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Original Article

Comparison of Liver Function Test Results between Architect C8000 and COBAS C501 Automatic Chemistry Analyzer

Liana, P[1 *], Jenica, A[2], Suciati, T[3], Rahmawati, E[1], Pariyana, P[4], Umar, T. P[2]

1. Department of Clinical Pathology, Faculty of Medicine, Universitas Sriwijaya, Mohammad Hoesin General Hospital, Palembang, Indonesia
2. Faculty of Medicine, Universitas Sriwijaya, Palembang, Indonesia
3. Department of Anatomy, Faculty of Medicine, Universitas Sriwijaya, Palembang, Indonesia
4. Department of Public Health and Community Medicine, Universitas Sriwijaya, Palembang, Indonesia

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Corresponding Author: pheyliana@fk.unsri.ac.id

Abstract

Liver function tests are frequently used to screen liver function, monitor therapy, and determine the severity of liver problems. The present study aimed to assess the consistency of the results of the liver function parameters between the two analyzers, Architect c8000 and Cobas C501. This laboratory-based analytical observational study was conducted in a cross-sectional manner. Sample collection was performed through a consecutive sampling procedure from June to December 2019 in the Clinical Pathology Laboratory, Dr. Mohammad Hoesin General Hospital, Palembang, South Sumatra, Indonesia. The research sample consisted of the liver function examination results of patients, carried out using the Architect c8000 and Roche Cobas c501 chemistry analyzers. Serum albumin, alanine transaminase, aspartate aminotransferase, and total protein were the studied variables. The Spearman, Mann-Whitney, and Bland-Altman tests were used to evaluate the comparison test. In total, 100 blood samples were obtained in this study. The results revealed a highly significant correlation ($r>0.90$, $P=0<001$) among the four liver function parameters. The results of the liver function parameters inspected by the two analyzers did not differ significantly ($P>0.05$). In addition, there was a solid agreement on all parameters, with a near-perfect level (concordance correlation coefficient>0.90) and more than 95% of data points falling within the acceptable range. The Architect c8000 and Cobas c501 analyzers produced similar results for liver function tests; hence, these devices can be used interchangeably.

Keywords: Agreement test, Laboratory, Liver Function Tests, Medical Device

1. Introduction

The history and physical examination of patients are frequently insufficient to determine the diagnosis and treatment, especially when the disease is equivocal. In this case, the role of ancillary investigations in confirming the diagnosis or obtaining more specific information is crucial (1). Laboratory examinations, such as clinical chemistry examinations, which are now commonly performed with a clinical chemistry analyzer, are among the most essential supporting examinations (about 80% of the disease) (2). A clinical chemistry analyzer is an automatic laboratory equipment used to measure the concentrations of specific parameters in blood, urine, other bodily fluids, microbiology sample, or any other substance in clinical laboratory medicine. It comes in handy when performing multiple sample examinations in a short time (3).

The Roche Cobas c501 and the Abbott Architect c8000 are two commonly used automatic chemistry analyzers for serum indices measurement (4). In Dr. Mohammad Hoesin General Hospital, these two

analyzers are used interchangeably in examinations. However, a comparison test is required since the results may differ. According to Suwannaboot, Ketloy (5), Abbott Architect c8000 and Roche Cobas c501 have similar overall performances. Meanwhile, findings of a study performed by Nikolac Gabaj, Miler (4) revealed that performance quality varies across several parameters. In a study, Chen, Li (6) used two chemistry analyzers, the Mindray BS-2000M and the Roche Cobas c702, and discovered that these analyzers produced comparable result.

The settlement between two measurement techniques is frequently assessed in medical laboratories. The changes in method, evaluation of a new or alternative approach, and the problem with device synchronization are continually happening. Therefore, some instruments are needed to assess and appraise the discrepancies and the causes of the variability (7). As a consequence, this study aimed to assess the consistency of the chemical test results of the Abbott Architect c8000 and Roche Cobas c501 analyzers regarding liver function parameters, which have not been thoroughly investigated in Indonesia. This study is expected to significantly impact diagnosis, treatment, and prognosis by determining whether the two analyzers produce similar results and can be used interchangeably or simultaneously.

2. Materials and Methods

2.1. Study Overview

This cross-sectional laboratory-based analytical observational study was performed from June to December 2019. This study was carried out at the Clinical Pathology Laboratory, Dr. Mohammad Hoesin General Hospital, Palembang, South Sumatra, Indonesia (a tertiary-level hospital).

2.2. Sample Collection, Processing, and Analysis

The sample was obtained through a consecutive sampling procedure from the liver function results of patients, which was assessed with the chemical analyzer, Architect C8000, series AS1242 (Abbott Diagnostics, USA) and Roche Cobas c501, series BX1432 (Roche Diagnostics, Mannheim, Germany) (8, 9). The serum used in this study was centrifuged at 4,000 rpm for 20 min. It should be mentioned that the serum was excluded in case of being lysed, lipemic, or icteric. According to the Institute of Clinical and Laboratory Standards, at least 40 samples were needed for a comparison test (10). Therefore, 100 blood samples were collected consisting of the liver function examination results of patients during the observation period.

In this study, several variables, namely the chemical analysis of albumin, alanine transaminase (ALT), aspartate transaminase (AST), and total protein, were evaluated by each chemical analyzer utilizing spectrophotometric measurement methods. Albumin (Abbott Cat No. 32423, Roche Cat No. 354234) was examined using the Bromocresol green procedure, which uses observations at a wavelength of 628 nm, directly proportional to the concentration of the albumin sample (11). The ALT (Abbott Cat No. 13242, Roche Cat No. 32233) and AST (Abbott Cat No. 45678, Roche Cat No. 46985) were examined using the NADH to NAD oxidation method and quantified at a wavelength of 340 nm (12). The biuret method was used to investigate proteins (Abbott Cat No. 58764, Roche Cat No. 58234), which was evaluated at a wavelength of 340 nm (13).

2.3. Statistical Analysis

Data normality was assessed using the Kolmogorov-Smirnov and the Shapiro-Wilk test. If the data were normally distributed ($P>0.05$), they were presented as the mean±2SD. On the contrary, when the analysis showed abnormal data distribution ($P<0.05$), the median (minimum-maximum) value was used. The bivariate test was carried out using the Pearson and Spearman correlation test, t-test, Mann-Whitney U test, and the Bland-Altman comparison test (14) with Passing-Bablok regression (15). The statistical analyses were performed in the SPSS software for Windows (version 24.0, Armonk, USA: IBM Corp.) and MedCalc (version 18.11, Ostend, Belgium: MedCalc Software bv.).

3. Results

All liver function parameters were abnormally distributed and did not differ significantly between the Architect c8000 and Cobas c501 analyzers, as summarized in table 1. The examination results were highly correlated and significantly unidirectional between both analyzers (P<0.001). The comparison test for the liver function parameters obtained a concordance correlation coefficient of greater than 0.90 for all parameters. These findings show that all parameters are almost perfectly in agreement. The Bland-Altman scatter plot revealed that more than 95% of the data points on every parameter were within the acceptable range.

Figure 1a shows the albumin parameter regression graph based on the equation y=0.167+0.917x. The albumin parameter scatter plot showed that 2 out of 100 data points were outside the acceptance range which was -0.22 to 0.47. In total, 98% of albumin parameter data points were within the acceptance range. Figure 1b depicts a scatter plot for the ALT parameter, where 3 out of 100 data points were outside the acceptance range which was -7.13 to 3.19. In total, 97% of the ALT parameter data points were within the acceptance range. The AST parameter scatter plot in figure 1c presents that 3 of the 85 data points were outside the acceptance range, which was -1.53 to 2.47. It should be noted that 96% of AST parameter data points were within the acceptance range. Scatter plot of total protein parameters in figure 1d illustrates that 3 points out of 100 data points were outside the acceptance range which was -0.50 to 0.26. Moreover, 97% of the total protein parameter data points were within the acceptance range.

Table 1. Results Distribution of Liver Function Test on Architect c8000 and Cobas c501

Parameter	Sample size	Architect c8000	Cobas c501	P*	r**	Mean Difference	Limit of Agreement	Concordance Correlation Coefficient	Regression Equation
Albumin (g/dL)	100	3.40(1.30–4.70)	3.50(1.10–4.80)	0.208	0.981	0.13	-0.22–0.47	0.9703	y= 0.167 + 0.917 x
ALT (U/L)	100	25.50(6.00–458.00)	24.00(6.00–461.00)	0.478	0.997	-1.97	-7.13–3.19	0.9986	y= 0.729 + 1.029 x
AST (U/L)	85	21.00(7.00–77.00)	21.00(8.00–77.00)	0.808	0.991	0.47	-1.53–2.47	0.9988	y= 0.0000 + 1.0000 x
Total Protein (g/dL)	100	7.10(3.50–8.70)	6.90(3.30–8.50)	0.328	0.976	-0.12	-0.50–0.26	0.9780	y= -0.204 + 1.043 x

* Mann Whitney Test
**Spearman Test
Note: Data on Architect c8000 and Cobas c501 was presented as median (minimum-maximum). ALT: Alanine transaminase; AST: Aspartate transaminase

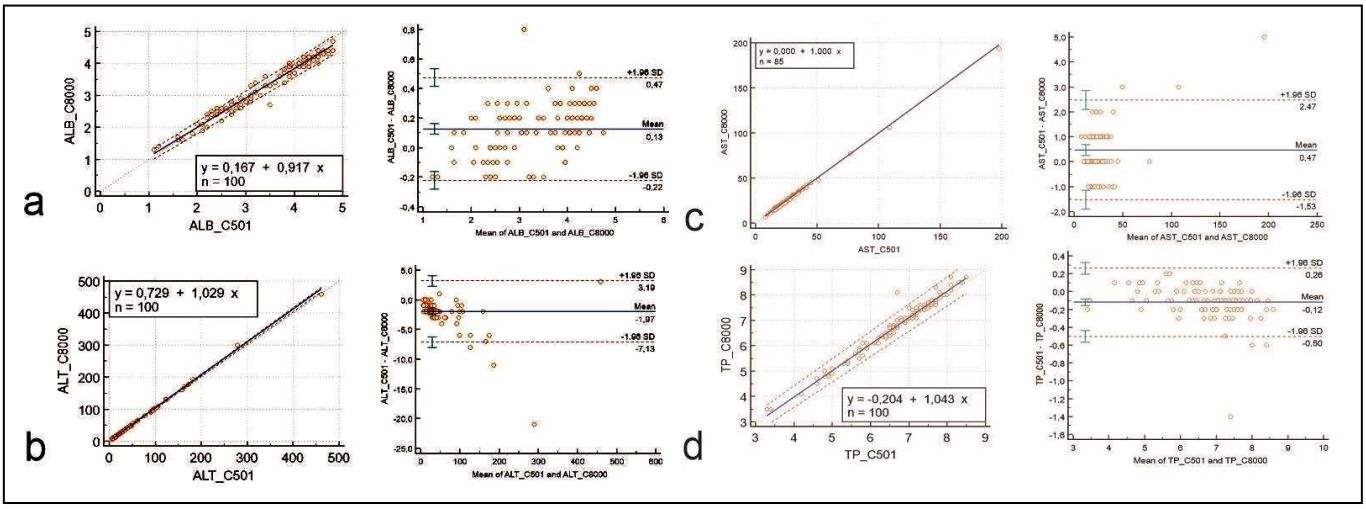

Figure 1. Passing-Bablok Regression and Bland-Altman Scatter Plot Graphs (a. Albumin; b. ALT; c. AST; d. Total Protein)

4. Discussion

According to this study, the Architect C8000 and Cobas c501 analyzers have a robust and significant correlation. The correlation test results in this study were similar to those of a study performed by Suwannaboot, Ketloy (5) in Thailand. They analyzed 25 parameters, including four components studied in our research, and found an excellent correlation (r values ranging from 0.975 to 0.999) as assessed by the chemistry analyzer Architect c8000 and Cobas c501. Another study conducted by Chen, Li (6) found that the Mindray BS-2000M and Roche Cobas 702 chemistry analyzers performed well in correlation tests. Total protein, albumin, ALT, AST, total bilirubin, direct bilirubin, uric acid, urea nitrogen, creatinine, glucose, total cholesterol, triglycerides, high-density lipoprotein, low-density lipoprotein, calcium, and phosphate were the parameters used in their study (6).

The results of data analysis for the mean difference in this study showed no difference between Architect c8000 and Cobas c501 chemistry analyzers in terms of the mean and median of the chemical examination results. The correlation between the chemistry analyzer Architect c8000 and Cobas c501 without significant differences was probably due to the fact that the two analyzers used the same method, namely the spectrophotometric technique (16). Several reaction methods on the parameters also showed similarities between the two analyzers. For example, in the albumin parameter, both analyzers have the bromocresol green reaction method (17).

In the present study, the results of the concordance correlation coefficient showed that all parameters have a high level of agreement, ranging from 0.9703 to 0.9988. All parameters of the Architect c8000 and Cobas c501 analyzers meet the acceptance range in the Bland-Altman scatter plot that is ≥95% of data points within the interval of 1.96 to 1.96 of the mean difference (18). This finding indicates that the comparison test results in this study meet the hypothesis.

Results of a research conducted by Sutton, Dawson (19), who compared the Hitachi 911 and VetScan chemistry analyzers with 13 parameters from dog blood samples were different from those of the present study. In the present research, it was found that 8 out of the 13 parameters had an excellent concordance correlation coefficient, while albumin, potassium, and calcium had poor clinical correlations (19). The difference between the results of the comparison test in the aforementioned study and those of the present study was most likely due to sampling dissimilarities. Animal blood samples were used in that study, whereas human blood samples were used in this study, which led to differences, particularly in the erythrocytes (20, 21).

The concordance correlation coefficient and the Bland-Altman scatter plot obtained in this study demonstrated that the Architect c8000 and Cobas c501 chemistry analyzers were consistent. Scatter plots can be reviewed based on data distribution, with similarity presented by relative data points close to the mean difference line. The mean difference and limits of agreement can determine the consistency of the two methods. If the data distribution meets the permissible limit of agreement, the two methods can be used interchangeably (22).

This study used three forms of data analysis to determine the differences between the two analyzers, namely the correlation test, difference test, and comparison test, based on the objectives. The correlation test yielded promising findings regarding the Architect c8000 and Cobas c501 analyzers. The use of correlation analysis to test agreement between the two methods is frequently regarded as less meticulous. A significant correlation between the two methods indicates that the two variables have a linear relationship (23). Since correlation only evaluates the linear relationship between the two observed groups, the correlation coefficient (r-value) is sometimes insufficient for the assessment of agreement (7, 24). The correlation test results in this study showed cohesion with the comparison test results (25). It also applies to the results of the mean and median difference test with the comparison test in this study.

The limitation of this study was that the data was not classified into low, normal, or high values. Therefore, it could not be determined whether the agreement between the two analyzers for liver function parameters was substantial for each value range.

Overall, there was no difference between the Architect c8000 and Cobas c501 analyzers in terms of the results of liver function tests. This indicates that these two analyzers can be used interchangeably or concurrently in the clinical laboratory for both diagnosis and therapy monitoring purposes.

Authors' Contribution

Study concept and design: P. L., E. R, and A. J.
Acquisition of data: P. L. and A. J.
Analysis and interpretation of data: P. L., A. J., and T. P. U.
Drafting of the manuscript: P. L., E. R., A. J., T. S., and T. P. U.
Critical revision of the manuscript for important intellectual content: P. L., P. and T. P. U.
Statistical analysis: P. L., P., A. J., and T. P. U.
Study supervision: P. L, E. R., and T. S.

Ethics

This study obtained ethical approval from the Ethics Committee of the Faculty of Medicine Research, Sriwijaya University, Palembang, Indonesia (Registration Number: 335/kepkrsmhfkunsri/2019).

Conflict of Interest

The authors declare that they have no conflict of interest.

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References

1. WHO. Good clinical diagnostic practice: a guide for clinicians in developing countries to the clinical diagnosis of disease and to making proper use of clinical diagnostic services 2005 [
2. Teshome M, Worede A, Asmelash D. Total Clinical Chemistry Laboratory Errors and Evaluation of the Analytical Quality Control Using Sigma Metric for Routine Clinical Chemistry Tests. J Multidiscip Healthc. 2021;14:125-36.
3. Armbruster DA, Overcash DR, Reyes J. Clinical chemistry laboratory automation in the 21st century-amat victoria curam (Victory loves careful preparation). Clin Biochem Rev. 2014;35(3):143.
4. Nikolac Gabaj N, Miler M, Vrtaric A, Hemar M, Filipi P, Kocijancic M, et al. Precision, accuracy, cross reactivity and comparability of serum indices measurement on Abbott Architect c8000, Beckman Coulter AU5800 and Roche Cobas 6000 c501 clinical chemistry analyzers. Clin Chem Lab Med. 2018;56(5):776-88.
5. Suwannaboot S, Ketloy C, Ganokroj P, Ujjin P. Correlation of analytical performance of automatedchemistry analyzer between Abbott Architectc8000 and Roche Cobas c501. Chula Med J. 2012;56(4):411-9.
6. Chen F-h, Li N, Zhang W, Zhang Q-y, Wang Y, Ma Y-y, et al. A comparison between China-made Mindray BS-2000M biochemical analyzer and Roche cobas702 automatic biochemical analyzer. Front Lab Med. 2017;1(2):98-103.
7. Giavarina D. Understanding Bland Altman analysis. Biochem Med (Zagreb). 2015;25(2):141-51.
8. Pauli D, Seyfarth M, Dibbelt L. The Abbott Architect c8000: Analytical performance and productivity characteristics of a new analyzer applied to general chemistry testing. Clin Lab. 2005;51(1-2):31-42.
9. van Gammeren AJ, van Gool N, de Groot MJ, Cobbaert CM. Analytical performance evaluation of the Cobas 6000 analyzer - special emphasis on trueness verification. Clin Chem Lab Med. 2008;46(6):863-71.
10. Jensen AL, Kjelgaard-Hansen M. Method comparison in the clinical laboratory. Vet Clin Pathol. 2006;35(3):276-86.
11. Doumas BT, Watson WA, Biggs HG. Albumin standards and the measurement of serum albumin with bromcresol green. Clin Chim Acta. 1971;31(1):87-96.
12. Huang X-J, Choi Y-K, Im H-S, Yarimaga O, Yoon E, Kim H-S. Aspartate Aminotransferase (AST/GOT) and Alanine Aminotransferase (ALT/GPT) Detection Techniques. Sensors. 2006;6(7):756-82.

13. Artiss JD, Strandbergh DR, Zak B. Spectral study of bichromatics: Biuret-protein and glucose-hexokinase reactions as visible-ultraviolet models for turbidity. Microchem J. 1989;40(2):152-65.
14. Bland JM, Altman DG. A note on the use of the intraclass correlation coefficient in the evaluation of agreement between two methods of measurement. Comput Biol Med. 1990;20(5):337-40.
15. Bilic-Zulle L. Comparison of methods: Passing and Bablok regression. Biochem Med (Zagreb). 2011;21(1):49-52.
16. Ren Z, Liu G, Huang Z, Zeng L, Shao B, editors. Research of Spectrophotometer for Bio-Chemical Analyzer Based on Automatic Adjustment of the Integration Time of Linear CCD. 2008 2nd International Conference on Bioinformatics and Biomedical Engineering; 2008 16-18 May 2008.
17. Duly EB, Grimason S, Grimason P, Barnes G, Trinick TR. Measurement of serum albumin by capillary zone electrophoresis, bromocresol green, bromocresol purple, and immunoassay methods. J Clin Pathol. 2003;56(10):780-1.
18. Myles PS, Cui J. Using the Bland-Altman method to measure agreement with repeated measures. Br J Anaesth. 2007;99(3):309-11.
19. Sutton A, Dawson H, Hoff B, Grift E, Shoukri M. Analyte comparisons between 2 clinical chemistry analyzers. Can Vet J. 1999;40(4):255.
20. Namdee K, Carrasco-Teja M, Fish MB, Charoenphol P, Eniola-Adefeso O. Effect of variation in hemorheology between human and animal blood on the binding efficacy of vascular-targeted carriers. Sci Rep. 2015;5:11631.
21. Weng X, Cloutier G, Pibarot P, Durand LG. Comparison and simulation of different levels of erythrocyte aggregation with pig, horse, sheep, calf, and normal human blood. Biorheology. 1996;33(4-5):365-77.
22. Dogan NO. Bland-Altman analysis: A paradigm to understand correlation and agreement. Turk J Emerg Med. 2018;18(4):139-41.
23. Sedgwick P. Limits of agreement (Bland-Altman method). BMJ. 2013;346:f1630.
24. Gray TE, Pratt MC, Cusick PK. Determination of agreement between laboratory instruments. J Am Assoc Lab Anim Sci. 1999;38(2):56-9.
25. Miler M, Šimundić A-M, Štefanović M, Ferenec-Ružić D, Kvaternik M, Topić E, et al. A model for results comparison on two different biochemistry analyzers in laboratory accredited according to the ISO 15189. Biochem Med. 2009;19(3):287-93.