Comparison of the Efficacy of Povidone-Iodine and Normal Saline Wash in Preventing Surgical Site Infections in Laparotomy Wounds-Randomized Controlled Trial

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Abstract

**Background:** Povidone-iodine has been utilized as a broad-spectrum antiseptic irrigation solution in the wound management processes for many years. However, some recent studies showed that the infection rate in laparotomy wounds decreases more by using normal saline.

**Objective:** The study aims to examine the decreasing infection rate in laparotomy wounds by comparing the effectiveness and safety of povidone-iodine solution with normal saline.

**Method:** The patients undergoing elective laparotomies were included and randomly assigned to 2 groups. In the first group (90 patients), incision wounds were flushed with 5% povidone-iodine solution. In the second group (90 patients), incisions were flushed with 0.9% normal saline solution. By comparing the infection rates of the wound outcomes were measured between the two groups.

**Result:** Surgical site infections were seen in 16 of 180 (12.5%) patients 9 in povidone-iodine versus 7 in normal saline groups. The difference in the infection rates in the two studied groups (p=0.6) has no statistical significance.

**Conclusion:** The infection rate in laparotomy wounds did not increase or decreased when the wound was irrigated with 5% Povidone-iodine solution or with 0.9% saline solution.

Keywords: Povidone-iodine; Normal saline; Wound irrigation; Infection

Introduction

Povidone-iodine has been utilized as a broad-spectrum antiseptic irrigation solution in the wound management processes for many years. However, some recent studies showed that the infection rate in laparotomy wounds decreases more by using normal saline. There are different types of irrigation solutions but their effectiveness and safety are controversial. Since the selection of an irrigation solution is generally based on the preference and experience of the medical practitioner's, institutional policies, economic issues, and procedures used [1].

Povidone-iodine (Betadine) is an antiseptic medicine composed of polyvinylpyrrolidone with water, iodide and 1% available iodine. It has bactericidal properties against a large number of pathogens [2]. Although its use as an antibacterial agent in surgery has been studied in many kinds of literature, using it against Surgical Site Infection (SSI) as a prophylactic irrigation solution has been examined to a lesser degree.

Normal saline (0.9%) is an isotonic solution generally selected for wound irrigation and cleaning because it's safe, doesn't interfere with normal skin flora, wound healing process and is inexpensive. However, it has no antiseptic effects [3]. In new research, it is found that surgical site infections accounted for 31% of all Healthcare-Associated Infections (HAIs) amongst hospitalized patients [4].

SSIs still remain a substantial cause of morbidity, prolonged hospitalization, and death after advanced infection control practices, improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis. A Surgical Site Infection (SSI) is identified with a 3% mortality rate, and 75% SSI identified deaths [5].

The postoperative infection has extreme surgical outcomes which often requires repeat surgery and extended hospital stay. In the background of postoperative infection and associated morbidity-mortality, this prospective study compares the efficacy of Povidone-iodine and Normal Saline in Preventing Surgical Site Infections in laparotomy wounds.

Material and Methods

Study design

A prospective randomized study was done on patients undergoing elective laparotomy involving gastrointestinal tract causing clean contaminated wounds. Study period over 3 years from August 2015 to July 2018, in Vydehi Institute of Medical Sciences and Research Institute Hospital. The study was accomplished in agreement with the...
Declarations of Helsinki and was approved by the ethical committee of the institute. Written consent was obtained from all patients.

Methods

Cases undergoing elective laparotomy, who met the inclusion criteria and willing to participate were included in the study. A total of 180 cases that underwent exploratory laparotomy were included. The patients of age >18 year were included in this study. Randomization was done with computer-generated third-party applications. In Group A, the incision site was treated with 400 ml, 0.9% normal saline and 100 ml 5% povidone-iodine solution. In Group B, the incision site was treated with 500 ml 0.9% normal saline solution. After wash, incisions were closed with standard suturing techniques. Post-operatively, wound dressings changed after 72 hrs. Saline and Betadine dressings were repeated, corresponding to the initial study. Suture removal was done at the discretion of the primary surgeon.

Statistical analysis

Statistical analysis performed for primary, secondary and safety outcomes. Data were processed using mean value (standard deviation, SD) and were tested with an unpaired mean difference (median). The data was analyzed using a software program of SPSS version 22.0.

Outcome evaluation

Follow-up of 30-day after surgery was considered. The postoperative complications were graded by the Clavien-Dindo classification of surgical complication. Surgical site infections were the main focus of this study. The difference in infection rates between the two studied groups were as the outcome measures. Infection was defined as per CDC, Atlanta, 1992 guidelines as the wound discharge within 4 weeks after surgery or a positive culture of fluid from the wound.

Results

In both groups the baseline characteristics of the patients were similar (Table 1). Study patients variables are compared as detailed in the table below. Similar suturing techniques and layers were used in wounds closure. During follow up 16 (12.5%) patients documented wound infection.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patients (n=180)</th>
<th>Povidone-Iodine (n=90)</th>
<th>Normal Saline (n=90)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex no (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>128 (71.1%)</td>
<td>58 (64.4%)</td>
<td>69 (76.6%)</td>
<td>0.072</td>
</tr>
<tr>
<td>Female</td>
<td>52 (28.8%)</td>
<td>32 (35.5%)</td>
<td>21 (23.3%)</td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
<td></td>
<td>0.052</td>
</tr>
<tr>
<td>Biliary</td>
<td>48</td>
<td>28</td>
<td>20</td>
<td></td>
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<tr>
<td>Pancreatic</td>
<td>67</td>
<td>37</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>Small bowel</td>
<td>22</td>
<td>11</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>large bowel</td>
<td>43</td>
<td>14</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>SSI</td>
<td>16 (12.5%)</td>
<td>9 (10%)</td>
<td>7 (7.8%)</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Table 1: Baseline characteristics of the patients.

In Povidone-iodine group wound infection in 9 (10%) out of 90 patients was observed. In normal saline group wound infection was observed in 7 (7.8%) out of 90 patients. In both groups, no wound bursting was observed. There is no statistically significant difference in the rate of wound infection and dehiscence in both groups.

Antibiotics were provided to all patients with wound infections as per institutional protocol and according to the culture-sensitivity reports and regular wound dressing.

Discussion

In our study, Surgical Site Infections (SSI’s) rate was 16 in 180 (12.5%) with approximately equal distribution in both groups. The conclusion made by our study was similar to the results that showed decreased infection rate and infection-related morbidity and mortality in different types of wounds and different patient groups by using antisepic irrigation solutions and traditional sterile techniques.

A similar study conducted by HB Ghafouri et al., showed 29 (7.40%) out of 320 patients experienced wound infection during follow up period. 15 (7.65%) patients in the Povidone-iodine group and 14 (7.26%) patients in the normal saline group showed sign of wound infection [6].

Lammers et al., the study compared quantitative wound bacterial counts of 33 heavily contaminated acute traumatic wounds. According to his study, there is no superiority in soaking wounds for 10 minutes in 1% povidone-iodine as compared to soaking them in normal saline or nothing (control group) [7].

The results of our study are contradictory to other mentioned studies on surgical wounds. The wound infection rate in patients undergoing abdominal, gastrointestinal and urologic procedures was compared in a study by Sindelar et al. He showed that the effectiveness in decreasing the rate of infection of 10% povidone-iodine is more than normal saline in these groups of patients [8]. Another study by Singah et al., on clean-contaminated surgical wounds, found that infection rate is higher in wounds irrigated with normal saline than wounds irrigated with 5% povidone-iodine or 5% povidone-iodine plus metronidazole [9,10].

Conclusion

The infection rate in laparotomy wounds did not increase or decrease in irrigation with 5% Povidone-iodine compared to irrigation with 0.9% saline solution.

Limitations

Blinding was not done as a primary physician was involved in surgery and closure of the surgical incision. Long term follows up of patients were not done.

References


