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The effect of 7.5% Povidone-Iodine versus 0.2% Chlorhexidine on Microbial Count of Surgical Site in Abdominal Surgery: A Randomized Clinical Trial

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Abstract

Background: One of the most common preventive methods of Surgical Site Infection (SSI) is preoperative skin preparation. Selecting the skin antiseptic before surgery is an important step that can reduce SSI risk.

Aim: The present study was performed with aim to compare the effect of 7.5% povidone-iodine (PVP-I) and 70% alcohol versus 0.2% chlorhexidine (CHG) and 70% alcohol on the microbial count of the surgical site in the abdominal surgery.

Method: This double-blind randomized clinical trial study was conducted between March 2017 and July 2018 at the educational-therapeutic centers of Iran University of Medical Sciences. The patients aged ≥18 years who underwent elective abdominal surgery were randomly assigned into two groups to have their skin cleaned before surgery with CHG-alcohol or PVP-I-alcohol. Also, before skin prep, after the primary prep and after the secondary prep, microbial cultures were taken. Data analysis was performed using SPSS (version 16) and Chi-square, Fisher's exact, Kolmogorov-Smirnov, Wilcoxon and U-Mann-Whitney tests. $P<0.05$ was considered statistically significant.

Results: The microbial counts mean differences before and after skin preparation with PVP-I-alcohol were significant ($P<0.05$). Also, the microbial counts mean differences before and after skin preparation with CHG-alcohol were significant ($P<0.05$). Overall, both antiseptic groups significantly reduced microbial counts. Although the skin preparation with CHG-alcohol was better than the PVP-I-alcohol solution, the difference between the two groups was not significant ($P>0.05$).

Implications for Practice: This study did not demonstrate an overall superiority of 2% CHG over 7.5% PVP-I skin preparation solution or vice versa. Both groups can be used to prepare patients' skin before abdominal surgery due to the affordability conditions and availability.

Keywords: Anti-Infective Agents, Chlorhexidine, Colony Count, Microbial, Povidone-Iodine, Surgical Site Infection

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Introduction

Surgical Site Infection (SSI) is the second most common cause of healthcare-associated infection (1). Patients who develop SSI are prone to long-term hospitalization, pain, disability, poor healing, and the use of many antibiotics, representing the financial and psychological burden on patients (2,3). In addition, severe SSI is associated with significant morbidity and mortality (4,5).

One of the most common preventive methods of SSI is preoperative skin preparationthat can reduce SSI risk (6). Selecting the skin antiseptic before surgery is an important step in preventing SSI (7). In 2016, WHO recommended 29 antiseptics for prevention of SSI including alcohol, chlorhexidine Gloconate (CHG), and Povidone-Iodine (PVP-I) (8). These antiseptics quickly reduce the number of microorganisms in the surgical site and inhibit microbial growth for several hours (9,10). In the study of Bazi et al. (2015), the results showed that the combination of alcohol and betadine, and also in the study of Malekzadeh et al. (2015), the results showed that betadine is an effective disinfectant in reducing inflammation and infection of the vascular access in hemodialysis patients (11,12). The research of Mimoz et al. (2015) demonstrated that both chlorhexidine and povidine-iodine have broad-spectrum antimicrobial properties that are effective against a wide range of bacteria, fungi, and viruses (13).

Some studies perform more than one skin prep per surgery to achieve greater success (14). Also, combining two antiseptics, each of which has a separate action of destroying microbes, may increase the effectiveness of antiseptics; In addition, if there is resistance to one antiseptic, a second antiseptic may be more effective (14). Therefore, it seems reasonable to use the combination of povidone-iodine with alcohol or chlorhexidine with alcohol.

On the other hand, according to some studies, preoperative skin cleansing with CHG-alcohol reduces SSI as compared with PVP-I solutions (15,16). Also, some studies reported that both CHG-alcohol and PVP-I solutions are equally effective antiseptic agents for the prevention of infections (17,18).

To our knowledge, surgical site infection remains as one of the side effects of surgeries and no powered RCTs have evaluated the effect of combining various skin preparations on microbial count in patients undergoing abdominal surgery. Therefore, this study was performed with aim to assess and compare the effect of 7.5% povidone-iodine (PVP-I) and 70% alcohol versus 0.2% chlorhexidine (CHG) and 70% alcohol on the microbial count of the surgical site in the abdominal surgery.

Methods

This double-blind randomized clinical trial study with parallel groups and pretest-posttest design was conducted between March 2017 and July 2018 at the educational-therapeutic centers of Iran University of Medical Sciences. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Out of 94 registered patients, 80 were included in the study and 14 were excluded. The participants were placed in the two groups of PVP-I and CHG (Figure 1). Patients aged 18 years or older who underwent an elective abdominal surgery were included. The exclusion criteria were: history of inflammatory skin diseases, history of sensitivity to antiseptics (alcohol, PVP-I, and CHG), presence of wounds or any visible skin lesion in the abdomen, immune system deficiency and taking immunosuppressive drugs. The sample size was estimated according to a previous study (19) and considering the reliability coefficient ($Z_{1-a/2}$: 1.96), 80% power (Z_{1-B}: 0.84), P_0=0.6 and P_1=0.285; so 38 people were estimated for each group. According to the possibility of sample dropout, 40 people were calculated in each group and a total of 80 participants were studied. The patients were allocated to two groups A and B by simple randomization method and by flipping a coin. Group A: abdominal skin preparation with 7.5% PVP-I, 70% alcohol and 10% PVP-I solutions**.** Group B: abdominal skin preparation with 2% CHG, 70% alcohol and 10% PVP-I solutions. Patients and assessors were blinded to the solution used.

After initiation of anesthesia and before preoperative skin preparation, two primary culture samples were taken by the researcher from the surgical site with a swab moistened with physiological serum. The first swab was smeared on the blood agar medium and the second swab sample was rubbed on the McConkey agar medium. Then, skin painting with antiseptic solution started by circulator nurse from the planned incision site with gentle pressure and proceeded to the periphery by widening circular motion for three minutes. After four minutes the solution was dried, the second culture samples was taken by the researcher with two swabs moistened with physiological serum. The first swab was

smeared on blood agar medium and the second swab sample was smeared on McConkey agar medium. Then, secondary prep was done by 10% PVP-I by rubbing on the skin for two minutes (According to AST's recommendation, the minimum time for skin preparation with antiseptic solutions should be 5 minutes (20)). after four minutes the solution was dried, the third culture sample was collected using two swabs moistened with physiological serum. Then, the first swab was smeared on blood agar medium and the second swab sample was smeared on McConkey agar medium.

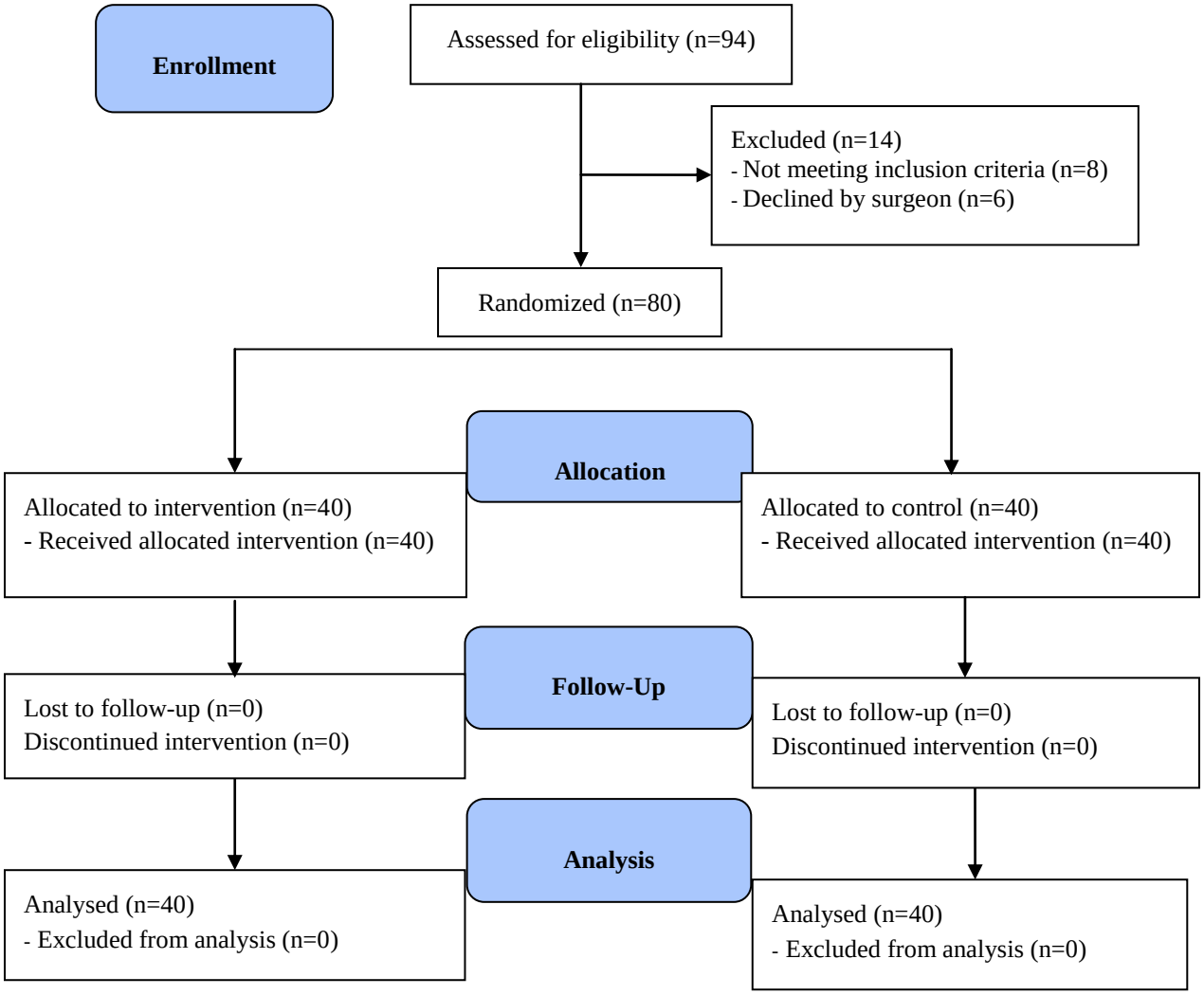

Figure 1. CONSORT flow diagram of the study

Samples taken were immediately transferred to the microbiological laboratory, where the blood agar and McConkey agar medium were placed in an incubator under 37 degrees Celsius for 24 hours, and in case of no colony growth, they were incubated again for another 24 hours. The number of colonies grown in blood agar and McConkey agar medium was counted. Diagnostic and differential tests were performed for gram-positive and gram-negative bacteria to determine the type and gender of the bacteria. A code was assigned to each sample to avoid bias. Only the researcher knew which group each patient belonged to and the rest of the research team members were not aware of this issue.

The primary outcome was to compare the microbial count before and after skin preparation with antiseptic solutions and the secondary outcome was the difference between microbial count among the 2 types of skin preparation.

Data analysis was performed using SPSS software (version 16; IBM Corp, Armonk, N.Y, USA). Chi-square and Fisher's exact tests were used to examine the relationships between categorical variables. The normality of the data was tested using the Kolmogorov-Smirnov test. Mann-Whitney and Wilcoxon tests were used to compare the mean microbial counts in the studied groups. $P<0.05$ was

considered statistically significant.

Results

The majority of the participants were in the age range of 28-37 years (32.5%), male (50%), single (50%) with bachelor's degree (46.3%). Most people had insufficient income (86.3%) and were city residents (77.5%). The distribution of patients in terms of demographic variables was the same in both groups (Table 1).

Table 1. Demographic characteristics of the study participants

Variable	Group A N (%)	Group B N (%)	P-value*
Sex			X^2= 0.050
Male	21 (52.5)	20 (50)	df=1
Female	19 (47.5)	20 (50)	0.823*
Age			
18-27	7 (17.5)	7 (17.5)	
28-37	13 (32.5)	13 (32.5)	X^2= 3.925
38-47	3 (7.5)	7 (17.5)	df=4
48-57	9 (22.5)	10 (25)	0.440**
58-67	8 (20)	3 (7.5)	
Marital status			
Single	21 (52.5)	19 (47.5)	X^2= 1.005
Married	12 (30)	16 (40)	df=2
Other	7 (17.5)	5 (12.5)	0.605*
Education			
Illiterate	5 (12.5)	3 (7.5)	X^2= 0.860
Diploma	14 (35)	16 (40)	df=3
Bachelor's degree	19 (47.5)	18 (45)	0.872**
Master's degree	2 (50)	3 (7.5)	

* Chi-Square **Fisher exact

According to the results presented in Table 2:

The mean count of micrococcus before the intervention in the two groups did not show a statistically significant difference (p=0.723). Moreover, this value after the intervention did not show a statistically significant difference in the two groups (p=0.320). The results showed that the mean count of micrococcus in group A significantly decreased by 14.2 ± 28.93 units after the intervention (p=0.0001). Also, the mean difference count of micrococcus in group B significantly decreased by 13.25±27.09 after the intervention (p=0.0001).

The mean count of streptococcus before the intervention in the two groups did not show a statistically significant difference (p=0.836). This value also after the intervention did not show a statistically significant difference in the two groups (p=0.999). The results showed that the mean count of streptococcus in group A significantly decreased by 3.45±7.91 units after the intervention (p=0.011). Also, the mean difference count of streptococcus in group B significantly decreased by 1.92±5.12 after the intervention (p=0.012).

Comparison of the mean count of coagulase-negative staphs before the intervention in groups A and B did not show a statistically significant difference (p=0.571). The mean count of coagulase-negative staphs after the intervention did not have a statistically significant difference in groups A and Bicantly decreased by 42.07±157.54 units after the intervention (p=0.0001). Also, the mean count of coagulase-negative staphs in group B significantly decreased by 29.8±49.6 units after the intervention (p=0.0001).

The mean count of diphtheroid before the intervention did not show a statistically significant difference in the two groups (p=0.562). Also, the mean count of diphtheroid after the intervention was significantly different in the two groups (p=0.317). The results showed that the mean count of diphtheroid in group A significantly decreased by 6.8±3.82 units after the intervention (p=0.0001). Also, the mean difference count of diphtheroid in group B significantly decreased by 16.55±6.07 after the intervention (p=0.0001).

Table 2. Mean of microorganisms at the surgical site scores in the two groups

		Group A		Group B		Between group test**
		Mean±SD	Median (IR)	Mean±SD	Median (IR)	
Micrococcus	Before	14.3±28.94	1 (11.50)	13.3±27.07	0 (0)	*P*=0.723 *Z*= -0.355
	After initial	0.1±0.37	0 (0)	0.05±0.31	0 (0)	*P*=0.320 *Z*= -0.994
	Mean difference	14.2±28.93	-1 (11.50)	13.25±27.09	-1 (10)	
Within group test*		*P*=0.0001 *Z*= -4.11		*P*=0.0001 *Z*= -4.38		
Streptococcus	Before	3.45±7.91	0 (0)	1.92±5.12	0 (0)	*P*=0.836 *Z*= -0.207
	After initial	0	0 (0)	0	0 (0)	*P*=0.999 *Z*= 0.00
	Mean difference	3.45±7.91	0 (0)	1.92±5.12	0 (0)	
Within group test*		*P*= 0.011 *Z*= -2.53		*P*= 0.012 *Z*= -2.52		
Coagulase-negative staphs	Before	42.07±157.54	10 (18.75)	29.8±49.6	10 (18)	*P*=0.571 *Z*= -0.576
	After initial	0	0 (0)	0.05±0.31	0 (0)	*P*=0.317 *Z*= -1.000
	Mean difference	42.07±157.54	-10 (18.75)	29.75±49.42	-22 (18)	
Within group test*		*P*=0.0001 Z= -4.94		P= 0.0001 Z= -5.24		
Diphtheroid	Before	3.85±6.82	0 (6.25)	6.07±16.55	0 (4)	*P*=0.562 *Z*= -0.580
	After initial	0.025±0.15	0 (0)	0	0 (0)	*P*=0.317 *Z*= -1.000
	Mean difference	3.82±6.8	0 (6.25)	6.07±16.55	-0.5 (4)	
Within group test*		*P*=0.0001 *Z*= -3.52		*P*=0.0001 *Z*= -3.92		
Staphylococcus aureus	Before	1.02±4.78	0 (0)	1.07±4.80	0 (0)	*P*=0.816 *Z*= -0.233
	After initial	0	0 (0)	0	0 (0)	*P*=0.999 *Z*=0.000
	Mean difference	1.02±4.78	0 (0)	1.07±4.8	0 (0)	
Within group test*		*P*=0.027 *Z*= -2.21		*P*= 0.042 *Z*= -2.03		
Bacillus spore-forming	Before	0.65±3.16	0 (0)	0.45±2.37	0 (0)	*P*=0.492 *T*= -0.687
	After initial	0	0 (0)	0	0 (0)	*P*=0.999 *Z*= 0.000
	Mean difference	0.65±3.16	-0.11 (0)	0.45±2.37	0 (0)	
Within group test*		*P*=0.024 *Z*= -2.26		*P*=0.059 *Z*= -1.89		

*Wilcoxon ** Mann–Whitney

The mean count of staphylococcus aureus before the intervention and also after the intervention did not show a statistically significant difference in the two groups (*p*=0.816 and *p*=0.999, repectively). The results showed that the mean count of staphylococcus aureus in group A

significantly decreased by 4.78±1.02 units after the intervention (p=0.027). Also, the mean difference count of staphylococcus aureus in group B significantly decreased by 4.8±1.07 after the intervention (p=0.042).
The mean count of bacillus spore-forming before the intervention and also after the intervention did not show a statistically significant difference in the two groups (p=0.492 and p=0.999, respectively). The results showed that the mean count of bacillus spore-forming in group A significantly decreased by 3.16±0.65 units after the intervention (p=0.024). Also, the mean difference count of bacillus spore-forming in group B significantly decreased by 2.37 ± 0.45 after the intervention (p=0.059).

Discussion

The purpose of the current study was to compare the effect of 7.5% povidone-iodine (PVP-I) and 70% alcohol versus 0.2% chlorhexidine (CHG) and 70% alcohol on the microbial count of the surgical site in the abdominal surgery. The result of this study revealed that there is not a significant difference in mean skin microbial count after skin preparation with PVP-I-alcohol and 10% PVP-I solution compared with CHG-alcohol and 10% PVP-I solution. The findings complemented previous studies that found no evidence to suggest one antiseptic preference over the other (21-23), but it was inconsistent with some other studies (24,25). Dorfel et al. (2021) showed that alcohol-based povidone-iodine had more substantial benefits over alcohol-based chlorhexidine concerning the anaerobic flora of the shoulder (24). Also, the results of Peel et al.'s study (2019) showed that iodine-alcohol had greater efficacy than chlorhexidine-alcohol for preventing surgical site infection (25). It seems that this different finding is due to the essence of two antiseptic groups which had similar effects on the microorganisms due to their broad-spectrum and fast-acting effects and were able to significantly reduce the microbial count.
Beside the present study's main result, although there was not a significant difference in microbial count between the two groups, skin preparation with CHG-alcohol and 10% PVP-I solution was better to reduce microbial count. Similar to our study, the study of Obamuyide et al. (2015) showed that both PVP-I and CHG-alcohol are effective on reducing bacterial colonization of the skin of orthopaedic patients after skin preparation. However, CHG-alcohol is better to eradicate aerobes from the skin of orthopaedic patients and demonstrates a more persistent action on anaerobes even to the post-closure period and suppress the generally observed increase in skin organism counts which occur during surgery (26).
Our study indicated that there was a significant difference between the mean microbial count before and after the skin preparation with PVP-I-alcohol and 10% PVP-I solution; the result is consistent with the findings of the study of some studies (13,14,22,27-29). Our findings also demonstrate that the mean microbial count was significantly different before and after skin preparation with CHG-alcohol and 10% PVP-I solution. Similar to our finding, the results of the studies of kavi et al.(2017) (19), Rao et al.(2017) (30), Cheng et al.(2009) (31), Broach et al.(2017) (32) and Boisson et al.(2019) (28) showed the same result. It seems that this finding is due to the fact that these antiseptics have been able to effectively affect the microorganisms and significantly reduce the microbial count. Non-cooperation of some patients and surgeons in sampling was the limitation of the current research, so it was tried to obtain the consent of the participants by fully explaining that all antiseptics are approved. It is suggested that these approved antiseptics should be examined in other areas of the body as well as in terms of economic efficiency, skin complications, etc.

Implications for practice

This study did not demonstrate an overall superiority of CHG-alcohol and 10% PVP-I over PVP-I-alcohol and 10% PVP-I skin preparation solution or vice versa. Both groups can be used to prepare patients' skin before abdominal surgery due to the affordability conditions and availability.

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Conflicts of interest

The authors declared no conflict of interest.

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