

PMDA Alert for Proper Use of Medical Devices

Pharmaceuticals and Medical Devices Agency

 July 2018

Adverse Events involving the Use of Bioprostheses for Transcatheter Aortic Valve Implantation

Serious adverse events associated with bioprosthetic devices used for transcatheter aortic valve implantation (TAVI) have been reported (see next page) when such devices are used under the following conditions:

- Heavily calcified lesions in the native aortic annulus predictive of complications such as aneurysm
- Narrow access vessels
- Mural thrombosis and atheromatous plaques

1. Precautions required under the conditions mentioned above have been included in the package inserts of individual devices. When the TAVI procedure is considered, the Warnings section or statements listed as Precautions in such package inserts should be confirmed in order to prevent serious adverse events.
2. The adverse events reported may be avoidable through proper preimplantation diagnosis. When considering TAVI, patient risk factors should be carefully assessed together with the staff involved in the procedure to reach a comprehensive decision on whether to perform TAVI with sufficient preparatory measures and careful prosthesis manipulation identified through the assessment, or to seek alternative treatment options including surgery.

Please report any occurrences of medical device malfunctions or serious patient problems promptly to the marketing authorization holders (MAHs) of the devices or PMDA.

Specific cases

Note on listed cases: This information offers general information, and therefore is not meant to endorse or criticize the treatment policies in the listed cases. Treatment policies for individual cases should be determined through discussion between the patients and their physicians as well as other parties involved while accounting for patients' specific pathological conditions, etc.

Annulus rupture (Case) For a native aortic annulus with a diameter in between the large and small bioprosthetic valves used for TAVI, the large valve was selected and successfully implanted. However, when the delivery system was removed, decreased blood pressure, cardiac tamponade, and dissection of the aortic root or other sites were observed. The patient was converted to thoracotomy.

Paravalvular regurgitation (Case) A bioprosthetic valve used for TAVI implanted in a lesion where calcification was observed in the noncoronary and right coronary cusps resulted in paravalvular regurgitation from the noncoronary cusp and exacerbation of the patient's cardiac failure.

Ruptured Valsalva sinus (Case) Blood effusion outside the Valsalva sinus, pericardial effusion, and decreased blood pressure were observed via transesophageal echocardiography following preimplantation valvuloplasty performed in association with implanting a bioprosthetic valve used for TAVI. The patient's treatment was changed to thoracotomy.

Coronary artery occlusion (Case) Post-procedural contrast imaging subsequent to implanting a bioprosthetic valve used for TAVI identified complete occlusion of the right coronary artery by the native aortic valve. Myocardial infarction developed.

Extended hypotension (Case) Prolonged rapid pacing resulted in extended hypotension.

Embolism (Case) Catheter manipulation triggered plaque dispersal inside the shaggy aorta, which caused intestinal necrosis.

Access vessel rupture (Case) An angiography performed after sheath removal revealed contrast agent leakage in a patient exhibiting access vessel diameter smaller than the lower limit value of the sheath for applicable vessels. A stent graft was placed inside the vessel while blood transfusion and other measures were performed.

About this information

•“PMDA Alert for Proper Use of Medical Devices” communicates to healthcare providers with clear information from the perspective of promoting the proper use of medical devices. The information presented here includes such cases where the reporting frequencies of similar reports have not decreased despite relevant alerts provided in package inserts, among medical device failure /infection cases reported in accordance with the PMD Act.

•We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future

•This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided to promote the proper use of the medical devices.

Access to the most up to date safety information is available via the PMDA medi-navi.

