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New clinical study compares catheter-assisted therapy with surgical treatment for aortic valve stenosis

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One of the most common acquired heart diseases in the over 75's is aortic valve stenosis. Normally, it requires the replacement of the valve. In principle, there are two ways to do this: the patient's thorax is opened surgically and an artificial valve is implanted; or a new valve is advanced through a femoral artery up to the heart using a catheter. A clinical study of the German Centre for Cardiovascular Research (DZHK) shall investigate for the first time which of the two methods is better for patients with medium to low surgical risk. The study comprises 1,600 patients and costs 4.5 million euros. It is not an industry initiated trial, so the valves of all established manufacturers may be used.

Just a few years ago, very elderly or multimorbid patients had no chance of receiving a new heart valve. The only treatment method - open heart surgery - would have been too risky. Only since the first successful minimally invasive transcatheter aortic valve implantation (TAVI) in 2002 could these patients be treated. However, even TAVI is not without risk: because of the catheter, vessel wall deposits can rupture and lead to a stroke or heart attack. Moreover, the long-term durability of the TAVI valves, which unfold like an umbrella in the calcified aortic valve, is still under intense discussion.

The advantage of TAVI for younger individuals is not documented enough

Therefore, for years, TAVI was reserved for patients with a high surgical risk. For some time now, however, there has been a paradigm change: more and more physicians are also treating younger and healthier patients with TAVI, even though there are no long-term clinical observations in these patients. The situation unsettles physicians, patients and health insurance companies; and this thus gives rise to conflicting treatment and reimbursement procedures.

The DEDICATE study (DZHK6) is now comparing the surgical therapy procedure to the catheter-supported TAVI method in patients with medium to low surgical risk (STS score of 3 to 6) in order to achieve a higher procedural

safety. Only patients who are eligible for both methods may participate in the study. They will be assigned randomly to two groups and their survival rate will be determined over five years. Previous studies have only evaluated considerably shorter periods.

Two treatment methods are being compared

In comparison to other studies, DEDICATE is distinctive in another way: for the first time, not only TAVI valves of one manufacturer will be compared to the surgical procedure, but the physician can choose the valve according to accuracy of fit and size from various models and manufacturers. The same applies to the surgical valves.

"Therefore, we are not comparing one valve model to the surgical method, but one treatment method to another", says the study's principal investigator, Prof. Stefan Blankenberg, cardiologist at the University Medical Center Hamburg-Eppendorf. "Heart surgeons and cardiologists have therefore planned the study together. Together we want to determine the best treatment for our patients", adds Prof. Jochen Cremer of UKSH, Campus Kiel, who represents the surgical branch. All partner hospitals of the DZHK and other leading hospitals in Germany are participating in the study.

Currently, health insurance companies usually only reimburse TAVI, which is almost twice as expensive, for patients with a high surgical risk or if someone is inoperable. Prof. Blankenberg also hopes that the study's outcomes will provide the chance for more objectivity and procedural safety for patients, physicians and health insurance companies.

Source:

https://dzhk.de/en/news/latest-news/article/catheter-or-surgery-clinical-study-on-heart-valve-replacement-begins/
