Comparison of Surgical Wound Infection after Preoperative Skin Preparation with 4% Chlohexidine and Povidone Iodine: A Prospective Randomized Trial

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Background: *Antiseptic scrub and paint can reduce bacterial colonization and postoperative wound infection. Two forms of antiseptics, povidone iodine and chlorhexidine, are commonly used in the operating theater.*
Objective: *To study the efficacy of the reduction of bacterial colonization and surgical wound infection among these antiseptic.*
Material and Method: *Five hundred surgical patients were randomly divided into two groups. Povidone Iodine and Chlorhexidine were used for skin preparation in group 1 and 2 respectively. Bacterial colonization and postoperative wound infection were examined after skin preparation. Demographic data was analyzed by student's t test; the culture result and surgical wound infection were analyzed by Mantel-Haenszel method for relative risk and 95% CI.*
Results: *There was a significant reduction of bacterial colonization and wound infection after skin preparation in group 2 compared with group 1.*
Conclusion: *Colonization of bacterial and postoperative surgical wound infection were significantly reduced in the chlorhexidine group. Chlorhexidine antiseptic should be the first consideration for preoperative skin preparation.*

Keywords: *Chlorhexidine, Povidone-iodine, Skin, Surgical wound infection*

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Surgical wound infections are infections of the tissues, organs, or spaces exposed by surgeons during performance of an invasive procedure[1]. The use of preoperative skin preparation by effective antiseptic plays an important role in reducing post-operative wound infection. There are several kinds of antiseptics available for preoperative skin preparation. However, chlorhexidine gluconate in isopropyl alcohol and povidone iodine are commonly used and convenient in clinical practice. Bacterial colonization at the skin and wound infection are reduced by several antiseptic agents under the different pharmacologic actions. A previous study showed that chlorhexidine in alcohol provided better result in the reduction of bacterial contamination of the skin in foot and ankle operation[2]. One study showed that chlorhexidine gluconate was more effective than povidone iodine in decreasing the bacterial colony counts that were found in the operative field for vaginal hysterectomy[3]. The meta-analysis confirmed that the incidence of blood stream infections was significantly reduced in patients with central vascular lines who received chlorhexidine gluconate versus povidone iodine for insertion-site skin disinfection[4]. However, there has not been a comparative study between chlorhexidine and povidone iodine antiseptic skin preparations in general surgery patients.

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Material and Method

The present study was approved by the Human Research Ethic Committee of Thammasat University. Five hundred patients in the department of surgery between June 2006 and November 2008 were enrolled in the present study.

Inclusion criteria were age 18-60 years, clean, clean contaminated and contaminated wounds and ASA class 1 and 2. The exclusion criteria were patient refusal, dirty wound, uncontrolled diabetes, on immunosuppressive drugs, serum albumin less than 3.0 mg/dl, and history of allergy to study agent. The patients were divided into two groups randomly. Group 1 was the povidone iodine group; 5 minutes scrubbed by povidone iodine scrub solution followed by povidone iodine paint. Group 2 was the 4% chlorhexidine in 70% isopropyl alcohol; 5 minutes scrubbed by hibitane scrub solution followed by hibitane paint. Skin swab culture was performed at the pretended incision site after skin preparation. Specimens were transferred to the laboratory by stewart transport media and were swabbed into blood or McCongee agar plates within 24 hours. The agars were incubated in 37 degree Celsius oven. The plates were examined every 24 hours until 3 days. The authors allowed other preoperative preparations under the standard guideline. The surgical wounds were examined twice a week in the first week and every week up to 1 month. An incisional surgical site infection had occurred if a surgical wound drained purulent material or if the surgeon judges it to be infected and opens it[1]. Demographic data was analyzed by student's test. The culture result and surgical wound infection were analyzed by Mantel-Haenszel method for relative risk and 95% confidence interval of relative risk.

Results

Five hundred patients were enrolled in the present study. The demographic data is shown in Table 1. These patients were divided into two groups. Group 1, included 250 patients (122 females, 138 males), was the povidone iodine group and group 2 (250 patients, 91 females and 159 males) was the chlorhexidine in alcohol group. The mean age was 56.2 years (20-79) in group 1 and 50.5 years (18-78) in group 2. There was no significant statistical difference of the age between the two groups (p-value = 0.27). The average operation time was 1.43 hours (40 min-3 hours) in group 1 and 1.45 hours (45 min-3 hours) in group 2 (p-value = 0.93). The wounds were classified into class 1 (clean wound), class 2 clean contaminated wound, and class 3 contaminated wound in both groups. In group 1, 87 (34.8%) were clean wounds, 112 (44.8%) were clean contaminated wounds, and 51 (20.4%) were contaminated wound. In group 2 96 (38.4%), 118 (47.2%) and 46 (18.4%) were clean, clean contaminated, and contaminated wounds respectively. There were no significant statistical differences in terms of wound types between the two groups (p-value = 0.91) (Table 1).

There was a significant reduction of bacterial colonization after skin preparation in group 2 compared with group 1 (14.4% vs. 31.2%). Relative Risk was 2.69, and 95% Confidence Interval Relative Risk was 2.15-3.55 (Table 2). The organisms found in the culture specimen included *Streptococcus epidemidis*, *Staphylococcus aurers*, *Streptococcus* sp., and *Enterococci* sp. The bacterial colonizations reduced significantly after skin preparation in all types of organisms as shown in Table 2.

There were eight cases (3.2%) of surgical wound infection in group 1.

The culture showed staph. aureus in five cases (2%); four from Arterio-Venous Shunt operation, one from Modified Radical Mastectomy operation. The *Enterococci* spp. was found in two cases (0.8%) in this group; one from appendectomy and one from gastrectomy operation. The remaining was *E. coli* was found in appendectomy operation (0.4%). In group 2,

Table 1. Demographic data

	n	Mean age (years)	Operative time (hours)	No. of wound class (%)	No. of gender
Group 1 (povidone iodine)	250	56.2 (20-79)	1.43 (40 min-3 hr)	I 87 (34.8)	Female 122
				II 112 (44.8)	Male 138
				III 51 (20.4)	
Group 2 (chlorhexidine)	250	50.5 (18-78)	1.45 (45 min-3 hr)	I 96 (38.4)	
				II 118 (47.2)	Female 91
				III 46 (18.4)	Male 159
		p = 0.27	p = 0.93	p = 0.91	

Table 2.

Post-op colonization (> 103 CFU/ml)*	Group 1 n = 250	Group 2 n = 250	RR**	95% CI RR***
Total [no.(%)]	78 (31.2)	36 (21.2)	2.69	2.15-3.55
S. epidermidis	53 (14.4)	26 (10.4)	2.31	1.91-2.70
S. aureus	7 (2.8)	3 (1.2)	2.37	2.08-2.65
Streptococcus sp.	18 (7.2)	7 (2.8)	2.69	2.34-3.03
Enterococcus sp.	1 (0.4)	-		

* Colony forming unit
** Relative risk
*** 95% confidence interval relative risk

Table 3. Postoperative surgical wound infection

	Group 1	Group 2	RR*	95% CI RR**
Postoperative infection [no.(%)]	8 (3.2)	5 (2)	1.61	1.40-1.81
Organism [no.(%)]				
S. aureus	5 (2)	3 (1.2)		
Enterococcus sp.	2 (0.8)	-		
E. coli	1 (0.4)	1 (0.4)		
Bacteroides fragilis	-	1 (0.4)		

* Relative risk
** 95% confidence interval relative risk

five cases (2%) had surgical wound infection. *Staph. aureus* were found in three cases (1.2%); two from Arterio-Venous Shunt operation, one from appendectomy operation. *E. coli* was found in one case (0.4%) from right half colectomy operation. A case of *Bacteroides fragilis* was also found in Appendectomy wound. The statistical significant reduction of surgical wound infection was demonstrated in group 2 patients; RR 1.61 (1.40-1.81) (Table 3).

In addition, there were two cases of skin irritation from povidone iodine scrub in group 1 patients but there was no allergic reaction to chlorhexidine detected in group 2 patients.

Discussion

The development of surgical site infections is related to three factors, 1) the degree of bacterial contamination during the operation, 2) the duration of procedure, and 3) underlying diseases of the patients such as immune deficiency, diabetes, and malnutrition[1]. Preoperative skin preparation is one of the important local factors concerning the development of surgical site infection. In the present study, the authors controlled risk factors for development of surgical site infection except preoperative skin preparation using two different antiseptic agents. According to Table 1, there was no significant statistical difference of the risk factors between the two groups of the sample patients such as age, operative time, wound classification, or underlying host factors. The authors standardized the two groups of sample by the inclusion criteria. The authors also prepared both groups under the same standard guidelines. Gram-positive bacteria was the predominant organism on the skin. The authors demonstrated that pharmacologic action against gram-positive organism of chlorhexidine might be superior to povidone iodine. There was significant statistical difference in the colonization reduction in the chlorhexidine group. The colonization count, mainly gram-positive organism, was reduced more in the chlorhexidine group than povidone iodine group. In addition, wound infection could be decreased from 3.2% to 2% after chlorhexidine skin preparation. However, some cases were infected by gram-negative bacilli or anaerobic organism such as *Enterobacter* in appendectomy and gastrectomy, *E. coli* in right half

colectomy, or *Bacteroides fragilis* in appendectomy. Normal flora at the skin should be gram-positive organism such as *Staph.* spp. or *Strep* spp. Therefore, it should consider that some wound infections occur by the surgical technique such as microspillage from the intestinal content that cannot be totally prevented by skin antiseptic only. Color staining and hypersensitivity are another disadvantage of povidone iodine solution. There is no report of hypersensitivity in the chlorhexidine group in the present study.

Conclusion

The present study suggests that colonization of the bacteria is significantly reduced in the chlorhexidine group. Post-operative surgical wound infection is also reduced in chorhexidine group. Other disadvantages of using povidone iodine are hypersensitivity and color staining. Chlorhexidine antiseptic should be the first consideration for preoperative skin preparation.

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การศึกษาแบบสุ่มไปข้างหน้าเพื่อเปรียบเทียบการติดเชื้อในแผลผ่าตัดระหว่างการเตรียมผิวหนังเพื่อการผ่าตัดด้วยสารละลาย chlorhexidine 4% และ povidone iodine

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***ภูมิหลัง**: การเตรียมผิวหนังเพื่อการผ่าตัดเป็นขั้นตอนสำคัญแต่ยังไม่มีผู้ศึกษาถึงการใช้ chlorhexidine 4% สำหรับการเตรียมผิวหนังเพื่อการผ่าตัดในแผนกศัลยกรรมมาก่อน*

***วัตถุประสงค์**: เพื่อเปรียบเทียบการลดจำนวนแบคทีเรีย และการติดเชื้อหลังผ่าตัดของแผลผ่าตัด ระหว่างการเตรียมผิวหนังด้วย chlorhexidine 4% และ povidone iodine*

***วัสดุและวิธีการ**: ผู้ป่วยที่เข้ารับการผ่าตัดในภาควิชาศัลยศาสตร์ คณะแพทยศาสตร์มหาวิทยาลัยธรรมศาสตร์ จำนวนรวม 500 คน จะถูกแบ่งเป็น 2 กลุ่ม กลุ่มละ 250 คน กลุ่มหนึ่งได้รับการเตรียมผิวหนังด้วย povidone iodine ส่วนอีกกลุ่มได้ chlorhexidine 4% ผู้ป่วยได้รับการตรวจหา จำนวนเชื้อแบคทีเรียที่ยังเหลือบนผิวหนัง และการติดเชื้อหลังผ่าตัดที่แผลผ่าตัด*

***ผลการศึกษา**: ผู้ป่วยทั้งสองกลุ่มมีลักษณะพื้นฐานไม่แตกต่างกัน จำนวนแบคทีเรียบริเวณแผลผ่าตัดในกลุ่มที่ได้รับการเตรียมแผลด้วย chlorhexidine 4% ลดลง มากกว่ากลุ่มที่ได้รับ povidone iodine อย่างมีนัยสำคัญทางสถิติ นอกจากนี้กลุ่ม chlorhexidine 4% ยังมีการติดเชื้อที่แผลผ่าตัดน้อยกว่ากลุ่ม povidone iodine*

***สรุป**: การเตรียมผิวหนังที่จะผ่าตัดด้วย chlorhexidine 4% สามารถลดจำนวนแบคทีเรียที่ผิวหนัง และลดอัตราการติดเชื้อหลังผ่าตัดบริเวณแผลผ่าตัด ได้มากกว่าการเตรียมด้วย povidone iodine*