

Letters

RESEARCH LETTER

Reduction in Planned Percutaneous Coronary Interventions After the Policy Change for Ischemia Assessment in Japan



Percutaneous coronary intervention (PCI) is a commonly performed invasive cardiac procedure worldwide, playing an important role in the treatment of patients with ischemic heart disease. Clinical practice guidelines emphasize the importance of patient selection using ischemia assessment tests to ensure that the benefits of PCI outweigh the risks.¹ However, higher proportions of elective PCI without prior noninvasive ischemia assessment were reported in Japan.²

The Japanese Ministry of Health, Labour, and Welfare introduced a new reimbursement policy: to reduce unnecessary PCIs, ischemia assessment was required for planned PCI beginning in April 2018. However, no studies have assessed PCI trends since the change. In this study, we investigated the association between the policy changes and the proportion of planned PCIs with ischemia assessment and the total number of planned PCIs, using nationwide administrative data.

We used the National Database of Health Insurance Claims and Specific Health Checkups of Japan, provided by the Ministry of Health, Labour and Welfare, including administrative data on inpatient and outpatient services in Japan. We included patients who underwent planned PCI from April 1, 2014, to March 31, 2021 (fiscal years 2014-2020). We assessed whether patients underwent ischemia assessment 3 months before index PCI and excluded patients without 3-month observation periods before index PCI or with preceding planned PCI within 3 months. The exposure of interest was the period of the change in requirements for ischemia assessment (April 1, 2018 [the first month of fiscal year 2018]). Ischemia

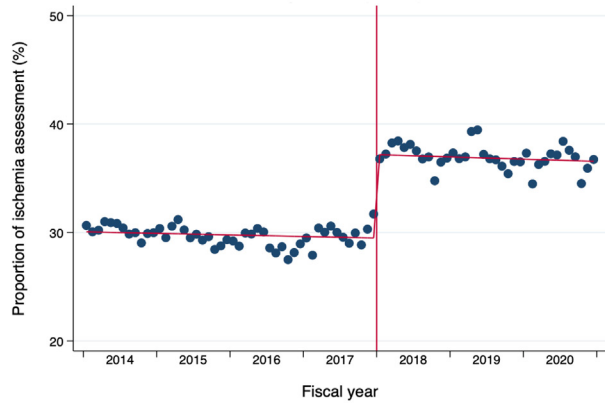
assessment included noninvasive testing (treadmill test, master's double test, stress single-photon emission computed tomography, stress echocardiography, cardiac perfusion magnetic resonance imaging, and computed tomography-derived fractional flow reserve) and invasive testing (such as fractional flow reserve) of the coronary arteries. The outcomes were change in the proportion of planned PCIs with ischemia assessment among all planned PCIs, change in the total number of planned PCIs, and change in all-cause 30-day mortality after index PCI. Ethics committees of the National Cerebral and Cardiovascular Center (registration number R20110) and Nara Medical University (registration 1123-2) approved the study protocol, with a waiver of the requirement to obtain informed consent, as only administrative data were used.

We used an interrupted time-series design to assess whether the monthly outcomes were associated with the reimbursement policy change. The level and slope changes were modeled using an ordinary least squares regression before and after the policy change, fitted using the Prais-Winsten method to account for data autoregression.³ For the sensitivity analysis, we limited the study period from April 2014 to January 2020 to exclude the COVID-19 pandemic period in Japan. We analyzed the data using Stata version 16 (StataCorp).

Overall, 1,073,847 PCIs were analyzed in this study. Most patients were 71 to 80 years of age ($n = 411,977$ [38%]), and 25% ($n = 263,778$) were women. The proportion of planned PCIs with ischemia assessment was 33% ($n = 351,385$). For the ischemia assessment test, the treadmill test or master's double test, single-photon emission computed tomography, and invasive testing before or at the index PCI were performed in 132,875 (12%), 103,892 (10%), and 165,632 (15%) patients, respectively. Stress echocardiography, cardiovascular magnetic resonance imaging, and computed tomography-derived fractional flow reserve were rarely performed throughout the study period (<1%). The proportion of planned PCIs with ischemia assessment increased by 7.7% (95% CI: 6.29% to 9.11%; $P < 0.001$) after the implementation and was accompanied by a decrease of 862 planned PCI cases (95% CI: $-1,611$ to -113 cases; $P = 0.03$) (Figure 1). However, 30-day mortality did not change after the policy change (level

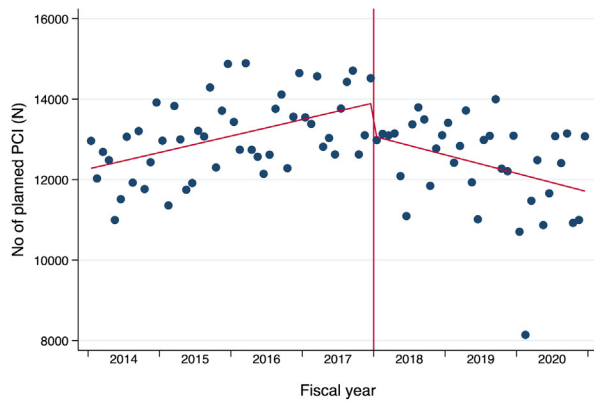
FIGURE 1 Changes in Planned PCIs Before and After the Policy Change

A Proportion of planned PCI with ischemia assessment



| | Estimate (95% CI) | P value |
|--------------------------|--------------------------|---------|
| Pre-implementation phase | | |
| Slope | -0.012 (-0.040 to 0.016) | 0.75 |
| Implementation phase | | |
| Level change | 7.70 (6.29–9.11) | <0.001 |
| Slope | -0.017 (-0.071 to 0.037) | 0.52 |
| Slope change | -0.005 (-0.066 to 0.056) | 0.87 |

B Number of planned PCI analyzed



| | Estimate (95% CI) | P value |
|--------------------------|-----------------------|---------|
| Pre-implementation phase | | |
| Slope | 34 (16–52) | <0.001 |
| Implementation phase | | |
| Level change | -862 (-1,611 to -113) | 0.03 |
| Slope | -38 (-72 to -4.1) | 0.03 |
| Slope change | -73 (-112 to -34) | <0.001 |

An interrupted time-series design was used to assess whether the monthly outcomes were associated with the change in reimbursement policy. **(A)** The proportion of planned percutaneous coronary interventions (PCIs) with ischemia assessment increased after the policy change. **(B)** The total number of planned PCIs decreased after the policy change.

change 0.004%; 95% CI: -0.004% to 0.011%; $P = 0.33$). The results were consistent when the model was adjusted for age and sex. The sensitivity analysis for the total number of planned PCIs (excluding COVID-19 pandemic period cases) yielded consistent results (-1,058 cases; 95% CI: -1,809 to -307 cases; $P = 0.006$).

The main findings of this nationwide cohort study using a quasiexperimental study design revealed an increased proportion of planned PCIs with ischemia assessment. Although the database did not include test results of ischemia assessment or details of PCI-associated complications, the total number of planned PCIs decreased without an increase in all-

cause mortality after implementation of the new reimbursement policy. Our results have a potential clinical benefit because the policy change led to a reduction in the number of unnecessary PCIs in patients with coronary artery disease. However, the proportion of ischemia assessments after the policy change was not high compared with that in the United States, and the change in slope did not decrease. These results indicate that PCIs based on computed tomographic angiography without anatomical or functional assessment were still frequently performed in Japan. The reasons are currently unclear, but we need to carefully observe the trends after the study period.

Koshiro Kanaoka, MD, PhD

Yoshitaka Iwanaga, MD

Michikazu Nakai, PhD

Yuichi Nishioka, MD, PhD

Tomoya Myojin, MD

Katsuki Okada, MD, PhD

Tatsuya Noda, MD, PhD

Yoshihiro Miyamoto, MD, PhD

Yoshihiko Saito, MD, PhD

*Tomoaki Imamura, MD, PhD

*Department of Public Health,
Health Management and Policy
Nara Medical University
Shijo-cho 840

Kashihara, Nara 634-8521, Japan

E-mail: imamurat@naramed-u.ac.jp

Twitter: [@koshiroook](https://twitter.com/koshiroook)

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

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