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Research Article

AN OBSERVATIONAL STUDY TO EVALUATE THE EFFICACY AND HEMODYNAMIC STABILITY OF PROPOFOL- KETAMINE & PROPOFOL- FENTANYL IN PATIENTS UNDERGOING DILATATION AND CURETTAGE

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ABSTRACT

Background: The study was done to compare the efficacy of combination of propofol-ketamine and propofol-fentanyl in terms of sedation, haemodynamic variables and side effects.
Methods: The study was done on 60patients of (age 18-35 years, weight 40-70 kilograms) ASA grade 1&2. These were randomly allocated in 2 groups of 30 each. They were undergoing Dilatation and Curettage procedures lasting up to 30 minutes. Group A received Inj. Ketamine 0.75 mg/kg body weight IV slowly over 2 minutes, after 5 minutes Inj. Propofol given at rate of 1ml/3 seconds till loss of consciousness. Group B received Inj. Fentanyl 2 mcg/kg body weight as slow IV injection, after 5 minutes Inj. Propofol given at rate of 1ml/3 seconds till loss of consciousness. Ramsay Sedation Score, hemodynamic variables were recorded intra-operatively and hemodynamic variables recorded post-operatively at regular intervals. Use of rescue analgesia and side effects was also assessed. The results were tabulated and analysed statistically.
Conclusion: Propofol-ketamine compared to propofol-fentanylgives good sedation as higher Ramsay sedation score was achieved and is more efficacious and provides better peri-operative hemodynamic stability during anaesthesia and also produces good analgesia with less requirement of rescue drug in post-operative period with fewer peri-operative complications.

INTRODUCTION

Dilatation and Curettage (D&C), is a short but painful surgical procedure, performed for the diagnosis and treatment of endometrial and intrauterine disorders. It causes significant pain due to cervical dilatation with dilators and tissue extraction. Drugs that are used for this procedure should ensure fast onset of action and rapid recovery and an adequate level of sedation and good analgesia. The most important objective in the intra-operative period is to maintain the hemodynamic-respiratory stability and minimising the side effects of the drug. Propofol is a sedative agent with rapid onset of action and fast recovery time, but it causes cardiovascular and respiratory depression in a dose dependent manner. Also it might be insufficient in painful processes because it lacks analgesic properties. Combining propofol with other drugs such as opioids or ketamine is used for improving the quality of sedation, analgesia and minimising the potential adverse effects with maintenance of a stable cardiovascular and respiratory status in the peri-operative period.

Ketamine is a NMDA receptor agonist, in sub-anaesthetic doses with propofol has gained attention in total intravenous anaesthesia because of its powerful analgesic action without causing myocardial and respiratory depression. Ketamine also causes some degree of sympathetic stimulation, which tends to counter-balance the cardiovascular side-effects of propofol.

Fentanyl on the other hand is synthetic opioid analgesic which has rapid onset and short duration of action and can be used in combination with propofol satisfactorily.

The present study is designed to assess the intra-operative Ramsay sedation score, hemodynamics, post-operative stability of hemodynamics and use of rescue analgesia in both the propofol-ketamine and propofol-fentanyl groups. Overall benefits and use of rescue analgesia were assessed by vas score and which group offers more advantage will be evaluated.

METHODS

The present study was carried out in the Department of Anaesthesiology at SMS Medical College and Hospital, Jaipur, Rajasthan. After obtaining institutional ethical committee approval and patients written informed consent, the study was conducted in 60 patients, aged 18-35 years of ASA Grade 1&2 scheduled for Dilatation and Curettage procedures lasting up to 30 minutes. The patients were randomly allocated using sealed envelope method in 2 groups (30 of each). Patients with respiratory, cardiovascular, neurological, liver diseases, patients on narcotic therapy were excluded from study. Pre-

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anaesthetic evaluation including history and a thorough general and systemic examination and all relevant investigations were done for all the patients.

Patients were kept fasting for at-least 8 hours prior to anaesthesia. Pre-operative baseline heart rate, systolic blood pressure, diastolic blood pressure, mean blood pressure, spo2 was recorded. A peripheral iv line was established. All patients were pre-medicated with Inj. Glycopyrrolate 0.004 mg/kg and Inj. Midazolam 0.02 mg/kg. Group A received Inj. Ketamine 0.75 mg/kg body weight IV slowly over 2 minutes, after 5 minutes Inj. Propofol given at rate of 1ml/3 seconds till loss of consciousness. Group B received Inj. Fentanyl 2 mcg/kg body weight as slow IV injection, after 5 minutes Inj. Propofol given at rate of 1ml/3 seconds till loss of consciousness.

Intra-operatively heart rate, blood pressure, oxygen saturation and Ramsay sedation score was recorded at different time intervals of 5, 10, 15, 20, 25, 30 minutes following induction of anaesthesia in both groups. Throughout the procedure patients were allowed to breathe spontaneously on room air and oxygen supplementation was given to some patients during apnoea. Top-up dose of Inj. Propofol 0.5 mg/kg was given when patient became light during anaesthesia as indicated by rise in heart rate, blood pressure or any other movement to surgical stimulus. Total dose of propofol required for the patients was noted.

Post-operatively all vital parameters like heart rate, blood pressure, oxygen saturation and visual analogue score was recorded every 30 minutes for first 2 hours then every 2 hours till 12 hours.

Any complication like nausea, vomiting, delirium, sedation, painwas noted.

Statistical Analysis

Continuous variables like age, heart rate, systolic blood pressure, diastolic blood pressure, Ramsay sedation score, spo2, total dose of propofoletc were presented as Mean ± SD. Continuous variables were compared at different time intervals between ketamine and fentanyl groups by performing unpaired t-test, $p<0.05$ was considered as statistically significant.

Observations

A total of 60 patients who underwent Dilatation and Curettage lasting up to 30 minutes were enrolled for the study and were randomly divided into 2 groups. The demographic profiles with regard to age and weight was comparable. The distribution as per ASA status was similar.

Pre-induction heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, spo2 were comparable in both the groups with a statistically no significant difference between them ($p<0.05$).

At 15 min and 20 min the SBP of Group A and that of Group B was statistically significant. ($P<0.05$).At 25 mins and 30 mins the SBP of Group A and that of Group B was statistically significant ($P<0.05$).

At 10 and 15 mins the DBP of Group A and that of Group B was statistically significant ($P<0.05$).

Table 1 Comparison of Heart Rate in both Groups

Heart rate	Baseline	1 min	5 min	10 min	15 min	20 min	25 min	30 min
Group A Mean ± SD	84.56±3.34	81.20±4.93	87.62±5.2	83.30±6.33	83.0±5.58	80.45±6.02	80.22±6.2	80.7±6.1
Group B Mean ± SD	86.86±3.86	88.05±6.04	82.66±6.00	77.20±5.27	78.34±4.85	76.45±6.63	80.65±6.16	79.55±6.31
P-value	0.01	0.0001	0.0005	0.0003	0.0007	0.03	0.741	0.497

Table 2 Comparison of Systolic Blood Pressure (SBP) in both Groups

SBP	Baseline	1 min	5 min	10 min	15 min	20 min	25 min	30 min
Group A Mean ± SD	123.64±5.48	119.14±12.17	120.60±11.30	119.14±9.90	116.35±10.97	114.10±11.87	114.78±10.56	115.07±10.23
Group B Mean ± SD	123.35±4.52	119.85±9.67	117.21±8.35	116.57±9.19	111±7.44	108.42±8.21	109.85±8.68	107±18.77
P-value	0.823	0.803	0.191	0.301	0.030	0.04	0.05	0.001

Table 3 Comparison of Diastolic Blood Pressure (DBP) in both groups

DBP	Baseline	1 min	5 min	10 min	15 min	20 min	25 min	30 min
Group A Mean ± SD	72.47±4.91	69.65±7.04	69.38±2.95	67.42±5.56	67.22±5.34	67.35±5.97	67.47±4.39	69.25±3.78
Group B Mean ± SD	73.37±4.51	69.77±4.88	69.47±3.51	64.75±3.59	64.45±3.59	65.58±4.71	67.37±4.39	25
P-value	0.370	0.858	0.802	0.013	0.017	0.060	0.033	0.926

Table 4 Comparison of Ramsay Sedation Score in both groups

RSS	Baseline	1 min	5 min	10 min	15 min	20 min	25 min	30 min
Group A Mean ± SD	1.92 ±0.27	1.92±0.27	4.40±0.57	4.82±0.56	5.46±0.57	5.86±0.35	5.96±0.19	5.95±0.20
Group B Mean ± SD	1.94±0.23	1.94±0.23	3.94±0.74	4.06±0.72	5.10±0.57	5.72±0.49	5.9±0.30	5.97±0.14
P-value	0.70	0.70	0.009	<0.0001	<0.0001	0.20	0.35	0.65

Table 5 Comparison of VAS in both groups

VAS	30 min	1 hour	1 hour 30 min	2 hour	4 hour	6 hour	8 hour	10 hour	12 hour
Group A Mean ± SD	2.87±1.22	2.33±1.12	1.57±0.9	1.33±0.76	1.17±0.53	1.1±0.4	1±0	1±0	1±0
Group B Mean ± SD	4.37±1.54	3.27±1.34	2.8±1.13	2.3±0.84	1.63±0.85	1.23±0.5	1±0	1±0	1±0
P-value	0.0001	0.004	<0.0001	<0.0001	0.013	0.262	-	-	-

DISCUSSION

Over a period of years, the role of Total Intra-venous Anaesthesia (TIVA) in the short surgical procedures like dilatation and curettage has increased the need for anaesthetic technique with smooth induction, good intra-operative anaesthesia and analgesia and rapid recovery with minimal side effects so that early discharge is possible. Dilatation and curettage is a short and painful procedure. It causes pain because of cervical dilatation and tissue extraction. Thus intravenous sedation techniques are widely used for D&C for good sedation, maintaining hemodynamic and respiratory stability and good analgesic management while minimizing the side effects of drugs.

Propofol, when introduced in 1986 shown to have many of these properties. Many studies have been performed to assess propofol both as a sole anaesthetic agent and in combination with fentanyl and ketamine in different doses. However, there are no studies about comparisons with the combinations of propofol along with either Fentanyl 2 mcg/kg or Ketamine 0.75 mg/kg for D&C under general anaesthesia. Hence whether pre-induction with ketamine 0.75 mg/kg or fentanyl 2 mcg/kg in combination with propofol as an inducing agent in a dose of 2 mg/kg for short surgical procedures like D&C offered any advantage in terms of better quality of anaesthesia, hemodynamic stability, good recovery profile & minimal side effects was studied and compared to know the advantage of one combination over the other in the intra-operative and post-operative period in our study.

All patients in both the groups were comparable with respect to age and weight. The mean age of patients in Group A was 27.52 ± 4.15 and that of Group B was 28.30 ± 5.74. The difference was statistically not significant. (P> 0.05)

Also, the weight of patients in Group A was 56.62 ±10.39 and that of Group B was 57.88 ± 7.66. The difference was not statistically significant. (P value > 0.05).

In the present study, Group A received ketamine 0.75 mg/kg as well as Group B received Fentanyl 2 mcg/kg 5 minutes before induction. After giving ketamine and fentanyl, propofol was given at the rate of 1ml/3 seconds till loss of consciousness. The rate of injection of propofol was kept constant at approximately 1ml/ 3 second.

In our study we observed that during intra-operative period in Group B there was fall in HR at all times except at 25 and 30 min as compared to Group A, which was statistically significant. The decrease in the HR in Group B can be attributed to the action of fentanyl on the cardiovascular system. Similar findings were found in Brajesh K[1]. Also in M. Arikan[2] *et al* studythey found significant fall in HR in fentanyl group as compared to ketamine group at all times intra-operatively.

The fall in SBP, DBP, MBP was statistically significantly higher in Group B than Group A. There was minimal fall in SBP, DBP and MBP in Group A as compared to Group B in intra-operative period, due to the sympatho-mimetic activity of ketamine which counteracts with the cardiovascular depressant action of propofol thus maintaining a stable hemodynamic profile as compared to fentanyl. In 2012, Khutia SK[3] *et al*, compared combination of propofol-fentanyl infusion with propofol-ketamine infusion in paediatric short term procedure. Similar findings like our study were noted, that is more hypotension was found in B group (38.6%) as compared to A group (14.6%).

The peripheral oxygen saturation in intra-operative period in Group A was found to be in the range of 98.1 ± 0.96 % to 99.41 ± 0.90 % whereas in Group B SpO2 was 97.21 ± 1.50 % to 98.18 ± 1.44 %. The change in peripheral oxygen saturation at different time interval were statistically not significant (p>0.05). In M. Arikan[2]study there was no significant difference in fall in SPO2 in both the group.

The RSS (Ramsay sedation score) was higher in Group A than Group B at all times but was statistically significant at 5, 10, 15 minutes. In M. Arikan[2] study the RSS scores of A were higher than those of Group B for all recording times.

The mean total dose of propofol required in Group B (112.6 ± 11.09mg) was higher than that in Group A (105.3 ± 15.43 mg) which was statistically significant (P value < 0.05). Similarly, in M. Arikan[2], the mean consumption of propofol was higher in fentanyl group as compared to ketamine group.

We have noted in our study that intra-operative complications (desaturation, hypotension) were significantly higher in Group B than in Group A (P value < 0.05). In Group A out of 30 patients, 3 patients had episodes of desaturation and 4patients had hypotension, whereas, in Group B out of 30 patients, 7 patients had episodes of desaturation and 7 patients had hypotension. In study of Khutia SK[3] *et al* more hypotension was found in Group B (38.6%) as compared to Group A (14.6%).

In our study the VAS was statistically higher in Group B than in Group A. (P value <0.05). The analgesic property of ketamine could be attributed to the inhibitory action of Ketamine at NMDA receptors which are important in pain processing and the modulation of pain. And hence the requirement of rescue analgesia was lower in Group A than in Group B (P value<0.05). In Yuce HH[4], they observed that Ketamine has been shown to decrease pain scores and reduce post-operative analgesic consumption by 35-40%.

The post-operative complications like nausea- vomiting, desaturation, hypotension, post-operative pain were higher in Group B than in Group A (P value <0.05). There were no incidences of psychedelic effects of ketamine like hallucination, dysphoria. Similar findings in study of M. Arikan[2] where prevalence of hypotension and apnoea found in Group B more than Group A. Also the occurrence of nausea and vomiting were higher in Group B. These findings correlate well with the study of Brajesh K[1], where there higher incidence of apnoea in Group B as compared to Group A.

CONCLUSION

It may be concluded from our present study that propofol with ketamine as an adjuvant in the dose of 0.75 mg/kg compared to propofol with fentanyl as adjuvant in the dose of 2 mcg/kg provides deep sedation. But propofol-ketamine group is more efficacious and provides better peri-operative hemodynamic stability during anaesthesia as compared to propofol-fentanyl group. Also the propofol-ketamine combination produces good analgesia with less requirement of rescue drug in post-operative period with fewer peri-operative complications than propofol-fentanyl combination. We have not encountered any psychotomimetic effects of injection Ketamine in the 0.75mg/kg dose. Hence propofol-ketamine combination is a better choice especially when hemodynamic stability is of

great importance in patients undergoing dilatation and curettage.

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