Comparison of six risk scores for the prediction of atrial fibrillation recurrence after cryoballoon-based ablation and development of a simplified method, the 0-1-2 PL score

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Abstract

Introduction: There are several prognostic scores for the assessment of risk of atrial fibrillation (AF) recurrence post ablation procedure. However, the use of these complex scores is difficult and the validation on different populations brought divergent results. Our goal was to compare the performance of these risk scores as the basis for the development of a new, simplified score based only on few universally predictive variables.

Methods: All cryoballoon-based AF ablations performed in a single-center over a 10-year period were prospectively analyzed with regard to AF recurrence. This served to analyze the performance of APPLE, CAAP-AF, SCALE-CryoAF, MB-LATER, CHADS2, and CHA2DS2-VASc risk scores.

Results: A total of 597 patients, mostly (78.1%) with paroxysmal AF were studied. Analyzed risk scores performed poorer than in the original publications because some risk factors were not predictive of AF recurrence. A simplified score named 0-1-2 PL, composed of just two universally predictive variables, AF type (1 point for Persistent AF) and LA dimension (1 point for LA size >45 mm) was developed. The 0-1-2 PL score stratified patients into low risk (0 points), intermediate risk (1 point), and high risk categories (2 points) which were related to a 2-year risk of AF recurrence of 21%, 37%, and 55%, respectively. This score had C-statistics (0.620) higher/comparable to other investigated much more complex scores.

Conclusion: The assessment of risk of AF recurrence at the pre-ablation stage can be simplified without compromising accuracy. This could help to popularize risk assessment and standardization of AF management.

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CABG, coronary artery bypass grafting; ECG, electrocardiogram; HR, hazard ration; LA, left atrium; LAd, left atrial dimension; LV EF, left ventricular ejection fraction; LVEDd, left ventricular end-diastolic dimension; NYHA, New York heart association; PCI, percutaneous coronary intervention; PV, pulmonary vein; PVAC, pulmonary vein ablation catheter; TIA, transient ischemic attack.

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1 | INTRODUCTION

Pulmonary vein isolation with catheter based ablation was shown to be superior to antiarrhythmic drugs for atrial fibrillation (AF) treatment. Natural progression of the disease and suboptimal results of the index ablation is responsible for AF recurrence that is seen in 15%-50% of patients within the first year, with a steadily increasing percentage of recurrences in the subsequent years. It is well established that the recurrence rate of AF ablation strongly depends on the clinical profile and the stage of left atrial disease. Several predicting scores for the assessment of risk of AF recurrence were developed for better patient selection and appropriate counseling (CAAP-AF, PLAAF, SCALE-CryoAF, BASE-AF2, APPLE, MB-LATER, ALARME, ATLAS, etc). However, the use of these scores is, in our experience, rather difficult: several variables have to be remembered, perception of risk strata is not intuitive because the number of assigned points is wide (eg, 0-15 in SCALE-CryoAF) and often varies, even within a particular variable (eg, 0-4 for left atrial size in CAAP-AF). Moreover, some necessary data are difficult to obtain (eg, “abnormal PV anatomy” in PLAAF or indexed left atrial volume in ATLAS). Furthermore, the validation of these scores on different populations brought divergent results. This limits the popularity and a “real life” clinical application of these risk scores. A novel prognostic method that would be both universal, ie, based on variables predictive in various populations, and straightforward in use, is needed to help standardize AF management, patient counseling, and popularize pre-procedural risk assessment.

Our goal was to compare risk scores for AF recurrence in patients who underwent first pulmonary vein isolation procedure—as a basis to develop a novel prognostic tool, focusing on universality, and simplicity of application.

2 | METHODS

2.1 | Study population

This study enrolled consecutive patients with symptomatic paroxysmal, persistent, and long-standing persistent AF who underwent pulmonary vein isolation procedure using cryoballoon technique. On the basis of our prospectively maintained registry of all consecutive AF ablation procedures performed over a 10-year period (June 2009-September 2019), we analyzed potential clinical, biochemical, electrocardiographic, and echocardiographic predictors of AF recurrence after the first ablation. The study was approved by the institutional ethical committee and it adheres to the provisions of the Declaration of Helsinki.

2.2 | Ablation procedure

All procedures were performed by two operators (MJ or TS) using 28-mm cryoballoon (CryoCath, Medtronic). All ablation procedures were performed under conscious sedation. Single transseptal puncture using Brockenbrough needle and 8F transseptal sheath was performed under fluoroscopy using only contrast injection to confirm LA access. No prior pulmonary vein anatomy assessment was performed; if considered necessary, pulmonary vein anatomy was assessed with contrast/angiography during the procedure. A His bundle catheter and coronary sinus catheter was used to facilitate the transseptal puncture and also for phrenic nerve pacing and electrophysiological assessment of PV isolation. During the procedure, intravenous heparin was administered to achieve an activated clotting time of >350 s; measurements were performed every 30-40 minutes. The procedure generally followed published expert consensus recommendations and was described by us in detail elsewhere. Optimal vein occlusion with total contrast retention, ie, no back flow to the atrium was aimed for; when this was not possible, a “pull-down” maneuver or overlapping applications was used. On the basis of published data, freeze time was shortened from 5 minutes to 3-4 minutes for left pulmonary veins and to 2-3 minutes for the right pulmonary veins and the number of applications was decreased from 3 per vein to 1-2 per vein. Both the freeze time and the number of applications per vein were at the operator’s discretion, guided by the “time to effect,” the minimal achieved temperature, thaw time, grade of the vein occlusion, the use of “pull-down” maneuver, the perceived arrhythmogenic potential of a particular vein, etc.

2.3 | Follow-up and study endpoints

The analyzed endpoint of this study was freedom from AF recurrence. AF recurrence was defined as the first episode of AF lasting >30 s diagnosed after the blanking period of 3 months. AF had to be documented by ECG, Holter monitoring or intracardiac electrogram from the implanted device. All patients were advised to obtain an ECG each time they experienced palpitations. Holter monitoring (24-72 hours long) was scheduled after 3 and 6-9 months post-ablation and then advised once a year. Additionally, all patients received a telephone call at the time of conducting this study to ensure the accuracy of gathered data.

2.4 | Analyzed risk scores

The predictive value of several clinically important variables was analyzed including: sex, age, AF type (paroxysmal, persistent, long-standing persistent), stroke/transient ischemic attack, diabetes mellitus,
myocardial infarction, percutaneous coronary intervention / coronary artery bypass grafting, congestive heart failure, glomerular filtration rate, QRS duration >120 ms, cigarette smoking status (past, current, never), body mass index, echocardiographic left atrial dimension in parasternal M-mode, left ventricular ejection fraction, left ventricular end diastolic dimension in parasternal M-mode, AF observed within the 3-month blanking period, and presence of structural heart disease.

Some of these variables were used in various combinations and various assigned weights by others to formulate risk scores (Table 1). We analyzed the following risk scores specifically developed for prediction of AF recurrence post ablation: APPLE, CAAP-AF, SCALE-CryoAF, and MB-LATER. Moreover, the predictive value of CHADS₂ and CHA₂DS₂-VASc scores, originally developed for the prediction of the risk of stroke, but reported to be useful for predicting AF recurrence, were also analyzed. All scores were calculated as described in the original publications by authors that have introduced these methods. SCALE-CryoAF was also additionally assessed without the post-procedural data (ie, without points for “early return of atrial fibrillation”).

2.5 | Statistical analysis

Continuous variables are presented as means and standard deviations, while categorical variables are presented as numbers and percentages. The Kaplan-Meier method was used to estimate the survival functions for each endpoint. Univariate and multivariate Cox proportional hazard models were used to describe the effect of predictors on survival. All variables believed to be clinically important were pre-specified and entered into multivariate Cox proportional hazard models. Results of Cox models were presented as hazard ratios (HRs) along with tests of significance and 95% confidence intervals (CIs). There were no significant violations of the proportionality assumption that underlies the Cox proportional hazard method. Final risk score model will be based on the smallest number of variables resulting in highest value of the C-statistics. Statistical analysis was performed in R 3.2. P-values <.05 were considered statistically significant.

3 | RESULTS

3.1 | Patient characteristics

A total of 617 consecutive patients was identified who had undergone catheter-based isolation of the pulmonary veins in our center between the period of 2009 and 2019. Of these, 20 cases were excluded due to prior AF ablation in other institutions (n = 17), due to ablation performed with other technique or other causes (n = 12). Consequently, 588 patients aged 58.1 ± 10.6 years were analyzed with regard to AF recurrence after the first ablation. The 10-year observation period resulted in an average follow-up time of 28.6 months (520 571 patient-days).

Most of the patients had paroxysmal atrial fibrillation (78.1%), were overweight or obese (83.1%), and/or had some comorbidities

### TABLE 1  Risk factors included in the scoring systems analyzed in the current study

|                    | APPLE | CAAP-AF | SCALE-CryoAF | MB-LATER | 0-1-2 PL | CHADS₂ | CHA₂DS₂-VASc |
|--------------------|-------|---------|--------------|----------|----------|--------|--------------|
| Age                | 1     | 1-3     |              |          |          | 1      | 1-2          |
| Sex                | 1     | 1       |              | 1        |          |        |              |
| Atrial fibrillation type | 1     | 2       | 3            | 1-2      | 1        |        |              |
| Left atrial dimension | 1     | 1-4     | 1            | 1        | 1        |        |              |
| Early recurrence   | 4     |         |              |          |          |        |              |
| Hypertension       |       |         |              | 1        | 1        |        |              |
| Coronary artery disease | 1     | 3       |              |          |          |        |              |
| Diabetes mellitus  | 1     |         |              |          |          | 1      | 1            |
| Chronic kidney disease | 1     |         |              |          |          |        |              |
| Stroke/TIA         |       |         |              | 2        | 2        |        |              |
| Antiarrhythmic drugs failure | 1     |         |              | 1-2      |          |        |              |
| Vascular disease   |       |         |              |          |          |        | 1            |
| Bundle branch block | 1     |         |              |          |          |        |              |
| Left ventricular EF | 1     |         |              |          |          |        |              |
| Chronic heart failure | 1     |         |              |          |          | 1      | 1            |
| Structural heart disease* | 1     |         |              |          |          |        |              |

Abbreviations: EF, ejection fraction; TIA, transient ischemic attack.

*Including cardiomyopathy and severe valvular disease.
(84%). Detailed baseline clinical characteristics of this cohort are presented in Table 2.

All studied patients underwent cryoballoon (Arctic Front 28 mm, Medtronic)-based ablation. On average, there were 3.7 (±2.3) days of Holter ECG monitoring per patient; additionally, 36 patients had data available from the implanted device capable of AF detection. During the blanking period, AF was observed in 72 (12.2%) patients. AF recurrence, after the 3-month blanking period, was observed in 191 (32.5%) patients.

### 3.2 | Predictors of AF recurrence

Several variables in univariate analysis showed predictive value (Table 3). Predictors with the highest hazard ratio were: early recurrence, persistent/long-standing persistent AF and left atrial dimension, followed by hypertension, stroke, body mass index, and left ventricular ejection fraction. Kaplan-Meier AF free survival curves with regard to the strongest pre-procedural predictors in univariate analysis are presented in Figure 1 and Figure S1. In multivariate analysis, (Table 4) independent predictors of AF recurrence were left atrial diameter, AF type, stroke, and AF episodes within the blanking period.

### 3.3 | Comparison of risk scores

All scores were the predictive of AF recurrence (Figure 2), each additional point in a particular score increased risk (HR of 1.17-1.49 per point). CHADS$_2$ and CHA$_2$DS$_2$-VASc scores were less predictive than scores specifically designed for AF recurrence prediction. Of these, the SCALE-CryoAF score had the highest predictive value with C-statistics of 0.640 (Table 5). When SCALE-CryoAF was assessed on the basis of pre-procedural data, (ie, without points for AF recurrence during the blanking period) the C-statistics of this score was lower - 0.601. A simplified, novel score named 0-1-2 PL composed of only two variables, AF type (Persistent vs paroxysmal) and Left atrial dimension > 45 mm—and each assigned 1 point was developed and assessed. This score stratified patients into three categories of 0, 1

### TABLE 2 Baseline patient characteristics (n = 588)

| Parameters                                      | Value     |
|-------------------------------------------------|-----------|
| Age (years)                                     | 58.1 ± 10.6 |
| Male gender                                     | 382 (65.0%) |
| BMI (kg/m$^2$)                                  | 29.1 ± 4.3 |
| AF type                                         |           |
| Paroxysmal                                      | 460 (78.2%) |
| Persistent                                      | 102 (17.3%) |
| Long-standing persistent                        | 26 (4.4%)  |
| Duration of AF history (months)                 | 59.6 ± 70.3 |
| Number of failed antiarrhythmic drugs           | 1.5 ± 0.9  |
| Current/past smoker                             | 171 (29.1%)/38 (6.5%) |
| Comorbidities                                   |           |
| Hypertension                                    | 390 (66.4%) |
| Diabetes mellitus                               | 75 (12.8%) |
| Coronary heart disease                          | 60 (10.2%) |
| Heart failure                                   | 27 (4.6%)  |
| Structural heart disease$^a$                     | 50 (8.5%)  |
| Stroke/TIA                                      | 53 (9.0%)  |
| CHA$_2$DS$_2$-VASc score                        | 1.8 ± 1.3  |
| eGFR < 60 mL/min/1.73m$^2$                      | 63 (10.7%) |
| Echocardiography                                |           |
| Left atrial dimension (mm)                      | 42.8 ± 5.7 |
| Left ventricular ejection fraction (%)          | 60.4 ± 8.6 |
| Left ventricular end-diastolic dimension (mm)   | 50.1 ± 5.6 |

Abbreviations: AF, atrial fibrillation; BMI, body mass index; eGFR, estimated glomerular filtration rate; TIA, transient ischemic attack.

$^a$Defined as cardiomyopathy or artificial valve or severe valvular disease or left ventricular ejection fraction <50%.

### TABLE 3 Predictors of AF recurrence in univariate analysis

| Predictor                  | HR      | CI      | P-value | C-statistics |
|----------------------------|---------|---------|---------|--------------|
| Male sex                   | 0.91    | 0.68; 1.21 | .506 | 0.505 |
| Age per 10 years           | 1.16    | 1.01; 1.34 | .033 | 0.525 |
| BMI per 10                  | 1.44    | 1.05; 1.97 | .025 | 0.550 |
| Current smoker             | 1.06    | 0.77; 1.45 | .730 | 0.512 |
| Past smoker                | 0.90    | 0.47; 1.71 | .737 | 0.512 |
| Hypertension               | 1.42    | 1.04; 1.94 | .029 | 0.533 |
| Stroke                     | 1.56    | 1.04; 2.33 | .032 | 0.521 |
| Diabetes mellitus          | 1.47    | 1.00; 2.16 | .050 | 0.521 |
| Myocardial infarction       | 1.37    | 0.78; 2.41 | .272 | 0.510 |
| PCI / CABG                 | 1.19    | 0.74; 1.91 | .479 | 0.506 |
| NYHA class >2              | 1.76    | 0.98; 3.15 | .060 | 0.517 |
| Structural heart disease   | 1.22    | 0.74; 2.01 | .434 | 0.508 |
| eGFR < 60 mL/min/1.73m$^2$ | 1.24    | 0.79; 1.93 | .350 | 0.507 |
| AF during blanking          | 3.05    | 2.19; 4.24 | .000 | 0.585 |
| Persistent AF              | 2.02    | 1.45; 2.80 | .000 | 0.578 |
| Long persistent AF         | 2.27    | 1.28; 4.03 | .005 | 0.578 |
| LAd per 10 mm              | 1.66    | 1.36; 2.03 | .000 | 0.622 |
| LV EF per 10%              | 0.98    | 0.97; 1.00 | .018 | 0.552 |
| LV EDD per 10 mm           | 1.25    | 0.97; 1.62 | .080 | 0.531 |
| MI per 1 grade             | 1.29    | 1.08; 1.54 | .004 | 0.559 |
| QRS > 120 ms               | 1.12    | 0.65; 1.92 | .694 | 0.498 |

Abbreviations: AF, atrial fibrillation; BMI, body mass index; CABG, coronary artery bypass grafting; LAd, left atrial dimension; LV EF, left ventricular ejection fraction; LV EDD, left ventricular end-diastolic dimension; MI, mitral insufficiency; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.
or 2 points, each corresponding to a distinctly different risk strata in Kaplan-Meier analysis (Figure 3). The C-statistics of 0-1-2 PL score was higher/comparable to C-statistics of any other score based on pre-ablation data (Table 5).

The data that support the findings of this study are available from the corresponding author on reasonable request.

4 | DISCUSSION

In this study, we analyzed the predictors of AF recurrence post pulmonary vein isolation in a sizable cohort of patients with a long follow-up. The main findings of our study were that for the pre-ablation assessment of risk of AF recurrence, the novel 0-1-2 PL score

FIGURE 1 The Kaplan-Meier AF-free survival curve after AF ablation with regard to the strongest preprocedural predictors in univariate analysis. AF, atrial fibrillation; LA, left atrium; BMI, body mass index; LV EF, left ventricular ejection fraction
performed better than SCALE Cryo-AF, APPLE, CAAP-AF, MB-LATER, CHADS\textsubscript{2} and CHA\textsubscript{2}DS\textsubscript{2}-VASc scores. When post-ablation data were employed, the SCALE Cryo-AF was the best method to predict AF recurrence, followed closely by the much simpler 0-1-2 PL score.

Studies that analyzed the predictors of AF recurrence provided divergent results with regard to several variables. For example, smoking status reported by Canpolat et al as an important predictor divergent results with regard to several variables. For example, smoking status reported by Canpolat et al as an important predictor of AF recurrence was found to be nonsignificant by Bavishi et al,\textsuperscript{8,10} and also by us in the current study; most of the components of the PLAAF score were nonsignificant in other studies.\textsuperscript{10} These contradictory results are reflected in the choice of variables included in various risk scores, eg, in the CAAP-AF and PLAAF, female sex was related to an increased risk of AF recurrence while in the MB-LATER, it was the male sex that was related to increased risk.\textsuperscript{6-6} Table 2 shows that variables used in one risk score are seldom used by other scores. For example, chronic kidney disease used in APPLE is not used by SCALE Cryo-AF, CAAP-AF or MB-LATER.\textsuperscript{1,2,4,6} While QRS duration >120 ms, exploited by MB-LATER and SCALE Cryo-AF, is ignored by other scores. This raises the question if variables used in these risk scores are the universal predictors of risk of AF recurrence or rather subject to some local bias, methodological nuances, length of follow-up, population differences, AF ablation technique or even chance findings. The lack of universality of these variables probably explains the weaker performance of risk scores when original studies, that introduced these scores, are compared with independent validation studies that analyzed these scores later. For example, the MB-LATER boasted area under the curve in receiving operator characteristic analysis of 0.782 while in another large study, on different population it was only 0.575, (similar to our result for this score).\textsuperscript{4,10}

This obvious limitation of the risk scores, uncertainty which one should be used and a broad spectrum of variables that have to be assessed/obtained together with a plethora of corresponding non-intuitive risk strata lowers the popularity and clinical application of these methods. Moreover, some of these scores use variables that are obtainable only after the ablation procedure (eg, occurrence of AF during 3-month post-ablation blanking period included in SCALE-CryoAF) limiting their use of the pre-ablation stage for patient selection, counseling or the modification of ablation technique.

### TABLE 4 Predictors of AF recurrence in multivariate analysis

| Predictor             | HR    | CI     | P-value | C-statistics |
|-----------------------|-------|--------|---------|--------------|
| Age per 10 years      | 1.24  | 1.07; 1.44 | .004   | 0.650\textsuperscript{a} |
| LA diameter per 10 mm | 1.64  | 1.30; 2.05 | .000   | -            |
| Stroke/TIA            | 1.94  | 1.28; 2.95 | .002   | -            |
| Persistent AF         | 1.86  | 1.33; 2.60 | .000   | -            |
| Long persistent AF    | 2.48  | 1.39; 4.43 | .002   | -            |

\textsuperscript{a}C-statistics value for the whole model.

### 4.1 Development and performance of 0-1-2 PL score

The above considerations have directed us to develop a prediction model that would be simple in application (maximum of 2-3 variables), easy to remember (only 0/1 point per variable), and based on factors that are both universal (widely accepted and validated by several studies) and easily available before ablation. There is high consistency of data with regard to the type of AF, left atrial size, and reduced left ventricular ejection fraction as potent risk factors which suggests that these might be universal predictors, less influenced by local population, ablation technique or length of follow-up. The success rate of patients with persistent atrial fibrillation in the present study was very similar like in other recent studies that investigated the usefulness of cryoballoon ablation in such patients.\textsuperscript{15,16} Since the left atrial dimension and AF type were the only variables that were included in all other AF recurrence risk scores, had the highest C-statistics in univariate analysis, and inclusion of other variables (age, stroke) increased C-statistics only marginally, we decided to base the novel risk score on just these two variables. A cut-off point of 45 mm for the left atrial dimension was selected on the basis of Kaplan-Meir analysis. This value was between the cut-off of 43 mm used by APPLE and SCALE-CryoAF scores and 47 mm used by MB-LATER.\textsuperscript{1,4} To underline the simplicity of application, we named this novel method 0-1-2 PL score for the two variables (P for Persistent AF and L for Left atrial dimension >45 mm) and for the three risk strata into which it categorizes patients: 0, 1 and 2. Kaplan-Meir analysis confirmed that this score stratified patients into low risk category (0 points), intermediate risk category (1 point, ie, either persistent AF present or LA was >45 mm), and high risk category (2 points); see Figure 3. These categories were related to a 2-year risk of AF recurrence of 21%, 37%, and 55%, respectively, which correspond well with the current clinical perception of low, intermediate, and high risk of AF recurrence post pulmonary vein isolation. Interestingly, the C-statistics of the 0-1-2 PL score (Table 5) was higher than C-statistics of any other scores based on pre-ablation data including the scores that exploited the same variables: a left atrial dimension and AF type. We believe that this supports our concept that some variables are not universal risk factors and that incorporating them into a risk score not only increases the score complexity but also can lower the accuracy when the score is used by others. Although the SCALE-CryoAF score had higher C-statistics than the 0-1-2 PL score, it included “early AF recurrence”—a variable closely connected to what this score intends to predict. AF recurrence during the first three months is partially the same as AF recurrence during later periods as the 3-month cut-off is arbitrary, and probably too long when cryoablation outcomes are assessed.\textsuperscript{17} Therefore, this variable can be considered a kind of predicting recurrence on the basis of recurrence, a kind of glimpse into the future to predict future. Since the main application of scores is balancing indications and expected outcomes for pre-ablation counseling, patient selection, and choice of ablation strategy (more extensive ablation), we have concentrated on scores that can be used at the pre-ablation stage. Although SCALE-CryoAF uses one post-ablation risk factor, it was suggested in the original
publication that this score can still be also applied at the pre-ablation stage by calculating the score without the “early return of atrial fibrillation” variable. However, the predictive power of such a new prognostic model was not provided by its authors. In our current assessment, the C-statistics of SCALE-CryoAF when eliminated of this potent risk factor was not impressive, lower than predictive power of the straightforward 0-1-2 PL score.

4.2 Limitations

This was a single-center observational study with related potential referral and treatment bias and ablation method was limited to the cryoballoon technique. It is necessary to validate our results with multicenter data analysis including patients treated with radiofrequency current ablation. However, since the 0-1-2 PL score was based on

**FIGURE 2** The Kaplan-Meier AF-free survival curves after AF ablation with regard to the results of risk scores. AF, atrial fibrillation
variables that are known to perform well in various settings/studies, and the ablation endpoint was universal (PVI isolation) it is unlikely that the results in other centers/populations would be much different.

Since arrhythmia recurrences can be asymptomatic and periodic ECG monitoring is far from perfect, undoubtedly we missed some episodes of asymptomatic AF. However, since AF ablation is performed mainly for symptom control and asymptomatic episodes are likely to be distributed equally in all three score strata, this should not influence the clinical application of the 0-1-2 PL score nor the conclusions of our study.

5 | CONCLUSIONS

This study suggests that despite the significant differences between risk scores in terms of the choice of risk factors and the relative weights assigned to them, their performance for pre-ablation risk assessment is quite similar and weaker than originally reported. It seems that the assessment of risk of AF recurrence at the pre-ablation stage can be simplified by the novel 0-1-2 PL score instead of more complex methods. This would help in popularizing pre-ablation risk assessment as well as facilitate the standardization of AF management.

CONFLICT OF INTEREST

Dr Jastrzębski declares consulting fees from Medtronic; other authors declare no conflicts of interest.

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SUPPORTING INFORMATION
Additional Supporting Information may be found online in the Supporting Information section.

How to cite this article: Jastrzębski M, Kielbasa G, Fijorek K, et al. Comparison of six risk scores for the prediction of atrial fibrillation recurrence after cryoballoon-based ablation and development of a simplified method, the 0-1-2 PL score. J Arrhythmia. 2021;00:1–9. https://doi.org/10.1002/joa3.12557