Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: A systematic review and meta-analysis of randomized trials

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Background Small randomized trials have demonstrated that radial access reduces access site complications compared to a femoral approach. The objective of this meta-analysis was to determine if radial access reduces major bleeding and as a result can reduce death and ischemic events compared to femoral access.

Methods MEDLINE, EMBASE, and CENTRAL were searched from 1980 to April 2008. Relevant conference abstracts from 2005 to April 2008 were searched. Randomized trials comparing radial versus femoral access coronary angiography or intervention that reported major bleeding, death, myocardial infarction, and procedural or fluoroscopy time were included. A fixed-effects model was used with a random effects for sensitivity analysis.

Results Radial access reduced major bleeding by 73% compared to femoral access (0.05% vs 2.3%, OR 0.27 [95% CI 0.16, 0.45], $P < .001$). There was a trend for reductions in the composite of death, myocardial infarction, or stroke (2.5% vs 3.8%, OR 0.71 [95% CI 0.49-1.01], $P = .058$) as well as death (1.2% vs 1.8% OR 0.74 [95% CI 0.42-1.30], $P = .29$). There was a trend for higher rate of inability to the cross lesion with wire, balloon, or stent during percutaneous coronary intervention with radial access (4.7% vs 3.4% OR 1.29 [95% CI 0.87, 1.94], $P = .21$). Radial access reduced hospital stay by 0.4 days (95% CI 0.2-0.5, $P = .0001$).

Conclusions Radial access reduced major bleeding and there was a corresponding trend for reduction in ischemic events compared to femoral access. Large randomized trials are needed to confirm the benefit of radial access on death and ischemic events. (Am Heart J 2009;157:132-40.)

Femoral access for coronary angiography has been the dominant access site for the last 2 decades. Small randomized trials summarized in a previous meta-analysis have demonstrated that radial access reduces access site complications (a composite of local ischemic and minor and major hemorrhagic complications) with similar rates of major adverse cardiac events.[1] Unfortunately, radial access still accounts for less than 10% of procedures worldwide and 1% of procedures in the United States, suggesting that many interventional cardiologists remain unconvinced and that further data is necessary to change practice.[2] Many interventional cardiologists perceive that the decrease in minor vascular complications (large hematoma, femoral pseudoaneurysm) with radial access are balanced by technical difficulties and increased radiation exposure required for radial access.

In multiple studies, major bleeding events have been shown to be independently associated with a marked increase risk of death and ischemic events in patients undergoing percutaneous coronary intervention (PCI) and those with acute coronary syndromes.[3,4] Recent trials with agents that reduce the risk of bleeding with similar efficacy to standard therapy have shown reductions in mortality in acute coronary syndromes.[5] These data suggest a causative link between major bleeding and death and recurrent ischemic events. This has led to a new paradigm that therapies that preserve efficacy and reduce bleeding can improve overall outcome in these populations.

The mechanism of increased ischemic events with major bleeding may include (i) activation of coagulation cascade with bleeding, (ii) cessation of antiplatelet and antithrombotic therapies and (iii) adverse effects of blood transfusion. Because radial access procedures reduce

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vascular access site complications, which account for a substantial part of major bleeding in patients undergoing PCI, it is possible that mortality and ischemic events may also be reduced by this technique.

The purpose of this meta-analysis is to determine whether a radial approach reduces major bleeding and to explore whether this reduction in bleeding translates into a reduction in mortality and ischemic events.

Methods

Search strategy for identification of studies

MEDLINE, CENTRAL, and EMBASE were searched for eligible studies between 1980 to April 2008, week 2. A sensitive search strategy with no language restriction was used. Conference abstracts for the American Heart Association, American College of Cardiology, Transcatheter Therapeutics, and European Society of Cardiology were hand-searched from January 2003 to April 2008. Prior systematic reviews and other studies references were hand-searched to include all relevant studies.

Eligibility criteria

We selected all published and unpublished randomized trials comparing radial versus femoral access in patients undergoing coronary angiography or intervention with any of the following outcomes available: major bleeding or components of major bleeding, death, myocardial infarction (MI), procedural time, fluoroscopy time or hospital length of stay.

Outcomes

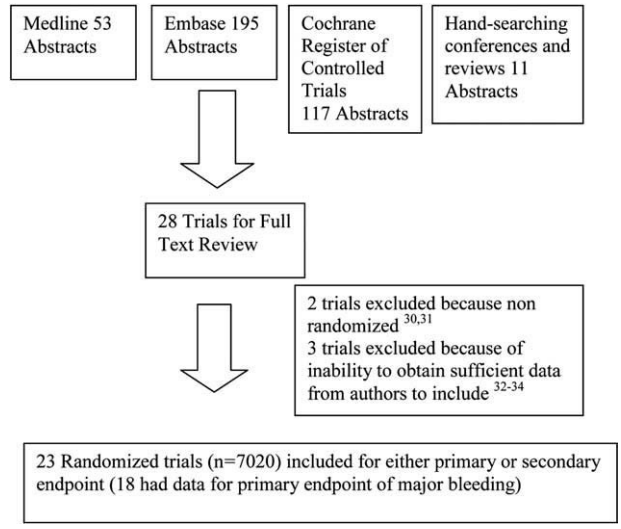
Outcomes were obtained for longest available follow-up. A standardized major bleeding definition was used and defined as one of the following: fatal bleeding, intracranial hemorrhage, or bleeding associated with ≥3 g/dL hemoglobin drop or requiring transfusion or requiring surgery (pseudoaneurysms requiring thrombin injection or ultrasound compression were excluded). This definition was based on available data from the various trials and is similar to the OASIS (Organization to Assess Strategies in acute Ischemic Syndromes) definition of major bleeding but differs in that it includes any blood transfusion rather than ≥2 units as in the original OASIS major bleeding definition. For trials where the composite was not available then either transfusion rates or proportion with bleeding associated with a ≥3 g/dL hemoglobin drop was substituted for major bleeding. A sensitivity analysis was performed to exclude trials where only a component of major bleeding was available.

Death, MI, or stroke as a composite as well as access site complications, access site crossover, inability to cross coronary lesion with wire, balloon or stent, procedural time, fluoroscopy time, and hospital length of stay were obtained. Access site crossover was defined as need to puncture a second arterial access site.

Data abstraction and validity assessment

Data validity assessment and abstraction was performed in duplicate by reviewers. The individual components of quality including randomization, blinded allocation, blinded outcome assessment, and description of withdrawals were collected. Quality was assessed by a score, the Jadad score,[6] for assessment of randomized trials and a high quality score was set at a score of ≥3 as per the validated scale.[6]

Figure 1



Flowchart of literature search and trial selection.

Statistical analysis

We used a fixed-effects model based on the Peto method for combining results from the individual trials for odds ratios and risk differences with their respective 95% confidence intervals. For continuous variables, the inverse variance method was used, and weighted mean differences with 95% confidence intervals were reported.

For the outcome of major bleeding, a secondary analysis was performed using risk differences. Statistical software used was Comprehensive Meta-Analysis V 2.0 (Biostat Inc, Englewood, NJ), and $P < .05$ was defined as significant. Heterogeneity was assessed with a χ^2 heterogeneity statistic with a $P < .10$ for significance or an i^2 statistic >50%. A sensitivity analysis was performed analyzing the data with a random effects model for the major bleeding and death, MI, or stroke.

Radial expert studies were defined as studies that stated operators' preferred route was radial or the center performing the study was known to be an expert transradial center. Routine use of femoral artery closure devices was defined as more than 50% of procedures for diagnostic studies and more than 50% of PCI procedures in interventional studies.

Results

As shown in Figure 1, 376 abstracts were retrieved from MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and hand-searching conference proceedings and reviews, and 28 were chosen for full text review. Of the 28 chosen for full text review, 23 randomized trials based on the inclusion criteria were selected (Table I). Two trials were excluded because on full text review, they were not randomized trials.[30,31] Two trials were excluded because

Table I. Characteristics of included studies

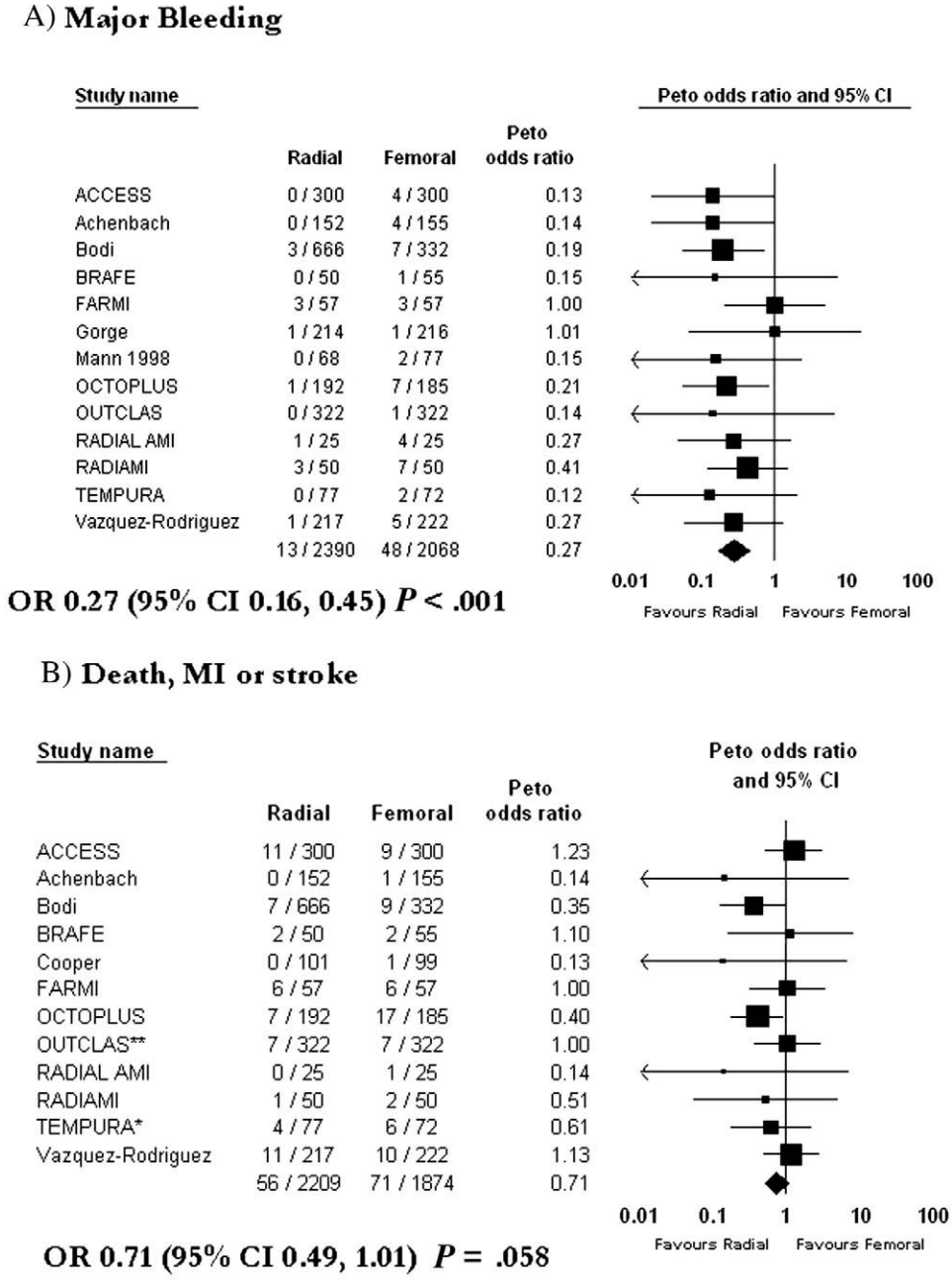
Study	Years of enrollment	N	Population	Intervention and control access	Definition of major bleeding used	Quality score	Follow-up
Grinfeld et al[7]	1994-1995	279	Diagnostic coronary angiography	Radial vs brachial vs femoral*	Not reported	1	Inhospital
Mann et al[8]	1994-1995	152	PTCA	Right radial (6F) vs femoral (6F)	Full standardized†	2	Inhospital
ACCESS[9]	1993-1995	600	PTCA	Radial (6F) vs brachial (6F) vs femoral (6F)*	Full standardized†	3	1 month
BRAFE[10]	1994-1995	112	Elective PCI with stent	Radial (6F) vs brachial (6F) vs femoral (6F)*	Full standardized†	2	1 month
Cooper et al[11]	1996-1997	200	Diagnostic coronary angiography	Radial (4F) vs femoral (5F or 6F)	Full standardized†	2	In hospital
Mann et al[12]	1997	142	Patients with ACS undergoing PCI with stent	Radial (6F) vs femoral (6F or 7F)	Full standardized†	1	In hospital
Monsegu et al[13]	1999	379	Diagnostic coronary angiography	Left radial (5F) vs femoral (4F)	Not reported	1	In hospital
CARAFE[14]	1998-1999	210	Coronary angiography or PCI	Radial (5 or 6F) vs femoral (5F or 6F with perclose if PCI)	Full standardized†	2	In hospital
Gorge and Kirstein[15]	2001‡	430	Coronary angiography or PCI	Radial vs femoral	Bleeding requiring surgical intervention	2	In hospital
Moriyama et al[16]	2002	200	Diagnostic coronary angiography	Radial (4F) vs femoral (4F)	Not reported	1	In hospital
TEMPURA[17]	1999-2001	149	Patients with STEMI for primary PCI	Radial (6F) vs femoral (6F)	Bleeding requiring transfusion, surgical intervention or cerebral hemorrhage	2	9 months
OCTOPLUS[18]	2003‡	371	Patients age >80 undergoing coronary angiography or PCI	Radial vs femoral	Bleeding with a drop of ≥3 g/dL hemoglobin	1	In hospital
Tian et al[19]	2003‡	400	Diagnostic coronary angiography	Radial vs femoral	Full standardized†	1	In hospital
Reddy et al[20]	2004‡	75	Diagnostic coronary angiography	Radial (6F) vs femoral (4F) vs femoral with angioseal closure (6F)	Full standardized†	2	In hospital
RADIAL AMI[21]	2005‡	50	Patients with STEMI for primary or rescue PCI	Radial vs femoral	Bleeding with a drop of ≥3 g/dL hemoglobin	2	1 month
Achenbach et al[22]	2005	307	Patients age >75 undergoing coronary angiography	Radial vs femoral	Full standardized†	1	In hospital
OUTCLAS[23]	2005	644	Outpatients referred for PCI	Radial (6F) vs femoral (6F)	Blood transfusion	2	1 month
FARMI[24]	2004-2005	116	Patients with STEMI for primary or rescue PCI	Radial (5F) vs femoral (5F)	TIMI major bleeding	2	In hospital
Lange and von Boetticher[25]	2006‡	297	Coronary angiography or PCI	Radial vs femoral	Not reported	2	End of procedure
Vazquez-Rodriguez et al[26]	2004	439	Patients with STEMI for primary or rescue PCI	Radial vs femoral with closure device	Full standardized†	1	1 month
RADIAMI[27]	2007	100	Patients with STEMI for primary PCI	Radial vs femoral	Full standardized†	1	In hospital
Bodi et al§[28]	2007	998	Coronary angiography or PCI	Right vs Left radial vs femoral	Full standardized	1	In hospital
Li et al[29]	2006	370	Patients with STEMI for primary PCI	Radial vs femoral	Not reported	1	In hospital

PTCA, Percutaneous coronary angioplasty; *STEMI*, ST-elevation myocardial infarction.
*Only femoral and radial arms included.
†Full standardized = fatal bleeding, intracranial hemorrhage, bleeding associated with ≥3 g/dL hemoglobin drop or requiring transfusion or requiring surgery (pseudoaneurysms requiring thrombin injection or ultrasound compression were excluded).
‡Year of publication.
§Left and right radial groups combined for analysis.

the abstracts did not provide enough data for analysis, and when contacted, authors did not provide further data.[32,33] One trial was excluded because the control arm could have either brachial or femoral access.[34]

Of the trials included, 6 trials were diagnostic only and did not include patients undergoing coronary interventions.[7,11,13,16,19,20] Two trials were performed exclusively in the geriatric population.[18,22] Six studies were performed in

Figure 2



(A) Forest plot for major bleeding of radial versus femoral access. Tests for heterogeneity ($P = .93$, $i^2 = 0\%$). Fixed-effects OR shown in figure; random effects OR 0.29 (95% CI 0.16-0.53). **(B)** Forest Plot for composite of death, MI or stroke of radial versus femoral access. Tests for heterogeneity $P = .59$, $i^2 = 0\%$. Fixed-effects OR shown in figure; random effects OR 0.72 (95% CI 0.51-1.04).

acute ST-elevation MI, in the setting of primary or rescue angioplasty.[17,21,24,26,27,29] Finally, femoral vascular closure devices were routinely used in 4 studies.[14,18,20,26] With regard to adjunctive therapies for PCI, 6 trials[12,18,21,24,26,27] used glycoprotein IIb-IIIa inhibitors in a proportion of patients, and no trials used bivalirudin.

Methodologic quality of included studies

Five studies had evidence of blinded allocation.[9,10,18,21,23] No studies reported blinding of outcome assessment and only one of the 20 trials received a high quality based on the Jadad scoring system (individual study scores shown in Table I).[9]

Table II. Sub-group analysis for major bleeding by clinical characteristics of studies

Subgroup	No. of studies (no. of patients)	OR (95% CI)	*P*
Mean age > 70	2 (684)	0.18 (0.06, 0.57)	.003
Mean age < 70	16 (4807)	0.30 (0.17, 0.53)	<.001
Radial expert	12 (4531)	0.23 (0.13, 0.42)	<.001
Non–radial expert	6 (960)	0.39 (0.15, 1.01)	.05
Diagnostic-only studies	3 (1030)	1.01 (0.06, 16.2)	1.0
Intervention studies	15 (4461)	0.25 (0.15, 0.43)	<.001
Primary or rescue PCI	5 (852)	0.39 (0.18, 0.82)	.013
Closure device studies	4 (1101)	0.21 (0.09, 0.49)	<.001
Unpublished	5 (2274)	0.28 (0.13, 0.56)	<.001
Published	13 (3217)	0.26 (0.12, 0.54)	<.001
Modern era (1999-present)	10 (3608)	0.29 (0.17, 0.50)	<.001

Effects of radial access on major bleeding

For the end point of major bleeding, 18 trials had data available; however, a number of the small trials had no events.[8-12,14,15,17-24,26,27] Major bleeding occurred in 13 (0.05%) of 2,390 patients in the radial access group compared with 48 (2.3%) of 2,068 patients in the femoral access group (OR 0.27 [95% CI 0.16-0.45], $P < .001$) as shown in Figure 2. A sensitivity analysis was performed by removing studies (6/17)[15,17,18,21,23,24] where only data on a component of major bleeding was available (ie, transfusion rates) and radial access was associated with a similar benefit (OR 0.28 [95% CI 0.15-0.51], $P < .001$) for the reduction of major bleeding.

Subgroup analyses were performed, and the benefit for radial access for major bleeding appeared similar in nearly all subgroups (Table II).

The absolute risk reduction for major bleeding was 1.4% (95% CI 0.7%-2.1%) for radial access with significant heterogeneity ($P = .02$, $I^2 = 47\%$). However, the greatest absolute benefit appeared in the setting of primary or rescue angioplasty for acute ST-elevation MI with an absolute risk reduction of 3.1% (95% CI 0.01-5.5, interaction $P = .001$). The absolute risk reduction for studies that included coronary interventions was 1.8% (95% CI 1.0%-2.5%, interaction $P = .001$), yielding a number needed to treat of 56 patients to prevent one major bleeding event.

Effects of radial access on death, MI, and stroke

For the composite of death, MI, or stroke, 56 (2.5%) of 2,209 patients had events in the radial group compared to 71 (3.8%) of 1,874 patients in the femoral group (OR 0.71 [95% CI 0.49-1.01], $P = .058$) as shown in Figure 2. Sensitivity analyses were performed and demonstrated consistency of results favoring radial access in various subgroups, including trials performed after 1999 (OR 0.62 [95% CI 0.42-0.93], $P = .020$), trials published in a peer review journal (OR 0.74 [95% CI 0.48-1.13], $P = .16$) and unpublished trials (OR 0.65 [95% CI 0.35-1.23], $P = .19$) and when diagnostic-only studies were excluded (OR 0.72 [95% CI 0.50-1.03], $P = .07$).

For mortality, 22 (1.2%) of 1,906 patients died in the radial group compared to 28 (1.8%) of 1,565 patients in the femoral group (OR 0.74 [95% CI 0.42-1.30], $P = .29$) as shown in Figure 3. The rates of MI and stroke individually were similar in the radial and femoral arms (Table III).

Access site crossover and inability to cross the lesion with a wire, balloon, or stent

The rate of access site crossover was significantly higher with radial access with 150 (5.9%) of 2,542 patients in the radial group requiring puncture of another access site compared to 34 (1.4%) of 2,460 patients in the femoral group (OR 3.82 [95% CI 2.83-5.15], $P < .001$), as shown in Figure 4. When studies were divided into studies performed in the early era of radial access (prior to 1999), the odds of access site crossover with radial was 5-fold higher (OR 5.63 [95% CI 3.50-9.07], $P < .001$) versus the modern era (1999-2008) where radial access had a 3-fold increase in access site crossover (OR 2.96 [95% CI 2.02-4.35], $P < .001$, interaction $P = .04$), suggesting that improvements in expertise and technology have narrowed the gap.

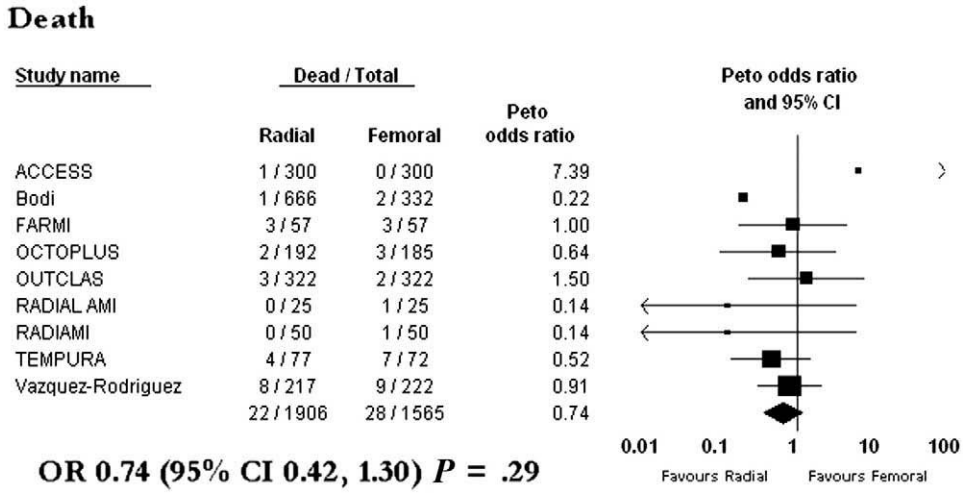
There appeared to be a trend towards higher failure rate of crossing lesion with wire, balloon, or stent with radial access with a rate of 60 (4.7%) of 1,274 patients in the radial group compared to 40 (3.4%) of 1,186 patients in the femoral group (OR 1.31 [95% CI 0.87-1.96], $P = .20$), as shown in Figure 4. For studies performed by radial experts, the rates were similar with radial and femoral access (OR 1.18 [95% CI 0.77-1.81], $P = .44$), whereas studies by nonradial experts had a 3-fold risk of not being able to cross the lesion with wire balloon or stent with radial access (OR 3.47 [95% CI 0.91-13.21], $P = .07$) suggesting expertise may be important.

Procedural, fluoroscopy times, and hospital length of stay

Radial access was associated with a significantly longer procedural time with a weighted mean difference (WMD) of 3.1 min (95% CI 2.4-3.8, $P < .001$). However, there was significant heterogeneity ($P < .001$, $I^2 = 87\%$) with a larger difference in procedural time in studies performed by non–radial experts (WMD 4.8 minutes [95% CI 3.7-5.8 minutes] compared to radial experts (WMD 1.7 minutes [95% CI 0.7-2.6 minutes], interaction $P < .001$).

For fluoroscopy time, which is a surrogate of radiation dose, radial access was associated with a longer fluoroscopy time, WMD 0.4 minutes (95% CI 0.3-0.5 minutes, $P < .001$). Finally, there was a lower hospital length of stay

Figure 3



Forest plots for death for radial versus femoral access. Tests for heterogeneity and mortality ($P = .92$ and $i^2 = 0\%$).

Table III. Summary of outcomes of radial versus femoral access for coronary angiography or intervention

	No./total (%)			
	Radial	Femoral	Odds ratio (95% CI)	P
Major bleeding	13/2390 (0.05)	48/2068 (2.3)	0.27 (0.16, 0.45)	<.001
Death, MI, or stroke	56/2209 (2.5)	71/1874 (3.8)	0.71 (0.49, 1.01)	.058
Death	22/1906 (1.2)	28/1565 (1.8)	0.74 (0.42, 1.30)	.29
Myocardial infarction	39/1931 (2.0)	46/1595 (2.9)	0.76 (0.49, 1.17)	.21
Stroke	2/1428 (0.1)	5/1107 (0.5)	0.39 (0.09, 1.75)	.22
Access site crossover	150/2542 (5.9)	34/2460 (1.4)	3.82 (2.83, 5.15)	<.001
Inability to cross the lesion with a wire, balloon or stent during PCI	60/1274 (4.7)	40/1186 (3.4)	1.31 (0.87, 1.96)	.20

with radial access with a WMD of −0.4 days (95% CI −0.2 to −0.5, $P < .001$) compared to femoral access.

Discussion

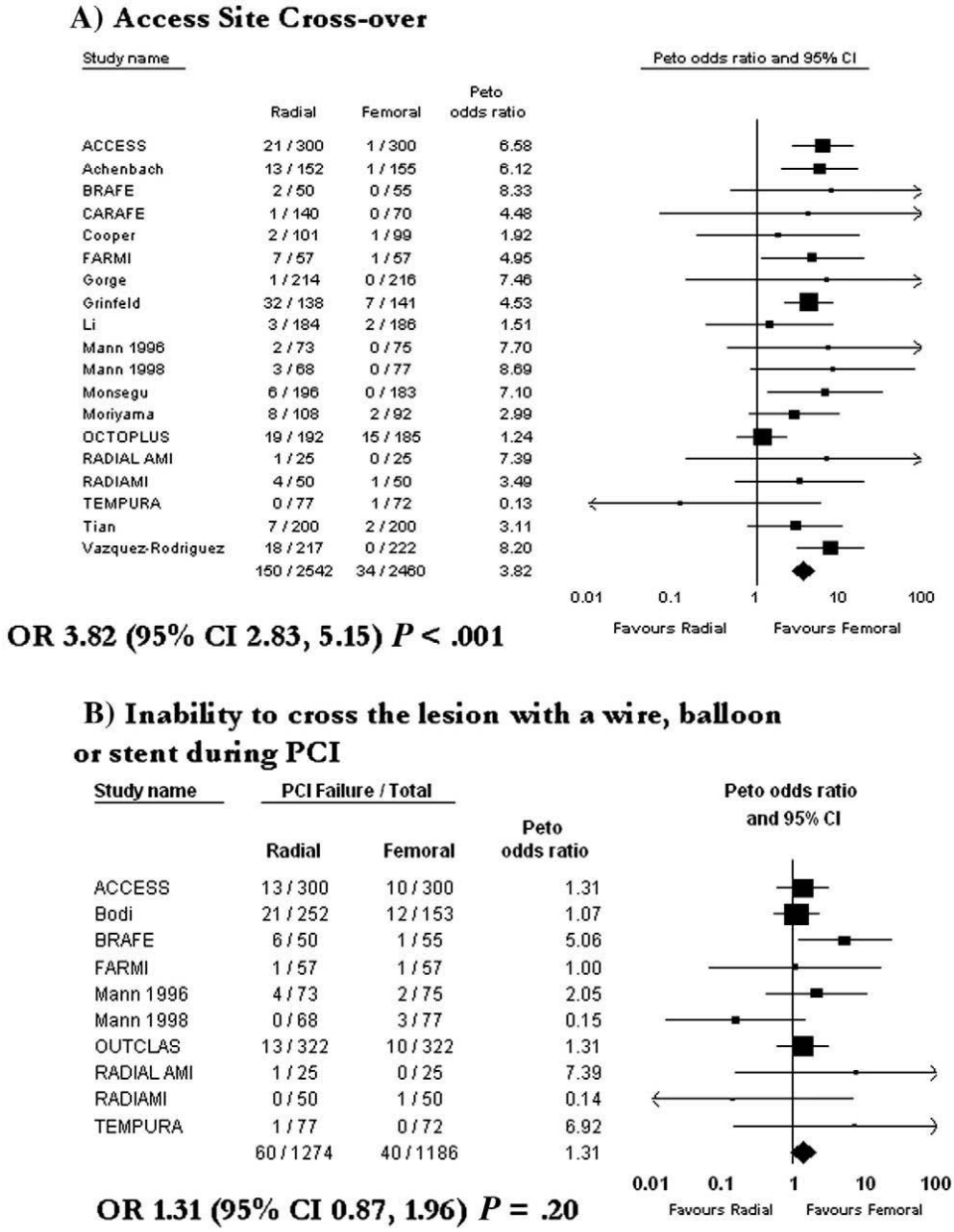
Radial access reduced the odds of major bleeding by 73% in patients undergoing coronary angiography or intervention compared to femoral access. There was a trend toward reduction in the composite of death, MI, or stroke comparing radial vs. femoral access but, because of low event rates, lacked statistical power. The point estimate suggests a possible clinically relevant 30% reduction in cardiovascular events, emphasizing the need for adequately powered randomized trials.

These findings differ from a meta-analysis performed in 2004, which showed similar rates of major adverse cardiac events with radial access (death, MI, stroke, emergent PCI, or coronary artery bypass surgery). This may be due to the current meta-analysis' increased power with the addition of 5 randomized trials (3 of which were in STEMI) composed of more than 2,000 additional patients.

There was a nonsignificant trend for a higher rate of failure to cross lesions with wire, balloon, or stent with radial access, but this appeared to vary depending on radial expertise. In the previous meta-analysis by Agostini, the definition of procedural failure included access site crossover. We specifically differentiated access site crossover from inability to cross the lesion with a wire, balloon, or stent in order to help differentiate the relative impact of reduced guide support with radial access versus inability to gain radial access. Further trials are necessary to determine if radial access reduces PCI success rates in operators with sufficient expertise.

The previous meta analysis had demonstrated that radial access reduced all access site complications.[1] Those access site complications included hematomas prolonging hospital discharge, pseudoaneurysms requiring ultrasound guided compression or thrombin

Figure 4



Forest plots for access site cross-over and inability to cross the lesion with a wire, balloon or stent for radial versus femoral access. Tests for heterogeneity, access site crossover ($P = .26$, $i^2 = 16\%$) and inability to cross the lesion with wire, balloon, or stent ($P = .71$, $i^2 = 0\%$).

injection, as well as major bleeding and ischemic complications. We restricted our analysis to major bleeding because of the increasing evidence relating major bleeding with mortality and recurrent ischemic events and found a similar benefit with radial access.[3,4]

Several large observational studies have demonstrated that radial access reduces major bleeding compared to femoral access.[2,35,36] An analysis of >32 000 PCI procedures demonstrated that radial access was associated with a reduction in mortality (OR 0.83 [0.71-0.98]) after adjustment for covariates.[36] Similarly, a large international registry demonstrated that radial access was independently associated with a lower risk of death or MI after PCI (OR 0.52 [0.31-0.89]) but these results from observational studies need to be confirmed in randomized trials.[35]

Study limitations

Individual patient data were not available for the trials so we cannot determine if the patients that developed a major bleeding event had ischemic events. However, our findings are consistent with reports of other therapies that reduce bleeding and improve overall outcome.[5] Furthermore, many of these studies were small and did not detail the number of patients screened and were performed in highly expert radial centers which may limit the external validity of these results.

Radial access reduced the odds of major bleeding by 73% and reduced hospital length of stay after coronary angiography and intervention compared to femoral access (summary Table III). This reduction in major bleeding corresponded to a trend for reduction in ischemic events with radial access. Large randomized trials are needed to confirm that radial access has an impact on mortality and ischemic events compared to femoral access and maybe necessary to change practice worldwide.

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