ORIGINAL ARTICLE

The Effect of Preoperative Naproxen Sodium on the Efficacy of Inferior Alveolar Nerve Block in Patients with Symptomatic Irreversible Pulpitis

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ABSTRACT

OBJECTIVE: To inspect the effects of naproxen sodium pre-operatively on the potency of Inferior alveolar nerve block in patients suffering from symptomatic irreversible pulpitis.
METHODOLOGY: A cross-sectional study was conducted at Operative Department, Hamdard University Dental Hospital Karachi, from July 2018 to February 2019 using a non-probability consecutive sampling technique, including patients between 18-45 years of age. One hundred patients with symptomatic irreversible pulpitis in the posterior teeth of the mandible were randomly given 550 mg naproxen sodium or similar placebo capsules 60 minutes before the delivery of a conventional inferior alveolar nerve block. Patients having allergies, contraindications to naproxen sodium, pregnancy, lactating mothers, not giving consent, patients experiencing only mild pain (verified with Visual Analog scale) or taking pain medication in the last 6 hours were excluded. Fifteen minutes after the inferior alveolar nerve block delivery, sufficient lip numbness was confirmed, and endodontic therapy was commenced. Success determined if the subjects remained pain-free or showed mild pain (≤54mm on a 170mm Visual analog scale) on access or instrumentation. SPSS version 22 was utilized for data analysis.
RESULTS: The success of the inferior alveolar nerve block demonstrated by the placebo group was 40%, and the experimental group was remarkably 98%. A substantial significant difference was evident between the two research groups.
CONCLUSION: Variations in the two groups support that a significant rise in the success rate of the inferior alveolar nerve block was observed in subjects who consumed a pre-operative dose of 550 mg naproxen sodium with symptomatic irreversible pulpitis.

KEYWORDS: Local anaesthesia, Inferior alveolar nerve block, Naproxen Sodium, Symptomatic Irreversible Pulpitis, Pre-operative Analgesics, and Endodontic treatment.

INTRODUCTION

Successful anaesthesia is the first step during endodontic treatment, which psychologically impacts the patient and boosts his dentist's confidence[1]. Painless dentistry significantly reduces the fear and anxiety affiliated with various dental procedures. Proper administration of local anaesthesia reduces anxiety and improves the efficacy of dental treatment. For compliance, it is vital to anaesthetize the patient before starting painful dental procedures. Pain during endodontic therapy makes a patient anxious, produces dental fear and decreases confidence in the dentist[2]. Therefore, profound local anesthesia is crucial for the success of endodontic treatment and for building patients' trust in the dentist.

The most popular local anaesthetic technique practiced during root canal treatment of mandibular teeth is to block the inferior alveolar nerve, thus named the Inferior alveolar nerve block. Clinically, this block successfully achieves anaesthesia in 85-90% of cases, but this becomes challenging, and the percentage reduces to 20% in patients with symptomatic irreversible pulpitis (SIP), often presenting as a "hot tooth" [3]. In such cases, the efficiency of IANB to successfully anaesthetize mandibular teeth with inflamed pulp tissue seems questionable because of the hyperalgesic state. Also, due to inflammation, the nociceptor channels that circulate sodium become four times more resistant to local anaesthesia than healthy nerve fibrils[4]. Treatment becomes cumbersome and negatively affects the success of endodontic treatment, and thus success rate declines to be 23% to 64.2%[5]. With this poor success rate, it is essential to explore ways to improve IANB. Anaesthetic failure is witnessed among 13% of injections given overall, where the majority of anaesthetic failures, i.e. 88%, are associated with IANB, among which 30-80% of the cases have symptoms of irreversible pulpitis[6].

Different methods are proposed to augment the success of popular IANB during SIP, including the consumption of pre-operative analgesics and supplemental anaesthetic techniques. Literature supports the use of pre-operative analgesics in augmenting the effect of IANB. Nonsteroidal anti-inflammatory drugs (NSAIDs) are frequently reported to be advantageous in the literature when used pre-operatively before applying IANB[7]. NSAIDs block the local production of prostaglandins by acting peripherally, thus popular in treating dental pain[7].

Naproxen Sodium is an NSAID propionic acid derivative, a nonselective inhibitor of the cyclooxygenase pathway with immense analgesic and anti-inflammatory activity. Naproxen is as effective as aspirin but tolerates better gastro-intestinally, thus enabling more patients to continue with this drug regime. To the best of our knowledge, there is no local and international research on the efficacy of naproxen sodium, particularly when given pre-operatively before administering an anaesthetic nerve block in cases of SIP. Thus the rationale of our study here is to observe the impact of consuming pre-operative naproxen sodium on the efficacy of IANB in patients suffering from SIP.

METHODOLOGY

This cross-sectional study was carried out in Operative Dentistry and Endodontics department, Hamdard University Dental Hospital Karachi, from July 2018 to February 2019. The study was approved by the Ethical Committee of Research and Diagnostics Hamdard University ERC letter No. (1148-08-18), dated 16-08-2018. At a 95% confidence level using the prevalence of cases of SIP, the power of the test was 80%. The proportion of the group with naproxen sodium is 35%, and the placebo is 10%. The sample size was calculated to be n=86, i.e. 43 in each group. Software' WHO calculator" has been applied to calculate the sample size. The sample size was improved to 100 as a safety margin. Data was gained using the technique of non-probability consecutive sampling comprising patients who fall in the age category between 18-45 years, irrespective of both genders having symptoms of irreversible pulpitis in the posterior tooth of the mandibular arch. The patients had been excluded from our study if they had allergies or any other contraindications to naproxen sodium, those who were pregnant, lactating mothers, those who were not capable of giving proper consent, those who were experiencing only mild pain verified with Heft-Parker Visual Analog Scale (VAS) or had taken pain medication in the last six hours[8].

Informed consent was acquired from all patients fitting the inclusion criteria after completing Corah's Dental Anxiety Scale[9]. Two groups were made, and one hundred subjects identified with SIP of a mandibular tooth-bearing moderate to severe pain were randomly divided among them through SNOZ protocol. Initially, the patient's tooth was tested with the spray Endo-Ice® applied to a cotton pellet placed appropriately on the buccal surface of the tooth[10]. A stern test, with a corresponding VAS for pain, was marked, and this procedure was repeated every ten minutes until 60 minutes. The endodontist recorded the patient's reaction to the cold test. Group A (n=50) patients received oral capsules containing 550 mg naproxen sodium before administering the mandibular nerve block. Group B (n=50) patients received similar placebo capsules containing powder of Avicel PH-105 containing microcrystalline cellulose NF. A registered compounding pharmacist compounded all capsules.

Sixty minutes after the capsules were ingested, a cotton tip applicator was used to apply a topical anaesthetic (20% benzocaine) at the IANB site for 60 seconds[10]. The degree of pain was rated on the above scale of 1-170mm, applying the VAS score after performing a cold test using Green Endo ice spray (Hygienic) before administering anaesthesia. After 60 minutes of ingestion of the placebo/experimental capsule, all patients received standard IANB. Under aseptic techniques, IANB was given using 8 mL 2% lidocaine containing 1:100,000 parts epinephrine (Medicaine, Huons Co. Ltd) with a 27gauge 1½-inch needle. The effectiveness of the technique was evaluated by subjective (absence of pain on asking patient, lip numbness) and objective (no pain on exploration with a sharp probe) responses in the patients[11,12]. Patients' response was recorded for each test. When no symptoms of anaesthesia of a particular nerve are witnessed after 7 minutes denotes failure that requires repetition of the technique. Pain levels were assessed with a 170 mm VAS during needle insertion and solution deposition. If sufficient anaesthesia of the lower lip was not achieved even at 15 minutes, then the block was labelled as missing, and the patient was administered another injection of 1.8 mL 2% lidocaine with 1:100,000 epinephrine. After 15 minutes post-injection, the tooth was isolated using a rubber dam and initiating an endodontic procedure. During the commencement of the endodontic procedure, the pain felt, if any, was rated. If the pain was felt, then treatment was immediately stopped. The location of pain was keenly observed, whether the pain originated within the dentin while entering the pulp

chamber or during the initial placement of the file. If the patient remained pain-free or suffered mild discomfort, treatment continued. Those patients who suffered from pain of a moderate to severe nature (VAS rating greater than 54 mm) were given buccal infiltration of 1.8 mL of 4% articaine containing 1: 100,000 epinephrine (Septocaine, Septodont France) directly buccal to the tooth over 1 minute. The pain involved with the buccal infiltration was again noted, according to VAS. In case the buccal infiltration was deemed unsuccessful, another shot of intraosseous injection was given containing 1.8 mL 2% lidocaine with 1: 100,000 parts epinephrine as described in previous studies[13-16]. If moderate to severe pain persisted after intraosseous injection, intrapulpal injections were given using 2% lidocaine with 1: 100,000epinephrine. A patient who failed to respond affirmatively, irrespective of any group, was excluded from this study. Along with the prescription of post-operative analgesics, the patient was then reappointed for completion of root canal therapy at a later date.

Data Analysis: SPSS version 22 software was used to analyze the data. Standard deviation and Mean values were taken for variables like age and initial and post-injection VAS Score. The frequency, along with percentages, were measured for efficacy. Effect modifiers of this study, like age, gender, and socioeconomic status, were controlled through stratification. Chi-Square Test analyzed the success rates of the IANB in both groups (taking $p<0.05$ as significant).

RESULTS

The initial mean pain experienced by subjects in the placebo group was 2.30±0.20, and the mean pain felt by patients in the naproxen sodium group was 1.22±1.15. No statistically proven difference was witnessed between these groups. **Table I** illustrates the VAS patient response to cold test using green EndoIce ® prior to local anaesthesia administration. **Table II** shows pain results upon cold stimulation with EndoIce ® Pain to cold was assessed using a 170 mm VAS starting with initial pain, which was recorded as time 0. Assessments were continued for 60 minutes before anaesthesia was administered. In both groups, mean pain decreased with each time. **Table III** illustrates the VAS patient response during endodontic treatment and compares the efficacy of group A versus group B, where Group A, with naproxen sodium, found IANB to be 98% effective. In contrast, Group B with a placebo found IANB to be 40% effective. A statistically proven significance in the potency of IANB was observed in patients who presented with SIP using naproxen sodium versus those without pre-operative medication.

69% of patients achieved profound lip anaesthesia, whereas 31% remained un-anaesthetized after receiving a block of the inferior alveolar nerve. Following the IANB, 30 placebo patients and one patient over naproxen sodium needed additional anaesthesia using a buccal infiltration of articaine 4% with 1: 100,000 parts epinephrine. Following the buccal infiltration, 25 placebo patients and one naproxen sodium patient required additional anaesthesia using an intraosseous technique with 2% lidocaine containing 1: 100,000 parts epinephrine. Fifteen placebo subjects and none of the naproxen sodium patients required intrapulpal injections, all resulting in pulpal anaesthetic success. An additional amount of anaesthetic has been witnessed to have played a small role in increasing the effect. Even if these discussed factors played any significance, this even distribution would nullify any impact on our results.

TABLE I: VISUAL ANALOGUE SCALE PATIENT RESPONSE TO COLD TEST USING GREEN ENDOICE PRIOR TO LOCAL ANAESTHESIA ADMINISTRATION

Group	Low (1-3)	Moderate (4-6)	Severe (7-10)
Naproxen Group(A)	0 (0%)	2 (4%)	48(96%)
Placebo Group (B)	0 (0%)	1 (2%)	49 (98%)

TABLE II: PRE-OPERATIVE PAIN USING ICE STIMULATION (VISUAL ANALOGUE SCALE RATINGS IN MM)

Group	Moderate (5mm)	Moderate (6mm)	Severe (7mm)	Severe (8mm)	Severe (9mm)	Severe (10m)	Total	Mean	SD
A	0	2	5	11	12	20	50	-	-
B	1	0	13	8	15	13	50	-	-
Total	1	2	18	19	27	33	100	2.97	0.171

TABLE III: VAS PATIENT RESPONSE DURING ENDODONTIC TREATMENT AND EFFICACY OF THE TWO GROUPS

Group	No pain (0mm)	Mild (1-3mm)	Moderate (4-6mm)	Severe (7-10mm)	Total	Mean	SD	Efficacy		
								Yes	No	p Value
A	21	25	2	2	50	-	-	49(49%)	1(1 %)	0.001
B	29	20	1	0	50	-	-	20(20 %)	30(30 %)	0.001
Total	50	45	3	2	100	1.2200	1.15102	69	31	

DISCUSSION

This study observes the effect of consuming naproxen sodium on the efficacy of the IANB in subjects who showed symptoms of SIP. The success rate of IANB following naproxen sodium administration pre-operatively in our study was 98% compared to 40% in the placebo group. In our study, success was labeled as the potential to achieve adequate access and thorough instrumentation of the root canals painlessly (VAS score of zero) or with mild pain (VAS rating less than or equal to 54 mm). The present study depicted results similar to those concluded by the previous studies regarding the efficacy of naproxen sodium in achieving pain relief[17-19]. Most studies evaluated naproxen sodium's effectiveness in relieving post-operative endodontic pain. Our study is among a few studies to assess the efficacy of naproxen sodium pre-operatively in achieving the efficacy of IANB in patients with SIP. Kiersch T 1994[20] demonstrated that Naproxen sodium has superior efficacy in the post-operative dental pain model.[20] Cooper revealed that in postsurgical dental pain of moderate-to-severe nature, naproxen sodium could be selected as a favorable alternative to opioid combinations. Cooper also proved that more extended duration pain relief could be obtained after consuming naproxen sodium pre-operatively compared to ibuprofen.

In contrast, Iranmanesh P et al.[14] in his study displayed that ibuprofen or ketorolac administered pre-operatively showed no benefit in improving the success rate of IANB in subjects who suffered from SIP. At the same time, pre-operative ibuprofen (600 mg), ketorolac (10mg), etodolac with a combination of paracetamol (400 mg + 500 mg), aceclofenac with paracetamol (100 mg + 500 mg) when taken pre-operatively give better results and potentially increase the effectiveness of the IANB in patients with SIP compared to the placebo group[21,22]. Naproxen sodium is advocated in relieving severe pain as this drug is potent, better-tolerated gastro-intestinally, cost-effective and generally prescribed by dentists in cases of severe toothache[23,24]. Our study showed the statistical significance of pre-operative naproxen sodium administration for achieving profound IANB in SIP patients experiencing active, moderate to severe pain. Naproxen sodium augments the success rate of IANB due to the multi-site and multi-action qualities of this drug's mechanisms of action[25]. We also administered intra-osseous injections in cases where IANB failed to achieve pain relief. It is challenging to accurately conclude the success rates of buccal infiltration and intra-osseous injections as the sample sizes are smaller than those of the IANB groups.

CONCLUSION

The inferior alveolar nerve block was statistically significant for the experimental group. Considerable variation between the two groups was observed, so it can be safely stated that pre-operative administration of 550 mg of naproxen sodium for patients diagnosed with Symptomatic irreversible pulpitis augments the success rate for inferior alveolar nerve block.

Ethical Permission: Hamdard University Karachi ERC letter No. HCM&D/HUDH/1148-2018, dated: 16-08-2018.
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Data Sharing Statement: The corresponding author can provide the data proving the findings of this study on request. Privacy or ethical restrictions bound us from sharing the data publically.

AUTHOR CONTRIBUTIONS

Khan H: Concept, write up
Rehman A: Sample size calculation, statistical analysis
Ali SA: Data collection
Irfan T: Write up
Akhtar H: Results compilation, Data collection
Hammad M: Manuscript write-up

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