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ORIGINAL ARTICLE

EFFICACY AND SAFETY OF PROPOFOL V/S KETAMINE IN SHORT SURGICAL/DIAGNOSTIC PROCEDURES IN PAEDIATRIC AGE GROUP

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ABSTRACT: In the era of day care surgery there is growing need for the anaesthetic technique which provides stable haemodynamics, adequate analgesia, and minimal complications and at the same time rapid recovery and early ambulation. This prospective study is aimed to compare efficacy and safety of propofol with ketamine in short surgical/diagnostic procedures in paediatric age group. We randomly allocated 100 patients in to two equal groups receiving either propofol (Group I) or ketamine (Group II). It was observed that in propofol group, mean systolic and diastolic blood pressures decreased by 5.28% to 9.98% and 7.40% to 11.40% respectively, while in ketamine group mean SBP and DBP increased by 7.53% to 12.32% and 11.98% to 13.24% respectively and the difference between the two groups was statistically significant. Heart rate and respiratory rate increased in both the groups, the difference was statistically insignificant ($p>0.05$). Propofol has the properties of smooth induction and rapid recovery associated with transient perioperative complications which makes it an ideal intravenous anaesthetic agent for day care surgery.

KEYWORDS: Ketamine, Propofol, Paediatric age group.

INTRODUCTION: Surgery and anaesthesia both are a traumatic experience for a child and can cause considerable emotional stress to the child as well as the parents. As the children react with different psyche and physiology when subjected to surgical procedure, the priority wise anaesthetic management should always utilize effective and safe method, with proper counselling.

Anaesthesia by intravenous route has become the most convenient and acceptable method of induction. Ketamine, a very popular agent for day care anaesthesia is preferred by most of the anaesthesiologists. It has intrinsic analgesic and amnestic properties, protects airway reflexes and can be administered by multiple routes of administration. It has the potential for undesirable side effects that include sympathetic cardiovascular stimulation, prolonged recovery period, postoperative nausea and vomiting, excessive salivation, lacrimation, increased intraocular and intracerebral pressure. Due to its dissociative anaesthesia, it is associated with emergence delirium, intraoperative and postoperative dreams and hallucinations.

Propofol is an intravenous sedative–hypnotic agent with amnestic properties that causes loss of consciousness reliably and rapidly. Because it is a poor analgesic, propofol usually requires the use of an adjunctive analgesic agent. Propofol is uniquely titrable and unlike ketamine, it has intrinsic antiemetic properties. It provides a smooth recovery without dysphoria. There is no interaction with haem synthesis (porphyria) or steroid synthesis. The disadvantages with propofol are its high cost, pain on injection and slight fall in blood pressure, respiratory depression or even apnoea and thrombophlebitis.

Propofol has been extensively investigated for anaesthetic induction and maintenance in adults but experiences with its use in children for anaesthetic maintenance is limited and very few people are well versed with the use of propofol in paediatric patients. Children require higher

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infusion rates of propofol than adults to maintain clinical anaesthesia due to their high volume of distribution.

The study was designed to evaluate efficacy and safety of propofol and fentanyl in comparison to ketamine and midazolam for short surgical/diagnostic procedures in paediatric age group patients.

AIMS AND OBJECTIVES: The objectives of study were to assess onset, characteristics of induction and duration of action, evaluate dose effectiveness and quality of sedation, recovery time and recovery characteristics, effect on cardiovascular and respiratory system and side effects/ complications of propofol and ketamine.

MATERIAL AND METHODS: After obtaining institutional ethical committee approval, and caregiver written informed consent hundred patients between 3-12 years of age of ASA grade I and II of either sex undergoing short duration surgeries or diagnostic procedures were included in this prospective study.

Children below 3 years of age and patients having full stomach, hiatus hernia, respiratory illness, open globe injury, psychiatrics or patients with seizure disorder, known allergy to egg and soya, morbid obesity and h/o adverse reaction to anaesthesia and sedation were excluded from the study.

After a detailed history, general and systemic examination and necessary investigations patients were randomly allocated into two groups.

Group I received i.v. propofol 2.5mg/kg over 15-30 seconds and i.v. fentanyl 2μg/kg for induction and i.v. propfol infusion @ 100-3000μg/kg/min in 5% dextrose for maintenance (final concentration of 2mg/ml)

Group II received i.v. ketamine 2mg/kg over 30-60 seconds and i.v. midazolam 0.05mg/kg for induction and i.v. ketamine infusion @ 30-90μg/kg/min in 5% dextrose for maintenance (final concentration of 1mg/ml)

After securing i.v. access with appropriate canula all patients were pre-medicated with i.v. ranitidine 1-2mg/kg and i.v. glycopyrolate 5μg/kg just before induction. Noninvasive monitors viz (ECG, NIBP, Pulse oximeter) were attached and vital parameters like heart rate, blood pressure, oxygen saturation, respiratory rate were continuously monitored and recorded preoperatively, after premedication, immediately after induction, at 5min. interval for first 30minutes and every 10minutes there after upto 2hrs postoperatively.

Procedure related parameters like onset and characteristics of induction, induction time, total induction dose, total maintenance dose, total dose requirement, total duration of surgery, total duration of anaesthesia, recovery time and adverse events or complications with the two study drugs were recorded and tabulated. Effectiveness of anaesthesia was assessed on the basis of induction and maintenance, haemodynamics, respiratory stability, recovery characteristics, and postoperative complications. The doctor performing the procedure was asked to rate the child's level of anaesthesia by indicating a point on a 10cm line between the labels "quiet and still or asleep (at 0cm) and "uncontrolled crying and struggling" (at 10cm).

Patients were observed in postoperative period for signs of complete recovery and were assessed by fast track eligibility criteria. A score over 12 with no individual score <1 is required for fast tracking and after fulfilling the criteria the patient was discharged.

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Any untoward incidences like pain or redness at injection site, spontaneous movements, hypertonus, twitching, tremor, flushing and rashes, cough, hiccough laryngospasm, apnoea, nausea and vomiting, bradycardia, hypotension were recorded and tabulated.

Emergence phenomenon: may be graded as:

1. None.
2. Mild (Mild hallucinatory experience)–no intervention.
3. Moderate (Agitation/restlessness)–require drug therapy.
4. Severe (Frank delerium)–require drug therapy.

Induction time was defined as the time (In minutes) for initial administration of propofol/ketamine for achievement of adequate sedation and analgesia, as determined on the basis of minimal response to painful stimuli (i.e. nail bed pressure).

Duration of sedation administration was defined as the time (In minutes) from administration of the initial propofol/ketamine dose to termination of surgical stimulation. The drug administration was always discontinued at the termination of surgical stimulation.

Duration of procedure was defined as the time (In minutes) from initiation of interventional procedure (Including sterile preparation of patient) to termination of procedure (i.e. end of painful stimuli).

Recovery time was defined as the interval (In minutes) from the time the patient arrived in the recovery room to the time he or she fulfilled the established criteria for discharge from the recovery room.

Criteria	Score
Levels of conciousness	
Awake and oriented	2
Arousable with minimal stimulation	1
Responsive only to tactile stimulation	0
Physical Activity	
Able to move all extremities on command	2
Some weakness in movement of all extremities	1
Unable to voluntarily move the extremities	0
Haemodynamic Stability	
Blood pressure <15% of the baseline MAP value	2
Blood pressure between 15% and 30% of the baseline MAP value	1
Blood pressure >30% below the baseline MAP value	0
Respiratory Stability	
Able to breathe deeply	2
Tachypnea with good cough	1
Dyspneic with weak cough	0
Oxygen Saturation Status	
Maintain value > 90% on room air	2
Requires supplemental oxygen (nasal prongs)	1
Saturation < 90% with supplemental oxygen	0
Postoperative pain assessment	
None or mild discomfort	2
Moderate to severe pain controlled by i.v. analgesics	1

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Persistent severe pain	0
Postoperative Emetic Symptoms	
None or mild nausea with no active vomiting	2
Transient vomiting or retching	1
Persistent moderate to severe nausea and vomiting	0
Total Score	14

Criteria used to determine fast track eligibility after ambulatory anaesthesia

All the observations were recorded and tabulated. Results were analysed statistically by paired t test ($P<0.05$ was considered significant otherwise insignificant) and Z-test.

OBSERVATIONS AND RESULTS:

The two groups were comparable with respect to age, gender and weight.

PARAMETER	GROUP I	GROUP II
No. of patients	50	50
Mean Age (yrs)	7.68±2.76	7.66±2.74
Sex distribution (M/F)	31/19	30/20
Mean Weight (kg)	19.74±5.41	19.54±5.17

TABLE 1

The two groups were comparable with respect to distribution of cases.

Type of surgery	Group I (%)	Group II (%)
Amnion grafting	2	2
Biopsy	4	6
Circumcision	8	8
Collagen grafting	2	2
Correction of squint	2	2
DCR	4	6
ECCE – PCIOL	12	16
Evisceration	2	2
Evisceration of sac	4	4
Ophthalmic Examination	2	0
Excision of dermoid and rhinosac	12	12
Herniotomy	10	12
Incision and drainage	6	4
AC WASH	2	0
Paracentesis	0	2
MRI	4	2
Orchidopexy	8	8
Removal of foreign body	2	2
Repair of corneal tear	2	2
Second degree implant	2	2
Septoplasty	2	2
Skin Grafting	4	4
Trabeculectomy	4	0

TABLE 2

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Table 3: Shows range and mean of induction times & dose, infusion rate, maintenance dose and total drug dose required for conducting anaesthesia in the two groups.

	Group I		Group II	
	Mean±SD	**Range**	**Mean±SD**	**Range**
Induction Time(sec)	40.78±5.60	30–48	42.02±5.55	30–50
Induction Dose (mg)	2.48±0.14	2.22-2.81	2.20±0.21	1.7-2.5
Total induction dose (mg)	49.00±13.74	25-79	42.4±9.75	20-60
Infusion rate (µg/kg/min)	226.14±26.60	104.17-255	79.16±5.35	52.08-88.89
Total maintenance dose (mg)	218.90±104.96	75-460	70.90±26.14	30-135
Total dose (mg)	241.80±106.62	100-540	118.30±32.87	60-195

TABLE 3

Table 4 shows the incidence of bolus supplementation for maintenance of anaesthesia in addition to infusion.

Group	**Patients (%) Requiring Supplementation**	**Supplementary dose given (mg) - Range**
I	28	20 – 30
II	22	20 – 30

TABLE 4

Table 5 shows the distribution of cases according to duration of anaesthesia. Least duration of anaesthesia was 25 min in both the groups while the longest duration was 90 min in Gr. I & 80 min Gr. II.

Duration Range (min)	**Group I (%)**	**Group II (%)**
25 – 30	20	22
36 – 45	34	36
46 – 55	12	10
56 – 65	22	24
66 – 75	6	4
> 75	6	4
Total	**100**	**100**
Mean ± SD	48.24±15.44	47±13.85

TABLE 5

Table 6 shows distribution of cases according to duration of surgery. Shortest duration of surgery in both the groups was 20 min. longest duration of surgery was 90 min. in group I & 80 min in group II.

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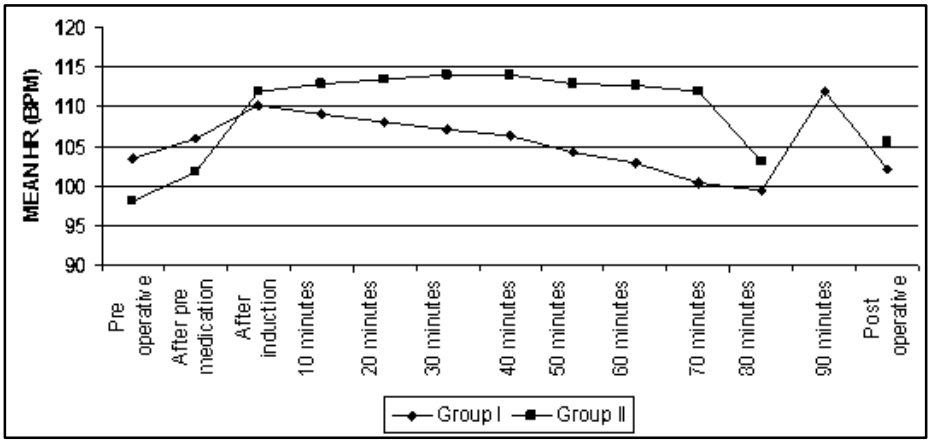
Duration (min)	Group I (%)	Group II (%)
15 – 25	22	22
26 – 35	34	32
36 – 45	20	24
46 – 55	12	16
56 – 65	10	4
> 65	2	2
Range of duration (min)	20 - 90	20 – 80
Mean ± SD	37.5 ± 14.54	36.2 ± 13.04

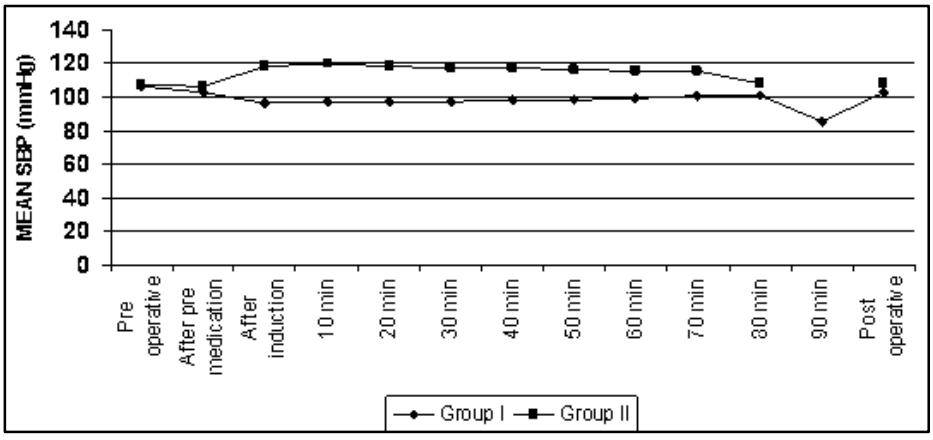
TABLE 6

The mean heart rate increased in both the groups immediately after induction till the postoperative period, which was statistically insignificant. (Graph1).



Graph 1

The systolic blood pressure decreased in propofol group and increased in ketamine group from immediately after induction till the postoperative period. The difference in systolic blood pressure between the two groups was statistically significant ($p<0.05$). No severe hypotension or hypertension was observed in either group. (Graph 2)



Graph 2

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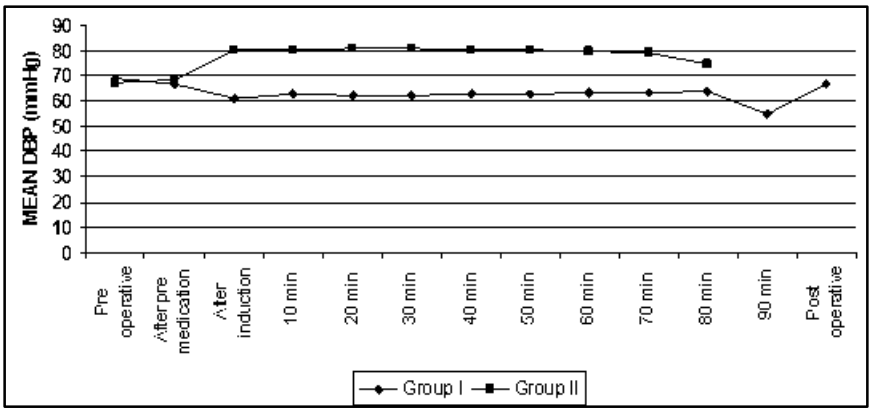
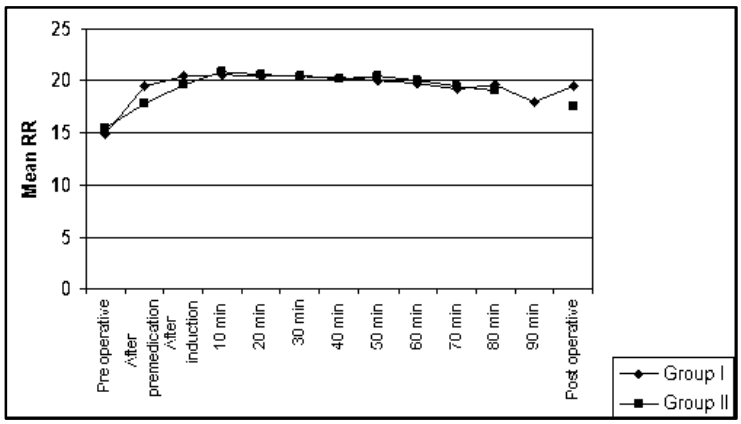
Graph 3 shows the mean diastolic blood pressure at various time intervals. The diastolic blood pressure decreased in propofol group and increased in ketamine group from immediately after induction till the postoperative period. No severe fall or rise in DBP was observed in either group.



Graph 3

Respiratory rate increased in both the groups. The difference in respiratory rate between the two groups was statistically insignificant. (Graph 4).



Graph 4

Table 7 shows the incidence of perioperative complications with the two drugs and their statistical comparison.

SL. No.	Complication	Group I (%)	Group II (%)	P value
1	Pain on injection / Thrombophlebitis	14	00	<0.05
2	Spontaneous movements	24	10	<0.05
3	Apnoea	28	8	<0.05
4	Laryngospasm / Bronchospasm	2	10	<0.05
5	Nystagmus	00	26	>0.05
6	Emergence phenomenon	8	12	<0.05
7	Nausea / Vomiting	4	16	<0.05

TABLE 7

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Table 8 shows the percentage of patients who achieved the fast track eligibility criteria of twelve at various time intervals. The difference in the recovery profile was statistically significant in the two groups. This indicates the rapid recovery character of propofol.

Sl. No.	Fast track Eligibility Criteria Score of 12 Postoperatively	Group I (%)	Group II (%)
1	Up to 30 min	92	28
2	Up to 60 min	96	46
3	Up to 120 min	100	80

TABLE 8

Table 9 shows the incidence of overall quality of anaesthesia with propofol and ketamine. The difference between the two groups was statistically significant.

Sl. No.	Group	Excellent (%)	Good (%)	Poor (%)
1	I	80	20	00
2	II	40	50	10

TABLE 9

DISCUSSION: The aim of this study was to compare propofol and fetanyl with ketamine and midazolam in paediatric day care surgery.

The induction time of propofol was found to be 30 to 48 sec. The induction time in our study was comparable to that of Hannallah Raafat S et al.[1]

The induction time of propofol in our study was less as compared to that of Hertzog JH et al.[2]

The difference was due to the different definitions adopted for induction time. Hertzog JH et al.[2] defined induction time as the time from administration of first dose of propofol or other sedative to when the patient was totally unresponsive to verbal and tactile stimuli while in our study the definition adopted is the time required to achieve adequate sedation and analgesia determined on the basis of minimal response to painful stimuli.

The induction time of ketamine in our study was comparable to that of Cheuk DK et al [3], and Mason Keria P et al [4].

The required induction dose varied between 2.22 to 2.81mg/kg (mean 2.48±0.14mg/kg) with propofol and 1.7 to 2.5mg/kg (mean 2.20±0.21mg/kg) with ketamine. (Table 4) The difference between the doses was statistically insignificant.(p value >0.05).

Induction dose of propofol in our study was comparable to that of Cortinez LI et al.[5] It was slightly less than that of Hannalah Raafat S et al [6] probably due to the synergistic action of fentanyl with propofol in our study and no premedication in their study.

Induction dose of ketamine in our study was comparable to that of Mason Keria P et al [4]. It was in slight higher range in our study than those of Pun M S et al[7] probably because of use of 0.2mg/kg diazepam as premedication in their study and 0.05mg/kg midazolam and in our study.

Mean propofol infusion rate required to maintain anaesthesia was 226.14±26.60µg/kg/min (range 100-250µg/kg/min) while for ketamine it was 79.16±5.35µg/kg/min (range 50-90µg /kg/min).

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Total maintenance dose was 218.90±104.96 mg (range 75–460mg) for propofol and 70.90±26.14 mg (range 30–135mg) for ketamine.

The total drug consumed for conducting the anaesthesia during the procedure was 241.80±106.62mg (range 100–540mg) for propofol and 118.30±32.87mg (range 60–195mg) for ketamine (Table 8)

The infusion rate of propofol required for maintenance of anaesthesia in our study was comparable to that of Short T G et al[8] & Mcfarlan C S et al.[9] The infusion rate of propofol required for maintenance of anaesthesia in our study was quite lower than those used by Hannallah Raafat S et al[1] because of synergistic action of fentanyl premedication in our study.

The infusion rate of ketamine was more in our study than those of M S Pun et al[7] probably because of use of diazepam as premedication in their study.

During maintenance of anaesthesia, supplementary 20–30 mg was required in 14 patients of propofol group and 11 patients of ketamine group. (Table 6).

The supplementary drug over the induction dose for maintenance of anaesthesia used in our study was similar to the studies of Pun M S et al.[7] Vardi A et al.[10] & Meyer S et al.[11]

Just after induction, there was 6.48% increase in the mean heart rate from the basal heart rate, which settled down to 0.75% rise 50minutes after induction in group I.

The heart rate changes due to induction and maintenance with propofol in our study were comparable to those of Gray C et al.[12]

The heart rate changes due to ketamine in our study were comparable to those of Meyer S et al.[11]

Both propofol and ketamine appear to be associated with acceptable cardiovascular stability but significant difference were noted between them.

There was a decrease in mean SBP of 5.28% to 9.98% during the intraoperative period in the propofol group while in the ketamine group an increase of 7.53% to 12.32% in the mean SBP was recorded. The percentage variation in mean SBP was statistically significant between the groups ($p<0.05$). The percentage change in mean systolic blood pressure after induction with propofol was comparable to that of Gottschling S et al[13] and Gray C et al.[12]

Changes in SBP after ketamine infusion in our study were comparable to those of Meyer S et al [11] and Gottschling S et al.[13]

There was a decrease in mean DBP of 7.4% to 11.4% during the intraoperative period in the propofol group while in ketamine group an increase of 11% to 13% in the DBP was recorded. The percentage variation in mean DBP was statistically significant between the groups ($p<0.05$).

The percentage change in mean DBP after induction with propofol in our study was comparable to that of Gottschling S et al.[13]

Changes in DAP after ketamine infusion in our study were comparable to those of Meyer S et al (2003), & Gottschling S et al.[13]

The mean respiratory rate (RR) after premedication was 19.42±2.99 per min in propofol group and 17.88±2.23 per min in ketamine group. The difference in the respiratory rate between the groups was statistically insignificant ($p<0.05$). (Graph 4)

The respiratory rate increased from 19.42±2.99 per min to 20.38±3.33 per min just after induction and 20.6±2.11 per min 10 minutes after induction in group I. In group II, respiratory rate increased from 17.88±2.23 per min to 19.56±3.52 per min just after induction and further increased

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to 20.82±1.90 per min 10 minutes after induction. The increase in respiratory rate during the intraoperative period in both the groups was statistically insignificant (p>0.05). (Graph 4)

Apnoea was observed in 28% of cases in propofol group and 8% of cases in ketamine group.

The apnoea was transient of around 20 seconds' duration and was self-limiting. No assisted ventilation was required in either group. All patients of both groups were already getting supplementary oxygen through nasal catheter. The difference in incidence of apnoea between the two groups was statisticslly significant (p<0.05). (Table 9)

The incidence of apnoea in our study was comparable to those of Hannallah Raafat S et al[6] and Hertzog J H et al.[2] The respiratory depression and instances of apnoea in our study were comparable to those of Cheuk DK et al,[3] Costen Vardi A et al[10] & Godambe SA et al.[14]

Most frequent and noticeable side effect associated with propofol is pain on injection. Though major veins in forearm and antecubital fossa were secured for drug injection in our study, pain was observed in 7 patients (14%) during injecting the drug. No single patient felt pain on injecting ketamine. The difference in incidence of pain on injection was statistically significant (p<0.05). (Table 9). The incidence of pain on injection with propofol in our study was comparable to that of Hannallah Raafat S et al.[6]

The incidence of pain on injection of propofol in our study was less as compared to Borgeat A et al,[15] probably it might have been due to the altered perception of pain caused by fentanyl premedication in our study.

The incidence of spontaneous movement was 24% in propofol group and nil in ketamine group in our study, which was statistically significant (p<0.05). (Table 9)

The incidence of spontaneous movement in our study was comparable to that of Hannallah Raafat S et al.[6]

Laryngospasm/Bronchospasm was seen in 2% patients of propofol group while 10% patients of ketamine group suffered it but was easily managed by assisted ventilation with facemask. The surgical procedure was allowed to continue after resumption of normal respiration without any unfavourable outcome. (Table 9)

In our study emergence phenomenon was of mild degree. Its incidence was 8% and 16% with propofol and ketamine groups respectively. (Table 9). The incidence of emergence reaction in our study with ketamine was comparable to that of Vardi A et al.[10]

The occurrence of nausea followed by vomiting remains one of the most distressing side effects following anaesthesia. The incidence of nausea and vomiting is even higher in children undergoing strabismus surgery.

The postoperative nausea and vomiting was 4% in propofol group and 16% in ketamine group, which was statistically significant (p<0.05). (Table 9)

The incidence of nausea and vomiting in our study was comparable to that of Hannallah Raafat S[1] & Cheuk D K et al[3] in propofol and ketamine groups respectively.

The incidence of nausea and vomiting in the study of Doze Van et al (1986) with propofol might have been due to 70% N2O and meperidine premedication in them.

Recovery was objectively evaluated in the Post Anaesthesia Care Unit (PACU) by recording the time required to reach score of 12 on the fast track eligibility criteria. A maximum score of 14 was given when the child was fully awake.

A fast track elegibility criteria of 12 was achieved within 30 minutes in 92% patients of Gr. I and in only 28% patients of Gr. II. A fast track eligibility criteria of 12 was achieved within 1 hour in 96% patients of Gr. I and 46% patients of Gr. II.

At 2 hours, the same was achieved in 100% patients of Gr. I and 80% patients of Gr. II. This difference in recovery profile was statistically significant in the two groups ($p<0.05$). (Table 10).

The overall quality of anaesthesia was assessed on the basis of quality of induction and maintenance, haemodynamic and respiratory stability, principally recovery character and ultimately the postoperative complications.

The overall quality of anaesthesia was excellent in 92% patients of propofol group whereas only 30% patients of ketamine group, which was statistically significant ($p<0.05$). Good quality of anaesthesia was seen in 8% patients of propofol and 56% patients of ketamine group. The poor quality of anaesthesia was seen only with ketamine. (Table 11)

Quality of anaesthesia in our study was comparable to that of Vardi A et al,[10] Gottschling S et al[13] & Ozdemir D et al.[16]

CONCLUSION: Our study revealed that ketamine causes rise in all pressures due to sympathetic stimulation and has more incidence of perioperative complications and most importantly is associated with delayed recovery as compared to propofol.

Propofol has the properties of smooth induction, lowering all pressures and rapid recovery, which is clearheaded without any hangover. The perioperative complications associated with propfol are transient and easily manageable.

Based on our experience in the present study, we conclude that propofol is an ideal intravenous anaesthetic agent for short surgical/diagnostic procedures in paediatric age group.

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