Diagnostic Imaging in Oncology—
What's the Picture?

ILLUSTRATION/THE I SPOT

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Many people think of medical imaging as "diagnostic" imaging. While imaging is often an essential tool in serving to identify a particular disease (i.e., diagnosis), the ability to track disease progression and treatment is becoming increasingly important. Medical imaging is becoming a vital tool in patient management and not solely a diagnostic tool.

Disease and healing are dynamic processes. Fourteen years ago, a review of the use of imaging in oncology concentrated on the ability of computed tomography (CT) to stage and quantify tumor response to treatment.[1] The only quantitative tool available to most practitioners was measuring tumor size, i.e., morphological assessment. It was well understood that such simple measurements cannot accurately assess a tumor's response to treatment because the form of a tumor does not necessarily change during successful treatment.

Since that time, functional imaging techniques such as positron emission tomography (PET), which show physiological activities within tissue or organs, have become widely available. These techniques are profoundly changing the practice of oncology.

This article briefly discusses the potential impact on oncology of some recently introduced medical imaging technologies and comments on reimbursement issues.

Breast Imaging

From a medical physics perspective, detecting and monitoring breast disease are very challenging since the contrast is low and the normal anatomy often hides cancerous lesions. As a result, no other organ has as many dedicated imaging devices.

Digital Mammography

Positive results from large national clinical trials accelerated the adoption of this costly technology, which now accounts for more than 60 percent of all screening mammography systems. In general, digital studies are reimbursed at a slightly higher rate compared to conventional film studies. However, workflow efficiencies (more patients) are necessary to be profitable. Further developments in the technology and increased competition between manufacturers have the potential to reduce pricing. However, the Food and Drug Administration has been very slow in reclassifying digital mammography so that expensive and time-consuming clinical trials are no longer required. Until now, the requirement for such trials has hindered the development of new systems. In October 2010, the FDA reclassified digital mammography (from class 3 to class 2) so new developments should be commercialized more quickly now.

Digital Tomosynthesis

Overlying anatomy in a two-dimensional image is a perpetual problem when detecting pathology. Digital tomosynthesis uses modified mammographic equipment to acquire images from multiple angles around the breast. The images are then digitally processed to generate multiple slices, which have the appearance of standard mammograms. The difference is that each image represents a narrow slice, rather than the entire breast. This technology is not yet approved; however, indications are that approval is imminent. At this stage, of course, reimbursement issues are unanswered. So, predicting the impact of this technology is extremely difficult.

Breast Specific CT

While digital tomosynthesis provides individual slices, thinner slices and true three-dimensional data sets require that the detector rotates around the subject. In other words, a breast-specific CT is needed. Prototype devices have been developed. Early results indicate that both masses and microcalcifications are better depicted without the need to compress the patient's breast. However, full commercialization and reimbursement for this technology are a considerable way off.

Ultrasound Elastography

The use of palpation to examine patients is one of the physician's most fundamental skills since many diseases change the stiffness (elasticity) of anatomy. Several ultrasound systems now have the capability of measuring tissue stiffness, and this technology is proving to be a useful tool when assessing a lesion. However, no additional reimbursement is yet available for these services.

Breast MRI

While magnetic resonance imaging (MRI) is ideal for imaging soft tissue, breast MRI has only recently become a routinely offered study. Positive results from clinical trials, demonstrating high sensitivity in women who had equivocal screening mammograms, and clear reimbursement criteria have led to dramatic growth of breast MRI. Specialized scanners are available, although standard MR scanners equipped with specialized breast coils can be used. However, low specificity remains an issue and the study is technically demanding and time consuming. Recent developments in 3T MRI, which provides higher quality images compared to lower field strengths, have improved image quality. The technological challenges mean that breast MRI is best performed by experienced facilities.

Molecular Breast Imaging

Standard gamma cameras used in nuclear medicine are poorly suited to breast imaging due to geometric and resolution limitations. Several manufacturers have developed breast specific gamma imaging (BSGI) and positron emission mammography (PEM) systems. BSGI is now reimbursed, though PEM remains experimental and reimbursement is very limited.

The indications for BSGI are similar to those for breast MRI (i.e., patients with equivocal findings on other modalities) and the study is less expensive to perform than breast MRI. Compared to breast MRI, BSGI provides higher specificity and is well suited to patients with very dense breasts since normal anatomy does not obscure the findings. The main limitation of BSGI today is the lack of access to systems and knowledge regarding the technology among referring physicians.

Optical Breast Imaging

Several years ago a non-invasive optical imaging device garnered some attention. The technology promised zero radiation exposure, patient comfort, and technical simplicity. However, the device never achieved marketing clearance and has become discredited. Today, however, a completely different technology, optical coherence tomography, is showing promise as a means to characterize tissue to a depth of 2 mm during surgery. This technology, which is still in the experimental stage, has the potential to take the guesswork out of tumor resection surgery, though it is not yet reimbursed.

Premium CT

Over the past decade, the capabilities of CT have advanced spectacularly. While most of the interest has been in cardiac imaging, other applications are also reaping the benefits of these advances. In oncology imaging, the usefulness of analyzing the dynamics of contrast enhancement to help differentiate malignant from benign anatomy has long been known. However, the clinical application has been limited since dynamic CT studies had very limited coverage, i.e, these can only cover a small anatomical area.

Today, several manufacturers have commercialized premium CT systems that can acquire wide coverage (up to 16 cm) dynamic studies. As a result, whole abdominal organs can now be routinely studied and characterized. Another innovation is dual energy CT, which can automatically and accurately characterize tissue types. This technology means that automatic measuring tools can be applied, which removes the human variability of measurements. For example, contrast-enhanced lung nodules can be reliably extracted and tracked over time. It is very early days for these applications, so clinical guidelines and reimbursement are lagging. The bottom line is that CT is becoming a functional imaging tool.

MR Spectroscopy

Spectroscopy is used to determine the constituents and the relative abundance within a sample. MR has been used for spectroscopy for considerably longer than MR has been a medical imaging modality. However, almost all medical imaging relies on the abundance of hydrogen in our bodies and is not used for spectroscopy. The signal strength from other elements has been just too small to be reliably imaged. However, with the growing installed base of high field strength (3T) MR systems, MR spectroscopy is becoming a practical option for medical imaging.

MR spectroscopy enables the chemical composition of individual voxels (bits of tissue) to be determined *in vivo* and the precise location of malignant processes to be identified. A spectroscopy option is available on many MR systems. However, reimbursement is not yet available and more data supporting the clinical use of MR spectroscopy is needed.

Hybrid Imaging

Combining images and data from different modalities can have a significant impact on the value of the information. A common everyday example is superimposing meteorological radar data on a physical map data. It is, of course, possible to simply merge (fuse) data obtained from two sources. However, even small differences in patient positioning

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compromise the value of the merged image. The success of hybrid PET/CT systems, despite the very high cost, is testament to the value of hybrid modalities, and more hybrids are being developed.

PET/CT. The ability of PET to identify regions of high metabolic activity has proven to be an effective means to identify and quantify tumor activity. The high cost of the radionuclides, which have a very short half-life (two hours) and, therefore, must be used very quickly, means that insurance companies were initially slow in reimbursing the scans. However, well-organized clinical studies demonstrated the value of PET in determining the optimum treatment strategy in a number of clearly defined applications. Trials are ongoing for additional clinical applications, most notably assessing the efficacy of a treatment strategy.

A recent development in PET is the introduction of time of flight (ToF), which enables images to be acquired more quickly without compromising image quality. ToF adds about $1 million to the cost of a PET/CT. However, ToF reduces image time from 45 minutes to less than 10 minutes. From a workflow perspective, the short half-life radionuclides can be used more efficiently (one delivery can be used on more patients). Since the profitability of medical imaging devices largely depends on how many patients are scanned, a busy facility could justify the higher cost of ToF. Furthermore, the ongoing development of new, and more specific, PET tracers will likely expand the clinical uses of PET. It is also worth noting that as the clinical applications for PET increase (as clinical data becomes available), the number of patients seeking scans will also likely increase.

SPECT/CT. Single photon emission computed tomography (SPECT) has been used for many years to improve the usefulness of nuclear medicine. Rudimentary CT was added to SPECT to improve the quality of the necessary attenuation correction and, consequently, the resulting images. More recently, several manufacturers have added higher quality CT to SPECT systems. Today, several options for the CT exist, which affect cost and diagnostic quality of the CT. While CT is not as crucial to SPECT as it is to PET, results show that adding CT increases the confidence of SPECT findings. In addition, SPECT has the benefit of having a wide range of existing radioisotope tracers that are specifically developed, tested, and clinically proven for many specific diseases and organs, which is not yet the case in PET. Also the tracers are significantly less expensive than PET tracers. However, adding the CT does not affect reimbursement, and additional reimbursement, for the CT, is only available if the CT is separately ordered.

MR/PET. New PET detectors are now being prototyped that are small enough to fit inside the bore of an MR system and still allow a patient's head to fit into the hybrid system. Three major modality manufacturers have recently introduced a means to achieve MR/PET imaging. One solution is to transfer patients between two scanners without having to move the patient from the table, so minimizing changes in patient position, which is not trivial. Another solution is a truly combined system with the ability to acquire PET and MR images simultaneously, which is now possible. These devices are aimed at the research community, and it is for them to determine what, if any, the clinical benefits of this expensive technology are. It will be several years before evidence can support routine use of this technology.

Future Prospects and the Importance of Clinical Trials

No medical application will thrive unless it is adequately reimbursed. In the past, high-technology medical imaging (e.g., MR and CT) was well reimbursed and became known as a major source of revenue and profit. Reality caught up, and medical imaging is now facing substantial reimbursement cuts. What is more, allegations of over utilization and concern over radiation dose mean that insurance carriers and even some patients are skeptical about the need for some studies.

Evidence-based medicine is regarded by some as the key to reducing waste in the delivery of healthcare. Historically, medical imaging has not been supported by high-quality clinical trials. The required gold standard randomized controlled trials are often very difficult to apply to imaging studies due to the lack of a definitive endpoint and the very large patient numbers needed to demonstrate significant differences and value. Reimbursement is now usually withheld until such data are available. As a result, many advanced applications listed above are not reimbursed despite being available for some time.

The success of the National Oncology PET Registry (NOPR) is a model for future imaging techniques and modalities. During the trial period, the imaging studies were reimbursed on the condition that relevant pre-study and post-study data were submitted to the study. More studies like this are required to help imaging prove its value, particularly in monitoring the efficacy of oncology treatment plans. If imaging can demonstrate real savings—both financially and in patient morbidity from ineffective treatments—then it is more likely that advanced imaging will be fairly reimbursed and patients will benefit. Only with adequate reimbursement will these technologies be widely used.

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References

[1] MacVicar D, Husband JE. Assessment of response following treatment for malignant disease. *Br J Radiol.* 1997 Nov;70 Spec No:S41-9.