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Recombinant soluble human thrombomodulin (thrombomodulin alfa) in the treatment of neonatal disseminated intravascular coagulation

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Background: Recombinant soluble human thrombomodulin (TM- α) has been shown to be useful in the treatment of disseminated intravascular coagulation (DIC) in a heparin controlled study and has been available for clinical use in Japan since 2008. However, data on its use for neonatal DIC have not been reported from any clinical studies, so efficacy and safety were analyzed in 60 neonatal DIC patients identified in post-marketing surveillance.

Methods: The standard dose of TM- α was 380U/kg/day and dose adjustment was based on their renal function levels. Therapeutic effects of TM- α on DIC and on the survival of DIC patients were evaluated with the DIC diagnostic criteria of the Japanese Ministry of Health, Labor and Welfare established, and with the survival rate on day 28 after the completion of TM- α administration, respectively. Adverse events as well as adverse side effects associated with TM- α administration also were analyzed.

Results: The DIC resolution rate as of the day after last administration of TM- α was 47.1%, and the survival rate at 28 days after last administration was 76.7%. Hemostatic test result profiles revealed decreased levels of fibrin/fibrinogen degradation products and increased platelet counts and antithrombin activity. Incidences of adverse drug reactions, bleeding-related adverse drug reactions, and bleeding-related adverse events were 6.7, 6.7, and 16.7%, respectively, with no significant differences between neonatal, pediatric (excluding neonates), and adult DIC patients.

Conclusion: This surveillance provided real-world data on the safety and effectiveness of TM- α in the treatment of neonatal DIC in general practice settings.

Biography

Satoshi Ibara has completed his PhD from Nihon University and postdoctoral studies from University California Irvine. He is the Director of Perinatal Medical center, Kagoshima City Hospital, Japan. He has published more than 30 papers in reputed journals.

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