

TWO - VERSUS ONE-STAGE INFERIOR NERVE BLOCK – IS THERE A DIFFERENCE IN THE APPLICATION PAIN LEVELS? A PROSPECTIVE CLINICAL STUDY

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Intraoral local anesthesia is essential for dental care. However, it is often perceived by some patients as unpleasantly painful and in some cases as the only painful part of the treatment. The purpose of this prospective single blinded clinical study was to compare pain in one of the most commonly used conventional single-stage injections of traditional inferior alveolar nerve (IAN) block with a two-stage IAN block technique. *Subjects and methods:* Upon approval of the ethics research committee, a prospective parallel two-group single blinded comparative *in vivo* study was performed in which the Heft-Parker visual analog scale was used to assess pain by subjectively assessing the entire injection procedure. Data were statistically analyzed using the Statistical Package for Social Sciences v. 17.0 using independent sample Mann-Whitney U test. *Results:* A total of 102 adult subjects (mean age 4.15 ± 17.13 years) with uncomplicated medical history participated in the study. Statistical analysis confirmed that difference in the results on pain assessment between the two compared groups was not significant, i.e. there was no difference in pain perception between the conventional single-stage and modified two-stage IAN block injection technique. *Conclusion:* The two-stage injection did not reduce pain from needle insertion significantly in female and male patients regardless of age, as compared to the traditional IAN techniques. The results of the present study suggest that dental operator should be aware of pain and discomfort of injecting local anesthesia, along with the efficacy of various techniques.

Key words: inferior alveolar nerve (IAN) block; injection pain; local anesthesia

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INTRODUCTION

Anxiety is an obstacle to regular dental visits (1). One of the reasons for the patient to worry about dental treatment is the fear of pain. Therefore, local anesthetics are considered to be the most widely used drugs in medicine and dentistry (2). They prevent nociception generated during surgical and dental procedures, and without them many medical and dental procedures simply could not be performed. Unfortunately, the most common form of pain control in dentistry, namely local anesthesia, can itself cause pain and anxiety. Injection of local anesthetics is often the only painful part of a dental procedure, and fear associated with local anesthesia has been reported as a factor in avoiding dental treatment (3). Various techniques have been

used to overcome injection discomfort (4,5). Previous studies examined different variables that may be involved in painful local anesthetic injections and tested the possible ways to minimize discomfort associated with the injection (2,6-17). Findings from all research suggest that when local anesthetics are included, dentists should consider not only the efficacy of antinociception, but also the perception of pain, pressure, and discomfort caused by the injection itself. In this chain of thought, new techniques of traditional nerve blocks were tested and their effectiveness and efficiency were carefully evaluated (5,9,10,18). Further research is also needed on the latest devices and techniques for local anesthesia, which can lead to lower pain and discomfort.

Kaufman *et al.* (19) investigated four forms of the most commonly used traditional intraoral techniques for injecting local anesthesia in a longitudinal uncontrolled study. The inferior alveolar injection is rated as the most painful and causes the highest rate of discomfort. Levine (20), and Walton and Torabinejad (21) suggest a two-stage injection as a way to reduce injection pain by anesthesia of the inferior alveolar nerve (IAN) block. This method involves initial placing an anesthetic solution just below the surface of the mucosa. After waiting for a few minutes for regional numbness to occur, the injection is repeated and the remaining anesthetic solution is deposited at the target site. Fewer clinical trials looked at the two-stage injection technique the goal of which is to reduce injection pain (22). Thus, the aim of the present prospective single blinded study was to compare the pain caused by one of the most commonly used conventional one-stage IAN block injections with that experienced with two-stage IAN block technique.

SUBJECTS AND METHODS

A parallel *in vivo* single blinded comparative study was performed. It met the necessary medical research and ethics protocols fixed in the informed consent obtained from each of the participants. Two equal groups of 51 adult subjects participated in the study. In all cases, an IAN block injection was indicated. All adults in the study were blindly randomized to the technique. They were divided into two groups: group A (standard one-stage IAN block injection technique) and group B (modified two-stage IAN block injection technique) by simple randomization. Patients were in good general health, as determined by a written health history and an oral questionnaire. They did not take any medications that could change their perception of pain. All patients were asymptomatic and participated voluntarily in the study. Exclusion criteria were patients taking anti-inflammatory drugs; patients having abused drugs or alcohol; patients with a history of personality disorders; patients at medical risk with a status higher than ASA II. Patients who did not show subjective signs of anesthesia or needed a secondary or additional injection, patients who needed sedatives for dental treatment and patients who reported previous or continued severe pain were also excluded from the study as this may affect their response.

All blindly randomized patients received a conventional one-stage or two-stage IAN block injection using 1.7 mL of 4% articaine with 1:200,000 epinephrine (Septanest®, Septodont, France). A total of 102 injections of IAN block were administered with a 0.4x35 mm needle attached to a standard aspiration-type dental syringe. A new needle was used for each penetration into the

tissues using the two-stage technique. They were all performed by one operator (B. B.). No local anesthetic was used before inserting the needle (Fig. 1).

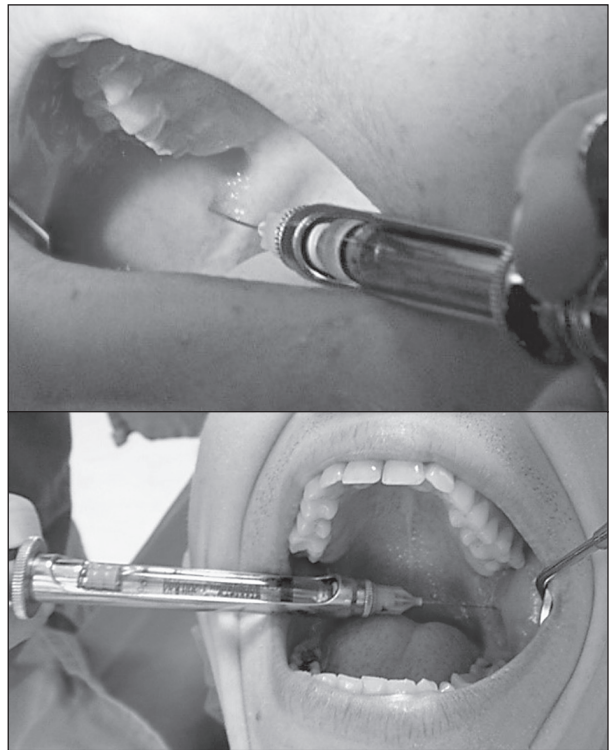


Fig. 1. *Inferior alveolar nerve (IAN) block anesthesia technique.*

The conventional IAN block was administered as follows: after initial penetration of the needle to a depth of 2-3 mm, the needle moved for about 10 seconds to the target site until the bone was gently touched. As the needle was advanced, 0.4 mL of the anesthetic solution was deposited. The remaining 1.3 mL of the solution was then deposited at the target site for a period of 1 minute (2).

The two-stage IAN block was administered as follows: after initial penetration of the needle to a depth of 2-3 mm, 0.4 mL of the anesthetic solution was deposited for a period of 1 minute and the needle was then withdrawn. During this phase, the needle did not pass to the target site. After a 5-minute pause, a new needle was inserted back into the mucosa at the same site and moved to the target site for about 10 seconds. No anesthetic solution was deposited during needle insertion. Once the target site was reached, 1.3 mL of the solution was deposited for a period of 1 minute (23).

Prior to starting the dental procedure, patients evaluated their subjective assessment of the entire injection procedure on a 170 mm paper Heft-Parker visual analog scale (VAS) questionnaire (24) (Fig. 2). The VAS was divided as follows: no pain corresponded

to 0 mm; mild pain was defined as greater than 0 mm and less than or equal to 54 mm. Mild pain included the descriptors of faint, weak and mild pain; moderate pain was defined as greater than 54 mm and less than 114 mm; severe pain was defined as equal to or greater than 114 mm. Severe pain included the descriptors of strong, intense and maximum possible.

The data obtained were analyzed statistically using the Statistical Package for Social Sciences v. 17.0. Comparisons between the two injection techniques for pain assessment were performed using independent samples Mann-Whitney U test. Comparisons were considered significant at $p < 0.05$ (confidence interval of difference, 95% CI).

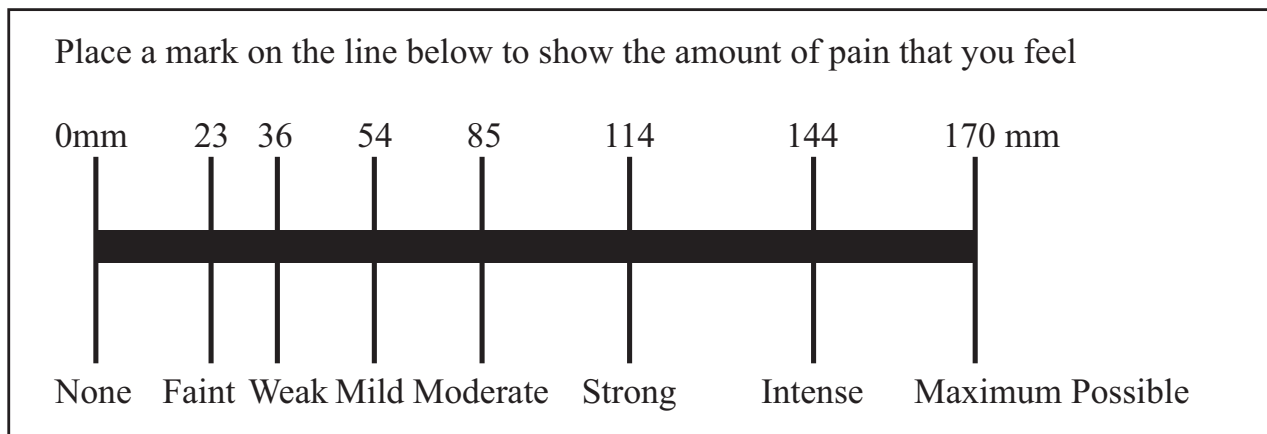


Fig. 2. Heft-Parker visual analog scale (VAS) – pain scale used for assessment of pain. Millimeter demarcations were not shown on patient VAS (24).

RESULTS

This prospective single blinded clinical study examined pain levels by inserting a needle into the modified two-stage IAN block injection compared to the traditional IAN anesthesia technique. The study included 38 males and 64 females with uncomplicated medical history, mean age 34.15 ± 17.13 years, ranging from 18 to 76 years (males, 37.61 ± 18.84 , range 19-76; females, 32.08 ± 15.83 , range 18-76) (Tables 1 and 2).

Table 1
 Distribution of participants within the groups according to sex

Sex	1-stage technique			2-stage technique		
	n	p	Sp	n	p	Sp
Male	21	41.18	6.89	17	33.33	6.60
Female	30	58.82	6.89	34	66.67	6.60
Total	51	100	---	51	100	---

n – number; p – percentage [%]; Sp – sum of products of deviations [%].

Table 2
 Distribution of male and female participants according to the technique applied and side of anesthesia

Side	1-stage technique						2-stage technique					
	Male			Female			Male			female		
	n	p	Sp	n	p	Sp	n	p	(Sp)	(n)	(p)	(Sp)
Left	10	47.62	10.90	15	50.00	9.13	7	41.18	11.94	14	41.18	8.44
Right	11	52.38	10.90	15	50.00	9.13	10	58.82	11.94	20	58.82	8.44
Total	21	100	---	30	100	---	17	100	---	34	100	---

n – number; p – percentage [%]; Sp – sum of products of deviations [%].

All volunteers ranked their perception of pain upon needle insertion through VAS pain scoring. All reported discomfort assessments when performing the two tested IAN block techniques are comprehensively

presented in Table 3. None of the patients complained of pain greater than 'moderate' with conventional technique and 'severe' (only one female) with the tested two-stage modification.

Table 3.
Distribution of participants within the groups according to sex and pain assessment

Pain	1-stage technique						2-stage technique					
	Male			Female			Male			Female		
	n	p	Sp	n	p	Sp	n	p	Sp	n	p	Sp
None	7	33.33	10.29	6	20.00	7.30	6	31.58	10.66	10	30.30	8.00
Faint	9	42.86	10.80	11	36.67	8.80	8	42.11	11.33	16	48.48	8.70
Weak	2	9.52	6.41	8	26.67	8.07	2	10.53	7.04	4	12.12	5.68
Mild	1	4.76	4.65	2	6.67	4.55	1	5.26	5.12	1	3.03	2.98
Moderate	2	9.52	6.41	3	10.00	5.48	0	10.53	7.04	2	6.06	4.15
Strong	0	0.00	0.00	0	0.00	0.00	0	0.00	0.00	1	0.00	0.00
Intensive	0	0.00	0.00	0	0.00	0.00	0	0.00	0.00	0	0.00	0.00
Maximum possible	0	0.00	0.00	0	0.00	0.00	0	0.00	0.00	0	0.00	0.00
Total	21	100	---	30	100	---	17	100	---	34	100	---

n – number; p – percentage [%]; Sp – sum of products of deviations [%].

Before data analysis, the normality of distribution between the groups was statistically tested. The results

did not show difference between the groups according to age, sex and side of anesthesia (Table 4).

Table 4.
Normality of distribution testing between groups: normal distribution

Technique		Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Side	1-stage	0.344	51	0.000	0.637	51	0.000
	2-stage	0.385	51	0.000	0.625	51	0.000
Sex	1-stage	0.385	51	0.000	0.625	51	0.000
	2-stage	0.425	51	0.000	0.595	51	0.000
Age	1-stage	0.206	51	0.000	0.837	51	0.000
	2-stage	0.281	51	0.000	0.715	51	0.000

^aLilliefors Significance Correction.

Comparison of all patients using one-sample χ^2 -test, following distribution by sex, age and side of administration did not yield statistical difference in the levels of discomfort ($p > 0.05$) (Fig. 3).

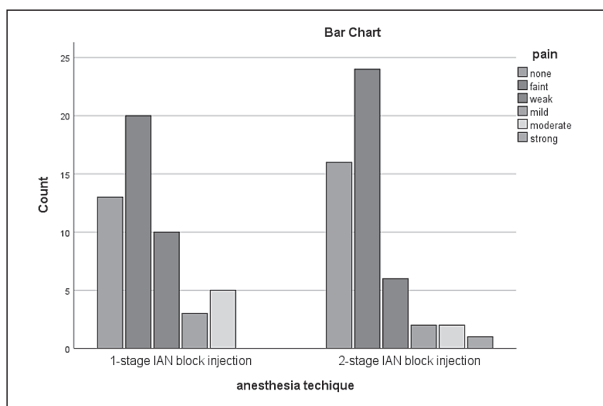


Fig. 3. Distribution of participants within groups according to pain assessment.

Using independent samples Mann-Whitney U test, it was statistically verified that difference in the pain assessment results between the two groups was not significant ($p > 0.05$) (Fig. 4, Table 5). This confirmed the null hypothesis that there is no difference in pain perception between the conventional one-stage and modified two-stage IAN block injection technique.

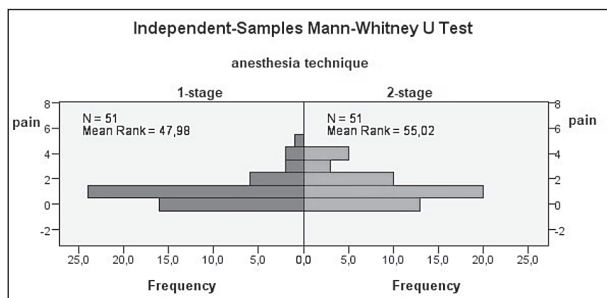


Fig. 4. Illustration of the lack of significant difference in pain assessment in patients between the IAN block anesthesia techniques tested.

Table 5.
Statistical testing of difference in pain perception by comparison of modified two-stage to conventional IAN block anesthesia technique

Null hypothesis	Test	Sig.	Decision
Distribution of 'pain' is the same in the two groups	Independent samples Mann-Whitney U test	0.204	Retain the null hypothesis

Using one-sample χ^2 -test, there was no significant difference in pain level between the first and second injections in the two-stage IAN block anesthesia in group B participants ($p>0.05$) (Fig. 5). Sex, age, and side of administration were not statistically significant factors for pain assessment ($p>0.05$).

Total N	102
Mann-Whitney U	1 121,000
Wilcoxon W	2 447,000
Test Statistic	1 121,000
Standard Error	141,159
Standardized Test Statistic	-1,272
Asymptotic Sig. (2-sided test)	,204

Fig. 5. Distribution of participants within the two-stage IAN block anesthesia group according to pain assessment.

DISCUSSION

One of the most important aspects of any dental or oral surgical practice is to ensure that patients are free of pain during treatment. When pain is felt, the central nervous system detects and processes information based on tissue damage and/or somatic imminence (18). In general, type A and type C nerve fibers are involved during the dental injection process (25). The process of local anesthetic injection and nerve fiber activation includes needle penetration through mucosa and advancement to the target area (type A), anesthetic deposition (type A and type C), and removal of the needle (type A and type C) (18).

Insertion of the needle into the mucosa is the first step in the pain caused by the injection. A previous analysis of pain perception during this stage showed a 14% to 22% incidence of moderate to severe pain with standard injection protocols (26). Considered to be the more painful stage of anesthetic injection, solution deposition causes intense reactions due to tissue expansion, rich intraoral sensory innervation, and chemical complexation and pH of local anesthetic (18). Anesthesia pain analysis revealed an 18% to 56% incidence of moderate to severe pain during the anesthetic deposition stage (26). In addition, needle withdrawal may be associated with postoperative pain due to tissue damage or accelerated removal of the anesthetic delivery device (18). Postoperative pain is also associated with anesthetic pH, multiple injections, inadequate needle design, and poor injection technique (2,17-19).

Because the injection technique is part of the assessment of patient care, oral health professionals are advised to give the least painful injection possible (18). This led Levine to propose the 'one-two injections technique' (or two-stage injection) in 1968, using two stages of anesthesia deposition to reduce pain. The first deposition is shallow and the second is directed to the target area (20). More recently, Walton and Torabinejad (21) have suggested that the technique itself may reduce injection pain at any surgical dental appointment. The general idea of offering this method is to wait for the second injection at the same site to monitor the effect of the initial anesthesia, which should mask the second penetration.

Although anecdotal reports and opinions of dentists are behind the favorable view of the two-stage injection technique, the evidence basis for confirming the methodology is fragmented. Although many dentists prefer this technique, there is currently no professional consensus on the best practices for this technique. Clinical trials evaluating the success of the two-stage injection technique to reduce pain are limited. Recent reports suggest the two-stage injection technique as a solution to the unreliable effect of local anesthesia for IAN block injections (25,26). We believe that further research is needed to confirm the two-stage injection technique and to reach a professional consensus.

This article presents analysis of the two-stage anesthesia of IAN block injection and comparison with the classic single-stage block. Discomfort with intraoral injections can be attributed, as suggested above, to needle penetration and solution deposition. The present study is limited to the assessment of needle penetration discomfort against the background of the same type of anesthetic solution used in each case. The results showed that needle penetration discomfort did

not vary statistically in both sexes within and between the two groups, regardless of age or side of administration (Table 5, Fig. 4). Other clinical trials have been reported to produce different perceptions of pain between males and females (28); however, the reason for difference in these studies is not entirely clear. Wahl *et al.* (29) report that females experienced more pain than males during dental injections, but this difference was not significant, as also found in our clinical trial. In addition, Nusstein *et al.* (26) found no difference in pain levels between males and females either when using a two-stage injection technique to insert an IAN block needle.

Martin *et al.* (30) report that in patients receiving several intraoral injections, the second injection was assessed as significantly less uncomfortable than the first administration. The data from the present study do not support such findings after comparing penetration of the first and second needles, thus not proving that the first injection of a pair of identical injections was more or less painful. We also could not confirm the findings reported by Kaufman *et al.* (19) that local infiltration is generally the least painful and uncomfortable procedure. These findings suggest that an alternative technique should be considered to minimize pain at the injection site in the oral cavity.

CONCLUSION

In conclusion, two-stage injection has not been shown statistically to reduce needle insertion pain in both males and females, regardless of age, as compared to conventional IAN block anesthesia. Unfortunately, the available research supporting the two-stage injection technique, as well as the best anesthetics and pain response, is limited. Scoring VAS for pain with comparisons of anesthetics is usually a secondary finding if evaluated. There also are too few studies and reviews to reach a professional consensus on the benefits, risks and best practices of the two-stage injection technique. In addition, no studies were found to evaluate all available anesthetics within a cohort. Thus, further research should consider ways to reduce pain during anesthetic solution deposition using nerve block techniques in the oral and maxillofacial areas. In daily routine, dentists, mainly surgeons, must take into account the variety of factors that are marked individually for each patient, especially those who are fearful or apprehensive of surgical procedures to improve their experience.

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S A Ž E T A K

USPOREDBA DVOSTUPANJSKOG I JEDNOSTUPANJSKOG BLOKA DONJEG ALVEOLARNOG ŽIVCA – POSTOJI LI PRI PRIMJENI RAZLIKA STUPNJEVA BOLI – PROSPEKTIVNA KLINIČKA STUDIJA

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Intraoralna lokalna anestezija je vrlo važna u dentalnoj skrbi. Međutim, često ju neki pacijenti smatraju jako bolnom i u pojedinim slučajevima jedinim bolnim dijelom liječenja. *Cilj* ove prospektivne slijepo kliničke studije bio je usporediti bol kod primjene jedne od najčešće upotrebljavanih konvencionalnih jednostupanjjskih injekcija kod tradicionalnog blokiranja donjeg alveolarnog živca (IAN) tehnikom dvostupanjjskog blokiranja IAN. *Ispitanici i metode:* Nakon odobrenja etičkog istraživačkog odbora učinjena je prospektivna paralelna dvostruko slijepa studija in vivo u kojoj se za procjenu boli koristila Heft-Parkerova analogna vizualna ljestvica za subjektivnu prosudbu cijelog postupka injiciranja. Podatci su statistički analizirani uporabom Statističkog paketa za društvene znanosti v. 17 korištenjem nezavisnih uzoraka Mann-Whitneyeva U testa. *Rezultati:* U istraživanju su sudjelovala 102 odrasla ispitanika srednje dobi 34,15±17,13 godina s anamnezom bez komplikacija. Statistički je potvrđeno da razlika procjene boli između dviju uspoređivanih skupina nije bila značajna ukazujući na to da nije bilo razlike u percepciji boli između jednostupanjjske tehnike blokiranja injekcijom donjeg alveolarnog živca i modificirane dvostupanjjske tehnike. *Zaključak:* Dvostupanjjska tehnika injiciranja ne smanjuje bol značajno ni kod muškaraca ni kod žena bez obzira na dob u usporedbi s tradicionalnom jednostupanjjskom tehnikom injiciranja donjeg alveolarnog živca. Rezultati ove studije ukazuju na to da dentalni kirurg mora biti svjestan kako i uz učinkovitost različitih tehnika pri davanju lokalne anestezije postoji bol i neugoda.

Ključne riječi: blokiranje donjeg alveolarnog živca, bol kod injiciranja, lokalna anestezija