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Research Letter

Clinical utility and limitations of FibCare® for the rapid measurement of fibrinogen concentrations: The first clinical experience

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Dear Editor:

For managing obstetrical hemorrhage, rapid and accurate determination of fibrinogen concentrations is necessary to establish a timely hemostatic intervention [1]. However, conventional plasma fibrinogen assays commonly use the Clauss method (Standard-Fib) that usually takes 30–60 min [2,3], thus limiting prompt treatment. FibCare® (Atom Medical Co., Tokyo, Japan), a novel and commercially available device approved for clinical use by the Ministry of Health in Japan, enables rapid measurements of fibrinogen concentrations in whole blood using modified Clauss methods (FibCare-Fib). Herein, we report the time-saving efficacy and accuracy of FibCare® compared to conventional assays in actual clinical settings.

After obtaining Institutional Review Board approval and informed consent, 25 sample pairs of Standard-Fib and FibCare-Fib analysis were simultaneously collected from 23 pregnant/postpartum women who needed fibrinogen concentration measurements due to obstetrical diseases, including massive hemorrhage. Standard-Fib was measured using CS-5100 (Sysmex Co., Hyogo, Japan) with Thrombocheck Fib(L) (Sysmex Co.) as the standard. FibCare-Fib was measured according to the manufacturer's instructions. All measurements were performed by trained laboratory technicians or doctors.

As shown in Fig. 1A, a simple linear regression analysis revealed an extremely strong correlation between Standard-Fib and FibCare-Fib results ($r = 0.99$, $p < 0.0001$). Moreover, FibCare® required 4.4 min on average (range, 2.68–6.55 min) to obtain the results, which shortened the overall measurement time by an average of 35.7 min (range, 20.8–109.1 min). The FibCare® showed significantly higher mean fibrinogen concentrations compared with conventional methods (314.3 ± 142.3 vs 264.2 ± 115.3 mg/dL, respectively; $p < 0.0001$). To decrease the differences, the results of FibCare-Fib were corrected based on the following calculation: adjusted FibCare-Fib = the FibCare-Fib × 0.84 (264.2/314.3: ratio of each average value). By using the adjusted FibCare-Fib, the Bland–Altman analysis showed excellent agreement between the conventional assay and the FibCare® measurement. The bias was −0.2 mg/dL, the SD of the differences was 16.3 mg/dL, and the 95% limits of agreement were −32.2 to +31.8 mg/dL (Fig. 1B).

The only problem with FibCare® that has been identified is the experimental cost increasing nearly four times as much per measurement compared with the conventional assay. However, the cost is expected to be reduced by market expansion, and thus

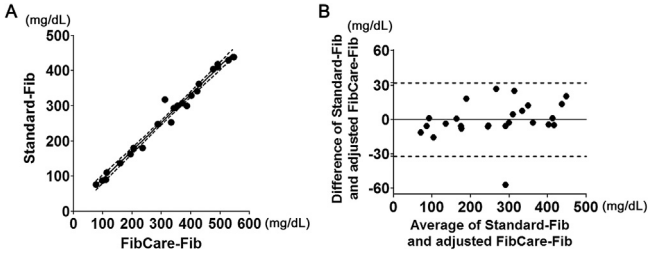

Fig. 1. (A) Simple linear regression analysis. $r = 0.99$, $p < 0.0001$. (B) Bland–Altman plot. The bias and the 95% limits of agreement are shown as a solid line and dashed lines, respectively.

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it could be improved with growing popularity of the device in the future.

Our findings suggest that, although adjustments might be required in each hospital, the FibCare® can achieve rapid and accurate measurements of fibrinogen concentrations, and would be highly useful as a point-of-care testing method in critical care settings where massive obstetrical hemorrhage is a concern.

Conflict of interest

The authors have no conflicts of interest relevant to this article.

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