Editorial

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The Present and the Future of Drug-Coated Devices: What to Expect in the Next 5 Years?

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Between 2015 and 2019, more than six societal guidelines came to different recommendation and conclusions given the published evidence about drug-coated devices to treat femoropopliteal and crural lesions. Showing that there is still room for discussion about drug-coated devices, especially concerning the arisen safety concerns in paclitaxel-coated devices [1-4]. Recently, Katsanos et al concluded that there is an increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery and that further investigations are urgently warranted [5]. In a second meta-analysis, the same authors concluded worse outcomes including amputation-free survival for below the knee treatment [6].

First of all, looking back few years, paclitaxel-based drug-coated balloon (DCB) or drug-coated stent (DCS), became the preferred treatment for revascularization of femoropopliteal lesions in peripheral arterial occlusive disease, especially to avoid restenosis. This was true despite the fact that sirolimus-eluting stents showed to have a more potent anti-proliferative effect than paclitaxel [7].

Today, the ongoing paclitaxel controversy illustrates that neither randomized controlled trials nor real word data can really claim to determine "reality" results [8]. International collaborations like VASCUNET (www.vascunet.org) or the International Consortium of Vascular Registries (ICVR) and the Medical Device Epidemiology Network (MDEpiNet) can help by developing a scientific framework and reaching a broad consensus among real word data specialists [8,9].

A large propensity score matched analysis of health insurance claims from Germany included some 40,000 patients to determine long-term follow-up after drug-coated devices in femoropopliteal arteries [10]. Between 2010 and December 2018, 37,914 patients and 21,546 propensity score matched patients with an index revascularization were included. A rapid adoption of drug-coated devices was shown for Germany during the study period, but the authors found no sign of increased mortality following use of drug-coated devices [10]. Another follow-up study from the same group of authors concerning below the knee treatments was most recently submitted to support the ongoing warm discussion.

Last news about drug-coated devices:

Preliminary results were published on first-in-human experience with sirolimus-eluting self-expanding stent for femoropopliteal lesions [11]. The NITIDES stent (CID, Saluggia, Italy) represents a novel drug-coating/eluting strategy, as it uses the amphilimus formulation consisting of sirolimus formulated with an amphilic carrier that is released through an abluminal reservoir technology [11].

What do we learn from those data?

The future of drug-coated devices: What to expect in the next 5 years?

The velocity of information will further increased exponentially and we will launch ideas for improvements in data driven medicine. The desire to accelerate the efficiency is central and aims to improve people`s quality of life and reduce health care costs [9].

Open question for the Vascular Community to discuss, in which cases evidence from real world data may complement evidence from the sometimes inadequate RCTs [8].

More sufficiently powered studies on the immunosuppressive drugs, on the specifications and design of the releasing catheter, and the excipient that joins the drug to the surface of the balloon or stent to the artery wall are needed.

Use of nanotechnology, paclitaxel and sirolimus in different formulations and excipients from those used up to now, for better delivery, action and prolonged maintenance of the drug in the artery wall.

More studies and research development on the dependence of the dose of the drug on the effectiveness of tissue proliferation inhibition.

The excellence of observation and the continuous evaluation of our results maintain the expectation of better care and quality of life for patients with severe extensive vascular disease.

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