

Economic evaluation of drug-eluting stents in Japan

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Abstract. Stenting with a sirolimus-eluting stent (SES) dramatically reduces the risk of restenosis compared to bare metal stent (BMS) implantation. However, before SES can be widely adopted in clinical practice, it is essential to conduct an economic evaluation of this effective but expensive device. Our study was undertaken to estimate the three-year cumulative medical costs of stenting using SES compared to BMS. The data on clinical sequelae of stenting using BMS were derived from our previous study, based on data collected from three Japanese hospitals. We estimated that the probability of PTCA required for revascularization would be 0.224 times in SES implantation compared than in BMS implantation based on the SIRIUS study result. The medical costs for procedures were obtained from published articles and were adjusted to the March 2005 level. Our simulation showed the expected three-year cumulative medical cost per patient to be approximately ¥200,000 lower in the SES group (¥2,233,000) than in the BMS group (¥2,431,000). Sensitivity analyses with different presumptions confirmed that the economic advantage of SES over BMS was quite robust. We concluded that the use of SES would be a cost-saving option as compared with BMS implantation within the context of the Japanese healthcare system. (*Keio J Med* 55 (1): 15–22, March 2006)

Key words: sirolimus-eluting stent, medical cost, restenosis

Introduction

Percutaneous coronary intervention (PCI) involves insertion of a catheter into the narrowed region of the coronary artery, followed by balloon dilatation or stent placement. This procedure has been used for the treatment of ischemic heart disease in many countries around the world. According to the Survey of Social Medical Care Insurance Service 2002, during the 1-month period of June 2002, a total of 8,201 patients underwent PCI, including percutaneous transluminal coronary angioplasty (PTCA), percutaneous coronary thrombectomy, percutaneous coronary angioplasty with a percutaneous transluminal rotational atherectomy catheter or percutaneous coronary stent placement. In the past, PTCA was associated with a high incidence of restenosis of the affected coronary artery. While the introduction of a coronary artery stent (hereafter simply called “stent”) has made it possible to reduce the incidence of restenosis to some degree, it has been reported that even when a stent is used, the incidence

of restenosis is still as high as 10–40%, taking into consideration all types of lesions.^{1,2}

Drug-eluting stents, i.e., stents coated with a drug effective in the prevention of restenosis, have recently been developed, and clinical trials have been carried out. Among these, a sirolimus-eluting stent (SES), coated with the immunosuppressive agent sirolimus, has been evaluated in clinical trials conducted in foreign countries, and been shown to yield excellent results. At present, SES is used in about 80 countries. In Japan also, the SES was approved for use in the end of March 2004.

The first-in-man studies of SES in the world were carried out in Sao Paulo (Brazil) on 30 subjects, and in Rotterdam (the Netherlands) on 15 subjects. In these studies, none of the subjects developed restenosis during the follow-up period of 4–6 months.³ The long-term outcome in patients treated with this type of stent was also excellent. Of the 30 patients enrolled in the study at Sao Paulo, 28 were followed up for 2 years, and none of these patients developed in-stent restenosis, and only

1 required re-intervention because of in-lesion restenosis.⁴

Later, a *R*andomized study with the sirolimus-eluting *V*elocity balloon-expandable stent in the treatment of patients with de novo native coronary artery Lesions (RAVEL) was carried out on 238 patients at 19 facilities in Europe and Middle and South America, comparing the sirolimus-eluting stent with a conventional stent (bare metal stent; BMS). In this study, the event-free survival rate was significantly higher in the SES patient (94.1%) than in the BMS patient (70.9%).⁵

Only patients with 1-vessel lesions of the coronary artery (2.5–3.5 mm in diameter), which can be covered by an 18 mm-long stent, were enrolled in these studies. It therefore was unknown whether or not this intervention would yield a similarly favorable outcome when applied to patients with other common lesions of the coronary artery.

In the *S*IRIUS-eluting bx velocity balloon expandable stent in the treatment of patients with de novo native coronary artery lesions (SIRIUS) trial, a randomized comparison recently carried out at 53 facilities in the USA, 1,058 patients with various underlying diseases (diabetes mellitus in 26%, hyperlipidemia in 74%, hypertension in 68%, etc.) were enrolled, and the coronary artery lesions were diverse, including multiple-vessel lesions (42%) and longer lesions (14.4 mm, on average). In this study also, the outcome was found to be excellent in the SES patient. Evaluation by angiography revealed that the incidence of in-stent restenosis was 91% lower in the SES patient (3.2% vs. 35.4%, $P < 0.001$), and that of in-lesion restenosis (including the 5 mm-wide areas at both ends of the stent) was 75% lower in the SES patient (8.9% vs. 36.3%, $P < 0.001$).⁶

These results suggest that the use of SES might serve as a radical solution for resolving the problem of restenosis which has been a major shortcoming of PCI. However, before this treatment technique is adopted more widely in clinical practice and covered by health insurance, it would be essential to conduct an evaluation of such therapy from the economic point of view. Since the cost of developing and manufacturing SES is higher than that of conventional stents, the cost of PCI using SES is inevitably high (For example, in the United Kingdom, an SES is sold at a price about 5 times as high as the price of a conventional stent.⁷ In the USA, Cohen *et al.*⁸ reports an SES is sold for \$2,900, while a BMS is \$900.). Such a high price can adversely affect sound management of medical resources.

In developed countries, increased medical costs due to an aging of the population, advances in medical care technology, etc., have become a serious social issue. Stemming the increase of medical costs to reasonable levels has become a major political agenda in these

countries, and various strategies have been taken towards this end. One such is that there is a growing trend to analyze the cost-effectiveness of medical technology to provide criteria for judging the appropriateness of providing insurance cover for a given medical service and for determining the costs of medical care services. For example, in the United Kingdom, the National Institute for Clinical Excellence (NICE), an advisory organization on medical care technology under the National Health Service (NHS), is preparing the Technology Appraisal Guidance, primarily pertaining to high-priced pharmaceuticals and medical technology. This guidance is planned to contain criteria for judging whether or not a given medical technology can be recommended for insurance coverage on the basis of evaluation of clinical and economic evidence. The NICE requested the industry to submit data on cost-effectiveness of medicines as reference information for preparing the guidance.⁹

In Japan also, the upward trend in medical costs and slump in the economy have pushed the National Health Insurance (NHI) system to the brink of financial collapse. Various measures to suppress medical costs have been introduced in this country to defuse this crisis. The prices of medicines and medical materials under the NHI have, as a rule, been reduced every 2 years. Furthermore, the reward for medical care was reduced during the periodical review of the reward system for the year 2002. In the year 2003, a new payment system for the cost of inpatient care named “DPC (Diagnosis Procedure Combination)” was introduced in university hospitals and national centers. To facilitate efficient utilization of medical resources under these circumstances, it would seem desirable to promote cost-effectiveness analysis of medical technology and utilize the findings as appropriate for policy adoption in Japan, as in other developed countries.

The present study was undertaken to evaluate the economic impact of PCI using SES, considering its potential widespread use in Japan.

Methods

From the payer’s perspective, the 3-year cumulative medical costs for patients who underwent PCI with SES were analyzed, in comparison to PCI with BMS.

Basic analyses

(1) Clinical results

The probability of target lesion revascularization (TLR) i.e., re-intervention or coronary artery bypass grafting (CABG), being required in the BMS patient was determined on the basis of data collected from 3 Japanese hospitals.¹⁰ It was found that the probability

Table 1 Probability of TLR in the BMS Group

	1 year	1–2 years	2–3 years
PTCA	28.0%	1.5%	1.0%
CABG	2.1%	0.5%	0.5%
myocardial infarction	1.0%	2.0%	2.0%
death	1.5%	0.0%	0.0%

Table 2 Outcome of Treatment in the SIRIUS

	BMS group	SES group	p-value
PTCA	19.2%	4.3%	<0.001
CABG	1.7%	0.9%	0.295
myocardial infarction	3.4%	3.0%	0.730
death	0.8%	1.3%	0.547

of PTCA being required within 1 year was 28.0%, that within 1–2 years was 1.5%, and that within 2–3 years was 1.0%. The probability of CABG being required within 1 year, 1–2 years, and 2–3 years was 2.1%, 0.5%, and 0.5%, respectively (Table 1).

The reported outcome of treatment in the SIRIUS study on the 360th day is shown in Table 2.¹¹ On the basis of these data, we estimated that the probability of PTCA being required would be 0.224 times higher in the SES patient than in the BMS patient, and assumed that the percent decrease in this probability observed on the 360th day would be maintained after the 360th day.

In the SIRIUS study, there were no significant inter-patient differences in the percentage of cases needing CABG, the incidence of myocardial infarction, or the death rate when the data on the 360th day were analyzed. Therefore, the incidence of myocardial infarction and the death rate previously recorded for the BMS patient in Japan (Table 1¹⁰) were applied to the SES patient of the present study.

(2) Data on medical expenses

The medical expenses in this study were used after they were adjusted to the price levels prevailing as of March 2005. The correction used the percent modification of medical service fee (hereafter simply called “modification rate”) effected in April 2000 (+0.2%), the modification rate effected in April 2002 (–2.7%), and the modification rate effected in April 2004 (–1.05%). Since the amount paid for PTCA and stenting was markedly reduced, for reasons of price differences between Japan and foreign countries, the application of the overall modification rate of the medical

Table 3 Cost of PCI Using the BMS

	price levels as of April 1998	price levels as of March 2005	difference after modification
BMS technical charge	¥199,000	¥228,000	¥29,000
cost of BMS	¥338,000	¥318,000	–¥20,000
cost of balloon catheter	¥263,000	¥192,000	–¥71,000
technical charge + BMS(1) + balloon catheter(1)	¥800,000	¥738,000	–¥62,000
other cost	¥821,487	¥792,496	–¥28,991
total cost for 1-vessel lesions	¥1,621,487	¥1,530,496	–¥90,991
technical charge + BMS(2) + balloon catheter(2)	¥1,401,000	¥1,248,000	–¥153,000
other cost	¥594,946	¥573,950	–¥20,996
total cost for 2-vessel lesions	¥1,995,946	¥1,821,950	–¥173,996
technical charge + BMS(3) + balloon catheter(3)	¥2,002,000	¥1,758,000	–¥244,000
other cost	¥924,849	¥892,210	–¥32,639
total cost for 3-vessel lesions	¥2,926,849	¥2,650,210	–¥276,639

service fee to these 2 services would lead to an excessive lag from the actual state. Therefore, the technical charge and material costs (costs of balloon and stent) for PTCA and stenting were adjusted using the official technical charge and material cost prevailing as of March 2005. For the other medical expenses, the overall modification rate of medical service fee was used for the correction.

The costs of inpatient care in cases of PCI using the BMS in the year 1998 were reported by Noda *et al.* to be 1,621,487 Japanese yen (¥) for patients with 1-vessel lesions, ¥1,995,946 for patients with 2-vessel lesions, and ¥2,926,849 for patients with 3-vessel lesions.¹² These costs were adjusted to the price level as of March 2005 using the method mentioned above, to yield ¥1,530,496 for patients with 1-vessel lesions, ¥1,821,950 for those with 2-vessel lesions, and ¥2,650,210 for those with 3-vessel lesions (Table 3). The average cost of rehabilitation at outpatient clinics was reported by Ikeda *et al.* to be ¥9,600 in the year 1998.¹⁰ This amount was adjusted to the price level using the modification rate, to ¥9,261.

The cost of inpatient care in cases undergoing repeat PTCA for restenosis was reported in the year 1998 by Noda *et al.* to be ¥1,368,990 for 1-vessel lesions,

Table 4 Cost of PTCA

	price levels as of April 1998	price levels as of March 2005	difference after modification
PTCA technical charge	¥205,000	¥228,000	¥23,000
cost of balloon catheter	¥263,000	¥192,000	-¥71,000
technical charge + balloon catheter(1)	¥468,000	¥420,000	-¥48,000
other cost	¥900,990	¥869,193	-¥31,797
total cost for 1-vessel lesions	¥1,368,990	¥1,289,193	-¥79,797
technical charge + balloon catheter(2)	¥731,000	¥612,000	-¥119,000
other cost	¥876,228	¥845,305	-¥30,923
total cost for 2-vessel lesions	¥1,607,228	¥1,457,305	-¥149,923
technical charge + balloon catheter(3)	¥994,000	¥804,000	-¥190,000
other cost	¥1,482,769	¥1,430,441	-¥52,328
total cost for 3-vessel lesions	¥2,476,769	¥2,234,441	-¥242,328

¥1,607,228 for 2-vessel lesions, and ¥2,476,769 for 3-vessel lesions.¹² These costs were adjusted to the price level as of March 2005 by the above-mentioned method, to yield ¥1,289,193 for 1-vessel lesions, ¥1,502,621 for 2-vessel lesions, and ¥2,301,589 for 3-vessel lesions (Table 4). The average cost of rehabilitation of these patients at outpatient clinics reported for the year 1998 by Ikeda *et al.* was ¥19,200,¹⁰ which was adjusted to the costs as of 2005 by the medical service fee modification rate, to ¥18,522.

The percentages of 1-vessel, 2-vessel, and 3-vessel lesions for which stenting with BMS, stenting with SES, or PTCA for restenosis are applied were determined on the basis of the number of cases undergoing elective surgery (excluding cases of acute myocardial infarction) at 143 facilities as reported by Shihara *et al.* (3,757 cases with 1-vessel lesions, 2,283 cases with 2-vessel lesions, and 1,047 cases with 3-vessel lesions).¹³

The cost of inpatient care in patients undergoing CABG in the year 1998 was reported by Noda *et al.* to be ¥4,989,161 for 2-vessel lesions and ¥4,255,033 for 3-vessel lesions.¹² These costs were adjusted by the modification rate. Since the cost of inpatient care for patients undergoing CABG for 1-vessel lesions had not been reported, ¥343,000 (the difference in the cost between 3-vessel and 2-vessel lesions) was deducted from the cost for 2-vessel lesions to yield the cost for 1-vessel lesions. The percentages of 1-vessel, 2-vessel, and 3-vessel lesions undergoing CABG were determined on

the basis of the number of cases undergoing elective surgery (excluding cases of acute myocardial infarction) at 62 facilities reported by Shigematsu *et al.* (455 cases with 1-vessel lesions, 889 cases with 2-vessel lesions, and 400 cases with 3-vessel lesions).¹⁴ The average cost of rehabilitation at outpatient clinics reported for the the year 1998 by Ikeda *et al.* was ¥192,000, which was adjusted by the modification rate to ¥185,224.¹⁰

The average cost of treatment of myocardial infarction reported by Ikeda *et al.* for the the year 1998 of ¥591,460 was adjusted by the modification rate to ¥570,587.¹⁰

The cost of an SES as of March 2005 (¥421,000/set) was used in this study. The other costs of stenting using SES were deemed to be equal to those of stenting using BMS. It was assumed that the length of hospital stay and the incidence of complications at the first admission did not differ between the BMS patient and the SES patient.

The analyses covered a 3-year period, and no discounts rate for time preference was incorporated.

Sensitivity analysis

(1) Percentage of patients undergoing CABG for restenosis

In the SIRIUS study, the percentage of patients who underwent CABG on the 360th day of the initial stenting using the SES was 0.547 times that of the BMS patient, although this difference was not statistically significant.¹¹ In the sensitivity analysis, therefore, the percentage of patients undergoing CABG in the SES patient was assumed to be 0.547 times that of the BMS patient.

(2) Cost of inpatient care in patients undergoing CABG

Two reports, each from a single facility, were available concerning the cost of inpatient care for patients undergoing CABG. Two analyses of sensitivity were performed on the basis of these 2 reports.

In the first, Okawa *et al.* reported that the cost of inpatient care was ¥2,924,040 for CABG with cardiopulmonary bypass (on-pump CABG, ONCAB), ¥1,693,650 for CABG without cardiopulmonary bypass (off-pump CABG, OPCAB), and ¥1,138,580 for minimally invasive direct coronary artery bypass grafting (MIDCAB).¹⁵

In the other, Tsuda *et al.* reported that the cost of inpatient care was ¥3,243,000 for ONCAB and ¥2,082,000 for OPCAB.¹⁶ Using these price data and the results of the questionnaire survey at 262 facilities conducted by the Japanese Association for Coronary Artery Surgery in the year 2002 for 7,850 cases who underwent ONCAB, 5,397 cases who underwent OPCAB, and 231 cases who underwent MIDCAB, we

calculated the average cost of inpatient care for patients undergoing CABG for restenosis.

(3) Time preference

Since there is no international consensus over the discount rate to adjust time preference, we applied 2 discount rates to costs: (1) An annual discount of 3% in accordance with the recommendation of the Washington Panel, USA,¹⁷ and (2) annual discount of 3.5% in accordance with the guidelines of NICE, UK.¹⁸

Results

Base-case analyses

Table 5 shows the results of the base-case analyses. The expected medical cost per patient during the first year was about ¥170,000 cheaper for the SES patient (¥2,155,000) than for the BMS patient (¥2,324,000). The medical costs expected for the second and third years were also lower for the SES patient than for the BMS patient. The 3-year cumulative medical cost per patient was about ¥200,000 cheaper for the SES patient (¥2,233,000) than for the BMS patient (¥2,431,000).

Figure 1 compares 3-year cumulative medical costs specifying items. Although the cost of stenting itself in SES patient was higher, as the number of PTCA for restenosis decreased, 3-year cumulative medical cost resulted lower.

The price of the SES set which would make the 3-year cumulative medical cost equal to that for the BMS patient was ¥543,694 (1.29 times the current price).

Sensitivity analysis

(1) Percentage of patients undergoing CABG for restenosis

Table 6 shows the results of analysis based on the assumption that the percentage of patients undergoing CABG for restenosis would decrease after stenting using the SES. The expected medical cost per patient during the first year was about ¥200,000 cheaper for the

Table 5 Results of the Basic Analyses

	expected medical cost		2-year cumulative medical cost	expected medical cost for third year	3-year cumulative medical cost
	first year	second year			
BMS patient	¥2,324,000	¥57,000	¥2,381,000	¥50,000	¥2,431,000
SES patient	¥2,155,000	¥40,000	¥2,195,000	¥38,000	¥2,233,000

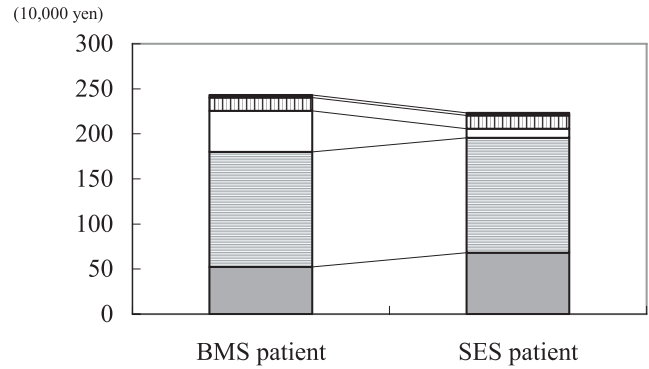


Fig. 1 Three-year cumulative medical cost. ■ cost of subsequent hospitalization for acute myocardial infarction ▨ cost of subsequent hospitalization for CABG □ cost of subsequent hospitalization for PTCA ▩ cost of initial hospitalization excluding stenting ■ cost of stenting

Table 6 Results of Sensitivity Analysis Based on the Assumption of Decreased Percentage of Patients Undergoing CABG

	expected medical cost		2-year cumulative medical cost	expected medical cost for third year	3-year cumulative medical cost
	first year	second year			
BMS patient	¥2,287,000	¥49,000	¥2,336,000	¥41,000	¥2,377,000
SES patient	¥2,090,000	¥25,000	¥2,114,000	¥23,000	¥2,137,000

SES patient (¥2,090,000) than in the BMS patient (¥2,287,000). The medical costs for the second and third years were about 50% lower for the SES patient than in the BMS patient. The 3-year cumulative medical cost per patient was further reduced by the use of SES as compared to the results from the basic analysis: ¥2,167,000 for the SES patient and ¥2,431,000 for the BMS patient.

(2) Cost of inpatient care in patients undergoing CABG

Table 7 shows the results of the sensitivity analysis conducted under different presumptions regarding the cost of inpatient care for patients undergoing CABG. Under all presumptions, the cost for the first year, the 2-year cumulative cost and the 3-year cumulative cost were smaller for the SES than for the BMS patient.

(3) Time preference

Table 8 shows the results of sensitivity analysis conducted under varying annual discount rates of time

Table 7 Results of Sensitivity Analysis Using Different Presumptions on CABG Cost

		expected medical cost		2-year cumulative medical cost	expected medical cost for third year	3-year cumulative medical cost
		first year	second year			
assumed cost A	BMS patient	¥2,287,000	¥49,000	¥2,336,000	¥41,000	¥2,377,000
	SES patient	¥2,118,000	¥31,000	¥2,149,000	¥30,000	¥2,179,000
assumed cost B	BMS patient	¥2,280,000	¥47,000	¥2,326,000	¥39,000	¥2,366,000
	SES patient	¥2,110,000	¥29,000	¥2,140,000	¥28,000	¥2,167,000

Table 8 Results of Sensitivity Analysis Using Different Annual Discount Rates

		expected medical cost		2-year cumulative medical cost	expected medical cost for third year	3-year cumulative medical cost
		first year	second year			
3%	BMS patient	¥2,324,000	¥56,000	¥2,380,000	¥47,000	¥2,427,000
	SES patient	¥2,155,000	¥39,000	¥2,193,000	¥36,000	¥2,230,000
3.5%	BMS patient	¥2,324,000	¥56,000	¥2,379,000	¥47,000	¥2,426,000
	SES patient	¥2,155,000	¥39,000	¥2,193,000	¥36,000	¥2,229,000

preference. Whether the annual discount rate was set at 3% or 3.5%, the cost for the first year, the 2-year cumulative cost, and the 3-year cumulative cost were smaller for the SES than for the BMS patient.

Discussion

The SES analyzed in the present study is a medical device of higher cost as compared to the existing BMS. The introduction and diffusion of the use of SES may have non-ignorable effects on medical resources. According to the present study, the introduction of the SES is expected to significantly reduce the incidence of restenosis and thus save medical costs. Therefore, from the standpoints of society and health insurers, it would

seem that introduction of SES for stenting deserves to be promoted actively, not only for clinical but also economic reasons.

While promoting the diffusion of economically dominant medical technology like SES and ensuring the stable supply of medical devices needed for such technology, we must consider not only the economic impact for the society but also the management of medical facilities, the cost of developing and manufacturing medical materials, and the expenses borne by patients.

In the United States, it has been pointed out that the reimbursement prices of drug-eluting stents (e.g., SES) do not appropriately match the costs incurred for their development and manufacture. For example, the amount paid under the DRG/PPS system for the use of a drug-eluting stent in Medicare beneficiaries has been set at a level only \$1800 higher than the amount for conventional stents per patient, and this amount does not cover the extra cost needed for the manufacture of this new stent. This reimbursement fee policy may make hospitals hesitant to use the drug-eluting stents. Furthermore, it is expected that the introduction of drug-eluting stents would reduce the number of patients requiring CABG or re-PTCA, leading to additional decreases in hospital revenues. These factors may work against the use of drug-eluting stents. The William Beaumont Hospital in Michigan, USA, has published its estimate that hospital revenue will be decreased by \$3.8 million if drug-eluting stents are used in 50% of patients undergoing stenting.¹⁹ The Duke University Medical Center, North Carolina, estimates that if drug-eluting stents are used in 85% of all stent operations, the hospital will suffer a loss of \$4.75 million in the first year and \$5.6 million each year thereafter.²⁰

In Europe, SES was launched in the market on April 15 2002. However, it has been pointed out that since most of the additional cost for SES stenting is borne by the patients, SES has occupied just 12% or less of the entire stent market even 1 year after its launch.²¹

When viewed from the standpoint of Japanese hospitals, introduction of SES will reduce the hospital's profits due to the inevitable decrease in the number of patients requiring re-PTCA or CABG. To facilitate utilization of medical technology that has excellent clinical efficacy, and is expected to cut long-term medical expenditures, it is necessary to ensure appropriate payment policies and measures to stimulate their use. The results of the present economic analyses will be of some help in judging the appropriateness of the prices set in individual cases.

This study has several important limitations. First, the results of SIRIUS study may not be generalizable to the full population of PCI patients. In particular, the SIRIUS trial included a large percentage of complex PCI lesions, including long lesions, smaller vessels, and

diabetic patients. As a result, the observed clinical restenosis rate was relatively high compared with routine clinical practice.²²

Second, our analysis was limited to a 3-year follow-up period. Although longer-term follow-up would have been enlightening, previous studies suggest that the restenosis process is largely complete after 12 months.²³ Thus, it seems unlikely that the cost-effectiveness of SES would be less favorable with longer follow-up.

Third, the present study did not take into account the outpatient medication costs and follow-up costs. These costs were considered to be similar except that patients receiving SES stenting need to be treated with antithrombotic drugs for 3 months or longer.²⁴ In Japan, ticlopidine (Panaldine) has been authorized as an antithrombotic agent for use after PCI. The cost of this drug administered for 3 months at the dose level of 300 mg/day is ¥6,831. Therefore, even when the additional cost of this drug is taken into account for the SES patient, the economic dominance of SES remains unchanged.

Finally, since no large-scale clinical trials of SES have been conducted in Japan, it is an open question whether or not the clinical results of the foreign SIRIUS study are applicable to Japan.

It would be too hasty to evaluate the appropriateness of the price of SES in Japan at present. A careful review of whether or not the price set will induce inefficient selection of treatment and become disadvantageous to patients would be necessary.

Conclusion

We estimated how the use of SES instead of the conventional BMS for PCI would affect the medical costs over a period of 3 years in Japan, on the basis of available published data. The use of SES is expected to significantly reduce the percentage of patients requiring revascularization for restenosis, and thereby reduce the cumulative 3-year medical costs as compared to stenting using the BMS.

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