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Clinical Efficacy of a New Hypertonic Draining Cream in the Treatment of Cellulite: A Randomized, Double Blind Right-vs-Left Placebo-Controlled Trial

Massimo Milani*, Mario Puviani
1. Difa Cooper Medical Department Caronno Pertusella (VA), Italy
2. Poliambulatorio Medica Plus Modena, Italy
Email: Massimo.Milani@difacooper.com

ABSTRACT

Cellulite (gynoid lipodystrophy) is a common skin disorder that primarily represents a cosmetic concern rather than a pathological condition. Cellulite affects up to 98 per cent of post-pubertal women at varying levels of severity. The initial process of cellulite is characterized by oedema with fluid accumulation in the subdermal tissue. Recently a new topical product with draining action (HTC) has been developed which contains escine, beta-sytosterols, caffeine, and hypertonic sodium chloride. In an experimental analysis of the human skin model, HTC has shown that when applied over the skin specimen, a water volume of 5 percent of its weight can be removed from the surface.

A total of 30 women (mean age 34 years) with Grade I or II cellulite were enrolled in a randomized, double blind, intra-patient (right vs. left) controlled trial after their informed consent. HTC and placebo cream were randomly distributed for 28 days once daily on the lower limb's right or left position, in a double-blind manner. Primary outcomes of the trial were the evolution of thigh circumference measurements, evaluated at baseline, day 14 and day 28, adipose panniculus and elastometry ultrasonography assessment, evaluated at baseline and after 28 days of treatment. Secondary findings were the 5-point International efficacy tests (IGE and PGE) of orange peel presence (from 0 to 4).

The thigh diameter of the treated sites in the HCT was significantly decreased (p=0.003) by -0.61 cm and by -1.06 cm, respectively after 14 and 28 days of treatment compared with the baseline value. The VC application reduced the circumference of the thickness by -0.19 cm (day 14) and -0.23 cm (day 28): this difference was not statistically significant compared to the base. Ultrasonography assessment of adipose tissue showed significant (p=0.05) reduction (-1.73 mm after 28 days) compared with baseline after application of HTC.

Ultrasonography evaluation of the site handled in the VC revealed a non-significant reduction after 28 days compared with the baseline of -0.77 mm, respectively. Elastometry in HCT improved in HCT by 1.4 per cent and in VC by 0.89 per cent. The IGE analysis of the presence of orange peel showed an increase (without pinch test) of 33% in HCT and 7% in VC (p=0.02 between treatments) and 40% in HTC and 20% in VC (after pinch test) (p=0.05, between treatments). For both HCT and VC groups the no-pinch IGE score was 2.3 at baseline. By day 28, no-pinch IGE score decreased significantly (p=0.0019) to 1.9 only in sites treated with HCT. In VC the IGE score for no-pinch was 2.2 at day 28. PGE assessment of the orange peel appearance showed that 73 percent of subjects observed a substantial change in the sides treated with HTC versus 37 percent in the sides treated with VC (p=0.004). All goods had managed well.

This new HTC has demonstrated superior clinical efficacy in improving both objective and subjective assessments of cellulite parameters compared with the vehicle cream.

Keywords: Lipodystrophy; Randomized controlled trial

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