Original Article

Domestic versus imported drug-eluting stents for the treatment of patients with acute coronary syndrome

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BACKGROUND: The application of coronary stents, especially drug-eluting stents (DESs), has made percutaneous coronary intervention (PCI) one of important therapeutic methods for CHD. DES has reduced the in-stent restenosis to 5%–9% and significantly improved the long-term prognosis of patients with CHD. The study aimed to investigate the long-term efficacy and safety of domestic drug-eluting stents (DESs) in patients with acute coronary syndrome (ACS).

METHODS: All patients with ACS who had undergone successful percutaneous coronary intervention (PCI) in the First Affiliated Hospital of Zhengzhou University from July 2009 to December 2010 were included in this study. Patients were excluded from the study if they were implanted with bare metal stents or different stents (domestic and imported DESs) simultaneously. The included patients were divided into two groups according to different stents implanted: domestic DESs and imported DESs.

RESULTS: In the 1 683 patients of this study, 1 558 (92.6%) patients were followed up successfully for an average of (29.1±5.9) months. 130 (8.3%) patients had major adverse cardiovascular events (MACEs), including cardiac death in 32 (2.1%) patients, recurrent myocardial infarction in 16 (1%), and revascularization in 94 (6%). The rates of cardiac death, recurrent myocardial infarction, revascularization, in-stent restenosis, stent thrombosis and other MACEs were not significantly different between the two groups (all $P>0.05$). Multivariate logistic regression revealed that diabetes mellitus ($OR=1.75$, 95%CI: 1.09–2.82, $P=0.021$), vascular numbers of PCI ($OR=2.16$, 95%CI: 1.22–3.83, $P=0.09$) and PCI with left main lesion ($OR=9.47$, 95%CI: 2.96–30.26, $P=0.01$) were independent prognostic factors of MACEs. The Kaplan-Meier method revealed that there was no significant difference in cumulative survival rates and survival rates free from clinical events between the two groups (all $P>0.05$).

CONCLUSIONS: The incidences of clinical events and cumulative survival rates are not statistically different between domestic DESs and imported DESs. Domestic DES is effective and safe in the treatment of patients with ACS.

KEY WORDS: Acute coronary syndrome; Percutaneous coronary intervention; Drug-eluting stent; Cardiovascular adverse events

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INTRODUCTION

Coronary heart disease (CHD) is a disease of cardiac ischemia, anoxia, and necrosis, caused by coronary artery atherosclerosis. In recent years, the incidence of CHD has increased markedly.^[1] The application of

coronary stents, especially drug-eluting stents (DESs), has made percutaneous coronary intervention (PCI) one of important therapeutic methods for CHD. DES has reduced the in-stent restenosis to 5%–9% and significantly improved the long-term prognosis of

patients with CHD.^[2] The wide use of DES has made it possible for the treatment of complex coronary lesions with PCI, and the clinical effect of imported DES has been proved by numerous clinical trials.^[3–5] After domestic DES, Firebird, was put into use, other DESs have been developed. With the improvement of manufacturing technology of domestic stents and interventional techniques, domestic DESs have been widely used in clinical practice. But the long-term efficacy and safety in a large scale clinical trial of domestic DESs was sparsely determined. The aim of the present study is to estimate the long-term efficacy and safety of domestic DESs in patients with ACS.

METHODS

Ethics statement

The present study was approved by the Research Ethics Committee of First Affiliated Hospital of Zhengzhou University. The data were anonymous and therefore no additional informed consent was required.

Study population

This study was carried out in consecutive patients with acute coronary syndrome (ACS) who had undergone PCI from July 2009 to December 2010 at the Cardiovascular Department, First Affiliated Hospital of Zhengzhou University, China. Only patients who were treated with at least one DES and had a long-term follow-up were recruited in the current study. Patients were excluded from the study if they were implanted with bare metal stents or different stents (domestic and imported DESs) simultaneously. The patients were divided into a domestic DES group and an imported DES group according to different stents implanted. Qualitative and quantitative coronary angiographic analyses were performed according to the standard methods. PCI was performed using standard techniques. All patients were given loading doses of aspirin (300 mg) and clopidogrel (300 mg) before the coronary intervention, unless they had already received these antiplatelet medications more than 5 days. Treatment strategy, stenting techniques, selection of stent type, as well as use of glycoprotein IIb/IIIa receptor inhibitors or intravascular ultrasound were all left to the operator's discretion. Aspirin (100 mg) and clopidogrel (75 mg) were prescribed daily for at least the first 12 months after the procedure.

Clinical outcomes and data collection

Data of the patients were put into a database

containing demographic, clinical, angiographic, and procedural information. Primary end points included all-cause death, occurrence of myocardial infarction (MI), in-stent restenosis, stent thrombosis, and revascularization. The composite end points were defined as major adverse cardiac events (MACEs), namely death/non-fatal MI/revascularization. Stent thrombosis was proven by angiography, or assumed as probable if an unexplained sudden death occurred within 30 days after stent implantation, or if a Q-wave MI was diagnosed in the distribution area of the stented artery. This classification was issued according to definitions proposed by the Academic Research Consortium (ARC): acute (<24 hours), subacute (24 hours to 30 days), late (1–12 months), and very late (>12 months).^[6] All deaths were considered to be cardiac unless an unequivocal noncardiac cause could be established. Cardiac deaths included all events related to a cardiac diagnosis, any complication of a procedure and treatment thereof, or any unexplained cause. Unexpected death, even in patients with a coexisting and potentially fatal noncardiac disease (e.g., cancer or infection), was classified as cardiac unless their history relating to the noncardiac diagnosis suggested death was imminent. Clinical follow-up was carried out through patient visits, telephone interview, and medical record review. The data of the patients were put into the database by independent research personnel, and clinical events were defined by an independent committee. Between July 2009 and December 2010, 1 683 patients met the criteria. At last, the data of 1 558 patients (92.6%) were collected in a follow-up period of 29.1±5.9 months (range 25.3–33.4 months).

Statistical analysis

Continuous variables were expressed as mean±standard deviation. Categorical variables were expressed as percentages. Normally distributed continuous variables were analyzed using Student's *t* test. The variables whose distribution could not be assumed to be normal were analyzed using Wilcoxon's rank-sum test. Categorical variables were analyzed using the Chi-square test or Fisher's exact test. Cumulative survival was constructed using the Kaplan–Meier method. The log-rank test was used to compare curves. Logistic regression analysis was made to identify the independent predictors of MACE. All statistical tests were two-tailed, and *P* value<0.05 was considered statistically significant. All data were analyzed using SPSS 18.0 software (SPSS, Inc., Chicago, Illinois, USA).

Table 1. Baseline clinical characteristics (n, %)

Variables	Imported DES (n=506)	Domestic DES (n=1052)	Total (n=1558)	t/χ^2 value	P value
Age (years)	59.57±11.66	59.95±11.29	59.83±11.4	-0.608	0.543
Male gender	360 (71.1)	718 (68.3)	1 078 (69.2)	1.344	0.246
Hypertension	234 (46.2)	518 (49.2)	752 (48.3)	1.227	0.268
Diabetes mellitus	111 (21.9)	230 (21.9)	341 (21.9)	0.001	1.000
Smoker	166 (32.8)	374 (35.6)	540 (34.7)	1.137	0.286
Peripheral vessel disease	0 (0)	4 (0.4)	4 (0.3)	1.929	0.311
AMI					
Urgent PCI	40 (7.9)	30 (2.9)	70 (4.5)	20.33	0.000
Delayed PCI	109 (21.5)	224 (21.3)	333 (21.4)	0.013	0.911
Shock	2 (0.4)	3 (0.3)	5 (0.3)	1.29	0.662
Prior myocardial infarction	31 (6.1)	111 (10.6)	142 (9.1)	8.076	0.040
COPD	4 (0.8)	11 (1.0)	15 (1.0)	0.233	0.785
Heart failure	49 (9.7)	121 (11.5)	170 (10.9)	1.162	0.281
Renal failure	3 (0.6)	2 (0.2)	5 (0.3)	1.733	0.337
Stroke	27 (5.3)	42 (4.0)	69 (4.4)	1.457	0.227
Prior PCI	27 (5.3)	73 (6.9)	100 (6.4)	1.462	0.227
Prior CABG	2 (0.4)	9 (0.9)	11 (0.7)	1.032	0.519
TC (mmol/L)	4.29±1.02	4.25±1.03	4.26±1.03	0.709	0.478
TG (mmol/L)	1.94±1.33	1.94±1.34	1.94±1.33	-0.067	0.947
LDL (mmol/L)	2.74±0.95	2.72±1.12	2.73±1.07	0.377	0.706
HDL (mmol/L)	1.10±0.35	1.07±0.32	1.08±0.33	1.839	0.066
Glycemia (mmol/L)	6.31±2.87		6.25±3.59	0.466	0.606
Creatinine (μmol/L)	74.82±44.27		73.40±32.78	1.918	0.109
LVEF (%)	60.73±8.7	60.64±7.9	60.67±8.2	0.144	0.885
Medication at discharge					
Aspirin	488 (96.4)	1 025 (97.5)	1 513 (97.2)	1.46	0.227
Clopidogrel	504 (98.8)	1 048 (99.7)	1 552 (99.7)	0.102	1.000
ACEI/ARB	247 (49)	638 (60)	885 (56.9)	18.82	0.000
Beta-blocker	303 (59.9)	736 (70)	1 039 (66.7)	15.84	0.000
Statins	447 (88.5)	936 (89)	1 383 (88.8)	0.072	0.788

ACEI: angiotensin converting enzyme inhibitor; AMI: acute myocardial infarction; ARB: angiotensin receptor blocker; CABG: coronary artery bypass graft; COPD: chronic obstructive pulmonary disease; DES: drug-eluting stents; HDL: high density lipoprotein; LVEF: left ventricular ejection fraction; LDL: low density lipoprotein; PCI: percutaneous coronary intervention; TC: total cholesterol.

RESULTS

Characteristics of the study groups

Demographic characteristics of the 1 558 patients are shown in Table 1. Of the patients, 1 078 (69.2%) were men and the mean age of the patients was 59.8±11.4 years. There were 752 (48.3%) patients with hypertension, 341 (21.9%) with diabetes mellitus, 540 (34.7%) patients with a history of smoking, and 403 (25.9%) patients with acute MI.

The proportion of patients who underwent urgent PCI was significantly higher in the imported DES group than in the domestic DES group, but the proportion of patients with a history of old myocardial infarction was significantly lower. The percentage of patients treated with β -blocker, angiotensin converting enzyme inhibitor/angiotensin receptor inhibitor, and low weight molecular heparin was significantly higher in the domestic DES group than in the imported DES group. There was no significant difference in age, gender, left ventricular

ejection fraction (LVEF), and the history of hypertension, diabetes mellitus, smoking, peripheral vascular disease, heart failure, renal failure, and stroke between the two groups.

Angiographic and procedural characteristics

Angiographic and procedural characteristics of the patients are shown in Table 2. Over 98% cases of PCI were performed through the radial artery. There were 382 (24.5%) patients with multi-vessel lesions and 50 (3.2%) patients with left main stem (LM) lesions. Compared with the domestic DES group, the frequency of single vessel lesion was significantly higher (47.4% vs. 35.5%, $P<0.01$), and the frequencies of LM lesion, two-vessel or multi-vessel lesion, right coronary artery lesion, and long lesion were significantly lower in the imported DES group. In contrast, patients treated with domestic DESs involved more vessels and received more and longer stents than those treated with imported DESs.

Table 2. Baseline angiographic and procedural characteristic (n, %)

Variables	Imported DES (n=506)	Domestic DES (n=1052)	Total (n=1558)	t/χ^2 value	P value
Radial artery access	494 (97.6)	1 034 (98.3)	1 528 (98.1)	0.789	0.374
Number of diseased vessels					
1-vessel disease	240 (47.4)	373 (35.5)	613 (39.3)	20.53	0.000
2-vessel disease	160 (31.6)	389 (37)	549 (35.2)	4.296	0.038
Multi-vessel disease	100 (19.8)	282 (26.8)	382 (24.5)	9.158	0.002
Location of lesion					
LM	9 (1.8)	41 (3.9)	50 (3.2)	4.937	0.026
LAD	410 (81)	884 (84)	1 294 (83.1)	2.189	0.139
LCX	211 (41.7)	511 (48.6)	722 (46.4)	6.578	0.481
RCA	215 (42.6)	543 (51.6)	758 (48.7)	11.166	0.001
Ostial lesion	50 (9.9)	124 (11.8)	174 (11.2)	1.264	0.261
Bifurcation lesion	69 (13.6)	177 (16.8)	246 (15.8)	2.613	0.106
Total chronic occlusion	94 (18.6)	209 (19.9)	303 (19.5)	0.373	0.541
Long lesion	33 (6.5)	119 (11.3)	152 (9.8)	8.9	0.003
Number of treated vessels ^a	1 (1–2)	1 (1–2)	1 (1–2)		0.000
Location of target lesions					
LM	8 (1.6)	28 (1.7)	36 (2.3)	1.767	0.184
LAD	354 (70)	748 (71.1)	1 102 (70.7)	0.215	0.643
LCX	152 (30)	384 (36.5)	536 (34.4)	6.323	0.012
RCA	153 (30.2)	444 (42.2)	597 (38.3)	20.706	0.000
Number of stents per patient ^a	1 (1–2)	2 (1–3)	2 (1–3)		0.000
Total stent length per patient ^a	33 (23–51)	42 (24–66)	38 (23–61)		0.000
Stent diameter (mm) ^a	3 (2.75–3.5)	3 (2.76–3.44)	3 (2.75–3.5)		0.925

LAD: left anterior descending artery; LCX: left circumflex artery; LM: left main stem; DES: drug-eluting stents; RCA: right coronary artery; ^a: median and quartiles.

Table 3. Baseline angiographic and procedural characteristics (n, %)

Variables	Imported DES (n=506)	Domestic DES (n=1 052)	Total (n=1 558)	t/χ^2 value	P value
Follow-up angiography	93 (18.4)	153 (14.5)	246 (15.8)	3.846	0.050
All cause death	18 (3.6)	33 (3.1)	51 (3.3)	0.191	0.670
Cardiac death	9 (1.8)	23 (2.2)	32 (2.1)	0.282	0.595
Recurrent myocardial infarction	8 (1.6)	8 (0.8)	16 (1.0)	2.263	0.132
Revascularization	33 (6.5)	61 (5.8)	94 (6.0)	0.315	0.574
MACE	44 (8.7)	86 (8.2)	130 (8.3)	0.121	0.728
In-stent restenosis	15 (3.0)	38 (3.6)	53 (3.4)	0.436	0.509
Stent thrombosis (definite/probable)	4 (0.8)	10 (1.0)	14 (0.9)	0.001	0.979

DES: drug-eluting stents; MACE: major adverse cardiac event.

The percentages of ostial lesion, bifurcation lesion, total occlusion lesion, and the diameter of stent were not significantly different between the two groups.

Clinical outcomes

The incidence of MACE was approximately 8.3%, including 2.1% for cardiac death, 1% for recurrent myocardial infarction, and 6% for revascularization. The frequencies of all deaths, such as recurrent myocardial infarction, revascularization, in-stent restenosis, stent thrombosis, and MACE were not significantly different between the two groups (Table 3).

Multivariate analysis

Multivariate logistic regression analysis was used

to assess the independent risk factors for MACE. The following variables were examined: age, gender, arterial hypertension, diabetes mellitus, smoking, peripheral vessel disease, cerebrovascular disease, left ventricular ejection fraction, prior PCI, prior coronary artery bypass graft, heart failure, renal insufficiency, location of lesion, number of diseased vessels, location of target lesion, number of treated vessels, urgent PCI, number of stent, total stent length, stent diameter, and the type of stent. The results showed that the independent risk factors for MACE were diabetes mellitus ($OR=1.75$, 95%CI: 1.09–2.82, $P=0.021$), number of treated vessels ($OR=2.16$, 95%CI: 1.22–3.83, $P=0.09$), and target vessel =LM ($OR=9.47$, 95%CI: 2.96–30.26, $P=0.01$) (Table 4). The Kaplan–Meier method revealed that the cumulative

Table 4. Multivariate logistic regression of risk factors for major adverse cardiac events

Variables	<i>B</i>	<i>S.E.</i>	<i>Wals</i>	<i>OR</i>	<i>95%CI</i>	<i>P</i> value
Diabetes mellitus	0.79	0.342	5.329	1.75	1.088–2.818	0.021
Number of treated vessels	0.954	0.420	5.156	2.159	1.215–3.834	0.090
Target lesion=LM	1.515	0.597	12.364	9.465	2.960–30.264	0.001

LM: left main stem; LVEF: left ventricular ejection fraction; MACE: major adverse cardiac event.

Figure 1. The cumulative survival rates of the two groups. **Figure 2.** The cumulative survival rates free from clinical events of the two groups.

survival rate ($P=0.67$, Figure 1) and the cumulative survival rate free from clinical events were not significantly different between the two groups ($P=0.527$, Figure 2).

DISCUSSION

PCI has opened a new era of CHD treatment. Although bare metal stent implantation has significantly reduced the incidence of early cardiac adverse events of PCI, in-stent restenosis has been a problem. The main mechanism of in-stent restenosis is the hyperplasia of intima and vascular smooth muscle. Rapamycin, paclitaxel and their derivatives are currently main drugs contained on DES. Both the two types of drugs could inhibit the hyperplasia of intima and vascular smooth muscle. The clinical trials have proved that DES can not only prevent the in-stent restenosis caused by early postoperative vascular wall recoil and long-term negative remodeling, but also can significantly reduce the in-stent restenosis caused by smooth muscle cell proliferation and neointimal hyperplasia. Though some studies^[7,8] have found that DES could increase the risk of late stent thrombosis, clinical trails have proved that DES could significantly improve the long-term prognosis of patients with CHD.^[3,4,8–10]

Since domestic DES Firebird was marketed in 2003, several other types of domestic DES have been

put into clinical practice. With the improvement of manufacturing technology of domestic DESs, they have been used clinically in recent years. Domestic DESs have accounted for over 60% of total stents used in our hospital. Some studies^[11–14] compared the clinical efficacy of domestic DESs with imported DESs, but they had a small sample size, limited to single stent comparison and specific patients. The present study enrolled the patients with ACS who underwent successfully PCI from July 2009 to December 2010 in our hospital, including use of domestic DESs available at that time.

In our study, there were no statistical differences in causes of death, cardiac death, recurrent MI, revascularization, in-stent restenosis, stent thrombosis, and MACE between the two groups. These results were consistent with those of previous studies.^[13–16]

The proportion of patients treated with urgent PCI was significantly higher in the imported the DES group than in the domestic DES group (7.9% vs. 2.9%) in our study. Some studies showed higher incidences of adverse events in patients treated with urgent PCI. Because of the lower proportion of patients treated with urgent PCI (4.5%), the impact on the overall results was limited in our study. The frequency of single vessel lesion was significantly higher and the number of stent implanted was significantly lower in the imported DES group than in the domestic DES group. Whereas the frequency

of long lesions, the number of treated vessels, and the total stent length were significantly higher in the domestic DES group than in the imported DES group. This result is consistent with the actual condition in our hospital. In this study, most of the patients came from rural areas, and when more stents were needed domestic DES was the first choice in consideration of the cost. Previous studies^[17,18] indicated that the degree of vascular lesions, multi-vessel diseases, and stent length were predictive factors of in-stent restenosis. The present study also found that the number of treated vessels was an independent predictor of MACE, which further confirmed the efficacy and safety of domestic DES.

Because of the lack of small diameter domestic DESs, only imported DESs with a 2.25 mm diameter were used. The incidence of in-stent restenosis was higher in patients treated with small diameter stents.^[17] When patients treated with small diameter stents were removed from the population in our study, the incidence of clinical events was not significantly different between the two groups. Since XIENCE V stent was marketed after the enrollment of our study, the production of cypher stent was stopped, the significance of this study on future clinical practice needs to be further evaluated.

In the present study, the incidence of clinical events was lower than that previously reported.^[3] There are several explanations for this finding. First, the low frequency of follow-up angiography may underestimate the incidence of in-stent restenosis. Second, China is a developing country where health insurance and costs are likely to deter most patients from undergoing subsequent revascularization procedures. Third, our study included all eligible patients, and some of them were lost to follow-up, which may have a higher incidence of clinical events.

In our study, the proportion of patients who were prescribed β -blocker, angiotensin converting enzyme inhibitor or angiotensin receptor blocker was significantly higher in the domestic DES group than in the imported DES group. But its precise reason is not clear. Both of the drugs may have an impact on the long-term prognosis of patients with CHD, but the impact of these drugs on the results of the present study is unclear.

Limitations

Our study also has some limitations that should be considered. First, the present study is a retrospective observational study based on registration data, there are some differences in baseline clinical characteristics which may affect the results. Second, the study is a

single-center registry study. Third, the small proportion of patients undergoing follow-up angiography, may underestimate the frequency of in-stent restenosis. Last, the rates of successful PCI with different stents were not reported. Nevertheless, to our knowledge, this study was a large-scale study estimating the long-term efficacy and safety of patients with ACS who were implanted domestic DES. Large-scale randomized controlled studies are needed to further estimate the efficacy and safety of domestic DES.

In conclusion, the incidences of clinical events and cumulative rates of survival were not statistically different between the domestic DES and imported DES groups in this study. Domestic DES is effective and safe in patients with ACS. Given the large price difference between imported DES and domestic DES as well as the huge population of patients with CHD in our country, the promotion of domestic DES can greatly reduce medical costs and make more patients benefit from it.

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Ethical approval: This study was approved by the Ethical Committee of First Affiliated Hospital of Zhengzhou University, Zhengzhou, China.

Conflicts of interest: We have no conflicts of interest to this report.

Contributors: Yao HM proposed the study and wrote the paper. All authors contributed to the design and interpretation of the study and to further drafts.

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