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" *Comparison Between Propofol-Ketamine and Propofol-Thiopentone as a Sedative agent for bone marrow biopsy procedures* "

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Abstract

Background: Sedation and analgesia are currently commonly utilized for diverse types of short duration interventions as bone marrow biopsy. Bone marrow biopsy is necessary for the diagnosis, staging and follow up of haematological disease. The sedation is to reduce the pain and to ease the procedure performance, and satisfaction of patient and provider.

Aim: A comparative evaluation of anaesthetic drug combinations, propofol–ketamine versus propofol–thiopentone was conducted with a primarily focus on intraoperative parameters namely hemodynamic stability and sedation quality Secondary outcomes included recovery characteristics and cost efficiency.

Materials and Methods: This prospective randomized double-blind, clinical study incorporated thirty patients between 18-70 years old, divided into two equivalent groups randomly by closed envelope technique.

Group propofol-thiopentone (PT): they were given propofol 1% and thiopentone 2.5% mixture in the ratio 10 ml (100 mg) to 10 ml (250 mg), in single syringe.

Group propofol-ketamine (PK): they were given propofol 1% and ketamine 0.5% mixture in the ratio 10 ml (100 mg) to 10 ml (50 mg), in single syringe.

Heart rate and Mean blood pressure had been recorded preoperatively and at end of the procedure (procedure take only 10 minutes.) also four-point scale was used to assess injection pain. The Modified Aldrete Score was used for assessment of Recovery from sedation after 10 minutes, after the procedure end.

Results: In Group PT, Mean blood pressure and Heart rate values were 80.67±8.902 and 76.93±10.559 respectively, while in Group PK, Mean blood pressure and Heart rate values were 79.67±9.263 and 78.93±8.548 respectively. These results showed no statistical differences (P>0.05) between the two groups regarding the mean blood pressure and heart rate (P=0.765 and 0.573 respectively). Moreover, recovery scores and pain scale were (15.00 and 16.50 respectively) in Group PT, while in Group PK were (16.00 and 14.50 respectively). Consequently, there was no statistical differences (P>0.05) observed between the two groups, regarding recovery and pain on injection (P=0.630 and 0.291 respectively).

Conclusions: Both regimens demonstrated comparable outcomes across all parameters, with no significant differences observed in sedation depth, recovery time, or hemodynamic control. Therefore, both combinations exhibit favourable safety profiles, contribute effectively to hemodynamic stability, and offer notable cost-efficiency.
Keywords: Propofol, Thiopentone , ketamine , hemodynamic, recovery

Introduction

Sedation and analgesia are currently commonly utilized for several types of short duration interventions as bone marrow biopsy. Bone marrow biopsy is necessary for the diagnosis, staging and follow up of haematological disease. It also a key for diagnosis of non-haematological disorders such as storage disorders, infectious diseases and nonhematological malignancies infiltrating of the bone marrow. [(1)] The aim of the sedation is to reduce the pain and to ease the procedure performance, and satisfaction of patient and provider. [(2)] The ideal agent for sedation, should provide analgesia, amnesia, rapid onset, rapid recovery and safe with minimal adverse outcomes. No single agent could offer all these advantages, mixing various sedative, analgesic, drugs had been studied. [(3)]

In general anesthesia, propofol is broadly utilized induction drug and has numerous benefits, including quick onset, short duration, smooth and rapid recovery. Though, it can cause bradycardia and hypotension, which can cause instability in hemodynamics during anesthesia induction in cardiovascular risk patients. [(4)] propofol administration causes pain on injection and there had been multiple attempts to decrease its incidence, including pre-treatment with lignocaine or fentanyl or mixing with lignocaine, and using a large vein. [(5)]

Thiopental sodium, intravenous anesthetic drug, and an ultrashort-acting barbiturate, with brief period of action and fast onset due to redistribution of the drug. But thiopentone produce hangover sensation and impair fine motor abilities. Laryngeal spasm may happen after thiopentone induction which may be due to direct irritation of airway passages or stimulation of some areas which is more frequent in hyperactive airway disease patients. [(6)]

Ketamine is a sedative dissociative drug with quick onset and short duration. Unlike propofol, ketamine activates the sympathetic system, resultant in hypertension and tachycardia. This sympathomimetic and psychotomimetic consequences cause

ketamine to be unsuitable as a single agent in patients with cardiovascular disorders, high intracranial pressure, high intraocular pressure, and schizophrenia. [4]

Considerably, no intravenous anesthetic agent is ideal. Thus, the use of drug combinations often permitted a reduction in the dose of each individual agent, thereby diminishing the risk of adverse effects, allow rapid recovery, hemodynamic steadiness, and maintaining airway with negligible respiratory depression. [7,4,2]

Study objectives

A comparative evaluation of anaesthetic drug combinations, propofol–ketamine versus propofol–thiopentone was conducted.

primarily objectives

focus on intraoperative parameters namely hemodynamic stability and sedation quality.

Secondary objectives

Focus on recovery characteristics, pain on injection and cost efficiency.

Patients and methods

This prospective randomized double-blind, clinical study. After the approval of the medical ethical committee and after written informed consent from the patients, the study was conducted.

Thirty patients aged between 18-70 years old, with ASA (American Society of Anesthesiology) classification of I-II, and with no contraindication for conscious sedation scheduled for biopsy from bone marrow were included in this study.

Patients who had history of cardiovascular disease or endocrine or metabolic disease or had allergy to propofol, egg, soybean oil, ketamine and thiopentone Or patients with problems in communication. Or patients taking benzodiazepines, opioids, antihistamines, barbiturates, or other psychotropic agents. Or patients unable to provide informed consent. ASA III or more or patients with upper respiratory system infection, glaucoma, or patients taking regular opioids or sedation drugs. patients with

pain syndromes either acute or chronic; and patient with porphyria were excluded from this the study.

History taking, clinical examination and laboratory investigations was done for all patients on the day before operation. written informed consent was taken form patients before the procedure. No premedication was given.

Anaesthetic technique

Non-invasive blood pressure, electrocardiogram, and peripheral oxygen saturation had been monitored in the operation theater, securing an intravenous route using a 20-gauge cannula in the non- dominant hand, on dorsum and had been flushed with 0.9% normal saline.

Patients were divided into two equivalent groups randomly by closed envelope technique.

Group propofol-thiopentone (PT): they were given propofol 1% and thiopentone 2.5% mixture in the ratio 10 ml (100 mg) to 10 ml (250 mg), in single syringe.

Group propofol-ketamine (PK): they were given propofol 1% and ketamine 0.5% mixture in the ratio 10 ml (100 mg) to 10 ml (50 mg), in single syringe.

All solutions were at room temperature.

The drug admixture was injected till there was loss of consciousness.

Patients, Providers and Outcome Assessors were unaware of the specific treatment administered to prevent bias in reporting, eliminate performance bias and reduce detection bias respectively.

All syringes were labelled with coded identifiers, and administration followed a standardized protocol to maintain concealment.

Data collection was performed using pre-designed forms that did not disclose treatment groups.

Heart rate (HR) and Mean blood pressure (MBP) had been recorded preoperatively and at end of the procedure (procedure take only 10 minutes.)

also, the patient was inquired about the existence of injection pain. four-point scale was used to assess injection pain. [8]

0=no pain

1=mild pain (pain reported only in response to questioning)

2=moderate pain (pain reported in response to questioning and accompanied by a behavioural sign or pain reported spontaneously without questioning)

3=severe pain (strong vocal response or response accompanied by facial grimacing, arm withdrawal or tears). [8]

The Modified Aldrete Score was used for assessment of Recovery from sedation after 10 minutes, after the procedure end. The MAS is the standard post-anaesthetic recovery scoring system. patient discharge from the recovery room when MAS ≥9 was needed before. [9]

Motoric activity	
▪ Spontaneous movement when addressed	2
▪ Weak spontaneous movements when addressed	1
▪ No movement	0
Breathing	
▪ Coughs on comment or cries	2
▪ Keeps the airway open	1
▪ Obstructed airways	0
Blood pressure compared to reference measurement*	
▪ Δ < 20 mm Hg	2
▪ Δ = 20 – 50 mm Hg	1
▪ Δ > 50 mm Hg	0
Consciousness	
▪ Awake	2
▪ Response to stimulus, reflexes intact	1
▪ No answer, reflexes absent	0
Oxygen saturation	
▪ 100 - 98 %	2
▪ 97 - 95 %	1
▪ < 95 %	0

*Reference measurement was performed 1½ minutes after administration of the spasmolytic agent.

Although oxygen saturation was continuously monitored, it was not included as a formal outcome measure within the scope of this study. Nonetheless, no adverse events related to oxygen desaturation were observed.

The sample size

The sample size was determined based on a priori power analysis, taking into account an estimated effect size, a significance level (α) of 0.05, and a statistical power (1–β) of 0.80 to detect meaningful differences between groups. These parameters ensure sufficient sensitivity to identify true effects while minimizing the risk of Type II error.

Statistical analysis

Data were analyzed using the software statistical package SPSS for Window Version 25. Quantitative data (Age, mean blood pressure and Heart rate were evaluated using student t test and presented as means ± standard deviation (SD). Sex was analysed using chi-square(x2) test and were expressed as count and percentage. Recovery score and pain on injection were analyzed using Mann Whitney U test and expressed in mean rank. P-value <0.05 would consider significant unless stated otherwise.

Results

Thirty patients were included and analyzed in this study. The demographic data of the two groups were shown in Table 1. There was no statistical difference between two groups.

Table 1. Comparison between Group PT and Group PK on Demographic data of the patients. Age was expressed as mean± standard deviation with 95% CI lower and upper bound were supplied below between brackets respectively). Sex was expressed as count and percentage.

Measurement	Group PT (n=15)	Group PK (n=15)	P-value
Age	53.27 ±14.028 (45.50, 61.04)	55.07±9.787 (49.65, 60.49)	0.687
Sex	Male 9 (60.0%) Female 6 (40.0%)	Male 6 (40.0%) Female 9 (60.0%)	0.273

Chi square = 1.200

When comparing between the two groups regarding mean heart rate values (P=0.573) and mean blood pressure (P=0.765), that showed there was no statistical difference among two groups. (P>0.05) as shown in Table 2.

Table 2. Effect of Group PK and Group PK on MBP and HR measurements were assessed by student t test. (Data is presented as mean ± standard deviation; with 95% CI lower and upper bound were supplied below between brackets respectively).

Measurement	Group PT (n=15)	Group PK (n=15)	t-value	P-value
Preoperative				
MAP	82.73±9.407 (77.52, 87.94)	79.93±9.438 (74.71, 85.16)	0.814	0.423
HR	76.87±10.239 (71.20, 82.54)	79.13±8.717 (74.31, 83.96)	0.6530	0.519
At the end of procedure				
MBP	80.67±8.902 (75.74, 85.60)	79.67±9.263 (74.54, 84.80)	0.301	0.765
HR	76.93±10.559 (71.09, 82.78)	78.93±8.548 (74.20, 83.67)	0.570	0.573

MBP: mean blood pressure HR: heart rate

When analysed the recovery scores revealed that, there is no statistical difference among the two groups (P=0.630). About pain on injection, there was no significant difference among the two groups (P=0.291) (Table 3).

Table 3. Effect of Group PT and Group PK on Recovery score and pain scale measurements with scale range (9-10 recovery and 0-1 pain) evaluated by Mann Whitney U test. Data is expressed as mean rank.

Measurement	Group PT (n=15)	Group PK (n=15)	Z- value	P-value
Recovery score	15.00	16.00	0.482	0.630
Pain on injection	16.50	14.50	1.056	0.291

Furthermore, there is no adverse effect encountered during the procedure.

Discussion

Day-case anesthesia as bone marrow biopsy demand anesthetic drugs with a fast onset and recovery, with trifling adverse effects, acceptable depth, and with a minimal cost in developing countries. Different anesthetic drugs such as, propofol, midazolam, thiopentone fentanyl, and ketamine had been used for day case surgery, each having its own side effects. But thiopentone, ketamine, and propofol had got a unique role in practice. [10]

Propofol is judged as gold standard drug in surgeries. Ketamine had limited disadvantages as postoperative vomiting and nausea and emergence delirium Thiopentone is prototypic intravenous anesthetic induction drug with brief duration of action and quick onset resulting from redistribution of the drug. But it yields a hangover sensation on recovery and make worse fine motor abilities. Due to these problems, ketamine and thiopentone combination with propofol established an excellent alternative. [7]

Regarding Mean blood pressure remained steady following induction with Group PT and Group PK admixtures. It is reported in this study, that Mean blood pressure remained steady following induction with Group PK mixture, which may be due to Ketamine cause stimulation of myocardium and rise in systemic vascular resistance, thus increasing blood pressure (systolic and diastolic) counteracting the hypotension caused by propofol. [10]

In agreement with this study, Srivastava presented in their study that ketamine was effective in offsetting the haemodynamic depression of propofol by its sympathomimetic actions. Also, Hwang et al, showed that ketamine in combination with propofol during Fibreoptic bronchoscopy provides stability in hemodynamics. Moreover, Talisetti Jamuna T, Suraj K et al, reported in his study that ketamine propofol mixture administration was relatively superior in preserving the haemodynamic stability. [11]

Nevertheless, Furuya and colleague et al, their study reported slight increase in blood pressure instantly after intubation and 3 minutes after it. These results were not coherent with this study which may be due to stress of intubation. [12]

In agreement with this study, Kalpana S et al, reported that propofol thiopentone mixture produced steady heart rate and mean blood pressure than propofol. This was due to reduction in propofol dose being used during induction, with probably less effect on myocardium. [8]

When comparing heart rate among the two groups, did not show any changes significantly. Most of the authors attributed steady heart rate following induction with propofol-thiopentone or ketamine admixture to be multifactorial in origin and exact mechanism needs further evaluation. They attributed that the dose of propofol being used during induction had been decreased, with likely decreased effect on myocardium and afterload. In this study, our explanation that propofol causes bradycardia, due to its central vagal activity, Ketamine increase heart rate due to stimulation of myocardium, also thiopentone causes tachycardia. Consequently, propofol combination with ketamine and thiopentone counterweighs for bradycardia caused by propofol. [10]

Tho, other previous study reported increase in heart rate with propofol thiopentone admixture this could be attributed to anti-analgesic effect of thiopentone providing no guard against catecholamine released by painful stimulus. On the other hand, analgesia effect of ketamine could explain steady heart rate in propofol ketamine mixture. [12]

In agreement with this study, Furuya and colleagues stated that heart rate stayed unaffected following propofol–ketamine mixture induction which is also revealed by Ozkocak et al. [12]

Several approaches had been studied to decrease the occurrence of pain caused by injection of propofol with varying rate of success. These approaches include lignocaine addition, dilution of propofol, and many ways of mixing with ondansetron, opioids, thiopentone and ketamine with the propofol injection. [13]

The process of pain on propofol injection still unclear. Several mechanisms had been described. Scott et al advocated that the pain possibly due to direct irritation or an indirect consequence through the kinin cascade. It had proposed that propofol concentration in the aqueous phase might be a crucial factor for pain accompanying injection of propofol. Thus, by decreasing the propofol concentration in the aqueous

phase with intralipid, pain had been diminished. lately, Eriksson et al showed that the propofol pH altered after combining with 1% lignocaine. [13]

The cause of ketamine analgesic effect is not obvious. It had advocated that the way by which it lessens injection pain is due to effect on peripheral N-methyl-D-aspartate receptors. While this study recommend that pH alteration could have a superior part in reduction injection pain of propofol. The relationship between pH and the amount of ketamine used is an inversely which is analogous to propofol-lignocaine mixtures. Also, the Propofol thiopentone mixture might be less pain on injection because propofol had been diluted. The approach by which pain is diminished might be due to the high pH of the mixture leading to drive propofol from aqueous phase into lipid phase. [14]

In agreement with this study, Hwang J et al, reported that propofol-ketamine admixture was very efficient in reducing injection pain than pre-treatment with ketamine. [13]

In dissimilarity to this study, Koo et al stated that a propofol-ketamine admixture (ketamine 100 μg/kg) did not diminish propofol injection pain when compared with saline pre-treatment. But volume mixture ratio had not been explained in that study. [14]

Physiochemical stability and compatibility of mixing propofol with thiopentone or ketamine had been supported by previous studies.PH range between 6-8 is a good media for most pathogenic bacteria. The pH of propofol is 7.8 and combination of propofol with thiopentone increase the pH to 10.29 and pH of propofol-ketamine mixture is 5.4. The deviation of pH from this physiological range imparts bacteria growth in these admixtures. [8]

Thiopentone stored safely at room temperature for a minimum 24 hours and may be extended. Propofol-thiopentone mixture usage within six hours might not be mandatory thus prolonged self-life of propofol in developing countries. [14]

In agreement with this study, Cherin and Smiler used propofol-thiopentone mixture as an illustration of cost effectiveness, while having benefit of both drugs, as it could be stored for a day at operating theater room temperature, reducing wastage of drugs and consequently being more cost effectiveness. [11]

Emergence delirium or hallucinations, occur more frequently with ketamine when used as single agent for sedation. In our study, the mixture of propofol ketamine get rid of this drawback of ketamine. [13]

In agreement with this study, Amornyotin S, found that combination of ketamine and propofol had many advantages as good recovery, hemodynamic stability, and lack of respiratory depression. [8]

However, Coulter et al., had studied the propofol-ketamine mixture in various ratios for general anesthesia induction in paediatric age group. They found that, this mixture infusion could delay recovery, if the rate of infusion were not decreased. [7]

Recovery data gathered from patients who had enrolled in this study, showed that mixture of propofol with thiopentone did not delay recovery.

In agreement of this study, Chilvers M et al reported that all patients had been discharged from the ward without any delay, also there was no significant change in perceptual or psychomotor recovery between admixture of propofol thiopentone group and group of propofol lignocaine. Also, these data support by the results of Sanders et al using subjective and psychometric tests. [5]

However, Ahuja, et al reported in their study that recovery time had been earlier with propofol-thiopentone mixture when compared to propofol-ketamine mixture. [10]

Though, this study did not discuss the cost-effectiveness of these drugs, the estimation of the cost-effectiveness could improve the value of this study as well as the safety and effectiveness. [15]

Besides, the additive hypnotic effect of these agents might cause a financial benefit by decreasing the dose of propofol used with rapid recovery or early discharge. Although target of our work was not to study the comparability of the cost effectiveness of the mixtures, we reported reduction of cost in mixtures groups in comparison to propofol alone. [8]

Finally, when comparing mixing of propofol-thiopentone and propofol-ketamine to propofol alone, they prove well tolerability and effectiveness in hemodynamic

stability, dose adjustment, minimal adverse effects, and cost effectiveness without affection of recovery and discharge. [8]

Study limitations

However, this pharmacologic difference was clinically offset by the brief procedural duration and the implementation of a standardized postoperative pain management protocol across both groups. Notably, the focus of our investigation was limited to injection-associated pain rather than postoperative analgesia.

Conclusion

Both regimens demonstrated comparable outcomes across all parameters, with no significant differences observed in sedation depth, recovery time, or hemodynamic control. Therefore, both combinations exhibit favourable safety profiles, contribute effectively to hemodynamic stability, and offer notable cost-efficiency.

Declarations

Ethics approval and consent to participate

- The study was approved by the ethical committee of Faculty of Medicine, Alexandria University (IRB No. 00012098, FWA No. 00018699).
- Written informed consents were obtained from participants before inclusion
- All study related procedures were performed in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Availability of data and materials

The raw data supporting the conclusions of this article will be made Available by the corresponding author.

Competing Interests

The authors declare no competing interests.

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Authors' contributions

NA was involved in.:Conceptualization; Methodology; Project administration; Resources; Investigation; Supervision; Validation; Visualization; Writing - original draft; Writing - review & editing.

MW collected the data,

RA revised manuscript

All authors read and approved the final manuscript.

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