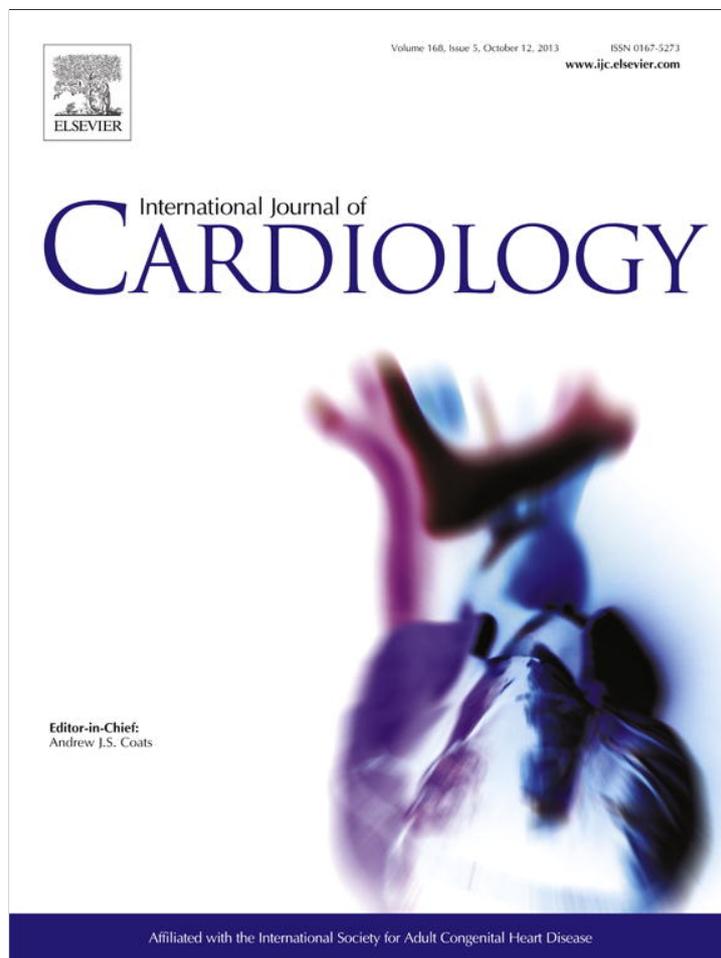


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In-hospital results of transcatheter aortic valve implantation (TAVI) in a district hospital – An approach to treat TAVI patients in rural areas[☆]

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ARTICLE INFO

Article history:

Received 25 June 2013

Accepted 3 July 2013

Available online 7 August 2013

Keywords:

Valves

Aging

Transcatheter aortic valve implantation

Aortic valve stenosis

District hospital

Transcatheter aortic valve implantation (TAVI) is the current therapy of choice for elderly patients with severe aortic valve stenosis [1–7]. European valvular heart disease guidelines restrict TAVI to centers with cardiac surgery on site (highly ranked, low evidence: class I, level C) [8]. The definition of “cardiac surgery on site” is unclear. Does it mean “established and institutionalized in-hospital cardiac surgery”, or does it mean the procedure should be performed with “a heart team including cardiologists and cardiac surgeons from external established institutions”? This definition is critical because health insurance companies refer to the postulate of “cardiac surgery on site” to refuse TAVI-reimbursement in smaller hospitals. Thus, in rural areas TAVI cannot be provided. Elderly patients, and specifically TAVI-candidates, are often immobile and do reject being sent to the big city centers. Furthermore, social integration of these patients into their homely environment may contribute to post-procedural success. Lastly, limited capacity in the city heart centers in parallel to an increasing number of elderly patients in the countryside may delay treatment of this life-threatening disease.

Immenstadt is a small town settled in the Allgäu Alps, one of the major German country side tourist attractions. Its 155-bed district hospital belongs to Clinic-Association Kempten-Oberallgäu. The next institutionalized cardiac surgery center is >100 km away. Kempten-Oberallgäu, although being a major tourist area, belongs to the remotest German areas concerning cardiac surgery healthcare.

66 consecutive TAVI-patients admitted to Immenstadt hospital (November 2010 to November 2012) were included into this retrospective analysis (Table 1). A CoreValve device (Medtronic Inc., Minneapolis, NM, USA) measuring 26 mm, 29 mm and 31 mm in diameter was used exclusively. Written informed consent was obtained from every patient. Data were compared to the 2011–12 pilot European TAVI Sentinel Registry [9]. Data analysis was approved by the Ethical Committee of Ulm University (06.03.2013). Continuous variables (Microsoft Excel 2000) are reported as mean ± SD. Comparative

statistics between our cohort and the European Registry of TAVI [9] was not possible as, in spite of two (unanswered) email enquiries to the corresponding author, Registry raw data were not provided. Thus, we directly compared mean values (CoreValve to CoreValve, Table 2).

Cardiac surgery expertise, team-training and continuous stand-by were provided by the Sana Heart Center Stuttgart (SHS). Diagnosis of severe aortic valve stenosis was made according to ESC guidelines [10]. Extracardiac arteriopathy was evaluated by computer tomography. TAVI-patients were approved by the Heart Team (cardiologist, cardiac surgeon, anesthesiologist, cardiotechnician, theater-nurse).

TAVI-procedures were performed in a hybrid operation room under general anesthesia. Femoral artery was prepared by the surgeon, TAVI-

Table 1
Patient characteristics.

Variable	2011–12 pilot European Sentinel Registry of TAVI (total n = 4571) nb of observations; (%) [nb of patients]	Cardiovascular Center Oberallgäu–Kempten (total n = 65) nb of observations; % [nb of patients]
Male/female	2291 (50.1)/2280 (49.9) [4571]	28 (43.1)/37 (56.9) [65]
Age (years)	81.4 ± 7.1 [4571]	83.6 ± 5.7 [65]
BMI (kg/m ²)	26.6 ± 4.9 [4571]	26.0 ± 4.6 [65]
NYHA III or IV	(76.9) [4571]	45 (69.2) [65]
AVA (cm ²)	0.68 ± 0.26 [4571]	0.59 ± 0.15 [63 ^a]
Diameter CoreValve implanted (mm)	Ø26: (40.8) Ø29: (53.1) Ø31: (no data available) (62.9)	Ø26: 20 (30.8) Ø29: 37 (56.9) [65] Ø31: 8 (12.3) 65 (100.0) [65]
General anesthesia (transfemoral procedures)		
Diabetes mellitus	1259 (27.7) [4547]	12 (18.5) [65]
Hypertension	2709 (73.9) [3664]	54 (83.1) [65]
Current smoking	185 (4.2) [4357]	2 (3.1) [65]
Atrial fibrillation	557 (20.1) [2773]	28 (43.1) [65]
COPD	981 (25.5) [3844]	15 (23.1) [65]
Dialysis	265 (6.9) [3821]	1 (1.5) [65]
Previous stroke	206 (12.1) [4282]	8 (12.3) [65]
Previous MI	769 (16.9) [4549]	5 (7.7) [65]
Previous cardiac surgery	824 (18.0) [4505]	9 (13.8) [65]
Previous PCI	463 (20.2) [2289]	24 (36.9) [65]
Previous PM	430 (11.7) [3676]	8 (12.3) [65]
Extracardiac arteriopathy	671 (24.8) [2707]	16 (24.6) [65]
Previous AVR	74 (3.4) [2141]	0 (0.0) [65]
LVEF	<30%: 40 (5.7)	Severely reduced: 8 (12.3)
	30–50%: 191 (27.2) [701]	Moderately reduced: 15 (23.1) [65]
	>50%: 470 (67.0)	Good: 42 (64.6)
Significant CAD (stenosis > 50%)	669 (20.0) [3,343]	31 (47.7) [65]
Significant LM (stenosis > 50%)	215 (6.7) [3,343]	0 (0.0) [65]
Logistic EuroSCORE	20.2 ± 13.3 [4,394]	21.6 ± 12.6 [65]

nb: number; BMI: body/mass index; NYHA: New York Heart Association Functional Class; AVA: aortic valve area; AVR: aortic valve replacement; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; MI: myocardial infarction; LM: left main coronary artery; LVEF: left ventricular ejection fraction; PCI: percutaneous coronary intervention; PM: pacemaker.

^a Due to anatomical difficulties hindering accurate measurement of AVA two values are missing.

[☆] All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Table 2
Procedural and in-hospital complications (CoreValve to CoreValve).

Variable	2011–12 pilot European Sentinel Registry of TAVI (total n = 1943) (nb of observations; %)	Cardiovascular Center Oberallgäu–Kempten (total n = 65) (nb of observations; %)
Unsuccessful valve delivery	67 (3.6)	1 (1.5) [n = 66]
Surgical conversion	106 (5.5)	0 (0.0)
Second valve implanted	60 (3.7)	2 (3.1)
Cardiac tamponade	37 (2.3)	3 (4.6)
Device embolization	10 (0.6)	2 (3.1)
Major vascular complications	20 (2.8)	1 (1.5)
Pacemaker implantation	321 (23.4)	12 (18.5)
Hemodialysis/filtration	17 (1.1)	6 (9.2)
Need transfusion(s)	268 (16.7)	4 (6.2)
Stroke	33 (2.1)	0 (0.0)
In-hospital MI	20 (1.2)	1 (1.5)
New onset AF	74 (6.3)	0 (0.0)
Hospital stay > 10 days	386 (25.1)	31 (47.7)
Aortic regurgitation grade 2	105 (9.9)	10 (15.0)
Aortic regurgitation grade 3	25 (2.3)	2 (3.1)
Death	131 (6.7)	3 (4.6)

nb: number; MI: myocardial infarction; AF: atrial fibrillation.

procedure (18 French-sheaths) was performed by the cardiologist. Balloon valvuloplasty (balloon-size 2 mm < aortic annulus-size) included “rapid pacing”. Valve delivery was performed as high as possible to avoid severe aortic valve insufficiency. Left ventricular diastolic pressure served as the major hemodynamic parameter to decide on final placement of the valve. Two procedures were live-transmitted to Tongji University, Shanghai (<http://www.prnewswire.co.uk/cgi/news/release?id=333215>). Immediately after the procedure, patients were extubated and transferred to intensive care unit. The SHS-Team left Immenstadt on the same day. Usually, temporary pacemaker and central vein catheter could be removed within 24 h. Patients were mobilized the next day and then visited twice a day until discharge. None of the patients were transferred to another hospital.

Aortic insufficiency after TAVI was graded 0–III with first transthoracic echocardiography: 0 – no aortic valve insufficiency, I – mild insufficiency, II – medium insufficiency, and III – severe insufficiency. In case of intermediate grading (0–I, I–II or II–III), an alternating final assignment to lower or higher grade was used.

For direct comparison: in the pilot European Sentinel Registry [9], a total of 4571 patients underwent TAVI in 137 centers of 10 European countries. Average age was 81.4 ± 7.1 years (vs. 83.6 ± 5.68 in our retrospective analysis). Logistic EuroSCORE was 20.2 ± 13.3 (vs. 21.6 ± 12.58 in our analysis). Access site was femoral approach in 74.2% only (vs. 98.5% in our analysis – one patient was transferred to transapical procedure at SHS).

In-hospital mortality in the Registry was 7.4% overall, 5.9% for transfemoral (vs. 4.62% in our analysis) and 12.8% for transapical approach. Surgical conversion rate was 5.5% (vs. 0.0% in our analysis). Postprocedural pacemaker implantation was the most frequent complication in our population with an incidence of ~20%. Less blood transfusions (6.2% vs. 16.7%), less strokes (0% vs. 1.8%) and less major vascular complications (1.5% vs. 2.8%) were seen in our population compared with the Registry. The latter may be explained by routine surgical preparation of femoral artery in our study. The only observed vascular complication was an aneurysma spurium closed with thrombin

injection after 3 days. In contrast, Registry patients received various closing systems which are associated with more bleeding complications [9]. Postprocedural aortic regurgitation in our study was graded as significant in 18.1% (grade II – 15% and grade III – 3.1% of the patients) vs. 12.2% in the Registry. Higher grades of aortic insufficiency may partly be explained by our grading system. Also, retrospective analysis may be more objective than prospective inclusion of quality data into a Registry by the study center itself. Mean duration of in-hospital stay for TAVI-procedure was 12.5 ± 5.9 days. This is longer compared to 9.3 ± 8.1 days in the Registry, but is in accordance with the German Diagnosis Related Group (DRG)-based Healthcare-System (16.7 days median in-hospital stay). Also, general anesthesia is associated with a prolongation of in-hospital stay [9].

Our study has a number of limitations and conclusions. The number of patients in our retrospective analysis is relatively low. Statistical analysis comparing our data with the European Registry was not permitted [see above]. Nonetheless, non-inferiority can be concluded: mean age and logistic EuroSCORE were higher, and in-hospital mortality was lower in our study population. Surgical access to the femoral artery may be considered as standard access for TAVI. The definition of “cardiac surgery on site” should be clarified. Given that elderly patients are often immobile and do not regularly reach the big city centers, TAVI should be performed and reimbursed also in district hospitals provided that a well-trained and professional Heart Team is involved.

- Clinic Association Kempten–Oberallgäu.
- German Chancellor Fellowship (Alexander von Humboldt Foundation) to Dr. Kefei Li.

References

- [1] Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* 2002;106:3006–8.
- [2] Leon MB, Smith CR, Mack M, et al. PARTNER trial investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363:1597–607.
- [3] Makkar RR, Fontana GP, Jilaihawi H, et al. PARTNER trial investigators. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. *N Engl J Med* 2012;366:1696–704.
- [4] Thomas M, Schymik G, Walther T, et al. One-year outcomes of cohort 1 in the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) registry: the European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. *Circulation* 2011;124:425–33.
- [5] Zahn R, Gerckens U, Grube E, et al. German Transcatheter Aortic Valve Interventions—Registry investigators. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. *Eur Heart J* 2011;32:198–204.
- [6] Eltchaninoff H, Prat A, Gilard M, et al. FRANCE Registry investigators. Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) Registry. *Eur Heart J* 2011;32:191–7.
- [7] Moat NE, Ludman P, de Belder MA, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry. *J Am Coll Cardiol* 2011;58:2130–8.
- [8] Vahanian A, Alfieri O, Andreotti F, et al. Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC); European Association for Cardio-Thoracic Surgery (EACTS). Guidelines on the management of valvular heart disease (version 2012). *Eur Heart J* 2012;33:2451–96.
- [9] Di Mario C, Eltchaninoff H, Moat N, et al. The 2011–12 pilot European Sentinel Registry of Transcatheter Aortic Valve Implantation: in-hospital results in 4571 patients. *EuroIntervention* Apr 22 2013;8(12):1362–71.
- [10] Leon MB, Piazza N, Nikolsky E, et al. Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the Valve Academic Research Consortium. *Eur Heart J* 2011;32:205–17.