

Use and Long-Term Outcome of Bare Metal Stent Implantation in the Drug-Eluting Stent Era

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Abstract

Background. Although drug-eluting stents (DES) are widely used today, bare metal stents (BMS) are still frequently employed. We investigated the utilization and clinical outcomes of BMS implantation since we first began using DES.

Methods. The clinical course following percutaneous intervention with de novo implantation of BMS was studied beginning in July 2004, when sirolimus-eluting stents (SES) were first used in our hospital, to August 2006. Outcomes following BMS and SES implantation were compared.

Results. BMS implantation was carried out in 160 lesions and SES implantation in 242 lesions. Follow-up coronary angiography was performed for 208 lesions (78 lesions in which BMS were implanted and 130 lesions in which SES were implanted) within 1 year. There were no significant differences in patient characteristics between the SES and BMS groups. Regardless of the reason for BMS implantation, the rates of in-stent restenosis and target lesion revascularization were higher in the BMS group than in the SES group. However, the rate of in-stent restenosis and target lesion revascularization of BMS in lesions with a diameter of 4.0 mm or greater was 0%.

Conclusions. In order to reduce the risk of in-stent restenosis and target lesion revascularization, we recommend implantation of BMS with a diameter of 4.0 mm or greater or SES unless it is contraindicated.

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Key Words

Stent (bare metal stent implantation)
 Coronary artery disease

Restenosis

Revascularization

INTRODUCTION

Currently, drug-eluting stents (DES) are widely used for percutaneous coronary intervention (PCI). Implantation of DES is reported to significantly

reduce the rates of in-stent restenosis (ISR) and target lesion revascularization (TLR)¹⁻⁴⁾ but even in the current DES era we still use bare metal stent (BMS) for reasons such as the absence of need to implant DES for a focal simple lesion in a large

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vessel because restenosis may be unlikely; inability to carry out DES implantation in stenotic lesions with severe vessel tortuosity or calcification, *i.e.* lesions in which flexible BMS implantation or simple balloon angioplasty may be effective; and prescription in Japan of DES implantation in acute coronary syndrome (ACS) patients. Accordingly, BMS remains important even in the DES era.

In order to clarify the appropriate indications for and results of BMS implantation in the DES era, we investigated the utilization and the short- and long-term outcomes of BMS implantation performed in our institution since we first initiated the use of DES.

SUBJECTS AND METHODS

Subjects

From July 2004 to April 2006, 242 lesions in 214 patients underwent stent implantation in our hospital. Among the 242 lesions, 208 were studied by coronary angiography 6 to 12 months after stent implantation. Among these 208 lesions, SES (Cypher stent, Johnson and Johnson) had been implanted in 130 lesions, and BMS had been implanted in 78 lesions. We classified the lesions in which BMS were implanted by the reason for BMS implantation rather than SES: Group A - lesions for which SES did not seem to be the preferred approach because of short lesion length and large vessel diameter, both findings compatible with a good outcome using BMS; Group B - lesions in ACS patients, whom SES implantation is not officially permitted in Japan; Group C - lesions to which SES could not be delivered or in which SES seemed difficult to deliver because of severe vessel tortuosity or calcification; Group D - lesions in patients who could not take ticlopidine because they were allergic to this agent, or who had a high risk of hemorrhage; Group E - lesions with a small vessel diameter (less than 2.5 mm), making SES difficult to implant.

Primary endpoints

The primary endpoint was a composite of major adverse cardiac and cerebrovascular events (death from cardiac causes, myocardial infarction, and ischemia-driven TLR) within the first 12 months of follow-up. TLR was defined as revascularization for a stenosis within the stent or in the adjacent 5 mm of the distal or proximal edge of the stent.

Successful stenting was defined as a final steno-

sis of less than 50% of the vessel diameter after implantation of the study stent, and treatment success was defined as a final stenosis of less than 50% of the vessel diameter with the use of any percutaneous intervention.

Quantitative coronary angiography

Coronary angiograms were digitally recorded at baseline, post procedure, and at follow-up, and were assessed at an angiographic core laboratory with an automated edge-detection system (CAAS, Pie Medical Imaging) by experienced personnel unaware of the patients' profiles. All measurements were performed on cineangiograms recorded after the intracoronary administration of nitroglycerin. The single projection in which the stenosis appeared to be most severe was used at all times. The contrast-filled nontapered catheter tip was used for calibration, and the reference diameter was determined by interpolation. Quantitative measurements included the diameter of the reference vessel, the minimal luminal diameter, and the extent of diametric stenosis defined as [(reference vessel diameter - minimal lumen diameter) / reference vessel diameter] × 100. We defined ISR as stenosis of at least 50% of the minimal luminal diameter in the stented area and within the margins 5 mm proximal and distal to each stent edge.

Statistical analysis

Quantitative data are presented as mean ± SD, and the categorical data as frequencies (percentage). Continuous variables were compared using the unpaired *t*-test. Binary variables were compared by the Fisher exact test. Statistical significance was defined as *p* value less than 0.05. All statistical analyses were performed using JMP 5 software (SAS Institute).

RESULTS

Ratio of BMS implantation and SES implantation in our hospital

Since July 2004 to August 2006, BMS implantation was carried out in 160 lesions and SES implantation in 242 lesions. Percentages of BMS and SES implantation in our hospital are shown in **Fig. 1** and the reasons for BMS implantation are shown in **Fig. 2**. Since July 2004, BMS has been consistently used in about 40% of stent implantations in our hospital. Follow-up coronary angiography was performed for 208 lesions (78 lesions in which BMS

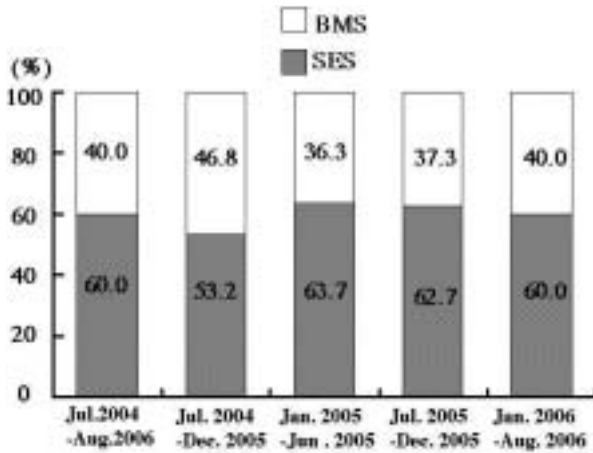


Fig. 1 Ratio of SES and BMS implanted in our hospital
 SES = sirolimus-eluting stent ; BMS = bare metal stent.

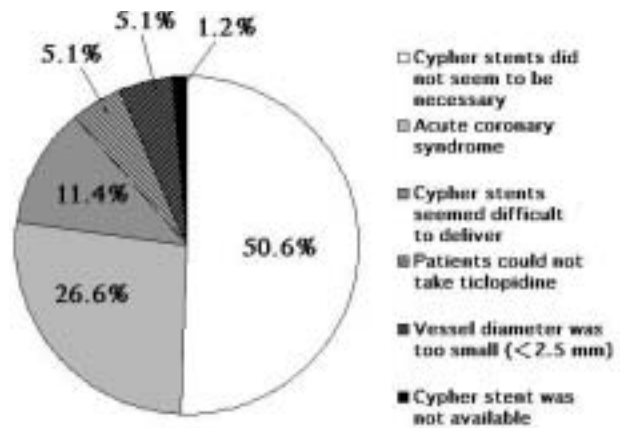


Fig. 2 Rationale for BMS implantation
 Abbreviation as in Fig. 1.

Table 1 Baseline patient and lesion characteristics

	SES group (n = 130)	BMS group (n = 78)	p value
Age(yr, mean ± SD)	66.6 ± 10.0	67.1 ± 8.7	0.74
Male(%)	82.2	92.0	0.24
Hypertension(%)	56.2	55.1	0.89
Hyperlipidemia(%)	67.7	71.8	0.54
Diabetes mellitus(%)	45.4	38.5	0.33
Smoking(%)	62.3	62.8	0.94
Hemodialysis(%)	6.2	5.1	0.76
Body mass index(kg/m ² , mean ± SD)	24.2 ± 3.0	24.1 ± 3.7	0.79
Family history of coronary artery disease(%)	16.2	19.2	0.57
Medication(%)			
Statin	57.5	60.2	0.82
ACE inhibitor	12.3	16.7	0.63
ARB	10.1	11.5	0.73
Calcium channel blocker	43.8	44.8	0.92
Beta-blocker	15.1	16.7	0.78
Left anterior descending artery(%)	38.5	34.6	0.58
Left circumflex artery(%)	16.2	16.7	0.92
Right coronary artery(%)	36.2	43.6	0.07
Left main trunk(%)	5.4	5.1	0.94
Saphenous vein graft(%)	3.8	0	0.08
Type A(%)	2.7	0	0.41
Type B1(%)	20.1	12.0	0.35
Type B2(%)	27.4	20.0	0.47
Type C(%)	49.3	68.0	0.11
Bifurcated lesion(%)	2.3	5.1	0.28
Chronic total occlusion(%)	10.8	3.8	0.08

Lesion types of A, B1, B2, and C are defined according to the American Heart Association/American College of Cardiology(AHA/ACC)classification.⁵⁾

ACE = angiotensin converting enzyme ; ARB = angiotensin receptor blocker. Other abbreviations as in Fig.1.

Table 2 Procedure characteristics

	SES group (n = 130)	BMS group (n = 78)	p value
Lesion length (mm)	17.1 ± 3.1	20.0 ± 6.2	0.003
Number of stents	1.3	1.6	0.08
Kissing balloon technique (%)	2.1	5.1	0.28
PTCRA (%)	0	7.7	0.01
Reference diameter (mm)			
Preintervention	2.85 ± 0.45	2.91 ± 0.41	0.30
Postintervention	3.04 ± 0.53	3.18 ± 0.51	0.59
Follow-up	2.93 ± 0.49	2.97 ± 0.48	0.55
MLD (mm)			
Preintervention	0.24 ± 0.21	0.21 ± 0.21	0.27
Postintervention	2.89 ± 0.49	2.92 ± 0.47	0.65
Follow-up	2.59 ± 0.74	1.94 ± 0.97	< 0.0001
Diametric stenosis (%)			
Preintervention	91.7 ± 7.1	93.0 ± 7.2	0.21
Postintervention	6.4 ± 2.1	5.6 ± 1.9	0.10
Follow-up	11.7 ± 19.6	35.6 ± 29.5	< 0.0001
Stent length (mm)	20.7 ± 4.1	19.5 ± 5.0	0.06
Stent diameter (mm)	2.98 ± 0.37	3.37 ± 0.50	< 0.0001
Number of stents	1.15 ± 0.40	1.03 ± 0.23	0.015
Final balloon diameter (mm)	3.00 ± 0.38	3.38 ± 0.49	< 0.0001
Final inflation pressure (atm)	14.6 ± 3.3	14.3 ± 3.8	0.70
PCI-follow-up CAG period (month)	7.3 ± 1.4	7.9 ± 1.2	0.08
Late loss (mm)	0.30 ± 0.56	0.98 ± 0.85	< 0.0001
ISR rate (%)	3.8	19.2	0.0002

Continuous value are mean ± SD.

PTCRA = percutaneous transluminal coronary rotational ablation; MLD = minimal lumen diameter; PCI = percutaneous coronary intervention; CAG = coronary angiography; ISR = in-stent restenosis. Other abbreviations as in Fig.1.

were implanted and 130 lesions in which SES were implanted within 1 year.

Baseline and procedural characteristics

The characteristics of the patients and the 208 lesions examined by follow-up coronary angiography are shown in **Tables 1** and **2**. Baseline patient characteristics were not significantly different between the BMS and the SES groups, and vessel diameter also did not differ between the groups. Stent diameter was larger in the BMS group than in the SES group (3.37 ± 0.50 vs 2.98 ± 0.37 mm, $p < 0.0001$; **Table 2**).

Lesion characteristics of each subgroup of the BMS group classified according to the reason for BMS implantation are shown in **Table 3**. In each subgroup of the BMS group, reference vessel and stent diameters tended to be larger in Group A

(lesions in which SES implantation was not clearly indicated because of short lesion length and large vessel diameter, both consistent with a good outcome using BMS) and lesion type according to the American Heart Association/American College of Cardiology (AHA/ACC) classification⁵) tended to be simpler than in other groups. That is, there were more type A and B1 lesions in Group A than in other subgroups (**Table 3**).

Types of BMS

Types of BMS used from July 2004 to April 2006 are shown in **Fig. 3**. Driver stents (Medtronic Co.) were most frequently used (59.8%).

Clinical outcome: SES vs BMS

Clinical outcomes are shown in **Table 4**. Major adverse cerebral and cardiac events did not occur in

Table 3 Lesion characteristics of each subgroup of the BMS group classified according to the reason for BMS implantation

	Group A (n = 40)	Group B (n = 21)	Group C (n = 9)	Group D (n = 4)	Group E (n = 4)
Lesion length(mm)	14.4 ± 5.2	16.3 ± 4.3	14.6 ± 4.0	14.0 ± 5.7	15.5 ± 4.8
Vessel diameter(mm)	3.27 ± 0.44	3.04 ± 0.33	2.76 ± 0.38	2.97 ± 0.36	2.44 ± 0.64
Stent length(mm)	18.4 ± 4.5	22.3 ± 5.5	18.6 ± 4.3	18.3 ± 4.7	19.8 ± 3.9
Stent diameter(mm)	3.62 ± 0.38	3.42 ± 0.35	2.78 ± 0.34	3.13 ± 0.25	2.31 ± 0.13
Number of stents	1.05	1.00	1.00	1.00	1.00
Type of lesion(A + B1/B2 + C)	0.40 / 0.60	0.29 / 0.71	0.30 / 0.70	0.75 / 0.25	0.25 / 0.75

Continuous value are mean ± SD.
Abbreviation as in Fig. 1.

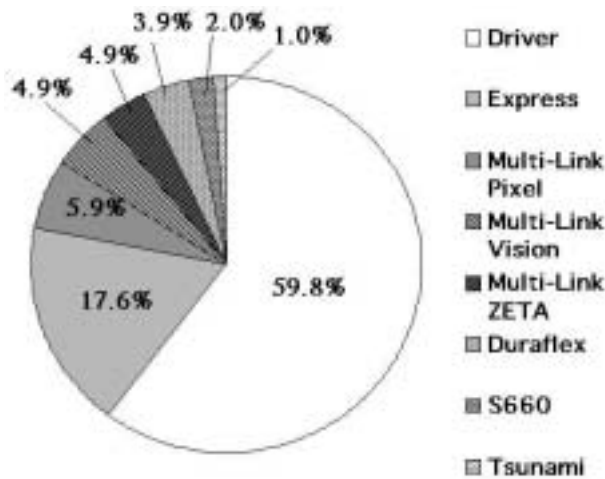


Fig. 3 Types of BMS implanted
Abbreviation as in Fig. 1.

any patient in either the SES group or the BMS group. TLR rates of the two groups were 3.8% (SES group), and 11.5% (BMS group) (p = 0.032; Table 4).

Angiographic analysis and clinical outcome: Subgroups in BMS group

The ISR rates in each subgroup of the BMS group are shown in Fig. 4 - left. The ISR rate was statistically significantly higher for BMS than SES implantation in Group A as well as in Groups C and D, in which BMS were used due to vessel calcification or tortuosity (Group C) and to ticlopidine allergy or high risk of hemorrhage (Group D). There were similar findings for TLR in Groups C and D (Fig. 4 - right). In contrast, ISR and TLR rates did not differ in Groups B and E, in which ACS and small vessel diameter, respectively, were present. ISR occurred in 4 patients in Group E, but

Table 4 Clinical outcomes

	SES group (n = 130)	BMS group (n = 78)	p value
Primary success rate(%)	100.0	100.0	-
Acute or late thrombosis(%)	0	0	-
Cardiac death(%)	0	0	-
Myocardial infarction(%)	0	0	-
Cerebrovascular events(%)	0	0	-
TLR rate(%)	3.8	11.5	0.032

TLR = target lesion revascularization. Other abbreviations as in Fig. 1.

none of them underwent TLR because these lesions were in distal segments of the coronary arteries (three in the distal segment of the right coronary artery and one in the distal segment of the left anterior descending coronary artery). The restenosis was not clinically significant in any of these patients.

We also investigated ISR and TLR rates according to BMS diameter (Fig. 5). For lesions with a stent diameter of 4.0mm or greater (n = 19 total lesions, with 17 in Group A and 2 in Group B) the ISR rate was 10.5% (Fig. 5 - left) and the TLR rate was 0% (Fig. 5 - right). In addition, we compared the ISR and TLR rates of BMS and SES implantation in 24 BMS vs 92 SES lesions in Group A vessels having a diameter of 3.0 to 3.5 mm (Fig. 6). Both ISR and TLR rates for BMS were significantly higher than for SES, even when BMS was implanted because SES utilization was not clearly indicated.

DISCUSSION

In this study, we showed that the ISR of BMS with a diameter up to 3.5 mm was higher than that

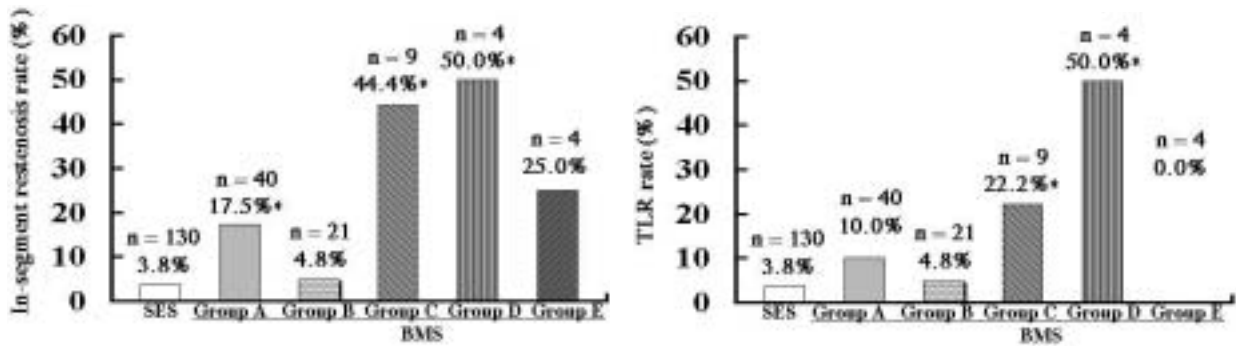


Fig. 4 ISR(left)and TLR(right)rates in BMS

* $p < 0.05$ compared with Cypher.

Abbreviations as in Fig. 1, Tables 2, 4.

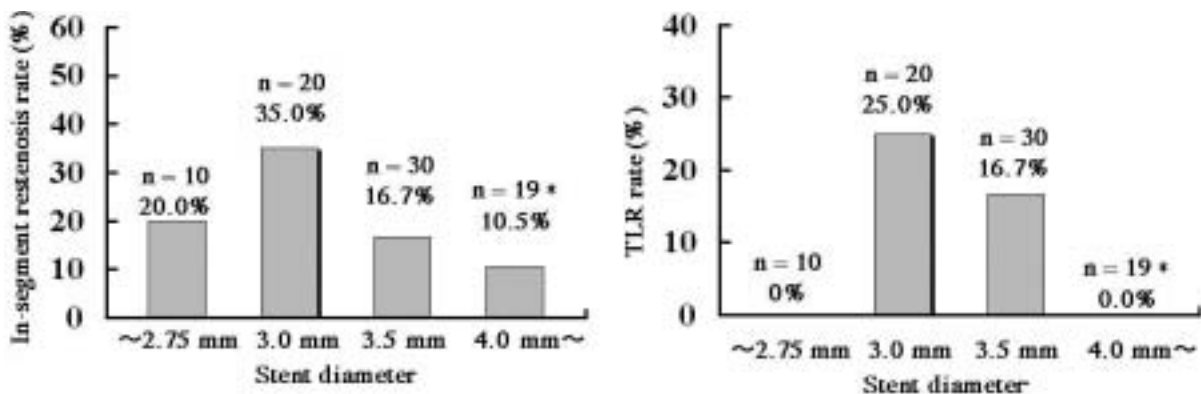


Fig. 5 ISR(left)and TLR(right)rates in BMS classified according to stent diameter

* Group A: 17 lesions, Group B: 2 lesions.

Abbreviations as in Fig. 1, Tables 2, 4.

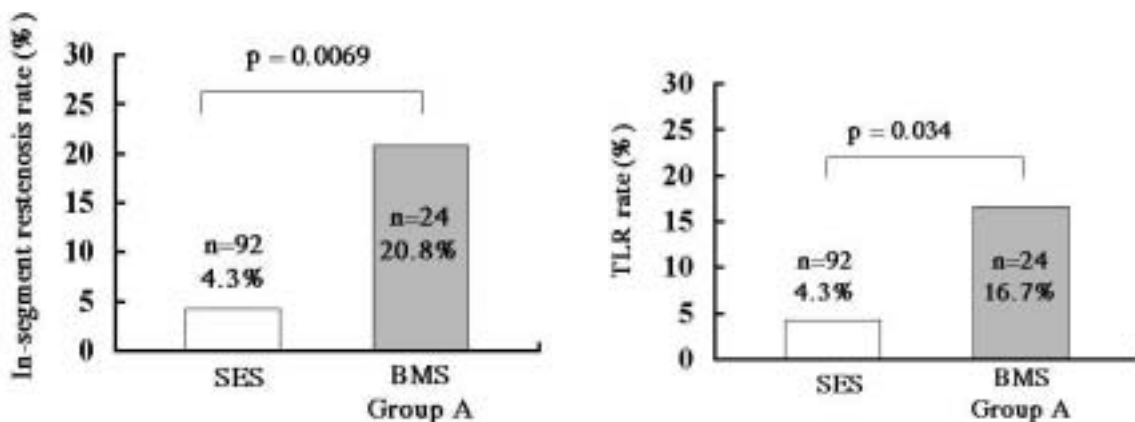


Fig. 6 ISR(left)and TLR(right)rates in Group A in vessels with a diameter of 3.0 - 3.5 mm

Abbreviations as in Fig. 1, Tables 2, 4.

of SES even when BMS was implanted because SES was not clearly indicated based upon vessel size and lesion characteristics. It is well recognized that use of SES has significantly reduced the rates of both ISR and TLR. However, we still implant

BMS in a considerable number of PCI cases for various reasons. Although from our data it is difficult to predict the long-term outcome of BMS implantation based solely upon vessel size and lesion length, we recommend that BMS implanta-

tion be restricted to lesions with a diameter of 4.0 mm or greater, or in which use of SES is contraindicated, to reduce the risk of ISR and TLR.

In our institution about 11% of BMS were implanted because SES could not be delivered or because SES seemed difficult to deliver due to severe tortuosity or calcification of the vessel. It is sometimes pointed that the Bx Velocity stent, which is the platform stent of SES, is less flexible than several new BMS models, and SES may be difficult to deliver to lesions in markedly tortuous or calcified vessels. Accordingly, it will be important to develop DES that have greater flexibility and which can be safely used in ACS patients.

Several studies have reported upon the safety and efficacy of SES implantation in patients with ACS.⁶⁻⁸⁾ However, SES implantation is not officially permitted in this group in Japan. In our study, the rates of ISR and TLR following BMS implantation in ACS patients were similar to those of SES implantation for stable stenotic lesions. Recently results of randomized trials comparing DES and BMS for the treatment of acute myocardial infarction have been reported.^{6,9)} One study reported that SES significantly reduces the rate of restenosis and TLR,⁶⁾ and another study reported that paclitaxel-eluting stent implantation did not significantly reduce restenosis.⁹⁾ The difference between the two studies may be partly due to the rates of restenosis

and TLR following BMS implantation. Whatever the explanation, the rates of restenosis and TLR following BMS implantation for acute myocardial infarction reported in both of these two randomized trials were lower than the rates following BMS implantation for stable atherosclerotic lesions reported in other randomized trials comparing DES and BMS.^{1-4,10)} In our study, ISR and TLR rates following BMS implantation in ACS patients were both 4.8%, which were also lower than the rate following BMS implantation for stable atherosclerotic lesions. These findings may relate to the fact that the pathophysiology of ACS in many respects differs from that responsible for progression of stable atherosclerotic lesions.¹¹⁾ Several other studies have also indicated that the mechanism of restenosis after stent implantation in ACS lesions differs from that observed in stable atherosclerotic lesions.^{12,13)} Further investigation will be required to clarify the usefulness of SES vs. BMS in ACS patients.

CONCLUSIONS

We recommend that BMS implantations be carried out in lesions having a diameter of 4 mm or greater, or in situations in which SES implantation is contraindicated to reduce the risk of ISR and TLR. It is also important to develop DES with improved flexibility, and which can be safely used in ACS patients.

要 約

薬剤溶出性ステント時代における通常型金属ステント留置術の現況と成績

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背景: 今日, 薬剤溶出性ステントが広く用いられるようになったが, なお通常型金属ステントも多く用いられている. 我々は薬剤溶出性ステント使用開始後における通常型金属ステント使用の現況と臨床成績を検討した.

方法: 当院でシロリムス溶出性ステントを使用開始した2004年7月-2006年8月にかけて, 新規病変に対して施行された通常型金属ステント留置術後の臨床経過を, シロリムス溶出性ステント留置術と比較検討した.

結果: 通常型金属ステントは160病変, シロリムス溶出性ステントは242病変に留置され, そのうち208病変(通常型金属ステント留置病変78, シロリムス溶出性ステント留置病変130)は1年以内に追跡冠動脈造影が施行された. 通常型金属ステントが留置された理由は, 1) 対照血管径が大きく, 病変長が短いため通常型金属ステントを留置しても再狭窄が起こらないと予測されたため, 2) 急性冠症候群症例であったため, 3) 血管の屈曲・石灰化が強くシロリムス溶出性ステントを留置できなかったため, 4) 患者がチクロピジンの内服できなかったため, 5) 血管径が小さくシ

ロリムス溶出性ステントを留置できなかったため、に分類された。シロリムス溶出性ステント留置群と通常型金属ステント留置群で患者・病変背景に大きな差はなかった。通常型金属ステントを留置した理由のいかんにかかわらず、通常型金属ステント留置群の再狭窄率・血行再建率はシロリムス溶出性ステント群よりも高率であった。ただし、径が4.0mm以上のステントを留置した場合の通常型金属ステントの再狭窄率・再血行再建率は0%であった。

結論：再狭窄率・再血行再建率を低減させるには禁忌でない限り、シロリムス溶出性ステントが径4.0mm以上の通常型金属ステントを留置することが望ましい。

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