



**UNIVERSITY OF SÃO PAULO
SCHOOL OF DENTISTRY OF RIBEIRÃO PRETO**



JOÃO HENRIQUE PARISE FORTES

**INFLUENCE OF RETROMOLAR CANAL ON THE ANESTHETIC BLOCK
OF THE INFERIOR ALVEOLAR NERVE: A CLINICAL RANDOMIZED STUDY**

Ribeirão Preto

2019

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Doctoral Thesis presented to the School of Dentistry of
Ribeirão Preto, University of São Paulo, to obtain the
Doctoral of Science Degree - Program: Postgraduate
Dentistry - Concentration Area: Oral Rehabilitation

Advisor: Profa. Dra. Camila Tirapelli

Co-Advisor: Prof. Dr. Christiano de Oliveira Santos

Ribeirão Preto

2019

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1. Retromolar canal, 2. Inferior alveolar nerve, 3. Dental anesthesia, 4. Clinical study

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FORTES, J. H. P. Influence of retromolar canal on the anesthetic block of the inferior alveolar nerve: a clinical randomized study. 2019. 73p. Thesis (Doctorate) – Dentistry School of Dentistry of Ribeirão Preto, University of São Paulo, Ribeirão Preto, 2019.

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Abstract in portuguese

FORTES, J. H. P. Influência do canal retromolar no bloqueio anestésico do nervo alveolar inferior: um estudo clínico randomizado. 2019. 73p. Tese (Doutorado) - Faculdade de Odontologia de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, 2019

Objetivos: O objetivo deste estudo clínico foi avaliar a influência do (RMC) na eficácia do bloqueio do nervo alveolar inferior (IANB), medindo a resposta dos pacientes aos testes térmicos e de pressão antes e após o procedimento anestésico.

Material e Métodos: em pacientes diagnosticados com RMC por tomografia computadorizada de feixe cônico, a IANB foi avaliado em um modelo experimental randomizado, duplo-cego e “split-mouth”. Os testes de vitalidade pulpar e pressão na mucosa foram realizados antes e após o IANB de um lado da mandíbula. Após uma semana, os testes foram repetidos com bloqueio do nervo alveolar inferior no lado oposto. A resposta dos pacientes aos estímulos foi avaliada pelas escalas visual analógica (EVA) e Mc Gill (McG). As variáveis de resposta foram a porcentagem de diminuição na resposta do paciente aos testes térmicos e de pressão. Os dados foram comparados entre os lados com RMC presente e ausente no teste de Friedman.

Resultados: Das 273 TCFC: 89 (32,7%) homens, 184 (67,3%) mulheres, 31 (11,35%) apresentaram RMC unilateral, indicando que a prevalência deste estudo foi de 11,35%. Foi observada uma redução estatisticamente significativa (EVA e McG) após o IANB com a presença e ausência de RMC. Houve uma maior redução na resposta de sensibilidade nos lados sem RMC em 5 de 9 pacientes (EVA) e 6 de 9 (McG), no entanto, não houve diferenças estatisticamente significantes entre o lado com a presença e ausência de RMC (Wilcoxon $p > 0,05$)

Conclusão: A presença de RMC pode influenciar a eficácia do IANB.

Palavras-chave: canal retromolar, nervo alveolar inferior, anestesia dental, estudo clinico

Abstract

FORTES, J. H. P. Influence of retromolar canal on the anesthetic block of the inferior alveolar nerve: a clinical randomized study. 2019. 73p. Thesis (Doctorate) – Dentistry Faculty of Ribeirão Preto, University of São Paulo, Ribeirão Preto, 2019

Objectives: The purpose of this clinical study was to evaluate the influence of (RMC) on the efficacy of inferior alveolar nerve block (IANB) by measuring patients response to pressure and thermal tests before and after the anesthetic procedure.

Material and Methods: in patients with RMC diagnosed by cone beam computed tomography IANB was evaluated in a randomized, double-blind and split mouth experimental model. Pulp vitality and mucosal pressure tests were performed before and after IANB of one side of the mandible. After one week, the tests were repeated with inferior alveolar nerve block on the opposite side. The patients response to stimuli was assessed by visual analogue scale (VAS) and Mc Gill (McG) scale. Response variables were the percentage of decrease in patient response to thermal and pressure tests. Data were compared between sides with RMC present and absent with Friedman test.

Results: Of 273 CBCTs: 89 (32.7%) men, 184 (67.3%) women, 31 (11.35%) had unilateral CMR, indicating that the prevalence of this study was 11.35%. A statistically significant reduction (VAS and McG) was observed after IANB with present and absent RMC. There was a greater reduction in sensitivity response on the sides without RMC in 5 of 9 patients (VAS) and 6 of 9 (McG), however, there were no statistically significant differences between the side with present and absent RMC (Wilcoxon $p > 0.05$).

Conclusion: The presence of RMC can influence the efficacy of IANB.

Keywords: Retromolar canal, inferior alveolar nerve, dental anesthesia, clinical study

Introduction

INTRODUCTION

Several studies have shown the prevalence of the retromolar canal (RMC) in different regions of the world, which range from 5 % to 75 % (POTU et al. 2013; HE et al. 2017; PALMA et al. 2017; TRUONG et al. 2017). Despite some speculations, the clinical relevance of this anatomical variation remains unclear, particularly regarding eventual interference with anesthetic procedures involving inferior alveolar nerve block (IANB) (FILO et al. 2015; KIM et al. 2017; TRUONG et al. 2017; KIKUTA et al. 2018).

The RMC is a neurovascular anatomic variation, consisting of a bifurcation of the mandibular canal towards the retromolar area (TRUONG et al. 2017; KIKUTA et al. 2018). Divided in two parts, bifid mandibular canals can carry, per branch, its own neurovascular bundle (KANG et al. 2014; TRUONG et al. 2017). This neurovascular bundle are related mainly in the tendon of temporalis muscle, buccinator muscle, alveolar process, lower third molar tooth and the gingiva in the retromolar area (Potu et al. 2013). According with He et al. (2017), the RMC may contain innervations related to various structures ranging from muscles to teeth, gums and mucous membranes, which may lead failures of the standard inferior alveolar nerve block (IANB). Truong et al. (2017), also cited IANB failure as a clinical outcome from RMC presence, however as commented by Potu et al. (2013), there is a need for studies clinically proving that influence.

Regarding IANB procedures, according to Potocnik and Bajrović (1999), even applying the technique correctly and properly, failure occurs in about 30 to 45% of cases. One of the reasons for such percentage of failure in this anesthetic technique is the regional anatomy, which may vary from individual to individual (MADAN et al. 2012). Literature have suggested that the RMC bundle can be connected to the complications and failures of local anesthesia (SINGH 1981; OSSENBERG 1987; BILECENOGLU et al. 2006; VON ARX et al. 2011; GAMIELDIEN et

al. 2016). However, as far as is known, such studies did not clinically evaluate the influence of the presence of RMC on the anesthetic efficacy of the IANB technique.

Proposition

PROPOSITION

The purpose of this study was to clinically evaluate the influence of RMC on the efficacy of IANB by measuring the patient response to pressure and thermal stimuli before and after the anesthetic procedure. The null hypothesis was that the RMCF does not influence the IANB.

Material and Methods

MATERIAL AND METHODS

This study was approved by the Research Ethics Committee of FORP USP registration n° 69603817.0.0000.5419, REBEC number: RBR-4SNTGT.

Prevalence and presentation of RMC on CBCT exams

Consecutive CBCT examinations acquired between 2017 and 2018 were retrieved from the institutional imaging databank and retrospectively screened for the presence of RMC. All examinations were acquired with OP300 (Instrumentarium, Tuusula, Finland) and adjusted at diagnostic task and patient-specific exposure parameters. CBCT should present a field-of-view encompassing the retromolar areas of both left and right lower jaws in order to be included. Presence of lesions or artifacts impairing the visualization of the retromolar area were exclusion criteria.

A single trained and experienced observer assessed all CBCT exams using OnDemand3D (Cybermed, Seoul, South Korea) software. The analyses were performed in a quiet and dimly-lit room. The observer was free to use reconstructed images in all planes to assess the presence and features of RMC, as well as use software tools to adjust the images (e.g. zoom, brightness/contrast).

When RMC was present, the type of canal was classified according to Osseberg (1987). If the RMC presented a foramen, the following measurements were carried out (in reformatted sagittal view): diameter of the foramen, distance to the 2nd molar, distance to the 3rd molar, and distance to the buccal and lingual cortex. Figure 1 and 2.

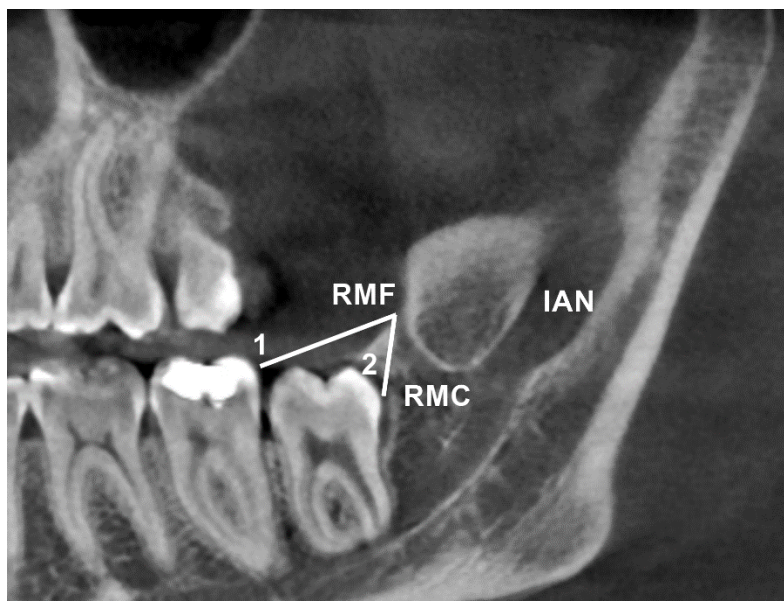


Figure 1. Sagittal CBCT image. RMC: the retromolar canal branching from the mandibular canal, IAN: inferior alveolar nerve, RMF: retromolar foramen, line 1: distance to the 2nd molar and line 2: distance to the 3rd molar.

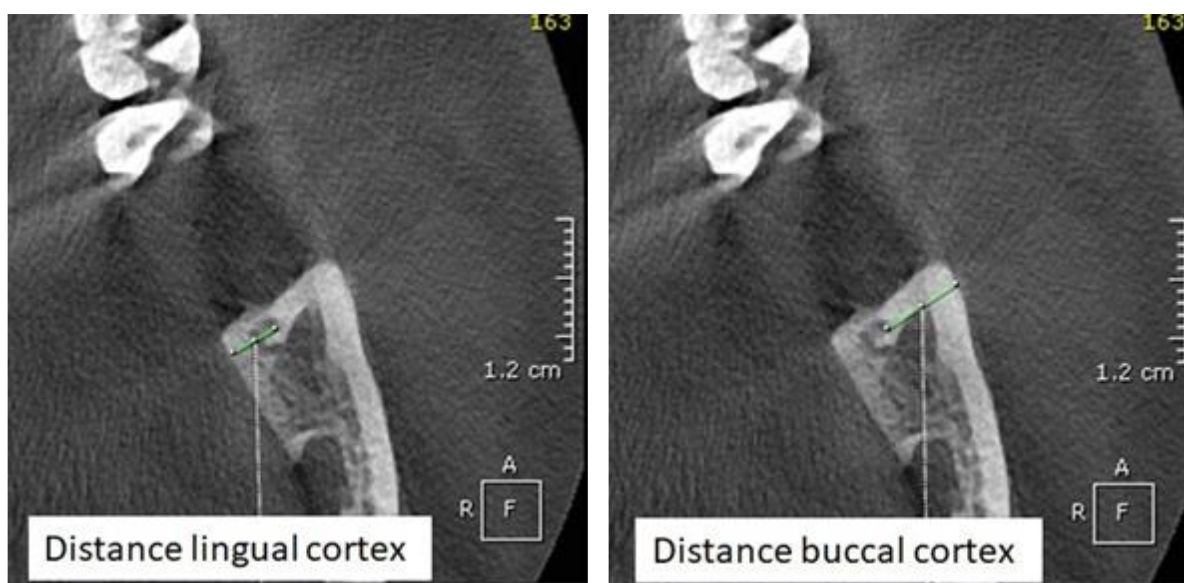


Figure 2. Axial CBCT image. Foramen distance to the buccal and lingual cortex.

Influence of RMC on the efficacy of IANB

In order to test the influence of RMC on the efficacy of the IANB anesthetic procedure, a clinical, randomized, double blind and split-mouth study was designed. Patients with unilateral RMC were invited to join the study.

Participants

Patients that presented unilateral RMC identified on CBCT exams and with clinical indication of dental procedures requiring anesthetic block of the inferior alveolar nerve were invited to take part in the anesthetic efficacy test. The exclusion criteria were allergy to mepivacaine, presence of mucosal lesions in retromolar area, and use of systemic medications that may interfere with oral sensitivity.

Interventions

Anesthetic efficacy tests were carried out on both left and right sides of patients who agreed to participate and signed the informed consent term. The initial side for each patient was randomly assigned using coin flip. The same procedures (IANB, and pre- and post-anesthesia tests) were performed on the other side after one week. A single experienced dentist, blinded to the side of the mandible that had an RMC, performed all the tests and anesthetic procedures.

Assessment of patient response to thermal (pulp vitality test) and pressure (compression of soft tissue) stimuli were done before and 5 minutes after the IANB technique, using both visual analogue (VAS) scale and Mc Gill (McG) pain questionnaire.

For the thermal stimulus, Endo-Frost® (Roeko-Germany). It was applied for 5 seconds according to the manufacturer's recommendation in the cervical buccal region of the 1st and 2nd molars (near the marginal gingiva).



Figure 3. Applying Endo Frost on cotton swab.



Figure 4. Thermal test applying Endo-Frost® for 5 seconds

For standardized mechanical pressure stimuli, the Florida Probe® (Florida Probe Co. Gainesville, FL, USA) was used (DO COUTO et al., 2017). The probe was electronically calibrated to have a contact pressure of 25 g (0.25 N) of the active tip with the tissue. The pressure was applied perpendicularly, for 5 seconds, in the following regions: 3mm below the cervical buccal gingiva of the 1st and 2nd molar, 3mm below the cervical lingual gingiva of the 1st and 2nd molar and two occlusal regions after the 2nd molar in the anteroposterior direction, the first one being 2 mm after the distal of the 2nd molar and the other 2 mm after this point.



Figure 5. Pressure test in cervical buccal gingiva



Figure 6. Pressure test 2mm after the distal of 2nd molar (first point)



Figure 7. Pressure test 2mm after the first point in the distal of 2nd molar

Anesthetic block of the inferior alveolar nerve was performed using a carpule-type syringe supplied with 1.8 mL of mepivacaine 2% 1:100.000 with epinefrine and a long needle for adult use. IANB was performed by introducing the needle into the mucosa in the medial aspect of the mandibular ramus, at the intersection of two lines: one horizontal, representing the height of the injection, and the other vertical, representing the anteroposterior plane of the injection, three-quarters of the anterior-posterior distance of the coronoid notch to the deepest part of the pterygomandibular raphe. Once in the correct position, the operator injected the entire content of the anesthetic cartridge over 60 seconds. With this technique, the regions expected to be under anesthetic effect are the lower teeth (unilateral posteriors and anteriors), mandible body and inferior ramus, buccal mucoperiosteum and mucous membrane distal to the mental foramen (mental nerve). Due to concomitant block of the lingual nerve with this technique, the anterior two thirds of the tongue, the floor of the oral cavity, periosteum and lingual soft tissues are also expected to be anesthetized (MALAMED, 1944).

Data Analysis

The study primary outcome was the patient response (assessed with VAS and McG) to thermal and pressure stimuli before and after IANB. The analyzed variable was the percentual decrease of patient response to thermal and pressure stimuli. The efficacy of anesthesia was considered in terms of decrease of patient response. Therefore, higher values are interpreted as better efficacy of the IANB. The data were compared for the sides with and without RMC (split-mouth) with Wilcoxon test. The null hypothesis was that there is no difference between the anesthetic efficacy of the IANB in regions with and without RMC.

Results

RESULTS

CBCT sample profile

In this study, 273 CBCTs were evaluated. Of 273 exams 89 (32,7%) were from males while 184 (67,3%) were from females. In the 273 exams 242 (88,64%) showed a single canal (IAN) and 31 (11,35%) showed the IAN and RMC, indicating that the prevalence of this study is 11,35%.

In those 32 exams with RMC, 31 were unilateral and 1 were bilateral. The average in millimeter (mm) of distance from the 2nd molar was 14,6mm, distance from the 3rd molar was 5,76 mm, distance from the buccal cortex was 7,37mm, distance from lingual cortex was 3,72mm, foramen diameter was 1,15mm. The canal's type absolute frequency was: A1- 7, A2 -1, B1- 11, B2 -1 C 10, NI -1.

From the 31 unilateral RMC patients, nine patients agreed to participate in the tests and completed the study. Figure 12 illustrate their flow and Box 1 detailed the data collected for each of those patients.

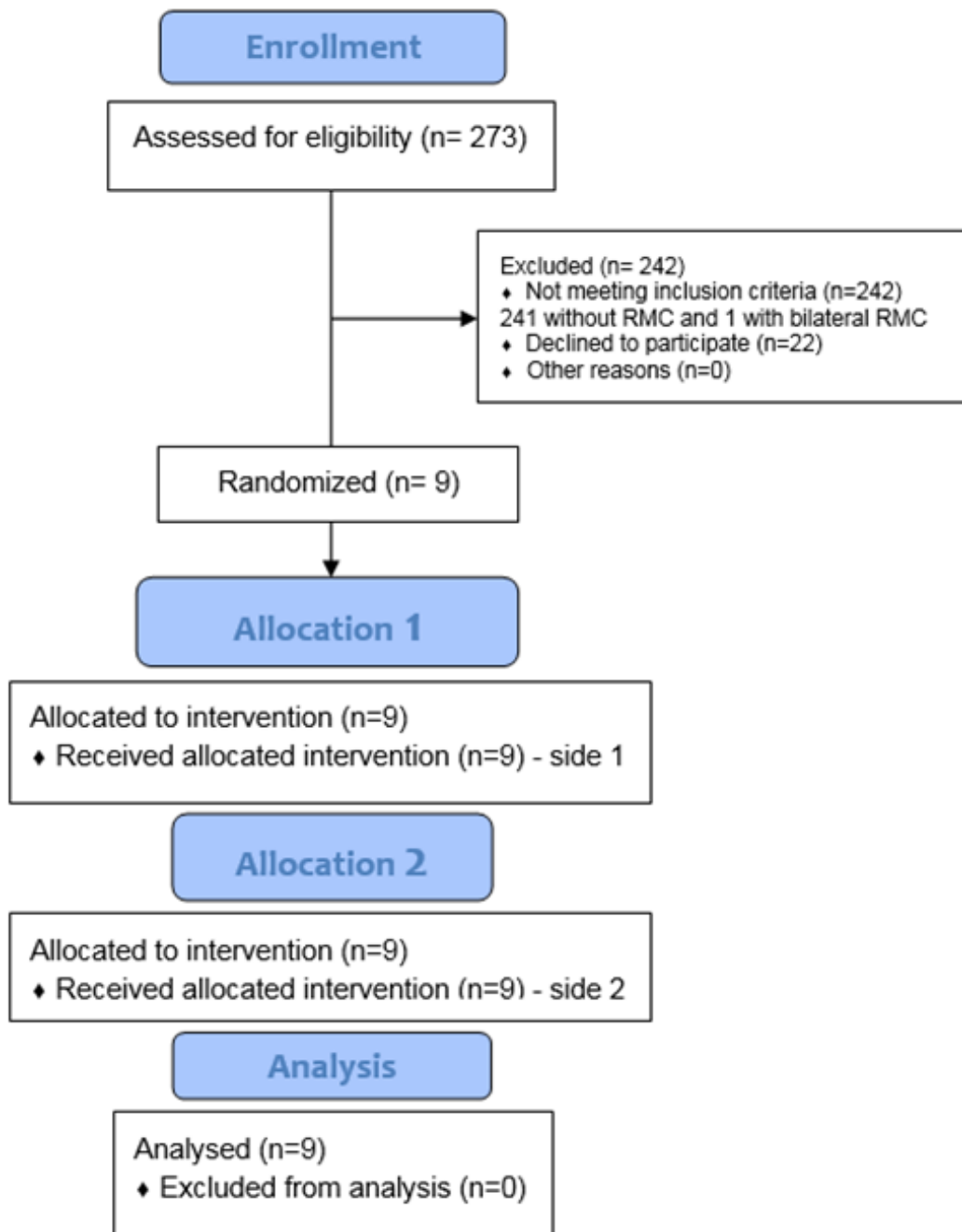


Figure 8. Study flow chart

Table 1. Clinical study sample profile and percentual patient response decrease on the IANB

Patients	Type	Side	Pressure												Thermal			
			VAS						McG						VAS		McG	
			Dist 2M	Dist 3M	Dist Lcortex	Dist Bcortex	Dist Foramen diameter	With RMC	Without RMC	With RMC	Without RMC	With RMC	Without RMC	With RMC	Without RMC	With RMC	Without RMC	
1	B1	Left	13.48	5.77	4.59	4.59	6.71	6.71	2.32	0.63	0.83*	0.16	0.19*	0.57	0.67*	0.70	0.50	
2	B1	Right	14.31	4.03	6.84	4.87	4.87	1.38	0.37	0.16	0.29	0.30*	0.90	0.00	0.00	0.00	-0.50	
3	A1	Left	14.65	6.02	4.43	7.53	7.53	1.18	0.50	0.83*	0.36	0.47*	0.00	0.71*	0.20	0.20	0.50*	
4	A1	Left	15.49	5.42	2.39	7.11	7.11	0.8	0.62	0.75*	0.22	0.33*	0.20	0.50*	0.30	0.30	0.60*	
5	C	Left	14.76	5.75	3.53	8.36	8.36	0.62	1.00	0.77	0.41	0.41	1.00	0.93	0.50	0.00	0.00	
6	NI	Right	14.90	6.71	2.01	8.89	8.89	2.33	0.23	0.84*	0.25	0.38*	0.5	0.00	0.00	0.50*	0.00	
7	A1	Left	12.25	7.72	2.07	8.61	8.61	0.57	0.69	0.83*	0.00	0.16*	0.00	1.00*	0.50	0.67*	0.00	
8	A1	Left	14.62	6.46	4.08	7.13	7.13	0.54	0.72	0.33	0.25	0.25	1.00	1.00*	0.25	0.50*	0.00	
9	A1	Right	12.10	3.96	3.58	7.12	7.12	0.66	0.89	0.58	0.48	0.33	0.00	0.00	0.00	0.00	0.00	

Legend:

With RMC: presence of RMC;

Without RMC: absence of RMC;

Type: types of RMC;

Side: side where the RMC is;

Dist 2M: distance from foramen to 2nd molar;Dist 3M: distance from foramen to 3rd molar;

DistLcortex: distance from foramen to lingual cortex;

DistBcortex: distance from foramen to buccal cortex;

VAS: visual analog scale; McG: McGill scale.

Numbers with asterisks (*) indicate a greater reduction of patient response on the side without RMC compared with the side with RMC.

A statistical significant reduction of patient response (VAS and McG) after anesthesia administration for both stimuli was observed for side with RMC and without RMC. (Figure 13).

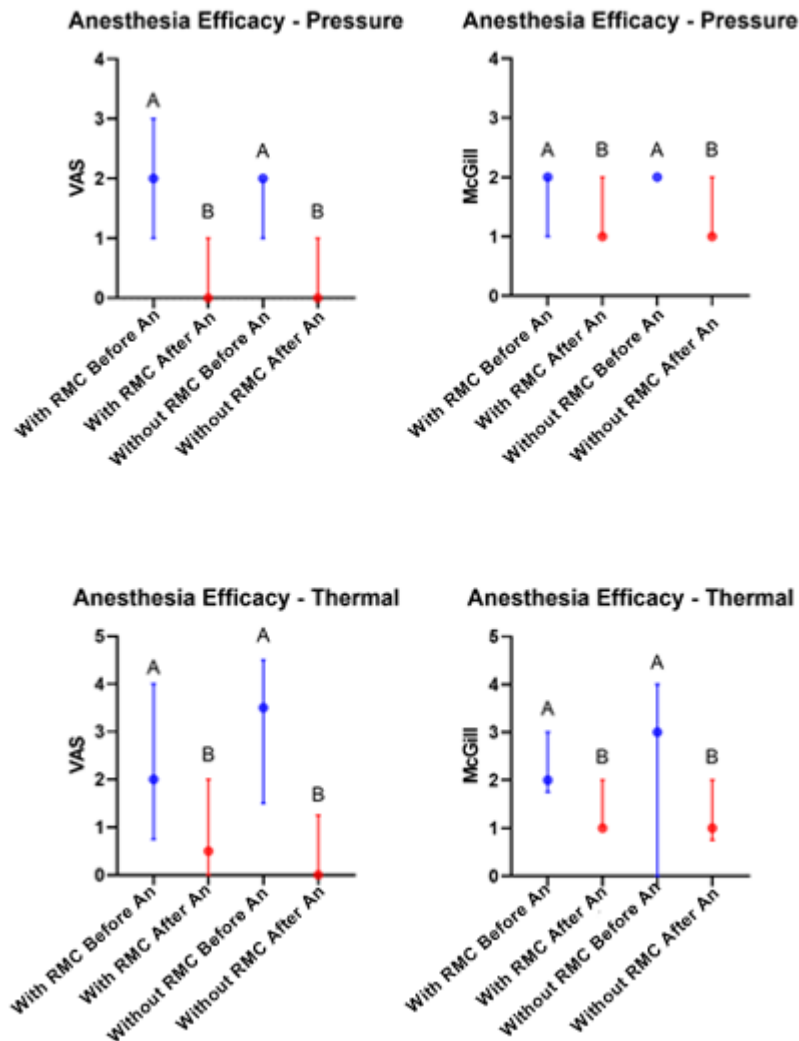


Figure 9. Graphic illustration for anesthesia efficacy regarding the different patient response (VAS and McGill) to tests (pressure and thermal) used. Data are displayed in median and interquartile range. Different letters indicate a statistically significant difference between the groups, according to Wilcoxon test ($\alpha=0.05$).

In Box 1, is possible to observe that there was a greater reduction in patient response to pressure in five patients of nine on the side without RMC (VAS). For McG, this greater reduction was observed in six patients of nine. The same pattern was observed for patient response to thermal stimuli; there was a greater reduction in patient response in five patients of

nine on the side without RMC (VAS and McG). However, statistically, there was no significant difference in patient response to stimuli with RMC and without RMC in both scales (Wilcoxon matched pairs signed rank test; $p > 0.05$).

Discussion

DISCUSSION

This clinical study indicates that RMC presence may influence the efficacy of IANB as, comparatively, the expected decrease of patient response to thermal and pressure stimuli was greater on the jaw side without RMC. As far as we know, anatomical variations such as RMC have been related to dental anesthesia failures (POTU et al., 2013; TRUONG et al. 2017; HE et al., 2017) without clinical studies to support it; therefore, it is the novelty that this study brings.

The prevalence and patterns of anatomical variations are being reestablished since the use of nowadays-available image exams. The RMC has been described as a rare anatomic structure and an uncommon anatomic variation (LANGLAIS, BROADUS and GLASS, 1985; OSSENBERG, 1987; SAWYER and KIELY, 1991; POTU et al., 2014), however, some authors have shown more recently that RMC is observed more frequently, which therefore requires attention during surgical procedures in the retromolar area of the mandible (SISMAN et al., 2015; MOTAMEDDI et al., 2016). Indeed, Kim et al. (2017) found 43% in Republic of Korea and a Japanese (PATIL et al., 2013) study observed 75% of prevalence; those data can change the nomination of RMC as such a rare anatomic structure and an uncommon anatomic variation. In this study to reach a sample of nine patients, we examined 273 CBCT exams and organized their data regarding RMC and foramen. The prevalence of RMC in the CBCT sample was 11.35 %; that is similar to the national prevalence related on published studies (FREITAS et al., 2017; PALMA et al., 2017).

We found a significant ($p < .005$) reduction of patient response (VAS and McG scales) comparing before and after IANB for both stimuli (pressure and thermal) at same jaw side. When comparing jaw sides with and without RMC, even not being statistical significant; a greater reduction of patient response was observed on the jaw side without RMC, indicating that for the two types of stimuli, on two different pain scales, the presence of RMC had

influenced on the expected reduction of patient response. On the way to identify RMC patterns that could interfere on that results, from data on Table 1, it is impossible to correlate , for example, RMC classification or presence of foramen with the level of efficacy of IANB.

The available literature describing mandibular canal and its contents may help to explain the results and this lack on pattern. Ikeda et al. (1996) observed the mandibular canal of cadavers using magnetic resonance and showed that in its content the inferior alveolar nerve is typically divided in three independent branches that vary their trajectory dividing the space with the inferior alveolar artery, venules and arterioles. Carter and Keen (1971) demonstrated the complexity of the neurovascularization of the posterior mandible from dissections. They found several neurovascular bundles leaving the temporal muscle and entering foramina in retromolar area. Singh (1981), during a third molar surgery, encountered an a neurovascular anatomical variation, which was described as an aberrant buccal nerve, exiting the mandible at the retromolar foramen. Jablonski et al. (1985) reported a dissection where the retromolar canal contained the buccal nerve, which had an unusual course exiting the mandible through the RMC after separating from the IAN within the ramus of the mandible. Then it had a course to the buccinator muscle. Latter, Von Arx et al. (2011), commented that the scarce but consistent information available about RMC; and indeed, such studies taken together shown the uncertainty that exists about where nerves enter or exit the bone and even what anatomical structures they are innervating.

Therefore we conjecture that the presence of RMC interfered with AINB in patients where additional innervation is present particularly nerve bundles entering the RMF foramen distantly the region where the IANB is being executed; and due to this missing the mepivacaine, which leads to a more sensitive patient. Cases where the nerve bundle may be exiting the RMF foramen are assumed as the cases where the presence of RMC had no influence.

In addition, the study limitations may justify the lack of statistical significance. On this context, the sample size of nine patients can be pointed out; nevertheless, it is very difficult to find out such patients on a prevalence of 11.35% and convince them to undergo the tests performed in this study, mainly because there is the involvement of expected pain before the anesthesia by thermal and pressure tests. Another limitation is that even with all the literature support and widespread used scales to assess patient response to stimuli, assessment can still be very subjective and it is very difficult to quantify. Finally, as this is the first clinical study to observe the RMC influence on the IANB there is no data to compare. In this sense, future studies are needed, with larger samples.

Conclusions

CONCLUSIONS

According to the study, the presence of retromolar canal can influence the efficacy of inferior alveolar nerve block.

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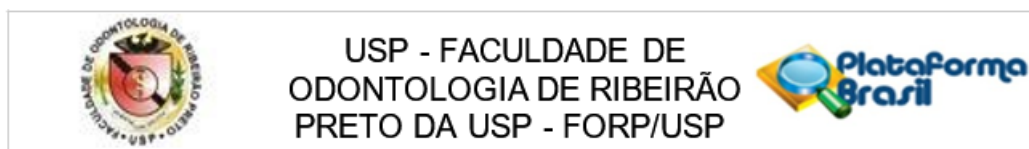
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Attachment

ATTACHMENT

Attachment 1. Document of Ethics Research Committee Approval.



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: EFICÁCIA DA ANESTESIA DENTAL EM PACIENTES COM PRESENÇA DE FORAME E CANAL RETROMOLAR VISUALIZADO ATRAVÉS DE TOMOGRAFIA COMPUTADORIZADA DE FEIXE CÔNICO.

Pesquisador: João Henrique Parise Fortes

Área Temática:

Versão: 3

CAAE: 69603817.0.0000.5419

Instituição Proponente: Universidade de São Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.369.510

Apresentação do Projeto:

A sensibilidade dolorosa é definida como uma experiência sensorial e emocional desagradável associada a um dano tissular real ou em potencial. A dor representa assim, importante ganho do ponto de vista evolutivo, pois funciona como um mecanismo sinalizador contra danos teciduais ou elementos potencialmente prejudiciais ao organismo, evocando resposta sensorial e motora de proteção. Porém é necessário um controle da dor no contexto odontológico, visando uma boa relação do cirurgião dentista com o paciente e evitando a ocorrência de emergências médicas causadas pelo ciclo dor/ansiedade/medo. Dentro das técnicas utilizadas na Odontologia para o controle da dor durante procedimentos dos mais variados, uma das mais comuns é o Bloqueio do Nervo Alveolar Inferior, porém as falhas anestésicas são muito comuns nessa região e vêm sendo estudadas por diversos autores. De acordo com Potocnik e Bajrovic, mesmo aplicando a técnica correta e apropriadamente, a falha ocorre em cerca de 30 a 45% dos casos. Uma das razões para tamanha porcentagem de falhas nessa técnica anestésica é a anatomia regional, que pode variar de indivíduo para o outro, principalmente relacionada à variabilidade no canal mandibular. Estudos recentes sugerem que a presença de canal e forame retromolar varia de 14,6 a 65,3% na população e passou a ser melhor estudada nos últimos 15 anos com o uso da tomografia computadorizada de feixe cônico. Entretanto, até onde se sabe, tais estudos

Endereço:	Avenida do Café s/nº		
Bairro:	Monte Alegre	CEP:	14.040-904
UF:	SP	Município:	RIBEIRAO PRETO
Telefone:	(16)3315-0493	Fax:	(16)3315-4102
		E-mail:	cep@forp.usp.br



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Continuação do Parecer: 2.369.510

não avaliaram clinicamente a influência da presença do canal retromolar na eficácia anestésica da técnica de bloqueio do nervo alveolar inferior.

Será feita a análise de 100 Tomografias por 2 pesquisadores para identificar o canal e forame retromolar. A partir dessa análise, serão selecionados 20 participantes que apresentam canal e forame retromolar e 20 participantes sem canal ou forame retromolar. Os 40 participantes, serão submetidos a anestesia da região posterior da mandíbula e a eficácia da anestesia será avaliada considerando a sensibilidade dos participantes ao teste de compressão através do uso do Algometro.

Objetivo da Pesquisa:

O objetivo deste estudo é avaliar a eficácia anestésica através da mensuração do limiar de dor antes e após Bloqueio do Nervo Alveolar Inferior em pacientes com canal e forame retromolar observado na Tomografia Computadorizada de Feixe Cônico.

Avaliação dos Riscos e Benefícios:

Os principais riscos relatados no projeto de pesquisa são: hematoma na região anestesiada, parestesia temporária do nervo alveolar inferior e ardor durante a injeção do sal anestésico. Somente receberão a anestesia àqueles pacientes que necessitarem de tratamento odontológico.

O principal benefício apontado refere-se ao tratamento das necessidades gerais do paciente.

Comentários e Considerações sobre a Pesquisa:

Projeto de pesquisa importante para a área. Os pesquisadores relatam falhas na anestesia do Nervo Alveolar Inferior e reforçam a necessidade de estudos clínicos.

Projeto bem delimitado.

Considerações sobre os Termos de apresentação obrigatória:

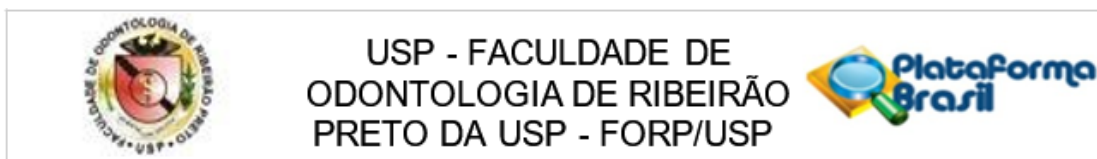
Os termos de apresentação obrigatória foram adequados mediante solicitação do Parecer consubstanciado 2.246.029 de 29 de Agosto de 2017.

O Termo de consentimento livre e esclarecido atende aos requisitos da resolução CNS 466/12 e as alterações de infra estrutura e acesso ao banco de imagens foram apresentadas.

Recomendações:

Ressalta-se que as assinaturas do Termo de consentimento livre e esclarecido devem constar em uma mesma folha, não devendo ser separadas. Solicita-se que o mesmo seja impresso frente e verso.

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Bairro:	Monte Alegre	CEP:	14.040-904
UF: SP	Município:	RIBEIRAO PRETO	
Telefone:	(16)3315-0493	Fax:	(16)3315-4102
		E-mail:	cep@forp.usp.br



Continuação do Parecer: 2.369.510

Conclusões ou Pendências e Lista de Inadequações:

Projeto aprovado.

Considerações Finais a critério do CEP:

Aprovado conforme deliberação na 209ª Reunião Ordinária do CEP de 6/11/2017.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_925725.pdf	28/09/2017 09:26:51		Aceito
Outros	autorizacaoinfraestrutura.pdf	28/09/2017 09:26:15	João Henrique Parise Fortes	Aceito
Outros	autorizacaotomos.pdf	28/09/2017 09:25:16	João Henrique Parise Fortes	Aceito
Projeto Detalhado / Brochura Investigador	ProjetodoJoaofortesCEPNovo.docx	28/09/2017 09:23:37	João Henrique Parise Fortes	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.doc	28/09/2017 09:23:15	João Henrique Parise Fortes	Aceito
Folha de Rosto	Folhaderostoassinada.pdf	24/05/2017 08:36:50	João Henrique Parise Fortes	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

RIBEIRAO PRETO, 07 de Novembro de 2017

Assinado por:
Simone Cecilio Hallak Regalo
(Coordenador)

Endereço: Avenida do Café s/nº
Bairro: Monte Alegre CEP: 14.040-904
UF: SP Município: RIBEIRAO PRETO
Telefone: (16)3315-0493 Fax: (16)3315-4102 E-mail: cep@forp.usp.br