

## iFR-SWEDEHEART: No Difference in Outcome at 5-yrs of iFR vs FFR

My name is Matthias Götberg. I'm an Interventional Cardiologist at Skåne University Hospital in Lund, in Sweden. And the topic of today's lecture is iFR versus FFR-guided coronary revascularization. And it's a five-year data of iFR-SWEDEHEART.

### Importance of the study

What we know that iFR is equally good as FFR when it comes to accurately detecting ischemia. But previously we didn't have any outcome trials.

In other words, no trials saying whether iFR was equally good as FFR in terms of outcome, both short-term and long-term outcome.

### Study design and patient population

iFR-SWEDEHEART was a 2000 patient register-based randomised clinical trial. Our RCT is a trial based on utilising national quality registers as an electronic case report form. So for us, it's a way of inputting baseline characteristics, data inputs, online randomization and also follow-up. And it's a proven pragmatic and cost-effective trial design that utilises these registers and is facilitated by the fact that we have unique personal identifiers in Scandinavia, allowing us to track all patients with 100% follow-up.

iFR-SWEDEHEART was a non-inferiority trial. In other words, we checked if iFR was non-inferior to FFR regarding composite of all-cause mortality, MI, and unplanned revascularization at one year. And we needed 2000 patients with 85% power to test the hypothesis.

The patients were randomised in a one-to-one fashion between iFR and FFR guided revascularization, depending on the cut-off points for iFR and FFR respectively. And the primary outcome that proves that percentage and published that in the New England Journal of Medicine. And today I'm presenting the final five-year follow-up of the trial.

### Key findings

So, the key findings in terms of long-term outcome, is that looking at the composite endpoints at five years of all-cause deaths, Myocardial infarction, non-planned revascularization, the iFR event rate was 21.5%. And the FFR event rate was 19.9%, with a hazard ratio of 1.09, showing no difference in the composite endpoint compared with FFR at five years.

We also looked at the components of the composite endpoints. In other words, All-cause mortality, Myocardial infarction, and nonplanned revascularization separately, and we couldn't find any difference between the two groups.

We also looked at the composite endpoint, but did a subgroup analysis looking at age, gender, hypertension, and other pre-specified subgroups. And we couldn't see any difference at all between the two groups. So, we can say that in all different subgroups and all the constituents, and then the composite endpoint we couldn't find any difference between iFR and FFR at five years.

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What patients will benefit from an iFR-guided revascularization strategy  
iFR-SWEDEHEART had about two-thirds of patients were stable angina, a little more than one-third of patients were other unstable angina or non-STEMI. So, it's really those two populations that we can say that with certainty, that iFR has no difference, in terms of long-term outcome compared with FFR.

We haven't investigated any other group than that, but it's mainly the STEMI subgroup that could be of interest to investigate further in terms of outcome.

### Take-home messages

So, the take home messages of iFR-SWEDEHEART long-term outcome is that there's no difference between the two groups in terms of long-term outcome, any of subgroups when the constituents of department composite outcome. In other words, iFR is quicker, easier, cheaper, and has no side effects for the patients. And I think this is important because what it really does, it lowers the threshold for performing physiology.

And now that we know that long-term outcome is no different from FFR, that's really the last piece of the puzzle. Then the next steps, is really investigating further whether iFR has any benefit beyond what FFR has proven to have.

And we know for instance, that when you perform an iFR-guided pullback, you actually miss out on one in five patients that actually have ischemia if you do an angio-guided revascularization.

### Next steps

So, the next step really is trying to integrate that, combining iFR pullback with a co-registration using SyncVision and see whether that improves outcome. And DEFINE PCI showed obviously that there was more defined in terms of ischemia, but DEFINE GPS is really looking at outcome. And this is very important and we've actually started enrolling in the trial and we probably see data in the coming few years.