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Effect of Topical Application of Dentol Drop on the Success of Inferior Alveolar Nerve Block for Teeth with Irreversible Pulpitis: A Double-blind Randomized Clinical Trial

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ABSTRACT

Introduction: The failure rate of inferior alveolar nerve (IAN) block is high for mandibular molars with irreversible pulpitis. This double-blind, randomized, clinical trial aimed to assess the effect of topical application of Dentol drop on the rate of successful anaesthesia of mandibular molars with irreversible pulpitis due to deep carious lesions. **Methods and Materials:** Seventy-two patients with mandibular first and second molars with irreversible pulpitis and deep cavitated carious lesions participated in this study. The patients were randomly assigned to the test and control groups (n=36). In the test group, a cotton pellet, dipped in Dentol drop, was placed in the cavity for 10 min. A placebo was used _in the same manner_ in the control group. Level of pain was measured before the intervention, 15 min after anaesthesia (when patients reported numbness at the corner of the mouth), during access cavity preparation, upon pulp exposure and after introduction of the initial file into the root canal; using a Heft-Parker "Visual Analog Scale" (VAS). Data were analysed using ANCOVA. **Results:** Levels of pain were recorded during access cavity preparation (P<0.001), pulp exposure (P<0.001) and file introduction into the canal (P=0.018). In the test (Dentol) group, the obtained levels of pain were significantly lower than those of the corresponding values in the control group. **Conclusion:** Topical application of Dentol drop increased the success rate of IAN block for root canal treatment of mandibular molars with irreversible pulpitis.

Keywords: Dentol Drop; Inferior Alveolar Nerve Block; Irreversible Pulpitis

Introduction

Numerous investigations have studied various aspects of reduced pain during dental procedures [1-7]. A successful local anaesthesia is imperative for root canal treatment. However, achieving a 100% successful local anaesthesia is not always feasible, and local anaesthetic agents are less effective for anaesthesia of teeth with irreversible pulpitis; especially symptomatic mandibular molars [1, 8]. Rate of anaesthesia failure in inflamed teeth is eight times higher than that for non-inflamed teeth [9].

Local anaesthesia of mandibular posterior teeth is administered *via* inferior alveolar nerve (IAN) block. However, the IAN block is not always successful. For instance, the nerve sheath may prevent efficient distribution of the anaesthetic agent towards the nerve trunk [10]. Decreased success rate of anaesthesia in teeth with inflamed pulp may be owing to the activation of pain receptors by inflammation [8]. It has been demonstrated that use of different anaesthetic agents such as articaine, bupivacaine and prilocaine [11] and also different anaesthetic techniques such as Gow-Gates and Akinozi

techniques do not make any difference in the success rate of pulpal anaesthesia in mandibular teeth [12, 13]. The IAN block alone is not effective in 30 to 80 percent of patients with irreversible pulpitis [14]. Clinically, this problem is often resolved by supplemental injections such as buccal infiltration, intrapulpal, intra-osseous and intraligamentary injections. Evidence indicates that the buccal infiltration anaesthesia is efficient for pulpal anaesthesia of mandibular first molars [2, 15, 16]. Although, this method cannot be done for the second and third molars due to increase in the thickness of buccal bone plate. Intrapulpal injection is often administered when patients feel pain and discomfort during pulp exposure. However, this technique is highly painful [16, 17]. Failure of IAN block may be related to various factors. One theory explains that the high failure rate of local anaesthesia for symptomatic teeth with irreversible pulpitis is owing to the attendance of prostaglandins that increase the sensitization of peripheral nociceptors. Pulpal inflammation is believed to activate and sensitize the peripheral nociceptors, resulting in pain and discomfort [9, 14, 18-20]. The inflammatory mediators decrease the threshold of activation of pain receptors such that the neurons are provoked with minimal stimulation. Such an inflammatory process is mediated by the activity of prostaglandins, which are the final products of the metabolism of arachidonic acid. Prostaglandins sensitize the nerve terminals to bradykinins and histamines and therefore, increase the pain and sensitivity due to inflammation. Evidence shows that inflamed pulp tissue has high levels of arachidonic acid and its metabolites, which are related to pain perception. Nociceptors can recognise physical and chemical stimuli and pro-inflammatory mediators exert their effects by binding to these receptors [21, 22].

Dentol drop, manufactured by Khorraman Pharmaceuticals (Khorramabad, Lorestan, Iran), is made of *Satureja khuzistanica* (Lamiaceae) extract. The anti-inflammatory, analgesic, antioxidative and antihyperlipidemic properties of *Satureja khuzistanica* extract have been previously confirmed [23]. It exerts its anti-inflammatory effects *via* inhibiting the synthesis of prostaglandins and release of pro-inflammatory cytokines. Its anti-inflammatory properties are comparable to those of indomethacin while its analgesic properties are comparable to those of morphine [24]. Carvacrol is the main constituent responsible for the aforementioned favorable properties of *Satureja khuzistanica* extract. Aside from its analgesic and anti-inflammatory properties, carvacrol has disinfecting, antimicrobial and antifungal effects as well [23-26]. Dentol drop contains 10% carvacrol. Thus, this study aimed to assess the effect of topical application of Dentol drop on the rate of successful anaesthesia of mandibular molars with irreversible pulpitis due to deep cavitated carious lesions.

Materials and Methods

In this double-blind, randomized, clinical trial, 72 patients with mandibular first or second molars with irreversible pulpitis and deep cavitated carious lesions, who were referred to the Endodontics Clinic of School of Dentistry, Kermanshah University of Medical Sciences, were selected using convenience sampling. A pilot study was carried out to calculate the sample size. In the pilot study, the standard deviation of pain score upon pulp exposure in the test and control groups was found to be 33.41 and 50.34, respectively. Also, the mean pain upon pulp exposure was 34.75 and 70.26 in the test and control groups, respectively. Considering α=0.05 and study power of 90%, minimum sample size was calculated to be 62 (n=31 in each group). To increase the accuracy, 72 patients were enrolled (n=36 in each group).

The inclusion criteria were systemic health, patients with mandibular first or second molars with irreversible pulpitis and a deep-cavitated carious lesion, being able to use and comprehend the "Visual Analog Scale" (VAS) to express the level of pain, and signing the informed consent form.

The exclusion criteria were systemic diseases, mental disability, age <18 years, pregnancy or nursing, periodontal disease, teeth with periodontal ligament widening or periapical radiolucency, teeth with necrotic pulp, intake of medications affecting anaesthesia within the past two weeks, and self-use of Dentol drop before the procedure.

Patients were enrolled in the study after signing the informed consent forms. They were free to leave at any time if they wished to do so. The study was approved in the Ethics Committee of Kermanshah University of Medical Sciences (ethical approval code: 372) and registered in www.irct.ir (code: IRCT2016110617880N5).

The clinical diagnosis of irreversible pulpitis was made using an electric pulp tester (D624; Parkell, USA) and a cooling spray (Denronic, Aeronova GmbH & Co., KG, Germany). Teeth that gave a positive response to the electric pulp test and had severe, long-lasting pain upon the use of the cooling spray were diagnosed with irreversible pulpitis.

Patients were randomly assigned to the test and control groups using sealed envelopes (random allocation) containing A (test, Dentol drop) or B (control, placebo) code. Patients, the clinician who performed the injections and the statistician were all blinded to the group allocation of patients (allocation concealment).

Prior to the intervention, level of pain experienced by patients in response to cold test was determined using a VAS and recorded [27]. The teeth were then isolated by cotton rolls. In

the test group, a cotton pellet was dipped in Dentol drop (IRC: 1228025389; Khorraman Pharmaceuticals, Khorramabad, Lorestan, Iran) and placed in the cavity. The cavity was then temporarily sealed with Cavit. In the control group, a cotton pellet dipped in placebo that mimicked the smell and consistency of Dentol drop (a combination of liquid paraffin and 0.1% carvacrol essence manufactured in the School of Pharmacy, Kermanshah University of Medical Sciences) was placed in the cavity and the cavity was then temporarily sealed with Cavit. Ten min after the application of Dentol drop and placebo, 2% lidocaine plus 1:100,000 epinephrine (Daroupakhsh, Iran) was injected for IAN block (1.8 mL); using a 27-gauge needle with 38 mm length (Juya, Kashmir, Pakistan). Fifteen min after the injection, the patients had to feel numbness at the corner of their mouth. Those who did not feel numbness at the corner of their mouth were excluded. Next, the teeth were tested with the cold spray and the level of pain was recorded using a VAS [27]. Those who felt severe pain were recorded and did not go through the next steps of the study. They received supplemental anaesthetic injections and underwent root canal treatment. Level of pain in the remaining patients was assessed again during access cavity preparation, upon pulp exposure and also at the time of introduction of initial file into the root canals using a VAS.

The Heft-Parker VAS was used in this study with a range of 0-170. It was a straight horizontal line with two stickers at its two ends that read "no pain" and "severe intolerable pain". It had four segments: a) 0 indicated no pain at all, b) 0< scores ≤54 mm indicated mild pain, c) scores <114 indicated moderate pain, and d) scores ≥114 indicated severe pain [28, 29].

Patients were requested to express their level of pain at the aforementioned time points using the VAS. At each time point, no or mild pain were considered as successful IAN block while moderate and severe pain were considered as failure of the IAN block.

Statistical analysis

Data were analyzed using SPSS version 18 (SPSS Inc., IL, USA) *via* descriptive and inferential statistics. The mean and standard deviation of descriptive data were reported in tables and diagrams. Normal distribution of inferential data was assessed using the Kolmogorov-Smirnov test. The chi-square test was applied to assess and compare the distribution of age, sex and type of tooth between the two groups. Level of pain in the two groups was compared after controlling for the possible confounders using ANCOVA. Tukey's test was applied for pairwise comparisons. The level of significance was set at 0.05.

Table 1. Distribution of age and sex of patients and type of tooth treated in the two groups

		Group			*P*-value†
		A	B	Total	
		Number (%)	Number (%)	Number (%)	
Sex	**Female**	21 (58.3%)	20 (55.6%)	41 (56.9%)	0.812
	Male	15 (41.7%)	16 (44.4%)	31 (43.1%)	
Age (yrs.)	**<25**	10 (27.8%)	8 (22.2%)	18 (25.0%)	0.934
	25-34	9 (25.0%)	11 (30.6%)	20 (27.8%)	
	35-40	8 (22.2%)	9 (25.0%)	17 (23.6%)	
	>40	9 (25.0%)	8 (22.2%)	17 (23.6%)	
Tooth number	**6**	20 (55.6%)	17 (47.2%)	37 (51.4%)	0.479
	7	16 (44.4%)	19 (52.8%)	35 (48.6%)	

† *Chi-square test*

Table 2. Mean pain score of patients pre-operatively

		VAS (before anesthesia)				*P*-value
		Mean (SD)	Min	Max	Median	
Group	**A**	97.44 (30.99)	36	170	85.00	0.292
	B	104.56 (36.14)	36	170	114.00	
Sex	**Female**	110.66 (29.94)	36	170	114.00	0.002
	Male	88.23 (34.39)	36	170	85.00	
Age (yrs.)	**<25**	92.39 (33.91)	36	144	85.00	0.111
	25-34	95.90 (32.43)	36	170	85.00	
	35-40	101.47 (36.42)	36	170	85.00	
	>40	115.65 (29.55)	85	170	114.00	
Tooth number	**6**	98.97 (31.59)	36	170	85.00	0.937
	7	103.14 (35.97)	36	170	114.00	

Results

In this study, all patients felt numbness at the corner of their mouth 15 min after the injection of the anaesthetic agent. Of 72 patients, adequate depth of anaesthesia was not achieved in 41, such that 4 patients expressed moderate or severe pain in response to the cold test 15 min after anaesthetic injection; and 37 patients did not respond to the cold test but had moderate or severe pain during access cavity preparation, pulp exposure or introduction of initial file into the root canal.

Table 1 demonstrates the distribution of age and sex of patients and type of tooth treated in the two groups. As shown, the two groups were not significantly different in terms of gender, age or type of tooth ($P>0.05$).

Data regarding level of pain had a normal distribution in both groups. Table 2 shows the mean pain score of patients pre-operatively. All patients had moderate to severe pain before the injection of the anaesthetic agent in both groups. The difference in pre-operative pain between the two groups was not significant (ANCOVA, $P=0.235$). The difference in pre-operative pain score was significant between males and females in both groups (ANCOVA, $P=0.002$) such that the level of pain in males was lower than that in females (Table 2).

Table 3 presents the mean pain score 15 min after the injection of the anesthetic agent. As shown, the difference in this respect was not significant between the test and control groups (ANCOVA, 0.442).

Table 4 shows the mean pain score during access cavity preparation. A significant difference was noted at this time point between the two groups such that Dentol drop group had significantly (ANCOVA, $P<0.001$) less pain than the placebo group. The difference in pain score between males and females was also significant at this time point and males experienced significantly less pain than females (ANCOVA, $P=0.023$).

Table 5 presents the mean pain score upon pulp exposure. Upon pulp exposure, level of pain in Dentol drop group was significantly lower than that in the control group (ANCOVA, $P<0.001$).

Table 6 shows the mean pain score upon the introduction of initial file into the root canals. A significant difference existed in pain upon introduction of the initial file into the canal between the two groups such that Dentol drop group experienced significantly (ANCOVA, $P=0.018$) less pain than the control group.

Overall, the success rate of anaesthesia was 58.3% ($n=21$) in Dentol drop and 27.7% ($n=10$) in the placebo group. The success rate of anesthesia in Dentol drop group was significantly higher than that in the control group (chi-square test, $P=0.009$). Figure 1 compares the mean pain score in the two groups at different time points.

Table 3. Mean pain score 15 minutes after the injection of the anaesthetic agent

		VAS (after anesthesia)				*P*-value
		Mean (SD)	Min	Max	Median	
Group	**A**	20.92 (33.62)	0	144	0.00	0.442
	B	16.11 (21.97)	0	85	0.00	
Sex	**Female**	22.24 (31.94)	0	144	0.00	0.127
	Male	13.58 (22.16)	0	85	0.00	
Age (yrs.)	**<25**	13.11 (19.02)	0	54	0.00	0.145
	25-34	25.70 (30.98)	0	85	23.00	
	35-40	9.06 (14.90)	0	36	0.00	
	>40	25.24 (39.59)	0	144	0.00	
Tooth number	**6**	17.08 (24.93)	0	85	0.00	0.646
	7	20.03 (31.78)	0	144	0.00	

Table 4. Mean pain score during access cavity preparation

		VAS (during access cavity preparation)				*P*-value
		Mean (SD)	Min	Max	Median	
Group	**A**	21.00 (27.96)	0	85	0.00	0.001
	B	46.39 (36.78)	0	144	36.00	
Sex	**Female**	40.73 (38.65)	0	144	36.00	0.04
	Male	25.03 (27.57)	0	85	23.00	
Age (yrs.)	**<25**	40.17 (35.23)	0	85	45.00	0.325
	25-34	37.95 (40.87)	0	144	23.00	
	35-40	24.35 (32.97)	0	85	0.00	
	>40	31.81 (28.84)	0	85	29.50	
Tooth number	**6**	31.65 (35.45)	0	114	23.00	0.353
	7	36.29 (34.71)	0	144	29.50	

Mean values with the same superscripted letters within a row show insignificant difference (P>0.05)

Discussion

The results of this study showed that the level of pain recorded during access cavity preparation, pulp exposure and file introduction into the canal in the test (Dentol) group was significantly lower than the corresponding values in the control group. Application of Dentol drop, to increase the success rate of IAN block in this study, was because of its confirmed analgesic and anti-inflammatory properties. Dentol is an essential oil of *Satureja khuzistanica* (SKEO). The main component of this essential oil is Carvacrol; which has a broad spectrum of antimicrobial activity against bacteria. Bacterial exposure to carvacrol results in the leakage of intracellular ATP and potassium from cell membrane, and ultimately cell death [23].

It is known that level of prostaglandins increases in teeth with inflamed pulp. Thus, these teeth have a higher rate of anaesthesia failure. To overcome this problem, anti-inflammatory agents can be used to decrease the level of prostaglandins [14]. Dentol drop contains *Satureja khuzistanica* extract [23]. Amanlou *et al.* [24] evaluated the anti-inflammatory and analgesic properties of hydro-alcoholic extract of *Satureja khuzistanica* and reported that its anti-inflammatory effects were comparable to those of indomethacin while its analgesic effects were comparable to those of morphine [24]. Dentol drop contains 10% carvacrol, which is responsible for the aforementioned favorable properties. Our findings revealed that Dentol drop group had a significantly higher success rate of anaesthesia than the placebo group. The two groups were not significantly different in terms of gender, age and type of tooth treated; thus, these parameters had minimal effect, as confounders, on the results. Level of pain at 15 min after anaesthesia injection was not significantly different from the baseline pain score in the two groups but males had significantly less pain than females. This finding may be due to higher level of anxiety in females. However, we did not assess the level of anxiety of patients in this study; therefore, a definite conclusion cannot be drawn in this respect and this topic should be addressed in future studies. Fillingim *et al.* [30] in their review study discussed that females have a lower pain threshold and are more sensitive to pain than males. They added that level of pain experienced by female patients during and after treatment is often higher than that experienced by male patients [30].

Table 5. Mean pain score upon pulp exposure

		VAS (pulp exposure)				*P*-value
		Mean (SD)	Min	Max	Median	
Group	**A**	37.51 (40.31)	0	144	23.00	0.001
	B	71.59 (46.05)	0	144	85.00	
Sex	**Female**	58.92 (49.09)	0	144	54.00	0.286
	Male	48.65 (42.53)	0	144	36.00	
Age (yrs.)	**<25**	60.94 (48.65)	0	144	69.50	0.47
	25-34	51.72 (41.83)	0	114	45.00	
	35-40	42.29 (46.32)	0	144	36.00	
	>40	62.50 (49.32)	0	144	45.00	
Tooth number	**6**	55.94 (44.46)	0	144	54.00	0.74
	7	52.52 (48.68)	0	144	36.00	

Mean values with the same superscripted letters within a row show insignificant difference (P>0.05)

Table 6. Mean pain score upon the introduction of initial file into the root canals

		VAS (Initial file)				*P*-value
		Mean (SD)	Min	Max	Median	
Group	**A**	47.24 (40.12)	0	144	36.00	0.025
	B	73.32 (50.00)	0	170	85.00	
Sex	**Female**	55.62 (44.88)	0	170	36.00	0.45
	Male	63.74 (48.77)	0	144	54.00	
Age (yrs.)	**<25**	75.29 (46.80)	0	144	85.00	0.073
	25-34	59.38 (39.29)	0	144	54.00	
	35-40	59.40 (47.79)	0	144	36.00	
	>40	37.77 (48.94)	0	170	23.00	
Tooth number	**6**	55.70 (41.77)	0	144	54.00	0.272
	7	63.36 (51.85)	0	170	36.00	

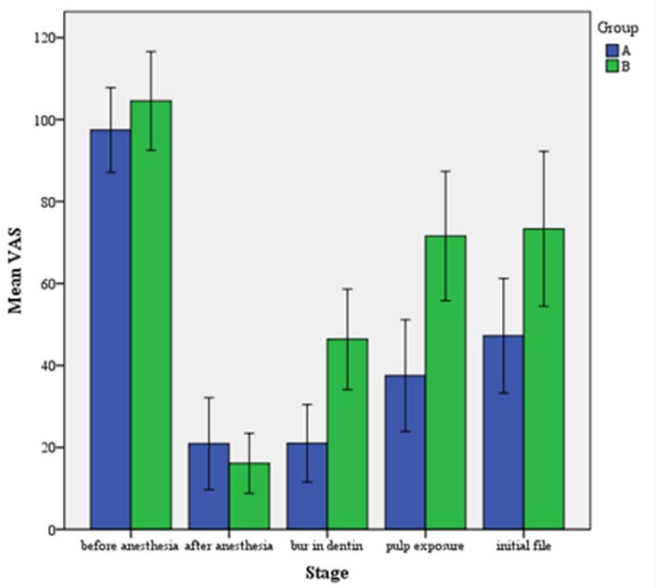

Figure 1. Comparison of the mean pain score in the two groups at different time points

The Heft-Parker VAS [2] was used in the current study to assess the level of pain experienced by patients. This scale has been extensively used for the same purpose in previous studies [2-4, 8, 10, 14, 15, 18, 21-24]. It determines the level of pain subjectively and reflects the patient's perception of pain. It provides a quantitative scale for the level of pain perceived and simplifies the statistical analyses [31].

Sooraparaju *et al.* [16] topically used 20% benzocaine gel combined with hyaluronic acid to decrease pain due to intrapulpal injection and demonstrated that pain during injection was significantly lower in the test compared to the control group [16]. Aminsobhani *et al.* [32] recommended the topical use of tubes, containing amitriptyline powder, to enhance pulpal anaesthesia of mandibular molars with irreversible pulpitis [32]. Their methodology was different from ours since they surveyed the efficiency of a various compound and also placed it on the exposed pulp after the inferior alveolar nerve block in patients with inadequate anesthesia; whereas, we placed a cotton pellet dipped in Dentol drop in the cavity for 10 min prior to the injection of anaesthetic agent. Abazarpoor *et al.* [33] evaluated the efficacy of different volumes of articaine (1.8 mL and 3.6 mL) for IAN block for mandibular first molars with irreversible pulpitis and found no significant difference in pain score of patients in the two groups at 15 min after anaesthetic injection, during access cavity preparation and during instrumentation of root canals. However, the test group (3.6 mL articaine) felt significantly less pain during pulp exposure compared to the control group [33]. In our study, the test group experienced significantly less pain during access cavity preparation, pulp exposure and instrumentation of canals compared to the control group. This difference between the two studies may be due to the use of Dentol drop in our study. According to the manufacturer, Dentol drop can be directly applied on the cavitated carious lesions in teeth with severe pain [34].

Parirokh *et al.* [35] evaluated the effect of supplementary injections such as buccal infiltration and intraligamentary injection on the success rate of IAN block for mandibular first molars with irreversible pulpitis. They reported a success rate of 58% in patients who received a combination of buccal infiltration and intraligamentary injections plus IAN block compared to 22% in those who only received an IAN block. The level of pain in the test group was also lower than that in the controls [35]. However, they only evaluated mandibular first molars in their study while we evaluated mandibular first and second molars. In another study, Parirokh *et al.* [2] evaluated the efficacy of a combination of buccal infiltration and IAN block for mandibular molars with irreversible pulpitis. They reported a success rate of 14.8% for those that received an IAN block with injection of 1.8 mL lidocaine, 39.3% for those that received an IAN block with injection of 3.6 mL lidocaine and 65.4% for those that received an IAN block combined with buccal infiltration [2].

In general, our findings supported the use of Dentol drop to increase the success rate of IAN block for mandibular molars with irreversible pulpitis. Application of Dentol drop is easier than supplemental injections and has no reported side effects so far. Nevrtheless, the side effects of other methods such as premedication with NSAIDs or supplemental injection techniques have been well recognized [4, 11, 36]. Dentol drop is available over the counter and its use is cost-effective for dental clinicians.

One limitation of this study was that we only included teeth with deep cavitated carious lesions, since Dentol drop can only be applied into cavitated carious lesions. Future studies are required to assess the efficacy of other topical agents so as to increase the success rate of IAN block for endodontic treatment of mandibular molars with irreversible pulpitis.

Conclusion

Taking the results of this clinical trial into consideration, topical application of Dentol drop increased the success rate of IAN block for root canal treatment of mandibular molars with irreversible pulpitis. It seems that using Dentol drop in such teeth is beneficial.

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Conflict of Interest: 'None declared'.

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