Efficacy and Safety of Dexmedetomidine Versus Propofol for the Sedation of Tube-Retention After Oral Maxillofacial Surgery

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Purpose: To compare the safety and efficacy of sedation induced by dexmedetomidine and propofol after oral and maxillofacial surgery.

Materials and Methods: In this trial, 66 patients 18 to 50 years old received oral and maxillofacial surgery and required postoperative nasal endotracheal intubation under overnight sedation with dexmedetomidine or propofol. The dexmedetomidine group (group D) received dexmedetomidine 1.0 μg/kg intravenously for 10 minutes after entering the recovery room. The dose was maintained by giving an intravenous injection of dexmedetomidine 0.4 μg/kg. The injection rate could be modulated from 0.2 to 0.7 μg/kg/hour in the intensive care unit (ICU). If the Ramsay score was lower than 2 and involuntary limb movement occurred, other sedatives were used. The propofol group (group P) was given propofol 0.1 mg/kg intravenously for 10 minutes after entering the recovery room and then maintained with intravenous injections of propofol 1 to 2 mg/kg/hour in the recovery room and ICU.

Results: The oxygen desaturation of group P was higher than that of group D (at the first sedation time of 30 minutes), but the mean blood pressure of group P was significantly lower than that of group D at the 10-minute time point. The Ramsay score was higher in group D after the first 3 hours of sedation than in group P ($P < .05$).

Conclusion: Dexmedetomidine showed similar safety and efficacy as propofol and could be used for tube-retaining sedation after oral and maxillofacial surgery.

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A nasotracheal tube is often introduced in the recovery room and intensive care unit (ICU) after oral and maxillofacial surgery (OMS) because surgery frequently involves the upper airway and some important vessels and structures in the neck. Prompt extubation in the recovery stage can result in complete or partial airway obstruction owing to wound swelling or bleeding.[1,2] Intubation using a nasal tube has been popular in anesthetic procedures used in OMS because of improved tolerance. The extubation time point is often at the first postoperative day or later, as determined by the surgeon and anesthesiologist. Therefore, the aim of sedation in the recovery room and ICU is to keep patients comfortable and breathing spontaneously without pain. Furthermore, most patients require sedation to obtain enough natural sleep to adapt to the stress of surgery.[3,4] Several sedatives, narcotics, and analgesics are often used alone or in combination to achieve this goal. Despite the use of vital sign monitors and assisted ventilators in the ICU, a good sedative protocol should seek to make patients maintain sleep and

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awaken easily without dynamic changes and heavy sedation.

Propofol is an effective short-acting γ-aminobutyric acid agonist and has been used as a mainstay sedative in general anesthesia and the ICU. Some adverse events that frequently occur when using propofol for sedation include hypotension, dyspnea, and hypertriglyceridemia.[5] The incidence of propofol infusion syndrome may be rare but can have potentially fatal consequences with continuous use of the drug.[6]

Dexmedetomidine is a highly selective adrenergic α_2 agonist that has sedative and analgesic properties, because it decreases endogenous norepinephrine release in the brain and spinal cord.[7] Several studies have reported on the safety and efficacy of dexmedetomidine as a sedative for various surgical procedures, such as cataract surgery and flexible bronchoscopy,[8-11] or after surgeries, such as coronary artery bypass grafting and extensive cervical spine surgery.[12,13] A multicenter trial reported that dexmedetomidine can offer earlier extubation and decreased delirium compared with midazolam when used in predominantly medical patients in the ICU.[14] However, no data are available comparing dexmedetomidine with propofol for sedation after OMS. Therefore, this prospective and randomized trial was designed to compare dexmedetomidine with propofol as a sedative after OMS. A preliminary study showed that the use of dexmedetomidine results in lower rates of respiratory depression and more stable hemodynamic changes after OMS. Therefore, the efficacy and safety of dexmedetomidine versus propofol was compared by assessing sedation level, respiratory depression, hemodynamic stability, and adverse events.

Materials and Methods

PATIENTS

The study protocol was approved by the institutional ethics committee and conducted in the recovery room and ICU of the Ninth People's Hospital affiliated with Shanghai Jiao Tong University School of Medicine from November 2011 to September 2012. Each patient or the patient's legal representative provided written informed consent for participation in the clinical study. Included in this randomized and double-blinded trial were 66 patients 18 to 50 years old with American Standards Association physical classification system status of I to II who were undergoing OMS and required postoperative nasal endotracheal intubation under overnight sedation. Exclusion criteria included patients in a pregnant or lactating state, those with respiratory or cardiac disease (eg, oxygen desaturation[SpO_2] <90%, asthma, chronic obstructive pulmonary disease, obstructive sleep apnea syndrome, congenital cardiac disease, angina, cardiac infarction). Also excluded were patients with bradycardia (baseline heart rate [HR] <60 beats/minute), arterioventricular block, or hypotension (baseline systolic arterial pressure <90 mm Hg), those who abused alcohol or drugs, those intolerant to or with an allergy to dexmedetomidine or propofol, and those unable to or who refused to give informed consent (Fig 1). All patients underwent OMS and were transferred to the recovery room breathing spontaneously through a nasotracheal tube. Then, dexmedetomidine or propofol was administrated as a sedative.

Patients in the dexmedetomidine group (group D) received dexmedetomidine 1.0 μg/kg intravenously for 10 minutes after entering the recovery room; drug levels were maintained by giving intravenous injections of dexmedetomidine 0.4 μg/kg during the recovery period. The injection rate could be modulated from 0.2 to 0.7 μg/kg/hour in the ICU. However, if a patient's Ramsay score was lower than 2 and involuntary limb movements occurred because of surgical pain, other sedatives, such as propofol, were used. Patients in the propofol group (group P) were given propofol 0.1 mg/kg intravenously for 10 minutes after entering the recovery room; drug levels were maintained with intravenous injections of propofol 1 to 2 mg/kg/hour in the recovery room and ICU. Additional propofol injections at specific intervals could be used to keep a patient's Ramsay score higher than 2 until the morning of the next day. When the sedatives had been withdrawn postoperatively and the patients were conscious, the tubes were removed without bleeding or serious swelling in the proximity of the upper airway. Patients who could not be extubated because of postoperative bleeding or swelling were excluded from the study. All patients in the study were randomized using sealed envelopes to 1 of the 2 groups before surgery by an anesthesiologist not involved in the study.

STUDY DRUGS AND PROCEDURES

On the day of the operation, general anesthesia through a nasal tube was given to each patient. The type of surgery for each patient is presented in Table 1. After entering the recovery room, noninvasive measurements were made of blood pressure (BP), respiratory rate (RR), and HR, an electrocardiogram was obtained, and percutaneous SpO_2 was monitored by a hemodynamometer. These measurements were conducted without problems and confirmed stable vital signs for the patients. All patients were kept in a supine position and a continuous intravenous drip was inserted into a peripheral vein through an intravenous catheter (20 gauge; Insyte, Braun, Penang, Malaysia). Supplemental oxygen (4 L/minute) was given to all patients through a connection device with the nasotracheal tube. Then, patients in group D received