

World Journal of *Clinical Cases*

World J Clin Cases 2021 September 6; 9(25): 7292-7613



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The *WJCC* is now indexed in Science Citation Index Expanded (also known as SciSearch®), Journal Citation Reports/Science Edition, Scopus, PubMed, and PubMed Central. The 2021 Edition of Journal Citation Reports® cites the 2020 impact factor (IF) for *WJCC* as 1.337; IF without journal self cites: 1.301; 5-year IF: 1.742; Journal Citation Indicator: 0.33; Ranking: 119 among 169 journals in medicine, general and internal; and Quartile category: Q3. The *WJCC*'s CiteScore for 2020 is 0.8 and Scopus CiteScore rank 2020: General Medicine is 493/793.

RESPONSIBLE EDITORS FOR THIS ISSUE

Production Editor: Yan-Xia Xing; Production Department Director: Xiang Li; Editorial Office Director: Jin-Lai Wang.

NAME OF JOURNAL

World Journal of Clinical Cases

ISSN

ISSN 2307-8960 (online)

LAUNCH DATE

April 16, 2013

FREQUENCY

Thrice Monthly

EDITORS-IN-CHIEF

Dennis A Bloomfield, Sandro Vento, Bao-Gan Peng

EDITORIAL BOARD MEMBERS

<https://www.wjgnet.com/2307-8960/editorialboard.htm>

PUBLICATION DATE

September 6, 2021

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INSTRUCTIONS TO AUTHORS

<https://www.wjgnet.com/bpg/gerinfo/204>

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<https://www.wjgnet.com/bpg/GerInfo/287>

GUIDELINES FOR NON-NATIVE SPEAKERS OF ENGLISH

<https://www.wjgnet.com/bpg/gerinfo/240>

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<https://www.wjgnet.com/bpg/GerInfo/288>

PUBLICATION MISCONDUCT

<https://www.wjgnet.com/bpg/gerinfo/208>

ARTICLE PROCESSING CHARGE

<https://www.wjgnet.com/bpg/gerinfo/242>

STEPS FOR SUBMITTING MANUSCRIPTS

<https://www.wjgnet.com/bpg/GerInfo/239>

ONLINE SUBMISSION

<https://www.f6publishing.com>

Agranulocytosis following injection of inactivated Japanese encephalitis vaccine (Vero cell): A case report

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Author contributions: Wang L reviewed the literature and drafted the manuscript; Zhang X was responsible for the revision of the manuscript for important intellectual content; Liu YT reviewed the literature and contributed to manuscript drafting; all authors issued final approval for the version to be submitted.

Informed consent statement: Written informed consent was obtained from the patient's parents for publication of this case and accompanying images.

Conflict-of-interest statement: The authors have no conflict of interest to declare.

CARE Checklist (2016) statement: The authors have read the CARE Checklist (2016), and the manuscript was prepared and revised according to the CARE Checklist (2016).

Open-Access: This article is an open-access article that was selected by an in-house editor and fully peer-reviewed by external reviewers. It is distributed in accordance with the Creative Commons Attribution

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Abstract

BACKGROUND

Japanese encephalitis virus (JEV), a mosquito borne flavivirus, is the leading cause of viral encephalitis in Asia, in terms of frequency and severity. JEV infection is thought to confer lifelong immunity. With the near eradication of poliomyelitis, JEV is now the continent's leading cause of childhood viral neurologic infection and disability. The most common clinical manifestation of JEV infection is acute encephalitis, and currently there is no specific antiviral therapy. Japanese Encephalitis Vaccine (JE-VC) is an effective prevention measure, including JE-VC, Live (JE-MB), and Inactivated JE-VC.

CASE SUMMARY

A 9-mo-old girl received injection of Inactivated JE-VC (Vero cell) (Liaoning Chengda, batch number 201611B17) on August 31, 2017. On that night, she developed a fever with the body temperature up to 38.5 °C, for which Ibuprofen Suspension Drops 1.25 mL was given as antipyretic treatment. On September 1, the patient developed apocleisis, and her parents noticed herpes in her oral cavity. The patient was sent to our hospital on September 3. Physical examination led to a

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Manuscript source: Unsolicited manuscript

Specialty type: Medicine, research and experimental

Country/Territory of origin: China

Peer-review report's scientific quality classification

Grade A (Excellent): 0
Grade B (Very good): 0
Grade C (Good): C
Grade D (Fair): 0
Grade E (Poor): 0

Received: December 25, 2020

Peer-review started: December 25, 2020

First decision: May 11, 2021

Revised: May 25, 2021

Accepted: July 16, 2021

Article in press: July 16, 2021

Published online: September 6, 2021

P-Reviewer: Wang S

S-Editor: Gao CC

L-Editor: Wang TQ

P-Editor: Li X



diagnosis of herpetic stomatitis, for which Stomatitis Spray 1 puff, tid, Kangfuxin Liquid 2 mL, tid, and vitamin B₂ 0.5 tablet, tid, were prescribed. Routine blood tests for low fever on September 6, 2017 revealed an absolute neutrophil count (ANC) of $0.62 \times 10^9/L$, hemoglobin (Hb) of 109 g/L, and platelet count (PLT) of $308 \times 10^{12}/L$, and the tests were monitored regularly thereafter. The patient was followed until July 26, 2020, when routine blood tests revealed ANC $1.72 \times 10^9/L$, Hb 138 g/L, and PLT $309 \times 10^{12}/L$, indicating that the neutropenia count had normalized.

CONCLUSION

This report attempts to bring to clinical attention that Inactivated JE-VC (Vero cell) might cause prolonged granulocytopenia or even agranulocytosis.

Key Words: Inactivated Japanese Encephalitis Vaccine (Vero cell); Neutropenia; Agranulocytosis; Japanese Encephalitis virus; Case report

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Core Tip: So far, there has been no report of vaccine-induced neutropenia that persisted for 2 years until recovery. Japanese Encephalitis virus, a mosquito borne flavivirus, is the leading cause of viral encephalitis in Asia, in terms of frequency and severity. This report attempts to bring to clinical attention that Inactivated Japanese Encephalitis Vaccine (Vero cell) might cause prolonged neutropenia or even agranulocytosis.

Citation: Wang L, Zhang X, Liu YT. Agranulocytosis following injection of inactivated Japanese encephalitis vaccine (Vero cell): A case report. *World J Clin Cases* 2021; 9(25): 7468-7471

URL: <https://www.wjgnet.com/2307-8960/full/v9/i25/7468.htm>

DOI: <https://dx.doi.org/10.12998/wjcc.v9.i25.7468>

INTRODUCTION

Japanese Encephalitis virus (JEV), a mosquito borne flavivirus, is the leading cause of viral encephalitis in Asia, in terms of frequency and severity[1].

JEV infection is thought to confer lifelong immunity. With the near eradication of poliomyelitis, JEV is now the continent's leading cause of childhood viral neurologic infection and disability[2]. The most common clinical manifestation of JEV infection is acute encephalitis, and currently there is no specific antiviral therapy. Japanese Encephalitis Vaccine (JE-VC) is an effective prevention measure, including JE-VC, Live (JE-MB), and Inactivated JE-VC[2]. Inactivated Vero cell culture-derived JE-VC is the only JE vaccine licensed and available in the United States. In 2009, the U.S. Food and Drug Administration licensed JE-VC for use in persons aged > 17 years. In 2013, licensure was extended to include children aged > 2 mo. The studies on adverse events with JE-VC have reported fever ($\geq 38^\circ\text{C}$) within 7 d after the first dose or second dose [3].

CASE PRESENTATION

Chief complaints

A 9-mo-old girl received injection of Inactivated JE-VC (Vero cell) on August 31, 2017. On that night, she developed a fever with the body temperature up to 38.5°C .

History of past illness

No special history of past illness.

Physical examination

Physical examination led to a diagnosis of herpetic stomatitis.

Laboratory examinations

Routine blood tests for low fever on September 6, 2017 revealed an absolute neutrophil count (ANC) of $0.62 \times 10^9/L$, hemoglobin (Hb) of 109 g/L, and platelet count (PLT) of $308 \times 10^{12}/L$, and the tests were monitored regularly thereafter (Table 1). The patient was followed until July 26, 2020, when routine blood tests revealed ANC $1.72 \times 10^9/L$, Hb 138 g/L, and PLT $309 \times 10^{12}/L$, indicating that the neutrophil count had normalized. Routine blood tests revealed ANC $2.18 \times 10^9/L$ before injection of Inactivated JE-VC (Vero cell) on May 24, 2017 and ANC $2.12 \times 10^9/L$ on July 3, 2017, indicating a normal neutrophil count.

FINAL DIAGNOSIS

Neutropenia.

TREATMENT

No treatment was given for neutropenia, but treatment for complications such as fever was administered.

OUTCOME AND FOLLOW-UP

The patient developed neutropenia. After September 2017, regular tests were performed to monitor the neutrophil values, as shown in Table 1. The blood test showed that the lowest of ANC was $0.06 \times 10^9/L$, indicating neutropenia developed agranulocytosis. The patient was followed until July 26, 2020, when routine blood tests revealed ANC $1.72 \times 10^9/L$, Hb 138 g/L, and PLT $309 \times 10^{12}/L$, indicating that the neutrophil count had normalized.

DISCUSSION

It is important to evaluate the safety profile of new vaccines. Abnormal hematological values, such as neutropenia, are often reported. We should not only identify potentially important safety signals but also understand their implications and clinical relevance.

In many cases, neutropenia occurs in people of African descent because they have a lower ANC compared to other ethnic groups. Neutropenia is not listed as a potential adverse reaction in the package insert of Inactivated JE-VC (Vero cell), nor have there been literature reports on neutropenia induced by inoculating such vaccine. There have been few literature reports on vaccine-induced neutropenia. Only one article on randomized, controlled clinical trials and systematic review[4] suggests that several cases of neutropenia were reported as post-inoculation adverse events within the first 2 wk after inoculation. However, such cases of neutropenia were generally transient, and expected to have favorable clinical outcome after receiving various novel or widely recognized licensed vaccines. Furthermore, vaccine recipients with neutropenia typically have a lower baseline ANC than those without neutropenia. Neutropenia is usually caused by a variety of diseases, including infections, drug treatments, autoimmune diseases, nutritional deficiencies, or hematological malignancies, but there is also genetic conditions such as benign ethnic neutropenia (BEN). Those of African descent are particularly affected by BEN which is believed to be caused by the regulatory variation of the chemokine gene Duffy Antigen Receptor and has no connection with the increase in the incidence of infection.

CONCLUSION

So far, there has been no report of vaccine-induced neutropenia that has persisted for 2 years until recovery. This report attempts to bring to clinical attention that Inactivated JE-VC (Vero cell) might cause prolonged neutropenia or even agranulocytosis.

Table 1 Results of blood tests

Date	ANC ($\times 10^9/L$)	Hb (g/L)	PLT ($\times 10^{12}/L$)
September 9, 2017	0.52	113	459
September 16, 2017	0.13	118	460
October 7, 2017	0.06	120	335
October 27, 2017	0.34	110	311
November 28, 2017	0.15	113	353
January 2, 2018	0.35	116	375
February 12, 2018	0.21	115	365
April 22, 2018	0.11	118	313
May 25, 2018	0.37	124	252
November 15, 2019	3.98	129	287
June 2, 2020	1.49	131	297
July 26, 2020	1.72	138	309

ANC: Absolute neutrophil count; Hb: Hemoglobin; PLT: Platelet count.

ACKNOWLEDGEMENTS

Heartfelt thanks to Miss DeAnn.

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