## INTRODUCTION

Kidney stones or often referred to as nephrolithiasis, are cases that are quite often found in daily practice. Changes in lifestyle and technological advances have many influences on this increase in incidence. In Indonesia, kidney stones are the most common case in the field of urology. However, currently, there is no data on the prevalence of urinary tract stones in Indonesia. Kidney stone not only causes medical problems but also social and economic problems because it has an impact on the quality of life of both the patient and families. The classification of kidney stones by their etiology is divided into infectious stones, non-infectious stones, genetic disorders stones, and drugs-induced stones.

The consideration of urinary tract stone management is based on the size and location of stones, stone composition, kidney anatomical abnormalities, complications, hospital facilities and infrastructure, and patient choices in certain conditions.

Currently, Extra Corporeal Shockwave Lithotripsy (ESWL) is one of the options to treat patients with nephrolithiasis. The European Association of Urology (EAU) currently suggests ESWL as the first-line treatment for patients with a stone size of less than 2 cm in the upper pole kidney and the second-line treatment for lower pole kidneys of more than 1 cm with consideration of favorable factors.

ESWL is assisted by imaging devices during the session to visualize the location of the stones where the shock wave should be targeted. The imaging devices to visualize the stone are Fluoroscopy and Ultrasonography.
Fluoroscopy, which is familiar to most urologists, involves ionizing radiation to visualize stones. The disadvantage of this treatment is its ionizing radiation affects both the patient and the medical officer and is useless for localizing radiolucent stones.6 The use of ultrasound reduces the patient’s exposure to ionizing radiation.4,7,9 Although ultrasound has the advantage of preventing exposure to ionizing radiation, it is technically limited by its ability to visualize ureteral stones, usually due to air-filled intestinal loops.6

Efficacy is a pivotal thing in health care services. The efficacy of ESWL in the management of kidney stones is rated as the stone-free rate (SFR). The SFR of ESWL for treating kidney stones ranges from 47% to 92%. The variability magnitude of the cleaning rate is due to many predictive factors that affect the outcome, including the size of the stones, the location and composition, the distance of the skin to the stones, the anatomy of the kidneys, the position of the patient, the strength and frequency of the lithotripter.10 The efficacy of ESWL can also be determined by other parameters such as pain and recurrence. Various conditions need to be observed because they have the potential to reduce the success of ESWL, including stone resistance to shock waves (stones contain calcium oxalate monohydrate, cystine or brushite), a steep pelvic infundibulum (< 5 mm), and a skin-to-stone distance (> 10 mm).3,8,10

Alternative endourological options can be considered to minimize the repetition of the procedure and shorten the time to reach a stone-free state.3,12,13

In addition to efficacy, ESWL measures should take into account safety related to the potential for post-ESWL complications that vary in number and can occur in a variety of forms ranging from mild symptoms such as fever and mild bleeding to severe symptoms that require additional treatment.

Currently, health services in Indonesia are managed by the National Health Insurance, which divides medical facilities based on several categories: first-stage medical facilities consist of primary clinics and main clinics; second-stage medical facilities consist of type B, type C and type D hospitals, and third stage medical facilities called the type A hospitals. ESWL treatment cost based on National Health Insurance creates problems, including the unequal cost in various health care facilities. This can have a direct impact on the ability to carry out ESWL actions in hospitals due to negative harmony, then ultimately also have an impact on the quality of services in hospitals. This financing system is an important consideration for the implementation of ESWL services.14

Based on aspects of quality control and cost control, hospitals can conduct a review of various actions carried out based on clinical guidelines and clinical pathways and then provide input to professional organizations to be able to conduct a comprehensive study and improve the preparation of national health insurance rates. The purpose of preparing The Clinical Practice Guidelines is to justify the basis for diagnosis, therapy and monitoring of diseases applied in health care services. In addition, there are further considerations, especially related to the issue of the availability of healthcare facility infrastructure, human resources, and health infrastructure. Thus, the guidelines must be adapted to the varied conditions and capabilities of health facilities.15

The ESWL procedure has an impact not only on the patients but also on the hospitals. With the national health insurance system, the costs obtained from the claims are not different even though they use different imaging devices, in this case, Ultrasound or a combination of Fluoroscopy and Ultrasound. Cost Effectiveness Analysis (CEA) needs to be assessed by considering the primary output of the ESWL treatment in addition to the SFR. It also needs to be analyzed re-treatment rate (RTR) and the auxiliary procedure rate (APR). In addition, an analysis of perceived costs (ESWL costs only) and actual costs (including ESWL costs and additional procedure costs and differences in costs to be incurred in the event of complications). The CEA stages include defining the problem, identifying alternative therapy, describing the relationship between intervention and output, identifying the measurement of output and cost of the intervention, and interpreting and presentation of the results that will be put in corresponding quadrant positions (trade-off, dominant and dominated). Furthermore, the Average Cost Effectiveness Ratio (ACER) can be calculated in a way cost/day symptom-free (IDR/day) in this case, the ESWL cost/efficacy of the SFR, the SFR; Incremental Cost Effectiveness Ratio (ICER), which is an additional cost/additional day of recovery (IDR/day) and Incremental Net Benefit Ratio (INB) which is the cost per day if not cured X difference in effects-difference in costs ( IDR). In addition to ACER calculations, efficiency quotient calculations are carried out by including elements of re-treatment and auxiliary procedures; perceived costs, namely unit costs plus the cost of drugs, consumables, support and treatment; also, actual costs, i.e., perceived costs plus transportation costs and loss of livelihoods.9,15,16

To this date, there has been no research in Indonesia on the efficacy, safety and suitability between ESWL cost and the ability to perform in various hospitals. This research aims to compare the efficacy, safety and cost of using the ESWL tool and its target tool, which is ultrasound, compared to a combination of fluoroscopy and ultrasound.

METHODS

The type of this study is a quantitative study with a prospective cohort approach. The research design used two groups of post-test design. The intervention was done with ESWL with ultrasound (U-ESWL) or a combination of fluoroscopy-ultrasound (FU-ESWL) as the target devices. Selection of the hospitals based on the availability of the devices. An effort to minimize bias is to do the ESWL with a single operator. Observations are made before the action in the form of basic data such as patient demographic data, weight, height, body mass index, blood pressure, stone length, creatinine serum, random blood sugar, hemoglobin, blood leukocytes and blood uric acid. Furthermore, re-observation is done after taking action by measuring efficacy, safety and cost.

This research was conducted in Denpasar, Bali, from April 2022 to August 2022. The population of this study was
all kidney stone patients with stones less than 1.5 cm who were managed by ESWL treatment. The approximate size of the sample was calculated based on a categorical data formula in two unpaired groups of up to 40 subjects in each group. The sampling technique used is consecutive sampling, which is a sample that comes to each hospital that meets the inclusion and exclusion criteria. The inclusion criteria are patients with kidney stones less than 1.5 cm who have indications for ESWL, patients over 17 years old and under 65 years old, willing to be a respondent, and patients using national health insurance. In comparison, the exclusion criteria for this study are patients with heart rhythm alterations, immobilization state, pregnant women, patients with blood clotting disorder, severe spinal deformities, and impaired renal function.

The variables used in this study consisted of independent variables and dependent variables. The independent variables in this study are ESWL with the ultrasound target device and fluoroscopic-ultrasound target device. The dependent variables in this study are efficacy, safety and cost. Success is determined by the following criteria: asymptomatic, stone-free on X-ray/ultrasound/CT-KUB or clinically insignificant stones (<4 mm).

The complication rate is one of the outcomes that can be predicted following ESWL, including persistent hematuria for more than 3 days and hematomas. Stone Free Rate (SFR) is defined as post-ESWL stone size < 4 mm. Re-treatment is defined by multiple ESWL procedures (2 times or more). The auxiliary procedure is an action taken after the ESWL is deemed to have failed, which is the size of the stone > 4 mm after the 6th ESWL.

The T-test independent is used to analyze numerical/continuous data with one independent variable with 2 observations or groups (Ghozali, 2016). In this study, an independent t-test was carried out for stone size, perceived cost, and actual cost when the data is normally distributed. If the data is not normally distributed, the Mann-Whitney test is used. The Chi-square test is used to analyze both comparative and correlational nominal/categorical data.

Before being recruited, the researcher has explained to the research subjects the flow of research, the purpose and benefits of the research, as well as the rights and obligations as research subjects. All research subjects stated that they were willing to participate in the research and had signed an approval sheet. None of the study subjects dropped out or resigned at the time the study took place.

RESULTS

The total subjects of this study are 95 patients who are taken by consecutive sampling. Consecutive sampling is a form of sampling in which a sample that came into the selected hospital met the inclusion and exclusion criteria. The characteristics of the research subjects are as follows on the Table 1.

The baseline data in Table 1 describes the two groups. There are no significant differences based on age, body mass index (BMI), mean arterial pressure (MAP), and stone size before ESWL. The different tests for numerical data on clinical parameters are shown in Table 2.

In Table 2, significant differences were found regarding the stone size of the U-ESWL group (2.8 ± 1.2 mm) compared to the FU-ESWL (2.0 ± 1.4 mm) after ESWL (p=0.041). ESWL frequency is also one of the efficacy parameters whereby the higher the frequency means the lower the efficacy. The ESWL frequency in the U-ESWL group is significantly higher (2.5 ± 1.4 times) compared to the FU-ESWL (1.7 ± 0.7 times) (p=0.004).

FU-ESWL shows a higher complication rate than U-ESWL but did not differ significantly (p=0.53), as shown in Table 3. Regarding complications, not a single patient experience hematuria more than 3 days after treatment. Re-treatment in both groups was found to be significantly different (p=0.024), whereby 75.56% of patients in the U-ESWL group underwent re-treatment, compared to 54% of patients in the FU-ESWL. Two clinical parameters showed no significant differences (SFR and Auxiliary procedure).

There were no significant differences between the two groups regarding the serum creatinine level (p=0.941), random blood sugar level (p=0.971) and hemoglobin level (p=0.066) pre- and post-treatment, as shown in Table 4. However, there were differences in Table 4. However, there were differences in Table 4. However, there were differences in Table 4.
### Table 1. Baseline data

<table>
<thead>
<tr>
<th>Baseline data</th>
<th>U-ESWL</th>
<th>FU-ESWL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td>44.4 ± 12.7</td>
<td>47.5 ± 12.3</td>
<td>0.385</td>
</tr>
<tr>
<td>Body Mass Index (BMI) (kg/m²)</td>
<td>25.8 ± 3.1</td>
<td>26.3 ± 4.2</td>
<td>0.887</td>
</tr>
<tr>
<td>Mean Arterial Pressure (MAP) (mmHg)</td>
<td>92.2 ± 7.4</td>
<td>90.3 ± 6.0</td>
<td>0.102</td>
</tr>
<tr>
<td>Stone size before ESWL (mm)</td>
<td>8.0 ± 3.3</td>
<td>8.2 ± 3.1</td>
<td>0.712</td>
</tr>
</tbody>
</table>

Data are shown as mean ± SD.

### Table 2. Clinical parameter difference test

<table>
<thead>
<tr>
<th>Clinical data</th>
<th>U-ESWL</th>
<th>FU-ESWL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stone size after ESWL (mm)</td>
<td>2.8 ± 1.2</td>
<td>2.0 ± 1.4</td>
<td>0.041</td>
</tr>
<tr>
<td>Difference in stone size before and after ESWL (mm)</td>
<td>5.2 ± 3.3</td>
<td>6.2 ± 3.2</td>
<td>0.117</td>
</tr>
<tr>
<td>ESWL Frequency (times)</td>
<td>2.5 ± 1.4</td>
<td>1.7 ± 0.7</td>
<td>0.004</td>
</tr>
</tbody>
</table>

Data are shown as mean ± SD.

### Table 3. Differences in data on the proportion of clinical parameters

<table>
<thead>
<tr>
<th>Data</th>
<th>U-ESWL</th>
<th>FU-ESWL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stone Free Rate (n/total (%))</td>
<td>43/45 (95.6)</td>
<td>50/50 (100)</td>
<td>0.220</td>
</tr>
<tr>
<td>Complications (n/total (%))</td>
<td>0/45 (0)</td>
<td>1/50 (2)</td>
<td>0.530</td>
</tr>
<tr>
<td>Re-treatment (n/total (%))</td>
<td>34/45 (75.56)</td>
<td>27/50 (54)</td>
<td>0.024</td>
</tr>
<tr>
<td>Auxiliary procedure (n/total (%))</td>
<td>2/45 (4.4)</td>
<td>0/50 (0)</td>
<td>0.220</td>
</tr>
</tbody>
</table>

Data are shown as mean ± SD.

### Table 4. Laboratory data

<table>
<thead>
<tr>
<th>Data differences before and after ESWL</th>
<th>U-ESWL</th>
<th>FU-ESWL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum creatinine (mg/dL)</td>
<td>0.03 ± 0.2</td>
<td>0.02 ± 0.2</td>
<td>0.941</td>
</tr>
<tr>
<td>Random blood sugar (mg/dL)</td>
<td>3.8 ± 25.6</td>
<td>-3.1 ± 13.8</td>
<td>0.971</td>
</tr>
<tr>
<td>Hemoglobin (g/dL)</td>
<td>0.03 ± 0.14</td>
<td>0.24 ± 0.9</td>
<td>0.066</td>
</tr>
<tr>
<td>White blood cell (10⁶/µL)</td>
<td>-0.89 ± 1.9</td>
<td>0.06 ± 1.9</td>
<td>0.021</td>
</tr>
</tbody>
</table>

Data are shown as mean ± SD.

### Table 5. Cost components of each group

<table>
<thead>
<tr>
<th>Cost component</th>
<th>U-ESWL</th>
<th>FU-ESWL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td>84,923.1 ± 47,603</td>
<td>63,782.8 ± 34,984</td>
<td>0.016</td>
</tr>
<tr>
<td>Consumables</td>
<td>163,156.6 ± 92,308.5</td>
<td>110,130 ± 46,711.8</td>
<td>0.004</td>
</tr>
<tr>
<td>Support</td>
<td>1,034,257.8 ± 585,148.2</td>
<td>698,124 ± 296,108</td>
<td>0.004</td>
</tr>
<tr>
<td>Treatment</td>
<td>516,444.4 ± 292,186.8</td>
<td>348,600 ± 147,858</td>
<td>0.004</td>
</tr>
<tr>
<td>Unit cost</td>
<td>362,581.3 ± 205,136.3</td>
<td>587,837 ± 249,330</td>
<td>0.00</td>
</tr>
<tr>
<td>Average Perceived Cost</td>
<td>2,161,363.3 ± 1,218,934</td>
<td>1,808,474.6 ± 770,499.7</td>
<td>0.799</td>
</tr>
<tr>
<td>Average Actual Cost</td>
<td>2,973,710.7 ± 1,789,955.7</td>
<td>2,330,024 ± 992,217</td>
<td>0.555</td>
</tr>
</tbody>
</table>

All cost components are shown in Indonesian Rupiah (IDR) and mean ± SD.

### Table 6. Data differences in the proportion of cost parameters

<table>
<thead>
<tr>
<th>Data</th>
<th>U-ESWL</th>
<th>FU-ESWL</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Cost Effectiveness Rate (ACER)</td>
<td>2,161,363 / 95.6%</td>
<td>1,808,474 / 100%</td>
<td>0.016</td>
</tr>
<tr>
<td>Efficiency Quotient (EQ)</td>
<td>95.6 / (100 + 75.56 + 4.4)</td>
<td>100 / (100 + 54 + 0)</td>
<td>0.066</td>
</tr>
</tbody>
</table>

The data of SFR, re-treatment and auxiliary procedure are shown in Table 3

The data of average perceived cost and average actual cost are shown in Table 5

The total maintenance cost (IDR 207,500) consists of an administration fee (IDR 20,000), ECG (IDR 37,500), install infusion (IDR 40,000), clinic fee (IDR 50,000), observation room fee (IDR 36,000), and additional outpatient fee (IDR 24,000).

To obtain the average maintenance cost, the use of maintenance cost was multiplied by the ESWL frequency of each subject and then divided by the number of subjects (45 in U-ESWL and 50 in FU-ESWL). Therefore, the average maintenance cost of the U-ESWL was IDR 516,444.4 ± 292,186.8, and the FU-ESWL group was IDR 348,600 ± 147,858.

Actual cost consists of perceived costs, transportation costs and loss of livelihood. Transportation costs are divided into cities (IDR 100,000) and out-of-town (IDR 300,000). The cost of loss of livelihood per day corresponds to the regional minimum wage of each subject. The average actual cost is the sum of all components divided by the number of subjects in each group. Therefore, the actual cost of the U-ESWL was IDR 2,973,710.7 ± 1,789,955.7, and FU-ESWL was IDR 2,330,024 ± 992,217.

In Table 5, all cost parameters, including medicines, consumables, supports, treatments, unit costs, perceived costs and actual costs, show that FU-ESWL is lower than U-ESWL. However, of the 7 parameters, only 5 parameters were significantly different, such as medicines, consumables, supports, treatments and unit costs.

The medication consists of an infusion of NaCl 0.9%, four tablets of Dextroprofen 25 mg and a two-ml of Fentanyl citrate or a 100-mg of Ketorolac. Significant differences were found in the cost of medication based on the average after multiplying the frequency (p=0.016), which was IDR 84,923.1 ± 47,603.3 and IDR 698,124 ± 34,984.1 on U-ESWL and FU-ESWL, respectively.

Consumables consist of one waterproof tape dressing (size 5 cm x 7.2 cm), a macro infusion set, disposable gloves, an alcohol swab, a 22-stera inflo IV 22, and a 3-cc syringe. Significant differences were found in the cost of consumables based on the average after multiplying the frequency.
DISCUSSION

To the best of our knowledge, this is the first study to compare U-ESWL and FU-ESWL. Several studies have been conducted to compare the efficacy of fluoroscopy-guided ESWL and ultrasound-guided ESWL. Goren et al. reported that U-ESWL has a higher success rate compared to fluoroscopy-guided ESWL (F-ESWL).4 Their research was conducted on the cysteine stone type, which is relatively poorly visualized and also the most resistant stone to ESWL, so it has a high level of difficulty when detecting stones with fluoroscopy. In addition, they also reported that the median rate of ESWL sessions was lower on U-ESWL. However, no significant differences were obtained between the two groups regarding the average shock wave and the energy level used.9,10 Chang et al. compared the combination of FU-ESWL with F-ESWL with the advantages of F-ESWL on efficacy, which are stone size, SFR, re-treatment and auxiliary treatment.10 Moreover, a recent systematic review reported comparable results regarding the stone-free rate and complications between U-ESWL and F-ESWL.17

The new generation of lithotripsy devices provides simultaneous fluoroscopic and ultrasound guidance. The existence of 2 guiding devices to target stones will increase the accuracy of lithotripsy in both radiopaque and radiolucent stones.1 Regarding Indonesian national health insurance, it is necessary to conduct further research to provide input not only to hospital management that provides ESWL but also to provide information to professional organizations, patients and insurance.

The efficacy of a modality cannot be separated from the safety aspect by the standards of the patient center care hospital where patient safety is the main thing in health care services. Ionizing radiation in fluoroscopy is one of the aspects that need to be considered both for patients and medical workers.6 The mean dose area product (DAP) fluoroscopy in 178 seconds is 3,005 mGy/cm²/ESWL session. This dose can still be declared safe when compared to other intervention procedures. However, it is necessary to pay attention to the accumulation of doses, especially in pediatric patients who have a tendency to have recurrent urinary tract stones and the possibility of patients undergoing other imaging examinations.7,9 Radiation exposure in medical workers should receive special attention, especially because of the potential risk of occupational cancer.7,9

The combination of fluoroscopy and ultrasound is expected to have an impact on the efficacy and safety of ESWL but not all urologists choose this method.8 Most urologists use the fluoroscopic method because it is easier to operate despite the presence of ionizing radiation with potential side effects to visualize stones.6,9 Another reason for the selection of fluoroscopy is time efficiency, where the difference is almost twice as efficient as ultrasound.5

This research analyzed the differences in the safety of U-ESWL compared to FU-ESWL in kidney stones less than 1.5 cm. Our research evaluates the safety based on complications, namely hematomas and changes in various clinical and laboratory parameters. Chang reported that in the case of large and small stones, the complication rate of U-ESWL is lower than F-ESWL. This can occur due to better accuracy, so it might minimize the damage to the surrounding tissue.10 Research on complications rate in pediatric patients following ESWL showed that U-ESWL was better (32.3%) compared to F-ESWL (70%), with the most common complication being steinstrasse.4

In urological management, it is necessary to pay attention to pediatric subjects because this group is vulnerable and about 2-7 times more sensitive than adult patients. Safe ionizing radiation in pediatric patients is not yet known for certain; however, radiation-free modalities (ultrasound) are the best choice for the pediatric group. The latest recommendations for radiation exposure for pediatric patients in one year with a maximum occupational associated dose of 50 mSv, while in 5 years, an average of <20 mSv/year.4,9

The main component of pharmacoeconomics is the combination of cost components (the value of resources needed by the management modality) and outcomes. These considerations are...
needed as part of a cost-control evaluation strategy. Costs in the pharmacoeconomic review include unit cost, perceived cost and actual cost. In addition, cost also can be discussed per unit, per person, per preventable case, per treatment/action, per DALY (disability-adjusted life year/year of life adjusted to disability) and per life that can be saved. Total costs consist of unit costs, drugs, consumables, support, treatment, perceived costs and actual costs.

The direct costs covered by the health care services are staff costs, capital costs, and medication procurement costs, as well as indirect costs experienced by the patient's family. The above cost model describes the cost category for evaluating the economic aspects of medication therapy/action. Costs are divided into direct costs, such as medical and non-medical costs, and indirect costs, such as tangible and intangible costs.

Perceived medical costs are funds that are compensated for certain therapies and services. Perceived cost is the cost of the ESWL procedure per session (unit cost) calculated based on the cost of the lithotripter machine, the cost of lithotripter maintenance and service, the cost of medical staff and nurses and overhead costs for administration, pharmacy and utility costs. In addition, medical costs are directly related to the time spent by employees in the preparation and administration of medicines as well as laboratory costs for monitoring the effectiveness and adverse drug reactions.

The discussion above shows that the unit cost, cost of medications, consumables, supports and treatments separately obtained significant differences between U-ESWL compared to FU-ESWL. However, no significant differences were found in the perceived cost between the two groups (IDR 2,161,363.3 ± 1,218,934 in U-ESWL and IDR 1,808,474.6 ± 770,499.7 in FU-ESWL (p=0.799)). This may happen due to uneven and wide data distribution in this study.

Non-medical costs are the costs required to allow a person to receive health care, such as lodging, special diets, and transportation. It also includes lost working time that is valuable to the employer. The actual cost is defined as the perceived cost combined with additional procedure costs and overhead costs for a hospital stay; administration, pharmacy, radiology, anesthesia, medical and treatment costs. The comparison of perceived costs and actual costs provides a more realistic reflection of the cost burden incurred by hospitals.

In this study, the actual cost consisted of perceived costs plus transportation costs and loss of livelihood when patients were treated. Transportation costs are divided into the inner city and outside the city, while the cost of loss of livelihood per day is in accordance with the regional minimum wage of each patient. The actual cost in the two groups did not show any significant difference (p=0.555). However, as in perceived cost, the actual cost of U-ESWL was higher (IDR 2,973,710.7 ±1,789,955.7) than FU-ESWL (IDR 2,330,024 ± 992,217).

In the study of Plano, CEA in 4 quadrants has different consequences, as an example: in quadrant II (dominant), the drug or action can be directly used without study because it is more effective and cheaper, while in quadrant IV the medication or action directly does not need to be used because it is less effective and more expensive. Further studies of CEA need to be performed if they are in quadrant I and quadrant III (trade-off), namely, if the medications or actions are more effective but more expensive or vice versa.

The CEA can provide comparisons of standard and alternative governance programs based on safety and effectiveness profiles. In addition, CEA is also used to compare the costs and significant consequences of such alternative management. Costs are measured in units of money, while results are measured in certain units. The CEA results were stated in ratios and expressed in units of cured cases. In this study, the stone-free rate was used as a component of success. The CEA method, among others, is the average cost-effectiveness ratio (ACER/Average Cost Effectiveness Ratio).

This study analyzed the differences in ACER on U-ESWL compared to FU-ESWL in patients with kidney stones of less than 1.5 cm. In this study, CEA deserves to be carried out because it lies in the ‘trade-offs’ quadrant, whereby in the aspect of ESWLs efficacy, FU-ESWL is superior to U-ESWL. However, on the price aspect, U-ESWL is more reliable than FU-ESWL. The CEA performed as ACER (Average Cost Effectiveness Ratio), which is a comparison of the average action costs/effects of actions on both groups. The average cost of action is obtained from the actual cost, which is the unit cost added to the cost of medications, consumables, support, treatment, transportation and livelihoods lost due to treatment. At the same time, the effect of the action is based on SFR.

The actual cost of U-ESWL is IDR 2,973,710 with an SFR of 95.6%, while the actual cost of FU-ESWL is IDR 2,330,024 with 100% SFR. Thus the ACER of U-ESWL and FU-ESWL are IDR 3,110,575 and IDR 2,330,024, respectively. Therefore, FU-ESWL is more cost-effective than U-ESWL.

In addition to CEA, there is an effectiveness calculation commonly used by urologists in kidney stone research, namely Efficiency Quotient (EQ), which is the result of calculating the percentage of overall stone-free divided by the sum of 100 and the percentage of re-treatment and the percentage of auxiliary procedures.

In this study, the SFR, percentage re-treatment and percentage auxiliary procedure on U-ESWL are 95.6%, 75.56% and 4.4%, consecutively. Therefore, the EQ of ultrasound-guided ESWL is 0.53. On the other hand, the SFR, percentage of re-treatment and percentage of auxiliary procedure on FU-ESWL are 100%, 54% and 0%, consecutively. Therefore, the EQ of FU-ESWL is 0.65. Taken together, FU-ESWL is more efficient than U-ESWL. This evidence supports the ACER calculation, whereby FU-ESWL is better than U-ESWL.

Recently, there have been no studies that elaborate EQ on FU-ESWL compared to U-ESWL. Research conducted by Koo in 2005 used EQ to compare the use of a slow delivery rate with a fast delivery rate on U-ESWL. Therefore, the current study is the first research to elaborate on the comparison of the efficacy, safety, effectiveness and efficiency of ESWL in kidney stones patients conducted with fluoroscopy-ultrasound and ultrasound target devices. However, there are some
limitations of this study, including the nature design of the cohort study, the hospital is different for each device, the composition of the stone is not considered, and also the patient follow-up is relatively short-term. In the future, authors suggest conducting multi-center RCT studies and radiation safety observation.

CONCLUSION

The combination of FU-ESWL is better than U-ESWL. The results explain that there is a significant role of the independent variable (type of ESWL device) on all dependent variables (clinical and laboratory findings as well as cost parameters).

ETHICAL CONSIDERATIONS

The Certificate of Ethics has been issued by the Health Research Ethics Commission of STIKES Bina Usada Bali with No: 047/EA/KEPK-BUB-2022, following the guidelines of the Declaration of Helsinki.

CONFLICT OF INTEREST

No competing interests were declared.

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AUTHOR CONTRIBUTION

GWKD: conceived the study, designed the study, analyzed the data, and wrote the manuscript. FP: supervised and reviewed the manuscript.

REFERENCES