

# Comparative evaluation of intraligamentary injection and traditional inferior alveolar nerve block in endodontic management of mandibular molar with symptomatic irreversible pulpitis: A randomized double-blinded clinical trial



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## ABSTRACT

**Background:** Intraligamentary anesthesia (ILA) injection using a single-tooth anesthesia (STA) system has been used as a supplementary technique for pulpal anesthesia in cases of irreversible pulpitis. **Aims and Objective:** The current clinical trial was undertaken to assess and compare the effectiveness of the conventional inferior alveolar nerve block (IANB) and the ILA technique utilizing the STA system for endodontic management of mandibular molars presenting symptomatic irreversible pulpitis. **Materials and Methods:** Patients diagnosed with symptomatic irreversible pulpitis in mandibular molar were allocated into two groups: Group I IANB (n = 30) and Group II- STA system (n = 30). The onset of anesthesia was evaluated using the electric pulp test, whereas for pain perception the Heft-Parker Visual Analog Scale score was recorded before, during, and after anesthesia. Post-anesthetic pain was recorded at 3 h, 24 h, and 1 week. The collected data was evaluated for effectiveness pain perception, and acceptability of the anesthetic technique, using appropriate statistical tests. **Results:** The mean time of onset for the Group II STA system ( $2.93 \pm 1.80$ ) was significantly higher ( $P = 0.0001$ ) than Group I IANB ( $1.40 \pm 0.86$ ). Pain at the site of injection was insignificant ( $P > 0.05$ ) between both groups. The severity of pain during the root canal procedure was significantly different ( $P < 0.0001$ ) in both cohorts. For both groups, the patient's acceptance of the anesthetic procedure was statistically insignificant ( $P = 0.21$ ). **Conclusions:** The STA system reported similar effectiveness in terms of effectiveness, pain perception, and acceptability of anesthetic technique when compared to IANB. Hence, the primary anesthetic treatment for conducting endodontic procedures on molars with symptomatic irreversible pulpitis appears to be the utilization of the ILA-employing STA system.

**Key words:** Single tooth anesthesia system; Symptomatic irreversible pulpitis; Articaine; Inferior alveolar nerve block; Intraligamentary injection; Irreversible pulpitis; Mandibular molars

## INTRODUCTION

The perception of endodontic pain is strongly subjective and varies according to the patient. Local anesthesia technique

plays a crucial role in effective pain management during endodontic therapy creating a positive impact toward treatment. However, achieving successful pulpal anesthesia in irreversible pulpitis is still a clinically challenging situation.<sup>1</sup>

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A localized inflammatory response to bacterial invasion of the pulp-dentin complex is irreversible pulpitis which leads to hyperalgesia and allodynia, preventing profound anesthesia during the endodontic procedure.<sup>2</sup> In addition, it can be due to activation of nociceptors by inflammation leading to sprouting of the nerve fibers, increasing expression of neuropeptide, release of inflammatory mediator, and tumor necrosis factor.<sup>3</sup> This results in an altered resting potential of the nerve, reducing the amount of anesthetic solution penetrating the membrane. Tetrodotoxin-resistant sodium channels and accessory innervation may also vary the success rate of anesthesia.<sup>4</sup>

Articaine, the dental anesthetic frequently employed as the second-most common choice, characterized by increased liposolubility and the presence of a thiophene ring has proven to be effective in producing pulpal anesthesia.<sup>5</sup> The inferior alveolar nerve block (IANB) is a widely utilized technique to induce anesthesia for endodontic procedures. Matthews et al., reported a success rate of 33% for INAB in cases with irreversible pulpitis.<sup>6</sup>

With the advent of additional gadgets in the 20<sup>th</sup> century, intraligamentary anesthesia (ILA) was introduced as a novel and effective method of achieving effective anesthesia as a mode of supplemental technique. The ILA injection produces an immediate desensitization of these nerve endings surrounding the tooth and of the pulpal nerves.<sup>7</sup> In mandibular molars with asymptomatic irreversible pulpitis, Lin et al., evaluated the success rate of ILA syringe (ErgojectIntralig Syringe, Anthogyr SAS, Sallanches, France) utilizing both two and four-site injection techniques. The researchers found that ILA anesthesia was effective in 92.1% of the treated teeth. The study also suggested the potential of utilizing four-site ILA injections as an anesthetic approach to mandibular molars with asymptomatic irreversible pulpitis.<sup>8</sup>

The single tooth anesthesia (STA) System (2006) is a computer-controlled device featuring dynamic pressure sensing technology. With the help of this innovation, fluid pressure and flow rate may be precisely controlled and continuously monitored at the needle tip throughout the injection process. Using the Wand system, successful pulpal anesthesia was achieved in 86% of cases with the articaine solution and 74% of cases with the lidocaine solution.<sup>9,10</sup>

The research aimed to evaluate the effectiveness of the STA System in comparison to the traditional IANB injection technique, both using 4% articaine (1:100,000 epinephrine), with symptomatic irreversible pulpitis, in mandibular molars.

### Aims and objectives

The present clinical trial was undertaken to assess and compare the effectiveness of the conventional IANB

and the ILA technique utilizing the STA system for endodontic management of mandibular molars presenting symptomatic irreversible pulpitis.

## MATERIALS AND METHODS

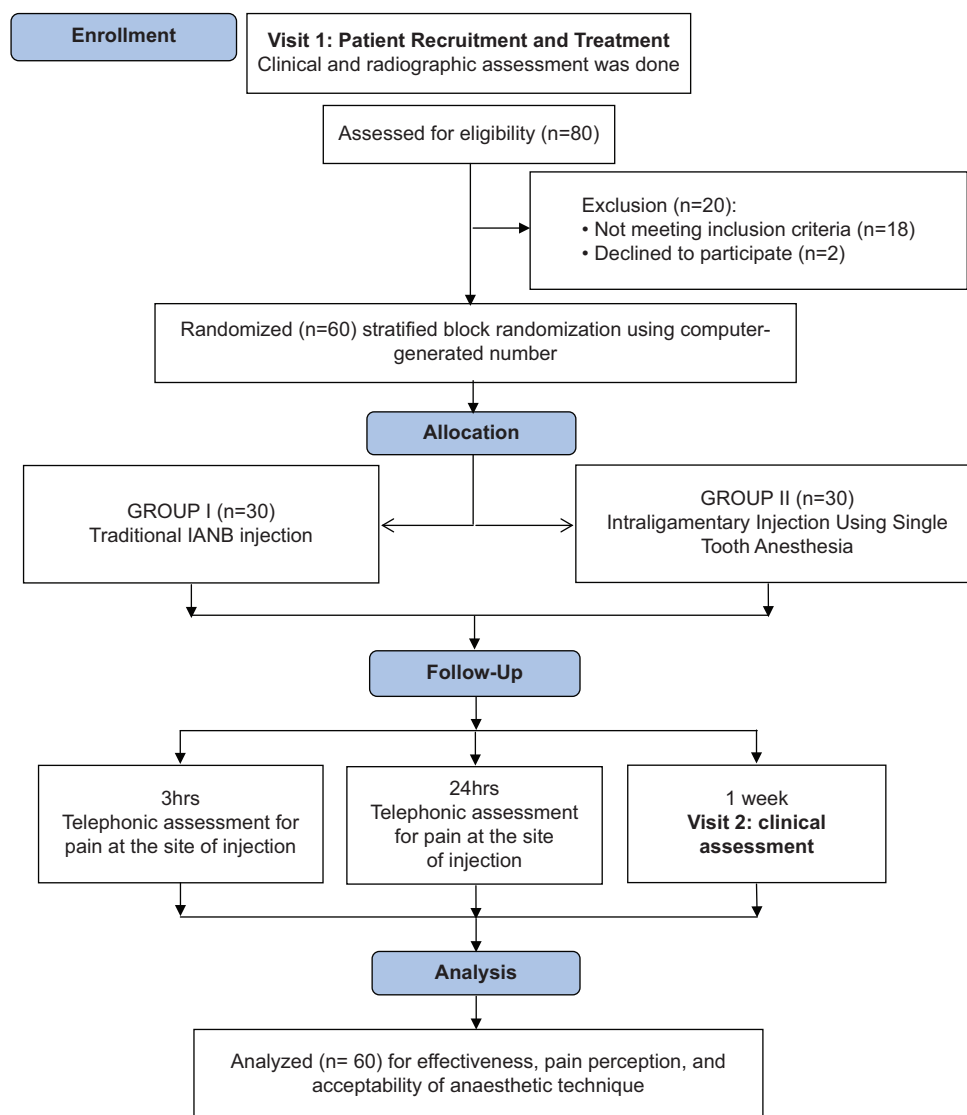
After approval from the institutional ethical committee, this clinical trial was registered with the Clinical Trial Registry of India (<http://www.ctri.nic.in/>) CTRI/2018/05/013890. All patients reporting to the outpatient department of the Department of Conservative Dentistry and Endodontics with a history of acute pain associated with mandibular molars for 4 months were evaluated for the study. All 80 patients were assessed, out of which 18 patients did not fulfill the inclusion criteria (Table 1) whereas two of them declined to participate in the research. Setting a Type 1 error level at 0.05 and a Type 2 error level at 0.20 served as a reference for the determination of sample size. It was determined through a power calculation and data from an earlier study [9], that a participant pool of 60 individuals would have 80% power to detect a 15% difference in the rate of success in the test group. Stratified block randomization of samples was done by the open Epi random program (<https://www.openepi.com/Random/Random.htm>). According to the block number generated the cases were allocated into two cohorts: Group I (n=30) IANB and Group II (n=30) STA system to maintain the double-blind design, one trained clinician examined and selected the patients, another trained clinician performed the endodontic treatment procedure including anesthesia and an independent observer recorded all the responses Figure 1.

Success was determined as the operator's capacity to attain entry to the pulp and perform canal instrumentation with minimal or slight discomfort, as signaled by a Heft-Parker Visual Analog Scale (HP VAS) score measuring <55 mm.

**Table 1: Inclusion and exclusion criteria**

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>Active pain in the mandibular molars (&gt;54 mm on the HP VAS).</li> <li>Prolonged response to cold test and an electric pulp testing (EPT).</li> <li>Lack of periapical radiolucency is evident on X-rays, except in cases of the widened periodontal ligament.</li> </ul>	<ul style="list-style-type: none"> <li>Large periapical radiolucency with mandibular 1<sup>st</sup> and/or 2<sup>nd</sup> molars, periodontal disease other than acute apical periodontitis</li> <li>History of any medication that would alter pain perception</li> <li>History of allergy or sensitivity to local anesthetic drug or suspected drug abuse, history of bleeding problems</li> <li>Pregnant or breastfeeding women and patients requiring supplementary injections to achieve anesthesia</li> </ul>

HP VAS: Heft-Parker Visual Analog Scale



**Figure 1:** Representing the PIRATE Flowchart of previously conducted randomized control trial

Patients were thoroughly briefed about the treatment and utilization of pain measurement scales. Before treatment, participants recorded their initial pain levels on the 170-mm HP VAS. Subsequently, the scale was categorized into four sections: “absence of pain” for measurements under 1 mm, “slight, feeble, or mild” pain for measurements between 1 and 54 mm, “moderate” pain for measurements between 55 and 114 mm, and “intense, powerful, and utmost possible” pain for measurements over 114 mm.<sup>11</sup>

Group I received traditional IANB using 1.7 mL 4% articaine (1:100,000 epinephrine) using a 27 gauge needle; the subjective symptoms, i.e., profound lip numbness were evaluated for the time of onset of local anesthesia. Whereas Group II received an Intraligamentary injection with STA System (Milestone Scientific) using 0.9 mL (per side) 4% articaine (1:100,000 epinephrine) by 30 gauge ½ inch needle as subjective symptoms were absent, the attached gingiva

adjacent to tooth structure was probed every 10 min and the response was evaluated on HPVAS score. The participants were asked to rate their pain during anesthetic administration utilizing the HPVAS score for both techniques.<sup>11</sup>

The root canal treatment procedure was carried out under magnification (2.5×) using rubber dam isolation by a single operator. Access opening was done and a 10 no. K file (SybronEndo, Mexico) was used as a pathfinder file followed by 15. K file (SybronEndo, Mexico) for working length determination. Biomechanical preparation was done using Protaper next files (DentsplyMaillefer, USA) with intermittent irrigation with Sodium hypochlorite 5.25% (Hyposept UPS Hygienes, India) and normal saline (0.9% w/v, Nirlife, India). After the completion of root canal treatment, the participants were requested to rate the pain experienced by them during an endodontic procedure on HP-VAS score for both cohorts.

The duration of anesthesia for Group I was evaluated by wearing off subjective symptoms. The subjective symptoms of Group II were evaluated by asking the patient to press the attached gingiva with fingernails every 10 min until they experienced normal pressure and this response was recorded. In addition, post-anesthetic pain was recorded by patients at an interval of 3 h, 24 h, and 1 week. All relevant data regarding effectiveness, pain perception, and acceptability, were collected, and evaluated using descriptive-analytics statistics.

### Statistical analysis

We utilized SPSS RevMan Statistics version 20.0 for the statistical analysis. The significance level ( $\alpha$ ) was established at 0.05, and a confidence interval of 95% was applied. To assess the association between gender and drug groups concerning the efficacy of IANB, we employed the Pearson Chi-square test.

## RESULTS

### Demographic data

Participants in Group I were substantially older than the average age of Group II indicated by a  $P=0.0034$ , obtained using a t-test for independent samples. The distribution of patients according to gender was insignificant in both groups as indicated by a  $P=0.6054$ , obtained using Pearson's Chi-square test (Table 2).

### Effectiveness of anesthetic techniques

The mean commencement of anesthesia in Group II was significantly higher than in Group I as indicated by a  $P=0.0001$ , obtained using a t-test for independent samples. The mean electric pulp testing (EPT) reading before anesthesia in both groups was statistically insignificant ( $P>0.05$ ). The average EPT reading after anesthesia for both groups was statistically significant as compared to before testing ( $P<0.0001$ ) (Table 2).

### Pain perception of anesthetic techniques

The significance of pain intensity before anesthesia was evident in both groups, with a  $P=0.0209$  ( $P<0.05$ ) determined through Pearson's Chi-square test. The result from Pearson's Chi-square test yielded a  $P=0.0552$  ( $P>0.05$ ), and the severity of pain at the injection site was insignificant in both groups. The severity of pain during RCT was significant in both cohorts as indicated by a  $P<0.0001$ , obtained using Fisher's exact test. The pain perception at the site of injection after completion of endodontic procedure at different time intervals in Group I, at 3 h, the presence of pain at the site was experienced by 8 patients, while at 24 h and 1 week, none of the patients experienced the pain. On the other hand,

in Group II, not a single patient experienced pain at these 3 time intervals (Table 2).

### Acceptability of anesthetic techniques

The acceptability of anesthetic techniques for both groups was statistically insignificant as indicated by a  $P=0.21$  using the Chi-square test of homogeneity (Table 2).

## DISCUSSION

The local anesthetic technique is the most consistently used technique for endodontic pain management. The IANB is the prevailing technique employed to achieve pulpal anesthesia in mandibular molars during endodontic procedures. Potocnik and Bajrovic, Aggarwal et al., have reported a higher IANB failure rate (30–45%, 7–77% respectively) mainly in teeth with irreversible pulpitis.<sup>12,13</sup>

Supplemental injections become necessary when the anesthesia achieved through conventional injections is insufficient. The computer-controlled local anesthetic delivery system provided a high level of injection control. A local anesthetic solution supply is automatically delivered at a constant pressure-to-volume ratio regardless of variations in tissue resistance. A recent advancement is the introduction of the STA system (2007). It has the advantage of proper placement of the needle through real-time visual and audible feedback, which provides information about the pressure of anesthetic solution and tissue when compared to the Wand system.<sup>9,10</sup>

In this study, the smaller gauge needles were used, i.e., for IANB 27 gauge and STA system 30 ½ gauge, which reported mild pain during anesthetic administration. Hamburg found that patients could not distinguish between 23-, 25-, 27-, and 30-gauge needles. Similarly, in adult INAB, Fuller et al., found no appreciable differences in pain perception caused by 25-, 27-, and 30-gauge needles. Lehtinen conducted a study that involved a comparison between 27-gauge and 30-gauge needles. The findings indicated that insertions with the 30-gauge needle demanded lower force, although the difference in pain perception was not as significant.<sup>14-16</sup>

The selection of anesthetic medications relies on the quantity of anesthetic solution and its concentration, which can influence the effectiveness of anesthesia. Lidocaine (1942) is the local anesthetic solution frequently utilized which is considered as a gold standard for comparing new local anesthetic drugs. An additional noteworthy anesthetic solution is Articaine (1969), which is identified as 4-methyl-3-(2-[propylamino]propionamido)-2-thiophene carboxylic acid, methyl ester hydrochloride). This compound falls under the category of amide local

**Table 2: Demographic data, effectiveness, pain perception, and acceptability of the anesthetic techniques**

Study characteristics	Group I (IANB) n=30				Group II (STA System) n=30			
	Before	After	Before	After	Before	After	Before	After
Age, mean±SD		39.10±9.76		31.73±8.87				
Gender: Female		17 (56.67)		14 (46.67)				
mean±SD (%)								
Gender : Male		13 (43.33)		16 (53.33)				
mean±SD (%)								
The mean time of onset of anesthesia (minutes)		1.40±0.86		2.93±1.80				
Effectiveness by electric pulp testing mean±SD	6.47±0.86	10.00	6.63±0.61	9.87±0.35				
	Mild	Moderate	Mild	Moderate	Severe			
Severity of pain before anesthesia (HP-VAS scale) (%)	6 (20)	23 (76.67)	16 (53.33)	14 (46.67)	1 (3.33)			
	No pain	Faint	No pain	Faint	Moderate	Severe		
Severity of pain during drug administration at site of injection (HP-VAS scale) (%)	11 (36.67)	6 (20)	11 (36.67)	6 (20)	2 (6.67)			
	No Pain	Faint	Mild	Mild	Moderate	No Pain	Faint	Moderate
Severity of pain during RCT (HP-VAS scale) (%)	25 (83.33)	1 (3.33)	4 (13.33)	25 (83.33)	0	4 (13.33)	25 (83.33)	1
	3 h	24 h	24 h	24 h	3 h	1 week	24 h	1 week
	Yes	No	Yes	No	Yes	No	Yes	No
Severity of pain After completion of RCT (HP-VAS scale) (%)	8 (26.67)	22 (73.33)	-	30 (100)	-	30 (100)	-	30 (100)
	Agree	Partially Agree	Partially Agree	Agree	Agree	Partially Agree	Partially Agree	Agree
Acceptability of anesthetic technique	21 (70)	9 (30)	26 (86.67)	4 (13.33)				



anesthetics and comprises a thiophene ring as well as an additional ester ring. Poorni et al., reported that mandibular molars with irreversible pulpitis could benefit from pulpal anesthesia produced by buccal infiltration with 4% articaine.<sup>17</sup> Malamed et al., reported that 4% articaine with epinephrine 1:100,000 ensures a secure and efficient local anesthetic. In addition, the anesthesia's onset time and duration align appropriately with the requirements for conducting clinical procedures.<sup>18</sup> Kung et al., Su et al., and St. George et al., noted that articaine exhibited a success rate of 1.15–2.3 times higher than lidocaine. However, Brandt et al., concluded that there were no differences between the two solutions.<sup>19–22</sup> Nagendrababu et al., conducted a meta-analysis incorporating eight clinical trials and determined that articaine demonstrated a 1.16 times higher rate of anesthetic success compared to lidocaine, with the IANB technique.<sup>23</sup> Hence, in the current study, articaine was used as an anesthetic drug of choice for endodontic procedure.

Sixty patients (n=60) diagnosed with symptomatic irreversible pulpitis in need of endodontic treatment were selected for the research and informed consent was acquired from participants before the treatment procedure. The appropriate diagnosis was made using intraoral periapical radiographs, EPT, and Cold tests. Due to its subjective characteristics, pain management is challenging to establish. The traditional methods used for measuring pain are quantitative and linguistic self-rating scales. The HP-VAS score utilized in the current research is a standardized, noninvasive, and validated method. It incorporates the arrangement of six descriptive words on a 170-mm horizontal line to measure pain. An Independent blinded observer was allotted to record reading before, during, and after the procedure. The HP-VAS score was taken before the anesthetic procedure to evaluate pain before anesthesia and equalize the patient's pain threshold.

Säkkinen et al., reviewed various post-operative complications associated with IANB.<sup>24</sup> Fowler and Reader, reported that after intraligamentary injection was administered, the periodontal ligament experienced minimal localized irritation after 24 h.<sup>25</sup> Hence, in the present study for both anesthetic techniques, the patient's follow-up was done after 3 h, 24 h, and 1 week to rule out any complication and post-anesthetic pain. The participants were requested to rate their pain score if they had reported any pain.

#### Demographic variation

In the current study, the range of mean age for both groups was 31–39 years and equal gender distribution was reported.

#### Effectiveness of anesthesia

The mean EPT value recorded before the administration of anesthesia for Group I was 6.47, and for Group II 6.63. This suggests that the pain threshold of both the group were same, suggesting equal distribution or normalization of the sample size. After administration of anesthesia, EPT was recorded for both groups. The mean value calculated for Group I was 10, 9.87 for Group II. This suggests that both techniques were effective. The current study is by Reader and Nusstein who used the EPT to monitor pulpal anesthesia and they reported that the lack of response of the EPT indicates pulpal anesthesia obtained clinically.<sup>26</sup>

The initial time of anesthesia for both groups was evaluated by subjective symptoms and EPT readings before and after anesthetic procedures. The mean time in the STA group was  $2.93 \pm 1.80$  min, which was significantly higher than the IANB group's  $1.40 \pm 0.86$  min, as demonstrated by a  $P=0.0001$ , obtained using a t-test for independent samples. The anatomical position of mandibular molars and bone density can alter the success rate of IANB. Waikakul and Punwutikorn reported the onset between 3 and 10 min post-injection and the pulpal anesthesia 7.7–8.8 min for IANB, respectively.<sup>27</sup>

#### Evaluation of pain perception and acceptance of anesthetic technique

The pre-anesthetic pain in irreversible pulpitis in our study was moderate and lingering in nature requiring endodontic treatment; these findings of our study were by Pak and White who reported 80% of patients experiencing severe pain before endodontic treatment.<sup>28</sup>

Patients' perceptions of pain can differ as they exhibit diverse emotional reactions to equivalent levels of stimulus intensity. Segura-Egea et al., discovered a notable correlation between pulp condition and the degree of discomfort encountered during root canal therapy, with increased pain occurring in teeth afflicted by irreversible pulpitis and acute apical periodontitis.<sup>29</sup> In our study, Group I reported that 83.33% of patients experienced no pain, followed by 13.33% of patients who went through mild pain. While in the STA group, 83.33% of patients experienced mild pain, and 13.33% of patients suffered from no pain condition.

In the current research, the acceptance of anesthetic techniques was analyzed by patient feedback; both groups reported no significant difference regarding the acceptability of anesthetic techniques. This suggests that both techniques were acceptable to the patients.

The post-anesthetic pain represents a discomforting fusion of sensory, perpetual, and emotional sensations of the

patients. The needle perforating the mucosa, and the rate of deposition of anesthetic solution might be an attributing factor for post-anesthetic pain at the site of injection. In the present study, Group I reported mild pain after 3 h in eight patients, while no pain was reported at 24-h and 1-week time intervals. On the other hand, in Group II, not a single patient experienced post-anesthetic pain at the site of injection. Both groups reported an absence of substantial variation in anesthetic effectiveness, pain discomfort, and acceptability. Thus, the alternate hypothesis, ILA using the STA System will prove an effective anesthetic technique as IANB in cases with symptomatic irreversible pulpitis was accepted. Hence, to conclude, the STA system could serve as an initial anesthetic agent for mandibular molars in cases with irreversible pulpitis. However, further clinical trials are required to evaluate the effectiveness of Intraligamentary injection using the STA System.

### Limitations of the study

Pain is a subjective phenomenon hence it is difficult to assess the accuracy of pain. The anatomical variation and absorption of local anesthesia could impact the efficacy of anesthesia. A study with substantially large sample size is necessary for the benefits of the STA system and its clinical implementation.

## CONCLUSION

Given the constraints inherent in this study, both the groups reported similar effectiveness of anesthesia, pain perception by participants, and acceptability of anesthesia technique. Hence, to conclude; Intraligamentary injection using the STA system could serve as a primary anesthetic method for cases dealing with symptomatic irreversible pulpitis. However, further clinical trials are required for the same.

Flow diagram of traditional INAB compared with intraligamentary injection using STA system for endodontic management of mandibular molars with symptomatic irreversible pulpitis. The diagram includes the distribution of participants using the double-blind clinical trial.

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