

# RADIOLOGY ALERT®

*A monthly update on developments in imaging*

American Health Consultants Home Page—<http://www.ahcpub.com>

CME for Physicians—<http://www.cmeweb.com>

**EXECUTIVE EDITOR**  
**Lynne S. Steinbach, MD**  
Professor of Radiology,  
Department of Radiology,  
University of California San  
Francisco, San Francisco, CA

**EDITORIAL ADVISORY  
BOARD**

**R. James Brenner, MD, JD**  
Clinical Professor of Radiology,  
UCLA School of Medicine,  
Eisenberg Keefe Breast Center,  
Santa Monica, CA

**James H. Ellis, MD**  
Professor of Radiology,  
Department of Radiology,  
University of Michigan Hospital,  
Ann Arbor, MI

**Nancy J. Fischbein, MD**  
Assistant Professor of  
Radiology, Department of  
Radiology, University of  
California San Francisco,  
San Francisco, CA

**Elliot K. Fishman, MD**  
Professor of Radiology and  
Oncology, Director, Diagnostic  
Imaging and Body CT, Johns  
Hopkins University School of  
Medicine, Baltimore, MD

**Jeffrey S. Klein, MD**  
Assistant Professor of  
Radiology, Department of  
Radiology, Medical Center  
Hospital of Vermont,  
Burlington, VT

**Faye C. Laing, MD**  
Professor of Radiology,  
Harvard Medical School  
Department of Radiology,  
Brigham & Women's Hospital,  
Boston, MA

**David M. Panicek, MD**  
Professor of Radiology,  
Department of Radiology,  
Memorial Sloan-Kettering  
Cancer Center, New York, NY

**Gautham P. Reddy, MD**  
Assistant Professor of Radiology  
University of California San  
Francisco, San Francisco, CA

**Geoffrey D. Rubin, MD**  
Assistant Professor,  
Department of Radiology,  
Stanford University School  
of Medicine, Stanford, CA

**Moni Stein, MD**  
Assistant Professor of  
Radiology, UC Davis Medical  
Center, Sacramento, CA

**Beverly P. Wood, MD**  
Professor of Radiology,  
Pediatrics, and Medical  
Education, Keck School of  
Medicine, University of Southern  
California, Los Angeles, CA

## Magnetic Resonance Imaging of Paralabral Cysts

ABSTRACTS & COMMENTARY

**Synopsis:** Paralabral cysts are occasionally identified in the shoulder and hip. They are usually associated with adjacent labral tears. Two recent studies emphasize the use of MRI for identification of these cysts and the associated labral pathology. The second article about paralabral cysts in the shoulders cautions against using direct cyst aspiration as the sole treatment of this disorder.

**Sources:** Magee T, Hinson G. Association of paralabral cysts with acetabular disorders. *AJR Am J Roentgenol* 2000;174:1381-1384; Tung GA, et al. MR imaging and MR arthrography of paraglenoid labral cysts. *AJR Am J Roentgenol* 2000;174:1707-1715.

**T**ears of the acetabular labrum can cause hip pain. Some orthopedists are now repairing these tears via an arthroscopic approach. Since this is a condition that can be treated, it is important to identify a labral tear when doing an MRI to evaluate hip pain. The paralabral cyst is an occasional finding seen in association with these labral tears and it can be well seen on MRI.

This retrospective study identified a subset of 13 patients who had paralabral cysts around the hip in a group of 87 patients who underwent MRI at their institution. MRI arthrography was not obtained in any of these studies. All patients had a history of remote hip trauma. No patients had developmental dysplasia of the hip. Three patients had degenerative changes in the hip joint on conventional radiographs. Cysts were located on the posterior aspect of the hip in eight patients and along the anterior aspect in five patients. One patient has a percutaneous aspiration of the cyst using sonography. That cyst reaccumulated fluid, as seen six months later on an MR arthrogram.

Surgery was performed on 10 of these hips and all were found to have labral tears. Magee and colleagues conclude that paralabral cysts have a high incidence of association with labral pathology and demonstration of a paralabral cyst on MRI is a useful indirect sign of acetabular labral disorders.

## INSIDE

*Ethics and  
clinical  
research*  
**page 79**

*CTA for  
cerebral  
vasospasm*  
**page 80**

*CT findings  
of various  
cystic  
pancreatic  
tumors  
overlap*  
**page 81**

*Effect of  
obesity on  
screening  
mammography*  
**page 82**

Volume 1 • Number 8 • August 2000 • Pages 77-88

**NOW AVAILABLE ONLINE!**  
Go to [www.ahcpub.com/online.html](http://www.ahcpub.com/online.html) for access.

Paraglenoid cysts are a red flag on MRI, usually indicative of a neighboring glenoid labral tear, just as they are in the hip of an acetabular labral tear. These cysts can also cause nerve entrapment in the shoulder region. This investigation found 51 paraglenoid cysts on MRIs of the shoulder of 46 patients. MR arthrography was performed on five of the patients. One patient had cystography. Arthroscopic surgery was performed on 17 shoulders and four patients had percutaneous needle aspiration of the cysts.

Cysts were best seen on T2-weighted images where they were high signal intensity. Mean cyst diameter and volume were 2.2 cm and 2.8 cm<sup>3</sup>, respectively. Fifty-seven percent of cysts were located adjacent to the posterior labrum. Thirty-nine cysts were located in the right shoulder and 12 cysts in the left shoulder. Shoulder pain was the chief complaint in 40 (87%) of the patients. Twenty (43%) of the patients had a history of trauma.

On MR imaging and arthroscopy, a labral tear was identified in 27 and 15 patients, respectively. Eight cysts that caused compression neuropathy were large and located next to the posterior or inferior labrum. In four of five patients, MR arthrograms showed no intra-articular contrast material in the cyst. Cystograms showed no communication with the glenohumeral joint space, and cyst aspiration resulted in temporary symptom relief; however, cysts recurred in three of four patients, including one case where the cyst had been injected with steroid.

Some cysts caused denervation changes in the distrib-

ution of the suprascapular nerve. One cyst, located along the inferior labrum, produced denervation of the axillary nerve with characteristic pathologic changes in the teres minor muscle. Tung and associates report that this is the first time to their knowledge that a paralabral cyst has been shown to cause axillary neuropathy. This has actually been reported before in one patient.<sup>1</sup> It is of interest that denervation identified through electrodiagnostic studies was seen on MRI in all but two patients. Tung et al postulate that some of these may have been neuropraxic injuries with myelin damage but axonal sparing resulting in normal signal intensity in the muscle on MRI. This form of neuropathy contrasts with axonometric nerve injuries where axonal loss distal to the site of nerve injury and abnormal signal intensity appear in the affected muscles. The images were obtained with Fast spin echo T2-weighting. Tung et al also postulate that short tau inversion recovery (STIR) imaging, with its known hypersensitivity to edematous change, might have detected the denervation in the two patients without those changes on MRI.

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

These retrospective studies reaffirm the knowledge that paralabral cysts are secondary findings associated with labral tears in the hip and the shoulder. The imaging findings of these studies have been published before.<sup>1-7</sup> The strength of these papers is that there is surgical proof in a larger group of cases. It has been difficult for other authors to obtain good surgical correlation.

These cysts are analogous to the meniscal cysts of the knee. Synovial fluid is pushed through a fibrocartilage tear into the surrounding soft tissues. Identification of cysts in these locations should alert the imager to take a careful look at the adjacent fibrocartilaginous structures and to suggest the presence of a labral tear when the labrum has not been adequately imaged with high-resolution studies or MR arthrography. It is of interest that the larger cysts were the ones that tended to produce muscle denervation in the shoulder.

When symptomatic, paralabral cysts have been treated by percutaneous aspiration, steroid injection, arthroscopic decompression, or open excision. It is of interest that cysts recurred in three of the four patients who underwent percutaneous aspiration of the shoulder cysts and in the one patient who had her hip cyst aspirated. This is an argument for repairing the tear first and aspirating the cyst later if it is still present.

Only a few of the MR examinations in the shoulder study were MR arthrograms and there were no MR arthrograms performed in the hip study. Although paralabral cysts can be a marker of labral pathology, the mes-

**Radiology Alert**, ISSN 1044-0577, is published monthly by American Health Consultants, 3525 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.

#### VICE PRESIDENT/GROUP PUBLISHER:

Donald R. Johnston.

**EDITORIAL GROUP HEAD:** Glen Harris.

**ASSOCIATE MANAGING EDITOR:** Robin Mason.

**GST Registration Number:** R128870672.

Periodical postage paid at Atlanta, GA.

**POSTMASTER:** Send address changes to *Radiology Alert*, P.O. Box 740059, Atlanta, GA 30374.

Copyright © 2000 by American Health Consultants. All rights reserved. No part of this newsletter may be reproduced in any form or incorporated into any information-retrieval system without the written permission of the copyright owner.

This is an educational publication designed to present scientific information and opinion to health professionals, to stimulate thought, and further investigation. It does not provide advice regarding medical diagnosis or treatment for any individual case. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Professional counsel should be sought for specific situations. The publication is not intended for use by the layman.

#### Statement of Financial Disclosure

In order to reveal any potential bias in this publication, we disclose that Dr. Brenner is a stockholder of Veritas, Dr. Higgins is involved in research with Novartis, Schering, and AstraZeneca, and Dr. Rubin serves on the speaker's bureau of Athena and is involved in research with Astra Medica. Drs. Steinbach, Ellis, Fischbein, Fishman, Klein, Laing, Panicek, Stein, and Wood report no financial relationships with companies having ties to this field of study.

#### Subscriber Information

Customer Service: 1-800-688-2421.

Customer Service E-Mail Address: [customerservice@ahcpub.com](mailto:customerservice@ahcpub.com)

Editorial E-Mail Address: [robin.mason@ahcpub.com](mailto:robin.mason@ahcpub.com)

World-Wide Web: <http://www.ahcpub.com>

#### Subscription Prices

##### United States

\$249 per year (Student/Resident rate: \$149).

##### Outside the United States

\$279 per year plus GST (Student/Resident rate: \$179 plus GST).

##### Back Issues

\$42 per issue. Missing issues will be fulfilled by Customer Service free of charge when contacted within one month of the missing issue's date.

#### Accreditation

American Health Consultants designates this continuing medical education (CME) activity for up to 30 hours in Category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

AHC is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide CME for physicians.

This CME activity was planned and produced in accordance with the ACCME Essentials.

#### Questions & Comments

Please call **Robin Mason**, Associate Managing Editor, at (404) 262-5517 or **Neill Larmore**, Assistant Managing Editor, at (404) 262-5480 between 8:30 a.m. and 4:30 p.m. ET, Monday-Friday.

sage in this day and age should be that we need to try to diagnose labral tears with high-resolution studies and MR arthrography. When doing an arthrogram, one should make sure to include a T2-weighted or STIR sequence to identify the cyst, since contrast does not usually flow into these cysts. ❖

## References

1. Sanders TG, Tirman PF. Paralabral cyst: An unusual cause of quadrilateral space syndrome. *Arthroscopy* 1999;15:632-637.
2. Schnarkowski P, et al. Magnetic resonance imaging of labral cysts of the hip. *Skeletal Radiol* 1996;25:733-737.
3. Haller J, et al. Juxtaacetabular ganglionic (or synovial) cysts: CT and MR features. *J Comput Assist Tomogr* 1989;13:976-983.
4. Tirman PF, et al. Association of glenoid labral cysts with labral tears and glenohumeral instability: Radiologic findings and clinical significance. *Radiology* 1994;190:653-658.
5. Fritz RC, et al. Suprascapular nerve entrapment: Evaluation with MR imaging. *Radiology* 1992;182:437-444.
6. Moore TP, et al. Suprascapular nerve entrapment caused by supraglenoid cyst compression. *J Shoulder Elbow Surg* 1997;6:455-462.
7. Steiner E, et al. Ganglia and cysts around joints. *Radiol Clin North Am* 1996;34:395-425.

# Ethics and Clinical Research

ABSTRACT & COMMENTARY

**Synopsis:** *Informed consent is the cornerstone of the ethics of clinical research; however, more subtle but equally important considerations are value, scientific validity, fair subject selection, favorable risk-benefit ratio, independent review, and respect for enrolled subjects.*

**Source:** Emanuel EJ, et al. What makes clinical research ethical? *JAMA* 2000;283:2701-2711.

**I**nformed consent is generally considered to be the factor that renders research involving human subjects ethical. Emanuel and associates assert that although informed consent is necessary in most but not all cases, in no case is it sufficient for ethical clinical research. Some of the most contentious contemporary ethical controversies in clinical research raise questions

of the ethics of subject selection, appropriate risk-benefit ratios, and the value of research to society. Since obtaining informed consent does not ensure ethical research, it is necessary to have a systematic and coherent framework for evaluating clinical studies that incorporates all relevant ethical considerations.

Emanuel et al delineate seven requirements that provide a framework synthesizing traditional codes, declarations, and relevant literature on the ethics of human subject-based research. The objective of clinical research is to develop generalizable knowledge to improve health and increase understanding of human biology. That knowledge can be gained by having subjects participate. Ethical requirements minimize the possibility of exploitation of subjects. Seven tenets of ethical research are proposed.

## Value

The research must evaluate a diagnostic or therapeutic intervention that could lead to improvements in health or well-being. The research is an etiological, pathophysiological, or epidemiological study to develop such an intervention, or tests a hypothesis that can generate important knowledge about structure or function. The evaluation of clinical research should ensure that the results will be disseminated. Comparative evaluation of value is necessary in considering finite scientific resources.

## Scientific Validity

Research is conducted in a methodologically rigorous manner. For a clinical research protocol to be ethical, the methods must be valid and practically feasible. The research must have a clear scientific objective. The study must definitively test the objective and offer a plausible data analysis plan.

## Fair Subject Selection

Selection requires decisions about who will be included and the strategy for recruiting subjects. The scientific goals of the study drive fair selection. Groups or individuals should not be excluded without scientific reason. Subject selection cannot affect the risks and benefits of the study.

## Favorable Risk-Benefit Ratio

Uncertainty about the risks and benefits of drugs, devices, and procedures must be justified by the planned research. Requirements are that the potential risks to individual subjects are minimized, the potential benefits are enhanced, and the potential benefits to individual subjects and society are proportionate to or outweigh the

risks. If the benefits do not outweigh the risks, the subjects are being exploited.

### **Independent Review**

Multiple interests of investigators include conducting high-quality research, completing the research expeditiously, protecting subjects, obtaining funding, and advancement of career. These diverse interests generate conflicts and may distort judgment. With research with little or no risk, the review may be expedited, but for much of clinical research, review should be done by a committee with a full range of expertise and with the authority to approve, amend, or terminate a study.

### **Informed Consent**

This requirement has received the most explication. The purpose is to ensure that individuals control whether or not they enroll in clinical research and participate only when the research is consistent with their values, interests, and preferences. It also indicates that individuals are accurately informed of the purpose, methods, risks, benefits, and alternatives to the research.

### **Respect for Potential and Enrolled Subjects**

Individuals must be treated with respect throughout their participation and after their participation in a study. This issue includes privacy, permission to change their minds, and provision of new information relating to the study.

The tenets listed above are all necessary elements of the ethical requirements of clinical research. They must be adjusted and balanced in different types of research. They are necessary requirements that could be challenged and serve as protection of individuals who are subjects of studies as well as protecting investigators.

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

Informed consent is not enough in planning, designing, and recruiting individual participants in a clinical research study. These ethical requirements emphasize the training and skills needed for clinical investigators and those reviewing proposals for investigations. Potential investigators must recognize, affirm, and implement these ethical requirements, and review committees should consist of persons with scientific training, statistics, ethics, law, and reflective persons who are aware of social values, priorities, and vulnerabilities. We should be sure to train our young researchers in these requirements. ❖

## **CTA for Cerebral Vasospasm**

ABSTRACT & COMMENTARY

**Synopsis:** *Vasospasm is a significant cause of morbidity and mortality in survivors of subarachnoid hemorrhage (SAH). Digital subtraction angiography (DSA) has been the gold standard for diagnosis of vasospasm and also offers the opportunity for endovascular therapeutic intervention. DSA is, however, an invasive procedure with its own set of associated risks. The opportunity to accurately assess spasm using a minimally invasive modality such as CTA could help appropriately triage patients to continued observation or a more invasive test such as DSA. Anderson and colleagues report a prospective comparison of CTA with DSA in the detection and quantification of vasospasm in 17 patients with aneurysmal SAH.*

**Source:** Anderson GB, et al. CT angiography for the detection of cerebral vasospasm in patients with acute subarachnoid hemorrhage. *AJNR Am J Neuroradiol* 2000; 21:1011-1015.

Dsa has been the standard of reference for detection of vasospasm complicating aneurysmal subarachnoid hemorrhage. The development of minimally invasive methods for imaging the cerebral vasculature (such as CT and MR angiography) raises the question of whether one of these methods could be substituted for DSA. MR-based methods are limited by patient cooperation and also the presence of ferromagnetic aneurysm clips in some patients. Most post-SAH patients undergo follow-up CT when vasospasm is a concern to look for ischemic complications, and CTA can easily be performed in conjunction with a noncontrast head CT. Anderson and colleagues prospectively compared CTA with DSA in their ability to accurately detect cerebral vasospasm in patients with SAH.

A baseline CTA was performed in 17 patients with CT-documented SAH using a helical scanning protocol during bolus injection of contrast material, with coverage from the craniocervical junction to 30 mm above the sellar floor. Five to 10 days later, patients underwent repeat CTA followed within 24 hours by DSA. Maximum intensity projection (MIP) reconstructions were performed on the CTAs by the same experienced investigator. The initial and delayed CTA studies were assessed for spasm by comparing vessel caliber on the two studies, and these results were compared with DSA. Overall, six arterial locations were assessed: four proximal loca-

tions (ICA, A1, M1, and basilar) and two distal locations (A2 and M2 segments).

The overall agreement between CTA and DSA for all locations and degrees of vasospasm was 86%. Agreement between CTA and DSA was greater for no spasm and severe (> 50% lumen reduction) spasm than for mild or moderate spasm. CTA was highly accurate for no spasm or severe spasm in proximal locations, and less accurate for distal locations. Nine percent of arteries were not visible at follow-up CTA because of aneurysm clip artifact, and it was noted that titanium clips are not routinely used at Anderson et al's institution.

#### ■ COMMENT BY NANCY J. FISCHBEIN, MD

Cerebral vasospasm of varying degrees affects as many as 50% of patients with aneurysmal subarachnoid hemorrhage. Vasospasm typically occurs seven to 10 days following the hemorrhage, and its prompt diagnosis is necessary to institute therapy to avoid complicating ischemic insult to the brain. Patients can be screened noninvasively with transcranial Doppler sonography, but this method is operator dependent and limited in accurately depicting vasospasm at sites other than the proximal middle cerebral artery.<sup>1</sup> MRA can depict vasospasm, but it is difficult to perform on severely ill and uncooperative patients and it cannot be performed in patients who have been treated with ferromagnetic aneurysm clips.<sup>2</sup> DSA is the gold standard for diagnosis, but it carries a total complication rate of ~5% and ideally would be reserved for those who are likely to require an endovascular therapeutic intervention in combination with diagnostic arteriography. There is therefore a potential need for a modality that can accurately and noninvasively assess the patient at risk for vasospasm such that the patient can be accurately triaged to continued observation or DSA for definitive diagnosis and endovascular therapy, and CTA may offer a solution to this problem. Significant limitations of CTA include the somewhat labor-intensive and operator-dependent postprocessing required for MIP reconstruction, as well as limited visualization of A2 and M2 branches and artifacts related to nontitanium aneurysm clips. Anderson et al's results demonstrate, however, that a patient with no evidence of spasm on CTA can probably be spared DSA, while for the time being those with evidence of vasospasm can be further evaluated with DSA. Future developments with multidetector scans and automated MIP reconstruction may eventually refine this modality to the point that it can replace DSA for all but therapeutic purposes. ❖

#### References

1. Okada Y, et al. Comparison of transcranial Doppler investigation of aneurysmal vasospasm with digital subtraction angiographic and clinical findings. *Neurosurgery* 1999;45:443-450.
2. Tamatani S, et al. Detection of delayed cerebral vasospasm, after rupture of intracranial aneurysms, by magnetic resonance angiography. *Neurosurgery* 1997;40:748-754.

## CT Findings of Various Cystic Pancreatic Tumors Overlap

ABSTRACT & COMMENTARY

**Synopsis:** *Substantial overlap exists in the CT findings of benign and malignant cystic pancreatic neoplasms, so differential diagnosis requires a cautious approach.*

**Source:** Curry CA, et al. CT of primary cystic pancreatic neoplasms: Can CT be used for patient triage and treatment? *AJR Am J Roentgenol* 2000;175:99-103.

Although pseudocysts are the most common cystic lesions of the pancreas, other cystic lesions also are encountered occasionally at CT, including simple cysts, serous (microcystic) neoplasms, and mucinous (macrocytic) neoplasms. Serous pancreatic neoplasms are cystadenomas without malignant potential, whereas mucinous pancreatic neoplasms can be cystadenomas that have a definite potential to become malignant, or they can be frankly malignant cystadenocarcinomas. Serous pancreatic neoplasms can be managed by periodic imaging follow-up (to assess for lesion stability), but mucinous pancreatic neoplasms should be surgically excised.

Curry and colleagues tested the ability of three radiologists to retrospectively distinguish serous from mucinous primary cystic pancreatic neoplasms at CT in 50 patients. They found that the reviewers could correctly diagnose serous neoplasms in only 23-41% of cases. Serious errors occurred; for example, eight mucinous tumors were categorized as benign serous tumors by two of the three radiologists. Using a consensus between at least two of the radiologists, all of the mucinous tumors were correctly categorized as either mucinous or indeterminate. Multivariate logistic regression analysis revealed that a tumor whose largest cyst was smaller

than 2 cm had a statistically significant likelihood of being a serous tumor. Peripheral calcifications were seen only in mucinous tumors. Curry et al concluded that CT is not an accurate technique for distinguishing between serous and mucinous cystic neoplasms of the pancreas, and thus the findings at CT must be interpreted cautiously to appropriately guide patient triage and treatment.

■ **COMMENT BY DAVID M. PANICEK, MD**

Cystic lesions of the pancreas are commonly found at CT in patients with current or previous pancreatitis, and occasionally as incidental findings in patients being scanned for indications unrelated to the pancreas. The nature of many cystic pancreatic lesions can be deduced from the combination of clinical, laboratory, and radiologic findings. However, particularly in the case of the cystic pancreatic lesion incidentally discovered on CT, the exact diagnosis may remain elusive. Some serous cystadenomas of the pancreas exhibit classic radiologic features, with all cysts measuring smaller than 2 cm and some coarse calcifications occurring in the center of the tumor; similarly, some typical mucinous pancreatic neoplasms consist of large cysts containing mural nodules, with calcifications in the periphery of the tumor. However, as Curry et al illustrated, a serous cystadenoma can manifest as a large unilocular cyst (9 cm in diameter in the case illustrated in their figure 5), and a mucinous cystadenoma can be quite small (1.8 cm in diameter in the case illustrated in their figure 6). And, as Curry et al note, other types of pancreatic lesions (including pseudocysts) that could mimic cystic pancreatic neoplasms at CT were not included in their study, further emphasizing the difficulties one can anticipate when evaluating cystic pancreatic lesions.

The existence of such overlap mandates that the radiologist use considerable caution in formulating an appropriate differential diagnosis of a primary cystic pancreatic lesion, with particular attention to specifying the need for further evaluation. Careful integration of clinical, laboratory, and radiologic features may allow a specific diagnosis of pancreatic pseudocysts, cysts, and some serous cystadenomas with a high degree of certainty; in such cases, periodic follow-up imaging to assess for stability of the lesion should be recommended. For cystic pancreatic lesions that exhibit any atypical features for these particular diagnoses, or that show features typical of mucinous cystadenoma or cystadenocarcinoma, surgical biopsy and/or excision are indicated. ❖

## Effect of Obesity on Screening Mammography

ABSTRACT & COMMENTARY

**Synopsis:** *Among cohorts of increasing obesity compared to normal women, there were higher rates of recall, biopsy, and screening-detected prevalent cancers of the breast, supporting but not validating a relationship between adiposity and breast cancer.*

**Source:** Hunt KA, Sickles EA. Effect of obesity on screening mammography: Outcomes analysis of 88,346 consecutive examinations. *AJR Am J Roentgenol* 2000;174:1251-1255.

Epidemiological studies have indicated obesity as a risk factor for the development of breast cancer in postmenopausal women, although specific body habitus (shape) may modify such models. Moreover, higher levels of "adiposity" have been associated with larger tumor size and nodal involvement at the time of initial diagnosis, as well as with higher rates of breast cancer recurrence and mortality in all women.

Such studies have not specifically evaluated women undergoing screening mammography or asymptomatic patients. This work reviewed data from a large series of screening patients, assigning them to four categories as follows, based normative values: a) underweight by greater than 10%, 3,475 patients; b) ideal weight  $\pm$  10%, 39,656 patients; c) overweight by 11-24%, 20,789 patients; d) overweight by 25-39%, 12,345 patients; and e) overweight by  $\geq$  40%, 12,081 patients.

Prevalent detection rates were determined for mammographically identified lesions and by linkage to a local SEER (Surveillance, Epidemiology, and End Results, a national data analysis project) tumor registry; interval cancers and follow-up data were obtained.

An increase in recall rates was identified with progressively increased adiposity: 3.88%, 4.89%, 5.11%, 5.47%, and 5.55%), as well as rate of biopsy: 0.98%, 1.31%, 1.35%, 1.59%, and 1.65%. This increased rate was at least commensurate with the rates of screening detected cancer/1000 women: 3.74, 4.29, 5.34, 4.70, and 6.04. These trends were also reflected in increased median cancer size and more advanced stage of diagnosis.

Detection rates might be improved by assuming that increased adiposity would also be correlated with decreased mammographic density, as denoted by the American College of Radiology BI-RADS system, and indeed this was the case.

A suggested trend showed increased interval cancer

rates in underweight women as well as overweight women compared to ideal weight women.

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

While much controversy exists regarding diet and breast cancer risk—consider the considerable increased rate of breast cancer among second generation decedents of Japanese women now living in the United States as well as the increasing incidence now seen in Japan (there is no shortage of McDonalds restaurants now in Tokyo)—most epidemiological studies show a relationship between obesity and breast cancer incidence. Biochemical models have been considered that attempt to reconcile this observation. Following menopause, the main source of endogenous estrogen is the conversion in adipose tissue of the androgen precursor androstenedione to estrone. Obesity is associated with decreased production of sex-hormone-binding globulin, which may result in unbound estradiol, the biologically active form of estrogen.

If these theories are correct, then obesity may not only be a direct risk factor for breast cancer, but may also bear a causative relationship to growth and spread. The observations in this study lend credence to this premise.

However, the real answer to this question would be derived by observing similar trends and comparisons for interval cancers, compared to prevalent cancers. In other words, are the tumors in overweight women that develop within a year of a prior normal examination also larger and more aggressive than their counterparts in ideal weight women? Unfortunately, there were too few interval cancers in this study to reach substantive conclusions regarding this aspect of the study. For example, if a higher percentage of stage II cancers would be physically palpated in a smaller breasted woman than a larger breasted (e.g., obese) woman (where the physical examination would be more difficult to feel deeper lesions), then one would expect a higher prevalence at the first screening examination of stage II tumors to be present in an asymptomatic population of obese women. This phenomenon would thus explain the results in this study, without implying a cause-and-effect relationship between adiposity and cancer growth. In other words, the results may be secondary to the difficulty of palpating tumors in a large-breasted woman compared to a small-breasted woman, although I suspect this is not a sufficient explanation for Hunt and Sickles' results.

As mentioned, this issue can be addressed, but only in a longer, larger study of interval cancers. Data in this study are derived from one of the largest and longest-running databases from a single institution in the country, demonstrating how difficult such determinations can be. Perhaps

collaborations among several institutions or databases may provide statistical power to either corroborate or defeat the notion that increased obesity has a direct bearing on the development and/or progression of breast cancer. ❖

## CME Questions

**11. Obesity has been shown to be associated with all of the following except:**

- a. increased size at detection.
- b. increased stage at detection.
- c. increased recall rate.
- d. decreased biopsy rate.
- e. decreased breast density.

**12. Vasospasm typically occurs:**

- a. at the time of initial subarachnoid hemorrhage.
- b. 1-2 days following subarachnoid hemorrhage.
- c. 7-10 days following subarachnoid hemorrhage.
- d. 2-3 weeks following subarachnoid hemorrhage.

**13. Serous cystic pancreatic neoplasms:**

- a. are the most common benign cystic lesion of the pancreas.
- b. can have CT features identical to those of mucinous pancreatic neoplasms.
- c. often contain peripheral coarse calcifications.
- d. usually contain individual cysts larger than 2 cm in diameter.

**14. When torn, all of the following joint structures can be associated with cysts except:**

- a. meniscus.
- b. lateral collateral ligament of the ankle.
- c. hip labrum.
- d. shoulder labrum.

**15. Which one of the following statements is true?**

- a. Direct percutaneous aspiration of paralabral cysts is not associated with recurrence.
- b. MRI can demonstrate muscle atrophy in all cases with abnormal EMG.
- c. Cysts usually fill with gadolinium immediately following direct injection into the glenohumeral joint.
- d. Glenoid labral cysts can lead to denervation of the axillary nerve.

**16. What is the critical factor in pursuing clinical research?**

- a. Funding
- b. Statistical consultant
- c. Human subjects
- d. Duplication of a method previously used.

**17. Which factor listed below is a requirement in evaluating the ethics of clinical research studies?**

- a. Counseling the family
- b. Payment of participants
- c. Favorable risk-benefit ratio
- d. Prospective studies only

## Attention Readers

American Health Consultants is happy to announce that we are opening up our *Primary Care Reports* author process to our readers. A biweekly newsletter with approximately 5000 readers, each issue is a fully referenced, peer-reviewed monograph.

Monographs range from 25-35 Microsoft Word document, double-spaced pages. Each article is thoroughly peer reviewed by colleagues and physicians specializing in the topic being covered. Once the idea for an article has been approved, deadlines and other details will be arranged. Authors will be compensated upon publication.

Readers who have ideas or proposals for future single-topic monographs can contact Associate Managing Editor Robin Mason at (404) 262-5517 or (800) 688-2421 or by e-mail at [robin.mason@ahcpub.com](mailto:robin.mason@ahcpub.com). We look forward to hearing from you. ❖

## AHC Online Your One-Stop Resource on the Web

More than 60 titles available.  
Visit our Web site for a complete listing.

1. Point your Web browser to:  
<http://www.ahcpub.com/online.html>
2. Select the link for "AHC Online's Home page."
3. Click on "Sign On" at the bottom of the page.
4. Click on "Register now." (It costs nothing to register!)
5. Create your own user name and password.
6. Sign on.
7. Click on "Search" at the bottom of the page.
8. Perform a search and view the results.

If you had a subscription to a product, the price next to the search results for that product would say "FREE." Otherwise, the pay-per-view cost per article is displayed. To take a look at a sample article, click on "Content" at the bottom of the screen. Select Clinical Cardiology Alert, Archives, 1997, January 1, and the first article, "More Good News About Beta Blockers." We've made this article free so you can see some sample content. You can read it online or print it out on your laser printer.

**Test Drive AHC Online Today!**

Site updated for ease-of-use!



### The Global Continuing Medical Education Resource

Exciting **site improvements** include advanced search capabilities, more bulk purchasing options, certificate printing, and much more.

With **more than 1000 hours** of credit available, keeping up with continuing education requirements has never been easier!

### Choose your area of clinical interest

- Alternative Medicine
- Cardiology
- Emergency Medicine
- Geriatrics
- Infection Control
- Internal Medicine
- Medico-Legal Issues
- Neurology
- OB/GYN
- Oncology
- Pediatrics
- Primary Care
- Psychiatric Medicine
- Radiology
- Sports Medicine
- Travel Medicine

### Price per Test

\$15 per 1.5 credit hours \*Purchase blocks of testing hours in advance at a reduced rate!

Log onto  
**[www.cmeweb.com](http://www.cmeweb.com)**  
today to see how we have improved your  
online CME

#### HOW IT WORKS

1. **Log on at <http://www.cmeweb.com>**
2. **Complete the rapid, one-time registration process** that will define your user name and password, which you will use to log-on for future sessions. It costs nothing to register!
3. **Choose your area of interest** and enter the testing area.
4. **Select the test you wish to take** from the list of tests shown.  
Each test is worth 1.5 hours of CME credit.
5. **Read the literature reviews and special articles**, answering the questions associated with each.
6. **Your test will be graded online** and your certificate delivered immediately via e-mail.

CALL **1-800-688-2421** OR E-MAIL  
[CUSTOMERSERVICE@CMEWEB.COM](mailto:CUSTOMERSERVICE@CMEWEB.COM)



## The Right Use of Technology Boosts Care, Saves Big Bucks

*A Clinical Imaging System can Change Your Culture, Care, and the Bottom Line*

*By Julie Crawshaw*

**B**y tapping into a new breed of technology, the Cape Fear Valley Health System (CFVHS) in Fayetteville, NC, reports it is saving money for the system, time for physicians, and improving the care of critically ill patients.

The new technology is a clinical image management system (CIMS) that captures images from a variety of radiology systems and makes them available instantaneously to physicians throughout the system. The system is saving \$2.5 million a year in costs, primarily by reducing lengths of stay (LOS) and providing physicians with the information they need much more quickly, says David Dillehunt, CSP, chief information officer for the health system.

Dillehunt oversees information issues for an integrated health care delivery network of four hospitals, 16 primary care physician practices, and six specialty physician practices. This year, he says, Cape Fear will handle between 400,000-500,000 outpatient visits and receive gross revenues of more than \$5 million.

At the outset of his search for a CIMS he had two goals, he says. "We wanted a system that could provide superior access to clinical images and corresponding diagnostic information on an enterprise-wide level. We also wanted to sharply reduce film and film-related expenses within the radiology department."

Year after year, Dillehunt and fellow CIMS proponent George Binder, MD, reviewed new market offerings, but could not find any that met their needs. When they found ImageACCESS, a Windows NT-based CIMS from StorCOMM in Jacksonville, FL, they bought it.

"When we initially got the machine, of course, we were all used to films and regular radiology reports," says Anita Lee, RN, head of critical care nursing staff at Cape Fear. "Now, we can pull up images immediately. As nursing staff, we know what normal images look like, and we can immediately alert physicians to potential problems." Lee says that when doctors put in a Swan Ganz line to monitor cardiac output, for example, critical care staff can view the line on ImageACCESS.

"The system also has value as a teaching tool because doctors can use it to show us what a mediastinal shift actually looks like," she says.

CFVHS staff also use the CIMS system to educate nursing students who come to the hospital from the local college. "When we recently had a patient with a broken leg, we could see the fracture on the machine, not just read about it on the chart. I think it gives us a much better understanding, and that makes it easier for us to provide high-quality care."

CFVHS does not film its trauma cases now. The information is in its CIMS system, and can be retrieved by anyone who needs it. Binder says that when the system was a little bit slow in bringing up images, the culprit turned out to be a redundant system the hospital had built to protect itself. When the time-consuming loop it created was removed, speed increased. CFVHS recently acquired new, faster Pentium processors. Now the digital images are instantaneous.

Binder stresses that using CIMS images is much faster than using film. "I can be in another department and immediately read an image presented in the emergency room," he says. In one instance, Binder had two cases read

before technicians could get another case filmed. Binder, an angiographer, says he can now read chest X-rays between reading angiograms without having to move from one area to another, which saves him a good deal of time.

The system also is useful at a 150-bed hospital about three miles away, which Cape Fear recently bought. "At night, we can cover them directly from here, instantaneously," Binder says. "Their radiological information is immediately available to us. For example, I can read a CAT scan or MRI and report back as soon as I see it. I don't have to wait for film, or work with digitized film, which loses resolution. CIMS has no degradation in image quality."

Binder says the radiology department isn't getting nearly as many physician visitors as it used to because other physicians can now pull up the images and read the accompanying dictation from their own workstations. He also points out that reduced reliance on file room personnel improves efficiency as well.

### **How CIMS Technology Works**

- Captures images for use in the system.
- Stores and files electronic images.
- Retrieves and distributes, moving images to the end user.
- Display allows users to review images.

At CFVHS, the Image Access system acquires images from CT, magnetic resonance (MR), ultrasound, and plain film via film scanners. The CT and MR devices at the medical center are DICOM-compliant modalities. DICOM (digital imaging and communications in medicine) is a standard protocol that formats image information at the device level. The CIMS can use raw and processed DICOM data directly imported from those devices. It acquires images from the non-DICOM-compliant devices via its image capture software. Both DICOM and the image capture software acquisition interfaces result in an electronic collection of data that contains all the clinical images in the exam, plus associated patient information. Users also can add reports, annotations, or comments.

Electronic exams are stored on a centralized electronic database. The image server acts as a "traffic cop" for the entire system, processing requests and retrieving and distributing exams on demand. Images are processed and uncompressed in two phases.

The system initially stores image information on what are called a redundant array of inexpensive drives (RAID), a series of high-capacity hard drives that have fast access speeds. After seven days on RAID, exams are transferred to less expensive archive storage media.

"We chose a seven-day active period since demand for exams is considerably less after one week," Dille-

hunt says. Cape Fear currently uses two types of archive storage: WORM drives (write once, read many) and a magneto optical jukebox. The two-phase storage strategy is a compromise between slightly slower access speeds and less expensive storage media.

Dillehunt says he did some personal struggling with the issue of cost justification for the project because all the systems reviewed were initially designed to make things better for the radiologist. Radiologists' productivity would improve dramatically because they could read more film much faster. "But that doesn't do much for the hospital," Dillehunt observes. "The radiologists, after all, are in private practice. They don't even work for us, and spending a lot of money to make things better for them only goes so far."

Just before Dillehunt looked at the system he eventually purchased, he attended a presentation that articulated the very issues with which he'd been struggling. From that he realized that the ability to distribute images across a health system quickly would put needed information into the hands of the decision-makers at the point of patient care level.

"That has a tremendous positive impact on the quality of care and cost savings within your health care system," he says.

The system's CIMS retrieval and distribution mechanisms are built on an open client/server architecture. Display stations located throughout the medical center run the CIMS's view station software. CFVHS currently has stations in radiology, emergency medicine, the operating room, and five intensive care units—surgical, medical, coronary, neonatal, and cardiac surgery. The view station software can be customized based on user name, so that no matter where a user logs onto the software, he or she will encounter the same interface.

### **Shortening Patient Stay Creates the Biggest Dollar Savings**

Dillehunt points out that manufacturers typically try to sell a CIMS system based on the fact that it will reduce film costs. There are film cost savings, but Dillehunt sees the real benefit of a good CIMS system is that it can reduce patient length of stay. Every day the patient remains in the hospital longer than necessary translates to money coming off the bottom line.

"You have to expend money to take care of that patient, even if it's just for taking up a bed, but you're not going to get paid any more for it given today's reimbursement methodologies," Dillehunt says.

Dillehunt's research revealed two major time frames within each day to get information to physicians they need to decide the next step in their patients' care. This could

mean anything from moving a patient from a critical care room to a regular floor to performing another laboratory test. Physicians spend their time in between morning rounds seeing patients in their offices. If they don't receive the information they need while they are at the hospital it means the patient stays for at least another half a day.

When Dillehunt did a financial audit, he found that patients who went through hospital areas that used the CIMS technology had hospital stays that averaged three-quarters of a day less than those of non-CIMS patients. That translated into a savings of \$647,000 over a three-month audit period, which adds up to \$2.5 million per year of actual dollars saved. "In health care, that's a big, big deal," Dillehunt says.

Dillehunt's audit covered the length of stay (LOS) for 1306 patients who had been admitted to the surgical, medical, or coronary intensive care units. Approximately 632 patients had been admitted during a preimplementation span from December 1997 to February 1998, and 674 had been admitted during the postimplementation span from December 1998 to February 1999.

His methodology measured all direct costs that comprise patient care, such as unit staffing, actual procedure costs, and supplies. Indirect (overhead) costs such as electricity and administration were not taken into account. The LOS reduction was accomplished at a time when the case mix index actually rose by 6.8%, meaning that the patients were actually sicker.

A previous study, conducted by CFVHS ultrasound supervisor Carmen Perri, also demonstrated CIMS-based savings to the health system. This study showed that the savings and increase in productivity brought about by the CIMS were projected to increased revenue in the ultrasound department alone by nearly \$1.2 million per year. Combining the results of these two studies shows an annualized benefit of from \$1.2 million to \$3.7 million in increased revenue and \$2.5 million in actual reduced costs.

### **First Get it Accepted, Then Use it Appropriately**

To be used correctly, a CIMS system must first find acceptance. Dillehunt observes there are still a number of clinicians and physicians, both hospital- and non-hospital-based, who are reluctant to use some of the modern technologies. "By the time the younger physicians graduate from medical school, they are well immersed in computers," he says. "But a well-respected older physician does not want to risk looking stupid in front of others and may resist the technology."

Dillehunt emphasizes that the technology is phenomenal if it's used appropriately; faster data transmission and shorter stays are what justify spending money on a

CIMS system. "The real 'bang for the buck' with this technology is in changing your culture to make more efficient use of the data and treat the patients faster with better quality information," he says.

Though all CIMS technology captures, stores, and files images, the StorCOMM system Cape Fear uses also distributes the data to anyone who has a need for it. Dillehunt says that because it takes a long time to move a radiology image through a network, most CIMS systems distribute the image directly to the workstation on the floor where the patient is staying.

However, he observes that most physicians will go to where their first patient is and call up an image, but don't want to log into a computer on every floor where they have a patient. "They want to be able to call up all the information they need quickly, at one terminal," he says. "If the technology is not well designed, there's too much lag time in calling up the images. If you can make it work fast and consistently, the doctors will love it." StorCOMM's ability to call up images from any location was a major point in its favor.

The next goal for using CIMS at Cape Fear is viewing the progression for wound care. "For instance," Binder says, "we can now document the effects of, say, hyperbaric therapy, bring the patient back in four weeks for another picture, and compare it with the old one for a true objective pictorial 'description' rather than a subjective written statement."

Finally, as an example of the care improvement the system can provide, Dillehunt tells of a patient who had just undergone a radiological diagnostic test. The supervising nurse became concerned because the patient was behaving strangely. She called up the image and saw it looked peculiar and immediately called the neurosurgeon, who got the patient into the operating room post-haste.

"Had we been using the old manual process for moving an image, it would have been more than 30 minutes before the physician got the information that the patient was in critical condition," Dillehunt says. "Having the CIMS system kept the guy from becoming a vegetable. I don't know how to put a dollar value on that." ❖

### **Sources**

1. David Dillehunt, CPS, Cape Fear Valley Health System, P.O. Box 2000, Fayetteville, NC 28302-2000.
2. Anita Lee, RN, Cape Fear Valley Health System, 1715 Empress Lane, Fayetteville, NC 28304.
3. George Binder, MD, 1329 Robeson Street, Fayetteville, NC 28305.
4. Image Access system manufacturer: StorCOMM, 7 Corporate Plaza, 8649 Baypine Road, Jacksonville, FL 32256; (888) 731-0731.

# Smart Shirt Provides Wireless Body Data

By Don Long

In a decade or two, the aftermath of the Human Genome Project could change the face of medicine. But a more immediate and achievable advance in health care could come from “a rich source of data, acquired continuously, concerning how the body acts in real situations,” says Sundareyan Jayaraman, PhD, a professor in the School of Textile and Fiber Engineering at the Georgia Institute of Technology, Atlanta.

Achieving the rich data stream envisioned by Jayaraman may be just around the corner, and can be produced by the shirts on our backs. They could be interwoven with plastic polymer optical sensors and then made into a basic T-shirt. Dubbed the Smart Shirt, the special optical fibers in the material can provide an ongoing stream of vital sign information while a person goes about his or her day-to-day activities—that is, truly at the point of care.

The challenge to develop a type of monitoring clothing first came from a U.S. Navy grant, but Jayaraman says he soon realized that the concept’s greatest benefit would be in a variety of potential health care applications. These could range from shirts worn by congestive heart failure patients to pajamas for infants feared at risk for sudden infant death syndrome.

These and other broad applications for the material will now be developed through an agreement between Georgia Tech Research Corp. and SensaTex, New York, a start-up company funded by Seed One Ventures of New York.

Jeffrey Wolf, chief executive officer of SensaTex, said that, in essence, the shirt is a “wearable motherboard, providing information from a wearable environment.” He said an additional key to the system is its wireless technology: “You can monitor patients, for instance, with a Holter monitor, without wires down through patient’s body,” Wolf says. “What it also means, he says, “is that you can integrate additional sensors to get even more information than you can get now because of reducing the need for wires, and you can have these [sensors] speak to one another.”

SensaTex plans to seek Food and Drug Administration clearance for the device, and sees the technology’s commercialization coming as early as early 2001.

Besides monitoring heart patients and others at risk,

the next most usable application will be in monitoring subjects participating in clinical trials, to continuously read their reactions to drugs or devices, for measuring sports performance, and in geriatrics. These can then be expanded to a wealth of uses in the military, and police and fire protection.

Smart Shirt’s ability to produce accurate, real-time results, says Wolf, “represents a quantum leap in health care monitoring.”

## The Heart That Wears a Jacket

In another recent development in medical “clothing,” the heart of a 41-year-old woman was recently fitted with a kind of jacket to provide it greater support. Performed at the Hospital of the University of Pennsylvania, Philadelphia, the procedure involved implanting a special mesh-like polyester material around her heart to give it support and constraint. The surgeons also repaired a leaking mitral valve in the process. The woman was suffering cardiomyopathy, a balloon-like expansion of the heart muscle, resulting in a gradual loss of pumping function.

Known as the Cardiac Support Device (CSD) and made by Acorn Cardiovascular, St. Paul, MN, the jacket was slipped around the heart and then stitched in place. It is designed to prevent further enlargement of the heart muscle and boost its compromised efficiency. The jacket is slipped around the heart through open-chest surgery similar to that required during coronary-artery bypass grafts.

Michael Acker, MD, led the first U.S. implantation. He had previously participated in an implant procedure at a hospital in Berlin, Germany, where a clinical trial is showing positive results, according to Acorn.

Five million Americans are diagnosed with congestive heart failure, and 400,000 new cases are discovered every year, according to the American Heart Association (Dallas, Texas). The CSD “may offer a new approach for treating heart failure,” said Donald Rohrbaugh, president and CEO of Acorn. He called the first U.S. implant “an important step in our clinical investigation and is supported by the broad-based research we have conducted.”

The continuing U.S. trials will involve two randomized patient groups: those treated with the CSD and those without. “It is our belief, based on extensive studies, that those patients in whom the jacket is implanted will have improved heart function,” says Acker. “If we can sustain the clinical improvement for an appropriate length of time, the heart ‘jacket’ may prevent the need for transplantation in some patients.” ❖

In Future Issues:

Editorial Content Survey