ORIGINAL ARTICLE

Effect of Hospital-Wide Chlorhexidine Patient Bathing on Healthcare-Associated Infections

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BACKGROUND. Chlorhexidine gluconate (CHG) bathing has been used primarily in critical care to prevent central line-associated bloodstream infections and infections due to multidrug-resistant organisms. The objective was to determine the effect of hospital-wide CHG patient bathing on healthcare-associated infections (HAIs).

DESIGN. Quasi-experimental, staged, dose-escalation study for 19 months followed by a 4-month washout period, in 3 cohorts.

SETTING. Academic medical center.

PATIENTS. All patients except neonates and infants.

INTERVENTION AND MEASUREMENTS. CHG bathing in the form of bed basin baths or showers administered 3 days per week or daily. CHG bathing compliance was monitored, and the rate of HAIs was measured.

RESULTS. Over 188,859 patient-days, 68,302 CHG baths were administered. Adherence to CHG bathing in the adult critical care units (90%) was better than that observed in other units (57.7%, P < .001). A significant decrease in infections due to *Clostridium difficile* was observed in all cohorts of patients during the intervention period, followed by a significant rise during the washout period. For all cohorts, the relative risk of *C. difficile* infection compared to baseline was 0.71 (95% confidence interval [CI], 0.57–0.89; P = .003) for 3-days-perweek CHG bathing and 0.41 (95% CI, 0.29–0.59; P < .001) for daily CHG bathing. During the washout period, the relative risk of infection was 1.85 (95% CI, 1.38–2.53; P = < .001), compared to that with daily CHG bathing. A consistent effect of CHG bathing on other HAIs was not observed. No adverse events related to CHG bathing were reported.

CONCLUSIONS. CHG bathing was well tolerated and was associated with a significant decrease in *C. difficile* infections in hospitalized patients.

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An estimated 1.7 million healthcare-associated infections (HAIs) occur in United States hospitals annually, resulting in approximately 100,000 deaths and a cost of up to \$45 billion.¹⁻³ Chlorhexidine gluconate (CHG) has broad-spectrum antimicrobial effects and has been used to disinfect the skin for surgical procedures and intravascular catheter insertion.^{4,5} Recently, CHG has been used for whole-body cleansing of critical care patients, with associated decreases in central lineassociated bloodstream infections (CLABSIs) and infections due to methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant enterococci (VRE).6-10 CHG bathing has also been employed in a long-term acute care hospital and in general-medicine units of an acute care hospital, with results similar to that observed in critical care settings.^{11,12} These studies have generally used 2% CHG-impregnated wash cloths. The purpose of this study was to evaluate, in a

real-world hospital setting, the effectiveness of CHG bathing via bed baths in preventing HAIs in hospitalized patients.

METHODS

Setting

All inpatient care areas of a 689-bed academic medical center, except the neonatal intensive care unit, the newborn nursery, and the labor and delivery unit, were included. This protocol was reviewed and approved by the institutional review board with an exemption from individual informed consent.

Design

The study consisted of a quasi-experimental, dose-ranging, staged-introduction trial in 3 cohorts of inpatients. CHG bathing was introduced to cohorts of patients on a 3-month

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staggered schedule beginning in February 2009 (Table 1). The cohorts were determined by hospital geography. Cohort 1 consisted of patients housed in 5 adult and pediatric critical care units (93 beds). Cohort 2 consisted of patients housed in Bed Tower A (110 beds, general adult and pediatric patients). Cohort 3 consisted of patients housed in Bed Tower B (237 beds, adult medical and surgical subspecialty patients). Each cohort followed the same schedule for introduction of CHG bathing. Initially, CHG bathing was performed 3 days per week, on Monday, Wednesday, and Friday; after 6 months, CHG bathing was performed every day. The every-day bathing period continued for 7-13 months (depending on cohort and staged introduction of CHG bathing). In September 2010, at the conclusion of the 19-month intervention period, a 4month washout period was conducted in which CHG bathing was discontinued.

Product and Intervention

Hibiclens 4% CHG aqueous solution (Mölnlycke Health Care) was used. For bedbound patients, healthcare personnel were instructed to substitute 4 oz of the CHG solution for regular soap in administering a routine bed bath per usual nursing protocol. CHG exposure to eyes and ears was avoided. CHG exposure to open wounds was not prohibited. Patients capable of taking a shower were instructed to scrub with 4 oz of the CHG solution from the neck down, allow the solution to dwell on the skin for 1 minute, and then rinse thoroughly. Several nonmedicated soaps and shampoos were available for patient bathing during nonintervention periods and for patients who were allergic or intolerant to CHG.

Definitions and Outcome Measures

Compliance. Compliance with CHG bathing was assessed by comparing the unit patient census, calculated daily at 12:01

AM, with the use of CHG as measured by inventory assessment. It was assumed that removal of a bottle of CHG from the inventory supply cabinet equated to receipt of 1 CHG bath. Unit-specific compliance data were issued to unit managers monthly throughout the study. Direct observation of bathing or bathing technique was not performed. An educational program, directed primarily toward nursing staff, was conducted prior to initiation of the protocol, and reminder signs were placed in all patient rooms and staff break rooms. When CHG bathing was introduced and when the step-up to daily CHG bathing occurred, study personnel were present on the wards to remind staff of the CHG bathing schedule.

HAIs. Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network surveillance definitions and techniques were utilized.¹³ The monitored HAIs were CLABSI, catheter-associated urinary tract infection (CAUTI), ventilator-associated pneumonia, newly defined infection or colonization due to VRE or MRSA, bloodstream infection due to MRSA or VRE, and infection due to *Clostridium difficile* (CDI). Denominator data for device utilization were obtained from electronic charting, and device-associated infections were expressed as a rate per 1,000 device-days. Nondevice-associated infections were expressed as a rate per 1,000 patient-days. Active surveillance cultures for MRSA or VRE were not performed. Infections due to *C. difficile* were defined per CDC recommendations, and infections meeting criteria for healthcare-facility onset were prospectively monitored.¹⁴

Adverse Events. Nursing staff examined the skin of patients on a daily basis. Healthcare providers were encouraged to report any adverse event due to CHG bathing through the institutional medication safety-adverse-event tracking system (Risk Monitor Pro, RL Solutions) or to study personnel.

TABLE 1. Study Design Chart Indicating Chlorhexidine Gluconate (CHG) Bathing Periods

Study period	Dates	CHG bathing				
		Cohort 1	Cohort 2	Cohort 3		
1	Baseline 1 (January-March 2008);	None (baseline)	None (baseline)	None (baseline)		
	Baseline 2 (April–June 2008);					
	Baseline 3 (July–September 2008);					
	Baseline 4 (October 2008–January 2009)					
2	February–April 2009	M/W/F	None	None		
3	May–July 2009	M/W/F	M/W/F	None		
4	August–October 2009	Daily	M/W/F	M/W/F		
5	November 2009–January 2010	Daily	Daily	M/W/F		
6	February–April 2010	Daily	Daily	Daily		
7	May–June 2010	Daily	Daily	Daily		
8	July-August 2010	Daily	Daily	Daily		
8	September-December 2010	None (washout)	None (washout)	None (washout)		

NOTE. Cohort 1, critical care units; cohort 2, general adult and pediatric units in Bed Tower A; cohort 3, adult medical and surgical specialty units in Bed Tower B; M/W/F, CHG bathing performed on Monday, Wednesday, and Friday.

Statistical Analysis

Data are presented as rates and risk ratios (RRs). The χ^2 test was used to compare compliance rates between cohorts. The incidence of HAIs over the study period was evaluated using a Poisson regression general linear model that allowed for correlation of incidence rates over time within the 3 treatment cohorts. Incidence rates were modeled as a function of treatment unit cohort and bathing regimen (none, Monday-Wednesday-Friday, daily, washout). The null hypothesis that the rate of HAIs during the intervention periods was the same as that for the baseline period was tested using SAS software, version 9.2 (SAS Institute). Further modeling considered the effect of CHG bathing compliance on infection rates. Additional analyses were performed that excluded pediatric intensive care unit patients and oncology-hematology special care unit patients from cohort 1 because of the low CHG bathing compliance in those units. The rates of MRSA and VRE colonization or infection were combined as a prospective composite HAI measure. The P values reported are nominal P values and have not been adjusted for multiple comparisons. A planned interim analysis was conducted in February 2010, and results were presented to the study advisory committee composed of key clinicians and hospital administration.

RESULTS

The baseline soap-and-water bathing observation period (January 2008–January 2009) consisted of 121,562 patientdays. The CHG bathing intervention period (February 2009–August 2010) consisted of 188,859 patient-days, and the washout period (September–December 2010) consisted of 36,621 patient-days.

Adherence

During the intervention phase of the project, 68,302 CHG baths were administered, resulting in an overall adherence rate of 60.6%. Adherence in the adult critical care units (90%) was considerably greater than that in the non-critical care units (57.7%; P < .001). Adherence in the oncology-hematology special care unit and the pediatric intensive care unit was lower (45.6% and 37%, respectively) than that in other patient care units (P < .001). There was no significant difference in CHG bathing adherence between cohorts 2 and 3 (P = .12).

HAIs

C. difficile *Infection*. A significant decline in infections due to *C. difficile* was observed in all cohorts of patients during the CHG bathing intervention, followed by a significant increase during the washout period (Figure 1). The modelestimated RR for cohort 1 (intensive care unit patients) suggests that there was not a significant risk difference between the baseline and 3-days-per-week periods (RR, 0.91 [95%)

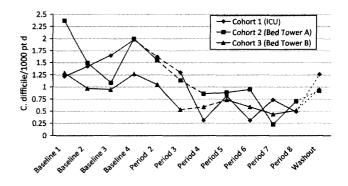


FIGURE 1. Effect of chlorhexidine gluconate (CHG) bathing on *Clostridium difficile* infection. Trends in incidence of *C. difficile* infection are shown for the 3 cohorts of patients over the course of the study. The long-dashed line depicts the 3-days-per-week bathing period. The solid line starting after the 3-days-per-week bathing period in each cohort depicts the every-day CHG bathing period. The short-dashed line indicates the washout period. pt d, patient-days.

confidence interval (CI), 0.54-1.53]; P = .72), whereas there was an approximately 70% decline in CDIs during the daily bathing period (RR, 0.30 [95% CI, 0.19–0.49]; P < .001). During the washout period, a significant increase in CDIs was noted, compared to that in the daily bathing period (RR, 2.52 [95% CI, 1.32–4.80]; washout vs daily bathing, P = .005). A similar pattern was observed in the other cohorts. During the 3-days-per-week bathing period, the relative risk of CDI was 0.67 (95% CI, 0.51-0.88; P = .004) and 0.63 (95% CI, 0.47–1.85; P = .002) in cohorts 2 and 3, respectively. The rate of CDI continued to decrease during the daily bathing period: relative risk of 0.44 (95% CI, 0.25-0.77; P = .004) and 0.50 (95% CI, 0.25–0.97; P = .04), compared to the baseline rate, for cohorts 2 and 3, respectively. In cohort 2, although the rate of CDI increased during the washout period (RR, 1.27 [95% CI, 0.85-1.87]; washout vs daily bathing), this difference was not significant (P = .25), whereas in cohort 3, a significant increase in CDI rate during the washout period was observed (RR, 1.85 [95% CI, 1.26-2.71]; P = .002). For all cohorts, the model-estimated risk of infection, compared to the baseline, was 0.71 (95% CI, 0.57-0.89; P = .003) for the 3-days-per week bathing period and 0.41 (95% CI, 0.29–0.59; P < .001) for the daily bathing period. The relative risk of CDI in the washout period was 1.85 (95% CI, 1.38–2.53; P < .001), when that period was compared with the daily bathing period. CDI rates were similar among the three cohorts (P = .29) but differed significantly on the basis of CHG bathing frequency (none vs 3 times per week vs daily; P = .03).

Other HAIs. The model-estimated rates of infection for CHG bathing periods, compared to soap-and-water bathing periods, for the 3 cohorts are presented in Table 2. The rate of newly detected colonization or infection due to VRE de-

	M/W/F CHG bathing		Daily CHG bathing		Washout period*	
Infection type, patient cohort	Risk ratio (95% CI)	Р	Risk ratio (95% CI)	P	Risk ratio (95% CI)	Р
Vancomycin-resistant enterococci						
Cohort 1	0.62 (0.45-0.86)	.004	0.50 (0.33-0.76)	.001	0.81 (0.30-2.23)	.92
Cohort 2	0.77 (0.50-1.19)	.24	0.49 (0.20-1.21)	.12	0.97 (0.52-1.80)	.92
Cohort 3	0.64 (0.39-1.04)	.073	0.64(0.47 - 0.87)	.004	0.75 (0.37-1.51)	.42
Methicillin-resistant Staphylococcus aureus						
Cohort 1	1.25 (0.64-2.45)	.51	0.76 (0.52-1.10)	.15	1.82 (1.43-2.36)	<.001
Cohort 2	1.66 (1.26-2.19)	.001	1.42 (1.01-1.98)	.041	0.20 (0.07-0.52)	.001
Cohort 3	0.95 (0.65-1.38)	.79	0.92 (0.57 - 1.48)	.72	0.69 (0.40-1.20)	.19
Central line-associated bloodstream infection						
Cohort 1	0.59 (0.30-1.17)	.13	0.67 (0.43-1.04)	.08	0.43 (0.30-0.62)	<.001
Cohort 2	1.10 (0.72-1.67)	.67	0.99 (0.64-1.52)	.95	0.53 (0.41-0.67)	<.001
Cohort 3	1.10 (0.65–1.87)	.72	0.64 (0.44-0.96)	.03	0.82 (0.45-1.49)	.52
Catheter-associated urinary tract infection						
Cohort 1	0.60 (0.25-1.46)	.26	1.04 (0.84-1.27)	.73	1.26 (0.92-1.72)	.15
Cohort 2	0.61 (0.60-0.63)	<.001	0.26 (0.16-0.41)	<.001	1.63 (0.82-3.22)	.16
Cohort 3	0.72 (0.52-0.99)	.046	0.72 (0.55-0.94)	.015	1.12 (0.68-1.87)	.65
Ventilator-associated pneumonia						
Cohort 1	0.27 (0.01-4.03)	.34	1.2 (0.88-1.63)	.24	0.78 (0.08-7.40)	.82

TABLE 2. Effect of Chlorhexidine Gluconate Bathing on Healthcare-Associated Infections: Model-Estimated Rate of Infection during Intervention Periods, Compared to Soap-and-Water Bathing

NOTE. M/W/F, Monday/Wednesday/Friday; CHG, chlorhexidine gluconate; CI, confidence interval.

^a Comparison of washout period and daily CHG bathing period.

creased significantly in all 3 cohorts of patients during the intervention period but did not rebound during the washout period. The rate of CLABSI in cohort 1 evidenced some decline during the 3-days-per-week and daily CHG bathing periods. However, during the washout period, the rate of CLABSI continued to decline. In the non-critical care units, no consistent pattern of response between CLABSI rate and CHG bathing was evident. Although the rate of CAUTI decreased significantly in the non-critical care unit cohorts during the intervention period, no significant change was noted in the washout period.

In general, the rates of other HAIs were low, making it less likely that a statistically significant effect would be demonstrable. The rates of CLABSI and CAUTI for the entire study were 2.237 per 1,000 central venous catheter (CVC)–days and 2.951 per 1,000 urinary catheter–days, respectively. The rates of newly diagnosed infection or colonization due to VRE and MRSA over the entire study period were 0.781 and 0.615 per 1,000 patient-days, respectively. No substantial impact was observed when the rates of colonization or infection due to VRE and MRSA were combined as a composite measure (data not shown). The rates of bloodstream infection due to VRE and MRSA were too low to allow for meaningful statistical comparison. The overall rates of VRE and MRSA bacteremia during the entire study period were 0.077 and 0.096 per 1,000 patient-days, respectively.

HAI and Variation in CHG Bathing Compliance. There was little variation in CHG bathing compliance from period to period. CHG bathing compliance ranged from 84.5% to 95%,

from 45.4% to 67%, and from 54.6% to 64.7% in cohorts 1 (excluding pediatric critical care and oncology-hematology special care patients), 2, and 3, respectively. To assess whether the variation in CHG bathing compliance influenced the rate of HAI, compliance was included as a covariate in the general linear model examining CDI. Periods with no CHG bathing (baseline and washout) were excluded because compliance during these periods was 0. CHG bathing compliance was not associated with reduced incidence of CDI (P = .83).

Adverse Events

No adverse events were reported to study personnel or via the hospital adverse-event reporting system.

DISCUSSION

Because of its ease of use, broad-spectrum activity, prolonged residual effect, and low adverse-event profile, general patient bathing with CHG may be an excellent example of a "horizontal" infection prevention intervention that could have an impact on a variety of HAIs.¹⁵ Our study adds support for the use of CHG patient bathing as an effective general horizontal intervention for infection prevention. Several aspects of our experience warrant additional emphasis and consideration.

A quasi-experimental design allowed for an assessment of the effectiveness of CHG bathing in 3 large cohorts of inpatients in a staged, dose-response fashion. Although matched concurrent control groups were lacking, the cohorts allowed for a measure of reproducibility, and the dose escalation allowed for assessment of dose response. In addition, the concluding washout period helped to identify the possible existence of secular trends unrelated to CHG bathing. It should be noted that without a washout period, declines in rates of VRE infection and CAUTI may have been inappropriately attributed to CHG bathing.

Most studies regarding CHG bathing, with the notable exception of that by Kassakian et al,¹² do not report bathing compliance. In our study, a high rate of compliance was observed in the adult critical care units and a lower one in other units. However, direct observation of bathing was not performed, and compliance determination based on inventory assessment may have been influenced by pilferage or waste. The difference in compliance between units may be attributable to a variety of causes, include critically ill patients' inability to defer bathing, staffing levels, unit-specific culture, and effectiveness of protocol-related communication. Future work should be directed at factors that influence CHG bathing compliance and the impact of compliance on effectiveness.

CHG bathing was associated with a decrease in CDIs. This was unexpected and deserves closer scrutiny. There is biologic plausibility to accompany this observation. Although CHG is not sporicidal, it is active against vegetative cells and inhibits spore germination.⁵ Because CHG was applied via a traditional "bed bath," physical removal of spores from the skin may have occurred and may have resulted in decreased environmental contamination. Most studies involving CHG bathing have utilized CHG-impregnated wash cloths, with which physical removal of spores would not be expected. The CHG product used in this study contains a surfactant that may aid in physical removal of spores.¹⁶ Although such a conclusion would be speculative, the educational program accompanying the study may have improved the rate of patient bathing, which may also potentially explain the results if physical spore removal is important in CDI prevention.¹⁷ As shown in Figure 1, the rate of CDI declined in cohorts 2 and 3 prior to the initiation of CHG bathing, which may have been due to unit-to-unit transfer of patients.

Other factors may have had an effect on CDI rates in this study, and these results should be interpreted with caution. First, changes in diagnostic laboratory procedures occurred during the study, in which an enzyme-linked immunoassay (EIA) test for A/B toxin was replaced by a combined assay for glutamate dehydrogenase antigen and A/B toxin. Later, a DNA amplification test for toxin genes was introduced and utilized when there was disparity between the glutamate dehydrogenase assay and the A/B toxin EIA. However, the changes in CDI incidence do not appear to chronologically match changes in lab procedures. The assay for glutamate dehydrogenase antigen and A/B toxin was introduced in the latter part of July 2009 (end of study period 3), and the toxingene DNA amplification test was added in October 2010 (latter part of period 9). The diagnostic laboratory changes should have improved the sensitivity for detection of C. difficile. Therefore, if there was an effect of the laboratory

changes, it would be expected to have resulted in an increase in detection of CDI and thus weigh against demonstration of a significant decline. Furthermore, after the washout period, the rate of CDI continued to rise (data not shown), which makes it less likely that laboratory changes played a significant confounding role. Also, a variety of CDI control measures have been put into place, including presumptive isolation, extension of isolation, and bleach environmental disinfection. These measures were put into place in 2006 and 2007, prior to the start of the CHG bathing protocol. However, it is not possible to exclude the potential impact of these measures or unknown changes in C. difficile strain types. Strains of C. difficile from our institution were sent to a reference lab (Hines Veterans Affairs Hospital, Chicago), and the presence of the BI/NAP1/ribotype 027 epidemic strain was confirmed at our facility in 2007 (D. Gerding, personal communication). It is unknown whether there have been significant changes in strain types more recently. It is known that antibiotic exposure predisposes to CDI, and we cannot rule out the possible impact of changing antibiotic prescription practices at our institution. The incidence of CDI has been noted to have a seasonal predilection favoring the winter months.¹⁸ The pattern of CDI noted in this study did not follow this known variation. This study should be regarded as hypothesis generating, and other investigators should examine the effect of CHG bathing on CDI in various patient care settings before CHG bathing is accepted as a CDI-preventative measure.

CHG bathing has been associated with a decrease in CLABSI rate, primarily in critical care settings.^{6,10,11,19} The impact of CHG bathing on CLABSI rate in this study was ambiguous. In adult critical care unit patients, the baseline rate of CLABSI was 3.2/1,000 CVC-days. A decrease in CLABSI rate was observed during the 3-days-per-week CHG bathing period (1.08/1,000 CVC-days; P = .002), and the incidence rate remained relatively stable (1.91/1,000 CVC-days; P <.001) during the daily CHG bathing period. During the washout period, rather than rebound, the CLABSI rate continued to fall (0.656/1,000 CVC-days; P = .002). Therefore, it appears that a secular trend of decreasing incidence of CLABSI was present. Reinforcement of the CLABSI-preventative bundle²⁰ was ongoing, as were efforts to reinforce CVC maintenance procedures. In previously published studies, the baseline rates of CLABSI were frequently much higher than currently observed levels (5.31-16.8/1,000 CVC-days).^{6,10,11,19} The lower baseline rate of CLABSI and ongoing preventative efforts may have precluded our ability to discern the effect of CHG bathing on CLABSI rate. The other cohorts of patients had even lower baseline rates of CLABSI (2.42 and 1.86/1,000 CVC-days for cohorts 2 and 3, respectively).

Although the rate of VRE colonization and infection declined significantly during the intervention (Table 2), a significant rebound was not observed during the washout period. Because of concern that the rate of VRE colonization and infection seemed to be increasing following the conclusion of the study, a post hoc analysis was conducted on data from an additional 6 months (January–June 2011), during which soap-and-water bathing was in use. Although the rate of VRE colonization or infection increased in all cohorts during the post hoc period, these changes were not statistically significant. Again, the low rate of infection may have precluded the power to document statistically significant changes.

CHG bathing was well tolerated. There were no reports of adverse events attributed to CHG bathing. Recently, concern has been expressed regarding staphylococci for which susceptibility to CHG was reduced due to *qac* genes that encode for efflux pumps.²¹⁻²³ CHG susceptibility testing in staphylococci was not performed during this study. The emergence of CHG resistance in staphylococci is a topic of interest and should be examined in centers utilizing CHG for infection control purposes.

CHG bathing is an attractive horizontal infection prevention intervention that may have beneficial effects on a number of HAIs. CHG bathing in this hospital-wide study was associated with a reduction in CDI rate. Although there are biologically plausible explanations linking CHG bathing and CDI prevention, confirmatory studies should be performed. Factors surrounding CHG bathing compliance should be better delineated. The emergence of CHG resistance should be monitored, and its clinical significance should be assessed.

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