comparison 2 alat

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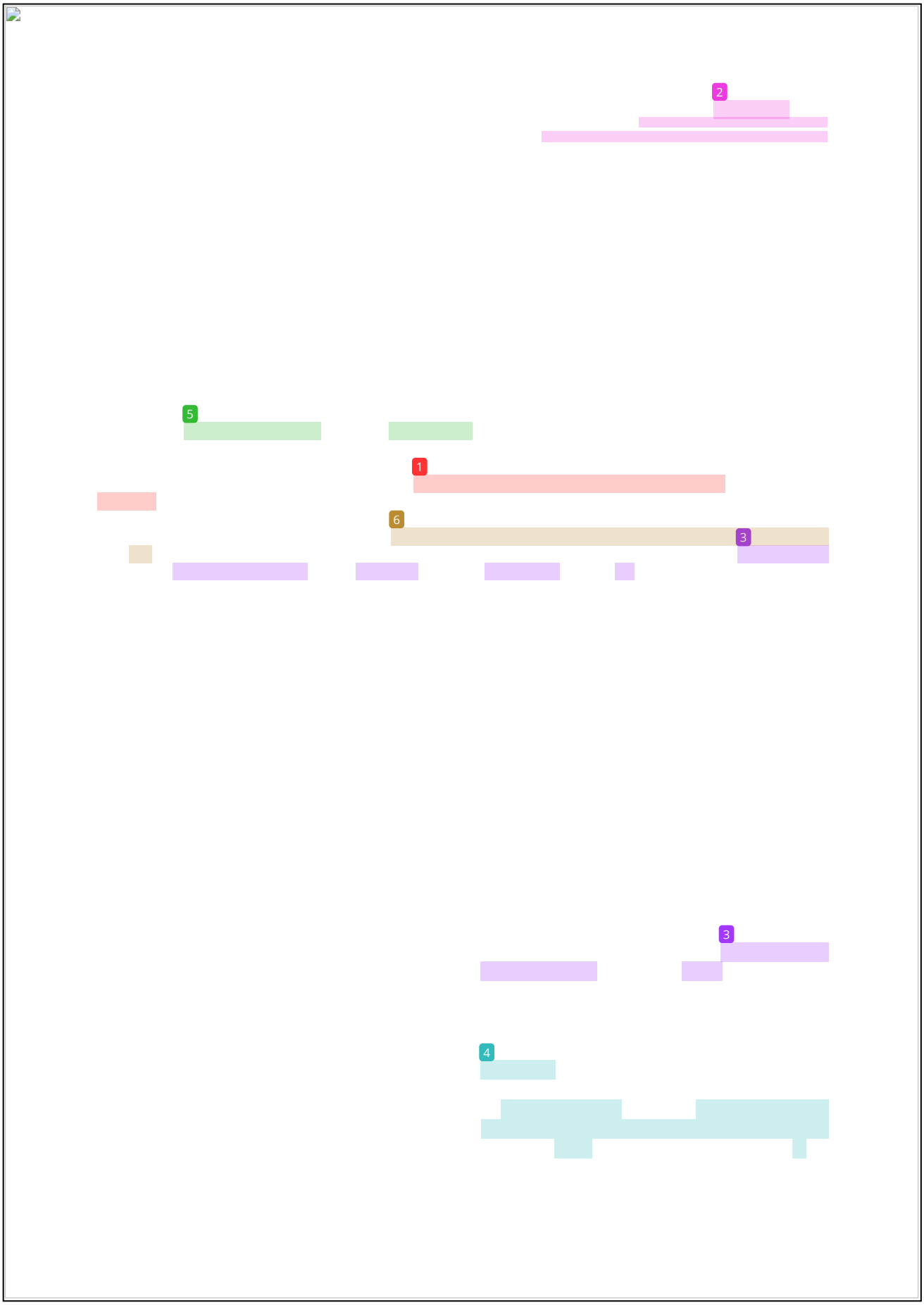
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and November 2019. Samples of the study were the patient's arterial blood that was sent for blood gas analysis to the central laboratory. A total of 42 arterial blood samples were examined with Abbott i-STAT handheld POC device and Nova pHox Ultra benchtop device. According to the Clinical Laboratory Standards Institute (CLSI) guidelines, a minimum of 40 samples are needed for method comparison study (NCCLS document EP9-A2).[5]

Arterial blood samples from patients were formerly measured with Nova pHox Ultra and immediately with Abbott i-STAT afterward with a time difference of fewer than 10 minutes. CG4+ disposable cartridges 03P85-50 by Abbott point of care, USA on Abbott i-STAT and Stat Profile pHOx Ultra cartridges 488831 by Nova Biomedical, USA were used. The parameters evaluated in this study were pH, pCO2, and pO2. Data were analyzed using SPSS and MedCalc. The correlation of the results from both devices was determined by the Spearman correlation coefficient. A comparison between both devices was analyzed with the Mann-Whitney test and the Bland-Altman agreement test. The research was approved by the Health Research Ethics Committee of the Faculty of Medicine, Sriwijaya University and Dr. Mohammad Hoesin Central General Hospital (number 446/kepkrsmhfkunsri/2019).

RESULTS AND DISCUSSION

Table 1 showed the results of blood gas analysis using the Nova pHox Ultra and i-STAT. This study found significant strong correlation coefficients (r) between Nova pHOx Ultra and Abbott i-STAT for all parameters that were examined ($r > 0.8$). This result was consistent with several previous studies. In research conducted by Indrasari *et al.* using i-STAT and Nova pHox Plus L with a total of 100 samples, the correlation test showed the value of $p < 0.05$ and $r > 0.8$ for the parameters of pH, pCO2, and pO2. This analysis showed a strong correlation in the results of blood gas analysis between the POCT device and laboratory blood gas analyzer.[6] A study conducted by Lukkonen *et al.* using the POCT EPOC device with the Rapidlab RL1265 laboratory device and the RP500 Rapid point, the correlation test showed results of $p < 0.001$ for pH, pCO2, and pO2 parameters.[7]

Table 1. Blood gas analysis results of both devices

Parameters	Nova pHOx Ultra (n=42)	Abbott i-STAT (n=42)	R; p-value[a]	p-value[b]
pH	7.388 (7.001 – 7.502)	7.382 (6.944 – 7.522)	0.935; 0.000	0.854
pCO2	36.6 (13.8 – 115.7)	40.4 (13.2 – 109.9)	0.955; 0.000	0.285
pO2	105.3 (33.0 – 295.4)	111.0 (27.0 – 260.0)	0.944; 0.000	0.929

[a]Spearman test [b]Mann-Whitney test

Table 2. Bland-Altman agreement test results of arterial blood gas analysis between Abbott i-STAT and Nova pHox Ultra

Parameters	Mean Difference	Limit of Agreement	Concordance Correlation Coefficient	Regression Equation
pH	0.02	(-0.08) – (0.11)	0.9249	y = -1,693886 + 1,228790 x
pCO2	-2.5	(-12.2) – (7.2)	0.9500	y = -1,73889 + 1,111111 x
pO_2	4.8	(-35.6) – (45.3)	0.9337	y = -2,793478 + 0,978261 x

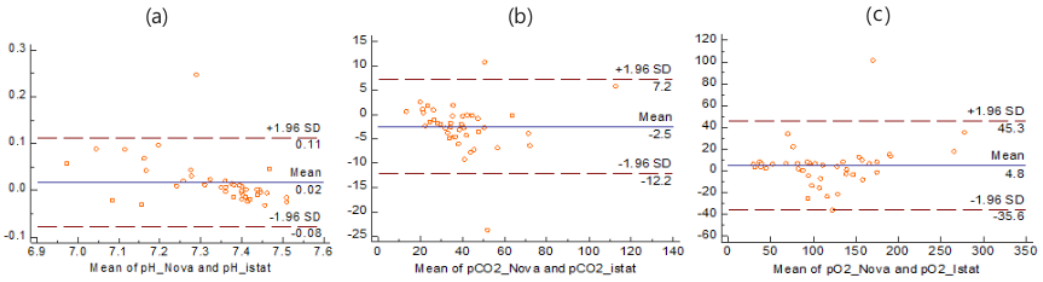

Figure 1. Bland-Altman plots (a) pH; (b) pCO2; (c) pO2

Strong correlation coefficient (R2) value between the EPOC POCT device and RL1265 Rapidlab laboratory instrument and between the EPOC POCT device and RP500 Rapid point laboratory instrument were observed for pH, pCO2, and pO2 parameters.[7] Plathe found a good correlation between results of POCT i-STAT and blood gas analyzer 288 laboratories with R values > 0.8 for parameters pH, pCO2, and pO2.[8]

A comparative test showed p-value > 0.05 for all parameters (pH, pCO2, and pO2), indicating that there was no significant difference between the results of i-STAT and pHox Ultra. These results were consistent with the results of the Spearman correlation test.

The results of the Bland-Altman test for pH parameters showed that 97.6% of blood gas analysis results were within the acceptance limit of -0.08 to 0.11 with a mean bias of 0.02. The study also found that 95.2% of the results of the blood gas analysis for pCO2 were within the acceptance limit of -12.2 to 7.2, with an average bias of -2.5. In addition, for the O2 parameter, the data showed that 97.6% of the results were within the acceptance limit of -035.6 to 45.3 with a mean bias of 4.8.

This study showed that > 95% of the plots were within the range of acceptable limits for all three parameters. This result was consistent with research conducted by Indrasari *et al.*[6] That study found an agreement between the results measured with i-STAT and Nova pHox Plus L with 96% of the results of pH tests were still within the acceptance limit, and 95% of the pCO2 and pO2 examination results were still within the acceptance limit.[6] Another study conducted by Gray *et al.*, which compared POCT i-STAT and ABL 500 meters using rat blood samples, showed that > 95% of the samples were within the range of acceptance.[9]

Centers for Disease Control and Prevention (CDC) has made a regulation called Clinical Laboratory Improvement Amendments (CLIA); one of the objectives of the regulation is to monitor the quality of the laboratory test results by setting limits or the target value standards of the test results. The standards-based on CLIA 1988 were compared with the results of the analysis in this study. Acceptance between handheld and benchtop equipment was evaluated from the average bias results of blood gas analysis between handheld and benchtop equipment. The average bias of 0.02 was obtained for pH (target value ± 0.04), -2.5 mmHg for pCO2 (target value ± 5 mmHg or ± 8%), and 4.8 mmHg for pO2 (target value ± 3 SD, SD: 20,626). The results showed that all of the average bias was still within the accepted standards in the CLIA 1988, indicating that the results of the measurement results of the two devices can be used alternately.[10]

Blood gas analysis is a laboratory test to identify changes in the status of acid-base and oxygenation. This test was often performed at the ICU and emergency. Precise and accurate results are expected in this test. Measurement using benchtop laboratory equipment requires a longer time because operation must be based on the existing procedures. Point-of-care testing devices are one of the devices that are relied upon to get fast results. However, this device can not be used continuously because it requires more costs. The analysis in this study was conducted to determine the possibility that both methods could be used interchangeably.[2-4]

A comparative test was performed to evaluate the mean difference between both methods. However, this analysis merely gave little information about the accuracy of the method. Consequently, the mean difference test is not commonly used for the comparison of measurement methods.[11]

Correlation test analysis is often used for comparative study. Correlation analysis can be used to determine the linear relationship between two methods but not the acceptance of the device. Agreement test analysis is considered appropriate to determine acceptance because the analysis is carried out by considering the data distribution of each test result.[11]

CONCLUSION AND SUGGESTION

Differences in the results of blood gas analysis between i-STAT handheld and Nova pHox Ultra benchtop devices can be neglected; therefore, both devices can be used interchangeably for analyzing the patient's blood gas. Both devices can also be replaced by each other with minimal error and effect in clinical decision making. It was suggested to perform an agreement test by comparing two laboratory devices for clinical use to assess clinical difference or significance of results between both devices.

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