Incidence and Determinants of Complications in Rotational Atherectomy
Insights From the National Clinical Data (J-PCI Registry)

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Background—The usage of rotational atherectomy (RA) is growing in the current percutaneous coronary intervention (PCI) because of the expansion of PCI indication to more complex lesions. However, the complications after RA have been linked to procedure-related morbidity and mortality. The purpose of this study was to investigate the incidence and determinants of complications in RA using a large nationwide registration system in Japan (J-PCI).

Methods and Results—The primary composite outcome of this study was defined as the occurrence of in-hospital death, cardiac tamponade, and emergent surgery after RA. A total of 13335 RA cases (3.2% of registered PCI cases) were analyzed. The composite outcome was observed in 175 cases (1.31%) and included 80 in-hospital deaths (0.60%), 86 tamponades (0.64%), and 24 emergent surgeries (0.18%). The clinical variables associated with occurrence of the composite outcome were age (odds ratio [OR] 1.03 per unit increment, 95% confidence interval [CI] 1.02–1.05), impaired kidney function (OR 1.59, 95% CI 1.15–2.19), previous myocardial infarction (OR 1.69, 95% CI 1.21–2.35), emergent PCI (OR 4.02, 95% CI 1.66–8.27), and triple-vessel disease (versus single-vessel disease: OR 2.17, 95% CI 1.43–3.28). Notably, institutional volume of RA cases was inversely associated with the composite outcomes (high- versus low-volume institution: OR 0.56, 95% CI 0.36–0.89).

Conclusions—The reported incidence of important procedure-related complication rate was 1.3%, with each component ranging between 0.2% and 0.6% in J-PCI. Its determinants were both patient related (age, impaired kidney function, and previous myocardial infarction) and procedure related (emergent procedures, number of diseased vessels, and institutional volume of RA).

Key Words: atherectomy ◼ complication ◼ incidence ◼ registry ◼ rotational atherectomy

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Methods
National Clinical Data (J-PCI Registry) and Study Design
The J-PCI Registry, which was launched in November 2011, is a national, prospective, multicenter registry designed to collect clinical data on patients undergoing PCI in Japan and is operated by the Japanese Association of Cardiovascular Intervention and Therapeutics. Since January 2013, the J-PCI Registry has been incorporated into the National Clinical Data system, which is a nationwide prospective web-based registry linked to the surgical board certification system, and the registry is linked to the board certification system in interventional cardiology. The National Clinical Data continuously communicates with data managers responsible for data collection through the National Clinical Data web-based data management system and consistently performs random site visits to validate the submitted data (20 sites/year).

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WHAT IS KNOWN

- The use of rotational atherectomy is growing because of the complexity of patients undergoing percutaneous coronary intervention in the current era.
- Unique complications have been reported in rotational atherectomy, such as burr entrapment or vessel perforation, and those complications are closely associated with cardiac tamponade, emergent surgery, and death.
- Estimates of the incidence and determinants of severe complications of rotational atherectomy in the real world are unknown.

WHAT THE STUDY ADDS

- The present study included 13 335 rotational atherectomy cases from the J-PCI Registry, which is a national, prospective, multicenter registry operated by the Japanese Association of Cardiovascular Intervention and Therapeutics.
- The incidence of procedure-related complications was 1.3%, and patient- and procedure-related determinants were identified.

Reports of the Japanese Registry of All Cardiac and Vascular Disease, 255 416 PCIs (69 867 PCIs for acute indications and 185 549 PCIs for nonacute indications) were performed during the current study period (http://www.j-circ.or.jp/jittai_chosa/, accessed on January 18, 2016). Given that we included a total of 415 025 PCIs over 2 years, around 80% of all procedures in Japan were estimated to be registered in our registry.

The present study included the cases that needed RA for coronary artery disease from January 2014 to December 2015 in the J-PCI Registry. In Japan, RA is only permitted to the institution that has both >200 PCIs and >30 open-heart surgeries per year. The cases that had missing value in complications were excluded. The cases whose sex or age was unknown were also excluded. The primary composite outcome of this study was the occurrence of in-hospital death, cardiac tamponade, and emergent surgery. The cases that had the primary composite outcome were categorized as the complication group, whereas the cases that did not have the primary composite outcome were categorized as the noncomplication group. The determinants of the primary composite outcome were also sought by using multivariable logistic regression model.

In August 2015, the Japanese Association of Cardiovascular Intervention and Therapeutics publicly advertised for the research proposal using J-PCI Registry (http://www.cvit.jp/news/2015/08/05_005353.html), and the proposal named as “the research proposal using J-PCI Registry (http://www.cvlt.jp/registry/jpci_definition.pdf)” Institutional class was categorized into tertile as low volume, middle volume, and high volume according to the number of RA in each institution with approximately equal numbers of institutions in each class.

Clinical Variables in J-PCI Registry

Clinical characteristics included age, sex, history of PCI, history of coronary artery bypass surgery, history of myocardial infarction, diabetes mellitus, hypertension, hyperlipidemia, smoking, impaired kidney function, and chronic renal failure on hemodialysis. Diabetes mellitus was defined as a fasting plasma glucose level ≥2126 mg/dL, a casual plasma glucose level ≥200 mg/dL, a 2-hour plasma glucose level during the 75 g oral glucose tolerance test ≥200 mg/dL, a hemoglobin A1c level ≥6.5%, or treatment of diabetes mellitus. Hypertension was defined as systolic blood pressure >140 mm Hg, diastolic blood pressure >90 mm Hg, or medical treatment for hypertension. Hyperlipidemia was defined as a total cholesterol level ≥220 mg/dL, a low-density lipoprotein cholesterol level ≥140 mg/dL, a high-density lipoprotein cholesterol level <40 mg/dL, a triglyceride level ≥150 mg/dL, or treatment for hyperlipidemia. Impaired kidney function was defined as the presence of proteinuria, a serum creatinine level ≥1.3 mg/dL, or an estimated glomerular filtration rate level ≤60 mL/min per 1.73 m². Lesion characteristics included the culprit vessel of acute coronary syndrome, number of diseased vessels (single, double, or triple), the presence of left main coronary artery disease, emergent or elective PCI, and the target vessel (right coronary artery, left main coronary artery, left anterior descending coronary artery, left circumflex coronary artery, or bypass graft vessel). The definitions of these J-PCI variables are available online (http://www.cvlt.jp/registry/jpci_definition.pdf). Continuous variables were compared between the complication group and the noncomplication group. Continuous variables were compared between the groups using an unpaired Student’s t test, whereas categorical variables were compared using a χ² test. A trend test for institutional class was performed by using a Cochran–Armitage test. In multivariable logistic regression analysis, the primary composite outcome was used as a dependent variable. Clinical variables that showed a marginal difference (P < 0.20) in comparisons between the complication group and the noncomplication group were used as independent variables. Odds ratio (OR) and 95% confidence interval (CI) were calculated. All reported P values were determined by 2-sided analysis, and P values <0.05 were considered significant. All analyses were performed with the R statistical software system (Free Software Foundation, Inc, Boston, MA).

Results

The J-PCI Registry contained 415 025 PCI cases from January 2013 to December 2014. Of 415 025 PCI, 13 495 (3.2%) used RA during their procedure. For the outcome analysis, we excluded 26 cases (<0.01%) that had missing value in complications and 134 cases whose age or sex was unknown (0.01%). The final study population consisted of 13 335 cases. The study flow chart is shown in Figure. Table 1 shows in-hospital outcomes. The primary composite outcomes, including in-hospital death, tamponade, and emergent surgery, occurred in 175 cases (1.31%). On the contrary, the number of in-hospital deaths, tamponades, and emergent surgeries in 415 025 PCI cases were 2595 (0.63%), 560 (0.13%), and 403 (0.10%), respectively.

Table 2 shows the baseline characteristic and comparisons between the complication group and the noncomplication group. There was a substantial overlap between culprit of acute coronary syndrome and emergent PCI. All (100%) of the culprit of acute coronary syndrome cases were categorized into emergent PCI, whereas 83% of emergent PCI cases were categorized into culprit of acute coronary syndrome. For the volume outcome analysis, participating institutions were divided into 188 low-volume institutions (1–10 RA cases over 2 years), 181 middle-volume institutions (11–24 cases), and...
The present study included 13,335 rotational atherectomy cases from 547 institutions. The rate of composite complication in low-, middle-, and high-volume institutions were 1.86%, 1.59%, and 1.06%, respectively (P = 0.001).

The multivariable logistic regression model to find the determinants of composite complication is shown in Table 3. Age (OR 1.03, 95% CI 1.02–1.05), impaired kidney function (OR 1.59, 95% CI 1.15–2.19), history of previous myocardial infarction (OR 1.69, 95% CI 1.21–2.35), emergent PCI (OR 4.02, 95% CI 1.66–8.27), double-vessel disease (versus single-vessel disease: OR 1.55, 95% CI 1.04–2.32), triple-vessel disease (versus single-vessel disease: OR 2.17, 95% CI 1.43–3.28), and left main disease (versus single-vessel disease: OR 2.54, 95% CI 1.51–4.17) were significantly associated with the composite complication. When hospital volume was considered as a covariable, high-volume institution (versus low-volume institution: OR 0.56, 95% CI 0.36–0.89) was inversely associated with the composite complication.

**Discussion**

The present study included 13,335 RA cases from the J-PCI Registry, which is a national, prospective, multicenter registry operated by the Japanese Association of Cardiovascular Intervention and Therapeutics. The reported incidence of important procedure-related complication rate was 1.3%, with its each component ranging between 0.2% and 0.6% in J-PCI. Its determinants were both patient-related (age, impaired kidney function, and previous myocardial infarction) and procedure-related (emergent procedures, number of diseased vessels, and institutional volume of RA). These results would help interventional cardiologists to consider the strategy for severely calcified lesions, as well as the indication of RA in their institution.

Although the incidence of complications after RA has been reported, the incidence varies among studies, probably because the sample sizes of those studies were relatively small. Recently, Arora et al² compared 103,759 conventional PCI with 3,372 atherectomy PCI using Nationwide Inpatient Sample database and found that atherectomy utilization was significantly associated with a higher rate of post-procedural complications. Although they did not analyze the determinants of complications after RA, they reported in-hospital mortality after atherectomy as 3.32%, which was 5× greater than the in-hospital mortality of the present study (0.60%). To date, the present study included the largest study population (n=13,335) and showed the incidence of complications including in-hospital mortality.

In lesion and procedure characteristics, emergent PCI was the significant determinant of the composite outcome. The most common indication for emergent PCI is ST-segment-elevation acute myocardial infarction,¹⁴ which is closely associated with visible thrombus. Because the use of RA is contraindicated (off-label) for the lesion with visible thrombus, it is preferable not to use RA for the lesion with visible thrombus. However, RA could be the only option to dilate the complex calcified lesion even in the setting of ST-segment-elevation acute myocardial infarction. It should be important for interventional cardiologists to know the fact that the risk of severe complications after RA was 4× greater in emergent PCI as compared with elective PCI. Even for the severely calcified stenosis, switching from emergent to elective setting could be the reasonable option if TIMI (Thrombolysis in Myocardial Infarction) flow grade 3 was obtained after balloon angioplasty. Number of diseased vessels, especially left main disease, was the significant determinant of the composite outcome. Although several groups reported the acceptable clinical outcomes after RA to the unprotected left main stenosis, it does not mean that RA to unprotected left main stenosis is as safe as RA to other lesions. Furthermore, the use of circulatory support devices, such as intra-aortic balloon pump or Impella (Abiomed Inc, Danvers, MA), may reduce the incidence of severe complications even in high-risk RA patients, such as those with left main disease or left ventricular dysfunction.

In institutional class, the rate of the composite outcomes in high-volume institutions was approximately half of that in low-volume institutions. As Badheka et al³ reported that an increase in operator and institutional volume of PCI was associated with a decrease in adverse outcomes, institutional volume of RA should be the important factor for the occurrence of adverse events. Because RA requires special equipment, such as burr, advancer, console, foot pedal, air tank, and cocktail, including nitroglycerin and heparin, substantial cases per year may be needed for catheter laboratory staffs, as well as operators. Centralization of RA cases may decrease the overall rate of catastrophic complications.

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**Table 1. In-Hospital Outcomes After Rotational Atherectomy**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Events, n</th>
<th>Rate, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital death</td>
<td>80</td>
<td>0.60</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>86</td>
<td>0.64</td>
</tr>
<tr>
<td>Emergent surgery</td>
<td>24</td>
<td>0.18</td>
</tr>
<tr>
<td>Composite outcomes</td>
<td>175</td>
<td>1.31</td>
</tr>
</tbody>
</table>
Study Limitations

Because the present study used the J-PCI Registry, there are several limitations inherent to a registry design. The indications of RA varied among each institution, which were subject to selection bias. Periprocedural myocardial infarction was not included in the composite outcomes because a clear definition of periprocedural myocardial infarction was not available at the time of this study. Idris et al.\textsuperscript{24} reported that the incidence of periprocedural myocardial infarction varied widely in a single group of patients depending on the definition used (2.6\% by Society for Cardiovascular Angiography and Interventions [SCAI] definition to 23.2\% by 2007 universal myocardial infarction definition). Furthermore, it seemed impractical to collect meaningful information on periprocedural myocardial infarction from over 600 institutions across the nation in the present study. On the contrary, the definitions of in-hospital death, cardiac tamponade, and emergent surgery should be clear for every person entering data. Therefore, we used in-hospital death, cardiac tamponade, and emergent surgery as the composite outcome. Nevertheless, there is a possibility that data managers in some institutions did not check in-hospital death, cardiac tamponade, and emergent surgery thoroughly, which might underestimate the overall risk of those complications. The incidence of in-hospital death may reflect the severity of illness and not

Table 2. Baseline Characteristics Between the Complication Group and the Noncomplication Group

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>All (n=13335)</th>
<th>Complication Group (n=175)</th>
<th>Noncomplication Group (n=13160)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>72.6±9.6</td>
<td>75.3±10.1</td>
<td>72.5±9.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>9310 (69.8)</td>
<td>108 (61.7)</td>
<td>9202 (69.9)</td>
<td>0.023</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>10587 (79.4)</td>
<td>143 (84.6)</td>
<td>10444 (82.3)</td>
<td>0.489</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>7126 (53.4)</td>
<td>100 (59.2)</td>
<td>7026 (55.3)</td>
<td>0.359</td>
</tr>
<tr>
<td>Hyperlipidemia, n (%)</td>
<td>7666 (57.5)</td>
<td>94 (55.6)</td>
<td>7572 (59.6)</td>
<td>0.327</td>
</tr>
<tr>
<td>Smoker, n (%)</td>
<td>3136 (23.5)</td>
<td>29 (17.2)</td>
<td>3107 (24.5)</td>
<td>0.035</td>
</tr>
<tr>
<td>Impaired kidney function, n (%)</td>
<td>3739 (28.0)</td>
<td>66 (39.1)</td>
<td>3673 (28.9)</td>
<td>0.005</td>
</tr>
<tr>
<td>Chronic renal failure on hemodialysis, n (%)</td>
<td>2789 (20.9)</td>
<td>43 (25.4)</td>
<td>2746 (21.6)</td>
<td>0.271</td>
</tr>
<tr>
<td>History of previous PCI, n (%)</td>
<td>6888 (51.7)</td>
<td>83 (48.0)</td>
<td>6805 (52.0)</td>
<td>0.331</td>
</tr>
<tr>
<td>History of previous CABG, n (%)</td>
<td>1136 (8.5)</td>
<td>17 (9.8)</td>
<td>1119 (8.6)</td>
<td>0.670</td>
</tr>
<tr>
<td>History of previous myocardial infarction, n (%)</td>
<td>3076 (23.1)</td>
<td>58 (33.7)</td>
<td>3018 (23.6)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Lesion and procedure characteristics

| Emergent PCI, n (%) | 1366 (10.2) | 51 (29.1) | 1315 (10.0) | <0.001 |
| Culpit of acute coronary syndrome, n (%) | 1138 (8.5) | 44 (25.1) | 1094 (8.3) | <0.001 |
| Number of diseased vessels |           |           |             | <0.001 |
| Single-vessel disease, n (%) | 6700 (50.2) | 55 (31.4) | 6645 (50.5) |       |
| Double-vessel disease, n (%) | 3599 (27.0) | 51 (29.1) | 3548 (27.0) |       |
| Triple-vessel disease, n (%) | 2085 (15.6) | 45 (25.7) | 2040 (15.5) |       |
| Left main disease, n (%) | 951 (7.1) | 24 (13.7) | 927 (7.0) |       |

Target vessel

| Right coronary artery, n (%) | 3896 (29.2) | 59 (33.7) | 3837 (29.2) | 0.217 |
| Left main–left anterior descending artery, n (%) | 8377 (62.8) | 113 (64.6) | 8264 (62.8) | 0.686 |
| Left circumflex artery, n (%) | 3002 (22.5) | 40 (22.9) | 2962 (22.5) | 0.985 |
| Bypass graft, n (%) | 102 (0.8) | 0 (0.0) | 102 (0.8) | 0.464 |

Institutional class

| Low-volume institution (n=188): 1–10 cases/2 y, n (%) | 1666 (12.5) | 31 (17.7) | 1635 (12.4) |       |
| Middle-volume institution (n=181): 11–24 cases/2 y, n (%) | 3900 (29.2) | 62 (35.4) | 3838 (29.2) |       |
| High-volume institution (n=178): 25–564 cases/2 y, n (%) | 7769 (58.3) | 82 (46.9) | 7687 (58.4) |       |

Data are expressed as mean±SD or number (percentage). Student’s t test was used for continuous variables, and \( \chi^2 \) test was used for categorical variables. CABG indicates coronary artery bypass grafting surgery; and PCI, percutaneous coronary intervention.
necessarily reflect the effect of RA treatment. Furthermore, we could not include specific lesion or procedural features, such as lesion length, degree of calcification, number of burrs, and burr size, that would be associated with complications.25 Although RA was only permitted to the institution that had >200 PCIs per year in Japan, the number of RA varied widely between institutions, partly because indications of RA were not consistent between institutions. The procedure-related complications might be associated with indications of RA in each institution, which were not incorporated into the present analysis. It may be important to define appropriate indications for RA to decrease the overall incidence of severe complications.

Conclusions
The reported incidence of important procedure-related complication rate was 1.3%, with its each component ranging between 0.2% and 0.6% in J-PCI. Its determinants were both patient- and procedure-related. Notably, the risk of severe complications after RA was ≈4× greater in emergent PCI as compared with elective PCI. The risk of severe complications was approximately half in the high-volume institutions as compared with the low-volume institutions.

Appendix
Member of Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT) Scientific Committee: Kazushige Kadota (Kurashiki Central Hospital), Nobuo Shioide (Hiroshima City Hospital), Nobuhiko Tanaka (Tokyo Medical University), Tetsuya Amano (Aichi Medical University), Shiro Uemura (Kawasaki Medical School), Takashi Akasaka (Wakayama Medical University), Yoshihiro Morino (Iwate Medical University), Kenishi Fujii (Sakurabashi Watanabe Hospital), Hiroshi Hikichi (Saga University). Member of CVIT Registry Subcommittee: Tetsuya Amano (Aichi Medical University), Kenshi Fujii (Sakurabashi Watanabe Hospital), Shun Kohsaka (Keio University), Hideki Ishii (Nagoya University), Kengo Tanabe (Mitsui Memorial Hospital), Yukio Ozaki (Fujita Health University), Satoru Sumitsuji (Osaka University), Hidehiko Hara (Toho University Ohashi Medical Center), Hiroaki Takashima (Aichi Medical University), Shinichi Shirai (Kokura Memorial Hospital), Shinichi Shirai (Kokura Memorial Hospital), Mamoru Nansato (Nagoya Daini Red Cross Hospital), Taku Inohara (Keio University), Yasunori Ueda (Osaka National Hospital), Yohei Numasawa (Japanese Red Cross Ashikaga Hospital), Shigetaka Noma (Saiseikai Utsunomiya Hospital).

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References
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