A Prospective Randomized Controlled Trial of the Efficacy of External Physical Vibration Lithecbole after Extracorporeal Shock Wave Lithotripsy for a Lower Pole Renal Stone Less Than 2 cm

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Purpose: We evaluate the efficacy and safety of external physical vibration lithecbole in improving the clearance rates of lower pole renal stones after shock wave lithotripsy.

Materials and Methods: A total of 71 patients with lower pole renal stones (6 to 20 mm) were prospectively randomized into 2 groups. In the treatment group 34 patients were treated with external physical vibration lithecbole after shock wave lithotripsy. In the control group 37 patients underwent shock wave lithotripsy only. External physical vibration lithecbole was performed without anesthesia by the same team using the Friend-I External Physical Vibration Lithecbole (Fu Jian Da Medical Instrument Co., Ltd, Zhengzhou, China). The stone-free rate, stone expulsion rate, stone expulsion time and incidence of complications were monitored.

Results: External physical vibration lithecbole was successful in assisting the discharge of stone fragments. The stone-free status was 76.5% in the treatment group and 48.6% in the control group (p=0.008). Stone expulsion rates at day 1, week 1 and week 3 were 76.5% (26), 94.1% (32) and 94.1% (32) in the treatment group vs 43.2% (16), 73.0% (27) and 89.2% (33) in the control group, respectively. Mean stone fragment expulsion time was 11.2 minutes in the treatment group and 9.17 hours in the control group (p=0.016). There was no significant difference in complications between the 2 groups (p >0.05).

Conclusions: External physical vibration lithecbole was efficacious in assisting the discharge of lower pole renal stone fragments and can be used as an adjunctive method of minimally invasive stone treatment. However, additional investigations are needed to confirm the efficacy.

Key Words: lithotripsy, high-energy shock waves, kidney calculi

Abbreviations and Acronyms

CT = computerized tomography

EPVL = external physical vibration lithecbole

SFR = stone-free rate

SWL = shock wave lithotripsy

Accepted for publication November 2, 2015.

Supported by grants from National Natural Science Foundation of China (81472376) and the Shanghai Health and Family Planning Commission (14ZR1406300).

No direct or indirect commercial incentive associated with publishing this article.

To view the accompanying video, please see the online version of this article (Volume 195, Number 4) at www.jurology.com.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

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MORE than 90% of stones in adults may be suitable for shock wave lithotripsy treatment[1–3] and lower pole stones account for 30% to 48% of these cases.[4,5] However, the stone-free rate for lower pole stones after SWL has been observed to be inferior to that of stones in other renal locations. The reported SFR has a wide variation from 25% to 85%,[6–10] which means that about 15% to 75% of patients still have residual stones. Residual stones may become a source of future symptomatic episodes such as persistent

0022-5347/16/1954-0965/0
THE JOURNAL OF UROLOGY®

http://dx.doi.org/10.1016/j.juro.2015.10.174
Vol. 195, 965-970, April 2016
Printed in U.S.A.

infection, recurrent stone growth, localized obstruction and renal colic.[11,12] Studies of asymptomatic residual stones reveal that 43% to 77% of patients have disease progression.[13,14] Therefore, improvement in the SFR of lower pole stone cases after SWL is an urgent unmet medical need.

Many interventions have been suggested to assist fragment discharge but the efficacy remains controversial.[15,16] Recently some new methods have been described. Shah et al developed a new device using focused ultrasound to expel calculi.[17] Tan et al also successfully extracted small stone fragments using iron oxide microparticles.[18] Although these methods demonstrated improved efficacy in aiding residual stone expulsion, a new device aimed at assisting the expulsion of residual fragments is still in demand. EPVL was recently developed and has demonstrated improved discharge of lower pole renal stone fragments. Therefore, we designed this prospective, randomized clinical study to evaluate the efficacy and safety of EPVL in the treatment of lower pole renal stones after SWL.

MATERIALS AND METHODS

The Friend-I External Physical Vibration Lithecbole, a novel device, has been used at our institute since January 2014. It consists of an associate oscillator (in the base), a master oscillator (in the handle) and a treatment couch (fig. 1). Simple multidirectional harmonic motion technology was applied. The lateral acceleration was provided by the physical vibration device in the base through the harmonic vibration wave in a horizontal direction (power 150 W, vibration frequency 1,300 to 1,900 blows per minute, amplitude 5 mm). This induced the urinary stone to separate from the kidney or ureter and expanded a moving space for the stone. Meanwhile an axial effect was produced by the physical vibration device in the handle to push the stone with the multidirectional harmonic vibration wave (power 40W, vibration frequency 2,800 to 3,500 blows per minute, amplitude 5 mm). Finally, with the change in position and direction of the extracorporeal physical vibration machine (−26 to 26-degree angle rotating couch), the stone was actively discharged from the urinary collecting system. The schema of stone discharge is shown in the supplementary video (http://jurology.com/). Ultrasound could be used to monitor stone location and movement during the procedure.

To evaluate the efficacy and safety of our device 71 patients with lower pole stones smaller than 2 cm were enrolled in this prospective randomized trial from May to September 2014. The primary outcome was the stone-free rate, and secondary end points were stone expulsion rate, stone expulsion time and side effects related to adjunctive therapy. Original study power estimation was set at 0.8 with a 2-sided significance level of $\alpha = 0.05$. This study

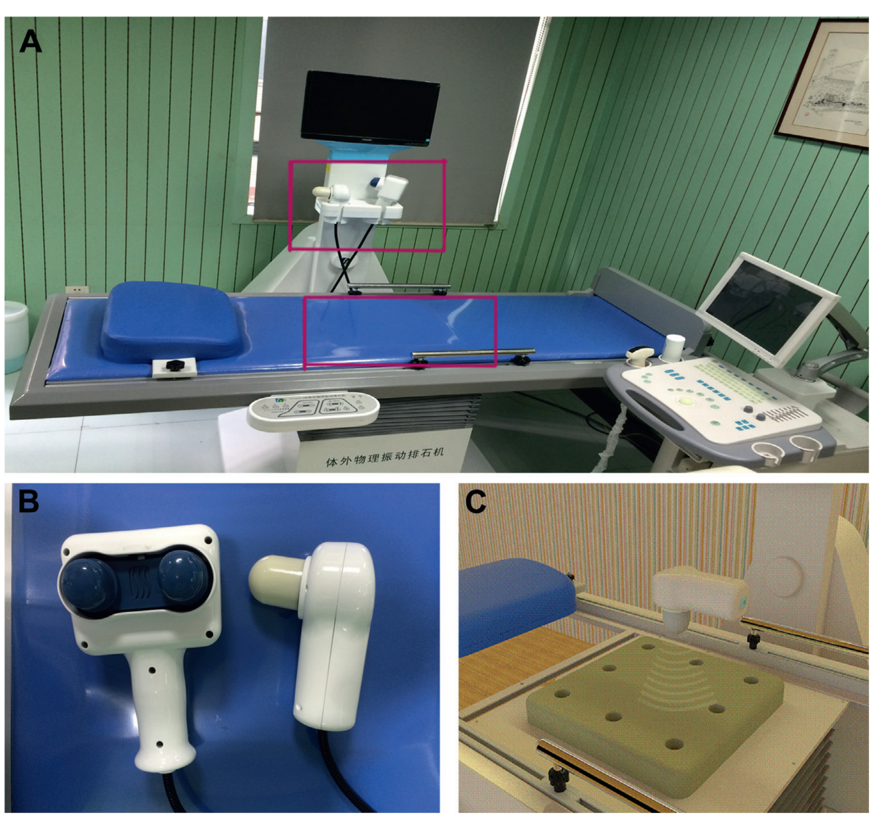

Figure 1. Prototype of Friend-I EPVL, showing whole view (*A*), master oscillator (*B*) and associate oscillator (*C*)