Int Cardiovasc Res J.2017;**11**(3):96-102.icrj.11030

International Cardiovascular Research Journal
www.ircrj.com

Initial Experiences of Transcatheter Aortic Valve Implantation (TAVI) in Iran with Midterm Follow up

Ali Mohammad Haji Zeinali [1, *], Kyomars Abbasi [2], Mohammad Sahebjam [3], Mojtaba Salarifar [1], Mahmood Shirzad [2], Narges Yoosefpour [1], Seyedeh Hamideh Mortazavi [1]

[1] Department of Interventional Cardiology, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, IR Iran
[2] Department of Cardiovascular Surgery, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, IR Iran
[3] Department of Echocardiography, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, IR Iran

ARTICLE INFO

Article Type:
Research Article

Article History:
Received: 16 Feb 2017
Accepted: 22 May 2017

Keywords:
Aortic Valve Stenosis
Transcatheter Aortic Valve Replacement
Iran

ABSTRACT

Background: Surgical Aortic Valve Replacement (SAVR) is the gold standard method for treatment of symptomatic severe senile Aortic Valve Stenosis (AS). For inoperable patients, due to severe co-morbidities, Transcatheter Aortic Valve Implantation (TAVI) has been suggested as a new and safe alternative with significant follow up superiority to medical treatment; recently, it was suggested for patients at intermediate risk, as well. Since its introduction in 2002, TAVI has well developed in more than 40 countries.

Objectives: We made an attempt to transfer this technology to Tehran University for the first time and then evaluated the feasibility and safety of this new technique with midterm closed clinical and echocardiographic follow up.

Patients and Methods: Eight patients (5 males), with a mean age of 77 ± 6.7 years old underwent transfemoral TAVI from 2010, as the first sequential patients in Tehran University, by Balloon expandable bioprosthetic Edwards SAPIEN transcatheter heart valve, under general anesthesia in hybrid operation room.

Results: There were 7 tricuspid valves and one bicuspid aortic valve (AV). All the patients had symptomatic severe senile valvular AS with severe co-morbidities so that the surgeons did not agree with open SAVR. Closed preprocedural, procedural, in hospital, one and 6 months clinical and echocardiographic assessments and follow up were done. Results: Procedural success rate was 100% with good implantation of the valve. A decrease in the AV mean gradient (MG) from preprocedural mean AVMG 52.2 ± 19.7 mm Hg to 9.8 ± 3.7 mm Hg was observed in the 6 month follow up. One patient had procedural papillary muscle damage and moderate mitral regurgitation (MR), which needed hemodynamic support. No in hospital mortality or major complications were seen. In the follow up period, one patient had unexplained sudden death in sleep 3 weeks after the discharge. The other 7 patients had good 6 months of follow up with improvement of Functional Class (FC) and Left Ventricle Ejection Fraction (LVEF) from mean 43 ± 13.5 % preprocedural to 50.7 ± 7.8% within 6 months.

Conclusions: Inoperable symptomatic senile valvular AS could be treated safely with TAVI. In- hospital results of the first sequential experience of TAVI in Tehran University of Medical Sciences were successful. TAVI in bicuspid AS and concomitant MR patients needs more caution in the procedure and follow up.

1. Background

The most common type of Aortic stenosis (AS) in senile patients is degenerative valvular AS (1). The gold standard treatment for these patients is surgical Aortic valve replacement (AVR), but, due to usual senile co-morbidities, more than one third of them were not operable (2, 3). Balloon Aortic valvuloplasty (BAV) alone for Aortic Stenosis yields no good results because of low and temporary increase of aortic valve area and high complications (2, 4).

*Corresponding author: Ali Mohammad Haji Zeinali, Tehran Heart Center, Tehran University of Medical Sciences, North Karegar Street, Tehran, Iran, P. O. Box: 1411713138, Tel: +98-2188029620,
E-mail: ali_zeinali_cardio@yahoo.com

Now based on the reliable studies, the standard treatment for symptomatic severe senile valvular AS with severe co-morbidities, making them unsuitable for open surgical AVR, is TAVI (5, 6).

First, TAVI was done on man in 2002 by pioneer Alian Cribier, MD, and then rapidly developed worldwide to thousands of cases (7). Now, two different types of TAVI Bioprosthetic valve are widely used: Self-Expanding valve and Balloon-Expanding valve.

The Balloon-Expandable Edwards SAPIEN Transcatheter Heart Valve (Edwards Life sciences, Irvine, CA, USA) (8) had FDA premarket approval in the USA (Figure 1). We did our initial TAVI in IRAN with this type of valve in January 2010 in hybrid operation room under general anesthesia and transfemoral access with guidance of pioneer Alian Cribier, MD (7, 9); then, we did 7 cases in other months. Here, our acute results and six month clinical and echocardiographic follow up findings are reported.

The study population included patients with severe symptomatic senile AS who were treated in hybrid operation room under general anesthesia and full standby open surgical support. The study was approved by local review board of Tehran Heart Center, a tertiary high-volume cardiac center, affiliated to Tehran University of Medical sciences. The patients also signed the written consent form before the procedure. TAVI was done with retrograde transfemoral approach for all patients, 7 from the right femoral arteriotomy and one from the left. In the contralateral leg, venous and arterial 6 Fr sheath was inserted for temporary pacemaker lead implantation on RV Apex and arterial pigtail catheter for aortography during delivery of the prosthetic valve.

After good femoral arteriotomy and special 22 Fr sheath insertion, testing of RV rapid pacing was done until we were sure that the arterial pressure was decreased under 50 mmHg with a rate of 180 - 200 bpm. Aortography with pigtail was done to choose the good position for prosthetic aortic valve delivery. In a better position, we could see the three cusps of the aorta in one line and the good distance between the left main and annulus. After double checking, balloon aortic valvuloplasty was done under rapid pacing and simultaneous aortography for the opening of the aortic valve, observing the left main flow and presence of AI, and ensuring the aortic annulus size. Transesophageal echocardiography (TEE) controlled these findings simultaneously with cine angiography.

Then Edwards sapine Balloon Expandable Bioprosthetic aortic valve that was prepared on the other table over the special delivery system and balloon was inserted on the 22 Frsheath over the 0.035 super stiff long Gide wire that was previously inserted in LV. The valve was crossed from the aortic arch and the native aortic valve slowly. Then, the position was rechecked with some aortography and TEE control; finally, under rapid RV pacing (180 - 200 bpm) and aortography the prosthetic valve was implanted in the aortic annulus with rapid inflation of the prepared inflator. The serial ordering of pacing, injecting for aortography and inflating in some seconds is very important and must be ordered by the main interventionist.

Based on the previous TEE sizing, we used 23 mm prosthetic valve (that had Aorta Annulus 20 mm) for two patients, and for the other 6 patients with an annulus size of more than 21 mm, the 26 mm Edwards valve was used. The size of the Balloon for pre-dilation of the native aortic valve, for 23 mm Bioprosthetic valve, was 20 mm balloon and for 26 mm Bioprosthetic valve it was 23 mm balloon. After the procedure, by final aortography the function of the prosthetic valve for AI and the left main flow and other complications like aortic dissection were evaluated. Also, TEE controlled the prosthetic valve position and function, especially the valve gradient, AI, MR and EF. The success rate for primary implantation of the valve was 100%. Two patients, had mild paravalvular AI with Aortography, and TEE revealed faint trivial AI in the other 3 patients. All patients were transferred to open heart ICU with closed monitoring and 7 patients were extubated successfully on the same day.

For all patients, clinical evaluation, electrocardiogram, chest radiography, transthoracic (TTE) and transesophageal echocardiography, coronary angiography, aortography and CT angiography for the aortic arch and ilio femoral access size were performed.

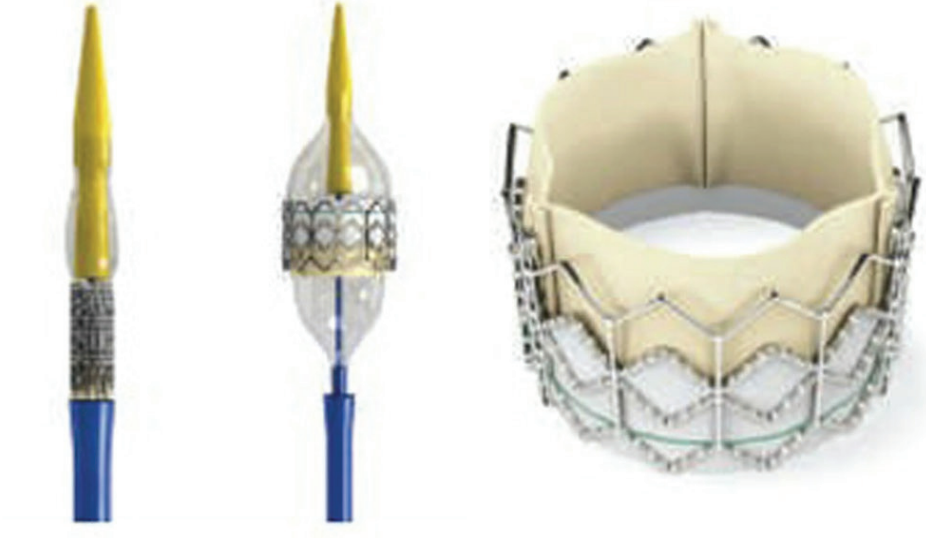

Figure 1. The Balloon-Expandable Edwards SAPIEN Transcatheter Heart Valve (Edwards Life sciences, Irvine, CA, USA)

TEE evaluated the LVEF and LV hypertrophy, aortic valve for evaluation of tricuspid or bicuspid type, calcification volume, severity of AS (PG, MG), aortic valve area (AVA), aortic annulus size, aortic insufficiency (AI), ascending aorta size, other valves function, pulmonary artery pressure (PAP) and other important characteristics. In angiography, coronary problems, distance of the left main origin from the aortic annulus, thoracic aorta and arch shape and diameter, carotid and renal arteries and ilio- femoral diameter and tortuosity or calcification were evaluated. If we did not have any data from the aorta and peripheral arteries in the previous routine coronary angiography, the thoracic aorta and ilio femoral arteries were evaluated using CT angiography.

2. Objectives

Here, our acute results and six month clinical and echocardiographic follow up findings are reported.

3. Patients and Methods

The study population included patients with severe symptomatic senile AS who were treated in hybrid operation room under general anesthesia and full standby open surgical support. The study was approved by local review board of Tehran Heart Center, a tertiary high-volume cardiac center, affiliated to Tehran University of Medical sciences. The patients also signed the written consent form before the procedure. TAVI was done with retrograde transfemoral approach for all patients, 7 from the right femoral arteriotomy and one from the left. In the contralateral leg, venous and arterial 6 Fr sheath was inserted for temporary pacemaker lead implantation on RV Apex and arterial pigtail catheter for aortography during delivery of the prosthetic valve.

After good femoral arteriotomy and special 22 Fr sheath insertion, testing of RV rapid pacing was done until we were sure that the arterial pressure was decreased under 50 mmHg with a rate of 180 - 200 bpm. Aortography with pigtail was done to choose the good position for prosthetic aortic valve delivery. In a better position, we could see the three cusps of the aorta in one line and the good distance between the left main and annulus. After double checking, balloon aortic valvuloplasty was done under rapid pacing and simultaneous aortography for the opening of the aortic valve, observing the left main flow and presence of AI, and ensuring the aortic annulus size. Transesophageal echocardiography (TEE) controlled these findings simultaneously with cine angiography.

Then Edwards sapine Balloon Expandable Bioprosthetic aortic valve that was prepared on the other table over the special delivery system and balloon was inserted on the 22 Frsheath over the 0.035 super stiff long Gide wire that was previously inserted in LV. The valve was crossed from the aortic arch and the native aortic valve slowly. Then, the position was rechecked with some aortography and TEE control; finally, under rapid RV pacing (180 - 200 bpm) and aortography the prosthetic valve was implanted in the aortic annulus with rapid inflation of the prepared inflator. The serial ordering of pacing, injecting for aortography and inflating in some seconds is very important and must be ordered by the main interventionist.

Based on the previous TEE sizing, we used 23 mm prosthetic valve (that had Aorta Annulus 20 mm) for two patients, and for the other 6 patients with an annulus size of more than 21 mm, the 26 mm Edwards valve was used. The size of the Balloon for pre-dilation of the native aortic valve, for 23 mm Bioprosthetic valve, was 20 mm balloon and for 26 mm Bioprosthetic valve it was 23 mm balloon. After the procedure, by final aortography the function of the prosthetic valve for AI and the left main flow and other complications like aortic dissection were evaluated. Also, TEE controlled the prosthetic valve position and function, especially the valve gradient, AI, MR and EF. The success rate for primary implantation of the valve was 100%. Two patients, had mild paravalvular AI with Aortography, and TEE revealed faint trivial AI in the other 3 patients. All patients were transferred to open heart ICU with closed monitoring and 7 patients were extubated successfully on the same day.

For all patients, clinical evaluation, electrocardiogram, chest radiography, transthoracic (TTE) and transesophageal echocardiography, coronary angiography, aortography and CT angiography for the aortic arch and ilio femoral access size were performed.

TEE evaluated the LVEF and LV hypertrophy, aortic valve for evaluation of tricuspid or bicuspid type, calcification volume, severity of AS (PG, MG), aortic valve area (AVA), aortic annulus size, aortic insufficiency (AI), ascending aorta size, other valves function, pulmonary artery pressure (PAP) and other important characteristics. In angiography, coronary problems, distance of the left main origin from the aortic annulus, thoracic aorta and arch shape and diameter, carotid and renal arteries and ilio- femoral diameter and tortuosity or calcification were evaluated. If we did not have any data from the aorta and peripheral arteries in the previous routine coronary angiography, the thoracic aorta and ilio femoral arteries were evaluated using CT angiography.

4. Results

4.1. Patients Characteristics

There were 8 patients (5 male) with a mean age of 77 ± 6.7 years old and severe symptomatic senile AS with Dyspnea FC II to IV (6 with FC III, one FC II and one FC IV) that usually had the history of admission with unstable angina or pulmonary edema presentation. They had a mean logistic Euro score of 25.8 for morbidity and mortality for open surgical operation (Table 1).

Three patients had diabetes mellitus and 7 were hypertensive. The mean serum creatinine was 1.14 mg/dL. All of the patients had some obstructive or restrictive lung disease (4 severe, 2 moderate, 2 mild). 4 patients had a history of MI, and one patient had a history of subdural hematoma surgery. In 5 patients, previous coronary revascularization was done (one CABG 18 years ago, one CABG + MVR 6 years ago, 3 had PCI from 4 months to 10 years ago) (Table 2).

In our patients, the mean LVEF was 43.7% ± 13.5, mean AVA 0.65 ± 0.21, cm2, mean AVMG gradient 52.2 ± 19.7 mmHg, mean annulus size 21.6 ± 1.15mm. 7 patients had

Table 1. Patients' Characteristics Based on Risk of Operation Score

No	Age	Sex	Height (cm)	Weight (kg)	Logistic Euro Score	
					(Mortality+Morbidity) *	FC
1	78	M	162	71	37.8	III
2	62	M	173	68	20.5	III
3	81	M	185	98	21.4	IV
4	77	F	150	73	20.4	II→III
5	83	M	175	90	16.5	II
6	75	M	165	68	19.4	III→IV
7	83	F	154	85	23.4	III
8	77	F	144	52	47.5	III→IV

Abbreviations: FC, Functional Capacity
* Logistic Euro Score System for Cardiac Operative Risk Evaluation for both Morbidity and Mortality

Table 2. Patients' Comorbidities

No	DM	HLP	HTN	Smoking	HX of MI	HX of CVA	Creatinine (mg/dL)	Lung Disease	CAD	EKG Block
1	+	+	+	+	+	-	2.0	Mild	3VD CABG-	-
2	+	+	+	+	+	-	0.7	Sever		-
3	-	+	+	-	-	-	1.2	Sever	MVR 3VD	MobitZI
4	-	-	+	-	-	-	1.1	Moderate	Normal	LBBB
5	-	+	+	-	-	-	0.8	Mild	PCI	LBBB
6	-	-	-	-	+	-	1.2	Moderate	PCI	-
7	-	+	+	-		-	0.8	Sever	PCI	-
8	+	+	+	-	+	-	1.3	Sever	CABG	LBBB

Abbreviations: DM, Diabetes Mellitus; HLP, Hyperlipidemia; HTN, Hypertension; HX of MI, History of Myocardial Infarction; CAD, Coronary Artery Disease

tricuspid aortic valve, but one patient had bicuspid aortic valve and his clinical situation did not allow us perform open SAVR. Four patients had moderate to severe aortic insufficiency (AI) before TAVI and three had moderate MR. 7 patients had mild to moderate LVH (Table 3).

4.2. Procedural, in Hospital Results and Complications

There were no death, MI or stroke in the admission period for our patients. One patient on the second day had tamponade due to RV perforation from the pacemaker lead, so emergency thoracotomy and RV repair was done for him. One patient had transient sinus node (SA) arrest on the third day of admission that needed external pacing for some hours; it was stabilized with medical treatment.

In two patients during rapid pacing in the procedure, ventricular fibrillation (VF) occurred which then converted with DC shock. One patient (Bicuspid aortic valve patient) after Balloon pre-dilating valvuloplasty showed some degree of papillary muscle damage and MR and prosthetic aortic valve implantation was done rapidly and IABP was inserted, but in ICU the patient needed inotrope medication for increased BP and blood transfusion. After one day, his condition was stable. There was one access side complication and femoral artery was repaired by limb venous graft.

All patients were admitted for 7 days for complete recovery and evaluation. On discharge, the mean serum creatinine was 1.1 ± 0.5 mg/dL and the mean Hb concentration was 10.9 ± 1 mg/dL. All patients were discharged with good condition without any major complications. Clopidogrel 75 mg and ASA 80 mg daily for one month was prescribed. One patient used ASA 325 mg because of recent PCI, two patients had previous MVR and AF rhythm and used warfarin too; thus, before the procedure, Warfarin changed to heparin and the day after the procedure warfarin was started.

Pre-discharge echocardiography revealed a mean LVEF of 46.8% ± 11.6 with good function of the Bioprostethic aortic valve with a mean of PG 21.7 ± 6.5 mmHg and mean MG

Table 3. Echocardiographic (TEE) Findings of the Patients before TAVI

No	LV EF	AVA (mm2)	MG (mm/Hg)	PG (mm/Hg)	MR	AI	Aorta Annulus (mm)	Septal Hypertrophy (mm)
1	25%	0.4	36	50	Mild	Mild	20	18
2	50%	0.7	43	66	Mild to Moderate	Mild to Moderate	22	12
3	60%	0.7	61	85	Mild	Mild	21	15
4	55%	1	44	75	Moderate	Mild	22	13
5	50%	0.5	75	111	Moderate	Moderate	22.8	14
6	25%	0.9	21	34	Mild to Moderate	Moderate	23	7
7	50%	0.64	64	84	Moderate	Moderate to Severe	22	14
8	35%	0.4	74	114	Moderate	Mild	20	15

Abbreviations: TEE, Transesophagial Echocardiography; LVEF, Left Ventricle Ejection Fraction; AVA, Aortic Valve Area; MG, Mean Gradient; PG, Peak Gradient; MR, Mitral Regurgitation; AI; Aortic Insufficiency

of 11.3 ± 4.1 mmHg. Paravalvular AI in pre-discharge TTE was seen in 6 patients, in one of them it was mild and in the other 5 it was trivial. In patients with papillary muscle problem due to the procedure, moderate MR was seen.

4.3. Mid Term Follow-up Results

In the first month, clinical and echo follow-up, one patient died because of sudden death during sleep and he was the bicuspid aortic valve patient who developed new MR during the procedure His family said that he had not had any new problem after discharge for 3 weeks and had sudden death in sleeping. The other seven patients had improved FC, and there were no patients with FC over II.

During the 6 month follow-up, all 7 patients were alive and there were FC I to II in them. In Echocardiography, the EF was raised and there were a mean LVEF of 50.7% ± 7.8 with a mean AVPG of 18 ± 4.8 mmHg and mean AVMG of 9.8 ± 3.7 mmHg. Para-valvular AI was seen in 5 patients, two mild and three trivial.

Comparison of the clinical and echo findings in patients, from pre-procedure situation to 6 months of follow-up revealed that the LVEF was increased and the mean AVPG and AVMG were decreased.

5. Discussion

The most common type of AS seen in the elderly is senile degenerative valvular AS (1), but more than one third of these patients were not good candidates for open surgical AVR because of severe co-morbidities (3, 10). Balloon Aortic valvuloplasty alone for Aortic Stenosis had no good results because of low and temporary increase of the aortic valve area and high complications, (Stroke, Aortic Insufficiency), mortality (10 - 20% in hospital), and high restenosis rate in the first year (2, 4). There were no difference between this procedure and medical treatment in long term and BAV had only palliative role, as a bridge to surgery or TAVI, for very ill patients (11).

TAVI had some superiority over medical treatment in one year mortality, days of hospital admission, and improvement of function class (12, 13). Even in comparison to open SAVR in severe symptomatic AS with co-morbidities, TAVI had better effect on increasing the LVEF (14, 15). TAVI had 95 - 97% primary success rate, but in multiple studies some complications were seen that must be reduced with new generation of the valves and increasing of interventionist skills for complications like myocardial infarction, stroke, silent ischemia of the brain, heart block, aortic dissection, acute coronary occlusion, tamponade, and vascular access complications (16-18).

After beginning of TAVI in 2002 with balloon-expandable SAPIEN valve (7), and increasing the number of successful patients (13, 18, 19), this less invasive transcatheter technique improved in two directions:

Firstly, a new approach for challenging cases such as transapical, trans-auxiliary and transthoracic approach via minimally invasive surgery and designing and secondly, making the new valves like self-expanding corevalve, direct flow, Lutos, etc. (20-23).

Other countries have tried to begin this alternative management for their inoperable patients and it has reached over 40 countries now (24, 25). In the Middle East and nearby areas, firstly Turkey began this technique. Thus, we decided to transmit this medical technology to our country, IRAN. Therefore, after passing a good learning curve in Roen city with Alean crebia and their working group, the first patient was done in IRAN in 2010 with proctoring of professor Alian Crebia.

The beginning of new and expensive methods of management in underdeveloped countries had some difficulties that restricted case selection. We had similar experiences in the beginning of Endovascular Treatment of Aorta Disease (26-28). The most important problem was the price of the valve, and then the resistance of surgeons about the better outcome of TAVI than open AVR in high risk patients. Saudi Arabia began this technique at the same time, but now they report more cases than us in local congresses. Philippe Genereux et al. in a review paper at European Heart Journal (June 2012) (29) presented a 10 year anniversary of the current evidence and clinical implications of TAVI from over 40 countries and this is an opportunity for us that IRAN is now one of the countries that routinely performs TAVI. Nowadays, multiple high volume registry and trials are designed about TAVI, like the PARTNER trial, the world's first prospective, randomized, and controlled trial (12, 30), but we think the primary results of countries that have recently begun this procedure must be compared with the first world feasibility studies, like the 1-REVIVER, the first feasibility French experience of TAVI on 36 patients with 85% procedural success and 16.7% one month mortality (31), or the Siegburg's first-in-man study on 86 patients with 74% procedural success and 11.6% one month mortality (32), or the United States REVIVAL trial on 40 patients with 100% procedural success and 12.5% one month mortality (33).

One of the largest results about Edwards valve has been reported in the SOURCE (SAPINE aortic Bioprosthesis European outcome) registry (8), to which 32 European centers contributed. Their procedural success for transfemoral TAVI was 95.2% and 30 day mortality was 6.3%. In our first Iranian feasibility study, the procedural success rate was 100% and 30 day all-cause mortality was 12.5%.

The Journal of medical Economics in 2013 published an Editorial (34) about the cost- effectiveness of TAVI in the non-surgical population based on the results of large scale studies, like PARTNER trial and explained that TAVI has remained a field still in the early stages of development and important current uncertainties related to health economics including the relative benefits and costs of TAVI and AVR in intermediate risk surgical candidates.

Evaluation of the association of TAVI availability and hospital AVR volume and mortality in the United States revealed that, since the introduction of TAVI, the total volume of AVR has significantly increased (34).

With progression of TAVI success in the world, the PARTNER 2 trial evaluated the possibility of the usefulness of this procedure for intermediate- risk patients for surgery (35), and 2032 patients at 57 centers in USA and Canada from 2011 to 2013 underwent TAVI with second generation valve system and compared with conventional surgical AVR. They concluded that in intermediate-risk patients

TAVI and SAVR had similar outcomes with respect to the primary endpoint of death or stroke at 2 years and lessening of cardiac symptoms. The lancet Journal Recently published a paper based on a propensity score analysis from PARTNER 2 trial results and suggested that TAVI might be the preferred treatment alternative in intermediate- risk patients (36).

5.1. Conclusion

TAVI is an acceptable procedure in symptomatic severe senile AS patients with severe co-morbidities that were not suitable for open surgical AVR. Our initial TAVI experiences in Tehran University of Medical Sciences in IRAN were successful with good feasibility and safety, without any procedural and in hospital death or major complications, and acceptable midterm follow up results in patients who were alive. Good learning curve is very important for the first TAVI experiences. TAVI in bicuspid AS and concomitant MR patients needs more caution in the procedure and follow up. The main problem for developing of TAVI in more candidates is the price of the prosthetic valve.

Acknowledgements

The authors thank pioneer professor Alian Cribier, MD for proctoring of our team for doing the first TAVI in our center in IRAN.

Authors' Contribution

Drafting of the article: Ali mohammad Haji zeinali, Narges Yoosefpour, Seyedeh Hamideh Mortazavi; Critical revision of the article for important intellectual content: Ali mohammad Haji zeinali, Kyomars Abbasi, Mohammad Sahebjam, Mojtaba Salarifar, Mahmood Shirzad; Final approval of the article: Ali mohammad Haji zeinali, Kyomars Abbasi, Mohammad Sahebjam, Mojtaba Salarifar, Mahmood Shirzad, Narges Yoosefpour, Seyedeh Hamideh Mortazavi; Provision of study materials or patients: Ali mohammad Haji zeinali, Kyomars Abbasi, Mohammad Sahebjam, Mojtaba Salarifar, Mahmood Shirzad; Statistical expertise: Seyedeh Hamideh Mortazavi, Narges Yoosefpour; Administrative, technical, or logistic support: Ali mohammad Haji zeinali, Mohammad Sahebjam, Mojtaba Salarifar, Narges Yoosefpour; Collection and assembly of data: Ali mohammad Haji zeinali, Kyomars Abbasi, Mohammad Sahebjam, Mojtaba Salarifar, Mahmood Shirzad, Narges Yoosefpour, Seyedeh Hamideh Mortazavi

Funding/Support

There is no funding/support.

Financial Disclosure

The authors have no financial interests related to the material in this manuscript.

References

1. Herrmann HC. Transcatheter aortic valve implantation: past, present, and future. *Circ Cardiovasc Interv*. 2008;**1**(3):159-60.
2. Klein A, Lee K, Gera A, Ports TA, Michaels AD. Long-term mortality, cause of death, and temporal trends in complications after percutaneous aortic balloon valvuloplasty for calcific aortic stenosis. *J Interv Cardiol*. 2006;**19**(3):269-75.
3. Rodes-Cabau J, Webb JG, Cheung A, Ye J, Dumont E, Feindel CM*, et al.* Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. *J Am Coll Cardiol*. 2010;**55**(11):1080-90.
4. Kapadia SR, Goel SS, Svensson L, Roselli E, Savage RM, Wallace L*, et al.* Characterization and outcome of patients with severe symptomatic aortic stenosis referred for percutaneous aortic valve replacement. *J Thorac Cardiovasc Surg*. 2009;**137**(6):1430-5.
5. Bonow RO, Carabello BA, Chatterjee K, de Leon AC, Jr., Faxon DP, Freed MD*, et al*. 2008 Focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Circulation*. 2008;**118**(15):e523-661.
6. Van Brabandt H, Neyt M. Safety of percutaneous aortic valve insertion. A systematic review. *BMC Cardiovasc Disord*. 2009;**9**:45.
7. Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F*, et al.* Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation*. 2002;**106**(24):3006-8.
8. Thomas M, Schymik G, Walther T, Himbert D, Lefevre T, Treede H*, et al.* Thirty-day results of the SAPIEN aortic Bioprosthesis European Outcome (SOURCE) Registry: A European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. *Circulation*. 2010;**122**(1):62-9.
9. Bauer F, Lemercier M, Zajarias A, Tron C, Eltchaninoff H, Cribier A. Immediate and long-term echocardiographic findings after transcatheter aortic valve implantation for the treatment of aortic stenosis: the Cribier-Edwards/Edwards-Sapien valve experience. *J Am Soc Echocardiogr*. 2010;**23**(4):370-6.
10. Bach DS, Siao D, Girard SE, Duvernoy C, McCallister BD, Gualano SK. Evaluation of patients with severe symptomatic aortic stenosis who do not undergo aortic valve replacement. *Circulation: Cardiovascular Quality and Outcomes*. 2009;**2**(6):533-9.
11. Dixon SR, Safian RD. The year in interventional cardiology. *J Am Coll Cardiol*. 2013;**61**(15):1637-52.
12. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG*, et al.* Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;**363**(17):1597-607.
13. Webb J, Cribier A. Percutaneous transarterial aortic valve implantation: what do we know? *Eur Heart J*. 2011;**32**(2):140-7.
14. Clavel MA, Webb JG, Rodes-Cabau J, Masson JB, Dumont E, De Larochelliere R*, et al.* Comparison between transcatheter and surgical prosthetic valve implantation in patients with severe aortic stenosis and reduced left ventricular ejection fraction. *Circulation*. 2010;**122**(19):1928-36.
15. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG*, et al.* Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;**364**(23):2187-98.
16. Kahlert P, Knipp SC, Schlamann M, Thielmann M, Al-Rashid F, Weber M*, et al.* Silent and apparent cerebral ischemia after percutaneous transfemoral aortic valve implantation: a diffusion-weighted magnetic resonance imaging study. *Circulation*. 2010;**121**(7):870-8.
17. Rodes-Cabau J, Dumont E, Boone RH, Larose E, Bagur R, Gurvitch R*, et al.* Cerebral embolism following transcatheter aortic valve implantation: comparison of transfemoral and transapical approaches. *J Am Coll Cardiol*. 2011;**57**(1):18-28.
18. Tamburino C, Capodanno D, Ramondo A, Petronio AS, Ettori F, Santoro G*, et al.* Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. *Circulation*. 2011;**123**(3):299-308.
19. Zajarias A, Cribier AG. Outcomes and safety of percutaneous aortic valve replacement. *J Am Coll Cardiol*. 2009;**53**(20):1829-36.
20. Grube E, Buellesfeld L, Mueller R, Sauren B, Zickmann B, Nair D*, et al.* Progress and current status of percutaneous aortic valve replacement: results of three device generations of the CoreValve Revalving system. *Circ Cardiovasc Interv*. 2008;**1**(3):167-75.
21. Van Mieghem NM, Rodriguez-Olivares R, Ren B, Ouhlous M, Galema TW, Geleijnse ML*, et al.* Transcatheter lotus valve

implantation in a degenerated carpentier-edwards bioprosthesis. *JACC Cardiovasc Interv*. 2015;**8**(2):e27-8.
22. Vavuranakis M, Voudris V, Vrachatis DA, Thomopoulou S, Toutouzas K, Karavolias G*, et al*. Transcatheter aortic valve implantation, patient selection process and procedure: two centres' experience of the intervention without general anaesthesia. *Hellenic J Cardiol*. 2010;**51**(6):492-500.
23. Wolf A, Schmitz T, Latib A, Naber CK. Successful repositioning of a direct flow medical 25-mm valve due to acute occlusion of right coronary artery during transcatheter aortic valve replacement procedure. *JACC Cardiovasc Interv*. 2015;**8**(2):e33-4.
24. Buellesfeld L, Wenaweser P, Gerckens U, Mueller R, Sauren B, Latsios G*, et al*. Transcatheter aortic valve implantation: predictors of procedural success--the Siegburg-Bern experience. *Eur Heart J*. 2010;**31**(8):984-91.
25. Godino C, Maisano F, Montorfano M, Latib A, Chieffo A, Michev I*, et al*. Outcomes after transcatheter aortic valve implantation with both Edwards-SAPIEN and CoreValve devices in a single center: the Milan experience. *JACC Cardiovasc Interv*. 2010;**3**(11):1110-21.
26. Ghazi P, Haji-Zeinali AM, Shafiee N, Qureshi SA. Endovascular abdominal aortic stenosis treatment with the OptiMed self-expandable nitinol stent. *Catheter Cardiovasc Interv*. 2009;**74**(4):634-41.
27. Haji-Zeinali AM, Ghazi P, Alidoosti M. Self-expanding nitinol stent implantation for treatment of aortic coarctation. *J Endovasc Ther*. 2009;**16**(2):224-32.
28. Zeinali AMH, Mehrab Marzban M, Reza M, Zafarghandi M, Mahmood Shirzad M, Shapoor Shirani M*, et al*. Short-Term Outcome of Endovascular Repair of Aortic Aneurysms with Stent Grafts: Initial Results of the First Consecutive Series of Endovascular Aortic Repair in Iran.
29. Genereux P, Head SJ, Wood DA, Kodali SK, Williams MR, Paradis JM*, et al*. Transcatheter aortic valve implantation 10-year anniversary: review of current evidence and clinical implications. *Eur Heart J*. 2012;**33**(19):2388-98.
30. Kapadia SR, Leon MB, Makkar RR, Tuzcu EM, Svensson LG, Kodali S*, et al*. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet*. 2015;**385**(9986):2485-91.
31. Cribier A, Eltchaninoff H, Tron C, Bauer F, Agatiello C, Nercolini D*, et al*. Treatment of calcific aortic stenosis with the percutaneous heart valve: mid-term follow-up from the initial feasibility studies: the French experience. *J Am Coll Cardiol*. 2006;**47**(6):1214-23.
32. Grube E, Laborde JC, Gerckens U, Felderhoff T, Sauren B, Buellesfeld L*, et al*. Percutaneous implantation of the CoreValve self-expanding valve prosthesis in high-risk patients with aortic valve disease: the Siegburg first-in-man study. *Circulation*. 2006;**114**(15):1616-24.
33. Kodali SK, O'Neill WW, Moses JW, Williams M, Smith CR, Tuzcu M*, et al*. Early and late (one year) outcomes following transcatheter aortic valve implantation in patients with severe aortic stenosis (from the United States REVIVAL trial). *Am J Cardiol*. 2011;**107**(7):1058-64.
34. Reardon MJ, Reynolds MR. Cost-effectiveness of TAVR in the non-surgical population. *J Med Econ*. 2013;**16**(4):575-9.
35. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK*, et al*. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med*. 2016;**374**(17):1609-20.
36. Thourani VH, Kodali S, Makkar RR, Herrmann HC, Williams M, Babaliaros V*, et al*. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. *Lancet*. 2016;**387**(10034):2218-25.