

Guidelines for Transcatheter Aortic Valve Replacement in Korea: Past Obstacles and Future Perspectives

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Background: Analyses of the efficacy and safety of transcatheter aortic valve replacement (TAVR) in most countries have been based on outcomes obtained in accordance with national practice guidelines and monitoring protocols. The purpose of this study is to share our experience regarding the process for establishing guidelines and monitoring protocols for the use of TAVR in Korea, in the hopes that it may be helpful to others undergoing a similar process in their own country. **Methods:** The Korean guidelines for TAVR were established on June 1, 2015 in through a tri-party agreement involving the Department of Health and Welfare, the Korean Society of Thoracic and Cardiovascular Surgery and the Korean Society of Cardiology. We agreed to monitor the guidelines transparently and to exchange opinions regarding amendments or continuation of its contents after 3 years of monitoring. **Results:** The monitoring meetings were not held as regularly as agreed, and monitoring was also made difficult by insufficient and incomplete data. Nevertheless, during the meetings, measures to improve the monitoring process were discussed, and accordingly, an agreement was made to continue the monitoring process, with the aim of completing data collection by 2018. **Conclusion:** Compliance with guidelines is critical for assessing the efficacy and safety of TAVR. Moreover, the TAVR monitoring process must be properly conducted for an accurate evaluation to be made. Any country planning to introduce TAVR may encounter difficulties with regards to the optimal initiation strategy and subsequent monitoring. Nevertheless, continued efforts should be made to persuade the government and the corresponding medical societies to facilitate the optimal application of TAVR.

Key words: 1. Transcatheter aortic valve replacement/implantation
2. Aortic valve stenosis
3. Guidelines
4. Monitoring
5. Safety and efficacy

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Introduction

Aortic stenosis is becoming an increasingly common valvular heart disease in the elderly. Recently, transcatheter aortic valve replacement (TAVR) has emerged as a viable treatment option for patients with high-risk or inoperable severe aortic stenosis. The volume of TAVR has dramatically increased since its seminal case presented by Cribier et al. [1] in 2002. The success of this case led to more and more surgical aortic valve replacements (SAVR) being replaced by TAVR as the primary therapy of choice.

Despite the increasing importance of TAVR, many Western countries with high-volume TAVR practices have come to recognize certain limitations of TAVR in comparison with surgical treatment as experience has accumulated. Consequently, many countries have established their own practice guidelines and monitoring protocols for the safe and effective application of TAVR. For this purpose, a multidisciplinary team approach seems to be the best method for identifying ideal candidates and devising intraoperative and postoperative management strategies. Serial publications regarding the outcomes of TAVR have attributed significant improvements over time to not only an increasing depth of experience, but also to the evolution of newer-generation devices aimed at addressing the limitations of earlier devices.

The Korean Society of Thoracic and Cardiovascular Surgery (KTCVS) has continually stressed the necessity of developing adequate guidelines and monitoring protocols for these purposes since the first TAVR procedure was performed in Korea in 2010. The Korean guidelines for TAVR were established in June 2015 through a tri-party agreement that included the Korean government and the Korean Society of Cardiology, as well as the KTCVS. Currently, data collection for monitoring the outcomes of TAVR in Korea is an ongoing process. Through this study, we aim to share our experiences in establishing the TAVR guidelines and monitoring protocols.

The enactment process of the Korean guidelines for transcatheter aortic valve replacement

After the first TAVR procedure was performed in Korea in 2010, it was primarily performed in several

select hospitals without medical insurance coverage. Meanwhile, the Korean government and the Korean Medical Association came to recognize TAVR as a potentially effective and useful procedure for treating patients with high-risk or inoperable severe symptomatic aortic stenosis. However, data were lacking to compare the intermediate- to long-term outcomes of TAVR to those of SAVR with regard to cost-effectiveness, safety, and efficacy. In August 2013, the medical practice assessment committee of the Korean government concluded that further evaluation of TAVR was needed in this regard. The TAVR advisory committee, composed of members from the KTCVS, the Korean Society of Cardiology, and the Korean government, was organized in 2014 to address this very issue. The development of Korean guidelines for TAVR was initiated in April 2014. Discussions were held with the specific aim of establishing the indications, contraindications, and standards for the implementation of TAVR and related evaluation methods. We made efforts to follow the original guidelines for TAVR established by the United States [2], European Union [3], and Japan [4]. However, subsequent negotiations were needed to develop our own guidelines adapted to our medical situation. In addition, medical expenditures related to TAVR were supposed to be reimbursed following Korean guidelines, and a corresponding administrative decree was enacted. Previously, a tri-party agreement was arrived at for a similar model, involving a heart team approach, for the treatment of coronary artery disease in Korea. However, in reality, there were limitations regarding the degree to which the ideal role of the heart team was fulfilled for this disease entity. Based on previous experiences, negotiations resulting in a tri-party agreement were conducted to develop the Korean guidelines for TAVR, with the goal of improving its implementation. After a total of 3 TAVR advisory committee meetings, held from May 20, 2014 to October 27, 2014, all members were satisfied that the newly enacted Korean guidelines for TAVR adequately reflected our national circumstances. In addition, further clauses to reinforce standards for qualified manpower, facilities, and equipment were added. The Korean guidelines, including stipulations for further monitoring, were finalized on December 27, 2014, after all members of the advisory committee agreed to the content.

The major difference between the Korean TAVR guidelines and those of other nations (e.g., the United States and Japan) is that all aspects of our regulations regarding indications, contraindications, and standards for TAVR application were loosened to provide greater opportunities for hospitals wishing to perform TAVR. The committee ultimately agreed that all TAVR procedures should be performed by a heart team during the mandatory 3-year monitoring period, after which further revisions could be made to the guidelines as needed. During this period, the government decided on a policy of 20% reimbursement for medical expenditures related to TAVR by the national medical insurance program, which was the first model of conditional coverage in Korea. Any future amendments modifying the reimbursement proportion would only become possible after June 2018, following the final analysis of the 3-year TAVR monitoring period. Based on these provisions, the Korean guidelines for TAVR were established by an administrative decree on June 1, 2015 (Appendices 1, 2).

The course of transcatheter aortic valve replacement monitoring since the establishment of the Korean guidelines

A preliminary meeting for monitoring activities was held under the auspices of the Health Insurance Review and Assessment Service (HIRA; March 30, 2015) prior to the launch of the advisory committee for establishing the Korean guidelines for TAVR and the monitoring protocol. The monitoring advisory committee members consisted of 2 reviewers from the HIRA, 2 members of the medical practice assessment committee, 3 members each of the KTCVS and the Society of Cardiology, and a statistical advisor. The statistical advisor was included in the monitoring advisory committee for assistance with analyzing the results of the upcoming 3-year monitoring period (June 2015 to May 2018). It was agreed that the participating hospitals should monitor outcomes at 5-time points after TAVR (before discharge, 30 days to 6 months, 1 year, 2 years, and 3 years) and submit their results for scrutiny by the advisory committee. The first monitoring meeting took place with the HIRA 6 months after the Korean guidelines were implemented (December 14, 2015). Upon review of the monitoring results during the previous 6

Table 1. Follow-up monitoring data of TAVR (June 1, 2015 to November 30, 2015)

Variable	No. of patients (%)
Heart team approach	
Total	64 (100.0)
All participants	46 (71.9)
Some participants	18 (28.1)
Cardiologist: 2 cardiologists	
Cardiac surgeon	64 (100.0)
2 Participants	62 (96.9)
1 Participants	2 (3.1)
Anesthesiologist	
Participation	60 (93.7)
No participation	4 (6.3)
Radiologist	
Participation	46 (71.9)
No participation	18 (28.1)
Reason for deciding to perform TAVR	
Total	64 (100.0)
Following indications	14 (21.9)
Consideration of risk due to old age and comorbidities	33 (51.6)
Patient's wish	13 (20.3)
No reason	4 (6.2)
Standby staff (cardiac surgeon, perfusionist)	
Total	64 (100.0)
Standby	20 (31.3)
No standby	44 (68.7)

TAVR, transcatheter aortic valve replacement.

months (June 1, 2015 to November 30, 2015), the committee found that the data were insufficient and that no reasons were provided for not strictly abiding by the set indications for TAVR (Table 1). The committee decided to collect further revised monitoring data within the next 3 months from the participating hospitals, and held a follow-up meeting. The administrative decree for TAVR was modified accordingly on February 2, 2016, after the first meeting (Appendix 2).

The second monitoring meeting was not held as scheduled, although the KTCVS made several requests through February 2017 that the HIRA hold the meeting. It was not until March 2, 2017 that the second monitoring meeting was held (Table 2). However, the meeting was not productive, as the monitoring data submitted by the HIRA for review were generally incomplete. After this meeting, it was agreed that further monitoring meetings should be

Table 2. Follow-up monitoring data of TAVR (December 1, 2015 to June 30, 2016)

Variable	No. of patients (%)
Heart team approach	
Total	153 (100.0)
All participants	145 (94.8)
Some participants	8 (5.2)
Cardiologist: 2 cardiologists	153 (100.0)
Cardiac surgeon	
2 Participants	147 (96.1)
1 Participants	6 (3.9)
Anesthesiologist: participation	153 (100.0)
Radiologist	
Participation	151 (98.7)
No participation	2 (1.3)
Reason for deciding to perform TAVR	
Total	153 (100.0)
Following indications	53 (35.3)
Consideration of risk due to old age and comorbidities	80 (51.7)
Patient's wish	12 (7.8)
No reason	8 (5.2)
Standby staff (cardiac surgeon, perfusionist)	
Total	153 (100.0)
Standby	93 (60.8)
No standby	50 (32.7)
No answer	10 (6.5)
Standby of heart-lung machine or extracorporeal membrane oxygenation	
Total	153 (100.0)
Yes	91 (59.5)
No	62 (40.5)

TAVR, transcatheter aortic valve replacement.

routinely held at least every 6 months, with HIRA submitting complete monitoring data with all relevant information for proper evaluation.

The last monitoring meeting was held on July 4, 2017, at which time all advisory committee members agreed to stricter enforcement of the TAVR guidelines, revisions of some clauses to improve the guidelines, and clearer representation to avoid misinterpretation or confusion. The committee also agreed to ensure that the statistical data analysis would be objective through outsourcing to a third party; on this basis, the cost-effectiveness of TAVR, its outcomes, and medical reimbursement will be discussed in 2018 after 3 years of monitoring.

Discussion

TAVR is a relatively new and evolving technology for treating patients with high-risk or inoperable severe symptomatic aortic stenosis. Since the indications for TAVR have been updated to include intermediate-risk patients as a class IIa indication in the most recent American College of Cardiology (ACC)/American Heart Association TAVR guidelines [5], it has become increasingly likely that TAVR will be applied to even lower-risk patients in the real world, without the scrutiny of objective clinical trials. TAVR has already been performed in over 100,000 cases worldwide, and in the United States alone, which is one of the leading nations performing TAVR, over 50,000 TAVR procedures have been conducted since Food and Drug Administration approval in 2011 [6].

Many clinical trials, including the PARTNER (Placement of Aortic Transcatheter Valve) and SURTAVI (Surgical Replacement and Transcatheter Aortic Valve Implantation) trials that are underway, have published comparative TAVR outcomes for a variety of endpoints, including survival, associated complications, cost-effectiveness, and quality of life. However, the objective evaluation of each step of TAVR implementation is complex, as the usual TAVR candidates are high-risk patients with multiple comorbidities. Furthermore, the evaluation of TAVR must account for several issues, including standards regarding the facility where the procedure is performed, the pre-operative evaluation for deciding upon suitability for TAVR, the experience of the surgeon, and the adequacy of training, not only for conducting the actual procedure, but also (perhaps more importantly) to effectively deal with difficult complications and post-operative care. Therefore, for the overall success of TAVR, it is essential for the heart team to function properly; this involves obligatory cooperation between the cardiac surgeon and the cardiologist. Historically, TAVR was launched in 2010 in Korea by several hospitals, without the benefit of government reimbursement by the national health insurance system. However, the Department of Health and Welfare and the relevant professional medical societies have recognized TAVR as a new technology that should, in principle, be managed through a multidisciplinary heart team approach. With this general

consensus, the advisory committee for establishing TAVR guidelines in Korea was formed. The KTCVS led efforts to revise, rather than to simply adopt, the existing published guidelines from other nations in order to accommodate the differences in the medical systems and conditions under which TAVR may be performed in Korea. Therefore, to design and establish our own TAVR guidelines that would be optimally suited to the Korean medical environment, the current TAVR guidelines and standards of use were modified, using those in the United States [2], European Union [3], and Japan [4] as references.

The original TAVR guidelines were revised during 3 TAVR advisory committee meetings with regard to the indications, contraindications, and all standards for human resources, facility, and equipment appropriate to the Korean medical environment. As the role of the heart team approach was fully recognized as essential for successful TAVR, the importance of using a heart team approach for TAVR was specified in the Korean guidelines (Appendix 1).

The detailed standards of TAVR implementation in Japan and the United States are as follows:

1) Qualifications to begin a TAVR program in the United States [2]

(1) ≥ 50 total aortic valve replacements (AVRs) in the previous year prior to TAVR, including ≥ 10 high-risk patients

(2) ≥ 2 physicians with cardiac surgery privileges

(3) $\geq 1,000$ catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year

2) Qualifications to begin a TAVR program in Japan [4]

(1) ≥ 20 AVRs per year

(2) ≥ 3 Cardiac surgeons

(3) ≥ 100 PCIs per year

(4) ≥ 10 Aortic stent grafts per year

(5) ≥ 200 Instances of transesophageal echocardiography

However, in contrast to these strict conditions, the prerequisite criteria for the institutional initiation and continuation of a TAVR program in Korea are considerably laxer (Appendix 1).

In terms of the role of heart team, the Korean guidelines, approved by all members of the advisory committee, also eased the regulatory requirements

for institutional TAVR application to include even cases that would otherwise be deemed controversial and possibly contraindicated for TAVR according to published international guidelines. However, as a safeguard, the administrative decree on the practice of TAVR in Korea specified that the heart team in each hospital should faithfully submit any and all reasons for not strictly abiding by the set indications for TAVR for monitoring purposes.

At the outset, it was agreed that only 20% of the medical expenditures relating to the device fee would be reimbursed by the national medical insurance system starting in June 2015. It was also decided that any amendments to this proportion would only be made after the final assessment of the mandatory monitoring outcomes in 2018. Thus far, despite succinct publication of the official guidelines and the administrative decree for TAVR, several factors have hindered the monitoring process. TAVR monitoring meetings were held only twice during the past 2 years (from June 2015 to May 2017). This was further compounded by poor data preparation, which significantly hindered any meaningful discussions during the monitoring meetings (Tables 1, 2).

With an international platform provided by the annual meeting of the Asian Society of Cardiovascular and Thoracic Surgery in late March 2017, the KTCVS was able to share the current status of TAVR in Korea and to hold discussions with international colleagues on overcoming obstacles relating to establishing nationwide TAVR practices. During this meeting, discussions were also held with Asian and Western colleagues on the role of cardiac surgeons in the heart team. The discussions showed that in most nations with well-established nationwide TAVR programs, TAVR was implemented by following clearly defined protocols accompanied by an accurate analysis of monitoring data on outcomes. We also discussed ways to overcome the difficulties relating to TAVR monitoring with government officials and parliamentary members. We informed them of the importance of monitoring TAVR procedures, and presented arguments supporting the importance of accurate monitoring for ensuring the safety and efficacy of TAVR implementation. Thus, the meeting held on July 4, 2017 was concluded by all members of the advisory committee agreeing to concentrate future efforts to ensure complete and faithful data collection

and objective statistical data analysis through outsourcing to a third party, as well as to hold regular TAVR monitoring meetings.

In 2017, the ACC suggested an expert consensus decision pathway for TAVR in the management of aortic stenosis [7]. They stated that patient management relies on a shared decision-making approach based on a comprehensive understanding of the risk-benefit ratio of different treatment strategies and integration of patient preferences and values. In addition, the heart valve team should emphasize that the purpose of valvular intervention is to improve symptoms and/or to prolong survival, while minimizing adverse outcomes associated with the intervention [8]. We cannot avoid all the possible complications of TAVR, despite a strongly collaborative heart team, as urgently occurring adverse events are not completely predictable or preventable. Nevertheless, data collection as part of an accurate monitoring process will provide valuable information that will minimize the risk of such complications and ultimately make the implementation of TAVR safer and more effective.

Finally, quality assessment of the entire spectrum of the medical landscape is of paramount import, and TAVR quality metrics are important for assessing the appropriateness of TAVR in an objective and widely applicable manner. The 2 fundamental components determining the quality of health care at TAVR centers of excellence are the use of a heart team and the active participation and management of a registry program [8]. Maintaining a well-run registry is essential for tracking and monitoring adverse events, prevents missed follow-up evaluations, and allows institutions to implement necessary measures or treatment in a timely manner, thereby preventing the occurrence of more serious adverse events. Objective analysis and retrospective reflection upon past practices allow revisions of current limitations to be implemented where necessary and lead to optimal step-wise improvements in patient care based on past experiences. Patient safety should be the top priority in any TAVR program, above all other considerations. To ensure the optimal implementation of the system, the will of the government is also important. To this end, maintaining a program of prospective monitoring is of paramount importance.

Conclusion

Compliance with TAVR guidelines is essential for ensuring efficacy and safety in treating high-risk or inoperable patients with severe aortic stenosis. Moreover, the TAVR monitoring process should be appropriately conducted to ensure accurate evaluation of all aspects of activities relating to TAVR, as well as the directly related outcomes. Although each country has unique circumstances, those planning to initiate TAVR will inevitably encounter various difficulties relating to the initiation and subsequent monitoring of TAVR. However, continued efforts should be made to persuade members of the relevant governmental institutions and professional societies to take steps promoting the seamless application of TAVR.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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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. Centers for Medicare and Medicaid Services. *Decision memo for transcatheter aortic valve replacement (TAVR) (CAG-00430N)*. Baltimore (MD): Centers for Medicare and Medicaid Services; 2012.
3. Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC); European Association for Cardio-Thoracic Surgery (EACTS), Vahanian A, et al. *Guidelines on the management of valvular heart disease (version 2012)*. *Eur Heart J* 2012;33:2451-96.
4. Transcatheter Aortic Valve Replacement Society Association. *Implementation facility standards in council for Transcatheter Aortic Valve Replacement Society Association* [Internet]. Osaka: Transcatheter Aortic Valve

- Replacement Society Association; 2013 [cited 2013 Jul 18]. Available from: <http://j-tavr.com/guideline.html>.
5. Nishimura RA, Otto CM, Bonow RO, et al. *2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines*. *Circulation* 2017;135:e1159-95.
 6. Webb JG, Wood DA. *Current status of transcatheter aortic valve replacement*. *J Am Coll Cardiol* 2012;60:483-92.
 7. Otto CM, Kumbhani DJ, Alexander KP, et al. *2017 ACC expert consensus decision pathway for transcatheter aortic valve replacement in the management of adults with aortic stenosis: a report of the American College of Cardiology Task Force on clinical expert consensus documents*. *J Am Coll Cardiol* 2017;69:1313-46.
 8. Pollak PM, Mack MJ, Holmes DR Jr. *Quality, economics, and national guidelines for transcatheter aortic valve replacement*. *Prog Cardiovasc Dis* 2014;56:610-8.

Appendix 1. Korean guidelines for TAVR	
Variable	Guidelines
Condition of implementation	<ol style="list-style-type: none"> The TAVR application of the relevant hospital can be approved after all requirements for human resources, equipment, and facilities have been satisfied. <ol style="list-style-type: none"> > 10 AVRs, > 10 aortic stent graft or aorto-iliac stent grafts, > 100 PCIs > 2 Cardiac surgeons with more than 5 years of cardiac surgery experience > 2 Cardiac interventionists with more than 5 years of cardiac intervention experience Hospital should install fluoroscopic devices that are amenable to TEE and emergency cardiac surgery conversion TAVR should be done after an evaluation by the heart team. The heart team should decide whether a patient is a suitable candidate for TAVR. <ol style="list-style-type: none"> Heart team: > 2 cardiologists including 1 echocardiographer, > 2 cardiac surgeons, > 1 anesthesiologist and radiologist. Their opinions can be replaced by consultation replies if they are not available for heart team meetings. The recommendation for TAVR should be based on the indications, contraindications, risks, and benefits of TAVR after all members of the heart team have agreed to the implementation of TAVR.
Indications for TAVR	<p>Symptomatic severe aortic stenosis with high or inoperable surgical risk</p> <ol style="list-style-type: none"> Cardiac symptoms: NYHA functional class > 2 Grade of severity <ol style="list-style-type: none"> Mean pressure gradient of AV ≥ 40 mm Hg or peak jet velocity ≥ 4 m/sec Initial echo-derived AVA < 1.0 cm² or AVA index ≤ 0.6 cm²/m² High surgical risk: predicted risk of operative mortality $\geq 15\%$, STS score ≥ 8
Contraindications for TAVR	<ol style="list-style-type: none"> Absolute contraindications <ol style="list-style-type: none"> Clinical <ol style="list-style-type: none"> Life expectancy ≤ 1 yr No expectation of quality of life improvement due to severity of comorbidities Presence of concomitant major valvular disease amenable to surgical treatment only Anatomic <ol style="list-style-type: none"> Aortic annular diameter (< 18 mm, > 29 mm) LV thrombus Active IE High risk of coronary OS obstruction (asymmetric valve calcification, short coronary OS and annular distance, small aortic sinus) Mobile thrombotic plaques in ascending aorta and aortic arch Poor transfemoral and transsubclavian access due to size, presence of calcification, and extreme tortuosity Relative contraindications <ol style="list-style-type: none"> Bicuspid or non-calcified AV CAD requiring coronary intervention or surgery Hemodynamically unstable condition or LV EF < 20% Contraindication for transapical route: severe lung disease or otherwise not accessible through the transapical route
Heart team documentation	<ol style="list-style-type: none"> Documentation of heart team records should include the time and location of the heart team meeting, the name and signature of the participating doctors, treatment plan, and the reasons for the decisions regarding TAVR, which should also be recorded in the medical records. A heart-lung machine or ECMO, as well as a cardiac surgeon, anesthesiologist, and perfusionists, should be on standby in case of an emergency operation during TAVR. Names of on-call staff should be recorded in the medical records.

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Appendix 1. Continued

Variable	Guidelines
	3. The relevant hospitals should submit clinical records including the reason for conducting TAVR, pre- and post-TAVR patient status, any complications after TAVR, and whether TAVR was successful within 30 days of TAVR.
	1) Submission time: before discharge, between 30 days and 6 months, 1 year, 2 years, and 3 years after TAVR
	2) The hospital should submit a statement of the reasons if follow-up clinical data collection was not done or if the data are unavailable.
	4. The chairman of HIRA should monitor clinical data relating to TAVR by the relevant hospitals that grant TAVR approval and report the data to the Minister of Health and Welfare

TAVR, transcatheter aortic valve replacement; AVR, aortic valve replacement; PCI, percutaneous coronary intervention; TEE, transesophageal echocardiography; NYHA, New York Heart Association; AV, aortic valve; AVA, aortic valve area; STS, Society of Thoracic Surgeons; LV, left ventricle; IE, infective endocarditis; OS, ostium; CAD, coronary artery disease; EF, ejection fraction; ECMO, extracorporeal membrane oxygenation; HIRA, Health Insurance Review and Assessment Service.

Appendix 2. Administrative decree for the approval of TAVR in relevant hospitals

No.	June 2015	February 2016 revision
1	The objective of this administrative decree is to define the necessary procedures for pre-approval of the relevant hospital and clinical data submission.	
2	The hospital should submit the documents relating to TAVR application to the chairman of HIRA.	
3	<ol style="list-style-type: none"> 1) The special advisory board should report the results of the evaluation of the relevant hospitals for the TAVR application to the Minister of Health and Welfare within 45 days upon receipt of the application. 2) The chairman of HIRA can ask the relevant hospital to submit all data necessary to make a decision regarding the approval of TAVR. 3) The chairman of HIRA can ask HIRA staff to check the conditions of the hospital, if doing so is necessary for the decision to approve TAVR according to 3.1). 4) Hospitals confirmed by the Minister of Health and Welfare should report any change in the standards of TAVR applications to the chairman of HIRA without delay. 	
4	<ol style="list-style-type: none"> ① The chairman of HIRA can reject a TAVR application after consultation with the special advisory board, for the following reasons: <ol style="list-style-type: none"> 1) The relevant hospital does not submit TAVR application data by 3.2) within the required period. 2) The hospital submits false data or data based on false information. ① The chairman of HIRA should report the rejection to the Minister of Health and Welfare without delay if the rejection is confirmed by the special advisory board according to 4.①. 	

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Appendix 2. Continued		
No.	June 2015	February 2016 revision
5	<p>① The relevant hospital should submit clinical pre-discharge data of TAVR within the required period. The data should be submitted together with medical care expenses if medical care expenses are claimed before discharge or within 30 days after discharge.</p> <p>② Hospital should submit follow-up data of TAVR within the following periods:</p> <ul style="list-style-type: none"> - Between 30 days and 6 months after TAVR - 1 Year after TAVR - 2 Years after TAVR - 3 Years after TAVR <p>③ The chairman of HIRA can ask the hospital to submit associated data to verify whether the conditions for the TAVR application have been satisfied.</p> <p>④ The chairman of HIRA can routinely verify items associated with clinical data for the approval of TAVR application.</p>	
6	<p>① The chairman of HIRA may allow the special advisory board to investigate a hospital to decide whether they should restrict TAVR based on the items below:</p> <ol style="list-style-type: none"> 1. The hospital does not meet the requirements for TAVR approval by 3.4). 2. The hospital does not submit data or submits falsified data, by 5.①-③. 3. The hospital denies or avoids the investigation of the requirements for approval by 5.④. 4. The hospital does not meet the requirements for approval of TAVR after investigation by 5.③,④. <p>② The chairman of HIRA should inform the Minister of Health and Welfare of the results of the investigation promptly by 6.①.</p>	<p><Additional items > The hospital should submit the data for the requirements for approval of TAVR without delay when they have been requested.</p> <p>① The Minister of Health and Welfare can cancel a TAVR application after review by the special advisory board if the hospital does not meet the requirements for approval or does not follow the required conditions.</p> <p>5. The hospital does not meet the requirements for a TAVR application.</p>
7	<p>① The chairman of HIRA should permit medical care expenses of TAVR approved by the Minister of Health and Welfare after investigation by the special advisory board.</p> <p>② The chairman of HIRA should suspend medical care expenses of TAVR cancelled by the Minister of Health and Welfare after investigation by the special advisory board.</p>	

TAVR, transcatheter aortic valve replacement; HIRA, Health Insurance Review and Assessment Service.