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Is elevated troponin T reliable enough to be the only screen-out factor in pre-treated lymphoma patients?

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Introduction: Summarizing our experience of medical monitoring in clinical studies in patients with relapsed diffuse large B-cell lymphoma (DLBCL) pre-treated with standard Rituximab based scheme, we were surprised by a rather high incidence of increased Troponin T (TnT) in patients that had no detectable cardiac pathology. Such patients were screened out even if this lab finding was the only contraindication for inclusion.

Purpose: To accumulate literature data confirming that in this particular group of patients mildly elevated TnT measured by immunoassay and not supported by any overt cardiovascular manifestations can be caused by reasons other than cardiovascular pathology. Therefore such patient can be included in the study and have potential benefit from treatment.

Findings: About 10-11% of patient's serum samples may contain HAMA (human anti-mouse antibodies), which lead to false positive results of troponin immunoassay. Oncology patients, especially treated with monoclonal antibodies (Mab)-based immunotherapy are at significantly higher risk of HAMA development. Available literature data suggest that quantitative measurement of HAMA in oncology patients has far more practical impact than simple confirmation of ambiguous immunoassay results. Survival benefit associated with HAMA in patients with B-cell malignancies and with non-Hodgkin's lymphoma treated with anti-lymphoma Mab had been demonstrated.

Conclusion: HAMA measurement in potentially eligible patients who had previously received Mab immunotherapy and whose only contraindication for inclusion into the clinical study is mildly elevated TnT, seems justified. First, the patients with the false-positive TnT results caused by HAMA, will be included and may have potential benefits from study treatment. Second, the result of the HAMA test may have predictive value for treatment benefit.

Biography

Nickolai Usachev has substantial practical expertise in cardiology and intensive care, combined with more than decade's experience in the field of clinical studies. Since 2009 he heads the Pharmacovigilance unit of PSI CRO.

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