Int. J. Oral Maxillofac. Surg. 2007; 36: 1177–1182
doi:10.1016/j.ijom.2007.06.001, available online at http://www.sciencedirect.com

International Journal of
Oral & Maxillofacial Surgery

Clinical Paper
Oral Surgery

A blinded randomized controlled trial comparing lignocaine and placebo administration to the palate for removal of maxillary third molars

M. E. Badcock[1,2], I. Gordon[3], M. J. McCullough[1]
[1]School of Dental Science, University of Melbourne, 720 Swanston Street, Parkville, Vic. 3010, Australia; [2]Private Practice, Melbourne, Australia; [3]Statistical Consulting Centre, University of Melbourne, Vic. 3010, Australia

M. E. Badcock, I. Gordon, M. J. McCullough: A blinded randomized controlled trial comparing lignocaine and placebo administration to the palate for removal of maxillary third molars. Int. J. Oral Maxillofac. Surg. 2007; 36: 1177–1182. © 2007 Published by Elsevier Ltd on behalf of International Association of Oral and Maxillofacial Surgeons.

Abstract. Routine use of a palatal injection for the removal of maxillary third molars has never been validated. The purpose of this blinded, randomized, controlled trial was to assess the requirement of a separate palatal injection for the extraction of maxillary third molars.

Fifty-one patients requiring the removal of bilateral maxillary third molars were enrolled. Each patient acting as their own control received buccal infiltrations of lignocaine bilaterally, then 0.2 mL of lignocaine without vasoconstrictor was administered to one side of the palate and the same amount of normal saline administered to the other side. Sides were randomized as to the active ingredient and both the patient and operator were blinded. All extractions were performed by a single operator using a consistent technique and no additional sedative or anaesthetic agents were utilized. Data relating to the pain of the extractions and of the palatal injection were obtained on a Visual Analogue Scale (VAS). Verbal Response Scale (VRS) data were obtained additionally for a subset of 21 patients.

Statistical analysis confirmed clinical equivalence between saline and lignocaine to the palate (95% CI −1.7 to 6.2 mm, equivalence range −6.75 to 6.75 mm). No patients requested additional lignocaine to the palate in order to ensure comfortable extraction.

This study provides evidence that the poorly tolerated palatal injection of local anaesthetic for the removal of maxillary third molars may not be required.

Key words: third molar; wisdom teeth; palatal; anaesthesia; extraction.

Accepted for publication 4 June 2007
Available online 19 November 2007

Maxillary third molars are frequently amenable to removal under local anaesthesia, with or without additional sedation. This is a result of the low rate of intraoperative complications and the favourable local anatomical considerations: relatively thin bone, generally favourable root morphology and reliable anaesthesia[19]. The procedure is predictable, rapid and well

0901-5027/1201177 + 06 $30.00/0 © 2007 Published by Elsevier Ltd on behalf of International Association of Oral and Maxillofacial Surgeons.

tolerated in the great majority of cases[5]. The more common complaints expressed during extraction include: the pain of the palatal injection, the experience of numbness of the soft palate, the sensation of pressure and the sounds experienced. The sensation of numbness of the soft palate can be controlled to some degree by the technique of palatal anaesthesia[14]. The pressure and unpleasant noise are largely unavoidable and generally of little consequence to the majority of patients. However the pain of the palatal injection is well known to any practitioner or patient who has experienced it and is universally detailed in textbooks and papers describing palatal anaesthetic regimes[1,10,12,14]. Although a number of adjunctive techniques have been described in order to reduce the discomfort of the palatal injection they have not gained universal acceptance[1,6,12]. Malamed illustrates this in the latest edition of his text where he states: 'the discomfort of palatal injections is a concern to most dentists and indeed many dentists avoid the use of palatal injections unless they are absolutely necessary[10].' Research has shown that direct experience is the most common source of dental fear and it has been reported that 5% of the population may avoid dental care due to fear of dental injections[17]. It has also been shown that for the dentist giving the injection the administration of palatal anaesthesia is rated as one of the most traumatic procedures in dentistry![7]

The routine use of this palatal injection is based on the anatomical description of the sensory innervation of the palate, hence for the removal of maxillary third molars conventional teaching has recommended the blocking of both the posterior superior alveolar nerve and the greater palatine nerve[2]. The administration of a separate palatal injection may be avoided when the greater palatine nerve or maxillary nerve is blocked in the pterygopalatine fossa, however potential morbidity and technical difficulty have prevented the routine acceptance of such techniques[3,14]. Malamed suggests a regime of 0.45 mL of local anaesthetic solution to the palate as a greater palatine nerve block or infiltration for the removal of maxillary third molars[10]. Li, in a clinical communication, has described the removal of maxillary teeth without a separate palatal injection, however he suggested that this was due to blocking the palatal nerves in the pterygopalatine fossa[9]. More recently Uckan et al. reported successful removal of permanent maxillary teeth without a separate palatal injection utilizing articaine as a buccal infiltration and waiting 5 min[22].

The purpose of this blinded, randomized, controlled trial was to assess the requirement of this poorly tolerated palatal injection for the extraction of maxillary third molars. This was done by comparing the extraction pain when lignocaine and placebo (saline) were administered to the palate. The palatal injection pain was also assessed to allow comparison.

Material and methods

Fifty-one adults, recruited from patients referred to the Royal Dental Hospital of Melbourne, Department of Oral and Maxillofacial Surgery, were enrolled in this study. Recruitment was at the discretion of experienced clinicians with no involvement in the research. No data relating to the non-responders or response rate were kept. The inclusion criteria were: bilateral maxillary third molars indicated for removal and assessed as suitable for removal under local anaesthesia and also a good understanding of written and spoken English. Exclusion criteria were: patients not expected to comfortably tolerate the removal of maxillary third molars under local anaesthesia using the currently accepted anaesthetic techniques, and an inability to give informed consent or allergy to lignocaine. The University of Melbourne, Human Research Ethics Committee and the Ethics in Clinical Research Committee of Dental Health Services Victoria approved this study. Following recruitment and written informed consent patients were reappointed for the surgical procedure. One author (M.B.) performed all surgical procedures at a single institution.

Prior to the administration of local anaesthetic, each patient had an explanation of the Visual Analogue Scale (VAS). The VAS was a 135 mm line with no markings and the words 'no pain at all' and 'worst pain imaginable' at opposite ends. The final 23 patients were asked to additionally record the level of pain of the first palatal injection on a VAS prior to the extractions. This was added to the protocol to allow comparison of the injection pain with any possible benefit of the injection. A single side only was recorded for reasons of simplicity.

To the right and left maxillary third molars 2.2 mL of local anaesthetic, lignocaine 2% with adrenaline 1:80,000 (Xylocaine, Dentsply, York, PA, USA) was administered as a maxillary infiltration adjacent to each third molar to anaesthetise the pulpal tissue and buccal periodontium. Patients acting as their own control then received an injection to both sides of the palate, on the control side, 0.2 mL of lignocaine 2% without vasoconstrictor and on the test side, 0.2 mL of normal saline. This was blinded to both patient and researcher by drawing the solutions from identical vials which were prepared under sterile conditions at the Royal Melbourne Hospital Pharmacy, Clinical Trials Department, according to their usual protocol. They were coded and presented as paired vials labelled 'left' and 'right' the contents (normal saline or lignocaine 2%) being determined by a computer generated randomized list, the single copy of the code was held by the pharmacy. This code was broken only after the VAS markings had been measured in order to reduce bias. The palatal infiltrations were given at the anterior aspect of the third molar and in the fleshiest part of the palate 10–15 mm from the gingival margin and delivered with a 0.5 mL 29-gauge U-100 insulin syringe (Terumo Medical Corporation, Elkton, MD, USA). The right-sided injection was given first on all occasions. Slow rate of administration, approximately 10 s, was the only adjunctive technique used to lessen the palatal injection pain.

Following completion of all injections and after an interval of 5 min to allow for anaesthetic effect, both teeth were extracted using a consistent technique utilizing buccal manipulation only, with a curved or straight elevator. If unerupted or partly erupted a buccal mucoperiosteal flap was raised, by placing an incision over the tuberosity, positioned slightly to the buccal of the crest, with or without an anterior relieving incision depending on the depth of impaction. Bone removal was performed when required, with a dental elevator or round burr depending on bone thickness and amount of bone removal required. No suturing was performed.

If an unacceptable level of pain or discomfort was experienced during extraction a further 2.2 mL of lignocaine 2% with adrenaline (Xylocaine) was injected, initially as a second maxillary infiltration, identical to the first. Then if, after a further 5 min interval, the level of pain or discomfort was still unacceptable 0.2 mL of lignocaine 2% with adrenaline (Xylocaine) was administered to the palate and recorded. The upper right third molar was extracted first on all occasions.

The study design included provision for breaking the code should palatal lignocaine be required for comfortable extraction in greater than 10% of the patients. This was incorporated into the design to abort the trial if it was shown that comfortable extraction could not be performed in more than 90% of cases with the absence of palatal lignocaine.

Download English Version:

https://daneshyari.com/en/article/3134987

Download Persian Version:

https://daneshyari.com/article/3134987

Daneshyari.com