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To Compare the Efficacy of Midazolam and Triclofos as Oral Premedicant in Paediatric Patients

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Abstract

Context: The primary goals of premedication in children are to facilitate a smooth separation from the parents and to ease the induction of anesthesia. *Aims:* To compare the efficacy of midazolam and triclofos when given orally as premedicants in children. *Material and methods:* 50 patients aged 2-6 years of ASA I & II were divided randomly into two groups equally. Group M received syrup midazolam, 0.5 mg kg-1 and group T received syrup triclofos 75 mg kg-1, orally as premedication. Level of sedation and behavior [1,3] at the time of separation from parents and during mask acceptance [1,3]. *Statistical analysis:* Unpaired t-test was used for statistical analysis. p-value <0.05 is significant. *Results:* In group-M 56% and 40% patients while in group-T 24% and 8% patients achieved a sedation score of 4 and 5 respectively ($p<0.05$). In group-T 64% and 24% while in group-M 8% and 12% patients achieved a behavior score of 1 and 2 respectively at the time of separation from parents ($p<0.05$). In group-M 68% and in group-T 24% patients achieved a mask acceptance score of 4 ($p<0.05$). *Conclusion:* Oral midazolam 0.5 mg kg-1 was better in terms of level of sedation and behavior at the time of mask acceptance whereas, triclofos 75 mg kg-1 was better in terms of behavior at the time of separation from parents in paediatric age group 2 to 6 years. Hence, midazolam was found to be superior to triclofos.

Keywords: Paediatric; Midazolam; Triclofos; Sedation; Behaviour score

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Introduction

Paediatric patients are to be given special considerations not only with respect to anatomic, physiologic and pharmacologic differences but also behavioral aspect. Children admitted to hospitals are displaced from their comfort zone of home and family. The primary goals of premedication in children are to facilitate a smooth separation from the parents and to ease the induction of anesthesia. This study was conducted to compare the efficacy of midazolam and triclofos when given orally as premedicant in children.

Materials and Methods

This study was carried out in the department of Anaesthesiology after getting approval from the institutional ethical and research committee. Written and informed consent was taken from parents.

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Inclusion Criteria

- Children belonging to American Society of Anaesthesiologists (ASA) physical status I or II
- Age: 2-6 years.
- Either gender.
- Scheduled for elective surgery.
- Body weight up to 20 kg.
- No known history of drug allergy, sensitivity or other form of reaction.
- Patient whose parents were willing to sign informed consent.

Exclusion Criteria

- Patients with ASA III or IV or V.
- Children on anticonvulsant therapy and other sedative medications.
- Those likely to have anticipated difficult airway.
- Known sensitivity to benzodiazepines.
- Scheduled for neurosurgical procedures.
- Children with mental retardation.
- Risk of pulmonary aspiration.
- Those patients whose parents were not willing to participate in the study.
- Patient allergic to any drug.
- Patient with renal, hepatic, cardio vascular and respiratory disease.

50 patients aged 2-6 years of ASA I & II were divided randomly into two groups equally.

Baseline heart rate (H.R.), systolic blood pressure (SBP), diastolic blood pressure (DBP), temperature and pulse oximeter (SpO_2) were monitored and recorded. Intravenous (i.v.) line was secured and isolyte p was started. All patients received inj. glycopyrolate 0.004 mg kg^{-1} and inj. ondansetron 0.1 mg kg^{-1} i.v. Patients were allocated into either of the two groups. Group M received syrup midazolam, 0.5 mg kg^{-1} and group T received syrup triclofos 75 mg kg^{-1}, administered orally as premedication 30 minutes and 60 minutes respectively before surgery. Level of sedation at the time of separation from parents [1,3]. Behaviour at the time of separation from parents and during mask acceptance were assessed [1,3].

Patients were pre-oxygenated with face mask with 100% oxygen for 3 minutes. Anesthesia was induced by a standard technique of intravenous induction with inj. sodium thiopentone 5 mg kg^{-1} i.v.. Endotracheal intubation was done after giving inj.succinyl choline 2 mg kg^{-1} i.v. Anaesthesia was maintained on O_2, N_2O, sevoflurane and inj. atracurium 0.5 mg kg^{-1} i.v. Intra-operatively children were monitored for HR, SBP, DBP, SpO_2 every 15 minutes till end of surgery. At the end of surgery, neuromuscular blockade was reversed with inj. Neostigmine 0.05 mg kg^{-1} and inj.glycopyrolate 0.008 mg kg^{-1} i.v. Trachea was extubated after fulfilling the recovery criteria and shifted to recovery room.

Postoperatively, HR, SBP, DBP, SpO_2, any adverse events such as nausea, vomiting, rigor, hypotension, bradycardia, and respiratory depression were observed every 15 minutes upto 2 hours.

Results

Total 50 patients were allocated for the study. Both groups were comparable in respect to age, sex, weight and duration of surgery ($p > 0.05$).

There were no any complications or side effects in any of the groups. There was no statistically significant difference in mean heart rate, systolic blood pressure, diastolic blood pressure and SpO_2 in both groups intraoperatively and postoperatively ($p > 0.05$).

Table 1: Level of sedation scores [1,3] between the groups

Level of sedation	Group-M	Group-T	p-value
Score 1 = Child awake and oriented	0	0	-
Score 2 = Drowsy	0	2 (8%)	<0.05
Score 3 = Eyes closed but arousable to command	1 (4%)	15 (60%)	<0.05
Score 4 = Eyes closed, but arousable to mild physical stimulation	14 (56%)	6 (24%)	<0.05
Score 5 = Eyes closed, but unarousable to mild physical stimulation	10 (40%)	2 (8%)	<0.05

Table 2: Behaviour at the time of separation from parents between the groups.

Behaviour at the time of separation from parents [1,3]	Group-M	Group-T	p-value
Score 1 = excellent-happily separated	2 (8%)	16 (64%)	<0.05
Score 2 = good-separated without crying,	3 (12%)	6 (24%)	<0.05
Score 3 = fair-separated with crying,	12 (48%)	3 (12%)	<0.05
Score 4 = poor need for restraint	8 (32%)	0	<0.05

Table 3: Behaviour during mask acceptance between the groups.

Behaviour during mask acceptance [1,3]	Group- M	Group-T	p-value
Score 1 = Poor – afraid, combative, crying	0	0	-
Score 2 = Fair – moderate fear of mask, not easily calmed	0	13 (52%)	<0.05
Score 3 = Good – slight fear of mask, easily calmed	8 (32%)	6 (24%)	>0.05
Score 4 = Excellent – unafraid, cooperative, accepts mask easily	17 (68%)	6 (24%)	<0.05

Table 4: Surgeries undergone by the patients between the groups.

Type of surgery	Group-M	Group-T	p-value
Colostomy closure	5 (20%)	3 (12%)	>0.05
Circumcision	2 (8%)	3 (12%)	>0.05
Hernioplasty	13 (52%)	12 (48%)	>0.05
Lords placation	4 (16%)	2 (8%)	<0.05
Hypospadias repair	1 (4%)	5 (20%)	<0.05

Discussion

Midazolam & triclofos were compared to identify effective and safe premedicant for pediatric patients aged between 2 and 6.

In the current study midazolam syrup was given in the dose of 0.5 mg kg^{-1}. Studies by Kolathu PR et al. [1], Choudhary S et al. [2], Geetha L [3] showed that the dose of 0.5 mg kg^{-1} of midazolam orally has proven to be efficacious in children with fewer side-effects. Hence a dose of 0.5 mg kg^{-1} was chosen for midazolam.

Triclofos syrup was used in the dose of 75 mg kg^{-1}. Choudhary S et al. [2] and Parameshwari A et al. [4] used triclofos 75 mg kg^{-1} and concluded that this was the safe dose with fewer side effects, hence the dose of 75 mg kg^{-1} was chosen for triclofos.

Midazolam is rapidly absorbed in gastrointestinal tract and produces its peak effect in 30 mins [6].

Triclofos oral solution is well-absorbed and shows efficacy within 30-40 minuites [7]. Choudhary S et al. [2] and Geetha L et al. [3], reported that maximum percentage of patients achieving excellent sedation scores at 60 min. Hence, the time for assessment of sedation for triclofos was selected as 60 minutes [2].

In our study differences in demographic data between the two groups were statistically not-significant ($p>0.05$), similar to the studies conducted by Chaudhary S [2], Kolathu PR et al. [1] and Jose MR et al. [5].

On comparing level of sedation in both the groups, it was observed that in the group-M, 40% patients had achieved a score of 5 (eyes closed, but unarousable to mild physical stimulation) while only 8% patients in group-T achieved a score of 5 which is depicted in table 1. Our study was comparable to studies carried out by Kolathu PR et al. [1] and Geetha L et al. [3]. Jose MR et al. [5] observed that in midazolam group 88% of patients had sedation score of 2 whereas in triclofos group 84% had sedation score 4, which was differed to our study.

In our study behavior score at the time of separation from parents was excellent (score 1 = happily separated) in 64% patients & good (score 2 = separated without crime) in 24% patients in group-T as compared to group-M wherein only 8% and 12% patients achieved score-1 and score-2 respectively. Thus triclofos resulted in excellent behavior at the time of separation from parents as compared to midazolam (Table 2). Kolathu PR et al. [1], Choudhary S et al. [2], Jose MR et al. [5], Geetha et al. [3] have observed no difference in separation score.

When behavior during mask acceptance was compared in both the groups, it was seen that a significantly higher proportion of patients in

group-M achieved a score 4 = Excellent – unafraid, cooperative, accepts mask easily (68%) as compared to group-T wherein only 24% patients achieved score-4 and this difference was clinically significant ($p<0.05$) (Table 3). Thus midazolam resulted in excellent behavior during mask acceptance as compared to triclofos which correlates with the studies carried out by Chaudhary S et al. [2], Parmeshwari A et al. [4].

Midazolam exerts it effects through reversible interactions with GABA receptor in the CNS which is an inhibitory neurotransmitter. It produces sedation, anxiolysis, amnesia and hypnosis.

Triclofos is converted to Trichloroethanol in the body which induces sedation by acting as melatonin agonist. It has rapid onset of action and produces drowsiness.

In our study, there was no statistically significant difference in mean heart rate, systolic blood pressure, diastolic blood pressure and SpO_2 in both groups intraoperatively and postoperatively ($p > 0.05$).

Similar observations were seen in the study by Kolathu PR et al. [1], Chaudhary S [2], Jose MR et al. [5], Parmeshwari A et al. [4] and Geetha L et al. [3] wherein there was no significant difference seen in vitals or oxygen saturation in the intraoperative and post-operative periods.

None of the patients in any of the groups had side effects like nausea, vomiting, rigors, hypotension, bradycardia etc. which was similar to the studies carried out by Kolathu PR et al. [1], Chaudhary S [2], Jose MR et al. [5], Parmeshwari A et al. [4] and Geetha L [3].

Conclusion

We concluded that oral midazolam 0.5 mg kg^{-1} was better as compared to triclofos 75 mg kg^{-1} in terms of level of sedation and behaviour at the time of mask acceptance whereas, triclofos was better in terms of behaviour at the time of separation from parents in paediatric age group 2 to 6 years. Hence, midazolam was found to be superior to triclofos.

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Conflict of Interest: None

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