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**Research** article

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Single incision laparoscopic appendectomy with surgical-glove port is cost-effective and reliable in complicated acute appendicitis: A casecontrol multicenter study in Colombia

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## ABSTRACT

Background: The single-port (SPL) and multi-port (MPL) laparoscopic approach are the gold standard of management of acute appendicitis, due to its multiple advantages over open surgery, mainly because of its direct effects on recovery, esthetics and costs of the procedure. However, in third-world countries, the laparoscopic approach is not yet fully reproducible due to the costs of the technique. The surgical-glove port single incision laparoscopic appendectomy (SGP-SILA) has been proposed as a viable option. However, it has never been studied in Colombia. Objective: To evaluate the cost-effectiveness and reliability of SGP-SILA in the management of complicated acute appendicitis, compared to traditional MPL approach.

Materials and methods: A retrospective case control study was carried out comparing patients undergoing laparoscopic appendectomy by SGP-SILA vs. MPL, evaluating operating costs associated with intraoperative and postoperative variables in two tertiary centers in Bogota, Colombia. The data were analyzed and expressed according to their nature and distribution.

Results: 116 patients were included (SGP-SILA: 62 and MPL: 54). The median surgical time for SGP-SILA was 60 min vs. 39 min for MPL. SGP-SILA was shown to cause lower frequency of surgical site infection (4 vs. 8 patients; p = 0.047). It was found a significant correlation between Grade III surgical site infection and surgery time (p = 0.047) in the MPL group; also, with hospital stay (p < 0.001). Also, a lower risk of surgical site infection was found with the SGP-SILA technique (22% vs. 31%). SGP-SILA generated a reduction in both direct and indirect operating costs of approximately 10% (616 USD vs. 683 USD).

Conclusion: SGP-SILA and MPL are feasible and comparable procedures in the resolution of complicated acute appendicitis. SGP-SILA turns out to be more cost-effective compared to MPL, due to the use of more easily accessible instruments. This may be a reproducible technique in lowand middle-income countries.

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#### 1. Introduction

Acute appendicitis is one of the most frequent causes of acute abdomen with economic implications in all health systems. About 6–8% of subjects in Western countries could develop appendicitis at some point in their life [1,2]. Also, this is one of the main surgical emergencies in the gestational period [3,4]. The ideal treatment is the laparoscopic appendectomy [2].

Laparoscopic appendectomy is a feasible procedure with multiple advantages compared to open surgery. This surgical procedure can be performed using two main techniques: Multi-port approach (MPL) or single-port approach (SPL). The choice of the surgical technique depends on the skills of the surgeon, and the institution's resources [2,5,6]. Single-incision laparoscopic appendectomy (SILA) was developed to improve esthetics, postoperative pain, and return to normal activity. However, in many randomized clinical trials (RCT), SILA had shown similar outcomes to the multiport approach but with higher costs [7]. In order to solve this, several authors have described in recent years [6,8–10], a self-made and inexpensive surgical-glove port single incision laparoscopic appendectomy (SGP-SILA). This technique is associated with substantially decreased costs compared with commercial devices for single port surgery [6,8–10].

To date, few countries have attempted to compare the cost-effectiveness and performance reliability of this technique with MPL, despite the results obtained. According to the objectives of global surgery for the year 2030, it is necessary to develop techniques and produce evidence that will allow the control of the surgical disease burden, as well as reduce operating costs and catastrophic expenditure, especially in low- and middle-income countries, where there are still difficulties in access to specialized services, tertiary level centers, insufficient resources to ensure high quality services, and lack of training in high-tech techniques [11–13]. Colombia, is a country with difficulties in several areas, especially in the health field. Laparoscopic surgery is not yet reproducible throughout the country. Therefore, the use of open surgery is very common. However, the development of a low-cost technique that can use more readily available resources may change this trend. Based on the above, the aim of this study was to assess the SGP-SILA in complicated acute appendicitis, in a middle-income Latin American country.

### 2. Methods

The reporting of this study conforms to The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines that were created to aid the authors in ensuring high-quality presentation of the observational studies [14].

#### 2.1. Study design

Retrospective case-control study.

### 2.2. Setting

This study was performed including all cases of acute complicated appendicitis treated with SGP-SILA compared with a control group of MPL appendectomy (Fig. 1) between January 2017 and December 2019 in two tertiary institutions and referral centers in



Fig. 1. Visualization of the use of multi-port laparoscopy technique. Source: authors.

Bogotá, Colombia (Clinica El Bosque and Centro Policlinico del Olaya). The duration of case enrollment was 2 years.

#### 2.3. Participants

Patients were included if they met all of the following criteria: (1) Age >18 years old; (2) Patients who had a diagnosis of complicated acute appendicitis (perforated); (3) Hemodynamically stable patients (no signs of shock, lactate levels <2 mmol/L); (4) Patients who did not present chronic obstructive pulmonary disease or severe pulmonary hypertension. Patients with incidental appendiceal tumors, pregnant women with complicated acute appendicitis, and patients with appendiceal stump appendicitis were excluded. Patients were selected at the rate of one control for each case. However, the groups were not balanced, because fewer controls (patients undergoing MPL) than cases (patients undergoing SGP-SILA) were found.

### 2.4. Variables and surgical technique description

Acute complicated appendicitis was defined as perforated appendix and/or presence of purulent collection or abscess or diffuse peritonitis. Conversion to open was defined as any case in which laparoscopy was used with therapeutic intent with the subsequent creation of a laparotomy incision, regardless of the extent of the attempted resection [6]. Preoperatively, patients received ampicillin/sulbactam (3 g) intravenously, or metronidazole (500 mg) plus ciprofloxacin (400 mg) if allergic to penicillin. Postoperatively, antibiotics were used if evidence of appendiceal abscess or diffuse peritonitis were found, using a 3–5 days cycle depending on the clinical evolution of the patient.

Patients were placed in the supine position with both arms tucked along their sides, under general anesthesia. The patient was securely strapped to the surgical bed to facilitate maximum tilting and lateral rotation of the operating table. The surgeon and the first assistant stand on opposite sides of the table. The surgical team should move around the patient according to the operative findings.



**Fig. 2.** Low-cost glove port device for SGP-SILA: How to do it. **A.** Wound retractor and protector device plus two sterile surgical gloves. **B.** Introduction of the wound retractor and protector device into the umbilical incision. **C.** Fusion of the two sterile surgical gloves and the wound retractor and protector device. **D.** Creation of the glove port opening incisions in the fingertips of the surgical sterile gloves to allow the introduction of the laparoscopic ports. Source: authors.

Then the surgeon stood in the traditional left cholecystectomy position. The first surgical assistant stood at the right of the surgeon and the scrub nurse to the right of the first assistant.

The SGP-SILA technique, it's a procedure that started with a 2.5 cm skin incision with an open Hasson's technique in the umbilicus and the double ring wound protector (Alexis-O® wound protector, size small or extra small, from Applied Medical, CA, USA) is positioned and tightened within the incision. Two surgical gloves (size 7.5, powder-free surgical glove made of natural rubber latex) are slide down on the external ring of the wound protector and small cuts are then made at the tip of the fingers of the gloves in order to get the access for the ports and create the surgical-glove port for single port surgery following the technique of Di Saverio et al. [6] (Fig. 2 [A-D] and Fig. 3 [A-D]). Pneumoperitoneum was created using 12 mm reusable port with a 12–15 mmHg intra-abdominal pressure. Two additional 5-mm reusable ports were inserted in two fingers of the glove port. The tip of the appendix was seized for the mesoappendix by a grasper clamp. The mesoappendix was dissected and sectioned from the top to the base using electro-coagulation with a monopolar laparoscopic hook device. After that, two Hem-*o*-lok size XL clips were placed, one Hem-*o*-lok is placed close to the caecum and the other one is placed 1 cm distal to the first one. The appendix is transected between the two Hem-*o*-lok, leaving one Hem-*o*-lok on the caecum end. After resection of the appendix we didn't need to use a surgical specimen removal bag for the appendix structure because we have the wound protector in the glove port. After removal of the appendix, drainage of the diffuse peritonitis was performed using a reusable suction tube.

#### 2.5. Data sources/measurement

Clinical, intraoperative and postoperative variables as well as operative and hospital costs were retrospectively collected from each institutional database in all patients who underwent SGP-SILA and multiport laparoscopic appendectomy. Information was taken on operating costs according to the chosen approach, taking into account the following variables: hospitalization cost (calculated in a oneperson room, and based on the average hospital stay according to procedure), cost per hour of the operating room (includes instruments, laparoscopy tower, sterile clothing, anesthesia and other personnel available for the procedure), the requirement for Alexis Wound Protector and gloves to perform SGP-SILA according to Di Saverio et al. [6] and the number of trocars used. In addition,



**Fig. 3.** In vivo low-cost glove port for SGP-SILA. **A.** Fusion of the two sterile surgical gloves and the wound retractor and protector device. **B.** Introduction of the wound retractor and protector device into the umbilical incision. **C.** Creation of the glove port opening incisions in the fingertips of the surgical sterile gloves to allow the introduction of the laparoscopic ports. **D.** Initial diagnostic laparoscopy using the glove port. Source: authors.

variables such as type of procedure, intraoperative bleeding, conversion requirement, and duration of procedure and length of hospital stay were taken into account.

## 2.6. Bias

To avoid Berkson bias [15], only patients with complicated appendicular pathology were included, without choosing specific patient groups such as hospitalized populations, and therefore the controls were patients operated on with the conventional technique. No factors were identified that attenuated or increased exposure and therefore biased the work.

## 2.7. Study size

The sample corresponded to a convenience sample with a sample calculation. To calculate the sample, the monthly average number of cases of perforated appendicitis treated in both hospitals was taken into account, being approximately 4 cases. This gives a total of approximately 144 cases in the study period.

#### 2.8. Statistical analysis

The normality of quantitative variables was tested using the Kolmogorov–Smirnov test. Data were presented as mean  $\pm$  standard deviation (SD) for continuous variables and median (interquartile, IQR) for skewed variables. Qualitative variables were summarized using frequency and percentages. Comparative analysis was carried out using Pearson's Chi-square test or Fisher's exact test for categorical variables. Spearman's correlation was also used. The strength of association was measured using Cramer's V. Survival curves were obtained using the Kaplan–Meier method. A p < 0.05 was defined as statistical significance. All analyses were performed using IBM SPSS Statistics v25.

#### 2.9. Ethical statements

This study was reviewed and approved by the ethics committee of Clínica el Bosque. Written informed consent was obtained from all participants involved in the study.

#### 3. Results

During the study period, a total of 116 patients with acute complicated appendicitis underwent laparoscopic appendectomy (Fig. 4 [A-D]). 62 patients were taken SGP-SILA and 54 appendectomies MPL. In the MPL group, age, bleeding, surgery time and hospital stay in days had a nonparametric distribution; the median age was 29 years (36–22); median bleeding was 5 cm<sup>3</sup> (20–5); surgery time in



**Fig. 4.** A-B. Complicated acute appendicitis with appendiceal stump compromise treated with a partial colectomy using a laparoendoscopic stapler plus generalized peritonitis laparoscopic lavage and drainage. C. Appendiceal phlegmon with periappendicular abscess secondary to complicated (perforated) acute appendicitis. D. Pelvic peritonitis secondary to complicated (perforated) acute appendicitis. Source: authors.

minutes had a median of 39 min (55–29.25) and hospital stay had a median of 5 days (7–3). The average body mass index (BMI) had a parametric distribution and its mean was  $33.7 \text{ cm/m}^2 (\pm 5.8)$ .

In the SGP-SILA group, age, BMI, bleeding, surgery time in minutes and hospital stay in days had a nonparametric distribution. The median age was 34 years (47.25–24.75); median bleeding was 5 cm<sup>3</sup> (10–5); BMI had a median of 32 (35–24); surgery time in minutes had a median of 60 min (84.25–33.75) and hospital stay had a median of 5 days (5–3). The need for conversion to multiport surgery in the SGP-SILA group was 8.1% (n = 5) and the need for conversion to open surgery was 3.7% (n = 2) in the MPL group (Table 1). Grade III surgical site infection was identified in 4 patients in the SGP-SILA and 8 patients in the MPL. Spearman's correlation showed a significant correlation between Grade III surgical site infection and surgery time in minutes (p = 0.047); also, with hospital stay (p < 0.001) in the MPL group. Another association found was between hospital stay and age (p = 0.02). In the SGP-SILA group there was also an association between Grade III surgical site infection and surgery time in minutes (p = 0.032); as well as hospital stay (p < 0.001). Additionally, a significant difference was found between the risk of Grade III surgical site infection and patient age between the two techniques (SGP-SILA 22% vs. MPL 31%) (Fig. 5 [A-B]).

When analyzing the qualitative variables, a statistically significant association was found between the SGP-SILA with conversion to MPL and the Grade III surgical site infection (p = 0.03) with a moderate likelihood ratio (p = 0.018; Cramer's V = 0.4). Regarding the relationship between conversion to open surgery in patients with MPL and Grade III surgical site infection, an association was found (p = 0.02); if conversion to open surgery was considered as a dependent variable; it was found a moderate association (Cramer's V = 0.5). No other associations were found.

The 100% of the cecal appendices were sent to pathology and only two showed neuroendocrine tumors smaller than 2 cm, without involvement of the serosa, negative nodes and without involvement of the appendiceal base, without lymphovascular invasion. Only one patient presented an adenocarcinoma of the cecal appendix in the middle third of the appendix, for which he was taken to radical right hemicolectomy with D3 dissection by laparoscopy at 6 weeks.

The operational costs of SGP-SILA vs multiport appendectomy approach are shown in Table 2. Each individual cost of length of hospital stay, operating room and surgical devices were translated from Colombian pesos to dollars based on the representative market rate (RMR) of 19/04/21. With the SPG-SILA, operational costs are saved at 9.74%, compared to MPL appendectomy, mainly due to the use of the Alexis Wound Protector.

#### 4. Discussion

The evidence provided in this study demonstrated that the laparoscopic appendectomy is an effective procedure for the resolution of the acute complicated appendicitis. However, SGP-SILA and MPL both are comparable surgical techniques in terms of performance since they turned out to have the same effectiveness [16,17]. This study indicates that SGP-SILA resulted to be the most cost-effective option for complicated acute appendicitis since it has a lower cost than MPL based on a comprehensive review of the operating costs. Otherwise, MPL had a significant increment of the total costs due to the use of disposable surgical devices like laparoscopic ports. Nevertheless, the MPL group has a lower average operative time versus SGP-SILA, with a difference of 17 min. This result could be explained due to the absence of laparoscopic triangulation in the SILA and a minor surgical experience of the surgeons with this approach.

Mosquera et al. [2] compared open vs laparoscopic approach in acute appendicitis based on the costs, with a sample of 20 patients in each group, matched by hospital stay, supplies, and stage of appendicitis. It was observed a 42% cost overrun for laparoscopic appendectomy compared to open. The factor that increased the costs in the laparoscopic group was the use of the laparoscope and disposable supplies as ports, which correspond to 33.2 and 33.9%, respectively, of the total cost of the procedure [2]. In our study, we compared 116 patients taken to SGP-SILA vs. MLP approach, showing that SGP-SILA approach has a lower cost with the same effectiveness due to the use of reusable devices as we described in our surgical technique.

There was a lower risk of bleeding and surgical site infection, no incidence of incisional hernia at one year without missed bowel injuries in the SGP-SILA group with the same hospital stay. The results found in this study are comparable to those observed in other regions [1,18–21]. Nevertheless, in the study published by Watanabe et al. [20], a comparison between SGP-SILA vs MPL approaches for minimally invasive colectomy. They did not find superiority between any of the two procedures, with no differences in surgical time and postoperative outcomes. These results differ from our study where the SGP-SILA group has a longer surgical time. On the other side in our results, the SGP-SILA approach generated a decrease of 9.74% in the costs of the procedure without modification of the clinical outcomes.

Table 1

Summary of sociodemographic, clinical and surgical characteristics of the study population.

	MPL $n = 54$	SGP-SILA $n = 62$
Age in years, med (IQR)	29 (14)	34 (23)
BMI, mean (SD)	33.7 cm/m <sup>2</sup> (5.8)	32 cm/m <sup>2</sup> (11)
Bleeding, med (IQR)	5 cm <sup>3</sup> (15)	5 cm <sup>3</sup> (5)
Surgical time, med (IQR)	39 min (25.7)	60 min (50.5)
Hospital stay in days, med (IQR)	5 (4)	5 (2)
Conversion to MPL	-	5
Conversion to open surgery	2	-
Surgical site infection	8	4



Fig. 5. Kaplan Meyer analysis showing the risk of grade III surgical site infection according to age, between SGP-SILA (A) vs MPL techniques (B).

 Table 2

 Comparison of SGP-SILA vs. MPL appendectomy operating costs.

Item	SGP-SILA	MPL
Day of hospitalization (Night in a one-person room floor)	26.52 USD	
Operating room time (Instruments for laparoscopy, anesthesia)	154.52 USD	
Alexis Protector	75.69 USD	-
Ports 12 mm (2 units)	227.18 USD	
Ports 5 mm	113.59 USD	
Sterile gloves unit (2 units)	5.96 USD	-
Monopolar laparoscopic dissector	3 USD	3 USD
Reusable suction tube	10 USD	10 USD
Graspers clamps	_	72.62 USD
Surgical specimen retrieval bag	_	75.58 USD
Total	616.46 USD	683.01 USD

In summary, the term "opportunity cost" applied to medicine can be defined as the value of the best surgical option. When evaluating the use of a new technology, this opportunity cost and the variables related to the operating time must be taken into account when making a decision [2,6,22,23]. The cost-effectiveness of choosing the procedure to be used comes to play a determining role,

especially in developing countries where the impact on the health system requires a better distribution of resources. Laparoscopic appendectomy has been constantly discussed due to its high operating costs secondary to the use of disposable instruments [1-5], which represents a limitation for its choice. Taking into account the importance of the incremental cost-effectiveness in performing frequent surgical procedures. Based on our study, related to the surgical field, all resources must be included (diagnostic process, hospital stay, equipment and personnel), to define the ideal surgical approach.

The main limitation of our study is that it is a comparative retrospective study that lacks randomization of patients, which may be related to selection biases with a small sample of patients. Additionally, we found was that the costs of the supplies change according to the providers that each hospital had, for that reason our study is an approximation of the operative costs. Another point to be addressed in the future that was not evaluated in our study was the esthetic evaluation and patient satisfaction between the two surgical techniques.

## 5. Conclusions

SGP-SILA and MPL are feasible and comparable procedures in the resolution of complicated acute appendicitis. SGP-SILA turns out to be more cost-effective compared to MPL, due to the use of more easily accessible instruments. This may be a reproducible technique in low- and middle-income countries. It is necessary to emphasize that the choice of the type of procedure will depend on the availability of resources and the skills of the surgeon. However, more studies are needed to make a comprehensive analysis of operating costs where opportunity costs are considered to make cost-effective decisions to the health systems in special situations for developing countries.

## Author contribution statement

Andrés Felipe CarrilloMontenegro: Conceived and designed the experiments, Performed the experiments, and Analyzed and interpreted the data.

Soffa AristizabalRojas: Conceived and designed the experiments, Performed the experiments, and Analyzed and interpreted the data.

Jean André PulidoSegura: Conceived and designed the experiments, Performed the experiments, and Analyzed and interpreted the data.

Ivan David Lozada-Martinez: Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, and Wrote the paper. Luis Felipe CabreraVargas: Conceived and designed the experiments, Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, and Wrote the paper.

MauricioPedraza: Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, and Wrote the paper. LauraPadilla: Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, and Wrote the paper.

Alexis Rafael Narvaez-Rojas: Analyzed and interpreted the data, Contributed reagents, materials, analysis tools or data, and Wrote the paper.

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## Data availability statement

Data will be made available on request.

#### Declaration of interest's statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

### Additional information

No additional information is available for this paper.

#### **Ethics** approval

This study was approved by the ethics committee of our hospital.

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