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Ketamine Alone versus Ketamine Propofol Mixture as an Induction Anesthetic Agent a Comparative Study -

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ABSTRACT

Ketofol is a relatively new idea for most medical practitioners. It is a mixture of ketamine & popofol. Ketofol has additive effects so that we can decrease the dose used from each drug and benefit from advantages regarding amnesia, analgesia, hypnosis, and hemodynamic stability while decreasing the side effects attributed to either drugs. Theoretically, the intrinsic antiemetic and anxiolytic effects of propofol could reduce emergence nausea and agitation from ketamine. Ketamine, with its propensity toward cardiovascular stimulation and preserved respiratory reflexes, could minimize the hypotension and respiratory depression associated with propofol. Ketofol proponents also argue that recovery is quicker and the potential for untoward side effects is smaller because each agent is given at less than full dose.

It is known that the mixture of ketamine & propofol in a polypropylene syringe is chemically stable, the agents are physically compatible &the mixture can be stored at room temperature with exposure to light.

The purpose of this study was to evaluate a single syringe ketofol (a 1:2 mixture of ketamine / propofol) as an induction anesthetic agent in emergency room compared to ketamine regarding its hypnotic criteria, hemodynamic parameters, respiratory parameters, and postoperative complication.

This study was carried out on 54 adult patients aging 18–60 years old, ASA I and II, presented for short procedures in emergency hospital in the patients were randomly classified into two equal groups, 27 patients each: -

K group: patients received 1.5 mg/ kg ketamine I.V. as an induction agent.

KF group: patients received a 1:2 mixture of ketamine/ propofol I.V.

(0.75mg/kg ketamine&1.5mg/kg propofol) in the same syringe.

Results: There were no significant differences in demographic data between the two groups as regards patients' age, sex, height, body weight, and ASA physical status. As regards hemodynamics, MAP remained comparable to baseline in KF group but increased in K group. There was minimal decrease in heart rate in KF group while it remained comparable to baseline in K group. Apnea had occurred more frequently in KF group than in K group. Patients in KF group took less time to sleep relative to K group. there was no significant difference between both groups as regard need of additional doses. There was equal number of patients who experienced postoperative pain. There was no significant difference according to mean of VAS between both groups. There was no significant difference between the two groups as regard PONV or postoperative hallucination.

Conclusion: A single-syringe mixture of ketamine and propofol in a 1:2 ratio is a safe, effective alternative induction anesthetic agent for patients undergoing short procedures in ED.

It provides excellent intra operative conditions, stable hemodynamics and respiratory parameters and post-operative analgesia with low incidence of PONV and post-operative hallucination.

INTRODUCTION

Ketamine is an intravenous anesthetic developed in 1960s from its precursor phencyclidine and its mode of action is through causing dissociative anaesthesia. Several advantages have been attributed to ketamine starting from its amnestic and analgesic effects, maintenance of muscle tone, protecting airway reflexes and spontaneous respiration [1]. However, ketamine has many side effects that limited its frequent use as an anesthetic. These side effects include nausea, vomiting, emergence hallucinations, elevation of blood pressure and heart rate due to its sympathomimetic effects additionally, it was presumed to increase intracranial pressure [2].

Propofol is a 2,6-diisopropylphenol which was developed in Europe in the 1970s. It produces general anesthesia by facilitation of inhibitory neurotransmission mediated by GABA. Its main advantages are its rapid induction and recovery, antiemetic effects, and anticonvulsant effects. Its main disadvantages lie in its dose dependent hypotension and respiratory depression [3].

Ketofol is a mixture of ketamine and propofol. Ketofol has additive effects so that we can decrease the dose used from each drug and benefit from advantages regarding amnesia, analgesia, hypnosis, and hemodynamic stability while decreasing the side effects attributed to either drugs [1].

Ketamine, with its propensity toward cardiovascular stimulation and preserved respiratory reflexes, could minimize the hypotension and respiratory depression associated with propofol. Ketofol proponents also argue that recovery is quicker and the potential for untoward side effects is smaller because each agent is given at less than full dose. It is known that the mixture of ketamine and propofol in a polypropylene syringe is chemically stable, the agents are physically compatible, and the mixture can be stored at room temperature with exposure to light [4].

AIM OF THE WORK

The aim of this work is to evaluate a single syringe ketofol (a 1:2 mixture of ketamine / propofol) as an induction anesthetic agent in emergency room compared to ketamine, regarding its hypnotic criteria, hemodynamic parameters, respiratory parameters, and postoperative complication.

PATIENTS AND METHODS

After approval of the ethical research committee in our institute, obtaining informed written consent from patients, this study was carried out on 54 adult patients aging 18-60 years old, ASA physical status I and II, presented for short procedures (less than 30 min. duration) in emergency theater, during the period from September 2018 to January 2020.

It is randomised controlled trial. Blindness to the treatment group involved the surgical and anesthesia teams. Sampling was done by physical method of randomization by using coin, front face for participate in the study, the other face for not participate in the study. Again use coin for allocation of subject in one arm of study, front face

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for Ketamine group, the other face for Ketofol group, until 27 subjects was selected in one arm so after that any participate will went directly to the other arm.The patients divided into 2 equal groups, each of 27 Patients:

Group (I): *n* = 27 patients (K group): patients received 1.5 mg/kg ketamine as an induction agent.

Group (II): Group II *n* = 27 patients (KF group): patients received a mixture of 0.75 mg/kg ketamine & 1.5 mg/kg propofol in the same syringe.

Inclusion criteria

- Age: 18-60 years.
- Sex: male & female.
- Physical status: ASA I & II.
- Patients undergoing short procedures.

Exclusion criteria

- Refusal of the patient.
- Patients with hemodynamic instability.
- Patients with history of allergy to drugs used.
- Patients with renal or hepatic impairment.
- Patients with history of epilepsy or signs of increased Intracranial Pressure (ICP).
- All patients were evaluated by taking full history, clinical examination, including airway evaluation using Mallampati classification, and by lab investigation including Complete Blood Picture (CBC), coagulation profile, liver functions and renal functions.

Monitoring

Standard monitors (Diascope G2 monitor) including 3 -leads electrocardiogram, non-invasive blood pressure and pulse oximetry were attached to the patient. Also, BIS electrodes were attached to the patient forehead all through the procedure and connected to a BIS Vista monitor.

Anesthetic technique

At the operating room, which is equipped with a complete airway and resuscitation cart, baseline vital parameters were recorded including Blood Pressure (BP), Heart Rate (HR), Oxygen Saturation (SpO2), and Bispectral Index (BIS). Anesthetic machine was checked.

Patients were randomized into two groups, 27 patients each,

Group K (ketamine).

Group KF (ketofol).

No premedication was given to the patients. Preoxygenation by face mask was supplied to patients.

Group K received intravenous ketamine(as ketamine hydrochloride 50 mg/ml, produced by Sigma –Tec pharmaceutical industries) in a dose of 1.5 mg/ kg over 20 s, 10 ml syringe contained 100 mg ketamine HCL (10 mg/ml) mixed with normal saline. Group KF received intravenous ketofol, prepared in a ratio of 1:2 in the same syringe as follows, a mixture of 0.75 mg/kg ketamine & 1.5 mg/kg propofol (propofol –lipuro 10mg/ml, produced by B/BRAUN) in a 20 ml syringe (without dilution) given over 20 s.

All patients the following parameters were measured:

- Assess time from inducing the patient till the patient sleep which is time needed for loss of verbal contact in seconds.
- Record intra operative hemodynamic (HR, MAP, &SPO2 every 5, 10, 15 minutes after induction of anesthesia.
- Record the need for additional doses of ketamine, propofol or inhalational anesthesia to achieve targeted BIS of (40-60) all through the procedure.
- Record any respiratory complications in the form of apnea, airway obstruction or spasm.
- Postoperative adverse events (e.g. nausea, vomiting and hallucination) were recorded.
- Usage of Visual Analogue Scale (VAS) for Postoperative pain as if "0" is no pain and "10" is severe pain.

Statistical analysis

Statistical analysis is done by SPSS win version 11. For categorical qualitative data the appropriate test for dependency & association is Chi-square (χ^2) test with significance of association is determined in both side so we consider test result is significant if Chi-square ($\chi 2$) is equal to or less than P/2 (0.05/2 or 0.025) & Highly significant if Chi-square ($\chi 2$) is equal to or less than 0.005 but if Chi-square ($\chi 2$) is more than P/2 (0.05/2 or 0.025), we consider result non significant. For quantitave data the appropriate test is Mann-Whitney U test for independent two groups of non-normality distributed data & Friedman test for dependent more than two groups of non-normality distributed data.

RESULTS

The current study included 54 patients who randomized into 2 equal groups, each is 27 patients: (K group): patients received 1.5 mg/kg ketamine as an induction agent. (KF group): patients received a mixture of 0.75 mg/kg ketamine & 1.5 mg/kg propofol in the same syringe. Parameters recorded were time to sleep, intra operative hemodynamic (HR, MAP & SPO2) need for additional doses of anesthetics, respiratory complication, postoperative pain using VAS and postoperative complication including nausea, vomiting and hallucination.

Table 1 shows that, there were no significant differences in demographic data between the two groups as regards patients' age, sex, height, body weight, and ASA physical status. Table 2 shows the distribution of studied groups according to surgical procedures.

Mean blood pressure (MAP)

- 5 minutes after induction, MAP increased significantly in K group while it remained comparable to baseline in KF group. The difference between groups was analyzed and found to be statistically significant.
- 10 minutes after induction, MAP started to decrease in K group & this decrease was statistically significant while it remained comparable to MAP after 5 minutes in KF group. The difference between groups was analyzed and found to be not statistically significant.
- 15 minutes after induction, MAP continued to decrease in K group & this decrease was statistically significant while

it started to decrease in KF group. The difference between groups was analyzed and found to be not statistically significant.

Heart rate

- At baseline heart rate was comparable between groups.
- 5 minutes after induction, heart rate decreased in KF group while it remained comparable to baseline in K group. The difference between groups was analyzed and found to be statistically significant.
- 10 minutes after induction, heart rate started to decrease in K group & this decrease was not statistically significant while it remained comparable to heart rate after 5 minutes in KF group. The difference between groups was analyzed and found to be not statistically significant.
- 15 minutes after induction, heart rate continued to decrease in K group & this decrease is statistically non-significant while it started to increase in KF group. The difference between groups was analyzed and found to be not statistically significant.

Oxygen saturation (SpO2)

- At baseline oxygen saturation was comparable between groups.
- 5 minutes after induction, oxygen saturation decrease in KF group while it remained comparable to baseline in K group. The difference between groups was analyzed and found to be statistically significant.
- 10 minutes after induction, oxygen saturation remained comparable in K group also remained comparable to oxygen saturation after 5 minutes in KF group. The difference between groups was analyzed and found to be statistically significant.
- 15 minutes after induction, oxygen saturation decrease in K group & this decrease is statistically not significant while it increases in KF group & this increase is statistically significant. The difference between groups was analyzed and found to be not statistically significant.

Time to sleep

Patients in K group showed higher readings which were statistically significant relative to KF group.

Additional doses

There was a significant difference in between both groups as regard additional doses need where the number of patients who required extra doses of ketamine or Ketofol was 6 *vs* 13 patients in K group and KF group, respectively.

Respiratory complications

Patients in KF group showed more apnea than K group while comparable airway obstruction.

Postoperative complications

- There were no significant differences between the two groups as regard number of patients who experienced postoperative pain.
- In K group, none of the patients experienced nausea & vomiting.

Table 1: Demographic data (data expressed as mean ± SD ratio).

Parameter	Group	
	Ketamine Group (*n* = 27)	Ketofol Group (*n* =2 7)
Sex (F / M)	17 / 10	18 / 9
Age (years)	30.26 ± 8.8	37 ± 12.3
Weight (Kg)	75.9 ± 14.2	76.8 ± 11.4
ASA grade (I / II)	23 / 4	20 / 7

- There were no significant differences between the two groups as regard postoperative nausea& vomiting (PONV) and

Table 2: Distribution of studied groups according to surgical procedures.

Type of procedure	Group	
	Ketamine Group (*n* = 27)	Ketofol Group (*n* = 27)
Amputation	0	2
Abscess	1	5
Evacuation of hematoma	0	1
Debriment	5	5
BM biopsy	1	1
Dressing	4	2
Removal of packs	0	1
Orthopedic procedures	4	3
Gynecologic procedures	12	7

Table 3: Comparison between Ketamine and Ketofol groups as regard MAP in mmHg (data expressed as mean ± SD).

MBP (mmHg)	Group		
	Ketamine Group (n = 27)	Ketofol Group (n = 27)	P value (MW)
Pre-induction	91.9 ± 11.8	89.3 ± 11.4	0.446
Post-induction 5 min	102.2 ± 14.2	91.2 ± 12.2	0.008 #
Post-induction 10 min	99.2 ± 14.8	95.8 ± 11.6	0.492
Post-induction 15 min	97.3 ± 14.2	95.3 ± 10.5	0.755
P value (F)	0.001*	0.020*	----

MW Mann-Whitney U test for two independent samples.
F Friedman test for more than two dependent samples.
*denotes significant in the same group, as demonstrated in table 8, 9.
#denotes significant difference in post-induction MAP at 5 min between both groups.

Table 4: Comparison between Ketamine and Ketofol groups as regard heart rate (HR) in beat/min (data expressed as mean ± SD).

HR (b/m)	Group		
	Ketamine Group (n = 27)	Ketofol Group (n = 27)	P value (MW)
Pre-induction	96.9 ± 15.8	98.1 ± 15.3	0.663
Post-induction 5 min	104.3 ± 19.1	91.8 ± 15.37	0.020 #
Post-induction 10 min	103.04 ± 19.2	91.4 ± 17.06	0.04
Post-induction 15 min	100.7 ± 18.8	92.5 ± 17.7	0.144
P value (F)	0.215	0.001*	----

MW Mann-Whitney U test for two independent samples.
F Friedman test for more than two dependent samples.
*denotes significant significant in the same group, as demonstrated in table 2.
# denotes significant difference in post-induction HR at 5 min between both groups.

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Table 5: Comparison between Ketamine and Ketofol groups as regard Oxygen saturation (SpO_2) in % (data expressed as mean ± SD).

SpO2 (%)	Group		
	Ketamine Group (*n* = 27)	Ketofol Group (*n* = 27)	*P* value (MW)
Pre-induction	97 ± 2.1	97.2 ± 2.4	0.533
Post-induction 5 min	97.4 ± 2.04	95.7 ± 3.1	0.017 #
Post-induction 10 min	97.4 ± 2.23	95.6 ± 2.4	0.008 #
Post-induction 15 min	96.7 ± 2.26	96.2 ± 2.6	0.571
P value (F)	0.287	0.002*	----

MW Mann-Whitney U test for two independent samples.
F Friedman test for more than two dependent samples.
*denotes significant in the same group, as demonstrated in table 5.
# denotes significant decrease in post-induction SpO2 at 5,10 min in KF group compared to K group.

Table 6: Comparison between Ketamine and Ketofol groups as regard time to sleep in seconds & number of patients who needed additional doses (data expressed as mean ± SD).

Parameter	Group		
	Ketamine Group (*n* = 27)	Ketofol Group (*n* = 27)	*P* value (MW)
Time to sleep (seconds)	61.1 ± 35.7	44.07 ± 27.3	0.018 #
Pts needed additional doses (n)	6	13	0.046*

MW Mann-Whitney U test.
# denotes significant decrease in time to sleep KF group compared to K group.
*denotes significant increase in number of patients who needed additional doses in KF group compared to K group.

Table 7: Comparison between Ketamine and Ketofol groups as regard respiratory and pain complications.

Complication	Group		
	Ketamine Group	Ketofol Group	*P* value (χ2)
Apnea	4	15	0.002 #
Airway obstruction	2	2	1
Pain	12	12	1

χ^2 Chi square test.
# denotes significant increase in apnea in KF group compared to K group.

Table 8: Comparison between Ketamine and Ketofol groups as regard postoperative pain degree (VAS).

VAS	Group		
	Ketamine Group (*n* = 27)	Ketofol Group (*n* = 27)	*P* value (χ2)
0	15	15	0.313
1	0	0	
2	0	2	
3	5	6	
4	3	1	
5	1	3	
6	0	0	
7	2	0	
8	1	0	
9	0	0	
10	0	0	

χ^2 Chi square test.

Table 9: Comparison between Ketamine and Ketofol groups as regard VAS.

Complication	Group		
	Ketamine Group (*n* = 27)	Ketofol Group (*n* = 27)	*P* value (χ2)
VAS	2 ± 2.5	1.5 ± 1.8	0.435

χ^2 Chi square test.

Table 10: Comparison between Ketamine and Ketofol groups as regard postoperative complications.

Complication	Group		
	Ketamine Group	Ketofol Group	P value (χ2)
PONV	0	4	0.038
Hallucination	7	5	0.513

χ^2 Chi square test.

hallucination (Table 1).

Surgical procedure

Table 2 -10

DISCUSSION

Propofol, a popular anesthetic agent, is a short-acting non-opioid, non-barbiturate, and sedative-hypnotic agent with rapid onset and short duration of action. It possesses antiemetic effects and reliably produces sedation. Its adverse effects include dose-related respiratory and cardiovascular depression and bradycardia. Propofol is known to be amnestic, but lacks analgesic effect and, therefore, is commonly combined with an analgesic agent [5].

Ketamine is a fast-acting dissociative anesthetic that produces a profound analgesic effect. It causes little or no respiratory or cardiovascular depression. However, it has some drawbacks such as the incidence of emergence reactions at increasing doses, which may include nightmares or vivid hallucinations [5].

In theory, the opposing hemodynamic and respiratory effects of these drugs might be complementary and minimize the overall adverse effects.The use of ketamine in combination with propofol (Ketofol) has been shown to decrease the dose of propofol required to achieve sedation, and is believed to result in less toxicity than that caused when either drug is used alone, because their complementary effects enable the use of lower doses of each drug [6].

Ketofol is a relatively new idea for most medical practitioners. However scientific literature demonstrated that a single-syringe mixture of ketamine and propofol appears to provide reliable, effective, deep sedation and analgesia with a short recovery time, low incidence of adverse effects, and a high degree of patient and provider satisfaction [7].

The present study included patients aging 18-60 years old, ASA(I) and (II) and a wide range of ED procedures .We compared the uses of a single-syringe mixture of ketamine and propofol in a 1:2 ratio (0.75 mg/kg ketamine & 1.5 mg/kg propofol) and ketamine (1.5 mg/kg) as induction anesthetic agents for short procedures in the emergency hospital.

In our study, as regards hemodynamics, MAP remained comparable to baseline in KF group but increased significantly in K group. There was minimal decrease in heart rate in KF group while

it remained comparable to baseline in K group. Similar results to our study were obtained by previous studies, as follows:

Abdellatif [8] who used different ketofol mixtures (ketamine/ propofol) 1:1 and 1:2 to provide sedation and analgesia for Transrectal Ultrasound Prostate Biopsy (TRUSP) patients.He stated that both groups were hemodynamically stable.

Another study conducted by Phillips, et al. [9] who compared the effect of ketofol (10 mg/mL concentration of ketamine & 10 mg/ mL concentration of Propofol) with propofol for patients undergoing joint dislocation reduction or fracture manipulation in ED .he found that ketofol group was more hemodynamically stable.

Doses of ketamine and propofol used in this study were lower than our doses. This may explain the difference between this study and our study.

Arora [3] recorded that hypoxia occurred in 2.6% of patients who received 1:1 mixture of propofol and ketamine. This lower incidence of hypoxia might be due to lower dose of propofol used which was 0.75 mg/kg.

On contrary, Aboeldahab, et al. [1] found that apnea did not occur in any case of KF group which might be explained by lower dose of propofol used (1 mg/kg) and a higher dose of ketamine (1 mg/ kg) than doses used in our study.

Regarding K group our findings are in agree with Miner [10] who showed that a larger proportion of adults receiving ketamine alone for moderate sedation in ED displayed signs of subclinical respiratory depression. On the other hand, Newton and Fitton [11] reported no cases of hypoxia when 92 patients of the ED received an initial dose of 0.5 mg/kg ketamine intravenously then 0.5 mg/kg after 5 min if sedation was inadequate. This finding might be due to low dose of ketamine used which also divided into 2 doses.

In the current study, Patients in KF group took less time to sleep proved by the time needed for loss of verbal response, relative to K group. Aboeldahab, et al. [1] supported this result as he found that KF group showed more rapid onset of clinical hypnosis than K group proved by the time needed for loss of verbal response and loss of eyelash reflex.

In this study, there was a statistically significant difference in between both groups as regard need of additional doses. Six patients of K group needed additional doses compared to thirteen in KF group.

Similar results were obtained by Erden, et al. [12] who Compared two ratios of ketofol; ketamine: propofol (1:1) versus (1:2) for interventional radiology procedures and found that patients who received 1:2 concentration required more propofol rescue doses. In another study by Singh, et al. [13] Children requiring sedation for Spinal anaesthesia before lower abdominal surgery were enrolled in double-blind trial that compared propofol 10 mg/mL with a combination of ketamine 2 mg/mL and propofol 8 mg/mL. After premedication with 0.5 mg/kg oral midazolam 30 minutes prior, study solutions were administered as a 0.2-mL/kg i.v. bolus dose followed by a 0.2-mL/kg/hr infusion. Additional 0.1-mL/kg i.v. bolus doses were administered for inadequate sedation.

The median number of additional bolus doses in the combination group (one dose; range, zero to two doses).

The number of additional bolus doses here is lower than in our study may be due to premedication with 0.5 mg/kg oral midazolam also may be due to a 0.2-mL/kg/hr ketofol infusion that followed the initial bolus dose.

In this study, there was equal number of patients (12 of each group) who experienced postoperative pain. There was no significant difference according to mean of VAS between both groups. This means that higher dose of ketamine used in K group, did not achieve more postoperative analgesia than KF group. These results are comparable to results of:

Daabiss, et al. [14] randomized 100 patients, undergoing procedural operations, into 2groups received i.v infusion of propofol: ketamine 1:1 (group I) or propofol: ketamine 4:1 (group II).He found that 4% of patients in group II had pain and 2%of patients in group I had pain. Also, Saeed [15] who assigned 90 patients into 3 groups, number of each is30. They received sedation solution using propofol (0.5 mg/kg/hr) and ketamine (0.5 mg/kg/hr) infusion mixture in 1:1 ratio (Group A), 2:1 ratio (Group B), and 3:1 ratio (Group C). He demonstrated that Patients received 2:1 ketofol infusion reported significantly higher satisfaction about both sedation and analgesia, while those received 1:1 were less satisfied because of higher postoperative pain, VAS scores and more requirement for rescue analgesia. On contrary, patients received 3:1 ketofol infusions were the least satisfied.

Recovery agitation and vomiting are adverse effects of ketamine that are of concern for many clinicians. The incidence of vomiting in adults receiving ketamine is reported to be between 5 and 15%, while the rate of problematic recovery agitation in adults receiving ketamine is estimated to be between 10 and 20% [7].

In current study There was no significant difference between the two groups as regard Post Operative Nausea and Vomiting (PONV) (1%in KF group &0%in K group). This goes with the results of Abdellatif [8] who reported that incidence of nausea was 2.9% &only one case of vomiting in patients who received a 1:1 mixture of (ketamine / propofol).

However, Aboeldahab, et al. [1] stated that none of the patients experienced PONV in KF group while only 2 patients experienced nausea in K group. Low dose of ketamine used in ketofol mixture in his study, beside patients were undergoing hernia repair operations, intubated were given general anaesthesia. This might explain little different results from ours.

In our study, no significant difference in postoperative complication as regards hallucination between both groups, seven patients of K group while five patients of KF group had postoperative hallucination. This result is consistent with:

Shah, et al. [16] who found there was no difference between ketamine monotherapy group and ketamine -propofol combination (1:1) group, as regards hallucination. Another study by Hashemi, et al. [17] conducted with an aim to compare the efficacy and the side effects of two various doses of Ketofol, equal amount of propofol and ketamine (1:1) or two parts of propofol plus one part of ketamine (2:1), in children with Acute Lymphoblastic Leukemia (ALL) undergoing BMA and Lumbar Puncture (LP), it was observed that, there was increased postoperative psychomimetic side effects with the largest ketamine dosage. Therefore, it was concluded that the adjunctive use of smaller dose of ketamine in Ketofol combination minimizes the psychomimetic side effects and shortens the recovery time.

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CONCLUSION

A single-syringe mixture of ketamine and propofol in a 1:2 ratio is a safe, effective alternative induction anaesthetic agent for patients undergoing short procedures in ED.

It provides excellent intra-operative conditions, stable hemodynamics and respiratory parameters and post operative analgesia with low incidence of PONV and post-operative hallucination.

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