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Acute Hemodynamic Changes in the Immediate Phase Post Transcatheter Aortic Valve Replacement

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Background: Aortic stenosis imposes a chronic pressure overload on the left ventricle. TAVR leads to an abrupt removal of the mechanical impediment to left ventricular outflow. We examined the immediate hemodynamic changes that occur in patients with severe aortic stenosis following successful T.A.V.R
Methods: Consecutive patients undergoing T.A.V.R. were eligible for inclusion. Exclusion criteria were contraindications to pulmonary artery catheterization and periprocedural complications requiring conversion to surgery. Hemodynamic measurements were performed in all patients at baseline, and at 6 hours and 24 hours following the procedure. Pertinent clinical and echocardiographic data were assessed as well.
Results: Fifty-six patients (54.4% male) with severe aortic stenosis (mean AVA 0.69cm^2, mean gradient 48.3±12mmHg) were included in the study and underwent TAVR via transfemoral (87.7%) or alternative route (12.3%), with either of the two commercially available valves Edwards Sapien XT (66.7%) or Medtronic CoreValve (33.3%), and either under general anesthesia (73.7%) or with conscious sedation (22.3%).Table 1 summarizes the hemodynamic changes between baseline and 24 hours post procedure.

VARIABLE	N	BASELINE	24HRS	p-value
Arterial Pressure-mean (mmHg)	50	84.6±16.5	82.3±10.8	0.298
Diastolic Arterial Pressure(mmHg)	46	59.9±13.8	55.1±10.3	0.018
Heart Rate (/min)	49	63.8±11.9	78.6±12.2	0.001
CVP/RA-mean(mmHg)	51	13.0±5.2	8.8±3.7	0.001
Pulmonic Pressure-mean (mmHg)	49	30.7±8.6	27.2±7.7	0.004
Wedge Pressure-mean (mmHg)	49	22.9±6.7	19.1±6.6	0.001
Cardiac Output (l/min)	48	3.8±1.2	5.6±1.5	0.001
Cardiac Index (l/min/m2)	46	2.0±0.5	3.0±0.7	0.001
Stroke Volume (ml)	32	58.5±15.5	71.5±18.2	0.001
Stroke Volume Index (ml/m2)	32	32.1±7.7	39.1±8.8	0.001
SVR (dynes*sec/cm5)	47	1556 ±491	1062±319	0.001
SVRI (dynes*sec/cm5/m2)	46	2833±811	1957±513	0.001
PVR (dynes*sec/cm5)	44	168±121	116±74	0.001
PVRI (dynes*sec/cm5/m2)	43	302±210	207±128	0.001

Conclusions: The hemodynamic profile of patients in the immediate post TAVR period is noted for substantial rise in stroke volume and cardiac output; significant drop in pulmonary and peripheral vascular resistances; and a significant decline in the ventricular filling pressures. Patients commonly require support with intravenous fluids and occasionally with vasoconstricting agents during the first 24 hours.

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Transcatheter Aortic Valve Implantation With CoreValve For The Treatment Of Severe Aortic Stenosis: Results From A UK Perspective Cost-effectiveness Analysis Using 12 Month Data From The ADVANCE Study

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Background: The cost-effectiveness of transfemoral/transapical TAVI vs. medical management (MM) has been established in a number of studies using data from the PARTNER B trial. To date no cost-effectiveness analysis has employed prospective data collected solely for the CoreValve device. This study uses one year patient level data (PLD) from the ADVANCE registry to assess the long term cost- effectiveness of CoreValve for the treatment of aortic stenosis (AS).
Methods: ADVANCE enrolled 1015 patients; 996 underwent attempted CoreValve implantation. A Markov model was developed in Microsoft Excel for CoreValve vs. MM. Key information for the MM arm (mortality, adverse events, health related quality of life (HRQoL) were sourced from PARTNER B (3 year follow-up). Where possible, all information for the CoreValve arm was taken from the ADVANCE study, and the PLD was also used to stratify mortality by STS risk score. CoreValve related stroke events were included in the model design. Unit costs were taken from national databases. HRQoL in both arms was incorporated via utility decrements applied to age-specific EQ-5D population norms to generate quality adjusted life years (QALYs). Results are reported as means and 95% confidence intervals. Extensive deterministic and probabilistic sensitivity analyses were conducted. Costs and benefits were discounted at 3.5% per annum.
Results: In the ADVANCE dataset there were 42 stroke events through 1 year; 12 occurred after 30 days post-procedure. Over a 10 year time period the model generated survival estimates of 5.76 and 1.63 years for CoreValve and MM, respectively. The incremental cost-effectiveness ratio (ICER) is £14,255 (£11,844 to £17,190) per QALY gained. CoreValve is more costly than MM but nonetheless a cost-effective treatment. The ICER for CoreValve patients in the highest STS category is £16,891 (£13,565 to £21,855) per QALY gained. The model was insensitive to changes in the approach to model utility benefits, baseline survival curves and hospitalization rates.
Conclusions: From a UK perspective, CoreValve is a cost-effective treatment for inoperable patients with severe AS patients compared to medical management.

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Transcatheter Aortic Valve Implantation without prior balloon dilatation – a non-randomized single centre experience

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Background: Standard procedure for transcatheter aortic valve implantation (TAVI) using the Sapien™ stent valve (Edwards Lifesciences Corporation, Irvine, California) incorporates balloon dilatation (+BAV) prior to valve deployment. Earlier studies have shown limited effect of BAV. Echocardiography may underestimate the actual area of the valve compared to the surgical impression. By combining this knowledge with thoroughly imaging the valve and coronary arteries with TOE and CT prior to intervention we decided to implant the Sapien™ stent valve without BAV (-BAV).
Methods: This non-randomized study includes 160 consecutive patients from September 2008 to April 2013. +BAV was performed in the first 96 patients and –BAV in the following 64 patients. Parameters regarding procedural success, valve function and 30 day mortality are compared.
Results: Mean age in both groups were 80 years, 57% were women in +BAV vs 47% in -BAV. Euroscore 1 and STS in + BAV were 17.5 and 5.6, in -BAV 18.7 and 7.0. Aortic stenoses were degenerative in 91% in both groups, the rest valve-in-valve or post-radiation. For further results see table. We had good valve positioning in all patients, no coronary artery occlusion, no problems crossing the valve in –BAV patients and no variation between transapical or transfemoral approach.
Conclusions: TAVI with the Sapien™ valve without predilatation is feasible, with good valve positioning and function, and no increased associated complications.

PATIENTS	+BAV (96)	-BAV (64)
Previous BAV (n)	3	3
Vmax/mean grad/area	4.6/55/ 0.6	4.4/49/0.6
AR≥ grade 1 (%)	61	52
TAVI		
TF/TA/TaO (n)	63/32/1	48/16/0
Valve size (23/26/29) (n)	39/52/5	21/36/7
Postdilatation (n)	10	7
Complications (n)	10 - 5 pericard effus;4 ECC ;1 stuck cusp	7 - 2 TIA;2 peric eff;2 balloon rupt;1 root rupture
1 MONTH f/u		
Vmax/mean grad	2.2/11	2.1/10
PVL≥ grade 1 (n)	25	16
Stroke (n)	6	3
New PPM (n)	2	0
Death (n)	8	4