Neutral Superoxidized solution vs. benzoyl peroxide gel 5% in the treatment of acne vulgaris: a randomized open-label clinical trial.

Summary.

Superoxidized solution (SOS) is an electrochemically processed aqueous solution manufactured from pure water and sodium chloride. Inflammatory skin disorders have all improved their outcomes with the use of SOS. These indications point that SOS could be useful in acne.

Forty patients were enrolled in this open label, clinical trial. Patients had present with 10-50 inflammatory lesions (papules and pustules) and an abscess of nodulocystic lesions.

Improvement was excellent in 7 patients (47%) using SOS compared with 5 patients (31%) using BP ($p=0.378$), good in 5 patients (33%) using SOS compared with 5 patients (31%) using BP ($p=0.794$), fair in 2 patients (13%), compared with 4 patients (25%) ($p=0.713$) and in 1 patient (7%), the response was poor, compared with 2 patients (13%) using BP ($p=0.725$). We did not require changing a dose during the study period and no systemic effect was observed.

We found that SOS is an important choice to treat inflammatory acne; nevertheless, a larger sample in a double-blind, controlled clinical trial is needed.

Keywords.

Superoxidized solution (SOS) is an electrochemically processed aqueous solution manufactured from pure water and sodium chloride. During this electrolysis process, reactive species of oxygen and chlorine are formed. This reaction creates an unbalanced osmolarity that affects microbial homeostasis.¹ There are some reports showing beneficial effects of SOS in other disorders besides infections. Skin ulcers, burns, peritonitis and inflammatory skin disorders (e.g. pemphigus, psoriasis) have all improved their outcomes with the use of SOS.² Some of these indications point that SOS could be useful in other inflammatory skin disorders like eczema, acute contact dermatitis or even acne and rosacea.

Forty patients were enrolled in this open label, clinical trial: 20 women and 20 men, age ranged 18 - 25 years. To be included, patients had present with 10-50 inflammatory lesions (papules and pustules) and an absence of nodulocystic lesions. No other inflammatory cutaneous disease could be present on the face. Patients were not to have used any other topical treatment for 14 days, systemic antibiotics for 30 days, or systemic retinoids for at least 6 months prior to initiation of treatment.

Patients were randomly assigned to treatment with SOS or benzoyl peroxide (BP) gel 5% using a balanced blocks method (columns of 5 patients), followed by random numbers generated by a computer and assigned to the patients by the second investigator. The same investigator assigned treatments, while the assessment of efficacy was performed by the first and third investigator. Patients apply a thin amount of the study products to the entire face once daily at night during the 12-week treatment period. Patients were evaluated at
baseline, weeks 4, 8 and 12. Efficacy was evaluated by counting the changes in the numbers of facial inflammatory lesions. Response was graded as excellent (≥75-100% reduction of lesions), good (≥50-74% reduction), fair (≥25-49%), poor (<25%). Tolerance was assessed by determining erythema, scaling and burning or pruritus in a scale of 0-3 points (0 = none to 3 = severe).

Statistical analysis was performed using the Friedman test to evaluate differences between the values of the four time-points. To compare efficacy between treatments at the different time-points, Mann-Whitney test was used. Tolerance was evaluated with a $\chi^2$ test (Fisher test for expected values less than 5).

Thirty one patients completed the study, 15 in the SOS group and 16 in the BP group. All patients who discontinued were lost in the follow up with no apparent cause.

There was a gradual, significantly reduction in the counts of inflammatory lesions in both groups. The group of SOS showed a greater reduction in inflammatory lesion counts than BP in all follow-up visits. These differences were more pronounced in the last week of follow-up. In the last weeks of treatment, the improvement was excellent in 7 patients (47%) using SOS compared with 5 patients (31%) using BP ($p= 0.378$), good in 5 patients (33%) using SOS compared with 5 patients (31%) using BP ($p= 0.794$), fair in 2 patients (13%), compared with 4 patients (25%) ($p= 0.713$) and in 1 patient (7%), the response was poor, compared with 2 patients (13%) using BP ($p= 0.725$).

In general, irritation was mild in both treatments. Erythema, scaling, but no burning or pruritus, started from week 4 and reduced or solved by week 12
without treatment. We did not require changing a dose during the study period and no systemic effect was observed.

The results of this study indicate that SOS and BP were highly effective in treating inflammatory facial acne. Superoxidized solution showed a great improvement in inflammatory lesion counts, comparable with the BP group. Tolerance was equal in both treatments.

It is well known the efficacy of SOS in skin infections and ulcers, but in the case of acne, it is probably that the efficacy of SOS is related in part to the antiseptic effect of SOS, or to an anti-inflammatory effect. The precise mechanism by which SOS acts as an anti-inflammatory agent is unknown. Medina-Tamayo et al. showed that SOS can inhibit mast cells degranulation. They explained that this effect is made by the SOS without altering the main signal transduction pathway, which may be useful to control localized allergic and inflammatory reactions. In acne, mast cell plays an important role in inflammation with the production of IL-6 and TNF α, moreover, there is an increased number of mast cells in adjacent areas to the sebaceous glands, suggesting that inflammation in acne is not only related to lipogenesis or P. acnes, but via mast cells. In summary, our study is the first clinical trial to compare the effectiveness and tolerance of SOS in the treatment of acne. We found that SOS is an important choice to treat inflammatory acne; nevertheless, a larger sample in a double-blind, controlled clinical trial is needed.

References.

