ESWL

Extracorporeal Shock Wave Lithotripsy

Clinical Data and Reports

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*This basic research on Dual Shock waves was performed with the Duet Electro-hydraulic system. The system is similar to the Duet Magna in which the 2 Reflectors contain an Electromagnetic coil instead of 2 spark plugs.
Assessment of Renal Injury With a Clinical Dual Head Lithotripter Delivering 240 Shock Waves per Minute

Rajash K. Handa,* James A. McAteer, Andrew P. Evan, Bret A. Connors, Yuri A. Pishchalnikov and Sujuan Gao

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**Abbreviations and Acronyms**

- EPRAL = PAH renal extraction
- ERPF = effective renal plasma flow
- FRV = functional renal volume
- GFR = glomerular filtration rate
- MRI = magnetic resonance imaging
- PAH = para-aminohippuric acid
- SW = shock wave
- SWL = shock wave lithotripsy

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**Purpose:** Lithotriptors with 2 treatment heads deliver shock waves along separate paths. Firing 1 head and then the other in alternating mode has been suggested as a strategy to treat stones twice as rapidly as with conventional shock wave lithotripsy. Because the shock wave rate is known to have a role in shock wave lithotripsy induced injury, and given that treatment using 2 separate shock wave sources exposes more renal tissue to shock wave energy than treatment with a conventional lithotripter, we assessed renal trauma in pigs following treatment at rapid rate (240 shock waves per minute and 120 shock waves per minute per head) using a Duet lithotripter (Direx Medical Systems, Petach Tikva, Israel) fired in alternating mode.

**Materials and Methods:** Eight adult female pigs (Hardin Farms, Danville, Indiana) each were treated with sham shock wave lithotripsy or 2,400 shock waves delivered in alternating mode (1,200 shock waves per head, 120 shock waves per minute per head and 240 shock waves per minute overall at a power level of 10 J) to the lower renal pole. Renal functional parameters, including glomerular filtration rate and effective renal plasma flow, were determined before and 1 hour after shock wave lithotripsy. The kidneys were perfusion fixed in situ and the hemorrhagic lesion was quantified as a percent of functional renal volume.

**Results:** Shock wave treatment resulted in no significant change in renal function and the response was similar to the functional response seen in sham shock wave treated animals. In 6 pigs treated with alternating mode the renal lesion was small at a mean ± SEM of 0.22% ± 0.09% of functional renal volume.

**Conclusions:** Kidney tissue and function were minimally affected by a clinical dose of shock waves delivered in alternating mode (120 shock waves per minute dose and 240 shock waves per minute overall) with a Duet lithotripter. These observations decrease concern that dual head lithotripsy at a rapid rate is inherently dangerous.

**Key Words:** kidney, lithotripsy, swine, instrumentation, high-energy shock waves

New concepts in lithotripter design have emerged that include SW delivery from dual treatment heads.1–5 The Duet lithotripter has 2 independent spark plug generator/deflector systems at a 72-degree angle to each other, such that SWs from each treatment head converge at a common focal point. This machine is approved in the United States for patient treatment in synchronous/simultaneous (2 heads are fired simultaneously) or asynchronous/alternating (firing alternates between the 2 heads) modes.
at up to 120 SWs per minute per head. A potential benefit of dual head firing in alternating mode is that the stone can be exposed to 240 SWs per minute and, thus, a given dose of SWs can be delivered in half the time.

Safety is an important issue in SWL. Numerous reports have described SW induced renal trauma in patients and there is growing awareness of a link between acute tissue damage and the potential for long-term adverse effects. Studies in experimental animals have characterized acute SWL trauma as primarily a vascular lesion that can trigger an inflammatory response leading to parenchymal scarring and loss of functional renal mass. The hemorrhagic lesion is focal in the sense that tissue damage is most pronounced in the region of the kidney targeted by the focal volume. That is, injury occurs along the acoustic axis, along the SW path through the kidney. In SWL with a conventional lithotriptor this can be seen to produce tissue damage extending from the renal papilla through the full thickness of the medulla and cortex. In treatment using a dual head lithotriptor SWs follow 2 paths through the kidney, raising the possibility that a greater volume of kidney tissue may be subjected to injury.

The rate of SW administration has emerged as a potentially important factor in SWL injury. A rapid SW rate has been shown in experimental animals to enhance injury and a recent study demonstrated that slowing the SW rate to 30 SWs per minute significantly decreases lesion volume compared to treatment at 120 SWs per minute. With this in mind it seems important to assess the safety of SW exposure at the increased rate of 240 SWs per minute that occurs with dual head lithotripsy in alternating mode.

To our knowledge we report the first study of the renal bioeffects of a clinical dose of SWs delivered in asynchronous/alternating mode using a Duet lithotriptor in an established in vivo porcine model that is commonly used in SW research.

**METHODS AND MATERIALS**

Adult female pigs weighing 45 kg were rendered unconscious with an intramuscular injection of ketamine (15 to 20 mg/kg) and xylazine (2 mg/kg) with anesthesia maintained with 1% to 3% isoflurane and 100% oxygen. The animals were prepared for renal function measurements as previously described, including catheter placement into the ear vein for the intravenous infusion of fluids, the infrarenal aorta for blood pressure and heart rate monitoring and arterial blood sampling, each renal vein for renal venous blood sampling and each ureter for urine collection. Saline (150 mmol/l) was infused intravenously at 1% body weight per hour throughout the experiment to maintain adequate hydration and urine flow.

**Duet Lithotriptor Experimental Protocol**

The pig was placed supine on the adjustable lithotriptor treatment table. Baseline cardiovascular and renal function measurements, which were begun 30 minutes following the completion of all surgery and coupling with castor oil of the pig to the lithotriptor SW generator heads, consisted of 2, 25-minute clearances. The lithotriptor was targeted on the left kidney lower pole calix under fluoroscopic guidance with a small amount of contrast medium injected through the left ureteral catheter. Eight animals each underwent no SWs (group 1) or 2,400 SWs (group 2) at 1,200 SWs per head, 120 SWs per minute per head and 240 SWs per minute overall at a power level of 10. The latter is recommended for clinical treatment in alternating mode. Lithotripsy was temporarily halted every 500 SWs to confirm targeting. Three 25-minute clearances were then obtained after a 30-minute post-lithotripsy recovery period.

**Renal Function Measurements**

Inulin and PAH were intravenously administered as a bolus, followed by infusion at 70 ml per hour to achieve a steady state plasma concentration of 20 and 2 mg/dl, respectively. Plasma and urine samples were analyzed for inulin and PAH and their renal clearance was used as an estimate of GFR and ERPF, respectively. PAH was calculated using the formula, $\text{PAH}_{\text{oral}} = \text{PAH}_{\text{oral conv}} \times 100$, providing an estimate of the efficiency of renal tubular organic anion transport.

**Morphological Analysis**

The kidneys were perfusion fixed in situ at the end of the experiment and removed for histological and quantitative morphological analysis, as previously described. Hemorrhagic regions in the parenchyma were identified and expressed as a percent of FRV using computer assisted segmentation of digital images from 150 µm serial sections of the entire kidney. The smallest lesion that can be accurately measured with this system is 0.1% of FRV.

**In Vitro Stone Breakage Studies**

Experiments were done in a test tank fitted with 2 latex acoustic windows that were coupled to the treatment heads using castor oil. The tank was filled with tap water, which was then degassed with a pinhole degasser to maintain gas content at about 2 mg/l (approximately 20% of saturation). The focal point of the lithotriptor was identified using the device alignment stylus and then marked by crossed lasers. All studies were performed with artificial Ultracal® 30 gypsum stones placed in a 2 mm mesh metal wire basket positioned at the focal point. SWs were administered in alternating (asynchronous) mode at 120 SWs per minute per head and 240 SWs per minute at a power level of 10 in 26 stones and in simultaneous (synchronous) mode with dual SWs at 120 SWs per minute per head at a power level of 5 in 20 stones. Stone breakage was assessed by counting the number of SWs needed to remove all stone material from the basket. Different power settings were used in the 2 modes, including power level 10 for alternating mode and power level 5 for simultaneous mode, because these settings are recommended for clinical treatment.
Statistical Analysis
All values are presented as the mean ± SEM. Comparison of renal function in and across groups was done with 2-factor ANOVA with repeated measures. Stone breakage analysis was done using the unpaired Student t test. Differences between means were considered significant at the 5% level.

RESULTS
Cardiovascular Measurements
Blood pressure and renal responses to dual pulse SW application were similar to those observed in sham SW treated animals. A small time related 6 to 10 mm Hg decrease in mean arterial pressure was seen with no significant alteration in GFR, ERPF or EPAH (fig. 1). Likewise renal filtration and perfusion, and tubular PAH transport were unaltered in the contralateral untreated kidney in each group (data not shown).

Morphological Measurements
Visual examination of the kidney anterior and posterior surfaces revealed small focal sites of subcapsular bleeding in 5 of the 8 Duet treated kidneys. The 3 remaining SW treated kidneys were similar to sham SWL treated kidneys in that they showed no evidence of subcapsular hemorrhage.

Hemorrhagic lesion size was quantified in 6 SW treated kidneys. The degree of intraparenchymal hemorrhage induced by lithotripsy was 0.22% ± 0.09% FRV (p = 0.0022), that is no detectable lesion in 2 kidneys, a focal papillary lesion in 1 (less than 0.1%) and small discrete lesions in the papillae and cortex of 3 (0.37%, 0.40% and 0.46%, respectively). No tissue damage was observed in sham SWL treated pigs. Figure 2 shows 3 consecutive unstained 5 mm cross sections of an SWL treated kidney. Lesion sites appeared to correlate with the SW path from the upper and lower treatment heads when these cross sections were overlaid on the MRI image of a pig and the superimposed location of the dual treatment heads.

In Vitro Stone Breakage Studies
Stone breakage in alternating mode required 679 ± 24 SWs compared to 601 ± 35 SWs (approximately 300 dual SWs) delivered in simultaneous mode. Because the SW rate of 120 SWs per minute of the 2 treatment heads was the same in alternating and simultaneous modes, overall treatment time was 170 and 150 seconds, respectively. These results suggest a trend toward a slightly higher (approximately 13%) total SW number and treatment time for stone comminution in alternating vs simultaneous mode (each p = 0.0666).

Figure 1. Blood pressure and renal responses in sham SWL and SWL treated kidneys. MAP, mean arterial pressure. Asterisk indicates p < 0.05 vs pretreatment values.
per minute per head) might enhance tissue damage. Results show otherwise. It has been noted in animal studies with single head lithotriptors that treatment at a slow SW rate of 30 SWs per minute produces little injury and treatment at an extremely rapid rate of 900 SWs per minute or greater causes dramatically increased tissue damage. The lesion produced by 2,400 SWs (1,200 SWs per head at a power level of 10) at 120 SWs per minute in alternating mode was quite low at 0.22% ± 0.09% FRV, which compares favorably with the 1.08% ± 0.38% FRV lesion produced by 2,400 SWs delivered with the Dornier® HM3 lithotripter at 120 SWs per minute and 24 kV. The injury observed in this study using SWs fired in alternating mode was statistically similar, even if somewhat lower, than in a previous study in which SWs were delivered as simultaneous dual pulses (0.22% ± 0.09% vs 0.36% ± 0.38% FRV, p = 0.1044). These results are difficult to compare directly since treatment conditions were different. Whereas in alternating mode the SWs fired from the 2 treatment heads arrive at the focal point independently, the SWs fired in simultaneous mode intersect at the target. These coincident SWs produce a focal zone in which acoustic pressures are doubled. In addition, in simultaneous mode the kidney location of the combined focal zones depends on the timing of the 2 SWs, such that this zone shifts in position throughout treatment. Regardless of these differences it seems noteworthy that the injury observed in each mode was indeed quite slight. A potential explanation is related to the efficiency of acoustic coupling in dry head lithotriptors. In vitro studies have shown that air pockets at the coupling interface of a dry treatment head can dramatically decrease SW energy transmission. Even under ideal conditions in vitro it is difficult to attain coupling that is free of defects and having 2 treatment heads could only compound the difficulty with achieving good coupling. However, to our knowledge there is currently no means to determine the quality of coupling with any dry head device and, thus, there was no way to assess coupling in this study of the Duet lithotripter. The coupling protocol used in these experiments in pigs followed the accepted clinical protocol for this device. Thus, in regard to coupling the results may well be consistent with what occurs during patient treatment.

A potentially important aspect of these studies of renal injury in pigs using the Duet and HM3 lithotriptors involves the sequence that was followed for SW delivery. In particular it should be noted that treatment was not continuous and periodic pauses were built into the treatment protocol to assess alignment and targeting. Recently we observed that a brief pause in treatment can have a protective

**DISCUSSION**

An important motivation for the current study was concern that delivering SWs to the kidney at the combined SW rate of 240 SWs per minute (120 SWs...
ESWL – CLINICAL DATA AND REPORTS

RENAL INJURY ASSESSMENT WITH CLINICAL DUAL HEAD LITHOTRIPTOR

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effect, acting to decrease the severity of renal injury.21,22 For example, when pigs were treated with a primary dose of 100 SWS at 24 kV with the HM3, followed by a 3-minute break before the main dose of 2,000 SWS was delivered, injury was significantly decreased compared to treatment with the main SW dose alone (0.51% ± 0.14% vs 3.93% ± 1.29%; FRV, p = 0.0135).23 In regard to the current and previous studies of the Duet lithotripter as well as background data cited on the HM3 device it is important to recognize that the renal injury values pertain only to the specific treatment protocols that were followed. Because pauses in SW treatment could potentially evoke a protective response, one might predict a higher level of injury with the Duet and HM3 devices if treatment were continuous. Thus, it seems prudent to use a brief 3–4-minute pause in SW delivery as part of the treatment protocol regardless of the type of device used.

A potential advantage of dual pulse lithotripsy compared to conventional SWL is the idea that SWS delivered from 2 sources may be able to break stones more efficiently than SWs from a single source. Others have presented in vitro data to suggest that this is the case.24 In the current study we limited our analysis of stone breakage to the 2 conditions most relevant to the efficacy and safety of treatment involving 2 shock sources. Our in vitro results demonstrate that the number of delivered SWS and treatment time needed to achieve stone comminution were essentially similar under the alternating and simultaneous SW firing modes of dual head lithotripsy. With this in mind a possible benefit of dual pulse lithotripsy in alternating mode is that renal function was not significantly changed after treatment. This is in contrast to the renal vasoconstriction normally observed following simultaneous delivery of dual SWS25 or SWs delivered from a conventional single head lithotripter.16,18

CONCLUSIONS

Treatment of the pig kidney with a clinical dose of SWS delivered in alternating (asynchronous) mode with the Duet dual head lithotripter caused minimal alteration in renal function and produced only a small hemorrhagic lesion. This demonstrates that the delivery of SWS from 2 treatment heads is not inherently dangerous and firing 2 SW sources at a combined rate of 240 SWS per minute does not cause significant morphological injury to the kidney.

ACKNOWLEDGMENTS

Cynthia D. Johnson and Philip M. Blomgren assisted with the study and Dr. James C. Williams, Jr. commented on the manuscript.

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Initial experience with a New Dual Shockwave Lithotripter in the Management of Upper Urinary Tract Calculi.


The Stone Center, Department of Urology, Darent Valley Hospital, Dartford, UK.

Introduction

New dual shock wave lithotripters (Duet Direx) installed at Darent Valley Hospital since August 2007.

We report our preliminary results with this new lithotripsy technology in the management of upper urinary tract calculi.

The lithotripter has two independent generator/reflector systems at 72 degrees to each other. It can be used synchronous (simultaneous) or asynchronous (alternate) modes.

The dual shock waves produce a butterfly shaped focal volume which contributes to better fragmentation, and probably lower kidney damage.

Initially we used the Duet Electrohydraulic version but lately we started to use the Duet Magna Electromagnetic version.

Materials & Methods

Data was collected prospectively from 184 consecutive patients undergoing ESWL from August 2007 to September 2009 – performed under analgesia at 240 shock waves/min (120 shock waves/min/head).

All patients were reviewed in the clinic at 4-6 weeks post ESWL with an X-RAY KUB. Stone free rates (success) was defined as completely stone free or with fragment <3mm.
Results

Of 184 patients: 152 had a single session, 23 had two sessions and 2 of them had 3 sessions. 7 were excluded from the study (3 did not tolerate the analgesia and 4 had parenchymal stones). Twenty nine patients had a ureteric stent in situ. The stone distribution included upper calyceal (10%), mid calyceal (11%), lower calyceal (60%), renal pelvic (14%) and proximal ureteric (5%). The dual shockwave asynchronous mode was utilized in 89% of the patients. Nine patients (5%) did not tolerate the procedure well and one patient was admitted overnight for analgesia. Initial Stone Free rate using the Electro hydraulic version was 78.11%. Lately, using the Duet Magna Electromagnetic Version, (which reduces pain to the patient, allowing the use of higher energy), the Stone Free Rate increased to 83%.

Discussion / Conclusions

In an animal model using a Duet Lithotripter, the kidney tissue and function were minimally affected by a clinical dose of shock wave delivered in alternating mode (120 shock waves per minute per head and 240 shock waves per minute.)

These observations decrease concern that dual head lithotripsy at a rapid rate is inherently dangerous (Handa et al., 2009 J Urol).

Dual Shock wave lithotripsy is safe, quick and effective in treating upper urinary tract calculi.

The above abstract was presented at the EAU 2010, in Barcelona, Spain.
Use of Oral Analgesia in Extracorporeal Shockwave Lithotripsy: Analysis of Effectiveness and Pain Tolerance using a Dual Electromagnetic Shockwave System.

Sandro M. Varea, Gustavo Minuzzi, Belén Leithold, Sanatorio Allende Cerro. Córdoba, Argentina

Introduction and Objectives
Extracorporeal shock wave lithotripsy remains the Gold Standard treatment modality for most urinary stones.
A new technology has been developed, that uses 2 electromagnetic shock wave generators concentrating the energy on the stone from 2 different angles. Since the total energy is distributed between 2 reflectors, patient pain is reduced notoriously. The aim of this study was to evaluate the efficacy and pain tolerance of patients treated with Dual Shock Wave Electromagnetic lithotripsy using oral analgesia only.

Material and methods
We performed a prospective descriptive study of all patients with urinary stones treated with extracorporeal shockwave lithotripsy between January 2011 and January 2012. The device used was the Duet Magna (Direx Group) using 2 electromagnetic generators at 76 degrees between them that can be fired individually or simultaneously. The treatments were performed under oral analgesia with diclofenac sodium 75 mg. The variables were: age, sex, BMI, size and location of the stone, analog pain score, number of sessions, complications and complementary treatments. Patients were followed with KUB X-Ray, ultrasound or CT as appropriate, Treatment success was considered in case the patient was Stone Free or with fragments smaller than 4 mm.
Results

189 lithotripsy treatments were performed in 123 patients, leading to an average number of sessions per patient of 1.53. There were 81 men and 42 women, mean age were 43.9 years. Of them 48% were located in the kidney and 52% in ureter. The average size of the stones was 10 mm.

According to the analog pain scale (1 to 10), 91.8% of patients reported to be between 3 and 5.

**For kidney stone treatment the success rate was 94%** (stone free: 60.9% + <fragments 4 mm: 33.7%) and **for ureteral stones the success rate was 76.5%** (stone free: 67.2% + <fragments 4 mm: 9.2%).

As for complications: 8.9% of patients had renal colic and no major complications were observed.

Conclusions

Our experience, confirms the feasibility to treat renal and ureteral calculi with Dual Technology Electromagnetic Shock Wave, using only oral analgesia with satisfactory results comparable to other lithotripsy systems.

The above abstract was presented at the *CAU 2012*, in Cartagena, Colombia.

The Stone Center, Department of Urology, Darent Valley Hospital, Dartford, UK

Introduction
We report our preliminary results with this new Duet Magna Electromagnetic Shockwave lithotripter in the management of upper urinary tract calculi.
The lithotripter has two independent generator/reflector systems at 76° to each other. It is used in synchronous mode.
The dual shock waves produce a butterfly shaped focal volume which contributes to better fragmentation and probably lower kidney damage.

Material and Method
Data was collected prospectively 138 consecutive patients undergoing ESWL from June 2009 to September 2010 - performed under analgesia at 120 double shocks/min (120 shocks from each shock head).
All patients were reviewed in the clinic at 4-6 weeks post ESWL with an X-Ray KUB.
Success was defined as completely stone free or with fragment < 3mm.

<table>
<thead>
<tr>
<th>Total number of patients studied</th>
<th>138</th>
</tr>
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<tbody>
<tr>
<td>Male:Female ratio</td>
<td>95:43</td>
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<tr>
<td>Mean stone size</td>
<td>8.8 mm (range 5-20 mm)</td>
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<tr>
<td>Mean shockwave time</td>
<td>30 minutes</td>
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</table>
Results
Of the 138 patients: 108 had a single session, 25 had two sessions & 5 of them had 3 sessions. The stone distribution included upper calyceal (16%), mid calyceal (10%), lower calyceal (57%), renal pelvic (15%) and proximal ureteric (1%). Three patients (2%) did not tolerate the procedure well. The stone free rate were 88% (5-10 mm), 73% (10-15 mm) and 80% (15-20 mm). Overall success rate is 83%.

Discussion/Conclusion
An animal model study using a Duet Lithotripter, showed a significant reduction in kidney damage. "The lesion produced by 2400 SWs (1200 SWs/head, power level 10) at 120 SWs/min in alternating mode was quite low (0.22 ± 0.09% FRV)" and compares favorably with the lesion (1.08 ± 0.38% FRV) - "produced by 2400 SWs delivered with the HM3 lithotripter at 12 SWs/min (24 Kv)..." (Handa et al., 2009 J Urol).
Dual shock wave electromagnetic lithotripsy is safe, quick and effective in treating upper urinary tract calculi.

The above abstract was presented at the WCE 2011, in Kyoto, Japan.
Double Shockwave Electromagnetic Lithotripsy - Initial Experience.

S. Varea
Clinica Privada de Mar del Plata, Argentina.

Introduction
The Extracorporeal lithotripsy developed 26 years ago, has undergone many changes in technology, imaging systems and architecture, but always used a single shock wave generator focused on the stone to be treated.

A new technology has been developed – this technology uses two shock wave generators which focus the waves at the same time, producing a unique "butterfly" focal area in contrast to the traditional "cigar" focal area produced by a single shock wave.

The objective of the study is to evaluate the safety and effectiveness of a Dual Shock Wave device.

Material and Methods
This is a cross sectional study.

The device used: Duet Magna (Direx Group) with two independent electromagnetic generators positioned at 76 degrees between them. They can be used simultaneously or each one individually.

Thirty patients with renal and ureteral stones were treated between March 17th and May 10th, 2010. All patients were treated with I.V. sedation.

Patients were followed up a week later with X-ray, ultrasound or CT. Successful treatment was considered when the patient was Stone Free or with fragments less than 4 mm.
Results

33 urinary calculi were treated in 30 patients, 24 males and 6 females with an average age of 53.1 years (31-76). 58% were right stones.

Regarding the stone size, the average was 10.9 mm in diameter, distributed as follows: 3 stones smaller than 5 mm (9%), 18 stones between 6 and 10 mm (55%), 8 stones between 11 and 15 mm (24%) and 4 stones over 16 mm in diameter (12%).

Locations: 51% in the calyxes (12% upper calyx, 12% middle calyx and 27% lower calyx), 11 stones in the renal pelvis (34%), 3% (1 stone) in Ureteropelvic Junction-UPJ) and 12% of ureteric stones (3 stones in upper ureter and 1 in middle ureter).

100% of the stones were successfully fragmented (fragments smaller than 4 mm) without complications and with a clearance rate of 85%.

Conclusions

The treatment with the Duet Magna is safe and effective.

Further studies needed to be done with a bigger number of patients and follow-up to confirm our results.

The above abstract was presented at the CAU 2010 in Santiago de Chile.
Initial results with Duet Magna, a new Electromagnetic Dual-Shockwave lithotripter, utilizing a sedation free protocol.

The Stone Center, Department of Urology, Darent Valley Hospital, Dartford, UK.

Introduction
The first generations' ESWL devices were developed using the Electro-hydraulic technology. Although results and side effects were optimal, they generally require anesthesia or sedation to control patient’s pain.
During recent years there is a continuous shortage of anesthesiologists in Europe which require lithotripsy treatments to be done without the use of anesthesia or sedation.
Electromagnetic lithotripters generally deliver more stable and less energy compared to Electro-hydraulic ones and hence may be more suitable for a no-sedation treatment.
All lithotripters used today have a single source generator of shockwaves.
Pain depends partially on the contact area between the lithotripter and the patient. It is accepted that the bigger the above area, the lower the pain.
Therefore, a dual shockwave lithotripsy unit, in which the shock energy is divided between two reflectors with a contact area twice as large compared to a single reflector may be very effective in reducing the pain and maintaining effectiveness.
We report our preliminary results of safety and efficacy using a new Electromagnetic dual shockwave lithotripter (Duet Magna, Direx-Initia) for upper urinary tract calculi using a no sedation protocol.
Materials & Methods

Patient demographic, procedure & stone data were collected prospectively from 40 consecutive patients attending for ESWL from July 2009 to October 2009 treated with Analgesia.

The patient data were as follows:
1) Male / Female proportion

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<table>
<thead>
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<tr>
<td>Male</td>
<td>28</td>
<td>70 %</td>
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<tr>
<td>Female</td>
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<td>30 %</td>
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2) Left/right

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<tr>
<td>Right kidney</td>
<td>10</td>
<td>25 %</td>
</tr>
<tr>
<td>Left kidney</td>
<td>30</td>
<td>75 %</td>
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</table>

3) Average patient age was 55.5 years (Range 27 to 75 years).
4) Seven patients had stents placed in situ.
5) Intra-renal Location

<table>
<thead>
<tr>
<th>Stone Location</th>
<th>Upper Calyx</th>
<th>Middle Calyx</th>
<th>Lower Calyx</th>
<th>Pelvic</th>
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<tr>
<td>Number</td>
<td>8</td>
<td>6</td>
<td>19</td>
<td>7</td>
</tr>
<tr>
<td>Percentage</td>
<td>20 %</td>
<td>15 %</td>
<td>48%</td>
<td>18 %</td>
</tr>
</tbody>
</table>

6) The mean stone size was 7.95 mm (range 5-12 mm).
7) Analgesia used was 1g Paracetamol (PO/PR), Voltarol 100mg PR and Pethidine 50-100 mg IM.

Results

According to the purpose of the study, we aimed to evaluate safety and effectiveness of the Duet Magna. Out of the 40 patients, 2 had previous treatments (URS lithotripsy and ESWL), therefore we calculated the effectiveness on 38 patients.

All patients were reviewed in the clinic at 4–6 weeks post ESWL with a plain X-ray. Success was defined as stone free or stone fragment 4 mm or less.

After the first session and follow up, 27 out of 38 (71%) of the treatments were successful. Final success rate will be established after second session which will increase the success rate.

Side effects were minimal with bruises in 7 patients.
Conclusion
The treatment with the Duet Magna appears to be highly safe and effective. A 71% success in the first session with No Sedation Protocol, shows the validity of this unique design by which energy is divided between two reflectors allowing to apply a much higher energy compared to a single reflector electromagnetic lithotripter, and therefore a much higher success rate. The treatment is applied while reducing pain by dividing the energy / patient surface by two and hence allowing a highly effective / low pain treatment.

The above abstract was presented at the EAU 2011, in Vienna, Austria.
Initial Multi-center experience with Duet Magna, a new Electromagnetic dual shockwave lithotripter in High Energy /Anesthesia Mode.

Soroka Medical Center, Ben Gurion University, Beer Sheva, Israel;
Wolfson Medical Center, Tel Aviv University, Israel;
Kaplan Medical Center, Rehovot, Israel.

Introduction
The majority of ESWL devices in the market are built with a single source generator of shockwaves. Electromagnetic lithotripters seem adequate to treat urinary tract calculi with minimal sedation requirements, especially for small/medium size calculi. But, in our daily practice we also encounter larger calculi which generally require more energy to fragment and hence anesthesia/deep sedation to be applied to the patient. We have tested the Duet Magna, (Direx-Initia) in High Energy anesthesia mode and report our preliminary results.

Materials & Methods
Patient demographic, procedure & stone data was collected prospectively from 124 consecutive patients attending for ESWL from January 2009 to October 2009, in 3 medical centers, treated with either general or epidural anesthesia according to each center’s preference. All patients were reviewed in the clinic at 4-6 weeks post ESWL with a plain X-ray. Success was defined as stone free or stone fragments 4mm or less.

Results
The patient data was as follows:
1) Male / Female proportion

<table>
<thead>
<tr>
<th>Male</th>
<th>91</th>
<th>73 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>33</td>
<td>27 %</td>
</tr>
</tbody>
</table>

2) Left/right

<table>
<thead>
<tr>
<th>Right kidney</th>
<th>46</th>
<th>37 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left kidney</td>
<td>78</td>
<td>63 %</td>
</tr>
</tbody>
</table>
3) Average patient age was 51.5 years (Range 16 to 83 years).
4) Weight (kg): Average 76.1, Max 114, Min 46
5) Intra-renal Location

<table>
<thead>
<tr>
<th>Stone location</th>
<th>Number of cases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Calyx</td>
<td>36</td>
<td>29 %</td>
</tr>
<tr>
<td>Middle Calyx</td>
<td>5</td>
<td>4 %</td>
</tr>
<tr>
<td>Upper Calyx</td>
<td>12</td>
<td>9.6 %</td>
</tr>
<tr>
<td>Renal Pelvis</td>
<td>24</td>
<td>19.2 %</td>
</tr>
<tr>
<td>Renal Pelvis Junction</td>
<td>4</td>
<td>3.2 %</td>
</tr>
<tr>
<td>Lower Ureter</td>
<td>14</td>
<td>11.3 %</td>
</tr>
<tr>
<td>Middle Ureter</td>
<td>4</td>
<td>3.2 %</td>
</tr>
<tr>
<td>Upper Ureter</td>
<td>25</td>
<td>20.5 %</td>
</tr>
<tr>
<td>Total</td>
<td>124</td>
<td></td>
</tr>
</tbody>
</table>

6) The mean stone size range was: 5–18 mm

Results as follows:

<table>
<thead>
<tr>
<th>Results</th>
<th>%</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>75.8</td>
<td>94</td>
</tr>
<tr>
<td>PF</td>
<td>16.9</td>
<td>21</td>
</tr>
<tr>
<td>NF</td>
<td>7.3</td>
<td>9</td>
</tr>
<tr>
<td>Other</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>124</td>
</tr>
</tbody>
</table>

Results as follows:
Conclusion

Duet Magna, electromagnetic dual shockwave lithotripsy is safe and effective treating urinary tract calculi at high energy including for large or hard stones. Stone free rates are adequate considering we have treated stones up to 18 mm.
ESWL using Electromagnetic Dual Shock Lithotripsy

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Introduction and Objectives
ESWL is still the gold standard treatment for most urinary tract stones. We have started to use a new lithotripter system including 2 electromagnetic shockwave sources that can fire simultaneously. The goal is to improve the efficiency and eventually reduce kidney damage. Our objective was to assess safety and efficacy as a result of a different focal area in this electromagnetic version, which is firing the 2 shockwaves sources at the same time. This allows reduced sedation as the total energy is divided into 2 halves traversing different parts of the body.

Materials & methods
From August 2011 to August 2012 we treated 67 patients using the Duet Magna lithotripter (Direx Group) with fluoroscopic localization. The variables were: age, sex, size and location of the stones, number of sessions, complications and complementary treatments.

There were 44 men and 23 women. Average age was 44 years (range 22 to 67). The procedure was performed under sedation (midazolam 0.1mg/Kg plus fentanyl 50mic) on 58 patients, diclofenac sodium analgesia on 3, and without any on 6 patients. All patients tolerated the treatment well. Success was defined as either stone free or fragments of <4 mm, partial success as fragments of >4 mm and failure as no fragmentation. Patients were followed by KUB at 3-5 weeks after ESWL.

Results
We have performed 109 sessions on the 67 patients with 82 stones giving an average of 1.7 number of sessions/patient.

Fifty eight patients presented with 1 stone, 6 patients with 3 adjacent stones residuals to PCNL, 3 with 2 big adjacent fragments residuals to RIRS.

The average size of the stones was 11 mm (Range 7 to 15 mm).
Location of the stones: 7 in upper calyx (8.5%), 11 in mid calyx (13.4%), 9 in lower calyx (11%), 25 in renal pelvis (30.4%), 8 in UPJ (10%), 7 in mid ureter (8.5%) and 15 in proximal ureter (18%).

A double J stent was inserted before the treatment, on 21 patients with stone size >1.2 cm, 9 of them with multiple stones close to each other.

We were successful in 60 patients (89.5%) with stone free or small fragments, 6 patients (8.95%) with partial fragmentation (single stones) and 1 patient with no fragmentation (1.5%).

All 9 patients with multiple stones were stone free.

2 ureteroscopy procedures were needed in 2 cases (2.9%).

Side effects: 15 patients had colics solved with painkillers, 17 patients had mild hematuria in the first 24 hours which resolved spontaneously. We had no case of fever.

We had no serious complication such as peri renal hematoma nor sepsis.

Conclusions

In our opinion the Dual Shockwave lithotripsy using electromagnetic generators firing simultaneously is safe, effective to treat urinary tract stones, with satisfactory results and minimal side effects.