URTICARIA, ANGIOEDEMA

SUBCUTANEOUS AUTOLOGOUS SERUM THERAPY VS. CONVENTIONAL INTRAMUSCULAR AUTOLOGOUS SERUM THERAPY IN CHRONIC URTICARIA: A RANDOMISED, CONTROLLED TRIAL COMPARING THE EFFECTIVENESS AND SAFETY

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Introduction: Autologous serum therapy (AST) aims to supplement the existing pharmacotherapy in chronic urticaria by decreasing the high daily antihistamine pill-burden and maintaining the symptom-free interval. Subcutaneous AST(s-AST) further modifies the amount of serum (1mL) and gauge of needle (31G) to improve compliance and facilitate ease of application.

Objective: To assess clinical effectiveness and safety of s-AST versus conventional intramuscular AST (c-AST) and to compare quality of life in both treatment arms

Materials and methods: Institution based, assessor-blind, prospective, randomised (balanced un-stratified randomisation with allocation ratio 1:1, allocation concealment with SNOSE), parallel group, active-controlled trial, analysed on modified intention-to-treat principle, with 32 patients in each treatment arm. Autologous serum skin test (ASST) was done at baseline and autologous serum was injected as per randomization every week for 9 consecutive weeks.

Results: Among study population(n=64, mean age 35.312±12.681 years), c-AST(n=32; M:F=1:2.2) and s-AST(n=32; M:F=1:1.9) had comparable duration of disease(P=0.164, Mann Whitney U test), auto-reactive status(P=0.796), Urticaria Total Severity Score(TSS)(P=0.637) and Urticaria Activity Score(UAS-7)(P=0.982). Both UAS-7 and TSS along with antihistamine pill-burden reduced significantly (P<0.001, Friedman's ANOVA) in both s-AST and c-AST from 1st follow-up onwards (P<0.05, Post-hoc Dunn's test). Significant improvement was noted in patient's as well as physician's global assessment of disease activity improvement scale (P<0.001, Friedman's ANOVA). Dermatology Quality

Life Index (DLQI) showed marked improvement in both treatment arms(P<0.0001, Wilcoxon test). Pain at injection-site was more with c-AST(n=13) than s-AST(n=4) (P=0.0219, Fischer's exact test). Younger age (P=0.027, ANOVA) and lower baseline TSS (P=0.003, Kruskal-Wallis test) were associated with better therapeutic response. Baseline UAS-7 (rho=0.256) and TSS(rho=0.428) scores and diameter of lesions(rho=0.270) showed positive correlation with response pattern.

Conclusion: Subcutaneous-AST(s-AST) is comparable to conventional-AST(c-AST) in effectiveness and safety, with less adverse effects and ease of operation, thus having the potential to replace c-AST in the treatment of unresponsive chronic urticaria.