Eliminating Bacterial Colonization of Infant Bathtubs Through the Use of Disposable Liners and Disinfecting Wipes

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Abstract

Background: Patient wash basins are frequently contaminated with pathologic organisms that may lead to hospital acquired infections. This study assessed the TurtleTub™ infant bathtub with the TurtleTub™ disposable liner to determine if the system could reduce the risk of patient cross-contamination.

Methods: The study was conducted in a lab setting where a worst-case contamination situation could be achieved. Three tubs (study group) were grossly contaminated with *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella aeruginosa* and *Escherichia coli*. Two additional tubs served as positive and negative controls. Thirty minutes after contamination all the tubs except the positive control had their liners discarded, were wiped out with a disinfecting cloth for 30 seconds and were allowed to dry for 3 minutes. All devices were then extracted to determine bacterial concentrations.

Results: The positive control tub cultures grew 1.66×10^9 organisms. The negative control and all three study tubs grew no contaminating organisms.

Conclusion: Despite gross contamination, simply removing the TurtleTub disposable liner followed by brief disinfection and drying led to complete elimination of bathtub contamination. This data suggests that the TurtleTub disposable liner and simple disinfection procedures can markedly reduce the risk of patient cross-contamination with the TurtleTub.

Keywords: Bath Basin, disposable liner, Cross contamination, hospital acquired infection, infant bathtub

Introduction

Infant bathing in the hospital is a parent friendly activity with the emotional impact of being the infant's "first bath." In the NICU, an infant bath can be one of the few typical parenting activities for the family. Tub bathing techniques such as immersion bathing and swaddled immersion bathing decrease temperature loss and decrease motor stress for infants during bathing: however, a bath basin can be a potential source for nosocomial infections. This study was designed to assess whether the TurtleTub cleaning and disinfecting system, which includes its own disposable liner, is sufficient to avoid the risk of cross- contamination and HAIs with this device.

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Background

Healthcare-Associated Infections (HAI) are defined as infections that patients acquire during the course of receiving healthcare treatments for other conditions.[1] HAIs are a major problem in US hospitals. They are estimated to occur in 5 to 10% of admitted patients, are the most common complication seen in hospitalized patients and cost billions of dollars a year to treat.[2-4] The result of these potentially preventable infections is higher resource consumption as well as increased morbidity and mortality.[4] In fact it is estimated that deaths from HAIs are in the top 10 causes of hospital mortality.[4]

In the early 2000's the National Quality Forum and Centers for Medicare & Medicaid Services (CMS) introduced patient care guidelines designed to reduce patient harm from preventable errors including some HAIs.[5] CMS refers to these errors as "never events" because these events are preventable if basic evidenced-based guidelines are followed. However, CMS is also aware that evidence based guidelines provide insufficient motivation for hospitals to introduce meaningful change. Therefor they have introduced a more motivating item: Money. Substantial financial penalties are incurred by the institution should a "never event" occur, including denying payment for portions of the hospital stay.[6,7] Some private insurers, such as United Health Care, have adopted similar non-payment criteria.

A potential source of HAI is the bath basin. Conventional bath basins are known to harbor human pathogens and are potential sources of nosocomial infections as shown in two prior studies.[8,9] Johnson et al cultured ninety bath basins in 3 separate hospitals on a single predefined date. They found 98% of the basins were contaminated with bacteria, including enterococci, gram negative bacteria, staph aureus (including methicillin resistant Staph Aureus - MRSA), Vancomycin resistant enterococci (VRE), Pseudomonas aeruginosa and Escherichia Coli (E coli). These authors also noted that some of the human pathogens found in the bath basins were not present on the patient on admission (MRSA and VRE) but were later found in surgical wounds of the patients, suggesting the basin may have been the fomite that led to the patients' infections. These wound infections are often considered "never events" by CMS, and their presence could result in denial of payment for portions of the hospital stay. A few years later, Marchaim and colleagues revisited the issue, culturing 1103 bath basins from 88 hospitals in the USA

and Canada. They looked only for serious pathogens, such as MRSA, VRE, E coli, and Pseudomonas and found that 62% of all basins were contaminated with these serious pathogens. Both authors conclude that current conventional bath basins are used improperly to store various materials in the patients' rooms (such as items used for incontinence episodes, emesis and indwelling catheter care), that they are cleaned, disinfected and stored improperly, and that they are reservoirs for transmission of pathogenic bacteria and a potential cause of serious HAIs. These authors suggest that greater awareness of this issue is necessary and recommend adoption of more evidence based guidelines for bath basin cleaning and storage to deal with this problem.

The current CDC recommended evidence based guidelines for bath basin cleaning and disinfection are based on the "Spaulding classification."[10] In these guidelines, devices are divided into three categories based on their infectious risk to the patient: Critical, Semi-critical and Noncritical. Bath basins and infant bathtubs are considered noncritical because they primarily come into contact with intact skin. While noncritical items pose a low risk of HAI, they still need to be treated as potential sources of HAI because at times they may contact semi-critical areas such as non-intact skin (diaper rash, abrasions, etc.), surgical wounds or mucous membranes. Therefore, they require appropriate cleaning, disinfection and storage to reduce the possibility of introducing a nosocomial infection. Failure to follow these simple steps should be avoided.[8,9]

The literature makes it clear that bath basins are often potential sources of nosocomial infections due to improper cleaning and storage. This study was designed to assess whether an infant bathing system with its disposable bath liner and the recommended cleaning process, was adequate to overcome the limitations of traditional bath basins. The study was conducted in a lab setting where it was possible to create a worst-case contamination situation with highly pathogenic microorganisms. The study goal was to determine if the cleaning and disinfecting Instructions-For-Use (IFU) were sufficient to avoid the risk of cross-contamination and HAIs with this device.

Methods

The FDA requires all critical product disinfection procedures to be validated prior to sale of a device. Microchem Laboratory, Round Rock Texas, is an approved laboratory that conducts disinfection validation studies which comply with the FDA guidelines for medical device reuse. Given Microchem Laboratory's expertise and lack of conflicts of interests, they were commissioned to develop a validated study design and conduct the study outlined here. All data presented is from their lab testing and was not influenced by the manufacturer.

Study procedure: See Table 1 for overview of the procedure

Creation of the solution containing infectious contaminants: *Staphylococcus aureus* ATCC 6538, *Pseudomonas aeruginosa* ATCC 15422, *Klebsiella aeruginosa* ATCC 4352, and *Escherichia coli* ATCC 11229 cultures were initiated in Tryptic Soy Broth (TSB) and allowed to incubate at 36±1°C overnight before use in testing. The test microorganisms were pooled into an inoculum solution with an estimated concentration greater than 1×10^9 (1 billion) colony forming units per ml (CFU/ml). See table 2 for the micro-organism concentrations determined at the start of the study procedure.

Device sterilization and preparation: Infant bathtubs and disposable liners (TurtleTub, Catapult Products LLC, Salt Lake City Utah, USA) were disinfected with alcohol spray and allowed to rest under UV light for approximately 15 minutes per side before use in testing. The liners were then aseptically put onto the tub in a manner simulating use prior to the testing. Five bathtubs and liners were prepared in this fashion—three test devices, one positive control and one negative control.

Device contamination procedure: The assembled bathtubs and liners were inoculated with 1.5 milliliters (ml) of the infectious solution. The solution was then spread across the bathtub and rubbed into the liner using a sterile gloved fingertip. The area of the seat, head and indicator strip were the focus of this rubbing. The device and its contaminated liner were then allowed to dry for 30 minutes. After drying, the infant bathtub cleaning instructions for use (FDA/Spaudling compliant) were followed: The liner was removed and discarded, the bathtub was wiped for 30 seconds using a disposable wipe (PDI Super Sani-cloth, PDI HealthCare, Woodcliff Lake, NJ, USA) and the bathtubs were allowed to dry for approximately 3 minutes.

Extraction of contaminants from the test devices: (Extraction is a technical microbiology lab term that refers to the collection of any microorganism contaminants in a sample in an effort to determine the intensity or concentration of contaminants present.) After the tubs were dried, bacterial contaminants were extracted using the following method: 100 ml of Letheen broth was swabbed onto the surface of the tub in four areas using 2 inch by 3 inch swatches of the brush. The fluid was then collected, vortexed and diluted as needed back to 100 ml for culturing. These dilutions were plated onto agar plates designed to enhance growth of each of the four contaminants to determine the amount of contamination present.

Extraction of contaminants from the positive control device: The positive control device differed only in that the liner was not removed, no disinfection wipe was used, and it was extracted 4 times rather than a single time in order to plate each microorganism concentration individually for comparison to the test devices.

Extraction of contaminants from the negative control device: The negative control device differed only in that the liner was never contaminated with the infectious solution. Otherwise the procedure was identical to the test devices.

Calculation of the extent of contamination: The percentage of contamination and the $\log_{10}$ reductions of contamination were calculated based on the number of surviving microorganisms recovered from the extraction of each device compared to the positive control device.

Criteria used for defensibility of cleaning: The Association for the Advancement of Medical instrument technical information report 2020 (AAMI tir12:2020) criteria are an industry standard used by the FDA to validate cleaning and storage of re-usable medical devices. The following criteria are required to be met to scientifically defend the cleaning process:

- The average number of bacteria recovered from the positive control sample must exceed 1×10^6 (1 million) CFU.
- The efficacy of the extraction procedure must be ≥ 70%
- The positive control must demonstrate growth of the

appropriate test microorganisms
- The negative control must demonstrate no growth.
- In order to pass the disinfection test, the test devices must demonstrate a ≥ 6 $\log_{10}$ reduction of four vegetative microorganisms when compared to the positive control for that organism.

Table 1. Study Procedure overview

Culture Growth Media	Tryptic Soy Broth
Inoculum Supplement	5% Fetal Bovine Serum
Test Surface	Liner of infant bath basin
Inoculation Technique	Micropipette
Contact Timed	30 Seconds
Recovery Fluid	Letheen Broth
Extraction Technique	4 swatches, 2" x 3"
Culture Growth Time	19 hours, 44 minutes
Test Device	Infant bath basin, Liner Inoculated
Inoculation Area	Base of Seat, Indicator Strip, Head Area
Inoculum Dry Time	30 minutes–36 minutes
Contact Conditions	Ambient
Recovery Volume	100mL

Results

Tables 2, 3 and 4 validate the reliability of the test design and its compliance with regulatory guidelines. Table 2 demonstrates the test culture concentrations of each microorganism showing that all were in excess of 1 billion CFU/ml with the exception of *S. aureus* which reached a concentration just over 400 million CFU/ml.

Table 2. Test Culture Concentrations

Test Microorganism	CFU/ml
S. aureus ATCC 6538	4.05E+08
K. pneumoniae ATCC 4352	1.67E+09
P. aeruginosa ATCC 15442	1.68E+09
E. coli ATCC 11229	2.22E+09
Pooled Inoculum	1.66E+09

Table 3 confirms the validity of the positive control for comparison as it demonstrates a nearly 98% recovery efficiency of the extraction (over 70% is the required efficiency).

Table 3. Extraction Efficiency of Positive Device Control

Positive Sample ID	CFU/Surface	Recovery Efficiency
Positive Device Control Extraction 1	1.10E+09	97.81%
Positive Device Control Extraction 2	1.72E+07	
Positive Device Control Extraction 3	5.45E+06	
Positive Device Control Extraction 4	2.02E+06	

Table 4 shows that the control solutions and organism cultures all remained intact and uncontaminated so any results from the device cultures shown in Table 6 are be reliable.

Table 5 is the actual results of test device culturing. The negative control showed no growth (limit of accuracy to less than 100 CFU – 1×10^2). The positive control was grossly contaminated with over 1 billion CFU on the surface (1.1×10^9). The three test device bathtubs also showed no growth (limit of accuracy to less than 100 CFU – 1×10^2) with a $\log_{10}$ reduction of microorganism greater than 1×10^9. The combination of these results comply with industry standards and confirm that the bathtub cleaning instructions result in a safe, reusable device that is not contaminated with any detectable bacteria despite gross exposure to billions of microorganisms.

Table 4. Incubation Time and Sterility Observations

Sample ID	Incubation Conditions	Control Result
Letheen Broth Sterility	43 hours, 20 minutes at 36°C	Sterile
PBS (dilution) Sterility		Sterile
Nutrient Agar Sterility		Sterile
FBS Sterility		Sterile
S. aureus ATCC 6538		Pure, Adequate Growth
K. pneumoniae ATCC 4352		Pure, Adequate Growth
P. aeruginosa ATCC 15442		Pure, Adequate Growth
E. coli ATCC 11229		Pure, Adequate Growth

Discussion

Reduction or elimination of hospital acquired infections (HAIs) should be a major focus of hospitals for two primary reasons. First and foremost it will improve patient outcomes by decreasing the number of patients who unnecessarily develop nosocomial infections. The result will be shorter overall lengths of stay, less consumption of medical resources and improved morbidity and mortality for the patients. A second major reason to reduce HAIs is the financial implications it has for the institution (and the patient and their insurance). Since the introduction of the "never event" rulings, hospitals may be denied payment for a patient's hospital stay should an HAI occur. This is a substantial financial penalty that needs to be avoided when at all possible.

Older model bath basins are proven fomites and could lead to HAIs.[8,9] However, this study shows that bathtub contamination and bacterial transmission can be easily and inexpensively avoided. Despite contamination with billions of pathogenic bacteria, using the test device bathtub and disposable liner, combined with the disinfecting procedure as outlined by the manufacturer, pathogen contamination of the bathtub is completely eliminated. This prevents the device from introducing a nosocomial infection to a patient. The minor costs associated with the disposable liner and the disinfection wipes pale in comparison to revenue that will be lost from a reimbursement denial resulting from a preventable HAI.

Given that traditional bath basins are known reservoirs of pathologic bacteria, it is imperative that the caretaker has confidence that the bath basin they use, especially if used on multiple patients, is safe. This study used a worst-case contamination scenario by covering the bathtub liner with over a billion pathogenic bacteria. Despite this contamination, simply removing the disposable liner followed by 30 seconds of wiping a disinfectant cloth and allowing 3 minutes to dry led to complete elimination of detectible pathogens.

Conclusion

Removal and disposal of the TurtleTub single use bathtub liner

Table 5. Device culture results: Number of colony forming units cultured from each device.

Sample ID	CFU/Surface	Log_{10} Reduction From Positive Device Control	Percent Reduction From Positive Device Control
Negative Device Control	< 1.00E+00[2]	NA	
Positive Device Control	1.10E+09		
Test Replicate 1	<1.00E+00[2]	>9.04	>99.99999991%
Test Replicate 2	<1.00E+00[1,2]	>9.04	>99.99999991%
Test Replicate 3	<1.00E+00[2]	>9.04	>99.99999991%

[1]Single external contaminant was noted on filter plate. Not thought to affect study outcome, not included in results of this study.
[2]Values fell below the limit of detection. As a result, the limit of detection (1.00E+00) was used in calculations.

followed by brief disinfection of the TurtleTub completely eliminates pathogenic bacterial device contamination even under a worst-case scenario where billions of bacteria are placed on the liner. These results provide compelling evidence that when properly used and disinfected, this infant bathtub system will not result in cross-contamination of patients. Caregivers can offer infants the benefits of swaddle bathing and immersion bathing, which include decrease in temperature loss and decrease in stress, knowing that the system is safe from cross-contamination.

Conflicts of interest

This research was funded (i.e. the research lab fees required to conduct the lab study) by Catapult Products, the manufacturer of the TurtleTub infant bathing system which was the bath basin product evaluated in this research study. The study lab that conducted the microbiologic testing was paid a standard fee but has no conflict in terms of the results of the testing they conducted. Tim Wolfe, the author of this paper, is a retired academic clinician and businessman. He has no financial conflict of interest related to this research and was not paid any fees nor provided any form of compensation. However, he is associated with the owners of Catapult Products through prior business dealings a decade in the past and he agreed to write the paper as a friend who has the academic credentials and skill set to do so.

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