Strategy for successful transcatheter closure of multiple atrial septal defects

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Strategy for successful transcatheter closure of multiple atrial septal defects

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Lastly, I want to give thanks to my family who support me.

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ABSTRACT

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Clinical outcomes and fate of residual defects after device closure of multiple ASDs in various defect anatomies has not been clearly documented. Patients with transcatheter closure of multiple ASDs from 2005 to 2015 were reviewed (225 patients, 17.3 % of total 1295 procedures). Subjects were divided into 4 groups; Group I (n=107, 47.6%): two nearby defects, Group II (n=52, 23.1%): two distant defects, Group III (n=45, 20%): multiple (≥ 3) defects, Group IV (n=18, 8%): multi-fenestrated defects. Patients' and procedural parameters, outcomes and closure rate during follow-up were investigated. Patients' median age was 22.9 years and mean follow-up duration was 82 ± 14 months. Procedural success rate was 99.5%, 2 major complication (0.9%; 1 device embolization, 1 complete heart block) and 4 minor complications (1.8%) were occurred. Overall, the residual shunts tended to reduce in size or close spontaneously with time. Complete closure rates after procedure and at last FU in each group were as follows; group I; 83.2% and 98.1%, group II; 19.2% and 90.3%, group III; 16.7% and 91.7%, group IV; 6.2% and 87.5%. A hundred sixteen (98%) in Group I and 44 (81.4%) in Group II patients were treated using a single device. In these groups, we tended to use slightly oversized device. In Group III, mean 1.4 devices were used. (2 devices in 12 patients, 3 devices in 3 patients) Most of the residual shunts were small (≤ 3 mm) without

hemodynamic significance. Transcatheter closure is an effective and safe therapeutic option in patient with multiple ASDs. Small residual shunt tends to reduce in size or close spontaneously according to the follow-up duration.

Key words: multiple atrial septal defects, transcatheter closure, residual shunt

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I. INTRODUCTION

Atrial septal defects (ASD) occur in approximately 1 of 1,400 live births and constitute 7–10% of all congenital heart diseases[1]. With device improvements and experience, over the years, transcatheter treatment of ASDs has become routine and is now the method of choice for most patients[2]. Moreover, transcatheter closure of ASDs is considered suitable in complex cases, such as ASDs with deficient rim, large ASDs, and multiple inter-atrial communications.

For multiple ASDs, there are many considerable factors for successful transcatheter closure including numbers/size of the defects, location/spatial relationship between the defects, properties of supporting or intervening septum. When performing transcatheter closure of multiple ASDs, whether use of one device or multiple devices for multiple holes is also considerable factor. Usually, a small additional defect nearby to a larger defect (< 7 mm in distance) can be closed by implantation of a single device to the major defect[3]. While multiple devices are frequently required when there are sizable two or more defects especially the defects are in distance in each other, although there are still concerns of interference between the devices or residual shunt despite of multiple devices. There were a few numbers of studies regarding device closure of multiple ASDs, and the studies generally focused on immediate efficacy and result of the procedure[4]. Thus, the fate of residual shunt after closure of

multiple ASD was not documented well. In this article, we aimed to investigate the follow-up result after closure of multiple ASD with various morphologies in relatively large cohort.

II. MATERIALS AND METHODS

1. Patients

A retrospective analysis of patients, from Jan 2005 to February 2015, was performed. A total of 1295 patients underwent transcatheter closure of ASD at Severance Cardiovascular Hospital within this period. Among them, 225 (17.2%) patients with multiple ASD fulfilled at least 3 years of follow-up were included in this study. The patients were divided into four groups according to the numbers and relationship between the defects: Subjects were divided into 4 groups; Group I (n=107, 47.6%): two nearby defects, Group II (n=52, 23.1%): two distant defects, Group III (n=45, 20%): multiple (≥ 3) defects, Group IV (n=18, 8%): multi-fenestrated defects. Patients' and procedural parameters, outcomes and closure rate during follow-up were investigated.

The institutional ethics committee approved the study (4-2019-0037), and informed consent was waived due to its retrospective nature.

2. Treatments

ASD closure

Percutaneous closure of the ASD was usually performed via femoral vein under local anesthesia with intracardiac echocardiography (ICE) guidance, and selectively performed under general anesthesia with transesophageal echocardiography (TEE) guidance, and fluoroscopic guidance in all cases.

For echocardiographic guidance, all ASD closure was performed under TEE guidance until June 2006 and thereafter selective cases were performed under TEE guidance for patients with two distant defects or multiple defects based on individual approach. We usually preferred ICE for children less than 30 kg or for two nearby defects. For TEE, Philips® echocardiography equipment (Philips) was used and for ICE, the ACUSON AcuNavTM 8-Fr ultrasound catheter (ACUSON,Issaquah, WA, USA) with an 8- or 8.5-Fr short sheath catheter introducer was used. Echocardiographic examinations and transcatheter closure of ASD were performed according to the current guidelines and described detailly in our previous articles[5-8].

All patients were premedicated with acetylsalicyclic acid (100mg or 5mg/kg). Cardiac catheterization was performed to measurement of pressures of ventricle, atrium, pulmonary artery, and aorta. Shunt volume was measured by stepwise oxymetric measurements of superior and inferior vena cava, and pulmonary artery blood sample using the Fick principle, and expressed as the ratio of pulmonary blood flow to systemic flow (Qp/Qs ratio). Before entering the left atrium, 5000 IU or 80 IU/kg of intravenous heparin was injected. Native and balloon occlusive diameter (BOD) using “stop-flow technique” of the ASD were measured in echocardiography and by fluoroscopy. Depending on the sizing diameter, the size of device(s) was chosen, usually same as the BOD or a slightly larger device. A long sheath (9 to 12 Fr) was positioned via the ASD into left atrium, usually near the left superior pulmonary vein. With extreme

caution for preventing air embolism, the device was introduced through the sheath and deployed under ICE or TEE guidance. After confirming of device position by gentle pull-and-push, “Minnesota Wiggle” maneuver, the device was released. The position of the device and relationship with adjacent structures were evaluated by ICE or TEE, and by fluoroscopy. Post-interventional treatment consisted of acetylsalicyclic acid (100mg) once daily for 6 months. For peri-interventional prophylaxis, the patients were given three doses of cefazolin. For patients with pulmonary arterial hypertension, criteria for ASD closure were pulmonary vascular resistance <8WU m^2, and persistent left-to-right shunt, and reasonable results of pulmonary vasoreactivity test and balloon occlusion test.

Device closure of multiple defects was performed based on the size, morphology, and characteristics of the defects. Simultaneous balloon occlusion test and real-time three dimensional (RT-3D) transesophageal echocardiography (TEE) was performed to determine the policy of device closure of multiple ASDs[9]. Two nearby defects (distance < 7mm) were usually closed with one device[3], while multiple defects or multi-fenestrated defects were individually treated.

Procedural success was defined as successful detachment(s) without peri-procedural major complications, and well-positioning of the device without migration as assessed by chest x-ray and TTE after 24 hours. Procedure- or device-related death, cardiac tamponade, erosion, thromboembolism, stroke, complete artrioventricular block, ventricular arrhythmias were considered major complications. We included vascular damage requiring surgery into major complication. Other any adverse events were regarded as minor complications. Late complications were defined as any adverse events occurred after 6 months from device closure.

Follow-up

A physical examination, 12-lead ECG and chest x-ray were performed 2

hours and the next morning after the procedure. TTE was routinely performed the next day after the procedure. A physical examination, 12-lead ECG, chest x-ray and TTE were done 1 week, 1, (3), 6, 12 months, and thereafter each year. The size of residual shunt was measured as largest diameter in various views. Residual shunts were classified according to previous research as: trivial-color jet ≤ 1 mm; small – 1mm < color jet ≤2mm: moderate – color jet 2-4 mm and large -color jet > 4 mm[10]. Oral antiplatelet was prescribed for 6 months, and routine prophylaxis for infectious endocarditis for 6 months in cases without complication. Complications were evaluated at every visit, at any event or at last follow-up.

3. Statistical Analysis

Continuous data are reported as mean ± SD and categorical data as frequencies and percentages. Nonparametric Mann-Whitney tests were used to assess differences between continuous variables. Differences in categorical data were analyzed using Fisher's exact test. Kaplan-meier estimates were performed to investigate spontaneous closure rate of the residual shunts.

Significance was defined as a p-value < 0.05, and analysis was performed using SPSS version 25.0 (SPSS, Inc., Chicago, Illinois).

III. RESULTS

During the study periods, a total of 1295 patients underwent transcatheter closure of ASD and among those 225 patients (17.3%) with multiple ASDs were enrolled in this study. Baseline demographics of the patients are presented in Table 1. The median age was 27.0 years (range 0.6 to 79.6) and children (defined as age ≤ 18 years) was 52.4% (118 of 225 patients). The female to male ratio is 2.4. For baseline hemodynamic characteristics, thirty (13.3%) patients were complicated by pulmonary arterial hypertension, 15 (6.7%) patients had tricuspid regurgitation ≥ Grade 2, and 7 (3.1%) had mitral regurgitation ≥ Grade 1. The mean follow-up duration is 82.4 ± 14.0 months (range, 36.0-135.0). Clinical outcomes and complication were described in Table 2. Procedural success rate was excellent (99.1%) and major complication was occurred only in two (0.9%) patients. One patient with multi-fenestrated ASD and other two distant ASDs was converted to surgical ASD closure. Two devices were positioned well, but the acute angulation between devices caused significant residual shunt. Additional third device was also considered, but it might not solve the situation. Other one patient with multi-fenestrated ASD treated with a single FSO device was complicated complete atrioventricular block, which was resolved after transcatheter device retrieval. The patient underwent surgical ASD closure after stabilization. Lastly, a patient with three large defects experienced device embolization after detachment of 2nd 40-mm ASO device despite of accurate measurement by simultaneous balloon sizing of three defects and Minesota wiggle maneuver. We retrieved the device percutaneously without further complication and succeed device closure with two devices during same session (with upsizing of 1st FSO device 30 mm to 32 mm, and with same size of 2nd 40 mm ASO). The first two cases were regarded as procedural failure, and the latter two case were counted as major complications. There were 4 (1.8%) minor complications.

The rate of residual shunts immediate after procedure is high as 51.6% but tends to decrease as time goes on. The rate of residual shunt at last follow-up was 5.8 % (13 of 223). The detail data according to type of multiple ASDs was shown in Table 3. For two nearby defects (n = 107), most patients (98.2%) were treated with one device. In this group, the residual shunt rate immediate post-procedure is relatively low (16.8%) and tended to be spontaneous closured. Two patients (1.9%) showed residual shunt at last follow-up; one with trivial shunt and one with small shunt. For two distant defects, 8 patients (18.6%) were treated with two devices. The residual shunt rate immediate post-procedure was high as 90.4%, but only 5 (9.7%) showed residual shunt at last follow-up. For multiple defect group and multi-fenestrated group, around 25% were treated with two or more devices. The residual shunt rates immediately post-procedure was high as 83.3% and 93.8% respectively (after exclusion of two surgically treated patients in multi-fenestrated group) but also tended to be spontaneously closed. The residual shunt rates at last follow-up were 8.3 % and 12.5% respectively.

Among 13 residual shunts at last follow-up, most (84.7%) was trivial or small shunts[10]. There was no statically significant difference of major or minor complication rate between multiple ASD types. The Kaplan-Meier estimates showed that spontaneous closure of residual shunt in two nearby defects groups were occurred usually within six months and extended up to two years (Figure 1). In other groups, spontaneous closure was occurred usually within two years and extended to 4~5 years.

Table 1 Baseline characteristics of total patients (N=225)

Sex (Female: Male)	159: 66 (2.4:1)
Children (Age ≤ 18)	118 (52.4%)
Mean age (years)	27.0 (0.6~79.6)
Mean body weight (kg)	54.0 (8.0~95.0)
Mean PAP (pre)	18.8 ± 5.6 (15.0~38.0)
PAH[+]	30 (13.3%)
TR ≥ Grade 2	15 (6.7%)
MR ≥ Grade 1	7 (3.1%)
Qp/Qs	2.5 ± 1.0 (1.5~3.4)
Follow-up (Months)	82.4 ± 14.0 (36~175.0)

Data was presented as number (%), mean ± SD (range), and median (range) as appropriately. The data of sex was presented as number (ratio).
Abbreviations: mPAP, mean pulmonary artery pressure; MR, mitral regurgitation; PAH, pulmonary arterial hypertension; Qp/Qs, the pulmonary-to-systemic blood flow ratio; TR, tricuspid regurgitation
[+] defined as mPAP ≥ 25mmHg during catheterization, pre means before device closure

Table 2. Clinical Outcomes of Total Patients (N=225)

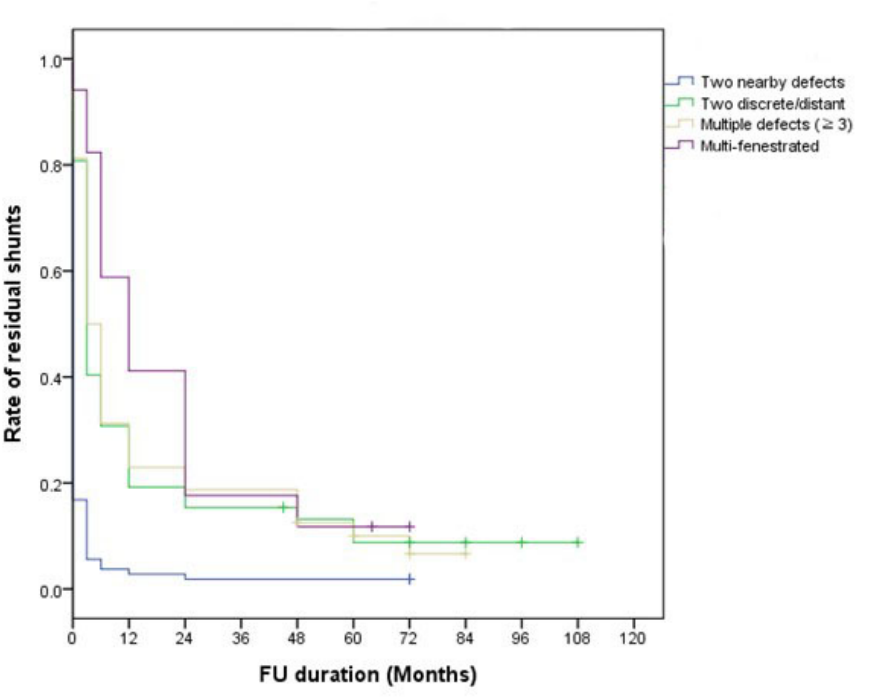
Procedural Success Rate (%)	223 (99.1%)
Major Complication Rate (%)	**2/225 (0.9%)**
Device embolization	1 (0.5%)
Complete AV block	1 (0.5%)
Minor Complication Rate (%)	**4/225 (1.8%)**
Transient Arrhythmias	2 (0.90%)
Hematoma & Oozing	1 (0.45%)
Allergic reactions (contrast)	1 (0.45%)
Residual shunt immediately after closure	116/223 (52.0%)
Residual shunt at Last follow up (%)	13/223 (5.8%)

Table 3. Comparisons according to multiple atrial sepal defect type.

	Two nearby defects (d ≤ 7 mm), n = 107	Two distant defects (d > 7 mm), n = 52	Multiple (≥ 3) defects, n = 48	Multi-fenestrated defects, n = 18
Large defects (mm)	16.5 ± 8.3 (6~37)	18.0 ± 9.5 (8~29)	14.0 ± 5.5 (5~29)	Number of defects: Median 5, (4~around 30)
Smaller defects (mm)	5.4 ± 4.6 (1~15)	7.5 ± 3.8 (1~15)		
Closure with multiple devices	Two: 2 (1.8%)	Two: 8 (18.6%)	Two: 12 (25.0%) Three: 3 (6.3 %)	Two: 4 (22%)
Closure with one device	ASO (69), FSO (35), Cocoon (1)	ASO (21) FSO (11)	ASO (22), FSO (11)	ASO (4), FSO (1) GSO (4), Cribriform (3)
Residual shunt immediately after closure/ Last FU	18 (16.8%) / 2 (1.9%)	42 (80.8%) / 5 (9.7%)	40 (83.3%) / 4 (8.3%)	15/16+ (93.8%) / 2/16 (12.5%)
Spontaneous close rate during FU	88.9%	88.1%	90%	86.7%
Major complication rate	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (5.6%)
Minor complication rate	1 (0.9%)	2 (3.8%)	1 (2.1%)	0 (0.0%)

+ Two previously mentioned patients were treated surgically, and the residual shunt rate was calculated from the remained 16 patients.

ASO, Amplatzer septal occluder; FSO, Figulla flex septal occluder; FU, follow-up



	Immediate	1-year	2-year	5-year
Group 1 (N=107)	18 (16.8%)	4 (3.7%)	3 (2.8%)	2 (1.9%)
Group 2 (N=52)	42 (80.8%)	10 (19.2%)	8 (15.4%)	5 (9.7%)
Group 3 (N=48)	40 (83.3%)	11 (22.9%)	9 (18.8%)	4 (8.3%)
Group 4 (N=16)	15 (93.1%)	6 (37.5%)	3 (18.8%)	2 (12.5%)

Figure 1. Kaplan-Meier estimates of rate of residual shunt according to the type of multiple defects.

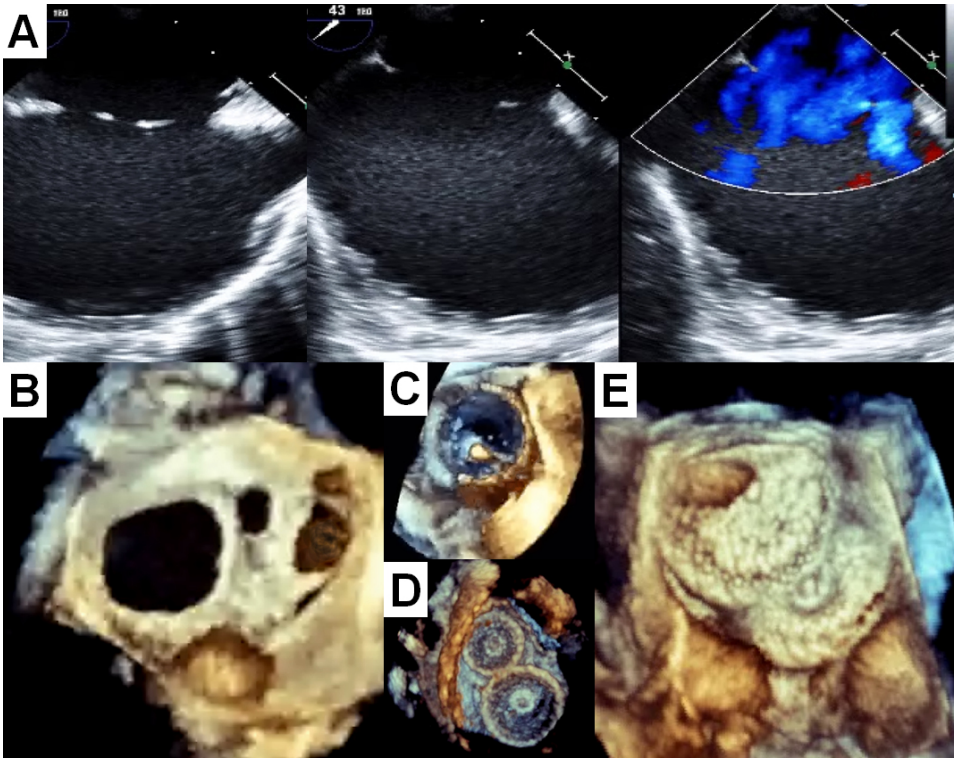


Figure 2. Advantages of real time 3-dimensional (RT3D) transesophageal echocardiography (TEE) guidance in device closure of multiple ASDs.
True anatomy of multiple defects is difficult to understand by 2-dimensional TEE images even in multiple views with color flow Doppler (A), however the anatomic characteristics including number of the defect, shape/size of each defect and spatial relationship between the defects are clearly shown on RT3D image (B). RT3D echocardiography also provides excellent images during balloon sizing (C) and post-assessment of the device position (D, E) from right atrium and left atrium respectively.

IV. DISCUSSION

Transcatheter closure of multiple ASDs is challenging with diverse considerable factors. There was no universal guideline or expert consensus regarding the number of devices to treat multiple ASDs. Nevertheless, a small additional defect adjacent to a larger defect (<7 mm in distance) usually treated with a single device with excellent results[3]. Our study was concordant to the findings since 98.2% of this group was treated with single device with 100% procedural success rate and 0.9% of minor complication rate. For two distant (>7mm) defects, two devices were usually considered but one article showed that there was no difference in success rate between using single device and two device group and risk of residual shunt is greater with dual occluders[11]. Other study also showed the feasibility of interventional treatment using a single device for multiple ASD, even in patients with a larger defect distance using a 3D printing model[12]. In our study, majority of this group (81.4%) was treated with a single device without major complications. We intended to minimize the residual shunt as < 5 mm by simultaneous balloon sizing when using a single device and intended to reduce the acute angulation or interference between two devices when using two devices. The

Residual shunt rate was high as 90.4%, mostly trivial or small. The residual shunt was spontaneously closed or tended to be reduced in size. For multiple defects or multi-fenestrated defects, the treatment should be individualized. Understanding the accurate anatomy and properties of surrounding/intervening rims of multiple defects is the cornerstone of successful device closure. To overcome these problems, proper use of real time 3-dimensional echocardiography is invariably helpful especially in these groups[13-16]. In case of device closure of multiple defects using multiple devices, the optimal combination of devices based on the comprehensive information from RT3D echocardiography and balloon occlusion test is required to prevent unfavorable interference between multiple devices (Figure 2). In our study, around one

fourth patients were treated with two or more devices without increased risk of complications.

Previous study revealed that the residual shunt tended to decrease and disappear in time with relatively small sample size[3], and our study added the evidence of spontaneous closure of residual shunt after device closure in various morphology in multiple ASDs. Our findings could help the interventionist dealing with complex conflict between residual shunt and spatial relationship/interference between devices.

Our study was a non-randomized retrospective study with some inherent limitations. First, all procedures were performed by highly skilled and experienced interventionist, therefore, this excellent success rate and low complication rates of transcatheter closure of multiple ASDs is not guaranteed. We emphasized the importance of meticulous approach using RT3D TEE and simultaneous balloon sizing once again. Second, the number of device or the types of devices were not selected randomized. Thus, we could not draw the relationship between the types of devices and procedural outcome including residual shunt. Finally, risk factor for residual shunt at last follow-up was not illuminated due to a relatively small number of residual shunts.

Further study adopted artificial intelligence might be helpful to solve the most important question in this topic. Nevertheless, our study is valuable with high success rate with considerably low complication rate. Moreover, our study demonstrated that most residual shunts after transcatheter closure of multiple defects tended to reduce in size or close spontaneously even in complex morphology.

V. CONCLUSION

Our study showed that Transcatheter closure is an effective and safe therapeutic option in patient with multiple ASDs. Small residual shunt tends to reduce in size or close spontaneously according to the FU duration. Meticulous and individualized strategy for each patient is warranted to maximize the efficacy and safety in these group.

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ABSTRACT (IN KOREAN)

다발성 심방중격결손의 경피적 중재술 치료전략

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정세용

다양한 해부학적 형태에 따른 다발성 심방중격결손의 중재술적 치료의 임상적 결과와 잔존결손의 시간에 따른 변화는 많이 알려져 있지 않다. 이에 본 연구는 2005년부터 2015년까지 심방중격결손 경피적 중재술을 받은 환자 중 다발성 심방중격결손이 확인된 225명 (같은 기간 내 1295명 중 17.3%)의 결과를 후향적으로 분석하였다. 결손의 해부학적 특성에 따라 다음과 같이 네 그룹으로 분류하였다. 그룹 1 (107명), 두개의 가까운 (<7 mm) 결손; 그룹 2 (52명), 두개의 크고 먼 (>7 mm) 결손; 그룹 3 (45명), 3개 이상의 다발성 결손; 그룹 4 (18명), 다중 천공성 결손. 전체 환자의 중앙 연령은 22.9세였고 평균 추적관찰 기간은 82개월이었다. 시술 성공률은 99.5%였으며 2례(0.9%)의 주요 합병증 (1례의 기구 색전, 1례의 완전 방실 차단) 및 4례(1.8%)의 작은 합병증을 보였다.

전체적으로 잔존 결손은 시간이 흐름에 따라 크기가 작아지거나 자연 폐쇄되는 경향을 보였다. 그룹 1의 경우 시술 직후 잔존 결손의 비율이 16.8%였고 최종 추적관찰시 1.9%였다. 그룹 2-4의 경우 시술 직후 잔존비율이 80%를 넘었으나, 최종

추적관찰시는 10% 전후였다. 최종 추적관찰시 잔존 결손의 크기는 대부분 작은 (<2 mm) 크기였다. 그룹 1,2의 경우 대부분 1개의 기구를 사용해서 시술하였고, 그룹 3,4의 경우에는 약 1/4에서 두개 이상의 기구를 사용하였다. 결론적으로 다발성 심방중격결손 환자에서 경피적 중재술은 효과적이고 안전한 치료 방법이며, 작은 잔존 결손은 시간이 지남에 따라 크기가 줄어들거나 자연 폐쇄되는 경향이 있어서 다발성 심방중격결손 폐쇄술의 환자 개별 치료 전략에 이를 고려한 접근이 필요하겠다.

핵심되는 말: 다발성 심방중격결손, 중재술, 잔존 결손