

A comparative study of propofol, thiopentone sodium, and ketofol as induction agents for electro convulsive therapy

Nagraju R. Gaddam, Vasanti P. Kelkar (Sasturkar), Sanhita J. Kulkarni, Pradnya S. Joshi, Pramod V. Bhale

Department of Anesthesia, MGM's Medical College, Aurangabad, Maharashtra, India

Abstract

Background and Aims: Thiopentone and propofol are most commonly used induction agents for electro convulsive therapy (ECT). Recently, ketofol, an admixture of propofol and ketamine, is being tried in ECT. We aimed to compare propofol, thiopentone, and ketofol as induction agents during ECT regarding their effects on ECT-induced hemodynamic changes, seizure duration and recovery parameters.

Material and Methods: This prospective randomized double blind study was conducted in 30 patients between 18 and 65 years with ASA status I and II scheduled for ECT. All patients received all study agents for first three sessions of ECT. The observations were compiled as Group K (Inj. Ketofol i.e., Inj. propofol 0.5mg/kg + Inj. ketamine 0.5mg/kg), Group P (Inj. propofol 1mg/kg), and Group T (Inj. thiopentone 3mg/kg). Heart rate (HR) and blood pressure (systolic, diastolic, and mean) was recorded at pre op, 0, 5, 10, and 20 min after ECT. The seizure duration, time to spontaneous eye opening, and obeying verbal commands and agitation score were recorded.

Results: Statistically significant difference was seen in HR at 10 min after delivery of shock; in systolic BP at 2 min after shock; in diastolic BP after administration of study drug and immediately after shock and in mean arterial pressure at post induction, 0 and 2 min after shock with group T showing higher values compared to group K and P ($p < 0.05$). At all other times HR and BP was comparable in all the three groups. Seizure duration was more in group T than Groups P and K although the difference was statistically insignificant. Time to spontaneous eye opening and obey verbal commands was comparable in all groups. Mean agitation score was highest in group T than Groups P & K with Group P showing least value ($p = 0.003$).

Conclusion: Propofol and ketofol showed superior hemodynamic stability than thiopentone but comparable seizure duration and recovery parameters. Thus, propofol and ketofol can be effectively used as induction agents for ECT although propofol is associated with lesser agitation than ketofol.

Keywords: Electroconvulsive therapy, ketamine, ketofol, propofol, thiopentone

Introduction

Electro convulsive therapy (ECT) is used to treat depression in the patients not responding to antidepressant therapy. ECT may be associated with untoward consequences such as hypotension and bradycardia followed by hypertension

and tachycardia. After awakening, patient may experience confusion, agitation, headache, and muscle stiffness.^[1]

Anesthetic induction agents routinely used in ECT are thiopentone and propofol. Thiopentone provides rapid, smooth induction but delayed recovery and is associated with side effects

Address for correspondence: Dr. Vasanti P Kelkar (Sasturkar), 131, Parimal, Chintamani Housing Society, Tilaknagar, Aurangabad, Maharashtra - 431 001, India.
E-mail: vasantims@rediffmail.com

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such as laryngospasm, arrhythmias etc., It has anti-convulsant properties increasing seizure threshold and shortening duration of seizure activity in dose-dependent manner which is undesirable in ECT.^[2] Propofol has fast induction, smooth recovery, and minimal post-operative agitation. Its hypotensive effect is beneficial in counteracting ECT induced hypertension;^[3] however, disadvantage of propofol is dose-dependent decrease in seizure duration. Ketofol, (an admixture of ketamine and propofol), is recently being tried as an induction agent in ECT. The cardiovascular properties of both propofol and ketamine balance each other in maintaining hemodynamic stability.^[4]

Lot of research has been done in past comparing thiopentone sodium and propofol as induction agents for ECT. There are also studies where effectiveness of ketamine has been observed during ECT. Very few studies of ketofol as inducing agent in ECT are available. However we did not come across any study which has compared the effects of all the three drugs, i.e., thiopentone, propofol and ketofol in ECT. We therefore thought of comparing propofol, thiopentone sodium, and ketofol as induction agents in ECT regarding their effects on ECT-induced hemodynamic changes, recovery parameters, and seizure duration. We hypothesized that ketofol would be a better induction agent for ECT in terms of hemodynamic stability and seizure duration.

Material and Methods

After approval from ethical committee this prospective randomized double-blind study was conducted in 30 adult patients. The study was registered with the clinical trial registry of India (CTRI/2018/09/015856).

Sample size was calculated^[12] as follows:-

$$n = \frac{2 \times SD^2 (Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

Where SD = Pooled standard deviation

$$Z_{\alpha/2} = Z_{0.005/2} = 1.96 \text{ at Type I error}$$

$$Z_{\beta} = Z_{0.20} = 0.84 \text{ at 80\% power}$$

d = effect size = difference between two mean

$$n = \frac{2 \times (31.82)^2 \times 7.84}{28^2} = 20.25$$

Minimum sample size required was 21. We included 30 patients in each group.

Patients of both sexes between the ages of 18 and 65 years with American Society of Anesthesiologists (ASA) physical

status I and II scheduled for ECT were enrolled for the study. Patients on chronic opiate use, pregnant females, and lactating mothers, patients with known allergy to the study drugs and patients with cardiovascular diseases were excluded from the study.

The primary outcome of the study was to compare hemodynamic stability and seizure duration during ECT, whereas recovery parameters were secondary outcome.

Patients scheduled to undergo ECT at our hospital usually receive 6-8 sessions on alternate days depending on the clinical response of the patient. First three sessions of ECT in each patient were included in our study. Informed and written consent of the patient and patient's relative was taken. Patients were kept NPO (nil per oral) for 6 h prior to ECT.

Patients were randomly divided into three groups of 10 each using sealed envelope method. Group A received Inj. ketofol (Inj. propofol 0.5mg/kg & Inj. ketamine 0.5mg/kg), Group B received Inj. propofol (1mg/kg), and Group C received Inj. thiopentone sodium (3mg/kg) for first session. The patients in group A received inj. propofol for second session and inj. thiopentone sodium for third session of ECT, patients in group B received inj. thiopentone for second session and ketofol for third session, whereas patients in Group C received inj. ketofol for second session and inj. propofol for third session of ECT. All the three drugs were used in each patient so as to avoid influence of patient and disease variables on the effects of the drugs. One anesthesiologist who was not part of the study prepared the induction agents used for the ECT in covered syringes as per the allotted group and sequence and also injected the drugs during ECT. The second anesthesiologist conducted the anesthesia and observed the parameters. The observer anesthesiologist and patient both were blind to the study drug used making the study double blind. If a patient needed more drug than the calculated amount, then the patient was excluded from the study.

In the ECT room, an intravenous cannula of 20G was inserted into the arm and RL was started. All patients were monitored non-invasively for blood pressure (BP), heart rate (HR), oxygen saturation (SpO₂), and ECG changes. The baseline BP (systolic, diastolic, and mean), HR and SpO₂ were recorded. Inj. glycopyrrolate (0.004 mg/kg) was given as premedication. Vital parameters (BP, HR, and SPO₂) were noted. After a period of 2 min the patient was induced with the given study drug and hemodynamic parameters were noted. One of the upper limbs was isolated with sphygmomanometer cuff inflated to 100mmHg above the systolic blood pressure to observe the duration of seizure activity. After isolating the limb, succinyl choline was given in a dose of 0.75 mg/kg and

manual ventilation was performed with Bain's circuit using 100% oxygen at flow rate of 8L/min. A bite block was used to avoid trauma to structures in the patient's oral cavity. A supra threshold electrical stimulus was given via bi fronto temporal electrodes and ventilation was assisted with oxygen during the procedure. The seizure duration, i.e., the time from the administration of shock to cessation of tonic-clonic motor activity in the "isolated" limb was recorded. Systolic BP (SBP), diastolic BP (DBP), mean BP (MAP), HR and SpO₂ were recorded at 0, 1, 2, 3, 4, 5, 10, and 20 min after the delivery of shock. The patients were ventilated with 100% oxygen till return of spontaneous breathing. Time to eye opening and time to obeying verbal commands were also noted. If patients had any complaint of nausea and vomiting inj. ondansetron 4mg IV was given. Post recovery agitation was evaluated, using an emergence agitation score.^[5]

The parameters of sessions where thiopentone was used as induction agent were compiled under the heading of Group T. Similarly findings were compiled as group P and Group K where propofol and ketofol were used as induction agents, respectively.

Statistical analysis

All the data was presented as mean \pm SD (standard deviation). Demographic data were analyzed using Chi-square test and statistical significance in mean difference was done using analysis of variance test. Frequency and percentage was calculated by SPSS 17 software. "P" value of < 0.05 was considered as statistically significant and $P < 0.001$ was taken as statistically highly significant.

Results

Mean age of patients in our study was 31.63 ± 10.19 years and the mean weight was 56.53 ± 12.50 Kg with male: female ratio of 43: 57%. Pre-operative (Baseline) vital parameters (HR, SBP, DBP, MAP) in all the groups were comparable ($p > 0.05$) [Figure 1].

After administration of premedication (Inj. glycopyrrolate), HR increased in all the three groups. Further increase in heart rate was observed after the delivery of shock. HR gradually decreased over a period of time but remained higher compared to baseline till the end of study period, i.e., 20 min after the shock in all the three groups. The percentage increase in heart rate was less in propofol group than ketofol and thiopentone group. There was statistically significant difference in heart rate at 10 min after delivery of shock in the study groups with group T showing higher values compared to group K and P ($p = 0.009$) [Graph 1].

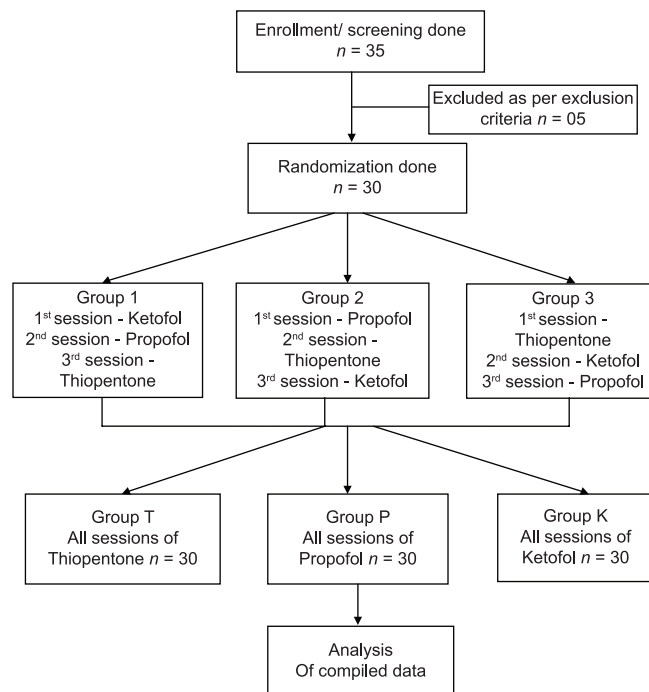


Figure 1: Study design

After administration of study drug there was statistically significant decrease in mean SBP compared to baseline in Group P (4.84%), whereas Group K showed statistically non significant decrease (1.13%) and Group T showed non-significant increase in SBP (3.66%). All the study groups showed statistically significant increase in SBP after delivery of shock ($P < 0.05$) where the percentage increase in Group P (9.8%) was less than Group K (19.7%) and Group T (22.83%). The rise in SBP persisted up to 5 min in Group K, 4 min in Group T, whereas only till 2 min in Group P after delivery of shock. There was statistically significant difference in SBP at 2 min after delivery of shock where group T showed higher value compared to group K and P ($p = 0.012$) [Graph 2].

Compared to baseline, a statistically insignificant decrease in DBP was observed in Group P, whereas Group K and T showed statistically significant increase in DBP after administration of study drug ($P < 0.05$). After delivery of shock DBP further increased in all the three groups. The percentage rise in Group P (7.80%) was less compared to Group K (23.37%) and Group T (21.06%). This rise in DBP persisted up to 3 min in group K and T and only up to 1 min in group P. There was statistically significant difference in DBP after administration of study drug and immediately after shock where group T showed higher value than group K and P ($P < 0.05$) [Graph 3].

After administration of study drug insignificant increase in MAP was seen in Group K. Group T showed statistically significant rise, whereas Group P showed statistically significant decrease in MAP ($P < 0.05$). After delivery of shock there was statistically significant increase in group K and Group T which persisted up to 3 min. The percentage increase was more in Group T than Group K. Except at 1 min after delivery of shock; Group P did not show any statistically significant increase in MAP during the study period. There was statistically significant difference in MAP after induction, at 0 and 2 min. after delivery of shock in all the three groups with group T showing higher value than group K and P ($p < 0.05$) [Graph 4]. None of the patient showed ECG changes at any time during the study period.

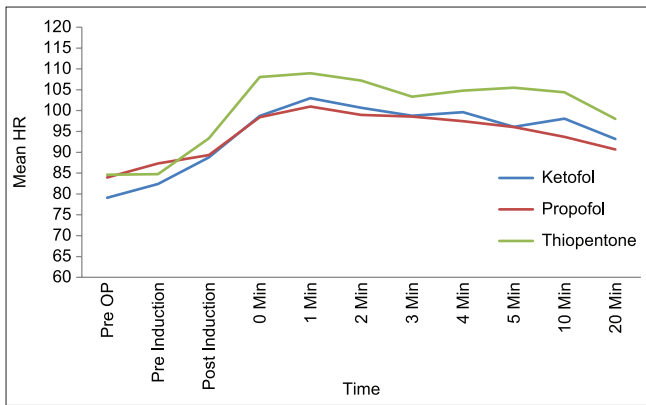
Seizure duration observed was more in Group T (30.78 ± 12.80) compared to Group P (24.85 ± 10.72) and Group K (25.88 ± 12.25), though the difference was statistically not significant. Time to spontaneous eye opening ($p = 0.431$) and time to obey verbal commands ($p = 0.265$) were comparable in all the three groups [Table 1].

Agitation score of >2 was observed in 10% patients in ketofol group, 23.33% in thiopentone group. None of the patient in

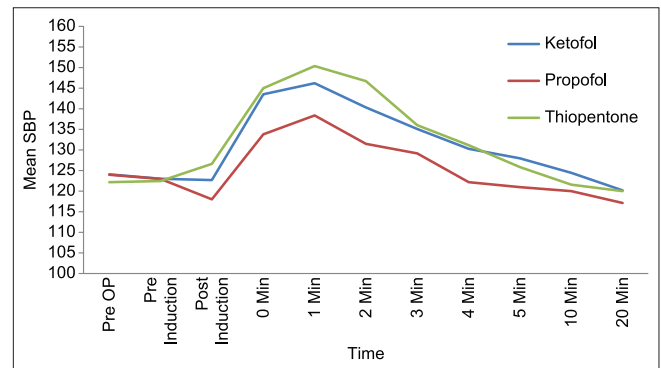
propofol group had agitation score of >2 [Graph 5]. Mean agitation score was highest in Group T (2.13 ± 0.57) showing statistically highly significant difference compared to group P (1.63 ± 0.49) and group K (1.77 ± 0.63) (P value 0.003).

Discussion

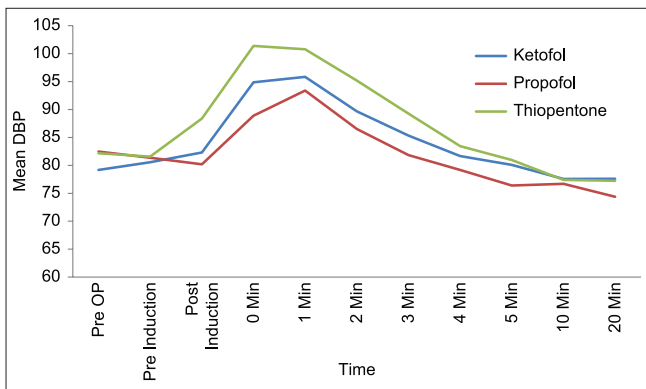
ECT is a mode of treatment used for patients with severe depression and other psychiatric disorders resistant to medical management. At present general anesthesia with muscle paralysis is the most common anesthetic technique used for ECT. During the procedure, it is important to maintain depth of anesthesia and at the same time there should be adequate seizure duration to have desired therapeutic effects. ECT is also associated with hemodynamic disturbances such as bradycardia followed by tachycardia and hypertension which may be deleterious especially in patients with coexisting cardiovascular diseases. An induction agent who effectively counteracts these hemodynamic changes without influencing the seizure duration is the most desirable one for ECT. Thiopentone sodium, an ultrashort acting barbiturate and an age old drug that is used as an induction agent in ECT, provides rapid and smooth induction but recovery is delayed



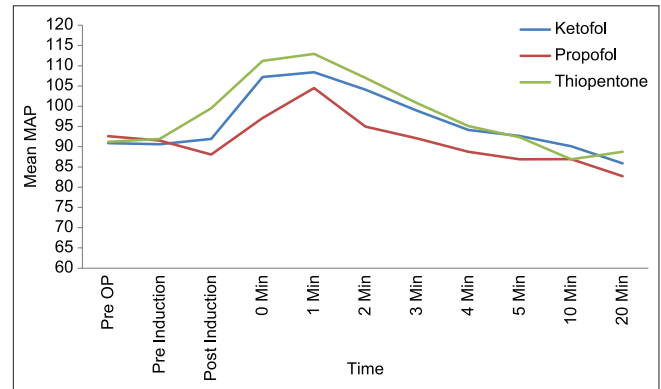
Graph 1: Comparison of mean heart rate at different time interval in three groups



Graph 2: Comparison of systolic blood pressure at different time interval in three groups



Graph 3: Comparison of diastolic blood pressure at different time interval in three groups

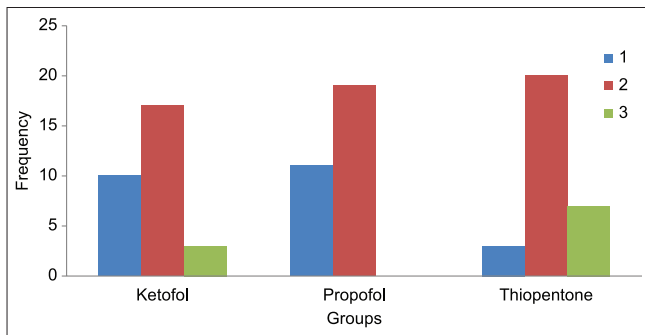


Graph 4: Comparison of mean arterial pressure at different time interval in three groups

Table 1: Comparison of seizure duration and recovery parameters in the three groups

Parameters	Ketofol	Propofol	Thiopentone	F	P
	Mean ± SD	Mean ± SD	Mean ± SD		
Seizure duration (in seconds)	25.88 ± 12.25	24.85 ± 10.72	30.78 ± 12.80	2.10	0.128 NS
Spontaneous eye opening time	4.80 ± 2.69	4.20 ± 2.81	5.06 ± 2.39	0.85	0.431 NS
Time to obey Verbal commands	6.33 ± 3.38	5.90 ± 3.71	7.26 ± 2.69	1.35	0.265 NS
Mean agitation score	1.77 ± 0.63	1.63 ± 0.49	2.13 ± 0.57	6.29	0.003 HS

NS=Not significant, HS=Highly significant

**Graph 5:** Comparison of agitation score in three groups

and it may affect seizure duration due to its anticonvulsant effect. Propofol, a 2, 6-diisopropylphenol, has good hemodynamic stability during ECT owing to its vasodilatory effect but it also reduces seizure activity due to its strong anticonvulsant property. Ketamine can produce cognitive and behavioral disturbances including psychosis. On the contrary, it has antidepressant action which helps in improving clinical response of ECT. Ketamine has a lesser anticonvulsant action and prolongs seizure duration during ECT.^[7,12] Ketamine also has stimulating action on cardiovascular system which may aggravate tachycardia and hypertension seen during ECT.^[6-8]

Ketofol (an ad-mixture of propofol and ketamine) is a relatively newer induction agent that is being used in ECT. The additive effects of both the drugs help in decreasing the dose of each drug in the admixture taking benefit from the advantages regarding amnesia, analgesia, hypnosis. Since hemodynamic effects of propofol and ketamine balance each other, the admixture is advantageous in maintaining hemodynamic stability. Hallucinations associated with ketamine are reduced by propofol when both the drugs are used simultaneously.^[9] Action of ketamine on seizure duration counteracts anticonvulsant action of propofol thus improving seizure duration when used in combination.^[10]

During ECT, induction agents are used in slightly lower concentrations so as to minimize their effect on seizure duration. After thorough literature search we found that in ECT commonly used induction dose of thiopentone is 2–4 mg/kg, of propofol is 0.75 to 2 mg/kg and of ketamine is 0.7 to 2.8 mg/kg. In our study, we used 3 mg/kg of thiopentone, 1 mg/kg of propofol, and admixture of 0.5 mg/kg ketamine + 0.5 mg/kg

propofol as ketofol. These doses coincide with those used by Omprakash *et al.*^[11] and Erdogan *et al.*^[12] respectively in their studies.

ECT is associated with parasympathetic stimulation in the initial period leading to bradycardia and sometimes asystole. To minimize these vagal effects of bradycardia and increased secretions, anticholinergic agents, such as atropine and glycopyrrolate, are used as premedication before ECT.^[13] Though there are some studies which have questioned the role of anticholinergic premedication in each and every patient undergoing ECT, still in many centers including our hospital anticholinergic premedication is a routine practice before ECT. Since we have used anticholinergic premedication (glycopyrrolate) that might have contributed to the persistent increase in heart rate compared to baseline in our study.

Manjula *et al.*^[14] in their study with propofol and thiopentone observed significant rise of heart rate at 1, 2, 3, 5, and 10 min post ECT when compared to baseline parameters. Our results coincide with their study. Erdogan *et al.*^[12] conducted study using ketofol and propofol. Their study showed a significant rise of heart rate at T0 and T5 in propofol group, whereas heart rate was higher than baseline at T0 and lower than baseline at T1 with ketofol group. As they did not use anticholinergic premedication, the increase in HR was not persistent.

In our study, there was decrease in SBP, DBP, and MAP in group P after administration of study drug. After delivery of shock, there was statistically significant increase in BP in all the three groups though percentage increase was least in group P and highest in group T. Also, the BP values returned to baseline earlier in group P than Groups K & T.

Erdogan *et al.*^[12] in their study with ketofol (0.5/0.5) and propofol (1 mg/kg) observed similar increase in SBP in both the study groups compared to baseline values, but the comparison of two groups revealed lesser increase in propofol group ($P < 0.05$). Mir *et al.*^[15] compared thiopentone, propofol, and etomidate as induction agents for ECT. Their study showed a rise in SBP after delivery of shock till 2 min

and after 2 min there was a decreasing trend. The variability was statistically significant in thiopentone group. Propofol group showed less rise compared to baseline. Jaitawat *et al.*^[16] in their study of propofol (1.5mg/kg), etomidate (1.5mg/kg) and ketofol (ketamine 0.8mg/kg + propofol 1.5mg/kg) did not observe any statistically significant difference in SBP at any time interval compared to baseline. This is in contrast with our study. They have used higher doses of propofol and ketamine in their study which might have contributed to this difference.

Erdogan *et al.* also found significantly higher DBP values at all-time points in the Ketofol group compared with the baseline values ($P = 0.001$). DBP values were determined to be higher at T0, T1, T3, and T5 in ketofol group than propofol group ($P < 0.029$). Miret *et al.* observed a statistically significant rise in DBP after delivery of shock till 2 min in all the groups ($P < 0.05$). However, the rise was statistically significant with thiopentone group. The observations of our study agree with both these studies.

Manjula *et al.*^[14] in their study comparing thiopentone and propofol, also observed higher increase in MAP in thiopentone group compared to propofol, a finding similar to our study. Saban *et al.*^[17] in their study of propofol, ketamine and ketofol did not observe any significant difference in MAP among the three groups. They did not observe any statistical significant change in MAP in ketofol group during the study. They had prepared ketofol as 1:1 mixture (10mg: 10mg) in 20 ml syringe and it was administered to the patient till the patient showed loss of eye reflex. They did not use any fixed dose for the drug. This may be the reason why they got different observations in their ketofol group compared to our study. Their observations of MAP values in propofol group are similar to our study.

Research suggests that ECT induced seizure activity of < 25 s duration does not have therapeutic effect.^[18] In all patients in our study we observed mean seizure duration of ≥ 25 s. Observations by Erdogan *et al.*^[11] and Manjula *et al.*^[14] are similar to our study. Saban *et al.*^[17] found shorter seizure duration in propofol group than ketofol group ($P < 0.01$). They have used higher dose of ketamine while preparing ketofol. This might have contributed to longer seizure duration in their ketofol group. Hashemet *et al.*^[19] in their study observed higher seizure duration in thiopentone group compared to propofol group ($P = 0.001$). Use of higher dose of propofol and lower dose of thiopentone in their study might have contributed to their observation which is in contrast to our study.

We did not observe any statistically significant difference in recovery parameters in all the three groups. Erdogan

et al.,^[12] Saban *et al.*,^[17] and Bodkhe *et al.*^[20] also found comparable recovery parameters in ketofol/propofol and propofol/thiopentone groups, respectively. In contrast, Jaitawat *et al.*^[16] observed shorter spontaneous eye opening time and time to obey verbal commands in propofol group compared to ketofol group. They used higher dose of propofol and ketamine in ketofol group which might have caused delayed recovery.

The reported incidence of post-ECT delirium ranges from 3.23% to 18%.^[21] Not many studies in literature have observed for post ECT agitation while comparing effects of various induction agents. Both thiopentone and ketamine may be associated with increased post procedure agitation whereas propofol has least incidence of agitation. Butterfield *et al.*^[22] in their study observed that cognitive impairment in the early recovery period after ECT are reduced with propofol compared to thiopental anesthesia. Our observations agree with their study. In ketofol, the effect of ketamine is counterbalanced by propofol. Hence, incidence and severity of agitation is also less compared to ketamine alone. Tarek *et al.*^[6] observed that 8.6% of patients in ketofol group had agitation score of > 2 . These findings are similar to our study.

Limitations

Ideally during ECT, seizure duration is monitored using electroencephalogram (EEG). We could monitor only motor seizure duration as in our hospital EEG is not used while giving ECT. As we did not have the facility of BIS monitoring, we could not monitor depth of anesthesia. A study design in which induction agents were given in a dose to achieve similar depth of anesthesia would have given better comparison of hemodynamic parameters.

Conclusion

In ECT, propofol (1mg/kg) and ketofol (propofol 0.5mg/kg + ketamine 0.5mg/kg) showed superior hemodynamic stability than thiopentone (3mg/kg) but comparable seizure duration and recovery parameters. Thus, propofol and ketofol both can be effectively used as induction agents for ECT although propofol is associated with lesser post procedure agitation than ketofol.

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Conflicts of interest

There are no conflicts of interest.

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