Final Degree Project

Degree in Medicine, Faculty of Medicine

University of Vic - Central University of Catalonia (UVic-UCC)

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UVIC·UCC

RANDOMISED CLINICAL TRIAL ON THE EFFICACY AND SAFETY OF THE ENDOSCOPIC TREATMENT OF PILONIDAL CYST (ENDOSCOPIC PILONIDAL SINUS TREATMENT, EPSIT) COMPARED WITH CONVENTIONAL SURGERY FOR RECURRENCES AT 6 MONTHS FOLLOW-UP. PILOT STUDY.

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Abstract

Background and aims: Although traditional pilonidal sinus surgery has good long-term outcomes, it requires long-periods of post-operative care. Endoscopic Pilonidal Sinus Treatment (EPSiT), as a minimally invasive surgery, can improve post-operative cures; however, there is little evidence of recurrence or post-operative persistence.
This project proposes a study to evaluate the efficacy and security of both types of surgery at 6 months.

Material and methods: Pilot trial, randomized prospective cohort study.
Eligible patients were assigned to the control group (complete sinus excision) and the intervention group (EPSiT). Wound healing, pain (VAS), need for outpatient care, emergency department visits and patient satisfaction (PGI-I) were assessed at 1 month and 6 months after surgery.

Results: 31 patients who met inclusion criteria were randomized of whom 3 were excluded. Control group (n=14) and intervention group (n=16), 22 men and 6 women, with an average age of 35, with no differences between groups. 40% of patients in the intervention group (IG) were still receiving wound care at the 30 days post-operative control compared to 84.6% of patients in the control group (CG) (p=0.02). At 6 months after surgery, a total of 20% of patients in the IG and 7.7% of patients in the CG had persistent pilonidal cysts (p=0.35) and 6.7% of patients in the IG had recurrences (p=0.34).

Conclusion: Taking into account the results of the series, EPSiT reduces wound healing time, but this is associated with higher persistence/recurrence of pilonidal cysts at 6 months.

ENSAYO CLÍNICO ALEATORIZADO SOBRE LA EFICACIA Y SEGURIDAD DEL TRATAMIENTO ENDOSCÓPICO DEL QUISTE PILONIDAL (TRATAMIENTO ENDOSCÓPICO DEL SINUS PILONIDAL, EPSIT) COMPARADO CON LA CIRUGÍA CONVENCIONAL EN LAS RECIDIVAS A LOS 6 MESES DE SEGUIMIENTO. ESTUDIO PILOTO.

Resumen

Introducción y objetivos: Aunque la cirugía tradicional de los sinus pilonidales tiene buenos resultados a largo plazo, requiere largos periodos de cuidados postoperatorios. El tratamiento endoscópico de los sinus pilonidales (EPSiT), como cirugía mínimamente invasiva, puede mejorar las curas postoperatorias; sin embargo, hay pocas pruebas de recidiva o persistencia postoperatoria.
Este proyecto propone un estudio para evaluar la eficacia y seguridad de ambos tipos de cirugía a los 6 meses.

Materiales y métodos: Ensayo piloto, estudio de cohortes prospectivo aleatorizado.
Los pacientes elegidos fueron asignados al grupo control (escisión completa del sinus pilonidal) y al grupo de intervención (EPSiT). Se evaluaron la cicatrización de la herida, el dolor (EVA), la necesidad de atención ambulatoria, las visitas a urgencias y la satisfacción del paciente (PGI-I) al primer mes y al sexto mes de la cirugía.

Resultados: Se aleatorizaron a 31 pacientes que cumplían los criterios de inclusión, de los cuales 3 fueron excluidos. Grupo de control (n=14) y grupo de intervención (n=16), 22 hombres y 6 mujeres, con una edad media de 35 años, sin diferencias entre grupos. El 40% de los pacientes del grupo de intervención (GI) seguían recibiendo cuidados de la herida a los 30 días del control postoperatorio, frente al 84,6% de los pacientes del grupo de control (GC) (p=0,02). A los 6 meses de la intervención, el 20% de los pacientes del GI y el 7,7% de los pacientes del GC presentaban quistes pilonidales persistentes (p=0,35) y el 6,7% de los pacientes del grupo de intervención presentaron recidivas (p=0,34).

Conclusiones: Teniendo en cuenta los resultados de la muestra, el EPSiT reduce el tiempo de cicatrización de la herida, pero se asocia a una mayor persistencia/recidiva de quistes pilonidales a los 6 meses.

ASSAIG CLÍNIC ALEATORITZAT SOBRE L'EFICÀCIA I SEGURETAT DEL TRACTAMENT ENDOSCÒPIC DEL QUIST PILONIDAL (TRACTAMENT ENDOSCÒPIC DEL SI PILONIDAL, EPSIT) COMPARAT AMB LA CIRURGIA CONVENCIONAL EN LES RECIDIVES ALS 6 MESOS DE SEGUIMENT. ESTUDI PILOT.

Resum

Introducció i objectius: Encara que la cirurgia tradicional dels abscessos pilonidals té bons resultats a llarg termini, requereix llargs períodes de cures postoperatòries. El tractament endoscòpic dels abscessos pilonidals (EPSiT), com a cirurgia mínimament invasiva, pot millorar les cures postoperatòries; no obstant això, hi ha poques proves de recidiva o persistència postoperatòria.
Aquest projecte proposa un estudi per a avaluar l'eficàcia i seguretat de tots dos tipus de cirurgia als 6 mesos.

Material i mètodes: Assaig pilot, estudi de cohorts prospectiu aleatoritzat.
Els pacients triats van ser assignats al grup control (escissió completa de l'abscés pilonidal) i al grup d'intervenció (EPSiT). Es van avaluar la cicatrització de la ferida, el dolor (EVA), la necessitat d'atenció ambulatòria, les visites a urgències i la satisfacció del pacient (PGI-I) al primer mes i al sisè mes de la cirurgia.

Resum: Es van aleatoritzar a 31 pacients que complien els criteris d'inclusió, dels quals 3 van ser exclosos. Grup de control (n=14) i grup d'intervenció (n=16), 22 homes i 6 dones, amb una edat mitjana de 35 anys, sense diferències entre grups. El 40% dels pacients del grup d'intervenció (GI) continuaven rebent cuidats de la ferida als 30 dies del control postoperatori, enfront del 84,6% dels pacients del grup de control (GC) (p=0,02). Als 6 mesos de la intervenció, el 20% dels pacients del GI i el 7,7% dels pacients del GC presentaven quistos pilonidals persistents (p=0,35) i el 6,7% dels pacients del grup d'intervenció van presentar recidives (p=0,34).

Conclusions: Tenint en compte els resultats de la mostra, l'EPSiT redueix el temps de cicatrització de la ferida, però s'associa a una major persistència/recidiva de quistos pilonidals als 6 mesos.

1. Introduction

1.1. Scientific background

The pilonidal cyst is a benign pathology with an estimated incidence of 26 cases per 100,000 population[1], occurring rarely before puberty or after the age of 40 years[2]. The male to female ratio is between 3:1 and 4:1[3]. A common risk factor is the presence of abundant hair in the area[1].

The clinical presentation varies; it can be asymptomatic, presenting acute infection with localized cellulitis and/or abscess, or progress to its chronic form of persistent subcutaneous cyst with persistent suppuration and chronic pain[1].

The cyst is an acquired condition and is caused by the traction of the hair follicles due to movements, such as sitting or bending, which stretch the natal cleft. The reaction of a foreign body is generated and makes its way into the skin, opening a pore or "pit"[1,2,4]. A cavity can be formed with its tracts, which in most cases are oriented cephalad[4]. The cavities can contain hair, debris and granulation tissue.

The diagnosis is made when the examination reveals midline pores (pits) in the intergluteal region, a tender mass or sinus orifices draining mucoid, purulent or bloody fluid[1].

The traditional definitive surgical treatment is a complete excision with secondary closure, which is associated with bloody wounds, long outpatient treatments and a slow return to full daily activities[5].

The need to obtain a technique that improves the morbidity of surgery, maintains a low incidence of recurrence and allows a faster recovery has led to the modification of traditional procedures such as reconstructive techniques such as flaps[5] or minimally invasive techniques.

Currently, the Endoscopic Pilonidal Sinus Treatment (EPSiT)[6] technique stands out because it is an endoscopic surgery of the pilonidal cyst using a cystoscope or fistuloscope, which allows cauterisation and complete excision of the entire cyst. It shows positive short-term results[7]; disappearance of post-operative pain and 100% complete healing of surgical wounds in the first month after surgery[5], improving patients' quality of life[8,9]. Recurrence <5%[8,10] or above 5%[11] in six months.

As this is a new technique, there are no studies comparing long-term (6 months follow-up) recurrence with total excision.

In general, systematic reviews and meta-analyses present few randomised clinical trials, making it difficult to reach high-level recommendations to guide decision-making[12,13]. Some of the trials were biased because they were based on a pediatric population[5], did not collect long-term data comparing recurrences[12], or were pilot studies with small sample sizes[7].

1.2. Objectives

The primary aim of this study is to evaluate the efficacy of EPSiT endoscopic surgery in the persistence/recurrence of pilonidal sinus treatment at 6 months, compared to the conventional treatment, which involves total excision and, if necessary, marsupialisation.
The secondary objectives of the study, according to the surgical technique used, are to evaluate:

- Surgical morbidity:
    - Immediate intra- and post-operative complications at 30 days.
- Duration of the procedure.
- Hospital stay.
- Pain using the VAS scale in the immediate post-operative period.
- Pain using the VAS scale at 1 month and at 6 months.
- Complications in the first month and six months related to the healing process: suppuration, bleeding, dehiscence, granuloma, infection.
- Need for emergency consultation (Hospital, Primary Care Center or external consultation of the surgical service) during the follow-up period due to superinfection or sinus pain.
- Healing time (complete epithelialisation, no pits present).
- Resumption of normal lifestyle/return to work.
- Date of recurrence of symptoms at 6 months in case of recurrence.
- Patient satisfaction at 1 month and 6 months after surgery.

2. Materials and methods

2.1. Trial design

Randomised, controlled and parallel pilot clinical trial to compare the efficacy and safety of endoscopic surgery (EPSiT), for the treatment of pilonidal sinus compared to conventional treatment with pilonidal sinus excision and marsupialisation if necessary. The protocol was approved by the Comitè d'Ètica d'Investigació Clínica de la Fundació Unió Catalana d'Hospitals, with protocol number CEI code 22/77. The study was conducted in accordance with current legal and regulatory requirements and international ethical guidelines for research involving human subjects.

The results were reported in accordance with the CONSORT 2010[14] statement.

2.2. Field of study

This is a unicentric study in which the patients were previously seen in the outpatient clinic. Interventions were carried out in the surgical area and follow-up was carried out in the general surgical outpatient clinics of Fundació Althaia, Xarxa Assistencial Universitària de Manresa-Sant Joan de Déu Hospital.

2.3. Study participants

The sample of the study was obtained from patients previously seen at the outpatient clinics with a diagnosis of pilonidal sinus who were on the waiting list for full excision surgery.

2.3.1. Eligibility criteria for participants

- Patients over 18 years.
- History of symptomatic pilonidal sinus with suppuration, superinfection and/or the need for previous debridement as assessed by Althaia's General Surgery External Consultation and tributary to surgery.
- Consent to participate in the study and sign the informed consent form.

2.3.2. Exclusion criteria for participants

- Patients who underwent pilonidal sinus surgery.
- Sinus debridement in the month prior to surgery.
- Patients receiving antibiotics for sinus infection in the month before surgery.

2.4. Randomisation

2.4.1 Sequence generation

Randomisation of patients to GC or GI was performed using a computer program for random sequence generation (http://www.randomization.com).
A list of 5 groups was generated, for each day of surgical programming, with 6 patients per group, except for one group which had 7 patients. The Althaia Innovation and Research Unit was responsible for generating the randomisation sequence and controlling the allocation to each study group.

2.4.2. Allocation concealment mechanism and implementation

Patient recruitment was the responsibility of the investigators, and the patient's allocation group was not known until the patient signed the informed consent form on the day of the intervention.

2.5. Study groups

Patients in the control group (CG) received conventional treatment, which consisted of resection of the cyst in its entirety, including all sinus tracts. In addition, marsupialisation was performed in cases where the surgical wound was greater than 3 cm in length and 2 cm in width.

Patients in the intervention group (IG) underwent endoscopic treatment using the EPSiT technique, which consists of making one or two 3mm holes[1], to allow the entry of the fistuloscope, connected to a video and irrigation system with a glycine solution, to perform an inspection, extraction of debris with a brush and weeding spoon. Then, endoscopic electrocoagulation of the canals and cavities was performed, and the cavity entrance holes were not sutured (Appendix 1).

[1] The holes are also called punches, because the tool that is used is called a punch and it is a circular scalpel.

2.6. Study procedure

Patients on the surgery waiting list for the total excision of sinus were informed of the possibility of participating in the study.

If accepted, an informed consent for surgery and a study participation was explained and signed. They were then randomly assigned to surgery and assessed and visited by the anaesthesia team.

If the patient did not agree to participate in the study, the patient underwent conventional surgery (total excision) and a follow-up with external consultation after 1 month.

2.6.1. Surgical procedure

In both cases, the surgery was performed in the operating theatre on an outpatient basis and the patient was discharged on the same day if there were no immediate post-operative complications.

On the day of surgery, spinal anaesthesia and antibiotic prophylaxis with cefuroxime (1.5 g intravenous single dose) were used. The patient was positioned prone and inclined in 10º Trendelenburg on the operating table.

Some of the data that were compiled in the operating room were sinus measurements, estimated and actual, operative time and preoperative complications. Hospital stay and VAS (Visual Analogue Scale) were obtained before discharge.

On discharge, the nursing team gave guidelines on the use of analgesia and the treatments to be carried out, in the primary care centre or at home, with physiological serum washings and, in the absence of epithelialisation, Algesite M dressings. Referral standards for reconsultation in the event of superinfection, pain or dehiscence were also given, to the hospital emergency room, at the primary care centre or at external surgical consultations.

2.6.2. Follow-up

A 24-hour telephone check was made by the nursing staff to ask about pain (VAS), overall satisfaction (PGI: Appendix 2), and reminders about wound care and use of analgesia.

The face-to-face follow-up visits were carried out in the first and sixth months after the surgery; patients were asked if they had to go to the emergency department of a primary care centre or the hospital because of any complication related to the surgery (local/general infection, fever >38ºC, dehiscence of the suture, severe pain that was unsolved with the

prescribed medication and purulent exudate), the time needed for care and the time to return to work. During the physical examination, the area was inspected looking for signs of sinus persistence such as suppuration, epithelization, among other signals.

The web REDCap application, hosted on a server in Althaia's institution, was used for data collection and management[15].

2.7. Sample size

Other studies provided insufficient, inconsistent and heterogeneous information about the evidence for the effectiveness of this type of intervention on the incidence of recurrence and persistence at 6 months. For this reason, it was not possible to estimate the sample size and it was considered that a pilot study of 31 patients randomised to the two available surgical techniques was necessary to assess the feasibility of the trial. It is also required to collect data on the size of the effect in order to estimate the sample size needed for a multicentre trial.

2.8. Blinding

This was conducted during data analysis, as it would not be possible to mask the patient or the surgical team due to the surgical techniques with characteristic incisions.

The outcome assessors were masked when administering the questionnaires at the follow-up visits.

2.9. Dependent variables

2.9.1. Primary dependent variable

- Sinus persistence or recurrence at 6 months after surgery.

Sinus persistence was considered if:

- The patient had continued to be painful or with suppuration.
- There was a pilonidal abscess or dehiscent scar and/or superinfection at exploration that required antibiotic treatment and/or surgical debridement for persistent signs.
- The patient was not completely asymptomatic at any time during follow-up.

Sinus recurrence was considered if:

- There was a new onset of pain or suppuration during the 6-month follow-up period.
- There was a pilonidal abscess or dehiscent scar and/or superinfection requiring antibiotic treatment and/or surgical debridement at exploration that was previously asymptomatic.
- Symptoms appear after an asymptomatic follow-up period.

2.9.2. Secondary dependent variables

- Safety of surgery: immediate intra and post-operative complications at 30 days.
- Duration of surgery.
- Outpatient hospital stay on the day of surgery.
- Pain at discharge, at 24 hours, 1 month and 6 months after surgery (VAS scale).
- Complications related to the healing process at 1 month and 6 months.
- Duration of post-operative outpatient care wound healing
- Resumption of normal lifestyle/return to work.
- Need for emergency consultation during follow-up at 1 month and 6 months for sinus-related reasons: the dates of consultation and reasons for consultation (suppuration, type of suppuration (serous, purulent, hematic), frequency of suppuration, abscess, bleeding, pain).
- In case of recurrence, date of recurrence of symptoms.
- Subjective patient satisfaction (PGI-I, Appendix 2) at 1 month and 6 months.

2.10. Independent variables

The independent variables were the group allocation, demographic data (age, sex, weight, height), smoking, diseases such as diabetes, immunosuppression, personal history of proctological surgery or previous debridement (date of last episode), characteristics of the sinus: size of cyst estimated preoperatively, number of pits, scars from previous debridement, operation time, actual size of sinus, size of scar and if marsupialization is realised (in case of total excision in CG), number of punchs (in case of endoscopic technique in IG).

2.11. Statistical methods

Exploratory univariate analysis: assessment of atypical and extreme values. Debugging the data. Identify and label missing and/or non-applicable values. Describe the distribution of each variable. Kolmogorov-Smirnov tests of normality for continuous variables.
Categorical variables are summarised in absolute values and relative frequencies. For quantitative variables, the mean and standard deviation, and in the case of non-normal distribution, the mean and interquartile range.

The homogeneity analysis will be confirmed by the homogeneity between the control group and the intervention group, using the chi-squared test for categorical variables (or Fisher's exact test in 2 x 2 contingency tables when the expected frequencies are less than 5) and the t-Student test for continuous variables with normal distribution. For non-parametric continuous variables, the Mann-Whitney U test is used.

Efficacy analysis: For each of the follow-up visits, the chi-squared test was used for categorical variables (or Fisher's exact test in 2 x 2 contingency tables if the expected frequencies were less than 5) and the t-Student test for continuous variables with a normal distribution. For non-parametric continuous variables, the Mann-Whitney U test was used.
IBM SPSS Statistics v.27 will be used for all statistical analyses.

All statistical analyses will be performed on an intention-to-treat basis. The level of statistical significance will be set at 5% bilateral ($p<0.005$).

3. Results

3.1. Participant flow

Between July and August 2022, 31 patients were screened for eligibility and randomised. 15 patients were selected for the control group (CG) and 16 for the intervention group (IG). 3 patients (9.7%) were excluded; 2 of them reported that were not available on the surgery day, and the other one did not come on the day of surgery. No patients were lost to follow-up. Twenty-eight patients (90.3% of those meeting the inclusion criteria) agreed to participate and signed the informed consent.

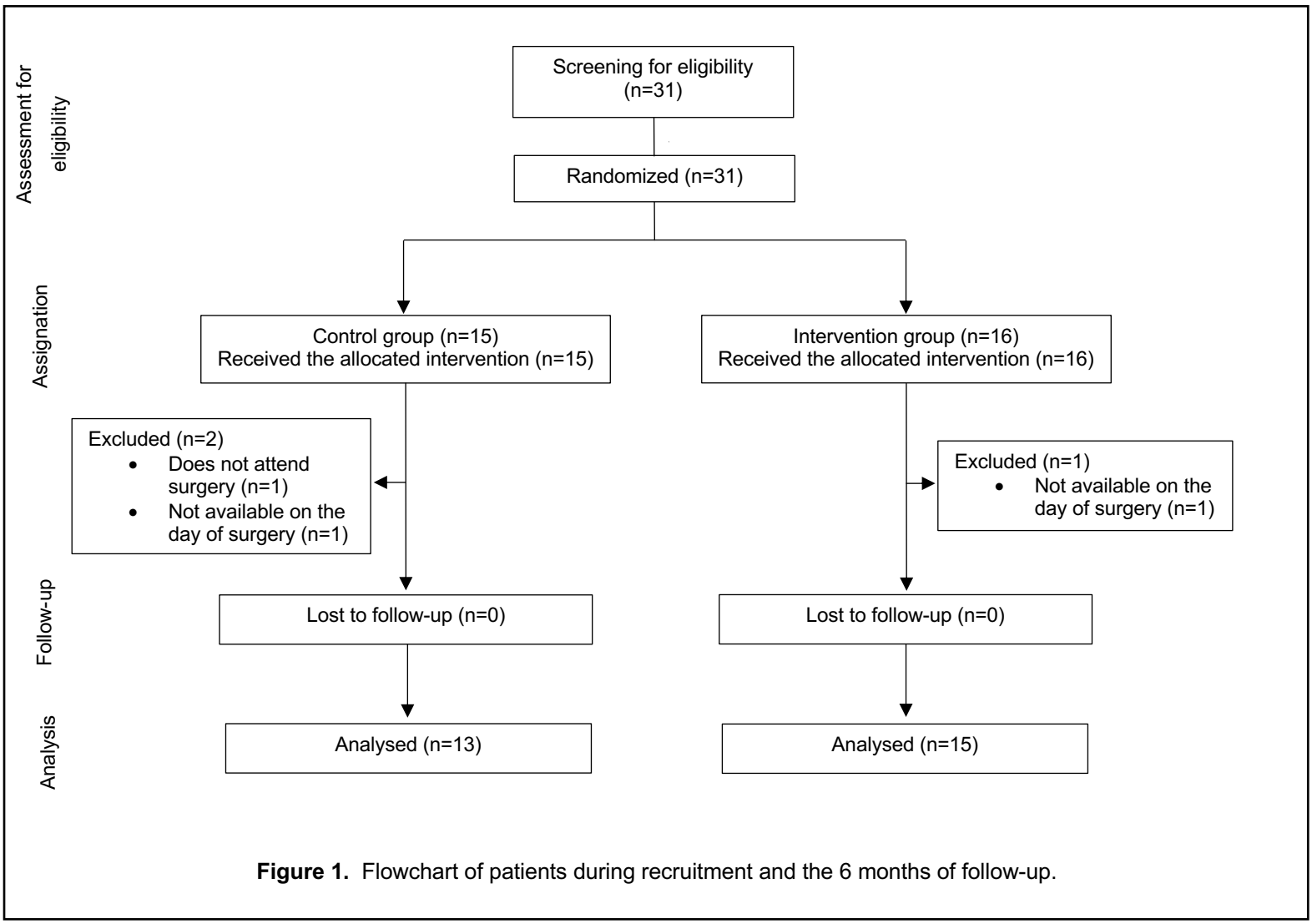

Figure 1. Flowchart of patients during recruitment and the 6 months of follow-up.

3.2. Baseline characteristics

Table 1 shows the baseline characteristics of the 15 patients in the IG and the 13 patients in the CG. The sample consisted of 22 men and 6 women with an average age of 35 years. There were no statistically significant differences in demographic characteristics between the two groups.

There were 66.7% men and 33.3% women in the IG and 92.3% men and 7.7% woman in the CG (p=0.10). The mean age was 29.18 years in IG and 40.84 years in CG (p=0.19). Most patients were overweight, with a global BMI mean of 27.37. Diabetes was present in 6.7% of the IG and in 7.7% of the CG.

Smoking was reported by 46.7% of the CG and 46.2% of the IG, and 7.7% of the people in GC had undergone proctological surgery.

Immunosuppression and history of proctological surgery variables, such as fistulas or haemorrhoids were not recorded in the tables as none of the patients had these.

Previous cyst debridement was reported by 46.7% of the IG and 30.7% of the CG.

	Intervention ***n*** **= 15**	**Control** ***n*** **= 13**	***p*-value**
Sex			
Male	10 (66.7)	12 (92.3)	0.10[b]
Female	5 (33.3)	1 (7.7)	
Age (years)	29.18	40.84	0.19[a]
Body mass index (BMI) (kg/m^2)	27.31	27.44	0.47[a]
Diabetes mellitus	1 (6.7)	1 (7.7)	0.92[b]
Smoking	7 (46.7)	6 (46.2)	0.98[b]
Proctological surgery	0	1 (7.7)	0.27[b]
Previous debridement	7 (46.7)	4 (30.7)	0.49[c]

Data are presented as: n (%); mean (SD); or median [25th percentile-75th percentile].

[a]Kolmogorov-Smirnov.

[b]Pearson χ^2.

[c]Fisher exact statistics.

Table 1: Baseline characteristics: comparison between the IC and CG.

3.3. Outcomes and estimation

3.3.1 Main outcomes

Data from outpatient consultations show that 6 months after surgery, a total of 20% of patients in the IG and 7.7% of patients in the CG had persistent pilonidal cysts (p=0.35) and 6.7% of the IG had recurrences (p=0.34).

3.3.2 Secondary outcomes

The results of the surgical characteristics in Table 2 show that of those who underwent debridement, 40% of the IG and 31.1% in the CG had a debridement scar (p=0.34).

The cysts in the CG had more pits (2.07 in the IG vs. 2.77 in the CG) (p=0.10).

The average number of punches that were done in IG was 1.6 punches. Marsupialisation in CG was performed in 66.7% of cases.

The estimated preoperative sizes of the IG cyst were 1cm width (95%CI: 1.0-2.0) and 4.33cm length and in the CG, 2cm width (95%CI: 1.0-2.0) and 4.62cm length.

The surgery time was longer in the IG with a mean of 23.2 minutes and 17.7 minutes in the CG, although not significant (p=0.08).

The real sizes of the sinus in the CG were bigger than those of the IG; 1cm width (95%CI: 1.0-2.0) and 4cm length and in the CG 2cm width (95%CI: 1.0-2.25) and 4.04cm length in the CG.

The average hospital stay was similar between groups, 5.31 hours in the IG and 5.41 hours in the CG (p=0.45).

There was only 1 patient with immediate surgical complications in the IG.

Regarding the pain reported by the patients using the VAS scale, it was reported to be 0.07 (SD 0.26) in the IG and 0.31 (SD 0.86) in the CG in the immediate post-operative period (p=0.44). The average VAS 24 hours after surgery was 1 (95% CI: 0.0-2.0) in the IG and 0 (95% CI: 0.0-2.5) in the GC (p=0.29).

At first month follow-up, 13.3% of patients in the IG and 23.1% of patients in the CG required emergency consultation at the hospital, primary care centre or external consultation in the surgery service (p=0.50). The reasons for consultation were suppuration in 6.7% of IG and 7.7% of CG (serous suppuration in all cases) (p=0.92). Pain occurred in 6.7% of IG patients (p=0.34), and other reasons for consultation, which in all cases were lack of epithelialisation, in 15.4% of CG patients (p=0.12).

On average in the IG, it took 5 days from the operation to the first consultation in the emergency department (ED), with a mean of 3 to 7 days. In the CG, 19 days passed, with a mean of 8 to 31 days (p=0.10).

The healing variable at 30 days was statistically signifying as only 40% of patients in the IG were still in the process of wound care compared to 84.6% of patients in the CG (p=0.02).

Other complications related to the healing process were the persistence of suppuration and in the first month, it was not statistically significant (p=0.83); 26.7% of the patients in the IG had suppuration, 2 patients had daily suppuration and the other 2 had sporadic suppuration. 23.1% of patients in the CG had suppuration, including 1 person with daily suppuration and 2 with sporadic suppuration.

In the first month control, patients in IG had 1.47 of pain versus 0.15 in the CG, without being statistically remarkable (p=0.15). As for PGI scale, the satisfaction was 2.47 for the GI and 2.77 for the CG (p=0.29).

During the sixth month of follow-up, 13.3% of IG patients consulted for emergencies compared to 30.8% of CG patients (p=0.50). 6.7% of the IG and 23.1% of the CG consulted for suppuration (p=0.31). 6.7% of IG and 7.7% of CG consulted for pain (p=0.92). A 6.7% of the IG consulted for abscess (p=0.34).

As no patient reported bleeding as a reason for emergency consultation, this variable was not included in the table, in the first and sixth month follow-up.

The days between surgery and emergency consultation at month 6 were a mean of 123 days (range from 115-131 days) in the IG and a mean of 81.3 days in the CG (range from 32 to 116 days) (p=0.44).

A total of 7.7% of patients in the CG returned for a second visit at month six due to suppuration, 112 days after the surgery day (p=0.27).

Wound care was still being provided 6 months after surgery in 26.7% of the IG and 7.7% of the CG (p=0.19).

The date of recurrence of symptoms was 50 days after the surgery.

In 20% of the people in the IG and 7.7% in the CG, presented sporadic suppuration, without being statistically significant (p=0.35).

In the sixth month appointment, pain measured by VAS was 0 in the IG (mean of 0.1) and 0 in the CG (p=0.35). Satisfaction was 2 in the IG (CI: 1-5) and 1 in the CG (CI:1-1.5).

Resumption of normal lifestyle or return to work was statistically significant (p=0.01) and was on average 17 days in the IG (range from 1 to 47 days), and 40.6 days in the CG (range from 5 to 76 days).

The total number of healing days was not statistically considerable (p=0.18) but it had clinical relevance, with a total of 36.75 days of healing in the IG, with a mean of 5 to 180 days of healing, compared to 50.67 days in the CG, with a mean of 21 to 80 days of healing. Recurrences and persistence have been discarded from the initial sample to calculate this variable.

	Intervention *n* = 15	Control *n* = 13	*p*-value
Debridement scar	6 (40.0)	3 (23.1)	0.34[b]
Pit number	2.07	2.77	0.10[a]
Punch number	1.6		
Marsupialisation		8 (66.7)	
Estimated measures Width (cm)	1.0 [1.0-2.0]	2.0 [1.0-2.0]	0.25[d]
Estimated measures Length (cm)	4.33	4.62	0.37[a]
Surgery time (minutes)	23.2	17.7	0.08[a]
Real measures Width (cm)	1.0 [1.0-2.0]	2.0 [1.0-2.25]	0.12[d]
Real measures Length(cm)	4	4.04	0.48[a]
Hospital stay (hours)	5.31	5.41	0.45[a]
Immediate surgical complications	1 (6.7)	0	0.34[b]
VAS on discharge	0,07 (SD 0.26)	0.31 (SD 0.86)	0.44[d]
VAS at 24h	1.0 [0.0-2.0]	0.0 [0.0-2.5]	0.29[d]

Data are presented as: n (%); mean (SD); or median [25th percentile-75th percentile].

VAS: Visual Analogue Scale.

[a]Kolmogorov-Smirnov.

[b]Pearson χ^2.

[c]Fisher exact statistics.

[d]Man-Whitney U test.

Table 2: Surgical features.

		Intervention *n* = 15	Control *n* = 13	*p*-value
Emergency consultation[1]				
Emergency consultation (yes)		2 (13.3)	3 (23.1)	0.50[b]
Reason for consultation: suppuration		1 (6.7)	1 (7.7)	0.92[b]
Reason for consultation: pain		1 (6.7)		0.34[b]
Reason for consultation: others			2 (15.4)	0.12[b]
Days between surgery and emergency consultation		5 (SD 3-7)	19 (SD 8-31)	0.10[a]
Cures (yes)		6 (40.0)	11 (84.6)	0.02[c]
Suppuration[2] **(yes)**				
Total cases		4 (26.7)	3 (23.1)	0.83[b]
Frequency	Daily	2 (50)	1 (33,3)	1.00[c]
	Sporadic	2 (50)	2 (66.7)	
VAS 30d		1.47	0.15	0.15[a]
PGI 30d		2.47	2.77	0.29[a]

[1] The consultations could be done at the hospital, Primary Care Centre or external consultation in the surgery service.

[2] Serous type suppuration in all cases.

Data are presented as: n (%); mean (SD); or median [25th percentile-75th percentile].

VAS: Visual Analogue Scale.

PGI: Patient Global Impression of Improvement.

[a]Kolmogorov-Smirnov.

[b]Pearson χ^2.

[c]Fisher exact statistics.

[d]Man-Whitney U test.

Table 3: Characteristics 1 month follow-up.

	Intervention *n* = 15	Control *n* = 13	*p*-value
Emergency consultations[1]			
First Emergency consultation (yes)	2 (13.3)	4 (30.8)	0.50[b]
Reason for consultation: suppuration	1 (6.7)	3 (23.1)	0.22[b]
Reason for consultation: abscess	1 (6.7)	0	0.34[b]
Reason for consultation: pain	1 (6.7)	1 (7.7)	0.92[b]
Days between surgery and emergency consultation	123 (SD: 115-131)	81.3 (SD: 32-116)	0.15[a]
Suppuration second emergency consultation (yes)		1 (7.7)	0.27[b]
Days between surgery and emergency consultation		112	
Cures (yes)	4 (26.7)	1 (7.7)	0.19[b]
Persistence	3 (20.0)	1 (7.7)	0.35[b]
Recurrences	1 (6.7)		0.34[b]
Days between surgery and recurrence	50		
Sporadic suppuration[2] (yes)	3 (20.0)	1 (7.7)	0.35[b]
VAS 6 months	0 (SD 0.1)	0 (SD 0.0)	0.35[d]
PGI 6 months	2 [1-5]	1 [1-1.5]	0,19[d]
Resumption of normal lifestyle	17 (SD 1-47)	40.6 (SD 5-76)	0.01[a]
Days of cure[3]	36.75 (SD 5-180)	50.67 (SD 21-80)	0.18 [a]

[1] Including multiple reasons for consultation in the same patient. The consultations could be done at the hospital, Primary Care Centre or external consultation in the surgery service.

[2] Serous type suppuration in all cases.

[3] Patients with sinus persistence (3 from EPSiT and 1 from CG) were not included.

Data are presented as: n (%); mean (SD); or median (25^{th} percentile-75^{th} percentile).

VAS: Visual Analogue Scale. PGI: Patient Global Impression of Improvement.

[a]Kolmogorov-Smirnov.

[b]Pearson χ^2.

[c]Fisher exact statistics.

[d]Man-Whitney U test.

Table 4: Characteristics 6 month follow-up.

4. Discussion

There are no remarkable differences in the results for demographic characteristics, making them comparable; the study sample analyses men and fewer women, but is representative of the population as the pathology is two to four times more common in men[3].

The recurrence rate with EPSiT in other studies was 5% at one year [7,11,16] and a persistence of the cyst was 4.02% in a meta-anlasis[13]. In this sample, there were 6.7% recurrences in the IG, there were 20% of persistence in the EPSiT group at six months and 7.7% in the total excision group.
Re-intervention is proposed in all these patients using the total excision technique.

The duration of the procedure was longer in the IG, with a mean of 23.6 minutes, an average of 5.5 minutes longer than in the CG (17.7 minutes). The difference can be explained by the need to set up the endoscopic equipment in EPSiT.
The researchers thought it would take longer because in other studies included in a systematic review and meta-analysis, the average time for the EPSiT technique was 34.7 minutes[13].

The only immediate complication was a burn on a patient's leg due to problems with the laparoscopic connections.

Data obtained using the Visual Analogue Scale (VAS) indicate that patients in the IG had slightly more pain when they were discharged from hospital and at about 24h post-intervention. There were slight differences between the groups with no statistical or clinical significance. Other studies have reported similar pain rates in EPSiT[6,11].

The reduction in the need for outpatient treatment is statistically significant at first month follow-up; twice as many patients in the CG, still were receiving wound care.
One of the confounding variables would be the possibility that some patients had poor hygiene and wound disinfection habits, and this led to an increased overall care. This variable was taken into account in some studies, which conclude that it is one of the key factors in persistence/recurrence[9].

VAS was higher and PGI was lower in the first and sixth month in the IG than in the CG. This might happen because there were a few people in the GI that they had recurrence of the cyst. In fact, there is no evidence to support this, because in general, the relevant characteristics of the endoscopic technique in all the trials and meta-analyses reviewed were a reduction in pain and an increase in satisfaction[11,13].

There is no comparison with other studies on the variable number of emergency department visits; in the first month, 5 people from the sample visited the emergency department, 2 people from the IG and 3 people from the CG group.
The reason for the consultation was suppuration in one patient and pain in one patient in the IG. In the other group, one patient was seen for suppuration and the other two for lack of epithelialisation and wound dehiscence.
In the sixth month, 6 patients were seen; 2 patients from the IG, one with abscess and suppuration and the other with pain. There were 4 patients in the CG group, of whom 3 in the CG group presented with suppuration and the other with pain.
In each case, the treatment was different: suppuration was treated with wound care, those who had pain were given analgesics, and if they had an abscess, it was debrided or treated with antibiotics and it was suggested that they be re-intervened.

Hypothetically, the team of surgeons thought that smaller cysts might benefit from endoscopic surgery, but in this case patients were treated with total excision (conventional treatment) who were larger overall (with a median difference in width of 1 cm) and have a mean of more pits, showed less persistence (non-healing) and recurrence. Comparison with other studies is not possible because cyst size is not a variable considered in the literature reviewed. This could be a possible secondary objective in future studies.

The morbidity associated with surgery was higher in the IG patients because 3 patients had persistent sporadic serous purulence compared with 1 patient in the CG, in the IG 4 patients were still wound healing at 6 months, and 1 patient in the CG.
The results cannot be compared with other trials or revised meta-analyses because these variables were not included.

EPSiT has been associated with a shorter post-operative period compared to conventional open surgery, in several studies[6,7]. This is consistent with the results of this study, which showed that patients in the IG returned to a normal life in half the time of those in the CG, and it is statistically significant. Those with persistent or recurrent pilonidal cyst were not included in this variable.

The total number of days of wound healing does not include patients who had a persistent cyst (non-healing) and therefore had intermittent treatment during the study period and were not counted. Recurrences were included, as at first, they were considered cured and there has been a second superinfection. In this case, in the majority, the EPSiT group ended their wound healing 14 days earlier than the other group. The range of cure days was 5 to 180 days in the IG, because one patient required wound healing for 180 days due to failure of healing in one of the lateral sinus tracts; otherwise, the range would have been between 5 and 60 days of healing. The total excision group was more homogeneous, and the treatment duration ranged from 21 to 80 days.
A meta-analysis suggests that the average duration of treatment with the EPSiT technique is 27 days, ranging from 15 to 72 days depending on the study[13].

4.1. Limitations and strengths

The present study has some limitations. To begin with, it is the initial experience in a single Centre. The series has few patients and the results obtained in terms of the main outcome were not as expected.
Some variables that were not considered were the time of evolution of the cyst, the number of infections, the family history of the disease, hair in the area and other factors.
More information about the causes of delayed healing and recurrence could have been reported, such as patients with longer histories of pilonidal cyst, poor hygiene patient's[9] and taking samples of the tissue that seemed infected to see if there were some specific anaerobic infection[17].
One variable it has not been reported on was the recurrence rate related to laser hair removal, and it has been shown to be lower in pediatric population[18].

In this study, the variable of return to normal life was not separated between the mean time to cure and the mean time to return to work, as in many studies, and could be confounding[13].
A disadvantage of the endoscopic treatment would be the higher cost, as it requires a technical expert with a learning curve and special equipment for the operation.

However, the study also has strengths, as the technique selection was randomly made, with a follow-up time of 6 months. The same surgeons who were involved in the design of the trail also performed both surgical techniques of all surgeries and follow-ups.
In terms of treatment, the fewer cure days, the lower the cost of the nursing assistance is required.

Although the results of the primary endpoint were not as expected, it is valuable to publish studies that have negative results and thus not create publication bias in future research.
A variable that has been added that had not been studied before, if there was need of use of emergency services, the frequency of use and the reason for consultation.

4.2. Recommendations for future studies

To determine the true risk of persistence and recurrence, more comparative studies with larger sample sizes over a long follow-up period (at least 6 months), are needed.
Also, other more reliable questionnaires, such as the McGuill Pain Questionnaire (MPQ), could be used in the future to measure pain[19].

4.3. Conclusion

In conclusion, the pilonidal sinus approach using a less invasive procedure (EPSiT) was effective in reducing wound healing time and time off work.
Although the results were promising, this study was associated with a higher rate of persistence/recurrence of pilonidal cysts at the 6-month follow-up.

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6. References

1. Johnson, E.K. (2021). Pilonidal Disease. U: *UpToDate*. Edited by Weiser M, Chen W ed. [cited 2022 Jul 18]. Available from: https://www.uptodate.com/contents/pilonidal-disease?search=SINUS PILONIDAL&source=search_result&selectedTitle=1~23&usage_type=default&display_rank=1#H31072511

2. Harris CL, Laforet K, Sibbald RG, Bishop R. Twelve common mistakes in pilonidal sinus care. Adv Skin Wound Care. 2012 Jul; 25 (7): 324-332; quiz 333-4.

3. Lindholt-Jensen CS, Lindholt JS, Beyer M, Lindholt JS. Nd-YAG laser treatment of primary and recurrent pilonidal sinus. Lasers Med Sci. 2012 Mar; 27 (2): 505-508.

4. Pacheco, C. G. Quiste pilonidal. *Revista Médica de Costa Rica y Centroamérica*. 2015; *72* (614), 201-203.

5. Pérez-Bertólez S, Martín-Solé O, Moraleda I, Cuesta M, Massaguer C, Palazón P, Tarrado X. Advantages of endoscopic pilonidal sinus treatment. Cir Pediatr. 2021 Oct 1; 34 (4): 191-199.

6. Meinero P, Mori L, Gasloli G. Endoscopic pilonidal sinus treatment (E.P.Si.T.). Tech Coloproctol. 2014 Apr; 18 (4): 389-92.

7. Tien T, Athem R, Arulampalam T. Outcomes of endoscopic pilonidal sinus treatment (EPSiT): a systematic review. Tech Coloproctol. 2018 May; 22 (5): 325-331.

8. Manigrasso M, Anoldo P, Cantore G, Chini A, D'Amore A, Gennarelli N, Maione F, Marello A, Schettino P, Sorrentino C, Vertaldi S, Sosa Fernandez LM, De Palma GD, Milone M. Endoscopic Treatment of Pilonidal Sinus Disease: State of Art and Review of the Literature. Front Surg. 2022 Jan 4;8:812128.
9. Mahmood, D. D., & Abood, A. M. Opened versus closed procedures in management of pilonidal sinus (PMS). International Journal of Surgery. 2020; 4(1), 454-457.

10. Milone M, Musella M, Di Spiezio Sardo A, Bifulco G, Salvatore G, Sosa Fernandez LM, Bianco P, Zizolfi B, Nappi C, Milone F. Video-assisted ablation of pilonidal sinus: a new minimally invasive treatment-a pilot study. Surgery. 2014 Mar;155 (3): 562-6.

11. Giarratano G, Toscana C, Shalaby M, Buonomo O, Petrella G, Sileri P. Endoscopic Pilonidal Sinus Treatment: Long-Term Results of a Prospective Series. JSLS. 2017 Jul-Sep;21(3):e2017.00043.

12. Grabowski J, Oyetunji TA, Goldin AB, Baird R, Gosain A, Lal DR, Kawaguchi A, Downard C, Sola JE, Arthur LG, Shelton J, Diefenbach KA, Kelley-Quon LI, Williams RF, Ricca RL, Dasgupta R, St Peter SD, Sømme S, Guner YS, Jancelewicz T. The management of pilonidal disease: A systematic review. J Pediatr Surg. 2019 Nov; 54 (11): 2210-2221.

13. Emile SH, Elfeki H, Shalaby M, Sakr A, Giaccaglia V, Sileri P, Wexner SD. Endoscopic pilonidal sinus treatment: a systematic review and meta-analysis. Surg Endosc. 2018 Sep; 32 (9): 3754-3762.

14. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials. Open Med. 2010; 4 (1): e60-8. Epub 2010 Mar 24.

15. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronicdata capture (REDCap) a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009; 42: 377-381.

16. Sequeira JB, Coelho A, Marinho AS, Bonet B, Carvalho F, Moreira-Pinto J. Endoscopic pilonidal sinus treatment versus total excision with primary closure for sacrococcygeal pilonidal sinus disease in the pediatric population. J Pediatr Surg. 2018 Oct; 53(10): 2003-2007.

17. Bowler PG, Duerden BI, Armstrong DG. Wound microbiology and associated approaches to wound management. Clin Microbiol Rev. 2001 Apr; 14(2): 244-269.

18. Esposito C, Izzo S, Turrà F, Cerulo M, Severino G, Settimi A, et al. Pediatric endoscopic pilonidal sinus treatment, a revolutionary technique to adopt in children with pilonidal sinus fistulas: Our pre- liminary experience. J Laparoendosc Adv Surg Tech. 2018; 28 (3): 359-63.

19. Serrano-Atero MS, Caballero J, Cañas A, García-Saura PL, Serrano-Álvarez C, Prieto J. Valoración del dolor (II). Rev Soc Esp Dolor. 2002; 9: 109-121.

Appendix

Appendix 1

Surgical Technique: EPSiT - Endoscopic Treatment of the Pilonidal Sinus:

Standard Sinus Set (requires Volkmann spoon)

Number 3/4 punch

Water collection bag

2 suction devices (one for the bag and one for the Yankauer)

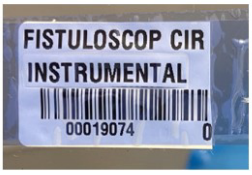
Camera case and cable

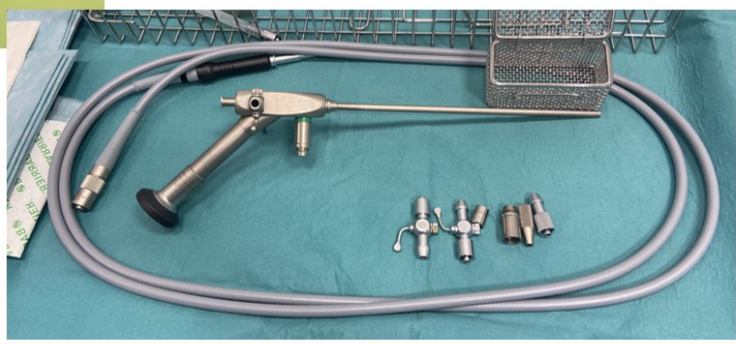
Monopolar cable

Standard endoscopic tower

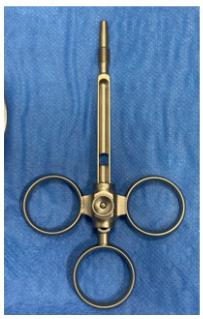
3000cc of Glycine 2% Serum

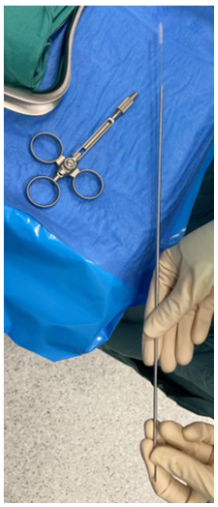
Cystoscope box + rear sealing cap called Hati.

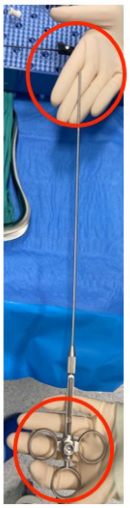


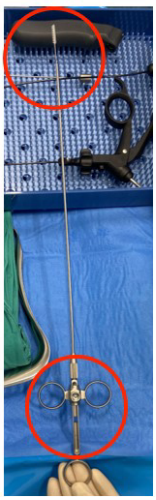


Brush assembly for the Volkmann spoon. Mount it in such a way that the brush is hidden with the handle facing inwards and comes out when the handle is being moved.

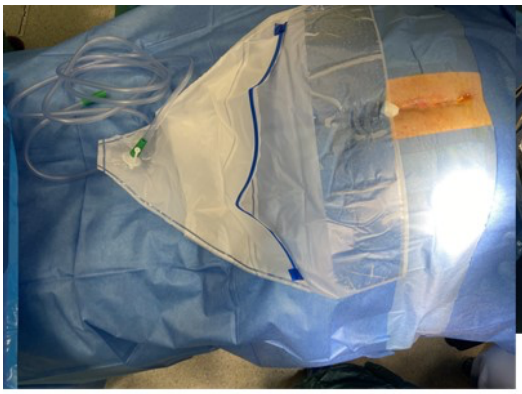


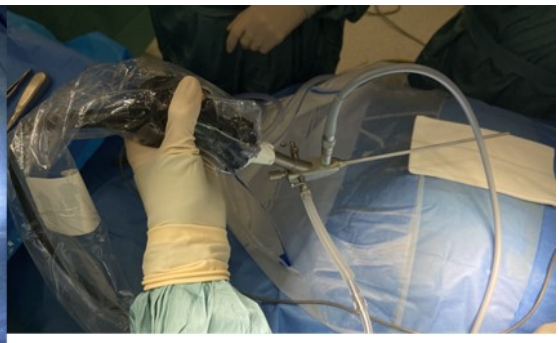




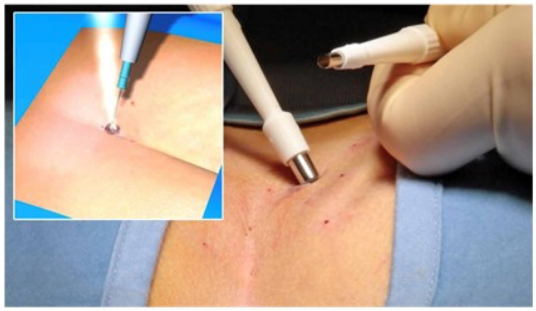


Setting up the surgical field.

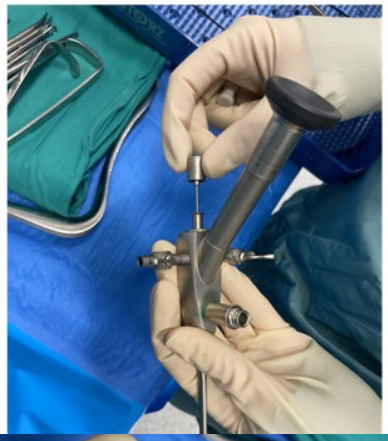




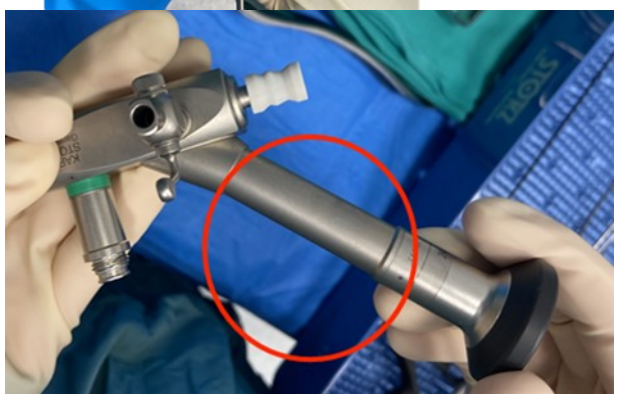
Start by making an opening of a pit with a punch.



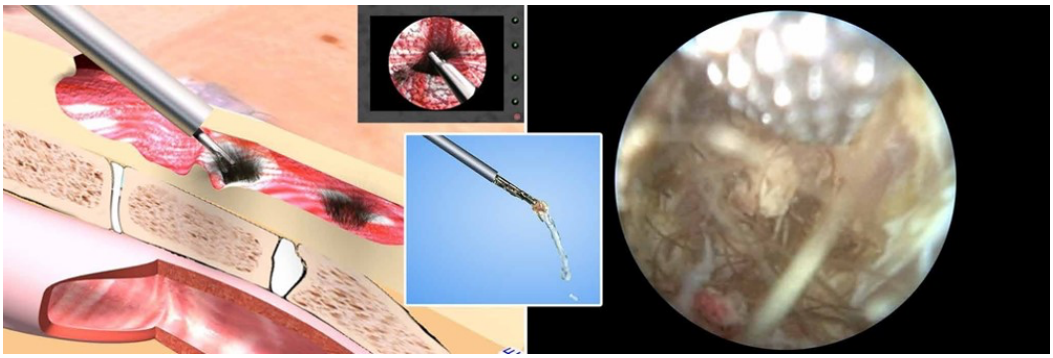
At the beginning it was entered without the Haiti but with the introducer.



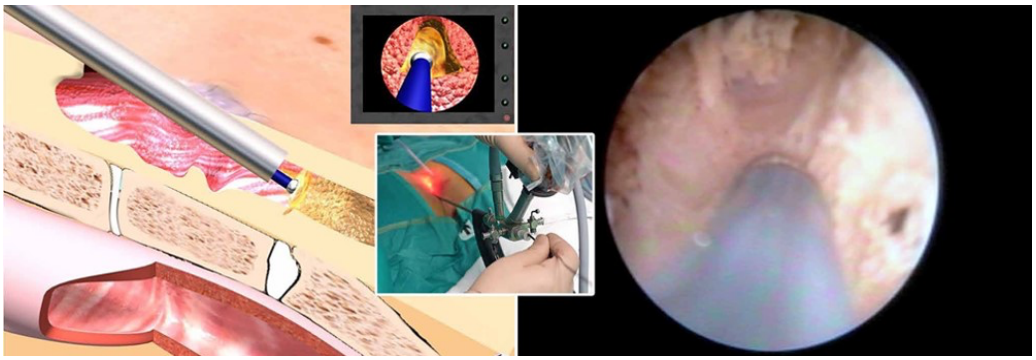
The introducer is then removed, and the Haiti is placed to avoid loss of serum. It is important to remark that if there is no instrument, the hole must be plugged to avoid getting wet.



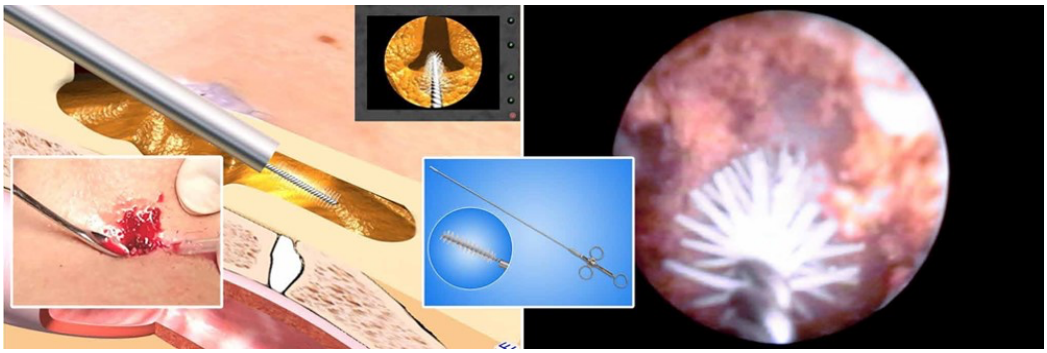
Remove the hair and debris with the grasping forceps.



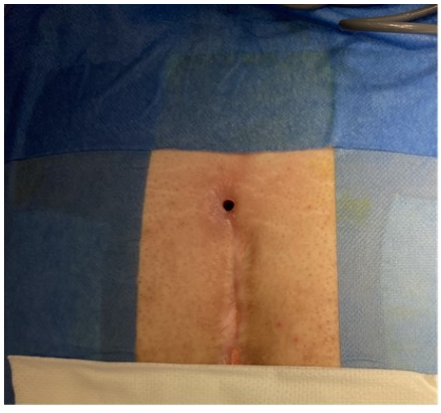
Electrocoagulate the pathway with the monopolar.

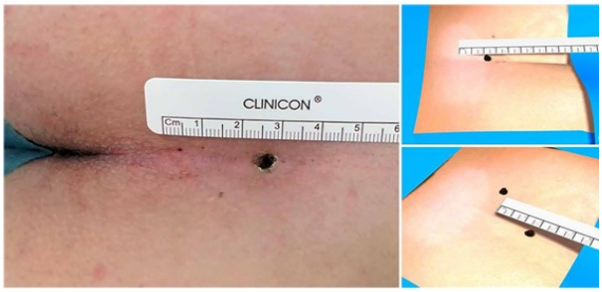


Curettage the path with a brush.

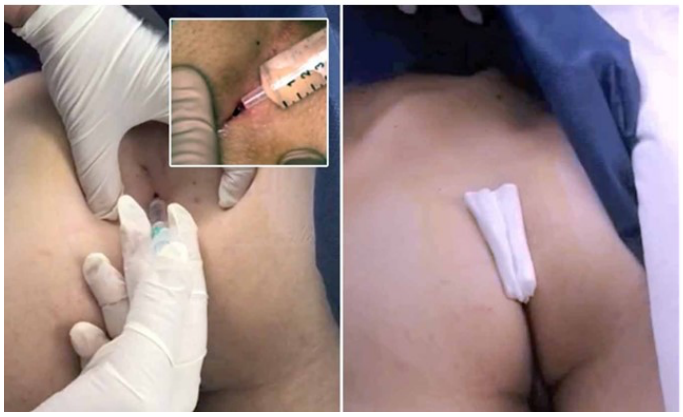


The result is shown below.





Post-operative care: Wash with physiological serum, 5cc syringe, twice daily. Gauze may be used in case of suppuration.



Procedure source taken from Althaia's surgery department and: Cahais, J. (2021). Endoscopic pilonidal sinus disease treatment (EPSiT). Journal of visceral surgery, 158(4), 337-342.

Appendix 2

Patient Global Impression of Improvement (PGI-I).

The PGI-I consists of a single question that asks the patient to rate the relief obtained after the treatment on a seven-point Likert scale:	
Very Much Improved	1
Much Improved	2
Minimally Improved	3
No Change	4
Minimally Worse	5
Much Worse	6
Very Much Worse	7