J. Pharm. Res. 2026;25(2):108-111

Print ISSN: 0973-7200
Online ISSN: 2454-8405

Journal of Pharmaceutical Research

CASE REPORT

A Rare ADR of Co-amoxiclav induced Stevens-Johnson Syndrome in a Young Patient: A Case Report

M Salguna Sambhannan Vivek[1*], Kantilal Chainkaran Chandaliya[2], Girish Raparti[3], Pankaj Digambarrao Patil[4], Rushikesh Ramkishan Dhamale[1]

[1]*Junior Resident, Department of Pharmacology, Dr. Shankarrao Chavan Government Medical College, Nanded, Maharashtra, India*

[2]*Professor and HOD, Department of Pharmacology, Dr. Shankarrao Chavan Government Medical College, Nanded, Maharashtra, India*

[3]*Associate Professor, Department of Pharmacology, Dr. Shankarrao Chavan Government Medical College, Nanded, Maharashtra, India*

[4]*Assistant Professor, Department of Pharmacology, Dr. Shankarrao Chavan Government Medical College, Nanded, Maharashtra, India*

ARTICLE INFO

Article history:
Received 07-02-2026
Accepted 27-04-2026
Published 03-06-2026

** Corresponding author.*
M Salguna Sambhannan Vivek
vivekssm7@gmail.com

https://doi.org/10.18579/jopcr/v25.i2.13

ABSTRACT

Stevens-Johnson Syndrome is a severe, life-threatening mucocutaneous disease associated with significant morbidity and mortality. Co-amoxiclav (Amoxicillin and Clavulanic acid) is one of the commonly prescribed antimicrobials. Previous incidence recorded with Co-amoxiclav is very rare (1 per million)[1]. A 13-year-old child presented to a local physician with a history of fever and sore throat, for which he was prescribed tablet Co-amoxiclav twice a day. After three days, he initially developed a maculopapular erythematous rash with central blisters first appearing over his four limbs, spread to chest and back and involved a total body area of around 70% on the 5th day. This further progressed to involve oral lesions, bilateral conjunctival congestion, and genital mucosa on Day 6. Patient was admitted for managing the case and a causality assessment was done using the Naranjo Adverse Drug Reaction Probability Scale resulting in a score of "7," indicating the ADR was "probable". The patient was managed with intravenous steroids, antibiotics, intravenous fluids, and other conservative measures. The child recovered and was discharged on 9th day of hospitalization. This ADR was reported to the Indian Pharmacopoeia Commission through the VigiFlow platform as part of India's Pharmacovigilance Program. A validated mathematical tool named "severity-of-illness score for toxic epidermal necrolysis (SCORTEN)" for the prognostication of SJS/TEN patients, predicted the mortality to be around 3.2%. This case highlights the potential for commonly used drugs like Co-amoxiclav to cause severe side effects such as SJS[3]. It underscores the importance of active pharmacovigilance for all medications and vigilant ADR monitoring and management.

Keywords: Co-amoxiclav, Stevens-Johnson Syndrome, Adverse Drug Reactions, Pharmacovigilance

INTRODUCTION

Drug-induced eruptions manifest in various forms and are triggered by medications like antimicrobials, antiepileptics, or NSAIDs. Maculopapular skin eruptions are the most common skin reactions to antimicrobials, whose presentations vary from mild skin irritation to severe diseases such as Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN).

SJS is a mucocutaneous illness which is associated with significant morbidity and mortality[4]. In SJS, they are commonly characterized by erythematous macules and hemorrhagic erosions of the mucous membranes[7]. The global incidence of drug-induced SJS is around 77% and among them, the antimicrobial Sulphonamide induced SJS is most common[5, 15]. The incidence in children is rarer than in adults[6].

Levine GA (2015) stated that with a 45.8% global usage, Co-amoxiclav is one of the most commonly prescribed antibiotics. This drug is also one of the five drugs that cause severe cutaneous adverse reactions (SCARs) and is known to cause maculopapular rashes, which is a mild and common cutaneous Adverse Drug Reaction (ADR)[8, 9]. Such reactions are commonly immune mediated and also occur in about 10 per cent of individuals treated with beta-lactams. Although they frequently cause mild cutaneous reactions, the progression to SJS due to Co-amoxiclav is uncommon and rare with a reported incidence of 1 per million people per year[1]. In this case report, we describe a case of SJS that was induced by Co-amoxiclav in a 13-year-old male child.

CASE REPORT

A 13-year-old child, a resident of Marathwada region, presented with a history of fever and sore throat to a local physician and was prescribed Tablet Co-amoxiclav - Amoxicillin (250mg) & Clavulanic acid (125mg) twice a day and Tablet Paracetamol (250mg) three times a day. On day 3, after starting the medications, the patient began to develop an erythematous maculopapular rash with central blisters initially over his four limbs. Then it spread all over his chest and back and gradually involved 70% of his total body area on day 5. This was then followed by the appearance of oral lesions, bilateral conjunctival congestion, and genital mucosa involvement on day 6. On the same day, he reported to the casualty of tertiary care Government Medical College & Hospital of Maharashtra and was advised to discontinue all previous medications and to get hospitalized.

On the day of hospitalization, general examination showed the child was well-built, nourished, conscious, and oriented. His vitals were normal, and a systemic examination showed no abnormal deficit. Cutaneous examination shows multiple well-defined bullae throughout the body. There were well defined post inflammatory hyperpigmentation over the back. The lips had well-defined, crusted, and bleeding erosions, and the patient experienced difficulty in opening his mouth. Bilateral conjunctival congestion was present and the genital mucosa was involved (Fig. 1 & Fig. 2). There was a history of a similar episode one year back, characterized by identical lesions and similar extent of body surface area involvement, after consumption of unknown tablets orally, and was managed by a local practitioner after hospital admission.

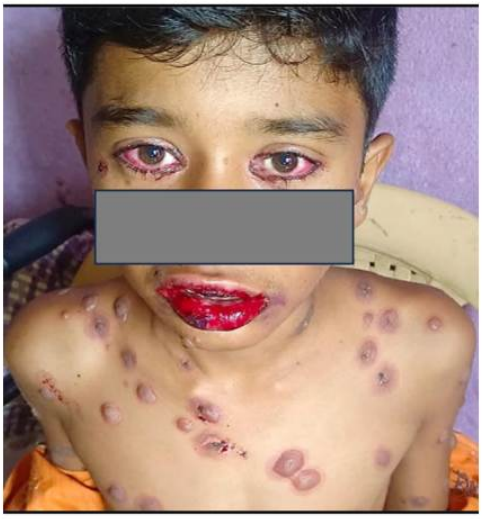

Fig. 1: Conjunctival congestion with crusted erosions and bleeding over lips

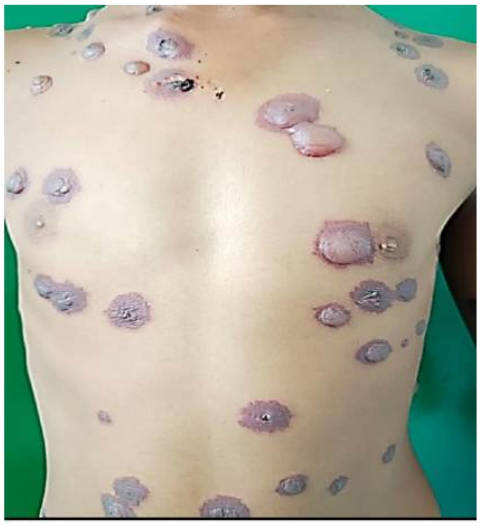

Fig. 2: Multiple well defined bullae over the body

Throughout his hospital stay for 9 days, the patient received intravenous steroids, antibiotics, intravenous fluids, antifungals, and other treatment according to standard hospital protocol[8]. Topical care involved saline soaks, chlorhexidine mouth wash, antibiotic cream, and moisturizing lotion applied all over the body and genitals. The inability of patient to open his mouth slowly disappeared as the healing of the erosion cured, and he could take oral feed. By day 8 of hospitalization, repeat photographs of the patient was taken (Fig. 3 & Fig. 4).

Lab tests revealed an initial count of White Blood Cell (WBC) was 13,000 cells/cm³, and it steadily decreased to 8,200 cells/cm³ over the course of the hospital stay. The Liver Function Tests (LFT) and Renal Function Tests (RFT)

were in normal range. HCV test was negative. The child recovered subsequently and was discharged on day 9 of hospitalization.

The patient provided written informed assent and the patient's parent also provided informed written consent for this manuscript and photograph to be published. Institutional Ethics Committee approval was obtained.

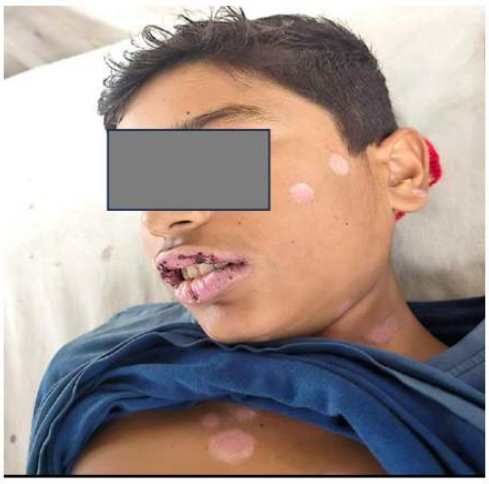

Fig. 3: Post treatment – healed scars over the lips and face

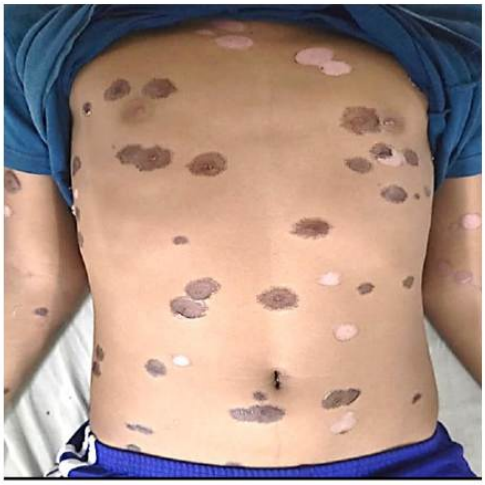

Fig. 4: Post treatment – healed scars over the body

DISCUSSION

The event showed a reasonable temporal relationship with drug intake, and the clinical response to drug withdrawal was appropriate, with no rechallenge been done. Given that the patient had previously tolerated paracetamol without any similar reaction, the adverse drug reaction was decided as "probable" using the WHO causality assessment scale[11]. The Naranjo Adverse Drug Reaction Probability Scale was also used as an assessment of causality criterion of the suspected ADR. The total score in the evaluation was "7", and it was determined that the causality of the ADR due to Co-amoxiclav was "probable"[10] (Table. 1).

As part of the Pharmacovigilance Program of India (PvPI), this case was reported to the Indian Pharmacopoeia Commission via the VigiFlow platform through AMC (ADR Monitoring Centers). Reporting ADRs to national centers like PvPI and to the WHO is essential for enhancing overall drug safety[12].

For prognostic purposes in SJS/TEN patients, a validated mathematical tool known as SCORTEN (severity-of-illness score for toxic epidermal necrolysis) was used. This score predicted a mortality of 3.2%[13] (Table. 2). The SCORTEN score on the day of admission was 3.2%, with only one prognostic parameter positive (epidermal detachment >10%). Repeat assessment on day 3 showed no change in the score. At the time of discharge, the score had reduced to 0%, correlating with complete healing of all cutaneous lesions. Early identification of SJS, discontinuation of triggering medicine, and prompt initiation of supportive therapy had improved the prognosis in this patient. Early detections and interventions such as issuing drug alert cards to patients can aid in preventing future re-exposure and reactions, thus decreasing the mortality and improving the chances for survival[14].

Table 1: Naranjo Assessment Scale

Question	Yes	No	Don't Know	Score
Are there previous conclusive reports on this reaction?	+1	0	0	Yes
Did the adverse event appear after the suspected drug was administered?	+2	-1	0	Yes
Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	Yes
Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0	DNK
Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	No
Did the reaction reappear when a placebo was given?	-1	+1	0	DNK
Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	DNK
Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	DNK
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	Yes
Was the adverse event confirmed by any objective evidence?	+1	0	0	No
Total Score				**7**

Table 2: SCORTEN

No.	Prognostic Parameter	Cut-off Value	Point
1	Age	> 40 years	0
2	Presence of malignancy	Yes	0
3	Tachycardia	Heart rate > 120 beats/min	0
4	Epidermal detachment	> 10% body surface area	1
5	Blood urea nitrogen	> 28 mg/dl	0
6	Serum glucose	> 252 mg/dl	0
7	Serum bicarbonate	< 20 mmol/L	0
	SCORTEN Score	**Mortality Rate (%)**	
	1	3.2	
	2	12.1	
	3	35.3	
	4	58.3	
	≥ 5	90	

CONCLUSION

Though Co-amoxiclav is considered among one of the safe antimicrobial used and very commonly used antimicrobial among all age groups, it can show a serious, life threatening ADR like SJS, very rarely. We have reported SJS related to Co-amoxiclav, which is very rare (1 per million). It further highlights the importance of attentive ADR observation and its management, the need for pharmacogenetics interventions and proactive pharmacovigilance of all drugs, even they are traditionally considered safe.

ACKNOWLEDGEMENT

Thanks to my professors and fellow residents for their support. I express extreme gratitude to Dr. Rajkumar (Junior Resident, Dept. of Skin & VDRL) for his continued assistance in this research.

References

1. Rodríguez-Martín S, Martín-Merino E, Lerma V, Rodríguez-Miguel A, González O, González-Herrada C, *et al*. Incidence of Stevens-Johnson syndrome/toxic epidermal necrolysis among new users of different individual drugs in a European population: a case-population study. *European Journal of Clinical Pharmacology*. 2019; 75 (2) :237-246 . Available from: https://doi.org/10.1007/s00228-018-2569-3
2. Ferrandiz-Pulido C, Garcia-Patos V. A review of causes of Stevens–Johnson syndrome and toxic epidermal necrolysis in children. *Archives of Disease in Childhood*. 2013; 98 (12) :998-1003 . Available from: https://doi.org/10.1136/archdischild-2013-303718
3. Fakoya, AOJ, Omenyi P, Anthony P, Anthony F, Etti P, Otohinoyi DA, *et al*. Stevens - Johnson Syndrome and Toxic Epidermal Necrolysis; Extensive Review of Reports of Drug-Induced Etiologies, and Possible Therapeutic Modalities. *Open Access Macedonian Journal of Medical Sciences*. 2018; 6 (4) :730-738 . Available from: https://doi.org/10.3889/oamjms.2018.148
4. Tee C T, Abdullah NH, Kristummoonthy P, Lee CS. Severe cutaneous adverse reactions: A 5-year retrospective study at Hospital Melaka, Malaysia, from December 2014 to February 2020. *Medical journal of Malaysia*. vol. 77,4 (2022): 409-414.
5. Fukasawa T, Urushihara H, Takahashi H, Okura T, Kawakami K. Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated With Antibiotic Use: A Case-Crossover Study. *The Journal of Allergy and Clinical Immunology: In Practice*. 2023; 11 (11) :3463-3472 . Available from: https://doi.org/10.1016/j.jaip.2023.07.012
6. Singalavanija S, Limpongsanurak W. Stevens-Johnson syndrome in Thai children: a 29-year study. *Journal of the Medical Association of Thailand = Chotmaihet thangphaet*. vol. 94 Suppl 3 (2011): S85-90.
7. Shukla AK, Jhaj R, Misra S, Ahmed SN, Nanda M, Chaudhary D. Agreement between WHO-UMC causality scale and the Naranjo algorithm for causality assessment of adverse drug reactions. *Journal of Family Medicine and Primary Care*. 2021; 10 (9) :3303-3308 . Available from: https://doi.org/10.4103/jfmpc.jfmpc_831_21
8. Prakash J, Joshi K, Malik D, Mishra O, Sachan A, Kumar B, *et al*. "ADR PvPI" Android mobile app: Report adverse drug reaction at any time anywhere in India. *Indian Journal of Pharmacology*. 2019; 51 (4) :236-242 . Available from: https://doi.org/10.4103/ijp.ijp_595_18
9. Torres-Navarro I, Briz-Redón A, Botella-Estrada R. Accuracy of SCORTEN to predict the prognosis of Stevens-Johnson syndrome/toxic epidermal necrolysis: a systematic review and meta-analysis. *Journal of the European Academy of Dermatology and Venereology*. 2020; 34 (9) :2066-2077 . Available from: https://doi.org/10.1111/jdv.16137
10. Mulkalwar S, Khan U, Chitale S, Tilak A, Rane B, Patel A. Reimagining the ADR Alert Card: a novel approach to recurrence prevention in low-cost settings for adverse drug reactions. *European Journal of Hospital Pharmacy*. 2025; 32 (4) :361-366 . Available from: https://doi.org/10.1136/ejhpharm-2024-004131
11. Chan HL, Stern RS, Arndt KA, Langlois J, Jick SS, Jick H, *et al*. The Incidence of Erythema Multiforme, Stevens-Johnson Syndrome, and Toxic Epidermal Necrolysis. *Archives of Dermatology*. 1990; 126 (1) :43-47 . Available from: https://doi.org/10.1001/archderm.1990.01670250049006
12. Brayfield A, editor. *Martindale: The complete drug reference*. 38th ed. London: Pharmaceutical Press; 2014. p. 217.
13. World Health Organization. *The use of the WHO-UMC system for standardised case causality assessment*. Geneva: WHO; 2018 [cited 2025 Dec 24]. Available from: http://www.who-umc.org/Graphics/24734.pdf
14. Levine GA. *Project PEPIDaP. Global estimates of the relative pediatric consumption and cost of oral amoxicillin and amoxicillin-plus-clavulanic-acid*. 2015