

Comparison of intravenous infusion of dexmedetomidine and magnesium sulfate on bleeding volume and surgeon satisfaction during tympanoplasty

Abstract

Background: Increased Bleeding Volume during Tympanoplasty (BDT), in addition to disturbing the surgeon's vision, increases the need for transfusion of blood products and the risk of a hemolytic reaction. This study aimed to compare the effect of intravenous infusion of Dexmedetomidine (D) and Magnesium Sulfate (MS) on BDT.

Methods: In this clinical trial, 40 candidates for tympanoplasty were selected. They were randomly divided into two groups of 20, which included intravenous infusion of D at a dose of 1 µg/kg and MS at a dose of 40 mg/kg. The two groups were compared in terms of BDT, surgeon satisfaction level, surgery time, amount of drug use, and complications. Data were analyzed using SPSS26 ($P < 0.05$).

Results: In the D and MS groups, the mean±standard deviations of age were 44.05 ± 14.10 and 43.65 ± 12.71 . The findings showed that the differences in the mean of the variables were not significant ($P > 0.05$); BDT= 52.75 ± 15.52 , 49.50 ± 15.21 CC; Surgeon satisfaction level=30%, 35% (very good) and 20%, 50% (good); Surgery time= 116.25 ± 25.02 , 109.00 ± 17.82 minutes; Narcotic used= 6.25 ± 1.37 , 6.00 ± 1.57 CC; Frequency of complications (bradycardia, dry mouth, nausea)=55%, 65%; Mean arterial pressure= 80.85 ± 13.36 , 76.50 ± 7.09 ml; Mean heart rate= 75.85 ± 9.68 , 77.00 ± 5.71 per minute; Anesthesia termination time= 15.26 ± 4.85 , 15.40 ± 5.03 minutes; Success rate of surgery=0.95%, 0.85%.

Conclusion: D and MS seem to have relatively similar effects in tympanoplasty. But since fewer complications were observed in patients receiving D. We suggest that D infusion is preferred in tympanoplasty.

Elnaz Shariatpanahi¹; Mohamad khajavi²; Mahshid Nikooseresht³; Mohamadali Seifrabiei⁴; Seyede Faranak Emami^{5}*

¹Assistant Professor, Department of Otorhinolaryngology, School of Medicine, Hearing Disorder Research Center, Hamadan University of Medical Sciences, Hamadan, Iran.

²Otorhinolaryngologist, Department of Otorhinolaryngology, School of Medicine, Hamadan University of Medical Sciences, Hamadan, Iran.

³Associate Professor, Department of Anesthesiology, School of Medicine, Hamadan University of Medical Sciences, Hamadan, Iran.

⁴Professor, Department of Community Medicine, School of Medicine, Hamadan University of Medical Sciences, Hamadan, Iran.

⁵Associate Professor, Department of Audiology, School of Rehabilitation Sciences, Hearing Disorder Research Center, Hamadan University of Medical Sciences, Hamadan, Iran.

*Corresponding author: Seyede Faranak Emami

Associate Professor, Department of Audiology, School of Rehabilitation Sciences, Hearing Disorder Research Center, Hamadan University of Medical Sciences, Hamadan, Iran.

Email: faranak_imami@yahoo.com

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Keywords: Tympanoplasty; Bleeding; Etiology.

Abbreviations: D: Dexmedetomidine; MS: Magnesium Sulfatems; BDT: Bleeding Volume During Tympanoplasty; BVI: Bleeding Volume Intraoperative.

Introduction

Chronic purulent otitis media is a disease associated with middle ear discharge and perforation of the tympanic membrane. Its common consequences are hearing loss, infection and Otorrhea. Tympanoplasty is performed to repair the tympanic membrane and bony chain, improve hearing loss and stop ear discharge [1]. Intra operative Bleeding Volume (BVI) control is a common goal of all surgeries. If the BVI exceeds a certain limit, it causes hemodynamic instability, decreased oxygen carrying capacity and blood pressure, weakened cardiac output, perfused vital organs, disturbed the surgeon's view, increased the surgery time and worsened of surgical complications, such as meningitis, *cerebrospinal fluid* leakage, damage to the facial nerve, Bell's palsy, labyrinthitis, and increases the duration of surgery [2]. Considering the smallness of the middle ear field and the microscopic nature of tympanoplasty, even a very small amount of BDT affects the results and increases the possibility of negative outcomes. Indeed, it is very important to use drugs that reduce BDT [3]. Various drugs are used to prevent BDT, including D and MS. In terms of features, D is a sedating, analgesic, anti sympathetic, adrenergic receptor agonist with mild respiratory depression, that has minimal adverse effects on consciousness after administration, and it is a suitable option for surgery. MS also has useful pharmacokinetic and pharmacodynamic properties in the management of patients undergoing surgery, which is associated with the features of analgesia, sedation, hemodynamic stability, reduction of postoperative nausea/vomiting and the need for narcotics/hypnotics [4]. Microscopic surgeries such as tympanoplasty are highly dependent on the surgeon's vision. Despite many advances in surgical techniques, BDT is still a significant problem [2]. Therefore, this study aimed to compare the effect of intravenous infusion of D and MS on volume of BDT.

Material and methods

This study was a randomized controlled clinical trial that was conducted in the otolaryngology department of University of Medical Sciences in 2023. The participants were 40 patients, who were candidates for tympanoplasty using the posterior ear incision method. The data collection tool included a checklist designed by the researchers and according to the research variables, including age, sex, BDT, duration of surgery, complications, drug consumption, surgeon satisfaction level and success of the operation.

Inclusion criteria: Age 18 to 61 years, no history of bleeding disorders and abnormal coagulation tests (PT, PTT, INR, BT, CT, platelet count), no history of thromboembolic events and heart failure/acute or chronic kidney disease, not taking anti-coagulant drugs up to five days before surgery, not having liver cirrhosis/neuromuscular diseases, not being pregnant, cardiac arrhythmia.

Exclusion criteria: Allergy to D and MS, occurrence of complications during surgery or anesthesia that require special measures, patients requiring bone reconstruction, mastoidectomy and having any pathology in the middle ear.

Procedures: In this study, patients with chronic otitis media who did not respond to conventional medical treatments and were candidates for tympanoplasty were selected. After signing the research consent form, they underwent pure tone audiometric evaluation, speech reception threshold, speech discrimination score in silence and tympanometry. Their demographic

information, findings of clinical examinations and audiological evaluations were recorded in research questionnaires and they divided into two groups by random block method; D and MS recipients {D group was 9 men (45%) and 11 women (55%); MS group was 10 men (50%) and 10 women (50%)}. The day before CBC surgery, coagulation tests (PT, PTT, INR, BT, CT) were performed for all patients. Induction of anesthesia was standardized for patients with intubation and infusion of Fentanyl 5-7 µg/kg, Propofol 1-2 mg/kg [5]. Midazolam 1/mg/kg, and Atracurium relaxant 5 mg/kg [4]. Fentanyl infusion at the rate of 1-3 µg/kg/h and Propofol infusion at the rate of 100-200 µg/kg/min were used to maintain mean arterial blood pressure (range 60 to 70 mmHg) and anesthesia management. Immediately after induction of anesthesia, in the first group D was injected intravenously with a dose of 1 µg/kg for 15 minutes and in the second group MS with a dose of 40 mg/kg. Mean arterial blood pressure was recorded before the start of surgery and then the work was started by a surgical team. During surgery, according to BDT and patient weight, normal saline serum was prescribed. The volume of BDT was measured according to the amount of blood collected in the suction bottle, and after subtracting the volume of normal saline serum, the mean arterial blood pressure was recorded. At the end of the operation, the duration of surgery, the degree of satisfaction of the surgeon and the duration of anesthesia of the patient were recorded. Three months after the operation, the success rate of tympanoplasty was checked.

Randomization method: The randomization method was based on block randomization using ABAB quadruple blocks. A Table containing 4 rows and 10 columns, where two letters A and two letters B (one letter per house) are randomly placed in each row. Patients were divided into two groups, D or MS, according to the type of letter in the cell, each letter was removed after selection.

Blinding method: This study was conducted in a double-blind manner. The syringe of drugs of group D and MS only had a code of one of the letters A or B on which the name of the drug was written. Only one of the operating room personnel who was responsible for coding and writing them on the syringe knew about this. Until the end of the investigation, the surgeon, patient and other operators were unaware.

Limitations of the research: It was the lack of trust and cooperation of the patients, which was resolved by the project manager with reassurance and proper explanation.

Ethical considerations: This study was approved by the ethics committee of the University. The participants were informed about the side effects of the drugs and written consent was obtained from them. The tests and examinations used in this study were among the common diagnostic and treatment processes of patients and no extra cost was imposed on them. Patients were assured that the results of the study would be published anonymously. This study hindered their diagnostic and therapeutic measures and they were allowed to withdraw from the research at any stage of the work.

Results

The findings showed that there were no significant differences between the groups receiving D and MS in terms of age ($P=0.925$, Student's T-test) and gender ($P=0.752$, Chi-square test). In order to compare the quantitative variables in the two groups, the normality of the variables were first evaluated with

the Shapiro-Wilk test. The surgical time variable had normal distribution ($P < 0.05$) and the rest of them had non-normal distribution ($P > 0.05$). Therefore, parametric T-Student test was used to compare the surgery time in two groups and Mann-Whitney non-parametric test was used to compare the other variables. No significant differences were observed between the mean of two groups in terms of the following variables; surgery time ($P = 0.508$), BDT ($P = 0.529$), amount of narcotic drug use ($P = 0.698$), anesthesia termination time ($P = 0.945$), arterial pressure ($P = 0.211$), heart rate ($P = 0.583$), (Table 1), complications of the surgery (Table 2), level of surgeon's satisfaction during the operation and success of tympanoplasty three months after surgery (Table 3). In the D group, 11 people (0.55%) and in the MS group 13 people (0.65%) had complications.

Table 1: Mean and Standard Deviation (SD) of surgery time, Bleeding volume During Tympanoplasty (BDT), amount of narcotic used, anesthesia termination time, heart rate and arterial pressure in dexmedetomidine and magnesium sulfate groups ($n = 40$).

Variable	Type of intravenous infusion		
	Magnesium sulfate	Dexmedetomidine	P value
	Mean \pm SD	Mean \pm SD	
Surgery time (minutes)	116.25 \pm 25.02	109.00 \pm 17.82	*0.508
Bleeding volume during tympanoplasty (CC)	52.75 \pm 15.52	49.50 \pm 15.21	**0.529
Amount of narcotic used (CC)	6.25 \pm 1.37	6.00 \pm 1.57	**0.698
Anesthesia termination time (minutes)	15.26 \pm 4.85	15.40 \pm 5.03	**0.945
Arterial pressure (ml)	80.85 \pm 13.36	76.50 \pm 7.09	**0.211
Heart rate (minutes)	75.85 \pm 9.68	77.00 \pm 5.71	**0.583

*Student's t test.

**Mann-Whitney test.

Table 2: Frequency of complications of the participants in the research entitled comparison of intravenous infusion of dexmedetomidine and magnesium sulfate on bleeding volume and surgeon satisfaction during tympanoplasty ($n = 40$).

Variable	Type of intravenous infusion		
	Dexmedetomidine	Magnesium sulfate	Pvalue
	Number (Percentage)	Number (Percentage)	
Tachycardia	0(0.00)	0(0.00)	-
Bradycardia	3(15.00)	5(25.00)	*0.695
Dry Mouth	0(0.00)	3(15.00)	*0.231
Nausea	5(25.00)	6(30.00)	*0.998
Vomit	2(10.00)	7(35.00)	*0.127
Hypotension	1(5.00)	0(0.00)	*0.998
Hypertension	2(10.00)	0(0.00)	*0.487

*Fisher exact test

Discussion

In this study, no significant difference was observed between the D and MS groups in terms of BDT, which may be due to the type of surgery. In fact, most similar studies have been conducted on endoscopic sinus surgery, rather than tympanoplasty. Compared the effect of Remifentanyl, MS and D on the BVI during endoscopic sinus surgery and tympano-mastoidectomy.

Table 3: Level of surgeon's satisfaction during the operation and success of tympanoplasty three months after surgery of the participants in the research entitled comparison of intravenous infusion of dexmedetomidine and magnesium sulfate on bleeding volume and surgeon satisfaction during tympanoplasty ($n = 40$).

Variable	Type of intravenous infusion		Pvalue
	Dexmedetomidine	Magnesium Sulfate	
Level of surgeon's satisfaction	Number(%)	Number(%)	
Very Bad	0(0.00)	1(5.00)	
Bad	2(10.00)	3(15.00)	
Medium	5(25.00)	2(10.00)	*0.538
Good	7(35.00)	10(50.00)	
Very Good	6(30.00)	4(20.00)	
Total	20(100.00)	20(100.00)	
Tympanoplasty Success	Number(%)	Number(%)	
Successful	19(95.00)	17(85.00)	*0.605
Unsuccessful	1(5.00)	3(15.00)	
Total	20(100.00)	20(100.00)	

*Fisher exact test

The BVI in the group receiving D was significantly lower than the other two groups [6]. Also compared the effect of MS and D on the BVI in patients undergoing endoscopic sinus surgery. Their findings showed that D was more effective in controlling the hemodynamic status of patients and provided better conditions for surgery [7]. Observed that D compared to MS significantly reduced BVI during endoscopic sinus surgery [8].

Investigated the effect of D compared to normal saline (placebo) on BVI and recovery rate after endoscopic sinus surgery [9]. Also, studied the effect of D compared to normal saline during middle ear surgery. Their findings showed that in the group receiving D, BDT and recovery rate after surgery was significantly lower than the placebo group (13/30). For this reason, they recommended the use of D to improve the surgeon's vision and reduce BVI for middle ear surgery [10].

In our study, the surgeon's satisfaction with the operation conditions was relatively similar with D infusion (very good=30% and good=35%) and MS (very good=50% and good=20%). Conducted a review study on the use of D in middle ear surgery and reported that D is effective in improving the visibility of the surgical field and increasing surgeon satisfaction in middle ear surgery [11]. Compared the effect of D on improving the conditions of sinus endoscopic surgery and reported that in the group receiving D, the level of surgeon satisfaction was significantly higher than the control group [9]. Compared the effect of D and MS on hypotension during functional endoscopic sinus surgery and reported that the surgeon's satisfaction with the surgical conditions was significantly higher in the D group than in the MS [12]. In our study, the mean surgery time in the D and MS groups was 116.25 and 109.00 minutes, respectively. There was no significant difference between the two groups in terms of surgery time. In the study of, the mean time of middle ear surgery in intravenous administration of D was 103.67 minutes [13]. In the study of the mean time of middle ear surgery in the group receiving MS was 195.9 minutes [14]. Investigated the effect of MS and D on patients undergoing endoscopic si-

nus surgery and observed that D significantly reduced the duration of the operation time compared to the other group [15]. In addition to controlling BVI and improving surgical conditions, surgical instruments and equipment, surgeon expertise, and patient characteristics seem to have important effects on surgical conditions. In our study, no significant difference was observed between the mean groups receiving D and MS in terms of heart rate and arterial pressure. Confirmed that MS can be effective for controlling BV in patients undergoing tympanoplasty [16]. Also reported that D causes less drop in blood pressure and HR in people with Propofol administration [17]. Concluded that D is effective in controlling the hemodynamic status of patients undergoing endoscopic sinus surgery [7].

In our study, no significant difference was observed between the group receiving D and MS infusion in terms of the amount of Narcotic consumption. Studies have confirmed that both D and MS in spinal anesthesia surgery [18]. And in general anesthesia cause a delay in the first time of Narcotic request and reduce the need for Narcotic consumption in recovery [19]. In our study, the most common complications in the D and MS groups were nausea, bradycardia, and vomiting. Adverse outcomes in group D were also lower than in MS. However, no significant difference was observed between the mean of two groups in terms of frequency of consequences. Compared the effects of D and MS to control blood pressure in functional endoscopic sinus surgery. They reported the most common side effects to be nausea, vomiting, and the frequency of side effects were lower in the group receiving D than in MS [20]. Investigated the effect of D in hemodynamic control, BVI, surgical field of surgeon's vision, and the rate of recovery of patients. Their sample size included 40 patients aged 18 to 65 years, who underwent trans-sphenoidal pituitary surgery and divided them into two groups, receiving D and placebo. Their findings showed that there were no significant difference between the two groups in terms of heart rate during surgery and recovery speed. The mean systolic and diastolic pressure in group D was significantly lower, also the BVI during surgery and recovery was similar in the two groups [21].

Conclusion

It seems that during tympanoplasty, the use of D and MS infusions have relatively similar effects in terms of BDT, anesthesia termination time, surgery time, heart rate, arterial pressure, surgeon satisfaction level, amount of narcotics used, and frequency of complications. Since in our study, less complications were observed in patients receiving D, such as bradycardia, dry mouth, nausea and vomiting, we suggest to prefer D infusion for tympanoplasty surgery.

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