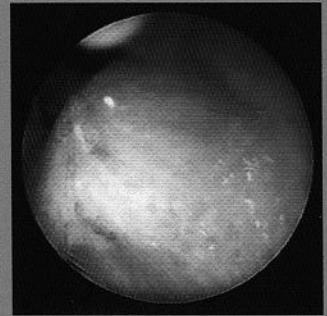
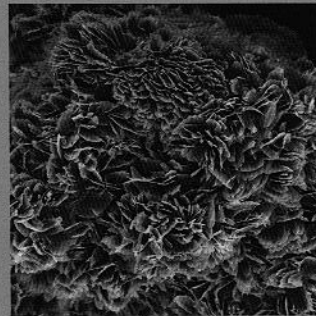
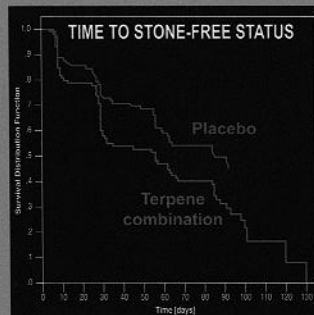


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Terpenes in Urolithiasis

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Improving Stone Clearance After Extracorporeal Shock Wave Lithotripsy in Urolithiasis Patients by a Special Terpene Combination (Rowatinex[®]): Results of a Placebo-Controlled, Randomized Trial

Imre Romics^{a,*}, György Siller^b, Ralf Kohnen^c, Stelios Mavrogenis^a, József Varga^d, Endre Holman^e

^a Department of Urology, Semmelweis University, Budapest, Hungary

^b Károlyi Kórház, Budapest, Hungary

^c RPS Research Germany GmbH, Nuremberg, Germany

^d Uzsoki Utcai Kórház, Budapest, Hungary

^e Kiskunhalasi Semmelweis Kórház, Kiskunhalas, Hungary

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Abstract

Background: Extracorporeal shockwave lithotripsy (ESWL) is the first-choice treatment for most renal stones. Rowatinex[®], a special terpene combination, has been used therapeutically in the supportive treatment of urolithiasis and for assistance in the expulsion of stones of the renal system for many years.

Objective: The aim of the study was to investigate the safety and efficacy of Rowatinex[®] in the treatment of patients with urolithiasis after ESWL.

Design, setting, and participants: In a randomized, double-blinded, placebo-controlled, multicenter trial, 222 patients with clinically unapparent kidney or ureter stones who had undergone complication-free ESWL were included between June 2003 and December 2006. The study consisted of a 12-wk active treatment phase and a 2-wk follow-up phase. All patients underwent physical examination, and diagnosis of kidney stones was made by x-ray, intravenous pyelogram (IVP), or ultrasound at weeks 1, 4, 8, and 12 as well as after 2 wk of follow-up.

Intervention: Patients were randomized to receive either 3 × 2 Rowatinex[®] capsules per day or placebo.

Measurements: The primary end point was the rate of stone-free patients (without any fragments) after 12 wk of treatment.

Results and limitations: Significantly more patients treated with the terpene combination were stone free at the end of the study compared to placebo (intention-to-treat [ITT]—verum vs placebo: 72 patients [67.9%] vs 49 patients [50.0%]; $p = 0.0009$; per-protocol [PP]—verum vs placebo: 69 patients [78.4%] vs 48 patients [52.2%]; $p = 0.0004$). The treatment was even more effective when analyzed with respect to the size of the treated stone. In addition, the terpene combination treatment significantly reduced the median time to stone-free status (ITT—placebo vs verum: 85.0 d vs 56.0 d; $p = 0.0061$; PP—placebo vs verum: 85.0 d vs. 49.5 d; $p = 0.0028$). Tolerability was excellent.

Conclusions: The terpene combination Rowatinex[®] was found to be an efficacious, well-tolerated, and safe treatment for eliminating calculi fragments generated by ESWL compared to placebo.

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* Corresponding author. Department of Urology, Semmelweis University, Budapest, Üllői út 78/B, H-1082 Hungary. Tel. +36 1 2100796; Fax: +36 1 2100796.
 E-mail address: romimre@urol.sote.hu (I. Romics).