# DOUBLE BLIND PLACEBO CONTROLLED STUDY ON "EFFICACY OF LIGNOCAINE PRETREATMENT IN REDUCING PAIN DURING INJECTION OF PROPOFOL" IN PATIENTS UNDERGOING ELECTIVE MAXILLOFACIAL SURGERIES

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### ABSTRACT

This study was undertaken to evaluate the incidence and severity of pain on Injection of Propofol and to find the efficacy of lignocaine pretreatment in reducing such pain.

150 patients undergoing different Maxillofacial Surgeries with American Society of Anesthesiologists class 1 and 2 (ASA 1 and 2) were randomly allocated in two groups, Group A (Saline group) and Group B (Lignocaine group) who received saline and lignocaine as pretreatment respectively. Another anesthetist who was blinded to study recorded pain on a 4-point pain scale.

The incidence of pain on giving Propofol was 57.33%. There was reduction of pain by 32% in the patient group who received Lignocaine pretreatment.

It was concluded that lignocaine is an effective measure to decrease the incidence and severity of pain on injection of Propofol.

**Key words:** Pain, Propofol, Lignocaine Maxillofacial surgery

# INTRODUCTION

Propofol (2, 6 di Isopropyl phenol) is a rapidly acting induction agent and has many characteristics of an ideal anesthetic agent with low incidence of excitatory side effects. <sup>1</sup> It is also used an antiemetic<sup>2</sup>, intubating agent without neuromuscular blockers<sup>3</sup>, intravenous conscious sedation and as a part of balanced intravenous anesthesia. <sup>4</sup> Pain on injection is the most common side effect of Propofol ranging from 28% to 90. <sup>5</sup>

The cause of pain during injection is thought to be due to direct stimulation of nociceptive receptors or free nerve endings of the venous walls. Injection into large antecubital veins decreases the incidence of pain but there is a risk of inadvertent injection to brachial artery.<sup>6</sup>

Lignocaine mixed with Propofol have been found to decrease the pain of Propofol injection.<sup>7</sup> The mechanism of action of lignocaine in reducing such pain is controversial. It is presumed that it can be due to local anesthetic action, stabilizer of Kinin cascade or due to reduction of Propofol PH.<sup>8</sup>

# METHODOLOGY

This study was conducted on 150 patients belonging to American Society of Anesthesiologists Class 1 and 2 (ASA 1 and 2) who underwent elective maxillofa-

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cial surgeries at a tertiary Care Hospital. The study was conducted after the approval given by the Hospital Ethics Committee. These groups of patients were selected because the first two authors of present study were having special interest in anaesthetizing the patients for maxillofacial surgical procedures and were experienced in managing difficult airways. Patients with liver and renal dysfunction, history of allergy to local anesthetics and egg allergy and who refused to participate in the study were excluded. No patient received any premedication.

On arrival of patient to operating room, an intravenous line was established on dorsum of the hand and monitors instituted for ECG, Noninvasive blood pressure and transcutaneous oxygen saturation.

Patients were allocated randomly in two groups of 75 patients each. Group A received Normal Saline followed by Propofol 2mg/kg and Group B received lignocaine hydrochloride 1 mg/kg followed by Propofol 2mg/kg. This was a double blind study as neither the patient nor the second anesthetist who studied the effect of pretreatment were aware of the pretreatment solution. Quantity of Normal Saline used was calculated as per 1mg/kg body weight of 2% Lignocaine hydrochloride solution. The pretreatment solution was given over 5 second after applying a tourniquet to occlude the venous drainage of the hand. After 15 seconds the tourniquet was released and Propofol was injected at dose rate of 2 mg/kg. Within 10 seconds of injection of Propofol if the patient did not voluntarily complained of pain on injection site, then the surveyor asked him whether there was any pain or discomfort at the injection site.

The pain was scored on a 4-point scale (Table 1) by the second anesthetist who was unaware of the group allocation of the patients. At this point study was terminated and rest of the anesthesia procedure was carried out as appropriate to the surgery.

The incidence of pain with Propofol injection, different between pain scores of two groups and efficacy of Lignocaine pretreatment in reduction of such pain was evaluated and the data obtained were statistically analyzed.

# **RESULTS**

One hundred fifty patients undergoing elective maxillofacial surgeries were recruited for the study. Both study groups were comparable with respect to age, gender and body weight (Table 2).

In Normal saline pretreatment group (A), 32 patients experienced no pain on Propofol injection, 33

TABLE 1: DESCRIPTION OF PAIN SCORE

Score	Severity of pain	Description
0	None	No pain
1	Minimal	Patient complains of pain only when asked
2	Moderate	Patient spontaneously complaining of pain
3	Severe	Patient cries out with pain or pain accompanied by Gri- maces or withdrawal of arm

TABLE 2: DEMOGRAPHIC PATTERN

Parameters	Group-A Mean ± S D	Group-B Mean ± S D	P- value
Age (years)	$39.09 \pm 9.49$	$37.77 \pm 10.80$	≥0.05
Sex (M/F)	14/61	11/64	≥0.05
Weight (kg)	$52.77 \pm 5.83$	$55.18 \pm 4.80$	0.008

TABLE 3: COMPARISON OF PAIN SEVERITY IN TWO GROUPS

Pain score	Group A (Control Group)	Group B (Study Group)
0 No pain	32(42.66%)	56. (74.66%)
1 Mild pain	33(44.0%)	19(25.33%)
2 Moderate pain	10(13.33%)	_
3 Severe pain	_	_
Total	75  (100%)	75  (100%)

patients were having pain score of 1 while 10 patients had pain score of 2.

In Lignocaine pretreatment group (B) 56 patients experienced no pain on Propofol injection, 19 patients were having pain score of 1 and no patients experienced severe pain. These results are shown in Table 3.

On comparing the pain scores between the two groups, it was observed that in Group A (Saline pretreatment group) incidence of pain was 57.33%, while in Group B (Lignocaine pretreatment group) the incidence of pain was 25.23% meaning that lignocaine pretreatment reduced the pain by 32%.

# **DISCUSSION**

Propofol though possessing many characteristics of an ideal induction agent for general anesthesia is most commonly reported as painful injection, which can be very distressing to the patient. The best way of measuring pain on injection of Propofol in clinical settings is by verbal response or its derivative Visual Analogue Scale, the letter seems to be more sensitive. We used four points verbal categorical scoring system in present study as it was simple to apply and readily understood by the patients.

There are many methods, which have been used to reduce pain on injection of Propofol. The results of all such methods are variable. These include use of premedication, larger veins, cooling of Propofol solution and pretreatment or mixing with Lignocaine. <sup>10</sup>

In present study the overall incidence of pain was 57.33% in-group A (Saline pretreatment group). No patient experienced severe pain (pain score 3). Incidence of pain was reduced by 32% in the patients who received Lignocaine pretreatment. The incidence of pain in this study were in agreement with many studies. Nicole et al<sup>11</sup> reported the incidence of pain as 51%. Same results were reported by Ganta R and Free JP.<sup>12</sup> New Gomez<sup>13</sup> reported pain incidence on injection of Propofol as high as 86.6%. In present study no patient in-group B (Lignocaine pretreatment group) experienced moderate or severe pain where as 10 patients in group A (saline pretreatment group) experienced moderate pain. This showed that Lignocaine pretreatment besides reducing the incidence of pain on injection of Propofol also reduced the severity of pain.

Mangar et al<sup>14</sup> showed that pain on injection of Propofol was abolished if Lignocaine was retained in the vein for one minute. Present study was different to the Mangar study as in this study it was observed that use of tourniquet reduced the incidence and severity of pain but did not abolish it. The possible explanation to this difference may be due to the use of higher dose of Lignocaine used by Manger et al. However Gehan et at<sup>15</sup> found that lower dose of Lignocaine was as effective as higher dose.

Mallick A<sup>16</sup> found that choice of Propofol formulations have no effect on injection pain. In his study he observed that pain reduction was due to addition of lidocaine. The results of his study were the same as that of the present study.

In the recent past many methods have been devised to reduce injection pain of Propofol. Honarmand A and Safavi M<sup>17</sup> found remifentanil more effective in reducing pain than Sufentanil. Salman et al<sup>18</sup> found that intravenous pretreatment with methylene blue was effective in reducing the pain on Propofol injection. Aggarwal et al<sup>19</sup> reported that there was stastically significane reduction of pain on dilution of Propofol.

# CONCLUSION

This study concluded that injection of Propofol causes mild to moderate pain. The incidence and severity of pain can be effectively reduced by pretreatment with Lignocaine.

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