Routine Preprocedural Transesophageal Echocardiography Might Not Necessary for Stroke Prevention Evaluation in AF Patients on Anticoagulation Therapy

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Directed by Professor Boyoung Joung

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ABSTRACT

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BACKGROUND Preprocedural transesophageal echocardiography (TEE) is used to reduce the stroke during atrial fibrillation (AF) ablation. This study evaluated whether routine preprocedural TEE in addition to MDCT is necessary to prevent periprocedural stroke in AF ablation.

METHODS Each patient underwent MDCT and TEE (Group 1, n = 247) or MDCT alone (group 2, n = 103) for the initial evaluation before AF ablation. In group 2, TEE was performed only in patients who had left atrial (LA) thrombus or blood stasis in MDCT.

RESULTS There was no difference in sex, $CHADS_2$ score, or LA dimension

between the two groups. In group 1, a thrombus was detected in 12 (5%) and 6 (2%) patients by the MDCT and TEE, respectively. All (100%) patients, who were revealed to have thrombus in TEE, also had a thrombus in MDCT. In group 2, 3 (3%) patients exhibited LA thrombus in MDCT, among whom thrombus was observed in only one patient (1%) in TEE. AF ablation was not performed in patients with thrombus. While one patient had a periprocedural stroke in group 1, no patient had in group 2 (P = 0.52).

CONCLUSION The overall periprocedural stroke rate was low (0.3%) in AF patients on anticoagulation therapy. The preprocedural MDCT detected all patients with the LA thrombus. In AF patients with low CHADS2 score and relatively preserved left ventricular ejection fraction, routine preprocedural TEE in addition to the MDCT might not be necessary to decrease the periprocedural stroke rate.

Key words : anticoagulation, atrial fibrillation, stroke, transesophageal echocardiography

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1. Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, occurring in 1–2% of the general population [1,2]. Both persistent and paroxysmal AF are potent predictors of a first as well as recurrent strokes. Indeed, AF confers a five-fold increased risk of stroke, and one in five strokes is attributed to this arrhythmia. In the United States, >75,000 cases of stroke per year are attributed to AF. Radiofrequency catheter ablation (RFCA) for AF is a widely accepted successful treatment for drug refractory AF [3,4]. However, it also has a risk of thromboembolism independent of the rhythm at the time of the procedure. According to single-center studies, this risk has been reported as

1.5% to 5.4% [5,6]. Preprocedural transesophageal echocardiography (TEE) is used to exclude the presence of a left atrial appendage (LAA) thrombus in order to minimize risk; however, TEE is an invasive and painful procedure.

Recently, 64-channel multidetector computed tomography (MDCT) of the heart has been introduced as a novel noninvasive imaging modality with high spatial and temporal resolution. MDCT of the heart is often performed prior to pulmonary vein isolation in patients with atrial fibrillation for construction of left atrium (LA) and pulmonary vein maps [7]. Current-generation MDCT can successfully identify LA thrombus and dense nonclearing blood stasis with high sensitivity and moderate specificity [8]. The aim of the present study was to examine whether TEE in addition to MDCT are necessary to evaluate LA thrombus and prevent periprocedural stroke in AF RFCA.

2. Materials and Methods

2.1. Study Population

The study protocol was approved by the Institutional Review Board of Severance Cardiovascular Hospital, Seoul, Korea and complied with the Declaration of Helsinki. Between March 2009 and September 2011, 350 consecutive patients with nonvalvular AF who underwent RFCA at Severance Cardiovascular Hospital in Seoul, Korea were enrolled in this study. Patients were randomly assigned to a routine preprocedural TEE strategy (Group 1, n=247) or selectively to a preablation strategy (Group 2, n=103). Patients in group 1 underwent both TEE and 64-channel MDCT, while patients in group 2 received only 64-channel MDCT during the initial evaluation. TEE was

performed for all patients who had thrombus or blood stasis according to MDCT. All antiarrhythmic medications (including beta blockers and calcium blockers) were suspended > 5 half-lives before the study.

The paroxysmal AF (PAF) group included patients with a history of one or more episodes of self-terminating AF that lasted less than 7 days. The persistent AF (PeAF) group consisted of patients who had an AF episode that either lasted longer than 7 days or required termination by cardioversion, either with drugs or by direct current cardioversion. Normal left atrial diameter and ejection fraction were regarded as ≤40 mm and ≥ 50%, respectively. These criteria were standardized for the analysis and took into account minor variations at individual centers.

2.2. Cardiac CT

Contrast-enhanced cardiac CT scans were performed using a 64-slice MDCT (Somatom Sensation 64, Siemens Medical Solutions, Forchheim, Germany). A bolus of 60-80 mL iopamidol (Iopamiro 370, Bracco, Italy) was injected into an antecubital vein at a flow rate of 5 mL/s, followed by a 50-mL saline-chasing bolus at 5 mL/s. The start delay was defined by bolus tracking in the ascending aorta, and the scan start was automatically initiated 5 seconds after reaching a threshold of 140 Hounsfield Units (HU). Scanning was performed using the following parameters: retrospective electrocardiogram (ECG)-gated acquisitions, 80-120 kVp, 500-700 mAs depending on patient size, and 64 x 0.6 mm slice collimation. Scans were performed from the tracheal bifurcation to the diaphragm. The field of view was adjusted according to the size of the heart. The cardiac CT was reconstructed at the end-systolic and the

mid-diastolic phases using a slice thickness of 0.75 mm, an increment interval of 0.5 mm, and a medium-smooth convolution kernel of B36f. We used end-systolic CT images for this study. A thrombus was defined as LAA /ascending aorta (AscAo) HU ratios <0.75 with definite margins. Blood stasis was defined as LAA/AscAo HU ratios <0.75 without definite margins. Two radiologists (with four and eight years experience in cardiac MDCT) analyzed MDCT results.

2.3. Echocardiography

TEE was performed using a 5- to 7-MHz multiplane probe with a Philips 7500 machine (Philips Medical Systems, Andover, MA) positioned at the appropriate level within the esophagus. LAA-emptying velocity and the presence thrombus or SEC (spontaneous echo contrast) were evaluated. SEC was characterized by dynamic clouds of echoes curling slowly in a circular or spiral shape within the LAA cavity.

2.4. Anticoagulation

Warfarin was used routinely prior to the procedure and continued during the procedure. Therapeutic international normalized ratio (INR) target ranges were maintained between 2 and 3. During catheter ablation, following transseptal punctures, initial bolus doses of unfractionated heparin were administered according to body weight (75–100 IU/kg). Activated coagulation time was routinely monitored throughout the procedure and was maintained with either periodic boluses of heparin and/or with a constant infusion. The intensity (activated coagulation time range) of heparinization was targeted to more than 300 seconds.

At the conclusion of each case, heparin therapy was stopped for 4–6 hours to achieve an empirically determined reduction in activated coagulation time to allow sheath removal. If the activated coagulation time was longer than 300 seconds, the anticoagulation effect of unfractionated heparin was reversed by the administration of protamine (1 mg of protamine for every 100 units of heparin). Unfractionated heparin was used in patients with INR less than 1.5 after the removal of sheaths. Lastly, patients were again anticoagulated with warfarin at a maintenance dose.

2.5. Radiofrequency Ablation

Electrophysiologic study and RFCA were performed in the postabsorptive state after sedation with midazolam and fentanyl. Multipolar catheters were positioned in the coronary sinus, His, and right atrium. A 3-dimensional geometry of the LA was reconstructed with a CARTO or NavX electroanatomic mapping system. Before RFCA, triggers were evaluated after direct current cardioversion of AF. Circumferential pulmonary vein isolation was performed in all patients using a 3.5-mm irrigated-tip catheter (ThermoCool). We used a circular mapping catheter (Lasso, Biosense Webster) to confirm isolation of pulmonary veins. Successful ablation was defined by the elimination of all of the pulmonary vein potentials along the antrum or inside the veins. If AF was not terminated after the elimination of all of the pulmonary vein potentials, linear ablation and complex fragmented atrial electrogram ablation were performed. Cavotricuspid isthmus ablation was performed in all patients.

2.6. Follow-up

During hospitalization, all the patients were monitored by continuous ECG recordings. Oral anticoagulation therapy was prescribed for at least 3 months. Strokes that occurred within 7 days after the procedure were considered to be related to the procedure. Stokes taking place more than 7 days after the procedure were considered not to be related to the procedure.

2.7. Statistical analysis

Continuous data was expressed as mean ± SD, and categorical data was reported as an absolute number or percentage. The baseline characteristics of the two groups were compared using the Student's *t*-test for continuous variables and the Chi-square test and Fisher's exact test for categorical variables. Statistical significance was established at a value of $P < 0.05$. Statistical analysis was performed by SPSS version 18.0 (SPSS Inc, Chicago, IL, USA).

The authors of this manuscript have certified that they comply with the Principles of Ethical Publishing in the International Journal of Cardiology [9].

3. Results

3.1. Baseline Characteristics of Patients

Clinical characteristics of Group 1 and Group 2 are presented in Table 1. There was no difference in mean age (57 ± 11 vs. 56 ± 11 years, p=0.58) or male gender (74% vs. 78%, p=0.41) between the two groups. The type of AF (PaAF 78% vs. 72%, P=0.24), $CHADS_2$ score (0.8 ± 1.1 vs. 0.7 ± 0.9, P = 0.40), CHA_2DS_2-VASc score (1.3 ±1.3 vs. 1.2 ± 1.1, p=0.40), LA size (41 ± 6, vs. 41 ± 6 mm, p=0.56), and left ventricular ejection fraction (63 ± 8% vs. 62 ± 7%,

p=0.23) showed no difference between the two groups. HAS-BLED scores were higher in group 1 (2.0 ± 1.0) than in group 2 (1.7 ± 1.0, p=0.007).

The number of patients using clopidogrel or clopidogrel with aspirin was higher in group 1 than group 2. All patients underwent RFCA of AF on warfarin for 11.9 ± 19.3 months prior to the procedure. In 226 patients with $CHADS_2$ score less than or equal to 1, warfarin was use for 2.5 ± 3.6 months. The mean level of INR before the procedure was not different between the two groups (1.9 ± 0.6 vs. 2.0 ± 0.7, P=0.11). There was an average delay of 19 ± 9 days after MDCT to RFCA. The mean duration from MDCT to the procedure was significantly longer in group 2 (19.4± 9.0 days) than group 1 (13.3 ± 8.9 days, p<0.001). The mean duration from TEE to the RFCA (10.5 ± 8.5 vs. 8.6 ± 9.8 days, P=0.61) and the mean duration from CT to TEE (4.2 ± 7.0 vs. 3.0 ± 3.0 days, P=0.49) were also not different between the two groups.

Table 1. Comparison of Baseline Characteristics between Group 1 and Group 2.

	Group 1 (n=247)	Group 2 (n=103)	P value
Age, years	57 ± 11	56 ± 11	0.58
Male, n	184 (74)	81 (78)	0.41
Type of AF, n			
PaAF	192 (78)	74 (72)	0.24
PeAF	55 (22)	29 (28)	0.24
Comorbidity, n			

Congestive heart failure	9 (4)	3 (3)	0.73
Hypertension	107 (43)	45(43)	0.95
Age > 75 years	11 (4.5)	4 (3.9)	0.81
Diabetes mellitus	28 (11.3)	9 (8.7)	0.47
Stroke/TIA	18 (7.3)	7 (6.8)	0.87
$CHADS_2$ score	0.8 ± 1.1	0.7 ± 0.9	0.40
CHA_2DS_2-VASc score	1.3 ± 1.3	1.2 ± 1.1	0.40
HAS-BLED score	2.0 ± 1.0	1.7 ± 1.0	0.007
LA size, mm	41 ± 6	41 ± 6	0.56
Ejection fraction, %	63 ± 8	62 ± 7	0.23
INR level before procedure	1.9 ± 0.6	2.0 ± 0.7	0.11
Medication, n			
Warfarin	247 (100)	103 (100)	1.0
Aspirin	115 (47)	40 (39)	0.18
Clopidogrel	12 (5)	0(0)	0.023
Aspirin and clopidogrel	40 (16)	1 (1)	<0.001

The numbers in parentheses represent percentages.

AF indicates atrial fibrillation; LA, left atrium/atrial; PAF, paroxysmal AF; PeAF, persistent AF; TIA, transient ischemic attack.

3.2. Thrombus, Blood Stasis, and Progress of AF patients

The thrombus, blood stasis, and progress of AF patients are presented in Figure. In group 1, thrombus and blood stasis were observed with MDCT in 12 (5%) and 10 (4%) patients, respectively. Interestingly, all patients, in whom thrombus were also observed with TEE, were detected by MDCT. RFCA was performed in 241 patients, excluding 6 (2%) patients with thrombus in TEE. One patient had a periprocedural stroke and recovered after anticoagulation therapy. In group 2, 3 (3%) and 7 (7%) patients showed LA thrombus and blood stasis in MDCT, respectively. TEE was performed in only these 10 patients. A thrombus and SEC were observed in 1 (1%) and 2 (2%) patients, respectively. RFCA was performed in 102 patients, excluding one (1%) patient with thrombus.

Patients with LA thrombus are presented in Table 2. The size of LA and $CHADS_2$ score were significantly larger in patients with thrombus (41 ± 6 vs. 53 ± 5 mm, $p<0.001$: 0.8 ± 1.1 vs. 1.4 ± 0.8, $p=0.027$, respectively). Likewise, persistent AF ratio, congestive heart failure ratio, and hypertension ratio were significantly larger in patients with thrombus (23% vs. 86%, $p<0.001$: 3% vs. 29%, $p <0.001$: 43% vs. 86%, $p=0.02$, respectively). However, no other parameters were different between patients with and without thrombus.

While one patient in group 1 had a periprocedural stroke, none was observed in group 2 ($p=0.52$). Therefore, the overall periprocedural stroke rate was 0.3% in patients on anticoagulation therapy. The patient, who suffered from a stroke, had an INR level of 1.4 at 1 day before the RFCA of AF and was treated with 1 dose of enoxaparin 80 mg (1 mg/kg). The thrombus was not

observed by both TEE and MDCT, which were performed 1 day before the RFCA of AF. He had motor aphasia 3 hours after the RFCA and showed an acute infarct on the left middle cerebral artery territory in brain MRI. He still was not completely recovered 28 months after RFCA.

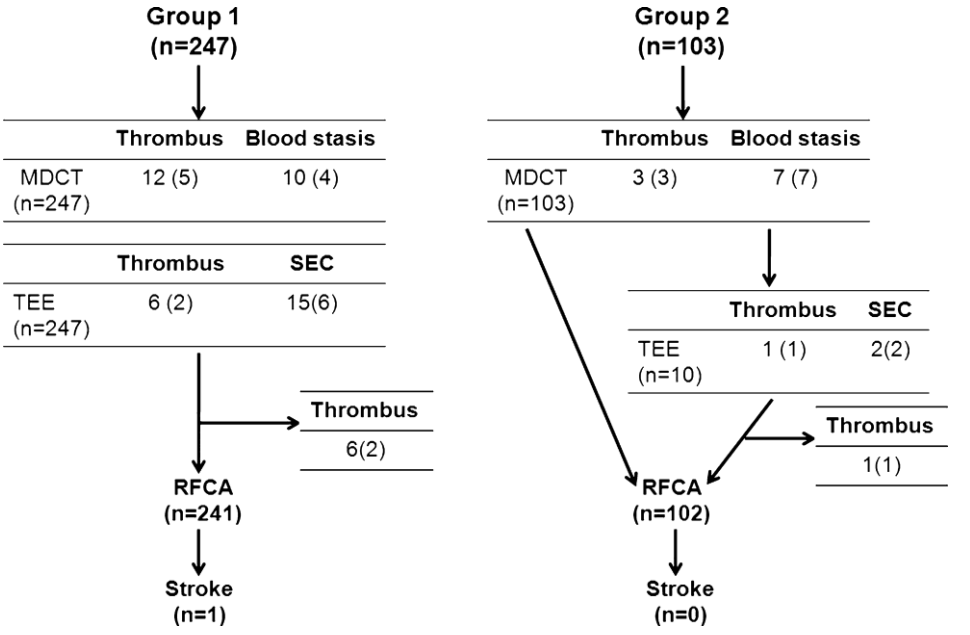

Figure. Flow diagram and results of the present study. Multidetector computed tomography indicates. MDCT = multidetector computed tomography; RFCA = radiofrequency catheter ablation; SEC = spontaneous echocardiographic contrast; TEE = Transesophageal echocardiography.

Table 2. Comparison of Baseline Characteristics in patients with or without thrombus

	No thrombus Group (n=343)	Thrombus Group (n=7)	P value
Age, years	56±11	61± 9	0.23
Male, n	259(76)	6(86)	0.53
Type of AF, n			
PaAF	265(77)	1 (14)	<0.001
PeAF	78(23)	6 (86)	<0.001
Comorbidity, n			
Congestive heart failure	10(3)	2(29)	<0.001
Hypertension	146(43)	6(86)	0.020
Age > 75 years	15(4)	0 (0)	0.57
Diabetes mellitus	35(10)	2 (29)	0.12
Stroke/TIA	25(7)	0 (0)	0.46
$CHADS_2$ score	0.8 ± 1.1	1.4 ± 0.8	0.027
CHA_2DS_2-VASc score	1.2 ± 1.3	2.0 ± 1.0	0.06
HAS-BLED score	1.9 ± 1.1	1.9 ± 0.7	0.94
LA size, mm	41 ± 6	53 ± 5	<0.001
Ejection fraction, %	63 ± 8	58 ± 20	0.60
Medication, n			

Warfarin	343(100)	7 (100)	1.0
Aspirin	153 (45)	2 (29)	0.40
Clopidogrel	12 (4)	0(0)	0.61
Aspirin and clopidogrel	40 (12)	1 (14)	0.83

The numbers in parentheses represent percentages. Abbreviations same as in Table 1.

Table 3. Characteristics of patients with thrombus in the left atrium.

Group	Age, years	Sex	AF classification	LA size, mm	EF, %	CHADS2	CHA_2DS_2-VASc	TEE	F/U TEE	F/U TEE Result
2	67	M	persistent	54	63	1	2	LAA obliteration by thombus	1 month	No interval change
1	70	M	persistent	56	81	2	3	LAA thrombus, 0.98 x 0.48 cm	5months	No thrombus
1	70	M	persistent	58	63	1	2	LAA thrombus, 1.5 x 0.8 cm	1 year	LAA thrombus, 2.2 x 1.0 cm
1	60	M	persistent	55	61	2	2	Fresh thrombus	7months	No thrombus
1	54	M	paroxysmal	45	57	0	0	LAA thrombus 1.5x1.5 cm	f/u loss	N/A
1	62	F	persistent	53	69	2	3	LAA thrombus , 2.0 x 1.1 cm	f/u loss	N/A
1	47	M	persistent	48	17	2	2	LAA thrombus, 2.8 x 1.4 cm	f/u	No f/u TEE

EF indicates Ejection fraction; LAA, left atrial appendage; N/A, not available; TEE, transesophageal echocardiography. Other abbreviations same as in Table 1.

3.3. The Accuracy of MDCT to Detect Thrombus

We evaluated the diagnostic accuracy of LAA/AscAo HU ratio <0.75 of MDCT in thrombus detection. The sensitivity, specificity, positive predictive value of LAA/AscAo HU ratio <0.75 for detecting thrombus were 100%, 98%, 50%, respectively. Importantly, the negative predictive value of LAA/AscAo HU ratio >0.75 was 100% in exclusion of LA/LAA thrombus.

4. Discussion

4.1. Major Findings

In the present study, we evaluated whether routine preprocedural TEE in addition to MDCT was necessary to prevent periprocedural stroke in RFCA of AF. The overall periprocedural stroke rate was low in AF patients on anticoagulation therapy. Second, if AF patient had conditions with low risk of thrombus such as paroxysmal AF, low CHADS2 score, normal or mild dilated left atria size and relatively preserved left ventricular ejection fraction, routine preprocedural TEE in addition to MDCT did not prevent periprocedural stroke in AF patients on anticoagulation therapy. Finally, LAA/AscAo HU ratios >0.75 showed a 100% negative predictive value for exclusion of LA/LAA thrombus. These results suggest that, in AF patients with low CHADS2 score and relatively preserved left ventricular ejection fraction, routine preprocedural TEE in addition to the MDCT might not be necessary to decrease the periprocedural stroke rate.

4.2. Preprocedural TEE

The LAA is an important source of emboli from the heart in 70%–90%

cases of AF. TEE is considered the gold standard for detection of LAA thrombus, with a sensitivity of 100% and specificity of 99% [10-12]. The presence of thrombus and spontaneous echocardiographic contrast as well as low blood velocities within the LAA as assessed by TEE may indicate increased risk for cardioembolic stroke [13,14]. Therefore, preprocedural TEE has been employed by many centers in an attempt to reduce thromboembolic complications. Although TEE is effective in identifying LAA thrombus, it is a semi-invasive procedure associated with intrinsic risk [15]. However, the impact of using TEE to reduce embolic events from RFCA of AF has not been assessed to date.

4.3. Preprocedural MDCT

Our study shows that the routine preprocedural TEE in addition to the MDCT is not necessary to prevent stroke in patients on continuous anticoagulation therapy with relatively low risk of stroke. In this study, the sensitivity and specificity of MDCT to detect thrombus were 100% and 98%, respectively. This result is consistent with previous reports showing that MDCT has the sensitivity of 100% and specificity of 70% to detect thrombus [8,16]. Importantly, LAA/AscAo HU ratios > 0.75 showed 100% negative predictive value for exclusion of LAA thrombus. Moreover, the MDCT could provide anatomic information of LA, pulmonary vein, thoracic structure and electroanatomical mapping. However, MDCT overestimated thrombus with the false positive rate of 50%.

In this study, we used warfarin in patients with low $CHADS_2$ score ($\leq$ 1) for at least 1 months before the RFCA. However, the bleeding complication was not observed in these patients. The overall periprocedural stroke rate was

low (0.3%) in patients on anticoagulation therapy. Interestingly, the patient, who experienced a stroke, showed no abnormal finding in both MDCT and TEE which was performed 1 day before RFCA. However, he had a low INR level of 1.42. Therefore, it was reasonable to speculate that the thrombus was produced during RFCA. Previous studies reported that the stroke rate after RFCA is 1.5~5.4% in patients on OAC therapy [5,6].

4.4. Study Limitations

The present study had several limitations. Most patients in this study had a low $CHADS_2$ score, normal LA size, and a preserved left ventricular ejection fraction. Therefore, we could not preclude the role of routine preprocedural TEE in AF patients at high risk of stroke. There was an average delay of 19 ± 9 days after MDCT to RFCA. While thrombus could have developed during this delay, only one patient suffered a stroke, and the delay between MDCT and AF RFCA in that case was only 1 day. Finally, because we evaluated stroke using clinical examination, we could not exclude silent strokes.

5. Conclusion

The overall periprocedural stroke rate was low in patients on anticoagulation therapy. Second, the routine preprocedural TEE in addition to MDCT did not prevent periprocedural stroke in AF patients on anticoagulation therapy and with low risk of stroke. Third, interestingly, LAA/AscAo HU ratios > 0.75 showed 100% negative predictive value for exclusion of LAA thrombus. These results suggest that, in AF patients with low CHADS2 score and relatively preserved left ventricular ejection fraction, routine preprocedural TEE

in addition to the MDCT might not be necessary to decrease the periprocedural stroke rate.

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ABSTRACT(IN KOREAN)

심방세동 환자에서 RFA 시술 전 routine 한 TEE 의 시행이 stroke 예방에 미치는 영향

< 지도교수 정 보 영>

연세대학교 대학원 의학과

한 재 현

배경 : RFA 시술 전 TEE 는 시술 동안 stroke 을 줄이기 위해 사용되고 있다. 이 연구는 시술 전 MDCT 에 추가하여 TEE 를 시행하는 것이 시술 관련 stroke 예방에 필요한가에 대해 조사하였다.

방법 : 각각의 환자들은 MDCT 와 TEE 를 모두 시행한 그룹 1(n=247)과 MDCT 를 시행한 후에 MDCT 상 thrombus 또는 blood stasis 소견을 보인 환자들에 대해서만 TEE 를 시행한 그룹 2(n=103) 으로 나누어서 stroke 발생률을 확인하였다.

결과 : 두 그룹간에 성별,CHADS2 score, LA dimension 등에 있어서 차이가 없었다. 그룹 1에서는 thrombus 가 MDCT상 12명(5%) TEE

상에서 6명(2%) 발견되었다. MDCT 상에서 thrombus 가 발견되었던 환자들은 모두(100%) TEE 에서 thrombus 가 발견되었다. 그룹 2에서는 MDCT 상 3명(3%)에서 thrombus 가 발견되었고 3명에 대해 추가로 TEE 를 시행하였다. 그 중 1명(1%) 에서 thrombus 가 발견되었다. RFA 는 thrombus 가 있는 환자들에 대해서는 시행하지 않았고 그룹 1에서 RFA 시행 중 stroke 이 1명의 환자에서 발생하였으며 그룹 2에서는 발생하지 않았다. (P=0.52)

결론 : 항응고요법을 시행하고 있는 심방세동 환자에서 전체 시술관련 stroke 발생률은 0.3%로 낮았다. 시술 전 MDCT 는 LA thrombus 를 모든 환자에서 발견하였다. 본 연구에서 낮은 CHADS2 score 와 좌심실 수축능력이 보존되어 있는 환자에서 적절한 항응고요법을 하고 있을 경우 MDCT 에 추가하여 TEE 를 시행하는 것이 시술관련 stroke 발생률을 줄이는데 도움을 주지 못하였다.

핵심되는 말 : 항응고요법, 심방 세동, 뇌졸중, 경식도 초음파