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Prospective Double Blind Randomised Controlled Study on Effect of Dexmedetomidine on Quality and Ease of Extubation.

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KEYWORDS

Extubation hemodynamics, dexmedetomidine, sedation.

ABSTRACT:

Introduction: Tracheal extubation much like laryngoscopy and intubation is associated with haemodynamic derangements. The objective of our study is to see the effect of Dexmedetomidine an alpha 2 agonist infusion 15 minutes prior to extubation on the haemodynamics and extubation process.

Objectives: To evaluate the effect of dexmedetomidine on haemodynamic and recovery responses during extubation and the quality of extubation.

Methods: Prospective double blinded randomized controlled study. Sample size was calculated based on findings of Barkha et al. using the formula for comparison of two means. Study conducted at tertiary teaching hospital January 2014 to June 2015, 60 indoor patients (30 in each group) of ASA grade I and II , 18-60 years of age , scheduled for elective surgery under general anaesthesia with tracheal intubation.Population was randomized into two groups by closed envelope technique. Patients in C group received 100 ml of 0.9% Normal saline and group D received 0.5 mcg/kg of Dexmedetomidine in 100 ml Normal Saline over 15 minutes about 15 minutes prior to anticipated end of surgery.Heart rate, systolic, diastolic and mean arterial pressures were recorded at the start of the infusion and there after at every 1, 5, 10 and 15 minutes. Residual neuromuscular blockade was reversed. Ones patient is fully awake, obeying oral commands, patient extubated after thorough oral suctioning. Vitals noted at the time of reversal of neuromuscular bloackade and extubation and at 1,5, 10, 15 and 30 minutes post extubation. Any untoward event noted. Respiratory rates noted in both the groups following extubation.

Results: Heart rate and blood pressure were evidently lower in the dexmedetomidine group during and after extubation. Sedation score was 3 in group D and 2 in group C. Quality of extubation score of most patients in dexmedetomidine group was 2 and 3 in placebo group. No side effects were seen in any of the patients.

Conclusions:Dexmedetomidine, 0.5mcg/kg given as an infusion 15 minutes prior to extubation, provides stable haemodynamics and smooth extubation.

1. Introduction

Laryngoscopy and tracheal intubation cause significant haemodynamic derangements in the patient. Similar changes are noted during tracheal extubation as well. It is invariably associated with reflex sympathetic stimulation caused by epipharyngeal and laryngopharyngeal stimulation, leading to hypertension, tachycardia and arrhythmias (1). Although these effects are momentary , unpredictable and inconstant; they can prove to be dangerous in patients with myocardial insufficiency , cerebrovascular diseases or hypertension etc. It is particularly crucial to avoid increases in heart rate and blood pressure in intraocular, neurosurgical or

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vascular surgeries. At the same time, extubation can also be associated with coughing, straining, breath holding or laryngospasm due to airway irritation by secretions or blood. These may contribute to the rise in blood pressure post extubation. Smooth tracheal extubation is devoid of straining or coughing or laryngospasm (2).

Alpha-2 agonists decrease the sympathetic outflow and noradrenergic activity, thereby can annul haemodynamic fluctuations at the time of extubation. Dexmedetomidine provides excellent sedation with minimal cardiovascular instability or respiratory depression. It decreases heart rate and blood pressure through its sympatholytic effects. Therefore theoretically, it is appropriate for reducing airway and circulatory reflexes during emergence from anaesthesia (3) (4).

2. Objectives

To assess the degree of attenuation of haemodynamic responses and airway reflexes to extubation, by administering dexmedetomidine at a dose of 0.5 mcg/kg body weight as an infusion over 15 minutes prior to extubation and the side effects of the drug if any. The aim of the study was to evaluate the effect of dexmedetomidine on haemodynamic and recovery responses during extubation and the quality of extubation.

3. Methods

This prospective double blinded randomized controlled study was conducted at a tertiary teaching hospital from January 2014 to June 2015, on 60 indoor patients (30 in each group) of ASA physical status I and II, between 18-60 years of age and scheduled for elective general surgical, neurosurgical, gynaecological and otorhinolaryngology surgeries, under general anaesthesia with tracheal intubation.

Patients with anticipated difficult airway, obesity, cardiovascular or respiratory diseases, uncontrolled hypertension or diabetes, emergency procedures, pregnant or lactating women, those with history of sleep apnoea and those on medication affecting the heart rate or blood pressure were excluded from the study.Institutional ethical committee clearance was obtained before the start of study and written informed consent taken from each patient. Pre anaesthetic check up of all patients was conducted, including detailed history and examination and routine blood investigations. The study population was randomized into two groups by closed envelope technique.Patients in group C received 100 ml of plain 0.9% normal saline IV over 15 minutes and in Group D received 0.5 mcg/kg dexmedetomidine IV in 100 ml saline over 15 minutes. The normal saline burette with or without the dexmedetomidine for each study was prepared by a personnel, who had no role in the assessment of patients. Standard anaesthetic techniques were used for all patients using propofol, fentanyl, sevoflurane, vecuronium and nitrous oxide-oxygen mixture. Standard monitoring was done with pulse oximetry, non invasive blood pressure, electrocardiogram and capnography. All patients were intubated with oral or nasal endotracheal tube of appropriate sizes. About 15 minutes prior to anticipated time of end of surgery, inhalational agent was cut off and patients in each group received the allocated solution intravenously over 15 minutes.

Heart rate, systolic, diastolic and mean arterial pressures were recorded at the start of the infusion and thereafter at every 1, 5, 10 and 15 minutes. Residual neuromuscular blockade was then reversed with IV neostigmine 0.05 mg/kg and IV glycopyrrolate 0.01 mg/kg combination. Once good spontaneous respiratory efforts returned and patient could obey oral commands , trachea was extubated after thorough oral suctioning. Heart rate,systolic, diastolic and mean arterial pressures were recorded at the time of reversal and extubation and thereafter at 1, 5, 10, 15 and 30 minutes post extubation. Any untoward event such as laryngospasm, bronchospasm, bradycardia, hypotension or undue drowsiness was noted. Respiratory rates were noted in both the groups following extubation.

In our study, we defined hypotension as a systolic blood pressure of less than 60 mmHg or a drop in systolic blood pressure of more than 30 mm Hg. Hypotension was treated with IV fluid bolus or if required with IV ephedrine bolus 6mg. Bradycardia was defined as a heart rate less than 50 beats per minute and was corrected wherever associated with haemodynamic instability with IV atropine 0.6 mg Postoperative sedation was evaluated on a 6 point scale (Ramsay scale). 1= Anxious or agitated and restless or both, 2= Cooperative, oriented, tranquil, 3= Drowsy but responds to oral commands, 4 = Asleep, brisk response to glabellar tap or loud auditory stimulus,

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5 = Asleep, sluggish response to light glabellar tap or loud auditory stimulus, 6 = Asleep and unarousable

Quality of extubation was evaluated based on cough immediately after extubation, using a 5 point rating scale (Extubation quality score):

1= no coughing, 2= smooth extubation, minimal coughing (1-2 times), 3 = moderate coughing (3-4 times), 4= severe coughing (5-10 times) and straining, 5= poor extubation (laryngospasm and coughing>10 times)

Sample size was calculated based on findings of Barkha et al. using the formula for comparison of two means. According to statistical power analysis, 23 patients per group were needed to get a 90% power in detecting a 15% difference between treatment groups with a 5% type I error.Assuming a five percent drop out rate, the final sample size was set at 60 patients (30 per group).

Descriptive and inferential statistical analysis were carried out in the study. Results on continuous measurements were presented on Mean +/- SD and results on categorical measurements were presented in number (%). Significance is assessed at 5% level of significance. Student t test was used to find the significance of study parameters on continuous scale between two groups on metric parameters. Chi-square/Fischer Exact test was used to find the significance of study parameters on categorical scale between two or more groups. Strongly significant was a P value <0.01, moderately significant was a P value 0.01 < P < 0.05 and suggestive significance P value: 0.05< P < 0.10. The statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for analysis of data (5) (6) (7) (8).

4. Results

Dexmedetomeidine group had significantly lesser increase in heart rate post extubation (p <0.05). Blood pressure remained more stable in dexmedetomedine group. Quality of sedation was better and need for rescue sedation is less with dexmedetomidine and it has no adverse effects on respiratory function. Dexmedetomidine group could be extubated smoothly with minimal coughing as compared to control group where most patients had moderate cough.Dexmedetomidine causes conscious sedation without any decrease in respiratory rate.

5. Discussion

Tracheal extubation is as important a part of general anaesthesia as intubation. Extubation is defined as the discontinuation of an artificial airway when the indication for its initial placement no longer exists. Extubation is performed usually with the patient in lighter plane of anaesthesia and hence it is associated with a pressor response causing a rise in heart rate and blood pressure which persists into the recovery period. These changes although transient and well tolerated, may be harmful for certain subgroup of patients, like those with severe cardiovascular diseases and neurosurgery procedure. Smooth extubation requires the absence of straining, movement, coughing, breath holding or laryngospasm (9). The pressor response, which is part of a huge spectrum of stress response, results from the increase in sympathetic and sympathoadrenal activity, as evidenced by increased plasma catecholamine concentrations in patients undergoing surgery under general anaesthesia.

Alpha-2 agonists are routinely used by anaesthesiologists due to its many desirable effects, like anxiolysis, analgesia, sedation, anaesthetic sparing and haemodynamic stabilizing properties. Dexmedetomidine, highly selective alpha-2 agonist with a relatively high ratio of alpha-2:alpha-1 activity (1600:1 as compared to 220:1 for clonidine), possesses all the above properties but lacks respiratory depression, making it a useful and safe adjunct in diverse clinical applications. It has a half life of 2.3 hours, although its distribution half life is less than 5 minutes, thus making its clinical effect quite short (10).

Dexmedetomidine has been used successfully to attenuate the pressor response to tracheal intubation (11). Based on its characteristics of sedation, haemodynamic stability and lack of respiratory depression, along with a short half life, the present study was conducted to evaluate the effect of dexmedetomidine in a dose of 0.5 mcg/kg IV on haemodynamic responses during tracheal extubation, the quality of extubation, postoperative sedation and prevalence of complications.

The dose of dexmedetomidine ranges from 0.25 – 1 mcg/kg. The dose of dexmedetomidine we used in our study was 0.5mcg/kg. This dose was selected based on a study by Guler et al (12) who found that the cough reflex and increase in systolic blood pressure, diastolic blood pressure and heart rate associated with emergence from

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anaesthesia were attenuated by a bolus IV dose of 0.5mcg/kg dexmedetomidine. Turan et al (13) concluded from their study that dexmedetomidine 0.5 mcg/kg IV administered 5 mins before the end of intracranial surgery stabilizes haemodynamics, allows easy extubation, provides a more comfortable recovery and early neurological examination following intracranial operations. Barkha et al 1 conducted a similar study but with a higher dose of dexmedetomidine of 0.75mcg/kg. They had a higher incidence of bradycardia and hypotension in their study after starting the dexmedetomidine infusion. Hence we conducted our study with a dose of 0.5 mcg/kg dexmedetomidine IV, as it is proven to have lesser incidence of hypotension and bradycardia with that dose, and give the desirable effect on controlling the pressor response to extubation and recovery responses.

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