RANDOMIZED PROSPECTIVE STUDY ON THE USE OF EUFISS IN THE PREVENTION OF INFECTIONS IN PATIENTS TREATED WITH EXTERNAL FIXATION

A. AMANTI, G. POTALIVO, F. PELOSI, R. RENDE and G. CERULLI

Orthopedic and Traumatology Residency Program, Department of Orthopedic Surgery and Traumatology, University of Perugia, Perugia, Italy

Received July 19, 2010 - Accepted October 8, 2010

Percutaneous synthesis using K-wires or external fixation in orthopedics and traumatology is extremely common. Postoperative management of external fixation includes frequent wound care which is demanding for both the patient and the healthcare professionals. In literature the most frequently reported complication is infection. The use of ionic silver goes back to the beginning of the last century and there are many articles describing its antimicrobial efficacy even for antibiotic-resistant bacteria. In this study we assess the reduction in both superficial and deep infections by using ionic silver in patients with external fixation for orthopedic diseases or traumatology. Furthermore, we show how this method could also contribute to reducing wound care costs. The data collected shows an overall infection incidence of 10%, concordant with data in literature. There appears to be no correlation between the probability of superficial infections and predisposing diseases, such as diabetes, nor the fracture site or position. The presence of loose pins increases the probability of infection. There appears to be no correlation between the clinical examination and the microbiological culture. The data analysis shows that wound care with ionic silver reduces the incidence of superficial infection of the pins. Furthermore, this method guarantees greater cleanliness of the skin and the external fixator which increases patient satisfaction in the management of the external fixation. To date, an insufficient number of patients have been studied to gather enough data to establish which wound care method is the most economical. Certainly, we can state that treatment with ionic silver reduces infection incidence and enables better management of the external fixators and percutaneous synthesis in orthopedics and traumatology.

External fixation for percutaneous synthesis in orthopaedics and traumatology is often resorted to (1-4). Unfortunately, the management of this treatment of synthesis is extremely demanding both for the patient and for the health carers. Furthermore, external fixation is accompanied by a high incidence of complications, the most frequent of which are percutaneous infections (5-7). Published data report the frequency of infections caused by external fixation which varies from 2 to 30%, with a predominance for superficial infections as opposed to deep ones (8-10). The most frequently isolated bacteria are *Staphylococcus epidermidis*, *Staphylococcus aureus* and *Escherichia coli* (11-14).

Post-op management of percutaneous fixation includes frequent dressings. These procedures can be performed at various intervals and with

Key words: ionic silver, infection prevention, external fixation management, percutaneous synthesis management

Mailing address: G. Cerulli, MD
Orthopedic and Traumatology Residency Program,
University of Perugia,
Via G.B. Pontani 9,
06127 Perugia, Italy
Tel: ++39 075 5058485 Fax: ++39 075 5010921
e-mail: g_cerulli@tin.it

0393-974X (2010)

different medicinal substances - Chlorhexidine and iodine-based compounds are undoubtedly the most commonly used (3-4, 15).

In the treatment of superficial and deep bacterial infections an important role is played by metal ions, in particular silver ions, although recently the antimicrobial activity even of zinc-based compounds and gallium compositions has been demonstrated, while lithium has been shown to have antiviral properties (16-19).

The use of ionic silver as an antiseptic dates back to the early 900's and numerous studies have been published confirming its effective antimicrobial action even in antibiotic-resistant microbial populations (9, 11, 13). This property makes it particularly suitable for the treatment of subjects suffering from specific diseases of the immune system (20-21). Generally, "silver exhibits low toxicity in the human body, and minimal risk is expected due to clinical exposure," when silver or silver compounds are used in the treatment of external infections or in medical appliances, however some authors have described a possible skin complication, argyria, due to the cutaneous accumulation of silver (22-23). In orthopedics, silver has been used as a coating for devices employed in percutaneous synthesis with conflicting opinions from the different authors (4).

The aim of this study is to verify the decrease in the incidence of superficial and deep infections using ionic silver band aids in patients treated with percutaneous fixation in orthopedic and trauma diseases. Furthermore, we wanted to verify whether using these dressings would lead to a decrease in management costs of these diseases.

MATERIALS AND METHODS

Forty patients treated percutaneously with external fixation for open and closed fractures were included in the study. Patients with systemic or local infections at the time of the procedure were excluded. Subjects suffering from diseases which may favor infections (diabetes, immunosuppression or in therapy with corticosteroids) were included in the study in a well-defined subgroup.

The patients were randomized in the progressive order they were admitted to the Perugia University Orthopaedic and Trauma Clinic and divided into two groups. The subjects in Group A were treated with the ionic silver band-aids and the dressings were applied according to the manufacturer's instructions at time 0 and then every 7 days until fixation was removed. Patients in Group B were treated with dressings using antiseptics with an iodine base at time 0 and then every 7 days until fixation removal.

All subjects underwent clinical and microbiological evaluations. Clinical evaluation, examination of the skin, was performed weekly in order to observe any signs of infection such as erythema, swelling or secretions. These signs and symptoms were noted down and graded according to the Checketts-Otterburn classification. Grade I-III were considered minor infections while grade IV-VI were considered major infections. Furthermore, we assessed the motility of the fixation, its sensitivity to pain and the presence of secretions.

Microbiological evaluation was performed by swab samples of the skin next to the fixation device at week I, VI, X and at fixation removal.

RESULTS

Twenty patients were included in Group A, 18 males and 2 females, average age 35.3 years (16-58 years). None of the patients included had immunosuppression or was in therapy with corticosteroids; 2 patients had diabetes mellitus.

Thirteen open fractures, 10 of which were punctiform, and 7 closed fractures were treated. Eight fractures of the upper limb were included in this group: 5 wrist and hand fractures and 3 humerus fractures. There were 12 fractures of the lower limb: 2 femur fractures, 8 leg fractures and 2 foot fractures. The average implantation time of the pins

Table I. *Data on patients.*

	Patients	Pins	Average implant time (days)	Clinically evident infections	Positive cultures
Group A	20	85	42.4 (28-90)	1	15%
Group B	20	93	45.8 (30-85)	3	25%

was 42.4 days (28-90 days). Eighty-five pins were put into place, 2 of which were mobile and painful so were removed before the end of treatment.

Only one case of infection was observed (equivalent to 5%), and according to the Checketts-Otterburn classification it was a grade I infection. No grade II-VI infection was observed. 85% of the microbiological cultures were negative for pathogens (Table I). The isolated bacteria were coagulase-negative *Staphylococcus* (10%) and *Corynebacterium* (5%). The patient with an infection was treated with the specific antibiotic according to the antibiogram and recovered completely. Twenty patients were included in Group B, 16 males and 4 females, average age 28.8 years (12-72 years). No patient was immunosuppressed or in therapy with corticosteroids, 1 patient suffered diabetes mellitus.

Fifteen open fractures, of which 12 were punctiform, and 5 closed fractures were treated. Six fractures of the upper limb were included in this group: 4 wrist and hand fractures, 2 fractures of the humerus bone. There were 14 lower limb fractures: 2 femur fractures, 9 leg fractures and 3 foot fractures.

Average pin implantation time was 45.8 days (30-85 days). Ninety-three pins were placed, 4 of which were mobile and painful so were removed before the end of treatment.

Three cases of infection were observed at clinical examination, 2 of which were considered Grade II according to the Checketts-Otterburns classification and one patient had a Grade IV infection. 75% of the microbiological cultures were negative for pathogens (Table I).

The isolated bacteria were 15% coagulase-negative *Staphylococcus*, 7% *Corynebacterium* and 3% *Staphylococcus Aureus*.

All patients received the specific antibiotic treatment according to the antibiogram and they all recovered completely from the infection.

DISCUSSION

The management of trauma patients with external fixation is very demanding for both the patients and the healthcare personnel as this method needs continuous dressing and there is a continued risk of complications, in particular superficial infections. The overall frequency of infection in our study was 10%, confirming published data.

Based on the data collected, it was observed that there was no correlation between the probability of superficial infection and the presence of predisposing diseases such as diabetes. There is no correlation between the location of the fracture, its being open and the probability of developing a superficial infection. Undoubtedly, mobile pins increase the risk of developing superficial infections. We also observed that there is no correlation between the clinical evaluation of the infection and the culture results, indeed cultures may be positive even in totally asymptomatic patients.

From the data collected we conclude that the use of ionic silver dressings reduces the incidence of pin track infection. This approach furthermore guarantees greater cleanliness of the skin and the external fixation which in turn promotes greater patient compliance in the management of the fixation system and a greater degree of satisfaction.

Finally, it appears that, despite the limited number of cases, treatment with ionic silver keeps down the costs considering the material used, the dressing times and the pharmacological treatment.

REFERENCES

1. Checketts RG, Otterburn M, MacEachern AG. Pin track infection; definition, incidence and prevention. Int J Orthop Trauma 1993; 3(S):16-8.
2. Gordon JE, Kelly-Hahn J, Carpenter CJ, Schoenecker PL.Pin site care during external fixation in children: results of a nihilistic approach. J Pediatr Orthop 2000; 20:163-5.
3. Lethaby A, Temple J, Santy J. Pin site care for preventing infections associated with external bone fixators and pins. Cochrane Database Syst Rev 2008; 8:CD004551.
4. Coester LM, Nepola JV, Allen J, Marsh JL. The effects of silver coated external fixation pins. Iowa Orthop J 2006; 26:48-53.
5. Checketts RG, Moran CG, MacEachern AG, Otterburn M. Pin track infection and the principles of pin site care. In: Orthofix external fixation in trauma and orthopaedics. Springer-Verlag, London Berlin Heidelberg 1999; 11:97-103.
6. Mahan J, Seligson D, Henry SL, Hynes P, Dobbins J.

Factors in pin tract infections. Orthopedics 1991; 14: 305-8.
7. McKenzie LL. In search of a standard for pin site care. Orthop Nurs 1999; 18:73-8.
8. Meléndez EM, Colón C. Treatment of open tibial fractures with the Orthofix fixator. Clin Orthop 1989; 241:224-30.
9. Olson RS. Halo skeletal traction pin site care: toward developing a standard of care. Rehabil Nurs 1996; 21:243-6.
10. Paley D, Jackson RW. Surgical scrub sponges as part of the traction apparatus: an alternative to pin site care to reduce pin track infections. Injury 1985; 16:605-6.
11. Moroni A, Aspenberg P, Toksvig-Larsen S, Falzarano G, Giannini S. Enhanced fixation with hydroxyapatitecoated pins. Clin Orthop 1998; 346: 171-7.
12. Moroni A, Heikkila J, Magyar G, Toksvig-Larsen S, Giannini S. Fixation strength and pin tract infection of hydroxyapatite-coated tapered pins. Clin Orthop 2001; 388:209-17.
13. Sims M, Saleh M. Protocols for the care of external fixator pin sites. Prof Nurse 1996; 11:261-4.
14. Sims M, Saleh M. External fixation–the incidence of pin site infection: a prospective audit. J Orthop Nursing 2000; 4:59-63.
15. D'Ercole S, Tetè S, Catamo G, Sammartino G, Femminella B, Tripodi D, Spoto G, Paolantonio M. Microbiological and biochemical effectiveness of an antiseptic gel on the bacterial contamination of the inner space of dental implants: a 3-month human longitudinal study. Int J Immunopathol Pharmacol 2009; 22:1019-26.
16. Marchisio P, Esposito S, Bianchini S, Desantis C, Galeone C, Nazzari E, Pignataro L, Principi N. Effectiveness of a propolis and zinc solution in preventing acute otitis media in children with a history of recurrent acute otitis media. Int J Immunopathol Pharmacol 2010; 23:567-75.
17. DeLeon K, Balldin F, Watters C, Hamood A, Griswold J, Sreedharan S, Rumbaugh KP. Gallium maltolate treatment eradicates Pseudomonas aeruginosa infection in thermally injured mice. Antimicrob Agents Chemother 2009; 53:1331-7.
18. Jones N, Ray B, Ranjit KT, Manna AC. Antibacterial activity of ZnO nanoparticle suspensions on a broad spectrum of microorganisms FEMS Microbiol Lett 2008; 279:71-6.
19. Rybakowski JK. Antiviral and immunomodulatory effect of lithium. Pharmacopsychiatry 2000; 33:159-64.
20. Driver VR. Silver dressings in clinical practice. Ostomy Wound Manage 2004; 50:11-5.
21. Ferrara G, Losi M, D'Amico R, et al. Interferon-gamma-release assays detect recent tuberculosis re-infection in elderly contacts. Int J Immunopathol Pharmacol. 2009; 22:669-77.
22. Robert O. Becker Silver ions in the treatment of local infections Metal-Based Drugs 1999; 6:4-5.
23. Lansdown AB. Silver in health care: antimicrobial effects and safety in use. Current Problems in Dermatology 2006; 33:17-34.