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Evaluation of the analytical performances of a portable, 18-parameter hemometric system using capillary blood samples for blood donor enrolment

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Background and Objectives Blood donor enrolment process is frequently based on the sole capillary haemoglobin (Hb) evaluation while platelet donors by apheresis also requires platelet (Plt) count. The 'sole Hb' approach prevents a complete donor evaluation and does not allow Plt donor enrolment. To extend blood counts before donations, we evaluated the performances of a multiparametric counter using capillary blood.

Materials and Methods The ABX Micros 60 (Micros 60) blood analyzer was employed on capillary blood and compared with venous counts by a reference counter (Coulter AcT 5diff) in a first series of 416 donors and in a second series of 136, after a 3-month period of routine use of this study counter. An average of 50 μl of capillary blood was collected whose 10 μl had been aspirated by Micros 60.

Results High correlations were found between capillary counts using Micros 60 and venous counts using the reference counter. Mean Plt counts differed of 37×10^9/l less for capillary approach in the first series of comparisons, but decreased to 10×10^9/l less in the second series due to a greater expertise of operators in capillary sampling. All other parameters were accurate and never reached clinical relevance albeit they showed statistically significant differences.

Conclusion Data on Micros 60 demonstrated that capillary predonation counts may represent a feasible and effective approach to realize an accurate enrolment process of blood and Plt donors.

Key words: blood donations, capillary blood counts, portable blood cell analyzer.

Introduction

The enrolment process of whole or blood component donors is based on anamnestic and clinical investigations at the time of donor coming in blood collection unit [1,2]. Although donors' general evaluation requires a common medical expertise in transfusion medicine, the opportunity to check the haematological characteristics of each volunteer donor is often lacking due to the unavailability of most parameters to judge the peripheral blood count profile of a given subject. In fact, the fast measure of haemoglobin (Hb) on capillary blood is the common approach in predonation phase because the rapidity of such a test and the will of avoiding a preliminar venipuncture before donation. Consistently with current European Community (EC) requirements, complete blood counts and leukocyte differentials do not concur to the validation process of collected units but are used for defining donor health, as a part of global donor clinical investigation [1,2]. In this context, the routine use of the mono-parametric Hb evaluation limits the entire predonation clinical/laboratory investigations, preventing a careful donor vigilance prior to donation as a mandatory part of the entire haemovigilance process [3,4]. As far as

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plateletapheresis donors are concerned, the rapid availability of predonation platelet (Plt) count, as a part of a complete blood counts and leukocyte differential, represents a mandatory requirement to enrol these donors into the apheresis procedure [1,2]. Although a venous blood sample could be obtained prior to plateletapheresis by donor's venipuncture, most donors do not comply with multiple venipunctures or some of them might suffer from puncture-related damage of the proper venous access to establish extracorporeal circulation for apheresis device. In this view, we have evaluated the performances of the portable, multiparametric blood analyzer ABX Micros 60 (Micros 60; Horiba ABX, Montpellier, France) aspirating 10-microliter (μl) of capillary blood samples to attempt the widening of predonation blood analysis to a real multiparametric profile. Previous reports on capillary blood counts showed variable results due to discordant results on Plt count that were comparable to venous counts in half of them and underestimated in the remaining reports [5–9]. Particularly, Schalk *et al.* [8] observed statistically significant, but clinically irrelevant, overestimation of Hb, haematocrit (Hct), red blood cell (RBC) and white blood cell (WBC) counts associated with a statistically comparable Plt count in an etherogeneous group of individuals using the Bayer Advia 120 (Bayer, Fernwald, Germany) blood analyzer and about 160 μl of capillary blood. However, the study of Schalk *et al.* [8] was not specifically designed to verify the efficacy of this laboratory device in blood donor enrolment and has been planned for Bayer Advia 120 which is a complex, expensive haematology system for high laboratory routine, requiring the aspiration of a large volume of capillary blood.

Materials and methods

Study population, blood sampling and measurements

A total of 549 whole blood or blood component donors were enrolled in this study into blood collection and component production section area at Transfusional Department Roma Ovest/Immunohematology and Blood Transfusion of S. Camillo Forlanini Hospital of Rome. All donors were enrolled for donation according to current EC guidelines for blood and blood component donor selection [1,2]. Capillary blood was obtained from the lateral site of the third or fourth finger of left hand, after appropriate skin disinfection and puncture with a sterile single-use lancet. The first drop of blood obtained from the finger-puncture was discarded. The next drop (approximately 50 μl) was collected into a capillary blood collection micro-test tube (with a sample capacity up to 200 μl of capillary blood; Horiba ABX Montpellier) with ethylenediaminetetra-acetic acid (EDTA) for anticoagulation. Venous blood was drawn from the sampling-site of the collection bag-systems for whole blood donation or from the sampling-site of apheresis sets in blood component donors. Venous samples were collected in a vacuum tube (4·5 ml, BD Vacutaine; BD, Plymouth, UK) with EDTA. Capillary samples were measured by the portable Micros 60 haematology analyzer that provides a complete blood count with a three-part leukocyte differential and by the standard HaemoCue haemoglobinometer (HaemoCue AB, Angelholm, Sweden). Venous samples were analyzed by Micros 60 and by Coulter AcT 5diff (Beckman-Coulter, Miami, Fl) used as our reference haematology analyzer. Although Micros 60 was designed to work also on venous samples, we chose our routine analyzer Coulter AcT 5diff to generate donors' blood counts that were used as term of comparison because it represents our laboratory reference blood analyzer. The blood count parameters Hb, Hct, WBC, Plt, RBC, mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean platelet volume (MPV; data not shown), mean corpuscular haemoglobin concentration (MCHC), red blood cell distribution width (RDW; data not shown) and leukocyte differentials were all measured by study and reference counters. Reagents and calibration controls were provided by analyzers' manufacturers. Micros 60 performs the quantitative analysis of WBC distribution according to their volume, subdividing them into three subpopulations represented on the dedicated histogram. The principle of determination is based on the volume analysis after the action of a patented lysis reagent, which acts selectively on the cytoplasmic membrane. A system of flags, whose sensitivity can be changed, is dedicated to the analysis of WBC. For leukocyte differentials Micros 60 generated a WBC classification through the identification of three populations, which consisted, respectively, of so-called mid-population including monocytes, of granulocyte population including segmented neutrophils plus eosinophils and basophils and of a lymphocyte population including lymphocytes alone, while the Coulter AcT 5diff worked by classifying the five classical leukocyte populations. Abnormalities in the composition of the three WBC cell population by Micros 60 such as an excessive presence of eosinophils and basophils are detected by specific flags that indicate the presence of a large number of these cells in defined areas suggesting a possible eosinophilia or basophilia, where the detection of these elements exceed respectively 15 and 8% of the total number of granulocytes. In this context, comparison of leukocyte differentials between Micros 60 and Coulter AcT 5diff was limited to the lymphocytes as both absolute and per cent counts.

A first set of comparisons on 413 donors

A first series of 413 consecutive whole blood or blood component donors were enrolled in the study in a time interval of 20 days. All enrolled donors were evaluated for blood counts in a predonation phase by the Micros 60 haematological analyzer using capillary blood samples of 50 μl (aspiration of 10 μl). This first series of donor blood analysis was carried out immediately after the training course had been completed among our involved nurses by the Micros 60 manufacturer. The first 161 capillary samples out of total 413 were measured by both the portable Micros 60 haematology analyzer and the standard HaemoCue haemoglobinometer, to compare the capillary value of Hb obtained by these different systems. In this series, venous samples were also analyzed by Micros 60 in 254 cases out of 413 (to judge the performance of this study counter also on venous samples) and, in all cases, by Coulter AcT 5diff used as our reference haematology analyzer.

The second set of comparisons on 136 donors

A second set of blood count analysis was carried out in a time period of 10 days in 136 additional cases after a 3-month routine introduction of the study Micros 60 system into blood collection and component production section area at our Department. In this time interval, all nurses who were daily in charge of capillary blood measurement by the study Micros 60 system had a complete and prolonged training on capillary blood sampling, according to CLSI H04-A6 'Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens' (http://www.clsi.org/) and on Micros 60 functioning, maintenance and calibration. In this series, all parallel venous samples were analyzed by Coulter AcT 5diff used as our reference haematology analyzer.

Statistical analysis

Statistical analyses were carried out by Statistical Package Stata/SE 10, a version of Stata Software (StataCorp LP, College Station, TX), to create a database and compare obtained data series through the use of paired Student's *t*-test, regression analysis, variation coefficient (CV), mean parameter difference as measure of accuracy. Sensitivity and specificity of the study analyzer Micros 60 were calculated as the ratio between the number of donors excluded by both study and reference analyzers divided by the number of donors excluded by the reference analyzer ×100 (sensitivity) and as the ratio between the number of donors enrolled by both study and reference analyzers divided by the number of donors enrolled by the reference analyzer ×100 (specificity) .

Results

Evaluation of the general performances of the Micros 60 during the first set of comparisons

Data analysis on the first 161 donors indicated that the haemoglobinometer assay overestimated Hb values of a mean figure of 0·36 and 0·37 g/dl (the mean Hb g/dl generated by this test was 15·17) as compared with the correspondent counts obtained by Micros 60 on capillary and AcT 5diff on venous blood, respectively, which, in their turn, generated identical counts averaging 14·81 and 14·80 g/dl respectively. In 254 enrolled donors out of 413, data obtained from venous samples after analysis by study and reference analyzers showed a very high degree of correlation between Micros 60 and AcT 5diff parallel data which for WBC (10^9/l), RBC (10^{12}/l), Hb (g/dl), Hct (%) and Plt(10^9/l) had the following average figures, respectively, in terms of mean parameter difference (correlation coefficient): −0·12 (r = 0·91), 0·10 (r = 0·95), 0·18 (r = 0·97), 0·63 (r = 0·94) and −3·51 (r = 0·91). In the same series (254 donors), the comparison between counts obtained by Micros 60 on capillary and corresponding venous samples showed similar favourable results in terms of mean parameter difference (and correlation coefficient) for WBC (10^9/l), RBC(10^{12}/l), Hb(g/dl) and Hct(%) as follows: 0·24 (r = 0·91), −0·04 (r = 0·94), −0·1 (r = 0·94) and −0·32 (r = 0·90); conversely, Plt(10^9/l) mean difference averaged −31·65 (r = 0·84), anticipating the results obtained in the whole series during Micros 60 capillary and AcT 5diff venous count comparison.

Capillary counts by Micros 60 vs. venous counts by reference analyzer in the first set of comparisons

Table 1 shows this set of results, which indicate high degrees of correlation between Micros 60 capillary data and AcT 5diff venous ones. As revealed by parameter data comparison table, mean differences of counts obtained by Micros 60 and AcT 5diff were never clinically relevant (intended as values consistently < 5% of the mean reference count; mean differences ranged from 0·27 to 3·39% for all non-Plt Micros 60 capillary counts), except Plt (mean difference as referred to the mean reference count was 16·21%.). Particularly, Plt count mean difference averaged $37{\cdot}8 \times 10^9$/l elements less for Micros 60. To note, MCHC was the only count parameter for which we observed a suboptimal degree of correlation between Micros 60 and AcT 5diff (r = 0·23, P < 0·001). On 413 enrolment, we excluded for the sole Hb parameter 13 donors (exclusion rate of 3·1%) by the reference AcT 5diff; 11 out of 13 were also excluded by Micros 60 for a sensitivity of 85%; specificity for Hb was 99% since we included 400 donors by the

Table 1 Comparison of Micros 60 and AcT 5 diff working on capillary and venous samples respectively

		Micros 60 (study)					AcT 5diff (reference)					
Parameters	No of Observations	Mean	SD	CV%	Min	Max	Mean	SD	CV%	Min	Max	Mean differences	*r*
WBC $\times 10^9$/l	413	6·31*	1·6	25·36	1·2	13·8	6·13*	1·48	24·14	2·83	12·04	0·18	0·91*
RBC $\times 10^{12}$/l	413	5·09*	0·4	7·86	3·85	6·31	5·02*	0·41	8·17	3·61	6·21	0·07	0·91*
Hb g/dl	413	14·87*	1·1	7·4	11·6	18·1	14·78*	1·00	6·77	11·5	17·5	0·09	0·89*
Hct %	413	43·24*	3·1	7·17	34	52·8	42·89*	2·93	6·83	33	51·7	0·35	0·87*
MCV fl	413	85·09*	3·5	4·11	72	96	85·65*	3·98	4·65	70·2	98·1	−0·55	0·95*
MCH pg	413	29·28*	1·4	4·78	23·9	33·6	29·52*	1·44	4·88	23·8	33·8	−0·25	0·92*
MCHC g/dl	413	34·39*	0·5	1·45	32·6	36·7	34·47*	0·50	1·45	33	35·9	−0·08	0·23*
Plt $\times 10^9$/l	413	195·84*	40·5	20·68	108	340	233·73*	51·63	22·09	123	428	−37·89	0·82*
Lymphocytes %	413	35·01*	6·9	19·7	12·5	58·5	34·17*	6·61	19·34	11·7	52·9	0·84	0·89*
Lymphocytes $\times 10^9$/l	413	2·13*	0·6	28·17	0·4	4·3	2·06*	0·52	25·24	0·8	4·27	0·07	0·81*

Mean analyzed parameter values, standard deviation (SD), coefficient of variation (CV), minimum (Min), maximum (Max) and correlation coefficients (*r*) are shown. Data analysis was carried out by paired Student's *t*-test, parameter mean differences as a measure of accuracy and regression analysis.
*$P < 0·001$ at Student's *t*-test and regression analysis.

reference system of which 399 were also included by Micros 60. On the same series, we excluded for non-Hb parameters (WBC, Plt, MCV and leukocyte differentials) 12 donors (exclusion rate of 2·9%) by the reference AcT 5diff; 10 out of 12 were also excluded by Micros 60 for a sensitivity of 83%; specificity for non-Hb parameters was 99% since we included 401 donors by the reference system of which 400 were also included by Micros 60.

Capillary counts by Micros 60 vs. venous counts by reference analyzer in the second set of comparisons

This additional comparison showed improved results in terms of accuracy of Plt count, as revealed by regression and comparison data ($r = 0·86$; mean counts 206·9 vs. 216·95 $\times 10^9$/l, standard deviation 45·15 vs. 46·25 $\times 10^9$/l, CV% 21·82 vs. 21·32 for Micros 60 and reference analyzer respectively). As compared with the reference analyzer, the mean difference for Plt count decreased to 10×10^9/l with the maintenance of identical difference and correlations between the remaining blood cell counts and indexes (data not shown). The mean difference between Plt counts generated by Micros 60 and the reference system on capillary and venous blood, respectively, translates into a per cent value of the mean Plt reference count of 4·95%, which, as observed for the other counts both in first and second set of comparisons, represents a clinically irrelevant analytical difference.

Discussion

The results shown in the present report point out that Micros 60 represents a reliable and accurate hemometric system, which generates rapid capillary counts with values showing differences, as compared with values obtained in reference venous samples, within the range of acceptable variability of haematological counters [8]. In addition, the comparison among Micros 60, Haemocue haemoglobinometer (both on capillary blood) and the reference counter (on venous blood) confirmed previous results [10–12], which showed Hb overestimation by haemoglobinometer (higher than 0·35 g/dl in the present study) as compared with a mean difference lower than 0·1 g/dl between capillary Hb by Micros 60 and venous determination by the reference counter. Similar to other reported experience on capillary counts [5–9], consistent and statistically significant differences between the mean values of each counts (capillary vs. venous) had been observed, which, on the other hand, never translated into relevant difference from a clinical point of view. Our results agree with those reported by Daae *et al.* [5], Ozbek *et al.* [6], Kayiran *et al.* [7] and Schalk *et al.* [8] who founds clinically irrelevant overestimation of capillary WBC/RBC/Hb and Hct and underestimation of Plt counts, respectively, as compared with a venous reference approach. MCHC was the sole value for which we found a suboptimal correlation and this fact could be due to the very narrow variation of this parameter into our study population (MCHC coefficient of variation was close to 1·4% in our donors) that could prevent a powerful outcome of linear regression analysis, which works well when sample variation is significantly wide. As additional considerations, we must underline that MCHC showed a lower correlation between capillary and venous counts also in the study of Schalk *et al.* [8] who used the same counter and in our additional comparisons between Micros 60 and the

reference analyzer on parallel venous samples (data not shown); collectively, it can be argued from previous points and from the nature of MCHC, as calculated (and not measured) parameter that MCHC mild variations are calculated without adequate proportions by different counters both on venous and capillary samples. Data on system sensitivity showed satisfactory results with a reduced value as compared to that reported by Schalk *et al.* [8] and higher specificity. Reduced sensitivity of our approach could lie in the use of different counters in the present study while Schalk *et al.* [8] used the same counter for comparison between capillary and venous samples. One of the additional results of this study was the nascent need of defining blood count intervals for additional predonation parameters to enrol donors checked by our multiparametric approach. So, in the area of Lazio, a regional guideline defining multiple blood count safety intervals for donors' enrolment has been introduced after a general consensus, with the following values: 3×10^9/l ≤ WBC ≤ 12×10^9/l, 1×10^9/l ≤ lymphocytes ≤ $4{\cdot}5 \times 10^9$/l, 120×10^9/l ≤ Plt ≤ 500×10^9/l for whole blood donors and 150×10^9/l ≤ Plt ≤ 500×10^9/l for plateletapheresis donors. Our study also demonstrates that, once the ability of nurses in charge of capillary blood collection had been improved by routine use of micro-test tube following the practical principle described by CLSI H04-A6 'Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens' (http://www.clsi.org/), the average difference in Plt counts between capillary counts by Micros 60 and venous counts by the reference system decreased from about 37×10^9/l to 10×10^9/l. This fact indicates the importance of operators' expertise in assuring the good performance of haematological counters working on capillary blood samples. Taken together these data indicate that the portable Micros 60 multiparameter-haematological counter, working on capillary blood, may represents a valid tool to anticipate at the time of donor enrolment most haematological counts which define donors' health status. The entire process lasts no more than 1 min and requires no more than 50 μl of capillary blood to be collected followed by aspiration of 10 μl for each test. These characteristics identifies Micros 60 as well as (as declared by manufacturers) the Abbott Emerald (Abbott, Abbott Park, IL; this instrument is not available yet in Italy), the Mindray BC 3200 (Mindray Bio-Medical Electronics, Shenzen, China) and the Nihon Kohden Celltac Alfa (Nihon Kodhen, Tokyo, Japan) but are currently lacked by other counters of the same class such as Diatron Abacus Plus (Diatron, Vienna, Austria), Beckman Coulter Act Diff (Beckman Coulter, Fullerton, CA), Abbott Cell Dyn 1800 (Abbott) and Sysmex KX 21 (Sysmex Corporation, Kobe City, Japan). In conclusion, our data on multiparametric capillary counts are in line with previous reported experiences on similar analytical approaches [5–9] and appear useful, time-sparing and, likely, cost effective as compared with the more common process that includes predonation capillary blood Hb evaluation followed by complete blood counts performed on venous samples after donations. From a general point of view, the approach described of anticipating more analyses during the predonation phase should be limited to those laboratory parameters that give a substantial contribution to donors' enrolment process (in our view only blood counts belong to them) and may help physicians also to defer of some days or weeks donations of those donors who are experiencing a reversible alterations of their haematological status deriving from temporary infections, avoiding the elimination of donations which could be easily postponed.

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