ASITN
American Society of Interventional & Therapeutic Neuroradiology

The Embolus

Fall 2002

Inside *this issue*

President's Message 2

ASITN Makes Strides at ACR 2

Editor's Column 3

ASITN Launches Foundation 4

Implications of new HIPPA guidelines for INR Research 4

Tomsick Speaks to Family Practitioners 5

We Want You! 5

How to Apply for ACGME Accreditation 6

Sixth Annual Joint Meeting 6

ASITN Attends ACR Summer Conference 7

People in News 7

Lancet Study Shows Interventional Neuroradiology Safer than Surgery to Treat Ruptured Brain Aneurysms

A new study published in the October 26 issue of *The Lancet* shows that using an interventional neuroradiology technique (endovascular coil embolization) to treat cerebral hemorrhage from a ruptured aneurysm substantially reduces the relative and absolute risk of subsequent severe disability or death compared to surgical repair in those patients judged to be equally treatable by surgery or coil embolization. The study showed a 22.6 percent reduction in the relative risk of severe permanent disability or death, and an absolute risk reduction of 6.9 percent for the interventional neuroradiology technique compared to the neurosurgical technique. When a brain aneurysm ruptures, the blood usually goes into the space that closely surrounds the brain, known as the subarachnoid space. Rupture of a brain aneurysm causing subarachnoid hemorrhage occurs in six to eight people out of 100,000 in most western populations. A subarachnoid bleed is a medical emergency which can have serious consequences such as stroke or death.

About Cerebral Hemorrhage Treatments

The International Subarachnoid Aneurysm Trial (ISAT) is the first multi-center, prospective randomized study comparing endovascular coiling, the interventional neuroradiology technique, with surgical clipping for patients with a ruptured cerebral aneurysm causing acute subarachnoid hemorrhage (SAH), a condition that can lead to death or dependency. Although there have been advances in neurosurgery, relatively few patients return to a normal lifestyle after SAH surgery, and many have persistent and disabling neurological or cognitive defects. Surgery had been the primary treatment available until the platinum coil device was introduced into investigational clinical use in 1990 and approved by the FDA in 1995. The coil occludes the aneurysm and was thought to reduce the risk of further rupture without the need for craniotomy, a surgical procedure. There was an urgent need for a large, multi-center trial to determine the safety and efficacy of the interventional neuroradiology technique compared to the surgical technique and to determine which treatment provides the best outcomes for patients.

ISAT Study Results

ISAT is a multicenter, randomized clinical trial to compare neurosurgical clipping to the interventional treatment with detachable platinum coils in patients with ruptured intracranial aneurysms considered suitable for either treatment. A total of 2143 patients with ruptured intracranial aneurysms were enrolled and randomized to neurosurgical clipping (n=1070) or interventional treatment by detachable platinum coils (n=1073). The primary outcome was the proportion of patients with a modified Rankin scale score of 3-6 (dependency or death) at 1 year. One hundred ninety of 801 (23.7%) of patients assigned to the interventional treatment were dependent or dead at 1 year compared with 243 or 793 (30.6%) of patients allocated to the neurosurgical treatment. The relative and absolute risk reductions in dependency or death after allocation to an interventional neuroradiology versus neurosurgical treatment were 22.6% and 6.9% respectively. The risk of rebleeding from the ruptured aneurysm after one year was two in 1276

continued on page 7

President's Message

Randy Higashida, MD

Welcome to the Fall Issue of The *Embolus*! We hope that you enjoyed our newly designed issue last quarter and will continue to provide you with timeless information about the Society and our specialty.

What an exciting time it has been since our last issue! In this newsletter, you will read articles about our new ACR Council seat, our first ACGME approved fellowship, the incorporation of the Interventional Neuroradiology Research and Education Foundation, and, most exciting, the announcement of our first stand-alone meeting!

I sent out a letter in October informing you that we moved all administrative functions to our office in Fairfax. We feel that having consolidated operations will increase the efficiency of the Society. We still value our relationship with our good friends at ASNR and will maintain strong ties with our diagnostic colleagues.

We look forward to a very exciting and successful 2003. Wishing you and yours a very happy Holiday Season!

Randall T. Higashida MD

ASITN – On the Move!

As mentioned in the President's Message, ASITN has moved all administrative functions from Oak Brook, Illinois to Fairfax, Virginia. You should have received a letter and notepad from Randy Higashida notifying you of this change. We are very excited to have everything in one place and believe that having consolidated operations will increase the efficiency of the Society.

Please make a note in your records that the new contact information for ASITN is:

10201 Lee Highway
Suite 500
Fairfax, VA 22030
703-691-2272 (phone)
703-691-1855 (fax)

ASITN Makes Strides at ACR

At the American College of Radiology (ACR) Meeting September 30-October 1, ASITN was granted a seat on the ACR Council! This will enable us to have a greater voice in the Radiology Community and we are very excited about this opportunity. John Barr will be serving as the ACR Councilor for ASITN with Tom Tomsick as the Alternate Councilor.

One other exciting development at the ACR Meeting was the passage of Resolution #5 calling for clinical services for INR within radiology groups. We would like to thank the Society of Interventional Radiology (SIR) for their initiation of this resolution and for allowing us to be a part of it! The text is outlined below

Interventional Radiology and Interventional Neuroradiology Clinical Practice Resource Task Force

BE IT RESOLVED,
that the ACR establish a task force, addressing interventional radiology and interventional neuroradiology clinical practice resources and business planning in collaboration with the appropriate interventional radiologic subspecialty societies. The goal of the task force will be to address the establishment and continued enhancement of IR clinical services within the practice of radiology groups. The issues that would be addressed may include:

- Creation of a white paper by March 2003 and subsequently, a framework for a Standard;
- Establishment of an adequate clinical team (nurse practitioners, radiology assistants);
- Continuous quality improvement program(s);
- Dedication of adequate space for clinical visits;
- Inpatient admitting service;
- Dedicated time for seeing inpatients and patients in a clinic;
- Noninvasive vascular laboratory;
- Clerical services for scheduling, insurance authorization and billing of procedure and evaluation/management services; and
- Support for time and materials for promotional and educational efforts.

Editor's Column

Chuck Kerber, MD

"I can predict anything but the future"
—anonymous

Having just returned from the Western Neuroradiology meeting, I can tell you that there is palpable unease in our tight little community. We feel, well, threatened. Our future is, we feel, in doubt.

And with good reason. The cardiologists have more physicians in training than we and SIR combined have practitioners. And they, the cardiologists, control their patients. In fact, it seems that everybody controls the patients except us. Correctly or not, most family physicians and ER docs see us as technicians.

That perception must change, or we will not survive as a specialty.

Let me ask some difficult questions.

1) When was the last time you gave an informal talk to Primary Care or ER physicians?

2) Do you have your own dedicated clinic space where you see outpatient referrals?

3) Do you see patients in consultation outside the radiology department before you do the procedure? Do you or your own physicians assistant do your pre therapy physical exams? After the consult, do you generate a letter to the referring physician on your own letterhead?

4) Do you have a person in your own team who handles ALL of the patients billing concerns and problems? Does your team person ensure that appropriate insurance prequalifications are done?

5) Do you generate your own bill?

6) After performing your surgical procedure, do you send a consultant's letter to the referring physician?

7) Do you follow your patients at appropriate intervals in your own clinic?

We may have grown-up sitting back expecting "the system" to guarantee patients coming in to the radiology suite, but those days are gone. Is it time to learn what our clinical colleagues have known all along about building a practice? It's up to us to guarantee our own future.

"If I have seen further than other men, it is because I have stood on the shoulders of giants."
—Isaac Newton, 1676.

A humble but accurate statement. We have been fortunate to have had giants in our past. But now we live in a time of change, and must be prudent about our future.

Recommended reading: HOW TO SWIM WITH SHARKS, a primer. Voltaire Cousteau, Perspectives in Biology and Medicine, summer 1973, p. 525 – 528. A good reference for the new physician who is just starting practice. Not a bad article for the rest of us either.

From the "I'm not kidding" department: everyone heaps abuse on us Californians about living in the land of fruits and nuts, but this one takes the cake. In this election, we have the Section C initiative on the Berkeley ballot. I know, I know, it's Berkeley, but this is far out even for them. The initiative is labeled "Sec C" and is of course pronounced Sex-C – get it? Its real name is – I'm not making this up – Socially and/or Environmentally Consciously Cultivated Coffee. If passed by the voters, only coffee beans certified as organic, fair trade, shade grown could be sold in Berkeley. To do otherwise is six months in jail and a $100.00 fine. I'm giving odds that it will pass.

When you worry about our malpractice issues, our embarrassing reimbursement schedules, the intrusions by others into our field, let this critical issue give you a little perspective.

One of the main reasons we have comparatively low malpractice premiums in California is the state statute called Medical Injury Compensation Reform Act. This act limits noneconomic damages to $250,000, among other things to make physicians problems less. Do you think that the lawyers would take that lying down? No. In the Perry vs. Shaw decision (2001 88Cal Appl 4th 658, 667), the attorneys argued successfully that the physician did not have "adequate" informed consent – and thus he committed a

continued on page 7

Spotlight on: Corporate Advisory Council

Since the Corporate Advisory Council was announced in the last newsletter, two more companies have joined. We are pleased to announce that BOSTON SCIENTIFIC TARGET and MICROVENTION, INC. have both become members of our Council. We hope to add many more companies in the coming months. If you work with any companies who would benefit from an enhanced relationship with ASITN, please send their contact information to Marie Williams at marie@asitn.org.

Implications of New HIPPA Guidelines for INR Research

Colin Derdeyn, MD, on behalf of the ASITN Research Committee: Chair, Gary Nesbit, MD, Colin Deredyn, MD, David Kallmes, MD, and John Pile-Spellman, MD

Research is defined as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge (45 CFR 46.102). Any efforts at the gathering of information involving humans for the purpose of analysis and dissemination is considered research and must be done in accordance with Institutional Review Board (IRB) approval. This is a broad definition and many IRBs have developed different mechanisms to grant approval to conduct human research.

IRBs will be required to add an additional step with the upcoming adoption of the final privacy rule of the Health Insurance Portability and Accountability Act (HIPPA) of 1996. This rule, published on August 14 with required compliance by April 14, 2003, mandates that patients must authorize the use or disclosure of their protected health information (PHI) – individually identifiable health information like their name, birthdate, and medical records. While originally intended to apply to health insurance companies and the transfer of PHI, the final rule broadened the interpretation of this legislation to include researchers who provide treatment to research participants. These new regulations demand that physicians may only access medical records and quality assurance databases for information that will be used for clinical – patient care – purposes. There are a number of exceptions to this: quality-assurance reviews and public health purposes, for example. The use of this information for research purposes, however, – defined above as gathering information for analysis or dissemination (publication) – is forbidden, *unless patients have consented to this use of their health information, or the researcher has obtained a waiver* of authorization for PHI from their IRB that relieves them of having to get their patients' consent.

Your institution's IRB has likely been working overtime grappling with implications of this rule on clinical research and for workable solutions. The waiver of PHI process for retrospective reviews will be administered by your IRB. The major criteria for a waiver will be the relative practicality of obtaining consent – easier to justify if most of your patients are dead, for example – and the sensitivity of the research – easier for stroke-related research than for studies involving HIV.

Prospective clinical trials will be the least affected by these regulations. Patients enrolled in such a study will sign a consent form authorizing the release of their PHI to the investigator, for use in publications, and for use by other researchers – on entry in the study. It is possible that this consent form may be rolled into an existing consent form for the study.

Retrospective reviews and case series, which represent the bulk of human research in our field, will require either getting consent from the patients to gain access to their information or getting a waiver from the IRB. The waiver of authorization may or may not be difficult to obtain, and will depend upon the philosophy and approach of your IRB to this new rule. Even the initial chart or database review to initially identify patients and determine if a study is feasible will require a waiver of authorization for PHI from the IRB. The approval for this initial, exploratory, review is likely to be easy, but will introduce an additional step to the current process.

One approach that may minimize the burden of obtaining a waiver is to pro-actively anticipate the retrospective reviews by setting up targeted, prospective, registries. For example, one could design a prospective registry to investigate the complication rates, technical success and outcome of endovascular treatment of aneurysms. All patients would need to sign the consent form(s) for the study, but then their data would be legally retrievable in the future for analysis. The degree of focus and willingness to support registries will also depend upon your specific IRB.

In summary the new privacy rule will add an additional step, but not a barrier, to the conduct of human research. Retrospective studies will become more burdensome. As a consequence, our challenge is to prospectively define research questions, perhaps in the form of registries, as many questions or problems are difficult to anticipate.

First ACGME Fellowship Approved!

Our congratulations go out to Colin Derdeyn, MD and his team at the Mallinckrodt Institute of Radiology and the Department of Neurology and Neurological Surgery
at Washington University School of Medicine. They have the first ACGME-accredited fellowship in Endovascular Surgical Neuroradiology.

It is very important that more sites become accredited so that the fellowship continues. Please see Colin's article on Page 6 for more information on how to apply

ASITN Launches Foundation

ASITN is pleased to announce that we are in the process of incorporating the **Interventional Neuroradiology Research and Education Foundation**. Tom Tomsick will serve as the first President of the Foundation and will work with Marie Williams at the ASTIN office to secure funding for this important initiative.

More information on the Foundation and its mission will be forthcoming in future issues of *The Embolus*.

Tomsick Speaks to Family Practitioners

Out of the many interventional papers submitted to the American Academy of Family Practice's annual meeting, only our own Tom Tomsick's was accepted. Tom and a panel of fellow interventionalists spoke to about 150 family practice doctors about uterine fibroid embolization, vertebroplasty, and stroke.

This is an important audience for us to reach and educate on interventional procedures. They are, in most cases, the first line that a patient reaches before being referred to a surgeon or an interventionalist. The more they learn, the more likely they will be to refer to an interventionalist!

ASITN also exhibited for the first time at this meeting, sharing a booth with SIR. We handed out copies of *The Embolus* and the vertebroplasty article that appeared in the American Family Practice Journal.

We Want You!

ASITN Committees are looking for a few good men and women to swell their ranks! Listed below, please find committee descriptions. If you see anything that strikes your fancy, please contact Marie Williams at marie@asitn.org and she'll get you in touch with the Committee Chair.

Billing/Coding

The Billing/Coding Committee monitors and responds to coverage and payment challenges. It develops positions and advocates these positions on such relevant areas as Medicare coverage, facility and physician payment, and managed care reform. The committee authors model coverage policies on interventional neuroradiology procedures as a resource for local Medicare carriers. The committee fosters relations with the Centers for Medicare & Medicaid Services (CMS) and its local Medicare carriers. In addition, the committee provides educational resources to ASITN members including the Interventional Neuroradiology Coding Users' Guide, coding advice, and programs.

Communications

The Communications Committee serves as a resource to the Society. Committee members will be able to respond rapidly to requests for interviews from the media when comments are needed and may be called on to act as a spokesperson on specific issues. The committee will also focus on increasing the profile of interventional neuroradiology among other physicians and the lay public.

FDA

The FDA Committee shall develop and maintain a constructive relationship between the Society and the FDA and increase awareness of FDA programs within the Society's membership.

Research

The Research Committee shall promote quality research by informing the Society of new ideas for basic, applied/clinical, and health services research, identifying research priorities, serving as a source of research information, promoting the communication of research information amongst members of the Society, providing research training opportunities to members of the Society, and serving as the Society's liaison with other research organizations.

Technology Assessment

The Technology Assessment Committee's charge is to advise the Society on device matters related to interventional neuroradiology. The Committee shall produce guidelines that ensure that devices used in the practice of interventional neuroradiology are applied safely and appropriately to patients. In addition, the Committee will ensure that patients have timely access to important new technological advances. The Committee also reviews documents produced by the Standards of Practice Committee.

We're Hungry for News…

About You!

One of the most valuable services that ASITN performs is to provide various forums to help members keep up with industry trends, swap war stories, and share good news. To do that, ASITN has to hear from YOU!

How can you keep us informed? It's easy. Add us to your mailing list for all press releases, newsletters, and other publications. Call us or drop a note to let us know about new personnel, procedures, or studies. Send us copies of newspaper, magazine, or journal articles in which you are featured.

Send your materials to **info@asitn.org**, via fax at **703-691-1855**, or by mail at 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

How to Apply for ACGME Accreditation

Colin Derdeyn, MD

The purpose of this article is to bring the general membership up to date on recent developments affecting Interventional Neuroradiology Fellowship programs. First, we are adding a list of active fellowship programs and contact information to the ASITN website, as a resource for residents interested in fellowship training. If you are a program director and have not received our mailings, please let us know so we can add your program to the list.

Through the hard work of many people, ACGME accreditation of interventional neuroradiology fellowship training programs is now available. The fellowship is named Endovascular Surgical Neuroradiology (ESN) and accreditation is administered through a residency review committee (RRC) that is jointly staffed by representatives from Neuroradiology and Neurosurgery. Fellowship training in these programs is open to Neuroradiologists and Neurosurgeons, after completion of their residency and one year of diagnostic neuroradiology. This fellowship formalizes the training program that is already in place in many of our institutions.

Participation in this process is critically important for our emerging specialty. This program will be dropped if it is under-subscribed in the upcoming years. At present, we are the only specialty with ACGME-approved training guidelines for work in the vessels of the nervous system, as well as for percutaneous spine intervention. Support of this fellowship will help to ensure that our patients continue to be treated by properly-trained physicians. One program has been approved so far several other programs are preparing to apply.

The application can be down-loaded at http://www.acgme.org/. The important forms can be selected from the menu on the left of the home page and then specifically for Endovascular Surgical Neuroradiology. There are three documents that are useful in filling out the application: the ESN Program Information Form or PIF, the Institutional Requirements, and the Radiology Subspecialty Requirements.

There are a few important financial issues to be aware of. The ACGME has no policy regarding billing for the services of, or payment to, fellows in ACGME-approved programs. All issues revolve around Medicare/Medicaid (CMS, formerly HCFA) reimbursement and are institution-specific. Basically, Medicare\Medicaid cannot be billed for the services of residents in ACGME-approved programs, as the hospital gets some (nominal, see below) payment from CMS to fund these residents. The fact that our fellows have completed their residencies and a year of fellowship may or may not allow them to provide staff services, depending on the position of your institution.

A second financial issue is the ACGME pay scale. The GME pay rate for a PGY 6 or 7 is less than most second year Neuro fellows currently receive. We are required, as participants in the Hospital/GME consortium, to issue a letter promising to pay salary at the going GME rate. There is nothing to prohibit a supplemental stipend from the Department, however.

Finally, some words about duty hours. As many of you are aware, the ACGME has mandated that duty hours for residents and fellows in ACGME-approved training programs cannot exceed 80 hours per week on average. They have recently decided, however, that this applies to time spent in the hospital. Call from home is not counted. Therefore, this should not be a problem for most of our programs.

Please feel free to contact me if you have any questions regarding the process.

Sixth Annual Joint Meeting

Mark your calendars for February 15-19, 2003 for the Sixth Annual Joint Meeting of the ASITN and the AANS/CNS Section on Cerebrovascular Surgery. ASITN Program Chair Buddy Connors, MD has put together a fantastic program with the assistance of AANS/CNS Program Co-Chair Gregory Thompson, MD.

The 2003 meeting has the added excitement of joint sessions with the American Stroke Association meeting. On Saturday, February 15, ASITN members will be able to attend two special sessions of the American Stroke Association meeting – one on Vertebrobasilar Ischemic Disease and the other on Diffusion and Perfusion Imaging in Patient Selection for Recanalization Therapy. You may register for these sessions by going to www.strokeconference.org.

Preliminary programs will be mailed in the next few weeks. Watch your mail!

ASITN Attends ACR Summer Conference

ASITN was invited, for the first time, to attend the American College of Radiology (ACR) InterSociety Conference. Gary Duckwiler, MD and Colin Derdeyn, MD attended on behalf of ASITN and joined representatives from over 40 specialty radiology societies.

The topic this year was "Radiology 2002: Today's Research is Tomorrow's Practice". Radiologists have to be the leaders in getting more research into radiology. We must create and define the research to own the field. Not only do we have to be research leaders, but we must get more money for these positions and the field. This can and is being done with industry, government and intellectual property.

Another problem addressed was the job market in academic leadership. The market is extremely tight and it's hard to keep people in academic positions when they are short staffed and underpaid.

Finally, a group discussed radiology training programs. Current radiology training is problematic. Fourth year residents are lost as they study for the boards, but moving the boards later impacts fellowships. ASITN and SIR leaders feel that perhaps moving the boards earlier and providing alternate tracts for individuals headed for subspeciality training (ie, neuroradiology or interventional) would be a viable option.

The final report from the meeting will be in an upcoming issue of the *American Journal of Radiology* – watch your mail!

Lancet Study **continued from page 1**

patient-years for the interventional treatment and zero per 1081 patient-years for the neurosurgical treatment.

"The study shows that survival free of disability at one year is significantly better with the interventional procedure than with surgery," says Andrew J. Molyneux, MD, ISAT principal investigator and president of the British Society of Neuroradiologists.

An interim analysis of the results had been planned at the outset, but the interim results were so compelling that further recruitment into the trial was stopped immediately for ethical reasons, because there is a clear advantage for patients receiving the interventional treatment. Patients already enrolled in the trial will continue to be followed to assess other outcomes of the trial. In addition to the interim data, ISAT is designed to assess the differences between interventional treatment and neurosurgery in prevention of rebleeding, quality of life at one year, the frequency of epilepsy, cost-effectiveness, and neuropsychological outcomes (a substudy conducted in seven UK centers). In addition, ISAT will determine the long-term outcome of treatment, over at least five years, with a particular assessment of the frequency of further hemorrhage, and assess the long-term significance of angiographic results.

Editors Column **continued from page 3**

battery, an intentional tort, not negligence or malpractice. As you might expect, good news travels fast, and this approach has been picked up in at least two other states I know of.

So a new caution is appropriate.

Some guidelines:

1) Document everything. Everything.
2) Note on the consent form that the patient signed it before medicating her.
3) Remember, if you do a procedure other than that you have written down on the consent form, no matter what the clinical indication is, you are at great risk.
4) If the patient is "wobbly", have the consent witnessed by others. If you are really worried, videotape it.
5) Finally, if something adverse happens, it's the family you will be dealing with. If they are not part of the informed consent discussion, you are at risk.

People in the News

Congratulations to ASITN member **Rich Berger** who was first featured in the Wichita Eagle on August 13, 2002 after performing a life-saving operation on a 23-year old stroke victim. The story was then picked up by the Houston Chronicle on September 15, 2002. The combined readership of these two papers is about 1.5 million people. This is great exposure for interventional neuroradiology!

Several of our members, including **Andy Molyneux**, **Charles Strother** and **Kieran Murphy**, were featured in major publications following the release of ISAT, including *US News & World Report*, the *Baltimore Sun*, and the *New York Times*.

If you have been featured in a local or worldwide publication, please let us know! Contact Marie Williams at **703-691-2272** or via e-mail at **info@asitn.org**.

Calendar of Events

Improving the Chain of Recovery for Acute Stroke in Your Community
December 12-13, 2002
Hyatt Regency Crystal City
Arlington, Virginia
Contact: NINDS, 888-352-9424

American Stroke Association Stroke Conference
February 13-15, 2003
Phoenix, Arizona
Contact: ASA, 214-706-1575

ASITN/JSCVS Annual Meeting
February 15-19, 2003
Phoenix Civic Plaza
Phoenix, Arizona
Contact: ASITN, 703-691-2272

Society of Interventional Radiology
March 27-April 1, 2003
Salt Lake City Convention Center
Salt Lake City, Utah
Contact: SIR, 703-691-1805

American Society of Neuroradiology
April 28-May 2, 2003
Marriott Wardman Park Hotel
Washington, DC
Contact: ASNR, 630-574-0220

1st Annual ASITN Practicum
May 2-4, 2003
Marriott Wardman Park Hotel
Washington, DC
Contact: ASITN, 703-691-2272

The Embolus

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The Embolus is published quarterly by the American Society of Interventional & Therapeutic Neuroradiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

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POSTMASTER: Send address changes to ***The Embolus***, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

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