Lithotripters

Robert M. Dondelinger

Kidney stones affect up to 4% of the population with mostly men experiencing them. A kidney stone is typically a very small mass—although some have been found as large as one inch in diameter—usually composed of calcium oxalate derivatives and other solids that can block the urinary tract. When this happens, a patient often experiences excruciating lower back pain that can radiate to the groin. The pain stops once the stone passes into the bladder. An infection often develops if the stone is not rapidly passed or dissolved. Sometimes the stone passes without any intervention; however, some 200,000 people are hospitalized for this condition each year in the United States alone. There are medical treatments for kidney stones, but if these fail, a lithotripter is used to break up stones less than one-half inch in diameter. Larger stones typically require conventional surgery for their removal.

Current Technology

Lithotripters use a series of focused shock waves to break up the kidney stone or stones in a manner similar to a jackhammer breaking up concrete. Multiple shock waves, directed with pinpoint precision, provide enough energy to fracture the hard stone while leaving the surrounding soft tissue virtually unaffected. Lithotripters fall into two general categories: extracorporeal (outside the body) and intracorporeal (within the body). Specific clinical considerations govern which category of device is best suited for a particular patient.

Extracorporeal lithotripters (also known as extracorporeal shock-wave lithotripsy or ESWL) are in their second and third generations, but their basic operating principles remain unchanged. ESWL units use focused shock waves of appropriate intensity and duration to pulverize both gallstones and kidney stones. The resultant sand-like particles pass harmlessly through either, respectively, bile ducts or the urinary tract to exit the body. First-generation units required the patient's torso be immersed in a tub of water, but current designs do away with the need for partial immersion by utilizing a water-filled cylinder.

ESWL systems consist of four primary components: an examination and treatment table, an imaging system, a shock-wave generator, and a control console. The examination and treatment table is similar to the type used in a fluoroscopy (fluoro) suite, containing an undertable X-ray tube and often a film cassette holder. Near the exam table are the electronics for the fluoro system, along with its associated video monitors. The imaging system is used to locate the stone or stones prior to treatment. Typically, gallstones are located using ultrasound, and while fluoroscopy is often used to locate kidney stones prior to treatment, one manufacturer employs digital slit-scan radiography. After the exact location of the stone or stones has been determined, the patient is positioned over the head of the shock-wave generator so that the waves are focused onto the stones.

The shock-wave generator delivers the real power of the system. The shock waves it produces pulverize the stones virtually to dust. Over the typically 30 to 90 minute treatment, the generator produces up to 2,000 pulses, often in groups of 100 shock waves in rapid succession, with a pause between groups to re-evaluate both the location and size of the stones. Typically, the shock-wave groups are delivered one of three ways: triggered manually, delivered at a fixed rate, or in synchronization with the heartrate or respiration pattern to minimize disruption of other critical functions. For very large stones, additional treatments on successive days may be required.

The shock-wave generator can be one of four types: electrostatic spark discharge (or spark gap), electroconductive, electromagnetic, or piezoelectric. Spark-gap generators produce an electrical discharge between two

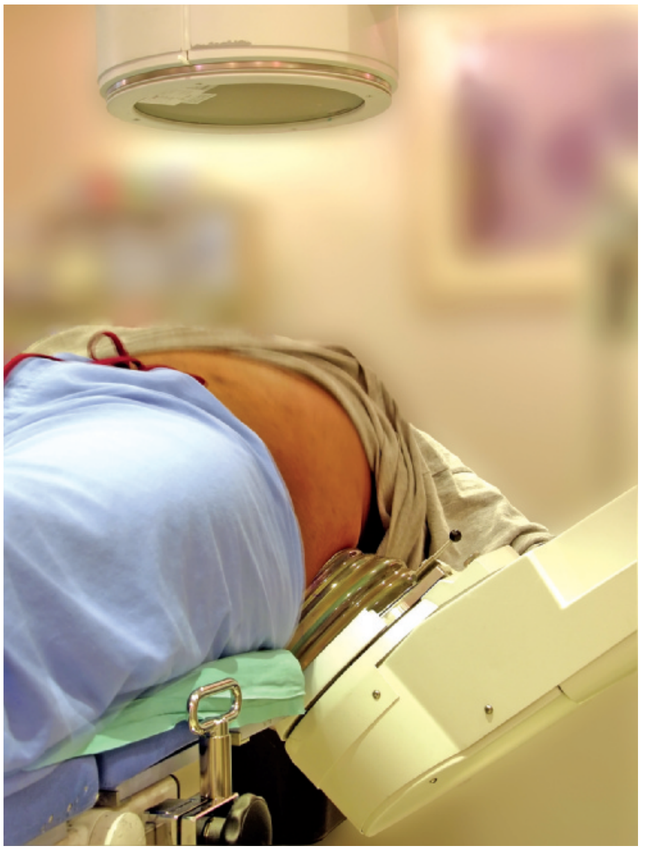
Robert Dondelinger, CBET-E, MS, is the senior medical logistician at the U.S. Military Entrance Processing Command in North Chicago, IL. E-mail: robert.dondelinger@mepcom.army.mil

submerged electrodes that instantly and explosively boils the small amount of water (visualize using a spark plug that arcs underwater) between the electrodes. The resultant shock wave travels through the water, focused by an ellipsoidal reflector, to the stone. Electroconductive generators operate in a similar manner, except that the electrodes are immersed in a highly conductive solution. Electromagnetic generators employ a magnetic field produced by sending an electric current through a coil attached to thin metallic membrane similar to a speaker cone. The shock waves are produced when the membrane is moved by the magnetic field. Piezoelectric generators employ a spherical array of up to 4,000 ceramic elements. Shock waves are generated when short high-voltage pulses are applied to the elements of the array.

Regardless of how they are produced, the generated shock waves are delivered to the head of the shock-wave generator through a cylinder filled with degassed water. Once the shock waves are delivered to the patient—who has been anesthetized and positioned over the head of the shock-wave generator—they are transmitted through the soft tissue, which is mostly water, to the stones, where the repeated shock waves fragment the stones. The disintegrated fragments exit the body through the urinary tract.

Intracorporeal lithotripters are used to break up large stones that the extracorporeal lithotripters cannot, typically impacted stones in the upper ureters or those located in the lower urinary tract. Although intracorporeal lithotripsy is minimally invasive and poses a lower risk than open surgical stone-removal procedures, it poses a greater risk to the patient than extracorporeal lithotripsy. The surgeon has several options in accessing the body to dissolve the stone. After administration of an anesthetic, the surgeon inserts a nephroscope (for percutaneous lithotripsy) or an ureterorenoscope (for transurethral lithotripsy) into the ureter and guides it, with the aid of a fluoroscopy unit, so that it is in intimate contact with the stone. The lithotripter probe is introduced via the working channel of the scope to break up the stone, then the fragments are removed by irrigating and suctioning through the appropriate channels of the scope, with a stone basket or grasper, or by leaving a nephrostomy drainage tube in until X-rays show the that the stone fragments have passed.

As with extracorporeal lithotripsy, intracorporeal lithotripsy also employs several different methods of generating the stone-shattering shock waves. Electrohydraulic lithotripters generate plasma (highly ionized gas) from an electric spark to generate the shock wave and a probe to deliver it to the stone. The operator visualizes the stone through the scope and places the probe against it. The operator then triggers the lithotripsy generator to fire plasma bubbles through the saline irrigated probe which fragments the stone when the bubbles collapse. In laser lithotripsy, the operator again visualizes the stone through an ureteroscope, places the quartz fibers of the probe directly against the stone and activates the laser. The laser produces pulses of light between 755 and 2,100 nm, which cause a differential thermal expansion of the stone that fragments it into 1 to 2 millimeter pieces. Ultrasonic impact lithotripsy incorporates an external ultrasonic generator powering a transducer consisting of multiple piezoelectric elements vibrating at approximately 30 kHz, similar to the ultrasonic prophylaxis unit used by dental technicians for cleaning teeth. The transducer is connected to a hollow tube terminating in a moveable impact tip. Its vibrations shatter the stone on contact. Electromechanical and pneumatic impact units operate in a similar manner, except that the oscillations of the tip



With a lithotripter, the kidney stones are broken up by shock waves from below the patient. A doctor uses fluoroscopy above the patient to view the progress.

are produced either electromechanically or pneumatically, typically by compressed air. Most lithotripter probes are disposable, intended for a single use, while the fibers of laser lithotripters are reusable.

Extracorporeal and intracorporeal lithotripters have their indications and contraindications. The surgeon decides which lithotripter category and method to use for a particular patient. Each category has its distinct advantages and disadvantages, and which to use is determined by the physician's training and experience as well as the location, type, and size of the stone, and a host of ancillary factors. In making the decision, the physician will weigh the likelihood of complications (for both the anesthetic and the lithotripsy method) in light of the patient's age and condition.

How to Manage the Device

As with the majority of the medical devices used throughout a healthcare facility, lithotripters should be intensively managed. This is especially true with the higher-cost units, which can approach $1.5 million each. This means individually scheduled services—preventive maintenance, calibration (where required), electrical safety testing, and scheduled parts replacement (where applicable) for the

Origin and Evolution

Lithotripsy is regarded by many as the first minimally invasive surgical procedure and was introduced into medical practice during the early 19th century. Lithotripsy at this time required a skilled surgeon to manipulate an instrument through the urethra and into the bladder to either drill holes in the stone, crush into passable pieces, or a combination of both. This operation gained wide acceptance as an alternative to the century-old treatment to relieve the excruciating suffering caused by a bladder stone, the gruesome and highly morbid open lithotomy. As one might expect, patients preferred to postpone this operation until the pain of the condition was worse than the cure. Typically, about one out of five patients either bled to death during the operation or died from sepsis afterwards. Many of those who survived the operation suffered from erectile dysfunction, incontinence, or persistent draining as a result of the operation.

Intracorporeal lithotripsy as practiced in the 1800s was vastly different than the so-called first-generation complete-torso-immersion units of the 1980s. Initially, surgeons could neither directly see what they were doing, nor had the benefit of fluoroscopy to locate the stone, so they operated literally "by feel." In 1877, the first practical cystoscope coupled with a radically new device called "the electric light bulb" allowed urologists to actually see what they were doing inside the bladder for the first time. Being able to view the stone directly did not change the actual procedure much since surgeons still drilled and crushed the stone into passable fragments. Only in 1908 did Hugh H. Young of Baltimore introduce a "lithotriptoscope," which was able to view the stone, grasp it, and employ an electrohydraulic lithotripsy unit to literally hammer the stone to passable fragments. Incremental improvements on all fronts continued well into the 1950s and continue today. Intracorporeal lithotripsy is still the preferred treatment under certain conditions.

Meanwhile, a radically new extracorporeal method of dealing with these calculi was beginning to gain a following. In the 1950s, the first reports appeared documenting the fragmentation of both kidney and gallstones using continuous wave ultrasound. Subsequent research was not able to reproduce the results, but by 1971 the first successful kidney stone destruction in an animal was reported using a completely non-invasive technique. This technique used focused shock waves that penetrated the skin, passed virtually harmlessly through the intervening soft body tissue, and fractured the hard stone. Further research led to the introduction of the first generation of human shock wave lithotripsy in 1980. Despite the fact that this unit required the patient's torso to be immersed in a tub of water, over the next five years it became the standard treatment for kidney stones. Second and third generation units no longer required virtually total immersion of the patient, which meant less patient preparation, shorter treatment times, and higher patient throughput for the system. Additionally, extracorporeal lithotripsy units available today handle gallstones as well as kidney stones, employ ultrasound to continuously monitor stone location and size during the procedure, and employ multiple heads to increase cavitation, resulting in quicker and more complete stone disintegration.

lithotripter by serial number and/or healthcare facility unique identification number. Likewise, a detailed maintenance history should be maintained, documenting all services, both scheduled and unscheduled, performed on the system. Considering the cost of lithotripsy units and systems, biomed maintenance facilities should consider either first-call or billable service versus a full service contract.

Regulations

Aside from the normal Food and Drug Administration (FDA) designation as medical devices, there is no national regulation of lithotripters.

Risk Management Issues

Whether the surgery is noninvasive, minimally invasive, or conventionally invasive, there is always risk of a mishap. There are minimal and normal biomed-related risk factors with either category of lithotripter. The majority of risk management issues are in the hands of the physician. Although extracorporeal lithotripsy has an extremely low mortality rate (≈ 0.02%), it is contraindicated in pregnant patients and those with stones larger than about two centimeters. Since the patient is under anesthesia during the procedure, this is an additional risk that requires clinician management. Lastly, the radiation used during patient positioning must be included in the list of risks the user must manage. Intracorporeal lithotripsy additionally adds the minimal risk of infection, hemorrhage, and small perforations in the collecting system of the renal pelvis. Lasers, of course, can inadvertently heat surrounding tissue to the point of thermal damage, and ultrasonic lithotripsy has caused the formation of venous air emboli during percutaneous treatment. To minimize risk, clinicians must understand the limitations of the instruments at their disposal.

Troubleshooting

Despite the breadth of technology found in both categories of lithotripters, quite conventional circuitry is used to generate the shock waves necessary to fragment and, in some cases, remove the stone. Due to the various designs employed, there are no common problems or solutions and failures are rare.

Training and Equipment

Although model-specific training is a plus, basic troubleshooting can be performed by biomeds having only a general knowledge of lithotripters. Additionally, since some lithotripters are multi-specialty systems, additional knowledge of fluoroscopic X-ray, diagnostic ultrasound, lasers, etc., is beneficial. No special test equipment or service aids are required for lithotripter servicing.

Future Development

Several product generations have evolved since the introduction of extracorporeal lithotripsy, to the point that existing units are often incrementally upgraded in the field. This is expected to continue with future improvements in the area of stone location and monitoring, even during the procedure. Additionally, research is underway using multiple confocal shock-wave generators simultaneously triggered to produce more localized cavitation, improved stone disintegration, reduced collateral damage, and shorter treatment times.

Likewise, incremental improvements in intracorporeal lithotripsy continue. In instances where medical treatments are ineffective, smaller-diameter ureteroscopes, lithotripter probes, and quartz fibers have made the removal of stones from previously inaccessible areas much safer than conventional surgery. The relatively recent addition of both electromechanical and pneumatic impact lithotripsy has increased the possibilities for additional miniaturization and refinement of the instrumentation. One innovation, the Detler stone cone, prevents stone migration during treatment.

Clearly, there is, and will continue to be, room for both categories of lithotripters, complementing both the current conservative medical treatments and the more radical surgical procedures to treat kidney and gallstones. ■

References

1. Google. Timeline History Lithotripsy. Available at: http://www.google.com/search?q=timeline+history+lithotripsy&hl=en&sa=X&rls=com.microsoft:en-us:IE-SearchBox&rlz=1I7HPIB_en&tbs=tl:1&tbo=u&ei=eyNzTJDiGsmgnQeKqvnDDg&oi=timeline_result&ct=title&resnum=11&ved=0CEIQ5wIwCg. Accessed July 2010.
2. Science Encyclopedia. Lithotripsy History. Available at: http://science.jrank.org/pages/3962/Lithotripsy-History.html. Accessed July 2010.
3. **Herr H.** 'Crushing the Stone': A Brief History of Lithotripsy, the First Minimally Invasive Surgery. Available at: http://www.urotoday.com/images/british/bju%20mini%20rev%20aug%202.pdf. Accessed July 2010.
4. **Delius M.** History of Extracorporeal Shock Wave Lithotripsy. Available at: http://www.dpi.physik.uni-goettingen.de/isna/invited-lectures-abstracts/M.Delius.html. Accessed July 2010.