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CLINICAL RESEARCH

Antimicrobial Gauze as a Dressing Reduces Pin Site Infection

A Randomized Controlled Trial

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Abstract

Background Pin site infection is a common problem in external fixation. Plain gauze wetted with normal saline is commonly used for a pin site dressing owing to the simplicity and low cost. Evidence to support adding an antimicrobial agent in the dressing material is lacking.

Questions/purposes We compared the rate of pin tract infection using plain gauze and gauze impregnated with polyhexamethylene biguanide in patients undergoing limb lengthening procedures.

Patients and Methods We included 38 patients (40 limbs) undergoing limb lengthening or deformity correction using an external fixator between July 2009 and June 2010. There were 23 male patients and 15 female patients, with a mean age of 26.3 years (range, 5–68 years). The patients were randomized into two groups: a polyhexamethylene biguanide group (22 limbs) and a control group (18 limbs). The metal-skin interfaces were assessed by a researcher blinded to the type of gauze at 2, 4, 8, and 12 weeks after surgery for the pin site infection based on a predetermined grading system. There were a total of 483 metal-skin interfaces, with 1932 total observations. Infection rates were compared using the chi square test and relative risk with 95% confidence interval.

Results The infection rate was lower (χ^2 [1, n = 1932] = 23.00) and the risk for infection was lower (relative risk, 0.228; 95% confidence interval, 0.118, 0.443) for the polyhexamethylene biguanide group (n = 1068; 1.0%) than for the control group (n = 864; 4.5%).

Conclusions Use of polyhexamethylene biguanide-impregnated gauze can reduce the risk of pin tract infection in external fixation.

Level of Evidence Level I, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

External fixation has been an important component of orthopaedics and trauma surgery, especially for treatment of open fractures. Its indication has broadened after Ilizarov's introduction of the principles of distraction osteogenesis [13, 14] and includes correction of congenital and acquired deformities, mobilization of stiff joints, and healing of infected nonunions. However, external fixation is associated with high rates of morbidity, especially when prolonged application is necessary [23]. Infection of the metal-skin interface, more commonly known as pin site infection, is one of the most common problems, with reported rates ranging from 1% to 80% [9, 17].

Protocols for pin site care have been described, varying in nearly all aspects of care, including the types of cleansing solutions, cleansing methods, dressing material, and frequency of dressing changes [17]. For decades, there has not been a general guideline or consensus achieved on pin site care [17]. One of the reasons is the lack of a clear

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definition of pin site infection and lack of a validated grading system to evaluate the severity of this problem. In addition, variation in clinical practices, socioeconomic background, and environment all contribute to the lack of a standardized protocol. Published studies mostly have been retrospective where diagnoses have been made by different assessors [2, 24]. There have been few comparative studies providing good evidence for the effectiveness of any particular method of pin site care [4, 10, 24, 25].

Dressing of pin sites with gauze wetted with normal saline is popular because it is simple and inexpensive. Adding an antimicrobial agent to the gauze might improve its effectiveness as a barrier and also reduce the local bacteria load [27, 29]. Polyhexamethylene biguanide (PHMB) is a bacteriostatic agent that has been used in different types of dressings for surgical wounds, gunshot wounds, and ulcers [11, 20, 21, 26]. Studies have shown PHMB is effective against a diverse range of bacteria, including Staphylococcus aureus, methicillin-resistant S. aureus, S. epidermidis, Pseudomonas aeruginosa, Escherichia coli, and Klebsiella pneumonia [3, 6, 7, 15], which are common organisms cultured from infected pin sites.

We hypothesized PHMB-impregnated gauze would lower the rate of pin site infection as compared with plain gauze. Therefore, we (1) assessed the overall infection rate in a group of patients; (2) compared the infection rates between two groups, one receiving PHMB-impregnated gauze and the other receiving plain gauze for pin site dressing; (3) compared the infection rates between the two groups according to various infection grades; and (4) compared the infection rates between the two groups according to types of bone fixation.

Patients and Methods

This is a randomized, controlled, double-blinded study. We included consecutive patients scheduled for limb lengthening or deformity correction using external fixation in our institution between July 2009 and June 2010. We excluded patients with multiple underlying medical problems and patients who could not return for regular followups in our hospital. The sample size was predetermined using the Altman nomogram [1].

Forty-three patients initially were enrolled for the study. Five patients were later excluded because they were unable to attend the clinic according to study schedules owing to transportation problems. Of the remaining 38 patients, there were a total of 40 limbs because two patients had both limbs treated simultaneously. After randomization, 22 limbs were assigned to the PHMB group and 18 limbs to the control group (Fig. 1). Of the five excluded patients, three initially were assigned to the control group and two to the PHMB group. All their data were excluded from analysis.

There were 23 (60.5%) male patients and 15 (39.5%) female patients. Their mean age was 26.3 years (range, 5–68 years), with 24 patients (63.2%) aged from 16 to 60 years, 12 patients (31.6%) younger than 16 years, and two (5.35%) older than 60 years. Patients in the control group were slightly older (mean age, 29.3 years) than patients in the PHMB group (mean age, 23.8 years) ($p = 0.265$). Both groups were comparable in terms of gender distribution, diagnosis, side of fixation, site of fixation, and pin-skin interface to wire-skin interface ratio (Table 1). There were a total of 483 metal-skin interfaces, 270 wire-skin interfaces, and 213 pin-skin interfaces.

The primary procedure was performed by two of the authors (YPC, AS). Half pin tracts were predrilled with 3.2- or 3.5-mm drill bits. Stainless steel half pins of 5.0-mm diameter then were inserted manually. Tensioned wires were drilled directly through the bone. They were tensioned to between 90 and 110 kg before fixation onto the external fixator frame. After application of the external fixator, all patients or their caretakers were taught how to perform pin site dressing according to a standard protocol used in our hospital [28]. The protocol involved daily change of the dressing gauzes that were wet with normal saline. It also included a management plan of pin sites with

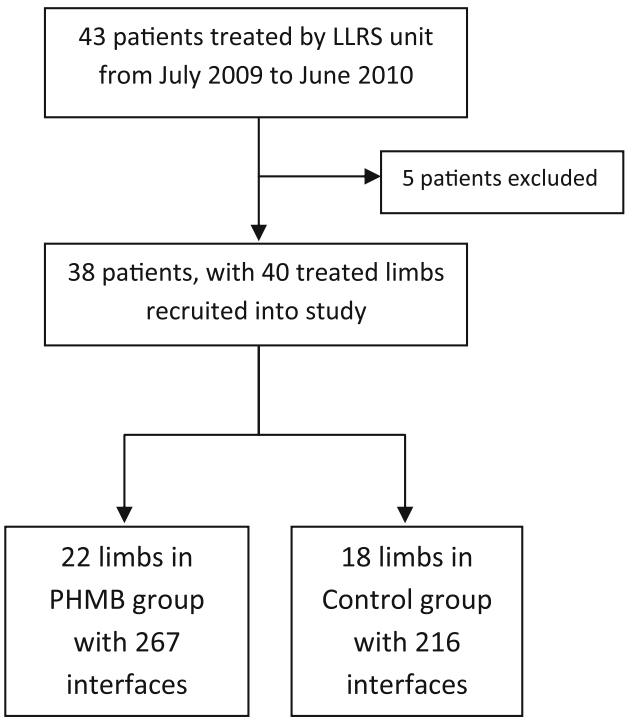

Fig. 1 A flowchart shows sample recruitment and randomization. LLRS = Limb Lengthening and Reconstruction Surgery.

Table 1. Demographic comparison between the two treatment groups

Variable	PHMB group	Control group
Number of patients (limbs)	20 (22)	18 (18)
Age (years)*	23.8 ± 12.0	29.3 ± 18.7
Male: female ratio	1.86:1	2:1
Diagnosis (% of the group)		
Infection	31.8	33.3
Trauma	31.8	33.3
Congenital/developmental	36.4	33.3
Side of fixation		
Left: right ratio	1.2:1	1:1
Site of fixation (number of limbs)		
Tibia	13	9
Femur	5	3
Other	4	6
Metal-skin interface	267	216
Pin: wire ratio	1:1.2	1:1.3

* Values are expressed as mean ± SD; PHMB = polyhexamethylene biguanide.

clinical evidence of infection. The patients were randomly assigned into either the PHMB group or the control group by means of drawing lots. All randomizations were done by the first author (CKL). Patients in the PHMB group received gauze impregnated with 0.2% PHMB (Excilon™ AMD™ I.V. Sponges; Covidien, Mansfield, MA, USA) whereas those in the control group received plain gauze (Excilon™ I.V. Sponges; Covidien). A research assistant (MLC) was responsible for providing the dressing materials to the patients in the ward and also at followup. The container, package covering, and physical appearance of the gauze were identical, and all patients were blinded to the type of gauze they would be using.

The patients were reviewed in the outpatient clinic at 2, 4, 8, and 12 weeks after surgery. The pin sites were assessed by two of the authors (YPC, AS) who were blinded to the type of dressing gauze used. All pin tracts were coded and their condition graded according to the criteria used by Saw et al. [28] (Table 2). A pin tract infection was defined as any presence of erythema surrounding or purulent discharge from the metal-skin interface. As each of the metal-skin interfaces was assessed four times during the study, this resulted in 1932 total observations (Table 3). The data were collected, tabulated, and analyzed using SPSS® for Windows® (SPSS Inc, Chicago, IL, USA). The data were compared using the chi square test with the level of statistical significance set at $p < 0.05$. Relative risk (RR) with 95% confidence interval (CI) and relative risk reduction (RRR) also were calculated.

Table 2. Grading system for pin site infection

Grade	Description
0	No skin erythema and no purulent discharge
1	Skin erythema only or purulent discharge only
2	Skin erythema and purulent discharge
3	Grade 2 findings and radiographic evidence of osteomyelitis

(Reproduced with permission from Saw A, Chan CK, Penafort R, Sengupta S. A simple practical protocol for care of metal-skin interface of external fixation. *Med J Malaysia.* 2006;61(suppl A): 62–65.)

Results

Of the total of 1932 pin site observations, 50 showed signs of infection, representing an overall rate of infection of 2.6%. Of these infections, 1.9 % (37 of 1932) were Grade 1 infections whereas only 0.7% (13 of 1932) were Grade 2. There were no Grade 3 infections.

Overall, the PHMB group had a lower infection rate ($\chi^2 = 23.00$; $p = 0.00$) and lower risk for infection (RR, 0.228; 95% CI, 0.118, 0.443) than the control group. The PHMB group had a RRR of 0.78 for overall pin tract infection as compared with the control group. In the PHMB group, 11 of 1068 (1.0%) observations showed infection, whereas in the control group, 39 of 864 (4.5%) observations showed infection (Table 3).

When we consider only the Grade 1 infections, the PHMB group also showed a lower infection rate ($\chi^2 = 26.62$; $p = 0.00$) and lower risk for infection (RR, 0.126; 95% CI, 0.049, 0.323) than the control group. The PHMB group had a RRR of 0.86 for Grade 1 infections as compared with the control group. In the PHMB group, five of 1068 (0.5%) observations showed Grade 1 infection, whereas in the control group, 32 of 864 (3.7%) observations showed Grade 1 infection. There were no differences ($\chi^2 = 0.44, p = 0.51$; RR, 0.693; 95% CI, 0.234, 2.056) in infection rate and risk between the two groups when only the Grade 2 infections were considered (Table 3).

When we consider the wire-skin and pin-skin interfaces separately, the PHMB group again showed a lower infection rate (wire-skin: $\chi^2 = 15.18$; $p = 0.00$; pin-skin: $\chi^2 = 8.03$, $p = 0.01$) and lower risk for infection (wire-skin: RR, 0.185; 95% CI, 0.071, 0.482; pin-skin: RR, 0.285; 95% CI, 0.113, 0.722) than the control group. The PHMB group had RRRs of 0.80 and 0.72 for wire-skin and pin-skin interfaces, respectively, as compared with the control group (Table 3). There were no differences ($\chi^2 = 0.00$; $p = 0.99$; RR, 1.004; 95% CI, 0.579, 1.742) in infection rate and risk between wire-skin and pin-skin interfaces (Table 4). There was no unintended side effect noted in the PHMB group.

Table 3. Comparison of infection rate for both treatment groups

Variable	PHMB group (n = 22)			Control group (n = 18)			Pearson chi square (p value)	Relative risk (95% CI)	RRR
	Number of infections	Number of observations	%	Number of infections	Number of observations	%			
Type of fixation									
Wire-skin	5	584	0.9	23	496	4.6	15.18 (0.00)	0.185 (0.071, 0.482)	0.80
Pin-skin	6	484	1.2	16	368	4.3	8.03 (0.01)	0.285 (0.113, 0.722)	0.72
Grade of infection									
Grade 1	5	1068	0.5	32	864	3.7	26.62 (0.00)	0.126 (0.049, 0.323)	0.86
Grade 2	6	1068	0.6	7	864	0.8	0.44 (0.51)	0.693 (0.234, 2.056)	0.25
Grade 3	0	1068	NA	0	864	NA	NA	NA	NA
Overall	11	1068	1.0	39	864	4.5	23.00 (0.00)	0.228 (0.118, 0.443)	0.78

PHMB = polyhexamethylene biguanide; CI = confidence interval; RRR = relative risk reduction; NA = not applicable.

Table 4. Comparison of infection rate according to type of metal-skin interface

Type of interface	Number of observations	Number of infections	Infection rate (%)	Pearson chi square test (p value)	Relative risk (95% CI)
Wire-skin	108	28	2.6	0.00 (0.99)	1.004 (0.579, 1.742)
Pin-skin	852	22	2.6		

CI = confidence interval.

Discussion

Pin site infections remain a challenge to many orthopaedic surgeons. However, there have not been adequate comparative studies to provide good evidence for effective pin site care. We therefore compared the infection rate of external fixator pin sites using two types of gauze, PHMB impregnated and normal saline-soaked, on patients treated with prolonged application of external fixators. The results showed the PHMB-impregnated gauze had a lower infection rate and risk for infection than the plain gauze in overall infection, Grade 1 infection, wire-skin infection, and pin-skin infection with RRRs of 0.78, 0.86, 0.80, and 0.72, respectively.

This study has limitations. Our study was designed to look for infection rate per number of observations rather than per number of pin sites or per patient because we believe a busy clinician can easily estimate the infection risk for pin sites of a patient during consultation at any stage of treatment. In a patient with 10 pin sites, an infection rate of 10% per observation would mean one of the pins is at risk of being infected at any observation or followup. This concept was similar to the study performed by Gordon et al. [8] and our results in the control group were comparable. It is logical to assume only slight variation may exist in this rate even if the observations were made every 2 weeks or every 2 months, but our study was not able to provide any analysis to support this assumption. Currently, available diagnostic criteria for pin tract infections are relatively subjective. Checketts et al. [5] divided pin tract infections into six grades, and some of the observations were based on response to treatment, indicating the retrospective nature of its usage. Another grading system included pain as a criterion despite the fact that threshold to pain varies between individuals based on cultural or social background [23]. We graded the pin sites based mainly on physical findings (supplemented with radiographic images in selected cases) and believe it is more useful and reproducible [4, 28]. Currently, there is no validated grading system available for pin site infection. As both treatment groups used the same method of calculation for infection rate and grading for infection severity, they would not affect the outcome of this comparative study.

Our overall infection rate of 2.6% compares favorably with those reported in other studies [12, 18, 19, 24]. There have been several studies reporting various methods of pin site care or the use of particular solutions for this purpose [4, 10, 24, 25]. One of the few controlled studies [4] compared the rates of infection between the use of normal saline and diluted povidone-iodine as the dressing solution. Our study reduced the selection bias by randomly allocating the study and control groups. However, with a double-blind design, we also were able to reduce the observation bias by the assessors. This is especially important where the study endpoint cannot be objectively evaluated.

Currently, there is no validated grading system to evaluate severity of pin tract infection, and by blinding the observer, we can expect a more reliable assessment of this endpoint.

The wire-skin interface was found to have equal risk for infection as compared with the pin-skin interface (Table 4), although previous studies have shown half pins were associated with higher infection risk [4, 28]. Excessive soft tissue motion has been shown to increase the risk of pin site infection [18]. In our study, half pins were used mostly for fixation of diaphyseal bones where soft tissue movement was minimal. However, wires were preferred for bones close to the knee and ankle. This invariably reduced the infection rate of pin-skin interfaces.

PHMB is a commonly used antiseptic and is used in various products, including wound care dressings, contact lens cleaning solutions, perioperative cleansing products, and swimming pool cleaners [22]. It has been shown to be effective against most microorganisms associated with pin tract infections [3, 6, 7, 15] and therefore further enhances the efficacy of a gauze dressing for external fixation by reducing the bacterial load on the gauze during a 24-hour period between dressing changes. A review of the literature shows in vivo and in vitro safety of PHMB for numerous applications [16, 21, 30]. To date, PHMB does not have a history of resistance or cytotoxicity [20, 22], has been shown to promote healing [16, 22], and might play a new and important role as an antimicrobial agent in dressings.

Our overall rate of pin tract infection was 2.6%. PHMB-impregnated gauze was more effective than plain gauze for pin site dressings for external fixators, and the majority of pin tract infections can be treated without antibiotics. For long-term application of external fixators, the rate of pin site infection would be more accurately reflected by several observations at regular intervals.

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