



Original article

Relation between stent thrombosis and calcium channel blocker after drug-eluting stent implantation Kumamoto Intervention Conference Study (KICS) registry



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ABSTRACT

Background: Stent thrombosis (ST) has emerged as a severe complication of percutaneous coronary intervention (PCI). Since the occurrence of ST is lower in Japan than Western countries, there are few data to predict ST after drug-eluting stent (DES) implantation in Japan. We examined the independent predictors of ST incidence after DES implantation in Japanese patients, including the use of calcium channel blockers (CCBs).

Methods and results: We used data from the Kumamoto Intervention Conference Study registry. There were 6286 consecutive patients enrolled from June 2008 to March 2011. Among them, we analyzed 3493 patients who underwent DES implantation. The incidence of definite/probable ST throughout a median follow-up period of 364 days was 0.57% (20 patients). There were 8 patients with early ST (within 30 days), 8 patients with late ST (between 31 and 365 days), and 4 patients with very late ST (after 1 year). The frequency of CCB use was significantly lower in ST than non-ST patients (25.0% versus 51.4%, respectively, $p = 0.016$). Multiple regression analysis showed that longer stent length ($p = 0.034$), acute coronary syndrome ($p = 0.039$), and the absence of CCB use ($p = 0.046$) were significant and independent predictors of ST within 1 year.

Conclusions: These results suggest that CCB use may be associated with a decreased risk of ST after DES implantation within 1 year in Japanese patients.

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Introduction

Percutaneous coronary intervention (PCI) is an established treatment for coronary heart disease (CHD) [1]. Stent thrombosis (ST) has emerged as a severe complication of PCI with stenting [2]. Regardless of the drug-eluting stent (DES) or bare metal stent (BMS), concern about ST has been raised including the timing, such as early, late, and very late phases, especially in acute coronary

syndrome (ACS) patients [3,4]. Although DES implantation is reported to be associated with very late stent thrombosis [5,6], recent studies demonstrate that there is no concern about stent thrombosis regarding second generation DESs [7]. The occurrence of ST is lower in Japan than Western countries [3,4]; therefore, there are few data to predict ST after DES implantation in Japanese patients. Dual antiplatelet therapy (DAPT) is currently recommended for the prevention of adverse cardiovascular events in patients undergoing PCI and patients with ACS [8–10]. However, ST also may occur in patients who are taking DAPT. It remains unknown whether any other drug therapy affects the occurrence of ST after DES implantation. The present study was therefore conducted to examine the independent predictors of ST after DES implantation in Japanese patients, including prescription drug therapy.

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Methods

Study population

We used data from the Kumamoto Intervention Conference Study (KICS) registry. KICS is a physician-initiated, non-company-sponsored, multicenter registry enrolling consecutive procedures undergoing PCI in 16 centers in Japan. Written informed consent was obtained from all patients. There were 6286 consecutive patients who underwent PCI between June 2008 and March 2011. The exclusion criteria were: (1) percutaneous balloon angioplasty or thrombus aspiration without coronary stent implantation, (2) unsuccessful PCI, and (3) in-hospital death. We excluded in-hospital death because we would like to examine the effect of any prescriptions for ST. We excluded 2 in-hospital deaths by ST because both cases occurred before stable conditions. The selection of treatment was left to the discretion of the attending physicians at each hospital. After excluding 557 patients based on the criteria above, there were 5729 patients who underwent stent implantation. Among these patients, 3493 had successful DES implantation and were used in the final analysis (Fig. 1).

Clinical outcomes and definitions

The endpoint of this study was the occurrence of definite/probable ST. ST was defined according to the Academic Research Consortium criteria [11]. Cardiovascular (CV) events were defined as CV death, non-fatal myocardial infarction (MI), and ischemic stroke. CV death was defined as death from MI, congestive heart failure or documented sudden cardiac death. The universal definition of MI was used [12]. We performed a follow-up survey to evaluate clinical outcomes throughout a median follow-up period of median 364 days (261–523 days).

Statistical analysis

Continuous variables are expressed as the mean \pm SD. Categorical variables are expressed as frequencies and percentages. Continuous variables were compared between groups using a Student's *t*-test, and categorical variables were compared using a chi-square test. Univariate and multivariate logistic regression analyses were performed to determine the predictors of ST. The odds

ratios (ORs) and 95% confidence intervals (CIs) were determined from the logistic regression analysis. A *p*-value <0.05 was regarded as significant. We performed all statistical analyses with SPSS 19 (Chicago, IL, USA).

Results

Subject characteristics

In 3493 patients who underwent DES implantation, the incidence of definite/probable ST throughout a median follow-up period of 364 days was 0.57% (20 patients). There were 18 (90%) definite and 2 (10%) probable ST. There were 8 patients with early ST (EST, within 30 days), 8 patients with late ST (LST, from 31 to 365 days), and 4 patients with very late ST (VLST, after 1 year). The longest duration until ST occurrence was 810 days after PCI. Table 1A shows the clinical characteristics according to ST incidence. The rate of ACS was significantly higher in the ST than the non-ST group (65.0% versus 36.3%, respectively, $p = 0.009$). When we replaced ACS with unstable angina pectoris or acute MI, the results were similar. Other parameters, such as general health status and classical risk factors, were similar between the two groups. Table 1B shows the angiographic characteristics of each group. The presence of emergency PCI, severe pre-stenosis, and acute occlusion (as a complication) was significantly higher in the ST than non-ST group. In the ST group, the mean stent diameter was significantly smaller (2.5 ± 0.7 mm versus 2.9 ± 0.8 mm, $p = 0.033$) and stent length was significantly longer (23.8 ± 4.5 mm versus 20.6 ± 6.7 mm, $p = 0.001$) than in the non-ST group. Lesion complexity, the use of mechanical supports, and the complication rate were similar between the two groups. Fig. 2 shows the occurrence of ST based on the actual number of DES implanted (5371) rather than the number of patients (3493). Sirolimus-eluting (SES) (26.4%), paclitaxel-eluting (PES) (27.6%), and everolimus-eluting (EES) (25.8%) stents were the major stent types used in this study. The occurrence of ST was 0.49% in SES, 0.40% in PES, 0.35% in zotarolimus-eluting stent (ZES), and 0.25% in EES. EES showed lower rate of ST occurrence compared with any other stents, especially first-generation DES (SES and PES). These results corresponded with a previous study [7]. The occurrence of ST after 1 year (VLST) was lower in second-generation DES (ZES and EES) (14.3%) compared with first-generation DES (SES and PES) (23.1%).

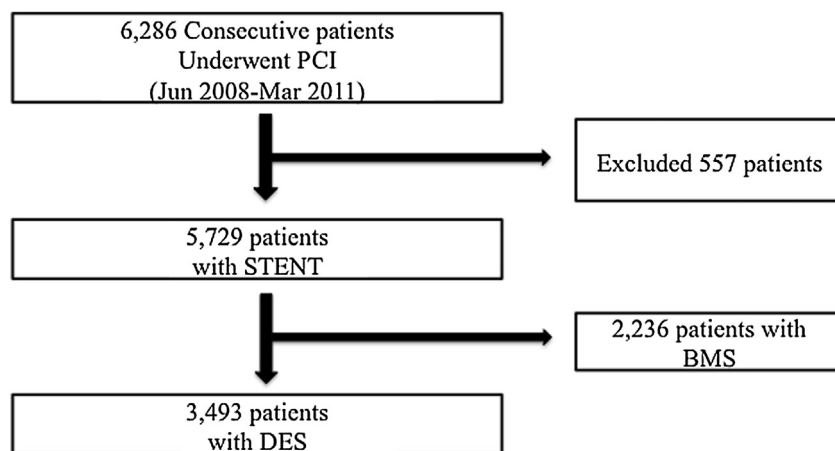


Fig. 1. Study population. There were 6286 consecutive patients who underwent PCI between June 2008 and March 2011. After excluding 557 patients based on the criteria above, there were 5729 patients who underwent stent implantation. Among these patients, 3493 had successful DES implantation and were used in the final analysis. PCI, percutaneous coronary intervention; DES, drug-eluting stent; BMS, bare metal stent.

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