PIGMENTATION

COMPARISON OF THE EFFICACY, TOLERABILITY AND SAFETY OF 10% TRANEXEMIC ACID CREAM VERSUS 20% AZELAIC ACID CREAM IN MELASMA: A SPLIT FACE, DOUBLE-BLIND RANDOMISED CONTROLLED TRIAL

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Introduction: Melasma poses the threat of steroid-abuse in recent times. Need for a non-steroidal anti-melasma agent is need-of-the-hour. Tranexamic acid, by its anti-plasmin activity reduce alpha-melanocyte-stimulating hormone. Azelaic acid on the other hand causes direct cytotoxicity on melanocyte by inhibiting DNA synthesis and mitochondrial enzymes. Thus both have potential as anti-melasma agent.

Objective: To assess efficacy, safety of 10% Tranexemic acid cream(TA) vs. 20% Azelaic acid cream (AA) in treatment of Melasma

Methodology: Single-center, split-face, double-blind, randomized (1:1), active-controlled, parallel group phase IV trial conducted on
adult patients of melasma of either sex having involvement of malar area. Each hemiface received either TA or AA as per computer-generated random number sequence. Fortnightly follow-up was done for 12 weeks(End-of-treatment visit). Primary outcome measures was the composite malar area pigment score (CMAPS) calculated by the area of involvement(A), homogeneity(P) and pigmentation(P) on the malar area. Treatment-emergent adverse events were monitored.

Results: Being a split-face study, the comparator groups (n=16 each) were a perfect match with respect to the clinico-demographic profile, mean age 31.82±6.30 years, mean duration of sunexposure 3±1.61 hrs, duration of illness 21.19±15.31 months, mean MASI 9.08±4.34, and were having predominantly epidermal (62.5%) melasma. Baseline CMAPS of TA and AA was comparable (P=0.7695, Wilcoxon's test). At final visit the CMAPS of TA (1.73±1.68) was less than AA (2.08±1.70), though not statistically significant. With both TA and AA there was significant reduction (P<0.001, Friedmen's test) in CMAPS from 1st

follow-up visit (P<0.05, Post hoc test); though with AA the plateau is reached after 5th follow-up but for TA reduction continued till study end. Burning and stinging sensation (5% with TA vs 45% with AA) was found to be significantly more with AA.

Conclusion: Both TA and AA are useful non-steroidal treatment options for melasma, though TA is better tolerated than AA.