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Prognostic Importance of Defibrillator Shock

PROGNOSIS OF A DEFIBRILLATOR SHOCK IN A PATIENT WHO HAS HEART FAILURE.

You are listening to ReachMD XM 157, the channel for medical professionals. Welcome to the clinician's roundtable. I am your host Dr. Matthew Sorrentino from the University of Chicago Medical Center and with me today is Dr. Jeanne Poole. Dr. Poole is the professor of medicine and the director of the Arrhythmia Service in the Division of Cardiology, Department of Medicine at the University of Washington, Seattle, Washington. Today, we will discuss a recent paper called prognostic importance of defibrillator shocks in patients with heart failure. This is a report from the sudden cardiac death and heart failure trial reported recently in the September 4, 2008, issue of the New England Journal of Medicine.

Dr. SORRENTINO:

Dr. Poole, welcome to the show.

Dr. POOLE:

Thank you it is my pleasure.

Dr. SORRENTINO:

I would like to start first by going over the SCD-HeFT trial (the sudden cardiac death and heart failure trial). What type of patients were studied in that trial?

Dr. POOLE:

Those were patients who were identified based upon New York Heart Association Class for moderate symptoms of heart failure, so they needed to be New York Heart Association Class II or III and also a left ventricular ejection fraction of 35% or less and no prior history of life-threatening ventricular arrhythmias.

Dr. SORRENTINO:

So these were symptomatic patients in a large part, but not ICU-type patients.

Dr. POOLE:

Correct, so they were not the sickest, which would be considered a class IV patient neither were they the most healthy as you will heart failure patient the class I patient.

Dr. SORRENTINO:

And what type of procedures were done in the trial? How were patient's randomized to different therapies?

Dr. POOLE:

They were randomized in equal proportions to either receive an implantable cardiac defibrillator or to receive amiodarone compared to placebo drugs, so the amiodarone was double blinded with placebo, so there were three arms to the trial. One-third got amiodarone blinded, one-third got a placebo pill, and the other third received an implanted defibrillator.

Dr. SORRENTINO:

Now, you mentioned that these were symptomatic heart failure patients. Did it matter what the underlying etiology of the heart failure was, ischemic versus dilated cardiomyopathy?

Dr. POOLE:

No, patients could have either etiology of heart failure to be included in this trial.

Dr. SORRENTINO:

And how many patients were ischemic versus not ischemic, do you recall?

Dr. POOLE:

Yes, it was about 50% split for ischemic and nonischemic out of the total of 2521 patients.

Dr. SORRENTINO:

I know that this was one of the pivotal ICD trials. What was the overall result of the trial, which group did better?

Dr. POOLE:

The group did best who has received the implantable defibrillator. They had a marked and significant reduction in all cause mortality. On the other hand, the amiodarone arrhythmic drug did not benefit patients at all. Their mortality was the same as those who were given the placebo drugs.

Dr. SORRENTINO:

So your paper now is looking at this group a little bit differently. What was the main issue that you want to look at in your subpopulation of this trial?

Dr. POOLE:

We were interested in looking at just the patients who received the implantable defibrillator and we were asking the question now that we had the implanted this device into people who have never had ventricular tachycardia or ventricular fibrillation, what does the group of patients look like who then go on to have one of those rhythms treated by the device. Are they a higher risk group of patients compared to those who never had a rhythm abnormality over the course of the followup in this trial, which was very long. It was about 4-1/2 years, the longest clinical ICD trial that has been completed to date. So, really our question is now that patients have an abnormal rhythm, are they are a higher risk subpopulation?

Dr. SORRENTINO:

No, in the trial some patients had what were called an appropriate shocks and others had what was called an inappropriate shock. What do you mean by that difference?

Dr. POOLE:

Well, we want defibrillators to only treat life-threatening arrhythmias, so ventricular arrhythmias. However, some times the patients can have arrhythmias that are coming from the atrium such as atrial fibrillation a common rhythm problem in heart failure patients and these rhythms can also go fast enough that it triggers therapy from the device. The device is functioning normally, but treats this rhythm abnormality that we would prefer to treat in another way and not with the shock, that is probably the most common cause for what we term an inappropriate shock. There are, however, some other instances where the device again can be functioning as it is asked to do so, but it is picking up other signals. So, for instance, if a patient gets too close to some sort of external electrical interference, those signals may be picked up by the device and interpret it as an arrhythmia and then the device will deliver a shock to the patient.

Dr. SORRENTINO:

So in another words, if a patient has atrial fibrillation that causes the heart rate to go very fast, it goes faster than the limit that the ICD is meant to detect and that is what delivers the shock?

Dr. POOLE:

That is correct.

Dr. SORRENTINO:

So how many of the patients in your population received an appropriate shock, how many an inappropriate shock?

Dr. POOLE:

Hundred and eight two of the patients that had the device implanted, which was a total of 811 had an appropriate shock and a total of 141 patients received an inappropriate shock.

Dr. SORRENTINO:

Does that seem like a high number of inappropriate shocks?

Dr. POOLE:

Well, it is too high for all of us who would wish that it was not treating these other rhythms. However, if you compare to other trials, it is very similar. So, in all clinical trials that had been done, the rate of inappropriate shocks vary somewhere between about 14% and 18% depending upon the length of followup in the trials, so certainly longer the followup the more of these events you are going to identify, but I think all of us that are in this business would agree that an inappropriate shock rate that is in that range is certainly much higher than what we would like to see.

Dr. SORRENTINO:

Now in looking at the patients who received an appropriate shock was there some way to determine who was more likely to get an appropriate shock?

Dr. POOLE:

That was not part of this study; however, we have looked at those kinds of characteristics in patients. We have also seen data that came out of other trials such as the MADIT II trial that have looked at predictors of shock and certainly patients who have atrial fibrillation heading into this trials are a group of patients that are more likely to have an inappropriate shock and it turns out that this is often a predictor for appropriate shocks. Also, we might wonder why that might be, but we know that atrial fibrillation is in itself a risk factor of poor outcome in heart failure patient. Also, patients who are not treated with beta-blocker therapy are a group of patient in whom we have identified are more likely to have an appropriate shock as well as an inappropriate shock.

Dr. SORRENTINO:

So, patients who are receiving shocks I guess in general can be considered sicker patients would you say?

Dr. POOLE:

They can be and I think that has been a consistent finding also amongst the number of these trials and again that was not part of this specific study, but patients who have lower ejection fractions and worse heart failure such as a higher class New York Heart Association class III versus class II in some trials are the group that have a higher shock rate.

Dr. SORRENTINO:

So, let us talk about the results of your trial, what is the prognosis of patients after receiving a shock?

Dr. POOLE:

Well, the groups are at a significantly higher risk of future death compared to patients who did not receive any shock at all and that was to for both patients who had an appropriate shock as well as those patients who had an inappropriate shock.

Dr. SORRENTINO:

How much higher is their risk of death compared to those who did not get a shock?

Dr. POOLE:

For patients who had any appropriate shocks compared to those who did not over the course of the trial the risk was 5 times greater. For patients with inappropriate shocks, it was about 2 times greater than those who had had no inappropriate shock over the course of the followup of the trial, so that is a significant increased risk.

Dr. SORRENTINO:

So, you mention there is as much as 5 times increased risk of future death if you have received a shock. Is this again just a way of identifying a sicker group of patients or could the shock have led to worsening heart failure and leading to the outcome down the road.

Dr. POOLE:

The primary reason for the increased risk is likely to be the arrhythmias. We know that patients with heart failure who develop ventricular tachycardia or ventricular fibrillation are a higher risk group, that has been known for a long time. The study that we did gave us the ability to really assess how much greater that risk is, so if we try to say do the shocks for patients, I think the answer would be overwhelming a small percentage of patient if that all are actually harmed by a shock because if patients were harmed, then we would not have multiple clinical trials that have now proven and substantiated that implantable defibrillator stabilize because the primary modality for these devices to save patients is shock therapy. Having said that, is there some instance in which a shock itself might be

danger? Perhaps in a very rare instance if somebody has end-stage heart failure, one could imagine the shock might be harmful to that patient, but overall the most reasonable approach to thinking about this study and these results is that the rhythms are the marker of increased risk and the ICD shock is simply the therapy being delivered to that patient.

Dr. SORRENTINO:

I guess, I am still concerned about the patients who received only an inappropriate shock. In those patients, they did not have ventricular tachycardia or ventricular fibrillation and yet they have a 2-fold increased risk of death further on in the trial. Is that surprising or again is it the atrial fibrillation that you think is the signal here?

Dr. POOLE:

Well, the numbers are small to really completely sort that out, but at least half of the patients who had an inappropriate therapy, a shock therapy, had it because of atrial fibrillation. So, I think it is a reasonable assumption that if the atrial fibrillation that is the increased marker of subsequent increased mortality. Again, it is hard to know whether or not in an end-stage situation, shocks themselves might be harmful to an individual. Probably, it is the atrial fibrillation. Often times, the atrial fibrillation was also occurring around the same timeframe as a ventricular arrhythmia. Some of those patients were in the group in our study that actually did not live longer than 24 hours after their therapy was delivered and if you then look at the risk for patients who had inappropriate shocks that if survive longer than 24 hours; the increased risk is much smaller. So, it makes you wonder about that particular group of patients. Where they particularly high-risk group at the end stage of their heart disease or where they perhaps even dying from other terminal diseases? and we simply do not have enough clinical information on that group of patients to really sort that out at this time.

Well, I want to thank Dr. Jeanne Poole who is the professor of Medicine in the Division of Cardiology at the University of Washington, Seattle. We have been discussing a recent paper about the prognosis of a defibrillator shock in a patient who has heart failure. I am Dr. Matthew Sorrentino. You have been listening to the Clinician's Round Table on ReachMD XM-157, the channel for medical professionals. Please visit our web site at www.reachmd.com which features our entire library through on-demand podcasts or call us toll-free with your comments and suggestions at 888MD XM157, and thank you for listening.

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