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A Comparative Evaluation Of 6% HydroxyEthyl Starch Versus 2% LignocainePre-Administration for Reducing Propofol Injection Pain: A Randomized Controlled Trial

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SUMMARY
A randomized double-blind study was conducted to compare two pre-administration regimens for preventing the pain of propofol injection. 6% HES pre-administration was compared with 2% Lignocaine (diluted with 0.9%NS)pre-administration IV.Patients were divided into two treatment groups of 63 patients each.50ml of 6% HES pre-treatmentor50 ml of (4 ml of 2% Lidocaine with 46ml saline) were followed by 1% propofol IV. Pain assessment was done using a 100 mm visual analogue scale during induction and in recovery. The incidence of injection pain was 29% in the HES group, and 52% in the lignocaine pre-treatment group. This difference is statistically significant (P=0.018). Incidence of severe (0.5 % vs 6%) and moderate pain (4% vs 12%) was also lesser in the HES group, while the incidence of mild pain was comparable (31% vs 27%)inthe HES vs L group. Lignocaine pre-treatment does not improve the immediate or delayed comfort of patients during propofol induction when compared to HES. It is concluded from our study that Hydroxy Ethyl Starch should be pre-administered for induction with propofol.

Key Words*: Intra venous,Propofol,Hydroxy Ethyl Starch,Lignocaine,Pain*

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I. Objective:

To evaluate and compare the effect of 6% Hydroxyethyl starch (HES)and 2% Lignocainepre-administration on propofol injection pain.

II. Background:

Propofol is one of the most commonly used induction agents, but the reported incidence of pain on its intravenous injection is considerably high ataround 30-90%. [1].It is mainly attributed to the Phenol moiety of propofol. Immediate pain is caused due tothe Irritation of veinswhereas kininrelease causesdelayed pain [1]. [1,2,3]Many approaches have been used to allay this pain but no breakthrough has been achieved yet.[1]

Colloids, which have been safely used for long for fluid replacement[4],have the capacity as macromolecules, to modify endothelial cell junctions. They act by inhibiting the endothelial contact activation by various substances and molecules. [5,6] Therefore, pre-administration of colloids may, thereby reduce pain during injection.

Lignocaine probably due to a direct effect of local anesthetics on vascular smooth muscle helps in reducing the local site pain. It may also reduce pain at the more proximal sites [7] as it is a weak free base–cation solution which, after exposure to lipids, liberates protons (as the free base dissolves in the lipids);This results in a fall ofthe pH of the mixture; as a result, an increased amount of propofol migrates into the lipid phase leading to reduced pain on injection.[7]

We thereforepostulated that the pre-administration of 6% hydroxyethyl starch (HES) or 2% Lignocaine will reduce pain on propofol injection and weaimed to evaluate and compare the effect of their pre-administration on pain due to propofol injection during induction.[8]

III. Methods:

A prospective randomized double-blind study was carried out after the approval of the Institutional Ethics Committee and written informed consent.

The primary objective of our study was to compare and evaluate the incidence of pain due to propofol injection in patients receiving 6% HES vs.2% Lidocaine pre-administration; the secondary objective was to compare the severity of propofol injection pain in the two groups

ASA physical status I and II patients 18-65 years of age, posted for elective surgery under general anaesthesia in our institute were recruited for this study. Exclusion criteria were emergency surgeries, known history of allergy to propofol, HES or Lidocaine, those on opioids preoperatively, and those in whom the dorsum of the hand vein was not accessible.

126 adult patientsundergoing elective surgery under general anaesthesia were enrolled in this study of which 124 patients completed the study. Premedication was not administered.Patients were randomized into two groups,

Group H (n=62) received 50 ml HES 6% pre-administration, followed by propofol, and Group L (n=62) received 46ml saline with 4 ml of 2% lignocaine pre-administration followed by IV propofol.

An 18-gauge cannula was inserted in the dorsum of the hand. Randomization was carried out using a computer-generated random number sequence. Allocation concealment was carried out with opaque sealed envelopes. The agents were taken ina 50 mL syringe by an anaesthesiologist blinded to the study and then administered by the other to the patient over two to five minutes. Patients were randomized to receive a 50 mL bolus of either HES or Lidocaine with NS before propofol injection.

After the 50 mL bolus, an induction dose of 1% propofol was then given to the patient, till loss of verbal response. After induction and confirmation of mask ventilation, intravenous fentanyl and vecuronium were administered. A tourniquet was not applied over the injectant arm.Pain during propofol injection was assessed every 10 seconds till the loss of verbal response. Pain severity was studied as

0-No pain

1-Mild Pain (evident on questioning after 10 seconds without any obvious discomfort)

2-Moderate Pain, Self-reported within 10 seconds with some discomfort

3-Severe pain accompanied by withdrawing of hand, Facialgrimace/Wincing and/or Howling/Crying Pain during propofol injection was assessed every 10 seconds till the loss of verbal response

The data was checked for normal distribution.Continuous variables in the two groups were compared with the unpaired *t*- test and Categorical variables were compared with Pearson's Chi- square test. Significance was set at $P < 0.05$.Data were analyzed by using R (R studio 3.5, Vienna,Austria)

IV. Results

One hundred and twenty-six patients were recruited, of which 124 patients completed the study [62 in the H group and 62 in the L group]. Two patientscould not complete the study. The demographic characteristics were comparable in the two groups. Overall, the incidence of pain was significantly higher in the L group compared to the H group (52% vs 29%; P = 0.018); relative risk 1.53, 95% confidence interval 1.13-2.09). The incidence of severe (6% vs 0.5%) and moderate pain (12% vs 4%) was higher in the L group, while the incidence of mild pain was comparable (31% vs 27%)in the L vs HES group. A significant difference was seen as well in the severity of pain between the two groups (no pain-mild pain vs moderate-severe pain) (P = 0.002).

We concluded that as compared to the pre-administration of 2% Lignocaine,50 mL of 6% HES, pre-administered before injection propofol, significantly decreases the pain on injection

V. Discussion:

We observed that pre-administration of 50 mL HES reduced the incidence as well as the severity of pain on propofol injection in adults.[9] Other agents and interventions that have been studied and found to be efficacious are, lidocaine-propofol admixture, ketamine, opioids, non-steroidal anti-inflammatory drugs,[9] steroids (methylprednisolone) [10] and (5-HT3) antagonists (ramosetron, ondansetron) [11]. Pretreatment with opioids and 5-HT3 antagonists is more effective than placebo in decreasing propofol injection pain.[12] Amongst opioids, meperidine 40 mg administered with a tourniquet has an NNT of 2.7 in adults. [9] Our study found that the pre-administration of lignocaine does not significantly decrease the incidence of pain on induction with propofol despite the theoretical assumption of a longer time to act on the vein before the propofol exposure. This suggests that the pain may not be caused by direct nerve stimulation by the propofol but rather as a secondary effect possibly by endothelial or smooth muscle stimulation which is better taken care of by colloid pre-administration. This study supports the pre-administration of 6% HES as the more effective way of providing analgesia during induction] Our results for the NNT with HES (4) [8] are similar to injection pain relief with opioid pretreatment such as alfentanil, fentanyl and lesser than the NNT with Lignocaine pre-administration (4.3) [13].

Limitations of our study were an arbitrary selection of 4 ml of 2% Lignocaine with 46 ml of normal saline and 50 ml volume of Hydroxyethyl starch.

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