

Transcatheter Closure of Atrial Septal Defect in Children: Short and Long Term Follow-up Results

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Research

Keywords: Atrial Septal Defect, Catheterization, Congenital Heart Disease, Device

Posted Date: November 19th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-110585/v1>

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Abstract

Background: Atrial septal defect (ASD) is a congenital heart disease which is usually diagnosed in childhood. However the large part of studies in literature include adults. In this study, we aimed to evaluate the follow-up results of patients who had transcatheter closure of ASD to understand the factors effected success and complications of this procedure in children.

Methods: 232 patient files were evaluated retrospectively. 24 of the patients excluded from the study as the files of these patients could not be found in archive or the data needed to be evaluated was missing. Demographical data, family history, accompanying syndromes, complaints of patients, symptoms, echocardiographical (ECO) findings, transesophageal echocardiogram (TEE) findings if performed, the size of defect in balloon-sizing, the size of device used in procedure, major and minor complications evaluated.

Results: In our study, 208 children [39.9% (n = 83) male, 60.1% (n = 125) female] included who were diagnosed with ASD. The mean age of the patients are $88,06 \pm 56,52$ months (3 days to 220 months). When the family history is examined; heart disease was not found in 87.0% (n = 181) of the patients whereas 13.0% (n = 27) of the patients had family history of heart disease. 81.7% of the patients (n = 170) had no complaint and 18.3% (n = 38) had complaints. There was a statistically significant correlation between diameter and length of defect measured with ECO, TEE and by balloon-sizing. Success rates of procedure found to be 95.7%. While the major complication of the procedure was device embolization; arrhythmia was the most common minor complication. None of our patients died due to device embolization. The procedure complication rate is not statistically different according to the device type. ($p = 0.075$; $p > 0.05$)

Conclusion: In our study, we found that device diameters measured by different methods correlated with each other. The procedure complication rates do not differ according to the device type. When the transcatheter ASD closure process is performed with an experienced and qualified team; mortality and morbidity rates compatible with developed countries can be achieved.

Background

Atrial septal defects (ASD) are common; accounting for approximately 8 to 10 percent of congenital heart diseases with prevalence of approximately 56 per 100.000 live births (1). The incidence of ASDs have increased lately. Even more frequent usage of echocardiography (ECO) is thought to be the reason of that increase, prevalence of ASD at birth is thought to be 1 to 2 per 1000 live births (2). The basis of race and ethnicity is not understood completely yet (3). The closure of ASD can be performed by surgical sternotomy or transcatheter method. The first attempt of transcathatery closure of ASD performed by Mills and King in 1976 (4).

Surgical closure of ASDs has been the mainstay of treatment but there is still significant mortality and morbidity associated with surgical repair (5). Transcatheter closure of secundum ASD has been

established as an alternative treatment to surgical procedure. Studies show that transcatheter closure of secundum ASD is less invasive, complication risk is lower and duration of hospital stay is shorter when compared with surgical closure (6, 7).

Transcatheter closure of ASD is being formed in Istanbul University Medical Center for 12 years and patients diagnosed with ASD have been followed in our clinic for long years. In our study we aimed to understand the effects of transcatheter closure of ASD on children in a long term follow-up study. There is no clinical research on long term follow-up of patients admitted to our clinic. There is limited published outcome data on transcatheter closure of ASD and long term follow-up in children.

Methods

In our retrospective study the follow-up results of the patients who were admitted to Division of Pediatric Cardiology of Istanbul University, between 2008 and 2017 after transcatheter closure of ASDs are evaluated retrospectively in order to understand the factors effected success and complications of the procedure. Ethical approval for this study was obtained from Istanbul University Faculty of Medicine Ethics Committee (approval number: 2018/1286). The transcatheter ASD closure procedure records were evaluated respectively; 232 of 248 files were appropriate for evaluation but 24 of these files are not taken under review because of imperfect data. Consequently 208 patients are included to our study.

Patients included in our study were evaluated by 2D transthoracic echocardiography (TTE) and colour doppler echocardiography. In all patients while frontal and caval view evaluated by subxiphoidal position; apical four-chamber, parasternal long-axis and short axis were evaluated by precordial position. Defect's margin to pulmonary vein, coronary sinus and atrioventricular valve were evaluated by apical four chamber view. Defect's margin to superior and inferior vena cava also anterior and posterior rim's were calculated by aortic view. Rims that surrounding the defect were evaluated as 'short rims' if they measured under 5 millimeters.

Patients older than 2 years old and weighted more than 15 kilograms were included in our study. Also patients assessed by TTE and findings supporting dilatation in right atrium and ventricle or pulmonary/systemic flow rate higher than 1,5 were included. Patients required to have rim longer than 5 millimeters between ASD and atrioventricular (AV) valves, inferior vena cava (IVC), superior vena cava (SVC), coronary sinus and pulmonary vein also one of posterior or inferior rims required to be longer than two millimeters for being eligible transcatheter closure of ASD procedure. Patient whose files which could not be found in archives were excluded from the study.

Transesophageal echocardiography (TEE) was performed to 168 of patients before or after the procedure. The highest number accepted as the widest diameter of defect which calculated by TTE and TEE performed before procedure. Only conventional angiography performed to patients who couldn't meet the criteria for transcatheter ASD closure operation and action cancelled. Stretched diameter of defect was measured by balloon-sizing. The balloon was inflated just to the point where there was absent

colour flow across the ASD. Balloon sizing procedure was performed to all patients. Diagnostic right heart catheterization was done in all patients before the procedure.

“Solysafe Septal Occluder”, “Amplatzer Septal Occluder”, “Occlutech Occluder”, “SearCare Occluder”, “Biostar Septal Occluder”, “Gore Septal Occluder” devices were used in procedures.

NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) programme was used for statistical analysis. Defining statistical methods (mean, standart deviation, median, frequency, percent, minimum and maximum) were used for evaluation of study data. Shapiro-Wilk test and graphical investigations were used to evaluate suitability of quantitative data to normal distribution. Student t test was used to compare two groups of quantitative variables with normal distribution. Pearson Chi-Square and Fisher Freeman Halton test were used to compare qualitative data. Pearson correlation analysis was used to evaluate correlation between quantitative variables. $P < 0,05$ is considered as statistically significant.

Results

In this study which included 208 patients who were diagnosed with ASD; consisting 83 (39.9%) male and 125 (60.1%) female patients. Ages of patients changed between 3 days to 220 months with an average age of $88,06 \pm 56,52$ months.

The average age of patients diagnosed with ASD was $80,99 \pm 58,24$ months (range 3 days to 209 months). Family history of heart disease was positive in 13% ($n = 27$) of patients and was negative in 87% ($n = 181$) of patients. Distribution of baseline characteristics of patients was shown in Table 1.

Table 1
Distribution of Baseline Characteristics

		n (%)
Age at admission (ay)	<i>Min-Max (Meian)</i>	0,1-220,4 (81,4)
	<i>Mean ± Sd</i>	88,06 ± 56,52
Gender	Male	83 (39,9)
	Female	125 (60,1)
Diagnose Center	Istanbul University, Faculty of Medicine	76 (36,5)
	Other Centers	132 (63,5)
Diagnose Age (month)	<i>Min-Max (Median)</i>	0,1-209 (74)
	<i>Mean ± Sd</i>	80,99 ± 58,24
Patient age at procedure (month)	<i>Min-Max (Median)</i>	26–211 (96,5)
	<i>Mean ± Sd</i>	107,16 ± 42,49
Family history of heart diseases	No	181 (87,0)
	Yes	27 (13,0)
	1st degree relatives with ASD	8 (29,6)
	Other Relatives	13 (48,2)
	Non-ASD Heart Diseases	6 (22,2)

Seven (3,4%) of infant patients diagnosed with heart failure as 201 (96.6%) patients had no clue of heart failure. The number of patients who had no complaint was 170 (%81.7), while 38 (18.3%) patients had complaints related to ASD. Seven infants were diagnosed with heart failure and three of them were diagnosed with severe heart failure as they needed combined medical therapy. The study population included 33 (18,3%) patients with an additional heart failure, 24 (63,2%) of them were structural anomalies as 24 (11.5%) with a genetic syndrome. Down Syndrome was the most common one with 25% of ratio. Other extracardiac comorbidities and syndromes were shown in Table 2.

Table 2
Distribution of Disease Characteristics

		n (%)
Heart failure before procedure	No	201 (96,6)
	In infancy	7 (3,4)
Severity of heart failure (n = 7)	Mild	4 (57,1)
	Severe	3 (42,9)
Complaints before procedure	No	170 (81,7)
	Yes	38 (18,3)
Additional Cardiac Anomalies	No	170 (81,7)
	Yes	38 (18,3)
	Additional structural anomalies	27 (71,1)
	Atrial Aneurism	7 (18,4)
	Cardiomyopathy	1 (2,6)
	RBBB*	1 (2,6)
	AV Block	1 (2,6)
	SVT	1 (2,6)
Extra-cardiac co-morbidities and syndromes	No	184 (88,5)
	Yes	24 (11,5)
	Orthopedic diseases	1 (4,2)
	Hematolojik-Onkolojik hastalık	3 (12,5)
	Neurological diseases	4 (16,6)
	Obesity	1 (4,2)
	Down syndrome	6 (25,0)
	Other syndromes	5 (20,8)
	Preterm birth history	3 (12,5)
	Situs inversus totalis	1 (4,2)

On TTE, the median defect size found to be $12,60 \pm 3,77$ mms (range 4,5 to 24 mms) as the mean diameter measured by TEE was $13,78 \pm 3,85$ mms (range 7 to 30 mms) and the mean diameter measured

by balloon-sizing was $15,64 \pm 4,45$ mms (range 9 to 33 mms). Different types of devices and complication rates were explained in Table 3.

Table 3
Distribution of Procedural Characteristics

		n (%)
Defect size measured by ECO (mm)	<i>Min-Max (Median)</i>	6–24 (12)
	<i>Mean ± Sd</i>	12,60 ± 3,77
Defect size measured by TEE (mm)	<i>Min-Max (Median)</i>	7–30 (13)
	<i>Mean ± Sd</i>	13,78 ± 3,85
Defect size measured by ballon-sizing (mm)	<i>Min-Max (Median)</i>	9–33 (14)
	<i>Mean ± Sd</i>	15,64 ± 4,45
Devices	No procedure	22 (10,6)
	Amplatzer	92 (44,2)
	Occlutech	53 (25,5)
	Solysafe	24 (11,5)
	Sera Occluder	14 (6,8)
	Biostar	3 (1,4)
Size of device (mm) (n = 186)	<i>Min-Max (Median)</i>	10–35 (16)
	<i>Mean ± Sd</i>	17,44 ± 4,95
Complication (n = 186)	No	173 (95,7)
	Major	5 (3,0)
	Minor	7 (4,1)

Major complications included device embolisation, new valvular insufficiency, thromboembolism and major complications occurred only in 5 (2.7%) of patients. There was no deaths or device erosion. Four patients needed emergent cardiovascular surgery due to device embolisation as devices couldn't be caught by snare but in one of the patients embolised device caught by snare. Minor complications comprised headache, minimal pericardial effusion, residual shunt, persistent therapy-requiring arrhythmias. Complications and complaints detailed in Table 4.

Table 4
Distribution of Post-Procedural Characteristics

		n (%)
Procedure Cancelled	No	186 (89,4)
	Yes	22 (10,5)
	Unable to place the device despite recurrent trials	1 (4,5)
	Unable to place the device due to VCI rim deficiency	6 (27,2)
	Insufficient total interseptum	12 (54,4)
	Floppy interseptum	3 (13,6)
Post-procedural complaint or complications	No	173 (93,0)
	Yes	12 (7,0)
	Headache	2 (15,3)
	Arrhythmia	3 (23,0)
	Device Embolisation	4 (38,4)
	Residual Shunt (Mild)	1 (7,6)
	Neurological Complications – Trombus associated	1 (7,6)
	Pericardial effusion (Mild)	1 (7,6)
Follow-up period (month)	<i>Min-Max (Median)</i>	0,03-208,1(52,4)
	<i>Mean ± Sd</i>	57,38 ± 50,83
Post-procedural follow-up period (month)	<i>Min-Max (Median)</i>	0-117,1 (29,4)
	<i>Mean ± Sd</i>	36,58 ± 34,20

The procedure canceled in 23 (11,1%) patients. Three of these patients had floppy interseptum, 6 patients had short IVC rim, 13 of patients had insufficient total interseptum. In one patient procedure could not be practiced despite repetitive trials. Post-procedural complications or complaints were recorded in 13 patients.

The follow-up period ranged from 1 to 208 days (mean 57,38 ± 50,83months). Maximum follow-up period after the procedure was 117 months (mean 36,58 ± 34,20 months), 5 patients did not continue the follow-ups.

Male and female groups compared about existence of family history of heart diseases, heart failure and additional cardiac anomalies, there were no significant difference between groups spotted ($p > 0,05$). The mean ASD diameters on TTE, TEE and balloon-sizing had no difference between gender groups ($p > 0,05$). There were no significant difference of complications shown between female and male groups ($p > 0,05$).

Diameter of defect calculated by TTE were significantly positively correlated with diameter calculated by TEE, by level of 73.8% ($r:0,738$; $p = 0,001$; $p < 0,01$). There were significantly positive correlation between diameter of defects calculated by balloon-sizing and TTE, by level of 69,0% ($r:0,690$; $p = 0,001$; $p < 0,01$). There were significantly positive correlation between diameter of defects calculated by TEE and balloon-sizing, with level of 81.7% ($r:0,817$; $p = 0,001$; $p < 0,01$) (Fig. 1).

There were no statistically significant difference between complication rates of procedure with different devices ($p = 0,075$; $p > 0,05$) Also post-procedural complications were not significantly different from each other with different devices ($p > 0,05$) (Table 5).

Table 5
Complication rates of different transcatheter ASD closure devices

		Complication			<i>d</i> _p
		No	Major	Minor	
Device; n (%) <i>(n = 186)</i>	Amplatzer	87 (93,5)	2 (2,5)	3 (3,8)	0,075
	Occlutech	50 (94,3)	1 (2,2)	1 (2,2)	
	Solysafe	22 (91,6)	0 (0)	2(8,2)	
	Sera Occluder	12 (85,7)	1 (7,1)	1 (7,1)	
	Biostar	2 (66,7)	1 (33,3)	0 (0)	
<i>^bFisher Freeman Halton Test</i>					

Discussion

ASD prevalence at birth found to be 1 to 2 per 1000 live births but it's distribution by nations is still a study subject (2, 3). Female and male ratio in community was found to be 2:1 (8). In our study we also determined that female ASD prevalence was higher than male but our ratio was 1,5:1.

Infants and adolescents with isolated ASD are frequently asemptomatic and presenting with murmur (8, 9). ASDs may be symptomatic rarely in children and may cause growth retardation, tachypnea, recurrent upper reaspiratory system infections and heart failure (9). Thirty-eight (18,3%) of our patients had active complaints on admission even literature stated that most of ASD patients are asymptomatic.

In our study the mean age at hospital admission was $80,99 \pm 58,24$ months and median age was found 74 months. Youngest patient admitted to our clinic was 3 days old. The mean age at diagnosis of ASD

was found 4.5 years in literature (10). We believe that the reason for our clinic has the older patients in admission, is patients were referred from other clinics for procedure.

As reports of familial clusters of secundum ASDs have noted different modes of inheritance, secundum defects also encountered in genetic syndromes. Exposure to several substances has also been associated with ASDs (11). A study stated that 19% of patients with ostium secundum atrial septal defect had at least one relative with congenital heart disease (12). The list of genes associated with isolated heart diseases is rapidly expanded (13). ASDs can be related with genetic syndromes like Holt-Oram syndrome, Down syndrome and Kabuki syndrome (14). In our study, 6 of our patients had diagnosed with Down syndrome and 11 patients in total had diagnosed different syndromes like Kabuki syndrome, Marfan syndrome and Klinefelter syndrome. Only one patient had diagnosed situs inversus totalis which is rarely accompanied by ASDs (15).

Children diagnosed with isolated secundum ASD are often asymptomatic and the only finding on physical examination is cardiac murmur. Isolated secundum ASDs rarely develop heart failure and only 3.4% of our patients developed heart failure so our results were compatible with literature (16). Seven child in our study had heart failure and three of them were classified as severe heart failure due to their need for combined medical treatment. Even heart failure in infancy is rare in patients with isolated secundum ASD; all patients need to be evaluated for heart failure.

In our study defect sizes that calculated by TTE, TEE and balloon-sizing was statistically correlated. But some studies state that the ASD size could be overestimated by oblique passage of the balloon through the ASD. On the other hand some studies are standing on that balloon sizing might not be essential for transcathatery closure of ASD and TEE-guided sizing is presented as a successful alternative to balloon sizing (17). In recent studies intracardiac echocardiography guided closure is suggested for closure of ASDs without balloon sizing (18).

Twenty-two of the procedures canceled in procedure room mainly due to total interseptum deficiency or IVC rim deficiency. Amedro P. et al (19) emphasized in their study that transcathatery closure of ASDs with posterior-inferior rim deficiency cannot be recommended.

Abacı A. et al (20) stated their success of transcathatery closure of ASD as 96.9% while ours was 95,7% which is very close to that number and compatible with literature. Chessa M. et al (21) carried out a similar study with adults and major complication indicated as divice embolization just like in our study and the study that Abacı A. et al conducted (20). In four cases the device embolised and in one patient shunt developed after procedure which were major complications in our study group.

Atrio-ventricular block and arrhythmias are the most frequent types of complications on adults after transcathatery ASD closure which might lead to need of heart pace. In our study we evaluated arrhythmias as minor complication which was the second most frequent complication in our study and encountered in 3 patients. All of our patients responded well to medical therapy and none of them needed

heart pace. On the other hand Alnasser S. et al (22) evaluated long term complications on adults and atrial arrhythmia occurred in 6,5% and atrial fibrillation in 4,9%.

Kato Y. et al (23) indicated new onset migrane after transcathatery closure of ASD in their patient likewise two of our patients developed headaches after procedure and diagnosed as migrane by child neurology consultants. On the other hand Motelmans K. et al (24) found transcathatery closure of ASD was not realated to a decrease on prevalance of migraine but in a subgroup, patients who suffered from typical migraine before ASD closure, the frequency of migraine attacks decreased significantly.

Patients received prophylactic heparin treatment before the procedure but one patient had stroke due to mid-cerebral artery thrombosis despite prophylaxis. Though the patient consulted to Division of Pediatric Haematology of Istanbul University and treatment of the patient started immediately, muscle weakness of the patient was permanent. Thromboembolism is a rare complication of transcathatery ASD closure procedure but may lead to serious results and permanent damages in patients which is more oftenly seen in adult patients. Abacı A. et al (20) indicated thromboembolic diases as the most common complication of transcathatery ASD closure complication and in their study 1,3% of adult patients had cerebrovascular disease after procedure.

Pericardial effusion that responds well to anti-inflammatory drugs were seen in one patient and categorized as minor complication. The patients was full recovered after a year of medical therapy. Wilson N. J. et al (25) studied 227 patients which included both adults and children also remarked one patient with pericardial effusion. Some studies in literature also indicated complications like haematoma in procedure area, press on sciatic nerve, nicel hypersensitivity, atrio-ventricular fistula, cardiac tamponade, cardiac perforation; which none of them were seen in our patients. (12, 25, 26)

The brands of the devices used for the procedure are Amplatzer", "Occlutech", "Solysafe", "Sera Occluder" and "Biostar". The most used brands in our clinic are "Amplatzer" and "Occlutech". We compared the complications rates of each brands with each other and there was no statistical significance. Also in another clinical study compromised on 110 chilren "Occlutech" compared with "Amplatzer" and assesed similar results both with each two brands (27).

The mean follow up period of patients in total and after procedure in our clinic were $57,38 \pm 50,83$ months and $36,58 \pm 34,20$ respectively; also maximum follow-up durations were 208 months and 117,1 months respectively. A group of patients who were consulted for procedure from other clinics, continued their follow-ups in the clinics they referred from after the procedure. That's why the follow-up periods after procedure is calculated shorter. There was no other study included only child patients as broad in scope as ours in literature. Thats's why we couldn't compare the follow-up periods with other researches.

The defect diameters calculated by ECO, TEE and balloon sizing were statistically positively correlated with each other and there were no statistically significant difference between genders. Also there were no statistical difference between gender specific complication rates. Major and minor complication rates in both genders were similar.

In literature we came across to plenty of studies which compared the brands of ASD closure devices, their performance on large defects and complication rates. However most of these studies were supported or sponsored by the device brands. In our study five different device brands were used in the procedures of 186 cases. In his review, Daniel De Wolf (28) stated that “CardioSEAL/STARflex” devices has higher risk of device embolisation which is supported by our study too. In another study Kim A. Y. et al. (29) compared “Amplatzer” with “Occlutech” and “Gorehelex” devices and their mid-term experiences and they found “Occlutech” and “Gorehelex” devices were safe as “Amplatzer” devices. Complication rates of the devices in this study were close to our study and there were no statistically significant difference between brands. Roymanee S. et al. (30) compared succes rates and complications of “Amplatzer” and “Occlutech” devices in their study and both of these brands were the most frequently used devices in our study too. They found both devices safe and effective for transcathatery closure of ASD like we did.

Our study also has some limitations; as our study is a retrospective, some of patient files were unavailable or soma data was missing so these patients excluded from the study.

All in all our study is unique as our study has one of largest child population in literature. Also we reviewed the literature and we found no studies which has only child case population and has long follow-up period as long as like ours.

Conclusion

The rate of congenital heart diseases is increasing and this present as an important public health problem. As a conclusion, we found that the measurements performed by TTE, TEE and balloon sizing were compatible with each other and device type did not change the complication rates in long term follow-up in children and also more comprehensive studies are needed on this topic.

List Of Abbreviations

ASD : Atrial Septal Defect

ECO: Echocardiography

TTE: Transhoracic echocardiography

AV: Atrioventricular

IVC: Inferior vena cava

SVC: Superior vena cava

TEE: Transesophageal echocardiogram

Declarations

Declaration of Interests:

The authors declare that they have no competing interests. We have no funding to declare.

Authors' contribution:

KN contributed to study by statistically analyzing qualitative and quantitative data collected. Collection and interpretation of data was accomplished by YSO. All authors read and approved the final manuscript.

Acknowledgements:

Not applicable.

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YSO is social pediatrics PhD student in Istanbul University, Faculty of Medicine and especially interested in public health.

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Figures

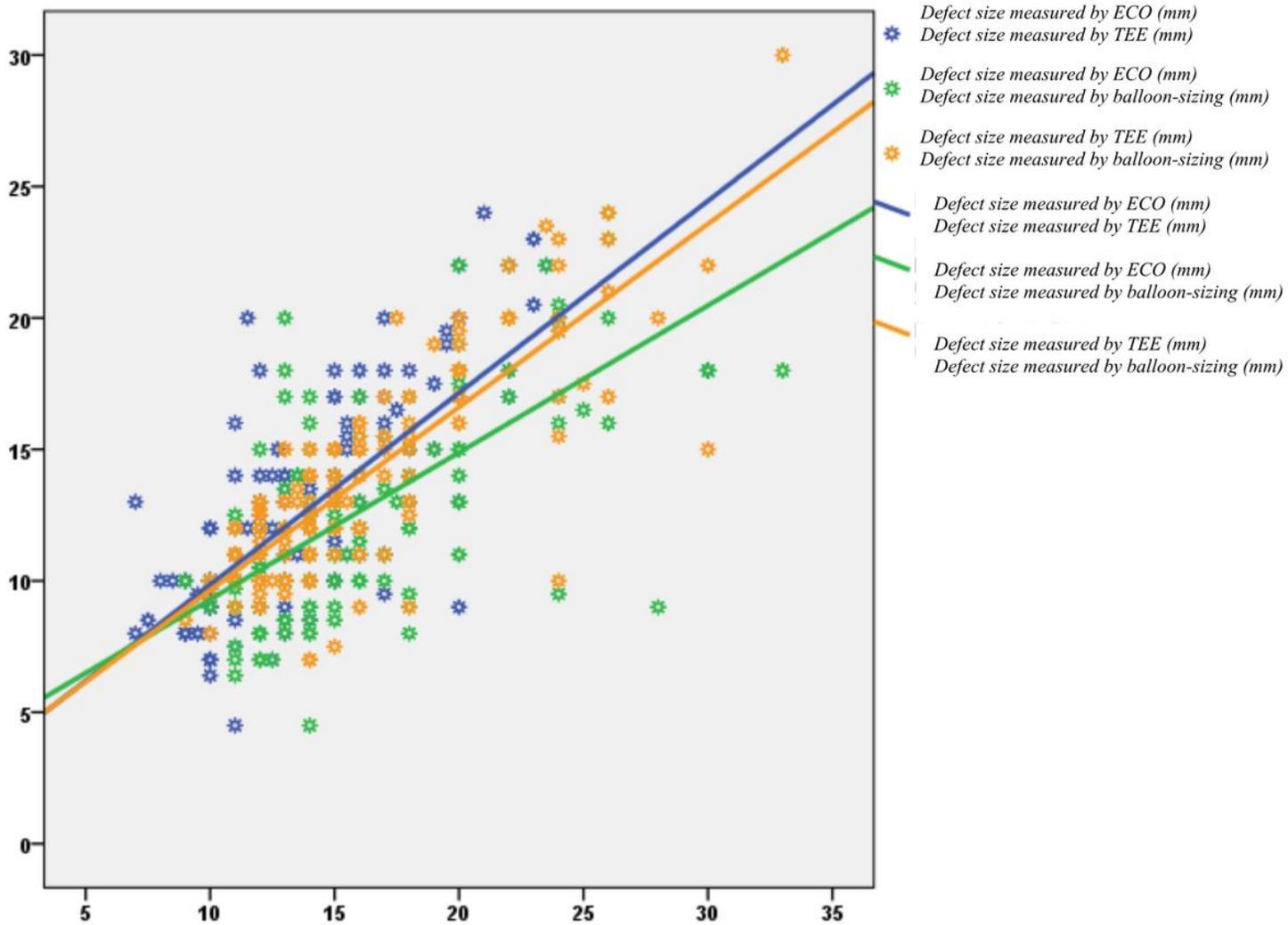


Figure 1

Distribution of Defect Sizes Measured by ECO, TEE and Balloon Sizing