

Red Vine

EFLA® 266⁺



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A red vine leaf extract reduces leg swelling in healthy women

PRESENTING:

Kazama A., Fujii F., Hashimoto T., Verbruggen M., Suzuki N., Ichikawa S., Yamamoto K., Mohri K. (2012).
[The improvement effect for swellings of lower limb of preparation of red vine leaf extract]. *Pharmacometrics* 83 (1/2), 1-7. [Article in Japanese]

Introduction

The knowledge of the medicinal use of grape vine (*Vitis vinifera*) can be traced back far in history. In East-Mediterranean countries the grape vine leaf is an important ingredient for the preparation of traditional dishes. The leaf of *Vitis vinifera* is plentifully documented in the literature of traditional medicine of different European countries, where its astringent and homeostatic properties are utilized in the treatment of diarrhoea, bleedings, haemorrhoids or varicose veins [1]. The use of the grape vine leaf in both traditional medicine and food preparation speaks for its high degree of safety and good tolerability. In evidence-based phytotherapy, the red vine leaf is used in case of venous diseases, its efficacy has been shown by different trials [2].

Swelling of the lower legs is a common affliction in many people [3], caused especially by prolonged standing, sedentary activities or sitting for longer periods such as during air travel. Peripheral oedema may be uncomfortable and can be a sign of a more serious condition, such as chronic venous insufficiency (CVI). The available evidence for the activity of red vine leaf is based on trials conducted with one well-known market product in a serious medical condition such as chronic venous insufficiency or CVI. With this study, we aimed to assess the efficacy of an alternative preparation in a rather preventative use, addressing the more common leg swelling as a symptom of nascent venous insufficiency.

Objective

The aim of this study was to evaluate the efficacy and safety of the intake of a red vine leaf extract on leg swelling in healthy Japanese women.

Materials and Methods

Study design: This was a single-blinded, placebo-controlled, crossover clinical trial conducted at the Jakara Clinic in Tokyo, Japan, under the monitoring of Orthomedico Co., Ltd, Tokyo, Japan. It was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of the clinic. Written informed consent was obtained from all participants prior to study start.

Participants: 17 healthy Japanese female subjects aged 25-58 years recurrently suffering from swollen legs volunteered for the study. Pregnant women were excluded.

Tested extract: A powder extract from dried red vine leaves (RVLE) (DER 3.6-6.3=1, extraction solvent 30% (m/m) ethanol, containing 0.5 % (m/m) anthocyanins, 9 mg/100g trans-resveratrol and 40.5 % (m/m) polyphenols) provided by ASK Intercity Co. Ltd., Japan and manufactured by Frutarom Switzerland Ltd., Switzerland (Art.Nr. 0085266).

Interventions: Participants ingested 3 capsules each containing 200 mg of the RVLE daily after breakfast during 6 weeks, resulting in daily dosage of 600 mg. After a washout period of 2 months, the treatment was repeated with matching placebo capsules.

Measurements: Volume of lower legs was assessed before and after 6 weeks of treatments by water displacement volumetry, twice a day, in the morning and in the afternoon (6 hours after morning measurement) of the assessment day. Diurnal leg swelling was determined by the change in leg volume from morning to afternoon and was calculated by subtracting the volume in the morning from the one measured in the afternoon. To assess the safety of the interventions, complete blood analysis and a medical examination were conducted at the beginning and at the end of the treatments.

Results

Demography and baseline data

All study participants were female (n=17), the mean age was 40±11 years. All participants concluded the study.

Efficacy

Lower legs volume:

After 6 weeks of treatment with RVLE, the lower leg volume decreased significantly, both in the morning and in the afternoon, in both legs; however, the reduction observed for the right legs in the morning only showed a trend towards significance. Placebo did not result in any significant changes. (Table 1).

		Before treatment (cm ³)	After 6 weeks (cm ³)	% reduction compared to start	p
RVLE	Right leg - a.m.	3481 ± 429	3448 ± 415	-1.0	0.147
	Left leg - p.m.	3470 ± 414	3415 ± 401	-1.6	< 0.001
	Right leg - p.m.	3546 ± 434	3466 ± 409	-2.3	0.002
	Left leg - a.m.	3520 ± 430	3445 ± 398	-2.1	0.001
PLACEBO	Right leg - a.m.	3473 ± 425	3452 ± 415	-0.6	0.258
	Left leg - p.m.	3449 ± 417	3434 ± 404	-0.4	0.335
	Right leg - p.m.	3570 ± 428	3493 ± 413	-0.8	0.205
	Left leg - a.m.	3503 ± 438	3475 ± 413	-0.8	0.155

Table 1: Leg volumes by treatment group before and after treatment. Mean values (cm³) of right and left leg, respectively, as measured in the morning (a.m.) or in the afternoon (p.m.) p values after two-tailed test. * indicates differences at p < 0.05. Data represent means ± SD of volumes of right and left leg, respectively.

Diurnal leg swelling:

The swelling of the legs from morning to afternoon was significantly reduced thanks to RVLE after 6 weeks of treatment, while placebo did not result in significant changes compared to study start (Table 2).

		Before treatment (cm ³)	After 6 weeks (cm ³)	% reduction compared to start	p
RVLE	Sum of both legs	115.2 ± 76.3	47.7 ± 75.9	-58.6	0.027
PLACEBO	Sum of both legs	101.2 ± 73.1	82.8 ± 77.1	-18.2	0.223

Table 2: Diurnal leg swelling. Mean difference of leg volume in the morning and in the afternoon (cm³) for both legs. Data represent means ± SD of values after a two-tailed test. * indicates differences at p < 0.05.

As shown in Fig. 1, the reduction was significantly greater in the RVLE group than in the placebo group, especially in the right leg and when considering both legs together.

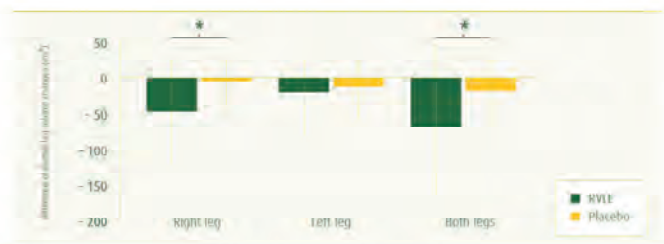


Fig. 1: Reduction of diurnal leg swelling after 6 weeks of treatment. Bars represent the mean difference of diurnal leg volume (change) from study start after 6 weeks of treatment. * indicates differences at p < 0.05 for two-tailed test.

Safety

No adverse events occurred. Blood analysis and medical examination did not reveal any anomalous results.

Conclusion

The findings of this study indicate that the RVLE was able to reduce lower limb swelling in otherwise healthy women. Additionally, the extract was safe and well-tolerated. It may therefore be concluded that the RVLE has oedema-preventing properties and can be helpful to prevent and alleviate symptoms of venous insufficiency.

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