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Role of Sirolimus-Coated Angioplasty Balloons: A Review of Current Status and Emerging Applications in Peripheral Arterial Disease

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Abstract

Sirolimus-coated angioplasty balloons (SCBs) have recently received CE mark and US FDA device breakthrough designation for use in treating peripheral arterial disease (PAD). Pre-clinical results have demonstrated their anti-inflammatory and anti-restenotic effects, while novel technologies have allowed for more efficient delivery of the drug into the peripheral arterial wall. Amidst recent controversies surrounding a medium-term mortality signal (at 2 and 5 years) and worse amputation free survival rate with paclitaxel-coated balloons (PCBs) vs. uncoated angioplasty balloons, newer studies have emerged to assess the efficacy and value of SCBs in the peripheral vasculature. We present a review of the current role of these newly introduced SCBs for treatment of arterial lesions in PAD.

Keywords: Drug-coated balloon; Drug-eluting technology; Drug-eluting stent; Mortality; Paclitaxel; Sirolimus; Peripheral vascular disease

Abbreviations: PAD: Peripheral Arterial Disease; CLTI: Chronic Limb Threatening Ischemia; PCBs: Paclitaxel-Coated Balloons; PTA: Percutaneous Transluminal Angioplasty; NIH: Neointimal Hyperplasia; AFS: Amputation-Free Survival; CAD: Coronary Artery Disease; ISR: In-Stent Restenosis; TLR: Target Lesion Revascularization; CAT: Cell Adherent Technology; SFA: Superficial Femoral Artery

Background

Peripheral arterial disease (PAD) is a progressive atherosclerotic disease of the lower extremities affecting more than 200 million people globally [1]. Chronic limb threatening ischemia (CLTI) represents the most severe form of PAD and is characterized by ischemic rest pain, non-healing lower extremity ulcers, and/or gangrene for more than 2 weeks, all attributable to restricted blood flow to lower extremities as a result of significant arterial occlusive disease [2]. CLTI profoundly impacts patient quality of life, and is associated with high mortality and amputation rates [3]. CLTI patients usually have multi-level infra-inguinal arterial stenoses and/or occlusions which leads to greatly decreased distal limb perfusion, a condition in which the metabolic requirement of distal foot tissue exceeds the available oxygen and nutrient supply. The primary goals of treatment are to relieve rest pain, heal wounds and restoration of a functional limb to improve quality of life. A cornerstone to management is timely arterial revascularization, without which the rates of major lower extremity amputation approaches 40% [2]. In patients with tissue loss at the foot, the re-establishment of direct pulsatile blood flow down to the ankle through at least one tibial artery is the preferred strategy for achieving these goals.

Endovascular-First Approach to CLTI

The advent of percutaneous transluminal angioplasty (PTA) through novel interventional techniques and devices, such as stents and balloons, have allowed minimally-invasive endovascular interventions to become first-line therapies for treating PAD [4,5]. An endovascular-first approach employing lower limb angioplasty as first line treatment to re-establish blood flow has been shown to be associated with a better amputation-free survival rate when compared with an open surgical approach [6]. Reintervention rates, albeit higher in the endovascular-first approach, have not impacted overall mortality, which was not different between the surgical and endovascular first groups. It has

been shown that standard balloon angioplasty in patients with long-segment and diffuse PAD, typically in the tibial arteries, has over 90% technical success rates, low frequency of complications and high limb-salvage rates [7]. However, the long-term primary tibial patency is often limited by the development of vessel recoil and restenosis, within 3 to 12 months due to barotrauma, inflammation and subsequent neointimal hyperplasia (NIH) [8].

The Role of Drug Elution & the Paclitaxel Controversy Issue

In order to mitigate the NIH effect, drug-coated devices predominantly centred on paclitaxel-based balloon platforms have been shown to achieve better outcomes in terms of long-term angiographic and clinical results, as opposed to standard uncoated devices, [9,10]. The European Society of Cardiology and the Society for Cardiovascular Angiography and Interventions have also since labelled the use of Paclitaxel coated balloons (PCB) as first line endovascular treatment for a wide range of femoro-popliteal indications in PAD [11,12]. However, the use of paclitaxel-based technology to minimize NIH in the peripheral vasculature has been thrown into doubt with the landmark *Journal of the American Heart Association (JAHA)* 2018 meta-analysis by Katsanos, et al. [13] which suggested an increase mortality risk in patients with femoropopliteal disease in the medium term (2 and 5 years) following the use of paclitaxel-eluting devices [risk ratio (RR) 1.68, 95% confidence interval (CI) 1.15 to 2.47] [13]. Albeit statistically insignificant, pooled data from a recent meta-analysis by Ipema, et al. [14] also noted lower 12 month amputation-free survival (AFS) rates in a cohort of predominantly CLTI patients, treated with PCB vs standard uncoated devices (82.5% vs. 88.7%; OR 0.79; 95% CI 0.23-2.75) [14]. Katsanos's group has also recently looked into the use of PCB for below the knee (BTK) infrapopliteal arteries and showed a worse AFS at 12 months compared to standard plain balloon angioplasty [(13.7% crude risk of death or limb loss compared to 9.4% in case of uncoated balloon angioplasty; hazard ratio 1.52; 95% CI: 1.12–2.07, p = 0.008)] [15].

Sirolimus Coated Balloons in the Peripheral Vasculature

Amidst the paclitaxel controversy, novel sirolimus coated balloons (SCBs) have been introduced into the peripheral arena as a potential substitute for PCBs. Sirolimus, like paclitaxel, is an anti-proliferative drug, which may be employed in an angioplasty balloon coating. It is cytostatic in nature and places the cell into the G_1 resting phase of the cell cycle, rendering the cell viable while still preventing activation of smooth muscle cell migration and proliferation. In contrast, paclitaxel acts on the M phase of the cell cycle, interfering with microtubule formation during mitosis, resulting in apoptosis [16]. Compared to paclitaxel, sirolimus also has a 100-fold higher margin of safety, broader therapeutic range, lower late lumen loss (LLL). Unlike paclitaxel, sirolimus is both anti-inflammatory and anti-restenotic [17].

As compared to paclitaxel-eluting stents, a lowered restenosis rate following the use of sirolimus-eluting stents has been a main driver for the use of sirolimus-eluting devices over paclitaxel-based technology for coronary artery disease (CAD) [18]. Within the coronary bed, SCBs have proven to be efficacious in the treatment of coronary artery lesions and in in-stent restenosis (ISR). In the RAVEL trial, the immunosuppressive and anti-inflammatory effects of sirolimus eluting stents were shown to inhibit the volume of neointimal hyperplasia (NIH) at 6 month [Sirolimus (0.9 ± 1.2 mm^3) vs. the bare metal stent (34.9 ± 28.9 mm^3); p = 0.01], consequentially reducing restenosis rates [19]. The 12-month data from the Nanoluté prospective registry to assess the clinical performance of a newly introduced SCB [20] also reported high procedural success rate (99.7%), low target lesion revascularization (TLR) rates (3.6%) and device-related adverse cardiac events (4.2%), in the coronary circulation despite a high rate of diabetes in the cohort (47%) [21].

However, sirolimus, as released from SCBs, absorbs and spreads slower throughout the entire artery wall, reducing its retention in tissues, and rapidly diluting its concentration to sub-therapeutic levels [22]. Hence SCBs, when used to treat larger surface areas in the periphery as compared to the coronary bed, appeared to have a much lower bioavailability, necessitating co-solvents, phospholipid nano-carriers, and reservoirs that act as frequent refills, in order for the drug to be delivered to the vessel wall at sustained therapeutic levels [22]. Development of new novel sirolimus-delivery technologies have since encouraged the use of SCBs in the treatment of occluded below the knee tibial arterial lesions in PAD cohorts. Currently there are 2 SCBs on the market for use in PAD - *MagicTouch™* (Concept Medical Inc., Surat, India) and *Selution SLR™* (MA Med Alliance SA, Mont-sur-Rolle, Switzerland), both of which have been granted breakthrough device designation for PAD from the US Food and Drug Administration (FDA) and both have gained *Conformité Européenne* (CE) mark.

Concept Medical's *MagicTouch™* improves bioavailability of sirolimus, through the use of unique phospholipid coating technology, allowing for 100% sirolimus sub-micron drug particle coating (circumferential coating) on balloon surfaces, facilitating controlled drug delivery into the vessel wall. Earlier animal studies on drug delivery using *MagicTouch™* have shown successful delivery of sirolimus into the medial layer of the vessel wall, with some presence of the drug extending into the adventitia, a promising solution to inducing vessel wall remodeling while preventing late lumen enlargement [22]. The Xtreme Touch Sirolimus Coated Ballons (*XTOSI)* trial, is an ongoing single-center clinical study to investigate the safety and efficacy of the *MagicTouch* PTA™ SCB catheter in the treatment of PAD in BTK infrapopliteal lesions [23]. *XTOSI* trial patients were highly complex CLTI patients with the majority having diabetes and end stage renal failure and Rutherford category stage 5 and 6 foot wounds. Preliminary results have shown 100% device and technical success, 100% freedom

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from device and procedure related mortality, and 97% limb salvage rate at 30 days. At 6 months, freedom from clinically driven TLR was 91% and primary patency, as assessed by Duplex ultrasound, was 82%. A moderate attrition rate was also reported.

Another new SCB, MedAlliance's *Selution SLR™* SCBs utilizes the amphipathic lipid properties of MedAlliance's *Cell Adherent Technology* (CAT™) coating, along with unique biodegradable micro-reservoirs of sirolimus on surfaces of the balloon. The micro-reservoirs and CAT amphipathic coating increases drug uptake into vessel walls, reducing dose loss to circulation during transit and inflation, thereby achieving extended elution kinetics [24]. The Selution SLR™ pharmacokinetics are more ideal to allow elution over a longer period of time, which may be required to reduce NIH effect and restenosis in the setting of tissue loss in diabetic foot wounds, which can take up to 6 months or longer to heal. Pre-clinical animal data for Selution SLR™ demonstrated successful delivery of sirolimus to vessel tissues and maintenance of therapeutic levels of the drug in tissues for over 60 days post-application [25].

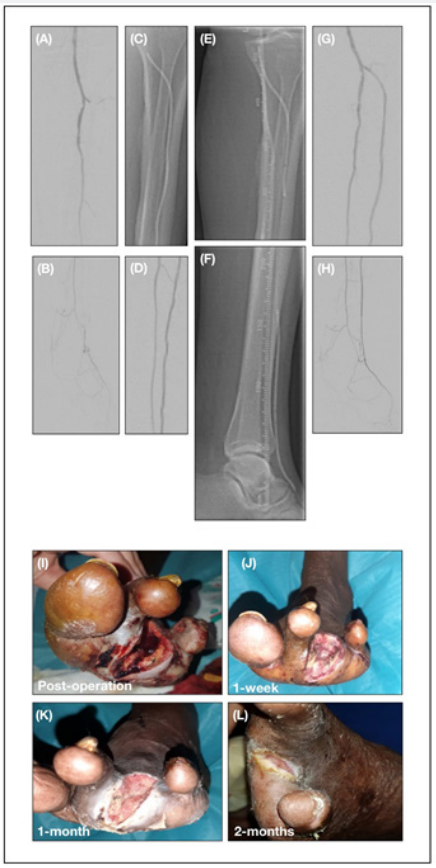

Figure 1: Angiographic findings showing (A) long anterior tibial artery (ATA) occlusion with reconstitution of a diseased dorsalis pedis artery and with only peroneal artery runoff in the pre-intervention angiographic run (B); (C) antegrade subintimal wiring of the ATA and ballooning with non-compliant (NC) high pressure JADE™ balloons (2x180mm and 3 x180mm) with subsequent fast flow in the ATA (D). The ATA was treated with SELUTION SLR™ from knee to foot (E & F) to cover 1cm proximally and distally to where the NC balloons were placed to avoid geographical miss. (G) & (H) show excellent fast flow through the ATA post SELUTION™ elution. The corresponding clinical picture showing the diabetic foot wound trajectory (I) immediately post 3rd and 4th toe amputation (J) at 1-week post procedure (K) 1-month post procedure and (L) 2-months post procedure (almost healed).

In the *SELUTION* first-in-man trial (NCT02941224), 50 patients were treated with *Selution SLR™* SCBs for complex superficial femoral and popliteral artery disease (mean lesion length 64.30 mm, 30% total complete occlusion, 34% moderate-severe calcification) [26]. The study achieved its primary endpoint at 6 months with a 0.19 mm median late lumen loss (-1.16 - 3.07), along with a TLR rate of 2.3%, zero incidences of major amputation and death, and improvements in at least 1 category of Rutherford Classification in 73% of patients. Analysis of percentage drug delivery 1-hour post-application from animal pre-clinical studies showed higher transference of drug to vessel using *Selution SLR™*, as compared to PCBs in the LUTONIX and IN. PACT studies [27]. At 12 months, improvement in at least 2 categories of Rutherford Classification from baseline were reported in 78% of patients ($p < 0.0001$), along with a TLR rate of 4.3% and zero incidences of major amputation and death [27]. Kaplan Meier estimates reported an 85% freedom from TLR 1 year post-procedure within the *SELUTION* CLI cohort [28]. Recently reported 2-year data from the

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same study showed sustained improvement in Rutherford classification (67% more than 2 categories, 84% more than 1 category), a TLR rate of 4.3%, zero incidences of major amputation or death, improvement in walking (walking distance score 20.1 at baseline to 72.5 at 24 months), and in ankle-brachial pressure index (0.75 at baseline to 0.97 at 2 years, p = 0.02). The *SELUTION* trial investigators concluded that *Selution SLR*™ SCBs were safe and effective in treating superficial femoral artery (SFA) and popliteal lesions, having shown clinical improvements in the Rutherford classification, ankle-brachial index and walking-impairment at 6, 12 and 24 months.

In the Physician initiated, prospective, non-Randomized single-center trial, investigating the safety and Efficacy of the Treatment with the Selution Sirolimus Coated Balloon in TASC C and D Tibial occlusive disease In patients with critical limb Ischemia from SinGaporE (*PRESTIGE*) trial (NCT04071782), *Selution SLR™* was studied for the treatment of complex tibial artery occlusive disease (100% TASC C-D; 63.3% moderate-severe calcification) in 25 patients with CLTI within a multi-ethnic Asian cohort from Singapore [29]. Patients were complex, having high rates of co-morbidities such as diabetes (88%) and end stage renal failure (44%). Screening and enrollment occurred across a relatively quick 3-month time window (October 2019 and December 2019), allowing for a forecasted completion 6-month follow-up data by June 2020. The study's endpoints include technical and clinical (improvement of Rutherford Classification at follow-up) success, freedom from device- or procedure-related mortality at 30 days, freedom from TLR at 6 months and 12 months, freedom from major target limb amputation, and successful wound healing (defined as >70% wound closure). Early results are promising in terms of primary patency and successful wound healing. We illustrate below an early case example of a patient from the *PRESTIGE* study (Figure 1).

PRESTIGE Case Example

61-year-old Indian male, community ambulant with a past history of diabetes, hypercholesterolemia and hypertension presented with a 4-week history of worsening left third and fourth toes gangrene. A left lower limb angioplasty of the anterior tibial artery (ATA) with third and fourth toe ray amputation was performed. Using a 0.018 inch wire support platform, a long ATA occlusion was crossed subintimally (TASC D, 300mm occlusion length). Pre-dilation was performed over an 0.014 inch wire using the senior author's (TYT) preferred non-compliant high pressure *JADE™* balloon (OrbusNeich, Hong Kong). *Selution SLR™* was then used to treat the proximal and distal ATA (3x150mm and 2.5x150mm, respectively). Technical success was achieved - the final outcome showed <30% residual stenosis and the post-angioplasty angiogram findings showed two-vessel run off via the anterior tibial and peroneal arteries. Follow-up at 2 months showed primary patency of the target vessel and 90% wound closure.

A variety of balloon diameters were utilized (2-4mm) during the PRESTIGE study. Experience so far has been positive using *Selution SLR™*. In contrast to the use of PCB technology, the balloon was noted to have good trackability over an 0.018-inch wire platform, a short deflation time, and minimal slow flow phenomenon after application to arterial wall even below the ankle. No serious adverse events have occurred during usage of *Selution SLR™*. A post-market SFA/BTK study in CLTI patients is planned in the near future at Singapore General Hospital, Singapore.

Conclusion

The various trials studying SCB efficacy in the treatment of both CAD and PAD appear to provide promising angiographic (low late lumen loss, high patency rates) and clinical results (low TLR and adverse device-related events). It will be interesting to see how SCB efficacy, in the peripheral circulation, will hold up against the test of time and whether we see any adverse signals from their use, as we have seen with paclitaxel. The quest for the ideal balloon continues as future studies using sirolimus-based technology should address the short-comings of earlier paclitaxel-based trials, including the effects of the drug on late lumen enlargement vs. restenotic efficacy in complex patients, and the lack of long-term follow-up.

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