Fragmentation Devices and Principles of Shockwave Therapy

KS Ngoo
Hospital Angkatan Tentera Tuanku Mizan, Kuala Lumpur

Advanced Urology Course
Hospital Selayang-Malaysian Urological Association Building
23 March 2014
Introduction

• Shockwave Urinary Stone therapy (Extra-corporeal Shockwave Lithotripsy, ESWL)
  – Dornier HM-3 still has the best efficacy for stone fragmentation

• Outline of presentation
  A) Shockwave Lithotripsy (SWL) Principles
    – Physics of acoustic wave and shockwave
    – Shockwave lithotripsy: Mechanism
    – Components of Extracorporeal-SWL
    – Bioeffects of SWL
  B) Intracorporeal Fragmentation Devices
    – Components and Mechanism of Action
    – Utility and Limitations
Principles of Shockwave Therapy
- Physics of Acoustic Wave -

• Sound waves (audible): 50 to 20,000 Hz

• ULTRAsound waves: 30,000 to 1 Mega Hz

• A wave...
  – carries vibrations through a medium (solid/liquid/gas)
  – is created whenever an object moves within a fluid, i.e. gas or liquid.
    • Compression of molecules adjacent to it, and compression is transmitted to further adjacent molecules, so on and so forth
  – has measurable speed
    • Depends on characteristics and temperature of medium
  – has wavelength and frequency
The Shock Wave (1)

• Characteristics
  – Non-sinusoidal
  – High energy, high amplitude wave
  – Extremely short build-up time
  – Short duration (5μs)
  – Two phases
  – Near instantaneous leap to PEAK POSITIVE PRESSURE: the SHOCK (compressive phase)
  – Near instant drop to zero and below with a PEAK NEGATIVE PRESSURE (tensile phase)
The Shock Wave (2)

• When a shockwave (SW) encounters a medium...
  – part will continue through (transmitted wave)
  – part will be reflected (reflected wave)
• Acoustic impedance provided by a medium
  – depends on its density and sound speed of medium
• Transmission of SW
  • From water to tissue...efficiency 99%
  • From water to stone...75-95%
  • From water to air...99.9% energy is REFLECTED
• Application:
  – SW generators in lithotripsy are water filled
    • Both patient and generator in water (classical)
    • Waterpads directly applied to patient (modern)
Stone Fragmentation by SW (1)

- SW focused on stone to minimise surrounding tissue damage
- Acoustic pressure highest at one point (focus=stone) with surrounding area of high amplitude
  - The focus and the area form the FOCAL CORE
  - Ellipsoid in shape (from 0 to tens of millimetres)
  - Power of lithotripter depends on
    - Volume of focus (stone)
    - Peak Pressure at the focus (stone)
    - High energy delivered by spark-gap lithotripters for high Focal Point and high Peak Pressure target
Figure 11 Spark-gap lithotripter. A spark, generated at F1, causes a hydrodynamic pressure wave that is focused at a set distance to the target area (F2) by an ellipsoid reflector.
Stone Fragmentation by SW (2)

- **Compression phase of SW**
  - Positive pressure reflected at stone surface
  - As compressive wave travels through stone
    - **Erosion ('spallation')** occurs at entry and exit points
      - Due to cavitational forces
    - **Shattering** occurs
      - Shear stress on stone due to shear and compressive waves
    - **Superfocusing**: amplification of stresses inside stone (by refraction or diffraction of waves)
    - **Squeezing**: differing sound speeds of waves travel between stone and surrounding fluid, producing tensile stress and stone breakage
Stone Fragmentation by SW (3)

- **During negative pressure phase** of SW
  - **Cavitation** takes place
    - Rapid expansion of gas bubbles in liquid medium at stone surface
    - Occurs when negative pressure > ambient pressure in a liquid, which fails under stress
    - Unstable bubbles collapse, forming microjets that strike stone surface (microjet velocity: 130-170 m/s)

- **Dynamic fracture process**
  - Cumulative damage induced by SW (throughout)
  - Nucleation, growth and coalescence of flaws within stone
Stone Fragmentation by SW
Components of SW Lithotripsy (1)

• A lithotripsy device requires...
  – An energy source
  – A focusing mechanism for SW
  – A coupling medium
  – Stone localisation system

• Energy Source: Modes of SW generation include
  – Electrohydraulic
  – Electromagnetic
  – Piezoelectric
Modes of SW Generation (1)

• The Electrohydraulic (EH) mode:
  – High voltage current applied across 2 electrodes (1mm apart), under water ➔ sparks discharged
  – Water around tip of electrode vaporised ➔ rapidly expanding gas bubble
  – Rapid expansion and collapse of bubble ➔ SW
  – SW is focused by a metal reflector (hemi-ellipsoid)
  – Eg. Dornier HM-3 Lithotriptor
Electrohydraulic SW Generator

Diagram of patient positioning for ESWL

KS Ngoo

Advanced Urology Course 2014 – Radiology and Technology in Urology
Modes of SW Generation (2)

- The Electromagnetic (EM) mode:
  - Two electrically conducting cylindrical plates, separated by a thin membrane of insulator, or a coil
  - Current passes through plates $\rightarrow$ strong EM field in between and subsequent plate movements $\rightarrow$ SW; or
  - Strong EM field through coil $\rightarrow$ reflects and thrusts a metallic disc upward to strike a metallic plate $\rightarrow$ SW
  - An acoustic lens or a parabolic reflector is used to focus SW
Electromagnetic SW Generator

**Figure 12**: Electromagnetic lithotripter. Application of an electric current to the coil results in a strong magnetic field that repels a metallic disk upward to strike a fixed metal plate. Shock waves are focused by an acoustic lens or parabolic reflector.

**Figure 48-16**: Schematic view of an electromagnetic shockwave generator that uses a parabolic reflector to focus the shockwave. An electromagnetic coil is used to generate the shockwave.
Modes of SW Generation (3)

• Piezoelectric modality:
  – A spherical dish with about 3000 pieces of small ceramic elements
  – Ceramic elements rapidly expand with high Voltage current applied across them
  – Rapid expansion of elements $\rightarrow$ SW
  – Focusing mechanism enables very high Peak Pressure at F2 as well as other small focal points
  – Safe for use in patients with pacemakers
Piezoelectric-based SW Generator

Figure 13 Piezoceramic lithotripter. Application of an electric current to piezoceramic crystals causes a sudden conformational change, resulting in the generation of an acoustic shock wave.
Components of SW Lithotripsy (2)

• Coupling medium
  – SW is coupled to the body using water
    • Interfaces between gas and tissue can cause tissue damage
      – Hair and bandages may entrap unwanted gas bubbles
    • Coupled directly, by Open water bath (Dornier HM-3) with patient immersed
      – Caution: submersion ➔ profound haemodynamic change to patient
      – Peripheral venous compression, raised right atrial pressure, increased pulmonary capillary wedge pressure, and increased cardiac index
    • Or indirectly, through water filled SW generator head, mounted in ‘therapy head’.
      – Less water demand
      – Thin membrane jelly pressed against patient with a coupling jelly or oil to reduce air
      – Less efficient in stone clearance
Components of SW Lithotripsy (3)

• **Focusing mechanism**
  – EHL: metal reflector (hemi-ellipsoid)
  – EM: acoustic lens or parabolic reflector
  – Piezoelectric: concave arrangement of ceramic in a sphere

• **Stone localisation system**
  – X-ray/Fluoroscopy *versus* US
    • US can be in-line, or off-line, with therapy head
    • US provides real-time monitoring, no radiation, inexpensive
    • BUT, US is poor at locating mid- and upper- ureteric stones, or if there is indwelling catheter; needs highly trained operator
    • X-ray advantages: familiarity, iodinated contrast to aid visualisation of stone, displays anatomic detail
    • BUT, X-ray high maintenance, radiation involved, radiolucent stones
Bioeffects of SWL (1)

• Acute EXTRA-RENAL Injury
  – Non-cardiac: liver and skeletal muscle
  – Measurable damage: bilirubin, LDH, CPK in ↑ 24hrs, subsides 3-7 days of Rx, normalises 3mths
  – Cardiac arrhythmias: ungated is safe

• Acute RENAL Injury
  – Virtually all SWL: 200 SWs leads to hematuria
  – Structural damage
  – Functional damage: 2000 SW (24kV) SW delivered at 2Hz causes 5-6% loss of functional renal volume
  – Mod to severe injury manifested has hematoma (1-20%)
Renal Injury from SWL

**Renal Side Effects of Shockwave Lithotripsy in Experimental Animal Models (Canine and Porcine)**

- **Acute Histologic Changes**
  - Venous thrombi
  - Cellular disruption and necrosis
  - Mild tubular necrosis (ischemic changes)
  - Intraparenchymal hemorrhage
  - Tubular dilation and cast formation
  - Damage and rupture of veins and small arteries
  - Rupture of glomerular and peritubular capillaries

- **Chronic Histologic Changes**
  - Nephron loss
  - Dilated veins
  - Streaky fibrosis
  - Diffuse interstitial fibrosis
  - Calcium and hemosiderin deposits
  - Hyalinized and acellular scars from cortex to medulla

**Acute Renal Side Effects: Risk Factors for Shockwave Lithotripsy**

- Age
- Obesity
- Coagulopathies
- Thrombocytopenia
- Diabetes mellitus
- Coronary heart disease
- Preexisting hypertension

**Reversible and Irreversible Injury**

- **Reversible Changes**
  - Mild tubular necrosis
  - Casts and red blood cells in tubular lumen
  - Vascular changes of tubular lumen
  - Mild interstitial edema and hemorrhage

- **Irreversible Changes Resulting in Loss of Renal Tissue**
  - Disruption of nephrons
  - Extensive interstitial edema
  - Large hematomas of cortex and medulla
  - Rupture and occlusion of veins and arteries
  - Fracture of glomerular and peritubular capillaries
Bioeffects of SWL (2)

• Chronic RENAL Injury
  – Hemorrhage $\rightarrow$ Inflammation $\rightarrow$ scar formation
  – Parenchymal fibrosis $\rightarrow$ 1 mth after SWL
  – Injuries:
    • Accelerated rise in BP
    • Reduced renal function
      – $\downarrow$renal plasma flow 17-21 mths post ESWL
    • Increased rate of stone formation
      – Debris and gravity $\rightarrow$ nidus for new stone formation
    • Induction of brushite stone formation
Optimising SWL Performance

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acoustic Output &amp; Focal Volume</td>
<td>-Influences Peak Pressure and Acoustic Field</td>
</tr>
<tr>
<td></td>
<td>-Focal Zone: wide</td>
</tr>
<tr>
<td>Optimal Coupling</td>
<td>-Best couping is direct with water</td>
</tr>
<tr>
<td></td>
<td>-Coupling gel, changing patient’s position: traps air bubbles</td>
</tr>
<tr>
<td>No. of SW administered</td>
<td>-60 SW/min more effective than 120 SW/min</td>
</tr>
<tr>
<td></td>
<td>-Cavitation and dynamic bubbles theory</td>
</tr>
<tr>
<td></td>
<td>-Less vasculature injury</td>
</tr>
<tr>
<td>Rate of SW delivered</td>
<td>-Low power pretreatment</td>
</tr>
<tr>
<td></td>
<td>-Slowly ramping up to standard energy levels</td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>-Gen Anaesthesia stabilises stone location at F2</td>
</tr>
<tr>
<td></td>
<td>-better stone clearance outcome</td>
</tr>
</tbody>
</table>
Intracorporeal Device for Stone Fragmentation

• Various modalities available
  – Electrohydraulic Lithotripsy (EHL)
  – Pneumatic (Ballistic)/Mechanical/Kinetic
  – Ultrasonic Lithotripsy
  – Laser Lithotripsy
Electrohydraulic Lithotripter

• Similar to ESWL; first modality developed for intracorporal lithotripsy
• High Voltage current applied across concentric electrode (under water) $\Rightarrow$ spark
• Water is vapourised
• Expansion and collapse of gas bubble $\Rightarrow$ SW
• SW generated is not focused
• EHL probe should be
  – Applied within 1mm distance of stone target
  – Kept as far away as possible from mucosal wall of urinary tract (15% risk of ureteric perforation)
  – Be placed $\geq$ 2mm away from for endouroscope (lens fracture risk)
• Utility: Bladder stone (narrow safety margin in ureter)
Pneumatic (Ballistic)/Mechanical Lithotripter

• Concept of mechanical (kinetic) energy transference
  • A metal projectile inside a handpiece is propelled forwards/backwards at high speeds by bursts of compressed air
  • The projectile strikes a long thin metallic probe at one end of handpiece (12 Hz), transmitting SW to the probe → fragment stones
• Low cost, low maintenance, low morbidity
  – Tip of probe excursion ~1mm
  – Tip bounces off pliable wall of ureter
• But it causes stone/fragment to migrate proximally, metal probe cannot bend around corners
• Utility: ureteric stones ± renal stones
Mechanical Lithotripter Prototype

Figure 15 Mechanical lithotripsy. A compressed-air jet propels the metal projectile to strike the base of the probe (pneumatic lithotripsy). An electromagnetic field may be substituted for compressed air (electrokinetic lithotripsy).
Ultrasonic Lithotripsy

• Current applied across piezoceramic plate, located in US transducer → US waves (23000-25000 Hz)
• US energy → hollow metal probe (moving transversely and longitudinally (20 μm displacements) → stone
• Stone resonates, fragments and sucked out (via centre of probe)
• Heat generated (needs continuous water cooling), so not useful in ureter
• Limitation: only via straight instruments
• Utility: renal calculi (PCNL)
Ultrasonic Lithotripter Prototype

Figure 14 Ultrasound probe. Piezoceramic elements oscillate, causing longitudinal and transverse vibration of the probe.
Laser Lithotripsy

- Holmium:YAG most notable laser (2100 nm wavelength)
- Photo-thermal stone vaporisation (pulsed dye laser fragmentation)
- Energy produced rapidly absorbed in water
- Depth of laser penetration 0.4mm, zone of thermal injury from laser tip is 0.5 to 1mm
- Fibre thickness: 200 to 360 μm, thicker less flexible
- Can bore through stone, so use ‘sweep/paint surface’ technique
- Minimal SW produced
  - Smaller fragments (‘powder’) of stone
  - Fragments less likely to migrate
Summary

• SWs have unique characteristics and cause stone fragmentation in both compressive and negative pressure phases of its propagation
• SW Lithotripsy requires an energy source, an energy focusing device, a coupling mechanism and a localisation device
• The most efficient fragmentation using extracorporeal means is by the earlier lithotripter Dornier HM-3
• Devices for intra-corporeal stone fragmentation use either, electrohydraulic, ultrasonic, ballistic/mechanical or laser modality
• The utility is limited by device flexibility, stone location and stone burden