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Original article

Comparison of the efficacy of Smart Litho Plus and standard extracorporeal shock wave lithotripsy for renal calculi treatment

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Abstract

Background: Urinary stones are one of the most common urological problems in Thailand. Extracorporeal shock wave lithotripsy (ESWL) is one of the most frequently used treatments because it is noninvasive and widely available. However, how the effectiveness of lithotripters with power sources produced in Thailand (Smart Litho Plus) compares with that of standard machines is poorly established.
Objective: This study aimed to evaluate how the effectiveness of Thai-manufactured replacement components compared to those of conventional electromagnetic shock wave systems used in the treatment of kidney stones.
Methods: We conducted a multicenter retrospective cohort study involving 121 patients with renal stones across three sites in Thailand. All subjects underwent urinary tract imaging at their initial visit and were followed up four weeks after stone treatment. A patient was considered stone-free if residual stones measured less than 4 mm.
Results: A significant difference in stone-free rates was recorded between the two groups. The smart Litho Plus group showed a 44.0% stone-free rate, whereas the standard machine group achieved a 64.0% stone-free rate ($P = 0.048$). However, we noted a difference in the number of shock waves used in the standard machine group.The treatments did not differ significantly in number of adverse events. One patient in the standard machine group developed sepsis after ESWL. Additionally, one patient in the standard machine group and three patients in the Smart Litho Plus group experienced stone street. No findings of renal injury were observed in either group during a follow-up four weeks after imaging.
Conclusion: The standard electromagnetic lithotripter had a higher stone-free rate than the Smart Litho Plus system for renal stone treatment. The Smart Litho Plus system has demonstrated effectiveness and good tolerability. It offers effective and promising stone fragmentation coupled with low adverse event rates.

Keywords: Efficacy, Extracorporeal shock wave lithotripsy (ESWL), safety, smart litho plus

Urolithiasis is a widespread urological problem impacting millions of people globally. In the northeastern region of Thailand, the prevalence of urolithiasis is notably high, with a rate of approximately 16.9%.[1, 2] This condition causes considerable discomfort and pain in patients, and also places a substantial burden on healthcare systems.Extracorporeal shock wave lithotripsy (ESWL) has been the primary, noninvasive method for managing kidney stones since its introduction in 1980. [3]

ESWL revolutionized the treatment of urinary tract stones by offering a nonsurgical alternative to open stone surgery. ESWL uses high-energy shock waves generated externally to break kidney stones into smaller fragments that can be passed naturally through urination. ESWL is recommended for kidney stones smaller than 2 cm in size. However, for stones located in the lower pole of the kidney, ESWL is usually only indicated for stones up to 1 cm in size due to the

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anatomical challenges of that location. The reduced size threshold for lower pole stones aims to improve stone clearance rates, as larger fragments may be difficult to pass from that part of the kidney. [4]

ESWL technology has undergone a remarkable evolution since the introduction of the first-generation Dornier HM3 lithotripter. Modern ESWL machines consist of four essential components: a shockwave generator, a focusing system, a coupling mechanism, and an imaging/localization unit. [5] Each of these components plays a crucial role in ensuring effective and precise fragmentation of kidney stones. Interestingly, the first three components can be manufactured locally in Thailand, whereas the imaging/localization unit is usually imported. The combination of locally produced and imported parts has led to the development of alternative ESWL machines that are cost-effective and accessible.

The efficacy of ESWL machines varies widely, with success rates of 35.0%–89.0%.[6] Several factors influence the success rates of ESWL machines. They include stone size, composition, location, and patient characteristics, such as age and body mass index (BMI).[7] Small stones and low stone volumes are generally associated with high stone-free rates. In Thailand, approximately 86.0% of stones are calcium-based, 9.0% are uric acid stones, and the remainder of the stones are composed of magnesium ammonium phosphate or other materials.[8, 9]

The response of various stone types to ESWL varies considerably. ESWL often has low success rates for calcium oxalate monohydrate stones, which are typically dense and hard. In contrast, uric acid stones, which tend to be less dense than other types of stones, generally respond well to ESWL treatment. Struvite (magnesium ammonium phosphate) stones are brittle and fragment easily during ESWL.[10]

The location of renal stones within the urinary tract also determines the success of ESWL. Stones in the renal pelvis and upper calyx generally have high success rates, whereas those in the lower calyx have low success rates due to anatomical challenges that may impede stone fragment clearance.[11]

Patient factors, such as age and BMI, also influence ESWL outcomes. Young patients generally experience high stone-free rates after ESWL, although the effect of age can vary depending on individual characteristics. High BMI (> 30 kg/m^2) is often associated with low success rates, primarily due to the long distance the shock waves must travel through adipose tissue, which reduces their effectiveness in fragmenting stones. [12]

The number of ESWL sessions is another important factor affecting stone-free rates, with multiple sessions often required to achieve optimal outcomes. This situation highlights the importance of patient follow-ups and the need for repeated treatments in some cases.

In Thailand, the high cost of imported ESWL machines, estimated at nearly one billion Thai Baht per year for machine imports and services, has generated interest in developing cost-effective alternatives. Local manufacture of components combined with importing imaging units offers a promising solution for reducing costs while maintaining treatment efficacy.

However, the comparative effectiveness of Thai-made replacement parts (such as Smart Litho Plus) versus that of standard electromagnetic shock wave systems in treating renal calculi has not yet been investigated. Understanding the relative efficacy of these systems is crucial for informed decision-making in healthcare resource allocation and ensuring optimal patient outcomes. As Thailand, like many other countries, seeks to balance the need for advanced medical technologies with cost-effectiveness, the evaluation of locally produced ESWL components is crucial. This study aimed to compare the efficacy of Thai-made replacement parts with that of standard electromagnetic shock wave systems in treating renal calculi. The findings are envisaged to provide valuable data for future healthcare planning and procurement decisions in the management of urolithiasis.

Materials and methods

We conducted this multicentered, nonrandomized retrospective cohort trial in Thailand from November 2018 to January 2021 at three participating institutions (Ubon Ratchathani Center, Bangkok Center, and Pathum Thani Center). The population consisted of patients with renal stones meeting the following eligibility inclusion criteria: age > 18 years with a solitary opaque stone less than 2 cm in greatest diameter located within the upper and middle renal calyx or renal pelvis. For stones located in the lower calyx, patients with solitary opaque stones with less than 1 cm in greatest diameter were also included in the study. The exclusion criteria were as follows: patients with prior lithotripsy, active urinary tract infection, uncorrected bleeding diathesis or coagulopathy, distal ureteral obstruction, obesity defined as BMI > 30 kg/m^2, kidney transplant history, abnormal renal anatomy, renal impairment, pregnancy, or orthopedic/spinal deformities.

The patients were assigned to each group without randomization. Those at the Ubon Ratchathani Center underwent treatment with Smart Litho Plus, whereas those at the Bangkok and Pathum Thani centers underwent treatment with standard shockwave systems. All patients received intravenous analgesic medication prior to ESWL. The energy and number of shock waves administered to each patient depended on the physicians' discretion, and the energy levels of the shock waves were categorized as low, medium, and high**.** This study was conducted according to good clinical practice guidelines and the Belmont Report, and was approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University (IRB no. 0194/67). The requirement for patient consent was waived for this retrospective study.

Procedures

The preparation of patients for lithotripsy, whether using a standard machine or the Smart Litho Plus, involves similar steps. These preparatory steps are standard for ESWL procedures, regardless of the type of machine used. All patients underwent urinary tract imaging at the first visit (baseline) and again four weeks after shockwave therapy to assess the efficacy of ESWL. The key measure of success was the stone-free rate, defined as having residual stone fragments less than 4 mm after ESWL, as assessed through urinary tract imaging at week 4. Safety evaluation results, including reports of adverse events and occurrence of complications, such as pain, sepsis, and stone street were recorded.

Study outcomes

The primary objective of this study was to compare the efficacy of Smart Litho Plus with that of standard electromagnetic shock wave systems for the treatment of renal stones. The secondary objective was to compare the safety profiles of these machine systems.

Statistical analysis

Outcomes, including age, stone size, and number of shock waves, were assessed as continuous variables and represented as mean ± standard deviation (SD). These outcomes were compared using the independent samples *t*-test. Categorical data, including stone locations, sides, energy power, and stone-free rates, were compared using Pearson's Chi-square test with Yates' correction. Statistical significance was established when the $P < 0.05$. Adverse events were reported as the number of occurrences.

Results

A total of 132 patients with renal stones were enrolled between November 2018 and January 2021. Fifty-six patients at the Sunpasitthiprasong Hospital received the Smart Litho Plus treatment, whereas 76 patients at the Chulalongkorn Hospital and Thammasat Hospital received the standard electromagnetic shockwave treatment. After excluding one patient who could not be followed up and one patient with previous ESWL in the Smart Litho Plus group, as well as seven patients lost to follow-up and two patients with previous ESWL in the standard group, a total of 121 patients successfully completed the study **(Figure 1).**

The demographic data and baseline characteristics of each treatment group are shown in **Table 1.** No significant difference between the two treatment systems was observed. The total number of shock waves and energy used are shown in **Table 2**. Although the levels of energy used did not significantly differ, the number of shock waves used was higher in the standard electromagnetic system group than in the Smart Litho Plus group ($P < 0.0001$).

There was a significant difference in stone-free rates between the treatment methods, indicating differences in efficacy. The standard electromagnetic system group demonstrated higher efficacy than the Smart Litho Plus group, with the standard electromagnetic system and Smart Litho Plus groups showing stone-free rates of 64.0% and 44.0%, respectively ($P = 0.048$) **(Table 2).**

No patients experienced immediate adverse events after ESWL. However, one patient in the standard electromagnetic group developed sepsis two days after ESWL. Additionally, one patient in the standard electromagnetic system group and three patients in the Smart Litho Plus group developed stone street (a condition wherein stone fragments obstruct the urinary tract). No renal injuries, such as perinephric hematoma or renal laceration, were reported during the four-week imaging follow-ups.

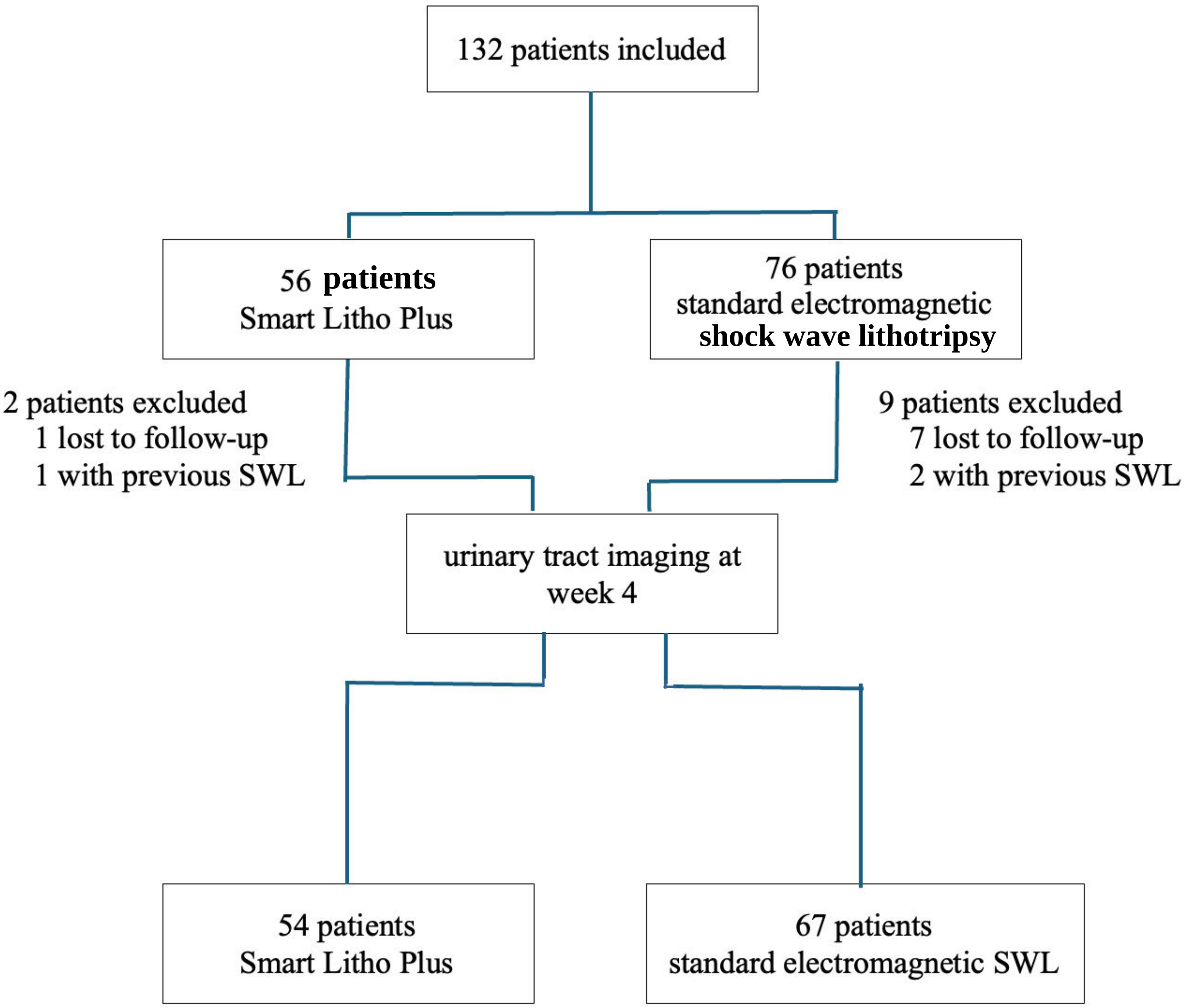

Figure 1. Flow diagram of patient enrollment process for extracorporeal shock wave lithotripsy (ESWL).

Table 1. Demographic and baseline characteristics.

	Smart Litho Plus (n = 54)	**Standard electromagnetic ESWL (n = 67)**	***P*-value**
Age (years), mean (SD)	57.1 (10.5)	58 (10.6)	0.657
Gender			
Male/female	26/28	30/37	0.26
Left/right	28/26	35/32	0.96
Stone location (%)			0.60
Upper calyx	11 (20.4)	7 (10.4)	
Middle calyx	5 (9.2)	5 (7.5)	
Lower calyx	27 (50.0)	41 (61.2)	
Pelvis	11 (20.4)	14 (20.9)	
Stone size (mm), mean (SD)	8.8 (4.1)	9.0 (3.5)	0.82

ESWL, Extracorporeal shock wave lithotripsy.

Table 2. Compairison of efficacy between Smart Litho Plus and standard electromagnetic ESWL.

	Smart Litho Plus (n = 54)	Standard electromagnetic ESWL (n = 67)	*P* - value
No. of shock wave, mean (SD)	3731 (452.6)	4613 (929.3)	< 0.0001
Power of energy (%)			0.35
Low	2 (3.7)	2 (3.0)	
Medium	44 (81.5)	48 (71.6)	
High	8 (14.8)	17 (25.4)	
Primary efficacy			0.048
Stone fragment < 4 mm (%)	24 (44.0)	43 (64.0)	
Stone fragment ≥ 4 mm (%)	30 (56.0)	24 (36.0)	
Adverse events			
Colicky pain	0	2	
Renal injury	0	0	
UTI or sepsis	0	1	
Stone street	3	1	

ESWL, Extracorporeal shock wave lithotripsy; SD, standard deviation.

Discussion

This multicenter retrospective cohort trial compared the efficacy and safety of Smart Litho Plus, a Thai-made ESWL machine, with that of standard electromagnetic shock wave systems in treating renal calculi. The findings revealed some important differences between the two systems, and areas for further research.

Our findings showed a significantly lower success rate in the Smart Litho Plus group than in the standard electromagnetic machine group. This difference indicates the inferior performance of the Thai-made systems for renal calculi clearance. However, the success rates of both machines still fell within the globally acceptable range of 35.0%–89.0% for ESWL stone-free rates. The wide variation in reported ESWL success rates highlights the multifactorial nature of treatment outcomes, which depend on factors, such as renal calculi characteristics, patient factors, and operator technique, as well as how the term "stone-free" is defined and assessed.

Although Smart Litho Plus had low efficacy, its performance is still clinically acceptable, especially considering its cost-effectiveness. The significantly lower price of the Thai-made systems and high treatment accessibility offset its low efficacy. These findings raise important questions about the trade-offs between treatment efficacy and economic considerations in healthcare technology adoption.

Our results showed low rates of complications in both ESWL groups, and no serious adverse events were reported for either system. These findings suggest that the safety profile of Smart Litho Plus is similar to that of standard electromagnetic machines. This similarity is reassuring from a patient safety perspective. The ability to provide ESWL treatment with minimal complications is a key consideration alongside efficacy.

Several factors may have contributed to the observed differences in efficacy. The standard electromagnetic system used a higher number of shock waves than Smart Litho Plus. This difference in shock wave delivery could partly explain the superior renal calculi clearance of the standard system. Potential variations in renal calculi composition between study sites may have influenced success rates. Patients from different geographic regions of Thailand most likely have different dietary habits and environmental exposures that influence renal calculi formation and composition. Dual-energy CT (DECT) can be used to enhance the similarity between two study groups when determining the composition of kidney stones. This advanced imaging technique offers several advantages in urological applications, particularly in the analysis of urinary calculi. DECT allows for finer identification of renal calculi types based on their chemical composition, which is crucial for treatment planning and management of patients with urolithiasis.[13] Further studies should attempt to control for or analyze stone composition as a variable.[14] Differences in operator familiarity and experience with each system across study sites could have been a confounding factor that affected outcomes. Standardized training and experience levels would be important in future comparative studies. The quality of imaging and accuracy of renal calculi localization might have differed between the systems, thereby influencing measurements of treatment efficacy.

There were several limitations of this study. As a retrospective observational study, this study lacked randomization and controlled group assignment. This may cause selection bias and confounding factors. The multicenter nature of the study, with each site determining the type of treatment for its respective group, might have introduced site-specific variables that affected outcomes. Geographic differences between study sites could have led to variations in renal calci characteristics that were not fully accounted for in the analysis.

This study highlights several areas for future research. Prospective randomized controlled trials comparing Smart Litho Plus and standard systems would provide high-quality evidence on their relative efficacy and safety. Analyses of cost-effectiveness incorporating clinical outcomes and economic factors would help inform decision-making on ESWL technology adoption. Research into optimizing the shock wave delivery parameters of Smart Litho Plus could potentially improve efficacy. Research on the development and testing of Thai-made imaging and localization components could further advance the ultimate goal of producing a fully domestic ESWL system.

Although Smart Litho Plus exhibited lower efficacy than standard electromagnetic systems, its performance is still clinically acceptable because of its remarkably low cost. From a health economics and healthcare access perspective, the Thai-made system could offer a cost-effective option for ESWL treatment, particularly in resource-limited settings.

Our results support the continued development and refinement of domestically produced medical technologies in Thailand. As it has identified areas for improvement in Smart Litho Plus, this study can guide further innovation in the Thai medical device industry. Producing a fully Thai-manufactured ESWL system, including imaging and localization components, appears feasible and could have remarkable economic and healthcare benefits for the country.

Conclusion

Although Smart Litho Plus had lower efficacy and a lower stone-free rate than the standard electromagnetic ESWL systems, its acceptable safety profile and cost advantages justify its continued use in Thailand. Future research should focus on optimizing the performance of the Smart Litho Plus system, conducting rigorous cost-effectiveness analyses, and exploring its potential role in expanding access to ESWL treatment in Thailand and beyond. This study is an important step in the evaluation and advancement of domestically produced medical technologies in emerging economies.is

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Conflicts of interest statement

All authors have completed and submitted the International Committee of Medical Journal Editors Uniform Disclosure Form for Potential Conflicts of Interest. None of the authors disclose any conflict of interest.

Data sharing statement

All data generated or analyzed during the present study are included in this published article. Further details are available for noncommercial purposes on reasonable request from the corresponding author.

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