Terpenes in Urolithiasis
Proceedings of the ROWA Symposium
Düsseldorf, Germany, September 2010

Guest Editor:
Thomas Knoll, Sindelfingen, Germany
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 Körház, Budapest, Hungary
c RPS Research Germany GmbH, Nuremberg, Germany
d Uzsoni Úti Kórház, Budapest, Hungary
e Kiskunhalas Semmelweis Kórház, Kiskunhalas, Hungary

Article info

Keywords:
Extracorporeal shock wave lithotripsy
Urolithiasis
Kidney stones
Terpenes
Rowatinex®

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 ultrasonography 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 [67.5%] vs 49 patients [50.0%]; p = 0.0006; 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 calcui fragments generated by ESWL compared to placebo.

© 2010 Published by Elsevier B.V. on behalf of European Association of Urology.