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Original Article

Clinical study to evaluate the role of preoperative dexmedetomidine in attenuation of hemodynamic response to direct laryngoscopy and tracheal intubation

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ABSTRACT

Objectives: Dexmedetomidine, an α2 agonist, has been evaluated for its hypnotic, analgesic, and anxiolytic properties in the intraoperative period and critical care setting. However, data on the effect of dexmedetomidine on attenuation of pressor response to direct laryngoscopy and tracheal intubation are limited. We studied the effect of a single preinduction intravenous dose of dexmedetomidine of 0.5 μg/kg on hemodynamic responses to tracheal intubation, and dose requirements of anesthetics for induction and their adverse effects.

Methods: Eighty adult patients scheduled for elective surgery under general anesthesia requiring tracheal intubation were included. Patients were randomized into two groups: dexmedetomidine and placebo ($n = 40$ each). The study drug was administered intravenously over a period of 10 minutes prior to induction. Direct laryngoscopy and endotracheal intubation were performed. Hemodynamic parameters, the total dose of propofol, and adverse effects were recorded during induction and postintubation periods for 15 minutes.

Results: The maximum percentage increase in the heart rate after intubation was 19.6% less in the dexmedetomidine group than that in the placebo group (12.96% vs. 32.57%). The maximum percentage increases in systolic blood pressure, diastolic blood pressure, and mean blood pressure after intubation were significantly lower in the dexmedetomidine group than in the placebo group (12.38% vs. 45.63%, 19.36% vs. 60.36%, and 15.34% vs. 50.33%, respectively). There was a significant reduction of the mean total dose of propofol required for induction, 1.04 mg/kg in the dexmedetomidine group versus 2.01 mg/kg in the placebo group ($p < 0.001$). No serious side effects or adverse reactions were observed in either group.

Conclusion: Administration of a single preinduction intravenous dose of dexmedetomidine of 0.5 μg/kg resulted in significant attenuation of the rise in the heart rate, systolic blood pressure, diastolic blood pressure, and mean blood pressure, until 5 minutes postintubation. It significantly reduced the dose requirements of propofol for induction and caused minimal side effects.

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1. Introduction

Laryngoscopy and tracheal intubation (TI) may trigger reflex responses causing profound variation in cardiovascular physiology, and may cause serious complications in patients with underlying coronary artery disease, hypertension, or intracranial neuropathology.[1] Various drugs have been used to attenuate these responses, but none have been entirely successful.[2,3] Dexmedetomidine, the pharmacologically active d-isomer of medetomidine, is a selective α2-adrenoceptor agonist. Its short half-life makes it an ideal drug for intravenous (IV) titration.[4] Various studies have evaluated its hypnotic, analgesic, and anxiolytic properties in the intraoperative period and critical care

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setting.[5–8] However, there are limited data on its effect on attenuation of pressor response to direct laryngoscopy and TI. Most of the studies have used higher doses of dexmedetomidine, 1–2 μg/kg[9–19]; very few studies have evaluated the role of lower doses of dexmedetomidine (0.5–0.6 μg/kg) in attenuation of pressor responses.[20–23] The purpose of this study was to evaluate the effects of a single preinduction IV dose of 0.5 μg/kg dexmedetomidine on hemodynamic response to TI, and dose requirements of propofol for induction and its adverse effects in adult patients undergoing surgery under general anesthesia.

2. Methods

After the protocol was approved by the Institutional Ethics Committee (Government Medical College, Chandigarh, India) and written informed consent was obtained, 80 adult patients of either sex, American Society of Anesthesiologists (ASA) physical status I/II, in the age group of 18–60 years, who were scheduled to undergo elective surgery under general anesthesia requiring TI, were included in this study. The Clinical Trials Registry of India registered this interventional trial (registration number: CTRI/2013/08/003885). The exclusion criteria were as follows: anticipated difficult airway, body mass index > 30 kg/m^2, preoperative medication with clonidine or alpha methyldopa, hiatus hernia, gastroesophageal reflux, known allergy to dexmedetomidine, and known case of coronary artery disease.

The study design was prospective, randomized, double blind, and placebo controlled. Using a computer-generated random-number table, patients were randomly allocated to either the dexmedetomidine group ($n = 40$) or the placebo group ($n = 40$). Allocation concealment was performed using sequentially numbered, coded, sealed envelopes. The study drugs were prepared in identical-looking syringes by an independent investigator who was not involved in the recording of observations. The contents of syringes were unknown to the anesthesiologist involved in the administration of the drug and recording of observations. Decoding was performed on completion of the study.

Patients were premedicated with oral alprazolam 0.25 mg and kept fasting for 6 hours prior to surgery. In the operating room, standard monitoring [pulse oximetry, noninvasive arterial blood pressure, electrocardiography, and capnography (S/5: Datex-Ohmeda Division, Instrumentarium Corp., Helsinki, Finland)] was applied, and baseline parameters such as heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), and arterial oxygen saturation (SpO2) were recorded. After securing IV access, the study drug was administered over a period of 10 minutes as per group allocation using a syringe infusion pump (EMCO Meditek Pvt Ltd, Mumbai, India).

The study drug dexmedetomidine (Dexem; Themis Medicare Limited, Mumbai, India) was prepared as a 20 mL solution with a concentration of 5 μg/mL. This concentration was achieved by diluting 100 μg of dexmedetomidine in 20 mL of 0.9% normal saline. In addition, 20 mL of 0.9% normal saline was prepared for the placebo group in identical-looking syringes. Thereafter, the independent investigator calculated the volume of dexmedetomidine (0.5 μg/kg) to be administered, according to the weight of the patients. The volume of 0.9% normal saline to be infused in placebo group was kept equivalent to the volume of the dexmedetomidine drug infusion (as per calculation of dose 0.5 μg kg^{-1}) prepared for dexmedetomidine group. The anesthesiologist administering the study drug was blinded to the contents of the identical-looking syringes. Only the independent investigator who prepared the drug was aware of the contents of the syringes, and he or she directed the anesthesiologist to infuse a particular volume of the study drug/placebo as per group allocation.

Five minutes after the administration of the study drug, all patients received IV glycopyrrolate 0.2 mg and fentanyl 2 μg/kg. After preoxygenation for 3 minutes, anesthesia was induced with a manual bolus injection of 1% propofol until the loss of verbal contact. Neuromuscular blockade was achieved with vecuronium bromide 0.1 mg/kg, and the patient's lungs were manually ventilated for over 3 minutes with 67% nitrous oxide in oxygen. After 3 minutes, direct laryngoscopy was performed with a Macintosh laryngoscope, followed by TI with a cuffed endotracheal tube of appropriate size. The ventilator setting was adjusted to achieve SpO_2 of $\geq$ 95% and end-tidal carbon dioxide ($EtCO_2$) of 30–35 mmHg. Anaesthesia was maintained with nitrous oxide–oxygen combination (67%:33%), intermittent bolus administration of fentanyl (20 μg IV) and vecuronium (0.02 mg/kg IV), as and when required during surgery. NB: Fentanyl (20 μg/kg IV) is a higher dosage and was not administered as bolus during the surgical period in our study. Rate-controlled infusion of propofol was initiated with a manual rate-adjustment pump following the 10–8–6 manual infusion scheme.[24,25] Roberts et al[24] formulated and validated the aforesaid regimen based on pharmacokinetic predictions, and found that by following this manual infusion scheme, the blood propofol concentration of 3 μg/mL can be achieved within 2 minutes and maintained for nearly 90 minutes, which is adequate for achieving surgical anesthesia when combined with nitrous oxide.[25] Hypotension (SBP < 70 mmHg) was managed with 5 mg ephedrine IV. In the event of bradycardia (HR < 40 bpm), 0.5 mg of atropine was administered IV. At the end of surgery, all the patients received IV diclofenac sodium 1 mg/kg for over 30 minutes and ondansetron 0.1 mg/kg, to reduce pain and emesis, respectively. After completion of surgery, anesthesia was discontinued, and residual neuromuscular blockade was antagonized with neostigmine and glycopyrrolate in the doses of 0.05 mg/kg and 0.01 mg/kg, respectively. Once awake and responsive, the patient was extubated and shifted to the postanesthesia care unit. HR, SBP, DBP, MBP, SpO_2, and $EtCO_2$ were continuously monitored and recorded before infusion of the study drug (T0: baseline), after completion of infusion (T1), at 5 minutes (T2), after induction (T3), just before intubation (T4), and after intubation at 1-minute (T5), 3-minute (T6), 5-minute (T7), 10-minute (T8), and 15-minute (T9) intervals. After recording the observations for 15 minutes, the rest of the anesthetic procedure was carried out at the discretion of the attending anesthesiologist. During the study, the total dose of propofol required for induction was recorded. Side effects of the study drugs, if any, were also recorded. Cases were excluded from the study if there was inadequate jaw relaxation, Cormack–Lehane grade[26,27] was > 2, the patient moved or bucked during laryngoscopy or intubation, or the number of attempts for intubation was > 1.

All quantitative variables were estimated using measures of central location (mean and median) and measures of dispersion (standard deviation and standard error). Normality of data was checked by measures of skewness and Kolmogorov–Smirnov tests of normality. Demographic data were analyzed by Student *t* test and Chi-square test. Analysis of variance was used to analyze changes over time. When statistical significance was found, the difference between two different data for each variable was analyzed by *post hoc* multiple comparison test with Bonferroni's correction. Intergroup comparisons for hemodynamic parameters were performed with *t* test. Power analysis was carried out by statistical software package (SPSS, version 15.0 for Windows; SPSS Inc., Chicago, IL, USA). A sample size of 40 patients per group was required to detect a 15% change in HR, SBP, DBP, and MAP between baseline and postintubation, with a power of 90% at the 5% significance level. All data were expressed as mean ± standard deviation (95% confidence intervals) and $p < 0.05$ was considered significant.

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