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A RANDOMISED CONTROLLED TRIAL OF ONDANSETRON AND LIDOCAINE FOR PROPOFOL INJECTION PAIN.

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ABSTRACT:

Introduction:

The induction of general anesthesia often results in discomfort due to the infusion of propofol. It has been reported that between 28% and 90% of people experience discomfort upon receiving an injection [1]. The best results were achieved by first administering lidocaine and then occluding the veins prior to injecting propofol. Pain relief from propofol injection was significantly affected by ondansetron. We postulated that giving ondansetron before injecting propofol would make the latter more bearable.

Methods:

After receiving clearance from the Institutional Ethics Committee of Shyam Shah Medical College Rewa (IECSSMC-137), a randomized controlled study was carried out. Between January 2020 and November 2023, we included 140 patients of both sexes having elective procedures under general anesthesia who had an ASA physical status of I to III and were between the ages of 18 and 65. Patients who did not receive propofol during induction due to an allergy, an allergy to ondansetron, lidocaine, or propofol, or cardiac arrhythmias were excluded from the study. Seventy-five individuals were randomly assigned to receive either 8 mg of ondansetron (Group A) or 40 mg of lidocaine (Group B). Postoperative nausea and vomiting (PONV) were evaluated, and patients were asked to quantify their discomfort at the injection site using a verbal numerical rating scale (VNRS).

Results:

There were no significant differences in gender, age, or BMI across the groups (Table 1). Table 2 shows that there was a statistically significant difference between the group A and group B in the percentages of those reporting no pain, mild discomfort, moderate pain, and severe pain. The incidences of nausea and vomiting after surgery did not vary significantly across the groups.

Conclusion:

Premedication with 8 mg of intravenous ondansetron before propofol induction did not significantly reduce the frequency or severity of discomfort after induction. Furthermore, there was no benefit to avoiding postoperative sickness.

Keywords: propofol; lidocaine; pain

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MANUSCRIPT

Introduction:

Propofol is the most often used intravenous anesthetic, and it may be used to produce general anesthesia or sedation during minor surgical operations. During the induction of a general anesthetic, however, injection discomfort is common and causes discomfort. The prevalence of injection pain is believed to be between 28 and 90% [1].

Propofol delivery in the forearm's antecubital fossa, a rapid injection of propofol, modifying the lipid emulsion form, and pretreatment with lidocaine, opioids, or NSAIDs have all been used to minimize the intensity of propofol pain. The most successful technique was pretreatment with lidocaine and vascular occlusion prior to propofol administration. This approach, however, is not therapeutically useful nor widely utilized [2]. In our practice, ondansetron is often utilized to prevent postoperative nausea and vomiting. According to Rahimzadeh P et al. [3], ondansetron had a significant influence on pain reduction after propofol injection when compared to placebo. Nonetheless, the findings of numerous trials were ambiguous, and the bulk of them combined pretreatment medications with venous ligation, which is unacceptable.

We hypothesized that ondansetron pretreatment would minimize the discomfort associated with propofol injection. The study's main goal was to assess the efficacy of 8 mg ondansetron against 40 mg lidocaine in minimizing propofol injection discomfort. The secondary goal was to compare the frequencies of nausea and vomiting after surgery in each group.

Methods:

The Institutional Ethics Committee of Sham Shah Medical College Rewa (IECSSMC-137), a randomized controlled study was carried out. Between January 2020 and November 2023, we included 140 patients of both genders, ASA physical status I-III, and ages 18-65, who were undergoing elective procedures under general anesthesia at Sanjay Gandhi Memorial Hospital Rewa. All patients provided written informed consent. Patients weighing less than 50 kg, who were allergic to ondansetron, lidocaine, or propofol, and who did not receive propofol during induction were all excluded from the study.

Using a computer program, all patients were randomly assigned to one of two groups. Each of the 70 patients in each group got either 8 mg of ondansetron (Group A) or 40 mg of lidocaine (Group B). Current analgesic medications were discontinued, and no premedication was administered. A 20-gauge intravenous catheter was inserted into the superficial vein on the dorsal side of the hand on the morning of the operation, and the patients received intravenous fluid infusion. In the operation room, the nurse-maintained track of demographic data. All of the patients were pre-oxygenated using a face mask and 100% oxygen. A 20-gauge intravenous catheter was placed on the hand dorsum, followed by a small dose of propofol (50 mg) administered by syringe pump at a rate of 600 ml/hr. for 30 seconds. The propofol syringe pump was then briefly switched off, and participants were asked to assess their pain at the injection site using a verbal numerical rating scale (VNRS), with 0 signifying no pain and 10 being the most severe pain. After that, the remaining propofol dosage was given, followed by opioids and

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neuromuscular blocking medications. Systolic and diastolic blood pressures, heart rates, oxygen saturation, and an electrocardiogram were all monitored and recorded during and after intubation. The postoperative nausea and vomiting (PONV) were evaluated by the post-anesthetic care unit.

The Statistical Package for Social Sciences (SPSS) version 13.0 computer software was used to analyze all of the data. The ANOVA F-test and the Kruskal-Wallis test were used to analyze continuous variables.

Fisher's exact test or the Chi-square test were used to examine categorical variables. The p value (0.05) was deemed statistically significant.

Results:

There were no significant variations in gender, age, or body mass index (BMI) across the groups (Table 1). No pain, mild (VNRS of 1-3), moderate (VNRS of 4-6), and severe pain (VNRS of 7-10) were also significantly different in group B (32.8 %, 40 %, 20%, and 7.1 %, respectively) when compared to the group A (14.4 %, 30%, 30.1%, and 24.4%, respectively) (P = 0.01). There were no significant variations in postoperative nausea and vomiting rates between the two groups, and no patients reported any significant problems.

Table 1- Demographic data

Variables	Group A ($n = 70$)	Group B ($n = 70$)	P value
Age (years)	51.5	50	0.254
Gender Male; n (%) Female; n (%)	 23(32.8%) 47(67.2%)	 24(34.2%) 46(65.8%)	 0.864
BMI (kg/m^2); mean	23.4	24.3	0.458

Table 2- comparison of the severity of the propofol injection pain in both groups

Pain severity, *n* (%)	Group A ($n = 70$)	Group B ($n = 70$)	P value
No Pain	10(14.4%)	23(32.8%)	0.01
Mild	21(30%)	28(40%)	
Moderate	22(30.1%)	14(20%)	
Severe	17(24.4%)	5(7.1%)	

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Discussion:

Pretreatment with 8 mg ondansetron did not reduce the incidence or intensity of propofol injection discomfort when compared to pretreatment with 40 mg lidocaine in this study. Propofol induces pain by directly and indirectly stimulating afferent nerve terminals in the venous endothelium through the Kinin cascade. Prostaglandin E2 (PGE2) is produced when the Kinin cascade is engaged, resulting in local vasodilation and increased vascular permeability. As a consequence, propofol and free nerve terminals are more often in touch [4]. In a meta-analysis, Pei and colleagues discovered that ondansetron, a unique 5-HT3 antagonist, may effectively reduce propofol injection discomfort when used in combination with the occlusion approach, with efficacy similar to magnesium sulphate and lidocaine [5]. In our investigation, the efficacy of pain relief with ondansetron and lidocaine was lower than in previous trials. The absence of utilization of the venous occlusion approach in our investigation might be the cause. The direct irritating effect of propofol on the inner wall of blood vessels may activate pain-transmitting nerve fibres, which might be the main or major mechanism of injection pain.

Furthermore, lidocaine's primary mechanism of action as a local anesthetic medication is the blockage of voltage-gated sodium channels, which inhibits direct activation of afferent nerve terminals after propofol injection by preventing action potential propagation. As a consequence, when lidocaine was delivered for an extended period of time during the venous stasis produced by tourniquet occlusion, the direct analgesic action of the medication was more effective [6]. In animal models, ondansetron has previously been found to block sodium channels and serotonin (5-HT3) receptors [7]. According to our hypothesis, ondansetron's decreased analgesic properties owing to sodium channel blockage were not the principal action of ondansetron. Furthermore, unlike ondansetron, local anesthetics contain hydrophilic and hydrophobic structures separated by an intermediate amide or ester link. As a consequence, even after increasing the dosage to 8 mg, ondansetron's efficacy may have decreased. In comparison to prior studies, this one showed a lower incidence of propofol pain. The cause might be the variable quantities of propofol administered to patients before to pain assessment. In our trial, each patient got 50 mg of propofol, which was 1/4 the induction dosage, which had previously been changed in each patient.

A research constraint was the administration of a sub-hypnotic dose of propofol prior to pain assessment. As a consequence, establishing a valid pain assessment may be difficult.

Conclusion:

When compared to 40 mg intravenous lidocaine pretreatment, preparation with 8 mg intravenous ondansetron before induction did not significantly reduce the occurrence and severity of propofol-induced discomfort. Furthermore, there was no benefit to avoiding nausea and vomiting following surgery.

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