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## CLINICAL RESEARCH

# Significant persistent ductus arteriosus in infants less or equal to 6 kg: Percutaneous closure or surgery?

Persistance de canal artériel significatif chez le nourrisson inférieur ou égal à 6 kg : fermeture percutanée ou chirurgie ?

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### KEYWORDS

Persistent arterial duct;  
Transcatheter closure;  
Low-body-weight infants;

### Summary

**Background.** — Percutaneous closure of large persistent ductus arteriosus using the Amplatzer® duct occluder is an alternative to surgery. However, this device is not recommended in infants weighing less than 6 kg.

**Aim.** — To evaluate the safety and effectiveness of this procedure in low-body-weight infants.

**Methods.** — We reviewed retrospectively data for infants weighing less or equal to 6 kg who underwent percutaneous closure of significant persistent ductus arteriosus using the Amplatzer® duct occluder in France between 1998 and 2007.

**Abbreviations:** 2D-TTE, two-dimensional transthoracic echocardiography; ADO, Amplatzer® duct occluder; LPA, left pulmonary artery; PDA, persistent ductus arteriosus; ROC, receiver operating characteristic; SD, standard deviation.

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## Amplatzer® duct occluder

**Results.** — Data for 58 patients (mean weight: 5 kg, range: 3.4–6; mean age: 5.5 months, range: 2.1–15.3) were reviewed. Mean angiographic persistent ductus arteriosus minimal diameter was 3.7 mm (range: 1–7.5). Implantation of the Amplatzer® duct occluder was successful in 89.7% of cases. In six (10.3%) patients, the device was not implanted because it would have led to significant aortic obstruction. One procedure-related death occurred in a 4 kg infant (1.7%). Major and minor complications occurred in 6.9 and 31.0% of patients, respectively. Persistent ductus arteriosus diameter greater than 3.7 mm, type C (tubular shape) and diameter/patient weight ratio greater than 0.91 were significantly associated with an unsuccessful procedure and/or major complications. During a median 10-month follow-up, no late device embolization occurred.

**Conclusions.** — Although percutaneous closure of significant persistent ductus arteriosus with the Amplatzer® duct occluder is effective in low-body-weight infants, the level and severity of complications indicate surgery as first-line treatment, at least until further studies are done to assess the safety and effectiveness of the new Amplatzer® duct occluder II in low-body-weight infants.

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## MOTS CLÉS

Canal artériel persistant ;  
Fermeture percutanée ;  
Nourrissons de petit poids ;  
Prothèse Amplatzer® duct occluder

## Résumé

**Contexte.** — La fermeture percutanée de large canaux artériels persistants (CAP) avec la prothèse Amplatzer® Duct Occluder (ADO) est une alternative au traitement chirurgical. Cette prothèse est déconseillée chez les nourrissons de moins de 6 kg.

**Objectif.** — Notre objectif a été d'évaluer l'efficacité et la sécurité d'utilisation de cette prothèse dans cette population.

**Méthodes.** — Les dossiers d'enfants de moins de 6 kg ayant subi une fermeture de CAP par la prothèse ADO en France entre 1998 et 2007 ont été analysés rétrospectivement.

**Résultats.** — Cinquante-huit patients (poids moyen: 5 kg [3,4–6]; âge moyen: 5,5 mois [2,1–15,3]) ont été inclus. Le diamètre minimal angiographique du CAP était de 3,7 mm (1–7,5). La prothèse a été implantée avec succès dans 89,7% des cas. Chez six patients (10,3%), la prothèse n'a pas été implantée en raison du risque de subocclusion aortique. Un nourrisson de 4 kg est décédé (1,7%) secondairement à l'intervention. Le taux de complications majeures et mineures était de 6,9 et 31,0%, respectivement. Un CAP de diamètre supérieur ou égal à 3,7 mm, de type C (forme tubulaire) et un ratio diamètre du CAP/poids de l'enfant supérieur à 0,91 étaient significativement associés à un échec d'intervention et/ou complication majeure. Aucune embolisation tardive n'est survenue après dix mois de suivi médian.

**Conclusions.** — La fermeture de CAP significatifs avec la prothèse ADO chez les enfants de petit poids est efficace. Cependant, la fréquence et la sévérité des complications devraient conduire à choisir la ligature chirurgicale comme traitement de première intention, en attendant les résultats de la fermeture percutanée avec la nouvelle prothèse ADO II dans cette population.

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## Introduction

Surgical closure of PDA has been performed for more than 60 years [1]. PDA transcatheter closure was introduced by Porstmann in 1967 [2]. Since then, many devices designed to occlude PDA have been developed [3–7]. However, most of these devices are associated with major drawbacks, including a high incidence of residual shunt and/or embolization, complex delivery systems and the need for a large delivery sheath. In cases of large and symptomatic PDA in infants, multiple coils can be implanted with low-profile delivery sheaths, but the incidence of residual shunt and embolization is high [8–13]. Thus, surgery is currently advised in infants with symptomatic PDA [14–16]. More recently, the ADO has been developed for the closure of moderate to large PDA [17] and many groups have reported encouraging results with this device [16,18–20]. Indeed, many centres favour transcatheter closure in adults and older children

with large PDA because of the lower complication rate, the cost-effectiveness and the less invasive nature of the procedure. However, there are few data on its use in low-body-weight infants. Moreover, the use of the ADO device is not recommended by the manufacturer in children below 6 kg and 6 months of age. The aim of our study was to evaluate the safety and effectiveness of the ADO for percutaneous closure of significant PDA in infants weighing less or equal to 6 kg. To address this issue, data were collected retrospectively from all paediatric catheterization centres in France.

## Methods

### Patients

Data were collected for infants weighing less or equal to 6 kg, who underwent percutaneous closure of significant PDA

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