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Sedation effects of intranasal dexmedetomidine delivered as sprays versus drops on pediatric response to venous cannulation☆

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ABSTRACT

Objectives: Mucosal atomization device (MAD) was designed to increase the bioavailability of intranasal medications by facilitating absorption, the present study aimed to evaluate and compare the sedation effects of intranasal dexmedetomidine delivered as drops versus sprays on pediatric responses to intravenous cannulation.

Methods: One hundred and six pediatric patients (aged from 2 to 5 years) scheduled for elective ophthalmic surgery were intranasally received a dose of 2 µg/kg in 20 µl/kg of dexmedetomidine for sedation to reduce response to venous cannulation. The patients were randomized into syringe group and MAD group in which dexmedetomidine was delivered as drops or sprays via syringe or MAD respectively. The primary outcome was the response to peripheral vein cannulation assessed by the FLACC scores (faces, legs, activity, cry and consolability) 30 min after intranasal administration of dexmedetomidine. The secondary outcomes included acceptance for intranasal medication, sedation onset time, and needle insertion times and any adverse event at the preoperative holding area.

Results: The FLACC scores in MAD group were significantly decreased than that treated by drops ($P = 0.021$). The acceptance for intranasal administration between both groups was comparable ($P > 0.05$), the onset time and the incidences in two and more times of needle insertion did not differ significantly between syringe and MAD groups (all $P > 0.05$). None of patients were required to clinically intervene in heart rates reduction and none suffered respiratory depression after administrations of dexmedetomidine in either group.

Conclusion: Intranasal dexmedetomidine by sprays offers better sedation effects to reduce responses to venous cannulation than drops.

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1. Introduction

There are millions of children undergo surgery each year in the world, of those children, >50% experience significant fear and anxiety during preoperative period [1]. Intravenous cannulation, separation from parents, as well as anesthesia induction by inhaling sevoflurane via mask are the main causes to pediatric fear and preoperative anxiety [2], and it remains a challenge because preoperative anxiety can usually result in many unfavorable postoperative outcomes, such as emergency agitation and postoperative regressive behavioral disturbances.

☆ Institutional Review Board: Name: Zhongshan Ophthalmic Center; Tel: +86-20-87332702; Fax: +86-20-87334825; Address: Xianlie South Road 54#, Guangzhou, Guangdong 510060, China. Email: zocethics@163.com. Equipment: Mucosal atomization device (MAD, Wolfe Tory Medical, Inc., US). Dexmedetomidine: (Ai Bei Ning; Jiang Su Heng Rui Medicine Co. Ltd., Jiangsu Province, China). Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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Routine sedation by sedatives or anesthetics to minimize preoperative anxiety is strongly recommended [2]. Although the children can be quickly sedated by intravenous administration, the fear of pain of intravenous cannulation often induces severe anxiety during the process of needle insertion at the preoperative holding area [3]. Oral premedication is a more convenient alternative method for sedation [4], but it may increase the risk of aspiration during the period of anesthesia, and the sedatives with bad taste may be spitted out of the mouth by uncooperative children. Because a rich blood supply exists in the nasal mucosa, nasal routes to administrate sedatives has become practicable [5].

Dexmedetomidine has sedative and mild analgesia properties [6], it has been safely administrated in pediatric sedation [7], further, the use of dexmedetomidine can alleviate pain during third molar surgery [8]. Based on previous findings, we speculated that intranasal dexmedetomidine could be applied to attenuate pediatric responses to intravenous cannulation at the preoperative holding area.

Unfortunately, it has been reported that many children had been frightened by the mode of intranasal premedication [9], and the

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bioavailability can be reduced when intranasal administration with a large quantity of sedatives which can swallow into mouth. Mucosal atomization device (MAD) has been demonstrated to deliver drugs well into the nasal cavity as sprays avoiding spillage and swallowing, which improved medication bioavailability as well as acceptance as compared with drops methods [10,11]. In contrast, another previous study found that the bioavailability of diazepam after intranasal drop was similar to atomized nasal administration in dogs [12]. The paradoxical findings suggest that the medication bioavailability may not only relate to methods of intranasal administration, but also be associated with the characterizations of delivered drugs.

The commercial concentration of dexmedetomidine is 100 µg/ml which makes it easy to administer as drops with a small volume. It remains largely unknown the advantages of intranasal administration with small quantity of dexmedetomidine by MAD. The present study aimed to compare the sedation effects of dexmedetomidine on pediatric responses to intravenous cannulation between intranasal sprays and drops by MAD or syringe.

2. Methods

This study was approved by the institutional review board of the Zhongshan Ophthalmic Center (Reference number: 2015MEKY009). Informed written consent was obtained from at least one parent/guardian of each participating child, and the tenets of the Declaration of Helsinki were followed throughout this study.

2.1. Pediatric patients

Patients undergoing elective ophthalmic surgery were recruited from Zhongshan Ophthalmic Center between July 2015 and January 2016, and 106 children of American Society of Anesthesiologists (ASA) physical status 1–2 aged between 2 and 5 years were enrolled. In this current study, children with gastro-esophageal reflux, nausea and vomiting, apnea in the past three months, recent pneumonia, exacerbation of asthma, bronchitis and upper respiratory tract infection, severe arrhythmias, heart failure and cardiac structural abnormalities, facial

abnormalities, severe neurological disease, moyamoya disease, allergy to dexmedetomidine, those on digoxin and beta blockers, and cardiac disease with bradycardia were excluded.

2.2. Randomization grouping

Prior to the trial, randomized treatment allocations with no further stratification were generated by an independent person using a computer random number generator with a 1:1 allocation. The patients were randomly divided into two groups (Mucosal atomization device group and Syringe device group), which received 2 µg/kg intranasal dexmedetomidine delivered as sprays or drops by Mucosal atomization device (MAD, Wolfe Tory Medical, Inc., US) or syringe device, respectively. (A flowchart of participants can be seen in Fig. 1.)

2.3. Protocols of sedation

At the preoperative holding area, the patients were accompanied with the parents/guardians and assessed for the level of anxiety using modified Yale Preoperative Anxiety Scale [13], and undiluted preservative-free dexmedetomidine (Ai Bei Ning; Jiang Su Heng Rui Medicine Co. Ltd., Jiangsu Province, China) was prepared at commercial concentration of 100 µg/ml and drawn up into a 1-ml tuberculin syringe or mucosal atomization device (Fig. 2), thus, the final volume in each group was 0.02 ml/kg. A masked research assistant dropped or sprayed half of the volume of the solution into each nostril, and the patient was encouraged to remain in the lying supine position for at least 2 min to facilitate dexmedetomidine absorption. After intranasal administration, the sedation status was evaluated by sedation scores [14]. 30 min after intranasal administration, intravenous cannulation was carried out by the same nurse (Liwen Xiao) whom has experiences over 300 times of insertion for pediatrics, and the response for needle insertion was assessed by the Faces, Legs, Activity, Cry and Consolability (FLACC) scale. Vital signs, including the pulse oximetry and heart rate, were monitored every 10 min after intranasal drug administration and continuously measured after the patient fall asleep until transferred to operating room for anesthesia induction.

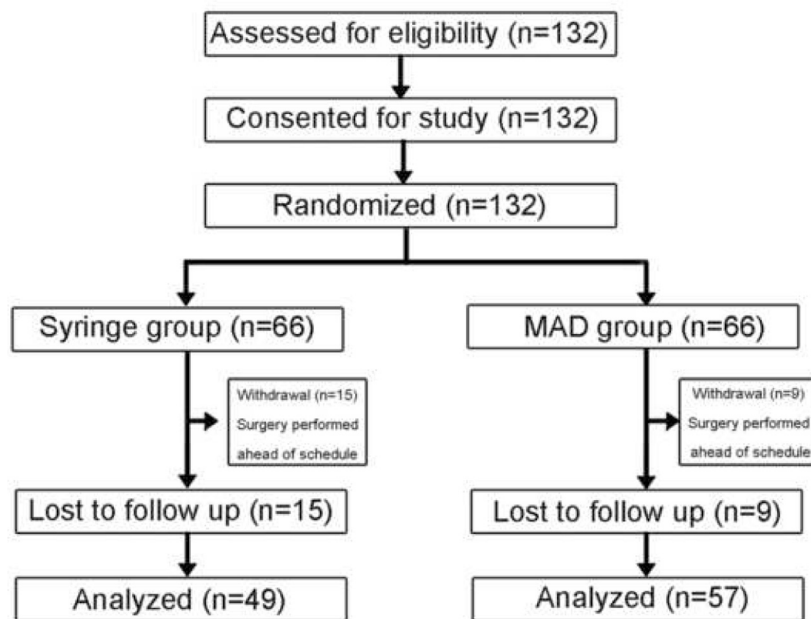


Fig. 1. Flow chart of the study. CONSORT diagram showing the flow of participants throughout each stage of the randomized trial. Patients in MAD group were intranasally received 2 µg/kg dexmedetomidine delivered as sprays via mucosal atomization device (MAD), and patients in syringe group were intranasally received 2 µg/kg dexmedetomidine delivered as drops via syringe.

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