Preoperative use of amoxicillin and gentamicin in elective orthopaedic surgery in horses – a randomised controlled study

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Summary: This randomised controlled trial evaluates the necessity of preoperative antimicrobial prophylaxis in equine clean, elective orthopaedic surgery. 75 horses undergoing clean orthopaedic surgery were randomly assigned to either a treated or a control group. Treated horses received 10 mg/kg amoxicillin and 6.6 mg/kg gentamicin once 30 to 45 minutes prior to first incision. The horses remained in the clinic for at least six days. During the first three days after surgery, rectal body temperatures were measured twice and on day four and five once daily. Surgical incisions received score points for exudation, swelling, skin temperature, and dehiscence. A two-factorial ANOVA was used to test for statistically significant differences between groups and over time. For pairwise comparisons between groups or time points, Fisher’s exact test and the (exact) Wilcoxon-Mann-Whitney-test were used. 59/75 horses (78.7 %) were included in statistical analysis. Significantly higher scores for swelling (p = 0.002), and skin temperature (p = 0.007) were observed in treated patients (n = 28), which caused the total score to be significantly higher in treated horses, too (p = 0.002). In both groups, body temperatures were significantly higher in the evening of the day of surgery (p < 0.0001). On the third day after surgery, temperatures in the morning were significantly higher than in the evening (p = 0.007). All other statistical comparisons revealed no significant differences. After the seven-day observation period, one control horse (day 8 postoperatively) and one horse (day 9 postoperatively) in the treated group, that was excluded from statistical analysis due to additional antibiotic administration directly after the operation, developed septic arthritis in the operated joint. Preoperatively administered amoxicillin in combination with gentamicin failed to reduce reactions at incision sites after elective surgical orthopaedic procedures. The routine administration of preoperative antimicrobial prophylaxis in clean, elective orthopaedic surgery in horses lacks scientific data to prove a beneficial effect. Antibiotic administration before or after these procedures should be based on an individual risk-benefit assessment.

Keywords: surgical site infections, preoperative amoxicillin and gentamicin, elective surgery

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Introduction

With antibiotic resistance as one of the main world-wide health concerns, the antibiotic use and resistance in veterinary medicine is subject to close public attention (Johns et al. 2012). In any species, antibiotics induce bacterial resistance to the administered agents, e.g. in the gastrointestinal flora (Gibbens 2013). Resistance develops not only due to new mutations, but also through selection of already unsusceptible bacteria (D’Costa et al. 2011).

Nosocomial infections are recognised as a widely spread problem in human as well as in equine clinics. According to a study of antibiotic prophylaxis in 72 German human hospitals, 3.5 % of all patients develop a hospital-acquired infection (Wacha et al. 2010). Approximately 15 % of these are surgical site infections (Wacha et al. 2010). Additionally to antisepsis, which was introduced by Joseph Lister (Daeschlein et al. 2015), the proliferation of bacteria can be suppressed if antibiotics are administered before the tissue is contaminated (Burke 1961). To be effective, the tissue concentration of the antibiotic agent must exceed 90 % of the minimum inhibitory concentration (Kujath et al. 2006). During surgery, the tissue drug levels need to remain effective, so that after two half-live times of the antibiotic used, a second dose needs to be given (Wacha et al. 2010). However, in human medicine it is suggested that in clean orthopaedic surgeries, that do not exceed three hours, a repletion dose is not necessary. Routine administration of prophylactic antimicrobial agents for arthroscopic surgeries is no longer indicated, except if implants remain in the body (Széll et al. 2006). In a recent study on humans undergoing lesser toe fusion surgery, even despite an implant, no significant difference in the development of wound infections between antibiotic-receiving (48/100) and control (52/100) patients were found (Mangwani et al. 2017).

Rates lower than 1 % for the development of a septic arthritis after equine arthroscopy have been reported (Olds et al.
2006, Borg and Carmalt 2013). Even though these overall low joint infection rates, prophylactic antimicrobials still are very often routinely administered before or after clean orthopaedic surgical procedures in equines, because consequences of joint infections are severe (Borg and Carmalt 2013). Impaired healing after clean orthopaedic surgery was reported to range from 8.1–39.1%; depending on the definition of complicated wound healing (MacDonald et al. 1994, Stöckle et al. 2018). Nearly all equine studies reported so far have a retrospective design. As a typical problem of retrospective analysis, surgical wounds of antibiotically treated and untreated patients are not directly comparable, mainly due to different treatments.

Material and methods

A randomized controlled clinical study was planned with a total of 60 patients. Horses undergoing elective orthopaedic surgery were examined repeatedly within seven days. Study probands had to be clinically healthy except for the orthopaedic purpose of surgery. Patients were assigned to the treated or control group in the evening before surgery according to a randomization list.

Patients in the treated group received 10 mg/kg amoxicillin (Belamox®, bela-pharm, Vechta, Germany) and 6.6 mg/kg gentamicin (Genta 100 mg/ml, CP-Pharma, Burgdorf, Germany) through an i.v. catheter. Between administration and the initial incision 30 to 45 minutes passed. Horses of the control group received an i.v. catheter in the same time span as the verum group, but did neither receive antibiotics nor placebo. Drop-out criteria were contraction of a disease not associated with the surgical procedure, e.g., respiratory tract infection or surgical colic. Also dropped out of the study were horses that were not followed up according to the planned examination schedule or had their antibiotic protocol changed by the responsible surgeon. Patients leaving the hospital after less than five days after surgery were also dropped out.

Rectal temperatures were obtained at day 0–3 in the morning and evening and at days 4–5 just in the morning. Wounds were evaluated three times postoperatively with a semi-quantitative scoring system considering exudation, swelling, skin temperature and dehiscence; all score points were added to a total score (Table 1). Skin temperature was determined by palpation of the area surrounding the incision with the back of a gloved hand. In patients with more than one surgical intervention, the highest score reached in a lesion was included in the results.

Distal limb bandages consisted of a layer of mull (Vetrol Mullwatterolle, Farm and Stable KG, Wiehl/Germany) fixed with an elastic bandage (Raucolast®, Lohmann-Rauscher, Neuwied/Germany) and then covered with a self-adhesive bandage (Prowrap, Farm and Stable KG, Wiehl/Germany). If the operated joint was the coffin joint, the bandage was fixed distally with adhesive tape to the hoof (Gewebe Reparaturband silber, engelbert strauss GmbH, Biebergemünd/Germany). After tarsus arthroscopies, bandages consisted of a layer of mull and an adhesive bandage (Optiplaste®-C, BSN medical GmbH, Hamburg/Germany). In patients recovering from a knee surgery, a bandage was not applied. Instead the incision sites were covered with ESS Zinc Cover (ESS GmbH, Bakum/Germany). Surgical lesions at the knee were looked after daily but evaluation results just of the first, third and fifth day after surgery entered statistical analysis.

Horses not registered for food production received phenylbutazone (2.5 mg/kg b.i.d. orally; Phenylbutariem® Ecuphar NV/SA, Oostkamp/Belgium), whereas horses with the option to be slaughtered received meloxicam (0.6 mg/kg once a day orally; Metacam® 15 mg/ml, Boehringer Vetmedica Ingelheim, Ingelheim, Germany). The medication started on the evening prior to surgery and ended in the morning on the fourth day after surgery.

For statistical analysis, the program package BMDP/Dynamic, Release 8.1 (Statistical Solutions Ltd., Cork, Ireland) was used to conduct different ANOVAs, the t-test, and the Wilcoxon-Mann-Whitney test (WMWT). The statistical program package StatXact-9 (9.0.0 Cytel, Cambrige, Massachussettes, USA) (15) was used additionally for Fisher’s exact test, the exact WMWT, and the chi-square test.

Two-factorial ANOVAs were calculated to evaluate the influence of antimicrobial treatment and time (repeated measures) including the interaction between these factors on scores (in a manner of exploratory data analysis) and body temperatures (program BMDP2V). On day 1–3, horses’ temperatures were taken twice a day, therefore a three-factorial ANOVA with repeated measures was performed to test for influences of daytime, day and perioperative antimicrobial prophylaxis including their interactions (BMDP2V). In cases with incomplete

| Table 1 Wound scoring system | Wundbeurteilungen mit Score Punkten |
|-----------------------------|-----------------------------------|
| Parameter                   | Score |
| Exudate                     | None, wound is dry and clean 0 |
|                             | Serous or serosanguinous 1       |
|                             | Purulent or haemopurulent 3      |
| Swelling and pain           | No swelling 0                    |
|                             | Low-grade swelling, not painful 1 |
|                             | Middle-grade swelling, mildly painful 2 |
|                             | High-grade swelling, severely painful 3 |
| Extend of color             | Normal skin temperature 0        |
|                             | Mild increase 1                  |
|                             | Moderate increase 2              |
|                             | Severe increase 3                |
| Dehiscence                  | No sutures dehiscent 0           |
|                             | 1–2 sutures dehiscent 1          |
|                             | ≤ 50% of sutures dehiscent if more than 2 sutures were applied 2 |
|                             | > 50% of sutures dehiscent 3     |
The aim of the study was the recognition of conspicuous differences between the treatment groups. Therefore no adjustment for multiple testing (correction of error probability of the first kind due to multiple testing) was done to avoid the reduction of statistical power.

**Ethical statement**

In comparison to the usual procedures in the clinic, no additional examinations or additional blood samples were taken, just the blood volume was increased to a total volume of 25–30 ml per sample. According to the relevant authority (Regierungspräsidium Gießen), at that time, the animal welfare laws in Germany therefore did not require an approval procedure.

**Results**

**Drop outs**

In total, 75 horses needed to be included and randomised in order to reach a total of 28 antibiotically treated patients and 31 controls. Sixteen patients (21.3%) dropped out of the study. Seven were randomised into the amoxicillin/gentamicin group (“treated”), nine were intended to be controls. Thirteen of the 16 drop-outs underwent arthroscopy. Tendovaginoscopy, fasciotomy, and fasciotomy/neurectomy were performed on one patient each. The reasons for drop-out were as follows: Three horses in the treatment group received additional antibiotics due to concerns of the surgeon. One patient (control) developed a severe respiratory infection and one horse (treated) had surgical implants placed. Six horses (1 treated, 5 controls) were discharged earlier than planned. Five more horses could not be examined as scheduled.

**Patient data**

Of the 59 horses fulfilling the study plan, 28 received preoperative amoxicillin/gentamicin and 31 served as controls. Fifty warmbloods (26 treated, 24 controls), three ponies, two Arabian horses, two Quarter Horses, one Frisian as well as one Icelandic horse were included (2 treated, 7 controls). Eleven were stallions (6 treated, 5 controls), 31 geldings (16 treated, 15 controls), and 17 mares (6 treated, 11 controls). Statistically, gender was distributed evenly between the groups (p = 0.57).

There were no significant differences between treated and control group in age (5.3 ± 2.8 versus 5.3 ± 1.9 years), weight (525.6 ± 109.7 versus 541.7 ± 73.2 kg), duration of the surgery (60 ± 23 versus 55 ± 19 minutes) and hospitalisation time. The median (min – max) hospitalisation time of the control group was 11 (6–43) days, whereas patients in the treated group stayed 10 (5–77) days.

As NSAID, 44 horses received phenylbutazone and 15 meloxicam. Controls received statistically significantly (p = 0.03) more often phenylbutazone (27/31; 87%) than patients in the treated group (17/28; 61%).

**Types of surgical interventions**

Most study participants (36/59; 61%) underwent arthroscopy (Table 2). Of these, 19 were controls and 17 received preoperative antimicrobial prophylaxis. For the different types of surgeries, there was no significant difference between the number of horses per groups.

Often simultaneously performed and therefore summarised in one group for statistical analysis were tendovaginoscopy and tenotomy. One horse underwent a tendovaginoscopy, tenotomy, and a splint bone extraction on the same leg. As the tendovaginoscopy/tenotomy took longer than the splint bone extraction, the horse was assorted to the tendovaginoscopy/tenotomy group. Fasciectomy, neurectomy and their combination were summarized for statistical evaluation, because in the hind limbs these surgeries were mainly performed simultaneously.

Forty-six horses had one surgical intervention, 22 (48%) of these received antibiotics. Eleven horses underwent two interventions during their surgery session, 5 of them were treated with antibiotics. Two horses (1 treated) had three arthroscopies during their one surgery session. Horses with one and patients with two or more surgical lesions were distributed evenly between treatment and control group.

| Types of Surgery                        | Treated (n = 28) | Controls (n = 31) |
|----------------------------------------|-----------------|-------------------|
| Arthroscopy                            | 17 (60.7%)      | 19 (61.3%)        |
| Tendovaginoscopy/Tenotomy              | 5 (17.9%)       | 4 (12.9%)         |
| Splint bone extraction                 | 2 (7.1%)        | 6 (19.4%)         |
| Neurectomy/Fasciectomy                 | 4 (14.3%)       | 2 (6.5%)          |

**Table 2**

This table shows the patient distribution according to the type of surgery. The numbers represent the number of surgeries performed on each leg. The percentages indicate the proportion of surgeries of the respective type in both groups. The data are representative of mean ± standard deviation (minimum – maximum), if not mentioned differently. For qualitative variables frequency tables were formed. The significance level was set as usual at 0.05.
8 procedures (5 treated, 3 controls). There was no significant
difference in distribution of antimicrobial prophylaxis between
the surgeons.

Body temperatures

It was not possible to take temperatures in 10 patients at
all occasions because they were very uncooperative. In four
horses, of which three were in the control group, temperature
measurements never were possible. In a further six horses (5
control, 1 treated) only 23 out of the planned 66 measure-
ments per horse could be taken.

Five horses (4 controls, 1 treated) showed body tempera-
tures > 38.5°C at least once (Fig. 1). In the evening after sur-
gery, two controls developed fever (40.2°C and 39.1°C) and
one treated horse a slightly elevated (38.6°C) temperature.

Between groups, no statistically significant difference in mean
body temperatures of day 1 to 3 was seen. However, between
days temperatures were significantly different (p = 0.02) and
a significant interaction of day and daytime was detected
(p < 0.0001). On the day of surgery, body temperatures were
significantly higher in the evening (37.8 +/- 0.54°C) than they
had been in the morning 37.4 +/- 0.48°C; p < 0.0001). On
the third day after surgery, temperatures in the morning (37.6
+/- 0.48°C) statistically were significantly (p = 0.007) higher
than in the evening (37.4 +/- 0.42°C).

Wound scores

Over time, the total score decreased significantly during the
five-day evaluation period (p < 0.0001, Table 3). Total scores
were significantly higher in the treated group than in the
control group (p = 0.002). Analysis on a daily basis (Wilcoxon-
Mann-Whitney Test) revealed, that the total score in treat-
ed horses was significantly higher at day 1 (p = 0.03) and 5
(p = 0.01). On day 3, the difference between the groups was
not significant (p = 0.06).

However, in both groups, most horses only had an absolute
total score of 3 points or less (figure 1 – figure 6). The highest
scores (total score treated: 3.38 ± 1.54; control: 1.48 ± 1.12)
were observed in the treated group on day one.

Purulent wound discharge (3 score points) was only observed
in one horse (horse 61) in the treated group on day 5. This
patient underwent neurectomy. Like in the previous evalua-
tions, the wound additionally showed a low-grade swelling (1
score point), no increase in skin temperature (0 score points),
and no dehiscence. The patient responded well to local treat-
ment. After the evaluation at day 5, the wound was cleaned
daily, disinfected with octenidine (Octenisept®; Schülke and
Mayr GmbH, Norderstedt/Germany) and an antibiotic oint-
ment was applied.

Dehiscence developed in three of the 59 patients. On the first
day after surgery, sutures were not in situ in two patients of the

Fig. 1  Individual wound scores in controls on day 1. x-axis: horse
number, y-axis: score points | Individuelle Wundscores der Kon-
trollgruppe an Tag 1. x-Achse: Pfer-
denummer, y-Achse: Score Punkte

Fig. 2  Individual wound scores in controls on day 3. x-axis: horse
number, y-axis: score points | Individuelle Wundscores der Kont-
trollgruppe an Tag 3. x-Achse: Pfer-
denummer, y-Achse: Score Punkte
antibiotically treated group. In horse 21, none of the two sutures was in place at an arthroscopy portal. A splint bone was extracted in horse 64. Two skin sutures out of seven were dehiscent. On day five, one control (splint bone removal) the lowest two of seven sutures became dehiscent (1 point). All three patients responded to local treatment and were discharged sound.

During the first five days after surgery, the treated horses showed significantly more swelling at the incision site than horses in the control group (p = 0.002). The swelling decreased significantly during the observation period (p < 0.0001). Horses in the treated group had significantly higher swelling scores on the first (p = 0.02) and fifth (p = 0.002) day after surgery than controls. However, there was no significant difference between groups on the third day (p = 0.1). On the first day after surgery, the surgical wounds in eleven horses did not show any swelling at all (treated: 2; control: 9). On day one, the swelling around the incision in most horses (treated: 14; control: 16) was scored with one point. The highest score given on this day was 2 points, which was attributed to 6 horses in the treated and to 2 horses in the control group. Only one treated patient developed swelling scored with three points on the fifth day after surgery. Additional complications did not occur in this horse.

During the study period, treated horses had statistically significant higher skin temperatures around their incisions than the horses in the control group (p = 0.007). The skin temperature differed significantly over time (p = 0.0002). Regarding each time point individually, the skin temperature around the in-
incisions was significantly higher in horses that had received perioperative antimicrobials on the days 1 (p = 0.04) and 3 (p = 0.03) after surgery. To the incisions in the control group, 0 or just 1 point was given during the study period. Four horses in the treated group received 2 points on day one due to their skin temperature around the incision. On days 3 and 5, it was one treated horse that received 2 points on each day.

Post-operative septic arthritis

Septic arthritis developed in one (treated) drop-out and one control patient at day 8 and 9 post-operatively, after the end of the study. The treated horse already dropped out of the study due to additional gentamicin on day 1 and 2 after surgery.

Discussion

To the authors’ knowledge, this is the first prospective, controlled clinical study on preoperative antimicrobial prophylaxis in elective, clean orthopaedic surgery in horses. Due to the prospective study design, all probands were examined and treated at the same time points and received the antibiotics in the same dosages, which allows directly comparable wound evaluations. Additionally, a scoring system was established before the start of the study, therefore wound evaluations were possible in a standardised manner.

The total wound evaluation score was significantly higher in the treated than the control patients on days one and five. Randomly allocated, antibiotic-receiving horses showed significantly higher scores for local swelling and skin temperature on days one and three. On the other hand, overall and even initial wound scores were quite low with many patients showing uncomplicated healing with 0 score points at all times. Nevertheless, total as well as scores for swelling and elevated skin temperature decreased significantly over time, showing that the score system is sensitive enough to detect differences. A bias due to knowledge of the examiners concerning the group association of the patient, has to be considered. A systematic influence was avoided to the best of the authors knowledge by defining the criteria for score point assignment before the start of the study and by enhancing the awareness of a possible bias. A blinded study design would have been better but was not possible to realize.

| Table 3 | Wound scores: statistical results (two-factorial ANOVA with repeated measures; exploratory data analysis) |
|---------------------------------|---------------------------------|
|                                 | Statistische Ergebnisse der zweifaktoriellen ANOVA mit Messwiederholungen als explorative Datenanalyse für die Wundscores |

|                         | Difference between groups | Difference between days | Interactions |
|-------------------------|---------------------------|-------------------------|--------------|
| Total score             | 0.002                     | < 0.0001                | n. s.        |
| Exudation               | n. s.                     | n. s.                   | n. s.        |
| Swelling                | 0.002                     | < 0.0001                | n. s.        |
| Skin temperature        | 0.007                     | 0.0002                  | n. s.        |
| Dehiscence              | n. s.                     | n. s.                   | n. s.        |

MacDonald et al. (1994) found a significantly higher risk of developing surgical site infections under antibiotic cover in their retrospective analysis. The authors assumed that this was caused by the identification of additional risk factors by the responsible surgeon. Despite the antibiotic cover, those high-risk patients remained to have an increased risk of complications – which probably would have been even higher if they had not received antibiotics. The study presented here allowed additional antibiotics, if the surgeon felt that they were needed. Three patients dropped out due to this reason. Due to randomization, the remaining horses in both groups should have the same risk of developing surgical site infections, especially since age, duration and types of surgery, hospitalisation time etc. were not different between groups. The results in body temperatures as well as wound scores underline, that the healing process in the control group was certainly not inferior in comparison to the group receiving “prophylactic” antibiotics.

In this study 47 arthroscopies were performed in 36 horses. One control developed a septic coffin joint on day 8 after surgery, after the end of the study observation period. With an antibiotic cover, none of the 22 joints in the 17 horses involved showed such a complication. However, one excluded horse, initially randomised into the treatment group, developed a septic coffin joint despite receiving the routine amoxicillin/gentamicin combination preoperatively and additional gentamicin for two days after the arthroscopy. This dropped-out horse emphasizes the importance of including a sufficient number of horses in order to produce valid recommendations. As the onset of the septic arthritis was 8 or 9 days after surgery, the observation period of five days was probably not long enough to cover this severe complication after arthroscopy, which is underlined by retrospective studies, in which in total 14 out of 1145 horses developed a septic joint after arthroscopy. (Olds et al. 2006, Borg and Carmall 2013, Stöckle et al. 2018). In one study, septic joints occurred after 2–27 days after surgery (Stöckle et al. 2018), in the other after a median of 20 days (mean 47 days) after surgery (Olds et al. 2006). Horses in our study were continuously monitored either by the clinic or the owner/trainer, who with a very high probability would have contacted the clinic in any case of complications. Therefore, it is unlikely, that septic arthritis was missed in any of the patients reported here. Furthermore, surgical site infections are defined to occur within 30 days after the surgical procedure if no implant was placed and within a year when an implant remains in the body (Waguespack et al. 2006). It was already hypothesized that the contamination of operated joints can occur at some point after surgery (Smith et al. 1982). Therefore it seems very unlikely that preoperative application of antibiotics as a single shot will prevent any infections occurring at some point after surgery. It needs to be emphasized, that after arthroscopy, a joint may still develop an infection within the following weeks and then requires intensive therapy immediately. During the first five days after surgery, increased swelling or increased skin temperature occurred, which can be indicative of developing septic arthritis or more superficial surgical site infections. Horses showing these signs were monitored closely even after finishing the study period. Furthermore, if there would have been any concern in the owner or the trainer about the healing of a discharged horse after surgery, due to overall intense contact with the clients, the clinic certainly would have been informed. Therefore, it seems very unlikely that any complications occurring after discharge were missed.
Unfortunately, a significant difference between the treated and control group was detected regarding the NSAID applied. The treated horses received significantly more often meloxicam than the controls ($p = 0.03$). Forty-four horses did not receive meloxicam because of the higher costs. Fifteen horses were intended for human consumption, so an administration of phenylbutazone was not an option due to legal reasons. A recent study compared the efficacy of meloxicam and phenylbutazone in two experimental pain models in horses. In a lipopolysaccharide (LPS)-induced synovitis model, in which 16 horses received 50 mg of LPS in 0.5 ml Ringer’s solution into one intercarpal joint, both meloxicam and phenylbutazone reduced the joint temperature compared to a placebo. The inflammatory pain was evaluated by scoring pawing the floor or pointing a foot, movement, position in the stall, ear position, and orbital tightening. Regarding lameness, there was no significant difference between meloxicam and phenylbutazone, but meloxicam was more effective than phenylbutazone in reducing synovitis-associated changes in head movement (Banse and Cribb 2017). In the study presented here, neither lameness after surgery nor pain on palpation was observed in any of the patients. As a systemic inflammatory response, fever was present in 3 horses that received meloxicam as well as in 2 patients receiving phenylbutazone. The total scores were highly variable after meloxicam as well as after phenylbutazone so that an influence of the NSAID on the score points in each group was not assumed. Furthermore, in three of the phenylbutazone-receiving horses, suspected adverse reactions were seen: two patients showed elevated creatinine levels, and one horse was anorectic. After discontinuing the NSAID on the day after surgery, the creatinine levels returned to normal limits, and the third horse started eating again. In these patients, excessive elevations of the inflammatory parameters were not observed, so an effect of the absent non-inflammatory medication on wound healing seems implausible. Therefore, it seems reasonable to critically evaluate the type and the duration of postoperative analgesia with NSAIDs.

**Conclusion**

Preoperative antimicrobial prophylaxis failed to reduce postoperative wound scores and should therefore not be initiated routinely in uncomplicated equine clean orthopaedic surgery.

**Conflict of interest**

The authors declare no conflict of interest.

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