

CTSI: FULL SPEED AHEAD

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In the face of naysayers, hucksters, and scrutinizing colleagues, a few radiologists are persevering to offer full-body CT scans in a professional atmosphere according to select patient criteria. CT Screening International (CTSI) is a Newport Beach, Calif-based venture formed in January 2001 by Richard Penfil, MD, a former radiologist and entrepreneur, and Michael N. Brant-Zawadzki, MD, medical director of radiology at Hoag Memorial Hospital, Newport Beach, and a visiting clinical professor of radiology at Stanford University School of Medicine.

CTSI opened its first center in February 2001 in Newport Beach, followed by another dozen centers over the next 13 months in New York, New Jersey, and California. Financing for the centers has derived largely from private investors, and a few corporate sponsors. Ed Finkelstein, CTSI's retail expert, says the first center cost just over \$900,000 to build, and the rest vary between \$700,000 and \$900,000, not including equipment charges. The focus of each clinic is on detecting heart, lung, and colon disease, which Penfil says are "the three major killers, and they can be predicted ahead of time and successfully treated when they are caught early."

CTSI technician Bryon Rose positions a patient for a scan at the Beverly Hills, Calif, location

Penfil first came across information about full-body screening in August 2000 and approached Brant-Zawadzki to inquire about his position on the procedure. Brant-Zawadzki had been writing articles about CT screening since 1996, and believed the procedure was extremely beneficial to patients.

"Physicians were already using full-body CT scans as an extension of their diagnostic capabilities, especially in the emergency department in place of the physical examination due to the greater sensitivity for detecting abnormalities," Brant-Zawadzki says. "Many were using it to screen for lung cancer, although they usually put down the indication for the study as difficulty breathing.' These practitioners knew the CT scan was more sensitive, but they also knew that insurance wouldn't reimburse for a screening' CT."

Such scans were already being done in Hoag Memorial Hospital's outpatient facilities as well for calcium scoring and lung cancer screening. However, the environment proved far from ideal for the patient population.

"We found that people didn't like to come to the hospital or the diagnostic facilities because those without significant disease processes don't like to be around sick people," Brant-Zawadzki says. "They don't want their wait times interrupted by emergencies. When a patient is paying out of pocket for a service, they want a streamlined experience."

Penfil and Brant-Zawadzki were in agreement that it would not be a big stretch to offer that same screening service to individuals who did not have physicians or who could not get in to see them, such as

an HMO situation. They wanted to see the screenings offered in a place dedicated to preventive medicine. While Brant-Zawadzki admits that the entrepreneurial nature of many such centers makes it difficult to exclude any individual willing to pay for a study, most centers attempt to exclude individuals under the age of 40.

"The financial incentive clearly tempts some to lower the threshold," he says. "But at CTSI, patients must be over 40 and have certain risk factors before they can come in."

The Patient Experience

CTSI's centers are designed to make the patient's experience more enjoyable and comfortable, with as little wait time as possible. Patients are seen within 5 to 10 minutes of their scheduled appointment time, and each center is staffed by a greeter whose sole job is to make the patient feel comfortable. The entire procedure from stepping in the front door to leaving the facility is under 1 hour, which means that each center can see roughly two patients per hour.

"When the patient comes in, they are taken to a comfortable, private room relatively quickly," Penfil says. Each room is equipped with a computer that allows the patient access to a tutorial on the CT screening process. The scan is then carried out by a radiologist using CTSI's technology, formerly four-slice CT units now being replaced with 16-slice CT units.

"Though radiologists have screened with everything from electron beam CT technology (EBCT) to single-slice CT to four-slice CT, EBCT cannot be used with anything but coronary calcification, and single-slice cannot be used for that purpose at all," Penfil says.

Coronary calcium detection with EBCT was the earliest form of CT screening, and while its speed is suited to whole body scanning, its overall image quality suffers from heat limitations of the electron beam target and the amount of photon flux produced, according to Brant-Zawadzki.

"Diagnostic CT body scanning was therefore first relegated to conventional CT scanners, which have now evolved to multidetector, multislice, helical technology. This has all but erased the speed advantage of EBCT while maintaining the quality of imaging necessary for optimal diagnosis," Brant-Zawadzki says. "Nevertheless, multislice, multidetector CT-based outpatient screening centers are still in the minority compared to ones equipped with EBCT, the latter being predominantly organized by entrepreneurial ventures and staffed only variably by radiologists."

"The four-slice units we currently have can be used for everything short of coronary angiography," Penfil says. "The shift to the 16-slice and further generations are for use in the latter case."

The decision to change equipment places CTSI in the category of the newer radiologist-run facilities, which Brant-Zawadzki defines as those that concentrate on image quality and patient interaction. CTSI also prides itself on attracting high-quality personnel. Trained radiologists staff each center, and are selected predominantly by Brant-Zawadzki and the rest of CTSI's medical advisory board.

Table 1. Abnormalities found January 15, 2001, through July 3, 2001, for 1,807 patients; 855 men, 922 female. Source: CT Screening International database.

The Patient Process

Every patient meets with the radiologist after the examination to go through the results. Patients at each of CTSI's locations receive a CD-ROM of their procedure that they can take with them. All images, which are archived digitally, can be electronically transported among the 13 centers via a network of T1 lines.

CTSI regularly refers patients back to their own doctor and makes suggestions on further study sources.

Brant-Zawadzki says this is essentially the same as the mammography model, which includes a follow-up with the patient by phone or letter to make sure they understand the need to see a physician for subsequent evaluation of any significant abnormalities. Repetition of the screening varies from individual to individual and on the results of the first examination. Some patients whose scan shows an abnormality may need to have a repeat CT within 3 to 6 months.

"CTSI represents a more direct gateway to specialists when patients need it," Brant-Zawadzki says.

"Radiologists interact with specialists on a daily basis, and therefore tend to be very aware of the kinds of referral pathways brought about by an abnormal x-ray or CT finding, as opposed to the delay that occurs when primary care practitioners order a study. In turn, our patients view the radiologist as a knowledgeable diagnostic physician with whom they can interact."

Market Positioning

Making it apparent to patients that knowledgeable radiologists are staffing its centers has been a factor in CTSI's marketing, which is overseen by Finkelstein. Initially, CTSI was marketed directly to patients predominantly through mixed media, with the heaviest emphasis on radio spots. The next significant phases of marketing involved an awareness program to referring physicians and targeted marketing to corporations and associations.

"The biggest portion of the business comes from client referrals, and now we are getting tremendous referrals from physicians as well," Finkelstein says. "Up until recently, a lot of them didn't know what we were doing."

Lastly, CTSI launched a national marketing program to coincide with its expansion plans. An additional 10 centers are in the process of opening, and Penfil anticipates adding another 30 in 2002. Finkelstein says the goal is to have approximately 200 to 300 in the United States and an equal number outside the United States over the next few years. While CTSI also receives daily requests from communities to open new centers, the choice of location is critical to CTSI's focus on quality care by professionals.

"The choice of location relied on the existence of outstanding radiologists in those areas who could deliver excellent care to our clients," Penfil says. "There are hucksters out there, and that is a problem, so we really differentiate on the basis of quality. For instance, if we had a location where we knew the center could do well because there would be a large target population, we still would not build there if we couldn't identify a qualified radiologist."

Sanjy S. Gianchandani, MD, radiologist, reviews a fullbody scan with patient Ryan Corbett at the Beverly Hills, Calif, location.

"Right now, there is not a lot of competition, but there also is no such thing as remaining alone in business," Finkelstein says. "Competition does spring up, but with our infrastructure of quality control and staffing, our modelstrengthened by the reputation of physicians who have been in the radiology business a long timewill be hard to duplicate."

Penfil hopes to add clinics in certain areas across the country, but notes that they must meet certain demographic and need issues. The most difficult aspect of setting up the centers, in fact, is making sure that sufficient referral resources exist, and that other physicians in the area understandand supportwhat CTSI is doing.

"That takes a lot of time and legwork," Finkelstein says. "But we are interested in having clinics open 5, 10, and 20 years from now. We are not looking for a quick in-and-out. That goes back to practicing good preventive medicine. If we offer quality service, our patients will not only come back but they will send other patients to us."

The Value Vs The Controversy

It is the issue of patient's self-referring, and of referring their friends, that strikes a nerve among those in the field who do not support full-body CT screening. Brant-Zawadzki calls that an issue that goes beyond the scope of radiology, however, and cites an article in last year's Journal of the American Medical Association that noted the booming consumer movement in medicine.

"Today we can get blood tests done in the local drugstore and women can get mammography by self-referral," he says. "When knowledgeable patients refer themselves for radiology, however, that is a break in the culture. Interventionalists are used to that and welcome it, but conventional diagnostic radiologists are not. Likewise, the same radiologists who object to the mammography concept don't have a problem when physicians send over inappropriate patients for CT scans. If patients are well informed and refer themselves for something reasonable, I don't see the problem."

Screening also suggests a break with traditional practice patterns by putting radiologists at the forefront of patient management. As with mammography, screening CT takes the radiologists from the back room of doctor-to-doctor consultation, and places them in the front office, according to Brant-Zawadzki. The result is that some physicians, including radiologists, fear that their role will be diminished when the consumer is allowed to direct health care.

"Many radiologists went into this business so they would not have to deal with patients," Brant-Zawadzki says. "However, there also are those who enjoy those kinds of interactions. Full-body CT scanning is an interesting and more direct patient interaction process than things radiologists typically do."

However, Brant-Zawadzki points out, it is not whole body scanning that he is actually endorsing or recommending.

"We do this type of screening to look for early signs of coronary artery disease, lung cancer, and colon cancer in those at risk," Brant-Zawadzki says. "By the time you get done with those areas, by default you have scanned the whole body. In reality, we are targeting those areas of the body that harbor the common killers today."

Another aspect of the controversy over CT scanning is whether it would be used as a substitute for a physical examination, but many proponents see the two as working hand-in-hand rather than being in competition. "A physical examination is relatively useless in detecting abnormalities compared to CT, so it should be used in conjunction," Brant-Zawadzki says. "Physicians know the value of CT, and that's why 33 million [studies] were done last year. Patients should not be barred from having that useful test as long as it is safe and beneficial."

Catching Silent disease

Perhaps the greatest value of the screening process can be seen in the clinical commentary on the modality thus far. Both Penfil and Brant-Zawadzki point out that the high prevalence of silent coronary disease makes the potential of CT in early detection particularly exciting. In fact, the American Heart Association and the American College of Cardiology consensus statement supported "use of the coronary artery calcium score as a validated test adding an additional risk factor to the traditional ones for estimating the presence for silent heart disease, and predicting future events." 1

In cases of lung disease, the role of CT has been commented upon in the Early Lung Cancer Action Project, which documented that "low-dose CT can greatly improve the likelihood of detection of small nodules and thus lung cancer in earlier and potentially more curable stage." 2 Skepticism regarding the value of such screening persists due to the issue of whether early detection of lung cancer translates to a decrease in overall mortality. The current 5-year survival from detected lung cancer is 14%, a statistic that has not significantly improved for the last 25 years.3

Table 2. Patholgical entities found in 1,807 patients scanned by CTSI, January 15, 2001, through July 6, 2001

CT colon screening has been shown to have great benefit not necessarily because it can detect polyps of one centimeter or larger in the colon, and with similar sensitivity as conventional colonoscopy, but because of patient acceptance of the modality.

"The New England Journal of Medicine reported recently on colon cancer and noted that the best test is one that you are willing to have," Brant-Zawadzki says. "Many people are unwilling to undergo a sigmoidoscopy or a colonoscopy, but they usually are willing to undergo a virtual colonoscopy."

In addition to the targeted diseases of lung cancer, colon cancer, and coronary arteriosclerosis, CTSI has discovered evidence in its patients of emphysema, bronchitis, fluid buildup in the lungs, infection, aortic aneurysms, liver cancer, gallstones, kidney stones, kidney cancer, pancreatic cancer, adrenal tumor, ovarian and uterine masses, bladder cancer, spinal problems, and osteoporosis.

"The bottom line is that it's one thing to talk about one or two patients out of thousands, but approximately 22% to 23% of those scanned have significant abnormalities," Penfil says. "We have been able to marry great technology with extremely high quality physicians to perform preventive medicine."

Radiation exposure risk

A final key issue at the heart of the controversy over full-body CT scanning is that of excessive radiation exposure. To compare the presumed risk from diagnostic imaging, Brant-Zawadzki considers that the death rate from cancer in the general population is quite high. He notes that approximately 23% of all individuals will die of cancer, equivalent to 540,000 deaths per year.

"Accepting the conservative estimates that cancer induction risk is 0.04% per rem, one can calculate that of every 100,000 people scanned, 40 will have life-threatening cancer induced by radiation over their lifetime," he says. "Of the same 100,000 people, 23,000 are likely to die from cancer. Assuming even a one half of 1% early detection rate and resulting cure, 115 people may derive the benefit versus the potential 40 who might have cancer induced sometime in their lives.

"This controversy over CT screening really is a case of logical thought sacrificed at the altar of emotional, knee-jerk reaction," Brant-Zawadzki continues. "It is about the question of how much this will cost the health care system, which has already been answered in part by people who are willing to pay out of pocket for this kind of care.

"Simply put, as imaging becomes more sophisticated, it is clear that radiology can identify early markers of disease before clinical manifestations ensue," he says. "Given the lack of evidence regarding life benefit for many interventions in diseases that are already manifest, it is intuitively arguable that the study of diagnostic detection in preclinical stages of disease should be encouraged."

Elizabeth Finch is a contributing writer for Decisions in Axis Imaging News.

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