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Randomised clinical trial to test the phenolization in sacrococcygeal pilonidal disease

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Abstract

To test the efficacy and safety of phenolization in uncomplicated Sacrococcygeal pilonidal disease (SPD) the phenolization in uncomplicated SPD is feasible and secure in selected patients in observational studies. The greatest benefits are obtained to reduce the length of sick leave (LSL) and complications. Single-center randomised controlled clinical trial. Patients were recruited at University Hospital of Tarragona Joan XXIII of Spain. Patients were randomised into two treatment groups. All patients with uncomplicated sacrococcygeal disease, localised in the midline and with only 1 fistulous orifice. The patients were randomly assigned to the phenolization group (PhG) or conventional-surgery group (CsG). Both groups were managed without admission. The main endpoint was the recurrence of sacrococcygeal disease. Secondary endpoints included time of sick leave, complications, and readmission. 124 patients were included in the study. No disease recurrence was observed in either group. Clinical follow-up was carried out with a mean of 493.8 days (SD 6.59). The LSL was shorter in the PhG (mean 19.63 days, SD 28.15) than in the CSG (43.95 days, SD 38.60). The LSL reduction was −24.31 days (*P* .002). The phenolization in selected SPD is a safe and feasible procedure in selected patients. This approach could become the standard of care for patients with selected Sacrococcygeal pilonidal.

KEYWORDS

phenol, phenolization, pilonidal disease, pilonidal disease of natal cleft, sacrococcygeal fistula pilonidal sinus

1 | BACKGROUNDS AND AIM

Sacrococcygeal pilonidal disease (SPD) is a common and well-recognised entity. In 1833 Herbert Mayo described a hair-containing sinus. In 1880, Hodge suggests the term 'pilonidal' (Latin: pilus = hair and nidus = nest), to indicate a disease consisting of hair-containing sinus in the sacrococcygeal area. The first

official description by Abraham Wendell Anderson dates from 1847.[1] The clinical presentation is relatively similar in many cases: acute inflammation on the natal cleft. However, the underlying physiopathology remains controversial and management depends on a variety of treatment modalities, none of which are unanimously accepted.

Infected pilonidal disease affects approximately 0.7% of the population.[2] The incidence is 25/100000 habitant per year. Is more frequent in men, usually between the ages of 15 and 30.[3,4]

A hairy body, thick skin, overweight, a deep gluteal cleft, lack of hygiene, sedentarism, repeated chafing (during the second World War, the American military surgeons nicknamed the affection 'Jeep seat' disease, because of the increased prevalence among Jeep drivers) and previous familial history are commonly admitted as predisposing factors.

In England, a total of 11 534 admissions to the emergency department were recorded for pilonidal disease by the Department of Health in 2001.[5] The sick leave and effect on hospital resources have led to a renewed interest in understanding the mechanics and exploring an ideal method of treatment for this disease.

The aetiology of SPD is currently under discussion.[5] New treatment methods for pilonidal sinus have evolved following the determination of etiologic physiopathology. Recently, the cause of SPD is accepted as hair from the head, back and gluteal regions that fall into the intergluteal sulcus over time. These are believed to penetrate the skin and reach the subcutaneous tissue, then microorganisms cause chronic anaerobic inflammation that in turn leads to abscess formation.[6] There are various surgical and non-surgical methods for its treatment.[7] Approximately 15 different surgical techniques have been defined.[5] None of these surgical techniques are defined as 'gold standard'. Despite improvements in surgical treatment of the disease, the delay to return to work due to the prolonged length of hospital stay and healing time increase cost.[7,8] As a result, operated patients might be unsatisfied. The success of phenol treatment in pilonidal disease is related to its easy application, low cost, and early healing process. The initial use of pure phenol was described by Notaras and Goodall under local anaesthesia in 1964 as a form of non-surgical treatment.[9]

This is a single-center RCT designed to determine the effectiveness and safety of the use of phenol in the treatment of SPD to assess the recurrence, the sick leave, and the complications of the patients.

2 | METHODS

2.1 | Study design and participants

This is a single-center randomised controlled clinical trial consisting of two treatment groups. This study was designed in accordance with the Declaration of Helsinki guidelines and approved by the Ethics Committee of Pere Virgili Institute (Ref. CEIm: 041/2020). This study was approved by Clinical trial gov (NCT05404243). Patients were recruited at University Hospital of Tarragona Joan XXIII of Spain from January to December 2021.

All patients with uncomplicated sacrococcygeal disease, localised in the midline and with only 1 midline fistulous orifice in the natal cleft were likely to enter the study.

The inclusion criteria were the following: patients over 18 years old, ASA (American Society of Anesthesiology) less than or equal to III, patients who live accompanied in a home at a maximum distance of 30 min from the hospital and an adequate cognitive capacity.

The exclusion criteria were the following: pregnancy or breastfeeding, complicated SPD or a non-randomised surgical management.

When the patients met the criteria and after consenting the admission in the study, they were included. The patients were randomly assigned to the phenolization group (PhG) or conventional-surgery group (CSG). A unique anaesthetic protocol was established for both groups.

In case of not accomplishing the inclusion criteria or presenting any exclusion one, the patient was excluded from the study and followed the usual clinical management according to our center protocol.

2.2 | Anaesthetic and surgical protocol

To ensure consistency, an anaesthetic and surgical protocol were established for both groups.

Anaesthetic management begins with the intraoperative monitoring: non-invasive blood pressure, oxygen saturation and heart rate. The subarachnoid space was entered using a 25-gauge Quinke spinal needle at the L3–4 interspace with the patient in the sitting position. After confirming the free flow of cerebrospinal fluid, 1 mL of 0.5% bupivacaine (5 mg) in 8% glucose solution was administered. The patient remained in the sitting position for 5 min after the local anaesthetic injection. Subsequently, the patient was moved to the Jack-Knife position. The sedation is done with propofol at a dose of 2 mg/kg and remifentanil in bolus. Intraoperative

analgesia is performed with Dexketoprofen 50 mg and Metamizole 2 g after the begging of the procedure.

The surgical protocol: In the conventional surgery group, entire exeresis is performed by an electric scalpel. Postoperative haemostasis is performed to avoid bleeding. Finally, Vaseline gauze is introduced together with topical antiseptic such as Furacin. Finally, a compressive bandage is applied.

In the PhG, it begins with a shaving of the surgical area. Curettage of the sacral cyst is performed using a disposable ear or a bone curette. The perimeter of the cyst is covered with petroleum jelly to protect the skin, and an Abbocath catheter is introduced into the cystic cavity. Undiluted 88% phenol is instilled into the cavity, ensuring that the cystic cavity is filled. It is maintained for 5 min until complete coagulation of the cyst is achieved. Finally, haemostasis is performed, and a compressive bandage.

All the patient is referred to the same-day surgery unit, where they will be discharged home at 6 h if he meets ALDRETE criteria.[10]

2.3 | Randomization and interventions

Randomization was performed using a computer-generated random code. Surgeons were responsible for enrollment and treatment allocation according to each sequentially numbered envelop. Enrollment was unblinded for patients and physicians due to the type of intervention. To reduce biases, the investigators assessing the outcome did not participate in the following-up or discharge of patients. All patients received detailed written information about their diagnosis and hospital treatment plan.

After obtaining the informed consent for the study, the patients were admitted and operated on following the same anaesthetic technique and the surgical protocol previously commented. Once the patient was explored and a non-fistulated SPD was confirmed, the patient was randomised to one of the two experimental branches: the PhG or CsG.

Both groups were managed without admission and discharged within 6 h if they met ALDRETE criteria. They were followed daily by the home hospitalisation team.[11,12]

2.4 | Study endpoints

The main endpoint was the recurrence of sacrococcygeal disease. For this purpose, a clinical follow-up was performed in outpatient clinics. The patient was assessed and explored for signs of recurrence every month. The number of recurrences per group and the time from surgery to recurrence were assessed. Secondary endpoints included time of sick leave, complications, unplanned emergency visits and readmissions

2.5 | Data collection

The anthropomorphic and pathologic previous medical history were collected for the study. Categorical data were obtained from medical history. The anaesthetic variables and the characteristics of the surgical act were individually assessed to confirm that they met the requirements for inclusion in the study. The postoperative complications were evaluated according to the Clavien-Dindo score[11] and Comprehensive Complication Index punctuation.[12] A clinical follow-up was performed in specialist consultation where the patient was assessed and explored regularly for signs of recurrence. Outpatient follow-up was carried out until completion of the study or loss to follow-up.

The data were collected in a standard form by the research coordinator ensuring the anonymity of the patients. The data was monitored and included in a database using Access Microsoft 2013. The statistical study was performed with Stata inc. 16 version, by a biostatistical.

2.6 | Sample size and statistical analysis

In literature, the risk of recurrence of Pilonidal disease after surgical management was 7.5% (with a median follow-up of 584.4 days, or 1.6 years).[13] The population sample was calculated using Stata, based on an 5%-α and 10% β-risks. A sample size and power statistic of a one-sample proportion equivalence z test were used. Based on this, to detect a non-inferiority technic (the risk of recurrence of Pilonidal disease after surgical management was 7.5%), a total of 62 patients per group were assigned. A noninferiority analysis was conducted.

Differences between groups were analysed using Fisher exact test for categorical variables and *t*-test or ANOVA test for quantitative variables. *P*-values <.05 were considered significant. If after realising the Shapiro–wilk test the variable did not follow a normal distribution, the *P*-values were obtained through a permutation test. Multiple comparisons were conducted using Wilcoxon nonparametric test for the categorical variables. Fisher and McNemar test were used to ana-

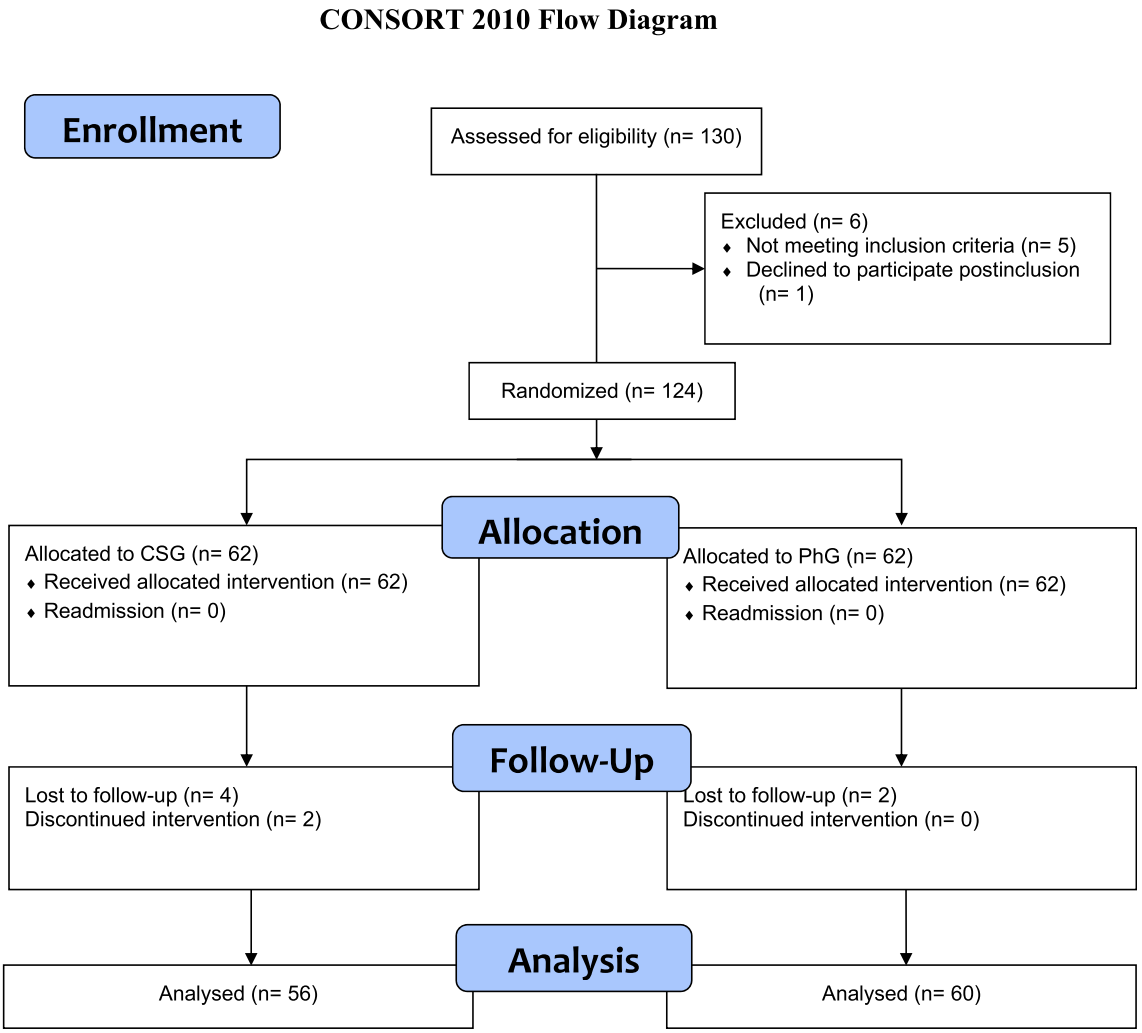

FIGURE 1 Consort Flow diagram-SPQF trial. Initial numbers assessed, randomised, followed up, and analysed with the reason for inclusion

lyse the results of contingency tables. Valid variables were considered if they presented a maximum of 10% of missing values. All analyses were performed by a statistician.

3 | RESULTS

3.1 | Selected patients and clinical characteristics

According to the clinical guidelines of the Consolidated Standards of Reporting Trials (CONSORT),[14] Figure 1 shows the patient selection scheme.

A total of 130 patients with SPD were likely to enter the study. From 130 patients included in the study, five were excluded to enter the study at the time of surgery due not meeting inclusion criteria, and 1 patient declined to participate postinclusion. Then, 124 patients with SPD were randomised, 62 per group. There were some patients lost in the follow-up. Finally, 56 in the CSG and 60 in the PhG were followed. All patients met the inclusion criteria.

Table 1 shows the descriptive analysis of the groups. Demographic anthropometric were comparable in the two groups.

3.2 | Primary endpoint

No disease recurrence was observed in either group. Clinical follow-up was carried out with a mean of 493.8 days (SD 6.59). In the CSD group 498.91 days (SD 8.93), and in the PhD group 487.6 days (SD 9.78). No differences were observed between the two groups (P .3956).

TABLE 1 Descriptive analysis of the groups: patients characteristics and comorbidity

	CSG (n = 56)	PhG (n = 60)	*P*
Sex			
Male, n (%)	34 (60)	34 (57)	.9223
Female, n (%)	12 (40)	26 (43)	
Age, mean (sd)	26.2 (11.14)	24.44 (8.01)	.4714
BMI, mean sd	27.49 (5.39)	24.64 (3.53)	.0772
HTN, n (%)	1 (1.7)	0 (0)	.1988
DM, n (%)	0 (0)	0 (0)	–
DLP, n (%)	1 (1.7)	0 (0)	.1988
Cardiac diseases, n (%)	1 (1.7)	1 (1.67)	.1180
Respiratory diseases, n (%)	0 (0)	0 (0)	–
Another comorbidity, n (%)	0 (0)	0 (0)	–
Smoker, n (%)	5 (8.92)	2 (3.33)	.0547
Enolism, n (%)	1 (1.7)	1 (1.67)	.6502

Abbreviations: BMI, body mass index; CSG, Conventional Surgery group; DLP, Dyslipidemia; DM, diabetes mellitus; HTN, arterial hypertension; PhG, Phenolization group.

3.3 | Secondary endpoint

3.3.1 | Sick leave

The length of sick leave (LSL) was significantly shorter in the PhG group (mean 19.63, SD 3.83) than the CSG (43.95 days, SD 4.82), *P* .0002. The average LSL reduction was −24.31 days. Figure 2 shows the boxplot graph.

3.3.2 | Anaesthetic and surgical protocol

The same anaesthetic and surgical technique were used in both groups, following the study protocol in all cases. The global time of surgery was 11.54 min (SD 3.26). No differences were observed, in the CSG was 11.79 min versus PhG 11.25 min (*P* .3578).

3.3.3 | Complications, readmission, and unplanned hospital appointments

Table 2 shows the analysis of the groups concerning complications, readmissions, and hospital appointment. In both groups, the Clavien-Dindo 1 complications were poor pain control requiring analgesia. In the CsG, there were 12 patients with Clavien-Dindo 2 complications: 10 complicated wounds requiring chemical debridement and two infections requiring oral antibiotics. Significantly fewer complications developed in the PhG group than in the CSG group ($P = .02$). No further emergency consultations or readmission were observed in either group.

4 | DISCUSSION

The SPD commonly presents as an abscess or painful discharging sinus. The SPD is a frequent cause of consultation in the emergency department. The pain caused by SPD results in significant morbidity, leads to repeated hospital visits and time off work. SPD is a common condition affecting 26/100000 person/year.[15] The SPD mainly affects young and active people of working age group. Pilonidal cyst is usually diagnosed in Caucasian young males, most commonly after puberty.[16,17]

A very rare complication of SPD can be malignancy. A squamous cell carcinoma rarely arises following a 25-year history of untreated pilonidal cyst. Approximately 100 cases have been reported around the world.[18]

The aetiology of SPD is currently under discussion. Due to its location around the caudal end of the neural tube, it was thought that the pilonidal cyst is a congenital disease. However, this hypothesis has not been confirmed by pathology studies.[19,20] In 1992, Karydakis presented mechanism of developing pilonidal cyst, indicating three important factors: the hair, friction, and skin susceptibility.[21] The development of pilonidal cyst needs the following important factors: hair structure and shape, number of ingrowing hairs, deep and narrow intergluteal cleft resulting in great friction, skin structure and any changes to it. The most important factor is the penetration of hair to the subcutaneous tissue, which causes chronic inflammation. Subsequent hairs can penetrate the sinus, resulting in chronic conditions. The fistulas indicate points at which hairs leave the subcutaneous tissue. In some cases, spontaneous healing is possible.[21] There is nearly a

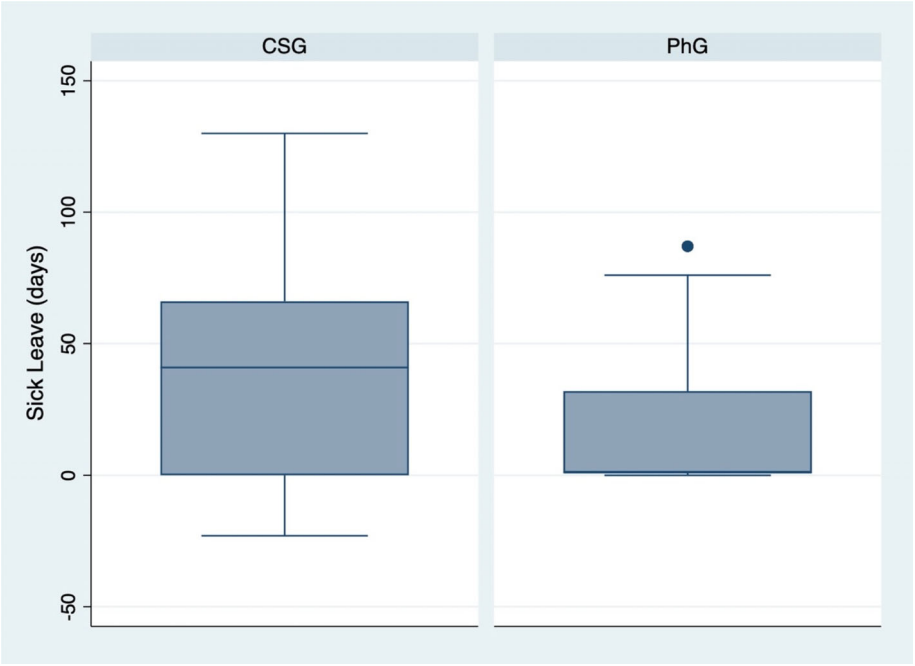

FIGURE 2 Days of sick leave. CSG: Conventional Surgery Group; PhG: Phenolization Group.

TABLE 2 Descriptive analysis of complication, readmissions and unplanned hospital appointments

	CSG (n = 56)	PhG (n = 60)	*P*
Clavien Dindo			
0	42 (75.00)	54 (90.00)	.018
I	12 (21.42)	3 (5.00)	.002
II	2 (3.57)	3 (5.00)	.3407
III	0 (0)	0 (0)	1
IV	0(0)	0 (0)	1
CCI	1.57 (3.38)	0.43 (2.98)	.02
Readmission	0 (0)	0 (0)	.320
Unplanned hospital visit	2 (3.57)	2 (3.30)	1

consensus that pilonidal cyst is acquired, hair being the agent that causes the disease.

As the aetiology of SPD, there is no classification for SPD. One systematic review of classification systems for SPD found eight classification systems, none of which have been vigorously assessed for their prognostic characteristics, been adopted to guide management, or been used routinely in surgical practice or comparative trials.[15] All articles found used judgmental methodology to develop their classification systems. They identified homogeneous categories based on the experience of the investigators, based on researcher practice and observation.

In all the articles, the classification was mainly used to select patients for different procedures ranging from pit picking procedures for the lowers stages to flap closures for the most advanced stages of disease. However, no article provided analyses to demonstrate reliability or predictive criterion validity. Three articles list outcomes according to the stage without a formal analysis.[20,22,23] In these articles different treatments had been selected for each subgroup, meaning it was impossible to distinguish the effect of the treatment or classification system from the prognosis of the condition. Despite these drawbacks this review gives some insight into what components may create a classification that is clinically useful and statistically valid.

The position of the pits is likely to be important in defining complex and difficult to manage disease. For instance, the proximity of the pits to the anus is crucial because it impacts on healing.[24] Also, the proximity to the anus may influence the surgical management for 47% of surgeons,[15] and the location of secondary extensions may also affect the type of surgery performed.[15]

A pragmatic classification system could be interesting to be integrated into clinical practice. That pragmatic classification could help to support treatment decisions and the counselling of patients on likely outcomes. Such a system should be simple to use, reflect clinical practice and be meaningful in terms of prognostication. Commonly utilised examples outside cancer surgery do exist (e.g., Goligher's system for haemorrhoids,[25] and Park's system for fistula in anus[26]) but few to date have undergone rigorous validity testing. The development of such a system is one component of an ongoing cohort trial on pilonidal disease.

For the treatment of SPD are described different options. The most-used surgical procedure is the excision

of the cyst, with an open or closed wound for healing. However, many authors prefer to use the method of incision and curettage.[27] Currently, there are no consensus on the best treatment for SPD. In addition, there is a trend towards minimally invasive techniques in patients with primary SPD, including phenolisation, laser, and endoscopic treatments.[28,29] Therefore, the ideal treatment would be quickly healing with early return to work and minimal morbidity and recurrence rate.[17]

The phenol was proposed for the first time during the 1960 s. This conservative treatment is based on the antiseptic and keratolytic characteristics of phenol. Hair debris, granulation tissues or eventual remaining pus are first removed by curettage. The phenol is injected as a liquid or crystallised form without pressure through the cutaneous orifice, adapting the quantity to the number and size of the cavity. The phenol is left in place for 1–3 min, and then it must be aspirated. The remaining debris is removed by compression of adjacent tissues. Finally, the sinus is rinsed with saline. Some authors recommend repeating the injections two or three times. The skin must be protected because phenol can burn the skin if misplaced. No specific postoperative care is necessary. Healing usually occurs within two to 3 weeks, but the failure is described (up to 30%–40% in some series), especially when the sinus is purulent or complex with multiple secondary tracts.[30]

There are some RCT that evaluate the experience of phenol. Furnee et al., published an RCT that demonstrate that phenolization of the sinus tract compared to radical excision reduces the total number of days unable to perform normal activity, but no recurrence was described. After that, in 2022 Fegul et al., demonstrate phenol treatment and excision/primary closure methods for pilonidal sinus disease have similar complication and recurrence rates. However, phenol treatment seems to be the method of choice in the adolescent age group as it has the advantage of being a minimally invasive method and it does not affect subsequent surgical treatments. We design a study to evaluate de the efficacy and security of the phenol and the length of the sick leave of de adult patients.

In the present study, no disease recurrence was observed in either group. Clinical follow-up was carried out with a mean of 493.8 days (SD 6.59). No differences were observed between the two groups in the follow-up by groups (P .3956).

The number of hospital readmissions to the emergency department was also considered to demonstrate the clinical safety. No readmissions were observed in both groups. In both groups, the Clavien-Dindo 1 complications were poor pain control requiring analgesia. In the CsG, there were 12 patients with Clavien-Dindo 2 complications: 10 complicated wounds requiring chemical debridement and two infections requiring oral antibiotics. We observed two unplanned visits in CsG due wound bleeding. We observe three unplanned visits in the PhG due to an unexpected wound suppuration. Based on similar studies, we have shown that following phenol protocol surgery in an uncomplicated SPD in adult patients is a safe procedure, with low complications and readmission rates ranging from 0% to 4.6%.

LSL was our secondary endpoint. LSL was significantly lower in the PhG, 19.63d (SD 3.83), while in the CSG it was 43.94d (SD 4.82). A difference of 24.07d (SD 6.32), $P = .0002$.

In addition, the fact of not need a wound care by health personnel and avoiding unnecessary health visits allowed a significant economic savings.

In terms of costs, SPD is associated with a considerable financial burden due to its high incidence and the cost of postoperative surgical wound care and LSL. The effective use of resources by minimising costs and maintaining quality is the goal of health care. In the present study, no economic cost was calculated, however, a significant reduction in sick leave was observed. This implied an earlier return to work, losing less indirect costs. No economic costs were incurred due to the difficulty of quantifying the cost of sick leave. However, in the bibliography, it is described that patients treated with phenolization and the median loss of days of normal daily activities was 5.0 (1.0–12.0) days and 89.5% of patients resumed normal daily activities after 2 weeks.[31]

The statistical studies developed by Calvo et al., showed that the average sick leave of patients with SPD was 50 days. The predictive factors of longer sick leave were evaluated. These factors were comorbidities, educational level, manual labor, and surgical technique performed. Given these factors, the only modifiable factor is the technique performed, so this is the one we can influence.

Assessing the possible limitations of this trial, the study design is not blinded. The nature of the interventions performed (CSG versus PhG) made it clear to patients and physicians which group was assigned treatment. Furthermore, the main variables are objective measures, so they are unlikely to be affected by this fact.

Another possible limitation of the study is that the COVID-19 pandemic occurred during the patient recruitment period, which spanned 2021. In addition, a PCR test was added to the protocol. However, outpatient management during the pandemic allowed a greater availability of hospital beds to care for patients with medical conditions. Thus, outpatient management allows better optimization of resources, and avoid more complications of the SPD. The fact of phenolizing SPD managed to avoid the

surgical wound and the successive visits to the outpatient clinic for treatment. Thus, avoiding the need for visits by the health system, which in the COVID era was oversaturated.

Our results agree with those reported in other studies.[15,17,21,32,33] Therefore, in our experience, it is possible to start and phenol protocol in selected SPD with an experienced team. Several studies showed a reduction of return normal activity in selected patients.[32,34] We have shown that phenolization protocol in the SPD is safe in selected patients, due to the improvement in terms of quality of care, clinical and potential economic benefits, and a significant reduction of sick leave.

5 | CONCLUSION

The phenolization of SPD is a safe and feasible procedure in selected patients with non-complicated SPD. It can be achieved with low recurrence, reduction of sick leave, low morbidity, few readmissions, high patient satisfaction and probably cost reduction. This approach will become the standard of care for patients with uncomplicated SPD in the future.

AUTHOR CONTRIBUTIONS

All the phases of the study were participated with the help of other authors in the different parts: Conception and design: Jordi Elvira Lopez, Jorge Escuder Perez. Administrative, technical, or logistic support: Jordi Elvira Lopez, Jorge Escuder Perez, Ricard Sales Mallafré. Collection and assembly of data: Jordi Elvira Lopez. Data Access Statement: The data were collected in a protected database ensuring the anonymity of the patients. The data access statement was protected. Drafting of the article: Jordi Elvira Lopez, Jorge Escuder Perez. Critical revision of the article for important intellectual content: Jordi Elvira López, Jorge Escuder Perez, Rosa Jorba Martin, Ricard Sales Mallafré. All authors read and approved the final manuscript.

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The study was not funded by any grant.

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

This Randomised Clinical Trial received ethical approval from the Ethics Committee of Pere Virgili Institute (CEIm 041/2020). This study was designed in accordance with the Declaration of Helsinki guidelines and approved by the Clinical Trial (NCT05404243).

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