

Original article

Cold or hot sitz baths in the emergency treatment of acute anal pain due to anorectal disease? Results of a randomised clinical trial[☆]

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A B S T R A C T

Introduction: The popular belief advocates the use of sitz (sitting) baths with cold water for the treatment of acute anal pain, but clinical practice guides recommend the use of hot water for its known effect on the at-rest anal pressure.

Aim: The objective of the study was to examine the analgesic effect on the quality of life, manometer data and clinical progress, of the two temperatures in sitz baths in patients with anal pain.

Material and methods: A randomised clinical trial on patients with acute anal pain due to haemorrhoids or anal fissures, divided into Group 1: Sitz baths with water at a temperature of less than 15°C, and Group 2: Baths with a water temperature above 30°C. The analgesia was the same in both groups. An analysis was made of the pain at 7 days (visual analogue scale), quality of life (SF-36), anal at-rest pressure and disease progress.

Results: Of the 27 eligible patients, 24 were randomised (Group 1: n=12 y Group 2: n=12). There were no statistical differences in pain, but it remained stable in Group 1, but gradually decreased in the patients of Group 2, the difference being in the pain scores on the first day compared to the seventh in Group 2 (P=.244). The rest of the variables were similar.

Conclusion: There were no statistically significant differences in pain control from day 1 to day 7 in the Group with sitz baths with hot water.

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Tratamiento del dolor anal por patología anorrectal aguda en urgencias: ¿baños de asiento con agua fría o caliente? Resultados de un ensayo clínico aleatorizado

R E S U M E N

Palabras clave:

Dolor anal
Patología anorrectal
Baños de asiento
Urgencias

Introducción: La creencia popular propugna el uso de baños de asiento con agua fría para el tratamiento del dolor anal agudo, pero las guías de práctica clínica recomiendan el uso de agua caliente por su efecto conocido sobre la presión anal de reposo.

Objetivo: El objetivo fue estudiar el efecto analgésico, sobre la calidad de vida, datos de manometría y evolución clínica, de 2 temperaturas en los baños de asiento en enfermos con dolor anal.

Material y métodos: Ensayo clínico aleatorizado en pacientes con dolor anal agudo por enfermedad hemorroidal o fisura anal divididos en Grupo 1: baños de asiento con agua a T.^a inferior a 15 °C y Grupo 2: baños con agua a T.^a superior a 30 °C. La analgesia fue la misma en ambos grupos. Se analizó: el dolor durante 7 días (escala visual analógica), calidad de vida (SF-36), presión anal de reposo y evolución de la enfermedad.

Resultados: De 27 pacientes elegibles, 24 fueron aleatorizados (Grupo 1: n = 12 y Grupo 2: n = 12). El dolor no mostró diferencias estadísticamente significativas, pero se mantuvo estable en el Grupo 1 y por el contrario fue disminuyendo progresivamente en los pacientes del Grupo 2, siendo la diferencia en los valores del dolor del primer día respecto al séptimo superior en el Grupo 2 (p = 0,244). El resto de las variables fueron similares.

Conclusión: No hubo diferencias estadísticamente significativas en el control del dolor del 1.^{er} al 7.^o día en el Grupo con baños de asiento con agua caliente.

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Introduction

Acute anal pain is frequently observed in emergency services due to the high prevalence of acute anorectal disorder, especially haemorrhoidal disease and anal fissure.¹

The treatment of both diseases involves a specific therapy for each case (e.g. reduction of haemorrhoidal prolapse) and the administration of an analgesic regimen, while clinical guidelines also recommend the prescription of general measures.¹ These measures include a diet rich in fibre and the use of sitz baths with hot or warm water, which are known for their effect on internal anal sphincter pressure, the hypertonia of which has been linked to anal pain.^{2,3}

Despite these recommendations, the general population and part of the medical community believe that sitz baths should be taken with cold water. The lack of scientific evidence on this issue means that the use of sitz baths with cold or hot water is still controversial.^{4,5}

Our main hypothesis was that the hot water baths had a greater analgesic effect than the cold water ones, because they reduce internal anal sphincter pressure. The main objective of this study was therefore to analyse the possible analgesic effect of different water temperatures of sitz baths in patients with acute anal pain who had visited the emergency services. The secondary objectives were to analyse the clinical course of the anorectal disease treated, the changes in internal anal sphincter pressure and the impact of pain development on the quality of life of the patients in the study groups.

Materials and methods

We designed a prospective, randomised, parallel-group study, which was submitted to and approved by our hospital's Ethics and Research Committee. The study's ISRCTN registration number was No 501.05.150.⁶ All eligible patients were fully informed about the study, and those who agreed to participate signed an informed consent form.

Inclusion and exclusion criteria

The study included all patients between 18-75 years old who were diagnosed by a general surgeon, using a structured clinical history and a compatible physical examination, with acute anal fissure and/or symptomatic haemorrhoidal disease between February 2007 and December 2008.

Those who had undergone previous anorectal surgery, those who suffered from inflammatory bowel disease and those who did not sign the informed consent form were excluded.

Randomisation

We proceeded to randomisation using a computer programme. When a new patient was included, they were assigned to one of the following groups: Group 1, involving general treatment rules and the recommendation to take cold sitz baths (below 15°C) twice a day, and Group 2, involving the same rules but

with the recommendation of taking hot sitz baths (above 30°C) twice a day. All patients included in the study were given the same analgesic regimen.

Treatment

The treatment to follow was explained verbally to all patients, and written information was given to them. In addition, the patients received a data collection sheet with a visual analogue pain scale with values ranging from 0 (no pain) to 10 (maximum pain) and a standard thermometer to measure the bath's water temperature.

For the application of cold water baths, we recommended the use of cold tap water, adding ice cubes until attaining a temperature between 5°C and 15°C. In the case of hot water baths, we recommended using hot tap water at a temperature between 30°C and 40°C. Patients were instructed to measure the temperature before and after bathing for approximately 5 min.

In the personal data collection sheet, patients recorded the following variables: date and time of each sitz bath (twice a day) for 7 days; water temperature before and after bathing; and pain, according to the visual analogue scale, before bathing.

The analgesic regimen for all patients was Metamizole magnesium (25-mg tablet every 8 hours). Patients were asked to write down the need for extra analgesics during the 7 days of the study.

Finally, patients were delivered the Spanish version⁷ of the SF-36 quality of life questionnaire, which they completed in a self-administered way at baseline and after completion. This test includes eight subscales.

Follow-up

On the third day of the diagnosis, we carried out anorectal manometry before and 15 min after the sitz bath (at the temperature assigned to each study group) to those patients who accepted.

The questionnaires were collected on the seventh day, and at the end of the first month and we evaluated the course of the disease for which the patient had gone to the emergency services by carrying out a physical examination in the outpatient services.

Variables studied

The main variables were as follows: anal pain during the first 7 days, measured using the visual analogue scale; maximum basal internal anal sphincter pressure, measured using anorectal manometry before and after the sitz bath; quality of life before and after the study, determined by the Spanish version of the SF-36 test, which consists of eight subscales (Mental Health [MH], Role-Emotional [RE], Social Function [SF], Vitality [VIT], General Health [GH], Body Pain [BP], Role Physical [RP] and Physical Function [PF]). Finally, we evaluated the course of the disease treated, considering as good development the clear improvement of pain and of the disorder treated with regard to pain control and the physical

examination carried out in the emergency services. Moreover, we recorded the presence or absence of complications associated with the prescribed treatment.

Statistical analysis

Prospective data was collected in a database specially designed for the study.

Quantitative variables are shown in absolute numbers, with the median and range in parentheses, while qualitative variables are shown in absolute numbers and/or percentages.

The comparison of qualitative variables was performed using the ² test (and Fisher's exact test when indicated). The quantitative variables were compared using non-parametric tests (Mann-Whitney U test and Wilcoxon test).

We calculated that a minimum sample of 24 patients (12 per group) was needed to detect a 60% difference between the values of the visual analogue scale from the first and seventh day in Group 2 (hot water sitz baths), assuming a 5% alpha risk and an 80% beta risk.

The difference was considered as statistically significant when P value was less than 0.05. The statistical analysis was carried out with the SPSS® programme.

Results

Patients included

During the recruitment period, 27 patients were diagnosed with acute anal pain due to haemorrhoidal disease or acute anal fissure and were asked to participate in the study. Two patients refused to participate, while one was excluded for having a previous anal surgery. As a result, 24 patients were randomised: 12 in the cold water bath group and 12 in the hot water bath group (Figure 1).

Table shows the main characteristics of both groups. There were no statistically significant differences concerning age,

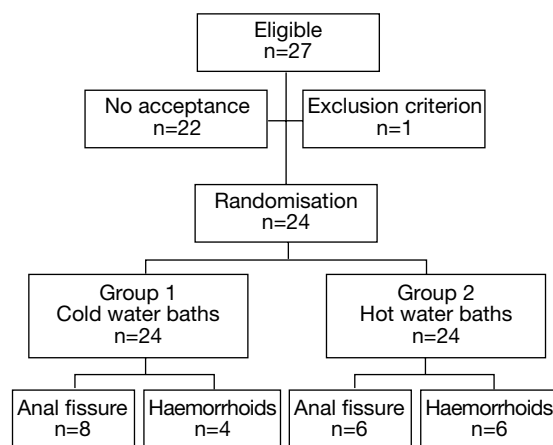


Figure 1 – Flowchart of the patients included in the study.

sex, type of perianal disease and baseline data of anorectal manometry. Table also shows that the median temperature in Group 1 was 10.8°C (range 5-13) vs 38.5°C (range 20-40) in Group 2 ($P=.01$).

Anal pain

In the analysis of the pain data, there were no statistically significant differences when comparing the values of the visual analogue scale between the two groups for each separate day. No patient required more analgesia than the standard one administered to both groups. Nonetheless, as shown in Figure 2, there was a large and progressive decrease in pain in Group-2 patients (hot baths) during the first 7 days of the study. The difference between the pain median in the visual analogue scale (from the 1st to the 7th day) was higher in Group 2, but it was not statistically significance (median difference 1.0 vs median difference 5.0, $P=.244$).

Follow-up

There were no complications related to the treatment in any patient from the study. With regard to the development of the anal disease, in one case in each group the disease treated did not present a correct development in terms of pain control. There were no significant differences between the two groups. When the patients were physically examined, none of them had worsened.

The variation in maximum anorectal resting pressure, measured before and after the sitz bath, showed no statistical differences between the two groups. Nonetheless, there was an increased pressure in Group 1 ($P=.19$) and a decrease in Group 2 ($P=.06$) (Figure 3).

Figures 4 and 5 show the results of the different items of the SF-36 test at the beginning and end of the study. Despite the differences detected, they were not statistically significant in any of the questionnaire's items.

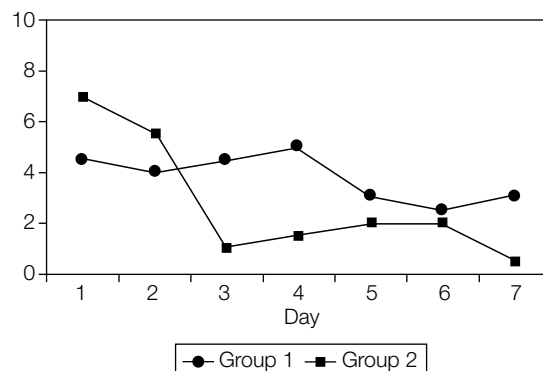


Figure 2 – Progression of the pain in the first 7 days in both groups (Group 1: cold water baths; Group 2: hot water baths) measured with visual analogue scale (values from 0=no pain to 10=maximum pain).

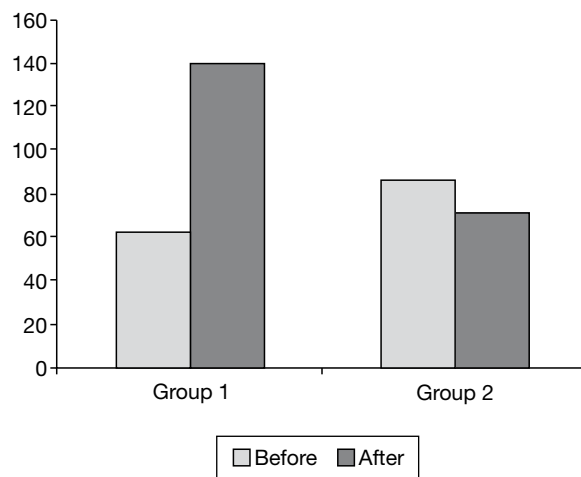


Figure 3 – Maximum resting pressure values (mmHg) in anorectal manometry before and 15 min after taking the bath in both groups.

Table 1 – Patient characteristics in both groups

	Group 1 Cold water baths (n=12)	Group 2 Hot water baths (n=12)	P
Age, years ^a	64 (52-75)	54 (27-73)	.346 ^b
Sex, %			
Male	6 (50%)	5 (41.6%)	1.0 ^c
Female	6 (50%)	7 (58.4%)	
Disease			
Haemorrhoids	4 (33.3%)	6 (50%)	.340 ^c
Anal fissure	8 (66.7%)	6 (50%)	
Water temperature of the sitz bath, °C ^a	10.8 (5-13)	38.5 (20-40)	.01 ^b
Maximum basal resting pressure, mmHg ^a	61.7 (53-71)	80 (55-101)	.267 ^b

^aMedian (range).

^bU Mann-Whitney test or Wilcoxon test.

^c χ^2 test (and Fisher's exact test).

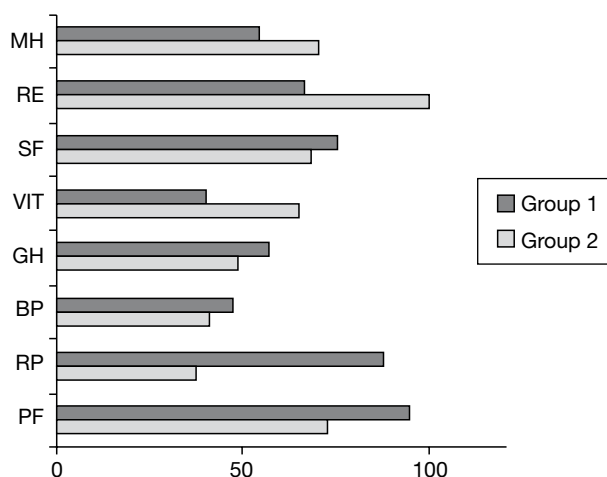


Figure 4 – Variations in the results of the 8 subscales of the SF-36 test with its 8 subscales (Mental Health [MH], Role-Emotional [RE], Social Function [SF], Vitality [VIT], General Health [GH], Body Pain [BP], Role physical [RP] and Physical Function [PF])⁷ to assess the quality of life in both groups at baseline.

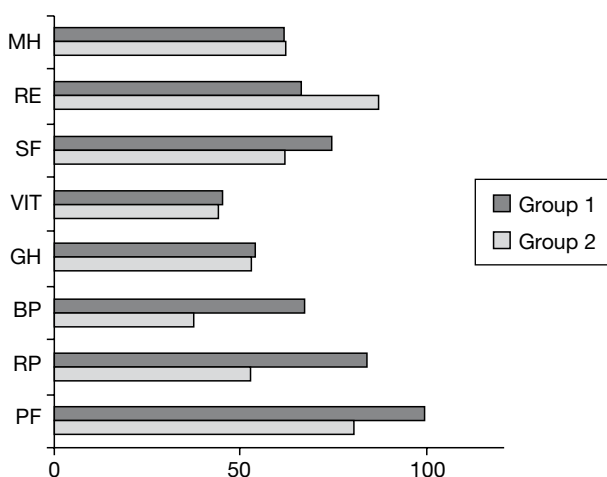


Figure 5 – Variations in the results of the 8 subscales of the SF-36 test with its 8 subscales (Mental health [MH], Role-Emotional [RE], Social Function [SF], Vitality [VIT], General Health [GH], Body Pain [BP], Role Physical [RP] and Physical Function [PF])⁷ to assess the quality of life in both groups at the end of the study.

Discussion

Although Clinical Practice Guidelines³ recommend the use of hot water sitz baths for the treatment of anal pain for its known effect on resting anal pressure, popular belief encourages the use of cold water baths. This study showed a statistically insignificant decrease in anal pain in patients taking hot baths during the first week of treatment. Nevertheless, the

analgesic effect was not significantly related to changes in the quality of life and in the values of the internal anal sphincter pressure.

Despite the high prevalence of anorectal disorder in both emergency and outpatient services, very little is known about the most suitable temperature for sitz baths, or even if this knowledge is irrelevant. Indeed, there is little scientific evidence on this issue.⁵ That is why in the design of this study we considered the possibility of providing sufficient data to recommend a standard treatment to the population. For this reason we decided to include the treatment of sitz baths and their water temperatures in the design of the study. This was also a reason for criticism.

Droegmuller's⁸ reference study examined postpartum perineal pain, as that group of patients is also advised to take sitz baths. Through his experience, Droegmuller showed that there was a greater analgesic effect with cold water perineal baths, although it is clear that postpartum perineal pain has a different pathophysiological origin than that of acute anal pain caused by anorectal disease. A more recent study compared the analgesic effect of treatment with and without sitz baths in patients with anal fissure through a randomised clinical trial.⁹ The authors showed that there was no significant pain relief or wound healing in patients taking warm water sitz baths, although there was greater overall patient satisfaction.⁹

There is controversy about the pathophysiological origin of anal pain and its association with changes in internal anal sphincter pressure.⁴ While some studies have suggested that this manometric change causes pain, others consider it as one of its own consequences.⁵ An interesting study carried out a few years ago considered that the decrease in internal anal sphincter pressure by applying heat could be mediated via somatoanal reflex.¹⁰

Despite these unknown areas, specialists recommend the use of hot water sitz baths to reduce internal anal sphincter pressure, thereby helping or contributing to pain control.³ This recommendation is based primarily on the most important study that has so far been able to prove this hypothesis. The 1986 study by Dodi et al.,¹¹ carried out using a methodology that is extremely difficult to recreate, could lay the foundation for this treatment. Therefore, with this clinical trial our group wanted to reproduce some of the hypotheses developed in that study.

There is scientific evidence of the frequent association between the presence of chronic anal fissure and increased internal anal sphincter pressure.¹² Nevertheless, scarce information is available on the control of the pain caused by haemorrhoidal disease. This is limited to the analgesic effect produced by the internal anal sphincter relaxation in patients after haemorrhoidectomy, an effect which caused a decrease in internal anal sphincter pressure with the use of topical nitroglycerine ointment, while even sphincterotomy was suggested by several authors.^{13,14}

In a recent article, Tejirian et al.⁵ reviewed the literature on the use of sitz baths in anorectal disease and were able to conclude that there is no conclusive scientific evidence and studies on its effect. This was the starting point of our study. However, we should note that our study has certain

limitations. First, due to the prevalence of anorectal disorder in the emergency services, we decided to include patients with haemorrhoidal disease and anal fissure similar to previous studies.¹¹ Moreover, it is well known that the pathophysiology of both diseases is different, and therefore the effect on anal sphincter pressure could also be different. On the other hand, the sample size was calculated to study the primary variable, pain control, and perhaps we were too optimistic in calculating the difference in pain at the start and end of the study. This was probably insufficient to assess the secondary objectives, which were considered by our group as original and interesting, given the high prevalence of the disease studied. These objectives were to determine whether the disease also influenced the progression of the quality of life differently between the groups. Lastly, the wide temperature range in each group could have a different effect on patients, and therefore is a factor to consider in the future design of other studies. For these reasons we consider it necessary to conduct more comparative studies on this subject by including a greater number of patients in order to obtain conclusive data.

In conclusion, despite noticing an improvement in the levels of pain with warm baths, there were no differences in the clinical course of the disease between the two groups, nor in the values of anorectal manometry.

Conflict of interest

The authors affirm that they have no conflicts of interest.

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