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Original article

Relationship between hospital volume and major cardiac complications of rotational atherectomy: A nationwide retrospective cohort study in Japan

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ABSTRACT

Background: Previous studies on life-threatening complications of rotational atherectomy (RA) were based on small sample sizes from a limited number of cardiovascular centers. No study has examined the relationship between hospital volume of RA and complications.

Methods: Using the Diagnosis Procedure Combination database in Japan, we identified inpatients aged ≥20 years who underwent RA. Hospital volume was defined as the annual number of patients undergoing RA at each hospital and eligible patients were categorized into hospital-volume tertile (low-, medium-, and high-volume) groups. The composite outcome consisted of cardiac complications requiring urgent procedures (covered stent implantation, coronary artery bypass grafting, or pericardiocentesis) or death on the day of RA. We examined the association between hospital-volume categories and the composite outcome by using a multivariable logistic regression model fitted with a generalized estimating equation.

Results: A total of 9970 patients (median age, 73 years; male, 69.8%) underwent RA in 309 hospitals. The 309 hospitals were categorized into 215 low-volume (≤15/year), 67 medium-volume (16–30/year), and 27 high-volume hospitals (≥31/year). Overall, the composite outcome occurred in 62 (0.62%) patients (36 covered stent implantation, 11 coronary artery bypass grafting, 9 pericardiocentesis, and 14 death). Patients in the high-volume group had a significantly lower rate of the composite outcome (0.29%) than those in the low-volume (0.72%, $p = 0.010$) or medium-volume group (0.89%, $p = 0.001$). With reference to the low-volume group, risk-adjusted odds ratios (95% confidence intervals) of the medium-volume and high-volume groups for the composite outcome were 1.10 (0.64–1.89) and 0.42 (0.20–0.88), respectively.

Conclusions: This study showed that higher hospital volume was significantly associated with lower complication rates of RA. Our results also suggested that the major complication rates were low even in low-volume hospitals.

Introduction

Rotational atherectomy (RA) is one of the treatment options in percutaneous coronary intervention (PCI) for calcified lesions that interfere with device delivery or expansion of a balloon or stent [1,2]. It is performed with a rapidly rotating burr, which is coated with microscopic diamonds and grinds calcified plaques into small particles that can pass through capillary vessels.

In the 1990s and early 2000s, several randomized studies failed to show better long-term outcomes in patients who underwent RA compared with those who underwent balloon angioplasty [3–6]. Furthermore, a randomized study in 2013 revealed that lesion preparation using RA before drug-eluting stent (DES) implantation for complex calcified lesions showed no long-term benefits compared with stenting without RA [7]. With the advances in other devices in addition to the discouraging results of the above

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trials, RA appears to be currently less frequently used than ever [8,9]. However, treatment of heavily calcified lesions is technically challenging in the current era of DESs, because their plaques often lead to failure of stent delivery or expansion. Although introduction of DESs has led to substantial reduction in restenosis rates [10,11], DESs need to be successfully implanted to obtain long-term effectiveness. Under these circumstances, RA can effectively ablate calcified plaques and facilitate stent delivery and expansion [12,13]. Therefore, RA remains an important tool for uncrossable or undilatable lesions and improves procedural success in the treatment of heavy calcified lesions. Indeed, current guidelines recommend the use of RA for preparation of heavily calcified lesions that cannot be crossed by a balloon or adequately dilated before stent implantation [14–16].

Previous studies reported that cardiac complications, such as coronary perforation and cardiac tamponade, occurred more frequently in PCI with atheroablative devices, including RA, than in PCI without these devices [17–19]. Owing to the invasiveness of RA, its benefits should be weighed against its complications. To date, several studies have reported serious complications associated with RA followed by DES implantation (death, 0.0–1.7%; coronary dissection, 1.9–5.9%; coronary perforation, 0.0–2.0%; no/slow flow phenomena, 0.0–2.6%) [7,20–28]. However, these studies were based on small sample sizes (n = 50–391) from a limited number of cardiovascular centers. Thus, the risk of RA remains to be fully defined by a large-scale multicenter study.

Although volume–outcome relationships have been shown for many surgical and nonsurgical procedures in previous studies [29–31], no study has examined the relationship between hospital volume of RA and complication rates. We hypothesized that hospital volume of RA was inversely associated with the cardiac complication rate. The purpose of the present study was to examine the relationship between hospital volume of RA and cardiac complications, using a nationwide inpatient database in Japan.

Methods

Study design and data source

This is a retrospective cohort study using the Diagnosis Procedure Combination (DPC) database, which was explained in detail elsewhere [32]. The database includes approximately 18 million inpatient data for 33 months between 1 July 2010 and 31 March 2013 from approximately 1000 hospitals in Japan. In 2012, the DPC database included data of 6.9 million inpatients from 1057 hospitals, representing approximately 50% of all inpatient admissions to acute care hospitals in Japan. The hospitals participating in the DPC study are distributed in all the 47 prefectures across Japan and include 70.8% (704/995) of all the Japanese Circulation Society-certified training hospitals [33]. The database includes the following data: unique hospital identifiers; patient age and sex; main diagnoses and comorbidities, which were recorded with International Classification of Diseases Tenth Revision (ICD-10) codes and text data written in the Japanese language; drugs and devices; diagnostic and therapeutic procedures, recorded using original Japanese codes; length of stay; and discharge status. The present study was approved by The Institutional Review Board at The University of Tokyo. Because all the data were anonymized, the requirement for informed consent was waived.

Patient selection and variables

In Japan, RA can be performed only in institutions which meet the criteria for Institutions Providing Percutaneous Coronary Angioplasty Using RA [14]. We identified adult inpatients aged ≥20 years who underwent an RA procedure between 1 July 2010 and 31 March 2013. We excluded patients who underwent two or more RA procedures during the index hospitalization. For the baseline variables, we extracted the following data: age; sex; a main diagnosis for admission; comorbidities present at admission, which were identified in reference to ICD-10 codes used in previous studies [34,35] (heart failure, cerebrovascular disease, peripheral vascular disease, and diabetes mellitus with complications); use of hemodialysis; type of hospital (academic or non-academic); hospital volume; day of RA performance during index hospitalization; timing of PCI using RA during index hospitalization (first PCI or second PCI and thereafter); and intra-aortic balloon pumping (IABP) use on the day of RA. Using both, the diagnosis written in Japanese and the ICD-10 codes, we identified acute coronary syndrome (acute myocardial infarction [I21.0], unstable angina [I20.0], or acute coronary syndrome [I24.8]) as a main diagnosis for admission. Hospital volume was defined as the annual number of patients undergoing an RA procedure at each hospital, and categorized into tertile (low-, medium-, and high-volume) groups, with approximately equal numbers of patients in each group.

Outcome definitions

We focused on serious cardiac complications related to coronary arteries. Due to data availability, we identified the occurrence of the complications by the devices and procedures used on the day of RA. The composite outcome included (i) covered stent implantation, (ii) coronary artery bypass grafting (CABG), (iii) pericardiocentesis, and (iv) death on the day of RA. We also identified the blood transfusion (red blood cells, fresh frozen plasma, or platelets) which was initiated on the day of RA in reference to type 3a bleeding of the Bleeding Academic Research Consortium definition [36].

Statistical analysis

Categorical variables were presented as numbers and percentages and were compared using the chi-square test. Age and length of stay were presented as medians and interquartile ranges (IQRs). We conducted a multivariable logistic regression analysis of the composite outcome with adjustment for baseline variables. In the DPC database, data were structured in two levels, a patient level and a hospital level. In a study using such data, the outcomes of patients in the same hospital would be correlated. Therefore, we used the regression model with a generalized estimating equation to take clustering within hospitals into consideration [37]. We then determined odds ratios (ORs) and 95% confidence intervals (CIs) for each covariate. All hypothesis tests had a two-sided significance level of 0.05. We conducted all statistical analyses using IBM SPSS Statistics, version 22 (IBM Corp., Armonk, NY, USA).

Results

Study population

We identified 10,295 inpatients aged ≥20 years who underwent an RA procedure. We excluded 325 patients who received two or more RA procedures during the index hospitalization. Thus, the study population was 9970 patients in 309 hospitals. Among the eligible patients, 9043 (90.7%) patients received stent implantation (DES, n = 8482; bare-metal stent, n = 660). The 309 hospitals consisted of 79 academic and 230 non-academic hospitals. The 309 hospitals were categorized into 215 low-volume (≤15/year), 67 medium-volume (16–30/year), and 27 high-volume hospitals (≥31/year). The overall in-hospital mortality was 2.1%