Nonsurgical Closure of Oversized Patent Ductus Arteriosus with Pulmonary Hypertension
Report of a Case

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SUMMARY
Safe and permanent closure of patent ductus arteriosus (PDA) can be accomplished with an ivalon plug introduced by catheterization from the femoral artery. The authors' experience thus far obtained from treating more than a hundred patients suggests that the technique described in this paper is a feasible alternative to the surgical approach. A prerequisite has been the size and shape of the PDA, the lumen of which had to be conical in shape and smaller than the lumen of the femoral artery. Now safe closure of oversized PDA complicated by pulmonary hypertension has become possible, using a plug designed with a special mechanism for anchorage to the PDA. The technique of this closure is described in detail in this report of its successful use in a 50-year-old woman patient with an oversized, calcified PDA complicated by pulmonary and systemic hypertension and cystic lung disease. Treating such high-risk cases with transfemoral closure means real improvement in therapy over surgical treatment.

Additional Indexing Words:
Catheter closure of patent ductus arteriosus
Transfemoral approach with oversized catheters
Patent ductus arteriosus in adults
Pulmonary hypertension in patent ductus arteriosus

IT IS A GENERALLY ACCEPTED VIEW that uncomplicated patent ductus arteriosus (PDA) should be treated surgically in spite of the possible adverse hemodynamic effect. We have suggested in several publications that by using a percutaneous technique, introduced in the femoral artery, simple, safe, and permanent closure of PDA can be achieved and a thoracotomy avoided.

Our experience with more than a hundred patients has convinced us that our method is a real alternative to surgery, although as we are fully aware, many surgeons do not share this opinion. Our confidence is supported by other working teams who have adopted our method and have achieved similar positive results
(Dr. K. Sato, Osaka, Japan, personal communication).

The shunt sizes in our series of patients ranged between 15% and 75% of pulmonary flow (average, 35%), calculated by dye dilution. Pulmonary artery pressure was normal or slightly elevated in 72 cases. In 34 cases systolic pressure was higher than 40 mm Hg and it exceeded 80-90 mm Hg in three. There was no mortality and only minor morbidity in this series or in those reported by others\textsuperscript{4,5} (personal communication with Dr. Sato). In eight patients out of 106, the method was unsuccessful. In five cases the PDA was too large and the plug slipped into the pulmonary artery. Since the plug was still on the guide wire, with a thrust catheter on the wire, the dislocated plug could be moved to the femoral vein from which it was removed by venectomy in every case. With increasing experience, the procedure could be repeated in the same session using a larger plug. In the remaining three cases, because of rigidity or the small size of the PDA, the plug could not be fixed. In such situations the plug was allowed to embolize to the aortic bifurcation. There it was turned and pulled down into the external iliac artery. From this position it could be removed by arteriotomy.

The lower age limit for transfemoral closure of PDA is between three and four years.\textsuperscript{3,7} Closure of PDA in newborns and infants in whom cardiac failure is present is not practical with the transfemoral approach. Basically, the success of the transfemoral technique depends on the ratio of the lumen of the femoral artery to that of the PDA which is to be closed. If the lumen of the femoral artery is not wider than the
NONSURGICAL CLOSURE OF PDA

PDA, the plug cannot be safely fixed within the PDA. The principle of this closing technique is shown in the diagram of figure 1.

In the past, plugs for closure were designed in a conical shape, under the assumption that since most PDA tapered conically, a plug of that shape could be more securely anchored to the lumen wall. Aerated plastic (ivalon), precompressed to four or five times of its original density, is used for the plug. While this preparation limited further compression during plug transport through the pelvic arteries, we felt that precompression of the aerated plastic was essential, since the plug was designed to self-attach inside the PDA and then had to stay in place. With follow-up observation periods up to seven years, plug dislocation or recanalization of PDA has never occurred.

The above considerations are likely to infer that oversized PDA with pulmonary hypertension (diameters larger than those of the femoral arteries of the patients) are not really amenable to the technique of transfemoral closure. In these cases, the shape of the PDA is usually cylindrical. Such cases also will present problems to the surgeon and are associated with increased surgical mortality. In an adult oversized PDA is usually accompanied by wall changes (sclerosis, aneurysmal conversion) and quite often additional complications may develop from pulmonary hypertension.1, 8-18

We attempt in this paper to extend the transfemoral technique to this latter group of PDA patients in whom surgical closure is a high risk procedure. With due consideration of all aspects so far discussed, such expanded application is not feasible unless the ivalon plug is redesigned with the following principles in mind:

1) The self-locking principle based on static friction must be abandoned and another kind of attachment mechanism sought. Reduced precompression of the foam material will allow the plug to move through the relatively narrow pelvic arteries.

2) The improved fixing mechanism must lock equally with the aortic and pulmonary sides of the PDA taking into account the fact that in most of these cases the ductus will be cylindrical in shape, and it must not obstruct plug transport from the femoral artery to the PDA.

3) The fixing mechanism must not occur until the PDA has been closed by the aerated plastic, and not before the patient has been found to tolerate the resulting acute and often extreme change of his or her hemodynamic condition. Fixation should be reversible, even to the extent of plug removal, if needed. Withdrawal might be essential in severe pulmonary hypertension.

A diagram of a possible approach to these principles is shown in figure 2. This modified transfemoral PDA closure technique has now been applied successfully to man, following a series of model tests.

Case History

The patient was a 50-year-old woman with a large cylindrical PDA (diameter wider than that of the femoral artery,

Figure 1

Principle of transfemoral ductus closure. Conical ivalon plug travels on percutaneously laid arterio-transdural-venous guide wire and is wedged into the conical ductus. The wire is removed toward the venous side, and the plug remains inside the ductus.

Figure 2

Principle of plug anchorage in oversized PDA with a diameter larger than that of femoral artery. A) Transarterially introduced plug with springs at both ends fitted between the two catheters prepared for transportation through the pelvic arteries and aorta; B) plug in position fixed by latches at both aortic and pulmonary ends.
The pulmonary artery pressure was 70/50 Torr; left-to-right shunt was 60% of pulmonary volume. The PDA showed tubular calcification. The left heart was substantially enlarged; the pulmonary vessels showed hypervascularization; and a cyst was present in the left lower lobe (fig. 5). In addition there was systemic hypertension (170/100 Torr). The ECG indicated left ventricular hypertrophy, severe dyspnea developing with the slightest physical exercise. Surgical closure of the PDA had been ruled out by several heart surgeons.

Transfemoral closure was successfully accomplished. The patient exhibited a decline of her dyspnea within one day after the intervention and was released from the hospital after nine days. Follow-up checks after three and six months showed further essential improvement in the patient’s general condition and physical capabilities. The ductus remained closed. The locking mechanism of the plug had not changed position (fig. 9).

Catheterization Technique

Transfemoral closure was performed with the patient under general anesthesia after exposure or percutaneous catheterization of the femoral vessels and heparization (3 mg/kg/body weight). A long catheter was placed through the exposed artery, up to the aorta, across the ductus, through the right heart, down the inferior vena cava, and out through the corresponding femoral vein. A steel guide wire approximately 3 meters long and 0.4 mm in diameter, lying within the lumen of the arterio-transductal-venous

**Figure 3**

Short PDA with diameter of 1.5 cm at pulmonary end in 50-year-old woman presented in this paper.

**Figure 4**

Pelvic angiograph of the patient — femoral artery is 0.8 cm in diameter, which renders the introduction of self-retaining plug into PDA (1.5 cm in diameter) impossible.

**Figure 5**

Chest X-ray of the patient: strong leftward enlargement of heart; dilatation of pulmonary artery; volume of pulmonary vessels increase; semicircular calcification of PDA; partially calcified cyst in left lung behind the heart.
catheter loop, was positioned so as to project about a meter from both the arterial and venous ends of the catheter. This wire, at a later stage, served as a track over which a closure plug would be guided into the ductus from the aortic side. Two coaxial No. 10 and 6 catheters equal in length but staggered against each other by 2 cm were then slipped over the guide wire from the venous side, inserted, moved through the duct, and exposed from the femoral artery. A 25 cm teflon hose (applicator) was moved along the guide wire and protruding coaxial catheters and inserted into the artery. Then the plug was placed in transport position on the guide wire, with its aortic latch in the direction of travel and firmly coupled to the locking cannula.

The plug, inside the applicator, was advanced to the aorta by pull from the venous side and slight push from the arterial side. As the plug was advanced into the PDA, the locking cannula was pushed forward to move the aortic latch from transport into locking position. The plug could no longer slip off into the pulmonary artery (fig. 6). The plug then was pulled from the venous side and thus firmly fitted into the PDA.

Complete closure can be tested by auscultation, dye-dilution, and possibly aortography. With the plug in this position, closure is reversible. If necessary, the resulting changeover of circulation may be kept under observation for several hours. At this stage, particular attention should be given to pressure in the right ventricle. In the case described, with the patient under halothane anesthesia, systolic ventricular pressure dropped from 70 to 25 mm Hg in 20 min.

Once circulation was stabilized, but only then, the venous inner catheter is given a thrust, and the locking mechanism on the pulmonary end of the plug, which consists of a teflon-coated spring, was released. The ends of the spring immediately had tight contact with the walls of the pulmonary artery, and consequently, prevented the plug from sliding back into the aorta (fig. 7). The guide wire was removed toward the venous side. The locking cannula was separated from the aortic latch in the final phase of the closing procedure. The plug has then been mechanically secured on both sides to prevent its sliding out of the duct (fig. 8). Theoretically, reopening of the duct would have been possible at any moment prior to the onset of this final phase by turning the locking cannula to change the aortic latch from locking to transport position, allowing the entire plug with its locking mechanisms to be removed through the femoral artery by firm pulling on the locking cannula.

Discussion

We described a new method for PDA closure without thoracotomy in 1966. Since then the method has been used on more than a hundred patients. At present, the technique is being used on children above

![Figure 6](image)

**Figure 6**

Demonstration by means of ductus model of stepwise closure procedure. A) Plug during transport across aorta. Its pulmonary spring mechanism is encased in a catheter. The aortic latch is connected to a locking instrument adjacent to the wire loop. B) The plug enters PDA. The aortic latch is pushed across base of plug thus preventing its passage through PDA. C) The plug is pulled into the oversized PDA for transient closure. If necessary, removal to the aortic side is possible by pulling back the locking instrument. D) The plug has been released at both ends but is still on the guide wire. E) The final position of plug after removal of wire.

![Figure 7](image)

**Figure 7**

Plug (A) has been placed in PDA but still connected to guide wire; (E) its locking mechanisms on pulmonary (C) and aortic (B) sides are already extended but its aortic latch still is held back by the locking cannula (D). Even in this advanced position plug removal through the arterial side is still possible. A catheter is in right ventricle for continuous measurement of pressure during the closing procedure (G). Semicircular calcification of PDA (F) is present.
that transfemoral closure of PDA, based on cardiac catheterization, had many advantages over surgical treatment. Such advantages were conspicuous mainly in PDA patients with small to medium shunt volumes where surgical success was often obscured by complaints related to the thoracotomy. We, therefore, felt some justification in proposing our method as a real alternative to surgical closure. This view is likely to be supported by other teams that have also obtained positive results.5–7

The transfemoral closure would have greater application if it could be used in patients with PDA and pulmonary hypertension as a viable alternative to surgery. One successful case is reported in this paper. In similar cases and in cases of postsurgical recurrent patency, transfemoral closure might prove to be the treatment of choice.

One additional case has been treated successfully in the period since this paper was accepted for publication: a 20-year-old woman with a large cylindrical PDA, pulmonary artery pressure of 110/70 Torr, and left-to-right shunt of 65% of pulmonary volume.

Acknowledgment

The authors feel a debt of gratitude to Herr G. Fürstenberg and Herr P. Liebe, Medical Engineering Sector of Charité, who prepared the instrumentation needed to carry out the above work. Added appreciation goes to Mrs. Bette King for her assistance in editing this manuscript.

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Circulation. 1974;50:376-381
doi: 10.1161/01.CIR.50.2.376

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1974 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

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