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ORIGINAL PAPER

Remission rate of implant-related infections following revision surgery after fractures

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Abstract
Purpose In contrast to a large amount of epidemiological data regarding the incidence of implant infections after fracture management, surprisingly few have been published concerning the success of their treatment.
Methods This was a single-centre cohort study at Geneva University Hospitals from 2000 to 2012 investigating the remission rates of orthopaedic implant infections after fracture repair and associated variables.
Results A total of 139 episodes were included: There were 51 women (37 %) and 28 immunosuppressed (20 %) patients with a median age and American Society of Anaesthesiologists (ASA) score of 51 years and 2 points, respectively. The infected implants were plates ($n=75$, 54 %), nails (24, 17 %), wires (20), screws (10), cerclage cables or wires (3), hip screws (4) or material for spondylodesis (3). A pathogen was identified in 135 (97 %) cases, including *Staphylococcus aureus* (73, 52 %), coagulase-negative staphylococci (20), streptococci (7) and 19 Gram-negative rods. All patients underwent antibiotic treatment, and 128 (92 %) remained in remission at a median follow-up time of 2.6 years (range one to 13 years). In multivariate logistic regression analysis, the plate infections were significantly associated with lower remission rates [65/75, 87 %, odds ratio (OR) 0.1, 95 % confidence interval (CI) 0.01–0.90]. No associations were found for gender, age, immune status, ASA score, additional surgical interventions (OR 0.4, 95 % CI 0.1–4.1) or duration of antibiotic treatment (OR 1.0, 95 % CI 0.98–1.01).
Conclusions Among all infected and removed orthopaedic implants, plates were associated with slightly lower remission rates, while the overall treatment success exceeded 90 %. The duration of antibiotic therapy did not alter the outcome.

Keywords Implant-related infection · Implant removal · Antibiotic therapy · Remission rate · Post-traumatic osteomyelitis

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Introduction

There is a large amount of epidemiological data regarding the incidence (approximately 1–5 %) [1] of orthopaedic implant infections after fracture repair. In contrast, surprisingly little has been published concerning the success of their treatment [1]. Expert recommendations pertain to other osteoarticular infections and advocate at least one surgical drainage, implant removal if feasible and concomitant antibiotic therapy until osseous consolidation or for six weeks post implant removal [2–4]. This is the case even though implant-associated infections are conceptually different from other orthopaedic infections. They usually lack the ongoing presence of an implant (usually removed and which hampered infection cure [1, 2]), and they usually do not have sequestra, the hallmark of chronic osteomyelitis.

In the literature the duration of antimicrobial administration after implant removal, and the variables associated with remission, have been investigated thus far for arthroplasty-associated infections [5–7], but less for chronic osteomyelitis cases [3, 8], and even less for fracture device-associated infections, the latter often with fewer than 30 episodes included per publication [9–13]. Theoretically, complete implant removal is the essential part of treatment, and therefore a relatively short period of antibiotic administration might be sufficient for sterilisation of superficial bone layers adjacent to the implant. In this single-centre cohort study, we investigated remission rates of orthopaedic implant infections after fracture management and associated variables, with an emphasis on the duration and form of antibiotic treatment. We think that antibiotic therapy concomitant with surgery might be significantly reduced to some few weeks in an oral form. We did not address risk factors for infection occurring after primary osteosynthesis [4] or the incidence of infections after elective implant removal for mechanical reasons.

Patients and methods

Setting and data collection

The Orthopaedic Department of Geneva University Hospitals has 132 acute care beds (24 on the Septic Ward). Several dedicated infectious diseases (ID) consultants (since the year 2000) have established a number of databases regarding orthopaedic infections as approved by our local hospital Ethics Committee. Usually, infected fracture devices are treated with a combined medical and surgical approach with little variation at the discretion of the treating surgeon and physician. If bone is consolidated, all infected fracture devices are removed completely. In cases of non-consolidated bone, transient external fixation is applied. Debridement involves thorough removal of all infected tissue, including bone layers, to the maximum extent possible. After nail removal, the intramedullary cavity undergoes thorough reaming. The decision for surgical re-intervention for the initial treatment depends on clinical parameters and the surgeon's individual opinion. Normally, a second look is routinely performed. After surgery, infected patients are followed up actively by the corresponding surgeon and the ID physician for at least one year. Given that Geneva University Hospitals are the only public hospital in the area, many patients return for various reasons later in their lifetime and are reassessed for all former diseases by physicians or surgeons of the hospital (e.g. infection active or not). Thus, the follow-up time for this study involves an active evaluation by a surgeon or physician, who however does not need to be the same person in charge during infection.

Patients

A total of 139 episodes of implant-related infections were available for further analysis with a median hospital length of stay of 18 days (range four to 139 days). A minority of patients were women (51, 37 %) or immunosuppressed (28, 20 %), the latter mostly secondary to diabetes mellitus, Child's class C cirrhosis, dialysis or active cancer or immunosuppressive therapy. The median age and American Society of Anaesthesiologists (ASA) scores were 51 years (range 17–93 years) and 2 points (range 1–4 points), respectively. The median time delay between initial implant insertion and the first clinical signs of infection was five months (range 0–240 months).

The infected implants involved plates ($n=75$, 54 %), nails ($n=24$, 17 %), wires (20), screws (10), cerclage cables or wires (3), hip screws (4) or material for spondylodesis (3). Twelve plates revealed one additional material such as screws or wires. No hardware was embedded in antiseptics, antimicrobials or silver. The implants were localised at different sites, including lower extremity ($n=115$), upper extremity (15), spine (4), pelvis (3), and clavicle (2). A pathogen was identified in 135 (97 %) cases. *Staphylococcus aureus* was the most frequent organism ($n=73$, 52 %, of which 15 were resistant to methicillin), followed by coagulase-negative staphylococci (20), streptococci (7) and 19 Gram-negative rods, of which seven were *Pseudomonas aeruginosa*. Polymicrobial infection occurred in 24 episodes (17 %).

Study questions

We investigated two study questions: (1) the incidence of subsequent osteomyelitis after treatment of an infected implant and (2) the variables associated with treatment success or failure. We collected 48 variables per episode on an Excel™ spreadsheet. All osteomyelitis databases were cross-referenced with the Hospital's Coding Office files for patient identification. All eligible patients with non-arthroplasty-associated orthopaedic implant infections from January 2000 to December 2012 were included. The diagnosis of infection was based upon the presence of intraoperative pus, together with clinical signs of infection (new onset of pain, fever, discharge and/or radiographic signs of implant loosening). The identification of the infecting organism required that the same pathogen be present in at least two intraoperative samples. Remission was defined as the absence of any clinical, laboratory or radiological signs of recurrence after a minimum follow-up of one year. Only the first episode of the same infection was included and recurrent episodes were eliminated from further analysis. Other exclusion criteria were as follows: insufficient data, orthopaedic patients with prosthetic joint infections or non-orthopaedic implant infections such as vascular implants or pacemakers [14], chronic osteomyelitis cases marked by sequestrum or

involucrum, absence of surgical debridement in the operating room (e.g, very ill patients or superficial implant removal on the ward), amputation for cure or an insufficient follow-up. The latter was defined as follow-up in another hospital or for less than one year after treatment. Moreover, we excluded patients with septic non-unions, those requiring major soft tissue coverage and patients requiring external fixation after internal implant removal.

Statistical analyses

Group comparisons were performed using Pearson's χ^2, Fisher's exact or the Wilcoxon rank sum tests, as appropriate. An unmatched logistic regression analysis determined associations with the outcome "remission". Independent variables with a p value ≤0.30 in univariate analysis were introduced stepwise in the multivariate analysis, while surgical and antibiotic-related variables were included in every case. We included five to ten outcome events per predictor variable [15]. Key variables were checked for confounding, colinearity and interaction, the latter by Mantel-Haenszel estimates and interaction terms. Age, duration of antibiotic administration and time delay between initial implant insertion and subsequent infection were analysed as continuous and categorised variables; p values ≤0.05 (all two-tailed) were significant. Stata™ software (version 9.0, StataCorp, College Station, TX, USA) was used.

Results

Therapy and remissions

All episodes underwent combined surgical and antibiotic treatment, and 128 remained in remission (92 %) after a median follow-up time of 2.6 years (range one to 13 years) (Table 1). The 11 recurrences occurred at the same site with the same pathogen between six weeks and three years after the first treatment. There were no arthrodeses, amputations or partial implant removals performed. Thus, if an implant was removed, it was complete. The majority of episodes had two interventions (second look in 114 cases, 82 %), and only a minority had a single surgical intervention (25 cases). None had three or more interventions. Among all infected materials, 20 were left in place: 11 plates, seven nails, one dynamic hip screw and one screw. Retrospectively, there were no differences in the proportion of material types and the decision for implant removal or retention, with one potential exception: The subgroup "screw, cerclage and wire" witnessed a tendency to more removal [odds ratio (OR) 0.16, 95 % confidence interval (CI) 0.1–1.1] but was not statistically significant (29/130 vs 1/20; Fisher's exact test, $p=0.07$), whereas the number of surgical interventions for this group was the same compared to other larger implants (26/144 vs 4/25; Fisher's exact test, $p=0.60$).

Antibiotic therapy varied considerably. We noted 72 different regimens with a median duration of total and parenteral antibiotic administration of 42 and four days, respectively. Episodes with or without implant removal had a similar duration of total antibiotic therapy (Wilcoxon rank sum test, median 42 vs 53 days, $p=0.27$) as were patients with or without a second look (Wilcoxon rank sum test, median 42 vs 42 days, $p=0.58$).

Group comparison and univariate analysis

The groups of patients with and without remission did not differ significantly (Table 1), with the exception of pseudomonal infections and plates. In univariate analysis targeting the outcome "remission", plate infection yielded a lower remission rate compared to all other implants (OR 0.1, 95 % CI 0.01–0.82, $p=0.03$). Of note, plate-associated infections showed no interaction (effect modification) when stratified according to staphylococcal, pseudomonal or tibial infections. Likewise, plate-related infections failed to show another outcome when stratified upon retention or retention vs removal cases (Mantel-Haenszel estimates, all $p>0.45$).

Multivariate adjustment

Due to differences in crude group comparisons (Table 1), a multivariate logistic regression analysis adjusted for case mix (Table 2). The only significantly associated variables remaining were once again plate infection (OR 0.1, 95 % CI 0.01–0.90) and pseudomonal infection (OR 0.1, 95 % CI 0.01–0.81) (Table 2). No associations were found for gender, age, immune status, ASA score, additional surgical interventions or modalities concerning antibiotic therapy. Compared to 42 days or less of total post-operative antibiotic administration, 43–63 days or over 63 days were equivalent in terms of remission. Likewise, the duration of the initial parenteral administration route did not alter the outcome (Table 2). Of note, the goodness-of-fit test was insignificant ($p=0.168$) and the receiver-operating characteristic (ROC) curve value was 0.86 (95 % CI 0.74–0.98), highlighting a more than acceptable performance of our final model.

Discussion

In our case–control study, remission rates of combined surgical and medical treatment of established implant infections after fracture management (128/139, 92 %) were significantly higher than for the treatment of chronic osteomyelitis [7] or arthroplasties [9, 10], with remission rates ranging between 75 and 90 % in the literature [4]. Our remission rate is also higher than the 73 % published regarding young healthy individuals with ankle fractures [14] or the 72 % among 25 early

Table 1 Group comparison with treatment failure and success of infected orthopaedic implants after fracture (non-arthroplasty)

$n=139$	Failure $n=11$	Comparison p value[a]	Remission $n=128$
Female gender	5 (45 %)		46 (36 %)
Age group≤40 years	5 (45 %)		45 (35 %)
Age group 41–62 years	2 (18 %)		40 (31 %)
Age group>63 years	4 (36 %)		43 (34 %)
Immunosuppression[b]	2 (18 %)		26 (20 %)
Plate-related infection	10 (91 %)	0.010	65 (51 %)
Nail-related infection	1 (9 %)		23 (18 %)
Screw, cerclage and wire	0 (0 %)		30 (23 %)
Implant on lower extremity	10 (91 %)		101 (80 %)
Tibial implant infection	5 (45 %)		64 (50 %)
Implant on upper extremity	1 (9 %)		13 (10 %)
Due to *S. aureus*	4 (36 %)		69 (54 %)
Due to *P aeruginosa*	2 (18 %)	0.038	5 (4 %)
Second surgical look	9 (82 %)		105 (82 %)
Implant retention (vs removal)	3 (27 %)		17 (13 %)
Total antibiotic therapy<6 weeks	3 (27 %)		75 (59 %)
Total antibiotic therapy 6–9 weeks	2 (18 %)		8 (6 %)
Total antibiotic therapy>9 weeks	6 (55 %)		45 (35 %)
Parenteral antibiotic therapy≤4 days	5 (45 %)		57 (45 %)
Parenteral antibiotic therapy>4 days	6 (55 %)		71 (55 %)

[a] Only p values ≤0.05 (two-tailed) are displayed, χ^2 or Fisher's exact test

[b] Diabetes mellitus, immunosuppressive therapy, dialysis, Child's class C cirrhosis, active cancer

staphylococcal infections following rigid internal fixation [9]. We cannot explain the exact reasons for the difference inasmuch as the duration of our antibiotic treatment was much shorter, while the distribution of the pathogens, the duration of follow-up and surgical approach were shared with other authors [5, 16]. It may be that our study population had a higher proportion of screws and wires. Screws and wires tended to be more easily removed than other implants with potentially higher remission rates, but the number of surgical debridements was equal when compared to larger implants.

In both univariate and multivariate analyses, plate-related and pseudomonal infections were formally associated with a worse outcome [17]. However, our finding has to be interpreted with caution. Two recurrences among seven infections are a very small base for proving the difficult treatment for *P. aeruginosa*. At best, this is only giving a little hint that the experiences about the difficulties of treatment are supported. Theoretically, the Gram-negative rod *P. aeruginosa* is known to be particularly difficult to eradicate from osteoarticular and prosthetic joint tissue due to its extended biofilm-producing capacities, its natural resistance to a variety of antimicrobial agents and development of rapid resistance even during ongoing therapy. In the literature, osteoarticular infections due to *P. aeruginosa* regularly yield higher failure rates as compared to Gram-positive microorganisms, even if the difference is not always statistically significant [18–20].

In contrast, plate-associated infections revealed more robust statistical evidence to be associated with lower remission rates, for which the exact reason remains unknown. In our study, plates accounted for the largest part of infected fracture implants and were not particularly associated with pseudomonal or staphylococcal infections or those due to other germs. We equally were unable to find a link with a particular localisation site, such as ankle or distal tibia [21]. To the best of our knowledge, this finding has not been investigated in the literature. Indeed, when it comes to the evaluation of treatment success most publications regarding implant infections after fracture management have only looked for risk factors for infection or provided results for all implant material without distinction. Theoretically, one might predict that nails with an internal surface infected inside the bone would be associated with more treatment failures. On the other hand, there exists a well-known procedure for nails to minimise recurrence of infection: medullary reaming. For plates there is no such safe procedure known. They could be the real reason for the difference. Moreover, plates are removed without "reaming" of adjacent bone surface, and removal involves more soft tissue damage, a point which has already been mentioned [21]. Perhaps the extent of the soft tissue damage and wound healing problems might explain our findings.

All other variables were not significantly associated with recurrent infection. Age, immunosuppression, ASA score, staphylococcal infection or time delay from the time of insertion of the hardware did not play a role. Of note, supplementary surgical debridements and the duration and route of concomitant antibiotic therapy equally failed to alter the

Table 2 Associations with continuous remission after 1 year

	Number	Univariate analysis	Multivariate analysis
Female gender	$n=51$	0.7 (0.2–2.3)	0.6 (0.1–2.9)
Age (continuous variable)		1.0 (0.98–1.04)	1.0 (0.96–1.06)
Age≤40 years	$n=50$	1	n.a.
Age 40–63 years	$n=42$	2.2 (0.4–12.1)	n.a.
Age >63 years	$n=47$	1.2 (0.3–4.7)	n.a.
Immunosuppression[a]	$n=28$	1.1 (0.2–5.6)	0.9 (0.1–6.9)
ASA score[b]		1.2 (0.5–2.7)	0.9 (0.2–2.8)
Delay implantation-infection		1.0 (0.98–1.06)	1.0 (0.97–1.09)
≤ 5 months	$n=71$	1	1
> 5 months	$n=68$	0.5 (0.1–1.9)	0.5 (0.1–2.5)
Infection due to *S. aureus*	$n=73$	2.0 (0.6–7.3)	n.a.
Coagulase-negative staphylococci	$n=20$	1.7 (0.2–14.4)	n.a.
Pseudomonas spp.	$n=7$	0.2 (0.03–1.07)	**0.1 (0.01–0.81)**
Tibial implants	$n=69$	1.2 (0.3–4.1)	n.a
Upper extremity implants	$n=15$	1.1 (0.1–9.6)	n.a
Plates	$n=75$	**0.1 (0.01–0.82)**	**0.1 (0.01–0.90)**
Nails	$n=24$	2.2 (0.3–18.0)	n.a.
Total antibiotic therapy (continuous variable)		1.0 (0.98–1.01)	1.0 (0.98–1.01)
≤42 days	$n=78$	1	1
43–63 days	$n=10$	0.2 (0.1–1.1)	0.1 (0.1–2.5)
> 63 days	$n=51$	0.3 (0.1–1.3)	0.2 (0.1–1.1)
Parenteral therapy (continuous variable)		1.0 (0.97–1.04)	1.0 (0.96–1.06)
≤4 days	$n=62$	1	1
> 4 days	$n=77$	1.0 (0.3–3.6)	0.9 (0.2–4.1)
Implant retained[c]	$n=20$	2.4 (0.6–10.1)	4.6 (0.5–45.0)
Second look[d]	$n=114$	1.0 (0.2–5.0)	0.8 (0.1–4.1)

Results are displayed as OR (95 % CI). Variables in boldface are statistically significant (two-tailed p value <0.05)

[a] Diabetes mellitus, immunosuppressive therapy, dialysis, Child's class C cirrhosis, active cancer

[b] ASA score, continuous variable

[c] Implant not removed, only debridement

[d] Second look or debridement

outcome. Compared to 42 days or less of post-operative antibiotic administration, 43–63 days or more than 63 days were equivalent in terms of preventing subsequent osteomyelitis. These findings are not surprising. The adequate administration route and the duration of antibiotic agents in implant infections are not based on randomised trials or other forms of evidence. They rely on expert opinion with some indirect information from past animal studies or in vitro experiments [3, 4]. Traditionally, a six- to 12-week course of antibiotic therapy is recommended [5, 9, 10, 13, 16], of which the first two to four weeks are usually given intravenously [1, 11]. This general recommendation has been continuously challenged in recent years in favour of shorter antibiotic administration time with decreased parenteral regimen [7, 10, 11]. One further result of interest was the influence of implant retention on remission rates. In our study lack of implant removal did not significantly influence remission at a one-year follow-up. There is a debate in the literature whether infected implants after fracture management should always be removed. Although most experts would advocate their removal, others report up to 70 % success with the hardware in place when bone union was achieved [16, 18].

In conclusion, our retrospective study revealed that plates (and maybe *P. aeruginosa*) were associated with lower remission rates in orthopaedic implant infections after fracture repair. Both variables are difficult to influence since *P. aeruginosa* escapes the majority of perioperative antibiotic agents [8] and the choice of plates cannot always be replaced by other implants in daily practice. Even with these two variables our treatment success already exceeded 90 % in the first instance, almost independently of whether the implant was removed or retained. It might be that implant-related infections differ from chronic osteomyelitis or infected artificial joint replacements inasmuch as bacteria usually lie beneath the foreign body without additional bone alterations in terms of sequestra, fistula or involucrum [3]. Therefore, the removal of the infected foreign body and adjacent bone layers [1] may usually be sufficient for remission. Concomitant antibiotic therapy might require shorter courses than generally recommended for all osteoarticular infections. These presumptions need confirmation in other trials.

Our study has the following limitations: (1) It only includes adults and comes from a single institution in a high-income country, aspects that might limit extrapolation of its findings. (2) Although many variables have been accounted for, others remain unanalysed, such as smoking status [17,

21], serum albumin values [10, 16], hypothyroidism [12], arteriosclerosis [12] and co-morbidity indexes [16] other than the ASA score. (3) The indication for implant removal was influenced by the surgeon and the previous complaints of the patients. While implant removal upon infection in consolidated bone does not provoke much discussion, implant removal without infection or wound dehiscence remains controversial in the current literature [19, 21]. Hence, for the first part of our study the low incidence of post-removal osteomyelitis might be biased by young and healthy trauma patients. They harbour fewer risks for surgical site infections [4] than elderly patients with co-morbidities who are not undergoing implant removal if they are not obliged to do so. (4) Follow-ups may have been missed in patients who were treated elsewhere after their initial surgery. However, given that the Geneva University Hospital is the largest and only public hospital in the area we consider this selection bias to be minimal. (5) The minimum follow-up time was one year. In the current literature on arthroplasty infection, this delay has been arbitrarily set at one to two years [10]. In contrast, classic chronic osteomyelitis can recur after 40 years [22] and a consensus is more difficult to establish. Therefore, the required minimum follow-up time remains unknown for cases of osteomyelitis without implants, let alone for implant-induced osteomyelitis after the removal of all of the foreign material, as in our study. The existing literature in this area yields follow-up times of less than 12 months [10]. (6) We excluded patients with septic non-unions, such as those requiring external fixation after the removal of the internal implant. These patients may form a substantial part of all implant-related infections, for which the surgical approach is complex and highly individualised [11]. (7) It is possible that patients who appeared less ill clinically, regardless of co-morbidities, received a shorter course of antibiotic therapy. Our cohort study cannot compete with randomised trials when it comes to upgrading of evidence. We emphasise that our study was purely epidemiological and not interventional. This potential bias reinforces the need for randomised studies.

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Conflict of interest The authors declare that they have no conflict of interest.

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