Development of a Point Of Care Testing device for bedside pre-transfusion ABO assay.

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Introduction

Between 1996 and 2004 the Serious Hazards of Transfusion Scheme in UK estimated that the risk of ABO incompatible transfusion was 1:100000. Since 2003, the French authorities have introduced a systematic bedside ABO agglutination test checking that the right blood is given to the right patient and the incidence of ABO incompatible transfusions significantly decreased. This strategy requires an extremely time-consuming learning program and relies on a subjective interpretation of cardboard agglutination. At present, there is no commercially available automated Point-Of-Care-Testing (POCT) for bedside ABO agglutination assay. We developed a prototype of a fully automated device performing the agglutination bedside test that could be completed by reading the bar-coded wristband. (*Patent WO 2013/083619*)

Materials and methods

The evaluated device is a prototype mostly developed in our laboratory including 6 assay positions enabling it to determine simultaneously the ABO group of the blood donor and the recipient. Each test unit contains a fixed membrane. If the corresponding antigen is present on the red cells, the specific antigen-antibody reaction will result in a hemagglutination on the surface of the membrane. Only free erythrocytes can pass through the membrane, in the case of hemagglutination, red cells will stay at the surface of the membrane. The presence of free erythrocytes is detected by Infrared absorption measurements. The results are translated into a graph (**figure 1**). The prototype results were validated in comparison with a gel assay (Bio-Rad).

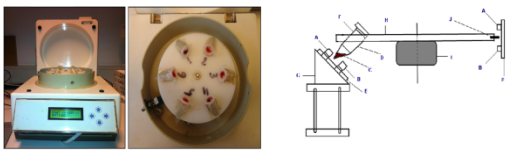

Figure 1: Prototype for bedside ABO determination including 2x3 assay units containing anti-A, anti-B and buffer as an internal control.

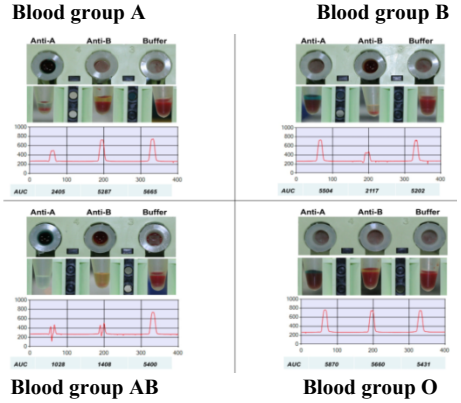

Figure 2: Hemagglutination tests results and graph representation of the ABO blood group determination using the prototype

Overall 450 samples were tested in 3 successive series of validation. The first validation was performed on samples from 238 blood units. The second validation phase was performed on 137 random EDTA blood samples collected from consecutive unselected patients for whom a blood group had been requested. The third validation was performed on 76 pathological EDTA blood samples (Table1).

Table 1: Pathological samples

Pathological parameters	N=
MCV ↑ (85-118fl)	20
MCV ↓ (67-80fl)	16
Sickle cells	10
Poly-transfused patients	8
HCT ↓ (17.6-35.8%) with DAT-	4
DAT+ with normal HCT	7
DAT+ with cold agglutinins	1

DAT: Direct antiglobulin test; HCT: hematocrit; MCV: Mean corpuscular volume

Results

We observed 100% concordance between POCT groups and the ABO determined with the automates for all samples from blood donors and patients (**Table2** and **Table3**).

Table2. First validation: results obtained from the prototype compared with the known blood group of the donor

Blood group Prototype	Donor blood O	Donor blood A	Donor blood B	Donor group AB
O	100	0	0	0
A	0	80	0	0
B	0	0	38	0
AB	0	0	0	20

Table3. Second validation: results obtained from the prototype compared with known patient group

Blood group Prototype	Blood group O	Blood group A	Blood group B	Blood group AB
O	60	0	0	0
A	0	45	0	0
B	0	0	22	0
AB	0	0	0	10

However among pathological samples 3 blood groups (**Figure3a**) could not be reported, one for agglutination in the control due to cold agglutinins (**Patient#2**), one for a double population secondary to previous transfusions (**Patient#1**) and the third was due to the discordance with the A blood group result in the medical blood bank file due to iterative transfusions in a new born with O blood (**Patient#3**).The routine gel technique gives the same results (**Figure 3b**).

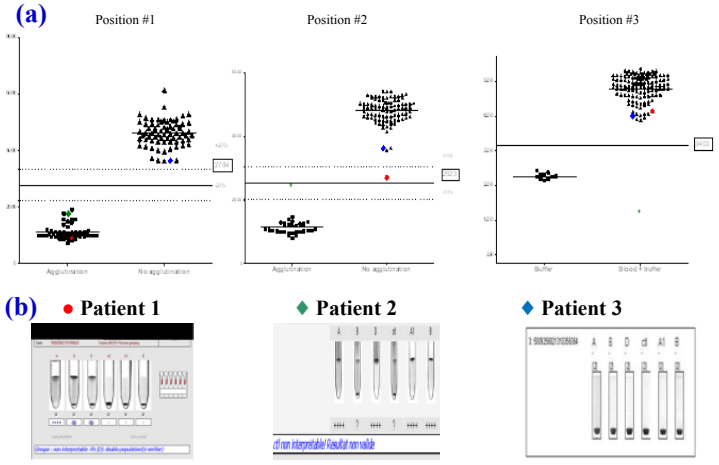

Figure 3: Agglutination data obtained for three samples giving ininterpretable results (**a**) using the prototype or (**b**) the gel technique (● Patient 1; ♦ Patient 2; ♦ Patient 3).

Conclusion

These preliminary results demonstrate the feasibility of ABO determination with a POCT that eliminates manipulation and subjective interpretation responsible for ABO errors. Such a device should be linked to the blood bank information system allowing both cross check of the results obtained with the record of the patient and the blood bag, and alarm to the blood banker in case of incompatibility. Such a device could increase transfusion safety by reducing ABO testing failure.