

Clinical Studies to Demonstrate the Efficacy of a Liquid Cleanser Containing 0.15% Trichlorocarbanilide (TCC).

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ABSTRACT:

DATE D, GUPTA V, BHADSAWALE M, AYACHIT U, PATEL K, MORTILLO S, BHANDARE SP, VANDEVEN M, CHATDAMRONGMONGKOL S. CLINICAL STUDIES TO DEMONSTRATE THE EFFICACY OF A LIQUID CLEANSER CONTAINING 0.15% TRICHLOROCARBANILIDE (TCC). THAI J DERMATOL 2011; 27: 247-259.

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Background: Hand washing is an effective procedure to protect against infection risk. Health care associated infections or HCAI are associated with hospital-acquired infection, the prolongation of hospitalization as well as enhanced morbidity and mortality rates. Reducing HCAI by an effective hand washing technique using antibacterial cleansers or soaps is recommended.

Objective: To demonstrate the effectiveness of a liquid cleanser with 0.15% trichlorocarbanilide (TCC) to eliminate transient microbial flora from the hands when used in a handwashing procedure, and to inhibit the growth of transient bacteria compared to an ordinary soap.

Materials and Methods: The clinical studies were designed to demonstrate the efficacy of a liquid cleanser containing 0.15% TCC against marker organisms such as Gram negative (*Escherichia coli*) or Gram positive (*Staphylococcus aureus*) bacteria. The handwash method used *E. coli* as the marker organism and was based on ASTM (American Society for testing and materials) E1174. The cup scrub method used *S. aureus* as the marker organism and was based on a modification of ASTM E1874.

Results: Twenty subjects completed these 2 studies. After a single hand wash with liquid cleanser containing 0.15% TCC the log₁₀ reduction of *E. coli* was 3.24 (99.94%). The log₁₀ reduction of *S. aureus* compared to an ordinary bar soap using the modified cup scrub method was 2.05 for the liquid cleanser containing 0.15% TCC.

Conclusion: A liquid cleanser containing 0.15 % TCC was highly effective against both Gram negative and Gram positive bacteria. The liquid cleanser eliminated 99.94% of *E. coli* and showed significant residual antibacterial protection against *S. aureus* bacteria compared to an ordinary bar soap.

Key word: Liquid cleanser, antibacterial ingredient, trichlorocarbanilide, TCC

บทคัดย่อ :

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บทนำ: การล้างมืออย่างถูกวิธีเป็นวิธีการที่ง่ายและมีประสิทธิภาพสูงในการลดปัญหาการแพร่เชื้อจากการสัมผัสจากการศึกษาวิจัยพบว่าปัญหาการแพร่เชื้อจากบุคลากรทางการแพทย์ยังเป็นปัญหาที่สำคัญ โดยทำให้ผู้ป่วยต้องพักรักษาตัวในโรงพยาบาลยาวนานขึ้นจากการติดเชื้อแทรกซ้อน และที่สำคัญทำให้ผู้ป่วยเสี่ยงต่อการเสียชีวิตมากขึ้นด้วย สำหรับข้อแนะนำที่สำคัญในการลดปัญหาปัญหาการแพร่เชื้อจากบุคลากรทางการแพทย์ ก็คือการณรงค์ให้การล้างมืออย่างถูกวิธีร่วมกับใช้สบู่ที่มีสารต่อต้านเชื้อแบคทีเรีย

วัตถุประสงค์: เพื่อศึกษาประสิทธิภาพของสบู่เหลวที่มีส่วนผสมของสารต่อต้านเชื้อแบคทีเรีย 0.15% trichlorocarbonilide (TCC) ในการกำจัดเชื้อแบคทีเรียบริเวณมือ และเพื่อศึกษาผลการยับยั้งการเพิ่มจำนวนของ เชื้อแบคทีเรียเมื่อเทียบกับสบู่ชนิดธรรมดา

ขั้นตอนและวิธีการ: งานวิจัยนี้ทำการศึกษาประสิทธิภาพของสบู่เหลวที่มีส่วนผสมของสาร 0.15% TCC โดยทำการศึกษาจากเชื้อแบคทีเรียชนิดแกรมลบ (*Escherichia coli*) และเชื้อแกรมบวก (*Staphylococcus aureus*) สำหรับการศึกษาด้วยเชื้อ *E.coli* ใช้วิธีการล้างมือและการฟอกสบู่ซึ่งได้พัฒนาตามวิธีของ ASTM E1174 และ การศึกษาด้วยเชื้อ *S.aureus* ใช้วิธีการล้างมือและการฟอกสบู่ตาม ASTM E1874

ผลการศึกษา: จากผู้เข้าร่วมวิจัยทั้งหมด 20 คน จากทั้ง 2 การศึกษานี้ พบว่าการล้างมือเพียงครั้งเดียวด้วยสบู่เหลวที่มีส่วนผสมของสาร 0.15 % TCC สามารถลดจำนวนเชื้อแบคทีเรียชนิด *Escherichia coli* ได้เท่ากับ $\log_{10}$ 3.24 หรือ ร้อยละ 99.94 และ การล้างมือด้วยสบู่เหลวที่มีส่วนผสมของสาร 0.15% TCC ด้วยวิธี modified cup scrub นั้นสามารถ ลดจำนวนเชื้อแบคทีเรียชนิด *Staphylococcus aureus* ได้เท่ากับ $\log_{10}$ 2.05 เมื่อเปรียบเทียบกับสบู่ชนิดธรรมดา

สรุป: สบู่เหลวที่มีส่วนผสมของสาร 0.15% TCC มีประสิทธิภาพสูงในการยับยั้งเชื้อแบคทีเรียทั้งชนิดแกรมลบและแกรมบวก โดยสบู่เหลวสามารถกำจัดเชื้อแบคทีเรียชนิด *Escherichia coli* ได้ถึงร้อยละ 99.94 และสามารถกำจัดเชื้อแบคทีเรียชนิด *Staphylococcus aureus* ได้อย่างมีนัยสำคัญเมื่อเปรียบเทียบกับสบู่ชนิดธรรมดา

คำสำคัญ: สบู่เหลว, สารต่อต้านเชื้อแบคทีเรีย, สารไตรคลอโรคาร์บานิลได์, ที่ชีชี

Introduction:

Bacterial infections are a significant health problem around the world, especially in vulnerable populations, such as children and the elderly. The WHO (World Health Organization) guideline for hand washing with antibacterial soap or cleanser was published in 2009¹. For the prevention of various infections including bacterial pneumonia, septicemia and importantly, diarrhea that was associated with the death of 3.5 million infants and children per year, regular hand washing is an easy, highly effective and inexpensive procedure².

The United States Centers of Disease Control and Prevention (CDC) strongly recommend that medical personnel and health care providers best practices to include proper hand washing during procedures³. Numerous published data support the evidence that hand washing can reduce health-related illness and reduce the spread of the pathogen to others^{4,5}. There is a higher risk of infection in cases of ineffective or lack of concern for this preventive procedure³. Hand washing before each meal and after toilet use was more effective in reducing mortality rates from infection than vaccination or some medications, and could reduce the death rate from diarrheal disease by greater than 50%⁶.

By conducting and launching a health policy about community awareness for regular hand washing in Thailand, Simmerman et al. successfully reported lowering the rate of influenza virus contamination in households⁷. Other reports demonstrated that

antibacterial soap can more effectively reduce the transmission of bacterial pathogens from hands to food than ordinary soap^{8,9}. Additional published reports demonstrate the superiority of antibacterial soaps in reducing bacteria compared to plain soap¹⁰.

TCC is an antibacterial ingredient with activity against bacteria especially Gram positive organisms, which are commonly found on the skin^{11,12}.

For skin infections caused by *Staphylococcus* or *Streptococcus*, soap containing antibacterial agents is essential, since not only can it eradicate the bacterial pathogen but also be persistent on the skin to prevent bacterial re-growth or new infections¹³. Soap with antibacterial properties is important to reduce the risk of bacterial infection in the general population, and for people with underlying skin disorders and high-risk populations with illnesses such as diabetes, the immune-compromised or burn patients.

The objective of this research was to demonstrate the ability of a liquid cleanser with 0.15% trichlorocarbanilide (TCC) to eliminate bacteria from the hands and to inhibit the growth of bacteria compared to an ordinary soap without antibacterial ingredient.

Material and Methods:

The study protocols were developed by the Colgate-Palmolive Dermal Clinical Research Group. The hand wash study was performed at the Colgate-Palmolive Technology Center, Piscataway, New Jersey. The modified cup scrub study was performed at the Kelkar

Education Trust Scientific Research Center, Mumbai, India and was approved by Kelkar's Scientific Research Center Ethics Committee.

The protocols used to test the efficacy of the liquid cleanser containing 0.15% TCC followed industry published standards^{14,15} and were designed to demonstrate efficacy against marker organisms such as Gram negative (*Escherichia coli*) or Gram positive (*Staphylococcus aureus*) bacteria. The inclusion/exclusion criteria for both studies are described below.

Inclusion criteria—Eligible study subjects had to be female, between the ages of 18 and 55 and in good general health. They were required to abstain from the use of antibacterial or medicated bar soaps, liquid soaps, hand gels, towelettes or wipes, talcs, lotions/creams, dishwashing liquid and shampoos, including those labeled antidandruff. They were required to refrain from using topical steroids and topical/systemic antibiotic medications for at least one week prior to study start and for the duration of the entire study. Forearms, hands and wrists should be free of dermatoses, cuts, lesions, hangnails or other skin disorders.

Exclusion criteria - Individuals were excluded from the study if they had known sensitivities to the test

microorganisms or the antibacterial ingredient TCC, a medical history of rheumatic fever, heart murmur, mitral valve prolapse, endocarditis or congenital valvular lesion, medically diagnosed with herpes virus or varicella infection or other contagious skin diseases, diabetes, hepatitis, HIV-positive or immunocompromised. Individuals with any illness or disease, specifically heart, lung, kidney, endocrine, dermatologic or other abnormality or pathologic condition were also excluded. Organ transplant recipients, and individuals with any dermatological disease or any other acute or chronic disease were also excluded. Individuals currently using any systemic, oral or topical antibiotics two weeks prior to study start were excluded. Pregnant or breastfeeding females were also excluded.

Clinical Procedure (Hand Wash Study)—The objective of this study was to evaluate the ability of a liquid cleanser containing 0.15% TCC to eliminate bacteria from the hands after a single hand wash. The method used was based on the ASTM E1174¹⁴. A Gram negative bacteria, *E. coli*, was used as the marker organism. Twelve subjects were recruited for the hand wash test.

Table 1 Test material evaluated in this study**Test Product**Liquid Cleanser¹¹Protex Shower Crème containing 0.15% TCC**Test Organism:**

Escherichia coli ATCC 11229 was used and prepared for the test as follows:

Transfer a colony from the stock culture of the bacteria to 10 mL of Tryptic Soy Broth (TSB).

Incubate the stock culture in a shaker for 24 hours at $35 \pm 2^\circ\text{C}$.

Take 0.5 mL of overnight culture and transfer to 500 mL TSB. Incubate overnight at 35°C (bacterial suspension used for testing)

Experimental Procedure:**Washout Period:**

Participants were asked to refrain from using any antibacterial or medicated bar soaps, liquid soaps, hand gels, towelettes or wipes, talcs, lotions or creams, dishwashing liquid and shampoos including those labeled antidandruff during the one week washout period.

They were given a personal hygiene kit including a non-antibacterial soap and an antiperspirant/deodorant which does not contain any known antibacterial ingredients for normal use throughout the study. Participants used these products exclusively during their participation in the study.

The participants were not to come in contact with materials such as detergents, solvents, acids, or bases. If contact with could not be avoided, the hands were to be protected by use of rubber gloves. Rubber gloves were issued with instructions they be used to avoid contact with detergents, acids, bases or solvents.

Participants were instructed to refrain from swimming in chlorine-treated pools, hot tubs, and spas 24 hours prior to the test. They were instructed to refrain from using any cosmetic products on their hands such as lotions, perfumes and hair fixatives (mousses, gels, etc.) 24 hours prior to the start of the wash phase of the study.

Study Baseline Pre-Wash:

All jewelry on the hands and wrists were removed. All participants, prior to their baseline bacteria count, performed a pre-wash to remove oil and dirt using the following procedure:

Wet both hands under running warm ($40 \pm 2^\circ\text{C}$) tap water. Using a pipette, dispense 5 mL of a mild, non-antimicrobial liquid soap into cupped hands and spread soap all over hands. Add a small amount of water from the tap and wash both hands and lower third of the forearms in a vigorous manner for 30 seconds.

Rinse under running warm tap water for 30 seconds.

Dry hands with disposable paper towels.

Baseline Bacteria Count:

After the pre-wash, baseline bacterial counts were measured for each subject using the following procedure: A total of 4.5 mL (approximately 10^8 organisms/mL) of the contaminant culture was dispensed onto the hands of all participants then rubbed thoroughly over the surfaces of the hands, not going above the wrist, using the following procedure:

A technician applied 1.5 mL of contaminant culture onto each subject's cupped hands.

Subjects rubbed the contaminant culture thoroughly over the surfaces of their hands for 20 seconds, making sure to not go about the wrist and allowed it to air dry for 30 seconds.

The steps above were repeated two more times such that a total of 4.5 mL of contaminant culture had been applied. After the last 1.5 mL contaminant culture had been applied, the hands were allowed to air-dry for an extra 30 seconds so that the total drying time was 2 minutes.

Food storage plastic bags (approximately 11.5 in x 12.5 in) were placed on each of the right and left hands. A 75 mL aliquot of bacterial collection fluid was aseptically added into each bag and the bacterial sampling procedure was carried out as described below. The hands and forearms were then washed thoroughly with a mild, non-antibacterial soap.

Treatment Procedure:

Prior to the hand wash with the test product, 4.5 mL of the contaminant culture was dispensed onto the hands of all participants as described above. Immediately after the contamination step, the participants' hands were treated with the liquid cleanser under close supervision.

The test product was applied in the following manner: Dispense 1.5 mL of the test product using a pipette into the subject's cupped hands. Add a small amount of water from the tap and lather the hands for 30 seconds (palm, back of hand and fingers to be included), rinse for 30 seconds and allow hands to air-dry for 5 minutes.

Bacterial Sampling Procedure:

Plastic food storage bags were placed over the right and left hands immediately after washing and rinsing. A 75 mL aliquot of bacterial collection fluid was aseptically added into each bag. The plastic bag on each hand was secured and massaged for one minute in a uniform manner by a lab technician. An aliquot of the fluid was aseptically obtained directly from the bagged hand without touching the hand in the process. The sample was appropriately diluted in neutralizing phosphate buffer (0.1% Triton X-100 in 0.075M phosphate buffer containing 11.7 g/L lecithin and 2% Tween-80, adjusted to pH 7.8)

After bacterial sampling, participants washed their hands under running warm tap water to wash off the

bacterial collection fluid from the skin. Both hands were then dried with disposable paper towels.

The participant's hands were disinfected by immersing hands in 70% isopropanol for 3 minutes at the end of the study.

Bacterial Counts of Sampling Solution:

An aliquot (0.1 mL) of the bacterial suspension collected from the hands was plated in duplicate on the surface of Mac Conkey's agar plates. The prepared plates were incubated for approximately 24 hours at 35°C. Standard plate counting procedures were used to count only the E. coli colonies.

Data Analysis:

The colony forming units (cfu) were calculated as follows:

CFU/hand = cfu/plate x dilution factor x 10 (since only 0.1 mL plated) x 75 (volume of bacterial collection fluid)

The cfu for the left and right hands of each participant were averaged and transformed to $\log_{10}$.

The difference in the averaged $\log_{10}$ cfu/hand between baseline and post-treatment for each participant was calculated and mean determined. A two-tailed paired t-test was used to compare the level of significance between the mean log bacterial counts at baseline to the mean log bacterial counts post-treatment at $\alpha = 0.05$.

Clinical Procedure (Modified Cup Scrub Study) - The objective of this study was to evaluate the antibacterial efficacy of a liquid cleanser containing 0.15% TCC against a Gram positive organism, *Staphylococcus aureus*, using a modified cup scrub method based on ASTM E1874¹⁵ and previously published research^{12,16}. The test measured the residual antibacterial efficacy of the liquid cleanser with 0.15% TCC compared to an ordinary bar soap without antibacterial ingredient. Eight⁸ subjects were recruited for the modified cup scrub test.

Table 2 Test materials evaluated in this study

Code	Test Product
A	Liquid Cleanser ¹
B	Ordinary Bar Soap ²

¹ Protex Shower Crème containing 0.15% TCC

² Ordinary Bar Soap without antibacterial ingredient
TCC or Trichlorocarbanilide

Two materials were evaluated in this study. The experimental tested product was liquid soap with 0.15% TCC and ordinary bar soap without antibacterial agent as a control.

Test Organism:

Staphylococcus aureus ATCC 6538 was used and prepared for the test as follows:

Transfer a colony from stock plate culture of the bacteria to 30 mL of Tryptic Soy Broth (TSB)

Incubate the stock culture in a shaker incubator for 24 hours at $35 \pm 2^\circ\text{C}$.

Centrifuge the stock culture at 3200 rpm for 20-30 minutes.

Discard the supernatant and re-suspend the pellet in 10 mL TSB.

Adjust the test organism to 0.1 OD units in Phosphate Buffered Saline (PSB) solution containing 0.05% Pluronic L-44.

Experimental Procedure:**Treatment Procedure:**

The participants were advised to wear clothing on test days that allowed easy access to the hands and forearms and to remove all jewelry from the wrists and hands before washing was done. Each panelist conducted their own supervised wash regimen observed by the trained study personnel.

Prior to washing on the first day, each forearm was marked into two sections: an upper and a lower section. Each section was washed with one of the test products following a randomization scheme. There were 7

washes over a 3 day period. There were three washes on Days 1-2 and one wash on Day 3. On Days 1-2, the washings occurred at least one hour apart.

Washing directions for Liquid Soaps:

Test sites were wetted with warm ($40 \pm 2^\circ\text{C}$) tap water. Technicians dispensed 1.5 ml of the liquid cleanser to their gloved hand. Test sites were lathered for 60 seconds followed by rinsing for 30 seconds with running tap water ($40 \pm 2^\circ\text{C}$). The sites were patted dry with a disposable paper towel. On day three, after washing, the site was air dried for 15 minutes. The test bacterial organism was then applied to the test sites.

Washing direction for Bar Soaps:

Test sites were wetted with warm ($40 \pm 2^\circ\text{C}$) tap water. The wetted test bar was rotated ten¹⁰ times by the technician. The wetted bar soap was then rubbed against the test site by a gloved technician for fifteen¹⁵ seconds. The site was then lathered by a gloved technician's hand for forty-five (45) seconds. Test sites were rinsed under running warm tap water for fifteen¹⁵ seconds, and then patted dry with a disposable paper towel. On day three, after washing, the sites were air dried for 15 minutes. The test bacterial organism was then applied to the test sites.

Bacterial Sampling Procedure:

On day three, prior to the washing process described above, two circular sites, area = 7.1 cm^2 , were delineated on each forearm section. After the forearms had been air-dried for 15 minutes after the wash on day

three, the participants were taken to a designated area and asked to sit with their arms straight out. Each site was applied with 0.025 ml of overnight bacterial suspension (10^6 colony forming unit (cfu) by the trained technicians. Then the test site was occluded with a plastic chamber and secured with transparent, adhesive tape (Tegaderm®) for 5 hours. The participants were asked to sit at the test facility for 5 hours.

Five hours later, the bacteria were harvested by the technicians using a glass cylinder cup, (area = 7.1cm^2). Harvesting of each site was done by pipetting 1 mL of Lethéen Broth into the hollow glass cylinder and the massaging the skin for 60 seconds with a sterile glass rod, removing the fluid, and adding a second 1 mL of Lethéen Broth for another 60 second massage, removing the fluid and pooling the two samples. The samples were plated on Microbial Content Agar (MCA) and incubated at 37°C for 48 hours. Standard plate counting procedures were used to count only the *S. aureus* colonies.

Data Analysis:

An Analysis of Variance (ANOVA) was performed on the calculated log colony forming units (CFU/ cm^2) of each site using participants and treatment as the effects, to determine if overall significant differences exist among the treatments at the 5% significance level

($\alpha=0.05$). If the F-test showed significant differences among treatments, a Tukey's test was done on each treatment pair as a post-hoc multiple comparisons. The means and standard error of the log CFU's were computed for each treatment with the difference in the means from the baseline providing a measure of the antibacterial efficacy expressed in log CFU's reduction/recovery.

Results – Hand Wash Test:

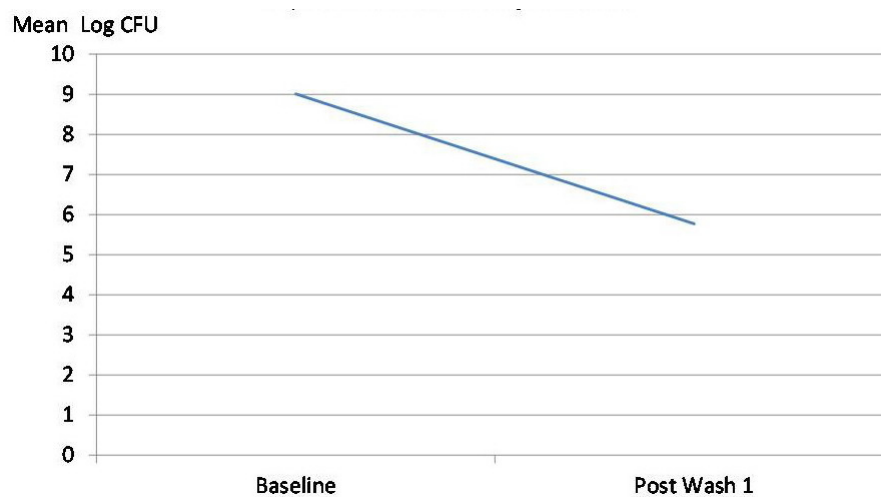
Summarizing the results of all participants, the mean of log CFU of the marker bacteria (*E. coli*) at baseline and after single handwash with liquid cleanser containing 0.15% TCC was 9.01 and 5.77, respectively as shown in Table 3. The mean (SE) log reduction from baseline was 3.24 or 99.94% (Table 3, Figure1). This result demonstrated that the liquid cleanser with 0.15% TCC significantly reduced the marker bacteria.

Results Modified Cup Scrub Study:

Summarizing the results of all participants, the mean (SE) of log CFU of the marker bacteria (*S. aureus*) for the liquid cleanser with 0.15% TCC and ordinary bar soap was 2.87 (0.18) and 4.92 (0.08), respectively as shown in Table 4 and Figure 2. The log reduction of the liquid cleanser with 0.15% TCC from the ordinary bar soap was 2.05. This result demonstrated that the liquid cleanser with 0.15% TCC significantly inhibited the growth of *S. aureus* compared to the ordinary bar soap.

Table 3 Mean Log CFU of E.coli (n=12)

Tested agent	Log CFU		
	Baseline Mean (SD)	After 1 handwash Mean (SD)	Log reduction (from baseline) Mean (%)
Liquid Cleanser (0.15%TCC)	9.01 (0.28)	5.77 (0.42)	3.24 (99.94)

**Figure I:** Comparison of Log CFU before (Baseline) and after a single handwash with Liquid cleanser containing 0.15%TCC

Mean Log CFU at baseline was 9.01 and after 1 handwash for 5.77

TCC or Trichlorocarbanilide

CFU or Colony Forming Unit

Table 4 Mean log CFU¹ of S. aureus (n=8)

Product	Test Product	Post-wash		Test statistic
		Mean Log CFU/ cm ² (SE) ⁴	Log reduction from Ordinary Bar Soap (B)	P value ⁵
A ²	Liquid Cleanser with 0.15% TCC ⁶	2.87 (0.18)	2.05	<0.0001
B ³	Ordinary bar soap	4.92 (0.08)	----	----

¹ CFU or Colony Forming Unit

⁴ SE or standard error

² Product A or Protex Shower Crème containing 0.15% TCC

⁵ Tukey test

³ Product B or Ordinary Bar Soap without antibacterial ingredient

⁶ TCC or Trichlorocarbanilide

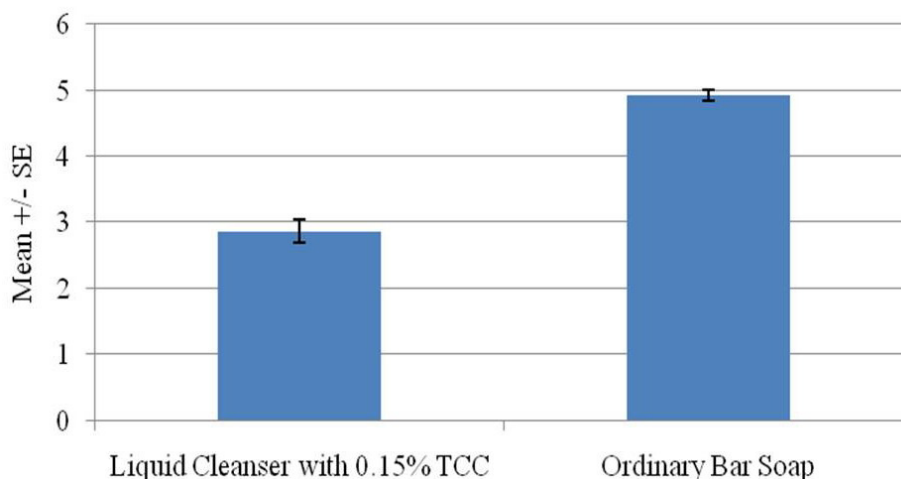


Figure 2: Comparison of log CFU¹ of Liquid Cleanser with 0.15% TCC² to an Ordinary Bar Soap

Mean (SE³) Log CFU of Liquid Cleanser with 0.15% TCC was 2.87 (0.18) and Ordinary Bar Soap for 4.92 (0.08).

¹ CFU or Colony Forming Unit

² TCC or Trichlorocarbanilide

³ SE or standard error

Discussion and Conclusion:

Handwashing is important for hygienic medical practice since this procedure can reduce infection risks especially for hospital-acquired infection. Not only is proper handwash technique necessary but the use of a soap or cleanser containing an effective antibacterial agent is also desirable for maximum bacterial reduction.

Today's generation of topical antimicrobial products provide a public health benefit by reducing or eliminating bacteria on skin. Such products are formulated with active ingredients that have the capability of reducing resident and transient organism populations with greater effectiveness and efficiency than can be achieved through the use of plain soap. This additional reduction translates to risk reduction in

the transmission of potentially pathogenic organisms and in the potential for disease acquisition⁴.

In these studies a liquid cleanser containing TCC has been shown to be highly effective against both *E. coli*, and *S. aureus*. In the hand wash study the liquid cleanser containing TCC reduced the marker organism by greater than 3 log₁₀. In the United States, healthcare antiseptic drug products that are regulated by the U.S. Food and Drug Administration (USFDA) are required to demonstrate at least a 2 to 3 log reduction following a handwash¹⁷. In addition, the cup scrub study, which used *S. aureus* as the marker organism, demonstrated that the antibacterial ingredient, TCC, that was present in the liquid cleanser, was able to significantly inhibit

the growth of *S. aureus* when compared to the ordinary bar soap.

These studies have provided the clinical evidence that a liquid cleanser with TCC eliminated more than 99.9% of *E. coli* and significantly inhibited the growth of *S. aureus* compared to an ordinary bar soap. This evidence supports the use of antibacterial hand washing for reducing infection risks for health care providers and the general population and should encourage physicians and health care providers in the best hygienic practices.

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