Single-Incision Versus Conventional Laparoscopic Appendectomy: A Multi-Center Randomized Controlled Trial (SCAR Trial)

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Study protocol

Keywords: Acute appendicitis, single-incision laparoscopic appendectomy, conventional laparoscopic appendectomy

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Abstract

Background: Although single-incision laparoscopic appendectomy (SILA) was introduced decades ago, it is still considered a difficult technique to perform compared to conventional laparoscopic appendectomy (CLA). In addition, controversy about the benefits of SILA compared to CLA abounds and no definite criteria for choosing SILA over CLA in patients with appendicitis currently exist. Therefore, we have planned a multi-center randomized controlled trial to compare SILA with CLA in terms of cosmetic satisfaction and pain reduction.

Methods: Patients diagnosed with appendicitis at the participating centers will be recruited and allocated into either a CLA or an SILA groups using a 1:1 randomization. Patients in the CLA group will receive a conventional 3-port laparoscopic appendectomy and patients in the SILA group will receive a laparoscopic appendectomy using a single-incision at the umbilicus. The primary trial endpoint is cosmetic satisfaction assessed using the Patients and Observer Scar Assessment Scale (POSAS) at 6 weeks after surgery. Secondary trial endpoints include cosmetic satisfaction assessed via the Body Image Questionnaire, pain levels assessed via the Visual Analog Scale and International Pain Outcomes questionnaire, and the presence of postoperative complications. The target sample size of this superiority trial is 120 patients, as this will provide 80% power at the 2.5% level of significance to detect a 3-point difference in POSAS.

Discussion: The results of this planned multi-center randomized controlled trial will provide substantive evidence to help surgeons choose when to use SILA over CLA in patients with appendicitis.

Trial registration: Clinical Research Information Service (CRIS), Registered on 21 May, 2020 (KCT0005048). https://cris.nih.go.kr/cris/en/search/search_result_st01.jsp?seq=16171

Introduction

Background and rationale {6a}

Acute appendicitis is one of the most common causes of emergency gastrointestinal surgery worldwide. Even though controversy regarding the medical management of acute appendicitis using antibiotics exists, appendectomy is currently considered the gold standard treatment.

Open appendectomy rather than laparoscopic appendectomy was performed universally until the 1990s, even though Kurt Semm, a German gynecologist, first introduced laparoscopic appendectomy firstly in 1983 [1]. Currently, most appendectomies are laparoscopic because of the advantages including early recovery, less pain, and improved cosmetic satisfaction compared with open appendectomy [2].

A conventional laparoscopic appendectomy (CLA) usually requires insertion of three port trocars with two working ports and one camera port. Additionally, single-incision laparoscopic appendectomy (SILA) has become popular since it was first introduced in 1992 [3]. Recent meta-analysis reported that SILA is a
safe and feasible procedure compare to CLA, though SILA is a considered more technically demanding than CLA [4-6].

Theoretically, SILA would be expected to produce less pain, encourage faster recovery, and result in better cosmetic satisfaction than CLA. However, several previous reports comparing SILA and CLA have yielded conflicting results and only a few studies have reported that SILA is superior to CLA with respect to pain and/or cosmesis [7-11]. One randomized control trial (RCT) failed to show the superiority of SILA over CLA with respect to pain and cosmesis [12]. Furthermore, a recent meta-analysis reported no differences in the pain and cosmesis scores between SILA and CLA [5, 13]. Several studies, rather, have even reported that postoperative pain is more severe after SILA than after CLA [14, 15].

Previous RCTs compared between SILA and CLA used simple visual analog score (VAS) for the assessment of both pain and cosmetic satisfaction. Results originated from this type of assessment have limitations with regard to their objectiveness.

There are several patient-reported outcomes measures (PROMs) used for assessing the pain and cosmetic satisfaction after surgery including the International Pain Outcome (IPO) Questionnaire [16], the Patient and Observer Scar Assessment Scale (POSAS) [17], and the Body Image Questionnaire (BIQ) [18]. However, there is a paucity of literature reporting outcomes comparing SILA and CLA using these tools.

Objectives {7}

Our trial aims to investigate the clinical benefits of SILA over CLA using these more objective PROMs for pain and cosmetic satisfaction.

Trial design {8}

This study is a multi-center, prospective, open-label, randomized trial. Patients diagnosed with acute appendicitis at participating centers will be screened for study enrollment. Enrolled participants will be randomly allocated to either the SILA group or the CLA group. This study follows the recommendations of the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines. The study flowchart is shown in Fig. 1.

Methods: Participants, Interventions And Outcomes

Study setting {9}

This study protocol is a multi-center, RCT that will be conducted at three academic hospitals and one public hospital in Daegu, Korea. Participants will be recruited from the patients diagnosed with acute appendicitis in Yeungnam University Medical Center, Dongsan Medical Center, Daegu Catholic University Medical Center and Pohang Medical Center.

Eligibility criteria {10}
**Inclusion criteria**

Patients 19-75 years of age diagnosed with acute appendicitis who will receive a laparoscopic appendectomy will be recruited.

**Exclusion criteria**

Patients who have one or more of the following will be excluded from this study: (1) patients with a suspected abscess or appendiceal perforation; (2) patients with symptoms of pan-peritonitis symptom; (3) patients with a history of major abdominal surgery; (4) patients who have an inability to express themselves due to conditions such as dementia or intellectual disability; (5) patients with chronic pain who need to take analgesics; (6) patients with severe medical disease such as pulmonary, cardiovascular, hepatic, or renal insufficiency; (7) Pregnancy; and (8) patients unable to provide consent.

**Who will take informed consent?** {26a}

The investigating study member in each hospital is responsible for obtaining written, informed consent from the participant. The consent form must be signed before randomization.

**Additional consent provisions for collection and use of participant data and biological specimens** {26b}

On the consent form, participants will be asked if they agree to use of their data. Participants will also be asked for permission for the research team to share relevant data. This trial does not involve collecting biological specimens for storage.

**Interventions**

**Explanation for the choice of comparators** {6b}

The two choices of comparators include, CLA is performed via a conventional 3-port laparoscopic appendectomy and SILA is performed laparoscopic appendectomy using a single-incision at the umbilicus.

**Intervention description** {11a}

**SILA (Fig. 2A.)**

A single 2cm incision will be made at the umbilical area and a custom multi-channel single port (Octoport, Dalim company, Co. Ltd., Korea) will be inserted into the incision site. There will be no restrictions placed on the type of laparoscopic instruments used, and all such decisions will be left to the discretion of the surgeon. The mesoappendix and appendiceal artery will be ligated and resected with an energy device or bipolar cauterization. The appendiceal base will be ligated with a loop tie or clip as per the surgeon’s preference. After the appendectomy, the facia will be closed with an absorbable suture and the skin will be closed using a nylon suture, an absorbable subcuticular suture, or a topical skin adhesive as per the surgeon’s preference.
Additional port insertion or conversion to an open surgery will be possible at the surgeon’s discretion to ensure patient safety.

**CLA (Fig. 2B)**

A standard three-trocar technique will be used with incisions made at the peri-umbilical, left lower quadrant, and supra-pubic sites. All other techniques for the appendectomy will be similar to those used in the SILA procedure.

**Criteria for discontinuing or modifying allocated interventions (11b)**

Criteria for discontinuing or modifying include: (1) Participant requests to quit the study after allocation. (2) The main outcome is not recorded or incomplete, which will affect further statistical analysis. Also, Conversion to multiport or open surgery will be possible at the surgeon’s discretion if the patient’s safety is threatened by surgical difficulties, such as severe adhesion, generalized peritonitis or intraoperative complications. In these cases, we will describe the reasons for the conversion.

**Strategies to improve adherence to interventions (11c)**

Not applicable, this trial does not have strategies to improve adherence.

**Relevant concomitant care permitted or prohibited during the trial (11d)**

Not applicable, this trial does not have concomitant care permitted or prohibited.

**Provisions for post-trial care (30)**

Not applicable, once the study is completed, the effect of interventions is minimal.

**Outcomes (12)**

The primary trial endpoint is cosmetic satisfaction at 6 weeks after surgery as measured by POSAS. The secondary endpoints are cosmetic satisfaction assessed via BIQ, pain assessed via the IPO questionnaire and VAS, and the presence of general postoperative complications.

**Baseline characteristics**

Baseline demographics for each participant such as age, sex, body mass index, medical history, etc. will be obtained prior to surgery but after informed consent is given.

**Perioperative findings**

Intraoperative findings including operative time, estimated blood loss, incision length, intraperitoneal findings, method of appendiceal base ligation, additional port insertion, conversion to open
appendectomy, and skin suture technique will be recorded. Postoperative analgesics use, hospital stay, and morbidities within 30 days after surgery will be also collected.

**PROMs for postoperative pain**

VAS and IPO will be used for comparing postoperative pain between treatment groups. VAS will be obtained 6 hours after surgery, as well as on the morning of postoperative day 1 and 2. IPO will be obtained on postoperative day 1.

**PROMs for cosmetic satisfaction**

POSAS and BIQ will be obtained 6 weeks after surgery in the outpatient clinic. If any participant is unable to attend the clinic, a telephone interview will be permitted for completion of the survey.

**Participant timeline**

Participant timeline is presented in Fig 3.

**Sample size**

The target sample size will be 120 participants, as this will provide 80% power at the 2.5% (two-sided) level of significance to detect a three-point difference in the POSAS score between the SILA group and the CLA group at 6 weeks after surgery. Our target sample size allows for 10% attrition.

**Recruitment**

All candidate patients diagnosed with acute appendicitis will be recruited in the trial. Based on the incidence of acute appendicitis and average amount of the patients in emergency department, the investigators have confidence to recruit enough subjects as planned.

**Assignment of interventions: allocation**

**Sequence generation**

All participants will be randomized to either the SILA group or the CLA group in a 1:1 ratio. The randomization allocation will occur just to surgery using a computerized randomization system.

**Concealment mechanism**

Allocation numbers and related information are concealed in sequentially numbered, opaque, sealed envelope. Interventions are assigned to the enrolled participants according to the sequence.

**Implementation**
The central registry of the surgical department of Dongsan Medical Center, School of Medicine, Keimyung University takes charge in the allocation sequence generation, participants enrollment and assigning.

**Assignment of interventions: Blinding**

**Who will be blinded (17a)**

Not applicable, this trial is open-label design.

**Procedure for unblinding if needed (17b)**

Not applicable.

**Data collection and management**

**Plans for assessment and collection of outcomes (18a)**

Data will be recorded in the CRF and completed after 6 months after surgery. A study monitoring committee independent from the sponsor and investigator will check the study process and participants’ safety. Any adverse events related to the study will be reported to the study monitoring committee. All data will be stored for 3 years after completion of the study.

**Plans to promote participant retention and complete follow-up (18b)**

We will offer regular follow-up after the participants are discharged. If the participant cannot come for clinic, a telephone follow-up will be arranged.

**Data management (19)**

All data for this RCT will be collected after obtaining consent from the participants prior to surgery. All data will be recorded on a paper case report form as well as a digital record form. A participating surgeon or trained researching nurse will perform the postoperative interview to collect the necessary PROMs data.

**Confidentiality (27)**

All the information collected from this trial will always be protected and all electronic material will be duly stored and backed up in the researcher's computer equipment with a safe password. All the data acquired for this study will be anonymized through the assignment of a trial identification number which will be used only for this study and accessed by only authorized persons.

**Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use (33)**

Not applicable as no biological specimens were collected as part of this trial.
Statistical methods

Statistical methods for primary and secondary outcomes (20a)

All analyses of the primary and secondary endpoints will be conducted with the intention-to-treat population. A per-protocol analysis will also be performed for further comparisons. Normally distributed data will be conducted with Student’s t test. Non-normally distributed data will be examined using the Mann-Whitney U test. The chi-square or Fisher’s exact test will be used to examine categorical variables. Statistical significance will be declared for tests with p values < 0.05.

Interim analyses (21b)

Not Applicable. Interim analyses will not be performed in the present study.

Methods for additional analyses (e.g. subgroup analyses) (20b)

Not Applicable. Additional analyses are not planned in the present study.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data (20c)

Enrolled participants will be excluded if they do not accept randomization or receive intervention after randomization. Participant missing operative information or follow-up data will be excluded.

Plans to give access to the full protocol, participant level-data and statistical code (31c)

We plan to share the data to the public within 6 months after finished the trial.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee (5d)

Not Applicable. This trial was approved by the institutional review board at Daegu joint on February 27, 2020 (No: 19-12-001-001) and does not require monitoring by a steering committee.

Composition of the data monitoring committee, its role and reporting structure (21a)

A study monitoring committee independent from the sponsor and investigator will check the study process and participants’ safety. Any adverse events related to the study will be reported to the study monitoring committee.

Adverse event reporting and harms (22)

Any adverse events related to the study will be reported to the study monitoring committee.

Frequency and plans for auditing trial conduct (23)
Not Applicable. Auditing trial conduct is not planned for this study.

**Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees)**

In case of any change to the current protocol, the lead research will be responsible to inform and send the new version the ethical committee for their approval. After the approval the clinical register will be updated and all the amendments will be informed.

**Dissemination plans**

The trial results will be published in international medical and scientific journals and presented at national and international conferences.

**Discussion**

Laparoscopic abdominal surgery is generally regarded as a minimally invasive surgery with advantages such as less pain, faster recovery and better cosmetic results compared with open surgery. Many types of laparoscopic abdominal surgeries are currently used including single-incision procedure and conventional multi-port procedures [19–21]. Single-incision laparoscopic abdominal surgery is still a challenging procedure even among experienced laparoscopic surgeons [22, 23]. Nevertheless, Appendectomy is one of abdominal surgery that is well-suited for a single-incision laparoscopic approach.

Surgeons and patients believe that reduced port surgery has advantages in terms of cosmetic satisfaction and pain reduction. This belief is based on the results of previous studies comparing open and laparoscopic surgery. In addition, among laparoscopic surgical techniques, SILA would be expected to outperform CLA with regard to cosmetic satisfaction and pain reduction because of further reductions in invasiveness. However, it has been difficult to prove the superiority of SILA over CLA because patient expectations are raised.

In this context, as mentioned above, there are controversies about the efficacy of SILA with respect to cosmetic satisfaction and pain reduction compare to CLA. However, previous studies including RCTs have used only a simple VAS and/or analgesic usage as indicators for pain reduction [8, 10, 24, 25]. Although Anthony et al [26] used a pain score that assessed overall pain as well as pain during specific activities (e.g. at rest, coughing for 10 time, after standing for 5 minutes), it was too detailed a score to get via PROM and provided only a subjective profile. Therefore, we decided not to use this pain evaluation scale.

For evaluation of cosmetic satisfaction, most previous studies used a subjective numeric rating from 5 to 100 [12, 24, 26, 27]. The Vancouver Scar Scale and BIQ were used in two RCTs, but these studies were limited by their small sample size [8, 10]. POSAS was used for the evaluation of cosmetic satisfaction in one recent study, but this study evaluated cholecystectomy and was not not an RCT [28]. Therefore, we think that it is necessary to investigate the detailed differences in cosmetic satisfaction and pain...
reduction between SILA and CLA for appendectomy using objective scales in a study with an adequate sample size.

This study has some limitations even though it was designed as a prospective multi-center RCT. First, there are no Korean validated versions of the PROMs which will be used. However, investigators discussed the bases of clinical similarity and significance of the original version and translated the PROMs into Korean. In addition, all PROMS will be administered under the guidance of investigators or trained clinical nurses. Second, we will not be specifying which appendiceal base ligation or wound closer method must be used and instead will leave these decisions to the surgeon's preference. This may act as a source of bias affecting the results. However, all the participating surgeons are colorectal surgery specialists who have performed hundreds of laparoscopic colorectal resections including SILA and CLA techniques. As a result, surgical skill should have a minimal impact on postoperative morbidities between surgeons.

In summary, this study is a prospective multi-center RCT designed to compare SILA and CLA with regard to cosmetic satisfaction and postoperative pain. We believe that the results of this study will clarify the efficacy of SILA for the treatment of acute appendicitis and will be helpful for determining which patients would benefit from SILA instead of CLA.

**Abbreviations**

BIQ  
Body Image Questionnaire  
CLA  
Conventional Laparoscopic Appendectomy  
CRF  
Case Report Form  
CRIS  
Clinical Research Information Service  
IPO  
International Pain Outcomes  
POSAS  
Patient and Observer Scar Assessment Scale  
PROMs  
Patient-Reported Outcomes Measures  
RCT  
Randomized controlled trial  
SILA  
Single Incision Laparoscopic Appendectomy  
SPIRIT  
Standard Protocol Items:Recommendations for Interventional Trials
VAS
Visual Analogue Scale

Declarations

Trial status

This trial is in the ongoing-recruitment phase, which started on July 30, 2020. The first participant was not yet enrolled as of December 20, 2020. Recruitment is expected to be completed by approximately December 31, 2021.

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Authors’ contributions (31b)

CSY and SUB designed the study. SIK, ITW wrote this protocol. All the authors revised the manuscript. All authors read and approved the final manuscript.

Funding (4)

This work was supported by a grant from the Daegu-Gyeongbuk Surgical Society research foundation, Korea, 2019. The funder had no role in the study design. The funder also will have no role in data collection, analysis, interpretation, or presentation of the results. We declare that there was neither any support from, nor a relationship with, the company manufacturing the dressing material device in this study.

Availability of data and materials (29)

Data sharing is not applicable to this paper as no datasets were generated or analysed during the current study.

Ethics approval and consent to participate (24)

This study will be conducted in accordance with ethical standards of the Declaration Helsinki. This trial was approved by the institutional review board at Daegu joint on February 27, 2020 (No: 19-12-001-001) and registered with the clinical research information service (CRIS) (KCT0005048). Researcher will obtain written informed consent from the participants.

Consent for publication (32)

Not applicable.
Competing interests {28}

The author declares that he has no competing interests.

Authors’ information (optional)

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Figures
Figure 1
Study flow chart. CLA, Conventional Laparoscopic appendectomy; ITT, intention-to-treat; PP, per-protocol; SILA, Single-Incision Laparoscopic Appendectomy
Figure 2

Incision and trocar position of SILA (A) and CLA (B)
| TIMEPOINT | ER or OPD | Allocation | Operation | Post-operation | OPD |
|-----------|-----------|------------|------------|----------------|-----|
| ENROLLMENT | 0 ± 1 day | 0 day | 0 day | 6 hours | 1 day | 2 day | 2 weeks | 4 weeks | 6 weeks |
| Eligibility screen | ✓ | | | | | | | | |
| Informed consent | ✓ | | | | | | | | |
| Allocation | ✓ | | | | | | | | |
| INTERVENTION | | | | | | | | | |
| SILA | ✓ | | | | | | | | |
| CLA | ✓ | | | | | | | | |
| ASSESSMENT | | | | | | | | | |
| Baseline characteristics | ✓ | | | | | | | | |
| Perioperative findings | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| VAS | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| IPO | ✓ | | | | | | | | |
| BIQ | | | | | | | ✓ | | |
| POSAS | | | | | | | | ✓ | |

**Figure 3**

Schedule of assessment. BIQ, Body Image Questionnaire; CLA, Conventional Laparoscopic Appendectomy; ER, Emergency Room; IPO, International Pain Outcome questionnaire; OPD, Out-Patient Department; POSAS, Patients and Observer Scar Assessment Scale; SILA, Single-Incision Laparoscopic Appendectomy; VAS, Visual Analog Score

**Supplementary Files**

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