

Editorial



The Operator Volume of Primary Percutaneous Coronary Intervention for ST Segment Elevation Myocardial Infarction Does Not Guarantee Its Quality in Korea

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Conflict of Interest

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► See the article “Effect of Operator Volume on In-Hospital Outcomes Following Primary Percutaneous Coronary Intervention for ST-Elevation Myocardial Infarction: Based on the 2014 Cohort of Korean Percutaneous Coronary Intervention (K-PCI) Registry” in volume 50 on page 133.

Percutaneous coronary intervention (PCI) was a complex and risky procedure at the beginning of the procedure, and its success was not guaranteed if the operator expertise and skill were not mature. In addition, there were lots of complications which needed cardiac surgeons on standby for emergent operation. Particularly, left main disease or chronic total occlusion were believed to be beyond the PCI scope and only exploratory intervention was attempted by experienced operators in few advanced centers. Primary PCI for ST segment elevation myocardial infarction (STEMI) was introduced as an alternative treatment to thrombolysis. But its use was also limited to special centers which were capable of 24/7 cathlab availability by an experienced operator.

A learning curve with PCI was first reported in 1984, showing that operators with a cumulative experience of 50 cases had a success rate of 55% compared with 77% among operators with 150 cases.¹⁾ This kind of analysis continued over the years observing that a volume-outcome relationship in patients undergoing PCI at both operator and institutional levels.^{2,3)} Associations between PCI volume and outcomes were believed to be causal—that is, higher volume operators were presumed to be better. Because of the ease of collection and reporting volume data, we obsessively have counted PCI volume as a surrogate for operator and center experience and even quality of care. The American College of Cardiology/American Heart Association guideline document from 1993 recommended that 1) primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year and 2) ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.⁴⁾

Recently, much has changed driven by innovative development and evidences from randomized controlled trials. Drug-eluting stents incredibly improved PCI's efficacy and decreased periprocedural and long-term complications. Interventional cardiology training

programs in collaboration with the many academic societies have played a pivotal role in spreading the learning experience and have standardized techniques of PCI. Therefore, PCI of left main disease is no longer specialized skill and PCI of chronic total occlusions is growing rapidly across the world. The wide adoption of mechanical circulatory support devices has further stabilized percutaneous approaches of complex lesions and patients previously felt to be contraindicated for PCI before. The necessity of cardiac surgery onsite for back-up plan of PCI is not emphasized any more in these days. Particularly, pharmacologic advances for acute coronary syndrome has dramatically reduced acute thrombotic complications which may attenuate hazards due to technical imperfection in primary PCI.

Therefore, because of these remarkable changes, it is questionable that the operator and institutional volumes still remain as a key aspect of quality assessment in PCI in determining competency and quality. Particularly, the relationship between operator volume and outcomes of PCI in patients with STEMI has not been fully investigated in Korea.

The current study by Lee et al.⁵⁾ in this issue of the journal addresses this key knowledge gap. In this analysis from the Korean nationwide, retrospective registry (K-PCI registry), 8,282 patients treated with PCI for STEMI by 373 operators were analyzed. PCI volumes above the 75th percentile (>30 cases/year), between the 75th and 25th percentile (10–30 cases/year), and below the 25th percentile (<10 cases/year) were defined as high, moderate, and low-volume operators, respectively. In-hospital outcomes including mortality, non-fatal myocardial infarction (MI), stent thrombosis, stroke, and urgent repeat PCI were analyzed. The average number of primary PCI cases performed by 373 operators was 22.2 in a year. Most of the high-volume operators were affiliated with high-volume centers (65.7%) and none with low-volume center. But low-volume operators were affiliated with moderate- (45.9%) or low- (36.1%) volume centers. Patients' characteristics was different among the operator volume groups. The incidence of cardiogenic shock was similar, but cardiac arrest occurred more frequently in the low-volume operator group than in the mid- and high-volume operator groups (9.0% vs. 8.8%/6.7%, respectively, $p=0.002$). In terms of techniques in primary PCI, high-volume operators were more likely to perform PCI by radial approach, whereas low-volume operators were more likely to employ intravascular ultrasound (IVUS) guidance. Overall in-hospital mortality after PCI for STEMI was 571 cases (6.9%). In-hospital outcomes by operator volume showed no significant differences in the death rate (high/moderate/low, 6.9%/6.9%/7.2%) as well as cardiac death, non-fatal MI, and stent thrombosis. However, the rate of urgent repeat PCI tended to be lower in the high-volume operator (0.6%) than in the moderate- (0.7%)/low- (1.5%) volume operator groups ($p=0.095$). They reported an interaction between operator volume and hospital volume. The rate of in-hospital major adverse cardiovascular and cerebrovascular event (MACCE) showed no difference according to operator volume in high-volume centers. There was no high-volume operator in low-volume center. However, the MACCE rate was significantly lower in the high- (9.25%)/moderate- (10.03%) volume operator than in the low-volume operator (17.59%) in moderate-volume center. The adjusted odds ratios for adverse in-hospital outcomes were similar in the 3 groups. Multivariate analysis also showed that operator volume was not a predictor for adverse in-hospital outcomes. They concluded that in-hospital outcomes after primary PCI for STEMI were not associated with operator volume in the K-PCI registry.

This paper opens us a new horizon about quality assessment in primary PCI for STEMI. First and foremost, PCI performed in the contemporary era is fundamentally different from PCI in the previous angioplasty era. The procedure including medical treatment for STEMI now is

very standardized and well-trained compared to the recent elective PCI which is vastly more complex and variable than before. This may reduce operator-dependent factors in primary PCI and thus abolish the relationship between operator volume and in-hospital outcomes.

Second, we need to appreciate that PCI volume can be a very complex number to define. Institutional and operator volumes are both important, but so is lifetime volume or experience which was not evaluated in this study. Nine primary PCI by an interventional cardiologist who has performed over 1,000 PCI in his/her career cannot be the same as 40 PCI by a new staff. And there are many factors in experience from related procedures such as fractional flow reserve, IVUS, mechanical support devices and even peripheral and structural interventions.

Third, the outcomes after primary PCI for STEMI in Korea is already very low.⁶⁾ Therefore, operator competency and the quality of PCI may not be reflected in the outcomes, particularly in the mortality or new MI during the index admission.

Finally, these real data showed that operators and hospitals in Korea maintain quality with good access irrespective of volume. Although there are regional differences in operator volume as demonstrated in this study, many operators and hospitals provide primary PCI for STEMI in each region without quality difference. Therefore, we should not push operators or hospitals to reach an arbitrary volume threshold which could perversely incentivize interventional cardiologists to do less-appropriate cases to reach the target that keeps their privileges active and their cathlabs open.

This important paper by Lee et al.⁵⁾ thus raises as many questions as it seeks to answer. The bottom line is that we need to seriously break our obsession with volume thresholds. Volume may be among the factors, but it should be only considered under a more comprehensive quality assessment program that should be redesigned in the contemporary PCI era.

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