

Full Length Research Paper

Evaluation of povidone Iodine 10% versus 7.5% hand scrub in cesarean section wound infections: A prospective trial

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Evaluate the efficiency of hand scrubbing by povidone-iodine solution 10% over 7.5% concentration in decreasing post-cesarean section wound infections. Applying a double blinded randomized controlled trial, the surgical team in maternity ward of Assiut University Woman's Health Center scrubbed using povidone-iodine solution 10% before doing 1574 cesarean sections and by 7.5% before doing 1657 cesarean sections. The number of surgical site infection (post cesarean sections septic wounds) and adverse effects of the scrubbing solution occurring to surgical team members were recorded and compared in both groups. A total of 3231 women were included in the study in 2 groups (povidone-iodine solution 10% before cesarean sections n= 1574, povidone-iodine solution 7.5% before cesarean sections n=1657). Post cesarean sections septic wounds occurred with povidone-iodine solution 10% (n=3) less than with 7.5% (n=12, $P = 0.026$). While contact dermatitis occurred with povidone-iodine solution 10% (n=6) more than with 7.5% (n=2, $P = 0.136$). Povidone-iodine solution 10% is more efficient than 7.5% as a hand scrub in terms of less post cesarean section septic wounds but it causes more contact dermatitis.

Key words: Betadine, povidone Iodine, hand scrubbing, cesarean section wound infections, hygiene.

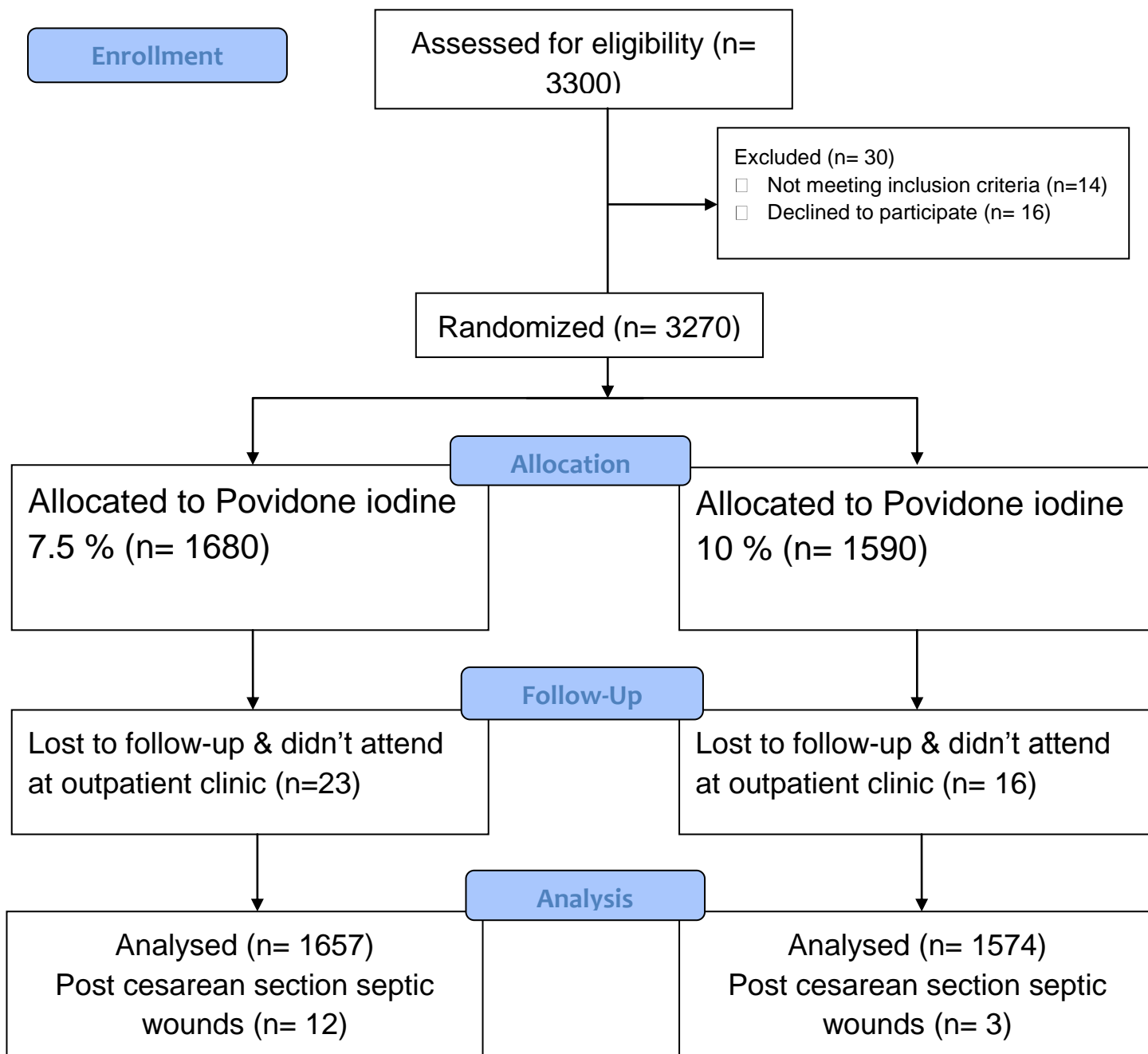
INTRODUCTION

For centuries, hand washing using soap and water has been considered the main procedure for personal hygiene (Jumaa, 2005). However, the presence of association between hand washing and the spread of infection has been established only in the last 200 years. In the 1800s, studies by Ignaz Semmelweis revealed that the hands of health care workers were the main source of transmission of hospital-acquired diseases. Accordingly, Joseph Lister succeeded to establish a relation between hand antisepsis and reduction of surgical site infections (Mackenzie, 1988). In the community, hand hygiene has been known to prevent infectious diseases (Aiello et al., 2002) and to decrease the general burden of disease in the community (Luby et al., 2005). A prospective controlled trial conducted in a hospital nursery (Mortimer et al., 1962) and investigations conducted during the last

40 years have confirmed the role of the hands of health care workers in the transmission of pathogens. One study revealed that serial cultures from healthcare workers revealed that 100% of them got contaminated with gram-negative bacilli at least once & 64% with *Staph. aureus* at least once. Accordingly, hand hygiene represents the most significant approach to control the spread of pathogens in health-care settings (Boyce and Pittet, 2002).

Agents used for surgical hand scrubbing may include alcohol, chlorhexidine, iodine/iodophors, parachlorometaxyleneol and triclosan. For the antiseptic to be optimal, it should have a broad spectrum of activity against pathogens and it should be persistent and fast (Hardin and Nichols, 1997). Aside from these issues, the antiseptic should not be hazardous to the surgical team and should be acceptable for them when used repeatedly. Unfortunately, most currently available studies evaluated antiseptic agents on basis of measuring hand bacterial colony counts. When comparing results of studies of in vivo efficacy of antimi-

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Figure 1. Povidone Iodine 10% versus 7.5% hand scrub and cesarean section wound infections Flow Diagram.

crobial soaps versus alcohol based scrubbing agents, results were not conclusive because some of these studies demonstrated efficacy as percentage of reduction in bacterial counts while other studies demonstrated efficacy as log₁₀ reductions of bacterial counts achieved. One RCT identified the in vitro advantage of alcohol in

surgical hand scrubbing over chlorhexidine but the study did not identify a reduction of surgical site infections (Parienti et al., 2002). This is what makes this trial unique in nature.

The aim of this prospective study is to compare the efficiency of hand scrubbing by povidone-iodine solution

Figure 2. Betadine (Antiseptic solution, Povidone Iodine 10 %, Nile Company, Egypt).



10% over 7.5% concentration in decreasing post-cesarean section wound infections and compare side effects of both agents.

MATERIALS AND METHODS

Study design

The study is conducted as a double blinded randomized clinical trial in the maternity ward of Woman's Health Center, Department of Obstetrics and Gynecology, Assiut University, Egypt. Trials were conducted from the period of 1st September till 31st December 2011. During this period, 3300 women were initially recruited. However, thirty women were excluded (16 women denied participation and 14 women did not meet our inclusion criteria). The remaining 3270 women, who were planned for elective cesarean section, were randomized into 2 groups in which the surgical team scrubbed by 7.5% in the period (Group A) and by povidone iodine 10% in period (Group B). Group A included all women undergoing elective cesarean section in September and October 2011 ($n = 1680$) while pregnant women having cesarean section done in November and December 2011 were included in group B ($n = 1590$). The surgical team and the patients were blinded concerning the nature of the scrubbing solution. Excluding women who were missed during follow up, the remaining women in each

arm were 1657 in group A and 1574 in group B. The flow chart of the study is shown in figure 1.

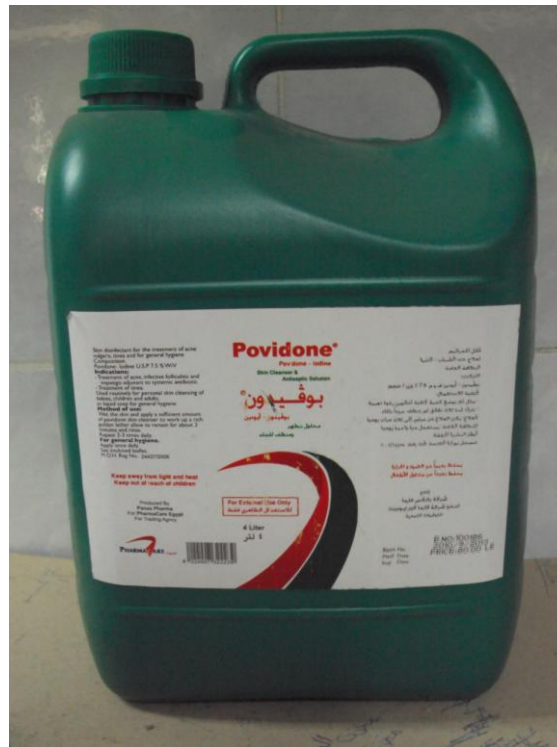
Surgical Team

The surgical team included 33 volunteers (14 obstetrics residents and 19 nurses) between ages of 20 and 29 years. The volunteers had no visible lesions on their hands with short and clean finger nails. Pregnant women and subjects who were under antibiotic treatment were not included in the study. Before the volunteers participated in the study, they were given a full explanation of its purpose and anticipated side effects.

Patients

Patients who were diabetic or immune-compromised were excluded from the study. All patients included in the trials didn't take preoperative antiseptic showers or have preoperative shaving of surgical site hair. In the operative room, the patients' skin was prepared by applying betadine (povidone iodine 10%) in concentric circles extending from xiphisternum up to the knees. For surgical antimicrobial prophylaxis, all patients received 2 grams of antibiotic (Ampicillin-Sulbactam) intravenously immediately preoperative. The cesarean sections were done using pfannenstiel incision and transverse lower segment uterine incision. The uterine incisions were closed in two layers using vicryl suture size 1, followed by

Figure 3. Povidone (Skin cleanser & anti-septic solution, Povidone Iodine USP 7.5%, Panax Pharma, PharmaCare, Egypt).



vicryl suture size 0/2 for the peritoneal layers. The rectus sheath was closed continuously using vicryl suture size 2 and vicryl suture size 0/2 for apposition of subcutaneous layer. Finally, the skin was closed subcuticularly using vicryl suture size 0/2.

The duration of cesarean section didn't exceed 1 hour. Postoperatively, the incision was covered by a single sterile dressing for 5 days without changing it. All patients received combination antimicrobial agents against gram positive, negative bacteria and anaerobes in the 1st 24 hours postoperative. All patients were discharged within 48 hours postoperative and were educated about home incision care and about signs and symptoms of infection and were advised to return to the out-patient clinic 10 days postoperative for check up. Patients who returned with post cesarean section infected wounds were re-admitted and received the appropriate medical care.

Prophylactic antibiotics play a crucial role not only in decreasing the incidence of cesarean sections wound infections but also in decreasing postpartum febrile morbidity, endometritis and urinary tract infection and it is now the policy of many institutions to use them in cesarean sections (Hofmeyr and Smaill, 2010).

Hand Scrubbing agents

Betadine

(Antiseptic solution, Povidone Iodine 10%, Nile Company,

Egypt) (figure 2) and povidone (Skin cleanser and anti-septic solution, Povidone Iodine USP 7.5%, Panax Pharma, PharmaCare, Egypt) (figure 3).

Scrub technique

The patients were divided into 2 groups. The surgical team scrubbed by 7.5% in the period including September and October 2011 (Group A) and by povidone iodine 10% in period including November and December 2011(Group B). The scrubbing time was 5 minutes using standardized surgical hand scrubbing starting from fingertips including forearms ending by elbows (without sponge or brush). Hands were dried by cloth towels. The scrub procedure was monitored for standardization by the trial researchers.

Data Analysis

Data were summarized by using standard statistical procedures. Mann-Whitney test and Chi-square test were applied to calculate the significance of difference ($P \leq 0.05$ is considered significant) between the 2 groups.

Evaluation method

The number of surgical site infection (post cesarean sections septic wounds) and adverse effects of the scrub-

Table 1. Demographic data of the Patients.

	Group A: Betadine 7.5%	Group B: Betadine 10%	P value
Median of age (in years)	25	26	0.102*
Median of parity	3	4	0.870*
Residency			
Urban (n, %)	812 (49%)	728 (46.3%)	0.063**
Rural	845 (51%)	846 (53.7%)	
Median of postoperative hemoglobin	10.3	10.00	0.250*
Total	1657	1574	3231

* P value was estimated using the Mann-Whitney test. P value < 0.05 is considered positive.

** P value was estimated using Chi-square test. P value < 0.05 is considered positive.

Table 2. Surgical site and surgical team complications among study population.

	Group A: Betadine 7.5% (n, %)	Group B: Betadine 10% (n, %)	P value*
Wound infection	12 (0.7%)	3 (0.2%)	0.026
Dermatitis (among surgical team)	2 (0.1%)	6 (0.4%)	0.136
Total	14 (0.84%)	9 (0.57 %)	

* P value was estimated using Chi-square test. P value < 0.05 is considered positive.

bing solution occurring to surgical team members were recorded and compared in both groups. A wound is considered infected if there were indurations and swelling of the wound edges, discharge of pus or wound dehiscence.

Ethical Approval

Institutional review board has exempted this study from ethical approval because both povidone iodine preparations are already used in the hospital as skin antiseptics and accordingly, patients as well as surgical team are not exposed to additional risk that can be attributed to the study.

RESULTS

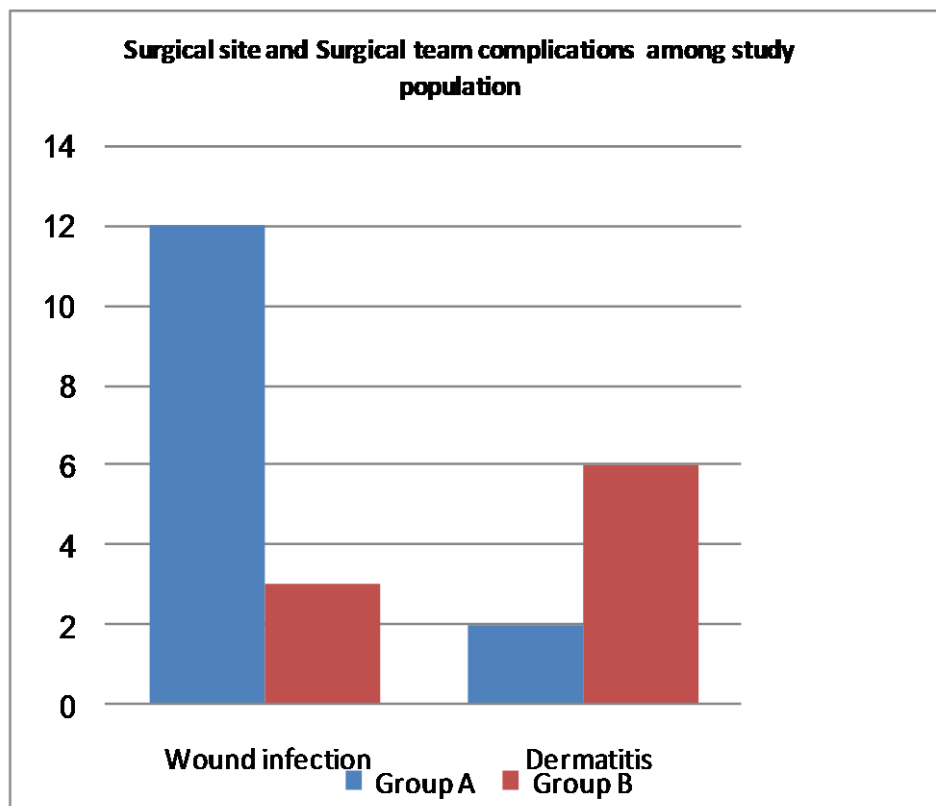
As shown in Table 1, which summarizes the median of the demographic parameters of the study population, there was no significant statistical difference between age, parity, residency or postpartum haemoglobin level ($P \geq 0.05$). Women in both groups were followed up during hospital stay and outpatient clinic visits for surgical site complications and surgical teams in both groups were assessed for contact dermatitis. Table 2 summarizes the incidence of surgical site infection and

dermatitis occurring in both groups (Figure 4). Post cesarean sections septic wounds occurred with povidone-iodine solution 10% (n=3) less than with 7.5% (n=12) with ($P=0.026$). The septic wounds occurred with both groups were superficial incisional surgical site infections. As for adverse effects, contact dermatitis occurred with povidone-iodine solution 10% (n=6) more than with 7.5% (n=2) with no statistical significant difference ($P=0.136$). One of the surgical team members scrubbing by povidone-iodine solution 10% suffered from severe irritant contact dermatitis in the form of cracking and bleeding and had to withdraw from the trial (figure 5).

Comment

Iodine has been identified as an effective antiseptic since the 1800s. Their action is based on their ability to penetrate the cell wall of the pathogens and to form chemical complexes that finally alter protein synthesis and disrupt the cell membrane (Gottardi, 1991). However, because of the adverse outcomes of iodine including irritation and skin discoloration, Iodophors have been used instead. Iodophors are composed of elemental iodine, iodide or triiodide, and a high molecular weight carrier. The term "Available iodine" means the total amount of iodine that can be titrated with sodium thiosulfate. 10% povidone-iodine contains 1% available

Figure 4. Surgical site and Surgical team complications among study population.



iodine and it produces free iodine concentrations of 1 ppm (Anderson, 1989).

Iodine and iodophors have wide bactericidal activity against Gram-positive, Gram-negative, some spore-forming bacteria, mycobacteria, viruses and fungi (Larson, 1995). However, it should be clear that the commercially available concentrations of iodophors are not usually sporicidal. They reduce the number of viable organisms harboring health care workers' hands (Cardoso et al., 1999). The extent to which their antimicrobial effect lasts after they have been washed off the skin is indefinite. One study showed that the effect lasted for 6 hours while in another study it only lasted from 30-60 minutes (Boyce and Pittet, 2002). Iodophors are known to cause less skin irritation and allergic reactions than iodine, but more than other antiseptics that may be used for hand hygiene (Food and Drug Administration, 1994). In this clinical trial, cesarean section wound infections occurred with povidone iodine 10% hand scrubbing solution ($n = 3$, 0.2%) were less than with 7.5% solution ($n = 12$, 0.7%).

There are two major types of skin reactions in relation with hand antiseptics that may be difficult to differentiate. The first and the most common type is the irritant contact dermatitis; it is associated with varying symptoms that

range from mild to debilitating; this includes dryness, irritation, itching and up to cracking and bleeding. The second category of skin reactions is rare and is known as allergic contact dermatitis; it is thought to be attributed to an allergic reaction to some ingredients. Symptoms range from mild and localized to severe and generalized and in some rare serious instances, it may cause respiratory distress and anaphylaxis. Iodophors are more commonly associated with irritant contact dermatitis than other antiseptic agents (Larson et al., 1986). It is also important to clarify that the shearing forces of wearing or removing gloves, as well as the possible allergy to latex proteins are another risk factors for contact dermatitis in health care workers that may be attributed inaccurately to iodophors (Kownatzki, 2003). This clinical trial has demonstrated that contact dermatitis occurred to the surgical team with povidone iodine 10% ($n = 6$, 0.4%) is more than with 7.5% concentration ($n = 2$, 0.1%).

However, health care workers who are exposed to irritant contact dermatitis may use additional skin moisturizing including hand lotions and creams that contain humectants.

They help to increase skin hydration and replace altered skin lipids; they also act as a barrier to protect the skin. The benefit of these agents to protect against con-

Figure 5. Severe irritant contact dermatitis in the form of cracking & bleeding in the hands of one of the surgical team members.



tact dermatitis is supported by several controlled trials (Berndt et al., 2000).

CONCLUSIONS

Povidone-iodine solution 10% is more efficient than 7.5% as a surgical hand scrub solution in terms of less post cesarean section septic wounds but it causes more contact dermatitis. Skin moisturizing agents are advised to be used in case of mild contact dermatitis while substitution of the scrubbing agent in case severe contact dermatitis.

CONFLICT OF INTEREST

None of the authors has a conflict of interest.

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