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Short-term Heart Function Change of Catheter Ablation in Persistent Atrial Fibrillation and Heart Failure: A Meta-analysis of Randomized Controlled Trials

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Abstract

Background: The effect of catheter ablation (CA) versus drug therapy on cardiac function improvement is not clear for patients with persistent atrial fibrillation and heart failure. To compare the short-term therapeutic effects between CA and conventional drug therapy, we conducted a meta-analysis of the current randomized controlled trials (RCTs).

Objective and method: The analyses systematically collected PubMed, Embase, and the Cochrane Library for RCTs comparing catheter ablation with medical therapy in patients with persistent atrial fibrillation and heart failure. In order to reduce the impact of other factors on cardiac function, we limited the maximum follow-up time to two years. The primary outcome is changes in left ventricular ejection fraction (LEVF), second outcomes are changes in 6-minute walk test (6MWT), Minnesota Living with Heart Failure Score (MLHFQ), B-type natriuretic peptide (BNP). SMD was used for the results measured by different methods. Random-effects model or fixed-effects model was used to estimate relative risks (RRs) with 95% confidence intervals (CIs).

Results: A total of six randomized controlled trials included 775 patients included in the final analysis, compared with drug therapy, catheter ablation has a better improvement in left ventricular ejection fraction (SMD, 0.57; 95% CI [0.40, 0.94], p<0.00001), 6-minute walk distance(MD 23.35, 95% CI [5.51, 41.19], p<0.00001), Minnesota Living with Heart Failure Score (MD -11.13, 95% CI [-2.52, -19.75], p=0.01), and B-type natriuretic peptide (110.93, 95% CI [82.84, 139.3], p<0.00001).

Conclusion: Catheter ablation has a better improvement than medical treatment in heart function for patients with persistent atrial fibrillation and heart failure.

Keywords: Atrial fibrillation; Heart failure; Catheter ablation

Introduction

Atrial fibrillation (AF) and heart failure (HF) are epidemics of 21st century. The two diseases are often co-existing and affect each other in pathogenesis and prognosis [1-3]. AF in patients with HF is associated with an increased risk of heart function deterioration, leading to a severe limitation of excise toleration and life quality. Considering such poor outcomes for these patients, identifying the optimal therapies is of great importance and urgency.

Antiarrhythmic and heart control drugs have been the cornerstone of atrial fibrillation treatment and are recommended by various guidelines [4-7]. But even treated with optimal drug therapy, most patients' heart function still can't achieve the desired improvement, and long-term drugs also lead to some adverse reactions. Catheter ablation (CA) is a well-established therapy for maintaining sinus rhythm, and it also has positive outcomes in people with HF [8]. But there is lack of study whether it is superior to medicine in improve cardiac function. When evaluating the effects of two treatments, we usually affected by two problems: first, limited research on such issues could be found and existing researches remain controversial [9-15]; second, some studies focus on long-term prognosis, this may lead to a large number of lost follow-up and cardiac function may be affected by the development of other diseases.

Therefore, we conducted a meta-analysis of the existing randomized controlled trials of catheter ablation and traditional drug therapy for the short-term improvement of cardiac function in patients with atrial fibrillation and heart failure, expected to better evaluate the effect of different treatment regimens on cardiac function improvement.

Methods

This meta-analysis was performed mainly according to the recommendations of the Cochrane Handbook and PRISMA guidelines, all analyses were based on previous published RCTs. There was no registered protocol for this meta-analysis. No ethical approval and patient consent are required.

Literature search strategy and selection criteria

We systematically searched the published literature in PubMed, Embase and the Cochrane Library from inception through June 10, 2018. The electronic searches were conducted using exploded Medical Subject Headings (MeSH) terms and the corresponding keywords in title/abstract. The search terms used in this meta-analysis were MeSH exp 'Atrial Fibrillation', and keywords 'Auricular Fibrillation', 'fibrillation', 'fibrillations'; MeSH exp ' Heart Failure', and keywords

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'Cardiac Failure', 'left ventricular systolic dysfunction', 'reduced left ventricular systolic function'; MeSH exp 'Catheter Ablation' and keywords 'ablation', 'pulmonary vein isolation'; MeSH exp ' Medical Treatment' and keywords 'medical', 'medicine', 'drug'. Only radomized controlled trials (RCTs) in the English were included. Two reviewers (Xiong Q and Chen Y) independently conducted the initial search, deleted duplicate records, screened the titles and abstracts for relevance, and identified records as included, excluded or uncertain. In case of uncertainty, full-text article was acquired to identify eligibility. Doubts and disagreements were solved by a third investigator (Ling Z).

Published RCTs meeting the following criteria were included: (1) Population: AF patients with persistent AF and LEVF <50%; (2)The RCT associated with original date on catheter ablation versus medical treatment; (3) If the trial related both persistent AF and paroxysmal AF, only the data about persistent were included; (4) Outcomes should include all or part of the patient's cardiac function related indicators such as left ejection fraction(LEVF), heart failure questionnaire scores, improvement in 6-minute walking test(6-MWT), B-type natriuretic peptide (BNP); (5) The follow-up duration should not less than 6 months but not more than 24 months, if beyond 24monthes,only use data on 24 months; (6) The patient had not received radiofrequency ablation before this treatment.

Data extraction and quality assessment

Data extraction was conducted independently by Xiong Q and Shangguan J. The following information was obtained: first author, year of publication, country, and study population, number of patients, left ventricular ejection fraction, ablation procedural data and follow-up duration. Additionally, we also reviewed supplementary appendices of included RCTs. Discrepancies during data extraction were resolved by discuss with co-authors. The end point events were related changes in cardiac function such as changes in LEVF, 6MWT, MLHFQ and changes in BNP after different treatments. The qualities of included trials were assessed by the modified jaded scale, which include randomization, allocation concealment, blinding and loss to follow-up. High-quality trials had 4 and more scores.

Assessment of risk of bias in included studies

Risk of bias was independently assessed by two reviewers (Xiong Q and Shangguan J) using the Cochrane risk-of-bias tool. According to the tool, each included trial was reviewed and scored as 'high', 'low', or 'unclear' risk with the following criteria: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Trials with high risk of bias for any domain were considered as at high risk of bias, while trials with low risk of bias for all key domains were considered as at low risk of bias, otherwise they were considered as at unclear risk of bias.

Statistical analysis

Statistical analyses were performed using Review Manager 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). Mean different (MD) with 95% CIs were calculated for all related continuous outcomes. STD Mean different (SMD) were used if the results are measured by different methods. P value <0.05 was considered statistically significant. Heterogeneity across studies was quantified using the I2 statistics [16]. studies with an I2 statistic of 25% to 50% were considered to have low heterogeneity, those with an I2 statistic of 50% to 75% were considered to have moderate heterogeneity and those >75% were considered to have a high degree of heterogeneity. For the meta-analyses with significant heterogeneity, then a random-effect model was used and sensitivity analysis was performed to evaluate the influence of single studies on the summary estimates and the consistency of the outcome.

Results

The results of literature search and selection are shown in the PRISMA flowchart (Figure 1). Our initial search yielded 433 records. After removing duplicates and screening the titles and abstracts, 9 articles were thought to be potentially eligible for inclusion. After full-text review, 6 full-text articles with 775 patients were finally included in this meta-analysis [17-22]. All studies were RCTs. One had a mix patient population with paroxysmal AF, and we only include the persistent AF patients in our analysis.

The main characteristics of 6 included RCTs with 775 patients are shown in Table 1. The population sizes of trials ranged from 41 to 363. A total of 388 patients in CA group and 387 patients in medical therapy group were included in analyses. Most of the RCTs included patients with persistent AF except the trial by Marrouche et al. [17] which enrolled patients with paroxysmal AF. The mean age ranged from 55 to 64 years, and the proportion of men ranged from 77% to 96%, baseline LVEF <50%. All enrolled patients underwent catheter ablation with PVI-based strategy. Patients in medical therapy group received ACEI/ABR, `beta-block, anti-arrhythmic drugs and others. And mean follow-up duration of RCTs is 11 months.

The results of quality assessment are shown in Table 2; all studies had a jadad score of 5 points. Due to the experimental nature, the blinding method could not be achieved and the quality was reduced, but according to the scoring results, all RCTs had a high quality.

Risk of bias assessment

Details of risk of bias are summarized in Figures 2 and 3. According to the Cochrane risk-of-bias tool, all the included RCTs are open-label studies without blinding of participants and personnel, resulting in high risk of performance bias. All of the included RCTs were random

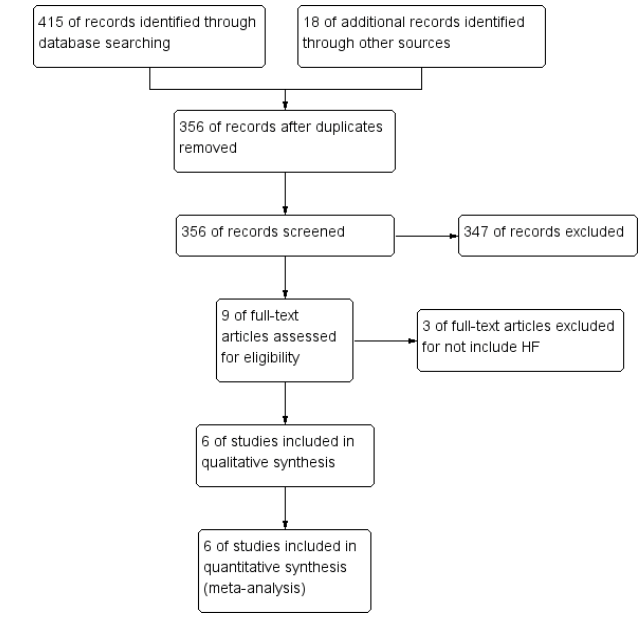

Figure1: Selection of randomized controlled trials for this meta-analysis.

Article	Type	Population	Total patients	Ablation method	Medicine method	AF type	NAYH	Follow-up	No. of patients		Mean age		LEVF		6MWT		MLHFQ		BNP	
									Ablation patients	Medicine patients	Ablation patients	Medicine patients	Ablation patients	Medicine patients	Ablation patients	Medicine patients	Ablation patients	Medicine patients	Ablation patients	Medicine patients
MacDonald et al. [21]	RCT	single-centre	41	PVI+substrate modification	rate	persistent AF	II-IV	6-month	22	19	62.3	64.4	36.1 ± 11.9%	42.9 ± 9.6%	317.5 ± 125.8	351.8 ± 117.1	55.8 ± 19.8	59.2 ± 22.4	2550 ± 2150	1846 ± 1687
Jones et al. [20]	RCT	single-centre	52	PVI+substrate modification	rate	persistent AF	II-IV	12month	26	26	64	62	22 ± 8%	25 ± 7%	416 ± 78	411 ± 109	42 ± 23	49 ± 21	412 ± 324	283 ± 185
Hunter et al. [19]	RCT	single-centre	50	PVI+substrate modification	rate	persistent AF	II-IV	6-month	26	24	55	60	31.8 ± 7.7%	33.7 ± 12.1%	NA	NA	NA	NA	NA	NA
Biase et al. [22]	RCT	single-centre	203	PVI+substrate modification	AAD+rate	persistent AF	II-IV	24month	102	101	62	60	29 ± 5%	30 ± 8%	348 ± 111	350 ± 130	52 ± 24	50 ± 27	NA	NA
Prabhu et al. [18]	RCT	multi-centre	66	PVI+substrate modification	rate	persistent AF	II-IV	6-month	33	33	59	62	32 ± 9.4%	35 ± 9.3%	491 ± 147	489 ± 132	NA	NA	266 ± 210	256 ± 208
Marrouche et al. [17]	RCT	multi-centre	363	PVI+substrate modification	AAD+rate	persistent AF+paroxysmal AF	II-IV	12month	179	184	64	64	32.5 ± 8.1%	31.5 ± 7.4%	NA	NA	NA	NA	NA	NA

Table 1: Characteristics of the 6 included randomized controlled trials in this meta-analysis.

Trials	Randomization	Allocation concealment	Blinding	Loss to follow-up	Jadad score
MacDonald et al. [21]	2	2	0	1	5
Jones et al. [20]	2	2	0	1	5
Hunter et al. [19]	2	2	0	1	5
Biase et al. [22]	2	2	0	1	5
Prabhu et al. [18]	2	2	0	1	5
Marrouche et al. [17] 2018	2	2	0	1	5

Table 2: The results of Jadad score of the 6 included randomized controlled trials.

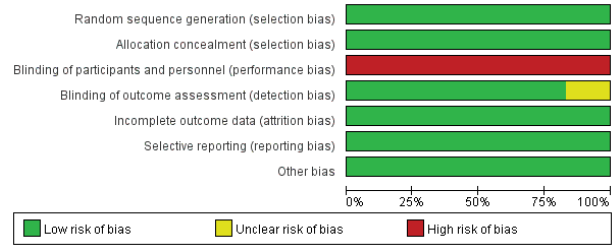

Figure 2: Risk of bias for this meta-analysis: judgements about each risk of bias item presented as percentages across all included randomized controlled trials.

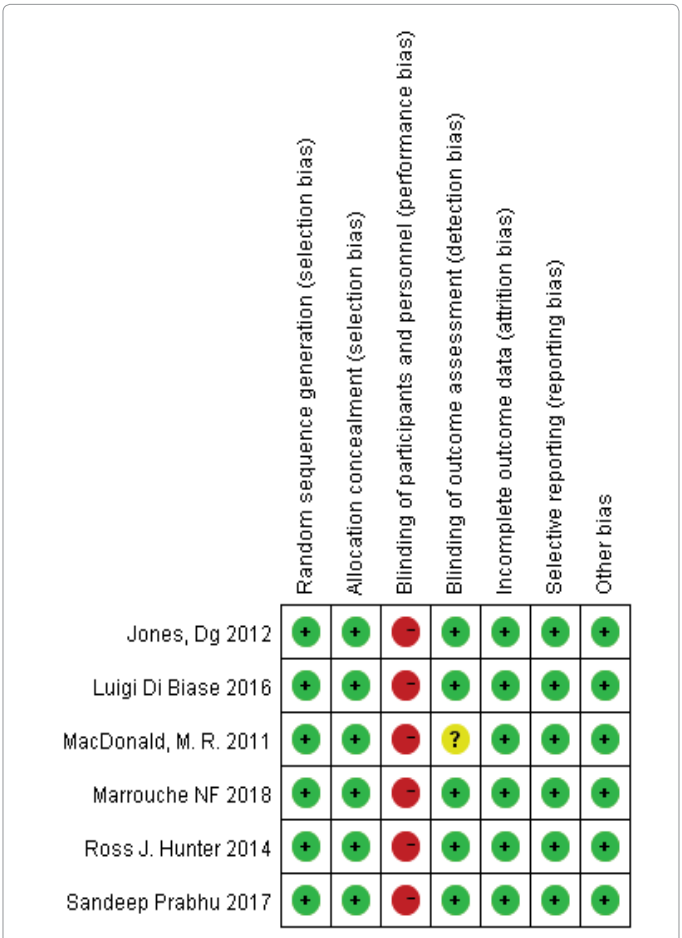

Figure 3: Risk of bias summary of the included randomized controlled trials: details about each risk of bias item for each included trials. Green=low risk of bias, Yellow=unclear risk of bias, Red=high risk of bias.

by computer; two RCTs didn't report adequate information about allocation concealment. These problems resulted in the unclear risk of selection bias.

Primary outcome

LEVF change: For the primary outcome of LEVF, 6 included RCTs with 595 patients provided the related information. To reduce heterogeneity caused by different measurements for LEVF, only radionuclide ventriculography or echocardiography was selected to meta-analysis, and the datas are analyzed using SMD. Compared with medical therapy group, catheter ablation significantly increased LEVF (SMD, 0.57; 95% CI [0.40, 0.94] p<0.00001), with no heterogeneity (I2=0%; p=0.420) (Figure 4). The analysis showed that the catheter ablation is better than medicine therapy in improving LEVF.

There is also no significant publication bias was found in the funnel plot show (Figure 5), to evaluate the influence of single studies on the pooled estimate and the consistency of primary outcome, sensitivity analysis with consecutively excluding one single trial each time was performed. The meta-analyses after excluding every trial one at a time had no significant effect on the pooled estimate.

Second outcome

6-minute walk test (6MWT): The main purpose of the 6MWT

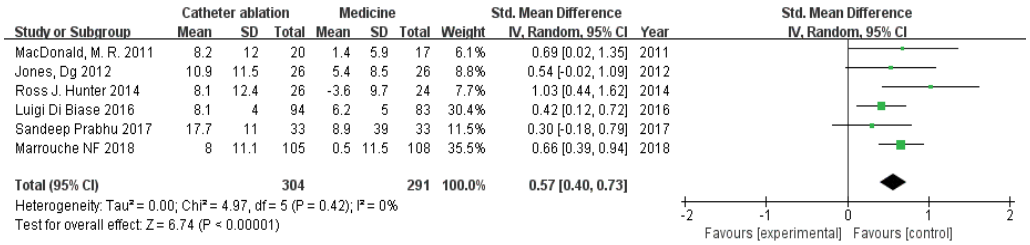

Figure 4: Catheter ablation versus medical therapy for persistent AF with heart failure: LEVF change.

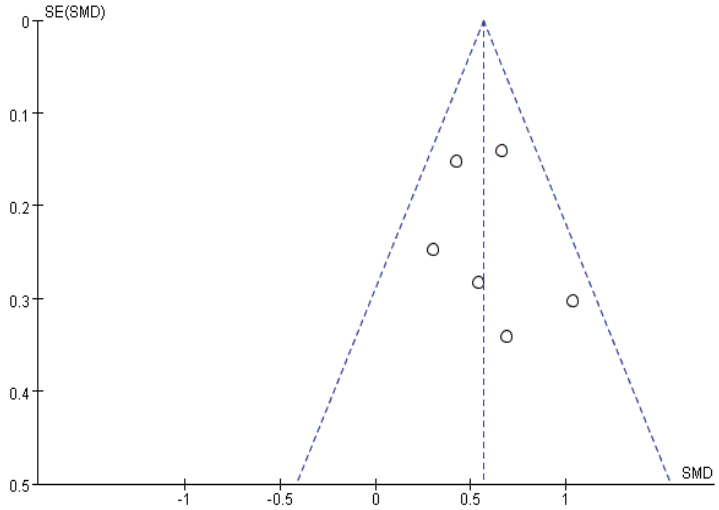

Figure 5: Funnel plot shows no significant publication bias was found.

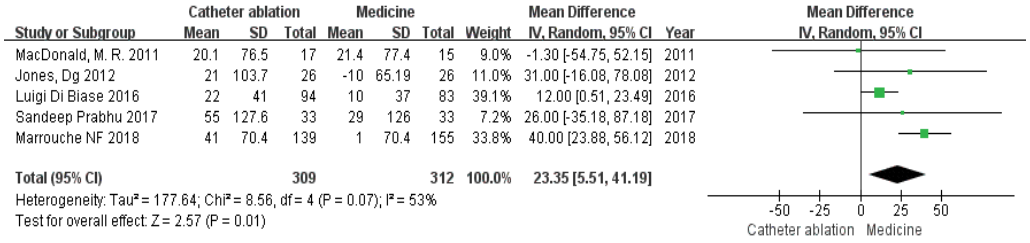

Figure 6: Catheter ablation versus medical therapy for persistent AF with heart failure: 6-minute walk test.

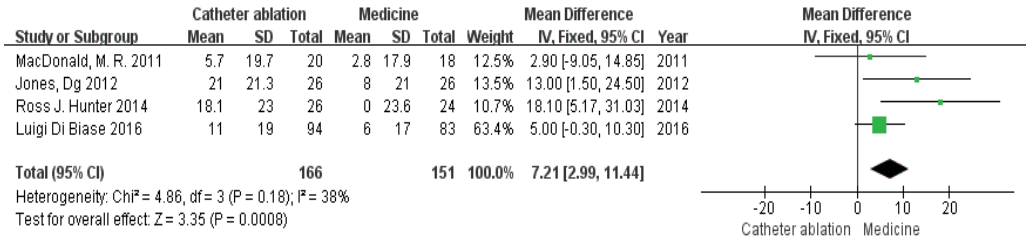

Figure 7: Catheter ablation versus medical therapy for persistent AF with heart failure: Minnesota Living with Heart.

was to assess the patient's activity tolerance test. A total of 5 articles were included in the meta-analysis. The data from Marrouche et al. [17] study summarized the results of paroxysmal AF and persistent AF. Pool analysis shows that catheter ablation can significantly increase

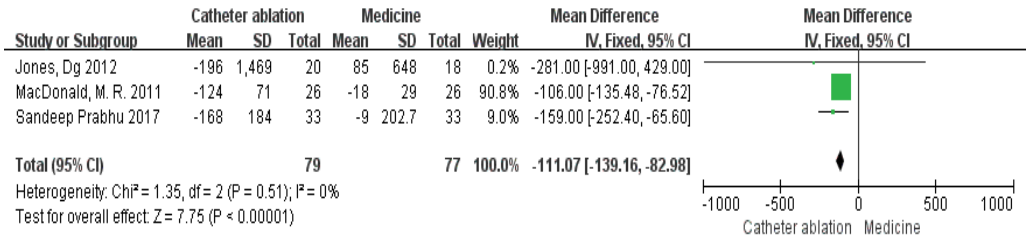

Figure 8: Catheter ablation versus medical therapy for persistent AF with heart failure: B-type natriuretic peptide.

the patient's 6-minute walking distance compared to traditional drug therapy (MD 23.35, 95% CI [5.51, 41.19], p<0.00001) with middle heterogeneity (I2=53%; p=0.07) (Figure 6).

Sensitivity analysis showed that the heterogeneity was reduced to 0% after the removal of the study by Marrouche et al. [17], but did not change the meta-analysis results, suggesting that catheter ablation is superior to drug therapy. The study included some patients with paroxysmal atrial fibrillation, which may be the cause of heterogeneity.

Minnesota living with heart failure score and B-type natriuretic peptide: There were only three trials related MLHFQ score changes, and also three trials related BNP. The pooled analysis showed a significant decrease in MLHFQ scores and BNP levels in the catheter ablation group compared with the drug treatment group. The change in MLHFQ was (MD -7.21, 95% CI [-11.44, -2.99], p=0.01) with low heterogeneity (I2=38%; p=0.0008) (Figure 7). The change in BNP was (MD -111.07, 95% CI [-139.16, -82.98], p<0.00001), without heterogeneity, Failure Score Changes (I2=0%; p=7.74) (Figure 8).

Discussion

This is the first meta-analysis of RCTs to evaluate the effect of catheter ablation on cardiac function in patients with persistent atrial fibrillation and heart failure. After summary analyses of 6 RCTs include 775 patients, we found that catheter ablation can significantly improve patient's LEVF, 6-MWT, MLHFQ, and BNP compared to conventional drug therapy (Rhythm control/heart rate control or a combination of both). The sample size after summary analysis is considerable and the heterogeneity is small, which can provide an evidence for clinical decision.

When assessing the effects of different treatments on cardiac function, long-term follow-up may lead to loss of follow-up, and patient's heart function may interfered by other factors such as other diseases, age and living habit [23,24]. In this analysis, we limited the maximum follow-up time to two years to reduce the impact of above factors on cardiac function, expect to reflect the treatment effect more accurately.

It is worth noting that while explaining this meta-analysis, although all included studies are RCTs, some factors may still influence the results. In this meta-analysis, only the LEVF could be found in all RCTs, other outcomes were only found in part of included trials, thus the small sample size may affect the accuracy of partial second outcome results. Marrouche et al. [17] study did not distinguish between persistent atrial fibrillation and paroxysmal atrial fibrillation in the 6-minute walk test, although the number of such patients is small and has no serious effect on the heterogeneity, it may still have a certainly impact on the results of the analysis. In addition, other factors such as patient age, comorbidity, and duration of atrial fibrillation also have an effect on the improvement of cardiac function.

The optimal treatment of patients with atrial fibrillation and heart failure has become a hot topic, several meta-analyses have been published, but there are still some differences in this meta-analysis. Three previous meta-analyses compared rhythm control with heart rate control, confirmed that rhythm control significantly improved cardiac function in patients [25-27]. But in these studies, heart rate control included atrioventricular node ablation and ventricular pacing therapy, which is not recommended as a routine. Chen et al. [28] work compared ablation and antiarrhythmic drug therapy on maintaining sinus rhythm, secondary outcomes include changes in cardiac function, but analysis just bring in few RCTs, Reduced the quality of the outcome. Zhu et al. work include three RCTs and 143 patients, smaller sample sizes also affect the accuracy of the analysis [29]. In our analysis, a total of 775 RCTs were included in 6 RCTs, the larger sample size improves the accuracy of the conclusion prognosis, controversy over catheter ablation and drug treatment has been going on for a long time.

Compared with anti-arrhythmia, catheter ablation can maintain sinus rhythm more effectively in patients with simple atrial fibrillation. It has become the first-line treatment recommended by the guidelines. However, the success rate of ablation is still lower for patients accompany with heart failure, most patients require at least two ablation procedures to maintain sinus rhythm effectively [30]. Changes in heart structure make it more dangerous to achieve complete pulmonary vein isolation. The above reasons make catheter ablation in patients with AF and HF has not yet been classified as a Class I recommendation in the current guidelines. Recently research and meta-analysis demonstrate that there was no significant difference between ablation- or drug-related complications. This meta-analysis has expanded all current RCTs and confirmed the advantages of CA ablation in improving cardiac function.

Conclusion

Catheter ablation has a better improvement than medical treatment in heart function for patients with persistent atrial fibrillation and heart failure after a meta-analysis of 6 randomized controlled trials.

Limitations

This meta-analysis also has some limitations. First of all, since all literatures were included in randomized controlled studies, the number of documents included and the number of patients was small, and some articles did not contain all the indicators of the analysis. Second, the inclusion of literature in the implementation of the process of random and blind choices as strict restrictions may lead to a certain amount of cheap existence. Third, different literatures have inconsistent inclusion criteria for cardiac insufficiency. Treatment programs do not distinguish between heart rate treatment and rhythm therapy, which may affect the results of the meta-analysis.

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