



## Original Research Article

# A COMPARATIVE STUDY OF KETAMINE AND DEXMEDETOMIDINE VERSUS KETAMINE AND FENTANYL FOR INTRAVENOUS SEDATION IN CHILDREN UNDERGOING INFRAUMBILICAL SURGERIES UNDER SPINAL ANAESTHESIA

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### ABSTRACT

**Background:** Ketamine is a commonly used anaesthetic for sedation in children during spinal anaesthesia but is associated with side effects such as delirium, tachycardia, and hypertension. To mitigate these, ketamine is often combined with other anaesthetics. Aim of study is to know the efficacy of ketamine combined with either dexmedetomidine or fentanyl for intravenous (IV) sedation in children undergoing infraumbilical surgeries under spinal anaesthesia.

**Materials and Methods:** This randomized controlled trial included 60 children, aged 2-8 years, of ASA physical status I or II. All children were premedicated with inj. glycopyrrolate 0.01mg/kg and inj. midazolam 0.05mg/kg IV. After 3min of premedication all study participants received a loading dose of inj.ketamine (0.5 mg/kg IV). Patients were then randomly allocated by computer generated randomization to one of the two groups: KD (ketamine-dexmedetomidine) or KF (ketamine-fentanyl). Group KD received dexmedetomidine (0.5 mcg/kg IV), while Group KF received fentanyl (2 mcg/kg IV). An additional dose (1 mg/kg) of inj. ketamine was given IV before the induction of spinal anaesthesia. Sedation levels were assessed using the Modified Observer's Assessment Alertness/Sedation (MOAA/S) scale. Additional dose of ketamine required in each group to achieve MOAA/S score 3 were noted.

**Results:** The KD group required significantly fewer additional doses of ketamine for positioning for spinal anaesthesia and intraoperative maintenance than the KF group. Haemodynamic parameters dropped more in the KD group (up to 20%) compared to the KF group (up to 10%). Both groups maintained stable SpO<sub>2</sub> and respiratory rates. The KF group needed more ketamine doses for intraoperative sedation. Postoperative recovery was delayed in the KD group.

**Conclusion:** Ketamine in combination with dexmedetomidine lead to improved quality of sedation and reduced need for additional doses of ketamine during the procedure. Conversely, ketamine with fentanyl provided more stable haemodynamics and relatively faster recovery.

**Keywords:** Dexmedetomidine, Ketamine, Fentanyl, Pediatrics, Spinal anaesthesia.

## INTRODUCTION

Spinal anaesthesia (SA) in children is considered as a safe technique for lower extremity surgeries due to its favorable characteristics such as cardiovascular stability, satisfactory analgesia and muscle relaxation, the possibility of performing surgical procedures in patients at risk of general anaesthesia, and the ability to administer small doses of local anaesthetic with consequent reduced toxic effects.<sup>[1]</sup> Particular advantage suggested for SA in children was the avoidance of general anaesthesia (GA) in those at risk of postoperative apnea. Several studies demonstrated that SA had a particular role in high-risk former preterm neonates undergoing inguinal herniorrhaphy.<sup>[2]</sup>

Infra-umbilical surgeries are commonly performed under spinal or caudal anaesthesia. Some of the surgeries done in this category are inguinal herniotomy, and hydrocelectomy. Various types of spinal needles have been described depending upon the length, gauge, tip design (cutting/ pencil point), bevel (long/short), and presence /absence of stylet. The length of spinal needle varies from 25-50 mm (25-30 mm for infants, 50mm for small children).<sup>[3]</sup> Both cutting and pencil point needles have been used with similar success.<sup>[4,5]</sup> Local Anesthetic (LA) solutions and additives — Isobaric and hyperbaric Bupivacaine or Tetracaine (0.5%) remain the most popular agents for pediatric SA. Newer drugs like Ropivacaine and L-bupivacaine are also safe and effective.<sup>[6]</sup>

Given the level of neurocognitive development, children require sedation and analgesia during performance of regional anesthetic techniques to ensure immobility, as well as to alleviate anxiety & provide sedation during performance of surgical procedure.<sup>[7]</sup> Several anaesthetic agents such as propofol, ketamine, and dexmedetomidine are used for this purpose alone or in combination with another drug. Performing spinal puncture in a struggling, agitated child may injure delicate neurovascular structures and should be avoided.

Ketamine is one of the commonly used anaesthetic agents to achieve deep sedation during spinal anaesthesia in children with side effects, such as increased salivation, delirium, muscle rigidity, tachycardia and hypertension.<sup>[8]</sup> To overcome some of these, ketamine is usually combined with one of the drugs such as propofol, dexmedetomidine, midazolam and fentanyl. But the best combination is not yet known.

Hence this study was undertaken to compare the efficacy of ketamine either combined with dexmedetomidine or fentanyl for intravenous (IV) sedation in children undergoing infraumbilical surgeries under spinal anaesthesia.

## MATERIALS AND METHODS

The Randomized controlled trial study was conducted in children of age group 2 to 8 years, of

ASA physical status I & II undergoing elective infraumbilical surgeries done under spinal anaesthesia, at Medical College Hospital, Ballari Medical College and Research center (BMCR), Ballari over a period of one year (AUGUST 2022-JULY 2023), after obtaining clearance from Institutional ethics committee (No. 40/PG Thesis/2021-22). This study was registered with Clinical trial registry of India (No. CTRI/2022/10/046610) before the commencement of study.

Sample size is calculated based on a previous study, done by Ayman A.El Sayed et al, (9) with type I error of 0.05 and a power of study at 80% , minimum sample size needed to conduct the study found to be 25 cases in each group. Considering the 10% drop out rate, final sample size is fixed at 30 in each group.

Inclusion criteria were ASA physical status I & II, children of either sex in the age group of 2 to 8 years, Posted for elective infra umbilical surgery. Exclusion criteria were parent's refusal for the study, children with any contraindication for spinal anaesthesia and known allergy to the study drugs.

Thorough pre anaesthetic evaluation was performed & necessary investigations were ordered. Parents of the eligible children were explained about the procedure and informed written consent obtained. Intravenous (IV) access obtained in the ward and Ringer Lactate started as per Holliday Segar formula. Children were then shifted to premedication room along with their parents. In premedication room, all basic monitors (SpO<sub>2</sub>, NIBP, ECG) were connected and basal values were recorded. Children were put on paediatric oxygen mask with 100% O<sub>2</sub> @ 4l/min flow and received pre-medication with inj. glycopyrrolate 0.01 mg/kg and inj. midazolam 0.05 mg/kg intravenously. After 3 minutes of premedication a loading dose of inj. ketamine 0.5mg/kg was given IV. Patients were then randomly allocated by computer generated randomization table obtained from website [www.randomizer.org](http://www.randomizer.org) to one of the two groups; Group KD and Group KF.

Group KD received inj Dexmedetomidine 0.5mcg/kg IV over 10 minutes. Group KF received inj Fentanyl 2mcg/kg IV over 10 minutes, and then shifted to operation theatre. These drugs were prepared by a junior resident not involved in the study in a 10ml syringe. After positioning for spinal anaesthesia, additional dose of ketamine 1mg/kg given intravenously. Anaesthesia with appropriate volume of Bupivacaine (heavy) was given. Successfulness of spinal anaesthesia was confirmed by haemodynamic response and motor response to skin incision. Any increase in HR and SBP more than 5% is considered as failure of spinal anaesthesia. Sedation level was evaluated by using Modified Observer's Assessment Alertness/Sedation scale (table 1).

**Table 1. Modified Observer's Assessment Alertness/Sedation (MOAA/S) scale (10)**

- 1= Not responsive to mild shaking (unarousable)
- 2= responsive to mild shaking.
- 3= responsive to only his name when spoken repeatedly or loudly
- 4= responsive to name spoken in normal tone
- 5= Awake and alert
- 6=Agitated

Haemodynamic changes observed were HR, SBP, DBP and MAP at various intervals – before premedication, after administering premedication, and after spinal anaesthesia every 5 minutes till completion of surgery.

Additional dose of ketamine required in increments of 0.5mg/kg in each group to maintain MOAA/S score of 3 also assessed.

Postoperative recovery time was assessed by using Stewards Simplified Post Anaesthetic Recovery Score [Table 2]. A score of 6 was considered as recovery to discharge patient from PACU.

**Table 2. Stewards scoring system (11)**

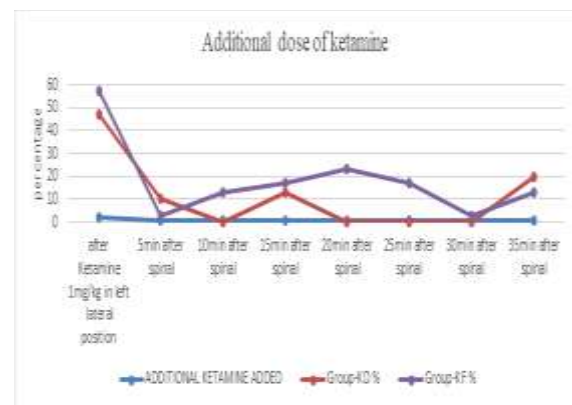
- Consciousness (Awake=2, responding to stimuli=1, not responding=0)
- Airway (Coughing on command or crying=2, maintaining good airway=1, airway requires maintenance=0)
- Movement (Moving limbs purposefully=2, non-purposeful movements=1, Not moving=0)

All data were entered in MS excel sheet, data then filtered and analyzed. Categorical data was represented in the form of frequency and percentage. Association between variables was assessed with Chi Square Test. Quantitative data was represented as Mean & Standard deviation. Comparison of Groups was done with Unpaired t test. Follow up assessments were done with Paired t test. P value of <0.05 was considered statistically significant. Data was analyzed with IBM SPSS Version 22 for windows.

## RESULTS

In our study 80 patients were assessed, out of which 60 patients met the inclusion criteria and all 60 patients completed the study. The mean age of the patient in this study in Group KD was 3.70±1.99 in Group KF was 4.03 ± 1.65. There was no significant difference in age of patients between two groups. Sex distribution was similar in two groups. The Group KD all 30 patients belonged to ASA I whereas in Group KF except one all patients belonged to ASA I.

During spinal anaesthesia, 57% of patients in the KF group required one additional dose of ketamine for positioning compared to 23% in the KD group, a difference that was statistically significant (P<0.001). During surgery, the KF group required additional doses of ketamine at 10, 20, and 25 minutes, whereas the KD group required no additional doses, these differences were statistically significant (P<0.05, P<0.003, and P<0.027, respectively) [Figure 1].



**Figure 1: Additional dose of ketamine requirement in two groups**

The KF group showed a transient increase in systolic blood pressure (SBP) up to 5 minutes after spinal anesthesia, while the KD group experienced a significant decrease (P<0.002). Throughout the procedure, the KD group showed significantly greater reduction in SBP compared to the KF group (P<0.0) [Table 3].

**Table 3: Comparison of systolic blood pressure in between group KD and group KF**

Systolic blood pressure (mm of Hg)						
Time interval	Group- KD		Group- KF		Unpaired t test	
	Mean	Sd	Mean	Sd	T value	P value
After dexmedetomidine (0.5mcg/kg)/fentanyl (2mcg/kg)	111.70	9.17	115.13	13.16	-1.172	0.246
After ketamine 0.5mg/kg	107.17	8.87	114.67	11.03	-2.903	P<0.005
After ketamine 1mg/kg in left lateral position	104.90	8.54	118.57	9.43	-5.883	P<0.001
5 min after spinal	97.07	7.95	104.93	10.47	-3.278	P<0.002
10min after spinal	97.00	7.47	102.50	6.91	-2.959	P<0.004
15min after spinal	94.43	6.82	103.80	8.58	-4.681	P<0.001
20min after spinal	93.67	6.37	105.50	10.21	-5.275	P<0.001
25min after spinal	94.75	4.02	103.96	5.99	-5.822	P<0.001
30min after spinal	95.93	4.13	103.13	8.00	-3.112	P<0.001
35min after spinal	98.25	4.43	111.75	7.38	-4.423	P<0.001

Diastolic blood pressure (DBP) transiently increased in the KF group up to 5 minutes post spinal anaesthesia, whereas it decreased in the KD group, which was statistically significant ( $P<0.01$ ). During surgery, significant decrease in DBP were observed in the KD group at 20, 25, and 35 minutes compared to the KF group ( $P<0.001$ ,  $P<0.002$ ,  $P<0.001$ , respectively).

The mean arterial pressure (MAP) was significantly increased in the KF group for up to 5 minutes post spinal anaesthesia compared to the KD group ( $P<0.024$ ). However, throughout the procedure, the KD group had a significantly greater reduction in MAP compared to the KF group ( $P<0.001$ ).

**Table 4: Comparison of heart rate between group KD and group KF**

Heart rate (bpm)						
Time interval	Group KD		Group KF		Unpaired t test	
	Mean	Sd	Mean	Sd	T value	P value
After dexmedetomidine (0.5mcg/kg)/ fentanyl (2mcg/kg)	123.50	14.39	134.87	19.46	- 2.573	$P<0.013$
After ketamine 0.5mg/kg	130.60	16.96	148.40	19.74	3.746	$P<0.001$
After ketamine 1mg/kg in left lateral position	130.00	17.29	156.33	16.92	- 5.961	$P<0.001$
5 min after spinal	123.73	16.35	143.50	18.61	4.370	$P<0.001$
10min after spinal	123.90	17.52	140.90	19.84	-3.517	$P<0.001$
15min after spinal	121.37	18.53	139.07	18.50	- 3.702	$P<0.001$
20min after spinal	118.30	17.46	139.54	26.58	- 3.578	$P<0.001$
25min after spinal	110.80	16.30	133.78	17.53	4.428	$P<0.001$
30min after spinal	114.0	12.5	129.8	17.5	2.868	$P<0.007$

Baseline heart rates were similar in both groups, but after administering fentanyl, the KF group experienced a mild increase in heart rate compared to dexmedetomidine in KD group ( $P<0.001$ ), while positioning for spinal anaesthesia. After 5 minutes

and throughout the procedure, a reduction in heart rate was observed in the KD group compared to the KF group ( $P<0.001$ ), with the difference becoming insignificant after 35minutes [Table 4].

**Table 5: Comparison of sedation scores between group KD and group KF**

	MOAA/S				
	Group KD		Group KF		
	Median	Q Range (25 -75)	Median	Q Range (25 -75)	
After ketamine 1mg/kg in Left lateral position	2	2 -3	2	2 -2	0.011
5min after spinal	1	1 -3	2	1 -2	0.045
10min after spinal	1	1 -2	2	1 -3	0.035
15min after spinal	1	1 -3	3	1 -3	0.035
20min after spinal	1	1 -3	3	1 -3	0.009

Children in KF group exhibited a significantly high sedation scores (decreased depth of sedation) for up to 20 minutes after spinal anaesthesia compared to children in KD group ( $P<0.05$ ) [Table 5]. There was no significant change in respiratory rate (RR) compared to baseline and between the children of two groups.

Significant decrease in peripheral arterial oxygen saturation (Spo2) was observed in KD group at 5min,15min and 25 min in comparison to KF group

with p values  $<0.041$ ,  $<0.036$ ,  $<0.02$  respectively. But it was clinically not significant as it was maintained within 1% of baseline on 4L of oxygen with Hudson mask.

The children in KD group required significantly more time ( $29.67\pm 13.51$  VS  $23.67 \pm 7.65$ ) for postoperative recovery (SSS-6) when compared to the KF group ( $P<0.03$ ) [Table 6]

**Table 6: Comparison of postoperative recovery time between group KD and group KF.**

Parameter	Group-KD		Group-KF		Unpaired t Test	
	Mean	Sd	Mean	Sd	t Value	P Value
TIME REQUIRED FOR POST OP RECOVERY in min (SSS 6)	29.67	13.51	23.67	7.65	2.116	$P<0.03$

## DISCUSSION

In our study, the demographic profiles of children in both groups were comparable. Children in KD group required significantly fewer additional doses of ketamine for positioning during spinal anaesthesia and intraoperatively compared to the KF group ( $P<0.05$ ). Patients in both groups experienced drop in haemodynamic parameters (HR, SBP, DBP,

MAP) from baseline, with a more pronounced drop of up to 20% seen in the KD group compared to up to 10% in KF group. Although there was a statistically significant drop in SpO2 at 5, 15, and 25 minutes in the KD group ( $P<0.04$ ,  $P<0.036$ ,  $P<0.022$ ), it was clinically insignificant as it was within 1% of baseline. No significant difference in respiratory rates was observed between the groups. Though the sedation was effectively maintained in

children of both groups, children in KF group required more additional doses of ketamine for sedation and exhibited higher sedation scores (i.e decreased depth of sedation) for up to 20 minutes post-spinal anaesthesia. Postoperative recovery time was significantly delayed in children of KD group.

Ayman A et al,<sup>[9]</sup> compared effectiveness of combination of dexmedetomidine and ketamine (DK) with fentanyl and ketamine (FK) in adult patients undergoing extracorporeal shock wave lithotripsy. In FK group fentanyl 1mcg/kg administered before the procedure and 0.5mg/kg bolus of ketamine, in DK group patients received 1mcg/kg dexmedetomidine over 10min before the procedure and 0.5mg/kg bolus of ketamine. Additional dose of ketamine was used when needed at a dose of 0.25mg/kg in both groups. Authors found that no significant difference in sedation scores between the two groups throughout the procedure while there was delayed request of first dose of analgesia in KD group. There was reduction in haemodynamic parameters after 5min and all over the procedure. This reduction was within 15% from the baseline values and it was not found to be significant. In our study both groups experienced a drop in haemodynamic parameters (HR, SBP, DBP, MAP) from baseline, with a more pronounced drop of 20% seen in the KD group compared to 10% in the KF group. They also observed that no significant difference between the two groups regarding respiratory rate and no significant difference in comparison with the baseline. This was in line with our study.

Tosun et al,<sup>[12]</sup> in a RCT compared a sedation regimen of dexmedetomidine and ketamine with propofol and ketamine in 44 children with acyanotic heart disease undergoing cardiac catheterization. Ketamine(1mg/kg) and dexmedetomidine (1mcg/kg) were administered together over 10mins followed by dexmedetomidine infusion of 0.7mcg/kg/hr and a ketamine infusion of 1mg/kg/hr. In the other arm of the study propofol 1mg/kg and ketamine 1mg/kg were given as the loading dose followed by propofol infusion at 100mcg/kg/hr and ketamine 1mg/kg/hr. Supplemental bolus doses of ketamine 1mg/kg were given as required. They observed that patients sedated with ketamine-dexmedetomidine more often required supplemental doses of ketamine, this may be because of deep sedative property of propofol in ketamine-propofol group.

Mohammad Abdelslam et al,<sup>[13]</sup> in their study compared the effects of Midazolam Ketamine versus Dexmedetomidine Ketamine combination for haemodynamic parameters, sedation level, and recovery period in paediatric patients undergoing cardiac catheterization. Patients were randomly allocated to one of two equal groups: Midazolam-Ketamine group (group M) and Dexmedetomidine-Ketamine (group D). Group M received IV midazolam 0.1mg/kg and ketamine 1mg/kg as bolus for induction, followed by an IV midazolam infusion of 0.1mg/kg/hr and ketamine infusion of

1mg/kg/hr for maintenance, whereas patients in group D received IV Dexmedetomidine 1mcg/kg and ketamine 1mg/kg as a bolus for induction, and then received an IV dexmedetomidine infusion of 0.5mcg/kg/hr and ketamine infusion of 1mg/kg/hr for maintenance. They observed that the sedation was satisfactory in both groups with more requirement of ketamine in midazolam group compared to dexmedetomidine group.

Mohammad Abdelslam et al,<sup>[8]</sup> study results showed that there was no intergroup significant difference regarding SpO<sub>2</sub> (P>0.05), two patients developed oxygen desaturation (SpO<sub>2</sub><92 percent) in each group which responded promptly to oxygen supplementation at a rate of 4l/min using nasal cannula. In our study children-maintained oxygen saturation within 1% from baseline as they received 4l/min oxygen by Hudson mask.

Tosun et al,<sup>[12]</sup> in their study on dexmedetomidine and ketamine versus propofol and ketamine combination, noted that dexmedetomidine plus ketamine was associated with a markedly longer recovery time (49min) compared with propofol plus ketamine combination (23min). This was probably due to faster offset of action of propofol when compared to dexmedetomidine. Our study showed significant delay in postoperative recovery in KD group (29.67±13.51) compared to KF group (23.67±7.65).

However, the study had few limitations. We faced difficulty in accurate recording of basal parameters as many of the children were non co-operative before premedication, additional doses of ketamine were administered based on MOAA/S score. Monitoring depth of sedation would have been a better technique to time the additional doses. This study was done in ASA I and ASA II patients and hence the study results cannot be extrapolated to critically ill patients.

Future scope of the study could involve further studies in higher ASA grades, with lower doses of dexmedetomidine and in other age groups, with using depth of anaesthesia monitoring tools.

## CONCLUSION

Ketamine-Dexmedetomidine combination resulted in better quality of intra-operative sedation and lesser requirement of ketamine to maintain the level of intra-operative sedation.

On the other hand, Ketamine-Fentanyl combination resulted in stable intra-operative haemodynamics and relatively faster recovery in children undergoing infraumbilical surgeries done under spinal anaesthesia.

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