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Device Size/Septal Length as Predictors of Atrial Fibrillation After Percutaneous ASD Closure: 15-Year Follow-Up

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SOUHRN

Kontext: Ze sledování pacientů po perkutánním uzávěru defektu síňového septa (atrial septal defect, ASD) je známo, že dochází ke vzniku fibrilace síní (FS). Primárním cílem naší studie bylo zkoumat vznik a prediktory vzniku FS při dlouhodobém sledování pacientů po uzavření ASD.
Metody: Do studie bylo zařazeno 56 pacientů, u nichž byl mezi lety 2008 a 2010 na našem pracovišti proveden perkutánní uzávěr ASD. Sledovaná populace byla rozdělena do dvou skupin: s diagnózou FS a bez této diagnózy.
Výsledky: Ke vzniku FS došlo u 13 pacientů (dva muži, 11 žen; věk 41,02 ± 7,02 roku; ejekční frakce levé komory [EF LK] 62,39 ± 8,32 %); u 43 pacientů ke vzniku FS nedošlo (sedm mužů, 36 žen; věk 39,55 ± 9,26 roku; EF LK 64,76 ± 8,08 %). Regresní analýza prokázala, že nezávislým prediktorem vzniku FS je dlouhodobě pouze poměr velikosti okluderu a celkové délka septa.
Závěry: Podle této studie byl se vznikem FS v dlouhodobém horizontu spojen vyšší poměr velikosti okluderu a celkové délky septa. Doporučujeme, aby k uzavření defektu používali operatéři co nejmenší okludery.

Keywords:
Atrial fibrillation
Atrial septal defect
Device size/total septum length

ABSTRACT

Background: Atrial fibrillation (AF) is known to develop during the follow-up of patients who have undergone percutaneous atrial septal defect (ASD) closure. The primary aim of our study was to investigate the development and predictors of AF in the long-term follow-up of patients after ASD closure.
Methods: Fifty-six patients who underwent percutaneous ASD closure at our center between 2008 and 2010 were included in the study. The study population was divided into two groups: patients with and those without an AF diagnosis.
Result: There were 13 patients with AF (two males, 11 females; age = 41.02 ± 7.02 years; left ventricle ejection fraction [LVEF] = 62.39 ± 8.32%) and 43 patients without AF (seven males, 36 females; age = 39.55 ± 9.26 years; LVEF = 64.76 ± 8.08%). In regression analysis, only the device size/total septum length ratio was found to be an independent predictor of long-term AF development.
Conclusions: This study revealed that an increased device size/total septum length ratio was associated with the development of AF in the long term. We recommend that operators use the smallest size closure device that adequately covers the defect.

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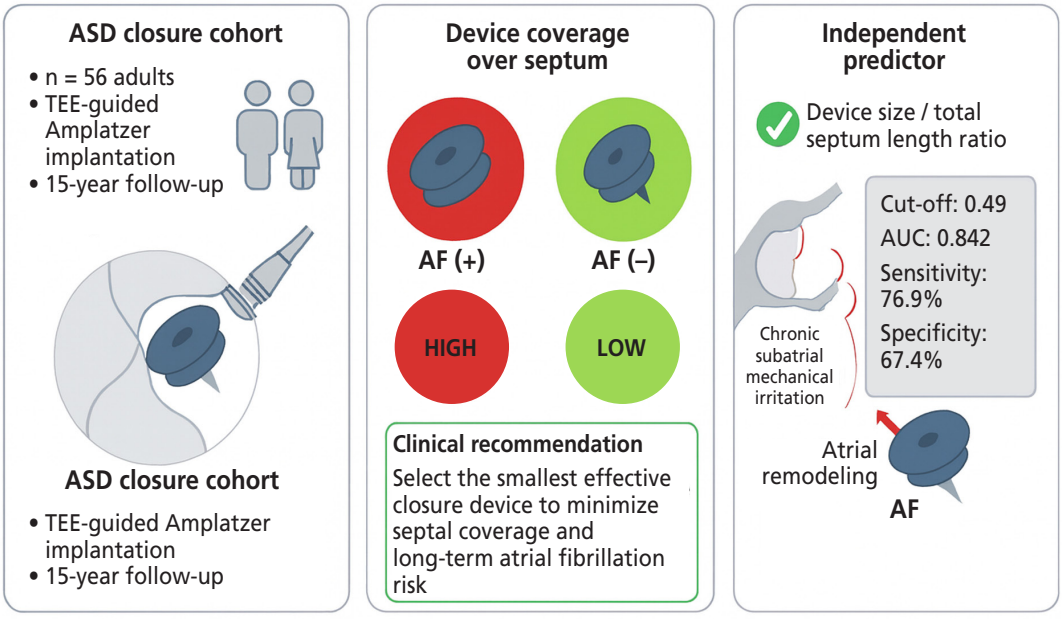
OVERSIZING OF SEPTAL OCCLUDER DEVICES PREDICTS LONG-TERM ATRIAL FIBRILLATION ASD CLOSURE



WHAT'S NEW?

- In patients with atrial septal defect (ASD), several echocardiographic parameters—including A-wave velocity, left ventricular ejection fraction, left atrial diameter, and ASD size—were significantly associated with long-term atrial fibrillation (AF) development.
- In addition to previous literature, our study demonstrated that the ratio of closure device diameter to total septal length is an independent predictor of late AF after transcatheter ASD closure.
- During long-term follow-up, pre-closure factors lost prognostic value, whereas the extent of interatrial septal coverage by the device became crucial. Therefore, operators should choose the smallest device ensuring complete closure to minimize AF risk.

Introduction

Atrial septal defect (ASD) is the most common congenital heart disease diagnosed in adults and is treated by interventional cardiologists.[1] Today, percutaneous closure is widely used and successfully used in line with current guidelines and under appropriate indications.[2] With increasing operator experience and newly developed devices, complications during percutaneous closure and in the acute phase are now more easily managed.[3] However, the long-term effects of these devices are still being investigated in current studies and meta-analyses.[4] The fact that these ASD closure devices remain in mechanical contact with the atria for an extended period suggests that they may predict the development of atrial arrhythmia in the long term, which has also been a main topic of research.[5] As the frequency of percutaneous ASD closure procedures continues to grow, identifying the development of AF and predicting which patients may develop it constitute important research topics. Some studies have demonstrated predictive parameters for AF based on follow-up duration, advanced age, or type of closure device.[6] Although the presence of an ASD with a clinically significant shunt size has been found to be a predictor for AF development,[3] some studies have reported that closure device size is not a predictor for AF development.[7]

Our hypothesis is that selecting the smallest device that can cover the patient's ASD may provide more effective protection against AF. Therefore, we calculated the device length/total septum length ratio, which was previously studied in a pediatric patient group.[8] In this study, we examined the average 15-year follow-up of patients who underwent percutaneous ASD closure in our clinic. We investigated the frequency of AF and echocardiographic and procedural technique-related factors, such as the device size/total septum length ratio, which would predict AF.

Material and methods

Study design and population

In this single-center, cross-sectional, retrospective study, patients who underwent percutaneous ASD closure in our center between 2008 and 2010 were reviewed, and 70 patients were identified. The baseline demographic data, echocardiography and 12-lead electrocardiogram findings, and anticoagulant use history of the patients were retrieved from the hospital information system. Twelve patients whose follow-up data within the last three months were not available and two patients with AF detected on their baseline electrocardiogram were excluded from the study. The remaining 56 patients were included in the

study and divided into two groups: those who developed AF and those who did not. To investigate the presence of AF, patients' ECGs from the past 3 months were reviewed, and AF was considered present if detected. For patients whose ECGs did not reveal AF, their Holter monitoring from the past 3 months was reviewed, if available. If Holter monitoring was not available, patients were called for a follow-up appointment, and the presence or absence of AF was determined based on 24-hour Holter monitoring. The study protocol was approved by the local ethics committee in accordance with the Declaration of Helsinki and good clinical practice guidelines.

Echocardiographic evaluation

Echocardiographic examinations were performed using the Philips IE33 system (Philips Medical Systems, Andover, MA, USA). Left ventricular ejection fraction (LVEF) was calculated using the Simpson biplane method. Measurements of the left atrial diameter, left ventricular end-diastolic diameter (LVEDD), left ventricular end-systolic diameter (LVESD), interventricular septal thickness, and posterior wall thickness were obtained from the parasternal long-axis view.

In the apical four-chamber view, the right atrial diameter, right ventricular basal diameter (RV-BD), and total septum length were measured. Mitral early diastolic filling velocity (E wave), late diastolic filling velocity (A wave), and the mitral annular early diastolic velocity (E′ wave) obtained from the lateral mitral annulus using tissue Doppler imaging were recorded. Tricuspid annular plane systolic excursion (TAPSE) was measured using M-mode at the junction of the right ventricular lateral wall and the tricuspid annulus.

The right ventricular outflow tract (RVOT) diameter and RVOT velocity-time integral (RVOT-VTI) were measured in the parasternal short-axis view, whereas the left ventricular outflow tract (LVOT) diameter was measured in the parasternal long-axis view. The LVOT velocity-time integral (LVOT-VTI) was obtained from the apical five-chamber view using pulsed-wave Doppler. The Qp/Qs ratio was calculated using the following formula: Qp = RVOT VTI × ϖ × (RVOT diameter/2)², Qs = LVOT VTI × ϖ × (LVOT diameter/2).² It was obtained by dividing Qp by Qs. Systolic pulmonary artery pressure (PAP) was calculated by adding estimated right atrial pressure to the pressure measurement taken with continuous wave Doppler over the tricuspid valve in the apical four-chamber view. ASD width was measured at three different angles via transesophageal echocardiography, with the largest measurement recorded. All echocardiograms followed the recommendations of the American Society of Echocardiography.

Reproducibility

Intraobserver variability was assessed by repeating all measurements on separate occasions. Interobserver variability was assessed by having a second observer, blinded to the clinical data and initial echocardiographic results, repeat the measurements (M.G.Y).

Device information

All patients were treated under conscious sedation in the catheterization laboratory under the guidance of transesophageal echocardiography. An appropriately sized Amplatzer septal occluder device (AGA Medical Corp., Golden Valley, MN, USA) was implanted in the interatrial septum using a femoral access system. When selecting device dimensions, transesophageal echocardiography was performed, and ASD balloon sizing was also done during the procedure, supported by echocardiographic measurements.

Statistical analysis

Statistical analyses were performed using SPSS version 20.0 for Windows (SPSS Inc., Chicago, IL, USA). The Kolmogorov–Smirnov test and homogeneity of variances tests were performed to examine parametric and non-parametric data distributions. The independent-samples t-test was used to compare two groups in terms of variables showing parametric distribution, and the Mann–Whitney U test was used to compare two groups in terms of variables that did not show a parametric distribution. Categorical variables were compared using the chi-square test. Univariable and multivariable logistic regression analyses were undertaken to determine predictive parameters of AF development. Receiver operating characteristic (ROC) analysis was used to determine the cut-off levels of the device size/total septum length ratio for predicting AF development. A *p*-value of <0.05 was considered statistically significant.

Results

The study included a total of 56 patients with a follow-up period of 15 (range: 14–16) years. Thirteen patients developed AF, resulting in an incidence of 23.2%. The patients were divided into two groups: those with and those without AF (of the 13 patients, 5 continued to have sinus rhythm after one paroxysmal AF attack; 4 patients were started on amiodarone for rhythm control due to recurrent paroxysmal AF attacks. Sinus rhythm was achieved in 2 patients after electrical cardioversion due to persistent AF. Two patients were diagnosed with permanent AF.) **Table 1** presents the comparison of the demographic data and baseline echocardiographic parameters between the two groups. Significant differences were found between the

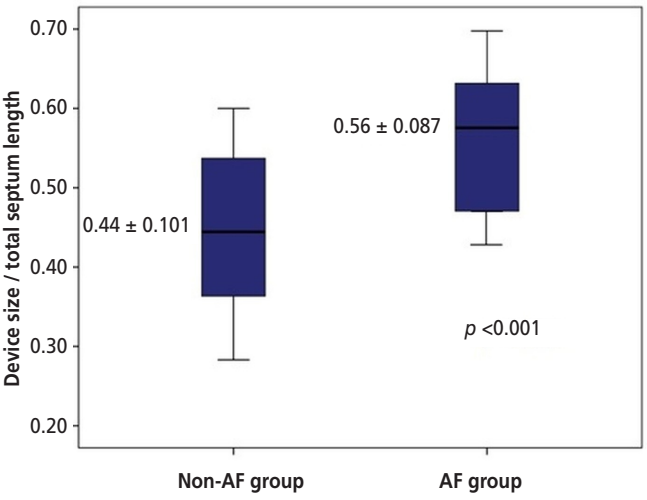


Fig. 1 – Relationship between the device size / total septum length ratio and the development of atrial fibrillation.

Table 1 – Clinical, echocardiographic, and implantable device characteristics of the study population

	AF group n = 13	Non-AF group n = 43	*p*-value
Age (years)	41.02 ± 7.02	39.55 ± 9.26	0.795
Gender (M/F)	2 / 11	7 / 36	0.655
HT (n)	2 (15.8%)	3 (6.9%)	0.580
DM (n)	1 (7.7%)	2 (4.65%)	0.555
CAD (n)	1 (7.7%)	2 (4.65%)	0.555
CVA (n)	0 (–)	0 (–)	–
LVEF (%)	62.39 ± 8.32	64.76 ± 8.08	0.180
LV-EDD (mm)	43.35 ± 7.44	42.38 ± 4.85	0.660
LV-ESD (mm)	27.43 ± 5.53	25.53 ± 4.62	0.250
LA (mm)	36.69 ± 5.41	33.44 ± 5.68	0.073
RA (mm)	45.84 ± 7.18	42.57 ± 8.10	0.197
RV – BD (mm)	42.38 ± 8.66	39.89 ± 7.12	0.137
IVS (mm)	9 (7.5–13)	9 (8–14)	0.298
PW (mm)	9 (7–13)	9 (7–12)	0.383
E wave (cm/s)	67 (50–125)	80 (45–120)	0.655
A wave (cm/s)	64 (40–83)	76 (43–104)	**0.018**
E' wave (cm/s)	16 ± 6.92	12.02 ± 4.79	0.052
sPAP (mmHg)	36.61 ± 5.31	34.88 ± 7.58	**0.009**
TAPSE (mm)	3.03 ± 0.44	2.91 ± 0.55	0.577
Qp/Qs	3.66 ± 1.21	3.03 ± 1.03	0.069
ASD size on TEE (mm)	23.41 ± 4.25	17.32 ± 5.97	**0.001**
Total septum length (mm)	50.33 ± 6.48	49.75 ± 6.61	0.781
Device size (mm)	28.30 ±5.40	22.12 ± 5.75	**0.001**
Device size / total septum length ratio	0.56 ± 0.087	0.44 ± 0.101	**<0.001**

A wave – late diastolic wave; CAD – coronary artery disease; CVA – cerebrovascular accident; DM – diabetes mellitus; E' – early diastolic myocardial velocity; E wave – early diastolic wave; HT – hypertension; IVS – interventricular septum; LA – left atrium, LV-EDD – left ventricular end-diastolic diameter; LVEF – left ventricular ejection fraction; LV-ESD – left ventricular end-systolic diameter; PW – posterior wall; Qp/Qs – ratio between pulmonary and systemic flow; RA – right atrium; RV-BD – right ventricle basal diameter; S' – tricuspid lateral wall annular systolic velocity; sPAP – systolic pulmonary artery pressure; TEE – transesophageal echocardiography.

Table 2 – Results of univariate and multivariate regression analyses showing the relationship between AF development and investigated parameters

	Univariable			Multivariable		
Variables	**OR**	**95% CI**	***p***	**OR**	**95% CI**	***p***
A wave (cm/sec)	0.014	0.001–0.655	**0.030**	0.020	0.004–9.471	0.073
LVEF (%)	1.094	1.010–1.185	**0.027**	1.066	0.917–1.239	0.404
LA (mm)	1.117	0.986–1.264	0.081	1.896	0.983–3.657	0.056
ASD size (mm)	1.235	1.066–1.430	**0.005**	0.739	0.469–1.666	0.194
Device size (mm)	1.218	1.062–1.396	**0.005**	0.885	0.582–1.344	0.565
Device size/total septum length ratio	1.028	1.014–1.072	**0.002**	1.066	1.010–1.112	**0.039**

AF – atrial fibrillation; ASD – atrial septal defect; A wave – late diastolic wave; CI – confidence interval; LA – left atrium; LVEF – left ventricular ejection fraction; OR – odds ratio.

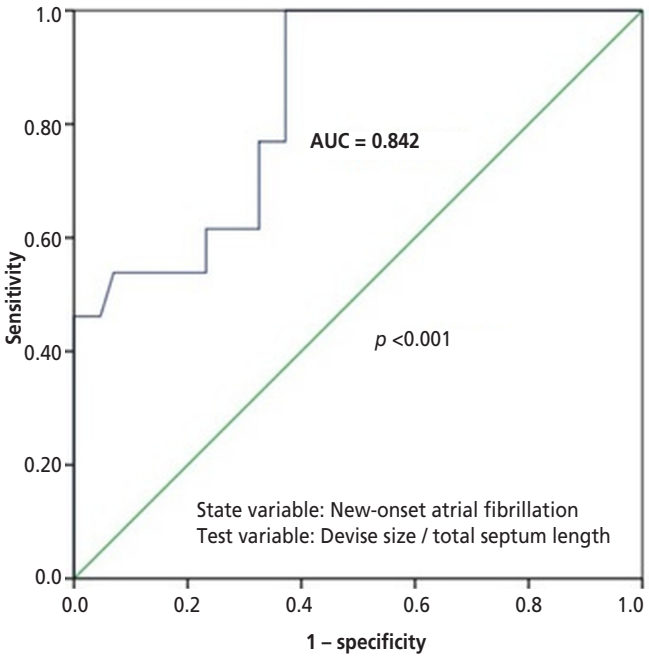


Fig. 2 – Receiver operating characteristic curve of the device size / total septum length ratio for predicting AF development.

groups in terms of A wave (p = 0.018), sPAP (p = 0.009), ASD size measured by transesophageal echocardiography (p = 0.001), device size (p = 0.001), and the device size/total septum length ratio (p <0.001; **Fig. 1**).

In regression analysis performed to determine the predictors of AF development during the 15-year follow-up, the A wave, LVEF, LA, ASD size, device size, and the device size/total septum length ratio were identified as dependent predictors in the univariable regression analysis (**Table 2**). According to the multivariable regression analysis, only the device size/total septum length ratio was an independent predictor. Receiver operating characteristic (ROC) analysis showed that the optimal cut-off value of the device size/total septum length ratio was 0.49 (area under the curve: 0.842, 95% confidence interval: 0.729–0.954, p <0.001; **Fig. 2**), with a sensitivity of 76.9% and a specificity of 67.4%.

During the annual follow-up, coronary artery disease was detected in one patient and hypertension in two patients in the AF group. In the group without AF, coronary artery disease was identified in two patients and hypertension in three patients. No cerebrovascular disease or mortality was observed in any patient.

Discussion

In this study, we examined the frequency and predictors of AF in the long-term follow-up of patients who underwent percutaneous ASD closure. Real-life data from our country shows that 2.7% of patients diagnosed with AF experience stroke and 7.5% die during a 12-month follow-up, which highlights the importance of diagnosing and treating AF.[9] We found that the frequency of AF development was 23.2% in our population. Previous studies have reported AF rates reaching 17–25% in the early period following ASD closure.[10] Abrahamyan et al., who conducted one of the longest follow-up studies available in the literature, reported an AF incidence of 14.9% with a mean follow-up of 10.6 years after ASD closure.[4] Our study covers an important period, with an average follow-up duration of 15 years. We believe that the high incidence of AF development (23.2%) in our study is due to this extended follow-up period.

While exploring predictors of AF following ASD closure, it is necessary to emphasize the importance of studies proving that ASD closure actually reduces the frequency of AF.[11] Pathophysiologically, the presence of ASD is known to lead to atrial structural and electrophysiologic remodeling, thereby triggering AF. Although the literature agrees that a large ASD can cause AF, there are conflicting results regarding whether the size of the device used during ASD closure can predict AF. For example, while Spies et al.[7] found no correlation between device length and AF development, Chiu et al., evaluating 517 patients, reported that device length was an important parameter for AF development.[12] In this study, we aimed to investigate whether device size played a significant role in AF development. We hypothesized that an increase in the ratio of device length to total septum could result in greater mechanical contact with the LA, affecting atrial contraction movement and potentially causing more electrophysiologic effects. Therefore, in addition to ASD size and device size, we calculated the device size/total septum length ratio. Our findings indicate that patients with a higher ratio experienced more frequent AF development in the long term.

In our study, ASD size and device size were also statistically significantly larger in the AF group, which aligns with expectations. However, in our regression analysis, only the device size/total septum length ratio emerged as a significant long-term predictor.

We also observed associations between AF and echocardiographic parameters such as PAP and A wave. The relationship between PAP and AF has been well-documented in previous publications in patients with ASD[13] and is consistent with our findings. The A wave, also known as the ventricular late diastolic wave, was first described as an indicator of atrial contraction strength and was found to be significantly reduced in patients with AF.[14] The relationship between A-wave reduction and AF development appears to be a logical consequence of flow physiology. In the regression analysis model, LA diameter did not emerge as an independent predictor. However, we included it in the regression analysis model both to demonstrate this and because it is one of the most important predictors of atrial fibrillation in the literature. We believe the reason why initial LA diameter was not found to be a long-term predictor of AF is that after ASD closure, the atria enter a new modeling process, and the initial LA diameter is no longer significant.

In our study, age did not significantly differ between the two groups. While age is generally considered an important parameter for AF in both the general population and ASD studies,[15,16] the narrow age range of our cohort and the absence of elderly patients may have mitigated age-related effects in our findings.

The literature also explores the relationship between different brands of ASD closure devices and AF.[3] However, in our study, only the Amplatzer septal occluder device was used, ensuring a homogeneous population.

The absence of differences between the two groups in terms of known risk factors for AF, such as hypertension and coronary artery disease, in our 15-year follow-up data allowed us to focus on baseline echocardiographic values as predictors. Our study provides valuable insights due to its extended follow-up period of 15 years, which is longer than most studies in the literature. We demonstrated the significance of the device size/total septum length ratio.

Previously identified predictors of AF were generally non-modifiable factors.[17] However, our findings suggest that more precise measurements during percutaneous ASD closure and careful selection of the smallest appropriate device may protect patients from AF development in the long term.

Study limitations

Our study had a single-center and retrospective design and was conducted with a relatively small number of patients. Age, hypertension, and various echocardiographic measurements, which are known predictors of AF, were not found to be statistically significant, likely due to the small sample size and the exclusion of patients with additional risk factors.

Conclusion

This study found that the long-term risk of AF increased as the device size/total septum length ratio increased in patients who underwent percutaneous ASD closure. To mitigate the risk of AF, we recommend that interventional cardiologists carefully measure ASD size and select the smallest appropriate device.

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Conflict of interest
There are no conflicts of interest in the conception or production of this study.

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Data availability statements
Data can be made available upon reasonable request.

Author contributions
All authors (1) contributed to the conceptualization and design, or acquisition of data, or analysis and interpretation of data; (2) drafted the article or revised it critically for important intellectual content; and (3) each author has read and approved the final version to be published.

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