

When you have three eminent physicians talking about revolutionizing the gold standard of care for patients presenting at the emergency room with chest pain, the conversation is bound to be interesting – even intense. *Medical Solutions* recently hosted a roundtable discussion with physicians Udo Hoffmann, Gilbert Raff, and Harold I. Litt to talk about how individual research shows promise for the use of cardiac computed tomography angiography to help define – quickly, accurately, and cost efficiently – which patients are and are not at risk for a cardiac incident.

By Louisa Kasdon

Saving Money and Lives in Chest Pain Triage

The three of you have been at the forefront, in your hospitals and in your profession, for looking at how computed tomography (CT) scanning as a triage method can impact patient care, patient treatment, and workflow. Can you explain how the use of cardiovascular CT addresses the problem of patients and influences the workflow in your emergency department [ED]?

RAFF: Best estimates are that six million patients a year in the U.S. come to the emergency room reporting chest pain. Here's the crux of the problem: Less than ten percent of patients reporting chest pain are actually having a heart attack. Here's the second problem: We generally say that the ideal door-to-balloon time is 90 minutes. This is the time lapse from the moment a patient enters the ED until a definitive treatment with an angioplasty balloon. What we don't talk about is what happens to the 75 to 85 percent

of patients who are not having a heart attack. In our hospital a few years ago, we did a survey: The average time that it took to make the diagnosis and discharge the patient was 22 hours. Here's the third problem: We can't send people home without deciding whether their heart is diseased or not. Those of us sitting here today had reasons to think that CT might be particularly helpful in making that diagnosis more effectively.

HOFFMAN: The work-up of those patients who do end up not having a heart attack costs us about eight billion dollars a year. A big chunk, with the potential for big healthcare savings! Before the 'CT era,' there was no tool available to directly visualize the coronary arteries, including coronary artery plaque and coronary stenosis. We now have a unique tool with the spatial and temporal resolution that can help us noninvasively visualize the disease.

LITT: Our goal is an event rate – the rate of people sent home who actually end up having a heart attack – of less than one percent. This sounds like a large number, but out of 100 people, it's very difficult to figure out which 99 people to send home. The Holy Grail in emergency medicine chest pain evaluation is to find a technique that can do that quickly, reliably, efficiently, and cost effectively. CT – which is available in almost all hospitals – is a test that can be performed quickly and fits this application.

HOFFMANN: Having the CT test take place immediately means two things: First, the care of other patients is improved when you can clear out patients with suspicion of acute coronary syndrome from the emergency room, and second, more can gain access to advanced technology because it's so quick. At MGH [Massachusetts General Hospital], we have started a randomized trial where we take very





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you may save many
more lives.”

Udo Hoffmann, MD, MPH,
Director of Cardiac MR PET CT Program,
Massachusetts General Hospital,
Boston, Massachusetts, USA



“We are really able to
zero in on the sickest
patients.”

Gilbert Raff, MD, Director,
Ministrelli Center for Advanced Cardiovascular Imaging,
William Beaumont Hospital, Royal Oak, Michigan, USA



“Now we have a new
gold standard.”

Harold I. Litt, MD, PhD,
Assistant Professor of Radiology and Medicine, Chief,
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low-risk patients with a suspicion of pulmonary embolism, aortic dissection, or acute coronary syndrome, and put them in the CT scanner. In those patients, the SOMATOM® Definition scanner is extremely helpful because it can scan at high heart rates and still guarantee excellent image quality. You do have to image the entire chest, but you are then able to rule out or rule in each of those three diagnoses.

Was there a new technology that suddenly made the CT scan more attractive as a diagnostic tool?

LITT: Yes. In order to get images without artifacts from the motion of the heart, you need to be able to scan as quickly as possible. For some patients – with asthma, lung problems, cocaine users, or pulmonary emboli, for example – you can't use beta-blockers to slow the heart down. Dual Source CT can freeze the motion of the heart twice as fast as other competing CT technologies. We can scan patients with higher heart rates and have confidence that we're going to get good image quality.

About three-and-a-half years ago, we started using CT as a surrogate for catheter angiography, which used to be the gold standard for evaluating narrowing of the coronary arteries. During that time, we conducted a large trial, with more than 640 individuals, about the actual financial comparison of different strategies to evaluate patients with potential acute coronary syndrome. We compared the CT angiography [CTA] group with the two groups being treated the standard or current way: the clinical decision unit group with serials of biomarkers and stress test, and the usual care group, which was defined as admission with serial biomarkers and hospital-directed evaluation. The main parameters were actual cost of care – that is, facility direct and indirect fixed, facility variable direct labor and supply costs – length of stay, the 30-day readmission rate, as well as safety, measured in 30-day death or myocardial infarction rate.

The study showed overwhelming results. The standard-of-care group and the usual-care-group revealed median costs of 2,913 to 4,024 US-dollars per patient and an average length of stay of 26.2 to 30.2 hours. The rate of myocardial infarction and death was 0.7 to 3.1 percent. The readmission rate was between 2.3 and 12.2 percent – so you have to consider additional costs for further tests and treatment for those patients.

The cost per patient in the CTA group was only 1,239 US-dollars, which is a 57 to 69 percent savings. Similar results for length of stay with eight hours in the CTA group, which is a time advantage of 69 to 73 percent. Interestingly, the rate of myocardial infarction or death in the CTA group was zero, which can be explained with the almost 100 percent negative predictive value of Dual Source CT. Also the 30-day readmission rate was zero, which means no patient came back for further tests or treatment – saving additional time and money.

We found that, using total facility cost, immediate CTA was the least costly method of evaluation. It also resulted in reduced length of stay, decreased rate of admission, lower rate of return visits, and at least equivalent 30-day outcomes. Other strategies that required inpatient or observation unit admission were more costly, had a more prolonged length of stay, and did not detect any more disease than the immediate CTA strategy. The subset of patients who received 'usual care' accompanied by cardiac testing – stress echo, treadmill testing, or cardiac catheterization – had a mean cost of 4,154 US-dollars, compared to 1,239 US-dollars.

RAFF: We are really able to zero in on the sickest patients. So what we're doing now is concentrating all the tests, all the hospitalizations, all the operations on the 20 percent of patients who have risky coronary disease – not on the 80 percent who don't. We are excited about the potential for saving enormous amounts of money in this terribly difficult medical environment.

Summary

Challenge:

- Finding a more accurate, more time-efficient, and less invasive way to identify which of the six million patients a year who present at the emergency room with acute chest pain are actually having a heart attack
- Providing the estimated ten to 20 percent of patients who are having a cardiac event with rapid treatment, while allowing the remaining 80 to 90 percent to return home secure that they are not at risk
- Reducing the US\$8 billion annual cost currently borne by the national healthcare system for diagnosing patients not having a heart attack
- Being able to include difficult patients, e.g., obese patients and patients with high heart rates

Solution:

- Use of Dual Source CT scans to triage suspected cardiac patients in 80 percent less time and at 50 percent less costs
- Changing the standard of care for chest pain patients in the ED from a 22- to 25-hour protocol with enzyme studies and stress tests to the immediate use of the high-resolution SOMATOM Definition and SOMATOM Definition Flash scanners to rule out cardiac damage
- Using SOMATOM Definition and SOMATOM Definition Flash scanners to achieve accurate and quick imaging for difficult patient populations, including obese patients, patients who cannot take beta-blockers, and comatose patients

Result:

- Reduction of total radiation dose over the life of the patient with submillisievert scanning by reducing radiological follow-up for early detection and prevention

HOFFMANN: Patients really follow visual evidence. Studies show that if you can actually show a picture to patients and say, "This is the disease you have," they will adhere much better to medical therapy, compared to information based merely on talking about the functional capacity of their heart. With CT, you can identify many more patients who have coronary artery disease, and potentially treat them in a more preventive fashion. Over the long term, you may save many more lives.

LITT: Or even prevent them from having their first heart attack.

RAFF: That's another point. Somewhere between ten and 20 percent of stress tests are not definitive. But even if a test is definitive, you might tell the patient, "There's nothing serious right now, but come back in a year. We'll give you a medicine to lower your cholesterol, we'll do this, we'll do that, and we'll do another stress test next year." And the whole protocol ends up being repeated every year. It isn't only the superficial cost of coming to the emergency room; it's the future cost of every office visit and every cholesterol pill for the rest of their lives. And when you think about that, it's even bigger.

LITT: People say that the radiation dose is a downside to CT. If we can show that a patient has normal coronary arteries, no coronary disease, they will need fewer studies in the future. They won't need to have a stress test year after year. So we might be able to lower the amount of radiation that they're exposed to over the course of their lifetime.

Why isn't everybody doing this? What are the impediments to this becoming the new standard of care?

HOFFMANN: The biggest impediment is that most physicians have been trained to work-up cardiac pain patients in a certain way. Over the years, every hospital has organized its own way to deal with those patients. Change is always difficult.

LITT: We don't yet have long-term follow-up studies where we've seen what happens to patients five or ten years later. We're trying to do those studies, so that people will feel comfortable knowing

that even in the long term, CT is a safe technology.

HOFFMANN: Research takes a long time. For example, people knew that high blood pressure was probably not helpful, but it took years to recognize that as a risk factor. It will take some time to gather the data and the evidence that will lead towards CT as the new standard for acute chest pain diagnoses.

RAFF: Here's another problem: insurance. National Medicare and other large-scale insurers have decided that new diagnostic tests should be treated like new drugs. We now have to show specifically that this new diagnostic test adds an advantage to the old diagnostic test. Otherwise, it won't get approved.

And better is not just a function of its efficiency or its cost effectiveness?

RAFF: No. Efficiency and cost effectiveness is a valid demonstration of superiority, but there needs to be more. The National Institute of Health [NIH] and the National Heart, Lung, and Blood Insti-

tute have convened a working group to decide the big questions relevant to these issues, and they are looking at very large scale trials with thousands and thousands of patients.

The problem with large-scale trials is that they get definitive answers, but they take decades. In these times of financial crisis, how do you develop the evidence, where do you get the financing for these trials yet not push off the potential benefits of society for a decade or two decades?

Is the radiation dose one of the reasons people are slow to accept CT?

RAFF: CT is a radiation-intensive procedure because the amount of X-rays you get is dependent on the resolution. The higher the resolution, the higher the X-ray dose. The Dual Source CT is quite dramatic in that not only do you get very rapid imaging and very high, submillimeter resolution, but you also get much lower radiation dose, about 50 percent lower. The new SOMATOM Definition



The latest Dual Source technology in the SOMATOM Definition Flash can complete dedicated cardiac investigations in about 250 milliseconds at less than one millisievert radiation dose.

Flash scanner will raise the bar even higher and is probably going to reduce radiation dose by 90 percent.

Do patients feel less cared for because you give them one quick test and then send them home?

HOFFMANN: I can tell you in one sentence. I show them the CT image and tell them, "See, you have clean coronary arteries." And they say, "Awesome." They feel relieved.

Does the CT scan work well for obese patients? I understand that's a very difficult clinical situation to evaluate.

LITT: That's a very good question. Typically, image quality is lower in obese patients and radiation dose is higher. With the CT technology, and specifically Dual Source, we're able to get better image quality at lower radiation doses in obese patients. With patients who weigh more than 350 pounds [159 kilograms], particularly shorter patients who have a lot of their bulk in the chest, this may not be the right test.

RAFF: I volunteered to do a development project in Michigan to see if we could use some of Siemens new *syngo*® CT software in combination with Dual Source CT. We used a new approach, which was called the Dual Source cardio obese mode. We found that 90 percent of the obese patients could have diagnostic scans, which is really great for this challenging situation. We can currently scan patients in the ED who weigh as much as 450 pounds [240 kilograms].

With SOMATOM Definition Flash, how will split-second thorax capabilities affect outcomes?

LITT: Typically, a chest CT on an average high-end scanner might take five to ten, perhaps twenty seconds. With the new technology, you will be able to image the entire chest in less than one second. That will help us to get very clear images of the heart, the pulmonary arteries, and the aorta without the patient needing to hold his breath. Similarly, in children and infants who can't understand the direction to take a deep breath and hold it, it supports you to get motion-free images

of the entire chest or the body in a time-frame where the patient can remain still.

RAFF: Our hospital recently made a decision to upgrade two scanners to SOMATOM Definition Flash – taking out two scanners and replacing them with one. Now, we're reducing the radiation and taking the whole picture in less than a second.

What about submillisievert heart scanning?

RAFF: Currently, a single-source CT exam of the heart in most hospitals involves radiation doses of about ten millisievert. You have to have a very well-trained staff to get that dose that low, because sometimes it's 20 millisievert or more. With the CT of the heart being less than one millisievert, radiation will basically no longer be an issue.

LITT: To put that in perspective, here in Philadelphia, the average yearly background radiation dose that you get just from walking around and living in the city is about three millisievert. With the new technology going to less than one millisievert, it would only be the equivalent of a few months' worth of that radiation.

HOFFMANN: I believe that due to its low dose it is even conceivable that this technology can be used for early detection and prevention of acute myocardial infarction in the future.

What's next for you?

HOFFMANN: We've really just scratched the surface of the capabilities of cardiac CT. There is really tremendous information you can derive from a CT scan. We hope to make those measurements more quantitative, especially for plaque and stenosis. We mentioned that now we can see disease, but we cannot exactly say whether it is 50 or 60 or 70 percent. We hope to identify high-risk plaque with CT scanning, identifying which plaques pose a danger for the patient's future.

RAFF: My first focus is on a national registry being organized called CT Care. It will study long-term outcomes and questions: What is the warranty period for a normal result? What does it mean for a patient to have a normal result?

Does the patient really need to take high doses of statin drugs to reduce his cholesterol to less than 100?

My second focus is education and training. We have shown that the average radiation dose from CT in Michigan was actually 25 millisievert, higher than we wanted to see it. Within a year, we got it down to nine. That's a massive decrease, and that's where education and training comes in. Over time, we could see it go down to less than one. Also, there simply aren't enough physicians trained to do CT. In five years, virtually every significant, sophisticated hospital will be practicing cardiovascular CT because of its benefits. We need to train the next generation of physicians to be ready.

LITT: My plan for the immediate future is a multicenter trial in Pennsylvania looking at coronary CT in emergency departments. It's a long process and will involve two or three years' worth of collecting data and one or two years' worth of analysis. Many of us are trying to figure out how we can correlate what we see on CT with the new generation of blood tests for markers of atherosclerosis and inflammation and with high-sensitivity markers of damage to the heart, both in the acute-pain settings and actually in outpatient settings. The goal – and the NIH actually has a very large group of people working on this – is to have a kind of escalating pyramid of techniques for evaluating vulnerable patients in order to avoid very invasive, expensive procedures where they may not be necessary. Over the next five years, we'll probably still have a lot of questions, but hopefully we will be closer to some answers.

Louisa Kasdon is a Cambridge, Massachusetts-based writer who specializes in health, medicine, nutrition, food, and business. She writes about health issues for Fortune magazine, the Boston Globe, and the Christian Science Monitor.

Further Information

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