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A RANDOMIZED CONTROLLED TRIAL COMPARING ONDANSETRON AND LIDOCAINE FOR REDUCING PROPOFOL INJECTION PAIN.

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ABSTRACT **Introduction:** Propofol injection pain is common and causes people to suffer during general anesthetic induction. The incidence of injection pain has been estimated to range between 28 - 90% [1]. Pretreatment with lidocaine and venous occlusion before propofol injection proved to be the most effective strategy. Ondansetron had a substantial influence on pain reduction following propofol injection. We hypothesized that pretreatment with ondansetron would reduce the pain associated with propofol injection. **Methods:** A randomized controlled trial was conducted after approval by the Institutional Ethics Committee of Sham Shah Medical College Rewa (IEC-SSMC-150). We recruited 150 patients of both genders, American Society of Anesthesiologists physical (ASA) status I–III, and aged between 18–65 years old, undergoing elective surgeries under general anesthesia between November 2020 to November 2021. Patients who weighed less than 50 kg, were allergic to ondansetron, lidocaine, or propofol, and had cardiac arrhythmias, who did not receive propofol for induction, were all excluded from the study. Each group of 75 patients received either 8 mg. of ondansetron (Group RDO) or 40 mg. of lidocaine (Group RDL). Patients were asked to rate their pain at the injection site using a verbal numerical rating score (VNRS), The post-anesthetic care unit assessed postoperative nausea and vomiting (PONV). **Results** There were no significant differences between the groups in terms of gender, age, and body mass index (BMI) (Table 1). The incidences of no pain, mild, moderate, and severe pain were also significantly different in the RDL group (33.3 percent, 40 percent, 21.3 percent, and 5.3 percent, respectively) when compared to the RDO group (14.5 percent, 30.6 percent, 30.6 percent, and 14.2%respectively) (P = 0.01) (Table 2). There were no significant differences in the rates of postoperative nausea and vomiting among the two groups In conclusion preparation with 8 mg. intravenous ondansetron before induction did not significantly lower the incidence and intensity of propofol-induced pain. Also, there was no advantage to preventing nausea and vomiting after surgery.

KEYWORDS :

Introduction:

Propofol is the most often used intravenous anesthetic medication, and it can be used to induce general anesthesia or sedation during short surgical procedures. However, injection pain is common and causes people to suffer during general anesthetic induction. The incidence of injection pain has been estimated to range between 28 - 90% [1]. Propofol administration at the antecubital fossa of the forearm, a quick injection of propofol, changing the lipid emulsification form, and preparation with lidocaine, opioids, or NSAIDs have all been utilized to reduce the severity of propofol pain. Pretreatment with lidocaine and venous occlusion before propofol injection proved to be the most effective strategy. However, this method is neither clinically applicable nor extensively used [2]. Ondansetron is commonly used in our practice to avoid postoperative nausea and vomiting. Ondansetron had a substantial influence on pain reduction following propofol injection when compared to placebo, according to Rahimzadeh P et al. [3]. Nonetheless, several studies' findings were equivocal, and the majority of them coupled pretreatment medicines with venous occlusion, which is not acceptable.

We hypothesized that pretreatment with ondansetron would reduce the pain associated with propofol injection. The primary outcome of this study was to compare the efficacy of 8 mg ondansetron to 40 mg lidocaine in reducing propofol injection pain. The secondary objective was to compare the rates of nausea and vomiting post-surgery in each group.

Methods

A randomized controlled trial was conducted after approval by the Institutional Ethics Committee of Sham Shah Medical College Rewa (IEC-SSMC-15) in accordance with the Declaration of Helsinki (1964). we recruited 150 patients of both genders, American Society of Anesthesiologists physical (ASA) status I–III, and aged between 18–65 years old, undergoing elective surgeries under general anesthesia in Sanjay Gandhi Memorial Hospital Rewa, between November 2020 to November 2021. Written informed consent was taken from all the patients. Patients who weighed less than 50 kg, were allergic to ondansetron, lidocaine, or propofol, and had cardiac arrhythmias did not receive propofol for induction, were all excluded from study. All patients were randomly allocated into 2 groups by simple random sampling with the computer program. Each group of 75 patients received either 8 mg. of ondansetron (Group RDO), 40 mg. of lidocaine (Group RDL). The current analgesic medicines were stopped and no premedication was given. On the morning of the surgery, a 20-gauge intravenous catheter was placed into the superficial vein on the dorsal aspect of the hand, and the patients underwent intravenous fluid infusion. The nurse kept track of demographic data in the operating room. All of the patients were pre-oxygenated with 100% oxygen given using a face mask. Patients received study medicines by a 20-gauge intravenous catheter inserted on the hand dorsum, followed by a modest dosage of propofol (50 mg) delivered via syringe pump at a rate of 600 ml/hr. for 30 seconds. Following that, the propofol syringe pump was momentarily turned off, and patients were asked to rate their pain at the injection site using a verbal numerical rating score (VNRS), with 0 representing no pain and 10 being the most severe pain. The remaining propofol dose was then administered, followed by opioids and neuromuscular blocking drugs. During induction and after intubation, systolic and diastolic blood pressures, heart rates, oxygen saturation, and an electrocardiogram were all monitored and recorded. The post-anesthetic care unit assessed postoperative nausea and vomiting (PONV).

All the data were analyzed using Statistical Package for Social Sciences (SPSS) version 13.0 computer software. Continuous variables were analyzed by ANOVA F- test, and Kruskal–Wallis test. Categorical variables were analyzed by Fisher's exact test or Chi-square test. p value (<0.05) was considered statistically significant.

Results:

There were no significant differences between the groups in terms of gender, age, and body mass index (BMI) (Table 1). The incidences of no pain, mild (VNRS of 1–3), moderate (VNRS of 4–6), and severe pain (VNRS of 7–10) were also significantly different in the RDL group (33.3 percent, 40 percent, 21.3 percent, and 5.3 percent, respectively) when compared to the RDO group (14.5 percent, 30.6 percent, 30.6 percent, and 14.2%respectively) (P = 0.01) (Table 2). There were no significant differences in the rates of postoperative nausea and vomiting among the two groups, and none of the patients experienced any significant complications.

Discussion:

In this study, we discovered that pretreatment with 8 mg ondansetron did not lessen the occurrence or severity of propofol injection pain when compared to pretreatment with 40 mg lidocaine.

Propofol causes pain by irritating afferent nerve endings in the venous

endothelium directly and indirectly through the Kinin cascade. When the Kinin cascade is activated, prostaglandin E2 (PGE2) is released, causing local vasodilation and enhanced vascular permeability. As a result, propofol and free nerve endings come into contact more frequently [4]. Pei and colleagues did a meta-analysis and found that ondansetron, a unique 5-HT3 antagonist, can successfully prevent propofol injection pain when used in conjunction with the occlusion technique and that the efficacy is comparable to magnesium sulfate and lidocaine [5]. In our study, the efficacy of pain alleviation in both the ondansetron and lidocaine groups was inferior to prior studies. The explanation could be owing to the lack of use of the venous occlusion technique in our study. The activation of pain-transmitting nerve fibers as a result of propofol's direct irritant action on the inner wall of blood vessels could be the primary or principal mechanism of injection pain. Furthermore, the main mechanism of action of lidocaine as a local anesthetic drug is the inhibition of voltage-gated sodium channels, which prevents direct stimulation of afferent nerve terminals following propofol injection by blocking action potential propagation. As a result, the direct analgesic effect of lidocaine was more effective when the drug was administered for a long enough time during the venous stasis caused by tourniquet occlusion [6]. Ondansetron has previously been shown to inhibit sodium channels and serotonin (5-HT3) receptors in animal models [7]. Ondansetron's weaker analgesic characteristics due to sodium channel inhibition were not the primary action of ondansetron, according to our hypothesis. Furthermore, local anesthetics have hydrophilic and hydrophobic structures separated by an intermediate amide or ester bond, which ondansetron lacks. As a result, even after raising the dose to 8 mg, ondansetron may have reduced efficacy. When compared to previous research, this one had a reduced rate of propofol pain. The varying amounts of propofol given to the patients before to pain evaluation could be the reason. In our study, every patient received 50 mg of propofol, which was 1/4 times the induction dose, which was varied in each patient in the prior studies.

The delivery of a sub-hypnotic dosage of propofol before pain evaluation was a study limitation. As a result, determining a reliable pain evaluation might be difficult.

Conclusion:

When compared to pretreatment with 40 mg. intravenous lidocaine, preparation with 8 mg. intravenous ondansetron before induction did not significantly lower the incidence and intensity of propofol-induced pain. Also, there was no advantage to preventing nausea and vomiting after surgery.

Tables

Table 1- Demographic data

Variables	Group RDO (n = 75)	Group RDL (n = 75)	P value
Age (years)	51.5	48	0.214
Gender Male; n (%) Female; n (%)	25(33.3%) 50(66.6%)	22(29.3%) 53(70.7%)	0.876
BMI (kg/m2); mean	23.2	24.5	0.568

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

Pain severity, n (%)	Group RDO (n = 75)	Group RDL (n = 75)	P value
No Pain	11(14.6%)	25(33.3%)	0.01
Mild	23(30.6%)	30(40%)	
Moderate	23(30.6%)	16(21.3%)	
Severe	18(24.2%)	4(5.3%)	

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