

Clinical evaluation of the efficacy and safety of calcium dobesilate in patients with chronic venous insufficiency of the lower limbs.

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Several venotonic drugs have been used in the treatment of chronic venous insufficiency (CVI) of the lower limbs, most of them from natural sources. Calcium dobesilate, from synthetic origin, has been shown to improve clinical symptoms of these venous conditions. **Three hundred fifty-two patients** with CVI in grades I and II of Widmer's classification were included from an open population between January 1999 and June 2000; patients received calcium dobesilate 500 mg **every 8 hours for 9 weeks**. A basal recording and recordings every **3 weeks** were made of heaviness, pain, cramps, and paresthesias of the lower limbs with a severity scale, and edema was assessed by measurement of the circumference of ankles and calves. Two hundred eighty-six patients (81.3%) were women and 66 (18.7%) were men with a mean age of 45.7 +/-14.1 years; 200 patients (56.8%) were grade I and 150 (42.6%) were grade II of Widmer's classification, and two patients had no classification, with a mean duration of symptoms of 6.5 +/-7.4 years. **All of the symptoms had a significant reduction from the first to the final visit of treatment**; 70% of the patients complained of moderate to severe heaviness of the lower limbs at the beginning of the study, whereas 10% of the patients presented this symptom at the end of treatment. Likewise, 75%, 37%, and 41% of the patients, respectively, complained of moderate to severe pain, cramps, and paresthesias of the lower limbs at the beginning of the study, with a reduction in this prevalence to 6%, 2%, and 4%, respectively, at the end of treatment ($p < 0.001$, Wilcoxon test). In regard to edema of ankles and calves, a significant reduction in circumferences was registered in both sites at the end of treatment; for instance, the mean circumference of the right ankle was reduced from 23.78 +/-0.27 to 22.71 +/-0.31 cm while the right calf had a reduction from 35.08 +/-0.41 to 33.83 +/-0.5 cm ($p < 0.001$, paired t test). Side effects were registered in 17.9% of the patients. **This trial shows that calcium dobesilate had significant efficacy in the improvement of all the symptoms in patients with CVI, achieving this effect with an acceptable safety profile.**