Trakia Journal of Sciences, Vol. 4, No. 2, pp 18-22, 2006

Available online at:
http://www.uni-sz.bg

ISSN 1312-1723

Original Contribution

MEASUREMENT OF C- REACTIVE PROTEIN BY TWO CLINICAL CHEMISRTY ANALYZERS

P. Yordanova-Laleva, A. Ruseva, V. Petkova, I. Gencheva, J. Pastuhov, Vl. Ivanov

Clinical Laboratory, University Hospital "G. Stranski", Pleven, Bulgaria

ABSTRACT

Clinical laboratory of the University Hospital, Pleven has the capacity to perform C-reactive protein (CRP) assay with high sensitivity tests by two biochemical analyzers closed type: Pentra 400 (Horiba ABX) and Cobas Integra 400 (Roche). This study is fulfilled to compare CRP- results obtained from the both analyzers with respect to investigate the possibility for interchangeability of these instruments. Both analyzers are based on the same method for determination of C-reactive protein - latex immunoturbidimetric. The analytical variation at different intervals of the referent range and outside is assayed**.** High correlation (r > 0.9) between CRP values, obtained from the both analyzers has been shown for all investigated groups. However, a statistical significant difference in the mean values was established between the results from both instruments for some concentration groups. Analysis of the results obtained demonstrates that when CRP was used as a prognostic parameter despite, the high correlation between the results obtained from both analyzers, repeated measurements of CRP of a definite patient had to be made by one and the same analyzer.

Key words: CRP test, CRP assay with high sensitivity

INTRODUCTION

Recent evidence has shown that inflammation plays a leading role in the inception and progression of atherosclerosis. In a number of studies has been concluded a strong and independent association between baseline concentrations of inflammatory biomarkers and future coronary events. In fact, the majority of individuals with coronary events are not in a high-risk group according to the Framingham risk assessment of traditional risk factors for coronary heart disease; half of those who suffer myocardial infarctions have normal lipid values. In view of that, measurement of inflammatory markers has been suggested as an addition to lipid testing to a better identification individuals at increased risk. According the evaluation of American Heart Association, only CRP met the analytical requirements for outpatient clinical use (1). More than 25 prospective epidemiological studies have shown that CRP is a strong and independent predictor of future myocardial infarction ischemic stroke, peripheral arterial disease, and sudden cardiac death in apparently healthy men and women. Physicians have become accustomed to use the terminology "high sensitivity CRP" when considering measurement of CRP for vascular disease risk stratification (2). Concentrations less then 1.0 mg/l are considered as low risk, 1.0 – 3.0 mg/l – as average risk, and higher than 3.0 mg/l – as high-risk groups (3).

The goal of this study is to compare CRP-results obtained from two biochemical analysers closed type: Pentra 400 (Horiba ABX) and Cobas Integra 400 (Roche) and to check the possibility for interchangeability of the two instruments.

MATERIALS AND METHODS:

The principle of the method of CRP-assays by both analyzers – Pentra 400 and Cobas Integra 400, is identical: lateximmunoturbidimetric. Both analysers use 5-point calibration curve, have identical linearity range: 160 mg/l and reference range: < 5 mg/l. The two different reagents use different anti-CRP antibodies: rabbit and mouse respectively (4, 5)

For determination of CRP either by Pentra 400 or Cobas Integra 400 we have performed parallel tests of 105 sera. All necessary reagents, calibrators and controls were

provided by the producer companies. CRP results were grouped into five ranges, based on CRP values obtained: 0- 1.0 mg/l ; 1.0- 3.0 mg/l; 3.0 – 5.0 mg/l ; 5.0 – 10.0 mg/l and above 10 mg/l. The analysis was performed with patients hospitalized in the University Hospital, Pleven. The venous blood was drowning fasting in serum blood collection tubes.

The statistical analysis of results was carried out by SPSS v.13 computer program. Paired sample test was used for correlation and comparison of the average values.

RESULTS AND DISSCUSSION:

For each of the five groups we compared the correlation of CRP values obtained by the two analyzers. Results are presented on **Table 1**. A high level of correlation for all concentration ranges was observed.

Table 1: *Correlation coefficients for CRP results obtained by both analyzers*

Level CRP mg/l Pentra/Integra		N	Correlation
1	0 - 1	21	r= 0.878
2	1 - 3	21	r= 0.975
3	3 - 5	21	r= 0.930
4	5 - 10	21	r= 0.972
5	> 10	21	r= 0.993

The distribution of the frequency of CRP values up to 1.0 mg/l is shown on **Figure 1** and **Figure 2**.

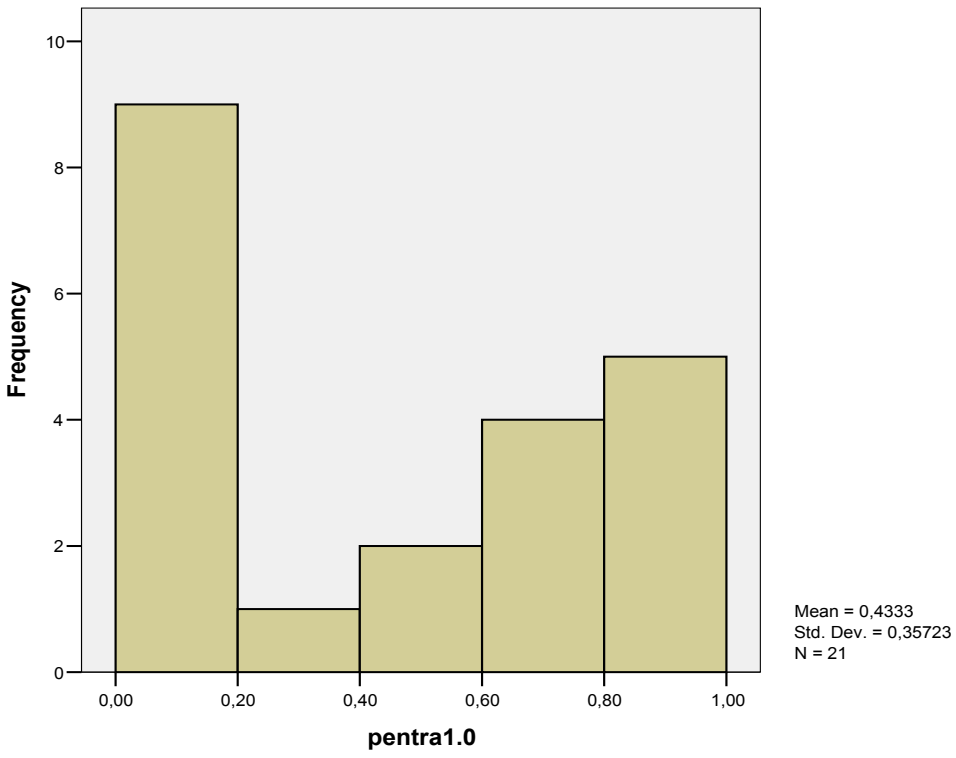

Figure 1. *Distribution of CRP values in the range up to 1.0 mg/l obtained on Pentra 400*

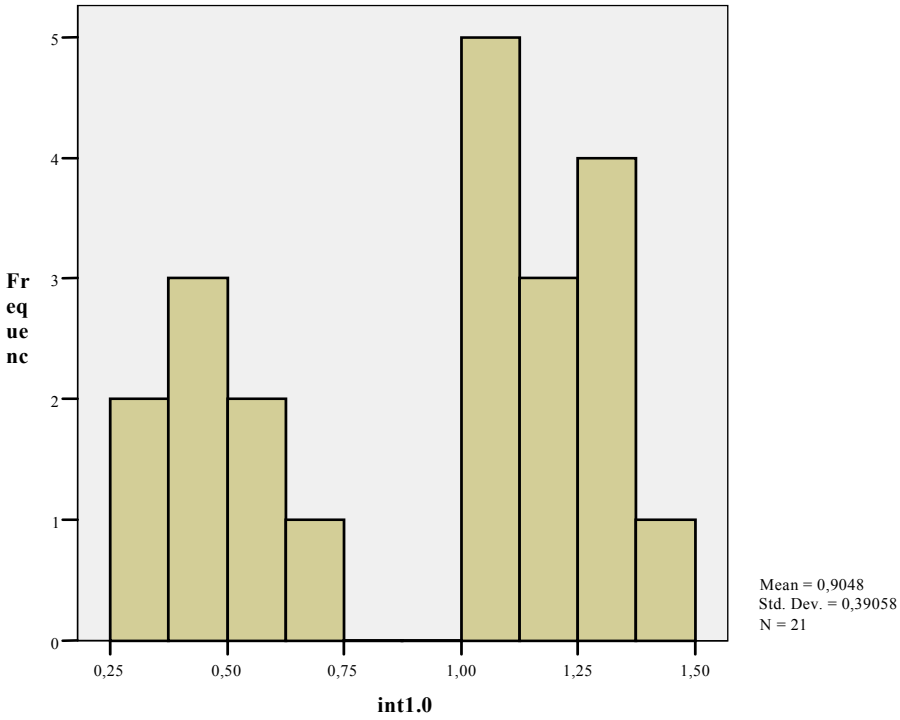

Figure 2: *Distribution of CRP values in the range up to 1.0 mg/l obtained on Cobas Integra 400*

As is evident from **Figure1** and **Figure 2**, although, the high correlation, there are some differences in the distribution of the results obtained by the two analyzers: the results from Pentra 400 are up to 1.0 mg/l and from Cobas Intega go up to 1.5 mg/l.

The same distribution was found for CRP values in the range 1.0 - 3.0 mg/l: those obtained by Cobas Integra were higher that those obtained by Pentra 400. (**Figure 3** and **Figure 4**)

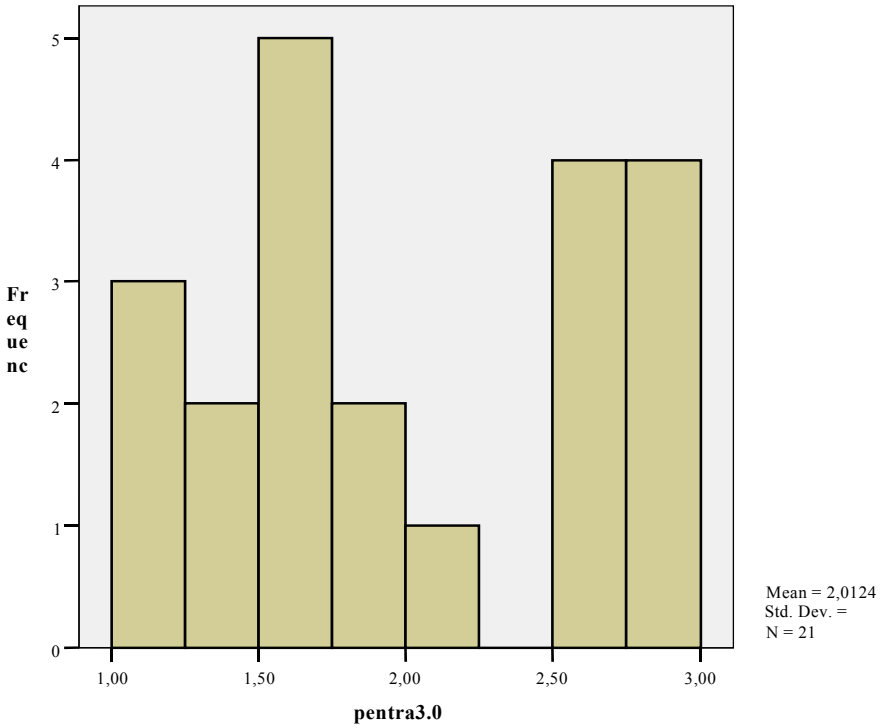

Figure 3: *Distribution of CRP values in the range 1.0 – 3.0 mg/l obtained by Pentra 400.*

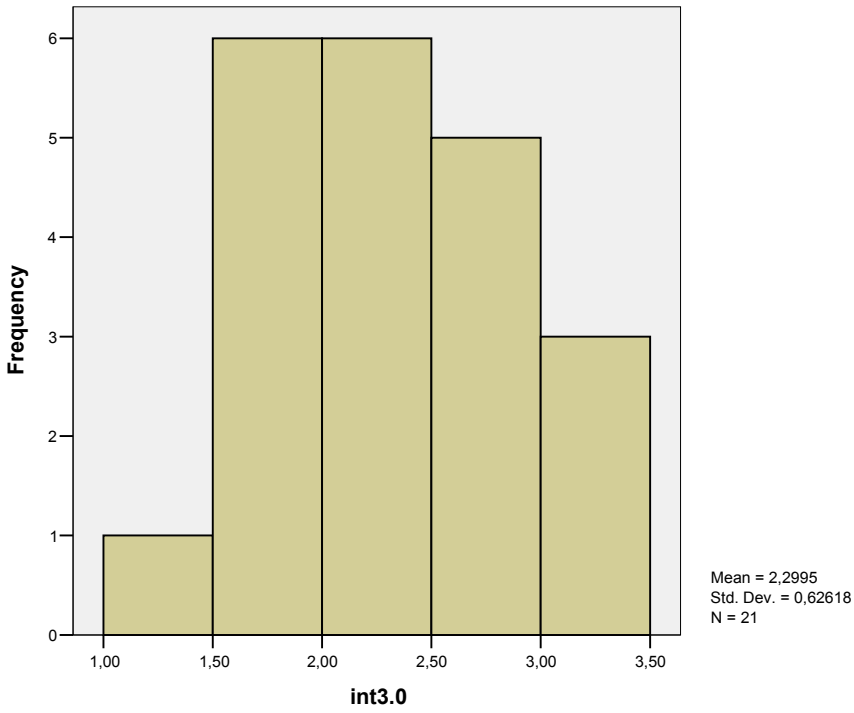

***Figure 4**: Distribution of CRP values in the range 1.0 - 3.0 mg/l obtained by Cobas Integra.*

When the mean CRP values obtained for the two groups were compared, a statistical significant difference ($p < 0.001$) was found (see **Figure1** and **Figure 2**).

Results in the range 3.00 – 5.00 mg/l are presented on **Figure 5** and **Figure 6.** As is seen for this range 5.00 mg/l were the highest values measured by Pentra 400, while these values were 4.50 mg/l measured by Cobas Integra. In spite of lower values measured by Cobas Integra, there was no statistical significant difference when the mean CRP values were compared.

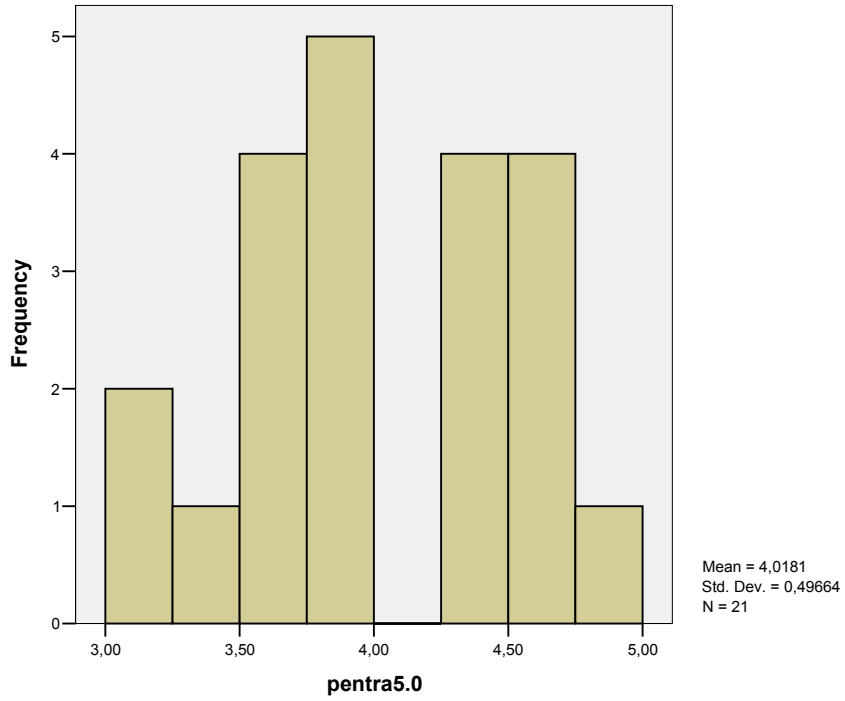

***Figure 5:** Distribution of CRP values in the range 3.0 – 5.0 mg/l obtained by Pentra 400.*

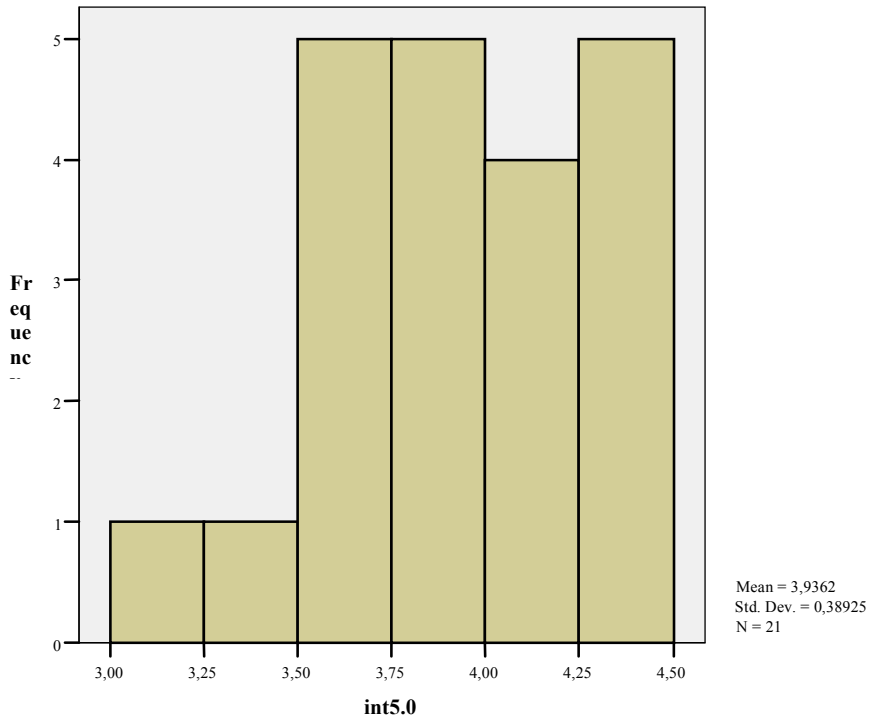

Figure 6: *Distribution of CRP values in the range 3.0- 5.0mg/l obtained by Cobas Integra 400*

Determination of CRP, and more precisely hs CRP, necessitates high accuracy and precision of the results, which would ensure more reliable evaluation of a cardio-vascular risk.

Based on the current findings, we can make the following conclusions:

- There is a high correlation in all concentration ranges for the CRP results obtained by the two chemistry analyzers.
- CRP results up to 3.0 mg/l obtained by Cobas Integra are higher than those, obtained by Pentra 400. The differences are statistically significant.
- When CRP would be used as a prognostic parameter despite, the high correlation between the results obtained from both analyzers, repeated measurements of CRP of a

definite patient had to be made by one and the same analyzer.

REFERENCES

1. Rifai, N., Ch. Ballantyne, M. Cushman et al Point : High-Sensitivity C- reactive Protein and Cardiac C- Reactive Protein Assays: Is There a Need to Differentiate? *Clin.Chem*.2006; 52:1254 – 1256
2. *Guidelines for CRP Testing Lab Medicine* 2005, 17.04, 1-2
3. Pearson T. A, G. Mensal, R. W. Alexander et all. Markers of Inflammation and Cardio-vascular Disease: Application to Clinical and Public Health Practice: A Statement for Healthcare Professionals From the Centers for Disease Control and Prevention and the American Heart Association Circulation, Jan 2003; 107: 499 – 511
4. *ABX Pentra reagent Guide*
5. Cobas Integra 400 Method Manual 3-4; 12/2000 Version1.0