VI Fórum Internacional sobre Segurança do Paciente
Erros de Medicação

THE PRACTICE OF CLINICAL PHARMACOVIGILANCE IN THE IDENTIFICATION OF THE CIPROFLOXACIN-RELATED STEVENS-JOHNSON SYNDROME: A case report

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BACKGROUND

Adverse drug reactions (ADRs) provoke negative impacts on health services resources availability and may result in death[1].

The Stevens–Johnson syndrome is a dermatological condition (skin and mucous membranes), but it can harm multiple systems. It is often caused by an adverse hypersensitivity reaction and presents a mortality rate between 30% and 50%[2].

We describe here a Stevens-Johnson syndrome case fostered by ciprofloxacin. This study was conducted and reported in line with the consensus-based clinical case report guideline (CARE guideline 2013).

CASE PRESENTATION

❑ Patient Information

The pharmacovigilance service from a teaching hospital found, assessed and accompanied a ADR case in a patient (gender: female; age: 86; race: brown; weight: 60 lb.), who had begun to use ciprofloxacin following medical prescription received in the attendance at primary health care.

The patient had a heart disease, hypertension and acute renal failure. She was receiving, at the time, treatment with the continuous use of other drugs.

Due a bacterial infection, was suggested the use of ciprofloxacin taken in doses of 500 mg every 12 hours.

❑ Clinical Findings

According to informations provided by her family, during the pharmacotherapy, the patient complained of gastric discomfort and fatigue, but, even though, she decided to keep on with the treatment. After that, roughly in the seventh day of ciprofloxacin intake, the patient developed a facial edema (lip and eyelids) as well as eating difficulties.

Because of it, she looked for health care service, which culminated with her hospitalization. Thereafter, due to a worsening of her clinical conditions, she was transferred to a second hospital, where the pharmacovigilance was established.

❑ Diagnostic Assessment

At the patient admission, she presented hyperemic and desquamative injuries through the body, including oral cavity. It was intensified with the increase of the skin desquamation, more intense in dorsal region. She was unable to open her eyes – which presented secretion - neither spontaneously nor with help, while complaining of pain. Given the situation, the patient was diagnosed, likely, with Stevens-Johnson syndrome.

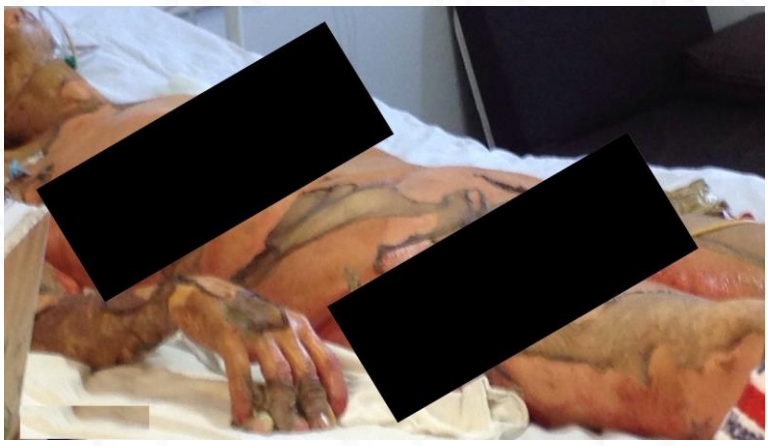

Fig 1. Hyperemic and desquamative injuries through the body.

❑ Therapeutic Intervention

The treatment was led with scientific evidences in health science. There was, however, opposition to the adopted clinical measures.

❑ Follow-up and Outcomes

The patient condition worsened considerably, with increase of desquamation (blood injuries), infection, cardiac arrest and death after resuscitation protocol (period of hospitalization: 9 days).

It was determined that the whole event was prompted, at first, by an adverse reaction to the ciprofloxacin and, accordingly with the causality analysis (WHO-UMC[3]), the reaction was classified as probable.

A notification of this case was sent to the Agência Nacional de Vigilância Sanitária, which classified the event as disturbing and worthy of reporting to the Uppsala Monitoring Centre.

Ethics Approval: An written informed consent form was obtained. The study was approved by the Research Ethics Committee (Protocol no. 1.201.825).

CASE TIMELINE

FACTS	Days 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Use of ciprofloxacin	■	■	■	■	■	■	■												
Development of ADR					■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Hospitalization											■	■	■	■	■	■	■	■	■
Death																			■

CONCLUSION

The monitoring of drugs adverse effects, as well as the incidents implicated in it, is extremely important. The basic training of the population is important too. Consequently, with the health education, the objective is that ADRs may be avoided, not only reported after the occurrence.

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