

Clinical and Procedural Outcomes of 5-French versus 6-French Sheaths in Transradial Coronary Interventions

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Abstract: The radial artery has been increasingly used for its favorable safety profile. However, no conclusive data are available on the optimal sheath size. In particular, it is seemingly difficult to weight both advantages and disadvantages of narrower versus larger sheaths size. Despite several studies were performed to compare the use of 6-Fr to the smaller 5-Fr sheaths, these were mostly small, single center-studies, yielding various results.

We performed a comprehensive meta-analysis of all available studies comparing the use of 5-Fr versus 6-Fr sheaths in coronary procedures through the TRA.

Studies comparing a 5-Fr versus a 6-Fr sheaths were searched for in PubMed, the Cochrane Library, and ISI Web of Knowledge databases.

Studies were deemed eligible if they only included patients undergoing transradial cardiac catheterization with 5-Fr or 6-Fr system and reported at least one of these parameters: contrast dye volume, procedural success, procedural time, access complications, radial artery occlusion, and bleedings.

Odds ratio (OR) and the mean difference (MD) were respectively used for dichotomous and continuous variables as summary measures. Both the random-effects model and the fixed effect models were used for computation of meta-analyses. Heterogeneity was assessed by means of the Cochrane *Q* test. Metaregression was calculated using the unrestricted maximal likelihood random effects model.

The use of a 5-Fr system is associated with a significant lower contrast medium administration (MD = -22.20 [-36.43 to -7.96], $P < 0.01$) and significantly reduces bleedings (OR = 0.58 [0.38–0.90], $P = 0.02$), without compromising procedural success (OR = 0.95 [0.53–1.69], $P = 0.86$) or procedure length (OR = 0.55 [-2.58 to 3.69], $P = 0.73$), compared to the 6-Fr system. Despite no significant difference was observed between the groups (OR = 0.88 [0.50–1.56], $P = 0.67$), at metaregression RAO incidence in the 5-Fr group was increasingly lower as the percentage of women included into the study increased ($P = 0.02$).

Some potentially interesting technical details, such as sheath length, hydrophilic coating, or periprocedural anticoagulation, were not homogeneously reported in individual studies.

Results of the present meta-analysis confirm the excellent safety profile of transradial procedures both with 5-Fr and 6-Fr system. A 5-Fr system could be preferred in patients with a higher bleeding propensity or kidney injury.

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Abbreviations: 5-Fr = 5 French, 6-Fr = 6 French, MD = mean difference, NRS = non-randomized study, OR = odds ratio, PCI = percutaneous coronary intervention, RAO = radial artery occlusion, RCT = randomized controlled trial, TFA = transfemoral access, TRA = transradial access.

INTRODUCTION

The radial artery has been increasingly used as the preferred access site for coronary procedures because of lower rates of access site complications, shorter hospital stay, and improved patient comfort, compared with the transfemoral access.^{1,2}

The substantial benefits over the transfemoral approach (TFA) drove the progressive adoption of the transradial approach (TRA) worldwide, especially after it was shown to be safe, even during the implementation phase.³

Despite the current widespread use of the TRA, no conclusive data are available on the optimal sheath size. If on one hand, some operators prefer a 5-Fr system to minimize the risk for spasm or access site bleedings, 6-Fr sheaths are widely used since they allow the use of a larger selection of devices and techniques.⁴ Despite several studies were performed to compare the use of 6-Fr to the smaller 5-Fr sheaths,^{5–7} they are mostly single center-based and included a limited number of cases, which strongly limit their discrimination potential.

For this reason, we performed a comprehensive meta-analysis of all available studies comparing the use of 5-Fr versus 6-Fr sheaths in coronary procedures performed through the TRA.

METHODS

Search Strategy and Study Selection

Published trials comparing 5-Fr versus 6-Fr sheaths were searched for in PubMed, the Cochrane Library, and ISI Web of Knowledge electronic databases up to January 16, 2015. The following search syntax was used: (“transradial” or “radial”) and (“sheath” or “catheter”). Time of publication was not a limiting criterion for our analysis. Only articles reported in English were included. All reports, including the search terms, were independently screened by 2 independent investigators (AP, FP) for relevance and eligibility. Additionally, references from relevant articles were also scanned for eligible studies. The authors discussed their evaluation and any disagreement was

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resolved through discussion and re-reading. All selected studies were thoroughly checked and classified by the author's institution in order to avoid any bias from duplicity of data.

Studies were deemed eligible if they only included patients undergoing transradial cardiac catheterization with 5-Fr or 6-Fr sheaths and reported at least one of these parameters: contrast dye volume, procedural success, procedural time, radial artery occlusion, and bleedings. Exclusion criteria were (just 1 was sufficient for study exclusion) duplicate publication, endpoint measure not specified.

Data Abstraction and Validity Assessment

Baseline characteristics, procedural variables, as well as the number of clinical events were extracted from the single studies, through carefully scanning of the full article by 2 independent reviewers (AP, FP). Divergences were resolved by consensus. In particular, the following data were abstracted: year of publication, site of patient recruitment, number of patients, study design, and baseline patients' characteristics (Table 2). Quality assessment was performed according to the Prisma guidelines.⁸

Statistical Analysis

For dichotomous variables the summary measure used was odds ratio (OR) with 95% confidence intervals. For computation of the meta-analysis OR were converted to a logarithmic scale.

To facilitate interpretation of the results by the readers, the resulting summary effect (on a log scale) was converted back to OR. For continuous variables the mean difference was used as the summary measure. The random-effects was used to assess the effect of model assumptions on our conclusions.⁹

Heterogeneity was assessed by means of the Cochrane *Q* test using a chi-squared function, with *P* values <0.10 considered significant for heterogeneity as previously described.¹⁰ Additionally *I*² values were calculated for estimation of variation among studies attributable to heterogeneity. A fixed effect or a random-effects model was used as appropriate, with a 2-sided *P* value <0.05 considered significant. Small study effects were evaluated through graphical inspection of funnel plots and statistically using Egger's test (See Supplementary Figure 1).¹¹ Metaregression analyses were calculated using the unrestricted maximal likelihood random effects model, as already previously described.¹⁰ Analyses were performed by means of Excel spreadsheets and Review Manager 5.3.

All analyses were based on previous published studies; thus, no ethical approval and patient consent are required.

RESULTS

Study Search, Selection, and Baseline Evaluation

Our database search retrieved a total of 3361 studies after removal of duplicates, which were reduced to 122 studies after

TABLE 1. Characteristics and Endpoint Definition of Studies Included in the Meta-Analysis

Study	Year	Location	N	Randomization 5Fr vs 6Fr	Procedural Success Definition	Access-Site Complications Definition
Dahm et al	2002	Germany	171	Yes	Successful arterial puncture, cannulation of the guiding catheter in the coronaries, coronary angioplasty with <30% residual stenosis after PCI, absence of major catheterization complication, unimpaired TIMI, and absence of need for repeat myocardial revascularization.	Radial spasm, major hematoma, minor hematoma, radial artery occlusion.
Gobeil et al	2004	France, Germany	216	Yes	A procedure performed with the randomized guiding catheter size, adequate stent delivery when needed, residual stenosis of <20%, and a final TIMI 3 flow in the targeted artery.	Radial artery occlusion.
Gwon et al	2006	Korea	200	Yes	N/A	Hematoma, ecchymosis, edema, rebleeding, radial artery pulse loss.
Yu et al	2007	Korea	115	No	Successful cannulation of the guiding catheter in the coronaries, the postprocedural residual stenosis was <50% and there was TIMI 3 antegrade flow with the absence of major complications.	Major hematoma, minor hematoma, difficulties in sheath removal, radial artery occlusion
Kindel et al	2008	Germany	100	No	N/A	Radial artery occlusion
Plante et al	2010	Canada	397	No	N/A	Radial artery occlusion
Wu et al	2011	Taiwan	121	No	A procedure exclusively performed with adequate stent delivery when needed, residual stenosis of <30%, and with a final TIMI 3 flow in the dilated artery.	hematoma
Uhlemann et al	2012	Germany	455	No	N/A	Bleeding events, pseudoaneurysm, and arteriovenous fistula, radial artery occlusion
Honda et al	2012	Japan	418	No	N/A	Bleeding events, radial artery occlusion
Buturak et al	2014	Turkey	409	No	N/A	Radial artery occlusion
Markovic et al	2015	Germany	369	No	N/A	Relevant hematoma, small hematoma, radial dissection, aneurysm, arteriovenous fistula, radial artery occlusion

Fr = French, N/A = not available, PCI = percutaneous coronary intervention, TIMI = thrombolysis in myocardial infarction.

TABLE 2. Baseline Patient's Characteristics

	Dahm et al 2002	Gobeil et al 2004	Gwon et al 2006	Yu et al 2007	Kindel et al 2008	Plante et al 2010	Wu et al 2011	Uhlemann et al 2012	Honda et al 2012	Buturak et al 2014	Markovic et al 2015	Total
No. of patients, n	87	102	100	54	50	25	81	153	183	226	45	1847
Age, years	60.1	64.8	63.2	61.5	N/A	N/A	66.1	65.1	N/A	N/A	N/A	63.5
Male, n	51	50	71	33	46	N/A	34	97	N/A	N/A	N/A	80%
Hypertension, n	34	35	47	31	36	N/A	62	145	N/A	N/A	N/A	85%
Dyslipidemia, n	N/A	N/A	71	76	N/A	N/A	63	25	N/A	N/A	N/A	67%
Current smoker, n	N/A	N/A	30	16	31	N/A	38	22	N/A	N/A	N/A	33.8%
Diabetes, n	23	23	20	18	16	N/A	21	53	N/A	N/A	N/A	35.3%

5-Fr = intracoronary adenosine, 6-Fr = placebo, CAD = coronary artery disease, MI = myocardial infarction.

an initial prescreening. Hundred and six studies were then excluded for one of the following reasons: (a) they were not related to our research question; (b) they were not original articles. The remaining articles were checked through their full text, resulting in further exclusion of 5 studies, which did not meet our prespecified inclusion criteria.¹²⁻¹⁶ Finally, a total of 11 studies were available for the analysis, 3 randomized studies⁵⁻⁷ and 8 nonrandomized studies.¹⁷⁻²⁴ The study selection procedure is reported in detail in Figure 1, whereas Table 1 summarizes the most relevant characteristics of the selected studies. Clinical characteristics of the study population are summarized in Table 2.

Impact of 5-Fr Sheaths on Procedural Performance

The procedural success rate and mean procedural time and the mean amount of contrast medium administered during the procedure were analyzed separately.

A total of 5 studies reported the incidence of procedural success, including 826 procedures. We found no evidence of funnel plot asymmetry for any of the analyzed studies (See Supplementary Figure 1, $P > 0.10$). No statistically significant difference in the rate of procedural success (OR = 0.95 [0.53-1.69], $P = 0.86$) was observed between 5-Fr versus 6-Fr arms (Figure 2A). As both randomized (RCT) and nonrandomized studies (NRS) were included in this analysis, we performed a subgroup analysis, revealing a similar result for both study subgroups.

In addition, analyzing the 4 studies reporting results on mean procedural time, no significant differences were observed between the study arms (OR = 0.55 [-2.58 to 3.69], $P = 0.73$) (Figure 2B). Of note, a similar result was observed in the RCTs

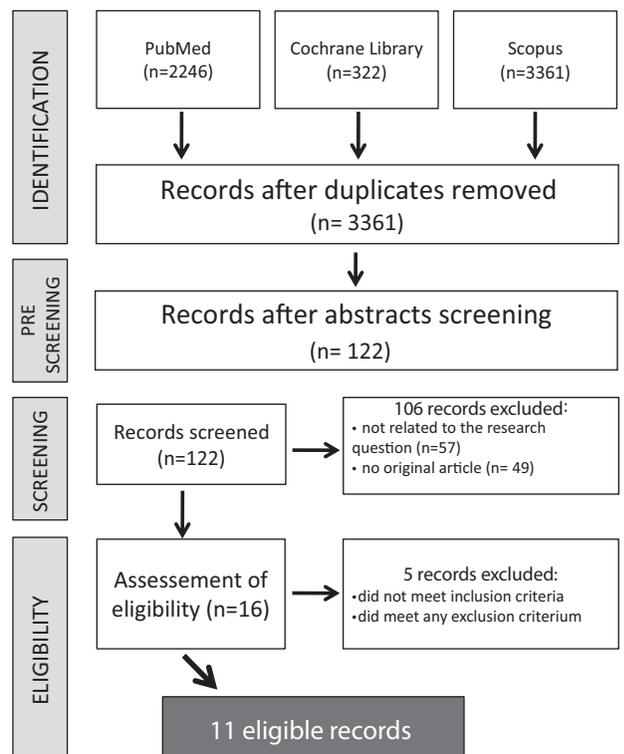


FIGURE 1. Flowchart of study search, screening, and selection.

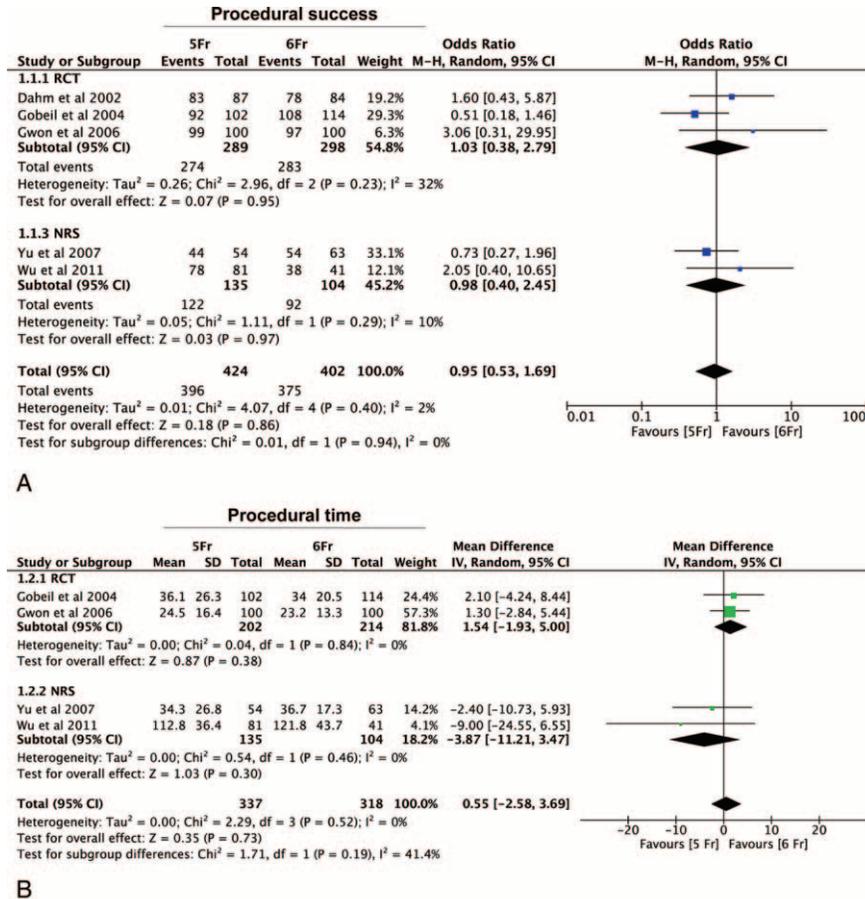


FIGURE 2. Impact of 5-Fr catheter on procedural performance. Panel A—meta-analysis of difference in procedural success showing no statistically significant difference in procedural success between 5-Fr and 6-Fr arms ($P=0.86$). Panel B—meta-analysis of difference in procedural time between 5-Fr and 6-Fr arms demonstrating no significant differences in procedural time between the groups ($P=0.73$). Procedural time (minutes) is reported as mean for each study arm.

and the NRS subgroups, despite the minimal, nonsignificant, numerical difference.

Interestingly, a statistically significant difference in the amount of contrast medium administered during the procedure was found in favor of 5-Fr group (MD = -22.20 [-36.43 to -7.96], $P < 0.01$), corresponding to a saving of ~22.2 mL of contrast medium per procedure (Figure 3). Although the same trend was observed both in the RCT- and the nonrandomized subgroups, this difference was statistically significant only within the nonrandomized subgroup (MD = -32.30 [-39.56 to -25.04], $P < 0.01$).

Impact of 5-Fr Sheaths on Access-Site Complications

Seven studies reported the incidence of bleedings events, for a total of 1849 procedures. Comparing the incidence of bleedings between the study arms, we found a significant reduction in the incidence of bleeding events in the 5-Fr arm (OR = 0.58 [0.38–0.90], $P = 0.02$) (Figure 4A). Although the same trend was observed both in the RCT- and the NRS subgroups, this difference was statistically significant only for the NRS subgroup (OR = 0.58 [0.35 – 0.94], $P = 0.03$). Interestingly, at metaregression analysis, this advantage was progressively lost in those studies with a higher percentage of

PCI performed in addition to the diagnostic angiography ($P = 0.01$) (Figure 4B).

Finally, we evaluated the incidence of radial artery occlusion (RAO). Nine studies reported the incidence of an RAO, for a total of 2735 procedures. No statistically significant difference was observed in RAO incidence (OR = 0.88 [0.50–1.56], $P = 0.67$) between the 5-Fr and the 6-Fr arms (Figure 5A). Subgroup analysis did not disclose any substantial difference between the RCT and the NRS study subgroups. However, at metaregression an increasing benefit was evident with the 5-Fr sheaths as the percentage of women included into the study increased ($P = 0.02$) (Figure 5B).

Metaregression Analysis

Given the potential differences between diagnostic and interventional procedures, we used the percentage of interventional procedures in every single study as a moderator in a metaregression analysis with the effect size of all endpoints evaluated. Consequently, we used this information—namely the percentage of interventional procedures in single studies as to moderator variable to compute a metaregression analysis. Interestingly, we found a significant interaction across the studies between sheaths caliber and the percentage of interventional procedures on the incidence of bleedings ($P = 0.01$) and on the

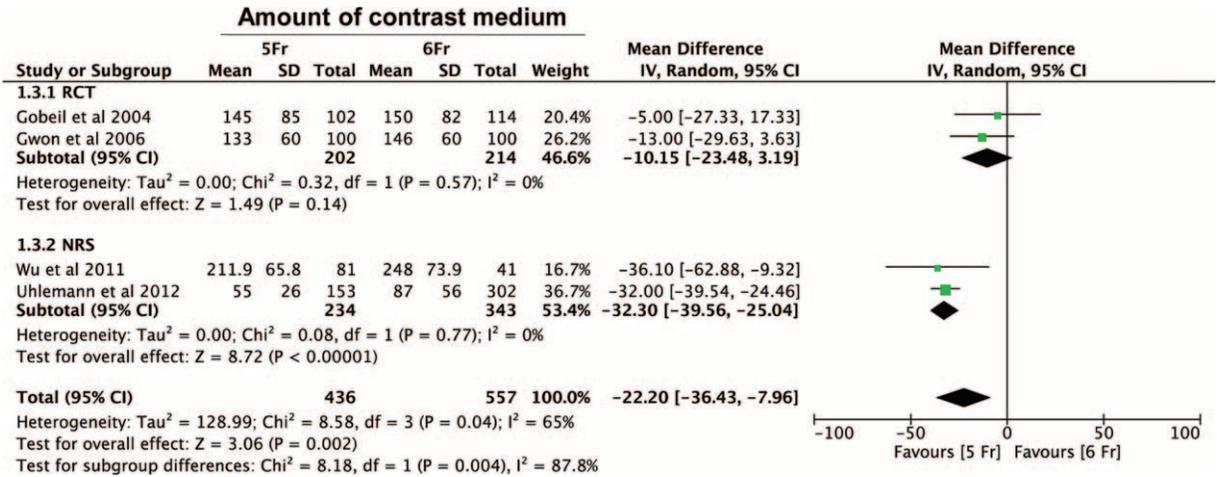
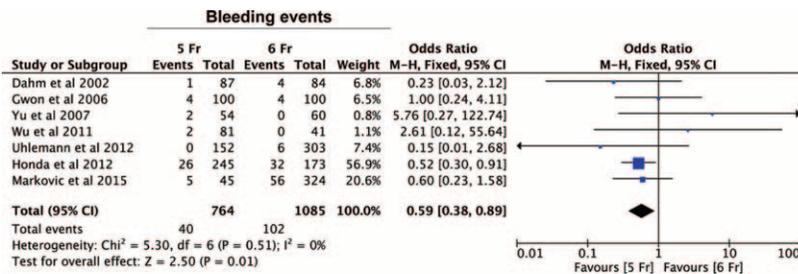
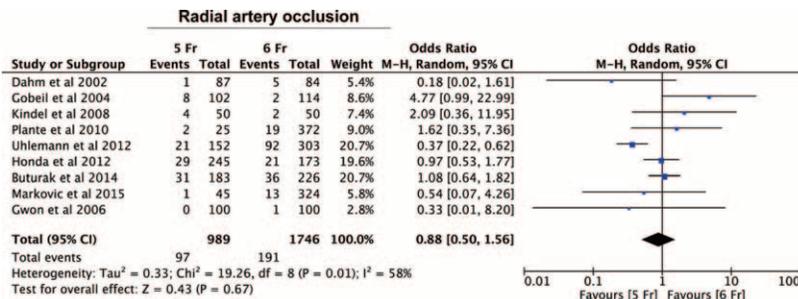


FIGURE 3. Meta-analysis of standardized mean difference in the amount of contrast medium administered during the procedure showing a statistically significant difference between the groups in favor of the 5-Fr arm ($P < 0.01$). RCT = randomized controlled trial; NRS = nonrandomized study.



A

FIGURE 4. Impact of 5-Fr catheter on bleeding events. Panel A—meta-analysis of the difference in the incidence of bleedings between the groups demonstrating a significant reduction of bleeding events in the 5-Fr arm ($P = 0.02$).



A

FIGURE 5. Impact of 5-Fr catheter on radial artery occlusion (RAO). Panel A—meta-analysis of the difference in the incidence of radial artery occlusion between the 5-Fr and 6-Fr arms showing no statistically significant difference in RAO incidence between the arms ($P = 0.67$). RAO = radial artery occlusion.

amount of contrast medium administered ($P = 0.001$), whereas no significant interaction was observed for procedural success ($P = 0.61$) or access site complications ($P = 0.34$). Results of metaregression analyses with percentage of interventional procedures are displayed in Figure 6.

Furthermore, as local access site complications are often more frequent in women than in men, we evaluated the

interaction between the effect size and the percentage of women included in single studies by means of metaregression analysis. Interestingly, we found a significant interaction across the studies between sheaths caliber and the percentage of female patients included in single studies on the rate of RAO ($P = 0.02$), whereas no significant interaction was observed for procedural success ($P = 0.87$), amount of contrast medium

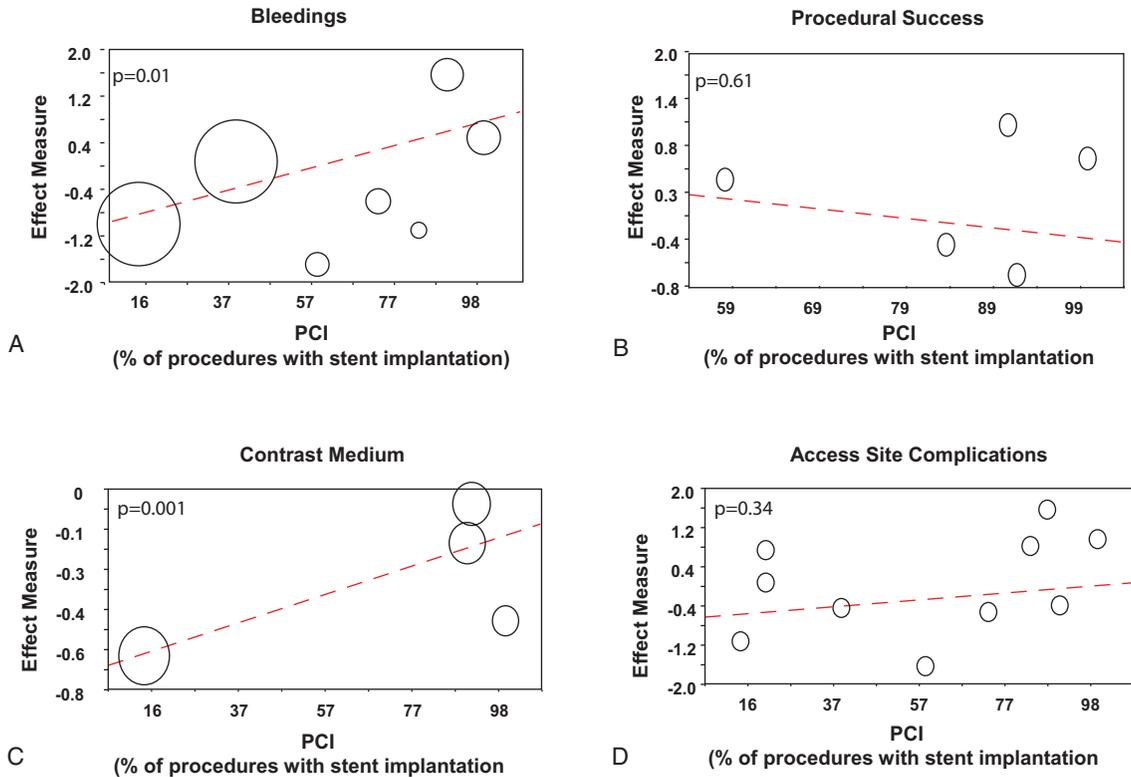


FIGURE 6. Metaregression analyses on the influence of PCI on bleeding events, procedural success, contrast medium administration, and access site complications. Panel A—metaregression analysis on the influence of PCI on bleeding events. A significant correlation is evident from the graph ($P=0.01$), indicating that the benefit on bleedings observed with the 5 French system is progressively lost in those studies with a higher percentage of PCI performed in addition to the diagnostic angiography. Largeness of circles represents the weight of each individual study. Panel B—metaregression analysis on the influence of PCI on procedural success. A not significant correlation is evident from the graph ($P=0.61$). Panel C—metaregression analysis on the influence of PCI on contrast medium administration. A significant correlation is evident from the graph ($P=0.001$). Panel D—meta-regression analysis on the influence of PCI on access site complications. A not significant correlation is evident from the graph ($P=0.34$). PCI=percutaneous coronary intervention.

administered ($P=0.70$), or total access site complications ($P=0.06$).

Results of metaregression analyses with percentage of female patients included are displayed in Figure 7.

DISCUSSION

The major findings of the present meta-analysis are: (a) the total amount of contrast medium necessary to complete the procedure are significantly lower using a 5 French approach, compared to the 6 French; (b) significantly less access-site bleedings were observed with the 5-Fr approach; (c) the benefits observed with the 5 French approach did not affect the procedural success rate, which was virtually comparable between the arms; (d) although no frank evidence of a lower post-procedural radial occlusion rate was observed in the 5-Fr arm, a significant benefit was evident at metaregression, with a larger effect in the studies with a higher percentage of women.

The present meta-analysis is the first comparing the procedural success with the 5 French versus the 6 French transradial approach. Our findings, based on 3 randomized and 8 prospective nonrandomized studies, are of large interest for interventional cardiologists. In fact, we provide the first demonstration that use of a 5 French system for transradial catheterization is associated to a significant reduction in the amount of contrast medium administered, compared to the 6 French, with relevant implications for patients’ safety. A lower amount of

contrast medium is associated to a lower risk of contrast-induced nephropathy (CIN) and, therefore, the 5 French strategy could be considered in patients with kidney failure or when repetitive procedure is needed.²⁵

In addition, the novel evidence of a significantly lower bleeding rate with the 5 French also represents an interesting finding, given the impact of bleeding complications on patients’ clinical outcome.^{26,27} In fact, despite it was shown to be safer that the transfemoral access, diffusion of the transradial access did not undergo the expected fast and large acceptance, yet.³ In this regard, our results of an even better safety profile with a 5 French system could propel the diffusion of the transradial approach. Interestingly, as demonstrated at metaregression, the benefit on bleedings observed with the 5 French system was actually progressively larger as the number of procedures including a PCI increased in single studies.

Altogether, a lower complication rate—including bleedings and contrast-induced nephropathy—also contributes to reduce the social costs of coronary procedures. In fact, an uneventful hospital stay avoids the adjunctive treatment costs associated to eventual complications, reduces patients’ hospital stay, allowing a quick return of patients to their social duties, as well as a higher patient turnover, in a time where several healthcare systems are facing the issue of long waiting queues for patients.

Given the excellent results with the 5-Fr system, this should be the preferred default choice, especially at the

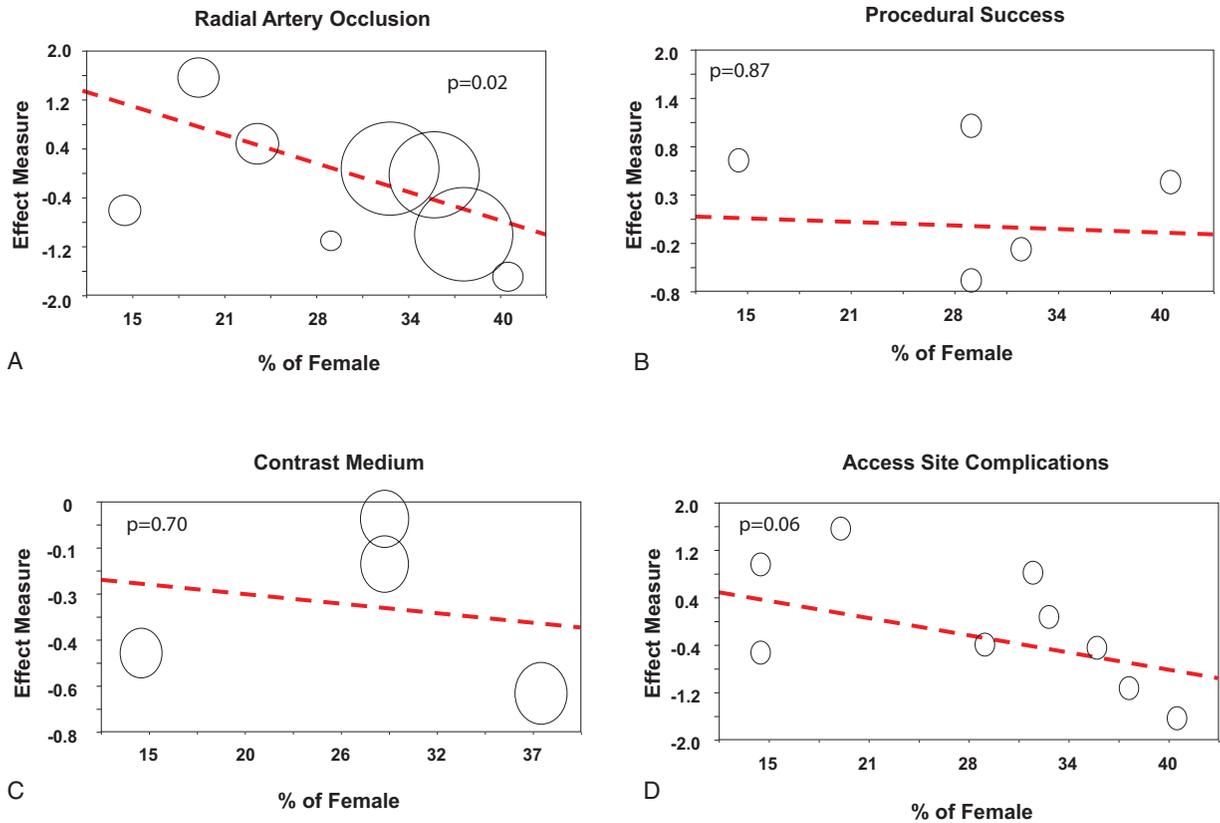


FIGURE 7. Metaregression analyses on the influence of female sex on radial artery occlusion, procedural success, contrast medium administration, and access site complications. Panel A—metaregression analysis on the influence of female sex on radial artery occlusion. A significant correlation is evident from the graph ($P=0.02$), indicating an increasing benefit with the 5-Fr sheath as the percentage of women included into the study increased. Largeness of circles represents the weight of each individual study. Panel B—metaregression analysis on the influence of female sex on procedural success. A not significant correlation is evident from the graph ($P=0.87$). Panel C—metaregression analysis on the influence of female sex on contrast medium administration. A not significant correlation is evident from the graph ($P=0.70$). Panel D—meta-regression analysis on the influence of female sex on access site complications. A not significant correlation is evident from the graph ($P=0.06$).

beginning of a radial program. Interestingly, at metaregression the benefit observed in terms of RAO rate was larger as the number of women included into the single studies grew. This could be a consequence of the average thinner radial artery diameter in women, making the use of larger arterial sheaths more traumatic than for men. In fact, 1 potential advantage with the 5-Fr sheath could be the consequent reduction of traumatism to the arterial wall, which is not irrelevant. In fact, a recent study showed that the presence of microdissections at the radial access site, evaluated by means of optical coherence tomography (OCT), is a potent risk factor for radial artery occlusion,²⁸ one of the sneakiest complications of the transradial approach, frequently asymptomatic and underdiagnosed, but not a clinically irrelevant complication.^{29,30}

However, it should be pointed out that a learning curve is necessary for successful use of the 5 French strategy, to get familiar with the different trackability of 5-Fr guiding catheters through a TRA. In addition, a large number of different catheters are available nowadays, which is quite helpful to the operator especially during the learning phase. The most important characteristic 1 should pay attention to include the net internal lumen, the amount of support, selection of the most appropriate catheter shape and size, getting used to support-enhancing interventional techniques such as deep engagement,

buddy wire, and so on. The most relevant potential advantages and pitfalls of 5-Fr over 6-Fr catheters are reported in Table 3.

LIMITATIONS

Information about the length of radial sheets or the use of hydrophilic coating is not homogeneously reported in the studies analyzed. Unfortunately, the included studies did not report the study outcomes separately for diagnostic and

TABLE 3. Advantages and Pitfalls of 5F Catheters

5 French Catheters	
Potential Advantages	Potential Pitfalls
Deep engagement safer with the lower crossing profile	Cannot perform kissing balloon or kissing stenting
Easier crossability through small or tortuous vessels	Not compatible with thromboaspiration catheters
Lower propensity to spasm	Cannot use distal protection devices
	Lower trackability, visibility, and backup

interventional procedures. However, the percentage of interventional procedures was reported for most single studies, which could be used as the moderator variable for metaregression. There is no information on periprocedural anticoagulation to allow a metaregression analysis. In addition, despite the observed benefit with the 5-French system, use of a 6-French approach still remains the only choice in specific situations, especially in complex PCIs (eg requiring kissing-balloon), or in the case of unsatisfactory support with the 5-Fr catheters. In this regard, the level of procedural complexity for the study arms was not reported for all studies.

In conclusion, the present meta-analysis—the first comparing procedural performance of 5-Fr versus 6-Fr system for transradial endovascular procedures—demonstrated that the use of a 5-Fr system is associated with a significantly lower contrast medium administration, and significantly reduces bleeding complications, without compromising procedural success. These results confirm the excellent safety profile for the transradial procedure with a 5-Fr system and suggest preferring a 5-Fr system in patients with a higher propensity to bleeding complications or kidney injury, where possible.

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