

SHORT- AND LONG-TERM EFFECTS OF HANDWASHING WITH ANTIMICROBIAL OR PLAIN SOAP IN THE COMMUNITY

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ABSTRACT: Little is known about effects of public use of antimicrobial handwashing soap. A double-blinded, randomized clinical trial of hands of primary caretakers in 238 inner city households was conducted in which effects of plain or antimicrobial (containing 0.2% triclosan) handwashing soap on bacterial counts of the hands were compared before and after a single wash and before and after handwashing following a year of product use. The randomly assigned product was provided without cost to each household during monthly home visits, and compliance with product use was monitored. Households were contacted by telephone weekly and with a home visit monthly for 11 months. Hand cultures were obtained before and after handwashing at baseline and after 11 months, using a modified glove juice technique.

Overall, there were no significant differences in pre-to-post handwashing counts at baseline ($p = 0.41$), but by the end of one year, post-wash counts were significantly lower than pre-wash ($p = 0.000$) for those using either antimicrobial or plain soap. There were no significant differences in mean log counts either before or after handwashing between those using the antimicrobial or plain soap at baseline or after a year of use (all p values >0.28). For the group using antimicrobial soap, higher counts were observed post-handwashing in 31.3% of paired samples at baseline and 26.7% after one year ($p = 0.03$). A single handwash had minimal effect on quantity of hand flora, but there were significant effects over time, regardless of whether antimicrobial or plain soap was used. In the absence of more definitive evidence, the risk-benefit ratio argues

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Funded in part by 1R01NR05251-01, "Home Hygiene Practices and Infection Transmission in Households," National Institutes of Health, National Institute for Nursing Research.

in favor of targeted rather than ubiquitous, general household use of antimicrobial soap.

KEY WORDS: handwashing; sanitation.

INTRODUCTION

While hand hygiene is touted as one of the most important measures to prevent the transmission of infections in the community and in healthcare settings, little research has been done to examine the short and longterm effects of traditional handwashing with antimicrobial or plain, non-antimicrobial soap on total microbial counts of hands among persons in the community. The purpose of this study was to measure the effects of handwashing with a plain or antimicrobial soap on bacterial counts of the hands before and after a single wash and before and after handwashing following a year of product use.

METHODS

Setting and Sample

Subjects for this study were volunteer participants (n = 238) in a longitudinal double blind, randomized clinical trial of the effect of home hygiene products on prevalence of infectious diseases in the home. They were the primary caretakers in households in northern Manhattan recruited to this study through local pediatric clinics, posters placed in the neighborhood and on the Columbia University Health Sciences Campus, and by word-of-mouth. More than 90% of participants were of hispanic ethnicity and approximately half were born outside the U.S. There were 14 dropouts (5.9%) during the course of the longitudinal data collection period: 9 (64.3%) moved from the study area, 4 (28.6%) stopped using the assigned products, and 1 (7.1%) were inadvertently given the wrong product.

Procedures

The study was approved by the Institutional Review Board of New York Presbyterian Medical Center, and each participant gave written informed consent. Samples were obtained by one of four trained interviewers during a one-hour home visit. Three of the interviewers were for-

eign-born physicians and the fourth was a professional community worker, all of whom spoke fluent English and Spanish. Interviewers underwent an extensive orientation and training period which involved demonstration and return demonstration of the interview and sample collection protocols. Hand cultures were obtained during a home visit. The Project Director attended a 10% random sample of home visits with the interviewers as a quality control measure. As part of an extensive home hygiene interview and assessment, each participant was asked to estimate the number of times she/he washed hands daily. Then participants were asked to wash their hands in their usual manner, and the handwash was timed in seconds by the interviewer.

During the first, baseline interview, the type of handwashing soap present in the house was recorded (i.e., antimicrobial or non-antimicrobial). Then each household was randomly assigned to one of two handwashing products, and these products were delivered to their home without cost each month. One product was a liquid non-antibacterial plain soap. The other was a similar liquid soap containing 0.2% triclosan (antimicrobial soap). Both were commercially available over the counter. All participants were also provided with non-antibacterial bar soap (Zest, Procter & Gamble, Cincinnati, OH). Participants were instructed to use only the product provided throughout the 12 month study. Both liquid soaps were supplied in plastic containers with a plunger-type dispenser. Each month, use of the product was monitored by weighing remaining product and by visual inspection for the presence of other products in the home. Compliance with use of the assigned product, as assessed by these procedures, was essentially 100%.

Hand Culturing Technique

Cultures were obtained immediately before and after handwashing with the assigned soap. Two sets of paired pre- and post-handwash samples were obtained—one at the beginning of the study (between 9/00–1/01) and the second after participants had used the same handwashing product for 12 months (between 9/01–2/02). Participants were asked to wash their hands in their usual manner and then dry them with a clean paper towel. The hand to be cultured (right or left) was randomly selected by the data collector by flipping a coin. The data collector timed the hand wash in seconds with a stop watch.

A modified glove-juice technique was used whereby the subject inserted the hand into a sterile polyethylene bag containing 50 ml of sampling solution (0.075M phosphate buffer, pH 7.9, containing 0.1% poly-

sorbate 80). This solution disperses macrocolonies into single cells for quantitation. The entire hand was massaged through the wall of the bag for 1 min and samples were taken to the Clinical Microbiology Laboratory at the study institution within a few hours for processing. Data collectors were trained in the sampling technique and demonstrated competence and consistency in the presence of the co-investigators before obtaining samples.

Laboratory Techniques

Samples were diluted 10-fold, up to 10^{-3} , and spread plated onto 5% sheep blood agar (Becton Dickinson Microbiology Systems, Sparks, MD), incubated at 35° C and observed daily for growth over 48 hours for bacteria and up to 7 days for yeast. Total counts were calculated from the blood agar plates.

Data Analysis

For the purposes of this study, only total counts were analyzed, and data on species are not included. Counts of colony-forming units (CFU) were converted to log base₁₀ to normalize the data. The Statistical Package for the Social Sciences 10 for Windows (SPSS, Chicago, IL) was used to compute paired t-tests to compare pre- and post-handwashing CFU counts for each individual, and unpaired t-tests between those using antimicrobial and non-antimicrobial soap. The Pearson correlation coefficient was used to examine the relationship between duration and frequency of handwashing and pre and post-wash counts. The highest detectable count in this study was 7.2 log CFU/hand. Chi square analyses and relative risks were calculated with Epi Info 6 (Centers for Disease Control and Prevention, Atlanta, GA) to compare the proportion of counts above the highest detectable range between those using antimicrobial or plain soap at baseline and between baseline and the end of year one for both groups combined. All tests were two-tailed and considered significant at $p < 0.05$.

RESULTS

A total of 220 paired pre and post wash samples were available at baseline and 224 at the end of one year. Counts ranged from 3.1 to >7.2 logs. At baseline 28.1% of households had an antimicrobial soap present

for handwashing; 71.9% had only plain, non-antimicrobial soap. There were no significant differences in CFU either before or after handwashing based on whether there was antimicrobial soap present in the home or not ($p = 0.66$ and 0.19 respectively). In paired samples, there was no significant reduction in counts after handwashing at baseline for persons using the antimicrobial soap ($p = 0.52$), but those using plain soap had lower counts after washing ($p = 0.04$). By the end of one year, post-wash counts were significantly lower than pre-wash ($p < 0.001$) for those using either antimicrobial or plain soap, Table 1. There were no significant differences in mean log counts either before or after handwashing between those using the antimicrobial soap and those using non-antimicrobial soap at baseline or after a year of use (all p values > 0.28), Figure 1.

At baseline, about one-fifth of samples (19.6% pre-handwashing and 20.8% post-wash) yielded a CFU count above the highest detectable range (7.2 logs or greater). There were no significant differences in the initial sample between the group using antimicrobial or plain soap in the proportion of samples that had the highest detectable log counts (7.2 or greater) either before handwashing (25.9% and 16.8% respectively, $p = 0.10$) or after handwashing (25.4% and 19.4% respectively, $p = 0.29$). By the end of one year, however, only two samples before washing and none after handwashing were above the detectable range (relative risk for pre-

TABLE 1

Mean Log Pre and Post-Handwashing Microbial Counts
(\pm standard deviation) at Baseline and One Year

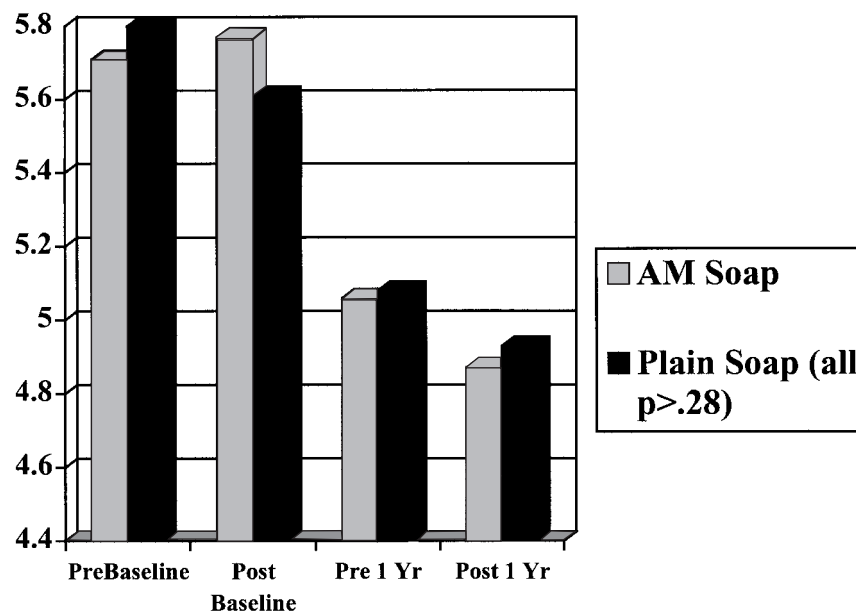
	<i>Baseline (n = 220)</i>			<i>One Year (n = 224)</i>		
	<i>Prewash (\pmSD)</i>	<i>Postwash (\pmSD)</i>	<i>p value* [95% CL]±</i>	<i>Prewash (\pmSD)</i>	<i>Postwash (\pmSD)</i>	<i>p value* [95% CL]±</i>
Antimicrobial soap	5.71 (1.04)	5.77 (1.03)	0.52 [-.23, .11]	5.06 (0.59)	4.87 (0.62)	0.000 [.09, .29]
Non-antimicrobial soap	5.80 (0.95)	5.62 (1.05)	0.04 [.009, .36]	5.08 (0.68)	4.93 (0.65)	0.003 [.05, .25]
Total group	5.76 (1.00)	5.71 (1.05)	0.41 [.07, .17]	5.07 (0.64)	4.90 (0.64)	0.000 [.10, .24]

*Difference between pre and post-wash CFU counts, paired t-test.

±95% Confidence Limits.

FIGURE 1

Comparison of mean pre and post-handwash CFU counts between groups using antimicrobial (AM) or plain soap.



wash samples comparing baseline and end of one year, 2.20; 95% confidence intervals (CI): 1.94, 2.49), and for post-handwash samples relative risk 2.33; 95% CI: 2.08, 2.61), Table 2.

For those individuals using a non-antimicrobial soap, post-handwashing CFU counts were higher than pre-wash counts in 31.5% of paired samples at baseline and in 37.6% after one year ($p = 0.34$). For the group using antimicrobial soap, higher counts were observed post-handwashing in 31.3% of paired samples at baseline and 26.7% after one year ($p = 0.03$). At one year, those using antimicrobial soap were less likely to have higher post-washing CFU counts when compared to pre-wash counts than those using plain soap (26.7% versus 37.6% respectively, $p = 0.08$).

Participants reported washing their hands 2–50 times/day (mean: 12.4 ± 8.6 standard deviation). There were no significant differences between the groups using antimicrobial or plain soap in self-reported frequency of handwashing or observed duration of handwash at either the baseline or after one year (all $p > 0.07$). There was no significant correla-

TABLE 2

Proportion of Colony-Forming Unit (CFU) Counts 7.2 Logs or Greater

	<i>Baseline</i>		<i>One Year</i>	
	<i>Prewash</i>	<i>Postwash</i>	<i>Prewash</i>	<i>Postwash</i>
Antimicrobial soap	25.9%	25.4%	0.8%	0
Non-antimicrobial soap	27.3%	22.5%	0.9%	0
p value	p = 0.10*	p = 0.29*	p < 0.0000 + (RR:2.20; 95% CI: 1.94, 2.49) ¹	p < 0.0000 + (RR: 2.33; 95% CI: 2.08, 2.61) ¹

*Comparing proportion with high counts between those using antimicrobial or non-antimicrobial soap, chi-square.

*Comparing proportion of high counts before and after handwashing between baseline and Year 1 for both antimicrobial and non-antimicrobial soap groups together, chi-square.

¹RR = Relative Risk; 95% CI = 95% Confidence Intervals.

tion between reported times hands were washed each day or observed duration of handwashing and log CFU counts either before or after handwashing or between the soap groups, Table 3.

DISCUSSION

The mean CFU counts in this population were slightly higher, 0.5–1 log on average, than those reported in healthcare personnel,¹⁻³ which is not surprising, given the probable variation in long term hand hygiene practices between individuals in the community and those working in hospitals. Despite this, however, it was striking in this study that there was very little measurable effect of handwashing on microbial counts on hands. In fact, following a single wash (i.e. the baseline sample) there was no significant reduction in CFU for persons using an antimicrobial soap. There was, however, a clear impact over time, since participants had significantly lower mean counts at the end of a year of consistent use of the handwashing soap provided to them, despite no difference in self-reported frequency of washing. It is possible, however, that hand hygiene habits changed over time because of availability of free products and because participants knew that their hygiene practices were being studied.

TABLE 3

Correlations Between Hand Hygiene Habits and Mean Post-Handwashing log CFU

<i>Hand Hygiene Factor</i>	<i>Baseline</i>		<i>After One Year</i>	
	<i>Antimicrobial Soap</i>	<i>Plain Soap</i>	<i>Antimicrobial Soap</i>	<i>Plain Soap</i>
Mean post-wash log CFU	5.77	5.62	4.87	4.93
Self-reported mean (\pm SD) frequency of hand-washing/day (p value)*	11.8 (7.28) (p = 0.47)	13.0 (9.74) (p = 0.23)	10.4 (5.09) (p = 0.34)	11.9 (6.82) (p = 0.07)
Observed mean duration of handwash [†]	16.5 (9.45) secs (p = 0.41)	15.4 (9.43) secs (p = 0.72)	18.6 (8.25) secs (p = 0.45)	18.7 (8.31) secs (p = 0.66)

SD = Standard deviation.

*Correlation between post-handwashing log CFU and reported frequency of handwashing, Pearson Correlation Coefficient.

[†]Correlation between post-handwashing log CFU and duration of handwash, Pearson Correlation Coefficient.

In about one-third of paired tests, the post-wash counts were actually higher than pre-wash. This has been reported in other studies and is likely the result of increased skin shedding during washing associated with mechanical friction.^{2,4,5} This increase in skin shedding associated with traditional handwashing and surgical scrubbing is one important rationale in health care settings for recommendations to minimize use of scrub brushes and to use alcohol hand rubs/sanitizers in lieu of handwashing for skin degerming.^{4,6,7} Further, there were few differences in CFU counts between those using an antimicrobial product when compared with those using a plain soap, except that those using the plain soap were significantly more likely to have a larger proportion higher post-wash counts (as compared with pre-wash) after one year of use.

This is not the first study to report a minimal effect of handwashing. Bettin and colleagues⁸ compared the effects of a plain soap with an

antiseptic containing chlorhexidine gluconate, and found no differences in residual counts of *Clostridium difficile* on bare hands and lower counts after plain soap wash on gloved hands. Bidawid⁹ reported a 30-fold reduction in virus transfer to lettuce from fingerpads treated with a topical handwashing agent, but surprisingly found no virus transfer from fingers rinsed with 15 ml of water alone. In one study, triclosan was reported to be much less effective than plain soap after a 3-min scrub against hand surface bacteria.¹⁰ Others have also reported the failure of soap handwashing to prevent microbial transfer from patients to healthcare providers.^{11,12}

In tests of the antimicrobial effectiveness of handwashing, it is important to differentiate whether the natural colonizing or the transient flora is being measured. Both approaches have advantages and disadvantages. Handwashing with a non-antimicrobial soap does little to modify the natural flora.¹³⁻¹⁵ In fact, such an effect would be undesirable. For healthy, community-dwelling persons, the primary purpose of handwashing is to prevent or reduce the acquisition of transient organisms which might be potentially pathogenic. This is unlike the healthcare setting in which hand hygiene is designed to minimize the clinician's own colonizing flora as well as to prevent the cross-transmission of organisms picked up in the course of patient care. Hence, studies of the effects of hand hygiene on the quantification of natural flora may not be the most appropriate outcome measure for application to general public health, and this is a limitation of our study. On the other hand, tests which involve the artificial contamination of hands or other surfaces with transient flora are fraught with threats to reliability and validity (e.g., variations in counts due to different environmental or test conditions, inoculum, organism death rates, etc.) and require strict adherence to protocol. As a result, such tests are less predictable and their clinical relevance is more difficult to assess.

Ultimately, the appropriate outcome measure to assess the value of handwashing is not a reduction in microbial counts, but effects on the ecology of the natural flora and on infection rates. Multiple community-based studies have demonstrated significant reductions in infections, usually gastrointestinal or respiratory, associated with hand hygiene interventions.¹⁶⁻²⁶ This seeming contradiction between a failure of handwashing to reduce microbial counts on hands and a protective effect against infections may be explained by several factors. First, there is the potential for publication bias, i.e. that only those studies which show a significant impact on infections are published. Further, there may be other methodologic weaknesses in the outcome studies. Despite such methodologic weaknesses, however, our recent analysis of the existing literature^{27,28} argue against these explanations.

A second reason for the discrepancy between poor log CFU reductions with handwashing and yet prevention of infections could be that most tests of handwashing quantitate bacteria and yeast, and yet the most common community-acquired infectious diseases are viral, not bacterial, in etiology. Generally, however, the effectiveness of specific handwashing products against viruses is often not measurably different (i.e. better or worse) overall than effectiveness against bacteria.²⁹⁻³⁴ While antiviral testing for hand hygiene products would certainly be advantageous,³⁵ it is not the likely explanation of the discrepancy.

A more likely explanation is that, as discussed above, handwashing with commercially available products marketed for the public may not have a noticeable effect on natural flora, but may be important in protecting against contaminating organisms picked up in person-to-person or environmental contacts. The same rationale could be applied to assessing the potential value of antimicrobial versus plain soap products. Although we found little difference in microbial counts on hands of those using either product, the important question is whether there is any differential effect on risk of infection. Keswick et al.³⁶ reviewed intervention studies which have attempted to assess the effects of handwashing in general, and of antimicrobial soaps specifically. He provided evidence that antimicrobial soaps may be beneficial for preventing or treating skin infections and for use in healthcare settings or with high risk populations, but no such evidence was available for general use of antimicrobial hand hygiene products by the healthy public.

One could argue that if antimicrobial products have no negative effects and might offer benefit, that is sufficient rationale for their use. There is, however, one theoretic concern regarding ubiquitous public use of antimicrobial skin products; some have cautioned regarding the potential for cross-resistance between triclosan and several antibiotics used to treat clinical infection.³⁷⁻⁴³ Others have suggested that this is quite unlikely to become a widespread problem,⁴⁴⁻⁴⁶ but the issue is unresolved at this time. In the absence of more definitive evidence for any general protective effect, the risk-benefit ratio argues in favor of targeted, situational use of antimicrobial soaps rather than ubiquitous, general household use.

In summary, the results of this study demonstrate the minimal effect of a single handwash with either plain or antimicrobial soap on the quantity of hand flora. On the other hand, the significant reduction in CFU counts after one year of use of products provided to participants indicates that sustained and consistent hand hygiene practices significantly reduce microbial counts over time. There may be misunderstanding about the primary purpose of handwashing in the general population (to remove

or reduce potential contaminating pathogens but *not* to reduce counts of normal, colonizing flora) as well as the effectiveness of handwashing (i.e., little effect on natural flora, and sometimes even an increase in microbial counts following handwashing, but potential protection against symptomatic infection). This study should help to diffuse myths and rituals about hand hygiene and provide a better perspective on its potential role in community health.

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