Ultrasound Makes Waves

by Margie Patlak

Ultrasound became a household word in the 1970s, when it was readily embraced by obstetricians, who used the high-frequency sound to peer into the womb. Many mothers "saw" their children before they were even born, thanks to ultrasound, which often suggested whether to buy pink or blue baby outfits, among other things.

With recent improvements in ultrasound's image quality and ease of use, this technology has found its way into almost every branch of medicine. Physicians now use ultrasound to detect tumors, aneurysms, blood clots, detached retinas, heart abnormalities, and kidney stones. Ultrasound can also map plaque buildup on arteries, and assess if a transplanted organ is being rejected.

On the treatment front, ultrasound is being used to treat glaucoma, speed the healing of bone fractures, and relieve the pain and stiffness of arthritis and other inflammatory disorders. Ultrasound also can aid surgery, cancer therapy, *in vitro* fertilization, and several dental procedures.

Seeing with Sound

Ultrasound's widespread popularity in the diagnostic arena stems from its relatively low cost, ease of use, and record of safety compared with other tools for diagnosing various disorders. Ultrasound also fares better than many imaging devices when it comes to picturing soft tissues in the body. It can also provide instant displays of moving structures and can offer other information on the functioning of an organ.

One way doctors use ultrasound to get the inside scoop on their patients' bodies is with a procedure known as pulse-echo imaging. During this procedure, a microphone-like device, known as a transducer, is moved across the skin over the part of the body the doctor wishes to view. The transducer emits sound waves (ultrasound) at a frequency too high to be heard by people.

When these waves bounce off various tissues and organs on their journey through the body, they generate distinctive echoes that are conveyed to a computer. The computer translates the timing and strength of these echoes into an image of the internal organs or tissues targeted by the ultrasound beam.

The ultrasound image (sonogram) is usually viewed on a television screen. When rapid pulses of ultrasound are used, a "movie" of a moving structure, such as a fetus or beating heart, can be seen.

There is no pain involved in pulse-echo imaging, although there may be some discomfort in procedures such as a pelvic sonogram, which requires the patient to maintain a full bladder while the womb (uterus) is imaged. The patient lies on an examination table for the procedure, which takes anywhere from five minutes for a pelvic sonogram to an hour for an ultrasonic exam of the heart. A gel is put on the patient's skin where the transducer makes contact. This gel improves the penetration of ultrasound waves.

A Womb with a View

Obstetricians frequently use pulse-echo ultrasound imaging to "see" what's happening inside the uterus. It can give valuable information, including:

- the size, number or age of fetuses in the womb. (Age is accurately assessed by measuring the length of the fetus or by measuring its thigh bone length and head circumference.)
- the presence of some types of birth defects
- location of the fetus or placenta (useful in the delivery of breech babies or during amniocentesis)
- fetal movement, breathing and heartbeat
- amount of amniotic fluid in the uterus (which helps in the assessment of fetal health).

Although most current studies do not indicate health risks to the unborn child from ultrasound imaging, more research needs to be done to determine this with certainty. Ultrasound imaging employs a different kind of radiation than x-rays, which clearly can harm the fetus. However, ultrasound can generate heat, microscopic bubbles, or vibrations, which could possibly affect fetal development.

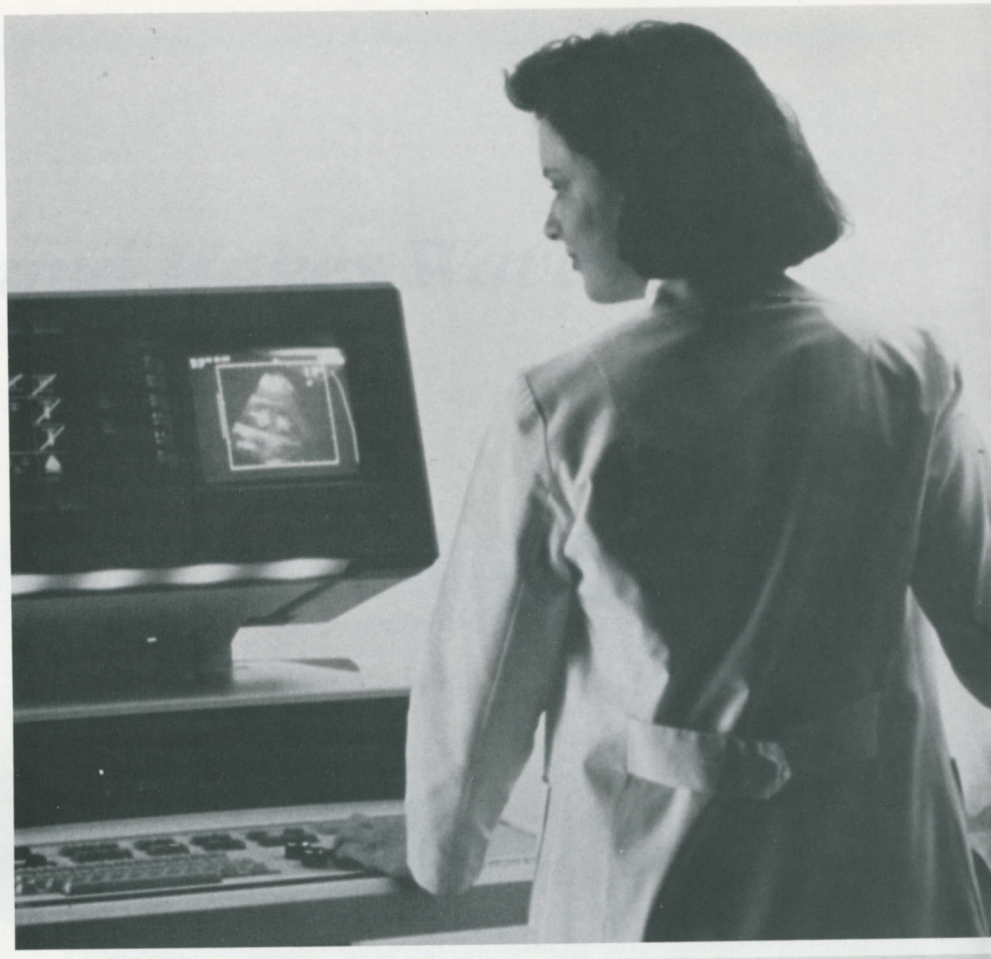
An FDA panel, consequently, has recommended that ultrasound imaging not be done on pregnant women unless there is a specific medical reason such as vaginal bleeding, signs that the fetus is not growing properly, or a family history of congenital abnormalities. Ultrasound imaging should *not* be used, for example, just to get a glimpse of a fetus or to determine its sex.

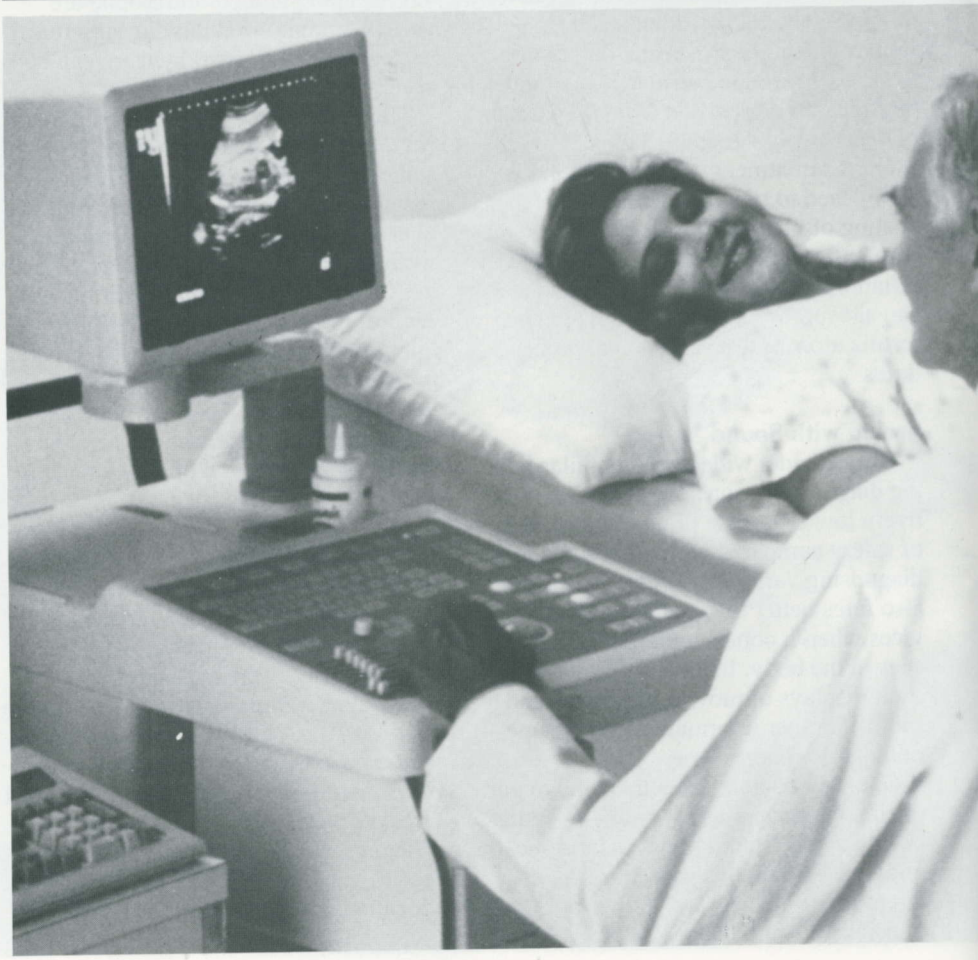
Probing Lumps and Bumps

Pulse-echo ultrasound imaging has many other uses as well. Because it's an excellent tool for sizing up organs and spying any internal lumps or bumps, doctors often use ultrasound imaging to probe tissues for tumors, cysts or abscesses. Ultrasound is one of the safest tools doctors have for this purpose.

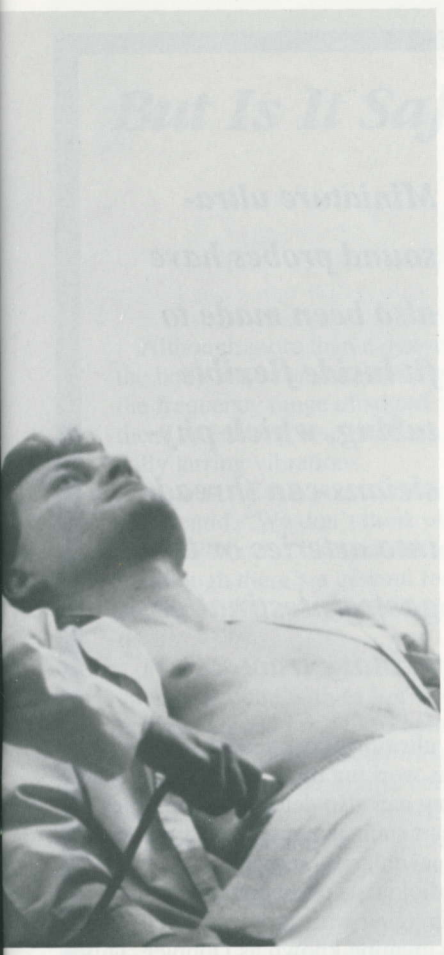
Unlike x-rays, sonograms can reveal not only whether there is a lump within a part of the body, such as the ovaries, but if that lump is likely to be a benign cyst or a solid tumor. Ultrasound is able to make this distinction, because a fluid-filled cyst has a different "sound signature" than a solid mass.

If a needle biopsy is warranted, ultrasound imaging can show doctors where





In the top photo, a practitioner performs an abdominal ultrasound exam, which may help doctors diagnose diseases of the liver or gallbladder. Below, the practitioner moves a transducer above the area of the uterus as ultrasound waves produce an image on the monitor that may show if there are birth defects or twins. The baby's position and sex may also be evident. (Photos on this page courtesy of the Society of Diagnostic Medical Sonographers)



Obstetricians frequently use pulse-echo ultrasound imaging to "see" what's happening inside the uterus.

to insert the needle to extract cells from abnormal tissue. Such needle biopsies can eliminate the need for surgery.

FDA has recently cleared more precise needle biopsy systems, in which a miniature ultrasound transducer is attached to the tip of the needle. From information gathered by the transducer and translated by a computer, doctors can see on a television monitor exactly where the needle tip is at all times during the biopsy.

Pulse-echo imaging can also spy stones in the kidney or gallbladder and indicate whether organs or tissues are abnormally enlarged. Oversized lymph nodes, for example, may suggest a cancerous condition.

A bulge in an artery detected by ultrasound, in addition, may signal an aneurism, which may need to be surgically treated to prevent it from bursting and causing life-threatening internal bleeding. Ultrasound can also detect dangerous buildups of plaque in the carotid artery, the main supplier of blood to the brain. Early detection and removal of plaque in the carotid artery can prevent strokes.

In ophthalmology, pulse-echo imaging is routinely used to measure the length of the eye to fit lenses after cataract removal. Ultrasound can also spot foreign bodies or bleeding within the eye, detached retinas, swelling of the optic nerve, and other eye disorders. (During eye ultrasound exams, the transducer is placed on the eyelid.)

Because ultrasound doesn't adequately penetrate air or bone, it can't be used effectively to image the lungs or skeletal system. Excessive fat deposits or large scarred areas can also hamper the quality of a sonogram.

Newer ultrasound probes have been developed that can be placed within the vagina or rectum. These wand-shaped probes are allowing physicians to use pulse-echo imaging to detect tumors in the rectum and prostate, as well as enabling them to watch for the release of eggs from follicles, so they can be collected for *in vitro* fertilization.

Over the past five years, miniature ultrasound probes have also been made to fit inside flexible tubing, which physicians can thread into arteries or the gastrointestinal or urinary tract. Because the ultrasound beam is closer to target organs or tissues, it can reveal much more detail than standard pulse-echo imaging done from the skin's surface.

Sonograms generated during such endoscopic exams can show how deeply cancerous tumors have penetrated within the intestines, esophagus, stomach, or rectum and whether they've entered the lymph nodes, the muscular wall, or adjacent organs. This information allows physicians to assess the best forms of therapy for the cancers.

Physicians also use endoscopic ultrasound to map the topography of plaque lining arteries, or to detect abnormalities in the urethra, bladder or kidneys.

Surgeons have begun using ultrasound during operations, in addition, to provide more complete views of the structures on which they are working. It can show the size and shape of the obscured portions of a tumor that needs to be cut out, for example.

The Tell-Tale Heart

More tried and true is the use of pulse-echo imaging in cardiology. Doctors have used this form of ultrasound imaging for decades to help assess the health of their patients' hearts. Often an ultrasound exam of the heart and its arteries eliminates the need for angiography, an invasive, riskier, and more uncomfortable way of assessing heart health.

By showing the size and shape of the chambers and valves of the heart as it

Ultrasound as Therapy

Ultrasound by itself is being used as therapy for a wide range of disorders, from sprained ankles to tumors. Although ultrasound has been used therapeutically since it was first developed in the 1950s, researchers are just beginning to document its safety and effectiveness in treating patients with various ailments. Most therapeutic uses of ultrasound apply sound waves at a higher frequency than those used to image tissues.

Glaucoma

About three years ago, FDA approved the use of ultrasound to treat patients with certain forms of glaucoma. With this treatment, a focused beam of ultrasound is targeted on the cilary body, a portion of the eye that creates fluid within the eyeball. A buildup of this fluid causes excess pressure—the hallmark of glaucoma—that can cause blindness. The heat and vibrations of the ultrasound waves destroy fluid-secreting cells in the cilary body, thereby stemming fluid buildup and subsequent pressure.

Muscles and Joints

Ultrasound is also used to treat patients with pain, muscle spasms, or stiff joints. Ultrasound can raise the temperature of patients' joints, and in animal studies has been shown to improve the flexibility of the joints. Some physicians prescribe ultrasound for patients with arthritis, bursitis, tendinitis, or other types of inflamed or sprained joints to relieve pain and stiffness.

Although ultrasound does seem to work for some patients, studies do not clearly show whether their pain relief and increased mobility stem from the actual treatment or a placebo effect (their belief that it can help). Well-designed clinical trials are needed to resolve this question, according to an article in the June 1990 issue of *Arthritis Care and Research,* by Judith Falconer, Ph.D., and colleagues at Northwestern University Medical School.

Broken Bones

James Heckman, M.D., of the University of Texas Health Science Center in San Antonio has reported that in a small, recently completed study, ultrasound treatment sped the healing of bone fractures in the shin in patients receiving 20-minute daily doses of ultrasound. Heckman told a meeting of the American Academy of Orthopedic Surgeons that the patients were able to shed their casts a month earlier than those given a placebo treatment.

In the study, patients administered the ultrasound themselves by putting a transducer into a hole cut into their casts above the fracture site. Once switched on, the transducer emitted ultrasound waves within the frequency range used for diagnostic ultrasound. According to Heckman, the patients experienced no adverse side effects from the treatment.

It's not certain how ultrasound might aid the healing of broken bones, although researchers speculate that it triggers the release of compounds used by the body to repair itself. FDA has not yet approved the use of ultrasound to treat bone fractures, although patients can receive the treatment as part of an experimental study.

Tumors

Ultrasound is also being used experimentally to heat and kill cancer cells, making tumors more susceptible to radiation therapy. Doctors are trying the same treatment on patients with noncancerous tumors of the prostate. These tumors can press shut the urethra, preventing the bladder from emptying. The conventional treatment for this painful condition is surgical removal of the tumors. Some studies show that ultrasound therapy can sometimes shrink the tumors so they no longer block the urethra; however, FDA requires more studies to assess the safety and effectiveness of this type of ultrasound therapy. ■

—M.P.

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beats, ultrasound can reveal whether the heart is working up to snuff. Pulse-echo imaging can also detect abnormalities in the heart such as tumors, calcium deposits, or an enlarged region.

Cardiologists often combine pulse-echo imaging with another form of ultrasound imaging known as Doppler. This type of ultrasound makes use of the commonly observed phenomenon that sound changes pitch when it strikes moving objects—a train whistle changes pitch, for example, as the train passes.

In the body, Doppler ultrasound can record the changes in pitch as sound waves bounce off circulating blood or the beating heart. A computer then uses the information to figure out how fast blood is flowing or the heart is beating.

Doppler ultrasound not only can indicate how well the heart is working, but it can also spot blockages in arteries and clots in veins and assess if artery grafts in the legs are working properly.

Obstetricians use Doppler ultrasound to "hear" fetal heartbeats. This form of ultrasound is also used in monitoring kidney transplant patients to detect any blood flow disturbances in the transplanted organ. Such disturbances can signal early on that the body is rejecting the organ.

Recently, systems have been developed that transform information gathered during a Doppler ultrasound exam into a color-coded map of the area imaged. Because different rates of blood flow are displayed in different colors, physicians can easily see blood flow patterns within an artery, vein, or the heart.

But Is It Safe?

Although more than a quarter of a century's use of ultrasound to peer inside the body has caused no obvious harm to patients, animal studies suggest that the frequency range of sound used to image tissues can potentially damage them by causing heat build-up, disruptive microscopic bubbles, or mechanically jarring vibrations.

Because of this potential for harm, FDA advises prudent use of diagnostic ultrasound. "We don't think ultrasound should be used frivolously," says Collin Pollard, a biomedical engineer at FDA's Office of Device Evaluation. "Although there's a general feeling that ultrasound is safe," Pollard adds, "you are depositing energy any time you use ultrasound, and that energy can affect tissues."

FDA takes the approach, according to Pollard, that ultrasound imaging should be done with as low an output of acoustic radiation as possible to achieve a good image. To help practitioners achieve this, the agency is currently developing a recommendation for a safety index system that could be incorporated into ultrasound imaging devices. The index would display the risks associated with each dosage level used during the imaging procedure.

Most ultrasound therapies carry greater risk than ultrasound diagnostic procedures because the sound waves are usually applied in larger doses. There's more potential for destroying tissue, consequently, by overheating or by mechanical disruption. When ultrasound is used to treat inflamed or sprained joints, for example, it can sometimes damage the muscle, bone, nerve, or other tissues on which it is focused.

FDA has established ultrasound treatment guidelines, however, to reduce the chances of such damage occurring. To prevent birth defects, in addition, the agency advises that therapeutic ultrasound not be delivered to the gonads, testes, ovaries, or uterus.

Ultrasound is also not recommended for the relief of pain or stiffness in parts of the body numbed by nerve damage or anesthetics. Such numbness prevents patients from feeling a burning or pinching sensation when ultrasound is overheating tissues. (Patients report these sensations to practitioners so they don't apply damaging levels of ultrasound.)

FDA is responsible for ensuring the safety and effectiveness of ultrasound devices. Many ultrasound devices used today (or their mechanically similar predecessors) were marketed before the law required pre-market approval of medical devices for safety and effectiveness. Much ultrasound equipment, consequently, has not undergone the rigorous scrutiny required for FDA's formal approval. The agency continues to monitor ultrasound devices for safety, however, and has the authority to require safety and efficacy data and to take off the market any device found to be unsafe. ■

—M.P.

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Aiding Treatment and Surgery

Ultrasound not only aids diagnosis, but frequently is a major player in various treatments. Ultrasound images show physicians where to place a needle to drain abscesses, for example, or where to put radioactive pellets for prostate cancer treatment.

In a procedure with an FDA-approved device called extracorporeal shock-wave lithotripsy, which can be an alternative to surgery, ultrasound images show physicians where to target high-pressure shock waves that shatter kidney stones so they can be passed in the urine. (The application of this technique to gallstones is under investigation.) Recently, scientists have begun studies of the use of an ultrasound device that can also *create* the shock waves that break up kidney stones. This device has not yet been approved by FDA.

Surgeons work with a device that uses ultrasound to rapidly vibrate a needle. This ultrasonically driven needle allows them to selectively destroy soft tissues, such as certain types of tumors, without damaging surrounding fibrous tissues. "It can destroy cancerous tissue in the lungs, for example," says Neil Ogden of FDA's general surgical devices branch, "without hurting the bronchial tubes or nerves and veins in the area."

Ophthalmologists often use this type of surgical device to break up cataracts that obscure vision. Similarly, dentists commonly use a tool that uses ultrasound to vibrate a small metal probe to help chip away at deposits on the surface of teeth during cleaning. This dental device, known as an ultrasonic descaler, can quicken dental work, as well as lessen patients' discomfort. Some dentists are using a modified ultrasonic descaler in an experimental procedure to break up tissues during root canals or tooth extractions.

Ultrasound is also being used as a therapy by itself (see "Ultrasound as Therapy"), but some of these uses are experimental. Although ultrasound is a relatively old medical tool, high-frequency sound may also be the wave of the future. ■

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