Infection Control & Hospital Epidemiology (2023), **44**, 517–519
doi:10.1017/ice.2021.506

SHEA

Concise Communication

Effect on the reduction of bacterial load after surgical hand antisepsis with triclosan 0.5% compared to triclosan 0.5% followed by 70% alcoholic solution

Luis Santé MD[1], María Luisa Gómez-Lus MD, PhD[2], Carlos Martin-Villa BSc, PhD[3], Ricardo Becerro-de-Bengoa-Vallejo BSc, PhD[3], Luis Alou BSc, PhD[2] and David Sevillano PharmD, PhD[2]

[1]Servicio de Anestesiología y Reanimación, Hospital Clínico San Carlos, Universidad Complutense, Madrid, Spain, [2]Área de Microbiología, Departamento de Medicina, Facultad de Medicina, Universidad Complutense de Madrid, Madrid, Spain and [3]Facultad de Enfermería, Fisioterapia y Podología, Universidad Complutense de Madrid, Madrid, Spain

Abstract

Triclosan 0.5% by scrubbing does not meet the UNE-EN12791 criteria to be used in the surgical hand preparation (SHP). Triclosan 0.5% by scrubbing followed by ethanol 70% hand rubbing is suitable without the additional characteristic of sustained effect. This limited effectiveness implies that triclosan should be avoided in SHP given the restrictions on its use in consumer antiseptic products. The trial was registered at ClinicalTrials.gov (ID: NCT04538365).

(Received 7 July 2021; accepted 30 November 2021; electronically published 22 December 2021)

Surgical site infections (SSIs) represent a major preventable cause of postoperative morbidity. The surgical hand preparation (SHP) by medicated-soap hand scrub or alcohol-based formulation hand rub remains the cornerstone of SSI control.[1]

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl-ether) and alcohols are 2 the main antiseptics marketed for SHP.[2] Triclosan is presented in an alcohol-free soap solution at 0.5% (TCS) for handwashing and in brush or sponges for surgical hand scrubbing. Triclosan exhibit powerful broad-spectrum antimicrobial activity and, unlike other medicated soaps, provides exceptional softness to the skin that promotes handwashing adherence.[2,3]

However, the clinical relevance of triclosan remains unclear given the superior effectiveness of other handwashing products.[3] In 2016 the European commission, banned triclosan as an active ingredient from consumer antiseptic wash products (1) in the absence of evidence proving additional protection against infections over nonantimicrobial hand soaps and running water and (2) according to the opinion that long-term exposure to triclosan could pose health and environmental risks.[4] Final rules did not affect healthcare antiseptic products, but a revision of restrictions seems reasonable if triclosan does not meet expectations of effectiveness in the healthcare setting.

In Europe, the norm EN12791 (UNE) must be implemented to test whether an antiseptic product, whatever the application procedure, is suitable to be used for SHP.[5] All products must fulfill the requirements for noninferiority for both immediate and 3-hour effects, with respect to the reference procedure. In addition, to claim an additional sustained effect, products shall display 3-hour effect significantly larger than that for the reference procedure. Currently, no data are available regarding the effectiveness of triclosan in SHP according to the UNE.

In this study, we sought to determine whether TCS by hand scrub or TCS by hand scrub followed by ethanol 70% (EtA) solution hand rubbed (TCS + EtA) fulfill the UNE criteria for SHP.

Material and Methods

A Latin-square crossover randomized controlled trial was conducted from September to December 2020 to test TCS by hand scrub and TSC + EtA, with respect propan-1-ol by hand rub (the reference procedure), according to the UNE.[5] The Ethics Committee for Clinical Research of the Hospital Clínico San Carlos, Madrid, approved the trial (ID-19/142-R_X_TFM), and the study is registered with ClinicalTrials.gov (no. NCT04538365).

In total, 23 participants were randomly divided into 3 groups to receive the reference procedure solution, TCS, or TCS + EtA in parallel. The test was repeated with changed roles in second and third sessions with a washout period of 1 week between runs to allow the reconstitution of skin microbiota.[5,6] Participants did not use antimicrobials or hand antiseptics for at least 3 days prior to the test.

Following the 2-stage UNE procedure, after a preparatory handwash using a diluted soft soap (1-minute per 5 mL) and hand drying, all fingertips were rubbed (1 minute) into the sampling fluid (10 mL per hand of tryptone soy broth-TSB (Becton Dickinson, New York) to assess the bacterial load before antisepsis (preintervention values). Sample dilutions (1:10–1:100) were spread (0.1 mL) on the surface of tryptone soy agar (TSA, Becton Dickinson) plates and incubated for 24 hours prior to counting colony-forming units (CFU). Results were expressed as the logarithm (log) of CFU per mL of sample.

Author for correspondence: Luis Alou, E-mail: luisalou@ucm.es

Cite this article: Santé L, *et al.* (2023). Effect on the reduction of bacterial load after surgical hand antisepsis with triclosan 0.5% compared to triclosan 0.5% followed by 70% alcoholic solution. *Infection Control & Hospital Epidemiology*, 44: 517–519, https://doi.org/10.1017/ice.2021.506

Table 1. Bacterial Counts (Preintervention Values and Postintervention Values in log_{10} CFU/mL) Determined According to the UNE Standard for the Reference Procedure Propan-1-ol (RPP) and for the Tested Products TSC and TCS + EtA

	Left Hand					Right Hand				
	Preintervention Value		Immediate Postintervention Value			Preintervention Value		3-Hours Postintervention Value		
Product	Mean ± SD (95% CI)	Median (IQR)	Mean ± SD (95% CI)	Median (IQR)	*P* Value*	Mean ± SD (95% CI)	Median (IQR)	Mean ± SD (95% CI)	Median (IQR)	*P* Value*
RPP	4.11 ± 0.56 (3.87–4.35)	4.25 (0.77)	2.49 ± 0.79 (2.15–2.83)	2.44 (1.47)	<.001	4.19 ± 0.68 (3.89–4.49)	4.34 (0.60)	2.91 ± 0.83 (2.56–3.27)	2.90 (0.92)	<.001
TCS	4.05 ± 0.62 (3.78–4.32)	4.07 (0.81)	3.32 ± 0.75 (3.00–3.65)	3.30 (1.13)	<.001	4.15 ± 0.61 (3.88–4.41)	4.07 (0.92)	3.80 ± 0.67 (3.50–4.09)	3.77 (1.23)	.026
TCS + EtA	4.10 ± 0.60 (3.84–4.36)	4.10 (0.97)	2.65 ± 0.71 (2.35–2.96)	2.66 (0.84)	<.001	4.23 ± 0.46 (4.03–4.43)	4.30 (0.64)	3.11 ± 0.77 (2.77–3.44)	3.07 (1.10)	<.001

Note. TCS, triclosan 0.5% by hand scrub; TCS + EtA, triclosan 0.5% by hand scrub followed by ethanol 70% solution by hand rub; SD, standard deviation; CI, confidence interval; IQR, interquartile range.
**P* value for preintervention values vs postintervention values using Wilcoxon matched-pairs signed-rank test (3-h postintervention values did not follow a Gaussian distribution according to the Shapiro-Wilk test). Statistical significance for a *P* value <.05, with a 95% confidence interval.

Table 2. Immediate (LogR Immediate) and 3-Hour Effects (LogR3-h) for the Reference Procedure Propan-1-ol (RPP) and the Tested Products (TCS and TSC + EtA) and Noninferiority/Sustained Effect Test According to the UNE Norm

	RPP		TCS		*P**	TCS + EtA		*P**	*P**
Effect	Mean ± SD (95% CI)	Median (IQR)	Mean ± SD (95% CI)	Median (IQR)	RPP-TCS (MdnD)	Mean ± SD (95% CI)	Median (IQR)	RPP-TCS + EtA (MdnD)	TCS-TCS + EtA (MdnD)
Immediate (LogR, in left hand)	1.62 ± 0.93 (1.21–2.02)	1.49 (1.64)	0.72 ± 0.62 (0.45–0.99)	0.57 (0.45)	.004 (0.99)	1.44 ± 0.70 (1.14–1.75)	1.38 (1.03)	.485 (0.15)	.002 (−0.75)
3-hours (LogR-3h, in right hand)	1.27 ± 0.84 (0.90–1.54)	1.07 (1.39)	0.35 ± 0.63 (0.07–0.62)	0.32 (1.00)	<.001 (0.88)	1.11 ± 0.67 (0.82–1.41)	0.98 (1.17)	.555 (−0.07)	<.001 (−0.80)
UNE criterion for non-inferiority					Not fulfilled			Fulfilled	
UNE criterion to claim a sustained effect					Not fulfilled			Not fulfilled	

Note. TCS, triclosan 0.5% by hand scrub; TCS + EtA, triclosan 0.5% by hand scrub followed by ethanol 70% solution by hand rub; SD, standard deviation; CI, confidence interval; IR, interquartile range; MdnD, median of the differences between RPP-tested product.
**P* value from nonparametric Friedman test; *P* value was set at < .025, with a 95% confidence interval to validate the non-inferiority criterion and at *P* < .01 to validate the sustained effect criterion.

Then, the surgical hand antisepsis was performed. The reference procedure group of volunteers used propan-1-ol (60%-V/V) by rubbing (10 mL for 3 minutes and wait until evaporate). The TCS group used a sterile surgical brush or sponge impregnated with 20 mL TCS (Triclonex T2, Nex Medical, Italy) to scrub all the hand, including nails, thoroughly (brushing each side for 2.5 minutes) and then forearms (sponging each side for 1 minute per forearm).[1] After rinsing, hands were dried with sterile towels. TCS + EtA group used TSC as describe above following by EtA rubbed (10 mL for 3 minutes and wait until evaporate). Immediately after antisepsis, the same sampling procedure described for the preintervention values was used on the left hand (immediate postintervention value), except that the TSB contained antiseptic neutralizers[4] and the undiluted 1-mL samples were also platted. Participants then donned surgical gloves and, three hours later the sampling procedure was repeated as described for the immediate postintervention value, this time on the right hand (ie, the 3-hour postintervention value).

The test results fulfilled the requirements for acceptance specified by the UNE[5] (ie, results of at least 23 subjects and overall means for Log_preintervention values ≥ 3.5). Accordingly, the immediate (LogR = Log_preintervention values − Log_postintervention values for the left hand), and at 3 hours (LogR3h=Log_preintervention values − Log_postintervention values in the right hand) effects were determined to evaluate whether the products being tested fulfilled UNE criteria.[5]

The Wilcoxon matched-pairs signed-rank test ($P = .05$) was used for the comparison of preintervention versus postintervention values. The Friedman test was used according to UNE to validate the noninferiority ($P = .025$) and the sustained effect ($P = .01$) criteria. We used SPSS version 19.0 software (IBM, Armonk, NY) for these analyses.

Results

In the TCS, TCS + EtA, and reference procedure groups, the skin bacterial load immediately decreased significantly ($P < .001$) and at 3 hours after hand antisepsis: reference procedure ($P < .001$), TCS ($P < .0026$), and TCS + EtA ($P < .001$) (Table 1).

As shown in Table 2, the immediate effect (LogR) obtained with TCS was significantly inferior to that obtained with the reference procedure ($P = .004$) or TCS + EtA ($P = .002$). The LogR for the reference procedure was greater than that for TCS + EtA, but no statistically significant differences were found ($P = .485$).

Similarly, the 3-hour effects (LogR3h) obtained with TSC (Table 2) were significantly inferior to those of the reference procedure ($P < .001$) and TCS + EtA ($P < .001$). The LogR3h

https://doi.org/10.1017/ice.2021.506 Published online by Cambridge University Press

for the reference procedure was greater but not statistically different than that obtained with TCS + EtA ($P < .555$).

Discussion

The SHP effectiveness is highly dependent on the antiseptic product and the method used.

TCS by hand scrub despite the significant bacterial load decrease immediately and after 3 hours of antisepsis did not meet the UNE requirements to be used for SHP. The immediate and 3-hour effects were significantly inferior to those obtained with propan-1-ol (the reference procedure), which was the most effective strategy of the 3 tested.

Among surgical teams, there is a perception of greater efficacy for the SHP using scrubbing (particularly for the first intervention of the day) than rubbing with nonalcoholic solutions.[1] However, our results with TCS by hand scrub are not superior to that described for triclosan hand soap, which has no proven benefit over nonantimicrobial soap.[7,8] Recently, it has been shown that hand scrub using a brush or sponge reduces the effectiveness of chlorhexidine digluconate 4%, parachloromethaxylenol 3%, and even the propan-1-ol (ie, the reference procedure solution of UNE) in SHP. None of them met the UNE criteria applied by scrubbing instead of by rubbing.[6,9] The scrub technique appears to promote the outcrop of bacteria from the deep folds of the skin.[1,6]

For TCS + EtA strategy, the immediate and 3-hour effects were lower but not significantly inferior to those of the reference procedure, meeting the UNE noninferiority criterion but not the requirement for claiming an additional sustained effect. The ethanol 70% is less effective than propan-1-ol in SHP.[1] However, the reported immediate effectiveness for ethanol 70% alone is close to that observed for TCS + EtA,[1,10] so its effectiveness had to be conditioned by the scrubbing procedure.

The overuse of hand antiseptics under the current COVID-19 pandemic was able to determine changes in the composition of the skin microbiota of the volunteers. However, this did not affect the noninferiority analysis for tested products because the preintervention values met the acceptance criterion of the UNE.

In conclusion, TCS by hand scrub does not meet the UNE criteria to be used in SHP. European restrictions on the use of triclosan can reasonably be enforced for this purpose. The TCS + EtA strategy is suitable to be used in SHP without the additional characteristic of prolonged effect. However, other alcohol-based formulations would have priority because the triclosan health and environmental risks outweigh the benefit. As a recommendation, if scrubbing with brush or sponge is included as part of SHP, the complementary products should exhibit sufficient activity to guarantee the effectiveness of the antiseptic strategy.

Financial support. No financial support was provided relevant to this article.

Conflicts of interest. All authors report no conflicts of interest relevant to this article.

References

1. WHO guidelines on hand hygiene in health care. World Health Organization website. https://www.who.int/publications-detail-redirect/9789241597906. Published 2009. Accessed December 10, 2021.
2. Jones RD, Jampani HB, Newman JL, Lee AS. Triclosan: a review of effectiveness and safety in healthcare settings. *Am J Infect Control* 2000;28:184–196.
3. Nicolay CR. Hand hygiene: an evidence-based review for surgeons. *Int J Surg* 2006;4:53–65.
4. Commission decision of 27 January 2016 not approving triclosan as an existing active substance for use in biocidal products for product type 1. J Eur Communities 2016;L21:8.
5. European Norm EN 12791. UNE EN 12791:2016+A1:2018 Chemical disinfectants and antiseptics—surgical hand disinfection—test method and requirements (phase 2, step 2). European Standards website. https://www.en-standard.eu/une-en-12791-2016-a1-2018-chemical-disinfectants-and-antiseptics-surgical-hand-disinfection-test-method-and-requirements-phase-2-step-2/. Published 2018. Accessed December 10, 2021.
6. De Bengoa Vallejo RB, Fernandez DS, Cervera LA, *et al.* Effectiveness of surgical hand antisepsis using chlorhexidine digluconate and parachlorometaxylenol hand scrub crossover trial. *Medicine (Baltimore)* 2018;97:e12831.
7. Giuliano CA, Rybak MJ. Efficacy of triclosan as an antimicrobial hand soap and its potential impact on antimicrobial resistance: a focused review. *Pharmacotherapy* 2015;35:328–336.
8. Kim SA, Moon H, Lee K, Rhee MS. Bactericidal effects of triclosan in soap both in vitro and in vivo. *J Antimicrob Chemother* 2015;70:3345–3352.
9. Martin-Villa C, Becerro-De-Bengoa-Vallejo R, Alou L, *et al.* Comparing rubbing and scrubbing surgical hand antisepsis with propan-1-ol 60% in accordance with European regulation UNE-EN 12791:2016+A1:2018. *Infect Control Hosp Epidemiol* 2021;42:1382–1384.
10. Rotter M. Hand washing and hand disinfection. In: Mayhall CG, ed. *Hospital Epidemiology and Infection Control*, second edition. Philadelphia: Lippincott Williams & Wilkins; 1999:1339–1355.

https://doi.org/10.1017/ice.2021.506 Published online by Cambridge University Press