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RADIOLOGY ALERT®

A monthly update on developments in imaging

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Lung Nodule Enhancement at CT

ABSTRACT & COMMENTARY

Synopsis: *The absence of enhancement of a solitary pulmonary nodule greater than 15 HU on CT is predictive of benignity.*

Source: Swensen SJ, et al. Lung nodule enhancement at CT: Multicenter study. *Radiology* 2000;214:73-80.

The characterization of the solitary pulmonary nodule (SPN) is one of the most common diagnostic problems encountered by radiologists. As approximately 50% of surgically resected SPNs are found to be benign, a noninvasive means of accurately distinguishing benign from malignant lesions would have a significant effect on the morbidity and cost of surgical resection for benign lesions. It has been shown that malignant lesions are relatively hypervascular as compared to benign lesions and, therefore, enhance to a greater degree on angiography, contrast-enhanced conventional tomography, positron-emission tomography using radioactive glucose analog fluorodeoxyglucose (FDG), gadolinium-enhanced magnetic resonance imaging, and contrast-enhanced computed tomography (CT). In this prospective multicenter study, Swensen and colleagues build on their previously published experience with the technique of CT nodule enhancement to distinguish benign from malignant SPNs.

The study enrolled 550 patients at six medical centers over a 22-month period, of which 356 patients had a definitive clinical or pathologic diagnosis and a technically adequate lung nodule enhancement study. The nodules had to meet the following entry criteria: between 5- and 40-mm diameter (calculated as the mean of the long and short axis diameters as measured on lung windows); relatively spherical, homogeneous attenuation on precontrast examination; absence of CT artifacts due to motion or beam hardening from adjacent bone; and absence of fat, calcium, or cavitation on thin-section CT scans. Patients allergic to iodinated contrast, creatinine greater than 1.5 mg/dL, and those unable to consistently breath-hold were likewise excluded. The technique of CT nodule enhancement consisted of preliminary unenhanced helical 3-mm collimated scans obtained in a single breath-hold using a pitch of 1:1 through the entire nodule, followed by serial 5-second, 3-mm collimated helical

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acquisitions performed at one, two, three, and four minutes after intravenous administration of iodinated contrast (420 mg/kg of 300 mg/mL) injected at a rate of 2 mL/s. The mean attenuation values of the SPN at baseline and at one, two, three, and four minutes post-injection were manually calculated by choosing the scan closest to the nodule equator and drawing a round or oval region of interest that approximated the nodule's shape and encompassed approximately 70% of the nodule's short- and long-axis diameter. The value of nodule enhancement was defined as the difference between the maximum mean attenuation value measurement in the four minutes after contrast administration and the pre-enhancement measurement as expressed in Hounsfield units (HU).

The findings showed that there was a significantly greater median enhancement of the malignant neoplasms than for benign neoplasms or granulomas (38 vs 10 HU; $P < 0.01$). More important, by setting an enhancement value greater than 15 HU as a marker for malignancy, the sensitivity and specificity of contrast-enhanced CT were 98% and 58%, respectively. Of 171 malignant neoplasms, only four failed to enhance more than 15 HU. Swensen et al conclude that the absence of significant nodule enhancement (≤ 15 HU) was a strong predictor of benignity.

They point out that since all four false-negative malignant SPNs enhanced 14-15 HU, retrospectively, lowering the threshold of a positive study to 10 HU would increase the sensitivity of the technique to 100%.

COMMENT BY JEFFREY S. KLEIN, MD

This study confirms the previous work of Swensen et al and several Japanese investigators by demonstrating a high sensitivity of CT nodule enhancement in the detection of malignant SPNs. This technique is much more practical than other methods of assessing nodular vascularity such as MRI and PET, and, as Swensen et al point out, CT nodule enhancement can be performed immediately following routine staging CT of chest and abdomen for suspected lung cancer without the need for additional contrast adminstration and with little additional scan time (< 5 minutes) and radiation dose.

The problems with this study relate to the large number of cases excluded due to insufficient follow-up or technically inadequate CT studies (35% in this series), and the lack of pathologic diagnosis of nonenhancing probably benign nodules, as these tend to be followed rather than biopsied or resected.

Caution should be exercised in using this technique to evaluate larger (> 2 cm) nodules or those with necrosis, as these have a greater tendency to be false negative on CT nodule enhancement studies.

The relative role of CT nodule enhancement in the evaluation of SPNs remains to be defined. I believe that the technique will prove most useful in situations where pathologic diagnosis via transthoracic needle biopsy is either unavailable, cannot be performed, or proves nondiagnostic. ❖

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Sonographic and CT Guidance

ABSTRACT & COMMENTARY

Synopsis: *In comparison to CT guidance for percutaneous hepatic biopsies, sonographic guidance is substantially more cost effective.*

Source: Kliewer MA, et al. Percutaneous liver biopsy: A cost-benefit analysis comparing sonographic and CT guidance. *AJR Am J Roentgenol* 1999;173:1199-1202.

In the united states, most liver biopsies are currently performed using CT, as opposed to ultrasound guidance. Most likely, this is due to a traditionally held belief that ultrasound should be limited to guiding large and/or superficial liver masses. As ultrasound technology, transducers and techniques have evolved and improved; however, sonographic guidance has been shown to be technically effective for guiding biopsies of

liver masses smaller than 1.5 cm, as well as for obtaining tissue from deeply located abdominal, pelvic, and retroperitoneal lymph nodes.

The purpose of the current study was to compare the cost of doing a liver biopsy using ultrasound guidance versus its cost using CT guidance. To do this, Kliewer and colleagues from Duke University evaluated 437 liver biopsies performed at their institution during a 31-month period. CT guidance was used for 137 (31%) biopsies, while sonographic guidance was used for 300 (69%) biopsies. Outcomes were considered adequate when sufficient tissue was obtained to characterize a specific abnormality, and inadequate when either insufficient or normal tissue was obtained.

To do their cost analysis, Kliewer et al analyzed two types of variables. Those categorized as probability variables included the probability of obtaining an adequate sample and the probability of a major complication. Cost variables were also analyzed and included the direct and indirect costs, the cost of a major complication, and the "opportunity" cost (i.e., the estimated cost of lost or foregone revenue that could have been generated with the machine had it been used for diagnostic studies, as opposed to the biopsy procedure).

The results of this study revealed that with ultrasound, an adequate sample was obtained in 261 of 300 biopsies (87%), while with CT, an adequate sample was obtained in 107 of 137 biopsies (78%). The mean time requirement to do the biopsies was 80 minutes ± 33 minutes for sonography, and 98 minutes ± 38 minutes for CT. Because actual dollar values could not be disclosed by Kliewer et al, relative values were reported instead. This revealed the overall cost for doing a CT-guided biopsy was 1.89 times greater than an ultrasound-guided biopsy. Further analysis indicated that CT and sonographic guidance costs would be equivalent if the success rate with sonography was only 40%, if the CT "opportunity" cost was 3.13 times less than estimated, or if the sonographic "opportunity" cost was 3.15 times greater than estimated.

COMMENT BY FAYE C. LAING, MD

This study is important because it not only confirms that sonography is technically at least as good as CT for guiding liver biopsies but, in addition, it is significantly more cost effective. Another way to understand the comparative "opportunity" costs is that for CT to be cost-equivalent with ultrasound, the CT-guided procedure could not exceed 31 minutes. In contrast, for the sonographically guided procedure to be cost equivalent with CT, the ultrasound-guided procedure could be extended to four hours and nine minutes. Furthermore, based on comparative cost effectiveness, sonography would be preferred if the biopsy success rate was as low as 40%.

Since cost estimates may vary somewhat from one institution to another, the values published in this article should be considered guidelines, and best approximate the cost generated in a large academic center. Nonetheless, the message is clear that with sonographic guidance, there is considerable latitude in both the success rate and in the time required to perform a liver biopsy before a sonographically guided biopsy approaches the cost of a CT-guided biopsy.

This article should prompt radiologists who rely primarily on CT for liver biopsy guidance to rethink their strategy. Obviously, to duplicate the results of Kliewer et al requires sonographic expertise in using this modality for biopsy guidance. Based on the results of this report, however, it seems well worth the effort to acquire this skill. Furthermore, although this article focused on cost effectiveness for percutaneous liver biopsy, it is reasonable to consider extending the use of sonography to guide biopsies of other intra-abdominal organs, and to also consider using this modality for performing biopsies of pelvic and retroperitoneal lymph nodes. ❖

MR Imaging of Asymptomatic Individuals After Rotator Cuff Repair

ABSTRACT & COMMENTARY

Synopsis: *MR findings should be interpreted with caution and correlated with symptoms in the postoperative rotator cuff.*

Source: Spielmann AL, et al. Shoulder after rotator cuff repair: MR imaging findings in asymptomatic individuals—Initial experience. *Radiology* 1999;213:705-708.

MRI has assumed an important role in evaluation of the postoperative rotator cuff. Criteria for retear are well established. Spielmann and colleagues have gone one step further to show the MR appearance of the rotator cuff in postoperative cuff repair patients who are asymptomatic.

Fifteen subjects with a mean age of 60 years who were considered surgical successes following rotator cuff repair were included in the study. All participants had good to excellent clinical scores according to the Constant scale. Routine MR imaging was performed on

both the postoperative as well as the contralateral shoulder of each patient using a 1.5T scanner (Horizon Echo-Speed; General Electric Medical Systems, Milwaukee, WI). An oblique coronal fast spin-echo fat-suppressed T2-weighted MR sequence was included in every study to provide optimal demonstration of rotator cuff abnormalities.

Three (10%) of 30 supraspinatus and infraspinatus tendons had normal signal intensity and 16 (53%) had mildly increased signal intensity on FSE T2-W images with fat suppression. This finding was found to be compatible with tendonitis/tendonosis. There were three partial and four complete tears of the supraspinatus tendon and two partial and two complete tears of the infraspinatus tendon. Other findings included subacromial-subdeltoid effusion (n = 10), joint effusions (n = 5), and bone marrow edema (n = 6).

Spielmann et al conclude that in asymptomatic postoperative rotator cuffs, signal intensity changes consistent with tendonitis/tendonosis are common and that clinically "silent" partial and complete rotator cuff tears may also be seen. These findings should be interpreted with caution and correlated with symptoms and clinical results.

COMMENT BY LYNNE S. STEINBACH, MD

While MRI is well established for preoperative assessment of the rotator cuff, less is known about MR evaluation of the postoperative rotator cuff. In general, criteria for an intact rotator cuff include low to intermediate signal intensity within the tendon on all MR imaging sequences. Several studies have found high sensitivity and specificity for postoperative diagnosis of a full-thickness rotator cuff tear in symptomatic patients.[1-3] Owen et al demonstrated an 86% sensitivity, 92% specificity, and a 90% accuracy for the MR diagnosis of a residual or recurrent full-thickness rotator cuff tear following repair.[1] Magee et al reported similar results with an 84% sensitivity and 91% specificity.[2]

This study is the first of its kind to assess the MRI appearance of the successfully repaired rotator cuff in an asymptomatic population. Although the findings are based on a small population of asymptomatic individuals, there are some important observations that should affect the way that radiologists interpret abnormal findings in these postoperative shoulders. It is known that partial- and full-thickness rotator cuff tears can be asymptomatic.[4] Why shouldn't the postoperative population have the same findings as the general population? The situation is similar to the lumbar spine where many "abnormalities," such as disk bulges and protrusions, are seen in asymptomatic individuals.

As Spielmann et al state, the study was limited by the small number of subjects and further investigation of a large group of asymptomatic individuals, perhaps through a multicenter study, would be warranted to confirm these results. The inability to obtain surgical confirmation was another limitation of this study that could not be avoided since asymptomatic individuals do not need diagnostic or therapeutic surgical confirmation of these findings. The major point of this study is that imaging abnormalities should always be correlated with the clinical scenario in order to determine their significance. ❖

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Diffusion-Negative Stroke

ABSTRACT & COMMENTARY

Synopsis: *The occurrence of normal diffusion-weighted imaging findings in the setting of impending infarction emphasizes the need for timely perfusion assessment in hyperacute stroke patients, especially if therapeutic intervention is contemplated.*

Source: Wang PY, et al. Diffusion-negative stroke: A report of two cases. *Am J Neuroradiol* 1999;20:1876-1880.

Diffusion-weighted mr imaging has been shown to be useful for the early diagnosis of stroke in humans. In general, it is considered highly sensitive for the detection of early changes associated with hyperacute stroke (< 6 hours since symptom onset), and is felt to be much more sensitive to these early changes than conventional T2-weighted MR images or CT. In this paper, two patients with negative diffusion-weighted studies obtained within four hours of symptom onset who later developed imaging evidence of infarction are presented. These patients represent a subset of a group of 10 patients studied at this institution within 24 hours of symptom onset, three of whom had negative findings

on initial diffusion-weighted images (DWI).

The first patient, a 67-year-old man with a history of transient ischemic attack (TIA), atrial fibrillation, and myocardial infarction (MI), presented with Wernicke's aphasia and mild right arm apraxia. He was clinically diagnosed with acute embolic stroke in the left temporal region, and an initial CT scan was negative. Conventional MR and DWIs were normal. Perfusion imaging was not performed, as the patient refused gadolinium. The patient was treated with intravenous heparin, and a follow-up MR scan obtained four days later showed clear-cut evidence of a new left temporal infarct. The second patient, a 65-year-old man with multiple cardiovascular risk factors, presented with two hours of expressive aphasia, slight left facial droop, and minimal left pronator drift. Findings on initial conventional and diffusion imaging were normal, though perfusion images showed a large region of markedly increased time-to-peak in the right major coronary artery (MCA) distribution. This latter information was not available for clinical decision making, as it required off-line post-processing. The patient deteriorated clinically, and follow-up MR imaging 13 hours later demonstrated normal T2-weighted images and interval development of an abnormality on the DWIs. Further follow-up four days later demonstrated hemorrhagic infarction in the right posterior MCA territory.

Both patients were symptomatic at the time of imaging but had normal findings on T2-weighted and isotropic DWIs, as well as average diffusion coefficient maps. Region of interest measurements showed the diffusion constant to be 4-9% lower in the eventual region of infarction as compared with the contralateral hemisphere, but this difference was not statistically significant, nor could this be visually detected by an observer. Wang and colleagues felt that there were three potential explanations for the lack of diffusion changes in the acute phase in these patients. First, it was considered that cerebral blood flow might have been at an intermediate level below the threshold for neuronal dysfunction but above that for reduced diffusion. A second possibility, applicable only to case 1, was that reperfusion had occurred, restoring the diffusion constant to normal but not preventing eventual delayed infarction. Third, is the possibility that a second ischemic event might have occurred, but this was not felt to be consistent with the clinical courses of these patients. Overall, Wang et al felt that the occurrence of normal DWI findings in the setting of impending infarction emphasizes the need for timely perfusion assessment in hyperacute stroke patients, especially if therapeutic intervention is contemplated.

COMMENT BY NANCY J. FISCHBEIN, MD

In the relatively brief period that DWI has been clinically available, it has revolutionized the evaluation of patients with acute stroke. Lesions that might have previously gone unrecognized on CT or conventional MR images are now obvious as bright regions on DWI. However, we must all recognize that this emerging technology is only partly understood, and may have some limitations in the assessment of patients with hyperacute stroke.

The paper by Wang et al cautions us that a negative finding on a DWI obtained within the first four hours after the onset of symptoms may not indicate that the patient is experiencing merely a TIA rather than a stroke, but simply that for whatever reason there has not been a reduction in diffusion of such a level that we are able to visually appreciate it. Persistence or even worsening of deficits on clinical examination would be expected in ongoing ischemia/infarction, so results, of course, must always be interpreted in a clinical context. In some cases early changes may be subtle, as illustrated in a companion article in the *American Journal of Neuroradiology* demonstrating two cases of hyperacute ischemic stroke "missed" by DWI but where, in fact, lesions are visible on retrospective review.[1] The combination of perfusion MR imaging with diffusion-weighted MR should be a powerful tool in the assessment of the acute stroke patient, but perfusion imaging continues to require significant post-processing, and the most reliable parameters to evaluate (time to peak, mean transit time, cerebral blood volume, etc.) have certainly not been agreed upon in the literature.

An additional caution is that not every entity presenting with acute neurological deficits and apparent reduction in diffusion on DWIs represents cerebral infarction, as a reduction in apparent diffusion coefficients has been demonstrated in other settings such as viral encephalitis,[2] Creutzfeldt-Jakob disease,[3] and cerebral abscesses.[4] Findings on conventional anatomic images and clinical examination must, therefore, always be incorporated into the overall interpretation. Furthermore, normal DWI in patients with strokelike deficits should stimulate a search for a nonischemic cause of symptoms, as some of these patients may prove to have migraine, post-ictal paresis or paralysis, or brain tumors.[5] ❖

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Chest CT Can Be Used to Exclude Aortic Injury

ABSTRACT & COMMENTARY

Synopsis: *Physicians in two busy trauma centers examined the usefulness of computed tomography of the chest as a screening examination for trauma patients with suspected aortic injury. More than 800 patients were examined with CT and approximately half had follow-up aortography, which is considered the gold standard for the diagnosis of aortic injuries. CT was positive in all cases of aortic injury and a negative CT accurately ruled out aortic injuries. It was concluded that chest CT is an excellent screening tool for traumatic aortic injuries.*

Source: Dyer DS, et al. Can chest CT be used to exclude aortic injury? *Radiology* 1999;213:195-202.

The majority of patients with blunt chest trauma and aortic rupture do not survive the initial injury. If the patient survives and arrives in the emergency department, the diagnosis of rupture must be made rapidly so that treatment may be initiated. Aortography is considered the reference-standard procedure for the diagnosis of aortic injury; however, it is invasive, expensive, and resource intensive. This study was conducted over a period of 4.5 years in two busy trauma centers and its purpose was to check the reliability of computed tomography (CT) in excluding aortic injury in blunt chest trauma. Eight hundred two patients with blunt chest trauma had chest CT as the initial exam, 382 of whom underwent follow-up aortography. All CT examinations, except seven, were contrast enhanced and approximately half were performed with a helical CT scanner. Aortography was performed using routine intra-arterial digital subtraction technique in two projections.

In the 382 patients who had both CT scan and aortography, when a positive scan was defined as that showing any mediastinal hematoma and/or direct signs of aortic injury, 10 CT scans were true positives, 230 were true negatives, 142 were false positives, and none was a false negative. Thus, the sensitivity of CT in the diagnosis of aortic injury was 100%, negative predictive value 100%, specificity 62%, and positive predictive value 7%. When only direct signs of aortic injury were considered positive on CT, the specificity increased to 96% and positive predictive value increased to 40%. Sensitivity and negative predictive value remained 100%. It was concluded that chest CT is an excellent screening test for the diagnosis of thoracic aortic injury in patients with blunt trauma.

COMMENT BY MONI STEIN, MD

Over the past 10 years, there has been a change in the approach to the diagnosis of aortic injury in trauma. Earlier, CT was not considered a reliable test to exclude aortic injury and the algorithm was to perform a plain chest film and, if necessary, perform aortography. Primarily trauma surgeons who wanted to expedite the diagnosis and send the appropriate patients as quickly as possible to the operating room promoted this algorithm.

In an article published in 1992, Raptopoulos and colleagues showed that chest CT was a reliable screening test to exclude thoracic aortic injuries.[1] Dynamic chest CT was positive (mediastinal blood) in all injuries and there were no false negatives. With CT there was a significant improvement over plain chest radiography in specificity, accuracy, and predictive value of positive results. With the addition of chest CT in the screening for traumatic aortic tear, the need for aortography decreased by 56%.

More recently, a wide variety of traumatic and nontraumatic emergency conditions are quickly and accurately diagnosed with helical CT.[2] The speed of helical technology allows expeditious CT examination of seriously ill patients. In addition, helical technology allows multiple, sequential CT scans to be rapidly obtained in the same patient, a great advantage for the multiple-trauma patient. Better quality CT examinations result from decreased misregistration, better intravenous contrast material opacification of vascular structures and parenchymal organs, and more flexibility in image reconstruction. Helical chest CT can also show a number of conditions that may be overlooked otherwise. Gavant et al reported a series of 1518 helical CT scans obtained for blunt trauma.[3] One hundred twenty-seven patients with abnormal CT scans underwent aortography. Helical CT was shown to be more sensitive (100% vs 94.4%) but less specific (81.7% vs 96.3%) than aor-

tography in the detection of aortic injuries. The earlier CT studies focused primarily on the presence of mediastinal blood to trigger performance of aortography. More recently, with more advanced scanners and cumulative diagnostic experience, even in the presence of mediastinal hematoma, if there are no direct signs of an aortic injury on the CT scan, then the study is considered to be negative for aortic injury.[2] ❖

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Fraud and Abuse

ABSTRACT & COMMENTARY

Synopsis: *Multiple laws passed by the federal and state governments are directed toward curbing what is considered excessive reimbursement patterns by health care providers. Known collectively as fraud and abuse issues, physicians need be familiar with the far-reaching provisions to avoid civil and criminal penalties.*

Source: Kalb PE. Health care fraud and abuse. *JAMA* 1999; 282:1163-1168.

From "medicaid mills" to physicians at teaching hospitals (PATH), audits of academic institutions, governmental scrutiny, and disciplinary action against health care industry personnel and institutions has escalated during the past several years. Journalistic headlines continue to highlight allegations of fraud by publicly traded companies such as Columbia/HCA or international clinical laboratories such as SmithKline Beecham. In a healthcare environment that emphasizes restricted resources and more limited referrals, the chilling message of accountability for wasteful spending has been directed as well to the individual practitioner. Intentional misrepresentation of billing practices is no longer required for prosecution, and "compliance plans" have become as common as medical staff bylaws.

Washington, DC, attorney Kalb summarizes the bases for legal action (criminal and civil) that can be taken by the U.S. Department of Justice, administrative actions by the Department of Health and Human Services' Office of Inspector General, as well as state actions. In an attempt to contain costs as well as regulate referral practices, the government interest in pursuing fraudulent behavior can be traced to three primary types of conduct. As if government oversight is not sufficient, quitam, or individual "whistle blower," lawsuits have been encouraged to incentivize citizen participation in identifying potential government targets.

The first basis for governmental action is for false claims. Although more than a half dozen federal and state prohibitions exist, the federal False Claim Act (FCA) is the most important of these, prohibiting "knowing" submission of false claims, statements, or certification, as well as causing or conspiring with others to do so. Damages of up to three times the amount of the false claim plus mandatory penalties of $5,000 to $10,000 apply regardless of the size of claim. The element of "knowing" has been the subject of legal interpretation, but generally applies to the submission of bills for services not provided or including nonreimbursable services on cost reports. Under this act, the government's PATH initiative has been pursued. Cases have arisen claiming that the submission of a bill implies a certification of compliance with the Anti-Kickback statutes. Enforcement has, in some cases, been extended to suggest that the provision of substandard care—a question of legal negligence usually under state jurisdiction—may violate the FCA. In this manner, medical conduct may be affected by the provisions of the act.

The second basis for action for fraud is the payment or receipt of kickbacks, bribes, or other inducements that are specifically intended to influence the purchase or sale of healthcare-related goods and services, highlighted by the federal Anti-Kickback statute, although most states have similar statutes. Persons offering (or paying) as well as accepting such remuneration have legal exposure. Given the broad range of interactions among healthcare personnel, the statute and Health Care Financing Administration (HCFA) have adopted exceptions or "safe harbors." Thus, where Holter monitor services paid physicians for interpretation fees that were deemed excessive, a false inducement was found. Often, cases are determined by what the nature of the "knowing" is with respect to the transaction.

The third major basis for action is self-referral prohibitions, the federal ones sometimes called the Stark I and Stark II laws, derived from the Ethics in Patient Referral Act. Services such as physical therapy, clinical laboratory work, radiology, and imaging facilities are governed by these provisions. As for the Anti-Kickback Act, "safe harbors'" are provided by Congress for the

Stark laws (named after Congressman Pete Stark) to except relationships where the ownership or investment interest of the party or the compensation arrangement do not violate the intended purpose of "kickback" prevention. These laws carry only civil penalties but are notable in that they apply only to physicians and do not require improper intent.

Violations of these laws carry penalties, fines, and potential exclusion from government programs.

COMMENT BY R. JAMES BRENNER, MD, JD

Between 1992 and 1996 the number of civil investigations by the FBI and the Department of Justice increased more than 900%, and the number of criminal investigations tripled. The Department of Health and Human Services (HHS) spends more than $600 million a year attempting to recoup losses to the Medicare program projected as wasteful spending secondary to fraudulent billing, and most cases result in some form of settlement. The once time-honored tradition of professional courtesy is now seen as an issue of fraud and abuse by the government (Inspector General) and contracts by managed care companies demanding reimbursement schedules less than Medicare violate federal provisions that the Medicare program receive the most favorable charges ("most favored nation status") by a provider who contracts to serve patients under the Medicare program. Few practices, especially few radiology practices, can either choose or survive without caring for this important population of patients. Third-party payers are also interested in preventing fraud. Audits, for example, of mammography practices that show a disproportionate number of diagnostic studies rather than screening studies for irreconcilable reasons have been the basis for private action against providers.

That fraud is a regrettable drain on the resources of this country invites little argument. Whether the multitude of provisions now available and used by private, state, and federal authorities to correct this problem has created a solution with its own Pandora's box is being debated around the country. As is often the case, the appropriate response to curtailing fraud has created an environment that subjects reasonable opinions to costly redress. Those who commit fraud and abuse should be identified and subject to accountability. The extension of laws from intent to simple negligence of inappropriate action may be reasonable, but is a precarious field of law. Hospital staffs, freestanding imaging centers, and billing companies have been advised as a matter of first response to develop "compliance plans" where systems are created that interfere with processes that may lead to fraud. Such an in-place system—the approach of which is being borrowed from penal sentencing guidelines—is viewed by the government as an act of good faith in case of investigation, but is attended by self-incriminating (and possibly self-defeating) provisions that may deter active participation. ❖

CME Questions

9. The basis for the PATH (Physicians at Teaching Hospitals) audit penalties or any similar set of circumstances is:
- a. the False Claims Act.
- b. the Anti-Kickback statutes.
- c. the Stark anti-self-referral laws.
- d. the legal concept of negligence.
- e. general jurisprudential notions of fraud.

10. MRIs of asymptomatic shoulders following rotator cuff repair:
- a. should demonstrate low signal intensity rotator cuff tendon on all imaging sequences.
- b. do not show subacromial-subdeltoid bursal fluid.
- c. may display a full-thickness rotator cuff tear.
- d. lack signal intensity changes consistent with bone marrow edema.

11. The percentage of resected solitary nodules found to be malignant is approximately:
- a. 10%.
- b. 30%.
- c. 50%.
- d. 70%.
- e. 90%.

12. With respect to cost effective performance of percutaneous liver biopsy, the results of this study suggest:
- a. ultrasound is more cost effective than CT.
- b. ultrasound is less cost effective than CT.
- c. ultrasound and CT are equally cost effective.
- d. neither CT nor US is cost effective.

13. Diffusion-weighted MR imaging performed in a patient who subsequently proves to have an ischemic infarction:
- a. always demonstrates acute infarction when performed more than one hour after the onset of symptoms.
- b. always demonstrates acute infarction when performed more than two hours after the onset of symptoms.
- c. always demonstrates acute infarction when performed more than three hours after the onset of symptoms.
- d. may be negative even if four hours have elapsed since onset of neurological deficit.

In Future Issues:

Nonenhanced Helical CT is Accurate in Suspected Acute Appendicitis

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EXPANDING YOUR FOCUS IN RADIOLOGY

Dramatic Changes Taking Place in the Role PACS will Play in Your Future

RSNA meeting provides insights on where technology is heading

By Philip G. Drew, PhD

Developments on display at the 85th scientific assembly and annual meeting of the radiological Society of North America (RSNA), held in Chicago, November 28 to December 3, 1999, promise that the technology and practice of medical imaging are in for big changes in the new millennium. As in every other technically based enterprise, the revolution being wrought by digital computation and the Internet extends into every aspect of modern medical imaging practice.

The obvious part of the revolution lies in computer applications for image management, a field that goes under the rubric of picture archiving and communication systems or PACS. These systems aim to replace film with their electronic alternatives—monitors on which to view images, networks on which to distribute images, and digital archives in which to store images. Beside avoiding the cost of film and film-handling, these systems introduce other benefits in streamlining radiology department operations and improving service to referring physicians. PACS that fully eliminate film are still more the exception than the rule, but eliminating film is the goal of many hospitals and imaging centers that have embarked on programs to install PACS in stages over a period of years.

Of the 600 or so companies exhibiting their wares at the meeting, fully half concerned themselves in one way or another with PACS. The field is broad, and the suppliers approach PACS from a variety of starting points. The imaging equipment manufacturers recognize in PACS an opportunity to expand their businesses in the radiology departments of the world, and after a slow start they have leapt enthusiastically into this business. The film companies—such as Agfa Medical (Ridgefield Park, NJ), Fuji America (Stamford, CT), Kodak (Rochester, NY), and Konica (Wayne, NJ)—see in PACS an eventual end to their film business, and they have embraced electronic systems, though with varying degrees of success. The hospital information systems companies see in PACS a new function for their networks and they have added PACS to their systems, though, it appears, with some reluctance because PACS introduces a new and difficult set of technical requirements.

PACS Vie for Attention

But the largest and most interesting group is made up of companies whose medical imaging business is confined to PACS. These companies are home to the novel concepts that vie for a place in the imaging departments of tomorrow. One new concept is web-based image distribution. It has become clear that systems to distribute images to the hundreds or thousands of referring physicians typically served by an imaging department cannot provide specialized terminals for each physician nor can they use a local area network to reach all of them. The apparent solution is a distribution system that uses personal computers already in place for terminals and an intranet or the Internet for distribution. Currently, transmissions of images on such networks take too much time, but data compression alleviates this problem. (As reported below, if prognostications from Lucent Technologies [the former Bell Labs] turn out to be correct, the problem may not persist.)

Several companies offer systems that address this aspect of PACS. Algotec (Raanana, Israel), Amicas (Watertown,

MA), Applicare (Zeist, Netherlands), eMed (formerly Access Radiology, Lexington, MA), Insite One (Wallingford, CT), Line Imaging (Atlanta, GA), and Medweb (San Francisco, CA) all start with the concept of Internet distribution, whereas most PACS suppliers include the Internet as an afterthought.

Using a compression scheme developed at the University of Pittsburgh, Stentor (South San Francisco, CA) provides software that compresses images and then transmits only as much of the image detail as is necessary to match the display capabilities of the destination terminal. Using a compression scheme from Los Alamos, LizardTech (Seattle, WA) provides software with a similar function. Both systems claim to speed up network operation by diminishing network traffic, transmitting only what is necessary for the viewer to make a decision.

New Reasons to Use 3D

Another aspect of PACS largely pioneered by small companies is 3D imaging. In the early days of 3D some 15 years ago, small companies developed 3D systems, but manufacturers of CT and MR systems quickly incorporated the software in their systems. As a result, most 3D companies failed, though some, like ISG Technologies (now Cedara Software, Mississauga, Ontario) continue to supply the software that the larger companies use. Although most buyers of CT and MR systems buy the 3D software, most of them do not use it because it is too slow and cumbersome. Now, however, there are new reasons to use 3D software. Because CT and MR machines are much faster, it is feasible to conduct studies that may comprise hundreds of slices, and interpreting the study by examining each slice can be unduly time-consuming. By presenting all the data in a single image—or in a more manageable number of views from various angles—3D images can make image interpretation faster. And 3D has always had the virtue of being more intelligible to surgeons, patients, and other users of CT and MR images.

Who's Doing What

AccuImage Diagnostics (South San Francisco, CA) showed software that produces 3D images and detects and quantifies calcification of coronary arteries. Dicomit (Richmond Hill, Ontario) offers a 3D system for ultrasound in addition to its connectivity systems. Taking advantage of years of development, Vital Images (Minneapoplis, MN) showed its successful Vitrea 3D software, which is now available to run on systems using Windows NT as well as more expensive machines. Voxar (San Antonio, TX) introduced Plug'n View 3D software at an unusually low price—$5,000. Voxel (Orem, UT) produces 3D images using holography, an approach totally different from that of the other 3D companies. Having embarked on this path a decade ago, Voxel hit hard times when it encountered difficulties in designing and manufacturing the camera that makes the holograms, and sought protection in bankruptcy. The new owners believe the concept still has merit, though the holographic presentation has received only tepid interest from the radiology community.

Several companies seek to exploit the ubiquity and convenience of the Internet in ways analogous to Yahoo! but specialized for radiology. AuntMinnie.com and radiology.com both aim to be sites where a user can find all kinds of information about radiology—case files, locations of imaging facilities, equipment for sale, current and archived patient images, maintenance services, discussions of current issues, classified ads, etc. As every reader of the business pages knows, companies of this kind in other venues are showered with venture capital and IPO enthusiasm. Their viability is sustained by their potential as places to advertise, but their effectiveness in this role is not yet clear. What is clear is that companies must stake out their territory on the Internet early or it will be taken up by someone else. This fact explains the urgency with which such companies add features to their sites.

DR vs. CR

Still on the front burner this year were direct radiography (DR) systems, which provide a means to capture X-ray images in digital form. Doing so is a necessity for PACS that aim to do away with film, since 70% of all imaging procedures in the United States are plain film X-ray procedures. Computed radiography (CR)—the system originated by Fuji (Tokyo, Japan) and available from Agfa (Mortsel, Belgium) Konica (Tokyo, Japan), and Kodak (Rochester, NY)—substitutes a reusable phosphor plate for film. After exposure, the image on the plate must be read out in a special reading device analogous to a film processor. Lumisys (Sunnyvale, CA) offers a low-cost desk-top CR processor, which can accept plates from any of the three manufacturers noted above.

In DR, the receptor plate is permanently installed in the X-ray machine and produces the digital image data immediately after exposure. Avoiding the need to handle a cassette and producing images slightly superior technically to those produced by CR, DR seems as if it should quickly replace CR. However, that is not the case, because DR is much more expensive. Where a CR processor that can service three or four rooms simultane-

ously costs $200,000 or less, a DR system for a single room costs around $400,000. The main reason for this high cost is the difficulty of fabricating the large transistor arrays necessary to convert image data to electronic form. In the long run, there is little doubt that DR will supplant CR, but the conversion will take years, probably decades.

In the meantime, there is no dearth of companies interested in DR. One version of the process was pioneered by DuPont (Wilmington, DE), which eventually sold both the X-ray film business and the DR development to a start-up called Sterling. Most recently, Agfa bought the film business from Sterling, but left the DR system on the table, where it was eventually acquired by Hologic (Waltham, MA). Kodak has indicated that it will market a system designed by Analogic (Peabody, MA) using the Hologic plate. Another version has been under development in Europe by Trixell (Paris, France), which announced that it will begin delivering plates early this year. Trixell is a joint venture of Siemens, Philips, and Thomson, but the company will sell plates to anyone. Having created an alliance with defense contractor EG&G, General Electric Medical Systems (Waukesha, WI) added a second product to it DR offerings, a general-purpose X-ray machine supplementing a chest system.

There is another approach to DR, which is more simple and less expensive. Instead of using a large array of transistors, these systems use a phosphor screen to convert incident X-rays to light, which can then be focused optically on charge-coupled devices (CCDs), which convert the light to electronic signals. The difficulty faced by designers is that CCDs are small—no larger than about 2 × 2 inches—while the area of the phosphor screen is large—as large as 17 × 17 inches. The focusing optics suffer in two respects—they are inefficient because they collect only a small fraction of the light produced, and they require considerable distance—several inches, at least—of stand-off to accommodate the focal length of the optics. The latter condition means that such structures tend to be thick, so that they cannot be retrofitted to existing machines without modification of the machine.

Nevertheless, a number of companies have built systems based on this approach. Swissray (New York, NY) is one of these, and the company has had some success selling its product, mostly abroad. Caresbuilt (Keyport, NJ) uses a 20 × 20 array of small lenses and, thus, is able to squeeze the thickness of their plate down to 2.5 in, making it possible to retrofit into existing machines. They have chosen an image array of 7000 × 7000 pixels, making it the most highly resolved digital X-ray detector on the market. Theoretically, film has even higher resolution for high-contrast objects, but numerous studies have shown that with the possible exception of mammography lower resolution does not affect diagnostic accuracy. Furthermore, the 49 million elements of data that make up a Cares Built image tax the data-handling capabilities of computers and networks.

Sharing Information

A highlight of this year's RSNA was a new program called the Integrated Health Enterprise (IHE), advertised as a meeting within a meeting. It is a response to what has become a perennial vexation for designers and users of PACS. Hospital information systems started out as accounting and billing systems and only gradually added the clinical functions that constitute most of the real work in a hospital; only recently have they addressed the issues of electronic archiving and retrieving of the full gamut of patient information that includes images, traces, and data. Partly for this reason, hospital information systems are often fragmented with different parts addressed by different suppliers. To facilitate interchange of information among systems provided by different manufacturers, the industry has adopted a standard called HL7 (for Health Level 7). This standard concerns alphanumeric data and is silent on the matters of concern when the data represent images.

Designers of PACS found that they needed a standard of their own to address the problems of interchanging images among systems from different manufacturers, and the PACS industry adopted the so-called DICOM (for Digital Image Communication in Medicine) standard. HL7 and DICOM are independent of one another, but system designers have need of both. Image management systems need data, such as patient demographics and insurance data, that come from information systems; when they address the electronic patient record, hospital information systems need data, such as images and traces, that come from PACS.

New Use of Existing Technology

This is the goal of the IHE program—not to develop new standards but to facilitate information exchange among medical information systems, whether they adhere to the HL7 standard, the DICOM standard, or any of the other standards now in development. To do this, IHE undertook a connectivity demonstration at RSNA involving 24 self-selected participants, who include some of the major HIS and PACs suppliers as well as a number of smaller companies. Terminals in their booths were connected to a common network over which they could exchange image and alphanumeric

data whether the data originated in accordance with the HL7 standard or the DICOM standard. The demonstrations showed that each participant could support all the data exchange necessary for a hypothetical medical scenario, such as a patient coming to the emergency room with a heart attack.

The key to this demonstration was a test node previously developed at which companies could exercise their systems to assure that their code worked properly when connected to the network. This approach worked well in the past, when the organization RSNA set up an equivalent network for companies to demonstrate their ability to work in accordance with the DICOM standard. Though only 24 companies participated, and two important companies—McKesson HBOC and SMS, were absent—this was just the first year of IHE, and many more companies can be expected to participate in future demonstrations. The program will be repeated at this year's Healthcare Information Management Systems Society meeting in Dallas next April.

Echoing a Theme

This theme—integration of PACS and RIS—was echoed by a number of companies at RSNA. Picker, reincarnated as Marconi (Cleveland, OH), chose the new name to emphasize its commitment to interoperative systems. Agfa announced an "Embedded-IS," expected to be available this year, which integrates an RIS into their highly successful PACS. Starting from the RIS side, Dynamic Healthcare Technologies (Lake Mary, FL), IDX, SMS, and others asserted their compatibility with PACS. Aiming at integrated products, GE has an alliance with Cerner, and Philips with Sectra Imtec (Linkoping, Sweden).

In addition, to the demonstrations, IHE at RSNA included 24 sessions on subjects of interest to all concerned with interoperability of information systems and PACS. There were two talks at plenary sessions, one delivered by Harry Bosco, the chief operating officer of optic networking at Lucent Technologies, the other by Selby Wellman, a senior vice presidentof Cisco Systems. Both were distinctly upbeat, and both laid great stress on the role of the Internet and broadband communications. Wellman talked about the semi-magical possibilities that the Internet may provide, like being able to look at the interior of your refrigerator while you are at the supermarket, or having your house brought to just the right temperature by a signal sent from your homeward bound car.

Emerging Role of Fiberoptics

Bosco spoke about matters more germane to the medical world. In his view, fiberoptic cable will make so much bandwidth available to everybody at low cost that virtually any system one could conceive will be technically possible. Exactly how this will come about is one of the great questions facing the communications industry. He placed his bet on fiberoptic cable on every telephone pole with wireless light communication for the short links from pole to house, where, he said, lie 80% of the costs of realizing a system as fully connected as the telephone system. He added that stringing the cable is already proceeding at a furious pace, undertaken by dozens of companies in major cities. If he is right about available bandwidth, the issues of response time for image transfer and compression will vanish.

All in all, it is clear that PACS is the fastest growing part of medical imaging. Already at $550 million per year, the market for PACS products in the United States exceeds that for nuclear medicine equipment and is approaching the markets for CT and MR. It is no wonder that so many companies are active. Whether they all will survive is another matter, but the situation is not so dire as it was with the multiplicity of companies that entered CT or MR in their early days. In both of the latter cases, there were 25 or 30 companies producing products, while there are now only a dozen or so, most of them the larger imaging equipment companies. On the other hand, while there are only a handful of large HIS companies, there are still dozens of smaller companies with niches in particular segments. PACS seems more like HIS than like CT or MR. It seems likely that many of the smaller companies listed above will make their marks in this field—some surviving on their own, and others transferring their technology and their customers to larger companies. ❖

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