Original Article

Effect of varying time intervals between fentanyl and propofol administration on propofol requirement for induction of anaesthesia: Randomised controlled trial

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ABSTRACT

Background and Aims: Administration of fentanyl before induction of anaesthesia with propofol should facilitate smooth induction, with a reduction in induction dose of propofol and its side effects. This study was designed to examine the effect of varying intervals between fentanyl and propofol administration on the dose of propofol required for induction of anaesthesia. **Methods:** After institutional ethical clearance, 129 American Society of Anesthesiologists physical status I--II patients, aged 18--65 years, undergoing elective surgery under general anaesthesia were randomised into three groups. Fentanyl 2 mcg/kg was administered immediately prior to, 3 and 5 min before induction with propofol in Groups 1, 2, and 3, respectively. Requirement of propofol induction dose and haemodynamic parameters was recorded. Statistical analysis was performed using software SPSS (SPSS Inc., Chicago, Illinois, USA). **Results:** Total dose of propofol required for induction was highest in Groups 1 and lowest Group 3 (Group 1 vs. 2 vs. 3: 86.28 ± 21.12 vs. 71.67 ± 21.68 vs. 59.98 ± 20.35 mg, $P < 0.00001$). Dose of propofol required per kg body weight was significantly higher in Group 1 (1.41 ± 0.34 mg/kg) compared to both Group 2 (1.14 ± 0.38 mg/kg) and Group 3 (0.97 ± 0.32 mg/kg) ($P < 0.00001$). Incidence of hypotension during induction was significantly lower in Group 3 (14%) and Group 2 (17.1%) than in Group 1 (35.6%; $P = 0.03$). **Conclusion:** Administering fentanyl 5 min prior to propofol causes marked reduction in the dose requirement of the latter along with a significantly decreased incidence of hypotension during induction.

Key words: Anaesthesia, fentanyl, propofol

INTRODUCTION

Propofol is the most commonly used intravenous induction agent today.[1] The reason behind its popularity is that propofol exhibits many of the properties of the elusive ideal anaesthetic agent, e.g., rapid onset of hypnosis and rapid awakening together with minimal excitation.[1-4] However, a few other characteristics make this drug less than ideal for use as a sole induction agent, most notable of them being significant reduction in cardiac output and systemic vascular resistance with a concomitant decrease in systemic blood pressure.[1-3] To mitigate this problem, the concept of balanced anaesthesia has been expanded to incorporate administration of an opioid prior to propofol, which markedly reduces the dose of the latter and improves haemodynamic stability.[1] Fentanyl, a potent synthetic mu-receptor

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agonist, is the most widely used intravenous opioid for intraoperative analgesia in most parts of the world.[5] When administered prior to intravenous induction, fentanyl acts synergistically with propofol and also attenuates haemodynamic response to laryngoscopy and endotracheal intubation.[6]

Although the dose--effect relationships of both propofol and fentanyl have been described separately[3,4,7] as well as together,[8,9] the temporal relationship of administration of these two drugs has not received proper attention. We believe that if propofol is injected after the peak effect of fentanyl is achieved it will lead to significant reduction in propofol dose and thereby associated side effects.

Therefore, this study was undertaken to examine the effect of varying intervals between fentanyl and propofol administration on the dose of propofol required to achieve loss of consciousness during induction of anaesthesia.

METHODS

After obtaining approval from the Institutional Ethics Committee (Reference IEC/NP-66/2013 dated 15/03/2013), this prospective randomised double-blind study was carried out in the Department of Anaesthesiology, Pain Medicine and Critical Care of a tertiary care Institute of India. The study was conducted in accordance with the principles of Declaration of Helsinki. The patients were recruited between January 2015 and December 2017. All patient scheduled for elective surgery of American Society of Anesthesiologists (ASA) physical status I--II patients, aged 18--65 years, undergoing any elective surgery with anticipated duration of more than 1 h under general anaesthesia were included in the study. A written and informed consent was obtained from all patients, who were randomly allocated to one of the three groups using a computer-generated random numbers chart: Group 1 received propofol immediately after fentanyl injection, and Group 2 and Group 3 received propofol three and 5 min after administration of fentanyl, respectively.

Patients refusing consent to participate in the study were not included. Other conditions selected for exclusion were: allergy to propofol and/or fentanyl, obesity (body mass index >30 kg/m^2), anticipated difficult airway; respiratory, cerebrovascular, renal, and cardiovascular diseases including hypertension; receiving any drugs likely to affect requirement of propofol and/or haemodynamic parameters; history of alcohol or drug use; dehydration and emergency surgery.

Every patient underwent preanaesthetic check-up and overnight fasting prior to induction of anaesthesia. None of them was premedicated with any sedative agent. In the operating room, standard preinduction monitors including electrocardiography, pulse oximetry, and noninvasive blood pressure were attached and baseline heart rate and blood pressure were recorded, followed by recordings at one-minute intervals. Intravenous infusion of Ringer's lactate at a rate of 10 ml/kg/hour was started and oxygen by nonrebreathing facemask was attached. Intravenous fentanyl 2 mcg/kg was administered. Subsequently, according to randomised group allocation using sealed opaque envelopes, Group 1 patients were given propofol immediately after fentanyl injection, patients in Group 2 received propofol 3 minafter fentanyl injection, and those in group 3 were given propofol 5 min after the fentanyl injection. Propofol was injected slowly at a rate of 1 ml/3 s while communicating verbally with the patient. Induction of anaesthesia was considered as complete when verbal contact was lost. The dose of propofol required for induction was noted. After confirmation of mask ventilation, atracurium 0.5 mg/kg was administered to facilitate tracheal intubation. If any movement, vocalisation or bucking was noted at the initiation of mask ventilation, additional doses of propofol in aliquots of 20 mg was administered. The total dose requirement (induction dose plus additional boluses) was also noted.

The anaesthesiologist posted in the operating room injected fentanyl and noted the time. An independent anaesthesiologist unaware of the time of fentanyl injection was called in to inject propofol according to group randomisation to achieve blinding. The second anaesthesiologist administered propofol and noted the total dose of propofol required for induction. In case of occurrence of any movement, bucking or vocalisation, additional doses of propofol were administered as deemed necessary by the second anaesthesiologist, and these data were also recorded.

Recording of heart rate, noninvasive systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) was done every minute, from fentanyl administration till the completion of induction of anaesthesia. In case of hypotension - which

was defined as fall of blood pressure of more than 20% from the baseline - an intravenous bolus of 300 ml of Ringer's lactate was administered. Hypotension not responding to fluid bolus was treated with a 100 mcg bolus of intravenous phenylephrine. Occurrences of hypotension, bradycardia, and requirement of fluid boluses and vasopressors for treatment hypotension were all recorded.

The following demographic parameters were noted: age, sex, and weight and ASA physical status. The primary outcome measures were the total dose of propofol and the dose of propofol required per kg body weight for induction of anaesthesia. Secondary outcome measures were heart rate, SBP, DBP, and MAP immediately after fentanyl injection and induction. Incidence of any movement, bucking, and vocalisation was also noted.

In the study by Kumar *et al*.,[10] the dose of propofol required for induction in patients who received 2 mcg/kg of fentanyl 5 min before was 120.94 ± 18.55 mg. To detect a difference of 15 mg in dose of propofol among groups with an alpha of 0.05 and a power of 90%, it was calculated that a minimum of 41 subjects in each group would be required (in random effects model of one-way analysis of variance).

Quantitative data are expressed as mean and standard deviation, whereas categorical variables are presented as numbers and percentages. One-way analysis of variance (ANOVA) was used to analyze the quantitative parameters. When ANOVA showed a significant difference, post-hoc Bonferroni test was performed to explore differences among the groups. On the contrary, categorical data were analyzed using the Chi-square test. A P value <0.05 was considered statistically significant. All statistical analyses were carried out using the software Statistical Package for the Social Sciences (SPSS) Statistics version 19.0.0 (SPSS Inc., Chicago, Illinois, USA).

RESULTS

During the period from January 2015 to December 2017, a total of 161 patients were assessed for eligibility, of whom 11 patients refused consent and 21 patients did not meet inclusion criteria. So, 129 patients were included in the study and complete data sets were obtained for all of them. The CONSORT[11] diagram depicting patient recruitment process has been illustrated in Figure 1.

The demographic parameters, i.e., age, sex, weight, and ASA physical status and the baseline haemodynamic parameters were comparable among the groups [Table 1]. The haemodynamic parameters were also not significantly different either immediately after fentanyl injection or just after induction of anaesthesia with propofol [Figure 2].

Dose of propofol required per kg body weight for induction of anaesthesia was significantly higher in Group 1 compared to both Group 2 and Group 3 [Table 2]. Total dose of propofol required was significantly different among all three groups, the highest and lowest being in Groups 1 and 3, respectively [Table 2]. Incidence of movement during induction was significantly less in Group 3 than in the other two groups [Figure 3]. Incidences of vocalisation and bucking were significantly higher in Group 1 than in the others [Figure 3]. Additional propofol was

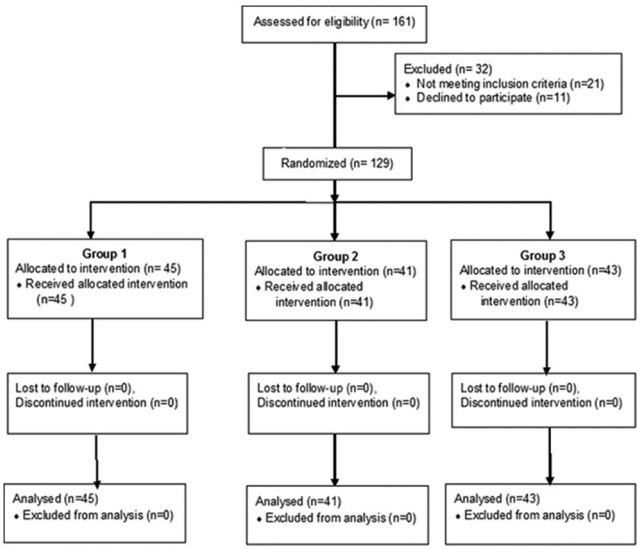

Figure 1: CONSORT flow diagram

Table 1: Demographic characteristics and baseline haemodynamic parameters [mean±standard deviation or number (percentage)]

	Group 1 (*n*=45)	Group 2 (*n*=41)	Group 3 (*n*=43)
Age (years)	37.42±10.56	40.19±13.1	38.13±12.29
Weight (kg)	61.77±9.15	64.12±10.33	62.25±12.33
Sex (male/female) (%)	12 (26.7%)/33 (73.3%)	16 (39%)/25 (61%)	12 (27.9%)/31 (72.1%)
ASA PS (I/II)	40/5	36/5	33/10
HR	83.02±12.59	85.9±12.75	85.32±13.33
SBP	128±12.16	129.7±12.39	131.32±10.57
DBP	79.06±7.63	81.68±8.92	79.86±8.73
MAP	95.37±8.21	97.69±8.52	97.01±8.14

ASA PS – American Society of Anesthesiologists physical status; HR – Heart rate; DBP – Diastolic blood pressure; MAP – Mean arterial pressure; SBP – Systolic blood pressure

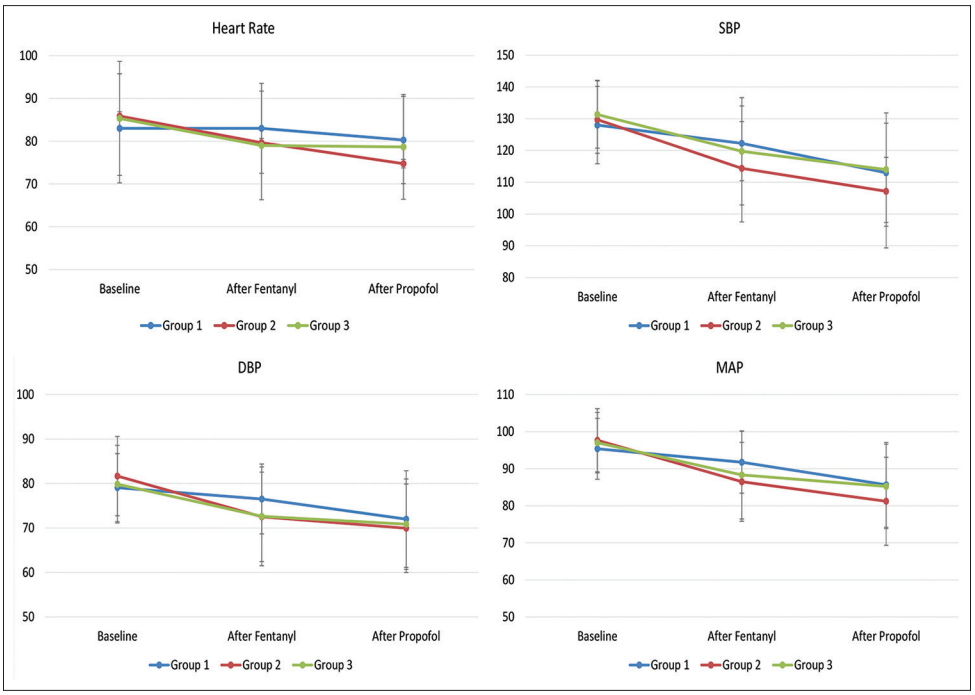

Figure 2: Intergroup comparison of heart rate (beats per minute), SBP, DBP, and MAP (mm of Hg) at 3 time points

Table 2: Outcome parameters

	Group 1 (*n*=45)	Group 2 (*n*=41)	Group 3 (*n*=43)	*P*
Total propofol dose (mg)	86.28±21.12	71.67±21.68	59.98±20.35	<0.00001
Propofol dose for induction (mg/kg)	1.41±0.34	1.14±0.38	0.97±0.32	<0.00001
Movement (%)	24.4	29.3	7	0.03
Vocalisation (%)	20	9.8	2.3	0.03
Bucking (%)	8.9	0	0	0.02
Additional propofol requirement (%)	53.3	36.6	9.3	*P*<0.0001
Hypotension and fluid bolus (%)	35.6	17.1	14	0.03

% = percentage of patients with that particular outcome

required in only 9.3% patients in Group 3 compared to in 53.3% and 36.6% patients in Groups 1 and 2, respectively [Figure 4]. Incidence of hypotension during induction and requirement of fluid bolus was significantly lower in Group 3 and Group 2 than in Group 1 [Figure 4]. All these outcome data have been depicted in Table 2.

No patient in any group had bradycardia or needed phenylephrine injection to treat refractory hypotension.

DISCUSSION

In the present study, fentanyl administered 3 and 5 min before propofol resulted in a significant reduction in the dose of the latter when compared to propofol injected immediately after fentanyl. Although overall haemodynamic parameters were comparable, hypotension was considerably more frequent in patients receiving propofol immediately after fentanyl.

Propofol has several ideal characteristics as an intravenous induction agent: it has a rapid onset of action (one arm-brain circulation time) and rapid recovery with minimal excitation.[1-4] Apart from having an antiemetic effect, propofol also suppresses airway reflexes, decreases intracranial pressure, and exhibits anticonvulsant properties.[1] However, its cardiovascular effects,[1-3] namely a significant reduction of systemic blood pressure (25--40% decrease in SBP) associated with a 15% drop in cardiac index and a 15--25% fall in systemic vascular resistance, preclude use of propofol in patients with haemodynamic instability, severe cardiovascular diseases, and dehydration.

Administration of opioids prior to propofol as part of a balanced anaesthetic induction technique has

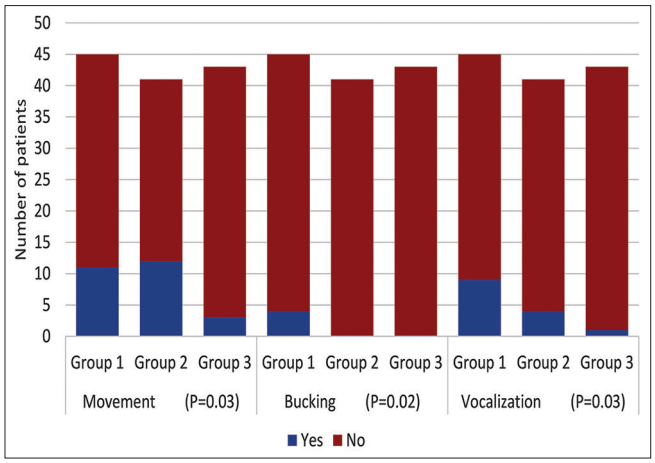

Figure 3: Intergroup comparison of incidences of movement, bucking, and vocalisation during induction

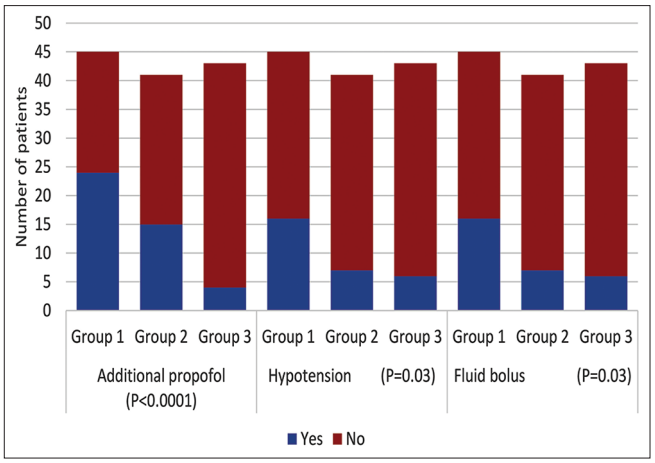

Figure 4: Intergroup comparison additional propofol requirement, incidence of hypotension, and requirement of fluid bolus during induction

been shown to decrease the dose of propofol required for induction, thereby improving haemodynamic stability.[1] The combination of propofol and fentanyl among other opioids has been studied extensively and their effects have been found to be synergistic.[12]

Smith *et al*.[8] demonstrated that arterial concentrations of propofol required for loss of response to verbal command and skin incision are significantly less when coadministered with fentanyl (63% and 89% reduction in propofol with fentanyl concentration 1 and 3 ng/ml, respectively). Analgesic concentrations of opioids may contribute to earlier loss of consciousness as was demonstrated by Lysakowski *et al*.[13] who used a target-controlled infusion device to attain desired effect-site concentration of various opioids and then used bispectral index and sedation scores to study the requirement of propofol to attain loss of verbal response in the presence of these drugs. They found that patients lost consciousness at lower effect-site concentrations of propofol with opioids. Similarly, we found that administration of fentanyl decreases requirement of propofol for induction of anaesthesia. This avoids unnecessary administration of higher dose of propofol and consequent adverse effects.

However, the ideal time interval between administrations of fentanyl and propofol is yet to be established. In various studies, fentanyl has either immediately preceded propofol[14] or there has been an interval of 3[15,16] to 5 min[10,17] between the drugs.

Moffat *et al*.[15] studied the effect of opioid supplementation on the induction dose of propofol. They administered fentanyl 1 mcg/kg 3 min before or alfentanil 5 mcg/kg 1 min prior to induction with propofol for day care surgeries. They did not find any reduction in dose requirement of propofol after administration of opioids compared to patients who did not receive any opioid. The haemodynamic changes were also comparable in all groups. This lack of any effect can be explained by the lower dose of opioid used in this study.

Aken *et al*.[18] evaluated the haemodynamic effects of fentanyl 3 mcg/kg immediately preceding propofol administration and reported significant drop in arterial pressure, cardiac output, and heart rate in patients receiving fentanyl. Injection of propofol immediately after fentanyl can be postulated to be the primary reason for such findings, although effects of a higher dose of fentanyl and lormetazepam premedication may also have contributed. Therefore, we used fentanyl 2 mcg/kg, which is commonly used clinically and observed reduction is propofol dose after allowing 3--5 min time between fentanyl and propofol. However, immediate administration of propofol after fentanyl resulted in significant haemodynamic disturbance in the current study as well.

Thomas *et al*.[19] administered 100 mcg of fentanyl 1--5 min before induction with propofol in patients undergoing day care gynaecologic procedures. Compared to the control group, there were significant decreases in induction time, propofol dose and mean blood pressure with the use of fentanyl. However, the changes were not deemed clinically relevant by the authors. This may be due to use of fixed dose of 100 mcg, which could be less than even 2 mcg/kg in many patients and varying time interval. Use of 2 mcg/kg fentanyl and at least 3 min time interval could

have resulted in a more clinically relevant outcome as in our study.

In pharmacokinetic and pharmacodynamic studies of fentanyl, the lag time between change in its plasma concentration and effect has been reported to range from 3 to 5 min[7] or as 6.4 ± 1.3 min.[20] This timeline corroborates the findings of the present study that administering fentanyl 5 min before propofol reduces the dose of the latter as well as decreases incidence of hypotension.

As many as one third patients had hypotension in Group 1 requiring fluid boluses, whereas the incidence of hypotension was significantly less in other two groups. However, none of the study patients had significant hypotension requiring vasopressor (phenylephrine/ephedrine) or any bradycardia requiring atropine. Incidences of movement, vocalisation, and bucking at the initiation of mask ventilation and thereby requirement of additional doses of propofol were lowest in Group 3 where propofol was injected after 5 min of administration of fentanyl in spite of the fact that actual dose of propofol administered was least in this group. This shows early administration of fentanyl before propofol also facilitates airway management.

There was no incidence of apnoea or desaturation during 3--5 min period before administration of propofol in any patient. Oxygen administration was continued via face mask during this period in all patients.

There are several limitations to this study, the most important of them being that plasma concentrations of fentanyl and propofol could not be measured because of logistic constraints. These data could have further elucidated the findings. Another limitation was that the end point of induction of anaesthesia was assessed only clinically, and electroencephalography-based monitors were not used. Third haemodynamically unstable patients, for whose management the findings of this study could be more pertinent, were not included. Fourth, different doses of fentanyl were not analyzed. The dose of 2 mcg/kg was selected because it has been widely studied in published literature.[10,14,16,17,21,22] Therefore, future studies should focus on temporal effects of varying doses of fentanyl on propofol dosage and haemodynamic parameters in a patient population at risk of haemodynamic instability, with incorporation of depth of anaesthesia monitors and biochemical measurements.

CONCLUSION

Administering fentanyl 5 min prior to propofol causes marked reduction in the dose requirement of the latter along with a significantly decreased incidence of hypotension, unwanted movements, vocalisation, and bucking during induction.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Ethics clearance

Obtained.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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