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ORIGINAL ARTICLE

Short-term outcomes of radical excision vs. phenolisation of the sinus tract in primary sacrococcygeal pilonidal sinus disease: a randomized-controlled trial

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Abstract

Background Phenolisation of Sacrococcygeal pilonidal sinus disease (SPSD) seems to have advantages over radical excision; however, a randomized-controlled trial (RCT) comparing both techniques is lacking. The aim of our study was to compare sinus pit excision and phenolisation of the sinus tract with radical excision in SPSD in terms of return to normal daily activities.

Methods This study was a single-center RCT. Fifty patients who presented with primary SPSD were randomized to phenolisation and 50 patients to excision. The primary endpoint was time to return to normal daily activities. Secondary endpoints were quality of life, complaints related to SPSD, surgical site infection, and wound epithelialization. Patients were treated in a 1-day surgery setting. Complaints related to SPSD were evaluated and symptoms were scored by the participants on a 6-point scale before surgery, and patients kept a diary for 2 weeks on complaints related to the surgical treatment (the same scoring system as preoperatively) and pain, evaluated with a VAS. Quality of life (QoL) was measured preoperatively with a VAS and the Short Form-36 Health Survey (SF-36). At 2, 6, and 12 weeks after surgery, patients were evaluated using a questionnaire containing the following items: patients' satisfaction (disease, compared with preoperatively, scored as cured, improved, unchanged or worsened), five complaints related to the surgical treatment (the same scoring system as preoperatively and in the diary), QoL (VAS and SF-36), and return to normal daily activities. The wound was assessed 2, 6, and 12 weeks postoperatively by one of the investigators (EF or NS), using an assessment form

Results The mean time to return to normal daily activities was significantly shorter after phenolisation ($5.2 \pm$ SD 6.6 days vs. 14.5 ± 25.0 days, $p = 0.023$). 2 weeks after surgery, all patients in the phenolisation group and 85.4% of patients in the excision group returned to normal daily activities ($p = 0.026$). Pain was significantly lower after phenolisation at 2 weeks postoperatively (0.8 ± 1.0 vs. 1.6 ± 1.3, $p = 0.003$). Surgical site infection occurred significantly more often after radical excision ($n = 10$, 21.7% vs. $n = 2$, 4.0%, $p = 0.020$). At 6 and 12 weeks, complete wound epithelialization was more frequently achieved after phenolisation (69.0% vs. 37.0%, $p = 0.003$ and 81.0% vs. 60.9%, $p = 0.039$, respectively).

Conclusions Pit excision with phenolisation of SPSD resulted in a quicker return to normal daily activities, less pain, and quicker wound epithelialization compared to radical excision. Surgeons should consider phenolisation in patients with primary SPSD.

Keywords Pilonidal sinus · Phenol · Minimally invasive surgical procedures · Randomized-controlled trial

Introduction

Sacrococcygeal pilonidal sinus disease (SPSD) is an acquired disorder at the natal cleft with a prevalence of 8.3% [1]. SPSD is most common in men between 20 and 30 years old [2]. For patients with symptoms of chronic SPDS (pain, itching and discharge with soiling of underwear) that interfere with their normal daily life, several treatment options have emerged. Radical surgical excision of the sinus with

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primary wound closure or secondary wound healing is most often used. However, a high rate of wound complications after surgical excision often results in a long healing time and, consequently, a long time to return to normal daily activities [2]. Since SPSD is mainly seen in the young healthy working population, this leads to a high socio-economic burden.

A minimally invasive treatment modality for SPSD is excision of the sinus pit(s) followed by application of phenol to the sinus tract. Phenol is a sclerosing agent that destroys the epithelium and debris in the sinus, and is, thus, able to promote healing of the sinus [3]. Expected advantages of this treatment modality over radical surgical excision of SPSD are smaller surgical wounds, less pain, and faster wound healing, and, therefore, faster recovery and return to normal activities. The previous series have shown a mean wound closure time ranging from 16 to 28 days, a surgical site infection (SSI) rate of 0–8.7%, and a time until return to work of 0–3 days [3–6]. However, comparison of phenolisation with excision and primary wound closure of SPSD focusing on the difference in time until return to normal daily activities has never been investigated in a randomized-controlled trial (RCT).

The aim of this RCT was to compare phenolisation of the sinus tract to radical excision of SPSD in terms of return to normal daily activities.

Materials and methods

Study design

The design of this randomized non-blinded, single-center controlled trial has been described previously [7]. Patients who presented with SPSD at the Department of Surgery of the Diakonessenhuis Utrecht (the Netherlands) were considered for participation in this trial. Patients with symptoms due to chronic SPSD, age ≥ 18 years, and written informed consent were eligible for inclusion in this trial. Exclusion criteria were no or only minimal symptoms related to SPSD, suspicion of an extensive subcutaneous network of sinus tracts (as these sinuses are not eligible for phenolisation), presence of pilonidal abscess, and previous surgery for SPSD, i.e., recurrent SPSD.

Randomization

Patients were randomly assigned to either pit excision and phenolisation or primary surgical excision with a 1:1 allocation. Surgeons performed randomization in the outpatient setting using sequentially numbered, sealed, and opaque envelopes (contained a folded paper with “phenolisation” or “excision”) which were opened one at a time.

Surgical interventions

Patients were treated in a day surgery setting under spinal or general anesthesia, depending on the preference of the patient and/or anesthesiologist. The patient was positioned in the prone position. The buttocks were separated with plasters optimizing the view. The operative area was shaved. No antibiotics were administrated. The skin was cleaned with antiseptic solution (Betadine 100 mg/mL). Probing via the pit(s) of the sinus was performed to determine the direction of the sinus. In the case of pit excision and phenolisation, a limited excision of the midline pit(s) was made. In addition, all off-midline openings were also excised and the openings were used perform curettage of the tract to remove hairs, debris, and granulation tissue. Hemostasis was obtained using electrocautery and external compression. The surrounding skin was protected by a coating of Vaseline (Pharmachemie BV, Haarlem, The Netherlands). Liquid phenol 85% (Meander Medical Centre, Amersfoort, The Netherlands) was injected with 1 or more 1 mL syringes, depending on the volume of the sinus tract. Phenol was left in place for 1 min and aspirated afterwards. This was repeated once. The sinus was then washed out with ethanol 70% (Fresenius, Schelle, Belgium) to neutralize the remnants of phenol.

In patients who had radical surgical excision of SPSD, a limited asymmetrical incision of the skin around the sinus was made using cautery to ensure off-midline closure of the wound afterwards. All midline and off-midline orifices were included. Subsequently, the sinus was radically excised after the tract was explored with a fistula probe. The subcutaneous tissue was mobilized to be able to close the wound off-midline. After complete hemostasis, the plasters were loosened, a gentamicin-containing collagen sponge (Garacol 130 mg sponge, EUSA Pharma (Europe) Ltd., Oxford Science Park, Oxford, United Kingdom) was positioned in small pieces on the sacrococcygeal fascia and the subcutaneous tissue was approximated off-midline with several absorbable sutures. The skin was closed with separate non-absorbable vertical mattress sutures.

Postoperatively, patients were advised to keep the area free of hairs by shaving/epilation which was also done during every postoperative outpatient clinical visit.

Data collection and follow-up

Preoperatively, baseline characteristics were collected. In addition, complaints related to SPSD were evaluated and symptoms were scored by the participants on a 6-point scale from 0 (no complaints) to 5 (daily complaints). Quality of life (QoL) was also measured preoperatively, both

with a visual analogue scale (VAS, scored from 0, worst, to 10, best) and the Short Form-36 Health Survey (SF-36) [8]. The SF-36 is a questionnaire designed to measure health-related QoL, consisting of 36 questions comprising nine different domains of QoL. For every domain, a score between 0 and 100 can be obtained; the higher the score, the better the QoL.

During both surgical procedures, the number of midline and off-midline pits, presence of hairs in the sinus, operating time, and intraoperative complications were recorded. In the case of phenolisation, the volume of the sinus was measured by the amount of phenol injected. During excision, the weight of the excised tissue and the size of the wound in three dimensions were measured.

After surgery, patients kept a diary for the first 2 weeks to record complaints related to the surgical treatment (the same scoring system as preoperatively). In addition, pain was evaluated with a VAS, scored from 0 (no pain) to 10 (extremely painful). Use of pain medication and whether the patient was able to perform normal daily activities, such as working or doing housekeeping work, was also recorded.

At 2, 6, and 12 weeks after surgery, a questionnaire was used to evaluate the following items: patient satisfaction (disease, compared with preoperatively, scored as cured, improved, unchanged, or worsened), five complaints related to the surgical treatment (the same scoring system as preoperatively and in the diary), QoL (visual analogue scale and SF-36), pain, and return to normal daily activities [9].

The wound was assessed 2, 6, and 12 weeks postoperatively by one of the investigators (EF or NS) using an assessment form. This form included wound closure (defined as complete epithelization of the skin), size of the wound in three dimensions in the case of no complete epithelialization, and SSI [10].

Endpoints

The primary endpoint was time to return to normal daily activities, measured from the day of operation. Secondary endpoints included symptoms related to, use of pain medication, QoL, time to wound closure, and SSI.

Study oversight

The study protocol was approved by the local Medical Ethics Committee (United Committees of Human Research, Nieuwegein, the Netherlands; reference number: NL43192.100.13) and written informed consent was obtained from all participants [7]. The study was conducted according to the Consolidated Standards for Reporting of Trials (CONSORT) guidelines and in accordance with the principles of the Declaration of Helsinki [11]. This trial was registered at the Dutch trial register (trialregister.nl, NTR4043).

Statistical analysis

The sample size of this study was based on a reduction of mean time until return to normal activities from 7.5 days in the excision group to 4 days in the phenolisation group. A more conservative estimation had been considered for both groups as the results from the literature show a relatively broad SD. The sample size calculation was based on two-sided alpha level of 0.05 and a power of 80%. This leaded to a required total sample size of 100 patients (50 per group).

Data were analyzed using SPSS for Windows version 23.0 (SPSS Inc., Chicago, IL, USA) and analysis was performed according to the intention-to-treat principle. Primary and secondary endpoints were compared between both treatment groups. Continuous values were reported as mean (± SD) or as median (range), depending on whether the data were normally distributed or not. Categorical values were reported as frequencies and percentage of the total number of patients. Statistical analysis of categorical values between both treatment groups was performed using the Pearson Chi-square test or Fisher's exact test, where appropriate. Continuous values between both groups were statistically analyzed by the independent samples *t* test. Differences were considered statistically significant when the p value was < 0.050.

Results

Between September 2013 and September 2017, a total of 565 patients with SPSD presented at the Diakonessenhuis and 100 patients were randomized for phenolisation or radical excision. Reasons for exclusion of the other patients are shown in Fig. 1. Phenolisation was performed in 50 and surgical excision in 46 patients as one patient in the excision group withdrew after randomization, another did not show up for surgery, one patient was suffering from mental illness (presenting after randomization) and the fourth patient unexpectedly moved abroad. Baseline characteristics of the included patients and intraoperative data are shown in Table 1. Most patients were male and approximately two-thirds of the patients had jobs that involved working in a sitting position. No intraoperative complications occurred in either group and hairs were found in the sinus in more than 80% of patients. Mean operating time was significantly longer in the excision group, 25.5 ± 7.6 min vs. 18.6 ± 6.8 min ($p < 0.001$).

All patients in both groups were discharged on the same day as surgery. SSI occurred significantly more often after excision ($n = 10$, 21.7% vs. $n = 2$, 4.0%, $p = 0.020$). One patient allocated to excision was readmitted 4 days after

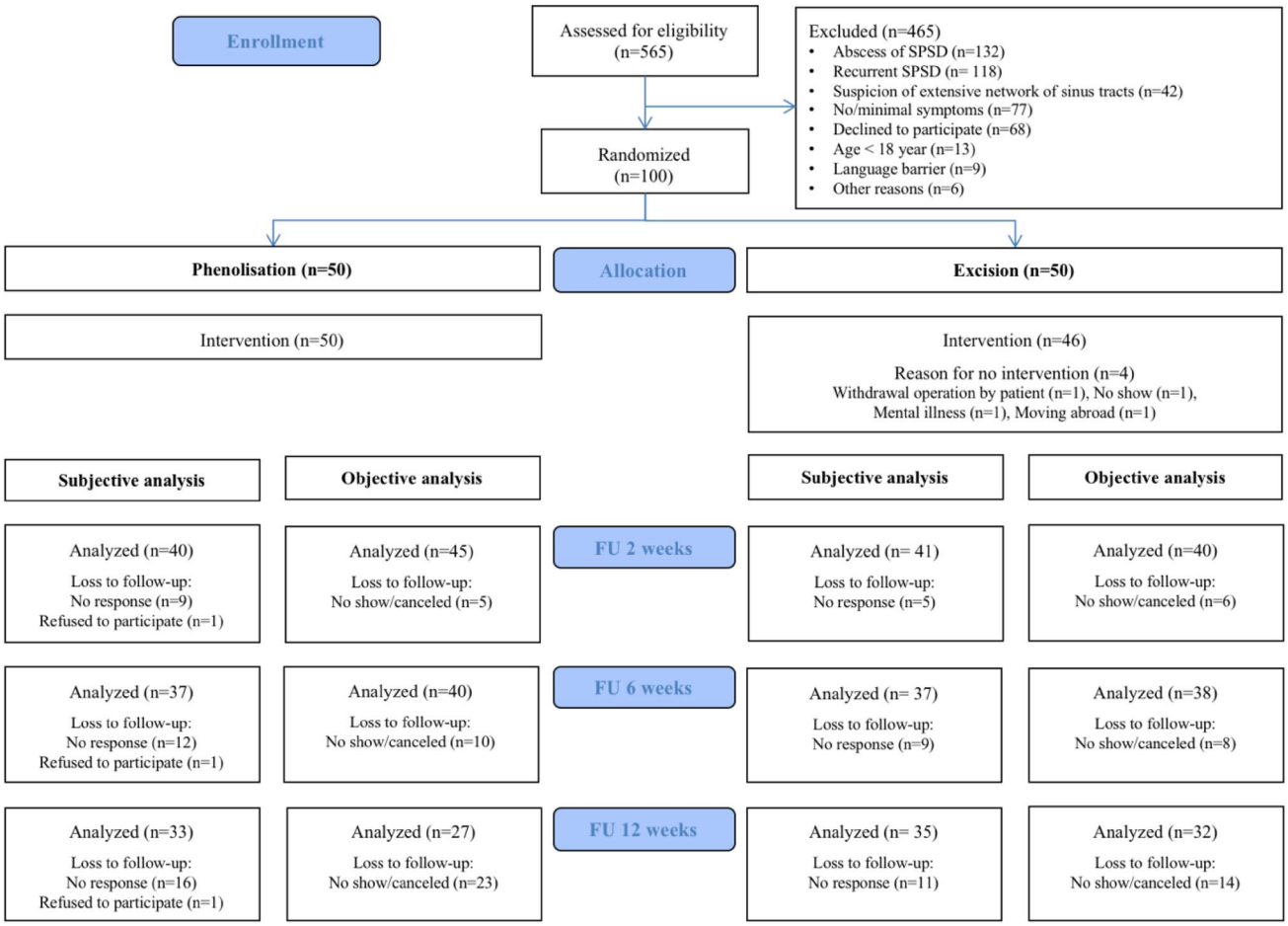

Fig. 1 Consolidated standards for reporting of trials (CONSORT) flow diagram. *SPSD* sacrococcygeal pilonidal sinus disease, *FU* follow-up

surgery for 1 day because of pain due to an infected hematoma. Removal of the stitches was required. No other postoperative complications occurred.

The postoperative diary was completed by 40 patients (79.0%) in the excision group and by 45 patients (90.0%) in the phenolisation group. Pain was scored significantly higher on days 5, 6, and 8–14 in the excision group (Fig. 2). In addition, significantly more patients used pain killers in the excision group on days 6–13. Fluid discharge was reported significantly more often on days 1–4 after phenolisation and on days 13–14 after excision (Fig. 3). In both groups, the scores for itching, irritation, and a burning sensation during the first 2 weeks were all < 1 with no significant differences between groups.

Follow-up data

In the excision group, a total of 41, 37, and 35 patients were available for subjective and 40, 38, and 32 patients for objective follow-up 2, 6, and 12 weeks after surgery, respectively, in the excision group. In the phenolisation group, 40, 37, and 33 were available for subjective and 45, 40, and 27 patients for objective follow-up, respectively (Fig. 1).

Subjective results

The primary endpoint, time to return to normal daily activities, measured from the day of surgery, was 5.2 (6.6) days after phenolisation compared to 14.5 (25.0) days after excision ($P = 0.023$). 2 weeks after surgery, all patients in the phenolisation group returned to normal daily activities, whilst this was the case in 85.4% of patients in the excision group ($P = 0.026$, Table 2).

QoL in both treatment groups, measured by VAS, was not significantly different (Table 2). Compared to excision, a significantly lower pain score was reported at 2 weeks after phenolisation. This difference disappeared after 6 and 12 weeks. No significant differences were seen with regard to postoperative fluid discharge, itching, irritation, and burning sensation.

SF-36 scores showed a significant higher score on the domains physical, physical role, and social functioning

Table 1 Baseline characteristics and intraoperative data of excision and phenolisation

	Excision ($n=50$)	Phenolisation ($n=50$)	P value
Male sex (%)	43 (86.0)	45 (90.0)	0.538
Age (years)	29.4 (10.1)	27.1 (7.8)	0.207
Body mass index (kg/m^2)	23.9 (2.2)	25.1 (4.7)	0.120
Smoking (%)	16 (32.0)	19 (38.0)	0.689
Family history of SPSD (%)	17 (34.0)	7 (14.0)	0.012
Working in sitting position (%)	33 (66.0)	35 (70.0)	0.505
Duration of preoperative symptoms (months)	16.4 (25.3)	13.1 (34.3)	0.599
Number of sinus pits in midline	2.6 (1.7)	3.0 (1.9)	0.205
Number of patients with off-midline sinus pit(s)			
Right side of midline (%)	6 (12.0)	10 (20.0)	0.318
Left side of midline (%)	13 (26.0)	21(42.0)	0.166
Data on surgical procedures	$n=46$	$n=50$	
Length of wound (mm)	56.0 (23.6)	N/A	N/A
Width of wound (mm)	27.7 (8.8)	N/A	N/A
Depth of wound (mm)	21.7 (8.1)	N/A	N/A
Weight of excised specimen (grams)	9.5 (8.9)	N/A	N/A
Volume of sinus (ml phenol)	N/A	1.2 (1.4)	N/A
Hair present in sinus (%)	38 (82.6)	43 (86.0)	0.642
Duration of operation (min)	25.5 (7.6)	18.6 (6.8)	0.000

Values are reported as mean ± SD, unless otherwise stated

SPSD sacrococcygeal pilonidal sinus disease, *N/A* not applicable

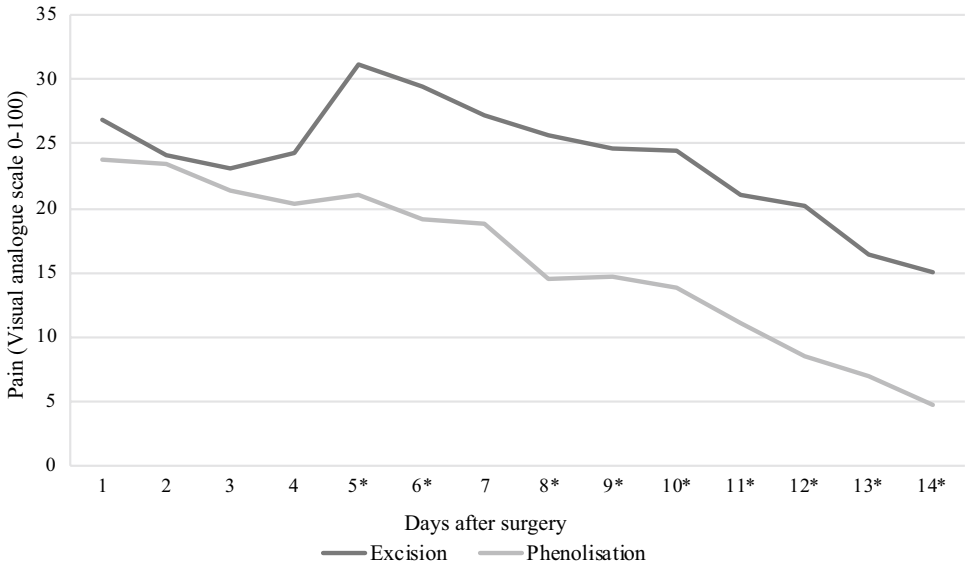

Fig. 2 Pain at natal cleft after surgery. *Statistically significant difference between groups ($p<0.05$)

2 weeks after phenolisation compared to excision (Fig. 4). This difference disappeared after 6 weeks for physical functioning and after 12 weeks for both other domains. In accordance with pain scored by VAS, pain measured by SF-36 was significantly less 2 weeks after phenolisation. The other domains of the SF-36 showed no statistically significant differences.

Compared to preoperatively, 33 patients (94.3%) in the phenolisation group and 31 patients (94.9%) in the excision group reported SPSD as cured or improved 12 weeks postoperative.

Objective results

Postoperative assessments showed a significantly higher rate of wound epithelialization after phenolisation than after excision at 6 and 12 weeks (Table 3). The length of the wound was significantly smaller 2 and 6 weeks after surgery

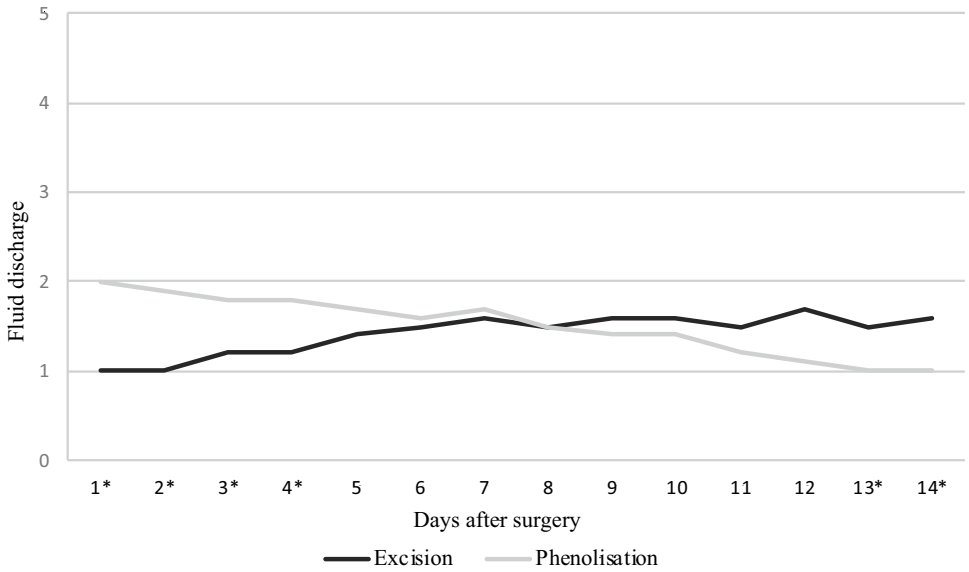

Fig. 3 Fluid discharge at natal cleft after surgery. Items scored on a six-point scale from 0 (no discharge) to 5 (daily discharge). *Statistically significant difference between groups ($p < 0.05$)

in the phenolisation group, while the width and depth of the wound was significantly smaller 6 weeks after phenolisation. 12 weeks after surgery, there was no statistically significant difference in any dimension of the wound between the groups.

Discussion

This RCT comparing phenolisation with radical excision in SPSD showed a significantly reduction of time until return normal daily activities in favor of phenolisation. In addition, the operating time in the phenolisation group was significantly shorter, patients had significantly less pain (first 2 weeks postoperatively), and wound epithelialization was significantly quicker.

The minimally invasive character of phenolisation resulted in an earlier return to normal daily activities. The wound was smaller which led to less postoperative pain, especially during the first 2 weeks. Another advantage was the quicker epithelialization at the natal cleft because of the small size of the wounds. Excision of SPSD is associated with lengthy wound healing due to the location close to the anus, an area with a lot of tension on the skin and a difficult location for wound care and hygiene. Complications such as wound infection and wound dehiscence might result in long-lasting symptoms, like fluid discharge and pain. In addition, this trial showed that phenolisation is safe as no major complications occurred. Minor complications after phenolisation, such as abscesses, occurred in 4% of the patients in the current study and have been described in the literature with a prevalence of 9% [12].

Despite the high prevalence of SPSD, there is no consensus about which treatment modality is the best. Although radical excision with primary wound closure with or without flap, including Bascom's, Limberg or V/Y-flap, are the most commonly used procedures, there are increasing reports of the use of minimally invasive procedures In addition to phenolisation, another minimally invasive treatment modality for SPSD is 'endoscopic pilonidal sinus treatment' (EPSiT). In this procedure, a fistuloscope is introduced through an external opening and the sinus cavity is ablated under direct vision. Meinero et al. reported, in a prospective cohort study, that the mean time to complete wound healing was 26.7 days, mean time to return to work was 2 days, the recurrence rate 5%, and a return of QoL to preoperative level [13]. In the study by Giarratano et al., mean time to return to work after EPSiT was 6 days, mean wound-healing time 26 days, and the recurrence rate 4% [14]. Laser ablation treatment of the pilonidal sinus is another recently developed minimally invasive technique. In this procedure, the sinus tracts are completely cleaned as in the phenolisation technique and subsequently the fistula tract(s) are destroyed by a laser probe. Only some small cohort studies on this technique have been published so far [15–17]. The laser technique seems to be safe. Wound infections were reported in 5–7% of patients. The recurrence rate was 3–10% after a follow-up of 15 months. Randomized trials on the laser technique have not yet been published. Another minimally invasive technique was described by Salih et al. who compared surgical excision and primary wound closure vs. injection of a mixture of petroleum jelly (Vaseline), henna powder (*Lawsonia inermis*), and tetracycline into the sinus cavity [18]. This mixture has been suggested to have sclerosant, antimicrobial, and enhanced wound-healing properties. After 6 weeks of follow-up, complete wound healing was achieved in 94% of patients after one injection as opposed to 89% of patients who had excision. Patients immediately returned

Table 2 Pre- and postoperative patient-reported outcomes

	Excision	Phenolisation	*P* value
Time until return to normal daily activities	14.5 (25.0)	5.2 (6.6)	0.023
Return to normal daily activities			
2 weeks postoperatively (%)	35 (85.4)	39* (100.0)	0.026
6 weeks postoperatively (%)	35 (94.6)	37 (100.0)	0.493
12 weeks postoperatively (%)	34 (97.1)	32* (100.0)	1.000
Quality of life (visual analogue scale, 0–100)			
Preoperatively	67.9 (19.6)	71.1 (16.6)	0.399
2 weeks postoperatively	61.5 (17.6)	64.8 (25.3)	0.505
6 weeks postoperatively	73.0 (13.2)	76.2 (17.0)	0.391
12 weeks postoperatively	71.1 (22.8)	75.8 (19.4)	0.361
Pain**			
Preoperatively	1.5 (1.1)	1.8 (1.2)	0.279
2 weeks postoperatively	1.6 (1.3)	0.8 (1.0)	0.003
6 weeks postoperatively	0.6 (0.8)	0.3 (0.8)	0.136
12 weeks postoperatively	0.5 (0.8)	0.5 (1.0)	0.794
Fluid discharge**			
Preoperatively	1.6 (1.2)	1.8 (1.2)	0.673
2 weeks postoperatively	1.6 (1.3)	1.1 (1.2)	0.069
6 weeks postoperatively	0.8 (1.0)	0.4 (0.9)	0.117
12 weeks postoperatively	0.5 (1.0)	0.5 (1.1)	0.916
Itching**			
Preoperatively	1.3 (1.1)	1.6 (1.3)	0.271
2 weeks postoperatively	0.8 (1.0)	0.8 (0.9)	0.700
6 weeks postoperatively	0.5 (0.8)	0.4 (0.8)	0.664
12 weeks postoperatively	0.3 (0.7)	0.6 (1.1)	0.196
Irritation**			
2 weeks postoperatively	0.7 (0.8)	0.4 (0.7)	0.056
6 weeks postoperatively	0.3 (0.5)	0.2 (0.6)	0.294
12 weeks postoperatively	0.2 (0.7)	0.6 (1.1)	0.125
Burning sensation**			
2 weeks postoperatively	0.3 (0.6)	0.2 (0.5)	0.477
6 weeks postoperatively	0.1 (0.2)	0.1 (0.3)	1.000
12 weeks postoperatively	0.1 (0.5)	0.3 (0.8)	0.178

Values are reported as mean and ± SD, unless otherwise stated

*One patient did not respond to this question

**Items were scored on a six6-point scale from 0 (no complaints) to 5 (daily complaints)

to work after injection, used analgesics for 1 day, and in 0.5% of cases, they developed a wound infection. Fibrin glue also shows promise as a minimally invasive procedure. In a recent report, patients with primary or recurrent SPSD were treated in a median of 9 min with healing in 126/130 (96.9%) of patients after two rounds of treatment [19].

Two other randomized trials comparing phenolisation and radical excision have been published, but with different end points to this study [20]. In the study by Calikoglu et al., excision of SPSD was followed by secondary wound healing and the primary endpoint was time to complete wound healing. The pain-free mobilization was 0.8 h after phenolisation and 9.3 h after excision ($p < 0.001$). No data on returning to daily activities have been reported. Pain was significantly lower after phenolisation, corresponding with our findings. Topuz et al. compared crystallized phenol treatment with surgical excision and primary wound closure in a randomized trial including 40 patients [21]. The mean number of days off work was 0.15 days after phenolisation and 16.2 days after excision. After 23.7 and 32.1 days after phenolisation and excision respectively, a significant difference in QoL in favor of phenolisation was reported.

There are some limitations of this study that should be considered. First, patients and physicians were not blinded for the type of treatment. However, due to the nature of the procedure with a visible difference at the natal cleft, blinding

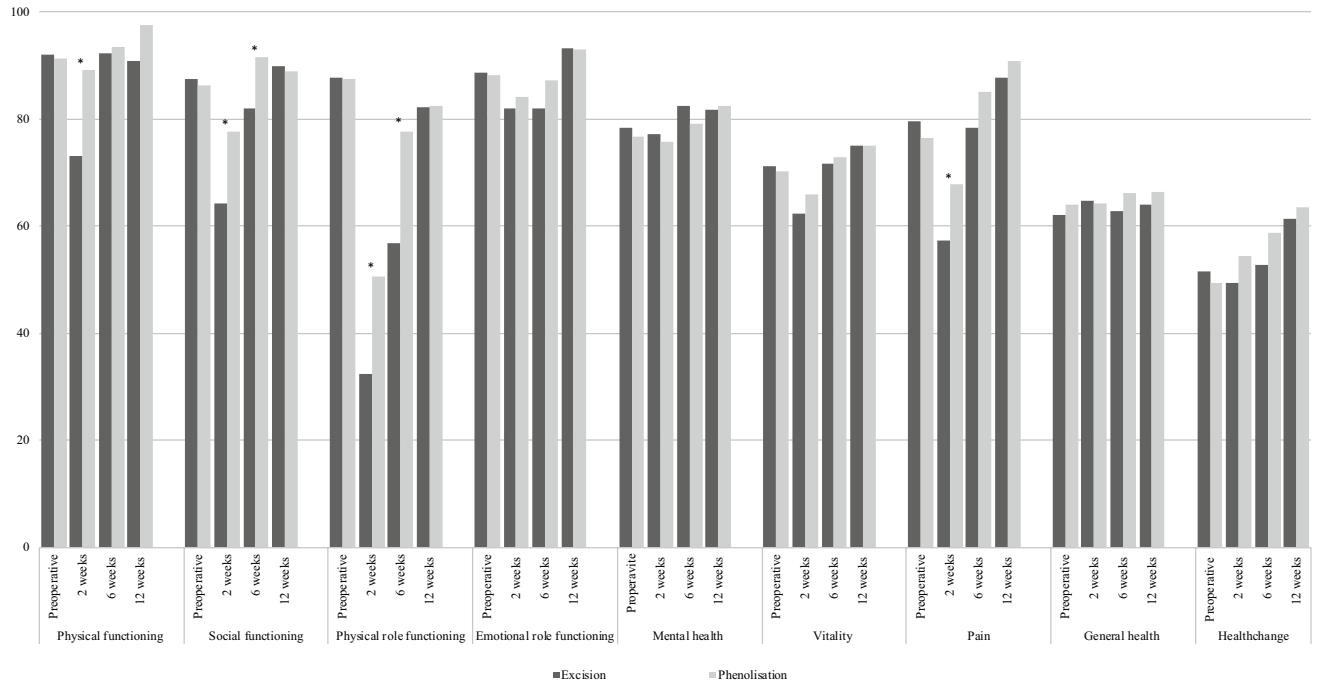

Fig. 4 36-Item Short Form Survey (SF-36), 2, 6, and 12 weeks after surgery. *Items showing a statistically significant difference between both groups ($p < 0.05$)

Table 3 Objective postoperative data

	Excision	Phenolisation	*P* value
Number of patients with wound epithelization			
2 weeks postoperatively (%)	6/43 (14.0)	6/45 (13.3)	0.932
6 weeks postoperatively (%)	17/46 (37.0)	29/42 (69.0)	0.003
12 weeks postoperatively (%)	28/46 (60.9)	34/42 (81.0)	0.039
Length of wound (mm)			
2 weeks postoperatively	61.1 (31.6)	14.6 (13.2)	< 0.001
6 weeks postoperatively	32.1 (26.3)	8.2 (12.4)	0.001
12 weeks postoperatively	28.3 (23.0)	10.1 (10.0)	0.064
Width of the wound (mm)			
2 weeks postoperatively	6.7 (5.4)	4.7 (3.4)	0.069
6 weeks postoperatively	6.8 (4.2)	3.9 (3.8)	0.019
12 weeks postoperatively	6.6 (4.4)	5.4 (4.9)	0.586
Depth of the wound (mm)			
2 weeks postoperatively	9.1 (8.5)	8.7 (11.2)	0.894
6 weeks postoperatively	8.0 (7.4)	3.6 (3.2)	0.048
12 weeks postoperatively	4.8 (3.3)	4.4 (3.2)	0.837

Data are shown as mean ± SD, unless otherwise stated

was not possible. Second, the loss to follow-up was relatively large. After 12 weeks, 76% of patients were available for subjective and 70% for objective follow-up in the excision group. In the phenolisation group, 66% and 54% were available for follow-up 12 weeks after surgery, respectively. In our opinion, this could be explained by the type of population, including young healthy working people focusing on daily and social activities and paying less attention to their health. Missing data during follow-up have possibly resulted in worse outcomes, in both groups, as it is probable that patients without complaints are more likely to cancel their visit. Third, the recurrence rate was not reported. In addition to short-term results, recurrence rate is an important outcome in the treatment of SPSD. Since our follow-up was 12 weeks, we were not able to reliably report recurrence rate as this requires a follow-up of at least 12 months. The primary endpoint in this study was the time to return to normal daily activities. As mentioned above, this primary endpoint was chosen as all advantages of phenolisation techniques, i.e., less pain, small wounds, and fast wound healing, contribute to it. We did not choose recurrence rate as the primary endpoint, because the difference in recurrence rate between surgical excision and phenolisation is very small [22, 23] and, therefore, would need a very large study to be adequately powered for recurrence as an endpoint [7]. We did not classify pilonidal sinus disease in our patient group [24]. Finally, only patients with primary SPSD were included and patients with suspicion of an extensive subcutaneous network of sinus tracts. Patients with a pilonidal sinus abscess or recurrent SPSD were not included in this trial, and therefore, the results of this trial are not transferable to those patient groups.

Conclusions

Phenolisation is a safe and effective treatment modality associated with less postoperative pain and faster wound epithelization.

Acknowledgements Cornelis Visser Stichting.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The study has been approved by the local Medical Ethics Committee (United Committees of Human Research, Nieuwegein, the Netherlands; reference number: NL43192.100.13).

Informed consent Written informed consent was obtained from all participants.

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