Transcript: DANCAVAS Results – Axel Diederichsen, PhD

The background for DANCAVAS trial is that cardiac diseases remain to be the most common cause of death in Western Europe and also in America. And also among men, it's the most common cause of premature death. So it remains to be a huge problem.

There have been other trials to how to decrease the prevalence and incidence of cardiac diseases. But they disagree on whether it's a good idea to do screening or not. With the DANCAVAS trial, we perform an imaging-based screening trial. So we use a CT scan just to find premature cardiac diseases. And then if we find disease, then we will offer treatment.

So let us speak about the background and the method: it is coming based. We identified for 6,000 men, aged from 65 to 74 years old in certain areas of Denmark. It was all men living in these areas. We identified them and then we randomized: One-third were randomized to a screening explanation, and one-third was not invited for the screening.

So, we invited approximately 16,000 men to the screening and approximately 30,000 men to no screening. Among these 16,000 randomized for the screening, 33% attended to the screening. So approximately 10,500 attended the screening.

And those who attended the screening, we told them if they were prematurely diseased and we offered treatment, and the premature disease was defined as coronary artery calcium score, scored for age and sex. And also if there were any reasons and other things and the treatment was aspirin, it was atorvastatin and guidance for healthy lifestyle and patients with severe aortic dilatation, they were referred for surgery or for a check-up depending on the size of the generation.

And now after five and a half years, we have collected outcome data from the Danish registries, so we compare all men in the screening group, approximately 16,000 were compared with the 30,000 in non-screening group and we investigated if there were any difference in the outcomes.

Our primary outcome was all-cause mortality, that's a tough one. And the second outcomes: stroke, myocardial infection, vascular surgery, aortic dissection, and aortic rupture. Regarding our priming points, it was a non-significantly decrease of 5%. So, the hazard ratio was 0.95. And the p-value was 0.06. So almost there.

Then we had pre-defines, subgroup analyses with age, previously cardiac diseases, hypertension, diabetes and so forth. And there was an interesting difference in age while all the other subgroups were in neutral.

But the age was really interesting: we found that there was an 11% decrease of risk, decreased mortality risk, 11% decreased mortality risk in the screening group. So the hazard ratio in this group in this case was 0.89 and had a significant p-value. And it found there's no benefit in the elderly group.

So, among men at the age from 65 to 69 years, there was a huge benefit, 11% decreased mortality risk, while there was no difference among men from the age from 60 to 64. We also found there was a decreased risk of stroke in the entire group. Hazard ratio was 0.93. There was a non-significant decrease in myocardial infection, hazard ratio was 0.91.

We defined a post hoc compass endpoint of death, stroke, and myocardial infection. And this was also highly significant, hazard ratio was 0.93. So we were able to decrease risk of all-cause mortality, stroke, and myocardial infection by 7%.

So hazard ratio in our compensating endpoint was 0.93, high significance, and that means that we were able to decrease the risk of mortal all-cause death, stroke, and myocardial infection by 7%.

Regarding our safety endpoints, we saw a non-significant increase in severe bleedings, small numbers though. There was no increase in cancer. We also looked at cost effectiveness and we found that the screening explanation was highly cost effective compared to all company-used cancer screening programs. The cost was from half-priced to one fourth our price to the coming cancer screening programs to the current cancer screening programs.

So in conclusion, we didn't meet our primary end point. In the entire group of men from age from 65 until 74 years of age, there was a non-significant decrease in all-cause mortality, hazard ratio was 0.95, but there was a highly significant decrease in all-cause mortality in the group of men aged from 65 to 69 years old.

These results are certainly very interesting from a social perspective. We might be able, at a relatively small cost, to decrease all-cause mortality in men from age from 65 to 69 years.

So, this may have very important implication in how we prevent cardiac diseases in the future. Whether we should implement this for use in our data-cleaning practice, will have to be discussed in the future.