

# Effectiveness of Chlorhexidine Impregnated Gauze versus Povidone Iodine Dressing in Post Trauma Wound Care

NCT Trial No. Not yet assigned

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## Introduction

Wound care in trauma is important to avoid infection and enhance healing especially in large wounds requiring skin grafts. Povidone-Iodine (PI) soaked dry gauze dressings are widely used for this purpose as it is cheap and easily available. It has a wide antimicrobial spectrum. It exerts activity against bacteria, viruses, fungi, and protozoa. But there are now concerns regarding its cytotoxicity toward granulation tissue and epithelial cells. Thus, it is hypothesized to have a negative role in wound healing [1-2]. This discovery makes Povidone-Iodine detrimental to wounds that require skin grafts as they require granulation tissue to survive.

Chlorhexidine is another easily available antiseptic agent. It also has a broad antimicrobial spectrum against both gram positive and negative bacteria. Chlorhexidine is available both in liquid form for dry gauze dressings as well as in the form of chlorhexidine impregnated paraffin gauze (CHG) dressings. CHG are nowadays favoured, because they provide decreased cytotoxicity compared with PI dressings [3-4].

Comparisons of povidone iodine and chlorhexidine as antiseptic liquids have shown mixed results. A meta-analysis concluded that dry chlorhexidine dressings are associated with a lower risk of wound infections [5, 6]. Another study reveals no significant decrease in infection rate with chlorhexidine [7]. So, some studies favour PI for its quick action, while others emphasise the prolonged action of chlorhexidine [8]. Chlorhexidine impregnated paraffin gauze also promotes faster healing by maintaining a moist environment and reduced cytotoxicity toward granulation tissue and epithelial cells [9].

Gray JG et. al reports an infection rate of 9.9% in wounds with dry povidone-iodine dressings [10]. Similarly, Wang HX et. al reported an infection rate of 1.3% in wounds applied with dry chlorhexidine dressing [11]. So a net reduction in infection rate is expected with use of chlorhexidine dressing however the use of chlorhexidine impregnated paraffin gauze has not been studied.

Kaya AZ et. al reports a wound healing rate of 54% in wounds applied with povidone-iodine gauze [12]. Similarly, Arslan NC et. al reported a healing rate of 94.2% in wounds irrigated with 0.05% Chlorhexidine [13]. So a stark improvement in wound healing rate was observed with the use of chlorhexidine. But there is no data on the use of chlorhexidine impregnated gauze for wound healing rate as well. The conventional paraffin gauze has been used but it has a higher infection rate than the newer chlorhexidine impregnated paraffin gauze available by the brand name Bactigras, Paratulle, etc [14].

This study aims to determine if chlorhexidine impregnated paraffin gauze dressings are superior to dry povidone-iodine dressings for decreasing infection and improving wound healing in post trauma large wounds requiring skin grafts.

## Objectives

To compare rate of infection and wound healing between chlorhexidine impregnated paraffin gauze and dry povidone-iodine dressings in post-traumatic large wounds requiring skin grafts.

## Operational Definition

Wound Infection: A wound will be considered infected if it reaches Grade IV (Pus present) or Grade V (Deep or severe infection with systemic upset) on the Southampton Wound Assessment Scale.

Wound Healing: Clinical improvement of the wound bed and peri wound area, measured by a decrease in the cumulative GRADES Score below 8.

## Hypothesis

Null Hypothesis (H0): There is no significant difference between Chlorhexidine-impregnated paraffin gauze and Povidone-Iodine dressings in terms of infection rate and wound healing in post trauma large wounds requiring skin grafts.

Alternative Hypothesis (H1): Chlorhexidine-impregnated paraffin gauze leads to a lower infection rate and improved wound healing in post trauma large wounds requiring skin grafts.

## Methodology

Study Design: This study will be a prospective, single blind randomised controlled trial (Unique Protocol ID: No.F.1-1/2015/ERB/SZABMU/1482).

Setting: This study will be carried out in the out-patient clinics, emergency and surgical wards of the Burn and Plastic Surgery Department at Pakistan Institute of Medical Sciences.

Duration of Study: 3 months after approval of synopsis.

Sample Size: The incidence of infection within the Povidone Iodine group is 9.9 % [10]. The incidence of infection within the Chlorhexidine Impregnated Paraffin Gauze group is 1.3 % [11]. The total required sample size calculated using WHO Calculator for incidence of infection was 176 patients with 88 patients per group [15].

Sampling Technique: Simple Random Sampling. Patients will be allocated to either Group A (CHG) or Group B (PI) using a computer-generated random number table.

### Sample Selection

Inclusion criteria:

- Patients 18-65 years of age with acute post trauma large wounds requiring skin grafts.
- Wounds that are clean contaminated at presentation.

Exclusion criteria:

- Patients with the known allergies to Chlorhexidine or Povidone-Iodine.
- Chronic wounds or those with underlying chronic conditions, such as diabetes.
- Patients with compromised immune systems.
- Pregnant females

### Data Collection

Ethical approval for the study will be obtained from the Ethical Review Board of SZABMU Islamabad. Patients with post trauma wounds requiring skin grafts will be first selected according to the inclusion and exclusion criteria. Informed consent will be obtained from all patients via a separate consent proforma. Patients will then be randomized into either the chlorhexidine impregnated paraffin gauze group (CHG) or dry povidone-iodine dressing group (PI) via computer-generated random number table. After initial assessment, removal of foreign bodies and debridement of wounds the dressing will be applied as per the group assigned to the patient. The dressing will then be covered using sterile gauze and an elasticated support bandage will be placed over it.

The operating surgeon will then fill out the form on day 1 of injury. The patient's hospital number, patient's group and assessment day will be noted. Patient demographic data such as age and gender will also be noted. The time between initial trauma and hospitalization, Southampton wound grade, Grades score for wound healing and post-op day when initial clinical suspicion of wound infection occurred will also be recorded.

The patient will then be reassessed similarly on post-op day 7, 14 and 21. Southampton wound grade, Grades score for wound healing and post-op day when initial clinical suspicion of wound infection occurred will then be recorded for each patient. Data confidentiality will be strictly maintained.

## Data Analysis

Statistical analysis will be performed using IBM SPSS Statistics (Version 26.0 or later). A p-value of  $< 0.05$  will be considered the threshold for statistical significance, with a 95% Confidence Interval (CI) reported where applicable.

Prior to the primary analysis, the data will be screened for outliers and missing values. The Shapiro-Wilk test and visual inspection of histograms will be used to assess the normality of distribution for continuous variables (e.g., Age, GRADES score).

Patient gender, presence/absence of wound infection (Southampton Grade IV or V), and wound healing (Grades score below 8) will be summarized as frequencies (n) and percentages (%). Normally distributed data (e.g., Age, time since injury to hospitalization, GRADES score) will be presented as Mean  $\pm$  Standard Deviation (SD), Median and Interquartile Range (IQR).

To determine the infection and healing rate between the CHG and PI groups, the Pearson Chi-Square test will be employed. If any cell count is less than 5, Fisher's Exact Test will be used instead.

Effect modifiers like age, gender, etc will be stratified by using post stratified chi-square test.

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## Day 1:

Patient's MR Number: \_\_\_\_\_

Patient's Group: \_\_\_\_\_

Assessment Day: \_\_\_\_\_

Participant Age: \_\_\_\_\_

Participant Gender (Tick the appropriate Gender):    M                      F

Time between initial trauma and hospitalization (in terms of hours): \_\_\_\_\_

Southampton Wound Grade: \_\_\_\_\_

Grades score for wound healing: \_\_\_\_\_

Clinical suspicion of wound infection (in terms of day 1-21, Mark NA for no infection): \_\_\_\_\_

## Day 7:

Southampton Wound Grade: \_\_\_\_\_

Grades score for wound healing: \_\_\_\_\_

Clinical suspicion of wound infection (in terms of day 1-21, Mark NA for no infection): \_\_\_\_\_

## Day 14:

Southampton Wound Grade: \_\_\_\_\_

Grades score for wound healing: \_\_\_\_\_






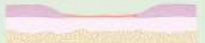



Clinical suspicion of wound infection (in terms of day 1-21, Mark NA for no infection): \_\_\_\_\_

Day 21:

Southampton Wound Grade: \_\_\_\_\_

Grades score for wound healing: \_\_\_\_\_

Clinical suspicion of wound infection (in terms of day 1-21, Mark NA for no infection): \_\_\_\_\_

SCORE			1	2	3	4
<b>G</b>	Granulation tissue		75-100%	50-75%	25-50%	<25%
			Absent	Slight +	Moderate ++	Abundant +++
			Erythema	Flushed	Pale yellow	Necrotic
			Absent	<25%	25-50%	50%>
<b>E</b>	Exudate	Amount	Absent	Slight 	Moderate 	Abundant 
		Type	Absent	Serous 	Cloudy 	Purulent 
<b>S</b>	Surrounding	Skin	Healthy	Peeling	Erythematous	Macerated
		Edge	Attached 	Raised 	Rolled 	Necrotic 

SOUTHAMPTON WOUND GRADING SYSTEM	
GRADE	APPEARANCE
0	Normal healing
I	Normal healing with mild bruising or erythema
Ia	Some bruising
Ib	Considerable bruising
Ic	Mild erythema
II	Erythema plus other signs
IIa	At one point
IIb	Around sutures
IIc	Along wound
III	Clear or haemoserous discharge
IIIa	At one point only (< 2cm)
IIIb	Along wound (>2 cm)
IIIc	Large volume
IV	Pus
IVa	At one point only (< 2 cm)
IVb	Along wound (>2 cm)
V	Deep or severe wound infection with or without tissue breakdown; hematoma requiring aspiration