**Introduction**

Anaphylaxis is a severe, life-threatening, systemic hypersensitivity reaction. In Vietnam, the number of anaphylaxis cases from pharmacovigilance (PV) database have increased by years. Thus, the aims of this study were:

1. To characterize anaphylaxis cases in the spontaneous reporting database in Vietnam.

2. To investigate the association between drugs and anaphylaxis in this database.

**Methods**

A retrospective and descriptive study on the 20488 spontaneous ADR reports from 2010 to 2014 in PV database.

**Data collection**

After excluding ADR reports lacking information on ADR description, suspected drugs, age and gender, the remaining reports were classified as cases of anaphylaxis or noncases referring the definition of the National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network. Indeed, cases are reports in which:

- ADRs were described as “anaphylactic shock”/“anaphylactic reaction” by reporters.
- OR adverse symptoms involved at least 2 of 4 organ systems (including cardiovascular, respiratory, skin/mucosal and gastrointestinal system) or there were severe hypotension AND these symptoms occurred within 24 hours after the last exposure to suspected drugs [1].

**Description of cases**

Describing the characteristic of cases, including:

- Reporting trend
- Gender and age of patients
- Time to drug after last exposure
- Severity of anaphylaxis (using Brown’s categories: “grade 1” cases involved hypoxia and/or hypotension and/or neuropsychologic compromise; the others were “grade 2”[2]).

**Symptoms of anaphylaxis**

- Allergic reaction to other/unknown
- Management of anaphylaxis.

**Signal detection using RORs**

Individual suspected drugs presenting in 8 cases were analyzed for signal detection using the reporting odds ratio (ROR). ROR = (a/b) / (c/d) with:

- a: the number of cases of this drug
- b: the number of all other drugs
- c: the number of noncases of this drug
- d: the number of noncases of all other drugs [3]


**Results**

**Reporting trend**

The percentage of cases in 5 years: 10.6%

**Characteristics of anaphylaxis cases**

- **Number**: 161
- **2010**: 231
- **2012**: 330
- **2013**: 80
- **2014**: 659

**Figure 1. Reporting trend of anaphylaxis cases**

Anaphylaxis occupied a quite high percentage. This rate was lower than that of skin reactions, which showed a reporting tendency in Vietnam: cases with anaphylaxis and serious reactions were more likely reported.

**Suspected drugs**

The most pharmacological classes were similar to those in the study in the Portuguese Allergy Departments [4], but quite different from other previous studies on anaphylaxis which involved other drug groups like muscle relaxants, systemic hormonal preparations, anesthetics, and antiepileptic agents.

**Drugs with signal of anaphylaxis**

Among 49 drugs performed ROR calculation, anaphylaxis signals were detected with 29 drugs.

**Conclusions**

In addition to signal detection with well-known drugs in literatures, some drugs with limited information of anaphylaxis in literatures were also noted including omeprazole, ranitidine, cimetidine, and ranitidine. Signal detection using statistical measures plays an important role in PV. If the ROR of one drug keep raising by time even a well-known drug, we need to pay more attention to find any possible causes and to give timely alerts. In addition, signals with drugs not having or limited information of a certain ADR need following to consider if further epidemiological studies should be implemented to verify the signals.

**References**
