PIGMENTATION

SAFETY AND EFFICACY OF MICRONEEDLING AND ORAL TRANEXAMIC ACID ON THE TREATMENT OF FACIAL MELASMA IN WOMEN: AN OPEN RANDOMIZED DOUBLE-BLINDED FACTORIAL CLINICAL TRIAL.

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Background: Tranexamic acid and microneedling have demonstrated depigmenting properties in the treatment of melasma. To date, no clinical trial has compared them to classic therapy (sunscreen and triple combination).

Objective: To evaluate the efficacy, safety, impact in quality of life and remission promoted by microneedling, oral tranexamic acid and their association for the treatment of facial melasma in women.

Materials and Methods: Open randomized controlled double-blinded factorial trial involving 64 women randomized into 4 groups: CG received oral placebo, opaque sunscreen and a triple combination cream containing fluocinolone acetonide 0.01%, tretinoin 0.05%, and hydroquinone 2% once daily; M was submitted to 2 sessions of microneedling (roller 1,5mm, moderate injury) with interval of 30 days between then in addition to CG regimen; TA received oral tranexamic acid 250mg twice daily, in addition to CG regimen. MT group received oral tranexamic acid, 2 sessions of microneedling in addition to CG regimen. After 8 weeks, all groups were maintained using just sunscreen and triple combination cream for other 8 weeks. MELASQoL, mMASI, colorimetry (ITA) and adverse effects were evaluated at T0, T30, T60 and T120.

Results: The groups didn´t differ regarding baseline data: phototype, pregnancies, mMASI, MELASQoL, age of onset, and colorimetry ($p>0.1$). mMASI has decreased at T60 for all groups ($p<0.05$): CG=-16%%, TA=-47%, M=-31%, MT=-39%; with superiority to TA ($p=0.05$). MELASQoL has decreased for all groups ($p<0.01$): CG=-34%, TA=-36%, M=-48%, MT=-64%; with superiority for the groups with microneedling ($p<0.05$). ITA has increased for all groups ($p<0.01$): CG=16o, TA= 16o, M= 14o, MT= 14o; without difference

among them (p=0.89). There were no serious adverse effects. At T120 all groups disclosed impairment of melasma without difference among them.

Conclusions: Oral tranexamic acid was safe and evidenced additional efficacy to classic treatment of melasma. Microneedling promoted greater improvement on quality of life.