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Surgery for complications of trans-catheter closure of atrial septal defects: a multi-institutional study from the European Congenital Heart Surgeons Association[☆]

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Abstract

Objective: This study aims to analyse the collective experience of participating European Congenital Heart Surgeons Association centres in the surgical management of complications resulting from trans-catheter closure of atrial septal defects (ASDs). **Methods:** The records of all ($n = 56$) patients, aged 3–70 years (median 18 years), who underwent surgery for complications of trans-catheter ASD closure in 19 participating institutions over a 10-year period (1997–2007) were retrospectively reviewed. Risk factors for surgical complications were sought. Surgical outcomes were compared with those reported for primary surgical ASD closure in the European Association of Cardio-thoracic Surgery Congenital Database. **Results:** A wide range of ASD sizes (5–34 mm) and devices of various types and sizes (range 12–60 mm) were involved, including 13 devices less than 20 mm. Complications leading to surgery included embolisation ($n = 29$), thrombosis/thrombo-embolism/cerebral ischaemia or stroke ($n = 12$), significant residual shunt ($n = 12$), aortic or atrial perforation or erosion ($n = 9$), haemopericardium with tamponade ($n = 5$), aortic or mitral valve injury ($n = 2$) and endocarditis ($n = 1$). Surgery (39 early emergent and 17 late operations) involved device removal, repair of damaged structures and ASD closure. Late operations were needed 12 days to 8 years (median 3 years) after device implantation. There were three hospital deaths (mortality 5.4%). During the same time period, mortality for all 4453 surgical ASD closures reported in the European Association of Cardio-Thoracic Surgery Congenital Database was 0.36% ($p = 0.001$). **Conclusions:** Trans-catheter device closure of ASDs, even in cases when small devices are used, can lead to significant complications requiring surgical intervention. Once a complication leading to surgery occurs, mortality is significantly greater than that of primary surgical ASD closure. Major complications can occur late after device placement. Therefore, lifelong follow-up of patients in whom ASDs have been closed by devices is mandatory.

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1. Introduction

Surgical repair of all types of atrial septal defects (ASDs) has been practised since the dawn of cardiac surgery in the 1950s with a large accumulated experience documenting nearly 100% efficacy, near zero mortality, minimal and only short-term morbidity, and, with the introduction of less invasive surgical techniques, improved cosmetic results [1,2]. Long-term complications are practically absent, leading to the American Heart Association/American college of Cardiology (AHA/ACC) recommendation that patients with surgically repaired secundum ASDs do not require follow-up in specialised centres [3].

Over the past decade, trans-catheter closure of ASDs by means of the percutaneous deployment of a variety of occluder devices, which avoids open-heart surgery and its associated (albeit minimal) mortality and morbidity, has been increasingly practised. In fact, it has been shown that the number of ASDs closed by means of catheter-delivered devices has risen dramatically, raising the question of whether the introduction of percutaneous closure may be driving use [4]. On the one hand, although many published series of trans-catheter ASD closure have shown high rates of successful closure, a low incidence of complications and favourable comparison to surgical closure in non-randomised comparison [5–7], the seriousness of the device-related complications has not been adequately described.

On the other hand, there is increasing concern, particularly in the surgical literature, regarding accumulating reports from various centres of death or major complications, both early and late [8–25] after percutaneous ASD closure, necessitating surgical intervention. Given the absence of and apparent impossibility of setting up a multicentric, prospective and randomised study, which would ensure optimal comparison of the safety and effectiveness of surgical and trans-catheter ASD closure, we sought to document and analyse the recent collective experience of participating European Congenital Heart Surgeons Association (ECHSA) centres in the management

of those complications of trans-catheter ASD closure, which have required surgical intervention.

2. Materials and methods

The study is a 10-year retrospective review of all operations performed in the 19 participating institutions (Table 1) to manage complications of trans-catheter ASD closure in paediatric or adult patients. The records of all 56 patients who had such surgical intervention between January 1998 and December 2008 were reviewed. Patients who had elective surgical closure of an ASD after prior failure of trans-catheter closure attempt (during which the device had been removed uneventfully) were excluded.

The European Association for Cardio-Thoracic Surgery (EACTS) Congenital Database was queried for the number of primary surgical ASD closures performed over the same time period, and the corresponding operative mortality was determined and compared with that observed in the study population using Fisher's exact test (GraphPad Software, Inc., La Jolla, CA, USA).

3. Results

Of the 56 patients, 32 (57%) were female. Median age was 18 years (range 3–74 years), and they included 29 children (median age = 8.5 years, range 3–18 years) and 27 adults (median age = 43 years, range 18–74 years).

The size of ASDs ranged from 5 to 34 mm (median = 18 mm) as had been measured by transthoracic echocardiograms. Eleven defects were smaller than or up to 10 mm in diameter. A variety of device types were used (Table 2), ranging in size from 12 to 60 mm (median = 27.5 mm). Thirteen devices were smaller or equal to 20 mm in diameter.

Complications leading to surgery are listed in Table 3 and included embolisation (i.e., complete dislodgement of the ASD device into any part of the cardiovascular system),

Table 1
Participating investigators and European Congenital Heart Surgeons Association centres.

| Investigator | Centre |
|-----------------------|---|
| Emre Belli | Marie Lannelongue Hospital, Paris, France |
| Hakan Berggren | Children's Heart Center, The Queen Silvia Children's Hospital, Gothenburg, Sweden |
| Thierry Carrel | University of Berne, Berne, Switzerland |
| Juan Comas | Pediatric Heart Institute, Madrid, Spain |
| Antonio Corno | Alder Hey Royal Children's Hospital, Liverpool, United Kingdom |
| Willem Daenen | University of Leuven, Linden, Belgium |
| Duccio di Carlo | Ospedale Pediatrico Bambino Gesù, Roma, Italy |
| Tjark Ebels | Univ. Medical Center, Groningen, Netherlands |
| Leslie Hamilton | Freeman Hospital, Newcastle, United Kingdom |
| Victor Hraska | German Pediatric Heart Center, St. Augustin, Germany |
| Jeffrey Jacobs | The Congenital Heart Institute of Florida, St. Petersburg, Florida, USA |
| Jose Fragata | Hospital De Santa Marta, Lisbon, Portugal |
| Stojan Lazarov | National Heart Hospital, Sofia, Bulgaria |
| Constantine Mavroudis | The Children's Memorial Hospital Chicago, Illinois, USA |
| Dominique Metras | Hospital De La Timone Enfants, Marseille, France |
| Jean Rubay | Clinique Universitaires Saint-Luc, Brussels, Belgium |
| George Sarris | Mitera Pediatric and Hygeia Hospitals, Athens, Greece |
| Christian Schreiber | German Heart Center, Clinic at the Technical University, Munich, Germany |
| Giovanni Stellin | University of Padova, Padova, Italy |

Table 2
Summary data of ASD occluder devices used.

| Device type | No. of devices | Size range |
|------------------------|----------------|-------------|
| Amplatzer | 29 | 12–40 |
| Cardio-seal/Starflex | 14 | 23–43 |
| Sideris | 8 | 50–60 |
| Das Angel Wing | 1 | Unavailable |
| ASD Star 2036 (Cardia) | 1 | 36 |
| Helex | 1 | 25 |
| Not specified | 3 | Unavailable |

thrombosis (formation of thrombus on the device), thrombo-embolism (i.e., embolisation of thrombotic material originating on the ASD device), transient cerebral ischaemia or stroke, incomplete ASD closure with significant residual shunt, atrial and/or aortic injury or erosion, haemopericardium with tamponade, aortic or mitral valve injury and endocarditis. Several patients had multiple complications, such as aortic and mitral erosion or perforation accompanied by tamponade, or device embolisation and thrombo-embolism/cerebral ischaemia.

Of the 56 operations performed, 39 (70%) were early and most also emergent operations, taking place, in most cases, immediately after the catheterisation procedure and no later than 24–48 h, and during the same hospitalisation. The remaining 17 (30%) operations were late, and of those, four (25%) were emergent. The time interval between device implantation and late surgery ranged from 12 days to 8 years (median = 3 years).

Early emergency operations (Table 4) were required to address device embolisation ($n = 22$), thrombo-embolism, cerebral ischaemia or stroke ($n = 4$), haemopericardium ($n = 5$) due to atrial or aortic injury including (in three cases)

Table 3
Complications leading to surgery.

| Complications | |
|--|----|
| Embolisation | |
| Right atrium | 1 |
| Tricuspid valve | 2 |
| Right ventricle | 2 |
| Pulmonary artery | 3 |
| Left atrium | 12 |
| Left ventricle | 6 |
| Aorta | 1 |
| Iliac artery | 2 |
| Total | 29 |
| Incomplete ASD closure | 12 |
| Thrombo-embolism cerebral ischaemia/stroke | |
| Stroke | 6 |
| Transient ischaemic attack | 2 |
| Thrombosis/other thrombo-embolism | 4 |
| Total | 12 |
| Tamponade | |
| Aortic perforation or erosion | 5 |
| Atrial perforation or erosion | 4 |
| Unknown second ASD | 2 |
| Endocarditis | 1 |
| Mitral valve injury | 1 |
| Aortic valve injury | 1 |
| Oesophageal perforation | 1 |

Table 4
Complications addressed by early emergency surgery (during same hospitalisation).

| Complications | |
|--|----|
| Embolisation | |
| Right atrium | 1 |
| Tricuspid valve | 2 |
| Right ventricle | 2 |
| Pulmonary artery | 3 |
| Left atrium | 7 |
| Left ventricle | 5 |
| Aorta | 1 |
| Iliac artery | 1 |
| Total | 22 |
| Incomplete ASD closure | 6 |
| Thrombo-embolism/cerebral ischaemia/stroke | 4 |
| Haemopericardium | |
| Aortic perforation | 3 |
| Atrial perforation | 2 |
| Total | 5 |
| Tamponade | 3 |
| Unknown second ASD | 2 |
| Endocarditis | 1 |
| Oesophageal perforation | 1 |

cardiac tamponade, significant residual shunt ($n = 6$), early endocarditis ($n = 1$) and oesophageal perforation ($n = 1$). In two patients, a previously undiagnosed significant second ASD was found. Although the two operations to close these unsuspected ASDs could possibly have been performed electively later, they were performed within 48 h and, accordingly, they were included in the early surgery group.

Late complications (Table 5) included embolisation or dislocation to the LA ($n = 8$), thrombo-embolism and cerebral ischaemia or stroke ($n = 8$), cardiac erosion (aortic or atrial) in four patients, of whom two suffered cardiac tamponade, aortic valve ($n = 1$) or mitral valve injury ($n = 1$) and incomplete ASD closure with significant residual shunt ($n = 6$).

All operations involved removal of the device, closure of the ASD (by direct suture in 16 patients and by patching in all others) and repair of the damaged cardiac structure,

Table 5
Complications addressed by late surgery (after initial hospital discharge).

| Complications | TOTAL |
|--|-------|
| Dislocation to LA/embolisation | |
| Left atrium | 5 |
| Left ventricle | 1 |
| Iliac artery | 1 |
| Total | 7 |
| Thrombo-embolism/cerebral ischaemia/stroke | 8 |
| Cardiac erosion | |
| Atrial erosion | 2 |
| Aortic erosion | 2 |
| Total | 4 |
| Tamponade | 2 |
| Mitral valve injury | 1 |
| Aortic valve injury | 1 |
| Incomplete ASD closure | 6 |

Table 6
Complications noted after surgery.

| Complications | |
|------------------------------|---|
| Pericardial effusion | |
| Treated medically | 4 |
| Required drainage | 1 |
| Total | 5 |
| Pleural effusion | 2 |
| Pneumothorax | 1 |
| Haemolysis | 2 |
| Endocarditis | 1 |
| Permanent pacemaker | 1 |
| Supraventricular arrhythmias | 1 |

including closure of cardiac perforations (right atrium, left atrium or aorta), and repair or replacement of the aortic ($n = 1$) and the mitral ($n = 1$) valves.

Three patients died (operative mortality 5.4%). The causes of death were embolisation of a 27-mm device into the left ventricle in a 66-year-old patient, thrombo-embolism with resulting major stroke in a 70-year-old patient and cardiac perforation/tamponade in a 48-year-old patient. In all three cases, at emergency surgical intervention, the devices were removed and the cardiac defects repaired, but death ensued by the third post-operative day in the intensive care unit.

Of the complications noted after surgery (listed in Table 6), the most common was pericardial effusion requiring drainage ($n = 4$), and also included one case of persistent major neurologic deficit and one case of complete heart block in a 5-year-old patient (in whom an Amplatzer Septal Occluder device had embolised to the left ventricle) necessitating placement of a permanent pacemaker.

Median stay in the ICU was 1 day (range 1–5 days) and median hospitalisation was 8 days (range 2–52 days).

During the same time period, in 4453 unselected patients who had undergone surgical secundum ASD closure (by patch or direct suture) and reported in the EACTS Congenital Database, mean operative mortality was 0.36% ($p = 0.001$).

Median hospital stay in this group was 8 days ($p = \text{NS}$).

4. Discussion

Trans-catheter ASD closure has gained wide popularity because it obviates an open cardiac procedure with its rare but existing attendant risks and discomforts, including the unavoidable scar, and many reports document high success rates and low morbidity [5–7]. However, there are increasingly more frequent reports of serious complications of device ASD closures, including fatalities or major events necessitating surgical intervention [8–25]. Although the incidence of such complications seems low, consideration of the remarkably safe track record of surgical ASD closure over several decades mandates thoughtful analysis of such adverse events, with the purpose of assuring that early and late patient safety is not compromised unnecessarily during efforts to avoid long-established minimal surgical risks or discomfort. Ideally, surgical and percutaneous ASD closure should be directly compared by means of large multi-

institutional prospective and randomised studies. Such studies do not exist at the moment and it seems doubtful that they can be organised in the near future. These considerations led our Association to undertake the present retrospective multicentric study, in which we sought to document our collective experience with complications of device ASD closures that have necessitated surgical intervention in the authors' institutions.

Importantly, these data demonstrate that surgical complications can occur even after percutaneous closure of small ASDs using small devices. This finding contradicts the loosely held and unsubstantiated concept that small ASDs and small devices are risk free. Furthermore, serious complications were reported for all types of devices. The overall limited number of patients did not allow detection of any association between the size or type of device and the kind of complication.

It is noteworthy that ASD device-related complications leading to surgery do not necessarily occur early, that is, in the catheter lab or even during the same hospitalisation. In almost one-third of cases, they occurred late. The seriousness of these complications is out of proportion to the severity of the lesion treated and the established track record of its surgical management. Documentation of serious late complications supports the recommendation that, after trans-catheter closure, patients should remain under permanent surveillance to detect potentially serious long-term device-related complications, in contrast to what is known for patients who have had successful surgical ASD closure (who do not require specialised long-term follow-up).

Furthermore, the finding that late complications most commonly involve thrombo-embolism, cerebral ischaemia or stroke suggests defective and incomplete endothelialisation of currently available devices. The occurrence of late cardiac erosion by these metal-containing artificial devices placed in the beating heart lends support to efforts to develop more biocompatible, possibly absorbable ASD occluders.

Despite the significant life-threatening potential of these complications, their surgical management is successful in the majority of cases. Nonetheless, once a surgical complication does occur, its management is associated with significant mortality, which is higher than that of primary surgical closure of ASDs. Of course, this reported mortality is 'not' the mortality associated with device closure of ASDs. This latter figure could not be calculated in our study because it was not possible to identify all the cases of ASD device closures in the participating institutions as well as in the referring institutions, from which patients with late-presenting complications were referred. Of course, the objective of the study 'was not to directly compare the rates of safety and effectiveness of the catheter and the surgical approach' (which, as stated previously, would require a prospective randomised study), but rather to document the spectrum of the surgical complications that do occur after percutaneous ASD closure in our institutions and to analyse our clinical experience and the outcome of such secondary, 'salvage' surgical interventions.

To obtain a quantifiable measure of the seriousness of the surgical complications encountered, we compared the operative mortality noted in this series (5.4%) with the overall mortality reported for all unselected cases of surgical ASD reported in the EACTS Congenital Database during the

same time period (0.36%), and found the latter to have been significantly smaller. This comparison underscores the fact that, regardless of how infrequently surgical complications arise after device ASD closure, once they do occur, salvage surgery is associated with significantly more risk than observed in standard primary ASD closure.

In summary, this study demonstrates that device closure of ASDs can lead to serious complications, both early and, importantly, also late, regardless of the size or type of current devices. These complications may necessitate surgical intervention, which is highly effective, but is nevertheless associated with higher mortality than primary surgical ASD closure.

There are three major implications of our study, about which patients and families should be informed when the option of device closure of an ASD is discussed: First, surgical backup for percutaneous ASD closure must be available in the hospital to deal with potentially lethal acute complications. Second, and more important, lifelong follow-up of patients whose ASD has been closed by devices seems mandatory to detect potentially serious late device-related complications, whereas patients who have undergone surgical closure are considered cured and do not require specialised follow-up. Third, since cardiac erosion and thrombo-embolism are prominent causes of late complications of the currently available less-than-ideal devices, continued research in the direction of improved and possibly biodegradable occluders may hold theoretical promise for the prevention of these rare but serious long-term problems.

4.1. Limitations

The main limitation of the study stems from its retrospective nature which precludes comparison with an appropriate control group. On the one hand, since many of the study patients had device placement in other referring institutions, it was not possible to ascertain the 'denominator', that is, the undoubtedly much larger overall number of percutaneous ASD closures, which were performed during the same time interval without resulting in surgical complications. On the other hand, there is also considerable uncertainty regarding the 'numerator', as in the absence of follow-up information for the patients who had device ASD closure during the study period, the true incidence of 'late' device-related complications remains unknown.

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Appendix A. Conference discussion

Dr W. Gaynor (Philadelphia, Pennsylvania): This is becoming an increasing problem with devices in the heart. This situation with ASD devices is analogous to what our adult colleagues deal with, with stents in the coronary arteries where there is a known safe surgical treatment, and yet, the physicians, who are the gatekeepers, who decide to refer a patient for therapy, are also the ones who perform the therapy.

Therefore, the indications may change. Patients who are appropriate for one therapy may not be referred. And as in the adult world, whenever there is a problem, there is always a better stent. There is always something better that is going to be better, and they don't seem to acknowledge the potential long-term complications.

I think the important findings of this study are both the ongoing risk of late complications, particularly very severe complications, dislodgement and erosion and stroke, and as well, the high mortality associated with the surgical therapy to salvage these patients. And I think these findings need to be publicised to our medical colleagues.

It would be nice to have long-term follow-up studies of these from the cardiologists. I don't know that we'll ever get them, and, unfortunately, there will never be a randomised trial.

I have three questions for Dr Sarris. The first is late dislodgement. You would think and hope that these would heal into the septum. What was the latest dislodgement that you saw? Were they all in the earlier period or were they still five, six, seven year patients at risk for dislodgement?

And, two, given you call for long-term follow-up, but were these events sudden events? I mean, is there actually a type of surveillance that we can do? I mean, you may have an echo that looks fine 1 day and then erode through the atrium. Are there warning signs that were present in any of these patients?

And finally, do you think there is a safe period? If a patient survives 10 years or 15 years with this device, do you think that they are at lower risk for a complication?

Dr Sarris: Regarding the first question of dislodgements. The overall number of patients is not large to be able to say with certainty, but some of these dislodgements occurred, as I recall, 3 and 4 years after occurrence. So if a device is seated, it doesn't seem that that guarantees that it will stay there forever.

Now, follow-up was the other question, and can we do anything about it? Were these events sudden? I suspect that it would unfortunately be very difficult to detect gradual erosion that may, on a given day, cause rupture into the pericardium and tamponade. But perhaps some of the other complications may show something on careful follow-up, for example, the development of thrombus and subsequent stroke.

The occurrence of a stroke 5 years after an uneventful device placement in a child is a very major event, but most patients are not on long-term

anticoagulation after these devices. Probably most patients have a short-term period of anticoagulants and then nothing.

Perhaps if development of thrombus is detected on a device, these patients should then be placed on permanent anticoagulants or perhaps plans should be made for removal of this device if the thrombus does not resolve or grows.

And so your last question pertained to?

Dr Gaynor: Do you think that with long-term follow-up, there is an interval? If we say that the child is 10 or 15 years, it's safe then?

Dr Sarris: I think we do not have this information. It would be ideal, in a multidisciplinary type approach, as we discussed in the previous session, if we could set up a prospective study directly comparing surgery and device closure in terms of safety, efficacy, and long-term outcome.

And really, I think this study indicates that follow-up ought to be quite long, at least 10 years because some of these complications occurred 8 years later. A lot of the ASD device implantation studies that have been published report success in low rate of complications but with really no follow-up or no lengthy follow-up.

Dr J. Amato (Chicago, Illinois): I'm aware through the literature and personally of at least two or three complications in the United States that have occurred such as erosions into the aorta or wall of the atrium because of a device being used inappropriately.

Unfortunately, the cardiologists give all of the nice things about 1-day hospital stay, no scar and so forth, but they don't tell the downsides of the device.

There is a booklet and CD that the Amplatzer company gives to the cardiologist to give to the patient that should be read by the patient prior to the placement of the device. For example, you need a 5 mm rim to put that device in accurately.

So I just wanted to lay caution to the fact that cardiologists do not give the downsides of the device. And that booklet and CD are available to all of the patients who are going to receive a device like that.

Dr Y. Yalcinbas (Istanbul, Turkey): The data is accumulating regarding the complications of these devices. For example, Dr Karamlou and colleagues presented a paper regarding the increased use of devices at the 2009 AATS Congress. Your presentation was very important for people who are doing these procedures and will help them to realise that there might be increased risks.

So do you think the interventional paediatric cardiologists or cardiologists will decrease the number of procedures after these data, or should we have new definitions to implant these devices?

Dr Sarris: I think this sort of study will certainly increase the awareness of the possibility of occurrence potentially very harmful device-related long-term effects. I hope it will have the effect of more caution being used in selecting patients for device closure.

But I really don't have a way to answer this question except to express my feeling that this study will not change current cardiology practice unless there is a cooperative effort between surgical and cardiology academic bodies to study this matter in a prospective fashion and come up with very strict guidelines about which devices ought to be used and when.