Section: Anesthesiology

Research

EFFECT OF DEXMEDETOMIDINE VERSUS KETOFOL ON THE INCIDENCE OF EMERGENCE AGITATION ASSOCIATED WITH SEVOFLURANE BASED ANAESTHESIA IN CHILDREN UNDERGOING ADENOTONSILLECTOMY

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Abstract

Background: The rapid emergence and recovery from sevoflurane anaesthesia is associated with high incidence of emergence agitation in children ranging up to 80%. Both ketofol and dexmedetomidine have been shown to successfully reduce the incidence and severity of emergence agitation if administered at the end of sevoflurane anesthesia, however it was not determined which agent has better efficacy. The purpose of this study was to compare the effectiveness of ketofol and demedetomidine, given 10 mins before the end of surgery in reducing emergence agitation. **Materials and Methods:** Ninety paediatric patients aged 6-12 years, ASA I or II and undergoing adenotonsillectomy under sevoflurane-based anesthesia were recruited into the study. They were randomly allocated into two groups: Group K received ketofol (ketamine 0.25mg/kg, propofol 1mg/kg). Group D received dexmedetomidine 0.3µg/kg. The study drugs were given 10mins before the end of surgery. In PACU, incidence of emergence agitation was evaluated with Aono's four-point scale and severity of emergence agitation was assessed using paediatric anaesthesia emergence delirium scale upon awakening(T0), -after 10mins (T10), 20mins (T20). After 30min(T30). Extubation time, duration of sevoflurane exposure, duration of surgery and duration of PACU stay are recorded. **Result:** The incidence of emergence agitation in Group D is significantly lower than Group K. The incidence of emergence agitation decreased significantly over time in both groups. Time to extubation and to get modified aldrete score>9 was significantly higher with Group D than Group K, but modified objective scale is higher with Group K than Group D. **Conclusion:** We found that dexmedetomidine (0.3µg/kg) was effective than ketofol in reducing emergence agitation with better analgesic effect but with prolongation of extubation time and time of discharge from PACU.

INTRODUCTION

Emergence delirium also referred to as emergence agitation is a well-documented phenomenon occurring in children in the immediate post-operative period.[1] Incidence of emergence delirium in all post-operative patients is 5.3% with more frequent in children 12 - 13%.[2,3]

Surgical procedures involving ears, eyes, tonsils thyroid have been associated with higher rates of emergence agitation.[1] When Eckenhoff et al,[1] first described Emergence agitation in 1961, he attributed the increased incidence among otolaryngologic procedures to the "Sense of suffocation". Adenotonsilectomy is one of the frequently performed surgeries in children.

Emergence agitation in children is a common problem with sevoflurane anaesthesia which include features such as crying, excitation, agitation, delirium and behavioural disturbances during early emergence from general anesthesia. This phenomenon must be prevented by providing smooth emergence to paediatric patients.[4,5]

High incidence of emergence agitation has given way to researchers to come up with numerous studies evaluating the incidence and severity of emergence agitation with inhalational and intravenous anaesthetic agent[13]. Parental presence at emergence, physical restraints, or pharmacologic interventions are the methods used to prevent emergence agitation. Various studies proved that medications such as fentanyl, ketamine, propofol, ketofol dexmedetomidine, clonidine and midazolam

have been effective in preventing emergence agitation with differing efficacies of individual agents.[4-12] Dexmedetomidine is a highly specific α_2 receptor agonist than clonidine and has sedative and analgesic properties without significant respiratory depression at clinical dosages. Propofol is a sedative hypnotic agent with rapid onset and short duration of action. Ketamine is a dissociative sedative that provides analgesia and amnesia.

However the efficacy of individual drugs in preventing emergence agitation remains the subject of debate. There are only limited studies on comparing effectiveness of ketofol and dexmedetomidine in prevention of emergence agitation in children. In this study we compare the efficacy of dexmedetomidine and ketofol in prevention of emergence agitation in children under sevoflurane-based anaesthesia in adenotonsillectomy.

Aim of the Study

The purpose of this study is to compare the effectiveness of ketofol and dexmedetomidine in reducing the incidence and severity of emergence agitation associated with sevoflurane-based anaesthesia in paediatric adenotonsillectomy.

Primary outcome

To compare the effectiveness of ketofol and dexmedetomidine in reducing emergence agitation.

Secondary outcome

To compare the hemodynamic changes, the emergence time, time of PACU stay, post operative analgesia with respect to ketofol and dexmedetomidine.

Statistical Analysis

All data were complied, tabularized and formulated as mean +/- standard deviation. The mean difference between groups is compared using unpaired t test. Mann whitney test was used to differentiate categorical data like sex distribution. Chi square test was used to analyze the risk among groups. A statistically significant difference was concluded if the p value was <0.05.

MATERIALS AND METHODS

This study is a prospective randomized double blinded study conducted in Tertiary care Government Hospital during December 2017- June 2018 in 90 patients undergoing adenotonsillectomy between 6-12years of age after obtaining Institutional ethical committee approval.

Based on previous studies we calculated that 45 patients were required in each group (for a level of significance of 0.05 and a power of 0.80).

Formula used was

$n = (Z_{\alpha/2}+Z_{\beta})^2 * 2*\sigma^2 / d^2$,

where $Z_{\alpha/2}$ is the critical value of the Normal distribution at $\alpha/2$ (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Z_{β} is the power and the critical value is 0.84), σ^2 is the population variance, and d is the difference to be detected.

Method of Randomisation

Patients were allocated into two groups Group K and group D by Sequential randomization**.**

- **Group K:** received ketofol (ketamine 0.25 mg/kg and propofol 1.0 mg/kg in combination diluted to a volume of 10 ml by addition of normal saline), 10 min before the end of surgery.
- **Group D:** received dexmedetomidine (0.3 µg/kg diluted in normal saline to a volume of 10 ml), 10 min before the end of surgery.

Blinding

This was a double blinded study. The patient's parents/guardian were explained about the procedure that they had equal chance of being given both the drugs and hence blinding was ensured. The principal investigator was also blinded. In order to ensure that, one junior resident and research assistant were involved in the study. The research assistant did a computer-based randomization and did random allocation of participants. The drug to be given for each participant was placed in an opaque envelope. This envelope was handed over to the junior assistant only in the morning of the particular surgery. He opened the envelope in theatre, loaded the mentioned drug in syringe and wrapped it in aluminum foil. The principal investigator who is an anesthesiologist will administer the drug. The data are collected by the investigator.

Inclusion criteria

1. Children undergoing Adeno tonsillectomy in the age group of 6-12 years.
2. American society of anesthesiologist physical status I and II.

Exclusion criteria

1. BMI >95th percentile.
2. ASA III or more.
3. Patients with known allergy to drugs used in the study.
4. Developmental delay.
5. Psychological and neurological disorders.
6. History of any chronic intake of sedative and analgesics were excluded.
7. Congenital disorders.

Methodology

On arrival at the operating room, standard monitors were applied to every child. Baseline heart rate, respiratory rate, noninvasive blood pressure, ECG, SpO_2 were recorded. All children were premedicated with intravenous glycopyrrolate 10µg/kg and fentanyl 2µg/kg. Induction started by inhalation of sevoflurane 8% with N_2O:O_2 ratio 60:40, which was maintained till loss of consciousness.

Then atracurium 0.5mg/kg intravenous was administered to facilitate nasotracheal intubation. Direct laryngoscopy was performed and trachea intubated with appropriate sized tubes. Anesthesia maintained with N_2O:O_2 and sevoflurane 2- 2.5 vol% while mechanical ventilation was performed

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to sustain end tidal CO_2 at 30-35mmHg. Children below 20 kg were ventilated with Jackson-Rees' modification of Ayer's T-piece.

All the study drugs were administered to the children by anesthetist who was unaware of the group allocation, 10 min before the completion of surgery and after discontinuation of sevoflurane. Reversal of neuromuscular blockade was done with glycopyrrolate 10µg/kg IV and neostigmine 50µg/kg IV on the attainment of signs of reversal. Children were extubated after criteria for extubation was attained.

Intraoperatively, HR, MAP, and SpO_2 were recorded at the following measurement times i.e. pre induction, pre intubation, post intubation, 5 min post intubation, every 10 min during the surgery, post extubation and then every 10 min for half an hour. Ten minutes before the completion of the procedure, the study drugs were administered to the patients by the principal investigator.

Extubation time

The time from sevoflurane discontinuation to the removal of endotracheal tube was recorded and defined as the extubation time.

Duration of sevoflurane exposure

Time from inhalational induction with sevoflurane to the discontinuation of the inhaled anaesthetic.

Post extubation

In PACU, the incidence and severity of emergence agitation was assessed using paediatric anaesthesia emergence delirium scale (PAED) at T_0, T_{10}, T_{20}, T_{30} and AONO's 4-point scale.

Table 1: Paed Scale

Behavior	Not at all	Just a little	Quite a bit	Very much	Extremely
The child makes eye contact with the caregiver	4	3	2	1	0
The child's actions are purposeful	4	3	2	1	0
The child is aware of his/her surrounding	4	3	2	1	0
The child is restless	0	1	2	3	4
The child is inconsolable	0	1	2	3	4

Paediatric anaesthesia emergence delirium (PAED) scale

The severity of emergence agitation was evaluated using PAED scale devised by Sikich and Lerman[4]. The incidence and severity were recorded upon awakening i.e. when the child had first response to command (T_0), thereafter every 10 mins up to 30 mins **(**T_{10}, T_{20}, T_{30}.).

Table 2: Modified Objective Pain Scale at Discharge

Criteria	Finding	Points
Crying	None Consolable Not consolable	0 1 2
Movement	None Restless Thrashing	0 1 2
Agitation	Asleep/calm Mild Hysterical	0 1 2
Posture	Normal Flexed Holds injury site	0 1 2
Verbal	Asleep/ no complaints Complains/cannot localize Complains/can localize	0 1 2

MOPS ≥ 5: supplemental analgesics are given

AONO's 4-point scale

1 =calm;

2= not calm but could be easily consoled;

3 =moderately agitated or restless and not easily calmed;

4= combative, excited, or disoriented, thrashing around.

Scores of 1& 2 were considered as the absence of emergence agitation, and scores of 3&4 were analysed as the presence of emergence agitation.

In case of agitation in PACU, the first action is to encourage parenteral contact and when this failed, midazolam 0.05 – 0.1 mg/kg was administered intravenously. Modified Objective pain scale was evaluated at discharge from PACU

Modified aldrete score was evaluated and adapted as discharge criteria, according to which, a score > 9 is needed for discharge from PACU

Criteria for discharge from PACU:

1. Fully awake
2. Calm
3. Stable hemodynamic status
4. PAED scale < 10
5. MOPS ≤ 3
6. Oxygen saturation > 92% on room air.

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Table 3: Aldrete scoring system

Assessment items	Condition	Points
Activity, able to move, voluntarily or on command	4 extremities 2 extremities No	2 1 0
Breathing	Able to breathe deeply & cough freely. Dyspnea, shallow or limited breathing Apnea.	2 1 0
Consciousness	Fully awake. Arousable on calling. Unresponsive.	2 1 0
Circulation +/-(BP) +/- +/-	20% to pre anesthesia level. 20% to 49% of pre anesthesia level 50% of pre anesthesia level.	2 1 0
SPO_2	Maintains SpO_2>92% in ambient air Maintain SpO_2> 90% with O_2 Maintain SpO_2<90% with O_2	2 1 0

RESULTS

The comparative study between 2 groups, Group K (ketofol) and group D (dexmedetomidine) was carried in 90 patients between 6-12years of age. The following observations were made. Out of 90 patients, 45 were randomized into group K, 45 were randomized into group D.

In group K, there were 24 males and 21 females. In group D, there were 22 males and 23 females.

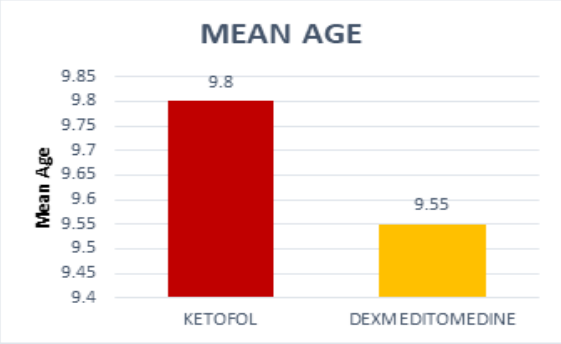

Figure 1: Age distribution between groups

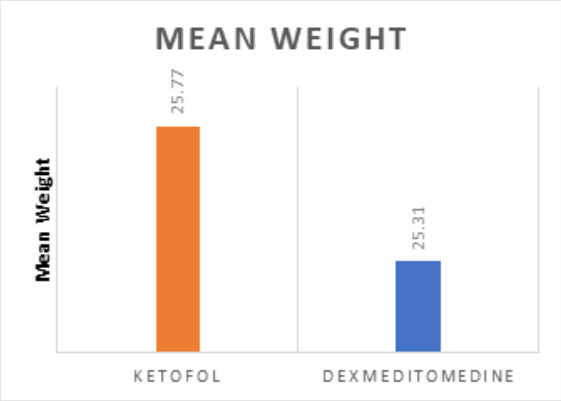

Figure 2: Mean weight between groups

There were no statistically significant difference in sex, age and weight distribution among two groups.

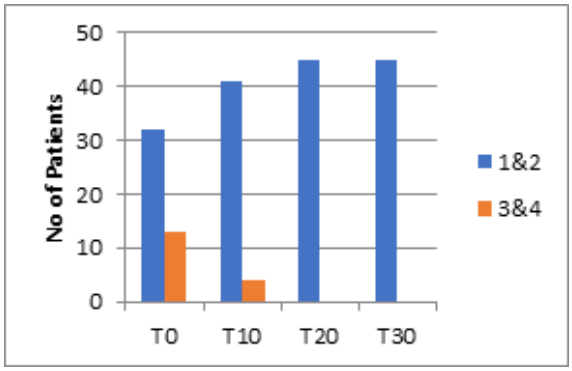

Figure 3: Ketofol - AONO score

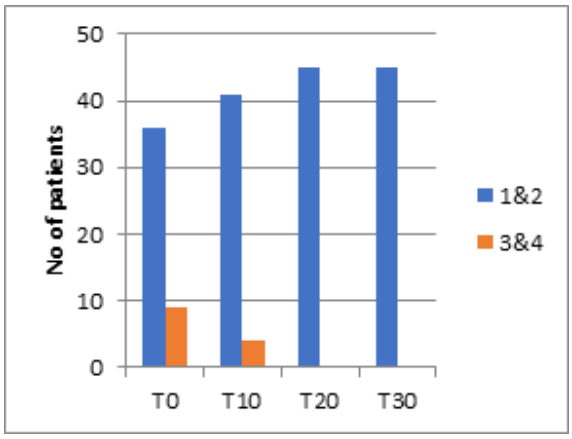

Figure 4: Dexmeditomidine -AONO score

Upon awakening, emergence agitation occurred in 28% and 20% of patients in Group K and Group D respectively. Over time the incidence of emergence agitation decreased to be 8.8% in ketofol and dexmedetomidine group. At T20 none of the patients in group K and group D developed emergence agitation.

Mean Heart Rate

Heart rate and mean arterial pressure decreased after induction in both the groups with no significant differences among them. Also there was no differences between the readings among two groups throughout the surgery till extubation time.

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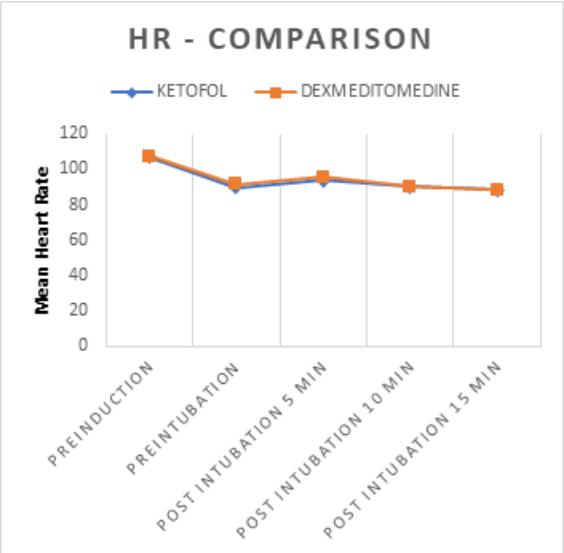

Figure 5: Heart rate between groups

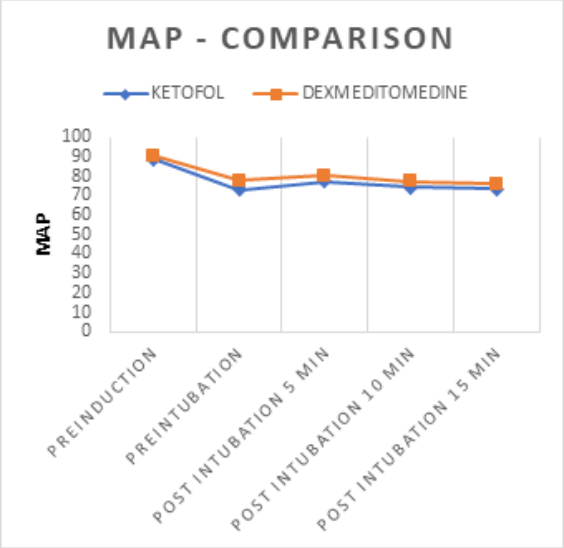

Figure 6: Mean MAP between groups

Post extubation mean heart rate between groups:
After tracheal extubation, the pressor response of extubation was significantly lower in both groups. Also hemodynamic variables recorded post extubation and 10 mins later were significantly higher in ketofol group than corresponding values in dexmedetomidine group. The differences in values are not statistically significant within each group, HR and MAP values did. not change significantly from baseline ones at any time during the study. Concerning SpO2, there were no significant changes in the readings among two groups throughout the surgery and recovery period.

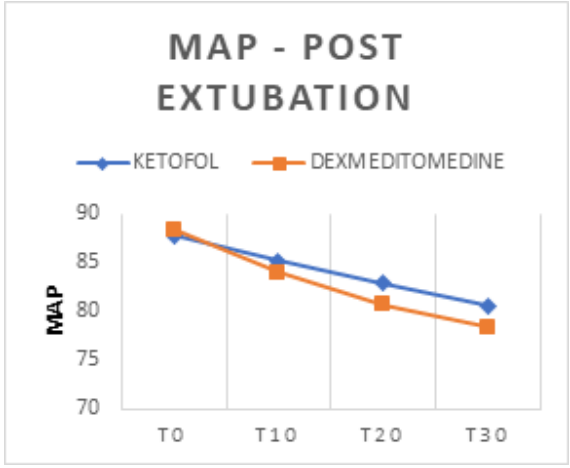

Figure 7: Post extubation map between groups

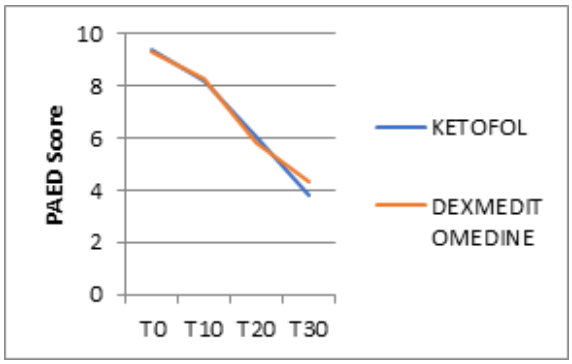

Figure 8: PAED score between groups

Pead Mean Score Comparision
Regarding severity of emergence agitation the mean values of PAED score in group K (9.4,8.2,6.06,3.8) and in group D (9.3,8.3,5.8,4.3) at T0,T10,T20,T30 respectively. There were no significant statistical differences between ketofol and dexmedetomidine group at any time during the assessment.

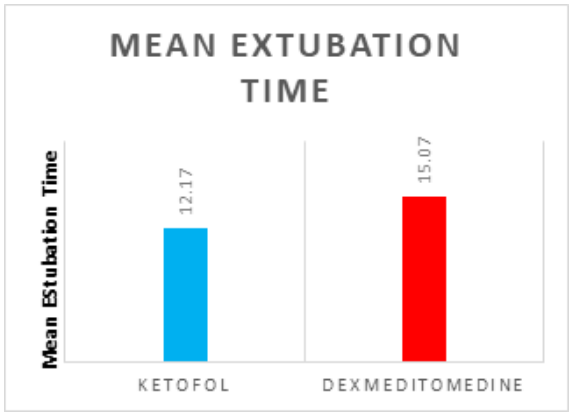

Figure 9: Mean extubation time between groups

Time to extubation was significantly longer in dexmedetomidine group than that in ketofol group (15.07 min in group D versus 12.17 mins in group K). The differences in values are statistically significant.
There was no significant difference in duration of surgery and duration of sevoflurane exposure between two groups.

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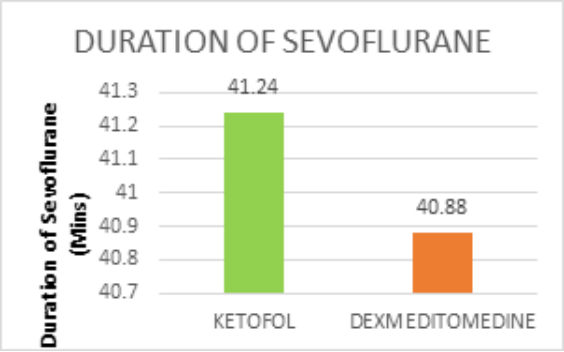

Figure 10: Duration of sevoflurane exposure

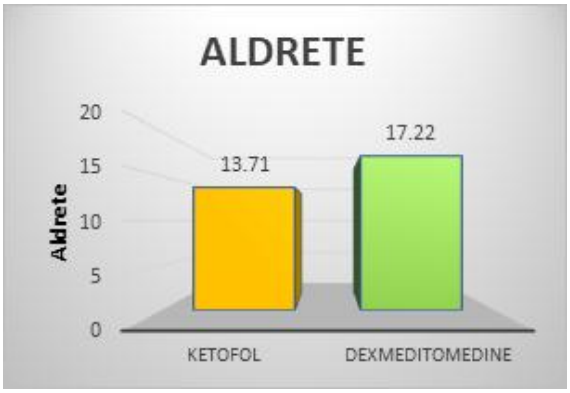

Figure 11: Modified Aldrete scoring

Patients in dexmedetomidine group had more sedation score as shown by the longer time to get modified aldrete score>9 (17.22 min) compared to ketofol group (13.71mins). There is a significant statistical difference in time to get modified aldrete score >9 between two groups.

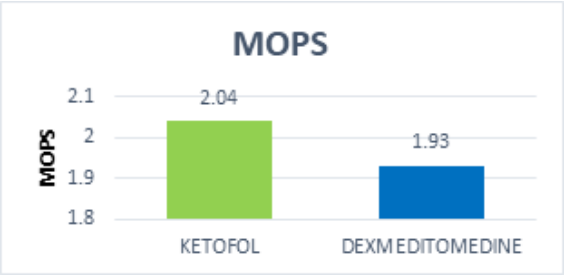

Figure 12: Modified objective pain scale between groups (MOPS)

The mean MOP score for ketofol is higher than dexmedetomidine but statistically no significant difference in MOP score between two groups.

The results were analysed using SPSS (statistical package for social sciences) version 21.0.

DISCUSSION

Emergence agitation is a troublesome phenomenon of uncertain aetiology. Prevention of emergence agitation depends mainly on reducing preoperative anxiety,[11,21] removing post-operative pain and administration of sedative and analgesic agents.[14,31] Many studies focused on pharmacologic preventive strategies against emergence agitation and found several drugs are efficient in reduction of this adverse event.

Emergence agitation

Isik et al in his study concluded that 1µg/kg dose of dexmedetomidine reduces emergence agitation after sevoflurane anesthesia in children undergoing MRI. The incidence of emergence agitation was 47% in placebo group in comparsion with dexmedetomidine group with 4.8%.

Dahmani et al,[12] conducted a meta-analysis focused on prevention of emergence agitation in children anesthetized with sevoflurane and found that propofol, ketamine, fentanyl and preoperative analgesia had a prophylactic effect in preventing emergence agitation. Abu-Shahwan I et al, assessed the effect of propofol in reducing the incidence and severity of emergence agitation in children and concluded that incidence decreased to 4% in propofol group compared to 26% in placebo group. Sherry N.Rizk et al in his study proved ketofol as a promising new option for controlling emergence agitation compared to propofol group and control group.

Ali et al,[13] showed ketofol as effective as dexmedetomidine in reducing emergence agitation compared to control groups (T_0 -90%). In our study, ketofol and dexmedetomidine were compared and it was concluded that dexmedetomidine (20% at T_0) was effective than ketofol (28% at T_0) in reducing incidence of emergence agitation. Over time (at T_{20}, T_{30}) none of the patients developed emergence agitation.

Scales

Sikich and Lerman[4] developed the PAED to assess the incidence and severity of emergence agitation by incorporating cognitive and agitation elements and proved its reliability and validity.[4] M. Somaini et al studied the difference between pain and incidence of emergence agitation using PAED scale compounded with FLACC score (Face, Leg, Acivity, Cry, Consolability scale) and CHIPPS scale (The Children and Infants Post-operative Pain Scale). Bajwa et al in his studies compared three delirium scales PAED (32%), Watcha(26%) and Cravero (37%) scales for assessing incidence of emergence agitation. All three scales correlated reasonably well with each other but have individual limitations in their potential to assess emergence agitation. A PAED score>12 shows the presence of emergence agitation with greater sensitivity and specificity. In our study we have used PAED score compounded with AONO scale and MOPS as assessment tool for emergence agitation.

Extubation time/discharge criteria

Ali and elshorbagy study concluded that extubation time and time to get modified aldrete score greater than 9 were significantly longer in dexmedetomidine group than ketofol group. Consistent with this study, dexmedetomidine group showed longer extubation time (15±2.03) and longer time to achieve aldrete score of 9(17.22±1.41) than

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ketofol group (12.1±0.94&13.71±1.77 respectively). Lee et al,[9] confirmed K0.25 and K0.5 given 10 mins before end of surgery in decreased the incidence of emergence agitation in children undergoing adenotonsillectomy. There was no difference in extubation time, time to discharge from PACU but K0.5 showed a lower pain score.[9] In our study we chose smaller dose of ketamine 0.25mg/kg in combination with propofol to avoid excessive delay in a PACU discharge time.

Guler et al showed that dexmedetomedine (0.5µg/kg) prolongs time to emergence and extubation in consistent with our study. Several studies have suggested that administration of 1mg/kg propofol at discontinuation of anaesthesia is effective in reducing emergence agitation without delay of discharge from PACU. This difference may be due to variable drug dosing route or timing of administration of drug.

Hemodynamic status

Dexmedetomidine produces dose dependent reduction in heart rate and blood pressure. Ibacache ME et al and Guler et al studies reported no significant hemodynamic effect has been observed with the dose of 0.1-0.5µg/kg i.v bolus. This is consistent with our study. There is no significant difference in mean heart rate & MAP in dexmedetomidine group (as we used 0.3µg/kg) and ketofol group. Concerning the hemodynamic effects throughout the study MAP and HR decreased after induction in both groups but this reduction was clinically acceptable and did not need any pharmacological intervention. Concerning Spo_2 there was no significant changes in both groups.

Analgesia

Ketofol has been used for procedural sedation in children and it was found that low dose ketamine effectively offsets the cardiorespiratory depression caused by propofol while providing adequate analgesia.[7] Rizk et al studies concluded ketofol provides adequate post-operative sedation and analgesia, good recovery criteria and hemodynamic stability compared to propofol and control groups. Ali and Elshorbagy,[13] concluded that ketofol group had better analgesic effect with lower MOPS score when compared to dexmedetomidine and control groups. In contrary, in our study, dexmedetomidine has better analgesic effect with lower MOP score.

Complication of drugs/side effects

Chen J-Y et al,[8] in his study in paediatric strabismus surgery reported a reduction in incidence of postoperative vomiting in dexmedetomidine group than in ketamine and placebo group. There is no incidence of vomiting in our study during PACU stay. The occurrence of delayed vomiting may have not been recorded by the investigators. Throughout the study hemodynamics within each group did not change significantly compared to baseline values at any time either after administration of study drugs or after extubation. This may be due to use of small doses of study drugs.

Limitation

Lack of validated uniform outcome scales as a tool to measure emergence agitation can be a limitation in this study. Effect of pain on children's behaviour was a potential confounder in determining the outcome.

CONCLUSION

The study "Effect of Dexmedetomidine versus ketofol on the incidence of emergence agitation associated with sevoflurane-based anesthesia in children undergoing adenotonsilectomy" thus concludes that dexmedetomidine 0.3µg/kg was effective than ketofol (ketamine 0.25mg/kg, propofol 1mg/kg) in the prevention of emergence agitation with better analgesic effect but with prolongation of extubation time and time of discharge from PACU.

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