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Division for Safety of Medical Devices
Office of Manufacturing Quality and Vigilance for Medical Devices
Pharmaceuticals and Medical Devices Agency (PMDA)

Paclitaxel-coated Balloons and Stents in the Femoropopliteal Artery

In December 2018, Katsanos et al. published the results of a meta-analysis for paclitaxel-coated balloons and stents in the femoropopliteal artery (hereinafter referred to as “paclitaxel-coated devices”) (J Am Heart Assoc. 2018 ; 7 : e011245). According to this article, although all-cause mortality in patients treated with paclitaxel-coated devices did not differ from the control arms using uncoated devices at 1 year, it was higher at 2 years and 5 years, suggesting a possible increased mortality rate associated with paclitaxel-coated devices. Please confirm the details of analysis results in the original article.

Since the publication of this article, the US Food and Drug Administration (FDA)¹⁾²⁾, the UK Medicines and Healthcare Products Regulatory Agency (MHRA)³⁾, and the French Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)⁴⁾ have been providing health care professionals using paclitaxel-coated devices with information on the content of this article and the fact that risk evaluations are being conducted in various countries. In addition, FDA communicated its second information on March 15, 2019 that the agency encourages treatment options other than paclitaxel-coated devices until completion of its risk evaluation based on the analysis of follow-up results of the pre-marketing clinical trials for the devices.

In order to deliberate safety measures based on this article, PMDA considers it important to evaluate the risk of mortality in Japanese population. The agency is to cooperate with related academic associations to analyze post-marketing survey data etc. held by individual marketing authorization holders (MAHs). In addition, PMDA is cooperating closely with foreign regulatory authorities regarding this issue.

For the result of data analysis of post-marketing survey etc., PMDA intends to communicate some other time. Since additional information may be provided by regulatory authorities in various countries and MAHs, healthcare providers are requested to be kept alert to such information.

Risk evaluation on this issue is still underway at PMDA. Please forward any occurrences of

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malfunctions and serious health damages associated with paclitaxel-coated devices you may identify to the relevant MAHs of the products. In addition, please report the information to PMDA according to the Drugs and Medical Devices Safety Information Reporting System. (<https://www.pmda.go.jp/safety/reports/hcp/pmd-act/0003.html>).

As of April 2019, paclitaxel-coated balloons and stents in the femoropopliteal artery marketed in Japan are as follows.

Brand Name	Marketing Authorization Holders
Zilver PTX Drug-Eluting Peripheral Stent	Cook Japan Incorporated.
Eluvia Drug-Eluting Stent	Boston Scientific Japan K.K.
Lutonix Drug-Coated Balloon (DCB) Catheter (for femoropopliteal arteries)	Medicon Inc.
IN.PACT Admiral Drug-Coated Balloon	Medtronic Japan Co., Ltd.

- 1) Information provided by FDA (January 17, 2019)
<https://www.fda.gov/medical-devices/letters-health-care-providers/treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel-eluting-stents>
- 2) Information provided by FDA (March 15, 2019)
https://www.fda.gov/medical-devices/letters-health-care-providers/update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel-eluting?utm_campaign=FDA+MedWatch+Paclitaxel-Coated+Balloons+and+Paclitaxel-Eluting+Stents&utm_medium=email&utm_source=Eloqua
- 3) Information provided by MHRA (March 8, 2019)
<https://www.gov.uk/government/news/expert-advisory-group-set-up-to-review-paclitaxel-drug-coated-balloon-catheters-and-drug-eluting-stents>
- 4) Information provided by ANSM (February 27, 2019)
<https://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Traitement-de-l-arteriopathie-oblitterante-des-membres-inferieurs-AOMI-a-l-aide-de-dispositifs-medicaux-au-paclitaxel-Point-d-Information>