Effect of Post-Operative Anesthetics on Post-Operative Pain in Patients Receiving Endodontic Treatment

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Study Protocol and Statistical Analysis Plan:

Participants: Participants were patients of the University of Washington School of Dentistry graduate endodontic clinic.

Exclusion and Inclusion Criteria: Exclusion criteria were the presence of any systemic diseases that precluded the administration of bupivacaine, lidocaine, or ibuprofen, pregnancy, and teeth that had periapical radiolucencies and a pulpal diagnosis of anything other than irreversible pulpitis. Inclusion criteria were healthy adults (18 years or older, ASA I or II), no contraindications to ibuprofen, mandibular posterior teeth with a pulpal diagnosis of irreversible pulpitis (symptomatic or asymptomatic, if pre-operative pain was present), and willing to undergo two-step nonsurgical root canal treatment.

Study Procedures: Patients were initially screened for inclusion and exclusion criteria at their consultation appointment at the University of Washington School of Dentistry graduate endodontic clinic. If the patient met the inclusion criteria, they were asked if they wanted to participate in the study. If they agreed to participate, the research consent forms were signed, and they were given a questionnaire prior to the start of their root canal treatment to rate the pain they were experiencing on a numerical rating scale. At the end of a root canal appointment, it is common to administer additional local anesthetic to keep the tooth numb for a period of time and in order to decrease the amount of post-operative pain a patient could experience even after the anesthetic wears off. However, there is no evidence that supports the use of one anesthetic solution over the other, which is what this study aims to find. Patients were randomized into either the Bupivacaine group (long-acting anesthetic) or Lidocaine (short-acting anesthetic) group. The patients were assigned a research number, which was used for the remainder of the study. The resident treating the patient reconfirmed the diagnosis of the tooth prior to the start of treatment and if the diagnosis changed (i.e.. if the tooth did not have pulpitis and the nerve was dead), the patient was not included in the study. Root canal treatment was initiated using routine root canal procedures, which includes local anesthetic to get the tooth numb and application of a dental dam for isolation. The root canal space was cleaned, and the inflamed nerve removed. An inter appointment medication was placed in the root canals and the root canal access (hole on the biting surface of the tooth) was restored with a temporary filling material to avoid food getting impacted into this space. Following this, the patient received the local anesthetic that they were randomly assigned to: 1 carpule (1.7 mL) of 0.5% Bupivicaine with 1:200,000 epinephrine (long-acting anesthetic), or 1 carpule (1.7 mL) of 2% Lidocaine with 1:100,000

epinephrine (short-acting anesthetic). The patient was handed the questionnaire (the one they used prior to the start of the appointment) and asked to rate their pain scale on a similar numerical scale at different time intervals after treatment (6, 12, 24, 48, 72 hours). This questionnaire/pain tracking form did not add any time to their root canal procedure, and took 5-10 minutes per day for the patient to fill out while at home in the 72 hours following treatment. The time and date were written on the questionnaire for each individual patient so they could remember to rate their pain at these intervals. The patients were also instructed to take 600 mg of Ibuprofen (Advil) every 6 hours for post-operative pain if needed and asked to document this (how many times a day, how many days) on the questionnaire. Patients were encouraged to track their post-operative pain levels. The patients were instructed to bring this questionnaire back with them when they came back to the clinic to get their root canal treatment completed. At the second treatment appointment, the questionnaire was collected from them and documented and the root canal treatment was completed at this appointment as it would be done for any patient not participating in the study.

Data Analysis: Data were analyzed using SigmaPlot (Grafiti LLC, Palo Alto, CA) for all statistical analyses. Intergroup comparisons were analyzed using a two-sample t-test, intragroup comparisons using a Wilcoxon signed-rank test, post-operative analgesic consumption comparisons using the Fisher Exact Test, and comparisons between male and female post-operative pain levels using the chi-square test.