World Journal of
Chemical and Pharmaceutical Sciences

Journal homepage: https://zealjournals.com/wjcps/

ISSN: 2945-3186 (Online)

(RESEARCH ARTICLE)

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Internal quality control of Na+ and K+ at clinical biochemistry laboratory

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World Journal of Chemical and Pharmaceutical Sciences, 2022, 01(01), 034–041

Publication history: Received on 16 January 2022; revised on 19 March 2022; accepted on 22 March 2022

Article DOI: https://doi.org/10.53346/wjcps.2022.1.1.0026

Abstract

Background: the blood electrolyte analysis is a routine laboratory test, the proper execution of which would help in the diagnosis of hydro-electrolyte disorders. We undertook to assess the quality of the sodium and potassium from the pre-pre-analytical phase to the post-analytical phase.

Material and Methods: This was a cross-sectional study which took in the laboratory of biochemistry at the Institute of Cardiology, Abidjan, Ivory Coast from March 1st to March 31, 2009. We used the flame photometer to measure the sodium and potassium electrolytes level in the internal control Exatrol-Normal from Biolabo® and those of the clinical samples. The pre-pre-analytical quality indicators depending on the physician's order, the pre-analytical quality indicators and the post-analytical indicators under the control of the laboratory and based on the NF standard ISO 15189 version 2012 have been determined. Data were captured into Microsoft Access [Microsoft Corporation, Redmond, WA] and then imported and analyzed using QI Macros SPC Software for Excel®. The monthly dispersion parameters of the Exatrol Normal were used to establish the Levey-Jennings diagram and the Wesgard's rules were used for the interpretation.

Results: a total of 112 electrolytes analysis order were received. For the pre-pre-analytical phase, the analysis of these requests revealed that 81 (72.3%) requests carried no clinical information. The non-compliance of the samples were mainly represented by the sampling under tight tourniquet 4 (3.6%), followed by the non-respect of the succession tubes during multiple sampling 3 (2.7%). For the analytical phase, the monthly Levey-Jennings diagram showed a dispersion of the Exatrol-Normal® values between the mean plus or minus 2 standard deviations [m ± 2SD]: 139.34 ± 2.84 mmol/L for sodium (Na^+). For the potassium (K^+), the values of Exatrol-Normal® were between [m± SD]: 4.2±0.78 mmol/L. The interpretation of the two Levey-Jennings diagrams by Wesgard's rules did not found any statistically significant mistake with regard to the distribution of Na^+ and K^+ levels. For clinical samples, isolated hyponatremia was the most common disturbance (30.4%) followed by isolated hypokalemia (12.5%). At the post-analytical phase we observed a mean turnaround time of 34 minutes with extremes ranging from 23 to 95 minutes. One case (0.9%) of transcription error was noted.

Conclusion: the internal quality control process is applied in the clinical biochemistry laboratory at the Institute of Cardiology, Abidjan. A systematic verification system of the different phases of the analytical process makes it possible to identify errors at all levels of the analytical process and to take corrective action if necessary. Better collaboration between clinicians requesting electrolyte analysis and biologists performing the analysis is necessary to improve the pre-pre-analytical phase and, beyond that, better patient care.

Keywords: Analytical phase; Blood electrolyte; Internal Quality Control; Pre-analytical phase; Post-analytical phase

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1. Introduction

Sodium is the main extracellular cation and its balance is essential for several activities involved in maintaining the homeostasis of hydro-electrolyte functions [1]. Hyponatremia are electrolyte disorders that are defined as a plasma sodium concentration < 135 mmol/L and can be classified as moderate (130 to 134 mmol/L), intermediate (120 to 129 mmol/L) and severe (< 120 mmol/L) [2]. They occupy a place of choice especially in patients with cardiovascular diseases [3-4]. The pathophysiological mechanisms explaining the occurrence of hyponatremia and potentially life-threatening in these patients have been described. These mechanisms range from neuro-hormonal disorders involving arginine vasopressin (AVP) to iatrogenic hyponatremia induced by the use of diuretics [3, 5]. Several studies have demonstrated the existence of an association between hyponatremia, morbidity and intra-hospital mortality in patients with cardiovascular disease [6-8]. An accurate biological diagnosis is therefore essential for their adequate management. The quality assurance process for biological analysis results recommends the use of ISO 15189 standards [9]. These standards involve the use of internal quality control, statistical methods to minimize systematic and random errors and, if necessary, actions to be taken to correct them [10-11]. There are several types of internal quality control and statistical methods used for the analysis of their stabilities. These statistical methods are generally based on the analysis of the dispersion of the values of the internal control around the mean and use the mean values plus or minus two standard deviations (m±2SD) as the alert threshold and the values m± 3ET as alarm threshold. The analysis of the stability of these methods based on the standard deviations (sigma metric methods) is done according to multiple pre-established rules including those described by Wesgard JO [12-14] offer a good precision of the biological results when they are used appropriately. The objective of this work was to assess the internal quality of the electrolytes analysis from its request to the rendering of the result with an emphasis on the pre-analytical, analytical, post-analytical stages and the internal quality control based on the method metric sigma at the Institute of Cardiology, Abidjan.

2. Material and methods

2.1 Study design

This was a cross-sectional study which took in the laboratory of biochemistry at the Institute of Cardiology, Abidjan, Ivory Coast from March 1st to March 31, 2009. Approximately 4 ml of blood was taken in heparinized tube from each fasting patient at least 8 to 12 hours at the elbow crease. After sampling, the tubes were subject to computer processing with a view to assigning an identification number. Whole bloods were centrifuged at 3000 G per minute for 15 minutes. The plasmas obtained after this separation were transported to the technical room for the execution of the analysis. Exatrol Normal from Biolabo® was used as the internal quality control material. We used the flame photometer to measure sodium and potassium electrolyte levels in Exatrol Normal® and those of the clinical samples.

2.2 Principe of flame photometer

The principle of this photometer is based on the measurement of the radiation intensity emitted when the excited atoms pass from the energy level E_0 to the energy level E_1. Indeed, the atoms of the element to be assayed receive an external energy provided by the flame which makes it possible to produce an atomic vapor of the element. These element leave from the fundamental energy level E_0 to a higher energy level E_1. When these atoms return to the ground state, they emit radiation characteristic of the electrolyte to be assayed (589 nm for sodium, 767 nm for potassium and 671 for lithium). These emitted radiations will undergo a selection through a filter. The selected rays will be picked up by a photoelectric cell which will transform them into electric signal. The electrical signal is proportional to the level of the electrolyte initially present in the sample according to the following relationship: $E= E_1-E_0 = h.\gamma = h.c/\lambda$.. The flame photometer incorporates into the test portion an internal standard of known concentration which is a lithium salt (15 mmol/L) whose signal is measured separately and automatically subtracted from the other results. The concentration of this standard must be the same at the end of the assay. This makes it possible to control unpredictable fluctuations during the measurement, in particular the instability of the flame and the flow of fluids (working solution, standard, test sample.

2.3 Data collection analysis

Data were captured into Microsoft Access [Microsoft Corporation, Redmond, WA] and then imported and analyzed using QI Macros SPC Software for Excel®. Quantitative data normality were assessed by using Shapiro-Wilk test. Descriptive statistics including mean, frequency, and standard deviation (SD) were determined for all variables and expressed as mean ± SD for variables with normally distribution or median plus IQR for not normally distributed variables both for clinical data and for data from Exatrol-Normal Biolabo®. For categorical parameters, Chi-square or Fisher exact tests were used. The monthly dispersion parameters of the Exatrol Normal: mean (m) and SD were used to establish the

Levey-Jennings diagram and the Wesgard's rules were used for the interpretation. The statistical significance threshold was set at $p \leq 5\%$.

2.4 Ethical consideration

The study was approved by the laboratory director. Verbal informed consent was obtained from all subjects. In particular, subjects were informed of the anonymous nature of the study.

3. Results

A total of 112 electrolytes analysis order were received. For the pre-pre-analytical phase, the analysis of these requests revealed that 81 (72.3%) requests carried no clinical information. There were no non-conformities concerning the other items of the pre-pre-analytical phase (Table I). There was a difference between the different clinical services regarding the presence of clinical information on their analysis request forms, $p = 0.01$ (Table II). The pre-analytical phase non-compliance of the samples were mainly represented by the sampling under tight tourniquet 4 (3.6%), followed by the non-respect of the succession of tubes during multiple sampling 3 (2.7%). Collection errors in an inappropriate tube (coming from the clinical department) 2/112 (1.8%) and insufficient volume collection errors (coming from the clinical department) 1/112 (0. 9%) were the other non-compliance of the pre-analytical phase. The rest of the items from the pre-analytical phase were absent or their follow-up was not possible due to the non-availability of information (Table 1). For the analytical phase, the monthly Levey-Jennings diagram showed a dispersion of the Exatrol-Normal® values between the mean plus or minus 2 standard deviations [m ± 2SD]: 139.34 ± 2.84 mmol/L for sodium (Na^+) (Figure 1). For the potassium (K^+), the values of Exatrol-Normal® were between [m± SD]: 4.2 ± 0.78 mmol/L (Figure 2). The interpretation of the two Levey-Jennings diagrams by Wesgard's rules did not found any statistically significant mistake with regard to the distribution of Na^+ and K^+ levels. For clinical samples, the mean of plasma sodium was 137 ± 5.7 mmol/L with extremes ranging from 112 to 156 mmol/L. For potassium the mean was 4.0 ± 2.1 mmol/L with extremes ranging from 2.1 to > 7 mmol/L (Table III). The electrolyte analysis was normal in 52 patients (46.4%). Isolated hyponatremia was the most common disturbance (30.4%) followed by isolated hypokalemia (12.5%). Hyperkalemia was found in 2 patients (1.8%) while the mixed form hyponatremia plus hypokalemia was found in 9 patients (8.0%). Finally, hyponatremia and hyperkaliemia were present in one patient (0.9%) (Table IV). Concerning the post-analytical phase, we found one transcription error (0.9%). The loss of results and the interpretation errors were not observed during our study. At the post-analytical phase we observed a mean turnaround time of 34 minutes with extremes ranging from 23 to 95 minutes (Table V). One case (0.9%) of transcription error was noted (Table VI).

Table 1 Pre-analytical quality indicators of the study

Pre analytical quality indicators	**N**	**%**
Pre-pre-analytics depending on the department of clinical		
Request without clinical information	81	72,3
Inappropriate request according to the clinical information	NA	NA
Patient identification errors	0	0
Patient identification error detected before result	0	0
Patient identification error detected after result	0	0
Collection at an inappropriate time (postprandial, diuretics, NaCl infusion) Pre-analytical under laboratory control	NA	NA
Recording error concerning the identification of the prescribing physician	0	0
Unintelligible recording error regarding the request	0	0
Error registering less than request	0	0
Save error in addition to request	0	0
Misinterpretation of the request during recording	0	0
Sample taken under tight tourniquet	4	3,6
Error of succession of tubes during multiple sampling	3	2,7
Sample identification error during collection	0	0
Inappropriate sample collection error	0	0
Collection error in an inappropriate tube (from the clinical department)	2	1,8

Insufficient volume collection error (come from the clinical department)	1	0,9
Sample destroyed during transport (from clinical service to laboratory)	0	0
Sample transported in inappropriate time	NA	NA
Sample transported under inappropriate temperature condition	NA	NA
Sample in bad storage condition during the transport	NA	NA
Sample lost during the transport	0	0
Anticoagulant-sample ratio not respected	1	0,9
Hemolyzed sample	3	2,7
Clotted sample	0	0
Lipemic sample	2	1,8
Icteric sample	1	0,9

Table 2 Presence of clinical information on the departments analysis request forms

Analysis request departments	N	Presence of clinical information	Absence of clinical information
Emergency unit	16	2(12.5%)	14(87.5%)
Department of Medicine	11	2 (18.2%)	9 (81.8%)
Intensive care unit	10	4 (40.0%)	6 (60.0%)
Surgery	5	4 (80.0%)	1 (20.0%)
Outpatients	66	16 (24.2%)	50 (75.8%)
Cardio-pediatrics department	4	3 (75.0%)	1 (0.25%)
Total	112	31 (27.7%)	81 (72.3%)

Fisher exact test, $p = 0.01$.

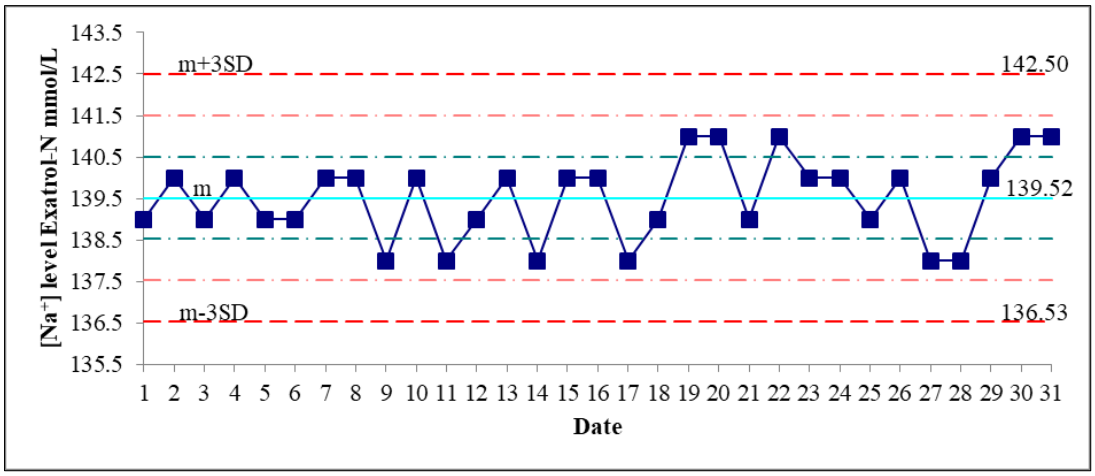

Figure 1 Levey-Jennings diagram of Exatrol-Normal Sodium. Flame photometer, Calibrator: SEAC® Control: EXATROL®-NORMAL

CL	n	31
139.516	Mean	139.5161
Stdev	Stdev	0.99569
0.996	Min	138
	Max	141
	%CV	0.713673

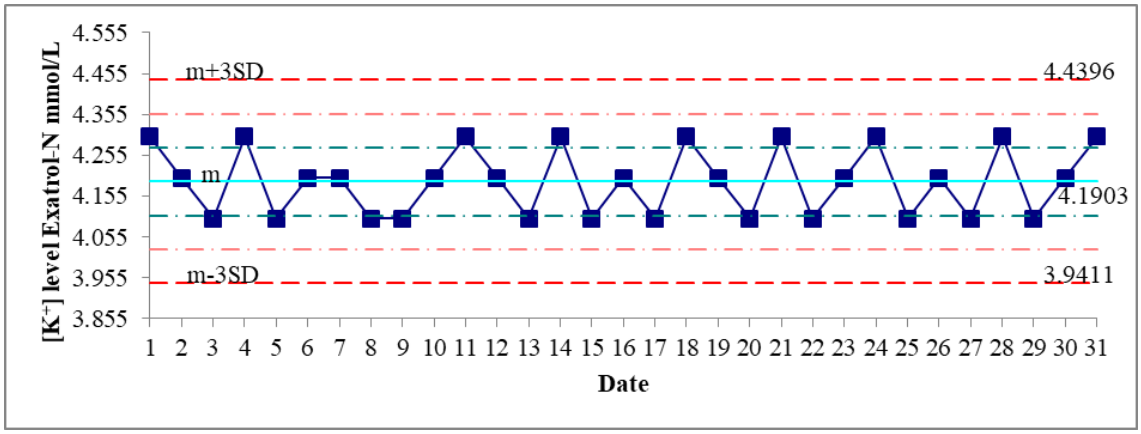

Figure 2 Levey-Jennings diagram of Exatrol-Normal Potassium (K^+). Flame photometer, Calibrator: SEAC® Control: EXATROL®-NORMAL

CL	n	31
4.190	Mean	4.190323
Stdev	Stdev	0.083086
0.083	Min	4.1
	Max	4.3
	%CV	1.982799

Table 3 Descriptive variables of electrolyte in the study population

Electrolytes	N	Minimum	Maximum	Mean	Standard deviation
Sodium (Na^+)	112	112	156	137,2	5,7
Potassium (K^+)	112	2,1	> 7	4,0	0,7

Table 4 Distribution according to electrolytes disturbances

Ionogramme	N	pour cent
normal	52	46.4
hyponatrémie	34	30.4
hypokaliémie	14	12.5
hyperkaliémie	2	1.8
hyponatrémie + hypokaliémie	9	8.0
hyponatrémie + hyperkaliémie	1	0.9
Total	112	100.0

Table 5 The average time between the arrival of the sample and the rendering of the result

Duration of laboratory requests	minimum	average	maximum
	23 mn	34 mn	95 mn

Table 6 Post-analytical quality indicators

Post-analytical quality indicators	N	Percentage (%)
Loss of result	0	0
Transcription errors	1	0.9
Misinterpretations	0	0

4. Discussion

We carried out a cross-sectional study to highlight the internal quality control of electrolyte in the biochemistry laboratory of the Institute of Cardiology of Abidjan (ICA). This study involved 112 requests for blood electrolyte determination between March 1st and March 31, 2009. The main objective of the study was to evaluate the internal quality control of the blood electrolytes. Flame photometry was used for the determination of sodium and potassium levels in control serum (Exatrol-Normal) and plasma of patients. The sex ratio was 1.5. We observed the absence of indication of sex on 3 reports (2.7%). With regard to age, we observed its absence on 5 requests for electrolytes analysis (4.5%). The mean age was 46.48 ± 21 years with the extremes ranging from 1 to 90 years. The age groups of 51-60 and < 30 years were the most represented with respectively 28.6% and 20.5%. Damorou F et *al*., reported a sex ratio of 1.9 and an average age of 56.9 ±13 years with extremes ranging from 20 to 97 years [15].

Arterial hypertension was the most observed information about 11 requests of electrolytes. analysis (9.8%), followed by preoperative and postoperative assessment 3 requests of electrolytes. analysis each accounting for (2.7%). We observed the absence of information on 81 requests of electrolytes. analysis (72.3%) making it difficult to safely manage the biological results. This pattern was difference between requesting clinical departments *p-value* = 0.01. Our result was in line with Alphonsine K.M et *al*., who reported 74.7% of overall non-compliance of analysis requested at the Institute Pasteur of Abidjan, Ivory Coast with a difference between the requesting departments [16]. We used EXATROL-Normal from Biolabo® as the material for internal quality control. The Levey-Jennings diagram and the Wesgard's rules were used to assess the results of internal quality control. According to Levey-Jennings, the control values must oscillate around an average and be at most between m± 2 SD to allow validation of the control series and subsequently of the clinical results of patient. Wesgard JO et *al*., [12-14] add that if control run results are between m ± 2SD and m ± 3SD, then the run results should be interpreted based on previous results. In 1981, Dr. James O Westgard published the standard guideline for interpreting Levey-Jennings diagrams. Wesgard's rules respond to a specific grammatical and numerical notation like A_L where A is the number of measures taken into account and L the limit used. For instance, the rule 1_{2s} corresponds to one value of measure beyond m ± 2SD and this is an alert but does not require the rejection of the series. On the other hand, the rule 1_{3s} means that one measure is beyond m ± 3SD and the series must be rejected. The rule 2_{2s} means that 2 consecutive measures exceed m ± 2SD on the same side and the series must be rejected. The rule R_{4s} violation comes when 2 measurements of the control exceed 2SD on either side of the mean and is also a rejection motif of the clinical series. The rule 4_{1s} violation means that 4 consecutive control values exceed the 1SD limit. The rules 10_x: Violation when 10 consecutive values are on the same side of the mean. In practice, if the results are between m ± 2SD, the series can be validated and the patient results are validated. If the results deviate from m ± 3SD, the series is not validated the patient results of the series are not validated. Analyze the type of errors and consider corrective action if necessary. If the results are between m ± 2SD and m ± 3SD, the rules defined by Wesgrad are used to interpret based on the previous results [17].

In our study, the sodium IQC series results were all within m ± 2 SD (139.34 ± 2.84 mmol/L) and we did not observe no violations of Wesgard's rules such as (1_s, 2_{2s}, 1_{3s}, R_{4s}, 1_{4s} and 10_x). About potassium, the results of the IQC series were all between m ± SD (4.2 ± 0.78 mmol/L), also no violations of Wesgard's rules were observed. The sodium and potassium means of the control serum used are comparable to the target values indicated by the manufacturer Biolabo® [18]. These results consolidate the technical validation of electrolytes analysis according to Levey-Jennings diagram and the rules defined by Westgard [13]. According to certain authors, rule out the IQC over at least 20 days is mandatory [19-20], however in our study the control was carried out throughout the month of March which confers a broad coverage of the month.

Natremia in patients fluctuated between 112 to 146 mmol/L with an average value of 137.2 mmol/L. Serum potassium ranged from 2.1 to > 7 with an average of 4.0 mmol/L. These means are all within the reference limits obtained by Yapo et *al*., [20] in presumed healthy Ivorians. This observation could be explained by the high rate of normal results of the

electrolytes analytes 52/112 requests of analysis (46.4%) and the very narrow distribution of electrolytes results materialized by restricted standard deviations.

Isolated hyponatremia was observed in 34/112 patients (30.4%). Hyponatremia was also reported by Claiton J.A et *al*., in patients followed in the department of cardiology. However, the rate of hyponatremia in our study was significantly higher than that of Claiton J.A et *al*., who obtained (13.7%) [21]. Isolated hypokalaemia was found in 14/112 patients (12.5%). This result is different from that obtained by Claiton J.A et *al*., who reported 8.5% of isolated hypokalemia [21]. We did not find any significant association between age, gender, clinical information and electrolytes disturbances. On the other hand, a significant association was observed between the requesting service and the disturbance of electrolytes $p = 0.02$. These results are different from those obtained by Claiton J.A et *al*., who found that age correlated significantly with serum potassium and that there was a significant association between these two variables. We observed 2/112 cases of hyperkaliemia (1.8%), 9/112 cases of hyponatremia + hypokalaemia (8%) and 1/112 case of hyponatremia + hyperkaliemia (0.9%). In our series, only 31/112 requests of analysis carried clinical information (27.7%). We found among the 11 hypertensive patients 2 cases of hypokalaemia + hyponatremia and 1 case of hypokalaemia + normal natremia. It was difficult to interpret these results given the lack of the clinical information on the requests of analysis. However, one could consider the use of antihypertensive treatment or any other treatment that would induce natriuresis and potassium leakage [22].

Given the importance of electrolytes analysis it is a frequently requested laboratory test in the department of cardiology and intensive care units because of the role that electrolytes play in cardiac activity and in water and electrolyte homeostasis in the body. Its good technical execution is therefore essential for better patient care. At the time of our study, the use of flame photometry for electrolytes analysis was still topical. Nowadays, this device has been abandoned in all laboratories in favor of device which uses the principle of indirect and direct potentiometer [23]. This last technique represents the advantage of being insensitive to pseudo hyponatremia induced by hyperlipidemia and hyperproteinemia. In addition, they use less bulky equipment devoid of the dangerous environment created by butane gas and the flame and in the end they are easily automated [24-25].

5. Conclusion

Electrolytes analysis is a frequently laboratory test in cardiology and intensive care units because of the role that ions play in cardiac activity and electrolyte balance. The internal quality control allowed the technical validation of the method used (flame photometry) and the validation of the patient samples. A systematic verification of the different of analytical phases process makes it possible to identify errors at all stage of the analytical process and to take corrective action if necessary. Better collaboration between clinicians requesting electrolyte analysis and biologists performing the analysis is necessary to improve the pre-pre-analytical phase and, beyond that, better patient care.

Compliance with ethical standards

Acknowledgments

We are grateful to all study subjects for participating in this study; the staff of the Institute of Cardiology, Abidjan, Ivory Coast, Faculty of Pharmaceutical and Biological Sciences, the department of biochemistry for their assistance.

Disclosure of conflict of interest

Authors certify that there is no actual or potential conflict of interest in relation to this article.

Statement of informed consent

Each participant gave fully verbal informed consent prior to enrollment. The protocol was reviewed and approved by the laboratory director.

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