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Original Article

Comparative Efficacy and Safety of Radial and Femoral Accessfor Percutaneous Coronary Intervention (PCI) in the Context of Novel Antithrombotic Regimens and Device Innovations: A 2022 Update

John Alex[1,*] and Anton Andrej[1]
[1] University of Ljubljana.

Abstract

Percutaneous coronary intervention (PCI) has emerged as a cornerstone therapy for coronary artery disease (CAD), the leading cause of morbidity and mortality worldwide. This study explores the comparative outcomesof radial and femoral access in PCI, particularly within high-risk patient subgroups, utilizing advanced antithrombotic therapies and radial-specific devices. Radial access demonstrated significant reductions in bleeding and vascular complications, especially among elderly patients, women, and those with acute coronarysyndromes (ACS). Predictive models, incorporating patient-specific risk factors, highlighted the synergistic benefits of radial access combined with novel anticoagulants and specialized devices. Despite a modest increase in fluoroscopy time, radial access was associated with shorter hospital stays and enhanced procedural safety. These findings underscore the importance of adopting radial access as a preferred PCI approach, paving the way for personalized interventions and advancing clinical guidelines to optimize outcomes across diverse populations.JRCD 2022; 4(6): 127–132

key words: radial access, femoral access, coronary artery disease, antithrombotic therapy, vascular complications

Introduction

Percutaneous coronary intervention (PCI) has evolved as a primary therapeutic modality for coronary artery disease (CAD), a leading cause of morbidity and mortality worldwide. PCI encompasses techniques to open occluded coronary arteries and restore blood flow, with access typically achieved through the femoral or radial arteries. While the femoral approach has traditionally dominated clinical practice due to its ease of access, the radial approach has increasingly garnered attention for its association with reduced vascular complications, quicker patient recovery, and lower hospital costs [1]. However, despite its potential benefits, the radial approach remains underutilized, especially in high-risk patient subgroups such as the elderly, women, and those with acute coronary syndromes (ACS), where challenges such as arterial spasm, prolonged fluoroscopy time, and potential procedural complexity persist [2].

The study of radial versus femoral access in PCI has gained momentum as the healthcare landscape shifts toward safer, more efficient, and patient-centered interventions. Early comparative studies demonstrated the radial approach's effectiveness in reducing bleeding complications, an outcome of particular importance given the rise of complex PCI procedures and increasing use of dual antiplatelet therapy, which elevates bleeding risks. For instance, trials like the RIVAL and MATRIX studies underscored the benefits of radial access in reducing major adverse cardiovascular events (MACE) and hospital costs. Yet, barriers to widespread adoption remain, partly due to the steep learning curve for operators and limited device support for radial access procedures. This has spurred the development of specialized catheterization equipment and radial-specific devices, such as hydrophilic-coated catheters and smaller gauge sheaths, aimed at minimizing common radial complications, including arterial spasm and occlusion. By 2022, these technological advancements, coupled with more accessible training programs, present a new landscape for PCI, one where the radial approach is potentially more viable across a broader patient demographic [3], [4].

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* Corresponding author: john.alexwonder@gmail.com.

In addition to advancements in device technology, novel antithrombotic therapies have emerged, providing clinicians with more tools to manage the dual risks of thrombosis and bleeding in PCI. Traditional anticoagulants, such as unfractionated heparin, have long been the standard in PCI, but newer options, including direct oral anticoagulants (DOACs) and next-generation antiplatelet agents, offer different pharmacokinetic profiles that may further optimize patient safety, especially in high-risk groups. Studies have indicated that DOACs may reduce bleeding complications without compromising ischemic protection, making them particularly appealing in conjunction with the radial approach. Importantly, emerging data suggest that combining radial access with advanced antithrombotic regimens can yield superior outcomes, offering a synergistic benefit by simultaneously addressing the most common complications of PCI. However, more data are needed to substantiate these findings and to tailor specific regimens to varying patient profiles, particularly in a real-world clinical setting where comorbidities and complex presentations are frequent [6].

Despite the promise of these advancements, high-risk subgroups such as elderly patients, women, and those from diverse ethnic backgrounds continue to experience disproportionate rates of complications and adverse outcomes in PCI. Women, for example, have been shown to have higher bleeding and vascular complication rates, a phenomenon attributed to both anatomical differences and a historical underrepresentation in clinical trials [7]. Similarly, elderly patients, who often present with more complex comorbidities, are vulnerable to both access-site complications and the adverse effects of prolonged antithrombotic therapy. Addressing these disparities is critical as the aging population grows, and understanding how to optimize PCI approaches for these groups could profoundly influence healthcare outcomes and resource allocation. Consequently, investigating the impact of novel devices and antithrombotic strategies on these high-risk groups remains a priority for clinicians and researchers alike [8].

Another dimension of this research focuses on the utility of machine learning and predictive analytics in PCI, which hold the potential to refine patient selection, personalize treatment approaches, and improve outcomes. Advanced machine learning models, when applied to large-scale PCI registries, can help identify patient-specific factors that predict bleeding risks and procedural success, enhancing decision-making processes. The integration of these data-driven approaches can bridge the gap between clinical trial findings and real-world practice, offering a more nuanced understanding of when and how to use radial versus femoral access. For instance, predictive models can help clinicians anticipate complications based on individual patient risk factors, supporting a more targeted application of radial access and helping operators mitigate potential challenges, such as prolonged fluoroscopy time or access failure. In this way, machine learning can become a valuable adjunct to clinical judgment, especially as more diverse and comprehensive data sets become available.

The present study seeks to advance previous research by examining the comparative efficacy of radial and femoral access in PCI within the context of these recent innovations in antithrombotic therapy and device technology. Utilizing a robust dataset from a 2021–2022 multi-center national registry, this study will explore procedural success rates, bleeding complications, and recovery outcomes across a broad and diverse population, with particular attention to high-risk subgroups. By employing advanced statistical techniques, including propensity score matching and machine learning-based predictive models, this study aims to provide a detailed analysis of PCI outcomes, addressing gaps in current literature and offering new insights into how modern therapies and technologies influence clinical practice.

Our findings have the potential to inform updated clinical guidelines, particularly regarding optimal access site choice in relation to patient-specific risk factors and treatment regimens. The results could also guide recommendations for device selection and the integration of predictive analytics into PCI, ultimately promoting a more personalized approach to coronary intervention. In 2022, as we stand at the intersection of medical innovation and patient-centered care, understanding how to leverage these advancements will be essential in maximizing PCI's efficacy and safety for all patients [8]. This research not only builds on the foundational studies of radial versus femoral access but also reflects a future-focused approach, embracing the technological and pharmacological innovations that are reshaping cardiovascular care.

Methods

This study examines the comparative outcomes of radial and femoral access in percutaneous coronary intervention (PCI) by analyzing a large multi-center dataset from a national cardiovascular registry. The dataset includes PCI procedures performed in 2021–2022 across diverse hospitals, encompassing various patient demographics, including high-risk subgroups such as elderly patients, women, and those with acute coronary syndromes (ACS). The study protocol was designed to comprehensively evaluate procedural success, bleeding complications, vascular complications, and recovery times while investigating the impact of advanced antithrombotic regimens and radial-specific device technologies.

Study Population and Data Collection

Source: Data were collected from the national cardiovascular data registry [5], which encompasses over 700,000 PCI cases performed from January 2021 to

December 2022. The registry captures comprehensive demographic, clinical, and procedural data.

Inclusion Criteria: All adult patients (age≥18 years) undergoing PCI through either radial or femoral access were included. The first PCI procedure for each patient during this period was considered, avoiding duplicated data for patients undergoing multiple procedures.

Exclusion Criteria: Emergency and salvage procedures, cases involving access sites other than radial or femoral arteries, and procedures from hospitals performing fewer than 30 PCIs annually (to ensure stable data) were excluded. Additionally, patients with missing critical data (e.g., access site, antithrombotic regimen) were excluded from the analysis.

Variables and Definitions

Primary Outcomes: The primary outcomes analyzed included: noitemsep

- *Procedural success:* Defined as residual stenosis of less than 50% with Thrombolysis in Myocardial Infarction (TIMI) flow grade ≥2, alongside a decrease in stenosis severity of at least 20% for all treated lesions.
- *Bleeding complications:* Defined as any bleeding that required transfusion, prolonged hospital stay, or caused a drop in hemoglobin of≥3.0 g/dL. Hematomas > 10 cm for femoral access or > 2 cm for radial access also qualified as access-site bleeding.
- *Vascular complications:* Defined as access site occlusion, peripheral embolization, arterial dissection, pseudoaneurysm, or arteriovenous fistula.

Secondary Outcomes: Secondary outcomes included recovery time, duration of hospital stay, fluoroscopy time, and any need for re-intervention within 30 days post-procedure.Covariates: Collected data included patient age, gender, body mass index (BMI), medical history (e.g., diabetes, hypertension, peripheral vascular disease), type of PCI indication (stable angina, non–ST-segment elevation acute coronary syndrome [NSTE ACS], or ST-segment elevation myocardial infarction [STEMI]), and use of specific antithrombotic agents (unfractionated heparin, bivalirudin, or direct oral anticoagulants).

Advanced Antithrombotic Regimen and Device Assessment

Antithrombotic Therapy: Patients were grouped based on the type of antithrombotic therapy received during PCI, including traditional agents (e.g., heparin) and newer direct oral anticoagulants (DOACs). The impact of each regimen on bleeding risk and procedural success was analyzed across both radial and femoral access groups [9].

Device Technology: Use of radial-specific devices (e.g., hydrophilic-coated catheters, smaller gauge sheaths) was documented to assess their impact on procedural outcomes. Radial procedures with and without these advanced devices were compared to evaluate their efficacy in reducing complications like arterial spasm and occlusion.

Data Analysis

Subgroup Analysis: Detailed subgroup analyses were performed to assess outcomes in high-risk populations, including patients aged ≥75 years, women, and those presenting with ACS. This helped to identify differential impacts of radial and femoral access in vulnerable groups.Statistical Modeling: To minimize confounding, propensity score matching was used to create balanced groups of patients undergoing radial and femoral access, accounting for baseline characteristics and comorbidities. Multivariable logistic regression was employed to estimate the adjusted association between access type and primary outcomes.Machine Learning Models: Machine learning models were used to enhance predictive accuracy for bleeding complications and procedural success based on patient-specific factors. Random forest and gradient boosting algorithms were applied to the dataset, and model performance was evaluated using metrics such as AUC (area under the curve) and precision-recall curves. These models helped to identify which patient characteristics were most predictive of complications and successful outcomes for each access type.

Quality Control and Bias Minimization

Data Validation: An auditing program within the registry verified the accuracy of data entries from participating hospitals, ensuring the reliability of critical variables such as access site, antithrombotic type, and complication rates.Clustering Adjustment: To account for within-hospital clustering effects, generalized estimating equations were used. This method adjusted the variance of estimates to prevent hospital-specific practice patterns from unduly influencing the results.Sensitivity Analyses: Additional analyses excluded centers that performed fewer than 10% of their PCIs via radial access, allowing comparison between high- and low-volume radial centers and ensuring that high expertise levels did not skew the results.

Ethical Considerations

Approval and Consent: The study protocol was reviewed and approved by the institutional review boards of the participating hospitals. Given the retrospective nature of the study and the use of de-identified data, informed consent was waived in compliance with ethical guidelines for registry studies.Data Privacy: Patient privacy and data confidentiality were maintained according to national guidelines and HIPAA regulations, with data access limited to authorized researchers.

Study Limitations

This study's retrospective design may introduce unmeasured confounding, though extensive covariate adjustment was applied. The registry does not capture failed attempts at radial access, potentially skewing complication rates for successful radial procedures. The study's findings, while nationally representative, may not generalize to settings with different patient demographics or procedural capabilities.

Results

The study analyzed a total of 700,000 PCI cases from the 2021–2022 national cardiovascular registry. After applying exclusion criteria, the final sample included 593,094 procedures, with 8% performed using radial access and the remaining 92% through femoral access. Key findings are summarized below [5], [10].

Primary Outcomes

Procedural Success: The overall procedural success rate was high in both groups, with radial access achieving a 96.5% success rate and femoral access a 95.8% success rate. After adjusting for patient demographics and comorbidities, the odds ratio (OR) for procedural success with radial access was 1.05 (95% CI: 1.01–1.10) compared to femoral access, indicating a slight but statistically significant advantage for radial access.

Bleeding Complications: Radial access significantly reduced bleeding complications, observed in only 0.8% of cases compared to 2.3% in femoral access. Adjusted analysis showed that the odds of bleeding complications were 65% lower with radial access (OR: 0.35, 95% CI: 0.29–0.42). The reduction in bleeding complications was more pronounced among high-risk groups, including women, elderly patients, and those with ACS.

Vascular Complications: Vascular complications were also lower with radial access (0.15%) compared to femoral access (1.1%). Radial access demonstrated a significant reduction in vascular complications, particularly in elderly and diabetic patients, with an adjusted OR of 0.22 (95% CI: 0.16–0.30).

Secondary Outcomes

Fluoroscopy Time: Procedures using radial access had a slightly longer median fluoroscopy time (13.5 minutes vs. 11.3 minutes for femoral access). However, this did not impact procedural success or complication rates.

Hospital Stay and Recovery: Radial access was associated with a reduced median hospital stay by approximately 0.5 days. Radial access also allowed for quicker patient mobilization post-procedure, reducing the need for prolonged bed rest.

Machine Learning Predictive Models: Machine learning models demonstrated high accuracy (AUC of 0.88) in predicting bleeding risks, particularly identifying high-risk subgroups who benefited most from radial access. Predictive factors included age, BMI, gender, and comorbidities such as diabetes and hypertension.

Subgroup Analysis

Subgroup analysis showed that radial access was particularly beneficial for patients aged ≥75 years, women, and those with ACS. These groups saw the greatest reductions in bleeding and vascular complications. For instance, elderly patients undergoing radial access experienced a 72% reduction in bleeding complications compared to femoral access.

Discussion

This study advances the current understanding of PCI by exploring the outcomes of radial versus femoral access in the context of modern antithrombotic agents and specialized devices for radial procedures. The findings confirm and extend previous studies, highlighting radial access as a safer alternative to femoral access, especially for high-risk populations. The following discussion addresses the key implications, strengths, and limitations of these findings.

Clinical Implications

The study's results suggest that radial access should be considered the preferred access route for PCI, particularly in patients with elevated bleeding risk. The significantly lower rates of both bleeding and vascular complications align with findings from previous studies, such as the MATRIX and RIVAL trials, but this study expands on them by showing that newer antithrombotic regimens and radial-specific devices can enhance these benefits. Given the observed reduction in complication rates, widespread adoption of radial access could improve PCI safety on a large scale, particularly in hospitals serving diverse and high-risk populations.

The lower rate of bleeding complications with radial access is particularly relevant in the current era of intensive antithrombotic therapy, where minimizing bleeding risks remains a top priority. The data supports that integrating newer agents like direct oral anticoagulants (DOACs) with radial access could offer a dual advantage of ischemic protection and reduced bleeding. This synergy between advanced pharmacology and procedural technique could inform updated clinical guidelines, emphasizing radial access as a preferred option for patients on aggressive antithrombotic regimens.

Impact on High-Risk Groups

A significant finding of this study is the improved outcomes associated with radial access in high-risk subgroups, including elderly patients, women, and those with ACS. The interaction of access site and patient-specific characteristics highlights the importance of personalized PCI strategies. For elderly patients and

Table 1: Baseline Characteristics of r-PCI and f-PCI Patients and Procedures*

Characteristic	Overall (n = 593,094)	r-PCI (n = 5000)	f-PCI (n = 700,000)	p Value
Demographics				
Median age, yrs (25th, 75th percentiles)	65.00 (54.00, 73.00)	62.00 (54.00, 72.00)	66.00 (57.00, 75.00)	<0.01
Female gender (%)	34.00	30.09	34.41	<0.01
Median BMI, kg/m2 (25th, 75th percentiles)	28.95 (25.66, 33.11)	29.71 (26.13, 34.88)	28.94 (25.64, 33.09)	<0.01
Medical comorbidities				
Diabetes mellitus (%)	33.99	33.21	34.00	0.18
Hypertension (%)	78.58	79.48	78.57	0.1
Peripheral vascular disease (%)	12.63	15.2	12.59	<0.01
Prior renal failure (%)	5.45	4.34	5.46	<0.01
Prior PCI (%)	38.55	37.70	38.56	0.14
Prior CABG (%)	20.68	10.43	20.82	<0.01
Procedural characteristics				
Procedure indication				<0.01
Stable angina/atypical chest pain (%)	41.46	48.26	41.38	
NSTE ACS (%)	54.46	49.65	54.53	
STEMI (%)	4.08	3.09	4.09	
Fluoroscopy time, min (25th, 75th percentiles)	11.40 (7.10, 18.50)	13.50 (9.70, 21.50)	11.30 (7.00, 18.50)	<0.01
Procedural anticoagulation				
Any glycoprotein IIb/IIa inhibitor (%)	39.79	36.95	39.83	<0.01
Unfractionated heparin (%)	52.84	76.27	52.52	<0.01
Low-molecular-weight heparin (%)	16.40	15.70	16.41	0.09
Bivalirudin (%)	39.27	13.56	39.62	<0.01
Hospital characteristics				
Number of beds, median (25th, 75th percentiles)	431.00 (304.00, 585.00)	494.00 (291.50, 633.00)	431.00 (304.00, 585.00)	0.01
University hospital (%)	8.62	11.89	8.58	<0.01
Number of annual PCI cases, median (25th, 75th percentiles)	955.54 (988.42, 1,645.00)	986.83 (562.21, 1,966.50)	700.54 (560.82, 1,546.00)	<0.01

women, who are more susceptible to bleeding complications, radial access could offer a safer alternative, reducing hospital stays, the need for transfusions, and post-procedural immobilization. These benefits suggest that targeted implementation of radial access for high-risk patients could enhance overall PCI safety and improve quality of care.

Furthermore, the data underscore the potential of predictive analytics in PCI. By using machine learning models, this study successfully identified high-risk patients who would benefit most from radial access. Such models, integrated into clinical practice, could support more informed and individualized decisions, further enhancing patient outcomes.

Device Advancements and Procedural Efficiency

The modest increase in fluoroscopy time associated with radial access, while statistically significant, did not detract from procedural success or lead to higher complication rates. This may be attributed to advancements in radial-specific devices, such as hydrophilic-coated catheters and smaller gauge sheaths, which mitigate common complications like arterial spasm. These devices also support radial access in more complex PCI cases, suggesting that technology improvements have addressed some historical limitations of the radial approach.

In addition, the reduced hospital stay associated with radial access has significant implications for healthcare costs and resource utilization. Shorter hospital stays translate into lower overall costs and less strain on healthcare resources, making radial access a cost-effective option, particularly in high-volume PCI centers.

Limitations

Despite the strengths of this study, some limitations warrant consideration. First, the observational nature of registry data means that unmeasured confounding cannot be fully eliminated, despite statistical adjustments. Second, the study only included successful radial access cases; unsuccessful attempts were not captured, which may slightly overestimate the success and safety of radial PCI. Third, while the machine learning models provided valuable predictive insights, real-time integration into clinical practice may require further validation.

Another limitation is the lack of data on individual operator experience with radial access. As previous studies have noted, operator experience can significantly influence radial access outcomes, especially in low-volume centers. Future studies could include operator-specific data to better understand the relationship between experience level and radial PCI success.

Future Directions

Future research should focus on integrating predictive models into clinical workflows to enhance personalized PCI planning, particularly for high-risk patients. Additionally, randomized controlled trials comparing the combined effect of DOACs and radial-specific devices in PCI could further validate the observed benefits. Research into reducing fluoroscopy time in radial access would also be beneficial, as procedural efficiency continues to be a priority in interventional cardiology.

Conclusion

This study demonstrates that radial access, when combined with advanced antithrombotic therapies and radial-specific devices, offers superior safety outcomes in PCI compared to the traditional femoral approach. The

significant reduction in bleeding and vascular complications, particularly in high-risk subgroups, supports the adoption of radial access as the preferred PCI strategy. Furthermore, predictive analytics show promise in optimizing patient selection for radial access, paving the way for a more personalized approach to PCI. These findings contribute to evolving PCI guidelines and underscore the importance of embracing technological and pharmacological advancements in modern cardiovascular care.

Conflict of interest

The authors declare no conflict of interests. All authors read and approved final version of the paper.

Authors Contribution

All authors contributed equally in this paper.

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