Effectiveness of bag bath on microbial load: clinical trial
Eficácia do banho no leito descartável na carga microbiana: ensaio clínico
Eficacia del baño en cama descartable respecto de la carga microbiana: ensayo clínico

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Abstract
Objective: To assess the effectiveness of bag bath on inpatient skin microbial load.
Methods: This was a parallel, randomized clinical trial with an intervention group (bag bath) and a control group (conventional bed bath), conducted in a public hospital in São Paulo, Brazil, from November 2014 to December 2015. The participants were adult and older inpatients, bedridden and depending on the procedure. The product assessed was Bag Bath®.
Results: The microbial load decreased in the intervention group (20 patients), while it increased significantly (p < 0.001) in the control group (20 patients). The estimated efficacy of the product for bag bath was 90%, compared with 20% for the conventional bed bath.
Conclusion: The product assessed was 4.5 times more effective to decrease the inpatient skin microbial load when compared with the conventional bed bath, suggesting the need for nursing teams to re-evaluate this procedure.

Resumo
Objetivo: Avaliar a eficácia do banho no leito descartável sobre a carga microbiana da pele de pacientes hospitalizados.
Métodos: Ensaio clínico paralelo, randomizado em grupo intervenção (banho no leito descartável) e grupo controle (banho no leito convencional), realizado em Hospital Público de São Paulo, Brasil, de novembro de 2014 a dezembro de 2015. Participaram deste estudo pacientes hospitalizados, adultos e idosos, acamados e dependentes do procedimento. Bag Bath® foi o produto avaliado.
Resultados: A carga microbiana nos grupos de seguimento: intervenção (20 pacientes) reduziu, enquanto a no controle (20 pacientes) aumentou significativamente (p<0,001). Estimou-se em 90% a eficácia do produto para banho de leito descartável, comparada à de 20% do banho no leito convencional.
Conclusão: A eficácia do produto avaliado foi 4,5 vezes maior sobre a carga microbiana da pele de pacientes hospitalizados, quando comparada a do banho no leito convencional, sinalizando à Enfermagem a necessidade de revisar esse procedimento.

Resumen
Objetivo: Evaluar la eficacia del baño en cama descartable respecto de la carga microbiana en la piel de pacientes hospitalizados. Métodos: Ensayo clínico paralelo, randomizado en grupo intervención (baño en cama descartable) y grupo control (baño en cama convencional), realizado en Hospital Público de São Paulo, Brasil, de noviembre 2014 a diciembre 2015. Participaron pacientes hospitalizados, adultos y ancianos, en cama y dependientes del procedimiento. El producto evaluado fue Bag Bath®.
Resultados: La carga microbiana de los grupos en seguimiento: intervención (20 pacientes) redujo, mientras que control (20 pacientes) aumentó significativamente (p<0,001). Se estimó la eficacia del producto para baño en cama descartable en 90%, en tanto que fue del 20% en la cama convencional.
Conclusión: La eficacia del producto evaluado fue 4,5 veces mayor sobre la carga microbiana de la piel de pacientes hospitalizados, comparada con baño en cama convencional, determinando Enfermería la necesidad de revisar dicho procedimiento.

Brazilian Clinical Trial Registry (ReBEC): RBR-52pq3b.

Keywords
Baths; Cross infection; Nursing care; Personal hygiene products; Evaluation of the efficacy-effectiveness of interventions

Descritores
Ammoterapia; Infección hospitalaria; Atención de enfermería; Productos para la higiene personal; Evaluación de eficacia-efectividad de intervenciones

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**Introduction**

Bed bath in a hospital setting is an intervention by the nursing staff(1) which promotes patients’ personal hygiene and skin integrity, in addition to preventing diseases.(2) Although the conventional bed bath (CBB) has its benefits,(3) this study supposes that it contributes to spreading microorganisms in the hospital environment, considering scientific evidence produced by microbiological studies proving that there are risks in the objects used, such as bowls,(4-6) soap,(7) and water,(8) in case there is no quality control for their (re)use.

Fortunately, those objects can be substituted by some specially developed and marketed products, such as bag baths (BBs), described by their manufacturers as supplies that contribute to preventing cross-infection and promoting continued patient skin care. However, these products still need to be assessed,(4) given the scarcity of research about their effectiveness on the microbial load on the skin of patients who depend on bed baths.(5)

Considering: (a) the responsibility of the hospital and nurses regarding patient safety against the presumed risk of hospital-acquired infection (HAI), microbiological scientific evidence, and the possibility that objects used for CBBs can be fomites; and (b) the scarcity of scientific evidence on the effectiveness of such marketed products as BBs on inpatient microbial load, we ask: does using BBs instead of CBBs reduce inpatient skin microbial load?

The microbial load on the skin of bedridden inpatients is presumed to be smaller when they receive only BBs than when they receive CBBs; therefore, BBs are considered effective in preventing and reducing skin colonization in inpatients that depend on bed baths.

This study aims to assess the effectiveness of a BB product on these patients’ skin microbial load.

We aim to produce scientific evidence to support nurses’ and hospital administrators’ decisions when choosing the safest option for inpatient bed baths, as well as to causing the CBB procedure to be re-evaluated.

**Methods**

This is a parallel, randomized clinical trial, approved by the Research Ethics Committee (opinion no. 712,386), Brazilian Clinical Trial Registry (ReBEC) number RBR-52pq3b, conducted in the stroke unit (UAVC in the Portuguese acronym) of a public hospital in the state of São Paulo, Brazil, from November 2014 to December 2015. The participants were adult and older inpatients, bedridden and depending on the nursing intervention bed bath.

The UAVC has 10 beds, with mean monthly occupancy and hospitalization rates of 70% and 25.9% in the studied period, respectively.

The sample consisted of 55 patients randomly divided into two groups: 28 in the control group and 27 in the intervention group, as shown in Figure 1. Calculations considered a margin of error of 10% and a 90% confidence interval(9) for the study population of 363 patients admitted to the UAVC in the studied period, 25% of them dependent on bed bath.

Inclusion criteria were: patients aged ≥ 18 years, hospitalized up to 48 hours before, with impaired physical mobility, bedridden at admission, and classified as highly dependent on nursing (21-26 points), semi-intensive care (27-31 points) or intensive care (> 31 points), according to Fugulin et al’s Grading of Care Complexity (GCAC) scale;(10) without any prior use of antimicrobials when the monitoring began; with preserved skin integrity, and no skin and soft tissue infection (bullous or infectious disease, cellulitis, erysipelas, abscess or eczema) or pressure ulcers, venous ulcers, infectious or neoplastic injuries; who accepted to participate, with an informed consent form signed by the patients or, in case they were not able to sign it, their legal representative.

To allocate participants into groups, 40 cardboard cards were made, 20 of them identified as group A (control) and the other 20 as group B (intervention). All cards were packed in manila envelopes for someone other than the researcher to draw the patients who fulfilled the inclusion criteria. The drawn card was put up above the patient’s bed, showing the nursing professionals which procedure to be used.
be performed exclusively for five consecutive days. In case the patient came to be excluded from the study, the researcher made a new card with the same procedure and put it in the envelope so it could be drawn again in order to replace that patient.

After allocating patients into groups, the exclusive protocols for each group were followed for five consecutive days. Participants from the control group took CBMs, while the intervention group took BBs (Bag Bath®, US patent 5702992), according to the standard operating procedures (SOP) in annex 1.

Bag Bath® is a package containing eight soft wipes (nonwoven) impregnated with vitamin E-enriched moisturizer, nonionic surfactants, deionized water, and preservatives (biguanide), free of chlorine and other minerals to preserve the pH of the skin acid mantle. A biguanide antiseptic impregnates the fibers of these wipes as a preservative, inhibiting the growth of bacteria, fungi, or yeast inside the package. Resolution RDC no. 29 of the Brazilian National Health Surveillance Agency (ANVISA), of June 1st, 2012, approves the Mercosur technical regulation on the list of permitted substances with preservative action for toiletries, cosmetics and perfumes, including the use of biguanides in concentrations equal to or less than 0.3%.

This same resolution defines preservatives as substances that, when added as ingredients to toiletries, are meant to inhibit the growth of microorganisms during manufacturing and storage, or to protect the product against contamination during use.

In order to ensure that participants received the interventions according to the SOP (Appendix 1), the practical nurses from the UAVC were trained in giving both CBMs and BBs, according to the draw. The unit nurse was also trained to ensure those protocols were being followed in the absence of the researcher, using the SOP as a checklist.

Participant characterization variables were: age (adult/older adult); sex (female/male); Fugulin et al.’s GCAC score (intensive > 31 points, semi-intensive = 27 to 31 points, high dependency = 21 to 26 points); use of antimicrobials after monitoring began (yes/no); skin integrity complications during monitoring, such as ulcers, dermatitis, and others (yes/no).

The outcome variable was the evolution of participant skin microbial load during monitoring of the interventions. To assess this, samples for microbiological analysis were collected from the patients in the control and intervention groups at two times: before the first bath and after the fifth one. A sterile swab with activated charcoal as a transport medium was used for collection. The right lower limb popliteal region was chosen for the collection, covered with a nonwoven sterile fenestrated surgical drape measuring approximately 20 cm² with a 1 cm² fenestration. The popliteal fossa was chosen because it is one of the folds of highest humidity and temperature in the human body, which favors the growth of microorganisms such as gram-negative bacilli, Corynebacterium spp., and S. aureus. Furthermore, it is distant from probes, catheters, and excretory orifices.

To make sample collection easier, the swab was moistened with sterile 0.9% saline, favoring bacterial adherence to the swab.

The material collected was sent to an accredited microbiology laboratory, where microorganisms were seeded in a semiquantitative manner, in quarters, on blood agar and MacConkey agar plates. Gram-positive and gram-negative bacteria, as well as yeast, were investigated. Following seeding on culture media, the swab was introduced into a 5 ml flask containing brain heart infusion (BHI) broth. The plates and flasks were placed in an incubator for 18 to 24 hours at 35 ± 1°C. Subsequently, plates were examined, and those showing growth were considered positive. When there was no plate growth, but the flask with BHI became turbid, the broth was applied on the plates for further investigation. In case of growth, the sample was classified semi-quantitatively, ranging from one to four crosses: (+/++++) = extremely rare, (++/+++++) = rare, (+++/++++++) = moderate, and (+++++/++++++) = numerous colonies. Afterwards, the antibiotic sensitivity of the isolated microorganism was tested, using an automated microbiology device (Vitek 2). Results were considered negative after 24 hours without any growth.

To evaluate the evolution of the microbial load in response to both interventions (CBB and BB),
the results of the cultures collected from each participant before the first and after the fifth bath were analyzed. This evolution was classified as: turned negative; remained negative; maintained the initial microbial load; and colonized. Colonization was considered the presence and growth of microorganisms in the second skin culture different from those found in the first sample.

The intervention was considered effective when it: turned negative, remained negative or maintained the initial microbial load. It was considered microbiologically ineffective in case of colonization.

The study was not double-blind, as the researchers and people responsible for the interventions knew which participants received each intervention. However, the results of the cultures were only known by researchers and other participants involved in the study after the data collection was over. The researchers did not take part in the microbiological tests.

In case the protocols were not followed during monitoring, participants were excluded from the sample and replaced, in accordance with the inclusion criteria, until there were 20 patients in each group: control and intervention (Figure 1).

Fifteen patients were excluded in that stage, eight from the control group and seven from the intervention group, due to modification of the SOP for CBB and BB, provided in Annex 1, or interruption of the baths due to unit transfer, hospital discharge, or death of the patient, as shown in figure 1.

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The study data were entered to an Excel spreadsheet, the variables were analyzed descriptively using SPSS 12.0 software, and subjected to tests specific to sex (Fisher’s exact test), age (t-test), microbial loads in the first and second skin cultures, and care complexity (chi-square). Multiple logistic regressions were also used to evaluate the relationship between type of bath and positive results in the second culture, adjusting for use of antibiotics.

The bowls and jugs used for CBB at the study local are made of stainless steel, cleaned using water and neutral-pH soap, then dried and disinfected using 70% ethanol.

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**Figure 1.** Flowchart of the procedures for inclusion, allocation, monitoring, and analysis of the study sample
This study was funded mainly by the São Paulo Research Foundation (FAPESP), Process no. 2014/25099-2. The company Commercial Nacional de Produtos Hospitalares Ltda. donated 150 Bag Bath® kits. Neither institution interfered in the conduction of the study at any moment.

Procedures for inclusion, allocation, monitoring and analysis of the study sample are shown in figure 1.

**Results**

The analyses showed homogeneity in the composition of the control (CBB) and intervention (BB) groups, since there were no statistically significant differences for the variables: age (p = 0.267); patient level of dependence regarding the required type of care (p = 435); sex (p = 1.000); and microbial load before the first bath (p = 1.000) (Table 1), with a prevalence of resident flora microorganisms (S. epidermidis, coagulase-negative staphylococci, S. haemolyticus, S. capitis, S. warneri), except for S. aureus, identified in one of the samples.

Women were predominant in the control (70%) and intervention (65%) groups, as well as older adults (80% and 100%, respectively). All participants remained highly dependent on nursing care from selection to the end of monitoring, with semi-intensive and intensive care complexity (Table 1), bedridden and with an indication for bed baths only.

Comparing the results from the first and second skin cultures (Chart 1), we found a statistically significant reduction in the microbial load in the intervention group (BB), while an increase was observed in the control group (p < 0.001) (CBB) (Table 1).

There was a favorable outcome regarding the efficacy of the BB product on participants’ skin microbial load: 60% turned negative, 25% remained negative, 5% maintained the initial microbial load and only 10% showed colonization. As for the control group, whose participants received CBBs, 80% showed colonization and only 20% turned negative (Chart 1).

**Table 1.** Number and percentage distribution of variables characterizing the participants of the control (conventional bed bath – CBB) and intervention (bag bath – BB) groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Group</th>
<th>Intervention Group</th>
<th>p-value</th>
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<tbody>
<tr>
<td></td>
<td>CBB (n = 20) n(%)</td>
<td>BB (n = 20) n(%)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>14(70)</td>
<td>13(65)</td>
<td>1.000(†)</td>
</tr>
<tr>
<td>Male</td>
<td>6(30)</td>
<td>7(35)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td>0.267(†)</td>
</tr>
<tr>
<td>Adults (18 to 59 years)</td>
<td>4(20)</td>
<td>0(0)</td>
<td></td>
</tr>
<tr>
<td>Older adults (≥ 60 years)</td>
<td>16(80)</td>
<td>20(100)</td>
<td></td>
</tr>
<tr>
<td>Microbial load before the first bath (result of the 1st culture).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Culture (+)</td>
<td>15(75)</td>
<td>14(70)</td>
<td></td>
</tr>
<tr>
<td>Culture (-)</td>
<td>5(25)</td>
<td>6(30)</td>
<td></td>
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<tr>
<td>Microbial load after the fifth bath.</td>
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<td></td>
<td></td>
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<tr>
<td>Culture (+)</td>
<td>16(80)</td>
<td>3(15)</td>
<td>&lt; 0.001(‡)</td>
</tr>
<tr>
<td>Culture (-)</td>
<td>4(20)</td>
<td>17(85)</td>
<td></td>
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<tr>
<td>Use of antibiotics during monitoring</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>10(50)</td>
<td>13(65)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>10(50)</td>
<td>7(35)</td>
<td></td>
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<tr>
<td>Results of the 2nd culture, with use of antibiotics during monitoring.</td>
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<td></td>
<td></td>
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<tr>
<td>Culture (+)</td>
<td>8(80)</td>
<td>2(15)</td>
<td></td>
</tr>
<tr>
<td>Culture (-)</td>
<td>2(20)</td>
<td>11(85)</td>
<td></td>
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<tr>
<td>Results of the 2nd culture, without use of antibiotics during monitoring.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Culture (+)</td>
<td>8(80)</td>
<td>1(14)</td>
<td></td>
</tr>
<tr>
<td>Culture (-)</td>
<td>2(20)</td>
<td>6(86)</td>
<td></td>
</tr>
<tr>
<td>GCAC(§); CBB(</td>
<td></td>
<td>) (N=100); BB(¶) (100)</td>
<td></td>
</tr>
<tr>
<td>High dependency</td>
<td>78(78)</td>
<td>51(51)</td>
<td>0.435(§)</td>
</tr>
<tr>
<td>Semi-intensive</td>
<td>19(10)</td>
<td>40(40)</td>
<td></td>
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<tr>
<td>Intensive</td>
<td>3(3)</td>
<td>9(9)</td>
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<tr>
<th>Footnotes</th>
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<td>(†) Fisher’s exact test; (‡) Chi-square test; (§) GCAC care complexity score; (</td>
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</table>
Thus, we estimated a 90% efficacy of BB on inpatient skin microbial load when compared with the control group (CBB), which showed low effectiveness (20%) since 80% of its participants were colonized.

To rule out bias in the interpretation of data, multiple logistic regressions were performed to evaluate the relationship between type of bath and positive results in the second culture, adjusting for the use of antibiotics. This analysis showed that there was no statistically significant association between the participants’ use of antibiotics (p = 0.966) and negative results from the cultures (p < 0.001). The effect of BB was independent of the use of antibiotics during the monitoring of the groups.

**Discussion**

BB (*Bag Bath*) had a 90% estimated efficacy on skin microbial load, while CBB’s was 20%, colonizing 80% of the participants.

Among the colonization cases, we isolated two instances of methicillin-resistant *Staphylococcus aureus* (MRSA), multidrug-resistant bacteria present in the hospital environment and difficult to treat due to their antimicrobial resistance profile.\(^{(14)}\)

Thus, this study proves the benefit of the product in the control of inpatient skin microbial load, and it is presumed to be a barrier to hospital microbial spread.

On the other hand, the low effectiveness of CBBs in preventing the spread of microorganisms alerts the nursing field to the need for investment in research to support re-evaluating this procedure, regarding both its execution and the qualitative and quantitative safety of the objects used, so that they do not act as fomites.

These principles guided American nurse Susan M. Skewes and collaborators, responsible for the invention and patenting of Bag Bath in 1994, after eight years of study and enhancements. The product was designed to abolish the use of basins, water, soap, bath gloves, and towels, in order to prevent cross-contamination between body parts and preserve patient skin integrity.\(^{(11)}\)

Skin integrity is preserved because bag bath eliminates the use of soap, especially bar soap, with an alkaline pH (between 10 and 12),\(^{(11)}\) which modifies skin pH, which is slightly acid (between 3 and 5) due in part to the secretion of fatty acids and lactic acid by sebaceous glands. These substances contribute to the high resistance of the skin and mucous tunics to microbial invasion.\(^{(15,16)}\)
We infer that the low effectiveness of CBB for preventing the spread of microorganisms is caused by the limited use of three washcloths and one towel for the whole procedure, as well as the quality of reprocessing and storage of basins, buckets, jugs, and bedpans.

It should be noted that the SOP for the CBB (Annex 1) evaluated in this study was based on references from the literature that are considered basic in nursing professional training. When the SOP was proposed, the nurses at the institution where this study took place noted that some books failed to even estimate the number of washcloths needed. These professionals thought it was prudent to use three washcloths, the first one to wash the body segments and the genitalia, the second one to rinse them, and the third one to wash the back, glutes and the perianal area. This causes the same rinsing washcloth to be used in the whole bed bath procedure.

Another relevant factor that might have contributed to the low efficacy of the CBB evaluated in this study is related to the objects used, such as basins, buckets, jugs, bedpans, water, soap, and fabric items (washcloths and towel), because they might have acted as fomites.

This inference comes from scientific evidence produced by research analyzing microbiologically the objects employed in the procedure, such as bowls, soap, and water. Our study was prompted by these evidence, as contextualized in the introduction section, with a special concern regarding the lack of care for the quality of these items when (re)using them.

In Brazil, water basins, buckets, jugs and bedpans, are made from stainless steel and reprocessed, while in hospitals from the United States and Canada, the basins are meant to be used individually.

Two studies conducted in hospitals from these countries showed bacterial growth in bed bath washbasins for individual use. When they were not cleaned, not dried outdoors, and were used in at least two baths, the percentage was 98%, reduced to 62.2% when cleaned with soap and water.

It is known that a large portion of Brazilian hospitals classifies basins, buckets, jugs, and bedpans as non-critical products, according to an ANVISA Resolution from March 15, 2012. This resolution considers health products as non-critical when they do not come into contact with the patient or only come into contact with intact skin. It recommends that those products undergo at least the process of cleaning.

However, in practice and in the institution where this study took place, these objects are normally used for patients of high complexity of care, who commonly present wounds and invasive devices such as vascular catheters and others, without reclassifying the objects as semi critical, as recommended by the aforementioned ANVISA resolution.

This resolution considers materials semi critical when they come into contact with non-intact skin or intact but colonized mucous membranes, requiring high-level disinfection, namely, a physical or chemical process that destroys most microorganisms of semi critical items, including mycobacteria and fungi, except for a large number of bacterial spores.

In Brazilian hospital health care practice, there is a noticeable lack of care in choosing the decontamination method according to the infection risk potential of products used in bedridden patient hygiene and as aids to excretion (non-critical, semi critical, or critical). In reality, water basins, buckets, jugs, bedpans, and urinals are indiscriminately subjected to low-level disinfection. This disinfection is performed by manually cleaning the object with neutral-pH soap and, after drying, applying 70% ethanol on the whole product, even for items with designs that hinder the applicability of the method, such as bedpans and urinals.

The literature recommends, for reprocessing semi critical items, high-level disinfection, which can be achieved by automated means that guarantee process uniformity and prevent the contact of the user with chemicals, e.g., thermal washer-disinfectors.

However, this procedure by itself is not sufficient to ensure a safe CBB, since other components of its execution can become fomites, such as water,
soap, and fabric items (towels, bath gloves/washcloths, among others).

The water from the distribution system can be contaminated by microorganisms introduced through taps or by leaks in the system. A study found that, after these organisms enter the pipeline, they can develop antibiotic- and disinfectant-resistant biofilms. Biofilm is the adherence of microorganisms to a surface, with production of extracellular polymeric substances (EPS), strengthening the adherence to surfaces and cells and forming a matrix that hinders the penetration of antimicrobials into the biofilm cells. Formed near the water point-of-use, the biofilm serves as a microbial repository, constantly sending viable microbes to the water flow. These microorganisms can colonize patients, surfaces, healthcare professionals, medical devices and instruments, utensils and sponges, dialysis machines, showers, taps, etc.

The fabric items used in bed baths (bath gloves, washcloths, and towels) or other components of the hospital linen can also become fomites, as shown by a study that detected strains of methicillin-resistant Staphylococcus aureus (MRSA), viable for six to nine weeks, in blankets.

Gram-negative bacterial growth was found even in residues from bar soap holders. Thus, we can assume the same happens with other items used in bed baths, such as buckets, bedpans, trolleys, combs, and bottles of shampoo, moisturizer, and deodorant, i.e., all items that are not of individual use or not disinfected or sterilized effectively, favoring cross-contamination and the transmission of microorganisms.

BB eliminates the need for using many of these items that contribute to intra- and inter-patient cross-contamination, such as water basins, buckets, water, soap, bath gloves, moisturizers, and even towels, since the BB solution naturally evaporates from skin in 30 to 45 seconds, rendering it hydrated and protected without any need for friction or drying.

During an extensive literature review, we found a study comparing the efficacy of CBB and BB (Comfort Bath®) on microbial load, conducted in New York with 40 patients from three intensive care units. However, it found no statistically significant difference between the two types of bath. We infer that this result is not consistent with the outcome of the present study because it assessed the immediate impact of the bath, while we compared the results of microbiological samples before the first and after the fifth bath.

Furthermore, a recently published systematic review concluded there is no research showing evidence of superior quality between BB and CBB, recommending future research on BB, including attention to costs, hygiene, and results related to the interested parties, such as the experiences and perceptions of patients, their families, and the nursing staff.

Thus, this study can be considered a national and international innovation for providing scientific evidence for hospital nurses and administrators to make safe decisions on the adoption of BBs, as well as for flagging the need for nursing professionals to conduct studies to re-evaluate the CBB procedure propagated through nursing textbooks, and finally as a method of evaluating the effectiveness of other BB-like products in the market.

We consider the small sample size one of the limitations of this study, as well as the difficulty in estimating costs and assessing the ability of BB to prevent microorganism spread and to contribute to the control and prevention of HAI.

Finally, this investigation raises the need to conduct further studies, including: (a) clinical trials comparing the efficacy of BB with CBB, but also controlling other variables that were not considered in this study and that supposedly contribute to the spread of microorganisms (water, basins, jugs, fabric items, soap); (b) evaluation of the impact of disposable bed-bath technology on HAI rates and, consequently, on costs, since unknown rates hinder cost estimation; (c) assessment of the effectiveness of disinfection and storage procedures for water basins and other stainless steel products (re)used in hygiene and excretion care; (d) comparison of the effectiveness of other BB products available on the market; (e)
assessment of the benefits of the product for skin integrity.

**Conclusion**

BB had an estimated 90% effectiveness in reducing inpatient skin microbial load when compared with the control group. CBB showed 20% effectiveness, since 80% of the participants were colonized. The 4.5-times higher effectiveness of BB in comparison with CBB in preventing the spread of microorganisms shows the nursing field that there is a need for investment in research to support re-evaluating this procedure regarding its execution, as well as the qualitative and quantitative safety of the objects used, so that they do not act as fomites.

**Acknowledgments**

We thank the São Paulo Research Foundation (FAPESP), Process no. 2014/25099-2, for the main funding of this research, and the company Comercial Nacional de Produtos Hospitalares Ltda. for donating 150 disposable bath bags (Bath Bag).

**Collaborations**

Paulela DC, Bocchi SCM, Mondelli AL, Martin LC, and Sobrinho AR contributed in the development of the project, as well as in all stages of execution, especially for data collection and analysis, formatting of the final report, and approval of the final version of the article to be published.

**References**

Appendix 1. Standard Operating Procedures (SOP) for conventional bed bath (CBB) and for the use of bag bath (BB) adopted at the institution where the study was conducted

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<thead>
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<th>CBB (Control group)</th>
<th>BB (Intervention group)</th>
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<tbody>
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<td>Materials: latex gloves, 1 disposable gown, disposable adult diaper, 1 bath trolley, 1 bucket, 1 water basin, 1 bar soap, 1 towel, 3 non-sterile washcloths, 1 bottle of body moisturizer, 1 patient gown, 1 pillowcase, 1 fitted sheet and 2 flat sheets for changing the bed, folding screen.</td>
<td>Materials: latex gloves, 1 disposable gown, disposable adult diaper, 1 bath trolley, 1 bag bath, 1 patient gown, 1 pillowcase, 1 fitted sheet and 2 flat sheets for changing the bed, folding screen, hamper.</td>
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<td>Technique: sanitize your hands; prepare the materials, placing them on the trolley; pull the trolley close to the bed; check patient ID; inform him/her about the procedure; close doors and windows; place folding screen and hamper next to the bed; sanitize your hands; fill the bucket with lukewarm water, distributing it in the basin on the trolley; sanitize your hands; put on the disposable gown and gloves; untuck the bedsheets; remove patient’s gown and protect him/her with a sheet; clean his/her eyes from the inner corner to the outer corner using a gauze washcloth moistened with lukewarm water; wash, rinse and dry his/her face, ears and neck; wash, rinse and dry his/her distal upper limb and axilla; wash, rinse and dry his/her proximal upper limb and axilla; wash, rinse and dry his/her distal lower limb; wash, rinse and dry his/her proximal lower limb; turn the patient to a lateral position, insert the bedpan and reposition the patient in the supine position; wash, rinse and dry the genital area; turn the patient to lateral position and remove the bedpan; keep the patient in lateral decubitus, buttocks and perianal area; moisturize the dorsal area with the moisturizer; push the damp linen to the middle of the bed and dry the mattress; change your gloves; proceed to making the bed, with the patient in lateral decubitus; turn the patient on the ready side of the bed; remove the dirty laundry and put it in the hamper; finish making the bed; put on the disposable diaper; moisten the rest of the patient’s skin; put on his/her gown; position the patient on the bed properly; send stainless steel utensils to the sluice room; remove your gloves; sanitize your hands; keep the unit in order; proceed to making nursing notes on the electronic patient record.</td>
<td>Technique: sanitize your hands; prepare the trolley with the materials; heat the bag bath in a microwave oven for 30 seconds; check patient ID; inform him/her about the procedure; close doors and windows; place folding screen and hamper next to the bed; sanitize your hands; put on the disposable gown and gloves; untuck bedsheets; remove patient’s gown and protect him/her with a sheet; clean his/her eyes from the inner corner to the outer corner using a gauze washcloth moistened with lukewarm water; open the bag bath package; remove the first washcloth and clean his/her face, ears, neck, thorax and abdomen; with the second washcloth, clean the proximal upper limb and axilla; use the third washcloth to clean the proximal lower limb and axilla; the fourth washcloth should be used to clean the distal lower limb; clean the proximal lower limb with the fifth washcloth; the genital area should be cleaned with the sixth washcloth; turn the patient to lateral position and clean the dorsal region with the seventh washcloth; the eighth washcloth should be used for perianal and gluteal hygiene; push the linen to the middle of the bed; change your gloves; proceed to making the bed, with the patient in lateral decubitus; turn the patient on the ready side of the bed; remove the dirty laundry and put it in the hamper; finish making the bed; put on the disposable diaper; put on his/her gown; position the patient on the bed properly; remove your gloves; sanitize your hands; keep the unit in order; proceed to making nursing notes on the electronic patient record.</td>
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