

Comparing intraosseous computerized anaesthesia with inferior alveolar nerve block in the treatment of symptomatic irreversible pulpitis: A randomized controlled trial

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Abstract

Aim: The aim of this study was to compare the cardiovascular effects [heart rate, oxygen saturation (SpO₂), systolic and diastolic blood pressure] and the anaesthetic efficacy of intraosseous computerized anaesthesia (ICA) versus inferior alveolar nerve block (IANB) in Symptomatic irreversible pulpitis (SIP).

Methodology: The study protocol was registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03802305) (NCT03802305).

In a randomized, prospective clinical trial, 72 mandibular molar teeth with SIP were randomly allocated to conventional IANB injection ($n = 36$) or ICA injection ($n = 36$), both with 1.8 mL of 4% articaine with 1:100 000 epinephrine. The primary objective was to assess the cardiovascular parameters (heart rate, oxygen saturation, blood pressure) before, during and after the anaesthesia. The secondary objectives were to compare ICA with IANB for success and postoperative outcomes for up to 3 days.

Results: The maximum increase in heart rate in the ICA group was greater than in the IANB. Other cardiovascular parameters did not show differences throughout the clinical procedure. There were no statistically significant differences ($p > .05$) between groups for sex, age, or anxiety. The total success rate of ICA (91.43%) was significantly higher ($p = .0034$) than that of IANB (69.44%).

Conclusions: This study establishes that ICA is safe and efficient in the first intention for the treatment of SIP of the mandibular molar.

KEYWORDS

dental anaesthesia, dental emergency, local anaesthesia, mandibular molars, pain management, pulpotomy, symptomatic irreversible pulpitis

INTRODUCTION

Symptomatic irreversible pulpitis (SIP) is characterized by intense and spontaneous orofacial pains that must

be treated as a dental emergency (Eren et al., 2018). In case of multirrooted teeth, the emergency treatment consists of pulpotomy (removal of the coronal pulp) or partial pulpectomy (Hargreaves & Keiser, 2004). Obtaining

a successful anaesthesia to perform the emergency procedure is often difficult to achieve with inferior alveolar nerve block (IANB) (Yadav, 2015). The failure rate of IANB in the case of inflammatory pulps is between 44% and 81% (Claffey et al., 2004; Reisman et al., 1997; Zanjir et al., 2019) and supplemental buccal infiltrations are usually necessary. These failures of the IANB can be explained by the anatomical variation between individuals, by the difficulty to perform blindly the anaesthesia and or by the lower pH in the inflamed tissue neutralizing the action of the anaesthetic molecule on the ion channels in the nerve sheath and membrane (Meechan, 2002; Potocnik & Bajrovic, 1999). In addition, emergency situations increase certain psychological factors such as fear or anxiety (Sharma et al., 2019).

Supplemental or alternatives techniques including periodontal ligament, intraosseous, pulpal and submylohyoid anaesthesia have been advocated (Farhad et al., 2018; Jensen et al., 2008; Moore et al., 2011; Pereira et al., 2013; Razavian et al., 2013). During intraosseous anaesthesia, the anaesthetic solution is directly delivered into the cancellous bone allowing fast diffusion of the anaesthetic agent. Several types of intraosseous anaesthetic systems have been commercialized and studied clinically, such as the Wand (Milestone Scientific), X-Tip (Dentsply International) and Stabident (Fairfax Dental) systems, and more recently, intraosseous computerized anaesthesia (ICA), such as the Quicksleeper5 system (Dental Hi-Tec).

Although intraosseous anaesthesia offers several advantages (no soft tissue numbness occurs, short duration of anaesthesia and relatively little anaesthetic solution is needed), the question to use it as a supplemental or an alternative technique to IANB still remains controversial regarding the success rate. A recent meta-analysis concluded that the anaesthetic efficacy was similar between IANB and intraosseous anaesthesia for mandibular third molar surgery (Kumar et al., 2022). Another meta-analysis in case of SIP, concluded that intraosseous anaesthesia given after the failure of primary IANB, increases the overall anaesthetic efficacy (Gupta et al., 2021). According to Zanjir et al., superiority of intraosseous injection to achieve pulpal anaesthesia of mandibular molars with SIP is only supported by very low-to-moderate quality evidence.

One drawback of intraosseous anaesthesia injection is the safety of intraosseous anaesthesia and the potential increase in heart rate. Blood pressure and cardiovascular monitoring can contribute to the safety of local anaesthesia through the early detection of potential side or adverse effects. Studies on the increase of heart rate during intraosseous anaesthesia showed that the Stabident System or the X-Tip System could increase in a reversible manner the heart rate by 8–28 beats/min (BPM) and 9–10 beats per minute on average, respectively (Kaufman et al., 1984;

Replogle et al., 1999; Susi et al., 2008; Wood et al., 2005). There are very few studies assessing the safety and the variations in cardiovascular parameters for ICA. As highlighted by Zanjir et al. (2019) well-designed randomized controlled trials (RCT) are required to further assess the efficacy and safety of intraosseous interventions.

The aim of this RCT was to compare the cardiovascular effects and the anaesthetic efficacy of ICA versus IANB in the SIP of mandibular molars. The primary objective was to assess the cardiovascular parameters (heart rate, oxygen saturation (SpO₂), systolic and diastolic blood pressure) before, during and after the anaesthesia. The secondary objectives were to compare ICA with IANB for success and postoperative outcomes.

MATERIALS AND METHODS

Protocol approval, registration and participants

This randomized clinical trial has been written according to Preferred Reporting Items for Randomized Trials in Endodontics (PRIRATE) 2020 guidelines (Nagendrababu et al., 2020).

The research was conducted following the approval from the Human Research Ethics Committee of France (CPP) under protocol #2018/89. The protocol for this prospective randomized controlled trial (RCT) was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT03802305). This RCT followed the 1964 Declaration of Helsinki. Patients that agreed to volunteer and met the inclusion and exclusion criteria for this research provided informed oral consent prior to participating in the trial. A written information containing the essential information of the study (description, duration, right to withdraw at any time, the Ethics Committee approval and the personal data privacy guarantee) was given to the patients. The study protocol is available as an open publication (Laham et al., 2022). A total of 91 patients seeking dental emergency consultation at the Nantes University hospital for SIP between March 2019 and June 2022 were examined.

Inclusion and exclusion criteria

A total of 72 patients that met the inclusion and exclusion criteria were included in this study. Medical history was collected from each individual, followed by a clinical and radiograph examination.

The inclusion criteria were (1) Patients suffering from spontaneous and/or diffuse pain with first or second mandibular molar with severe sensitivity to cold and/or heat

tests; (2) patients over 18 years old (of any gender); (3) patients with no medical history (ASA 1 score) and no drug treatment for cardiac rhythm disorders (antiarrhythmics, beta-blockers); (4) patients able to give his/her oral consent; (5) patients affiliated with health insurance; and (6) agreed to be contacted by phone 72 h after the emergency treatment.

The exclusion criteria were as follows: (1) contraindications to anaesthesia with vasoconstrictors; (2) diagnosis of reversible pulpitis, acute apical periodontitis, periodontal lesion of the endodontic origin, or dentin syndrome; (3) nonretainable tooth requiring extraction; (4) vital tooth serving as an abutment in the fixed prosthesis; (5) patients under 18 years old; (6) patients who do not understand French and (7) pregnant or breastfeeding women.

Sample size calculation

The sample size calculation was based on the noninferiority hypothesis in a pilot study that there will be an expected mean difference of 1 min 30 s between the two anaesthetic techniques with regards to the time taken for the values to return to the initial ones. According to our results from the pilot study and the reported results from the few studies available, the proportion of patients having successful anaesthesia and better pain control in ICA would be 93%. The noninferiority margin was defined as 20%. The significance was set at 1.7% for the three main criteria (heart rate, systolic and diastolic blood pressure) and 5% for the secondary criteria. Thus, using a bilateral test with an epiR package 0.98–87 (Biostatgv; <https://biostatgv.sentiweb.fr>), 72 patients (36 patients per arm) were included in the study.

Randomization

Patients were randomly assigned to one of the two arms: 'ICA' and 'IANB' at a ratio of 1:1. The randomization was computer-generated, and the randomization process was centralized through a secured clinical data processing website managed by Ennov© Clinical system software (Ennov). The investigators entered the patient's information and the software provided the randomization group (Figure 1). This study was a single-blinded study since only the three operators were familiar with the injection method and could not be blinded to randomization due to the different devices used for the two anaesthesia techniques. However, the patients were blinded to the assigned group and the subsequent type of injection. Only information regarding the necessity of anaesthesia and the anaesthesia molecule was provided to the patients.

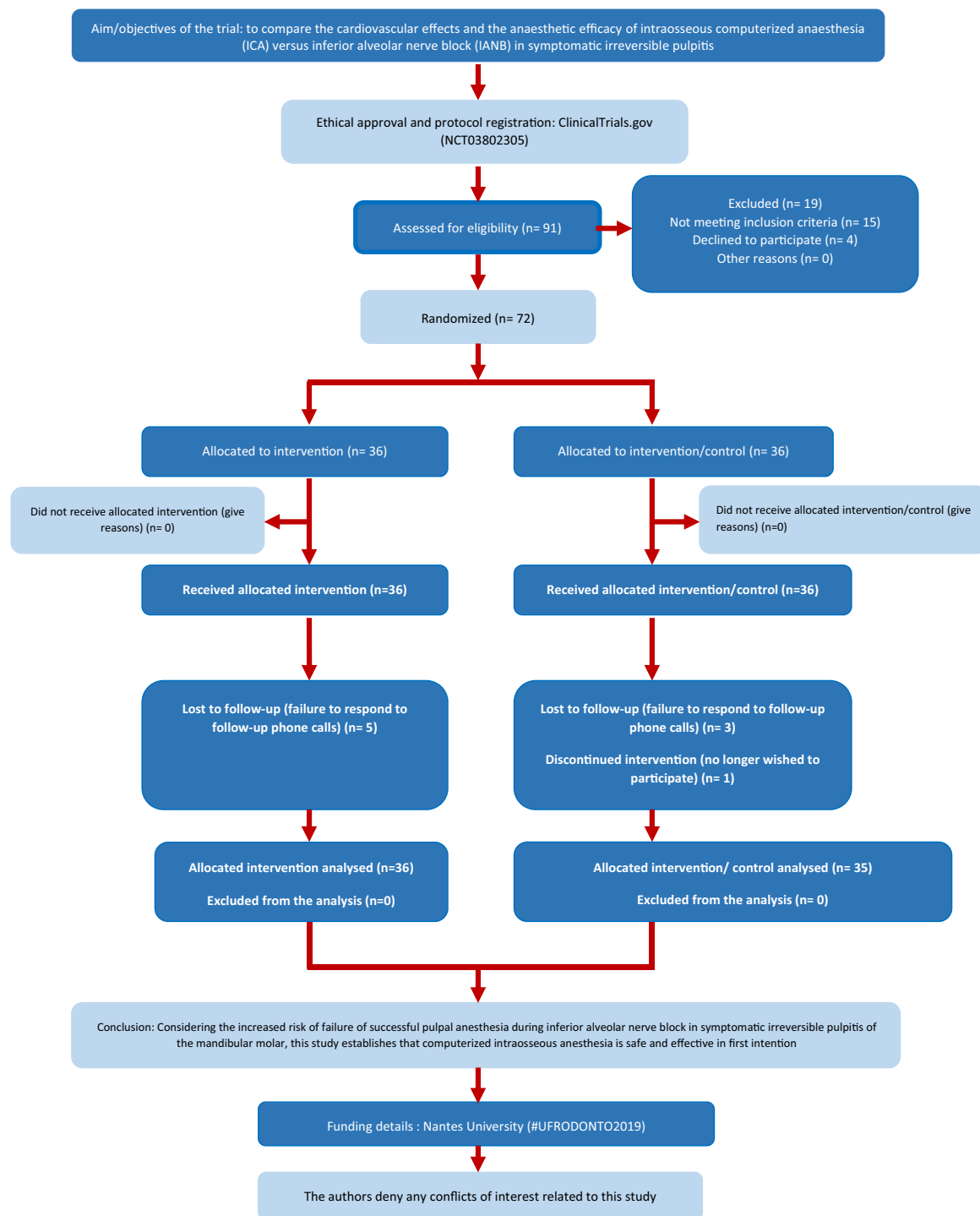
Intervention

The patients filled out the French version of Corah's dental anxiety scale (Table S1; Corah et al., 1978). Then, a blood pressure cuff was placed on the patient's arm and a pulse oximeter on a finger on the other arm to monitor cardiovascular parameters [heart rate and SpO₂ (every 15 s)], systolic and diastolic blood pressure (every 2 min), throughout the intervention.

Each patient, regardless of the study group allocated, received 1.8 mL of 4% articaine 1:100 000. The evaluated intervention consisted of the administration of ICA using the Quicksleeper5 (DHT) system. The system was used according to the manufacturer's recommendations. The Quicksleeper5 system is composed of a control pedal, an electronic box (with power supply), a handpiece mounted with a rotating container containing the anaesthesia cartridge and a needle placed in the axis of the handpiece (Figure 2). First, alveolar mucosa adjacent to the site of injection is infiltrated with a few drops of anaesthetic until a white halo appears on the mucosa. The needle is then positioned in the middle of the interdental space, at the top of the papilla, parallel to the axis of the roots in the mesiodistal plane; between 30° and 45° in relation to the axis of the teeth in the vestibulolingual plane and then inserted approximately of 12 mm by the cycles of rotation of the device (10 cycles maximum). Lastly, there is a slow injection (drop by drop for 10 s) then accelerated of the anaesthesia solution during the rotation phase, without pressure on the handpiece. When the entire cartridge is injected, the needle is removed from the site and the plunger automatically returns to zero.

For IANB, patients were sat in semi supine position, advised to open the mouth comfortably wide and the operator placed the tip of his thumb finger over the anterior border of ramus to help in retraction of tissues and to help in identifying anatomical landmarks. The location of the insertion of the needle was on an imaginary line drawn from the deepest part of the pterygomandibular raphe to the coronoid notch. The insertion point was parallel to—and about 1 cm above—the mandibular occlusal plane, at the vertical plane of the coronoid notch. The needle was slightly inserted in the mucosa and an aspiration was carried out to rule out intravascular placement. The anaesthetic syringe plunger was located at the opposite site close to the premolars and the injection was slow (between 1 and 2 min; Khalil, 2014).

The emergency treatment was the removal of the entire cameral pulp (pulpotomy). Absence of pain was checked after the anaesthesia and prior to rubber dam placement. All carious tissue was removed before pulpal parenchymal evulsion. Disinfection and haemostasis were performed using 2.5% sodium hypochlorite. After checking



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FIGURE 1 A PRIRATE flowchart of patients throughout the trial.

for bleeding, the site was filled with calcium hydroxide and a temporary filling (glass ionomer cement). At the end of the intervention, all patients, regardless of the randomization group, were recommended to take painkillers only if they experience pain, according to the good clinical recommendations.

Evaluation criteria

Primary outcome

The main outcome of this study was to compare the cardiovascular parameters (heart rate, SpO₂, systolic and



FIGURE 2 Photograph of the Quicksleeper5 system.

diastolic blood pressure) between the two groups: ICA versus the reference technique: inferior alveolar nerve block (IANB). The timing of the evolution of the parameters was based on three phases: 'baseline' from T0 to T + 4 min, 'anaesthesia' from T + 4 to T + 8 min and 'pulpotomy' from T + 8 to T + 14 min.

Secondary outcome

Secondary outcomes included the efficacy of the anaesthesia, where success was defined as the ability to complete the pulpotomy procedure on the tooth with no or mild pain [Visual Analogue Scale (VAS) score <2] and the requirement of supplemental injection via any technique was considered a failure.

Post-operative pain at Day (D)0 and D + 1, D + 2 and D + 3; and post-operative care were assessed using a questionnaire and by a phone call at day 3. To assess the post-operative pain, patients were asked to rate pain using a visual analogue scale (instructions and a scale were given at the end of the appointment) from 0 to 10, where 10 represented the worst pain possible. Parameters such as swelling, hematoma, bite injury, mouth opening limitation were recorded. To assess the perception of the anaesthesia the patients were asked to rate the comfort level based on the following criteria (very comfortable, comfortable, uncomfortable, very uncomfortable).

Statistical analysis

The Bartlett test was used to assess variance homogeneity and the Kolmogorov–Smirnov test to assess data distribution. The Mann–Whitney test was used to assess the differences in age, Corah anxiety scale, duration of

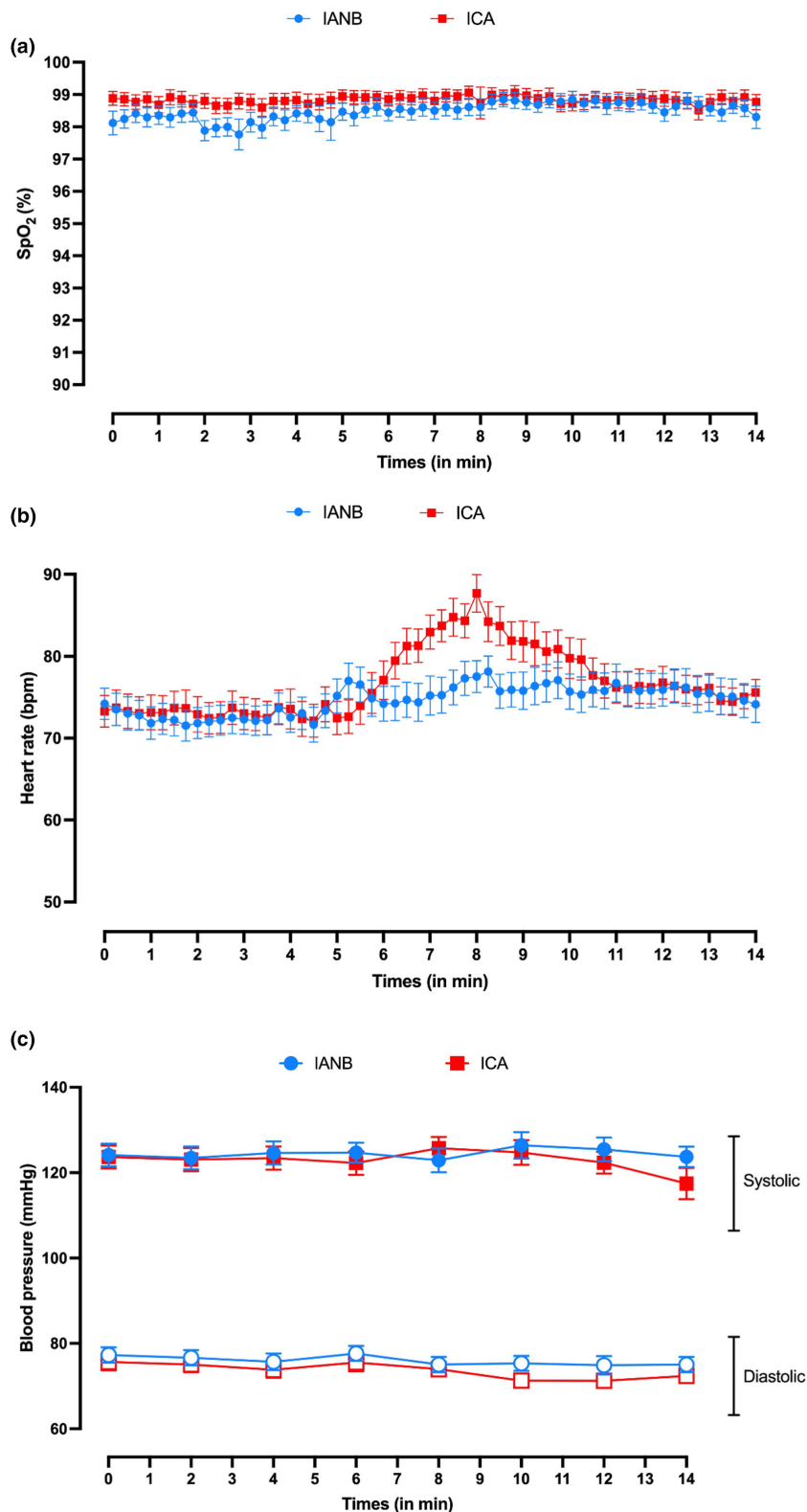
the anaesthesia and pain assessment. The anaesthesia success rate was assessed by Fisher's exact test. Data on heart rate, SpO₂ and blood pressure were submitted to Shapiro–Wilk tests to verify the similarity of variances and normal distribution. Two-factor analysis of variance (ANOVA) and Tukey tests were used to observe intra- and intergroup differences regarding heart rate, SpO₂ and blood pressure. All analysis was carried out using GraphPad Prism 9.0. The level of significance was set at 5%.

RESULTS

One of the 72 patients who initially participated in the study was excluded because the patient was unwilling to continue the treatment procedure (Figure 1). No side effects, such as syncope, central nervous system reaction, or allergic reactions, were reported by any of the patients. There were no statistically significant differences ($p > .05$) between groups for sex, age, or anxiety. The cardiovascular changes (Heart rate, SpO₂ and blood pressure recordings) are summarized in Figure 3. Considering SpO₂ records, no statistically significant differences were observed between groups or with time (Figure 3a). After the delivery of local anaesthesia, the heart rate increased in all groups, but this increase was greater in the ICA group. The maximum increase in heart rate in the ICA group (from 74.22 ± 11.47 to 87.67 ± 13.83) was greater than in the IANB group (from 73.31 ± 11.59 to 77.53 ± 11.62). Heart rate differences between groups were limited to within the first 8 min ($p < .05$; Figure 3b). There were no statistically significant differences between groups for both systolic/diastolic blood pressure (Figure 3c).

The total success rate of ICA (91.43%) was significantly higher ($p = .0034$) than that of IANB (69.44%). The ICA group had a significantly shorter duration of anaesthesia than the IANB group ($p < .0001$). According to the post-operative assessment, the average duration of the anaesthesia perceived by the patient was 76.50 ± 44.97 min for ICA and 191.5 ± 72.39 min for IANB. Both groups showed a median score of 8 for preoperative pain ($p = .1006$). The median score for pain on day 3 was 0 for both groups ($p = .0762$). There was no difference between the groups for the need to use painkillers. Post-operative discomfort included one case of bite injury for the IANB group and the comparison of the patient's comfort during treatment resulted in an equivalent outcome with overall low degrees of unpleasantness ($p = .7929$; Table 1). As cardiovascular parameters of patients who needed supplemental injections were not analysed, the influence of supplemental local anaesthesia on mean duration, post-treatment pain and post-operative care was not assessed in this study.

FIGURE 3 Comparison of the variation of cardiovascular parameters during complete emergency pulpotomy according to the groups. (a) Mean (\pm SD) of the percentage of partial oxygen saturation (SpO_2). (b) Mean (\pm SD) heart rate. *Statistically significant differences (ANOVA: $p < .05$) between groups. (c) Mean (\pm SD) of noninvasive systolic/diastolic blood pressure.



DISCUSSION

The use of intraosseous anaesthesia has generated considerable interest among practitioners since the first description in 1975 (Lilienthal & Reynolds, 1975). Specialized delivery systems have evolved to become computerized

up to the ICA and can be used as an alternative to conventional nerve block anaesthesia to compensate for the failure of IANB or be used as the first intention. However, few valid clinical trials exist on the subject.

There was no difference in terms of sex, age and level of anxiety between the two groups. This homogeneity

TABLE 1 Comparison of age, sex, anxiety profiles, intensity of preoperative pain, percentage of successful anesthesia, duration of the anaesthesia, and pain assessment at Day 3 according to the groups.

Profile	IANB	ICA	p Value	Statistical test
N	36	35	–	–
Mean age \pm SD	41.69 \pm 5.025	40.31 \pm 4.851	.2766	Mann–Whitney
Sex	Male = 21 (58.3%) Female = 15 (41.2%)	Male = 22 (61.1%) Female = 13 (37.1%)	.6966	Chi-square
Corah anxiety scale [(median (first-third quartiles)]	7 (5–13)	9 (6–12.75)	.6543	Mann–Whitney
Preoperative pain (VAS) [median (first-third quartiles)]	8 (7–10)	8 (7–9.25)	.1006	Mann–Whitney
Percentage of anaesthesia deemed comfortable by patients	25/36 (69.44%)	22/35 (62.85%)	.7929	Fisher exact
Anaesthesia success	25/36 (69.44%)	32/35 (91.43%)	.0034	Fisher exact
Need to use painkillers	20/36 (55.55%)	18/35 (51.42%)	.0518	Fisher exact
Mean duration of anaesthesia (min) \pm SD	191.5 \pm 72.39	76.50 \pm 44.97	<.0001	Mann–Whitney
Evaluation of pain assessment (according to patient) at day 3 (median (first-third quartiles))	0 (0–2)	0 (0–5.25)	.0762	Mann–Whitney

Abbreviations: SD, standard Deviation; VAS, visual analog scale.

between the groups makes it possible to avoid gender or age-related biases. Indeed, it has been demonstrated that anxiety causes significant cardiovascular changes in patients undergoing injection of local anaesthesia (Sharma et al., 2019). The level of anxiety assessed by the Corah anxiety scale in the present study was comparable to another study regarding patients suffering from SIP (Pereira et al., 2013; Sharma et al., 2019).

Although IANB is associated with an increased risk of burning sensations and/or lip or cheek bite injuries and, in very rare cases, nerve-related adverse effects (Aquilanti et al., 2022; Youssef et al., 2021), very few adverse events were noted (only one case of bite for the IANB group). None of the potential side effects described with intraosseous anaesthesia (high occlusion for a few days, swelling; Coggins et al., 1996; Reisman et al., 1997; Zanjir et al., 2019) were recorded in the present study. Moreover, unlike other studies, no pain during perforation and injection was described by patients (Penarrocha-Oltra et al., 2012; Zanjir et al., 2019). The advantages of the ICA over other intraosseous anaesthesia are that the computer system controls the speed and the pressure of the infiltration of the anaesthetic solution in order to reduce the patient's pain and discomfort; moreover, the needle possesses a double scalpel blade bevel, which incises the tissues without tearing.

As expected, the duration of anaesthesia was shorter with the ICA group. Surprisingly this was not correlated with perceived comfort since the comparison of the

patient's comfort resulted in an equivalent outcome with overall low degrees of unpleasantness.

The solution used in the study was 4% articaine with 1:100 000 epinephrine, as suggested by the manufacturer of the ICA system. Articaine has been described as a safe and efficient local anaesthetic in the dental armamentarium (Bigby et al., 2006; Costa et al., 2005; Sixou et al., 2009). To avoid bias, the same solution was used for the IANB group.

The mean measurement of SpO₂ was constant, in the normal range, and no difference was observed between groups before and after the local anaesthesia administration. This result is in line with a previous study (De Holanda Vasconcellos et al., 2008; Ryh nen et al., 1996; Sharma et al., 2019).

There were no statistically significant differences between groups for systolic/diastolic blood pressure, confirming that blood pressure is generally stable after administration of anaesthetic solutions (Chamberlain et al., 2000; Replogle et al., 1999; Susi et al., 2008). However, older studies have noted increases in blood pressure during IANB and rapid intraosseous injections with 2% lidocaine with 1:80 000 norepinephrine (norepinephrine) (Lilienthal & Reynolds, 1975). This discrepancy may be explained by the use of norepinephrine, which is known to be approximately four times less vasoconstrictive locally than epinephrine and to have severe and paradoxical bradycardic action (Balakrishnan & Ebenezer, 2013). Moreover, the technique used for the intraosseous injection (sterile root

canal reamer; Balakrishnan & Ebenezer, 2013) was more invasive than the ICA used in the present study.

After the delivery of local anaesthesia, the heart rate increased in all groups, and the increase was greater with ICA compared to IANB, with the peak increase after ~8 min in the ICA group (from 74.22 ± 11.47 to 87.67 ± 13.83). The patient may perceive the increase in heart rate at approximately 10 beats/min (Borg & Borg, 2002). This increase in ICA was also reported by various authors assessing the safety of intraosseous anaesthesia (Replogle et al., 1999; Susi et al., 2008; Wood et al., 2005; Zarei et al., 2012). This increase in ICA in the mandibular molars can be explained by the fact that the mandibular cancellous bone around the molars is well vascularized, and any injected vasoconstrictor is, therefore, rapidly absorbed (Coggins et al., 1996; Lilienthal & Reynolds, 1975). However, this elevation is transient, with a return to baseline within 4 min and does not pose a serious cardiovascular risk to healthy people. The only concern is for patients with high blood pressure or any medical conditions in which epinephrine is contraindicated, where alternative anaesthetic solutions (e.g. 2% mepivacaine) are advised (Zanjir et al., 2019).

Several methods have been used to improve the effectiveness of anaesthesia for the treatment of SIP of mandibular molar since IANB has a high rate of failure (44%–81%) (Aggarwal et al., 2014; Chavarría-Bolaños et al., 2017; Zanjir et al., 2019). A recent systematic review and network meta-analysis on the efficacy of pulpal anaesthesia strategies during endodontic treatment of permanent mandibular molars with SIP concluded that very low-to-moderate quality evidence suggests intraosseous injection are superior strategies to achieve pulpal anaesthesia during endodontic treatment of mandibular molars with SIP (Zanjir et al., 2019). In the present study, the total success rate of ICA (91.43%) was significantly higher than that of IANB (69.44%). One hypothesis of the superiority of the ICA used in this study is that this ICA is a recent specific device that enables an easy injection of an anaesthetic close to the apices of the teeth. When the IANB or ICA failed, additional anaesthesia (other ICA or intraligamentary anaesthesia) was performed, and the cardiovascular parameters of these patients were not analysed.

Given the efficiency and safety of this technique, one can ask the question of its underutilization or the ignorance of using it. A survey in the United States reported the difficulty and the extra time needed when using cortical bone perforating with intraosseous anaesthesia by endodontists (Bangertner et al., 2009). To overcome these drawbacks, hands-on training and ergonomic advice could be given to dental professionals.

One limitation of this RCT is that the operator could not be blinded to randomization due to the different devices used for the two anaesthesia techniques. Another

limitation is that only healthy patients were included. To optimize the success of anaesthesia, premedication with nonsteroidal anti-inflammatory drugs or opioids with or without paracetamol could have been used (Zanjir et al., 2019); however, such premedications were not used to avoid bias in the study.

CONCLUSION

To our knowledge, this is the first prospective RCT comparing the safety and efficiency of the ICA with IANB. Based on our findings, we conclude that ICA is safe and efficient in the first intention for the treatment of SIP of the mandibular molar.

AUTHOR CONTRIBUTIONS

Alexis Gaudin, Tony Prud'homme, Bénédicte Enkel and Hamida Martin contributed to the experimental design. Alexis Gaudin, Tony Prud'homme, Roselyne Clouet, Camille Boëffard and Amany Laham curated and analysed the data. Gilles Amador Del Valle Gilles supervised the study. Alexis Gaudin and Tony Prud'homme contributed to writing original draft preparation. All authors contributed to review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The research was conducted following the approval from the Human Research Ethics Committee of France (CPP) under protocol #2018/89.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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