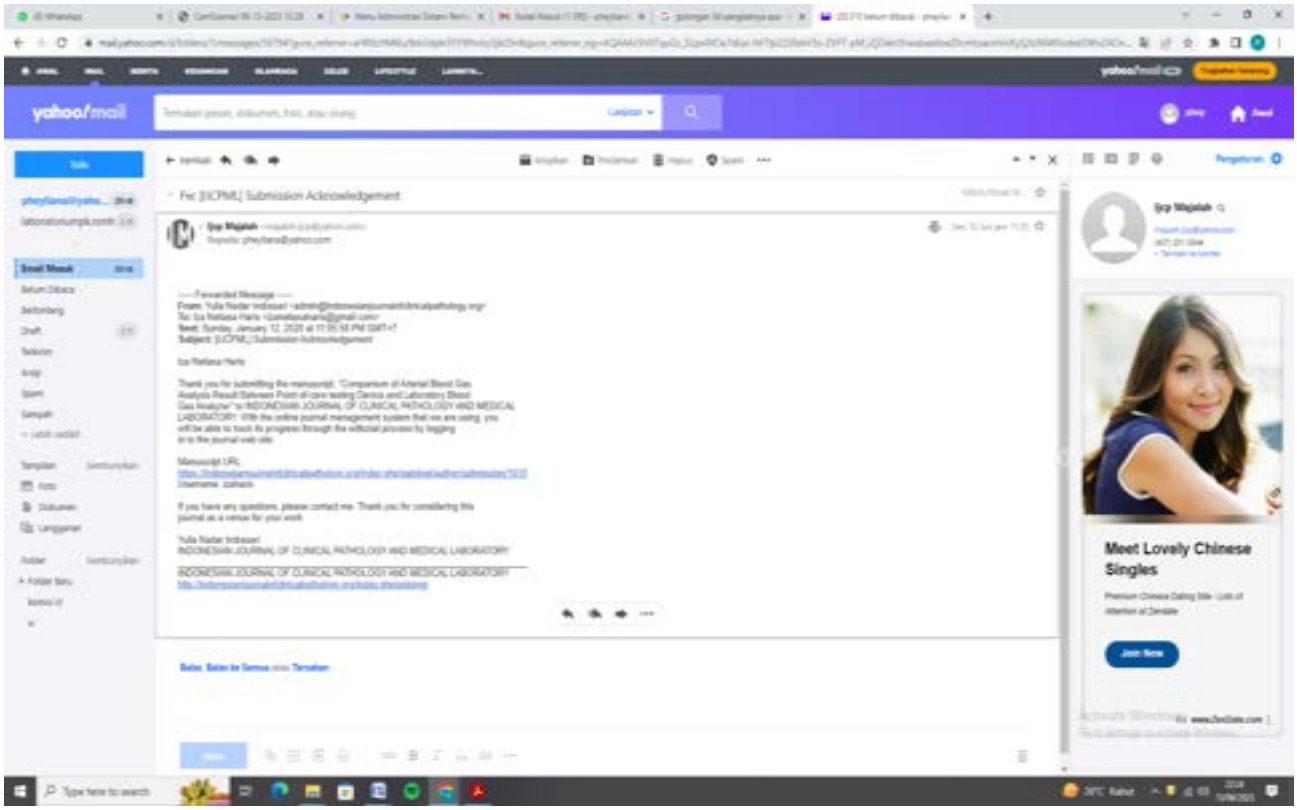
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Submission Acknowledgement
12 January, 2020

Dear: Phey Liana, Iza Netiasa Haris, Yan Effendi Hasyim:

Thank you for submitting the manuscript, "Comparison of Arterial Blood Gas Analysis Result Between Point-of-care testing Device and Laboratory Blood Gas Analyzer" to INDONESIAN JOURNAL OF CLINICAL PATHOLOGY AND MEDICAL LABORATORY. With the online journal management system that we are using, you will be able to track its progress through the editorial process by logging in to the journal web site.

If you have any questions, please contact me. Thank you for considering this journal as a venue for your work.

Sincerely,

Yulia Nadar Indrasari, dr, SpPK
Chief of Indonesian Journal of Clinical Pathology and Medical Laboratory
editor@indonesianjournalofclinicalpathology.org

Indonesian Journal of Clinical Pathology and Medical Laboratory
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Peer Review Results

6 July, 2020

Peer Review Results

Dear author(s),

Phey Liana*, Iza Netiasa Haris, Yan Effendi Hasyim has submitted the manuscript "Comparison of Blood Gas Analysis between Benchtop and Handheld Device" to Indonesian Journal of Clinical Pathology and Medical Laboratory. The decision : Revision Required.

Sincerely,

Yulia Nadar Indrasari, dr, SpPK
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Comparison of Blood Gas Analysis between Benchtop and Handheld Device

ABSTRACT

Background. The use of blood gas analysis to determine Acid-base status is required to treat ~~the~~ patients with ~~an~~ emergency conditions such as metabolic disorders and respiratory diseases. Benchtop device is commonly used in hospitals to analyze blood gas, but recently handheld devices ~~now~~ are more often used in emergency settings due to quick and simple process. This study was performed to compare blood gas analysis results between i-STAT handheld device and Nova pHox Ultra benchtop device that was currently used in central laboratory.

Method. This cross-sectional study was conducted by using 42 arterial blood patients that were measured with i-STAT handheld device dan Nova pHox Ultra benchtop device. We evaluated pH, pCO2 and pO2 parameters. The data were analyzed using Spearman's correlation coefficients, Mann-Whitney test and Bland-Altman plots.

Results. This study showed a very strong positive correlation for all parameters. There was no significant difference between the result of the two devices (p-value >0.05) by the Mann-Whitney comparison test. All parameters showed that ≥ 95% of plots were within the acceptable limit. There was no clinically significant on the mean biases of blood gas results between the two devices.

Conclusion. The i-STAT and Nova pHox Ultra devices showed a good agreement for blood gas measurement so the two devices can be used interchangeably with minimal effect on clinical decision-making.

Keywords: Blood Gas Analysis, benchtop, handheld device. ~~i-STAT, Nova pHox Ultra, Agreement~~

INTRODUCTION

Acid-base balance is important to human body. Acid-base balance refers to the accurate regulation of free hydrogen ions in body fluids.[1] Blood gas analysis provides information on ~~the~~ status of oxygenation, ventilation, and acid-base in the patient's body. Components examined in blood gas analysis are pH, pCO2, bicarbonate ions (HCO3-), pO2, base excess, and oxygen saturation.[2] Blood gas analysis using arterial blood samples because pCO2 in arterial blood can reflect the component of respiration in ~~the~~ patient's acid-base

Comment [m1]: Dibuat ….fluids[1]. Seharusnya …fluids.[1]

status. Blood gas analysis is often carried out in laboratories. Blood gas analysis can be faster using a handheld or point-of-care (POC) device. ~~A~~ Handheld device allows blood gas analysis to be done more closely with the patient. ~~The~~ Examination can be ~~run~~ done in the same room without having to bring the specimen to the laboratory.

Comment [m2]: Kepustakaan nya?

Decision making and management are ~~take~~ more quickly because ~~the~~ results of the test took immediately.[3] ~~A~~ Trained health workers can also do analysis using ~~a~~ handheld device in addition to laboratory personnel. Handheld devices are smaller than blood gas analyzers that are commonly available in the laboratory so that they can be taken anywhere. Therefore it is easy for monitor ~~the~~ response of therapy.

Comment [m3]: Diambil dari kepustakaan mana?

In our hospital, we have handheld and benchtop device for blood gas analysis. I-STAT handheld device is used in intensive care unit while Nova pHox Ultra benchtop device in central laboratory. A comparison test is needed to evaluate the agreement of the results between I-STAT and Nova pHox Ultra device. Therefore we performed this study to determine wheather the results of both devices are indeed comparable. If the results are agreeable, those devices can be used interchangeably for monitor patient's progress.

METHODS

This study was an analytic observational study with cross-sectional design. The research was performed in Clinical Pathology Laboratory of dr. Mohammad Hoesin Palembang in October and November 2019. ~~The~~ Samples of study were patient's arterial blood that were sent for blood gas analysis to central laboratory. As many as 42 arterial blood samples were examined with Abbott i-STAT handheld POC device and Nova pHox Ultra benchtop device. According to Clinical Laboratory Standards Institute (CLSI) guidelines, a minimun 40 is needed for method comparison study (NCCLS document EP9-A2).

Comment [m4]: Kepustakaan?

Arterial blood samples from patients were running first in Nova pHox Ultra and immediately after that on Abbott i-STAT with a time difference of less than 10 minutes. We used CG4+ disposable cartidges 03P85-50 by Abbott point of care, USA on Abbott i-STAT and Stat Profile pHOx Ultra catridges 488831 By Nova Biomedical, USA. 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 were determine by Spearman correlation coefficient. Both devices ~~also~~ were also compared with Mann-Whitney test and Bland-Altman agreement test. The research was approved by Health Research Ethics Committee of the Faculty of Medicine, Sriwijaya University and 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. ~~The~~ This study found strong correlation coefficients (r) significantly between Nova pHOx Ultra and Abbott i-STAT for all parameters that were examined (r>0.8). These result was consistent with several previous studies. In research conducted by Indrasari et al. (2018) using i-STAT and Nova pHox Plus L with a total sample 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 shows a strong correlation in the results of blood gas analysis between the POCT device and laboratory blood gas anayzer.[5] A study conducted by Lukkonen et al. (2015) 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.

Comment [m5]: Diambil dari?

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.[6] ~~A study conducted by~~ Plathe (1997) found ~~a~~ good correlation ~~was found~~ between ~~the~~ results of POCT i-STAT and ~~the~~ Blood Gas Analyzer 288 laboratory with R values for parameters pH, pCO2, and pO2 > 0.8.[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; 000	0.929

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

~~The~~ Comparative test showed ~~the~~ p-value > 0.05 for all parameters (pH, pCO2, and pO2), it indicated that there was no significant difference between the results of i-STAT and pHox Ultra. These results are consistent with the results of the Spearman correlation 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

The results of the Bland-Altman test for pH parameters showed that 97.6% of ~~the~~ blood gas analysis results ~~of blood gas analysis~~ are 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. Meanwhile, for O2 parameter, the data showed 97.6% of the results were within the acceptance limit of -035.6 to 45.3 with a mean bias of 4.8.

~~The~~ This study showed > 95% of the plots are within the range of acceptable limits for all three parameters. This result was consistent with research conducted by Indrasari et al. (2019). That study found an agreement results between the i-STAT and Nova pHox Plus L. with 96% of the results of pH tests are still within the acceptance limit, and 95% of the pCO2 and pO2 examination results are still within the acceptance limit.[5] Other study conducted by Tonya E. Gray et al. (1999) compared POCT i-STAT and ABL 500 meters using rat blood samples obtained > 95% of the samples were within the range of acceptance.[8]

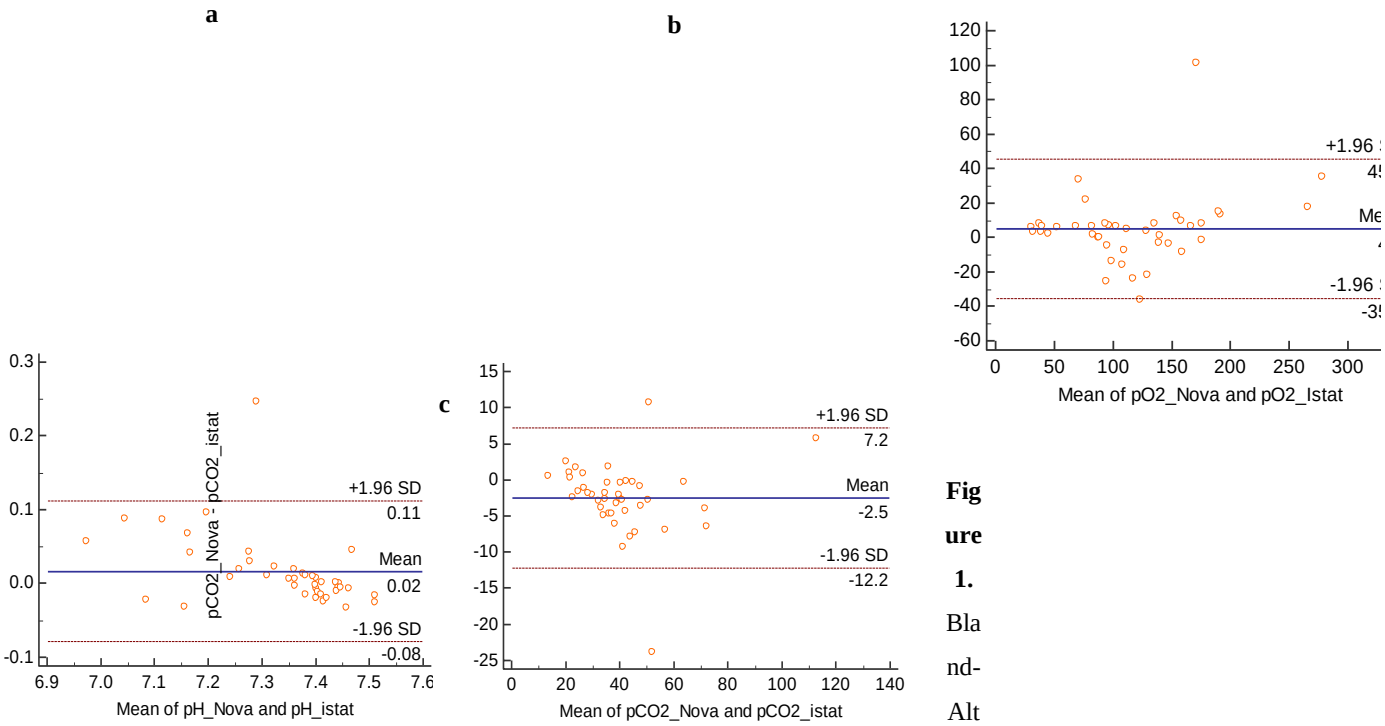

Figure 1. Bland-Altman plots (a) pH; (b) pCO_2; (c) pO_2

~~The~~ Blood gas analysis is an examination carried out to see changes in the status of acid-base and oxygenation ~~in the body~~. This examination was often done at the ICU and emergency. Precise and accurate results are expected in this examination. Examination using benchtop laboratory equipment requires a long time because they have to follow existing procedures. Point-of-care testing devices are one of the devices that are relied upon to get fast results. However, the use of this device can not be done continuously, considering the more costs needed. The analysis in this study was conducted to see the possibility that both methods could be used interchangeably.

Comment [m6]: Pustaka?

Comparative test was performed to evaluate ~~the~~ mean difference between two methods. But this analysis just gives little information about the accuracy of the method. Consequently, mean difference test is not commonly used for the comparison of measurement methods.[10]

Correlation test analysis is often done in comparative study. Correlation analysis can be used to see the linear relationship between the two methods but cannot see the acceptance of

the device. Agreement test analysis is considered appropriate to determine acceptance because the analysis is done by looking at the data distribution of each inspection result.[10]

CONCLUSION AND SUGGESTION

In Conclusion, ~~the~~ differences in the results of blood gas analysis between i-STAT handheld and Nova pHox Ultra benchtop device can be ignored so both devices can be used interchangeably for analyzing the patient's blood gas. Both devices also can be replaced each other with minimal error and effect in clinical decision making.

Comment [m7]: Suggestion?

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Letter of Acceptance
7 October, 2020

Dear; Phey Liana[1], Iza Netiasa Haris[2], Yan Effendi Hasyim[3]

[1] Department of Clinical Pathology, Faculty of Medicine, Sriwijaya University/Dr. Mohammad Hoesin General Hospital Palembang, Indonesia

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I am very excited to accept your paper entitled:

"Comparison of Blood Gas Analysis between Benchtop and Handheld Device"

Your paper will be published in the issue of Vol. 27 Number 1, November 2020

Indonesian Journal of Clinical Pathology and Medical Laboratory is indexed in indexing organization: https://www.indonesianjournalofclinicalpathology.org/index.php/patologi/index

Asean Citation Index; Indonesia One Search; Google Scholar; DOI Crossref; Garuda Indonesia; Sinta; PKP Index; WorldCat; Microsoft Academic; ISJD Neo

Please do not hesitate to contact me if you need anything. It has been a pleasure for us to proofread and edit your work and we are looking forward to your colleagues and your other papers in the near future.

Sincerely,

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