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USE of IMplanting the Biotronik PassEo-18 Lux drug coated balloon to treat failing haemodialysis arteRiovenous FIstulas and grafts (SEMPER FI Study)

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Tze Gek Ho[1], Tjun Yip Tang[2], Charyl Jia Qi Yap[3], Hao Yun Yap[3], Shaun Wen Yang Chan[1], Chuo Ren Leong[1] and Dexter Yak Seng Chan[1]

Abstract

Background: Plain old balloon angioplasty has been the mainstay of treatment for arteriovenous fistula (AVF) stenoses. Recent studies suggest that drug coated balloons (DCB) may significantly reduce re-intervention rates on native and recurrent lesions. The Passeo-18 Lux DCB (Biotronik AG, Buelach, Switzerland) is packaged with a 3.0 µg/mm^2 dose of paclitaxel. The hypothesis is that its use provides better target lesion primary patency (TLPP), primary assisted patency (PP), secondary patency (SP) rates and reduces the number of visits for re-intervention in a cohort of patients with stenotic AVF and arteriovenous grafts (AVGs).

Methods: The USE of IMplanting the Biotronik PassEo-18 Lux DCB to treat failing haemodialysis arteRiovenous FIstulas and grafts trial (SEMPER FI) was a prospective double-centre, multi-investigator, non-consecutive, non-blinded single-arm study investigating the efficacy and safety of the Passeo-18 Lux DCB in patients with stenotic AVF/AVG lesions between January 2021 and January 2022. Patient demographics, clinical characteristics, vascular access history, operative indications, details and outcomes were collected prospectively. TLPP, circuit access primary patency (CAP), PP, SP and deaths 6- and 12-months post-intervention were studied.

Results: Ninety-one patients with 110 lesions were recruited across the two centres. 62.6% ($n = 57$) were male with a median age of 63.5 years (SD = 10.5). 62.6% ($n = 57$) were taking anti-platelets. Eighty-five AVFs and six AVGs were treated. 60% ($n = 54$) of AVFs intervened were radiocephalic. 52.7% ($n = 58$) of targeted lesions were juxta-anastomotic stenosis (JAS) and one-third ($n = 33$) at the AVF/AVG outflow. 70.9% ($n = 78$) of lesions were recurrent. Median time from last intervention was 219 days. 78% of target lesions ($n = 85$) and circuits ($n = 70$) were patent at 6-months, of which 96.7% ($n = 87$) of those requiring assisted intervention were patent.

Conclusion: This study shows that the Passeo-18 Lux DCB can be an effective and safe tool in the treatment of failing haemodialysis AVFs/AVGs.

Keywords

Passeo-18 lux, drug coated balloon, arteriovenous fistulas, arteriovenous grafts, haemodialysis, balloon angioplasty

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Background

Stenosis is the commonest problem with haemodialysis arteriovenous fistulas (AVF) and arteriovenous grafts (AVG), leading to inadequate dialysis and eventual access thrombosis. Conventional plain old balloon angioplasty (POBA) is associated with high recurrence rates of stenosis and repeated interventions. The advent of successful

[1]Department of General Surgery, Khoo Teck Puat Hospital, Singapore, Singapore
[2]The Vascular & Endovascular Clinic, Gleneagles Medical Centre, Singapore, Singapore
[3]Department of Vascular Surgery, Singapore General Hospital, Singapore, Singapore

Corresponding author:
Dexter Yak Seng Chan, Department of General Surgery, Khoo Teck Puat Hospital, 90 Yishun Central, Singapore 768828, Singapore.
Email: chan.dexter.ys@ktph.com.sg

drug-eluting technology in the treatment of the coronary circulation and in the peripheral arterial circulation has prompted the use of drug-coated balloons (DCB) in the access fistula circuit for venous stenosis and in-stent restenosis. Recent studies suggest that DCBs may significantly reduce re-intervention rates on native and recurrent lesions.[1–3]

The restenosis process is in-part or in-whole the result of neo-intimal hyperplasia (NIH), considered the main culprit in access circuit target lesion stenosis. NIH is the blood vessel's healing response to barotrauma post-angioplasty.[1] A critical component of NIH is the cellular proliferative stage with mononuclear leucocytes being the primary inflammatory cell type. The rationale for drug elution is to block the NIH response with an anti-metabolite such as paclitaxel. The role of drug elution for vascular stenosis is not to obtain a good haemodynamic and luminal result but to preserve a good result following POBA, from later restenosis from NIH and minimise re-interventions and hospital readmissions.

A meta-analysis by Khawaja et al.[4] suggested that DCBs conferred some benefit in improving target lesion primary patency (TLPP) in AVFs. An updated meta-analysis showed that DCBs appeared to be a better and safe alternative to POBA in treating patients with stenosis based on 6- and 12-months primary patency and increased intervention-free period.[5]

The Passeo-18 Lux (Biotronik AG, Buelach, Switzerland) DCB is packaged with a 3.0 µg/mm^2 dose of paclitaxel. Recent studies have shown that high-dose paclitaxel coating with this DCB is useful for preventing restenosis, decrease lumen loss and target lesion revascularisation in the peripheral vasculature and has recently been tested in the dialysis access circuit.[6,7]

The aim of this study is to assess the safety and efficacy of the Passeo-18 Lux DCB in patients with stenotic lesions in the AVF and AVG (graft-vein junction) haemodialysis access circuit.

Materials and methods

Study design

The U**SE** of I**M**planting the Biotronik **P**ass**E**o-18 Lux DCB to treat failing haemodialysis arte**R**iovenous **FI**stulas and grafts trial (SEMPER FI) was a prospective double-centre, multi-investigator, non-consecutive, non-blinded single-arm study investigating the efficacy and safety of the Passeo-18 Lux balloon in patients with stenotic lesions in the AVF and AVG (graft-vein junction) haemodialysis access circuit.

The hypothesis was that the use of the Passeo-18 Lux DCB provides better TLPP, primary assisted (PP), secondary patency (SP) rates and reduces the number of hospital visits for re-intervention in a cohort of end-stage renal failure (ESRF) patients with stenotic AVF/AVGs than POBAs.

Ethical considerations

Ethics approval was obtained from the local Human Research Ethics Committee (CIRB ref: 2020/2902). The study was carried out in accordance with the *Declaration of Helsinki* and registered on *Clinicaltrials.gov* (NCT04381754). Informed consent was obtained from all participants.

Data collection and recruitment

ESRF patients with a failing AVF/AVG on follow-up with the Departments of Vascular Surgery at Singapore General Hospital and Khoo Teck Puat Hospital were recruited between January 2021 and January 2022. Patient demographics, clinical characteristics, vascular access history, operative indications, details and treatment outcomes were collected prospectively.

Eligibility

Patients with a native upper limb AVF/AVG currently in use for haemodialysis, with a significant inflow or outflow stenosis (defined as diameter reduction >50% compared to adjacent normal segment and/or other evidence of AVF malfunction). Malfunction was defined as the AVF performing inadequate dialysis and clinical signs of a failing dialysis access:

- Inadequate fistula volume flow – Qa as measured by ultrasound <500 mL/min
- Qb – significant stenosis suggested when pump speed is <200 mL/min, venous pressure is >140 mmHg and/or arterial pressure ⩾100 mmHg.
- Maximum of two discrete stenoses (separated by >3 cm) were allowed to be included

Inclusion criteria:

- Native AVF/AVG created >2 months prior to index procedure and had undergone ⩾10 haemodialysis sessions utilising two needles
- Target lesion located between the anastomosis to the axillary-subclavian vein junction, as defined by insertion of the cephalic vein for AVF. Only the graft-vein junction AVG lesions will be included.
- Target lesion stenosis had to be >50% on initial fistulogram angiographic assessment and in keeping with clinical indicators for intervention
- Stenosis had to be <10 cm in length (to allow for potential treatment with single paclitaxel-coated balloon (PCB) (length 12 cm))

Stenosis had to be initially treated successfully with a high-pressure plain balloon prior to PCB, defined by:

(a) No clinically significant dissection (flow-limiting)

(b) No extravasation requiring treatment/stenting

(c) Residual stenosis ⩽30% by angiographic measurement

(d) Ability to completely efface the lesion waist using the pre-dilation balloon

No more than one additional ('non-target') lesion in the access circuit that had to be successfully treated (⩽30% residual stenosis) before drug-elution. Separate lesion was defined by at least 3 cm in distance from the target lesion.

Exclusion criteria

Immature circuits, thrombosed AVFs/AVGs treated ⩽30 days prior to the index procedure, presence of central venous stenosis were excluded. Subjects with more than two lesions in the access circuit or a secondary non-target lesion that were not successfully treated or where final angioplasty treatment required a stent or drug-eluting balloon >8 mm in diameter were also excluded. Patients should not have paclitaxel, iodinated contrast or antiplatelet allergies.

Study protocol

Target lesions were treated in the standard fashion. A minimum 6 Fr sheath was used for all access procedures. An angiogram image was acquired with contrast media showing the Trial Index Stenosis before intervention, and to ensure that the fistula/graft was not thrombosed. Lesions were pre-dilated with a standard high-pressure balloon until balloon was fully effaced, followed by treatment with a Passeo18 Lux DCB. Completion angiogram images were acquired after DCB use and follow-up was with ultrasound duplex and monitoring of haemodialysis parameters.

Outcomes

Outcomes at 6- and 12-months post-intervention were studied:

- TLPP – patency with no re-intervention to the area 5 mm proximal to, within, and 5 mm distal to, the index treatment segment and a duplex-defined restenosis of ⩽50%.
- Circuit access primary patency (CAP) – duration of time measuring intra-access patency starting from date of Passeo-18 Lux DCB angioplasty to thrombosis or intervention to re-establish patency
- PP – interval date of angioplasty with Passeo-18 Lux DCB until thrombosis
- SP – duration of time measuring intra-access patency from date of angioplasty with Passeo-18 Lux DCB to time of vascular access abandonment,
- and deaths.

Statistical analysis

Statistical analysis was performed using R Version 4.0.4. Categorical variables were expressed as absolute numbers and percentage. Mean and standard deviation were measured for variables with normal distributions. The Kaplan-Meier estimator was used to determine the number of patients at risk of decreased TLPP, CAP, SP and PP over time.

Results

Patient demographics

Ninety-one patients were recruited across the two centres. (Table 1) 62.6% ($n=57$) were male. Median age was 63.5 (SD = 10.5) years old. Majority of patients were Chinese ($n=56$, 61.5%) and Malay ($n=29$, 31.9%). At least two-thirds were diabetic ($n=78$), hypertensive ($n=81$) or had hyperlipidaemia ($n=69$). 42% ($n=39$) had coronary artery disease. Only 8.9% ($n=8$) were smokers. 62.6% ($n=57$) of patients were taking anti-platelets, of which majority were on aspirin.

Eighty-five AVFs and six AVGs were treated. The left AVF/AVG was most commonly intervened on at 80.2% ($n=73$). Almost 60% ($n=54$) were radiocephalic AVFs, followed by brachiocephalic AVF/AVGs ($n=28$, 30.8%). 72.5% ($n=66$) of patients required intervention for dropping access flow, followed by 15.4% ($n=14$) for high venous pressures. Mean age of dialysis access was 2.77 years.

Lesion characteristics

About half of the 110 lesions ($n=58$) targeted was at the juxta-anastomotic stenosis (JAS) and one-third ($n=33$) at the AVF/AVG outflow (Table 2). 70.9% ($n=78$) of these lesions were recurrent and median time from last intervention was 219 days. An average 77.5% of stenosis was identified at each intervention, with a mean lesion length and diameter of 54.7 and 5.9 mm respectively.

Outcomes

There was a TLPP of 78% ($n=85$) of target lesions and 77.8% ($n=70$) CAP at 6-months, of which 96.7% ($n=87$) of those requiring assisted intervention were patent (Table 3).

By 12-months, TLPP was 45.4% ($n=44$) and CAP was 42.3% ($n=33$). 88.5% ($n=69$) of those requiring assisted

Table 1. Patient demographics.

	$n = 91$
Age (±SD – standard deviation)	63.5 ± 10.5
Gender (%)	
Male	57 (62.6)
Female	34 (37.4)
BMI (±SD)	25.6 ± 5.6
Race (%)	
Chinese	56 (61.5)
Indian	6 (6.6)
Malay	29 (31.9)
Co-morbidities (%)	
Diabetes mellitus	62 (68.1)
Smoking	8 (8.9)
Hyperlipidaemia	69 (75.8)
Hypertension	81 (89)
Cerebrovascular disease	9 (9.9)
Coronary artery disease	39 (42.9)
Malignancies	9 (9.9)
Medications (%)	
Diuretics	19 (20.9)
Beta blockers	64 (70.3)
ACE-inhibitors	9 (9.9)
Statins	73 (80.2)
Angiotensin receptor antagonists	14 (15.4)
Calcium channel blockers	22 (24.2)
Diabetic medications	47 (51.6)
Nitrates	21 (23.1)
Anti-coagulants	4 (4.4)
Anti-platelets	57 (62.6)
Aspirin	58 (63.7)
Clopidogrel	18 (19.8)
AVF/AVG side (%)	
Left	73 (80.2)
Right	18 (19.8)
AVF type (%)	
BA (brachioaxillary)	4 (4.4)
BB (brachiobasilic)	4 (4.4)
BC (brachiocephalic)	28 (30.8)
RB (radiobasilic)	1 (1.1)
RC (radiocephalic)	54 (59.3)
Median age of dialysis access, years (IQR – interquartile range)	2.77 (1.38–4.18)
Indication for intervention (%)	
Dropping access flow	66 (72.5)
Recirculation	4 (4.4)
High venous pressure	14 (15.4)
Cannulation difficulties	7 (7.7)
Prolonged bleeding	3 (3.3)

intervention were patent. Mean time to circuit re-intervention was 206.7 ± 87.1 days (CAP) and 211.6 ± 90.5 days (TLPP). SP was preserved at 6 and 12-months at 100% ($n = 90$) and 98.7% ($n = 78$) respectively.

Only one AVF was abandoned throughout the period of study at the 337th day. One patient (1.1%) died within

Table 2. Lesion characteristics (inter-needling = area between cannulation sites, cannulation zone = where AVF was cannulated i.e. 'a' and 'v' sites).

	Number of target lesions ($n = 110$)
Location of target lesion (%)	
Cephalic arch	7 (6.4)
JAS	58 (52.7)
Outflow	33 (30.0)
Inter-needling	5 (4.5)
Cannulation zone	1 (0.9)
Vein-graft junction	3 (2.7)
In-stent and stent-edge stenosis	3 (2.7)
De novo (%)	32 (29.1)
Recurrent (%)	78 (70.9)
Median time from last intervention, days (±SD)	219.0 (139.5–420.8)
Mean lesion length, mm (±SD)	54.7 ± 22.3
Mean lesion diameter, mm (±SD)	5.9 ± 0.84
Mean percentage stenosis, % (±SD)	77.5 ± 10.7

6-months and a total of 12 patients (14.3%) had died by the end of the study period. Causes of death were largely related to patients' underlying medical conditions and co-morbidities, unrelated to the procedure.

The Kaplan-Meier curves (Figures 1–5) illustrate the various outcomes described. All suggest that patients are increasingly at risks of restenosis and requiring re-intervention as time passes (within limits of the study period).

Discussion

AVF/AVG stenoses have long been known to cause difficulties with haemodialysis. Current KDOQI guidelines recommend endovascular intervention when stenosis of ⩾50% is present with associated reductions in fistula flow rates and high venous pressures.[8] Intervention with DCBs have been shown to have favourable TLPP and overall access flow outcomes.[2] PCBs had also shown to be effective in reducing rates of restenosis even within Asian populations.[1,8]

Our study showed similarly favourable outcomes with the Passeo-18 Lux DCB in terms of decreased time to AVF/AVG re-intervention and overall CAP, SP and TLPP rates compared to other DCBs. In keeping with other studies like the ISABELLA, IN.PACT AV Access (IN.PACT Admiral PCB (3.5 μg/mm^2 dose; Medtronic, Dublin, Ireland)) and Lutonix AV trials (Lutonix PCB (2.0 μg/mm^2 dose C.R. Bard, New Hope, Minnesota)), our study demonstrated the efficacy and success of the use of the Passeo-18 Lux DCB for AVF/AVG stenosis.[3,8–11]

78% of target lesions and circuit were patent at 6-months in our study – aligned with existing data supporting the efficacy of DCBs such as the Passeo-18 Lux in treating stenotic lesions.[4] Comparatively, 6-months TLPP results

Table 3. Outcomes.

	6-Months	12-Months
Target lesion primary patency	85/109 (78.0)	44/97 (45.4)
Mean time to re-intervention, days (±SD)	211.6 ± 90.5	
Circuit access primary patency	70/90 (77.8)	33/78 (42.3)
Mean time to re-intervention, days (±SD)	206.7 ± 87.1	
Primary assisted patency	87/90 (96.7)	69/78 (88.5)
Mean time to thrombolysis, days (±SD)	193.3 ± 79.8	
Secondary patency	90/90 (100.0)	78/79 (98.7)
Time to abandonment, days	337.0	
Deaths	1/91 (1.1)	12/91 (14.3)
Time to death, days (±SD)	258.7 ± 91.5	

91– 12 deaths at 12 months – 1 AVF Abandoned = 78.

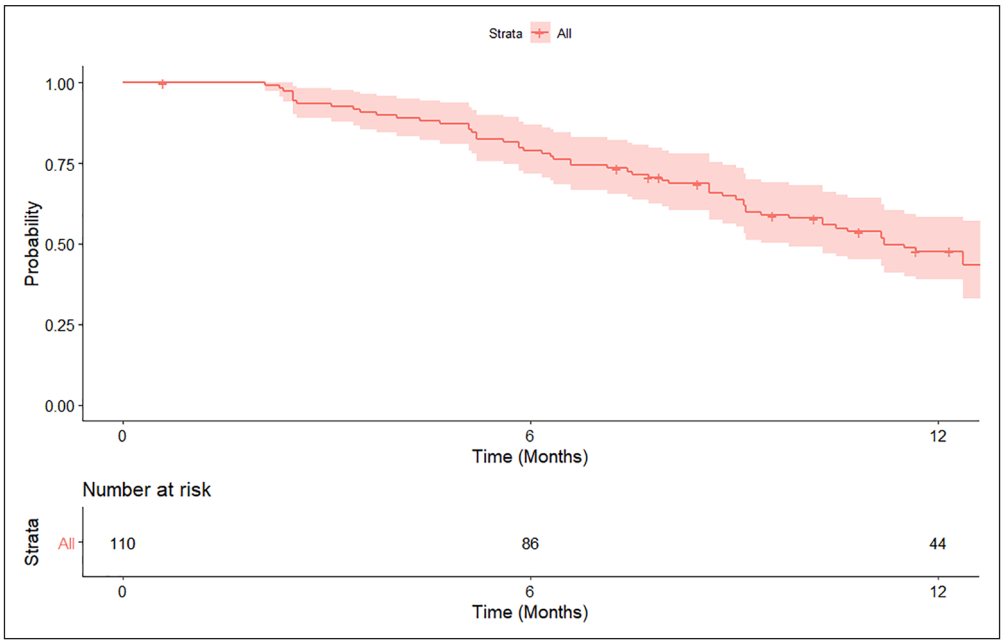

Figure 1. Target lesion primary patency (TLPP).

from the Passeo-18 Lux DCB were superior to that of Lutonix at 71.4% but inferior to IN.PACT at 82.2%.[9,11] The IN.PACT AV Access Study showed the clear utility of DCBs in maintaining TLPP.

Although only 42.3% of target lesions were patent at the end of this study, this could potentially be contributed to by older AVFs and that majority of these lesions were recurrent – as chances of restenosis were increased with both increased AVF age and multiple recurrences.[8] Moreover, the IN.PACT AV study had stricter inclusion and exclusion criteria, with fewer recurrent lesions and stricter use of antiplatelets which could have contributed to better outcomes. Nonetheless, results were similar to TLPP of 44% in the Lutonix trial at 12-months, which could suggest a weaning effect of the drug and recurrence of stenosis.[11]

PP and SP were preserved at both 6- and 12-months; only about 40% of patients required re-intervention by 12-months, suggesting that the Passeo-18 Lux DCB can be effective when coupled with other measures like thrombolysis, supported by a recent meta-analysis by Liu et al.[12] Additionally, only one AVF was abandoned approaching the end of the study period, indicating that intervention was useful.

The only other trial using the Passeo-18 Lux DCB by Therasse et al. showed that whilst there was no significant difference in their primary end-point of late lumen loss, their study demonstrated a decreased incidence stenosis (54.2% vs 61.7%) and binary restenosis ⩾50% (56.5% vs 81.1%). The number of AVF failures after 12-months was lower for DCB than for POBA (45% vs 66.7%).[7] These findings, in addition to ours, may indicate that the Passeo-18 Lux DCB could be effective in treating haemodialysis dysfunction.

However, an investigator-led multicentre trial by Karunanithy et al.,[13] showed no benefit for AVFs with

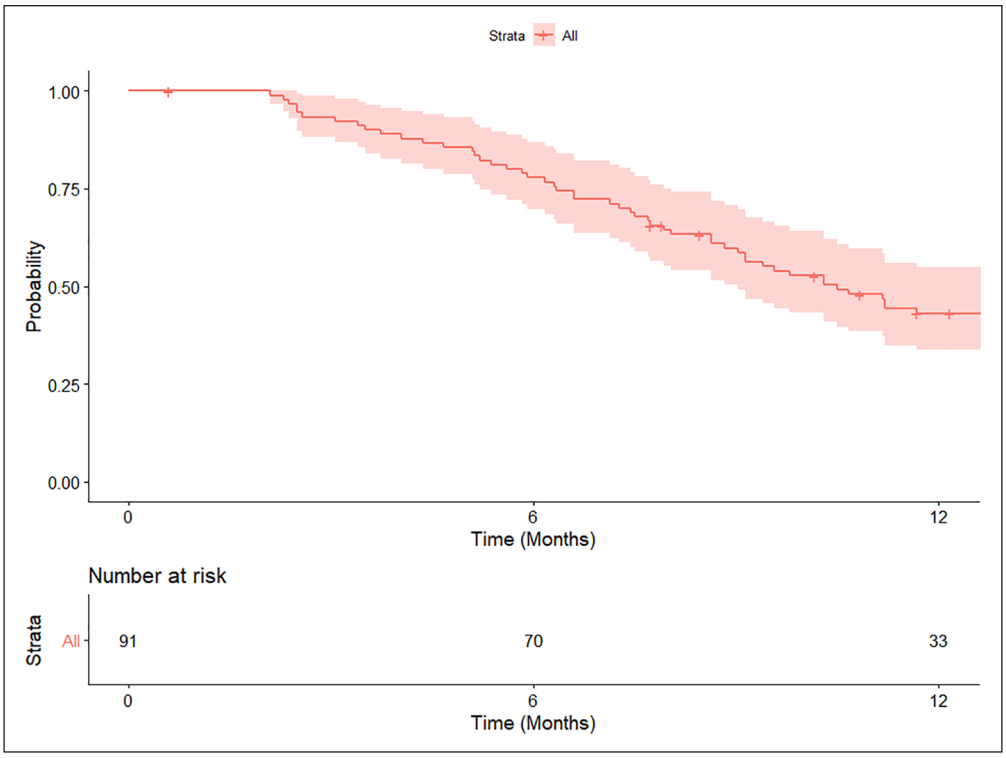

Figure 2. Circuit access primary patency (CAP).

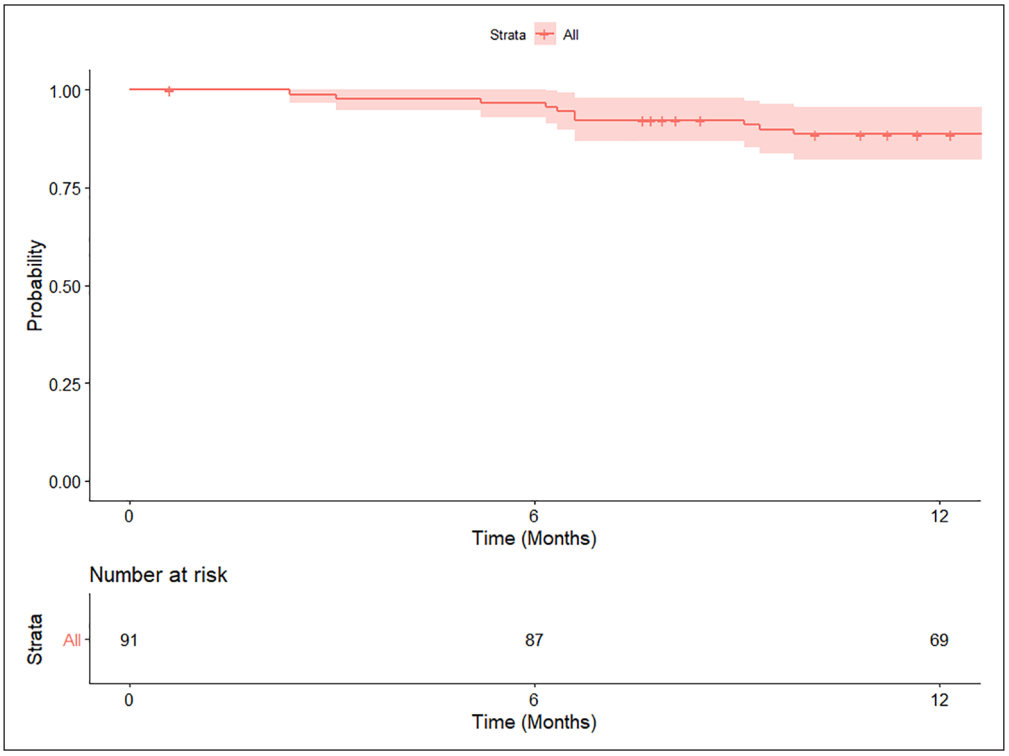

Figure 3. Primary assisted patency (PAP).

regards to time to end of TLPP. This casts doubt on the efficacy of PCB versus high-pressure balloon angioplasty AVF treatment. In that study, a low-dose PCB was used. At 6-months, the TLPP was 71.7% in the PCB group, compared with 84.5% in the POBA group. By 12-months, these figures were 52.5% and 58.8% respectively.

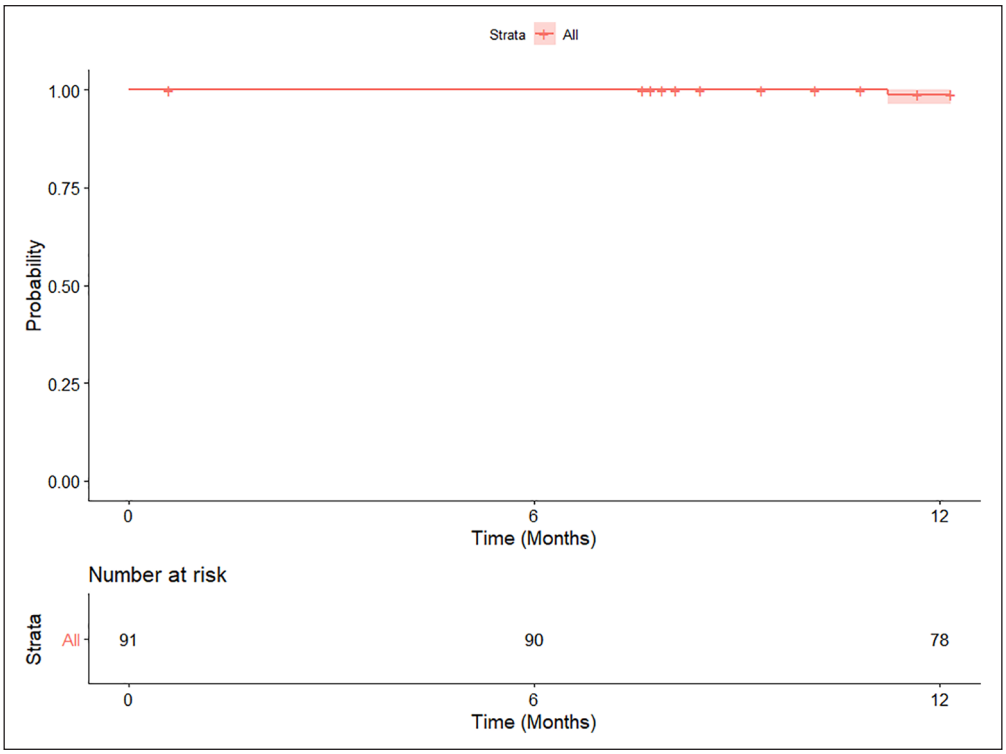

Figure 4. Secondary patency (SP).

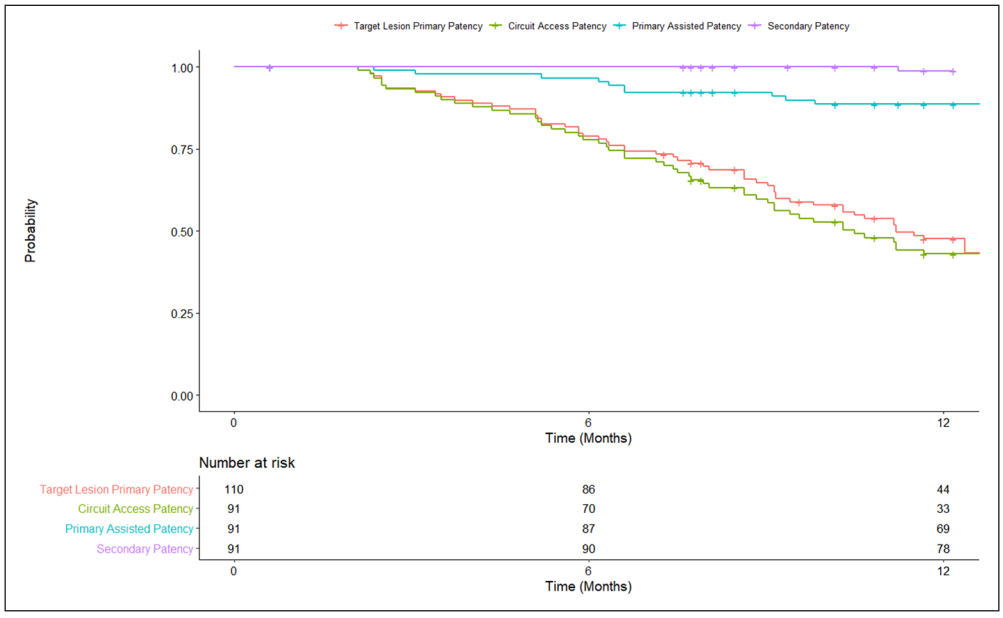

Figure 5. Overall outcomes.

Interestingly, angioplasty alone suggested a better outcome than those treated with PCB although this did not reach statistical significance. It is unsure if this was due to a short inflation time of the PCB. Nonetheless, this adds to uncertainty of the efficacy of paclitaxel use in AVFs.

Safety profiles showed that only 1% of the study population died at 6-months and 14.3% died at 12-months. Overall deaths were secondary to patients' underlying comorbidities, including metastatic malignancies, cardiac disease and other medical causes. No deaths were related to balloon-associated complications. This supports the overall safety profile of the Passeo-18 Lux DCB.

Although Troisi et al.[1] mentioned increased mortality risks after DCB applications – this was not evident in our

study. This may be due to the difference in paclitaxel levels used. Brodmann et al.,[6] reported rates of mortality of about 6.5% but that is likely attributed to the study being an investigation of infra-inguinal lesions which inherently carries with it increased risks of amputations, unlike in our study regarding AVF/AVG stenoses. The increased mortality risks observed in the meta-analysis by Katsanos et al.[14] following the use of PCB in peripheral arterial disease may contribute to the worry on the safety on paclitaxel.

There has not been evidence of a significant increase in mortality in patients post-DCB treatment when used in dialysis access circuits. A meta-analysis of 16 studies by Chen et al.[15] reported no all-cause mortality risk at 6-, 12- and 24-months. Another meta-analysis by Dinh et al.[16] of eight studies comparing mortality outcomes likewise did not find any statistically significant differences in mortality at 6- to 12-months follow-up between PCB and POBA subgroups. Pooled data from analysis across data from DRECOREST I and II trials and the FINNPTX trial by Björkman et al.[17] showed no significant difference in the overall mid- (3.5 years) and long-term (5-years) survival between both treatment and control groups. Hence, evidence does not suggest that paclitaxel use in access circuits leads to higher mortality.

In light of contradicting results in circuit and lesion patency, along with some concerns of mortality risks with the use of PCBs, sirolimus-coated balloons (SCB) have been suggested as an alternative. The MATILDA and ISABELLA trials assessing MagicTouch SCB (Concept Medical Inc., Tampa, FL, USA) and Selution sustained limus release (SLR)™ (M.A.MedAlliance SA, Nyon, Switzerland) had reported data on the use of SCB in the endovascular treatment of failing AVFs.[8,18] One-year results from the single-arm, prospective MATILDA trial reported the TLPP and CAP to be 58% and 44%, respectively, with no adverse events or death pertaining SCB use.[18]

This study presents several limitations. Firstly, it does not discriminate between JAS and non-JAS lesions, or recurrent or de novo lesions. Notably, JAS lesions and recurrent lesions were likely more prone to restenosis requiring repeat intervention.[14] It also did not explore other procedure-related complications except mortality. There remains further room for research regarding the efficacy of the Passeo-18 Lux beyond 12-months, as well as comparing results against POBA. There are also opportunities for monitoring outcomes beyond this 12-month interval to fully determine the efficacy and safety profile of the Passeo-18 Lux DCB.

Conclusion

This double-centre, non-blinded single-arm study showed that the Passeo-18 Lux DCB could be an effective and safe tool in treating failing haemodialysis AVFs/AVGs. Overall TLPP, PP and SP rates were improved, if not at least comparable, to outcomes conferred by traditional POBA. There remains room for further research regarding differences between treatment of de novo and recurrent lesions, procedural-related complications and its long-term effects.

Declaration of conflicting interests

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Ethical approval

All the authors have read and approved of the content to be submitted for publication. SEMPER FI is registered on *Clinicaltrials.gov* (NCT04381754).

ORCID iDs

Tze Gek Ho https://orcid.org/0009-0005-9943-5112
Tjun Yip Tang https://orcid.org/0000-0002-8524-7912
Charyl Jia Qi Yap https://orcid.org/0000-0002-8606-0842

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