

EFFECTS OF PRE-OPERATIVE BATH IN THE PREVENTION OF SURGICAL INFECTION: PILOT CLINICAL STUDY

EFEITOS DO BANHO PRÉ-OPERATÓRIO NA PREVENÇÃO DE INFECÇÃO CIRÚRGICA:
ESTUDO CLÍNICO PILOTO

EFFECTOS DEL BAÑO PRE-OPERATORIO EN LA PREVENCIÓN DE LA INFECCIÓN QUIRÚRGICA:
ESTUDIO CLÍNICO PILOTO

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ABSTRACT

Periprosthetic joint infections in hip arthroplasties are a major challenge for the patient, staff, and health institutions. A randomized, controlled, blinded pilot clinical trial to evaluate the effect of the preoperative bath using 4% chlorhexidine gluconate solutions, polyvinylpyrrolidone iodine (PVP-I) 10% degermant or non-antiseptic soap in the prevention of surgical site infection (SSI), in patients undergoing hip arthroplasty surgery. The sample consisted of 45 adult patients submitted to elective total hip arthroplasty, who had no reports of infection at the surgical site and allergy to the solutions used, and who were not nasal carriers of *Staphylococcus aureus*. The groups of patients randomized presented homogeneity in relation to the epidemiological and clinical characteristics. The SSI rate between the groups was 20% for chlorhexidine, 6.7 for PVP-I and soap without antiseptic, respectively. No statistical differences were found between the three intervention groups. Caution is needed when recommending preoperative chlorhexidine bath as a strategy to reduce surgical site infection. Clinical Trials n° NCT03001102.

Keywords: Baths; Perioperative Nursing; Surgical Wound Infection; Arthroplasty, Replacement, Hip; Anti-Infective Agents, Local.

RESUMO

As infecções articulares periprotéticas ocorridas nas artroplastias do quadril são um grande desafio para o paciente, equipe e instituições de saúde. Estudo do tipo ensaio clínico piloto, randomizado, controlado e cego para avaliar o efeito do banho pré-operatório utilizando as soluções gluconato de clorexidina 4%, polivinilpirolidona iodo (PVP-I) 10% degermante ou sabão sem antisséptico na prevenção de infecção de sítio cirúrgico (ISC), em pacientes submetidos à cirurgia de artroplastia do quadril. A amostra foi composta por 45 pacientes adultos submetidos à cirurgia eletiva de artroplastia total do quadril, que não tinham relato de infecção no local cirúrgico e alergia às soluções utilizadas e que não eram portadores nasais de *Staphylococcus aureus*. Os grupos de pacientes randomizados apresentaram homogeneidade em relação às características epidemiológicas e clínicas. A taxa de ISC entre os grupos foi de 20% para clorexidina, 6,7 para o PVP-I e sabão sem antisséptico, respectivamente. Não foram encontradas diferenças estatísticas entre os três grupos de intervenção. É necessária cautela ao recomendar o banho pré-operatório com clorexidina como estratégia para reduzir infecção de sítio cirúrgico. Clinical Trials n° NCT03001102.

Palavras-chave: Banhos; Enfermagem Perioperatória; Infecção da Ferida Cirúrgica; Artroplastia de Quadril; Anti-Infeciosos Locais.

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RESUMEN

Las infecciones articulares periprotéticas en las artroplastias de cadera son un gran desafío para el paciente, el equipo y las instituciones sanitarias. Se trata de un ensayo clínico piloto, randomizado, controlado y ciego para evaluar el efecto del baño preoperatorio con soluciones gluconato de clorexidina 4%, polivinilpirrolidona yodo (PVP-I) 10% degermante o jabón sin antiséptico en la prevención de la infección del sitio quirúrgico, en pacientes sometidos a la cirugía de artroplastia de cadera. La muestra consistió en 45 pacientes adultos, sometidos a cirugía electiva de artroplastia total de cadera, que no tenían relato de infección en el sitio quirúrgico ni alergia a las soluciones utilizadas, y que no eran portadores nasales de Staphylococcus aureus. Los grupos de pacientes randomizados presentaron homogeneidad en relación a las características epidemiológicas y clínicas. La tasa de infección del sitio quirúrgico entre los grupos fue de 20% para clorexidina, 6,7 para el PVPI y jabón sin antiséptico, respectivamente. No se encontraron diferencias estadísticas entre los tres grupos de intervención. Es necesario precaución para recomendar el baño preoperatorio con clorexidina como estrategia para reducir la infección de sitio quirúrgico. Clinical Trials nº NCT03001102.

Palabras clave: Baños; Enfermería Perioperatoria; Infección de la Herida Quirúrgica; Artroplastia de Reemplazo de Cadera; Antiinfecciosos Locales.

INTRODUCTION

Surgical site infection (SSI) in orthopedic surgeries is a major challenge for the patient, health team, and hospitals. Therefore, they increase morbidity, mortality, hospital readmission rate and generate a high cost for health services.¹⁻³ For the patient, removal from work for long periods, due to SSI causes financial expenses and damages to their social life.⁴

Periprosthetic joint infection is the most common complication in hip arthroplasty, with the incidence rate varying between 0.67 and 2.4%.⁵

Several strategies are used to minimize SSI, such as the attempt to reduce the microbial load of man's skin.

While acting as a barrier to microorganisms, the skin also houses pathogens that can cause SSI. Microorganisms such as Staphylococcus aureus and coagulase-negative Staphylococcus causing infections are located in the skin or in the open viscera of the man and they are significant pathogens in orthopedic surgeries, especially when they include procedures with prosthesis implants. The implant favors microbial growth, causing reduced microorganism load to cause SSI.⁶

Among the interventions that may contribute to the reduction of microorganisms on the skin near the surgical incision and minimize the risk of infection, the preoperative bath is highlighted.^{7,8} With an antiseptic solution, it is considered an important measure in the prevention of SSI in hip arthroplasties, even with the low evidence of the benefit of this practice.⁹

With the antiseptics and their properties of inhibiting microbial growth for a given period, the health services have begun to recommend its use in living tissues and inanimate objects.¹⁰ The preparation of the patient's skin in the preoperative and transoperative with antiseptic solution was adopted to remove skin soiling, reducing resident and transient microbial load and, consequently, minimizing SSI.¹¹

Thus, the SSI prevention guideline of the Hospital Infection Control Practices Advisory Committee (HICPAC - CDC-P) recommends the use of an antiseptic agent in the preoperative

bath in 1999. However, until the moment there is no evidence to prove the benefit of this procedure.^{12,13}

Some orthopedic services, even with the low evidence, maintain the CDC-P recommendation. For Shohat and Paravizi⁹ the preoperative bath with chlorhexidine, even in different formulations (solutions or tissues impregnated with the antiseptic), should be performed in all patients who will undergo elective arthroplasty surgery. This routine was driven by the results of two recent studies advocating the use of handkerchiefs impregnated with chlorhexidine gluconate solution before hip and knee arthroplasty.^{14,15}

The lack of consensus allows the health services using several solutions in the bath of the patient who will undergo the joint replacement surgery procedure, such as 4% or 2% chlorhexidine gluconate solutions, triclosan, soapex, polyvinylpyrrolidone iodine 10% (PVP-I) or soap without antiseptics. Other discussions are also raised in this area, such as the number of baths, the ideal moment for bathing, the technique that must be performed, whether the whole body should be washed with the antiseptic or only the place to be operated and if the antiseptic solution should be removed from the skin by rinsing.^{16,17}

Systematic review involving 10,157 patients who underwent different types of surgeries, with a distinct contamination potential classification, did not observe evidence of the efficacy of the chlorhexidine bath in the reduction of SSI.¹⁶ Corroborating these authors, Kamel et al.¹⁸ argue that independently of the solution used, the most important in this recommendation is to perform the patient's bath before being referred for surgery.

In view of the importance of the preoperative bath as a resource to reduce the microbial load of the skin and its lack of definition regarding the solution used, this study aimed to evaluate the effect of the preoperative bath in the prevention of SSI using two antiseptic solutions - gluconate of 4% chlorhexidine and 10% PVPI - and a soap without antiseptic, in patients submitted to elective hip arthroplasty surgery.

MATERIAL AND METHOD

This was a randomized, pilot-blinded clinical trial using a control group (non-antiseptic soap) and two intervention groups (chlorhexidine gluconate 4% and 10% depleting PVP-I) in the preoperative bath performance.

Although many researchers believe that a prior careful planning of a clinical trial and its preparation is sufficient for the success of the research, pilot clinical trials are critical, as they may reveal minor flaws in the design structure or implementation of the study that many are not apparent in the research plan.¹⁹

For this pilot study, the sample performed between August 2015 and March 2016 was composed of 45 patients (15 for each type of intervention) submitted to elective hip arthroplasty surgery, aged 18 years or older, without reports of surgical site that had no allergy to the iodine solution and were not nasal carriers of *Staphylococcus aureus* before the surgery.

The patients underwent two nursing consultations with the researcher to collect the nasal swab, to pass on the guidelines of the technique of bathing and the delivery of solutions for the bath.

Two tests called pre-test and post-test were applied to evaluate the level of knowledge and understanding of the patient in the guidance given.

The patient was instructed to take a shower at night the day before and on the day of surgery and to wash his hair twice with shampoo the night before surgery. Then, to wash the entire body with the solution according to the technique described in the manual, wipe the body with a clean towel, wear clean clothes and change the bedding before bedtime. On the day of surgery, the place to be incised was soaped for two minutes, during the bath that occurred in the hospital, accompanied by a nursing technique, which ensured the correct procedure.

The randomization was performed using the statistical program Minitab version 16 in the proportion 1:1:1, with the collaboration of a statistician.

The solutions distributed to the patients were packed in brown, closed and enumerated envelopes. For the baths, the patient had a flask with 100 mL of solution drawn, four sponges and a manual standardizing the bathing technique. The flasks with the solutions were wrapped with high-tack opaque tape, preventing patient's labeling of the product.

The primary outcome was the SSI and the criteria for the Centers for Disease Control and Prevention (CDC-P/NHSN) were used for the diagnosis.²⁰ The postoperative follow-up of the patient was performed by telephone calls with 30, 60 and 90 days. However, all the patients had their operative wounds evaluated by the researcher during outpatient discharge, with up to 30 postoperative days.

The losses during the patient's follow-up were analyzed by intention to treat (ITT). The descriptive analysis of the population, the overall SSI incidence rate and for each intervention,

the test for difference of proportion, χ^2 test with continuity correction and Fisher's exact test were obtained, all two-tailed with a significance level of 0.05 and 95% CI. The normality of the data was tested by the Shapiro-Wilk test. In the parametric variables, the ANOVA and the non-parametric Kruskal Wallis test were applied. Relative risk (RR) and absolute risk reduction (ARR) were calculated between the non-antiseptic soap groups, chlorhexidine 4%, and 10% PVPI.

This study was approved by the Research Ethics Committee of the Federal University of Minas Gerais: CAAE 30544114.0.0000.5149, enrolled in Clinical Trials NCT03001102 and followed the recommendations of the Consort Statement 2010 and the norms of Resolution 466/2012 of the National Health Council. Because it was a study involving human beings, the patients and the participating physicians expressed their consent through the Informed Consent Form.

RESULTS

During the period, 61 patients were recruited and 45 were randomized to the study. The 16 excluded patients had the following causes: they did not meet inclusion criteria (n=10), they refused to participate in the study (n=2), they decided not to operate (n=2), they chose another hospital for surgery (n=2).

There was a loss of follow-up of one patient due to death (1/45) due to cardiac complications. The remaining patients maintained the follow-up during the 90 days postoperatively or until the outcome occurred. The rate of adherence to both baths was 97.8% (44/45). However, all patients had a bath on the day of surgery.

Fifteen patients were analyzed for each intervention. The flowchart of recruitment of study participants in the three groups is shown in Figure 1.

There was no allergic reaction related to the solutions used.

In the three randomized groups, the patients presented homogeneity in the epidemiological and clinical characteristics. There was a predominance of female patients (64.4% - 29/45), the mean age was 59.9 years (SD \pm 12.3), minimum range of 18 and maximum of 81 years old, and body mass index (BMI) 28.05 (SD \pm 5.6), minimum of 19.4 and maximum of 46.1kg/m². Patients classified in category 2 by the American Society of Anesthesiologist (ASA) accounted for 68.9% (31/45) and in the Nosocomial National Infection Surveillance (NNIS) surgical index risk score of 62.2% (28/45).

All surgeries were classified as clean. Of them, 95.6% (43/45) were primary hip arthroplasties and 4.4% (2/45) reviews. Patients with a history of previous hip surgery totaled 22.3% (10/35). All patients received chemoprophylaxis with cefazolin and remained on the antibiotic for 24 hours after surgery.

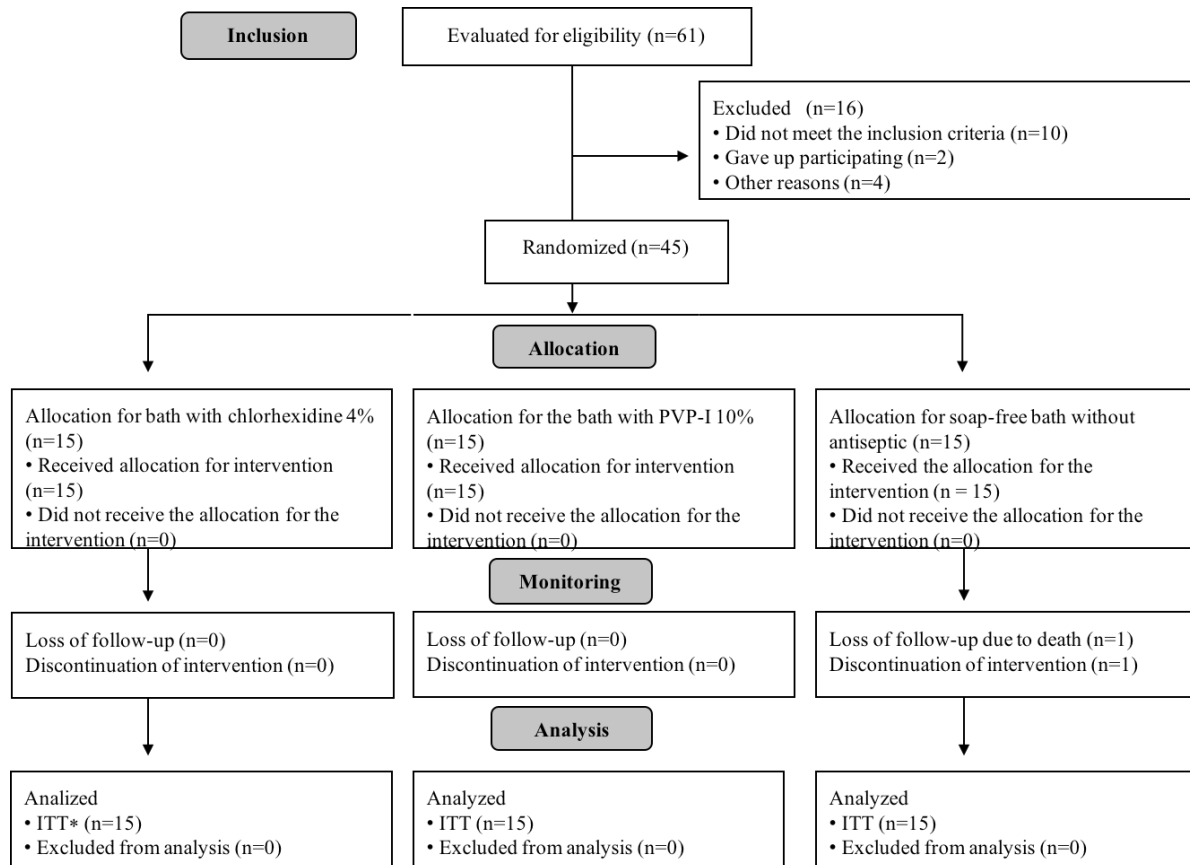


Figure 1 - Adapted flowchart-Consort 2010-Initial and final inclusion of study participants. Belo Horizonte, 2016.

*ITT: analysis by Intent to Treat.

The tonsure of the site to be incised was performed in the operating room in 11% (5/45) of the patients and all were male.

The mean time between the bath and the skin incision was 131 minutes (SD ± 45 minutes), the minimum time of 81 minutes and maximum of 306 minutes. The hospital stay was three days (SD ± 1.2), the minimum time of two and maximum of eight days and the duration of surgery was 142 minutes (SD ± 37 minutes), the minimum time of 75 minutes and maximum of 275 minutes.

There was no periprosthetic joint infection or osteomyelitis. The overall incidence of SSI was 11.1% (5/45), all classified as superficial incisional. The mean time to onset of infection was 22 days (SD ± 7.8), minimum amplitude of 14 and maximum of 29 days.

The incidence of SSI in patients who bathed with 4% chlorhexidine gluconate was 20% (3/15) and recorded as the highest incidence among groups. However, in the statistical analysis, no differences were observed between groups of interventions with p=0.59 (Table 1).

When comparing the control group and interventions: soap without antiseptic X PVPI 10% and soap without antiseptic X chlorhexidine 4% the relative risk was RR = 3.0 (95% CI = [0.35-25.68]) and RR = 1 (95% CI = [0.07-14.55]), respectively. Likewise, the absolute risk reduction was ARR = zero and ARR

= -0.13. These data showed that no statistical differences were found between the three intervention groups.

Table 1 - Distribution of patients in the development of SSI in the intervention groups. Belo Horizonte, 2016

Variables	PVPI 10% (n=15)	Chlorhexidine 4% (n=15)	Soap (n=15)	p-value
SSI	1(6.7)	3 (20.0)	1 (6.7)	0.59
Without SSI	14 (93.3)	12 (80.0)	14 (93.3)	

DISCUSSION

In this study, the overall incidence of infection was 11.1%, (5/45) and no periprosthetic infection or osteomyelitis was recorded. Veiga et al.¹⁷ that also evaluated the preoperative bath in patients undergoing plastic surgery in a clinical trial did not register deep infection.

Periprosthetic infections are devastating complications after arthroplasty, which can bring several limitations to the patient. The pharmaceutical industry has invested in resources that are used to prepare the skin of the patient undergoing surgery to minimize SSI. The tissues impregnated with 2% chlorhexidine

solutions and kept on the skin are used and considered effective by some researchers in reducing the risk of periprosthetic infection in patients submitted to hip arthroplasty.^{14,15,21}

Regarding the preoperative bath with the use of the 4% chlorhexidine solution, a study published in 2015 revealed that two sequential baths should be performed to ensure its effectiveness with a one-minute pause before rinsing and each bath should be dispensed with 118 mL of the solution. According to the author, this technique would provide maximum concentrations of chlorhexidine gluconate on the skin surface (16.5 µg/cm²), enough to inhibit or kill gram-positive and negative pathogens of the operative wound.²²

Recently, however, some systematic reviews with a meta-analysis have been carried out comparing the bath with chlorhexidine and other products in several types of surgeries and have pointed out that there is no plausible evidence to support the effectiveness of the antiseptic solution in the reduction of SSI when compared to other placebo solutions, PVP-I or soap without antiseptic.^{1,16,23}

The results of our study corroborate these systematic reviews and also no statistical difference was found when comparing the bath with antiseptic soap, chlorhexidine 4% and 10% PVP-I in the reduction of SSI in elective hip arthroplasty surgeries.

The latest guideline of the CDC-P (2017) reinforces that the preoperative bath has a strong recommendation for the prevention of SSI, washing the entire body at least the night before the surgery. However, in the antiseptic solution, it remains controversial. For this guideline, there is no evidence to standardize the type of solution used in the bath, as well as the number of applications in the body and the ideal time for the preoperative bath.¹³

CONCLUSION

This study has the sample size as a limitation, since it is a pilot whose main objective is to determine the minimum size of a sample to detect significant differences between the studied groups.

The non-occurrence of periprosthetic infection may be related to the improvement in the standardization of the bath technique, regardless of the use of antiseptics.

Given the lack of evidence regarding the preoperative bath with chlorhexidine 4%, caution is needed when recommending this practice as a strategy to reduce SS.

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