ORIGINAL RESEARCH

Impact of Contact Force Technology on Atrial Fibrillation Ablation: A Meta-Analysis

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***Background*—**Catheter–tissue contact is essential for effective lesion formation, thus there is growing usage of contact force (CF) technology in atrial fibrillation ablation. We conducted a meta-analysis to assess the impact of CF on clinical outcomes and procedural parameters in comparison to conventional catheter for atrial fibrillation ablation.

***Methods and Results*—**An electronic search was performed using major databases. Outcomes of interest were recurrence rate, major complications, total procedure, and fluoroscopic times. Continuous variables were reported as standardized mean difference; odds ratios were reported for dichotomous variables. Eleven studies (2 randomized controlled studies and 9 cohorts) involving 1428 adult patients were identified. CF was deployed in 552 patients. The range of CF used was between 2 to 60 gram-force. The follow-up period ranged between 10 and 53 weeks. In comparing CF and conventional catheter groups, the recurrence rate was lower with CF (35.1% versus 45.5%, odds ratio 0.62 [95% CI 0.45–0.86], *P*=0.004). Shorter procedure and fluoroscopic times were achieved with CF (procedure time: 156 versus 173 minutes, standardized mean difference −0.85 [95% CI −1.48 to −0.21], *P*=0.009; fluoroscopic time: 28 versus 36 minutes, standardized mean difference −0.94 [95% CI −1.66; −0.21], *P*=0.01). Major complication rate was lower numerically in the CF group but not statistically significant (1.3% versus 1.9%, odds ratio 0.71 [95% CI 0.29–1.73], *P*=0.45).

***Conclusions*—**The use of CF technology results in significant reduction of the atrial fibrillation recurrence rate after atrial fibrillation ablation in comparison to the conventional catheter group. CF technology is able to significantly reduce procedure and fluoroscopic times without compromising complication rate. **(*J Am Heart Assoc*. 2015;4:e002476 doi: 10.1161/JAHA.115.002476)**

Key Words: ablation • atrial fibrillation • contact force • meta-analysis

Atrial fibrillation (AF) is the most common cardiac dysrhythmia, with a lifetime risk between 22% and 26% by 80 years of age.[1] The current guidelines recommend catheter ablation in patients with symptomatic AF resistant to or intolerant of antiarrhythmic medications.[2] AF ablation accounts for about one-third of the caseload in electrophysiology laboratories in the Western world.[3] High recurrence rate remains a major concern for this complex ablation procedure, with up to 40% needing the procedure to be redone.[4] In addition, the risks involved are substantial, with some devastating complications related to stroke, atrial esophageal fistula, and death.[5,6] This risk would affect the decision of whether to repeat the procedure and mandates maximum efforts to ensure complete and durable isolation of the pulmonary veins during the initial procedure. Complete isolation of the pulmonary veins is related largely to the

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quality, size, and continuity of lesions delivered because recurrence is frequently related to recovery of conduction between the pulmonary veins and the surrounding left atrium after what is initially perceived to be complete isolation.[4,7–9]

Many advances have been introduced to enhance the quality of ablation applications in pulmonary vein isolation such as the use of irrigated and circular diagnostic catheters,[10] 3-dimensional tracking systems, robotics,[11] testing with adenosine to reveal dormant conductions,[12] and cardiac magnetic resonance imaging to assess the quality of lesions.[13]

Contact force (CF) is a fairly new technology that allows real-time contact feedback between the catheter tip and the targeted cardiac tissue. Theoretically, this approach improves the quality of the lesions and enhances safety outcomes.

We conducted a meta-analysis to assess the impact of CF on clinical outcomes and procedural parameters in comparison to conventional catheter (CC) for AF ablation.

Methods

Literature Search and Data Sources

An electronic literature search was performed by 3 investigators (M.S., D.B., A.K.) in accordance with the recommendations of the Cochrane Collaboration, using PubMed, Embase, Web of Science, Cochrane Central Register of Controlled Trials, and Scopus databases through March 25, 2015. The search terms were *atrial fibrillation* and *ablation* and *contact force*. Neither language nor demographic restrictions were applied. All references from papers obtained through the databases were reviewed manually. The electronic search was archived and is available on request. Our study was a systematic review and meta-analysis and thus did not require institutional review board approval.

Study Selection and Quality Assessment

The inclusion was limited to the studies (1) that compared CF with CC in radiofrequency catheter ablation of atrial fibrillation, (2) that included an adult population aged >18 years only, and (3) that provided data on outcomes of interest.

The selection of studies was assessed independently by 3 assessors (M.S., D.B., A.K.). We excluded noncomparative trials, case reports, editorials, letters, replies, and reviews. We also excluded any study that included other ablation technologies (eg, cryoablation or robotic navigation) that could affect our results and increase bias.

We used the Newcastle-Ottawa Scale to further assess the quality of the observational studies. Studies were judged on 3 broad perspectives: (1) selection of the study groups; (2) comparability of the groups; and (3) ascertainment of either the exposure or outcomes of interest for case–control or cohort studies, respectively.[14] The quality of the randomized studies was evaluated based on the 5-point scale outlined by Jadad et al, with the following criteria: randomization with proper concealment of the allocation sequence, blinding of the patient and investigator to treatment allocation with description of the blinding method, and completeness of follow-up.[15]

Data Extraction

Three reviewers (M.S., D.B., A.K.) independently extracted the data from published sources; disagreements were resolved by discussion and, as necessary, in consultation with a third person (E.C., L.D., H.N., D.N.). The primary outcome measure was recurrence rate. Secondary outcomes included procedure and ablation times, total fluoroscopic time, and complication rates.

Whenever possible, direct communication with the authors of the papers was undertaken in an attempt to obtain the data of interest if presentation in the manuscript was incomplete.

Definition of Outcomes

The following outcomes were identified as relevant measures to compare for the studied groups: (1) rate of recurrence, defined as any symptomatic or asymptomatic atrial arrhythmia recurrence after ablation (density of monitoring and cutoff for duration is manuscript specific); (2) major complications, including embolic events, cardiac tamponade or pericardial effusion requiring intervention, phrenic nerve palsy, pulmonary vein stenosis, atrial esophageal fistula, and death; (3) minor complications, including pericardial effusion (not requiring intervention) or vascular access complications (including hematoma, arteriovenous fistula, or aneurysm); (4) procedural parameters, defined as total procedural time, ablation time, and fluoroscopy time according to the individual study protocols.

The study-specific definitions of outcomes were slightly variable. Although the assessment of outcomes across the trials was not standardized, the same criteria were applied equally to the groups within each trial.

Statistics

The software package RevMan (version 5), provided by the Cochrane Collaboration, was used for combining outcomes from the individual studies and for statistical analysis. Outcomes were pooled using a random-effects model described by DerSimonian and Laird.[16] Summary estimates

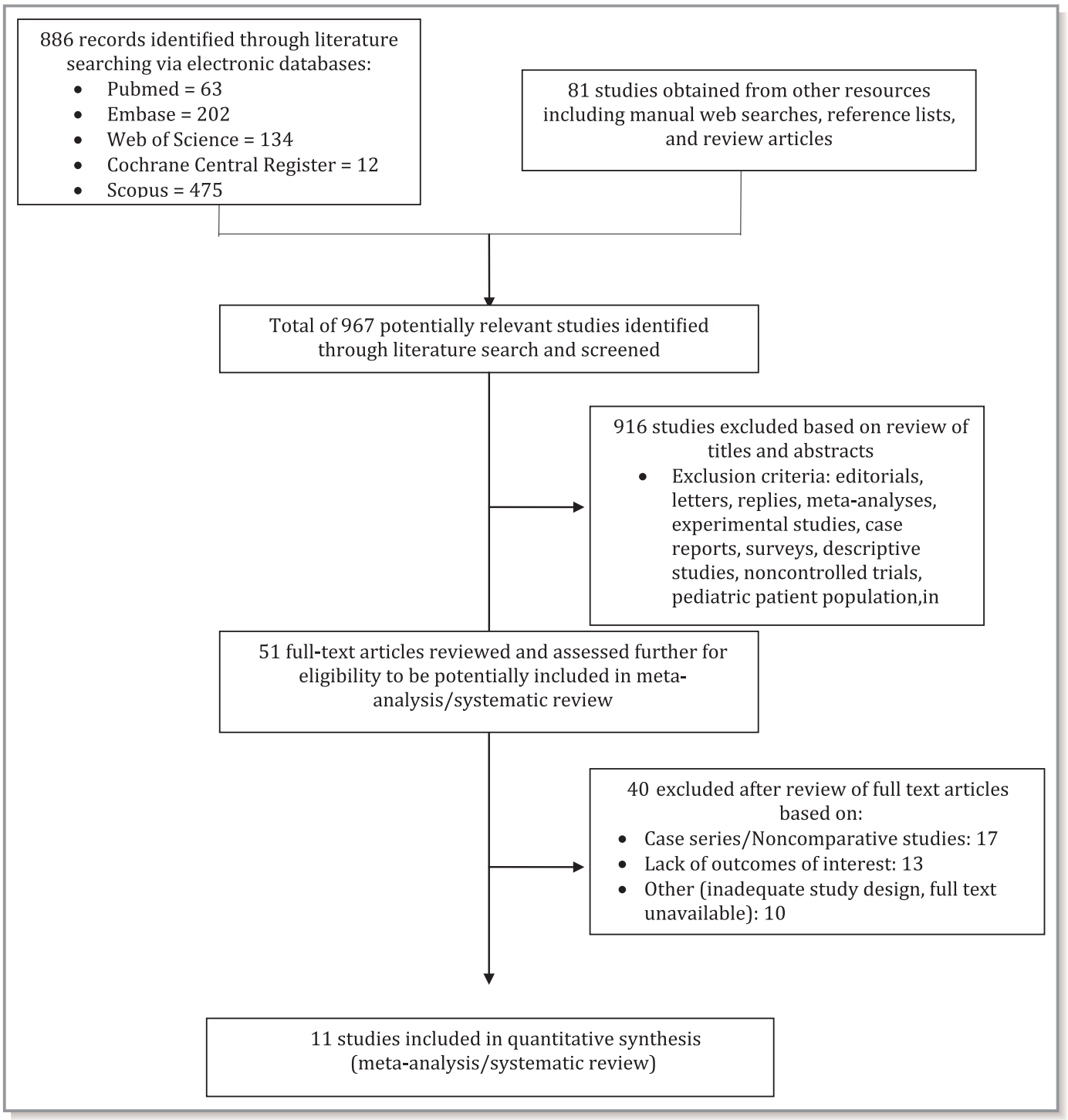

Figure 1. Flow diagram of literature search and study selection.

and 95% CI were reported for dichotomous variables as odds ratio (OR) and for continuous variables as standardized mean difference. The heterogeneity between studies was assessed using the Cochran *Q* test and I^2. An I^2 >50% was considered to represent significant heterogeneity.[17] Statistical significance was set as $P<0.05$. We calculated the weighted mean for the variable baseline characteristics and complications outcomes.

Results

Summary of the Studies

A thorough literature search resulted in 967 items (886 from electronic databases and 81 from other resources). Eleven studies (2 randomized controlled trials and 9 cohorts) were identified that compared the safety and efficacy of guided CF

Table 1. Summary of the Included Studies

Study (n=11)	Year	Type of Study	No. of Patients		Follow-up (months) (mean 10.6±3.34)	Ablation	CF Catheter
			CF (n=552)	Control (n=876)			
Martinek[23]	2012	Prospective nonrandomized study	25	25	n/a	Circumferential PVI	ThermoCool SmartTouch
Casella[19]	2013	Randomized controlled trial	20	35	12	Circumferential PVI	Tacticath or Contact Therapy Cool Path
Andrade[18]	2014	Prospective nonrandomized study	25	50	13.3	Circumferential PVI	ThermoCool SmartTouch
Kimura[21]	2014	Randomized controlled trial	19	19	6.7	Circumferential PVI	ThermoCool SmartTouch
Marijon[22]	2014	Prospective nonrandomized study	30	30	12	Circumferential PVI	ThermoCool SmartTouch
Sciarra[24]	2014	Prospective nonrandomized study	21	21	2.5	Circumferential PVI and additional RF applications	ThermoCool SmartTouch
Wakili[27]	2014	Prospective nonrandomized study	32	35	12	Circumferential PVI	TactiCath
Wutzler[28]	2014	Prospective nonrandomized study	31	112	12	Circumferential PVI	TactiCath
Jarman[20]	2014	Retrospective case–control study	200	400	11.4	PVI (for paroxysmal AF: additional linear ablation was performed only exceptionally; nonparoxysmal AF: use of additional lesions varied by operator, including linear lesions at the roof, mitral isthmus, posterior wall and CTI, targeting of complex fractionated electrograms, and ablation at the endocardial and epicardial aspects of the coronary sinus)	ThermoCool SmartTouch
Ullah[26]	2014	Prospective nonrandomized study	50	50	12	PVI or WACA plus CTI plus mitral isthmus plus roof line (CTI line added in patients with AFL hx; if remained in AF linear lesions added at mitral isthmus and roof, both point-to-point and drag)	ThermoCool SmartTouch
Sigmund[25]	2015	Prospective case-matched control trial	99	99	12	Circumferential PVI plus linear ablation plus CFAE (PVI only, PVI with lines, PVI with lines and CFAE, PVI with CFAE)	ThermoCool SmartTouch

AF indicates atrial fibrillation; AFL, atrial flutter; CF, contact force; CFAE, complex fractionated atrial electrogram; CTI, cavotricuspid isthmus; hx, history; PVI, pulmonary vein isolation; RF, radiofrequency ablation; WACA, wide area circumferential ablation.

and CC in the setting of AF ablation.[18–28] The studies met all applied inclusion criteria of this meta-analysis. The information relevant to the literature search is shown in Figure 1. Pulmonary vein isolation alone without additional ablation lesions was used as the targeted ablation procedural end point in most of the studies (7 studies); the ThermoCool SmartTouch Catheter (Biosense Webster Inc) was used in the majority of the studies for CF (8 studies). Different follow-up

Table 2. Summary of the Baseline Characteristics

Variable	CF	Control	*P* Value
Total patients, n	552	876	n/a
Paroxysmal AF no. (% mean)	59%	60%	0.948
Age, y (mean±SD)	61±2	60±2	0.046
Male sex (% mean)	73%	72%	0.343
Left ventricular ejection fraction, % (mean±SD)	60±5.4	59±4.5	0.609
Left atrial diameter, mm (mean±SD)	41±3.8	43±2.7	0.594
Hypertension (% mean)	43.5%	37.9%	0.695
Diabetes mellitus (% mean)	8.4%	7.7%	0.894

All means calculated as weighted means. AF indicates atrial fibrillation; CF, contact force; n/a, not applicable.

protocols were used among studies. The follow-up period ranged between 10 and 53 weeks (mean 42 weeks). Table 1 presents a summary of the included studies.

Baseline Characteristics of Patients

A total of 1428 patients were enrolled in both study and control groups; CF was deployed in 552 patients. Patients in the CF group were slightly older in comparison to the CC group (61±2 versus 60±2 years; *P*=0.046), and this might be related to selection bias in nonrandomized studies. The patients were predominantly male in both CF and CC groups (73% and 72%; *P*=0.343). The baseline clinical characteristics were similar between both groups. There were no significant differences in left ventricular ejection fraction (60%±5.4% versus 59%±4.5% *P*=0.609) or left atrial diameter (41±3.8 mm versus 43±2.7 mm *P*=0.594) between the 2 groups. Similar numbers of patients in the CF and CC groups had hypertension (43.5% versus 37.9% *P*=0.695) and diabetes mellitus (8.4% versus 7.7% *P*=0.894). Paroxysmal AF accounted for 59% of patients in the CF group and 60% in the CC group (*P*=0.948). Summary of the baseline characteristics are presented in Table 2.

Procedural Outcomes

Recurrence rate was reported in the majority of the studies (10 studies). In comparing CF and CC groups, a significantly lower recurrence rate was noted with CF (35.1% versus 45.5%, OR 0.62 [95% CI 0.45–0.86], *P*=0.004). No significant heterogeneity was noted for the comparison (I^2=23%, *P*=0.23) (Figure 2). The CF used ranged between 2 and 60 gram-force (mean 17±5 g). There were not enough studies on persistent AF to support a separate analysis of the recurrence rate. We had 4 studies that reported recurrence rate in patients with only paroxysmal AF, which showed a lower recurrence rate in the CF group, in line with our overall analysis (15% versus 31%, OR 0.38 [95% CI 0.19–0.76], *P*=0.007). The small number of the studies and patients for either paroxysmal or persistent AF did not support this subgroup analysis.

Shorter total procedure and ablation times were achieved with CF (total procedure time: 156 versus 173 minutes, SDM −0.85 [95% CI −1.48 to −0.21], *P*=0.009; ablation time: 47 versus 51 minutes, SDM −0.36 [95% CI −0.62 to −0.10], *P*=0.007) (Figure 3A and 3B). The use of CF technology was associated with reduced fluoroscopy time (28 versus 36 minutes, SDM −0.94 [95% CI −1.66 to −0.21] *P*=0.01) (Figure 4).

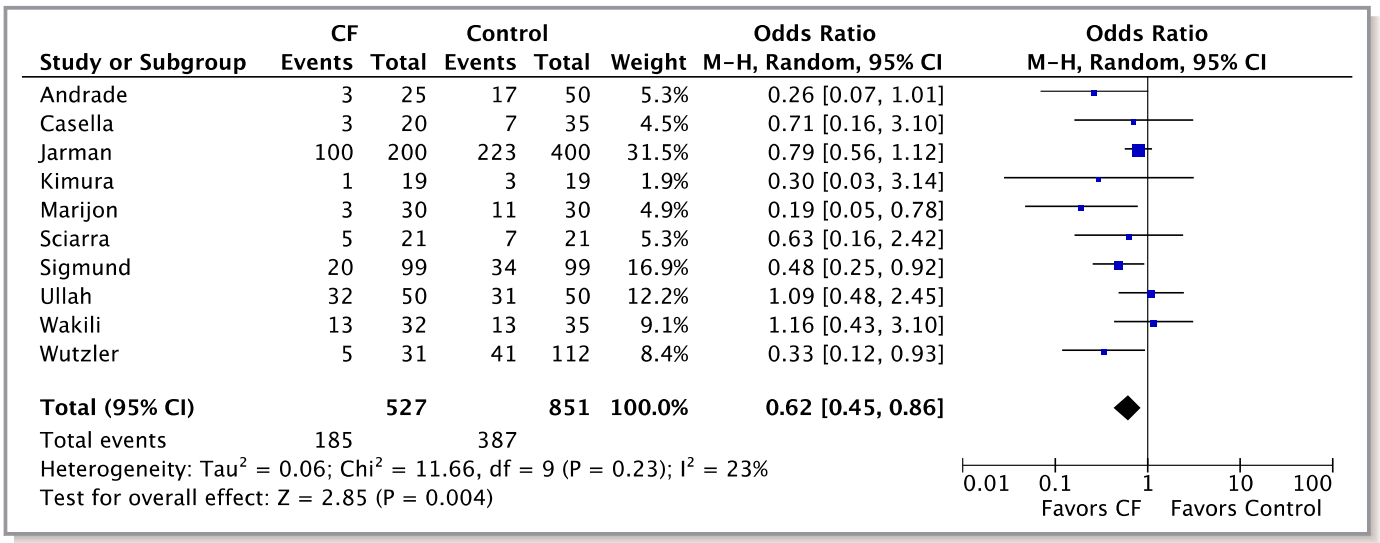

Figure 2. Forest plot of the individual and combined rates of recurrence. CF indicates contact force; M-H, Mantel-Haenszel test.

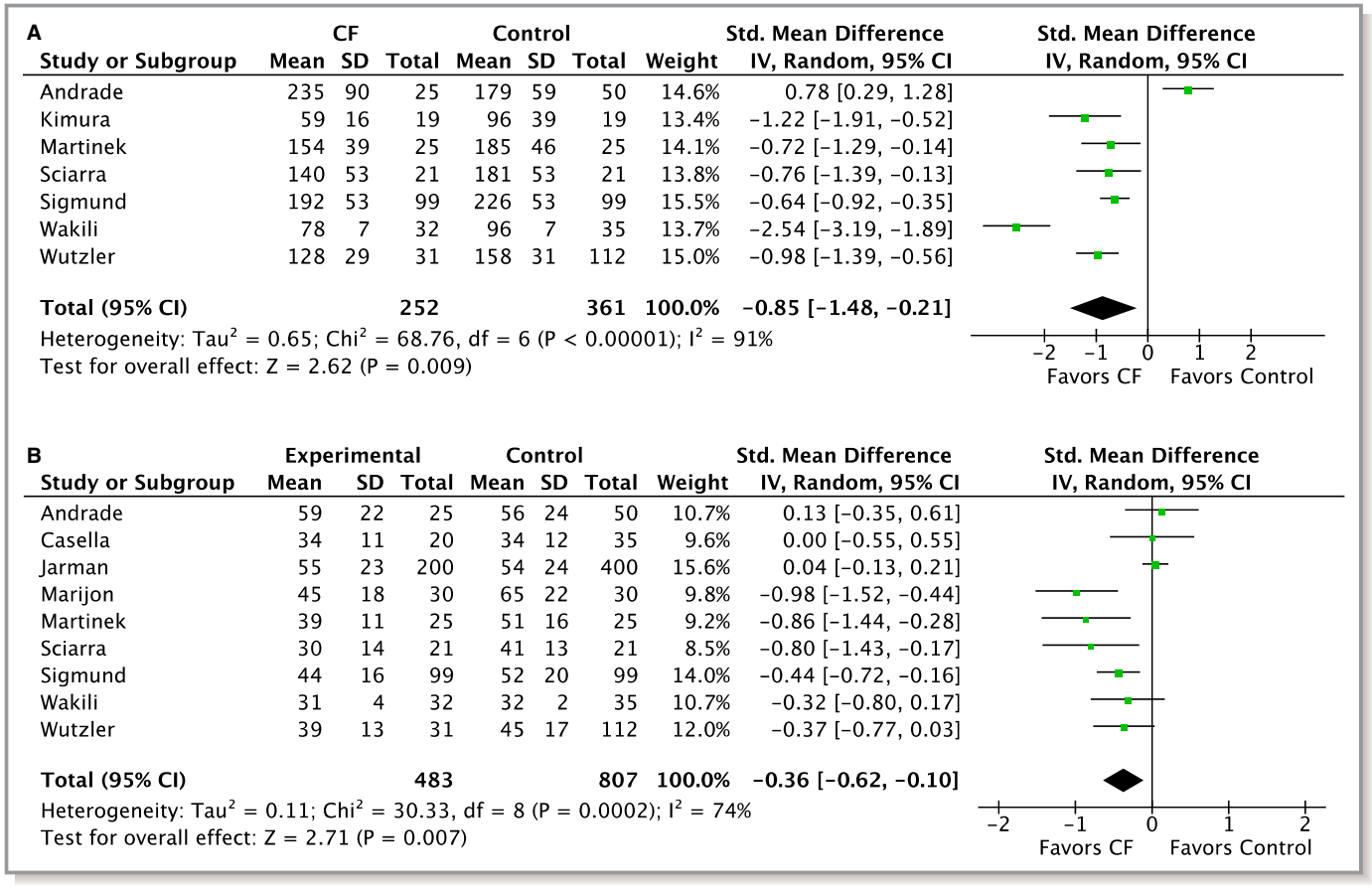

Figure 3. Forest plots of the individual and combined rates of (A) total procedure time and (B) ablation time. CF indicates contact force; IV, inverse variance.

Complication Rates

The major complication rate was numerically lower in the CF group versus CC group; however, this did not reach statistical significance (1.3% versus 1.9%, OR 0.71 [95% CI 0.29 to 1.73], *P*=0.45) (Figure 5A). There were 5 cases of cardiac tamponade or effusion requiring intervention in the CF group versus 10 cases in the CC group (1.2% versus 1.4%, OR 0.82 [95% CI 0.29–2.27], *P*=0.70) (Figure 5B). Minor complications, mainly related to vascular access, were similar between both groups (2.9% versus 2.6%, OR 0.99 [95% CI 0.48–2.05], *P*=0.98) (Figure 6).

Discussion

Our meta-analysis demonstrated the following key findings: (1) A lower recurrence rate was noted with CF in comparison

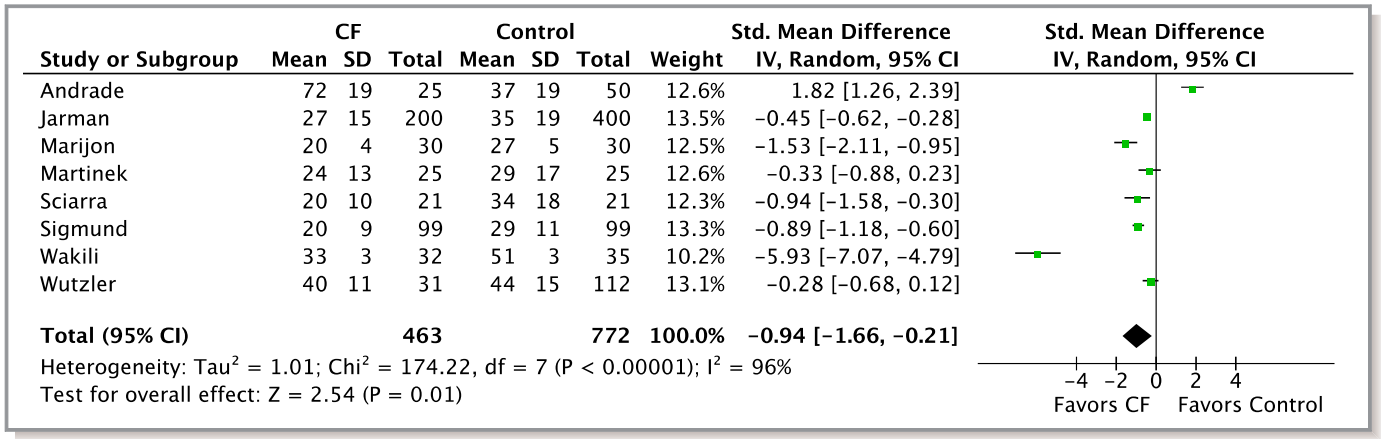

Figure 4. Forest plots of the individual and combined rates of total fluoroscopic time. CF indicates contact force; IV, inverse variance.

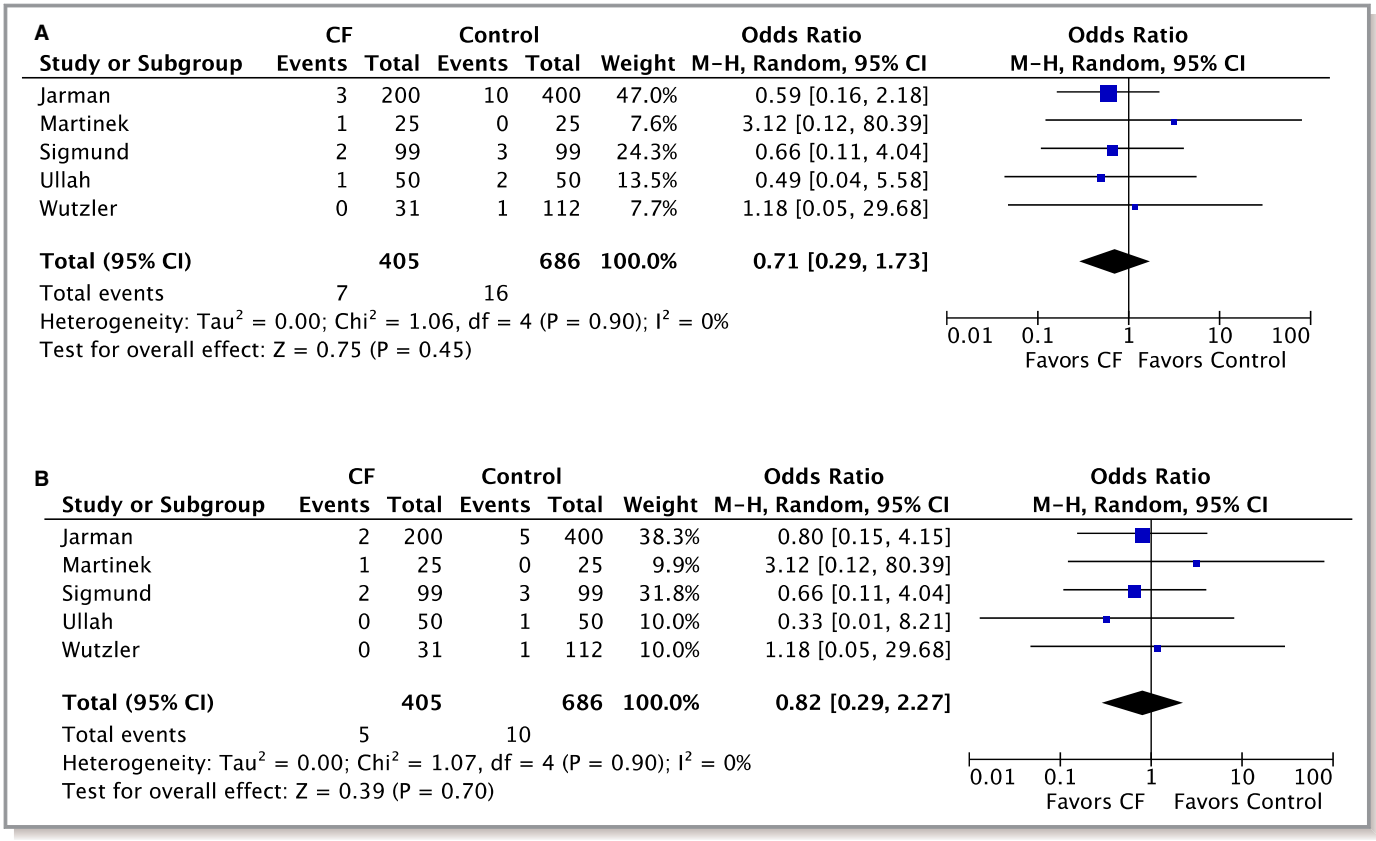

Figure 5. Forest plots of the individual and combined rates of (A) major complications and (B) cardiac tamponade. CF indicates contact force; M-H, Mantel-Haenszel test.

to CC; (2) shorter procedure, ablation, and fluoroscopic times were achieved with CF; and (3) major and minor complication rates were similar between both groups.

Many studies have demonstrated the importance of the CF technology as a determinant of adequate ablation lesion quality and size,[29–32] with a significant reduction in the prevalence of dormant conduction.[18] Measures like intracardiac electrograms, tactile feedback, and impedance are usually used to assess the catheter tip–tissue contact, but on many occasions, these measures are less accurate and do not provide real-time feedback.[33,34] CF technology provides operators with instant feedback allowing for adequate maneuvering of the catheter and avoiding inadequate lesion formation, suboptimal contact, or excessive contact with possible mechanical injury. The challenge remains to identify the optimal CF that should be applied during AF ablation to ensure adequate lesion formation and superior outcomes. Reddy et al in the TOCCATA study showed that 80% of patients treated with an average CF >20 g

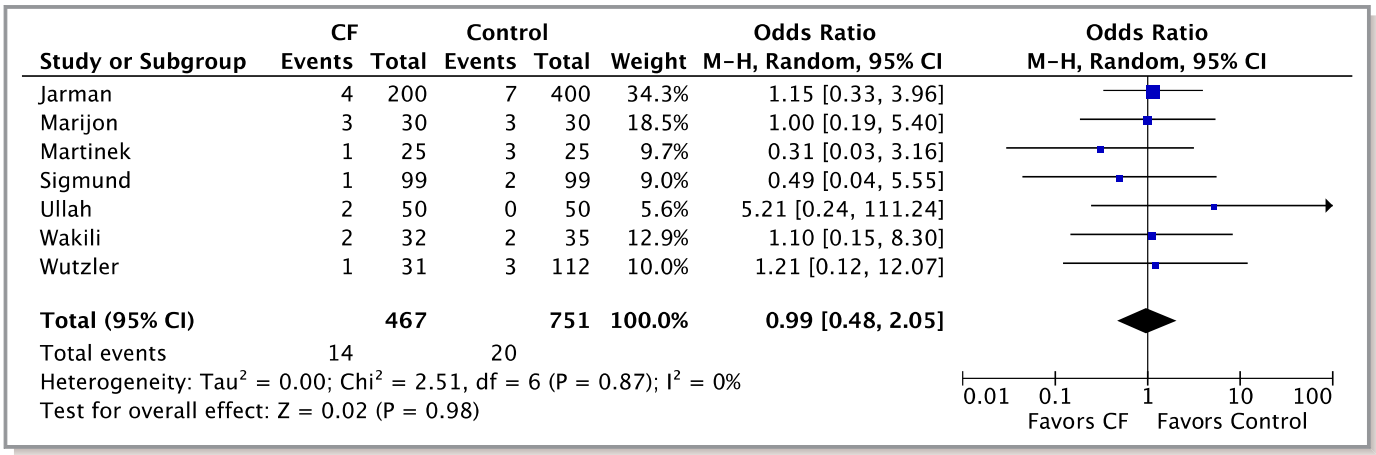

Figure 6. Forest plots of the individual and combined rates of minor complications. CF indicates contact force; M-H, Mantel-Haenszel test.

were free from AF recurrence at 12 months, whereas all patients treated with an average CF of <10 g experienced recurrences.[35] In contrast, it has been suggested that CF >5 g is associated with adequate lesion formation with impedance fall during 60 seconds of ablation.[36] In addition, CF varies widely in certain anatomic locations.[37] Our study provides important information regarding the optimal average CF of 17±5 g with acceptable recurrence and complication rates, especially the risk of pericardial tamponade or effusion requiring intervention.

There was significant reduction in procedure and ablation times not only in comparison to point-by-point manual radiofrequency ablation but also similar to what is seen in "single-shot" devices such as the Cryoballoon.[38] Using CF feedback as a main determinant of adequate lesion formation would minimize ineffective lesion formation and thus achieve pulmonary vein isolation faster without the need for additional ablation lesions to confirm isolation. Furthermore, operators would spend less time assessing signal or impedance drop during ablation. All of these factors would explain the shorter procedure and ablation times.

Radiation safety remains a major concern in invasive electrophysiology. In this analysis, fluoroscopic time was reduced by 8 minutes in CF compared with CC groups, with an average reported fluoroscopy time of 28 minutes in CF versus 36 minutes in CC groups. This reduction is largely related to the continuous monitoring of the catheter while using CF, enabling operators to manipulate and advance the catheter without the need of excessive fluoroscopic guidance. In contrast, more frequent visualization with fluoroscopy is typically used with CCs in an effort to prevent perforation or to assess contact by the tip of catheter appearance and movements. Attention to radiation exposure and a statistically significant decrease in exposure have clinical relevance for both operators and patients undergoing ablation procedures.[39,40]

This meta-analysis has proven the enhanced safety of using the CF technology with acceptable rates of minor and major complications and reduced risk of cardiac perforation (although it did not reach statistical significance). This is related mainly to the ability to continuously monitor the catheter while manipulating it in the cardiac chambers, with real-time instant feedback of the catheter tip–tissue contact. Moreover, avoiding ablation at suboptimal CF would reduce the need for excessive ablations and subsequent related complications.

Limitations

Some studies were of limited quality, given their retrospective and single-center designs. Assessing outcomes like procedural time and complication rate is complex and multifactorial. Factors like different levels of experience among operators, catheters used, instrumentation, ablation energy and duration, magnitude of ablation performed, antiarrhythmic drugs, and incomplete data may have altered our conclusions. Some operators performed, in addition to pulmonary vein isolation ablation, more complex lesion sets (eg, complex atrial fractionated electrogram, left atrial roof line, mitral isthmus line), and that may have affected the outcomes of these procedures compared with only pulmonary vein isolation procedures. We could not address this issue, given the heterogeneity of ablation protocols among different operators. There could have been a lack of statistical power for some outcomes studied. Some of the outcomes had high I^2 representing significant heterogeneity such as procedure, ablation, and fluoroscopic times. That said, outcomes like recurrence rate, major complications, cardiac tamponade, and minor complications had insignificant heterogeneity that could reflect some similarities among studies.

Conclusions

This meta-analysis suggests that the use of CF technology results in a significant reduction of AF recurrence rate after AF ablation in comparison to the CC group. CF technology is able to significantly reduce procedure and fluoroscopic times without compromising the complication rate.

Disclosures

Dr Di Biase is a consultant for Biosense Webster, Boston Scientific, Stereotaxis and St Jude Medical, and has received speaker honoraria/travel from Medtronic, Atricure, EPiEP and Biotronik. Rest of the authors: None.

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