Comparison of transradial and femoral approaches for percutaneous coronary interventions: A systematic review and hierarchical Bayesian meta-analysis

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Background Despite lower risks of access site–related complications with transradial approach (TRA), its clinical benefit for percutaneous coronary intervention (PCI) is uncertain. We conducted a systematic review and meta-analysis of clinical studies comparing TRA and transfemoral approach (TFA) for PCI.

Methods Randomized trials and observational studies (1993-2011) comparing TRA with TFA for PCI with reports of ischemic and bleeding outcomes were included. Crude and adjusted (for age and sex) odds ratios (OR) were estimated by a hierarchical Bayesian random-effects model with prespecified stratification for observational and randomized designs. The primary outcomes were rates of death, combined incidence of death or myocardial infarction, bleeding, and transfusions, early (≤30 days) and late after PCI.

Results We collected data from 76 studies (15 randomized, 61 observational) involving a total of 761,919 patients. Compared with TFA, TRA was associated with a 78% reduction in bleeding (OR 0.22, 95% credible interval [CrI] 0.16-0.29) and 80% in transfusions (OR 0.20, 95% CrI 0.11-0.32). These findings were consistent in both randomized and observational studies. Early after PCI, there was a 44% reduction of mortality with TRA (OR 0.56, 95% CrI 0.45-0.67), although the effect was mainly due to observational studies (OR 0.52, 95% CrI 0.40-0.63, adjusted OR 0.49 [95% CrI 0.37-0.60]), with an OR of 0.80 (95% CrI 0.49-1.23) in randomized trials.

Conclusion Our results combining observational and randomized studies show that PCI performed by TRA is associated with substantially less risks of bleeding and transfusions compared with TFA. Benefit on the incidence of death or combined death or myocardial infarction is found in observational studies but remains inconclusive in randomized trials. (Am Heart J 2012;163:632-48.)

The transradial approach (TRA) for coronary angiography was initially described by Campeau[1] in 1989 and for percutaneous coronary interventions (PCIs) by Kiemeneij and Laarman[2] in the early 90s. Although the technique was rapidly adopted by a few groups in Europe, Canada, United States, and Asia, widespread application has not occurred. The obvious advantage of the radial artery compared with the femoral artery is the superficiality of the vessel with no adjacent structures susceptible to be damaged during percutaneous procedures. Hence, despite the use of aggressive antithrombotic regimens required for PCI, the artery is readily compressible, and introducer sheaths can be immediately removed upon completion of procedures. Hemostasis can be achieved safely and rapidly using simple compressive hemostatic devices. Two previous meta-analyses reviewing randomized trials comparing TRA with the traditional transfemoral approach (TFA) for diagnostic coronary angiography or interventions estimated a 73% reduction in the risk of access site–related bleeding and an 80% risk reduction of major bleeding.[3,4] These benefits are associated with earlier ambulation, increased patient comfort, and reduced hospitalization duration with substantial cost containment. However, smaller caliber of the radial artery as well as the greater anatomical variability of vascular course and distribution in the arm has been associated with a steep learning curve resulting in an increase in procedural failure and a higher rate of cross-over to femoral route.[4]

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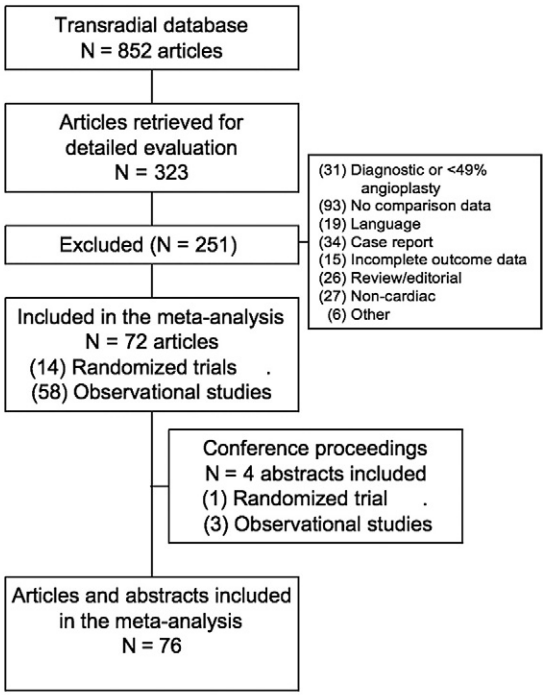
Figure 1



Conference proceedings: American College of Cardiology (1994-2011), American Heart Association (1994-2010), European Society of Cardiology (1994-2010), and Transcatheter Cardiovascular Therapeutics (2000-2010) annual scientific sessions.

Flow diagram of trials selection.

Multiple studies have identified the incidence of major bleeding (using several definitions) as a strong independent predictor of increased risks of early and late death or major adverse cardiovascular events (MACE) in patients presenting with acute coronary syndromes (ACSs) and undergoing invasive procedures.[5] More recently, a few pharmacologic trials in ACSs have demonstrated important reductions in the incidence of major bleeding with new agents compared with standard therapies. This impact on bleeding is, in turn, associated with a reduction in the periprocedural risk of mortality. In previous PCI trials, access site bleeding represented 50% to 80% of all major bleeding, and thus, it is possible that TRA through its association with lower bleeding risk could favorably influence the risk of death and MACE after PCI. We, therefore, undertook a systematic review and meta-analysis of all available data comparing TRA with TFA in PCI studies to estimate the potential benefits of TRA on clinical outcomes.

Methods

Search strategy and data collection

We carried out this review and meta-analysis with standard protocols recommended by the PRISMA group for randomized trials and MOOSE group for observational studies.[6,7] We searched the PubMed database, EMBASE, and the Cochrane Library, using the terms *radial*, *trans-radial*, and *coronary* (last update: June 30, 2011). We restricted our selection to publication in English, French, or Spanish. References of selected studies and all abstracts from international cardiology meeting programs (European Society of Cardiology, American College of Cardiology, American Heart Association, Transcatheter Cardiovascular Therapeutics [TCT], and Euro-PCR) were searched for relevant data. To be included, the studies needed to report clinical outcomes in TRA and TFA groups. When study results were reported in abstract form and subsequently in a full article, only results from the published manuscript were considered. When only abstracts data were available, authors were directly contacted to provide more complete data and/or full manuscript. Only abstracts with complete data were included. Three evaluators (O.C., D.J., and O.B.) performed literature searches, and 2 (O.C. and O.B.) extracted data independently. Discrepancies between data sets were resolved by consensus, if necessary after contact with authors.

Classification of studies and outcome definitions

We classified the studies based on randomized or observational design. Because the objective was to determine the clinical impact of TRA compared with TFA after PCI, only studies with ≥50% PCI rate were included. The clinical outcomes investigated both ischemic and bleeding outcomes. Ischemic outcomes included rates of all-cause mortality and the combined incidence of death or myocardial infarction (MI), early (within 30 days after PCI) and at late follow-up (>1 month). In those studies, MI was most commonly defined as a new increase in creatine phosphokinase-MB ≥3 times the upper limit of the normal reference range with or without electrocardiographic changes. Rates of nonfatal MI were not provided separately in some reports, so the reported rates of MI may have included a number of fatal MI. Bleeding complications included both standardized and study-specific definitions. Most major bleeding definitions involved fatal bleeding, intracranial bleeding, bleeding associated with either hemoglobin level drop ≥3 g/dL or ≥5 g/dL, or access-related bleeding/complications requiring transfusion or surgery. Transfusion rates were also compared.

Statistical analysis

Differences in study methods, patients' characteristics and practice patterns mean that the true effect from each study is likely to vary and a fixed-effects meta-analysis model would not account for this between-study variation. We, therefore, used a Bayesian hierarchical random-effects model to synthesize the results.[8,9] In this model, the probability of an event is allowed to vary both between the TRA and TFA groups within each study and between each study included in the meta-analysis. To model the between-study variability, the logarithm of the odds ratio (OR) of each outcome variable is assumed to follow a normal distribution. The mean of the normal distribution of log ORs across studies, therefore, represents the average effect in the studies, and the variance represents the variability in log ORs across studies. Bayesian analysis allows for the combination of existing knowledge with new information according to the existing rules of probability. Substantive prior knowledge can thereby be included into any Bayesian analysis by choice of initial (predata) distribution. However, because we

Table I. Characteristics of included studies

Author	Year	Rand	TRA, n	TFA, n	TRA male, n	TFA male, n	TRA age, y	TFA age, y	Heparin %	GPI, %	Bival, %	Bleeding definition
Kiemeneij et al[10]	1995	No	35	25	30	21	62	57	100	0	0	Requiring additional diagnostic or therapeutic procedures
Mann et al[11]	1995	No	50	100	39	N/A	60	N/A	100	0	0	Hematoma delaying hospital discharge, retroperitoneal bleed, pseudoaneurysm
Mann et al[12]	1996	Yes	73	75	53	52	64	62	100	0	0	Requiring transfusion, hematoma delaying discharge, surgical repair
Mann et al[13]	1996	No	175	202	128	139	63	60	100	0	0	Retroperitoneal bleed, AV fistula, pseudoaneurysm, large hematoma, delaying discharge
Benit et al[14]	1997	yes	56	56	56	56	58	58	100	0	0	Fatal bleeding, requiring blood transfusion or vascular surgery, Hb drop >3 g/dL, intracranial hemorrhage
Kiemeneij et al[15]	1997	Yes	300	300	221	220	61	62	100	0	0	Hb drop ≥2 mmol/L, blood transfusion, vascular repair
Mann et al[16]	1998	Yes	65	77	42	52	63	62	100	13	0	Access site bleeding delaying discharge
Saito et al[17]	1999	No	1360	793	987	559	65	68	N/A	N/A	N/A	Access site bleeding, hematoma or pseudoaneurysm requiring blood transfusion and/or surgical repair
Choussat et al[18]	2000	No	83	67	75	59	65	64	100	89	0	Access site bleeding: Hb drop ≥2 mmol/L, blood transfusion, vascular repair, or prolonged hospitalization
Kim et al[19]	2000	No	30	26	25	18	56	59	100	1.8	0	Access site bleeding complications
Mann et al[20]	2000	Yes	109	109	70	61	65	60	100	21	0	Access site bleeding delaying discharge
Morice et al[21]	2000	No	376	580	N/A	N/A	N/A	N/A	100	5.1	0	Access site complication: hematoma delaying discharge, hematoma requiring transfusion, surgical repair
Chugh et al[22]	2002	Yes	45	98	N/A	N/A	64	62	100	5.6	N/A	Hb drop ≥2 g/dL, blood transfusions, need for vascular repair
Louvard et al[23]	2002	No	267	947	223	725	60	62	100	13	0	Hb drop >3 g/dL
Galli et al[24]	2003	No	390	100	292	71	62	64	100	0	0	Access site complication: hematoma small and large
Saito et al[25]	2003	Yes	77	72	62	59	66	67	100	0	0	Requiring transfusion, surgical repair, or cerebral bleeding
Valsecchi et al[26]	2003	No	163	563	126	426	62	62	100	21	0	Intracranial hemorrhage, cardiac tamponade, Hb drop >5g/dL
Yang et al[27]	2003	No	153	24	127	15	64	62	100	0	0	–
Ziakas et al[28]	2003	No	100	67	80	39	59	67	N/A	64	0	Hb drop >3 g/dL, blood transfusion, surgical repair
Diaz et al[29]	2004	No	103	59	93	45	55	61	100	67	0	Access site–related hemorrhage (Hb drop ≥4g/dL) requiring transfusion, surgical repair, or hematoma delaying discharge
Kassam et al[30]	2004	No	47	64	39	49	56	56	100	100	0	Intracranial or retroperitoneal bleeding, drop in Hb >5 g/dL or Ht ≥15%, or transfusion
Louvard et al[31]	2004	Yes	192	185	106	94	83	83	N/A	29	0	Vascular surgery, blood transfusion, delaying discharge, Hb drop ≥3 g/dL, Ht drop ≥10%, acute arm/leg ischemia, forearm compartment syndrome
Philippe et al[32]	2004	No	64	55	48	40	59	60	100	100	0	Hb drop ≥ 2 mmol/l, blood transfusion, vascular repair, or prolonged hospitalization
Yip et al[33]	2004	No	42	101	31	80	62	61	N/A	30	N/A	Hb drop >3 g/dL, requiring blood transfusion
Ziakas et al[34]	2004	No	27	53	23	37	75	71	100	35	0	Vascular access complications requiring transfusion or surgical repair
Cantor et al[35]	2005	Yes	25	25	19	25	52	58	100	94	0	Intracranial or retroperitoneal bleeding, Hb drop >5 g/dL or Ht ≥15%, transfusion
Kim et al[36]	2005	No	220	132	147	82	62	64	N/A	N/A	0	Access site bleeding: Hb drop ≥2 mmol/L, blood transfusion, vascular repair, and prolonged hospitalization

Table I. (*continued*)

Author	Year	Rand	TRA, n	TFA, n	TRA male, n	TFA male, n	TRA age, y	TFA age, y	Heparin %	GPI, %	Bival, %	Bleeding definition
Slagboom et al[37]	2005	Yes	322	322	241	249	60	60	100		0	Access site bleeding complications
Ziakas et al[38]	2005	No	132	202	116	167	71	69	100	31	0	Vascular complication requiring transfusion
Brasselet et al[39]	2007	Yes	57	57	49	47	60	58	N/A	N/A	0	TIMI major bleeding
Cantor et al[40]	2007	No	413	8922	297	5889	66	67	50	N/A	0	TIMI major bleeding
Cruden et al[41]	2007	No	44	243	32	206	59	59	100	39	0	Access site bleeding, digital ischemia, hematoma, pseudoaneurysm, or AV fistula
Jaffe et al[42]	2007	No	97	131	65	70	82	83	100	57	0	Bleeding, large hematoma, transfusion, vascular repair
Yang et al[43]	2007	No	60	74	58	60	56	58	100		0	–
Ziakas et al[44]	2007	No	87	68	56	43	76	78	100	67	0	Blood transfusion, surgical repair, Hb drop >3g/dL
Chase et al[45]	2008	No	7972	30900	6003	22464	65	64	N/A	N/A		Requiring transfusion
Eichhofer et al[46]	2008	No	3214	10285	2494	7251	63	63	100	84	0	Hematoma delaying discharge, pseudoaneurysm, fistula, thrombosis, cellulites, limb ischemia, transfusion due to access site blood loss, retroperitoneal bleed
Hsueh et al[47]	2008	No	116	15	89	8	67	66	100	0	0	TIMI major bleeding
Montalescot et al[48]	2008	No	841	7059	N/A	N/A	N/A	N/A	47	19	0.2	Fatal, intracranial, intraocular, retroperitoneal hemorrhage, clinically overt blood loss and Hb drop >4 g/dL, transfusion
Rao et al[49]	2008	No	7804	585290	5534	383891	64	65	53	40	39	Retroperitoneal, gastrointestinal, genitourinary, requiring transfusion, prolonged hospitalization, or Hb drop >3 g/dL
Roberts et al[50]	2008	No	1212	112	902	74	62	64	N/A	N/A	N/A	Hemodynamic instability, Hb drop, transfusion, large hematoma, retroperitoneal hematoma, pseudoaneurysm
Yan et al[51]	2008	No	57	46	43	34	70	71	100	100	0	Hb drop ≥2 mmol/L, blood transfusion, vascular repair, prolonged hospitalization
Badri et al[52]	2009	No	263	903	201	710	60	62	99	93	0	Requiring transfusion
Blicq et al[53]	2009	No	509	117	378	65	68	69	100	31	N/A	Gastrointestinal, Ht drop, hematoma (major or requiring surgical repair), transfusion, neurologic hemorrhage
Chodor et al[54]	2009	Yes	50	50	35	33	60	59	100	43	0	Fatal bleeding, requiring blood transfusion or operation, Hb drop >3 g/dL, intracranial hemorrhage
De Carlo et al[55]	2009	No	531	130	428	89	62	66	N/A	100	0	TIMI major bleeding
Hamon et al[56]	2009	No	798	11989	610	8332	61	63	33	67	67	TIMI major bleeding
Hetherington et al[57]	2009	No	571	480	428	319	62	65	100	92	0	Access site hemorrhage/hematoma requiring transfusion or delaying discharge or proved false aneurysm formation
Rathore et al[58]	2009	No	318	150	257	123	65	63	100	66	0	Access site hematoma small (<5 cm) and large (>5 cm)
Rathore et al[59]	2009	No	51	64	46	56	65	63	100	64	0	Access site hematoma small (<5 cm) and large (>5 cm)
Ruzsa et al[60]	2009	No	167	372	120	273	62	64	100	29	0	Hb drop ≥2 mmol/L, blood transfusion, vascular repair, and prolonged hospitalization
Sciahbasi et al[61]	2009	No	307	863	223	566	65	68	31	39	0	Intracranial or retroperitoneal bleeding or other overt bleeding with Hb drop ≥3 g/dL
Watt and Oldroyd[62]	2009	No	75	76	55	45	68	68	100	46	0	Hemodynamic compromise and/or blood transfusion
Yip et al[63]	2009	No	506	810	413	682	61	62	100	12	0	Hb drop >3 g/dL requiring blood transfusion
Zimmermann et al[64]	2009	No	218	286	N/A	N/A	N/A	N/A	100	76	N/A	Substantial hemodynamic compromise requiring treatment

(*continued on next page*)

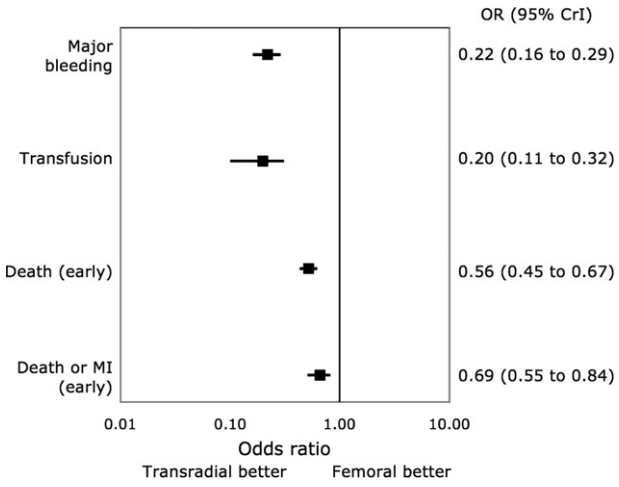
Table I. (*continued*)

Author	Year	Rand	TRA, n	TFA, n	TRA male, n	TFA male, n	TRA age, y	TFA age, y	Heparin %	GPI, %	Bival, %	Bleeding definition
Arzamendi et al[65]	2010	No	238	251	192	147	59	64	97	81	0	Intracranial, intraocular, access site bleed requiring intervention, hematoma ≥5 cm, Hb drop ≥4 g/dL without overt bleed or ≥3 g/dL with overt bleed, requiring transfusion or operation
Bertrand et al[66]	2010	No	90	13	51	5	85	82	89	32	11	Requiring transfusion
Caixeta et al[67]	2010	No	200	3134	146	2426	59	60	71	52	50	TIMI major bleeding
Hou[68]	2010	Yes	100	100	72	69	65	66	100	48	0	Hb drop ≥2 mmol/L, blood transfusion, requiring vascular repair
Jones et al[69]	2010	No	1472	6562	1137	4730	64	64	95	40	0	Requiring transfusion
Koutouzis et al[70]	2010	No	40	301	15	171	84	84	63	45	37	Hb drop >2 mmol/L, blood transfusion, requiring vascular repair or delaying discharge
Pancholy et al[71]	2010	No	109	204	77	125	64	66	100	98	N/A	Requiring transfusion
Rao et al[72]	2010	No	339	10578	234	6907	64	64	N/A	36	N/A	Requiring transfusion
Siudak et al[73]	2010	No	169	917	128	688	63	64	94	100	0.1	Requiring transfusion, intracranial hemorrhage
Tizon-Marcos et al[74]	2010	No	779	112	N/A	N/A	N/A	N/A	N/A	33	N/A	TIMI major bleeding
Vazquez Rodriguez[75]	2010	No	217	222	184	186	60	62	N/A	60	N/A	Fatal bleeding, intracranial hemorrhage, Hb drop ≥3 g/dL, requiring transfusion or vascular surgery
Weaver et al[76]	2010	No	124	116	102	92	60	61	N/A	N/A	N/A	TIMI major bleeding
Yang et al[77]	2010	No	400	19	341	17	62	61	100	N/A	N/A	Requiring transfusion
Yang et al[78]	2011	No	353	468	275	360	59	61	100	8	N/A	TIMI major and minor bleeding
Cayla et al[79]	2011	No	296	54	218	78	66	66	30	61	N/A	Fatal, retroperitoneal, intracranial, intraocular; requiring treatment or surgery or decompression, transfusion, Hb drop ≥3 g/dL with overt bleed
Deftereos et al[80]	2011	No	65	33	48	25	65	63	100	56	N/A	Blood transfusion, vascular repair, prolonged hospitalization
Hamon et al[81]	2011	No	872	7013	N/A	N/A	64	65	N/A	25	N/A	Clinically overt bleeding either fatal, intracranial, intraocular, retroperitoneal, Hb drop ≥3 g/dL, or requiring transfusion
Jen et al[82]	2011	No	85	37	70	20	60	68	100	30	N/A	Requiring transfusion, vascular access bleeding, gastrointestinal, intracranial
Jolly et al[83]	2011	Yes	3507	3514	2599	2561	62	62	32	25	2.6	Fatal; requiring transfusion, treatment, or surgery; intracranial; intraocular; Hb drop ≥5 g/dL
Olivecrona[84]	2011	No	6049	15290	4396	10797	66	66	N/A	65	20	Intracranial or other bleeding with Hb drop >5 g/dL
Wu et al[85]	2011	No	462	625	367	414	62	63	80	68	N/A	Entry site, retroperitoneal, gastrointestinal, and genital-urinary bleeding, requiring transfusion or prolonged hospitalization, Hb drop ≥3 g/dL

N/A, Not available; *Rand*, randomized, *GPI*, glycoprotein IIb-IIIa inhibitors; *Bival*, bivalirudin; *Hb*, hemoglobin; *AV*, arteriovenous; *Ht*, hematocrit.

incorporated all relevant past studies, we wanted our final (posterior) distributions to reflect the information in our data set only and not to be influenced by our choice of initial (prior) distribution. Therefore, low-information prior distributions were used throughout, so that the data from the studies dominated the final inferences. In particular, we used normal (mean 0, SD 1000) prior distributions for all means and uniform prior distributions on the range from 0 to 10 for all SD parameters. Therefore, our estimates of ORs and their associated 95% credible intervals (CrI) (which are the Bayesian equivalent of standard CIs) were not unduly affected by our choice of prior distribution. As most of our studies were observational, there is a risk of selection bias in our estimated treatment effect. We, therefore, adjusted for between-treatment differences in age and sex via a Bayesian hierarchical metaregression model. The structure of the model was identical to that described above, except that the treatment effect on the log-odds scale was allowed to depend on age and

Figure 2



Effects of TRA versus TFA in clinical outcomes. Graph with OR and 95% 95% CrIs for all studies for bleeding complication and transfusion, early death and early death or MI.

sex linear regression coefficients. Similar diffuse normal prior distributions were used for the regression coefficients. All inferences were carried out using WinBUGS software (version 1.4; MRC Biostatistics Unit, Cambridge, UK). Forest plots were produced to display the ORs and 95% CrIs for all major outcomes both for the individual trials and for the pooled results from our meta-analysis. Separate analyses were carried out for randomized and observational studies to compare effect sizes, and a third analysis combined all information from all studies regardless of design.

No extramural funding was used to support this work. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the manuscript, and its final contents.

Results

From our literature search, we identified 852 articles using TRA for coronary interventions. From these articles, we selected 72 articles comparing clinical outcomes between TRA and TFA in randomized trials (n = 14) or observational studies (n = 58). Over the same period, we also scrutinized abstracts from meetings of the European Society of Cardiology, American Heart Association, American College of Cardiology, TCT, and Euro-PCR. From this source of information, we retained only 4 abstracts with complete data comparing TRA and TFA, 1 randomized trial, and 3 observational studies (Figure 1).

Baseline characteristics

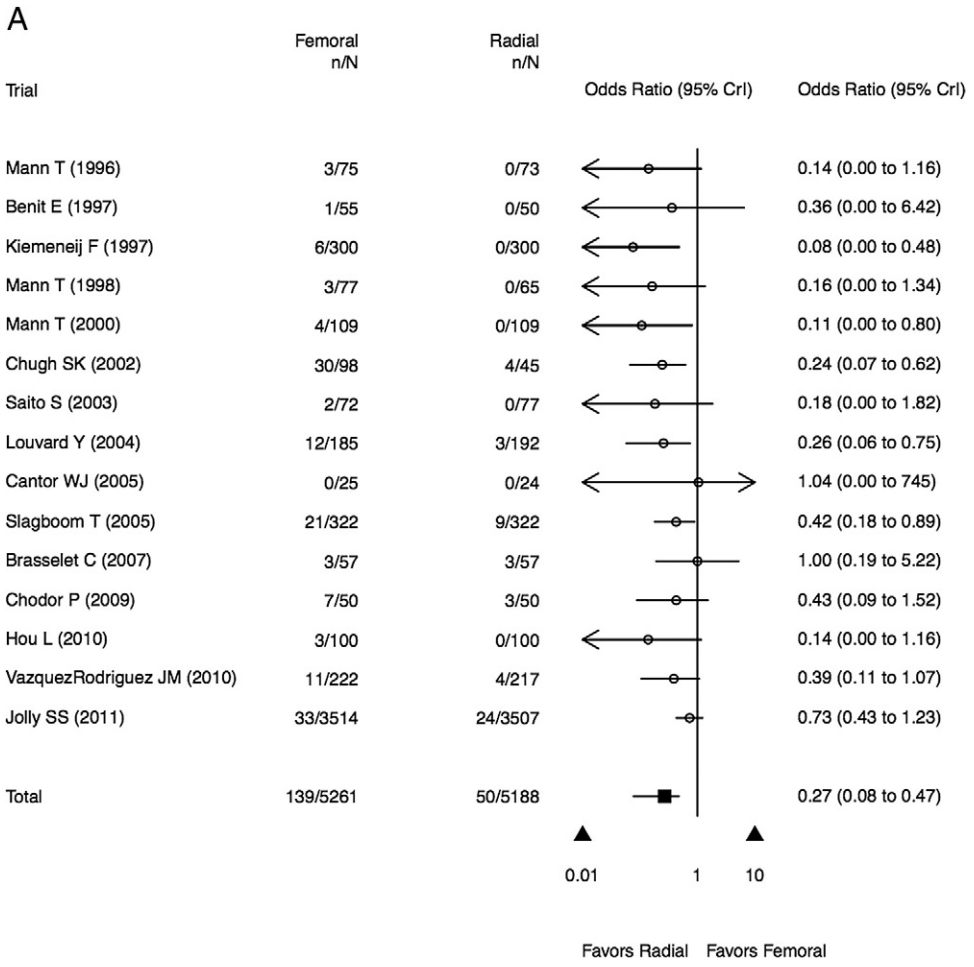
Characteristics of study populations are shown in Table I. Our comprehensive review involved a total of 761,919 patients with 47,385 treated by TRA and 714,534 treated by TFA. Patients in randomized trials included 5,195 and 5,262 treated by TRA and TFA, respectively. Studies were single center (n = 55), dual center (n = 4), or multicenter (n = 17). Sixteen studies were conducted in the United States, 39 in Europe, and 19 in Asia. The mean age of TRA patients was 64 years and 65 years for TFA patients. Patients in randomized trials were slightly younger (63 vs 65 years) and more often male (75% vs 74%) than in the observational studies. Most studies involved heparin only or heparin ± platelet glycoproteins IIb-IIIa inhibitors with only 12 studies using bivalirudin. The mean rates of cross-over were higher for TRA to TFA (4.5%) compared with TFA to TRA (0.6%). Most studies evaluated in-hospital (n = 56) or 30-day outcomes (n = 23) with 21 studies reporting clinical outcomes between 6 months and 5 years (only a single randomized trial reported long-term follow-up). Twenty-three studies excluded patients with cardiogenic shock.

Clinical outcomes. There was a major reduction in bleeding complications with TRA compared with TFA (OR 0.22 [95% CrI 0.16-0.29]) (Figure 2). The point estimate was similar in randomized trials (OR 0.27 [95% CrI 0.08-0.47]) and in observational studies (OR 0.21 [95% CrI 0.15-0.28]) (Figure 3). Furthermore, there was also a major reduction in transfusion rates associated with TRA compared with TFA (OR 0.20 [95% CrI 0.11-0.32]), with similar effects found in randomized (OR 0.25 [95% CrI 0.01-1.07]) and observational studies (OR 0.19 [95% CrI 0.09-0.30]) (Figure 4). Accordingly, we estimated that the number needed to treat (NNT) to prevent 1 major bleeding complication is 67 patients, and the NNT to prevent 1 transfusion is 47 patients.

The composite outcome of death or MI was also lower after TRA compared with TFA (OR 0.69 [95% CrI 0.55-0.84]) early after PCI. The effect was substantial in observational studies (OR 0.62 [95% CrI 0.47-0.80], adjusted OR for age and sex 0.62 [95% CrI 0.45-0.81]) and remained inconclusive in randomized trials (OR 0.94 [95% CrI 0.65-1.33]) (Figure 5). At late follow-up, the association between TRA and death or MI reduction was lower (OR 0.65 [95% CrI 0.35-1.02]). This analysis relied mainly on observational data (adjusted OR 0.62 [95% CrI 0.21-1.56]) because only 1 randomized study provided long-term data (Figure 6).

Considering all trials, the mortality rate was reduced by 44% after TRA compared with TFA (OR 0.56 [95% CrI 0.45-0.67]) early after intervention and at late follow-up (OR 0.56 [95% CrI 0.42-0.71]) (Figure 7). Early after intervention, this effect was mainly due to observational studies (OR 0.52 [95% CrI 0.40-0.63]), even after adjustment for age and sex differences (OR 0.49 [95% CrI 0.37-0.60]) compared with an OR of 0.80 (95% CrI 0.49-1.23) in randomized trials. We estimated an NNT of 230 patients to prevent 1 death.

Figure 3



Incidence of bleeding complication. Forest plot for bleeding complication in randomized (**A**) and observational studies (**B**). White circles are individual studies OR, and the black square is meta-analytic OR; horizontal lines are 95% CrI.

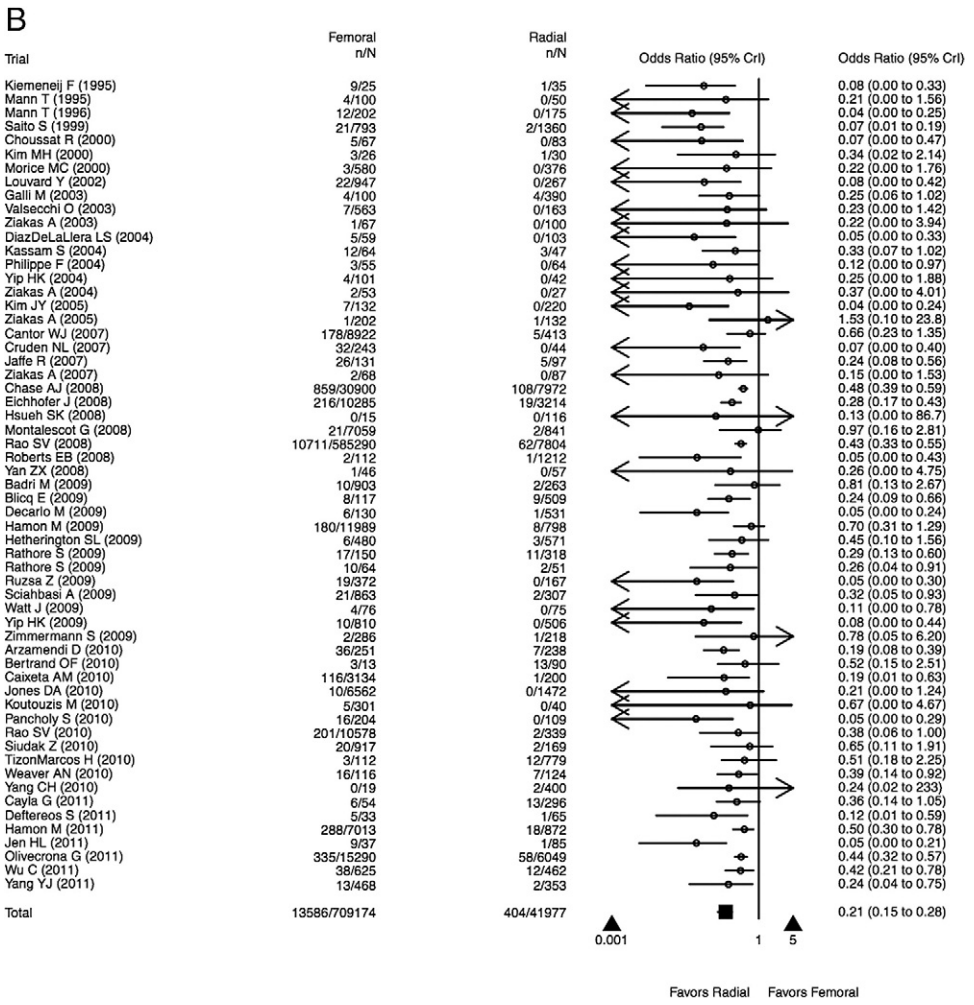
At late follow-up, the mortality benefit could only be inferred from observational studies (adjusted OR 0.53 [95% CrI 0.40-0.68]), as only 1 randomized trial provided long-term data (Figure 8).

Discussion

This comprehensive and systematic review of clinical data and large meta-analysis involving >760,000 patients demonstrates that there is a substantial reduction in the risks of periprocedural major bleeding and transfusion with PCI performed by TRA compared with TFA in both observational studies and randomized trials. Although observational studies seem to indicate a substantial and clinically relevant reduction in the risks of early and late death or combined incidence of death or MI, the same analysis applied to randomized trials remains inconclusive.

Two previous meta-analyses have compared TRA and TFA in randomized diagnostic angiography and coronary interventions studies.[3,4] Although both analyses found >70% reduction in entry site complications and major bleeding, sensitivity analyses suggested that this effect was maximal with PCI studies. Furthermore, although the first analysis in 2004 involving 1,155 PCI patients did not suggest a clinical benefit for TRA in terms of MACE (death, MI, stroke, urgent PCI, or coronary artery bypass graft) (OR 1.14, 95% CI 0.66-1.96), the second analysis performed in 2009 and involving 4,461 patients suggested a possible advantage for TRA in terms of the composite end point of death, MI, or stroke (OR 0.71 [95% CI 0.49-1.01]). Because these studies did not have sufficient sample size to accurately estimate effects on death and ischemic outcomes and included diagnostic procedures as well as PCI studies, we performed a comprehensive review of all clinical evidence generated

Figure 3



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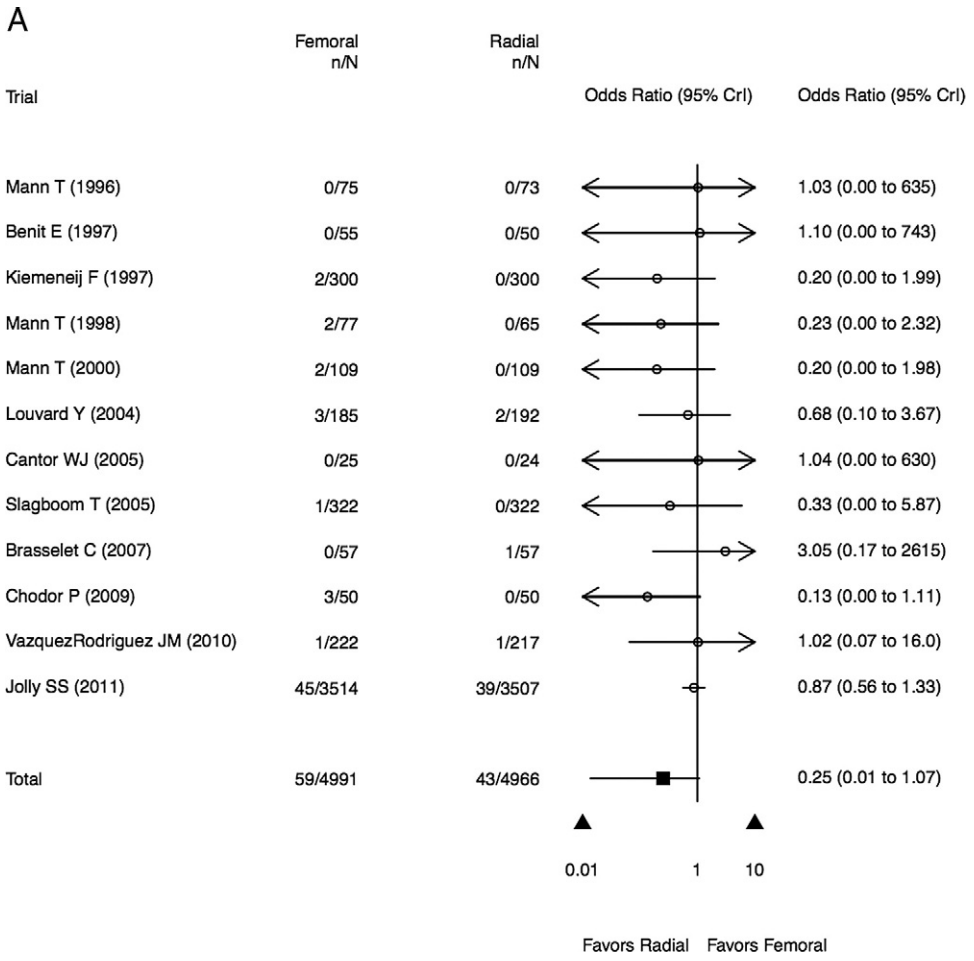
since the initial description of TRA and focusing on PCI studies. Using this considerable amount of patient data, we estimated a large benefit, with 78% reduction of bleeding complications and 80% reduction of transfusions. This effect is also of similar amplitude to the reduction of major bleeding found in a recent meta-analysis of observational and randomized studies in patients undergoing primary PCI.[86]

During PCI, it remains critical to control both ischemic and bleeding risks. Current antithrombotic and antiplatelet agents have been developed to prevent ischemic complications. Although peri-PCI ischemic risk has been better controlled with combinations of antithrombotic therapies, they are associated with a relative increase in bleeding complications. Although periprocedural bleeding has traditionally been considered as an acceptable risk of PCI, a large body of evidence has been accumulated showing the detrimental association between major bleeding and subsequent adverse outcomes.[87-90] Furthermore, related events such as anemia and transfusions have also been shown to be predictive of poorer outcomes in ACS or after PCI.[91]

In PCI trials, major bleeding can be categorized as access site–related and non–access site–related bleeding. Depending on the clinical setting (ACS vs non-ACS) and background antithrombotic regimen, access site–related bleeding accounts for 30% to 80% of major bleeding. New antithrombotic strategies using fondaparinux before PCI or bivalirudin during PCI have aimed to reduce bleeding risk while maintaining adequate anticoagulation to minimize ischemic complications. In ACS and high-risk patients, studies of these novel pharmacologic compounds have shown a significant reduction in the incidence of major bleeding, which has been associated

Figure 4



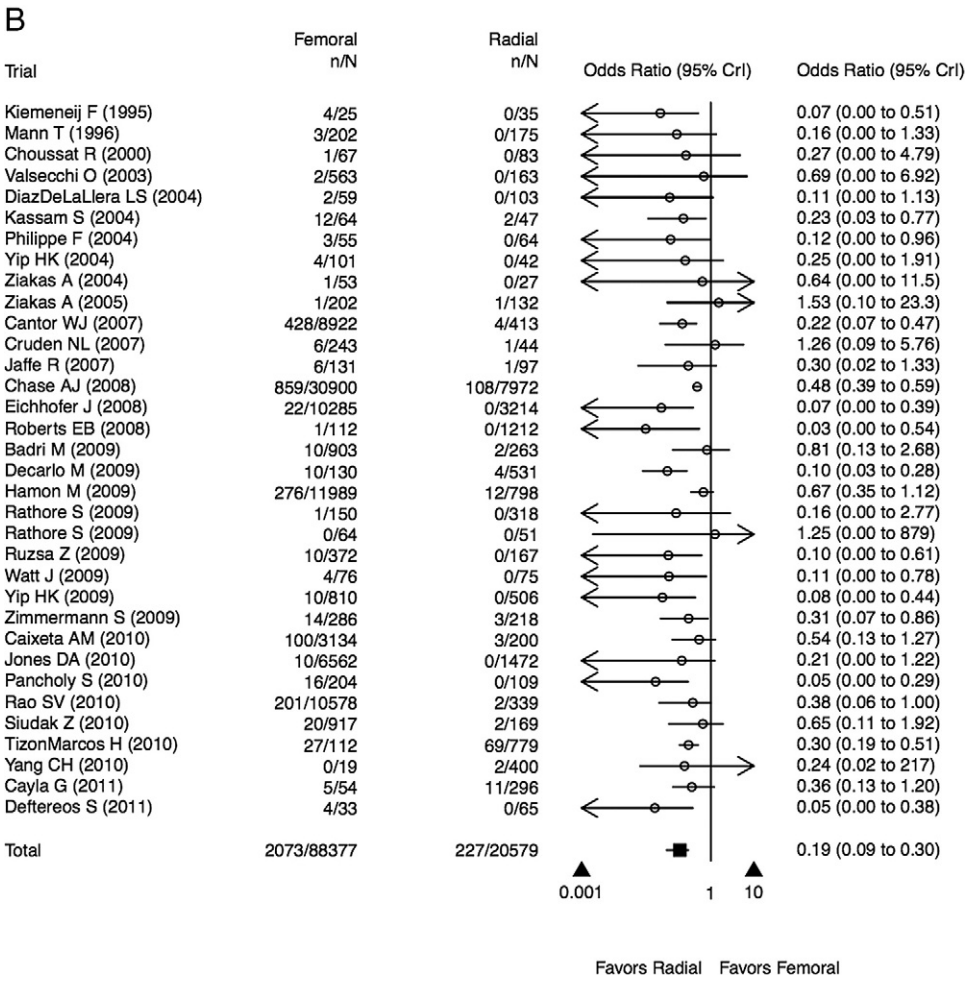
Incidence of transfusion. Forest plot for transfusions in randomized (**A**) and observational studies (**B**). Abbreviations as in Figure 3.

with a reduction in MACE.[88,92] However, much of the benefit has been attributed to a reduction in access site–related bleeding in patients treated by TFA.[56] Another approach to reduce access site bleeding is TRA. Although several bleeding definitions have been used across the clinical studies, there is strong evidence of a substantial reduction in bleeding complications and transfusion rates after TRA PCI. As shown in a study with TRA PCI and maximal antiplatelet therapy, it is likely that TRA minimizes the risks of access site–related bleeding even in the context of potent antithrombotic therapy.[87]

The mechanism by which a reduction in major bleeding and transfusion could impact survival directly or indirectly remains an open question. Major bleeding can lead to death through direct (eg, retroperitoneal hemorrhage) or indirect (eg, cessation of antithrombotic therapy with subsequent increase in thrombotic risk) mechanisms. It may also affect longer term mortality because patients having periprocedural bleeding may have transient or permanent interruption of recommended antithrombotic agents, hence leading to higher risk of recurrent ischemic events. Liberal use of blood transfusion has been associated with increased mortality risk after PCI.[91] Beyond traditional risks of contaminants or pathogen transmission, transfusion may be associated with impaired oxygen delivery to vital organs and tissues as well as promoting prothrombotic status and adverse inflammatory and immunomodulatory reactions.[5] In this regard, TRA seems an elegant yet simple technique to minimize both risks. Moreover, it has been surmised recently that TRA could reduce the risks of periprocedural incidence of kidney failure, hence indirectly influence post-PCI survival.[93]

In the recently completed and largest, to date, RIVAL randomized trial, the authors found no significant mortality benefit in the overall population but a statistically significant reduction in mortality with TRA in patients undergoing primary PCI for acute ST-segment elevation MI.[83] Thus, it may well be that maximum benefit for TRA can be found in higher risk population (with high

Figure 4



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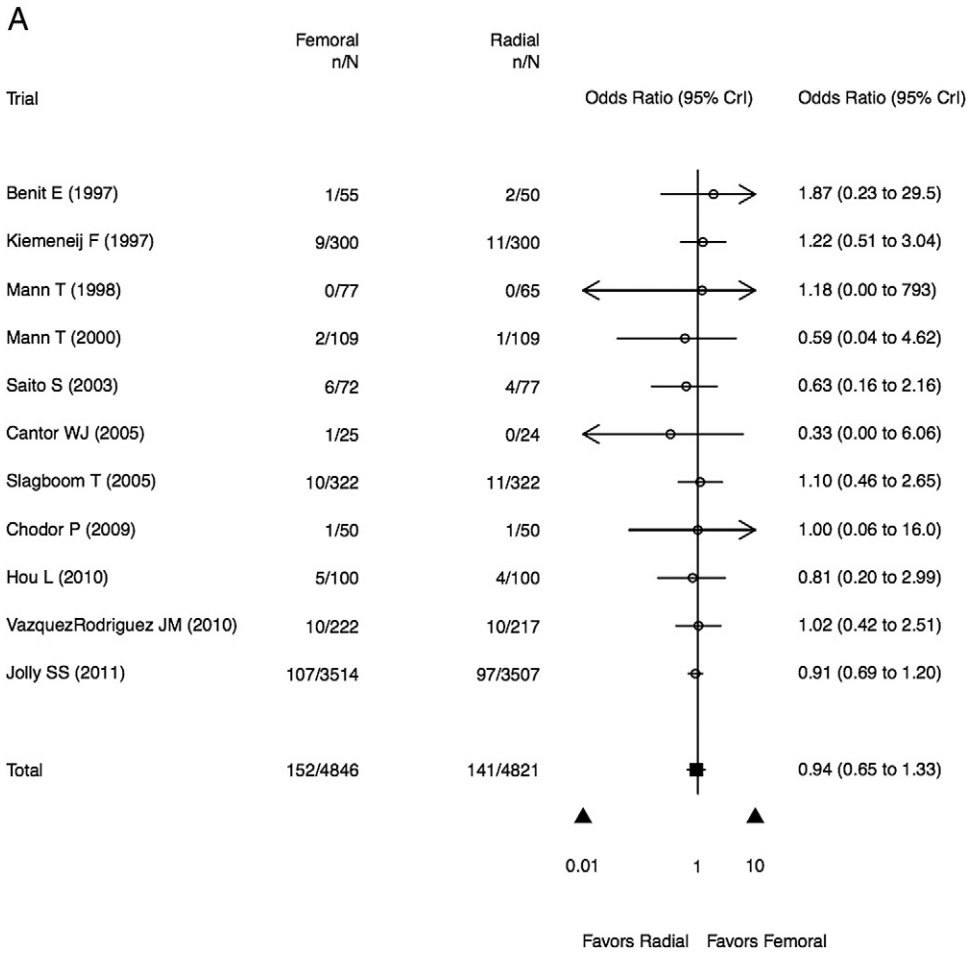
rate of PCI). In the RIFLE-STEACS trial Romagnoli et al (Late-Breaking Clinical Trial Session, TCT 2011, San Francisco, CA) reported a significant reduction in cardiac death from 9.2% in the TFA group to 5.2% in the TRA group ($P = .020$). A recent meta-analysis of 10 randomized trials in patients with ST-segment elevation MI (n = 3,347) found a 47% relative reduction in mortality with TRA (OR 0.53, 95% CI 0.33-0.84).[94] Because the benefit for TRA seems also linked to the experience of the centers, it appears logical from a health perspective to continue promoting education in TRA to expand the number of sites proficient with TRA techniques.[95]

There are several ongoing randomized trials comparing TRA with TFA. The RADIAL-CABG study (NCT 01446263) will randomize 128 patients after coronary artery bypass for diagnostic angiography and possible PCI. The STEMI-RADIAL (NCT 0113687) and SAFARI-STEMI trials (NCT 01398254) will randomize 700 patients and 1,274 patients in acute MI, respectively. The MATRIX trial (NCT 01433627) will randomize 6800 patients in ACSs. In the United States, the SAFE-PCI for WOMEN trial (NCT 01406236) will randomize 3,000 women referred for diagnostic angiography and possible PCI.

Several limitations of this meta-analysis should be acknowledged. The inclusion of observational studies may involve selection bias. To reduce this bias, we used 2 strategies: First, separate analyses for randomized trials and observational studies were conducted. Second, adjustment to take into account differences in age and sex was made. However, we cannot exclude that other selection bias or confounding variables such as differences in catheter sizes were present in observational studies and could not be taken into account in this analysis. In this study level meta-analysis, definitions for bleeding complications varied between studies. Whenever possible, data with the most

Figure 5



Incidence of early death or MI. Forest plot for composite of early death or MI in randomized (**A**) and observational studies (**B**). Abbreviations as in Figure 3.

conservative and standard definitions were used. Furthermore, although the threshold for transfusions may have varied among studies, it likely represented an objective way of comparing blood loss between TRA and TFA practices.

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Disclosures

There is no conflict of interest to disclose.

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Figure 5

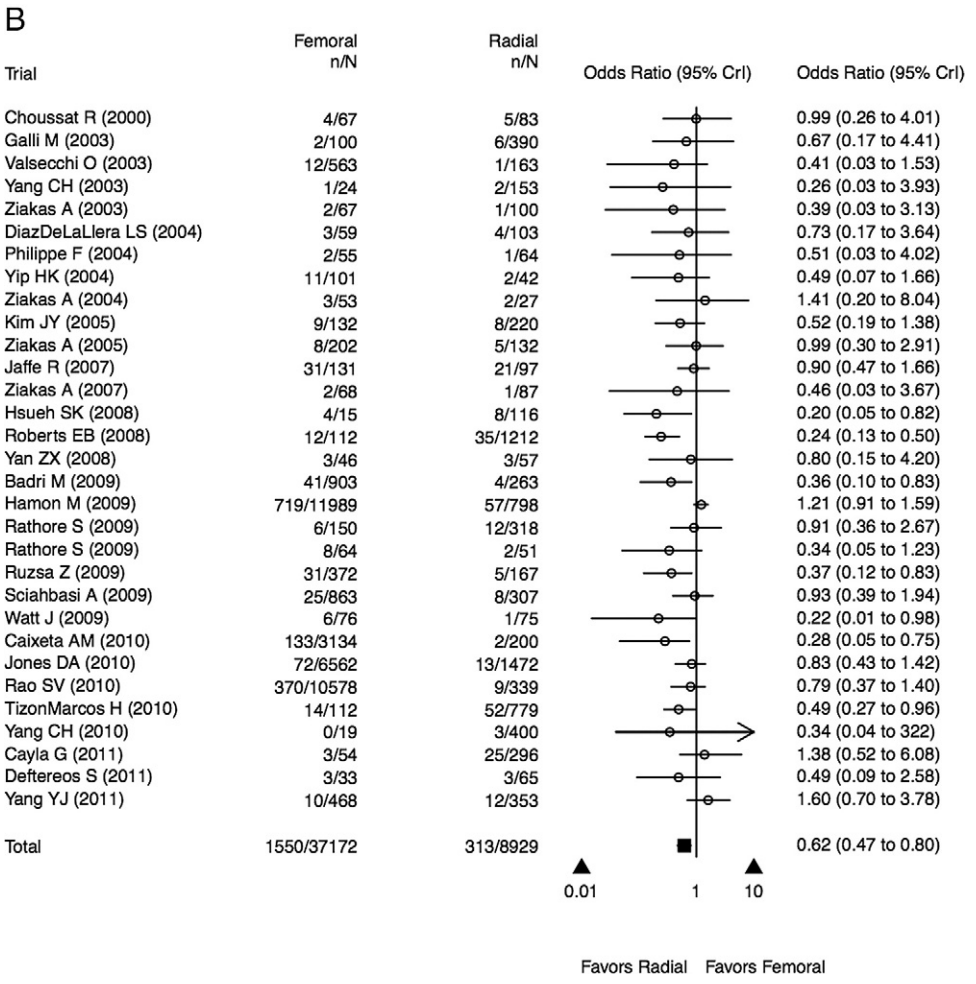

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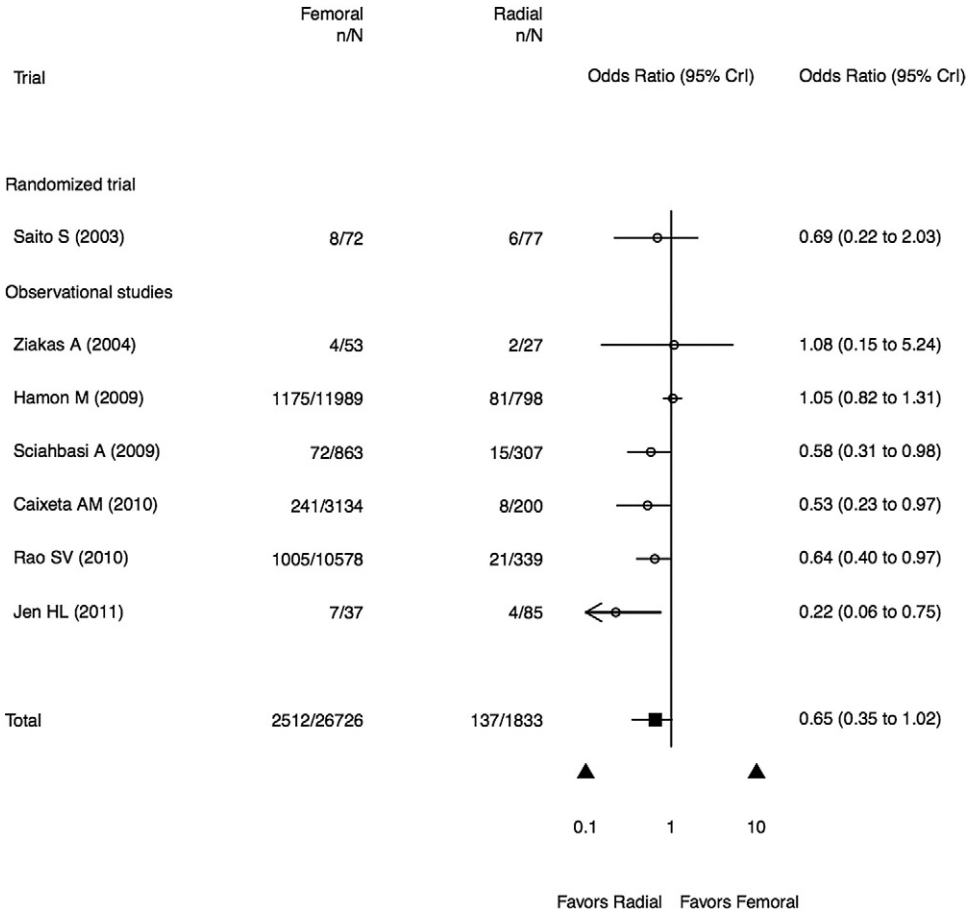
Figure 6



Incidence of late death or MI. Forest plot for late death or MI. Abbreviations as in Figure 3.

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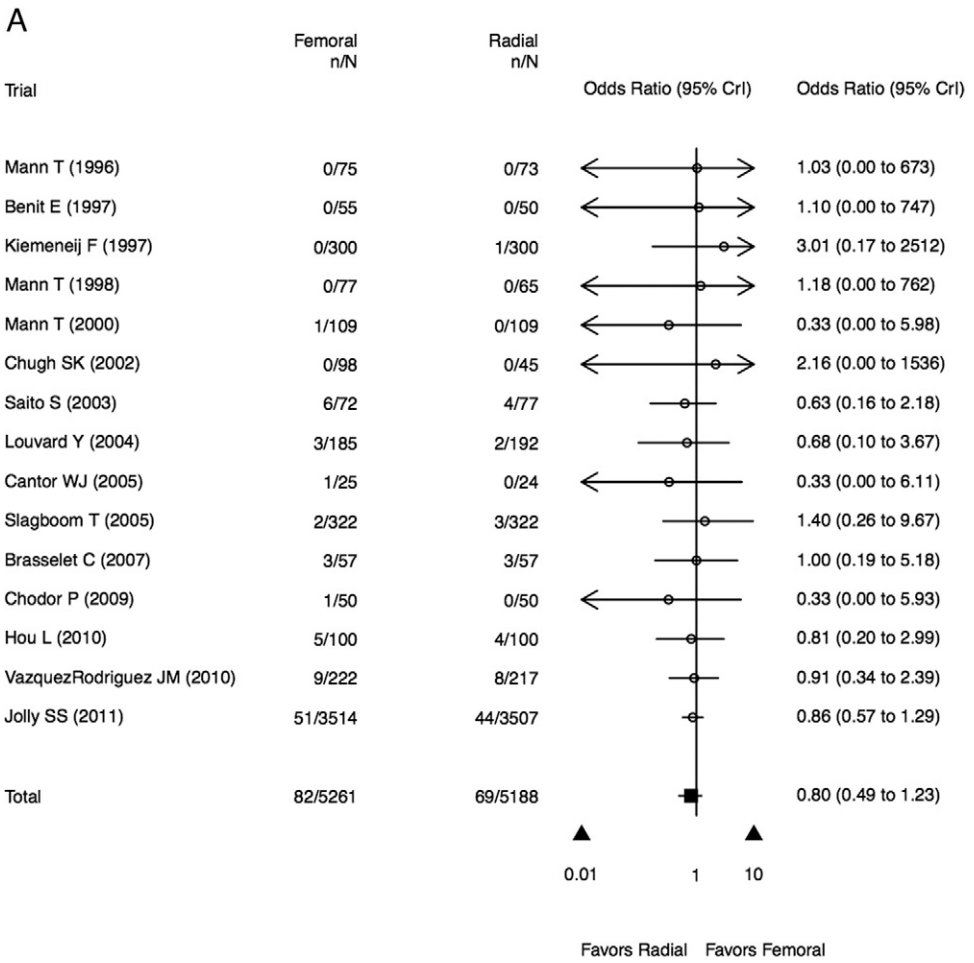
Figure 7



Incidence of early death. Forest plots for all-cause death in randomized (**A**) and observational studies (**B**). Abbreviations as in Figure 3.

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Figure 7

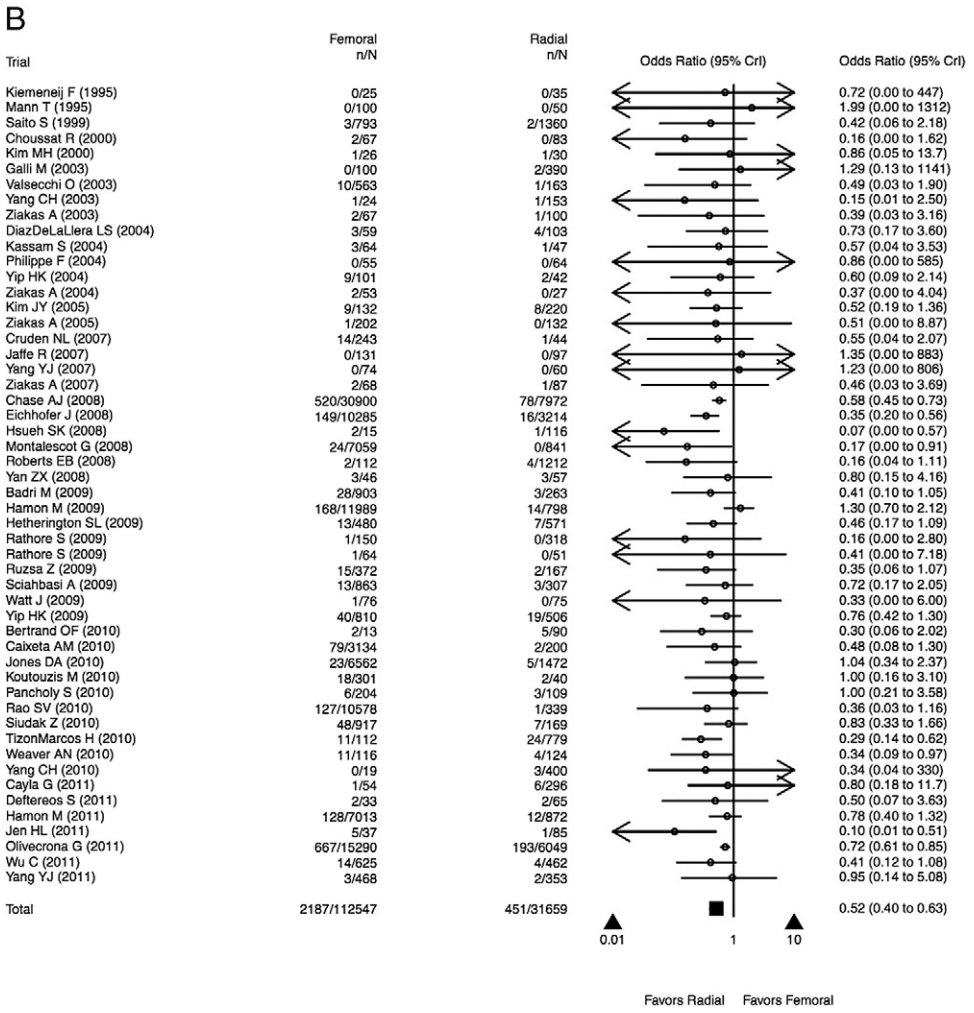

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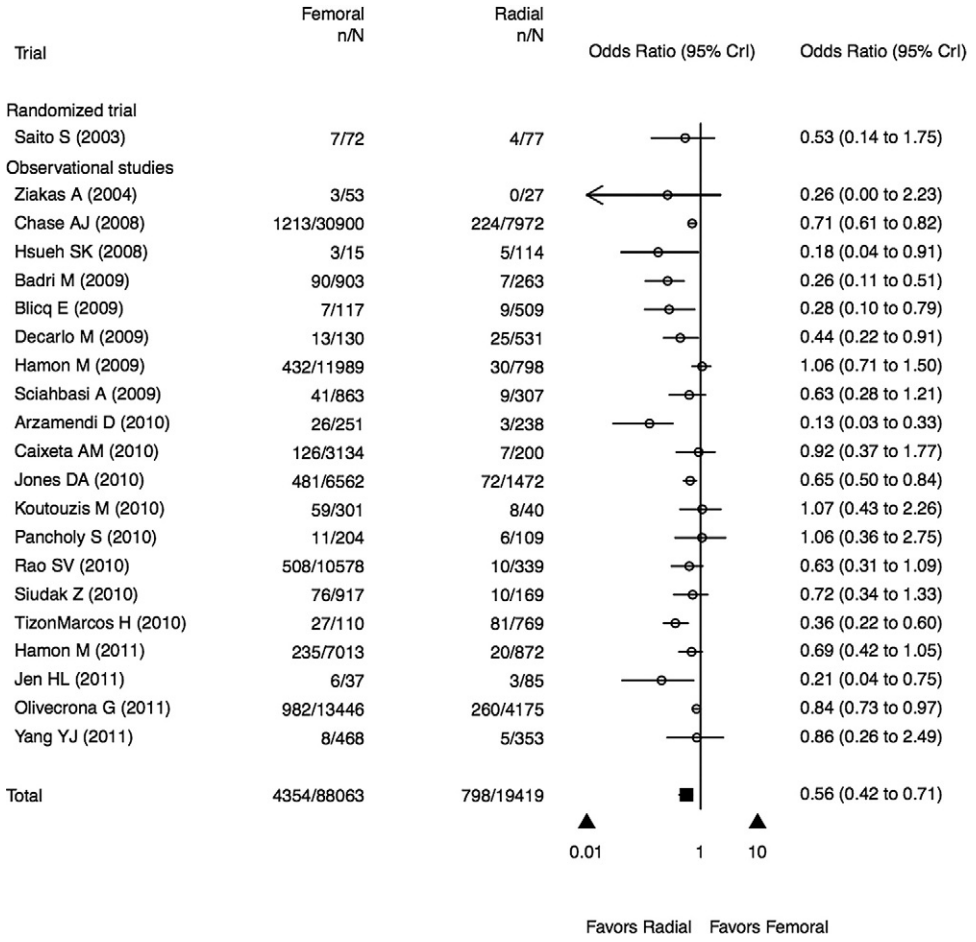
Figure 8



Incidence of late death. Forest plot for all-cause death at late follow-up. Abbreviations as in Figure 3.

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