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Coronary Angioplasty with a Drug-Coated Balloon Catheter in the Treatment of Acute Coronary Syndromes: Medico-Social Perspectives and Challenges of Use in the Setting of Diffuse Coronary Artery Lesions – a Literature Review

Abstract

This literature review explores the role of drug-coated balloon (DCB) angioplasty in the management of acute coronary syndromes (ACS), with a particular focus on patients with diffuse coronary artery disease.

Aim. To conduct a literature review on the benefits of using DCB in the treatment of patients with diffuse coronary artery disease and ACS.

Materials and methods. Unlike traditional drug-eluting stents (DES), DCB technology delivers antiproliferative drugs directly to the lesion site without leaving behind a permanent implant, offering significant advantages such as reduced risk of in-stent restenosis (ISR), lower rates of thrombosis, and shorter required durations of dual antiplatelet therapy (DAPT). These benefits are especially relevant in high-risk populations, including elderly patients, those at high risk of bleeding, or those requiring urgent non-cardiac surgery. The review synthesizes data from key randomized controlled trials (PEPCAD NSTEMI, REVELATION, BASKET-SMALL 2), and meta-analyses.

Results. The review demonstrates the non-inferiority of DCB compared to DES in terms of major cardiovascular outcomes, even in complex settings, such as ST-elevation myocardial infarction (STEMI) and out-of-hospital cardiac arrest (OOHCA). In addition, DCB has proven effective in treating ISR and preserving endothelial function, with evidence of late lumen enlargement and minimal vascular trauma. However, challenges remain, including the need for precise lesion preparation, proper balloon sizing, and operator expertise. Limitations in long-term data and heterogeneity in patient selection across studies highlight the need for further large-scale trials.

Conclusions. DCB angioplasty represents a promising, less invasive strategy in interventional cardiology, particularly in patients with diffuse or high-risk coronary lesions, though widespread adoption will depend on continued research and protocol optimization.

Keywords: dual antiplatelet therapy reduction, vascular wall regeneration, in-stent restenosis treatment, thrombotic risk minimization, interventional cardiology innovations, high-risk cardiac patients, urgent surgical intervention safety, endothelial function preservation

Problem statement. Modern interventional cardiology is constantly evolving, offering new technologies and strategies to optimize the treatment of coronary diseases. In particular, DCB demonstrates significant potential in the treatment of patients with ACS. The main principle of this approach is the local delivery of an antiproliferative drug via a balloon catheter without the need to leave a

permanent implant. This strategy opens new possibilities for vascular wall repair, lowers the risks of restenosis and thrombosis, and simplifies treatment in acute situations.

Significant interest in the use of DCB is due to the need to optimize the treatment of complex clinical cases, including STEMI and OOHCA. These conditions are characterized by rapid thrombus formation, vasospasm and blood flow disorders, which requires rapid and effective intervention. In such scenarios, the DCB strategy can offer new solutions, in particular by minimizing the risk of thrombosis and the possibility of avoiding long-term antiplatelet therapy.

Aim. To substantiate the use of drug-coated balloons (DCB) as the method of choice for revascularization of coronary artery lesions in acute coronary syndrome (ACS) and the prospects for its use in patients with diffuse coronary artery disease.

Analysis of recent studies and publications. The review is based on numerous randomized clinical trials (RCTs) and cohort observations conducted over the past decade. In particular, the results of such studies as PEPCAD NSTEMI, REVELATION and BASKET-SMALL 2 were taken into account, which evaluated the effectiveness of DCB compared with DES and other standard treatment methods. Additionally, retrospective data from registries of patients with ACS were analyzed to assess clinical outcomes and complication rates when using this technique.

Background. Patients with diffuse coronary artery (CA) lesions are a particularly challenging group, as their pathology is progressive and characterized by a significant decrease in vascular patency. This significantly complicates traditional approaches to revascularization and associated with an unfavorable prognosis, especially in the case of using standard treatment methods. Such patients are at increased risk of restenosis, which limits the effectiveness of stenting, as well as the possibility of developing thrombotic complications that can lead to repeated ischemic events. It is important not only to mechanically restore blood flow in the affected artery segments but also to minimize the risks of restenosis, which is a key factor in the long-term success of treatment.

One promising approach in such cases is the use of DCB, which provide local delivery of antiproliferative drugs without the need for stent implantation. The main advantage of DCB is the possibility of reducing the duration of dual antiplatelet therapy, which is of particular importance for patients with a high risk of bleeding [1]. This applies, in particular, to the elderly, patients with gastric or duodenal ulcers, as well as people taking anticoagulants due to concomitant pathology, such as atrial fibrillation. In such cases, reducing the duration of antiplatelet therapy reduces the risk of hemorrhagic complications and improves the overall treatment effectiveness and prognosis. In addition, the use of DCB is especially important for patients who require urgent surgical interventions, such as cardiac surgery or major orthopedic manipulations, where it is necessary to temporarily stop antiplatelet therapy. The use of stents in such cases may pose additional risks, since their withdrawal increases the likelihood of acute thrombotic complications. In contrast, DCB allows for effective angioplasty without the need for long-term antiplatelet therapy, making this method safer in such clinical scenarios [2,3].

Another important advantage of DCB is its effectiveness in the treatment of restenosis in already implanted stents (in-stent restenosis, ISR), which remains a serious problem in interventional cardiology. Repeated stenting in such cases can lead to further reduction of the vessel

lumen, which increases the risk of thrombosis and deterioration of coronary blood flow. The use of DCB allows for effective control of the intimal hyperplasia within the stent area without the need for additional metal structures, which contributes to a better long-term prognosis. This is especially important for patients with multiple lesions, where it is necessary to minimize intervention in the coronary bed while maintaining sufficient vascular patency [4,5].

Thus, angioplasty using DCB has significant advantages in the treatment of patients with diffuse CA lesions and stent restenosis. It reduces the risk of restenosis, reduces the need for long-term antiplatelet therapy, and minimizes complications associated with repeated stenting. Further studies of this method will help determine the optimal indications for its use and refine treatment protocols, contributing to increased effectiveness and safety of revascularization in complex clinical cases.

The PEPCAD NSTEMI study demonstrated non-inferior results of DCB compared with stenting. At 9.2 ± 0.7 months of follow-up, the rate of target lesion treatment failures was 3.8 % in the DCB group versus 6.6 % in the stent group ($p > 0.05$). At the same time, the rate of major adverse cardiac events (MACE) was 6.7 % versus 14.2 %, respectively.

In the REVELATION trial, which focused on patients with STEMI, DCB demonstrated non-inferiority in terms of fractional flow reserve (FFR) at 9 months: 0.92 ± 0.05 in the DCB group versus 0.91 ± 0.06 in the DES group. This data highlights the ability of DCB to effectively restore blood flow and vascular endothelial function [6].

The study results highlight the significant advantages of using DCB in the treatment of ACS. First, the DCB strategy provides a lower risk of thrombosis because there is no permanent implant that can act as a thrombogenic substrate. Second, the procedure is less invasive, which reduces the risk of vascular wall damage and facilitates endothelial repair.

However, challenges remain. In particular, additional vessel preparation is often required, which increases the cost and amount of equipment required for the procedure, and further studies of long-term outcomes and optimization of vessel preparation approaches are needed. The issue of choosing the right balloon size, the risks of dissection, and limitations in operator experience should also be considered for the full integration of this method into clinical practice [7].

We observed another systematic review and meta-analysis that assessed the practicality of using paclitaxel-coated balloon (PCB) angioplasty as a treatment option for patients with acute coronary syndrome (ACS), comparing its effectiveness and safety to that of modern drug-eluting stents (DES). Drawing from a cohort of over 2,000 ACS patients across multiple studies, the analysis found that PCB angioplasty demonstrated comparable results to DES placement in terms of key cardiovascular outcomes, including mortality, myocardial infarction, revascularization rates, and bleeding complications.

Historically, PCB angioplasty has been established as a viable strategy for chronic coronary syndromes. Recent guidelines and expert recommendations have begun to acknowledge its potential applicability in ACS, based on randomized clinical trials. However, meta-analyses evaluating PCB specifically in the context of ACS have been limited. This study sought to bridge that gap by including a diverse range of ACS presentations, such as ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina [10]. The clinical baseline characteristics were well-balanced across groups, ensuring meaningful comparisons, although patients with extreme clinical instability or severely calcified lesions were often excluded due to their known association with poor outcomes [17].

Some earlier trials were not included due to variations in revascularization strategies that did not align with the study's inclusion criteria. The overall analysis confirmed the non-inferiority of PCB compared to DES in terms of safety and angiographic outcomes. The findings suggest that PCB could be a promising alternative in emergent coronary interventions, expanding its use beyond stable patients.

The mechanism by which PCB angioplasty may offer benefits includes the localized delivery of paclitaxel to the site of the lesion without permanent implantation of a stent. This approach avoids complications such as very late stent thrombosis and in-stent restenosis, which can occur due to chronic inflammation or neointimal hyperplasia [8]. Furthermore, younger patients with ACS, who may benefit from long-term stent avoidance, could be ideal candidates for PCB therapy when combined with optimal medical treatment.

Angiographic data suggest that late lumen loss following PCB angioplasty tends to be minimal, mirroring results seen in elective procedures for stable coronary disease. In many cases, vessel remodeling and late lumen enlargement (LLE) have been observed, likely due to a combination of lesion expansion, plaque regression, and the resolution of minor procedural dissections. These effects may translate into lower rates of repeat revascularization and improved long-term vessel patency.

Compared to earlier balloon-only approaches, PCB angioplasty demonstrates enhanced outcomes when used with proper lesion preparation techniques [16]. Critical procedural steps – such as thrombus reduction, careful balloon sizing, and avoidance of significant dissection – are essential to achieve favorable results. Intravascular imaging has emerged as a valuable tool for guiding lesion preparation and evaluating suitability for PCB therapy, particularly in the heterogeneous population of ACS patients.

Preserving coronary vasomotion is another unique advantage of PCB angioplasty, which could be relevant in mitigating conditions like vasospastic angina and other functional coronary disorders often implicated in ACS and sudden cardiac death. Thus, expanding the use of PCB in ACS requires both procedural expertise and a nuanced understanding of lesion pathology.

This review also highlights the importance of balloon length and lesion morphology. PCB angioplasty using shorter, focused balloons has shown consistent efficacy in various coronary artery sizes and pathologies, suggesting an optimal balloon length around 20 mm may offer a balance between drug delivery and procedural safety. Lesions that are not extensively calcified and those with manageable thrombus burden appear most amenable to PCB treatment [11].

Despite its promise, several limitations exist. The overall number of patients in the included studies remains modest, and the follow-up periods are relatively short. Variations in inclusion criteria and procedural strategies across studies introduce potential bias. Moreover, the absence of detailed procedural data limits insights into the technical nuances that might influence outcomes.

Subgroup analysis in this study also explored the use of PCB in specific ACS presentations, such as ST-elevation myocardial infarction, finding no significant differences in key outcomes compared to DES treatment [12,13]. However, the dominance of a few studies with high statistical weight means that further data are needed to validate these preliminary findings.

Another area of interest is the potential for reducing dual antiplatelet therapy (DAPT) duration following PCB angioplasty. The reduced need for prolonged DAPT could lower bleeding risks – a known drawback of DES therapy, particularly in high-risk patients [14,15]. Although the present review suggests bleeding events are not increased with PCB despite shorter DAPT durations, future investigations are necessary to define optimal antiplatelet regimens.

In conclusion, while this analysis provides the first comprehensive synthesis of data supporting the use of PCB angioplasty in ACS, further large-scale, long-term studies are needed. These should focus on clinical endpoints such as mortality, myocardial infarction, and long-term vessel patency, as well as procedural standardization [18]. Identifying which patients are most likely to benefit from this stent-less approach will be critical in refining the role of PCB in the contemporary management of ACS.

Conclusions. Coronary angioplasty using drug-coated balloon catheters is a promising direction in modern interventional cardiology for patients with acute coronary syndromes (ACS). This method provides a number of important advantages, including a reduced risk of thrombosis, simplified technique, and improved regeneration and functional recovery of the vascular endothelium. Due to these characteristics, balloon angioplasty can be considered as an effective and less invasive alternative to traditional stenting, especially in patients with diffuse coronary artery disease for whom stent implantation is technically difficult or associated with high risks. Despite the significant potential of this method, it should be borne in mind that its widespread implementation requires large-scale clinical studies aimed at determining long-term efficacy and safety. It is especially important

to study the long-term effectiveness of the procedure, repeated ischemic events, the rates of restenosis and the likelihood of complications associated with the use of drug-coated balloon catheters. In addition, the cost-effectiveness of the method should be assessed compared with traditional approaches, including stenting and drug therapy. Thus, angioplasty with therapeutic coated bal-

loon catheters is a promising method that can significantly improve the treatment outcomes of patients with ACS, especially in difficult clinical situations. However, for its final implementation into widespread clinical practice, further detailed studies are needed to determine optimal indications, improve application protocols, and evaluate long-term efficacy in different patient groups.

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Коронарна ангіопластика з використанням балонного катетера з лікарським покриттям у лікуванні гострих коронарних синдромів: медико-соціальні перспективи та проблеми використання при дифузних ураженнях коронарних артерій. Літературний огляд

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Резюме

Вступ. Сучасна інтервенційна кардіологія постійно розвивається, пропонуючи нові технології та стратегії для оптимізації лікування коронарних захворювань. Зокрема, балони з лікарським покриттям (DCB) демонструють значний потенціал у лікуванні пацієнтів з гострим коронарним синдромом (ГКС). Значний інтерес до застосування DCB обумовлений потребою в оптимізації лікування складних клінічних випадків, зокрема інфаркту міокарда з елевацією сегмента ST (STEMI) та зупинки серця поза лікарнею (ООНСА). У таких ситуаціях стратегія використання DCB може запропонувати нові рішення – зокрема, шляхом мінімізації ризику тромбозу та можливості уникнути тривалої антитромбоцитарної терапії.

Мета – обґрунтувати доцільність використання ангіопластики із застосуванням балонного катетера з лікарським покриттям (DCB) як альтернативного методу реваскуляризації у пацієнтів з гострими коронарними синдромами (ГКС), зокрема при дифузному ураженні коронарних артерій (КА).

Матеріали та методи. Цей огляд літератури присвячено аналізу медико-соціальних аспектів та клінічних перспектив використання DCB у лікуванні пацієнтів з ГКС. У центрі уваги – ефективність, безпечність та особливості застосування цієї технології в порівнянні з традиційним стентуванням. Особливу увагу приділено пацієнтам з дифузними ураженнями КА, де звичайні стенти можуть бути малоефективними.

DCB дозволяє доставляти антипрофілаферативний препарат локально, не залишаючи імплантату, що сприяє зменшенню ризику рестенозу та тромбозу, знижує потребу у тривалій подвійній антиагрегантній терапії (ПАТ). Це особливо актуально для хворих з високим ризиком кровотеч, наявністю супутніх захворювань або необхідністю невідкладного хірургічного втручання.

Результати клінічних досліджень PERCAD NSTEMI та REVELATION свідчать про не менш ефективну роботу DCB порівняно з медикаментозними стентами, зокрема щодо відновлення функціонального кровотоку, зменшення кількості ускладнень та рецидивів ішемії. Також аналізується потенціал DCB у лікуванні рестенозу в стентах, що є актуальною клінічною проблемою.

Обговорення. Перевагами DCB є менша інвазивність, збереження природної структури судинної стінки, можливість уникнення повторного стентування та менший ризик ускладнень у довгостроковій перспективі. Разом із тим метод потребує додаткових досліджень щодо довгострокової ефективності, оптимізації техніки застосування та вибору пацієнтів.

Висновки. Отже, ангіопластика з DCB є перспективним напрямом у сучасній інтервенційній кардіології, який заслуговує на ширше впровадження в клінічну практику, особливо у складних клінічних випадках.

Ключові слова: *деескалація подвійної антиагрегантної терапії, регенерація судинної стінки, лікування рестенозу в стенті, мінімізація тромботичних ризиків, інновації в інтервенційній кардіології, пацієнти високого серцевого ризику, безпека термінової інтервенції, збереження функції ендотелію.*

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