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Implementation of a multi-parameter Point-of-Care-blood test analyzer reduces central laboratory testing and need for blood transfusions in very low birth weight infants

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ABSTRACT

Blood sampling for laboratory testing is a major cause of iatrogenic blood loss and anemia in neonatal intensive care unit [NICU] patients. The objective of the study was to assess whether the implementation of a multi-parameter Point of Care Test [POCT] (Roche, Cobas b221) analyzer affected blood loss for central laboratory testing and need for red blood cell transfusion in our NICU. This was a retrospective observational cohort study in a NICU with comparison of two serial cohorts of 2 years each. Implementation of a multi-parameter POCT decreased central laboratory performed testing for bilirubin (−32% per patient) and electrolytes (−36% per patient). On average, the net blood volume taken per admitted patient for electrolyte testing decreased with 23.7% and 22.2% for bilirubin testing in the second cohort. After implementation of POCT, fewer very low birth weight infants [VLBWI] required blood transfusion (38.9% vs. 50%, $p<.05$) as the number of transfusion/infants decreased by 48% (1.57 vs. 2.53, $p<0.01$). The implementation of POCT was cost-efficient for the Belgian national health insurance, cost reduction −8.3% per neonate. We conclude that implementation of a bedside multi-parameter POCT analyzer decreases transfusions among VLBWI by reducing iatrogenic blood loss for central laboratory testing.

1. Introduction

Point of care test (POCT) systems are frequently used in neonatal intensive care units (NICUs) for blood gas measurements. With POCT, results are immediately available and give the opportunity for prompt correction of treatment if necessary. Recently, more sophisticated multi-parameter analyzers became available. They can perform lactate, calcium, hemoglobin derivates and even bilirubin measurements. Its analytic performance was well established in NICU patients by others [1].

Multi-parameter POCT has the theoretical advantage of less iatrogenic blood loss because the assays can be performed on a smaller volume of capillary blood than the conventional laboratory tests. Very low birth weight infant require frequent laboratory testing causing anemia and need for transfusions. The volume transfused is correlated with the volume of blood removed [2]. Recently, others found an overall reduction in the need for blood transfusion after implementation of a bedside analyzer in their NICU, but they did not study the phlebotomy laboratory blood loss, nor the cost–benefit analysis, nor did they control for patient's morbidity and the impact on all birth weight categories [3].

In our NICU we introduced a bedside multi-parameter POCT analyzer that has the feature to measure bedside blood gases, hemoglobin, serum electrolytes and bilirubin. We hypothesized that the implementation of a multi-parameter POCT analyzer decreased iatrogenic blood loss by reducing the need of conventional laboratory testing in the NICU and as a result could reduce the need for red blood cell transfusion in our NICU patients.

2. Material and methods

This retrospective cohort study over a 4-year period (2006–2009) was carried out in a level III, 26-bed academic NICU at the Antwerp University Hospital, Edegem, Belgium.

All 1397 neonates admitted during the study period were entered into the study. Since 2006 the multi-parameter POCT analyzer (Cobas b221, Roche Diagnostics, Vilvoorde, Belgium) was used in our unit, but without using the chemistry and bilirubin functionality. During

Abbreviations: POCT, Point of Care Testing; NICU, Neonatal Intensive Care Unit; VLBWI, Very Low Birth Weight Infant.

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2006 the performance of the analyzer for bilirubin and blood chemistry was validated with our conventional laboratory tests using arterial blood samples by means of Passing–Bablok regression analysis and Bland and Altman plot.

Quality control materials were used to calculate bias, within-run variation and between-run variation. Correlation studies were performed with patient sera: (1) Omni S with Vitros Fusion (Johnson & Johnson, Beerse, Belgium) for Na, K, Cl, glucose, and bilirubin; (2) Omni S with ABL 605 (Radiometer, Zoetermeer, the Netherlands) for Na, K, Cl, glucose, pH, HCO_3^-, pO_2,and pCO_2; and (3) Omni S with Rapidlab 1265 (Siemens, Brussels, Belgium) for pH, HCO_3^-, pO_2, and pCO_2. Correlation coefficients and Passing–Bablok regression equations were calculated with MedCalc Software (Mariakerke, Belgium). The data are shown in Table 1. Finally, POCT analyzer, including pH, Pco_2, Po_2, base excess, hemoglobin, hematocrit, lactate, sodium, potassium, ionized calcium and total bilirubin measurement functionality, was formally introduced to the NICU on January 2008. In practice, a sample volume of 100 μl blood is needed for bilirubin measurement and 150 μl blood is needed for electrolytes by POCT. When all tests are combined a single capillary blood sample of 200 μl is enough to perform all tests including serum total bilirubin. On the contrary, at least 500 μl whole blood is needed when these tests are performed by conventional laboratory test methods.

Demographic data and comorbidity data of our patients were retrieved from an electronic patient database of the NICU. Data on the use of laboratory services were retrieved from the laboratory department database.

The criteria for transfusion of packed cells in neonates remained unchanged during the whole study period and were based on previously described guidelines. The transfusion threshold for preterm neonates on assisted ventilation ≤28 days was Hb ≤12 g/dl or packed cell volume (PCV) ≤0.40 when FiO2 ≥0.3. In case of FiO2 ≥0.3, the threshold was Hb ≤11 g/dl or PCV ≤0.35. Preterm neonates ≥28 days on assisted ventilation received a RBC transfusion in case of Hb ≤10 g/dl or PCV ≤0.30. Preterm infants on CPAP less than 28 days old had a RBC transfusion threshold of Hb ≤10 g/dl or PCV ≤0.30 while those older than 28 days had a threshold of Hb ≤8 g/dl or PCV ≤0.25. Preterm infants breathing spontaneously with FiO2 ≥0.21 received a RBC transfusion if Hb ≤8 g/dl or PCV ≤0.25. Those without supplemental oxygen therapy when Hb ≤7 g/dl or PCV ≤0.20 [4]. The number of red blood cell transfusions and financial charges for transfusions were retrieved from the central financial service of the hospital. We took into account the charges for blood transfusion refunded by the National Institute for Sickness and Invalidity Insurance in Belgium (RIZIV).

2.1. Statistical analysis

Data from the first cohort (no use of multi-parameter POCT analyzer in period 2006–2007) were compared with those from the second cohort (after the use of the multi-parameter POCT in the period 2008–2009). Dichotomized data were analyzed using Chi-square test or Fisher's-exact test where appropriate. Except for blood transfusions all continuous data were described as median and interquartile ranges and analyzed using the Kruskal–Wallis test. The software, Intercooled STATA 7.0 (1985–2001, Stata Corporation, Texas), was used for data analysis.

Table 2
Comparison of demographic data for the two cohorts.

Characteristics	Pre-POCT cohort[a]	Post-POCT cohort[a]	*P*-value[b]
n	677	720	
Demographic data			
Birth weight, g[c]	2180 (1500–3000)	2135 (1475–2965)	0.46
Weight of <1000 g[d]	57 (8.4)	58 (8.0)	0.80
Weight of 1000–1500 g[d]	113 (16.7)	135 (18.7)	0.31
Gestational age, weeks[c]	34 (31–38)	34 (31–37.5)	0.54
Male[d]	402 (59.4)	419 (58.2)	0.65
Outborn[d]	302 (44.6)	316 (43.9)	0.78
Mutiple birth[d]	90 (13.3)	144 (20)	<0.001

[a] Pre = before introduction Point-of-Care testing (year 2006–2007) and Post = after introduction of Point-of-Care testing (year 2008–2009).
[b] Kruskal–Wallis or X^2test were appropriate.
[c] Median (interquartile range).
[d] n, %.

3. Patients

The ethical review board approved the study and waived the need for parental consent since the study was retrospective, observational in nature and because all data were analyzed anonymously.

4. Results

4.1. NICU morbidity

Throughout the 4-year study period 1393 patients were entered into the study. The number admitted increased significantly from 677 before the implementation of POCT to 720 after the implementation of POCT (+6.2%, $p<.05$). Beside a significantly higher proportion (+6.7%) of twins in the second cohort, the overall morbidity of the 2 cohorts was comparable. Indeed, no differences were found for birth weight, gestational age, gender and place of birth. Also for respiratory, infectious and neurologic comorbidity, no differences were found before and after implementation of POCT. The groups were stratified by birth weight below or above 1500 g (Tables 2 and 3).

4.2. POCT and laboratory tests performed

In the second study cohort the total number of blood samples taken for conventional laboratory test decreased both for bilirubin (−36%) as for electrolyte testing (−32%). Although the blood samples sent to the laboratory decreased significantly in the second

Table 1
Validation of the Omni S instrument: results of the correlation and regression analysis.

Parameter	No. of samples	Correlation coefficient	Slope	Slope (95% CI)	Intercept	Intercept (95% CI)	Mean bias (%)
Na[a]	24	0.9468	0.9667	0.8500–1.1857	6.5	−24.5786–22.7500	0.3
K[a]	26	0.9576	1.098	0.9889–1.2625	−0.3432	−0.9469–0.02778	0.6
Cl[a]	26	0.9402	1.1	0.9667–1.3063	−16.95	−40.1375 to −1.8500	0.5
Glucose[a]	26	0.8792	1.0564	0.8750–1.2778	−2.777	−26.6389–16.0625	0.5
Bilirubin[a]	18	0.9811	0.9538	0.8559–1.0588	0.1192	−0.7588–0.9005	1.0
pH[b]	17	0.9755	0.8386	0.7576–0.9604	1.1707	0.2753–1.7703	0.1
pO_2[b]	17	0.7252	0.9826	0.06049–1.5354	9.8867	−38.8595–46.0173	3.3
pCO_2[b]	17	0.8472	0.9768	0.7895–1.1771	−0.0919	−7.8729–7.0316	2.1
HCO_3-[b]	17	0.9674	0.8554	0.7143–1.000	1.0993	−2.3000–5.0857	–

[a] Correlation between Omnis (Roche) and Vitros Fusion (Johnson & Johnson).
[b] Correlation between Omnis (Roche) and RapidLab 1265 (Siemens).