

Transradial Versus Transfemoral Artery Approach for Coronary Angiography and Percutaneous Coronary Intervention in the Extremely Obese

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Objectives This study sought to evaluate the safety and efficacy of transradial versus transfemoral access for coronary angiography and percutaneous coronary intervention in patients with a body mass index ≥ 40 kg/m².

Background Coronary angiography is most commonly performed via femoral artery access; however, the optimal approach in extremely obese (EO) patients remains unclear.

Methods Between January 2007 and August 2010, a cohort of consecutive EO patients who underwent coronary angiography was identified in our center's registry of angiography and percutaneous coronary intervention procedures. Of 21,103 procedures, 564 (2.7%) were performed in unique EO patients: 203 (36%) via the transradial approach; and 361 (64%) via the transfemoral approach.

Results The primary outcome, a combined endpoint of major bleeding, access site complications, and nonaccess site complications, occurred in 7.5% of the transfemoral group and 2.0% of the transradial group (odds ratio [OR]: 0.30, 95% confidence interval [CI]: 0.10 to 0.88, $p = 0.029$), an endpoint driven by reductions in major bleeding (3.3% vs. 0.0%, OR: 0.12, 95% CI: 0 to 0.71, $p = 0.015$), as well as access site injuries (4.7% vs. 0.0%, OR: 0.08, 95% CI: 0 to 0.48, $p = 0.002$). There were no differences in nonaccess site complications (1.7% vs. 2.0%, OR: 1.50, 95% CI: 0.41 to 5.55), but transradial access procedures were associated with an increase in procedure time and patient radiation dose ($p < 0.05$).

Conclusions Transfemoral access for coronary angiography and percutaneous coronary intervention was associated with more bleeding and access site complications when compared with a transradial approach. Important reductions in procedural associated morbidity may be possible with a transradial approach in EO patients. (J Am Coll Cardiol Intv 2012;5:819–26) © 2012 by the American College of Cardiology Foundation

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The obesity epidemic is expected to increase dramatically (1). As numerous studies link the degree of obesity to cardiovascular risk factors as well as overall morbidity and mortality, it is projected that coronary artery disease prevalence will continue to climb (2). The World Health Organization has classified obesity based on body mass index (BMI) into 4 categories: 1) overweight (BMI 25 to 29.9 kg/m²); 2) obese class I (BMI 30 to 34.9 kg/m²); 3) obese class II (BMI 35 to 39.9 kg/m²); and 4) obese class III (BMI ≥40 kg/m²). The latter patients, those with a BMI ≥40 kg/m², have also been termed as having extreme obesity (EO). EO patients represent 6% of the total U.S. population and nearly 3% of the Canadian population, with recent data suggesting that the prevalence of patients with EO is increasing at a rate nearly twice as fast as that for other obesity subgroups (3,4).

Coronary angiography remains the gold standard for establishing the coronary anatomy. However, performing angiography in patients with EO presents unique risks. For example, the risk of major bleeding (5) and in-hospital mortality (6) has been shown to follow a U-shaped curve—class I and II obesity conferring a protective effect with an increase in bleeding risk seen after the BMI rises above 40. Whereas modification to standard protocol (7) or utilizing a radial approach (8) have been suggested in these high-risk patients, the safety of angiography and percutaneous coronary intervention (PCI) in a large cohort of EO patients has yet to be established.

This is of particular importance in light of growing evidence linking bleeding complications with increased mortality (9). Given the paucity of data, we chose to evaluate the safety of a transradial approach for coronary angiography and PCI compared with the transfemoral approach in patients with EO.

Methods

Study design, data source, and patients. The University of Ottawa Heart Institute (UOHI) is the tertiary cardiac care center for a population of approximately 1.3 million residents of eastern Ontario, including a regionalized ST-segment elevation myocardial infarction program (10). Clinical and demographic data, including height and weight, are collected on all patients undergoing coronary angiography or PCI in the UOHI PCI registry. From January 2007 to August 2010, 21,103 consecutive coronary procedures were prospectively indexed in the UOHI angiography/PCI registry from which a cohort of patients with

a BMI ≥40 kg/m² was identified and included in the analysis.

Both the registry records and medical records were reviewed by 2 individuals for extraction of data. Inclusion in the analysis required a BMI ≥40 kg/m² and either coronary angiography or PCI being performed. Exclusion criteria consisted of incomplete data for analyzing events, procedure other than angiography or PCI (e.g., right heart catheterization, percutaneous valve implantation, patent foramen ovale closure), cardiac arrest with cardiopulmonary resuscitation in the preceding 24 h, or cardiogenic shock on arrival to the catheterization laboratory. Both femoral and radial procedures were routinely performed using 6-F sheaths. Choice of access site and use of larger sheaths were at the discretion of the operator. Patients were included in groups based on the first attempted access site. This study was reviewed and approved by the UOHI institutional human research ethics board and was deemed not to require informed consent.

Outcome measures and definitions. The primary outcome of this study was a combined endpoint of bleeding, access site, and nonaccess site complications. Bleeding endpoints comprised TIMI (Thrombolysis In Myocardial Infarction) major, minor (11), or non-TIMI bleeding requiring blood transfusion. Briefly, TIMI major bleeds were defined as intracranial or >5 g/dl in hemoglobin or a hematocrit drop of 15%. TIMI minor bleeds were observed blood loss with a >3 g/dl drop in hemoglobin or a 10% decrease in hematocrit or no observed blood loss with a >4 g/dl or a drop by >12% in hematocrit. Vascular access site complications included surgical repair or intervention on the access site (including percutaneous injections), pseudoaneurysm treated conservatively, or a large hematoma (documented as >5 cm). Nonaccess site complications included coronary artery dissection, coronary perforation, transient ischemic attack or cerebrovascular accident, and death during the index hospitalization. Secondary outcomes included each of the components of the primary endpoint. Procedural failure, defined as a combined endpoint of access site crossover, failed coronary angiography, or failed target vessel revascularization, was also assessed. Patient radiation exposure was estimated by total fluoroscopy time (min) and measured dose area product (Gycm²).

Statistical analysis. All continuous variables were described as mean ± SD with categorical variables described as number (%). For patient and procedural characteristics, categorical variables were compared by chi-square and continuous variables by *t* test or Mann-Whitney rank sum test as appropriate. Statistical significance was defined as a *p* value <0.05.

For analysis of the primary and secondary outcomes, multiple logistic regression was performed and odds ratios (OR) with adjusted *p* values are reported. Variables known or suspected to be associated with the outcomes were assessed individually versus primary and secondary

Abbreviations and Acronyms

BMI = body mass index

CI = confidence interval

EO = extreme obesity

OR = odds ratio

PCI = percutaneous coronary intervention

TIMI = Thrombolysis In Myocardial Infarction

UOHI = University of Ottawa Heart Institute

outcomes, and those demonstrating association with $p < 0.2$ were included as candidate variables in regression models. For the outcomes of TIMI bleeding and access site complications, an incidence of 0% in the transradial cohort necessitated the use of exact logistic regression to estimate OR and confidence intervals (CI), as indicated (12,13). Given the relatively small sample size and the sparse number of outcomes for individual components of the composite outcome, regression models included as many of the covariates as possible in order of univariate significance and stopped at the most fully adjusted model that successfully converged. Analyses were conducted using SAS software (version 9.2, SAS Institute, Cary, North Carolina).

Results

Baseline characteristics. We identified 564 procedures that were performed in unique EO patients between January 2007 and August 2010 that met inclusion criteria (Fig. 1). Of this group, 203 (36.0%) underwent angiography via a radial approach and 361 (64.0%) via a femoral approach. Interestingly, patients with EO represented only 3.95% of

all patients referred for angiography. Baseline and procedural characteristics are presented in Table 1. Basic demographic data were similar between the groups, with patients in the radial arm having modestly higher BMI ($47.3 \pm 5.9 \text{ kg/m}^2$ vs. $44.0 \pm 4.5 \text{ kg/m}^2$, $p < 0.001$). Notably, patients in the radial group also had higher rates of heparin use, reflecting, in part, routine use of heparin for radial procedures and higher rates of PCI being performed (32.5% of cases in the radial arm vs. 23.5% in the femoral arm, $p < 0.05$).

Outcomes. The composite primary outcome of bleeding complications, access site injury, or nonaccess site complications occurred in 2.0% of radial cases and 7.5% of cases in the femoral group (OR: 0.30, 95% CI: 0.10 to 0.88, $p = 0.029$) (Table 2). This endpoint was primarily driven by increased rates of bleeding complications (0.0% radial vs. 3.3% femoral; OR: 0.12, 95% CI: 0 to 0.71, $p = 0.015$) and access site injury (0.0% radial vs. 4.7% femoral; OR: 0.08, 95% CI: 0 to 0.48, $p = 0.002$). Nonaccess site complications did not differ significantly between the groups (Table 2). Regarding significant clinical events, 2 patients in the femoral group had emergency surgery for hemodynamically significant bleeds, and 1 patient died because of an access

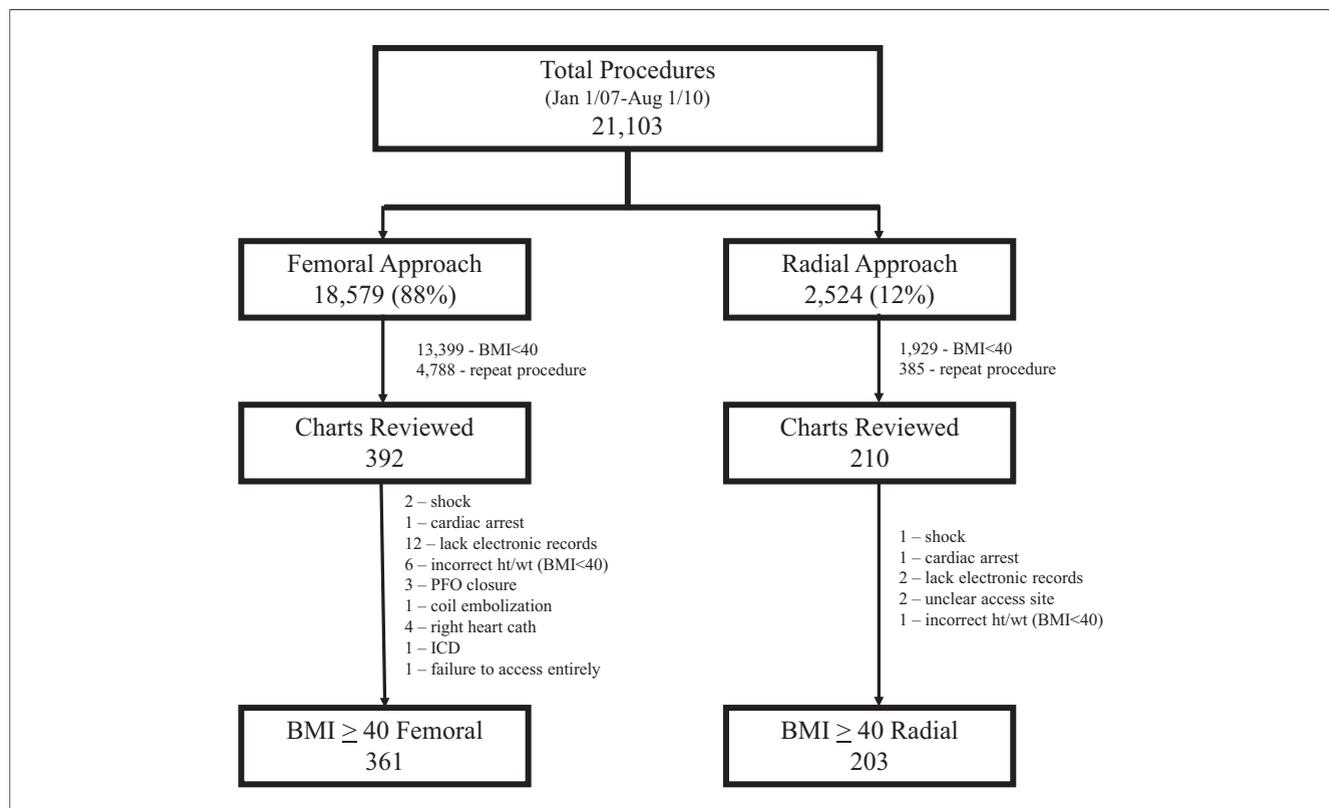


Figure 1. Study Flow

Procedures were retrospectively identified from July 1, 2007, to August 1, 2010, and were grouped based on approach. Exclusion criteria included body mass index $< 40 \text{ kg/m}^2$, repeat procedures in a single patient, incorrect dimensions reported, lack of electronic records, and procedure other than coronary angiography and/or percutaneous coronary intervention. BMI = body mass index; ICD = implantable cardioverter-defibrillator; PFO = patent foramen ovale.

Table 1. Baseline and Angiographic Characteristics

Characteristic	Femoral (n = 361)	Radial (n = 203)	p Value
Demographics			
Male	192 (53.2)	101 (49.8)	NS
Age, yrs	58.4 ± 10.7	56.4 ± 9.9	NS
Height, m	1.66 ± 0.12	1.67 ± 0.11	NS
Weight, kg	121.4 ± 18.6	132.8 ± 24.0	<0.001
BMI, kg/m ²	44.0 ± 4.5	47.3 ± 5.9	<0.001
Risk factors			
Hypertension	289 (80.1)	158 (77.8)	NS
Diabetes	195 (54.0)	127 (62.6)	NS
Smoking	206 (57.1)	121 (59.6)	NS
Hyperlipidemia	270 (74.8)	165 (81.2)	NS
Medications			
ACEI/ARB*	210 (78.1)	123 (77.8)	NS
Beta-blocker*	223 (82.9)	117 (74.1)	<0.05
Statin*	228 (84.8)	125 (79.1)	NS
ASA*	246 (91.4)	151 (95.6)	NS
Clopidogrel*	168 (62.5)	105 (66.5)	NS
Glycoprotein IIb/IIIa inhibitors	11 (3.0)	2 (1.0)	NS
Thrombolytics	10 (2.8)	8 (4.0)	NS
Heparin	77 (21.3)	157 (77.3)	<0.001
Bivalirudin	63 (17.5)	33 (16.3)	NS
Creatinine	89.6 ± 30.7	98.1 ± 52.8	NS
Previous history			
CVA	14 (3.9)	15 (7.4)	NS
MI	48 (13.3)	47 (23.2)	<0.01
PCI	51 (14.1)	41 (20.2)	NS
CABG	35 (9.7)	6 (3.0)	<0.01
Procedural characteristics			
Procedure time, min	30.5 ± 23.0	44.3 ± 25.3	<0.001
Fluoroscopy time, min	6.7 ± 6.3	12.5 ± 8.2	<0.001
Contrast volume, ml	154.8 ± 72.8	174.4 ± 90.2	0.06
Use of closure device	5 (1.4)	0 (0)	NS
Procedural outcomes			
Coronary angiogram	276 (76.5)	137 (67.5)	<0.05
Normal anatomy	83 (23.0)	50 (24.6)	NS
CAD for medical management	116 (32.1)	59 (29.1)	NS
Referred for CABG	37 (10.2)	20 (9.9)	NS
Referred for staged PCI	40 (11.1)	8 (3.9)	<0.01
Percutaneous coronary intervention	85 (23.5)	66 (32.5)	<0.05

Values are n (%) or mean ± SD. *Data available for 269 femoral patients and 158 radial patients. ACEI = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; ASA = acetylsalicylic acid; BMI = body mass index; CABG = coronary artery bypass graft; CAD = coronary artery disease; CVA = cerebrovascular accident; MI = myocardial infarction; PCI = percutaneous coronary intervention.

site hemorrhage before surgical intervention. In the radial group, 1 case of aortic dissection was identified 7 days after the angiogram and was successfully managed surgically. Overall, a radial approach significantly reduced the incidence of procedural-related morbidity in EO patients when compared with a femoral approach for coronary angiography or PCI.

Combined procedural failures, which was an endpoint composed of access site crossover, failure to complete angiography requiring repeat angiography at another time, or failure to complete target vessel revascularization, did not differ between approaches (7.3% radial vs. 5.8% in the femoral, $p > 0.05$) (Fig. 2). However, transradial access did result in a significantly longer procedure time (44.3 ± 25.3 min vs. 30.5 ± 23.0 min, $p < 0.001$) and fluoroscopy time (12.5 ± 8.2 min vs. 6.7 ± 6.3 min, $p < 0.001$) (Table 1) with a strong trend toward more contrast volume use ($p = 0.06$). The increased use of fluoroscopy resulted in greater radiation exposure to the patient as estimated by the dose area product (194.1 ± 260.1 Gy cm^2 vs. 123.3 ± 106.5 Gy cm^2 , $p < 0.001$) (Fig. 2).

Angiography versus PCI. We next divided the groups into coronary angiography alone or PCI alone to see whether differences were attributable to either subgroup (Table 3). Diagnostic angiography alone comprised most procedures (73%) with femoral procedures having significantly shorter procedure (22.0 ± 10.8 min vs. 35.7 ± 17.3 min, $p < 0.001$) and fluoroscopy time (4.9 ± 4.3 min vs. 10.3 ± 7.3 min, $p < 0.001$). In the PCI subgroup, radial access did not significantly lengthen procedure time but was accompanied by modest increase in fluoroscopy time (12.8 ± 8.1 min vs. 16.9 ± 8.3 min, $p < 0.01$). In either coronary angiography or PCI alone, radial access was not associated with significantly more contrast use.

Table 2. Procedural Outcomes

	Femoral (n = 361)	Radial (n = 203)	OR (95% CI)	p Value
Combined primary outcome	27 (7.5)	4 (2.0)	0.30 (0.10–0.88)*	0.029
Bleeding complications	12 (3.3)	0 (0)	0.12 (0–0.71)††	0.015
TIMI major bleeding	3 (0.8)	0 (0)		
TIMI minor bleeding	7 (1.9)	0 (0)		
Bleeding requiring transfusion	2 (0.6)	0 (0)		
Access site complications	17 (4.7)	0 (0)	0.08 (0–0.48)‡§	0.002
Access site surgery/intervention	6 (1.7)	0 (0)		
Pseudoaneurysm	4 (1.1)	0 (0)		
Hematoma >5 cm	7 (1.9)	0 (0)		
Nonaccess site complications	6 (1.7)	4 (2.0)	1.50 (0.41–5.55)†	0.54
Coronary perforation	0 (0)	1 (0.5)		
Coronary dissection	2 (0.6)	1 (0.5)		
TIA/CVA	1 (0.3)	0 (0)		
Death during hospitalization	3 (0.8)	1 (0.5)		
Aortic dissection	0 (0)	1 (0.5)		

Values are n (%). *Adjusted for age, sex, BMI, bivalirudin, glycoprotein IIb/IIIa. †Adjusted for age and sex. ‡Exact logistic regression methodology used to calculate exact OR and 95% CI. §Adjusted for age, sex, smoking, and glycoprotein IIb/IIIa.
CI = confidence interval; OR = odds ratio; TIA = transient ischemic attack; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.

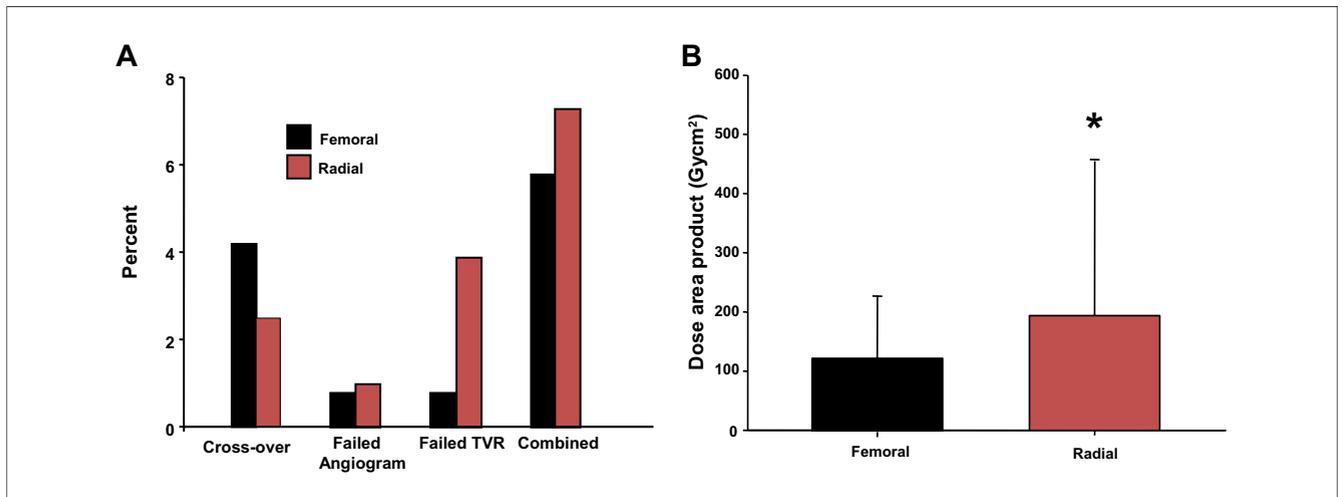


Figure 2. Combined Procedural Failure and Radiation Exposure for Transradial and Transfemoral Procedures

(A) Rates of access site crossover, failed completion of angiography, failed target vessel revascularization (TVR), and combined procedural failure. (B) Average dose area product (Gycm²) for the transfemoral and transradial groups. Data are expressed as means ± SD. *p < 0.05.

Regarding the combined primary outcome, PCI accounted for more complications than coronary angiography did. In the PCI group, radial access was associated with only a 4.5% complication rate compared with 14.1% in EO patients in whom femoral access was pursued (OR: 0.29, 95% CI: 0.05 to 1.22, p = 0.11). Similarly, in the coronary angiography group, there was a trend toward decreased risk of adverse events in the radial access group (0.7% vs. 5.4%; OR: 0.15, 95% CI: 0.003 to 1.04, p = 0.06).

Discussion

Our study is the first to our knowledge to examine the influence of access site selection on bleeding, vascular, and procedural complications following coronary angiography or PCI in EO patients. Among this high-risk group, we observed a significantly lower rate of bleeding complications and access site injuries when a transradial approach was used. Overall, the composite primary outcome was reduced from 7.5% in the transfemoral group to 2.0% in the transradial group, suggesting that using the radial artery preferentially for access in as few as 18 EO patients may prevent 1 serious adverse event.

Patients with EO represent a unique population because they are difficult to evaluate by standard noninvasive testing (14); they have more associated coronary artery disease risk factors; and they have an increased risk of morbidity and mortality from cardiac events (2). Moreover, their risk is compounded at the time of coronary angiography and PCI due to an increased risk of complications. In our study, PCI via a transfemoral approach markedly increased the complication rate compared with the rate in patients in whom transradial access was selected (14.5% vs. 4.5%, respectively). This finding is not surprising as others have reported

BMI ≥40 kg/m², transfemoral access, and transfusion are potent predictors of adverse outcomes following PCI (15). For example, Cox et al. (5) noted a bimodal U-shaped risk curve for vascular complications in their cohort study, with mild obesity (BMI 30 to 36 kg/m²) showing reductions in complication rates that then increased at higher BMI. Our study is the first to look exclusively at these higher risk individuals (i.e., World Health Organization class III, BMI >40 kg/m²) and contributes to the evidence that employing a radial approach in select high-risk patients, such as those with EO, may provide an opportunity to improve clinical outcomes.

The debate regarding the optimal vascular access site for coronary angiography and PCI continues to be studied extensively, with proponents of radial angiography often citing reductions in access site complications and bleeding as a rationale for its use (16). Indeed, the association between bleeding complications, need for transfusion, and mortality has been known to exist in myocardial infarction patients undergoing revascularization for some time (17,18). In a recent systematic review and meta-analysis of 23 randomized controlled trials, fewer bleeding complications were seen with radial access, leading to a trend toward reduced ischemic endpoints and death (19). By contrast, the RIVAL (Radial Versus Femoral Access for Coronary Intervention) study, a large randomized trial of radial versus femoral access, failed to significantly reduce death, myocardial infarction, or bleeding outcomes despite significant reductions in vascular access complications (20). However, high-risk subgroups, such as patients with ST-segment elevation myocardial infarction, did show reductions in adverse events. Despite this accruing evidence, developing the required expertise and marginally longer procedure times has limited radial access to

Table 3. Angiography or PCI Procedural Characteristics and Outcomes

	Angiography (n = 413)				PCI (n = 151)			
	Femoral (n = 276)	Radial (n = 137)	OR (95% CI)	p Value	Femoral (n = 85)	Radial (n = 66)	OR (95% CI)	p Value
Medications								
Glycoprotein IIb/IIIa Inhibitors	0 (0)	1 (0.7)		NS	11 (12.9)	1 (1.5)		0.02
Thrombolytics	0 (0)	1 (0.7)		NS	10 (11.8)	7 (10.6)		NS
Heparin	40 (14.5)	99 (72.3)		<0.001	37 (43.5)	58 (87.9)		<0.001
Bivalirudin	4 (1.4)	2 (1.5)		NS	59 (69.4)	31 (46.9)		<0.01
Procedural characteristics								
Procedure time, min	22.0 ± 10.8	35.7 ± 17.3		<0.001	57.7 ± 29.7	61.0 ± 29.9		NS
Fluoroscopy time, min	4.9 ± 4.3	10.3 ± 7.3		<0.001	12.8 ± 8.1	16.9 ± 8.3		<0.01
Contrast volume, ml	131.3 ± 50.2	134.8 ± 60.6		NS	232.8 ± 81.5	256.1 ± 86.7		0.09
Combined primary outcome	15 (5.4)	1 (0.7)	0.15 (0.003–1.04)*	0.06	12 (14.1)	3 (4.5)	0.29 (0.05–1.22)†	0.11
Bleeding complications	8 (2.9)	0 (0)	0.17 (0.0–1.13)‡§	0.07	4 (4.7)	0 (0)	0.24 (0.0–1.93)‡§	0.19
TIMI major bleeding	2 (0.7)	0 (0)			1 (1.2)	0 (0)		
TIMI minor bleeding	4 (1.4)	0 (0)			3 (3.5)	0 (0)		
Bleeding requiring transfusion	2 (0.7)	0 (0)			0 (0)	0 (0)		
Access site complications	10 (3.6)	0 (0)	0.19 (0.0–1.24)‡	0.09	7 (8.2)	0 (0)	0.13 (0.0–0.86)‡§	0.03
Access site surgery/intervention	3 (1.1)	0 (0)			3 (3.5)	0 (0)		
Pseudoaneurysm	3 (1.1)	0 (0)			1 (1.2)	0 (0)		
Hematoma >5 cm	4 (1.4)	0 (0)			3 (3.5)	0 (0)		
Nonaccess site complications	4 (1.4)	1 (0.7)	0.71 (0.01–8.19)‡¶	1.0	2 (2.4)	3 (4.5)	1.83 (0.19–24.4)‡##	0.86
Coronary perforation	0 (0)	0 (0)			0 (0)	1 (1.5)		
Coronary dissection	1 (0.4)	0 (0)			1 (1.2)	1 (1.5)		
TIA/CVA	1 (0.4)	0 (0)			0 (0)	0 (0)		
Death during hospitalization	2 (0.7)	1 (0.7)			1 (1.2)	0 (0)		
Aortic dissection	0 (0)	0 (0)			0 (0)	1 (1.5)		

Values are presented as n (%) or mean ± SD. *Adjusted for age and sex. †Adjusted for age and diabetes status. ‡Exact logistic regression methodology used to calculate exact OR and 95% CI. §No adjustment. ||Adjusted for sex, diabetes status, and smoking. ¶Adjusted for age. #Adjusted for statin use and smoking.

Abbreviations as in Tables 1 and 2.

between 1% and 2% of all cases performed in the United States and only 10% of cases in Canada (21,22).

The magnitude of benefit seen in our study (a 5.5% absolute reduction in combined primary outcome) is similar to the effect size seen in other bleeding reduction strategies that have been more widely implemented. For example, reductions in bleeding outcomes have led to the popularization of agents such as fondaparinux and bivalirudin. Notably, systematic reviews have repeatedly demonstrated that transradial access in unselected populations for coronary angiography results in approximately a 2.5% absolute reduction in bleeding complications, similar to results achieved in the OASIS 5 (Fifth Organization to Assess Strategies in Acute Ischemic Syndromes) trial, the ACUTY (Acute Catheterization and Urgent Intervention Triage Strategy Trial), and HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) trial (19,23,24). In high-risk populations, such as patients with EO, the magnitude of benefit may be even larger. For example, reductions in adverse events have been seen in octogenarians with a transradial

approach, resulting in a 5% absolute reduction in vascular complications (25). Similar to our findings, patients in the TROP (Transradial Approach in Overweight Patients) registry with World Health Organization class II and III obesity had a marked reduction in vascular complications delaying hospital discharge (0.8 vs. 5.1%) in patients with a BMI >35 when using a transradial approach (26). Thus, in patients considered high risk for access site complications, selecting a transradial approach for coronary angiography or PCI may be the single most important intervention for reducing procedural morbidity not currently being widely employed.

Although important reductions in access site complications were achieved, transradial access in our study came at a cost: namely increased procedure time and radiation exposure to the patients. However, these findings are not surprising given that transradial access (27) and patient size (28) are known to contribute to increased radiation exposure. Nonetheless, recent studies have demonstrated that effective use of radiation shielding (29,30) and increased operator experience (31) can markedly reduce radiation

exposure for the patient and operator alike. As well, Uhlemann et al. (32) recently demonstrated that radial artery occlusion occurs in as many as 13.7% of patients with 5-F systems and 30.5% of 6-F systems. In our cohort, no cases of radial artery occlusion required surgical intervention nor were any documented by imaging, which simply reflects the lack of systematic evaluation of radial artery patency. Nonetheless, this important complication limits repeat use of a transradial approach and is an important consideration in selecting the access site for future cardiac catheterizations.

Study limitations. The main limitation in our study is the nonrandomized nature of the cohort study, thus we identified and adjusted for known confounding variables. However, the low number of endpoints observed in our study (e.g., no bleeding or access site complications in the radial group) necessitated the use of exact regression models that may limit the precision of the effect estimates. We also could not control for differences in skill of the operators. It is conceivable that a radial approach may be preferentially selected by more skilled angiographers. However, we can report that all operators were represented in both groups and perform vastly more procedures (i.e., minimum 75 annually) than the American Heart Association/American College of Cardiology guidelines suggest; hence, operator experience likely did not influence outcome. Another limitation of our study is the low rate of percutaneous closure device use, as is our institutional practice. A recent observational study (33) has suggested they may be associated with lower rates of bleeding, but others have noted increased risks of major bleeds and need for surgical repair following closure device deployment. Indeed, a recent American Heart Association scientific statement has recommended against routine use, highlighting potential increased risks (34,35).

Conclusions

Our analysis suggests that a radial approach for coronary angiography and PCI in patients with EO can markedly reduce bleeding and vascular access complications. In view of the magnitude of the reduction in procedural morbidity, a randomized controlled trial is needed in the EO population to definitively establish impact on clinical outcomes.

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