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1. Introduction

The second division of the trigeminal nerve, the maxillary nerve (MN), exits the cranial region of the face via the foramen rotundum. From there, it travels laterally and forward through the pterygopalatine fossa, passes through the infra-orbital foramen at the bottom of the pterygomaxillary fossa, and ends up on the floor of the orbit. (1) The MN is a purely sensory nerve that delivers innervation to the lower eyelid, upper lip, cheek, upper dental arch, maxillary sinus, hard and soft palate, posterior nasal cavity, and nasal ala. (2) Effective anesthesia of the maxillary area can be achieved by surgeon's submucosal infiltration, witch appears to change the operative environment, or by inserting a needle in the pterygopalatine fossa (PPF). Although anesthetic infiltration around the mouth cavity or surgical site is simpler to execute than a selective nerve block, it might not be practical in some circumstances, such as when the surgical site is infected or inflamed. Therefore, the maxillary nerve block is preferred over local anesthetic infiltration when the surgical field covers the second third of the face and beyond the oral cavity, for example in maxillary osteotomy. The MN block can also be used for procedures of neurodestruction using neurolytic agents, for permitting anatomic differential neural blockade, and for the diagnostic evaluation of facial pain to determine whether pain is sympathetic or somatic in origin. (3,4) However, the MN block can result in a number of problems, including as temporal blindness, hematoma formation, diplopia, temporary ophthalmoplegia and ptosis, penetration of the orbit, and brainstem anesthesia. (10–12) Two approaches for maxillary nerve block in the pterigopalatina fossa have been described: infrazygomatic and suprazygomatic. Several risks associated with the infrazygomatic route of the maxillary block have been described, including the possibility of maxillary artery puncture and orbital or skull penetration. (5,6,7) The suprazygomatic approach to maxillary nerve block has been shown to be safer for treating people with

trigeminal neuralgia and for the anesthetic management of surgeries of the mid face. (9) The amount of anesthetic injected into the pterygopalatine fossa for MN block is linked to certain issues, whereas other complications are related to the specific anatomical approach used. The typical volume of the PPF in adults has been reported from investigations in dry skulls as close to one ml. (13,14) However, when executing this block clinically, two to five milliliters are usually injected. (14) As a result, the excess amount of local anesthetic may move intracranially or into the orbit through the infratemporal fossa. (13,14) Meanwhile, the location of this remaining volume has not been formally investigated.

Due to its many benefits, including safety profile, convenience of use, and low radiation exposure, the use of ultrasound guiding for regional anesthetic and pain mitigation has grown in popularity. Key anatomical features can be identified with its assistance, and by seeing the needle tip as it advances, it facilitates ideal needle insertion. The use of ultrasound pictures has been linked to a variety of superficial to deep nerve blocks in relation to head and neck blocks. (15–17) Thus, the use of ultrasound for maxillary nerve block for clinical purpose is now mandatory. Although a safe and reliable suprazygomatic MN block technique has been validated providing satisfactory analgesia for midface surgery and chronic maxillofacial pain syndromes, where the remaining local anesthesia diffuses after filling the pterygopalatine fossa in maxillary nerve block has not been formally investigated.

Some authors suggest that with the injection of sufficient volume into the PPF during the maxillary nerve block, some remaining volume could diffuse to the pterygomandibular space, suggesting a communication between the two. And these data could justify the reported high analgesic power of the maxillary nerve block in maxillofacial surgery, which in addition to blocking the branches of the maxillary nerve itself located in the PPF, could also block branches of the mandibular nerve located in the pterygomandibular space. Therefore, randomized controlled trials are needed to determine in greater detail the dispersion of the injected volume outside the PPF when the maxillary nerve block is performed.

The goal of this anatomical study is to identify the extent of local anesthesia spreaded that might influence anesthetic coverage and blockrelated complications.

2. Objectives

2.1 Main Objective

To analyze the spread of 2 and 5 ml of injected contrast to branches of the mandibular nerve after suprazygomatic ultrasound-guided single injection into the pterigopalatina fossa.

2.2 Secondary Objective
To analyze the spread of 2 and 5 ml of injected contrast to other locations after suprazygomatic ultrasound-guided single injection into the pterigopalatina fossa.
Compare different volumes (2 and 5ml) of contrast injected into the pterygopalatine fossa to investigate the location of its dispersion away from the maxillary nerve.

3. Work Hypothesis
H0: Cadavers that receive a volume of 2 and 5 ml of contrast into the pterigopalatina fossa when practicing the ultrasound-guided suprazygomatic maxillary nerve block do not reach branches of the mandibular nerve.

H1: Cadavers that receive a volume of 2 and 5 ml of contrast into the pterigopalatina fossa when practicing the ultrasound-guided suprazygomatic maxillary nerve block reach branches of the mandibular nerve.

4. Material & Methods
4.1 Study design

The researchers propose a comparative observational study where ten mildly embalmed cadaveric specimens will be randomized to receive two injections into the PPF with different volumes (2 or 5ml) and dissection of maxillary nerve dye (10 specimens, 20 injections). Volume of injected contrast randomization (2 or 5 ml) will be performed for each site. All specimens will be acquired lawfully and kept in the Universitat Internacional de Catalunya (Spain) Department of Anatomy. Donors will have consented that after death their bodies could be utilized at the Division of Anatomy for education and research purposes. If a specimen showed any indication of pathology, damage, or prior head surgery, it will be eliminated.

4.2 Procedure

The corpse will be weighed, measured and placed on the autopsy table with a stabilization device to prevent from moving while the injection is being administered. Maxillary nerve block and a volumen of 5ml of contrast will be performed for each side (ten specimens, twenty blocks). Injection in the PPF will be performed by the same anesthesiologist experienced in the ultrasound-guided suprazygomatic MN block technique. A portable ultrasound device with a linear array probe operating at 8–13 MHz, a 21 gauge 100 mm Locoplex (Vygon,

Ecouen, France) needle and a colouring solution will be used. After confirming the correct needle position into the PPF, 2 or 5ml of contrast will be injected. After the injection, the corpse will be submitted to autopsy by standard procedure. After removal of tissues the investigators will verify the dispersion of the contrast. Photographic records will be made and the number of levels by which the solution dispersed will be annotated.

Two or five mililiters of dye will be administered in a random order after certifying by ultrasound the needle is in the correct place into the PPF. An aqueous dye will be injected, with 0.5 mL of methylene blue mixed with 19.5 mL of water, roughly comparable in viscosity to the local anesthetic. Half of the injections will use 5 mL of dye, representing the volume traditionally used for MN block, and the other half will use 2 mL of dye, representing the previously observed PPF own volume (1 mL) and 1 mL remaining (2 ml in total).

For anatomical dissection, the orbital contents will be removed and the second division of the trigeminal nerve will be traced through the orbit floor. Its path will be identified as the intracranial channel of the trigeminal nerve and as high as the foramen rotundum. This dissection will made the pterygopalatine ganglion's entire region visible. Throughout the dissection, high-quality pictures will be taken one after the other.

After the injection into the PPF, 2 investigators blinded to injectated volume will perform dissection and will document and photograph the dye spread during and after dissection. All the relevant nerves of the face will be assessed through the whole cadavers. Positive nerve staining will be defined as direct dye uptake to target nerves. The investigators will compute the following observations: i) the region of intra/extra PPF dye spread; and ii) the frequency of capture of each nerve of the face and pterygopalatine ganglion with 2 and 5-mL injection volumes.

4.3 Statistical analysis

A convenience sample consisting of 10 cadavers (10 cadavers, 20 injections) was selected a priori as this sample size was compatible with that in most of the cadaveric studies(REF Echaniz, Kampitak) examining the staining of the dye to the nerves at study conclusion. The linear-by-linear association method was used to analyze whether the distribution of dye spread to target nerves tended to increase as the volume of injectate increased. All statistical analyses were performed using IBM SPSS Statistics version 24.0 (IBM Corp). Statistical significance was set at P values <.05.

4.4 Ethics and Data confidentiality

The research complies with the guidelines indicated by Good Clinical Practices in Research and with the Declaration of Helsinki and successive revisions (updated version at the 64th General Assembly, Fortaleza, Brazil, October 2013).

The confidentiality of patient data is respected, in compliance with the European Data Protection Regulation (EU) 2016/679 and Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights. The researcher will ensure the maintenance of the anonymity of the subjects, for which the patient's identity will be recorded using an alphanumeric identification code in all study documentation. The investigator will keep a record of patient inclusion showing codes. The researcher, the monitor designated by the promoter and representatives of the competent health authorities may have access to the confidential data of the study subjects. Access to the computerized database with information on the variables under study is also allowed to the statistician who performs the analysis. The study data collection sheets will be kept by the researcher in a locked place in the University's Endodontics office. The data sheet will be saved in an Excel and stored on an external drive that only the study investigators will have access to. Copies of the protocol, data collection notebooks, informed consents and other documents pertaining to the study must be kept in the study file by the researcher during the period of time established by legislation, reflecting the transfer of data at the appropriate time.

4.5. Timing

4.6. Financial Report:

This is a study led by a team of professionals who belong to the teaching staff of the International University of Catalonia. This University undertakes, at no cost to the researchers, to provide both the ultrasound devices and the necessary cadavers available in the Anatomy Unit, for the study and subsequent publication of the observed results.

5. LIMITATIONS

The limitations of this study include firstly the small simple size and the use of cadavers. Postmortem changes in tissue integrity and permeability can affect fluid dispersal. Previous cadaver studies used injection solutions with different properties. Differences in the composition of the solution may affect the dye staining of the relevant nerve in the cadavers. Furthermore the spread of the injectate in a cadaveric model may not be consistent or clinically correlated with the findings in human subject. Second, although the use of ultrasound imaging to assist selective maxillary nerve block is helpful to delineate the surrounding tissues, bony structures, and the PPF, the actual nerves cannot be visualized on ultrasound images. Therefore, a high level of expertise is required for visualization of the needle tip in order to avoid accidental injury to the surrounding structures during the procedure.

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