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Original Article

Impact of esophageal temperature monitoring guided atrial fibrillation ablation on preventing asymptomatic excessive transmural injury

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ABSTRACT

Background: Even with the use of a reduced energy setting (20–25 W), excessive transmural injury (ETI) following catheter ablation of atrial fibrillation (AF) is reported to develop in 10% of patients. However, the incidence of ETI depends on the pulmonary vein isolation (PVI) method and its esophageal temperature monitor setting. Data comparing the incidence of ETI following AF ablation with and without esophageal temperature monitoring (ETM) are still lacking.

Methods: This study was comprised of 160 patients with AF (54% paroxysmal, mean: 24.0 ± 2.9 kg/m^2). Eighty patients underwent ablation accompanied by ETM. The primary endpoint was defined as the occurrence of ETI assessed by endoscopy within 5 d after the AF ablation. The secondary endpoint was defined as AF recurrence after a single procedure. If the esophageal temperature probe registered >39 °C, the radiofrequency (RF) application was stopped immediately. RF applications could be performed in a point-by-point manner for a maximum of 20 s and 20 W. ETI was defined as any injury that resulted from AF ablation, including esophageal injury or periesophageal nerve injury (peri-ENI).

Results: The incidence of esophageal injury was significantly lower in patients whose AF ablation included ETM compared with patients without ETM (0 [0%] vs. 6 [7.5%], $p=0.028$), but not the incidence of peri-ENI (2 [2.5%] vs. 3 [3.8%], $p=1.0$). AF recurrence 12 months after the procedure was similar between the groups (20 [25%] in the ETM group vs. 19 [24%] in the non-ETM group, $p=1.00$).

Conclusions: Catheter ablation using ETM may reduce the incidence of esophageal injury without increasing the incidence of AF recurrence but not the incidence of peri-ENI.

1. Introduction

Pulmonary vein isolation (PVI) has become a standard therapy in the management of atrial fibrillation (AF) [1,2]. Although AF ablation is widely considered safe, serious esophageal complications, such as atrioesophageal fistulae, esophageal erythema, esophageal ulcerations, and periesophageal nerve injury (peri-ENI, e.g., acute pyloric spasms and gastric hypomotility), occasionally occur [3–8]. These serious esophageal complications may be caused by excessive damage beyond the left atrial (LA) posterior wall during radiofrequency (RF) energy deliveries. To avoid these complications, monitoring esophageal temperature is recommended during RF applications to the LA posterior

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wall [9]. Halm et al. reported that lesions occurred in patients with an esophageal temperature >41 °C, and for every 1 °C increase in esophageal temperature, the odds of an esophageal lesion increased by a factor of 1.36 (95% confidence interval [CI]=1.07–1.74; $p=0.012$) [10]. Yamasaki et al. reported that body mass index (BMI) (kg/m^2) was the only independent predictor of excessive transmural injury (ETI) (odds ratio [OR]=0.76; 95% CI 0.59–0.97; $p<0.05$) [5]. Most recently, we demonstrated that AF ablation with a lower-energy setting of 20 W strictly controlled by esophageal temperature monitoring (ETM) at 39 °C could reduce the esophageal injury even in patients with a BMI < 24.9 kg/m^2 [11]. As for the incidence of peri-ENI, Miyazaki et al. reported that BMI was the only independent predictor for identifying patients who would develop peri-ENI during RF applications to the LA posterior wall with a relatively higher setting of 25–30 W and a duration of 30 s (OR=0.77; 95% CI=0.64–0.92; $p=0.0045$) [12]. However, data comparing the incidence of ETI (including esophageal injury and peri-ENI) following AF ablation with and without ETM are still lacking. In the current study, we sought to investigate the safety and effects of AF ablation strictly controlled by ETM in patients who underwent PVI with a lower energy setting of 20 W and a duration of 20 s for each RF application.

2. Material and methods

2.1. Patient characteristics

Patients ($N=160$) with highly symptomatic, medically refractory AF who were treated with catheter ablation with or without ETM were retrospectively analyzed. Of these, 80 patients underwent AF ablation with ETM (the ETM group). During the same period, from a database of 312 patients who underwent AF ablation without ETM, a computer model created a control group of another 80 patients (controls; non-ETM group) matched to the ETM group according to age, sex, type of AF, and BMI. All procedures in both groups were performed in the following centers: Himeji Cardiovascular Center, Tsukuba University, and Kobe University. The baseline characteristics of the 2 groups are shown in Table 1. Ethical approval was obtained from the institutional review committees, and all patients in the ETM group gave their informed written consent before participation. Every researcher involved in this study acted in conformity with the Declaration of Helsinki (adopted by the 18th World Medical Association General Assembly, Helsinki, Finland in 1964).

2.2. Mapping and ablation procedure

Prior to the procedure, transesophageal echocardiography was performed to exclude any thrombus formation. Patients were studied under deep propofol sedation while breathing spontaneously. Standard electrode catheters were placed in the right ventricular apex and coronary sinus, after which a single transseptal puncture was performed. Unfractionated heparin was administered in a bolus form before the transseptal puncture to maintain an activated clotting time of >300 s. If AF occurred, internal electrical cardioversion was performed to restore sinus rhythm. Selective angiography of the pulmonary veins and barium esophagography were performed.

After integration of a 3-dimensional (3D) model of the anatomy of the LA and pulmonary veins (PVs) obtained from preinterventional computed tomography (CT) or magnetic resonance imaging (MRI), mapping and ablation were performed using the CARTO3 (Biosense Webster Inc., Diamond Bar, CA, USA) or NavX (St. Jude Medical, Inc., St. Paul, MN) system as a guide. Prior to the ablation, the circular mapping catheter (Lasso, Biosense Webster, Diamond Bar, CA; Optima, St. Jude Medical Inc., St. Paul, MN, USA) and ablation catheter–reconstructed LA posterior anatomies were aligned with the CT or MRI image [13–15]. Image integration was finely adjusted using 3 additional landmarks (top of the left superior PV [LSPV], right superior PV [RSPV], and bottom of the left inferior PV [LIPV]), and the tip of the ablation catheter (ThermoCool, Biosense Webster; IBI Therapy Cool Flex, St. Jude Medical, Inc.) was positioned at the landmarks based on fluoroscopic and electrographic information.

RF alternating current was delivered in unipolar mode between the irrigated-tip electrode of the ablation catheter and an external backplate electrode. The initial RF generator setting consisted of an upper catheter tip temperature of 43 °C, maximal RF power of 30 W, and irrigation flow rate of 17 or 13 mL/min using the CARTO3 and NavX systems, respectively. In patients requiring RF applications to the posterior wall, the initial RF generator setting consisted of a maximal RF power of 20 W. All patients underwent extensive encircling pulmonary vein isolation [16]. RF applications were performed in a point-by-point manner. The maximum time spent at the anterior and posterior walls was 40 s and 20 s, respectively. The encircling ablation line was created approximately 0.5–1 cm from the PV ostia. In the ETM group, the RF energy was routinely reduced by 10 W when ablating the posterior wall, based on the esophageal temperature measured with an esophageal temperature probe (SensiTherm, St. Jude Medical) [17]. If the esophageal temperature rose to >39 °C, the ablation was stopped immediately and the energy was further reduced. After the esophageal temperature decreased to the normal range (37 °C), the RF application was resumed. If ablation could not be performed with 20-W energy, the line placement was performed either more antral or closer to the PV, depending on the patient's anatomical characteristics (Fig. 1) [18]. The RF energy setting for the posterior wall far from the esophagus was 25 W for a duration of 30 s. In the non-ETM group, the RF energy for the LA posterior wall was titrated to 20 W with an RF duration of 20 s at the Himeji Cardiovascular Center and Kobe University, and to 20 W for 30 s at Tsukuba University. Furthermore, $a>50$-s break was applied between each RF energy application at Tsukuba University. Catheter navigation was performed with a nonsteerable sheath (Preface®, Biosense Webster) or a steerable sheath (Agilis, St. Jude Medical Inc.).

The procedural endpoint was electrophysiologically proven bidirectional block of the PV-encircling ablation lines, confirmed with a circular mapping catheter. After proving bidirectional block of the PVs, we performed a stimulation protocol (burst pacing from the coronary sinus at 300 ms, 250 ms, and 200 ms for 10 s each) to test the inducibility of AF. When AF was induced, additional ablation consisting of linear ablation at the LA roof and/or a bottom line connecting the bottom of the inferior PVs was performed. A pharmacological test consisting of high-dose isoproterenol infusion (20 μg/min) was performed to identify non-PV triggers. Ablation of the cavotricuspid isthmus was performed only if typical right atrial flutter was either documented previously or induced by burst pacing at the end of the procedure. Patients were started on proton pump inhibitors on admission and continued for 4 weeks at the Himeji Cardiovascular Center and Kobe University, and for 2 weeks

Table 1
Baseline characteristics of the 2 patient groups.

	ETM group	Non-ETM group	*p* Value
Sex (male) (*n*, %)	60 (75)	65 (81)	0.45
Age (years)	60.7 ± 8.2	58.2 ± 10.6	0.10
Paroxysmal AF (*n*, %)	45 (56)	41 (51)	0.63
AF history (month)	36 (12; 72)	36 (12; 66)	0.78
Hypertension (*n*, %)	44 (55)	31 (39)	0.06
Structural heart disease (*n*, %)	11 (14)	19 (24)	0.16
Diabetes mellitus (*n*, %)	8 (10)	11 (14)	0.63
Left atrial diameter (mm)	41.3 ± 6.3	39.2 ± 6.7	0.05
LVEF (%)	61.7 ± 8.3	64.0 ± 8.6	0.09
BMI (kg/m^2)	23.9 ± 3.1	23.9 ± 3.0	0.92

ETM=esophageal temperature monitoring, AF=atrial fibrillation, LVEF=left ventricular ejection fraction, BMI=body mass index.