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Comparative Evaluation of the Effects of Combinations of Fentanyl-Propofol with Ketamine-Propofol in Short Gynaecological Day Care Procedures: A Randomised Double Blind Study

Girijanandan D. Menon[1], Thankam P.[2]

[1]Assistant Professor, Department of anaesthesiology, M.O.S.C. Medical College, Kolenchery, Kochi, Kerala 682311, India. [2]Professor, Department of Anaesthesiology, SUT Medical College, Thiruvananthapuram, Kerala 695028, India.

Abstract

The advantages of ambulatory surgery is effective when patients get the benefits of day care anaesthesia.This is possible by using rapid acting intravenous anaesthetic agents. *Aim:* Comparative the effects of combinations of fentanyl -propofol with ketamine propofol in short gynaecological procedures. The null hypothesis was that there is no difference between the two groups. *Objective*: Primary outcome: To compare the induction dose and top up doses of propofol in the two groups, one pretreated with fentanyl and the other group pretreated with ketamine. Secondary outcome studied were the quality of immediate and intermediate recovery measured by time to eye opening, time to sit up and walk in the two groups. *Materials and Methods*:A randomised double blind study was conducted with Institutional review board and ethics committee approval. Forty ASA I and II physical status females with written informed consent for dilatation and curettage underwent the study. They were allocated to two groups by odd/even numbers by randomisation and blinded by by sealed cover method. Group I (F) received fentanyl citrate 1.5 microgram/kg intravenously and Group II (K) received ketamine 0.5mg/kg intravenously. Both groups of patients were induced two minutes later with tirated dose of propofol. In both groups anaesthesia was maintained with incremental doses of 25 mg propofol. The data was anlysed using unpaired t test. *Results*: The mean induction time and the total dose of propofol was more in the F group. The time taken for eye opening was shorter in group F. *Conclusion*: Anaesthesia with propofol-fentanyl was comparable with propofol-Ketamine for out patient anaesthesia. Recovery is rapid with fentanyl, with out emergence delirium and total absence of emetic sequelae.

Keywords: Outpatient Anaesthesia; Fentanyl; Propofol; Ketamine; Total Intravenous Anaesthesia; Early Recovery; Short Gynaecological Procedures.

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Introduction

The concept of day care anaesthesia has evolved because ambulatory surgery can offer a number of advantages for patients, health care providers and even hospitals including shorter operating room times and faster turnaround times.The ability to care for high volumes of patients reduces the waiting list of operations. Ambulatory surgery does not depend on the availability of a hospital bed, patients have greater flexibility to schedule the timing of surgeries. The reduced rate of infection for outpatient surgery is beneficial in immune compromised patients [1]. Ambulatory anaesthesia has become popular and currently many minor gynaecological procedures are performed on out patient basis [2]. Goal of outpatient anaesthesia is

Corresponding Author: Girijanandan D. Menon, Assistant Professor, Department of Anaesthesiology, M.O.S.C. Medical College, Kolenchery, Kochi, Kerala 682311, India.
E-mail: mosc.drdgmenon@gmail.com

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to provide good perioperative anaesthesia with minimal post operative side effects like nausea,vomiting, drowsiness etc. Speedy recovery is the end point in trials investigating day care anaesthesia.To fully evaluate patient recovery, all stages of recovery should be studied. Early recovery (emergence) is defined as time to eye opening and orientation.Intermediate recovery encompasses the return of cognitive and psychomotor function and the time to discharge ("home readiness or street fitness"). Currently intravenous induction agents like propofol and ketamine are used in combinations with fentanyl or alfentanyl and midazolam [3-5]. Faster immediate recovery with the new short acting intravenous anaesthetic propofol,yield significant savings in nursing hours [3,6-8]. Propofol also possess antiemetic action. Ketamine in low doses 10-20 mg is a useful alternative to opioid analgesic during induction of anaesthesia and maintenance [9-13]. Opioid analgesics are used during maintenance of general anaesthesia to prevent autonomic responses to painful stimuli. Opioids have been shown to decrease the incidence of pain on injection and involuntary motor activity associated with propofol. Small doses of fentanyl 1-2 µgm/kg provided excellent intra operative conditions and a more rapid emergence when it was used as part of a balanced anaesthesia technique [3,10,11,14,15].

In the present study an evaluation and comparison of induction, maintenance, quality of anaesthesia and the quality of immediate and intermediate recovery following administration of the above combinations in two groups of patients, each comprising twenty female patients scheduled for dilatation and curettage of the uterus (D & C) was conducted [16]. Speedy recovery is the primary end point in trials investigating day care anaesthesia.Ever since ambulatory surgery was introduced there is continued quest for an ideal anaesthetic agent which would have a rapid onset of action,quicker physical and faster psychomotor recovery (i.e. street fitness). To meet these requirements the currently used combination is propofol with fentanyl or alfentanil. As fentanyl could be procured in developing countries, combination of small doses of fentanyl for analgesia along with propofol is gaining attention similar to ketamine in subanaesthetic doses as analgesic alongwith propofol for total intravenous anaesthesia.

Aim

The aim of the study was to compare and evaluate the efficiency of combination of propofol-fentanyl with propofol-ketamine during induction and maintenance of general anaesthesia for minor gynaecological procedures.The quality of anaesthesia and quality of recovery from anaesthesia was also compared.

Objective

1. To assess the efficiency of the combinations of anaesthetics by measuring the cardiorespiratory changes during induction and maintenance of anaesthesia and recovery.
2. To measure the quality of anaesthesia by observing the depth of anaesthesia, adverse events if any and the recovery characteristics.

Materials and Methods

The present study was carried out in Sri Avittam Thirunal hospital allied to the Government Medical College,Thiruvanthapuram during 2001 April to August after approval from the Hospital Ethics Committee and Institutional Review Board.A convenient sample of forty females with written informed consent in the age group of 20-50 years with American Society of Anaesthesiologists Physical status grade I and II who were to undergo elective dilatation and curettage of the uterus (D & C) were included in this study.

Exclusion criteria: Patients with inability to communicate effectively, those who had received any narcotic or hypnotic medication within 24 hours before surgery, obese patients (body weight more than 80 Kg), patients with Haemoglobin less than 8 gms%, patients with hypersensitivity to the drugs used in the study and patients with more than 12 weeks gestation were excluded from the study. The patients were randomly allocated to two groups of twenty each to receive either a.Fentanyl 1.5 µgm/kg iv followed two minutes later by induction with propofol titrated to loss of consciousness-Group I (Group F)

b.Ketamine 0.5 mg/kg iv followed two minutes later by induction with propofol titrated to loss of consciousness-Group II (Group K). No premedication was given to the patients in both the groups. They were randomly allocated to receive one of the two anaesthetic combinations in a double blind manner.

Anaesthetic Technique

Blood pressure was monitored noninvasively.

ECG leads and pulse oximeter probes were attached to all patients prior to induction and the heart rate, blood pressure, respiratory rate and oxygen saturation were recorded.An intravenous line was started with an 18 guage cannula on the dorsum of the hand under local anaesthesia with 1% lignocaine. All patients were preoxygenated for three minutes with 100% oxygen through Mapleson A circuit. Patients were given intravenous fentanyl 1.5 µgm/kg in 30 seconds in Group I (F) and intravenous ketamine 0.5 mg/kg in 30 seconds in Group II (K). Anaesthesia was induced in both groups of patients with propofol by iv slow injection at a rate of 10 mg in 10 seconds titrating for loss of verbal contact and loss of eyelash reflex. An observer blinded to the nature of the drug being injected monitored patient responses (Figure 1).

Maintenance of Anaesthesia: As soon as the eyelash reflex disappeared the depth of anaesthesia was assessed by loss of jaw tone, patient was placed in lithotomy position and skin preparation for Dilatation and Curettage was begun. No muscle relaxant was used in this study. Airway was maintained by head tilt, chin lift and jaw thrust – manoeuvre with 100% oxygen inhalation through face mask and Magill's circuit.Anaesthesia was maintained by incremental top up doses of 25 mg propofol watching for abnormal movements related to surgical stimulation and hyperventilation (Figure 2).

Monitoring Parameters and Intervals

Depth of anaesthesia was monitored by presence of lacrimation, sweating, change of heart rate and blood pressure. Quality of anaesthesia assessed by looking for abnormal movements, laryngeal spasm, vocalisation, excess salivation, and episodes of desaturation. All monitored parameters were charted at the following intervals.

1. Preoperatively before induction
2. One minute after administration of induction agent
3. Thereafter every minute during maintenance of anaesthesia.
4. Full monitoring was continued until recovery period

Recovery: At the end of the procedure patients were transferred to the post anaesthesia recovery room. Patient's vital parameters were observed during post operative period.

Methods of Assessment of Recovery

Recovery time was taken from the last dose of propofol to the time of appearance of motor response or orientation. Motor response such as time to regain jaw tone, the return of eye lash reflex, and the ability to open the eyes on command were noted. Time to orientation based on the knowledge of the patient's name, current date and name of hospital were also judged. Thereafter the ability to sit up in bed, to stand up unsupported and the time of ambulation with out assistance, drink and voids were assessed every five minutes. Undesirable post operative side effects such as pain at the site of injection, nausea and vomiting were noted. At the time of discharge patients were interviewed for assessing quality of anaesthesia specifically asking about hallucination and pain during procedure.

Statistical Analysis

Data were collected with the help of a pre structural proforma and fed into the computer for construction of frequency tables. The statistical analysis was done with the help of SPSS (Statistical Package for social Scientist) for comparing the two groups mean and estimation of standard deviation of different assessment variables. The hypothesis formulated were tested statistically by unpaired t test.

Results

In this study that there was no difference in the mean age and weight of the participants in both groups and were identical with respect to demographic particulars has shown in Table 1. The anaesthetic induction time using propofol in the fentanyl group was more than in the ketamine group. The induction dose of propofol used was higher in the fentanyl Group than the ketamine pretreated group.The number of 25 mgs top up doses of propofol used for maintainance of anaesthesia were similar in both the groups whose duration of surgery was also similar. The incremental dose rate of propofol and the propofol utiliation rate and the duration of anaesthesia were similar in both the groups. Mean incremental dose rate of propofol was calculated by dividing total dose of incremental propofol in mgs by weight of patient in kgs. The propofol utilisation rate in mg/kg/minute was calculated by dividing the total dose of propofol in mg by the bodyweight in kgs and then multiplying by the duration of anaesthesia in minutes. The duration of recovery in minutes assessed by observing the time of eye opening on command, obeying of commands, ability to sit up,

Table 1: Demographic and clinical particulars measured

Mean & Standard Deviation of Particulars	Group I (F)	Group II (K)	't' value	p value
Age in years	42.95±8.9	44.3±4.8	0.6	>0.05
Body weight in Kgs	55.9±9.2	53.8±7.2	0.8	>0.05
Induction time in seconds	76.0±12.6	59.3±6.5	5.4	<0.05
Induction dose of propofol in mgs	114.5±40.3	85.3±21.4	2.9	<0.01
Number of top ups of propofol @ 25 mgs per top up	1.6±1.5	1.1±0.06	1.4	>0.05
Duration of surgery in minutes	6.7±4.5	4.9±2.2	1.6	>0.05
Incremental dose rate of propofol(mg/kg)	0.79±0.9	0.51±0.9	1.47	>0.05
Duration of anaesthesia in minutes	8.65±4.5	8.05±2.4	0.52	>0.05
Propofol utilisation rate mg/kg/mt	21.2±11	20.3±10.8	0.3	>0.05
Duration of recovery in minutes (assessed by eye opening)	2.4±1.5	3.8±0.7	3.9	<0.001
Duration of recovery in minutes (assessed by obeying commands)	3.4±1.6	6.1±1.1	6.4	<0.001
Dration of recovery time in minutes (assessed by ability to sit up)	33.2±2.3	37.71±3.5	4.89	<0.001
Dration of recovery time in minutes (assessed by ability to walk unaided)	56.5±3.4	59.5±2.6	3.19	<0.01
Dration of recovery time in minutes (assessed by ability to drink)	71±3.4	74.75±7.3	1.86	<0.05
Perioperative SpO_2	99.6±0.5	98.9±0.6	1.7	>0.05

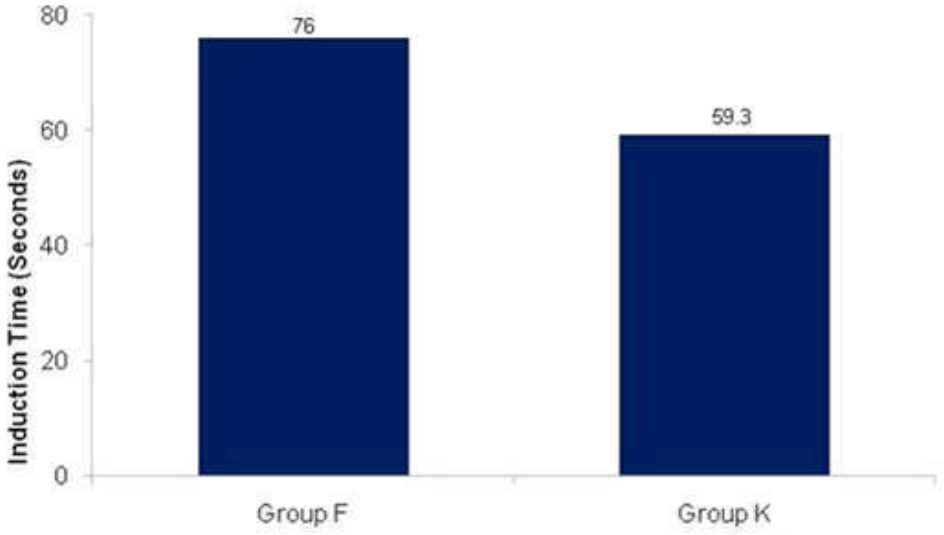

Fig. 1: Comparison of induction time ($p<0.05$)

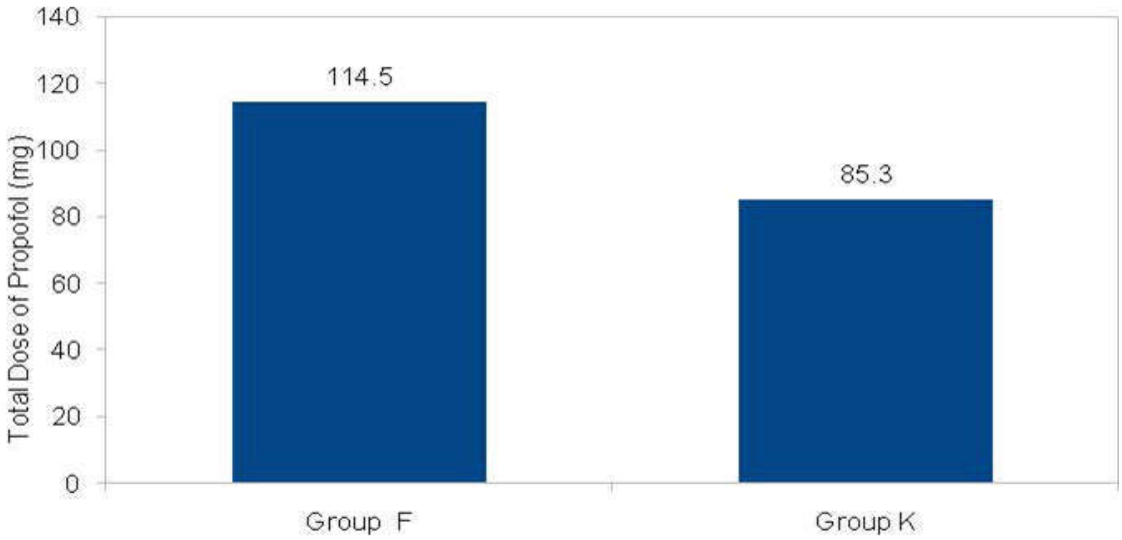

Fig. 2: Total dose of propofol used in mgs ($p<0.01$)

ability to walk unaided and ability to drink were significantly different between the two groups. Time for eye opening was calculated from the time of administration of last dose of propofol to eye opening upon commands after completion of the surgery. The mean recovery time to sit up and abiity to walk were more in the ketamine pretreatment group when compared with the fentanyl group.

There was a significant fall in the mean respiratory rate in Fentanyl group patients from the second minute of pretreatment onwards with maximum decrease of 29.8% at the seventh minute.The corresponding decrease in the mean respiratory rate in the ketamine group was only 3.1% (Fig. 3).

The change in mean heart rate noted every minute on pretreatment with fentanyl in group I and ketamine in group II followed after two minutes with induction with propofol showed a maximum increase of 5.2% and 6.2% respectively at the second minute.The maximum increase in mean heart rate of 7.9% was noted at the third minute in the ketamine group and the maximum decrease in mean heart rate of 12.4% was in the ninth minute in the fentanyl group (Fig. 4).

The mean blood pressure increased progressively in the first and second minute in both groups with

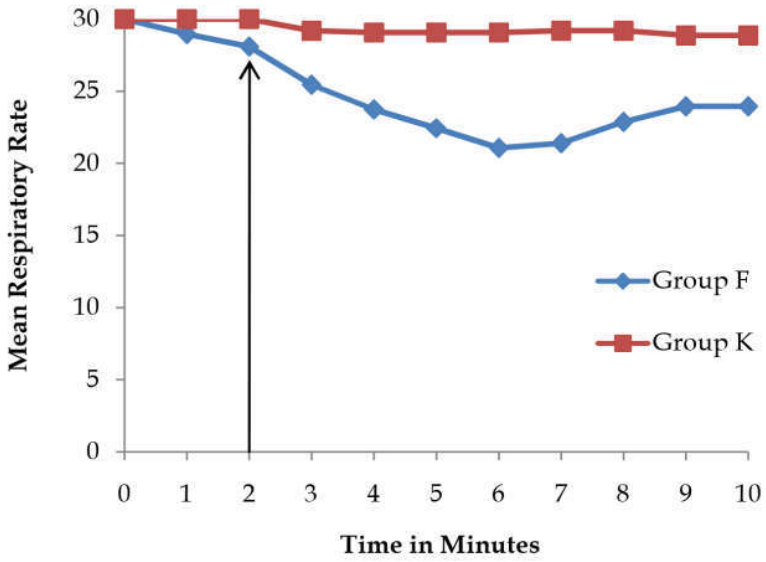

Fig. 3: Change in mean respiratory rate

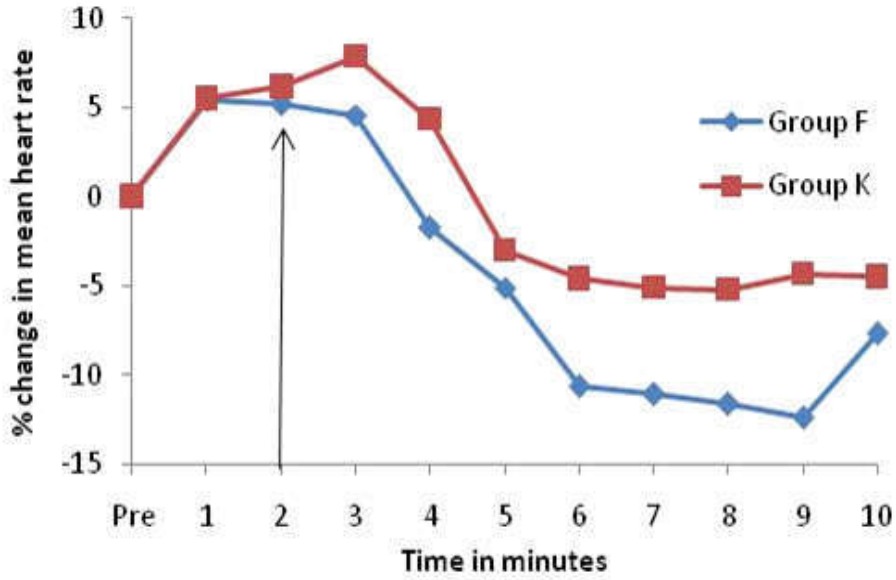

Fig. 4: Percentage change in mean heart rate

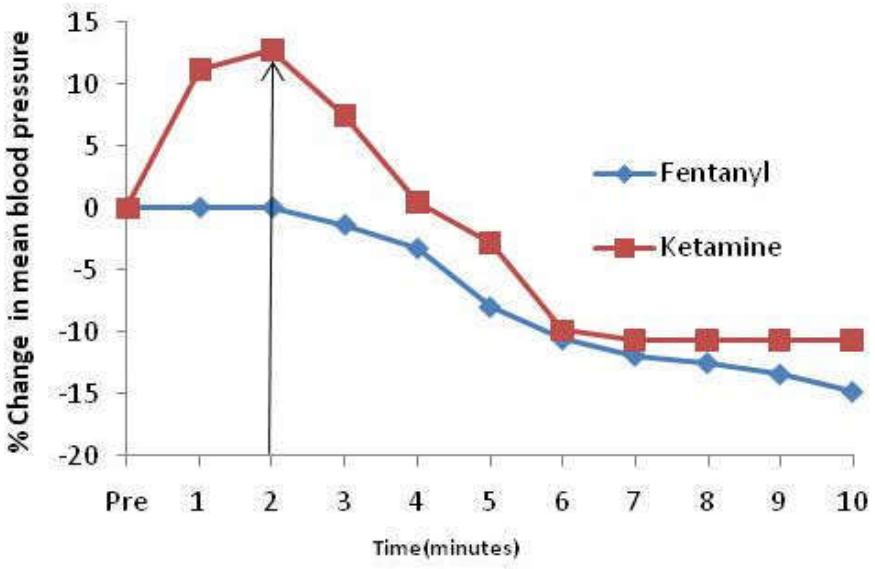

Fig. 5: Percentage change in mean systolic blood presure

higher increase noted in the ketamine group but with no significant difference between the two groups. On induction with propofol the fall in systolic blood pressure noted at fourth minute was less with the ketamine group than in the fentanyl pretreatment group. In Group I patients the blood pressure did not increase on pretreatment with fentanyl and were hamodynamically stable at near low normal levels whereas in group II patients the mean systolic pressure increased immediately on pretreatment with subanaesthetic doses of intravenous ketamine and on induction with propofol were maintained at ear high normal levels (Fig. 5).

Discussion

Day case surgery now widely practised has emphasized the need for an anaesthetic technique characterised by smooth, reliable and rapid onset of anaesthesia and quick recovery that allows discharge within a short time. By virtue of it's rapid induction and high plasma clearance, short elimination half life and absent emetic sequelae, many investigators have rcommended propofol as the specifically suitable agent for day care anaesthesia [17]. But it has little or no antinociception. Therefore propofol has to be combined with an analgesic. The purpose of this study was to compare the efficacy of combinations of propofol-fentanyl and propofol–ketamine during induction, maintenance and recovery phases during total intravenous general anaesthesia for minor gynaecological procedures.

The dose of propofol, fentanyl and ketamine used in this study was determined from available literature and these doses were equally adequate to provide anaesthesia and analgesia required for brief qynaecological procedures as long as ten minutes. Anaesthesia was maintained with top up doses of 25 mg of propofol depending on abnormal movements in response to surgical stimulation or hyperventilation. Time of induction, intraoperative haemodynamics and postoperative side effects were noted. Awakening and orientation to time and place were assessed by gross recovery parameters such as return of jaw tone, return of eyelash reflex, the ability to open eyes on command, ability to give correct name, current date and name of the hospital. Intermediate recovery which corresponds to the time the patients met the criteria for discharge home (Home readiness) was evaluated by noting the patients's ability to sit up and stand or walk.

The results of the present study has shown that all patients were identical with respect to age, weight, physical status, type of surgery and duration of anaesthesia.

The mean induction time in this study was 76±12.6 seconds in group I and 59.3±6.5 seconds in group II. The findings correlate with that reported in literature, Bowdle et al. [18]. In contrast to other studies by Johnston et al. the incidence of pain on

injection of propofol was low in this study [19]. Only two of the patients in group I complained of pain on receiving propofol or postoperatively.The lower incidence of pain in this study may be because of low incidence of pain with the injection of new formulation of propofol [20]. None of the patients in both the groups exhibited excitatory side effects. However, higher incidence of muscular movements have been reported by many other investigators [21].

Apnoea is a well known complication of propofol and the incidence was high in many patients in many previous studies in literature [22]. Apnoea was observed in three patients in group I and none in group II. There was a decrease in respiratory rate in group I from first minute to tenth minute where as the corresponding respiratory rate in group II was unchanged. This decrease in respiratory rate was statistically more significant from third minute onwards but was clinically not significant but for the three patients who had manageable apnoea.

There was a steady decrease in mean heart rate in group I, one minute after pre-treatment with fentanyl, and the mean heart rate continued to decrease from induction with propofol till the ninth mnute of anaesthesia, where as in group II there was an increase in mean heart rate in one minute after pretreatment with ketamine from preoperative values and started decreasing after third minute corresponding with induction with propofol and intraoperatively but the difference in heart rate between the two was not statistically significant.

The mean blood pressure in Group I remained unchanged till second minute after pretreatment with fentanyl and started decreasing till the ninth minute whereas in group II the mean blood pressure started increasing following first minute of pretreatment with ketamine and remained at the higher mean blood pressure level till the fourth minute and thereafter started decreasing from fifth minute.The onset of decrease in mean blood pressure in group II correspond with completion of induction with propofol [23]. The decrease in mean blood pressure in Group II persisted till the ninth minute. The percentage decrease in mean blood pressure from preoperative mean blood pressure was maximum by 8% at fifth minute and thereafter the mean blood pressure remained steady.The increase in mean blood pressure from preoperative mean blood pressure was maximum at 13% in Group II in the second minute and the maximum decrease in mean blood pressure was 2.8% at fifth minute. The changes in mean blood pressure were not statistically significant. Thus it was inferred that, propofol-fentanyl combination had a tendency to reduce mean systolic blood pressure from pretreatment with fentanyl and subsequently on induction with propofol to low normal levels. But with propofol-ketamine combination there was an immediate increase in mean systolic blood pressure from preoperative values upon pretreatment with ketamine and thereafter on induction with propofol the mean blood pressure was maintained at upper normal levels. The reduction in blood pressure in previous studies with propofol-fentanyl combination may be due to higher dose of rapidly injected propofol followed by fentanyl in fasting patients [24]. This may have clinical consequences in the hypovolaemic dehydrated patients and in patients with significant cardiovascular disease. However, the fall in mean blood pressure and mean heart rate in group I patients pre and intraoperatively and the initial increase in mean blood pressure and mean heart rate in group II patients preoperatively with pretreatment was well tolerated by the healthy patients in both the groups in this study. The relatively higher dose of propofol for induction with fentanyl may explain the decrease in blood pressure in Group I patients [24].

Quality of anaesthesia was assessed in this study by observing the incidence of abnormal movements, laryngeal spasm, vocalisation, excessive salivation and episodes of desaturation. None of the patients in both the groups exhibited salivation, laryngeal spasm or abnormal movements which affected the surgery. The arterial oxygen saturation levels in both the groups were practically the same.Immediate recovery (ie time of awakening and orientation to time and place) were assessed by recording the time after cessation of anaesthesia to the time when the patient opened eyes on command and gave her name, current date and name of hospital.

Early recovery was significantly different between the two groups statistically.Time to awakening was significantly shorter in Group I than in group II. Time to orientation was significantly shorter in group I than in group II with p value less than 0.01.

The intermediate recovery phase was assessed by observing patient's ability to sit up and stand and walk. The mean time to sit up by patients in Group I was less by four minutes when compared with Group was statistically significant ($p<0.001$). The difference in mean time noted between the two groups for walking and drinking were statistically significant. With respect to postoperative side

effects four patients in Group II had hallucinations and dreams which were clinically not significant. Postoperative nausea and vomiting were absent in both the groups due to inherent antiemetic activity of propofol.

Summary and Conclusions

The aim of the present study was to evaluate and compare the efficacy of propofol-ketamine and propofol-fentanyl for induction and maintenance of anaesthesia, along with quality of anaesthesia and recovery characteristics in minor gynaecological procedures. Forty healthy female patients, ASA grade I, scheduled for elective dilatation and curettage of the uterus participated in this study.

They were randomised into 2 groups to receive pretreatment with iv fentanyl 1.5 µgm /kg in group I (F) patients and IV ketamine 0.5mg/kg in group II (K) patients. Two minutes after pretreatment both groups of patients were induced with propofol titrated to loss of eyelash reflex, and loss of consciousness. Anaesthesia was maintained with incremental doses of 25 mg propofol watching for abnormal movements related to surgical stimulus and hyperventilation. Comparative evaluation was made regarding rapidity of recovery, haemodynamic and respiratory variables and side effects. At the time of discharge patients were interrogated regarding quality of anaesthesia, dreams, postoperative pain, nausea and vomiting and how they rated their experience during the recovery period.

Induction of anaesthesia was rapid and pleasant with both the combinations. There was no significant decrease in the respiratory rate in both the groups. Propofol-fentanyl combination caused reduction in both heart rate and blood pressure where as propofol-ketamine combination resulted in an initial increase in blood pressure and heart rate preoperatively on pretreatment with ketamine and later on induction with propofol haemodynamically stable anaesthesia was maintained. Early recovery was faster with propofol–fentanyl combination but with regard to orientation there was significant difference in the intermediate recovery phase in both the groups. Anaesthesia with fentanyl and propofol was comparable to the most commonly used combination of propofol and ketamine. It may be an appropriate choice when haemodynamic stability is of great importance or when post operative analgesia, post operative nausea and vomiting and rapid recovery to street fitness is required.

In conclusion, the results of this study suggest that propofol–fentanyl combination is a safe anaesthetic combination and is a better replacement for the commonly used propofol–ketamine combination for outpatient anaesthesia. It produces rapid and smooth anaesthesia with few untoward side effects. It produces no negative effects on the cardiorespiratory system. Recovery is rapid without emergence delirium and with total absence of emetic sequelae.

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