

# Impact of contact force technology on reducing the recurrence and major complications of atrial fibrillation ablation: A systematic review and meta-analysis

Xianhui Zhou, Wenkui Lv, Wenhui Zhang, Yuanzheng Ye, Yaodong Li, Qina Zhou, Qiang Xing, Jianghua Zhang, Yanmei Lu, Ling Zhang, Hongli Wang, Wen Qin, Baopeng Tang

Pacing and Electrophysiological Department, the First Affiliated Hospital of Xinjiang Medical University; Urumqi, Xinjiang-P. R. China

## ABSTRACT

Contact force (CF) monitoring can be useful in accomplishing circumferential pulmonary vein (PV) isolation for atrial fibrillation (AF). This meta-analysis aimed to assess the efficacy and safety of a CF-sensing catheter in treating AF. Randomized controlled trials or non-randomized observational studies comparing AF ablation using CF-sensing or standard non-CF (NCF)-sensing catheters were identified from PubMed, EMBASE, Cochrane Library, Wanfang Data, and China National Knowledge Infrastructure (January 1, 1998–2016). A total of 19 studies were included. The primary efficacy endpoint was AF recurrence within 12 months, which significantly improved using CF-sensing catheters compared with using NCF-sensing catheters [31.1% vs. 40.5%; risk ratio (RR)=0.82; 95% confidence interval (CI), 0.73–0.93;  $p<0.05$ ]. Further, the acute PV reconnection (10.1% vs. 24.2%; RR=0.45; 95% CI, 0.32–0.63;  $p<0.05$ ) and incidence of major complications (1.8% vs. 3.1%; OR=0.59; 95% CI, 0.37–0.95;  $p<0.05$ ) significantly improved using CF-sensing catheters compared with using NCF-sensing catheters. Procedure parameters such as procedure duration [mean difference (MD)=-28.35; 95% CI, -39.54 to -17.16;  $p<0.05$ ], ablation time (MD=-3.8; 95% CI, -6.6 to -1.0;  $p<0.05$ ), fluoroscopy duration (MD=-8.18; 95% CI, -14.11 to -2.24;  $p<0.05$ ), and radiation dose (standard MD=-0.75; 95% CI, -1.32 to -0.18;  $p<0.05$ ) significantly reduced using CF-sensing catheters. CF-sensing catheter ablation of AF can reduce the incidence of major complications and generate better outcomes compared with NCF-sensing catheters during the 12-month follow-up period. (*Anatol J Cardiol* 2017; 17: 82-91)

**Keywords:** atrial fibrillation; ablation; contact force-sensing catheter; meta-analysis

## Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia, and ablation procedures for AF have been shown to be safe and effective in a large number of cases worldwide (1–4). However, the recurrence rates of AF after catheter ablation are still considerably high (5, 6). Pulmonary vein (PV) reconnection due to ineffective ablation lesions has been identified as the main cause of AF recurrence (7, 8), and catheter–tissue contact is essential for effective ablation lesions (4, 9, 10). However, an accurate measurement of lesions and understanding the limitations of the contact force (CF) are crucial for avoiding complications (11). In recent years, radio-frequency (RF) catheter ablation with CF sensing, a novel method, has been claimed to be potentially responsible for effective ablation. When using it, the catheter–tissue CF can be measured at the catheter tip with fiber optic or magnetic sensors (12).

The safety and effectiveness of CF-sensing catheters have been evaluated in ex vivo models (10, 13) and in vivo experimental studies (14, 15) before their recent application in humans. Ex-

perimental data in previous studies have demonstrated a strong relationship between CF and lesion size when using an RF current for catheter ablation (14). However, the efficacy and safety of CF-sensing catheters, particularly for reducing the rate of complications, remain controversial.

The purpose of this meta-analysis was to evaluate the efficacy and safety of catheter AF ablation using CF-sensing catheters.

## Methods

### Literature search

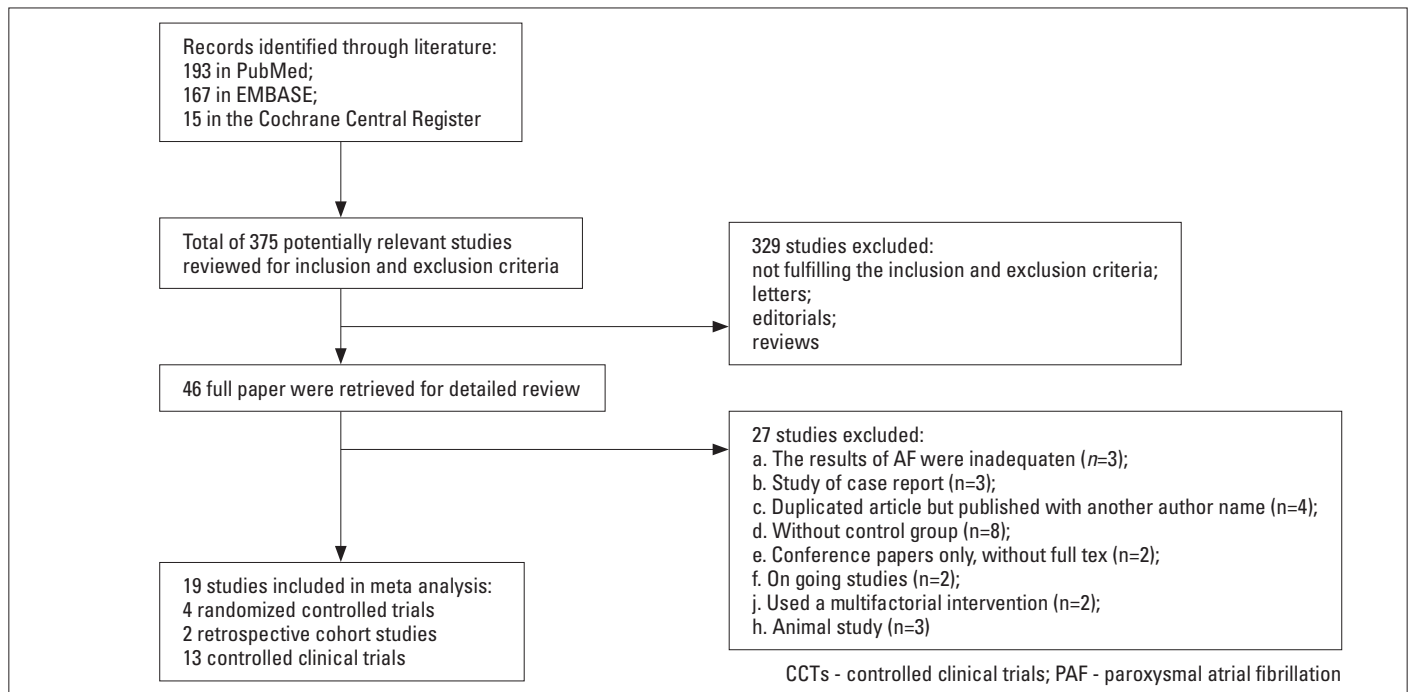
Electronic databases, such as PubMed, EMBASE, Wanfang Data, China National Knowledge Infrastructure (January 1, 1998–2016), and Cochrane Controlled Trials Register, for reports on all randomized controlled trials (RCTs) or non-randomized observational studies (NROSs) published in English or Chinese were searched using the following medical subject headings, “contact force-sensing catheter,” “ablation,” and “atrial fibrillation,” to capture data on catheter AF ablation using CF-sensing

**Address for correspondence:** Baopeng Tang, PhD, Pacing and Electrophysiology Department the First Affiliated Hospital of Xinjiang Medical University, No.137, South Liyushan Road, Xinshi Zone, Urumqi-China  
Phone: +86 13579881111 Fax: +86 0991 4366852 E-mail: tangbaopeng1111@163.com

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**Figure 1.** Flow diagram of the literature search stages

catheters. The abstracts of all identified RCTs or NROs were independently screened by two reviewers.

### Study selection and quality assessment

Studies fulfilling the following criteria were included: (1) patients undergoing AF ablation using CF-sensing catheters and standard non-CF (NCF)-sensing catheters, (2) patients with paroxysmal AF (PAF) or persistent AF (Per AF), and (3) human studies conducted in adults who were 18 years and older. Non-comparative trials, case reports, editorials, and reviews were excluded from this study.

We used PRISMA guidelines in this meta-analysis. Individual studies were checked for the following characteristics: adequate sequence generation, allocation concealment, attrition less than 15%, blinded assessment, intent-to-treat analysis, complete follow-up, and adequate AF monitoring.

### Data abstraction

The citations were also reviewed, and data were independently abstracted by two reviewers; disagreements were resolved by discussions. Abstracted data included the following: (1) study type, study size, study design, CF catheter used, mean CF used, and follow-up; (2) age and gender; (3) AF recurrence within 12 months (primary outcomes); (4) occurrence of acute PV reconnection; (5) primary safety endpoint including device-related serious adverse events (events were classified as major and minor complications; major complications included in-hospital death, cardiac perforation, cardiac effusion or tamponade, stroke, PV stenosis, esophageal fistula, severe hemoptysis, phrenic nerve lesion, and thromboembolic event, whereas minor complications were mainly related to vascular access

complications, including femoral/subclavian hematoma and arteriovenous fistula); and (6) procedure duration, ablation time, fluoroscopy duration, and radiation dose.

### Statistical analysis

Statistical analysis was performed using Cochrane RevMan version 5 (The Cochrane Collaboration, UK), and results were expressed as weighted mean differences (MDs) and relative risk for continuous and dichotomous outcomes, respectively, with 95% confidence intervals (CIs). Outcomes were pooled using the random-effects model when the heterogeneity was moderate or high ( $I^2 > 50\%$ ). However, the fixed-effects model was used when the heterogeneity was low ( $I^2 < 50\%$ ). Radiation doses used among the included studies were compared using a standard MD (SMD) as different radiation units had been used. The present study assessed the heterogeneity between studies using the Cochran's Q statistic and  $I^2$  index. All statistical testing was two tailed with statistical significance at  $p < 0.05$ .

### Results

The electronic search identified 193 references from PubMed, 167 from EMBASE, and 15 from the Cochrane Central Register of Controlled Trials. Among these abstracts, 329 were excluded. The full manuscripts for the remaining 46 studies were retrieved for a detailed review, and 27 were further excluded. Finally, 19 studies (16–34) [4 RCTs (16–19), 2 retrospective cohort studies (20, 21), and 13 NROs (22–34)] were identified that compared the safety and efficacy of CF-sensing or NCF-sensing catheters in the setting of AF ablation. Information relevant to the literature search is shown in Figure 1.

**Publication bias**

No significant publication bias was found for the primary outcome (AF recurrence at the follow-up) as assessed by a funnel plot (Fig. 2).

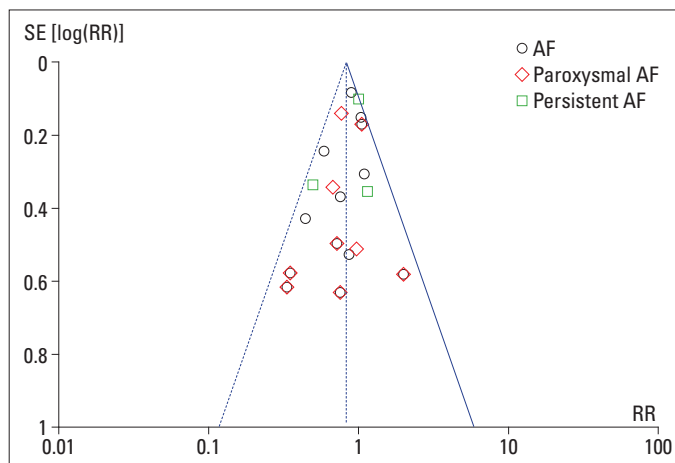
**Baseline patient characteristics**

Baseline patient characteristics are provided in Table 1. A total of 4053 patients were included in the CF-sensing (n=1546) and NCF-sensing (n=2507) catheter groups.

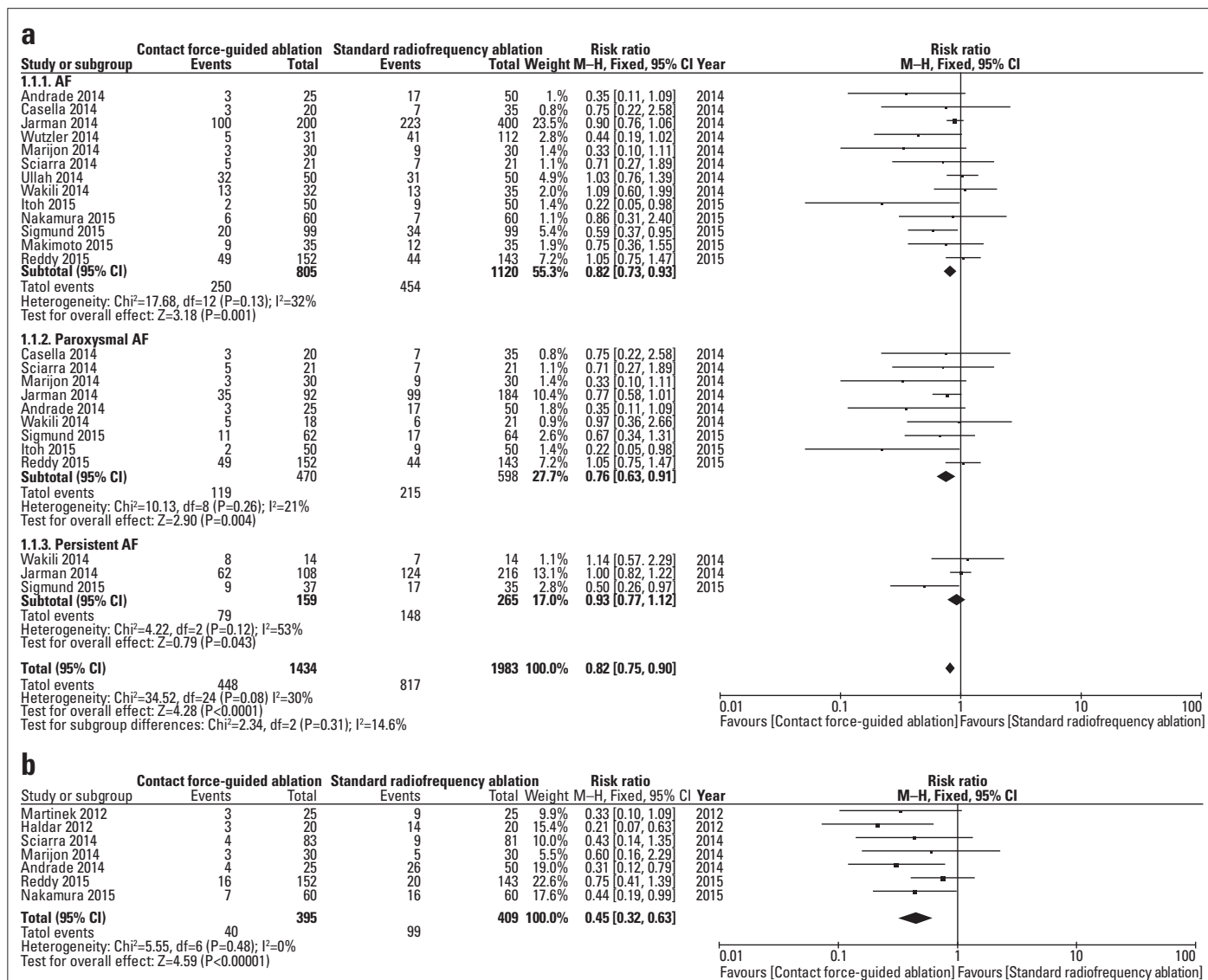
Ten studies provided detailed information on the PAF and/or Per AF patient subgroups, and relevant information was abstracted to compare the efficacy and safety in the AF, PAF, and/or Per AF subgroups.

**Efficacy of AF ablation using CF-sensing catheters**

AF recurrence within 12 months was compared in the AF (13 studies), PAF (9 studies), and Per AF (3 studies) subgroups. In



**Figure 2.** Funnel plot for the assessment of publication bias for the primary outcome. Effect size is plotted on the x-axis and SE on the y-axis. AF - atrial fibrillation; RR - risk ratio; SE - standard error



**Figure 3.** (a) Forest plot showing the RR and 95% CI for AF recurrence within 12 months for studies comparing the CF and NCF groups. (b) Forest plot showing the RR and 95% CI for the occurrence of acute PV reconnection for studies comparing the CF and NCF groups

**Table 1. Baseline clinical characteristics and follow-up of the patients**

	Type of study	AF (CF/NCF)	PAF (CF/NCF)	PerAF (CF/NCF)	Mean age y(CF/NCF)	Male, n(%) (CF/NCF)	Hypertension n(%) (CF/NCF)	Diabetes, n(%) (CF/NCF)	LA size mm (CF/NCF)	EF (%) (CF/NCF)	CF Catheter	Mean CF, g	Follow up months
Reddy 2015 (TOCCASTAR)	prospective, randomized, controlled, multicenter study	295 (152/143)	295 (152/143)	0	59.6±9.3 /61.0±10.8	100 (65.8) /91 (63.6)	75 (49.3) /69 (48.3)	16 (10.5) /17 (11.9)	39.9±5.9 /39.3±4.5	62.4±7.1 /62.4±6.2	TactiCath	NR	12
Nakamura 2015	prospective, randomized, controlled study	120 (60/60)	80 (38/42)	40 (22/18)	64/64.5	44 (73.3) /45 (75.0)	27 (45.0) /36 (60.0)	8 (13.3) /10 (16.7)	40±6/39±5	67/65	Thermocool SmartTouch	18	12
Wolf 2015	Prospective non-randomized study	36 (24/12)	27 (18/9)	9 (6/3)	58.6±11.3 /62.2±8.5	19 (79.2) /11 (91.7)	8 (33.3) /6 (50.0)	2 (8.3) /0 (0)	42.0±3.6 /43.0±4.3	56.0±7.9 /58.1±8.0	Thermocool SmartTouch	17.8	NR
Itoh 2015	Prospective non-randomized study	100 (50/50)	100 (50/50)	0	65±11 /61±10	30 (60) /31 (62)	32 (64) /26 (52)	5 (10) /8 (16)	37±7 /38±6	65±10 /65±7	Thermocool SmartTouch	NR	12
Makimoto 2015	Prospective non-randomized study	70 (35/35)	44 (19/25)	26 (16/10)	67±9 /60±11	24 (69) /27 (77)	25 (71) /29 (83)	4 (11) /4 (11)	44±6 /45±6	60±7 /60±6	Thermocool SmartTouch	16	12
Sigmund 2015	Prospective case- matched control trial	198 (99/99)	126 (62/64)	72 (37/35)	59.5±9.6 /59.5±9.4	71 (72) /68 (69)	46 (47) /52 (53)	4 (4) /3 (3)	40±6 /41±6	56±5 /57±7	Thermocool SmartTouch	NR	12
G. Lee 2015	retrospective observational cohort study	1515 (510/1005)	656 (238/418)	750 (255/495)	60.5±11.0 /60.8±11.3	349 (68.4) /264 (63.6)	77 (15) /140 (14)	31 (6) /50 (5)	NR	NR	Thermocool SmartTouch	NR	NR
Kimura 2014	prospective, randomized, controlled, study	38 (19/19)	28 (15/13)	10 (4/6)	62.5±10.1 /57.3±8.6	12 (63) /17 (89)	13 (68.4) /9 (47.4)	3 (15.8) /4 (21.1)	41.3±7.8 /42.0±6.8	65.7±5.2 /62.4±11.8	Thermocool SmartTouch	NR	6
Casella 2014	prospective, randomized, controlled, study	55 (20/35)	55 (20/35)	0	58±10 /56±13	16 (80) /28 (80)	6 (30) /12 (34)	NR	43.2±6.4 /41.9±5.5	62.3±7.4 /62.0±7.8	TactiCath	16	12
Ullah 2014	Prospective non-randomized multicenter study	100 (50/50)	NR	NR	63/62	41 (82) /39 (78)	11 (22) /7 (14)	3 (5) /2 (4)	4.4±0.6 /4.4±0.6	NR	Thermocool SmartTouch	13	12
Sciarrà 2014	Prospective non-randomized study	42 (21/21)	42 (21/21)	0	59.7±9.1 /54.6±11.0	18 (86) /18 (86)	NR	1 (5) /2 (10)	35±7 /36±6	56±5 /55±5	Thermocool SmartTouch	NR	2.5
Wakili 2014	Prospective non-randomized study	67 (32/35)	39 (18/21)	28 (14/14)	63.6±1.7 /59.3±1.9	21 (65.6) /23 (65.7)	21 (65.6) /25 (71.4)	NR	43.2±0.9 /42.1±0.9	68.5±2.2 /65.0±1.9	TactiCath	17.4	12
Andrade 2014	Prospective non-randomized study	75 (25/50)	75 (25/50)	0	58.8±12.7 /58.6±11.0	19 (76) /43 (86)	NR	NR	32.4±14.2 /39.2±4.7	63.3±5.5 /59.9±5.4	Thermocool SmartTouch	NR	13.2±0.9
Wutzler 2014	Prospective non-randomized study	143 (31/112)	104 (19/85)	39 (12/27)	59.8±10.9 /60.9±10.2	21 (67.7) /71 (63.4)	20 (64.5) /58 (51.8)	3 (9.7) /10 (8.9)	41.5±6.1 /42.4±6.7	56.8±4.9 /55.6±3.1	TactiCath	26.8	12

Continued next page

Continued Table 1. Baseline clinical characteristics and follow-up of the patients

	Type of study	AF (CF/NCF)	PAF (CF/NCF)	PerAF (CF/NCF)	Mean age y (CF/NCF)	Male, n(%) (CF/NCF)	Hypertension n(%) (CF/NCF)	Diabetes, n(%) (CF/NCF)	LA size mm (CF/NCF)	EF (%) (CF/NCF)	CF Catheter	Mean CF, g	Follow up months
Marijon 2014	Prospective non-randomized study	60 (30/30)	60 (30/30)	0	59.9±9 /61.0±10	21 (70.0) /22 (73.3)	NR	NR	NR	64.7±4 /65.4±5	Thermocool SmartTouch	21.7	12
Akca 2014	Prospective non-randomized study	449 (143/306)	NR	NR	55.7±15.1 /51.7±16.6	NR	NR	NR	NR	NR	Thermocool SmartTouch and TactiCath	NR	NR
Jarman 2014	Retrospective case-control study	600 (200/400)	276 (92/184)	324 (108/216)	63±12 /61±10	149(74.5) /282(70.5)	80 (40) /119 (30)	21 (11) /34 (9)	42±7 /44±7	NR	Thermocool SmartTouch	NR	11.4±4.7
Halidar 2012	Prospective non-randomized study	40 (20/20)	14 (7/7)	26 (13/13)	63±14 /61±12	15 (75) /11 (55)	7 (35) /6 (30)	NR	42±8 /41±5	57±12 /59±10	Thermocool SmartTouch	NR	NR
Martinek 2012	Prospective non-randomized study	50 (25/25)	50 (25/25)	0	60.5±9.5 /57.4±11.6	12 (48) /17 (68)	10 (40) /12 (48)	3 (12) /1 (4)	39±6 /37±6	53±4 /53±3	Thermocool SmartTouch	NR	NR
Mean													
Total		4053 (1546/2507)	2071 (849/1222)	1324 (487/837)								18.3	

AF - atrial fibrillation; CF - contact force; NR - not reported; PAF - paroxysmal atrial fibrillation. Statistical analysis was performed using the Cochrane RevMan version 5 software

the AF and PAF subgroups, AF recurrence significantly improved using CF-sensing catheters compared with that using NCF-sensing catheters in the AF [31.1% vs. 40.5%; risk ratio (RR)=0.82; 95% CI, 0.73–0.93;  $I^2=32\%$ ;  $p=0.001$ ] and PAF (25.3% vs. 40.0%; RR=0.76; 95% CI, 0.63–0.91;  $I^2=21\%$ ;  $p=0.004$ ) subgroups, which was similar with a previous meta-analysis that included nine studies (35). In the Per AF subgroup, the rate of AF recurrence was numerically lower in the CF group than in the NCF group; however, this did not reach statistical significance (49.7% vs. 55.8%; RR=0.93; 95% CI, 0.77–1.12;  $I^2=53\%$ ;  $p=0.43$ ; Fig. 3a).

Moreover, seven studies provided data on the rate of acute PV reconnection, and no evidence of heterogeneity was found among the studies ( $I^2=0\%$ ). The acute PV reconnection significantly improved using CF-sensing catheters compared with that using NCF-sensing catheters (10.1% vs. 24.2%; RR=0.45; 95% CI, 0.32–0.63;  $I^2=0\%$ ;  $p=0.00001$ ; Fig. 3b).

The CF used in the included studies ranged between 10 and 40 g, and the mean CF used was 18.3 g.

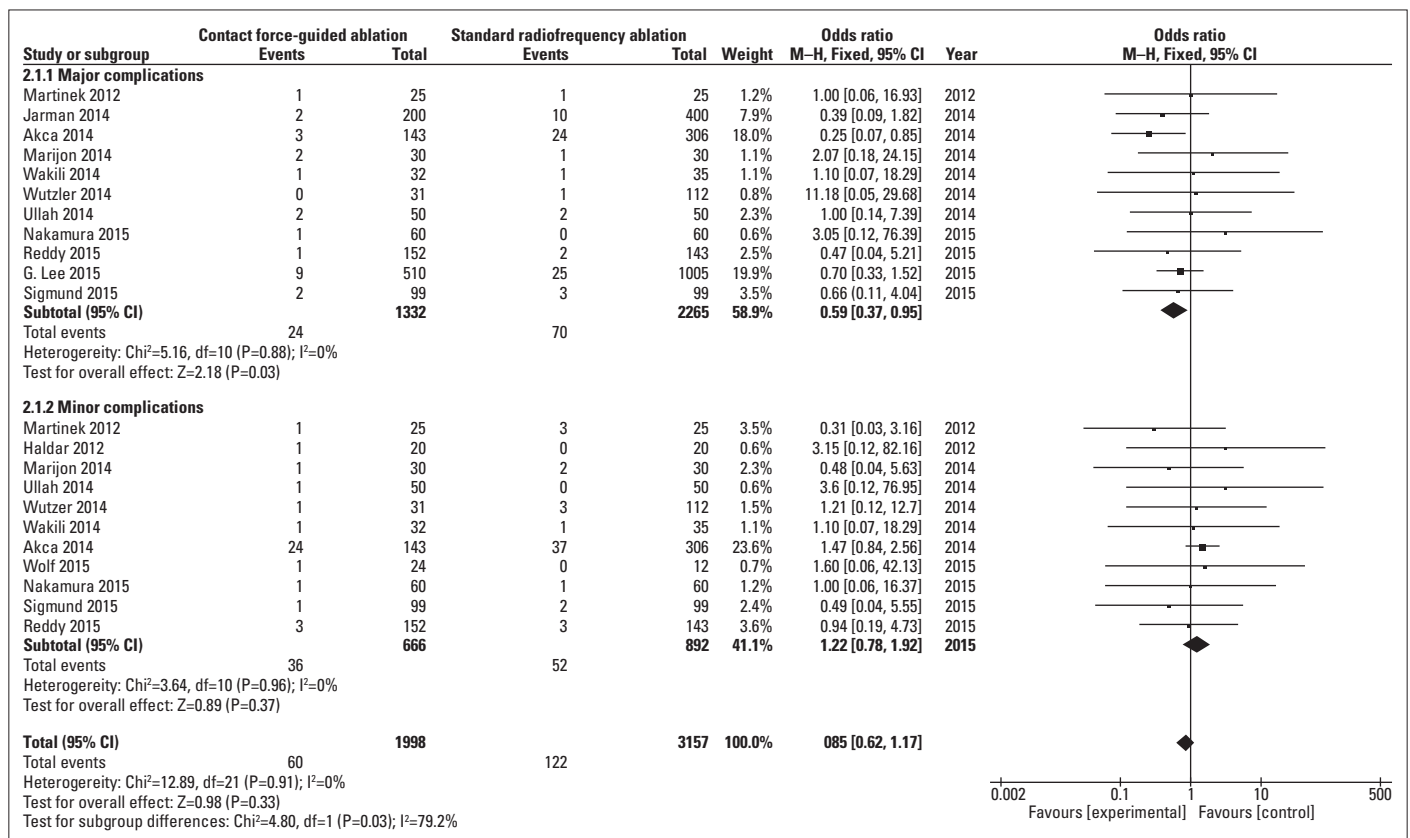
#### Safety of AF ablation using CF-sensing catheters

As shown in Figure 4, 11 studies assessed the incidence rate of major complications, and no evidence of heterogeneity was found among these studies ( $I^2=0\%$ ). The incidence rate of major complications was significantly lower in the CF group than in the NCF group (1.8% vs. 3.1%; OR=0.59; 95% CI, 0.37–0.95;  $I^2=0\%$ ;  $p=0.03$ ). The incidence rate of minor complications was numerically lower in the CF group than in the NCF group; however, the results did not reach statistical significance (5.4% vs. 5.8%; OR=1.22; 95% CI, 0.78–1.92;  $I^2=0\%$ ;  $p=0.37$ ).

Most included studies provided data on procedure parameters such as procedure duration, ablation time, fluoroscopy duration, and radiation dose in the AF and PAF subgroups. Figure 5 show that in the AF subgroup, the procedure duration [MD=–28.35; 95% CI, –39.54 to –17.16;  $I^2=85\%$ ;  $p=0.00001$ ], ablation time (MD=–3.8; 95% CI, –6.6 to –1.0;  $I^2=76\%$ ;  $p=0.008$ ), fluoroscopy duration (MD=–8.18; 95% CI, –14.11 to –2.24;  $I^2=97\%$ ;  $p=0.007$ ), and radiation dose (SMD=–0.75; 95% CI, –1.32 to –0.18;  $I^2=90\%$ ;  $p=0.01$ ) significantly reduced in the CF-guided group compared with in the NCF group. In the PAF subgroup, the procedure duration (MD=–49.64; 95% CI, –76.5 to –22.78;  $I^2=83\%$ ;  $p=0.0003$ ), ablation time (MD=–8.68; 95% CI, –13.83 to –3.52;  $I^2=67\%$ ;  $p=0.001$ ), fluoroscopy duration (MD=–13.9; 95% CI, –22.25 to –5.55;  $I^2=93\%$ ;  $p=0.0001$ ), and radiation dose (SMD=–0.56; 95% CI, –1.04 to –0.08;  $I^2=73\%$ ;  $p=0.02$ ) significantly reduced in the CF-guided group compared with in the NCF group.

#### Discussion

This meta-analysis showed that in contrast to AF and PAF ablation performed using NCF-sensing catheters, the use of CF-sensing catheters resulted in a significantly lower rate of acute PV reconnection and AF recurrence during the 12-month follow-up as well as reduced major complications and procedure parameters related to safety.



**Figure 4.** Forest plot showing odds ratio and 95% CI for the incidence rate of major complications and minor complications for studies comparing the CF and NCF groups

Achieving a lasting conduction block during the ablation procedure depends on a multitude of factors, including tissue depth, electrode–tissue interface temperature, and electrode tip–tissue contact pressure (29). Insufficient CF during initial lesion formation may result in edema and ineffective non-transmural lesions that allow subacute PV reconnection when the edema resolves (2, 12), whereas excessive contact can cause collateral tissue injury (31, 32, 36). Conventionally, the adequacy of contact between a catheter tip and tissue has been assessed using a combination of subjective factors and objective ablation parameters. Unfortunately, these parameters are poor predictors as they are unreliable and difficult to use (29, 37).

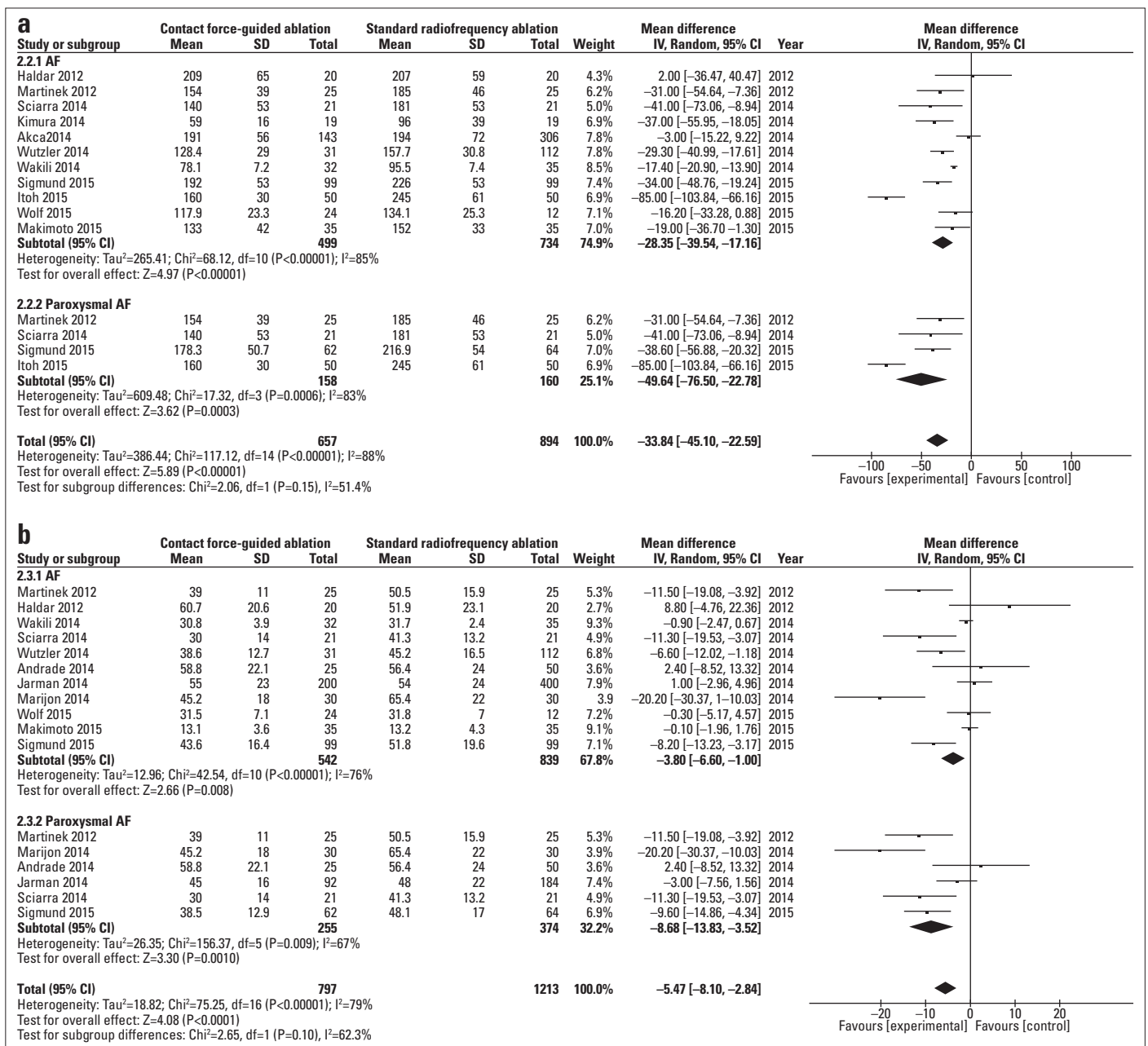
CF-sensing catheters offer a new paradigm in the invasive management of AF. Using these, continuous catheter–tissue CF can be measured, which ensures not only the optimal initial placement of the catheter but also the ability to detect catheter dislodging/sliding in real time (31). According to these features, the use of CF technology resulted in a significant reduction in the rate of acute PV reconnection and AF recurrence after AF ablation compared with the use of NCF.

However, it is a challenge to identify the optimal CF that should be applied during AF ablation to ensure adequate lesion formation, avoiding collateral tissue injury by the mean time.

The TOCCATA study (38) demonstrated that when PV isolation was performed with an average CF of <10 g, AF recurrence was

100%. When the average CF was >20 g, AF recurrence reduced to 20%. A recent published study (39) demonstrated that a CF threshold of >12 g predicts a complete lesion with high specificity. In the TOCCASTAR study, Reddy et al. (16) demonstrated that ablation with an optimal CF ( $\geq 90\%$  of lesions created with a CF of  $\geq 10$  g) resulted in a significantly higher success rate than that obtained for PV isolation with a non-optimal CF. The EFFICAS II study (40) prospectively applied CF guidelines for ensuring durable isolation of the PV of PAF patients, which demonstrated a target CF of 20 g; a range of 10–30 g resulted in a superior rate of durable PV isolation than the similar protocol without guidelines. The SMART-AF trial, a prospective, multicenter, non-randomized study (41), demonstrated that with an average CF of  $17.9 \pm 9.4$  g, 72.5% of patients were free from AF recurrence in a 12-month follow-up. The current meta-analysis provided important information regarding the use of an optimal average CF of 18.3 g (range, 10–40 g), with acceptable recurrence and complication rates.

Whether the use of CF-sensing catheters can decrease the rate of complications after AF ablation has always been a controversial issue. Akça et al. (32) demonstrated that CF procedures are associated with lesser major complications during AF ablation than NCF ones (2.1% vs. 7.8%,  $p=0.01$ ). A previous meta-analysis (42) that included 11 studies demonstrated that the major complication rate was numerically lower in the CF group than in the NCF group; however, this did not reach statistical signifi-



**Figure 5.** (a–c) Forest plot showing the unadjusted difference in the mean procedure duration, ablation time, and fluoroscopy duration for studies comparing the CF and NCF groups. (d) Forest plot showing the standard difference in the mean radiation dose for studies comparing the CF and NCF groups

cance (1.3% vs. 1.9%; OR, 0.71; 95% CI, 0.29–1.73;  $p=0.45$ ). With more studies included, the current meta-analysis demonstrated that the incidence of major complications was significantly lower in the CF group than in the NCF group (1.8% vs. 3.1%; OR=0.59; 95% CI, 0.37–0.95;  $p<0.05$ ).

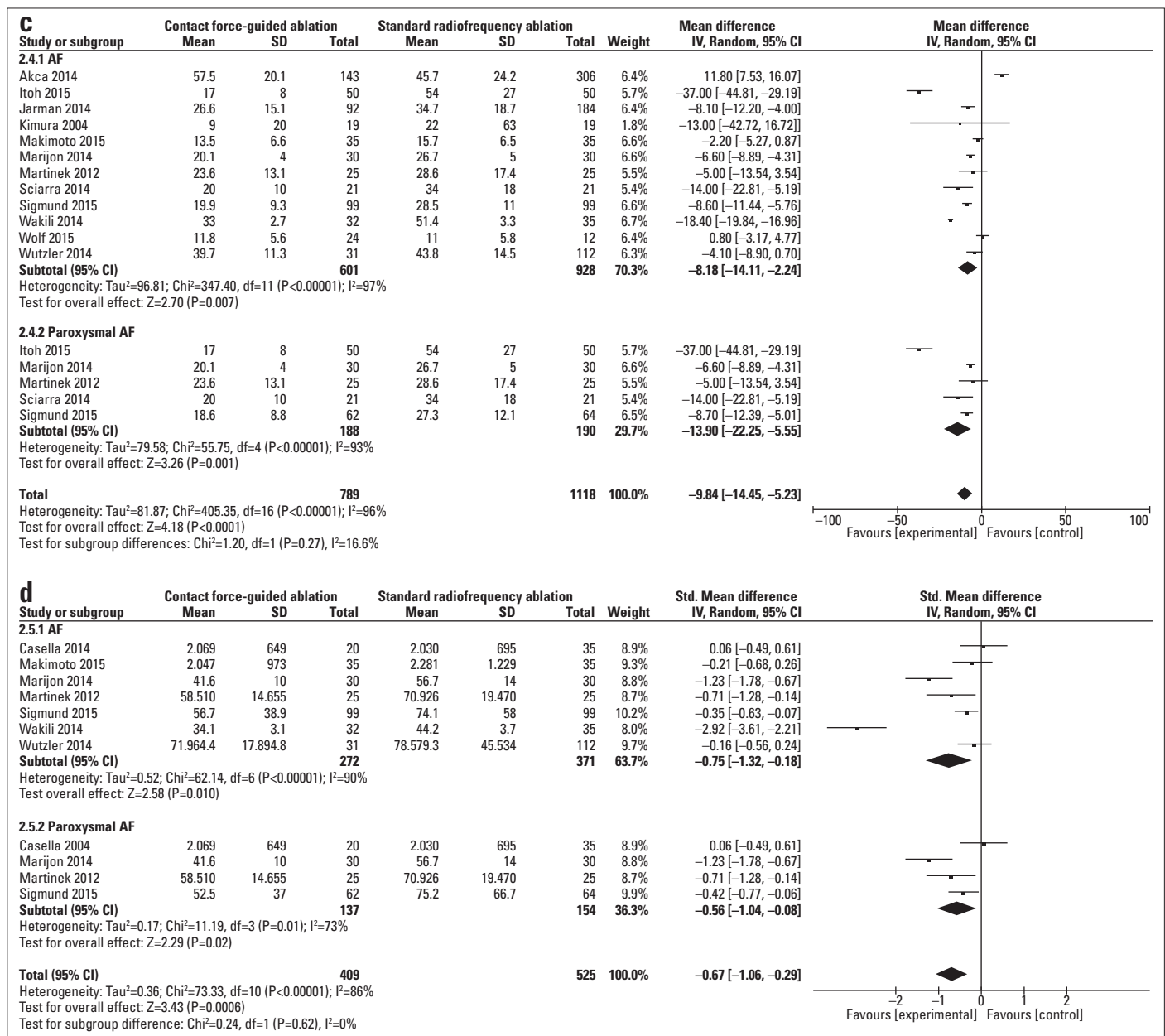
In the current analysis, the procedure duration, ablation time, fluoroscopy duration, and radiation dose significantly reduced in the CF group compared with in the NCF group in the AF and PAF subgroups. CF-sensing catheters may reduce reliance on fluoroscopy during navigation and the time to achieve intact linear lesions, which promote safety not only for patients but also for operators.

### Study limitations

The current analysis had the following limitations: some studies were of limited quality, given their retrospective and single-center designs. Differences in operators' experience and ablation protocols may have affected the outcomes of the included studies.

### Conclusion

AF ablation using CF-sensing catheters has better outcomes than those NCF-sensing catheters during the 12-month follow-up period. Furthermore, the incidence of major complications



**Continued Figure 5.** (a–c) Forest plot showing the unadjusted difference in the mean procedure duration, ablation time, and fluoroscopy duration for studies comparing the CF and NCF groups. (d) Forest plot showing the standard difference in the mean radiation dose for studies comparing the CF and NCF groups

using CF-sensing catheters was even lower than that using NCF-sensing catheters. The meta-analysis also demonstrated that using an optimal average CF of 18.3 g was associated with higher success and lower complication rates. Randomized controlled studies are required to assess whether catheter ablation using an optimized CF improves the long-term clinical outcome and to determine the exact optimal CF to be used in different patient subgroups.

**Conflict of interest:** None declared.

**Peer-review:** Externally peer-reviewed.

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