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Infection prophylaxis

A prospective study in 106 patients operated on by tibial osteotomy using the hemicallotasis technique

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Abstract

Introduction Tibial osteotomy by the hemicallotasis technique is a clean elective operation. With external fixation pins inserted, close to the knee joint, the infection prophylaxis should be considered. The primary aim was to investigate the differences in the postoperative use of antibiotics during the time in external fixation between administering prophylactic antibiotics for 3 days or as a single dose in patients operated on by the hemicallotasis technique for knee deformities. Secondary aims were to study the differences in pin-site infection rate and grade and complications.

Material and methods A total of 106 consecutive patients of mean age 52 years (range 18–69) operated on by the hemicallotasis technique for knee deformities were included in this prospective study. Sixty patients were prescribed prophylactic antibiotics for 3 days and 46 patients as a single dose. Chlorhexidine (5 mg/ml) in alcohol (70% ethanol) was used as cleansing agent in the pin-site care. The power of the study was calculated to 80% to detect a difference in the postoperative use of antibiotics for 7 days during the treatment in external fixation.

Results There were no differences in postoperative use of antibiotics between 3 days administration or a single dose of prophylactic antibiotics. This was the case with infection rate and grade, positive bacterial cultures, presence of *Staphylococcus aureus*, nor positive culturing from the tip of the pins at removal. Neither were there any differences in numbers of loose pins and complications.

Conclusion There were no differences between 3 days of administration of prophylactic antibiotics and one single dose. One single dose of prophylactic antibiotics is appropriate together with a pin-site concept preventing pin-site infection in patients operated on by hemicallotasis osteotomy.

Keywords Antibiotic prophylaxis · Infection control · External Wxators · Tibial osteotomy · Chlorhexidine

Introduction

The optimal duration of prophylactic antibiotics is unknown but reports have documented effective prophylaxis with a single dose in orthopedic joint-replacement surgery [1–4]. However, the use of prophylaxis for longer periods has been advocated [5–7]. Tibial osteotomy by the hemicallotasis technique is a clean elective surgery. With external fixation pins inserted, close to the knee joint, the infection prophylaxis should be considered. The risk for a severe infection is low, but the consequences can be serious. The development of bacterial resistance is associated with antimicrobial use. Prophylactic antibiotics should be used as little as possible and the spectrum of activity of drugs used should be as narrow as possible [8].

During several years, we have documented pin-site infection and in an attempt to decrease the infection problems and the use of antibiotics during the treatment by hemicallotasis osteotomy (HCO) [9, 10], we changed the pin-site care step by step together with the use of infection prophylaxis. The aim of the present study was to investigate the differences in pin-site infection and other complications between administering the prophylactic antibiotics for 3 days or as a single dose in patients operated on by the hemicallotasis technique for knee deformities.

Method

Patients

A total of 106 patients (64 men and 42 women) mean age 52 (range 18–69) years operated on by the hemicallotasis technique for knee deformities (Table 1) were included consecutively. The

patients were operated on consecutively, group 1 during the year 2000 and group 2 during 2001. The 60 patients, (27 women) in group 1, were given prophylactic antibiotics as one dose intravenous (Cloxacillin 2 g) before surgery, followed by two intravenous doses during the first 24 h followed by per oral prophylaxis (Flucloxacillin 1 g \times 3) for additional 48 h. If the patient were discharged within 24 h, the last intravenous dose was changed to oral dose. The 46 patients in group 2 (15 women) were given prophylactic antibiotics as a single intravenous dose (Cloxacillin 2 g) before surgery. In the case of known allergic reaction to penicillin, the patient was given Clindamycin 300 mg. The local recommendation was to administer the preoperative prophylactic antibiotics 20–30 min before the incision. Preoperative antiseptic showering DesCutan® 4% (Chlorhexidine gluconate 4 g) were done twice, the first in the evening before surgery and the second in the morning the day for the surgery.

Hemicallotasis osteotomy

Four conical pins were inserted, two hydroxyapatite (HA) coated in the metaphyseal bone and two standard pins (Orthofix®, Bussolengo, Italy) in the diaphyseal bone. The Orthofix® T-garche was used as the external fixator. A longitudinal skin incision, ventral to the tibial tuberosity, was done for the osteotomy. The operation was done without bloodless field. Sterile compresses moistened by Chlorhexidine (5 mg/ml) in alcohol (ethanol 70%) were draped around each pin site and an absorbent pad covered the incision and fixed by a bandage were used as the operative dressing. The dressing was in situ until the first outpatient visit 1 week postoperatively. Patients were allowed to do free mobilization and full weight bearing postoperatively. Fifty-five percent (58/106) of the patients was discharged at the same day as surgery. The distraction starts 7 to 10 days postoperatively. Eight weeks postoperation, the fixation was dynamized to stimulate the bone healing. At 12 weeks postoperation, a bone-healing control was done by radiographic and ultrasound investigation. If the osteotomy healing was satisfying, the patient did a weight-bearing test, i.e., walking an extended period of time varying from some hours to some days without the instrument but still with the pins in situ. If no symptoms arise, the pins were removed in the outpatient clinic. If the patient developed symptoms, the fixator was applied for additional 2–3 weeks.

Pin-site care

A nurse performed the pin-site care once a week in the orthopedic outpatient clinic. The clean technique (sterile material and clean gloves) was used in the orthopaedic outpatient clinic. All bandages were removed. Each pin site was cleaned by chlorhexidine alcohol (5 mg/ml) in alcohol (ethanol 70%). No crusts were removed unless signs of infection perceived. A sterile compress moistened with Chlorhexidine (5 mg/ml) in alcohol (ethanol 70%) was placed at each pin site and was fixed by a soft dressing around each pair of pins. When showering, the patient protected the pin sites using a plastic bag. The patients had full access to the outpatient clinic if they had questions or any problems occurred. In the case of pin-site infection or drainage, extra visits were made if needed.

Antibiotic treatment

Flucloxacillin 1 g \times 3 or the antimicrobial drug susceptible for the positive culture was used for 7 days as antibiotic treatment during the treatment period.

Outcome

The postoperative use of antibiotics was recorded for a number of days and used as the primary outcome of presence of pin-site infection during the treatment in external fixation. Pin sites were clinically classified according to the Checketts–Otterburns classification [11], bacterial culturing was taken from each pin site at the first, sixth and tenth week and from the tip of the pins at removal and complications were recorded. At removal, the pins were assessed as clinically loose or fixed. A loose pin was defined as a pin, which could be removed by hand without use of a wrench. The time for administration of the preoperatively prescribed prophylactic antibiotics was controlled retrospectively by analyzing the medical records. The time of the preoperative antibiotic dose given was classified in patients administered the preoperative dose \geq 60 min before the first incision and patients administered the preoperative dose at any other occasion or not at all. The extent of antibiotic treatment clinical infection graded according to the Checketts–Otterburns classification [11], number of positive cultures, the presences of *Staphylococcus aureus* and the number of loose pins at extraction were compiled as well as the complications. Grade I–III according to the Checketts–Otterburns classification [11] was classified as minor infections and grade IV–VI as major infections. Complications included delayed healing (>112 days in external fixation), pseudoarthrosis, septic arthritis, deep venous thrombosis, nerve damage and interrupted treatment. The patients were defined as non-smokers if they, at the preoperative visit, reported that they never had smoked or stopped smoking since more than 6 months. Frame time (from surgery until the external pins were removed) was documented.

Statistic analysis

The analysis of variance (ANOVA) test, and Chi-square test or Fisher's exact test were used for the statistical analysis, statistical level $P < 0.05$. A multiple logistic regression analysis (controlled for potential confounders) was used to estimate the odds ratio (OR) of positive bacterial cultures and presence of *S. aureus* at the pin sites at any occasion during the treatment and other complications. Starting with the univariate model and selected variables that had a P value < 0.25 was considered as candidates for the multivariate models [12]. We entered the variables into multivariate models if they changed the effect estimated by 10% or more, and we excluded them if the exclusion changed the estimate by less than 5% [13]. As potential confounders gender, age, body mass index (BMI), prophylactic antibiotics, hospital stay, smoking habits and administration time of the prophylactic antibiotics were entered in the multiple logistic regression model. The power of the study was calculated to 80% to detect a difference in the postoperative use of antibiotics for 7 days during the treatment in external fixation; 33 patients in each group were needed. The study was approved by the Ethics Committee, Lund University, Sweden.

Result

Antibiotics

The total mean antibiotic consumption per patient (prophylaxis plus antibiotic treatment) during the treatment in external fixation was 13 days (SD 14) for group 1 and 11 days (SD 11) for group 2. The mean difference was 2 days (95% CI -3.0–7.0, $P=0.4$). There were no differences in the number of patients treated by the antibiotic: 30/60 patients in group 1 and 32/46 patients in group 2, RR 1.4 (95% CI 1.0–1.9, $P=0.07$). Neither were there any difference in the mean antibiotic treatment per treated patient (prophylaxis excluded): 15 days (SD 12) in group 1 and 17 days (SD 10) in group 2, the mean difference was 2 days (95% CI -7.6–3.6, $P=0.5$).

Infection

There were no differences in the postoperative use of antibiotics during the treatment in external fixation administered 3 days or one single dose of prophylactic antibiotics. There were no differences for positive bacterial cultures or presence of *S. aureus* at the pin sites at week 1, 6 and 10 or at any time during the treatment by HCO (Table 2). Neither were there any differences for bacterial cultures from the pin tips at extraction (Table 3). There were no differences in the clinical assessment according to the Checketts–Otterburns classification (Table 2). There were no major infections. When adjusted for potential risk factors, patients who stayed for 1 day at the hospital [2 days OR 0.2 (95% CI 0.08–0.8, $P=0.02$)] and non-smokers [smokers OR 0.2 (95% CI 0.05–0.8), $P=0.02$] were the risk factors for the presence of *S. aureus* during the treatment by HCO (Table 4).

Complications

There were no differences in the number of patients with loose pins at extraction, positive bacterial cultures and presence of *S. aureus* in positive bacterial cultures at the pin tip at extraction (Table 3). The total number of loose pins at extraction was 14/256 in the group 1 and 11/200 group 2 [RR 0.5 (95% CI 0.2–1.1), $P=0.1$]. Neither were there any differences in the number of patients with complications 14/60 in group 1 and 12/46 in group 2, [RR 1.1 (95% CI 0.5–2.3), $P=0.9$] or in patients with more than one complication 4/60 in group 1 and 2/46 in group 2, [RR 0.6 (95% CI 0.08–3.9), $P=0.9$]. When the results were adjusted for risk factors, the hospital stay for more than 1 day and smokers were found to be risk factors for complications during the treatment by HCO (Table 4). The treatment was interrupted in one patient in group 1 due to pin-site infection (*Citrobacter diversus* in the two proximal pins and in one of the distal pins) and loose pins at week 6 (*S. aureus* at one proximal and one distal pin). The correction and healing was obtained by additional surgery. Two patients developed pseudoarthrosis (one patient with osteonecrosis after the treatment for leukaemia and one smoker). Both healed after additional surgery. One patient in the group 2 developed a septic arthritis (*Staphylococcus lugdunensis*) after 12 weeks in external fixation and has been converted to a total knee arthroplasty.

Timing of administered prophylactic antibiotics

In group 1, 16/60 and group 2, 2/46 patients were given the prescribed preoperative dose of antibiotics postoperatively, and 10/60 (group 1) and 5/46 (group 2) patients were not given any preoperative prophylactic antibiotics at all according to the medical records. There was a significant difference between the two groups regarding when the preoperative antibiotic dose was given. In group 1, 34/60 patients got the preoperative dose of antibiotics <60 min preoperatively and 39/46 in group 2 ($P=0.002$). However, there were no differences in numbers of positive bacterial cultures, presence of *S. aureus* or numbers of positive culturing from the pin tip at extraction. Neither were there any differences in number of loose pins, complications or the use of antibiotics between patients who had been given the preoperative dose of antibiotics <60 min before surgery or at any other occasion.

Discussion

There were no differences in the results using infection prophylaxis by antibiotics for 3 days or a single dose preoperatively in patients operated on by the hemicallotasis technique. Unexpected findings in the multivariate logistic regression analysis were that patients who stayed only 1 day at the hospital and non-smokers were the risk factors for the presence of *S. aureus*. The risk factors for the presence of *S. aureus* would be expected to be the opposite. Longer time of stay in the hospital environment ought to be a higher risk of infection. Reviewing the literature, no studies were found showing that a short hospital stay should be a benefit for minor wound infections. Several studies showed that a shorter preoperative stay was a benefit [14, 15] and patients with postoperative infections and complications had a prolonged hospital stay [15, 16]. Smoking has been shown to be a risk factor of wound infection [17–19]. The multivariate logistic regression analysis showed that patients, who stayed for more than 1 day in the hospital and smokers were the risk factors for developing complications. An optimal infection prophylaxis includes an antimicrobial drug, with a broad spectrum, covering the organisms most likely to cause infection and achieve adequate concentration before the first incision and maintain a sufficient concentration until closure of the skin [8, 20]. The timing of prophylaxis by antibiotics is important to get a high antibiotic concentration at the time for skin incision. This is considered to be optimal about 30 min before skin incision, i.e. at the induction of anesthesia [8, 20]. As the optimal timing of prophylactic antibiotics is unknown and different suggestions are made just before the incision [2], for instance, antibiotics given longer than 60 min preoperatively were associated with a higher rate of infectious complications [21]. Therefore, it was chosen in this study to divide the patients into a group that were given the preoperative prophylaxis <60 min preoperatively and a second group which got the prophylactic antibiotics at any other time or not at all. The intention of this study was to administrate for 3 days, one dose of prophylactic antibiotics and this prescription was given in the medical records. When we retrospectively controlled the medical records, 31% of the patients were given the prescribed prophylaxis postoperatively or not at all. Despite the fact that these patients did not follow the study protocol, we let them stay included in the study and controlled for the time of prophylactic antibiotics given when using the regression analysis. This raised the question if prophylaxis is necessary in patients operated on by HCO, but it also questions the effectiveness in the surgical organization. Three doses [22] as well as 1 [23] to 2 weeks [7] of antibiotics has been reported as infection prophylaxis for the hemicallotasis technique. Magyar et al. [7] found that the overall relative risk for pin-site infection decreased with prolonged prophylactic antibiotics up to 10–14 days. The effect of different infection prophylaxis by antibiotics performing HCO is difficult to evaluate when there are various definitions of infection. The results of this present study with 6 and 7% of

minor pin-site infection according to the Checketts– Otterburns classification using 3 days each of one dose of prophylactic antibiotics indicated that prolonged postoperative use of antibiotics has no benefit. One single dose of Cloxacillin 2 g intravenous 20–30 min before the first incision is the local recommendation as infection prophylaxis by antibiotics in surgery for more than 1 h in our department. The time of surgery of HCO is about 30 min. The half-life of Cloxacillin is relatively short (30 min in serum) but Cloxacillin reach a high concentration in serum proteins (94%) and has an appropriate spectrum of coverage of the most likely pathogens associated with pin-site infections. As *S. aureus* is the organism predominantly causing incision surgical infections [8, 20, 24] and pin-site infections [11], we used Chlorhexidine (5 mg/ml) in alcohol (70% ethanol) as the cleansing agent. Chlorhexidine has the advantages of a low toxicity, broad spectra of antimicrobial activity. Chlorhexidine together with alcohol reduces the skin micro flora and has a residual antimicrobial activity [25]. A clinical difference of 7 days was used to detect a difference between the two doses of prophylactic antibiotics in the power calculation. Seven days represented one cure of treatment in the case of pin-site infection. The choice of use of antibiotics during the treatment in external fixation as primary outcome of the study was done by the reason that a low use of antibiotics indicates a low pin-site infection rate. We conclude that one single dose of antibiotic prophylaxis is appropriate together with a pin-site concept preventing pin-site infection during the treatment of HCO.

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Table 1. Patient characteristics of the study group.

	All N=106	3 days prophylaxis n=60	One dose prophylaxis n=46
Gender (n)			
Men	64	31	33
Women	42	27	15
Age mean (years)	52	52	52
SD	9	11	7
<i>Antibiotic prophylaxis (n)</i>			
<i>Cloxacillin</i>	103	58	45
<i>Clindamycin</i>	3	2	1
Indication of operation (number of knees)			
OA medial	92	48	44
OA lateral	13	10	3
Other* medial	3	2	1
Other* lateral	7	5	2
Bilateral (n) (simultaneous surgery)	9	5	4
Frame time (days)	99	97	102
SD	18	19	18
Pre HKA-angle (degrees)			
Mean medial (lateral)	170(187)	170(188)	170(185)
SD medial (lateral)	5 (6)	5 (6)	5 (5)
Correction time (days)			

Mean	25	24	27
SD	11	10	12
BMI (kg/m ²)	29	28	30
SD	5	5	4
Smoker (n)	22	14	8
Diabetes (n) (tablet treatment)	1	0	1

* Sequel fracture, correction and osteonecrosis.

SD= Standard deviation, Inf prophylaxis= Infection prophylaxis by antibiotics, OA= osteoarthritis, Pre-HKA = radiographic Hip-Knee-Ankle angle, BMI = Body mass index

Table 2. Positive bacteria cultures, presence of Staphylococcus aureus in positive bacteria cultures and clinical pin site infection according to Checketts-Otterburns classification⁴ of 106 patients operated on by the HCO.

	Group 1 Bacteria culture, clinical infection/ patient n=60	Group 2 Bacteria culture, clinical infection/ patient n=46	RR (95% CI) Group 1 1.0 (Ref)	p value
Week 1				
Pos bact cult	21/60	11/44	0.7 (0.4-1.4)	ns
Staph aureus*	4/60	3/44	1.0 (0.2-5.2)	ns
Grade 1	2/60	0/46	-	
Grade 2	0/60	0/46	-	
Week 6				
Pos bact cult	18/52	17/36	1.4 (0.8-2.4)	ns
Staph aureus*	11/52	13/36	1.7 (0.8-3.7)	ns
Grade 1	8/55	9/42	0.7 (0.3-1.8)	ns
Grade 2	3/55	2/42	1.1 (0.2-9.7)	ns
Week 10				
Pos bact cult	19/52	15/42	1.0 (0.5-1.8)	ns
Staph aureus*	6/52	11/42	2.2 (0.8-6.5)	ns
Grade 1	10/56	7/42	1.0 (0.4-2.9)	ns
Grade 2	2/56	3/42	0.5 (0.06-3.5)	ns
At any occasion**				
Pos bact cult	41/60	25/45	0.8 (0.6-1.2)	ns
Staph aureus*	18/60	25/45	1.3 (0.7-2.4)	ns
Grade 1	17/60	20/46	0.7 (0.4-1.2)	ns
Grade 2	6/60	5/46	0.9 (0.3-3.2)	ns

* Presence of Staphylococcus aureus in positive bacteria cultures

** A positive bacteria culture/presence of Staphylococcus aureus in positive bacteria cultures/clinical pin site infection at week one and/or week 6 and/or week10

Group 1 = 3 days of infection prophylaxis by antibiotics, Group 2 = one dose of infection prophylaxis by antibiotics.

HCO = hemicallotasis osteotomy, Pos bact cult = positive bacteria cultures, RR = relative risk, 95 % CI = 95 % confidence interval, Ref = reference category.

Table 3. Positive bacteria cultures, presence of Staphylococcus aureus in positive bacteria cultures from the tip of the pins and presence of loose pins at removal of 106 patients operated on by the HCO.

	Group 1 N=60	Group 2 n=46	RR (95 % CI) Group 1 1.0 (Ref)	p value
Pos bact cultures	22/59	19/46	1.1 (0.6-1.9)	ns
Staph aureus*	14/59	12/46	1.1 (0.5-2.3)	ns
Loose pins	9/59	8/46	1.1 (0.4-3.0)	ns

*Presence of Staphylococcus aureus in positive bacteria cultures.

Group 1 = 3 days of infection prophylaxis by antibiotics, Group 2 = one dose of infection prophylaxis by antibiotics.

HCO = hemicallosis osteotomy, Pos bact cultures = Positive bacteria cultures, RR = relative risk, 95 % CI = 95 % confidence interval, Ref = reference category.

Table 4 Relationship of risk factors** to positive cultures, positive cultures with Staphylococcus aureus, loose pins at removal and complications of 106 patients operated on y the HCO.

	Pos culture*	Pos culture* Staph aureus	Loose pin at removal	Complication
<i>OR (95 % CI) and significant values</i>				
Gender				
Men	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
Women	0.6(0.2-1.4)	0.7 (0.2-2)	1.3(0.4-4.7)	1.7(0.6-5.1)
Age				
<50	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
50-59	1.8(0.6-5.3)	1.3(0.4-4.3)	3.4(0.7-17.9)	1.6(0.5-5.6)
60+	1.0(0.3-3.6)	0.2(0.03-1.3)	1.8(0.2-15.8)	1.0(0.2-5.4)
BMI				
<25	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
25-29	2.3(0.7-7.7)	1.0(0.2-3.9)	0.7(0.1-4)	0.5(0.1-2.2)
30+	1.4(0.4-4.5)	1.0(0.3-4.2)	1.7(0.3-8.1)	1.0(0.3-4.1)
Inf prophylaxis				
3 days	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
one dose	0.5(0.2-1.3)	1.6(0.5-4.7)	0.8(0.2-2.8)	1.0(0.3-4.1)
Hospital Stay				
1 day	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
≥2 days	0.7(0.3-1.8)	0.2(0.08-0.8)	1.9(0.5-6.9)	4.4(1.4-14.3)
Smoking				
Non-smoker	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
Smoker	0.6(0.2-1.8)	0.2(0.05-0.8)	0.6(0.1-3.1)	4.5(1.3-15.1)
Time of Inf prophylaxis***				
all other time	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)	1.0 (Ref.)
≤60-≥1 min	0.8(0.3-2.2)	1.3(0.4-4.2)	0.4(0.1-1.9)	0.7(0.2-2.5)

*Pos culture= Positive culture at week one and/or six and/or ten.

**Adjusted simultaneously for all other risk factors listed.

***Time of administration of infection prophylaxis.

HCO = hemicallosal osteotomy, Staph aureus = Staphylococcus aureus, BMI = body mass index,

Inf prophylaxis = infection prophylaxis, all other time = infection prophylaxis given >61 minutes preoperatively, postoperatively or not at all, OR = odds ratio, 95 % CI = 95% confidence interval, Ref. = reference category.