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Point-of-Care Versus Central Laboratory Potassium Comparison in Emergency Room

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Abstract

In today's setting, one of the great challenges is to fulfil the proper execution of measurements and compliance of various laboratory investigations, with the internal and external quality control specifications. Our aim was to compare the values of the highly critical parameter potassium(K^+) determined with Point of Care Testing (POCT) devices and central laboratory analysers (ZL) in a highly vulnerable setting of an emergency department in a tertiary care hospital and to assess the quality of POC devices performance. *Aim*- To find correlation between potassium (K^+) determined with Point of Care Testing (POCT) devices and central laboratory analysers (ZL). *Settings and Design*: Prospective observational study, conductedin 524 patients from June 2019 to December 2019 at Dept of Emergency Medicine ,Amrita Institute of Medical Science (AIMS), Kochi. *Methods and Material*: Data collected from patients satisfying inclusion criteria ,24*7 coming Emergency Medicine Department, POCT- (K^+) diagnosis is done with System RadiometerABL800 &central laboratory (K^+- ZL) measured with COBAS 800 &(K^+) using indirect ion selective electrode (ISE) method. *Statistical analysis used***:** To test the statistical significance of the correlation between K^+- ZL & POC-K^+, Pearson correlation method is used. To find the agreement between two measurements, intraclass correlation coefficient is calculated. P <0.05 was considered statistically significant. *Results***:** The correlation between both the parameters (POC-K^+&K^+-ZL) was highly significant (r = 0.536, p<0.001) (Fig 2) and the results were showing excellent agreement between POC-Hb & HB-ZL(ICC= 0.536,95% confidence interval (0.47,0.59). *Conclusions***:** Our comparison of POC devices with central laboratory potassium determination in emergency patients at a tertiary care hospital showed a highly significant correlation between the two analysed potassium concentration measurement methods, using POC devices and the indirect ion selective electrode (ISE) method

Keywords: Point of care devices; Point of care potassium; Emergency Medicine.

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Introduction

Implementation and utilization of point-of-care testing (POCT) has steadily increased over recent years in Emergency departments all over India. Using POC devices allows for rapid diagnosis right at the patient's bedside, allowing for prompt forward management, which integrates treatment processes, with immediate therapeutic and diagnostic advantages. The benefits of POC devices over routine laboratory investigations include low sample volumes, less invasive sample collection, and the absence of long transport periods and sample preparation procedures, especially in the emergency setting where time is of at most essence. Potentially, the main disadvantage which stands out is the relatively higher cost of procedure when weighed against typical routine blood investigations. Moreover, accuracy of POCT measurement results when compared with the results from other confirmed methods are not always warranted, though inconsistencies are generally rare. In an emergency setting, a parameter like potassium is of high critical value especially in diagnosing hypokalaemia, hyperkalaemia, diuretics use, dehydration,hypertension,Arrhy thmias , and to make various other therapeutic decisions. Therefore, the efficiency & reliability of POC devices is critical.

Aim of the Study

The aim of this study is to compare the results of Potassiumvalues determined with POCT Device with ZL, and review the quality of POCT testing in an emergency setup. For the study design, the Department of emergency medicine was deliberately chosen as a highly vulnerable area with a large caseload . Economic observations, such as a cost benefit analysis, were not the focus of the present study.

Methodology

Inclusion criteria: Patients of any age group whose blood samples are simultaneously checked in both point of care testing device & central laboratory diagnostics.

Exclusion criteria: Patients not willing to participate in this study, blood samples collected from 2 different sites / time ,multiple prick samples, Structure, material and location.

This was a prospective observational study which was conducted from June 2019 to December 2019 at Amrita Institute of Medical Science (AIMS), Kochi. The department of emergency medicine in AMRITA is visited by more than 20,000 patients per year. With total beds of 29,including triage area of 12 beds, adult resuscitation area of 5 beds, neonatal resuscitation area 1, decontamination area 1, procedure room 2, emergency critical care unit 8. Each of these areas is equipped with hydraulic beds, compact and portable monitors, defibrillators, AEDs, infusion pumps, ventilators etc. Our 24x7 in- hospital services include emergency dialysis facility, cardiac pacing and endoscopy, dedicated ultra-sonographic machine for aiding diagnosis and also for assisting emergency surgeries. Point of care devices for haemoglobin, elec- trolytes (potassium, potassium, calcium), creatinine, bilirubin, ABG,Procalcitonin, CBC, CRP &high sensitive TROP - I for aiding quick diagnosis are available.

Data Collection

Over the course of 24 hours, 50 nurses work on weekdays and 54 nurses on the weekend, in a mix of specialist nurses, employees with additional qualifications and paramedics. All medical staff members and all nursing staff were trained in POCT diagnosis.

The details of patients who satisfy inclusion criteria were collected along with their POC potassium values, all sample measurements carried out by the 24 hr care employees were included in the analysis. During the evaluation period, there was no change in observational conditions, e.g. number of staff or workflow; POCT training also remained unchanged. At the central laboratory, specialists in laboratory medicine, residents and laboratory technicians are in attendance 24 hours/day. During the evaluation period, potassium values from the central lab. was collected and tabulated.

Central laboratory measurements

The reference method results for the (K^+) value at the central laboratory (K^+- ZL) were established with COBAS 800 &(K^+) is measured with indirect ion selective electrode (ISE) method . Examination material for the central laboratory analysis consisted of venous whole blood. In all samples, analyses were performed within 15 minutes of arrival at the central laboratory.

POCT measurements

In Amrita Institute of Medical Science, POCT-(K^+) diagnosis is done with System RadiometerABL800.

For blood gas analysis, arterial, venous, capillary and mixed venous heparinized whole blood samples can be used. Examination material for the blood gas analysis was heparinized venous whole blood. In line with hospital quality control measures, this analyser is subject to internal and external quality control check under the responsibility of the medical director of the central laboratory at regular interval.

Statistical analysis

Data were statistically analysed (Microsoft Excel, Version 2010; IBM SPSS Statistics, Version 20.0). Continuous variables are expressed using mean and standard deviation. Categorical variables are presented using frequency and percentage. To test the statistical significance of the correlation between K^+- ZL & POC-K^+, Pearson correlation method is used. To find the agreement between two measurements, intraclass correlation coefficient is calculated. P <0.05 was considered statistically significant.

Results

Average age of the 524 analysed patients was 48.35 +/- 26.09 years (range 1–99 years); data of two emergency patients were excluded due to inconclusive identity. The Male-to-female ratio was 365/159 (69.6% male, 30.3% female)(Fig-1) and the mean value of (K^+) -ZL was 4.231mEq/L (SD 0.8421), while the mean value of POCT-(K^+) is 4.043mEq/L (SD 0.8662). The correlation between both the parameters (POC-K^+&K^+-ZL) was highly significant (r = 0.536, p<0.001) (Fig 2) and the results were showing excellent agreement between POC-Hb & HB-ZL(ICC= 0.536,95% confidence interval (0.47,0.59).

Discussion

In Amrita Institute of Medical Sciences, multiple point of care devices were developed and established and are in use effectively and with good compliance. In the current study, it was evaluated whether the POC implementation did in fact result in the expected quality and efficiency and for the first time, the success of a POC concept was verified in a highly vulnerable setting of emergency medicine department, using a surrogate parameter potassium. Main finding of this study is that the analytical accuracy of the point of care devices at the Emergency Medicine Department, meets diagnostic quality and thus complies with the therapeutic demands. Moreover, the benefits of POC over routine laboratory investigations include low sample volumes, less invasive sample collection, and the absence of long transport periods and sample preparation procedures, especially in the emergency setting where time is of the essence.

In this study, 524 samples were considered and (K^+) measured using point of care device and central lab devices were analysed, correlation between both the parameters (POC-Hb & Hb-ZL) was highly significant (r = 0.536, p<0.001) & The results were showing excellent agreement between POC-K^+&K^+-ZL(ICC=0.536, 95% confidence interval = (0.47,0.59)). However, some significant measurement deviations did occur. When examining these deviations more closely, it was found that only in 19 patients (i.e. 4% of the data) the difference exceeded >1mEq/L. These findings demonstrate a good conformity between both measurement methods, which proves the validity of the implemented POCT concept.

However, when looking at gender wise correlation both in Males and Females showed

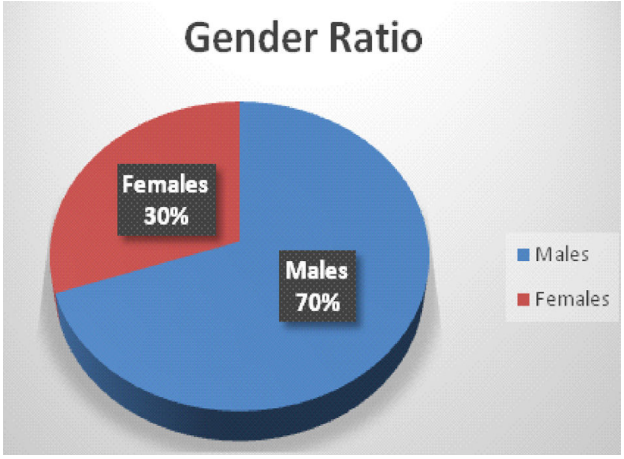

Fig. 1. Gender ratio of analysed patients.

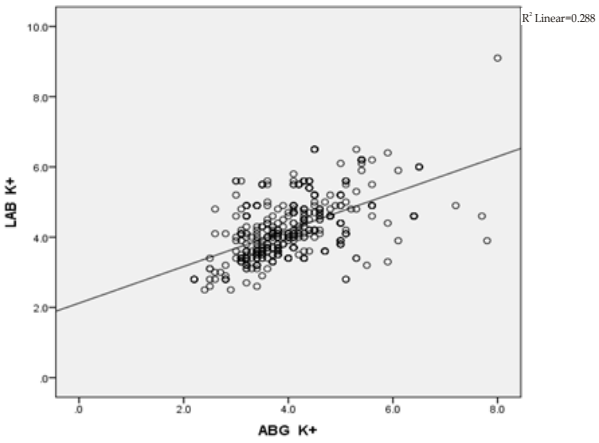

Fig. 2. Correlation between POC-K+ and K+-ZL values.

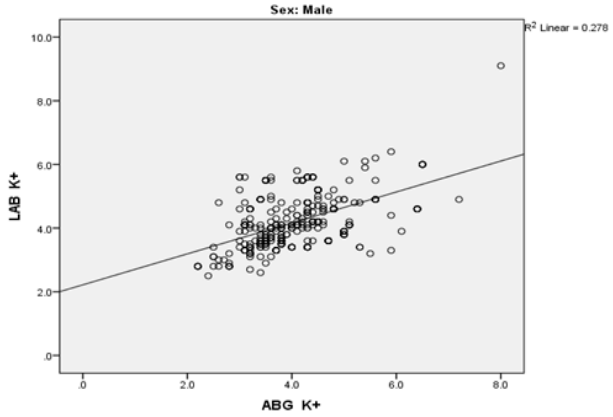

Fig. 3. Correlation between POC-K+ and K+-ZL values in males.

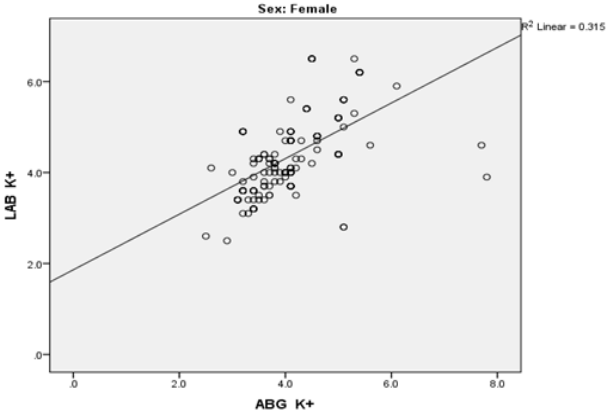

Fig. 4. Correlation between POC-K+ and K+-ZL values in females.

good correlation with (r=0.365, p<0.001)(Fig-3) and (r=0.159,p<0.001)(Fig-4) respectively . Intraclass correlation in males and females were also assessed and is found to have good agreement between (POC-K^+&K^+-ZL(ICC=0.526,95% confidence interval = (0.44,0.61)) and (ICC=0.559,95% confidence interval = (0.657,0.447)) respectively.

In some cases, we identified various interfering substances. However, in extreme situations, the enormous time pressure at the emergency centre may lead to pre-analytical errors, which are mainly due to comorbidities, difficulties with vein access and exsiccosis. The haematology analyser at the central laboratory analyses samples by overhead mixing to ensure sufficient and standardized mixing of the sample, whereas the POC analysis requires sufficient manual mixing of the ABG vial. Clearly, this is not always done correctly and long enough. For example, in some cases, clot formation or air bubbles in the vials resulted in incorrect measurement values. Despite the fact that the ABG device had flagged the Hb value, the error report was ignored by the users and the incorrect value were applied. Therefore, proper training of POC users is crucial to ensure that flagged values are recognized and incorrect measurement results are dismissed. As a consequence of the outlier evaluation, the areas of responsibilities of the POC coordinators now include follow-up training and on-site troubleshooting, which are now provided individually and when problems arise.

With increasing costs through diagnosis, a scientific confirmation of the benefits of POC in the decision making process in patient care has to be examined. Therefore, studies on the comparability of POC vs. laboratory results with an existing and lawful POC concept are particularly important.

In Amrita Institute of Medical Science, POC-(K^+) measurement is a standard procedure in patients with any suspected dyselectrolytemia, Chronic Kidney Disease, patients on Diuretics, arrythmias, cardiac arrest, sepsis, septic shock, metabolic acidosis etc.. . The K^+ value is used in the categorization of the priority level and can influence the next steps in the emergency treatment. The validity of the obtained measurement values has to be guaranteed. During implementation as well as continuous quality control of POC diagnosis in patient care, risks and benefits must be identified and minimized or maximized accordingly. In Amrita, all POC quality control measures are the responsibility of the medical director of the central laboratory and thus by law equivalent to the quality control measures at the central laboratory. If a POC device fails to pass the internal quality control, it is automatically disabled for the failed parameter and will only be released after successfully passing a follow-up control.

Conclusion

Our comparison of POC devices with central laboratory potassium determination in emergency patients at a tertiary care hospital showed a highly significant correlation between the two analysed potassium concentration measurement methods, using POC devices and the indirect ion selective electrode (ISE) method. This is an example of the successful implementation of point of care device in a highly vulnerable area like emergency medicine and critical care in Amrita Institute of Medical Sciences. Also, not only is continuous quality control of utmost importance both internally and externally, but also, a clear-cut area of well-defined training for the users. The study also holds good correlation between point of care potassium and

central lab potassium in sub collective gender wise analysis also.

***Key Message*:** This is an example of the successful implementation of point of care device in a highly vulnerable area like emergency medicine and critical care in Amrita Institute of Medical Sciences. Also, not only is continuous quality control of utmost importance both internally and externally, but also, a clear-cut area of well-defined training for the users

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