

Title: TCT 23: WATCH-TAVR: WATCHMAN for Patients with AF Undergoing TAVR
Participants: Dr Samir Kapadia
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Dr Samir Kapadia

"I'm Samir Kapadia. I'm a cardiologist. I am chairman of cardiology at Cleveland Clinic in Cleveland, Ohio.

Reasoning Behind this Trial

So, in 2016, the TAVR valve was approved for intermediate-risk patients and the Watchman device was approved for patients who have atrial fibrillation to prevent bleeding or complications related to stroke. So, the idea was that 40% of the patients who are undergoing TAVR have atrial fibrillation and they are at high-risk completely and they are at high risk of stroke. So, the idea was that many of these patients would benefit from Watchman device and then all these old people must come back again to the hospital and have the Watchman device placed. So, if there is a way to do the TAVR and Watchman procedures together, then we prevent them from coming back to the hospital and while we are doing one procedure, we can do the other procedure and if we can do it safely or not. So, the purpose of the trial was to say that if we can do TAVR and Watchman procedures together, would we pay additional complications risk with this kind of combined approach and if it will provide the benefits that normally, Watchman device would provide, which is an alternative to anticoagulation. So, this was the idea of the trial.

WATCHMAN Device

So, Watchman is a device that is placed in the left atrial appendage. The idea is that most of the strokes and most of the clots that happen in patients with atrial fibrillation happen because of the clot inside of the left atrial appendage. Watchman device is an umbrella-shaped device which has clot on the surface of the device. So, it prevents the clots from coming out of the appendage into the circulation and it is anchored by small

hooks which are on the Watchman device, and we size it and place it inside of the left atrial appendage.

Patient Population and Study Design

So, what we wanted to try was to have any patient who is undergoing commercial tower so anybody who is going TAVR procedure, these are the patients that are included in the trial, they must have atrial fibrillation. So, if there is paroxysmal continuous permanent atrial fibrillation, it doesn't matter. So, any atrial fibrillation history and they must be able to take anticoagulation for six weeks because once you put the Watchman device, you need to take anticoagulation for six weeks. So, this is a patient population that we targeted this study.

Key Findings

So, the most important finding was that first, when we did the procedure, combined procedure, we had to use more general anaesthesia. So instead of 30%, almost all patients had general anaesthesia. We took about 45 more minutes to do the procedure and there was about 40cc of extra dye used. However, the chance to have any major complications like bleeding, death also the kidney problems were no different compared to single procedures. So, if you need only TAVR versus TAVR plus Watchman the combining procedure did not add an additional risk. The only risk it added was that four patients had some pericardial effusion, meaning that some blood around the heart and that they required just a needle aspiration of this pericardial fluid. And this is from the Watchman device that was done is called Watchman 2.5, the model number of the Watchman. And now we have a newer Watchman that does not cause this complication as frequently because it is safer to use, which is called Watchman Flex. So right now, the device that is available in the market is Watchmen Flex because again, the trial took two years of follow-up. So, the older device is so-called retired.

Take-home Messages

So, the most important takeover message is that if the patients are candidates for Watchman device meaning that if they are looking for alternative to anticoagulation because they are high-risk of leaving or whatever the other reasons are for not taking anticoagulation if you are planning to do a Watchman device, you can safely do it at the time of TAVR procedure. So, this is a very important message because patients at that age, the families don't want to come back to the hospital. I also want to mention that the length of stay in the hospital was no different if you do combined procedure versus single procedure. So again, that tells you that you can do two procedures at one time without adding risk, substantial risk to the patient. The mortality was no different, stroke rate was no different.

Further Study and Next Steps

Two parts to the next step. One is to have a financial reimbursement for a combined procedure. So, we will try that in the United States this is particularly more important, but that is one important thing to provide some cost analysis to say that this is a cost-effective strategy, it makes sense, but still, we will try to address that issue. And the second I think more important part is that TAVR is one of the procedures when we can combine Watchman device but say for example the Mitraclip or atrial fibrillation ablation, there are several other procedures that are done in the left atrium that you can combine this Watchman procedure with. So, it is just the beginning of the combined procedures, and we may be able to see more procedures that are combined in the future.”