A Comparative Study of Propofol-Ketamine and Propofol-Fentanyl for Total Intravenous Anaesthesia

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ABSTRACT

BACKGROUND

Total Intravenous Anaesthesia (TIVA) is a modified form of general anaesthesia where induction as well as maintenance of anaesthesia is with intravenous agents alone. We aim to compare the drug combinations of Propofol-Ketamine and Propofol-Fentanyl in total intravenous anaesthesia.

METHODS

A prospective randomized study was conducted on 100 female subjects between 20 to 50years, posted for minor day-care gynaecological surgeries. The subjects were randomly allocated into 2 groups Propofol-Ketamine (PK) group and Propofol-Fentanyl (PF) group. Those in PK group were induced with Propofol 1 mg/Kg and Ketamine 1 mg/Kg and anaesthesia was maintained with Propofol infusion 2 mg/Kg/hr and Ketamine infusion 2 mg/Kg/hr. Patients in PF group were induced with Propofol 1 mg/Kg and Fentanyl 2µg/Kg and anaesthesia was maintained with Propofol infusion 2 mg/Kg/hr and fentanyl infusion 2µ/Kg/hr. Mean pulse rate, systolic and diastolic blood pressures, saturations (SpO_2) and respiratory rate (RR) were measured immediately after induction and at intervals of 1, 3, 5, 10, 20, 30 minutes of intraoperative period. Vitals immediately after surgery and in post-operative period were compared in both the groups at 15min interval for 1hour, along with the sedation and recovery scores in the postoperative period.

RESULTS

Demographic data were comparable in both the groups. The mean pulse rate, systolic, diastolic blood pressures immediately after induction were significantly more in group PK when compared to group PF ($p<0.05$). Statistically significant difference was not seen in the mean saturations (SpO_2) in the intraoperative period, immediately after surgery and 15 minutes after surgery. Mean RR was significantly higher in PK group as compared to group PF in the intraoperative and immediate postoperative periods. The mean sedation score was more in group PK than in group PF immediately after surgery and at 15minutes after surgery ($P=0.001$). The recovery score was slightly higher and recovery time was less in PF group. In group PK, 2 patients had post-operative excitation, 4 patients had secretions and 1 patient complained of post-operative nausea. In the PF group 3 patients had post-operative nausea.

CONCLUSIONS

In conclusion, Propofol-Ketamine and Propofol-Fentanyl combinations produce comparable rapid and safe anaesthesia with minor hemodynamic fluctuations and few side effects. Recovery score and recovery time were better in propofol-fentanyl group compared to propofol-ketamine group.

KEYWORDS

Ketamine, Fentanyl, Propofol, Total Intravenous Anaesthesia

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BACKGROUND

Total intravenous anaesthesia (TIVA) is a modified form of general anaesthesia where induction as well as maintenance of anaesthesia is done with intravenous agents alone. TIVA is administered as a combination of hypnotic and analgesic drugs without administration of any inhalation agents.[1] It can be an effective alternative to general endotracheal anaesthesia when rapid recovery from anaesthesia is desired. [2] Drugs used for TIVA should have quick onset, smooth induction, easy maintenance, quick recovery, and minimal side effects.

TIVA has many advantages over inhalational anaesthesia[1], such as no operating room pollution, minimal cardiac depression, less neurohumoral response, decreased oxygen consumption, evasion of distension of air-filled body spaces and provides optimum operating conditions for the surgeon. Disadvantages of TIVA are need for specific equipment such as a target-controlled infusion (TCI) set, syringe pumps or infusion pumps for accurate administration and drugs. TIVA needs optimal drug metabolism in the body for rapid recovery from anaesthesia. Recovery may be delayed in TIVA in patients with hepatic disease.

TIVA is administered as an initial Loading dose and a Maintenance dose. A Loading dose is determined based on the volume of distribution and the initial plasma drug concentration. Following initial administration, the drug is redistributed to tissues and eliminated as well. To maintain the desired plasma drug concentration, a Constant Rate Infusion (CRI) should be initiated. The infusion rate is determined by the clearance of the drug and the plasma drug concentration (based on pharmacokinetic studies). The depth of the anaesthesia can be maintained by either a continuous infusion or by intermittent boluses of drug.

To perform TIVA, the use of a target-controlled infusion (TCI) set is recommended. TIVA can also be administered manually (i.e. without a TCI pump), thorough a fixed infusion rate in syringe pump. Premedication with an anticholinergic like glycopyrrolate and a short acting benzodiazepine like midazolam is recommended as adjuvants in TIVA. The advantages and disadvantages of TIVA should be considered on individual case basis, while choosing it as an anaesthetic protocol.

METHODS

After approval from the Departmental Ethics Committee and after taking written informed consent from the patients, a prospective randomized study was conducted on 100 ASA grade I and II female patients aged between 20-50 years, who were posted for posted for minor day-care gynaecological surgeries, lasting for 30-40 minutes in Modern Government Maternity Hospital, Petlaburj, Hyderabad, affiliated to Osmania Medical College.

Patients with history of allergy to Propofol / Ketamine / Fentanyl and patients with duration of surgery of more than 45 minutes were excluded from the study. Patients were randomly allocated into two groups of 50 each, Propofol-Ketamine (PK) group and Propofol-Fentanyl (PF) group. All patients were pre-operatively evaluated. The basic investigations were conducted. The patients were explained in their familiar language in detail about the anaesthesia technique and the possible consequences. The patients were instructed to avoid solid food for a period of 8 hours before the procedure. Anaesthesia machine was checked. Appropriately sized cuffed endotracheal tubes were kept ready. A working laryngoscope, a working suction apparatus, 3 infusion and syringe pumps one each for propofol, ketamine and fentanyl and emergency drugs were kept ready. A multi para monitor was connected and the pulse rate (PR), non-invasive blood pressure (NIBP), respiratory rate (RR), ECG and saturations (SPO_2) were monitored.

All the patients were premedicated with intravenous (IV) glycopyrrolate 0.2 mg and Injection Midazolam 0.05 mg/Kg IV. The patients in group PK were induced with IV propofol 1 mg/Kg and IV ketamine 1mg/Kg and anaesthesia was maintained with propofol infusion 2 mg/Kg/hr and ketamine infusion 2mg/Kg/hr. The patients in group PF were induced with propofol 1mg/Kg IV and fentanyl 2µ/Kg IV and anaesthesia was maintained with propofol infusion 2 mg/Kg/hr and fentanyl infusion 2µ/Kg/hr. After induction, maintenance was started with syringe pumps.

Intra operatively PR, NIBP, the mean arterial pressure (MAP), SpO_2 and RR were monitored at 1,3,5,10,20,30, and 40 minutes. Anaesthesia drugs were stopped 5 minutes before the end of surgery. In the post anaesthesia care unit (PACU), the patients were monitored for PR, NIBP, MAP, SpO_2, RR, sedation, and recovery at 15min interval for 1hour. Vitals were noted immediate post-operative period, and at 15,30,45 and 60 minutes after surgery. Sedation was monitored using Ramsay sedation scale. Recovery was assessed using Aldrete recovery score. The overall recovery time was noted.

Statistical Analysis

The data collected was entered into Microsoft Excel sheet and subjected to statistical analysis in MS Excel and SPSS version 16 software. Data was expressed in percentages when qualitative and in Mean ± SD when quantitative. Unpaired Student t- test was used for comparing the trends of all parameters in the two groups. A 'p' value of <0.05 was considered statistically significant.

RESULTS

Mean age distribution in group PK was 25.86 ± 2.73 and PF was 24.90 ± 2.92. There was no statistically significant difference in mean age between the two groups [P value: 0.093 ($P>0.05$). $t=1.694$].

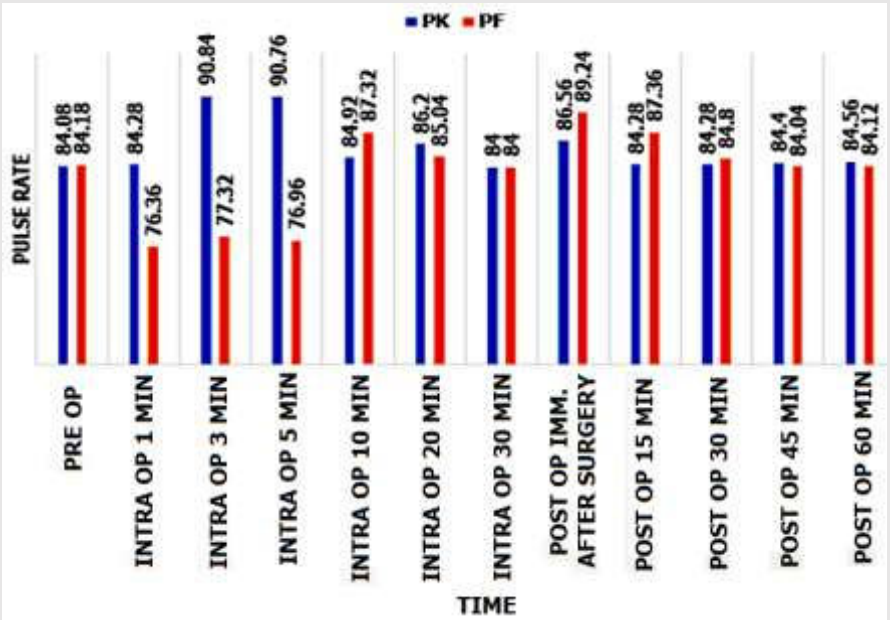

Figure 1. Comparison of Mean Pulse Rate between the Two Groups

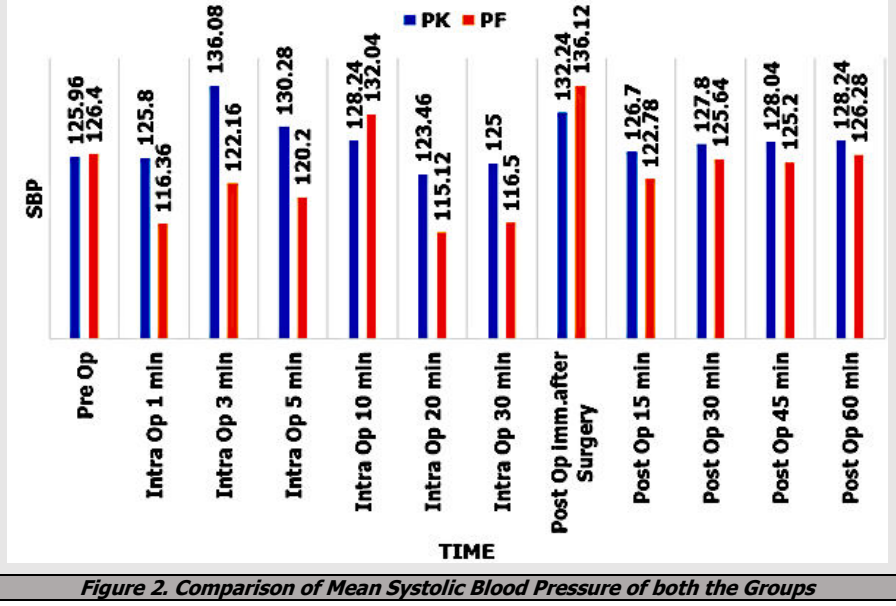

Figure 2. Comparison of Mean Systolic Blood Pressure of both the Groups

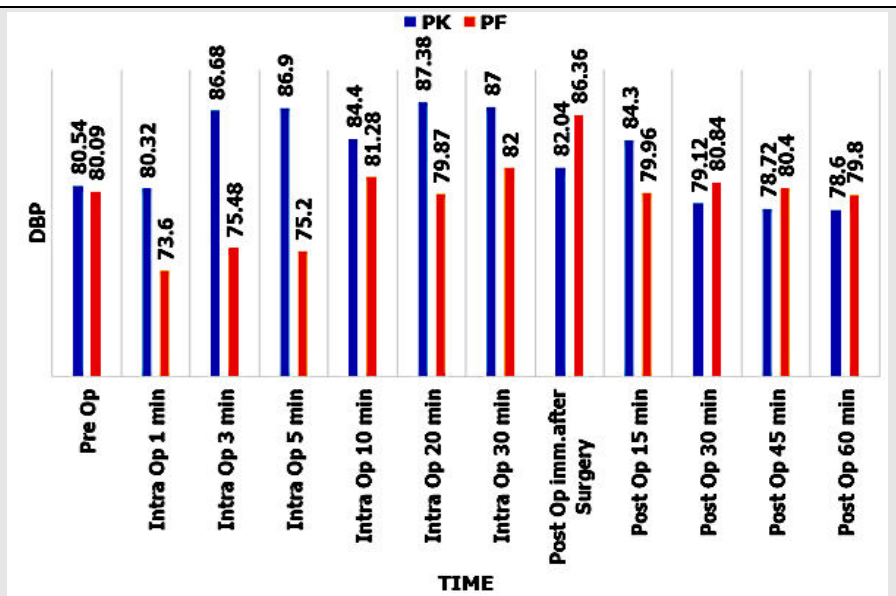

Figure 3. Comparison of Mean Diastolic Blood Pressure between the Two Groups

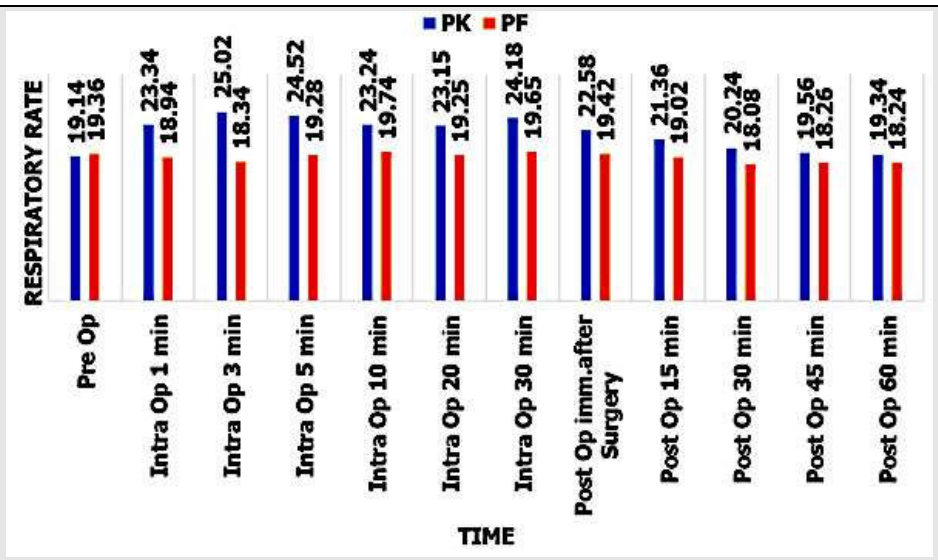

Figure 4. Comparison of Mean Respiratory Rate between the Two Groups

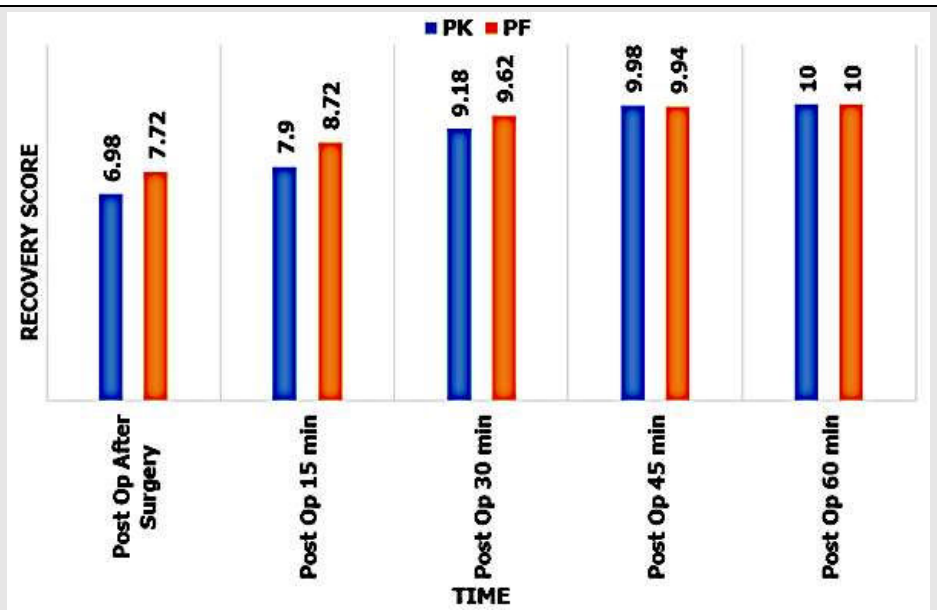

Figure 5. Comparison of Mean Recovery Score between the Two Groups

Mean weight distribution in group PK was 48.30 ± 5.039 and group PF was 48.20 ± 3.98. There was no statistically significant difference in the demographic data between the two groups. (P value 0.913 (P>0.05). t=0.110).

The mean pulse rate at 1,3 and 5 minutes of the beginning of surgery was more in group PK than in group PF and was statistically significant. However, there was no significant difference in the mean pulse rates at 30, 45, and 60 minutes in the post-operative period. (Figure 1)

The mean systolic pressure was significantly higher in group PK at 1,3 and 5minutes of the beginning of the surgery and in the intra- operative period. At 30, 45 and 60 minutes of post-operative period the difference in mean systolic pressures in both the groups was statistically non-significant. (Figure 2). The mean diastolic blood pressure in group PK was higher than in group PF at the beginning of the surgery and throughout the intra-operative period. The difference was not significant in the post-operative period at 15, 30, 45 and 60 minutes. The mean diastolic pressure in group PK was 78.60 and in group PF was 79.80. P=0.11(NS). (Figure 3).

Mean SpO_2 was compared immediately at the start of surgery and at 1,3,5,10,20, and 30minutes of intraoperative period, and was measured immediately post-surgery and at intervals of 15, 30, 45 and 60 minutes in the post-operative period. There was no statistically significant difference in the SpO_2 either in the intraoperative or post-operative periods between the two groups.

Sedation Score	PK Mean ± SD	PF Mean ± SD	T Test	P Value
Post Op immediately after Surgery	2.500 ± 0.5803	2.160 ± 0.3703	3.492	0.001 (S)*
Post Op 15 min	2.140 ± 0.6064	2.020 ± 0.4734	1.103	0.273 (NS)
Post Op 30 min	1.700 ± 0.7071	1.760 ± 0.4314	-0.512	0.610 (NS)
Post Op 45 min	1.340 ± 0.4785	1.440 ± 0.5014	-1.020	0.310 (NS)
Post Op 60 min	1.260 ± 0.4431	1.260 ± 0.4431	0.000	1.000 (NS)

Table 1. Comparison of Mean Sedation Score between the Two Groups

Mean respiratory rate compared between the two groups intra operatively at 1, 3, 5, 10, 20, 30 minutes, and was more in group PK than in group PF and the difference was statistically significant. The mean respiratory rate remained higher in PK group compared to PF group immediately after surgery (P=0.001 S). There was no statistically significant difference in the RR at 15, 30, 45, 60 minutes after surgery in the post-operative period.

Immediately after surgery the mean sedation score was more in group PK group when compared to group PF and the difference was statistically significant (P=0.001). The sedation score was more at 15 minutes after surgery in PK group, but the sedation scores were comparable at 30,45 and 60minutes in the post-operative period.

The mean recovery score immediately after surgery and at 15 and 30-minutes post-operative period in group PF was 7.72 and was significantly higher compared to 6.98 of group PK (P=0.001). At 45 and 60 minutes of post-operative period, there was no statistically significant difference in mean recovery scores of the two groups.

Post-operative recovery time was compared between the two groups. It was observed that mean recovery time in group PK was more. Recovery time was 32.00 minutes in group PK and in group PF it was 21.10 minutes. The difference was statistically significant (P=0.0001).

Of the 50 patients in group PK, 2 patients had post-operative excitation, 4 patients had secretions and 1 patient complained of nausea in the post-operative period. Of the 50 patients in group PF, 3 patients complained of nausea in the post-operative period.

DISCUSSION

General anesthesia should provide quick and pleasant induction, predictable loss of consciousness, stable operating conditions, minimal adverse effects, rapid and smooth recovery of protective reflexes and psychomotor functions. The development of anesthesia since its introduction has been erratic, long periods of stagnation being occasionally broken by improvement and advances. General anesthesia has undergone a vast number of improvements and modifications and even its recently modified form total intravenous anesthesia (TIVA; induction as well as maintenance of anesthesia with intravenous agents only) has undergone many improvements ever since its introduction into clinical practice.

Total Intravenous Anaesthesia (TIVA), can be administered with a combination of drugs, with or without opioids. Opioids interact synergistically with Propofol and markedly reduce the dose of propofol required for loss of consciousness during noxious stimulation such as skin incision. In the present study TIVA with Propofol-Ketamine (PK) and Propofol-Fentanyl (PF) combinations were compared.

Both the groups were comparable in the demographic features. All patients were between 20-50 years of age and belonged to either ASA grade I or II. Mean age in group PK was 25.86 years and in group PF was 24.90 years. The mean weight in group PK was 48.30 kgs and in group PF was 48.20 kgs. The difference in mean values of age and weight were not statistically significant.

The demographic data of our study were comparable with studies of Pawar et al[3] and Ramdev et al[4]. Ramdev et al compared the efficacy of Propofol-ketamine and Propofol-fentanyl as TIVA techniques in patients undergoing short surgical procedures of less than 30 minutes duration.[4] Pawar et al compared Propofol-ketamine and Propofol-fentanyl for minor surgical procedures[3] like Incision and drainage of abscesses, closed reduction of fracture upper limb, Dilatation and curettage, Dilatation and evacuation. Both the studies were conducted to seek the better combination that provided stable intra operative conditions, early post-operative recovery, and minimal post-operative side effects. In the present study, we aimed to compare the peri operative hemodynamic stability of the two combinations of TIVA. TIVA was chosen as the mode of anaesthesia as the study population recruited were of ASA I and II categories, the surgeries chosen were short day care gynaecological procedures, where airway manipulation by intubation can be avoided.

The mode of anaesthesia and the decision of securing definitive airway with endotracheal intubation, depends on the invasiveness of the surgical procedures undertaken, the duration of the surgery and the associated co morbidities in the subject. The laryngosympathetic response to direct laryngoscopy and endotracheal intubation can lead to unwanted haemodynamic fluctuations. The haemodynamic fluctuations with endotracheal intubation was emphasized in several studies. Afzal[5] in his study on Laryngeal Mask Airway vs. Endo tracheal tube for airway management, found that LMA has the advantage of improved hemodynamic stability during induction and emergence and reduced anaesthetic requirements for airway tolerance. When TIVA was considered for short day care surgeries, the safety and early recovery of the patients were the major concerns. TIVA has the advantage of avoiding extreme hemodynamic fluctuations associated with tracheal intubation and at the same time, maintaining the hemodynamic stability. The avoidance of muscle relaxants and inhalation agents can help in rapid recovery from anaesthesia.

In our study there was an increase in the mean pulse rate after induction in PK group. These findings were consistent with the study by Ramdev et al.[4] and Pawar et al.[3] Ramdev et al studied Propofol 40 mg, ketamine 0.5 mg/Kg I.V., fentanyl 1.5µ/Kg I.V. with the maintenance dose of Propofol 25 mg intermittently. Pawar et al. used propofol 1 mg/kg titrated till the loss of consciousness, ketamine 0.5 mg/Kg, fentanyl 1.5µ/Kg in study. In the study by Ramdev et al.[4] pulse rate increased in PK group and decreased in PF group after induction. (PR-84.52 in PK, 74.44 in PF compared to the pre-induction values 84.20 in PK, 84.16 in PF) and returned to base line in post-operative period. Similar results were seen in the study by Pawar et al. [3] where the authors documented an increase in pulse rate in PK group and decrease in pulse rate in PF group after induction

(PK-95.23 vs 91.33, PF-83.5 vs 87.13). This can be attributed to the cardiovascular stimulant effect of ketamine,[6] which lead to increase in PR and is usually seen with the first dose of ketamine, irrespective of the dose of used. The decrease in PR in fentanyl group is due to vagomimetic action of fentanyl.[7] In the study by Mayer et al[8], Propofol-fentanyl group showed bradycardia with PR less than 40. This may be due to the higher doses of fentanyl used in this study (fentanyl 0.1 mg for induction with intermittent boluses for maintenance of analgesia and as rescue dose in case of pain). Dose of fentanyl was not titrated to body weight of the patients. In the present study the fentanyl dose was titrated to body weight for both induction and maintenance (2 µ/Kg for induction, 2µ/Kg/hr for maintenance) contributing to haemodynamic stability.

In our study systolic blood pressure (SBP), was increased in PK group (136.08) after induction, decreased in PF group (122.16) compared to the pre-operative values (PK-125.96, PF-126.40). In both the groups SBP returned to baseline in the maintenance period. In the immediate post-operative period, SBP increased in both the groups (PK-132.24, PF-136.12) and it returned to pre-induction values in the recovery period. Ramdev et al.[3] documented an increase in SBP in ketamine group after induction (127.48 ± 9.32 compared to 125.96 ± 9.40 preoperatively) whereas in fentanyl group it decreased (116.36 ± 9.51 compared to 126.84 ± 9.55). In both the groups it returned to the baseline in the post-operative period. In the study by Singh et al [9] the SBP increased in PK group after induction (136.08 ± 9.67 compared to the pre-operative value 125.96 ± 9.55). During maintenance and recovery, SBP remained near pre-induction values. In PF group, after induction, SBP decreased (122.16 ± 9.31 compared to the pre-operative value 126.40 ± 9.67) and remained less intra operatively compared to PK group. Pawar et al., study showed no significant change in SBP after induction (115.4 ± 7.31 vs. 115.63 ± 6.43 pre-operatively) in PK group though there was slight decrease in PF group after induction (106.46 ± 4.93 vs. 110.26 ± 5.40 pre-operatively).

In the present study the Diastolic Blood Pressure (DBP), was increased in PK group (86.68) and decreased in PF group (75.48) compared to the pre-operative values (PK-80.54, PF-80.09). In both the groups DBP returned to baseline in the maintenance period. In the immediate post-operative period, DBP increased in both the groups (PK-82.04, PF-86.36) and it returned to pre-induction values in the recovery period. Ramdev et al[4] presented an increase in DBP in PK group after induction but the value was not statistically significant. DBP decreased significantly in PF group (73.60 ± 3.61 compared to 80.04 ± 3.56 pre-operatively). Post operatively DBP returned to the baseline values in both the groups. In the study conducted by Singh et al.[9], DBP increased in PK group after induction (86.24 ± 3.76 vs pre-operative 80.54 ± 3.56), decreased in PF group (75.72 ± 3.54 vs pre-operative 80.94 ± 3.55) and returned to pre-induction values in the post-operative recovery period in both the groups. Pawar et al[3] found no significant change in DBP in both the groups after induction in their study.

Comparing the Mean Arterial Pressure (MAP), in both the groups in our study, we observed that after induction MAP increased in PK group (96.06), decreased in PF group (88.68). In both the groups MAP returned to baseline in the maintenance period. In the immediate post-operative period, MAP increased in both the groups (PK-94.56, PF-90.22) and it returned to pre-induction values in the recovery period. Ramdev et al[4] in their study found similar results in MAP after induction in both the groups (PK-89.5 vs. 87.3; PF-72.6 vs. 89.5). The higher incidence of hypotension in PF group may be caused by a higher dose of Propofol for maintenance (5mg/Kg/hr) in their study.

Ketamine is a powerful analgesic without myocardial depression. The increase in BP in all these studies in PK group can be explained by the cardiocirculatory stimulant effect of ketamine. When compared to PF, PK combination provided stable hemodynamic intra operatively. This is because of the antagonistic effects of Propofol and ketamine. Propofol decreases blood pressure and ketamine increases blood pressure, thereby maintaining stable hemodynamic. The higher incidence of hypotension in PF group was due to the cumulative hypotension by Propofol and fentanyl. In the present study all the anaesthetic drugs were stopped 5 minutes before the completion of surgery. The hemodynamic parameters returned to the pre-induction values in the post-operative recovery period due to the decrease in plasma levels of Propofol, ketamine and fentanyl when the drugs were metabolised, and their effects weaned.

When comparing the Respiratory Rates (RR) between the two groups we observed significant fall in RR in PF group compared to PK group after induction (PK-23.34 vs 19.14; PF- 18.94 vs 19.36). Intra operatively mean RR was higher in PK group compared to PF group. RR returned to baseline in the post-operative period in both the groups. Propofol and fentanyl are profound respiratory depressants[7] whereas ketamine has minimal effects on central respiratory drive.[10] Findings in our study were consistent with the findings of Ramdev et al [4] where mean RR after induction was 17.24 in PK group and 12.64 in PF group (Pre-induction values were 17.20 in PK, 17.12 in PF). Pawar et al[3] in their study found no change in RR in PK group, whereas RR was decreased in PF group (16.97 vs. 19.9).

There was no statistically significant difference in SpO_2 trends in both PK and PF groups in our study. This may be because, the patients were receiving oxygen inhalation with Hudson mask @ 5L/min. Pawar et al[3] in their study used oxygen inhalation with Hudson mask @ 4 L/min for all patients and the findings were similar to our study. Ramdev et al[4] found decrease in SpO_2 in both ketamine and fentanyl groups, more in fentanyl group. This can be explained by the respiratory depression of Propofol aggravated by the addition of opioid to it.

We observed higher Sedation score in PK group compared to PF group. Ramsay sedation scale was used for the assessment of sedation. The findings of our study were comparable to the randomised double-blind trial by Kurdi et al [11] where the authors compared two different proportions of ketofol with fentanyl-Propofol for sedo-analgesia for tubal

sterilisation by mini-laparotomy. They observed that sedation scores were higher in ketofol 1:2 group. In ketamine: propofol 1:1 group the score was 5.60 ± 0.5, in ketamine: Propofol 1:2 group it was 5.85 ± 0.3, and in fentanyl: Propofol group it was 5.30 ± 0.5.

The study by Nejati et al.,[12]comparing ketamine/propofol versus midazolam / fentanyl (MF), for procedural sedation and analgesia (PSA), in the emergency department, found no significant differences in sedation time between the groups. The mean total sedation time was 25.1±13.8 minutes in the ketofol group and 26.1 ±12.6 minutes in the MF group (p = 0.77). Most patients in the ketofol group underwent PSA with a Ramsay score between IV and VI (87.1%), while most of the patients in the MF group had a Ramsay score of III or less (58.1%).

The recovery score was slightly higher in PF group compared to PK group in our study. Recovery was achieved much earlier in PF group than in PK group. Better recovery score in PF was most probably due to lesser sedative effects of fentanyl as compared to ketamine. In our study mean recovery time in group PK was 32.0 minutes and 21.10 minutes in group PF, the difference was statistically significant (p=0.0001). The findings of our study were similar to study by Guit et al.,[6] where recovery time was 17 minutes in PK group and 13 minutes in PF group which was statistically significant (p=0.02). In Pawar et al[3] study, the recovery time in PK group was 12.61 ± 2.83 and in group PF was 10.42 ± 1.90 minutes (p<0.001). The prolonged recovery in ketamine group in all these studies could be because of prolonged duration of action of ketamine due to its active metabolite Norketamine.

In the post-operative period, the increased incidence of oral secretions in 4 patients of group PK as compared to none in group PF might have been due to hypersalivation by ketamine. Slightly higher incidence of nausea in group PF may be due to the central emetic effects of fentanyl. But the overall lower incidence of nausea and no incidence of vomiting in the study, can be attributed to the anti-emetic effect of propofol. Similar findings were seen in Pawar et al[3] study where the post-operative nausea and vomiting was 10% in PF group. Two patients from group PK had excitation post operatively while no patient from PF had this side effect. There were no complications like awareness, mood changes, and agitation.

The results of this study suggest that both propofol–ketamine and propofol–fentanyl combinations produce rapid, pleasant and safe anesthesia with only a few untoward side effects and only minor hemodynamic fluctuations.

CONCLUSIONS

Propofol-fentanyl and propofol-ketamine combinations for TIVA, provide good haemodynamic stability during perioperative period. Increase in blood pressure with propofol-ketamine combination was due to the cardiac stimulant effect of ketamine. During maintenance and recovery, blood pressure remained near pre-induction values mainly due to the antagonistic properties of propofol (decrease in BP) and ketamine (increase in BP).

Recovery score and recovery time were better in propofol-fentanyl group compared to propofol-ketamine group, both propofol-ketamine and propofol-fentanyl groups were associated with smooth and swift recovery with minimal residual impairment of mental functioning, which is due to their significant metabolism, short elimination half-life and extremely high total body clearance.

In conclusion, the results of this study suggest that both propofol-ketamine and propofol-fentanyl combinations produce rapid and safe anaesthesia with minor hemodynamic fluctuations. So, it may be recommended that both propofol-ketamine and propofol-fentanyl can be used as combinations in TIVA for day care surgeries where minimal side effects and early recovery are desired.

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