ACRIN Research Associate Newsletter

American College of Radiology Imaging Network | September 2007

Clinical Research Trials: Focus on 6678

For many Americans diagnosed with advanced stage lung cancer each year, the prognosis is poor. Most will undergo palliative chemotherapy — but only about one third respond to treatment. Currently, it is difficult for doctors to know which patients are good candidates for therapy, and it can take several cycles to detect a response.

Researchers hope that, in the future, more customized approaches to lung cancer treatment will allow doctors to determine earlier which treatment will work best for a particular patient. One way to customize treatment is to use biomarkers as indicators of whether treatment is effective. A new ACRIN study, headed by Dr. Wolfgang Weber — and one of the first trial ever supported by the Biomarkers Consortium — may validate positron emission tomography with fluorodeoxyglucose (FDG-PET) as a treatment monitor in patients with advanced non-small-cell lung cancer (NSCLC). "ACRIN 6678: FDG-PET/CT as a Predictive Marker of Tumor Response and Patient Outcome" is designed to show whether changes in tumor metabolism as measured by FDG-PET/CT provide an early predictor of the effectiveness of therapy for NSCLC.

A First for Biomarkers Consortium

ACRIN 6678 has the distinction of being the first clinical trial supported by the Biomarkers Consortium, a public-private partnership launched in October 2006 whose membership includes the National Institutes of Health, the U.S. Food and Drug Administration, Centers for Medicare and Medicaid Services, as well as industry and patient advocacy groups.

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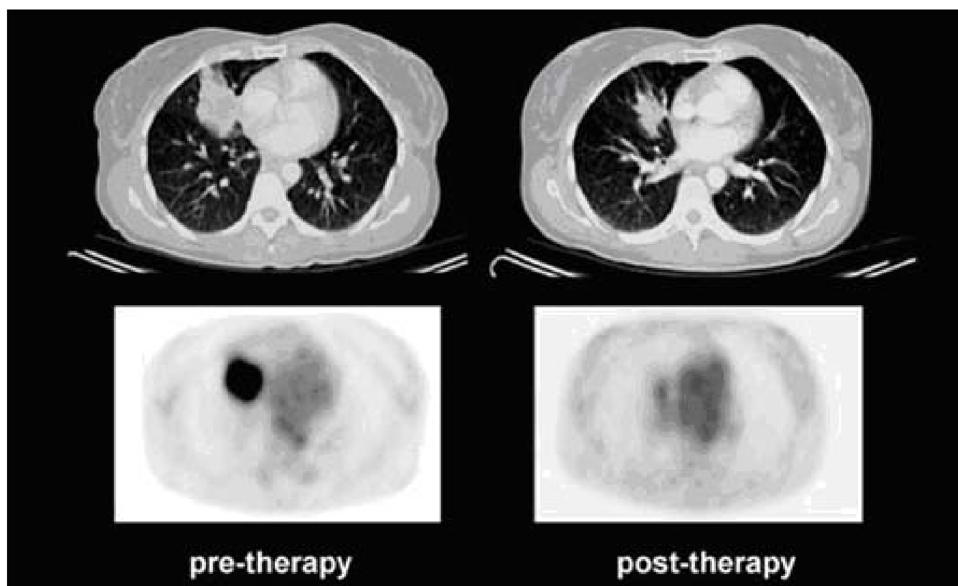

Axial images of CT above and PET below show a lung lesion pre-treatment (left) and post-treatment (right).

Fall Meeting Highlights

The day-long Research Associate Educational Session, on September 27th, is again packed with presentations to help RAs learn more about the tenets of clinical research in general as well as specifics related to ACRIN's medical imaging clinical trials. Some of this year's session highlights include:

- **Clinical research informatics initiatives, including an introduction to data standards**
- **From the patient's perspective -- lay descriptions of imaging exams**
- **About data safety and monitoring boards**
- **Know thyself - the Myers Briggs Type Indicator**

Breakout sessions will allow attendees to join discussions of particular interest including "RA Boot Camp" for new RAs presented by several of ACRIN's more seasoned RAs. And, of course, the traditional RA reception provides a great networking opportunity.

Visit www.acrin.org for a link to the registration page and more information.

See you on the 27th!

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Tech Corner: PET FAQ

What is nuclear medicine?

Nuclear medicine is a form of medical imaging that uses radioactive isotopes that are administered into the body. These isotopes are usually bonded with other molecules (called "tracers") so that they are absorbed in specific organs or diseased areas in the body. Using radiation detectors positioned around the patient, this absorption or "uptake" pattern can be imaged.

There are many types of nuclear medicine procedures. Using different combinations of tracers, isotopes and radiation detectors, these scans can aid in the diagnosis of cancer, heart disease, Alzheimer's, thyroid disorders, and many others. This article will focus on PET imaging.

What is PET?

Positron Emission Tomography, or PET, uses a specific type of isotope that emits positrons as part of its radioactive decay. During this emission, the positrons will convert into gamma rays. A ring of detectors surrounding the patient detects these gamma rays.

Physically, the PET scanner looks similar to a CT scanner. Patients lie flat on a table and are positioned inside the gantry (the part of the scanner that contains the detectors).

What does a PET procedure entail?

During the procedure, a patient is first injected with the radioactive tracer (typically FDG). The patient sits in a waiting area while the tracer circulates and uptakes in the body. After 30-60 minutes, the patient is positioned in the PET scanner. During the acquisition, the scanner detects the emitted x-rays and determines their location inside the body. This acquisition may take up to 45 minutes. Images are then reconstructed and processed to form the final images that are interpreted by the physician.

What is FDG?

FDG stands for fluorodeoxyglucose. This tracer uses a radioactive form of fluorine attached to a glucose molecule. This molecule will uptake in organs that have a high cell metabolism and energy usage. Cancer cells tend to have high metabolic rates due to their rapid cell division and will also uptake FDG.

What is quantitation?

Viewing a PET image will show an abnormality if one is present. However, additional processing, or quantitation, is needed to determine the actual quantity of FDG uptake in a tumor. It is theorized that by quantifying the uptake in a tumor, physicians will be able to determine if chemotherapy treatments will be effective during the initial stages of cancer treatment. In the long run, this may allow physicians to modify cancer treatment plans at an earlier stage, which could potentially improve survival rates.

Contributing author:
Thomas Oshiro, PhD Medical Physicist
University of California, Los Angeles

Members of the RA Executive Committee

Wendy Smith, BS RT(R)(CV), CCRP
Chair, RA Executive Committee
wsmith@lifespan.org
401-444-4233

Lorna Beccaria, BS, RN, CCRC
lornab@ocsi.us
707-762-6691

Cynthia Cobb, BS, RT(R)(CT)
ccobb@lifespan.org
401-444-4344

Roslynn Marzan, BS
rmcgill@mednet.ucla.edu
310-794-1702

Tracy Petro, CTR, CCRP
sitton-petro.tracy@mhsil.com
217-757-2055

D. Lynn Werner, RN, CCRC
lynn.werner@uphs.upenn.edu
215-349-8553

RA Survey Initiative

Attention! Attention! Read all about it! In the near future, all ACRIN research associates will be receiving a short electronic survey via Survey Monkey. Please complete and submit the survey at your earliest convenience. It has been several years since we last updated pertinent information, and we would very much appreciate a response in a timely fashion.

Should you know of any RAs who may not be on the distribution list, please contact Pam Harvey at ACRIN (pharvey@phila.acr.org) so that they will receive all future RA-related information. Thank you!

D'Amato Award

Thank you to everyone who submitted nominations for the Jo-Ann D'Amato Award of Excellence. We received a total of four nominations for three applicants. The awardee has been chosen and notified. We look forward to presenting this award at the ACRIN luncheon on Friday, September 28. Dr. Etta Pisano will again present the award in honor of our dear colleague and friend Jo-Ann D'Amato.

The ACRIN Research Associate Newsletter is developed in cooperation with the RA Executive Committee and ACRIN Headquarters and distributed to ACRIN's research community.

American College of Radiology Imaging Network
Administrative Headquarters
1818 Market Street
Suite 1600
Philadelphia, PA 19103

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RA Committees Provide Opportunities for Involvement

The Research Associate Executive Committee (formerly known as the RA Core Committee) exists to help integrate research associates into the work of ACRIN. One of our important tasks this year has been to actively recruit interested RAs to the four new subcommittees: Mentorship, Quality Assurance, Education, and Networking and Communications. These committees, which are now forming, offer opportunities for RAs to become more involved with ACRIN.

At the ACRIN Fall Meeting, the RA Executive Committee will provide opportunities for RAs to learn more about the subcommittees and their work. We have lots of ideas for future projects and would like to hear your ideas as well. Recently, several members of the Executive Committee have left, and we would like to replace these people from members of the subcommittees. We hope that, over time, active members of subcommittees will provide experienced members for the Executive Committee.

This fall, come get involved, and let your voice be heard! We look forward to meeting you.

Mentorship Subcommittee

Primary Goal:
To support the education of new or inexperienced RAs through mentoring by more experienced RAs on all issues relating to the development, initiation, implementation, and completion of ACRIN protocols.
New Members:
Tracey Petro, chair, welcomes the following members. **Monene Kamm**, AS: Monene is the study coordinator at the University of Cincinnati. She has actively been involved in ACRIN studies 6652, 6667, and 6666. **Svetlana Vassilieva**: Svetlana is the study coordinator for Yale University School of Medicine. She has most recently been involved in ACRIN 6664. **Ellen D'Orsi**, RT (R) (M): Ellen is the manager for the Breast Imaging Research division at Emory University. Ellen has participated in ACRIN studies including 6652.

Education Subcommittee

Primary Goal: To provide RAs with the knowledge, training, and support they need to effectively carry out ACRIN's research mission.
New Member:
Lorna Beccaria, chair, welcomes **JoAnn Lorenzo** from the University of Washington in Seattle. JoAnn received her MPA from Seattle University and has over 5 years of ACRIN research trial experience, including ACRIN 6667 and 6657.

Quality Assurance Subcommittee

Primary Goal:
To ensure the quality of data necessary for valid, robust clinical trials through pilot testing the instruments used to collect data in a real-word environment.
New Members:
Cindy Cobb, chair, welcomes three new members: **Dina DePaulo**, from Rhode Island Hospital, and **Lisa Camacho** and **Mary Klaus-Clark**, both from Boca Raton Community Hospital. All three RAs have been working on various ACRIN research projects over the last 4 years or more.

Networking & Communications Subcommittee

Primary Goal:
To link inexperienced and experienced RAs to the identified resources, including the RA Newsletter, the ACRIN website, and those available through ACRIN Headquarters and the American College of Radiology, necessary to carry out their responsibilities.
New Members:
Lynn Werner, chair, is currently seeking new members.

Best Wishes to Sophia and Karan

Thank you to Sophia Sabina and Karan Boparai for their work on the RA Executive Committee. As mentioned in our last newsletter, Sophia and Karan have left ACRIN to work just down the hall for the American College of Radiology. They will both be working closely with ACRIN to advance the ACR's efforts in data standardization, creating an imaging workspace, and the caBIG initiative.

Sophia was one of the founding members of the RA Executive Committee (which was then called the RA Core Committee) in 1999. She has been an invaluable member of our team, thanks to her support and work on behalf of ACRIN and all RAs. Sophia has many wonderful talents and will truly be missed by the RA Committee.

Karan joined our group more recently in 2005. She has worked tirelessly on our behalf by keeping us on track with deadlines, minutes, and meetings. Her spirit has kept us all going at times of great loss and stress.

Although Sophia and Karan are no longer part of our committee, they will always be our dear friends and colleagues. We wish them all the very best in their new positions with the ACR.

We will miss you!!!!

Wendy, Lorna, Cindy, Tracy, Lynn, and Roz

Welcome to...

Pam Harvey, director of data management, and research associate Tina Taylor as they join the RA Executive Committee. Danielle Hunter will lend her talents to the Networking and Communications Sub-committee.

New Faces at ACRIN: Terri Hill and Danielle Hunter

Terri Hill is ACRIN's new assistant director of data management. A registered nurse with extensive experience in both clinical and managed care, she received her BSN from Penn State University and her M.Ed. from Antioch University. Her clinical experience has run the gamut from medical-surgical nursing to director of nursing in a small home health agency. From there, she transitioned into the managed care field. She says, "A key part of my background has been working as a research nurse. In this position I performed on-site audits and medical record abstraction for provider credentialing, Medicare, and NCQA quality studies. These duties led to my previous position as a supervisor of quality management for a major managed care corporation." Terri is enthused about working with ACRIN. She says, "It's so much to learn, and so interesting. The people here are nice and easy to work with, and I'm looking forward to making a contribution to the company."

Terri Hill (left) and Danielle Hunter (right).

Danielle Hunter is a new administrative assistant for diagnostic imaging. She has worked for ACRIN since December 2006 in a temporary capacity, and previously has provided administrative support for other companies in Center City Philadelphia. Danielle is happy to be working for ACRIN on a permanent basis and is excited to learn more about the bigger picture of ACRIN's work. She says, "Working here has been amazing. My uncle passed from cancer just before I started, and I knew that while I couldn't help him, I could help others. My aunt is very proud that I took this job." Danielle is looking forward to attending the Fall Meeting and working with the Research Associate Executive Committee there.

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FDG-PET Measures Early Response

FDG-PET has the potential to improve patient management by signaling the need for early therapeutic changes in non-responders. Such changes can help patients avoid the side effects and costs of ineffective treatment. If FDG-PET is shown to be an early indicator of clinical benefit, it also may help promote the development of oncologic drugs by shortening Phase II trials and detecting clinical benefit earlier in Phase III trials. To determine whether the treatment is effective, researchers will use FDG-PET to examine tumors for a metabolic response, as shown by a decrease in the uptake of FDG.

ACRIN 6678, which opened this spring, involves 228 participants at approximately 10 institutions. Participants, all of whom will receive three FDG-PET/CT scans, will be randomized into two groups. Group A will receive two FDG-PET/CT scans prior to chemotherapy and one scan after the first cycle. The two FDG-PET/CT scans prior to therapy will be used to determine the reproducibility of quantitative measurement of tumor FDG uptake in a multicenter setting. Group B will receive one FDG-PET/CT scan prior to chemotherapy, one after the first cycle, and one after the second cycle. The two scans after start of treatment will establish the time course of metabolic changes during therapy in order to determine the best time to assess treatment response by FDG-PET.

The primary endpoint is the correlation between a specific definition of response in PET and patient survival, but the trial also includes exploratory data analyses that will help determine the best course of future research.

At many institutions, PET/CT has replaced stand-alone PET scanners and provides the combination of both metabolic and high-quality anatomical measurements of tumor size. The trial's use of CT scanning will provide researchers with further valuable information. PET/CT-based tumor volumes may provide a more robust anatomic measure of treatment response than simple diameters, particularly for irregularly shaped lesions. The use of PET/CT imaging in ACRIN 6678 will allow the exploratory analysis of changes in tumor metabolic activity with changes in tumor volume.

For more information about this trial, including site participation, contact Donna Hartfeil at 215-717-2765; dhartfeil@phila.acr.org.