CLINICAL STUDY REPORT – released 26.08.2016

EUDRACT: **2013-0017595-38**

Title of Study: **Transnasal sphenopalatine ganglion blockade for acute facial pain. A prospective randomized study with multivariate analysis of results**

Name of Active Ingredient**: Mepivacaine 2% solution**

Investigator: **Zanella Simone MD**

Study centre: **Department of Emergency, Santa Chiara Hospital, 38122 Trento**

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Introduction

The Sphenopalatine Ganglion (SP) is one of the four parasympathetic ganglia in the head. Located in pterygopalatine fossa, posterior to the middle nasal turbinate and anterior to pterygoid canal it contains the cells body of the post-ganglionic parasympathetic neurons and having connections with many sensory fibers especially somatic sensory afferent branches of the maxillary division of trigeminal nerve. Post-ganglionic sympathetic neurons as well as somatic sensory afferent branches pass through the ganglion so that all may be inhibited by blockade of the SPG. The sensory fibers connect the maxillary nerve to the SPG by way of five branches that extend from the nasopharynx, nasal cavity, palate and orbit. Three approaches are usually used to obtain ganglion blockade. Transnasal proposed by Sluder using a cotton tipped applicator dipped in 90% watery solution of cocaine hydrochlorate, transoral and lateral approach. The transnasal approach is simplest, most tolerable and may be realized using a cotton tipped applicator dipped in local anesthetic such as Mepivacain or Lidocain. The diffusion of topical anesthetic to the ganglion is unpredictable and the blockade is not durable according to several authors. Currently accepted indications for the SPG block are sphenopalatine neuralgia, trigeminal neuralgia, atypical facial pain, acute migraine, acute and chronic cluster headaches, herpes zoster involving the ophthalmic nerve and a variety of other facial neuralgias. The mechanism by which intranasal lidocaine alleviates the pain is not fully understood, however it is believed to reverse the parasympathetic contribution to intracranial vasodilatation by blocking the sphenopalatine ganglion.

The aim of our study was to evaluate the efficacy of transnasal approach for unilateral facial pain in the emergency department. The primary end-point of the present study was to evaluate pain reduction after SP blockade and secondary end-points were to compare the use of painkillers and SP blockade duration.

Patients and Methods

A group of 84 consecutive patients with unilateral facial pain were prospectively enrolled in the study and randomized in two groups (SP blockade group A and pharmacological treatment group B). Patients were admitted at our emergency department with facial pain located in one of three parts of the face (upper, middle and lower) or in all. Written informed consent was obtained from all participants. There were 34 in group A (SP blockade) (40.4%) and 50 in group B (pharmacological treatment) (59.6%). In group A 16 (47%) men and 18 (53%) women with an overall median age of 40 years (range, 17-72 years) and 20 (40%) men and 30 (60%) women with an overall median age of 41 years (range, 14-86 years) in group B. Exclusion criteria were previous psychiatric disorders, pregnancy, neurological symptoms such as TIA or ICTUS . Informed consent was obtained from all participants. All patients were assessed pre and post SP blockade with ad hoc questionnaires. For the quantification of pain, a visual analogue scale (VAS), which provides 11 possible values (from zero to 10) and Mc Gill Italian version to qualify the pain were used. The use of painkillers (paracetamol 500 mg plus codeine 30 mg, with maximum dosage 1,500/90 mg/day; ibuprofen 400 mg, with a maximum dosage 1200 mg/day) was reported as number of doses needed. Non-responder patients or in group B were treated using, according to our emergency department protocol for pain, paracetamol 1000 mg if pain perception evaluated with VAS was 5 or less or dicloreum 75 mg if pain perception was 5 or more. Other pharmacological treatments if there was not a pain reduction were ibuprofen 600 mg, betametasone 4 mg, tramadol 100 mg, ketoprofene 100 mg and diazepam 10 mg. The SP ganglion blockade procedure was similar to that reported by several authors and modified by Windsor *et al.* using sterile 10 cm cotton tipped applicators before dipped in the chosen anesthetic and then advanced along the superior border of the middle turbinate, until the posterior wall of the nasopharynx. In our study a two cotton tipped applicators

were firstly dipped in a Mepivacaina 2% solution before application and then inserted ipsilateral along the turbinates until they reache the posterior wall of the nasopharynx. The applicators were removed after 20-30 minutes.

Results

The age of the patients, male-to-female ratio and facial pain presentation did not differ significantly between groups. Median facial pain intensity was not different at the first time access in Group A (8 6-9) and Group B (8 7-9) (VAS) and Group A (11 8-14.75) and Group B (9.5 4.75-14.25) (McGill). Significantly differences were in pain intensity after 30 and 60 minutes in Group A and Group B VAS (p=0.04 and p=0.01). McGill questionnaire pain perception was not significantly different at 30 and 60 minutes (p=0.36 and p=0.16) in both groups such us use of painkillers at 24 hours (p=0.11), 48 hours (p=0.11) and pain duration at the hospital evaluation (p=0.26). Five patients in Group A (14%) with dental pain presentation was not responder to sphenopalatine ganglion block and required pharmacotherapy because of dental abscess or jaw localization. Two patients with acute migraine was responder to sphenopalatine ganglion block also after 48 hours pain perception and unresponsive to usual pharmacotherapy. Only four patients in Group A and two patients in Group B were recalled one and two days after treatments to evaluate efficacy.

Conclusions

Transnasal approach also in our opinion remains the most popular approach for the block because of its simplicity. Our data showed that SPG blockade is an effective and safety modality of treatment and our study is the first randomized study for patients with unilateral facial pain in emergency department. Other studies will be necessary to evaluate especially SPG blockade duration