MONASH University

MONASH INNOVATION

PHOTO-ACTIVATED DRUG ELUTING ANGIOPLASTY BALLOON

A drug eluting balloon (DEB) coated with a photo-labile drug linker conjugate. The drug-coated balloon can be moved to the target area, where the drug will be released to the target vessel walls using a photo-cleaving approach. The drug coating (HDAC inhibitor) shows reduced toxicity and neointimal hyperplasia with clear demonstration of superiority over the current standard.

- **Replacement for Paclitaxel DEB.**
- **Targeted delivery, photo activated.**
- **Successfully proven in large animal.**
- **Low toxicity.**

THE CHALLENGE

One of the negative after-effects on vessels which have been treated by percutaneous transluminal angioplasty (PTA) is restenosis due to induced neointimal hyperplasia (NIH). This negative effect is reduced by the use of stents, drug eluting stents, and drug eluting balloons. These mitigation steps have their limitations, such as:

- the vessel may not be suitable for stenting
- the area may be ineffectively targeted by the drug.

The use of drug eluting balloons and stents may also lead to negative side effects. Recent large clinical studies have shown that balloons coated in Paclitaxel (PTX) can have adverse side effects and in some cases cause an increased risk of mortality.[1]

There is therefore a need to replace Paclitaxel with a drug that can reduce restenosis/NIH as well as reduce minor and major side effects associated with current PTX drug-eluting balloon technology.

THE TECHNOLOGY

The team have identified a histone deacetylase inhibitor (HDACi) referred to as MCT-3 which has significant *in-vivo* anti-NIH activity and low systemic toxicity.[2]

Preliminary studies in large animals have shown the MCT-3 results to be potentially superior to PTX. These studies have also shown inhibition of molecular markers of cellular proliferation and inflammation when utilising the MCT-3 coated balloons.

A photo activated conjugate of MCT-3 which can be activated by ultraviolet light and a balloon delivery system which incorporates optical fiber technology has been developed. The MCT-3 conjugate is applied to the balloon using an ultra-sonic coating technique.

The device developed is referred to as “Lumi-Solve”. Testing of the device is shown in Figure 1. Figure 2 shows a UV-illuminated enlargement of the balloon.

The photo-angioplasty device allows for targeted delivery and activation of MCT-3.

THE OPPORTUNITY

Monash seeks a partner to co-develop this patented technology (provisional patent number: AU2019900058).

The team behind this innovative technology is led by Assoc. Professor Anthony Dear and includes a cross functional team from the Monash Institute of Pharmaceutical Sciences, the Baker Institute, Monash Faculty of Engineering and the CSIRO.

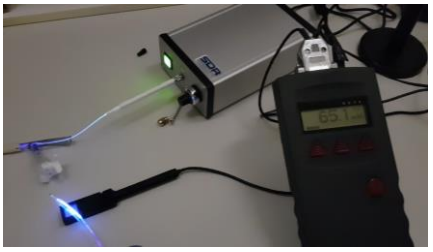

Figure 1. Light source connected to the Lumi-Solve device, along with a device for measuring the intensity of light emitted.

Figure 2. Enlarged image of the balloon illuminated by a UV light source.

References

1. Katsonos, K, et al. ‘Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials’ JAmHeartAssoc 7:e011245 (2018).

2. Rahmatzadeh, M, et al., 2014 ‘A Novel Agent with Histone Deacetylase Inhibitory Activity Attenuates Neointimal Hyperplasia’ Cardiovasc Drugs and Therapy, 28:395-406 (2014).

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