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Efficacy of 2% Chlorhexidine Gluconate in Water versus Povidone Iodine in Urological Surgery

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Abstract

Objective: This study aimed to determine whether 2% chlorhexidine gluconate in water is equivalent to povidone iodine in eradicating skin flora before urological surgery.

Methods: We used a prospective randomized controlled cohort trial to compare 2% chlorhexidine gluconate in water and povidone iodine solution for presurgical skin preparation. We included patients who underwent open urological surgeries in surgical operating rooms, with no differentiation regarding gender, age and procedure. Those patients with skin infections or unplanned reoperations were excluded. We randomized 100 patients into two groups using a computer-generated random allocation: those receiving 2% chlorhexidine gluconate in water and that receiving povidone iodine solution on their incision sites.

Results: We used Stat a version 13.0 and the Fisher's exact test to compare the differences between the two groups, and we found that the two antiseptic solutions gave similar results (P= 0.617). No surgical site infection cases were seen in this study.

Conclusion: Based on the results of this study, 2% chlorhexidine gluconate in water can be used safely to prepare the skin before surgery.

Keywords: Povidone iodine solution; Urological surgery; 2% chlorhexidine gluconate in water

Abbreviations: SSI: Surgical Site Infection; CHG: Chlorhexidine Gluconate; WHO: World Health Organization; RCPA: Royal College of Pathologists of Australia; EQA: External Quality Assurance; ASA: American Society of Anaesthesiologists

Summary Statement

What is already known about this topic?

a. Our study found that 2% CHG in water can be used safely to prepare the skin before surgery.
b. Our findings showed, for the first time, the non-inferiority of 2% CHG in water to PVP-I for surgical site skin preparation.

What this paper adds?

a. The results of this study can lead to quality improvement from "Routine to Research (R to R)"

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with the dissemination of the new knowledge that 2% CHG in water alone can be used as an antiseptic solution in operative preparations.

The implications of this paper

i. This study can be used to convince the head of management to use 2% CHG in water as an antiseptic solution in the operating theatre.
ii. This will lead to "Routine to Policy (R to P)" with the dissemination of the new knowledge that 2% CHG in water alone can be used as an antiseptic solution in operative preparations.

Introduction

A surgical site infection (SSI) is considered to be a major problem in the field of surgery. Povidone iodine (PVP-I) solution and 2% chlorhexidine gluconate (CHG) in alcohol are commonly used for presurgical skin preparations. In 2012, at our hospital, skin preparations with 2% CHG in alcohol (a solution containing 2% CHG and 70% isopropyl alcohol) followed by the use of a coagulating electrosurgical generator sparked surgical site fires. These caused severe burns to two patients who consequently had to endure much longer hospital stays. Therefore, the Hospital Director's office forbade the use of 2% CHG in alcohol in operating rooms, leaving only the PVP-I solution as an antiseptic for skin preparation. Unfortunately, many patients are allergic to PVP-I, leaving them with no viable antiseptic for skin preparation. Therefore, our Department of Pharmacy prepared 2% CHG in water to replace the 2% CHG in alcohol. There was study in minor skin excisions and they found that no significant difference SSIs between CHG in alcohol and CHG in water [1]. To the best of our knowledge, there have been no evidence-based studies comparing 2% CHG in water to PVP-I.

Literature Review

Iodophors, such as PVP-I, are antiseptics used for skin disinfection before and after surgery [2]. PVP-I is a chemical complex of providence, hydrogen iodide and elemental iodine [3], and it contains from 9% to 12% available iodine. However, PVP-I is not recommended for use in pregnant women(less than 32 weeks) or patients taking lithium [2]. It is on the World Health Organization's (WHO) List of Essential Medicines, which includes the most, effective and safe medicines needed in a healthcare system [4]. CHG may come mixed in alcohol, water or a surfactant solution [2]. It is both an antiseptic and disinfectant that is used for patient skin disinfection before surgery. It is also used to sterilize surgical instruments. Moreover, CHG is safe for use in pregnant women. However CHG is not recommended for use in infant less than 2 month of age [5]. In addition, there is tentative evidence that CHG is more effective than PVP-I [6], and CHG remains on the skin longer than PVP-I.

Several antiseptic agents are available for preoperative skin preparations at the incision site. Iodophors, alcohol containing products and CHG are the most commonly used agents [7]. The immediate antimicrobial activity of alcohol is stronger, and it kills more quickly than CHG or PVP-I, but it has no residual effect [8,9]. The most commonly used preoperative antiseptic skin preparations are PVP-I and CHG. Both are effective against a wide range of bacteria, viruses and fungi; however, CHG has more residual antiseptic activity on the skin after application [6].

Various studies have been carried out to compare the efficacies of different antiseptics, and they have shown that CHG in alcohol is superior to PVP-Iin reducing SSIs [10]. There are many factors contributing to SSIs, but the incidence can be lowered significantly with the use of effective antiseptics. CHG in alcohol was more efficacious than PVP-I in preventing SSIs in clean and clean-contaminated wound [11]. The incidence of SSIs with preoperative skin preparation using 10%PVP-I and 0.5% CHG in alcohol was similar [12]. The efficacy of CHG in alcohol was more effective in reducing the rate of SSIs and bacterial colonization than PVP-I [13]. The CHG in aqueous solution more effective in reducing risk of SSI in clean and clean-contaminated wound when compared to PVP-I [14]. The CHG in alcohol for skin antisepsis was found a significant effect in reducing early SSI compared with alcohol alone [15]. The recommendations are central to SSI prevention, but the World Health Organization (WHO) guidelines recognize that the availability of alcoholic CHG-based preparations is limited. Moreover, they can create an additional cost burden in developing countries [16]. Overall, the WHO recommendations are premature, and the available evidence does not support widely abandoning PVP-I-alcohol preparations at this point in time. Other relevant guidelines continue to recommend alcohol-based antiseptics with either CHG or PVP-I [17]. We conducted the present study because the outcomes of the use of CHG in water for presurgical skin preparation have not yet been properly studied.

Aim and Hypothesis

This study aimed to compare 2% CHG in water with PVP-I to determine whether there were any differences in eradicating the skin flora before urological surgery. The project hypothesis was that 2% CHG in water was

equivalent to PVP-I in eradicating the skin flora before urological surgery.

Methods

Design

This pilot study used a randomized controlled prospective trial with an aim to compare the effectiveness of eradicating skin flora between 2% CHG in water and PVP-I during presurgical skin preparation in patients undergoing urological surgeries at our hospital.

Ethical considerations

The project protocol was approved by the ethical review board of the Faculty of Medicine Ramathibodi Hospital at Mahidol University in Bangkok, Thailand (ID 11-56-41) before patient enrolment.

Sample and Setting

Those patients undergoing urological surgeries were included in this study. However, a patient was excluded from this research if they had a prior SSI history, unplanned surgery, re surgery during the same admission or a documented allergy to CHG or PVP-I. The random allocation of 100 patients, aged 1-75 years old, to either the 2% CHG in water group or the PVP-I group was achieved via computer-generated randomization. The 2% CHG in water group included those patients in whom 2% CHG in water was preoperatively applied to their incision site (group I). The PVP-I group included those patients in whom PVP-I was preoperatively applied to their incision site (group II). This project was conducted from January-December of 2014 in our operating theatre until a total of 100 cases were reached.

Data Collection

Before surgery, each patient's skin (100 cases) was scrubbed with PVP-I scrub by an assistant surgeon. This was done in both groups because the goal of this project was to determine the results of the different antiseptic solutions, not the antiseptic scrubs, so the same antiseptic scrub was used in both groups. Before applying the antiseptic solution, but after the PVP-I scrub; each patient's skin was swabbed for culturing. The aerobic cultures were procured by swabbing each incisional site with a dried, sterilized cotton-tipped swab (tube 1) with a label number. Afterward, the experimental antiseptic solutions, 2% CHG in water (group I) and PVP-I (group II), were applied. After the antiseptic solution was applied, it was allowed to dry, and the drapes and instruments were placed in the field. Then, during a "time-out" just before the incision (a total of 5 minutes), a second culture sample (tube 2) was swabbed from the surgical site. Two tubes each in a total of 100 patients were obtained by the same circulating nurse.The two tubes from each patient were then sent immediately to the microbiology laboratory for culture and sensitivity testing for 3 days before the culture results could be reported. Each patient also received preoperative antibiotics (intravenous ceftriaxone) at the time of anaesthesia induction, within 1 hour before the first incision was made. The microbiology laboratory undergoes the ISO15189 and External Quality Assurance (EQA) testing 8 times each year from the Royal College of Pathologists of Australia (RCPA).

Data Analysis

All of the data analyses were performed using stat version 13.0 (Columbia CP Ltd., Tsuen Wan, HKSAR, China). Percentages were calculated for the categorical data. The continuous variables were compared using an independent-test, and the categorical variables were compared using a chi-squared or Fisher's exact test. $P<0.05$ was considered to be significant difference. All of the data analyses were performed by an independent, unbiased statistician.

Results

As shown in Table 1 we included 100 patients in this project who were distributed into two groups of 50 each. The groups were comparable with respect to the demographic variables (age and gender), educational level and occupation. Table 2 shows the baseline clinical characteristics of the subjects, such as their diabetes status, American Society of Anaesthesiologists (ASA) score, wound classification, hair removed and surgical area, which were not significant risk factors for positive skin cultures after the skin preparation in our patient population.

After the PVP-I scrub was used in the surgical area, 50% of the cultures were positive in the 2% CHG in water group and 48% of the cultures were positive in the PVP-I solution group (P=1.000) (Table 3). After applying the 2% CHG in water solution in group I, 1 case (2%) exhibited a positive culture, but after applying the PVP-I solution in group II, 3 cases (6%) exhibited positive cultures (P=0.617). After applying the PVP-I scrub in the urological surgeries, the following organisms were isolated: *Corynebacterium* spp., Pseudomonas *aeruginosa* and *Staphylococcus epidermidis*. In the genital surgeries, Escherichia coli, Enterococcus *faecalis* and *Klebsiella* pneumonia were found. One patient had a negative culture after the PVP-I scrub, but it was positive for *Corynebacterium* spp. after the PVP-I solution was applied in the PVP-I group. In the other patients, the cultures were

positive for the same organisms before and after the skin preparation. We found no SSI, pruritus or erythema cases in the preparation sites in this study.

Characteristics	2% CHG in water n (%)	PVP-I n (%)	P-value
Gender			
Male	34 (68.00)	40 (80.00)	0.12
Female	16 (32.00)	10 (20.00)	
Age (years)			
15-Jan	18 (36.00)	10 (20.00)	0.18
16-60	17 (34.00)	19 (38.00)	
60 -75	15 (30.00)	21 (42.00)	
Current habitat			
Central	33 (66.0)	34 (68.0)	0.71
North	2 (4.0)	2 (4.0)	
South	2 (4.0)	5 (10.0)	
East	4 (8.0)	2 (4.0)	
West	4 (8.0)	3 (6.0)	
Northeast	3 (6.0)	4 (8.0)	
Foreigner	2 (4.0)	0 (0.0)	
Education level			
Primary school or less	27 (54.0)	24 (48.0)	0.69
High school education	12 (24.0)	11 (22.0)	
Bachelor or higher	11 (22.0)	15 (30.0)	
Occupation			
Government employee	7 (14.0)	10 (20.0)	0.41
Private employee	10 (20.0)	15 (30.0)	
Housewife	12 (24.0)	8 (16.0)	
Farmer	1 (2.0)	4 (8.0)	
Unemployed	20 (40.0)	13(26.0)	

Table 1: General characteristics of subjects enrolled in this study (n=100).

*P- values are based on Fisher's exact test.

Characteristics	2% CHG in water n (%)	PVP-I n (%)	P-value
Underlying disease			
DM	8 (16.0)	5 (10.0)	0.55
Non DM	42 (84.0)	45 (90.0)	
ASA score			
1	19 (38.00)	9 (18.00)	0.09
2	14 (28.00)	16 (38.00)	
3	17 (34.00)	24 (48.00)	
4	0 (0.00)	1 (2.00)	
5	0 (0.00)	0 (0.00)	

Wound classification (SSI)			
Clean	13 (26.00)	11 (22.00)	0.23
Clean-contaminated	34 (68.00)	39 (78.00)	
Contaminated	3 (6.00)	0 (0.00)	
Dirty	0 (0.00)	0 (0.00)	
Hair removed			
No	15 (30.00)	11 (22.00)	0.49
Clipped	34 (78.00)	39 (78.00)	
Antimicrobial prophylaxis			
No	7 (14.00)	7 (14.00)	0.99
Yes	43 (86.00)	43 (86.00)	
Day before operation (day)			
min-max	2-Jan	2-Jan	
Time before operation (min)			
min-max	May-55	5-105	
Duration of operation (min)			
min-max	25-530	50-580	

Table 2: Baseline clinical characteristics of the subjects enrolled in the study (n=100).

*P -values are based on Fisher's exact test.

Variable		**Group 1**	**Group 2**	**P -value**
		2%CHG in water (n=50)	PVP-1 (n=50)	
After povidone	No SSI	25 (50)	26(52)	1
Scrub (%)	SSI	25(50)	24(48)	
After antiseptic	No SSI	49 (98)	47 (94)	0.617
Solution plaint (%)	SSI	1 (2)	3 (6)	

Table 3: Comparing SSI rate between 2%CHG in water and PVP-1 (n=100).

* P-values are based on Fisher's exact test.

Discussion

SSIs occur commonly in the operating room. Most SSIs originate from the patient's own bacteria, which enter the wound during the surgical procedure; however, infections from exogenous sources can also occur [18,19]. In the operating room, skin preparations should be performed using an alcohol-based agent, unless contraindicated (Category IA is strongly recommended based on high-quality evidence) [17]. PVP-I solution and 2% CHG are the two agents most commonly used to prevent SSIs. CHG is a potent broad-spectrum germicide, and it is effective against nearly all nosocomial bacteria and yeasts [14]. There is tentative evidence that using CHG and denatured alcohol to clean the skin prior to surgery is better than using PVP-I with alcohol; however, as of 2015, the evidence is not strong enough to determine routine practice [6].

Although 2%CHG in alcohol is a more effective disinfectant than PVP-I, its flammability presents a problem in a surgical setting. Therefore, the present study evaluated whether 2% CHG in water is as effective as PVP-I for surgical-site preparation. Based on the results of this study, the use of 2% CHG in water for urological surgical

site preparations is comparable to using PVP-I for eradicating skin flora and preventing SSIs and complications in all patient groups. Our results confirmed that we can use 2% CHG in water instead of PVP-I or 2% CHG in alcohol in order to avoid skin irritation and fire hazards (respectively). Although we found no hypersensitivity reactions in our study, clinicians should be mindful of these and the other potential side effects, including erythema and bacterial resistance. Based on the literature, antiseptic solutions for operative preparations must be 2% CHG in alcohol or PVP-I (iodine mixed with polyvinyl pyrrolidone). The results of this study can lead to quality improvement from "Routine to Research (R to R)" with regard to the operators who work in this area. This development can be used to convince the head of management to use2% CHG in water as an antiseptic solution in the operating theatre. Moreover, this will lead to "Routine to Policy (R to P)" with the dissemination of the new knowledge that 2% CHG in water alone can be used as an antiseptic solution in operative preparations. Previously, only PVP-I was available, with which an increasing allergy rate has been found in our hospital.

Limitations and Recommendations

This research did have some limitations. First, this project did not show the strength of the aqueous CHG solution against a specific organism, such as encapsulated bacteria, and compare it to 2% CHG in alcohol. Second, this was a single-institution study with a rather small cohort; our results need to be confirmed using a larger study group. Third, we must not over-extrapolate the culture results to the effects of these organisms on SSIs, although optimizing skin antisepsis before surgery could result in a significant clinical benefit because two-thirds of SSIs are confined to the incision. Fourth, in this project, we did not rigidly enforce universal standard-of-care preventive measures (e.g., administering systemic prophylactic antibiotics and clipping hair immediately before surgery), which can affect the culture results before the skin preparation. Our project did not include a comparison of 2% CHG in water and2% CHG in alcohol because we did not use2% CHG in alcohol for any of the skin preparations during the study period.

Conclusion

Our findings showed, for the first time, the no inferiority of 2% CHG in water to PVP-I for surgical site skin preparation, thus indicating an additional option within this procedure for the surgical team. SSIs are a huge burden on the healthcare system. Surgical teams must understand the risk factors related to SSIs and control the process variability factors by strictly following aseptic techniques.

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