Preliminary Clinical Method Comparison of a Point-of-Care Platform for anti-Factor Xa in Pediatric Patients on Heparin Therapy

[1]Nsonwu-Farley J, [1]Aljudi A, [2]Basmajian M, [1]Lam W, [2]Sista R, [2]Pamula V, [1]Rogers B

[1]Children's Healthcare of Atlanta, Atlanta, GA 30322; [2]Baebies, Inc., Durham, NC 27703

Poster A-329

BACKGROUND

- Frequent monitoring for anti-Factor Xa activity (aFXa) and/or activated partial thromboplastin time (aPTT) is required for children receiving heparin therapy to achieve hemostatic balance, but current heparin tests require large blood volumes which may cause iatrogenic anemia.
- We performed a clinical method comparison (12/08/2022 – 6/15/2023) of a rapid (~14-minute), point-of-care digital microfluidic (DMF) platform for aFXa testing at the bedside in real-time directly from low whole blood sample volume (<50 µL) against an FDA-cleared comparator.

METHODS

- The aFXa assay is performed by separating whole blood into plasma on the DMF cartridge before incubation with exogenous FXa and fluorogenic substrate. The resulting fluorescence is inversely proportional to the concentration of heparin in the sample.
- All required reagents for the aFXa assay are dried within the cartridge, allowing for automated sample preparation and assay runs.
- To establish feasibility of the aFXa DMF assays, preliminary precision and method comparison studies were performed on two DMF instruments installed at Children's Healthcare of Atlanta (CHOA).
- Precision was obtained on the DMF platform with aFXa commercial controls.
- A preliminary method comparison study was performed using remnant whole blood samples (<50 µL) from pediatric patients (0.5 – 238 months in age with 27 males and 37 females) administered unfractionated or low molecular weight heparin during routine standard of care testing under an approved IRB protocol. Matched patient samples were measured on the DMF platform and the FDA-cleared comparator (STA®-Liquid Anti-Xa).

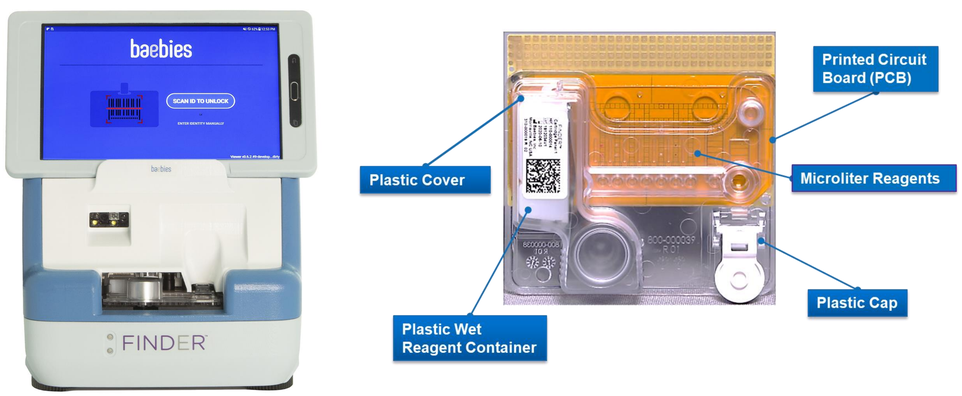

Figure 1. Baebies' point-of-care DMF platform for rapid aFXa testing during heparin monitoring.

RESULTS

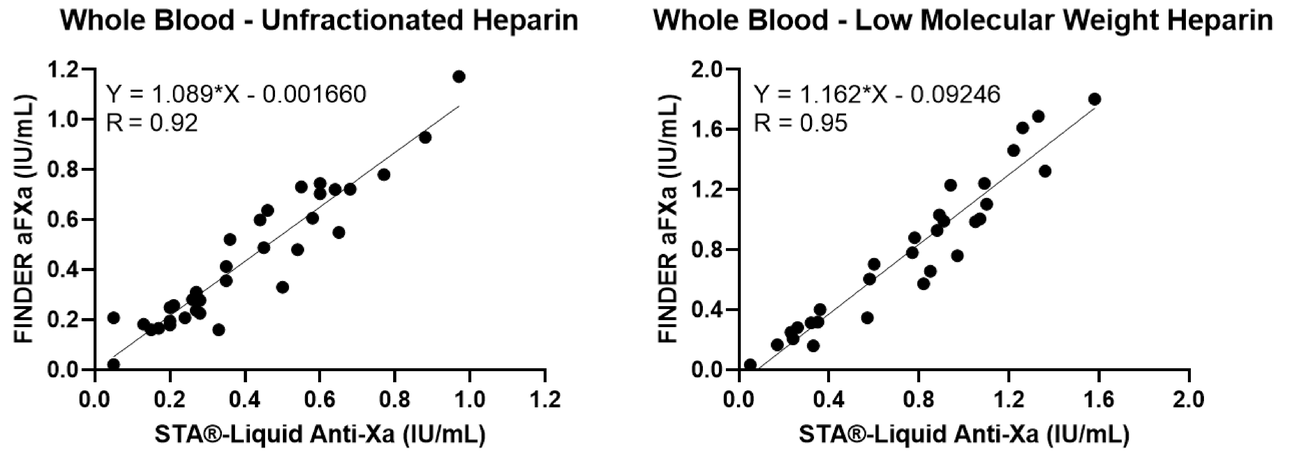

Figure 2. Method comparison for the aFXa assay in whole blood samples collected with either unfractionated (left; n=34) or low molecular weight heparin (right; n=30) and run on the digital microfluidic platform (y-axis), plotted against the STA®-Liquid Anti-Xa with matched whole blood samples (x-axis).

- For UFH precision, we measured assay coefficient of variation (CV) of 4.7% and 6.6% at 0.98 IU/mL (n=19) and 0.42 IU/mL (n=20), respectively.
- For LMWH precision, we measured assay coefficient of variation (CV) of 4.0% and 3.9% at 0.71 IU/mL (n=30) and 0.40 IU/mL (n=28), respectively.
- The aFXa assay on the DMF platform correlates well to the comparator device in both sample matrices tested, with an R value of 0.92 (n=34) and 0.95 (n=30) for whole blood samples collected in unfractionated or low molecular weight heparin, respectively.

CONCLUSIONS

- **The DMF aFXa test correlated exceptionally well with an FDA-cleared test using whole blood. A multi-site clinical method comparison is underway to establish clinical performance of the DMF aFXa test.**
- **Using <50 µL sample volume and a rapid ~14-minute turnaround time at the patient bedside, the DMF aFXa test is ideal for heparin monitoring — especially for pediatric patients susceptible to iatrogenic anemia.**

Research reported here was supported by the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health under award #R44HL140662. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. RS and VP have stock options at Baebies.

Not available at this time for sale or use in any territory