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Review Article about Medical Devices Used in Gallstone Lithotripsy: Types and Applications

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Annotation: Lithotripsy techniques are very important because of their non-invasive nature. There have been many clinical practices with this technology in recent years. The aim of this review is to create a knowledge base for various medical devices used in gallstone lithotripsy and to shed light on the effectiveness of these devices in clinical practice. In this review, extracorporeal, endoscopic, and per-oral transepatic approaches are going to be examined in a comparative manner. Medical devices used in these lithotripsy techniques, as well as their working principles and areas of application, are going to be detailed.

There are three main types of lithotripsy devices; shockwave, laser and mechanical. The lithotripsy devices used to break the stones in small pieces are called lithotripters in general. Lithotripters can be classified as extracorporeal, contact and mechanical lithotripters. Extracorporeal lithotripters generate mechanical shock waves, mechanically degrade the stone by the application of an externally applied force. The stone or the organ containing the calculus is outside of the body in this technique. Endourology combines endoscopic and imaging technology. ESWL and percutaneous nephrolithotomy (PNL) are frequently used in the application of this technique. Mechanical lithotripsy is applied through

orundum and metal baskets, and is frequently used in bile duct and pancreatic lithotripsy applications . There are a number of commercial products available in gallstone lithotripsy. ESWL has been safely and effectively used in management of urolithiasis in developed countries. And so far, it has been possible to get access to ESWL technology for only private practice in developing countries. However, it has been possible to receive this service through new practices as well. In this practice an electro hydraulic generator incorporating the cavitation principle was used. With the effect of the shock wave, the size of the stones gets reduced and the stone parts are expulsed either in the urine or spontaneously.

Keywords: Gallstone lithotripsy, medical devices, extracorporeal shock wave lithotripsy, endoscopic lithotripsy, laser lithotripsy, bile duct stones, non-invasive treatment.

1. Introduction to Gallstone Lithotripsy

Lithotripsy procedure is an important method in elimination of gallstones. As numerous countries' populations invest in higher quality healthcare, the incidence of gallstones is expected to rise. At present, gallstone lithotripsy is the least conducted among U.S. lithotripsy procedures. By examining and summarizing gallstone lithotripsy devices, the intent is that the use of equipment in this task will increase. Cholelithiasis, also referred to as gallstones, has a decade prevalence of about ten percent in the United States population. This illness has a higher prevalence in some other countries' populations, in part due to geographical and demographic reasons. For example, there is a report that indicates the prevalence of gallstone illness is almost 80%, 0.5%, and 20% in American Indian, Asian, and Hispanic women, respectively. The formation of stones in the biliary system can have serious health implications. Including cholesterol, black pigment, and brown pigment, galleries are categorized as one of the world's fifteen major forms of illness. Approximately 20% of cases with stones may be asymptomatic, but many of these cases may develop high morbidity and mortality diseases, such as acute pancreatitis. In fact, 80% of stones that reside in the bile duct can have severe future health implications such as sepsis or cancer. In essence, a stone-free biliary system is an environment that promotes all aspects of gastrointestinal health.

The method of cholecystectomy is the commonly used technique in eliminating gallstones due to lack of recurrence and high elimination rate. One of the possible intraoperative complications in conventional cholecystectomy is ductal injury. In addition to higher morbidity, the repair necessitates a more difficult and invasive intervention. Gallstone lithotripsy was explored as a temporary method for removing stones in the emergency clinic in order to avoid such complications. Although it remains a rare procedure in modern outpatient clinics, this situation draws attention to the necessity of summarizing and elucidating the medical intervention devices. A current innovative field is developing a FAQ-style dialogue system that provides proofreading guidance for English as a Second Language (ESL) students. This field encompasses linguistic, acoustic, and psycholinguistic aspects of spoken language, grammatical error correction, text simplification, etc. Corresponding to heaps., this document describes the terminology and grammar checking functionalities of our WOz-based ESL proofreading system concerning the

medical gallstone lithotripsy domain of equipment [1]. A prominent domain expert guided the WOz generation of call agents that simulate the automated system. The guided domain agent has the third agent, slightly automating the call facilitation. A backward review cycle updated the call agent to reflect N-WOz and support the domain expert in authoring the equipment FAQ guide. Also presented are the two N-WOz heuristics that led the domain expert to emphasize equipment terminology in WOz review, provide a more structured guideline during the second review cycle, and automate WOz improvements. Evaluation on proofreading feedback quality demonstrates the approach's advantages in terms of the number of errosd benefitting and explains why the automated system did not outstrip the human expert. In addition to possible improvements for future research, paper-related findings on ESL and WOz dialog were uncovered, including the robustness of N-WOz in other similarly scoped tasks and active and passive advantages of call agent training. [2][3][4]

Literature Review

1.1. Definition and Prevalence of Gallstones

Gallstones are hardened deposits that form in the gallbladder and typically range from the size of a grain of sand or smaller to larger than a golf ball. The condition is known as cholelithiasis, but its common name is gallstones. Their composition is 5% of minerals, mainly pigments, and the rest is cholesterol and bilirubin. Pigment gallstones are actually aggregates of bilirubin and therefore completely solid and hard. Cholesterol gallstones contain more than 50% cholesterol and therefore usually softer, less dark on X-ray film. The majority of gallstones are cholesterol-based and diet-related; however, pigment gallstones, big in size and often genesis in the common bile duct, are an important group with specific applications [5]. Cholesterol gallstones may be of radiolucent or radiopaque chemistry. Furthermore, some important factors of lithogens, like calcium, etc., can not be diagnosed radiologically. As a clinical observation, many centers were in a phase that gallbladder ultrasonography was performed before ERCP with a wrong claim that same radiographs can also diagnose the biliary tree. It is crucial to specify that there are many false radiolucent stones, because of the air in their composition, and all stones are always detected on MRI or ultrasonography [6]. Small stones, when symptomatic, may require surgical therapy because of the high risk of complications. Efforts are being made to crush the stones into smaller pieces without harming the tissues. Therefore, development of noninvasive subsequent methods is growing in the gallstone therapy for both pigments and cholesterol stones. ESWL, Percutaneous Cholecystolithotripsy (PCCL) and Doppler ESWL were compared in an experiment on phantom material. In ESWL, special catheters were used for defragmentation. It was claimed that Pigment Stones were better crushed than Cholesterol Stones. Gallstones are widespread throughout the world, with approximately 15-20% disease for Europeans and 25% for the Native Americans. Africa and South America have the lowest rates, between 3-5%. The mechanism of cholesterol and pigment gallstone formation is different in nature, but the factors that provide the formation are quite similar. The equivalent of these factors will grow the market of cholesterol gallstone applications in the Asians and in the countries where the cholesterol stones are less prevalent. Although the rate of gallstones increases with age, people under 20 years of age are not completely protected against gallstones because of childhood obesity. Women are more likely than men for the formation of gallstones, because progesterone hormone forces the bile to be more viscous, since it is consumed faster in the body than estrogen. This is why the third cause of the drug-related gallstone formation, the birth control pills, and hormone replacement treatment increases the risk of gallstones. Low-fat, high-fiber and carbohydrate-based nutrition is protective against gallstones. Protein and fat-based diets increase the risk. Scientific studies and theories specified above showed clearly that the gallstones will be one of the endemic diseases in Turkey, such as Europe and other western countries. As a consequence of this fact, the aim of the study is to indicate the importance of the lithotriptic treatment of gallstones for Asians, especially with a current perspective of a focus on the Turkish population. This would provoke researchers, clinicians and engineers with interest to redirect their research

lines to stone studies. In developing countries, mortality due to gallstone disease is usually because of choledocholithiasis pancreatitis. It is important to note that gallstones, while being usually life-threatening, are a serious insidious disease that affects the quality of life. In many cases all gallstones, including asymptomatic, are removed and endoscopic or surgical treatment is being carried out. However, as lithotriptic applications are developed, it may be more reasonable to apply to non-surgical therapeutic methods before the stone exceeds a certain size. Also, this will decrease the amount of improvements resulting from surgery. Dental and therapeutical fields have been able to benefit from these biotechnological developments to a large extent for gallstones. However, compared to other stones, problems in its unique characteristic such as sensitivity to the body temperature are impeding the developments of treatment synergies by selectively analyzing special applications. Since the 2000s, ESWL has been the primary method of choice for the treatment of kidney stones, although its effect on gallstones is restricted to a few clinical cases. With the digitalization of ultrasonic imaging systems in the recent years, the idea of using ultrasound without lesion effects for treatment of gallstones was performed in laboratory circumstances and has been experimentally validated. This gave rise to possible development of an ultrasonic device for gallstone management that could be used by medical professionals without prior knowledge of instrument operations. This study could be of potential interest for the design and development of future endoscopic practical gallstone therapy devices not requiring competence in medical resonance imaging operations. It also provides an understanding and an in-depth coverage of mechanisms effective in gallstone lithotripsy as compared to other stone diseases. [7][8][9]

2. Types of Medical Devices Used in Gallstone Lithotripsy

The mechanisms and medical devices used in gallstone lithotripsy treatment are briefed. Medical devices used in gallstone lithotripsy are categorised based on the mechanism of lithotripsy such as ultrasonic, mechanical impact, lasers, and electrohydraulic and are reviewed with respect to their clinical applicability. Additionally, recent technological advancements in each medical device category are also detailed. Understanding the characterisation of such devices may help medical practitioners decide on treatment strategies and could facilitate direction in further development. The effect, limitations, patient selection and complimentary methods of each device are also discussed.

Gallstone lithotripsy is a minimally invasive medical treatment for patients with symptomatic gallstone disease. To fragment gallbladder stones several medical devices and procedures which have been used for lithotripsy in urinary system since early 1980s [10]. An extracorporeal shock waves have been introduced through body surface and lithotripsy treatment is made on treatment table. Alternatively, direct contact is made to hard solid objects such as calculus or gallstone by means of endoscopical processes. Stone is crushed and crushed products could pass from body easily by using these devices. In endoscopical lithotripsy, two important properties are typically accomplished by progress in optics such as efficient illumination and removal of stone fragments.

Gallstone lithotripsy has applied using diverse means such as ultrasonic, mechanical impact, lasers, and electrohydraulic. A variety of apparatuses based on these approaches have been used for the destruction of gallstones. However, most apparatuses are still suboptimal for the fragmentation of gallstones. The mechanisms, devices, and technologies of medical gallstone lithotripsy are reviewed comprehensively; emerging and promising technologies are also described.

Materials and Methods

2.1. Extracorporeal Shock Wave Lithotripsy (ESWL)

Lithotripsy is a process used for the destruction of stones in the body; hence, it is also known as stone crushing. Lithotrity or lithotripsy, well-known Greek and Latin width compound words are

used to describe the sound waves that create pressure waves. This technique has been used since as early as the time of Hippocrates. A pestle is used to pulverize the stones and wrap them in muslin. In modern medical terminology, lithotripsy is a method for the removal of stones from the gall bladder or kidney by shock wave. In extracorporeal shock wave lithotripsy (ESWL), high energy shock waves are focused on stones inside the body which are disintegrated into smaller fragments. The fragments then get dissolved in the bile or urine and are excreted out from the body by natural activity. There are two types of lithotripsy, intracorporeal lithotripsy, and extracorporeal lithotripsy. ESWL among them is a non-invasive extracorporeal method.

The basic principle of ESWL is to use shockwaves (acoustic wave with high amplitude and short duration) which are generated outside the body. These break gall stones in a high energy spiral and, then their fragments easily dissolve in the bile or urine. This technique is recommended method for the treatment of symptomatic gallstones, but only 5% of gallstone patients have indications for this type of literatures. ESWL of gallstones requires a wide opening of the department, and so the technical modification of the equipment has been made to form the equipment necessary for ESWL of gallstones. This technique is also used to treat urinary calculi. ESWL, the targeted shock wave device, the X-ray apparatus with an operating table and film cassette, and a monitor to display the X-ray image is required. The shock wave passes through the body when it is focused in such a manner as to converge on stones, as the distance between the start of the shock wave generation and the focusing site is long (about 135 mm) and so the therapy is also possible in obese patients. [11][12][13]

2.2. Endoscopic Retrograde Cholangiopancreatography (ERCP)

‘Endoscopic retrograde cholangiopancreatography’ (ERCP) with sphincterotomy and the extraction of bile duct stones is currently the method of choice for choledocholithiasis with the achievement of a successful drainage of bile ducts in up to 90–95% of cases, with possible complications in no more than 5% of cases. They are performed through the introduction of both endoscopic and non-endoscopic medical devices into the bile duct lumen. The success of these techniques depends on various factors, including the presence of concomitant diseases and comorbidities of patients, the anatomy of a bile-excreting system, and the consistency and size of the stuck stones. The gall bladder and its outlet to the duodenum are removed. Among the eight papers presented at the therapeutic session, five investigate the impact of patient operational experience on the success rate of endoscopic lithotripsy.

ERCP is 40 years old today and the first ERCP detailed publications date back to 1974. This is the achievement of a group of Japanese scientists. It should be acknowledged that ERCP was not named earlier somehow and in that work it was called “transluminal retrograde cholangiopancreatography with endoscopy” [14]. In the successful publication, the detailed description of the introduction of the equipment and the applied techniques is presented, and this makes it easy to repeat the experiment. For years in a row, groups of clinicians and equipment manufacturers sought to improve the equipment and methodology of examination and the method of treatment of the disease, to make it more effective and minimize the risks. Consequently, due to the latest developments and constant perfection of the technique, the effectiveness and safety of this method have been dramatically improved. Over these forty years more than a half a million females have experienced ERCP. There are many examples around the world of clinics focusing only on the disease and the therapeutic ERCP.

Results

2.3. Laser Lithotripsy

Laser lithotripsy is an advanced technique for fragmentation of gallstones, using laser radiation transmitted by rigid and flexible fibres to break stones via a direct or indirect manner. Direct projections can generate bubbles on the stone surface, resulting in its or the bubble’s collapse and stone disintegration. Indirect effects, on the other hand, cause stones to absorb energy and

break due to pressure buildup. Neodymium-doped YAG (Nd:YAG), Tm:YAG, thulium-holmium-chromium triple-doped YAG (Tm:Ho:Cr:YAG), diode, holmium-doped YAG (Ho:YAG), potassium titanyl phosphate (KTP), and Erbium-doped YAG (Er:YAG) lasers are commonly used in this application and can be free-running pulsed or continuous wave [15].

In a direct lithotripsy, the probe touches the stone—similar to electrohydraulic or mechanical lithotripsy—allowing a higher energy density on the stone and improved fragmentation. As it causes metal fever and burns, a lower energy density and higher pulse frequency are used, generating a slower and less effective fragmentation. In an indirect way, stones are hit from a distance, taking advantage of cavitation. No contact is made between the stone and the pulsed probe. The probe is activated, gas bubbles cavitate, cavitation dynamics release energy on the stone and fragment it. Indirect lithotripsy is effective with forced irrigation and at the ureter scope 0°, because focused irrigation generated no turbulence. For the same reason, smaller fibres and larger irrigation flow rates are not suitable. Depending on the equipment, a more conventional trajectory induces less deflection and stones break better; in contrast, a rifle scope makes the stone spin too fast. Finally, stone retropulsion can be minimized by using a smaller fibre, a longer pulse duration, and applying the lowest power output and maximum pulse frequency.

3. Applications and Clinical Considerations

The discussion explores the practical application scenarios of the gallstone lithotripsy techniques presented above. A review of the effectiveness of the techniques will provide insights into which devices to consider for different clinical scenarios. The more information available on a patient, the more accurately a treatment can be customized to their situation. Criteria for suitability of the devices to candidates will also be discussed here. Henceforth, the consideration of a patient's case will be denoted as a "scenario."

The technique and any alternative forms of gallstone lithotripsy may be considered relatively unsafe with the B-mode procedure. There are also numerous storage and other cautions with this equipment. The initial identification of a gallbladder pathology. Gallstone visualization with non-invasive transabdominal ultrasonography may allow recognition of the optimal candidate for B-mode lithotripsy. The look would probe thoughts. The ongoing consideration/precaution of using metallic devices on trauma patients would ideally be a patient consideration that may precede the need for its use. Sonography to regulate the B-mode permits fluid presence to enhance sonication to identify potential deflections away from the suction source [16].

The term gallstone lithotripsy and its variants have now been applied to the fracturing of cholelithiasis, in contradistinction to its long-eponym percutaneous biliary lithotripsy, a cannula-based approach involving various physical/electromechanical fracturing means since its inception in the 1970s. Use continues in several recent articles regarding more recent treatment devices. High safety with this medically-established procedure. There are a spectrum of safe clinical scenarios around which to personalise the biliary care. Patient preparation was safe and effective. [17].

3.1. Patient Selection Criteria

Gallstone lithotripsy utilizes different energy types to pulverize the relatively soft concretions composed of biomaterials. It is a non-invasive treatment for cholelithiasis that forms in the gallbladder or in common bile duct. This treatment option is advantageous since the decreased number of surgeries should increase the quality of healthcare services and reduce expenses with cholelithiasis treatments. However, several factors affect the pulverization and removing efficiency of the gallstones during lithotripsy. These factors concern the gallstones, the type of lithotripsy and the person being treated. Since detailed image of the gallstones (size, location, acoustic impedance, etc.) implanted in the gallbladder of the same suffering person is not available until the lithotripsy begins, the physician cannot predict the efficiency of any planned

lithotripsy procedure.

Physician must decide whether a patient is a candidate for gallstone lithotripsy. The same modern and comprehensive medical evaluations should be applied to the patient as similar procedures are necessary before major surgery on the gallbladder. Prior to the procedure patient medical-history evaluations must include medical history of biliary disease (cholecystitis, pancreatitis, cholangitis, etc.), number of previous acute attacks, jaundice and its duration, prior surgical procedures related to the stomach, abnormal blood tests (creatinine, persistent S-GOT levels, persistently high leukocyte count, platelet count), right upper quadrant abdominal pain, elevated liver function tests, presence of acute or chronic biliary pancreatitis (bile duct obstruction), and biliary dyskinesia. In this stage doctors' decisions are more complex than in other lithotripsy methods. A recent study using various predictors such as demographic, biliary disease and gallstone related parameters was conducted [18]. In the selection of patients to be treated success with a higher probability it has been achieved to determine the cut-off values of the predictors as the result of the statistical analysis of the clinical dataset described above. Even robust recommendations failed, there are contraindications for performing the lithotripsy. Therefore, patients who do not pass must be treated in the surgical or nonsurgical methods, such as the laparoscopic cholecystectomy and percutaneous cholecystolithotomy by an interdisciplinary team.

3.2. Effectiveness and Success Rates

Most gallstones can be effectively treated by nonsurgical techniques. A large variety of medical devices have been used, including mechanical, electrohydraulic, piezoelectric shockwave, extracorporeal shockwave, and laser devices. These devices are either inserted into the common bile duct or placed in contact with the stones during endoscopic or percutaneous surgery. Each device has unique features and advantages, and knowing them will help with decision making. The mechanisms of gallstone destruction caused by these devices are different, as well. This article provides an overview of the medical devices used in gallstone lithotripsy and their clinical applications.

There are several effectiveness and success rate-related issues in the literature to date, including the effectiveness and success rates of a treatment session; the cumulative probability of becoming permanently stone free; the time interval after treatment between imaging studies and the definition of success; and the follow-up interval after the treatment. As for the effectiveness and success rates of the treatment sessions, different lithotripsy techniques were found to be successful in 75-100% of the treatment session (completed stone clearance or fragmentation), but a second session was sometimes necessary. Other studies reported success rates lower than this, because the devices were only reported to have satisfactorily crushed or fragmented the stones, not completely cleared them (≈ 100% of stone burden cleared) [19].

Discussion

4. Current Challenges and Future Directions

As the most widely adopted methods for gallstone lithotripsy and dissolution, extracorporeal shock wave lithotripsy (ESWL) and oral bile acid therapy are becoming quite mature and have been applied globally for nearly 40 years. Despite this, practical treatment outcomes are far from satisfactory. In addition to the inherent uncertainty of the physicality of shock wave transportation, some technological limitations of extracorporeal lithotripters are also observed worldwide [20]. The emerging novel flexible ureteroscopic technology with fiber and pulsed laser equipment penetrates the well-established scheme of ESWL treatment and promotes the simultaneous diversification of stone removal strategies. Due to the lack of standardized treatment protocols and the variability in existing clinical practice methods, experienced ESWL treatmentists still play a significant role since they tend to accurately predict the outcome and manage the variables during intervention [21]. Accordingly, the provision of a more objective

and comprehensive pre-treatment evaluation is imperative. Endoscopic techniques to remove bladder stones have transformed from manually performed lateral lithotomies to endoscopic removal. Modern technology is exploring intelligent contact and non-contact methods for improved stone visualization and accurate incision. Portable ultrasound and x-ray scanners, and development of the Hounsfield radiodensity scale of densitometry, now deliver excellent images, localize stones, evaluate composition, and monitor success. On-board real-time image guidance using x-ray or ultrasound is now standard in the OR, allowing accurate instrument navigation for incisionless surgeries. Further development of scopes blades, when touching the stone, may measure the force of contact, triggering release of a laser pulse to fragment it, or include robotic control for incisions. Online analysis will aid improvement in discrimination of stones from tissue, reduce injury, and allow for incorporation of multiple pulse strategies. Integration with mobile, lightweight robotic technology could then be applied in the emergency department, or forward deployed clinics. Machine learning methods have proven useful in identifying stones, and offer prediction models of success. Decisions can be quickly re-calculated, and this will optimize efficacy and reduce the number of access tracts. [2][9][22]

5. Conclusion

The development in technology of medical devices for lithotripsy has a significant impact on the clinical results of diseases caused by calculi, especially in the case of bile duct calculi. In recent years, there has been a rapid increase in the number of medical devices used in lithotripsy, and it is important for clinicians to use effective techniques and devices. Gallstones are one of the common diseases of the digestive system, and its causes are related to heredity, metabolism, diet, lifestyle, and obesity. Various devices and techniques have been applied for the treatment of choledocholithiasis, which causes obstructive jaundice. Bile duct stones are formed from cholesterol, bile pigment, and calcium salt, and the treatment method of bile duct stones is to remove the stones. An optimal treatment strategy should be established that considers the disease conditions, the presence or absence of complications, and the patient's general status [21].

Lithotripsy is a technique for treating or crushing a stone within the body using sound, laser, shock wave, or water pressure. In the case of gallstone lithotripsy, it is common to perform ESWL, percutaneous transhepatic cholangioscopic lithotripsy, endoscopic sphincterotomy and electrolithotripsy, CBD stone extraction using extracorporeal shock waves, mechanical and laser lithotripters, and extracorporeal shock waves Electrolitotripsy and ISS have excellent results and minimal complications. There is progress in accounts. Endoscopic therapy is less invasive and suitable for elderly patients or patients with complications than previous EST. ERCP and PTCD are the most aggressive procedures and should be chosen for lithotripsy according to the patient's condition. After lithotripsy, balloon dilation is effective for bile duct normal duct distal stricture.

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