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EDITORIAL

Who Would You Want to Do Your Unprotected Left Main Percutaneous Coronary Intervention?

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Patients with left main (LM) coronary artery disease are at substantial risk of major adverse cardiac events. The current practice guidelines assign a class I recommendation for revascularization of significant (ie, ≥50% diameter stenosis) unprotected LM (UPLM) disease.[1] The choice between percutaneous coronary intervention (PCI) or coronary artery bypass grafting for UPLM continues to be debated. In the 5-year outcomes of the NOBLE (Percutaneous Coronary Angioplasty Versus Coronary Artery Bypass Grafting in Treatment of Unprotected Left Main Stenosis) trial,[2] coronary artery bypass grafting was superior to PCI in the primary composite end point of all-cause death, nonprocedural myocardial infarction (MI), repeated revascularization, and stroke. This was driven by differences in MI and repeated revascularization. More recently, the EXCEL (Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease) trial[3] demonstrated similar incidence of the primary composite end point of all-cause death, MI (both procedural and nonprocedural), and stroke at 5 years with PCI versus coronary artery bypass grafting. All-cause death, for which the trial was underpowered, was higher with PCI. Therefore, improving outcomes with PCI for patients who are deemed eligible for UPLM intervention is critical.

See Article by Aikawa et al.

Prior studies have shown improved PCI outcomes at higher-volume institutions,[4,5] with a signal toward poor outcomes, including mortality, with institutional volume <200 PCI procedures per year.[6] However, the relationship between low operator volume and PCI-related mortality in the literature is less robust.[5,7] This, in part, is because of the low periprocedural mortality with PCI.[8] The volume-outcome relationship with UPLM PCI is even less studied. Only one study that included 1948 patients has examined the impact of operator volume on outcomes after UPLM PCI.[9] In that study, Xu et al demonstrated lower unadjusted and adjusted risk of cardiac death at 30 days and 3 years when UPLM PCI was performed by experienced (defined as operators performing >15 UPLM PCIs/year for at least 3 consecutive years) compared with less experienced operators.

In this issue of the *Journal of the American Heart Association* (*JAHA*), Aikawa and colleagues add an important study to the current literature.[10] Using the J-PCI registry, a Japanese prospective nationwide multicenter registry that captures ≈85% of all PCI procedures from >1000 centers, the authors examined the relationship between institutional and operator volume and in-hospital outcomes in 24 320 patients who underwent PCI for UPLM disease between 2014 and 2017. Patients presenting with ST-segment–elevation MI, non–ST-segment–elevation acute coronary syndrome, defined as non–ST-segment–elevation MI

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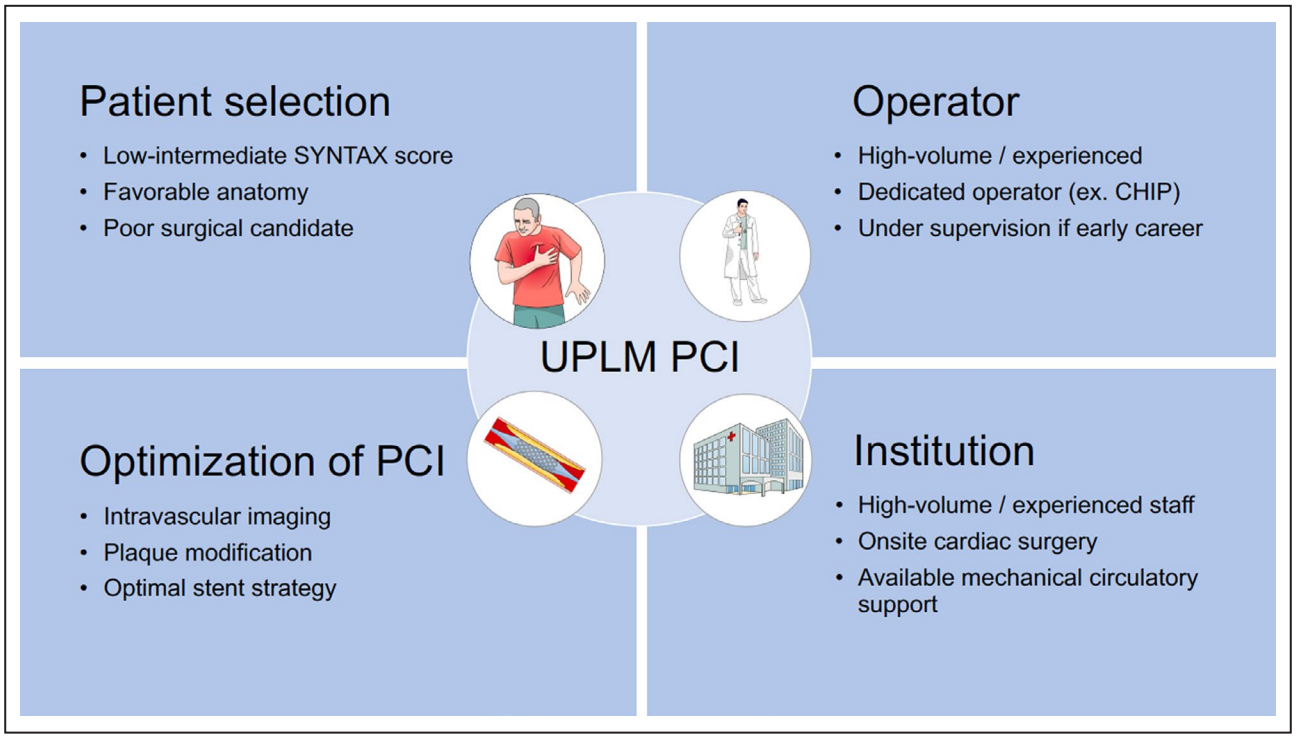

Figure. Multiple factors that help improve outcomes with unprotected left main (UPLM) percutaneous coronary intervention (PCI). CHIP indicates complex and higher-risk indicated patients.

or unstable angina, or stable ischemic heart disease were included. Compared with the first quartile of institutional volume (1–216 PCIs/year), the main outcome of in-hospital death was lower in the second (217–323 PCIs/year), third (324–487 PCIs/year), and fourth (488–3015 PCIs/year) quartiles (odds ratios [ORs], 0.75, 0.87, and 0.51, respectively), as was the secondary outcome of in-hospital death or any complication (ORs, 0.96, 0.88, and 0.64, respectively). A similar inverse volume-outcome relationship was not observed with operator volume after adjusting for potential confounders and institutional volume. As expected, a large proportion of patients who required UPLM PCI in the setting of ST-segment–elevation MI experienced concomitant cardiac arrest and/or cardiogenic shock.

The authors are to be commended on publication of this important study that provides much-needed knowledge aiming to improve outcomes with UPLM PCI. The large cohort allowed for examining rare events, such as death and stent thrombosis after PCI. Despite demonstrating a statistically borderline lower incidence of the primary outcome of in-hospital death (OR, 0.76 per log increase [95% CI, 0.58–1.00]; *P*=0.052) and the secondary outcome of in-hospital death or any complication (OR, 0.83 per log increase [95% CI, 0.68–1.00]; *P*=0.054) at higher-volume institutions, the study supports the current practice guidelines that recommend performing elective/urgent PCI at high-volume centers (>400 PCIs/year).[1]

The lack of operator volume-outcome relationship in the current study adds to the ongoing debate.[5,7,9,11] Although studies using inpatient national registries represent a good source of information when randomized trials are lacking or not feasible, they usually raise as many questions as they answer. In the current study, it is hard to account for all the confounders involved in each procedure. It is possible that the procedures performed by low-volume operators at high-volume centers or teaching hospitals benefited from the help/supervision of senior or more experienced mentors and from surgical backup. It is also less precise to estimate the competency of an operator using his/her PCI volume over a 4-year period rather than other factors, such as lifetime experience, years in practice, or even age of the operator at the time of the procedure. Many senior experienced interventional cardiologists tend to perform fewer PCIs, especially if they also perform non-PCI interventions, such as structural heart procedures,[12] or if they have administrative or research responsibilities at their institutions. The American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions clinical competency statement recommends against focusing on volume as the main measure of operator's competency.[6]

The results of the current study should be interpreted carefully. The retrospective and observational nature of the study comes with an inherent risk of bias. Also, outcomes after hospital discharge are unknown,

precluding a better interpretation of the volume-outcome relationship. In the study by Xu et al, clinical follow-up was performed up to 36 months.[9] Furthermore, the difference in operator volumes across different countries should be considered before generalizing the conclusions to other parts of the world. In the current study, >75% of the procedures were performed by operators with a mean annual volume >40 PCI procedures. In a study from the BCIS (British Cardiovascular Intervention Society) Registry examining the volume-outcome relationship in PCI, only 14% of operators performed <50 PCI procedures per year[13] versus 39% of operators in a similar study from the NCDR (National Cardiovascular Data Registry) CathPCI registry from the United States.[11] If we assume that the UPLM PCI volume was distributed evenly among the 7244 operators included in the present study, the average annual number of UPLM PCI procedures per operator would be less than one!

In the current study, the institutional and operator volumes were determined for all PCI procedures, rather than for UPLM PCI procedures. UPLM PCI is usually technically challenging because of the large territory of myocardium in jeopardy, especially if planned or bail-out bifurcation stenting is required. Optimizing stent implantation with intravascular imaging, and adequate plaque modification if needed, is critical. Mechanical circulatory support may also be required, as well as experienced staff who can provide adequate care for these high-risk patients. To count all PCI procedures toward the volume of an institution or operator when examining outcomes with more complex (eg, UPLM) PCI may provide an overestimation of experience, and hence could have confounded the results.

Several studies have shown an association between intravascular ultrasound and improved outcomes in complex PCI,[14] especially with UPLM PCI.[15] It would be of utmost interest to know the percentage of use of intravascular imaging in each cohort of the current study and the interplay of its use with outcomes. Interestingly, the rate of stent thrombosis was highest in ST-segment–elevation MI patients (0.8%) versus other cohorts (0.3% and 0.1% for non–ST-segment–elevation acute coronary syndrome and stable ischemic heart disease, respectively). It is possible that the emergent nature of UPLM PCI in the setting of ST-segment–elevation MI precluded the appropriate use of intravascular imaging, hence increasing the risk of stent undersizing or malapposition.

Although the institutional volume is likely to impact outcomes with PCI, especially for complex procedure, a relationship between operator volume and outcomes is hard to prove because of the interplay of multiple factors that may impact those outcomes (Figure). For now, and until more clear data are available on operator volume-outcome relationship in UPLM PCI, it is reasonable to refer those high-risk patients, if feasible, to "centers of excellence" where similar procedures are frequently performed, allowing the best possible patient outcomes.

ARTICLE INFORMATION

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Disclosures

Dr Brilakis reports consulting/speaker honoraria from Abbott Vascular, American Heart Association (associate editor *Circulation*), Biotronik, Boston Scientific, Cardiovascular Innovations Foundation (Board of Directors), CSI, Elsevier, GE Healthcare, InfraRedx, Medtronic, Siemens, and Teleflex; research support from Regeneron and Siemens; and shareholder in MHI Ventures. Dr Saad has no disclosures to report.

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