

Comparative study of two different disinfectant solutions used for pin site care in patients with Ilizarov ring fixation.

Abstract:

The Ilizarov ring fixation system is used to ~~support and control bone abnormalities, treat fracture therapy,~~ osteomyelitis, and bone lengthening. ~~The frame provides support and strength to the bone, allowing it to realise its full osteogenic potential.~~ Wires and pins ~~are used in order to fix the Ilizarov frame to the support the bone in the ring frame affected bone.~~ In patients with Ilizarov ring fixators, pin site infections (PSI) are the most prevalent problem seen by orthopaedic surgeons. ~~Septicemia can be caused by a variety of illnesses, including local soft tissue infections, cellulitis, bacterial endocarditis, and osteomyelitis.~~ Pin sites are prone to infection because the skin barrier is lost or broken, disrupting the body's natural barrier defence against bacterial infection.

This was a cross sectional study and a total of 30 patients devided in 2 equal groups, each contained 15 patients were taken under study. The present study included patients treated with Ilizarov external fixators post-injury and followed-up ~~patients who had been treated by the same procedure and reported to the~~ at Orthopaedic OPD. ~~The patients were then confirmed by history, clinical examination and radiological evidence.~~ A total of 235 pin sites were examined ~~of -in all the~~ 30 patients. Demographic information, socioeconomic status, and health status were asked and recorded in the patient identification forms. It was found that, Only 19 of the 125 pins cleaned with chlorhexidine showed evidence of infection, but 32 of the 110 pins cleaned with povidone iodine solution ~~were showed infected infection. With a(p value of = 0.05,-), there~~ This was found to be ~~was a~~ statistically significant ~~difference~~. In the participating groups, the location of infection was not important. The povidone iodine group had the most first-degree infections, followed by second- and third-degree infections. According to the Checketts otterburn classification scale, the chlorhexidine group did not report any third-degree infections.

Keywords: Pin Site Care, Ilizarov ring fixation, Orthopedics.

Introduction:

Ilizarov ring fixation is used to provide support and manage bone deformities, fracture treatment, osteomyelitis, and bone lengthening. The frame gives stability and strength allowing the bone to reach its osteogenic potential. The ring frame supports the bone through wires and pins. Pin site infections (PSI) are the most commonly faced predicament by orthopedic surgeons in patients with Ilizarov ring fixators. Local soft tissue infections, cellulitis, bacterial endocarditis, and osteomyelitis are all examples of infections that can lead to septicemia. (1)

Pin sites are susceptible to infection as there is loss or breakage of the skin, altering the body's natural barrier. Pin site infection rates have been estimated to be as high as 86.5 percent in

individuals who have had external fixation surgery. (2). Therefore, it becomes necessary to prevent or treat such infections as they may lead to compromised treatment goals and increase patient morbidity. (2)

The prevention and management of infection need to be done in a manner suitable to both patient and clinician. Cleansing solutions have high efficacy in the treatment of PSI. The solutions routinely administered include 10% w/v povidone-iodine (PI) solution or 2mg/ml chlorhexidine solution.

Povidone-iodine has been shown to be effective in the laboratory at eliminating a wide range of microorganisms commonly linked with wound infections. Povidone-iodine solution can be used at full strength i.e 10% w/v or diluted to any desired concentration before use. Berkelman et al discovered that a 0.1-0.5 % w/v of povidone-iodine solution was more successful in killing typical wound pollutants. (3)(4) Within 4 minutes of exposure, even a 10% solution was totally effective. At a concentration of 0.001%, PI is proven to be bactericidal. (3)

Chlorhexidine has been shown to reduce microbiological problems and the time it takes for wounds to heal. During a study in patients having surgery requiring external fixation, Traditional pin care participants had a considerably higher incidence of pin tract infections than those who used a polyurethane bandage coated with chlorhexidine gluconate.

Thus, the efficacy of both these cleansing agents is high.

Currently, there is no widely acknowledged procedure for optimum care at the site of the pin. (5) For the management and treatment of infections that arise at the pin site, numerous techniques have been used, ranging from a different strategy in disinfectant selection to the duration the pins and the fixator is placed for. As a result, many strategies ~~to for pin web website online~~ care exist, starting from a innovative method that advocates no lively pin care to a complete approach that emphasises lively pin care. (6) It additionally includes strict remedy measures, inclusive of twice-each day cleaning, dressing, and oral antibiotics for the duration of the outside fixator therapy. (7) Once the contamination ~~on of the pin web website online~~ has been identified, the contamination can be assessed and recorded the usage of the Checketts-Otterburn classification. (5) Based on medical signs and radiological data, Checketts et al. categorised pin web website online infections into 3 foremost and 3 minor classes. Redness, drainage, pain, and tenderness belong to the minor group, while gentle tissue contamination with bone involvement belongs to the foremost group. (5)(table1)

Infections at the location of percutaneous pins or wires are a common orthopedic issue. (8) Because it has demonstrated to have a corrosive impact on steel pins and a diminished antibiotic action when in contact with exudate, the use of povidone-iodine has been discouraged. (9)

Chlorhexidine gluconate is a swiftly acting antimicrobial cleansing solution. (10) It was more efficient against gram-negative bacteria than gram-positive bacteria, according to the study. The most efficient washing agent, according to the National Association of Orthopaedic Nurses (NAON), is chlorhexidine 2 mg/ml. (11) Chlorhexidine is used as a topical antiseptic during surgery and ~~the installation sterilization~~ of intravascular devices. The active molecule's attachment to the stratum corneum, which functions as an antiseptic reservoir, extending its activity and effect, explains its long-lasting impact. (12)

The knowledge about the effectiveness of the cleansing agent remains inconsistent because of the physicians' choice rather than evidence. Because the fixators were oft removed early within the medical care period, it' arduous to match the speed of pin website infection to different studies, that report a 30% pin tract infection rate. (13) once skeletal pin-sites are treated with associate degree medication medication, the chance of infection is reduced. a lot of analysis is

required to examine if the placement of the pin-anatomical site may be a risk issue for infection and if intervention may minimise inflammation and infection at the medial lower leg pin-sites. (14) Despite the actual fact that there's no statistically important distinction in infection rates between antiseptic and povidone-iodine solutions, Cam et al. (2015) claim that antiseptic may be a higher improvement solution. (15) In open fractures, the chance of pin website infection is higher. (16)

<u>Infection Grade</u>	<u>Description</u>
<u>Grade 1</u>	Slight erythema. little discharge. Treat with improved local pin care
<u>Grade 2</u>	Erythema, discharge, pain, warmth. Treat with improved local pin care and oral antibiotics
<u>Grade 3</u>	As per grade 2, but no improvement with oral antibiotics. Pins/ex fix can be continued
<u>Grade 4</u>	Severe soft tissue infection involving several pins ± pin loosening. Ex fix must be discontinued
<u>Grade 5</u>	As per grade 4, but with bone involvement visible on radiographs. Ex fix must be discontinued
<u>Grade 6</u>	Major infection occurring after ex-fix removal. Treatment requires curettage of pin track

(Table 1:Checketts-Otterburn classification)

Aims & Objectives:

To compare the two cleansing solutions and find out the most efficacious solution to treat PSI in Ilizarov patients.

1. Determine the infection rate in povidone-iodine solution-treated individuals.
2. To determine the rate of infection in patients receiving chlorhexidine gluconate solution.
3. To compare patients who received a povidone-iodine solution to those who received a chlorhexidine gluconate solution.
4. To find the most efficacious solution for the treatment of PSI.

Materials and Methods:

Study design: Cross-sectional, observational study

Study duration: 2 months

Sample size: Thirty patients were included in the study considering all patients with Ilizarov ring fixators (de-novo, and follow-up patients with Ilizarov fixators).

Selection of study subjects: The study was carried out after receiving clearance from the Institutional Ethical Committee and obtaining permission from the hospital to perform it. The patients in the study gave their written and verbal permission after being educated about the research's goals and implications.. The present study included patients treated with external

fixators post-injury and follow-up patients who had been treated by the same procedure and reported to the Orthopaedic OPD. The patients were then confirmed by history and radiological evidence. A total of 235 pin sites were examined of 30 patients. Demographic information, socioeconomic status, and health status were asked and recorded in the patient identification forms.

Ilizarov ring fixators were used in all patients. The patients were segregated into two treatment groups:

Group1: (n=15)

Fifteen patients and a total of 110 pins were treated with 10% povidone-iodine solution

Group2: (n=15)

Fifteen patients and a total of 125 pins were treated with 2mg/ml chlorhexidine solution

Inclusion criteria: 30 patients treated with Ilizarov ring fixation method of the age group 18-60, of either sex.

Exclusion criteria: Patients who did not give consent

The infection site was cleansed of scabs after administering the appropriate wound care solution, and the infection (if present) was rated and noted in the infection evaluation chart.

The infection grade was determined according to the classification provided by Checketts et al. [8]

Outpatients were informed about the clinical features like erythema, redness, and discharge, and radiological evidence was taken on follow-ups.

Antiseptic impregnated gauze (chlorhexidine/povidone-iodine) was administered on the pin sites, which were then monitored for bleeding, discharge, drainage, and infection symptoms, every day till discharge and on follow-ups.

To compare categorical data between the groups, Chi-square analysis or Fisher's exact test were employed when suitable.

Data analysis was carried by Statistical Package SPSS (version 25.0, IBM Corporation) and Microsoft Excel 2016 (Microsoft Corporation). P values were calculated and the ones less than 0.5 were considered.

Observations and Results:

The study involved patients of both the genders belonging to different age groups and professional backgrounds.

The final research study size included 30 (i.e n=30) patients out of which 15 patients were treated with povidone- iodine solution and the rest 15 patients were treated with chlorhexidine solution . In the comparative study out of 15 patients in the povidone-iodine group 7 were males and 8 were female patients . The age of the patient was also included in the study, among the 15 individuals in the group 5 were from the age group 18-27 years , 4 were between 28-37 years of age,4 were in age between 38-47 years and the rest 2 were of age between 47-60 years. The age criteria was considered as the severity varied in different age groups.

<u>Age Group</u>	<u>Povidone Iodine Group</u>		<u>Chlorhexidine group</u>	
	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>
18-27	5	33.4	6	40
28-37	4	26.6	2	13.4
38-47	4	26.6	6	40
47-60	2	13.4	1	6.6
X ² =1.49		p = 0.68 p>0.05		NS
<u>Gender</u>				
Male	8	53.3	6	40
Female	7	46.7	9	60
<u>Fisher's exact test</u>		p=0.46 p>0.05		NS
<u>Profession</u>				
Housemaker	4	26.6	3	20
Self employed	1	6.6	1	6.6
Worker	3	20	6	40
Student	7	46.8	5	33.4

(Table 2: Demographic details of the patients)

Similarly in the chlorhexidine group the patients included were 6 males and 9 females and 6 belonged to the age group of 18-27 years, 2 were between 28-37 years , 6 were between 38-47 years 1 of them belonged to the age of 47-60 years.

The assessment of their profession was also conducted and it was observed that 4 females were housemaker among total 7 of them rest 3 of the patient were working as daily wage worker , 7 among them were students and 1 was self-employed in povidone-iodine group and 3 were housemaker out of 9 females , 6 of the total patients were daily wage worker and 5 were students and 1 of the patient was self-employed in chlorhexidine group. (Table 2)

A total of 8 of all patients were treated with external fixators on closed fractures with 7 patients having open fractures. None of the patients had the fixator in the tibia, 4 in the femur, 5 in the radius and 6 of them had fixators in the humerus in the povidone iodine

group. Followed by 1 patient who had the fixator in the tibia, 7 in the femur, 4 in the radius and 3 of them were in the humerus in the chlorhexidine group. Kirschner wires were put in 12 patients of the povidone iodine group along with 3 of them were fixed with Schanz Pin and 11 out of 15 of the chlorhexidine group were fixed with Kirschner wire; 4 had schanz wire. The p values for the demographic details and type of fractures were >0.05 and therefore were not significant.

A total of 32 pins out of the 110 cleaned with povidone iodine solution were infected whereas only 19 out of 125 pins of the chlorhexidine group showed signs of infection. There was a significant statistical difference with p value being <0.05 . The site of infection in the involved groups was not significant. A majority of first degree infection was observed in the povidone iodine group, followed by second and third degree. The chlorhexidine group did not report any third degree infections according to the checketts otterburn classification scale. (Table 4)

Discussion:

There was no statistically significant difference between the two groups of patients in terms of age, gender, education status, career, or BMI ($p>0.05$). Many studies have attempted to determine how successful various cleaning procedures are at reducing the risk of pin site infection.

118–One hundred and eighteen patients receiving external fixator treatment were randomly assigned to one of three groups: (1) no washing solution, dry dressing (2) half-strength hydrogen peroxide provided daily, and (3) Biopatch® chlorhexidine-impregnated discs changed weekly, according to Egol et al. A appropriate and cost-effective alternative was identified to be sterile dry dressings changed once a week. When W-Dahl and Toksvig-Larsen tested 2 mg/ml chlorhexidine and normal saline solution, they discovered that infection rates were 0.5 percent in the chlorhexidine group and 3 percent in the saline solution group.

	Povidone Iodine solution		Chlorhexidine Solution	
Number of pins cleaned with the specified solution	110	-	125	-
Number of pins that develop pin tract infection	32	29.9	19	15.2
$X^2=6.45$	p =0.011 p<0.05		S	
Location of pin tract infection				
Radius	11	34.3	5	26.3
Tibia	-	-	3	15.8
Femur	9	28.1	6	31.6
Humerus	12	37.6	5	26.3
$X^2=5.79$	p =0.12 p>0.05		NS	
Degree of infection	Povidone Iodine solution		Chlorhexidine Solution	
First degree	24	75	16	84.2
Second degree	4	12.5	3	15.8
Third degree	4	12.5	-	-

(Table 4: Infection Grade and Sites)

In the current study 32 out of 110 pins were infected among 15 patients in povidone-iodine group, the majority of these pins were applied on humerus followed by radius and femur indicating 29.9% infection rate while 47.7% had a longer hospital stay and were addressed to dressing right from the second day postoperative . Compared to infection of 13 pin sites (18.1%) out of a total of 72 pin sites cleaned using povidone iodine solution by Grant et al. (14)

The next group in study were treated with 2% chlorhexidine solution, started 2nd day from operative procedure indicated infection of 19 pin sites out of a total of 125 pins applied. The majority of the pins were used on femur followed by humerus, radius and tibia, 86.6% patient in the group had a lesser hospital stay. The infection rates of the other studies in 2% chlorhexidine were better. On the Checketts–Otterburn scale, however, there was no remarkable difference in infection rates, pin loosening rates, or the occurrence of higher grade infections.

In the current study, pin site infection rates were twice as high in the povidone-iodine group (29.9%) as they were in the chlorhexidine group (15.2%). In the povidone-iodine group, 24 of the 32 contaminated pins had first-degree infections, four developed second-degree infections, and four developed third-degree infections. 16 contaminated pins in the chlorhexidine group had first-degree pin site infections, whereas 3 acquired second-degree infections. To date, however, there are very few studies that prove a considerable relationship between pin site infections and the type of cleansing solution used. (15-20)

Conclusion:

There was a statistical difference between the two groups, only 19 of the 125 pins in the chlorhexidine group acquired infection, compared to 32 of the 110 pins in the povidone-iodine group. Therefore the study concludes that 2gm/dl chlorhexidine solution is highly effective in reducing pin site infection rates in Ilizarov treated patients compared to 10% povidone iodine. Future research might improve on the findings of this study by evaluating the other aspects of pin site infection, such as the link between infection rate and age groups or infection in comorbid patients. In today's study fields, the type of cleansing solution utilised to decrease pin site infection is a subject of much interest. Accurate identification of the characteristics that prevent pin site infections is a topic of study that not only needs to be developed immediately, but also has a lot of practical value in terms of improved prognosis for surgeries that need Ilizarov fixators. This is the first research to compare the effectiveness of povidone iodine and chlorhexidine for pin tract care, as well as to verify the efficiency of the superior solution. The study of this correlation between type of solution used and pin tract infection can provide useful insight regarding :

1. The most efficacious solution for the treatment of PSI
2. Help in reducing the rate of PSI in external fixators.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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