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Original Research Paper

Anaesthesiology

A COMPARATIVE EVALUATION OF ORAL MELATONIN, (I.V) DEXMEDETOMIDINE AND COMBINATION OF BOTH FOR ATTENUATION OF HAEMODYNAMIC RESPONSES TO LARYNGOSCOPY AND INTUBATION IN MIDDLE EAR SURGERY

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ABSTRACT

Introduction: Airway management is the evaluation, planning, and use of medical procedures and devices for the purpose of maintaining or restoring ventilation in a patient. Endotracheal intubation is required to provide a patent airway when patients are at risk for aspiration, when airway maintenance by bag mask is difficult, and for prolonged controlled ventilation. This research aimed to investigate the impact of Melatonin with Dexmedetomidine in mitigating cardiovascular responses to laryngoscopy and endotracheal intubation in candidate supporting voluntary operation.

Aim and Objective : To compare the role of Oral melatonin with (i.v) Dexmedetomidine alone and in combination of both for attenuation of haemodynamic responses during Laryngoscopy and intubation and compare the effect on haemodynamic parameters - Heart rate, Systolic blood pressure; Diastolic blood pressure; Mean arterial pressure and SpO2.

Methods and methods: This study was a randomized prospective double blinded study conducted in Department of Anaesthesiology and Critical Care, MLB medical College, Jhansi (UP) in patients posted for elective middle Ear surgeries during the period of March 2018 to October 2019 and minimum 150 patients were selected for the study. Following the approval from the Ethical committee, ASA I and II patients between the age of 20 to 50 years of either gender and surgery requiring general anaesthesia for duration longer than 30 min, patients with normal airway with MPG I and MPG II, >90 degree neck movement, no buck teeth undergoing elective surgeries for middle EAR were included in this study. Exclusion criteria were diabetes, hypertension, psychiatric illness, intake of antipsychotics, sedatives and antiepileptic drugs, sleep disorders, obesity and drug allergy.

Result and Conclusion: Both Melatonin (6mg) and Dexmedetomidine (1g/kg) can attenuate the haemodynamic changes during laryngoscopy and intubation. In Dexmedetomidine large dose (1g/kg) there were more cases of hypotension and bradycardia are seen, than in comparison of (0.5 g/kg) of Dexmedetomidine. Combination of Melatonin (6mg) and Dexmedetomidine low dose (0.5g/kg) can attenuate the haemodynamic changes during laryngoscopy and intubation better than alone use of melatonin(6mg) and Dexmedetomidine (1g/kg).

KEYWORDS : Laryngoscopy, Intubation, Haemodynamics, Melatonin, Dexmedetomidine.

INTRODUCTION

Airway management is the evaluation, planning, and use of medical procedures and devices for the purpose of maintaining or restoring ventilation in a patient. Endotracheal intubation is required to provide a patent airway when patients are at risk for aspiration, when airway maintenance by bag mask is difficult, and for prolonged controlled ventilation[1].

This research aimed to investigate the impact of Melatonin with Dexmedetomidine in mitigating cardiovascular responses to laryngoscopy and endotracheal intubation in candidate in cases supporting voluntary operation[2].

Laryngoscopy and endotracheal intubation are considered potent noxious stimuli which provoke haemodynamic responses leading to a marked increase in heart rate and blood pressure[3]. This is probably of no consequence in healthy individuals. However, these events are especially detrimental in individuals who have limited myocardial reserve due to Coronary artery disease, Cardiac dysrhythmias, Congestive heart failure, Hypertension, Cardiomyopathy and in Geriatric age group[4].

Melatonin (*N*-acetyl-5-methoxytryptamine) is an endogenous sleep-regulating hormone secreted by pineal gland. Its inhibitory actions on central nervous system responsible for sedation and anxiolysis that have role in attenuating haemodynamic responses to laryngoscopy and intubation. While Dexmedetomidine (α2 adrenergic agonist), have been used to induce preoperative sedation, intraoperative reduction of anaesthetic and analgesic requirements and hemodynamic stability along with postoperative analgesia. These pharmacological effects made them suitable for premedication for general anaesthesia.

So a comparative evaluation of oral intake of melatonin with i.v Dexmedetomidine alone and in combination of both drugs was studied in order to measure the safety profile of these drugs in blunting the haemodynamic response during laryngoscopy and intubation in middle Ear surgeries for better airway management.

AIM

- To compare the role of Oral melatonin with (i.v) Dexmedetomidine alone and in combination of both for attenuation of haemodynamic responses during Laryngoscopy and intubation.
- To Compare the effect on haemodynamic parameters: - Heart rate (HR), Systolic blood pressure (SBP); Diastolic blood pressure (DBP); Mean arterial pressure (MAP) and Spo2.
- To observe complications that occurred during procedure if any hypotension and bradycardia, or O2 saturation (SpO2) is less than 90%.

This study was a randomized prospective double blinded study conducted in Department of Anaesthesiology and Critical Care, MLB medical College, Jhansi (UP) in patients posted for elective middle Ear surgeries during the period of March 2018 to October 2019 and minimum 150 patients was selected for the study. The study will be conducted after

obtaining permission from the Institutional ethics committee and the identity of the patients would not be revealed.

Patient selection:
Following the approval from the Ethical committee, ASA I and II, patients between the age of 20 to 50 years of either gender and surgery requiring general anaesthesia for duration longer than 30 min, patients with normal airway with MPG I and MPG II, >90 degree neck movement, no buck teeth undergoing elective surgeries for middle EAR were included in this study.

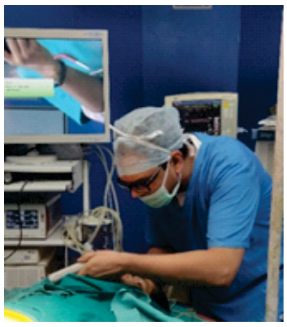
Exclusion Criteria:
Exclusion criteria were diabetes, hypertension, psychiatric illness, intake of antipsychotics, sedatives and antiepileptic drugs, sleep disorders, obesity and drug allergy.

Likewise, patients with anticipated difficult intubation and those requiring more than one attempt or more than 20 seconds for laryngoscopy were excluded from the study.

Sample size and allocation:
All the selected 150 patients were randomly assigned to one of the following 3 groups and each group were containing 50 patients each.

- **Group1**-Patients received oral Melatonin 6mg (2tablets) 2 hours before surgery with (i.v) Normal Saline (0.9%) 50 ml, 10 min before start of surgery.
- **Group 2**- Patients received oral Vitamin D3 (Placebo) 2 tablets 2 hours before surgery with (i.v) Dexmedetomidine 1 μ/kg in 50 ml, 10 min before start of surgery.
- **Group 3**- Patients received oral Melatonin (2 tablets) 2 hours before surgery with (i.v) Dexmedetomidine 0.5 μ/kg in 50 ml, 10 min before start of surgery.

Statistical analysis:
The statistical analysis was done by using the SPSS software V-16. Values will be expressed as mean ± Standard deviation (SD) and as percentage for categorial parameters. Differences between groups was compared with Student's *t*-test for parametric continuous variables. ANOVA *t*-test for comparison between three or more than three groups. Chi-square test was applied for estimating the occurrence of categorical variables. A *P* value <0.05 was used as the threshold of statistical significance.



RESULT

Fig.-1: Distribution of patients according to type of surgery.

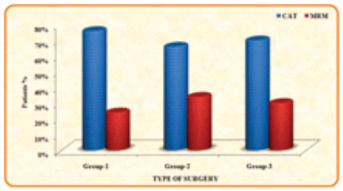


Fig 1: shows the distribution of patients according to type of surgery. There was no statistically significant difference between the mean of patients in these groups (p>0.05).

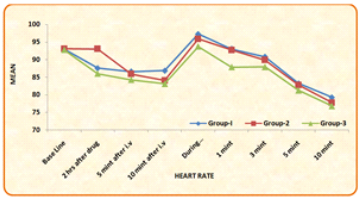


Fig 2: Mean Heart Rate (H.R) at different time intervals.

In Fig 2: Mean heart rate was lower in group 3 patients, followed by group 2 patients and was more in group 1 patients just after laryngoscopy and intubation. After intubation from (1 mint to 10 mint) the mean heart rate was more stable and shows less variation from the baseline in group 3 patients, followed by group 2 patients and then in group 1 patients.

Fig 3: Mean systolic blood pressure(S.B.P) at different time intervals.

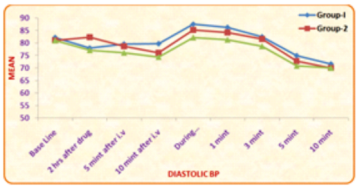


Fig 3:. Mean duration of S.B.P was lower in group 3 patients, followed by group 2 patients and was more in group 1 patients just after laryngoscopy and intubation. After intubation from (1 mint to 10 mint) the mean S.B.P was more stable and shows less variation from the baseline in group 3 patients, followed by group 2 and then in group 1 patients.

Fig 4: Mean Diastolic blood pressure (D.B.P) at different time intervals.

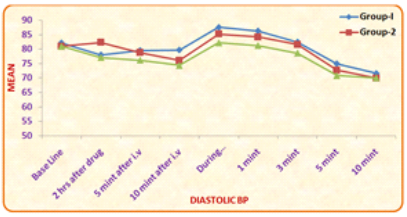


Fig 4: Mean D.B.P was lower in group 3 patients, followed by group 2 patients and was more in group 1 patients just after laryngoscopy and intubation. After intubation from (1 mint to 10 mints) the mean D.B.P was more stable and shows less variation from the baseline in group 3 patients, followed by group 2 and then in group 1 patient

Fig 5: Mean Arterial Pressure (M.A.P) at different time intervals.

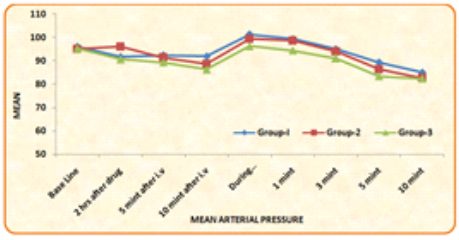


Fig 5: M.A.P was lower in group 3 patients, followed by group 2 patients and was more in group 1 patients just after laryngoscopy and intubation. After intubation from (1 mint to 10 mints) the M.A.P was more stable and shows less variation from the baseline in group 3 patients, followed by group 2 and then in group 1 patient

Fig 6: Mean SPO_2 at different time intervals.

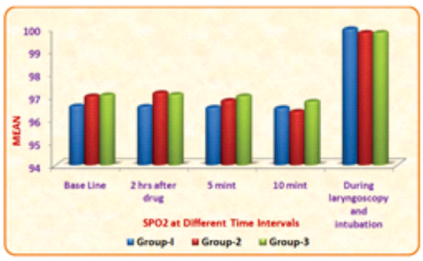


Fig 6: Mean arterial saturation (SPO2) was maintained above 99 % during laryngoscopy and intubation in all the three groups. Although fall in saturation are seen in group 2 patients before laryngoscopy and intubation due to sedation but it was not found significant. (p>0.05)

DISCUSSION

Laryngoscopy and Endotracheal intubation are potent stressful stimuli that provoke haemodynamic response like tachycardia and hypertension that can lead to myocardial ischemia, ventricular arrhythmia, left ventricular failure, and cerebral hemorrhage.

For it an orally administered drug i.e.Melatonin (N-acetyl-5-methoxy-tryptamine) with several unique properties that make it ideal for attenuation of haemodynamic changes which occurs during laryngoscopy and intubation in comparison to the (i.v) infusion of Dexmedetomidine (alpha 2 agonist) which can also blunt the haemodynamic changes but with more complications such as hypotension and bradycardia in comparison of oral Melatonin.

Premraj Nagarwal et. Al[5], (2019) conducted a study on Melatonin undergoing a Sternotomy (patients undergoing CABG) and concludes that Melatonin is an effective drug to attenuate cardiovascular responses of laryngoscopy, endotracheal intubation.

Adithi Devi E, et al[6],(2018) conducted a study on Melatonin (6 mg tablets) on 60 patients .The study concludes that exogenously administered Melatonin 6mg orally 120 min prior to intubation helps in attenuation of hemodynamic responses to laryngoscopy, intubation and extubation. It also helps in maintaining a stable hemodynamics intra-operatively.

Second, melatonin which is used to allay preoperative anxiety in patients have also antinociceptive, antidepressant anxiolytic, blood pressure reducing activity and pain modulating effects and that when combined with low dose of Dexmedetomidine of 0.5 μg/kg can attenuate the haemodynamic changes with less sedation property in better way when compared with large dose of Dexmedetomidine 1 μg/kg respectively.

Third, Dexmedetomidine in(0.5g/kg) causes minimal haemodynamic changes alterations and complications like respiratory impairment, hypotension and bradycardia when given in low dose. As compared to larger dose of (1 μg/kg).

The primary outcome of our current study showed that orally administered Melatonin(6mg) with low dose (0.5μg/kg) of Dexmedetomidine can attenuate the haemodynamic changes occurs during laryngoscopy and intubation during middle Ear surgeries.

Bon Sebastian, et. al[7] (2017) have used Dexmedetomidine in a dose of 0.5μg/kg and 1 μg/kg and found them to be effective in attenuation of stress response to laryngoscopy and endotracheal intubation but with more cases of decreased arterial saturation (SPO2) below 92% in some cases, similarly as we noted in group 2 where 3 patient need oxygen supplementation when there SPO2 falls below 92%.

Priyamvada Gupta, et. Al[4], (2016) took normal airway sample population and excluded MPG grade III and IV and with comorbidity (diabetes, hypertension, psychiatric illness, intake of antipsychotics, sedatives and antiepileptic drugs, sleep disorders, obesity and drug allergy).

In a study similar to ours, in this study also, we excluded the patients with difficult airway which need laryngoscopy more than 20 seconds and included the patients with MPG grade I and II with normal weight and BMI ; >90 degree neck movement ; no buck teeth and all the groups were comparable.

In a dose of 0.5 μg/kg and 1 μg/kg of Dexmedetomidine each and its was found that, both of them to be effective in attenuation of stress response to laryngoscopy and endotracheal intubation but with more cases of decreased arterial saturation (SPO2) below 92% in some cases of 1 μg/kg dose of Dexmedetomidine, similarly as we noted in group 2 of Dexmedetomidine (1μg/kg) dose where 3 patient need oxygen supplementation when there SPO2 falls below 92%.

CONCLUSIONS

Following conclusion were drawn in discussion after the present study:

- Demographic data i.e. age, male: female ratio, weight comparable in all the groups.
- Mean Heart Rate was more stable and showed less variation from baseline heart rate value in group 3 patients (Melatonin and Dexmedetomidine combination) till upto 10 minutes after intubation as compared to other groups.
- Mean Systolic blood pressure was more stable and showed less variation from baseline Systolic blood pressure value in group 3 patients (Melatonin and Dexmedetomidine combination) till upto 10 minutes after intubation as compared to other groups.
- Mean Diastolic blood pressure was more stable and showed less variation from baseline Diastolic blood pressure value in group 3 patients (Melatonin ad Dexmedetomidine combination) till upto10 minutes after intubation as compared to other groups.
- Mean Arterial blood pressure was more stable and showed less variation from baseline mean Arterial pressure value in group 3 patients (Melatonin and Dexmedetomidine combination) till up to 10 minutes after intubation as compared to other groups.
- Mean Arterial saturation (SpO_2) is >95 % in group 1,group 2 and group 3 patients, and in group 2 , there were 6 cases reported where arterial saturation (SPO2) falls below 95% and 3 cases were reported where arterial saturation falls below 92% which is supplemented by oxygen, after iv infusion of study drug (Dexmedetomidine 1 μg/kg).

It can be therefore be concluded that:-

- Both Melatonin(6mg) and Dexmedetomidine (1g/kg) can attenuate the haemodynamic changes during laryngoscopy and intubation.
- In Dexmedetomidine large dose (1g/kg) there were more cases of hypotension and bradycardia are seen, than in comparison of (0.5 g/kg) of Dexmedetomidine.
- Combination of Melatonin(6mg) and Dexmedetomidine low dose(0.5g/kg) can attenuate the haemodynamic changes during laryngoscopy and intubation better than alone use of melatonin(6mg) and Dexmedetomidine (1g/kg).

Combination of Melatonin (6 mg) and Dexmedetomidine low dose (0.5 g/kg)can attenuate the haemodynamics with less

sedation property in a better way as compared to larger dose of Dexmedetomidine

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