ATRIAL SEPTOSTOMY BY A NEW BALLOON CATHETER

KANJI INOUE, M.D., FUMIO KITAMURA, M.D.
HIROAKI CHIKUSA, M.D., AND NOBUAKI MIYAMOTO, M.D.

A special balloon catheter for creation of an adequate interatrial opening by expansile force was devised. This balloon catheter was used on 9 adult dogs and 5 sucking pigs for nonoperative creation or enlargement of an interatrial opening. The balloon catheter was introduced via femoral vein into the left atrium by transseptal left heart catheter technique in adult dogs using special guide wire, and across the existing foramen ovale in the sucking pigs. Then the atrial septum was torn by expansile force of the balloon which was fixed through the atrial septum during expansion by means of the specially transformed balloon figures.

Necropsy findings revealed that all animals had interatrial openings larger than fossa ovais with tearing the floor of fossa ovais completely and cleaving the limbus fossa ovais and sinus inferior venosus.

Since 1966, the balloon catheter technique of atrial septostomy introduced by Rashkind has become widely used. Though there is no doubt of the value of this procedure, it is impossible to tear the tough tissues such as the thick floor of the fossa ovais or the limbus fossa ovais by using the technique of pulling out a simple balloon catheter. Therefore, surgical septectomy is often required later on to provide more adequate atrial mixing of blood after this procedure.

This report describes the nonoperative creation of a large interatrial opening on adult dogs, and adequate enlargement of interatrial opening on sucking pigs using a new balloon catheter.

MATERIALS AND METHODS

Group I

Nine adult dogs weighing 8–20 kg were studied. The balloon catheter system used to produce the atrial septal defect consisted of a balloon catheter device, a guide wire with tip occluder and a metal cannula for stiffening the balloon catheter (Fig. 1).

The balloon catheter device was a single lumen cardiac catheter, which had a reinforced and self-transformable balloon on the tip and a side arm adapter with a short elastic tube on the other end. The special balloon was constructed as follows. A simple balloon was wrapped with a knitted, nylon, micromesh which was transversely belted with a rubber belt and compressively covered with a rubber sheath. The internal pressure of the balloon was 5 kg/cm², when maximally inflated, and the shape of the balloon was transformed into three different figures in pro-

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Department of Thoracic Surgery, Kochi City Hospital, Kochi, Japan
Address for reprints: Kanji Inoue, M.D., Department of Thoracic Surgery, Kochi City Hospital, 45-7-1- Marunouchi, Kochi 780, Japan

Atrial Septostomy by a New Balloon Catheter

Fig. 1. Photograph of the balloon dilating catheter system.
A: distal portion, B: proximal portion of the balloon catheter, C: guide wire with tip occluder, D: metal cannula for stiffening the balloon catheter, E: side arm adapter, F: elastic tube

portion to the volume infused (Fig. 2): small spherical shape of distally inflated balloon, hour glass shape with moderate inflation, and large spherical shape of a fully inflated balloon.

The guide wire consisted of a stainless steel wire with metal plug terminating in a flexible spring wire (Figs. 1 and 3). The metal plug was sized to occlude the balloon catheter tip orifice. The guide wire was 180 cm in length and was used to exchange a catheter, introduced into the left atrium via the femoral vein by using the trans-septal left heart catheter technique, for the balloon catheter device, and it was also used to obturate the tip orifice of the balloon catheter guided into the left atrium.

Fig. 3 shows the procedure for the creation of atrial septal defect by using the balloon catheter system. The balloon catheter was introduced into the left atrium via the femoral vein with the aid of the guide wire and the stiffening cannula. By pulling back the guide wire, the tip occluder was positioned into the tip orifice of the catheter. Then, the elastic tube attached to the balloon catheter was fastened with a clamp to close off the blood efflux around the wire.

The distal portion of the balloon was then inflated in the left atrium with a known amount of radiopaque solution injected through the side arm of the catheter hub.

By pulling back the balloon catheter until resistance was felt, the distally inflated balloon was fixed against the left side of the atrial

Fig. 2. Serial photographs of the special balloon transformed into the three different shapes in proportion to the infused volume.
A: deflated position, B: distally inflated position, C: hour-glass shape position, D: fully inflated position

Fig.3. Creation of atrial septal defect by use of the balloon catheter device.
1: The guide wire with tip occluder is introduced into the left atrium using the transseptal left heart catheter technique. The balloon catheter, with stiffening cannula inserted, is advanced over the guide wire having a tip occluder and pushed into the left atrium. Then the stiffening cannula is removed.
A: The tip orifice of the balloon catheter is obturated by tip occluder.
B: The elastic tube of the balloon catheter, with the guide wire inserted, is fastened by a clamp.
2: The distal portion of the balloon is inflated in the left atrium.
3: By pulling back the balloon catheter until resistance is felt, the distally inflated balloon is fixed at the atrial septum.
4: With the addition of more radiopaque solution, the balloon is transformed into an hour glass shape.
5: The balloon is inflated fully and the atrial septum is torn by the expansive force of the balloon without slipping out from the atrial septum.
Fig.4. Schematic illustration for the longitudinal section of the balloon catheter. 
- a: three layered balloon,  
- b: cardiac catheter,  
- c: fine stainless tube (23 gauge) used for stretching the balloon, blood sampling or infusing contrast medium,  
- d: side arm adapter, with side arm for air infusion to inflate the balloon and with main arm for the fine stainless tube,  
- e: short elastic tube, which is tightened with thread so that the fine stainless tube inserted can be slid air-tight fashion through it,  
- f: flexible spring wire for preventing atrial perforation  
A: The fine stainless tube is pushed to stretch and slenderize the balloon.  
B: The fine stainless tube is pulled back a fixed length to free the balloon to prepare it for inflation.  
C: The balloon is inflated with air injected through the side arm of the catheter hub.

Fig.5. Photograph of the proximal portion of the balloon catheter.  
A: cardiac catheter,  
B: side arm adapter,  
C: short elastic tube,  
D: fine stainless tube (23 gauge)

Atrial Septostomy by a New Balloon Catheter

By adding more radiopaque solution, the proximal portion of balloon was inflated. Thus, the isthmus of the hour glass shape of the balloon was automatically positioned at the atrial septum. Finally, the balloon was inflated to its full size, tearing the atrial septum by its expansile force without slipping out from the atrial septum.

Group II

Five sucking pigs weighing between 2.5 and 4 kg were studied. The balloon catheter described in Group I was modified as Figs. 4 and 5 to decrease the diameter of the deflated balloon in order to insert it via the femoral vein of sucking pig. The balloon was made more slender in the deflated position by belting the nylon micromesh.
with weak thread bands instead of the rubber belt.

The transformed shape of the balloon in proportion to the infused volume remained the same as that of the rubber band belted balloon. The slenderized balloon was passed via the femoral vein into the right atrium and then manipulated through the foramen ovale into the left atrium. Location of the balloon in the left atrium was verified by a sampling of the highly saturated blood or by selective angiography through a fine stainless tube. Then, the fine stainless tube was pulled back a fixed length to free the balloon in preparation for its inflation. The distal portion of the balloon was inflated with air, and the catheter was pulled so that the distally inflated balloon was fixed at the atrial septum. This position was maintained by exerting slight tension on the catheter. Then, by adding more air, the balloon was transformed into the hour-glass shape. By adding still more air, the weak thread bands around the nylon micromesh were broken by the high internal pressure (2.5 kg/cm²). Thus the hour-glass shaped balloon was abruptly inflated to full size, resulting in the rupture of atrial septum.

RESULTS

Group I

Three different sized balloons were used for this experiment. The procedure was performed successfully on all 9 dogs without any complications, such as atrial perforation or balloon rupture (Fig. 6). The balloon required an internal pressure less than 2 kg/cm² in this procedure. Arrhythmias during this procedure were uncommon, and no dog had conduction abnormalities after the procedure. All 9 dogs were sacrificed immediately. In all the dogs, necropsy studies revealed an adequate interatrial opening. The fossa ovalis was torn completely, and the limbus fossa ovalis and sinus inferior venosus were cleft, creating an opening that was much larger than the original fossa ovalis. Fig. 7 shows a typical example of the opening produced by using the balloon catheter device in which there were three clefts appearing superior-medially, inferiorly and laterally without injuring the tricuspid valve and main conduction system near by. These interatrial openings were produced in all dogs except dog No. 1, in which the cleft shown in Fig. 7-C was not found.

Table I shows the size of the openings created by using three different sized balloons. The diameter of the interatrial opening was determined by measuring the diameter of a simple balloon that could be pulled from left atrium to right atrium without resistance in extracted hearts.\(^9\)

Group II

Two different sized balloons were used for this experiment. The procedure was performed easily and successfully on all sucking pigs with-
Fig.7. Right atrial view of an interatrial opening produced by the balloon catheter device for dog No. 3. The floor of fossa ovalis is torn completely, and the limbus fossa ovalis is cleft in appearing superio-medially (A) and laterally (C), and sinus inferior venosus is cleft in appearing inferiorly (B).

TABLE I

<table>
<thead>
<tr>
<th>Dog No.</th>
<th>Weight of extracted heart (g)</th>
<th>Diameter of interatrial opening (mm)</th>
<th>Diameter of balloon in inflated and deflated position (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>150</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>100</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>95</td>
<td>23</td>
<td>30 and 6</td>
</tr>
<tr>
<td>4</td>
<td>85</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>85</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>140</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>90</td>
<td>20</td>
<td>25 and 5</td>
</tr>
<tr>
<td>8</td>
<td>90</td>
<td>14</td>
<td>20 and 4</td>
</tr>
<tr>
<td>9</td>
<td>80</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

out any complications such as atrial perforation or balloon rupture. It took only about 3 seconds to carry out the following three steps: to fix the distally inflated balloon at the atrial septum, to inflate it up to full size rupturing the atrial septum, and to completely deflate it.

Arrhythmias during this procedure were uncommon, and no animal had conduction abnormalities after the procedure. All 5 animals were sacrificed immediately after-wards. Necrop-
Fig. 8. Right atrial view of an enlarged interatrial opening for sucking pig No. 2 in which the atrial septum is torn in the same way as shown in Fig. 7.

### TABLE II SIZES OF ENLARGED INTERATRIAL OPENINGS IN 5 SUCKING PIGS

<table>
<thead>
<tr>
<th>Sucking pig No.</th>
<th>Weight</th>
<th>Diameter of interatrial opening (mm)</th>
<th>Diameter of balloon in inflated and deflated position (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Body (kg)</td>
<td>Heart (g)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>3.8</td>
<td>36</td>
<td>14</td>
</tr>
<tr>
<td>2</td>
<td>3.5</td>
<td>35</td>
<td>14.5</td>
</tr>
<tr>
<td>3</td>
<td>4.0</td>
<td>38</td>
<td>13</td>
</tr>
<tr>
<td>4</td>
<td>3.0</td>
<td>24</td>
<td>14</td>
</tr>
<tr>
<td>5</td>
<td>2.5</td>
<td>18</td>
<td>14</td>
</tr>
</tbody>
</table>

sy studies revealed an adequate interatrial opening in which the fossa ovalis were torn completely, and the limbus fossa ovalis and sinus inferior venosus were cleft in the same way as described in Group I, creating an opening much larger than the original fossa ovalis in all animals (Fig. 8).

Table II shows the size of the openings using two different sized balloons. The diameters of the interatrial openings were measured in the same way as described in Group I.

### DISCUSSION

The efficacy of balloon atrial septostomy (BAS), Rashkind's procedure, in enlarging the interatrial opening has been described in many reports.\(^1\)\(^-\)\(^8\) Clinically, BAS frequently produced good palliation for the severely hypoxic infants with transposition of the great vessels, but it could not produce consistent, long-term benefits in many patients.\(^3\)\(^-\)\(^6\),\(^8\)

In some centers, the enlarged interatrial open-
Atrial Septostomy by a New Balloon Catheter

ings were evaluated at autopsy or at the time of surgical correction. Their size, however, were the same as the fossa ovalis (in a baby this is at least 10 mm in diameter) or less, since BAS could fracture only the thin floor of the fossa ovalis. Surgical septectomy appeared to give more prolonged and higher elevation of the atrial oxygen saturation than BAS, and the larger size and posterior location of the defects created by septectomies were the reasons why surgical septectomies tend to have better responses than BAS over long periods of time. In our limited experiment, however, the long-term results of this procedure are unknown.

The present procedure should be useful when a sufficient interatrial opening cannot be achieved by BAS, since repeated BAS is usually ineffective. In older infants and children, the interatrial septum is usually thick and BAS is almost never effective. This new balloon septostomy may therefore be called for these patients as an initial therapeutic procedure.

The new balloon catheter technique was effective in creating an interatrial opening much larger than the fossa ovalis in adult dogs and in sucking pigs. In Group II, the diameter of the enlarged opening was as large as or slightly less than the diameter of the inflated balloon, since the balloon was very rapidly inflated from hour glass shape to full size. This provided the necessary force to tear the atrial septum rather than to stretch it.

In the animal experiments, there were no problems concerning the procedure per se using this technique. For clinical application, however, the following theoretical problems must be resolved. (1) Rupture of the balloon. (2) Injury of tricuspid valve or main conduction system near by. (3) Rupture of atrial wall. (4) During procedure, an existing interatrial opening is temporarily and completely occluded with the balloon. In a patient for whom the interatrial opening is the only mixing site between systemic and pulmonary circulations, the prolongation of this procedure might lead to profound hypoxemia. (5) In premature babies with transposition of the great vessels, the diameter of the balloon in the deflated position is too large to insert through the femoral vein.

These problems could be answered, respectively, as follows. (1) The balloon requires an internal pressure less than 2 kg/cm² to tear the atrial septum even for adult dogs, and also requires about 2.5 kg/cm² to break the weak thread bands around the micromesh of the balloon in Group II, and the balloon needs an internal pressure of more than 5 kg/cm² to rupture it. Therefore, our balloon provides a wide margin of safety to prevent accidental rupture. Moreover, it is even safer if the balloon is filled with carbon dioxide. (2) Necropsy studies revealed that there was no cleft appearing toward the tricuspid valve in any of the adult dogs and sucking pigs, demonstrating that the procedure did no harm to the tricuspid valve and main conduction system near by. (3) It is necessary to inflate the balloon to the size proportionate for each heart. (4) During the procedure, the existing interatrial opening is occluded by the balloon for less than 3 seconds. (5) The diameter of the present model in the deflated position could be further reduced by refinement such as the use of seamless, knitted, nylon micromesh.

The procedure for creating or enlarging interatrial openings should be successful in clinical application, regardless of patient age or patency of foramen ovale.

The new balloon catheter technique can easily and certainly produce an opening of a predetermined size by tearing tough tissue in a short time. These technique might be used for other diseases, such as pulmonary valve stenosis or atresia, mitral valve stenosis, and membranous obliteration of the inferior vena cava in the hepatic portion.

REFERENCES

1. RASHKIND WJ, MILLER WW: Creation of an atrial septal defect without thoracotomy: A palliative approach to complete transposition of the great vessels. *JAMA* 196: 991, 1966


3. VENABLES AW: Balloon atrial septostomy in complete transposition of great arteries in infancy. *Br Heart J* 32: 61, 1970


7. MENG CCL, WELLS CR, VALDES-DAPENA M,
