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Research Article

A RANDOMISED CONTROL TRIAL COMPARING DEXMEDETOMIDINE AND KETAMINE WITH MIDAZOLAM AND FENTANYL INFUSION FOR SEDATION IN ICU

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A B S T R A C T

Sedation is the main concern to ventilate the patient in icu. As there are many agent and combination used in ICU for sedation by an intensivist,so all drugs combination have some advantages and disadvantages. Dexmedetomidine is used as sedative and alpha2 adrenergic agonist and its haemodynamic effect is that it causes bradycardia and hypotension while ketamine used as sedative causes tachycardia and hypertension. Midazolam is also used as sedation in combination with opiod fentanyl. We used combination of dexmedetomidine and ketamine to neutralize the effect of each other and to have balanced haemodynamics and sedation in icu patient.

INTRODUCTION

MATERIAL AND METHODS

It was a prospective randomized double blind study involving 20 adult patient. Age group (18-60 year) which is in icu and are sedated .Patient having increased intracranial pressure, shock, and cardiac disease are excluded from the study. After approval from the institutional ethical committee patient were randomly divided into 2 group. each group has 10 patient

GROUP A: patient received dexmedetomidine and ketamine.
GROUP B: patient received midazolam and fentanyl.

In one group DK

After giving initial dose of dexmedetomidine 1microgram/kg and continuous infusion of 0.2-0.7 microgram/kg and ketamine 0.5 milligram/kg/hr is given to the intubated patient in icu.

In other group MF

We give midazolam and fentanyl combination then sedation and haemodynamic parameter was assessed using riker sedation agitation scale and haemodynamic parameter are also noted.

Statistical Analysis

Data will be analysed measured data are presented as the mean±standard error of mean.

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t-test and chi square tests will be used to analysed p value<0.05 will be consider statistically significant.

RESULTS

Comparison of Hemodynamic Variables at different time intervals

Table 1 Comparison of Hemodynamic Variables at different time intervals

Time Interval	Group DK (n=10)		Group MF (n=10)		Student 't' test	
	Mean	SD	Mean	SD	't'	'p'
			Heart rate			
Adm	104.40	10.15	98.50	9.12	1.368	0.188
2h	93.50	4.03	94.50	6.72	-0.403	0.691
4h	85.70	4.08	92.10	7.42	-2.391	0.028
8 h	82.00	7.16	84.20	4.66	-0.814	0.426
16 h	81.60	4.30	85.80	9.82	-1.239	0.231
24 h	75.40	7.31	86.40	5.85	-3.716	0.002
			Systolic BP			
Adm	109.80	9.21	117.80	12.05	-1.668	0.113
2h	113.40	6.40	109.80	7.39	1.165	0.259
4h	115.60	4.79	105.40	3.78	5.288	<0.001
8 h	112.80	6.34	104.20	3.71	3.704	0.002
16 h	117.60	6.24	101.80	4.05	6.717	<0.001
24 h	119.00	7.01	108.40	5.87	3.666	0.002
			Diastolic BP			
Adm	65.50	8.45	69.80	9.15	-1.092	0.289
2h	67.60	3.37	64.60	5.17	1.537	0.142
4h	65.80	4.05	62.00	3.89	2.141	0.046
8 h	66.20	3.82	61.60	2.80	3.070	0.007
16 h	62.40	3.86	63.00	4.45	-0.322	0.751
24 h	67.00	4.92	63.40	6.19	1.440	0.167
			Oxygen Saturation			
Adm	88.00	2.11	91.20	4.05	-2.216	0.040
2h	98.70	0.48	93.50	3.17	5.126	<0.001

4h	98.60	0.52	94.40	3.34	3.930	0.001
8 h	98.50	0.53	95.20	3.29	3.129	0.006
16 h	98.40	0.70	98.10	1.10	0.728	0.476
24 h	98.60	0.52	97.90	0.99	1.976	0.064

At admission HR of patient of group DK was higher as compared to group MF but this different was not significant. (p>0.005)

At rest of the period of observation 2 hrs, 4hrs 8hrs 16hrs and 24hrs, heart rate of group MF was higher as compared to group DK but this difference was statistically significant only at 4hrs and 24hrs. (p<0.00%)

Similarly, at admission systolic blood pressure of patients group MF was higher as compared to group DK but this difference was not significant (p>0.05) .At rest of the period of observation systolic blood pressure of group DK was higher as compared to group MF difference was significant at all the period of observation except at 2hrs.

Similarly, On admission diastolic blood pressure of patients group MF was higher as compared to group DK but this difference was not significant (P>0.05) .At rest of the periods except at 16hrs, DBP of group DK was higher as compared group MF difference was significant only at 4hrs and 8hrs (p <0.005).

Similarly, oxygen saturation of patients of group MF was significantly higher as compared to group DK. At rest of the period of observation oxygen saturation of group DK was higher as compared to group MF difference was significant at all the period of observation except at 16hrs and 24hrs.
Sedation score:

Table 2 Comparison of Sedation Score at different time intervals

Time Interval	Group DK (n=10)			Group MF (n=10)			Mann-Whitney U test	
	Md	Mn	SD	Md	Mn	SD	Z	'p'
2h	4.00	4.00	0.00	2.00	2.30	0.48	4.147	<0.001
4h	4.00	4.00	0.00	3.00	2.80	0.42	4.194	<0.001
8h	4.00	4.00	0.00	3.00	3.00	0.47	3.873	<0.001
16h	4.00	4.00	0.00	3.00	2.80	0.42	4.194	<0.001
24 h	4.00	4.00	0.00	3.00	2.60	0.52	4.119	<0.001

Complication

Comparison of Complications

Complication	Total (N=20)	Group DK (n=10)		Group MF (n=10)		Chi-square test	
		No.	%	No.	%	χ^2	'p'
Hypotension	5	0	0.0	5	50.0	6.667	0.010
Hallucinations	1	1	10.0	0	0.0	1.053	0.305

Table 4 Comparison of Awakening time after stoppage of infusion

Group	Min.	Max.	Mean	S.D.
Group MF (n=10)	30	50	39.70	6.04
Group DK (n=10)	10	17	12.50	2.42
Total (N=20)	10	50	26.10	14.65

't'=13.227; p<0.001

DISCUSSION

Sedation is our goal in icu and to check whether any combination which we are using have how much effect in haemodynamic stability. Dexmedetomidine is used as sedative and alpha2 adrenergic agonist and its haemodynamic effect is that it causes bradycardia and hypotension.while ketamine also used as sedative also causes tachycardia and hypertension. Midazolam belongs to benzodiazepine class and works by increasing the activity of the GABA neurotransmitter in the brain . Side effects are low blood pressure and sleepiness. It also preffered for sedation because of its short elimination half life. kidney or liver impairment causes elimination of midazolam prolonged and enhanced effect.

Fentanyl is an opiod and used as pain medication. It works primarily by activating mu-opiod receptor. Its side effect is it causes respiratory depression, shortness of breath, hypoventilation.

In our study we compared the two group for sedation in icu and we compared the haemodynamic stability first group is dexmedetomidine and ketamine and other group is midazolam and fentanyl combination .

We compared the heart rate of patient in both groups. we found the patient receiving dexmedetomidine and ketamine combination heart rate is well regulated as compared to midazolam and fentanyl group Similarly we compared blood pressure variability in both groups. systolic blood pressure of patient of group dexmedetomidine -ketamine is higher as compared to midazolam and fentanyl combination As we deal with diastolic blood pressure it is higher in dexmedetomidine-ketamineas compared to midazolam and fentanyl .

Oxygen saturation in dexmedetomidine- ketamine group of patient also higher as compared to midazolam and fentanyl group of patient.

As we see that sedation score of group dexmedetomidine-ketamine were significantly higher as compared to group midazolam and fentanyl combination.

We are measuring the awakening time after stoppage of infusion of dexmedetomidineend and ketamine and medas and fentanyl we observe that the awakening time is less in case of dexmedetomidine ketamine combination as compared to midazolam fentanyl combination.

Although incidence of hallucination is only found in only 1 patient of dexmedetomidine- ketamine group

CONCLUSION

Thus by this comparison we conclude that dexmedetomidine-ketamine combination is used as very good sedative as compared to midazolam and fentanyl combination regarding haemodynamic parameter and for sedation

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