radiation exposure to operator was measured by electronic dosimeter (Thermo Scientific, Siemens, UK)

RESULTS After PSM, baseline and demographic characteristics were similar in the 2 groups. Table shows operator and patient radiation exposure. Radiation exposure to operator was 2-fold higher in radial compared with femoral access. Median fluoroscopy time was not significantly different in patients undergoing radial versus femoral access. Furthermore, mean cumulative DAP and KAP were also similar in radial and femoral PCI.

	Radial	Femoral	P-value
Operator dose (μSV)	97.14	48.93	0.004
Cumulative DAP (mGycm(2)	174,169.46	172,518.27	0.924
Cumulative Air Kerma (mGy)	28,831.97	63,11.27	0.356
Fluoroscopy time (min)	18.57	17.03	0.309

CONCLUSION This PSM analysis from a contemporary cohort of patients undergoing PCI showed that radial access is associated with increased radiation exposure to the operators but with similar radiation exposure to the patient than femoral access. Improvement in radioprotection methods to the operators should be implemented for diminishing radial access associated radiation exposure.

CATEGORIES OTHER: Vascular Access

NEW TAVR TECHNOLOGIES - I

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TCT-318

A long-term pre-clinical animal study of a new self-expandable TAVI device

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BACKGROUND Transcatheter aortic valve implantation (TAVI) has become an effective therapy for severe aortic stenosis in high-risk surgical candidates. The current challenge for TAVI in the treatment of aortic regurgitation is exact positioning and stable fixation of the valve in the aortic annulus. We evaluated a new bovine pericardial self-expandable TAVI device with a novel mechanism of leaflet-fixation (Ken-Valve, Jenscare Ltd, China) by a long-term animal experiment.

METHODS The Ken-valves were implanted transapically in 20 healthy adult goats under fluoroscopic guidance through a 28F sheath via a specially designed delivery catheter. The deployment was performed on the beating heart without cardiopulmonary bypass or rapid ventricular pacing. Serial TTE and aortic root angiography were performed immediately after each operation and also during their recovery stage (6months). Aortic root specimens were collected for pathologic examination and calcification evaluation in leaflets.

RESULTS The Ken-Valves were successfully implanted and positioned accurately. Eighteen animals survived until they were sacrificed. TEE showed that the Ken-valves worked well with no stenosis or regurgitation in all animals, except for paravalvular leakage in 5 (4 mild and 1 mild-to-moderate). The mean transvalvular gradient at 3 months and 6 months were 3.2 ± 0.6mmHg and 2.4 ± 0.8mmHg, respectively, with no significant difference from that immediately after operation (2.3±0.4mmHg). Autopsy showed no stent fracture, stent displacement or coronary obstruction at 6 months. Histological examination showed well preserved leaflet collagen fiber structures. The calcium content of the pericardial leaflets was 37.7 ± 12.8ug / g at 6 months after operation, with no significant difference from that before implantation (30.8 ± 7.6ug / g).

CONCLUSION The Ken-valve provides an effective concept of fixation with a special clamping and anchoring mechanism that allows exact positioning and anchoring the valve to the native leaflets. The design of leakproof ring can effectively avoid the occurrence of paravalvular leakage. This bioprosthetic valve has a good safety and durability, and further investigations by clinical trial are necessary.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-319

Comparative effectiveness and safety of five leading new-generation TAVI devices: early results from the RISPEVA Study

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BACKGROUND Transcatheter aortic valve implantation (TAVI) for aortic stenosis is becoming an appealing alternative to surgical aortic valve replacement in high-risk patients and to medical therapy for inoperable ones. Several new-generation TAVI devices have been recently introduced, but comparative analyses are lacking. Equipoise cannot yet be assumed among them. We aimed to compare such five leading new-generation TAVI devices exploiting data collected in the prospective multicenter RISPEVA Study.

METHODS We queried the RISPEVA Study dataset to retrieve details on patients undergoing TAVI with Acurate neo devices, Evolut R, Lotus, Portico, Sapien3, and). Baseline, procedural features and early (within 1 month) clinical and echocardiographic results were compared with unadjusted bivariate analysis and adjusted inverse-probability-of-treatment weighting analysis obtained from propensity scores.

RESULTS A total of 1409 patients were included: 88 (6.2%) with Acurate neo, 823 (58.4%) treated with Evolut R, 91 (6.5%) with Lotus, 82 (5.8%) with Portico, and 325 (23.1%) with Sapien3. Several baseline and procedural differences were evident at unadjusted analysis, including valve disease type, surgical risk, ejection fraction, aortic gradient, aortic regurgitation, anesthesia, hemostasis, use of anti-embolic devices, predilation, post-dilation, contrast, and procedural time (all $p<0.05$). Nonetheless, device success and procedural success rates were all above 96% ($p>0.05$). In-hospital event rates were similar, with death rates all below 4% ($p=0.168$), despite a significant difference in the rate of permanent pacemaker implantation (with higher rates for Evolut R and Lotus, $p<0.001$). One-month event rates were also similar, with death rates all below 6% ($p=0.078$), despite significant differences for major vascular complications (with higher rates for Lotus and Sapien3, $p=0.024$) and permanent pacemaker implantation (with higher rates for Evolut R and Lotus, $p<0.001$). One-month echocardiographic follow-up showed significant differences in aortic regurgitation 2+ (with higher rates in Portico and Acurate neo, $p<0.001$), as well as in aortic gradients (with higher values in Lotus and Sapien3, $p<0.001$) and aortic valve area (with lower values in Portico and Acurate neo, $p=0.019$). Adjusted analyses for one-month outcomes showed similar results for key clinical outcomes, while highlighting that Acurate neo was associated with significantly lower rates of pacemaker pacemaker implantation ($p<0.05$), and that Lotus was associated with the lowest rate for aortic regurgitation 2+($p<0.05$).

CONCLUSION New-generation TAVI devices are not borne equal, and one-month data suggest that Acurate neo may minimize rates of permament pacemaker implantation whereas Lotus reduces the risk of aortic regurgitation. Longer follow-up of the RISPEVA study and others is required to confirm these findings.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-320

Transcatheter Aortic Valve Replacement with the ACURATE NEO – one year results

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