## Predictive Model of Intraoperative Pain during Endodontic Treatment: Prospective Observational Clinical Study

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#### Abstract

Introduction: This observational study sought to assess the incidence of intraoperative pain (IOP) among patients receiving endodontic treatment and to construct a model for predicting the probability of IOP. Methods: All patients attending the endodontic training clinic at Gazi University, Ankara, Turkey, during the spring term of 2014 were examined (N = 2785 patients; observation completed in 1435 patients; male: 628, female: 807; mean age: 39 years; 1655 teeth total). Demographic and clinical variables were recorded for patients requiring primary endodontic treatment. Local anesthesia was administered and routine endodontic treatment commenced. After the working length was established, each patient was asked to report any pain according to a visual analog scale. Supplementary local infiltration anesthesia was administered if necessary. If pain continued despite supplementary anesthesia, then the pain score was immediately assessed. A visual analog scale score corresponding to more than mild pain indicated IOP. A predictive model was constructed with multiple logistic regression analysis from the data of 85% of cases, with the remaining 15% of cases being used to test the external validity of the model. Results: The incidence of IOP was 6.1% (101/1655 cases). One tooth from each patient was randomly selected, with 1435 teeth being retained for further analysis. A multiple logistic regression model was constructed with the variables age, tooth type, arc, pulpal diagnosis, pain present within the previous 24 hours, and anesthetic solution (P < .05). Good fits were obtained for the final model and external control, with a correct classification rate (efficiency) of 0.78, sensitivity (true positive rate) of 0.63, and specificity (true negative rate) of 0.79 for the external control. Conclusions: A successful predictive model of IOP was constructed with demographic and clinical variables. (J Endod 2016;42:36-41)

#### **Key Words**

Dental anesthesia, endodontics, forecasting, pain assessment, root canal therapy, root canal treatment

**P**ain is a common problem during root canal treatment and may occur despite adequate local anesthesia. In this context, the terms intraoperative pain (IOP), pain associated with treatment, pain during treatment, ineffective pain control, and anesthesia failure have been used interchangeably in the literature (1-7). Reasons for IOP during root canal treatment include anatomic variations, technical errors of anesthetic administration, defective solutions, patient anxiety, and inflammation (8). In cases of inflammation, IOP has been related to peripheral and central sensitization events presenting as increased responsiveness to a stimulus and lowered pain threshold, with accompanying changes in the neuronal phenotype (9, 10).

Few clinical studies have investigated the effects of demographic and clinical variables on the occurrence of IOP during dental treatment (1, 2, 4, 11) or, more specifically, during endodontic treatment (3-7). Those studies that have addressed these effects have found that the rate of patients experiencing moderate to severe pain during root canal treatment ranges from 12%-35% (3-7). Overall, most studies concluded that mandibular molars with inflamed pulp are the teeth at greatest risk of IOP during root canal treatment.

Knowing the probability of IOP before treatment would be beneficial in many ways. First, communication with the patient about the probability of pain before treatment would increase the confidence of the patient in the operator. Second, the dentist could use preventive measures such as giving a preoperative medication known to increase the local anesthetic efficacy (prophylactic analgesics or N<sub>2</sub>O/O<sub>2</sub> inhalation) (12, 13), increasing the volume of the anesthetic solution (14), selecting a more potent anesthetic solution, or administering supplementary anesthesia in advance (15, 16). Furthermore, patient schedule times could be organized to allow longer treatment periods for patients at risk of anesthetic failure.

To predict IOP before treatment, a forecast model must be developed on the basis of known patient data. Multiple logistic regression analyses allow models to be constructed by using 2 or more measurement variables (independent variables) to predict the probability of a categoric-dependent variable (ie, observation or not of IOP). Given this background, the aims of this study were to assess the incidence of IOP among patients receiving root canal treatment at a dental faculty clinic and to create a model for predicting the probability of IOP in endodontic patients on the basis of demographic and clinical factors associated with IOP during root canal treatment.

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### **Materials and Methods**

This prospective observational clinical study was approved by the Ethical Review Board of Keçiören Training and Research Hospital, Ankara, Turkey (B.10.4.ISM.4.06.68.49; February 12, 2014).

#### **Radiographic Calibration of the Observers**

Before clinical data were collected, 3 observers (G.K., M.G., and E.S.) were calibrated to the periapical index (PAI; visual material kindly provided by Dr Dag Ørstavik). The PAI is a 5-score ordinal scale with descriptors ranging from "healthy" to "severe periodontitis with exacerbating features" in which scores 1 and 2 represent healthy periapical status and scores 3 to 5 represent diseased status (17). Cohen kappa  $(\kappa)$  values of the observers with respect to the true scores (G.K.: 0.66, M.G.: 0.74, and E.S.: 0.65) indicated substantial agreement with the reference values (18). Using the PAI as a reference, the observers independently examined 104 digital radiographs obtained on 5 consecutive clinical days. Periapical status was dichotomized as "healthy" or "diseased." The interobserver agreement  $\kappa$  value (Fleiss'  $\kappa$ ) was 0.78 (>0.75 indicates excellent agreement beyond chance) (19). At least 6 weeks after the first rating, the examiners performed a second rating of 50 randomly selected radiographs. The intraobserver agreement k values (G.K.: 1.00, M.G.: 0.92, and E.S.: 0.80) indicated substantial to almost perfect agreement. Thus, the investigators were considered to be authorized for assessing the study material.

#### **Terminology and Standards**

The pulpal and periapical diagnostic terminologies used in this article are in accordance with the 2012 edition of the American Association of Endodontists' *Glossary of Endodontic Terms* (20). For pulpal diagnosis, the terms normal pulp, reversible pulpitis, irreversible pulpitis (including both symptomatic and asymptomatic forms), and necrotic pulp (not found in the mentioned glossary) were used. Pulpal vitality was characterized on the basis of direct clinical observations; if bleeding was observed from tissue within the pulp chamber or root canal, then the pulp was considered to be vital (21). For periapical diagnosis, the terms normal apical tissue, symptomatic apical periodontitis, asymptomatic apical abscess, and chronic apical abscess were used. For diagnostic accuracy, the investigators reviewed the definitions of these terms and discussed clinical cases before the study.

In the medical anamnesis, which was similar to a previous study, health status was defined either as good or not good (22). The latter category included patients with allergies, chronic infectious diseases, or systemic conditions.

The anesthetic protocol followed the anesthetic administration guidelines of the Department of Endodontics of the Faculty of Dentistry at Gazi University, Ankara, Turkey (23). The protocol included administration of a local infiltration for all maxillary teeth and mandibular incisors (1-2 mL) and administration of regional anesthesia for the remaining mandibular teeth (inferior alveolar nerve block or mental nerve block, 1.5-2 mL). In cases in which the anesthesia was insufficient, supplementary buccal (1 mL) and lingual (1 mL) or palatinal (0.2 mL) local infiltrations were given. If the supplementary anesthesia was still insufficient, then intraligamentary anesthesia and intrapulpal anesthesia were administered. Techniques not mentioned in the guide-line (ie, posterior superior alveolar nerve block and infraorbital nerve block) were also used when swelling caused by an acute apical abscess made local infiltration impractical.

Pain was quantified by using the Heft-Parker visual analog scale (VAS), a 170-mm line with no marks on it. The scale was divided into 4 categories: no pain (0 mm), mild pain (0.1–54 mm), moderate pain (54.1-113.9 mm), and severe pain ( $\geq 114$  mm) (24).

#### **Clinical Setting and Patients**

The study was performed at the Dental Student Training Clinic of the Department of Endodontics of the Faculty of Dentistry at Gazi University during the spring term (February 17–May 23, 2014; 67 clinical days). The clinic contained 13 dental units. Patients were scheduled for treatment 36 to 42 days before the visit. Emergency patients were accepted without appointment. All treatments were performed by dental students (hereinafter, "operators") in their 4th and 5th years of study under the supervision of clinical instructors.

#### **Patient Inclusion and Exclusion Criteria**

Patients requiring primary root canal treatment were included in this study if they were able to communicate and give informed consent and were at least 18 years old. Exclusion criteria were patients being seen for retreatment or previously initiated root canal treatment as well as teeth with a history of pulpal amputation or replantation, teeth requiring conservative pulp treatment (ie, pulp capping), or teeth with endodontic-periodontic lesions. A patient was also excluded if he or she had multiple teeth requiring root canal treatment but could not differentiate the source or history of pain, if he or she had a fixed bridge prosthesis that could not be removed, or if the tooth was already anesthetized at the time the patient was admitted for treatment.

#### **Study Protocol**

The investigators of this study were clinic instructors. At least 1 investigator was present in the clinic throughout the study period. The investigators actively participated in the examination of patients and radiographs. Routine methods were used during examination (electric pulp test, thermal tests, percussion, and so on). For each patient, a set of demographic and clinical variables was recorded including age (years), sex (male/female), health status (good/not good), pulpal and periapical diagnosis (classification mentioned above), whether pain was present within the previous 24 hours (yes/no), whether the patient had taken analgesic for toothache within the previous 24 hours (yes/no/yes but for other reasons).

Anesthesia was always administered by the clinic instructor. A 2-mL dental syringe and 27-G needle were used for injection. The anesthetic solution was 4% articaine hydrochloride with 1:200,000 epinephrine (2-mL ampule [Maxicaine, VEM, Ankara, Turkey]). Anesthetic without epinephrine was administered in cases of cardiovascular or thyroid problems after consultation with a physician (3% mepivacaine hydrochloride, 2-mL ampule; Safecaine, VEM). Traditional methods were used for confirming anesthesia. These involved questioning the patient ("Is your lip numb?") and soft tissue testing (lack of mucosal responsiveness to a sharp explorer). After injection, the patient was asked to inform the operator if he or she felt pain during treatment. The operator also was asked to inform the investigator if the patient reported pain during treatment.

The patient was asked to rate his or her pain after the working length (WL) was established. If the patient complained of pain before the WL was established, then the numbness was checked followed by administration of supplementary local infiltration anesthesia. These patients were asked to rate their pain again as soon as the WL was established (specifically, the pain experienced after supplementary anesthesia). If the pain persisted despite supplementary anesthesia, then the observation was terminated, the patient was asked to rate the pain, and intraligamentary and intrapulpal anesthesia were administered before continuing treatment. A VAS score greater than 54 indicated that the anesthesia was unsuccessful, and the patient was recorded as having IOP (VAS score 0-54: code 0, >54: code 1).

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