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ROLE OF ROWATINEX IN THE TREATMENT OF RENAL STONE AFTER EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY

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ABSTRACT

Background: the efficacy of medical therapy after ESWL has been demonstrated to facilitate and accelerate the expulsion of renal stones. Our aim was to evaluate the effect of Rowatinex, an essential oil preparation of terpenic type, on kidney stone clearance after ESWL. Patients and methods: from March to September 2015, 30 patients age (20-60years old) with renal stone presented to Ghazi Al-Hariri Hospital for surgical specialist in Baghdad, Iraq were enrolled in this randomized single-blind study. All patients were examined by ultrasonography and IV urography. All patients were exposed to Extracorporeal Shock Wave Lithotripsy (ESWL) and then randomly divided into two groups: first group received Rowatinex 1 capsule (100mg) before food three times daily, and second group of 15 patients received starch as placebo and served as control group. The medication starts immediately after ESWL and followed up at 4, 8 and 12 weeks post-ESWL. Clinical success defined as total clearance of stone or clinically insignificant stone. Results: four weeks following ESWL (13.3%) and (6.7%) of the patients in Rowatinex group and control group had total stone clearance. After eight weeks the percentage raised to (53.3%) for Rowatinex group and (33.3%) for control group, the differences between two groups was not significant ($p>0.05$). after twelve weeks (93.3%) of the patients in Rowatinex group showed total stone clearance versus (80%) in control group, the difference between the groups still non-significant ($p>0.05$). The elevated stone free rate reported from fourth and twelfth week was significant ($p<0.05$). Conclusion: Rowatinex does not have a significant effect on clearance rate of kidney stones after ESWL. However, Rowatinex achieved calculus clearance in larger

number of patients and showed a significant faster rate of clearance which means Rowatinex can accelerate stone passage after ESWL.

KEYWORDS: ESWL; Renal stone; Rowatinex.

INTRODUCTION

Urinary stones (calculi) are abnormal crystallized aggregates of common dietary minerals normally present in the urine. Stone disease mostly present with renal, or ureteric, colic.[1,2] The management of renal stone needs a recent and good quality imaging. Extracorporeal Shock Wave Lithotripsy (ESWL) is the most common treatment for renal stone and considers the first line treatment for calculus less than 1.5cm in diameter.[3] However, calculus clearance not achieved immediately after ESWL and the presence of calculus fragments is common, small residual fragments (<4mm) may pass spontaneously through the urinary tract within 1 month post-ESWL but larger fragments require close follow up and adjuvant therapy, as the number and size of residual fragments increase the complications and recurrent chance will increase too.[4]

Several researches have demonstrated the efficacy of medical therapy in facilitating and accelerating the stones clearing rate and then improving ESWL outcomes. These researches have been done on different medical therapy like, tamsulosin, nifidipine and terpenes.[5,7]

Rowatinex, a combination of terpenes, have been proved its effect on urinary stones, particularly ureteral stones, by increasing the stone elimination rate after exposing to ESWL.[8,9] This study was designed to evaluate the efficacy of Rowatinex on clearance rate of kidney stones after ESWL since limited researches had been evaluate its effect on this type of stones.[10,11]

PATIENTS AND METHOD

A randomized single-blind clinical trial was performed from March to September 2015, at Ghazi Al-Hariri Hospital for surgical specialist in Baghdad, Iraq. We enrolled 30 participants aged between 20 to 60 years old who had renal pelvis or caliceal calculi sized (10-20 mm) in diameter and admitted to undergo ESWL. We exclude any case of urethral and bladder calculi, drug hypersensitivity, pregnancy and breast feeding. Calculus size and location were assessed by ultrasonography and intravenous urography. After Completion of matching process regarding age, sex, stone size and location, the study sample were randomly divided

in to two groups, first group of 15 patients received Rowatinex (100mg) capsule (Rowa Pharmaceuticals, Cork, Ireland) before food three times daily, and second group of 15 patients received starch as placebo and served as control group. The medication starts immediately after ESWL and followed for 12 weeks with three readings at week 4, 8 and 12 from ESWL.

A Modulith SLX-2 machine equipped with a cylindrical electromagnetic shock wave source (Storz Medical, Tuttlingen, Switzerland) was used to perform lithotripsy. All patients received 3000 shocks with an energy level of 7 KV and a mean frequency of 1.5 Hz with a variable focus.

All patients were followed up by clinical examination at week 4, 8 and 12 after ESWL; the primary outcome measurement was complete stone clearance or absence of fragments larger than 4 mm in diameter by ultrasonography.

Statistical tests to analyze our data were ANOVA test, chi-square test (x^2) and graphical presentation (by bar chart), Statistical analysis was performed using SPSS (Statistical Package for Social Sciences) version 12 and Microsoft Office Excel 2007, all p-value <0.05 was considered to be significant.

RESULTS

The mean age of the patients enrolled in the study was (42.4 ± 11.2) for Rowatinex group and (41.5 ± 9.5) for control group, males represent (60%) while females represent (40%) in Rowatinex group versus (66.7%) males and (33.3%) females in control group. Stone size in Rowatinex group was equal to control group (14.0 ± 3.38), stone in Rowatinex group located either in the calyx or renal pelvis (66.7%, 33.3%) respectively while for control group (60%, 40%) respectively.

There was not significant statistical differences between the age, the distribution of male and female, the size and location of the stones between the patients groups (p>0.05) so the groups matching is successful, as shown in table 1.

Table (1): Baseline characteristics of patients on Rowatinex and placebo groups after ESWL.

Characteristics		Groups		p-value
		Rowatinex	Control	
Number of patients		15	15	
Mean of age, mean±SD		42.4 ± 11.2	41.5 ± 9.5	0.8
Sex	Male, n (%)	9 (60%)	10 (66.7%)	0.9

	Female, n (%)	6 (40%)	5 (33.3%)	
Mean stone size, mm		14.0 ± 3.38	14.0 ± 3.38	1.0
Stone location	Calyx	10 (66.7%)	9 (60%)	0.9
	Renal pelvis	5 (33.3%)	6 (40%)	

Data presented as number (n) and percentage (%) or mean±SD

(P<0.05) is considered significant

Stone free rate which is consider as a clinical success achieved when the stone is totally cleared or there is insignificant residual fragments of 4 mm in diameter or less. The percentage of patients with stone free rate 4 weeks after ESWL was (13.3%) in Rowatinex group, (6.7%) in control group, this result increased in both groups to (53.3%, 33.3%) respectively 8 weeks after ESWL. The last reading after 12 weeks showed an elevation for Rowatinex group to (93.3%) while for control group (80%), Fig. 1.

Despite the elevation in clearance rate through the time of the study and the high percent of clearance in Rowatinex group (93%) compared to control group (80%) but the differences between the groups was not statistically significant (p>0.05), table 2.

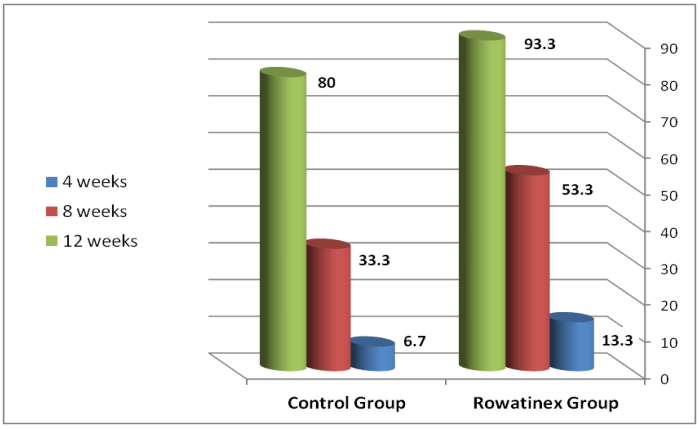

Figure (1) Comparison of clinical success among the study groups through the study time.

Table (2) Comparison of clinical success among the study groups through the study.

Four weeks	Total number	Clinical success, n (%)
Rowatinex group	15	2 (13.3%)[a]
Control group	15	1 (6.7%)[a]
Eight weeks		
Rowatinex group	15	8 (53.3%)[a]
Control group	15	5 (33.3%)[a]
Twelve weeks		
Rowatinex group	15	14 (93.3%)[b]
Control group	15	12 (80%)[b]

Data presented as number (n) and percentage (%)

Non-identical superscripts (a,b) between the durations are considered significantly different ($P<0.05$).

DISCUSSION

It has been generally approved that ESWL is the main line option for kidney stone disintegration.[12] but only small fragments (less than 4mm) may pass spontaneously through the urinary tract.[13] The use of medical therapy during the first month after exposing to ESWL showed a good efficacy in facilitating the passage of residual fragments and prevention of calculus recurrent like, α-adrenergic blocker and calcium channel blocker.[14,15] Many researches approved the effectiveness of Rowatinex, an essential oil preparation of terpenic type, in facilitating the rate of calculus clearance.[16,17]

Miller reported success of Rowatinex in the expulsion of ureteral stone reached to (65%).[18] Mukamel et al, noted an insignificant high rate of stone expulsion (60%) in patients with renal colic.[19] While Siller et al reported that about (82%) of patients had kidney stone experienced complete expulsion with Rowatinex within 1 month after ESWL.[10]

In our study we use Rowatinex on kidney stone after exposure to ESWL. Four weeks after ESWL (13%) of stones were totally cleared compared with only (7%) in control group. After eight weeks the percentage elevated to (53%, 33%) for Rowatinex and control group respectively. Twelve weeks post-ESWL the clearance rate elevated in Rowatinex group to (93.3%) versus (80%) in control group. Although the clearance rate was statistically insignificant between Rowatinex group and control group ($p>0.05$), but the rate of clearance was higher in patients took Rowatinex compared to placebo, which may suggest that Rowatinex can accelerate the passage of calculus as reported by Djaladat, that Rowatinex may accelerate the stone expulsion.[11] Actually the insignificant differences between the patients groups may be related to the small sample size approved by the study of Romics which involved more than 200 patients and achieved a significant increase in clearance rate within 12 weeks.[17]

This study observed that the rate of clearance showed a statistically significant increase with the increasing duration of observation (93% after 12 weeks versus 13% after 4 weeks, $p<0.05$), which is a reassured result for the patients regarding the need to repeat ESWL session or even surgical procedure.[20]

CONCLUSION

Rowatinex does not have a significant effect on clearance rate of kidney stones after ESWL. However, Rowatinex achieved calculus clearance in larger number of patients and showed a significant faster rate of clearance which means Rowatinex can accelerate stone passage after ESWL.

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