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Research article

# Controlled hypotensive anesthesia for endoscopic endonasal repair of cerebrospinal fluid rhinorrhea: A comparison between clevidipine and esmolol: Randomized controlled study

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ABSTRACT

*Background:* The aim of this study was to evaluate the efficacy of intravenous infusion of clevidipine or esmolol for producing controlled hypotension during endoscopic repair of cerebrospinal fluid (CSF) rhinorrhea.

*Patients and methods:* Fifty adult ASA I and II patients scheduled for endoscopic repair of CSF rhinorrhea were randomized into one of two groups. Group C (25 patients) received clevidipine 0.5 mcg/kg/min increased by 0.5 mcg/kg/min every 3–5 min to achieve the target mean arterial pressure (MAP) of 55–65 mmHg. Group E (25 patients) received esmolol infusion 50 mcg/kg/min increased by 50 mcg/kg/min every 3–5 min to achieve the target MAP. Surgical field Quality, blood loss, haemodynamic parameters, surgeons' satisfaction and adverse events were recorded.

*Results:* Time to reach target MAP was significantly shorter in group C compared to group E. Number of patients needed nitroglycerine was significantly higher in group E compared to group C (8 versus 2 respectively). The nitroglycerine dose needed/patient in group E was significantly more compared to group C. Surgeon satisfaction score was significantly higher in group C compared to group E. More patients in group E developed bradycardia compared to group C. Mean arterial pressure was significantly lower in group C compared to group E after 5 and 10 min from the start of the studied drugs infusion while it was significantly higher in group C after 25 min from the start of the studied drugs. The heart rate (HR) was significantly lower in group E compared to group C 10 min after starting drugs infusion till the end of surgery.

*Conclusion:* Both clevidipine and esmolol are effective for inducing controlled hypotension during endoscopic repair of CSF rhinorrhea. Clevidipine has the advantage of having shorter time to reach target MAP with less need of additional hypotensive agent and better surgeon satisfaction.

## 1. Introduction

Cerebrospinal fluid (CSF) rhinorrhea may be spontaneous or secondary to head injury, surgery, neoplastic invasion of the skull base or congenital malformations [1]. Endoscopic endonasal repair has become the surgical approach of choice for CSF leak as it is safe and less invasive with a high success rate [2,3].

Controlled hypotension during surgery allows better surgical field visibility with decreased blood loss, surgery duration and lower incidence of complications [4]. A lot of medications can be used for controlled hypotensive anesthesia. The ideal drug for controlled hypotension should be easily administered with dose-dependent effects, fast onset and short term effect without toxic metabolites and minimal adverse effects [5].

Clevidipine is an intravenous calcium channel antagonist that can rapidly control blood pressure by direct arterial vasodilatation [6–9]. It has a short half-life approximately one to three minutes due to rapid metabolism by blood and tissue esterases [10,11].

Esmolol is an ultrashort selective β1-adrenoreceptor blocker which has short elimination half-life with rapid clearance and can be used for controlled hypotension without reflex tachycardia [12,13].

The primary outcome of this study was to compare the efficacy of intravenous infusion of clevidipine and esmolol for producing controlled hypotension during endoscopic repair of CSF rhinorrhea. The secondary outcome was to compare between the two drugs regarding quality of surgical field, surgeons' satisfaction and adverse events.

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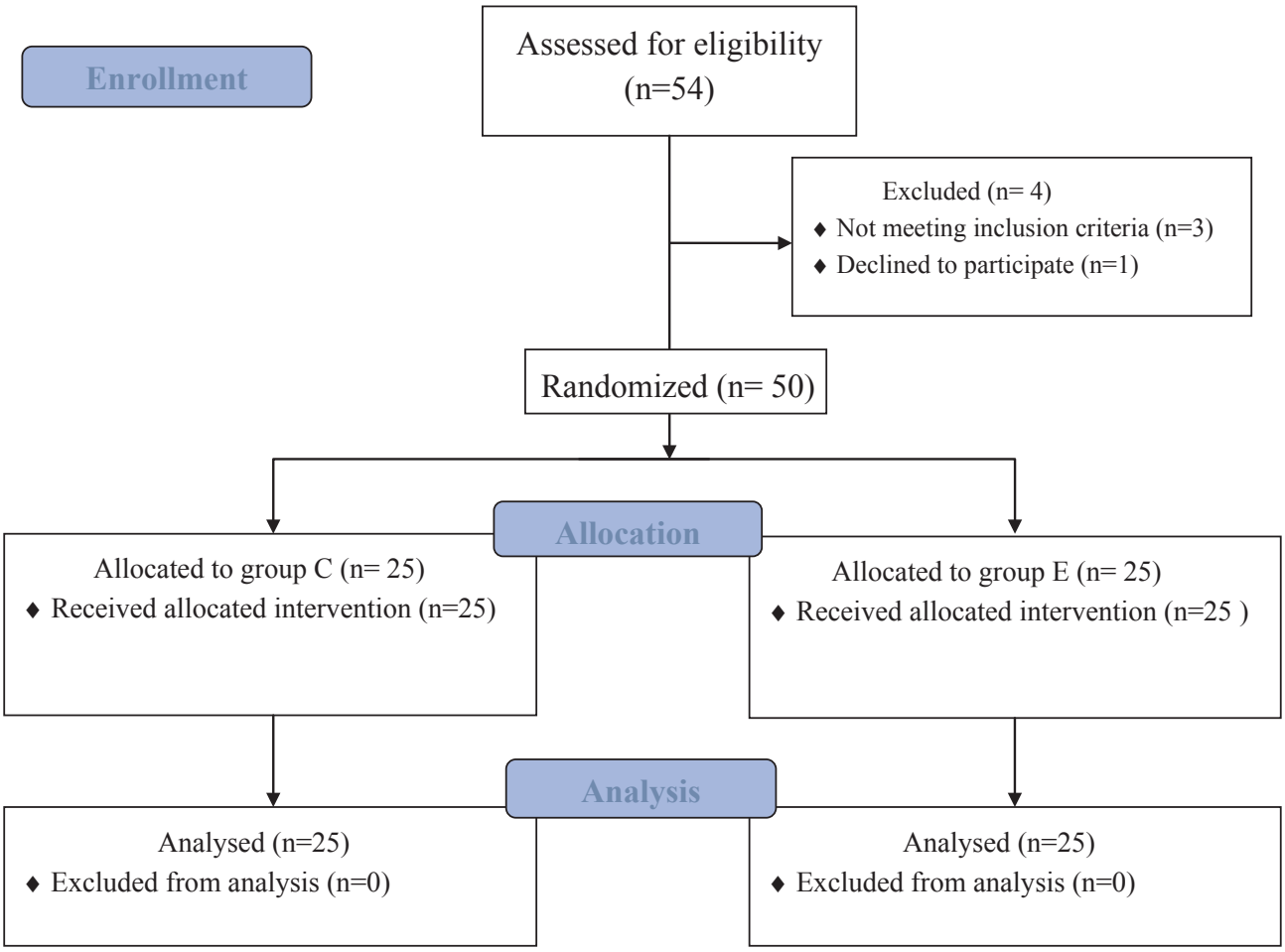


**Fig. 1.** Patient's flowchart demonstrating the number of patients eligible for inclusion into the study, enrollment, randomization and analysis.

## 2. Patients and methods

### *2.1. Study design*

This prospective, randomized double-blinded study was carried out in zagazig university hospital from January 2014 to August 2017 after our institutional review board approval and obtaining a written informed consent from all patients. Fifty adult ASA physical status I and II patients planned for endoscopic repair of CSF rhinorrhea under general anesthesia were randomly allocated to either clevidipine group (group C) or esmolol group (group E) (Fig. 1). Randomization was done using block randomization with block size of 6 and allocation ratio of 1:1 and sealed envelopes were used for allocation concealment. Patients with cardiovascular disease (hypertension, heart block, severe aortic stenosis, heart failure, arrhythmia or coronary artery disease), cerebrovascular insufficiency, coagulation disorders, renal or hepatic insufficiency, a known or suspected allergy to the study drugs or its components, or patients with disorders in lipid metabolism, were excluded from the study.

After proper preanesthesia evaluation two eighteen gauge intravenous cannulas were inserted and all patients were monitored by pulse oximetry, ECG and non-invasive blood pressure and baseline measurements were measured and recorded.

Midazolam 0.05 mg/kg was given intravenously and patients were placed in the sitting position and lumber puncture was done under complete aseptic precautions at $L_3$-$L_4$ or $L_4$-$L_5$ interspace via a midline approach using g 22 spinal needles.0.25 ml of a 10% sterile fluorescein dye was mixed with the aspirated CSF (total 10 ml) then reinjected slowly into the subarachnoid space. Patients were turned to Trendelenburg position for 20–30 min. Preoxygenation for 3 min then general anesthesia was induced with propofol 2 mg/kg, fentanyl 2 mcg/kg and rocuronium 0.6 mg/kg. Oral endotracheal intubation with cuffed endotracheal tube and oropharyngeal pack was inserted then mechanical ventilation was started to keep the $_{ET}CO_2$ 30–35 mmHg. Anesthesia was maintained using isoflurane 1–2%. All patients were monitored for Invasive arterial blood pressure via radial artery, oxygen saturation, ECG, temperature and Capnography.

Patients were put supine with head up 15–20°. Cotton soaked with a solution containing lignocaine 2% and epinephrine 1/10,000 was applied to nasal mucosa for 5 min.

Group C (25 patients) received clevidipine (cleviprex, Fresenius Kabi, Austria) (0.5 mg/ml) which was started at 0.5 mcg/kg/min and increased in increments of 0.5 mcg/kg/min every 3–5 min to a maximum of 8 mcg/kg/min to achieve the target mean arterial pressure (MAP) (55–65 mmHg).

Group E (25 patients) received esmolol (Baxter healthcare corporation, USA) (10 mg/ml) infusion started at 50 mcg/kg/min which was increased by 50 mcg/kg/min every 3–5 min if needed to achieve the target MAP with a maximum infusion rate of 300 mcg/kg/min. In both groups, if target MAP was not attained with the maximum dose of the studied drug, additional doses of fentanyl (0.5 mcg/kg) were given and if still not attained nitroglycerin infusion was started. Nitroglycerine was started in a dose of 0.5 μg/kg/min and increased gradually until the target MAP was achieved.

Hypotension was diagnosed if the MAP dropped below 55 mmHg and intravenous fluids were infused rapidly and the studied drug infusion was titrated down until temporarily stopped. If the MAP was still below 55 mmHg, ephedrine 6 mg was given intravenously and repeated