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Efficacy of Topical Phenytoin versus Povidone-Iodine in the Treatment of Contaminated Traumatic Wounds among Patients Attending Jinja Regional Referral Hospital

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ABSTRACT

In Uganda, like in other African countries, wound care is a significant health burden and a leading cause of hospital visits. Povidone iodine has been widely used for wound healing over the past century, while the efficacy of topical phenytoin has also been explored in various wound types, including traumatic wounds. This study aims to compare the efficacy of topical phenytoin versus povidone-iodine (PVP-I) in the treatment of traumatic wounds. This open-label trial was conducted in Eastern Uganda (August 2023 to January 2024) and included 88 patients with full-thickness contaminated traumatic wounds. Patients were randomly assigned to either topical phenytoin or PVP-I group using block randomization. Infection eradication, pain alleviation, and rate of granulation tissue formation were evaluated over 14 days using wound cultures, VAS score before treatment, and imitoMeasure smartphone application. Staphylococcus aureus was the most predominant organism isolated. On days 7 and 14, the phenytoin group showed a much lower positive culture compared with the PVP-I group with 7 out of 44 (15.9%) vs 14 out of 44 (31.8%) (p-value of 0.08 > 0.05) and 2 out of 44 (4.5%) vs 7 out of 44 (15.9%) (p-value of 0.079 > 0.05) respectively. The mean VAS score on days 7, and 14 were 3.8 ± 0.4 vs. 6.0 ± 1.0, and 2.6 ± 0.5 vs. 3.7 ± 0.6 in phenytoin group vs. PVP-I group 7 respectively ($p < 0.0001$). At Day 7 and 14, the mean percentage of granulation tissue formation was significantly higher in phenytoin group vs. PVP-I with 72.9% (SD = 7.3, 95% CI: 70.7-75.2) vs. 57.4% (SD = 4.30, 95% CI: 56.1-58.7) and 86.2% (SD = 7.2, 95% CI: 84.0-88.4) vs. 67.4% (SD = 4.4, 95% CI: 66.0 - 68.7) respectively ($p < 0.0001$). Topical phenytoin showed superior outcomes in pain reduction and granulation tissue formation compared to povidone-iodine. However, no significant difference was observed in antibacterial activity between the groups. Topical phenytoin is recommended as an alternative to povidone-iodine for treating contaminated traumatic wounds.

Keywords: Contaminated Traumatic Wound, Secondary intention, Granulation tissue, Topical phenytoin, Povidone Iodine, Eastern Uganda

INTRODUCTION

Traumatic wounds are prevalent across Africa, with injury rates ranging from 12.0% in rural Uganda to 28.3% in Nigeria [1]. The traumatic wound is a major reason for ED (Emergency Department) visits [2]. The treatment of surgical and traumatic wounds has evolved from cobwebs, rosewater, and a combination of egg and oil of turpentine [3]. Discovered in 1811 by Bernard Courtois, in 1839, iodide preparations were used to treat wounds [4]. Povidone iodine is known for its anti-inflammatory effects and is well-tolerated. It has a broad antimicrobial spectrum,

is effective against biofilms, lacks resistance issues, and promotes granulation tissue formation, making it highly beneficial for wound healing. However, iodine solutions, especially in aqueous or alcoholic forms, can cause excessive staining and skin irritation [5]. Besides, being instituted as an anti-seizure medicine, phenytoin is a medication that ameliorates wound healing [6]. Topical phenytoin sodium has been shown to promote wound healing through several mechanisms such as increased fibroblast proliferation, decreased bacterial contamination, decreased wound exudate formation, promotion of collagen disposition, inhibition of collagenase activity, and upregulation of growth factor receptors [7]. In addition, phenytoin has been described to alleviate the pain of episiotomy wounds and improve outcomes to promote the healing process of a massive, necrotizing soft tissue wound that was not responding to standard/conventional treatment [8, 9, 10, 11]. Various studies have assessed the effects of topical phenytoin on the wound-healing process in different types of wounds. However, a study comparing the efficacy of topical phenytoin versus povidone iodine (which is largely used in the treatment of traumatic wounds) is lacking. Therefore, this study tends to assess the efficacy of topical phenytoin versus povidone-iodine in the treatment of traumatic wounds among patients attending Jinja Regional Referral Hospital. This study aimed to compare the efficacy of topical phenytoin versus povidone-iodine 5% in the treatment of traumatic wounds in JRRH by evaluating the eradication of infection, the pain alleviation effect, and the percentage of granulation tissue formation.

METHODOLOGY

Study Design

This analysis conducted an open-label trial that included all patients who came with contaminated traumatic wounds where primary closure was not indicated.

Study Site and Setting

This study was conducted at Jinja Regional Referral Hospital, one hospital in eastern Uganda under the Ministry of Health. This regional referral hospital attends traumatic wound care through different departments such as surgical outpatient clinics, surgical departments, and orthopaedic wards. On average, the hospital attended to approximately 27 patients per month, with full-thickness contaminated traumatic wounds. All of these patients were admitted for proper wound care at least for some days. The pace of the wound dressings was done according to the wound evolution (daily or every other day). When necessary, the wounds were thoroughly debrided during the time of enrolment to the study. The hospital possesses the necessary facilities to conduct a range of laboratory investigations, including wound swabs culture, and sensitivity.

Target Population

All patients who presented with Contaminated Traumatic Wounds at the study center during the study period.

Study Population

All participants aged 18 years and older who presented with Contaminated Traumatic Wounds at the study site during the specified study period.

Inclusion Criteria

All patients aged 18 years and above are diagnosed with Full-thickness Contaminated Traumatic Wounds where primary closure is not indicated.

Exclusion Criteria

Patients with co-morbidities that influence wound healing including uncontrolled diabetes, hepatic and renal disease, vascular impairment, immunocompromised patients (HIV, severe malnutrition, etc.), patients on long-term steroids treatment, patient history of mental disability and those on oral phenytoin uptake or allergic to phenytoin alongside those who are not willing to participate were precluded from this survey.

Sample Size and Sample Size Determination

The formula for an equivalence design in randomized control trials by [12] was used to calculate the sample size since the null hypothesis of this study assumes that there is no difference in pain control between topical phenytoin and iodine povidone. Therefore, the sample size will be determined based on the formula below:

$$N = 2 \times \left[\frac{Z_{1-\alpha} + Z_{1-\beta}}{\delta}\right]^2 \times S^2$$

$$S = \sqrt{\frac{((1.08)^2 + (1.22)^2)}{2}} = 1.152$$

$$N = 2 \times \left[\frac{1.96 + 0.845}{0.63}\right]^2 \times (1.152)^2 = 52$$

N=52 participants per group.
For finite population correction: n=N/(1+(N-1)/N*) = 52/ (1+(52-1)/162) =40 patients.
To compensate for the loss to follow-up and non-responsiveness, a top10% was added in each group: **88** with **44** participants in each arm

Study Variable

The outcome variables were chosen based on the existing literature.
Primary outcome variables: The primary outcome variable is the eradication of infection of topical phenytoin versus povidone-iodine by measuring a negative culture report
Secondary outcome variables: The secondary outcome variable refers to the pain relief effect following wound care of traumatic wounds dressed with topical phenytoin versus povidone-iodine
Tertiary outcome variables: The tertiary outcome variables pertain to the proportion of granulation tissue formation with topical phenytoin versus povidone-iodine.

Study Procedure

The study participants' information was obtained using a pre-established questionnaire. Topical phenytoin 2 % was used for wound care in the study group. Because of the lack of the standard topical phenytoin in the market, improvised topical phenytoin suspension (2 %) was prepared in a small plastic dosage administration cup by mixing 100 mg of phenytoin capsule (phenytoin sodium) with 5 ml of 0.9 % sterile normal saline (NaCl). For the control group, povidone-iodine (5%) was used for wound care. The eradication of the infection on traumatic wounds was assessed by measuring a negative culture report of swabs from wounds of both groups before starting treatment, on days 7 and 14 from the day of the first dressing. The VAS was used to assess the occurrence of pain at the time 0, day 7, and 14 following wound care with either topical phenytoin or povidone-iodine. The percentage of granulation tissue formation was determined by the smartphone imitoMeasure (imito) application (app). Following the data collection process, patients continued with their routine care.

Data Collection

Data were collected by the principal investigator with the assistance of research assistants, who were doctors on duty in surgical outpatient clinics, surgical wards, and orthopaedic wards. The data collection utilized an administered, pre-tested questionnaire originally designed in English. For participants who did not understand English, the questionnaire was interpreted and translated into the local language understood by the patients. The data encompassed socio-demographic variables, patient characteristics, culture and sensitivity results of wound swabs, the VAS score, and rate of granulation tissue formation at the study initiation, on day 7, and on day 14 following wound care. The data that was collected were entered twice into Microsoft Excel 2019 and later transferred to STATA version 14.0 for analysis.

Data Quality Control

The assessment of pain and wound granulation was done by the principal investigator. The operating system of culture was strictly observed from sample collection to analysis. Quality control was observed during the process of data recording.
Inclusion and exclusion criteria were strictly adhered to. Each questionnaire was checked for discrepancies and incompleteness after completion.

Data Analysis

The data were initially coded and entered into Excel version 2019, followed by export to Stata 14.2 for subsequent analysis. The chi-square test was used to contrast the antibacterial activity of topical phenytoin versus povidone-iodine in the traumatic wound. Shapiro-Wilk test was employed to assess the normality of the data for the variable VAS at three different time points. The mean with their standard deviations or median resting pain scores. The mean with their standard deviations or median resting pain scores. Statistical significance was considered at a p-value <0.05 and the result was presented visually in a table.

Ethical Consideration

Approvals

Ethical permission was granted by the research ethics committee (REC) of Bishop Stuart University (BSU) under BSU-REC-2023-87. The survey was recorded with the Uganda National Council for Science and Technology. Another clearance to conduct the study at JRRH was granted from the REC-Jinja and the director of JRRH before conducting the research.

Informed Consent

After fully clarifying the details of the study in a language that they can comprehend (English and the local language (LUSOGA), a written declaration of consent was acquired and signed. A fingerprinter was secured for respondents who were not able to sign.

RESULTS

The study included 88 patients diagnosed with full-thickness contaminated traumatic wounds, recruited from the accident and emergency, surgical ward, orthopaedic ward, and outpatient surgery departments. The distribution of

the demographic characteristics between the Phenytoin and Iodine groups is presented in Table 1. None of the patients had developed allergic reactions. One patient in the study group has developed a hypertrophic scar.

Table 1: The Demographic characteristics of patients in the Phenytoin and Povidone Iodine treatment groups based on age, sex, profession, and mechanism of injury

		Treatment group	
Demographic characteristic	**Category**	**Phenytoin group (%)**	**Povidone Iodine group (%)**
Age in yrs	< 37	25(47.2)	28(52.8)
	≥ 37	19(54.3)	16(45.7)
Sex	Female	7(36.8)	12(63.2)
	Male	53.6)	32(46.4)
Profession	Businessman	7(63.6)	4(36.4)
	Motorcyclist	15(62.5)	9(37.5)
	Farmer	7(38.9)	11(61.1)
	Housewife	4(33.3)	8(66.7)
	Other	11(47.8)	12(52.2)
Mechanism of injury	Assault	9(50)	9(50)
	RTA	30(49.2)	31(50.8)
	Others	5(55.6)	4(44.4)

At the initial wound culture, 46 (52.3%) of the wounds had positive cultures, with Staphylococcus aureus as the most predominant organism isolated (25, 28.4%), Figure 1. No significant difference was noted in Growth at initial culture (day 0) between the phenytoin and povidone-iodine groups at 59.1% and 45.5% respectively with a p-value of 0.2 using the Chi-square test. After 7 days of wound care, the phenytoin group showed a lower growth (7 out of 44, 15.9%) compared to the iodine group (14 out of 44, 31.8%). Similarly, the phenytoin group showed a much lower growth (2 out of 44, 4.5%) compared to the povidone-iodine group (7 out of 44, 15.9%) by day 14. The phenytoin group showed a greater reduction in positive cultures over time, suggesting it may be more effective in eradicating infections. However, the differences were not statistically significant as shown in Table 2.

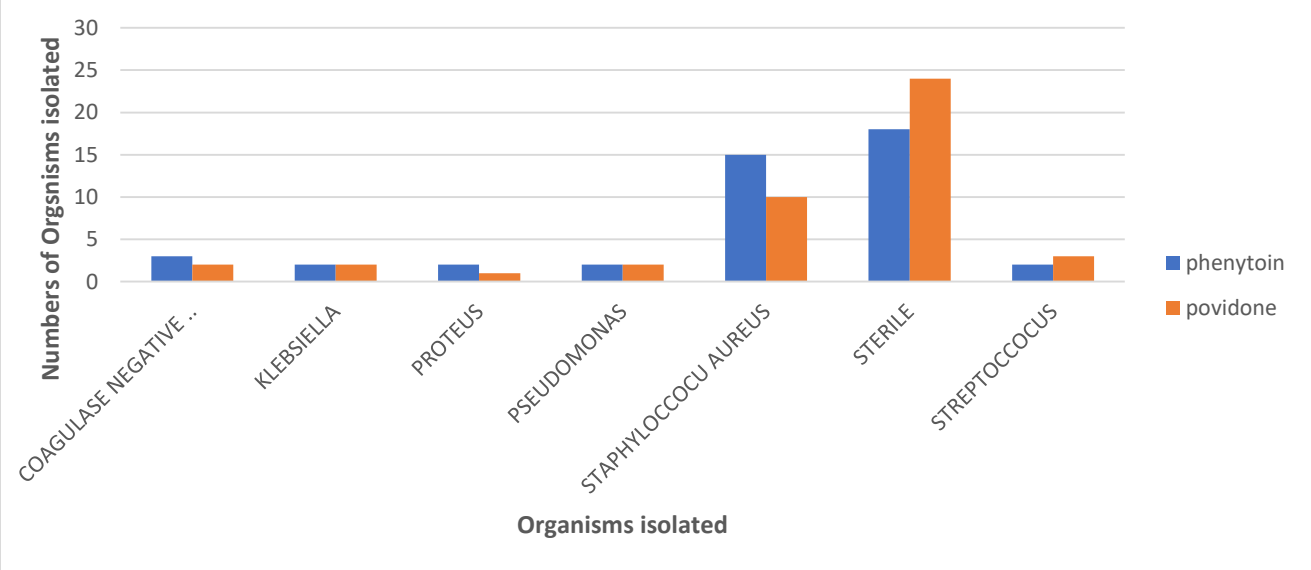

Figure 1: Graph showing the growth of various organisms obtained from wounds at day 0

Table 2: The eradication of infection evidenced by bacterial cultures taken from wounds at the start of treatment (day 0), on days 7 and days 14 with their respective p-values at Chi-square test.

Day of culture	Growth	Phenytoin Group (%)	Iodine Group (%)	p-value
0	Yes	26(56.5)	20(43.5)	
	No	18(42.9)	24(57.1)	0.2
7	Yes	7(33.3)	14(66.7)	
	No	37(55.2)	30(47.8)	0.08
14	Yes	2(22.2)	7(77.8)	
	No	42(53.2)	37(46.8)	0.079

Before treatment initiation, the mean VAS in both the Phenytoin and povidone-iodine groups were 6.3 ± 1.2 (95% CI: 5.9 - 6.6) and 7.3 ± 0.8 (95%: 7.0 - 7.5) respectively. The difference between the means was found to be statistically significant (**p < 0.0001).** The same, the mean VAS (table 3), remained statistically significant in both the phenytoin group and povidone-iodine group at days 7 (**p < 0.0001)** and 14 (**p < 0.0001).** At all assessed time points—Day 0, Day 7, and Day 14—the phenytoin group reported significantly lower pain scores than the povidone-iodine group, indicating a possibility of better pain control with phenytoin, figure 2.

Table 3: The mean pain levels at days 7 and 14 after initiation of treatment

	VAS at day 7		VAS at day 14	
Group	Mean ± SD	95% CI	Mean ± SD	95% CI
Phenytoin	3.8 ± 0.4	3.7-3.9	2.6 ± 0.5	2.4-2.7
Iodine	6.0 ± 1.0	5.7-6.4	3.7 ± 0.6	3.5-3.9

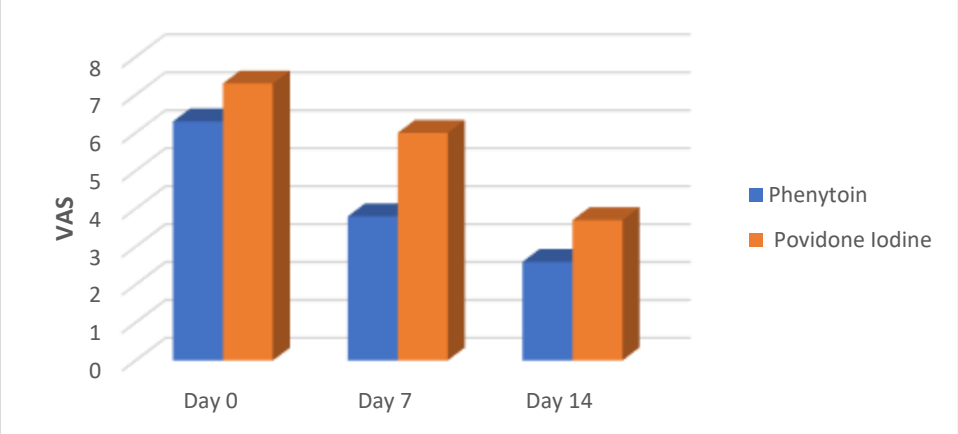

Figure 2: Graph showing visual analogue score (VAS) at days 0, 7 and 14

The granulation tissue formation was assessed at day 7 and day 14 post-treatment initiation. The mean percentage of granulation tissue formation in phenytoin group vs. povidone iodine at Day 7 and 14 were 72.9% (SD = 7.3, 95% CI: 70.7-75.2; median=72) vs. 57.4% (SD = 4.30, 95% CI: 56.1-58.7; median=56) and 86.2% (SD = 7.2, 95% CI: 84.0-88.4; median=84) vs. 67.4% (SD = 4.4, 95% CI: 66.0 - 68.7; median=66) respectively (Fig. 3). When the median is compared between the two groups at days 7 and 14 using the Mann-Whitney U tests, the differences showed statistical significance ($p < 0.0001$). Specifically, at both time points, Phenytoin Group exhibited significantly higher levels of granulation tissue formation compared to Povidone Iodine Group.

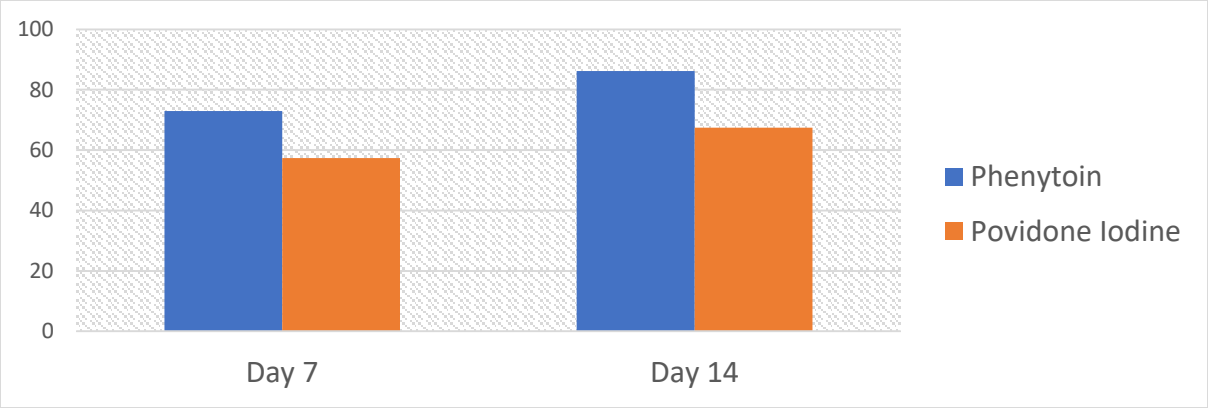

Figure 3: Graph showing the rate of granulation tissue formation among groups at day 7 and day 14 after initiation of treatment

The chi-square test results show a significant proportion of healthy granulation tissue formation in the phenytoin group compared to the povidone-iodine group on both day 7 and day 14, table 4. These findings suggest that Phenytoin may be more effective in promoting healthy granulation tissue formation, which is essential for wound healing (Table 4).

Table 4: Cross tabulation of healthy granulation at tissue among groups at days 7 and 14 after initiation of treatment

Day	Healthy granulation tissue	Phenytoin (%)	Povidone iodine (%)	p-value
7	No	3(13.0)	20(87.0)	
	Yes	41(63.1)	24(36.9)	< 0.0001
14	No	1(12.5)	7(87.5)	
	Yes	43(53.8)	37(46.2)	0.026

DISCUSSION

Staphylococcus aureus was the most common organism isolated in the positive cultures at 28.4%. Staphylococcus aureus is part of the skin's normal flora. Therefore, it could have early entered the wound and caused infection after the skin breaking. This is similar to the findings of studies that were done in India [13] who found Staphylococcus aureus as their most common isolated organism with 24 %. In contrast, Jung et al. (2023) highlighted gram-negative bacteria such as Escherichia coli (n = 48, 20.2%) and Acinetobacter spp. (n = 43, 18.1%) as their most common isolated pathogens. However, the latter performed wound swabs on traumatic wounds that were already infected.

A study done by [13] in India found that 72% of traumatic wounds had a negative culture after 14 days of topical phenytoin treatment against 48% in the study control group (P-value <0.05). In our study, the phenytoin group showed significantly lower bacterial growth compared to the iodine group, with 15.9% vs. 31.8% at day 7, and 4.5% vs. 15.9% at day 14. The phenytoin group showed a greater reduction in positive cultures over time, though not statistically significant. This can be explained by the fact that, whilst topical phenytoin decreased bacterial contamination by increasing lymphocyte infiltration and neovascularization [14], PVP-I has a broad antimicrobial spectrum. Further, most studies focused on chronic wounds whilst this study examined acute traumatic wounds [15].

This study showed significantly lower pain scores in the phenytoin group than PVP-I group with the mean VAS score at day 7 (3.8 ± 0.4 vs. 6.0 ± 1.0, p < 0.0001) following topical phenytoin versus PVP-I respectively. At day 14, the mean VAS remained lower in the phenytoin group compared to the PVP-I group (p-value < 001), which was statistically significant. On day 10 post-delivery, [10] found a mean pain intensity of 0.72 ± 1.04 and 3.45 ± 2.00 in the phenytoin and PVP-I groups respectively (p < 0.001). Similarly, in India, they showed that on day 14, the VAS score amongst cases was 4.52 ± 1.08, and that of controls was 6.52 ± 1.22, respectively [13]. This can be explained by the analgesic and anti-inflammatory effects of phenytoin. VAS subjectively could have contributed to the variability of a patient having a different threshold and tolerance for pain.

In our study, the rate of granulation tissue formation in the phenytoin group (Group 1) was higher compared to the PVP-I group (Group 2) i.e. (72.9±7.3 %, 95% CI: 70.7-75.2) vs. 57.4±4.30 %, 95% CI: 56.1-58.7) and 86.2% ±7.2, 95% CI: 84.0-88.4) vs. 67.4% ±4.4, 95% CI: 66.0 – 68.7) at Day 7 and Day 14 respectively. This higher rate of granulation tissue formation can be explained by the fact that phenytoin promotes collagen deposition, fibroblast

proliferation, and angiogenesis which could enhance granulation tissue formation [16]. [17], reported that granulation tissue formation was improved with topical phenytoin compared to conventional materials of dressings (PVP-I) in 89.2% versus 73.9% of cases respectively (SD 3.2 and 5.3; p<0.05). In addition, [10] found that on day 14, the percentage of granulation tissue that covered the wound surface was 82.12 ± 9.71 in the cases and 62.72 ± 9.01 in the controls.

CONCLUSION

Our findings have demonstrated that dressing contaminated traumatic wounds with topical phenytoin has a better outcome compared to those that are dressed with PVP with pain alleviation and higher rate granulation tissue formation in cases compared with the control group. Even though, the antibacterial activity between the groups did not show any statistical difference. Therefore, topical phenytoin which is available, easy to use, and safe with minimal adverse effects can be used as an alternative to PVP to dress contaminated traumatic wounds.

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