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The FAME Study, Fractional Flow Reserve and Reducing Heart Attacks

Its called the FAME study and doctors placing stents or conducting bypass surgery are going to be hearing more about it. Welcome to Focus on Heart Health on ReachMD Radio on XM160, The Channel For Medical Professionals. I am Bruce Japsen, the healthcare reported with The Chicago Tribune and joining me today is Dr. William Fearon, he is an Assistant Professor of Cardiovascular Medicine at Stanford University. Dr. Fearon has a general research interest in coronary physiology, in particular he is investigating invasive methods for evaluating the coronary microcirculation. His research is currently funded by National Institutes of Health K23 career developmental work. He received his medical degree from Columbia University in New York and his bachelor's degree from Dartmouth College and he joins us today from his offices in sunny California at Stanford University Medical Center.

BRUCE JAPSEN:

Dr. William Fearon welcome to ReachMD Radio on XM160.

DR. WILLIAM FEARON:

Thank you Bruce, thank you for having me.

BRUCE JAPSEN:

There are so many studies that come out that I follow and I know that a lot of doctors sort of get overwhelmed by studies, but you are going to tell us about something that they should really be paying attention to that was published this January in the New England Journal of Medicine and it was called FAME and it breaks some new ground in heart care. If you could tell us a little bit about this.

DR. WILLIAM FEARON:

The FAME study was a study looking at patients who have chest pain and are present to the what's called the catheterization laboratory from an area where we do what's called a coronary angiogram and that's a procedure where we inject dye into the arteries that bring blood to the heart and in people who have chest pain if we find a significant narrowing or blockage in one of those arteries, we will often place what's called a stent. It's a metal tube that helps scaffold or open up the artery and improve the blood flow to the muscle beyond the narrowing. Unfortunately what we find is many patients may have multiple narrowings in their arteries and its sometimes difficult to know which one or ones are causing a problem and in that case the angiogram, although currently the gold standard method for looking at blockages or narrowings is not always perfect and we can have moderate narrowings that you are not always sure whether or not they need a stent and in that case, there is a technique that we used in the study called Fractional Flow Reserve and it's a way of

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measuring the pressure of the blood flow beyond the narrowing and comparing it to the pressure in front of the narrowing and that additional information can help you determine whether or not a narrowing is causing a problem and so in this study, we compared the current strategy for deciding whether or not to place this stent which is just looking at the pictures on the angiogram to this newer strategy where you not only do an angiogram, but you also do these pressure measurements or measure the fractional flow reserve and we found that by doing that additional method, patients did significantly better. Fewer patients died, fewer patients had heart attacks and fewer patients needed repeat stenting or bypass surgery at 1-year followup.

BRUCE JAPSEN:

I know one of the issues now that a lot of people have written about you know some of the issues with the drug-coated stents, but generally some people have had stents placed in them more than once, did the study look at people who had just had 1 round of stenting or were they also others.

DR. WILLIAM FEARON:

We tried to keep this study as clinically relevant as possible, so we kept the inclusion criteria very broad and yes we did include patients who had had previous stenting procedures. The only group of patients that weren't included in the study that are of note are patients who had just suffered a what we call an ST segment elevation heart attack or a big heart attack where one of their arteries has completely blocked and in that case the general treatment is just to open up that blocked artery and not worry about any other narrowings. So those were not included and patients who had narrowing of the main trunk of their left coronary artery who traditionally undergo bypass surgery also weren't included, but otherwise it was a very broad population of patients who had symptoms of chest pain and were found to have multiple areas of narrowing on their coronary angiogram.

BRUCE JAPSEN:

Well if you are just joining us or even if you are new to our channel, you are listening to special Focus on Heart Health on ReachMD Radio on XM160, The Channel For Medical Professionals. I am Bruce Japsen, the healthcare reporter with The Chicago Tribune and joining me today is Dr. William Fearon. He is with Stanford University Medical Center and we are talking about a January published in the New England Journal of Medicine issue of the FAME study.

The whole idea of fractional flow reserve which if am reading you correctly this could reduce not only re-stenting procedures, but possibly the need for a lot of diagnostic tests, could it not.

DR. WILLIAM FEARON:

Well its interesting that that is a possible result of the study, more and more what we are finding our patients come to the catheterization laboratory without having had a prior stress test or noninvasive evaluation and in that setting if you do find multiple narrowings on their angiogram, some physicians will place a single stent and then refer the patient for a noninvasive stress test to look to see if the other narrowings are also causing a problem and then if so bring the patient back to the catheterization laboratory, but you are exactly right by measuring the fractional flow reserve in the other narrowings at the time of the initial procedure one can immediately determine whether or not additional stents are necessary.

BRUCE JAPSEN:

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Now I know this is a study and often times our friends in the health insurance industry want to see results and so forth. Could you envision a day where a patient could just go and get an angiogram and see all of this and perhaps get better diagnosis and treatment because that seems to be what its all about.

DR. WILLIAM FEARON:

Well I think there still is an important need to do a thorough noninvasive evaluation. We don't want to instrument patients which is necessary when you perform a coronary angiogram unless it is absolutely necessary because there is always a small risk of a complication, so I still think the, you know, clinical evaluation that's done before the catheterization laboratory will be critical, but the main message we were hoping to relay by doing the study is that when deciding to perform stenting procedure by using fractional flow reserve measurements one can more judiciously place the stents, it turned out that fewer stents were placed in the patients that were randomized to the so-called FFR guided strategy and one can improve the patients outcomes as I mentioned and importantly one can decrease healthcare expenditure. There is significantly lower costs associated with the FFR guided strategy.

BRUCE JAPSEN:

Well that's a great point that you bring up and unfortunately that is a huge issue with the rising number of uninsured and company is losing benefits. Could you tell us a little bit about the cost aspect, how does this save money and why is this a good thing?

DR. WILLIAM FEARON:

Using the pressure wire does add a little bit of cost initially, the wire itself, you know, roughly costs $600 or $700 and there is some expenditure for a medication that is necessary, another $50 or $100 cost, but by measuring FFR, we found that fewer stents were necessary and each stent costs roughly $2000 if you are using the most up-to-date drug-coated stents and in this study there were a third fewer stents placed, so instead of 3 stents being placed, 2 were placed and that led to significant cost savings.

BRUCE JAPSEN:

And how do you see this implemented over time, I mean is this the kind of thing that health insurers and hospitals will start to adopt?

DR. WILLIAM FEARON:

Yes, I would imagine that we need to be sure that we are doing the right thing when we take care of our patients obviously and in this case making sure we are placing our stents in the correct vessels and using the correct number of stents and I think that its possible that hospitals and other types of institutions will ask their physicians to document the necessity for stents by showing that the patient is actually having inadequate blood flow in that vessel whether its by a noninvasive stress test or by using the pressure wire.

BRUCE JAPSEN:

Well you bring up a really interesting point because in the wake of the issues about, you know, potentially the clotting issues that we saw from drug-coated stents and all the controversy that surrounded that and the market is really looking at the appropriate use of stents, this is probably a really good time for this study because the whole, you know, people in your field and hospitals are looking at

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this right and the appropriate use of stents, so this seems to be a good time to put this study out?

DR. WILLIAM FEARON:

I think you are exactly right, I think its very timely and the other are that we haven't really touched on that I think is interesting is this issue about comparing the best treatment strategy for people with what we call multivessel disease or multiple coronary narrowings, bypass surgery versus stenting and its interesting that if we were to apply this technique in the studies comparing bypass to stenting, we might envision even better outcomes in the patients randomized to stenting compared to what we have seen in the past.

BRUCE JAPSEN:

Well if you could elaborate on that a little bit, go right ahead because I think that that is something that hospitals and doctors are looking at all the time and that is you know comparing the best treatment and whether a stent is needed or bypass, I mean this kind of throws a new wrinkle in to that whole school of thought.

DR. WILLIAM FEARON:

Right, there was a recent study called SYNTAX which was a big multicenter study comparing bypass surgery to stenting in people with multivessel disease and using drug-coated stents and it showed that the death and heart attack rate were roughly similar between the 2 groups, but that the patients who underwent stenting had to come back for more repeat procedures. In that study, the stenting arm did not use fractional flow reserve and based on the results from the FAME study, we had similar rates of adverse events in our so-called angiographic guided arm which was similar to the SYNTAX stenting arm, yet our FFR guided arm had significantly improved outcomes and you could extrapolate these data and suggest if FFR guidance had been applied in SYNTAX and other studies comparing stenting to bypass, you might see even better outcomes in the stenting arm on the order or equivalent to the bypass arm.

BRUCE JAPSEN:

Do you see any further study needed, I know this was a rather large study looking at you know over a 1000 patients for a year which is something, that's also something that the FDA is always looking at with longer studies these days, is there going to be more study done here and how do you see this implemented?

DR. WILLIAM FEARON:

Well I think this study like we talked about was multicenter, it was internation, it was randomized and perspective and included more than 1000 patients. So I think the results are fairly reliable in this patient population. I do think that there is need to do further study in other groups and one would be this group that are being sent to bypass and perhaps comparing an FFR guided stenting strategy to bypass that would be one area, the other interesting area is the issue with medical therapy for patients with significant coronary disease, now the COURAGE study got a lot of press a few years ago and that compared medical therapy to stenting in people with significant coronary disease. Again in that study, the stenting was not performed using fractional flow reserve measurement and in that study there was no significant difference in events between the stenting and medical therapy and one could imagine if the fractional flow reserve guidance had been applied, that the stenting arm may have had even better outcomes than medical therapy, so it think that would be another group of patients that could be studied in the future.

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BRUCE JAPSEN:

And the other thing is that the whole industry, do you see physicians being receptible to this, I mean are your colleagues out in the field sort of you know worried about where when they place a stent and where in some open surgery, is that a big thing in your field right now.

DR. WILLIAM FEARON:

Yes I think it is and I think people are receptive in general. They are always competing forces and I think one of the messages that we don't want people to take away from this study is that by measuring FFR you do fewer procedures and less stents are placed. I think the messages that more judicious stent placement occurs in perhaps the same number of procedures or even more. Again if you convert some people who would normally be sent to bypass to stenting physicians may end up doing more of these procedures, but hopefully just in a safer and more effective manner.

BRUCE JAPSEN:

Well with that I would like to thank Dr. William Fearon who has been our guest who has joined us from his offices at Standord University Medical Center in California and we have been discussing the FAME study which was published in January in the New England Journal of Medicine is in regard to routine measurement of fractional flow reserve reducing the risk of death or heart attack by 35% after stent placement in patients with multivessel disease. I am Bruce Japsen of The Chicago Tribune and I have been your host and you have been listening to Focus on Heart Health on ReachMD Radio on XM160, The Channel For Medical Professionals, ReachMD, we are online, on-demand and on-air. Please visit us at ReachMD.com and I would like to thank you today for listening.

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