

# RADIOLOGY ALERT<sup>®</sup>

*A monthly update on developments in imaging*

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## Scapholunate Ligament Communicating Defects in Symptomatic and Asymptomatic Wrists

ABSTRACT & COMMENTARY

**Synopsis:** *Communicating defects are seen in the scapholunate ligament of both symptomatic and asymptomatic patients. This study finds that a complete ligamentous disruption or involvement of the dorsal portion of the ligament may indicate a traumatic cause rather than a degenerative change.*

**Source:** Linkous MD, et al. *Radiology* 2000;216:846-850.

Tears of the scapholunate ligament are a cause of radial-sided wrist pain. It is important to identify this lesion since it can be repaired. Many of these patients are referred for arthrography. It has already been shown that some communicating defects seen by arthrography can be asymptomatic and related to degeneration of the ligament with age.<sup>1,2</sup> Because of this asymptomatic communication that can exist, some studies have deduced that wrist arthrography is poorly predictive of symptoms.<sup>1,3-5</sup> Linkous and colleagues sought to determine whether the sizes and locations of scapholunate ligamentous communicating defects (SLLCDs) differed between symptomatic and asymptomatic groups, therefore helping to identify the more important and surgically correctable lesion.

Linkous et al reviewed the arthrographic data sheets, reports, and arthrograms of 213 consecutive patients who underwent bilateral wrist arthrography over a 15-month period at the Mallinckrodt Institute of Radiology. Of these, 30 patients met the criteria of having wrist trauma and unilateral wrist pain, and they demonstrated at least one SLLCD. As is customary in this institution, a triple compartment arthrogram was also performed on the asymptomatic wrist when a communicating defect was found in the symptomatic wrist, resulting in 60 arthrograms. The location and size of each ligamentous defect was recorded. Differences between symptomatic and asymptomatic wrists were analyzed with the  $\chi^2$  or Fisher exact test.

Most communicating defects in both groups were incomplete and ranged from pinhole size to large. There was a higher frequency of

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complete disruption in the symptomatic wrists (9 [32%] of 28 wrists) than in the asymptomatic wrists (2 [10%] of 20 wrists;  $P = 0.092$ ). Communicating defects involved the dorsal portion in 18 (64%) of the 29 symptomatic cases and in five (25%) of the 20 asymptomatic cases ( $P = 0.007$ ). Only one patient in the whole series had an isolated communicating defect in the volar portion of the ligament.

Linkous et al concluded that a complete ligament disruption or involvement of the dorsal portion of the SLL may favor a traumatic etiology rather than degenerative change. There is some question as to whether defects at the lunate attachment are also related to trauma.

#### ■ COMMENT BY LYNNE S. STEINBACH, MD

This well-written paper looks at the characteristics of (SLLCDs) in symptomatic and asymptomatic individuals using multi-compartment arthrography. The goal of determining a difference in size and location of these defects between the two groups was met. The significantly greater percentage of communicating defects in the dorsal segment of the SLL in the symptomatic group may have been related to the fact that the tears were larger in that group or that symptoms would be more forthcoming in this heavily innervated region of the ligament. The lack of involvement of the volar portion of the ligament may be related to the reinforcing extrinsic ligaments in this area. Linkous et al raise the question about whether degenerative perforation can be symptomatic.

This requires further investigation. Also, as Linkous et al point out, it may be that some of the defects that are asymptomatic in the population were the result of prior ligamentous trauma.

Linkous et al routinely perform bilateral triple compartment wrist arthrograms in patients with communicating ligament defects. This rigorous approach is not widely practiced in the radiology community, but it does add additional information about the significance of these defects if they are seen bilaterally in patients with unilateral wrist pain. This technique can provide valuable information for investigational studies such as this one.

I would suggest that magnetic resonance arthrography would be an excellent technique to further evaluate the hypothesis put forth in this paper. The multiplanar tomographic technique would allow one to precisely localize the defects. We would have to see how many patients would be willing to have both wrists evaluated in this manner! ❖

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GST Registration Number: R128870672.

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## Safety and Efficiency of Sedation for MR Imaging

### ABSTRACT & COMMENTARY

**Synopsis:** *Use of sedation for MR imaging results in a high percentage of good quality examinations. The use of skilled and trained radiology nurses to administer and monitor sedated patients has resulted in safe and highly effective sedation in both pediatric and adult patients.*

**Source:** Bluemke DA, Breiter SN. Sedation procedures in MR imaging: Safety, effectiveness, and nursing effect on examinations. *Radiology* 2000;216:645-652.

**M**agnetic resonance (mr) sedation is costly in terms of time for the procedure, scheduling prob-

lems, and personnel requirements of physicians and nurses. This study was undertaken to evaluate by review of records, the safety and effectiveness of sedation for adults and children undergoing MR imaging. Patients who were sedated were continuously monitored for hemoglobin oxygen saturation (SpO<sub>2</sub>) and pulse rate. Blood pressure measurement was performed at five-minute intervals during induction and recovery, and between MR pulse sequences. Visual patient monitoring with a camera of the magnet bore was required. Sedation screening included a physical examination, history of present illness, past medical history, and review of systems. The contraindications to sedation were allergy to a sedation medication, less than six hours of fasting from solids and less than two hours fasting from liquids; abnormal electrocardiogram; conditions that might result in airway compromise; hemodynamic instability; and coexistent morbid conditions. Condition was classified as American Society of Anesthesiologists system: Class I (normally healthy) and II (mild systemic disorder).

Medication and dose used were based on patient age and weight. Medications used were Chloral hydrate, Pentobarbital sodium, Diazepam, and Alprazolam.

From March 1991 to November 1998, 4761 patients received at least one sedation medication. Only 78% of scheduled sedation MR examinations were performed. Of these, 93.5% had successful sedation. Time to sedation was a mean of 23.6 minutes for specialized MR sedation nurses and 26.8 minutes for general radiology nurses. For inpatient nurses, the sedation time was 47.3 minutes and more variable. Mean duration of sedation was 63.6 minutes. Adverse events were recorded in 20 (0.42%) patients. Eight patients developed hypoxemia—four had cough and congestion so that associated motion did not allow completion of the examination; three patients had bronchospasm and stridor. All were discharged home and had no long-term complications.

The break-even costs were 37% more for general radiology nurses than for specialized MR sedation nurses performing the procedure. Conscious sedation is safe and effective. A trained specialized nursing staff reduces the cost and variability of effectiveness.

■ **COMMENT BY BEVERLY P. WOOD, MD, MSC**

Sedation of patients for prolonged procedures and those requiring immobility has been a longstanding practice in pediatric radiology, with protocols established for sedation preparation, monitoring, and discharge. However, sedation of adults with claustropho-

bia, agitation, or other causes of motion may ensure completion of an adequate examination. As in children, monitoring of the airway and respiration is essential, especially in the noisy and longer examination situation of MR.

The study includes a large number of children, but it also included 20% adults who required sedation. The study indicates that sedation is safe, adverse reactions are few, and nondiagnostic studies rarely occur.

Of particular importance is specialized training and expertise in the sedation staff. Sedation is more effective and more efficient when administered by trained nursing staff in the department.

Despite the low incidence of complications of sedation, continuous monitoring is essential and blood oximetry for even minor alterations is a sensitive indicator of pending airway and respiratory complications. When possible, blood pressure and respiratory monitoring are also advisable. Since good screening, development of effective pharmacologic protocols, and constant monitoring are the key to successful sedation, a dedicated nursing staff is advisable. ♦

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## Advanced Breast Biopsy Instrument

ABSTRACT & COMMENTARY

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**Synopsis:** *The percutaneous biopsy instrument known as the advanced breast biopsy instrument removes one large core of breast tissue, resulting in 90% of tissue sampling unrelated to the lesion in question and failed to provide margin-free malignant lesion recovery in 85% of cases.*

**Source:** Smathers RL. *AJR Am J Roenthenol* 2000;175:801.

**P**ercutaneous tissue sampling of nonpalpable breast lesions (and even palpable ones) detected by screening mammography has enjoyed increased acceptance in the United States during the past 10 years following the introduction of large bore needle techniques. This approach provides sufficient tissue for histologic analysis, distinguishing it from cytologic analysis,

which has been performed for 20 years in Europe. Both techniques are predicated upon precise placement of the sampling needle into the breast lesion, directed by computer-assisted stereotactic imaging.

Initial enthusiasm followed clinical validation using 14G needles with spring loaded biopsy devices, which were much more penetrating than earlier models. Improved sampling was noted for directional vacuum assisted needles, sometimes assisted by the use of 11G needles that were commercially available in the last few years. Understaging of disease (e.g., intraductal carcinoma being identified by core needle biopsy [CNB] as only atypical ductal hyperplasia, invasive carcinoma being identified by CNB as only intraductal carcinoma) as well as missed lesions are the main limitations of the procedure, recognizing that the latter problem applies equally to the alternative means of histologic analysis—namely, surgical excision. The advantages of percutaneous diagnosis relate primarily to decreased cost and morbidity, assuming that lesions that truly require tissue analysis are subject to the procedure. All such techniques involve the retrieval of multiple small core biopsy samples ranging from a maximum estimated 15mg (14 g) to 95mg (11 g) in weight.

The advanced breast biopsy instrument (ABBI) unit also uses stereotactic techniques to place a large cannula in front of a lesion, with a bore diameter of 10, 15, or 20 mm, and then advancing it in an attempt to remove one entire large biopsy sample. More closely designed to follow traditional excisional biopsy technique, the cannula takes tissue from the skin to beyond the lesion, the core separated from the breast with a wire “noose” that, with cautery, is retracted, allowing the operator to remove the entire unit and biopsy sample. In this way, only one sample is provided—with a large amount of tissue—and if the lesion is not recovered, then direct surgical excision follows.

The study of 101 ABBI-facilitated biopsies by six surgeons with localization assistance by a radiologist found 27 malignancies and 74 benign lesions, a profile consistent with most reported series. More than 90% of the tissue removed was unrelated to the lesion in question, with an average dimension of the removed specimen being  $5.51 \pm 2.18$  cm  $\times$   $1.65 \pm 0.46$  cm. Two lesions were missed by the technique.

Only four malignancies had “clean margins”—eight showing ductal carcinoma in situ (DCIS, intraductal carcinoma) at the margins and 23 showing invasive cancer at the margins. Tissue samples were often partially fragmented because of incomplete transection by the metal noose.

As a technique initially proposed for complete excision by percutaneous technique, the procedure fulfills its goal in a small number of cases.

■ **COMMENT BY R. JAMES BRENNER, MD, JD**

If it looks like an excisional biopsy, maybe it can be billed as an excisional biopsy. Not according to the Health Care Financing Administration.

The introduction of image-directed histologic tissue sampling for screening detected lesions have been validated for properly selected cases by its clinically efficacy and cost-effectiveness. CNB techniques are tantamount to incisional biopsy and, with recognition of anticipated tissue sampling errors requiring subsequent excision, have obviated the need for surgical biopsy in a large percentage of cases. Translation: fewer surgical cases and potential turf battles.

Originally reimbursed for a professional fee approximating \$70, CNB attracted little attention from the surgical community until an increasing number of cases were being diagnosed by radiologists instead of surgeons. With improved techniques, reimbursement increased, and cases continued to fall into the hands of radiologists.

US Surgical defined a technique in the ABBI that more closely approximated surgical excision and was primarily marketed to surgeons as the equivalent of excisional biopsy; thus, percutaneous cases could be accomplished with customarily higher professional reimbursement fees. Moreover, the difficult part of the procedure—the image-directed localization—could be performed for a relatively lower reimbursement fee by the radiologist. It was a promising proforma, especially because the surgical community often carried more influence with hospital administrators in being a source of patients. Besides, the concept of complete percutaneous removal of benign lesions as well as malignant lesions with free margins was medically appealing.

A number of papers have been published, including this one from one of the demonstration sites chosen by US Surgical to bring prospective customers, demonstrating that such goals have not been achieved. Mechanical problems, inability to retrieve entire lesions (for design reasons that are beyond the scope of this discussion), and inability to provide margin-free size estimates of malignant lesions, have failed to provide a basis for the increased morbidity associated with this percutaneous approach. In fact, the large amount of extraneous tissue obtained with this procedure has been modified by a different biopsy device using a similar design, but which suffers from the

same considerations.

Coupled with the denial of reimbursement for excisional biopsy (likely a major disincentive), the problems with this technique have quieted enthusiasm, even among institutions that purchased prone biopsy tables suited for these disposable devices that cost more than \$500 each (cost of CNB needles range from \$10 to \$220). Many of these users have changed to more traditional CNB techniques, with CNB instruments now available from the same vendor, as well as other vendors.

It may well be that future applications of complete lesion removal and adjuvant treatment by percutaneous means (e.g., radio-ablation) will have a distinct place for a select group of cases where imaging parameters are sufficiently specific to determine accurate size and devices adequate to ensure removal. But one cannot help but wonder if market-driven forces defined a need for a tool with questionable clinical application. ❖

## CT Scanning for Minor Head Injury

ABSTRACT & COMMENTARY

**Synopsis:** *This study indicates a sensitive set of clinical indicators for obtaining a brain CT in patients with minor head trauma: headache, vomiting, age older than 60 years, drug or alcohol intoxication, deficits in short-term memory, physical evidence of trauma above the clavicles, and seizure.*

**Source:** Haydel MJ, et al. *N Engl J Med* 2000;343:100-105.

Since the introduction of CT for evaluation of patients with potential head injury, selection of which patients should receive a CT scan remains controversial. While there is no question of use of CT in patients with major head injury, criteria for its use for screening patients with minor head injury have been variable. Approximately two-thirds of the patients with head trauma are classified as having minor head trauma and less than 10% of patients with minor head trauma have positive findings on CT scanning. The study in this report was undertaken to develop and validate a simple set of clinical criteria to use in identifying patients with minor head injury who should undergo CT.

Phase 1 consisted of 520 consecutive patients with

minor head injury, who were at least 3 years old and presented within 24 hours of injury; were evaluated to determine which clinical findings identified patients with positive findings on CT of the head. Phase 2 consisted of application of the predictive findings of Phase 1 to a group of 909 patients with minor head injury. The predictive value of the findings in Phase 1 was prospectively validated in the Phase 2 questionnaire. Patients were studied in two groups: those who had at least one of the seven findings established in Phase 1 and those who had none. The frequency of positive CT scans was determined for each group. The sensitivity, specificity, and negative predictive value of the criteria were calculated.

The results of Phase 1 showed 6.9% positive CT scans. This finding is consistent with the results of other studies. All of the patients with positive CT scans had one or more of seven findings:

- Headache
- Vomiting
- Age older than 60 years
- Drug or alcohol intoxication
- Deficits in short-term memory
- Physical evidence of trauma to the head or neck
- Seizure

Of the 909 patients in Phase 2, 6.3% had positive scans. The combined sensitivity of the seven findings above, was 100% (95% confidence interval, 95-100%). All the patients with positive CT scans had at least one of the findings. The results suggest that of patients with minor head injury, those selected for CT should be those with one or more of the clinical findings noted.

### ■ COMMENT BY BEVERLY P. WOOD, MD, MSC

Routine use of head CT for all patients with minor head trauma is generally considered to be a waste of resources; however, identifying those who may be at risk from minor trauma is difficult. Some previous studies have evaluated predictors of positive CT scans, but the sensitivity has been below 100%. The use of skull radiographs to detect a fracture, soft tissue injury, and neurologic abnormalities have not proved to be accurate predictors of positive CT scans.

This study with a large number of consecutive patients relied on a symptom questionnaire to gather clinical data. The correlation with CT sensitivity is excellent. Phase 2 was undertaken to search for false-negative presentations. Reliance mainly on symptomatology also allows more expeditious patient workup without the need to await a detailed neurologic examination. Correlation of these selec-

tion criteria in other corroborating studies will be helpful in management of this large group of patients with minor trauma who may develop significant problems related to unanticipated central nervous system trauma. ❖

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# Anticoagulant Therapy: Safe to Withhold?

## ABSTRACT & COMMENTARY

**Synopsis:** *It is safe to withhold anticoagulant therapy from patients who have a negative helical CT scan for pulmonary embolism.*

**Source:** Goodman LR, et al. *Radiology* 2000;215:535-542.

Since the advent of helical scanners in the early 1990s, there has been progressive improvement in the ability of CT angiography of the pulmonary arteries to detect emboli directly without the need for the more definitive but invasive pulmonary arteriogram. While many studies published to date have focused on the accuracy of helical CT for central pulmonary emboli, reported as more than 90%, there have been limited data on the safety of withholding anticoagulant therapy in patients whose helical CT pulmonary angiograms are interpreted as normal (i.e., the negative predictive value of CT pulmonary angiography). In fact, it is this limitation of available helical CT data that has led several authors to conclude that the use of helical CT in place of ventilation/perfusion scintigraphy or pulmonary angiography for the diagnosis of pulmonary embolism is not currently warranted. This study seeks to answer the question of the safety of withholding anticoagulant therapy in patients with suspected pulmonary embolism who have a CT pulmonary angiogram interpreted as negative for pulmonary embolism.

At Goodman and colleagues' institution, patients with suspected pulmonary embolism who had either helical CT angiography or ventilation/perfusion (V/Q) scan performed as the initial diagnostic test were

enrolled beginning in 1995. The study group consisted of 548 patients who were followed clinically for three months after one of the following three test results: a normal helical CT angiogram, a normal V/Q scan, or a low probability V/Q scan. The negative predictive values of each of these three test results were calculated based predominantly upon clinical followup of patients to determine whether they developed recurrent pulmonary embolism or thromboembolic disease in the three month period following the index examination.

The incidence of subsequent thromboembolic disease in the patients with negative helical CT exams, normal V/Q scans, and low probability V/Q scans was 1%, 0%, and 3%, respectively, resulting in negative predictive values of 99%, 100%, and 97% for each test, respectively. Goodman et al concluded that the incidence of recurrent thromboembolic disease following a negative CT exam is comparable to that following a normal V/Q scan, and the high negative predictive value of helical CT pulmonary angiography indicated that anticoagulation therapy can be safely withheld following negative examinations.

## ■ COMMENT BY JEFFREY S. KLEIN, MD

While this paper attempts to provide further rationale for using helical CT angiography in the evaluation of suspected pulmonary embolism by showing a high negative predictive value of this examination, there are some significant limitations that preclude drawing widespread conclusions regarding the exact utility of helical CT pulmonary angiography in this setting. The patient populations that comprised the two main study groups with negative test results, those who underwent helical CT and those who had V/Q scans, differed significantly in several respects, most importantly in the source of patient referral and in the performance of Doppler ultrasound examination of the lower extremities—the latter known as a reliable predictor of subsequent thromboembolism and patient outcome. The nature of the follow-up in the patients with negative study results makes it impossible to determine the true incidence of recurrent thromboembolic disease, and a significant number of patients were either lost to follow-up or excluded from consideration because of the administration of anticoagulants. Therefore, more outcome data, preferably with the combined use of CT pulmonary angiography and venography in a randomized, controlled trial with pulmonary angiography as the

gold standard and a standardized method of patient follow-up, will be needed before the precise role of helical CT in patients with suspected thromboembolic disease can be determined. ❖

## Reference

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# Radiology Reporting in an Academic Children's Hospital: What Referring Physicians Think

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## ABSTRACT & COMMENTARY

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**Synopsis:** *A survey of referring pediatricians as to their expectations and use of radiology reports indicates that residents are less confident in their interpretation of images, that the most important content of a report is the response to the question posed in the referral, and that clarity was the most highly regarded nondiagnostic characteristic.*

**Source:** Gunderman R, et al. *Pediatr Radiol* 2000;30:307-314.

Gunderman and colleagues conducted a survey of referring physicians (181 responses) regarding their needs and assessments of radiology reports they received. Rating a number of parameters for importance, the value of radiology rated good-excellent, but there were a broad range of responses as to whether the report changed decisions made in patient care. A rating of content characteristics of radiology reports rated most highly response to the specific question posed in the referral. Other desirable characteristics of the report were 1) correlation with the results of other imaging examinations; 2) the radiologist's opinion regarding the most likely diagnosis; 3) the radiologist's differential diagnosis; and 4) reference to the limitations of the examination. The least highly rated content characteristic was the radiologist's recommendations in light of the examination.

When rating the importance of nondiagnostic characteristics of radiology reports, most highly rated was clarity, followed by timeliness, ease of accessing images, responsiveness, completeness, and

conciseness.

Differences between attending physicians and resident physicians were mainly in their assessments of how well they were able to interpret radiology studies. The mean response for residents was 2.9 (1 low, 5 high) and the mean response for attendings was 3.4. There was also a difference between generalist and specialist pediatricians in their assessments of their ability to interpret imaging studies. General pediatricians rated themselves 3.0 and specialists rated themselves 3.5. Generalists estimated a higher percentage in which the information in the report changed healthcare management decisions and the generalists were less likely to view the images than were specialists. Specialists rely on the typed report less than generalists.

There was a strong positive relationship between the number of studies respondents order per week and the percentage of cases in which they view the images. The number of studies ordered per week is negatively related to the percentage of cases in which respondents read the radiology report. Similarly, there is a strong inverse relationship between the number of studies ordered per week and respondents' assessments of the frequency with which the radiology report changes health care management decisions.

## ■ COMMENT BEVERLY P. WOOD, MD, MSC

As images are more rapidly and widely available and as reports are generated to accompany images dispersed for viewing, the report increasingly is the way the radiologist is known to the referring physician. Knowing the needs and expectations of the referring physicians is a big step in validating the usefulness of radiology reports.

Gunderman et al asked questions about the key elements that radiology reports should include, how often referring clinicians read radiology reports, and how often radiology reports change the way patients are cared for. They asked the value of radiology.

Other questions that could be addressed are how radiology departments could improve their reports, what is bad about reports, and what is most frequently omitted that referring physicians expect to see. Do physicians read the whole report?

Overall, this is a good step in evaluating the use and usefulness of reports from one institution. Although radiologists spend large amounts of time performing studies and formulating differential diagnoses, they spend much less time and effort considering how to communicate results to other physicians. A consideration in training of residents should include communication of results of imaging studies

to referring physicians. More rapid preparation of reports so that they can accompany image dispersal makes this form of communication an even stronger focus for our consultation skills. ♦

## CME Questions

### 33. Which one of the following statements is false?

- a. Most communicating defects in both groups were incomplete.
- b. There was a higher frequency of complete disruption in the asymptomatic wrists.
- c. A larger percentage of the symptomatic defects were located on the dorsal aspect of the ligament compared to the asymptomatic defects.
- d. Some communicating defects of the scapholunate ligament as demonstrated by arthrography are asymptomatic.

### 34. Which staff is most efficient in management of patient sedation?

- a. Subspecialized radiology nurses
- b. Intensive care nurses
- c. General inpatient nurses
- d. Radiologists

### 35. Complete removal of malignant breast lesions by the ABBI device was accomplished in what percentage of cases in this study of 101 patients?

- a. 15%
- b. 30%
- c. 50%
- d. 70%
- e. 90%

### 36. Which of the following symptoms is an indication for CT in minor head injury?

- a. Paresthesias
- b. Weakness
- c. Age older than 50 years
- d. Deficit in short-term memory

### 37. In a study of referring physicians' use of radiology reports, what was the most important nondiagnostic element?

- a. Format
- b. Conciseness
- c. Clarity
- d. Completeness

### 38. Involvement of which portion of the scapholunate ligament favors a traumatic disruption?

- a. Scaphoid attachment
- b. Volar
- c. Central
- d. Dorsal

### 39. What is the most important parameter to monitor during sedation?

- a. Blood pressure
- b. Respiratory rate
- c. EKG
- d. Blood oximetry

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## Images on Demand: Why is Teleradiology so Underused?

*Licensing, HIPPA Concerns are Biggest Barriers*

*By Julie Crawshaw*

There may come a time when radiology will be practiced in a manner that allows any image to be available to any location at any time to any authorized user. At least that's the vision of Tom Johnson, MD, Chief Medical Officer for the Dallas-based radiology practice management firm of U.S. Radiology Partners.

So why isn't this the case now, when the required technology is already here? Johnson says the biggest thing holding teleradiology back is the licensing barrier. He points out that radiologists in one state don't want their colleagues in another state interpreting images without a license to practice medicine where those images are taken. Johnson, who spent two years acquiring medical licenses in 12 states, tells of a California radiologist who spent four years and \$60,000 to obtain licenses in 49 states. The only state he didn't get a license for is New Hampshire, which requires that the practice be physically located there. Johnson points out that this "circle the wagons" approach isn't unique to radiology. "Telemedicine includes psychiatry, dermatology, pathology—all of those things are threatening to medical societies everywhere."

The medical-legal issues are complex. "I'm a Texas radiologist," says Johnson. "Say I'm reading an image taken in Virginia, where I also have a license, and I miss something that leads to a lawsuit. Am I sued under Texas law or Virginia law? And is my professional liability insurance company going to cover me at the Texas rate or the Virginia rate? Somebody would have to decide where the venue would be."

Even with all these attendant problems, teleradiology can be the radiologists' best friend. The whole idea behind it is putting the image in front of the expertise, which benefits radiologists practicing in small or rural communities who lack nearby colleagues for backup.

"You have 400 hospitals nationwide that don't have radiologists on site, and a large number of radiologists congregated in the nice metropolitan areas," Johnson says. "Receiving the expertise at the site of care requires teleradiology."

A lot of practices are looking for backup in whatever form they can get it, and they are turning toward teleradiology as a solution. Johnson's brother-in-law practices at a 60-bed hospital in a town with a population of 9000 people in western Nebraska. "He's there by himself," Johnson says, "and his closest backup is 60 miles away. When he wants to leave town, he switches to telerad and gets coverage from Denver or Cheyenne, Wyoming."

In fact, the original driver for teleradiology was the physician's convenience. Some practices now use a "nighthawk" system, in which one radiologist at a central location reads images sent from several facilities.

Johnson points to four additional factors that also fuel the drive for teleradiology.

- **A nationwide shortage of radiologists that began in the early-to-mid 1990s is creating even more pressure.** Johnson says the radiology community actually closed down some residencies in response to the government's attitude that U.S. medicine needed more generalists than specialists. The number of radiology residencies decreased by about 9% as medical imaging increased by 8-12% per year. "The number of radiographs and medical images has skyrocketed," Johnson says. "The technology has improved, and you get a lot more information."

Everybody who comes into a hospital today gets at least one radiographic study.”

- **An aging population full of baby boomers who now require more medical care.** The demand for medical imaging is actually growing faster than the general medical demands. Ten years ago, only 30-40% of women got mammograms. Now 60-70% do, and somebody’s got to read those x-rays.
- **The days of an 8-10 hour work day for radiologists have ended.** Technological sophistication and demands being placed on the entire medical care system today mean radiology practices now require coverage 24 hours a day, seven days a week. “Instead of covering our hospitals in Dallas with 10 radiologists, we now need 12 or 15 to cover those same facilities,” Johnson says.
- **More radiologists are retiring early because they don’t want to work more to have less money.** Many radiologists who began practicing during the fat and happy days of the 1970s, 1980s, and early 1990s when fee-for-service indemnification plans were in place, have decided they don’t need to continue practice under today’s more restrictive, time-consuming reimbursement climate. A radiologist accustomed to earning \$300,000 a year, doing an 8-to-5 job and now 55 years old, is being called back to the hospital at 9 p.m., again at 11 p.m., and maybe at 2 a.m., all for less money than before. “It used to be that physicians practiced until they were 65 or 70 years old,” Johnson says. “Many of those who were the recipients of a very good previous 20 years during which they were able to build up their assets are bailing out at 50 to 55.” Right now, reimbursement is not an issue because Medicare reimburses for teleradiology as do most insurances. But successfully wooing new radiologists is another story. “This is the tightest radiology market I’ve ever seen,” Johnson comments. “It’s hard even to get a radiologist to go to a nice place for a good salary, let alone to somewhere in the snowbelt for less money.” ❖

## Will HIPAA be a Barrier to Spread of Teleradiology?

*Privacy Requirements Cause Concern*

*By Julie Crawshaw*

At first blush, the health insurance portability and Accountability Act (HIPAA) of 1996

appears to add privacy to teleradiology’s problems. After all, the proposed rule recognizes that “a clear and consistent set of privacy standards would improve the effectiveness and efficiency of the health care system.” Is there a way to accomplish this when images are floating all over the place?

Diana Haramboure, Vice President of Healthcare Consulting at Data Dimensions, a Bellevue, Wash.-based company that works with members of the health care industry to prepare for HIPAA implementation, points out that HIPAA mandates developing procedures for data security.

“I think they are calling for ‘guidelines’ because they don’t want to say ‘If you do these 10 things, then you’ll be fine.’ The government wants to tell people the kinds of things they should do and leave it up to individuals to figure out how to do them because being too prescriptive would create risk and liability.” Haramboure says that under HIPAA, penalties for violating patient privacy range from \$50,000 and one year in jail, to \$250,000 and 10 years in jail.

Just who can and can’t see transmitted medical information remains an issue yet to be clearly defined. “There’s a lot of paranoia because of the ambiguous interpretation of the requirements,” says Mark Bakken, Executive Vice President of U.S. Radiology Partners. “Interpreting HIPAA is more art than science. You’re seeing some manufacturers claiming they have the only HIPAA-approved server available, but all servers require security and firewalls.”

He adds that, teleradiologically speaking, HIPAA’s privacy requirement is a red herring. “It’s almost impossible to interrupt an image travelling over phone lines because the lines are proprietary,” he says. Modems are point-to-point operations and cannot be “hacked into” like databases. Even Internet transmission requires security codes to enter the server that contains the image.

Bakken points out that medical privacy is far more endangered by moving text that anyone can read and understand than in moving an image that only has meaning to a radiologist. “It would be quite a stretch to say that there’s a group of radiologists trying to hack into images, especially when the images ultimately result in a written report,” Bakken says.

Ultimately, an image is just an image until somebody interprets what it means. Since medical information fears are founded on how somebody is going to adversely use the information, the image has no value until someone makes a written interpretation. “It’s the written information people should be concerned about, which brings us to the issue of hospital

databases, physician databases, and insurance company databases,” Bakken says.

Bakken observes that teleradiology offers huge benefits from the quality of medicine, and operational and financial standpoints. “Teleradiology allows us to move from a hard copy film into a digital format—which is by many measurements a better way to hold it, because you can manipulate the image to get better reads and it saves money.”

One example is the Picture Archived Communications Systems (PACS), which store, move, and file electronic images. PACS consolidate information, reduce or eliminate film costs, and allow the image to be manipulated for a better read.

“The biggest problem with hard copy is that somewhere along the line it becomes worthless and has to be done over again,” Bakken says. “Doing it electronically allows the techs to do their jobs instead of being file clerks.”

He sees the concern over HIPAA regulations as more related to PACS than to teleradiology per se. Bakken argues that storing hard copies of films creates more interference exposure, because hard copy file rooms aren’t protected by a security guard whereas the PACS have firewalls and security systems built-in. “There are far more benefits to electronic security than there are risks,” Bakken says.

Though the benefits of teleradiology would seem to fit hand in glove with the need for specialist medicine in Third World countries with largely rural populations, this just isn’t happening. “There’s hardly any teleradiology going on in rural areas of the Third World. In the early 1990s, Harvard set up a teleradiology center and offered its services to the rest of the world, but it just hasn’t played out the way they thought it would,” Johnson says. “It’s altruistic and makes for good press, but it just doesn’t pay.” ❖

## Power Imaging System Merges Diagnostics, Therapeutics

*By Don Long*

*Staff Writer*

**A** star trek-type medicine has given us a look at the ultimate in noninvasive health care: A hand-

held device is passed over the patient and—voila!—he is able to return to his station on board the Enterprise. Whatever that device is, it is capable of both diagnosing and treating the injury or disease at one and the same time.

Combining the two modalities—let alone being able to do it noninvasively—is of course in the far future of health care. But it could be closer than we might think, given the proof of that concept in a new system from Photogen Technologies, of Knoxville, Tenn, a company focused on developing various leading-edge systems, in tandem. Its primary focus thus far has been phototherapeutics, that is, the combination of light with drugs for treating tissue diseases, with the announcement this week that it has received five international patents covering its Two-Photon Excitation system for treating cancer.

Growing from work in this area, Photogen earlier this year also announced the development of a two-photon diagnostic technology, an infrared light system that offers the possibility of noninvasive but even more precise imaging within the body, and potentially able to deliver therapy to the cells identified for treatment either with or without radiosensitive agents.

That is one of the advanced goals described by Photogen Senior Scientist Eric Wachter, PhD, who says the two-photon system offers the possibility of sidestepping biopsy while providing treatment “within a few centimeters, fairly near the surface.”

“Key to this system is the wavelength of photons,” he says. “The wavelength of the photon allows it to be delivered beyond just superficial portions of the body. In these very short pulses, we can produce the two-photon process very efficiently without risking any other sort of tissue-photon interaction to [healthy] tissues of the body.”

“What we’re doing is taking a beam and focusing it down to a very small volume,” he said, with the two photons becoming “coherent, both temporally and spatially—they’re present at the same time and they have the same trajectory, the same phase.”

“It sounds pretty exotic,” Wachter acknowledged. “What it means is that [the pulses] originate from a single laser pulse and a laser is by definition producing coherent light, by focusing that light.”

A key advantage Wachter cited for the system is its ability to produce clear images in the presence of various distracting artifacts, such as other light. Standard photon microscopy normally requires a “catastrophically dark room, totally sealed off, to collect very beautiful images. But if you allow any small amount of light into the system, the performance degrades very quickly,”

Wachter said. But with the two-photon system, “you can literally turn on overhead fluorescent lights and obtain data not markedly different than the profoundly dark conditions.”

Using a basic analogy, Wachter compared this new imaging system to a common radio transmission. “With AM radio,” he said, “we’re able to extract very small radio frequency signals out of the atmosphere in the presence of a tremendous amount of noise.” This advantage translates well to both research and clinical arenas, according to Wachter.

On the clinical side, two-photon imaging—and, more generally, multi-photon imaging—is being pushed forward by David Piston, PhD, a professor of biophysics at Vanderbilt University in Nashville, Tenn, who first worked on developing multi-photon imaging in a collaboration with two of his graduate students.

This type of imaging, Piston says, is best for “thick tissue work, something other imaging systems can’t do. We use it to look at auto fluorescence in the liver, pancreas and peripheral tissue, to look at metabolic state of the cells.”

The limiting factor, he says, is determining when to use this imaging modality. “It can’t do that much on a whole animal scale,” he says, “but you can get an order of magnitude and better resolution than PET [positron emission tomography] or NMR [nuclear magnetic resonance] or anything like that. But you have to figure out when you need that ‘betterness.’ That’s where we are now.”

Clinically, he predicts the most frequent uses in diagnosing skin cancer and other skin diseases, plus, in hard tissue uses, dental applications.

This latter is being developed by John Girkin, a professor at the University of Strathclyde (Glasgow, Scotland), according to Wachter, who says that this research may result in the commercialization of a two-photon imaging system for this application in 2-3 years.

The ultimate use of the system would come in combination with the company’s phototherapeutic products, as represented in its Two-Photon Excitation system. Two treatment patents for that system have been announced in Australia and Singapore, and three imaging patents have been issued in Australia, Singapore, and New Zealand. The technology is also covered by various U.S. patents.

Two-photon imaging could ultimately be used to help determine when to use phototherapy, and since the sys-

tems for delivering laser light are essentially the same in both the diagnostic and phototherapeutic applications, they could then be combined into one system. “The general apparatus would be virtually identical,” said Wachter, “so you have the potential for a modality where you would be able to diagnose and treat with a single unit.”

Wachter reported that Photogen is in the process of preparing various clinical trials of its phototherapeutic agents in treating cancers of the breast and for melanoma. And he said that the company should be able to bring its microscopy product to the market “about the same time as the therapeutic product. We’re very excited about the prospects.”

“We’re still in the learning phase of how to get from the laboratory to the market,” he added, “but these are some very good-looking technologies.”

Besides acceleration of the company’s development of a compound for treating cancer, President and CEO Taffy Williams reported progress in a joint venture with Elan to develop N1177, a minimally invasive lymphography product used to diagnose metastatic tumors in lymph nodes. “We expect to commence one or more Phase II studies for this product in 2001,” Williams says. ❖

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