Original research article

Is 1% povidone-iodine solution superior to normal saline for simple traumatic wound irrigation?

Hamed Basir Ghafouri[a], Mina Zavareh[a,b,*], Fatemeh Jalili[a], Salimeh Cheraghi[a]

[a] Emergency Medicine Management Research Center, Iran University of Medical Sciences, Tehran, Iran
[b] Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, Tehran, Iran

ABSTRACT

Background: Povidone-iodine is a broad spectrum antiseptic irrigation solution which has been used in wound management processes for decades but some recent studies have questioned its superiority to normal saline and even tap water in decreasing the infection rate in different types of wounds.
Objective: This study compares the efficacy and safety of diluted povidone-iodine solution with normal saline as in decreasing the infection rate in simple traumatic wounds repaired in emergency department.
Method: Patients with simple traumatic were included and randomly allocated to 2 groups. In 223 patients, wounds were irrigated with 1% povidone-iodine solution. In the other 223 patients, wounds were irrigated with 0.9% normal saline solution. Wound infection rates were compared by assessing the signs and symptomsof infection including cellulitis, abscess, lymphangitis and pus formation.
Result: Infectious complications were seen in 29 of 446 (7.4%) patients (15 in povidone-iodine versus 14 in normal saline groups). Nineteen (7.91%) patients in povidone-iodine group and 13 (6.68%) patients in normal saline group showed the evidences of infection in follow up visits. There was no statistically significant difference between infection rates in two studied groups (p = 0.86).
Conclusion: Irrigation with 1% Povidone-iodine did not increase or decrease the infection rate in traumatic wounds compared to wound irrigation with 0.9% saline solution.

© 2016 Elsevier GmbH. All rights reserved.

1. Introduction

Irrigationis a basic initial component of wound management. There are a variety of irrigation solutions but their efficacy and safety is an area of controversy yet, as the irrigation solution is still generally selected based on medical practitioner's personal experience and preference, institutional policies and procedures or even economic issues [1]. Although some studies have shown that the antiseptic solutions may compromise the micro-vascular flow, kill the fibroblasts and suppress the healing process in injured tissues [2,3], these agents are commonly used in different settings both for irrigating the intact skin and wounds. This may be due to traditional beliefs about the role of antiseptic solutions in inhibiting the microorganisms and decreasing the rate of infection [4].

Normal saline (0.9%) is an isotonic widely recommended solution for wound cleansing and irrigation because it is safe, available and inexpensive and does not interfere with the normal flora of the skin and wound healing process [5–7]. But it has no antiseptic effects which has been a concern in some studies. Povidone-iodine is an antiseptic solution with antimicrobial effect against a broad spectrum of pathogens which has been used in wound management processes for decades. It has different cellular effects in its different concentrations as according to some studies 5% povidone-iodine impairs the blood flow and kills the fibroblasts and solutions with 0.1% or even 1% concentration are safe enough to be used in wound irrigation [8]. Although according to some studies povidone-iodine can significantly decrease the bacterial load about 10 min after its application and decrease the wound infection rate [9,10], there are also other studies showing no decrease in infection rate in wounds irrigated with povidone-iodine [11].

This prospective multi-center study compares the efficacy and safety of diluted (1%) povidone-iodine solution with normal saline as irrigation solutions in decreasing the infection rate in simple traumatic wounds repaired in emergency department.

* Corresponding author at: Emergency Department,Rasoul-e-Akram Hospital, Niyayesh St, Sattarkhan Ave, Tehran, Iran.
E-mail address: mina_zavareh@yahoo.com (M. Zavareh).

2. Materials and methods

2.1. Study design and setting

This prospective randomized clinical trial enrolled a convenient sample of patients requiring wound management from May 2013 to February 2014, in 2 teaching hospitals with annual census of 40,000 and 80,000 adult patients. Study was approved by institutional ethics committee (Faculty of medicine, Iran University of Medical Sciences) and carried out in accordance with Declaration of Helsinki [1989]. Trial was registered in Iranian Registry of Clinical Trials (IRCT).Informed written consent was obtained from all patients or their legal guardians.

2.2. Selection of participants

We included adult (≥18 years old) patients with simple traumatic wounds who attended in emergency department. Simple traumatic wound was defined as a wound not caused by human/animal bites and not accompanied by vessel, nerve, tendon, bone or joint injuries with an age of less than 12 h.

Patients with immune-deficiency; prosthetic heart valves; diabetes mellitus; advanced cardiac, hepatic or renal failure; chronic steroid use; history of previous splenectomy; patients under antibiotic use or chemotherapy; patients with chronic substance or alcohol abuse and patients allergic to iodine (The patients with positive previous history of hypersensitivity to iodine products) were excluded from study.

2.3. Intervention

Demographic characteristic of patients and basic characteristics of wounds (including the site, size, age, shape of borders, and level of contamination) were documented. We used computer-generated randomization blocks of 4 to randomly allocate the patients to povidone-iodine (Behvazan Co., Rasht, Iran) or normal saline groups. Wounds were anaesthetized with 2 ml from 1% lidocaine and irrigated with 1% povidone-iodine solution (50 ml per each cm of wound length) in first group and with normal saline (50 ml per each cm of wound length) in second group. In both groups a 30 ml syringe/18 gauge catheter system was used to dispense the solution on wound. Irrigation was performed by a physician not involved in the wound repair and follow up process. After irrigation, wounds were repaired with standard suturing techniques. All wounds were repaired by polyamide strings (Teb-Keyhan Co, Isfahan, Iran). Suturing layers and technique of suturing and were documented after wound repair. Tetanus vaccination was administered if necessary. All patients received a wound care instructions sheet when discharged home from emergency department. They were re-visited for wound check 2, 5 and 10 days after their discharge. A telephone follow up was done one month after repair to assess the development of delayed complications. Patients who did not complete the follow-up visits and patients who did not answered to telephone follow up were considered lost to follow-up.

2.4. Outcome measures

Primary outcome measure was the difference in wound infection rates between two studied groups. Wound evaluations were based on assessing the signs (cellulitis >1 cm, lymphangitis, presence of discharge, presence of necrotic tissue and abscess) and symptoms (pain, dryness and itching) of wound infection and presence/absence of wound dehiscence. Wound infection was defined as the presence of any mentioned signs. Secondary outcome measures were the occurrence of skin irritation and wound dehiscence.

2.5. Data analysis

To obtain a power of 80% and by considering the baseline rate of wound infection as 10% [12], clinically important difference in rate of wound infection as 10% [13] and two-sided α as 0.05 we calculated the minimum sample size as 195 patients in each group.

Descriptive data are reported as maximum, minimum and mean. Continuous variables are compared with an independent samples t-test. Categorical data are presented with percentages and 95% confidence intervals and compared using Chi-square test. P value less than 0.05 is considered significant. All data analyses are performed with SPSS version 18.0 (SPSS, Inc., Chicago, IL).

3. Results

Study patients flow is shown as CONSORT diagram in Fig. 1. Baseline characteristics were similar in both groups (Table 1). Suturing layers and techniques used in wounds repair were similar (Table 2). Twenty-nine (7.40%) patients experienced wound infection during the follow up period. In Povidine-iodine group 15 (7.65%) patients showed the evidences of wound infection including the >1 cm cellulitis or pus formation. In normal saline group 14 (7.26%) patients showed the evidences of wound infection. There was no case of wound dehiscence in both groups. The rate of wound infection and dehiscence showed no statistically significant difference in Povidine-iodine and normal saline groups (Table 2). All patients with >1 cm cellulitis received oral antibiotics for treatment. None of these patients needed intravenous antibiotics and re-admission.

4. Discussion

Povidone-iodine solution with 1% concentration is not superior to normal saline in decreasing the infection rate in simple traumatic wounds repaired in ED. In our study, the overall infectious complications of repaired wounds were 29 in 390 (7.40%) with a relatively equivalent distribution in two studies groups.Our findings are compatible with results of other studies which have probed the benefits of antiseptic irrigation solutions and even traditional sterile techniques in decreasing the rate of infection and infection-related morbidity and mortality in different types of wounds in different groups of patients. A prospective trial on 816 patients with wounds repaired by using sterile gloves or clean non-sterile gloves, showed that there is no statistically significant difference in infection rate between the 2 groups (6.1% in sterile gloves versus 4.4% in the clean non-sterile gloves group) [14]. An earlier study by Ghafouri et al. showed that wearing of clean gloves rather than sterile ones do not increase the risk of infection in the contaminated simple wounds repaired in emergency department [15]. Ruthman et al. showed also that there is no increased infection rate in laceration repairs without using caps or masks during the wound repair procedure [16].

We have studied the role of irrigation solution in decreasing the infection rate. Another study by Lammers et al. on 33 heavily contaminated acute traumatic wounds showed also that based on the comparing the quantitative wound bacterial counts, soaking the wounds for 10 min in 1% povidone-iodine has no superiority to soaking them in normal saline or nothing (control group) [17]. We found that Povidone-iodine solution with 1% concentration is not superior to normal saline in decreasing the infection rate in simple traumatic wounds repaired in ED. There are some other studies which suggest the use of tap water instead of normal saline. For example, a review on clinical trials compared the rates of infection