

More Robust Evidence and Safety Checks are Required Before Autologous Serum Therapy as Treatment for Chronic Urticaria can be Recommended

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Sir,

The report by Patil *et al.* on use of autologous serum therapy (AST) for patients with chronic autoimmune urticaria (CAU), defined by the positive autologous serum skin test, needs to be critically reviewed for several reasons.[1] The reported response rate of 45% (9 of 20 patients) after use of AST is not followed-up by specific response parameters such as urticaria activity score over a time period. The authors have not provided other patient specific parameters such as thyroid autoimmunity or anti-nuclear antibody, concomitant medication use such as antihistamines or immunosuppressants to justify the conclusion.

The report does not elaborate on the details of the blood collection and serum preparation techniques including whether the screening tests for infectious diseases (HbsAg, antibodies to HCV or HCV-nucleic acid test, HIV-I/II, syphilis) were carried out on these patients before serum preparation. Previous published data on this procedure involves sterile collection of either 100 ml or one unit (470 ml) blood. Clot retraction is then allowed for 2 h at 21°C (room temperature), centrifuged for 15 min at 3000 g and supernatant serum removed in a laminar air flow hood. A third of the amount of whole blood collected is generally the yield of serum. The serum is then diluted with an equivalent amount of balanced salt solution and filter sterilized. Aliquots of serum are then stored and samples sent to exclude microbiological contamination before administration and used within 3 months.[2] The authors do not discuss why they decided to give nine once-weekly intramuscular injections of autologous serum, nor provide a workable hypothesis of how this might work in CAU. There was no data provided on how long the “remission” lasted in the nine patients in whom the AST was effective.

Although, it is widely recognized that there is a need for new and rational treatments for this difficult-to-treat chronic disorder, it does not merit a reason such as a “poor man's biological” therapy for using AST. High cost of therapy of effective biological such as anti-IgE monoclonal antibody (Omalizumab)[3] alone should not dictate on the use of such treatment options given the possible health and safety risks of use of autologous serum as “treatment” for patients. This is more so given our past knowledge of transmissible prion protein diseases, and perhaps also the reason why the British Committee of Standards in Hematology has adopted new guidelines for pre-deposit autologous blood donation.[4] Clinicians should try and find ways of sourcing the well-tested and effective biologic drug Omalizumab or conduct a well-designed rigorous clinical trial on AST to prevent serious medical disasters.

References

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