Safety of Live Case Demonstrations in Patients Undergoing Percutaneous Coronary Intervention for Chronic Total Occlusion

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The data regarding the risk and benefits associated with live demonstrations at interventional cardiology congresses are scarce and controversial. We aimed to assess the clinical safety of chronic total occlusion percutaneous coronary intervention (CTO-PCI) procedures during live demonstrations. From January 2008 to December 2013, 739 consecutive patients underwent CTO-PCI at our center, and 199 patients were scheduled to undergo live CTO-PCI demonstrations at cardiology congresses that were globally transmitted to international meetings. The baseline characteristics, procedural complications, and clinical outcomes were compared between the live demonstration group and nonlive demonstration group. The procedural success rates were similar in the live demonstration group than in the nonlive demonstration group (91.5% vs 86.7%, p = 0.076), although the CTO lesions were longer and more tortuous in the live demonstration group (p = 0.029, p = 0.022, respectively). No cases of 30-day mortality were noted in the live demonstration group (0% vs 0.7%, p = 0.28), and no significant differences in procedural complications, such as coronary dissection, coronary perforation, and cardiac tamponade, were observed between the groups (p = 0.53, p = 0.12, and p = 0.40, respectively). The survival rates were similar in the 2 groups at a median follow-up duration of 51.2 ± 28.9 months (log-rank test: p = 0.45). Compared with cases of unsuccessful CTO-PCI, the cases of successful CTO-PCI exhibited improved all-cause survival in both the live and nonlive demonstration groups (log-rank test: p = 0.045, p = 0.0056, respectively). In conclusion, we found that procedural and clinical outcomes of live demonstration CTO-PCI were not significantly different compared with cases undergoing routine CTO-PCI procedures. **(Am J Cardiol 2016;118:967−973)**

Although the technical developments of the recanalization method in percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) have been widely introduced in the clinical field, CTO-PCI remains challenging due to a certain degree of failure, as a result of procedural difficulties.[1−5] Interventional cardiologists need to acquire advanced technical skills and latent knowledge to achieve successful CTO-PCI. Live demonstrations are considered as effective educational tools for imparting the aforementioned skill and knowledge. Hence, many cardiologists and physicians participate in live case demonstrations of CTO-PCI at cardiology congresses. However, a recent discussion has highlighted the clinical concern for the balance between the risk for the patient and the beneficial educational effect of live demonstrations.[6,7] Clinical data regarding the safety of live demonstrations are limited in the reports[8−10]; moreover, data regarding the long-term follow-up of live cases are currently lacking. A relatively large number of live demonstrations of CTO-PCI cases (n = 199) has been globally transmitted from our center over the past decade. The clinical outcome of the live demonstrations could importantly answer whether the live demonstrations are acceptable or not. Hence, we aimed to investigate the early safety and long-term treatment effect of CTO-PCI between live and nonlive demonstration cases.

Methods

The data of consecutive patients who underwent CTO-PCI were extracted from the database at Toyohashi Heart Center, Toyohashi, Japan, wherein data are prospectively entered. In the present retrospective study, we collected

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clinical data before and after treatment from the PCI registry from January 2006 to December 2013. The data included relevant patient information as well as angiographic and procedural characteristics. Accordingly, we examined 739 patients with CTO lesions in the pooled registry population. Of these patients, 199 were considered as live case demonstrations during this period. These live demonstrations were conducted during global cardiology congresses in the United States of America, Europe, and Asia, including local meetings in Japan; these include American College of Cardiology, European Percutaneous Coronary Revascularization, Transcatheter Cardiovascular Therapeutics, Transcatheter Cardiovascular Therapeutics-Asian Pacific, Complex Catheter Therapeutics, CTO club, China Interventional Therapeutics, India live, Singapore live, Japanese Circulation Society, Japanese Association of Cardiovascular Intervention and Therapeutics, Tokai live, Toyohashi live, and other local live demonstrations. The patients undergoing CTO-PCI were assigned to 2 groups: cases that underwent live demonstrations and cases that did not undergo live demonstrations. Patients who underwent live case demonstration were provided informed consent to be the part of the global cardiology congress. All patients were treated with elective PCI, based on the presence of stable angina or asymptomatic myocardial ischemia. The technical aspects of the CTO-PCI procedures have already been described in detail.[11,12] Patients received aspirin (100 mg) and ticlopidine (200 mg) or clopidogrel (75 mg) daily before the intervention. Any other medication was continued during hospitalization. Regarding procedural anticoagulation, we used heparin to extend activated clotting time during procedure. Coronary CTO is defined as true total occlusion, with the complete interruption of anterograde blood flow, as assessed by coronary arteriography (Thrombolysis In Myocardial Infarction flow grade 0), and with an estimated occlusion duration of $\geq$3 months. To assess the background data of the procedure used in this study, we examined the total amount of contrast medium used, procedure time, and radiation dose. Procedure time was defined as the total duration for which the patient was in the catheterization room (from entry until exit). Fluoroscopy time and radiation dose were recorded automatically by the cine device. Coronary perforation was examined as a complication during the procedure. The following end points were evaluated to compare patients with a failed versus a successful procedure: all-cause death and a definite cardiac death. A definite cardiac death was defined as heart failure, myocardial infarction, or unexpected death presumed to be due to underlying cardiac disease, without clinical or postmortem evidence of another cause. Death from uncertain causes was also classified as cardiac death. Procedural success was defined as residual stenosis <50%, with a Thrombolysis In Myocardial Infarction flow grade of 3 and without major adverse cardiovascular events. The clinical data from all patients with CTO lesions who were treated invasively were prospectively recorded in a computerized database as a single-center PCI registry.[12] The recorded data included demographic, clinical and procedural characteristics of CTO lesions, and in-hospital mortality. The requirement of hemodialysis was also evaluated through individual patient charts. Information on the possible occurrence and/or cause of death was obtained from the hospital involved in the treatment or by directly phoning the patient or the patient's family. Thereafter, all the clinical information and data were compared between the live demonstration and nonlive demonstration groups. In addition, the success rates between the host operators working at Toyohashi Heart Center and the invited guest operators were also evaluated. The primary outcome of this study was all-cause mortality after PCI. Univariate logistic regression analysis was performed to evaluate associations between the clinical parameters and the live case group, and the clinical parameters and the nonlive case group. Thereafter, multivariate analysis was performed of the baseline clinical characteristics and periprocedural variables that had a p value <0.10 in univariate analysis and live case group to assess their independent association with all-cause survival. The results are presented as mean and SD or as numbers and percentage. A comparison was made between the study groups using one-way analysis of variance for continuous variables and the chi-square test. Long-term outcomes were determined through Kaplan−Meier survival curves and were compared by the log-rank test. Values of p <0.05 were considered statistically significant. The data were analyzed using the PASW statistics 22.0 software (SPSS Inc., Chicago, Illinois).

Table 1
Baseline patient characteristics between live and nonlive demonstration groups

Variable	Live Group (n = 199)	Non-Live Group (n = 540)	*p* Value
Age (years)	65.3 ± 10.2	66.1 ± 11.0	0.37
≧80 y	17 (8.5%)	60 (11.1)	0.31
Men	166 (83.4%)	448 (83.0%)	0.88
Diabetes mellitus	27 (13.6%)	62 (11.5%)	0.44
Hypertension	122 (61.3%)	316 (58.5%)	0.49
Hyperlipidemia	83 (41.7%)	212 (39.3%)	0.55
Prior coronary artery bypass grafting	21 (10.6%)	55 (10.2%)	0.88
Prior coronary intervention	55 (27.6%)	166 (30.7%)	0.41
Prior myocardial infarction	147 (73.9%)	368 (68.1)	0.13
Left ventricle ejection fraction	50.5 ± 12.2	50.2 ± 12.8	0.77
Smoker	55 (27.6%)	122 (22.6%)	0.15
Family history of coronary disease	30 (15.1%)	75 (13.9%)	0.68
Chronic kidney disease	47 (23.6%)	129 (23.9%)	0.94
Hemodialysis	17 (8.5%)	29 (5.4%)	0.11
estimated glomerular filtration rate (ml/min/1.73m^2)	70.9.3 ± 27.8	72.9 ± 26.4	0.38
Body weight (kg)	64.4 ± 12.0	64.4 ± 12.6	0.98
Body height (cm)	162.5 ± 8.2	162.6 ± 8.1	0.90
Body mass index (kg/m^2)	24.3 ± 3.5	24.2 ± 3.7	0.76

Values are numbers (%) or mean ± SD.

Results

The baseline patient characteristics between the live demonstration group (n = 199) and nonlive demonstration group (n = 540) are listed in Table 1. There were no significant differences in the age, gender, risk factors of coronary artery disease, baseline kidney function, and body characteristics between the groups. The procedural