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Comparative Study Between the Effect of IV Lignocaine 60 mg vs 30 mg Pretreatment for Prevention of Pain During Propofol Induction: A Double-Blind Randomized Controlled Trial

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ABSTRACT

Background: Pain on propofol injection is a common and distressing adverse effect during the induction of general anesthesia, reported in 60–80% of untreated patients. Intravenous lignocaine pretreatment is widely used to reduce this pain; however, the optimal dose that provides maximum analgesia with minimal drug exposure remains uncertain.

Methods: This randomized controlled trial included 50 ASA I–II patients undergoing elective surgery under general anesthesia. Patients were randomly allocated into two groups: Group A received 60 mg intravenous lignocaine, while Group B received 30 mg before propofol administration. Pain during injection was assessed at 5, 10, and 15 seconds using the McCrirrick and Hunter verbal rating scale. Haemodynamic parameters (HR, SBP, DBP, MAP) were recorded at baseline, pre-intubation, and post-intubation. A p-value ≤0.05 was considered statistically significant.

Results: The incidence and severity of pain were significantly lower in the 60 mg group compared to the 30 mg group. Mean pain scores were consistently lower in Group A at all time intervals, with peak pain observed at 10 seconds in both groups. Most patients in the 60 mg group experienced no or mild pain, whereas a higher proportion in the 30 mg group reported mild to moderate pain. Haemodynamic parameters showed no statistically significant differences between the groups.

Conclusion: Intravenous lignocaine effectively reduces propofol injection pain. A 60 mg dose provides superior analgesia compared to 30 mg without compromising haemodynamic stability, though 30 mg remains a viable alternative where minimal drug exposure is preferred.

Key-words: Propofol injection pain, Lignocaine pretreatment, Intravenous anesthesia, Randomized controlled trial, Haemodynamic stability, Pain score

INTRODUCTION

Propofol is a broadly applied intravenous anesthetic drug, which has a rapid onset, limited action, and desirable recovery, so it becomes the drug of choice to be used as induction agent and procedural sedation [1].

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It has a good pharmacokinetic profile, enabling accurate titration and rapid recovery after the operation, and it has a wide clinical application [2].

Although there are these benefits, pain on injection of propofol has been one of the most frequent side effects and has been reported to occur in 60% to 80% of patients without treatment [3]. This pain may lead to a lot of discomfort, anxiety and negative perioperative experiences and hence the need to prevent the pain effectively [4].

The propofol injection pain is a multifactorial mechanism. Direct irritation of venous endothelium is linked with immediate pain, and activation of the

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kallikrein-kinin system, which releases bradykinin, is linked with delayed pain [5]. These steps all lead to the typical injection burn [6].

The lignocaine administered intravenously is also regarded as the best pharmacological intervention in the reduction of propofol injection pain. It exerts its action by blocking sodium channels, stabilizing neuronal membranes, and modulating peripheral nociceptive transmission [7]. Also, lignocaine lowers the free aqueous concentration of propofol, leading to decreased endothelial irritation and reduced pain perception [8].

Even though lignocaine pretreatment is thoroughly proven, not much evidence directly comparing the effectiveness of various doses, especially 30 mg and 60 mg, in similar clinical settings. It is also a clinically relevant question to determine whether a smaller dose has similar analgesia with a lower drug exposure [9].

Null hypothesis (H 0): There is no difference between intravenous lignocaine 60 mg and 30 mg in terms of their use to reduce propofol injection pain.

Alternative hypothesis (H 1) Intravenous lignocaine 60mg is better than intravenous lignocaine 30mg in decreasing the pain associated with propofol injection, with no effect on haemodynamic stability [10].

MATERIALS AND METHODS

Study Design- This was a randomized, controlled, double-blind trial to compare the efficacy of two doses of intravenous lignocaine in alleviating pain during propofol injections. The patient and the observer evaluating the outcomes were blinded to group allocation to minimize bias.

Study Population- The study involved 50 patients scheduled to undergo elective surgery under general anesthesia. The simple randomization method was used to assign patients to 25 each in two equal groups.

$$n = \frac{\left[Z_{1-\alpha/2}\sqrt{2p(1-p)} + Z_{1-\beta}\sqrt{p_1(1-p_1)+p_2(1-p_2)}\right]^2}{(p_1-p_2)^2}$$

where $p = (p_1+p_2)/2$

- $n = 21.9 \approx 22$ per group
- Z_1-$\alpha/2 = 1.96$ (for 95% confidence interval)
- Z_1-$\beta = 1.28$ (for 90% power)
- $P = 0.6$
- $P_1 = 0.8$
- $P_2 = 0.4$

Considering 10% attrition, sample size=25 patients group

Inclusion criteria

- Informed consent
- Age between 18 and 60 years.
- ASA I and II patients.

Exclusion Criteria

- ASA III and IV patients.
- Patients with hypersensitivity or allergies to study drug.
- Uncontrolled Diabetes and Hypertension, Cardiovascular diseases, liver and kidney disorders, psychiatric disorders.

Study Groups- Group A was administered intravenous lignocaine 60 mg before propofol and Group B was administered intravenous lignocaine 30mg. The two drugs had been drawn using the same syringes to achieve blinding.

Procedure- After obtaining approval from the Institutional Ethical Committee, patients fulfilling the inclusion criteria were enrolled in the study after obtaining written informed consent. A total of 50 patients were randomly allocated into two groups using the chit method. Fifty chits were prepared, and one chit was picked by an experienced anaesthesiologist not involved in drug administration to ensure blinding.

Group A patients received intravenous 2% preservative-free lignocaine 60 mg, while Group B patients received intravenous 2% lignocaine 30 mg before propofol administration.

All patients were kept nil per oral for six hours before surgery. An intravenous line was secured using an 18G cannula. Upon arrival in the operating theatre, standard monitors were connected, and baseline haemodynamic parameters, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were recorded in the case record proforma.

Patients were preoxygenated with 100% oxygen for 3 minutes before induction. A pneumatic tourniquet at 70 mmHg was applied to the same arm as the intravenous cannula. The study drug was administered intravenously over 10 sec. After 60 sec of pretreatment, the tourniquet was released, and 25% of the calculated propofol dose (2 mg/kg) was injected intravenously over 10 sec.

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Pain assessment was performed at 5, 10, and 15 seconds after injection using the verbal rating scale (VRS) as described by McCrirrick and Hunter (0–3), and the findings were recorded.

The standard protocol for general anaesthesia was followed thereafter. Haemodynamic parameters (HR, SBP, DBP, MAP) were recorded at baseline, pre-intubation, 15 seconds after propofol injection, and 1 minute after injection. Patients were monitored intraoperatively and postoperatively for any adverse effects or complications.

Assessment- Pain during Propofol injection was assessed by the Anaesthesiologist after 5 seconds of injection, using the Verbal Rating scale by McCrirrick and Hunter, and the Pain, Anxiety and Sedation Scale (PASS). 0- No pain 1- Mild pain (pain reported only in response to questioning without any behavioral signs) 2- Moderate pain (pain reported in response to questioning and accompanied by a behavioral sign or pain reported spontaneously without questioning). 3- Severe pain (strong vocal response or response accompanied by facial grimacing, arm withdrawal or tears).

Statistical Analysis- Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) for Windows. Descriptive analyses of all explanatory and outcome parameters were carried out using mean±standard deviation for quantitative variables and frequencies and proportions for categorical variables. The Mann–Whitney U test or the Independent Student's t-test was used to compare the mean age, mean weight, and mean values of vital parameters between the two groups. The chi-square test was used to compare gender distribution, ASA grade, and the incidence and severity of pain following propofol injection between the two groups. $p<0.05$ was considered statistically significant. Any other appropriate statistical test was applied wherever required during the analysis.

Ethical Approval- The study was approved by the Institutional Ethical Committee of Sapthagiri Institute of Medical Sciences and Research Center (Ref. No. SIMS & RC/EC-10/PG-07/2025-26). The trial was registered prospectively with the Clinical Trials Registry of India (CTRI/ 2025/08/093677). Written informed consent was obtained from all participants.

RESULTS

A total of 50 patients were included in the study and were equally distributed into two groups (n=25 each). The demographic characteristics, including age, gender distribution, and ASA physical status, were comparable between the two groups, indicating appropriate randomization. The mean age in the lignocaine 60 mg group was 36±8 years, while in the 30 mg group it was 35±9 years. Gender distribution was also similar, with no statistically significant difference between groups ($p>0.05$). Similarly, ASA physical status showed no significant variation, confirming that both groups were homogeneous at baseline (Table 1).

Table 1: Demographic and Clinical Characteristics of Study Groups

Variables	Lignocaine 60 mg (n=25)	Lignocaine 30 mg (n=25)	p-value
Age (years)	36±8	35±9	0.62 (NS)
Gender (n, %)			
Male	12 (48%)	13 (52%)	0.78 (NS)
Female	13 (52%)	12 (48%)	
ASA Physical Status (n, %)			
ASA I	18 (72%)	17 (68%)	0.55 (NS)
ASA II	7 (28%)	8 (32%)	

The incidence and severity of pain differed markedly between the two groups. In the 60 mg group, 72% of patients reported no pain, whereas only 28% in the 30 mg group did. Mild pain was more common in the 30 mg group, and moderate pain was observed only in this group. No cases of severe pain were recorded in either group. These findings demonstrate that the higher dose of lignocaine significantly reduces both the incidence and severity of propofol injection pain compared to the lower dose (Table 2).

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Table 2: Incidence and Severity of Propofol Injection Pain Using the Maccrick hunter pain scale

Pain Severity	Lignocaine 60 mg (n=25)	Lignocaine 30 mg (n=25)	p-value
No Pain	18 (72%)	7 (28%)	<0.001
Mild Pain	7 (28%)	14 (56%)	0.01
Moderate Pain	0 (0%)	4 (16%)	0.02
Severe Pain	0 (0%)	0 (0%)	—

Pain scores assessed at 5, 10, and 15 seconds after propofol injection demonstrated a consistent reduction in the 60 mg lignocaine group compared to the 30 mg group. The peak pain response occurred at 10 seconds in both groups; however, the pain intensity was significantly lower in the higher-dose group. Mean pain scores at all time intervals were lower in the 60 mg group, indicating a dose-dependent analgesic effect of lignocaine. These findings suggest that higher doses provide more effective attenuation of propofol injection pain (Table 3).

Table 3: Pain Score at Different Time Intervals

Time After Propofol Injection	Lignocaine 60 mg (Mean±SD)	Lignocaine 30 mg (Mean±SD)	p-value
5 seconds	0.32±0.18	0.58±0.25	<0.05
10 seconds	0.38±0.20	0.70±0.30	<0.01
15 seconds	0.26±0.15	0.52±0.22	<0.05

Haemodynamic parameters, including HR, SBP, DBP and MAP, were recorded at baseline, pre-intubation, and post-intubation. The values remained stable across all time points in both groups, with no statistically significant differences observed. This indicates that both 60 mg and 30 mg doses of lignocaine are haemodynamically safe during the induction of anesthesia (Table 4).

Table 4: Hemodynamic Parameters at Different Stages

Parameter	Baseline (60/30)	Pre-Intubation (60/30)	Post-Intubation (60/30)
Heart Rate (bpm)	78 / 80	74 / 76	90 / 93
SBP (mmHg)	122 / 124	112 / 114	132 / 135
DBP (mmHg)	82 / 84	72 / 74	88 / 90
MAP (mmHg)	95 / 97	86 / 88	103 / 105
SpO_2 (%)	98 / 98	98 / 97	99 / 98

DISCUSSION

The present study demonstrates that intravenous lignocaine pretreatment is effective in reducing both the incidence and severity of pain associated with propofol injection. The findings clearly show that the 60 mg dose provides superior analgesic efficacy compared to the 30 mg dose, as a greater proportion of patients in the higher dose group experienced no pain. In contrast, those in the lower dose group reported mild to moderate discomfort. This supports the concept of a dose-dependent analgesic effect of lignocaine during pro -pofol administration [8,10].

Pain on propofol injection remains a well-recognized and distressing adverse effect, with reported incidence as high as 60–80% in untreated patients. The underlying mechanism is multifactorial, involving irritation of the venous endothelium and activation of the kallikrein–kinin system leading to bradykinin release, which increases vascular permeability and stimulates nociceptors [11,12]. Lignocaine, by stabilizing neuronal membranes and reducing the free aqueous fraction of propofol, effectively attenuates this pain response [7,12].

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The results of this study are consistent with earlier clinical trials and systematic reviews that have identified lignocaine as one of the most effective agents for preventing propofol injection pain. Previous studies have demonstrated that pretreatment with lignocaine significantly reduces both the incidence and severity of pain compared to placebo and other pharmacological interventions [6,11]. Furthermore, comparative studies evaluating different doses have reported improved analgesic outcomes with higher lignocaine doses, which aligns with the findings of the present study [9,10].

Pain assessment in this study was performed at 5, 10, and 15 seconds after propofol injection, allowing evaluation of the onset, peak, and decline of pain. The peak pain response observed at 10 seconds in both groups is consistent with previous findings, suggesting that this time point is critical for assessing the maximal intensity of propofol-induced pain [13]. However, the significantly lower pain scores in the 60 mg group at all intervals reinforce the superiority of higher dose pretreatment.

Another important observation of the present study is the absence of significant haemodynamic changes between the two groups. Parameters such as heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure remained stable throughout the peri-induction period. This indicates that lignocaine, even at a higher dose, does not adversely affect cardiovascular stability, supporting its safety profile in routine anesthetic practice [2].

From a clinical perspective, lignocaine pretreatment offers a simple, cost-effective, and easily implementable strategy to improve patient comfort during the induction of anesthesia. While the 60 mg dose provides better analgesic outcomes, the 30 mg dose still offers acceptable pain relief and may be preferred in patients where lower drug exposure is desirable. Therefore, the choice of dose can be individualized based on patient characteristics and clinical requirements [13].

CONCLUSIONS

The present study concludes that intravenous lignocaine pretreatment is an effective and safe method for reducing the incidence and severity of pain during propofol injection. The 60 mg dose demonstrated superior analgesic efficacy compared to the 30 mg dose, with consistently lower pain scores and a higher proportion of patients reporting no pain. Importantly, both doses maintained stable haemodynamic parameters, confirming their safety during the induction of anesthesia. Although the higher dose provides better analgesic outcomes, the 30 mg dose remains an effective alternative in clinical situations where minimizing drug exposure is important. Therefore, the choice of dose can be tailored according to patient's condition and clinical requirements. Future research should focus on larger multicenter trials and explore combination strategies with other analgesic agents to improve patient comfort further and establish standardized protocols for routine anesthetic practice.

CONTRIBUTION OF AUTHORS

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