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REVIEW VENOUS INTERVENTIONS

The Role of Drug-Coated Balloon in Haemodialysis Arteriovenous Fistula Stenosis Management

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Abstract Arteriovenous fistula (AVF) stenosis is a common problem leading to dialysis access dysfunction. The conventional balloon (CB) is the most commonly used device during angioplasty but suffers from poor durability of results due to neointimal hyperplasia-mediated recurrence. The drug-coated balloon (DCB) is an adjunct to balloon angioplasty that reduces neointimal hyperplasia, thereby improving post-angioplasty patency. Despite the heterogeneity of DCB clinical trials to date, the evidence suggests that DCBs of different brands are not necessarily equal, and that patient selection, adequate lesion preparation and proper DCB procedural technique are important to realize the benefit of DCB angioplasty.

Keywords Haemodialysis · Arteriovenous fistula · Stenosis · Drug-coated balloon · Drug-eluting balloon · Paclitaxel-coated balloon

Introduction

Stenosis is the Achilles heel of the arteriovenous fistula (AVF), leading to dialysis access dysfunction. While conventional balloon angioplasty is the standard of care, long-term results are disappointing due to recurrence. Ensuring optimal outcomes from angioplasty of AVF stenosis requires effective dilatation of the vessel wall and prevention of neointimal hyperplasia (NIH). Drug-coated balloons (DCBs) have been developed to prevent NIH following angioplasty, and there is now increasing literature addressing its role in haemodialysis access.

Definitions

The following terms are used in this review. Conventional balloon (CB) refers to any semi-compliant normal pressure balloon with a rated burst pressure (RBP) that is typically under 20 atmospheres (atm), while high-pressure balloon (HPB) refers to any non-compliant balloon with RBP higher than 20 atm.

Target lesion primary patency (TLPP) is defined as freedom from clinically driven target lesion revascularisation, while access circuit primary patency (ACPP) is defined as freedom from repeat intervention in the access circuit or access circuit thrombosis.

Rationale for DCB Use

There are several contributing causes of NIH, leading to vessel wall thickening and formation of AVF stenosis, such as uraemia-induced endothelial cell dysfunction, haemodynamic stresses from increased blood flow, vessel wall injury from needling for dialysis and barotrauma during balloon angioplasty [1]. DCBs are semi-compliant balloons coated with an anti-proliferative drug (most commonly paclitaxel) and excipient. The deposition of paclitaxel onto the vessel wall aims to limit NIH by preventing the disassembly of microtubules, thereby inhibiting proliferation of vessel wall smooth muscle cells and neointima formation.

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Evidence for DCB in Dialysis Access

While early retrospective studies suggested that DCB is promising in prolonging patency after angioplasty, several randomized clinical trials (RCT) have since been conducted with mixed results (Table 1). Comparison between these studies is difficult due to the heterogeneity that exists between these RCTs with regards to study population and technique. A review of the most pertinent studies will illustrate the challenges in interpreting the current evidence.

IN.PACT DCB RCTs

The IN.PACT AV Access study is a multi-centre RCT comparing the IN.PACT AV DCB (Medtronic) to CB angioplasty in 330 participants with AVF stenosis [2]. The RCT was positive with superior 6-month TLPP in the DCB arm (82.2% vs 59.5%, $p < 0.001$). Secondary endpoints such as ACPP and number of interventions to maintain patency at 6 months were also superior in the DCB arm. Recently published 12-month data continue to show DCB's benefit (TLPP of 63.8% vs 43.6%, $p < 0.001$) [3].

Similarly, Irani et al. [4] reported superior outcomes in a single-centre RCT comparing the IN.PACT Admiral DCB (Medtronic) to CB in 119 participants (98 AVFs, 21 AVGs). The 6-month TLPP was 81% versus 61% (HR 0.53, 95% CI 0.295–0.952, $p = 0.03$) in the DCB and CB arms, respectively. The benefit continued to be observed at 1 year with TLPP of 51% versus 34% (HR 0.615, 95% CI 0.381–0.993, $p = 0.047$).

Interestingly, Björkman et al. reported significantly worse TLPP with the IN.PACT DCB (Medtronic) compared to CB (88.9% loss of primary patency at 1 year in the DCB arm compared to 22.2% in the CB arm) in a single-centre RCT of 39 patients [5] which was discontinued due to slow recruitment (planned sample size: 140 subjects). While the small sample size may have explained these contrarian results to be due to chance, the AVFs in this study were relatively "young" (mean AVF age: 6 months), suggesting that DCB may not be suitable for vein walls which have not been fully arterialized. Indeed, subgroup analysis from the study by Irani et al. [4] showed that an older age of the dialysis access correlated with better response to DCB (loss of TLPP in the DCB arm was lower if the dialysis access was > 24 months old, HR: 0.46, 95% CI 0.21–0.98, $p = 0.045$).

Both Maleux et al. [6] and Roosen et al. [7] also reported negative RCTs with the IN.PACT DCB (Medtronic) failing to achieve significant improvement in primary patency compared to CB. The sample size of these two studies was small (Maleux: $n = 64$, Roosen: $n = 34$) which could explain the failure to demonstrate superior efficacy.

Lutonix DCB RCTs

The Lutonix AV trial randomized 285 participants in 23 centres from the USA with dysfunctional AVF to either the Lutonix AV DCB (BD) or CB [8]. The primary endpoint of 6-month TLPP was not met (DCB vs CB: 71 ± 4% vs 63 ± 4%, $p = 0.06$). The TLPP was statistically better in the DCB arm at 9 and 12 months, but not at 18 or 24 months [9].

The PAVE trial was a multi-centre RCT that randomized 212 patients across 20 centres in United Kingdom with AVF stenoses to either Lutonix AV DCB (BD) or CB [10]. The primary endpoint was similarly not met with no statistically significant difference in the 6-month TLPP (DCB vs CB: 71.7% vs 84.5%).

Passeo-18 Lux DCB RCTs

Moreno-Sánchez et al. reported negative results from a multi-centre RCT where 136 subjects with 148 AVF stenoses were randomized to Passeo-18 Lux DCB (Biotronik) or Passeo-18 CB (Biotronik) after achieving < 30% residual stenosis with Passeo 35 HP (Biotronik) HPB angioplasty. The TLPP at 6 months and 12 months was not significantly different between the two groups (DCB vs CB: 72.9% vs 57.7% at 6 months and 52.9% vs 47.4% at 12 months) [11].

Therasse et al. reported a multi-centre RCT with late lumen loss (LLL) as primary outcome. Despite a smaller LLL with the Passeo-18 Lux DCB group, the difference was not statistically significant (DCB vs CB: 0.64 vs 1.13 mm, $p = 0.082$). There was, however, a statistically significant improvement in TLPP with DCB at 12 months (62.6% vs 35.2%, $p = 0.0014$) [12].

Comparison of the Four Major RCTs

The two major IN.PACT DCB RCTs involving 330 (IN.PACT AV Access) [2, 3] and 119 (Irani et al.) [4] participants and the two major Lutonix AV DCB RCTs involving 285 (Lutonix AV) [8, 9] and 212 (PAVE) [10] participants represent the best data available currently and deserve further discussion (Table 2).

Study Population

The study population of the IN.PACT AV Access RCT is notable for a significant proportion of Japanese participants (112 of 330) [2], which may possibly contribute to better outcomes since the Japanese population has been reported

Table 1 Studies involving use of DCB in dialysis access

Study	Device	No. of centre(s)/ location	Type of study & sample size	Pre-dilatation	DCB technique	Results (DCB vs CB)	Trial outcome (Primary outcome)	Comments
Lookstein (2020), Holden (2022)	IN.PACT	29, US, Japan, New Zealand	RCT, 330 subjects, all AVF	HPB till < 30% residual stenosis	3 min inflation	TLPP (6 mo): 82.2% vs 59.5% * TLPP (12 mo): 63.8% vs 43.6% *	+	Recruited only if < 30% residual after pre-dilatation
Irani (2018)	IN.PACT	1, Singapore	RCT, 119 subjects (98 AVF)	Semi-compliant ± non-compliant HBP	1 min inflation	TLPP (6 mo): 81% vs 61% * TLPP (12 mo): 51% vs 34%*	+	Residual stenosis < 30% achieved for 89.8% and 78.3% in DCB & POBA arms
Maleux (2017)	IN.PACT	3, Benelux	RCT, 64 subjects, all AVF	HPB, 2 min inflation	2 min inflation	TLPP: 88 vs 80% (3mo), 67 vs 65% (6mo), 42 vs 39% (12 mo)^{NS}	−	
Roosen (2017)	IN.PACT	3, Netherlands	RCT, 34 subjects (29 AVF)	Nil	1 min inflation	TLPP: 130 days vs 189 days^{NS}	−	
Björkman (2019)	IN.PACT	1, Finland	RCT, 39 patients, all AVF	Undersized CB (1 mm < target)	1.5 min inflation	Loss of TL patency (1 yr): 88.9% vs 22.2%	−	Mean AVF age 6 months. Terminated (slow recruitment)
Trerotola (2020)	Lutonix	23, USA	RCT, 141 subjects, all AVF	HPB, till < 30% residual stenosis	At least 30 s (later increased to 2 min)	TLPP (6 mo): 71% vs 63% ^{NS} TLPP (12 mo): 44% vs 36%*	−	Recruited only if < 30% residual after pre-dilatation
Karunanithy (2021) (PAVE)	Lutonix	20, UK	RCT, 212 subjects, all AVF	HPB (Dorado, up to 24 atm)	At least 60 s (later increased to 2 min)	TLPP (6 mo): 71.7% vs 84.5% ^{NS}	−	No non-target lesions. Included patients not currently on haemodialysis (9.9%)
Karnabatidis (2021)	Lutonix	25, Europe & Asia	Registry, 320 subjects, 392 lesions, 75% AVF	Operator dependent. Not specified	Not specified	TLPP (6 mo): 73.9%	N.A	Includes central vein

Table 1 continued

Study	Device	No. of centre(s)/ location	Type of study & sample size	Pre-dilatation	DCB technique	Results (DCB vs CB)	Trial outcome (Primary outcome)	Comments
Moreno-Sánchez (2020)	Passeo-18 Lux	4, Spain	RCT, 136 subjects with 148 stenoses, includes AVG[#]	HPB (Passeo 35 HP) till < 30% residual stenosis	45 s, at 6 atm pressure	TLPP (6 mo): 72.9 vs 57.7% [NS] TLPP (12 mo): 52.9 vs 47.4% [NS]	–	
Therasse (2021)	Passeo-18 Lux	3, Canada	RCT, 120 subjects (109 AVF)	HPB, 60 s	60 s at nominal pressure	LLL (Primary outcome: 0.64 vs 1.13 mm [NS] TLPP (12 mo): 62.6 vs 35.2% *	–	Scheduled 6-month fistulogram

CB Conventional balloon. *HPB* High-pressure balloon. *LLL* Late lumen loss. *TLPP* Target lesion primary patency

*Statistically significant, [NS]Not statistically significant, [#]Moreno-Sánchez et al. included stenoses in the draining veins of arteriovenous grafts (AVG)

to have longer AVF patency when compared to the international population [13]. Most participants in the study reported by Irani et al. are Asian, and there is also a similar distribution of AVF location with approximately 50% below-elbow AVF in both IN.PACT DCB RCTs, compared to approximately 30% in both Lutonix DCB RCTs. This similarity in the type of AVF and participant ethnicity of both IN.PACT DCB RCTs may have explained the almost identical TLPP in both studies. A significant proportion of AVF in the PAVE study are of "young" vintage and likely non-maturing (21.7% of AVF have not been used once before trial entry), which could have explained the negative outcome of this study since other RCTs have suggested poorer response to DCB in relatively young AVF [4, 5].

Trial Design and Procedural Technique

All, except that reported by Irani et al. are multi-centre studies with independent clinical events committee and core laboratory. Core laboratory analysis would have increased the quality and objectivity of stenosis measurements but is unlikely to affect the primary outcome measure (TLPP) since the decision to treat (thus ending TLPP) was determined by visual estimate of stenosis (common to all other three RCTs) during repeat fistulography and the presence of corresponding clinical or haemodynamic abnormality.

The IN.PACT AV Access, Lutonix AV and PAVE RCTs performed HPB angioplasty to pre-dilate the stenosis in order to achieve < 30% residual stenosis (which was an inclusion criteria in these studies), while the RCT reported by Irani et al. performed pre-dilatation with CB and did not require < 30% residual stenosis before recruitment. However, most participants in Irani's study achieved < 30% residual stenosis after CB (DCB: 89.8%, CB: 78.3%) with inflation pressures (DCB: 16 ± 4.9 atm, CB: 20 ± 4.9 atm) that are similar to the other three RCTs (IN.PACT AV Access: 18.8 ± 6.7 atm, Lutonix AV: 22 ± 8 atm, PAVE: 24 atm), reducing the potential effect of this difference in trial design.

In both Lutonix AV DCB RCTs, the recommended DCB inflation duration was increased to 2 min towards the end of recruitment with only 25% and 24% achieving at least 2 min DCB inflation in the PAVE and Lutonix AV RCTs, respectively. A longer DCB inflation duration has been shown to increase vessel wall drug deposition in a porcine femoral artery model [14]. Furthermore, the Lutonix AV Global registry also showed that longer DCB inflation duration of > 120 s correlated with improved 6-month TLPP (120–180 s: 79.8%, 50–120 s: 67.9%) [15]. It is possible that both Lutonix AV RCTs could have met their primary endpoints if the protocol mandated DCB inflation duration was at least 120 s from the beginning. Similarly, it is also tempting to attribute negative outcomes from the Passeo-18 Lux DCB (Biotronik) RCTs reported by Moreno-Sánchez [11] and Therasse [12] to inadequate inflation durations of 45 and 60 s, respectively. Finally, the anti-platelet regimes following treatment are also different, as detailed in Table 2.

In the absence of a direct comparison between the different DCBs in a RCT to show their relative efficacy, it is uncertain if the difference in trial outcomes is related to the type of DCB or the above-mentioned factors.

Table 2 Comparison of the four major randomized clinical trials

Drug-coated balloon	IN.PACT AV		Lutonix AV	
Study name	IN.PACT AV Access, Lookstein (2020) & Holden (2022)	Irani (2018)	Lutonix AV, Trerotola (2018), (2020)	PAVE, Karunanithy (2021)
Study population	Global (USA, Japan, New Zealand), 29 centres, 112 Japanese (of 330 patients)	Singapore, single centre, 119 patients (98 AVF, 21 AVG),	USA, 23 centres, 285 patients	United Kingdom, 20 centres, 212 patients
Eligibility criteria of note	Require successful HPB pre-dilatation with < 30% residual stenosis Exclude if prior intervention was within 30 days or if there was prior thrombosis Exclusion: presence of non-target lesion requiring treatment within 30 days	Does not require < 30% residual stenosis	Require successful high-pressure balloon pre-dilatation with < 30% residual stenosis No more than 1 additional non-target stenosis	Requires < 30% residual stenosis after high-pressure balloon angioplasty Exclusion criteria: presence of non-target lesion that could not be treated in tandem
AVF characteristics	Age of dialysis access: 3.3 ± 3.4 years RC AVF: 50.3%/BC AVF: 36.4%	Age of dialysis access: 3.7 years (DCB) & 3.9 years (CB) RC AVF: 58.8%/BC AVF: 23.5%	Age of dialysis access: 3.0 ± 2.9 years Forearm AVF: 32% Upper arm AVF: 68%	Age of dialysis access: 1.9 years (DCB) and 1.3 years (CB) (21.7% of AVF have not been used once) RC AVF: 38.7%, BC AVF: 50.5%
Randomization	1:1, stratified based on lesion status (de novo vs restenotic)	1:1. No stratification	1:1. No stratification	1:1. Stratified to (i) whether patient was on haemodialysis, (ii) presence of prior intervention in the access circuit and (iii) operator
Pre-dilatation (lesion preparation)	Pre-dilatation with max. of 2 HPB (max pressure: 18.8 ± 6.7 atm), inflation time at operator discretion	Pre-dilatation with semi-compliant HPB (Reef HP, Medtronic), up to 22 atm, for 2 min Inflation pressure: 16 ± 4.9 atm vs 20 ± 4.9 atm, achieving anatomic success (< 30% residual stenosis): 89.8% vs 78.3% (DCB vs CB)	Pre-dilatation with HPB (max pressure: 22 ± 8 atm)	Pre-dilatation with HPB (Dorado, BD), up to 24 atm, for at least 1 min
DCB arm inflation duration	3 min inflation duration	1 min inflation	30 s inflation, later increased to 2 min	1 min inflation, subsequently increased to 2 min after 75% of study population recruited
Control arm technique	Angioplasty with uncoated low-pressure balloon	No further angioplasty	Angioplasty with uncoated low-pressure balloon	Angioplasty with uncoated balloon (Ultraverse, BD)
Clinical events committee and core laboratory	CEC: yes. Core lab: yes, Syntactx	CEC: no. Core lab: no	CEC: yes. Core lab: yes, Yale Cardiovascular Research Group	CEC: yes. Core lab: yes, Cardiovascular European Research Centre
Antiplatelet therapy	Single antiplatelet before and at least 1 month after	Aspirin and clopidogrel for 1 month, then aspirin for 5 months	Not mandated by study protocol, but approximately 50% on antiplatelet agent	Not specified

Meta-Analyses of DCB—Not the Definitive Answer

The results from meta-analyses depend on the included studies and become outdated with the arrival of new evidence [16]. Meta-analyses published prior to the IN.PACT AV Access study [2] have reported varying results. For instance, Kennedy et al. showed benefit after DCB use [17], while Abdul Salim et al. and Liao et al. did not [18, 19]. More recent meta-analyses which included the IN.PACT AV Access study, such as that by Fong et al., showed improved TLPP with DCB in a patient-level meta-analysis of 11 RCTs (TLPP: 75.3% vs 58.1%, 51.1% vs 37.1% and 31.4% vs 26.0% at 6-month, 1-year and 2-years, respectively) [20]. Han et al. similarly reported benefit in a meta-analysis of 16 RCTs where DCB use was associated with a lower risk of TLPP loss (6-months: HR 0.53, 95% CI 0.42–0.66 and 12-months: HR 0.60, 95% CI 0.47–0.76) [21].

As with the published RCTs on DCB in AVF, there is also significant heterogeneity in the results from meta-analyses due to differences in selection criteria for studies to be included. For instance, Luo et al. reported no benefit with DCB in their meta-analysis [22] but excluded some RCTs [4, 11] due to the inclusion of AVGs in their study populations and included the more recently published negative PAVE RCT [10].

Mortality Concerns with DCB

Since the initial concern was raised for possible increased mortality following the use of paclitaxel-coated balloon and stents in the femoropopliteal artery [23], subsequent large real-world cohort analyses of administrative databases have not confirmed this finding [24–26]. Currently, there is no suggestion of increased mortality with the use of DCB in dialysis access [21, 27]. Any potential increase in mortality should be considered in the context of the patient's life expectancy. Haemodialysis-dependent patients have a high background mortality rate and require repeated interventions to maintain dialysis access patency. Any increase in AVF patency could potentially provide significant improvement in their quality of life, such as the avoidance of repeat procedures and freedom from dialysis catheter dependence.

What have we Learnt About DCB in Dialysis Access Interventions?

Despite the heterogeneity in the evidence presented so far, there are certain points that are worth remembering when using DCBs in dialysis access interventions:

1. Drug dose is not the only balloon characteristic that affects DCB efficacy.
2. No "class-effect": DCBs of different brands are not equal and are therefore not interchangeable.
3. Maximizing outcomes when using DCB—adequate dilatation of stenosis (lesion preparation) and DCB procedural technique matter.

The Role of Drug dose on DCB Effect—Not Just a Numbers Game

There is evidence in animal models for increased NIH inhibition with greater doses of drug coated on DCBs [28, 29]. Data from meta-analyses show similar trend of greater efficacy with higher dose DCBs. For instance, Luo et al. reported that standard-dose DCBs (3.0 and 3.5 ug/mm2) were more effective than low-dose DCBs (2.0 ug/mm2) [22], while Fong et al. [20] reported TLPP advantage only with the standard dose DCB (3.0 and 3.5 ug/mm2) and not low-dose DCB.

While drug dose appears to influence DCB efficacy, there are other properties such as the excipient choice and drug crystallinity which can also affect the effectiveness of each DCB. The excipient plays important roles before (drug adhesion to balloon), during (drug transfer to vessel wall) and after (drug adherence to vessel wall for sustained response) DCB angioplasty [30]. Early studies show that paclitaxel-coated balloons without an excipient failed to inhibit neointimal hyperplasia [31]. Boitet et al. [32] postulated that the hydrophobic coating of certain DCBs led to lower distal drug embolization and higher vessel wall drug uptake, both desirable traits for a DCB. Furthermore, the crystallinity of paclitaxel affects its tissue uptake and persistence with crystalline paclitaxel showing a higher tissue concentration at 1 and 7 days after DCB inflation [33]. Therefore, the coated paclitaxel dose is likely just one of several parameters to affect the relative effectiveness of each DCB.

No "Class-Effect" with DCB

Animal studies have shown differences in the vessel wall drug deposition, distal tissue bed drug embolization and residual DCB drug concentration after inflation among the different DCBs [32, 34]. These differences are likely related to the unique characteristics of each DCB such as drug dose, excipient and coating uniformity [32, 35]. Given the potential effect of the various DCB's proprietary designs (drug crystallinity, drug dose, excipient) on efficacy, DCBs should not be considered to possess "class-effect" [36].

Maximizing Outcomes with DCB

There are procedural techniques that can be optimized to improve outcomes when using a DCB [37].

1. Avoid geographic miss with appropriate length of DCB.
   The length of DCB used should be slightly longer than the balloon used for lesion preparation and should exceed the stenotic lesion by 5 mm on either side of the stenosis to ensure that the entire lesion is covered [38]. Angiographic roadmap technique may help to ensure accurate placement of DCB.
2. Keep transit time to a minimum.
   Keeping the time from insertion through sheath to balloon inflation across the stenosis to a minimum (ideally within 30 s) is important to reduce drug loss in the blood. Schorn et al. showed that 30 s transit time results in greater vessel wall drug concentration compared to 180 s transit time [14].
3. Adequate DCB inflation durations.
   Adequate DCB inflation duration is recommended to allow increased drug deposition onto the vessel wall. The inflation duration of DCB should be guided by the manufacturer's instructions but generally be at least 2 min.
4. Lesion preparation before DCB use (pre-dilatation to achieve $< 30\%$ residual stenosis).
   The DCB is a semi-compliant balloon that serves to deposit the drug onto the vessel wall and cannot be expected to dilate the vessel wall effectively in all cases. Trerotola et al. reported that 20% of AVF stenoses required > 20 atm to efface the balloon waist [39]. This is much higher than the rated burst pressure of currently available DCBs. Unsurprisingly, Katsanos et al. [40] reported that 55% of subjects required HPB after DCB angioplasty to achieve satisfactory technical success in an earlier study where the DCB was used as the primary angioplasty balloon.

Performing optimal angioplasty to achieve satisfactory luminal diameter gain before the use of DCB is likely to improve outcomes with DCB by allowing increased drug penetration through intimal tears, facilitating DCB expansion and contact with the vessel wall [41]. This is reflected by the Lutonix AV global registry which demonstrated a significant improvement in the TLPP when vessel pre-dilatation was performed prior to DCB (77% vs 48.6%, $p = 0.0005$) [15]. Later studies such as the Lutonix AV [8] and IN.PACT AV Access [2] RCTs required $< 30\%$ residual stenosis after HPB angioplasty as inclusion criteria, reflecting the emphasis on optimal lesion preparation before DCB use.

Since failure to achieve $< 30\%$ residual stenosis after balloon angioplasty leads to a higher risk of failure after CB angioplasty [42, 43], all AVF stenoses should be treated with optimal angioplasty technique to achieve $< 30\%$ residual stenosis, even when DCB is not used. The standardization of pre-dilatation angioplasty techniques in recent RCTs may have led to better patency outcomes in the control groups of the IN.PACT AV and PAVE studies (12-month TLPP of 43.6% and 58.8%, respectively) [3, 10] compared to reported TLPP after CB angioplasty in meta-analyses (30–40%) [17, 20].

When Should DCB be Used?

Since using DCB entails an additional angioplasty balloon after adequate lesion preparation and added cost, it is prudent to select DCB for situations that will maximize its potential benefit. Subgroup analysis from Irani et al. showed greater benefit from DCB when used to treat re-stenotic lesions compared to de novo lesions. The better response of mature AVF to DCB has also been discussed earlier [4]. Therefore, the ideal situation to use DCB could be a restenotic lesion in a failing mature AVF.

Future Directions

Sirolimus is an anti-proliferative agent that has additional anti-inflammatory effects over paclitaxel. Sirolimus-coated balloons (SCB) have recently been developed after overcoming initial difficulties with coating sirolimus onto an angioplasty balloon. Tang et al. reported 6-month and 12-month TLPP of 83% and 58% in a single-arm pilot study of 33 patients with dysfunctional AVF [44]. The results from an ongoing multi-centre RCT comparing SCB to CB in AVF are keenly awaited [45].

The RCTs reported by Trerotola et al. [8] and Irani et al. [4] have selected a single stenosis as the study lesion, leaving other non-study lesions to be treated with CB. This may diminish the overall benefit of DCB since multiple stenoses in the AVF are common. Future RCTs conducted may benefit from studying the effect of DCB use on all stenotic lesions and use ACPP as the primary outcome measure. The ACPP measures the patency of the entire dialysis circuit and is arguably the better outcome measure than TLPP since it represents a more complete picture of the treatment burden to patients.

Favourable cost-effectiveness has been reported by Pietzsch [46] in the IN.PACT AV Access trial, Lau et al. in the Singapore healthcare perspective [47] and Kitrou et al. [48]. Despite these encouraging reports, it is not clear if treating more than one AVF stenoses in the circuit with DCB is cost-effective.

Conclusion

DCB is a welcome adjunct to CB for the treatment of AVF stenosis. Meticulous attention to lesion preparation and DCB technique is key to improved outcomes when using DCB.

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Declarations

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