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Clinical and Statistical Evaluation of 1st Automatic: A Pilot Study

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Abstract. Arterial blood gas analyses provide information about the patient's oxygenation, ventilation, and perfusion. Studies have shown that most errors occur during the pre-analytical phase (the processes prior to the actual analysis of the sample). 1st Automatic is an extra module to the existing blood gas analyzer and a partial automation of the pre-analytical phase which is designed to reduce these errors. The objective was to investigate whether 1st Automatic is compatible to the conventional method. Quantitative measurements of pH, pCO2, pO2, Na+, K+, Ca2+, cGlu, cLac and tHb were performed on 21 paired whole blood specimens collected into the standard blood gas syringes and safePICO syringes, both designed for the ABL800 FLEX. During the collection the pre-analytical errors were minimised. No clinically significant differences were observed in the nine blood gas parameters. The differences were statistically insignificant, with the exception of cNa+, cCa2+ and tHb. There was a good consistency between the results using the new automated procedure and the conventional method. It was not possible to show any clinically significant difference between the two procedures.

Keywords. 1st Automatic, ABL800 FLEX, safePICO, safeTIPCAP, FLEXQ, pre-analytical errors, arterial blood gas

1. Introduction

Patients with respiratory disease are at risk for inadequate lung ventilation and inadequate tissue oxygenation [1]. Patients with metabolic diseases are at risk of acid-base abnormalities [2]. An arterial blood gas analysis is a simple procedure that can be performed bedside and can provide important information about lung ventilation, tissue oxygenation and acid-base status. [3]

Medical personnel at the ICU are under considerable stress in their everyday clinical settings and therefore prone to make errors [3]. According to several studies, it has been estimated that 75% of all laboratory medical errors occur during the pre-analytical phase [4]. An error in the pre-analytical phase of an arterial blood gas analysis can influence the diagnosis and treatment of the patient [5, 6].

Studies suggest that an automation of the pre-analytical phase can reduce errors in this phase. Three common pre-analytical errors are wrong patient identification, air

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bubbles in the specimen and no mixing prior to analysis. Thus to address this issue, Radiometer Medical ApS has developed 1st Automatic, which is a partial automation of the pre-analytical phase. With automatic mixing of the specimen, the system ensures a consistently homogeneous specimen prior to analysis. A partially automated bar code scanning system minimises the risk of patient ID and specimen mix up significantly [5, 7]. The advent of 1st Automatic could prove to be an essential tool in reducing these pre-analytical errors [8].

The objective of this study was to assess whether 1st Automatic is a suitable alternative to the conventional method and examine whether there is a difference between the two methods.

2. Method

2.1. Patients and Specimens

A total of 21 pairs of specimens were collected from five patients at Department of Anaesthesia and Intensive Care, Aalborg Hospital. I.e., each pair consisted of two specimens, one processed by the conventional method and one by 1st Automatic. The patients were randomly selected.

2.2. Blood Gas Analysis

Quantitative analyses were performed on nine parameters: pH, pCO_2, pO_2, cNa^+, cK^+, cCa^{2+}, cGlu, cLac and tHb. Both specimens in a pair were processed by the same equipment, an ABL825 or an ABL837. One of the specimens in each pair was processed by the mounted FLEXQ module; the other specimen was processed manually. After the nurses had collected the two specimens, the 1st Automatic specimens were handled by the observer, to help the nurses reduce the number of pre-analytical errors.

2.3. Comparison of Procedures

Bland-Altman plots were used to compare the measured blood gas parameters using the two procedures. The nine Bland-Altman plots depict the difference in the blood gas parameters for each pair of specimens (conventional method – 1st Automatic) as a function of the mean of the two specimens in a pair. To describe the parameters statistically, paired-sample t-tests were performed. When assessing the mean difference between the conventional and the new automated procedure, a mean difference of 10%, or less, of the normal range for each parameter was considered to be clinically insignificant.

3. Results

The results of the t-tests are depicted in Table 1 and the Bland-Altman plots are presented in Figure 1.

Table 1. 21 paired samples from five patients. The table shows the p-values of the T tests. The blood gas pressures (pXX) are in kPa and the blood concentrations (cXX) in mmol/. Normal range indicates the accepted range the physicians utilise in the diagnosis of the patients. Data range is the range the data was inside in this experiment.

Parameter	Normal range			Data range	Mean difference (95% CI)	P
	M	M/F	F			
pH	7.35 – 7.45			7.342 – 7.471	-0.0012 (-0.0026, 0.0002)	0.082
pCO_2	4.67 – 6.40	4.27 – 6.00		4.24 – 6.57	0.0324 (-0.0156, 0.0803)	0.174
pO_2	11.07 – 14.40			7.5 – 22	0.0110 (-0.2898, 0.3117)	0.940
cNa^+	136 – 146			132 – 140	0.7143 (0.2127, 1.2159)	0.008
cK^+	3.4 – 4.5			3.4 – 5.4	0.0048 (-0.0346, 0.0442)	0.803
cCa^{2+}	1.15 – 1.29			1.01 – 1.23	0.0152 (0.0065, 0.0240)	0.002
cGlu	3.89 – 5.83			5.6 – 11.5	0.0905 (-0.0060, 0.1869)	0.065
cLac	0.5 – 1.6			0.5 – 2.2	0.0286 (-0.0216, 0.0787)	0.249
ctHb	8.4 – 10.9	7.4 – 9.9		5.0 – 8.2	-0.0286 (-0.0496, -0.0075)	0.010

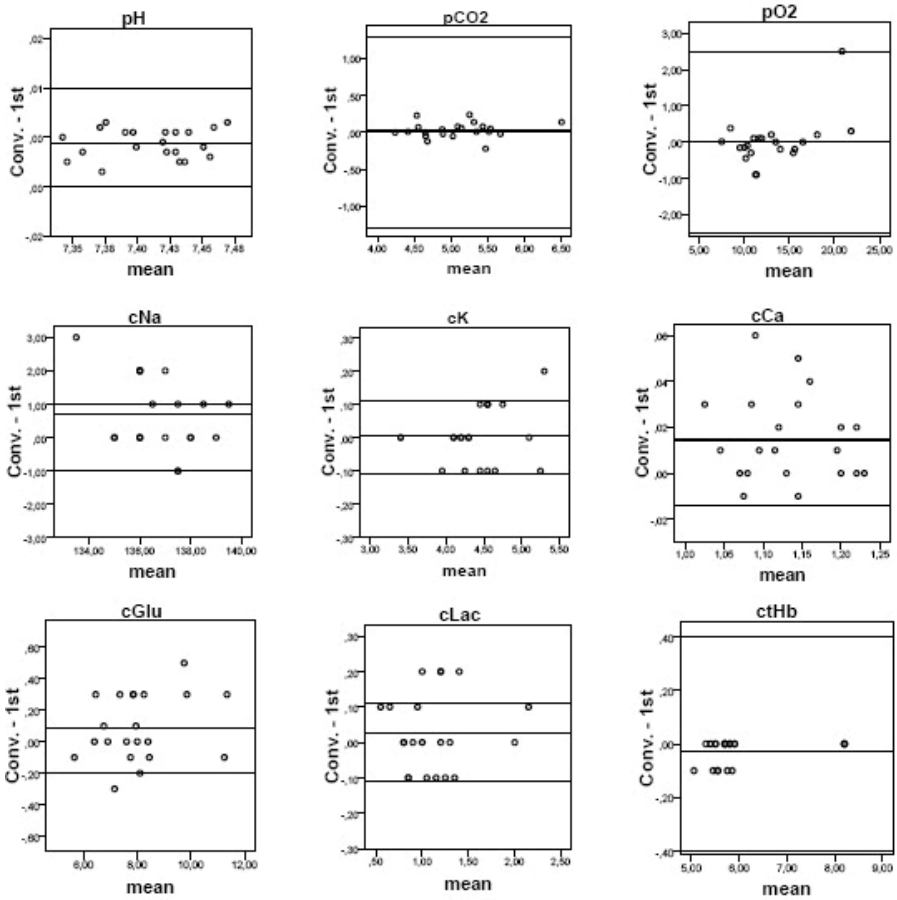

Figure 1. 21 paired samples from five patients. The nine Bland-Altman plots depict the difference in the blood gas parameters for each pair of specimens (conventional method – 1st Automatic) as a function of the mean of the two specimens in a pair. The solid line is the mean difference. The mean difference of 10% of the normal range is indicated for each parameter.

4. Discussion

21 paired analyses with minimised pre-analytical errors were acquired. Overall, there was good agreement between the two methods in most of the measured blood gas parameters. The differences were not statistically significant, with the exception of cNa^+, cCa^{2+} and tHb.

4.1. pH

The t-test gives p = 0.082, which indicates that there might be a bias. A bias could be caused by an occasional dilution with flush solution in one of the specimens and/or prolonged storage, which are not accounted for. However, the mean difference is around 1% of the normal range.

4.2. pCO_2 and pO_2

The t-test shows that p for pCO_2 is 0.17, which indicates that no bias is present, and that the mean difference is less than 2% of the normal range. The t-test for pO_2 shows p = 0.94 and a mean difference of less than 1%, which suggests no bias. The presence of air bubbles is one of the potential differences between the two procedures since the 1st Automatic procedure is using a new specimen cap, the safeTIPCAP. Presence of air bubbles in the specimens in one of the procedures will decrease pCO_2 and increase pO_2, which however, does not seem to have happened.

4.3. cNa^+

The t-test shows p = 0.008 for cNa^+, which is statistically significant and the mean difference is 0.71429, which is 7% of the normal range. Possible reasons include pre-analytical errors concerning dilution with flush solution in one of the specimens and haemolysis. The difference is however, not clinically significant.

4.4. cK^+

The study shows p = 0.80 for cK^+, and a mean difference of less than 1%, which indicates that that no bias is present. Insufficient dilution with heparin causes an increase in cK^+ (and a decrease in cNa^+). A study by Grenache and Parker concluded that manual mixing produced significantly more variation whereas automatic mixing consistently produced homogeneous specimens [8]. There is however, no indication of this playing a role in the present comparison of procedures.

4.5. cCa^{2+} and ctHb

The study shows p = 0.002 for cCa^{2+} and p = 0.010 for ctHb, the difference being 10% and 1% respectively. The difference is therefore, not clinically significant.

4.6. cGlu and cLac

The study shows p = 0.065 for cGlu and p = 0.25 for cLac, which is not statistically significant. The difference is 5% and 3% respectively, which is not clinically significant.

In summary, there was a good consistency between the results using 1st Automatic and the conventional method. It was not possible to show any clinically significant difference between the two procedures. The consequences on workflow using the two procedures have not been addressed in the present study.

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