Antibiotic Prophylaxis Does Not Decrease Infection Rate in Pediatric Supracondylar Humerus Fractures Treated with Closed Reduction and Percutaneous Pinning: A Prospective Double-Blinded Randomized Controlled Trial

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INTRODUCTION:
Supracondylar humerus fractures (SCHF) are the most common elbow fracture in the pediatric population. They are usually seen in children younger than 10 years old after a fall from height on an outstretched hand with a hyperextended or flexed elbow. In case of displaced extension- and flexion-type fractures, closed reduction and percutaneous Kirschner-wire pinning (CRPP) is the most used surgical intervention. CRPP is a safe and effective procedure with low incidence of complications. Infections are rare with rates reported between 0-7%, including superficial and deep infection, and with an overall average of 2.34%. Recent retrospective studies showed no benefit in using prophylactic antibiotics in the setting of SCHF treated with CRPP. However, there continues to be significant variability on antibiotic usage based on surgeon personal preference and local institutional policy, due to a lack of guidelines. This study aimed to assess the utility of antibiotic prophylaxis in preventing infection after CRPP in SCHF and to provide the strongest evidence for, or against, their routine use.
METHODS:
A prospective, double-blinded, randomized controlled trial study was conducted in a single level I trauma center from 2015 to 2022. Sample size was determined based on a non-inferiority study design, and a presumed infection rate of 2.34% from previous literature. Both surgeons and patients were blinded to treatment group. Patients with SCHF were randomized into two groups. Group I received one dose of preoperative antibiotics (25mg/kg Cefazolin IV up to 1g or Clindamycin 10mg/kg up to 600mg/kg IV in case of Cefazolin allergy). Group II received placebo (10mL pre-filled syringe of normal saline). All patients underwent CRPP and casting followed by pin removal 3 to 6 weeks after the initial procedure. Demographic and injury characteristics such as age, gender, Gartland fracture classification, time between fracture and fixation, and time to pin removal were collected. Presence of superficial infection (pin site erythema, granulation tissue, or drainage) and deep infection (septic arthritis and osteomyelitis), need for postoperative antibiotic, time to healing, need for repeat casting, and loss of fixation were recorded. Student t-tests were performed for continuous variables and Chi-squared tests were used to examine differences in categorical variables.
RESULTS: A total of 160 patients were enrolled in the study. Eighty patients were randomized in group I and 80 patients in group II. Patient demographics and injury characteristics were similar between groups. Preliminary analysis shows that the overall rate of superficial infection was 1.5% and deep infection was 0.5%, with no difference between the two groups. Presence of erythema at the pin sites was similar in both groups with 8 patients in the antibiotic group and 10 patients in the control group ($p=0.92$). Discharge was present in 19 patients in group I (all bloody discharge) and in 21 patients in group II (19 bloody, 1 serous, 1 purulent) with no difference in frequency nor type ($p=0.98$ and $p=0.39$ respectively). One patient in the antibiotic group and two patients in the control group reported fever during fracture healing ($p=0.74$). No significant difference in bony healing rates was seen between groups ($p=0.35$). Tenderness at the fracture site at the time of pin removal was more prevalent in the control group ($p=0.03$).
DISCUSSION AND CONCLUSION: This study shows that the routine use of prophylactic antibiotics for CRPP of pediatric SCHF does not significantly affect the rate of superficial and deep infection, nor the rate of fracture healing. Given the absence of overt infection, halting the unnecessary use of antibiotics may help reduce inherent risks associated with antibiotic use, such as drug resistance and allergic reactions. Furthermore, the abandonment of this practice in this field could help decrease the overall cost of the procedure for the patient and the healthcare system. The results of this study may also be applied to other low risk pediatric procedures. In conclusion, antibiotic prophylaxis is not required to prevent infection in SCHF treated with CRPP and guidelines should be updated for a better evidence-based practice.