

Radial Access: Operator Experience and Center Volume

To what degree do these factors affect the outcomes of PCI?

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Following the initial studies of radial access in coronary angiography, the cardiology literature has experienced significant growth in contemporary evidence suggesting that radial access is associated with more favorable outcomes compared to femoral access in coronary intervention.¹⁻²⁰ Percutaneous coronary intervention (PCI) procedures undertaken through the transradial approach are associated with significant reductions in mortality, major bleeding, and major vascular access site complications in high-risk patient groups.¹⁻²⁰ They have also been shown to be cost effective²¹⁻²³ and associated with better quality of life for the patient.²⁴ The benefits of a radial access strategy are particularly evident in individuals at high risk for bleeding complications,²⁵ elderly patients,¹ STEMI patients,^{1,7,26} those with acute coronary syndromes,^{4,26,27} women,^{17,28-31} and hemodynamically unstable patients¹⁸ (particularly those in cardiogenic shock).^{16,18,32} Nevertheless, radial access can be technically challenging in these individuals, the learning curve can take longer to master,³³⁻³⁶ and uptake has not been universal.

THE DATA AND THE DEBATE

Recently, the influence of center and operator volume in interventional cardiology has been a matter of debate and controversy.³⁷⁻⁴² Some studies have suggested that low operator/institutional volume may be related to increased rates of adverse events.⁴³⁻⁴⁵ These data have led the Society for Cardiovascular Angiography and Interventions⁴⁶ and the British Cardiovascular Interventional Society to issue guidelines⁴⁷ advocating a minimum prerequisite of 50 and 150 procedures,

respectively, over 2 years to maintain proficiency to perform PCI. A meta-analysis⁴⁸ of approximately 16,000 operators who had performed more than 200,000 PCIs suggested that the incidence of major adverse cardiac events (MACE) was inversely related to operator volume, with an odds ratio (OR) of 0.62 (95% CI [confidence interval], 0.4–0.97).

Badheka et al⁴⁰ performed the largest analysis, which encompassed 457,498 PCIs. The operator volumes were classified into four quartiles: the first quartile had performed ≤ 15 PCIs per year, the second had 16 to 44 PCIs per year, the third had 45 to 100 PCIs per year, and the fourth had > 100 PCIs per year. After adjusting for covariates, it was observed that improved in-hospital mortality outcomes were associated with high operator volumes: the second quartile had an OR of 0.8 (0.74–0.87; $P < .001$), the third quartile's OR was 0.81 (0.74–0.89; $P < .001$), and the fourth quartile's OR was 0.65 (0.58–0.73; $P < .001$) compared to the first quartile. A further meta-analysis⁴⁹ comprising more than a million individuals that compared outcomes in patients undergoing PCI at high- and low-volume centers suggested a mortality benefit with an OR of 0.87 (95% CI, 0.83–0.91) for patients treated at high-volume centers.

However, the evidence thus far has various limitations because there were different definitions of high- and low-volume operators, accounting for significant heterogeneity.^{37,50,51} For instance, Vakili et al⁵¹ compared outcomes in ≥ 11 versus one to two procedures per year, whereas Madan et al⁵² compared ≥ 100 with < 100 procedures per year. In addition, many studies did not adjust for various confounding factors,^{44,53} and most often, operator volume was a categorical variable

rather than a continuous variable.⁴⁰ Because of these highlighted issues, the evidence should be interpreted with caution.

The operator/institutional volume appears to be more important in primary percutaneous coronary intervention (PPCI) outcomes.^{51,53,54} Studies from New York^{51,54} showed a significant reduced mortality risk associated with high-volume operators (defined as ≥ 10 PPCIs/y⁵⁴ and ≥ 11 PPCIs/y).⁵¹ Similarly, Srinivas et al⁵⁴ observed a reduced risk of mortality in high-volume hospitals (≥ 50 PPCIs/y), with an OR of 0.58 (95% CI, 0.39–0.86). However, this benefit was not observed in low-volume hospitals (< 50 PPCIs/y), with an OR of 1.44 (95% CI, 0.68–3.03). On the other hand, Politi et al⁵³ suggested that there was no relationship between PPCI outcomes and operator volume.

Similarly, recent studies have suggested a relationship between center and operator volume and clinical outcomes associated with radial access site practice. A large study⁵⁵ from the Veterans Affairs health care system in North America between 2007 and 2010 reported outcomes from 24,143 patients. In this study, a high-volume center was defined as one that performs more than 50 radial PCIs per year. In a propensity-matched analysis, a reduced incidence of blood transfusion after PCI was demonstrated among the high-volume centers (hazard ratio [HR], 0.4; 95% CI, 0.3–0.7); however, no survival benefit was established. Similarly, a multicenter study of 10,000 patients with non-ST-segment elevation myocardial infarction⁵⁶ confirmed a mortality benefit at 1 year with radial access (compared to femoral access) in high-volume institutions with an HR of 0.7 (95% CI, 0.51–0.97), whereas no mortality benefit was observed among the low-volume institutions (HR, 0.8; 95% CI, 0.47–1.38).

The RIVAL trial^{126,57–59} is a randomized, controlled, multicenter trial of 7,021 patients with acute coronary syndromes who were randomized to radial versus femoral access for PCI. Although the composite endpoint of death, myocardial infarction (MI), stroke, or major bleeding unrelated to coronary artery bypass grafting was similar in the radial and femoral arms (HR, 0.92; 95% CI, 0.72–1.17), a subgroup analysis suggested superior outcomes in high-volume radial centers. The centers in the trial were classified into low (≤ 60 radial PCIs/y per operator), intermediate (61–146 radial PCIs/y per operator), and high-volume (> 146 radial PCIs/y per operator).⁵⁸ Operator volume was classified into low (≤ 70 radial PCIs/y per operator), intermediate (71–142 radial PCIs/y per operator), and high (> 142 radial PCIs/y per operator).⁵⁸ Transradial access at high-volume radial centers was associated with a significant reduction

in the primary endpoint compared to femoral access (HR, 0.49; 95% CI, 0.28–0.87). However, the statistically significant reduction in the primary endpoint in the radial access arm was not observed in the intermediate- or low-volume centers, and there was no link between individual operator radial volume and the primary endpoint.⁵⁸

The MATRIX trial²⁷ included 8,404 patients with acute coronary syndromes and is the largest trial to date comparing radial and femoral access in this context. The investigators classified contributing institutions' percentages of radial PCIs as low (14.9%–64.4%), intermediate (65.4%–79%), and high (80%–98%). Both MACE and net clinical adverse events (NACE) associated with radial access were significantly lower (compared to femoral access) in the high-volume radial centers, with HRs of 0.64. The improved MACE and NACE outcomes associated with radial access were not observed in low-volume radial centers, with HRs for MACE and NACE of 1.04 (95% CI, 0.79–1.36) and 1.01 (95% CI, 0.79–1.29), respectively. However, some have suggested that this could merely be a reflection of higher femoral events in the high-volume radial centers because of heterogeneity in access site expertise, leading to possible bias.^{60–62} This is unlikely because the worst crude femoral outcomes observed in the high-proportion radial centers were also accompanied by greater crude event rates in the radial arms, suggesting that the case mix in these centers was more complex. The authors of the MATRIX trial discarded this hypothesis by demonstrating that there was no heterogeneity in their meta-analysis, which included the RIVAL and MATRIX trials.⁶³

The literature^{16,55,56,58,64} prior to the MATRIX trial²⁷ only reflected outcomes with respect to radial total volumes and neglected the proportion of procedures done radially, which is an important variable. Table 1 illustrates the key studies assessing the relationship between radial volume and clinical outcomes. Much of the previous literature that has reported volume outcome relationships with transradial access is derived from North American centers where ≥ 50 radial procedures per year yields a definition as a high-volume radial center.²⁶ In many European countries, this volume of radial procedures would be considered extremely low.

Radial volume at both the operator and institutional level are not a true reflection of radial proficiency. Low-proportion radial operators/institutions with high total procedural volumes (radial + femoral) would have been considered high-volume radial operators/centers in the earlier studies.^{16,55,56,58,64} High-proportion radial operators are more likely to be experienced and proficient in

TABLE 1. SUMMARY OF KEY STUDIES ON RADIAL VOLUME AND CLINICAL OUTCOMES

First Author/ Trial Name	Year	Country/ Continent	Study Design	No. of Patients	Conclusion
Gutierrez et al ⁵⁵	2013	North America	Retrospective study	24,143	Reduced incidence of blood transfusion after PCI, and no survival benefit was observed among the high-volume radial centers
Iqbal et al ⁵⁶	2014	United Kingdom	Retrospective study	10,095	Mortality benefit at 1 year with radial access (compared to femoral access) in high-volume institutions
RIVAL trial ²⁶	2011	North America	Randomized controlled trial	7,021	No link between individual operator radial volume and the primary endpoint of death, myocardial infarction, stroke, or major bleeding unrelated to coronary artery bypass
MATRIX trial ²⁷	2015	Europe	Randomized controlled trial	8,404	Both major adverse cardiac events and net clinical adverse events associated with radial access were significantly lower (compared to femoral access) in the high-volume radial centers
BCIS registry ¹⁸	2016	United Kingdom	Retrospective study	164,395	Magnitude of survival benefit is further amplified with increases in radial proportion and total procedural volume at the operator level

the transradial approach and would be more likely to utilize this approach in high-risk individuals who have the most to benefit from a radial approach.²⁵

The British Cardiovascular Intervention Society (BCIS) registry¹⁸ was the largest study to systematically evaluate operator radial proportion and its relationship with outcomes. This analysis of 164,395 PCIs strongly supports the use of a radial approach, with a 39% decrease in mortality (OR, 0.61; 95% CI, 0.55–0.68). The magnitude of this benefit is further amplified with increases in radial proportion and total procedural volume at the operator level. Reductions in the risk of 30-day mortality by 11% per 100 additional procedures (95% CI, 3%–19%) and a 6% per 10 percentage point increase in radial proportion (95% CI, 1%–11%) was reported in this large-scale analysis. Interestingly, once other measures of experience were adjusted for, operator radial volume, center total volume, center radial volume, and center radial proportion were not independently associated with improved 30-day mortality outcomes. The authors performed a sensitivity analysis after excluding patients with cardiogenic shock from the analysis and found that the mortality benefit with high-proportion radial operators was maintained.

The mechanisms that explain the magnitude of the mortality benefit observed with high-proportion radial operators are likely to be increasing proficiency and the utilization of this procedure in critically ill individuals who are at highest risk for bleeding complications and therefore have the most to benefit from transradial access.²⁵ Initially, during the learning phase of radial procedures, low-proportion radial operators are more likely to utilize radial access in elective, stable cases with a lower bleeding risk in which the benefit of transradial access is less.

SUMMARY

The transradial approach has gained popularity, and as a result, a 13-fold increase in adoption of radial angioplasty has been observed across the United States.⁶⁵ In most European centers, radial access has become the default approach and the new gold standard. This practice is strongly supported by the European Society of Cardiology guidelines,²⁰ which provided a level IA recommendation for the transradial approach in managing patients with acute coronary syndromes soon after the publication of the MATRIX trial.²⁷ The BCIS registry data add robust evidence to

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the existing literature by providing key insights regarding the complex relationship between volume and access site–related outcomes.¹⁸ The results from this large cohort demonstrate that further significant survival benefit can be achieved in the hands of high-proportion radial operators and that the mortality benefit achieved by the transradial approach is not related to total volume or radial volume at the center level after adjusting for confounding factors. Currently, the European Association of Percutaneous Cardiovascular Intervention⁶⁶ recommends performing > 50% of all diagnostic angiography and angioplasty procedures radially, with a minimum of 80 procedures/annum per operator.

The future of coronary intervention via radial access is bright, and the results of the BCIS registry have implications for interventional cardiologists and cardiac catheterization labs globally. Some suggest that the transradial approach could be the next quality metric⁶⁷ and would set new standards for the proportion of angioplasties performed via the radial artery. ■

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