

## Editorial



# Clinical Effectiveness and Safety of Peramivir for Influenza Infection: Safe and Effective Antiviral Treatment

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► See the article “Safety and Effectiveness of Peramivir in Korean Adult Influenza Patients: Prospective Observational Study Based on Post-Marketing Surveillance Data” in volume 33, e212.

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Influenza is an acute respiratory disease caused by the influenza virus. In the temperate zone, influenza is widespread between late autumn and early spring, and the degree of epidemic may change every year. The mortality rate is about 0.5–1/1,000 patients, mainly in elderly people over 65 years of age. Influenza can lead to chronic worsening of the underlying disease, and indeed the number of deaths attributable to influenza is likely to be much higher than reported deaths.<sup>1</sup> Globally, it is estimated that 5%–10% of adults and 20%–30% of children are affected each year, and it is estimated that 250,000 to 500,000 deaths occur every year.<sup>2</sup>

Influenza virus is an RNA virus belonging to orthomyxovirus. Influenza A and B viruses cause infection in humans and influenza A viruses are classified according to the combination of 18 hemagglutinin (HA or H) antigens on the virus surface and 11 neuraminidase (NA or N) antigens. Antiviral agents such as oseltamivir, zanamivir, and peramivir are highly recommended for patients with complications or patients with high risk, and antiviral agents are also considered to previously healthy adults if the administration is possible within 48 hours of symptom onset.<sup>2</sup> Peramivir is the first intravenous neuraminidase inhibitor which blocks viral growth by selectively inhibiting neuraminidase (NA), an enzyme that releases viral particles from infected cells, in human influenza A and B viruses, and is administered once through an IV route. Clinical effectiveness was proved through randomized controlled trial.<sup>3</sup>

In this issue, Choi et al.<sup>4</sup> reported adverse events and effectiveness of peramivir from a prospective observational study based on the post-marketing surveillance data. What is noticeable from this report is that large number of patients are included for evaluation of safety and effectiveness. More than 2,500 cases were analyzed and few adverse events were reported. Forty-two adverse events from 35 patients (1.16%) were observed and fever was the most common adverse event. There were no significantly fatal adverse events and most cases were mild. Number of adverse events was relatively lower, and rate of fever as adverse event was higher than that of previous studies.<sup>5,6</sup> Actually, fever is one of the most common symptoms of influenza and it is not easy to judge whether this symptom comes from drug adverse event or influenza itself. More data are required to evaluate adverse events in the near future. Although fever is the most common adverse event, gastrointestinal disorder including diarrhea and nausea is the most common category of adverse events which is similar to previous studies.<sup>3,5,6</sup>

Effectiveness of peramivir was well evaluated using scoring scale. Symptoms significantly improved mostly in 3 days after the drug was administered. These findings are also in consistence with previous studies.<sup>5,6</sup> In this study, comparison with other patients treated with only symptomatic medication or other antiviral agents was not possible because of the study design. Nonetheless, this study is powered by large amounts of real-world data from about 3,000 patients. Korea Ministry of Food and Drug Safety (KMFDS) recommends single dose of 300 mg and US Food and Drug Administration (FDA) approved single dose of 600 mg.<sup>7</sup> More than 1,000 patients were excluded from a total of 4,056 collected cases in the study. Of these, 974 cases were administered dosage out of formal recommendation of KMFDS which means that there may be many cases including severe patients using higher or multiple doses in Korea. Safety and efficacy data of these patients are also needed.

In summary, peramivir is a safe and effective medication to treat influenza under routine clinical settings. Adverse events are rare and relatively mild in Korean patients. More studies about safety and effectiveness are also required in severe cases using higher or multiple doses.

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