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Re-Run of Panic-Valued Tests. Is it Really Necessary or is it A Waste of Time?

Panik Değerli Testlerin Yeniden Çalışılması. Gerçekten Gerekli mi Yoksa Zaman Kaybı mı?

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ABSTRACT

Aim: Panic value refers to a laboratory test result that is life-threatening and requires immediate corrective action by the physician. Although there is no recommendation to re-run the panic-valued test, some laboratory specialists report the result after repeating the test. However, this procedure leads to a certain loss of time and delays the treatment. In this study, it was aimed to determine whether the difference between the results of repeated panic values was significant and the delay due to repeat testing.

Material and Methods: In our laboratory, 1326 panic values repeated for amylase, glucose, calcium, creatinine, potassium, and sodium during 6 months were analyzed retrospectively. A 95% confidence interval was calculated according to the formula: "Bias% + Z x standard error of the mean" for each panic value. The results were compared with the total allowable error of the tests.

Results: Only the 95% confidence interval value of sodium was found to be above the total allowable error limits. The mean elapsed time between test repetitions was the minimum for sodium (34 minutes) and the maximum for creatinine (67 minutes).

Conclusion: As our findings showed that rerunning tests gave similar results and delayed notifying the physician about the panic value, we conclude that repeating critical values is unnecessary. It also causes waste of reagents and loss of labor, increasing laboratory costs.

Key Words: Panic, Confidence Interval, Patient Safety

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ÖZET

Amaç: Panik değeri, yaşamı tehdit eden ve hekimin acil düzeltici müdahalesini gerektiren bir laboratuvar test sonucunu ifade eder. Panik değerli testin tekrarlanması tavsiye edilmese de bazı laboratuvar uzmanları testi tekrarladıktan sonra sonucu bildirir. Ancak bu işlem belirli bir zaman kaybına yol açmakta ve tedaviyi geciktirmektedir. Bu çalışmada tekrarlanan panik değerlerin sonuçları arasındaki farkın anlamlı olup olmadığının hesaplanması ve tekrar testine bağlı gecikmenin belirlenmesi amaçlanmıştır.

Materyal ve Metod: Laboratuvarımızda 6 ay boyunca amilaz, glukoz, kalsiyum, kreatinin, potasyum ve sodyum için tekrar edilen 1326 panik değer retrospektif olarak değerlendirildi. Her bir panik değerin %95 güven aralığı "%Bias + Z x ortalamanın standart hatası" formülü ile hesaplandı. Sonuçlar, testlerin izin verilen toplam hatası ile karşılaştırıldı.

Bulgular: Sadece sodyumun %95 güven aralığı değeri, izin verilen toplam hata sınırının üzerindeydi. Test tekrarlarının arasındaki ortalama süre, sodyum için en kısa (34 dakika) ve kreatinin için en uzun (67 dakika) olarak belirlendi.

Sonuç: Çalışmamızda, benzer sonuçlar verdiği ve hekime panik değerin bildirilmesini geciktirdiği için kritik değer tekrarının gerekli olmadığı bulundu. Ayrıca reaktif sarfiyatı ve işgücü kaybı nedeniyle laboratuvar maliyetlerinin yükselmesine neden olduğu düşünüldü.

Anahtar Kelimeler: Panik, Güven Aralığı, Hasta Güvenliği

INTRODUCTION

The term "panic value" was first proposed in 1972 by George D. Lundberg. Lundberg (1) suggested that critical test results (panic values) that could endanger life if not acted upon promptly should be reported to the physician without delay. Timely reporting of critical results is essential for administering the necessary treatment as soon as possible, so the reporting of these results is a major concern for laboratories worldwide (2,3). For this reason, laboratory accreditation institutions have established requirements for reporting critical values, but there is no recommendation regarding re-running tests with panic values (4). While some laboratory specialists report the result to the physician immediately, others verify it by re-running the test (5). However, given the technical advances and developments in laboratory measurements, the necessity of re-running panic values has been challenged in recent years (6). A Q-Probes study by the College of American Pathologists (CAP) revealed that 61% of laboratories routinely repeated tests for panic values, causing a 10 to 14-minute delay in reporting. This period might differ across laboratories and postpone the patient's treatment. Therefore, the necessity of test repetition is questionable (7,8).

Total allowable error (TEa) is a quantitative value that combines random error and systematic error. The TEa is determined by the clinical significance of the analyte and its biological variability. Laboratories assess whether their analytical errors are acceptable by comparing them with TEa. If the observed errors are lower than the allowed error, the method demonstrates an acceptable performance.

The 95% confidence interval (CI) of means describes the range of values in which the result can be found with a 95% probability if you repeat your test. Confidence intervals are affected by the variability in results and sample size.

In our study, we aimed to determine whether the difference between the results of repeated panic values and the delay due to repetition was significant in our laboratory.

MATERIALS AND METHODS

Six tests (amylase, glucose, calcium, creatinine, potassium, and sodium) with panic values were selected for our study

between January 1 and June 30, 2022. They were analyzed in the Cobas 8000 Modular Analyzer System (Roche Diagnostics®, Mannheim, Germany) from serum samples obtained after centrifuging blood collected in vacuum tubes (Vacusera®, Izmir, Turkey) containing a separating gel and clot activator. The samples with the panic values were retested on the same device by laboratory experts.

The thresholds for panic values used in our laboratory were as follows: amylase, >1000 U/L; glucose, <50 mg/dL and >400 mg/dL; calcium, <6.5 mg/dL and >13 mg/dL; creatinine, >10 mg/dL; potassium, with <2.5 mmol/L and >6 mmol/L; sodium, with <120 mmol/L and >160 mmol/L (Table 1). Subgroups were created based on the threshold values determined by their suggestions from mutual interviews with the physicians of our hospital.

Laboratories compare their analytical error to TEa to determine whether it is acceptable. If the observed errors are lower than the allowed error, the method performs acceptably.

The 95% CI of the means is the range of values where the result would be found with a 95% probability if you repeated your test. Confidence intervals depend on the variability and sample size of the results. Therefore, we excluded tests with an insufficient number of immediate parameters from our study.

The absolute value of the difference between the two measurements of each sample was divided by the mean value of the group to get the bias. The mean of the percentage biases was calculated and the mean bias% was obtained. Then, the 95% CI of the mean bias for each test group was calculated. We used the following formula recommended by Westgard et al. (10) to calculate 95% CI for our data: 95% CI = $\bar{5}$ + Z × 5/√n.

Here, we used the Z value from the Z score table that corresponds to a 95% confidence level for a two-tailed test, which equals 1.96. The value represents the mean of Bias% (95% CI = Bias% + 1. 96 × SeM). The standard error of the mean (SeM) is calculated by dividing the standard deviation (s) by the square root of the sample size (n). Then, the 95% CI value was compared with the TEa limits. If the CI value exceeds TEa, it is concluded that there is a significant difference between test repetitions. The 95% CI and TEa values for our analytes are shown in Table 2.

The time between the first and repeat tests of each sample was noted. The obtained data were separated by tests and arranged according to shifts. Shifts were grouped under two main categories: morning and afternoon shifts (8 am – 4 pm) and night shifts (4 pm – 8 am) (Table 3).

Our study was conducted retrospectively with the approval of the Health Sciences University Izmir Bozyaka Education and Research Hospital Clinical Research Ethics Committee (No:2022/82, Date:11/05/2022).

RESULTS

Of the 1326 panic values that were repeated, 95% CI values calculated for amylase, glucose, calcium, creatinine, and potassium tests were below TEa. However, the 95% CI value for sodium was above the TEa limit (Table 2).

The mean time between test repetitions was minimum for sodium (34 minutes) and maximum for creatinine (67 minutes). It was also observed that the repetitions done on night shift took less time (Table 3).

Table 1. Panic Value Limits in Our Laboratory

Analyte (unit)	Panic Value
Amylase (U/L)	> 1000
Calcium (mg/dL)	< 6.5 or > 13
Creatinine (mg/dL)	> 10
Glucose (mg/dL)	< 50 or > 400
Potassium (mmol/L)	< 2.5 or > 6
Sodium (mmol/L)	< 120 or > 160

Table 2. 95% Confidence Interval Values of Panic Value Tests and Total Allowable Error Limits

Analyte	Group/ Subgroup	n	Mean Difference (%)	SeM* (%)	The Upper Limits of 95% CI**	Tea# (%)
Amylase (U/L)	All	33	2.34	0.45	3.22	14.6
Calcium (mmol/L)	All	163	2.23	0.19	2.61	6.1
	<6.5	147	2.21	0.19	2.59	6.1
	>13	16	2.42	0.84	4.07	6.1
Creatinine (mg//dL)	All	50	4.43	0.66	5.73	8.87
Glucose (mg/dL)	All	565	2.68	0.12	2.91	6.96
	<50	128	3.3	0.34	3.97	6.96
	>400	437	2.5	0.12	2.73	6.96
Potassium (mmol/L)	All	416	1.25	0.08	1.40	5.61
	<2.5	68	2.26	0.27	2.80	5.61
	>6	348	1.05	0.07	1.18	5.61
Sodium (mmol/L)	All	85	0.61	0.07	0.75	0.73
	<120	55	0.63	0.34	0.83	0.73
	>160	30	0.57	0.18	0.74	0.73

*Standard Error of the Mean
**Confidence Interval
#Total Allowable Error

Table 3. Observed Delay Distribution for Repetition Tests (in Minutes)

Tested Analyte (unit)	Morning and Afternoon Shift*	Night Shift**	Total Delay
Amylase (U/L)	45	30	42
Calcium (mg/dL)	64	38	55
Creatinine (mg/dL)	70	49	67
Glucose (mg/dL)	52	34	51
Potassium (mmol/L)	55	38	53
Sodium (mmol/L)	36	28	34
All	52	36	50

*8 am to 4 pm
**4 pm to 8 am

DISCUSSION

Timely and accurate reporting of test results is a vital component of good laboratory practice. Clinical laboratories are required to inform the physician immediately about any critical value (7). However, some laboratories re-run the test instead of delivering a critical value directly to the physician without wasting time (10–12). There is no literature evidence supporting the necessity and benefit of this repetition. In the past, a critical value was repeated to make sure of the result. However, developing technology has improved the analytical performance of devices and made test repetitions largely unnecessary (4,5).

In our study, out of the 1326 panic value results, only 95% CI of sodium analyte was above TEa (Table 2). The TEa limit set by Clinical Laboratory Improvement

Amendments (CLIA) for sodium is 0.73% (13). This TEa value corresponds to a difference of 1.168 mmol/L from a sodium result of 160 mmol/L. In our study, the 95% CI value was 0.74% which corresponds to a difference of 1.184 mmol/L in a result of 160 mmol/L. Although the difference between them is only 0.016 mmol/L, the result is still a panic value and is within the range of hypernatremia. The patient will be treated for hypernatremia in both results. Given these small differences, the TEa limit of sodium should be reconsidered. Although analytical performances have improved, it is thought that many laboratories will not be able to meet this goal.

In our study, we found that the 95% CI values of all our tests except sodium were lower than the TEa values. The improvements in the analytical performance of the devices have a big role in achieving these results. Moreover, we followed strict internal and external quality control procedures and performed regular device maintenance to ensure the reliability of our test results.

The mean delay due to repetition varied from 34 minutes (sodium) to 67 minutes (creatinine). These delays were similar to those reported by Onyenekwu et al. (7), but much longer than the 10–14 minute delay experienced by most of the participants in the Q-Probes study. They were also longer than the 15-minute delay reported by Deetz et al. (5). One of the reasons for this difference is that an additional device is reserved for the repetition of panic-valued samples. The second reason is the time interval in which the sample arrives at the laboratory. As can be seen in Table III, the mean delay in morning and afternoon shifts is higher in all subgroups. Blood from both outpatient clinics and inpatient wards causes overload on the devices. This delays the re-run of the tests. Another reason is the use of a modular system in our laboratory. Sodium and potassium tests are measured in about 2 minutes and the results are sent to the system. However, when the modular system is used, the test cannot be repeated without measuring all the other tests requested for the patient. Otherwise, all the tests that do not have a result are re-run automatically by the analyzer. This causes wasting of reagents and labor. For this reason, we suggest that such factors should be considered when configuring laboratory devices.

In the presentations made to the specialist doctors working in our laboratory, it was explained that the re-run of critical values did not make a difference between the initial and repeated test results. But despite all the objective evidence in our study, they tended to continue repeating tests because they were afraid of giving inaccurate results. However, the analytical systems used today send all the information and the warnings (data flags) about the reaction indicating the need for a re-run to the Laboratory Information System. Therefore, we think that it is unnecessary to repeat a test without any warning. The laboratory staff should be informed about this situation.

The limitation of our study is that we could not assess the impact of delays caused by re-running on patient safety objectively. The reason for this is that we examined the panic-valued results retrospectively in our study.

Our findings show that repeating tests, except for sodium analyte, yield similar results but delay the notification of the critical value to the physician. It also leads to waste of reagents and loss of labor, increasing laboratory costs. We consider that our study will guide the practices of whether to repeat critical results in different laboratories and facilitate standardization in this regard.

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Conflict of interest

None

REFERENCES

1. Lundberg GD. When to panic over abnormal values. MLO Med Lab Obs. 1972;4:47–54.
2. Fei Y, Zhao H, Wang W, et al. National survey on current situation of critical value reporting in 973 laboratories in China. Biochem Med. 2017;27:546–55.
3. Dighe AS, Rao A, Coakley AB, et al. Analysis of laboratory critical value reporting at a large academic medical center. Am J Clin Pathol. 2006;125:758–64.
4. Niu A, Yan X, Wang L, et al. Utility and necessity of repeat testing of critical values in the clinical chemistry laboratory. PLoS One. 2013;8. Article ID e80663
5. Deetz CO, Nolan DK, Scott MG. An examination of the usefulness of repeat testing practices in a large hospital clinical chemistry laboratory. Am J Clin Pathol. 2012;137:20–5.
6. Saffar H, Abdollahi A, Hosseini AS, et al. Necessity of Routine Repeat Testing of Critical Values in Various Working Shifts. Iran J Pathol. 2020;15:161–166.
7. Onyenekwu CP, Hudson CL, Zemlin AE, et al. The impact of repeat-testing of common chemistry analytes at critical concentrations. Clin Chem Lab Med. 2014;52:1739–45.
8. Paxton A. Critical value repeats: redundancy, necessity? CAP Today. 2010;24:1.
9. Westgard JO, Carey RN, Wold S. Criteria for judging precision and accuracy in method development and evaluation. Clin Chem. 1974;20:825–33.
10. Mountford J, Marshall M. Criteria for judging precision and accuracy in method development and evaluation.. BMJ Qual Saf. 2014;23:89–91.
11. Zeng R, Wang W, Wang Z. National survey on critical values notification of 599 institutions in China. Clin Chem Lab Med. 2013;51:2099–107.
12. Toll AD, Liu JM, Gulati G, et al. Does routine repeat testing of critical values offer any advantage over single testing? Arch Pathol Lab Med. 2011;135:440–4.
13. Westgard JO. CLIA requirements/tables on CLIA proficiency testing criteria for acceptable analytical performance. Available from: https://www.westgard.com/clia.htm. Accessed on March 1st 2023.