Case Report

A case report on ofloxacin-induced Stevens–Johnson syndrome: Scorten-based approach

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ABSTRACT

Stevens–Johnson syndrome (SJS) is a rare immune-mediated severe cutaneous adverse reaction with an incidence rate of 0.05–2 persons/million population/month. Drugs are the most commonly implicated in 95% of cases. In our report, a 52-year-old male patient presented with chief complaints of skin rashes over the body and was having a history of using a tab. ofloxacin for gastroenteritis. The severity of SJS was assessed using SCORTEN (=1). The drug can be considered as a probable/likely cause of adverse drug reaction as per causality assessment of the suspected adverse drug reactions. Early diagnosis helps the clinician to elude secondary infection and subsequent complications. It highlights the mandatory reporting of the offending drug and the necessity of pharmacovigilance in different countries.

Key words: Ofloxacin, Pharmacovigilance, Stevens–Johnson syndrome, Toxic epidermal necrolysis

Steven–Johnson syndrome (SJS) is rare immune-mediated severe cutaneous adverse reaction presenting as severe mucosal erosions with widespread erythematous, cutaneous macules, or atypical targets with an incidence rate of 0.05–2 persons/million population/month [1]. The condition is mainly caused by drugs (95% of cases) but also by infection and other risk factors. Recent case reports and studies show that more than 100 drugs have been implicated as a cause of SJS, of which major drug contributions to the disease are antibacterial (sulfonamides), anticonvulsants (phenytoin, carbamazepine), non-steroidal anti-inflammatory drugs (oxicam derivatives), and oxide inhibitors (allopurinol) [2]. SJS/toxic epidermal necrolysis (TEN) is a rare and unpredictable reaction to medication that involves drug-specific CD8+ cytotoxic lymphocytes, the Fas-fas ligand (FasL) pathway of apoptosis, and granule-mediated exocytosis and tumor necrosis factor-alpha (TNF-alpha)/death receptors pathway [3].

According to a study, the multivariate relative risk of SJS was found to be 10 (95% CI: 2.6–38) for quinolone antibiotics. Subjects exposed to quinolone antibiotics were 10 times more likely to experience either SJS or TEN as compared to others [4,5]. Compared to all other quinolones, ofloxacin acts as the offending antibiotic. The benefit-risk profiles need careful evaluation that the drugs can induce SJS. Here, we present the case report of SJS secondary to a drug therapy, associated with the use of oral ofloxacin. Identification of the cause is important for the individual patient and in the case of drug-induced disease; withdrawal of the inducing drug has an impact on the patient's prognosis.

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CASE REPORT

A 52-year-old male patient was admitted to the department of emergency with complaints of rapidly progressive skin rashes with itching over the left thigh, left foot, right hand, and groin along with diffuse redness of the oral mucosa, pain over the face, and swelling of the lip (Fig. 1). The patient had also complaints of hiccups and small wounds near the penis. The patient gave a medication history of gastroenteritis, for which he had taken the tabs Ofloxacin 200mg and ornidazole 500 mg. After 3 days of the medication course, he developed erythematous lesions over the oral mucosa and patchy erythematous lesions over the left thigh, left foot, right hand, and lesions on the genital areas. He revealed that he had COVID 1 year back, for which he has been hospitalized and received inj. Remdisivir and oral steroids.

On examination, the patient was conscious, well-oriented, and stable with mild febrile condition (38.5°C). The pulse rate was 66 bpm and the respiratory rate was 20/min.

Preliminary blood investigations were done which showed normal platelet count and prothrombin test/international normalized

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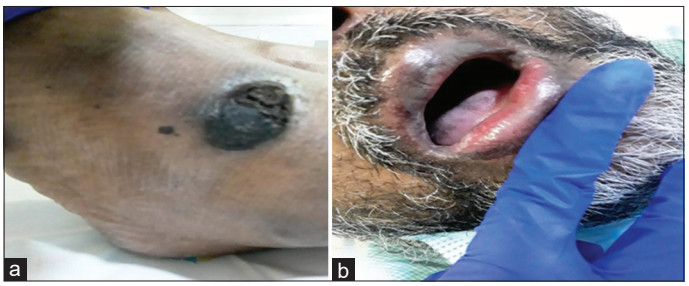

Figure 1: (a) Erythematous lesions over left foot and (b) erosive lesions over oral mucosa

ratio, but his white blood cells count was 7400/cumm and hemoglobin value was 10.3 g/dL (mild anemia). The erythrocyte sedimentation rate was 53 mm/h. Echocardiogram showed jerky movements of the intraventricular septum with an ejection fraction of 60%. There was no evidence of hepatosplenomegaly, lymphadenopathy, or cardiovascular collapse. Liver function tests showed mild elevation in aspartate transaminase (40 U/L). Systemic examination did not show any significant findings.

Based on the present medication history, clinical examinations, and findings, we confirmed that the patient was a case of drug-induced SJS which was due to ofloxacin intake. After 2 days of admission, the patient had shifted to ICU for further management. The severity of SJS was assessed using SCORTEN criteria. The patient's SCORTEN value was 1 showing a 3.2% mortality of the patient.

We treated him under the expert guidance of a dermatologist and internal medicine. Therapy was started intravenously (IV) with dexamethasone 4 mg BD for 5 days, Inj. Pheniramine BD for 5 days, and tab. Fexofenadine 120 mg BD was added for itching, along with other supportive measures for optimum care of the patient. Considering the dermatologist opinion, IV antifungal was added from day 2 onward, and Inj. Fluconazole 400 mg OD for 4 days has been continued.

After 5 days of ICU admission, the patient was stabilized and shifted to the ward. From the 6th day onward, 2% Fusidic acid cream was applied topically followed by the tab. Omnacortil 10 mg/day. Redness and itching were settled and the patient showed significant improvement. The skin lesions healed within 2 weeks and the patient was discharged from our department in good general condition with oral steroids along with topical antifungal creams. Almost all lesions totally resolved in a few weeks leaving his body without any other complications.

DISCUSSION

SJS and TEN are acute, rare, and potentially fatal skin reactions involving the loss of skin and in some cases, the mucosal membrane is accompanied by systemic symptoms. Numerous medications have been reported to trigger SJS or TEN [4]. The drugs that precipitate SJS tend to have a long half-life and are taken systemically.

The present patient was a case of drug-induced SJS (ofloxacin). Several studies suggested that ofloxacin has the capability for causing SJS. Previously, he had COVID, for which remdesivir and steroids were taken. However, he did not have any complaints of viral infection, systemic lupus erythematosus, and upper respiratory infection. Drug-induced SJS usually presented with fever and influenza-like symptoms after taking a suspected drug, but, in our patient, he only developed febrile symptoms along with the erythematous lesions that begin in the left thigh and then gradually to other areas [6].

There were no signs of TEN in our patient which is similar to a study done by Roujeau JC *et al.* which signifies that the drug is not associated with TEN [7]. A study carried out by Naveen *et al*. observed that ofloxacin is a commonly used antibiotic in India and has a risk of inducing SJS-TEN [1]. Injudicious uses of ofloxacin are the foremost common reasons behind SJS-TEN which may have higher morbidity and mortality as compared to anticonvulsants, antipyretics, and antimicrobials [8].

The severity of SJS-TEN was assessed using SCORETEN criteria in our patient. The score of SCORTEN is used to specify the severity of illness in SJS/TEN and to predict mortality. SCORTEN comprises seven clinical and biological parameters that are the risk factors for death which includes age >40 years, malignancy, heart rate >120 beats/min, initial percentage of epidermal detachment >10%, serum urea >10 mmol/L, serum glucose >14 mmol/L, and bicarbonate <20 mmol/L. Collectively, these comprise the SCORTEN with the predicted probability of mortality ranging from 3.2% to 90.0% [9]. Here, the patient was having a score of 1 which suggested that the patient was having only a 3.2% mortality rate. Although this scoring was found to be an overall good predictor of mortality, it tends to underestimate mortality for values <3 and overestimate for value >3 [10].

The mortality of SJS was estimated to be 1–3%, whereas the mortality rate for TEN was between 30% and 50% [11,12]. Early diagnosis along with prompt identification and withdrawal of the reasonable drug for causing SJS is essential for a favorable outcome. The risk-benefit ratio needs careful evaluation as it can induce SJS-TEN.

CONCLUSION

There is an upsurge use of fluoroquinolones in recent years. Injudicious use of fluoroquinolones is the foremost common reason behind SJS. Patients should be counseled with adequate information regarding the side effects of the offending drug and advice to report the adverse drug reaction. Since SJS has a strong temporal association with ofloxacin intake, increased clinical vigilance is required to identify erythematous lesions and other clinical symptoms. Early diagnosis helps the clinician to elude secondary infection and subsequent complications and highlights the mandatory reporting of the offending drug.

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