CASE STUDY

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Case Study on Severe Adverse Drug Reactions Caused by Rituximab

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ABSTRACT

Rituximab is a chimeric IgG1 immunoglobulin that attacks B cells' CD20 molecules. Its efficiency in the treatment of B cell malignant proliferative illness has been proven since 1997. Rituximab is also used to treat autoimmune illnesses involving B cells, such as autoimmune hemolytic anaemia, autoimmune thrombocytopenia, rheumatoid arthritis (RA), Sjogren's syndrome (SS), and systemic lupus erythematosus (SLE) (SLE). A 19-year-old female patient was admitted to the hospital with complaints of painful raw lesions all over the body for 6 months, burning sensation of eyes with redness, fever for 10 days. On Day 4 of admission, the patient was started on Injection Rituximab, and the patient had variations in ECG observed, complaint of fever, associated with chills, tachycardia and insomnia, observed on the very first day of use. Each form of HSR has its own set of characteristics, as well as its own course and management. In terms of a tailored and exact approach, the new proposed classification appears to have clinical implications. Skin tests are the first stage in the diagnostic process, and if they are negative, DPT should be performed if appropriate settings are available. As a result, the desensitisation strategy requires more awareness and acceptance.

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INTRODUCTION

Rituximab is a chimeric IgG1 immunoglobulin that attacks B cells' CD20 molecules. Its efficiency in the treatment of B cell malignant proliferative illness has been proven since 1997 [1, 2]. Rituximab is also used to treat autoimmune illnesses involving B cells, such as autoimmune hemolytic anaemia, autoimmune thrombocytopenia, rheumatoid arthritis (RA), Sjogren's syndrome (SS), and systemic lupus erythematosus (SLE) [3, 4]. Rituximab has been shown to be effective in the treatment of mixed cryoglobulinemia (MC) vasculitis, which is caused mostly by hepatitis C virus (HCV) infection [5, 6]. The clinical and biological tolerance is good generally [7]. Fewer than 20 cases of serum sickness syndrome have been reported as a result of systemic medication responses [8].

Adverse effects

Despite being generally well-tolerated, rituximab infusions, either alone or in combination with other agents, can cause adverse drug reactions (ADRs) that, while rare, can lead to the drug's discontinuation; as a result, these patients are unable to benefit from the monoclonal antibody's therapeutic potential.

There are two main categories of adverse medication reactions: Type A reactions are widespread and can happen to anyone. The Type B reaction, also

known as "Drug Hypersensitivity," is rare, unpredictable, and limited to those who are vulnerable. Drug hypersensitivity can be caused by immunological or non-immune processes.

Traditional Gell and Coombs classification is used to better explain these variances in clinical presentations. Allergic medication responses can appear with a variety of clinical manifestations.

CASE REPORT

A 19-year-old female patient was admitted to the hospital with complaints of painful raw lesions all over the body for 6 months, burning sensation of eyes with redness, fever for 10 days.

Medication history

The patient had no known history of drug or non-drug allergies, married, a non-alcohol user and a non-smoker with mixed diet habits. No familial history of skin infections was reported.

The patient was on OTC (over the counter) medication of a tradition tablet with the composition of Shilapushpha 130mg + Pasanabheda 98mg to help burning sensation, cream Framycetin Sulphate 1% w/w, for redness and itching sensation. Liquid paraffin for maintaining healthy skin.

EXAMINATION

On examination, the patient was afebrile, Reddish lesions were observed all over the body, temperature fluctuations were observed.

Lab investigations reported as PR- 80 bpm, RR- 20/min, BP- 110/80 mm Hg, SPO_2- 98%. Thyroid profile included total T_3 – 1.01, Total T_4 – 9.30, TSH- 2.103, Hb – 11.7 g%, RBC count – 4 million microns/mm, Total WBC count- 16,200, platelet count – 2.3, PCV – 32.6, MCH- 30.3, MCV – 84.7.

DISCUSSION

On the evaluation of lab data and existing medical history and presenting symptoms, the patient was diagnosed with pemphigus vulgaris with exogenous cushing syndrome.

Therapeutic approach

The patient was started on Tablet Azathioprine, 50 mg-OD, which is an immunosuppressant, indicated for cushing's syndrome inpatient. Tablet Vitamin D, for vitamin supplementation, Injection Dexamethasone 1cc, IV-OD, which is a corticosteroid, indicated for autoimmune disease in the patients, Tablet vitamin B –OD, for vitamin supplementation, Tablet Chlorpheniramine maleate, which is an antihistamine that reduces negative effects caused by chemicals.

ADR

On Day 4 of admission, the patient was started on Injection Rituximab, and the patient had variations in ECG observed, complaint of fever, associated with chills, tachycardia and insomnia, observed on the very first day of use.

Management of ADR

The patient was started with IVF saline to manage tachycardia by diluting the drug Rituximab in the body. Injection. Rituximab was completely withdrawn, dechallenge was positive, with fast recovery of all ADR symptoms. No rechallenge was performed. ADR were of serious reactions.

In our patient, ADR was managed by immediate withdrawal of suspect drug Rituximab. Therapy was continued by other alternative drugs available.

Probability Assessment of ADR

Probability refers to the likelihood that a suspect is responsible for an occurrence. The chance that Ceftriaxone would induce Rash was determined in this case using the FDA-approved Naranjo's scale. The likelihood of ceftriaxone-Rash was determined to be "6 Points" out of a possible maximum of 9. The data in Table 1 are accurate representations of the scores and observations.

Severity of ADR

The Modified Hartwig and Siegel Severity Scale was used to assessing the severity of this ADR, which suggests that the ADR was well controlled by delaying or discontinuing the suspect substance, as well as providing an antidote or other therapy. Furthermore, because the ADR was not present and was recovered with Sequelae, there was no prolonged hospitalisation, complication, or irreparable issues, which would have been the result of ADR.

CONCLUSION

Despite the fact that rituximab is well-tolerated, its widespread usage has resulted in a rise in the number of HSRs. HSRs to mAbs, including rituximab, have been classified in a variety of ways, with some overlap. Each form of HSR has its own set of characteristics, as well as its own course and management. In terms of a tailored and exact approach, the new proposed classification appears to have clinical implications. Skin tests are the first stage in the diagnostic process, and if they are negative, DPT should be performed if appropriate settings are available.

Table 1: ProbabilityAssessment by Naranjo's Scale

S. No.	Questions	Yes	No	Don't Know	Score
1.	Are there previous conclusion reports on this reaction?	+1	0	0	0
2.	Did the adverse reaction appear after the suspected drug was administered?	+2	-1	0	+2
3.	Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	+1
4.	Did the adverse reaction re-appear when the drug was re-administered?	+2	-1	0	0
5.	Are there alternative causes that could on their own have caused the reaction?	-1	+2	0	+2
6.	Did the reaction re-appear when a placebo was given?	-1	+1	0	+1
7.	Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8.	Was the reaction more severe when the dose was increased or was it less severe when the dose was decreased?	+1	0	0	0
9.	Did the patient have a similar reaction to the same or similar exposure?	+1	0	0	0
10.	Was the adverse event confirmed by any objective evidence?	+1	0	0	0
				Total Score	6

As a result, the desensitisation strategy requires more awareness and acceptance.

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Conflict of Interest

The author declares that they have no conflict of interest.

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