

Comparison of Dexmedetomidine with Midazolam during Monitored Care Anesthesia (MAC) in Patients Undergoing Septoplasty

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ABSTRACT

Objective: To compare the sedative and analgesic outcomes of dexmedetomidine with midazolam for monitored anesthesia care (MAC) in patients undergoing Septoplasty.

Methodology: This comparative study was conducted at Shalamar Medical and Dental College Lahore from March 2019 to August 2020. A total of 150 patients who were planned for Septoplasty under MAC having age 18-45 years, and ASA status I-II in Shalamar Medical and Dental College Lahore. Patients were randomly divided into two equal groups; in group D; IV dexmedetomidine 1 µg.Kg-1 was given over five mins after that IV infusion at the rate of 0.5 µg.Kg-1.hour-1 was started. In group M; midazolam 0.06 mg.Kg-1 was given as slow bolus after that continuous infusion at the rate of 0.01 mg.Kg-1.hour-1 was started. Sedation was monitored according to Ramsay sedation scale and VAS scale was used to measure the intensity of pain.

Results: The Mean age was 34.3±5.7 years in group D versus 35.7±6.1 years in group M. There were 49 (65.3%) male patients in group D and 47 (62.7%) in group M. Mean sedation and pain score was significantly less in group D as compared to group M (p-value 0.001 & 0.002 respectively). There were 12 (16.0%) patients in group D who required rescue sedation and 32 (42.7%) in group M required rescue sedation (p-value 0.003). There were 14 (18.7%) patients in group D who required rescue analgesia versus 29 (38.7%) in group M (p-value 0.006).

Conclusion: Use of dexmedetomidine for MAC is advantageous as compared to midazolam in-terms of better sedation and analgesia and reduced requirements of rescue doses of sedatives and analgesics.

Keywords: Monitored anesthesia care, Dexmedetomidine, Midazolam.

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Introduction

With advances in anesthesia techniques, the availability of modern drugs, and the availability of precise equipment's of drug delivery and patient monitoring, a new concept of anesthesia care has gained popularity known as monitored anesthesia care (MAC).¹ MAC in 2008 by American Society of Anesthesiology, was defined as it's a specific anesthesia used for diagnostic or therapeutic procedures to provide adequate sedation and analgesia while maintaining the patient's own spontaneous breathing and airway reflexes.² MAC either alone or with adjuvant to local anesthesia is gaining rapid popularity. The aim of MAC is to achieved three basic

goals; to provide safe conscious sedation with adequate pain control and to reduce patient's procedural anxiety. Because MAC minimally disturbs the patient's physiologic functions so it has rapid recovery in comparison to general anesthesia. Therefore, MAC is becoming the technique of choice for a variety of diagnostic and therapeutic procedures in and out of the operating room.² MAC is also routinely used for different types of ENT procedures, which needs adequate sedation and pain control but no respiratory depression, as is required for the comfort of surgeons is such procedures.³

For MAC induction, various drugs such as dexmedetomidine, midazolam, propofol, alfentanil etc. are used either alone or in combination.^{4,5} Midazolam is

routinely used for sedation during the induction of general anesthesia and has a very short onset of action and rapid recovery. It is also used for MAC, but its potential role is mainly limited because it can cause mild to moderate respiratory depression.⁶

Dexmedetomidine (DEX) is a highly selective α_2 -agonist and has sedative and, to some extent, analgesic properties.⁷ Dexmedetomidine, a novel agonist of the alpha-2 adrenergic receptor, produces adequate sedation and analgesia while causing only modest respiratory depressant effects in healthy volunteers. Due to the fact that it functions primarily on the sleep pathway and does not interfere with the activation of orexinergic neurons, it produces arousable sedation when administered. Furthermore, it has a sympatholytic effect, which means that it minimizes not only the stress response to surgery, but also the increase in heart rate and blood pressure that occurs as a result of the procedure. The alpha-2 adrenergic receptor antagonist atipamezole has been shown to be effective in reversing the hypnotic sedative effects of dexmedetomidine, which may aid in the development of a titratable type of sedation in the future.⁷ Moreover, DEX does not exert respiratory depression and therefore is now rapidly getting its place in MAC.^{8,9}

Midazolam is still the standard sedative drug for MAC. In our center we have started dexmedetomidine for MAC in patients undergoing Septoplasty. Therefore, the present study is conducted to compare the sedative and analgesic outcomes of dexmedetomidine with midazolam for MAC in patients undergoing Septoplasty.

Methodology

This comparative study was carried out at Shalamar Medical and Dental College in Lahore from March 2019 to August 2020, planned for Septoplasty under MAC in the ENT department of the hospital. Young adults of age 18-45 years, and ASA status I or II were included. Patients allergic to studied drugs were excluded. Written consent was taken from all patients. Approval from the ethical committee was obtained for this study, ERC Number: 26880-935, Dated; 10-10-2019.

The sample size was calculated by using the previous study results of Wahid et al., by taking estimated need of rescue sedation in 36% of patients in dexmedetomidine group and in 70% of patients in the midazolam group, at power of test $(1-\beta)=80\%$ and significance level $(\alpha)=5.0\%$. The calculated sample size was 39 patients in each group,

we took 75 patients in each group to increase reliability of study results.

Patients were randomly divided into two equal groups; In group D; IV dexmedetomidine $1 \mu\text{g.Kg}^{-1}$ was given over five mins after that IV infusion at the rate of $0.5 \mu\text{g.Kg}^{-1}.\text{hour}^{-1}$ was started. In group M; midazolam 0.06mg.Kg^{-1} was given as slow bolus after that continuous infusion at the rate of $0.01 \text{mg.Kg}^{-1}.\text{hour}^{-1}$ was started. Sedation was monitored according to Ramsay sedation scale. The target was to maintain sedation score ≥ 3 if sedation score falls below 3, propofol bolus (0.25mg/kg) was given to maintain the required sedation. VAS scale was used to monitor analgesia. If the VAS score became >3 rescue analgesic (Tramadol 50 mg bolus) was given.

Data interpretation was done using SPSS v25 software. The chi-square test was used to compare categorical variables between the groups. The independent sample t-test was used to compare continuous variables. P-value ≤ 0.05 was taken as significant.

Results

Mean age was 34.3 ± 5.7 years in group D versus 35.7 ± 6.1 years in group M. There were 49 (65.3%) male patients in group D and 47 (62.7%) in group M. There was no difference in baseline characteristics between the groups (Table I).

Table I. Baseline Characteristics.

	Group D (N=75)	Group M (N=75)	P-Value
Age (Years)	34.3 ± 5.7	35.7 ± 6.1	0.14
Male Gender	49 (65.3%)	47 (62.7%)	0.73
Weight (Kg)	63.6 ± 11.4	65.3 ± 12.2	0.37
ASA Status I/II	68 (90.7%) / 7 (9.3%)	65 (86.7%) / 10 (13.3%)	0.43

Mean RSS score was 3.6 ± 0.38 in group D versus in 2.83 ± 0.59 in group M (p-value 0.001). There were 12 (16.0%) patients in group D who required rescue sedation and 32 (42.7%) in group M required rescue sedation (p-value 0.003). Mean VAS score was 2.5 ± 1.6 in group D versus 3.3 ± 1.5 in group M (p-value 0.002). There were 14 (18.7%) patients in group D who required rescue analgesia versus 29 (38.7%) in group M (p-value 0.006). Details of sedative and analgesic variables is given in table II.

Table II: Comparison of Study Endpoints.

	Group D (N=75)	Group M (N=75)	p- Value
Mean RSS Score	3.6±0.38	2.83±0.59	0.001
Score 1	03 (4.0%)	11 (14.7%)	0.004
Score 2	09 (12%)	21 (28.0%)	
Score ≥3	63 (84.0%)	45 (57.3%)	
Need for Rescue Sedation	12 (16.0%)	32 (42.7%)	0.003
Mean VAS Score	2.5±1.6	3.3±1.5	0.002
No pain	06 (8.0%)	03 (4.0%)	0.02
Mild Pain	55 (73.3%)	43 (57.33%)	
Moderate to Severe Pain	14 (18.7%)	29 (38.7%)	
Need of Rescue Analgesic	14 (18.7%)	29 (38.7%)	0.006
No pain; VAS=0, mild; VAS 1-3, moderate to severe; VAS ≥4.			

Discussion

MAC is rapidly gaining acceptance in day care surgeries that are performed as out-patient procedures.¹¹ Deviated nasal septum (DNA) is a usual presentation in ENT departments. Septoplasty is surgical correction of deviated nasal septum, which includes excision and alignment of the bony and cartilaginous part of nasal cavity and is performed as day care surgery.¹² It can be performed under general as well as local anesthesia. The use of general anesthesia is time consuming and increases the cost of the surgical procedure and may cause complications. While MAC is a form of local anesthesia that can be administered with short acting sedative drugs, it is quick to administer and do not cause complication of GA.^{13, 14}

Nanda et al, compared the outcomes of septoplasty under MAC with general anesthesia and reported that the use of MAC helps to achieve better hemodynamic stability, less blood lose and shorter operative time as compared to general anesthesia and MAC can be used as first line choice for surgeries involving the ear, nose and throat.¹⁵

In present study we compared the sedative and analgesic outcomes of dexmedetomidine with midazolam during MAC. We found that dexmedetomidine is more effective than midazolam. Mean RSS score in present study was higher in dexmedetomidine group as compared to midazolam. Study conducted by Pauranik et al. also reported higher sedation score of 4.33±0.76 in dexmedetomidine group versus 2.83±0.46 in midazolam group.¹⁶ Study conducted by Dare et al. also reported similar results.¹⁷ While studies by Demiraran et al. and Karaaslan et al. did not reported any significant

difference in mean sedation scores in midazolam versus dexmedetomidine groups.^{18, 19}

In present study, there were 16.0% patients in dexmedetomidine group who required rescue sedation and in group midazolam 42.7% patients required rescue sedation. Mean VAS score was also less in dexmedetomidine group, 18.7% patients in dexmedetomidine group required rescue sedation versus 38.7% patients in midazolam group.

A study by Wahid et al, reported that dexmedetomidine provides better sedation. They reported need of rescue sedation in 36% patients in dexmedetomidine group versus in 70% patients in midazolam group. There were 26% patients who required rescue analgesia in dexmedetomidine group versus 54% in midazolam group.¹⁰

Bishnoi et al. compared the outcomes of dexmedetomidine with midazolam and fentanyl combination for MAC, they authors reported less intra-op movements and faster post-op recovery and better surgeon satisfaction rate in dexmedetomidine group as compared to the combination group in patients undergoing removal of subdural hematoma under MAC.²⁰

Another study reported that sedation with dexmedetomidine for MAC is associated with lower rescue doses of sedatives and analgesics as well as it is associated with higher surgeons and patient satisfaction score as compared to midazolam.²¹

Parikh and colleagues compared the effects of dexmedetomidine to the standard midazolam-fentanyl combination in patients undergoing tympanoplasty surgery under MAC. It boosted patient and surgeon satisfaction, indicating a better sedative profile; however, it decreased heart rate and blood pressure, needing regular monitoring. In terms of respiratory depression, dexmedetomidine had no statistical advantage over midazolam-fentanyl, and neither group experienced bradypnea.²²

Dexmedetomidine led to better patient satisfaction, less opioid use, and less respiratory depression than placebo rescue with midazolam and fentanyl, according to a multicenter study that looked at 321 people who had a wide range of surgical or diagnostic procedures done under MAC.²³ Dexmedetomidine was well-liked by people of all ages, and the hypotension and bradycardia it caused were easy to treat, too. When extracorporeal

shockwave lithotripsy is done, dexmedetomidine with fentanyl has been used safely and effectively to keep people calm and relieve pain.²⁴

The major limitation of present study is that we only included young adults, because many of patients of Septoplasty present in this age group in our hospital. So, there is a need to conducted studies in old age population to determine the safety of these drugs in old age patients.

Conclusion

Use of dexmedetomidine for MAC is advantageous as compared to midazolam in-terms of better sedation and analgesia and reduced requirements of rescue doses of sedatives and analgesics.

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