IMPACT OF CMS COVERAGE DECISION ON ACCESS TO TRANSCATHETER AORTIC VALVE REPLACEMENT

Poster Contributions
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Background: Transcatheter aortic valve replacement (TAVR) has become the standard of care for inoperable patients with aortic stenosis (AS). Prior to release of the Centers for Medicare and Medicaid Services (CMS) national coverage determination (NCD), the TAVR access route was at the discretion of the treating physicians. We sought to investigate the impact of the NCD on the treatment of patients with AS at a high volume tertiary care center.

Methods: A total of 94 inoperable AS patients were evaluated and treated between 12/2011 and 6/2012. Clinical characteristics and hospital outcomes were entered into a database. Outcomes were classified according to the Valve Academic Research Consortium (VARC) criteria. Transaortic, transapical or transseptal antegrade approaches were used in patients who were ineligible for Transfemoral (TF) access. TAVR via TF vs. non-TF access were compared. The CMS NCD was released on May 1, 2012 and on July 1, 2012, the non-TF access program was put on hold due to lack of reimbursement.

Results: Patients in the TF (n=33) and non-TF access (n=61) groups had similar age (85.2±6.3 vs. 84.8±6.6 p=0.74) and STS predicted risk of mortality (9.38 ±5.33 vs. 7.91 ±3.69 p=0.074). TF patients had significantly larger iliofemoral arteries (7.72±1.49 vs. 6.21±1.78, p<0.001). Men had larger arteries than women (7.39 ± 1.81 vs. 6.1 ±1.61 P<0.001). Non-TF access was performed in 61 patients, 10 using the transapical approach, 42 using the direct transaortic approach and 9 using an antegrade transeptal approach. A greater proportion of women underwent valve implantation via non-TF access (73% vs. 23%, p=0.03). Non-TF cases had fewer vascular complications (5% vs. 21% p=0.02). After the NCD was issued, the institution was informed that 18 patients who qualified for non-TF TAVR would not be reimbursed by CMS. Four of these patients later died.

Conclusions: After the NCD, the proportion of inoperable patients with severe AS that can be treated with TAVR was greatly reduced due the lack of reimbursement for TAVR via non-TF access. This effect is particularly pronounced in women. Recent expansion of the approved access route with the TA approach, may increase eligibility for treatment.