SHOCK WAVE LITHOTRIPSY:

A TECHNOLOGY UPDATE

An information paper by the

NATIONAL

HEALTH

TECHNOLOGY

ADVISORY

PANEL

DECEMBER 1987

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BY THE

NATIONAL HEALTH TECHNOLOGY ADVISORY PANEL

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December 1987

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ISBN 0 642 13183 X

AUSTRALIAN INSTITUTE OF HEALTH

THE NATIONAL HEALTH TECHNOLOGY ADVISORY PANEL

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INTRODUCTION

This information paper has been prepared by the NHTAP to provide an overview of developments in equipment for extracorporeal shock wave lithotripsy (ESWL). ESWL is a technique for non-invasive disintegration of stones in the kidney and ureteral tract. More recently it has been used to disintegrate biliary stones. A full NHTAP report on lithotripsy of biliary stones is expected to be completed during 1988.

In June 1985 the NHTAP issued a report on ESWL (1), noting that there might be rapid developments in the technology and that these should be monitored. Second generation devices have now been produced by a number of manufacturers and some are being used clinically overseas. These machines vary in the technique used for shock wave generation and imaging of stones. Acoustic coupling has been simplified through the use of an enclosed column of water in a plenum rather than a water bath. In some cases, the lithotripter is a dedicated single purpose machine. In others, the table design allows other procedures to be undertaken. The relative attractions of the two approaches for purchasers will depend on available workload and other resources.

DESCRIPTIONS OF LITHOTRIPTERS

Dornier Medizintechnik Lithotripters
(Federal Republic of Germany)

The Dornier HM-3 Lithotripter was the first device to use shock wave technology in the extracorporeal treatment of kidney stone disease. The device was approved for general marketing in the U.S.A by the Food and Drug Administration (FDA) in 1983. This machine has a biplane X-ray system for stone localisation and a spark discharge to produce the shock wave. The spark is produced by an electrode at one of the two foci of an ellipsoidal reflector. The patient, who is strapped to a support suspended in a water bath is manouvered to position the stone at the second focus. The average number of shocks per patient is 1350. The shock wave can be ECG-triggered. Three of these machines are now installed and operating in Australia. The cost of the HM-3 is now approximately $A 1.4 million.

A second generation machine, the Dornier HM-4, received FDA approval in May 1987. Unlike the original HM-3 it has no water bath, and the patient is coupled to the shock wave path by means of a water filled cushion and an acoustic gel. Air bubbles at the cushion surface would cause energy dissipation and care is taken to remove them with the aid of a video camera mounted inside the cushion to provide views of the area. The methods of shock wave generation and stone visualisation remain unchanged from those of the HM-3. The patient is transferred to the treatment table by means of a stretcher which is automatically coupled to the table.

The HM-4 unit incorporates a control desk on which all main functions are grouped to facilitate the operation of the lithotripter system. It includes four monitors, one for each X-ray plane and one showing patient monitoring data (ECG, respiratory trigger signals, water cushion coupling control). The fourth monitor with keyboard is connected to the computer system for user guided lithotripter operation and for entry and documentation of all treatment data. By use of a light pen the operator is able to control stone targeting and the progress of therapy. The cost of the HM-4 is currently $A2.1 million.

The HM-3 and HM-4 models can be used to treat most stones in the kidney and upper one third of the ureter. In addition, distal ureteral stones which can be radiologically viewed and targeted via the pelvic window can be treated on these machines. Ureteral stones in the pelvic shadow below the iliac crest cannot be treated.

The latest Dornier ESWL machine is the MPL-9000. This machine was originally designed as a biliary lithotripter, but following further research and development, Dornier considers that it is also suitable for treatment of kidney and upper ureteral stones. The MPL-9000 has FDA approval as a clinical investigation device only.

The MPL-9000 uses the same method of shock wave generation as the HM-3, but the shock wave unit is more compact and incorporates design modifications resulting in shock waves which cause less patient discomfort. A water cushion couples the shock wave transmission path to the patient's body. The coupling pressure of the water cushion is regulated to maintain adequate coupling during the course of therapy and gel is used to provide the final bridge between water cushion and the patient.

Respiratory triggering of the shock wave is used. Ultrasound, rather than X-rays, is used for stone location and positioning. Two ultrasound scanners are used, one integrated into the shock wave unit and the other mounted on a robot-arm. Final patient positioning is performed under computer control, with the assistance of a light pen which marks the stone position on the display screen and geometrical information from the robot-arm.

Treatment can be performed in a wide variety of different positions-supine, prone, lateral, inclined or declined. The ultrasound scanner on the robot arm can be used for standard diagnostic examination. The control panel incorporates monitors for ultra-sound imaging, ECG and respiratory triggering and computer control. The machine table can be used in conjunction with a C-arm X-ray unit for fluoroscopic examination.

Improvements to Dornier electrodes over the past three years have raised their expected life from 400 to 1100 shocks. It is expected that further developments will result in an electrode having a life of 1500 shocks. The manufacturers comment that improvement in electrode performance has contributed to the reduction in machine-related operating costs for the procedure as well as ensuring that the electrodes provide a consistent, uniform and well defined pressure/energy distribution. All electrodes can be used in all Dornier machines.

Dornier states that the new modified system for shock wave generation results in shock waves that are more concentrated, with an overall reduction in pressure peak. They allow anaesthesia-free treatment for most procedures,and oral analgesics in most instances are all that is required. The hardware modifications are retro-fittable to the HM-3 at a cost of approximately $A75,000.

The Australian agent for Dornier lithotripters is Hahn & Kolb (Aust) Pty Ltd.

Siemens Lithostar
(Federal Republic of Germany)

The Siemens' Lithostar lithotripter has been approved by the FDA for clinical investigation only.

In the Lithostar, shock waves are generated electromagnetically. The shock wave transducer consists of a coil mounted in a magnetic field and separated by a thin insulation layer from a metal membrane. A high voltage pulse in the coil induces a current in the membrane which is repelled rapidly by the coil resulting in a shock wave. The waves are propagated through water-filled bellows and focused by an acoustic lens system.

Left and right shock wave transducers are provided. Each is enclosed with water-filled plastic bellows which move forward through an aperture in the table to make contact with the supine or prone patient via a solid gel or liquid coupling disc.

A ceiling-suspended X-ray system is used to locate the stone. After the initial stone localization the patient is monitored fluoroscopically at regular intervals to determine the progress of treatment. The machine table is designed to allow general urological procedures.

Treatment of stones in the kidneys and upper ureter is carried out with respiratory gating. ECG gating is only used for patients with cardiac arrythmias. The average number of shocks per patient is 1500 and average time on the table is approximately 45 minutes.

The cost of the Siemens Lithostar is estimated to be $A1.6 million.

The Panel has been informed that there are 40 Lithostars installed world wide.

The Australian Agent for the Lithostar is Medical Applications Pty Ltd (NSW).

Technomed Sonolith 2000
(France)

The shock wave unit in the Sonolith 2000 is a development of the original Dornier spark discharge device and is designed to have a lifetime of 50-60 treatments. This is achieved by using long electrodes that are driven up under computer control as they wear down. Recent developments have resulted in a smaller and adjustable focal size which may be varied according to the type of stone. It is claimed that this focus combined with a narrower pulse shape will allow treatment without anaesthesia. The shock transducer is mounted in a stainless steel bath containing warmed, degassed water the level of which is adjusted to make contact with the patient through an aperture in the table. The shock wave is ECG triggered.

Localisation is by ultrasound. A scanner is mounted on a locating arm which transmits the probe's co-ordinates to a computer controlling the position of the shock transducer. The depth of the calculus is read directly from the ultrasound scanner and entered via the keyboard into the control system which adjusts the height of the transducer accordingly. However, continuous imaging during treatment is not possible since shock transducer and probe cannot both be in position at the same time. Radiographic monitoring of fragmentation is possible using a mobile X-ray unit with a cassette enclosed in a waterproof container positioned under the patient.

The average number of shocks per patient is 1700, which results in an average treatment time of 30-45 minutes. The progress of treatment is monitored at regular intervals without moving the patient.

The Panel has been informed that Technomed has 5 units installed world-wide.

The cost of the machine is estimated to be $A 1.3 million.

Wolf Piezolith Lithotripters
(Federal Republic of Germany)

Richard Wolf GmbH has produced two lithotripters, the Piezolith 2200 and the Piezolith 2300. The shock transducer in the Piezolith 2200 consists of a large number of linked piezo-electric elements mounted on a part-spherical dish. Four shock pressures are available. The dish forms the base of a cylindrical water bath which has flexible sides to allow movement and which is filled with warmed, degassed water to make contact with the patient through an aperture in the table. Ultrasound is used for stone localisation.

The scanner probe protrudes from the base of the dish to make contact with the patient and is motor driven so that both longitudinal and lateral views can be produced. The location of the shock wave focus is indicated by a cursor on the scan. Positioning is achieved by moving the transducer along three axes using controls on the console until the focus is at the stone. The unit can also be tilted to treat calculi lying behind ribs. Since the scanner images continuously, adjustments to the focal position can be made whilst the treatment is in progress.

The table is designed to take leg supports for percutaneous work in the lithotomy position and has a sliding top which allows a C-arm mobile image intensifier to be used for radiography without moving the patient.

The Panel has been informed that 30 Piezolith 2200 units have been installed world wide and have been used to treat approximately 3000 patients. The cost of the Wolf Piezolith 2200 is approximately $A 1.4 million.

The newer Piezolith 2300 lithotripter has replaced the earlier 2200 model. The major change is the use of a dual ultrasound location system. There are two ultrasonic real-time-B-scanners, which protrude from the base of the dish and which are used for the ultrasonic location of the stone and to provide continuous sonographic monitoring during lithotripsy. Depending on the anatomical situation the more suitable scanner can be selected to locate the stone. With this arrangement, it is said that difficulties caused by stones lying behind the 12th rib or symphysis can be better overcome. The improvement in the location system is said to facilitate the treatment of gallstones and biliary duct stones.

A zoom facility allows the target area to be displayed in different degrees of enlargement.

The Australian agent for the Piezolith lithotripters is Downs Surgical (Australia) Pty Ltd.

EDAP LT.01
(France)

This unit has similarities to the Wolf machine. The shock wave transducer works on the same principle, using piezo-electric elements. The transducer is mounted at the base of a water tank the top of which is a flexible membrane which makes contact with the patient with the assistance of coupling gel. The tank moves in three dimensions and tilts in two directions in order to position the beam appropriately. The shock rate is variable and no cardiac gating has been provided.

As with the Wolf units, an ultrasound localisation probe protrudes from the centre of the shock wave transducer. The ultrasound system, manufactured by EDAP, operates continuously throughout treatment. A hand-held probe is also included with the system.

The table has a top in two sections, one either side of the shock wave system. The whole top can swing away from the shock wave system to allow use of a C-arm fluoroscopic/radiographic unit.

The average number of shocks per treatment is 4800, the position of the focus being adjusted frequently throughout.

Treatment is undertaken without any anaesthesia. The machine is said to be able to treat urinary stones as well as gallstones without modification to the system.

The cost of the EDAP LT.01 is believed to be $A1.2 million. The Panel has been informed that there are 45 units installed world wide and 8000 patients have been treated (2500 in Paris).

Medstone 1050 ST
(USA)

The Panel understands that the Medstone device is still undergoing development and has been used with only about 120 patients. This lithotripter uses an electrode for shock wave generation, with transmission through a water chamber. The patient is positioned on a table and a C-arm fluoroscopic/radiographic unit is used for visualisation.

Treatment requires general or epidural anaesthesia. The cost of the machine is estimated to be $A1.2 million.

Northgate SD-3
(USA)

This machine comprises a mobile table and a separate console unit. Shock waves are generated electrohydraulically. The patient lies on a table, and coupling is achieved through an aperture by means of a membrane over the shock wave reflector. Real-time B mode ultrasound is used to locate the stone. The imaging system may also be used on a stand-alone basis for diagnostic procedures.

The table can be used for other urological procedures.

The Panel has been informed that the machine has FDA approval for human trials and that commencement of the human protocol began during October 1987. Northgate expects that export of the machine could be possible by mid 1988.

Currently the price is estimated to be $A0.6 million.

GENERAL COMMENTS

It should be noted that the various types of machine destroy stones in different ways and require different modes of operation. The electromagnetic and spark discharge types (Siemens/Technomed and Dornier) have a large focus which fragments the stone as a whole with a low retreatment rate. Typically the stone is imaged every two hundred shocks and between these breaks the system can be allowed to run without constant surveillance. Piezo-electric units (Wolf and EDAP) have small foci, work by erosion of the stone and have high retreatment rates for large calculi. Because of the small focus the operator is required to watch the treatment continuously and make frequent adjustments to keep the focus positioned at the calculus. Thus a continuous imaging system is mandatory.

The Panel is aware that other machines are being developed in the USA and Japan and the use of lasers to generate shock waves is being explored in West Germany (Dornier) and the USA. In Denmark a hand-held applicator has been developed which contains both the shock wave generator and the ultrasound imager.

While considerable development of second generation lithotripters has taken place, the Panel notes that there is a general absence of hard data on their operational cost, efficacy and reliability. There is a need to keep this area under review. The Panel suggests that it would be wise for Australia to proceed cautiously in assessing the need for additional lithotripters, bearing in mind the need for assured reliability, limited numbers of cases in this country, and the desirability of maintaining appropriate throughput. It is of interest that in the USA there may be overcapacity with this technology (2).

A summary of selected machine data on the lithotripters reviewed is in Table 1.

REFERENCES

1. Report by the National Health Technology Advisory Panel (NHTAP), "Shock Wave Lithotripsy", June 1985.

2. "ESWL: Overdiffusion of a Valuable Innovation?" Health Technology Critical Issues for Decision Makers (ECRI), 1987; 1(3):121

ACKNOWLEDGEMENTS

The Panel is grateful to the following for assistance, advice and comments:

Dr D Hill North East Thames Regional Health Authority, London

Hahn and Kolb (Aust) Pty Ltd

Medical Applications Pty Ltd

Richard Wolf GmbH, West Germany

Monaghan Medical Coporation, USA

EDAP, France

TABLE 1 : SUMMARY O

	DORNIER HM-3	DORNIER HM-4	DORNIER MPL-9000	SIEMENS LITHOSTAR	WOLF PIEZO
Country of Origin:	West Germany	West Germany	West Germany	West Germany	West Germa
Localisation Method:	Biplane X-ray	Biplane X-ray	Biplanar Ultra-sound	Biplane X-ray	Ultrasound
Continuous Imaging:	No	No	No	No	Yes
Shock Wave Transducer:	Spark discharge	Spark discharge	Spark discharge	Electromagnetic	Piezoelect
Focal Size:	Ellipsoidal Approx 1 x 1.5cm	See HM3	See HM3	1 x 0.9 cm	0.3 x 0.8
Shock Intensity	Variable 400-1200 Bar	See HM3	See HM3	Variable to 500 Bar	up to 1000 (selectabl
Shocks/patient-average:	1350	1350	1350 Urological 1500 max Gastroenterological	1500	1200-1500
Shock Wave Gating:	ECG and/or respiratory	See HM3	See HM3	ECG and/or respiratory	None
Anaesthetic:	Yes No with Retrofit (90% Cases)	No (90% Cases)	No (90% Cases)	No	No
Patient Contact:	Water bath	Water cushion	Water cushion	Water filled bellows and gel coupling disc	Warmed deg
Primary Use:	Kidney and distal ureteral stones	See HM3	See HM3 Gallbladder(GB) and common bile duct (CBD) stones	Kidney and and ureteral stones	
Other Urological Uses:	No	No	No	Yes	Yes
Gallstone Treatment:	experimental	Experimental	Yes(GB+CBD)	Experimental	Experiment
Room Size:	35 sq m	25 sq m	25 sq m	35 sq m	20 sq m
No. of Installations	270	10(as of Oct 1987)	8 as of Oct 87	40	30
Price (approx):	$A 1.4m	$A 2.1m	$A 2.0m	$A 1.6m	$A 1.4m*
FDA Status**:	Approved (12/1983)	Approved (5/1987)	10 IDE sites confirmed (6/1987)	IDE (clinical testing at 2 sites)	Applying

* The prices quoted are from overseas sources and therefore would not include such costs as frieght, duty, installation et

** Product approval by the US Food and Drug Administration (FDA) permits a manufacturer to distribute or use a new device. Investigational Device Exemption (IDE) does not permit the commercial distribution of a product; it only permits the man undertake clinical investigations to gather data, which then is used by the FDA to determine whether subsequent commerci approval is warranted.

NK = Not Known

OF SELECTED MACHINE DATA

LITH 2200	WOLF PIEZOLITH 2300	EDAP LT.01	TECHNOMED SONOLITH 2000
any	West Germamy	France	France
d	Dual Ultrasound	Ultrasound	Ultrasound
	Yes	Yes	No
tric	Piezoelectric	Piezoelectric	Spark discharge
cm	NK	0.4 x 1.5 cm	1.5 x 0.3 cm
0 Bar le in 4 steps)	4 levels available	Variable 1000 Bar	Fixed 800 Bar
	NK	4800	1700
	No	None	ECG
	NO	No	Yes-but not in the future
gassed water	Warmed degassed water	Water enclosed with Membrane	Degassed water
	Kidney and ureteral stones,gallstones and biliary duct stones	Kidney and ureteral stones	Kidney and ureteral stones
	Yes	No	No
tal	Yes	Yes	Experimental
	NK	30 sq m	25 sq m
	NK	45	5
	NK	$A 1.2m*	$A 1.3 m*
for IDE	NK	IDE (Clinical testing at 3 sites)	IDE (Clinical testing at 3 sites)

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An
ufacturer to
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