve patient quality of life (QOL) while maintaining oncological safety. Better QOL after surgical treatment has now become a crucial factor for choosing the right type of surgery for patients with EGC.

Single-incision laparoscopic surgery (SILS) is a rising new technique that has been applied to various types of laparoscopic surgery, including cholecystectomy, appendectomy, and colectomy [4, 5]. Development of new and innovative surgical tools, conjoined with better minimally invasive surgical skills, have made single-incision distal gastrectomy (SIDG) feasible [6]. In a previous retrospective study comparing SIDG with conventional multiport laparoscopic distal gastrectomy (MLDG), SIDG patients had significantly less pain scores on postoperative day (POD) 0 and POD#1 [7]. In the study by Omori et al. published in 2020 [8], 101 patients were randomized to SIDG or MLDG. Postoperative pain scores were significantly lower in the SIDG group throughout POD#0 to POD#7. However, there was no evaluation of postoperative patient QOL in this randomized controlled
trial (RCT). This study aims to validate the results of previous studies regarding postoperative pain and also compare postoperative patient QOL of patients undergoing SIDG and MLDG.

Methods

Study design and patient selection criteria

This study was designed as a prospective RCT from a single institution by a single surgeon. Patients between 20 and 80 years of age who were diagnosed with cT1N0M0 gastric cancer in the distal 2/3ds of the stomach were included. Patients who had history of other cancers and those who received chemotherapy were excluded. Patients who did not receive distal gastrectomy or had withdrawn their consent were dropped out. This study was approved by the institutional review board of Seoul National University Bundang Hospital (B-1707-409-006). The protocol of the trial can be found in ClinicalTrials.gov (NCT01938326). A formal written consent form was obtained from all participants, and the study was performed in accordance with the 1975 Helsinki declaration. The study protocol has been attached as a supplementary file (Supplementary File 1).

Primary and secondary endpoints

The primary endpoint was maximum pain score on POD#1 using the visual analogue scale (VAS). Other secondary endpoints included operation time, estimated blood loss (EBL), postoperative complications, maximum pain scores throughout POD#0 to POD#5, hospital stay, time to first flatus, time to first soft fluid diet (SFD), and QOL scores. Data for QOL were analyzed using European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) C30 and STO22 modules, which have already been previously validated [9]. Survey was taken prior to surgery, 2 weeks after surgery, 1 month after surgery, 6 months after surgery, and 12 months after surgery. Overall survival and recurrence were also observed during the study period.

Sample size calculation and randomization

In a previous retrospective analysis [7], maximum pain score using VAS on POD#1 was 4.6 ± 1.0 for SIDG and 5.5 ± 1.4 for MLDG (p < 0.001). According to these results, the sample size was calculated with a statistical power of 80% and an alpha of 0.025, yielding a sample size of 34 patients in each group. Adding a drop-out ratio of 20%, the final sample size was decided to be 43 patients in each group. Randomization was performed by a computerized block randomization (block size 2, 4, or 6), and results were contained in sealed opaque numbered envelopes which were kept by someone not part of this trial. Randomization results were announced right before the start of the operation.

Surgical procedures

Conventional MLDG was performed in supine position with 5 access ports, and SIDG was performed in lithotomy position using only a single transumbilical wound as previously described [10]. To compensate for the lack of assist ports in SIDG, intra-abdominal organ retractors were used. Patients underwent D1 + or D2 lymph node dissection (LND) depending on the presence of enlarged lymph nodes. For anastomosis, patients received either Billroth I (BI), Billroth II (BII), Roux-en-Y (RY), or uncut Roux-en-Y (uncut RY) depending on patient age, tumor location, and tumor size. All potential sites of internal hernia, such as the Petersen’s and mesenteric defects, were closed using suture. Bupivacaine injection was applied to the incision sites in both MLDG and SIDG groups.

Perioperative care

Perioperative regimen of the patients undergoing MLDG or SIDG were identical and followed many elements from the Enhanced Recovery After Surgery (ERAS) Program that was reported previously [11]. Surgical drains and Levin tubes were avoided as possible. Patients were given sips of water on POD#1, fluid diet on POD#2, and soft-blended diet on POD#3 if there were no postoperative complications. Every 8 h, including the day of the operation, patients recorded their pain scores using the VAS scale. After discharge, patients visited the outpatient clinical around 3 – 4 weeks from surgery, and patients with Stage II or more cancers were recommended for adjuvant chemotherapy. Otherwise, they were followed for routine surveillance.

Statistical analysis

Continuous variables were compared using the Student’s t test or Mann–Whitney U test, and categorical variables were compared using the χ² test or Fisher’s exact test. A p-value of < 0.05 was considered statistically significant. Mixed linear model was used to compare repeated measures in QOL analysis, and the Student’s t test was used to compare mean difference in each score at each specific point in time. Analysis was performed on an intention-to-treat basis, using R 3.6.1 (R Core Team, 2019), the ggplot2 (v3.3.5; Wickham et al., 2021) package, and the ggiraphExtra (v0.8.1; Gohel et al., 2021) package.
Results

Patient enrollment and demographics

A total of 86 patients were enrolled from September 2017 to February 2020, with 43 patients randomized to each group. Three patients in the MLDG group withdrew consent and thus a total of 83 patients were finally enrolled (Fig. 1). All patients underwent intervention as intended, and there was no conversion to multiport surgery in the SIDG group, nor was there any case of conversion to open surgery in both groups. Table 1 shows the overall demographics of both groups. Mean age was 58.9 ± 13.0 years in the MLDG group and 62.0 ± 9.7 years in the SIDG group ($p = 0.208$). There was no statistical difference in age, body mass index (BMI), American Society of Anesthesiologists (ASA) score, and history of previous abdominal operations.

The most common type of reconstruction was BI (MLDG = 45.0%, SIDG = 39.5%), and there was no statistical difference in the type of anastomosis in both groups ($p = 0.885$). More patients in the SIDG group underwent D2 LND ($n = 24, 55.8\%$) compared to the MLDG group ($n = 14, 35.0\%$), but there was no statistical difference ($p = 0.093$). There was no difference in tumor size, distal or proximal margin, and pathologic stages.

Postoperative outcomes and early complications

Postoperative outcomes and complications are summarized in Table 2. Mean operative time was 154.3 ± 53.3 min. in the MLDG group and 148.9 ± 50.1 min. in the SIDG group ($p = 0.631$). EBL was 18.0 ± 24.8 ml. in the MLDG group and 14.2 ± 27.5 ml. in the SIDG group ($p = 0.515$). There was no difference in the number of retrieved lymph nodes (MLDG = 62.9 ± 28.4, SIDG = 57.3 ± 18.8, $p = 0.298$). There was also no difference in day to first fluid diet, first flatus, and overall hospital stay days. C-reactive protein levels on POD#2 were 11.6 ± 6.2 mg/L in the MLDG group and 12.6 ± 5.5 mg/L in the SIDG group ($p = 0.449$).

Ten (25.0%) patients in the MLDG group and nine (20.9%) patients in the SIDG group showed early complications ($p = 0.858$). Pulmonary complications were the highest in both groups, followed by postoperative ileus. Among them, five (12.5%) patients in the MLDG group and eight (18.6%) in the SIDG group were classified as Clavien–Dindo grade II or more. One patient in each group received an

| Table 1 | Patient demographics and pathologic results between multi-port laparoscopic distal gastrectomy (MLDG) and single-incision distal gastrectomy (SIDG) |
|---------|---------------------------------------------------------------------------------|
|         | MLDG ($N=40$) | SIDG ($N=43$) | $p$-value |
| Age (years) | 58.9 ± 13.0 | 62.0 ± 9.7 | 0.208 |
| Sex | 1.000 | | |
| Male | 28 (70.0%) | 30 (69.8%) | | |
| Female | 12 (30.0%) | 13 (30.2%) | | |
| Body mass index (kg/m²) | 24.4 ± 3.6 | 24.3 ± 2.8 | 0.904 |
| ASA score | | | 0.712 |
| 0 | 9 (22.5%) | 11 (25.6%) | | |
| 1 | 25 (62.5%) | 28 (65.1%) | | |
| 2 | 5 (12.5%) | 4 (9.3%) | | |
| 3 | 1 (2.5%) | 0 (0.0%) | | |
| History of abdominal operations | | | 0.468 |
| No | 31 (77.5%) | 37 (86.0%) | | |
| Yes | 9 (22.5%) | 6 (14.0%) | | |
| Reconstruction type | | | 0.885 |
| Billroth I | 18 (45.0%) | 17 (39.5%) | | |
| Billroth II | 9 (22.5%) | 13 (30.2%) | | |
| Roux-en-Y | 10 (25.0%) | 10 (23.3%) | | |
| Uncut Roux-en-Y | 3 (7.5%) | 3 (7.0%) | | |
| Lymph node dissection | | | 0.093 |
| D1+ | 26 (65.0%) | 19 (44.2%) | | |
| D2 | 14 (35.0%) | 24 (55.8%) | | |
| Tumor size (cm) | 2.6 ± 1.8 | 2.6 ± 1.5 | 0.976 |
| Proximal margin (cm) | 4.0 ± 2.2 | 3.7 ± 2.3 | 0.532 |
| Distal margin (cm) | 5.1 ± 2.5 | 4.8 ± 2.8 | 0.569 |
| pT stage | | | 0.309 |
| pT1a | 29 (72.5%) | 27 (62.8%) | | |
| pT1b | 10 (25.0%) | 16 (37.2%) | | |
| pT4a | 1 (2.5%) | 0 (0.0%) | | |
| pN stage | | | 0.554 |
| pN0 | 36 (90.0%) | 38 (88.4%) | | |
| pN1 | 3 (7.5%) | 4 (9.3%) | | |
| pN2 | 0 (0.0%) | 1 (2.3%) | | |
| pN3a | 1 (2.5%) | 0 (0.0%) | | |

ASA American Society of Anesthesiologists
invasive intervention of Clavien–Dindo grade III or more. The patient in the MLDG group underwent laparoscopic adhesiolysis and jejuno-jejunal bypass due to postoperative ileus. The patient in the SIDG group had gastroduodenostomy anastomosis leakage which was controlled using percutaneous drainage.

**Postoperative pain assessment**

The primary outcome, maximum VAS score at POD#1, was 4.0 ± 1.3 in the MLDG group and 4.3 ± 1.3 in the SIDG group with no statistical difference ($p = 0.626$). Figure 2 compares the average of the maximum pain scores throughout the postoperative period. Pain scores

**Fig. 2** Maximum postoperative pain between MLDG and SIDG (abbreviations: MLDG—multiport laparoscopic distal gastrectomy, SIDG—single-incision distal gastrectomy)
were highest at POD#0 with 6.4 ± 1.2 in the MLDG group and 6.3 ± 1.5 in the SIDG group ($p = 0.372$). Pain scores decreased from POD#1, and there was no difference in pain scores all throughout POD#0 to POD#5 between the two groups.

**Quality of life assessment**

Figure 3 shows the change in functional scales of the EORTC QLQ C30 module, and the average changes in specific scores compared to baseline can be found in Supplementary Table 1. Global Health Status scale decreased by $-22.8 \pm 30.6$ in the MLDG group and $-17.4 \pm 30.8$ in the SIDG group 2 weeks after the operation ($p = 0.458$). Twelve months after the operation, the Global Health Status scale improved, showing average change of $-2.8 \pm 32.9$ in the MLDG group and $-6.7 \pm 28.1$ in the SIDG group compared to the baseline ($p = 0.601$). All other functional scales followed a similar trend, impairments in function improving over the 1-year postoperative course.

Most symptoms in the EORTC QLQ C30 module worsened after the operation and gradually improved over the course of one year (Fig. 4). Diarrhea, insomnia, and fatigue still persisted after 12 months. Appetite loss was higher in the MLDG group throughout the postoperative course, but there was no statistical difference. Constipation at POD 2 weeks was higher in the SIDG group without statistical difference, but gradually resolved showing similar outcomes with the MLDG group. In the EORTC QLQ STO22 symptom scales, although it did not reach statistical significance, pain scores tended to be better in the SIDG group at POD 2 weeks (MLDG = 18.2 ± 19.5 vs SIDG = 9.6 ± 22.9, $p = 0.088$) and at POD 1 month (MLDG = 12.4 ± 22.3 vs SIDG = 2.3 ± 19.9, $p = 0.076$) which gradually became similar after 6 months. Body image also tended to be better in the SIDG group at POD 2 weeks (MLDG = 28.7 ± 33.0 vs SIDG = 12.6 ± 31.4, $p = 0.062$) and POD 1 month (MLDG = 19.2 ± 26.4 vs SIDG = 6.1 ± 34.8, $p = 0.089$), although there was no statistical difference. All other symptom scales from the EORTC STO22 module showed no statistical difference between the two groups (Fig. 5).

**Discussion**

Innovative surgical devices and enhanced training in minimally invasive surgical skills have allowed surgeons to perform even less invasive laparoscopic surgery in the form of reduced ports or SILS. For gastric cancer, there have been several studies reporting the feasibility of reduced ports gastrectomy [12], single plus one gastrectomy [13], and SIDG. Although these options are gaining more attention from young surgeons, there is still a controversy on whether reducing the number of trocar incisions has more benefits than risks. Since the first report of SIDG by Omori et al. [6] on 2011, there is only one prospective RCT in literature [8] comparing SIDG to MLDG, which was also reported by the same group. In this study, a final number of 100 patients were enrolled with 50 patients in each group. The postoperative pain scores, analyzed using VAS at rest and during movement, were all significantly higher in the multiport group throughout POD#0 ~ 7. The pain score at POD#1 during movement was 5.1 in the multiport group and 3.3 in the SIDG group. In the current study, the maximum pain score
at POD#1 was 4.0 ± 1.3 in the MLDG group and 4.3 ± 1.3 in the SIDG group. The pain score for MLDG in this study was lower by nearly 2 points than the previously reported RCT. This score is also better than what was reported in a previous study from the current institution where the maximum pain score at POD#1 for the ERAS MLDG group was 4.48 and the conventional MLDG group was 5.65 [11]. The injection of bupivacaine to both MLDG and SIDG patients may have affected the results. Nonetheless, the maximum pain scores during immediate postoperative period for SIDG in this RCT were not significantly lower than the MLDG group, providing conflicting results compared to previous studies [7, 8].

Most comparative studies published up-to-date show that there are no differences in immediate short-term outcomes between SIDG and MLDG. Although the RCT by Omori et al. [8] reports a slightly shorter operation time compared to the multiport (difference of 13 min, $p = 0.04$), most other studies comparing single port to multiport distal gastrectomy show that there are no significant differences in mean operation time [7, 14, 15]. The learning curve for SIDG in terms of operative time is reported to be about 30 cases for an expert surgeon in LDG [16]. Some retrospective studies report less EBL in the SIDG group [7, 14], but the current study and the previous RCT [8] show no difference. Due to the high level of surgical skills required, some surgeons may be concerned that LND cannot be done completely during SIDG. Although in our study, the MLDG group had slightly high number of retrieved lymph nodes, there was no statistical difference between the two groups, and the mean number of retrieved nodes in both groups was higher than the minimal requirement of 16 nodes set by the 8th AJCC TNM staging manual. All other published studies show that there are no differences in the completeness of LND for EGC [7, 8].

There were no differences in overall early complications and type of early complications in the two groups, which was also in accordance with previously reported studies [7, 8, 14, 17]. There was one case of anastomosis leakage in each group, which were managed by either percutaneous drainage or antibiotics. According to a systematic review by Antoniou et al. on incisional hernia after SILS [18], which analyzed mostly single-incision cholecystectomy and appendectomy, SILS was associated with a higher risk of trocar-site hernia compared to the conventional laparoscopic method. However, in current reports of SILS distal gastrectomy, the incidence of incisional hernia does not differ between the single-port and multiport group [7, 8, 19]. A recent long-term follow-up study comparing SIDG and MLDG showed that although there were more cases of incisional hernia in

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Fig. 4 Symptom scales of the EORTC QLQ C30 module (abbreviations: MLDG—multiport laparoscopic distal gastrectomy, SIDG—single-incision distal gastrectomy)
the SIDG group (n = 5, 1.3% vs. n = 2, 0.5%) the difference failed to show statistical significance (p = 0.448). This may be because the umbilical wound in MLDG is extended to nearly the same size as the wound during SIDG to remove the large stomach specimen. However, there are only few reports that show long-term results of SIDG, and further studies are needed to compare the risk of incisional hernia for SIDG.

This is the first study to evaluate patient QOL after SIDG. Overall, both procedures showed adequate change compared to baseline without statistical difference. Patients in both groups showed a decrease in overall functioning scales at POD 2 weeks, which all gradually improved over the 12-month period. Although the difference in overall trend and in specific scores at a specific time was not statistically significant, pain and body image scales of the EORTC QLQ STO22 module tended to be better in the SIDG group. However, the difference regarding pain is less noticeable in the EORTC C30 pain scale, which evaluates general pain unlike the STO22 module which focuses on pain in the stomach area. Nevertheless, QOL, as evaluated by the EORTC QLQ modules, was not statistically different between the two groups. Although there have been no studies evaluating QOL after patients with reduced ports or SIDG, the results of this study is similar to the results reported in single-incision cholecystectomy [20, 21], appendectomy [22], and sleeve gastrectomy [23]. Unlike how QOL is reported to be higher in laparoscopic surgeries compared to open surgeries [24, 25], most studies show that there is no difference in QOL by reducing the number of ports.

This study has several weaknesses that may limit the interpretation of the results. A single center and single surgeon study make it difficult to generalize these results to the public. The surgeon in this study had 10-years of experience in laparoscopic gastrectomy and has 2–300 cases of laparoscopic gastrectomy per year. Also, for MLDG, there are more room for assistants to be involved in the operation, which may have affected the operative outcome. However, since this was a prospective randomized study, the main surgeon performed all of the procedures in attempts to avoid critical bias. Maximum pain at each postoperative day was set as the outcome. This made it difficult to compare the results with the previous and only other RCT regarding SIDG [8]. There were some missing questionnaires from patients who did not show up on their scheduled outpatient clinic (number of obtained questionnaires at each point in

Fig. 5 Symptom scales of the EORTC QLQ STO22 module (abbreviations: MLDG—multiport laparoscopic distal gastrectomy, SIDG—single-incision distal gastrectomy)
time can be seen in Supplementary Table 1). This missing data may have made the results statistically insignificant despite the differences. Also, this study did not sufficiently evaluate the cosmetic effect and scar satisfaction, which are major possible benefits of the SIDG procedure.

In this study, SIDG is not a superior procedure compared to MLDG. However, there is still a demand for SIDG in some gastric cancer patients, and there are some ways in which SIDG can prove to be beneficial. The cosmetic effect makes the procedure attractive to young women, and SIDG may be considered for young women with low BMI. Regarding the tumor characteristics, patients with EGC would be preferred because patients with advanced gastric cancer have bulkier and larger tumors that are difficult without the use of additional retraction and have more potential for lymph node metastasis. Also, the surgeon must have already overcome the learning curve for MLDG first before starting SIDG. In some situations, such as the lack of medical personnel during the COVID-19 era, SIDG requires less manpower compared to MLDG, which make the procedure more cost effective [19]. Also, new surgical devices are being released in the market to make this procedure more feasible. Needle-scopic devices can be used to assist the procedure similar to MLDG, but with barely other visible scars other than the main wound [26]. Nevertheless, since this study showed negative results, we believe that when the procedure becomes too difficult or risky or extremely stressful to the operator, there is no need to insist on performing SIDG instead of MLDG.

Conclusion
SIDG is safe in short-term postoperative outcomes, but with no difference in maximal pain scores compared to MLDG. SIDG and MLDG had no difference in postoperative QOL until 1 year after surgery.

Supplementary Information  The online version contains supplementary material available at https://doi.org/10.1007/s00464-022-09709-6.

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