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Original Research Article

Comparison of dexmedetomidine versus nalbuphine in ketamine based procedural sedation for pediatric cathlab procedures: A prospective double blinded randomized trial

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ABSTRACT

Background: The aim of the current study was to compare the effects of nalbuphine and dexmedetomidine as premedication sedative agent for ketamine based deep sedation on hemodynamics, sedation level and need for additional boluses of ketamine, and recovery time in pediatric patients undergoing various cardiac catheterization procedure.

Materials and Methods: Sixty pediatric patients undergoing cardiac catheterization were enrolled in the current study. Patients were randomly distributed to two equal groups of 30 patients each: Group D and Group N. Patients randomized to Group D received a bolus of dexmedetomidine at 1 μg/kg over 10 min and Group N received a bolus of nalbuphine 0.1 mg/kg over 10min. In both the groups patients were induced with Inj ketamine 2mg/kg. After induction dose inj ketamine 0.5mg/kg boluses were given to achieve and maintain the target Ramsay Sedation Score (RSS)≥ 4. Mean arterial pressure (MAP), heart rate (HR), peripheral oxygen saturation (SPO2), and sedation scores were recorded. Recovery time, perioperative adverse events, and total ketamine consumption required for anesthesia maintenance were also recorded.

Results: There was significant decreased in HR from baseline in group D at 10, 20, and 30min of the procedure with no significant difference as regards the MAP between the two study groups. Ketamine consumption in group N was significantly lower than in group D to maintain RSS in desired range. The recovery time was significantly shorter in group N when compared with group D. Respiratory variables were maintained in both the groups with two patients reported airway obstruction which was partial. No significant difference was found in intra and postoperative adverse effect between the groups.

Conclusion: The nalbuphine was found to be superior to dexmedetomidine as a premedication sedation for pediatric cathlab procedure in terms of reduced consumption of ketamine for adequate intraoperative sedation to conduct the procedure with better hemodynamic control and the shorter recovery time.

1. Introduction

General anesthesia with positive pressure ventilation can alter the intracardiac pressures as well as shunt fraction. Therefore, deep sedation with painfree and spontaneously breathing patient is preferred by the cardiac interventionist.[1,2] Anaesthetic agents in various combinations have been used successfully for anesthesia in cathlab procedures.[3–7]

Dexmedetomidine is widely investigated in combination with ketamine as a sedatoanalgesic for deep sedation in cardiac catheterization procedure.[8]

There are few studies where opioids are used along with other anaesthetic agents for cardiac cathlab procedure.[9,10]

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Nalbuphine is an agonist-antagonist opioid of phenenthrene series that has analgesic and sedative effects, and because of the ceiling effect, it does not cause respiratory depression.[11] Previous studies suggest that it is safe to use nalbuphine in neonates and children.[12]

Literature is available regarding use of dexmedetomidine as a sole agent or as an adjunct to other agents for procedural sedation in cathlab procedure[2,7,8,11] but Nalbuphine is majorly studied for its analgesic properties and studies regarding its use as sedative agent are few and that too in other procedure-based sedation than cardiac cathlab.[13–15]

So we conducted this study with the aim to observe the effect of nalbuphine as an adjunct to ketamine based procedural sedation and its comparison to dexmedetomidine for pediatric cathlab procedure to see the overall efficacy and safety. Primary outcomes being hemodynamic stability during the procedure and need for rescue sedation or general anesthesia. Respiratory depression and need of assisted ventilation or intubation, recovery from anesthesia and other adverse events were recorded as secondary outcome.

2. Materials and Methods

After obtaining approval from Institutional research Ethical board (GU/HREC/EC/2019/553) and written informed patient consent, this randomized double blinded study was conducted in cathlab; department of Cradiology at one of the tertiary care hospital over a period of one and half year from January 2019 to June 2020.

Study population was calculated using Cochrane formula. Assuming a 95% confidence level and a 20% prevalence of pediatric cardiac patients undergoing cathlab procedures, with a 15% margin of error, a sample size of 30 patients was determined for each group.

$n = \frac{Z^2\ pq}{e^2}$

$n = \frac{1.96 \times 1.96 \times 0.2 \times 0.8}{0.15 \times 0.15}$

n = 30

n = sample size

Z = Confidance interval 95% (1.96)

p = Prevalance (20%)

q = 1-p (80%)

e = Margin of error 15%

Infants and children from 1-10 years of age, of both sex and ASA Grade II –III, posted for following cardiac cath lab procedure: cath angiography, cath study, PDA closure, ASD closure, VSD closure were included in the study. Patients excluded were pediatric cases beyond the specified age group, ASA Grade IV and hemodynamically unstable patients on inotropic support or on mechanical ventilation, patients where GA was asked by Cardiologist for any reason and patients with associated congenital anomaly and neurological disorder and deficits.

After written informed consent for the procedure and enrolment for the study by parents, patients were randomized into two groups; group D or group N. For randomization, serially numbered opaque sealed envelopes were used. Routine preanaesthetic examination and investigations (Complete Blood Count, Prothombine Time, S Urea, S Creatinine, ECG, 2D Echocardiography) were done before proceedure. Basic cardiovascular examination including history of fatigability, dyspnoea, orthopnoea, paroxysmal nocturnal dyspnoea, and signs of congestive heart failure (hepatomegaly, pedal oedema, raised jugular venous pulsations, and basal crackles) were looked for. Patients were taken for procedure after confirming 6hrs of fasting. Intravenous (IV) cannula was placed in preoperative ward and Isolyte –P had been started according to weight slowly. On arrival in the cath- lab basic monitoring (pulse oxymetry, noninvasive blood pressure (NIBP), ECG were connected to the patient and baseline vitals were recorded. All the patients were premedicated with IV Ondensetron0.8mg/kg and glycopyrrolate 0.01mg/kg, 10 min before the procedure.

Oxygenation was started using PVC mask at 4-6 lt/min before giving any of the sedative agents except in case of cath study procedure; where various pressure values must be recorded before and after oxygenation. Sedation was assessed by 5-point Ramsay Sedation Score (RSS)[16] (Table 1) and maintained on spontaneous respiration. Airway obstruction due to tongue fall was managed by triple manuver (head tilt, chin lift and jaw thrust) or inserting oral or nasal airways if needed. Jackson Rees circuit or Bains circuit were used for assisted ventilation if there is period of apnoea or precipitous fall in saturation at any point of sedation.

Table 1: Ramsey sedation score (RSS)

1.	Patient is anxious, agitated, or restless.
2.	Patient is co-operative, oriented, and calm.
3.	Patient is responsive to verbal command only.
4.	Patient exhibiting brisk response to light glabellar tap or to an auditory stimulus.
5.	Patient exhibiting a sluggish response to light glabellar tap or to an auditory stimulus.
6.	No response to any of these stimulations.

Patients were randomly allocated to either of the group by computer generated random number tables. Patients randomized to Group D received a bolus of dexmedetomidine at 1 μg/kg over 10 min and Group N received a bolus of nalbuphine 0.1 mg/kg over 10min. Study drugs were prepared by anaesthesiologist who was not involved in giving anesthesia or recording the data. In both the groups patients were induced with Inj ketamine 1mg/kg. After induction dose inj ketamine 0.5mg/kg boluses were given until the target RSS ≥4was achieved, i.e., an unconscious patient with spontaneous ventilation and akinesia. Ketamine boluses of 0.5mg/kg were repeated depending on the need for rescue sedation or analgesia to maintain target RSS≥4 or when patient manifested signs

as coughing, bucking, lacrimation, sudden and purposeful movements of limbs or increase in HR and MAP>20% from baseline. If repeated administration of ketamine boluses causes excessive tachycardia then Injetomidate (0.2mg/kg followed by 0.1mg/kg repeat bolus if needed) was used as additional sedative agent in order to maintain a RSS in desired range and hemodynamic stability during the procedure. Rescue boluses and total dose of ketamine and etomidate were calculated and compared between the groups.

Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), respiratory rate (RR), SpO2, and RSS were recorded at baseline, after induction, and every 5 min throughout the procedure. Invasive SBP, DBP, and MAP were continuously monitored during the procedure on the cardiac catheterisation console. Procedures where TEE (Trans esophageal echocardiography) was needed to confirm the correct placement of the device, GA with intubation was administered in both the groups and patients were excluded from the study. Secondary outcomes include respiratory depression, which was defined as decrease in respiratory rate or depth of respiration below the normal physiological limit with a drop in SpO2 of ≥10% from the baseline. Before labelling an event as respiratory depression, airway obstruction was ruled out. Respiratory support meant a need for assisted ventilation during the procedure. Hypotension was defined as fall in MAP >20% from baseline and was managed by fluid bolus and inotropic support (noradrenaline @ 2.5mcg/kg/min infusion and titrated according to MAP).

After the procedure got over patients were taken to the recovery room, and were followed up every 10min. Recovery being assessed by using the 6 points Steward scoring system[17] (Table 2) and time to full recovery was noted from the point procedure is over till the patient achieves Steward score 6. After that, the patients were transferred to cardiac ICU.

Table 2: Stewart scoring system for post op recovery

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

2.1. Statistic al analysis

Quantitative data were expressed as mean ± standard deviation (SD) and categorical data as the incidence rate (absolute numbers and percentage) for statistical description. Categorical outcome variables were analyzed by Chi-square test. Hemodynamics data (continuous variable) between the two groups were analyzed using Student's t-test. P value of <0.05 was taken as significant. Statistical analysis was done using statistical software package SPSS version 20.0 and Microsoft Excel.

3. Results

Three out of 30 patients from each group dropped out from the study as procedure was abandoned due to instability of the margins of defect to hold the device, conversion to GA. (Diagram 1) Total of 27 patients in each group were finally analysed.

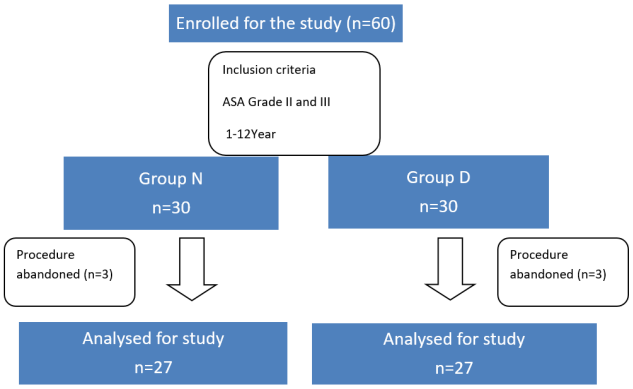

Diagram 1: Consort flow diagram

There were no statistically significant differences between the two study groups regarding age, weight, sex, type of procedure and the duration of cardiac catheterization. (Table 3) Baseline MAP was comparable between the two study groups with no statistically significant difference (P > 0.05). There was no significant fall in MAP from baseline in both the groups at various time intervals (P > 0.05). MAP again returned to baseline value in recovery in Group N but was persistently low in Group D (Figure 1). Baseline HR was comparable between the two study groups with no statistically significant difference (P > 0.05). In group D, the HR dropped significantly from baseline values after 10 min of induction and in all the subsequent recordings (P < 0.05) and this difference was significant when compared with group N (P < 0.05). Although the drop in the HR was statistically significant, it was clinically insignificant as no episode of bradycardia was reported in any patient. In group N, the HR was not changed significantly from baseline values during study period. (Figure 1)

Table 3: Demographic characteristics

		Group D (n=27)	Group N(n=27)	P Value
	Age (yr) (Mean±SD)	5.11±3.1	5.14±3.4	0.97
	Sex M	17	19	0.56
	F	10	8	
	Weight (kg) (Mean±SD)	18.5 ± 8.74	17.5±7.3	0.64
Type of procedure (n; %)	Cath angiography	8	9	0.98
	Cath study	5	4	
	PDA closure	9	10	
	VSD closure	2	2	
	ASD closure	3	2	
	Duration of procedure (min) (Mean±SD)	29.7±11.5	28.5±11.9	0.70

P<0.5; significant (S), p<0.0001; highly significant (HS)

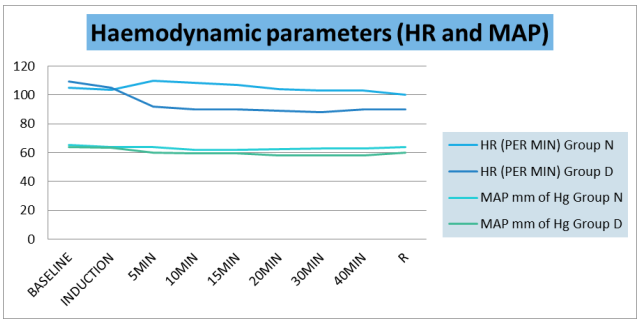

Figure 1: Comparison of Hemodynamic parameters (HR and MAP) between the groups

There was no statistically significant difference between the two study groups in terms of Ramsay sedation scores at various time periods during study (Table 4). Baseline RSS was 1 in both the groups as we have not used any sedative agents in preoperative area. Target sedation level (RSS 4 or more) was achieved in most of the patients in both the groups with induction dose of ketamine and only few required supplement dose of ketamine (group D 7 v/s 3 in group N). Sedation score was maintained 4-5 in both the groups throughout the procedure. At completion of the procedure patients achieved sedation score of 2-3 (median score 3 in group D and 2 in group N). RSS of 1 was achieved in all the patients in both the groups at full recovery ie; at SSS of 6.

Induction dose of ketamine was not significantly different between the groups. (p=0.64) Additional bolus at induction and maintenance to achieve and maintain RSS4 was significantly high in Group D (P<0.5). Eighteen patients in group D versus 11 patients in group N required supplemental doses of ketamine. (P > 0.05) (Table 5) Total ketamine consumption required for anesthesia induction and maintenance was higher in group D (718mg) when compared with group N (665mg) but it was not found to be significant. One patient in nalbuphine group and none in dexmedetomidine group required an additional dose of etomidate 0.2mg/kg in addition to ketamine to maintain RSS> 4, as there was tachycardia. Recovery period was significantly shorter in group N when compared with group D and the difference was statistically highly significant (5.9±1.7min v/s15.4±2.1min). (P >0.0001) (Table 4) Two patients in group D developed slight difficulty in respiration due to tongue fall which was successfully managed by putting Guedels airway and increase in oxygen flow rate from 4lt/min to 6lt/min using a nasal cannula. Baseline SPO_2 was 70% and 75% in group D and N respectively in patients with cyanotic congenital heart disease (CHD). Rest of the patients (non cynotic CHD) in both the groups had baseline saturation 97-99%. (Figure 2) No patient in either group had apnea or fall in saturation >5% from baseline which required the use of assisted ventilation. The other perioperative adverse events were evaluated and recorded in the two study groups and were found to be comparable. Most common cardiac complication seen in our study was tachyarrythmia which were transient in nature (due to direct stimulation of heart by guide wires) and resolved spontaneously as the stimulation subsides. In other cases where tachycardia was high (change in HR ≥30% from baseline) etomidate or iv xylocard was used. Single episode of hypotension was found in 2 patients in Group N and 3 patients in group D. It was following bleeding from puncture site and was successfully managed with fluid bolus and no inotropic support was required.

4. Discussion

Besides opioids related side effects; availability, narcotic control and record keeping are biggest hurdles using morphine and fentanyl for such short procedure. Nalbuphine is easily available with low cost and safety in children one year and above makes it a drug to be studied for procedural sedation.

Similar to our study Joshi et al and Tosun et al., also recorded significant fall in heart rate with dexmedetomidine compared to propofol when used in combination with ketamine.[18,19] In our study ketamine was used in both the

Table 4: Comparison of sedation score and recovery characteristics in two groups

	Group D	Group N	P Value
Sedation Score			
Baseline RSS	1-2	1-2	
(Median)	1	1	
RSS After Induction (Median)	4	4	
RSS Throughout the procedure	4-5	4-5	
(Median)	4	4	
Number of patients required additional Ketamine to achieve RSS 4 at induction	7/27	3/27	
RSS at completion of procedure	2-3	2-3	
(Median)	3	2	
RSS At Recovery			
(Median)	1	1	
Recovery time (min)	15.4±2.1	5.9±1.7	<0.0001

P<0.5; significant (S), p<0.0001; highly significant (HS)

Table 5: Ketamine consumption during study period in two groups

	Group D	Group N	P Value
Induction dose (Mean±SD)	18.5 ± 8.74	17.5±7.3	0.64
Additional bolus to achieve RSS 4 at induction (Mean±SD)	2.9±5.2 (n=7)	1.4±4.7 (n=3)	0.27
Bolus for maintenance of RSS 4 (Mean±SD)	6.4±9.2 (n=11)	4.5±7.5 (n=8)	0.40
Total number of patients required supplement dose during the procedure	18/27	11/27	
Total dose mg	718	665	

P<0.5; significant (S), p<0.0001; highly significant (HS)

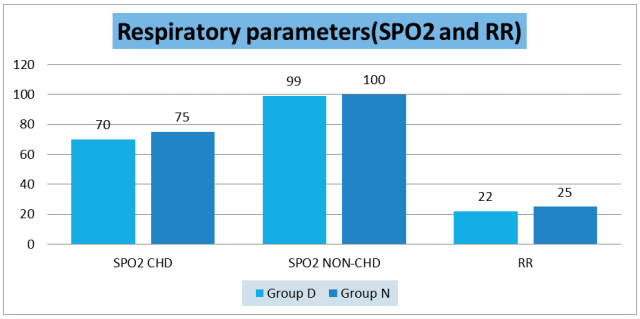

Figure 2: Comparison of respiratory parameters (RR and SpO_2) between the groups

groups so decrease in HR could be directly attributed to central sympatholytic action of dexmedetomidine and stable HR in Group N shows its stable hemodynamic property. Similar to our study Manshawi et al. also used ketamine in both groups and reported fall in HR from baseline with dexmedetomidine compared to midazolam.[20] Mean BP was reduced after induction in both the groups, with no intergroup significant difference (P > 0.05). In group D, the MAP dropped significantly after induction and in all the subsequent recordings when compared with baseline values (P < 0.05), but it was clinically insignificant as the MAP remained within the normotensive range in most patients except for two patients who developed hypotension and responded promptly to the fluid bolus.

Contrasting to our results Ali et al. reported no significant difference in the recovery patterns and hemodynamic status when dexmedetomidine and propofol were compared with ketamine in paediatric cardiac catheterization.[21] Similarly Mester et al. used ketamine and dexmedetomidine combination for sedation in paediatric cardiac catheterization, and they reported that this combination provides effective sedation for cardiac catheterization in infants and children without significant effects on cardiovascular or ventilatory function.[7]

Baseline Ramsay sedation score (RSS) was 1 in both the groups as we have not used any sedative agents in preoperative area. No significant difference regarding the Ramsay sedation score was observed between the two study groups as sedation score was maintained ≥4 by use of additional bolus of ketamine. These findings were consistent with similar studies by other authors who also kept target sedation level (RSS 4-5).[18,22,23] Sedation was satisfactory in both the groups which was achieved in most of the patients in both the groups with induction dose of ketamine and only few required supplement doses of ketamine at induction. This was because both drugs have analgesic, sedative and anxiolytic properties. But more consumption of ketamine in dexmedetomidine group compared to Nalbuphine can be attributed to difference in their mechanism of action.

Manshawmi et al. observed and confirmed that dexmedetomidine is better sedative as compared to midazolam for patients undergoing cardiac catheterization for hemodynamic study, and satisfactory sedation with midazolam was at the expense of the significantly higher ketamine consumption ($P < 0.05$).[20] It could be explained by the fact that midazolam is having only sedative and anxiolytic property whereas dexmedetomidine possesses analgesic action too, which leads to better anesthetic sparing effect of intravenous dexmedetomidine compared with intravenous midazolam.[24,25]

Joshi et al. also found prolonged recovery with dexmedetomidine compared to propofol in ketamine-based sedation.[18] In their study the duration of recovery was long i.e., 40.88±8.19 min as compared to our study (15.4±2.1min). This difference could be due to the fact that they have used continuous infusion of dexmedetomidine after bolus dose. Heard et al. also reported prolong recovery with dexemedetomidine in children undergoing magnetic resonance imaging.[26] In a study conducted by Thimmarayappa et al. airway patency was measured during dexmedetomidine sedation under radiographic guidance in spontaneously breathing paediatric patients scheduled for cardiac catheterization procedures.[27] They reported average recovery time from dexmedetomidine sedation after stopping the infusion to be 39.86 ± 12.22 min.

Both nalbuphine and dexmedetomidine-induced sedation qualitatively resembles normal sleep. This type of sedation is termed as co-operative or arousable, to distinguish it from sedation that is caused by drugs acting on G-aminobutyric acid receptors, such as benzodiazepines or propofol, which reduce consciousness.[28] A finding can be explained by the nature of dexmedetomidine as a sedative not hypnotic agent so patients receiving it will be sedated but easily arousable. Same observation was found by Nasreen et alwho reported significant reduction in the awakening time in patients receiving dexmedetomidine when compared to the placebo group.[29]

Ketamine bolus consumption was found to be more in Group D in our study compared to group N (2.9±5.2 V/S 1.4±4.7) for induction as well as for maintenance (6.4± 9.2 v/s 4.5± 7.5). Similarly, Tosun et al. also found more consumption of ketamine in dexmedetomidine-ketamine group compared to propofol-ketamine group (2.03 v/s 1.25 mg/kg/hr).[19] Study by Joshi et alreported 9 patients in dexmedetomidine- ketamine group versus 2 patients in propofol-ketamine group required extra bolus of ketamine.[18] Compared to this in our study the number of patients needed ketamine bolus were more in both the groups (18 v/s 11 in group D and Group N respectively) as in their study both the study drugs and ketamine infusion were running throughout the procedure.

We found that saturation of peripheral oxygen was maintained throughout the study in both groups and did not fall >5% of baseline. It was because of the fact that both the study drugs have minimal effect on respiration. Manshawi et al. in their study also found no intergroup significant difference regarding SPO2 recordings ($P > 0.05$). In their study 2 patients developed oxygen desaturation in each group (SpO2 dropped to be < 92%) which responded promptly to oxygen supplementation at a rate of 4 l/min using a nasal cannula, and no patient had apnea.[20] Frölich et al.and Koruk et al.also had similar findings.[22,23] El Sayed et alcompared dexmedetomidine ketamine and fentanyl-ketamine combinations for sedation in patients undergoing extracorporeal shock wave lithotripsy.[30] In their study, there was no significant difference between the two groups as regards the respiratory variables. And they attributed that to the usage of ketamine in both groups which keep the hemodynamics and respiration stable.

Xie CM et al. reported respiratory- and airway-related adverse events as the most common anesthesia-related complications and occurred in 3.88%. Main adverse events were respiratory depression, cough, bronchospasm, laryngospasm, increased respiratory secretion, and airway obstruction. Incidence of procedure-related complications was 12.14%. The highest incidence was arrhythmia, and the second highest was hypotension.[1] Similarly in our study anesthesia related complication was airway obstruction (3.07%) and procedure related complication were arrhythmias and hypotension (9.2%). All the complications in our study were managed with minimal interventions with no fatal outcome.

5. Conclusion

In conclusion, nalbuphine demonstrates clear superiority over dexmedetomidine for ketamine-based deep sedation in paediatric cardiac catheterization. This is evidenced by its ability to reduce the required dose of ketamine, ensuring adequate intraoperative sedation while maintaining balanced hemodynamics throughout the procedure. Furthermore, nalbuphine's use is associated with a notably shorter recovery time, making it a more efficient choice for managing sedation in this delicate patient population.

6. Sources of Funding

None.

7. Conflict of Interest

None.

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