LETTERS TO THE EDITOR

Paclitaxel-Coated Balloon Angioplasty for Dysfunctional Arteriovenous Fistulas

To the Editor:

We read with interest the article by Yin et al on efficacy and safety of drug-coated balloon (DCB) angioplasty using paclitaxel for dysfunctional arteriovenous fistula (AVF). To date, several randomized controlled trials have been conducted to determine the efficacy of DCB in AVF stenosis.1-7 However, diversity in study populations and end point selections led to controversy surrounding the benefit of DCB over high-pressure balloon (HPB) angioplasty (Table 1). The study by Yin et al used imaging instead of a clinical outcome as the primary end point. Ultrasound findings are operator-dependent, and the margin of error is likely to be higher in AVF imaging. Using peak systolic velocity ratio as end point in access-related studies is unique but lacks large validation studies in the AVF setting.

Of interest, almost 90% of the study population had de novo stenosis. It is known that de novo lesions usually have the best results with first angioplasty. In addition, there has been evidence to demonstrate stenosis without intimal hyperplasia, especially in de novo lesions, which may limit the efficacy of DCB.6 Lookstein et al6 also showed that the effect difference of DCB vs HPB was larger in restenotic compared to de novo lesions (26.5% vs 15.1%). A larger effect difference of DCB vs HPB was larger in restenotic lesions (26.5% vs 15.1%). Larger sample size is therefore needed to show a difference in target lesion patency in de novo lesions.

The study highlights to the vascular access community that a defined set of reporting standard parameters9-11 is needed for AVF trials to compare vascular access outcomes fairly, reduce heterogenous data generation, and improve study validity and interpretation.

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Table 1. Summary of 6-Month Patency Rates of Randomized Controlled Trials Comparing Drug-Coated Balloon to High-Pressure Balloon Angioplasty for Arteriovenous Fistula

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Participants</th>
<th>De Novo Lesions</th>
<th>Primary End Point Definition</th>
<th>6-Month Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maleux (2017)2</td>
<td>DCB: 33; HPB: 31</td>
<td>45.5% (DCB) vs 38.7% (HPB)</td>
<td>Patent AVF allowing successful and efficient dialysis</td>
<td>66.7% (DCB) vs 64.5% (HPB); P = 0.76</td>
</tr>
<tr>
<td>Irani (2018)3</td>
<td>DCB: 59; HPB: 60</td>
<td>Not reported</td>
<td>Absence of any repeat intervention in the target lesion</td>
<td>81% (DCB) vs 61% (HPB); P = 0.03</td>
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<tr>
<td>Trerotola (2018)4</td>
<td>DCB: 141; HPB: 144</td>
<td>31% (DCB) vs 27% (HPB)</td>
<td>Absence of clinically driven intervention in the target lesion</td>
<td>71% (DCB) vs 63% (HPB); P = 0.06</td>
</tr>
<tr>
<td>Swinnen (2019)5</td>
<td>DCB: 70; HPB: 62</td>
<td>0</td>
<td>Rate of late lumen loss</td>
<td>76.5% (DCB) vs 46.7% (HPB); difference in rate of late lumen loss: 0.18 ± 0.05 mm (P &lt; 0.001)</td>
</tr>
<tr>
<td>Lookstein (2020)6</td>
<td>DCB: 170; HPB: 160</td>
<td>30% (DCB) vs 30.6% (HPB)</td>
<td>Absence of clinically driven intervention in the target lesion</td>
<td>82.2% (DCB) vs 59.5% (HPB); P &lt; 0.001</td>
</tr>
<tr>
<td>Karunanthy (2021)7</td>
<td>DCB: 106; HPB: 106</td>
<td>Immature AVF: 20.8% (DCB) vs 22.6% (HPB)</td>
<td>Absence of clinically driven intervention in the target lesion</td>
<td>41.5% (DCB) vs 42.5% (HPB); P = 0.44</td>
</tr>
<tr>
<td>Yin (2021)1</td>
<td>DCB: 78; HPB: 83</td>
<td>90% (DCB) vs 89% (HPB)</td>
<td>Peak systolic velocity ratio ≤ 2.0</td>
<td>65% (DCB) vs 37% (HPB); P &lt; 0.001</td>
</tr>
</tbody>
</table>

Abbreviations: AVF, arteriovenous fistula; DCB, drug-coated balloon; HPB, high-pressure balloon.

References

3. Irani FG, Teo TKB, Tay KH, et al. Hemodialysis arteriovenous fistula and graft stenoses: randomized trial comparing...

In Reply to ‘Paclitaxel-Coated Balloon Angioplasty for Dysfunctional Arteriovenous Fistula’

We thank Tan et al for their comments on our study1; they have raised some important points about drug-coated balloon (DCB) angioplasty in vascular access treatment. Although there have been several trials focused on DCB angioplasty in the treatment of arteriovenous fistula (AVF) stenosis, there has been controversy surrounding its efficacy and safety. The higher proportion of de novo AVF lesions noted in our trial were in line with what is currently observed in China,2 and as such, we agree that this may have a positive impact on postangioplasty patency compared with recurrent lesions. In addition, many other factors besides the use of DCBs, such as characteristics of the study population and of the AVF—for example, AVF location, AVF age, and presence of calcification, diabetes, and intimal hyperplasia3-7—may also impact post-angioplasty AVF patency and requires further study. Furthermore, the follow-up period for primary outcomes in most studies was limited to 6 months, with a lack of persuasive evidence to make conclusions about long-term patency.

Based on existing data, our opinion is that some patients with certain characteristics may benefit from DCB angioplasty, while others may not. It is regrettable that the characteristics that may lead to better response to DCB angioplasty remain uncertain. Further studies may focus on finding the most appropriate treatment options for a given patient population with AVF stenosis, for instance conventional angioplasty, DCB angioplasty, stent implantation, fistula re-creation, and other potential treatments. In addition, we await future research on DCB angioplasty of arteriovenous grafts and other central venous diseases.

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References


Improving NSAID Prescribing in Older Adults With CKD—Beyond Guidelines

To the Editor:

The recent article from Hall et al1 highlighted that 3 or more potentially inappropriate medications, including