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Impact of Institutional and Operator Volume on Short-Term Outcomes of Percutaneous Coronary Intervention

A Report From the Japanese Nationwide Registry

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ABSTRACT

OBJECTIVES The aim of this study was to assess the volume-outcome relationship for PCI within the nationwide registration system in Japan.

BACKGROUND The effect of site and operator case load for percutaneous coronary intervention (PCI) on outcomes has not been investigated thoroughly in non-Western regions.

METHODS In the present study, PCI procedural data recorded between January 2014 and December 2015 in the Japanese PCI registry, a nationwide registration system, were analyzed. Institutions and operators were categorized into deciles based on the number of PCIs performed per year. Odds ratios (ORs) for in-hospital mortality and the composite endpoint (in-hospital death and periprocedural complications) were estimated for each decile (with the lowest volume group as a reference group).

RESULTS A total of 323,322 PCIs (at 625 hospitals [median PCI cases/year: 216; quartiles: 121 to 332] by 4,211 operators [median PCI cases/year: 28; quartiles: 10 to 56]) were analyzed, of which 2,959 patients (0.9%) and 7,205 patients (2.2%) experienced in-hospital mortality and the composite endpoint after PCI, respectively. The adjusted risk for in-hospital mortality and the composite endpoint was significantly higher in hospitals included in the lowest decile (<150 PCIs/year); the risk remained consistently low across the remaining deciles. Contrastingly, no significant volume-outcome relationship was observed between operator volume and outcomes. A similar trend was observed when the analysis was confined to emergency/urgent PCI cases.

CONCLUSIONS In contemporary Japanese PCI practice, lower institutional volume was related inversely to in-hospital outcomes, but the association of annual operator volume with outcomes was less clear. (J Am Coll Cardiol Intv 2017;10:918–27)

A high number of percutaneous coronary intervention (PCI) procedures are performed worldwide. In Japan, for example, >200,000 procedures are performed annually in >500 institutions. To date, numerous studies have investigated the volume-outcome relationship for PCI, and have reported that treatment in institutions and by operators with high case volumes favorably

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impacts short-term adverse outcomes, such as in-hospital mortality (1–8). Based on these findings, the 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) guideline recommends >400 PCIs per year per institute and ≥75 PCIs per year for operators (9). The 2013 ACCF/AHA/SCAI clinical competence statement has eased the minimum requirements for PCI performance (>200 PCIs per year per institute and ≥50 PCIs per year for operators) (10) to reflect the recent decline in the number of PCIs performed (11,12).

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However, despite the high number of PCI procedures performed globally, the volume-outcome relationship has been scarcely reported in regions other than Western countries. There are geographic differences in PCI performance; for example, we recently reported a higher incidence of adverse events such as bleeding or acute kidney injury in Japanese patients than patients in the United States (13,14). In addition, a large number of PCI centers have been created to promptly provide primary PCIs for patients with ST-elevation myocardial infarction; therefore, small institutions conducting ≤200 PCIs annually constitute >80% of the institutions providing PCI. Further, because of patient and institutional nonpreference for surgical procedures, on-site cardiac surgery is not available in 53% of PCI centers (15). Such differences could affect procedure quality and subsequent patient outcomes.

The purpose of this study was to determine the association of annual PCI institutional and operator volume with in-hospital mortality and periprocedural complications using the national registry database (Japanese PCI registry [J-PCI]). Clarifying this relationship could provide additional information for the universal understanding of the PCI volume threshold.

METHODS

DATA SOURCE. We analyzed patients who underwent PCI between January 2014 and December 2015 (n = 437,831) and were registered in the J-PCI. The J-PCI was established in 2007 and is a prospective Japanese nationwide multicenter registry of the Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT) designed to collect clinical variables and short-term outcome data on PCI patients (16–18). The relevant committee and the Board of Directors for the CVIT approved the registry protocol. Variables regarding patient background, clinical presentation, angiographic and procedural information, and in-hospital outcomes were collected for each patient. The definitions of J-PCI variables are available online (http://www.cvit.jp/registry/jpci_definition.pdf). The CVIT registry subcommittee designed the software for the web-based data collection system, and each data manager in the participating hospitals submits data through this system annually. Because registration in the J-PCI database is mandatory for the application for board certification and renewal, although participation in the J-PCI is voluntary, data completeness is high. According to the annual reports of the Japanese Registry Of All cardiac and vascular Disease, 508,786 PCIs (138,121 PCIs for acute indications and 370,665 PCIs for nonacute indications) were performed during the current study period (http://www.j-circ.or.jp/jittai_chosa/, accessed July 12, 2016). Because we included a total of 437,831 PCIs, approximately 85% of all procedures in Japan were estimated to be registered in our registry. The accuracy of submitted data is maintained by data auditing (20 institutions annually), which is operated by members of the CVIT registry subcommittee.

STUDY POPULATION. We analyzed the data of patients registered in the J-PCI between January 2014 and December 2015 (n = 437,831). We excluded the following cases from analysis: missing information regarding age and/or sex (n = 3,410), patients outside the age range of 20 to 100 years (n = 192), missing information regarding outcomes (n = 631), missing information regarding institute and/or operator (n = 43), and missing information on background characteristics (n = 7,698). We also excluded cases from institutions that performed <10 cases annually to exclude the influence of outliers (n = 219), and also restricted the dataset to institutions that reported >1 in-hospital death during the study period (n = 102,316). The final sample comprised 323,322 patients (**Figure 1**).

OUTCOME DEFINITIONS. The primary outcome measure of the J-PCI analysis was in-hospital mortality. The secondary outcome was a composite of in-hospital mortality and periprocedural complications, including tamponade, shock requiring mechanical and/or inotropic support, stent thrombosis ("definite" in a definition of Academic Research Consortium) (19), emergency surgery, and bleeding requiring transfusion. Periprocedural myocardial infarction was not included in the present analysis because a clear definition of periprocedural myocardial infarction has not been established (20) and only a limited number of institutions routinely evaluated cardiac biomarkers after PCI (21).

ABBREVIATIONS AND ACRONYMS

ACCF/AHA/SCAI = American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions

CI = confidence interval

CVIT = Japanese Association of Cardiovascular Intervention and Therapeutics

J-PCI = Japanese PCI registry

NCDR = National Cardiovascular Data Registry

OR = odds ratio

PCI = percutaneous coronary intervention