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ROLE OF BLOOD GAS ANALYZER AS A POINT OF CARE TEST FOR EARLY IDENTIFICATION OF HYPERKALEMIA IN PATIENTS WITH CHRONIC KIDNEY DISEASE.

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ABSTRACT **Background** Hyperkalemia is the most common life threatening electrolyte disorder in Chronic Kidney Disease (CKD) patients. Conventionally, diagnosis is done by standard laboratory test which takes about an hour or more to give results. Early evaluation of serum potassium levels in Emergency Department (ED) form a basis for immediate intervention and need for urgent hemodialysis. This article compared measurement of serum potassium by a point of care blood gas analyser machine and standard laboratory auto-analyzer. **Materials and Methods** This was a prospective observational study undertaken at a tertiary care hospital in New Delhi. CKD patients were identified in the ED and samples were drawn for blood gas analysis and laboratory for screening of hyperkalemia. The sample results were compared. Normally distributed continuous variables were analysed using Student's t-test and Mann Whitney U test. Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test as appropriate. The degree of agreement between two systems was quantified using Kappa statistic. The Bland-Altman plot was made to compare mean of difference between two measurements techniques. **Results** Blood Gas Analyser was found to be 87.7% sensitive in measuring serum potassium values with a specificity of 84.7%. It had a Positive Predictive value of 86.7% and Negative Predictive Value being 85.7% with an Accuracy of 86.3%. We found a significant positive correlation between blood gas analyzer and laboratory auto-analyzer. Pearson Correlation Coefficient (R) value being 0.932. **Conclusion** Results of Blood gas analyser correlate well with values obtained from reference laboratory in patients with chronic kidney disease and thus can be reliably used in Emergency Department

KEYWORDS : Blood Gas Analyser, Hyperkalemia, Point of Care test, Chronic Kidney Disease

INTRODUCTION:

Hyperkalemia is a life threatening electrolyte disorder requiring a rapid detection and treatment. With increasing burden of Chronic Kidney Disease (CKD), Emergency Departments (ED) are witnessing an upsurge of patients presenting with hyperkalemia. Conventionally, diagnosis is confirmed by standard laboratory test which takes about an hour or more to give results. A rapid point of care estimation of Potassium (POC-K) can help in preventing this serious complication, thereby reducing morbidity and mortality. With availability of Blood Gas Analysers (BGA) in major Emergency Departments, rapid estimation of Potassium and institution of antihyperkalemic therapy is feasible. However, many physicians prefer to wait for laboratory confirmation before starting therapy in the absence of Electro cardiographic (ECG) changes of hyperkalemia. Moreover, ECG changes are only seen in around 46% cases of hyperkalemia. [1] Literature is divided on the issue of reliability of POC-K estimation. [2-5] There have been no prospective studies in India studying the same in ED. We therefore undertook this study to evaluate the role of Blood Gas Analyser as a point of care test for early identification of hyperkalemia in patients with chronic kidney disease presenting to Emergency Department of our institution.

MATERIALS AND METHODS:

This was a prospective observational study conducted at a tertiary care hospital in New Delhi. Consecutive adult patients of CKD of either sex who presented to the ED were enrolled in the study after taking a written informed consent from patient or his/her attendant. Pregnant females and those who presented in cardiac arrest were excluded. Study was conducted from June 2018 to November 2019.

All patients received primary care as per advanced cardiac life support systematic examination protocol. Blood gas sample was drawn in dried heparin syringes and renal function test were ordered from the hospital's accredited laboratory. Blood gas analysis uses whole blood whereas laboratory measurement for potassium uses serum for measuring Potassium levels. The Blood Gas Analyser used in the emergency department for the study was ABL 800 Basic (Radiometer Medicals, Denmark) model that works via direct ion selective electrode technology. In laboratory, auto analyser(AA) used was ISE module which works on indirect ion selective electrode technology. Treatment of the patient was left at the discretion of the treating physician. Data was collected in a specially designed data collection form and entered into an excel sheet for analysis.

Statistics:

Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables were presented as mean ± SD, and categorical variables were presented as absolute numbers and percentage. The comparison of normally distributed continuous variables between the groups (K ≤5.5mmol/l and >5.5mmol/l) was performed using Student's t test and Mann Whitney U test for non-normally distributed data. Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test as appropriate. The degree of agreement between serum potassium values measured by BGA and Laboratory AA was quantified using Kappa statistic. The Bland-Altman plot was made to compare mean of difference between two measurements techniques.

RESULTS:

In our study a total of 1035 patients were included. They were divided into two groups- Group1 (those with serum K levels ≤5.5 meq/L) and group 2 (those with K levels > 5.5 meq/L). There were 483 patients in group I and 552 in group II. Subjects in each group were similar in their age and sex distribution. They were also comparable in their presentation with respect to heart rate and blood pressure measured in ED (Table 1)

A significant correlation was seen in serum potassium values measured by blood gas analyser and laboratory auto-analyzer in CKD patients. Amongst 483 patients in group 1; 409 (84.7%) had concordance in measurements by BGA and laboratory AA. Out of 552 patients in Group 2, 484 patients (87.7%) had similar values in both Laboratory and BGA. (Table 2)

Significant changes were seen in patient's ECG where serum potassium was > 5.5 meq/L. None of the patient in group I showed ECG changes while 30.8% in group II showed changes. (Table 3)

A significant difference was seen in creatinine values amongst two groups. Mean serum creatinine value in group 1 was 6.62 ± 4.25meq/L, whereas in Group 2 it was 4.53 ± 1.61 meq/L ($p < 0.001$) In the study, the Blood Gas Analyser was found to be 87.7% Sensitive in measuring Serum K values with a Specificity of 84.7%. It had a Positive Predictive value of 86.7% and Negative predictive value being 85.7%

with an Accuracy of 86.3% (Figure 1) We plotted the measured values on the correlation graph and found a significant positive correlation between BGA and laboratory auto-analyser. Pearson Correlation Coefficient R value being 0.932. (Table 4 and Figure 2)

To determine the agreement between the values of serum potassium measured by BGA and laboratory, data points were plotted on Bland Altman graph (Figure 3). The mean of difference between the measured values was found to be 0.672 with a standard deviation of 0.023(95% Confidence Interval- 0.627 to 0.717), 83.86% of values were within limits of agreement implying a significant agreement between the two methods.

DISCUSSION:

Potassium (K^+) is a predominant intracellular cation; only about 2% of total body K^+ is found in the extracellular fluid. In humans, normal range of serum K^+ lies within the narrow range of 3.5 to 5.0 mEq/L, which helps in maintaining a normal ratio between the intracellular and extracellular compartments. This homeostasis is important for maintenance of normal cardiac membrane action potential and neuromuscular activity. [6]

Hyperkalemia is a common complication seen in patients of CKD. In cases of severe hyperkalaemia, patients may have life-threatening arrhythmias; a delay in diagnosis may affect patients' outcomes in a deleterious manner.

The use of rapid POC-K^+ to determine hyperkalemia at bedside can help in making an accurate diagnosis and allow early treatments. It will enable reduction of turnaround times in the ED. Use of POC-K^+ has several advantages. It can be directly conducted at bedside in the ED. [7] Since the test is performed on whole blood; time taken for centrifugation is not needed, thereby giving rapid results. The values in BGA are not affected by serum protein levels [8,9] POC-K^+ takes only 2-3 minutes, while the reference laboratory test usually takes at least 40-60 minutes. [10]

The study by Chhapola, et al [11] done in a Pediatric Intensive Care Unit revealed that BGA underestimated K^+ levels. They reported a systematic bias and wider limits of agreement for and concluded that results of POC-K are not clinically acceptable. José and Preller, et al [10] in their study reported that majority of physician's want to confirm results obtained from POC-K by central laboratory assay. Although the agreement of potassium concentrations determined by two different assays is controversial, there is sufficient agreement between POC-K and the general laboratory AA to make a clinical decision for initiating treatment for hyperkalemia with use POC-K in the setting of Emergency Department in Chronic Kidney Disease Patients. Some other studies reported agreement between the values measured by the two methods [2,3,6,7,10,12-14] whereas some refute the agreement. [4,5,11,15,16]

To the best of our knowledge, the correlation has not been prospectively studied in an Indian Emergency Department, so far. This study conducted in a cohort of 1035 patients strengthens the argument in favour of BGA as POC-K for clinical use in ED.

We also found that, higher Serum Potassium levels were significantly associated with rising creatinine levels. Similar findings were reported in the study by Hsieh MF et al [17] which found rising serum K+ level in direct correlation with decline in the eGFR in the late stages of CKD. As renal failure progressed, the variation in serum potassium levels became wider.

In our study 30.8% of patients with hyperkalemia (Serum Potassium >5.5) had ECG changes such as tall T waves, prolonged PR interval or sine wave pattern. This is an established fact that higher potassium levels are associated with ECG changes needing treatment immediately. This is in concordance with study by An Jung Nam et al, [18] done in Korea, which showed that amongst patients needing Emergent admission 36.7% had ECG findings of hyperkalemia,

Hyperkalemia can be life threatening in emergency situations. Rapid changes of K^+ are associated with End Stage Renal Disease, as well as acute and chronic kidney diseases. Our study validates use of Point of Care Potassium testing with a blood gas analyzer in Emergency Departments with high levels of reliability. This will allow Emergency Physicians to take quick and effective clinical decisions for better patient outcomes.

CONCLUSION:

Blood Gas Analyzer correlates well with values obtained from reference laboratory tests in patients with Chronic Kidney Disease. If it can be made available, as a standard rapid diagnostic test for the detection of hyperkalemia in the ED, it has the potential to reduce mortality and morbidity, the time needed to achieve an accurate diagnosis and treatment, and the turnaround time in ED.

Ethical Statement

This study was conducted with approval of Institutes Ethics Committee. The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000.

Financial Support:

Nil

Conflicts of Interest:

Nil

Table1: Epidemiologic distribution of the study group

	Group I (≤5.5 meq/L))	Group II (>5.5meq/L)
No. of patients (n)	483	552
Age in years (mean± SD)	56.45 ± 16.11	56.94 ± 16.42
Gender (M/F)	269/214	300/252
Systolic Blood Pressure (mean ± SD)	133.95 ± 13.84	138.33 ± 15.71
Diastolic Blood Pressure (mean ± SD)	80.17 ± 8.40	81.12 ± 9.25
Heart Rate (mean ± SD)	83.56 ± 8.45	83.09 ± 8.91

Table 2: Serum Potassium levels measured by Blood gas analyzer and Laboratory Autoanalyser

K (BGA)	K (laboratory autoanalyzer)				P Value
	≤ 5.5		> 5.5		
	Frequency	%	Frequency	%	
≤ 5.5	409	84.7%	68	12.3%	<0.001
>5.5	74	15.3%	484	87.7%	
Total	483	100%	552	100%	

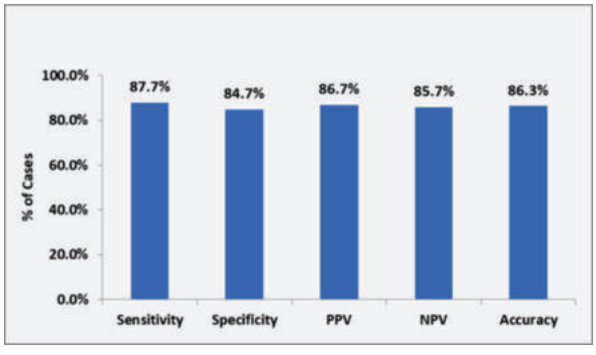

Figure 1: Performance of Blood Gas Analyzer

Table 3: Correlation of Potassium levels with ECG changes

ECG CHANGES	Potassium levels(meq/L)				P Value
	≤ 5.5		>5.5		
	Frequency	%	Frequency	%	
No	483	100.0%	382	69.2%	<0.001
Yes	0	0.0%	170	30.8%	
Total	483	100%	552	100%	

Table 4: Correlation between BGA and Laboratory values of Serum K

		K (BGA)	K (AA)	P VALUE
K (BGA)	Pearson Correlation	1	.932	<0.001
	N	1035	1035	
K (AA)	Pearson Correlation	.932	1	<0.001
	N	1035	1035	

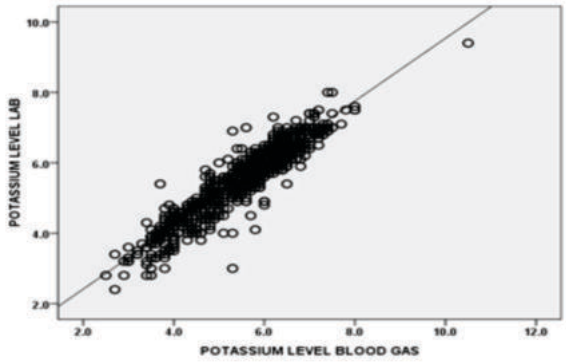

Figure 2: correlation between BGA and Lab

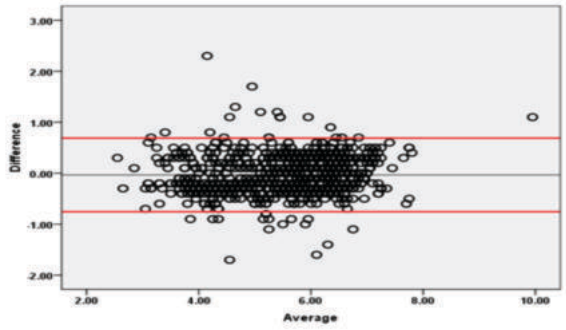

Figure 3: Bland Altman plot

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