

# Lower limb warming with orthopedic cotton and cotton wool: a pragmatic pilot clinical trial

Calentamiento de miembros inferiores con algodón ortopédico y algodón: un ensayo clínico piloto pragmático Aquecimento de membros inferiores com algodão ortopédico e algodão hidrófilo: um ensaio clínico piloto pragmático

### Abstract

Renata Ramos Nascimento<sup>1</sup> ORCID: 0000-0002-6143-7850 Adriana Carla Bridi<sup>1</sup> ORCID: 0000-0003-2018-4604 Sandra Regina Maciqueira Pereira<sup>1</sup> ORCID: 0000-0002-0550-2494 Milena Preissler das Neves<sup>2</sup> ORCID: 0000-0002-3890-924X

Roberto Carlos Lyra da Silva<sup>3</sup> ORCID: 0000-0001-4066-7451 Andrezza Serpa Franco<sup>1</sup> ORCID: 0000-0001-5008-1345

<sup>1</sup>Universidade do Estado do Rio de Janeiro. Rio de Janeiro, Brazil. <sup>2</sup>Universidade Veiga de Almeida. Rio de Janeiro, Brazil. <sup>3</sup>Universidade Federal do Estado do Rio de Janeiro. Rio de Janeiro, Brazil.

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**Corresponding author:** Renata Ramos Nascimento E-mail: renatanascimento95@hotmail.com

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The aim was to analyze the effectiveness of hydrophilic and orthopedic cottons, used for heating the lower limbs in patients hospitalized in intensive care. This is a pragmatic pilot single-arm clinical trial, in which control and intervention were performed in the same patient. The sample consisted of 16 patients. When performing the analysis of heating technologies in the different measurement intervals (30 minutes, 2 hours, 4 hours, 6 hours), none of the technologies showed statistical significance. Although there is no statistical significance of the heating of both technologies in the heating interval of 30 minutes to 6 hours, it was found that, although the averages were below the considered ideal temperature (360C), the temperatures increased with the prolonged time of heating in both technologies. The results of this pilot study show in an incipient way that there is no difference between the two proposed technologies. Furthermore, we note the importance of the time being greater than 6 hours to achieve a satisfactory warm up.

Descriptors: Thermoregulation; Peripheral Vascular Resistance; Heating; Hypothermia; Critical Care.

## Resumén

El objetivo fue analizar la efectividad de los algodones hidrófilos y ortopédicos, utilizados para calentar miembros inferiores en pacientes hospitalizados en cuidados intensivos. Se trata de un ensayo clínico piloto pragmático de un solo brazo, en el que el control y la intervención se realizaron en el mismo paciente. La muestra estuvo formada por 16 pacientes. Al realizar el análisis de tecnologías de calefacción en los diferentes intervalos de medición (30 minutos, 2 horas, 4 horas, 6 horas), ninguna de las tecnologías mostró significación estadística. Si bien no existe significación estadística del calentamiento de ambas tecnologías en el intervalo de calentamiento de 30 minutos a 6 horas, se encontró que, si bien los promedios estuvieron por debajo de la temperatura ideal considerada (360 ° C), las temperaturas aumentaron con el tiempo prolongado de calentamiento. en ambas tecnologías. Los resultados de este estudio piloto demuestran de forma incipiente que no existe diferencia entre las dos tecnologías propuestas. Además, notamos la importancia de que el tiempo sea superior a las 6 horas para lograr un calentamiento satisfactorio.

Descriptores: Termorregulación; Resistencia Vascular Periférica; Calefacción; Hipotermia; Cuidado Crítico.

#### Resumo

Objetivou-se analisar a efetividade dos algodões hidrófilo e ortopédico, utilizados para aquecimento de membros inferiores em pacientes internados na terapia intensiva. Trata-se de um ensaio clínico pragmático piloto, do tipo braço único (single arm), no qual o controle e a intervenção foram realizados no mesmo paciente. A amostra foi composta por 16 pacientes. Ao realizar a análise das tecnologias de aquecimento nos diferentes intervalos de aferições (30 minutos, 2 horas, 4 horas, 6 horas), nenhuma das tecnologias apresentou significância estatística. Ainda que não haja significância estatística do aquecimento de ambas as tecnologias no intervalo de aquecimento de 30 minutos a 6 horas, verificou-se que, embora as médias tenham ficado abaixo da temperatura considerada ideal (36ºC), as temperaturas aumentaram com o tempo prolongado de aquecimento em ambas as tecnologias. Os resultados deste estudo piloto demonstram de forma incipiente que não há diferenca entre as duas tecnologias propostas. Além do mais, constatamos a importância de o tempo ser maior que 6 horas para alcançarmos um aquecimento satisfatório.

Descritores: Termorregulação; Resistência Vascular Periférica; Aquecimento; Hipotermia; Cuidados Críticos.



# Introduction

Nurses in their daily care for critically ill patients are often faced with a scarcity of resources, generating uncertainty about the best technology available for carrying out intensive care. To improve the decision-making process for these patients, it is essential that this choice is based on evidence.

Evidence-based practice (EBP) is defined as the judicious use of research results in work processes, also considering the professional skill and patient preference, being used as one of the main strategies for decision making<sup>1</sup>.

We can use this practice in all phases of the Nursing Care Systematization (SAE), especially in the phase of elaboration of the care plan. The nurse must be based on scientific evidence in choosing the best technology to perform procedures to achieve the best clinical results, making the care provided evidence-based care, replacing the empirical<sup>1</sup>.

In intensive care units, warming the lower limbs with orthopedic cotton and crepe bandage seems to be a routine practice of the nursing staff for patients who need this intervention.

Many of the patients hospitalized in Intensive Care Units (ICU), due to severity, difficulty in body thermoregulation and use of vasoactive amines in high doses, present tissue hypoperfusion, further decreasing the temperature in the extremities, requiring lower limb heating<sup>2,3</sup>.

However, due to scarce and limited resources in public health, we realize that some standardized technologies need to be replaced, with heating being carried out sometimes with orthopedic cotton (AO), sometimes with cotton wool (AH), and in the absence of these, a blanket or blanket as an alternative medium.

Given the lack of standardization or even the imprecision of which technologies could provide better peripheral heating, we formulated as a null hypothesis that there is no difference between cotton wool and orthopedic for heating lower limbs in patients hospitalized in intensive care. The alternative hypothesis formulated was that there is a difference between the technologies presented.

Using the acronym PICO, the research question was structured as follows:

P: Adult patients, admitted to intensive care, with signs of slowed peripheral perfusion (digital palpation return longer than 7 seconds) and ankle brachial index between 0.9 and 1.30 in both lower limbs.

I: Hydrophilic cotton with bandage for heating the lower limbs.

C: Orthopedic cotton with bandage to warm the lower limbs.

O: Local heating, and consequent satisfactory peripheral perfusion.

Thus, the objective of this research was to analyze the effectiveness of hydrophilic and orthopedic cottons, used for heating the lower limbs in patients hospitalized in intensive care.

## Methodology

This is a pragmatic pilot single-arm clinical trial, in which the left lower limb (LIM) was the control (orthopedic cotton and bandage), and the right lower limb (MID) was the intervention (hydrophilic cotton and bandage). Although careful prior planning of a clinical trial and its preparation are sufficient for the success of the research, pilot trials seem to offer greater security before the application of a clinical trial itself, as it can know small flaws in the process and structure of investigation that are often not revealed in the research plan<sup>4</sup>.

This study was carried out in two intensive care units located in two public hospitals in the state of Rio de Janeiro, one state university hospital (10 beds) and a federal reference hospital in cardiology (42 beds), which was approved by the Committee of Ethics in Research under opinion number 3.138.254 and CAAE 04195018.4.0000.5259, belonging to the following institution Pedro Ernesto University Hospital. The free and informed consent form was signed by the participating patients or their families. The collection took place from March to August 2019.

Adult patients admitted to an intensive care unit, aged 18 years or over, with cold lower limbs to the touch, with signs of slowed peripheral perfusion (digital pressure return to palpation greater than 7 seconds) were eligible for the study. and ankle brachial index (ABI) between 0.9 and 1.30 in both limbs.

Exclusion criteria were patients who presented any reason for hypersensitivity to heating technologies; some lower limb amputated; skin lesions and recent invasive procedures/surgeries on limbs; those on cardiopulmonary bypass; with peripheral arterial disease diagnosed in the medical record, patients in therapeutic hypothermia; that evolved to death during collection.

The participant selection process took place as follows: in both fields, the researcher and the research assistant performed, on the days of data collection, the physical examination of hospitalized patients, in search of those who had a cold limb and slow peripheral perfusion. Upon finding them, the ABI was performed by the researcher himself, and those patients who had ABI between 0.9 and 1.3 in both limbs received the warm-up.

We chose to perform the ABI, as if the patient had an important difference between the limbs, it would not be possible to include them in the study, as changes could indicate the presence of chronic arterial disease. To perform the ITB, the following formula was used:

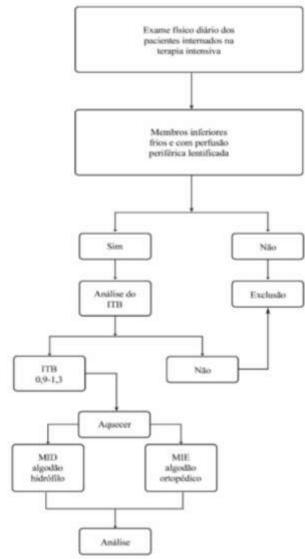
> ITB = <u>Increased ankle systolic pressure</u> Higher systolic pressure in the arm (right or left)

To illustrate, we present a flowchart of data collection (Figure 1).



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## Figure 1. Data collection flowchart. Rio de Janeiro, RJ, Brazil, 2019



Note: MIE: Lower left limb; MID: right lower limb. Source: Nascimento et al, 2019.

To measure all the values necessary for the study, the following devices were used: for Doppler, the Portable Vascular Monitor Df7001 - Medpej <sup>®</sup> (ANVISA: 80127840024) was used; for ITB adult cuff/cuff with 2 tubes for sphygmomanometer – Premium<sup>®</sup> (ANVISA: 80275310022); to check the body and limb temperature, we used the Omron<sup>®</sup> brand digital forehead thermometer (ANVISA: 80757580011), all of which were previously calibrated.

In the patients included in the study, after warming up, the temperature of the limb was measured in the plantar region, where a window was made in the region so that we could check and record the temperature in both limbs at the following times: 30 minutes, 2, 4 and 6 hours after heating. This window was opened and closed at each time of measurement so that there was no loss of heat to the medium and damaging heating.

This time interval for recording the temperature is justified, since local heating in healthy patients has a blood flow pattern that lasts 30 minutes, leading to transient vasodilation, which can last from 3 to 5 minutes, and, Nascimento RR, Bridi AC, Pereira SEM, Neves MP, Silva RCL, Franco AS subsequently, this phase of vasodilation, a plateau is reached, which can last from 25 to 30 minutes<sup>5</sup>.

Studies also state that patients in warming strategies can take up to 8 hours to reach higher core temperatures. Therefore, we chose to evaluate the temperature within 6 hours after the intervention, seeking the greatest possible reliability<sup>6</sup>.

We used the Microsoft Excel 2010<sup>®</sup> program for data tabulation and descriptive statistical analysis. For inferential analysis a free software RStudio Desktop 1.2.5033 was used. The Kolmogorov-Smirnov, Shapiro-Wilk, and Anderson Darlin statistical tests were used to verify normality, showing a non-normal sample. As a nonparametric hypothesis test, the Wilcoxon paired hypothesis test (paired).

## Results

The sample consisted of 16 patients, 62.5% male and 37.5% female.

A total of 160 measurements were taken over a period of 210 days (March to August 2019), carried out at different intervals (before heating, 30 minutes, 2 hours, 4 hours, and 6 hours after heating).

It was observed that in the period of 30 minutes to 6 hours of heating with the orthopedic and hydrophilic cotton technologies, the mean (50th percentile) of the temperature of the lower limbs remained below 360C. The lowest temperature measured was 340C and the highest 39.40C (Table 1).

When performing the analysis of heating technologies at different intervals of measurements, after the intervention (30 minutes, 2 hours, 4 hours, 6 hours), none of the technologies showed statistical significance (Table 1).

 Table 1. Analysis of temperature at the time of measurement, control and intervention. Rio de Janeiro, RJ, Brazil 2019

	AH 30 min	AO 30 min	AH 2 b	AO 2 h	АН 4 в	46	AH 6 h	A0 6 h
( <b>1</b> );	16	36	16	16	36	16	16	16
Min	34,0	34,0	34,0	34,0	34,0	34,0	34,0	34,0
Max	36,6	37,8	37,5	36,9	36,9	37,6	39,4	36,9
Percentil 25%	34,0	34,0	34,0	34,0	34,0	34,0	34,0	34,0
Percentil 50%	34,0	34,0	34,0	34,0	34,0	34,0	34,0	34,0
Percentil 75%	34,0	34,0	34,0	34,0	34,0	34,0	34,6	36,0

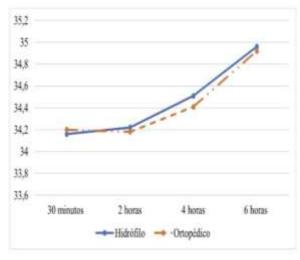
Nota: Algodão Hidrófilo (AH); Algodão Ortopédico (AO); Nimero de pacientes(n); Miximo(Max), Minimo(Min ); Minutos (min); Horas(h).

Source: Nascimento et al, 2019.



Although there is no statistical significance of the heating of both technologies in the heating interval of 30 minutes to 6 hours, it was found that, although the averages were below the considered ideal temperature (360C), the temperatures increased with the prolonged time of heating in both technologies - hydrophilic and orthopedic (Figure 2).

Figure 2. Mean heating of cotton wool and orthopedic over the time interval from 30 minutes to 6 hours of intervention. Rio de Janeiro, RJ, Brazil, 2019



Fonte: Nascimento, 2019.

When testing the hypothesis that orthopedic cotton is the most effective technology compared to cotton wool, both technologies showed no statistically significant difference (Table 2).

During the collection, we recorded the patient's body temperature before warming up and after warming up the lower limbs, which, although not part of the study Nascimento RR, Bridi AC, Pereira SEM, Neves MP, Silva RCL, Franco AS objectives, could influence body temperature. When performing the analysis, we found that warming the lower limbs can influence the increase in the patient's body temperature (Figure 3).

**Table 2.** Comparative analysis of warm-up time in the control group and inthe intervention group. Rio de Janeiro, RJ, Brazil, 2019

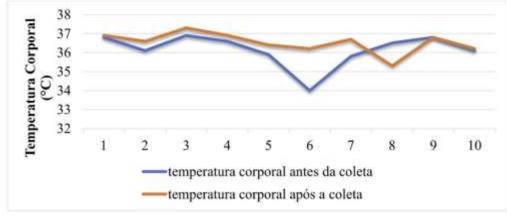
			Estatistica	p***	
Algodão	Algodão				
Hidrôfilo 30	Ortopédico 30	Wilcoxon W	0.00*	1.000	
minutos	minutos				
Algodio	Algodilo				
Hidrofilo 2	Ortopédico	Wilcovon W	1.00*	1,000	
horas	2 boras				
Algodão	Algodiio				
Hidrófilo 4	Ortopédico	Wilcoxon W	4.00*	0.789	
horas	4 horas				
Algodão	Algodilo				
Hidrofilo 6	Ortopédico	Wilcoxon W	9.004	0.787	
horas	6 horas				

Note: \*15 pares de valores foram testados \*13 pares de valores foram testados #11 pares de valores foram testados

\*\*\*#25/2000

Source: Nascimento et al, 2019.

Figure 3. Influence of lower limb heating on patients' axillary body temperature. Rio de Janeiro, RJ, Brazil, 2019



Source: Nascimento et al, 2019.

## Discussion

It was observed in this study that orthopedic cotton and hydrophilic cotton did not present a statistically significant difference in heating to guide the choice of the best technology, however, both presented an increase in local and body temperature over time. The respective temperatures started to rise with the increase of the heating time, especially in the measurement with 6 hours of heating in both technologies. This result leads us to infer that this heating technology should remain above 6 hours to achieve the effect of lower limb heating and better perfusion.



From a semiological point of view, temperatures diverge in different parts of the body, where at the extremities these variations can be more accentuated and can be influenced, for example, by the temperature of the environment. The skin temperature in the lower limbs is around 30°C, thus our results provide us with evidence that although none of the technologies have statistical significance for the exclusive recommendation of its use, the temperatures reached during the heating period demonstrate the effectiveness of heating the lower limbs with both cottons<sup>7</sup>.

Passive rewarming, when the patient is induced to hypothermia, for example, can take more than 8 hours for the patient to raise the temperature above 35°C<sup>6</sup>. Considering that cold lower limbs may have low tissue perfusion, it is important that, in addition to heating, the capillary refill time (TEC) is also assessed, which is defined as the time required for the distal capillary bed to recover its perfusion after I type applied pressure, which leads to a brief period of ischemia<sup>8</sup>.

The ECT is useful in the evaluation of patients in a state of shock, a situation that can bring about changes in the regulation of microvascular blood flow, leaving it impaired, due to changes in the balance of vasoconstrictor and vasodilator substances<sup>8</sup>.

Warming the lower limbs, in addition to offering known peripheral perfusion-related benefits, such as vasodilation and increased local perfusion, can raise the patient's body temperature, as demonstrated in this study<sup>9</sup>. This data seems to bring importance, both in the logic of intervention under some semiological finding of poor perfusion and hypothermia, as well as contributing to the perspective of comfort and relief in systemic body warming.

One of the contexts of Kolcaba's theory of comfort deals with the importance of understanding sensations, such as thermal comfort, which is a subjective and individual response to environmental and physiological conditions, where thermal heating interventions should be used to recover and maintain the individual's state of homeostasis<sup>10</sup>.

The patient's comfort and satisfactory evolution depend on the choice of assistive technologies, relevant to each nursing care situation.

In this study, the use of cotton wool and orthopedic plus bandages to warm the lower limbs and improve peripheral perfusion, even with no statistical difference when comparing the two technologies, showed evidence of local and body heating over time. In addition to demonstrating its importance in promoting thermal comfort<sup>11</sup>.

We assume as limitations of the study the unavailability of cuffs for the different biotypes of patients to perform the ABI, in addition to the impossibility of weighing hydrophilic and orthopedic cotton at the bedside at the time of data collection, which could influence the warming result. Furthermore, we found few studies referring to the theme.

# Conclusion

Lower limb warming is a routine practice of the nursing staff in Intensive Care Units. Currently, the units can have different technologies to perform this care. Given the scarcity of resources, the choice between cotton wool and orthopedic cotton leads to uncertainty as to which technology would be most effective for warming the lower limbs. Therefore, it is essential that evidence-based studies can guide the practice of the nursing team towards the best bedside choices.

Therefore, the results of this pilot study show in an incipient way that there is no difference between the two proposed technologies, suggesting that the bedside nursing staff can choose any of the technologies available in the institution (hydrophilic or orthopedic cotton) from the point of view of its effectiveness.

Furthermore, we note the importance of the time being greater than 6 hours to achieve a satisfactory warm-up.

Given the limited resources of the Unified Health System, this pilot may encourage further studies, especially in the context of Health Technology Assessment in order to support managers in choosing the best technologies, with regard to their effectiveness in addition to their cost.

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