

**Development of prognostic algorithm to predict infectious disease
incidence in patients with acquired hemophilia A**

by

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ABSTRACT

Background:

Acquired hemophilia A (AHA) is an infrequent bleeding disorder characterized by sudden serious bleeding episodes, arising from autoantibodies against coagulation factor VIII (FVIII inhibitors). Early initiation of intensive immunosuppressive therapies (ISTs) is common to eliminate FVIII inhibitors, yet fatalities from infectious diseases as a side effect pose significant medical challenges alongside managing fatal bleeding. Currently, no straightforward tool exists to quantitatively identify patients with a high infectious risk, necessitating alternative treatment options with lower, or zero IST doses to avert death from infection.

Objectives:

The aim is to develop a straightforward clinical prediction model, utilizing a Japanese real-world database, to predict individual infection risk during hospitalization in patients with AHA (PwAHA). This will subsequently enhance the prognosis of this disease.

Methods:

Leveraging Japanese claim real-world database (MDV database), comprising receipt data and DPC information from patients at acute care medical institutions, patient data from 547 patients was included in model development and validation. Multiple logistic regression analysis was conducted, and risk scores were assigned to identified factors correlated with infection risk. Receiver operating characteristic (ROC) analysis assessed the predictive performance of the model, yielding an area under the curve (AUC).

Results:

The final clinical prediction model incorporated four variables (prescribed types of anti-infectives, duration from hospitalization to first AHA diagnosis, history of infectious diseases before AHA diagnosis, and no transfusion use) without requiring laboratory data. ROC analysis demonstrated an AUC of 0.725 (95% confidence interval, 0.678–0.771) and similar results were obtained in the validation cohort (AUC, 0.783; 95% confidence interval, 0.651–0.915).

Conclusions:

1 The proposed simple clinical prediction model exhibits robust predictive potential for
2 estimating individual infection risk during hospitalization in PwAHA. This model enables
3 physicians, even those unfamiliar with AHA treatment, to easily calculate infection risk
4 levels for individual patients. This facilitates a personalized IST approach while effectively
5 managing bleeding, ultimately contributing to an improved prognosis for PwAHA.

7 **KEY WORDS**

8 Patients with acquired hemophilia A, Real-world data, Clinical prediction model, Infectious
9 diseases, Immunosuppressive therapies.

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