IMMUNOCHROMATOGRAPHIC TEST FOR THE DETECTION OF D-DIMER

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Relevance. Venous thromboembolism (VTE), which includes deep vein thrombosis and pulmonary embolism, remains a major challenge in clinical medicine due to its extremely high risk to patient health and life [3]. Among laboratory biomarkers of thrombogenesis, D-dimer is considered the most valuable. D-dimers are fibrin degradation products and serve as a direct marker of prior activation of the coagulation cascade [1,2]. Elevated concentrations of D-dimer in plasma are a consistent consequence of thrombotic states. In laboratory diagnostics, rapid and cost-effective assays are widely applied for D-dimer measurement [5,6]. These methods allow reliable exclusion of VTE in outpatient settings and do not require specialized equipment, which makes them clinically relevant and highly practical.

Objective. To develop an immunochromatographic assay (ICA) for the determination of D-dimer in human plasma samples and to evaluate its applicability in comparison with enzyme-linked immunosorbent assay (ELISA).

Materials and Methods. Immunochromatographic assay (ICA). Mouse monoclonal antibodies against human D-dimer (“Bialexa”, Moscow) were used for the test line, while goat anti-mouse IgG antibodies (“Imtek”, Moscow) served as the control line. Recombinant D-dimer antigen (“Bialexa”) with a defined concentration was employed as a calibrator for preliminary optimization of antibody concentrations in order to achieve the required test sensitivity (400 ng/mL FEU).

ELISA system. The “D-dimer-ELISA-BEST” kit (Vector-Best, Novosibirsk) was used for quantitative determination of D-dimer in plasma samples. This one-step solid-phase sandwich ELISA has a minimum detectable concentration of 10 ng/mL. The kit employs calibrators based on purified D-dimer, and results are reported in D-dimer units (DDU).

A total of 152 plasma samples obtained from individuals over 60 years of age were analyzed using ELISA and classified into three age groups. In parallel, ICA was evaluated with four groups of samples stratified by D-dimer concentration: <200 ng/mL DDU (n=58), 200–1000 ng/mL DDU (n=81), 1000–3000 ng/mL DDU (n=42), and >3000 ng/mL DDU (n=38).

Results. ELISA analysis demonstrated that more than half of the positive samples (52.4%) belonged to the oldest age group. The prevalence of elevated D-dimer levels (>285 ng/mL) increased with age, reaching 44.3%, 52.1%, and 58.5% in the first, second, and third groups, respectively. Within-group analysis revealed that the proportion of highly

positive results increased from 18.9% in the youngest group to 54.7% in the oldest group. In ICA testing, a progressive increase in band intensity (from 1+ to 3+) was observed with rising D-dimer concentrations. Samples from the oldest age group, which contained the highest proportion of specimens with markedly elevated D-dimer (>3000 ng/mL DDU), showed a greater frequency of maximum band intensity (3+).

Conclusion. The developed immunochromatographic assay demonstrated an overall agreement of 87.1% with ELISA results and achieved 100% concordance for samples with either normal (<400 ng/mL FEU) or elevated (>400 ng/mL FEU) D-dimer concentrations. These findings support the use of immunochromatographic testing as a reliable second-line diagnostic tool following clinical pre-test probability assessment of thrombosis.

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