TRIAL PROTOCOL

INTRODUCTION

Introduction of regional anasethetic techniques into modern anesthesia has revolutionized pain management. The most popular anesthetic procedure used for mandibular anesthesia, for example during the extraction of impacted mandibular third molars is the inferior alveolar nerve block (IANB), here referred to as the "conventional technique", also known as direct mandibular nerve block or the Halstead technique. There are, in addition, several other major alternative approaches to this nerve block like Gow-Gates (G-G) and Vazirani-Akinosi (V-A) techniques[1,2]

Mandibulectomy is a resection of part of the mandible for cancer of the oral cavity, especially of the floor of the mouth.
Mandibulectomies can be either marginal (in which only the bone, teeth and adjacent soft tissues are resected and the mandible's continuity is maintained) or segmental (where a complete segment of the mandible is removed) or hemimandibulectomy (where one half of the mandible is removed).

Inferior alveolar nerve block anesthetizes the body of mandible and the lower portion of the ramus, all mandibular teeth, floor of the mouth, anterior 2/3rds of tongue, gingivae on the lingual and labial surface of the mandible, mucosa and skin of the lower lip and chin. The inferior alveolar nerve block has the potential of providing excellent analgesia for mandibulectomy and reducing the consumption of opioids and anesthetic agents.

This prospective pilot trial is being undertaken to evaluate the effectiveness of inferior alveolar nerve block to provide effective intraoperative analgesia by comparing it with retrospective analysis of available data.

Aims & Objectives

Study Settings:

This study will be conducted in the department of Anaesthesiology in a tertiary level cancer center in South India.

Study Design- Single arm controlled trial.

Study Population- Adult patients (age > 18 years) posted for mandibulectomy. Written informed consent will be taken from all the patients.

Inclusion Criterion-
1.Adults posted for mandibulectomy.

Exclusion criterion-

1. Patients not consenting for nerve block
2. Allergy to local anaesthetics
3. Coagulation abnormalities or bleeding disorders

4. Patients posted for arch mandibulectomy
5. Patients with infection at the site of block
6. Patients with tumor at the site of block

Pre Anaesthetic Evaluation- A detailed pre anaesthetic check-up (PAC) with all investigations according to institutional protocol will be carried out in all the cases.

Anaesthetic technique-
Patient will be taken to the operative room and standard monitoring devices (electrocardiogram, pulse oximetry and non-invasive arterial blood pressure) and will be attached to the patient.
Conventional inferior alveolar nerve block will be administered to the patient.

Technique:
After application of local anaesthetic the nerve will be approached from the opposite side of the mouth by angling the syringe from the premolars on the opposite side. The point of insertion is along an imaginary line bisecting the finger nail with the finger resting on the deepest point of ascending ramus. Tissues will be kept stretched and taut for atraumatic insertion of needle. The penetration depth is 20-25 mm until bone is hit, withdraw, aspirate, if negative- inject^{3} over 1 minute. The local anesthetic used for the block will be 0.75% Ropivacaine.

Parameters noted after the block
Sensory loss will be detected in terms of loss to cold sensation and the time of onset on sensory loss will also be noted in the following areas

1. Numbness in the lower lip/chin
2. Numbness in tongue
3. Incidence of positive aspiration test

If sensory loss is not achieved in 15 minutes the block will be labeled a failure and the patient will be excluded from the study.

Before the surgery, premedication will be provided with injection fentanyl 2mcg/kg. Standard intravenous induction will be done with propofol and vecuronium 0.1mg/kg and anaesthesia maintained with o2 /Air/ Sevoflurane. Airway will be secured with a nasotracheal tube. Etc02 will be kept at a standard range of 30-35mm Hg and BIS will be maintained between 40-60. Fluid administration will be standardised at 2ml/kg/hour of crystalloid. Injection Paracetamol 1gram will also be administered. Injection fentanyl 0.5 mcg/kg/hour will also be administered.

Vital charting will be particularly noted at crucial events like tongue stitch, dental extraction, osteotomy, condylotomy, marginal resection along with the usual vital charting at 15 minutes interval.

The primary objective of the study will be to estimate opioid and propofol consumption to maintain hemodynamic stability in both the groups. Any raise in blood pressure or heart rate more than 20% of baseline will be managed with a bolus of propofol or fentanyl and the amount of doses shall be recorded. The study ends

after mandibulectomy is over. No further recordings will be done in the intraoperative or postoperative period.

Any complications encountered during the study will also be noted.

Statistical Analysis:
Sample size:
The pilot study with 10 samples in each group will be undertaken for patients fulfilling the eligibility criterion and consenting to the study.

Statistical Methods:
The categorical variables will be summarized using frequency or percentage and continuous variables using mean and standard deviation. The comparison between the groups will be done using students t-test for normally distributed continuous variables and Mann-whitney U test for non-normal variables. For comparing two categorical variables, chi-square or Fishers exact test will be used.

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