

# Randomized clinical trial of preoperative skin preparation with 2% chlorhexidine versus conventional hair shaving in percutaneous coronary intervention

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## Abstract

**Background:** Preoperative skin preparation is associated with surgical site infection (SSI). Traditional preoperative shaving fails to reduce the risk of SSI. The efficacy of 2% chlorhexidine for preoperative skin preparation in percutaneous coronary intervention (PCI) is sketchy. The aim of this trial was to evaluate whether preoperative skin preparation performed with chlorhexidine was not inferior to a conventional hair removal method.

**Methods:** Seventy-eight patients undergoing PCI were randomized into 2 groups of 39 patients, receiving either single sterilization with 2% chlorhexidine or hair shaving respectively between July 2016 and October 2016. The primary endpoints were wound infection rate and bacterial counts. Secondary endpoints were rate of SSI and adverse effects of 2% chlorhexidine.

**Results:** The results showed that 2% chlorhexidine significantly reduced the colonization of *Staphylococcus aureus* ( $P = .032$ ), *S. epidermidis* ( $P = .000$ ), and miscellaneous bacteria ( $P = .244$ ) in comparison with hair shaving, respectively. Redness in 24 hours after surgery was observed in 6 patients in the control group (15.4%) and 5 patients (12.8%) in 2% chlorhexidine group. There was no statistically significant difference in SSI rate between 2 skin preparations.

**Conclusion:** In PCI, preoperative skin preparation with 2% chlorhexidine was not inferior to conventional hair shaving in terms of the wound infection rate and SSI rate.

**Abbreviations:** CSMUH = Chung Shan Medical University Hospital, IRB = institutional review board, PCI = percutaneous coronary intervention, SSI = surgical site infection.

**Keywords:** 2% chlorhexidine, percutaneous coronary intervention, preoperative skin preparation, randomized trial

Editor: Robert Chen.

The authors have no funding and conflicts of interest to disclose.

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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How to cite this article: Tsai HY, Liao WC, Wang M, Ueng KC, Huang CY, Tseng YC. Randomized clinical trial of preoperative skin preparation with 2% chlorhexidine versus conventional hair shaving in percutaneous coronary intervention. *Medicine* 2021;100:14(e25304).

Received: 12 February 2020 / Received in final form: 26 February 2021 / Accepted: 8 March 2021

<http://dx.doi.org/10.1097/MD.00000000000025304>

## 1. Introduction

Surgical site infection (SSI) is defined as infection occurring in wound after surgical procedures. It is one of most common nosocomial infections, which is frequently caused by bacteria found on skin. SSIs substantially affect quality of life of patient and cause increases in healthcare costs.<sup>[1]</sup> Although several measures have been employed to reduce the infection, 1% to 10% of patients undergoing surgeries are affected by SSIs. Among hospitalized patients, patients undergoing cardiac surgical procedures are susceptible to SSIs. SSI rates vary from 3.5% to 21%, leading to a mortality rate of approximately 25%.<sup>[2,3]</sup> There are several factors associated with SSIs in cardiac surgical procedures, including inappropriate skin preparation and noncompliance with aseptic techniques.<sup>[4]</sup>

Preoperative skin preparation is traditionally performed by removing body hair from intended surgical sites. Hair is perceived to be unclean and its removal links to risk reduction for SSIs. Various measures of hair removal include shaving, clipping, and depilatory creams. Preoperative shaving has failed to reduce the risk of SSI.<sup>[5,6]</sup> Recent study has shown that shaving the skin results in an increase in the rate of SSI.<sup>[7]</sup> It has been reported that hair removal with a razor or clippers can disrupt the integrity of skin and lead to the development of pseudofolliculitis and subsequent SSIs.<sup>[8,9]</sup> In addition to hair removal, skin preparation by nonhair removal modality such as antiseptic techniques has

been considered as alternative measures to prevent SSIs.<sup>[10–12]</sup> However, clinical effects of antiseptic agents used during skin preparation on preventing SSI remain sketchy.

Chlorhexidine gluconate is a cationic biguanide, which kills bacteria through binding to cell wall and altering the bacterial osmotic equilibrium.<sup>[13]</sup> It exerts broad activity against wide spectrum of microorganisms including gram-positive and gram-negative bacteria, yeasts, and some lipid-enveloped viruses.<sup>[14]</sup> Chlorhexidine is advantageous as it is resistant to inactivation by blood or serum proteins and has a great residual activity.<sup>[15,16]</sup> Recently, use of chlorhexidine for intraoperative skin preparation has been demonstrated to reduce SSI rates in patients undergoing caesarean section.<sup>[17]</sup> Use of chlorhexidine for preoperative skin preparation is suggested to be superior to cleansing with povidone-iodine for preventing SSIs.<sup>[18]</sup>

We hypothesized that chlorhexidine were more useful for preventing SSI than hair shaving without increasing toxicity. In the present study, we evaluated whether hair shaving or chlorhexidine is useful for preventing SSI in percutaneous coronary intervention (PCI). The rates of SSI between 2 preoperative skin preparations were compared. Differences in bacterial colonization just before the skin incision between 2 approaches were determined.

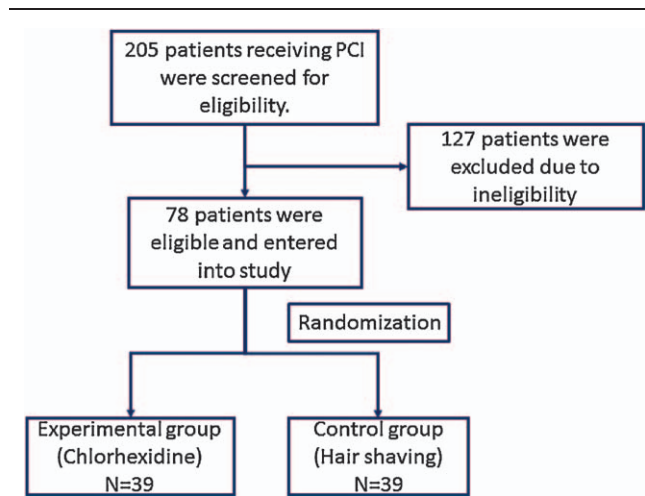
## 2. Subjects and method

### 2.1. Study design and subjects

This was a prospective single-blinded single-center randomized clinical trial conducted at the Department of Cardiovascular Center, Chung Shan Medical University Hospital (CSMUH), Taiwan from July 2016 to October 2016. The study protocol was reviewed and approved by the institutional review board (IRB) of CSMUH (IRB NO.: CS15148). The participants of the study were adults aged 20 to 80, who underwent inguinal catheterization. Exclusion criteria were patients who received antibiotics treatment or immunosuppression therapy, patients who underwent unexpected or emergency catheterization, and patients with severe liver failure or on hemodialysis. Participants were informed that the study compared 2 methods for skin preparation before catheterization. Participants were not informed how their group differed from the other. A random allocation sequence cards were generated using computer-generated random numbers by administrative personnel not otherwise involved in the trial. Participants were sequentially assigned a number corresponding to a random sequence on the list. Participants were primarily recruited and divided into 2 groups of 39 patients, namely experimental group (2% chlorhexidine) and the control group (hair shaving) (Fig. 1). Participants received skin preparation after providing written, informed consent for the study.

### 2.2. Preoperative skin preparation

Patients of the control group received standard routine skin preparation, including shaving the skin of inguinal and pubic area 2 hours and incorporating with iodine tincture antiseptic wiping before femoral artery catheterization puncture. Patients in the experimental group engaged with 2% chlorhexidine wipes cleaning the skin of inguinal and pubic area 2 hours and incorporating with iodine tincture antiseptic wiping before femoral artery catheterization puncture.



**Figure 1.** Study flow diagram. A total of 205 patients receiving scheduled PCI were screened, and 78 were randomized in a 1:1 ratio to receive skin preparation with 2% chlorhexidine (n=39) or hair shaving (n=39). PCI = percutaneous coronary intervention.

### 2.3. Skin sample collection

The skin samples were collected according to the manual of the infectious specimen collection issued by Taiwan Center for Disease Control, Ministry of Health and Welfare. In brief, sampling regions were cleaned with 75% alcohol followed by scrubbing around the front and rear of the inspection site for 10 seconds for fully absorption using a sterile swab. The swab was immediately placed in the sample collection tube and subsequently stored at 4°C less than 24 hours. The sampling process was performed by the same investigator for consistency.

### 2.4. Determination of surgical site infections

Infection was defined as a superficial or deep incisional SSI according to guidelines issued by the US Centers for Disease Control and Prevention.<sup>[19]</sup> Briefly, criteria for superficial incision SSIs were infections occurring at the incision site within 30 days of surgery, involving the skin and subcutaneous area, and together with at least one of the following: purulent drainage from the incision; an organism isolated from culture of fluid from the incision; and incisional pain, tenderness, localized swelling, redness, or heat, with the exception of cases with negative results for culture. The clinical observations to evaluate SSI were performed by 2 resident physicians who were unaware of the research project at designated time points, namely surgery day (day 0), 1 day postsurgery (day 1), 7 to 10 days postsurgery (day 7–10), and 30 days postsurgery (day 30).

### 2.5. Microbiological analysis

Skin samples were collected at 3 designated time points, namely time 1 (T1: before skin preparation), time 2 (T2: postskin preparation), and time 3 (T3: before arterial puncture). Bacterial strains of interest for culturing were *Staphylococcus aureus*, *S. epidermidis*, and miscellaneous bacteria. Miscellaneous bacteria are defined as the bacteria growing on blood agar but not on mannitol salt agar. The swab was placed in a test tube containing 3 mL of sterile phosphate buffer saline (PBS) and shaken thoroughly. The resulting solution was serially 10-time diluted

**Table 1**  
**Patient characteristics.**

Variables	Control group (N = 39)		Experimental group (N = 39)		$t/\chi^2$	P
	N (%)	M ± SD	N (%)	M ± SD		
Age		67.3 ± 10.9		68.4 ± 11.7	0.0440	.661*
Sex	23 (59%)				0.054	.817†
Male	16 (41%)		24 (61.5%)			
Female			15 (38.5%)			
Hypertension					1.393	.238†
Yes	30 (80%)		34 (87.2%)			
No	9 (20%)		5 (12.8%)			
Diabetes					0.253	.615†
Yes	27 (69.2%)		29 (74.4%)			
No	12 (30.8%)		10 (25.6%)			
PCI duration time (min)		53.7 ± 15.4 (30–95 min)		52.2 ± 16.8 (25–90 min)	−0.407	.685*
PCI finding					0.059	.808†
Stenosis	26 (66.7%)		27 (69.2%)			
Nonstenosis	13 (33.3%)		12 (30.8%)			

PCI = percutaneous coronary intervention.

\* *t* test.

† Chi-square test.

with PBS. 200 µL of each dilution was subjected to Mueller-Hinton agar followed by incubation at 37°C for 16 hours. Bacteria characterization was performed by following steps: plating bacteria on the blood agar to observe its hemolysis properties, transferring colony growing on the blood agar onto mannitol salt agar.

## 2.6. Statistical analysis

The numbers of subjects were decided in a reference to previous study.<sup>[20]</sup> Calculation by G-Power the effect size was 0.72, a significance level of 0.05 (2-tailed) and statistical power of 80%, at least 39 participants were required for each group. Participants were randomized in 2 groups by computer-generated randomization codes and lists. The statistical analysis was carried out using the SPSS software package, version 17 (SPSS Inc, Chicago, IL). Differences between parameters in the different patient

groups were evaluated using Fisher exact test and Student *t* test where appropriate. Differences between proportions were evaluated using the Chi-square test.

## 3. Results

A total of 205 patients receiving scheduled PCI were screened and 78 patients were eligible and entered into this study, followed by randomization into 2 groups of 39 patients. Of experimental group, 61.5% were men and the average age was 68.4 years, whereas 59% of patients in control group were men. There were no significant differences in distribution of age, sex, and comorbidities between 2 groups. The baseline and demographic characteristics of enrolled subjects are presented in Table 1.

Numbers of bacteria before and after skin preparation of both approaches are shown in Table 2. Before skin preparation with 2% chlorhexidine or by hair shaving, all skin samples displayed a

**Table 2**  
**Mean numbers of bacteria (cfu/mL) from skin swabs taken over the incision site before and after skin preparation and before percutaneous coronary intervention.**

Variable	Control (N = 39)		Experimental (N = 39)		$F^*$	P	$F^†$	P
	M ± SD	M ± SD	M ± SD	M ± SD				
<i>Staphylococcus aureus</i>					4.787	.032‡	0.016	.899
T1 <sup>§</sup>	391 ± 19.75		991 ± 49.55					
T2 <sup>  </sup>	509 ± 25.5		4 ± 0.2					
T3 <sup>¶</sup>	0		0					
<i>Staphylococci</i>					15.193	.000‡	1.494	.225
T1 <sup>§</sup>	287 ± 14.4		588 ± 29.4					
T2 <sup>  </sup>	639 ± 32		4 ± 0.2					
T3 <sup>¶</sup>	0		0					
Miscellaneous					1.376	.244	0.714	.401
T1 <sup>§</sup>	360 ± 13		365 ± 18.25					
T2 <sup>  </sup>	628 ± 31.4		0					
T3 <sup>¶</sup>	0		0					

\* within-subject effects.

† between-subject effects.

‡  $p < .05$ .

§ T1: before skin preparation.

|| T2: post skin preparation.

¶ T3: before arterial puncture.

**Table 3**  
Symptoms of superficial surgical site infection.

Variable	Control group (N = 39)		Experimental group (N = 39)		$\chi^2$	P
	N	%	N	%		
Symptoms						
Surgery (day 0)					0.106	.745
Redness	6	15.4%	5	12.8%		
Swelling	0		0			
Local heat	0		0			
Incisional pain	0		0			
Postsurgery (day 1)						
Redness	0		0			
Swelling	0		0			
Local heat	0		0			
Incisional pain	0		0			
Postsurgery (day 7–10)						
Redness	0		0			
Swelling	0		0			
Local heat	0		0			
Incisional pain	0		0			
Postsurgery (day 30)						
Redness	0		0			
Swelling	0		0			
Local heat	0		0			
Incisional pain	0		0			

growth of 3 bacteria of interest. At T2, mean numbers of *S aureus* was significantly lower in the experimental group than in control group ( $4 \pm 0.2$  vs  $509 \pm 25.5$  cfu/mL,  $P = .032$ ). In addition, mean number of Staphylococci was lower in the experimental group than that of control group ( $P = .000$ ). The reduction in mean bacteria count at T2 was observed to be greater in the group of 2% chlorhexidine compared with hair shaving group. Interestingly, in control group, bacteria count of 3 bacterial strains was increased after hair shaving. At T3, both skin preparation measures resulted in zero bacteria on 3 bacteria of interest. However, the difference in the mean bacteria count of 3 bacterial strains between both preoperative skin preparations was not statistically significant.

The surgical wounds were examined at 4 designated time points by attending surgeons. Signs of infection/inflammation were indicated by incisional pain, redness, swelling, and local heat. Six patients of the control group (15.4%) were reported to have redness in 24 hours after surgical procedures, and there was no other sign of infection or inflammation, whereas there are 5 patients (12.8%) in the experimental group exhibiting redness (Table 3). No adverse reaction or infection was reported in both groups in 30-day follow-up period. However, there was no statistically significant difference in SSI rate between hair shaving and 2% chlorhexidine groups.

#### 4. Discussion

In this randomized study, we showed a significant reduction in the microbial load at inguinal skin puncture site with use of 2% chlorhexidine versus hair shaving. We demonstrated that use of chlorhexidine was practical and simple for preparing the skin for surgery. There was no statistically significant difference in SSI rate between 2 skin preparation modalities. A recent study compared transradial and transfemoral approaches for coronary angiography in patients with coronary bypass grafts, showing

that of 2153 patients, 1937 were performed by femoral artery.<sup>[21]</sup> The result shows that a considerable proportion of patients accepts transfemoral approach. Therefore, the results of this study represent a meaningful contribution to clinical practice.

Appropriate preoperative skin preparation contributes to reduction in the risk of SSI and improves wound healing, which are associated with great deal of morbidity and mortality of surgical patients. Hair removal has been traditionally applied for preparing skin for surgery, which theoretically reduces bacterial load on the surgical site. Recently, it has been shown that no statistically significant effect on SSI rates of hair removal was revealed.<sup>[22]</sup> The several antiseptics have been considered for their uses for the preoperative skin preparation as in controlling SSIs.<sup>[23–25]</sup> In the present study, we compared the effect of hair removal by shaving or 2% chlorhexidine on reducing bacterial colonization on intended surgical site with hair. Our results revealed that single application of 2% chlorhexidine significantly reduced bacterial load on the surface of surgical site. The finding is in agreement with previous studies which reported chlorhexidine effectively reducing bacterial colonization.<sup>[23,26–28]</sup> It is suggested that use of chlorhexidine can achieve the satisfactory reduction in skin-hair microflora on surgical sites. Unexpectedly, hair shaving led to an increase in bacterial content on the intended surgical surface. The transient increase in bacterial count after shaving may be due to the disturbance to the microflora. We also observed relative high bacterial counts of *S aureus* and *Staphylococci* in the experimental group at T1. A recent study has shown that the bacteria counts in pubic region are significantly interpersonal variable.<sup>[29]</sup> However, further studies are required to determine the differences.

Conventional preoperative hair shaving is assumably associated with skin microinjuries leading to wound infection through contamination of surgical site with the normal skin flora.<sup>[30–32]</sup> In our study, the results showed no association between preoperative skin preparation and SSI. It is similar to the Poveda and

coworkers<sup>[133]</sup> study showing no association between shaving and SSI. We also found that there was no significant difference in SSI rate or sign of infection between hair shaving and 2% chlorhexidine groups. It is suggested that use of 2% chlorhexidine is an appropriate alternative to conventional hair shaving for skin preparation.

There were several limitations in the present study. First of all, the study was conducted at a single center, with potential bias in terms of evaluating efficacy and safety. Secondly, the patients were blinded, whereas the surgeons were not due to the nature of the study. In addition, study population of the present study was small; however, the paired experimental design was applied to reduce the influence of potential interperson differences among participants. Further studies are required to confirm the findings and to validate the feasibility of the measure in other surgical procedures.

## 5. Conclusion

Our results show that skin preparation for inguinal catheterization using 2% chlorhexidine was feasible and practical, resulting in acceptable clinical outcomes in term of low wound infection rate and SSI rate. 2% Chlorhexidine can be considered as a practical alternative to conventional hair removal for preoperative skin preparation.

## Author contributions

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**Resources:** Kwo-Chang Ueng.

**Supervision:** Cheng-Yi Huang.

**Writing – original draft:** Hsueh-Ya Tsai.

**Writing – review & editing:** Cheng-Yi Huang.

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