Extracorporeal shock wave lithotripsy in impacted upper ureteral stones

Thesis

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TABLE OF CONTENTS

Acknowledgement ……………………………………………………......2

Abstract ………………………………………………………………......6

Chapter 1:

Extracorporeal Shock Wave Lithotripsy: Overview of technology ……..7

Chapter 2:

Pathological consequences of impacted upper ureteral calculi ……......21

Chapter 3:

Management of Impacted Upper Ureteral Calculi ……………………..24

Chapter 4:

Pre-ESWL ureteric stenting ……………………………………....39

Chapter 5:

Patients and Methods ……………………………………………..45

Chapter 6:

Results ………………………………………………………………51

Case presentation …………………………………………………….61

Chapter 7:

Discussion ……………………………………………………………65

Summary and conclusion …………………………………………....75

References …………………………………………………………77

Arabic Summary …………………………………………………...87

List of Figures

No.	Figure	Page
1	Electro hydraulic shock wave generation.	10
2	Piezoelectric shock wave generation.	11
3a.	Electromagnetic shockwave generator with acoustic lens.	12
3b.	Electromagnetic shockwave generator with focusing reflector.	12
4	Incoming shock waves result in fragmentation from erosion and shattering.	19
5	Effect of a Shockwave passing through the body of a stone.	19
6	Sex distribution among the study sample.	52
7	Histogram for age distribution among the study sample.	53
8	Side distribution among the study sample.	53
9	Distribution of stone recurrence among the study sample.	54
10	Distribution of previous urologic surgery among the study sample.	54
11	Distribution of stone length among the study sample.	56
12	Distribution of stone width among the study sample.	56

List of Tables

No.	Table	Page
1	Characteristics in stented and nonstented patients.	55
2	Impact of stone size on ESWL.	57
3	Number of sessions in each group.	58
4	Treatment results in stented and nonstented groups.	59
5	Post-ESWL discomfort and morbidity.	61

Abstract

Introduction

ESWL has been demonstrated to be an effective, noninvasive, convenient and easy way in treatment of ureteric stones at all levels. However, ESWL in impacted ureteral stones is a challenge as they are considered to respond poorly to ESWL than stones lying in the renal pelvis. It was recommended to fix pre-ESWL ureteric stent for better fragmentation of the stone and to relieve the obstruction. However, insertion of a JJ stent is a more invasive procedure requiring anesthesia and it is associated with some discomfort and morbidity.

Aim of the work

Our prospective study was conducted between June 2007 and June 2008 to assess the efficacy of ESWL in management of impacted upper ureteral stones 2cm or less and to verify whether pre-ESWL ureteric stenting would affect the results.

Patients and Methods

Sixty patients with solitary, radio-opaque impacted upper ureteral stones 2cm or less were divided into 2 equal groups, stented group(Group 1) with a JJ stent fixed pre-ESWL and nonstented group (Group 2) who were treated by in situ ESWL. All patients were treated by ESWL using Dornier Do Li S lithotripter. Pretreatment KUB and IVP and post treatment KUB were used to follow up the clearance of fragments.

Results

At 3 months, overall stone free rate was 88.3%. There was no significant statistical difference in stone free rate between the 2 groups being 90% and 86.7% in the 2 groups respectively (p=0.688). One session was required in 28.3% of patients, while, multiple sessions were required in 71.7% of patients. There was no significant statistical difference in re-treatment rate, loin pain or fever in the 2 groups. However, patients in the stented group significantly complained of side effects attributable to the stent including: dysuria, urgency, frequency of micturition, suprapubic pain, haematuria, pyuria and positive urine culture.

Conclusion

ESWL is an effective and reasonable initial therapy in management of impacted upper ureteral stones 2cm or less. Pre-ESWL ureteric stenting provides no additional benefit over in situ ESWL in management of impacted upper ureteral stones 2cm or less. Moreover, ureteral stents are associated with significant patient's discomfort and morbidities.

Key Words : Extracorporeal shock **-** Pre-ESWL ureteric stenting .

CHAPTER ONE

EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY

OVERVIEW OF TECHNOLOGY

HISTORICAL ASPECTS:

The first commercially available lithotripter was produced by German aerospace firm Dornier (1). Dornier laboratories in Germany found that, during high-speed flight, shock waves generated by collision with raindrops caused pitting on the metal surfaces of supersonic aircraft. During 1966 a test engineer accidentally touched a target body at the moment of impact of a high-velocity projectile and felt something like an electrical shock. No damage from the shock waves could be demonstrated. Further studies in animals in 1971 showed that only the lungs sustained damage from experimental shock waves (2).

During 1974 an agreement was reached that research on the lithotripter would be conducted by the Institute for Surgical Research and clinical trials by the urology department at the university of Munich. Experimental animal studies and machine development were done by Chaussy, Brendel, Eisenberger, and Forssmann (3).

Dornier embarked on a program at the Klinikum Grobharden Hospital in Munich to develop a system for the production of reproducible focused shock waves. Once focused shock waves were being created by using an underwater spark discharge, the idea was germinated to apply the concept to human kidney stones. (1).

During the middle and late 1970s, an intensive research program by Ferdinand Eisenberger and then by Christian Chaussy showed that focused shock waves sufficient for stone fragmentation could be created and that these shock waves could be passed through biologic systems. Using an experimental lithotripter, dogs implanted with human kidney stones were treated successfully (3).

Following the successful completion of animal testing, the first patient was treated with Extracorporeal Shock Wave Lithotripsy (ESWL) in a prototype termed human model (HM-1) lithotripter on February 20,1980. With the patient and the generator both placed in a water bath filled with gasless water, shock waves were emitted from the generator, transmitted within the water bath to the skin surface and through tissues to reach the stone. Patient had to be removed from the water bath to change the electrode. Initially, only one or two patients were treated per month under very restricted indications (i.e., small, non- obstructive and renal pelvic stones). Initial results were encouraging, and therefore a more extensive clinical trial was undertaken using another prototype (HM2) lithotripter. The HM2 was much simpler as the electrode could be changed without removing the patient from the water bath. Although treatment indication still remained limited, the success of the HM2 lithotripter was impressive (stone-free rates approached 90%) (4).

Following minor modification of the HM2 device, Dornier introduced its first commercially produced lithotripter, the HM3 in 1984 launching a historic revolution in the management of urolithiasis patients. It is the most effective lithotripter and it has become the criterion standard to which other devices are compared. Localization was achieved with simultaneous fluoroscopy. (1, **5**).

The original Dornier HM3 lithotripter used two x-ray converters arranged at oblique angles to the patient and 90 degrees from each other to localize the stone effectively. To reduce the cost of lithotripters, an adjustable C-arm has been subsequently introduced on many devices. Several lithotripsy systems also have shown that ultrasound is capable of providing satisfactory imaging to treat many (but not all) upper urinary tract calculi. Now many lithotripters are combining ultrasonography and fluoroscopy for stone localization (1).

The remarkable success of Dornier's HM3 lithotripter quickly stimulated other approaches to the concept of extra corporeally generated shock waves for kidney stone lithotripsy. Shock waves have been generated successfully using piezoelectric crystals, electromagnetic membranes, focused lasers, and even micro explosions using lead-azide pellets (6, 7, and 8).

ESWL; Development and Instrumentation:

Shock wave lithotripters must carry out four steps in order to destroy calculi satisfactorily:

1- Generation of a high energy shock wave.
2- Accurate focusing of that shock wave on the specific target.
3- Coupling of the shock wave from its point of generation to its point of impact with minimal attenuation.
4- Accurate positioning of the target directly over the focus of the wave (10).

The first commercially available lithotripter (first generation) was the Dornier HM3 which was marketed in 1984. It accomplished successful lithotripsy by generation of high-energy shock wave from a spark gap electrode, focusing the wave with ellipsoid and biplanar fluoroscopy, coupling the wave from the electrode to the stone via deionized and degassed water in a tube, and positioning the patient with a hydraulically movable gantry. The release of the electrocardiogram-triggered shock wave, stone localization, and gantry movement are all controlled via a central unit (10).

Shortly after the introduction of the HM3, second-generation lithotripters were developed with new energy sources such as piezoelectric (1986) and electromagnetic (1987) energy sources e.g. the modified HM3, Siemens Lithostar, Wolf Piezlith 2300, Direx Tripter X-1, Breakstne, and Dornier HM4 lithotripters which have been designed to have greater portability. These systems can provide dual imaging systems (e.g. fluoroscopy and ultrasonography) and power adjustment to vary the intensity of shockwave according to stone consistency, progression of fragmentation, and patient compliance during the treatment. As a second-generation lithotripter, Dornier HM4 lithotripter had a low-pressure generator and a relatively smaller focal point (7,8, and 9).

The Dornier HM3 permanently altered the management of urinary stones disease and placed it in the domain of endourology. When comparing Dornier HM3 device with second generation shock wave lithotripters, we find that newer lithotripters are less efficacious and of a higher cost. However, second generation shock wave lithotripters produce fewer adverse effects, better patient compliance and avoid anesthesia.

SHOCK-WAVE SOURCE:

There are several types of shock-wave generators available today, and lithotripters often are categorized on the basis of their energy source. The three forms of energy source used most frequently are electrohydraulic, piezoelectric, and electromagnetic sources. Another potential source is the microexplosive energy, but there is no commercially available lithotripter using this type of generator. Electrohydraulic and microexplosive generators often are referred to as point-source generators. Point source generators create shock waves that diverge from the source (Fl focal point) and are reflected subsequently and concentrated at a distant target (F2 focal point). In contrast to point-source generators, electromagnetic and piezoelectric generators are extended source generators that create a shock wave directly focused to a treatment point (Fl focal point) (11).

Electrohydraulic lithotripters were among the first lithotripters available clinically in 1984 (6). This energy source relies upon an underwater spark-gap electrode to generate shock waves. A high-voltage discharge from the electrode vaporizes water at the Fl focal point, and this sudden gaseous expansion generates a shock wave that diverges from the point of origin until it hits an ellipsoid or parabolic reflector. The shock waves then are reflected and redirected to a second focal point (F2) the point at which the stone is situated (Fig. 1) (11).

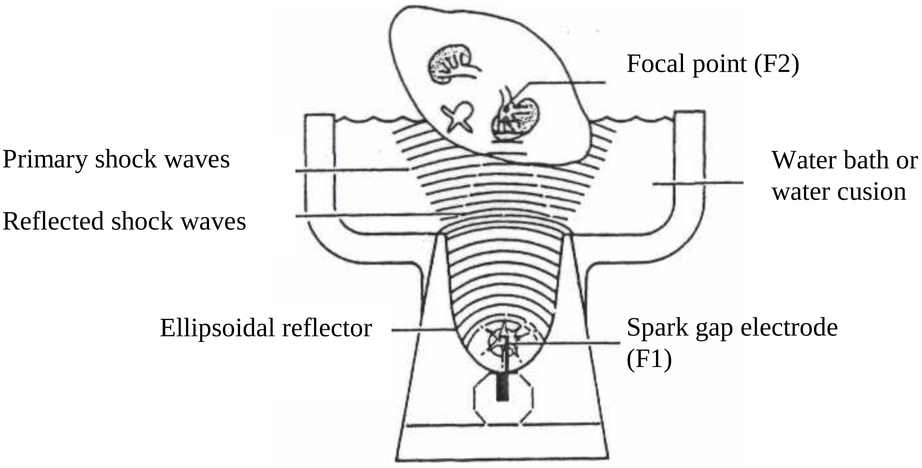

Fig.1, Electro hydraulic shock wave generation (from ZhongP, Preminger GM : Differing mode of shock wave generation. Semin Urol 1994; 12: 2.).

The next energy source developed was the **piezoelectric generator** in 1986. In that system, numerous piezoelectric crystals line a hemispheric dish. If a high-voltage current is applied to the dish, the piezoelectric crystals expand simultaneously, thereby generating a shock wave. The dish that houses the piezoelectric crystals is shaped in a fashion that permits the projection of the shock waves to converge at a focal point at which a calculus is targeted (Fig. 2) (11).

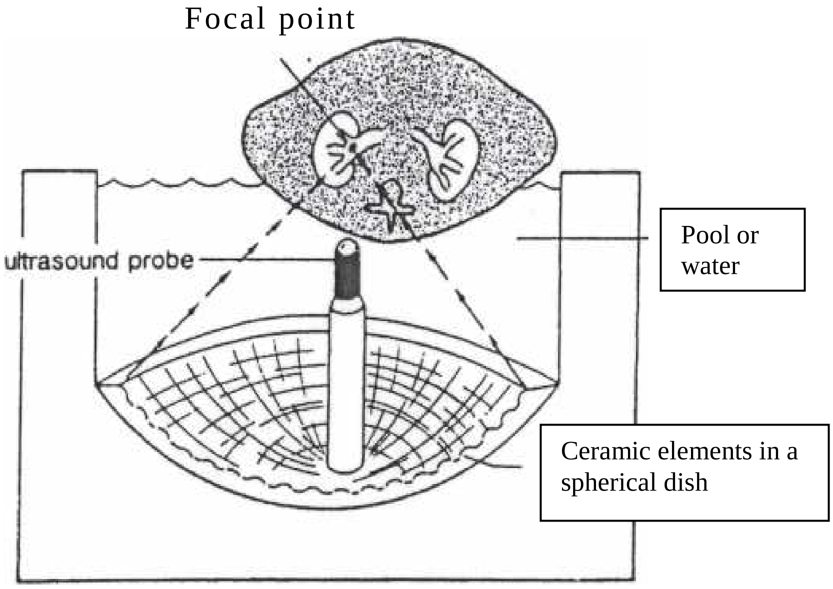

Fig.2, Piezoelectric shock wave generation (From Zhong P, Preminger GM: Differing mode of shock wave generation . Semin Urol 1994;12:2.)

The electromagnetic generator was first reported by *Wilbert et al.* in 1987 These lithotripters use a water-filled shock tube, inside which there is a metallic membrane backed by a magnetic coil (Fig. 3a + 3b). If high-voltage current is applied to the coil, the resultant charge on the coil repels the oppositely charged metallic membrane, and this magnetic repulsion generates a shock wave. The shock wave then is focused with an acoustic lens or parabolic reflector to the focal point for treatment of the targeted calculus (11).

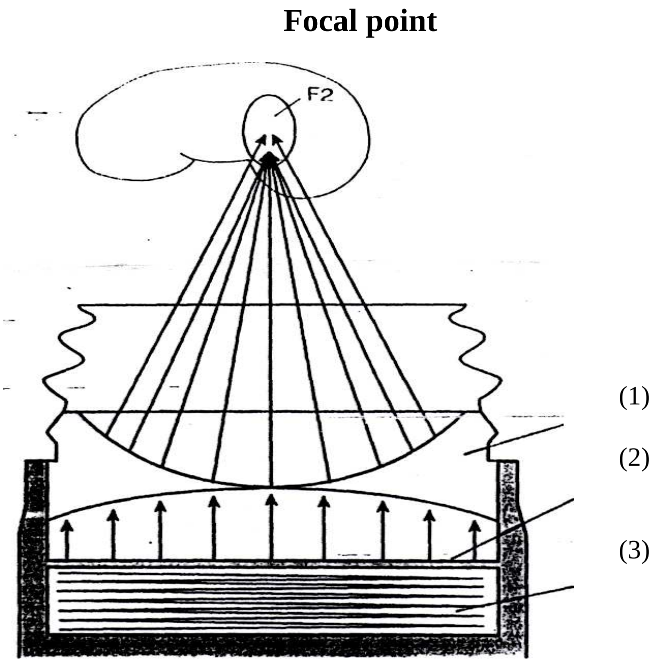

Fig: 3a, shows the electromagnetic shockwave generator with acoustic lens. (1) Acoustic lens, (2) membrane, (3) Electromagnetic coil.

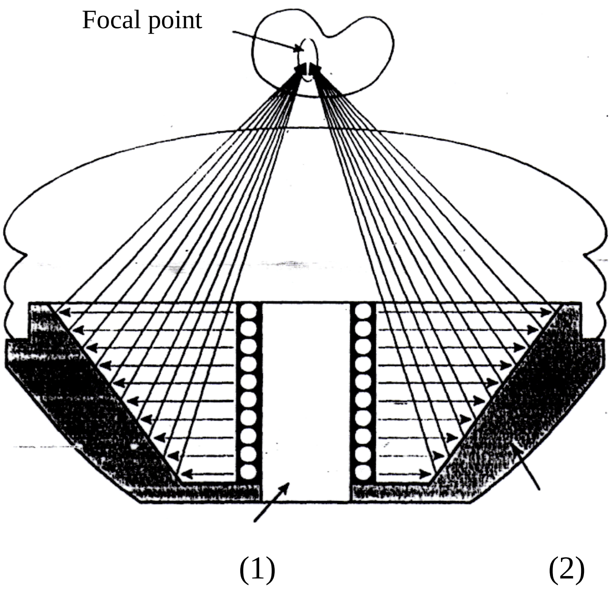

Fig: 3b, shows the electromagnetic shockwave generator with focusing reflector. (1) electromagnetic coil, (2) reflector.

Microexplosive generators represent a technology that has not gained mainstream acceptance. This energy source was first described by Kuwahara, et al in 1986. (6). The explosion of tiny lead-azide pellets within a parabolic reflector generates chock waves. Though effective in generating shock waves, this technology has not met with commercial success because of concerns regarding the storage and handling of the volatile lead-azide pellets (11).

Shock-Wave Focusing:

Shock-wave focusing relies on various means to direct and concentrate shock-wave energy to a defined focal point, and different energy sources rely on very different methods to achieve this. All of these methods, however, rely on some form of lens or reflector to alter direction of the shock waves. The most important attributes of given focusing device are aperture and focal zone.

The shock-wave aperture is the area of the acoustic lens, shock tube, or reflector and roughly corresponds to the body-surface area of the skin penetrated by the shock waves. Lithotripters with wide aperture, such as piezoelectric lithotripters, tends to have low energy density at the skin-entry point of the shock waves, because the same pressure is distributed over a wider area (7,12). This is why patients treated with these devices experience less pain.

The focal zone is the actual volume in which the shock waves are concentrated. Larger focal zones generally have more shock wave energy and higher peak pressures (1,12). Higher peak pressure means more effective stone fragmentation; however, larger focal zones also result in more shock wave energy being delivered to surrounding body tissues (11).

Shock-wave Coupling:

Shock-wave coupling refers to the medium through which the shock wave is propagated. A coupling system is needed to transmit the energy created by the shockwave generator and pressure wave to the skin surface and through body tissues to reach the stone. Ideally, this medium should dissipate shock-wave energy as little as possible. A water bath filled with gasless water served as the coupling mechanism in the first-generation lithotripters.

Subsequently, membranes of appropriate acoustic density were developed that obviate the need for a water bath. Instead, water cushions coated with an acoustic gel are substituted. These "dry" lithotripters may deliver less shock-wave energy to the target, but they make up for this in ease of patient positioning, including the ability to treat in the prone position e.g. mid ureteral stones (10).

Localization systems:

Imaging is employed to localize the stone and direct the shockwaves onto the calculus. The 2 methods commonly used to localize stones are fluoroscopy and ultrasonography.

In-line fluoroscopy allows continuous adjustments during a treatment session to pinpoint shockwave placement onto the stone . Advantages of fluoroscopy also include identification of both renal and ureteral calculi and tracking of migrating fragments in the ureter. The main disadvantages include exposure to ionizing radiation and failure to visualize radiolucent or minimally radio-opaque stones unless contrast is administered. Alternative methods to visualize these stones include the administration of intravenous iodine-based contrast during treatment or doing retrograde ureteropyelogram through a ureteral catheter inserted before the procedure by direct injection of contrast into the collecting system.

Ultrasound localization allows the visualization of both radio-opaque and radiolucent renal stones in the absence of fluoroscopy (without intravenous contrast administration) and the real-time monitoring of lithotripsy. Most second-generation lithotripters can employ this imaging modality. Advantages of ultrasound also include avoiding exposure to ionizing radiation and the costs are much lower than radiographic systems. Disadvantages include difficult localization of ureteral calculi with ultrasound alone because of interposed air-filled intestinal loops and smaller stones may be particularly hard to be identified. In addition, urologists are often more familiar with fluoroscopic localization than with ultrasound localization (11).

Comparison of Lithotripters

In general, the differences among the various models of lithotripters available today are based primarily on the form of energy source employed.

Electrohydraulic lithotripters have the advantage of large focal points, moderately high peak pressures, and flexible apertures (13). The disadvantages of the electrohydraulic energy source include a relatively short functional lifespan and the relatively inconsistent reproducibility of the shock waves. This lack of shock-wave consistency results from the variable current pathway from the positive to negative tips of the electrode. As the electrode suffers wear, the distance between the positive and negative tips increases. Because of the geometry of the ellipsoid reflector, even small changes in this distance can translate into large differences in the width of the focal zone at F2. Therefore frequent electrode changes are often necessary (11).

Piezoelectric lithotripters have the advantages of having a long functional lifespan, less patient discomfort, and allowing for variable shock-wave frequencies. The minimal pain experienced by patients is due to the fact that piezoelectric lithotripters have the widest apertures. But, this characteristic also results in relatively small focal zones and the actual energy density delivered is relatively low as a result of that, in spite of delivering fairly high-pressure pulses to the focal zone. However, a smaller focal zone also leaves a smaller margin of error for targeting a given calculus causing limitation of fragmentation. Another disadvantage of piezoelectric generators is that they have a limited energy range. Despite of this disadvantage they are still preferred by some centers as they offer a more comfortable patient experience (11).

Electromagnetic lithotripters differ from electrohydraulic lithotripters by the fact that they have long functional lives. They can deliver several hundred thousand shock waves between servicing, thereby obviating the need to replace electrodes continually. Also, they have a wide and continuous gradation of energy settings. The disadvantages of these machines; however, include the necessity to change the metallic membrane, although not often (10).