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Prevalence and outcomes of *trans*-radial access for percutaneous coronary intervention in contemporary practise

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ABSTRACT

Background: *Trans*-radial access for percutaneous coronary intervention (PCI) has been associated with lower vascular complication rates and improved outcomes. We assessed the current uptake of *trans*-radial PCI in Victoria, Australia, and evaluated if patients were selected according to baseline bleeding risk in contemporary clinical practise, and compared selected clinical outcomes.

Methods: PCI data of all patients between 1st January 2013 and 31st December 2014 were analysed using The Victorian Cardiac Outcomes Registry (VCOR). Propensity-matched analysis was performed to compare the clinical outcomes.

Results: 11,711 procedures were analysed. The femoral route was the predominant access site (66%). Patients undergoing *trans*-radial access PCI were younger (63.9 ± 11.6 vs. 67.2 ± 11.8; $p < 0.001$), had a higher BMI (28.9 ± 5.5 vs. 28.5 ± 5.2; $p < 0.001$), more likely to be male (80.0 vs. 74.9%;$p < 0.001$), less likely to have presented with cardiogenic shock (0.9 vs. 2.8%; $p < 0.001$) or have the following comorbidities: diabetes (19.8 vs. 23.1%; $p < 0.001$), peripheral vascular disease (2.9 vs. 4.3%; $p = 0.005$) or renal impairment (13.6 vs. 22.1%; $p < 0.001$). The radial group had less bleeding events (3.2 vs. 4.6%; $p < 0.001$) and shorter hospital length of stay (3.1 ± 4.7 vs. 3.3 ± 3.9; $p = 0.006$). There was no significant difference in mortality (1.0 vs. 1.4%; $p = 0.095$).

Conclusions: *Trans*-femoral approach remains the dominant access site for PCI in Victoria. The choice of route does not appear to be selected by consideration of bleeding risk. The radial route is associated with improved clinical outcomes of reduced bleeding and length of stay consistent with previous findings, and this supports the efficacy and safety of *trans*-radial PCI in real-world clinical practise.

1. Introduction

Trans-radial access for percutaneous coronary intervention (PCI) has been associated with lower vascular complication rates, increased cost-effectiveness and shorter hospital length of stay as compared to the femoral approach [1–4]. Furthermore, in patients with ST-elevation acute coronary syndromes (STEACS), it has been associated with reduced morbidity and cardiac mortality [3–5]. In a large registry analysis from the United States [6], the greatest benefit of *trans*-radial PCI in terms of absolute reduction of bleeding and vascular complications was seen in high-risk patients aged ≥75 years, women, and patients with acute coronary syndrome (ACS). Paradoxically, the use and growth of the radial approach were reported to be the lowest in these higher bleeding risk subgroups, despite the potential benefits. Other large registries have similarly shown benefits with *trans*-radial PCI in reducing mortality, vascular complications and bleeding [7–9]. In support of this, several prospective randomized trials of ACS patients with relatively smaller sample sizes have also demonstrated associations with

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reduced bleeding [10,11], vascular complications [5,11] and mortality with the radial approach [3,4,10]. Contemporary guidelines recommend the *trans*-radial approach over femoral in patients with higher bleeding risk [12].

The primary aim of our study was to assess the current uptake of *trans*-radial PCI in Victoria, Australia and to assess if patients with risk factors for bleeding are preferentially selected for *trans*-radial PCI in contemporary clinical practise, given its associated benefits of reduced bleeding. Our secondary aims were to compare selected clinical outcomes between patients undergoing *trans*-radial versus *trans*-femoral PCI, which include clinically significant bleeding, mortality, and hospital length of stay.

2. Methods

Data of all patients in the Victorian Cardiac Outcomes Registry (VCOR) who had PCI performed over a 2-year period between 1st January 2013 and 31st December 2014 was analysed. VCOR is a state-wide population-based clinical quality registry that is coordinated by the Victorian Cardiac Clinical Network. It catalogues data related to PCI procedures gathered from 21 public and private centres across Victoria. All participants require informed consent and an opt-out option given. A Steering Committee with representation from contributing centres oversees the registry activities and a peer-review committee has been established to audit and monitor data collection and outcomes from each site. The study was approved by the institutional ethics committee.

Patients receiving PCI via the brachial artery were excluded. Baseline demographic data, clinical characteristics and treatment profiles were compared between the radial and femoral approaches. Factors associated with bleeding and mortality were compared between *trans*-radial vs. femoral access for PCI to demonstrate differences in patient risk profiles. These included: age, body mass index (BMI), patient gender, ACS, cardiogenic shock or out-of-hospital cardiac arrest, diabetes mellitus requiring medication, peripheral vascular disease (PVD), cerebrovascular disease, prior revascularization with PCI or coronary artery bypass grafting (CABG), renal impairment (defined as an estimated glomerular filtration rate (eGFR) of ≤60 mL/min/1.73 m [2] or requiring renal replacement therapy), and the use of glycoprotein IIb/IIIa inhibitors. Clinical outcomes were compared between the two routes, including 30-day cumulative events of mortality, clinically significant bleeding and hospital length of stay. Bleeding was categorized according to the Bleeding Academic Research Consortium (BARC) classification [13], as type 1 (minor bleeding, not actionable), type 2 (overt, actionable sign of haemorrhage or more than expected bleeding for a clinical circumstance that requires non-surgical, medical intervention, hospitalization, increased level of care or prompting evaluation), type 3 (overt bleeding with a haemoglobin drop of >3 g/dL, intracranial haemorrhage, cardiac tamponade, or requirement of transfusion or surgical intervention), type 4 (CABG-related bleeding) and type 5 (probable or definite fatal bleeding). Clinically significant bleeding was defined as the occurrence of BARC 2, 3 or 5 bleeding events. A *trans*-radial subgroup analysis to compare *trans*-radial high and low volume centres was also performed. High-volume *trans*-radial centre was defined as ≥50% *trans*-radial cases in a centre performing >250 cases per year [4]. Based on this criterion, 8 centres were classified as high *trans*-radial volume, 12 as low *trans*-radial volume, and one centre was excluded as the contributed data was limited to 2 months only.

One-way ANOVA and Chi-Square tests were used to compare the baseline characteristics and clinical outcomes between *trans*-radial and femoral access groups. To adjust for the non-randomized selection of access site for PCI, we generated propensity scores to obtain matched pairs of patients based on the route of choice for PCI using the following predictors: age >75, BMI, patient gender, ACS, cardiogenic shock, cardiac arrest prior to PCI, history of comorbid diseases: diabetes mellitus requiring medication, PVD, cerebrovascular disease, previous CABG or PCI, use of glycoprotein IIb/IIIa inhibitors and renal impairment. Sampling without replacement was used with a match tolerance of 0.004. Standardized differences were calculated to compare variables between matched pairs. The Chi-Square and Independent t-tests were used to compare categorical and continuous variables between propensity-matched groups respectively. Continuous variables are presented as means ± standard deviations (SD). Categorical variables are expressed as the number of patients with proportions according to choice of arterial access. The IBM SPSS Statistics software (version 22) was used for all calculations and two tailed values of $P < 0.05$ were considered statistically significant.

3. Results

We analysed a total of 11,711 PCI procedures with the specified criteria. Baseline characteristics are shown in Table 1. The femoral approach was the predominant access route (66%). Variations (ranges) between sites for radial and femoral access were: radial: 1% to 71%; femoral: 28% to 99%. Compared to patients who underwent PCI through the femoral route, patients undergoing *trans*-radial access PCI were significantly younger (63.9 ± 11.6 vs. 67.2 ± 11.8 years; $p < 0.001$), had a statistically higher BMI (28.9 ± 5.5 vs. 28.5 ± 5.2 kg/m^2; $p < 0.001$) and were more likely to be male (80.0 vs. 74.9%; $p < 0.001$). Patients in the radial access group were also less likely to present with cardiogenic shock (0.9 vs. 2.8%; $p < 0.001$) or cardiac arrest (2.3 vs. 4.9%; $p < 0.001$), or to have the following comorbidities: diabetes mellitus (19.8 vs. 23.1%; $p < 0.001$), PVD (2.9 vs. 4.3%; $p = 0.005$), renal

Table 1
Unadjusted baseline variables and clinical outcomes of radial vs. femoral procedures.

	Overall ($n = 11.711$)	Radial ($n = 4040$)	Femoral ($n = 7671$)	*P* value
Age (years)	66.1 ± 11.9	63.9 ± 11.6	67.2 ± 11.8	<0.001
BMI (kg/m^2)	28.7 ± 5.3	28.9 ± 5.5	28.5 ± 5.2	<0.001
Male Gender	76.7	80.0	74.9	<0.001
Female Gender	23.3	20.0	25.1	<0.001
Clinical Characteristics at presentation				
Cardiogenic shock	2.1	0.9	2.8	<0.001
Cardiac arrest				
Out-of-hospital	2.2	1.5	2.6	<0.001
Pre-procedural	1.6	1.1	1.8	<0.01
Medical comorbidities				
Diabetes mellitus	22.0	19.8	23.1	<0.001
PVD	3.8	2.9	4.3	<0.005
Prior CVD	3.8	3.6	3.9	0.360
Prior PCI	33.5	28.4	36.2	<0.001
Prior CABG	8.6	2.4	11.9	<0.001
eGFR ≤60	19.2	13.6	22.1	<0.001
Procedure indication				
Elective/stable	47.9	43.9	50.0	<0.001
ACS				
NSTEACS	32.1	34.8	30.8	<0.001
STEACS	19.9	21.3	19.2	<0.01
Use of Glycoprotein IIb/IIIa inhibitor	12.4	10.1	13.7	<0.001
Clinical outcomes				
Clinically significant bleeding	4.4	3.2	5.0	<0.001
Length of stay (days)	3.4 ± 5.1	3.1 ± 4.7	3.6 ± 5.2	<0.001
Mortality at 30 days	2.2	1.3	2.6	<0.001

Data are means ± SD or n (%). BMI: body mass index; PVD: peripheral vascular disease; CVD: cerebrovascular disease; PCI: percutaneous coronary intervention; CABG: coronary artery bypass grafting; eGFR: estimated glomerular filtration rate; ACS: acute coronary syndrome; NSTEACS: Non ST-elevation acute coronary syndrome; STEACS: ST-elevation acute coronary syndrome.

Table 2
Baseline characteristics of pre-specified subgroups by access site.

	>75 years old		Females		STEACS	
	Radial ($n = 664$)	Femoral ($n = 2020$)	Radial ($n = 809$)	Femoral ($n = 1924$)	Radial ($n = 861$)	Femoral ($n = 1474$)
Age (years)	81 ± 4	82 ± 4*	67 ± 11	71 ± 12**	60 ± 12	63 ± 13**
BMI (kg/m^2)	27 ± 5	27 ± 5	30 ± 7	29 ± 6**	29 ± 6	28 ± 5*
Female gender	29.7	36.6**	–	–	18.8	23.1*
Medical comorbidities						
Diabetes mellitus	22.4	22.4	20.6	24.2^	14.9	17.0
PVD	6.0	7.1	3.3	4.2	1.7	2.9
eGFR ≤60	50.6	56.5*	23.2	34.8**	11.6	16.7**
Prior PCI	32.1	39.9**	22.0	30.1**	9.6	13.8*
Prior CABG	5.0	17.7**	0.9	8.2**	0.7	3.7**
Procedure details						
STEACS	15.4	13.5	20.0	17.7	–	–
NSTEACS	34.6	32.6	34.2	34.6	–	–
Elective/stable	50	53.9	45.7	47.7	–	–
Glycoprotein IIb/IIIa inhibitor	6.9	8.0	8.2	12.4**	27.6	48.5**

Data are means ± SD or n (%). **$P \le 0.001$, *$P \le 0.01$, ^$P \le 0.05$. BMI: body mass index; PVD: peripheral vascular disease; PCI: percutaneous coronary intervention; CABG: coronary artery bypass grafting; eGFR: estimated glomerular filtration rate; ACS: acute coronary syndrome; NSTEACS: Non ST-elevation acute coronary syndrome; STEACS: ST-elevation acute coronary syndrome.

impairment (13.6 vs. 22.1%; $p < 0.001$), prior PCI (28.4 vs. 36.2%; $p < 0.001$) or CABG (2.4 vs.11.9%; $p < 0.001$).

Subgroup analysis was performed for select predefined groups: Patients presenting with ACS were more likely to undergo *trans*-radial access PCI (Table 1) however this difference was not maintained in patients >75 years of age, and in women (Table 2). Association of less radial as compared to femoral access choice in patients >75 years old were older age, female gender, renal impairment, prior PCI and CABG. Similarly in females, the associations of reduced radial versus femoral access choice were older age, lower BMI, renal impairment, diabetes mellitus, prior PCI and CABG. There was no difference between the percutaneous access choice in the STEACS population in any subgroup, the selection bias for radial access in patients presenting with STEACS being younger age, male gender, higher BMI, better renal function, or no prior PCI/CABG history (Table 2). A sub group analysis according to radial volume found that results were similar in both low and high volume centres.

Propensity-matched pairs ($n = 3929$) were obtained with standardized differences <10.0 for all 15 matched variables (Table 3). Less bleeding occurred in the *trans*-radial group compared to femoral access, mainly driven by the in-hospital BARC 2 bleeding events (Fig. 1). Length of stay was shorter in the *trans*-radial group (3.1 ± 4.7 vs. 3.3 ± 3.9 days; $p = 0.006$). No statistically significant difference was found for mortality between the matched groups (1.0 vs. 1.4%; $p = 0.09$).

Table 3
Characteristics of the Propensity–Matched Patients.

	Radial ($n = 3929$)	Femoral ($n = 3929$)	*P*-value	Standardized difference
Age >75	16.5	16.7	0.856	0.5
BMI kg/m^2	28.9 ± 5.4	28.9 ± 5.2	0.529	−1.5
Male gender	79.9	79.5	0.715	−0.9
Female gender	20.1	20.5	0.715	0.9
Cardiogenic shock	0.9	1.0	0.638	1.3
OHCA	1.5	1.4	0.850	−0.6
IHCA	1.1	1.2	0.916	0.5
Diabetes mellitus	19.8	20.7	0.299	2.3
PVD	2.9	3.1	0.741	0.9
Prior CVD	3.3	3.7	0.360	2.2
Prior PCI	29.0	28.7	0.746	−0.8
Prior CABG	2.4	2.4	1.000	0.2
eGFR ≤60	13.3	13.7	0.668	1.0
Renal replacement therapy	0.0	0.0	1.000	−2.3
Elective/stable	44.8	45.2	0.734	0.8
ACS (NSTEACS or STEACS)	55.2	54.8	0.734	−0.8
Use of glycoprotein Iilb/IIIa	10.1	9.6	0.472	−1.6

Data are means ± SD or n (%). BMI: body mass index; OHCA: out-of-hospital cardiac arrest; IHCA: in-hospital, pre-procedural cardiac arrest; PVD: peripheral vascular disease; PCI: percutaneous coronary intervention; CABG: coronary artery bypass grafting; eGFR: estimated glomerular filtration rate.

4. Discussion

Our study looked at differences between the radial and femoral approach to PCI in a large unselected patient cohort, and provides a snapshot of contemporary Australian clinical practise. Our results show that *trans*-femoral access PCI remains the pre-dominant choice for PCI in Victoria, while the *trans*-radial approach was utilized in 34% of all cases. Uptake for radial access PCI in our registry is higher than older reports from other PCI registries [6,8,14] but lower compared to those recently published by the British BCIS Registry [9], where almost half of all patients received *trans*-radial access PCI.

Our primary aim was to assess the current uptake of *trans*-radial PCI and to assess if patients with risk factors for bleeding are preferentially selected for *trans*-radial access. We observed that the patients selected for *trans*-radial PCI had a lower proportion of risk factors that are associated with bleeding [15,16], in particular the sub-groups of the elderly, females, and patients with lower BMI. Although there was an increased proportion of ACS patients in the *trans*-radial compared to the *trans*-femoral group, the overall majority of ACS patients had access for PCI via the femoral route. A preference for the femoral route was also seen in other patient groups such as those with renal impairment, peripheral vascular disease and patients who received glycoprotein IIb/IIIa inhibitors. Paradoxically, it appears that these higher-risk patient groups that have greater potential to benefit from *trans*-radial access PCI continue to have PCI performed preferentially through the femoral route. This observation suggests that the choice of route for PCI may be influenced by other factors instead, which could include patient characteristics that are perceived to increase *trans*-radial procedural difficulty (such as smaller, elderly females).

Challenges with the adoption of the *trans*-radial route for PCI include a steep learning curve, even with operators experienced with the femoral route. In our study, although the choice of *trans*-radial approach did not appear to be related to a quick calculation of bleeding risk by the operators, it has been used for complicated cases like post CABG or cardiogenic shock. This may suggest that the selection bias was related to learning curve of *trans*-radial approach.

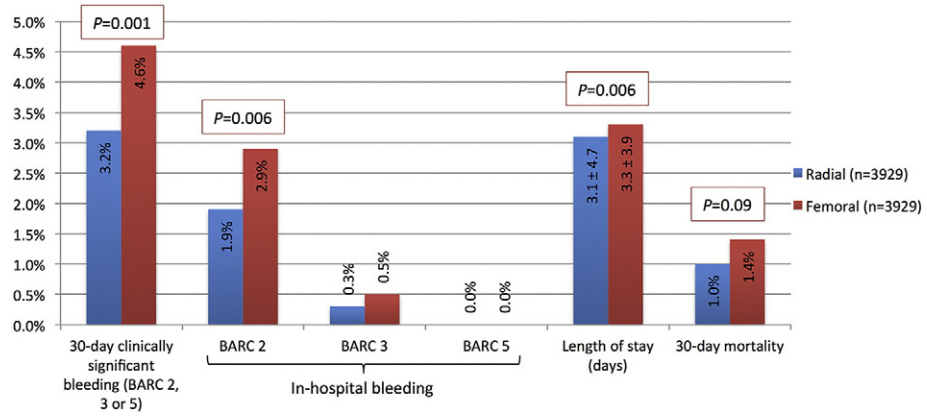

Fig. 1. Outcomes in the propensity-matched cohort. Legend: Data are means ± SD or n (%). BARC: Bleeding Academic Research Consortium classification.

Use of the radial route has been previously associated with increased fluoroscopy times with prolongation of the procedure [6] and crossover to the femoral route [5,10,11,17]. These issues may arise from anatomical factors such as the smaller diameter of the radial artery, vessel tortuosity or vasospasm, all of which may limit delivery of PCI. The perceived time-consuming nature of the *trans*-radial route may also be concerning, especially for higher acuity presentations such as cardiogenic shock or STEACS. Paradoxically, these groups of patients would potentially derive more benefit from the lower bleeding risks afforded through *trans*-radial access PCI. Several reports have now demonstrated that in centres with high-volume radial operators, the success rate of *trans*-radial PCI is comparable or even superior to the femoral access site [6,11,18], suggesting that these perceived challenges may be overcome through increased procedural volume and experience.

Our secondary aim was to compare selected clinical outcomes between patients undergoing *trans*-radial versus *trans*-femoral PCI. After propensity-matched analysis, we found that the radial approach was associated with reduced significant bleeding events (BARC 2, 3 or 5 events). This result appears to be driven by a significant reduction in BARC 2 bleeding, and is consistent with previous reports. Bleeding is the most common complication after PCI and is associated with increased morbidity and mortality [6]. The mechanism by which the *trans*-radial route reduces mortality is likely to be related to its lower rates of bleeding, where the magnitude of mortality reduction is related to the baseline bleeding risk [19]. The relationship between bleeding and all-cause mortality was shown in the randomized MATRIX study [10], which demonstrated a reduction of major bleeding together with all-cause mortality when the radial access site was used. In addition, further reductions in mortality may be due to reduced vascular complications and perhaps through reduction of ischemic events from more judicious use of anticoagulation and antiplatelet therapy when the radial site is used. These benefits are at least in part due to the easily accessible radial puncture site for PCI and its easy compressibility, facilitating haemostasis.

We did not find an association between mortality and the choice of access site after propensity-score matching, which may be due to several reasons. Firstly, the event rate for mortality was low in our two propensity-matched groups (1.0% and 1.4%). An absolute reduction of mortality in the radial group did not reach statistical significance, likely because the study was not sufficiently powered to demonstrate differences in mortality. Secondly, despite the significant reduction in bleeding events in the radial access group, the outcome was primarily driven by relatively minor BARC 2 events. Lastly, patients did not appear to be selected for *trans*-radial access according to their risk factors for bleeding, which may have further attenuated the outcome of mortality difference. It has been proposed that the magnitude of mortality reduction for the *trans*-radial route is related to the baseline bleeding risk [19].

Limitations of our study include its retrospective design and therefore the influence of potentially unmeasured confounders, as propensity matching does not eliminate all bias or confounding. However, the large cohort size with data from all-comers for PCI provides an opportunity to examine case-selection bias and perhaps modify current practise to improve utilization of the radial route, especially in patients at high-risk of bleeding. Also, our data were collected from multiple centres in Victoria, each with different levels of expertise with *trans*-radial PCI. Due to the nature of our database, we were unable to obtain crossover data or operator/centre adoption of *trans*-radial approach. Therefore this report does not reflect a particular institution's approach to PCI, but demonstrates the overall uptake of *trans*-radial PCI throughout our state.

The strengths of our analysis include in particular, the timeframe of our data analysis, which provides a contemporary Australian perspective in the rapidly changing landscape of *trans*-radial PCI and its evolving technologies. Our results are also consistent with the previous reports that have shown the radial route for PCI is associated with reduced bleeding.

5. Conclusion

The *trans*-femoral approach remains the dominant access site for PCI in Victoria. For those patients undergoing *trans*-radial PCI, the choice of access route does not appear to be based on consideration of bleeding risk, and this may be related to the learning curve. The radial route is associated with improved clinical outcomes of reduced bleeding and length of stay, consistent with previous findings. This supports the efficacy and safety of *trans*-radial PCI in real-world clinical practise.

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Conflicts of interest

The authors report no relationships that could be construed as a conflict of interest.

Authors' disclosure

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