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ICUS is the <u>only</u> international organization exclusively devoted to contrast-enhanced ultrasound ("CEUS"). Membership in ICUS is free. Sign up at:

www.icus-society.org

LETTER FROM THE CO-PRESIDENTS

Dear Colleagues,

Welcome to the International Contrast Ultrasound Society ("ICUS") -- <u>the</u> world's only international professional society exclusively devoted to the field of <u>contrast-enhanced ultrasound ("CEUS")</u>. There is no charge for membership.

ICUS brings together medical and scientific professionals from around the world representing the fields of <u>cardiology</u>, <u>radiology</u>, <u>gastro-intestinal medicine</u>, <u>vascular medicine</u>, <u>internal medicine</u>, <u>hepatology</u>, <u>and other specialties and basic</u> <u>science disciplines</u> -- all focused on improving patient care by expanding the safe and appropriate use of CEUS for more accurate and reliable noninvasive diagnosis of patients with diverse medical profiles and disease states.

ICUS also will provide the field of CEUS with its own voice for expressing principled, scientifically-based perspectives on the appropriate use and regulation of CEUS agents. In addition, with an unparalleled range of professional expertise and geographical perspectives, ICUS is uniquely capable of fostering education, research and collaboration to help move the field of CEUS forward. ICUS members currently represent 22 countries in North, Central and South America; Europe; Asia; Africa; and the Middle East. In addition, the structure of the organization is designed to guarantee that diverse medical and geographic backgrounds are always represented in leadership roles of the organization.

Please invite your colleagues to join ICUS today and help the organization promote better patient care worldwide through the safe and appropriate use of CEUS.

Sincerely yours,

Barry Goldberg & Steve Feinstein, Co-Presidents



The ICUS Founding Executive Board members smile proudly as the new organization is launched at the annual international contrast ultrasound conference in Chicago ("Bubble Conference").

Top row: Brian Fowlkes, Fuminori Moriyasu, Maria Cristina Chammas, Stephanie Wilson, Petros Nihoyannopoulos, Michael Main.

Bottom Row: Lennard Greenbaum, Paul Grayburn, David Cosgrove, Steven Feinstein, Barry Goldberg.

Not pictured: Kurt Jaeger, Shintaro Beppu, Mark Monaghan, Wilson Mathias, Jr.

International Contrast Ultrasound Society www.icus-society.org

Latest News

<u>Dr. Michael Main</u>, a cardiologist with Mid America Heart Institute, Kansas City, MO, prepared the following update on the clinical safety and FDA regulatory progress of ultrasound contrast agents. His update was presented at the 23rd Annual Bubble Conference in Chicago.

Clinical Safety of ultrasound contrast agents

The latest published, peer-reviewed clinical studies fail to reveal a safety signal in over 211,223 patients undergoing contrast-enhanced ultrasound imaging. Among the key findings:

No hemodynamic effects during cardiac surgery (Optison)

Adverse event rate similar to low-osmolar iodinated radiocontrast media

No difference in 24 hour mortality in hospitalized patients undergoing echo with or without contrast

Patients receiving Definity were 24% less likely to die within 1-day than patients undergoing echo without contrast

Incidence of severe adverse reactions to ultrasound contrast agents is lower than, or similar to, that reported for contrast agents commonly used in other cardiac imaging tests.

To view a summary of recent clinical safety studies, please click here

SAFETY STUDY REFERENCES can be viewed here

FDA news -- "Black Box" overview

CEUS has experienced considerable FDA attention since last fall, beginning with the agency's surprising new "black box" warnings and contraindications that were largely reversed in spring of 2008. For more information regarding FDA actions with regard to CEUS black box warnings and contraindications, please click <u>here</u>



Safety of myocardial flash-contrast echocardiography in combination with dobutamine stress testing.

C Aggeli, G Giannopoulos, G Roussakis, E Christoforatou, G Marinos, C Toli, C Pitsavos, C Stefanadis

The combination of perfusion assessment using myocardial contrast echocardiography (MCE) with DASE has shown very promising results for the diagnosis of coronary artery disease. Concerns have, however, been expressed regarding the safety of the use of echo-contrast agents in echocardiography.

A recent study of safety data regarding stress-contrast echocardiography in a large series of subjects suggests that the use of real-time flash-contrast echocardiography combined with dobutamine–atropine stress echo (DASE). is an exceptionally safe technique, given that in 5250 studies no study-related deaths or myocardial infarctions were encountered, whereas serious adverse events requiring hospitalization were extremely rare (one in 2625 studies).

The results of this study were published in Heart Online, and can be viewed here

Myocardial Contrast Echocardiography Update

By Dr. Roxy Senior, Department of Cardiovascular Medicine, Northwick Park Hospital, Harrow, UK

Two important CEUS papers are to be published in the January 2009 edition of the European Journal of Echocardiography (EJE):

"<u>Recommendation of Contrast Echocardiography</u>" by the European Association of Echocardiography (EAE) is a timely complement to the "Recommendations for Contrast Agent Use in Echocardiograms" recently published in JASE. The EAE's recommendation is more expansive in that it proposes the offlabel use of contrast agents for myocardial perfusion imaging based on evidence-based medicine.

The second paper reports on the first large international multicentre trial (28 centres) using the new contrast agent, Imagify, for simultaneous assessment of function and perfusion during real-time low-power echocardiography. This trial demonstrated that function and perfusion assessment during low-dose vasodilator stress is equivalent to gated-SPECT for the detection of CAD. Furthermore, echo images were evaluable in 99% of the patients, with inter and intra reader variability being similar to that of SPECT. This trial paves the way for the use of CEUS myocardial function and perfusion assessment in clinical cardiology, and effectively supports the EAE recommendation on contrast echo. Based on the successful results of the trial, Acusphere has filed an NDA seeking approval of Imagify.

A second large multicentre study (PHOENIX) using SonoVue is currently underway for myocardial perfusion and function assessment. This trial is expected to finish recruitment by the end of 2009. SonoVue is a contrast agent manufactured by Bracco, of Milan, Italy, and is currently approved and available in Europe and Asia for LV opacification.

MEDICAL EXPERTS FORGE HISTORIC CROSS-SPECIALTY TIES FOCUSING ON SAFE, LOW-COST "CONTRAST ULTRASOUND"

New international society, ICUS, unifies diverse medical specialties to focus on role of contrast ultrasound in improved patient care worldwide

<u>CHICAGO, ILLINOIS (USA) - September 18, 2008</u> -- Medical professionals from around the world are welcoming the formation of International Contrast Ultrasound Society (ICUS) -- <u>the only international and cross-disciplinary</u> professional society exclusively devoted to the field of contrast ultrasound and its role in improving patient care worldwide.

The new organization was launched today at the opening session of the 23rd annual international conference of contrast ultrasound specialists, "Advances in Contrast Ultrasound: Enhanced Atherosclerotic Imaging and Interventions," in Chicago.

ICUS brings together medical professionals from around the world representing the fields of cardiology, radiology, gastro-intestinal medicine, vascular medicine, internal medicine, hepatology, and other specialties and basic science disciplines -- all focused on improving patient care by expanding the safe and appropriate use of contrast ultrasound imaging for more accurate and reliable noninvasive diagnosis of patients with diverse, and sometimes life-threatening, abnormalities.

To download the full press release, please click Here

International Contrast Ultrasound Society www.icus-society.org

Shockwaves Subside from the FDA's Echo Contrast Warning



November/December 2008

BY JUSTINE CADET

Since the FDA placed a black-box warning on echocardiography contrast agents in October 2007, the market for the agents dropped tremendously. However, the subsequent movement to educate both regulators and providers led to a modification of the agency's contraindications and may have generated a resurgence in their use, along with a better understanding of their clinical value.

Two products are available on the U.S. market: Definity from Lantheus Medical Imaging and Optison from GE Healthcare. In Europe, Definity and Optison are approved, but only SonoVue from Bracco Diagnostics is currently being marketed.

Regulatory Action

In October of last year, the FDA changed the product labeling for perflutren cardiac ultrasound agents due to reports of about "200 serious adverse events shortly following administration of the products," including seven deaths, which were mainly attributed to allergic reactions. The cardiac or pulmonary complications included cardiac arrest, heart rhythm problems, hypotension and hypoxemia. "The approach that the FDA took in contraindicating contrast agents in various disease states was probably not the best approach. Since that time, we were able to demonstrate how patients with these disease states are the very patients who are most likely to benefit from the administration of contrast," says Michael L. Main, MD, of the Mid-America Heart Institute in Kansas City, Mo.

(Click <u>Here</u> to read full article)

National Association Endorses Recommendations for Contrast Agent Use in Echocardiograms

American Society of Echocardiography Lays out Clinical Applications and Safety Considerations

The American Society of Echocardiography (ASE) today backed the use of contrast agents, used to enhance echocardiogram images, and provided a guide for physicians who may be hesitant to use the contrast agents following a 2007 Food and Drug Administration (FDA) black box warning.

To read the full press release, please click Here

ASE GUIDELINES - Contrast agent guidelines updated 2008

For additional information presented at the 2008 "bubble conference" in Chicago, click <u>here</u> Save the date:



ICUS Bubble Conference 2009

Advances in Contrast Ultrasound

October 21 - 23, 2009 Chicago, IL

www.bubbleconference.com

ICUS Launch Sparks Worldwide Interest

Since the launch of the International Contrast Ultrasound Society (ICUS) on September 17, 2008, the requests for membership have created a truly international organization.

To date, ICUS has recruited medical professionals in the following 22 countries:

Australia
Brazil
Canada
China
Cyprus
Denmark
Egypt

France Greece India Italy Israel Japan Korea Mexico

Netherlands Norway Poland Romania Switzerland Turkey United Kingdom

For more information on ICUS membership, please visit ICUS Society Membership

ICUS MISSION

To promote the safe and efficacious use of contrast-enhanced ultrasound ("CEUS") in patients with diverse medical profiles and disease states.

To provide a global inter-disciplinary forum to foster education, research, and development of CEUS applications.

To facilitate open and dynamic communications among medical professionals and scientists in the fields of cardiology, radiology, gastro-intestinal medicine, vascular medicine, internal medicine, hepatology, and other medical specialties and basic science disciplines.

To foster education of the public on the safe and efficacious use of CEUS in patients.

To create awareness in the medical community about the clinical benefits of CEUS.

To sponsor a website and an annual international conference that will foster global inter-disciplinary education, research and development of clinical ultrasound and contrast ultrasound applications

Send us your news at info@icus-society.org

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