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ORIGINAL ARTICLE

Clinical study of the effectiveness of the ''3-sulphates solution'' on balanitis and balanoposthitis☆

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KEYWORDS
Balanitis;
Balanoposthitis;
''3 sulphates solution'';
Copper sulphate;
Zinc sulphate;
Potassium aluminum sulphate

Abstract

Objectives: Despite scientific literature mentions the application of'''3 sulphates solution'' (copper sulphate, zinc sulphate and alum) as a treatment for acute balanitis and balanoposthitis, no clinical trials evaluating its efficacy have been found. In our study we evaluate the efficacy of this solution in acute balanitis and balanoposthitis.

Materials and methods: A double-blind randomized study was designed to compare the efficacy of ''3 sulphates solution'' (intervention) with saline solution (control) in 50 patients (30 patients and 20 patients, respectively) who suffer from acute balanitis or balanoposthitis. Exudate, erythema, edema, burning, and itching were the clinical parameters assessed.

Results: For all clinical parameters assessed, the outcomes obtained with ''3 sulphates solution'' are higher than control, although significant differences only have been found for exudate.

Conclusions: In our study, the ''3 sulphates solution'' is significantly more effective than saline solution for removing exudates in acute balanitis and balanoposthitis. Tolerability was excellent in both treatments.

PALABRAS CLAVE
Balanitis;
Balanopostitis;
«Agua de 3 sulfatos»;
Sulfato de cobre;
Sulfato de cinc;
Sulfato alumínico-potásico

Estudio clínico de la eficacia del «agua de 3 sulfatos» en la balanitis y la balanopostitis

Resumen

Objetivos: La utilización del «agua de 3 sulfatos» (sulfato de cinc, cobre y alumínico-potásico) se cita en la literatura como un posible tratamiento para la balanitis y balanopostitis; ahora bien, no existen trabajos prospectivos que documenten su eficacia clínica. Pretendemos estudiar dicha eficacia.

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Material y método: Presentamos un estudio aleatorizado doble ciego sobre 50 pacientes con balanitis o balanopostitis en el que se comparan los resultados clínicos del «agua de 3 sulfatos» (30 pacientes) frente a una solución salina (20 pacientes). Los parámetros clínicos estudiados han sido: exudado, eritema, edema, escozor y prurito.
Resultados: Una vez aplicados los test estadísticos, hemos observado que el «agua de 3 sulfatos» ha sido superior al suero salino en todos los parámetros clínicos estudiados, aunque las diferencias solo han sido significativas para el parámetro exudado.
Conclusiones: El «agua de los 3 sulfatos» se ha mostrado significativamente más eficaz que el suero fisiológico en la eliminación del exudado de las balanitis y balanopostitis agudas de nuestro estudio. La tolerabilidad de los tratamientos ha sido excelente.

Introduction

Balanitis and balanoposthitis are frequent reasons for consultation in urology and dermatology.[1] Acute balanitis/balanoposthitis is the most common. It occurs abruptly or insidiously, and it presents with erythema, edema, exudate, maceration, smelly purulent discharge, itching, and stinging. The most common causes are often irritative, infectious, or traumatic, although in many cases they are unknown.[1–4]

In irritative and acute non-specific balanitis it is usual, along with proper hygiene and removing of irritants, to use astringent solutions (antiexudative) with antiseptic capacity. The local use of topical sulfates as non-specific treatment of balanitis is collected in multiple treaties of dermatology and urology[2,5,6]; however, we found no prospective study that it does.

With this study, we aim to evaluate the efficacy of a classic topical astringent formula ''3-sulfate water'' based on zinc sulfate, copper, and aluminum–potassium in the treatment of patients with acute irritative and non-specific balanitis/balanoposthitis. We have compared it with a control group, treated with saline solution.

Materials and methods

This study followed a double-blind design, with randomized distribution of the treatments, comparing the effectiveness of a solution of ''3-sulfate water'' (experimental treatment) and a physiological saline solution (control group).

Three health centers took part: the ''Lluis Alcanyís'' hospital in Xàtiva (Servei d'Urología), the ''Sagrat Cor'' hospital in Barcelona (Servei d' Urología), and the urological clinic of Dr. Peyri. The inclusion of patients was conducted from June 2012 to December 2013 (19 months). 50 adult patients diagnosed with non-specific or irritative balanitis or balanoposthitis were selected, who were randomized so that 30 patients received the solution of the ''3-sulfate water'' and another 20 patients saline solution as a control.

We excluded infectious or other-cause balanitis, patients with severe systemic diseases, those treated with other therapies that could interfere, and those who presented with other skin lesions in the genital area (herpes, syphilis, chancroid) or allergic dermatitis. The treatment consisted of the application of the solution 2 times a day (morning and evening) either by immersing the penis for 5–6 min in an aliquot of the solution using a small plastic cup or by fomentation with a soaked gauze applied on the penis for 5 or 6 min (in this case the operation was repeated 2 times). The composition of the ''3-sulfate water'' was: 2‰ zinc sulphate, 2‰ aluminum–potassium sulphate, and 1‰ copper sulfate. The duration of the treatment was 10 days.

Each patient underwent 2 controls, a baseline one (day 0) and a final one (day 10). In the baseline control, assessment of the initial symptoms was collected and the treatment was handed, and in the final control we evaluated the final symptoms and an overall assessment of both the physician and patient was issued on the efficacy and tolerability of the treatment. The symptomatology assessed was: exudate, erythema, edema, stinging, and itching according to the following score: 0 = absence; 1 = mild; 2 = moderate, and 3 = intense.

During treatment the patient had to note any adverse events that might be perceived and the physician assessed their intensity (mild, moderate, or severe) and their causation (probable, possible, unlikely, unrelated) with the treatment in the final control.

For the statistical analysis of results, we used the Chi-square test for qualitative characteristics, and Student–Fisher's *T* to compare quantitative parameters.

Results

Of the 50 patients who started treatment, 47 finished it; one of the patients did not perform successful treatment and the other two did not return to the final control, so they were excluded from the final analysis. Of those who completed the treatment, 27 received the ''3-sulfate water'' solution and the remaining 20 the physiological solution. The groups have been homogeneous in terms of age (54 years in the experimental group and 59 in the control), diagnosis (12 balanitis [44%]), and (15 balanoposthitis [56%] in the first group, and 9 [45%] and 11 [55%] in the control group) and in the method of treatment (immersion or fomentation) (Table 1).

After the treatment, there was a clear overall symptomatic improvement in both groups, as reflected in Fig. 1(a–e).

When comparing the symptoms, we observed a trend to a better evolution of the group treated with the ''3-sulfate water'' in all clinical parameters, and in one of them the differences were statistically significant: in the evolution of