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Current Status of Percutaneous Closure of Ventricular Septal Defects

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Introduction

Traditionally, closure of ventricular septal defects (VSDs) has been a surgical procedure, however in 1988 Lock et al. [1] ushered in the era of percutaneous ventricular septal defect closure when they reported on the results of transcatheter VSD closure using the Rashkind double umbrella device in six patients with congenital and acquired VSDs. These investigators also reported on the technique of using an arteriovenous wire loop as part of the closure that is still in use today. Since their initial report, multiple devices other than the Rashkind device have been used to close VSDs including devices that are specifically designed for this purpose. Percutaneous VSD closure has therefore become an acceptable alternative to surgical closure of muscular, traumatic, post-operative residual and post-infarct VSDs. Transcatheter device closure remains controversial for perimembranous VSDs however secondary to the risk of heart block. The purpose of this paper is to report on the current status of percutaneous closure of VSDs.

Ventricular septal defects are one of the most common forms of congenital heart defects accounting for approximately 20% of defects in isolation. VSDs may occur anywhere within the ventricular septum. Approximately 70-80% of defects are perimembranous (also called membranous or infracristal) in location with 5-20% being muscular in nature [2,3]. Outlet defects (infundibular, supracristal, subpulmonary or doubly committed subarterial) account for 5-7% of all VSDs. Inlet VSDs constitute another 5-8% of VSDs, however these are not amenable to transcatheter closure since there is no supporting tissue between the margins of the defect and the atrioventricular valve tissue.

In addition to congenital VSDs, VSDs can be acquired and result from trauma or following a myocardial infarction. VSDs complicating myocardial infarction occur in 0.2% of patients in the thrombolytic era and are associated with a very high mortality rate [4]. Traumatic VSDs have only rarely been reported and reports of percutaneous closure are scarce [5,6].

The technique of percutaneous VSD closure has been reported in detail previously [1,7-11]. A brief description can be seen in Figures 1 & 2.

Multiple devices have been used to close VSDs including the Rashkind double umbrella device, CardioSEAL device (NMT Medical, Boston, MA, USA), STARFlex device (NMT Medical, Boston, MA, USA), coils, Amplatzer Muscular and Membranous VSD device, Amplatzer Septal Occluder and the Amplatzer Duct Occluder and the Duct Occluder II (St. Jude Medical, Inc. St. Paul, Minnesota, USA) as well as Chinese symmetrical and asymmetrical occluders (Shanghai Memory Alloy Materials Co., Ltd, China and Huayishengjie Medical Corp., Beijing, China) which are variations of the Amplatzer devices [1,11-20]. The most extensive experience in North America and Europe is with the Amplatzer family of devices. The use of the Chinese devices is most commonly reported from China itself. The description of the various devices is included in the above references.

Currently in the United States the only FDA approved available device that is specifically designed to close VSDs is the Amplatzer Muscular VSD device. The Amplatzer Post Infarct VSD device is available on a compassionate use basis. The Amplatzer Perimembranous VSD device underwent a clinical trial in the US [21], however concerns regarding the development of complete heart block prevented the device from ever receiving FDA approval. The other devices listed above are either not available in the US or must be used off label.

Review

The results of transcatheter VSD closure have previously been summarized by Carminati et al. [11] who reviewed 12 papers published until 2006 and in addition reported the results of the European VSD registry. The papers reviewed by these authors reported technical procedural success rates of 87-100% with major complication rates of 0-15% and the need for pacemaker implantation in 0-8% of patients. The investigators also reported on 430 patients collected on an intention-to-treat basis from 23 tertiary referral centers as part of a registry. The patients included 119 muscular, 250 membranous, 16 multiple, and 45 post-operative residual VSDs. A variety of devices were used for VSD closure. The overall procedural success was 95.3%. There were early complications in 55 patients (12.7%) with significant complications in 28 patients (6.5%). One death was reported (0.2%) with vascular complications in 0.7%, hemolysis in 1.2%, infection in 0.5%, and device embolization in 0.9%. Tachyarrhythmias occurred in 3 patients (0.7%) with early complete heart block (CHB) in 12 patients (2.8%). Of the CHB patients, 6 developed the CHB during the procedure and in 2 of these the procedure was terminated and the patients were referred for surgical closure; the other 4 patients had devices implanted with restoration of sinus rhythm. Six additional patients developed CHB within 1 week of device implant and all of these patients received pacemakers. During the follow up period an additional 4 patients (0.9%) developed CHB from 4-18 months after device placement and all of these patients had received the Amplatzer Perimembranous VSD device. All 4 of these patients received pacemakers. Therefore a total of 10 patients (2.3%) received pacemakers. Complete closure of the VSD was achieved in 65% of patients by discharge and in 83% at a median follow up time of 2 yrs. The majority of the residual shunts were trivial or mild and only 3 patients (0.7%) were subsequently referred for surgery.

Complete heart block appears to be age related. Butera et al. [22] reported on 104 patients who underwent perimembranous VSD device closure at a single institution. Nine patients developed CHB with

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pacemaker implantation in 6. Multiviarate analysis demonstrated that age was a risk factor for CHB with a relative risk of 0.25. CHB was only noted to occur in children < 6 yrs of age.

Holzer et al. [23] reported the results of a large international registry of perimembranous VSD closure using the Amplatzer Perimembranous VSD device. One hundred patients were enrolled with procedural success in 93 (93%). Immediately after the procedure, complete closure was present in 58.1% of patients with ≤ 2 mm shunt in 98.7%. Adverse events were reported in 29 patients (29%) with the most common being arrhythmias in 13%. Transient CHB was noted in 2 patients and an additional 2 experienced CHB requiring pacemaker implantation. Therefore a total of 4% of patients experienced CHB with 2% requiring pacemaker implantation. These numbers are similar to those reported by Carminati et al. [11]. New or increased aortic regurgitation following the procedure was reported in 9.2% of patients, however in 4 patients this resolved during follow up and in 4 patients it was trivial or mild. New or increased tricuspid regurgitation was noted in 9.2% of patients following the procedure. This resolved in 3 patients

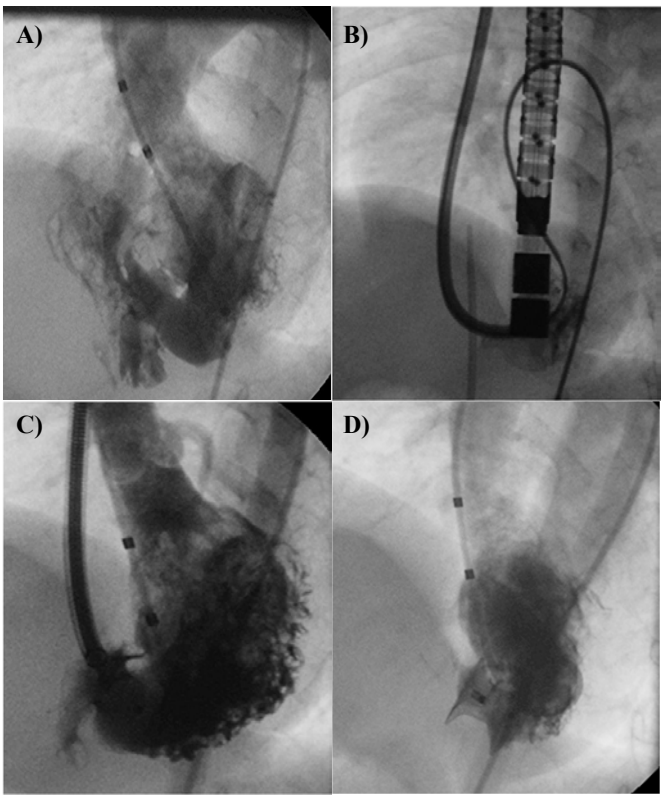

Figure 1: Steps in MVSD closure with the Amplatzer MVSD device.

(A) Left ventricular angiogram demonstrating a large apical muscular VSD. The VSD is crossed retrograde from the LV using a Judkins right catheter and a soft tipped wire which is advanced into the main pulmonary artery. The wire is snared in the main pulmonary artery from a right internal jugular vein approach and externalized forming an arteriovenous wire loop.

(B) The delivery sheath is advanced from the RIJV through the VSD and into the LV. The wire is removed.

(C) The defect is measured using transesophageal echocardiographic and angiographic measurements and a device 1-2 mm larger than the defect is chosen and advanced through the sheath and deployed across the VSD.

(D) The device is released from the delivery system and a repeat angiogram demonstrates appropriate placement of the device within the defect.

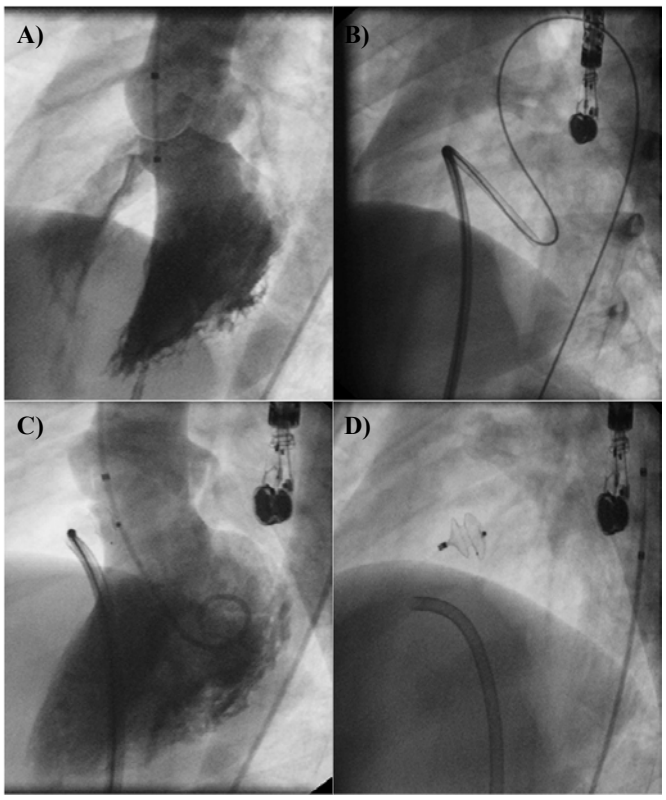

Figure 2: Steps in perimembranous VSD closure with the Amplatzer PMVSD device.

(A) Left ventricular angiogram demonstrating a perimembranous VSD. The defect is sized using angiography and TEE. The defect is crossed retrograde from the LV similar in a fashion to that described for Fig. 1

(B) An arteriovenous wire loop is formed from a femoral venous approach. As the delivery sheath is advanced across the defect the wire is prolapsed from the aorta into the LV so that the delivery sheath is placed in the apex of the ventricle.

(C) The device is loaded and advanced through the sheath and deployed in the defect under TEE guidance. The platinum marker on the LV disk should be pointing toward the apex of the LV. A left ventricular angiogram confirms appropriate device placement.

(D) The device is released from the delivery system. An aortogram is performed to assess for aortic insufficiency.

during follow up and was trivial or mild in 5 patients. In only 1 patient was there moderate or worse aortic or tricuspid regurgitation during a median follow period of 182 days.

Several very large series of percutaneous VSD closures have recently been reported from China [18,19,24,25] using either the Amplatzer devices or the Chinese symmetric and asymmetric occluders. Three of these papers are from the same institution and it is impossible to tell if some patients are being duplicated. The total number of patients reported is 2079 with the majority of the patients having perimembranous VSDs. The procedural success ranged from 94.9% to 99.8% with an overall success rate of 98.6%. The amount of residual shunt > 2mm during follow up ranged from 0% to 4.7%. Adverse events were reported to occur in 2.5% to 19.3% of patients with major complications ranging from 0.6% to 10.9%. Complete heart block occurred in 0.1% to 7.6% of patients with the vast majority being transient or responding to steroid therapy. Pacemakers were implanted in 5/2079 patients (0.2%) in these studies.

Device closure of VSDs can also be accomplished from a perventricular approach [26,27]. This technique can be especially useful in small infants in whom the adverse event rate for percutaneous closure is much higher than in larger children. The focus of this review is on percutaneous closure therefore readers interested in the perventricular approach are referred to the above references for additional details.

Post infarct VSDs (PIVSD) have a particularly poor prognosis with mortality rates for medically treated patients of 94% at 30 days post infarct and 97% at 1 yr post infarct [4]. Survival following surgical repair is likewise quite poor with mortality rates of 47% at 30 days and 53% at 1 year post infarct [4]. The results of transcather PIVSD closure compares favorably with surgical VSD closure and therefore transcatheter VSD closure has emerged as a reasonable alternative to surgical management in these patients [28-32]. Holzer et al. [30] reported on the results of the US registry for the Amplatzer PIVSD device. Device placement was attempted in 18 patients with a procedural success rate of 89%. It was used in 5 patients in the acute post-infarct setting and 13 patients in the subacute phase. The overall 30 day mortality was 28%. Twenty percent of patients had a moderate or large shunt on follow up. Thiele et al. [31] reported on attempted placement of a percutaneous device (Amplatzer muscular VSD, PIVSD, and atrial septal occluders) in 29 patients in the acute setting of a myocardial infarction. Cardiogenic shock was present in 55% of the patients. The procedural success rate was 86%. The overall survival rate at 30 days was 35% with a mortality rate in the cardiogenic shock group of 88% versus 38% in the non -shock group.

Conclusion

Percutaneous VSD closure is now an acceptable alternative to surgical closure of VSDs with very high procedural success rates. The overall rate of residual shunting is quite small and decreases with time with the vast majority of residual shunts being trivial or small and not hemodynamically significant. The adverse event rate remains significant, however the majority of the complications are minor. Significant adverse events continue to occur however and the problem of complete heart block, especially for perimembranous VSDs, is significant. Device modifications are currently underway and may result in a decreased incidence of CHB. Late CHB is an unpredictable complication that requires vigilance to detect and treat appropriately.

The era of percutaneous VSD closure has evolved significantly since Lock et al. [1] initial description of the procedure. Continued improvements in both the devices available as well as the technique of implantation are likely to result in decreases in complication rates and further improvements in procedural outcomes.

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