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研究報告の概要

入院 7 日前に発熱、頭痛、精神的変調をきたした男性が、アリゾナ州の病院に 2004 年 7 月 7 日に入院した。この患者の CSF（脳脊髄液）所見はウイルス性脳炎と一致してした。7 月 7 日及び 14 日に採取された CSF サンプルは ELISA による WNV IgM 抗体陽性で、血清サンプルについては PRNT 法により WNV の IgM が 7 月 7 日（急性期）から 14 日（回復期）に 4 倍上昇し、WNV 感染が確認された。発症 8 日及び 15 日目の尿サンプルの PRNT 検査は陰性であった。CSF は PRNT 及び分離に利用できなかった。ベロ細胞（ミドリサル腎細胞）および C6/36 細胞（ヒトスジシマカ）を用いて、発症 8、11、12、13、14、および 15 日目に集められた尿サンプルからウイルス分離はできなかった。同様に発症 8 及び 9 日目の血清検体からウイルスの分離はできず、確認試験の間接免疫蛍光法試験も陰性であった。
一方、発症から 8 日目（7 月 7 日に採取）の尿サンプルの RT-PCR の結果は陽性であった。11、12、13、14、および 15 日目の尿サンプルの RT-PCR 結果は陰性であった。8 日目の尿サンプル（WNV Arizona JW 2004）の遺伝子配列結果は WNV 株（NY 2000-crow3356）と 99.7%一致した。8 日目の血清サンプルの RT-PCR は陰性であり、ウイルスの分離もできなかった。
この報告は WNV 脳炎の患者である人の尿から WNV RNA が検出された最初の症例である。

報告企業の意見	今後の対応
WNV脳炎患者の尿（発症8日目に尿）からWNV RNAが検出された最初の症例報告である。 尿由来製剤からのWNV伝播の事例は報告されていない。また、万一原料尿にWNVが混入したとしても、WNVと類似した特徴を有しているSINVのウイルスバリデーション試験成績から、本剤の製造工程において十分に不活化・除去されると考えている。	本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。

使用上の注意記載状況・その他参考事項等

感染症に関連する記載はない。