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Review article

An update on the use of drug coated balloons in clinical practice - results from the most recent studies

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Abstract The role of drug coated balloons (DCB) for the treatment of in stent restenosis have been acknowledged by International Guidelines and robust data demonstrated their good performance for small vessels disease as well. Important trials have now also reported encouraging long-term results in this scenario and it is fair to assume that in the proximal future, this strategy might become the gold standard for small vessels disease as well.

With new evidence to support their feasibility in other complex lesions, such as bifurcations or diffuse coronary disease, large randomized clinical trials are awaited to investigate their safety and efficacy, as these devices could improve long-term outcomes, especially in current era frail patients.

The aim of the current paper is to review the most recent data regarding the use of DCB, including the mid- and long-term follow-up reports on the safety and efficacy of this novel strategy.

Kew words drug coated balloons, drug-eluting stents, complex coronary lesions

Introduction

Drug coated balloons (DCB) have emerged as a valid alternative for drug eluting stents (DES) implantation for in-stent restenosis (ISR), for which, the latest European Guidelines have granted a class I indication[1]. With solid evidence regarding their safety and efficacy for the treatment of de novo small vessels disease (SVD)[2-4], a tremendous effort has been made to investigate their still unclear role in a wide spectrum of different other scenarios, such as large vessels[5], bifurcations[6] or diffuse coronary disease[7], with promising results being published.

As the complexity of lesions and patients is continuously increasing it is now clear that a safe alternative for DES is needed, as this strategy is still limited by long-term complications, mainly in-stent restenosis and stent thrombosis[8]. In this context, DCB could provide improved outcomes, as no metal is needed, while the anti proliferative drug is homogeneously transferred to the vessel wall[9].

Despite improved outcomes with new generation DES[10], ISR and ST are still frequently encountered in patients with SVD, diabetes or prior coronary artery by-pass grafting[11], stent undersizing and underexpansion, stent malapposition, significant edge dissection, stent diameter and total stent length being the most important classical predictions for long-term complications[12]. Recently, the history of chronic obstructive pulmonary disease, higher levels of remnant cholesterol and LDL-C, higher neutrophil/lymphocyte ratio or monocytes have been suggested to predict stent failure in complex lesions[13]. What is more, the need for triple anti-thrombotic therapy in patients requiring oral anticoagulation is a major risk factor for bleedings, which has been demonstrated to independently increase mortality[14].

A) Angiographic indications

1. In-stent restenosis

Although most of the data on DCB's performance arise from studies on ISR, more head-to-head comparisons between DCB and DES have been conducted. As a consequence, some contradictory results have recently been published: the PREVAIL study[15] reported favourable angiographic (late lumen loss- LLL-) and low rates of revascularization and safety events through 6 months and one year, respectively, while Giacoppo et al[16] found repeated everolimus DES implantation to be more efficient than DES in reducing the TLR for patients with coronary DES-ISR at long-term follow-up.

What is more, several other recent studies focused on identifying new angiographic predictors for treatment failure in ISR and, as a result, low post-procedural quantitative flow ratio[17] and the presence of in-stent calcified nodule lesions at OCT[18] were found to independently predict adverse events.

2. De-novo small vessels

Not further than 2 years ago, three major trials which investigated the role of DCB in SVD reported no signifi-

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cant differences in target lesion failure (TLF) or target lesion revascularization (TLR) rates between DCB and DES at two year follow-up[19], as well as similar rates of major adverse cardiac events (MACE) and all-cause death at three-years follow-up[20], while PICCOLETO II trial showed the superiority of DCB versus DES in terms of LLL, with comparable clinical outcome at 12 months[21]. These encouraging results were consistent even after longer follow-up as reported during this year's TCT. Therefore, Shao-Liang Chen presented the 5 year follow-up for the RESTORE SVD trial, showing similar TLF rates (8.0 vs 7.3%; p=0.85) and clinical outcomes between the two groups. Moreover, Dr. Cortese reported a significant reduction in abrupt vessel closure and MACE in the DCB arm vs everolimus DES arm in the PICCOLETO II trial, but these results should be analyzed by taking into consideration the relatively small number of patients and the lack of a class effect for DCBs. In a similar note, the BASKET-SMALL 2 trial investigators conducted multiple sub-studies, with recent optimistic data being reported: efficacy and safety of DCB are similar irrespective of vessel size, with a trend towards a more pronounced beneficial effect of DCB over paclitaxel-eluting stents (PES) regarding target vessel revascularization (TVR), nonfatal myocardial infarction (MI) and MACE in very small coronary arteries[22]; the long-term efficacy and safety of DCB was similar in patients with and without chronic kidney disease (CKD), with significantly fewer major bleeding events in the DCB group[23].

3. De-novo large vessels

Following the optimistic results from initial studies on large vessels[5], a recent trial enrolled 288 consecutive patients with reference vessel diameter between 2.25 and 4.0 mm and reported low nine-month LLL (−0.19 ± 0.49 mm with the DCB versus 0.03 ± 0.64 mm with the DES (p=0.019)), as well as non-inferior clinical outcomes[24]. The stent-less strategy also appeared to be safe and efficient in another smaller study, as the authors found low TLF, TLR and TVR rates of 4.2%, 3.4% and 4.2% in 119 enrolled patients, after two years of follow-up[25]. As large trials are still lacking on large vessels, it is reasonable to expect future satisfactory results of DCB especially for ostial lesions, where this strategy could spare patients from multiple stents implantation and complex 2-stent strategy. As a starting point, two recent studies[26,27] have tested this hypothesis and reported non-inferior outcomes (TLR, post-interventional lumen gain and LLL) in patients with ostial coronary lesions (27.3% ISR and 72.7% de-novo) treated with DCB[26], as well as 12 months MACE rates[27].

4. Bifurcations

With the aim of avoiding stent implantation in the side branch, a hybrid strategy using a DES for the main vessel and a DCB for the side branch was proved to be superior to plain-old balloon angioplasty in side branch treatment in terms of LLL and MACE in a recent meta-analysis[6].
The effect was similar when compared to a two-stent strategy in the case of the left main bifurcation, as Liu et al reported improved LLL with DCB use both at the side branch ostium (-0.17 vs. 0.43 mm; p<0.001) and at the proximal main branch (0.09 vs. 0.17 mm; p=0.037)[28]. Moreover, in another study investigating the performance of DCB in the main vessel of bifurcation lesions, at 12-month follow-up TLR and restenosis were low (3.1% and 2.3%), as well as target vessel failure (TVF), suggesting their feasibility for this scenario as well[29].

5. Diffuse coronary artery disease

As long metal implants are associated with high rates of TVF[7] it fair to assume that reducing the total stent length by using DCB could be an effective strategy for improving long term outcomes. This hypothesis is now reinforced by scientific data, as the use of DCB alone or as part of a hybrid strategy outperformed DES in terms of LLL (0.06 ± 0.61 vs. 0.41 ± 0.64 mm; p<0.001) in a recently published study[30]. What is more, DCB was non-inferior to DES in terms of TLR (7.3 vs. 8.3%; p=0.63) and MACE (11.3 vs. 13.7%, p=0.32)[30].
During recent EuroPCR 2022, the results of the HYPER pilot study were presented. The study investigated the feasibility, safety and efficacy of a hybrid DES/DCB approach for the treatment of de-novo diffuse coronary artery disease, defined by lesions longer than 28 mm (ClinicalTrials.gov Identifier: NCT03939468). No thrombosis was reported in the treated segments, while device-oriented composite endpoints had a rate of only 3.7% at 12 months follow-up, with a further similar ongoing study, HYPER II, being awaited to validate these results in more than 500 patients.
As this complex subset of lesions has become part of the routine practice and the results obtained with railways of stents are still unsatisfactory, the need for large randomised clinical trials is urgent, as DCB might have the ability to overcome the current era DES.

B) Clinical indications

1. Diabetes mellitus

The most important implication of diabetes in patients with coronary artery disease is represented by the diffuse negative remodeling process that usually affects long segments and especially smaller vessels[31]. Current era DES have demonstrated their limitations in this setting, as clinical and angiographic adverse events are higher in diabetic patients[32], therefore, a stent-less approach is of great interest in this scenario.
The performance of DCB was satisfactory in diabetic patients from a clinical point of view (MACE cardiac death and myocardial infarction rates) in a recent prospective study, which enrolled 578 with DM and 578 without DM with similar propensity scores[33]. However, when compared with non-diabetic patients, TLF and TLR rates were (unsurprisingly) higher (2.77% vs. 5.36%; OR, 1.991; 95% CI, 1.077 to 3.681; *P* = 0.025 and 1.90% vs. 4.15%; OR, 2.233; 95% CI, 1.083 to 4.602; *P* = 0.026). Similar results were found in another study enrolling 1198 patients with small vessel disease treated with a DCB-only strategy[34]. In this study, DM was an indepen-

dent predictor of TLF and TLR, but without a significant influence on hard clinical end-points within 12 months from the index angioplasty.
While large studies in which a "leave nothing behind strategy" is compared to traditional stenting are not available, a recent subgroup analysis including 252 diabetic patients of the pivotal BASKET-SMALL 2 trial was published[35]. Paclitaxel-coated balloons (PCB) outperformed DES (both first- and second-generation) after 3 years of follow-up in terms of TVR (9.1% vs. 15.0%; p=0.036), without any significant impact on clinical outcomes (MACE (19.3% vs 22.2%; p=0.51), cardiac death (8.8% vs 5.9%; p=0.16) or nonfatal MI (7.1% vs 9.8%; p=0.24)).
Although outcomes in diabetic patients were not a prespecified end-point, other important studies included a large proportion of diabetic patients and in these studies, DCB use was associated with favourable outcomes[4,36]. For example, the EASTBOURNE registry included 41% diabetic PATIENTS[36], while PICCOLETO II included 38% diabetic patients and in this study DCB was superior to DES from an angiographic point of view, without any significant differences regarding MACE between the two groups[4].

6. High bleeding risk

DES implantation imposes a mandatory dual antiplatelet therapy (DAPT) regimen of variable duration, which significantly increases the bleeding risk and furthermore, mortality[1,14]. As several studies demonstrated the safety of a shorter DAPT regimen after DCB use and even good one-year results and no acute vessel closure with mono therapy[37,38], this strategy has become of particular interest in the setting of high-bleeding (HBR) risk patients.
BASKET-SMALL 2 trial included 155 HBR patients and a recent sub-analysis of this group was published[39]. The 3 years follow-up investigated the role of DCB in this frail population in head-to-head comparison with DES. The primary endpoint MACE, defined as a composite of cardiac death, nonfatal MI, and TVR, whereas the secondary end-points included the single components of the primary end-point, all-cause death, ST and major bleeding. These patients had higher mortality rates at three years (HR, 3.09; p<0.001), irrespectively of the treatment strategy. However, when compared to DES, DCB showed similar rates of major bleedings in HBR patients (4.5% versus 3.4%) and lower rates in non-HBR patients (0.9% versus 3.8%).
The safety and efficacy of DCB in elderly patients, which are most likely to have a HBR, was also investigated by Sella et al in a cohort of 446 patients with CAD treated with DCB divided into two groups based on age criteria[40]. No significant differences between the groups in terms of MACE and cardiac death were reported at mid- and long-term follow-up, thus highlighting the feasibility of this strategy, which safely allows a reduction of the DAPT regimen.
However, as appealing as it may seem, this clinical scenario is lacking large randomised trials to confirm the good performance of DCB in terms of bleeding and hard clinical events and in the context of the continuously increasing number of frail patients with multiple comorbidities, this studies are of vital importance.

7. Acute coronary syndromes

The efficacy of DCB was investigated in both STEMI and NSTEMI patients in several small trials and meta-analysis. In a prospective study, Wang Z et al[41] found similar rates of nine-month MACE and LLL (0.24±0.39 mm vs. 0.31±0.38 mm; p=0.21), while the REVELATION trial[42] reported consistent results after two years-follow up, as MACE (a composite of death, recurrent MI, TLR) was similar between the DCB and DES groups at two year follow-up (5.4% vs. 1.9%; p=0.34). Furthermore, a recent sub analysis of the BASKET SMALL 2 trial investigated the role of DCB in 214 patients with acute coronary syndromes and while at one year there were lower rates of cardiac death (HR, 0.66 [95% CI, 0.15–2.95]) and MI (HR, 0.00 [95% CI, 0.00–0.32]) in the DCB group, at three years of follow-up the differences disappeared[43].
The PEARL registry prospectively included 513 patients, of whom 131 had de-novo SVD treated with a new-generation PCB, in the setting of ACS in more than half of the cases. At two years of follow-up there was an acceptable rate of MACE given this critical context (9.7%) and a low incidence of TLF (2.9%). What's more, ACS presentation tended to be associated with higher MACE (HR, 1.59; p=0.07)[44].
Further confirmations of the efficacy of a stent-less strategy were brought by a meta-analysis conducted by Li QY et al, which reported lower LLL in the DCB group when compared to DES in a population of both STEMI and NSTEMI patients[45], with good clinical performance as well (MACE rate, RR, 0.85; p=0.66).
However encouraging, these data should be analysed in the light of the multiple studies limitations, such as small number of patients, lack of randomisation and long-term follow-up.

DCB – new data

Most of the available data on the performance of DCBs are coming from studies using paclitaxel coated balloons (PCB). However, as a class effect has not been proven, new devices using sirolimus as the coating drug have been developed and their performance has been tested in several studies.
Dr. Cortese presented during EUROPCR 2022 the latest results of the ongoing EASTBOURNE registry[36], in which a sirolimus coated balloon (SCB) (Magic Touch SCB (Concept Medical, India)) was used. The primary endpoint of TLR was reported to be 6% in the enrolled population, with a high variability between in-stent restenosis patients and de novo lesions. The other endpoints like MACE and bleedings were also very low.
During TCT 2022 the final 3-year follow up of the PICCOLETO II study was presented, showing a reduction in MACE with a paclitaxel-coated balloon vs EES in small coronary vessels (p=0.046) (B. Cortese, late breaking clinical innovation, TCT 2022).

Recently, Ahmad WAW et al published the results of the first-in-human direct comparison of a novel SCB (SeQuent SCB, B. Braun Melsungen; 4 µg/mm^2) with a PCB (SeQuent Please, B. Braun Melsungen; 3 µg/mm^2) in 70 randomised patients with coronary de novo lesions[46]. With similar LLL at 6 months follow-up, the study met the predefined non inferiority margin of 0.35mm. However, further trials are needed to validate these results, as the study had several limitations.

Conclusions

Drug coating balloons have been demonstrated to be a valuable alternative for stent implantation in patients with SVD or ISR. Recently published data not only validate their good performance in these settings, but are also suggesting their future role for the treatment of de novo coronary lesions, bifurcations, diffuse artery disease, diabetic patients, acute coronary syndromes or HBR patients. New larger studies are however needed to disperse the fog on the still unclear role of DCB in these scenarios.

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Sažetak

Savremeni pregled upotrebe balona obloženih lekovima u kliničkoj praksi – rezultati skorašnjih studija

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Uloga balona obloženih lekovima (DCB) u lečenju restenoze stenta je priznata međunarodnim smernicama, a čvrsti podaci su pokazali njihov dobar učinak i kod bolesti malih krvnih sudova. Ispitivanja su takođe objavila ohrabrujuće dugoročne rezultate i može se pretpostaviti da bi u bliskoj budućnosti ova strategija mogla postati i zlatni standard za bolesti malih krvnih sudova.

Sa novim dokazima koji podržavaju njihovu izvodljivost I u drugim složenijim lezijama, kao što su bifurkacije ili difuzna koronarna bolest, čekaju se rezultati velikih randomizovanih kliničkih studija kako bi se ispitala njihova bezbednost i efikasnost, jer bi ova sredstva mogla da poboljšaju dugoročne ishode, posebno kod "krhkih"pacijenata. Cilj ovog rada je da da savremeni pregled najnovijih podataka u vezi sa upotrebom DCB-a, uključujući srednjoročne i dugoročne ishode o bezbednosti i efikasnosti ove nove strategije.

Ključne reči: *baloni obloženi lekovima, stentovi koji oslobađaju lek, kompleksne koronarne lezije*