Author reply: Biologics or biosimilars: What is the difference?

Sir,

We thank the authors for their interest in the article "Clinical efficacy of rituximab in the treatment of pemphigus: A retrospective study" and their valuable comments.¹ In their letter, a query regarding the brand of rituximab (biologic/ biosimilar) used in our study has been submitted. We have deliberately not mentioned the name of rituximab company/brand used as our study was not supported by any pharmaceutical company and we did not want to inadvertently promote a brand. We used a biosimilar of rituximab (Reditux, Dr. Reddy's Laboratories) in all of our patients. We chose above brand as it was easily available and low priced. Recently, it has been found to have the same efficacy in depleting the B-cells, when compared to the original molecule.² We agree that biosimilars can have variable efficacy in different brands and sometimes in different batches of the same brand; hence, it is appropriate to mention the brand used in a study.

Regarding the observation of discordance between the text and table, whereas mentioning the past treatment of dexamethasone/dexamethasone-cyclophosphamide pulse therapy was concerned, we would like to clarify that the past treatment mentioned in the table refers to the treatment given in our institute. Ten out of 21 recalcitrant patients received dexamethasone/dexamethasone-cyclophosphamide pulse/cyclophosphamide pulse therapy from our institute while five patients (patient no. 3, 9, 14, 22, 24) received corticosteroid pulse treatment outside. Other six recalcitrant patients only received oral immunosuppressive therapy; however, as one of these patients received treatment outside our institute, the details were not available in the proforma.

Regarding the use of long-term maintenance immunosuppressive therapy after dexamethasone/ dexamethasone-cyclophosphamide pulse, as per the protocol described by Pasricha *et al.*, an adjuvant (cyclophosphamide 50 mg oral daily/azathioprine 50 mg twice daily orally) was used along with dexamethasone/dexamethasone-cyclophosphamide pulse/cyclophosphamide pulse therapy in eight patients though details were not available for other patients.³

The query regarding the benefit of rituximab on dexamethasone-cyclophosphamide pulse in recalcitrant pemphigus was not addressed in this study. We have observed that the number of hospital and day care visits is far less with rituximab as only two injections require hospitalization or day care visit and rest of the treatment regimen can be managed on outpatient basis. However, the paradoxical exacerbation after rituximab may require an additional inpatient care. The overall corticosteroid intake is significantly reduced with rituximab regimen compared to corticosteroid pulse therapy (mean cumulative dose = 3535.64 mg in our study). In our study, 21 patients were recalcitrant and we were able to achieve complete remission in 19 patients at 4.34 months. The main achievement of dexamethasone/ dexamethasone-cyclophosphamide pulse therapy is the long-term remission after stopping therapy though it is too early to compare rituximab with dexamethasone-cyclophosphamide pulse therapy.⁴ We have also observed that relapse rate after a single cycle of dexamethasone-cyclophosphamide pulse and rituximab is comparable (21% and 16%, respectively).^{1,5} In our study, we have used only one cycle of rituximab 1000 mg, at a 2-week interval; however, in future, we propose to use an additional cycle of rituximab if the patient at 6 months is not free of lesions or still needs prednisolone. There is an urgent need to agree on a rituximab regimen so that data from different studies being carried out in India can be compared.

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REFERENCES

- 1. Sharma VK, Bhari N, Gupta S, Sahni K, Khanna N, Ramam M, *et al.* Clinical efficacy of rituximab in the treatment of pemphigus: A retrospective study. Indian J Dermatol Venereol Leprol 2016;82:389-94.
- Gota V, Karanam A, Rath S, Yadav A, Tembhare P, Subramanian P, et al. Population pharmacokinetics of Reditux[™], a biosimilar rituximab, in diffuse large B-cell lymphoma. Cancer Chemother Pharmacol 2016;78:353-9.
- 3. Pasricha JS. Pulse therapy as a cure for autoimmune diseases. Indian J Dermatol Venereol Leprol 2003;69:323-8.
- 4. Pasricha JS, Khaitan BK, Raman RS, Chandra M.

Dexamethasone-cyclophosphamide pulse therapy for pemphigus. Int J Dermatol 1995;34:875-82.

 Pasricha JS, editor. AIIMS experience. In: Pulse Therapy in Pemphigus and Other Diseases. 3rd ed. New Delhi: Mehta Publishers; 2006. p. 67-71. This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

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