Analysis of maximum P-wave duration and dispersion after percutaneous closure of atrial septal defects: Comparison of two septal occluders

Atriyal septal defektlerin perkütan kapatılması sonrası maksimum P dalga süresi ve dispersiyon analizi: İki septal oklüderin karşılaştırılması

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ABSTRACT

Objective: Amplatzer septal occluder (ASO) is the most widely used device for closure of atrial septal defect (ASD). Figulla septal occluder (FSO) is a similar device to ASO with some structural innovations. The aim of study is to assess the maximum P-wave duration (Pmax) and dispersion (Pd) in patients who underwent ASD closure with both devices, to determine the effects of structural innovations on atrial electrical inhomogeneity.
Methods: The study is a retrospective cohort analysis. Between December 2005 and March 2010, 121 patients underwent percutaneous closure of secundum ASD were included in this study. FSO was used in 79 patients, ASO in 42 patients. Pmax and Pd were measured on the surface electrocardiography before and soon after procedure. For comparison of P-wave parameters initially and after procedure paired t-test was used. Correlation analysis was performed using Pearson correlation test.
Results: Pmax and Pd were significantly increased immediate after procedure ($p<0.001$). In FSO and ASO group pre/postprocedural Pd were 38.3±2.7/ 44.1±2.7 msec and 37.5±2.5/ 50.1±2.2 msec respectively. ASO group had a greater postprocedural Pmax and Pd ($p<0.001$). Left and right atrial disc diameter and device size were the strongest correlates of Pd ($r=0.52$, $p<0.001$; $r=0.58$, $p<0.001$; $r=0.35$, $p=0.001$, respectively). Moderate correlation was found between pre-intervention Pd and age ($p=0.008$).
Conclusions: Pmax and Pd were significantly increased soon after atrial septal defect closure procedure in both devices. Pd is significantly lower in patients closed with FSO device. Difference may be due to the distinctive texture of devices. There was no significant difference in terms of clinically apparent arrhythmia after closure with both device types. *(Anadolu Kardiyol Derg 2012; 12: 249-54)*
Key words: Transcatheter closure, arrhythmia, electrical inhomogeneity, congenital heart disease

ÖZET

Amaç: Amplatzer septal okluder (ASO) atriyal septal defektin (ASD) kapatılmasında yaygın kullanılan bir cihazdır. Bazı yapısal yenilikleri olan Figulla septal okluder (FSO) ASO'ya benzer bir cihazdır. Çalışmanın amacı, ASO ve FSO ile ASD kapatılan hastalarda maksimum P dalga süresi (Pmax) ve dispersiyonunu (Pd) ve bazı yeniliklerin atriyal elektriksel inhomojenite üzerine etkisini değerlendirmek.
Yöntemler: Aralık 2005, Mart 2010 tarihleri arasında sekundum ASD`li 121 hastaya transkateter kapatma işlemi uygulandı ve 79 hastada FSO ve 42 hastada ASO kullanıldı. Pmax ve Pd işlemden önce ve hemen sonra yüzeysel elektrokardiyografi de ölçüldü. İki cihazla ilgili işlem öncesi ve sonrası sonuçların karşılaştırılmasında eşleştirilmiş t-testi kullanıldı. Korelasyon analizi Pearson korelasyon testi ile yapıldı.
Bulgular: Pmax ve Pd işlemden hemen sonra önemli ölçüde arttı ($p<0.001$). FSO ve ASO gruplarında prosedür öncesi/sonrası Pd sırasıyla 38.3±2.7/ 44.1±2.7 msn ve 37.5±2.5/ 50.1±2.2 msn bulundu. ASO grubundaki hastalar işlem sonrası daha uzun Pmax ve Pd değerlerine sahipti ($p<0.001$). Sağ ve sol atriyal disk çapı, cihaz çapı ile Pd arasında önemli ilişki saptandı (sırasıyla $r=0.52$, $p<0.001$; $r=0.58$, $p<0.001$; $r=0.35$, $p=0.001$). İşlem öncesi Pd ve yaş arasında orta derecede korelasyon saptandı ($p=0.008$).
Sonuç: Her iki cihazla atriyal septal defekt kapatılmasından hemen sonra Pmax ve Pd önemli ölçüde artmıştır. FSO ile atriyal septal defekti kapatılan hastalarda Pd ileri derecede anlamlı olarak daha az artmıştır. Bu farklılık cihazların farklı doku yapısına bağlı olabilir. Her iki cihazla defektin kapatılması sonrası aritmi açısından belirgin fark yoktu. *(Anadolu Kardiyol Derg 2012; 12: 249-54)*
Anahtar kelimeler: Transkateter kapatma, aritmi, elektriksel inhomojenite, doğumsal kalp hastalığı

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Introduction

Maximum P- wave duration (Pmax) and P dispersion (Pd) is prolonged in patients with secundum atrial septal defect (ASD). Secundum ASD closure is thought to reverse electrical and mechanical changes in atrial myocardium. Pmax and Pd are reduced after approximately first month of surgical or transcatheter closure of secundum ASD (1). In has been shown that patients with advanced age prone to postoperative arrhythmia after surgical closure. Furthermore, patients with postoperative arrhythmia had higher baseline P dispersion values (2). In another study Pmax, P minimum and Pd were found to be similar in patients with pre- and immediately after procedure (3). The incidence of atrial fibrillation was found to be almost as common after transcatheter closure using Amplatzer septal occluder (ASO) (14% of patients) compared with surgical repair (16% of patients) (4-6).

Interestingly, the incidence of new-onset atrial fibrillation seems higher in patients after transcatheter patent foramen ovale closure and higher likelihood to be associated with the use of larger devices (7, 8). This may suggest that acute stretching of the interatrial septum can lead to changes in the atrial electrical activity.

Prolongation of maximum P-wave duration and increased P dispersion are thought to be indicators of interatrial conduction disturbance and are often used to predict paroxysmal atrial fibrillation (9, 10). Assessment of Pmax following secundum atrial septal defect closure may reveal the effects of atrial septal defect devices on electrical in homogeneity.

Thus, the aim of the present study is to determine the maximum P-wave duration and P dispersion immediately after procedure and to compare these values in groups of patients underwent implantation of different devices such as ASO and a new device Occlutech Figulla atrial septal defect occluder (FSO).

Methods

Study design and population This study is retrospective cohort analysis. Between December 2005 and March 2010 in Türkiye Yüksek İhtisas Education and Research Hospital, Ankara, 121 patients (69 females, 52 males) underwent percutaneous closure of moderate-to-large secundum ASD were included in this study. Patients included in the study had no previously documented arrhythmias. It was approved by institutional board.

Our indications for ASD closure, which were pulmonary-to-systemic flow ratio of 1.5:1 or more, echocardiographic evidence of right atrial and right ventricular enlargement, reversible pulmonary hypertension. A total of 121 patients (69 female, 52 male) with isolated secundum atrial septal defect who met the criteria for atrial septal defect device closure participated in this study. The mean ages of patients were 20.6 (4-65 years). All patients underwent successful percutaneous atrial septal defect closure. FSO device was used in 79 patients, while the ASO was used in 42.

Procedure

Informed written consent to the procedure was obtained in all patients or parents before the procedure. Following confirmation of an anatomically suitable defect by transesophageal echocardiography study, standard catheterization was performed. Operation was performed under general anesthesia with the same anesthetic agent. During process, blood pressure and heart rate did not change significantly in both groups. Shunt was calculated by the pulmonary to systemic blood flow ratio. All patients underwent balloon sizing of interatrial septal defects. Diameters of the defect were measured with stop-flow-technique (11). The device size was selected by angiographic measurement plus 1 to 2 mm for both procedures. Techniques of implantation with ASO device have been previously reported (12). FSO implantation procedure is analogous to the technique use for ASO implantation.

The devices

ASO (AGA Medical Corporation, Golden Valley, Minnesota, USA) has advanced over the last decade and have a high safety profile with low complication rates during follow-up. The ASO is constructed from 0.004-in to 0.0075-in Nitinol wires.

Recently, a new device Occlutech Figulla atrial septal defect occluder (Occlutech GmbH., Jena, Germany) has been introduced for transcatheter closure of secundum ASD and other interatrial communications. Although FSO device has similar construction and implantation procedures to ASO device, it has some important structural innovations such as braiding technique. The FSO device is constructed from 0.082 to 0.186 mm Nitinol wires that are tightly woven into two flat round discs with a 4 mm connecting waist. The device, developed using continues braiding technique with a single central pin on the right atrial side to create a smooth and flexible outer layer. There are both right and left sided pins in ASO device. Left atrial disc of both FSO and ASO device is larger than the right atrial disc. The prosthesis is filled with a polyester patch to enhance thrombogenicity in both devices. Different dimensions of the Figulla device is less than ASO device. The FSO device is available in 15 separate sizes compared with the ASO that is available in 27 different sizes (13-15).

Electrocardiography

Standard 12-lead electrocardiography was obtained simultaneously using a recorder set at 50 mm/s paper speed and calibration of 1milivolt/centimeter in a comfortable supine position. This was recorded before and the day after procedure. The P-wave was defined as the distance from the point of the first visible upward or downward departure from the baseline to the return to the baseline. The average P-wave of three consecutive beats from each lead was determined. If the P-wave was measurable in at least nine leads, the patient was kept for further analysis. Maximum P-wave duration was defined as the longest P-wave duration in all derivations. P dispersion was defined as the difference between the maximum and minimum P-wave durations from the 12 leads (9, 10, 16). Measurements of P-waves were done by four investigators who were unaware of the subjects' data. Two separate measurements performed by the same observer.

Post-implantation care and follow-up

All patients underwent clinical examination and transthoracic echocardiography before discharge, at 1, 6, and 12 months after the procedure, and yearly thereafter. Patients with complaints possibly related to an arrhythmia were followed with mandatory surface electrocardiography and Holter monitoring. Anti-aggregation with aspirin, orally per day, was prescribed for 6 months.

Statistical analysis

All analyses were performed using statistical package for the social sciences version 10.0 statistical software (SPSS Inc., Chicago, IL, USA). The results are expressed as the mean and standard deviation, unless otherwise stated. Differences between outcomes with different devices were analyzed by unpaired Student t-test or the Mann-Whitney U test. Incidences in the groups were tested for significance with the Chi-square test. For comparison of P-wave parameters obtained in the same individual initially and after procedure, the paired, two-sided Student's t-test was used. Pearson's correlation coefficients were used to investigate the associations between anthropometric, structural, hemodynamic variables and P- wave parameters. P value of 0.05 was regarded as statistically significant.

Results

Anthropometric, structural, hemodynamic values

Both groups were similar with respect to anthropometric, structural, hemodynamic values (Table 1). There was no significant difference between the groups with regard to age, gender and size of defect, mean size of devices. The difference between device waist size and balloon stop flow diameter of defect was significantly higher in the FSO group (p<0.001) (Table 1).

Atrial electrical properties before and after ASD closure

Pmax and Pd were significantly increased immediately after the atrial septal defect closure procedure in all our cases (p<0.001 for all) (Table 2). Comparison of initial and post-procedural P-wave parameters between ASO and FSO groups are shown in Table 3. Initial Pmax and Pd were similar in both groups (p>0.05). There was a significant increase in P-wave parameters after procedure in both ASO and FSO groups (p<0.001). However, Pmax and Pd values of ASO group were significantly higher as compared with FSO group after device implantation (p<0.001 for both) (Table 3).

Correlation of P-wave dispersion with clinical and procedural variables

Correlation coefficients for the patients' characteristics, structural, hemodynamic procedure variables and post-procedural P-wave parameters in patients are shown in Table 4. Among the variables, left and right atrial disc diameter and device size were the strongest correlates of Pd (r=0.52, p<0.001; r=0.58, p<0.001; r=0.35, p=0.001, respectively). A moderate correlation was also found between pre-intervention Pd and age (p=0.008). A significant but relatively weak correlation was found between Pd and right atrium area, pulmonary to systemic blood flow ratio, size of the defect (r=0.25, p=0.014; r=0.21, p=0.04; r=0.22, p=0.03, respectively).

Table 1. Anthropometric, structural, hemodynamic and disc diameter values

Variables	FSO (n=79)	ASO (n=42)	*p
Age, years	20.6 (4-65)	21.5 (4-65)	0.67
Sex, female/male, n	43/36	26/16	0.53
Height, cm	135.8 (94-180)	132.7 (92-179)	0.61
Weight, kg	55.3 (12-80)	51.1 (11-92)	0.56
Heart rate, beats/min	80±4.5	82±3.7	0.21
Pulmonary to systemic blood flow ratio	2.0±0.4	2.1±0.5	0.33
Mean pulmonary artery pressure, mmHg	16.2±4.4	16.9±4.6	0.87
Balloon stop flow diameter of defect, mm	15.8±4.7	15.2±3.7	0.54
Device size, mm	17.9±5.1	16.3±4.1	0.13
Device size-defect size, mm	1.9±1.1	1.1 ±0.8	<0.001
Right atrial disc diameter, mm	27.8±5.4	26.2±5.5	0.069
Left atrial disc diameter, mm	31.8±5.3	30.2 ±4.8	0.061

Values are expressed as mean±SD, medyan (min-max) values and proportions
*Chi-Square, unpaired t and Mann-Whitney U tests
ASO - Amplatzer septal occluder group, FSO - Figulla septal occluder group, n - number of patients

Table 2. P-wave parameters of all patients before and after atrial septal defect closure procedure

Variables	Before procedure	After procedure	95% CI for mean difference	*t	*p
Pd, msec	38.1 ±2.9	47.7 ±3.9	-10.7, -8.5	-17.6	<0.001
Pmax, msec	80.9 ±3.7	93.5 ±4.2	-13.7, -11.2	-19.9	<0.001

Values are expressed as mean±SD
*paired t-test for dependent samples
Pd - P dispersion, Pmax - maximum P - wave duration

Follow up

Post procedural new-onset arrhythmias were detected in 7 patients (%5.8), all of them were diagnosed with atrial fibrillation. Late onset atrial fibrillation was detected with 24-hour Holter monitoring during follow-up. The median of post-procedural Pd and Pmax of patients experienced new-onset arrhythmias was found to be 53 ms and 104 ms, respectively, which were significantly higher than the patients that did not experience arrhythmia (p<0.001). There was a slight relationship

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Table 3. Pre-procedural and post-procedural P-wave parameters of both groups

Groups	P-wave dispersion, msec			Maximum P-wave duration, msec		
	initial	post-procedure	*p	initial	post-procedure	*p
FSO (n=79)	38.3±2.7	44.1 ±2.7	<0.001	81.6±3.1	92.1±3.1	<0.001
ASO (n =42)	37.5±2.5	50.1 ±2.2	<0.001	80.2±3.6	97.9±2.3	<0.001
**p	0.12	p<0.001		0.18	<0.001	

Values are expressed as mean±SD
*-paired t test for dependent samples, **-unpaired t test for independent samples
ASO - Amplatzer septal occluder group, FSO - Figulla septal occluder group

Table 4. Correlation analyses between anthropometric, structural, hemodynamic variables and P wave parameters

Variables	P-wave dispersion		Maximum P-wave duration	
	r	p	r	p
Age, years	0.28	0.008	0.21	0.04
Weight, kilograms	0.11	0.31	0.15	1.15
Heart rate, beat per minute	0.12	0.23	0.16	0.11
Right atrium area, cm^2/m^2	0.25	0.014	0.19	0.06
Pulmonary to systemic blood flow ratio	0.21	0.04	0.17	0.09
Mean pulmonary artery pressure, mmHg	0.18	0.08	0.05	0.65
Balloon stop flow diameter, mm	0.22	0.03	0.19	0.15
Device size, mm	0.35	0.001	0.27	0.009
Device size-defect size, mm	0.17	0.09	0.16	0.22
Device left disc size, mm	0.52	<0.001	0.31	0.003
Device right disc size, mm	0.58	<0.001	0.33	0.002

*Pearson's correlation coefficients

between the ages of the patients and atrial fibrillation (p<0.03). Patients with atrial fibrillation had larger right atrial dimension and was used larger device.

Arrhythmias occurred in three subjects of FSO group and were precipitated by short duration atrial fibrillation immediately after implantation. It was subsided before discharge and required no treatment.

Arrhythmias occurred in four patients of ASO group. Two patients had short duration atrial fibrillation immediately after implantation. All were subsided within 24 hours and required no treatment. During follow-up, atrial fibrillation occurred in one subject two months after the procedure and in another one subject six months after the procedure. Both patients were controlled with medically and arrhythmias did not persist during one -year follow-up.

Discussion

In both groups Pmax and Pd were significantly increased immediate after the procedure. ASO group had a greater post procedural Pmax and Pd. Pd is significantly lower in patients closed with FSO device. Left and right atrial disc diameter and device size were the strongest correlates of Pd.

Previously it was shown that Pmax and Pd on12-lead surface electrocardiograms are significantly increased in patients with secundum ASD as in our study. Furthermore, after transcatheter or surgical closure of secundum ASD are decreased and returned to normal values within the first year in patient with secundum ASD (2). We investigated the effect of two devices with similar shape but different texture on Pmax and Pd immediately after transcatheter closure of secundum atrial septal defect. We have determined significantly prolongation of Pmax and Pd immediately after the secundum ASD closure in both groups when compared with pre-procedural values. Pmax and Pd values of both groups were similar before the procedure, but these values significantly increased in ASO group after the procedure. There was no significant difference in terms of clinically apparent arrhythmia after closure with both device types.

One study demonstrated that transcatheter secundum ASD closure with ASO could reverse electrical and mechanical changes in atrial myocardium, resulting in a subsequent reduction in Pmax and Pd with time. After the closure of secundum ASD electrical improvement occur in association with improvement anatomical and mechanical (1). We found increased Pmax and Pd after immediately transcatheter closure with both devices. The effects of acute stretch in studies have shown abnormal conduction slowing in response to atrial premature depolarization. The device via foreign body reaction might lead to an inflammatory response within the atrial myocardial tissue thus increasing the atrial conduction disturbances. Percutaneous secundum ASD closure may lead to a short-term positive atrial electrogeometric remodeling. The electrocardiographic predictors of atrial arrhythmias, moreover, tend to worsen early after device implantation despite a marked volumetric unloading, possibly owing to a 'foreign body' effect of the occluding device.

In a similar study (3), Pmax, P minimum and Pd were found to be similar in patients with pre- and immediately after transcatheter and surgery closure. There was no statistical significance in the comparison of Pd between the two groups. However, in the surgical group, Pd decreased more significantly compared with baseline values (3). This situation can be explained with the mechanical effect and foreign body reaction of device.

We found a significant relationship between device size, atrial disc diameters and Pd. Thus, we considered that amount of implanted material might alter the disturbances in the propagation of depolarization. Deployed occluder may function as an electrical barrier leading to the development of a new macro-reentry circuit favoring the occurrence of atrial fibrillation, similar to the reentry mechanism of scar-related ventricular tachycardia (8). Although we had to choose larger device in accordance with diameter of defect, results were better in patients closed with FSO. We considered that braiding geometry of the device might change the stretching of the septum, thus less affects allow abnormal atrial conduction. There is no general idea about the subject; extensive research will give further information about the topic.

Increased P-wave parameters were moderately related to age and slightly related to structural or hemodynamic features of ASD. It was shown that high prevalence of atrial fibrillation in the natural course of a secundum ASD in older patients and the established relation between abnormal atrial conduction (17), this finding suggests that the electric remodeling in older patients with hemodynamically significant secundum ASD was much more promoted by device closure. Patients with ASD have an increased risk for atrial fibrillation. Increased Pd predicts the development of atrial fibrillation. The majority of case series of transcatheter secundum ASD closure report the frequency of new-onset atrial fibrillation during follow-up. Those series reporting atrial fibrillation as a complication describe the frequency for new-onset atrial fibrillation to be in the 5% to 14% range depending on the patient population studied (4-6). In another study demonstrated that in patients with advanced age prone to postoperative arrhythmia has been shown after surgical closure. Furthermore, patients with postoperative arrhythmia had higher baseline Pd values. In these patients, Pmax and Pd values were not significantly decreased within the first year of follow up after surgery (2). Post-procedural P- wave parameters of patients experienced arrhythmia were significantly higher in our study. If Pmax and Pd were above a certain level, regression of normal values could be delayed and result in atrial fibrillation. We think that earlier closure of the defect may play an important role in avoiding permanent changes in the atrial myocardium and atrial fibrillation.

In our study, atrial disc diameters were the strongest correlate of both Pmax and Pd. These parameters are more strongly related to the amount of material implanted attributed to device size, atrial disc diameters rather than age of the patients or structural and hemodynamic features of secundum ASD. Although patent foramen ovale is not a structural defect and has little hemodynamic consequence, the incidence of new-onset atrial fibrillation also seems higher in patients after transcatheter patent foramen ovale closure (7, 8). Patent foramen ovale devices have very large retention skirts attached to the each atrial septal surface compared to ASD devices. Thus, one can only speculate about the possible mechanisms of new-onset atrial arrhythmias after patent foramen ovale closure, by which a deployed occlude device, potentially causes atrial fibrillation. Conduction delay at the atrial septum may persist beyond secundum ASD closure due to atrial septal stretching and may contribute to the long-term atrial arrhythmia substrate in this condition (18). The effects of acute stretch in studies have shown abnormal conduction slowing in response to atrial premature depolarization (19, 20).

Study limitations

Due to the small patient population, larger studies are needed on this topic.

Conclusions

Both Pmax and Pd were significantly increased soon after the secundum ASD closure procedure in both devices according to our study. Pmax and Pd are significantly lower in patients closed with FSO device. The finding of prolongation of the Pmax and Pd may be due to the fact of over sizing the devices and the short period between implantation and repeat electrocardiogram, rather than any type of inflammatory response. We considered that braiding geometry of the device might change the stretching of the septum, thus less affects allow abnormal atrial conduction. Post-procedural P-wave parameters of patients experienced arrhythmia were significantly higher in our study. The number of arrhythmias occurring after closure with both device types does not differ significantly.

Conflict of interest: None declared.

Authorship contributions: Concept - F.A.P., S.T.; Design - F.A.P., Ş.B.; Supervision - F.A.P.; Resources - Ş.B., İ.E., M.B.O.; Data collection&/or Processing - Ş.B., S.T., İ.E., M.B.O.; Analysis&/or Interpretation - F.A.P., S.T.; Literature search - Ş.B., M.B.O., Writing - F.A.P., Ş.B.

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