Postoperative Pain after the Application of Two Different Irrigation Devices in a Prospective Randomized Clinical Trial

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Abstract

Introduction: The extrusion of irrigation solutions beyond the apical constriction may result in postoperative pain. Sodium hypochlorite can cause severe tissue irritation and necrosis outside the root canal system if extruded into the periodontal ligament (PDL) space. Different delivery techniques were discussed to reduce this potential risk. The aim of this study was to compare the postoperative level of pain after root canal therapy using either endodontic needle irrigation or a negative apical pressure device. **Material and Methods:** In a prospective randomized clinical trial, 110 asymptomatic single-rooted anterior and premolar teeth were treated endodontically with two different irrigation techniques. The teeth were randomly assigned to two groups. In the MP group ($n = 55$), procedures were performed using an endodontic irrigating syringe (Max-i-Probe; Dentsply Rinn, Elgin, IL). The EV group ($n = 55$) used an irrigation device based on negative apical pressure (EndoVac; Discus Dental, Culver City, CA). Postoperatively, the patients were prescribed ibuprofen 200 mg to take every 8 hours if required. Pain levels were assessed by an analog scale questionnaire after 4, 24, and 48 hours. The amount of ibuprofen taken was recorded at the same time intervals. **Results:** During the 0- to 4-, 4- to 24-, and 24- to 48-hour intervals after treatment, the pain experience with the negative apical pressure device was significantly lower than when using the needle irrigation ($p < 0.0001$ [4, 24, 48 hours]). Between 0 and 4 and 4 and 24 hours, the intake of analgesics was significantly lower in the group treated by the negative apical pressure device ($p < 0.0001$ [0-4 hours], $p = 0.001$ [4-24 hours]). The difference for the 24- to 48-hour period was not statistically different ($p = 0.08$). The Pearson correlation coefficient revealed a strongly positive and significant relationship for the MP group ($r = 0.851$, $p < 0.001$) and the EV group ($r = 0.596$, $p < 0.0001$) between pain intensity and the amount of analgesics. **Conclusion:** The outcome of this investigation indicates that the use of a negative apical pressure irrigation device can result in

a significant reduction of postoperative pain levels in comparison to conventional needle irrigation. (*J Endod* 2010;36:1295–1301)

Key Words

EndoVac, irrigation, negative apical pressure, postoperative pain

Postoperative pain is an unwanted yet unfortunately common sensation after endodontic treatment. The incidence of postoperative pain was reported to range from 3% to 58% (1). Even severe pain may occur within 24 to 48 hours after therapy (2). After the treatment was finished, 12% of patients experienced severe pain within this time interval according to a visual analog scale (VAS) (2). The factors for postoperative pain are many-fold and can include microbial factors, the effects of chemical mediators, phenomena related to the immune system, cyclic nucleotide changes, psychological factors, and changes in the local adaptation and the periapical tissue pressure (3). Irritants to the periapical tissues that can evoke pain sensation include medications or irrigating solutions (3).

Antimicrobial debridement is a key step in root canal therapy. Bacteria play a primary role in the development of pulp necrosis, periapical pathosis, and posttreatment disease (4). Mechanical instrumentation alone is not enough to render canals free from microorganisms (5). Several studies have proven the effectiveness of sodium hypochlorite for bacterial reduction in addition to mechanical cleaning and shaping (6). Other irrigants with similar antimicrobial effects include chlorhexidine (7) and MTAD (8). Only sodium hypochlorite, however, has also proven highly effective in tissue dissolution (9) and the removal of bacterial biofilm (10). Because tissue dissolution is a prerequisite for antimicrobial action (11), sodium hypochlorite is considered the most important antimicrobial irrigant in root canal therapy (9). Sodium hypochlorite works because of its ability to hydrolyze and oxidize cell proteins, its release of free chlorine, and its pH of 11 to 12 (7).

Because of the strong cell toxicity, an associated risk with the use of sodium hypochlorite is the inadvertent injection into the periapical tissues through the apical constriction of the root canal, leading to severe, painful postoperative complications. Sodium hypochlorite accidents have been reported in the literature (12). Teeth with wide open foramina or with apical constrictions damaged by resorptive processes or by iatrogenic errors during instrumentation are at an elevated risk for the extrusion of sodium hypochlorite (13). Moreover, if excessive pressure is used during irrigation or the irrigation needle is bound within the root canal and prevents the safe coronal outflow of the solution, large quantities of sodium hypochlorite may be pushed out into the periapical tissues and subsequently lead to tissue necrosis and postoperative pain (13). This causes a dilemma because it is known that a high volume and frequency

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of irrigation (14) as well as the ability to reach the apical intraradicular tissues (15) are necessary for effective disinfection.

To prevent periapical tissue damage and lessen postoperative pain, a safe irrigation delivery system is desirable. Commonly, hypodermic or endodontic needles are used for irrigation. Recently, a new irrigation system, the EndoVac system (Discus Dental, Culver City, CA), was introduced to endodontics. Conventional irrigation works with positive pressure to flush the disinfecting solution into the root canal and force the irrigant out again coronally by displacement with new volumes of solution. The EndoVac system works with negative pressure. A detailed design and working mechanism have been described before (16). Briefly, an irrigation tip is attached to a conventional medical syringe containing the solution. Through this tip, irrigant is released into the pulp chamber. Overflow is prevented by a suction tip that is directly attached to the delivery tip and connects to the high-speed suction of the dental unit. A second tube, connected to the high-speed suction, is used for the attachment of cannulas of varying diameter for different levels of irrigation within the root canal. A stainless steel microcannula of size #32 with 12 small, lateral holes is used for the apical 0 to 3 mm. The tip is inserted to the working length and provides a constant flow of new irrigation solution to the apical third by sucking it apically from the fresh reservoir in the pulp chamber and disposing the used solution through the evacuation tube toward the high-speed suction of the dental unit.

In three recent *in vitro* studies, the EndoVac system showed significantly better apical debridement (17) and an equal performance in antimicrobial disinfection (18, 19) in single straight canals when compared with other irrigation techniques. Yet, no literature exists claiming whether the irrigation with a negative apical pressure device provides more or less favorable results in terms of postoperative pain when compared with positive-pressure irrigation protocols. The purpose of this study was to evaluate and compare the postoperative pain after the use of two different irrigation protocols.

Materials and Methods

In this prospective randomized clinical trial, single-visit root canal treatments were performed. A questionnaire was given to the participants to note the amount of analgesics taken postoperatively as well as the intensity of pain. A pain scale frequently used for medical studies, the CR10 Borg list (20), was implemented to quantify the participants' individual pain experience.

Patient Selection

Eighty volunteer patients with 110 teeth fitting the inclusion criteria described later were included in this study. All patients were treated by a single operator in a private practice specializing in endodontics over a period of 25 months. Only single-rooted teeth with one canal were selected for this investigation. Diagnoses were either asymptomatic irreversible pulpitis caused by carious exposures or normal pulp if the patient had been referred for intentional endodontic therapy for prosthetic reasons. The individual diagnosis was confirmed by obtaining the dental history, periradicular radiographs, periodontal evaluation, percussion, and cold test (EndoIce; Coltène/Whaledent Inc, Cuyahoga Falls, OH). The diagnostic findings were verified by comparing them with adjacent sound teeth with vital pulps. Only patients who had a noncontributory medical history and did not take analgesic medication at the initiation of the root canal treatment were asked to participate in the study. The treatment and the study design were explained to the qualifying patients. Patients were informed that participation was voluntary and did not affect the treatment. All patients who agreed to participate in this study signed an informed consent. Although the patients

were informed which irrigation devices were used in general, there was no information for the participant which system was used for the particular treatment.

Randomized Selection of Irrigation Device

The goal of the study was 100 patients, with at least 50 procedures in each group. In order to compensate for a possible dropout rate of 10%, the prospective sample size for each group was set at 55. To ensure randomization of the process, 55 red and 55 green chips were placed in a bag at the beginning of the investigation. Before each treatment, a dental assistant of the operator randomly determined the irrigation device by taking out one of the colored chips without replacement until all 110 procedures had been performed. The assistant could not see the color of the chip before it was removed from the bag. Group MP (red) was assigned for treatment with a conventional endodontic needle syringe (Max-i-Probe 30G; Dentsply Rinn, Elgin, IL). Group EV (green) received treatment with the negative-pressure device (EndoVac).

Endodontic Protocol

All patients received a topical anesthetic (Benzotop; DFL, Rio de Janeiro, Brazil) before infiltration. Local anesthesia was achieved by local infiltration with 3.6 mL of lidocaine with 1:100,000 epinephrine (Alphacaine, DFL). After anesthesia, a rubber dam was placed and disinfected with 3% hydrogen peroxide, and the tooth was accessed using sterile carbide burs under a dental operating microscope. In cases with deep carious lesions, the main decay was excavated before accessing the pulp to prevent the introduction of microorganisms into the root canal system. A glide path was established with stainless steel hand instruments up to a size #15. The canal was instrumented with Gates Glidden burs #4, #3, and #2 (Dentsply Maillefer, Ballaigues, Switzerland) followed by nickel-titanium rotary instruments (ProTaper; Dentsply Tulsa, Johnson City, TN). Patency was established and verified with #10 files. The working length to the apical constriction was confirmed by an electronic apex locator (Root ZX; Morita, Irvine, CA) and periapical radiographs. The established working length was checked repeatedly throughout the procedure. Depending on the individual tooth, the final instrumentation size was determined as three sizes larger than the first file binding at the working length. Final preparation ended either with ProTaper F3, F4, F5, or F5 plus additional apical enlargement with nickel-titanium hand instruments to size #60. A smaller taper #35 ISO nickel-titanium hand instrument was used for the F3 preparations in group EV to verify free access to the full working length for the microcannula. All teeth were obturated in the same session using gutta-percha with warm vertical compaction in the continuous wave technique (System B; Sybron Endo, Orange, CA) and a gutta-percha backfill (Obtura II; Obtura Spartan, Earth City, MO). Depending on whether a post placement was planned by the referring dentist, the tooth was either temporized using a sterile cotton pellet and Cavit (3M, St Paul, MN) or a direct adhesive buildup with a composite resin material (P60 Singlebond, 3M). After the treatment, all patients received postoperative instructions and eight tablets of ibuprofen 200 mg with the instructions to take only one tablet if it was needed within the 0- to 4-hour time interval after the treatment and then one every 8 hours in the event of pain.

Irrigation Protocols

All teeth received the same volume of irrigants. Altogether, 130 mL 2.5% sodium hypochlorite (Formula & Acao, Sao Paulo, Brazil) and 10 mL EDTA 17% (Formula & Acao) were used. For both groups, the sodium hypochlorite was held in and dispensed from a mechanical syringe pump (Aladdin Pump; World Precision Instruments, Sarasota, FL) providing a constant flow. Twenty milliliters of sodium hypochlorite

were used during access and initial coronal instrumentation for both protocols. Ten milliliters of sodium hypochlorite followed after every use of a rotary instrument. Twenty milliliters were reserved for the final flush after EDTA application. The remainder of the 130 mL was used up after the final preparation of the root canal space. In group MP, all irrigation was performed with the 30-G Max-i-Probe needle up to 2 mm short of the final working length, which was verified by rubber stops. In group EV various tips of the EndoVac system were used following the manufacturer's recommendation. An EndoVac Master Delivery Tip was applied for the initial irrigation followed by a macrocannula in a pecking motion during the main instrumentation and a microcannula for the final irrigation with EDTA and sodium hypochlorite. The insertion of the EndoVac microcannula was to the working length of the prepared root canal space. During the treatment, patients were prevented from seeing the irrigation device.

Patient Questionnaire

All participants received a questionnaire for the evaluation of pain and the frequency of analgesic use for each root canal procedure at 4, 24, and 48 hours after the endodontic treatment was completed. After 48 hours, the participants were called by telephone and asked for the answers to the questionnaire that they had to note on the form. The person calling was blinded to the irrigation device that was used during the treatment of the particular patient. The participants were asked about their general feeling in the area of the root canal, with options for feeling generally fine, slightly uncomfortable, having pain on chewing, or constant severe pain. The second question recorded the number of ibuprofen pills that had been taken by the patient up until this point. Furthermore, after 4, 24, and 48 hours, the pain intensity was also recorded using the CR10 Borg list or Borg scale. The participants labeled the intensity of pain by a numeric and verbal scale. Level 10, "extremely strong," represented the strongest pain the participant had ever experienced. The participant then verbally expressed the level of discomfort by choosing a number in comparison to level 10 pain and quantified the pain using the following values: level 0, "absolutely nothing"; level 1, "very weak"; level 2, "weak (light)"; level 3, "moderate"; level 4, "somewhat strong"; levels 5 and 6, "strong (heavy)"; levels 7 to 9, "very strong"; and level 10, "extremely strong, maximum pain." The participants also had the option to note other sensations. All participants were instructed to immediately contact the office or the emergency number in case the analgesics protocol did not provide pain relief or any other emergency occurred.

Statistical Analysis

Descriptive analysis, means, and standard deviations were calculated using SPSS 15.0 for Windows (SPSS, Chicago, IL). The nonpara-

metric Mann-Whitney *U* test ($p = 0.05$) and Pearson correlation coefficient ($p = 0.05$) were used for statistical analysis.

Results

All 110 questionnaires were obtained and evaluated by statistical analysis. The patients' age ranged from 16 to 89 years, with a median age of 48 years. Of a total of 80 patients, 46 were female and 34 were male. Table 1 shows the population distribution according to group MP and group EV. There were 15 lateral and central incisors and 40 canines and premolars (of which 21 were in the maxilla and 19 in the mandible) in group MP. Group EV had 17 lateral and central incisors and 38 canines and premolars (with 19 each in maxilla and mandible). In group MP, 22 teeth (40%) were treated for dental decay and 33 teeth (60%) for prosthodontic reasons. Fourteen teeth (25.5%) in group EV were treated because of decay, and 41 teeth (74.5%) were treated intentionally for prosthodontics. The difference in this ratio is explained by the random assignment of teeth. The distribution of final apical preparation dimensions were ProTaper F3 ($n = 10$), F4 ($n = 25$), F5 ($n = 13$), and F5 plus hand instrument 60, 0.02 ($n = 7$) for group MP and F3 ($n = 15$), F4 ($n = 28$), F5 ($n = 9$), and F5 plus hand instrument 60, 0.02 ($n = 3$) for group EV. The difference in the distribution was a result of the random allocation of teeth and the individual root canal morphology. After the 0- to 4-hour interval, two patients reported to have taken two ibuprofen 200 mg instead of one. No patient contacted the office to change the analgesic protocol or because of an emergency situation.

Pain Levels

Table 2 describes the minimum and maximum pain that was experienced by the participants as well as the statistical analysis of the patients' pain levels. For both groups, some patients did not experience any pain or did not take any analgesic medication, regardless of the time interval after treatment. In group MP, the maximum pain intensity described by one patient was 7 within the 0- to 4-hour time interval after treatment. For group EV, the maximum pain intensity was 3 consistently for all three time intervals. The maximum pain in group MP decreased over time. For both groups, the maximum pain values became more consistent over time. For group MP, 34.5% of the patients ($n = 19$) felt no pain during the 0- to 4-hour time interval, 10.9% ($n = 6$) felt 1 of 10, 27.3% ($n = 15$) felt 2 of 10 (weak) pain, and only 9.1% ($n = 5$) felt strong to very strong pain. In group EV, 94.5% of the patients ($n = 52$) felt no to weak pain. Only 5.5% ($n = 3$) reported moderate pain up to 4 hours. Within the 4- to 24-hour time period, the maximum pain intensity in group MP decreased to 5 of 10 (strong) in 3.6% of the patients ($n = 2$); during the 24- to 48-hour time interval, all patients experienced no pain or only weak pain levels. Between 24 and 48

TABLE 1. Descriptive Analysis of Patient Distribution, Minimum and Maximum Pain Levels, and Number of Analgesic Pills

Method	Min	Max	Median	SD
Group A	Age	16	49.80	15.65
	Pain 4 h	0	1.72	1.75
	Pain 24 h	0	1.45	1.42
	Pain 48 h	0	0.50	0.68
Maxi 1 Probe	Analgesics 4 h	0	0.49	0.57
	Analgesics 24 h	0	0.38	0.65
	Analgesics 48 h	0	0.05	0.22
	Age	17	46.95	12.90
Group B	Pain 4 h	0	0.39	0.82
	Pain 24 h	0	0.31	0.66
	Pain 48 h	0	0.18	0.64
	Analgesics 4 h	0	0.09	0.29
EndoVac	Analgesics 24 h	0	0.05	0.22
	Analgesics 48 h	0	0.00	0.00

TABLE 2. Pain Intensity Distribution During 0- to 4-, 4- to 24-, and 24- to 48-Hour Time Intervals

Pain intensity distribution	0-4 h				4-24 h				24-48 hrs			
	Method	Intensity	Frequency	Valid percent	Cumulative percent	Frequency	Valid percent	Cumulative percent	Frequency	Valid Percent	Cumulative Percent	
Group A		0	19	34.5	34.5	18	32.7	32.7	33	60.0	60.0	
		1	6	10.9	45.5	14	25.5	58.2	16	29.1	89.1	
		2	15	27.3	72.7	11	20.0	78.2	6	10.9	100.0	
		3	9	16.3	89.1	6	10.9	89.1	-	-	-	
		4	1	1.8	90.9	4	7.3	96.4	-	-	-	
		5	2	3.6	94.5	2	3.6	100.0	-	-	-	
		6	2	3.6	98.2	-	-	-	-	-	-	
Maxi 1 Probe		7	1	1.8	100.0	-	-	-	-	-	-	
	Total		55	100.0		55	100.0		55	100.0		
		0	42	76.4	76.4	43	78.2	78.2	0	50	90.9	
		1	7	12.7	89.1	8	14.5	92.7	1	2	93.8	
		2	3	5.5	94.5	3	5.5	98.2	2	1	95.9	
		3	3	5.5	100.0	1	1.8	100.0	3	2	97.9	
	Total		55	100.0		55	100.0		55	100.0		
p value (Mann-Whitney test)												
				p < 0.0001 *				p < 0.0001 *				

*Statistically significant.

hours, respectively, one (1.8%) and two (3.6%) patients in group EV experienced still moderate pain (3/10).

Pain intensity and analgesic intake were compared in regard to the time intervals. A normal distribution for pain intensity and analgesic intake was not accepted for statistical analysis; therefore, the Mann-Whitney *U* test for independent samples was applied at a significance level of 5%. For pain intensity, differences between the MP and EV groups were statistically significant with $p < 0.0001$ at all time intervals, with greater pain intensity in the MP group.

Independent from the individual time intervals, the overall pain intensity was less in the EV group than in the MP group. The median pain intensity was 1.22 (standard deviation = 1.06) in the MP group and 0.29 (standard deviation = 0.56) in the EV group. The Mann-Whitney *U* test revealed a statistically significant difference between the median pain intensity depending on the irrigation protocol. There was significantly less overall pain associated with the treatment in the EV group (EndoVac, $p < 0.0001$).

Analgesic Intake

Table 3 gives a detailed overview of the patients' intake of analgesics in the number of pills and statistical analysis. The maximum intake of analgesic medication was higher in the MP group than the EV group for all time intervals. In group MP, two patients (3.6%) took two pills within the first 4 hours after treatment. Both patients had reported 6 of 10 (strong) pain intensity for this time interval. These two participants were not excluded from the statistical analysis. The patients did not change the drug and followed the analgesic protocol in the following two time intervals. Also, it would more likely influence the validity of the results if patients who recorded pain were excluded from an analysis of occurrence and intensity of pain because they experienced more discomfort than other participants. For both groups, the consumption of analgesics decreased with time. In group MP, a total of 27 pills were taken within the 0- to 4-hour time interval, 21 between 4 and 24 hours, and only 3 between 24 and 48 hours. In the EV group, five patients took one pill within 4 hours after treatment and three between 4 and 24 hours. No patient in this group required pain medication during the 24- to 48-hour time interval.

The Mann-Whitney *U* test for independent samples showed that between 0 and 4 hours the number of pills consumed was significantly lower in the EV group with $p < 0.0001$ and $p < 0.001$ between 4 and 24 hours after treatment. There was no statistically significant difference in analgesic intake during the 24- to 48-hour interval between both groups ($p = 0.08$).

Independent from the individual time intervals, the overall number of analgesic pills was less in the EV group than in the MP group. The median consumption was 0.30 pills (standard deviation = 0.37) in the MP group and 0.04 pills (standard deviation = 0.13) in the EV group. The Mann-Whitney *U* test revealed a statistically significant difference between the median number of pills taken by the participants. The number of analgesics taken was significantly higher in the MP group ($p < 0.0001$).

Correlation of Median Pain Intensity with the Median Number of Pills

Calculation of the Pearson correlation coefficient for the measure of dependence between two variables revealed a strong positive and significant relationship ($r = 0.851$, $p < 0.001$) for pain intensity and the number of pills for the MP group (Fig. 1) and also a positive and significant correlation ($r = 0.596$, $p < 0.0001$) between the variables of pain and analgesics for the EV group (Fig. 2).

TABLE 3. Analgesic Intake Distribution During 0- to 4-, 4- to 24-, and 24- to 48-Hour Time Intervals

Analgesic intake distribution			0-4 h			4-24 h			24 - 48 hrs		
Method	Number of pills		Frequency	Valid percent	Cumulative percent	Frequency	Valid Percent	Cumulative Percent	Frequency	Valid Percent	Cumulative Percent
Group A Maxi I Probe	0		30	54.5	54.5	39	70.9	70.9	52	94.5	94.5
	1		23	41.8	96.4	11	20.0	90.9	3	5.5	100.0
	2		2	3.6	100.0	5	9.1	100.0	-	-	-
Group B	Total		55	100.0		55	100.0		55	100.0	
	0		50	90.9	90.9	52	94.5	94.5	55	100.0	100.0
	1		5	9.1	100.0	3	5.5	100.0	-	-	-
EndoVac	Total		55	100.0		55	100.0		55	100.0	
p value (Mann-Whitney test)				p < 0.0001 *			p < 0.001 *			p = 0.08 *	

*Statistically significant.

Discussion

The purpose of this study was to compare the differences in postoperative pain after endodontic therapy after using two different irrigation techniques. Mild discomfort after root canal treatment is a common experience for patients (21). The reasons for postoperative pain, however, can be many (22). The main causes are mechanical, chemical, or microbial injuries to the periapical tissues that result in acute inflammation (23). In a clinical investigation, it is difficult to determine if a single or multiple factors elicit pain. If a root canal system was not cleaned properly, residual infection may cause exacerbation by imbalances in the host-bacteria relationship, synergistic or additive microbial interactions, or the presence of decisively pathogenic bacteria before the initiation of treatment (23). A mechanical reason may be overinstrumentation; chemical factors include the extrusion of medications, filling materials, or irrigants (23).

In the present study, great care was taken to rule out avoidable preoperative factors and to minimize any unavoidable causes of postoperative pain. Teeth with apical periodontitis, necrotic teeth, or retreatment cases were not incorporated, and a meticulous aseptic protocol was maintained to reduce the risk of exacerbation by residual microorganisms or the introduction of bacterial contamination. Therefore, only teeth with the diagnosis of irreversible pulpitis or normal pulp were treated. The study was also limited to asymptomatic teeth because preoperative pain is one of the most predictable indicators for postoperative pain (24). Only teeth in which a single canal could be found under the microscope were incorporated to minimize the risk of iatrogenic errors because of missed or complicated root canal anatomy and to make sure the same amount of irrigation solution would pass by each canal. All teeth were instrumented and obturated in one session to eliminate intracanal medication as another possible factor for postoperative flareup. Furthermore, only patients without a contributing medical history who did not take analgesic medication recently were included so that no other pain source or drug interaction could interfere with pain resulting from the endodontic therapy.

Even with all the precautions taken, one cannot be sure in a clinical study if pain is coming from the single factor under investigation. All possible sources of pain can never be controlled completely. Therefore, under the particular circumstances of our study, postoperative pain may have been related to apical trauma because of overinstrumentation or extrusion of debris, sealer, or gutta-percha rather than sodium hypochlorite. Bacteria may have been introduced from decay, canal anatomy may have been missed, the soft tissues may have been hurt because of the application of the rubberdam or injection, or the patient may have developed unrelated orofacial pain. Taking into consideration that all patients underwent the same treatment protocol, with the only difference being the irrigation technique, the highly statistically significant outcome and the strong correlation of pain and analgesic intake allow the conclusion that, indeed, the particular irrigation protocol had significant impact on the level and time of postoperative pain.

In general, the pain levels the patients experienced in our investigation were very low, with only 12 of 330 (3.6%) total reports exceeding moderate pain, including one single report of very strong pain. No patient reported any other symptoms or complications like swelling or paresthesia. All these facts underline the level of care that was given to provide an atraumatic treatment protocol. However, when all forms of pain were considered, ranging from level 1 (very weak) to level 5 (strong), 44.5% of all treatment were associated with pain during the 4- to 24-hour time period. Of these, 67.3% were in group MP and 21.8% were associated with group EV. Other studies showed pain levels between 12 and 24 hours to be between 7.1% and 7.8% for teeth with no preoperative history of pain, respectively, treatment of vital pulps (20).

Figure 1. The correlation of median pain intensity with the median number of pills in the MP group (Max-i-Probe).

The difference here may lie in the use of different pain scales. A frequently used scale for the evaluation of dental pain is the visual analog scale (VAS) (24, 25). The reliability of the VAS as a measure of pain intensity for patients postoperatively with mild to moderate pain has been shown (26). The VAS ranks pain by a visual scale from 0 to 100. Commonly, these values are transferred to four intensity levels for pain: none (level 1), mild (level 2), moderate (level 3), and severe pain (level 4) (26). Although in this investigation the highest reported values were 7 of 10 and 6 of 10 (once and twice out of 110 reports) after 4 hours and 5 of 10 (twice out of 110 reports) after 24 hours according to the Borg scale, 4 of 4 referring to the VAS is a rather frequently reported value in studies on postoperative pain (22, 25). The choice of the Borg scale for the evaluation of pain in our study provided good results for statistical analysis. The Borg scale evaluates pain in 10 full steps yet is theoretically open ended. It was argued that when intermediate levels are too small, differences between groups might be statistically significant, but the results may not be clinically significant (27). A benefit of the Borg scale, however, is that strong pain (levels 5-6) is covered by two and very strong pain

Figure 2. The correlation of median pain intensity with the median number of pills in the EV group.

(levels 7-9) by three levels, which is supposed to address the logarithmic increase of pain sensation (20). The relatively low dose of ibuprofen 200 mg was chosen to allow a better measure of analgesic intake. High doses may have obscured the outcome, especially with the very low pain levels created by our endodontic treatment protocol in general.

The results that the irrigation protocol in the EV group resulted in less postoperative pain intensity and analgesic intake may fit with other findings. It was found that the use of the EndoVac system did not (28) or significantly less (29) result in the apical extrusion of irrigant; hence, chemical irritation of the periapical tissues leading to postoperative pain may not be likely. Because the majority of root canal irrigants are cytotoxic to the periapical tissues, the irrigation solution should be restricted to within the root canal system. In our study, both techniques were either used according to the manufacturer's recommendations or, if not available, according to the common protocol (28). To be safe, irrigation with Max-i-Probe was 2 mm from the working length, which is within the range of 1.5 to 3.0 mm used in comparable studies with Max-i-Probe or identical irrigation needles (17, 19, 28, 30, 31), whereas the EndoVac negative apical pressure tip was routinely used all the way to the working length (0 mm), thus fulfilling the claim for direct irrigation in the apical third (15).

In conclusion, the negative apical pressure irrigation system EndoVac resulted in significantly less postoperative pain and necessity for analgesic medication than a conventional needle irrigation protocol using the Max-i-Probe. From the results of this study, it may be assumed that it is safe to use a negative apical pressure irrigation protocol for antimicrobial debridement up to the full working length.

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