A one-way, valved, atrial septal patch in the management of postoperative right heart failure

An animal study

Patients who undergo surgical repair of congenital heart defects that are characterized by hypoplastic right ventricle or pulmonary hypertension are at high risk for the development of postoperative right heart failure. To minimize this risk, a new one-way, valved, atrial septal patch was developed that serves as an artificial one-way foramen ovale. The feasibility of this device was tested in five dogs in which reversible right heart failure had been induced. Use of the one-way valved patch significantly improved right ventricular performance and reduced right ventricular hydrostatic pressures. The interatrial pressure gradient was reduced from 10 ± 3.5 mm Hg during right heart failure to 4.4 ± 1.4 mm Hg. When the device was opened, cardiac output increased significantly. This hemodynamic improvement was achieved at the expense of systemic arterial desaturation, which was, however, well tolerated. When the state of right heart failure was reversed, the one-way valved patch spontaneously closed, allowing no interarterial shunting. The results of this experimental trial suggest that this device can play a useful role in selected patients in whom postoperative right heart failure can be anticipated after surgical repair of certain congenital heart defects. (J THORAC CARDIOVASC SURG 1994;108:134-9)

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Patients who undergo an operation for the correction of congenital heart defects that are characterized by hypoplastic right ventricle (RV) or pulmonary hypertension are at a high risk for the development of right heart failure (RHF) because of decreased compliance of the RV.¹⁻³ The conventional treatment for RHF usually improves the patient's hemodynamic status, but there are some cases in which this is not sufficient.⁴⁻⁷

Patients with patent foramen ovale may be less prone to the development of RHF than those without a patent foramen ovale.⁸ In such patients, right-to-left atrial shunting may serve to unload the RV.⁹ It has been reported that the artificial creation of an atrial septal

defect in patients with RHF dramatically improved their hemodynamic state, but at the expense of desaturation of the systemic arterial blood.⁹⁻¹² The major disadvantage of this procedure, however, is that the iatrogenic damage to the interatrial septum must be corrected by a subsequent invasive procedure.

The need for this further procedure can be obviated by the use of a one-way, valved, atrial septal patch. The one-way valved patch serves as a patent foramen ovale and provides a right-to-left shunt at the atrial level, but prevents any left-to-right shunt. The feasibility and effectiveness of this new technique was studied in animals. This paper describes the new technique.

Materials and methods

Five mongrel dogs weighing 20 to 25 kg were anesthetized, intubated, and the lungs ventilated. All animals received humane care in compliance with the "Principles of Laboratory Animal Care" (NIH Publication No. 86-23, revised 1985).

The new device (Fig. 1) is fashioned from two layers of woven Dacron fabric. A central circular opening, 0.5 cm in diameter,^{13,14} is created in one of the layers. This opening is then covered by a second, smaller Dacron fabric layer, which is sutured to the first along one side only, creating the simple mechanism of a one-way valve. Two side stitches (Fig. 1, *second panel*) are

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Fig. 1. Device illustrated is composed of two layers of woven Dacron fabric: first layer (*top panel*) with 0.5 cm circular opening to which second smaller layer is sutured along one side only (*second panel*). *U* suture, which maintains device in locked position, is seen in *third panel*. Lateral view of opened device is seen at *bottom*.

inserted and are important for maintaining the "curtain" in the correct position for closure. The patch used in the animal experiment contained a *U* suture locking mechanism (Fig. 1, *third panel*). It was implanted in the locked position and subsequently unlocked when required by withdrawing the *U* suture (Fig. 1, *third panel*). The "curtain" of the device was opened toward the roof of the atrium (Fig. 2).

Thoracotomy was done through a midsternal incision. The heart was cannulated in the usual manner and prepared for cardiopulmonary bypass. Cardiac arrest was induced by a cold (3° C) crystalloid cardioplegic solution (modified St. Louis). The entire body temperature was reduced to 28° C.

Through the right atrium a round opening, 2 cm in diameter, was made in the interatrial septum. The one-way, valved, atrial septal patch device was implanted in its locked position. Catheters were placed in the right atrium, left atrium, RV, and ascending aorta.

An isolated RHF model was induced by a combination of a severe reversible increase in RV afterload and mild tricuspid insufficiency. Reversible increase in RV afterload was achieved by inflating a balloon catheter placed in the distal main pulmonary artery. Tricuspid insufficiency was caused by mechanically dilating the tricuspid anulus with Tubbs dilators. The pericardium was left open during the entire experiment.¹⁵

Fig. 2. One-way valve partially opened. View from opened right atrium in dog No. 5.

Fig. 3. Phases of experiment: phase 1, baseline phase, 30 minutes after stopping cardiopulmonary bypass; phase 2, RHF phase with maximal afterload to RV; phase 3, opening of device allowing right atrial-to-left atrial shunting; phase 4, reversal of RHF by deflating balloon.

The following parameters were recorded and calculated: hydrostatic pressure and oxygen saturation in the right atrium, left atrium, aorta, and RV. Systemic and pulmonary blood flows were calculated by the Fick method.¹⁶ The changes in heart

Fig. 4. Right-to-left interatrial shunt was demonstrated by injecting aerated saline containing microbubbles to systemic venous system. *LA*, Left atrium; *LV*, left ventricle; *RA*, right atrium; *RV*, right ventricle.

geometry were followed and documented by intraoperative echocardiography. The presence and direction of the interatrial shunt was further demonstrated by contrast echocardiography with the use of aerated saline containing microbubbles.

Measurements were taken during four different experimental phases (Fig. 3):

Phase 1: Measurements were taken 30 minutes after cessation of cardiopulmonary bypass (recovery period), with the one-way valved patch device in its locked position.

Phase 2: Reversible RHF was induced by gradual inflation of the balloon in the distal main pulmonary artery.

Phase 3: The one-way valved patch device was unlocked, permitting a right-to-left atrial shunt.

Phase 4: The high pulmonary artery resistance was reversed by deflating the pulmonary artery balloon. The spontaneous closure of the shunt was tested during this phase.

Data analysis. The values for each parameter are reported as the mean plus or minus the standard deviation. The changes in the oxygen saturation in the left atrium were normalized for the saturation value at the baseline state (left atrial saturation at any given phase/left atrial saturation at phase 1). The ratio between the pulmonary flow and the systemic flow was calculated. The statistical analysis was made with the paired Student's *t* test. Differences were considered statistically significant at *p* values less than 0.05.

Results

Atrial and ventricular pressure. Table I shows the influence of the one-way, valved, atrial septal patch device on the right and left atrial pressures, RV systolic pressure, RV/LV (left ventricular) systolic pressure ratio, and the right-to-left shunt through the device during the different experimental phases. These results reflect that a state of RHF was induced in phase 2. The opening of the device

Fig. 5. No left-to-right interatrial shunt was found in phase 4 when aerated saline containing microbubbles was injected to left atrium. *LA*, Left atrium; *LV*, left ventricle; *RA*, right atrium; *RV*, right ventricle.

Fig. 6. Bar graphs of normalized left atrial oxygen saturation during experimental phases. Values given are ratio between left atrial saturation at any given phase of experiment and saturation at phase 1. In phase 2 there is insignificant drop in left atrial oxygen saturation to $96\% \pm 4\%$ ($p > 0.05$). In phase 3 there is steep drop to $60\% \pm 18\%$ ($p < 0.05$) caused by right-to-left atrial shunting. In phase 4 left atrial oxygen saturation returned to baseline levels of $98\% \pm 1.5\%$ ($p > 0.05$, when compared with phase 1).

in phase 3 led to an immediate improvement of this state. In phase 4, there was a clear tendency for all parameters to return to baseline values.

Right-to-left shunt. Contrast echocardiography dem-

Fig. 7. Estimated opening pressure gradient of device. This graph shows correlation between right atrial-to-left atrial mean pressure gradient and left atrial oxygen saturation. Biphasic character of graph leads us to assume that opening gradient of device lies between 2 and 4 mm Hg.

Table I. Pressure in the cardiac chambers in millimeters of mercury

	RA	LA	RA-LA gradient	RV	RV/LV ratio
Phase 1	6.0 ± 1.9*	3.6 ± 1.5*	2.4 ± 0.9*	23.6 ± 7.5	0.24 ± 0.08
Phase 2	11.2 ± 2.5 (<i>p</i> < 0.05)	1.2 ± 0.5 (<i>p</i> < 0.05)	10.0 ± 3.6 (<i>p</i> < 0.05)	49.6 ± 9.5 (<i>p</i> < 0.05)	0.83 ± 0.12 (<i>p</i> < 0.05)
Phase 3	7.1 ± 1.5 (<i>p</i> < 0.05)	3.2 ± 1.6 (<i>p</i> < 0.05)	4.4 ± 1.1 (<i>p</i> < 0.05)	44.2 ± 8.2†	0.6 ± 0.17 (<i>p</i> < 0.05)
Phase 4	4.0 ± 1.9 (<i>p</i> < 0.05)	3.0 ± 1.2†	1.0 ± 0.7 (<i>p</i> < 0.05)	34.6 ± 5.7 (<i>p</i> < 0.05)	0.44 ± 0.14†

All atrial pressures are expressed as mean pressure; ventricular pressures and ratios are peak systolic pressures. RA, Right atrium; LA, left atrium; RV, right ventricle; LV, left ventricle.

*Nonsignificant when compared with phase 4 value.

†Nonsignificant.

onstrated the flow through the opened one-way valved patch in phase 3 with a significant right atrial-to-left atrial shunt (Fig. 4). No left atrial-to-right atrial shunt was demonstrated during phase 4 (Fig. 5). Fig. 6 shows the clear reduction of left atrial oxygen saturation to $60\% \pm 18\%$ of baseline. During phase 3, as a result of right-to-left shunt in phase 4, this value returned to baseline levels.

Flow measurements. With the use of the Fick meth-

od¹⁶ it was shown that in phase 2 the pulmonic flow/systemic flow ratio was 0.84:1 and in phase 3 it was 0.51:1. The systemic flow was elevated from 3.2 L/min in phase 2 to 5.83 L/min in phase 3 (82.3% elevation).

Geometric changes. Echocardiography showed a significant dilation of the RV and a pushed-back LV during phase 2. The reversal of this state was observed during phase 3.

Discussion

The animal studies demonstrated the feasibility of the one-way, valved, atrial septal patch and its benefits in the RHF state. Right-to-left shunt at the atrial level was demonstrated by echocardiography (Fig. 4) and by the steep drop in blood oxygen saturation in the left atrium (Fig. 6). Leaving an opened atrial septal defect or patent foramen ovale is a well-known surgical option when patients who are at high risk for postoperative RHF are operated on.¹⁷⁻¹⁸ Using the one-way valved patch device to retain this option for interatrial shunt if required provides a safety valve for a temporarily failing RV. The question remains whether interatrial right-to-left shunt does improve the hemodynamic state.

In phase 2, there was an elevation of the RV pressure and a reduction of LV pressure, which led to a low cardiac output state. Echocardiography demonstrated a shift of the interventricular septum to the left and dilation of the RV cavity.

Opening the device reduced the RV pressure to 44 mm Hg, which was statistically significant. However, there was an improvement in the global function of the heart, as was demonstrated by echocardiography. The shunt also improved the LV preload, which in turn improved cardiac output as shown by flow measurements. RV/LV pressure ratio was reduced significantly as a result of the shunt (Table I). Right atrial pressure fell significantly during phase 3, which resulted in a reduction of RV end-diastolic pressure. The improvement in cardiac output and the reduction in RV end-diastolic pressure improved the RV coronary blood flow, which in turn improved RV function.

The reduction in arterial oxygen saturation could be life-threatening.¹⁹⁻²⁰ However, our data showed that when oxygen desaturation of 37.5% occurred, cardiac output doubled, so it can be assumed that the oxygen transport improved.²¹ Theoretically the device should be opened whenever there is a gradient between the right atrium and the left atrium. However, in phase 4, despite a gradient of more than 1 mm Hg, the device was closed, which showed that it was resisting opening. When does the device open? Fig. 7 shows the relationship between the left atrial oxygen saturation and the right atrial–left atrial gradient. The biphasic character of the graph indicates that the device was opened in a gradient between 2 and 4 mm Hg.

This resistance to opening of about 3 mm Hg can be controlled by clamping the diameter of the opening of the device or altering the site of the side stitches. The fact that the resistance can be controlled enables us to deal with critical malformations inasmuch as on the one hand

antegrade flow through the RV is maintained and on the other hand the option of venting the RV is retained. The one-way characteristic of the device was proved by echocardiography (Fig. 5) and by oxygen saturation measurements that clearly showed that in phase 4 there was no shunt.

This information forms the base for a prospective clinical trial, the results of which will be submitted for publication in a separate article.

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