


Localization of right ventricular non-apical lead position: comparison of three-dimensional echocardiography, computed tomography, and fluoroscopic imaging

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Abstract

Objective: Right ventricular (RV) septal pacing is considered a better pacing procedure compared with traditional apical pacing. This study aimed to investigate agreement among computed tomography (CT), three-dimensional echocardiography (3D-echo), and fluoroscopy for evaluating the tip of the RV pacing lead in the non-apical position in patients with permanent pacemaker implantation.

Methods: Fifty-four patients were prospectively enrolled. Data on patients' characteristics and imaging findings were analyzed. The agreement rate in distinguishing the RV septal lead position among the three imaging modalities was determined.

Results: Thirty-three (61%) patients were men and the median age was 76 years. Overall, the agreement rate among the three imaging modalities was 87% (47/54; Kappa ratio: 0.734). The agreement of 3D-echo compared with thoracic CT (Kappa ratio: 0.893) was better than that for

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thoracic CT and fluoroscopy (Kappa ratio: 0.658). Agreement between fluoroscopy and 3D-echo was lowest (Kappa ratio: 0.632).

Conclusions: Agreement in evaluating the position of the septal lead between thoracic CT and 3D-echo is better than that between other imaging modalities. Our findings indicate that 3D-echo imaging might be the best imaging tool for defining the tip of the RV non-apical lead position and be useful for guiding positioning of the RV lead.

Keywords

Computed tomography, fluoroscopy, right ventricular lead position, three-dimensional echocardiography, septal lead, apical position

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Introduction

In an attempt to reduce morbidity with apical pacing, right ventricular (RV) septal pacing is performed in patients with a rate of high ventricular pacing to decrease mechanical dyssynchrony, enable favorable cardiac hemodynamics, and preserve better left ventricular function.¹⁻⁴ Electrocardiographic (ECG) criteria and the standard fluoroscopic view are the most common tools traditionally used to guide septal lead placement at the time of implantation, but they are neither accurate nor reliable.⁵⁻⁸ Thoracic computed tomography (CT) is often used for validation and may offer the clearest definition of the lead position.^{7,8} Recent studies have shown free wall placement of the ventricular lead tip using CT, but patients who receive septal lead pacing using traditional ECG and fluoroscopic criteria is not uncommon.⁹ However, a retrospective study showed an increased risk of cardiac death and heart failure-related hospitalization with unexpected RV free wall pacing.¹⁰ In daily clinical practice, using CT imaging to guide the RV lead position during device implantation is almost impossible. However, three-dimensional echocardiography (3D-echo) is

a relatively convenient imaging tool to evaluate the tip of the RV lead position⁶ and to guide positioning of the lead instead of relying on fluoroscopic images alone during transvenous permanent pacemaker (PPM) implantation. However, there have been few studies on evaluating agreement among these different modalities in patients receiving RV septal pacing, especially for agreement between 3D-echo and CT.

This study aimed to assess the agreement of traditional fluoroscopic criteria, 3D-echo, and CT imaging for evaluating the tip of the RV pacing lead in the non-apical position in patients with atrioventricular (AV) block receiving PPM implantation. We hoped to determine if 3D-echo is a better tool than traditional fluoroscopic imaging during PPM implantation.

Methods

Study design and enrollment of patients

We prospectively enrolled patients who had advanced or complete AV block and received transvenous PPM from April 2015 to December 2018. Patients who agreed to have 3D-echo and a thoracic CT imaging

survey performed, who did not fulfill the exclusion criteria, and who signed informed consent were included in this study. Patients who had a history of heart failure with dilated cardiomyopathy, chest wall abnormality, emphysema, and obesity with a body mass index $\geq 30 \text{ kg/m}^2$ were excluded because these diseases may affect the image quality and analysis of 3D-echo. Patients whose RV lead tip was located in the apex were also excluded. Fluoroscopic images were acquired during device implantation, 3D-echo images were acquired within 1 week, and chest CT was performed within 1 month after device implantation as soon as possible. Data regarding patient age, sex, comorbidities, fluoroscopy, ECG, thoracic CT, and 3D-echo findings were collected. This study was approved by the Institutional Review Board of Chang Gung Memorial Hospital (IRB number: 102-4685A3). Informed consent was obtained from all study subjects before the study started.

Pacemaker implantation procedure and fluoroscopic protocol

All atrial leads were placed in the right atrial appendage and all ventricular leads

were placed in the non-apical sites. Initially, the stylet was manually adjusted into a U-shape (Figure 1a). The U-shaped stylet was then loaded into the active-fixed lead, and the lead was advanced from the right atrium into the RV and through to the pulmonary artery. The stylet was then withdrawn approximately 2 to 4 cm from the lead, followed by retraction of the lead through the pulmonary artery to the RV and fixation of the lead to the RV septal wall. If difficulty with lead fixation to the RV septal wall was encountered, the stylet and lead were withdrawn completely. A secondary bend with posterior angulation was then implemented approximately 2 cm distal to the original U-shaped stylet (Figure 1b). Additionally, the stylet was loaded into the active-fixed lead and the lead was re-inserted as described above.

A fluoroscopic-guided technique with right anterior oblique (RAO) and left anterior oblique (LAO) views was used to confirm the position of the RV lead.¹¹⁻¹³ From the RAO 30° view, we divided the RV into three equal partitions by horizontal lines (upper, middle, and lower zones). From the LAO 40° view, a lead tip facing the spine was classified as the septal site and a lead

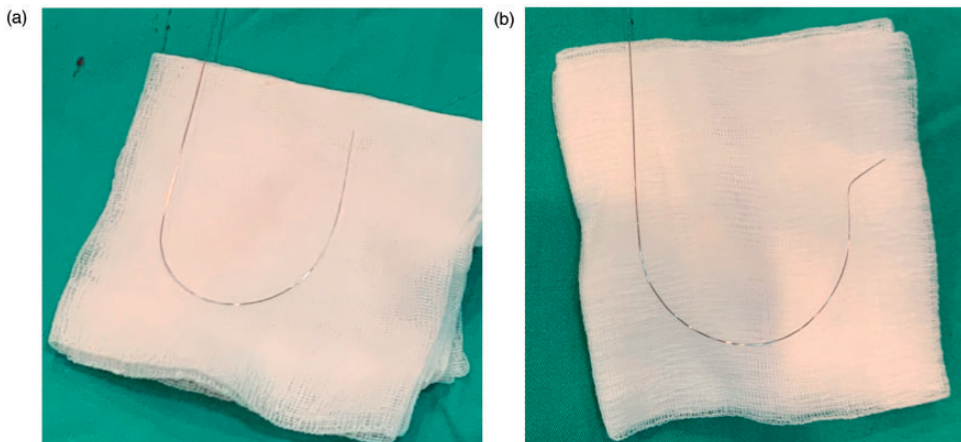


Figure 1. a) Hand-adjusted stylet with a U-shaped curve. b) The original U-shaped stylet bent distal 2 cm with posterior angulation.

tip facing the sternum was classified as the free wall site. If the lead tip was facing the upward direction, we also classified it as the free wall site for analysis. All RV leads were intended to be placed in the middle or upper RV septal sites if possible. Results were accepted for analysis if the RV leads were placed in the middle or upper RV free wall or in the lower RV septal sites. These sites were chosen because the electrophysiological doctors who performed implantation considered that the sensing and pacing parameters were acceptable in these areas (R wave >5 mV and pacing threshold <1 mV with impedance within the normal range). The position of the RV lead was defined as being in the apex if the RV pacing lead was placed in the inferior third by the RAO view with the lead tip pointing downwards and towards the RV apex.

Thoracic CT protocol

Non-contrast enhanced CT imaging was performed for patients using a dual-source 128-slice Siemens Definition Flash CT scanner (Siemens Healthcare, Forchheim, Germany). Automatic tube current modulation in the x, y, and z directions (Care Dose 4D; Siemens Healthcare) and double prospectively ECG-triggered high-pitch (3.4) spiral acquisition (FLASH Spiral Cardio, Siemens Healthcare) were adopted. The double flash mode was prospectively initially triggered at 60% and later at 30% of the R-R interval within two cardiac cycles. The CT scanning parameters were as follows: X-ray source of 2, detector collimation of $2 \times 128 \times 0.6$ mm with double sampling by rapid alteration of the focal spot in the longitudinal direction (Z-flying focal spot), rotation time of 0.28 s, and tube voltage of 100 or 120 kV (depending on patient's body mass index). During acquisition of images, breath holding was the only approach for managing respiratory motion. To familiarize the patient with the protocol, breath holds were practiced before the

examination. The entire volume of the heart was covered during one breath hold in approximately 3 s with simultaneous recording of the ECG trace. Studies were acquired in the cranio-caudal direction from the level of the carina to just below the diaphragm. A medium convolution reconstruction kernel (B36f) was used to reconstruct the images with a slice thickness of 0.75 mm and an increment of 0.5 mm. Additional images for the purpose of analysis for magnetic resonance imaging (MRI) of conditional pacemaker leads were reconstructed using a sharp-tissue convolution kernel (B46) to compensate for blooming artifacts. All images were transmitted to a workstation (Vitrea 7.4; Vital Images Inc., Minnetonka, MN, USA) for post-processing and evaluation.

Three-dimensional-echo protocol

The protocol used for 3D-echo was described previously in published recommendations.¹⁴ Three-dimensional echocardiography was performed using a Vivid E9 Dimension machine equipped with a 4V probe (GE Vingmed Ultrasound AS, Horten, Norway) from the left apical approach and the echocardiographic data set was then analyzed using dedicated software (EchoPACTM version 202; GE Vingmed Ultrasound AS). Multiple-beat 3D-echo was used for exact documentation of the anatomical location of pacing leads. The 3D full-volume echocardiographic data sets were acquired in the RV-focused view. In this view, the central axis of the pyramidal scan volume was aligned with the RV long axis and 3D-echo images were reconstructed by the machine using ECG-gated acquisitions. The concept of cropping was used to classify the lead positions as longitudinal or transverse planes. The precise position of the lead was defined as the location of the lead attached to the myocardium using the full-volume 3D-echo data set. Using these true transverse cropping

planes, which were equivalent with the parasternal short-axis view, we classified the position of the leads as RV septal if the tip of the lead was attached to the interventricular septum or in the groove made by the RV free wall and the septum (also defined as the anterior ridge of the septum). We also classified the position of the leads as RV free wall if the tip of the lead was attached to the RV free wall. Two observers who were blinded to the results of fluoroscopy and thoracic CT assessed all 3D-echo images and defined the positions of the leads. When there were disagreements between observers, a final decision of consensus was made after discussion.

Blinding

All observers for CT and 3D-echo were blinded to the documented lead position at the time of implantation and to the analysis of other imaging modalities.

Statistical analysis

Descriptive summaries are presented for all patients and for subgroups of patients. Quantitative data are described as median and interquartile range and categorical variables are reported as percentages. Fleiss' Kappa test was used for analysis of interrater agreement.¹⁵ A *P* value of <0.05 was considered statistically significant. Statistical analyses were performed using SPSS Statistics 17.0 software (SPSS Inc., Chicago, IL, USA) or R with Package 'irr' software (www.r-project.org).

Results

Baseline characteristics of the patients and device implantation

We excluded five patients from this study because of their history of heart failure with dilated cardiomyopathy, chest wall

Table 1. Characteristics and imaging findings of the patients.

	n = 54
Characteristics	
Age, years	76 (69, 81)
Male sex	33 (61)
Comorbidity	
Hypertension	37 (68.5)
Diabetes mellitus	121 (38.9)
Coronary artery disease	9 (16.7)
Chronic kidney disease	7 (13.0)
Old stroke	5 (9.3)
Lead position	
Fluoroscopy	
Septum	45 (83)
Free wall	9 (17)
3D-echo	
Septum	43 (79.6)
Free wall	11 (20.4)
Chest CT	
Septum	41 (75.9)
Free wall	13 (24.1)

Data are expressed as n (%) or median (interquartile range).

3D-echo, three-dimensional echocardiography; CT, computed tomography.

abnormality, emphysema, or obesity with a body mass index >30 kg/m², and two patients with suboptimal echo images. Fifty-five patients were then included in this study, which included a patient without chest CT images. Therefore, 54 patients were finally included for examination of images and evaluation of agreement among different imaging modalities. No patients had periprocedural adverse events during pacemaker implantation and evaluation of images. The baseline patients' characteristics are shown in Table 1. A total of 61% of the patients were men and the median age for the study population was 76 years. Forty-five (83%) patients had the lead tip in the RV septal wall recorded at the time of implantation as defined by RAO and LAO fluoroscopic views and

Table 2. Agreement analysis among the different modalities.

Imaging modalities	Agreement, n (%)	Kappa ratio	P value
Overall	47/54 (87)	0.734	<0.001
Fluoroscopy and CT	48/54 (88.9)	0.658	<0.001
Fluoroscopy and 3D-echo	48/54 (88.9)	0.632	<0.001
3D-echo and CT	52/54 (96.3)	0.893	<0.001

CT, computed tomography; 3D-echo, three-dimensional echocardiography.

nine (17%) patients had the lead tip in the RV free wall.

RV lead position as shown by 3D-echo and chest CT

Three-dimensional-echo showed that the position of the RV lead tip was in the septal wall in 43 (79.6%) patients and in the free wall in 11 (20.4%) patients. Chest CT showed that the position of the lead tip was in the septal wall in 41 (75.9%) patients, including at the anterior edge of the septum in 5 (9.3%) patients, and in the free wall in 13 (24.1%) patients. The intraclass correlation coefficients for inter-observer agreement were 0.893 and 1.000 for lead position by 3D-echo and thoracic CT, respectively.

Agreement among different modalities

The agreement rate in distinguishing the RV septal lead from the RV free wall lead among different modalities is shown in Table 2. Overall, the agreement rate among the three imaging modalities was 87% (47/54) and the agreement was substantial (Kappa ratio: 0.734, $P < 0.001$). There was some discrepancy in agreement among the three imaging modalities. The agreement rate was better between 3D-echo and chest CT (Kappa ratio: 0.893, $P < 0.001$) than that between fluoroscopy and chest CT (Kappa ratio: 0.658, $P < 0.001$). The agreement rate was lowest between fluoroscopy and 3D-echo (Kappa ratio: 0.632, $P < 0.001$).

A different RV lead site was identified by each of the three imaging modalities in seven (13%) patients (Table 3). Among them, an identical RV lead tip position was later identified by CT and 3D-echo (4 in the free wall and 1 in the septum) for five (5/7, 71%) patients, but different results were identified by fluoroscopy. For the remaining two (2/7, 29%) patients, different lead tip positions were identified by CT and 3D-echo. In these two patients, the RV lead position was identified in the free wall by CT, but in the septum by 3D-echo. Examples of patients with the same agreement by the three types of imaging studies are shown in Figure 2, and a patient with disagreement between CT and 3D-echo is shown in Figure 3.

Discussion

In this cohort study of patients with AV block, the major findings were as follows. First, the rate of agreement in distinguishing the RV septal lead from the RV free wall lead among fluoroscopy, chest CT, and 3D-echo was substantial. Second, the rate of agreement between chest CT and 3D-echo was better than that between fluoroscopy and chest CT or 3D-echo. Third, different sites of RV leads were identified by chest CT and 3D-echo in only two (3.7%) patients. In these two patients, RV leads were identified in the free wall by chest CT, but in the septal wall by 3D-echo.

A previous study evaluated the agreement rates of pacemaker lead implantation

Table 3. Identification of the right ventricular lead tip position among the different imaging modalities.

Case no.	Age, years	Sex	Fluoroscopy	CT	3D-echo
10	95	Male	Septum	Free wall	Free wall
20	81	Female	Free wall	Free wall	Septum
24	84	Female	Septum	Free wall	Free wall
27	80	Female	Septum	Free wall	Septum
32	78	Female	Septum	Free wall	Free wall
44	78	Female	Free wall	Septum	Septum
47	63	Male	Septum	Free wall	Free wall

CT, computed tomography; 3D-echo, 3-dimensional echocardiography.

among chest X-ray, electrocardiogram, echocardiography, thoracic CT, and MRI and concluded that there was marked heterogeneity among modalities.⁶ MRI results were frequently deviated by an artifact and 3D-echo was not well developed for generating clear images, and most times, 2D-echo was relied on to identify the RV lead tip position. Therefore, CT might provide a more precise anatomical identification of RV leads than other modalities. However, there were many limitations and weaknesses in this previous study, which included the following: 1) the number of non-apical RV leads was small (only 12 patients), 2) the anteroposterior and lateral views for chest X-ray were used to evaluate the lead position rather than the LAO and RAO views, and 3) the echocardiography machine and software were old (Vivid 7 or E9; General Electric Medical Systems, Horten, Norway and EchoPAC 8.0; General Electric Medical Systems). Discrepancies between fluoroscopy and 2D-echo have also been described in some studies and 3D-echo has been proposed to be the gold standard to assess the RV lead position owing to the ability of well-defined RV geometry.^{6,16} However, some cases with suboptimal echo images were excluded in these studies and chest CT was not used as a comparator. CT images were also frequently used to define the RV lead position in previously published studies for the benefits of high

resolution and rapid acquisition time (reducing lead tip artifact).^{7-10,17} However, widespread use of CT to delineate the position of the RV lead may be limited by the requirement for intravenous contrast medium and ionizing radiation, and it is almost impossible to be used to guide lead positioning during PPM implantation. In the current study, we used ECG-gated non-contrast CT to define the position of the RV lead tip. We could not compare the accuracy in determining the position of RV lead tip between contrast-enhanced CT and non-contrast CT. However, whether contrast medium is used may not play a major role in accurate determination of the lead tip.^{18,19} ECG-gated non-contrast CT should be the first consideration for elderly people for evaluating the RV lead position to avoid the risk of contrast-induced nephropathy.^{7,18-20} Furthermore, we used a relatively new echocardiography machine and software, which can acquire real-time images from every beat and images are analyzed on-line. This process can be used to evaluate the lead position with minimal artifacts. Because of the substantial agreement between CT images and 3D-echo images in our study, 3D-echo could be used to define the tip of the RV lead position (the extended fixation helix) in clinical studies. Additionally, 3D-echo could be used to guide positioning of the RV lead during PPM implantation under sterile

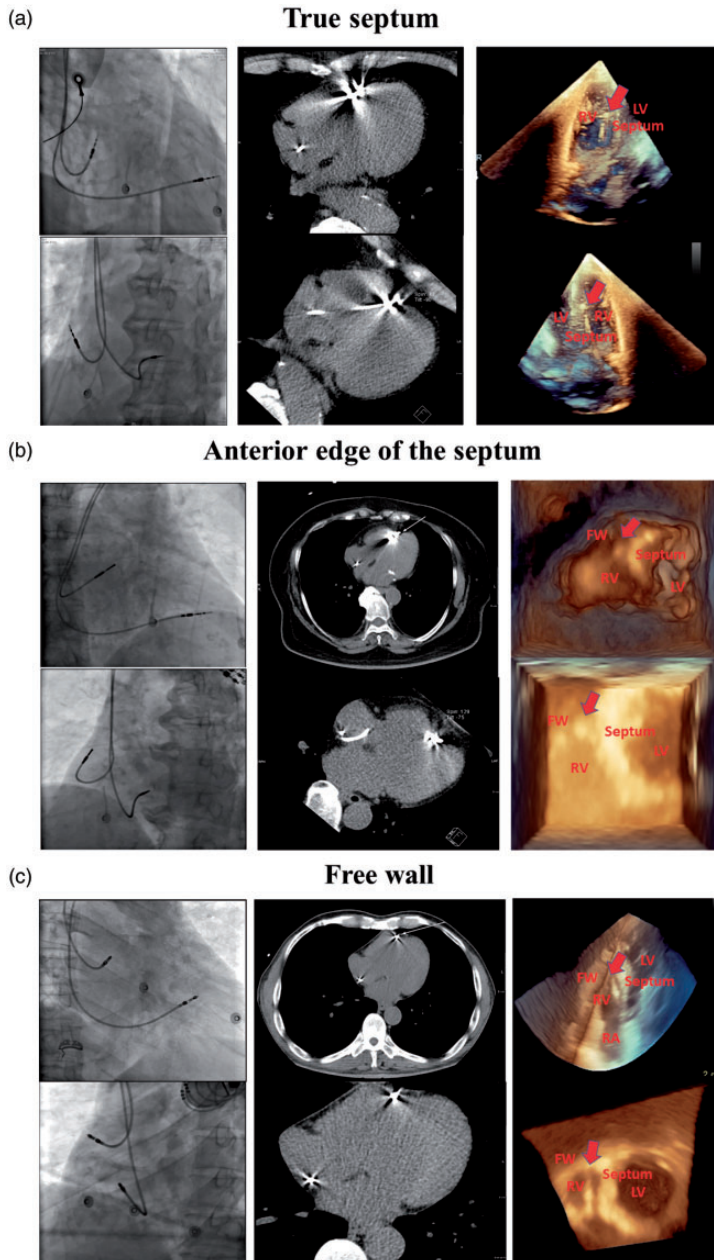


Figure 2. Cases with the same agreement of right ventricular lead position in the three types of imaging studies. Images show axial sections of fluoroscopy in 30° right anterior oblique and 50° left anterior oblique views (left panels), thoracic computed tomography (middle panels), and three-dimensional echocardiography (right panels) after pacemaker implantation. Right ventricular lead tips were located at the true septum (a), at the anterior edge of the septum (b), and at the free wall (c). Panels a and b combined comprise the septal pacing group. Arrowheads indicate the tip of the right ventricular lead. FWV, free wall; LV, left ventricle; RA, right atrium; RV, right ventricle.



Figure 3. Case with disagreement regarding RV lead position as shown by fluoroscopy, thoracic computed tomography, and three-dimensional echocardiography. In this patient, the tip of the RV lead position was identified in the free wall by thoracic computed tomography (middle panels), but in the septum by three-dimensional echocardiography (right panels). Fluoroscopic images are shown in the left panels. Arrowheads indicate the tip of the RV lead. LV, left ventricle; RV, right ventricle.

preparation, especially through the right subclavian vein approach instead of using traditional fluoroscopic images alone. A recent study also suggested that echo could be used to confirm the depth of the lead in the septum during delivery of left bundle branch block pacing leads.²¹

In this study, we used a manually adjusted stylet rather than the sheath delivery system because the stylet has shown a higher success rate of accurate RV septal site positioning.¹³ Although non-apical/septal RV pacing is considered to be better for patients than apical RV pacing, results on this issue are controversial. A meta-analysis of randomized, controlled trials failed to show a superiority for non-apical RV pacing for patients with preserved left ventricular function.²² To date, international guidelines do not specify recommendations on placement location for RV leads.²³ Further large, randomized, controlled trials are required to compare

the safety and efficacy of RV non-apical/septal and RV apical pacing.

Acquiring good images without artifacts may be difficult, especially in patients with obesity or in respiratory distress. Five patients were excluded from this study because of their history of heart failure with dilated cardiomyopathy, chest wall abnormality, emphysema, or obesity with a body mass index $>30 \text{ kg/m}^2$, and two patients had suboptimal echo images. Real-time, single beat acquisition of echocardiographic images may overcome these difficulties.

There are some limitations to this study. First, there was disagreement of the RV lead tip position between ECG-gated non-contrast CT and 3D-echo in two patients in whom the tip position was close (3–5 mm) to the septal wall. Because the time interval between the two imaging modalities was noticeably short, this disagreement was much more likely to be related to the

imaging technique rather than a displaced lead or the chance of cardiac remodeling within 1 month.²⁴ We cannot be sure which modality was correct for defining the RV lead tip position in these two cases. However, we consider that 3D-echo with a single beat echo technique under sterile preparation, rather than CT imaging, may be helpful during implantation of a pacemaker to accurately define the lead position. Second, the sample size of the study was small and this might have limited its generalizability. A well-designed prospective study on a larger scale is required to better test the outcomes of agreement among traditional fluoroscopic criteria, 3D-echo, and CT in evaluating the tip of the RV pacing lead in the non-apical position in patients with atrioventricular block receiving PPM implantation.

Conclusion

The agreement rate in evaluating the position of the septal lead between thoracic CT and 3D-echo is better than that between fluoroscopy and chest CT or 3D-echo. Three-dimensional echocardiography has the advantages of real-time image acquisition and a portable imaging tool. This method may be widely used to define the tip of the RV lead position in clinical studies and to guide positioning of the RV lead during PPM implantation instead of traditional fluoroscopic imaging alone.

Data availability

All data generated or analyzed during this study are included in this published article and its supplementary information file.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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