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PRACA POGLĄDOWA REVIEW

Ideal coronary stent: development, characteristics, and vessel size impact

Wzorcowy stent wieńcowy: rozwój, charakterystyka i wpływ średnicy naczynia

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ABSTRACT

The invasive treatment of coronary artery disease (CAD) has been a well-established therapeutic method for many years. Bare-metal stents (BMS), followed by subsequent generations of drug-eluting stent (DES) implantation in a narrowed coronary artery is the most effective treatment, especially in patients with acute coronary syndromes. Restenosis and stent thrombosis are the most important complications of this method. The long-term results of percutaneous coronary intervention (PCI) depend not only on the type of the implanted stent, operator skills, but also on the clinical characteristics of the patient, including the size of the treated vessel. In the era of DES, small vessels (< 3 mm) proved to be one of the most important factors significantly worsening the clinical outcomes of PCI. Among the most important features of the stents available on the market, i.e. the type of drug released, the type of polymer and the strut thickness, the latter seems to be crucial, particularly for the treatment of small vessels.

KEY WORDS

coronary artery disease (CAD), bare-metal stent (BMS), drug-eluting stent (DES), percutaneous coronary interventions (PCI), vessel size

STRESZCZENIE

Inwazyjne leczenie choroby wieńcowej od wielu lat stanowi ugruntowaną metodę terapeutyczną. Implantacja najpierw stentów metalowych (BMS), a następnie kolejnych generacji stentów uwalniających leki (DES) w miejscu zwężonej tętnicy wieńcowej jest najskuteczniejszą metodą leczenia, zwłaszcza u pacjentów z ostrymi zespołami wieńcowymi. Restenoza i zakrzepica w stencie to główne powikłania tej metody. Wyniki odległe przezskórnej interwencji wieńcowej (PCI) zależą nie tylko od rodzaju implantowanego stentu, umiejętności operatora, lecz także od charakterystyki klinicznej pacjenta, w tym rozmiaru stentowanego naczynia. W erze stentów DES małe naczynia (< 3 mm) okazały się jednym z najważniejszych czynników w istotny sposób pogarszających rezultaty kliniczne PCI. Spośród najistotniejszych cech dostępnych na rynku stentów, tj. rodzaju uwalnianego leku, typu polimeru oraz grubości przęseł, ta ostatnia wydaje się kluczowa, szczególnie w przypadku leczenia małych naczyń.

SŁOWA KLUCZOWE

choroba wieńcowa (CAD), stent metalowy (BMS), stent uwalniający lek (DES), przezskórne interwencje wieńcowe (PCI), rozmiar naczynia

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INTRODUCTION

The invasive treatment of coronary artery disease (CAD) has been a well-established therapeutic method for many years. Percutaneous coronary intervention (PCI), has developed over years regarding the type of stent, the technique of the procedure and adoption to clinical settings. The long-term results of PCI also depend on the angiographic and in-situ characteristics of the treated lesion, including the size of the vessel.

Historical perspective

The beginning of interventional cardiology in terms of CAD dates back to 1977 when Andreas Grüntzig, a German physician who lived in Zurich, for the first time applied a balloon-tipped catheter to perform angioplasty in a conscious patient with significant left anterior descending artery stenosis. Despite the excellent immediate and long-term outcomes, an increasing number of plain old balloon angioplasty (POBA) procedures revealed the problem of so-called restenosis, i.e. a recurrence of stenosis in the dilated part of the vessel. This complication was observed even in 30-50% of patients. In addition, approximately 3% of patients presented with myocardial infarction secondary to acute occlusion of the artery [1,2,3,4]. The clinical application of the concept of stent implanting dating back to 1964 was not undertaken until 1986, when the self--expanding woven mesh stent (Wallstent) was used for the first time (Schneider) [5]. Soon other structures appeared on the market - the first two stents, the use of which was approved in 1994 by the Food and Drug Administration (FDA) included the Palmaz-Schatz Stent (Johnson & Johnson) and Gianturco-Roubin Flex Stent (The Cook Inc.) [6]. Two large multicenter randomized clinical trials (STRESS and BENESTENT) showed (based on the Palmaz-Schatz stent) that the new technology allowed restenosis to be reduced by 20-30% compared to POBA [7,8]. This success, however, was soon overshadowed by subacute stent thrombosis in even 18% of patients. Initially, attempts were made to address this problem using aggressive anticoagulant treatment with vitamin K antagonists, which resulted in further complications (i.e. bleeding). Soon, there was even a temporary suspension of the routine use of stents that were applied only in the case of balloon angioplasty failure. At that stage, many cardiologists predicted the early end of this technology.

The safety of percutaneous angioplasty with stent implantation was restored by Prof. Colombo, who postulated for the first time the replacement of warfarin with ticlopidine, prepared some form of instruction describing the methodology of proper stent implantation (still valid until today) and drew attention to the absolute necessity for the use of high pressure balloon inflation during stent implantation (min. 14–18 atm), which was confirmed by intravascular ultrasound technology that was revolutionary at that time [9]. A similar opinion was shared by Prof. Serruys in the paper with the controversial title: "Who was thrombogenic: The stent or the doctor?" [10].

First-generation des

In the case of bare-metal stents (BMS), including the most studied cobalt-chromium Multi-Link Vision (Abbott), there was still a concern about repeat revascularization. Restenosis was still found in 15-30% of patients. Studies on the etiopathogenesis showed that it was caused by excessive neointimal proliferation in response to periprocedural vascular wall injury followed by inflammatory response [11,12]. As a result, interventional cardiologists were soon provided with a new tool – antiproliferative drug-eluting stents (DES). They were aimed at improving the efficacy of the percutaneous treatment of CAD. And indeed, during the first period of their application (i.e. from the publication of the results of the RAVEL trial in 2001 to the World Congress of Cardiology in Barcelona in 2006), it seemed that the new technology met the challenges. Taxus (Boston Scientific) and Cypher (Cordis) were the precursors of DES. They were structures made of 316 L stainless steel with a strut thickness of 132-140 µm coated with a durable, non-biocompatible polymer matrix that provided a controlled release of the drug, i.e. anti--cancer paclitaxel (Taxus; PES) and sirolimus (Cypher; SES), that is an immunosuppressive macrolide antibiotic. The aim of these agents was to delay the "healing" of the vessel after stent implantation, and thus to prevent endothelial cell proliferation as the cause of restenosis by inhibiting the migration of smooth muscle cells toward the endothelium and disruption of the cell cycle. The clinical benefits of DES were shown in the TAXUS-IV study which found that restenosis occurred in 26.6% of patients with implanted BMS in a 9-month follow-up, while this percentage was only 7.9% in the group of patients after PES implantation [13,14].

Unexpectedly, the World Congress of Cardiology in Barcelona in 2006 with the speech of Professor Camenzind brought doubts regarding DES safety. Some alarming data were presented, according to which the number of myocardial infarctions and coronary angioplasty-related deaths was higher in the group of sirolimus-eluting stents (SES) (6.3%) compared to BMS (3.9%) [15]. The BASKET-LATE study confirmed an increase in major adverse cardiac events (MACE) after 7 to 18 months following DES implantations compared to BMS implantation [16]. The results of a series of studies and meta-analyses confirming this trend were soon published. Nonetheless, the discrepancies were related to the statistical significance of endpoints such as the overall mortality, cardiac mortality, and non-fatal myocardial infarction [17,18,19,20,21]. Thrombosis and its clinical consequences received a great deal of attention not only in the medical community, but also among patients. In American public media, DES were even compared to "tiny time bombs" [22].

Both Cypher and Taxus stents were approved by the FDA based on randomized clinical trials with a short



follow-up. Reevaluation of the safety of DES was carried out in 2006, by an FDA-appointed panel of 21 experts [23]. Considering a new definition of stent thrombosis developed by the Academic Research Consortium (ARC), attention was drawn to the necessity of continuing dual antiplatelet therapy consisting of acetylsalicylic acid and a platelet adenosine diphosphate receptor antagonist (Dual Antiplatelet Therapy: DAPT) for 12 months in patients with a low risk of bleeding (a 6-month DAPT period in the BASKET-LATE study). The implantation of DES in accordance with the manufacturer's recommendations ("on-label") was safe, while a higher risk of DES thrombosis in "off-label" cases (60% of DES use) was not associated with an increased risk of death or myocardial infarction compared to BMS [24].

Second-generation des

Due to the high heterogeneity of the clinical effects of the implantation of DES vs. BMS characterizing the ideal stent is challenging. From the clinical perspective, it should fulfill the criteria of high efficacy (low percentage of restenosis), and high safety (low thrombogenicity). From the procedural perspective, emphasis should be placed on easy delivery to the treated segment of the vessel. After introducing drug elution and DAPT, it was soon confirmed that thrombosis was the result of delayed stent strut endothelialization owing to antiproliferative drugs released by DES and a proinflammatory effect of the polymer [25,26,27]. As a result, the release of new drugs, a thinner strut platform as well as biocompatible, biodegradable polymers or even no polymer were introduced. The so-called second-generation DES, such as Endeavor/Resolute (Medtronic) releasing zotarolimus (ZES), and Xience (Abbott) releasing everolimus (EES) were approved for use as early as in 2008. The steel structure of first-generation DES was replaced by a cobalt-chromium structure with a significantly reduced stent strut thickness (81-91 µm), which was coated with a thinner, durable biocompatible polymer (durable-polymer DES; DP-DES). Comparisons of the long-term effects after Xience stent implantation (EES) vs. Taxus stent implantation (PES) showed the advantage of Xience in reducing overall mortality as well as improvement in individual safety and efficacy parameters [28,29]. In a 3-year follow-up, possible and definite stent thrombosis was reported in 1.4% of patients after EES implantation compared to 4.9% after PES implantation [28,29]. This was also confirmed by numerous large registers. The risk of very late stent thrombosis in the EES group decreased by 76% compared to PES and by 67% compared to SES [30]. Similar conclusions were also observed based on the Swedish SCAAR registry (about 95000 patients) in which the percentage of restenosis decreased by 38%, the percentage of stent thrombosis decreased by 43% and the risk of death decreased by 23% in the case of second-generation DES compared to first-generation DES [31]. The structures (ZES Resolute and EES Xience) provided similar long-term clinical results when they were directly

compared [32,33,34]. BMS and first-generation DES were completely supplanted by second-generation DES which became the treatment of choice for stable CAD and acute coronary syndromes. This was confirmed by the ESC guidelines (2012) on the management of ST-segment elevation myocardial infarction (STEMI), which recommended the use of DES during primary PCI as the preferred method in relation to BMS implantation (Recommendation Class IIa) [35].

Third-generation des

Another milestone in the development of stents was related to DES with a biodegradable polymer and polymer-free stents (referred to as third-generation DES) following the assumption that the polymer was responsible for maintaining the inflammatory process within the vessel wall and delayed stent strut endothelization crucial to restenosis and stent thrombosis [36,37]. Biodegradable polymer DES (BP-DES) appeared on the market and included Orsiro (Biotronik), Nobori (Terumo), Synergy (Boston Scientific) and Biomatrix (Biosensors International), followed by polymer-free DES (PF-DES) such as Coroflex ISAR (B. Braun), BioFreedom (Biosensors International) and Cre8 (Alvimedica). Stents based on a biodegradable polymer were the subjects of many prospective and retrospective observations. The Nobori stent did not achieve better safety or efficacy parameters compared to the Xience stent in a 5-year follow-up [38]. In turn, the Synergy stent, in which the everolimus-eluting biodegradable polymer is located only on the side of the vessel wall (abluminally) and the surface of the strut exposed to the blood stream is in essence a BMS, unexpectedly caused more acute stent thrombosis compared to the Xience stent (1.2% vs. 0.3%; p = 0.032) [39,40]. Similar conclusions were also found in other studies [41,42,43] and meta-analyses [44,45]. BP-DES did not contribute to a reduction in adverse clinical events compared to new-generation DP-DES, which are distinguished by the most favorable efficacy-to-safety ratio among all DES available on the market. This is particularly visible in the case of the Xience stent. In addition, BP-DES do not allow shortening of DAPT compared to new-generation DP--DES due to a worse safety profile than new-generation DP-DES during the first year after implantation. It is known that polymers which require active reabsorption significantly increase the local inflammation of the vessel wall compared to durable polymers [46,47]. In turn, in-vitro studies showed that a durable fluorinated copolymer (used e.g. in Xience and Promus stents) activated platelets to a lesser extent compared to other polymers [48,49] or even the uncoated metal surface of the stent, which had a thrombo-protective effect [50].

The concept of DES with no polymer resulted in the release of the BioFreedom polymer-free biolimus-eluting stent (PF-BES), which was characterized by an increased percentage of restenosis compared to DP-EES in an 18-month follow-up. However, after applying the propensity-score-matching method, the above trend lost statistical significance. No differences were reported in



terms of safety [51]. Nevertheless, in the case of this device the possibility of shortening DAPT to 1 month after stent implantation in stable CAD in patients with an increased bleeding risk (IIb) according to the 2017 ESC guidelines should be underlined [52]. Another polymer-free sirolimus- and probucol-eluting stent (Coroflex ISAR) did not improve the safety or efficacy parameters as compared to DP-ZES (Resolute) in a one-year follow-up [53].

Size of treated vessel. Stent strut thickness

In the era of first-generation DES, many comparisons were made between them and BMS. Detailed analyses in patient subgroups demonstrated that in large coronary arteries (> 3 mm) the advantage of first-generation DES in reducing the percentage of restenosis in relation to BMS was lower than in the case of small vessels [54,55,56,57]. Moreover, several registries showed that first-generation DES implantation in large vessels resulted in an increased prevalence of adverse events secondary to stent thrombosis, i.e. fatal myocardial infarction over a 6-month follow-up [56,58]. An inverse relationship was observed in the case of small vessels (< 3 mm) where the DES anti-restenotic potential was so significant that it outweighed all the DES-related disadvantages in terms of safety [56,59,60,61]. Moreover, the clinical presentation of stent thrombosis depends on the vessel size. In the case of large vessels, stent thrombosis often results in myocardial infarction or even death, while it may remain clinically silent in small vessels. In a large prospective study comparing the clinical and angiographic results after implantation of first-generation DES, i.e. SES-Cypher vs. PES-Taxus, Elezi et al. observed that the size of the treated vessel < 2.41 mm was an independent risk factor for restenosis. A statistically significant advantage in terms of target lesion revascularization (TLR) in favor of SES (8.6% for SES vs. 16.4% for PES; p = 0.002) was also observed only in the small vessel subgroup (< 2.41 mm). Furthermore, the size of the vessel did not affect the risk of myocardial infarction or death in patients undergoing SES or PES implantation [62]. Similar results were also obtained by other researchers [63,64].

After new-generation DES restored an acceptable level of safety to PCI, the efficacy of this method was again scrutinized. It was observed that in some groups of patients (sometimes referred to in Anglo-Saxon literature as "challenging"), the clinical outcomes were still worse than in the general population. A cohort of patients with CAD in small vessels is one of such groups. The treatment of lesions in small vessels has always been a challenge for interventional cardiology [65,66,67,68,69]. The DUTCH PEERS study (TWEN-TE II) showed that a subgroup of patients undergoing PCI with second-generation DES (DP-EES or DP-ZES) at least in one vessel with a diameter smaller than 2.5 mm had worse prognosis compared to patients in whom such revascularization was not required (target lesion failure - TLF 9.5% vs. 5.4%; P log rank = 0.001) as indicated in a 2-year follow-up [70]. In the pooled analysis comparing PCI with first-generation DES (PES) and second-generation DP-EES in a 2-year follow-up, the percentage of MACE was significantly higher in the subgroup of PCI in vessels with a diameter ≤ 2.65 mm and/or with a length > 13.4 mm compared to PCI in short lesions in large vessels. Of note, the prevalence of thrombosis after DP-EES implantation was low and was independent from the complexity of the lesion [71].

Second-generation DES appeared on the market more than 10 years ago. It seemed that the plateau was achieved in which most of the available structures provided good and comparable results crucial for the prognosis with slight DP-EES supremacy. In 2019, the results of two multicenter prospective trials were reported, both showing the advantage of BP-SES (Orsiro) over DP-ZES (Resolute Integrity): the first in terms of revascularization of the same target lesion in small vessels (< 2.5 mm) with a lower rate of TLR in favor of Orsiro in a one-year follow-up (2.1%, vs. 5.3%, respectively, p = 0.009 [72]; and the second, in primary angioplasty in STEMI, TLF was significantly less prevalent after BP-SES Orsiro implantation compared to DP-EES Xience (4% vs. 6%) [73]. Similar conclusions were observed later on [74]. Thinner stent struts (Orsiro - strut thickness dependent on the stent diameter: 60 µm for 2.25–3.0 mm diameter sizes and 80 µm for 3.5–4.0 mm, Synergy - 71 µm, Xience and Promus - 81 µm, Resolute Integrity $-91 \mu m$) are related to a smaller footprint within the artery, which is associated with reduced wall damage, reduced local inflammation and hence the promotion of healing, which is crucial for the prevention of excessive endothelial proliferation and stent thrombosis [75,76]. Thinner stent struts are also related to a lower percentage of occluded collateral vessels, which has a direct impact on a reduction in the number of periprocedural myocardial infarctions, mostly observed after anterior descending artery revascularization (multiple small septal and oblique branches, large vascular area) [74,77,78]. Studies using new visualization technologies, such as three-dimensional intravascular ultrasound (3D-IVUS) and computational fluid dynamics (CFD) allowed better understanding of the etiology of adverse postprocedural clinical events. It had been previously reported that the thickness of the stent struts had a key influence on the extent of blood flow disorders in the stented vessel [79,80,81,82,83].

The introduction of a fully bioresorbable scaffold (BVS) Absorb (Abbott) with a strut thickness of up to 157 μ m, which was the first representative of fourth-generation DES, was disappointing and eventually resulted in its withdrawal from the market. It was due to an increased incidence of myocardial infarction in the revascularized vessel (TV-MI 6% vs. 1%; p = 0.011) and more prevalent stent thrombosis (2.3% vs. 0.7%, p = 0.01) in a 3-year follow-up compared to DP-EES Xience. It was also demonstrated that a small vessel diameter (< 2.25 mm) was an independent risk factor for TLF [84,85]. However, extensive work is being continued on further development of the promising bioresorbable scaffold technology.

CONCLUSIONS

To conclude, revascularization with first-generation DES was associated with a lower risk of restenosis, but with a higher risk of late stent thrombosis compared to BMS. Second- and third-generation DES significantly

Author's contribution

Study design – D. Kawecki, B. Morawiec, J.F. Dola Literature research – J.F. Dola, P. Muzyk Writing the draft of the manuscript – J.F. Dola Critical review of the manuscript – E. Nowalany-Kozielska, D. Kawecki

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improved the long-term efficacy and safety in comparison to first-generation DES and BMS [86]. Based on the 15 years of experience in treating patients with DES, the strut thickness seems to have the greatest impact on the clinical outcomes, particularly in PCI for lesions in small vessels.

The development of interventional cardiology in terms of CAD is related to a further decrease in strut thickness [87] and improvement in the bioresorbable scaffold (BVS) [88,89].

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