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Major Article

Prospective cluster controlled crossover trial to compare the impact of an improved hydrogen peroxide disinfectant and a quaternary ammonium-based disinfectant on surface contamination and health care outcomes

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Background: Quaternary ammonium–based (Quat) disinfectants are widely used, but they have disadvantages.

Methods: This was a 12-month prospective cluster controlled crossover trial. On 4 wards, housekeepers performed daily cleaning using a disinfectant containing either 0.5% improved hydrogen peroxide (IHP) or Quat. Each month, 5-8 high-touch surfaces in several patient rooms on each ward were tagged with a fluorescent marker and cultured before and after cleaning. Hand hygiene compliance rates and antimicrobial usage on study wards were obtained from hospital records. Outcomes included aerobic colony counts (ACCs), percent of wiped surfaces yielding no growth after cleaning, and a composite outcome of incidence densities of nosocomial acquisition and infection caused by vancomycin-resistant enterococci, methicillin-resistant *Staphylococcus aureus*, and *Clostridium difficile* infection. Statistical analysis was performed using χ^2 test, Fisher exact test, Welch test, and logistic regression methods.

Results: Mean ACCs per surface after cleaning were significantly lower with IHP (14.0) than with Quat (22.2) ($P = .003$). The proportion of surfaces yielding no growth after cleaning was significantly greater with IHP (240/500; 48%) than with Quat (182/517; 35.2%) ($P < .0001$). Composite incidence density of nosocomial colonization or infection with IHP (8.0) was lower than with Quat (10.3) (incidence rate ratio, 0.77; $P = .068$; 95% confidence interval, 0.579-1.029).

Conclusions: Compared with a Quat disinfectant, the IHP disinfectant significantly reduced surface contamination and reduced a composite colonization or infection outcome.

Quaternary ammonium–based (Quat) disinfectants are widely used in health care, but they have several disadvantages.[1,2] Recently marketed hydrogen peroxide–based disinfectants with greater antimicrobial potency, so-called improved hydrogen peroxide (IHP) disinfectants,[2,3] have been shown to reduce bacterial contamination of surfaces, and offer an alternative to Quat disinfectants.[3-6] One IHP product containing 0.5% hydrogen peroxide was found to have some activity against *Clostridium difficile* spores; however, it does not have an Environmental Protection Agency (EPA)–registered sporicidal claim.[7] Use of the same product, when combined with high rates of com-

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pliance with recommended cleaning protocols, was associated with reductions in health care–associated infections caused by several multidrug-resistant pathogens.[8] Based on these earlier studies,[3-8] we conducted a quality improvement project to compare the effectiveness of IHP-containing wipes and a Quat disinfectant currently in use on reducing surface contamination and health care outcomes.

METHODS

Study design

A 12-month prospective cluster controlled crossover trial was conducted on 4 patient wards located on 2 campuses of a university-affiliated hospital. On each campus, 2 wards were randomized to have housekeepers continue performing daily and discharge cleaning using the Quat disinfectant (Hyperfect 256; Genesan, Gorham, ME) used in the rest of the hospital, or to perform daily and discharge cleaning using disinfectant wipes containing 0.5% IHP (Oxivir Tb; Diversey Care, Charlotte, NC). Both the IHP ready-to-use wipes and similar dry wipes used to apply the dilutable Quat disinfectant during the trial were made of melt blown polypropylene. During months when study wards were assigned to use the Quat disinfectant, rooms of patients with *C difficile* infection (CDI) were cleaned daily and at discharge with bleach wipes. When study wards were assigned to use the IHP disinfectant, all Quat-based wipes and bleach wipes were removed from the wards, bleach wipes were not used for daily or discharge cleaning of rooms occupied by patients with CDI, and the same IHP disinfectant in solution form was used to clean floors. The study was conducted in a medical intensive care unit (MICU) and its step-down unit on one campus, and on 2 general medical wards on the other campus. After 6 months, the ward assignments were reversed.

During the study, 5-8 high-touch surfaces in a convenience sample of several patient rooms on each of the 4 study wards were marked each month by fluorescent marker and cultured before cleaning, and were checked for the presence or absence of fluorescent marker and cultured again after daily cleaning by housekeepers. Rooms selected for tagging and culturing varied from month to month. High-touch surfaces were considered to have been wiped adequately if the fluorescent marker was removed. High-touch surfaces included bedside rails, remote control module, overbed tables, toilet seats, toilet grab bars, counters, supply cart keyboards, and work stations on wheels. Not all high-touch surfaces were present in all rooms. High-touch surfaces were cultured using 1 agar contact plate per surface on each occasion. All cultures of high-touch surfaces before and after cleaning were performed by a single microbiology laboratory technologist. Housekeepers, who were aware that the study was being conducted, received continued feedback during the study to increase the likelihood that high wipe rates would be maintained.[9]

Microbiologic methods

Cultures of high-touch surfaces were obtained by using Dey-Engley agar contact plates (Remel, Lenexa, KS), which were incubated at 36°C for 48-72 hours, followed by determination of aerobic colony counts (ACCs). ACCs were reported as the number of colony forming units (CFUs) per contact plate (ie, CFUs per high-touch surface). Plates with >200 CFUs per contact plate were classified as having 200 CFUs.

Outcome measures

Microbiologic outcome variables included the mean number of ACCs per high-touch surface and the percent of wiped surfaces yielding no growth after room cleaning. Because high-touch surfaces have sometimes been defined as clean if cultures yielded <2.5 CFUs/cm^2,[4] overall results were also expressed as the proportion of surfaces that yielded <2.5 CFUs/cm^2 (equivalent to <65 CFUs per contact plate).

A health care–related outcome measure represented a composite outcome of incidence densities (expressed as new, nosocomial cases per 1,000 patient days) of patients with a surveillance or clinical culture positive for vancomycin-resistant enterococci (VRE) or methicillin-resistant *Staphylococcus aureus* (MRSA), bloodstream infection caused by VRE or MRSA, and hospital-associated, hospital onset CDI. Surveillance or clinical culture results from patients with a history of colonization or infection by VRE or MRSA were excluded because such data would be unlikely to represent new acquisition (colonization) of these pathogens. Data on the occurrence of nosocomial cases of colonization or infection by target pathogens among patients on study wards were obtained from a TheraDoc database (TheraDoc, Salt Lake City, UT) maintained by the hospital epidemiology program.

Hand hygiene compliance rates on study wards, as determined by a single secret shopper throughout the study period, were obtained from a hospital database. Antimicrobial usage data for study wards (expressed as the number of defined daily doses [DDDs] per 1,000 patient days) were provided by the hospital pharmacy.[10] Antimicrobial agents were divided into 3 main categories: (1) anti–*C difficile* agents, including oral and intravenous metronidazole, oral vancomycin, and rifaximin; (2) agents with activity against MRSA or VRE; and (3) all other antibacterial agents.

Statistical analysis

ACCs after cleaning were excluded from further analysis if fluorescent markers revealed that surfaces had not been wiped or if cultures before cleaning revealed no growth because such surfaces cannot provide information regarding disinfectant efficacy and may overestimate the effectiveness of a disinfectant.[11,12] Our study protocol stipulated that only health care–related outcome data from months when fluorescent marker monitoring revealed that ≥80% of high-touch surfaces tested on a study ward had been wiped would be included in the data analysis, an approach used by others.[8] We assumed that a study in which disinfectants are not applied to a substantial proportion of high-touch surfaces in patient rooms would be unlikely to yield accurate estimates of the potential impact of the disinfectants on health care–related outcomes. Differences in proportions were tested by χ^2 or Fisher exact tests. Mean ACCs per high-touch surface obtained after cleaning on Quat and IHP wards were compared using Welch test. A multiple logistic regression model with a dependent variable of no growth versus ≥1 CFU on surfaces after cleaning included Quat ward vs IHP ward, high-touch surface cultured, and ACC before room cleaning as independent variables. The composite outcome measure of the incidence densities for VRE colonization or infection, MRSA colonization or infection, and CDI on Quat wards and IHP wards and antimicrobial usage data were compared as rates using univariate Poisson models (MedCalc, Ostend, Belgium).

RESULTS

Microbiologic findings

The total number of high-touch surfaces cultured before daily cleaning was 561 on IHP wards and 575 on Quat wards. On the IHP wards, 35 (6.2%) of the surfaces had not been wiped, and 25 (4.5%) yielded no growth before cleaning. On the Quat wards, 30 (5.2%) had not been wiped, and 28 (4.9%) yielded no growth before cleaning. The proportion of ACCs after cleaning that were excluded from further analysis of disinfectant efficacy was similar on IHP wards

Table 1
Number of MRSA, *Clostridium difficile*, and VRE health care outcomes and overall rate of health care outcomes (number of cases per 1,000 Pt-Days) by study ward, during ward months with wipe rate of ≥80%, for improved hydrogen peroxide product versus quaternary ammonium-based product

Ward	Pt-Days	MRSA	*C difficile*	VRE	Total (rate*)
Improved hydrogen peroxide product					
MICU	1,352	12	1	17	30 (22.2)
MICU-SD	4,188	8	2	41	51 (12.2)
Med 1	1,211	0	2	0	2 (1.6)
Med 2	3,990	1	1	1	3 (0.75)
Total	10,741	21 (1.96)*	6 (0.56)*	59 (5.49)*	86 (8.0)
Quaternary ammonium–based product					
MICU	4,208	16	5	45	66 (15.7)
MICU-SD	3,570	8	4	27	39 (10.9)
Med 1	3,082	8	2	4	14 (4.5)
Med 2	630	0	1	0	1 (1.6)
Total	11,490	332 (2.79)*	12 (1.0)*	76 (6.6)*	119 (10.3)

Med 1, general medical ward 1; *Med 2*, general medical ward 2; *MICU*, medical intensive care unit; *MICU-SD*, medical intensive care unit step-down unit; *MRSA*, methicillin-resistant *S aureus*; *Pt-Days*, patient days; *VRE*, vancomycin-resistant enterococci.
*Total number of health care outcomes per 1,000 patient days.

(60/561; 10.7%) and Quat wards (58/575; 10.1%) (χ^2 test, $P = .74$). ACCs after cleaning were available for 500 surfaces on IHP wards and 517 on Quat wards. One surface on an IHP ward that had been wiped was not cultured after cleaning because of patient-related issues. The distribution of types of high-touch surfaces cultured after cleaning that was included in the analysis was similar for IHP and Quat wards (χ^2, $P = .99$). Mean ACC per high-touch surface after cleaning was significantly lower with IHP (14.0 CFUs) than with Quat (22.2 CFUs) ($P = .003$). A logistic regression model revealed that the proportion of surfaces yielding no growth after cleaning was significantly greater with IHP (240/500; 48%) than with Quat (182/517; 35%) ($P < .0001$). If one uses a cutoff of <2.5 CFUs/cm^2 as a definition of a clean surface, 462 of 500 (92.4%) surfaces were clean after use of IHP compared with 457 of 517 (88.4%) after use of the Quat disinfectant ($P = .03$).

Composite health care outcome analysis

Fluorescent marker data on wipe rates were available for 23 of 24 IHP ward months and 22 of 24 Quat ward months. On IHP and Quat wards, the number of months with wipe rates <80% was 7 of 23 (30.4%) and 5 of 22 (22.7%), respectively (Fisher exact test, $P = .74$). Eighty percent or greater of monitored surfaces were wiped during 16 ward months (10,741 patient days) on IHP wards and during 17 ward months (11,490 patient days) on Quat wards. The mean proportion of high-touch surfaces wiped during these per protocol months on IHP and Quat wards was 93.3% and 90%, respectively. The overall composite incidence density measure for per protocol ward months was 8.0 cases per 1,000 patient days on IHP wards compared with 10.3 cases per 1,000 patient days on Quat wards ($P = .068$; incidence rate ratio, 0.77; 95% confidence interval, 0.579-1.029). Incidence density rates were lower on IHP wards for each of the 3 target organisms (Table 1). Use of the IHP disinfectant was associated with lower composite incidence densities on the 2 general medical wards, but not in the MICU or step-down unit (Table 1).

Hand hygiene compliance rates were 95.8% on IHP wards and 95.5% on Quat wards. Usage of anti–*C difficile* agents was nearly twice as high on Quat wards than on IHP wards ($P < .0001$) (Table 2). Similarly, there was significantly greater usage of agents effective against MRSA or VRE ($P = .03$) and of all other antibacterial agents on Quat wards compared with IHP wards ($P = .03$) (Table 2).

Table 2
Antimicrobial usage on units using IHP or Quat disinfectants

Antimicrobial agents	IHP units (10,741 Pt-days), DDD per 1,000 Pt-days	Quat units (11,490 Pt-days), DDD per 1,000 Pt-days
Anti–*Clostridium difficile* agents	85.6	141.4
Anti-MRSA or VRE	95.9	138.0
All other agents	895.3	922.3

DDD, defined daily dose; *IHP*, improved hydrogen peroxide; *MRSA*, methicillin-resistant *Staphylococcus aureus*; *Pt-days*, patient days; *Quat*, quaternary ammonium; *VRE*, vancomycin-resistant enterococci.

DISCUSSION

To our knowledge, this study represents the first prospective, cluster controlled crossover trial comparing a Quat disinfectant with an IHP disinfectant in a real-world health care setting. We found that mean ACCs after cleaning were significantly lower with IHP than with Quat ($P = .003$) and that high-touch surfaces yielded no growth after cleaning with IHP significantly more often than with Quat ($P < .0001$). Furthermore, we found that the incidence density of a composite measure of health care outcomes caused by VRE, MRSA, and *C difficile* was 23% lower in the IHP arm than in the Quat arm when wipe rates were ≥80%; however, the difference did not reach statistical significance ($P = .068$).

Our microbiologic results are consistent with several earlier studies of IHP-based disinfectants which found that such products effectively reduce contamination of inoculated disks and environmental surfaces in health care settings.[3-6,13] The degree of difference in the mean colony counts between the Quat and IHP arms may have been reduced somewhat because of the use of bleach wipes in the rooms of CDI patients on Quat wards. A recent randomized controlled trial of enhanced disinfection measures found that the study arm that used bleach alone for terminal disinfection of rooms yielded lower bacterial counts on surfaces after disinfection than use of a Quat disinfectant.[14] Greater reduction of ACCs after cleaning in the IHP arm of our study is supported by 2 other studies that evaluated the same IHP product used in this study. One study used an in vitro stainless steel disk assay,[3] whereas the other used a new ASTM protocol (E2967-15) to evaluate the effectiveness of wipes containing IHP or Quat.[13] Both studies found that the IHP product was more effective than the Quat disinfectants tested.[3,13] The results of the present study also expand on the findings of other studies which found that Quat disinfectants reduced bacterial counts on surfaces less effectively than disinfectants based on an active oxygen compound, electrolyzed water, or a combination of peracetic acid and hydrogen peroxide.[12,15,16]

During the early months of the study, wipe rates on some study wards were as low as 52%-79%. As a result, those ward months were excluded from per protocol analysis of health care outcomes because it is unlikely that they would provide an accurate assessment of ability of a disinfectant to reduce transmission of health care–associated pathogens. The relatively high proportion of monitored high-touch surfaces that were wiped during per protocol months was most likely because of 2 factors. Housekeepers were aware that a study was being conducted and that their performance was being monitored, which likely led to a Hawthorne effect. Also, housekeepers received regular feedback, which has been shown to be necessary to maintain high wipe rates.[9] We have no reason to suspect that the Hawthorne effect accounted for the different health care outcome rates because mean wipe rates on IHP wards and Quat wards during per protocol months were similar.

The composite health care outcome measure used in our study included patients with no history of VRE or MRSA who either de-

veloped a nosocomial VRE or MRSA bloodstream infection or had a new surveillance or clinical culture positive after admission, representing either newly recognized infection or colonization. Inclusion of new-onset acquisition (colonization) and infections in outcome measures when evaluating the effectiveness of cleaning practices has been recommended in a recent Agency for Healthcare Research and Quality technical brief on environmental cleaning practices.[17] Other investigators[14,18-21] have also included acquisition of pathogens as an outcome measure in studies of environmental decontamination because the thoroughness of room cleaning is as likely, or more likely, to affect acquisition of pathogens than development of infection.

The fact that a 23% reduction in the health care–related outcomes on IHP wards was not statistically significant may have been caused in part by having to exclude a number of ward months from both the IHP and Quat arms, resulting in the per protocol analysis being underpowered to detect a statistically significant difference. However, we cannot exclude the possibility that IHP and Quat disinfectants might yield comparable health care outcome rates in a larger study.

The greater reduction in surface contamination and lower incidence density of health care–related outcomes achieved with the IHP wipes cannot be attributed to differences in the proportion of monitored surfaces that were wiped because the mean percentages of high-touch surfaces wiped on study wards were similar. Because the IHP wipes and wipes used to apply the Quat disinfectant to surfaces were both made of melt blown polypropylene, it seems unlikely that wipe composition would explain differences in effectiveness of the 2 disinfectants. Also, the nearly identical hand hygiene compliance rates on IHP and Quat wards could not explain the lower rate of health care–related outcomes on IHP wards. Although the secret shopper observational method of determining hand hygiene compliance rates is very likely to have overestimated compliance rates,[22] we have no reason to believe that the rates were biased toward IHP or Quat wards.

The higher rate of usage of *C difficile* antimicrobial agents on Quat wards may well have been because of the greater incidence of CDI on Quat wards. Similarly, greater use of agents with activity against MRSA or VRE on Quat wards may have been caused in part by the higher incidence of MRSA- and VRE-related events on those wards. Usage rates of other antimicrobials not used for treatment of CDI, MRSA, or VRE were approximately twice as high in the MICU and step-down unit as on the general medical wards (data not shown). Whether this increased antibiotic pressure, or differences in the frequency with which MRSA or VRE surveillance cultures were obtained during IHP and Quat ward months, made it more difficult to achieve a reduction in health care outcomes by use of an IHP disinfectant in the MICU and step-down unit is not clear.

Our study differs in several respects from an earlier one that compared the impact of a hydrogen peroxide cleaning agent (not a disinfectant) and the same IHP-based disinfectant used in our study on health care outcomes. In that study, Alfa et al[8] found that a high rate (>80%) of compliance with cleaning protocols, and use of the 0.5% IHP-based disinfectant, was associated with a reduction in health care–associated infections caused by MRSA, VRE, and *C difficile*. However, unlike the present trial, the earlier study used data from another hospital as a control, lacked environmental cultures, and did not include analysis of hand hygiene compliance rates or antimicrobial usage.

Of interest, the incidence density of CDI in this study was lower on IHP wards than on Quat wards, even though the 0.5% IHP product used does not have an EPA-registered sporicidal claim. Perhaps this is explained in part by the fact that the IHP disinfectant used has been shown to reduce *C difficile* spores by 2-3 $\log_{10}$.[7] In contrast with the IHP disinfectant used, Quat disinfectants have poor activity against *C difficile* spores.[23-26] It is worth mentioning that even wipes that are not considered sporicidal may result in physical removal of *C difficile* spores,[23] but may also spread *C difficile* spores from one surface to another.[26] IHP-based disinfectants also have several other advantages when compared with Quat disinfectants, including short contact times, the lowest EPA toxicity rating (category IV), lack of reduced efficacy in the presence of organic material, and no significant binding to cloths made of cotton or cellulose, which does occur with Quat-based disinfectants.[2,27,28]

Our study has several limitations, including that it was conducted on only 4 wards in a single hospital. Housekeepers and the microbiology technician were not blinded as to which disinfectant was being used on a study ward. Only 1 Quat disinfectant was compared with 1 IHP-based product. Patient-level antimicrobial agent usage was not performed. Antimicrobial usage was expressed as DDDs per 1,000 patient days according to guidelines current at the time.[10] Recently, it has been recommended that antimicrobial usage be expressed instead as days of therapy (DOTs) per 1,000 patient days.[29] Given the results of a recent study that compared DDDs with DOTs,[30] it seems unlikely that expressing usage as DOTs would change the interpretation of our results. Also, our study did not evaluate other potential confounding variables, including colonization pressure and the frequency with which surveillance cultures were obtained. Such potential confounders would not however have explained the greater reduction of surface contamination achieved in the IHP arm, and the fact that units on each campus were randomly assigned to the study arms and the crossover design of the study should have reduced the likelihood that such potential confounders would have influenced the health care–associated outcomes observed.

In conclusion, our findings and those of others suggest that IHP-based disinfectants are more effective than Quat-based disinfectants in reducing bacterial contamination on surfaces. Our study also suggests that IHP-based disinfectants may be more effective than Quat disinfectants in reducing health care–related outcomes, but the lower rate of health care–associated outcomes observed in the IHP arm of the study did not reach statistical significance. Accordingly, further prospective controlled trials comparing IHP-based disinfectants with Quat-based disinfectants are needed to clarify the relative abilities of IHP and Quat disinfectants to reduce health care–related outcomes.

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