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Long-term Outcome of Radical Excision Versus Phenolization of the Sinus Tract in Primary Sacrococcygeal Pilonidal Sinus Disease: A Randomized Controlled Trial

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BACKGROUND: Phenolization of pilonidal sinus disease has been shown to have advantages over radical excision with regard to short-term outcome; however, long-term outcomes are essentially lacking.

OBJECTIVE: The aim of this randomized controlled trial was to compare the long-term outcome of pit excision and phenolization of the sinus tracts vs radical excision with primary wound closure in pilonidal sinus disease.

DESIGN: Single-center, randomized controlled trial.

SETTINGS: A primary teaching hospital in the Netherlands.

PATIENTS: The study population included patients with primary pilonidal sinus disease presented between 2013 and 2017.

INTERVENTIONS: Patients were randomly assigned to either pit excision with phenolization of the sinus tract(s) or excision with primary off-midline wound closure.

MAIN OUTCOME MEASURES: The main outcomes included recurrence, quality of life (Short-Form 36), and patient's satisfaction.

RESULTS: A total of 100 patients were randomized. Seventy-four patients (77.1%) were available for long-term follow-up. The mean (±SD) time to follow-up was 48.4 (±12.8) months for the phenolization group and 47.8 (±13.5) months for the excision group. No significant difference was found between both groups regarding quality of life. Two patients in the phenolization group (5.6%) and 1 in the excision group (2.6%) developed a recurrence ($p = 0.604$). The impact of the whole treatment was significantly less after phenolization ($p = 0.010$).

LIMITATIONS: The response rate was almost 80% in this young patient population, patients and assessors were not blinded for the type of surgery, and the results are only applicable to primary pilonidal sinus disease.

CONCLUSIONS: Because of the previously shown favorable short-term results and the currently reported comparable long-term recurrence rate and quality of life between phenolization and excision, phenolization should be considered the primary treatment option in patients with pilonidal sinus disease. See **Video Abstract** at http://links.lww.com/DCR/C27.

DUTCH TRIAL REGISTER ID: NTR4043.

RESULTADO A LARGO PLAZO DE LA ESCISIÓN RADICAL FRENTE AL TRATAMIENTO CON FENOL DEL TRACTO SINUSAL EN LA ENFERMEDAD DEL SENO PILONIDAL SACRO COCCÍGEO PRIMARIO: UN ENSAYO ALEATORIO CONTROLADO

ANTECEDENTES: El tratamiento con fenol de la enfermedad del seno pilonidal ha demostrado tener ventajas sobre la escisión radical con respecto al resultado

a corto plazo; sin embargo, los resultados a largo plazo aún se encuentran escasos.

OBJETIVO: El objetivo de este ensayo aleatorio controlado fue comparar el resultado a largo plazo de la escisión de la fosa del quiste y el tratamiento con fenol de los trayectos sinusales frente a la escisión radical con cierre primario de la herida en la enfermedad del seno pilonidal.

DISEÑO: Ensayo aleatorio controlado de un solo centro.

AJUSTES: Hospital de enseñanza primaria en los Países Bajos.

PACIENTES: Pacientes con enfermedad primaria del seno pilonidal presentados entre 2013 y 2017.

INTERVENCIONES: Los pacientes fueron asignados de manera aleatoria a la escisión de la fosa del quiste y posterior administración de fenol de los tractos sinusales o a la escisión con cierre primario de la herida fuera de la línea media.

PRINCIPALES MEDIDAS DE RESULTADO: Recurrencia, calidad de vida (Short-Form 36) y satisfacción del paciente.

RESULTADOS: Un total de 100 pacientes con enfermedad primaria del seno pilonidal fueron aleatorizados; 50 pacientes fueron sometidos al tratamiento con fenol y 50 a la escisión radical. Eventualmente, 74 pacientes (77,1%) estuvieron disponibles para seguimiento a largo plazo; 36 pacientes después del uso del fenol y 38 después de la escisión. El tiempo medio (± desviación estándar) de seguimiento fue de 48,4 (± 12,8) y 47,8 (± 13,5) meses, respectivamente. No hubo diferencia significativa entre ambos grupos con respecto a la calidad de vida. En el grupo tratado con fenal, dos pacientes (5,6%) desarrollaron recurrencia y un paciente (2,6%) en el grupo de escisión (p = 0,604). El impacto de todo el tratamiento fue significativamente menor después del uso del fenol (p = 0,010).

LIMITACIONES: La tasa de respuesta fue de casi el 80% en esta población de pacientes jóvenes, los pacientes y los evaluadores no estaban cegados por el tipo de cirugía, los resultados son solo aplicables a la enfermedad primaria del seno pilonidal.

CONCLUSIONES: Debido a los resultados favorables a corto plazo descritos y a la tasa de recurrencia a largo plazo y la calidad de vida comparables actualmente informadas entre la administración de fenol y la escisión con cierre primario de la herida para la enfermedad primaria del seno pilonidal, la administración de fenol del tracto sinusal debe considerarse como opción de tratamiento primario en pacientes con enfermedad del seno pilonidal. Consulte **Video Resumen** en http://links.lww.com/DCR/C27. *(Traducción—Dr. Osvaldo Gauto)*

Registro de prueba holandés-ID: NTR4043.

The optimal treatment for primary, uncomplicated sacrococcygeal pilonidal sinus disease (SPSD) is still a widely discussed topic with many different surgical treatment options available.[1] Because complications like wound infections and delayed wound healing are still a major problem after surgery, a criterion standard to treat patients with SPSD does not currently exist.[2] However, a trend toward minimally invasive techniques, such as phenolization, laser, and endoscopic treatment, is observed more and more.[3–7] The aim of these minimally invasive treatments is to reduce the risk of wound infections and delayed wound healing, and thereby reduce the disease burden and subsequent socioeconomic damage.[1]

Pit excision followed by phenolization of the sinus tract(s) is a minimally invasive technique to treat patients with primary, uncomplicated SPSD. Phenol is a liquid with sclerosing properties and, therefore, can be used to destroy remaining debris and epithelization in the sinus tract(s).[8,9] Recently, we reported the short-term results of a randomized controlled trial comparing local excision with primary off-midline wound closure vs the phenolization technique for SPSD. The results showed that the phenolization technique resulted in smaller surgical wound(s), less pain and discomfort, shorter wound healing times, and less loss of days of normal daily activities compared to the excision method.[10] Another randomized trial comparing phenolization vs excision and published in 2017 reported comparable short-term outcomes.[11] Additionally, there was no significant difference in recurrence rate between both treatments after >3 years of follow-up reported in this trial. However, in this study[11] excision was followed by secondary wound healing, and no long-term data are currently available from randomized trials comparing the phenolization technique with radical excision with primary wound closure for SPSD, especially with regard to recurrence rate.

The aim of this randomized controlled trial was to compare the long-term outcome of radical excision with primary wound closure vs pit excision with phenolization of the sinus tract for primary, uncomplicated SPSD focusing on recurrence rate.

MATERIALS AND METHODS

The design of this randomized, nonblinded, single-center controlled trial has been described previously.[12] The trial was approved by the local Medical Ethics Committee, conducted in accordance with the principles of the Declaration of Helsinki, and registered in the

Dutch Trial Register (NTR4043). Patients were considered for inclusion if they presented with primary SPSD at the Department of Surgery in the Diakonessenhuis Utrecht, the Netherlands. Inclusion criteria were chronic symptomatic SPSD, age of at least 18 years, and written informed consent. Patients were excluded if they had no or minimal symptoms of SPSD, an acute abscess, recurrent SPSD (defined as any previous surgery for SPSD), or a suspected extensive subcutaneous network of sinus tracts because these latter patients would not be eligible for phenolization as a treatment.

As calculated on the basis of the primary short-term end point "loss of days of normal daily activities," as described in the protocol of this randomized trial,[12] 50 patients were randomly assigned to radical excision and 50 patients were randomly assigned to phenolization (1:1 allocation) between 2013 and 2017. Randomization was performed by sequentially numbered, sealed, and opaque envelopes that were unsealed 1 at a time in the outpatient clinic after informed consent was obtained, as previously described.[12] A total of 4 patients in the excision group did not receive excision for various reasons (Fig. 1). All patients in the phenolization group were accordingly treated and there was no crossover in either of the groups. Except for 21.7% surgical site infection rate in the excision group and 4.0% in the phenolization group, and 1 patient who was readmitted after excision because of a subcutaneous hematoma, no unintended effects occurred during the postoperative period.[10]

Surgical Interventions

Both procedures were performed under spinal or general anesthesia with the patient in the prone position. No prophylactic antibiotics were used.

Sinus Pit Excision With Phenolization of the Sinus Tract(s)

The sinus pit(s) were probed to determine the course of the sinus tract(s), followed by limited excision of the sinus pit(s) in the midline. Drainage openings, if present outside the midline, were also excised with a limited margin. A curette was used to completely clean the sinus tract(s) and to remove granulation tissue, debris, and hair. Subsequently, the skin around the sinus pit(s) was protected by applying Vaseline (Pharmachemie BV, Haarlem, The Netherlands), and liquid phenol 85% (Meander Medical Centre, Amersfoort, The Netherlands) was injected into the sinus with 1-mL syringes until the sinus was completely filled. Phenol was removed after 1 minute and fresh phenol was injected for another minute. Phenol was removed again and neutralized and washed out using ethanol 70% (Fresenius, Schelle, Belgium). The wounds were left open and therefore, no oral or IV antibiotics were given. Patients were discharged the same day.

Radical Excision

After an asymmetrical skin incision including all midline sinus pits and off-midline drainage openings, if present, radical excision of the sinus was performed up to the
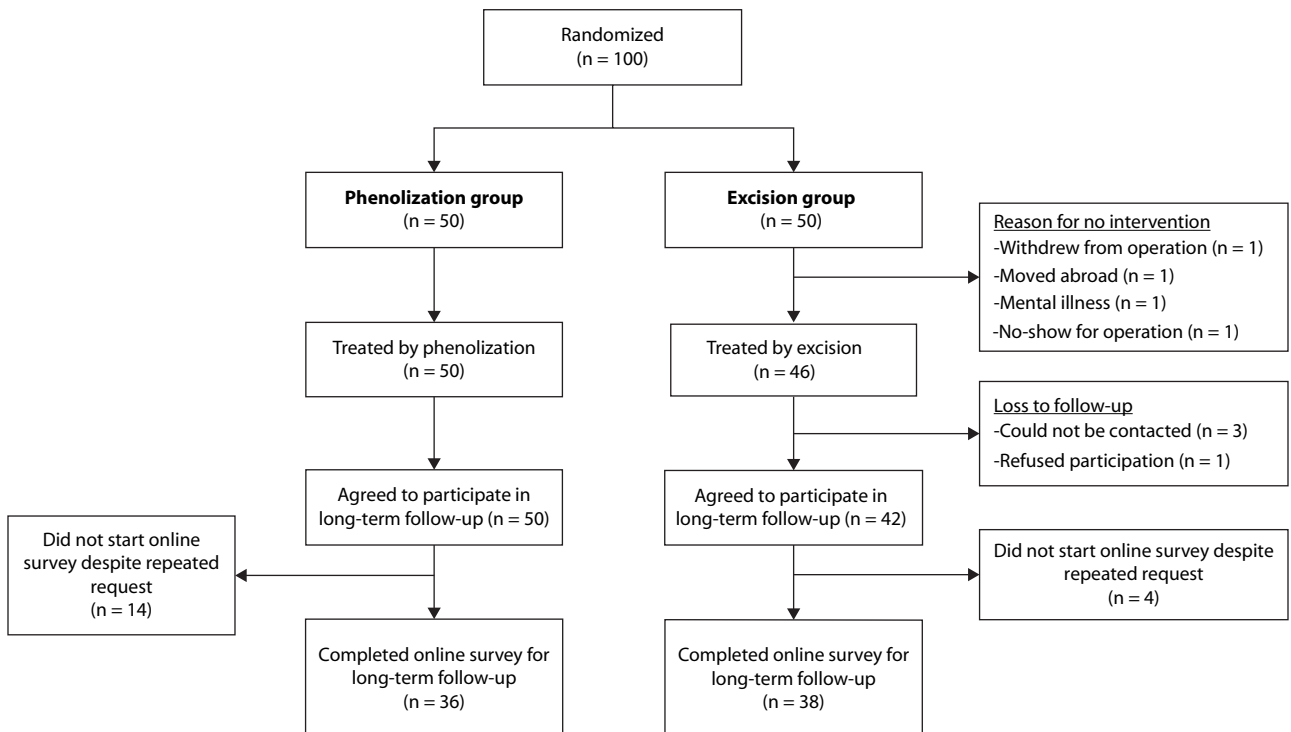

FIGURE 1. Flow chart of patients included in long-term follow-up.

sacrococcygeal fascia. After mobilization of the subcutaneous tissue, a gentamicin-absorbed collagen sponge (garacol 130-mg sponge, EUSA Pharma [Europa] Ltd, Oxford Science Park, Oxford, United Kingdom) was placed on the sacrococcygeal fascia in small pieces (therefore, no oral or IV antibiotics were given).[13] Subsequently, the wound was closed off-midline with absorbable sutures in different layers, and the skin was also closed off-midline with nonabsorbable sutures.

All surgical procedures were performed by 2 surgeons (N.S. and E.J.B.F.). Both surgeons performed at least 20 of both procedures before the start of this trial; in addition, several surgical procedures were performed jointly by both surgeons before the start of this trial to ensure that both the phenolization technique and radical excision were identically performed in the patients included in this trial.

Long-term Data Collection

After a follow-up of at least 2 years after the first surgical treatment for SPSD in this trial, all patients who were included in this study were contacted by phone call or e-mail. After consent was obtained, an online questionnaire was e-mailed, including questions about SPSD-related complaints, quality of life (QoL), and patient's satisfaction. SPSD-related complaints included current physical symptoms at the natal cleft, such as pain, itching, and fluid discharge, and all 3 were separately scored on a 6-point scale from 0 (no complaints) to 5 (daily complaints). The Short-Form 36 (SF-36) was used to evaluate QoL. The SF-36 is specifically designed to measure QoL in patient-related health care, containing 36 questions about 9 different domains of QoL.[14] Patient's satisfaction was assessed by 2 questions: 1) What was the personal impact of the whole treatment? This was scored on a visual analog scale (VAS) from 0 to 100, with a lower score indicating less impact. 2) Would you undergo the same treatment again?

Definition of Recurrence

SPSD was defined as recurrence when objectified by a physician after previous complete wound healing after the index operation. All patients' notes were reviewed to identify an objectified recurrence or an additional surgical procedure for recurrence after the index operation in our hospital. In addition, patients were asked in the questionnaire whether they underwent surgery for recurrent SPSD in another hospital after the index operation. Because a second phenolization procedure in case of noncomplete wound healing was part of the treatment protocol in the phenolization group, as previously described in the study protocol,[12] a second phenolization treatment in the phenolization group was not considered a recurrence.

Also, patients were asked in the questionnaire whether they had the impression of recurrent SPSD if this was never objectified by a physician. Patients who indicated in the questionnaire that they had the impression of recurrent SPSD that was never objectified by a physician received an invitation for an outpatient clinical visit to objectify whether there was a recurrence. Patients were scored as no recurrence if they denied the impression of recurrent SPSD in the questionnaire and never had an objectified recurrence or second procedure for recurrent SPSD.

Statistical Analysis

SPSS for Windows version 23.0 (SPSS Inc., Chicago, IL) was used to analyze the data. Depending on whether continuous data were normally distributed or not, data were reported as mean (±SD) when normally distributed or as median (range) when not. Categorical data were reported as frequencies with percentages. Outcome parameters were compared between the surgical excision group and phenolization group. Patients were examined in the excision or phenolization group, according to the intention-to-treat principle. Pearson χ^2 test or Fisher exact probability test was used for statistical analysis of categorical values, and continuous data between both groups were statistically analyzed using the independent samples t test. A p value <0.05 was considered statistically significant.

RESULTS

After a follow-up of at least 2 years after surgical treatment for SPSD, all 96 patients who underwent either surgical excision or phenolization for primary SPSD after randomization were contacted by phone call or e-mail; 3 patients could not be reached and 1 patient refused participation (Fig. 1). A total of 92 patients were sent an online composite survey after consent was obtained. The survey was completed by 74 patients (77.1%): 36 patients in the phenolization group and 38 patients in the excision group. The remaining 18 patients did not complete the questionnaire after repeated contact. Baseline characteristics of the patients who were available for long-term follow-up are reported in Table 1.

Recurrence

In the phenolization group, 2 patients underwent reoperation for a recurrence (5.6%); 1 patient underwent surgical excision with off-midline closure 24 months after the index operation and the other patient had recurrence after 2 subsequent phenolization treatments with 3 months between both procedures, and radical excision with rhomboid flap reconstruction was performed 27 months after the index operation (Fig. 2). Wounds in both patients were completely healed at follow-up. In addition, another 5 patients (13.9%) in the phenolization group underwent, varying between 3 and 14 months after the index operation, a second phenolization treatment because the wounds and sinus did not heal after the first treatment. Complete wound healing was

TABLE 1. Baseline characteristics		
Baseline characteristic item	Phenolization group (N = 36)	Excision group (N = 38)
Male sex, n (%)	31 (86.1)	32 (84.4)
Age, y	33.1 (±8.3)	34.3 (±11.0)
BMI	26.1 (±4.8)	24.7 (±2.1)
Smoking, n (%)	6 (16.7)	9 (23.7)
Family history of SPSD, n (%)	6 (16.7)	14 (36.8)
Working in sitting position, n (%)	29 (80.6)	26 (68.4)
Duration of preoperative symptoms (mo)	16.0 (±40.5)	16.2 (±21.9)
Duration of follow-up (mo)	48.4 (±12.8)	47.8 (±13.5)

Values are reported as mean (±SD), unless otherwise stated.
SPSD = sacrococcygeal pilonidal sinus disease.

reached after the second phenolization treatment in all 5 patients and no recurrence of SPSD occurred during follow-up. Because a second phenolization procedure was part of the treatment protocol in the phenolization group, those 5 patients who did not have a recurrence after the second phenolization treatment were not considered to have experienced recurrence, as defined in our study protocol.

In the excision group, 1 patient (2.6%) had an additional surgery for a recurrence 9 months after the index operation. The recurrence was treated by the phenolization technique (Fig. 2). The wound was completely healed after phenolization and no recurrence occurred during follow-up.

No other patients developed an objectified recurrence during follow-up after the index operation in the excision or phenolization group. In addition, none of the patients in either group indicated in the questionnaire the impression of recurrent SPSD. So, according to the definition, there was a recurrence in 2 patients (5.6%) in the phenolization group and in 1 patient in the excision group (2.6%; $p = 0.60$).

Subjective Long-term Outcome
Symptoms related to SPSD, including pain, fluid discharge, and itching at the natal cleft, were not significantly different between both treatment groups at long-term follow-up
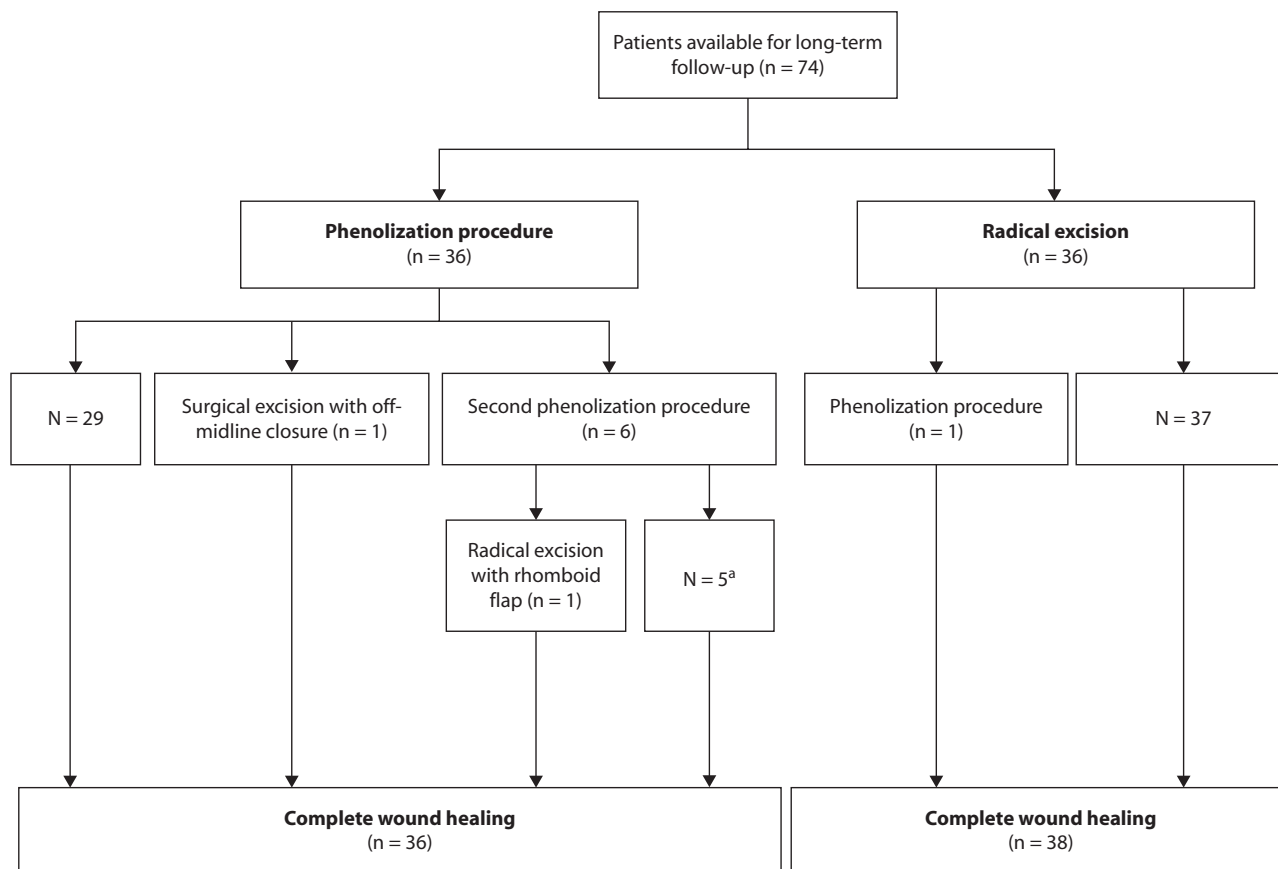

FIGURE 2.   Failures and additional surgical procedures after the index operation.
[a]Since a second phenolization procedure was part of the treatment protocol in the phenolization group, those 5 patients who did not have a recurrence after the second phenolization treatment were not considered to have experienced recurrence, as defined in the study protocol.[12]

(Table 2). The impact of the whole treatment for SPSD was significantly less after phenolization compared to excision, and in addition, significantly more patients in the phenolization group would undergo the same treatment again (Table 2). With regard to QoL, there was no significant difference in any of the 9 domains of the SF-36 between both treatment groups at long-term follow-up (Fig. 3).

DISCUSSION

In this randomized controlled trial comparing pit excision and phenolization of the sinus tracts vs radical excision with primary off-midline wound closure for primary SPSD, no significant difference in recurrence rate and QoL was found between both surgical treatment groups after a follow-up of 4 years. However, the impact of the whole treatment was significantly less after phenolization compared to radical excision, although 14% of patients in the phenolization group required a second phenolization treatment to reach complete wound healing.

In addition to the less personal impact after phenolization, a remarkably higher percentage of patients in the phenolization group would undergo the same treatment again (83% vs 58%). Smaller wounds, shorter wound healing times, and less pain during the first 2 weeks after the operation, as reported in the short-term outcome of our randomized controlled trial,[10] have probably contributed to this finding. In contrast, the relatively high surgical site infection rate in the excision group in this study (22%) might have negatively influenced the impact of treatment in the excision group and possibly also the opinion to undergo the same treatment again. However, approximately 14% of the patients in the phenolization group required a second phenolization treatment, which could possibly have negatively influenced the impact of the whole treatment in this group. Subgroup analysis of these patients who required a second phenolization treatment showed a mean VAS score for the impact of the whole treatment comparable to the VAS score of the total phenolization group, although this subgroup might be too small to draw any definitive conclusions. So, the short-term advantages of phenolization seem to outweigh the downside of a second phenolization procedure that might be required to reach complete wound healing.

Although this is, to our knowledge, the first randomized controlled trial comparing the phenolization technique and radical excision with primary wound closure in SPSD, some other studies have also been published reporting on the recurrence rate after phenolization. Calikoglu et al published the only other available randomized trial comparing phenolization and surgical excision. However, after surgical excision, they awaited secondary wound healing instead of performing primary wound closure. After a mean follow-up of approximately 40 months, there was no significant difference in recurrence rate reported between both treatment options: 18.6% after phenolization and 12.5% after surgical excision.[11] Bayhan et al reported a retrospective study comparing phenol application and excision with a modified Limberg flap. They reported a recurrence rate of 18.9% after phenolization after a mean follow-up of 16.5 months and a recurrence rate of 6.8% 17.9 months after excision, although this was not statistically significant.[15] The results of these studies were in line with the findings in the current randomized controlled trial, with also no significant difference in recurrence rate between the phenolization and excision group. However, the recurrence rate in both groups in the current study was lower compared to the figures reported in the literature. This might be because all surgical procedures in the current trial were only performed by 2 surgeons who have much experience with this type of surgery and who are very dedicated to this patient population. In many hospitals, this type of surgery is performed by almost all surgeons and even residents instead of a subgroup of dedicated surgeons, which probably negatively influences outcome.

Other studies also reported recurrence rates for phenol application, but they did not compare it with another

TABLE 2. Subjective long-term follow-up			
Subjective outcome measure	Phenolization group (N = 36)	Excision group (N = 38)	p
Pain at natal cleft[a]			
Preoperative	1.6 (±1.2)	1.6 (±1.1)	0.97
Follow-up	0.2 (±0.5)	0.3 (0.5)	0.49
Fluid discharge at natal cleft[a]			
Preoperative	1.5 (±1.0)	1.7 (±1.2)	0.42
Follow-up	0.2 (±0.5)	0.1 (±0.3)	0.54
Itching at natal cleft[a]			
Preoperative	1.2 (±1.1)	1.3 (±1.2)	0.70
Follow-up	0.2 (±0.5)	0.3 (±0.6)	0.28
Personal impact of the whole treatment (VAS, 0–100)	29.2 (±25.8)	48.2 (±33.2)	0.01
Patients who would undergo the same treatment again, n (%)	30 (83.3)	22 (57.9)	0.02

Values are reported as mean (±SD), unless otherwise stated.
VAS = visual analog scale (the lower the score, the less the impact).
[a]Items were scored on a 6-point scale from 0 (no complaints) to 5 (daily complaints).
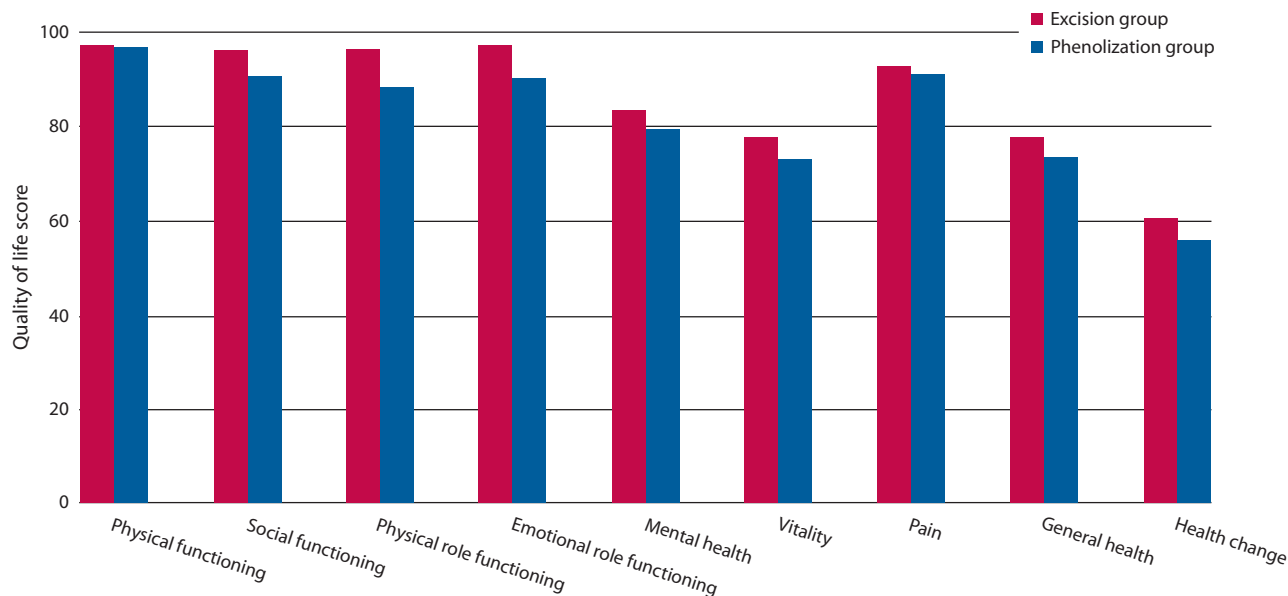
FIGURE 3. Short-Form 36 at long-term follow-up.

treatment modality for SPSD. Olmez et al[16] reported a recurrence rate of 2.5% in 83 patients after a mean follow-up of 25.7 ± 8.5 months, although recurrence was not defined in their study. Another study applied phenol in 143 patients with SPSD with a mean follow-up of 24 months. A recurrence rate of 8.3% was reported.[9] Topuz et al reported no recurrence in 20 patients who received phenolization as the first treatment for SPSD. However, the mean time to follow-up was not reported in the study.[17] In our study, we used at least 2 years of follow-up to assess whether a recurrence occurred or not after phenolization or excision for SPSD. In our opinion, this is the least follow-up time needed to determine whether SPSD has been completely cured. In addition, a clear definition of recurrence is often lacking in the studies published in the literature. We defined recurrence as objectified by a physician or an additional surgical procedure after the index operation. In addition, we asked patients whether they had the impression of recurrence that a physician did not previously objectify. In such cases, we would have invited those patients to return for evaluation regarding whether there was an objective recurrence, but this was not the case in any of the patients available for long-term follow-up. Ideally, we would have invited all patients to return to assess whether there was an objective recurrence. However, according to the study protocol, most patients were not willing to visit the outpatient clinic for long-term follow-up after their last follow-up 1 year after surgery.[12] Therefore, we decided to ask whether the patients had the impression of a recurrence and only asked those patients with a positive answer to the outpatient clinic. This was, in our opinion, an acceptable alternative, because the general

policy in patients with SPSD is to only treat SPSD if the related symptoms are influencing QoL. So, in the decision to proceed to surgery, symptoms related to SPSD are more important than an objective recurrence without complaints. Therefore, we defined patients without a subjective impression of a recurrence as no recurrence in the current study.

This study has some limitations. First, the response rate was 77%, although the patients were repeatedly contacted by e-mail and phone to participate. Second, patients and physicians were not blinded in this study. Both surgical procedures have different appearances at the natal cleft, so blinding for the patient and assessor was not possible. Third, the primary end point of this study was loss of days of normal daily activities, as described in the short-term results of this study.[10] So, power calculation was not based on recurrence rate, the most important outcome parameter for long-term follow-up after surgery for SPSD. However, as already described in the study protocol,[12] recurrence rate as the primary end point would require the inclusion of too many patients to reach statistical significance and is unattainable in our opinion. The difference in recurrence rate as found in the current study between phenolization and excision (5.6% vs 2.6%) was not statistically significant, but this is, in our opinion, also not relevant from a clinical point of view with 2 patients vs 1 patient with a recurrence, respectively. Fourth, the impact of the whole treatment was measured by a VAS score, and this was not validated for the current patient cohort. However, this convenient tool was used in this study because it has already been shown as a valid and reliable measure for many other QoL outcomes in other patient cohorts.[18,19]

Finally, patients with recurrent SPSD were not included in this study. Although the results of the current study are strictly only applicable in patients with primary SPSD, it is very likely that the results are also valid in patients with recurrent SPSD. However, the phenolization technique should be performed in an additional cohort of patients with recurrent SPSD to prove equal outcomes as for primary SPSD, as reported in the current randomized trial.

CONCLUSION

Pit excision with phenolization of the sinus tract has already been proven as a safe treatment option for primary SPSD with less postoperative pain, shorter wound healing times, and less loss of days of normal daily activity compared to radical excision with primary wound closure.[10] Therefore, because of the comparable long-term recurrence rate and QoL between both treatment options as found in the current randomized trial, phenolization of the sinus tract should be considered the primary treatment option in patients with pilonidal sinus disease.

ACKNOWLEDGMENT

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