Zero-fluoroscopy ablation for cardiac arrhythmias: A single-center experience in Japan

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Abstract

Background: Exposure to radiation during catheter ablation procedures poses a risk to the health of both the patient and electrophysiology laboratory staff. Recently, the feasibility and effectiveness of zero-fluoroscopy ablation have been reported. However, studies on the outcomes of zero-fluoroscopy ablation in Japan remain limited. This study investigated the outcomes of zero-fluoroscopy ablation for cardiac arrhythmias at a Japanese institute.

Methods and Results: We present a retrospective analysis of the safety, efficacy, and feasibility data from 221 consecutive patients who underwent zero-fluoroscopy ablation. Of these patients, 181 had atrial fibrillation, 17 had paroxysmal supraventricular tachycardia, 13 had atrial tachycardia, 6 had ventricular tachycardia, and 4 had ventricular premature contractions. We performed zero-fluoroscopy ablation using three-dimensional electro-anatomical mapping systems and intracardiac echocardiography imaging. Ultrasound-guided sheath insertion was performed on all cases. Our experience includes exclusively endocardial cardiac ablations. The mean follow-up was 24 months. The recurrence rates were 25.4% for atrial fibrillation, 5.9% for paroxysmal supraventricular tachycardia, 15.4% for atrial tachycardia, 33.3% for ventricular tachycardia, and 25% for ventricular premature contraction. Complications occurred in two patients (0.9%), and there was no occurrence of death. A fluoroscopic guide was used in three cases for the confirmation of vascular access (one case) and for complications (two cases).

Conclusions: Zero-fluoroscopy ablation was routinely performed without compromising on safety and efficacy. This approach may eliminate the exposure to radiation for all individuals involved in this procedure.

KEYWORDS
occupational health, radiation exposure, zero-fluoroscopy ablation
1 | INTRODUCTION

A fluoroscopic guide is the standard tool used for catheter visualization, electrophysiological (EP) studies, and ablation procedures. A major disadvantage of fluoroscopic guide ablation procedures is the risk posed to the health of both the patient (deterministic and stochastic effects) and EP laboratory staff (occupational health risks) by the exposure to radiation.\(^1\)\(^{-}\)\(^4\) It has been reported that DNA damage may occur even when ordinary protective measures are taken against exposure to radiation.\(^5\) The principle of "as low as reasonably achievable" is aimed at protection against radiation.\(^5\)\(^{-}\)\(^7\) The dose-threshold analysis does not indicate a threshold for safe exposure to radiation (ie, zero dose was the best value for the threshold).\(^8\) Recently, the multisociety position statement proposed that each stakeholder plays an important role in improving occupational health and safety in the catheterization laboratory.\(^9\) In the process of attempting to reduce exposure to radiation, the goal should be zero exposure.\(^4\) In recent years, the possibility of catheter ablations for cardiac arrhythmias without the use of fluoroscopy has been reported.\(^10\)\(^{-}\)\(^13\) In addition, the safety and efficacy of zero-fluoroscopy ablation have been demonstrated.\(^12\) However, zero-fluoroscopy ablation is rarely performed in Japan.\(^14\) Herein, we present our experience over the course of more than one year with regard to the safety, efficacy, and feasibility of zero-fluoroscopy endocardial catheter ablations for cardiac arrhythmias.

2 | METHODS

Following the approval of the institutional review board, a retrospective analysis was conducted to examine the endocardial catheter ablation procedures performed without the use of a fluoroscopic guide. We informed all patients regarding the risks, benefits, and alternatives of zero-fluoroscopy catheter ablation, and obtained informed consent prior to performing the procedures. The protocol for this research study was approved by the institutional Ethics Committee and conformed to the tenets of the Declaration of Helsinki.

We analyzed patients who underwent zero-fluoroscopy ablation procedures from October 2018 to September 2019. Zero-fluoroscopy ablation was performed using three-dimensional electro-anatomical mapping (EAM) systems (CARTO\(^\text{®}\)3 System, Biosense Webster; EnSite Precision\(^\text{™}\) Mapping System, Abbott; and RHYTHMIA HDx\(^\text{™}\) Mapping System, Boston Scientific). Procedures were classified as ablation for: atrial fibrillation (AF), atrial tachycardia (AT), paroxysmal supraventricular tachycardia (PSVT) including atrioventricular reentrant tachycardia (AVRT), atrioventricular nodal reentrant tachycardia (AVNRT), ventricular premature contractions (VPC), and ventricular tachycardia (VT). The procedure time was defined as the time interval from the initial venous or arterial access until the removal of all sheaths at the conclusion of the case.

2.1 | Pre-ablation management

All patients underwent chest x-ray examination with preoperative exposure to radiation. Patients suspected of coronary artery disease underwent computed tomography (CT) angiography or coronary artery angiography. In patients with AF, transesophageal echography was performed as a preoperative examination because of the detection of thrombus at the left atrium (LA). Seventy patients with AF underwent preprocedural CT or magnetic resonance imaging (MRI) to obtain anatomical information on the heart prior to ablation. Enhanced CT with contrast was performed on 44 patients with preserved renal function (estimated glomerular filtration rate [eGFR] ≥ 45) and without contrast allergy. Plain CT was performed on 25 patients with reduced renal function (eGFR < 45) and/or contrast allergy. MRI was performed on one patient. The patients with persistent AF or long-standing persistent AF who underwent ablations received anticoagulation therapy for at least three weeks before the procedure.

2.2 | Ablation procedures

We performed radiofrequency ablation using an open irrigation-tip catheter (THERMOCOOL SMARTTOUCH\(^\text{®}\), Biosense Webster; TactiCath\(^\text{™}\) SE, Abbott; or INTELLATIP MIFI\(^\text{™}\) OPEN-IRRIGATED, Boston Scientific). Some AF ablations were performed using a cryoballoon (Arctic Front Advance\(^\text{™}\), Medtronic). Anesthesia was induced by injection of fentanyl and propofol through a peripheral vein. The bispectral index (BIS) was used to evaluate the depth of anesthesia. During intravenous anesthesia, respiratory assistance was provided by bilevel positive airway pressure. In the presence of snoring, recognized by the subsidence of the root of the tongue following intravenous anesthesia, an oral airway was inserted to enable stable breathing. Blood vessel access was initiated in patients with a BIS ≤ 60.

2.2.1 | Sheath insertion and catheter positioning without fluoroscopic guidance

Ultrasound-guided sheath insertion was performed through the right femoral vein. Two long guide wires were inserted into the right femoral vein through two punctures. The distance from the right neck to the right inguinal region was measured with a guide wire prior to venipuncture. Subsequently, the guide wire was inserted through the femoral vein to reach the right internal jugular vein. In the presence of resistance during the advancement of the guide wire, the guide wire was retracted slightly and maneuvered along a different route with a slight bend and rotation. The presence of the guide wire in the internal jugular vein was confirmed using ultrasound (Figure 1).\(^15\) Subsequently, a long (25 cm) 9 Fr insertion sheath (Radifocus\(^\text{®}\) Introducer IIH, TERUMO) was introduced. Subsequently, an intracardiac echocardiography (ICE) catheter (CARTOSOUND\(^\text{®}\), Biosense
Webster, AcuNav™, Biosense Webster, or ViewFlex™ Xtra, Abbott) was advanced and positioned in the right atrium (RA) to image the heart (Video 1). Using an ICE image, the presence of the guide wire in the RA was verified and an 8.5 Fr steerable sheath (Agilis™ NxT Steerable Introducer, St Jude Medical) was introduced into the inferior vena cava. If additional sheath insertion was necessary, we performed ultrasound-guided sheath insertion through the left femoral vein, the right internal jugular vein, and the left femoral artery. We placed catheters using EAM and/or ICE image without a fluoroscopic guide (Video 2).

2.2.2 | Transseptal puncture without fluoroscopic guidance

In patients undergoing left-sided procedures, we performed transseptal puncture without a fluoroscopic guide. The atrial septum and the left superior pulmonary vein (PV) were visible on the ICE image. We performed all transseptal punctures under ICE guidance without a fluoroscopic guide and advanced the long sheath into the LA. Subsequently, an irrigated-tip contact force monitoring ablation catheter was inserted into the LA. After obtaining access to the LA, we conducted left and right atrial-inferior vena cava fast-automated mapping using an ablation catheter. The geometry created may subsequently be used as a roadmap for the blood vessels and heart chambers (Video 3).

2.2.3 | Catheter ablation of AF without fluoroscopic guidance

We performed AF ablation using the CARTO®3 System (Biosense Webster). The endpoint of AF ablation was the achievement of PV isolation. AF ablation was performed as follows. Esophageal temperature was monitored during AF ablation using the SensiTherm™ Esophageal Temperature Monitoring System (Abbott). The position of the temperature-monitoring catheter was determined by intravesophageal electrocardiogram monitoring without a fluoroscopic guide. A (atrial) and V (ventricular) waves shown by the proximal and distal electrodes (Figure 1), respectively, indicated the position of the catheter. After setting the temperature-monitoring catheter, patients underwent electrophysiologic studies under deep sedation. For recording and stimulation, a multipolar electrode catheter was positioned in the coronary sinus (CS). The LA geometry was constructed using this multipolar catheter. Subsequently, we performed PV isolation in all patients with AF. Adjuvant ablation (line ablation and complex fractionated atrial electrogram ablation) was performed on patients with persistent and long-standing persistent AF.
We performed cryoballoon ablation (CBA) using a direct pressure-monitoring guide \(^1\) in three cases. We performed CBA through the following maneuver. After a transseptal puncture, an 8 Fr long sheath (Swartz™ Introducer SL0™, St Jude Medical) was advanced into the LA. We created the LA geometry using a 10-pole circular mapping catheter and merged in the LA geometry and image of prior enhanced CT. A guide wire was advanced through an 8 Fr long sheath into the left superior PV, the location of which was confirmed under ICE. While maintaining a guide wire in the left superior PV, an 8 Fr long sheath was withdrawn from the body and exchanged for a 15 Fr steerable sheath (FlexCath Advance™, Medtronic). The 10.5 Fr (28 mm) cryoballoon and the Achieve™ mapping catheter (Medtronic) were placed through a 15 Fr steerable sheath into the LA. The Achieve™ mapping catheter was advanced into the PV. The cryoballoon was advanced and placed in apposition with the PV ostium using an ICE guide. The pressure from the tip of the cryoballoon catheter was recorded. The cryoballoon was inflated and moved to the antrum of the vein. During sinus rhythm, A and V waves were recorded. When occlusion was achieved, there was the loss of the A wave and an increase in the amplitude and morphology of the V wave (Figure 2). Cryotherapy was successively performed. The goal temperature was from –40 to –50°C. The duration of each application was 180 seconds. The same technique was utilized for the remaining PVs. Prior to CBA for the right-sided PVs, the 10-pole circular mapping catheter was used to pace the superior vena cava at the high output to monitor the integrity of the phrenic nerve during cryo applications. After CBA, each PV was mapped using a 10-pole circular mapping catheter. In the case of persistent conduction, electrical isolation was performed segmentally using an irrigated radiofrequency catheter. A fluoroscopic guide or contrast media were not used.

2.2.4 | Catheter ablation of AT without fluoroscopic guidance

We performed AT ablation using the CARTO®3 System (Biosense Webster). The endpoint of ablation was termination and no induction of AT. AT ablation was performed as follows. The patients underwent electrophysiologic studies under deep sedation. For recording and stimulation, a multipolar electrode catheter was positioned in the CS. AT was induced in the patients who were in sinus rhythm during the time of the study. The patients underwent AT mapping and ablation in the RA and/or LA.
2.2.5 | Catheter ablation of PSVT without fluoroscopic guidance

We performed PSVT ablation using the EnSite Precision™ Mapping System (Abbott) and RHYTHMIA HDx™ System (Boston Scientific). The endpoints of PSVT ablation were: (i) Elimination of the target VPCs in patients with VPC; and (ii) no induction after ablation in patients with PSVT. PSVT ablation was performed as follows. The patients underwent electrophysiologic studies under deep sedation. For recording and stimulation, a multipolar electrode catheter was positioned in the CS or RV. Following the induction of PSVT, the patients underwent mapping and ablation in the RA and/or LA. (Figure 2).

2.2.6 | Catheter ablation of ventricular arrhythmias without fluoroscopic guidance

We performed ablation of ventricular arrhythmias using the CARTO®3 System (Biosense Webster). The endpoints were: (i) Elimination of the target VPCs in patients with VPC; and (ii) no induction after ablation in patients with VT. VPC ablation was performed as follows. The patients underwent electrophysiologic studies under deep sedation. The RV and LV geometry was constructed using the CARTOSOUND®. For recording and stimulation, a multipolar electrode catheter was positioned in the CS or RV. Following the induction of PSVT, the patients underwent mapping and ablation in the RV and/or LA. (Figure 2).

2.3 | Post-ablation management and clinical follow-up

The O suture technique was used for hemostasis in all patients. The patients walked after resting for 2 hours following zero-fluoroscopy ablation. All patients were observed through outpatient follow-up. Holter monitor, event monitor, loop recorder, or cardiac implantable electronic devices were employed to confirm the efficacy.

3 | RESULTS

3.1 | Patient characteristics

The study included 221 consecutive patients. The average follow-up was 24 months. The mean age was 69.1 years, the majority of patients were males (n = 145), the average body mass index was 23.6 kg/m², and 28 patients had undergone prior ablation. Patients with structural heart disease included 5 with valvular heart disease (5 patients with the mechanical mitral valve, and 1 patient with the mechanical arterial valve), 18 with ischemic heart disease, 12 with cardiomyopathy, and 1 with congenital heart disease. Of note, 11 patients had reduced ejection fraction <35%. A total of 27 patients had cardiac implantable electronic devices, including cardiac resynchronization therapy devices (Table 1). The procedure endpoint was achieved in all cases. Major complications occurred in two patients (0.9%), and there was no occurrence of death. A fluoroscopic guide for catheter placement was not used in any cases. A fluoroscopic guide was used in three patients. In one patient, a fluoroscopy guide was used for 53 seconds to confirm venous access. In two patients, who required pericardiocentesis for the treatment of cardiac tamponade, a fluoroscopy guide was used for 320 and 410 seconds, respectively (Table 2).

3.2 | Atrial fibrillation

A total of 181 catheter ablations for paroxysmal AF (n = 73), persistent AF (n = 34), and long-standing persistent AF (n = 74) were performed. A total of 178 patients underwent radiofrequency ablation, three patients underwent CBA. The mean procedure time was 111 minutes for paroxysmal AF, 144 minutes for persistent AF, and 164 minutes for long-standing persistent AF. The rate of recurrence was 12.3%, 17.6%, and 41.9%, respectively. The average duration of the follow-up was 23.8, 24.9, and 23.9 months, respectively. Major complications occurred in two patients (ie, cardiac tamponade that required pericardiocentesis).

3.3 | Paroxysmal supraventricular tachycardia

A total of 17 catheter ablations for paroxysmal supraventricular tachycardia (AVRT: 6, AVNRT: 11) were performed. The six accessory pathways included five on the left side and one on the right side. In this group, the mean procedure time was 108 minutes.

| TABLE 1 | Baseline characteristics |
|---|---|
| Characteristics (N = 221 Follow-up periods = 24.2 ± 2.86 months) | |
| Age (years) | 69.1 ± 38.5 |
| Male sex (N, %) | 145 (66%) |
| Body mass index (kg/m²) | 23.6 ± 3.53 |
| Prior ablations (N) | 28 |
| Valvular heart disease (N) | 5 |
| Ischemic heart disease (N) | 18 |
| Cardiomyopathy (N) | 12 |
| Congenital heart disease (N) | 1 |
| Ejection fraction under 35% (N) | 11 |
| Cardiac implantable electronic device (N) | 27 |
procedural success was achieved in all patients. Of note, one recurrence (5.9%) was recorded. The recurrence occurred in an AVRT patient with delta waves lost due to a bump during the procedure. The average duration of the follow-up was 24.8 months. There were no complications observed in this group.

### 3.4 Atrial tachycardia

A total of 13 catheter ablations for AT were completed. The sites included six at the cavotricuspid isthmus and seven from other circuits or scars in the LA or RA. The mean procedure time was 151 minutes. Acute procedural success was achieved in all patients. Of note, there were two recurrences (15.4%). The average duration of the follow-up was 24.1 months. There were no complications recorded in this group.

### 3.5 Ventricular tachycardia

Six catheter ablations for VT were completed for four cases of ischemic VT and two cases of cardiac sarcoidosis with a mean LV ejection fraction of 41.5%. The mean procedure time was 206 minutes. Acute procedural success was achieved in all patients. The average duration of the follow-up was 23.3 months. Of note, two recurrences (33.3%) were recorded. There were no complications observed in this group.

### 3.6 Ventricular premature contractions

Four catheter ablations for VPCs were performed. In the RV, there was an outflow tract VPC. In the LV, there were two outflow tract VPCs. The mean procedure time was 113 minutes. Acute procedural success was achieved in all patients. The average duration of the follow-up was 27.5 months. Of note, one recurrence (25%) was recorded. There were no complications observed in this group.

### 4 DISCUSSION

Previously studies have shown the safety and efficacy of zero-fluoroscopy ablation. However, studies on the outcomes more than 12 months after this procedure have not been conducted yet in Japan. In this article, we present our experience with zero-fluoroscopy ablation for cardiac arrhythmias performed on 221 consecutive patients in Japan.

#### 4.1 Selection of an EAM system for zero-fluoroscopy ablation

The CARTO®3 System (Biosense Webster) can integrate ICE images with 3D mapping, leading to minimal puncture. Therefore, it was used for the treatment of AF, AT, and ventricular arrhythmias. After obtaining the ICE image, we integrated it into the 3D mapping. This approach reduced the need to continue using the ICE image during the procedure, replacing the ICE catheter with a mapping catheter. It also reduced the number of sheaths to be inserted. We treated AF and AT with two femoral vein punctures. Minimizing punctures can reduce the risk of complications associated with this procedure. This study showed that ablation with two femoral vein punctures did not cause any problems. We used the EnSite Precision™ Mapping System (Abbott) and RHYTHMIA HDx™ Mapping System (Boston Scientific) to evaluate the conduction mode during tachycardia with

#### TABLE 2 Ablation duration, complications, recurrence rates, and follow-up

| Ablation type   | Number of patients (N) | Procedure time (minutes) | Complications (N) | Fluoroscopy used (N) | Recurrences (N) | Follow-up (months) |
|-----------------|------------------------|--------------------------|-------------------|----------------------|----------------|-------------------|
| AF (PAF)        | 181                    | 139 ± 52.8               | 2                 | 3                    | 46 (25.4%)     | 24.1              |
| (PeAF)          | 73                     | 111 ± 38.5               | 0                 | 1                    | 9 (12.3%)      | 23.8              |
| (LAPeAF)        | 34                     | 144 ± 50.0               | 2                 | 2                    | 6 (17.6%)      | 24.9              |
| PSVT            | 17                     | 108 ± 30.8               | 0                 | 0                    | 1 (5.9%)       | 24.8              |
| (AVRT)          | 6                      | 123 ± 26.0               | 0                 | 0                    | 1 (16.7%)      | 24.3              |
| (AVNRT)         | 11                     | 100 ± 28.8               | 0                 | 0                    | 0 (0%)         | 25.0              |
| AT (Left-sided) | 13                     | 151 ± 75.5               | 0                 | 0                    | 2 (15.3%)      | 24.1              |
| (Right-sided)   | 5                      | 197 ± 42.3               | 0                 | 0                    | 2 (40%)        | 23.4              |
| VT              | 6                      | 206 ± 54.8               | 0                 | 0                    | 2 (33.3%)      | 23.3              |
| VPC             | 4                      | 113 ± 40.6               | 0                 | 0                    | 1 (25%)        | 27.5              |

Abbreviations: AF, atrial fibrillation; AT, atrial tachycardia; AVNRT, atrioventricular nodal reentrant tachycardia; AVRT, atrioventricular reentrant tachycardia; LS PeAF, long-standing persistent atrial fibrillation; PAF, paroxysmal atrial fibrillation; PeAF, persistent atrial fibrillation; PSVT, paroxysmal supraventricular tachycardia; ventricular premature contractions VT, ventricular tachycardia VPC.
high-resolution mapping in the treatment of PSVT. ViewFlex™ Xtra (Abbott) was useful in assessing the position of the catheter with crisp images. When used in combination with the EnSite Precision™ Mapping System (Abbott) and RHYTHMIA HDx™ Mapping System (Boston Scientific), ICE was very effective in providing information on the position of the catheter.

4.2 Safety, feasibility, and effectiveness of zero-fluoroscopy ablation

The overall incidence of periprocedural complications following catheter ablation ranges from 2.3% to 3.8%. The risk of complications varies with the type of ablation performed; AF and VT ablations are linked to higher complication rates. In this case series, major complications occurred in only two patients undergoing ablation for AF. The complication rate in this case series was 0.8%, which is lower than those previously reported for conventional ablations. The extensive use of ICE in most of our cases may have assisted in monitoring and preventing the development of complications. Moreover, there was no occurrence of procedure-related death. Accordingly, this evidence indicates that the zero-fluoroscopic approach is not associated with additional acute procedural risk.

Previous studies showed that there is no difference in procedure time between zero-fluoroscopy ablations and fluoroscopy ablations. Moreover, the procedure time for zero-fluoroscopy ablation decreased as the operators gained more experience.

In this study, zero-fluoroscopy ablation for various arrhythmias was as effective as the previously reported fluoroscopy-guided ablations.

4.3 Clinical significance

Ionizing radiation is carcinogenic, and the reduction of its use has been the focus of research studies for many years. In our EP laboratory, zero-fluoroscopy ablation could eliminate exposure to radiation during the procedure of endocardial catheter ablation. Patients and EP laboratory staff were free from the risks associated with exposure to radiation. During the ablation procedure, staff members do not need to wear lead aprons. Importantly, zero-fluoroscopy ablation may solve the problems associated with exposure to radiation during catheter ablation without compromising the safety and efficacy of the treatment or lengthening the duration of the procedure.

Relying solely on ICE and EAM has allowed us to maximize the imaging potential of these techniques and better define the anatomy and tissue-catheter interface during the application of ablative energy. Using ICE, we could confirm five chambers (both atria including the superior vena cava, inferior vena cava, CS, and all PVs, both ventriculi, and the aorta). In addition, it has permitted us to accurately define the cardiac structures. We were able to recognize and ensure contact with structures that fluoroscopy cannot visualize, such as papillary muscles. Our experience also includes LA and LV ablation in patients with mechanical mitral and arterial valves, respectively.

Use of contrast media is not required in zero-fluoroscopy ablation. This procedure can be safely performed even in patients with allergic or kidney disease.

4.4 Feasibility of performing zero-fluoroscopy ablation

We demonstrated the change in fluoroscopy time for AF ablation performed by the primary operator before initiating zero-fluoroscopy ablation (Figure 3). At the initiation of zero-fluoroscopy ablation, the operator used a fluoroscopic guide only for the sheath insertion, the positioning of catheters, and the transseptal puncture. After the first 10 cases of zero-fluoroscopy ablation procedures, the operator and EP laboratory staff performed zero-fluoroscopy ablation without a lead apron in routine clinical practice. The operator’s expertise in ablation and the interpretation of ICE images
and EAM data are prerequisites for performing zero-fluoroscopy ablation.\textsuperscript{12} Therefore, attempts to perform zero-fluoroscopy ablation should be preceded by adequate training on ICE. There is a concern regarding the difficulty of the training of operators on ICE maneuvers for zero-fluoroscopy ablation. However, a report allows operators to learn zero-fluoroscopy catheter ablation more easily.\textsuperscript{14} The currently available technology renders zero-fluoroscopy ablation feasible. Nevertheless, the feasibility of this technique is limited by the expertise of the operator.\textsuperscript{12}

4.5 Study limitations

The present study has several limitations. First, this was a single-center and retrospective case series. Second, the study involved only one primary operator. Nevertheless, the primary operator has performed more than 500 zero-fluoroscopy ablations. Finally, this was not a randomized controlled trial and was not intended to compare the safety and efficacy of procedures for widespread applicability. Therefore, a randomized controlled trial is warranted to determine the safety and effectiveness of zero-fluoroscopy ablation.

5 CONCLUSIONS

Zero-fluoroscopy ablation may be routinely performed for various arrhythmias without compromising the safety and efficacy of the treatment or lengthening the duration of the procedure. Additionally, zero-fluoroscopy ablation may eliminate exposure to radiation for all individuals involved in this procedure and reduces the occupational health risk for EP laboratory staff.

CONFLICT OF INTEREST

The authors have no conflict of interest to declare regarding this article.

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SUPPORTING INFORMATION
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