Impact of annular and cusps calcification on occurrence of paravalvular leak after transcatheter aortic valve replacement with intra- versus supra-annular devices

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Funding Acknowledgement: Type of funding source: None

Introduction: Severe annular and valve cusps calcification is frequent among patients treated with transcatheter aortic valve replacement (TAVR). Severe annular calcification increases the risk of paravalvular leak (PVL) and was associated with worse outcomes. Whether it is accompanied by an independent effect of calcifications localized on cusps and whether the impact of cusps/annular calcification depends on supra vs intra-annular valve design is unknown.

Purpose: To assess the impact of cusps/annular calcifications on occurrence of moderate PVL after successful TAVR with devices of either intra- or supra-annular design.

Methods: 282 consecutive patients (80.3±7.6 yrs, 63% female) with baseline 384-slice CT scan were successfully treated with TAVR between Jul 2012 and Oct 2017, either with intra-annular or supra-annular devices. Severe annular calcification (clear protrusion) and severe cusps calcification (Rosenhek 4 score) were identified using a Syngo Via.

Results: 138 (48.9%) patients were treated with intra-annular and 144 (51.15) with supra-annular devices. Whereas severe annular calcification was similar (23.9% vs 20.1%), there was more severe cusps calcification among intra-annular valves (52.9% vs 41.7%, p=0.073). Intra-annular devices were used less frequently among bicuspid aortic valves, were also of smaller diameter, less frequently deployed after pre-dilation, and less frequently post-dilated. Post-procedure mean aortic gradient tended to be higher among intra-annular devices. Moderate PVL was less frequent among intra- vs supra-annular valves (14.5% vs 34.0%, $p<0.001$). However, PVL occurrence was higher (30.3%) among those (33/138, 23.9%) treated with an intra-annular valve who had severe annular calcification vs 9.5% in pts treated with an intra-annular TAVR who did not have severe annular calcification (p=0.008) unlike in patients treated with a supra-annular valve who had a high frequency of PVL with or without severe annular calcium (37.9% vs 33.0%). After excluding patients with severe annular calcium (n=62, 22%), moderate PVL was similar between those with vs without severe cusp calcification whether treated with intra- or supra-annular valves (11.8% vs 7.4% and 29.3% vs 35.1%, respectively). Combined VARC-2 safety endpoints plus 2-yr mortality occurrence were lower for intra- vs supra-annular devices (30.4% vs 43.8%, p=0.026).

Conclusions: Moderate PVL after intra-annular TAVR device deployment occurs in 30% of patients with protruding annular calcification. Severe cusps calcification unaccompanied by annular calcium was not associated with PVL occurrence. Higher frequency of moderate PVL (34%) seen after supra-annular valve deployment appears to be related to other parameters rather than presence of severe annular or cusps calcification.