Analysis of the use of Extracorporeal Shock Wave Lithotripsy (ESWL) based on piezoelectric lithotripter for kidney stone

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Abstract: Extracorporeal shock wave lithotripsy (ESWL) is a non-surgical method that can be used to break stones in the urinary tract or kidney stones by focusing the shock wave from outside the body on the location of the stone. In its application, ESWL is classified as theranostics by applying the principles of medical physics in determining the location of kidney stones and biophysics in the therapeutic process. This study aimed to analyze the use of ESWL to treat kidney stones in Dr. Saiful Anwar Malang hospital. The ESWL machine analyzed was the ESWL PIEZOLITH 3000 Triple Focus, which used the Richard Wolf piezoelectric lithotripter, with serial number GA-A 175. This analysis was carried out by combining the results of the method of literature research, observation, and interview. Based on the results of the research, the therapy with the ESWL PIEZOLITH 3000 Triple Focus uses a shock wave generated by the piezoelectric effect of piezoelectric crystals that are arranged like a mosaic in a spherical cup and are then activated simultaneously by a pulse generator. During the observation from July 18, 2017 to July 27, 2017, the smallest dimension of the treated stone was 6 x 6 mm and the largest was 10 x 15 mm. The number of shock waves used is the same with an average of 4000. The power, frequency, and membrane pressure are adjusted with the patient's body condition. Various criteria and contraindications must be met to determine a candidate for a patient to gain satisfactory results. The therapy levels include the pre-therapy procedure, therapy implementation, and post-therapy. The success rate of therapy and the rate of retreatment are determined by the type of stone, the location of the stones, and the density of the stones.

***Keywords**: theranostics, medical physics, biophysics, piezoelectric effect*

1. Introduction

Current technological developments have different effects on different aspects of life, including health. This revolutionary change in healthcare was triggered by the discovery of various innovations in examination and treatment techniques. In urology, we know Extracorporeal Shock Wave Lithotripsy (ESWL) which can be used to treat kidney stones. Etymologically, ESWL consists of the words "extracorporeal" (from outside the body or above the skin), "shock wave", and "lithotripsy" (*litho* which means stone and *tripsy* which means destroy). Therefore, ESWL can be interpreted as a non-surgical method that can break stones in the urinary tract by focusing shock waves from outside the body on the location of the stone.[1]

Therapeutic methods using ESWL include early-stage or pre-therapy procedure,[2] method of performing therapy, and post-therapy procedure. Kidney stone therapy with ESWL must be well prepared, as not all types of stones can be destroyed with this method. Therefore, size, location of the stones, kidney anatomy, patient's health, and contraindications must also be taken into consideration because these factors contribute to the success rate and retreatment rate of ESWL therapy.[1]

In general, all lithotripsy machines consist of 4 main components. They are shock wave generator, focusing system, coupling mechanism, and imaging or localization unit.[3] In this study, analysis of the use of ESWL to treat kidney stones was performed on the ESWL PIEZOLITH 3000 Triple Focus using Richard Wolf's piezoelectric lithotripter with serial number GA-A 175.

The piezoelectric lithotripter uses the piezoelectric effect on crystals. In a piezoelectric shock wave generator, dozens to thousands of piezoceramic are arranged on a disk, which conducts energy from whole ceramic elements to the therapeutic focus. Piezoelectric generators have a hemisphere that is attached to many piezoelectric crystals. When a high voltage with a high frequency flows through the piezoelectric crystal, there would be a reverse piezoelectric effect in the piezoelectric crystal. The piezoelectric crystal then generates stretching vibration and water molecules will vibrate to generate shock waves. The shock waves are focused on the focal point of the hemisphere where the calculi is located so that the calculi can be destroyed.[3]

The piezoelectric shock wave generator is a type of direct focusing system (DFL = *direct focusing lithotripsy*). All ceramic elements are focused on the therapy focus. The stone will be fragmented by a combination of energy generated from a continuous discharge process. In order to increase the output energy without the need for a larger disk, the Wolf Piezolith 3000 has a double layer of piezoceramic elements.

The piezoelectric lithotripter has the advantage of a small focal point with high peak pressure. In addition, the piezoelectric energy source has a single frequency, less noise, and little damage to the tissue around the target. However, the weak penetration ability and the high attenuation that occurred, lead to low therapy efficiency and high retreatment rates. The complex piezoelectric structure also requires high technical skills, so the piezoelectric lithotripter is less used compared to electrohydraulic and electromagnetic ones (apart from the reason for its lower effectiveness compared to other types of lithotripters). The large diameter of the disk which contains many piezoceramic elements also makes it difficult to combine with multifunctional machines.[3]

The analysis of the use of ESWL PIEZOLITH 3000 Triple Focus for the treatment of kidney stones is intended to provide an overview of the application of medical physics and biophysics in kidney stone therapy with ESWL so that similar studies can be reproduced and developed in the future. With a detailed study and a keen understanding of the science involved in treating kidney stones with ESWL, it is hoped that kidney stone therapy with ESWL can be improved to be more efficient and produce satisfactory results. This study therefore explains the principles of medical and biophysical physics that are applied in kidney stone therapy using ESWL, therapy methods and results, and factors that influence the success rate of therapy and the rate of retreatment.

2. Materials and methods

The material used in this study focused on the ESWL PIEZOLITH 3000 Triple Focus for the therapy of kidney stones. This study was based on the results of the internship at Rumah Sakit Umum Daerah Dr. Saiful Anwar Malang from July 17 to August 11, 2017. The analysis was carried out by combining the results of the literature study method, observation, and interview. Literature study was conducted before activity, during activity, and after internship activity. This method used books, journals on related topics, and a manual book of ESWL PIEZOLITH 3000 Triple Focus. Thereafter, the collected data and materials were used to make reports and then being compared with the results or data obtained during the internship. Observation had conducted during the internship. This activity was carried out through direct observation on the process of treating kidney stones using the ESWL PIEZOLITH 3000 Triple Focus in Dr. Saiful Anwar, Malang. The recorded data sample was the sample of patient data from July 17, 2017 to July 27, 2017 (excluding Saturdays and Sundays). The recorded data included the date of therapy, gender, age, stone size, number of shock waves, force, frequency, membrane pressure, and stone type. This data collection was known and had been approved by the parties concerned. In the meantime, interviews had been conducted by asking supervisor, field supervisors, therapy operators, and patients. All data obtained were then analyzed and compared with a literature study that was already carried out. During the internship, the study was limited to the use of the ESWL PIEZOLITH 3000 Triple Focus for kidney stone treatment procedures.

3. Results and discussion

3.1 General description of ESWL PIEZOLITH 3000

The extracorporeal shock wave lithotripsy (ESWL) used at RSSA is the ESWL PIEZOLITH 3000 Triple Focus, which is produced by the Richard Wolf brand with the serial number GA-A 175. This type of ESWL uses a piezoelectric lithotripter. PIEZOLITH consists of a device trolley, a compatible therapeutic source with an ultrasound locator, a separate ultrasound device, and an X-ray unit. Besides, there is an electrically operated treatment table that enables the patient to be positioned vertically and horizontally relative to the focus point of the therapy. PIEZOLITH 3000 is intended to fragment urinary stones in the kidneys (renal pelvis and calyx) and the ureter (upper, middle, and lower ureter). PIEZOLITH 3000 is available in 3 versions, namely with LITHOARM, with a stand, and with an articulated arm.

The locating systems in PIEZOLITH are arranged isocentrically, with the aim that there is no deviation between the target cross and the focus of the shock wave, even if the direction of the shock wave is changed. For ultrasound locator, a suitable locating system enables precise localization, which can be visualized sonographically. Its result is as good as permanent sonographic control during therapy. For this purpose, an ultrasound probe is placed into the therapeutic source and can be rotated or moved along its longitudinal axis. The use of USG is also required for real-time monitoring during treatment. For X-ray locator, the therapeutic source is patented on a C-arm X-ray isocenter via a LITHOARM or laser-monitored stand, which enables X-ray localization by confocal setting of the piezo power source with the X-ray C-arm from the AP to oblique point of view approximately 30°. The thing to know is that X-ray cannot be used together with an articulated arm.

The fluoroscopy mode used in the ESWL PIEZOLITH 3000 Triple Focus is Ziehm 8000. Fluoroscopy is used to expose patients to X-ray. The Ziehm 8000 offers three different fluoroscopy modes, namely continuous fluoroscopy, continuous pulse fluoroscopy, and single pulse fluoroscopy.

During the use of ESWL for therapeutic purposes, functional and operational safety tests must be carried out by experts (at least every 12 months) to avoid incidents caused by the age of the device. Besides, the device's ability to break stones must be tested with a test stone. The density of the stone can be determined by HU (Hounsfield Unit). Stones with a density >1000 HU are usually difficult to break because the stone is hard. Uric acid stones can usually be treated with sodium bicarbonate.

3.2 Piezoelectric Effect

Piezoelectric comes from the Greek word *piezo* which means pressure and *electric* which means electricity. Piezoelectric is a material that generates an electric field when it is given mechanical stress and when an electric field is applied to it, mechanical deformations or changes in the material dimensions occurred. Piezoelectric was first discovered by Pierre Curie and Jacques Curie in 1880, and it was finally able to be applied to industrial tools in 1950. Thereafter, piezoelectricity is also used in various applications, such as medicine, aerospace, nuclear instruments, and on mobile pad touchscreen as pressure sensor.

Piezoelectricity is defined as the ability of some crystals or certain other materials to generate an electrical voltage when subjected to pressure or expansion. Piezoelectric has reversible effects. They are the direct piezoelectric effect (generating electrical potential due to mechanical stress) and the converse piezoelectric effect (pressure is generated due to the application of electrical voltage which leads to dimensional changes). Piezoelectricity is a phenomenon when a force exerted on a segment of a material creates an electrical charge on the surface of the material segment, caused by the distribution of the electrical charge in the crystal cells. The values for the piezoelectric charge coefficient are in the range from 1 to 100 pC/N.

The scientific basis for the process of generating shock waves from piezoelectrics is the spontaneous expansion of ceramic particles, which is caused by a high-voltage pulse that is given in a short time (short-term high-voltage pulse). This expansion of the ceramic material creates a pressure wave in the water that is able to generate shock waves in the focal point. The pressure that hits the piezoelectric then creates an electric field. As the electric field passes through the material, the polarized molecules will adapt to the electric field. And then, the induced dipole with the molecular or crystal structure of the material will be formed. The adjustment of the molecules will change the dimension of the material. This phenomenon is known as electrostriction (piezoelectric effect).

The piezoelectric effect can be used in transducers that convert sound waves into electrical fields or vice versa. It is important to know that the amount of electric potential created is proportional to the amount of pressure applied. The greater the pressure applied, the greater the electric potential generated. When an AC voltage is given to the piezoelectric crystal, the piezoelectric material also moves back and forth that it can generate high-frequency sound waves or ultrasound (US).

In PIEZOLITH, the piezoelectric elements are arranged like a mosaic in a spherical cup, which is then activated simultaneously by a pulse generator. The spherical design with a wide active surface and a large aperture enables a precise focus zone with high sound pressure in its focus.

The wide energy coupling area can reduce the energy density on the skin surface to relieve pain, especially when shallow penetration is required. The precise focus zone enables precise treatment and the best possible protection of the surrounding areas. The PIEZOLITH system also enables the use of single pulse and continuous pulse modes. The power of the shock wave used consists of 20 intensity levels that can be adjusted to the needs of the patient.

3.3 Ultrasound Wave and Shock Wave

Ultrasound (US) is a sonic vibration with a frequency of more than 20 kHz. Ultrasound is a type of mechanical wave.[4] In biological substances, there are mostly only longitudinal waves. The ultrasonic frequencies used in medicine are in the range from 1 to 15 MHz.[5] Medical devices that employ ultrasonic waves have a variety of functions, from non-invasive internal organ imaging to the therapy of muscle tissue using the mechanical and thermal effects of ultrasound on biological materials and for rheumatology. Besides, this technology is also used for non-invasive measurement of blood flow and blood pressure.

Ultrasonic waves are not only limited to medical diagnosis,[6] but it is also used for therapeutic purposes.[7] For example, the low-frequency US waves (20 to 100 kHz), which are used to treat chronic sinusitis,[8] dental,[9] eye surgery,[10] etc. Besides, high-intensity focused ultrasound (HIFU) technology can also be used to treat tumors that may develop into cancer,[11] psoriasis,[12] dermatological purposes,[13] etc. Other uses include fragmentation and removal of biological tissue,[14] activation of transplanted organs,[15] biopsy,[16] gynecology and obstetrics,[17] pediatric anesthesia,[18] forensic testing,[19] and sterilization of medical devices.[20]

The effects caused by ultrasound include chemical effect, biological effect, mechanical effect, and thermal effect. The chemical effect caused by ultrasound can cause oxidation and hydrolysis of the polyester bonds. The biological effect caused by the ultrasound are usually a combination of other effects. In general, biological effects are divided into thermal and non-thermal mechanisms.[21] For heat therapy, the principle is to use ultrasonic waves of a certain power or high intensity that can cause the material vibration in the tissue and then heat it. This heat creates the desired therapeutic effect.[22] Local heating is usually used to warm blood vessels (causing them to dilate) or to cause tumor necrosis. The power used for this purpose usually does not exceed 5 W/cm^2 for penetration into the tissue.[23] This biological effect later triggers the thermal effect. The mechanical effect of ultrasound can disintegrate some solid objects, such as kidney stones and gallstones.

The characteristic value of ultrasonic waves can be traced by the ultrasonic wave equation. This equation depends on the distance a, the time t, the amplitude A, and ω, which is the angular frequency of the mechanical disturbance emitted by the vibration source.

$$A_s = A\sin(\omega t - ka) \tag{1}$$

With $k = \frac{2\pi}{\lambda} = \frac{2\pi f}{c} = \frac{\omega}{c}$,

$$A_s = A\sin(\omega t - \frac{\omega a}{c}) = A\sin\omega(t - \frac{a}{c}) \tag{2}$$

Where As: elongation or oscillating particle distance of its rest position, ω: angular frequency, a: distance between the center of excitement and the site consideration.[5]

The ultrasound intensity used for medical diagnosis varies between 10 and 50 mW/cm^2, while an intensity range of 1 to 3 W/cm^2 is used for therapies such as diathermy. Another use of ultrasound with an intensity range of 10 to 20 W/cm^2 is for cavitation (ability to destroy molecules) used in lithotripsy or nebulization.[24]

Another quantity to consider is the ultrasonic velocity passing through the medium. The particle velocity v in mechanical motion can be formulated as follows:

$$v = \frac{dA_s}{dt} = A\omega\cos\omega(t - \frac{a}{c}) \tag{3}$$

Where $v_m = A\omega$ is the maximum instantaneous velocity.[5] The velocity of ultrasound passing through the medium is influenced by the density and compressibility of the medium. The denser the medium is, the faster the velocity is. If the ultrasonic velocity in the medium is already known, the point of reflection depth corresponding to the resulting echo can be known with the time required for the echo to return is provided.[25] In the human body, the ultrasound speed is between 1500 and 1600 m/s, while it is 3360 m/s when passing through the bone.[26]

Shock waves are sound waves or pressure waves that propagate through the medium through alternating compression and decompression process of the medium. At the interface between the medium with different acoustic impedances, absorption, reflection, or refraction of the shock waves can occur. Shock waves can be produced by the sudden release of mechanical, electrical, chemical, or nuclear energy in a confined space. This is usually accompanied by sudden changes in the pressure, density, temperature, entropy, and velocity of the particles. Shock waves can propagate differently than ordinary sound waves.[27]

The low-pressure shock waves generated by the generator are concentrated in one place where the kidney stones are located. Only at this focal point, the shock waves have enough pressure to destroy its target, so that is no part outside this focal point is damaged. Another important point is that, unlike ultrasound, shock waves do not transmit heat, so thermal damage to the kidneys from ESWL exposure is negligible.

Shock waves have properties similar to conventional ultrasound. Ultrasound is characterized by an alternation between compression and stretching. Besides that, ultrasound also consists of a sine wave or series of pulses at a specific frequency. Meanwhile, shock waves are high energy wave that consists of a single high-pressure peak with a steep start and a gradual decay.[27]

Thus, it can be seen that the shock wave frequency range is wider than that of ultrasound. Ultrasound has a characteristic frequency, while a shock wave is made up of many frequencies called the shock wave frequency spectrum. The advantage of using shock waves for various medical applications is that the shock wave attenuation when passing through the human body is less compared to ultrasound. This is because high frequencies are more attenuated than low frequencies. Sometimes shock waves are also intended for lithotripter pulses, which are non-linear high-pressure pulses with very short rise times and a wide frequency spectrum.[27]

It should be known that the velocity of every mechanical wave (such as audio sonic or ultrasound) increases as the compressibility of the medium decreases. Therefore, the velocity increases as the density of the medium increases. In the meantime, the density of the medium can also change as the waves move through the medium. Similarly, the propagation of shock waves causes the medium to become denser.

When a wave passes through the medium, energy is lost through friction. The absorption of this energy can lead to a decrease in the pressure amplitude. The pressure amplitude decreases exponentially as the depth of the tissue is traversed. The penetration into the tissue also depends on the frequency of the wave.[27]

The shock wave peak pressure attenuation in water ranges from 10 to 20% over a distance of 100 mm. As explained earlier, the velocity of the shock wave in water depends on the pressure. The higher the pressure, the higher the speed. The energy attenuation caused by the shock wave through the lithotripter membrane of the water cushion is up to 20%. However, if the voltage of the shock wave generator is increased, this can be overcome.[27]

In general, acoustic waves can cause a variety of effects when propagating through the medium. Common examples are heating, cavitation, compression, stretching, reflection, and turbulence. Heating occurs due to the absorption of acoustic energy, which is then converted into heat in the material or tissue. This effect depends on the physical properties of the material, the intensity of the acoustic radiation, the duration, and the frequency. Dynamic agitation and shear stress from the waves can affect the structure of properties. Acoustic cavitation can create free radicals. In addition, sound waves can cause rapid compression and expansion of tissue. Reflection occurs when the wave hits the interface (where there is a difference in acoustic impedance). If the difference in acoustic impedance between the two media at the interface is large enough, the amount of energy reflected is also large. Turbulence or "acoustic streaming" can occur at the interface between liquid and solid or between gas and solid.[27]

When the shock wave hits a stone with a different acoustic impedance to water, some of the shock wave will be reflected. The shock waves that go through the stone are reflected in the second acoustic difference between the rock and the surrounding liquid. It is this reflection of the shock wave that creates stone fragmentation. Stone fragmentation is obtained through erosion and grinding mechanisms. Since there is no difference in acoustic impedance between the water and the surrounding soft tissue, the shock wave is not reflected. It makes shock wave will be transmitted so that there is no fragmentation effect on the surrounding soft tissue. Shock wave interactions with stone usually involve a combination of different mechanisms, namely the Hopkinson effect, cavitation, quasi-static crushing, and dynamic fatigue. The resulting traumatic effect is frequency-dependent. Low-frequency components can cause larger amplitude displacement compared to the high-frequency range. The effective component for ESWL therapy is over 200 kHz meanwhile the ineffective component is between 20 and 200 kHz.

Cavitation is known to be the main mechanism of tissue damage during ESWL.[28] Although it is important in fragmenting stones, the effect of cavitation is also identified as the main cause of the adverse effects on tissues caused by shock waves. To minimize the damage caused by cavitation, the pressure (negative component) on the shock wave path must be made small.

The image generated in ultrasonic mode B shows that cavitation bubbles arise during the ESWL, which is resulted from the negative pressure of the shock wave. The bubble formation was also noted during ESWL treatment of the renal parenchyma. Bubble activity in tissues does not usually appear until after continuous treatment with hundreds of shock waves.[27]

The tensile component of the shock wave that is centered in the direction of the focal area can exceed the threshold for cavitation in urine, blood, or tissue. However, cavitation in tissues is different from that in blood or urine. The occurrence of cavitation can trigger the formation of bubbles. When the bubbles are deflated, the secondary shock waves and high-velocity microfluidics are created. The microjet effect can lead to tissue damage, especially in thin-walled blood vessels. This can cause bleeding/hematuria, which occurs temporarily within 1-2 days. The size of the microbubbles in commercially available ultrasound contrast materials is approximately 1 to 10 micrometers. With lithotripter pressure, cavitation can be produced in vessels with a core diameter of 20 nm. Not only can shock waves cause cavitation and cause bubbles to form, but they can also excite nerves. Even under certain circumstances, shock waves can increase the permeability of the cell membrane so that large molecules can become trapped in the cell without the cell dying.

3.4 Therapeutic procedure with ESWL PIEZOLITH 3000

3.4.1 Procedure before therapy

Before starting therapy with ESWL, patients must be consulted first. During the initial consultation, a medical history is reviewed along with the patient's medical records. Additionally, it is very important to tell your doctor about any medications, supplements, or herbs that you are taking. This is due to the types of antiplatelet drugs like aspirin, ibuprofen, Motrin, Advil, Alka-Selters, Vitamin E, Ticlid, Coumadin, Lovenox, Celebrex, Voltaren, Vioxx, Plavix, and various other drugs for arthritis or blood thinners like warfarin can affect the blood's ability to clot and cause bleeding. These drugs should be avoided for a week before the therapy date. This procedure must be done to obtain the last urine culture is free from these types of drugs before the therapeutic procedure. It is important to remember not to stop taking medication without asking for approval from the prescribing doctor.

After that, the patients should take medical urine test to determine kidney function, stone type, and physical fitness. The most important test is X-rays or USG to determine the location of the stone and its possible type. Preoperative tests that may be required include physical examination, electrocardiogram (EKG), complete blood count (CBC), blood coagulation profile (PT/PTT), comprehensive metabolic panel (blood chemistry profile), and urine analysis.

Good candidates for ESWL are:

- Stone size between 1-3 cm or 5-10 mm with bothersome symptoms
- Types of stones that contain calcium or uric acid are more brittle and easily fragmented
- Location of the stones in the kidney or ureter proximal and medial
- The lack of kidney obstruction (no obstruction distal or at the bottom of the duct) by stones and kidney function is still good
- The patient's state of health is eligible
- No bleeding disorders.
- Not pregnant as this therapy also uses X-rays

These criteria are critical to the success of ESWL. This is because this method cannot destroy all types of stone. Besides, the size, position of the stone, kidney anatomy, and the patient's state of health also affect. These criteria can be met by considering several things, one of which is a contraindication to performing an ESWL. Such contraindications include:

- Pregnancy or suspected pregnancy

- Coagulopathy (bleeding disorder) or so-called coagulation abnormality (usually indicated by abnormal prothrombin time, partial thromboplastin time, or bleeding time) or for those who have recently received anticoagulants (including aspirin).
- Uncontrolled high blood pressure
- Distal urinary tract obstruction
- The dysfunctional kidneys
- The presence of the active infection
- Arterial calcification or vascular aneurysm where the shock wave generated by the lithotripter passes through.
- Anatomical conditions that obscure or prevent the device from focusing on the target stone location, e.g. severe obesity or excessive spinal curvature.
- Immobile asymptomatic diverticulum stones or complicated staghorn calculi in the renal calyx.

Therefore, the risks and benefits of ESWL need to be carefully considered. Other things that need to be warned are:

- Bilateral stones: Treatment of bilateral stones should not be done in one treatment session as this can lead to bilateral kidney injury or complete obstruction of the urinary system with stone fragments. Therefore, this case must be treated with different therapy sessions for each side.
- Interfaces of air-filled shock wave paths: Shock waves should not be applied to air-filled areas of the body, e.g. on the intestines or the lungs. The shock wave quickly dispersed across the air-filled interface, which can lead to bleeding and other adverse effects.
- Arrhythmias during treatment: You can reduce the intensity of the shock waves and the repetition rate. In general, patients with a history of symptoms of this disease should have an ESWL-monitored EKG.

In addition, things that need to be considered for treatment are:

- Kidney Injury: To reduce the risk of injury to the kidney and surrounding tissues, it is recommended:
  a. The number of shock waves generated during treatment must be minimized.
  b. Retreatment for the kidney or the same anatomical part should be carried out at least one month after the first treatment.
  c. Any kidney or anatomical part should be restricted in the number of therapy sessions. The total number of therapy sessions allowed is three.
  d. The use of fluoroscopy must be done by minimizing the exposure that the patient receives during the therapeutic procedure.
  e. Electromagnetic interference.

If the patient is determined to be a suitable candidate for the procedure, the patient should meet with the patient service surgery coordinator to schedule an appointment for the procedure to be performed. Then the patient receives several forms. The forms include the ESWL report form, the ESWL firing form, and the ESWL status. The ESWL report form contains patient data, treating physicians, stone positions, etc. The ESWL firing form contains patient data, the treating physician, the number of shock waves and therapy sessions, and information about the shock wave firing. The ESWL status contains the patient's data as well as the required clinical data. This ESWL status is mandatory for the patient. This ESWL status is usually given to patients who are undergoing therapy for the first time.

3.4.2 Therapeutic implementation procedures

After reaching the established therapy plan, the patient is given medication for anesthesia and antibiotics to prevent infection. The type of anesthesia is general anesthesia. Kaltrofen is often used for this. Patients usually do not experience pain. Sometimes the patient can stay awake during the procedure and even follow the progress of the procedure on the ultrasound or X-ray monitor. During therapy, the patient is given hospital clothing and is asked to lie down on the operating table/on a pillow during the ESWL procedure. The patient is then taken to the recovery room for observation for two hours before being allowed to go home. However, some patients may need to be hospitalized for a day or two if there are other health issues. Therefore, the patient reports to the hospital or clinic on the day of the ESWL procedure and may be able to leave the hospital on the same day. The ESWL procedure can also be carried out on a basic outpatient.

Treatment steps with an ultrasound localizer and an articulated arm:

- Move the treatment table to the center

- Set the ultrasound probe to 0° or 90°
- For high penetration: low membrane pressure and the ultrasound probe is withdrawn.
- For low penetration: high membrane pressure and extended ultrasonic probe.
- Stabilize the patient's position on the treatment table
- Apply gel evenly and arrange it so that no air bubbles form on the coupling membrane and the patient.
- Place the therapy source relative to the patient so that the therapeutic area is visible on the ultrasound monitor. To do this, the articulated arm or individual joints must be moved.
- Set the required penetration depth of the therapeutic focus with the membrane pressure button. The inflation of the coupling membrane determines the depth of penetration of the therapeutic focus.
- Move the operating table horizontally and vertically until the therapy field is symmetrical to the target cross. The ultrasound probe must be moved radially to ensure that the therapy field and the target cross are completely aligned.
- If the ultrasound image is poor, more gel must be applied to both the coupling membrane and the patient. If the patient moves, shock wave therapy should be stopped and repositioned until the therapy field is exactly symmetrical to the target cross again.
- Carry out another ultrasound localization after at least 1000 shock waves and reposition the treatment table if necessary

Important informations for therapy are:

- Good ultrasound images indicate good transmission of shock wave energy, so there is a high probability that the treatment will be successful.
- The ultrasound probe must be rotated to obtain the optimal angle of view.
- For localizers, the ultrasound probe can be moved axially in the direction of the therapeutic focus to achieve a direct coupling of the ultrasound probe with the patient's skin by using the coupling membrane. This is done to prevent multiple reflections so that an optimal ultrasound image can be obtained.
- To avoid loss of energy during shock wave therapy, the ultrasound probe should be pulled as far as possible.
- The penetration depth is applied with a therapeutic focus distance of 152 mm in front of the shock wave rim. If it is possible to apply a small amount of compression to the patient's body, the depth of penetration can be increased up to 165 mm (e.g. for adipose patients). Treatment is gradual, especially if there are several stones. For example, for every 1000 shock waves that able to destroy stone up to 2.95 m-3mm.

3.4.3 Patient Data Sample

The recorded patient data were obtained from July 17, 2017 to July 27, 2017 (except Saturdays and Sundays).

No.	Date	Sex	Age	Stone Size (mm)	Shock Wave Number	Power	Frequency	Membrane Pressure	Stone Type
1.	18 July 2017	M	53	10	4000	18	F1-1	-	Right-UPJ
2.	18 July 2017	F	56	6	4000	17	F1-1	6-7	Upper pole sin
3	19 July 2017	M	36	13	4000	18	F1-1	8-9	Ren sin
4.	20 July 2017	M	42	10x15	4000	16,18	F1-1	9	Ren dex
5.	20 July 2017	F	56	10 x 15	4000	18	F1-1	7-8	Lower ren dex pole
6.	20 July 2017	F	54	10	4000	17	F1-1	8	Lower ren sin pole
7.	20 July 2017	M	43	13	4000	17	F1-1	6-7	Lower buli pole dex
8.	20 July 2017	M	39	-	4000	17	F1-1	8-9	Buli multiple sin

9.	20 July 2017	F	50	10	4000	14-18	F1-1, F1-2	7	Lower buli pole sin
10.	21 July 2017	F	59	15	4000	18	F1-1, F2-1	6-7	Pyelum dex
11.	21 July 2017	M	44	-	4000	17-18	F1-1	5-7	Pole tjal sin
12.	21 July 2017	M	55	-	4000	16-18	F1-1	5-7	Lower pole dex
13.	25 July 2017	F	-	8	4000	18	F1-1	5	Lower pole sin
14.	25 July 2017	M	78	8	4000	18	F1-1	7-8	Middle pole sin
15.	25 July 2017	M	-	-	4000	17	F1-1	8-9	Lower pole
16.	27 July 2017	M	66	12	4000	17-18	F1-1	6-8	Pyelum dex
17.	27 July 2017	M	41	13	4000	18	F1-1	7-8	Lower dex pole
18.	27 July 2017	F	28	6 x 6	4000	17	F1-1,F1-2	4-5	Ureter prox dex

Based on these data, it can be seen that the number of shock waves used is the same, i.e. 4000 in total. This number is considered to be an ideal number because if it is less it will reduce the effectiveness of the treatment, while if it is excessive it will cause adverse effects on the kidneys, such as hematuria. The membrane pressure used also varies because it is adjusted to the patient's body shape (adipose patients should be treated with high membrane pressure) and the patient's endurance. If the patient is in pain, the membrane pressure should be reduced. The same applies to the use of frequency and power.

3.4.4 After therapy

After therapy, patients can go home immediately unless they have not been approved by the doctor, as the patient's condition requires close observation. Patients can have normal activities for 24 hours after therapy. After returning home, patients should have adequate rest for a few days after therapy. Besides, patients are recommended to consume more water for several weeks to help the kidneys and make it easier to remove the kidney stone fragments. Stone fragments can pass several days while urinating and last up to 12 weeks. Most patients will excrete urine mixed with blood for 1-2 days.

A few weeks after the ESWL treatment, the urologist will do an X-ray to see if the stone has broken into small pieces and if those small pieces have passed through the kidney. If the stone breaks into small fragments, but the fragments are not visible, a repeated x-ray is taken after a few weeks. If the stone is not fragmented, the urologist may recommend further treatment. In many cases, subsequent ESWL treatment may not work if the stone is not fragmented in the first session of ESWL treatment. In this situation, other treatments such as ureteroscopy or percutaneous nephrolithotomy may be recommended.

Although ESWL is a relatively safe treatment, it is important to be aware of the possibility of side effects. Possible adverse effects when using ESWL are:

- Common (>20% of patients): hematuria, pain/renal colic, reddening of the skin where the shock wave was targeted
- Occasionally occurs (1-20% of patients): urinary tract infection, urinary obstruction/steinstrasse, bruising on the skin where the shock wave was targeted, fever (>38°C), nausea or vomiting
- Rare (<1% of patients): cardiac arrhythmia, hematoma (perirenal/intrarenal), renal injury

4. Conclusion

Based on this study, it can be concluded that Extracorporeal Shock Wave Lithotripsy (ESWL) is a non-surgical method to break the stones in the urinary tract or kidney stones by concentrating the shock wave on the position of the stone from outside the body. RSSA uses ESWL PIEZOLITH 3000 Triple Focus (with piezoelectric lithotripter) from Richard Wolf brand edition with a number GA-A series 175. The therapy success rate and the retreatment rate are determined by type of stone, stone location, and stone density. The smallest stone that was treated in the period from July 18, 2017 until July 27, 2017 (except Saturdays and Sundays) was 6x6 mm in diameter and the largest was 10x15 mm. The number of shock waves used was 4000. The power, frequency, and pressure membrane adjusted to the patient's body condition. To gain satisfactory results from therapy with ESWL, several criteria and contraindications must be fulfilled to determine the patient candidate. Therapy phases include procedure before therapy, performing therapy, and post-therapy. Besides, it is necessary to identify the possible side effects of therapy by doing observation after therapy.

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