Plug Closure of Patent Ductus Arteriosus by Transfemoral Catheter Method*

A Comparative Study with Surgery and a New Technical Modification

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Plug closure of patent ductus arteriosus without thoracotomy is reliable and can be a good alternative to surgical closure for selected patients. We report our experiences with plug closure in 87 consecutive patients (age range, 3 to 38 years). Closure was successful in 83 patients (95 percent). There has been no mortality, and the failure in four patients (5 percent) was mainly due to an oversized ductus. A major complication during the procedure was dislodgment of the plug into either the aorta or the pulmonary artery, which occurred in five patients (6 percent). The late results were quite satisfactory, with no recurrence of shunting or any other complications. Comparison of these results with those of 100 patients treated surgically showed that the new catheter method did not seem to carry a higher risk but had certain advantages over thoracotomy. A simpler and less time-consuming method using a single catheter has been devised and successfully used in the most recent nine patients without failure. Simplification of the technique has significantly reduced the time of the procedure and the dose of radiation.

In 1971, Forstmann et al1 reported a new catheter method to close a patent ductus arteriosus, with a plug inserted through the femoral artery and transported by catheters into the ductus along a previously placed arterio-transductal-venous loop wire. We adopted this technique in 1972 and in 1975 reported our initial experiences with favorable results.2 Since then, our experience has further expanded, and the original method has been simplified. We believe that plug closure of patent ductus arteriosus by the catheter method is unlikely to carry a higher risk than surgery and can be a good alternative to conventional surgical closure for selected patients. In this report, we describe the results, indications, and limitations of this method in comparison with a surgical method, the technical points needing attention in order to avoid complications, and a new and simpler single-catheter method applicable in the majority of patients.

Case Material

From February 1972 to August 1975, transfemoral plug closure of patent ductus arteriosus was attempted in 87 consecutive patients ranging in age from 3 to 38 years (mean age, 13 years). Table 1 shows the age distribution of our patients. Most of them were between 5 and 25 years of age. Twenty-one were male patients, and 66 were female patients, with a female-dominant sex ratio of 3.1/1. In selecting candidates, particular attention was paid to ruling out all other associated cardiac anomalies. The ratio of systemic to pulmonary flow ranged from 1.1 to 4.9 (mean, 1.8), the ratio of systemic to pulmonary peak pressures ranged from 0.16 to 0.49 (mean, 0.26), and the ratio of systemic to pulmonary resistance ranged from 0.01 to 0.21 (mean, 0.07). Pulmonary hypertension, with the criteria being a mean pulmonary arterial pressure of more than 25 mm Hg, was seen in 26 percent (23) of the 87 patients.

During the same period of time, 21 patients with an isolated patent ductus arteriosus underwent surgical closure because of one or more of the following reasons: doubt of the catheter method at the beginning; age less than four years; angiographic contraindication (oversized ductus); or the patient’s request.

As previously reported,1-5 preoperative evaluation of the morphologic features of the ductus is crucial to determine the feasibility of this method. Sato et al7 have classified the basic morphologic findings of patent ductus arteriosus into three groups according to the shape of the ductus and the aortic infundibulum. Patients in groups 1 and 2, in which the ductus is conical or cylindrical with an appreciable length, are good candidates for this method, as long as the size of the ductus is not much larger than that of the common femoral or external iliac artery. These groups comprised 98 percent (85) of our

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Carried out a day before the procedure, and the plug was boiled for sterilization. The diameter of the plug should be previously made plug was found to be inadequate size in the actual setting, a new plug was made during the procedure. It usually took 20 minutes for fabrication.

Within the lumen of the snare catheter, a double-folded snare wire is placed, by which a catching loop is formed in the pulmonary artery. Next, a track wire is inserted within the lumen of the previously placed arterial catheter and is advanced into the pulmonary artery.

The catching procedure, in which a flexible tip of the track wire is caught by the loop of the snare wire, is performed (Fig 1A). By withdrawing the snare catheter and wire together with a trapped track wire from the venous side, an arterio-transductal-venous loop (track wire) is made.

The previously made plug is introduced through the common femoral artery using a tubular applicator and threaded over the track wire. The plug is then advanced into the ductus easily with the aid of the pushing catheter. The track wire is withdrawn from the venous side, and the plug remains wedged in the ductus. A total of four catheters and two wires are necessary for the original method.

As our experience progressed, some technical improvements were made, although the basic principle of this method has remained unaltered. A new simple method using a single catheter has also been devised (Fig 1B).

In this new method, a No. 6 or 7 catheter 100 cm or longer is introduced from the saphenous vein and is passed through the ductus from the pulmonary artery into the aorta, using a flexible spiral guide wire. The catheter then can be easily led to the aortic bifurcation and, by the use of a J-shaped guide wire, further led into the femoral artery, which has already been dissected free. Thus, a veno-transductal-arterial loop is made by using only one catheter. A track wire can be easily placed within the lumen of this catheter. All the procedures following this are the same as in the previous method. The saphenous vein and the femoral artery of the right side were usually used.

By this simple method the use of a snare catheter and a snare wire and the tedious catching procedure in the pulmonary artery can be avoided. This method has apparently shortened the time of the procedure and reduced the dose of radiation to the patients. Local anesthesia with lidocaine was sufficient for the patients older than ten years of age. In younger patients, intramuscular injection of ketamine was used for anesthesia, when necessary.

**RESULTS**

**Success Rate**

There has been no mortality in the present series. Successful plug closure was accomplished in 83 (95 percent) of our 87 patients. Complete closure of the ductus was always confirmed by auscultation, dye-dilution curve, and the injection of contrast material into the aorta (Fig 2). Nevertheless, in four patients, (5 percent), this method of closure failed. The cause of failure in three of these patients was an oversized ductus in which the largest plug that could be inserted from the common femoral artery could not be wedged. Two of these three patients subsequently underwent surgical division of the ductus, and the remaining one patient (five years old) is awaiting the next trial a couple of years later. In one patient the plug slipped into the pulmonary artery when the track wire was being withdrawn. The new method using a single catheter has been successfully employed in the most recent nine consecutive patients.

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**Table 1—Age Distribution of Patients**

<table>
<thead>
<tr>
<th>Age, yr</th>
<th>Catheter Method</th>
<th>Surgical Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4</td>
<td>8*</td>
<td>35</td>
</tr>
<tr>
<td>5-9</td>
<td>29</td>
<td>30</td>
</tr>
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<td>10-14</td>
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</tr>
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<td>15-19</td>
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<tr>
<td>20-24</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>25-29</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Over 30</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>87</td>
<td>100</td>
</tr>
</tbody>
</table>

*All eight patients were three to four years old.

87 patients in this series. In selecting candidates for this procedure, most patients underwent cardiac catheterization and aortographic and femoral arteriographic studies approximately one month before the procedure of plugging; however, a few patients had these examinations immediately followed by plugging.

In evaluating the new catheter method, 100 consecutive patients who underwent traditional surgical division of an isolated patent ductus arteriosus in our department (mostly performed before the catheter method became available) served as cases for comparison. The age distribution of the surgical group is listed in Table 1. Their ages were shifted toward younger than those in the group undergoing plugging.

**METHODS**

**Fabrication of Closing Plugs**

A plug of Ivalon sponge is designed for each patient, according to the size and shape of the ductus as evaluated by aortograms. A piece of fine-textured Ivalon† sponge approximately 4 × 4 × 10 cm is softened by immersing it into hot water. Then the stainless steel central frame wire which has the shape of a hairpin with a circular head1 is inserted into the center of the sponge along the axis. The sponge is compressed against this central frame in a ratio of 5 or 6 to 1 between the circular head and the thin disk base plate1 placed through the frame wire. The compressed cube is then trimmed to the conical shape of the plug by scissors. The diameter of the plug should be 20 to 40 percent larger than that of the ductus shown on aortograms. The trimmed sponge is fixed to the central frame with 3-0 anchoring stitches. The plug is boiled for sterilization.

In the majority of cases, fabrication of closing plugs was carried out a day before the procedure, and the plug was kept in antibiotic solution after boiling; however, when the previously made plug was found to be inadequate size in the actual setting, a new plug was made during the procedure. It usually took 20 minutes for fabrication.

**Plugging Technique**

The details of the original plugging technique have been reported previously.1,2 Briefly, a preshaped arterial catheter introduced from the femoral artery is advanced proximally and passed through the ductus into the pulmonary artery. Another large catheter (snare catheter) is inserted from the saphenous vein and advanced into the pulmonary artery.

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Late Results

The late results were quite satisfactory. The follow-up period ranged from three months to three years and seven months after the procedure. There has been no late mortality, no late displacement of a plug, no recurrence of shunting, no adverse reaction to a plug made of Ivalon sponge, and no endocarditis. All of the patients in this series are doing quite well at the present time.

Complications

Once placed in the ductus the plug fell back into the aorta in four patients soon after the track wire had been removed from the plug. All of these four patients had successful replugging before or after the first fallen plug had been removed from the femoral artery or the aorta. One of these patients, in whom the plug was lodged above the renal artery, developed acute renal failure, with complete recovery a month later. In two of these patients, the plug which fell back into the aorta could not be evacuated from the femoral or the external iliac artery. These patients had a laparotomy to have the embolizing plug removed from the abdominal aorta.

In only one patient did the plug fall into the pulmonary artery when the track wire was being pulled out. The track wire was bent during manipulation, and during the attempt to withdraw the bent...
wire from the plug, the plug slipped into the pulmonary artery. This patient underwent successful emergency surgery to remove the embolizing plug from the pulmonary artery and to ligate the ductus.

Thus, complications occurred in a total of five patients (6 percent) out of our 87 patients, and three patients (3 percent) required further surgery to resolve the complication.

**Catheter Method vs Conventional Surgery**

The results and complications in 100 patients treated surgically in our department were compared to those of the patients treated with the new catheter technique. Most of the 100 patients underwent surgery before the new catheter method became available or popularized in our department. The mean age of surgical patients (eight years) was shifted to younger than that of patients undergoing plug closure (mean age, 13 years), but, in retrospect, there was an appreciable number of surgically treated patients (over 70 patients) for whom the catheter method could have been used.

Among the 100 patients treated surgically, one died from malignant hyperthermia probably due to damage to the central nervous system, giving a mortality of 1 percent. Complications which required reoperation or specific treatments included the following: atelectasis of the lung, five patients; hemothorax requiring reoperation, two patients; and patients. Two patients had arrhythmias requiring specific treatments. Transient hoarseness occurred in 16 patients, and permanent hoarseness due to injury of the recurrent laryngeal nerve was present in two patients. Thus, excluding pleural effusion and transient hoarseness, there were 14 patients (14 percent) with complications after surgical treatment.

**Discussion**

Plug closure of patent ductus arteriosus without thoracotomy is feasible for selected patients with minimal risk. The selection of patients is mainly based on the size and shape of the ductus. The diameter of the common femoral artery must be larger or equivalent to that of the ductus. Technically, it is difficult to make a plug in which the diameter of the base is less than 3 mm. Therefore, candidates should have a common femoral artery greater than 3 mm in diameter. For these reasons, three or four years would be the lowest age for the application of this method. Infants and younger children with a marked left-to-right shunt through a large patent ductus arteriosus resulting in congestive heart failure are not candidates for this method at the present time.

In regard to the shape of the ductus, group 3 of the classification of Sato et al. requires special care, although this group constitutes only 2 percent of our patients.
most in this group would not be good candidates for this method.

An oversized ductus, with or without pulmonary hypertension, is another difficult situation for the successful application of this catheter technique. Recently, Porstmann et al\(^7\) reported a case in which an elaborate hook mechanism was utilized to keep a plug stable in the oversized calcific ductus. Further development of the method, in combination with the use of an umbrella mechanism\(^7\) or a tissue adhesive\(^8\) or both, may increase the applicability.

The new single-catheter method is simple, and by this method the use of a snare catheter, a snare wire, and the tedious catching procedure in the pulmonary artery or the superior vena cava are no longer required. With this technique the time of the procedure and the dose of radiation used have been considerably reduced, since the catching procedure usually requires the longest period of fluoroscopic observation. In the single-catheter method, the ductus must be catheterized from the venous side. Catheterizing a patent ductus arteriosus was generally easier from the aortic side than from the pulmonary arterial side, but it could also be performed without difficulty from the pulmonary arterial side with the appropriate use of guide wires in most patients. Shimizu et al\(^8\) reported a similar experience. At present, plug closure of patent ductus arteriosus can be completed in two hours in the majority of patients.

Complications are rare, but can be serious and require emergency surgery as was performed in three (3 percent) of our 87 patients. Two of them underwent laparotomy for removal of an embolizing plug from the abdominal aorta. The remaining single patient in whom the plug slipped into the pulmonary artery had emergency thoracotomy. Great care should be taken not to bend a track wire during manipulation, because the bent wire may pull a plug down into the pulmonary artery when the wire is being withdrawn. Also, the plug lodged above the renal artery should be pulled down below it as soon as possible by a balloon catheter, in order to prevent resultant acute renal failure, which occurred in one of our patients. A surgeon should attend or stand by to deal with the possible complications.

Nevertheless, most of these complications can be minimized by increasing experience with the technique and by careful selection of candidates. It must also be stressed that all of these complications took place during or immediately after the procedure and that the plug, once wedged firmly in the ductus, has never been dislodged after the procedure was totally completed or after the patient was transferred from the catheterization room.

The recovery after the procedure was much faster, with much less pain and a much smaller scar than after surgery. There was no possibility of complications due to thoracotomy, such as bleeding, atelectasis, and injury to the recurrent laryngeal nerve. In addition, only local anesthesia was required, except in younger children.

The evaluation of the catheter method compared to a traditional surgical method has shown that the overall rate of complications was less with the catheter method, although new and different complications requiring surgery have occurred in 3 percent (three) of our 87 patients. From our experience, it seems unlikely to us that plug closure of patent ductus arteriosus by the catheter method carries any higher risk than the surgical method if the catheter method is used with caution in selected patients. The catheter method has certain advantages over thoracotomy. We do not think that the catheter method can completely replace the surgical method; however, we do think that this new method can be a good alternative to surgery for selected patients. The fact that we performed surgery on 21 patients during the same period of time in which we tried the catheter method on 87 patients reflected our present policy. In conclusion, for the patient over three or four years of age with a simple isolated patent ductus arteriosus, plug closure has now become the method of choice in our department.

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REFERENCES