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Original Article

The Severity of Wound Infection in Washing the Primary Prep Area with 70% Alcohol and Normal Saline in the Orthopedic Surgery Prepped with Povidone-Iodine: A Randomized Clinical Trial

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Abstract

Background: Despite significant advances in patient treatment, infection remains a complication after surgery. The present study compared the incidence and severity of wound infection with two methods of washing the primary prep area with 70% alcohol and normal saline in patients who are candidates for orthopedic surgery in Kowsar Hospital of Sanandaj, Iran.

Methods: This single-blinded randomized clinical trial was conducted on 190 candidates for upper limb orthopedic surgery aged 18 to 65. Patients were randomly assigned to two alcohol and normal saline groups based on the table of random numbers. The primary outcome of this clinical trial was the incidence and severity of wound infection after surgery, which was measured by the standard scale of the Asepsis index. The results were analyzed using SPSS version 23, and statistical values less than 0.05 were considered significant.

Results: Patients' hospitalization duration in the intervention group was (3.02±1.04 days) and in the control group (2.86±1.03 days) showed no significant statistical difference (p=0.297). The frequency of wound infection in the alcohol group was lower than in the normal saline group. this difference was statistically significant (p=0.023). Also, the severity of wound infection in the 70% alcohol group (Mean=5.12, SD=3.19) was lower than in the normal saline group (Mean=7.69, SD=4.12). This difference was statistically significant (p<0.001).

Conclusion: The present clinical trial showed that the incidence and severity of wound infection after surgery were lower in the group washing the skin of the surgical area with alcohol compared to the group washing with normal saline.

Keywords: Acute care surgery, Asepsis, Chi-square distribution, Control groups, Ethanol, Hospitalization, Hospitals, Humans, Incidence, Orthopedic procedures, Saline solution, Upper, Extremity, Wound infection

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Introduction

Despite significant advances in patient treatment, infection remains a complication after surgery (1). Currently, 500 to 920 thousand cases of surgical infection have been reported in 23 million surgeries performed in the United States (2). Wound infection severely affects the patient's quality of life and increases patient care costs. Complications of surgical wound infection can range from a slight increase in pain to septicemia and even death (3). Several methods have been used to reduce the infection rate, such as heat therapy, preparation of the surgical environment, sterilization of surgical instruments, and, most importantly, skin preparation before surgery (4).

The skin is suitable for many bacteria (up to three million microorganisms per square centimeter) to grow. The purpose of disinfecting the skin before surgery is to remove and prevent the growth and proliferation of microorganisms on the skin (5). There are methods for preparing the skin for surgery, one of which is skin disinfection with antiseptic solutions (PREP), performed by the surgeon in the operating room (6). Ideal antiseptics have the lowest cost and reduce the number of existing microorganisms with minimal irritation and skin damage (7,8). Microorganisms causing wound infection can be exogenous or endogenous. Exogenous microorganisms, such as surgical instruments, may enter the wound from the treatment team or the environment around the repair site. Endogenous microorganisms may cause infection from the damaged or other parts of the patient's body (9). Among operated patients, Surgical Site Infection (SSI) is the most common type and includes 67% of these cases (6). SSI refers to surgical wound infection up to one month after the operation in cases where no prosthesis was used and up to one year after the surgery where the prosthesis was used (4,10-14).

Povidone iodine, which is a combination of iodine and polyvinyl pyrrolidine, is a medium-level disinfectant that is effective against gram-positive and gram-negative bacteria, fungi, viruses, spores, protozoa, amoebic and has a lasting effect on less than six *hrs*. Alcohol also has a fast and widespread bactericidal effect, which has a short duration of effect due to its volatility. The American Association of Operating Room Nurses believes that 60-70% alcohol concentrations have an excellent effect on surgical scrubs, thus they can quickly and significantly reduce skin bacteria (1). In the research conducted by Shami *et al*, it was found that using the combination of 2% chlorhexidine gluconate with 35% ethanol compared to 10% betadine and 70% ethanol to prepare the catheter insertion site reduces the risk of phlebitis in internal wards. Therefore, utilizing a combination of different disinfectant solutions has different results (11). In the research by Nikeghbali *et al*, it was demonstrated that betadine (povidone-iodine) alone has an appropriate antimicrobial effect (12). However, in another study conducted by Mozafar *et al*, it was found that two-step washing with brown betadine and then green betadine does not have a more significant antimicrobial effect than one-step washing with green betadine (4). Although the skin of the surgical site can never be sterilized with these solutions, with these measures, the skin is disinfected to some extent (10). Generally, preparing the skin before surgery includes eliminating transient microbes, reducing resident microbes to the minimum possible, and suppressing these microorganisms for a long time since the dressing is a suitable environment for the growth and proliferation of microorganisms (13-17).

Currently, in various operating rooms, both alcohol and normal saline solutions are used to wash the primary preparation. According to the literature, there were few articles focused on evaluating these antiseptic solutions; consequently, due to the lack of valid data to suggest which antiseptic solution is the most effective. Disinfectant products are often mixed with alcohol or water, which makes it challenging to form overall conclusions regarding an active ingredient (18). The literature has strong evidence that optimizing specific preoperative, intraoperative, and postoperative variables can significantly lower the risk of developing an SSI (19). Since infection prevention is crucial due to its complications and problems, using suitable washing solutions is one of the main strategies for preventing and controlling infections after surgery. The present study compares the incidence and severity of wound infection with two methods of washing the primary prep area with 70% alcohol and normal saline in patients who are candidates for orthopedic surgery in Kowsar Hospital of Sanandaj.

Materials and Methods

This single-blinded randomized clinical trial was registered in the Iranian randomized clinical trials center with ID number IRCT20160301026861N3, and after obtaining the university ethics committee's approval (IR.MUK.REC.1398.222) and patients' written consent, it was conducted on 190 patients aged 18 to 65. The patients were randomly assigned to two alcohol and normal saline groups based on the table of random numbers. The statistical population included patients who were candidates for upper limb orthopedic surgery (trauma surgeries). A single surgical team performed all the surgeries. Additionally, the operating room conditions were consistent across all the cases (Figure 1).

Inclusion criteria

The participants were included in the study based on the following criteria: candidate for elective upper extremity orthopedic surgery (trauma surgeries), volunteer to participate in research, shaving the surgical area hair before the operation, patient's body mass index less than 30, lack of skin damage in the surgical site due to trauma, absence of underlying infectious diseases, digestive disorders, blood problems, immune system disorders, skin allergies, burns, and previous surgery in the prep area and no vascular problems in the organ under surgery.

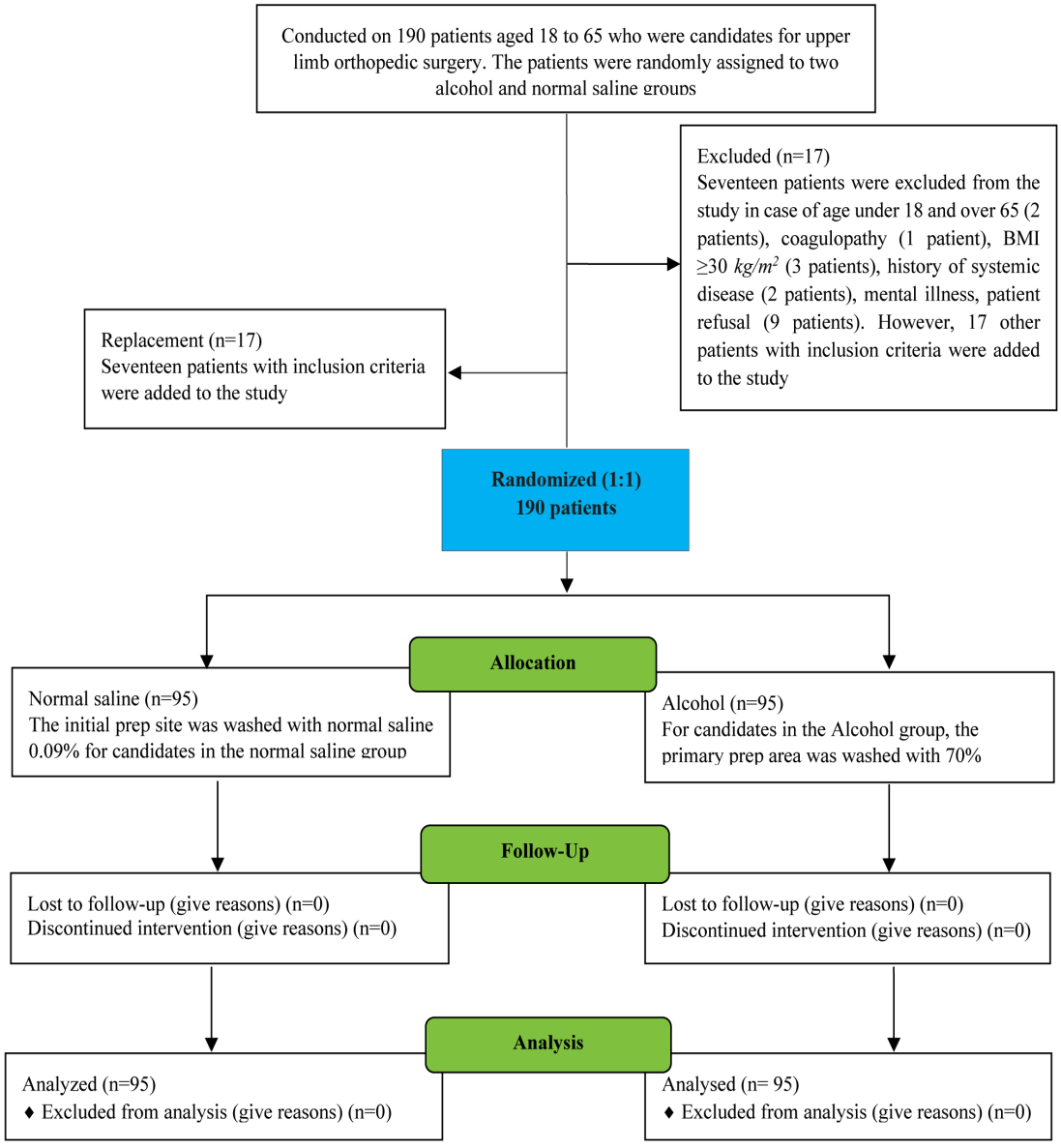

Figure 1. Study flow diagram.

Exclusion criteria

The exclusion criteria were as the following. The patient's refusal to continue participating in the investigation, pregnant women, unpredictable events during and after surgery (such as massive bleeding, acute compartment syndromes, anesthesia complications), non-sterilization of sterile parts due to contact with non-sterile equipment and parts during surgery, having underlying diseases, such as rheumatoid arthritis, diabetes, hypertension, and lack of necessary patient cooperation in the postoperative stage.

Sample size

The sample size was based on the following formula: an alpha of 5% and a beta of 20%, assuming that the minimum distribution difference of the ratio of independent variables is 10% (18). (p1=10% and p2=20%), 196 patients were determined in each group.

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 (p_1(1-p_1) + p_2(1-p_2))}{(p_1 - p_2)^2}$$

Considering that the size of the target community for each group is small, it is estimated to be around 180 individuals. Therefore, the sample size was adjusted using the following formula, and 94.3 patients were determined for each group. Finally, in this study, 95 individuals were included in each group.

$$n' = \frac{n}{1 + \frac{n}{N}}$$

$$n' = 196/1+196/180 = 94$$

Intervention design

Alcohol group (95 patients): for candidates in the alcohol group, the primary prep area was washed with 70% alcohol. Normal saline group (95 patients): the initial prep site was washed with normal saline 0.09% for candidates in the normal saline group.

After obtaining the written consent from the individuals and documenting their demographic and clinical characteristics, they were randomly divided into normal saline and alcohol groups. The operating site was prepared and scrubbed in both groups with 7.5% brown betadine diluted with normal saline for three *min*. After the initial prep, brown betadine 7.5% was on the skin surface for two *min*. In the alcohol group, the primary prep area was washed with 70% alcohol; in the normal saline group, the initial prep site was washed with normal saline. In the washing group with 70% alcohol, we waited until the alcohol was arid. Using a sterile towel, the primary preparation site was dried in the washing group with normal saline. The surgical site was shaved in all the patients before and after the intervention in both groups; secondary preparation was performed with 10% betadine and three gauzes for at least five *min*. In both groups, the surgical team used two gloves. Duplicate suture threads were used as much as possible to heal the tissue. In the postoperative phase, one nurse in both groups changed the dressing. Both groups were encouraged to follow a healthy diet. The perioperative antibiotics (Cefazolin 1 *g* IV) were administered half an *hr* before the operation, and the patients' dress was changed every other day by considering all the aseptic precautions. Cefazoline 1 *g* was administrated every 8 *hrs* after surgery for 24 *hrs* in the studied groups.

Randomization and blinding

The participating patients undergoing upper limb orthopedic surgery (trauma surgeries) did not know the type of intervention. The randomization process was done using a random number generator to ensure the allocation was truly random. In this clinical trial, the participants were randomly assigned to either the Alcohol group (95 patients) or the Normal saline group (95 patients). According to the random number table, the study began. Before the study, from an ethical point of view, the participants were informed that one of the two types of intervention would be done for them. The first researcher performed the necessary interventions in the intervention and control groups. The second investigator (orthopedic surgeon), who measured the incidence and severity of wound infection after surgery, must be made aware of the type of intervention and the groups. Therefore, as a second person, he was blinded to the study. Also, as a data analyst, the statistical consultant must know the groups.

Outcomes

The primary outcome of this clinical trial was the

incidence and severity of wound infection after surgery, which was measured by the standard scale of the Asepsis index. This tool (with high validity and reliability above 80%) has been used in numerous studies to evaluate the severity of wound infection. Based on this scale, a score of 0-10 indicates complete healing of the wound, a score of 11-20 represents impaired wound healing, a score of 21-30 shows partial wound infection, a score of 31-40 indicates moderate wound infection and a score greater than 40 demonstrates severe wound infection (17). Based on this form, at the time of discharge, the wound status was scored by one of the colleagues, and after discharge, a copy of the Asepsis Index tool was attached to the patient's notebook, and they were requested to deliver it during their visit (up to two weeks after the surgery). The patients were excluded from the study if the infection investigation forms were not returned during suture removal. The sampling continued until the number of samples in each group reached 95.

Statistical analysis

Descriptive tables, frequency charts, and statistics, including average and standard deviation were used to provide descriptive characteristics. An independent t-test was utilized to compare the mean scores obtained by measuring the variables with a proportional scale in the alcohol and normal saline groups. The chi-square test was used to compare the incidence of wound infection in the two groups and the nominal and rank variables in the alcohol and normal saline groups. The results were analyzed using SPSS version 23, and statistical values less than 0.05 were considered significant.

Ethical considerations

This clinical trial was approved by the Kurdistan University ethics committee (IR.MUK.REC.1398.222) and registered in Iran's clinical trial registration system with the number IRCT20160301026861N3. All the eligible patients signed the consent form. The trial goals were explained to all the participants. The individuals were assured that the information obtained would be confidential. It was reminded that there is no need to mention the name and family name in the questionnaire. The participants were reminded that their non-participation in the study would not affect their treatment process. The patients could voluntarily withdraw from the study whenever they desired. At the end of the study, the participants and the officials of the operating room were informed of the research outcomes if asked.

Results

According to the study results, the demographic and clinical characteristics of the participants in the intervention and control groups were homogeneous and had no statistically significant difference ($p>0.05$). The majority of participants in both groups were male. The chi-square test (0.08) showed that the statistical difference between the frequency distribution of males and females in the two groups was not significant ($p=0.25$) (Table 1). The mean and standard deviation of the participants' age in the intervention group was (28.05±9.87) and in the control group (28.17±9.80). The independent t-test indicated that this average difference (-0.12) was not significant [t (df) 188; t value=-0.08; $p=0.93$; (Table 2)].

Most participants in the intervention group (45 individuals) had high school levels, and 43 in the control group were university graduates. Radius fracture was the most common surgery in both intervention groups (35 individuals) and the control group (33). The chi-square test (2.58) demonstrated that the statistical difference in the frequency distribution of diagnosis type in the two groups was not significant ($p=0.62$) (Table 1). The mean and standard deviation of the participants' body mass index in the intervention group was (25.02±2.81). In the control group (24.26±2.63), according to the independent t-test, this difference (-0.12) was insignificant [t (df) 188; t value=1.98; $p=0.57$)]. The mean and standard deviation of the incision size of the surgical area in *cm* was in the intervention group (14.78±6.28) and the control group (14.56±5.55). The independent t-test showed that this mean difference (0.22) was insignificant [t (df) 188; t value=0.25; $p=0.79$; (Table 2, Figure 2)].

The mean and standard deviation of the duration of surgery were in the intervention group (86.57±36.27 *min*) and the control group (87.89±32.48 *min*). The independent t-test indicated that this difference (-1.31)

Table 1. Patients' demographic and clinical characteristics data in two groups

Variables		Groups		p-value
		Normal saline	Alcohol	
Incidence of wound infection after surgery	Occurrence	16(17.84%)	6(7.32%)	0.023*
	Non-occurrence	79(83.16%)	89(93.68%)	
	Total	95(100%)	95(100%)	
Smoking	Yes	37(38.95%)	39(41.05%)	0.825*
	No	58(61.05%)	56(58.95%)	
	Total	95(100%)	95(100%)	
Kind of surgery	Radius fracture	33(34.74%)	35(36.84%)	0.582*
	Dual-bone forearm fractures	18(18.95%)	25(26.31%)	
	Broken arm	10(10.53%)	10(10.53%)	
	Ulnar fracture	29(30.53%)	21(22.11%)	
	Metacarpal fracture	5(5.26%)	4(4.21%)	
	Total	95(100%)	95(100%)	
Gender	Male	73(76.84%)	66(69.47%)	0.311*
	Female	22(23.16%)	29(30.53%)	
	Total	95(100%)	95(100%)	
Level of Education	University	43(45.26%)	32(33.68%)	0.174*
	High school	42(44.21%)	45(47.37%)	
	Elementary	9(9.47%)	17(17.89%)	
	Illiterate	1(1.05%)	1(1.05%)	
	Total	95(100%)	95(100%)	
Marital status	Single	53(55.79%)	49(51.58%)	0.339*
	Married	42(44.21%)	46(48.42%)	
	Total	95(100%)	95(100%)	
Intra-operating bleeding volume (*ml*)		247.23±59.36	289.51±63.18	0.284**
Blood transfusion	No transfusion	90(94.74%)	89(93.68%)	0.461**
	One time	4(4.21%)	5(5.26%)	
	Two time	1(1.05%)	1(1.05%)	
	Total	95(100%)	95(100%)	

* Chi-square test, **Independent t-test.

was not statistically significant [t (df) 188; t value= -0.26; p=0.79]. Patients' hospitalization duration in the intervention group was (3.02±1.04 days) and in the control group (2.86±1.03 days) and the independent t-test showed no significant statistical difference [t (df) 188; t value=1.04; p =0.29; (Table 2, Figure 2)]. The frequency of wound infection in the alcohol group was lower than in the normal saline group, and using the chi-square test, this difference was statistically significant (p<0.02) (Table 1). Also, the

Table 2. The investigated variables in two groups

Variables	Groups				p-value
	Normal saline		Alcohol		
	Mean	Standard deviation	Mean	Standard deviation	
The severity of wound infection after surgery (sepsis index score)	5.1263	3.19987	7.6947	4.81592	0.000
Duration of surgery (*min*)	86.5789	36.27806	87.8947	32.48223	0.793
Incision length of the surgical area (*cm*)	14.7895	6.28557	14.5684	5.55562	0.798
Length of hospitalization (days)	3.0211	1.04147	2.8632	1.03770	0.297
Age (years)	28.0526	9.87191	28.1789	9.80553	0.930
Body Mass Index (BMI)	25.0200	2.81431	24.2621	2.63484	0.057

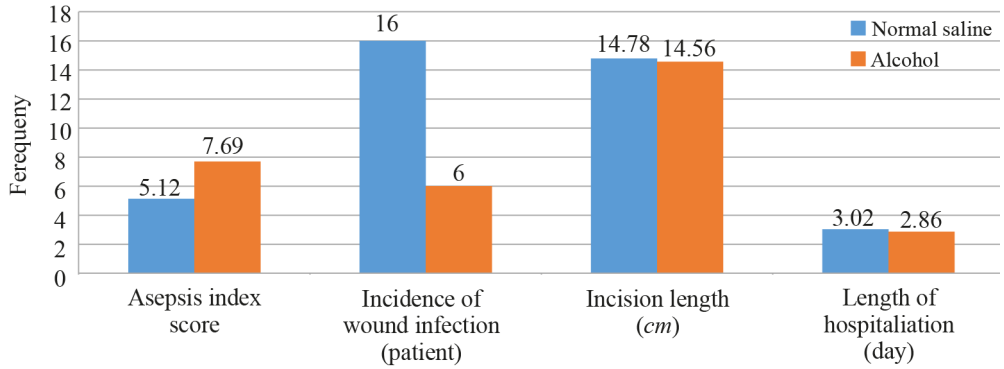

Figure 2. Frequency of wound infection, asepsis index score, incision length, and hospitalization duration in both groups.

results showed that the severity of wound infection in the 70% alcohol group (M=5.12, SD=3.19) was lower than in the normal saline group (M=7.69, SD=4.12). Based on the independent t-test, this difference was statistically significant [t (df) 188; t value=-4.330; p< 0.001; (Table 2, Figure 2)].

Discussion

SSI are one of the main concerns of operation and substantially burden medical costs for patients and healthcare systems due to different cures and lengthened patients' recovery. In this regard, hospital infection control committees have a crucial role in reducing superficial incisional infections through regular observation and evaluation (2,20-23). Based on the results of this study, the clinical and demographic characteristics of the patients in the alcohol and normal saline groups were homogeneous and had no statistically significant differences. Although in previous studies, the increase in body mass index (15) and age (16) were significantly associated with the increase in wound infection, in the recent study, the confounding of these variables was controlled by being homogenous and having no statistical differences in the two groups. In previous studies, underlying diseases (17), immune system disorders (20), increased body mass index (15), and skin damage in the surgical area (21) increased wound infection after surgery. In the present study, the confounding variables were controlled by preventing the samples from entering the study. Other possible confounding variables, such as nutritional status (20), type of suture and thread used (22), secondary prep with 10% povidone-iodine (21), type of antibiotic used, and method of care and dressing change (21), were controlled with homogenization in both groups

during the study.

In the current clinical trial, the incidence and severity of wound infection in the group using normal saline to wash the skin after the initial prep with povidone iodine 7.5% was higher than in the group using alcohol 70% to wash the skin after the initial prep with povidone iodine 7.5%. In this trial, the length of hospital stay in the alcohol group was lower than in the normal saline group, but the difference was not statistically significant. Other previous studies have also confirmed that normal saline was as effective as povidone 10% in disinfecting the skin of the surgical site (24,25). However, in the current study, alcohol was more effective than normal saline. Also, according to Green *et al,* washing the skin with alcohol 70%, followed by skin prep with povidone-iodine, was much more effective than povidone-iodine alone. The reason for that is probably due to the high rate of alcohol evaporation and the synergistic effect of alcohol with povidone-iodine (26). Gupta *et al* compared the efficacy of povidone-iodine alone and combined it with chlorhexidine gluconate 2.5% v/v in 70% propanol. Their investigation demonstrated that preoperative skin preparation with chlorhexidine gluconate 2.5% v/v in 70% propanol followed by aqueous povidone-iodine is an ideal regime as it has a broader antimicrobial spectrum, and the rate of postoperative wound infections is much lower as compared to povidone-iodine alone (27). Sistla *et al* study was designed to test whether chlorhexidine-ethanol has superior antimicrobial efficacy compared with povidone-iodine. The study revealed that infection rates with the use of povidone-iodine and chlorhexidine-ethanol groups were not significantly different and concluded that the antibacterial efficacy of chlorhexidine-ethanol and povidone-iodine is comparable in open hernia repair (28). This trial's findings were inconsistent with the present study's results, which can be due to the differences between the kind of surgery and other demographic and geographic variations.

Dockery reviewed the best surgical skin preparation solutions before surgery based on the operation area in orthopedic surgery (29). For upper limbs such as shoulder and elbow surgeries, they suggested that Povidone iodine® be applied with a 4×4 gauze, three-day pre-operative benzyl peroxide, and 3% hydrogen peroxide before skin preparation. For the hip and knee, they advised using 2% Chlorhexidine Gluconate (CHG) fabric the night before and morning of the operation and iodine-alcohol skin prep before surgery. In the foot and ankle surgeries, they suggested submersion of the foot in 70% ethanol or 10% isopropyl alcohol for five *min* before the procedure and a second vigorous scrub with 4×4 soaked gauze (29). Kick *et al* (30), in a laboratory study, evaluated the antiseptic effectiveness of 2 scrubbing regimens: povidone-iodine scrub (0.75%) combined with either 70% isopropyl alcohol and sterile saline methods on surgical incision healing. The incidence and severity of wound infection were investigated in mice on days zero, one, and seven days after surgery. Their study demonstrated no significant statistical difference between the groups. However, on the seventh day, in the histopathology sample, microbial growth and cell damage were significantly lower in the alcohol skin-washing group than in normal saline. However, both alcohol and normal saline methods reduced the risk of postoperative wound infection. This study's results were similar to ours, with the difference that this study was conducted on an animal sample. In a study conducted on a human sample, Strobel *et al* found that the effectiveness of normal saline serum 0.9% in preventing wound infection after laparotomy was less than polyhexanide solution 0.04 (31). A recent meta-analysis (32) indicated that using povidone-iodine before wound closure showed no significant reduction in SSI compared with normal saline. This trial confirms that povidone-iodine offers no benefit over normal saline for wound irrigation. In the current trial, the reason why alcohol 70% is more effective than normal saline in scrubbing the preoperative area of surgery and also in preventing wound infection after surgery is that alcohol has a synergistic effect on povidone-iodine and enhances the bacterio-septic effect of povidone-iodine. Another reason was the rapid drying of alcohol by air compared to normal saline serum. This caused the personnel to use a sterile towel to accelerate the drying of the prep area, which increased the possibility of non-sterilization of the surgical site. Considering that limited studies have been conducted in this field, more clinical trials with different approaches and a combination of clinical knowledge and experience will be necessary

in generalizing the results of evidence-based clinical studies regarding preventing and controlling infections after surgery (33,34).

Conclusion

The present clinical trial showed that the incidence and severity of wound infection after surgery were lower in the group washing the skin of the surgical area with alcohol compared to the group washing with normal saline. Although both alcohol and normal saline solutions effectively disinfect the skin after initial preparation, it is recommended to use alcohol to wash the surgical area after initial prep (if there is no wound or skin injury).

Limitations

This trial was conducted in a specific area of the world, and a particular population, hence conducting more clinical investigations with different methods, types of surgeries, used devices, and large sample sizes in this field and combining clinical knowledge and experience to generalize the results of evidence-based studies are suggested.

Ethical approval

Before the trial started, all the participating patients signed an informed consent form. Ethical approval was obtained from the Research and Ethics Committee (IR.MUK.REC.1398.222) of the Kurdistan University of Medical Sciences, Sanandaj, Iran.

Funding

No funding was used in this study.

Conflict of Interest

Authors declare no conflict of interest.

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