Risks and Performance of a New Guiding Device for Inferior Alveolar Nerve Block, EZ-Block®, Compared to Traditional Free Hand Techniques: A Pilot Study

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ARTICLE INFO

ABSTRACT

Introduction: In spite of a high failure rate and risk of complications, the inferior alveolar nerve block (IANB) is the most common anesthesia technique used in dentistry. The guiding medical device EZ-Block®, which relies on extra-oral landmarks easy to identify, would increase performance rate and reduce risks of IANB.

Materials and Methods: To test this hypothesis, analysis of 32 articles [1-32] between 2000 and 2020 about risks and performance of IANB free hand techniques was made. These results were compared with those of a pilot clinical study, carried out for a CE certification.

Results and Discussion: The success rate with EZ-Block® (95.9%) is higher than the rate observed in the scientific literature with the freehand technique (67.4%; IC 0.95 [57.2 – 77.6]). The 5-minutes onset time with EZ-Block® (92.0%) is higher than the rate observed in the scientific literature with the freehand technique (85.6%; IC 0.95 [78.2 – 93.0]). For the majority of risks, EZ-Block® provides lower complication rates than the rate observed in the scientific literature with the freehand technique. Only the trismus rate is higher with the EZ-Block®, although it remains within the same range.

Conclusion: The clinical data of the EZ Block® allow to evaluate the performance and the safety of the device. But this pilot study should be complemented with a larger clinical study to confirm the effectiveness of the device.

Introduction

The IANB is the most common anaesthesia technique used in dentistry [1,2,4,6-13,15,21,27,29,30,32]. The conventional method of blocking the inferior alveolar nerve requires the insertion of the dental needle near the area of the mandibular foramen, where the inferior alveolar nerve is located before it enters the foramen. Some important intraoral landmarks need to be identified by the operator in order to reduce the percentage of failure following the use of this technique [1]. The general anatomical landmarks of the mandible that the operator should be aware of and which can be used in the IANB, include the coronoid process and notch, the anterior and posterior border of the mandible, the sigmoid notch, and also the condyle. The most important clinical intra-oral landmarks used in the location of the IANB are the coronoid notch and the pterygomandibular raphe. The preferred site of needle insertion

lies between these two landmarks, and the point of insertion is determined by simple measurements: it is located on an imaginary line drawn from the deepest part of the pterygomandibular raphe to the coronoid notch.

The location of the insertion point on this line is one quarter the distance towards the pterygomandibular raphe above the occlusal plane of the lower teeth; the syringe barrel should be located at the opposite site close to the premolars teeth during injection [1,27]. The conventional IANB is associated with a failure rate of 15-20%, which represents the highest percentage of all clinical failures achieved using local anaesthesia [1,29]. Dunne [17] reported that the IANB was shown to have a success rate between 43% and 55.6% on healthy first permanent molar. Others studies that anaesthetised inflamed molar teeth, had success rates between 10% and 60% [17]. There are many reasons why the success rate of the IANB is low. One is that the dentist might make technique errors such as improperly locating a landmark or angling the syringe [32]. Other reason of failure IANB techniques is the high incidence of positive aspiration and intervascular injection, which counts for 10% to 15% [4].

Complication related to the IANB vary from being common to rare, and include pain and trismus produced by tearing the mucosa during the insertion or even the withdrawal of the needle, needle breakage at that point of injection, and facial paralysis caused by injection of the anesthetic solution in the parotid region: this problem mainly occurs when the needle is positioned more posterior towards the posterior border of the mandible. Hematoma may also develop due to the damage of blood vessels in the area to be anesthetized, as well as following the intravascular injection of anesthetic solution. Other reported complications include ptosis and extraocular muscles paralysis, aphonia, necrosis of the skin of the chin, diplopia, and abducent nerve palsy. Some rare complications include a reduction in visual acuity and atrophy of the optic nerve, diplopia (double vision), blurred vision, amaurosis (temporary blindness), mydriasis (papillary dilatation), abnormal pupillary light reflex, retrobulbar pain, miosis (papillary restriction), enophthalmos (recession of the eyeball within the orbit), and ophthalmoplegia (paralysis of muscles responsible for eye movement). It has been also reported recently that IANB could be a factor in third molar agenesis [1,12,13,30,32]. Ocular complications such as diplopia, loss of vision, or ophthalmoplegia are very rare [30]. Even though these symptoms tend to be temporary, they can be rather distressing to both patients and dental practitioners [13]. Most of the complications are localized and last for only a short period [30]. The guiding medical device EZ-Block ®, which relies on extra-oral landmarks easy to identify, would increase performance and reduce risks of IANB. To test this hypothesis, analysis of 32 articles [1-32] between 2000 and 2020 about risks and performance of IANB free hand techniques was made. These results were compared with those of a pilot study, carried out for a CE certification premarket study.

Materials and Methods

Clinical Data Sources Analysis

The research in the scientific literature was made with Pubmed, Cochrane, Google Scholar and clinicaltrials.gov databases between 2000 and 2020. This data appraisal plan concerns only the scientific literature and data unpublished but does not take into account the research in the competent authorities' databases. The most relevant research was obtained with the keywords "inferior alveolar nerve block". With the removal of the duplicates and the unpublished articles, 91 studies seem to be relevant for the analysis (Table 1). After reading the titles and the abstracts, 48 articles seem to be relevant for the writing of the state of the art. After analysis of these 48 studies, 16 articles were rejected. Indeed, these 16 articles did not respect these selection criteria:

a. Out of the scope;

b. No clinical data;

c. Non relevant clinical data

Finally, 32 articles [1-32] about the inferior alveolar nerve block were selected. These 32 articles are used for the writing of the state of the art (Figure 1).

Table 1: Databases search details.

Search Engine	Keywords	N° of documents
Pubmed	(("mandibular nerve"[MeSH Terms] OR ("mandibular"[All Fields] AND "nerve"[All Fields]) OR "mandibular nerve"[All Fields] OR ("inferior"[All Fields] AND "alveolar"[All Fields] AND "nerve"[All Fields]) OR "inferior alveolar nerve"[All Fields]) AND block [All Fields]) AND (Review[ptyp] AND "humans"[MeSH Terms])	54
	"Inferior alveolar nerve block"[All Fields] AND (Review[ptyp] AND "humans"[MeSH Terms])	21
	"Inferior alveolar nerve block"[All Fields] AND "benefits"[All Fields] AND (Review[ptyp] AND "humans"[MeSH Terms])	0
	"Inferior alveolar nerve block"[All Fields] AND "risks"[All Fields] AND (Review[ptyp] AND "humans"[MeSH Terms])	1

|		
Google Scholar	allintitle: "inferior alveolar nerve block" review	17
	allintitle: "inferior alveolar nerve block" guidelines	0
	allintitle: "Inferior alveolar nerve block" benefits	0
	allintitle: "Inferior alveolar nerve block" risks	0
Cochrane	"Inferior alveolar nerve"	6
	"inferior alveolar nerve block"	2
	"inferior alveolar nerve block" AND "benefits"	2
	"inferior alveolar nerve block" AND "risks"	2
Clinicaltrials.gov	"inferior alveolar nerve block"	56 (3 with clinical results)
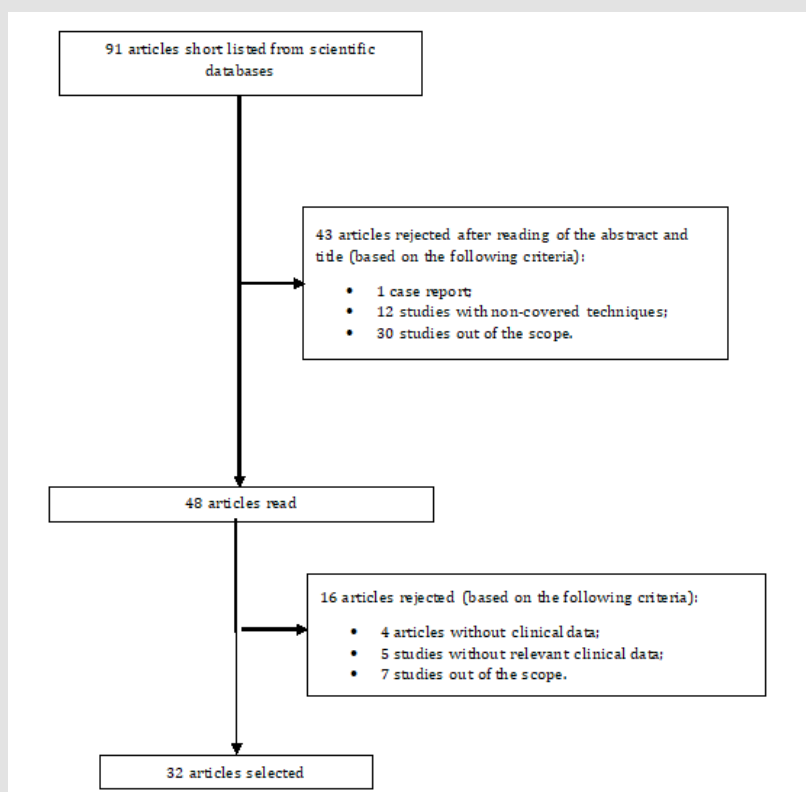
Figure 1: Screening and selection of literature.

Pilot Clinical Study

Caillieux [33] described the most appropriate configuration of the guiding device for IANB. Taking into account the variability among individuals, this device was designed so that its guiding axis would project at a distance of 14.0 mm anterior to the posterior edge of the mandibular ramus for all patients (that is, always behind the mandibular foramen). This site favors the diffusion of the solution toward the foramen, allowing it to infiltrate the inferior alveolar nerve. The system consists of a guide unit (a), a set of plunger rod/locking sleeve/O-ring (b), a syringe body (c) (Figure 2). These 3 elements are associated with dental needle and anaesthetic cartridge (Figure 3). The tip of the EZ-Block® is firmly held against the posterior edge of the mandibular ramus just under the ear inter-tragic notch, and the guide tube is placed against the occlusal surfaces of the contralateral upper premolars (Figure 4). For 3 months, 10 private practitioners used EZ-Block® systematically on their patients before dental care or extractions of mandibular molars and with the only following exclusion criteria:

a) Patients under 18 years,

b) Pregnant or breastfeeding women,

c) Known allergies to the anesthesia molecule or to a component of the anesthesia cartridge,

d) Contraindications to the use of vasoconstrictors.

139 patients were thus anesthetized with EZ-Block® (Table 2).

After each injection, a data collection was completed (Table 3).

Figure 2: Components of the EZ-Block® device.

Figure 3: EZ-Block® ready to use.

Figure 4: Positioning of EZ-Block® on the patient.

Table 2: Synopsis of the study.

Main objective	To evaluate the performance (success rate and onset time) and the benefits of the EZ-Block® (number of reinjection).
Main criteria	To evaluate the performance: • Success rate with the rate of realization of the entire intervention. • Onset time of 5 minutes with the number for patients. To evaluate the benefice with the rate of reinjection.
Secondary objective	To evaluate: • The side effects associated with the use of the EZ-Block®; • The positive aspiration.

Secondary criteria	The side effects and the positive aspiration are evaluated in percentage (expected adverse effects: hematoma, trismus, Oedema, nerve injury).
Devices	EZ-Block®
Number of patients	139 patients
Main criteria for inclusion	Any adult patient needing care or surgery on mandibular molar.
Exclusion criteria	Patients under 18 years, pregnant or breastfeeding women, allergies to the anesthesia molecule or to a component of the anesthetic cartridge, contraindications to the use of vasoconstrictors.

Table 3: Data collection.

N°	Local factors of anesthetic failures	Aspiration test	Onset time	Completion of the intervention in its entirety	Did the Intervention Require a 2nd injection?	Possible complications
1						☐ Any
	☐ Pulpitis		☐ < 2 min			☐ Hematoma
	☐ Apical lesion	☐ Negative	☐ 2 to 5 min	☐ Yes	☐ Yes	☐ Trismus
	☐ None known	☐ Positive	☐ > 5 min	☐ No	☐ No	☐ Oedema
						☐ Nerve injury
						☐ Other (describe)

Results and Discussion

Table 4: Data of performance and risks from the state of the art and from the pilot study.

	State of the art	Pilot study
	Rate [IC 0.95]	Rate [IC 0.95]
Performance		
Success rate (%)	$\overline{m}$ = 67.4 [57.2 – 77.6]	95.9
5-minutes onset time (%)	$\overline{m}$ =85.6 [78.2 – 93.0]	92
Risks		
Positive aspiration (%)	$\overline{m}$ = 15.9 [8.2 – 4.1]	11.6
Swelling / Oedema (%)	3.3	0.8
Hematoma (%)	3.7	0
Trismus (%)	2.5	4.1
Paresthesia / Nerve injury (%)	0	0
Local complication (%)	8	-
Numbness (%)	3.1	-
Reinjection (%)	$\overline{m}$ = 29.2 [19.2 – 39.2]	16.8

The success rate (Table 4) described in the state of the art is: 67.4%; IC 0.95 [57.2 – 77.6] and in the validation study of EZ-Block® is 95.9%. The success rate with the device is higher than the rate observed with the freehand technique. The 5-minutes onset time (Table 4) described in the state of the art is: 85.6%; IC 0.95 [78.2 – 93.0] and in the validation study of EZ-Block® is: 92.0%. The 5-minutes onset time with the device is higher than the rate observed with the freehand technique. For the majority of risks (Table 4), the EZ-Block® device provides lower complication rates. Only the trismus rate is higher with the EZ-Block®, although it remains within the same range. The rate found in the state of the art comes from a single study including 80 patients. The pilot clinical study includes 139 patients. Thus, the rate found in the pilot clinical study seems more relevant.

All complications identified in the pilot study of the EZ-Block® have been highlighted in the state of the art. Therefore, EZ-Block® does not cause any specific complications. In addition, all complication rates observed with EZ-Block® are lower than those found in the state of the art, except for trismus. Trismus is defined as a reduced opening of the jaws (limited jaw range of motion). It may be caused by spasm of the muscles of mastication and this situation is temporary. The trismus rate observed in the clinical validation is therefore considered acceptable.

Conclusion

After analysis, the EZ-Block® device does not cause any specific complications related to its use. Complications identified relate to the procedure only. In terms of performance, the use of the EZ-Block® provides a higher success rate (95.9%) and a higher percentage of patients anesthetized in 5 minutes (92.0%) than the free hand technique (success rate = 67.4%) (5-minutes onset time = 85.6%). The clinical data of the EZ Block® allow to evaluate the performance and the safety of the device. But this pilot study should be complemented with a clinical study to confirm the effectiveness of the device.

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