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Original Research Article

Comparison of the surgical and post-operative outcomes between single incision laparoscopic appendicectomy (cross triangulation method) with normal conventional laparoscopic appendicectomy

Pratheep Samraj Rajendran Paulraj[1], Kiran Kailas Chirayil[1]*, Renuka Jayakumar Bellasindhi[2], Punitha Thetraravu Oli[1], Mohith Mathew[1], Anish Jomy[1]

Department of Surgery, Dr. Somervell Memorial CSI Medical College, Karakonam, Trivandrum, India

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***Correspondence:**
Dr. Kiran Kailas Chirayil,
E-mail: kirankailasc@gmail.com

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ABSTRACT

Background: The usual multiport conventional laparoscopic surgeries (appendicectomy) are now being replaced by single incision laparoscopic surgeries (appendicectomy). In our study various aspects of SILS in comparison with the multiport conventional laparoscopic appendicectomy such as incision site pain, duration of surgery, morbidity and instruments used are discussed, duration of surgery, morbidity and instruments used are discussed.
Methods: A single blinded randomized control trial was done on patients presenting with acute appendicitis. Pain numerical scale, use of analgesics, time to return to routine activities, hospital re-admission, complication like port site infection, hernia, intra operative complications rates, conversion rates and duration of surgery were evaluated. Various statistics of pain and other parameters are studied and evaluated. The mean operation time, mean recovery time, post-operative pain were statistically analysed using unpaired t-test.
Results: Mean operating time was 44.16 minutes for SILS and 26.88 minutes for laparoscopic appendicectomy. The mean operative pain in scale of 1 to 4 was 1.40 and 0.40 for SILS and for laparoscopic appendicenctomy respectively making SILS more pain free and comfortable for the patient. The mean post-operative recovery time was 3.12 days for SILS and 7.88 days for laparoscopic appendicenctomy giving SILS patients more rapid recovery and resumption of work.
Conclusions: SILS offers better cosmetic outcome, lesser post-operative pain and shorter duration of hospital stay compared to classical 3 port conventional laparoscopic surgery but at the expense of time. Operative difficulties along with time constraint need to be overcome by the surgeon.

Keywords: Single incision laparoscopic appendicectomy, Conventional laparoscopic appendicectomy, Multiport laparoscopic appendectomy

INTRODUCTION

Laparoscopic surgery has become the preferred approach for many procedures because of reduced post-operative pain, better recovery, shorter hospital stays and improved cosmesis.[1] Single incision laparoscopic surgery (SILS) is one of the many recent variants where either standard ports or a specially designed single multi- channel port is introduced through a single skin incision (umbilical).[2] While the cosmetic advantage of this is obvious, the evidence base for claims of reduced morbidity and better post-operative recovery is weak. The fundamental difference of SILS to conventional multiport laparoscopic surgery is to place all the ports

through a single incision which when placed in the umbilicus can result in no visible scar in the abdominal wall.

Apart from a handful of reported randomized controlled trials (RCTs) the evidence base is weak and insufficient to robustly assess claims of reduced pain and morbidity with improved cosmesis and faster recovery. In general, it is perceived that the single port/incision technique takes longer initially than conventional laparoscopic surgery and the differences in costs and safety are unknown to the patients.[3,4] It is crucial that the technique be critically evaluated during this particular phase of implementation to provide objective data to inform further adoption and evaluation.

However, the difficulty of undertaking such an evaluation has been succinctly stated in Buxton's law: "It is always too early (for rigorous evaluation) until, unfortunately, it's suddenly too late".[5] It is hoped that the results of this study will lead to a large multicentre RCT of single versus standard three-port laparoscopic surgery.

This study compares the effectiveness of single port/incision laparoscopic appendicectomy with standard three-port laparoscopic appendicectomy in adult patients. Appendicectomy is the focus of this study because it is a common and relatively simple procedure to undertake.

Objectives

The objective of this study was to compare the interventions in terms of patient reported outcomes, clinical measures and resource use. This study aims to compare the effectiveness of single port/incision laparoscopic appendicectomy with standard three-port laparoscopic appendicectomy in adult patients intra-operative and post-operative at immediate, at 24 hours and during six weeks post-surgery.

METHODS

Study design

The study design was single blinded randomized controlled trial.

Study area

Study was carried out at Dr. Somervell Memorial CSI Medical College, Thiruvananthapuram, India.

Study subjects

Patients diagnosed with appendicitis undergoing laparoscopic surgery were the participants in the study.

Study period

The study period was September 2013 to September 2020.

Sample size

Sample size of patients undergoing SILS was 25.

Sample size of patients undergoing conventional three incision laparoscopy was 25.

Inclusion criteria

Patients aged 16 years and over presenting with suspected appendicitis for whom laparoscopic surgical management is judged appropriate are eligible for inclusion.

Exclusion criteria

Patients who have had (a) previous open abdominal surgery through midline incision; (b) previous umbilical hernia repair with mesh; and (c) patients unable to consent were excluded.

Participants received the allocated intervention, either single port/incision laparoscopic surgery or standard three-port laparoscopic appendicectomy surgery. Both surgical interventions were delivered by a surgeon who has expertise in the specific intervention. Patients likely to require surgery for acute appendicitis and who meet the eligibility criteria were identified by the consultant surgeon and was explained the purpose of the study and those who consented for the study were enrolled. Following consent and collection of baseline data, the consultant/designated surgical team member randomized the patients/participants in the study to one of the two study groups in equal proportion using randomization. Post-operatively, the study participants were contacted by post and phone as appropriate. In case of non-return of questionnaires, the participants were sent a postal reminder or a telephone call. Follow-up was continued for six weeks from the date of operation. Clinical data was collected on participants who needed to be followed-up in clinic, as part of their treatment plan. Outcome measures were obtained using CRF-case report form and PQ- patients questionnaire.

Laparo-endoscopic single site surgery (LESS)

'LESS' is the internationally accepted consortium approved abbreviation for all single port techniques whatever technique or type of instruments used. A single intra-umbilical incision was made and a multi-channel port was inserted. A 5 mm, 30-degree telescope was used to visualise the operative field. Roticulating/curved instruments were used for the procedure. Use of any additional instruments or ports were recorded. The musculo-aponeurotic layers of the port site were closed with absorbable sutures before closing the skin incision.

The covidien SILS port with SILS articulating instruments were used in our study which would be noted for each patient in the study.

Covidien SILS instruments

Figure 1: Covidien SILS port (1).

Figure 2: SILS hook.

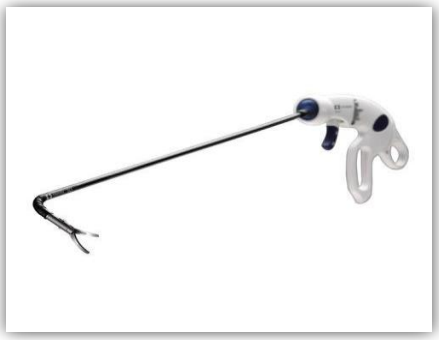

Figure 3: SILS shears.

Figure 4: SILS maryland.

Standard three-port laparoscopic surgery

Pneumo-peritoneum was established by an open technique through an intra/supra-umbilical incision with a 10 mm port for initial pneumo-peritoneum and inspection. A further 5 mm port was used in the left iliac fossa and a 5 mm port was used in the hypogastrium. Standard laparoscopic instruments were used. The routine surgical technique was dissection of the mesoappendix from the appendix with diathermy and division of the appendix base between two endo-loops.

In more complicated cases, alternative techniques may be used. Any variations to the regimen with justification were recorded. The musculo-aponeurotic layers of port sites of 10 mm were closed with non-absorbable sutures before closing the skin. A standard pain relief policy was followed, where possible. This included one or more of the following postoperative analgesics: paracetamol (1 g QID), diclofenac (doses were titrated and recorded).

Primary effectiveness outcomes

The patient reported outcome measure is the patient reported cosmesis and body image data obtained using the Body Image Questionnaire (BIQ) at six weeks; participants were asked five questions about their body image using the scale on a 4- point Likert scale of: (a) no not at all; (b) a little bit; (c) quite a bit; and (d) yes, extremely.

Two questions about their incision scar were rated on a scale of 1 (very unsatisfied/revolting) to 7 (very satisfied/beautiful); (b) one further question regarding the scar using a 10-point numerical rating scale (NRS), (c) a question regarding confidence on a 10-point numerical scale from 1 (not very confident) to 10 (very confident); and (d) the clinical outcome of severity of pain (pain NRS) was measured using a pain scale (scale from 0 (no pain) to 10 (worst imaginable pain) at one to seven days.

Other patient-reported outcomes

Patient reported measures are the Hospital experience questionnaire (HEQ) at six weeks where participants were asked four questions about their experience in hospital- (a) prior to the operation (much too long to much too short); (b) treatment received (very bad to very good); (c) pain after operation (no pain at all to a lot of pain); and (d) time to normal eating (no, not at all to I cannot remember).

Patients were rated subjectively using either a 4- or 5-level Likert scale and one rating question on their view of the importance of different items- (a) hospital stay; (b) size of scar; (c) no complications; (d) pain after surgery; and (e) resuming normal activities and diet.

Additionally, any analgesic usage and time to return to normal activities were collected.

Clinical outcomes

Clinical outcomes included analgesic use, duration of operation (in minutes), complication rates, conversion rates, infection rates, intra-abdominal and wound related re-admission rates up to six weeks, reoperation rates and port-site hernia up to six weeks.

Resource use

Resource use was limited to duration of operative procedure, operation theatre time and use of disposable instruments.

Statystical analysis

For feasibility measures, such as the proportion of eligible patients who consent to randomisation, the frequency and corresponding 95% confidence interval were calculated. Patient-reported and clinical measures summarized using appropriate summary measures (for example, frequency or mean and standard deviation) for each treatment group. The treatment groups were compared at the two-sided 5% significance level. BIQ and pain NRS (area under the curve over a seven-day period) were analysed using an independent t-test. Other outcomes were assessed using standard statistical methods as appropriate, for example, comparison of proportions Newcombe's CI method or Chi-squared test for trend and independent t-test for binary and continuous outcomes respectively.

Corresponding 95% confidence intervals were also calculated. A single principal analysis was anticipated at the end of the study following intention to treat principle (grouped according to allocation). No imputation for missing data were carried out.

BELLASINDHI

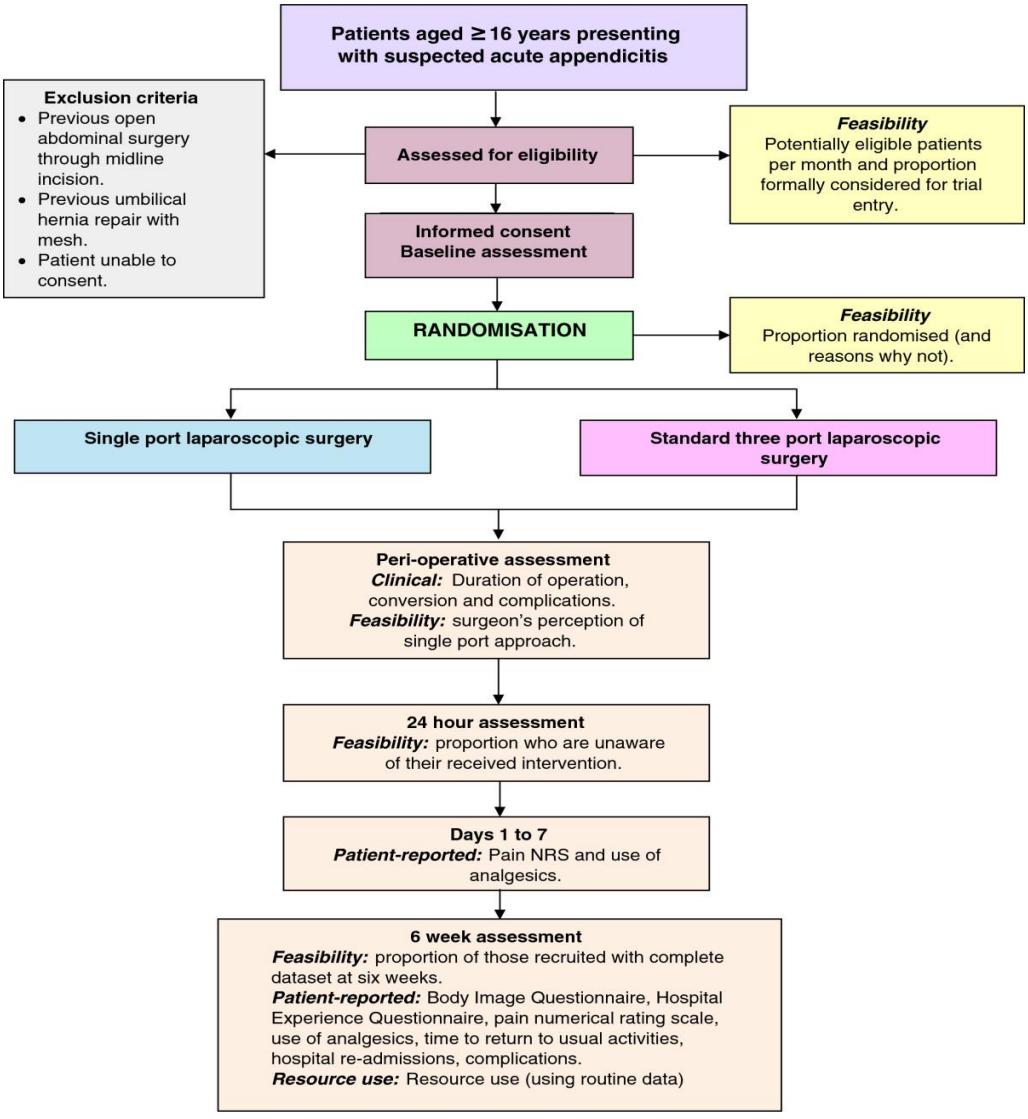

Figure 5: Flowchart of study procedure.

RESULTS

Unpaired t test results for operating time

P value and statistical significance

The two-tailed p value was less than 0.0001.

By conventional criteria, this difference is considered to be extremely statistically significant.

Confidence interval

The mean of SILS operating time minus 3 port laparoscopic appendicectomy operating time equals 17.28.

95% confidence interval of this difference: from 9.89 to 24.67.

Intermediate values used in calculation

The values were t=4.7001, df=48 and standard error of difference=3.677.

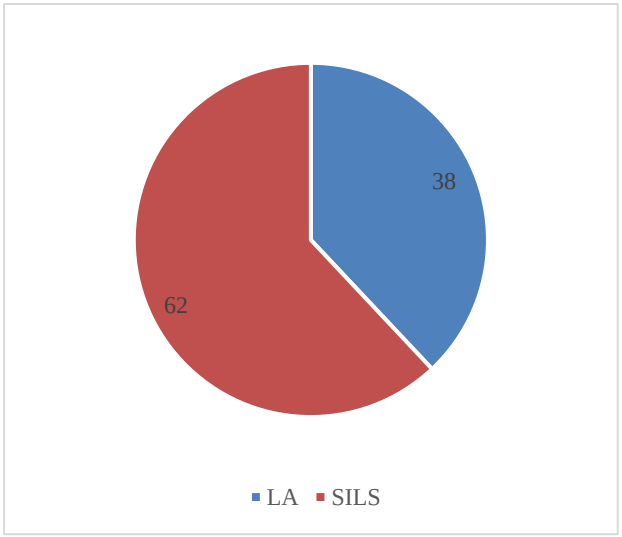

Figure 6: Pie chart of mean operating time.

Unpaired t test results for post-operative pain in scale of 1 to 4

P value and statistical significance

The two-tailed p value equals 0.0001, which was statistically significant.

Confidence interval

The mean of SILS post-op pain 1-4 scale minus 3 port laparoscopic appendicectomy post-op pain 1-4 scale equals- 0.77. 95% confidence interval of this difference: from -1.14 to -0.40.

Intermediate values used in calculation

The values were t=4.1829, df=47 and standard error of difference=0.183.

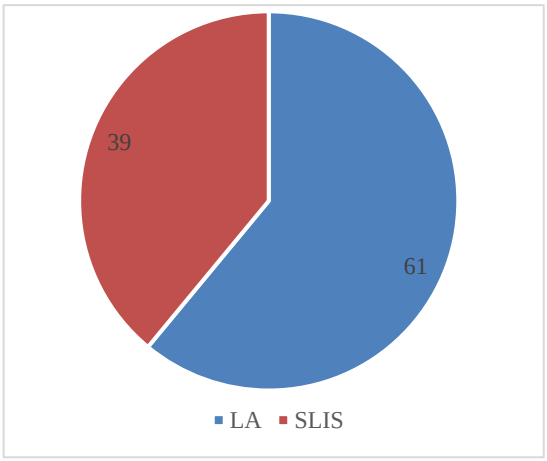

Figure 7: Pie chart of post-operative pain.

Unpaired t test results for post-operative recovery time

P value and statistical significance

The two-tailed was less than 0.0001, statistically significant.

Confidence interval

The mean of SILS recovery time minus 3 port laparoscopic appendicectomy recovery time equals- 4.76. 95% confidence interval of this difference: from -5.86 to -3.65.

Intermediate values used in calculation

The values were t=8.6661, df=47 and standard error of difference=0.549.

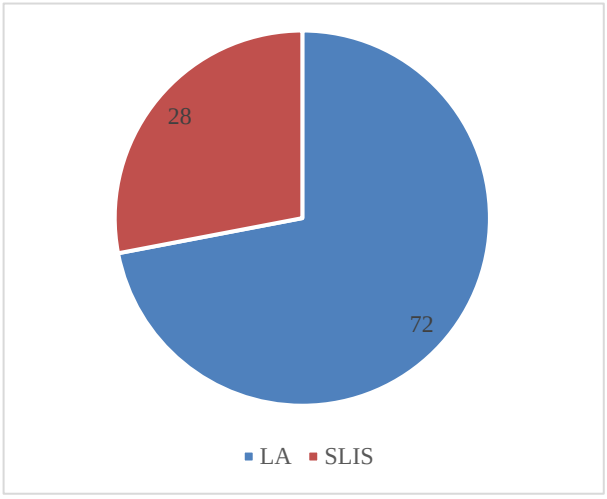

Figure 8: Pie chart of post-operative mean recovery time.

Unpaired t test results for body image (higher the value lower the image)

P value and statistical significance

The two-tailed was less than 0.0001, statistically significant.

Confidence interval

The mean of SILS body image minus 3 port laparoscopic appendicectomy body image equals -7.76. 95% confidence interval of this difference: from -10.87 to -4.65.

Intermediate values used in calculation

The values were t=5.0173, df=48 and standard error of difference=1.547.

Table 1: Unpaired t test for body image.

Group	SILS body image	LA body image
Mean	10.72	18.48
SD	1.24	7.63
SEM	0.25	1.53
N	25	25

DISCUSSION

With a total sample size of 50, 25 patients underwent SILS and 25 patients underwent conventional laparoscopic surgery. The unpaired t-test for operating time is statistically significant with two-tailed p value of 0.0001. Mean operating time was 44.16 minutes for SILS and 26.88 minutes for laparoscopic appendicectomy making SILS more time consuming. In a meta-analysis done by Zhou H and Jin K et al the operative time was significantly longer in the SILA group than in the CMLA group (WMD=6.62; 95% CI: 3.42-9.82; p<0.0001).[6,7]

The unpaired t-test result for post-operative pain in a scale of 1 to 4 yielded a two -tailed p value of 0.0001 which is statistically significant. The mean operative pain in scale of 1 To 4 was 1.40 and 0.40 for SILS and for laparoscopic appendicenctomy respectively making SILS more pain free and comfortable for the patient. A similar study conducted by Jawahar.K. et al noted similar findings 'The pain scores measured at 24 hours were similar between two groups with p value 0.72 however the pain scores were significantly lower in SILA group than CLA group with p value of 0.003'.[8,9]

On evaluating the post-operative recovery time with unpaired t-test, two- tailed p value of 0.0001 was obtained which indicated a clear statistical significance. The mean post-operative recovery time was 3.12 days for SILS and for 7.88 days for laparoscopic appendicenctomy giving SILS patients more rapid recovery and resumption of work. The unpaired t-test for body image (higher the value lower the image) yielded a statistically significant two -tailed p value of 0.0001. The mean body image (higher the value lower the image) in scale of 10 to 40 was 10.72 for SILS and 18.48 for LA making SILS more cosmetic for the patient.

Several studies have shown that SILS is a feasible, safe and preferred alternative to traditional laparoscopy or open Surgery for the right surgical candidates. In the publication on 29 April 2013 by Yu-Tso Liao and others under the heading learning curve of single port laparoscopic appendicetomy for uncomplicated appendicitis- a preliminary analysis compared with conventional laparoscopic appendicetomy concludes that single port. Laparoscopic appendicetomy is a safe and feasible procedure.[10] The learning curve should be overcome safely without major complication.

This study definitely has its limitations. The operating time and post-operative scar were definitely dependant on the experience of the operating surgeon. Only single blinding was used.

CONCLUSION

This study suggests that single-incision laparoscopic appendectomy shows excellent cosmetic results, lesser post-operative pain, shorter hospital stay duration but increased operative time. All these advantages come at the cost of increased operative time which might be a constraint in extremely high-volume centres. Operative difficulties along with time constraint need to be overcome by the surgeon which depends on the learning curve as well as time availability. The author says that with the availability of greater and better optics, instruments and visualizations SILS is a viable alternative and it is emerging as a safe novel option for selective group of patients. It is crucial that the technique be critically evaluated during this particular phase of implementation to provide objective data to inform further adoption and evaluation. It is hoped that the results of this study will lead to a large multicentre RCT of single versus standard three-port laparoscopic surgery.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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