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Short Communication

Observational Study about a New Gel Containing Beta Sitosterol Escin Application after Sclerotherapy and Superficial Vein Thrombosis (SVT)

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Introduction

Chronic Venous Insufficiency (CVI) is a consequence of macrovascular and microvascular changes in the lower extremities, including basement membrane thickening, capillary bed malformation (with an increased fluid permeability), and endothelial damage [1,2]. In cases of local inflammation, hypoxic damage to endothelial cells augments the local inflammatory process and leads to impairment of endothelial functions [3,4]. There is an hypoxic vulnerability of capillary vessels, and any treatment for CVI or edema should aim to restore normal oxygen levels (normoxia).

The mainstay of treatment for CVI is compressive stockings [1,5], with surgical and/or pharmacologic therapies also prescribed depending on severity [1]. However, a concomitant medication can protect endothelial cells from hypoxic damage, reducing the loss of capillary function.

Escin is the active component of *Aesculus hippocastanum*, the horse chestnut, which was itself used as a traditional medicine for centuries [6], and is used to treat certain conditions, including hemorrhoids [7], varicose veins, hematoma, and venous congestion [8].

Escin was first isolated in 1953 [6] and has demonstrated anti-edematous, anti-inflammatory, and venotonic properties in various preparations [9]. It has also shown effectiveness as an adjunct [10] or alternative [11] to compression therapy, and is known to act directly on endothelial hypoxia [9].

Raw escin 1.5% is extracted with methanol and water from a purified, concentrated, homogenized preparation of horse chestnut seeds. It is subsequently further purified and crystallized as pure escin [8]. The product is used a topical gel applied for varicose vein problem, after sclerotherapy (when indicated for the treatment of venous pathology) or in other multiple applications (for example sport injuries, contusion, hematoma ,crushing). Phytosomal beta sitosterol escin is a new technological formulation which guarantees the maximum disposability of escin and consequently its effect. It is the principal ingredient of a new formulation, Clarema® fitogel, which was analyzed in this study.

Methods

We have studied 50 patients, 30 females and 20 males, with an average age of 45 years old (range 28-65 years old). We used Clarema® Fitogel, a gel based on phytosomal beta sitosterol escin, guarantying maximum disposability of the ingredient, for two indications: post sclerotherapy (30 patients) and for superficial vein trombosis (20 patients). The product has been applied 2 times per day.

Follow-up visits were performed at time zero, after 15 and 30 days. Efficacy was evaluated on the basis of an observer assessment of symptom improvement classified from 1 to 10 (10 very good, 1 bad), pain during application or removal of the gel and adverse reactions.

Results

85% of the patients treated with clarema® fitogel increase in the scores for very good and good in a one month period of treatment with the gel, with a significant difference from the control patients. There were no problems during applications or removal of the gel and no adverse reactions were observed.

Conclusions

Many studies have demonstrated the anti-inflammatory, venotonic and endothelial protective properties of escin. Also in our observational study all patients achieved an improvement in symptoms with remission of swelling, pain on movement and pain on loading and local hyperthermia. There results indicate that the new technology on which Clarema® fitogel is based, maximizes the effects of escin without adverse reactions nor application problems. We do encourage more clinical studies to further demonstrate these properties in larger patient populations.

Disclosure

Edoardo Cervi has received consultant fees by Damor S.r.l. The author reports no other conflicts of interest in this work.

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