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The Effects of Dexamethasone on the Time to Pain Resolution in Dental Periapical Abscess

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Study Protocol

MATERIALS AND METHODS

A prospective, randomized, double-blind placebo-controlled study was undertaken at two academic medical center EDs between September 2017 and May 2019. All patients presenting with "dental pain" were screened for potential study enrollment. Patients 18 years and older with a clinical diagnosis of pulpitis or dental apical abscess were further screened for potential enrollment. Diagnosis was made based on physical examination revealing pain with percussion of the affected tooth or teeth with or without gingival erythema or swelling.

Patients were excluded for any of the following conditions: diabetes, treatment with systemic corticosteroids within the last 30 days, hospitalization due to intractable vomiting or pain, self-reported pregnancy, immunosuppression (diagnosed with human immunodeficiency virus, received transplantation, or receiving chemotherapy), or those who lacked a telephone number to participate in follow-up calls. Eligible patients were approached for potential study inclusion and, after providing informed consent, enrolled patients were randomized to receive either dexamethasone 10 mg or an identical placebo.

Study drug, placebo, and two separate randomization lists were prepared for each study site by the investigational drug pharmacist. Randomization was achieved by using a random number generator of blocks of four to maintain relatively equal group sizes. The study drug was prepared using capsules filled with either sucralose granules or crushed dexamethasone tablets. Four 2.5-mg tablets were crushed and mixed with sucralose granules for each active study drug preparation. Study drug and placebo were prepared using identical capsules to maintain blinding. The investigators, patients, and treating provider remained blinded. Only the investigational drug pharmacist, who was not involved in the care of these patients, had the ability to unblind the study if necessary for patient safety.

Medical management of each patient was performed at the discretion of the treating provider. Data on therapeutic modalities, including the use of local anesthetic blocks, analgesics, and antibiotics, were gathered for each patient to allow for comparison between the dexamethasone and placebo groups. Termination from study enrollment occurred if the patient required dental extraction or pulpectomy during the 72-h follow-up period.

Baseline pain scores were obtained after physical examination using the 0–10 Numeric Pain Rating Scale (NPRS). Patient demographic characteristics were also collected at this time. A second pain score and data on treatment regimens used in the ED and any new outpatient prescriptions were obtained at time of discharge. Follow-up pain scores were then obtained at 12-, 24-, 48-, and 72-h intervals thereafter. For follow-up pain scores, telephone calls were made by study coordinators as close as possible to 12, 24, 48, and 72 h after discharge. If the follow-up phone calls were made beyond the 12-, 24-, 48-, and 72-h timeframe, patients were requested to recall their pain scores at the approximate time. During these calls, information was collected about further medical or dental care, analgesic use, and the occurrence of adverse effects. All patients were offered to have a $10 gift card sent to their home at time of the completion of

Statistical Anaysis

We considered a 2-point difference in the 11-point NPRS to be clinically meaningful (19). Assuming a standard deviation (SD) of 3, power of 80%, and two-sided alpha of .05, we estimated a sample size of 37 patients per treatment group would be necessary to detect this difference. Statistical analysis was performed using Stata software, version 16.0 (College Station, TX). A two-tailed alpha of .05 was used as the threshold of significance for all statistical testing. Chi-square testing was performed for continuous, parametric data and Wilcoxon-rank sum testing was used for categorical and nonparametric data.