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Comparison of Kabilyte® and Ringer Lactate as Prime Solution on Cognitive Functions in Patients Undergoing Cardiopulmonary Bypass

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Abstract: ***Central nervous system dysfunction remains a major cause of morbidity and mortality after cardiac surgical procedures done on cardiopulmonary bypass. A novel brand of balanced salt solution, kabilyte® and Ringer lactate (RL) were used as prime solutions in the present study.We aim to compare the cerebral protective effects of kabilyte® and ringer lactate solutions in CPB using Mini Mental State Examination tests. Method: Patients were randomized into two groups. Open heart surgery was performed by using kabilyte® in group A (n = 32) and Ringer lactate solution in group B (n = 32). Preoperative and postoperative informative cognitive test scores, characteristics of the patients were compared. Results: No significant difference was found between the preoperative and postoperative cognitive test scores in group A as well as Group B (p ≥ 0.05). Conclusion:It may be suggested that Kabilyte® as well as RL may cause a reduction in the incidence of cerebral complications when used as prime solution in patients who undergo CPB.***

Keywords: Cognitive function, cardiopulmonary bypass, prime solution, kabilyte® , Ringer lactate

1. Introduction

Central nervous system dysfunction remains a major cause of morbidity and mortality after cardiac surgical procedures done on cardiopulmonary bypass[1] . The neurologic injury has been classified into two broad categories: type I includes focal injury,stupor or coma at discharge and type II includes deterioration in intellectual function, memory deficits,or seizures[2]. Another way of classification could be stroke, encephalopathy and cognitive dysfunction. The incidence of neurological complications following CPB is considerable with incidence of major strokes being approximately 1.6% while that of neuropsychological abnormalities being in excess of 50%. Important causes of neurological dysfunction are embolism and hypoperfusion leading to brain ischemia and hypoxia. Cardiopulmonary bypass per se does not cause changes in blood brain circulation, but hemodilution and decrease in oncotic pressure lead to edema in the brain and other organs[3]. The systemic inflammatory response associated with CPB produce a significant increase in microvascular permeability and/or blood-brain barrier[4]. A novel brand of balanced salt solution, kabilyte® and Ringer lactate (RL) were used as prime solutions in the present study. We aim to compare the cerebral protective effects of kabilyte® and ringer lactate solutions in CPB using Mini Mental State Examination tests.

2. Material & Method

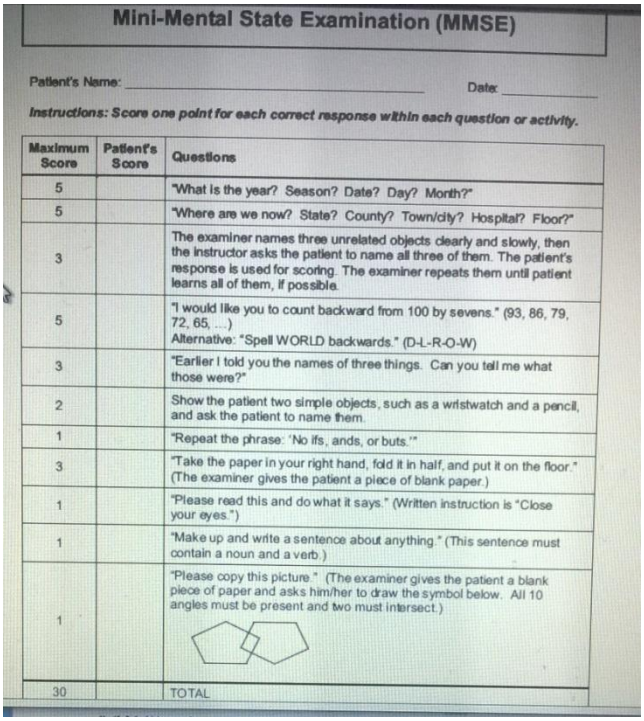
The study was conducted on 64 patients undergoing cardiac surgery on cardiopulmonary bypass in our institute.Due permission of institutional ethical committee and informed consent of the patient was obtained.

Preoperative and postoperative neurologic examinations were performed by the same neurologist. The neurologic tester was a single individual who was double blinded to both the prime solution used and to the group of patients. The patients were divided into two groups randomly by chit and box method.

Group A was the Kabilyte ® group and group B was the RL group. The mean ages of patients in group A and B were 62.4±3.02 years and 61.2±2.06 years respectively.

Following patients were included in the study: Patient undergoing cardiac surgery on cardio pulmonary bypass; ASA Grade II,III; Weight 40-60 Kilogram;Patient with Normal Coagulation Profile with normal liver and kidney function. Patient exclusion criteria of the study included:Patient refusal; inability to establish sufficient co operation; anxiety and depression symptoms; h/o previous syncope, TIA; clinical neurologic defect.

All patients were visited one day prior to the day of surgery and cognitive functions were assessed using Mini Mental State Examination (MMSE).



Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

Instructions: Score one point for each correct response within each question or activity.

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day? Month?"
5		"Where are we now? State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then the instructor asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible.
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.)
30		TOTAL

3. Procedure

After taking informed consent and confirming overnight fasting status, patient was taken on the operation table. Baseline vital parameters like HR,BP, respiratory rate were recorded. 18G i.v. cannula secured. All patient started fluid @ 5ml/kg/hr in peripheral line .12 lead ECG and pulse oxymeter were attached. Patient were premedicated with i.m. morphine 0.1 mg/kg and i.m. promethazine 0.5 mg/kg. After that femoral artery cannulation was performed and central venous catheter was inserted into right internal juglar vein under local anaesthesia.Patient was preoxygenated with 100% O2 for 3 minutes. Induction of anaesthesia was done with inj midazolam 0.05 mg/kg, inj. fentanyl 5µg/kg & Inj. Etomidate 0.3mg/kg IV slowly over a period of 60-90 second until there was loss of eyelash reflex and lack of response to verbal command. Inj. rocuronium bromide 0.9 mg/kg I.V. was given to facilitate the intubation . Oral tracheal intubation was done at 2 minute after induction. Position of tube was checked and fixed with adhesive. Maintainance of anaesthesia with 100% O2, inj. midazolam .01mg/kg hourly, inj. Vecuronium .05 mg/kg every half hourly. Nasopharyngeal temperature probe and nasogastric tube was secured. Patient was catheterised with foleys urinary catheter. After standard sternotomy, ascending aortacannula, and two-stage venous cannula were placed,extracorporeal oxygenation was maintained by a membraneoxygenator. Kabilyte® (1,500 Ml)and RL (1,500 mL) was used as the prime solution in groups A and B, respectively. Anticoagulation was maintained with heparin (3.0mg/kg) and activated clotting time was monitored to be kept between 300 and 400 seconds. Body temperature was reduced to 28°C to 32°C to achieve mild hypothermia. At the early stage after the operation, respiration was maintained with a volume-controlled respirator then the patients were extubated after they recovered from general anesthesia and started to breath normally. Extubation criteria included adequate level of consciousness and muscle strength, stable cardiovascular status, normothermia, adequate pulmonary function and minimal thoracotomy tube output.

4. Tests

Informative and cognitive tests were applied twice -2 days before the operation and 6 to 7 days after the operation. All neurologic tests were done blindly by one neurologist to maintain consistency of results. The preoperative and postoperative neuropsychological test scores were compared using student's t test.

Table 1: Demographic and Clinical Characteristics of Patients (Mean _ Standard Error of the Mean)

Characteristics	Group A	Group B	P value
Age	62.4±3.02	61.2±2.06	0.49
Cross-clamp time(min)	64.2±5.52	66.6±3.49	0.38
CPB Duration(min)	103.4±8.01	104.8±4.97	0.71
Post operative intubation period(hr)	6.1±0.85	6.3±1.8	0.59
Duratioin of ICU stay(days)	1.13±0.09	1.66±0.33	0.48
Discharge time(days)	8.33±0.92	7.73±0.92	0.41
Duration of surgery(hr)	4.5±0.8	4.8±0.6	0.25
Preoperative ejection fraction (%)	57.2±2.91	57.4±3.19	0.83

Table 2: MMSE Test Results

	Group A			Group B		
MiniMental StateExam (Max.score)	Preop	Postop	P value	Preop	Postop	P value
What is the year? Season? Date? Day? Month?(5)	4.9±0.3	4.9±0.3	1.000	4.22±0.42	4.41±0.50	0.109
Where are we now? State? County? Town/city? Hospital? Floor?(5)	4.91±0.39	4.97±0.18	0.41	4.91±0.30	4.94±0.25	0.647
Three names immediately(3)	2.91±0.3	2.97±0.18	0.39	2.94±0.25	3.00±0.00	0.162
Three names after 5minutes(3)	2.97±0.18	3.00±0.00	0.32	2.97±0.18	2.97±0.18	1.000
Counting backwards(5)	4.03±0.82	4.16±0.85	0.55	4.44±0.84	4.47±0.80	0.879
Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.(2)	1.97±0.18	2.00±0.00	0.32	1.91±0.30	1.84±0.37	0.457
Verbal accuracy(1)	0.88±0.34	0.88±0.34	1.000	0.88±0.34	0.91±0.30	0.694
Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)(3)	2.94±0.25	2.94±0.25	1.000	2.88±0.34	2.94±0.25	0.399
Please read this and do what it says." (Written instruction is "Close your eyes.")(1)	0.94±0.25	1.00±0.00	0.155	0.91±0.30	0.91±0.30	1.000
Abstract thinking(1)	0.94±0.25	0.94±0.25	1.000	0.94±0.25	0.94±0.25	1.000
Drawing two intersecting pentagons(1)	0.91±0.30	0.91±0.30	1.000	0.81±0.40	0.88±0.34	0.498

5. Results

Regarding the preoperative risk factors, hypertension was present in 18 patients (56%) in each group. Blood pressure was preoperatively regulated by antihypertensive drugs in these patients. Preoperative mean ejection fraction percentage measured with transthoracic echocardiography was found to be 57.2±2.91 in group A and 57.4±3.19 in group B.

None of the patients had a cerebrovascular disease such as ischemic cerebrovascular event or syncope. Physical and neurologic examinations were normal in both groups. No murmur was reported on carotid artery auscultation. The mean age, cross-clamp time, duration of CPB, duration of postoperative intubation, duration of stay in the intensive care unit, discharge time, duration of the operation, preoperative ejection fraction percentage are shown in Table 1. These measurements were not significantly different between the groups ($p \geq 0.05$).

Postperfusion syndrome with cooperation and orientation disorder, agitation, and confusion was not found in any patient in both the groups.

A total of 11 informative cognitive tests were applied to all patients in both groups. Between two groups, preoperative neurocognitive test scores were not found statistically different for each of the tests ($p \geq 0.05$). Preoperative and postoperative results of these tests (mean values and statistical analyses) are shown in Table 2. The differences were analyzed with student t test. Accordingly, no significant difference was found between the preoperative and postoperative cognitive test scores in group A as well as Group B ($p \geq 0.05$). When postoperative informative cognitive test scores of group A and B were compared, there was no statistically significant difference ($p \geq 0.05$).These results indicate that Kabilyte^{R} and RL (as a prime solution in extracorporeal circulation) had not caused damage to cerebral functions in terms of informative -cognitive test scores.

6. Conclusion

The ideal prime for CPB has not been fully established yet. The most common choice for prime solution have been RL, albumin, HES, and polygeline. Although it was reported that HES, as a prime solution in open heart surgery was more effective regarding its cardiac and systemic effects [5, 6], there are less studies in the literature that monitored cerebral functions. Iriz et al reported that HES is a better prime solution than RL[7] . Methods of diagnosis of cognitive disorders are complex, mostly specific for individuals and independent from CPB, and test results may be affected by surgical stress, anesthesia, sleep disorders, and environmental changes. The results of cognitive function tests in CPB patients are controversial in different studies. However, the general belief is that a postoperative cerebral dysfunction develops, but there is no objective and sensitive cognitive test to diagnose that mild dysfunction. Cerebral dysfunction is mostly transient, and was shown in many studies performed at 3 months to 5 years after CPB [8] . Klonoff and colleagues[9] examined the patients with neuropsychological dysfunction at 3, 12, and 14 months after coronary artery bypass grafting and reported that dysfunction gradually decreased. In the present study, there was no statistically significant difference found in informative cognitive functions after using either Kabilyte® or RL as prime solution. Therefore it may be suggested that Kabilyte® as well as RL may cause a reduction in the incidence of cerebral complications when used as prime solution in patients who undergo CPB.

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