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Stent length is a contributing factor of suboptimal stent expansion in drug-eluting stents

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Part of this work was presented in abstract format at the 2009 AHA Scientific Sessions.

Abstract

Background: Failure to achieve optimal stent expansion poses a risk of treatment failure in percutaneous coronary intervention (PCI). Although intravascular ultrasound provides useful information for suboptimal stent expansion, a substantial portion of PCIs are currently being performed under angiographic guidance only.

Aim: In order to evaluate the adequacy of stent expansion of four widely used drug-eluting stents in angiography-guided PCI, we performed a retrospective analysis of lesions undergoing PCI using quantitative coronary angiography.

Methods: A total of 112 de novo lesions were analysed. Minimal lumen diameter (MLD) was measured at peak pressure during stent deployment (MLD1), after stent deployment (MLD2), and after postdilatation (MLD3). Stent underexpansion, stent elastic recoil, and stent deficit were calculated. Optimal stent deployment was defined as final MLD \geq 90% of predicted diameter.

Results: For deploying a stent balloon, higher than nominal pressure was used in 83% of cases (93/112). However, optimal deployment was observed in only 32% (36/112). Adjuvant post-dilatation was performed in 59% (45/76) of lesions with suboptimal expansion, which increased the optimal deployment rate by 60% (27/45). Final optimal stent deployment rate was achieved in 56% (63/112). We found that the MLD1 (p = 0.04), MLD3 (p = 0.02), final MLD (p = 0.04), and optimal stent deployment rate (p = 0.036) were significantly reduced in longer stent deployment lesions (\geq 20 mm) compared to shorter lesions (\leq 20 mm).

Conclusions: Stent length may be a contributing factor of suboptimal stent expansion in angiography-guided PCI.

Key words: stent expansion, quantitative coronary angiography, percutaneous coronary intervention

Kardiol Pol 2015; 73, 8: 598-605

INTRODUCTION

It is well known that larger final dimensions of target vessel lumen represent a crucial factor for lower risk of recurrence and improvement of long-term patency after percutaneous coronary intervention (PCI) [1–3]. Failure of the delivery balloon to reach its target size during stent deployment and subsequent stent elastic recoil are representative mechanisms that contribute to suboptimal stent expansion and the severity of residual lesion after PCI [4–6].

Recently, despite innovative development of stent delivery technology and a new generation of drug-eluting stents (DES) improving their flexibility and endothelial coverage, there are still concerns about suboptimal stent expansion, despite the use of high inflation pressure. Takano et al. [7] reported that the cross-sectional area was only 62% of maximum achievable after insertion of the new generation of DES, despite using high inflation pressure by intravascular ultrasound (IVUS) observation. So far, several modalities such

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as quantitative coronary angiography (QCA), IVUS, and optical coherence tomography (OCT) have been performed to find out predisposing factors of suboptimal stent expansion.

Among them, IVUS is widely used and provides useful information about vessel size, calcium deposit, and severity of lesions, more precisely than coronary angiography, and it helps cardiologist to determine the adequate size of stent, and to evaluate and prevent inadequate stent expansion during PCI [8]. Although previous studies showed the beneficial role of IVUS [9–12], a substantial portion of PCIs are currently being performed under angiographic guidance only, in Korea as well as worldwide, due to cost effectiveness.

Therefore, to evaluate stent-related factors of suboptimal stent expansion in angiography-guided PCI, we performed a retrospective analysis to compare the adequacy of stent expansion of four widely used first- and second-generation DESs by QCA.

METHODS Study population

A total of 96 patients with de novo coronary artery lesions, who underwent elective PCI at Sanggye Paik Hospital, Seoul, Korea, were retrospectively reviewed for this study. Patients with re-stenotic coronary lesion, multiple stent deployment in a single coronary artery, reference diameter of estimated coronary lesion smaller than 2.5 mm, and inadequate angiographic image quality were excluded. In total 112 de novo lesions from enrolled patients were treated with one of the following four different types of stent: 25 received a Taxus Liberte (Boston Scientific, USA), 30 a Cypher (Cordis-Johnson and Johnson, USA), 27 an Endeavor Resolute (Medtonic, USA), and 30 a Xience V (Abbott Vascular, USA).

Procedural technique

All procedures were performed in a routine manner via femoral or radial routes. Intravenous heparin was given at the start of the procedure (10,000 to 15,000 IU IV) to maintain an activated clotting time of 220–300 s. All patients received aspirin 300 mg and clopidogrel 300–600 mg pre-procedure. The choice of guide wires, and the type, length, and size of the stents were left to the discretion of the operators. The use of supra-nominal pressure and adjuvant balloon inflation were allowed, if necessary. Stent implantation was successfully performed in all cases, and no major complications occurred during PCI.

QCA-derived parameters

All of the coronary angiographic records were analysed by QCA analysis using Cardiovascular Angiography Analysis System (CAAS) II v5.7 software [13] by an experienced angiographer. Minimal lumen diameter (MLD), length, and reference vessel diameter of stent deployment lesion were measured pre and post stent implantation. Lumen measurements

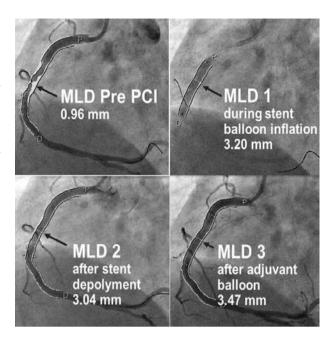


Figure 1. Definition of quantitative coronary angiography-derived parameters. Stent underexpansion was calculated as PD – MLD1. Stent elastic recoil was calculated as MLD1 – MLD2. Stent deficit was calculated as PD – final MLD (MLD 2 or MLD3 depending on the use of adjuvant balloon); MLD — minimal lumen diameter; PD — predicted diameter; PCI — percutaneous coronary intervention

were made using end diastolic frames, and the external diameter of the contrast-filled catheter was used as a calibration standard. MLD was measured at peak pressure during stent deployment (MLD1), after stent deployment (MLD2), and after postdilatation (MLD3). Predicted stent diameter (PD) was derived from the manufacturers' expected compliance charts. 1) Stent delivery balloon underexpansion (hereafter called "stent underexpansion"); 2) stent elastic recoil; and 3) stent deficit, were calculated as follows: 1) PD-MLD1, 2) MLD1-MLD2, and 3) PD – final MLD (MLD 2 or MLD3 depending on the use of adjuvant balloon), respectively (Fig. 1) [14]. Optimal stent deployment was defined as final MLD (MLD2 or MLD3 depending on the use of adjuvant balloon) ≥ 90% of PD. QCA data of all cases were independently analysed and obtained by three interventional cardiologists to avoid inter-observer and intra-observer variability. All QCA data are average values of the values obtained by three investigators. There are no statistical differences in the obtained values.

Statistical analysis

All data were analysed using PASW 18.0 software. Categorical variables were reported as percentages, and continuous variables as means \pm standard deviation. Normally distributed continuous variables were compared using unpaired student t-test or analysis of variance (ANOVA). P value < 0.05 was considered statistically significant.

RESULTS

Study population and angiographic characteristics

The baseline characteristics of the study population are shown in Table 1, and angiographic and procedural characteristics are described in Table 2.

Stent underexpansion, stent elastic recoil, and stent deficit by QCA

There was a significant difference between MLD1 and PD $(2.42 \pm 0.44 \text{ vs.} 3.19 \pm 0.42 \text{ mm}, p = 0.0001)$. The absolute stent underexpansion was $0.78 \pm 0.31 \text{ mm}$, representing $24 \pm 9.5\%$ of PD. Consistently there was a significant difference between MLD1 and MLD2 $(2.42 \pm 0.44 \text{ vs.} 2.26 \pm 0.49 \text{ mm}, p = 0.001)$.

Table 1. Baseline characteristics of the study population (n = 96)

Age [years]	64.2 ± 11.6
Sex:	
Men	70 (62.5%)
Women	42 (37.5%)
Diabetes	38 (33.9%)
Hypertension	81 (72.3%)
Hypercholesterolaemia	62 (55.4%)
Chronic kidney disease	10 (10.4%)
Smoker:	
Non-smoker	66 (58.9%)
Current smoker	29 (25.9%)
Ex-smoker	17 (15.2%)

Data are presented as mean \pm standard deviation for continuous variables, and number (percentage) for categorical data

The absolute stent elastic recoil was 0.14 \pm 0.33 mm, representing 8.5 \pm 10.7% of MLD1. Finally, there was a significant difference between median final stent MLD (MLD2 or MLD3) and PD (2.36 \pm 0.50 vs. 3.19 \pm 0.42 mm, p = 0.0001). The absolute stent deficit was 0.83 \pm 0.32 mm, representing 26.5 \pm 9.9% of PD. These data indicate that suboptimal stent expansion commonly occurs in angiography-guided PCI. QCA-derived parameters of all lesions are summarised in Table 3.

Impact of adjuvant postdilatation on stent expansion

Higher than nominal pressure (additional 1–8, mean 3.2 ± 1.8 atm) during stent deployment was used in 83% (93 of 112) of the cases for optimal stent expansion. However, optimal deploy-

Table 2. Angiographic and procedural characteristics (n = 112)

Left anterior descending artery	49 (43.8%)		
Left circumflex artery	26 (23.2%)		
Right coronary artery	36 (32.1%)		
Left main stem	1 (0.9%)		
Stent length [mm]	21.04 ± 6.26		
Stent nominal diameter [mm]	3.06 ± 0.39		
Stent nominal pressure [atm]	9.04 ± 0.78		
Stent deployment pressure [atm]	11.74 ± 2.22		
MLD pre-intervention [mm]	0.29 ± 0.27		
Postdilatation balloon size [mm]	3.11 ± 0.47		

Data are presented as mean \pm standard deviation for continuous variables, and number (percentage) for categorical data; MLD — minimal lumen diameter

Table 3. Quantitative coronary angiography-derived parameters of all lesions and two groups according to length of stent

Variable	All (n = 112)	≥ 20 mm (n = 56)	< 20 mm (n = 56)	P*
Reference vessel diameter [mm]	3.07 ± 0.41	3.01 ± 0.42	3.12 ± 0.39	0.15
MLD1, during stent balloon [mm]	2.42 ± 0.44	2.34 ± 0.48	2.48 ± 0.40	0.04
MLD2, after deployment [mm]	2.26 ± 0.49	2.24 ± 0.48	2.35 ± 0.44	0.15
MLD3, after adjuvant balloon [mm]	2.46 ± 0.50	2.39 ± 0.49	2.49 ± 0.44	0.02
Final MLD, MLD 2, or MLD 3 [mm]	2.36 ± 0.50	2.29 ± 0.49	2.42 ± 0.44	0.04
Predicted diameter [mm]	3.19 ± 0.42	3.12 ± 0.44	3.26 ± 0.39	0.74
Stent underexpansion [mm]	0.78 ± 0.31	0.78 ± 0.34	0.78 ± 0.29	0.9
Stent elastic recoil [mm]	0.14 ± 0.33	0.12 ± 0.33	0.14 ± 0.34	0.15
Stent deficit [mm]	0.84 ± 0.32	0.88 ± 0.30	0.79 ± 0.33	0.12
Use of supra-nominal pressure	93 (83%)	43 (76%)	50 (89%)	0.12
Use of adjuvant balloon	45 (40%)	21 (37%)	24 (42%)	0.70
Optimal stent deployment rate:				
Before adjuvant balloon	36 (32%)	14 (25%)	22 (38%)	0.15
After adjuvant balloon	63 (56%)	26 (46%)	37 (56%)	0.036

Data are presented as mean \pm standard deviation for continuous variables, and number (percentage) for categorical data; MLD — minimal lumen diameter; *p-value is comparison between longer (\geq 20 mm) and shorter (< 20 mm) stent deployment group

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Variable	Taxus Liberte	Cypher	Endeavor Resolute	Xience V
Stent diameter:				
2.50 mm	3	3	9	3
2.75 mm	4	3	7	4
3.00 mm	9	17	9	8
3.50 mm	6	7	2	12
4.00 mm	3	0	0	3
Stent length:				
10–19 mm	8	13	13	22
20–29 mm	13	11	7	8
≥ 30 mm	4	6	7	0

ment was observed in only 32% (36/112) of cases after stent deflation. Adjuvant postdilatation with noncompliant balloon was performed in 59% (45/76) of lesions with suboptimal expansion, which increased the optimal deployment rate by 60% (27/45). After additional balloon dilatation, final optimal stent deployment was achieved in 56% (63/112).

Impact of stent length on stent expansion

The stent deployment lesion was divided into two groups according to the length of the stent (Table 3). Longer stent (\geq 20 mm) deployment lesions showed significantly more stent underexpansion than shorter stent (< 20 mm) deployment lesions by MLD1 (2.34 ± 0.48 vs. 2.48 ± 0.40 mm, p = 0.04), MLD3 (2.39 ± 0.49 vs. 2.49 ± 0.44 mm, p = 0.02), and final MLD (2.29 ± 0.49 vs. 2.42 ± 0.44 mm, p = 0.04). Additionally, the final optimal stent deployment rate of longer stent deployment lesions was significantly reduced compared to shorter stent deployment lesions after adjuvant postdilatation (46% vs. 56%, p = 0.036).

Influence of stent type in stent expansion

We analysed the influence of stent types in stent expansion. The characteristics of four widely used DES are summarised in Table 4. We compared the adequacy of stent expansion in four different stents groups, excluding stents that are 4 mm in diameter and stents 30 mm in length, which were not used in all types of stents (Table 4). There were no significant differences in the degree of stent underexpansion, stent elastic recoil, and optimal stent deployment rate between the four groups (Fig. 2A–C, Table 5). These data indicate that the stent type is not a critical factor of optimal stent expansion in angiography-guided PCI.

DISCUSSION

Failure to achieve optimal stent expansion poses a risk of treatment failure such as in-stent restenosis and stent thrombosis after

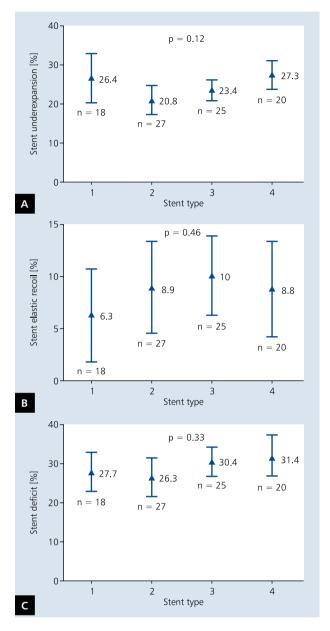


Figure 2. Comparison of quantitative coronary angiography-derived parameters (**A**. Stent underexpansion; **B**. Stent elastic recoil; **C**. Stent deficit) between the four different drug eluting stents (stent diameter < 4.0 mm, length < 30 mm). Stent type: 1 = Taxus Liberte (Boston Scientific, USA), 2 = Xience V (Abbott Vascular, USA), 3 = Cypher (Cordis-Johnson and Johnson, USA), 4 = Endeavor Resolute (Medtonic, USA)

PCI [15, 16]. Several factors, including diameters, characteristics of the lesions, calcification of the lesion at pre-intervention, residual plaque burden, and symmetrical index of stent expansion (the minor diameter divided by the major diameter) at post-intervention, may determine the adequacy of stent expansion [5]. In the present study, we found that stent length has an effect on optimal stent expansion in angiography-guided PCI. Previous studies showed that long stent length and longer

Table 5. Comparison of quantitative coronary angiography-derived parameters between the four different drug eluting stents (stent diameter < 4.0 mm, length < 30 mm)

Variables	Taxus Liberte	Cypher	Endeavor Resolute	Xience V	Р
Stent diameter 3.50 mm	N = 5	N = 6	N = 2	N = 12	
MLD1 [mm]	2.68 ± 0.57	3.08 ± 0.30	2.99 ± 0.51	2.95 ± 0.47	0.70
MLD2 [mm]	3.07 ± 0.16	3.18 ± 0.21	2.84 ± 0.28	2.87 ± 0.50	0.15
Stent diameter 3.00 mm	N = 7	N = 13	N = 8	N = 8	
MLD1 [mm]	2.59 ± 0.25	2.62 ± 0.34	2.81 ± 0.10	2.70 ± 0.14	0.29
MLD2 [mm]	2.69 ± 0.11	2.74 ± 0.38	2.79 ± 0.17	2.64 ± 0.24	2.44
Stent diameter 2.75 mm	N = 3	N = 3	N = 6	N = 4	
MLD1 [mm]	2.49 ± 0.34	2.29 ± 0.23	2.45 ± 0.18	2.34 ± 0.32	0.83
MLD2 [mm]	2.10 ± 0.45	2.45 ± 0.16	2.40 ± 0.23	2.23 ± 0.39	0.78
Stent diameter 2.5 mm	N = 3	N = 2	N = 4	N = 3	
MLD1 [mm]	2.22 ± 0.06	2.21 ± 0.19	2.35 ± 0.23	2.17 ± 0.23	0.48
MLD2 [mm]	2.08 ± 0.37	2.32 ± 0.19	2.12 ± 0.28	1.99 ± 0.43	0.52
Overall	N = 18	N = 24	N = 20	N = 27	
Reference diameter [mm]	3.03 ± 0.07	3.05 ± 0.14	3.01 ± 0.05	3.03 ± 0.09	0.78
MLD1 [mm]	2.59 ± 0.25	2.62 ± 0.34	2.81 ± 0.10	2.70 ± 0.14	0.32
MLD2 [mm]	2.69 ± 0.11	2.74 ± 0.38	2.79 ± 0.17	2.64 ± 0.24	0.74
Stent underexpansion [mm]	0.60 ± 0.42	0.51 ± 0.27	0.37 ± 0.20	0.58 ± 0.36	0.12
Stent elastic recoil [mm]	0.13 ± 0.24	0.07 ± 0.12	0.13 ± 0.16	0.13 ± 0.14	0.46
Use of supra-nominal inflation pressure	16 (88%)	19 (79%)	17 (85%)	21 (77%)	0.80
Use of adjuvant balloon	11 (61%)	7 (29%)	7 (35%)	11 (40%)	0.20
Optimal stent deployment:					
Before adjuvant balloon	4 (22%)	9 (37%)	7 (35%)	5 (18%)	0.39
After adjuvant balloon	8 (44%)	13 (54%)	9 (45%)	10 (37%)	0.68

Data are presented as mean \pm standard deviation for continuous variables, and number (percentage) for categorical data; MLD — minimal lumen diameter

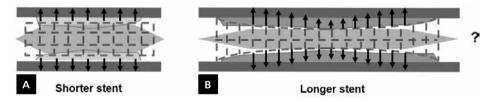


Figure 3. Schematic diagram of stent expansion in shorter (A) and longer (B) stent deployment lesions

lesion length are predictors of restenosis after DES implantation [17]. However, little is known about the contribution of stent or lesion length in optimal stent expansion. Our data demonstrated that MLD1, MLD3, and final MLD were significantly reduced in longer stent deployment lesions. In addition, the final optimal stent deployment rate of longer stent deployment lesions was significantly reduced compared to shorter stent deployment lesions after adjuvant postdilatation. These data indicate that stent and lesion length are among the contributing factors for optimal stent expansion in angiography-guided PCI. However, the characteristics of lesions should be evaluated bearing in mind

that stent length directly or indirectly affects stent expansion. QCA is not an appropriate tool for evaluating lesion characteristics, compared to IVUS or OCT [18]. Therefore, IVUS or OCT for comparison of longer and shorter stent deployment lesions may be needed to analyse lesion characteristics such as calcium deposit, plaque component, and eccentricity, otherwise the mechanical expansion force from the balloon inflation may not evenly distribute to the stent surface in longer stents compared to shorter stents (Fig. 3).

There are several procedural factors for optimal stent expansion, such as lesion preparation, compliance of postdilatation balloon, and time of stent balloon inflation. Adequate lesion preparation, including predilatation, rotational atherectomy, and cutting the balloon, is important before stent implantation in some subsets of lesions to achieve acceptable results [19]. Compliance of stent balloon also affects optimal stent expansion. The results of previous studies are somewhat divergent [20], showing that non-compliant balloons may be better than semi-compliant balloons [21] and vice-versa [22]. Occasionally, extremely high-pressure dilation with a non-compliant balloon (up to 40 atm) was used in un-dilatable lesions [23]. In addition, a few studies reported that longer balloon inflation time is also helpful to achieve optimal stent expansion [24, 25].

It is an important issue that stent implantation based on manufacturer's compliance chart might not achieve adequate stent expansion in DES [26, 27]. Although several strategies such as higher-pressure balloon inflation have improved the final MLD and clinical outcome in previous studies, the final stent area and MLD are still much lower than the predicted stent area and diameter [7, 14, 26]. The present study also showed that final stent MLD is on average 26.5% less than PD and stent underexpansion (24 \pm 9.5%), and stent elastic recoil (8.5 \pm 10.7%) contributes to suboptimal stent expansion despite the use of supra-nominal inflation pressure in the majority of patients (83%). Therefore, previous reports and our data suggest that further strategies with supra-nominal inflation pressure might be needed to achieve optimal stent expansion.

Adjuvant postdilatation after stent deployment is one of the solutions for suboptimal stent expansion. Previous studies showed that additional postdilatation after deployment of bare metal stents improved stent expansion and resulted in better outcome with lower rate of recurrence [28–31]. Several studies also provided some strong evidence for the potential benefit of postdilatation after DES deployment [17, 21]. In our study, a considerable proportion (59%) with suboptimal stent expansion were performed in adjuvant postdilatation with a noncompliant balloon, which increased the optimal deployment rate from 32% to 56%. Thus, previous reports and our results indicate that adjuvant postdilatation can improve the adequacy of DES expansion in angiography-guided PCI.

According to our findings and previous studies, we suggest that adequate lesion preparation, higher pressure or longer balloon inflation time, and adjuvant postdilatation may be needed to achieve optimal stent expansion in longer stent deployment lesions. Further large-scale prospective randomised studies using IVUS should be performed to confirm our suggestion.

Finally, we showed that the degree of stent underexpansion, stent elastic recoil, and stent deficit were not different among the four types of DES. However, Aziz et al. [14] showed a small but significant greater magnitude of stent underexpansion in the Taxus Express stent than other DESs. This discrepancy might be due to underlying differences in lesion characteristics between the two studies.

This study is a retrospective and single-centre study with a small number of stents. In addition, it was not randomised, and the choice of stent was left to the discretion of the operator. Also, adjuvant balloon type, inflation time, and pressure, which can influence stent expansion, were not standardised.

CONCLUSIONS

Stent length may be a contributing factor of suboptimal stent expansion in angiography-guided PCI. Therefore, several strategies, such as adjuvant postdilatation, might be needed to improve the adequacy of stent expansion, particularly in longer stent deployment lesions in angiography-guided PCI.

Conflict of interest: none declared

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w Centrum Kongresowym ICE w Krakowie (ul. Marii Konopnickiej 17, 30–302 Kraków)

KOMITET ORGANIZACYJNY: Piotr Jankowski, Andrzej Pajak, Grzegorz Kopeć, Wojciech Drygas, Agnieszka Serafin

Uprzejmie informujemy, że istnieje możliwość **zgłaszania streszczeń** do **30 września 2015 r.** Nagrodą w konkursie za najlepsze doniesienie oryginalne będzie **grant** wyjazdowy na Konferencję **EuroPRevent 2016** (Stambuł, Turcja).

Ramowy program i rejestracja na stronie: www.kardiologiaprewencyjna.eu

Długość stentu jest czynnikiem przyczyniającym się do suboptymalnego rozprężenia stentów uwalniających lek

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Część niniejszej pracy została zaprezentowana w formie streszczenia na AHA Scientific Sessions 2009.

Streszczenie

Wstęp: Nieuzyskanie optymalnego rozprężenia stentu powoduje ryzyko niepowodzenia przezskórnej interwencji wieńcowej (PCI). Mimo że ultrasonografia wewnątrznaczyniowa pozwala uzyskać przydatne informacje dotyczące suboptymalnego rozprężenia stentu, obecnie znaczną część zabiegów PCI wykonuje się wyłącznie pod kontrolą angiografii.

Cel: Przeprowadzono retrospektywną analizę zmian poddanych PCI z użyciem koronarografii ilościowej w celu oceny rozprężenia 4 stentów uwalniających lek powszechnie stosowanych w PCI pod kontrolą angiografii.

Metody: Przeanalizowano łącznie 112 nowych zmian. Minimalną średnicę światła naczynia (MLD) zmierzono w momencie osiągnięcia największego ciśnienia w trakcie rozprężania stentu (MLD1), po rozprężeniu stentu (MLD2) i po postdylacji (MLD3). Dokonano obliczeń dotyczących niedostatecznego rozprężenia stentu, elastycznego odkształcenia stentu i niedoboru końcowej średnicy stentu. Optymalne rozprężenie stentu definiowano jako końcową MLD ≥ 90% prognozowanej średnicy.

Wyniki: W balonach do rozprężania stentów w 83% (93/112) przypadków stosowano ciśnienie wyższe od nominalnego. Jednak optymalne rozprężenie stentu obserwowano tylko w 32% (36/112) przypadków. Dodatkową postdylację przeprowadzono w 59% (45/76) zmian z suboptymalnym rozprężeniem stentu, co spowodowało zwiększenie częstości optymalnego rozprężenia stentu do 60% (27/45). Ostatecznie osiągnięto częstość optymalnego rozprężenia stentu wynoszącą 56% (63/112). Zaobserwowano, że MLD1 (p = 0,04), MLD3 (p = 0,02), końcowa MLD (p = 0,04) i częstość optymalnego rozprężenia stentu (p = 0,036) były istotnie mniejsze w przypadku implantacji stentów w dłuższych zmianach (≥ 20 mm) niż w krótszych zmianach (< 20 mm).

Wnioski: Długość stentu może być czynnikiem przyczyniającym się do suboptymalnego rozprężenia stentu w PCI przeprowadzanej pod kontrolą angiografii.

Słowa kluczowe: rozprężenie stentu, koronarografia ilościowa, przezskórna interwencja wieńcowa

Kardiol Pol 2015; 73, 8: 598-605

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Praca wpłynęła: 01.04.2014 r. Zaakceptowana do druku: 07.10.2014 r. Data publikacji AoP: 23.02.2015 r.

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^{*}Byung Gyu Kim i Sung Woo Cho w równym stopniu przyczynili się do powstania niniejszego artykułu.