

A Comparative Study of Propofol and a Combination of Propofol with Fentanyl as Anaesthesia for Direct Laryngoscopic Biopsy of Laryngeal Growths

G. Ramya¹, C. Geetha², B. Deepraj Singh³

ABSTRACT

Introduction: Direct laryngoscopy guided biopsy (DLB) is a short procedure which can be safely done under general anaesthesia with only Propofol or in combination with Opioids, without using any muscle relaxants. The aim of the present study was to compare Propofol and a combination of Propofol with Fentanyl as anaesthesia for Direct Laryngoscopic Biopsy of Laryngeal growths without using muscle relaxants.

Materials and Methods: The present study was conducted on 60 patients aged between 30 to 70 years who presented with Laryngeal growths and were scheduled for elective Laryngeal Biopsy

Results: A total of 60 patients between the age group 30 to 70 years were included in the study. They were ASA grade I, II and III, scheduled for Laryngeal biopsy under anaesthesia. Patients were randomized into two groups, 30 patients in each Group P and Group PF. Group P received only Propofol and Group PF received a combination of Propofol and Fentanyl. Patients were monitored during anaesthesia using continuous ECG, NIBP and Pulse Oximeters. Intra-operative IV fluids were given according to the protocols. Vital data was recorded preoperatively and during direct laryngoscopy at every 5 minutes interval.

Preoperative vitals were same in both groups and statistically there was no significant difference in the data. Intraoperative pulse rates and mean arterial pressures during direct laryngoscopy and biopsy were raised in group P compared to group PF. Postoperative pulse rates and mean arterial pressures were raised in group P compared to group PF. Post-operative sedation was good in group PF patients compared to group P.

Conclusion: To conclude, the study confirms that general anaesthesia with a combination of Propofol and Fentanyl without apnoea is a simple, safe, suitable, devoid of hemodynamic stress is a better alternative compared to administration of only Propofol. Our findings also suggest that direct laryngoscopic guided biopsies can be done without administration of Succinylcholine.

Keywords: Propofol and a Combination of Propofol, Fentanyl, Anaesthesia, Direct Laryngoscopic Biopsy, Laryngeal Growths

INTRODUCTION

Direct laryngoscopy (DL) with rigid laryngoscope allows direct visualization of pharynx and larynx. This permits surgeons to perform biopsies, remove foreign bodies, polyps or cysts¹. Although DL can be performed under topical anaesthesia, there is no substitute for thorough examination and biopsy of a lesion with patient under general anaesthesia².

Direct laryngoscopy guided biopsy (DLB) is a short procedure which can be safely done under general anaesthesia without intubation during the apnic period after administration of succinylcholine, a short acting muscle relaxant. But the technique has certain drawbacks e.g. prolonged apnoea, hypoxia, bradycardia, hyperkalaemia, post-operative muscle pain. Recently few studies reported that DL could be safely done under general anaesthesia with only Propofol³ or in combination with Opioids⁴, without using any muscle relaxants. Present study compares the favourable conditions for DLB using only propofol and a combination of propofol with fentanyl⁵. We have aimed to compare Propofol and a combination of Propofol with Fentanyl as anaesthesia for Direct Laryngoscopic Biopsy of Laryngeal growths without using muscle relaxants.

MATERIAL AND METHODS

The present study was conducted on 60 patients aged between 30 to 70 years comprising of both sexes who presented with Laryngeal growths and were scheduled for elective Laryngeal Biopsy at the Government E.N.T Hospital, Koti, Hyderabad attached to Osmania Medical College, Koti, Hyderabad. After approval from the Departmental ethics committee and written informed consent from the patients, a randomized control study was conducted. They were divided into 2 groups with each group containing 30 patients. Inclusion Criteria was age group of 30 to 70 years, ASA grade I and II. Exclusion Criteria was patients with lipid allergy, hypersensitivity to drugs used in the study, long procedures and ASA grade IV. All the patients were pre-operatively evaluated for surgery. All necessary investigations were conducted before the surgery. Patients were informed about the procedure in detail before commencing the surgical procedure. Upon arrival to the operation theatre, after confirming adequate NBM status, patient's heart rate, Non-invasive blood pressure, oxygen saturation, respiratory rate

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and ECG were monitored. Intravenous access was secured with 20G cannula and Ringer’s lactate solution at 2 ml per kg body weight was started. All the patients were allocated into 2 groups randomly.

The patients in Group P received general anesthesia with only propofol while patients in Group PF received general anaesthesia with a combination of Propofol and Fentanyl. Group P patients were given premedication (30 min before) with Inj Glycopyrolate 0.04 mcg/kg IV, Inj Ondansetron 0.08 mg/kg IV and Inj Diclofenac 1.5 mg/kg IM. After pre-oxygenation for 3 min with 100% oxygen induction was done with Inj Propofol 2 mg/kg. Once the patient was induced, DLB was performed and biopsy done. After recovery of the patient from the induction dose of Inj Propofol, maintenance bolus dose of 0.5 mg/kg body weight was administered. In the event of saturation dropping below 95% SPO₂, the procedure was halted and patient ventilated with bag and mask. Group PF patients received premedication (30 min) - Inj Glycopyrolate 0.04 mcg/kg IV and Inj Ondansetron 0.08 mg/kg IV. Inj Fentanyl 2 mcg/kg was given and the patient was pre-oxygenated for 3 min with 100% oxygen. Inj Propofol 2 mg/kg IV was given and once induced DLB was performed. When the patient recovered from the induction dose of Propofol, bolus maintenance dose of 0.5 mg/kg body weight was administered. In the event of the saturation falling below 95% SPO₂ procedure was halted and the patient ventilated with bag and mask. Patients were monitored during anesthesia using continuous 5 lead ECG, NIBP and Pulseoximeter. Intra-operative IV fluids were given according to the protocols. Vital data was recorded at induction, during laryngoscopy and at every 5 minutes interval during intra-operative period. The parameters recorded were Pulse Rate, Systolic blood pressure, Diastolic blood pressure, Mean arterial pressures. In all the patients the duration of surgery was around 15 ± 5 minutes. After completion of the surgery patients were observed for 30 min, in postoperative period for hemodynamics and sedation using Ramsay sedation scores.

STATISTICAL ANALYSIS

The data collected was entered into an Excel sheet. It was

subjected to statistical analysis in MS Excel and SPSS Ver16. Data was expressed in frequencies and percentages when qualitative and in Mean ± SD when quantitative. Unpaired Student T test was used for comparing the trends for all parameters in the two groups. A “P” value of <0.05 was considered significant.

RESULTS

The present study was undertaken at the Upgraded Department of Anaesthesiology, Government E.N.T Hospital, Osmania Medical College, Koti, Hyderabad. A total of 60 patients in the age group 30 – 70 years with ASA grade I, II and III undergoing elective direct laryngoscopic biopsies were randomly chosen at the Govt E.N.T hospital for the present study to compare administration of only Propofol and a combination of Propofol with Fentanyl. Patients were divided into two groups P and PF consisting of 30 each. Group P patients received only Propofol and Group PF patients received a combination of Propofol with Fentanyl. The vital data was recorded preoperatively, intra-operatively and post-operatively. The vital data recorded was pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure and SPO₂. Post-operative sedation assessment was done with Ramsay sedation scale. There is no statistical difference in mean age among both the groups as the P value is more than 0.05 (0.63). Total number of males in group P is 21 whereas group PF has 19 males; Total number of females in group P is 9 whereas group PF has 11 females.

Table 2 shows the mean preoperative PR in group P was 82.6 compared to group PF 81.2 (p>0.05). There was no statistical difference in mean pulse rates in either groups. The mean Preoperative MAP in group P was 73.8 compared to group PF 73.1 (p>0.05) there was no statistical difference in mean MAP in either groups.

It was observed that Mean pulse rate at 0 minutes (the period during direct laryngoscopy) in group P was 95.5 / min compared to group PF 68.3 / min and there was statistical significant in mean pulse rates at 0 min (p<0.0001). Mean pulse rate at 5 minutes in group P was 99.1 / min compared to group PF 67.2 /min, there was statistical significant in mean pulse rates in at 5 mins (p<0.0001). Mean pulse rate at 10 minutes was significantly higher in group P 97.2 / min compared to group PF 68.9 / min (p<0.0001). Mean pulse rate at 15 minutes was significantly higher in group P 101.4 / min compared to group PF 71.1 / min (p<0.0001) (table-3). It was observed that, Mean arterial pressure at 0 minutes in group P was 82 mm Hg compare to group PF 63.2 mm Hg. There was statistical significant in MAP at 0 min (p<0.0001). Mean arterial pressure at 5 minutes in group P was 89.3 mm Hg compare to group PF 61 mm Hg. There

Age distribution	Group P	Group PF
30-40	0	1
41-50	3	1
51-60	3	7
61-70	24	21
Sex distribution	Group P	Group PF
Males	21	19
Females	9	11

Table-1: Age distribution and Sex distribution

Parameter	Group P		Group PF		t Value	P Value
	Mean	SD	Mean	SD		
Pre OP PR	82.60	4.90	81.23	7.10	0.87	0.39
Pre OP MAP	73.83	5.09	73.10	5.01	0.56	0.58

Table-2: Pre-Operative vitals

was statistical significant in MAP at 5 min (p<0.0001). There was statistical significant in MAP at 10 minutes (p<0.0001). Mean arterial pressure at 10 minutes was significantly higher in group P 87.4 mm Hg compared to group PF at 67.9mm Hg (p<0.0001). Mean arterial pressure at 15 minutes was significantly higher in group P 85.8 mm Hg compared to group PF 66.5 mm Hg (p<0.0001).

It was observed that, Mean pulse rate at 0 minutes in group P was 81.5 significantly higher when compared to group PF 71.4 (p<0.0001). At 10 minutes Mean pulse rate in group P was 80.9 significantly higher compared to group PF 70.7 (p<0.0001). Mean pulse rate at 20 minutes in group P was 84.8 significantly higher than the mean pulse rate in group PF 69.1 (p<0.0001). Mean pulse rate at 30 minutes in group P was 85.2 significantly higher than the mean pulse rate in group PF 65.4 (p<0.0001) (table-4).

Mean arterial pressure at 0 mins in group P was 85.9 significantly higher than the mean arterial pressure in group PF is 66 (p<0.0001). At 10 mins mean arterial pressure in group P was 85.6 significantly higher than the mean arterial pressure in group PF is 65.3 (p<0.0001). Mean arterial pressure at 20 mins in group P was 89.3 significantly higher than the mean arterial pressure in group PF is 64 (p<0.0001). Mean arterial pressure at 30 mins in group P was 88.2

significantly higher than the mean arterial pressure in group PF is 62.9 (p<0.0001).

It was observed that Mean RSS at 0 mins in group P was 2.4, significantly lower than group PF 3.0 (p<0.0001). The mean RSS at 10 mins in group P was 2, significantly lower than group PF 2.9 (p<0.0001). The mean RSS at 20 mins was significantly lower in group P, 2.0 compared to group PF, 2.6 p (<0.0001). The mean RSS at 30 mins in group P was 2.0 which is same as group PF with p = 1 (>0.05) and therefore statistically insignificant (table-5).

DISCUSSION

During Direct laryngoscopic biopsy, the surgeon requires a calm and quiet patient without coughing, a clear view of glottis and other structures along with adequate space for inspection and instrumentation. Good anaesthetic practice demands overall safety, adequate gaseous exchange, protection of lower airways, abolition of reflexes, good analgesia and quick recovery. The abolition of cough is a major issue during laryngoscopy as coughing exposes the patients to risk of injury by laryngoscope and impairs the precision of the surgery. Laryngeal and pharyngeal reflexes are depressed by Propofol. These effects are further potentiated by opioids. Thus provocation of reflexes due to mechanical stimulation

Pulse Rate	Group P		Group PF		t Value	P Value
	Mean	SD	Mean	SD		
0 MIN	95.50	8.37	68.33	8.07	12.81	<0.0001
5 MIN	99.07	10.66	67.20	4.45	15.11	<0.0001
10 MIN	97.20	7.71	68.90	6.09	15.77	<0.0001
15 MIN	101.43	6.85	71.07	7.03	16.94	<0.0001
Mean arterial pressure						
0 MIN	82.03	6.24	63.17	7.22	10.82	<0.0001
5 MIN	89.33	4.79	61.03	4.86	22.71	<0.0001
10 MIN	87.37	4.11	67.90	4.89	16.69	<0.0001
15 MIN	85.80	4.57	66.50	4.67	16.17	<0.0001

Table-3: Intra-Operative vitals in two groups intra-operatively

Pulse rate	Group P		Group PF		t Value	P Value
	Mean	SD	Mean	SD		
0 MIN	81.47	5.31	71.43	7.40	6.03	<0.0001
10 MIN	80.93	5.84	70.73	6.10	6.61	<0.0001
20 MIN	84.80	4.29	69.07	4.12	14.48	<0.0001
30 MIN	85.20	5.77	65.43	6.13	12.86	<0.0001
Mean arterial pressure						
0 MIN	85.87	2.74	66.03	3.61	23.97	<0.0001
10 MIN	85.63	3.55	65.27	2.55	25.51	<0.0001
20 MIN	89.33	3.98	63.97	3.32	26.8	<0.0001
30 MIN	88.23	5.54	62.93	4.45	19.5	<0.0001

Table-4: Post-Operative vitals in two groups

Parameter	Group P		Group PF		t Value	P Value
	Mean	SD	Mean	SD		
0 MIN	2.37	0.49	2.97	0.18	6.29	<0.0001
10 MIN	2.00	0.00	2.93	0.25	20.37	<0.0001
20 MIN	2.00	0.00	2.57	0.50	6.24	<0.0001
30 MIN	2.00	0.00	2.00	0.25	0	1

Table-5: Post-Operative Ramsay Sedation Scores

by laryngoscopy are reduced or abolished by combination of Propofol and opioids which in the present study is Fentanyl thus facilitating the procedure. In the present study, the incidence of coughing during laryngoscopy was significantly less in patients receiving Fentanyl - a finding in agreement with previous reports. The conditions of laryngoscopy were better in the group that received Fentanyl along with Propofol.⁷ Results indicates that combination of Propofol and Fentanyl provided optimal conditions of laryngoscopy and biopsy than only Propofol. The laryngoscopy may provoke reflexes due to mechanical stimulation resulting in undesirable cardiovascular disturbances. In this study it has been found that Fentanyl resulted in lesser increase in mean arterial pressure and pulse rate during laryngoscopy from the baseline values compared to the patients where no opioid was given. Opioids have been shown to attenuate the cardiovascular response to laryngoscopy during anaesthesia. The present study has been compared to other similar studies: C.E. Harris et al⁸ compared the effects of thiopentone, etomidate and propofol on the haemodynamic response to tracheal intubation. They conducted study on 303 patients in the age groups between 16-60 years belonging to ASA grade I and II undergoing surgery that required tracheal intubation. They randomly divided patients into six groups in whom anaesthesia was induced with thiopentone 4 mg/kg, etomidate 0.3 mg/kg or propofol 2.5 mg/kg with or without fentanyl 2mcg/kg. They also observed that use of fentanyl resulted in further decrease in arterial pressure, and it abolished sympathetic response to direct laryngoscopy and tracheal intubation.

Safiya I et al⁹ conducted a study on performing Tracheal intubation in children without neuromuscular blocker. In their study, they have assessed tracheal intubating conditions and haemodynamic responses in children aged 4 to 12 years by using combination of either fentanyl and propofol; or propofol and a neuromuscular blocker, suxamethonium. Intubating conditions were assessed on a 1-4 scale based on ease of laryngoscopy, position of vocal cords, degree of coughing and jaw relaxation. Tracheal intubation was successful in 95% of patients receiving fentanyl- propofol and 100% of patients receiving propofol- suxamethonium.

A similar study was done by Srivasthava U et al,¹⁰ on direct laryngoscopy (DL) without using succinylcholine and secondly, to ascertain the appropriate anesthetic regimen. During DL arterial pressure and pulse rate changes were minimal when propofol was administered along with opioids, (group F and S) compared to group N where only propofol was used. No serious side effects were seen in the three groups. Hence by these findings we concluded that better conditions of DL are achieved during anesthesia with propofol and fentanyl and sufentanil alone. The opioids provided additional benefit of stable hemodynamics.

Kavitha Meena et al,¹¹ conducted a study to compare the efficacy of 3 different anesthesia induction approach (Inj. Propofol, Inj. Etomidate and Inj. propofol plus Inj Etomidate) in maintaining hemodynamic stability during induction and following endotracheal intubation in elective

surgery. 90 patients aged 15 to 60 years of either sex and ASA physical status I or II scheduled for elective surgery under general anesthesia were taken for study. Written and informed consent was taken. The patients were randomly placed into three groups. Group I induced with Inj. Propofol (2.5 mg/kg) intravenous, Group II with Inj. Etomidate (0.3 mg/kg) intravenous and Group III with Inj. Propofol (1 mg/kg) plus Inj. Etomidate (0.2 mg/kg) intravenous. Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP) and oxygen saturation (SPO₂) were noted at different time interval. Results: Heart rate in all study groups decreases after induction and it was more in group I compared to group II and III ($p < 0.000$) and after intubation HR increases in all three groups but this increase is greater in group II than other two groups. MAP among all three groups decreases after induction and it was more in group I than group II and III. Significant increase in MAP was seen at 1 min after intubation in all three groups but this increase was not sustained and returned to baseline in group II and III. Conclusion: The combination of etomidate plus propofol has better hemodynamic stability than etomidate alone at 1 min after intubation, though etomidate was equally stable at other points of time. The combination proved to be significantly better than either propofol or etomidate alone.

Few studies have compared the clinical profile of target-controlled infusions of propofol with that of manually-controlled infusions. Targeting the effect-site concentration improved the time course of the propofol drug effect during direct laryngoscopy performed during spontaneous ventilation when compared with manual infusion. These implied that this study compares the clinical profile of propofol anesthesia for direct laryngoscopy with spontaneous ventilation when the drug is administered either as a manually controlled infusion or by targeting the effect-site concentration through a target-controlled infusion (TCI) device. TCI improves the time course of propofol effects.¹²

CONCLUSION

To conclude, adequate condition for direct laryngoscopy, less haemodynamic stress without any untoward effects confirm that general anaesthesia with Propofol and Fentanyl without apnoea is a simple, safe, suitable and better alternative compared to only Propofol. Our study also suggests that Direct laryngoscopic guided biopsies can be done without Succinylcholine.

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