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CLINICAL RESEARCH
Ablation for atrial fibrillation

Repeat procedure is a new independent predictor of complications of atrial fibrillation ablation

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Aims Atrial fibrillation (AF) ablation has made huge progress with respect to innovation, efficacy, and safety, however, complications are still present. Recent studies examined various predictors of complications. However, limited data exist regarding the role of a repeat procedure. Our aim was the prospective evaluation of the incidence and predictors of complications related to AF ablation procedures in consecutive patients, including repeat procedures.

Methods and results All ablation procedures for AF between January 2013 and December 2015 were analysed in our electrophysiology laboratory. During the study period 1243 procedures were analysed [394 female, median age 62 (55–69)]. Overall complication rate was 6.84%, major complication rate was 2.82%. Major complications were the following: 18 pericardial tamponades; 5 pseudoaneurysms; 1 arteriovenous fistula; 6 thromboembolic cerebrovascular events; 3 pulmonary vein stenosis; and 2 atrioventricular blocks. No atrio-oesophageal fistula or procedure related death occurred. Univariate analysis for overall complications showed that age $\geq$ 65 years ($P = 0.0231$), female gender ($P = 0.0438$), hypertension ($P = 0.0488$), CHA_2DS_2-VASc score ≥ 2 ($P = 0.0156$), and previous AF ablation procedure ($P < 0.0001$) is associated with higher risk for adverse events. Multivariate analysis showed that the only independent predictor of overall complications was previous AF ablation procedure ($P < 0.0001$). Similarly, the only predictor of major complications was previous AF ablation procedure ($P < 0.0001$).

Conclusion Incidence of complications associated with AF ablation in our high volume electrophysiology laboratory is similar to other cohorts. The only independent predictor of complications was previous AF ablation procedure in our series.

Keywords Complication • Incidence • Predictors • Ablation • Atrial fibrillation • Repeat procedure

Introduction

Catheter ablation is an effective method for treating atrial fibrillation (AF). Nature of these procedures expose patients to a considerable number of potential complications, which can range between 1% and 8%. Most common adverse events are pericardial effusion and vascular access site complications. However, less frequent complications also need attention as they can be life threatening or may cause severe disability such as stroke or transient ischaemic attack (TIA), atrio-oesophageal fistula, phrenic nerve palsy, or pulmonary vein stenosis. The relatively high number of complications drives a continuous quest for a more effective and safer ablation approach. With newer techniques and better understanding of the underlying arrhythmia mechanisms, ablation has made impressive progress with respect to efficacy and safety. Recent studies evaluated various predictors of complications arising from AF ablation procedures. However, most of these publications are limited to initial AF ablation procedures and limited data exist regarding the role of a repeated ablation procedure.[1–8] The objective of this prospective study was to

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What's new?

- We provided the first high number prospective observational dataset that analyses the overall and major complication rate for both initial and repeat atrial fibrillation (AF) ablation procedures.
- The only independent predictor of complications was previous AF ablation procedure in our cohort.

evaluate the frequency and predictors of complications in consecutive patients undergoing initial or repeat AF ablation in our high volume electrophysiology centre.

Methods

This prospective registry aimed to describe the incidence and characteristics of complications for AF ablation at our electrophysiology laboratory. All potential complications were analysed, including cardiac tamponade, pericardial effusion, stroke or TIA, pulmonary vein stenosis, vascular access complication, phrenic nerve palsy, atrioventricular (AV) block, atrio-oesophageal fistula, and procedure-related death. Major adverse event was defined in our analysis as a complication that required interventional treatment. Therefore, pericardial effusion and groin haematoma without the need of invasive treatment were considered as minor complication. Data on the complications from all AF ablation procedures performed at our electrophysiology laboratory from January 2013 to December 2015 were prospectively collected. All patients who were enrolled to the registry gave written informed consent. The protocol was reviewed and approved by our institutional review board and was in accordance with the declarations of Helsinki.

Procedural characteristics

The indications for AF ablation procedures and periprocedural anticoagulation were in accordance with the current guidelines. In patients who were anticoagulated with vitamin K antagonist, the ablation procedure was performed if the INR value was between 1.8 and 3.5. Conscious sedation was carried out in all cases with intravenous fentanyl, midazolam, and propofol. Basic vital parameters of the patients were monitored in all cases with non-invasive blood pressure measurements every 10 min and continuous pulse oximetry. Pre-procedural left atrial computed tomography (CT) or magnetic resonance (MR) angiography was obtained to evaluate the anatomy of the pulmonary veins. Immediately before the ablation procedure the presence of a left atrial appendage thrombus was excluded with transoesophageal echocardiography or intracardiac echocardiography (ICE). Femoral venous access was used for all procedures. Transseptal puncture was performed under fluoroscopy guidance and pressure monitoring. Whenever there was difficulty to perform a safe transseptal puncture ICE was used for direct visualization of the interatrial septum. All ablations were performed with the help of an electroanatomical mapping system (either CARTO, Biosense Webster, Inc., Diamond Bar, CA, USA; or ENSITE, St. Jude Medical, Inc., MN, USA), and left atrial fast anatomical map was merged/fused with the CT/MR images to guide ablation (temperature controlled mode, 43°C, 25–35 W, irrigated 4 mm tip catheter) in the overwhelming majority of cases. In a limited number of cases we used nMARQ catheter (Biosense Webster, Irwindale, CA, USA) or cryoballoon (Artic Front Advance, Medtronic, Minneapolis, MN, USA). Pulmonary vein isolation was the goal of each initial procedure. In cases of repeat ablation for persistent AF or ablation for long-standing persistent AF additional lines might have been drawn on the discretion of the operating physician. After the procedure a pressure bandage was applied for 3–6 h to prevent bleeding of the femoral puncture site. Transthoracic echocardiography was performed right after the procedure and on the morning of the next day to detect pericardial effusion. Patients were visited by medical staff and vital parameters were checked few hours after the procedure, in the evening hours and the morning after the procedure. All patients who developed neurological symptoms were immediately transferred to the hospital's radiology unit to perform brain CT or MR scan. Whenever there was any sign of vascular access complication an ultrasound was performed to rule out major complications. All patients without complications were discharged the day after the procedure. Outpatient clinical follow-up visits were scheduled at 3, 6, 12 months after the procedure and once yearly thereafter. The follow-up visits included clinical assessment of the patient, 24 h Holter ECG monitoring and we explored whether patients have had any adverse events since the last visit and those events were also included in the analysis. In case of shortness of breath a chest X-ray was performed to rule out phrenic nerve palsy and if it was negative a cardiac CT angiography was performed to detect potential pulmonary vein stenosis.

Statistical analysis

Our registry included all patients undergoing AF ablation during the study period. In our cohort study continuous variables showed non-parametric distribution according to the Shapiro–Wilk normality test. Continuous variables are reported as median with interquartile ranges, categorical variables as event numbers (percentages). Fisher's exact test and Mann–Whitney *U* test was performed for examining contingency between selected groups. To determine predictors, multivariate analysis, logistic regression was conducted. A two-tailed *P*-value <0.05 was considered as significant. Statistical analysis was performed with GraphPad Prism, version 6.01 (GraphPad Software, Inc., La Jolla, CA, USA) and IBM SPSS Statistics, version 25 (IBM Corp., Armonk, NY, USA) softwares.

Results

Study population

During the 3-year period, overall 1243 AF ablation procedures were performed, the median age was 62 years (55–69 years) and 32% were females. Ablation for persistent or long-standing persistent AF was performed in 397 cases (32%). Baseline characteristics for the study population are shown in *Table 1*.

Incidence and outcome of complications

Most complications occurred during the same hospitalization when the ablation was performed. Certainly, PV stenoses were diagnosed only during the follow-up of the patients; and there was one case of a late pericardial effusion, diagnosed on the 15th post-procedural day. No phrenic nerve paresis, atrio-oesophageal fistula, or procedure-related death was recorded after AF ablation in this cohort. The incidence of overall and major complications are shown in *Table 2* and *Figure 1*.

The overall number of complications was 85 (6.84%). Many of these were minor complications which did not require specific treatment (28 non-significant pericardial effusions and 22 groin haematomas). The rate of major complications which necessitated interventional treatment was 2.82% (35 cases).

Eighteen pericardial tamponades occurred, of which 15 could be managed solely with percutaneous pericardiocentesis. There were

Table 1 Baseline characteristics

	Total study population ($n = 1243$)
Female	32% ($n = 394$)
Age (years)	62 (55–69)
Hypertension	70% ($n = 876$)
Diabetes mellitus	16% ($n = 197$)
Coronary artery disease	11% ($n = 140$)
Kidney disease	2% ($n = 30$)
Heart failure	4% ($n = 48$)
Dilated cardiomyopathy	4% ($n = 49$)
Hypertrophic cardiomyopathy	0.4% ($n = 5$)
Peripheral vascular disease	3% ($n = 41$)
Previous stroke/TIA	6% ($n = 75$)
Left ventricular ejection fraction (%)	57 (55–60)
CHA_2DS_2-VASc score	2 (1–3)
Previous AF ablation	18% ($n = 221$)
Persistent AF	32% (397)

AF, atrial fibrillation; TIA, transient ischaemic attack.

Table 2 Distribution of complications

Type of complication	*De novo* ablation ($n = 1022$)	Repeat procedure ($n = 221$)	Summary ($n = 1243$)
Major complications	20	15	35 (2.82%)
Pericardial tamponade	8	10	18 (1.45%)
Stroke/transient ischemic attack	5	1	6 (0.48%)
Pseudoaneurysm	4	1	5 (0.40%)
Pulmonary vein stenosis	0	3	3 (0.24%)
III degree atrioventricular block	0	2	2 (0.16%)
Arteriovenous fistula	1	0	1 (0.08%)
Phrenic nerve palsy	0	0	0
Atrio-oesophageal fistula	0	0	0
Procedure related death	0	0	0
Minor complications	33	17	50 (4.02%)
Pericardial effusion	17	11	28 (2.25%)
Groin haematoma	17	5	22 (1.77%)
Overall complications	53	32	85 (6.84%)

Left column describes complications of initial (*de novo*) ablations. Adverse events of the repeat procedures appear in the middle column, while a summary of all complications is shown on the right side (with percentages).

only three cases where surgical haematoma evacuation was necessary. Exact cause of the bleeding was not found in these cases, the suspected mechanism of the tamponade was 'per diapedesis' bleeding. The duration of hospitalization prolonged in cases complicated by pericardial tamponade to 8.5 (6.0–14.5) days. Thirteen tamponades were obvious at the end of the procedure, in other four cases it developed 2–4 h after the end of the procedure and a late tamponade occurred at the 15th postoperative day in one case. Four patients required blood transfusion. The incidence of pericardial effusion which did not require any kind of intervention was 28/1243 (2.25%), all of these patients resolved spontaneously without sequelae.

The most common major vascular complication was pseudoaneurysm in our patient population. It occurred in five cases after AF ablation. Surgical intervention or percutaneous closure with thrombin injection was necessary in all cases (5/1243, 0.4%). One arteriovenous (A-V) fistula was found and treated surgically (1/1243, 0.08%). Twenty-two groin haematomas occurred in our study population which did not require active treatment (22/1243, 1.77%). All vascular complications were diagnosed by ultrasound and in the case of A-V fistula the diagnosis was confirmed by CT angiography, as well. All complications resolved without sequelae.

There were six thromboembolic events: four strokes and two TIA-s (0.48%). One stroke was clinically evident before the patient left the operating room. Three other strokes became manifest the morning after the procedure. Immediate brain magnetic resonance imaging and neurological consultation was organized after recognizing the symptoms. All patients were treated with parenteral anticoagulants only. Neurological symptoms resolved without sequelae in all cases.

Significant pulmonary vein stenoses occurred in three cases out of 1243 AF ablations. Number of ablation procedures for the individual patients were 2, 2, and 3, respectively. First patient developed stenosis of the left inferior, right inferior, and right superior pulmonary veins. Second patient was diagnosed with left superior pulmonary vein stenosis. Third patient had stenosis of the left superior, right superior, and right inferior pulmonary veins. Successful percutaneous transluminal angioplasty of the stenotic pulmonary veins was performed in all patients.

Two patients developed III degree AV block during repeated ablation of long-standing persistent AF with additional left atrial lines. The AV block occurred during the ablation of the anterior part of the septal line. Both patient underwent successful dual-chamber pacemaker implantation.

Majority of the patients were anticoagulated with vitamin K antagonists ($n = 865$) and less patients received direct oral anticoagulants ($n = 378$). We did not find any difference in the complication rates for different anticoagulation strategies (46/865 vs. 14/378; $P = 0.2517$).

We analysed the complication rates for the three different ablation techniques that were used in our institute in the study period. For nMARQ catheter based pulmonary vein isolations one groin haematoma occurred out of 25 cases (4.0%). For cryoballoon ablations one pericardial effusion and one groin haematoma occurred out of 32 procedures (6.25%). The overall complication rate for point-by-point ablation was 82/1186 (6.91%). There was no difference between the complication rates for the abovementioned ablation techniques ($P = 0.8419$), which might result from the dominance of point-by-point ablation method and the low number of cases with single-shot device.

Procedures were performed by five different operators. The number of procedures with and without complication in case of the

Table 3 Univariate analysis for predictors of adverse events

Examined parameters	Parameter present ($n = 1243$)	Overall complications		Major complications	
		P-value	OR (95% CI)	*P*-value	OR (95% CI)
Female	394 (32%)	0.0438	1.60 (1.03–2.48)	0.4671	
Age ≥65 years	525 (42%)	0.0231	1.67 (1.07–2.60)	0.4892	
Hypertension	876 (70%)	0.0488	1.73 (1.00–2.99)	0.2609	
Diabetes mellitus	197 (16%)	0.8777		0.2426	
Coronary artery disease	140 (11%)	0.7223		0.4184	
Kidney disease	30 (2%)	0.7167		0.5799	
Heart failure	48 (4%)	0.7677		1.0000	
Dilated cardiomyopathy	49 (4%)	0.2493		1.0000	
Hypertrophic cardiomyopathy	5 (0.4%)	0.2987		0.1333	
Peripheral vascular disease	41 (3%)	0.5209		0.6265	
Previous stroke/TIA	75 (6%)	0.0922		0.0548	
LVEF	57 (55–60)	0.9640		0.3078	
LA-LD	39 (35–44)	0.7500		0.8971	
LA-TD	49 (41–55)	0.7570		0.4419	
CHA_2DS_2-VASc ≥2	752 (60%)	0.0156	1.83 (1.12–2.99)	0.1139	
Previous AF ablation	221 (18%)	<0.0001	3.10 (1.94–4.93)	0.0004	3.65 (1.84-7.25)
Ablation for persistent AF	397 (32%)	0.9041		0.0656	
Spontaneous echocontrast on TOE	138 (11%)	1.0000		0.5764	
Atypical pulmonary vein anatomy	236 (19%)	0.8858		0.8285	
Use of a contact force sensing catheter	462 (37%)	0.1030		0.5952	
Anticoagulation with VKA (vs. DOAC)	865 (70%)	0.2517		0.2754	

AF, atrial fibrillation; CI, confidence interval; DOAC, direct oral anticoagulant; LA-LD, left atrium longitudinal diameter; LA-TD, left atrium transversal diameter; LVEF, left ventricular ejection fraction; OR, odds ratio; TOE, transoesophageal echocardiography; TIA, transient ischaemic attack; VKA, vitamin K antagonist.

individual operators were 38/539, 20/382, 27/225, 0/3 and 0/9, respectively. Statistical analysis did not show significant difference between the complication rate of the operators ($P = 0.0593$).

Predictors of complications

We analysed patients' baseline characteristics and procedural characteristics to evaluate the predictors of complications (*Tables 3 and 4*). Univariate analysis for overall complications showed that age ≥65 years ($P = 0.0231$), female gender ($P = 0.0438$), hypertension ($P = 0.0488$), CHA_2DS_2-VASc score ≥2 ($P = 0.0156$), and previous AF ablation procedure ($P < 0.0001$) is associated with higher risk for adverse events. Multivariate analysis showed that the only independent predictor of overall complications was previous AF ablation procedure [odds ratio (OR) 3.13; 95% CI 1.95–5.03; $P < 0.0001$]. Similar analysis was performed to determine the predictors of major complications. According to our results, the only predictor of major complications was previous AF ablation procedure (OR 3.69; 95% CI 1.85–7.35; $P < 0.0001$).

Discussion

Main findings

Our main finding is that the only independent predictor of complications is previous AF ablation procedure. In agreement with the literature, older age, female gender and higher CHA_2DS_2-VASc score were significant predictors at the univariate level, but they were not independent predictors according to the multivariate analysis in our cohort. Recent studies reported various predictors of complications, however, most of them were derived from cohorts where only first ablation procedures were included.[2,4–14] Therefore limited data exist regarding the role and predictive value of a repeat procedure on procedural outcomes.[2,11,14]

Incidence and outcome of complications

Our prospective observational study provides an update on the incidence and predictors of complications for AF catheter ablation procedures at a high-volume centre in consecutive patients, including repeat procedures. We showed, that catheter ablation for AF in general is associated with an acceptable low risk and complications can be treated properly, as neither procedure-related death occurred, nor major complication resulted in a significant permanent sequelae in our study cohort.

Complications from AF ablations were reported in a 1995–2002 worldwide survey showing a major complication rate of 6.0%, and update from 2003 to 2006, reporting a rate of 4.5%.[4,5] Deshmukh *et al.*[6,7] reported 6.9% overall complication rate for AF in the United States, whereas 4.5% was found in the Japanese registry. Recent data from ESC-EHRA AF long-term registry reported an overall in-hospital complication rate of 7.8%.[2] In our cohort of 1243 consecutive cases, the overall complication rate for AF ablation was 6.84% and the rate of major complications

was 2.82% which supports that incidence of adverse events in our centre is within a similarly low range as reported by other authors.

The AF survey reported a 1.2% incidence, the updated survey a 1.3% incidence of cardiac tamponade, another report from the United States showed 1.5%.[4–6] In our patient population the overall incidence of pericardial tamponade was 1.45%. Previous AF surveys reported an incidence of ischaemic cerebrovascular events between 0.94% and 1.4%.[4–6] In our series, the rate of transient thromboembolic cerebrovascular events and manifest stroke was 0.48% for AF ablations and all events resolved without sequelae. Complications related to the site of vascular access are very common major complications, but generally do not lead to long-term disability or mortality. The literature reports vascular access complications ranging between 1% and 3.3% regarding AF ablations.[2,4,5,7,9,15,16] In our registry major vascular complications that required interventional treatment occurred in 0.48% which might be explained partly with the pressure bandage applied in the early postoperative period in all patients.

Table 4 Multivariate analysis for predictors of adverse events

Examined parameters	*P*-value	OR (95% CI)
Overall complications		
Female	0.3550	
Hypertension	0.1060	
Age ≥65 years	0.0900	
Previous AF ablation	<0.0001	3.18 (1.99–5.08)
Major complications		
Previous AF ablation	<0.0001	3.65 (1.84–7.24)

AF, atrial fibrillation; CI, confidence interval; OR, odds ratio.

Mortality rate of AF ablation procedures was reported to vary between 0% and 0.46%.[2,4,5,7,9,15,16] There was no procedure related death in our patient population. Neither phrenic nerve palsy, nor atrio-oesophageal fistula occurred in our series.

Predictors of complications

Recent studies identified important factors that may be independent predictors of complications after AF ablation.[17] Female gender is an independent predictor of cardiac tamponade, according to a recent meta-analysis.[13] De Greef *et al.*[10] found that female gender and higher CHA_2DS_2-VASc score predict a higher incidence of adverse events. Besides higher CHA_2DS_2-VASc score, 'early institutional experience' also increases the occurrence of complications.[12] These studies investigated only initial AF ablation procedures but repeated ablations were not considered. Similarly to these findings, univariate analysis in our study cohort showed that older age, female gender, hypertension, and higher CHA_2DS_2-VASc score is associated with higher probability of complications. However, it could not be proven that these factors are independent predictors of complications in this group of patients. Nevertheless, we have to be aware of the potentially higher risk of adverse events in these patients.

Scarce data are available regarding the role and predictive value of a repeat procedure on the incidence of adverse events. Guhl *et al.* reported 450 patients who underwent pulmonary vein isolation with cryoballoon and they did not find any factor that predicts the occurrence of complications. Although they considered repeat procedures as well, their results may arise from the low number of cases with a low absolute number of complications.[11] The EORP registry also considered repeated ablations but the aim of this paper was the description of AF ablation procedures in Europe, and therefore, no statistical analysis was performed to evaluate the predictors of success or complications.[2] Murakawa *et al.* reported the incidence and predictors of pericardial effusion in a large multicentre registry including 8319 AF ablation procedures. They showed that use of three-

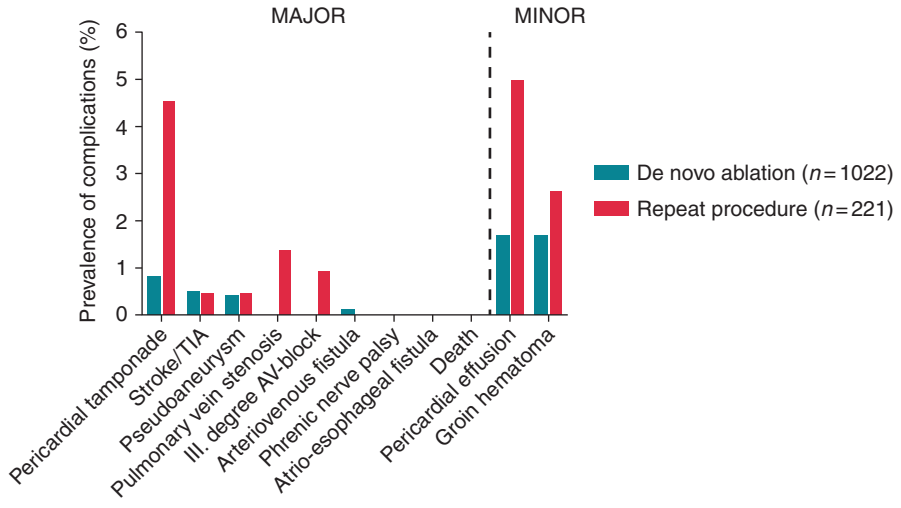

Figure 1 Distribution of complications of *de novo* ablations and repeat procedures. Major and minor complications are divided by the dashed black line.

dimensional mapping system and use of novel oral anticoagulants are independent predictors of lower incidence of pericardial effusion. Repeat ablation procedures were included in the analysis but they did not find significant difference regarding the incidence of pericardial effusion between initial and repeated ablation procedures.[14] Their statistical analysis investigated pericardial effusions only, which might be an explanation why these results does not converge with our findings.

In our cohort, previous ablation for AF was the only independent predictor of complications. Possible explanation of our finding is that in a patient with history of previous AF ablation procedure, adhesions may be present at the vascular access site that can cause difficulties when introducing the sheaths, moreover, the interatrial septum may also be thicker resulting in a more difficult transseptal puncture.[18,19] Sometimes a more extensive ablation is needed in case of repeat procedures which can expose patient to a higher risk, especially when ablating in an area with thin wall that was affected by a previous ablation session (e.g. posterior wall). Moreover, the risk of pulmonary vein stenosis is also higher in case of repeat procedures.[20] However, we also pointed out that ablation of additional lines by itself (including patients having their first procedure) is not associated with higher procedural risk.

Based on our findings heart failure, diabetes mellitus, kidney disease, peripheral vascular disease, previous stroke, type of AF, anatomical variations of the pulmonary veins did not affect the rate of adverse event. This supports that initial AF ablation procedure can be performed relatively safely in a high-volume centre even in patients with more comorbidities. However, repeated ablation for AF should be carried out with more caution. Routine monitoring of vital parameters during the procedure, non-invasive monitoring of the vital signs at wards in the early postoperative period, and control echocardiography after left atrial ablation procedures are important in terms of early recognition of complications. Certainly, avoiding complications is of high importance and with novel technological improvements the safety profile of these procedures is getting better.

Limitations

The major limitation of our registry is that it represents a single-centre experience. Our electrophysiology laboratory is a tertiary centre with a huge referral territory, which may have an important consequence: there is a possibility of missed complications from patients referred from longer distances. However, as the majority of the complications occurred in a short time period after the procedure, it is unlikely that a significant number of complications was missed.

Conclusions

The rate of minor and major complications for AF ablation in our electrophysiology laboratory is within the previously reported range. No procedure related death occurred in our cohort, due to the appropriate management of these patients. The only independent predictor of complications was previous AF ablation procedure in our series.

Conflict of interest: none declared.

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