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## Recent Strategies and Outcomes of Transcatheter Closure for Patent Ductus Arteriosus

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### Introduction

Patent ductus arteriosus (PDA) is a congenital heart disease defined as the arterial connection between the pulmonary artery and the aorta. The ductus arteriosus is an essential structure that shunts blood away from the lungs during fetal life, and only becomes abnormal if it remains patent more than three months after birth in term infants. Spontaneous delayed closure of the ductus arteriosus occurred in 79% of infants during the neonatal period.<sup>1)</sup>

The overall incidence in infants born prematurely is about 16 times higher than the incidence in full term infants. The rate of PDA in extremely premature neonates is close to 30%. Preterm infants with symptomatic heart failure secondary to persistent patency of the ductus arteriosus may be treated by surgical ligation or medically with conservative treatment such as indomethacin or ibuprofen. Medical intervention is usually the treatment of choice due to the risks involved with surgical ligation. Early surgical ligation was supported as the optimal therapy for PDA because it ensured definitive ductal closure with minimal morbidity and mortality in these high risk infants.<sup>12)</sup>

Diagnosis of PDA is usually based on clinical examination and transthoracic echocardiography. Now that co-

lor Doppler imaging has been introduced, it is possible to accurately assess even a tiny PDA.<sup>13)</sup>

PDAs are usually classified as small, moderate or large by size measurement, and as type A (conical ductus), B (window like ductus), C (tubular ductus), D (ductus with multiple narrowing) or E (elongated ductus) by its configuration on an angiogram of the aortic arch.<sup>3)</sup>

The traditional approach of PDA closure, either with surgery or, more recently, with transcatheter techniques, has been the mainstay of treatment. And management of PDA has continued to progress as innovative technologies have become available. Thus, the outcome and goals for PDA closure have changed and depend on the treatment modality. Indeed, strategies for management of PDA continue to evolve.

### Changing Treatment Modalities Over Time and in Association With Development of New Devices

After the first successful surgical closure of PDA was described in 1939, surgical procedures remained, for several decades, the only practical tools for closing the ductus.<sup>12)</sup> At that time, the only goals for treatment were to avoid pulmonary overflow and to decrease the risk of endocarditis. The next surgical modification occurred in 1991, when PDA closure by video-assisted thoracoscopic surgery was introduced.<sup>4)</sup>

In reviewing catheter interventions for PDA closure, Wierny et al.<sup>5)</sup> reported the first successful attempt using an Ivalon plug to do non-surgical closure in 1971. In 1979, Rashkind et al.<sup>6)</sup> described successful deployment of a percutaneously delivered double umbrella device in an infant with a body weight of only 3.5 kg. Thereafter, several different devices, including buttoned devices and stainless steel coils, became readily available for the transcatheter occlusion of a PDA. But, they have produced varying outcomes.<sup>6–14)</sup> Gianturco embolization

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coils, detachable coils (Cook Cardiology, Bloomington, IN, USA), and the Duct-Occlud (Pfm, Cologne, Germany) device have proven both safe and effective in the closure of small to moderate-sized PDAs. However, they have not been shown to be effective in the transcatheter approach to a large PDA.<sup>2(4)(7)(9)(15)</sup> These surgical or catheter-derived techniques became complementary applied for PDA closure at that time. Percutaneous embolization of coils has been used predominantly for smaller ducts, while larger ones were interrupted by open thoracotomy or, occasionally, by video-assisted ligation.

For the transcatheter closure of moderate to large PDAs, Nit-Occlud devices (Pfm, Cologne, Germany), which were developed from the original Duct-Occlud device, have had relatively favorable outcomes.<sup>10-14)</sup> Moreover the Amplatzer ductal occluder (ADO) device (AGA Medical Corporation, Golden Valley, MN, USA) permitted closure of larger ductus, even ones as large as 16/14 mm in diameter since 2003 and showed excellent outcomes.<sup>2(15)</sup>

The management of a silent ductus remains controversial because its risk for endocarditis is low. Transcatheter therapy for PDA closure is readily available and this has prompted physicians to offer elective closure of ductus to all patients.<sup>2(11)(14)(15)</sup>

### Outcomes and Complication of Transcatheter Closure of Patent Ductus Arteriosus

Currently, the advent of new technology has increased the proportion of patients who undergo successful percutaneous closure; there have been only a few of minor complications compared with initial interventional data.

Choi et al.<sup>7)</sup> reported comparative results for several devices from 'old' Sideris and umbrella devices to 'brand-new' Amplatzer devices. Even though the initial data were not remarkable, he showed the historical trends and patterns for the selection of devices in transcatheter PDA closure during the past 12 years. After the types of devices had evolved, the occlusion rates improved and there was an increase in the proportion of patients who had good results with transcatheter PDA closure.

In 1999 Rao et al.<sup>8)</sup> reported successful implantation of a buttoned device in 278 (98%) of 284 patients. Complete occlusion occurred only in 167 (60%), and a trivial shunt in 79 (28%) patients.

According to serial data with a controlled-release Cook coil, immediate and complete angiographic closure was achieved in 41%; color Doppler echocardiography 24 hours after the procedure revealed no detectable shunt in 33 of 36 patients (92%).<sup>9)</sup>

In a comparison of occluding coils and the Rashkind umbrella device, complete closure was achieved in 89% in the coil group as compared to 71% for the Rashkind umbrella device group ( $p < 0.005$ ). Eleven coils in six pa-

tients embolized to the pulmonary arteries.<sup>12)</sup>

Trometzki et al.<sup>10)</sup> reported that in PDA closure using Duct-Occlud devices, the devices were successfully deployed in 86% of patients; for detachable coils the rate was 91%. Embolization of the device occurred on 4 occasions. Two devices were not retrieved but caused no apparent clinical problems.

Gamboa et al.<sup>11)</sup> reported that PDA closures were done using Nit-Occlud devices in 28 patients who had a median age of 1.8 years (range 0.5-21 years) between 2003 and 2006. The occlusion rate immediately after embolization was 53.5%, which increased to 95.2% by 12 months and to 100% by 18 months. The Nit-Occlud device provided an effective and safely retrievable means for PDA closure, irrespective of ductus morphology.

In another study of closure of moderate to large PDAs, ADO was compared with Rashkind or Sideris devices and Cook detachable coils in 116 consecutive patients.<sup>13)</sup> In patients receiving an ADO, complete occlusion was achieved earlier after implantation, and the rate of complete occlusion was better (97%,  $p = 0.024$ ) than in patients using other devices.<sup>13)</sup> Complications included device embolization in 2 patients, hemolysis in 3 patients and repeat procedures to retrieve the device in 12 patients.<sup>13)</sup> Recently, transcatheter closure of moderate to large PDAs using the ADO showed that the ADO is easily retrievable and that the procedure is effective, and safe, and provides better results than can be achieved using other occluders.<sup>7(15)</sup>

For patients who undergo transcatheter closure with devices, the immediate occlusion rates are in excess of 90% and immediate complication rates are very low. There is a potential for left pulmonary artery and descending aortic obstruction in patients who are of low weight with a large ductus requiring a relatively large device for closure, which is rare and normally resolves with aging. Since new generation devices, which are easily retrievable and have a variety of different sizes, were introduced a few years ago, older devices such as the Rashkind double umbrella and the Sideris buttoned device, which had a significant risk for retrieval of malpositioned devices, are no longer used. Therefore the incidence of complications including residual leak, device embolization, protrusion into the aorta, obstruction of left pulmonary artery, and loss of peripheral pulses, have been further decreased, and even the number of these complications gradually decline within 36 months.<sup>10(14)</sup>

The current strategy for transcatheter closure of PDAs is to use coils for a small to a moderate ductus, and an ADO for a large ductus. The ADO can be recommended for a large ductus in infants, in young children with a ductus diameter  $> 3$  mm, and in older children or adults with a ductus diameter  $> 4$  mm. Several coils, including the Nit-Occlud, the Gianturco coil, and detachable coils can be used in patients with a small to a

moderate sized ductus. Using Gianturco coils or detachable coils is convenient to close small PDAs in small infants who weigh less. Using the current strategy, almost any PDA can be closed percutaneously without complication, regardless of their size and morphology except that in premature baby.<sup>7)14)15)</sup>

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