

# RANDOMIZED TRIAL COMPARING NEW CHITOSAN-BASED BANDAGE WITH KALTOSTAT HEMOSTATIC DRESSING TO CONTROL BLEEDING FROM HEMODIALYSIS PUNCTURE SITE.

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## INTRODUCTION

## RESULTS

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Atrial fibrillation (AF) occurs significantly more frequently in dialysis patients than in the general population. AF causes significant clinical and hemodynamic deterioration such as low blood pressure during HD. AF is of particular clinical importance mainly because of the increased risk of stroke, and approximately one-third of hemodialysis patients with AF were reported to have thromboembolic complications within 1 year. Although maintenance of sinus rhythm is the ideal therapeutic goal in AF patients, AF and adverse effects of antiarrhythmic drugs offset the benefits of sinus rhythm. Use of warfarin is not recommended because of high risk of mortality in hemodialysis patients. Up to year 2000, treatment options were limited to medications that regulate the heart's rhythm, electrical cardioversion to restore sinus rhythm, anticoagulation therapy, and the Maze procedure. More recently, radiofrequency catheter ablation with pulmonary vein isolation has been developed as a nonsurgical approach that may be recommended for patients with AF tolerant with medications.

## METHODS

Among 160 patients receiving dialysis therapy at Yokohama Minami Clinic, 16 (10 males and 6 females; mean age  $71.2 \pm 11.2$ , range 50-91 years; mean hemodialysis duration  $103.4 \pm 74.9$  months) with AF (13 paroxysmal, 3 persistent) were enrolled. We performed complete isolation of the whole posterior left atrium including all pulmonary veins (box isolation) guided by a 3D-mapping system (Ensite NavX) at The Arrhythmia Center, Hayama Heart Center.

Table 1. Background of the patients.

Age (Year)	$71.2 \pm 11.2$
Male/Female	10/6
Duration of HD (Month)	$103.4 \pm 74.9$
Persistent AF	3
paroxysmal AF	13

Table 2. Required ablation sessions to maintain sinus rhythm

	1time	2times	3times	4times
Persistent AF	1	1	0	1
Paroxysmal AF	9	3	1	0

Figure 1. Mapping and navigation tools for atrial fibrillation catheter ablation.

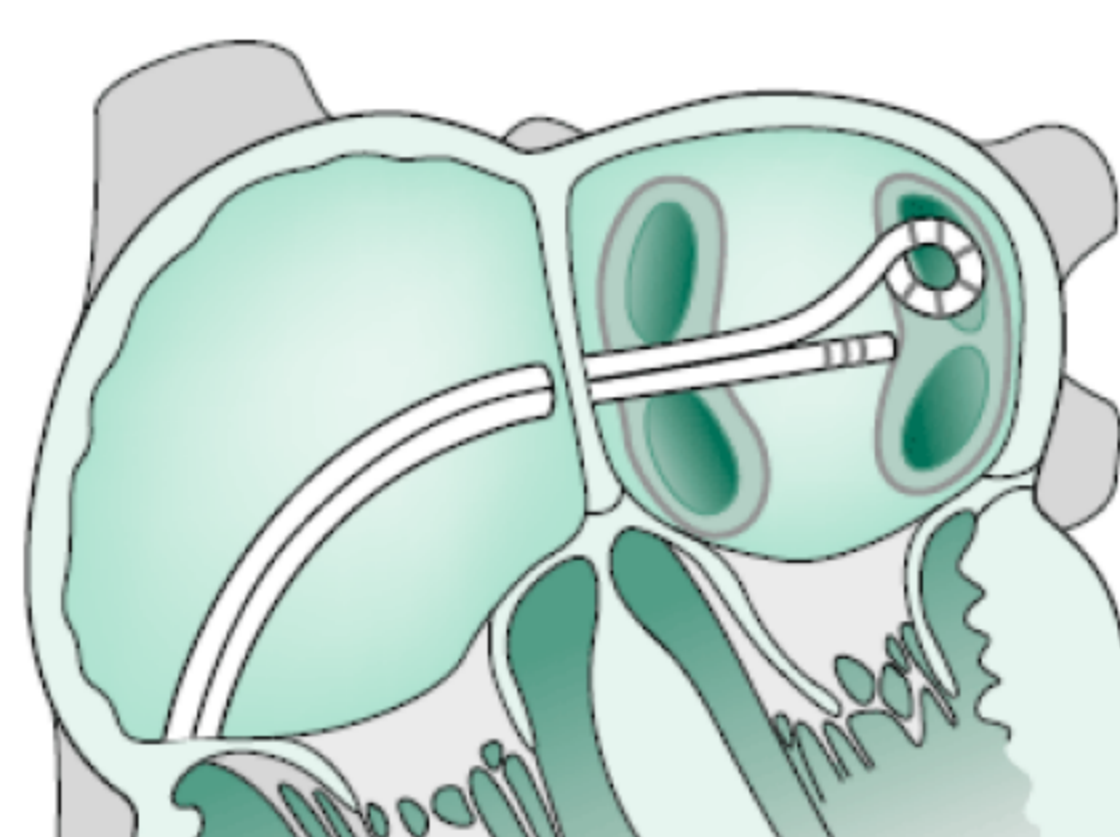
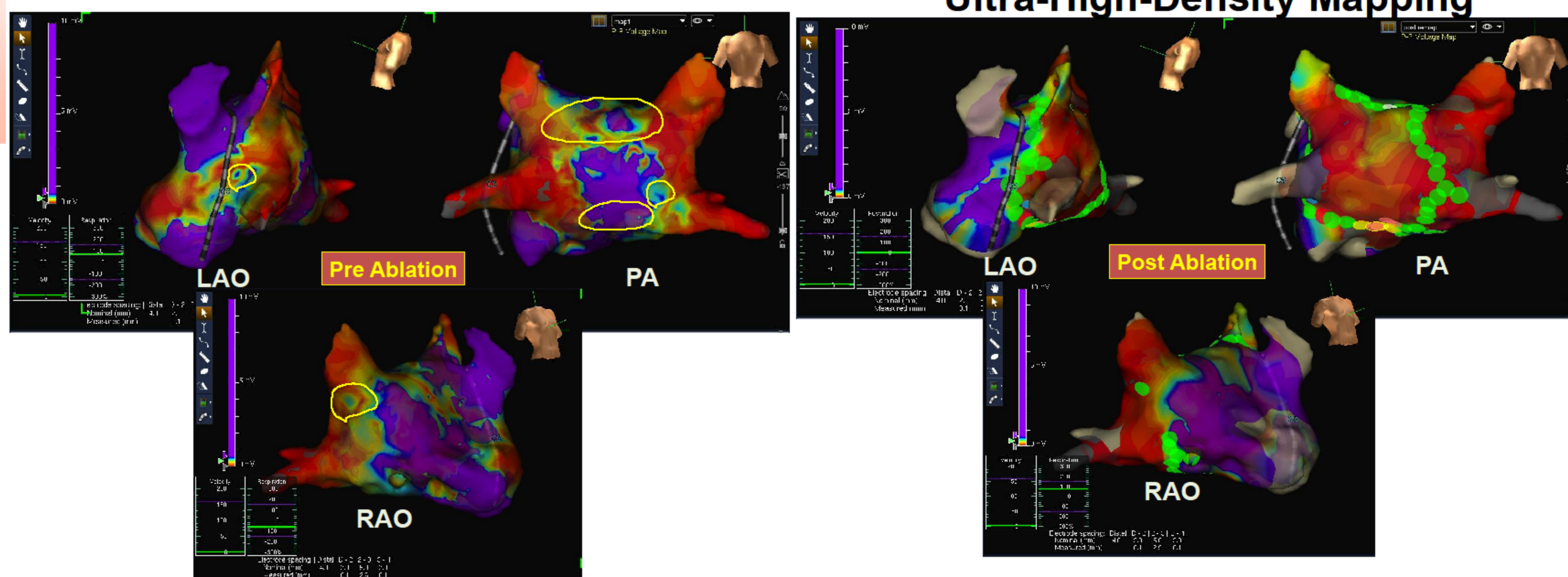


Figure 2. Identification of Gap in the second session

Figure 3. Box lesion set using Ultra-High-Density Mapping



Box isolation therapy was performed in all 16 patients. A second session was performed in 6 patients (38%) because of AF recurrence. In two patients with persistent AF, third and fourth sessions were needed to maintain sinus rhythm. At  $20.3 \pm 13.6$  months of follow-up, all patients (100%) with paroxysmal and persistent AF were free from recurrent AF or atrial tachycardia, and all patients with paroxysmal AF had no AF during dialysis. One patient developed cervical hematoma due to the patient's sudden motion during therapy. Mild cerebral infarction occurred in only one patient during the follow-up period. There were no other complications.

## CONCLUSIONS

In patient on dialysis, the optimal treatment for AF to restore and maintain sinus rhythm has not been established. In this collaborative investigation, radiofrequency catheter ablation in dialysis patients with AF achieved complete maintenance of sinus rhythm. Only one case of cerebral infarction occurred among 16 patients during  $20.3 \pm 13.6$  months of follow-up, compared to the reported incidence of over 30% within one year. Therefore, infarct-related disorders such as cerebral infarction may be reduced by this treatment. The effect of radiofrequency catheter ablation on prognosis should be further investigated.

