

THE EFFECT OF CONTROLLED FLUX ELECTROLYZED ACID SOLUTION (SAEFC) PROTOCOL IN THE RECOVERY OF PHENOL TOTAL MATRICECTOMY: A RANDOMIZED CONTROLLED TRIAL

EFFECTO DE LA SOLUCIÓN ÁCIDA ELECTROLIZADA DE FLUJO CONTROLADO (SAEFC) EN LA CICATRIZACIÓN DE MATRICECTOMÍAS QUÍMICAS TOTALES CON FENOL: ENSAYO CLÍNICO ALEATORIO

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RESUMEN

Introducción: Existen diferentes tipos de protocolos de curas en matricectomías químicas totales. Recientemente, la solución ácida electrolizada de flujo controlado (SAEFC) ha sido usada para tratar quemaduras. Así, el objetivo de este estudio fue comparar el tiempo de cicatrización total y la carga bacteriana en dos tipos de curas.

Pacientes y métodos: Sobre 28 matricectomías químicas totales, en la primera cura posquirúrgica, se realizaron aleatoriamente dos tipos de curas: grupo 1 aplicación de SAEFC (manteniendo húmedo el vendaje); grupo 2, curas diarias con povidona yodada en gel. Se realizó un conteo de unidades formadoras de colonias en la primera visita posquirúrgica y a los tres días. La evolución fue seguida cada tres días para determinar el tiempo de cicatrización total.

Resultados: La media de los días de recuperación fue menor (29.2 ± 3.2) en el grupo 1 que en el grupo 2 (34.3 ± 4.1), $p = 0.023$. En la primera visita posquirúrgica no hubo diferencias ($p > 0.05$) en la carga bacteriana entre los grupos. En el segundo cultivo (5 días después de la cirugía) la carga bacteriana en el grupo 1 fue $0.42 \pm 0.38 \times 10^4$ y en el grupo 2, $0.63 \pm 0.48 \times 10^4$ siendo la diferencia

estadísticamente significativa entre ambos ($p = 0.012$).

Conclusión: En las matricectomías químicas totales, el protocolo de curas con la solución ácida electrolizada de flujo controlado (SAEFC) proporciona una reducción de cinco días en el tiempo de recuperación. Además, la menor carga bacteriana observada con este protocolo de curas puede ayudar a prevenir las infecciones en la cirugía ungüeal.

Palabras clave: matricectomía total, fenol, protocolo, curas, solución ácida electrolizada de flujo controlado (SAEFC).

ABSTRACT

Introduction: There are different cures protocols to manage total chemical matricectomies. Recently, the controlled flux electrolyzed acid solution has been used to treat burns, so, the aim of the study was to compare the total healing time and bacterial load in two types of cures.

Patients and methods: In a sample of 28 chemical total matricectomies, in the first postoperative visit (48 h), two groups were made at random: group 1, applying of controlled flux electrolyzed acid solution (maintaining ever wet the bandage); group 2 (iodate povidone in gel) were made. A count of bacterial colony forming units was taken at this postoperative visit and three days later. Also, the evolution of both groups was followed every three days, to determine the total healing time.

Results: Mean days of discharge were lower (29.2 ± 3.2 days) in the Group 1 than in group 2 (34.3 ± 4.1), $p = 0.023$. The bacterial load at the 48 hours first visit was not different between groups, ($p > 0.05$). At the second culture (5 days after the surgery), the bacterial load at Group 1 was $0.42 \pm 0.38 \times 10^4$ and in Group 2, $0.63 \pm 0.48 \times 10^4$ with a statistical difference ($p = 0.012$) between both.

Conclusion: In total chemical matricectomies, the protocol of cures with the controlled flux electrolyzed acid solution (SAEFC) provides a 5 days reduction in the time of discharge. Also, a lower bacterial load was observed in this cures protocol, which could help to prevent infections in toenails surgery.

Key words: Total matricectomy, phenol, protocol, dressing, controlled flux electrolyzed acid solution (SAEFC).

INTRODUCTION

Total chemical matricectomies are safe and reliable techniques to surgically resolve some severe toenails diseases, like stage IV ingrown toenails¹, onychauxis or pincer nails². They are carried out by cauterizing the matrix zone with 88 % phenol³ or sodium hydroxide - NaOH⁴. Success rates of chemical matricectomies vary between 80-90 %, with only 1.1 % of recurrence^{5,6}. Indeed, is safe in general population and diabetic's patients^{7,8}. However, one of these procedure disadvantages is a long time of discharge-around 30 days⁹. Some research has focused in compare different drainages types, as honey vs tul grassum¹⁰, iodated povidone vs intrasite gel and paraffin gauze¹¹ or platelet rich plasma^{12,13}, with the aim of one of them could reduce days of cicatrisation. However, since to the best author knowledge there's no evidence of anyone improves the recovery time after a total matricectomy.

Recently, the controlled flux electrolyzed acid solution (SAEFC for its acronym in Spanish, *Solución Ácida Electrolizada de Flujo Controlado*) with a pH minor to 3 (creating an acid environment that prevents microbial reproduction), and has been used for disinfecting wounds (aerobic or anaerobic bacteria), cure of diabetic ulcers as well as in surgical infected wounds^{14,15}. The controlled flux electrolyzed acid solution is also used in prevent infections in burns. The SAEFC is in form of water, and needs to be applied directly to the bandage, maintaining it ever wet (around three or four applications per day).

Also, as there's an important bacterial load in the nail fold¹⁶, this solution could be useful to reduce this load and so, reduce healing times. So, the aim of the present study was to compare the healing time and bacterial load in two types of cures (standard with iodated povidone gel as a control group and controlled flux electrolyzed acid solution, as an experimental group) in the Phenol-Alcohol total matricectomy.

PATIENTS AND METHODS

Study design

The present study follows a parallel group prospective randomized clinical trial design. Allocation ratio was 1:1.

Study population

All participants gave their verbal and written informed consent, and the study was approved by the Human Research Committee of the University of Extremadura (ID: 17/2015). The inclusion criterion was ingrown toenail in stage IV (both lateral and nail fold hypertrophy), onychia or pincer nails¹⁷. The exclusion criteria were the presence of vascular or neuropathic disease, or infection in the laterals or nail fold (based on clinical judgment of an experienced podiatrist). All participants were consecutive patients that came to the Clínica Podológica of the University of Extremadura to treat their nail diseases described above.

Interventions

The same protocol and surgical procedure were applied to all, following Becerro de Bengoa et al technique². So, the groups differed only on the post-surgery cures protocol, selected at random. In both groups, the first postop cure was performed at 48 hours after surgery, where the initial bandage was removed, a serum lavage was made and a new bandage applied. After this first postoperative visit, subjects of group 1 (n = 16) applied the controlled flux electrolyzed acid solution (SAEFC, for its acronym in Spanish, from Electrobioral EJ[®] Lab, Mexico) in the bandage, maintaining it ever wet (around 2-3 times a day). In group 2 (n = 17) subjects applied a gel of iodated povidone every day. Two participants of group 1 and three of group 2 were lost for the follow up, due to lack of postoperative visits. So, 14 participants were located in each group (Figure 1).

Outcomes

The evolution of all cases were followed every three days, to determine the total recovery time of both groups. Also, a count of bacterial colony forming units was taken postoperatively, in order to assess bacterial load in the nail fold. Samples were collected with sterile swabs using Amies Viscosa as the transport medium. The first sample was taken immediately before the first postoperative cure (after removing the bandage), making a 5-second distoproximal smear along the nail fold involved. The second sample was taken after the first three days of cures, following the same procedure as for the first sample. The samples were taken to the laboratory for microbiological assay within 24 hours. The swabs were resuspended in 2 ml of 0.9 % controlled flux electrolyzed acid solution, and then 20 µl aliquots were plated in duplicate onto 5 % blood agar, and cultured for 24-48 hours at 35 °C. After this incubation time, the bacterial colony-forming units (CFU) were

counted, recording the results in units of (CFU)/cm².

Randomization

A block randomization method was elected to make groups that result in equal sample sizes. First patient arrived to the clinic were elected to be in control (group 2), and second at experimental (group 1). This sequence was followed with all patients, since arriving to the last patient included in the study. The study was not blinded, since investigator knows the group of each patient, and patients also knows the kind of protocol, as they are recognizable.

Statistical methods

A contrast hypothesis testing was performed by means of Student's t-test for independent samples to identify differences in the means of recovery days and bacterial load. Statistical significance was considered less than 0.05 value. All calculations were performed with SPSS software.

RESULTS

The sample consisted of 28 chemical total matricectomies, all of them of the hallux. All patients underwent only a single surgery, not being operated both hallux at the same time. The patients had a mean age of 61.5 ± 7.2 years (range, 49-77 years), with 64.3 % of the patients corresponding to women and 35.7 % to men. Figure 1 shows the flow diagram of the subjects of the study.

No significant differences were found in the time to discharge between men and women in the overall sample ($p > 0.05$). Mean days of discharge were 29.2 ± 3.2 days in the Group 1, 34.3 ± 4.1 days in the Group 2. The t test for independent samples detected significant differences between both groups ($p = 0.023$). The bacterial load at the 48 hours first visit was $1.41 \pm 1.98 \times 10^4$ CFU/cm² (Group 1) and $1.49 \pm 2.01 \times 10^4$ CFU/cm² (Group 2), with no statistical differences between groups ($p > 0.05$). At the second culture (5 days after the surgery), the bacterial load at Group 1 was $0.42 \pm 0.38 \times 10^4$ and in Group 2, $0.63 \pm 0.48 \times 10^4$ with a statistical difference ($p = 0.012$) between both groups. Negative cultures were obtained after the intervention in 27.9% of the Group 1 and in 16.3 % of the Group 2 at this second culture. No clinical symptoms of suspected infection were observed in the follow-up of the surgeries during the month following intervention in any of the cases of the study.

DISCUSSION

The controlled flux electrolyzed acid solution cures protocol provides a significant reduction in healing time of the surgical wound of 5 days with regard to the iodate povidone gel. Diverse studies focused to verify the effect of different types of drainages in the time of discharge and the appearance of associate complications. This way, Dovison et al.¹¹ compared three type of drainages (iodate povidone, intrasite gel and parafinated gauze). In case of the iodate povidone, the complete cicatrisation period was 33 days. In the case of intrasite was 34, and also 33 in the case of parafinated gauze. These times were not different between the three groups, so, it seems that not postoperative drainage was giving advantages regarding healing time. Comparing with our results, the iodate povidone protocol offers similar results of whatever drainage of Dovison et al.¹¹ study, with 34 days of discharge. However, the result of the controlled flux electrolyzed acid solution is clearly faster, with 29 days for complete healing. This reduction, although not very wide, is a clear advantage for the patients.

On other hand, Gils et al.¹⁸ compared different types of postoperative cures. They performed a study comparing collagen alginate drainage with saline daily baths, concluding that the alginate was providing a reduction in the days of discharge (average of 24,4 days). For it, the authors suggest the use of the alginate to obtain a reduction in the days of cicatrisation as well as in the rate of infections. Although our period of discharge is wider, the difference could be in the kind of surgery, being partial matricectomy in the study of Gils et al.¹⁸ and total matricectomy in the present study. The highest amount of phenol burned tissue, could explain the wider period in our study.

In the bacterial load count, our study reveal that at the first operative cure, were the groups were at same conditions, the amount of bacterial load was similar. After 3 days of cures (different between groups) bacterial load was lower in group 1 than in group 2. This shows that the controlled flux electrolyzed acid solution is bactericide and if not, bacteriostatic. In the second culture, the minor presence of bacteria in the group 1 is due to the low pH of the zone, maintaining a hostile environment for the bacterial growth. Also, in 27.9 % of the samples, there were no bacterial colony formation units, so was sterile in this moment. This results could be explaining for the kind of protocol, where the bandage was ever wet, and so, acting in every moment. The standard cure with iodate povidone, once a day, seems not equal effective. Maybe with more application of iodate povidone daily the results could be different. There were no

infections in the overall sample, so it's not possible to relationship the bacterial load with the prevalence of infections. However, it's positive to control the bacterial growth in the operated zones, that could prevent some infections of the hallux.

Although significant reduction of bacterial load was observed, no infections were noted in both groups. These results could be relevant from a microbiological point of view and in the reduction of healing times, but does not seem to be a relevant from a clinical point of view in terms of avoiding infections.

Our study have some limitations, one of them is that only two cultures were taken. A better follow up, taking cultures in every postoperative visit could be better to monitoring the evolution of the bacterial growth in both groups.

In conclusion, the present study has shown that in total matricectomies, the protocol of cures with the controlled flux electrolyzed acid solution provides a reduction in the healing time of the surgical wound, which supposes an advantage for the patient. Also, a lower bacterial load was observed in this cures protocol, which could help to prevent infections in toenails surgery, especially in patients with medical complications, i.e diabetes.

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CONFLICT OF INTEREST

None.

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Figure 1. Flow Diagram of the subjects of the study.

