ORIGINAL ARTICLE

Antiseptic Effect of Conventional Povidone–Iodine Scrub, Chlorhexidine Scrub, and Waterless Hand Rub in a Surgical Room: A Randomized Controlled Trial

Jui-Chen Tsai, RN, MSN;[1,2] Yen-Kuang Lin, PhD;[2,3] Yen-Jung Huang, RN, HN;[1] El-Wui Loh, PhD;[4] Hsiao-Yun Wen, RN, HN;[1] Chia-Hui Wang, RN, PhD;[1,2] Yin-Tai Tsai, MS;[5] Wen-Shyang Hsieh, MPH;[5,6,7] Ka-Wai Tam, MD, PhD[4,8,9,10]

OBJECTIVE. Effective perioperative hand antisepsis is crucial for the safety of patients and medical staff in surgical rooms. The antimicrobial effectiveness of different antiseptic methods, including conventional hand scrubs and waterless hand rubs, has not been well evaluated.

DESIGN, SETTING, AND PARTICIPANTS. A randomized controlled trial was conducted to investigate the effectiveness of the 3 antiseptic methods among surgical staff of Taipei Medical University—Shuang Ho Hospital. For each method used, a group of 80 participants was enrolled.

INTERVENTION. Surgical hand cleansing with conventional 10% povidone–iodine scrub, conventional 4% chlorhexidine scrub, or waterless hand rub (1% chlorhexidine gluconate and 61% ethyl alcohol).

RESULTS. Colony-forming unit (CFU) counts were collected using the hand imprinting method before and after disinfection and after surgery. After surgical hand disinfection, the mean CFU counts of the conventional chlorhexidine (0.5 ± 0.2, $P < 0.01$) and waterless hand rub groups (1.4 ± 0.7, $P < 0.05$) were significantly lower than that of the conventional povidone group (4.3 ± 1.3). No significant difference was observed in the mean CFU count among the groups after surgery. Similar results were obtained when preexisting differences before disinfection were considered in the analysis of covariance. Furthermore, multivariate regression indicated that the antiseptic method ($P = .0036$), but not other variables, predicted the mean CFU count.

CONCLUSIONS. Conventional chlorhexidine scrub and waterless hand rub were superior to a conventional povidone–iodine product in bacterial inhibition. We recommend using conventional chlorhexidine scrub as a standard method for perioperative hand antisepsis. Waterless hand rub may be used if the higher cost is affordable.

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Perioperative hand hygiene is one of the most critical factors affecting the risk of surgical site infection (SSI) as well as safety of medical staff.[1] Traditional surgical hand antiseptic methods involve scrubbing the hands, nails, and subungual areas with brushes and antimicrobial solutions for 5 minutes.[2,3] In contrast, the use of hand rub includes a 1-minute hand wash with a nonantiseptic soap and tap water, followed by 2 minutes of hand rubbing with only an aqueous alcoholic solution.[4] The use of waterless agents makes hand preparation easier without compromising patient safety.[5,6]

To our knowledge, 7 randomized controlled trials (RCTs) have evaluated the effectiveness of traditional surgical scrubbing and waterless hand rubbing; they reported that the hand rubbing procedure significantly reduced hand microorganisms.[5,7–12] However, some of these studies have combined participants who used 10% povidone–iodine and those who used 4% chlorhexidine gluconate into a single group.[5,10] This potentially biased the analysis because 4% chlorhexidine gluconate is a more effective antiseptic than povidone–iodine.[13] Moreover, 4 of these RCTs evaluated the effectiveness of alcohol gel, which is not a hand rub solution (alcohol and chlorhexidine gel), used worldwide.[5,7–9] In this RCT, we investigated the effectiveness of 3 antiseptic methods among surgical staff. The participants were divided into the following 3 antiseptic groups: (1) a conventional

Affiliations: 1. Department of Nursing, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan; 2. School of Nursing, College of Nursing, Taipei Medical University, Taipei, Taiwan; 3. Biostatistics Center, Taipei Medical University, Taipei, Taiwan; 4. Center for Evidence-Based Health Care, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan; 5. Department of Laboratory Medicine, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan; 6. Department of Education, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan; 7. School of Medical Laboratory Science and Biotechnology, Taipei Medical University, Taipei, Taiwan; 8. Division of General Surgery, Department of Surgery, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan; 9. Department of Surgery, School of Medicine, College of Medicine, Taipei Medical, University, Taiwan; 10. Cochrane Taiwan, Taipei Medical University, Taipei, Taiwan.

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povidone scrub group, in which participants performed traditional hand scrubbing with 10% povidone–iodine product (Sindine surgical scrub; Sinphar Pharmaceutical Co., Yilan, Taiwan); (2) conventional chlorhexidine scrub group, in which participants performed hand scrubbing with 4% chlorhexidine gluconate product (Antigerm; Panion & BF Biotech Inc., Taipei, Taiwan); and (3) waterless hand rub group, in which participants used a waterless hand rub solution of 1% chlorhexidine gluconate and 61% ethyl alcohol (Avagard; 3M, Maplewood, MN, USA).

MATERIALS AND METHODS

This study was a single-center, single-blind, randomized trial. Participants were recruited from the surgical staff members of Taipei Medical University—Shuang Ho Hospital between December 1, 2014, and January 31, 2015. This trial was approved by the institutional review boards of Taipei Medical University and was registered with ClinicalTrials.gov (identifier NCT02294604).

Study Design and Procedures

Inclusion and exclusion criteria. Practicing surgeons and scrub nurses who had previous experience with conventional surgical scrub and waterless hand rub protocols in an operating environment were randomly recruited and assigned to the 3 antiseptic groups (n = 80 per group). Participants were excluded if they did not provide samples for culture prior to the operation and after the operation or if they contaminated their hands during surgical procedures. In addition, participants having incomplete data on baseline characteristics were excluded. Medical and nursing students were ineligible for the study.

Experimental procedures. The participants were randomly assigned through computer-based blocked randomization (1:1:1) with concealed allocation to the 3 antiseptic groups by a central, independent randomization facility. Before surgical hand disinfection, the group assignment was revealed to the participants. Samples were imprinted from the hands onto Mueller–Hinton II agar, which is recommended for the antimicrobial disc diffusion susceptibility testing of common, rapidly growing bacteria using the Bauer–Kirby method.[14–16] The samples were obtained at the following 3 time points: before surgical hand disinfection, immediately after disinfection, and immediately after operation. The culture plates were maintained in an incubator at 35°C ± 2°C under a 5% CO_2 atmosphere for 48 hours. The colony-forming unit (CFU) count per plate was determined by a bacteriologist who was blinded to the method of hand disinfection using a dissection microscope. Surgery type, surgical wound classification, scrubbing time, operation duration, and duration of glove wearing were recorded.

Hand Preparation

Conventional scrub. After removing all jewelry, the participants in the conventional surgical scrub group followed standard disinfection procedures. Those in the conventional povidone group used a 10% povidone–iodine product and those in the conventional chlorhexidine group used a 4% chlorhexidine product. The 5-minute standard conventional surgical scrub procedure was as follows: (1) 3 full squirts of povidone or chlorhexidine product (6 mL) were placed into the cupped hands; (2) the hands were scrubbed for 5 minutes just up to the elbow by using a sterile scrub brush; and (3) the antiseptic was rinsed away with tap water and the hands were dried with sterile towels.

Waterless hand rub. The waterless hand rub was an alcohol-based solution containing 1% chlorhexidine gluconate and 61% ethyl alcohol. The standard hand rub protocol was as follows: (1) 1 pump of the solution (2 mL) was dispensed into the palm of the left hand; (2) the fingertips of the right hand were dipped into the solution to decontaminate the area under the nails; (3) the remaining solution was spread over the right hand and up to just above the elbow; and (4) a second pump of the solution (2 mL) was then placed into the palm of the right hand. This process was repeated by dipping the fingertips of the left hand into the solution, followed by spreading it over the left hand and up to just below the elbow. Another 2 mL of the solution was finally placed into cupped hands and was reapplied to all aspects of the hands up to the wrists. This solution was then allowed to dry. The 3-step application of the waterless hand rub was completed within 2 minutes.

Outcomes and Statistical Analysis

Required sample size was calculated based on an intermediate effect size of 0.25, power of 80%, and 2-sided test with type I error of 5%. G*Power was conducted to carry out the calculation.[17] Based on the aforementioned parameters, the estimated sample size was 231.

The primary outcome of this study was the CFU count per plate of each participant before surgical hand disinfection, after surgical hand disinfection, and immediately after surgery. The centrality of continuous variables was expressed as the mean, whereas the degree of variations was presented as the standard error of the mean. Analysis of variance (ANOVA) was used to examine the group difference in the antiseptic effect at specific time points and for specific surgery durations. Within-group comparisons of CFU count between time points were performed using the paired *t* test. To adjust for CFU count before disinfection, analysis of covariance (ANCOVA) was used to compare the effectiveness of the antiseptic methods. Multiple linear regression was used to adjust for potential risk factors to determine the effectiveness of the antiseptic methods. The Statistical Analysis System (SAS) version 9.4 (SAS Institute, Cary, NC, USA) was used for all statistical analyses.

RESULTS

From the conventional povidone group, we excluded 1 participant who did not provide imprinting samples at the 3 time points and 2 participants whose culture plates were

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contaminated. From the waterless hand rub group, we excluded 1 participant whose culture plate was contaminated. Finally, 77, 80, and 79 participants were recruited in the conventional povidone, conventional chlorhexidine, and waterless hand rub groups, respectively. The sampling flowchart of this study is presented in Supplementary Figure S1.

Baseline Characteristics and Duration of Antiseptic Procedures and Surgery

The baseline characteristics of the participants in the 3 antiseptic groups are listed in the upper part of Table 1. The study cohort was composed of 3 healthcare professional types: attending physicians, residents, and nurses. In total, 11 types of surgery were conducted during this research period; the 3 most common types were orthopedic surgery (n = 97), general surgery (n = 50), and neurosurgery (n = 23).

The antisepsis and surgery durations in the 3 antiseptic groups are summarized in Table 1. We observed a significant difference in the antisepsis duration among the groups ($P = .04$). Compared with the conventional povidone group (3.6 ± 0.2 minutes) and the waterless hand rub group (3.2 ± 0.2 minutes), the conventional chlorhexidine group required more time for hand cleaning (4.8 ± 0.8 minutes). Surgery duration did not significantly differ among the 3 groups ($P = .45$).

TABLE 1. Baseline Characteristics of the Participants in the 3 Antiseptic Groups[a]

Variable	Total (n = 236)	Antiseptic Group			P Value
		Povidone Scrub (n = 77)[b]	Chlorhexidine Scrub (n = 80)[c]	Waterless Hand Rub (n = 79)[d]	
Healthcare workers					.1681
Attending physician	28	13	10	5	
Resident	34	12	11	11	
Nurse	174	52	59	63	
Type of surgery					.0082
General surgery	50	10	15	25	
Chest surgery	2	0	1	1	
Cardiovascular surgery	13	2	5	6	
Plastic surgery	6	3	1	2	
Neurosurgery	23	6	12	5	
Ear–nose–throat surgery	6	5	1	0	
Ophthalmologic surgery	9	2	6	1	
Orthopedic surgery	97	42	31	24	
Urologic surgery	11	1	4	6	
Oral surgery	2	0	1	1	
Gynecologic surgery	17	6	3	8	
Surgical site					.1336
Head	40	12	17	11	
Chest	19	3	5	11	
Abdomen	51	12	16	23	
Pelvis	11	4	3	4	
Spine	29	13	8	8	
Extremities	86	33	31	22	
Wound classification					.9199
Clean	196	65	64	67	
Clean-contaminated	34	12	13	9	
Contaminated	10	3	3	4	
Duration, min					
Antisepsis		3.64 ± 0.2	4.8 ± 0.8	3.2 ± 0.2	.04
Surgery		118.3 ± 6.5	110.7 ± 6.2	124.8 ± 10.4	.45

[a]Statistical method: simple statistics were used for basic characteristics and analysis of variance was used for duration (data are expressed as the mean ± standard error).
[b]Povidone: hand scrubbing with 10% povidone–iodine product.
[c]Chlorhexidine: hand scrubbing with 4% chlorhexidine gluconate product.
[d]Waterless hand rub: hand rubbing with 1% chlorhexidine gluconate and 61% ethyl alcohol products.

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Antimicrobial Effectiveness

The results of the comparison of antimicrobial effectiveness among the 3 antiseptic groups are summarized in Table 2. The within-group comparisons revealed decrement in the mean CFU count after surgical hand disinfection ($P < .01$) and immediately after surgery ($P < .01$) in all the groups (P values are not marked in Table 2). Before hand disinfection, the mean CFU count was higher in the conventional povidone group than in the conventional chlorhexidine group (38.6 ± 4.4 vs 22.9 ± 3.6; $P < .05$) but did not differ between the conventional povidone group and the waterless hand rub group (38.6 ± 4.4 vs 29.0 ± 4.0; $P > .05$).

After hand disinfection. The mean CFU count was significantly lower in the conventional chlorhexidine group (0.5 ± 0.2; $P < .01$) and waterless hand rub group (1.4 ± 0.7; $P < .05$) than in the conventional povidone group (4.3 ± 1.3) after hand disinfection. To resolve the problem of preexisting differences, we used ANCOVA and treated the mean CFU count determined before surgical hand disinfection as the covariate. The immediate effect remained after adjustment. The mean CFU count was significantly lower in the conventional chlorhexidine group (0.8 ± 0.8; $P < .01$) and the waterless hand rub group (1.4 ± 0.8; $P < .05$) than in the conventional povidone group (3.9 ± 0.8).

After surgery. After surgery, the mean CFU count did not differ between the conventional povidone group (3.9 ± 1.6) and the conventional chlorhexidine group (4.1 ± 1.9; $P > .05$) or the waterless hand rub group (4.72 ± 1.77; $P > .05$) before adjustment. Similarly, no long-term difference was observed in the mean CFU count between the conventional povidone group (3.4 ± 1.8) and conventional chlorhexidine group (4.6 ± 1.7; $P > .05$) or the waterless hand rub group (4.8 ± 1.7; $P > .05$) after adjustment.

Variables Attributable to CFUs

We conducted a multivariate regression analysis to examine whether the antiseptic method, staff profession, surgeon specialty, surgical site, wound classification, and brush time predicted the mean CFU count. The results revealed that only the antiseptic method ($P = .0036$) in the model predicted the mean CFU count. Using the conventional povidone group as the reference, the β coefficient of the conventional chlorhexidine and waterless hand rub groups were −4.29 and −2.81, respectively (Table 3).

DISCUSSION

Several studies have examined and compared the effectiveness of antiseptic methods for perioperative hand sterilization, but only a few non-RCT studies that adopted the fingertip imprinting method for bacteria sampling are comparable with our study. Lai et al[18] compared the antimicrobial effectiveness of a waterless hand rub with that of a conventional 7.5% povidone-iodine product and found that the waterless hand rub significantly reduced CFU count. Chen et al[10] compared data on the antimicrobial effectiveness of a waterless hand rub with the pooled data of 2 conventional methods, namely 4% chlorhexidine gluconate in isopropyl alcohol and a 10% povidone iodine product. They reported that the waterless hand rub is as effective as the traditional hand scrub methods in removing microorganisms on the hands. Shen et al[19] compared data on the antimicrobial effectiveness of a waterless hand rub with the combined data of 4% chlorhexidine and 7.5% povidone–iodine products. Their statistical evidence supported the superiority of the waterless hand rub over conventional scrubbing methods. However, merging the antimicrobial effectiveness data of conventional povidone–iodine and chlorhexidine groups might have increased overall bacterial count and confounded the results in the aforementioned studies.[10,19]

In addition to the antimicrobial effectiveness of antiseptic methods for perioperative hand disinfection, several studies have compared the antimicrobial effectiveness of antiseptic methods in the prevention of SSI. In brief, for preventing

TABLE 2. Efficacy of Bacterial Inhibition Indexed by the Mean Colony Forming Unit Count Among the Antiseptic Groups[a]

Variable	Antiseptic Group		
	Povidone Scrub (n = 77) (reference)[b]	Chlorhexidine Scrub (n = 80)[c]	Waterless Hand Rub (n = 79)[d]
Before surgical hand disinfection	38.6 ± 4.4	22.9 ± 3.6*	29.0 ± 4.0
After hand disinfection			
Before adjustment	4.3 ± 1.3	0.5 ± 0.2**	1.4 ± 0.7*
After adjustment	3.9 ± 0.8	0.8 ± 0.8**	1.4 ± 0.8*
After surgery			
Before adjustment	3.9 ± 1.6	4.1 ± 1.9	4.7 ± 1.8
After adjustment	3.4 ± 1.8	4.6 ± 1.7	4.8 ± 1.7

[a]Between-group comparisons: ANCOVA, with the value before surgical hand disinfection as reference; P value: *$P < .05$, **$P < .01$. Data are expressed as the mean ± standard error.

[b]Povidone scrub: hand scrubbing with 10% povidone–iodine product.

[c]Chlorhexidine scrub: hand scrubbing with 4% chlorhexidine gluconate product.

[d]Waterless hand rub: hand rubbing with 1% chlorhexidine gluconate and 61% ethyl alcohol products.

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TABLE 3. Examination of Variables Attributable to Colony-Forming Unit After Hand Disinfection Using Multivariate Regression Analysis

Variable	No. (n = 236)	Mean ± SE	β	*P* Value
Type of antisepsis				.0036*
Povidone scrub[a]	77	4.3 ± 1.3	Reference	
Chlorhexidine scrub[b]	80	0.5 ± 0.2	−4.29	
Waterless hand rub[c]	79	1.4 ± 0.7	−2.81	
Role of staff				.8333
nurse	173	2.1 ± 0.6	1.00	
Resident	35	2.3 ± 0.9	0.94	
Attending physician	28	1.5 ± 0.7	Ref.	
Surgeon specialty				.6381
General surgery	50	0.9 ± 0.5	−2.26	
Chest surgery	2	0.5 ± 0.5	−0.26	
Cardiovascular surgery	13	0.8 ± 0.5	−2.40	
Plastic surgery	6	0.2 ± 0.2	−9.84	
Neurosurgery	23	0.4 ± 0.2	−2.43	
Ear-nose-throat surgery	6	0.8 ± 0.5	−3.79	
Ophthalmologic surgery	9	1.0 ± 0.8	−0.63	
Orthopedic surgery	97	3.3 ± 1.0	−0.42	
Urologic surgery	11	0.6 ± 0.3	−1.44	
Oral surgery	2	1.0 ± 1.0	0.04	
Gynecologic surgery	17	3.8 ± 3.0	Ref.	
Surgical site				.7863
Head	40	0.6 ± 0.2	−1.03	
Chest	19	0.9 ± 0.6	−1.46	
Abdomen	51	2.1 ± 1.1	0.07	
Pelvis	11	0.9 ± 0.4	−1.84	
Spine	29	1.4 ± 0.7	−2.12	
Extremities	86	3.3 ± 1.1	Ref.	
Wound classification				.066
Clean	193	2.0 ± 0.5	−7.57	
Clean-contaminated	33	1.3 ± 0.5	−7.61	
Contaminated	10	5.1 ± 5.0	Ref.	
Brush time, min				.1248
<3.85	130	1.5 ± 0.5	−1.63	
≥3.85	106	2.6 ±0.9	Ref.	

[a]Povidone scrub: hand scrubbing with 10% povidone–iodine product.
[b]Chlorhexidine scrub: hand scrubbing with 4% chlorhexidine gluconate product.
[c]Waterless hand rub: hand rubbing with 1% chlorhexidine gluconate and 61% ethyl alcohol products.

SSI, chlorhexidine-alcohol was superior to skin cleansing with povidone–iodine product in clean-contaminated surgery,[20] and chlorhexidine-alcohol product was superior to iodine–alcohol product for preoperative skin antisepsis in cesarean delivery.[21] These results indicated that compared with a povidone-iodine product, a chlorhexidine product is a more effective antiseptic solution.

The major determinants for selecting an antiseptic agent are its antimicrobial profile, ease of use and user acceptance, and cost. Regarding ease of use and user acceptance, waterless hand rubbing products are easy to use, require a shorter time to exert effects, and cause less irritation and fewer allergic reactions.[22,23] These characteristics lead to greater compliance among surgical staff. However, waterless hand rubbing products are more expensive than conventional scrubbing products. According to the prices provided by our pharmacy department, the costs of 10% povidone–iodine product per milliliter is NT$0.15 (US$0.47); the 4% chlorhexidine product costs NT$0.36 (US$0.01) per milliliter; and our experimental waterless hand rubbing product costs NT$3.11 (US$0.10) per milliliter. In practice, 5–10 mL of 4% chlorhexidine product, which costs NT$1.8–3.6 (US$0.06–0.11), is required to complete the scrubbing protocol. Furthermore, 6 mL of waterless hand rubbing solution, which costs NT$18.7 (US$0.58), is required to complete the rubbing protocol. Although the substitution of the conventional povidone–iodine scrub product with the chlorhexidine scrub product is beneficial, the benefits may be compromised by the increased costs. In addition, the 2 minutes saved to complete the waterless hand rubbing protocol does not seem to affect the overall performance of a surgery except in the emergency room. Decision makers should thoroughly consider the costs and benefits of using the waterless hand rub for each surgery type.

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Our study has some limitations. First, we did not collect additional information regarding the SSIs of the patients. Therefore, we could not evaluate the correlation of the antimicrobial effectiveness of the antiseptic methods with the SSIs of the patients. Second, the antimicrobial effectiveness of these methods against other microorganisms such as fungi and viruses was not evaluated. Third, although on-site researchers ensured that each participant followed standard antiseptic procedures and those who did not were excluded from the statistical analysis, information related to irritation and allergy was not collected. Thus, the comfort factor of using the antiseptic methods could not be evaluated.

In conclusion, our data showed that all 3 methods effectively decreased bacterial burden on the hands and that the decrease was maintained for the duration of the operative procedure. However, the conventional chlorhexidine scrub and waterless hand rub provided better antiseptic effectiveness than conventional povidone–iodine scrub product after hand disinfection. Although chlorhexidine exerted the highest antimicrobial effect among the 3 methods, the waterless hand rub may be a favorable choice for surgical staff for its comfort factor. A balance between costs and benefits should be considered when choosing a general antiseptic method in surgical departments.

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Address correspondence to Ka-Wai Tam, MD, PhD, Center for Evidence-Based Health Care, Taipei Medical University—Shuang Ho Hospital, 291, Zhongzheng Road, Zhonghe District, New Taipei City, 23561, Taiwan (kelvintam@h.tmu.edu.tw).

SUPPLEMENTARY MATERIAL

To view supplementary material for this article, please visit https://doi.org/10.1017/ice.2016.296

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