Intraoperative Antibiotic Prophylaxis
in Neurosurgery:
A Prospective Randomized Trial in 840 Patients

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Summary

The efficacy of a single dose of cefotiam as prophylaxis for postoperative infection was analyzed in a prospective randomized study of 840 patients undergoing either craniotomy (group I, n = 711) or cerebrospinal fluid shunting (group II, n = 129). The main interest was centered on the rate of bone flap infection and shunt sepsis requiring operative revision. Data were evaluated in the total groups and various subgroups formed for high risk patients. Our results show a highly significant difference for postoperative bone flap infection, with 0.3% in the cefotiam group versus 5.1% in the control group (p < 0.001). The overall rate of postoperative deep wound infections including meningitis and abscess (group I) was also significantly different (3.1% vs 9.0%, p < 0.005). This was also true for wound infections in high risk patients (3.1% vs 10.6%) as well as for postoperative sepsis and pneumonia. The overall rate of shunt infections (group II) was 7.5% in the cefotiam group and 12.9% in the control group, with the differences not being statistically significant either for the main group or for high risk subgroups. In summary, antibiotic prophylaxis has proven to be effective for prevention of postoperative infection in patients undergoing craniotomy. Although our results in shunt patients do not reach statistical significance, we also recommend single dose prophylaxis in these cases, since there is a clear difference of infection rate between patients receiving and not receiving the antibiotic.

Introduction

Postoperative infection rates in clean neurosurgical craniotomies range from 0.8% to 6.0%, with 3%-4% being the expected average [2, 3, 7, 14, 17, 18, 24, 26, 28]. The occurrence of shunt infections usually varies between 10% and 15% [1, 10, 22, 27]. Nevertheless, antibiotic prophylaxis in neurosurgery has always been a controversial subject [12]. This controversy, however, mainly results from the lack of careful studies of its efficacy. Therefore, we have focused again on this issue with a prospective randomized trial in order to clarify the value of antibiotic

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prophylaxis in neurosurgery with respect to patients undergoing craniotomy and cerebrospinal fluid (CSF) shunting.

Patients and Methods

During 2- and 1-year periods, respectively, all patients undergoing either craniotomy \((n=918, \text{ group I})\) or cerebrospinal fluid shunting \((n=134, \text{ group II})\) in the Neurosurgical University Clinic Freiburg were enrolled in this prospective and randomized trial. Only clean or clean-contaminated cases were included. Randomization was achieved by computerized lists. Patients operated on more than once in this period were counted separately for each occasion, except for immediate reoperation due to complications. Cefotiam was administered intravenously in a single 2-g dose with induction of anesthesia. The surgical procedure was standardized. The patient's hair was totally shaved the day before the operation with an electrical razor and again immediately before surgery using a razor blade in the region of skin incision, which was prepared with a polyvidone-iodine solution. Data analyzed in particular were medical history, actual diagnoses, details on operation, intensive care and medical therapy, the postoperative course and infectious complications, including late results obtained 6 months after surgery. Infections were defined as deep wound infections and/or bacterial meningitis with clinical symptoms and bacterial contamination of CSF requiring surgical and/or antibiotic therapy. Data collection and evaluation was computerized (dBASE III+) using 118 singular items per case.

Final data were available in 711 patients of group I (craniotomy) and in 129 patients of group II (shunt).

Statistical analysis was based on the confirmation of structural equality and comparability of the cefotiam and control groups followed by \(\chi^2\)-test with double-sided \(p\).

Results

**Group I: Craniotomy**

The overall wound infection rate including meningitis and abscess formation was 11 out of 356 cases (3.1%) in the cefotiam group and 32 out of 355 cases (9.0%) in the control group. The difference is statistically significant \((p < 0.005)\). Regarding bone flap infection alone, we found a 0.3% infection rate in the cefotiam group and 5.1% in the control group (Table 1).

Several subgroups were formed to evaluate the effect of cefotiam in high risk patients. The results are shown in Table 2. The total infection rate was 3.1% in the cefotiam group and 10.6% in the control group. The difference is statistically significant \((p < 0.005)\).

We encountered 14 patients with postoperative sepsis. Five (1.4%) belonged to the cefotiam and nine (2.5%) to the control group. Postoperative pneumonia was