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LETTER TO THE EDITOR
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Randomized trial of robotic percutaneous coronary intervention: feasibility achieved, but questions remain on generalizability and training

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The important work of Yu, *et al.*[1] who presented one of the first randomized controlled trials (RCTs) to directly compare robot-assisted and manual percutaneous coronary intervention (PCI), is commendable; offering important insights into the feasibility and outcomes of this emerging technology. While the analysis is timely, several issues warrant further consideration.

Firstly, the most significant concern was the baseline imbalance in the Thrombolysis in Myocardial Infarction (TIMI) flow, as illustrated in Figure 1. All patients in the robotic PCI group had TIMI grade 3 flow at baseline, whereas a subset of patients in the manual PCI group had TIMI flow ≤ 2. As baseline TIMI flow is a strong predictor of lesion complexity and clinical outcomes, this imbalance may have conferred a procedural advantage to the robotic arm. The absence of adjustment for this factor raises concerns regarding the comparability of the groups.[2]

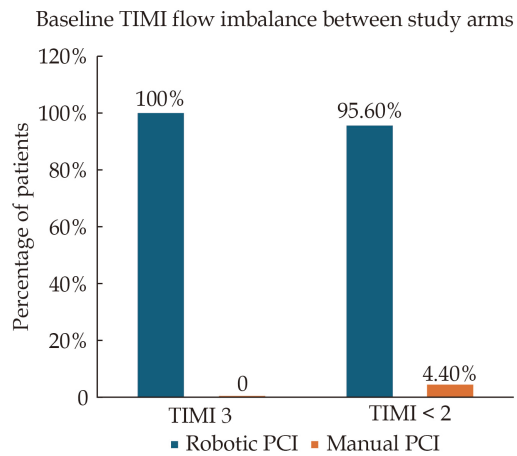


Figure 1 Baseline TIMI flow distribution in robotic PCI versus manual PCI. This plot shows the distribution of baseline TIMI flow grades in the two study arms, demonstrating an imbalance that might favor the robotic arm. PCI: percutaneous coronary intervention; TIMI: Thrombolysis in Myocardial Infarction.

Secondly, there is a lack of clarity regarding the analytical framework. The authors did not specify whether the outcomes were analyzed according to the intention-to-treat principle. In non-inferiority trials, both intention-to-treat and per-protocol analyses are recommended, and concordance between them is essential to ensure robustness of the results. Without explicit reporting of intention-to-treat analysis, this reported 100% success rate for robotic PCI cannot be considered fully validated.[3]

Thirdly, the trial excluded the most challenging lesions (e.g., chronic total occlusion, severe calcification, unprotected left main disease) and consequently reported 100% clinical success and 100% robotic completion with no conversion to manual PCI. However, because only less complex lesions were tested, the findings may not be generalizable to the broader PCI population. Evidence from a high-risk PCI program supports this concern: when robotic PCI was applied across a wider spectrum of lesion complexities, the rate of purely robotic completion fell to 81% for "CORA-PCI-like" lesions and 77% in very complex cases (chronic total occlusion, atherectomy, bifurcations with two stents). In these scenarios, manual conversion or assistance became increasingly necessary as lesion complexity rose.[4]

Last but not least, in this RCT, clinical success was solely determined by angiographic and procedural criteria: residual stenosis < 30% (by visual estimation) and absence of 30-day major adverse cardiac events. Patient-reported ou-

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tcomes, such as angina relief, functional status, and quality of life, were not assessed. Therefore, this study could not conclude whether robotic PCI provides patient-centered benefits beyond angiographic success. Future studies should incorporate standardized patient-reported outcomes instruments such as the New York Heart Association functional classification for heart failure symptom, the Canadian Cardiovascular Society angina grade, the EQ-5D-5L (EuroQoL 5-Dimensions, 5-level version), and the SAQ-7 (Seattle Angina Questionnaire, 7-item short form) to capture these important outcomes.[5]

In summary, although this RCT provides valuable evidence on the feasibility of robotic PCI, several limitations, including baseline imbalances, unclear analytic reporting, selective inclusion of lower-risk lesions, and a narrow endpoint definition, limit the strength and generalizability of its findings. Practical considerations remain unaddressed. For instance, although robotic PCI reduces operator radiation exposure, as shown in Figure 2, this benefit comes at the cost of longer procedure and fluoroscopy times, which can affect cath lab efficiency and workflow. Similarly, because the trial was conducted by highly experienced operators with dedicated robotic training, it is uncertain whether the same results would be reproducible in lower-volume centers or by less experienced teams. Accounting for the learning curve and variability across practice settings would provide a more realistic picture of the technology's utility in clinical practice. Ultimately, only larger, more inclusive studies with standardized outcomes, longer follow-up, and transparent reporting will determine the true clinical role of robotic PCI in contemporary practice.

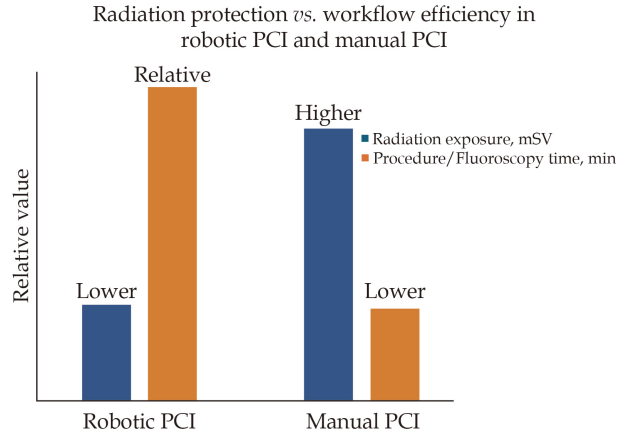


Figure 2 Relative trade-off between radiation protection and workflow efficiency in robotic PCI versus manual PCI. This figure illustrates that while operator radiation exposure is lower in robotic PCI, procedure and fluoroscopy times tend to be longer compared with manual PCI. PCI: percutaneous coronary intervention.

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