

Original article

THE MANAGEMENT OF PIN-CARE IN EXTERNAL FIXATION TECHNIQUE: POVIDONE- IODINE VERSUS SODIUM HYPOCHLORITE 0,05% (AMUKINA-MED®) MEDICATIONS.

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Summary

Purpose:

Currently, there is no universal approach to pin-site care for preventing infection. The medication of these pins is essential for obtaining good external fixation results. The purpose of this study is to evaluate the results obtained after pins were medicated with two different disinfectants: povidone-iodine (10%) and sodium hypochlorite 0,05% (Amukina-med®).

Methods:

237 pins of 40 patients treated with Hoffmann II external fixation have been analyzed in our study. The average age was 41.3 (ranging from 19-71). All pins were inserted by hand pre-drilling together with continuous irrigation with cold saline to reduce the risk of thermal necrosis. Patients were divided into 2 groups consisting of 20 patients each: in group A, 109 pins were medicated with povidone-iodine and in group B, 128 pins were medicated with sodium hypochlorite 0,05%.

Results:

24 pins (22%) medicated with povidone-iodine became infected, as well as 13 pins (10,1%) medicated with sodium hypochlorite. A few pins mobilized: 13 in group A and 6 in group B. In all cases, infections were resolved with oral antibiotic therapy.

Conclusions:

Our study showed that medication with sodium hypochlorite 0,05% reduced the percentage of pin-tract infection and mobilization with respect to povidone-iodine, demonstrated by significant statistical evidence (Chi-square's test: $p < 0.05$).

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Introduction

External fixation is a common method used in orthopedics and traumatologic surgery. The main aspect of this procedure consists of the body of the fixator being located outside of the skin and connecting it to the bone through transcutaneous pins [1].

This procedure is mainly used in long bone and pelvic fractures for both young and old patients. They are also used as span-joints in complex articular fractures and in exposed fractures to allow for the reconstruction of soft tissues [2]. It is important to know the anatomy and access roads in order to safely avoid vascular and nerve damage during pin insertion.

As with all such procedures, however, external fixation is associated with complications. The most frequent are: pin breakage, pin migration, loss of reduction, vascular and nerve damage, superficial infections and osteomyelitis (deep infections). These complications are an important cause of morbidity resulting in increased surgical procedures, hospitalization stay and costs [3-4].

During the evaluation of the risk of infection, it is important to take into consideration the pin sites, especially when they are located in areas with significant soft-tissue. Pin-tract infections are a common problem in clinical practice with an incidence reported in literature of 0% to 80% [5-6].

The colonization of bacteria on pins is the cause of infection, which is facilitated by local factors, such as, bone necrosis, skin damage, the decrease of immune response, and general factors like patient's conditions [7-8]. The infection can develop locally or diffuse to surrounding soft tissues and then to the bone causing osteomyelitis and loss of the mechanical seal of the pins.

The diagnosis of a pin-tract infection is determined based on clinical aspects, such as, local inflammation, pain, presence of pus as described in Checketts and Otterburn's classification [8], and there is no test that exists to confirm the diagnosis.

In a study of 214 pins, Mahan et al [10] found bacteria colonization at the time of

removal in 74,8% and loss of steal in 22,9%. The most common bacteria were non-virulent *Staphylococcus Epidermidis* (90.6%), followed by virulent *Staphylococcus Aureus* (37.5%) and *Escherichia Coli* (9.4%). There were 40 loose pins whose pin tips had positive cultures.

For this reason, since the 1970's, many surgeons have tried using different methods to decrease pin-tract infections, such as using particular alloys of pins coated with antibiotics, zinc or titaniumoxide and silver particles [11]. However, none of these methods solve the problem.

When an external fixation is used, it is important to create an environment that decreases the risk of infections and their consequences. We have performed a retrospective study with two different groups of patients who implemented various protocols for pin-site care.

Material and Methods

In our study, we included 237 pins from 40 patients treated with external fixation for various types of fractures. The ages ranged from 19 to 71 years old (average 41.3). We excluded patients with mellitus diabetes, immune diseases and patients hospitalized in intensive care units for more than 4 days. All cases were treated with Hoffmann 2 external fixation and pins were inserted by hand pre-drilling together with continuous irrigation with cold saline solution.

Patients were divided into two groups of 20 patients each: the first group was medicated with povidone-iodine and the second one with sodium hypochlorite 0,05%.

These groups did not have significant statistical differences for age, site of fractures (humerus, wrist, tibia), the length of hospitalization, or the number of pins: 109 povidone-iodine (group A) and 128 sodium hypochlorite 0,05%. (group B).

Of all fractures, only 6 were exposed (tibia) while the others were all closed. Before treatment, the patients with exposed fractures were treated with specific antibiotic therapy: gentamicin 80 mg and teicoplanin 400 mg three times a day.

In all cases, fixators were applied aseptically in the operating room, and antiseptic-impregnated (povidone-iodine)

gauzes were applied around pins at the end of surgery.

Gauzes were removed after 48 hours post-surgery and the medications were performed daily until the fixator was removed.

All patients had a check-up every two weeks, noting the situation of pins and the possible presence of infections. We defined superficial infection as the presence of exudate or pus around the pin, which could be resolved with oral antibiotic therapy, while deep infection was defined as the presence of infection that was difficult to resolve with oral antibiotic therapy and associated with pin mobilization.

The follow-up was between 2 to 8 weeks because a few of the patients underwent removal of the frame at that time.

We have used the Ck Chan's scale [12] (Table 1) to evaluate the presence of infection.

Results

We observed an infection in 24 pins (22%) medicated with povidone-iodine and 13 pins (10,1%) medicated with sodium hypochlorite 0,05%. Analyzing the grade of infection in accordance with Ck Chan's scale, we observed: in group A, 18 pins with grade 1 and 6 pins with grade 2, while in group B, 10 pins with grade 1 and 3 with grade 2. (Figure 1-2-3) In the cases of grade 1 infections, we found a significant statistical difference with a $p < 0.05$ (Chi square's test); in grade 2 infections, however, we didn't find a significant statistical difference. We didn't observe any grade 3 infections.

GRADE	DESCRIPTION
0	No skin erythema and purulent discharge
1	Either skin erythema or purulent discharge
2	Both skin erythema and purulent discharge
3	Grade 2 plus radiological evidence of osteomyelitis

Table 1: Chan's classification



Figure 1: Grade 1 infection (skin erythema)

The sites of infection were: in group A, 16 infections of the tibia, 6 of the humerus and 2 of the wrist; in group B, 10 infections of the tibia and 3 of the humerus with non-significant statistical difference. We also observed pin mobilization: 13 in group A and 6 in group B with a

significant statistical difference ($p < 0.05$) (Table 2).

In all cases, infections were resolved with oral antibiotic therapy with Amoxicillin plus Clavulanic Acid 875mg+125mg: 1 tablet three times a day for 7 days.



Figure 2: Grade 1 infection with skin erythema and purulent discharge



Figure 3: Grade 0 (no skin erythema and purulent discharge)

Discussion

Pin-tract infection decreases the stability of the pin-bone interface with destabilization of the total external fixation [13] and for this reason all effort should be made to decrease the incidence of infection. At the same time, pin loosening is the first event to develop the infection. An unstable fixer, in fact, creates an unfavorable environment for bone consolidation with an increase of movements at the pin-bone interface, which facilitates irritation and pin-site infection [14].

Moroni et al.[14] report in their study that the use of uncoated pins causes the formation of fibrous tissue around the pin-bone interface which leads to pins loosening, and for this reason they advise the use of coated pins with hydroxyapatite. It is very important to introduce pins by hand pre-drilling together with continuous irrigation with cold saline to reduce the risk of thermal necrosis. The heat created when drilling the pins into the bone can generate thermal necrosis of the surrounding bone and eventual pin loosening [13].

Skin cutting and positioning of pins near

soft tissues are important because they help avoid skin tension and, consequently, the risk of infection [13-16].

In the literature, there is no universal protocol for pin-site management; many protocols are proposed, ranging from no active pin site care to twice daily cleaning and dressing plus oral antibiotics [17-18].

The decision of which day post-operation to begin pin-tract care varies widely in the literature with a variable range from 24 hours to 10 days [13-17-19]. According to the clinical practice guideline, pin-site care should be done daily or weekly after the first 48 to 72 hours [4]. The frequency of medications is variable, ranging from once a day, twice a day, once a week or to when it is necessary [17-20-21-22].

Some authors propose various cleaning solutions such as: soap and water, sterile water, saline, peroxide, isopropilicalcool, or clorexidine [6-13-20-22-23].

W-Dahl [23] compared patients treated with clorexidine and saline solution. He reported that patients medicated with clorexidine had fewer bacteria positive

	Povidone-iodine	Sodium Hypochlorite 0.05%		
	n	%	n	%
Pins cleaned	109	45.99	128	54.01
Pin tract infection	24	22	13	10.1
Pins mobilization	13	11.9	6	4.68
Ck Chan's scale				
Grade 1	18	16.5	10	7.81
Grade 2	6	5.5	2	2.34
Grade 3	/	/	/	/
Location of pin tract infection	16	4.6	10	7.81
Tibia	6	5.05	/	/
Wrist	2	1.83	3	2.34
Humerus				

Table 2: Data regarding the development of pin-based infection in patients

crops, less risk of *Staphylococcus Aureus* infection, and less use of oral antibiotics. Our study showed a significant statistical difference between the use of povidone-iodine and sodium hypochlorite 0,05%. Additionally, we didn't observe any case of skin hypersensitivity to the disinfectants.

The dressing pin care is controversial. Parameswaran [17] uses gauze-packing with one to two drops of antiseptic solution per pin with belzalconiochlorido. Rose [24] claims that only in the case of exudate is it necessary to surround pins with gauzes, however, if there isn't any pin infection, it should be left off. In our study, after pin medication, we applied dry gauzes together with the elevation of the inferior limb post-operation. This elevation reduced the swelling around pins and created a favorable environment for healing the pin track [13].

Another important aspect is to instruct patients to wash their hands and use a fresh swab for each pin, remove any crust, and then dry with a fresh swab. Additionally, patients are instructed to clean the length of each pin and wrap with loose gauze for about 5 days until the pin sites are dry. [4]

We recommend showering after 2 weeks, but the complete and accurate drying of the skin and of the external fixation is important. Bathing in the tub or in the swimming pool, however, is forbidden.

Conclusion

Currently, there is no universally accepted protocol of the best technique for medicating pins. Any and all strategies to reduce pin-tract infections are important, and it can begin in the operating room with a meticulous surgery technique to avoid skin tension around pins. Results of our study showed that medication with sodium hypochlorite 0,05% reduced the percentage of pin-tract infection and mobilization.

CONFLICT OF INTEREST STATEMENT:

For this clinical study none of the authors received direct or indirect financial contributions from Amuchina s.r.l. to use AMUKINA-MED® product. All authors must disclose any financial and personal

relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

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