Foot and Ankle Surgery 23 (2017) 50–52

Contents lists available at ScienceDirect

Foot and Ankle Surgery

journal homepage: www.elsevier.com/locate/fas

Role of prophylactic antibiotics in lesser toe fusion surgery: A prospective randomised controlled trial

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ARTICLE INFO

Article history:
Received 25 November 2015
Received in revised form 10 January 2016
Accepted 4 February 2016

Keywords:
K-wires
Infection
Antibiotics

ABSTRACT

Background: This prospective randomised controlled trial was performed to determine whether the incidence of local infection is reduced in patients who are administered prophylactic antibiotics for lesser toe fusion surgery.
Methods: 100 adult patients undergoing toe fusion surgery that required K-wires to be left *in situ* for 4–6 weeks were randomly allocated into those who received prophylactic antibiotics (Group 1, $n = 48$) and those who did not (Group 2, $n = 52$). Patients were followed up regularly and during each visit K-wire insertion sites were assessed for signs of pin tract infection.
Results: The mean age of Group 1 was 58.0 (SD 17.5) and Group 2 was 62.7 years (SD 14.7). The overall infection rate was 4%. Three patients (6.2%) in Group 1 and one patient (1.9%) in Group 2 developed signs of infection, which required treatment by oral antibiotics. All infections were low grade. There were no features suggestive of osteomyelitis in any of the patients.
Conclusion: The overall infection rate in lesser toe fusion surgery is low and that using prophylactic antibiotics does not reduce the incidence. Inappropriate use of antibiotics, however, may contribute to the development of antibiotic resistance and adds to healthcare costs.

1. Introduction

Prophylactic antibiotics are used routinely in many orthopaedic procedures and have been shown to lower the risk of infection [1]. In particular, prophylactic parenteral antibiotics have greatly contributed to the present low rate of surgical site infections in arthroplasty surgery [2]. This practice has been extended, but is variably applied, to commonly performed percutaneous procedures that require K-wire fixation.

The risk of infection from percutaneous K-wires has been reported as between 0.3% and 34.4% [3–6]. Prophylactic antibiotics are not uniformly administered in percutaneous K-wire surgery within the United Kingdom (UK). Indeed a recent survey of practicing British orthopaedic surgeons revealed that 50% would always use prophylactic antibiotics while carrying out percutaneous K-wires. In contrast, 27% would never use them and 23% would use them only in special circumstances. The number of doses of prophylactic antibiotics prescribed was further subject to inconsistency [7]. There are no clear guidelines on their usage [8,9]. This survey, however, included a mix of responses from all grades of orthopaedic surgeons encompassing all primary orthopaedic subspecialties and not just those performing toe surgery.

Trying to prevent surgical site infection is clearly advantageous, however the unnecessary use of prophylactic antibiotics carries risks to both the individual and society. The use of broad-spectrum antibiotics has contributed to the rise in multi-drug resistant bacteria. Infections from these organisms are associated with worse clinical outcomes for the patient [2,10]. Their use may predispose the patient to further infections and place them at risk of adverse reactions. Furthermore, it is intuitive that stopping unnecessary use of antibiotics will also reduce healthcare costs.

2. Aim of the study

The aim of this study was to determine whether the incidence of local infection is reduced in patients who are administered

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http://dx.doi.org/10.1016/j.fas.2016.02.004
1268-7731/

prophylactic antibiotics for lesser toe fusion surgery performed using K-wires. The null hypothesis was that the pin-site infection rate after insertion of percutaneous K-wire(s) is the same with or without the administration of prophylactic antibiotics.

3. Patients and methods

The patients were sourced from the Orthopaedic Department of the Great Western Hospital, Swindon. All adult patients undergoing toe fusion surgery that required K-wires to be left *in situ* for 4–6 weeks were invited to participate. Patients who were unable to understand the patient information leaflet and provide a valid consent were excluded. Patients were also be excluded if there was a proven high risk of infection e.g. patients with an open, contaminated wounds, poor local skin condition, immune-suppressed patients, and other known co-morbidities which increase the possibility of an infection. Only the patients undergoing isolated toe fusions were included and those requiring toe surgery as a part of other forefoot procedures were excluded.

The Regional Ethics Committee (REC) and Medicines and Healthcare Products Regulatory Agency (MHRA) approved the study. The patients were first approached by one of the medical members of the team who after explaining the study, handed over the patient information leaflet. If the patients decided to participate, they were asked to sign the informed consent form. A careful history of drug allergies was obtained.

100 adult patients were randomly allocated into those who received prophylactic antibiotics (Group 1, $n = 48$) and those who did not (Group 2, $n = 52$). Stratified randomisation technique was followed. For the patients who were randomised to receive antibiotics; the type, dosage and the timing of antibiotic used were not altered from the usual practice of the operating surgeon or were based on the hospital's antimicrobial guidelines. Fluoclox-acillin was the antibiotic of choice in all patients unless the patients had an allergy to penicillin, in which case Teicoplannin was used.

The usual antiseptic cleaning prior to surgery and the surgical technique were followed and the patients were discharged as per the standard protocol. Patients were followed up regularly as per the hospital practice which included a follow-up one week after the surgery and a final follow up when K-wires were be taken out.

During each visit, the pin tracts were thoroughly cleaned and the K-wire insertion sites were inspected by one of the medical members of the team. If the insertion site showed signs of infection, the infection was graded into one of the six grades as per the modified Oppenheim's classification [11]. If the wound appeared infected, wound swab was sent for microbiological analysis and blood samples were taken to test for the rise in inflammatory markers. Antibiotics were started in those patients who were not already on antibiotics. The patients were then regularly followed up until the K-wires had been removed and skin wounds had healed.

Statistical analysis was performed using SPSS for Windows (version 18, Chicago, IL, USA). A significant difference was indicated by a p-value < 0.05. The power of the study was taken as 80%.

4. Results

The demographics and other variables in the two groups are shown in Table 1.

There were 3 infections (6.2%) in Group 1 and one infection (1.9%) in Group 2, which required treatment by oral antibiotics. All infections were Grade 1 except for one patient in Group 1 who had Grade 2 infection. This was in a 66 years old lady with high body mass index (BMI), asthma and psoriatic arthritis requiring methotrexate. She had bilateral second proximal interphalangeal joint fusion and received teicoplanin during anaesthetic induction. At four weeks from surgery, she presented with a swollen and erythematous second toe. The K-wire was removed and she was prescribed one-week course of oral antibiotics. Although the infection resolved, she had non-union and revision fusion was performed once the infection settled down. There were no features suggestive of osteomyelitis in any of the patients in either group.

Table 1
Demographic and other variables in the two groups.

	Group 1: antibiotics	Group 2: no antibiotics
Number of patients	48	52
Number of toes	93	78
Age (SD)	58 (17.5)	62.7 (14.7)
Number of diabetics	4	2

5. Discussion

This study adds valuable information to guide our use of prophylactic antibiotics in percutaneous K-wire surgery. In particular, the routine administration of prophylactic antibiotics was not found to significantly alter the infection rate after toe fusion surgery. On the contrary, in this study, the infection rate was actually higher in patients treated by prophylactic antibiotics (6.2%) as compared to those patients who did not receive prophylactic antibiotics (1.9%). This was not statistically significant however.

There has always been a debate about the potential for microorganism colonisation and infection when foreign material like a K-wire is implanted and left *in situ* for a while. The actual incidence of infection, however, is quite variable with a reported range from zero and very low to rates of 6.6%, 6.8% and 7.9% [12–16]. In cases where infection does occur, often metalwork removal leads to resolution [17,18]. Similarly, the overall infection rate in this study of about four per cent is similar to some studies. Subramanian et al. found an infection rate of 2% in distal radius fractures without prophylactic antibiotics and Kramer et al. reported a 0.3% infection rate in 2698 hammer toe corrections [3,19]. All infections in the current study were mild, i.e. Grade 1 or 2 on the Oppenheim classification and were treated successfully with K-wire removal and antibiotics.

There are several other variables that may affect infection rates in K-wire surgery. These include the length of time K-wires are kept *in situ*, type of wires used, pin-site management and whether the wire is left percutaneous or buried [4,20,21]. Botte et al. found that the incidence of infection increased the longer the K-wire was left *in situ* in the hand and wrist [20]. However, Klammer found no difference in infection rates in lesser toe K-wire transfixion whether the wire was left for 3 or 6 weeks *in situ* [22].

In a prospective randomised controlled trial, Clauss et al. observed that stainless steel K-wires were associated with significantly higher bacterial loads than titanium K-wires in lesser toe surgery [21]. In addition, toe deformities treated with titanium K-wires had a lower recurrence rate, less pain, and less swelling than toes treated with stainless steel K-wires. The authors, however, suggested that this effect should be further investigated before contemplating widespread usage. In the current study, all the implanted K-wires were made up of stainless steel and hence we are unable to comment whether using titanium K-wires would have altered the results.

Hargreaves et al. found a significantly lower infection rate in his percutaneous K-wires if they were buried rather than exposed [4]. In this study, none of the wires were buried and they were removed at a variable period ranging from four to six weeks.

The antibiotics are prescribed prophylactically to minimise the risk of infection particularly in surgical procedures that involve incorporation of an implant. When bacteria form around the metalwork, it usually forms a glycol biofilm, which protects the bacteria from the effects of an antibiotic. Eradication of the bacteria usually requires removal of the metalwork. However, we believe, as with others that infection from K-wires occurs due to a tracking of bacterial colonisation from the skin into the subcutaneous tissue at a later stage, rather than as a direct result of bacteria entering at insertion [19]. This is why the prophylactic dose would not protect against this form of bacterial contamination resulting in a pin site infection. In this study, four patients had infection but only one patient required removal of the K-wire. The rest of the patients had Grade 1 infection, which settled with oral antibiotics.

The use of prophylactic antibiotics for elective forefoot procedures is controversial. There are no clear guidelines on which to base this decision and it largely depends on the surgeon's individual training, experience and preference as to whether or not to provide antibiotic prophylaxis. A survey of more than 300 members of the British Orthopaedic Association highlighted this split of opinion [7]. The results of the current study confirm that prophylactic antibiotics for elective forefoot procedures do not help in reducing the incidence of postoperative infection. In fact, patients who received antibiotics had a higher rate of infection. Therefore, the routine use of prophylactic antibiotics in forefoot surgery does not seem to produce any benefit. On the contrary, inappropriate use of antibiotics may contribute to the development of antibiotic resistance and add to healthcare costs.

There are some limitations of this study. As we did not include all consecutive patients, we cannot apply our conclusions to the whole population. We included diabetics but their numbers were too low to allow meaningful statistical analysis to determine whether they benefitted from prophylactic antibiotics or not. Similarly, the effect of various other confounding factors such as co-morbidities and smoking could not be fully quantified. We feel that until further evidence emerges, the decision to use prophylactic antibiotics in patients deemed to be at a higher risk of infection should be left at the discretion of the treating surgeon. This study also did not investigate the difference in the severity of infection between the groups. The sample size analysis was performed expecting the infection rate to be much higher than the current study. This study, therefore, can be used as an exploratory study to estimate the sample size required for future studies. Assuming the power of the study to be 80% and statistical significance at 5%, sample sizes of 1145 and 425 would be required to determine a reduction of infection from 4% to 2% and 4% to 1% respectively. Since the infection rate is low even when prophylactic antibiotics are not prescribed, it is quite possible that the results would not be much different even with a larger sample size.

6. Conclusion

In low risk patients, there is no clear evidence to support the use of prophylactic antibiotics in routine toe surgery requiring percutaneous K-wire insertion. Instead, the questionable and inappropriate prophylactic antibiotic usage has a potential to contribute to often-profound post-antibiotic complications in some patients. Clear guidance, therefore, could result in reduced antibiotic usage and help reduce antibiotic resistance. Further multi-centre larger studies are required to investigate this subject.

Conflict of interest

No conflict of interest.

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