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COMPARSION OF EFFECTIVENESS OF LOW-DOSE INTRAVENOUS KETAMINE (0.2 MG/KG) WITH (0.5 MG/KG) INTRAVENOUS TRAMADOL FOR THE PREVENTION OF POST- SPINAL ANESTHESIA SHIVERING

Zafar Ali[1], Asim Abdul Sami Shah[2], Jawad Mabood*[3], Muhammad Imran[4], Muhammad Owais[5], Amina Sultan[6]

[1, 3, *4,5,6]*Anaesthesiology Resident, Hayatabad Medical Complex Peshawar*
[2]*Anaesthesiology Resident. Northwest General Hospital and Research Centre Peshawar.*

[1]dr.zafarali2019@gmail.com, [2]samishah3420@gmail.com, *[3]mabood.jawadl2@gmaiI.com, [4]generalsurgeon44@gmail.com, [5]owaisdurrani2@gmaiI.com, [6]pakki785@gmail.com

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Corresponding Author: *
Jawad Mabood

ABSTRACT

OBJECTIVE: *To differentiate between the efficacy of intravenous ketamine 0.2 mg/kg) and 0.5 mg/kg) intravenous tramadol using minimum dosage as remedy for the prevention of post-operative shivering due to anesthesia.*

STUDY SETTING: *Department of Anesthesia NWGH Peshawar.*

STUDY DESIGN: *Randomized controlled trial*

STUDY DURATION: *7th November 2021 to 7th May 2022.*

MATERIAL AND METHODS: *A total of 188 94 in each group) patients were added to the study using non probability consecutive sampling technique.*

RESULTS: *Distribution of Age among groups of 188 94 in each group) were analyzed as n= Among group A ketamine 0.2 mg/kg) the age category 20-30 Years) was 842.1%) and in group B 0.5 mg/kg) intravenous tramadol) was 1157.9%) The age category 31-40 years) group A ketamine 0.2 mg/kg)was 646.2%) and group B 753.8%)The age category 41-50 Years) group A ketamine 0.2 mg/kg)was 750.0%)and group B 0.5 mg/kg) intravenous tramadol) was 750.0%) The age category 51-60 Years) group A ketamine 0.2 mg/kg)was 964.3%) and group B 0.5 mg/kg) intravenous tramadol) was 535.7% Mean age was 51.56 years with standard deviation ±3.357 Distribution of gender among the groups of 188 94 in each group) were analyzed as n= Among group A ketamine 0.2 mg/kg) Male was 1961.3%) and group B 0.5 mg/kg) intravenous tramadol) Male was 1238.7%) Among Group A ketamine 0.2 mg/kg) Female was 1137.9%) and group B 0.5 mg/kg) intravenous tramadol) Female was 1862.1%)*

CONCLUSION: *Therefore, in accordance with our findings, we have come to the conclusion that tramadol is safe and effective in managing shivering in patients who have had spinal anesthesia. Another advantage is its maintenance of a hemodynamically stable profile.*

INTRODUCTION

Spinal Anesthesia which is administration of an anesthetic agent in the subarachnoid space is one of the commonest modes of anesthesia used worldwide and it is frequently associated with shivering in the post-operative period. The mechanism behind this spontaneous involuntary and repetitive muscular phenomenon is vasodilation of arterioles that causes peripheral dissipation of heat which results in heat loss thus lowering the threshold for hypothermia[1-2]. Though the agent is not lethal itself, it significantly increases the morbidity and even mortality in patients with cardiac and pulmonary pathologies. These co-morbidities increase the oxygen consumption of patients hence they are prone to develop severe hypoxemia. In addition, studies have shown raised intracranial pressure related symptoms, headaches from ocular pain and ECG findings due to fluctuations in blood pressure hampering the patients safety[3-4].

In order to coup well with this condition, a number of conservative measures are implicated to decease its occurance and severity which include using, warm clothes and blankets, maintaining a proper temperature in the theatre. These measures, though effective, prove costly and puts a a lot of burden on hospital resources[5]. A number of agents have been reported to be beneficial in reversing the effects of shivering which include magnesium sulfate, cholinnomimetics and opioids. One drug, ketamine, chemically an N-methyle D aspartate receptor antagonist NMDA) has shown promise in controlling this adverse event as published in many articles[6]. In comparison to ketamine, a more centrally acting analgesic in the form of tramadol[7] having more potency towards mu receptor and minimal stimulus on the kappa and delta receptors is also proven to be very beneficial in controlling this post spinal anesthesia shivering. Tramadol inhibits the absorption of serotonin and norepinephrine in the spinal cord and augments the release of hydroxytrptamine[12,17,18] hence resulting In alteration of the temperature check point[8]. According to one analysis, more patients responded to ketamine n=35 70%) as compared to tramadol n=18 36%)[9].

Therefore, the following study will be conducted to compare and contrast the capability of ketamine with tramadol, both in intravenous forms in controlling shivering in the post operative period following spinal anesthesia as a primary outcome and their association with other confounding variables such as hemodynamic stability and level of sedation. The findings of this project will enhance our understanding of these drugs and thus guide future research and planning.

MATERIALS AND METHODS

Study design: This will be a Double Randomized Controlled Trial.

Study Settings: This study will be conducted at Department of Anesthesia, MTI/ Hayatabad Medical Complex, Peshawar.

Study Duration: 7th November 2021 to 7th May 2022.

Sample size: In this study the total sample size will be 185 94) in each group using 56% efficacy of ketamine in preventing post spinal anesthesia shivering and 36% efficacy in the tramadol group[9], 95% confidence level and 80% power of test. According to WHO formula for sample size calculator

Sampling Technique: Non probability consecutive sampling

SAMPLE SELECTION

INCLUSION CRITERIA:

1.All the patients as American Society of Anesthesiologist ASA) I and II
2.Aged 21–60 years, who will be prepare for surgery under subarachnoid anesthesia
3.Both gender male/female

DATA COLLECTION PROCEDURE

The study will be conducted after approval from hospitals ethical and research committee. All patients meeting the inclusion criteria i.e. patient scheduled for elective surgery under spinal anesthesia and meeting American society of anesthesiologist's class 1 and 2 will be included in the study through OPD after taking informed consent.

Complete detail history, general physical and relevant anesthesia fitness examination will be performed. All the included patients will be randomly allocated in two groups. Patients in Group A will be subjected to low dose ketamine and patients in groups B will be subjected to Tramadol. As per protocol for spinal anesthesia, about 10ml/kg of normal saline was instilled carefully in the subarachnoid space while keeping an eye on the patient's vitals which included pulse, temperature, blood pressure, mean arterial pressure, saturation and ECG findings on the Holter monitor. At standard room temperature all patients were observed with no other medications given to control bias. Spinal anesthesia using 2.8ml 14mg) of heavy bupivacaine 0.5% was administered by a single blinded anesthetist in the standard landmark near L4-L5 in line with the anterior superior iliac spine. The block was assessed using the bromage scale. Using blankets and oxygen at 4L/min patients' internal temperature and saturation will be maintained as normal as possible. Using blocked randomization, patients were allotted into two groups: group A ketamine 0.2 mg/kg intravenous and group B tramadol 0.5 mg/kg intravenous. These agents along with normal saline will be instilled using coded 5ml syringes after provision of subarachnoid anesthesia by the same anesthetist who initially blinded in the study. The patients internal temperature and shivering grades will be monitored and recorded every 15 mins for about one hour.

DATA ANALYSIS PROCEDURE

Data will be analyzed with SPSS version 23. Frequency and percentages will be computed for categorical variables such as gender, indication of surgery and efficacy while continuous variables like age, duration of time, duration surgery weight, height and BMI weight in kgs divided by height in square metres) will be described as Mean ± SD. Chi square test will be used to compare the efficacy between the two groups. $P \leq 0.05$ will be considered significant. Effcay will be stratfied among age , gender , BMI indication of surgery, severity to control effect modification.Post stratification chi square test will be applied in which P value <0.05 will be considered as significant value. Post stratification chi square test will be applied to see the effect modifiers. All results will be presented in the form of tables and graphs.

RESULTS

Distribution of Age among groups of 188 94 in each group) were analyzed as n= Among group A ketamine 0.2 mg/kg) the age category 20-30 Years) was 842.1%) and in group B 0.5 mg/kg) intravenous tramadol) was 1157.9%) The age category 31-40 years) group A ketamine 0.2 mg/kg)was 646.2%) and group B 753.8%)The age category 41-
50 Years) group A ketamine 0.2 mg/kg)was 750.0%)and group B 0.5 mg/kg) intravenous tramadol) was 750.0%) The age category 51-60 Years) group A ketamine 0.2 mg/kg)was 964.3%) and group B 0.5 mg/kg) intravenous tramadol) was 535.7% Mean age was 51.56 years with standard deviation ±3.357 As shown in table No 1)

Distribution of gender among the groups of 188 94 in each group) were analyzed as n= Among group A ketamine 0.2 mg/kg) Male was 1961.3%) and group B 0.5 mg/kg) intravenous tramadol) Male was 1238.7%) Among Group A ketamine 0.2 mg/kg) Female was 1137.9%) and group B 0.5 mg/kg) intravenous tramadol) Female was 1862.1%) As shown in table No 2)

Distribution of BMI classification among the groups of 18894 in each group) were analyzed as n=Among ketamine 0.2 mg/kg) in A ketamine 0.2 mg/kg) was 2567.6%) and was absent in 1232.4%) among ketamine 0.2 mg/kg) in B 0.5 mg/kg) intravenous tramadol) was present 521.7%) and was absent in 38100.) among Non-ketamine 0.2 mg/kg) A ketamine 0.2 mg/kg) was 2676.5%) and was absent in 823.5%) among Non- ketamine 0.2 mg/kg) in B 0.5 mg/kg) intravenous tramadol) was 4875.0%) and was absent 1878.3%) As shown in table No 3)Distribution of Efficacy among the groups of 18894 in each group) were analyzed as n= among Efficacy in A ketamine 0.2 mg/kg) was 1970.4%) and was absent in 829.6%) among Efficacy in B 0.5 mg/kg) intravenous tramadol) among Efficacy A ketamine 0.2 mg/kg) was 1133.3%) and was absent in 2266.7%) As shown in table No 4) istribution of ASA classification among the groups of 18894 in each group) were analyzed as n= among anemic patients in A ketamine 0.2 mg/kg) was 2264.7%)and was absent in 1235.3%)hypertensive patients in B

0.5 mg/kg) intravenous tramadol) among Non-anemic patients A ketamine 0.2 mg/kg) was 830.8%) and was absent in 1869.2%) As shown in table No 05)

While stratifying w.r.t age 20-30 Years wise distribution of the in ketamine 0.2 mg/kg) was 2131.8%) and was absent in 4568.2%) having P value 0.012).In B 0.5 mg/kg) intravenous tramadol) group was present 2696.3%) and was absent 13.7%) having P Value 0.001) Stratification among age group 31-40 Years in ketamine 0.2 mg/kg) was 2978.4%) and was absent in 821.6%) having P value 0.001).In B 0.5 mg/kg) intravenous tramadol) group was present 1794.4%) and was absent 15.6%) having P Value 0.003) As shown in table No 6)Stratification W.R.T Gender Wise Distribution of the among Male in ketamine 0.2 mg/kg) was 2131.8%) and was absent in 4568.2%) having P value ≤0.001). among Male in B 0.5 mg/kg) intravenous tramadol) was 2131.8%) and was absent in 4568.2%) having P value ≤0.001) among Female in ketamine 0.2 mg/kg) was 2978.4%) and was absent in 8 21.6%) having P value 0.342) among Female in B 0.5 mg/kg) intravenous tramadol) was 2145.7%) and was absent in 2554.3%) having P value 0.003). As shown in table No 7)Stratification W.R.T Smoking status of the Efficacy among ketamine 0.2 mg/kg) in ketamine 0.2 mg/kg) was 2434.8%) and was absent in 4565.2%) having P value <0.001). Distribution the Surgical Site Infection among ketamine 0.2 mg/kg) in B 0.5 mg/kg) intravenous tramadol) bleeding was present 0.0%) and was absent in 38100.) having P value <0.001) The Surgical Site Infection among Non-ketamine 0.2 mg/kg) ketamine 0.2 mg/kg) was 2676.5%) and was absent in 823.5%) having P value 0.342) Distribution the Surgical Site Infection among Non-ketamine 0.2 mg/kg) in B 0.5 mg/kg) intravenous tramadol) was 4875.0%) and was absent 1625.0%) having P value 0.003) As shown in table No 8)

TABLE NO -1 AGE WISE DISTRIBUTIONS W.R. T GROUPS n=188)

Age wise Distribution	**Groups wise Distribution**	Frequency	Percent
21-30 Years	Group A ketamine 0.2 mg/kg)	30	66.7
	Group B 0.5 mg/kg) intravenous tramadol)	15	33.3
31-40 Years	Group A ketamine 0.2 mg/kg)	9	33.3
	Group B 0.5 mg/kg) intravenous tramadol)	18	66.7
41-50 Years	Group A ketamine 0.2 mg/kg)	27	34.2
	Group B 0.5 mg/kg) intravenous tramadol)	52	65.8
	Total	79	100.0
51-60 Years	Group A ketamine 0.2 mg/kg)	17	50.0
	Group B 0.5 mg/kg) intravenous tramadol)	17	50.0

Mean age was 51.56 years with standard deviation ±3.357 Mean age was 52.11 years with standard deviation ±1.112

TABLE: No 2: GENDER WISE DISTRIBUTION W.R. T GROUPS n=188)

Gender wise Distribution	**Groups wise Distribution**	Frequency	Percent
Male	Group A ketamine 0.2 mg/kg)	47	45.6
	Group B 0.5 mg/kg) intravenous tramadol)	56	54.4

	Total	103	100.0
Male	Group A ketamine 0.2 mg/kg)	36	43.9
	Group B 0.5 mg/kg) intravenous tramadol)	46	56.1
	Total	82	100.0

TABLE NO -3: BMI CLASSIFICATION WISE DISTRIBUTION W.R. T GROUPS n=188)

BMI classification	**Groups wise Distribution**	Frequency	Percent
Below 18.5 Underweight	Group A ketamine 0.2 mg/kg)	19	46.3
	Group B 0.5 mg/kg) intravenous tramadol)	22	53.7
	Total	41	100.0
18.5–24.9 Normal weight	Group A ketamine 0.2 mg/kg)	17	39.5
	Group B 0.5 mg/kg) intravenous tramadol)	26	60.5
	Total	43	100.0
25.0–29.9 Pre-obesity	Group A ketamine 0.2 mg/kg)	24	44.4
	Group B 0.5 mg/kg) intravenous tramadol)	30	55.6
	Total	54	100.0
30.0–34.9 Obesity class	Group A ketamine 0.2 mg/kg)	23	48.9
	Group B 0.5 mg/kg) intravenous tramadol)	24	51.1
	Total	47	100.0

Mean weight was 7.11 years with standard deviation ±3.357

TABLE NO: 4: EFFICAY WISE DISTRIBUTION W.R. T GROUPS n=188)

Efficacy	**Groups wise Distribution**	Frequency	Percent
Yes	Group A ketamine 0.2 mg/kg)	30	43.5
	Group B 0.5 mg/kg) intravenous tramadol)	39	56.5
	Total	69	100.0
No	Group A ketamine 0.2 mg/kg)	53	45.7
	Group B 0.5 mg/kg) intravenous tramadol)	63	54.3
	Total	116	100.0

TABLE NO: 5: ASACLASSIFICATION WISE DISTRIBUTION W.R. T GROUPS n=188)

ASA	Groups wise Distribution	Frequency	Percent
ASA score 1	Group A ketamine 0.2 mg/kg)	33	51.6
	Group B 0.5 mg/kg) intravenous tramadol)	31	48.4
	Total	64	100.0
ASA Score 2	Group A ketamine 0.2 mg/kg)	21	39.6
	Group B 0.5 mg/kg) intravenous tramadol)	32	60.4
	Total	53	100.0

ASA Score 3	Group A ketamine 0.2 mg/kg)	29	42.6
	Group B 0.5 mg/kg) intravenous tramadol)	39	57.4
	Total	68	100.0

TABLE NO: 6: INDICATION OF SURGERY WISE DISTRIBUTION W.R. T GROUPS n=188)

Indication Of Surgery	Groups wise Distribution	Frequency	Percent
Appendectomy	Group A ketamine 0.2 mg/kg)	26	66.7
	Group B 0.5 mg/kg) intravenous tramadol)	13	33.3
	Total	39	100.0
Appendectomy:	Group A ketamine 0.2 mg/kg)	25	39.7
	Group B 0.5 mg/kg) intravenous tramadol)	38	60.3
	Total	63	100.0
Abdominal Hysterectomy	Group A ketamine 0.2 mg/kg)	16	33.3
	Group B 0.5 mg/kg) intravenous tramadol)	32	66.7
	Total	48	100.0
Abdominal Hysterectomy	Group A ketamine 0.2 mg/kg)	16	45.7
	Group B 0.5 mg/kg) intravenous tramadol)	19	54.3
	Total	35	100.0

TABLE NO -7: STRATIFICATION OF AGE W.R.T EFFICACY AMONG GROUPS WISE DISTRIBUTION n=188)

Age wise Distributio n	Groups wise Distribution	Efficacy		Total	P.Value
		Yes	No		
21-30 Years	Group A ketamine 0.2 mg/kg) Group B 0.5 mg/kg) intravenous tramadol)	5	25	30	0.001
		16.7%	83.3%	100.0%	
		10	5	15	
		66.7%	33.3%	100.0%	
	Total	15	30	45	
		33.3%	66.7%	100.0%	
31-40 Years	Group A ketamine 0.2 mg/kg) Group B 0.5 mg/kg) intravenous tramadol)	6	3	9	0.001
		66.7%	33.3%	100.0%	
		6	12	18	
		33.3%	66.7%	100.0%	
	Total	12	15	27	

		44.4%	55.6%	100.0%	
41-50 Years	Group A ketamine 0.2 mg/kg) Group B 0.5 mg/kg) intravenous tramadol)	11	16	27	0.001
		40.7%	59.3%	100.0%	
		17	35	52	
		32.7%	67.3%	100.0%	
	Total	28	51	79	
		35.4%	64.6%	100.0%	
51-60 Years	Group A ketamine 0.2 mg/kg) Group B 0.5 mg/kg) intravenous tramadol)	8	9	17	0.001
		47.1%	52.9%	100.0%	
		6	11	17	
		35.3%	64.7%	100.0%	
	Total	14	20	34	
		41.2%	58.8%	100.0%	

TABLE NO -8: STRATIFICATION OF GENDER WISE DISTRIBUTION W.R.T EFFICACY AMONG GROUPS WISE DISTRIBUTION n=188)

Gender wise Distribution	Groups wise Distribution	Efficacy		Total	P.Value
		Yes	No		
Male	Group A ketamine 0.2 mg/kg) Group B 0.5 mg/kg) intravenous tramadol)	24	23	47	0.001
		51.1%	48.9%	100.0%	
		31	25	56	
		55.4%	44.6%	100.0%	
	Total	55	48	103	
		53.4%	46.6%	100.0%	0.001
Male	Group A ketamine 0.2 mg/kg) Group B 0.5 mg/kg) intravenous tramadol)	6	30	36	
		16.7%	83.3%	100.0%	
		8	38	46	
		17.4%	82.6%	100.0%	
	Total	14	68	82	
		17.1%	82.9%	100.0%	

DISCUSSION

Post anesthesia shivering is one of the commonest complications seen in patients undergoing various surgical procedures on a global scale. As previously discussed, some of the usual practices followed to control this phenomenon include using warm garments, blankets and maintaining a proper temperature in the operating theatre. Some of the pharmacological agents employed for this condition include clonidine, meperidine, anticholinergics[7], opiate agonists, dexamethasone and tramadol[8-16]. One added benefit of tramadol is its safer side effect profile: compared to other mu receptor agonists it causes less respiratory depression along with nausea and vomiting[12].Chan et al.,[12] compared 0.25 and 0.50 mg/kg of tramadol for prevention of shivering in pregnant women who had undergone spinal anesthesia.[9] Dewitt et al.,[12] studied 2mg/kg and Mathew et al.,[1] studied1mg/kg of tramadol for prevention and treatment of shivering. This prospective, double- blind, randomized clinical study was performed to evaluate one mg/kg of tramadol in prevention of shivering in post spinal anesthesia in patients who had undergone cesarean section. In this study, the incidence of shivering in the tramadol group 8.8%) was less frequent than in the control group 86.6%), which give a significant statistical difference P<0.001). According to shivering severity,

in tramadol group 50% experienced shivering grade[2] and 50% grade[22] whereas in control group only 13.3% experienced shivering grade[2] and 73.3% had shivering grade. [22] Therefore shivering severity was clearly lower in patients who used tramadol P<0.001).Tramadol is effective in preventing of post anesthetic shivering. Billota et al[13] compared tramadol and nefopam with placebo for shivering prevention and concluded that nefopam had a greater effect than tramadol and tramadol had a greater effect than placebo in prevention of shivering. Dewitt et al.,[15] compared tramadol of 0.5, 1 and 2 mg/kg with placebo and concluded that tramadol in treatment of post operation shivering is quite effective and has no unpleasant effects especially in patients with low cardio- pulmonary reserve.The main opioid effect of tramadol is mediated via the μ receptor, with minimal effect at kappa or sigma binding sites. The O-desmethyl metabolite M1) of tramadol and its enatiomers are bound with higher affinity than the parent compounds at μ-opioid receptors with less affinity for kappa and sigma opioid receptors, although still with a much lower affinity than morphine. Tramadol may induce its anti-shivering effect via the additive or synergistic action of both kappa opioid receptor and 2 adrenergic mechanisms. The interaction of kappa opioid and 2 adrenoceptor mechanisms working in a complementary or synergistic manner to produce anti shivering effects seems a possible explanation.[17,18,21-23]Anchalee Techanivate et al study[16] investigated whether 20μg of intrathecally administrated fentanyl would influence the incidence and severity of shivering. Seventy five percent of tramadol group and 100% of fentanyl group responded to anti-shivering effect of these drugs. Efficiency of anti-shivering effect of tramadol was similar to our report 80-87%). Talakoub et al study[20] efficacy and harm of tramadol for treatment of post spinal anesthesia shivering in cesarean section were evaluated. They compared tramadol 0.5mg/kg) with pethedin 0.5mg/kg) to control of shivering and concluded that tramadol is more effective to control of shivering but results in more nausea, vomiting and somnolence.Mathew et al study[1] used tramadol 1mg/kg for treating post operation shivering and no, undesirable side effects nausea and vomiting) were noted which is comparable with our study. In addition in other studies[1,8-10,15,20] tramadol had no effect on blood pressure, arterial oxygen saturation percentage and body temperature. Therefore these results are all in agreement with our findings.

CONCLUSION

The findings of the study are in favor of using tramadol as a pharmaceutical agent in patients who present with post-operative shivering from spinal anesthesia. Tramadol, being easily available over the counter drug, can be used as an alternative to ketamine in resource poor centers and hospitals worldwide. Its main advantage lies in controlling the amount of unnecessary sedation and hemodynamic stability. Further research is needed to augment and support this hypothesis in terms of testing other variables that might negatively or positively impact its utility in controlling post-spinal anesthesia shivering.

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