

# Operator volume and mortality in percutaneous coronary intervention: a call for better competency metrics

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**This editorial refers to ‘Operator volume is not associated with mortality following percutaneous coronary intervention: insights from the British Cardiovascular Intervention Society Registry’<sup>†</sup>, by W. Hulme *et al.*, on page 1623.**

In manual disciplines, increasing levels of practice are expected to parallel the individual's ability to perform a specific action or technique. In the field of interventional cardiology, a skilled operator is able to optimize all the steps of percutaneous coronary intervention (PCI), from vascular access to stent implantation, while reducing the total amount of contrast dye administered and procedural time. On top of sound clinical judgment, these factors may translate into a better prognosis. Improved outcomes with proficient operators are even more obvious in complex anatomical (e.g. left main disease or chronic total occlusions) and clinical (e.g. primary PCI or cardiogenic shock) settings, or at the time of managing procedural complications (e.g. perforations, dissections, or bleeding).

Based on European guidelines for myocardial revascularization,<sup>1</sup> interventional cardiologists are considered independent operators if they have personally performed at least 200 PCI procedures under the guidance of a supervisor, including a third of cases performed in the setting of an emergency or an acute coronary syndrome (ACS). Maintaining proficiency in interventional cardiology also requires a certain volume of procedures performed per year, e.g. at least 75 PCIs in the context of an ACS or at least 75 PCIs in the context of stable coronary artery disease. All these recommendations are class IIa, indicating conflicting evidence and/or a divergence of opinion about the true impact of practice volumes on the early prognosis of PCI (the so-called ‘volume–outcome relationship’). A study of more than 3 million procedures from the National Cardiovascular Data Registry CathPCI registry, which collects detailed information on >90% of PCIs performed in the USA, recently suggested an inverse relationship between operator volume and in-hospital mortality that persisted in risk-adjusted analyses.<sup>2</sup>

In this issue of the *European Heart Journal*, Hulme *et al.* add to the debate on the volume–outcome relationship with conflicting findings from the UK's perspective.<sup>3</sup> Using data from 133 970 PCI procedures performed by 540 interventional cardiologists in England and Wales, the authors did not find a significant relationship between 30-day mortality and operator volume (defined as the total number of procedures the operator was responsible for in the previous 12 months) after accounting for operator- and center-level effects and adjusting for case-mix and potential confounders. This finding, which was consistent across subgroups of patients presenting with ACS or undergoing primary PCI, and in a sensitivity analysis using in-hospital mortality as the outcome measure, applies to a quite contemporary (2013–14) scenario where radial access was the dominant strategy, most patients had an ACS, 30-day mortality was 2.6%, the median volume across all procedures was as high as 178 per year, and only 5% of procedures were performed by low-volume operators. These figures should be considered when generalizing the study findings outside the boundaries of the UK, where many countries have lower operator volumes. To put these results in perspective, for example, the proportion of operators who performed <50 PCI procedures per year was only 14% in this study vs. 44% in the CathPCI registry.<sup>2</sup>

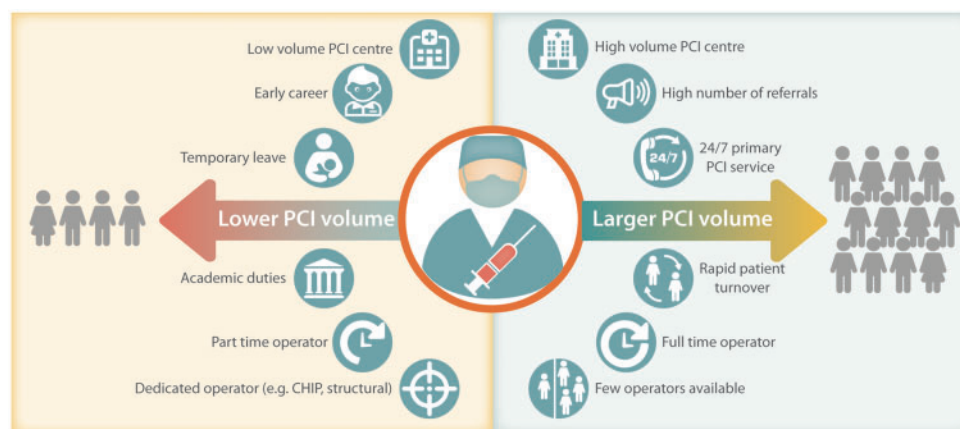
Compared with previous studies addressing the volume–outcome relationship in PCI, this report has several strengths. First, the definition of operator volume was based on a rolling measure that allowed the updating of operator volume every month instead of using the calendar year as a reference value. Through one year (i.e. from January to December), this approach overcomes the caveat of considering the total number of PCI procedures performed up to December (i.e. a future calendar date) when assessing 30-day mortality in January. Second, the British Cardiovascular Intervention Society registry is one of the few platforms in Europe offering complete national coverage of all consecutive patients undergoing PCI with subsequent administrative linkage to mortality outcomes.<sup>4–6</sup> Third, the authors must be congratulated for proficiently undertaking complex

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**Take home figure** Factors influencing the annual volume of percutaneous coronary intervention procedures over the course of an interventional cardiologist's career. CHIP, complex and higher-risk indicated patients; PCI, percutaneous coronary intervention.

statistical modeling that accounts for operator- and center-level clustering to look at the volume–outcome relationship.

A series of important limitations of this analysis also apply on top of the usual limitations of retrospective cohort studies. First, the principal outcome measure was 30-day mortality, one of the rarest complications of PCI. This outcome measure is imprecise when assessing the volume–outcome relationship for PCI operators because a plethora of post-procedural factors other than the operator may act as confounders. To corroborate 30-day mortality as a valid endpoint, consistent results about in-hospital mortality are presented, but similar concerns for this endpoint as a marker of the volume–outcome relationship have been noted as well.<sup>7,8</sup> Also importantly, separate analyses in high-risk clinical subsets (e.g. left main or chronic total occlusion PCI) are not available. Previous studies have suggested that a volume–outcome relationship exists in these particular anatomical contexts.<sup>9,10</sup> Another caveat is that >10% of patients undergoing PCI during the study inclusion period were excluded due to an inability to identify operators performing the procedures or missing information on outcomes. Finally, crucial information on total lifetime operator volume, number of years in practice, board certification, or at least the operators' age as a surrogate of experience at the time of PCI were not collected, thus raising concerns regarding the presence of hidden bias in adjusted analyses. Indeed, an interventional cardiologist can perform a large number of procedures every year for the entire duration of their career, or become less involved with age as a consequence of assuming greater academic or institutional responsibilities (*Take home figure*). Other contingent factors, including sickness or parental leave, also account for some length of temporary inactivity. A lower volume of activity does not necessarily imply losing specialized knowledge and skills.<sup>8</sup> The unadjusted U-shaped volume–outcome relationship in this study, meaning that low-volume operators had similar mortality rates as compared to high-volume colleagues, is even more provocative if we take into account the fact that low-volume operators were more frequently treating patients who presented with cardiogenic shock or mechanical ventilation. Indeed, the U-shaped

volume–outcome relationship may also suggest the instability of 30-day mortality as an endpoint at the extreme values of the volume curve, where a few random deaths may drastically increase the rate of mortality if the number of operators is low.

A genuine interpretation of the study findings is that the volume–outcome relationship might no longer be inverse in the era of radial access and technical iteration of the equipment made available to PCI operators. Significant efforts by national and international scientific societies have been devoted over the years to supporting the goals of educating operators while spreading knowledge to improve outcomes. As such, the number of PCI procedures has expanded over the years in a broad array of anatomical and clinical scenarios.<sup>11</sup> The combination of high-quality equipment and operators' skills has streamlined the procedures while broadening the landscape of lesion subsets that can be approached percutaneously. Based on the current findings by Hulme *et al.*, should international societies relax their recommendations on the minimum number of PCI procedures per year to be performed by operators? Probably not, at least on a cautionary note, because these data are indeed reassuring for the UK but do not necessarily apply to all country models and clinical contexts.

The most robust and straightforward message that can be drawn from this study is that mortality is a weak endpoint when looking at operators' proficiency, or at least when evaluated as a standalone measure.<sup>12</sup> As such, this study reinforces the need to identify more prevalent standardized outcome measures that can better reflect operators' skills. Similarly, volumes should not be surrogates for prospectively monitored and properly risk-adjusted outcomes.<sup>8</sup> As an example, looking at softer but clinically relevant endpoints, such as puncture site-related bleeding, the rate of contrast-induced acute kidney injury, procedural success, and completeness of revascularization, could be useful to complement mortality when assessing volume–outcome relationships in PCI. Both institutions and operators should be part of an active process to carefully assess whether their performance is adequate to maintain competence. All volumes of

activity (including those at the very high end of the spectrum) should be verified against compliance with suggested guidelines and appropriateness criteria. To date, the main reason for the exclusion of this information from the analysis of operators' proficiency has been the presence of significant concerns regarding underreporting bias. Since we are dealing with patients' safety and not the interventionalists' ego, fair and mandatory reporting of these outcomes is necessary to advance research in this field and develop reliable quality metrics for PCI practice.

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