PMDA Alert for Proper Use of Medical Devices
Pharmaceuticals and Medical Devices Agency

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Adverse Events Associated with the Use of Aortic Stent-Grafts

Regarding the use of abdominal/thoracic aortic stent-grafts, serious adverse events have been reported when particularly used under the following conditions, etc. (See the next page).

- Infective aneurysms
- Application to anatomically off label indication
- Shortage of fixation sites of stent-grafts

For precautions, etc. when used under the above-mentioned conditions, an alert has been given in the package insert of each product. To prevent the occurrence of serious adverse events, the “WARNINGS” and “PRECAUTIONS” in the package insert of each product should be checked, and sufficient attention should be paid to the following matters when a stent-graft is used.

1. The efficacy and safety of the aortic stent-graft have not been established for uses other than the intended uses described in the package insert.
2. Comprehensive decision making should be applied with thorough consideration of the risk factors affecting the patient with the staff involved in the endovascular intervention, as well as exploring other treatment methods such as surgical operation.

If any medical device malfunction or serious patient problem occurs, please report them promptly to the handling manufacturers or PMDA.

Specific Cases

Precautions on published cases
This information document describes general information, and therefore it does not explain the wrong or right of individual treatment policies etc. Treatment policy for individual case should be determined by discussion among patient him/herself and physicians under consideration on the pathological conditions etc. of the patient.

(1) **Application to infective aneurysms**
(Case) A stent-graft was placed in an infective ascending aortic aneurysm, and infection persisted and led to sepsis, leading to death, despite antibiotic treatments being performed.

(2) **Application to anatomically off label indication**
(Case) When a stent-graft was placed for a solitary iliac artery aneurysm, the stent-graft was dented due to the narrow terminal aorta, therefore an additional vascular stent was needed to be placed in order to secure the blood flow to the periphery.

(3) **Lack of sealing length**
(Case) A stent-graft was placed in a state where there were only three-fourths of the required sealing length for placement, and as a result, type I endoleak occurred, and the patient died due to the rupture of the aortic aneurysm.

(4) **Flexion**
(Case 1) After placement of a stent-graft at a severely flexed site beyond the indication, type I endoleak occurred even after touch-up. A stent-graft was additionally placed but blood pressure decreased, etc. occurred in association with aortic rupture, and eventually the patient died due to respiratory failure.

(Case 2) A stent-graft was placed at a severely flexed site beyond the indication and ballooning was performed, and retrograde aortic dissection occurred as a consequence of the load on the vascular wall, leading to death.

(5) **Mural thrombus**
(Case) A mural thrombus, which was found around an aortic aneurysm, scattered due to catheter manipulation, etc., and consequently, ischemic cerebrovascular disorder, paraplegia, renal failure, and bowel necrosis occurred, leading to death.

(6) **Stenosis**

(Case) In a case with marked stenosis of the femoral artery, access from the femoral artery was attempted, and as a result, thrombus-associated occlusion occurred, thereby blocking the blood flow to the lower limbs. The complication associated with resumption of blood flow caused death.

(7) **Combination with the Chimney technique**

(Case) Following the stent-graft being placed from the ascending aorta to the subclavian artery, the Chimney technique was combined to secure the blood flow in the brachiocephalic artery. A stent-graft for Chimney was placed from just below the right common carotid artery to the ascending aorta (off-label), but several days after the operation, aortic dissection led to aortic rupture, resulting in death.

(8) **A case of vascular graft prosthesis replacement**

(Case) After debranching in a case with the ascending aorta replaced, the guide wire was lodged into the anastomotic part between the ascending aorta and the vascular graft prosthesis during an attempt at placing two stent-grafts, which led to bleeding from the load to the anastomotic part.

(9) **Erroneous size selection**

(Case) Type I endoleak occurred, and it led to an additional stent-graft placement. However the maximum diameter of the newly added stent-graft was still under the patient's vascular diameter, and consequently endoleak recurred for several more months. After that, the lesion was treated but led to mediastinitis, resulting in death.

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 drugs.

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

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Patients should consult with their physician in charge.