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TECHNIQUE

Occlusion of congenital ventricular septal defects by the buttoned device

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Abstract

***Objectives*—To study the feasibility of congenital ventricular septal defect occlusion by the buttoned device and to establish guidelines for its safe and effective application.**

***Design*—A descriptive study of all patients with a congenital ventricular septal defect undergoing transcatheter occlusion with the buttoned device, from March 1994 to May 1995. These patients were otherwise candidates for elective surgery at their institutions because they had persistence of a significant shunt (Qp:Qs = 1·5–2·1:1, median = 1·7), with left ventricular enlargement and/or symptoms, although their systolic pulmonary artery pressure was invariably normal (20–28 mm Hg, median = 25). The angiographic diameter of the defect ranged from 2·5 to 14 mm (median 6 mm).**

***Setting*—A multi-institutional study.**

***Patients*—Out of 25 cases attempted, 18 children and adults aged 4–35 years had devices implanted. Fifteen of these patients had membranous ventricular septal defects and three had muscular defects. All patients with a membranous ventricular septal defect had an associated aneurysm of the membranous septum.**

***Interventions*—The buttoned device was introduced either directly or, in the last 12 cases, over a wire bridging the femoral artery and the femoral or jugular vein; the devices were delivered through 7–9 French (F) long sheaths. A membranous defect was regarded as suitable for device closure if the distance from the centre of the defect to the insertion of the right coronary aortic valve leaflet was more than 50% of the size of the required device. The device was guided by echocardiography and fluoroscopy. All muscular defects were corrected through the right jugular vein and all membranous ones through the femoral vein.**

***Results*—All 18 patients underwent initial successful implantation of the device. In thirteen patients the shunts were completely occluded and in the remaining five there were trivial residual shunts. In two patients with membranous ventricular septal defects a change from the original position was noticed at two weeks; mild aortic regurgitation developed in one and the murmur recurred in the other; the devices had to be removed surgically. One patient developed transient third degree atrioventricular block during implantation; no tricuspid regurgitation was observed.**

***Conclusion*—Clinical occlusion of congenital ventricular septal defects was achieved in 16 out of the 18 attempted cases (13 full occlusions). Membranous ventricular septal defect occlusion can be effective and safe if patients and device sizes are carefully selected.**

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Keywords: septal defects; buttoned device

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The buttoned device has been used extensively to occlude atrial septal defects[1–3] and patent ductus arteriosus[4] since 1988. We describe the extension of its application to the occlusion of ventricular septal defects. Occlusion of a defect of the muscular ventricular septum is anatomically relatively straightforward, because the defect does not lie near the critical structures (fig 1); therefore successful occlusion of muscular ventricular septal defects was reported early.[5–7] A membranous ventricular septal defect is more difficult to close safely by transcatheter means because of its proximity to critical structures (aortic valve, tricuspid valve), the lack of a sufficient rim, and its relatively large size in small children. Attempts at transcatheter occlusion of membranous defects using a modification of the Rashkind device were technically successful but clinically disappointing.[8] The buttoned device[9] may have some advantages over other devices for the occlusion of ventricular septal defects. These include its availability in various sizes which can be introduced through small sheaths; the ability of the occluder to be manoeuvred away from critical structures; and the fact that the counter-occluder is thin and is unlikely to interfere with the tricuspid valve. Furthermore the recent development of over-the-wire placement allows even greater device manoeuvrability. Because our goal was not the

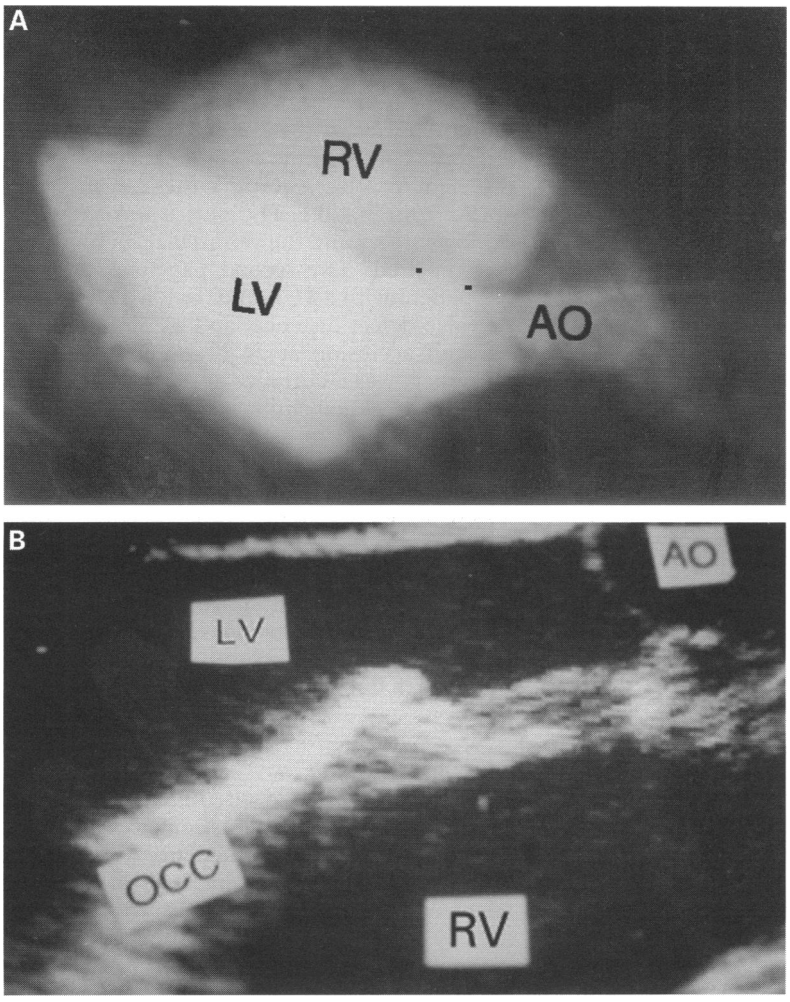

Figure 1 Occlusion of an outflow muscular ventricular septal defect in a 17 year old patient with a 2·5:1 pulmonary-systemic flow ratio. (A) Left ventricular angiogram shows the defect (dots) in the outflow muscular ventricular septum. (B) Transoesophageal long axial view showing the occluder well aligned with the septal surface of the left ventricular outflow. Ao, aorta; OCC, occluder; LV, left ventricle; RV, right ventricle.

palliation but the clinical occlusion of the defects, selection criteria were of great importance. In this study we describe the results of occlusion by the buttoned device of congenital ventricular septal defects in a selected group of patients.

Patients and methods

Between March 1994 and June 1995, 25 patients with congenital ventricular septal defects (five muscular and 20 membranous) were considered for transcatheter occlusion with the buttoned device (Custom Medical Devices, Athens, Greece). Thirteen of them were children or adolescents (4–17 years) and 12 were adults (18–51 years). All patients who participated in the study, or their parents, gave informed consent to an investigational protocol approved by their institution before being accepted in the study. These patients were otherwise candidates for elective surgery at their institutions because they had persistence of a significant shunt (Qp:Qs = 1·5–2·5:1, median = 1·7), with left ventricular enlargement and/or symptoms, although their systolic pulmonary artery pressure was invariably normal (20–28 mm Hg, median = 25). The angiographic defect diameter ranged from 2·5 to 14 mm (median 6 mm). Patients with malalignment type ventricular septal defects or with pre-existing aortic regurgitation were excluded. Echocardiographic screening was performed by transthoracic echocardiography, using the apical five chamber view. We considered as appropriate for entry into the study those membranous defects where the distance from the centre of the defect to the right coronary aortic valve leaflet was more than 50% of the size of the device required. The patients selected by the transthoracic echocardiography as good candidates underwent cardiac catheterisation and angiography. A left ventricular angiogram was performed in the long axis view (60 left anterior oblique, 30 cranial), and the size of the defect and the distance from the defect to the aortic leaflet were measured. None of the defects were balloon sized. Most patients underwent the procedure under sedation with the exception of eight patients who had general anaesthesia. Transthoracic[7] and transoesophageal echocardiography[9] were used in addition to fluoroscopy to guide device placement.

TECHNIQUE

A retrograde arterial right Judkins or modified Amplatz coronary catheter connected to pressure was used to cross the ventricular septal defect from the left ventricle. When entry into the right ventricle was verified by pressure recording and fluoroscopy, a 0·025 inch TSCF exchange wire (Cook, Bloomington, Indiana), was advanced into the pulmonary artery where it was snared to the appropriate vein (femoral for membranous defects or jugular for muscular defects). A Mullins type long sheath (Cook, Bloomington, Indiana) was then passed over the wire to just above the aortic valve (the position was verified by arterial pressure obtained with a transducer connected to the side-arm of the long sheath). The size of the long sheath varied from 7F to 9F depending on the size of the occluder used. In the last 12 cases the occluder was introduced over the exchange wire and all subsequent manipulations were done over the exchange wire. Other than these over-the-wire manipulations, buttoning and release of the device was done as described previously.[1] Echocardiographic guidance by transoesophageal or transthoracic approaches was used to demonstrate good alignment of the device without aortic or tricuspid valve encroachment (fig 1). For defects up to 4 mm in diameter the smallest device (15 mm) was used; for defects up to 8 mm a 20 mm device was used; for larger defects the criteria for device selection for atrial septal defects were used.[3]

FOLLOW UP

All patients were followed clinically and with electrocardiograms and echocardiograms and chest *x* rays for a period up to one year and nine months after implantation (median = one year).

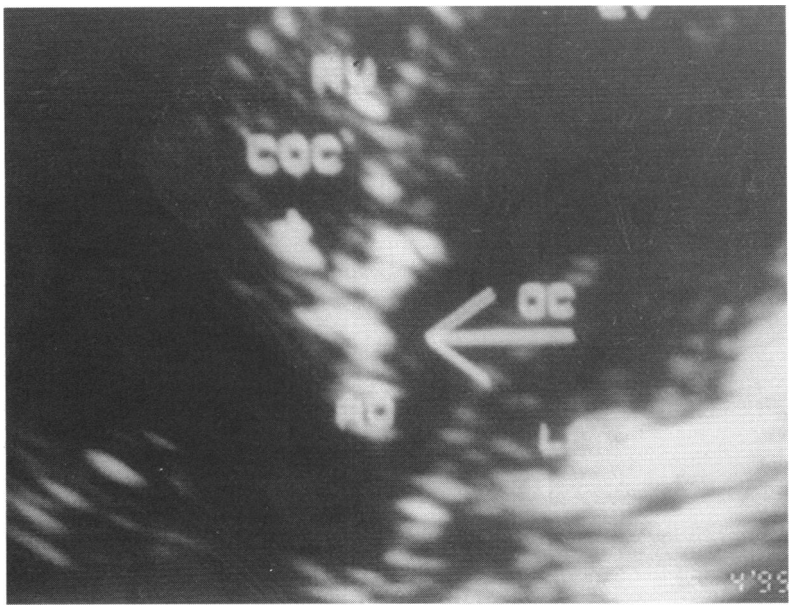

Figure 2 Modified apical five chamber view showing an occluder positioned in the associated aneurysm of a perimembranous ventricular septal defect. The device was close to the aortic valve but did not impinge upon it. Ao, aorta; OC, occluder; COC, counter-occluder; LA, left atrium; LV, left ventricle; RV, right ventricle.

Results

We failed to or decided not to implant a device in seven of 25 patients who we had intended to treat. In none of these cases was there release of the device. Two of the defects were low muscular (apical) and five were membranous. The apical defects were approached from the right jugular vein and the device could not be advanced through the sheath at the septal region. In three of the membranous defects, the occluder could not be manipulated into a good position and had to be withdrawn. In the last two cases the device (still connected to the loading wire) pulled through the defect and was removed.

Eighteen patients had devices implanted. The procedure lasted a mean of 2·5 hours and the fluoroscopy time ranged from 0 to 60 minutes (median = 35 minutes). Two patients received the smallest device (15 mm) and one patient with multiple muscular ventricular septal defects the biggest device (40 mm). The median device size was 25 mm. The defect size by angiography ranged from 2·5 to 14 mm (median = 6 mm); in one case with multiple muscular defects, the defect size could not be calculated accurately. Transient arrhythmias were common during placement. A 51 year old patient had transient third degree atrioventricular block and was left with a persistently prolonged P-R interval. In one patient the 25 mm occluder pulled through and was removed and the defect was recrossed and another 25 mm device was successfully implanted. Thirteen patients had immediate complete occlusion of their defects and five were left with trivial echocardiographic residual shunts. There was no evidence of tricuspid or aortic regurgitation and no persistence of significant arrhythmia. No patient developed haemolysis or vascular complications and all were discharged home within 24 to 48 hours. At the two week follow up studies the device had moved from its original position in two of the patients. In the first one, a 13 year old patient with a 10 mm defect and a 17 mm aortic valve-defect distance, a 35 mm device had been placed; two weeks later, the corner of the occluder encroached on the right coronary aortic cusp, causing mild aortic regurgitation. The device was extracted during surgery and the ventricular septal defect was repaired. The second patient, a 35 year old patient with a 10 mm defect, a 12 mm aortic valve-defect distance, and a 25 mm device, had full occlusion at 24 hours with no murmur; there was recurrence of the murmur and a moderate residual shunt at two weeks and the device appeared to have tilted and was therefore removed surgically and the defect closed. The remaining 16 patients were asymptomatic. Thirteen had complete occlusion and three continued to have a ventricular septal defect murmur with trivial shunts on echocardiography. The three with muscular defects with implanted devices had complete occlusion. Chest radiography showed no evidence of device wire fractures.

Discussion

Eighteen out of the 25 attempted cases with a congenital ventricular septal defect had a successful implantation; all patients with devices implanted appeared to have a good initial result. Very low muscular (apical) defects were difficult to cross with the long sheath, without kinking or narrowing of the sheath, which impedes easy device delivery.

Three of five muscular defects were occluded, which accords with results obtained by other investigators using different devices.[5-7] Indeed our three cases were remarkable by the absence of haemodynamic instability, hypotension, and the need for transfusions noted by the Boston group, probably because they were larger but also because the long sheaths used to deliver the devices are significantly smaller.[10]

Fifteen patients with membranous defects had devices implanted and two of these were removed surgically. We showed, by pulling two devices through the membranous defect, that angiographic estimation of the defect may result in undersizing as we have previously shown with atrial septal defect occlusion.[8] Balloon sizing was not performed in any of our cases because we did not want to prolong an already long procedure by one more step and there was concern that balloon sizing could disrupt the associated aneurysmal tissue. Indeed we thought that by using the largest allowed device we would easily exceed the device/defect ratio established during our experience with atrial septal defect occlusion.[11] Use of the largest allowed device was probably unwise because when we followed this rule we had our only case of aortic regurgitation; we now advocate selection of a device that is at least 2 mm smaller than the aortic valve-defect distance. A 30 mm device instead of the 35 mm used, may have avoided the observed aortic encroachment.

On an intention to treat basis our results with membranous defects are not quite as good as surgery in this group of patients and probably reflect a learning curve in terms of patient selection and procedure performance. However, surgery has a universal morbidity and also an incidence of residual shunts. Thirteen of the 15 patients in whom we implanted a device have an effective occlusion. Although three of these have a trivial residual shunt, the results in this group of patients are comparable to surgery.

We found no evidence of tricuspid regurgitation, haemolysis or thromboembolic episodes. A possible explanation for the absence of significant tricuspid regurgitation is the shape of the counter-occluder. The counter-occluder is a thin disc made with one wire which does not appear significantly to interfere with the tricuspid valve on the right side of the defect. The lack of observed haemolysis is probably related to the absence of sizeable residual shunts and the appropriate alignment of the device.

Our indication for the occlusion of membranous ventricular septal defects was the persistence of a significant shunt after early childhood in patients in whom surgery would otherwise have been planned. This indication is not as clear cut as for closure of ventricular septal defects in infancy.[1] Clearly there is concern that the persistence of a trivial residual shunt and a prosthetic device in three of the patients could increase their risk of endocarditis.

In conclusion, we found the occlusion of congenital ventricular septal defects by the buttoned device to be a feasible, effective, and safe treatment for a carefully selected subgroup of membranous and muscular defects. All double disc devices, including the buttoned device, have limitations for septal occlusion because they require large margins for stability which then results in the device encroaching on nearby critical structures. Better patient selection or different device design is needed to improve results and widen the applicability of transcatheter occlusion to ventricular septal defects.

Twenty eight patients with congenital VSDs have been repaired up to December 1996 (including the 18 reported here). Twenty three were membraneous. All patients were doing well and free from intervention at follow up (5–32 months).

1 Sideris EB, Sideris SE, Thanopoulos BD, Ehly RL, Fowlkes JP. Transvenous septal defect occlusion by the buttoned device. *Am J Cardiol* 1990;**66**:1524–6.
2 Lloyd TR, Rao PS, Beekman RH, Mendelsohn AM, Sideris EB. Atrial septal defect occlusion with the buttoned device (a multi-institutional trial). *Am J Cardiol* 1994;**73**:286–91.
3 Rao PS, Sideris EB, Hausdorf G, Rey C, Lloyd TR, Beekman RH, *et al.* International experience with secundum atrial septal defect occlusion by the buttoned device. *Am Heart J* 1994;**128**:1022–35.
4 Rao PS, Sideris EB, Haddad J, Rey C, Hausdorf G, Wilson AD. Transcatheter occlusion of patent ductus arteriosus with adjustable buttoned device. Initial clinical experience. *Circulation* 1993;**88**:1119–26.
5 Lock JE, Block PC, McKay RG, Baim DS, Keane JF. Transcatheter closure of ventricular septal defects. *Circulation* 1988;**78**:361–8.
6 Bridges ND, Perry SB, Keane JF, Goldstein SAN, Mandell V, Mayer GE, *et al.* Preoperative transcatheter closure of congenital muscular ventricular septal defects. *N Engl J Med* 1991;**324**:1312–7.
7 O'Laughlin MP, Mullins CE. Transcatheter closure of ventricular septal defect. *Cathet Cardiovasc Diagn* 1989;**17**: 175–9.
8 Rigby ML, Redington AN. Primary transcatheter umbrella closure of perimembranous ventricular septal defect. *Br Heart J* 1994;**72**:368–71.
9 Sideris EB, Walsh K, Chen C-R, Losay J. Occlusion of ventricular septal defects by the buttoned device: early international experience. *Cardiol Young* 1995;**5**:suppl 20.
10 Laussen PC, Hansen DD, Perry SB, Fox ML, Javorski JJ, Burrows FA, *et al.* Transcatheter closure of ventricular septal defects: haemodynamic instability and anesthetic management. *Anesth Analg* 1995;**80**:1076–82.
11 Rao PS, Langhough R, Beekman RH, LLoyd TR, Sideris EB. Echocardiographic estimation of balloon stretched diameter of secundum atrial septal defect for transcatheter occlusion. *Am Heart J* 1992;**24**:172–5.
12 Keith JD, Rowe RD, Vlad P. Surgery for ventricular septal defect. In: Heart disease in infancy and childhood. 3rd ed. New York: Macmillan, 1978:361–4.