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ORIGINAL RESEARCH

Prospective Randomized Comparative Clinical Study of Hemodynamic Changes with Etomidate versus Ketamine and Propofol Combination (Ketofol) during Induction under General Anaesthesia

Sukhbinder Singh[1], Macha Niranjan Reddy[2*], Payal Jain[3], Mukesh Kumar Prasad[4], MD Shahbaz Alam[5], GS Jheetay[6]

[1]PG Resident 3rd Year, Department of Anaesthesiology, Teerthanker Mahaveer Medical College & Research Centre, Mordadbad, Uttar Pradesh, India.
[*2]Assistant Professor, Department of Anaesthesiology, Teerthanker Mahaveer Medical College & Research Centre, Mordadbad, Uttar Pradesh, India.
[3]Associate Professor, Department of Anaesthesiology, Teerthanker Mahaveer Medical College & Research Centre, Mordadbad, Uttar Pradesh, India.
[4]Professor & HOD, Department of Anaesthesiology, Teerthanker Mahaveer Medical College & Research Centre, Mordadbad, Uttar Pradesh, India.
[5]Associate Professor, Department of Anaesthesiology, Teerthanker Mahaveer Medical College & Research Centre, Mordadbad, Uttar Pradesh, India.
[6]Professor & HOD, Department of Anaesthesiology, Venkateshwara Institute of Medical Science, Rajabpur, Jyotiba Phule Nagar, NH-24, Jyotiba Phule Nagar, Jyotiba Phule Nagar, Uttar Pradesh, India.

Corresponding Author: Dr Macha Niranjan Reddy, Assistant Professor, Department of Anaesthesiology, Teerthanker Mahaveer Medical College & Research Centre, Mordadbad, Uttar Pradesh, India.

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ABSTRACT

Background: Major necessary responsibility of the anesthesiologist is to maintain a clear pathway that facilitates the administration of anesthesic agent and maintain the flow of oxygen throughout the respiratory system. **Objective:** To compare the hemodynamic differences with Etomidate versus Ketamine and Propofol combination (Ketofol) during induction under General Anaesthesia.

Material and Methods: It was a Prospective Randomized Comparative Clinical Study in which, 80 patients of ASA I or II who were posted for elective surgery under general anesthesia, were enrolled to study hemodynamic changes with Etomidate versus Ketamine and Propofol combination (Ketofol) during induction under General Anaesthesia. This study wasdone in the Department of Anaesthesia at Teerthanker Mahaveer Medical College and Research Centre, Moradabad.

Results: Both the groups were comparable in terms of demographic parameters,ASA grading and the type of elective surgery.The difference is statistically unremarkable.The hemodynamic changes during induction and intubation using Etomidate when compared with Ketofol were insignificant.

Conclusion: Both etomidate and ketofol are able to produce stable hemodynamic responses and satisfactory induction conditions.

Keywords: Hemodynamic changes, Etomidate, Ketamine, Propofol, General Anaesthesia.

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INTRODUCTION

The discovery of endotracheal intubation in the late 80s was a landmark in the field of airway management.[1] It is associated with direct laryngoscopy under direct vision. General anesthesia is a medically-induced loss of consciousness with concurrent loss of protective reflexes due to anesthetic agents. Various medications may be prescribed to induce unconsciousness, amnesia, analgesia, skeletal muscle relaxation, and the loss of autonomic system reflexes.[1]Various Stages of Anesthesia Based on Guedel's Classification are: Stage 1 - Analgesia or Disorientation,Stage 2 - Excitement or Delirium, Stage 3 – Surgical Anesthesia, Stage 4 – Overdose.

Historically Ether was used as an anesthetic agent in 1846 for extraction of tooth. In 19th century nitrous oxide was also first used. Later chloroform was used in 1847for first time for relieving pain during childbirth. The 20th century has experienced a boom in development of various anesthetic agents. Thiopentone was first used in 1934 and propofol in 1980s. In the 1990s inhalational agents like halothane, enflurane and sevoflurane came into practice. This timeline has led to the pathway for the currently used most common anesthetic induction agents namely ketamine, propofol, etomidate, thiopentone etc.

Among the anaesthetic agents, propofol is the most commonly used drug for induction of anesthesia. .[2] It has been found to create less postoperative nausea and vomiting and rapid recovery.[3] The recommended dose of propofol to attain adequate jaw relaxation and inhibition of cough reflex is 1.5-2.5 mg/kg. Besides its safety profile, it has also shown side effects such as prolonged apnea, bradycardia, hypotension and pain on injection.[4]

Ketamine is another induction agent, often called as the wonder drug. It is utilized for both induction and maintenance of anaesthesia. It has been found to create dissociative anaesthesia which is a trans-like state that help in analgesia and sedation. Being a fast-acting drug, its redistribution from the brain to the blood circulation is seen within 1 minute. Following the injection there is development of hypertension which returns back to its normal state after around 15 minutes. A wide margin of safety has been reported with the use of ketamine. And even after unintentional overdose have been found to be followed by complete recovery.[5] It leads to increased heart rate and increased blood pressure.[6,7]

In the recent years, a blend of ketamine and propofol, commonly called asketofol came into practice. For makingketofol, ketamine and propofol are mixed. Various research works have carried out using this combination in different procedures like endotracheal intubation, bronchoscopy and gastrointestinal endoscopy. As ketamine shows dose related adverse effects, the concept was to reduce the dose in order to experience less side effects. The ketamine propofol combination can effectively balance the hemodynamic changes offering a smooth sedation prior to the intubation. The administration of ketofol has also shown to have better recovery in cognitive functions. [8-10]

Etomidate is another most commonly used induction agent, it is a known cardio stable drug most commonly used in patients with known cardiac disease. It can be used alone or in combination with other agents. It is also used for the maintenance of anaesthesia. Etomidate is found to create least hemodynamic changes and have cerebroprotective characteristics. Some of the desired properties like improved cardiac perfusion and undisturbed sympathetic nervous system are present in etomidate. Being a rapid acting anaesthetic agent, it has significantly less chance for cardiovascular and respiratory depression. Along with many advantages, etomidate has shown incidences of adrenocortical suppression and postoperative nausea and vomiting.[11]

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Hence, the present study has been done to contrast the hemodynamic differences with Etomidate versus Ketamine and Propofol combination (Ketofol) during induction under General Anaesthesia.

MATERIAL & METHODS

A Prospective Randomized Comparative Clinical Study on blood circulatory changes with Etomidate and Ketamine and Propofol combination (Ketofol) during induction under General Anaesthesia wasdone in the Department of Anaesthesia at Teerthanker Mahaveer Medical College and Research Centre.This study was time bound, beginning with Institutional Ethical Committee clearance, and continued until June 2022. Ethical clearance was given on 26-07-2021. Informed consentswere obtained from subjects involved and participation-information sheet was filled out. Based on the inclusion and exclusion criteria, the subjects were selected.

Inclusion Criteria

- Subjects giving written informed consent.
- Age of the subjects is ranging from 18 to 65 years.
- American Society of Anesthesiologist (ASA) physical status I or II.
- Mallampati Grade I and II.
- subjects with BMI of 18.5 – 22.9 kg/m^2.

Exclusion Criteria

- Patient with seizure disorders.
- History of allergy to study drugs.

Sample Size

80 participants were enrolled who fulfilled the inclusion and exclusion criteria, and were equally segregated in two categories.

Methodology

Pre anaesthetic assessment was conducted for all the subjects before operation. Randomization was done using the chit-and-box method, dividing the group into: GroupE and K. The category E was administered with Etomidate 0.3 mg/kg intravenously and category K was administered with Ketamine 1mg/kg plus Propofol 1.5mg/kg intravenously.

Routine lab investigations were carried out according to the hospital protocols.

Subjects were asked for NPO for 8 hours and were cannulated in pre-operating room. Inside the OT all routine monitors including Pulse oximeter, ECG and NIBP were connected and baseline values were recorded.

Subjects were pre administered with Injection Glycopyrrolate 0.01mg/kg, Ondansetron 0.1mg/kg, Butorphanol 0.05mg/kg and Midazolam 0.05mg/kg through I/V route.

Pre oxygenation with 100% O2 for 3 minutes was performed for all subjects. In both the groups Heart rate denoted as (HR), Systolic blood pressure denoted as (SBP), Diastolic blood pressure denoted (DBP), Mean Arterial Pressure (MAP) and Oxygen saturation (SpO2) were recorded.

Induction of anaesthesia was defined as the loss of verbal contact and disappearance of eyelash reflex. 100% oxygen administration was continued.

Ventilation was assisted when patient develops apnea and placing of intubation tubewas done aided with Vecuronium 0.1mg/kilogram. Confirmation of bilateral ventilation was done by adequate chest rise and auscultation.

All indices pertaining to the act of intubation was recorded & entered in the designated proforma.

Patient was connected to ventilator. HR, SBP, DBP, MAP and SpO2 werenotedprior to receiving any medication (baseline), one minute after premedication, after induction, after intubation and subsequently, 2 minutes, 4 minutes, 6 minutes and 8 minutes after intubation.

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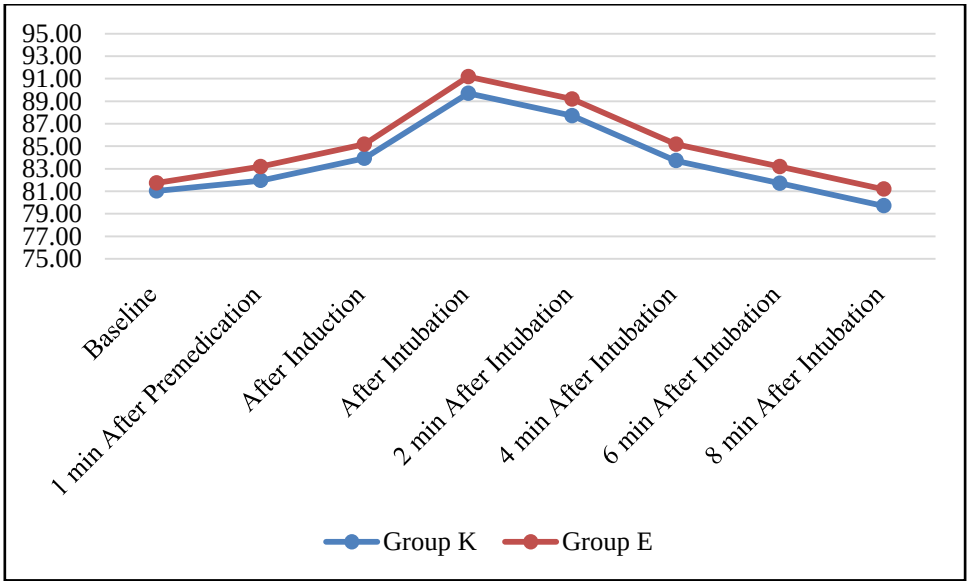
General anaesthesia was supported by O2, N2O in the proportion of 40:60, Isoflurane and Vecuronium. When the surgery is completed, reversal was done by administering Neostigmine 0.05mg/kg and Glycopyrrolate 0.01mg/kgthrough the intravenous route.
Extubation of subject was performed after sufficient recovery of muscle power. The patient was relocated to the recovery room whenever he was found to be able in keeping his eye open, elevating his hands and continue normal breathing.
Any complications observed during the surgery and post-operative period, itwas entered in the proforma.

Statistical Analysis

Microsoft excel was used to tabulate the data and tool used for analysis was SPSS V.24 software. The continuous variables are introduced with mean and SD. The categorical variables are introduced with frequency and percentage. For differentiation between two categories, independent t test and chi square test are utilized. The p value ≤0.05 is regarded as statistically remarkable.

RESULTS

Both the groups were comparable in terms of demographic parameters,ASA grading and the type of elective surgery.The mean age was 35.88±10.86 years in Group K and 33.73±8.19 years in Group E. Group K had 28 males and 12 females and Group E had 26 males and 14 females. The difference is statistically unremarkable (p>0.05).
The variation of HRin differentcategories showed that, in Group K, the HR was (81.03±6.53) in baseline,(81.95±5.31) 1 min after premedication, (83.93±5.34) after induction, (89.70±4.72) after intubation, (87.70±4.72) 2 min after intubation, (83.70±4.72) 4 min after intubation, (81.70±4.72) 6 min after intubation, (79.70±4.72) 8 min after intubation, and in group E, the heart rate was (81.73±5.42) in baseline,(83.18±4.71) 1 min after premedication, (85.18±4.71) after induction, (91.18±4.71) after intubation, (89.18±4.71) 2 min after intubation, (85.18±4.71) 4 min after intubation, (83.18±4.71) 6 min after intubation, (81.18±4.71) 8 min after intubation. None of the differences were statistically significant(p>0.05).



Graph 1: Comparison of heart rate in different intervals

The variation of SBP, in different categories showed that, in category K, the SBP was (121.85±6.80) in baseline,(123.40±4.97) 1 min after premedication, (125.40±4.97) after

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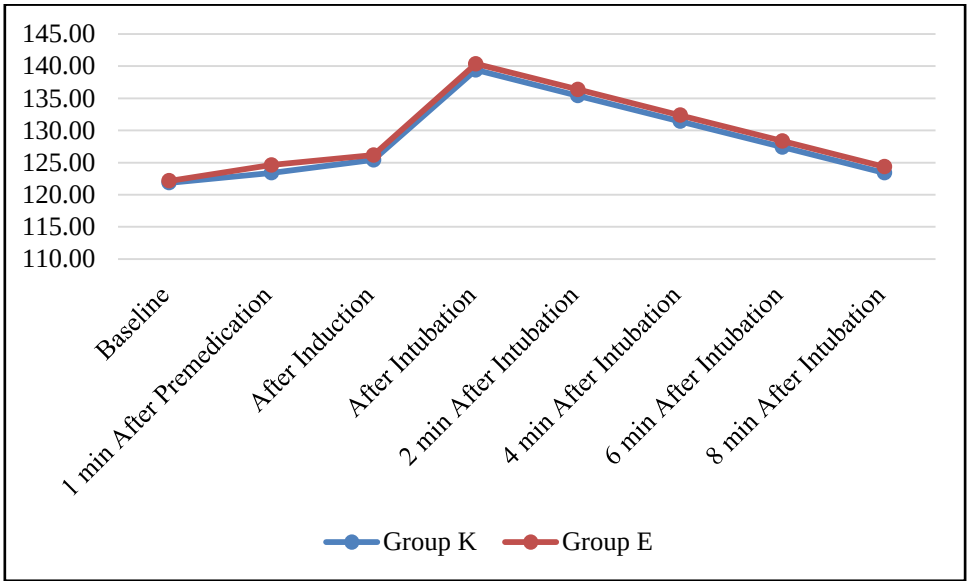
induction, (139.40±4.97) after intubation, (135.40±4.97) 2 min after intubation, (131.40±4.97) 4 min after intubation, (127.40±4.97) 6 min after intubation, (123.40±4.97) 8 min after intubation and in Group E, the systolic blood pressure was (122.15±4.42) in baseline,(125.65±5.04) 1 min after premedication, (126.15±4.35) after induction, (140.35±5.18) after intubation, (136.35±5.18) 2 min after intubation, (132.35±5.18) 4 min after intubation, 128.35±5.18) 6 min after intubation, (124.35±5.18) 8 min after intubation. None of the differences were statistically remarkable(p>0.05).



Graph 2: Comparison of SBP in different intervals

The variation of DBP in two different categories shows that, in category K, the DBP was (81.60±4.44) in baseline,(82.85±1.92) 1 min after premedication, (84.85±1.92) after induction, (88.85±1.92) after intubation, (86.85±1.92) 2 min after intubation, (82.85±1.92) 4 min after intubation, (80.85±1.92) 6 min after intubation, (78.85±1.92) 8 min after intubation and in Group E, the diastolic blood pressure was (82.40±2.27) in baseline,(84.15±1.83) 1 min after premedication, (86.35±1.86) after induction, (90.40±1.82) after intubation, (88.40±1.82) 2 min after intubation, (84.40±1.82) 4 min after intubation, (82.40±1.82) 6 min after intubation, (80.40±1.82) 8 min after intubation. None of the differences were statistically significant(p>0.05).

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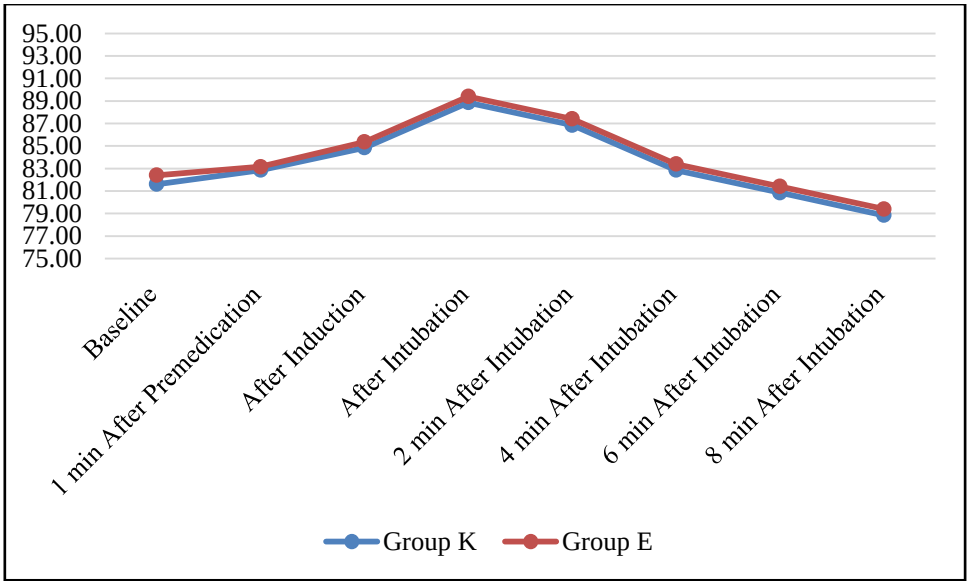
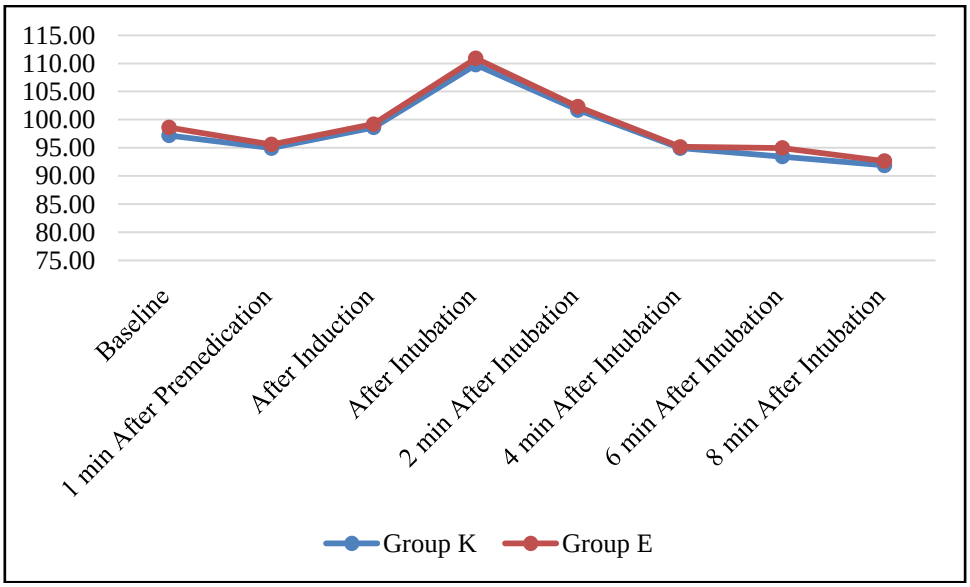


Graph 3. Comparison of DBP in different intervals

The variation of MAP in different categories showed, in Group K, mean arterial pressure was (97.20±3.30) in baseline,(94.95±3.19) 1 min after premedication, (92.08±3.29) after induction, (98.50±1.26) after intubation, (109.75±2.36) 2 min after intubation, (92.90±3.86) 4 min after intubation, (82.95±5.31) 6 min after intubation, (87.80±5.00) 8 min after intubation and in Group E, the mean arterial pressure was (95.60±2.26) in baseline,(95.60±2.26) 1 min after premedication, (91.18±2.17) after induction, (97.95±0.81) after intubation, (112.90±7.44) 2 min after intubation, (95.30±4.97) 4 min after intubation, (84.18±4.71) 6 min after intubation, (84.18±4.71) 8 min after intubation. None of the differences were statistically remarkable (p>0.05).



Graph 4: Comparison of MAP in different intervals

The comparison of SpO2 between the groups showed that, in Group K, the percentage of oxygen saturation was (99.18±0.50) in baseline,(99.23±0.42) 1 min after premedication, (99.30±0.46) after induction, (99.23±0.42) after intubation, (99.33±0.47) 2 min after intubation, (99.25±0.44) 4 min after intubation, (99.23±0.42) 6 min after intubation, (99.23±0.42) 8 min after intubation and in Group E, the percentage of oxygen saturation was

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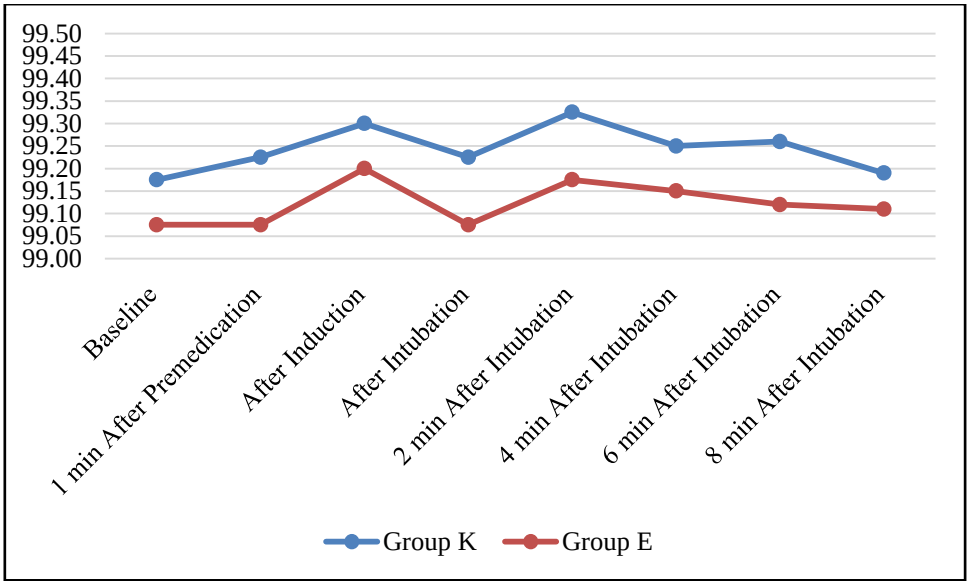
(99.08±0.27) in baseline,(99.08±0.27) 1 min after premedication, (99.10±0.30) after induction, (99.08±0.27) after intubation, (99.18±0.38) 2 min after intubation, (99.15±0.36) 4 min after intubation, (99.08±0.27) 6 min after intubation, (99.08±0.27) 8 min after intubation. None of the differences were statistically remarkable(p>0.05).



Graph 5: Comparison of SpO2 in different intervals

In category K, myoclonus was not found in subjects but 12 subjects of category E were found to have myoclonus. The difference was statistically significant.

In Group K, 3 subjects had post-surgical nausea and vomiting and in category E, 15 subjects had postsurgical nausea and emesis. The difference was statistically significant.

In Group K, 3 patients had pain on injection and in category E, 9 subjects had pain on injection. The difference was not statistically remarkable.

DISCUSSION

Hemodynamic steadiness is a major prerequirement for anaesthetic used for anaesthesia induction specifically subjects with a compromised cardiovascular function. Laryngoscopy and ET intubation causes raised HR, SBP&DBP due to sympathetic stimulation. In order to reduce hemodynamic fluctuations, studies are going on to develop various combinations of anaesthetic agents.[12]

Ketofol and etomidate are two routinely utilizedIV induction drugs. The hemodynamic steadinessnotedin regard to etomidate is due to its rare inability to act on baroreceptor function andsympathetic nervous system.[13]

As there were negative actions of propofol & ketamine on hemodynamics, combination of the two drugs at a lower dose can reduce the ill effect and add on advantages of individual drug.[14]

The inferenceof thisconducted study showsnearly similar hemodynamic steadinesswhileanaesthesia induction and intubation utilizing etomidate versus ketofol (p>0.05). Aghdaii N et al. conducted research to compare propofol-ketamine mixversus etomidate-midazolam mix onthehemodynamic effects. Theyreported that both were comparable and allowable for induction in given subjects(p>0.05).[15]

Habibi MR et al. reported that utilizing a ketamine-thiopental mix for anaesthesia inductiongives superior hemodynamic steadinessin contrast with etomidate (p<0.001) in patients with impaired ventricular function.[16]

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Yang et al. reported, in subjectshaving normal left ventricular function propofol brings down myocardial systolic& diastolic functions with vasodilation &fall in BP by bringing down sympathetic tone ($p<0.001$).[17] The myocardial depressant actioncan be related to change in the contractile function of the myocytes.[17, 18]Researches have shown that regardless of any underlying conditions, anaesthesiausing propofol is capable to decrease the blood pressure by 25% to 40%.[19]Combined administration of propofol and ketamine can minimize adverse effects.[20,21]The present research inferences are in line with this.

In given study, the hemodynamic response of etomidate versus ketofol for anaesthetic induction showed that both etomidate and ketofol produce stable hemodynamics and satisfactory induction conditions.

Singh R et al. [2] did research to differentiate the hemodynamic responses to propofol, etomidate, midazolam and thiopentone.They reported that no remarkablevariation in hemodynamic changes in these categories ($p>0.05$).

Aghdaii et al. stated, the hemodynamic steadiness using the mix made byetomidate& midazolam and combination of propofol and ketamine was comparable with no statistically remarkablevariation($p>0.05$). Safe&pleasantanaesthesia with limited a few side effects were observed with the combinations.[15] Given inference were same to manyanotherstudies [72-74]& addition of a less quantity of ketamine has been shown to lessen the act of cardiovascular depressing act of propofol.[22]

Pandey AK et al. [23] reported that etomidate is able to providemore stable hemodynamic parameters as it can prevent the cortisol flow on induction by temporarily suppressingthe synthesis of cortisol.($p<0.05$).

Baradari et al. [24] performed research to compare the action of etomidate, propofol-ketaminemix& thiopental-ketamine mix on hemodynamic responses. They found that the propofol-ketamine mix gives finer hemodynamic steadinessin comparison to the other categories ($p<0.05$). Saleem et al also reported, the amalgam of ketamine and propofol gives finer hemodynamic steadinessin contrast to mix made bypropofol and thiopental($p<0.05$).[25]

The inference of the present study is contradictory with the inference of Baradari AG et al. [12] possibly for the reason that the selection of patients was different as they had included subjects with compromising left ventricle, but in the present research, we tookgood condition patients (ASA Grade I & II).Abbasivash et al[19]reported thatmix of propofol-midazolam-ketamine provide better hemodynamic steadinesscompared to etomidate. The contradiction in inferencemay have arisen for moreinvolvement of midazolam to theketofolmix.

In our research 12 patients (30.0%) had myoclonus in etomidate group and no myoclonus was observed in ketofolcategory. This variation was statistically remarkable ($p<0.001$). This was in line with paststudies. [26-29]

Aghdaii et al also reported that only 10% of patients had myoclonus, due tobefore-treatment along with midazolam and lesser induction dosage of etomidate.[15]

In our research 15 patients (37.5%) had post-surgical nausea and emesis in etomidate group but only 3 patients (7.5%) had post-surgical nausea &emesis in ketofolcategory. This variation was statistically remarkable. Given finding was in line with the study of Singh et al. [2] who showed that etomidate causes more post-operative nausea & emesis as contrast to propofol.

The inference of research of Baradari AG et al. reported thatno one in propofol-ketamine group had post-surgical nausea and emesisand 30% in etomidate categoryand 10% in ketamine-thiopental groups had post-surgical nausea and emesis, respectivelyit can be due to the antiemetic action of propofol.[12]

Among major complications with propofol administration is pain on injection. The carrier (propylene glycol) carrying drug is identified as the reason for pain. But when etomidate is

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dissolved in lipofundin the pain is eliminated.[30] However, lesser pain on injection has been reported with aqueous solutions of propofol and etomidate.[31]
The findings of research of Aghdaiiet al. [15] shows utilization of etomidate (23.3%) increases chance of pain on injection in contrast to propofol (6.7%).

CONCLUSION

Both etomidate and ketofol are able to produce stable hemodynamic responses and induction conditions. Although a few incidents of side effects were observed, the quality of anaesthesia was pleasant, rapid, and safe. Throughout the surgery, no evidence of any hemodynamic fluctuations was noted. Hence both the drugs are reliable in induction and maintenance of anaesthesia. But, when cost effectiveness in a concern, especially in case of the patients from the poor background, ketofol is the drug of choice.

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