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SHORT ORIGINAL ARTICLE

CLINICAL UTILITY OF A WHITE BLOOD CELL AND DIFFERENTIAL COUNT POINT-OF-CARE TEST AND AGREEMENT WITH ROUTINE LABORATORY

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SUMMARY

White blood cell (WBC) and differential leukocyte counts are well-known markers of infection. This study was aimed at assessing the clinical utility and agreement of the results obtained with a point-of-care test known as WBC-DIFF compared to those obtained by a centralised laboratory. Capillary samples were taken from healthy subjects aged 14 or more in two consultations. Agreement analyses were performed comparing the two results. Forty-four subjects were recruited, with a mean age of 52.6 ± 15.3 years. The mean number of WBCs measured with the WBC-DIFF was 6,968,2 ± 1,910 cells/µL compared to 7,153,8 ± 2,005 cells/µL reported by the reference laboratory. Good agreement was observed, with no significant differences between the two measurements as the number of cases deviating more than 15% of difference between the two distributions was 22.7%. However, this deviation was 36.4% for neutrophils, 43.2% for eosinophils, 52.3% for lymphocytes, 68.2% for basophils and 100% for monocytes.

Utilitat clínica d'una prova ràpida de comptatge leucocitari i fórmula leucocitària i concordança amb l'anàlisi de laboratori de rutina en adults sans.

El comptatge leucocitari i fórmula són marcadors ben coneguts d'infecció. L'objectiu d'aquest estudi va ser avaluar la utilitat clínica i concordança dels resultats obtinguts amb una prova ràpida conegut com WBC-DIFF amb els resultats del laboratori. Es van prendre mostres capil·lars de subjectes sans d'edat ≥ 14 anys en dues consultes. Es realitzaren anàlisis de concordança comparant ambdós resultats. Es van reclutar 44 subjectes, amb una edat mitjana de 52,6 ± 15,3 anys. El nombre mitjà de leucòcits mesurat amb el WBC-DIFF fou 6.968 ± 1.910 cèl·lules/µL i 7.153 ± 2.005 cèl·lules/µL amb el laboratori de referència. S'observa una bona concordança, sense diferències significatives entre les dues mesures; el nombre de casos amb > 15% de desviació entre les dues distribucions va ser 22,7%. No obstant això, aquest desviament va ser 36,4% per als neutròfils,43,2% per als eosinòfils, 52,3% per als limfòcits, 68,2% per als basòfils i 100% per als monòcits.

Utilidad clínica de una prueba rápida de recuento leucocitario y fórmula leucocitaria y concordancia con el análisis de laboratorio rutinario en adultos sanos.

El recuento de leucocitos y fórmula son marcadores bien conocidos de infección. El objetivo de este estudio fue evaluar la utilidad clínica y concordancia de los resultados obtenidos con una prueba rápida conocida como WBC-DIFF con los resultados del laboratorio. Se tomaron muestras capilares de sujetos sanos de ≥14 años en dos consultas. Se realizaron análisis de concordancia comparando los dos resultados. Se reclutaron 44 sujetos, con una edad media de 52,6 ± 15,3 años. El número medio de leucocitos medidos con WBC-DIFF fue 6.968 ± 1.910 células/µl y 7.153 ± 2.005 células/µl con el laboratorio de referencia. Se observó una buena concordancia, sin diferencias significativas entre las dos mediciones; el número de casos con más del 15% de desviación entre las dos distribuciones fue de 22,7%. Sin embargo, esta desviación fue 36,4% para los neutrófilos, 43,2% para los eosinófilos, 52,3% para los linfocitos, 68,2% para los basófilos y 100% para los monocitos.

INTRODUCTION

White blood cell and differential leucocyte counts are well-known markers often used to differentiate between bacterial and viral infections[1,2]. The WBC-DIFF (HemoCue AB, Ängelholm, Sweden) is a point-of-care testing (POCT) instrument for white blood cell and differential counts. The main advantage of this test is its shorter turnaround time to obtain results compared with the classical determination in a central laboratory, with the results being available within five minutes after a

fingerpick procedure. This fact is crucial in primary care as these tests can be carried out in seven-to-ten-minute consultations. This study was undertaken to assess the clinical utility and agreement of the WBC-DIFF POCT results compared to those obtained by a centralised laboratory.

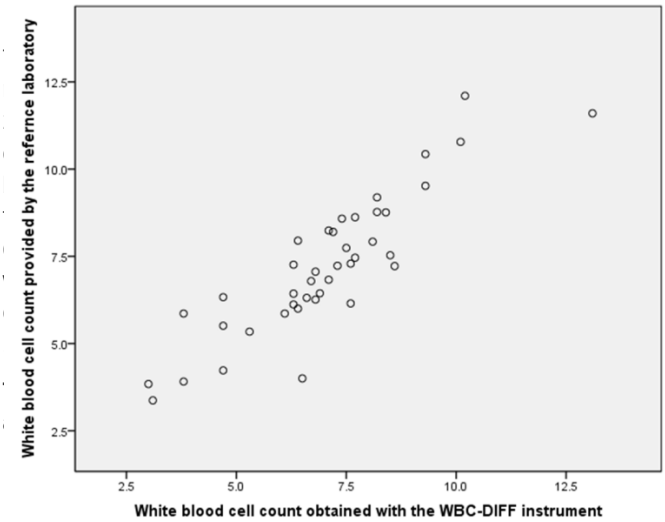
MATERIAL AND METHODS

Capillary samples were taken from healthy subjects aged 14 or more in two consultations at an urban healthcare centre. Individuals undergoing routine blood analyses on Friday from April to June 2015 were recruited to participate in the study. After signing the informed consent, the participants' temperature was measured, and venous blood was drawn by nurses and sent to the central laboratory and then the WBC-DIFF POCT was performed. Agreement analyses were performed comparing the results obtained with the POCT with those of the central laboratory analysed by the Automated Hematology Analyzer XN series XN-20. The Student's t tests were performed to determine the difference between the two measurements, and a Bland-Altman plot of the difference between the means of the two methods was made[3]. We also calculated the percentage of the test results deviating more than 15% between the determinations of the two methods recommended as a quality control measurement in the last Clinical Laboratory Improvement Amendments issued in 1988 (CLIA-88)[4].

RESULTS

A total of 45 subjects were recruited; however, one was discarded as WBC-DIFF did not provide a valid result. The mean age of the 44 individuals was 52.6 ± 15.3 years, 30 of whom were women (68.2%). The mean temperature was 35.7 ± 0.6ºC. The mean number of white blood cells measured with the WBC-DIFF POCT was 6.97±1.9 cells/mm^3 compared to 7.15±2.01 reported by the reference laboratory. Good agreement was observed, with no significant differences between the two measurements, indicating that the two distributions were related (**Figure 1**). The mean neutrophil counts were 3.63±1.34 and 4.04±1.60, respectively, whereas the mean lymphocyte counts were 2.72±0.96 and 2.33±0.86 (**Table 1**). No agreement was observed among the differences in the leukocyte counts between the two determinations. The number of cases not fulfilling the CLIA-88 recommendations (more than 15% of difference between the two distributions) was 22% for the white blood cell count, 36.6% for neutrophils, 43.9% for eosinophils, 51.2% for lymphocytes, 68.3% for basophils and 100% for monocytes.

Figure 1. Correlation between the white blood cell counts analysed by the Automated Hematology Analyzer XN series XN-20 and HemoCue WBC-DIFF instrument (the HemoCue WBC-DIFF values are presented on the x axis and the central laboratory values are presented on the y axis)



DISCUSSION

These results show that the WBC-DIFF POCT is a good instrument for the quantitative determination of whole white blood cell count in the general population. The instructions are easy to follow, and the instrument can be used by professionals with no previous experience in laboratory technology. However, with regard to the differential counts, the agreement was weaker, and less than half of the neutrophil and eosinophil results were not in accordance with CLIA-88. The small differences observed between these counts and the reference measurement may not be clinically meaningful, but the differences observed in the other counts (lymphocytes, monocytes and basophils), which were similar to what has been described in previous studies, might be clinically misleading[5-8]. In our study the count of neutrophils was higher with the POCT whereas the lymphocyte count was lower with the rapid test compared to those provided by the central laboratory, similarly to what Karawajcyk et al showed in a recent study with paediatric population[8].

In conclusion, WBC-DIFF appears to be a good instrument regarding the quantitative count of leucocyte, but its utility in terms of the differential count is not optimal. The utility of this POCT should now be analysed in patients with infectious diseases.

Table 1. Results obtained with the WBC-DIFF rapid test and those obtained by a centralised laboratory.

White blood cells	WBC-DIFF (mean of cells/µL, SD)	Central laboratory (mean of cells/µL, SD)	Difference between the two determinations (mean of cells/µL, SD)	Differences greater than 15% between the two determinations (n, %)
Overall WBC count	7,153.8 (2,005.2)	6,968.2 (1,910.0)	- 186.1 (95.6)	10 (22.7)
Neutrophils	4,040,5 (1,600.2)	3,634.1 (1,335.2)	-376.1 (59.1)	16 (36.4)
Lymphocytes	2,328.8 (858.2)	2,720.5 (958.1)	360.0 (51.2)	23 (52.3)
Monocytes	546.4 (155.6)	450.0 (140.6)	-87.6 (16.8)	44 (100)
Eosinophils	190.2 (139.1)	145.5 (84.8)	-51.0 (8.4)	19 (43.2)
Basophils	48.3 (21.5)	0 (-)	-49.0 (2.1)	30 (68.2)

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Conflicts of interest

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