Do we need second generation lithotripters in Hawaii?

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The Kidney Stone Center of the Pacific (KSCoP) currently provides statewide services for kidney lithotripsy. The non-invasive technique uses shock waves to disintegrate kidney stones. Extracorporeal shock wave lithotripsy (ESWL) can be used successfully in 85% to 90% of kidney stone patients when surgery is indicated[1].

The success of lithotripsy for the treatment of kidney stones aroused the interest of physicians treating biliary (gallbladder) disease as well as the vendors of lithotripsy devices; kidney stones affect only one-tenth as many people as do gallstones. Because of the anatomical problems in treating gallstones, design modifications had to be made to the first kidney lithotripters in order to adapt to the imaging, patient positioning, and specifically for therapy focusing required for treatment of gallstones. The Food and Drug Administration (FDA) approved clinical trials for biliary lithotripsy in the United States in 1988. It has been estimated that 15% to 30% of gallstone patients would be candidates for biliary lithotripsy[2].

The Kidney Stone Center of the Pacific initiated lithotripsy services for kidney stones in Hawaii in 1986 and is, therefore, the source of lithotripsy technological knowledge in the state. The KSCoP assumed the responsibility of assessing the status of the clinical efficacy of biliary lithotripsy and, if satisfied, planned to apply for a Certificate of Need (CON) to introduce biliary lithotripsy in Hawaii. A letter of intent was filed with the State Health Planning and Development Agency.

Methods

The KSCoP invited a group of physicians (gastroenterologists, general surgeons, radiologists, urologists), hospital administrators, technicians and consultants to organize themselves into a group to consult with the major vendors of biliary lithotripters and advise how to proceed with a CON application. The group met with 4 vendors during the period February to May 1990: Dornier, Siemens, Technomed and Medstone. Both a sales representative and a physician currently using the respective machines were present at each vendor meeting. Presentations included information pertaining to: Patient selection, procedure technique, technology used, localization method, results of clinical trials, comparison to other machines and acquisition and maintenance costs.

All of the lithotripters reviewed were second-generation, dual-purpose (kidney and biliary) devices. Whereas first generation devices required the patient to be partially immersed in a large water bath under general anesthesia, second generation devices are "dry", and the patient can be under either general anesthesia or intravenous sedation, but conscious. The "dry" devices included a patient-positioning treatment table and some type of fluid-filled coupling system, such as a fluid-filled bellows or a mini-water bath built into the treatment table, or a fluid-filled bag.

The Siemens Lithostar Plus, Technomed Sonolith 3000 and Medstone STS are already FDA-approved for kidney lithotripsy. The Dornier MPL 9000 does not yet have approval for kidney lithotripsy (no device has yet received FDA market approval for biliary lithotripsy).

The KSCoP's existing unit is a Dornier HM3, a first generation device. The group conducting the analysis also considered whether a second generation device should be acquired to replace the HM3, or be used as a back-up for kidney lithotripsy until FDA approval is obtained for biliary lithotripsy.

Subsequent to KSCoP's meetings with the vendors, the FDA announced a revised protocol for a Phase II of clinical testing for biliary lithotripsy. Under Phase II, the clinical test results must be presented and compared between lithotripsy alone, lithotripsy together with bile acid therapy, and bile acid therapy alone.

Results

A summary of the distinguishing characteristics of each vendor's lithotripter follows.

Dornier

The Dornier Multipurpose Lithotripter (MPL) 9000 was operated at 10 clinical test sites for biliary lithotripsy under FDA Phase I protocol. Clinical data was presented to the FDA in October 1989 to seek pre-market approval. The FDA denied approval and requested follow-up of patients for 12 months. Dornier plans to continue clinical test trials under FDA Phase II protocol, but at a reduced number of test sites.

The MPL 9000 uses a spark-gap power source and ultrasound for localization and visualization. The purchase price is $1.35 million. An x-ray attachment also is available for an additional $150,000 to $200,000. The annual maintenance fee is $105,000; the manufacturer recommends spark-plug replacement after each procedure. The cost per spark plug is $165; 2 are used per procedure.

A trade-in credit is available for the HM3 (the unit currently in use at the Kidney Stone Center), ranging from $250,000 to $400,000 depending on the age of the equipment.

The MPL 9000 does not yet have FDA approval for kidney lithotripsy, but the vendor is projecting market approval in 1991. The physician using the device reported that once the procedure has been mastered, average treatment time is approximately 30 minutes for kidney stones and 90 minutes for gallstones. The shock wave treatment technique involves first fragmenting the stone, then pulverizing it. He performed the procedures without general anesthesia and reported there were no complications. No adjustments are necessary to switch from a kidney to a biliary procedure except that the anesthesia machine had to be moved

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Received for publication June 13, 1991.

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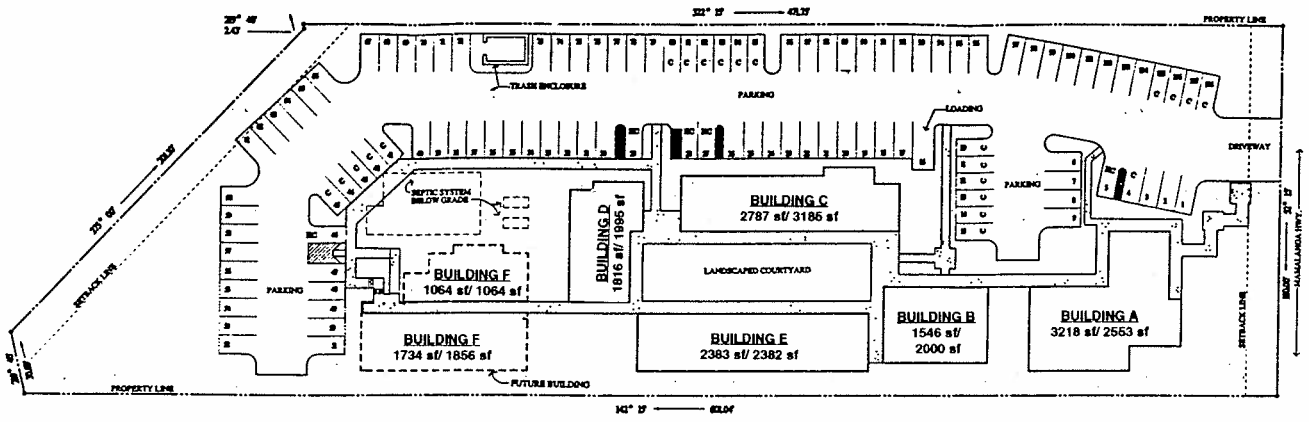

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from one end of the table to the other.

The MPL 9000 is a fixed device; a mobile model is not available. Anatomical positioning is done through the use of a 5-axis table. The therapeutic C-arm can be positioned above or below the treatment table. The therapeutic unit consists of an impulse generator, an electrode, an ellipsoid and a water cushion connected to a closed system of circulating water.

Siemens

The Siemens Lithostar Plus is available in both fixed and mobile models. There are 10 fixed clinical test sites and one mobile clinical test site for biliary lithotripsy. The Lithostar Plus is already FDA approved for kidney lithotripsy. Siemens plans to continue conducting clinical test trials under FDA Phase II protocol.

The Lithostar Plus uses an electromagnetic power source and has integrated ultrasound and x-ray localization. The electromagnetic source produces lower energy shocks than spark-gap power sources and pulverizes rather than fragments the kidney stones. For use on gallstones, a biliary attachment shock head capable of doubling the energy is attached. The gallstone is cracked at a higher energy level, then the power is lowered to pulverize the stone. Acquisition price is $1.4 million for the fixed model and $1.8 million for the self-contained mobile model. The biliary attachment is an additional $300,000, annual maintenance fee is $96,000 for kidney, and an additional $24,000 for biliary. The shock heads are recommended to be replaced every 1 million shocks (approximately 200 procedures). Replacement cost is $7,400 for the shock head. A trade-in credit for the HM3 is available for $400,000.

The Lithostar Plus is designed as a urologic work station. Its therapeutic unit is ceiling mounted to allow access from all sides of the treatment table. Standard urologic accessories can be mounted on the table. A radiographic bucky cassette is built into the table to permit x-rays for checking on stone fragmentation without moving the patient. The table is computer controlled on 3 axes for positioning. The shock wave tube is water-filled and coupling bellows are placed against the patient's skin.

Because of the lower energy used, the procedure is almost pain-free and the physician reported usually using no anesthesia and performing most procedures on an outpatient basis. The physician using the device noted that clinical tests in Europe were having better results than in the United States. The reason given was that the U.S. sites were not using the low energy technique properly; treatment time averaged about 1 hour per case.

Biliary clinical test trials on 101 patients averaged 2.3 treatments per patient to obtain fragments of less than 4 mm. More clinical test data is needed before the request for FDA biliary approval is filed.

Technomed

The Technomed Sonolith 3000 is available in fixed and trans/mobile models. There were 9 fixed and 3 trans/mobile clinical test sites for FDA Phase I protocol for biliary lithotripsy. The Sonolith 3000 is already FDA approved for kidney lithotripsy. Technomed plans to continue clinical test trials under FDA Phase II protocol; however, the number of sites has not yet been determined.

The Sonolith 3000 uses a spark-gap power source with continuous-feed electrodes that may be used on 100 patients before replacement. Replacement is included in the annual maintenance fee. Ultrasound is used for stone localization. Acquisition price is $1.09 million for the fixed and $1.235 million for the trans/mobile plus an additional $70,000 for the transport van. Annual maintenance fee is $110,000 for the fixed and $130,000 for the trans/mobile. The maintenance fee is reduced by $20,000 if ultrasound is excluded from the Technomed maintenance and arranged for separately. Portable x-ray also is available for $50,000.

The shock wave generator of the Sonolith 3000 is mounted at the base of the water basin/"minipool" coupling. The frame of the mobile sub-assembly supports the water basin. The water processing system is contained within the treatment module. Method of anesthesia is by intravenous sedation of the conscious patient or none at all.

Medstone

The Medstone Shockwave Therapy System (STS) is available in fixed and mobile models. There were 10 fixed clinical test sites and 2 mobile clinical test sites for FDA Phase I protocol for biliary lithotripsy. The STS is already FDA approved for kidney lithotripsy.

Medstone presented clinical data to the FDA in October 1989 to seek pre-market approval for biliary lithotripsy. The FDA denied approval and requested longer and more consistent follow-up on more patients. Medstone's use of historical controls did not adequately clarify the device's efficacy for gallbladder applications. Stone-free rates at six months, one of the outcomes reported varied at different test sites from 0% at 3 sites to 66% at one site. Medstone has temporarily discontinued biliary test trials and as of December 1990 did not plan to pursue the FDA Phase II protocol testing. The device is still marketed, however, for kidney lithotripsy.

The STS uses a spark-gap power source and integrated ultrasound and x-ray for localization and visualization. The acquisition price is $1.375 million for either the fixed or mobile device. The trailer for the self-contained mobile unit costs an additional $300,000, the annual maintenance fee is $125,000 and the device uses one spark plug which is replaced after each procedure. The cost of a spark plug is $270. Medstone also has an alternative pricing structure which includes a sliding-scale, fee-for-service cost based on patient volumes ranging from $2,000 a patient to $750 a patient. There is no maintenance fee or spark-plug replacement cost on the fee-for-service pricing.

The STS shock-wave generator is located beneath a customized x-ray treatment table. The shock-wave is focused by a curved reflector as it travels through water-based fluids contained in the reflector. A fluid-filled disposable bag couples the patient to the shock-wave generator and a computer assists in positioning the patient. The table is adjustable in 3 dimensions. The STS also can be used for general x-ray, ultrasound, and urological procedures. Lithotripsy procedures on the STS average 45 to 90 minutes in duration.

Table 1 compares the key features of each lithotripter analyzed.

Discussion

The use of drugs and biologicals

Although cholecystectomy today is considered the safest, most effective and most recommended treatment for gallstones, the pharmaceutical and biological approaches also are under study. Two types of dissolving agents being investigated with some success include: (a) Orally administered bile acid compound

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(ursodeoxycholic acid). The medication is administered over a 1- to 2-year treatment period. A dissolving effect has been achieved only in stones composed mainly of cholesterol and no calcium salts, pigments or mucus. A research study reported a 10% recurrence rate within 1 year after discontinuation of bile acid medication[3]; (b) Catheter-administered cholesterol-solvent methyl tert-butyl ether (MTBE) dissolves the stones more rapidly than do bile acid compounds. MTBE dissolves cholesterol stones in an average of 12.5 hours; advanced equipment may reduce the time to less than 4 hours. The treatment must be administered carefully through a percutaneous catheter[4].

A new surgical option

A new surgical procedure, laparoscopic cholecystectomy, has been introduced and now is being performed in Hawaii. The procedure involves the physician making only a few small (approximately half-inch) incisions in the patient's abdomen. An optical scope (laparoscope) is inserted through one incision into the abdominal cavity. The physician, viewing the operation on a video screen, removes the gallbladder through one of the small incisions. Electrocautery units and lasers are used to detach and remove the gallbladder. The advantages of the procedure include[5-6]:

- Only 2 to 3 days recuperation, compared to 3 to 4 weeks for conventional cholecystectomy surgery.
- Reduced hospital stay, thereby reducing costs to the patient.
- Reduced scarring due to the small incision.
- Greater comfort.

Conclusions

Following the analysis, the group reached the following conclusions: Lithotripter technology is still evolving; biliary applications of lithotripsy are still investigational; the clinical efficacy of biliary lithotripsy has yet to be proven; no vendor is likely to receive FDA approval to market biliary lithotripters in the United States much before 1993; only about 15% to 30% of gallstone patients would be candidates for biliary lithotripsy due to its limited indication under the current FDA protocol for investigational use for stones of only a certain size, composition and location; and the advent of laparoscopic cholecystectomy presents a cost effective, lower morbidity, surgical option to traditional cholecystectomy surgery for patients suffering from gallbladder disease.

Key Features For Lithotripter Comparison As Of December 1990

	Acquisition List Price	Trade in Credit	Annual Maintenance	Technology	Localization	FDA Approval Kidney	FDA Approval Biliary	FDA Phase II Biliary Test Trials
Dornier Fixed MPL 9000	$1.35 million	$250,00-400,00	$105,000	Spark Gap Single Use Electrode	Ultrasound X-ray Attachment Avail ($150,000-200,000)	No-Project 1991	No	Yes
Siemens Fixed Lithostar Plus	$1.4 million +$300,000 Biliary Attachment	$400,000	Kidney-$96,000+ Biliary $24,000	Electromagnetic	Ultrasound & X-ray Integrated	Yes	No	Yes
Siemens Self Contained Mobile Lithostar Plus	$1.8 million +$300,000 Biliary Attachment	$400,000	Kidney-$96,000+Biliary $24,000	Electromagnetic	Ultrasound & X-ray Integrated	Yes	No	Yes
Technomed Trans/ Mobile Sonolith 3000	$1.235 million +Van ($70,000)	Willing to Discuss	$130,000 (-$20,000 if Ultrasound excluded) (Includes replacement Electrodes if needed)	Spark Gap Continuous Feed Electrode	Ultrasound Portable X-ray X-ray Avail	Yes	No	Yes
Technomed Fixed Sonolight 3000	$1.09 million	Willing to Discuss	$110,000 (-$20,000 if ultrasound excluded) (Includes replacement electrodes if needed	Spark Gap continuous feed electrode	Ultrasound Portable X-ray avail ($50,000)	Yes	No	Yes
Medstone Fixed STS	$1.375 million or Fee-for-Service	Yes-Negotiate Amount ($2,000 to $750/patient)	$125,000 ($0 on Fee-for Service)	Spark Gap-Single Use Electrode	Ultrasound & X-ray Integrate	Yes	No	T/D*-
Medstone Self Contained Mobile STS	$1.375 million + Trailer ($3000,000)	Yes-Negotiate Amount	$125,000	Spark Gap-Single Use Electrode	Ultrasound & X-ray Integrated	Yes	No	T/D*

*Temporarily Discontinued

The overall conclusion of the analysis is that biliary lithotripsy should not be introduced in Hawaii until the clinical efficacy and cost benefit of the service can be demonstrated.

The KSCoP will continue to monitor the technologic progress of biliary lithotripsy and alternative treatments of gallstones. At such time that a responsible decision can be reached that Hawaii would benefit from the availability of biliary lithotripsy, the KSPoP will submit a CON application to establish the service in Hawaii.

The group further concluded that a second generation device should not be acquired at this time as either a replacement for the current Dornier HM3 or as a back-up. Major reasons include: The cost of health care would be unnecessarily increased without any improvement in the quality of care; additional capacity is still available from the existing HM3; the State does not have a need for a second kidney lithotripter as yet; physicians using the existing HM3 are satisfied with its performance and the device has rarely needed down time due to mechnical problems; physicians in the group conducting the analysis preferred the use of general anesthesia because of the controlled respiration which reduces the time required to perform the procedure as well as the number of shock waves required; and physicians noted that re-treatment appeared to be necessary more often when the second generation devices were used (21%)[7], were used as compared with the current experience with the HM3 in Hawaii (9%)[8].

ACKNOWLEDGMENTS

The group conducting the analysis for the Kidney Stone Center of the Pacific included: James Grobe MD, Howard Minami MD, Stanley Shimoda MD, William Morioka MD, Gene Robinson MD, Bradley Wong MD, Howard Arimoto MD, John Cieply MD, Curtis Kamida MD, Thomas Ito MD, James Stewart MD, Walter Strode MD, Kuakini Medical Center Gary Kajiwara, Queen's Medical Center Constance Wiletzky, Straub Clinic & Hospital Richard Stenson and Hospital KSC Administrative Manager Stephen Knoll; Supervisor, Doris Oshiro, Special Procedures Technologist, Marlaine Fern, Marketing, Ellen Kumata, KSC Marketing, Garrett Kawamura and Nancy Crocco Ernst & Young.

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