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ORIGINAL ARTICLE

Performance Evaluation of Automated Immunohematology Analyzer IH-500 for Blood Bank Testing

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Abstract The automated immunohematology analyzer IH-500 (Bio-rad, Cressier FR, Switzerland) was developed recently for blood bank tests and this study evaluated performance of IH-500. 200 blood samples for ABO/Rh typing were collected. ABO/Rh typing results measured by IH-500 was compared with conventional manual methods. Antibody screening tests were performed with 100 samples using both IH-500 and the Ortho BioVue System, and results were compared. Antibody identification tests were conducted on 5 samples using both IH-500 and the Ortho BioVue System and results were compared. Crossmatching was performed with both IH-500 and conventional manual tube method using 4 patient serum samples and 10 blood cell donors, and 40 results were compared. Isoagglutinin titer of anti-A and anti-B was determined in 10 samples using both IH-500 and the automated analyzer Ortho AutoVue Innova and concordance rates were obtained. The concordance rates of ABO/Rh typing, antibody screening test, antibody identification test, and crossmatching between comparative manual methods and the IH-500 were all 100%. In the evaluation of isoagglutinin titer, 8 (80.0%) results out of 10 samples (80%) showed results within ± 1 titer between the IH-500 and the AutoVue Innova, which indicates the concordance rates of 80.0%. IH-500 reported results with two titers lower than Ortho AutoVue Innova in two samples. The IH-500 demonstrated good concordance rates and provided reliable results compared to comparative manual methods in the blood bank testing. IH-500 would be useful as a possible replacement for conventionally performed manual methods in blood bank testing.

Keywords Blood bank testing · Evaluation · IH-500 · Performance

Introduction

In some clinical situations blood transfusion regards as the only intervention that is able to save life rapidly; however, blood transfusion is also therapy that involves life threatening risk [1]. The top priority for the blood bank tests is to provide safe and appropriate blood products to the right patient at the right time and for the right reasons. The regulatory guidelines and operational recommendations for blood bank tests are designed to minimize risk, laboratory errors remain as a function of human interventions and the number of steps in the testing procedures [2]. The Serious Hazard of Transfusion (SHOT) report also noted that there were a considerable number of errors due to mishandling and storage of blood products [3]. Automation of blood bank testing seems to be the only solution to cope with the sophisticated manual procedures in hospital blood banking [4]. Implementation of fully automated analyzers in the blood bank tests have facilitated human error reduction, technique standardization workflow and improved turnaround time. In addition, a traceable database of laboratory records can be achieved as the image captured in the interpretation of reactions can be stored permanently [5]. From an occupational safety and health perspective, the biological safety of the operators can also be improved by adoption of automated systems with minimal sample handling procedures that reduce the operators' exposure to potentially hazardous biological materials [6].

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In order to improve blood bank testing safety and efficiencies, automated instrument platforms have been developed in the past decade [7]. There are several published studies comparing the efficiency of different automated platforms with manual methods [8–15]. Although all these automated methods have significantly contributed to the improvement of test performance and finally to the patient's safety, none has been proven to be superior to others. The automated immunohematology analyzer IH-500 (Bio-rad, Cressier FR, Switzerland) was developed recently as automated analyzer for blood bank tests and this study evaluated performance of IH-500.

Materials and Methods

ABO/Rh Typing

This study was approved by the institutional review board of author's institution. For the performance evaluation of ABO/Rh typing results obtained from IH-500, total 200 samples collected at author's institution from 25 July to 27 July 2017 were enrolled. ABO/Rh typing results measured by IH-500 was compared with those obtained from the conventional manual tube and slide methods. The antiserums used in slide method for ABO/Rh typing were murine IgM monoclonal anti-A and anti-B and human IgG/IgM monoclonal anti-D (BioClone, Ortho Clinical Diagnostics, Raritan, USA), and laboratory-made cells were used in tube method for ABO/Rh typing. For the IH-500, the DiaClon ABO/Rh Reverse Grouping ID Card (Bio-rad, Switzerland) was used for ABO/Rh typing. For the conventional manual methods and IH-500, labeling of testing tiles and tubes, manual pipetting of sample and reagents are done by technicians following standard testing procedures as recommended by the manufacturer and laboratory guidelines. The comparison results were represented in Table 1.

Table 1 Comparison of ABO/Rh typing results between IH-500 and manual method

ABO typing	IH-500				Total
	Group A	Group B	Group O	Group AB	
Manual method					
Group A	50	0	0	0	50
Group B	0	50	0	0	50
Group O	0	0	50	0	50
Group AB	0	0	0	50	50
Total	50	50	50	50	200
Rh typing	IH-500				
	D-positive		D-negative		Total
Manual method					
D-positive	199		0		199
D-negative	0		1		1
Total	199		1		200

Table 2 Comparison of antibody screening test results between IH-500 and manual method

Antibody screening test	IH-500		
	Positive	Negative	Total
Manual method			
Positive	50	0	50
Negative	0	50	50
Total	50	50	100

Antibody Screening and Identification Tests

For the evaluation of antibody screening tests obtained from IH-500, total 100 samples collected during same evaluation periods of ABO/Rh typing were selected. Antibody screening tests were performed using both IH-500 which uses automated column agglutination technique and the Ortho BioVue System (Ortho Clinical Diagnostics, Raritan, USA) which uses manual column agglutination technique, and both results were compared. The Ortho BioVue System used Ortho BioVue AHG cassette with Selectogen I, II as reagents and the IH-500 used LISS/Coombs card. The comparison results were summarized in Table 2. Additionally, total 5 samples with positive results in the antibody screening tests in both methods were selected and antibody identification tests were subsequently performed. For the antibody identification tests, the Ortho BioVue system used Ortho BioVue AHG cassette with Resolve Panel A as reagents and the IH-500 used LISS/Coombs card. The antibody identification results obtained from two methods were compared.

Crossmatching

For the evaluation of crossmatching results measured from IH-500, total 40 results obtained from 4 patient serum samples and 10 blood cell donors were selected. Crossmatching tests were performed with both IH-500 and conventional manual tube method, and total 40 results obtained from two methods were compared. The comparison results were described in Table 3.

Table 3 Comparison of crossmatching results between IH-500 and manual method

Crossmatching	IH-500		
	Compatible	Incompatible	Total
Manual method			
Compatible	19	0	19
Incompatible	0	21	21
Total	19	21	40

Isoagglutinin Titer

Finally, the isoagglutinin titer of anti-A and anti-B was determined in 10 samples using both IH-500 and the automated analyzer Ortho AutoVue Innova (Ortho Clinical Diagnostics, Raritan, USA) and concordance rates between two results were obtained. Final results with ''1+'' were determined as the endpoint titer and the "concordance" was determined when the differences between two results are within 1 titer. The comparison results were summarized in Table 4. In addition, summary of equipments and reagents used in IH-500 and compared manual or automated methods in the present evaluation were given in Table 5.

Results

ABO/Rh Typing

Among 200 samples tested for ABO typing, blood group A, B, O and AB were identified in each 50 sample by manual method, and 199 Rh positive case and 1 Rh negative case also were also identified by manual method. The concordance rates between IH-500 and manual methods were determined to be 100% in ABO typing, and also to be 100% in Rh typing (Table 1).

Antibody Screening and Identification Tests

Among 100 samples, 50 cases were positive in antibody screening test and 50 cases were negative in antibody screening test by manual method. The concordance rates between IH-500 and manual method were determined to be 100% (Table 2). On antibody identification test, 5 samples with positive antibody screening test results showed 1 sample for anti-Jka antibody, 2 samples for anti-Fyb antibody, 1 sample for autoantibody, and 1 sample for unidentified antibody by manual method. In IH-500, results of antibody identification test were concordant with those by manual method, except for one case with unidentified antibody from IH-500, while results provided as autoantibody by manual method. Since RBC transfusion strategy in patient with autoantibody and unidentified antibody would be expected to be identical, which is transfusion of at-least incompatible RBCs, we expected that the difference between autoantibody and unidentified antibody in terms of clinical transfusion risk would not be significant and therefore, the concordance rate between comparative manual method and the IH-500 would be expected to be 100% (Data not shown).

Crossmatching

Among 40 results for crossmatching, 19 tests showed compatible and 21 tests showed incompatible by manual

Table 4 Comparison of isoagglutinin titer obtained from IH-500 and automated method Ortho AutoVue Innova

Titer (AutoVue)	Titer (IH-500)					
	Anti-B			Anti-A		
	≤ -2 titer	Within $\pm$ 1 titer[b]	≥ 2 titer	≤ -2 titer	Within $\pm$ 1 titer[b]	≥ 2 titer
1:1		1				
1:2						
1:4					1	
1:8		1			1	
1:16		2				
1:32					1	
1:64	1[a]					
1:128				1[a]	1	
Total (n = 10)	1	4		1	4	

[a]Indicates discrepant results between titers from IH-500 and Autovue, producing two titers lower in IH-500 compared to Autovue

[b]Within $\pm$ 1 titer regard as concordant results between two methods

Table 5 Summary of equipments and reagents used in IH-500 and compared manual or automated methods in the present evaluation

	IH-500	Compared manual or automated methods
ABO/Rh typing	DiaClon ABO/Rh Reverse Grouping ID Card	BioClone and laboratory-made cells
Antibody screening test	LISS/Coombs card	Ortho BioVue System using Ortho BioVue AHG cassette with Selectogen I, II
Antibody identification test	LISS/Coombs card	Ortho BioVue system using Ortho BioVue AHG cassette with Resolve Panel A
Crossmatching	LISS/Coombs card	Manual tube method
Isoagglutinin titer	LISS/Coombs card	Ortho AutoVue Innova used LISS/Coombs card

method, and IH-500 showed exactly identical results. The concordance rate between comparative manual method and the IH-500 was 100% (Table 3).

Isoagglutinin Titer

In the evaluation of isoagglutinin titer, 8 (80.0%) out of 10 samples showed results within ± 1 titer between the IH-500 and the AutoVue Innova, which indicates the concordance rates of 80.0%. Interestingly, IH-500 reported results with two titers lower than results measured by AutoVue Innova in two samples. Those two results included one case with titer of 1:32 for IH-500 and 1:128 for AutoVue Innova, and the other case with titer of 1:64 for IH-500 and 1:256 for AutoVue Innova (Table 4).

Discussion

Although there are some previous studies that evaluated performance of IH-500 for ABO/Rh typing [16] or ABO/Rh typing and antibody screening test [17], but to our knowledge, comprehensive study that evaluated performance of IH-500 for blood bank tests including ABO/Rh typing, antibody screening and identification test, crossmatching, and detection of isoagglutinin titer in single study has not been performed. Our present study evaluated detailed performance of IH-500 focused on these issues.

Our present study showed that the IH-500 yielded concordant results compared to conventionally used manual or automated methods in the testing of ABO/Rh typing, antibody screening and identification, and crossmatching. Although IH-500 and manual method showed one case with unidentified antibody from IH-500, while results provided as autoantibody by manual method in the evaluation of antibody identification test, it can be speculated that concordance rate between comparative manual method and the IH-500 would be still satisfactory because the RBC tansfusion strategy in patient with autoantibody and unidentified antibody would be expected to be identical, which is transfusion of at-least incompatible RBCs in both situations.

For detection of isoagglutinin titer, our present study also demonstrated satisfactory concordance rates between IH-500 and currently used automated analyzer AutoVue Innova, which is expected to be 80.0%. Of note, the IH-500 showed less sensitive isoagglutinin titers in two out of ten cases compared to AutoVue Innova. These results are partly concordant with the previous study which reported that AutoVue Innova is highly sensitive than manual method in the detection of isoagglutinins or RBC auto- and/or alloantibodies [9, 18], and may suggest that IH-500 would be more concordant with manual method which is considered to be current reference method in the detection of isoagglutinins compared to AutoVue Innova. Even though the presence of isoagglutinin or RBC auto- and/or alloantibodies with weak strength can be clinically significant findings, high sensitivity in the detection of isoagglutinin or RBC auto- and/or alloantibodies with weak strength can also lead to increased costs and delay in transfusion due to the repeat testing required resolving the anomalous results. Therefore, we rather could suggest that IH-500 would be superior to the AutoVue Innova in the detection of isoagglutinin titers. In addition, our present results may suggest that the application of IH-500 would reduce the unnecessary implementation of therapeutic plasmapheresis in patients with weak isoagglutinin titers when ABO-incompatible organ transplantation is considered. Since plasmapheresis has adverse reaction caused from use of significant amount of anticoagulants, the application of IH-500 may also decrease the adverse effect of plasmapheresis. However, it can be also expected that less sensitivity of IH-500 may increase the rejection induced by insufficient removal of isoagglutinin. Our present study did not evaluate the clinical usefulness of IH-500 in terms of isoagglutinin removal by plasmapheresis in patients who are candidates for ABO-incompatible organ

transplantation and it can be another important issue to be addressed in future study.

Our present study has some major limitations. As we discussed previously, our present study did not evaluate the clinical usefulness of IH-500 in terms of isoagglutinin removal by plasmapheresis in patients who are candidates for ABO-incompatible organ transplantation and also, our present study did not evaluate the performance of IH-500 compared to manual method in the detection of isoagglutinin titers. Therefore, our present results in terms of clinical usefulness of IH-500 caused from less sensitivity, in which we discussed previously, should be interpreted with caution and this issue should be evaluated in more comprehensive study in the future.

In conclusion, our present study showed that the IH-500 demonstrates good concordance rates and provided reliable results compared to comparative manual and/or automated methods in the blood bank testing. It can be expected that the IH-500 would be useful as a possible replacement for conventionally performed manual and/or automated methods in the era of blood bank testing.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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