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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**Summary**

Background. — Percutaneous closure of large persistent ductus arteriosus using the Amplatzer\textsuperscript{\textregistered} 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\textsuperscript{\textregistered} duct occluder in France between 1998 and 2007.

**KEYWORDS**

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

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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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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
Amplatzer® duct occluder in infants less or equal to 6 kg

Results

Patient characteristics

Between October 1998 and June 2007, 58 infants (72.5% female) weighing less or equal to 6 kg underwent attempted transcatheter occlusion of a significant PDA using the ADO in France. The procedure was carried out in one of nine French catheterization centres. Mean (SD) age was 5.5 (2.7) months (range: 2.1—15.3) and mean (SD) weight was 5 (0.7) kg (range: 3.4—6). All patients were symptomatic: weight stagnation or failure to thrive was present in 55 (94.8%) patients, difficulty in breathing and/or repeated respiratory tract infections were present in 24 (41.4%) patients and at least one episode of heart failure had occurred in 24 (41.4%) patients. The PDA was isolated in 29 (50.0%) patients. In the other 29 patients, the PDA was associated with another cardiac malformation (atrial \( n = 3 \) or ventricular \( n = 4 \) septal defect) or was part of a polymalformation syndrome \( n = 22 \), the most frequent being Down syndrome \( n = 6 \).

Echocardiographic signs of left atrial and ventricular overload were present in 43 (74.1%) patients (trivial, \( n = 8 \); moderate, \( n = 28 \); severe, \( n = 7 \)). Pulmonary hypertension was found in 33 (56.9%) patients (infra systemic, \( n = 22 \); isosystolic, \( n = 11 \)). On 2D-TTE, mean (SD) duct diameter at the narrowest point of the PDA was 4 (1.1) mm (range 2—6), as was the median duct diameter.

Persistent ductus arteriosus and procedural characteristics

Angiographic mean (SD) duct diameter was 3.7 (1.3) mm at the narrowest point of the PDA. Median duct size was 3.5 mm (range: 1—7.5). Fig. 1 shows the distribution of duct shapes in our population, according to Krichenko et al.’s classification \([21]\). The different sizes of ADO used in these patients are shown in Fig. 2.

Delivery of the device was successful in 52 (89.7%) patients. In six patients, no device was implanted because of a major risk of aortic subocclusion. One death related to the procedure occurred in a 4 kg infant, who had a 3.7 mm type C PDA. An 8 × 6 device had been implanted. The position was unsatisfactory as the device had toppled into the aortic lumen. While retrieving the impacted device, car-

Several risk factors were analysed to establish a possible significant association between these factors and an unsuccessful procedure or the occurrence of major complications. A procedure was considered to be unsuccessful when the device was not ultimately implanted.

The \( \chi^2 \) test was used to determine the existence of an association between the rate of success in our population and qualitative variables. Student’s \( t \)-test (or the Wilcoxon test) was used for numerical variables. ROC curves were obtained for one variable (PDA/W ratio) to find the best compromise between sensitivity and specificity. All tests were two sided. A \( p \)-value < 0.05 was considered to be significant. Statistical analysis was performed using SAS® for Windows® software (SAS Institute, 8.02 version; Cary, NC, USA). ROC curves were obtained using Medcalc® software, version 5.00.

Statistical analysis

Results are expressed as mean values (SD) and range, or as median values and range.

Follow-up

All patients underwent clinical and echocardiographic investigations, before discharge and at 1-month follow-up, to evaluate the effectiveness of the ADO and to monitor for possible LPA or aortic stenosis. If needed, a longer follow-up with additional echocardiograms was scheduled. Residual shunts were graded on colour Doppler echocardiograms as absent, grade I (smoke-like jet) or grade II (directional jet). LPA and/or aortic obstruction were considered to be significant if Doppler velocity measurements were greater than 2 m/s. Complications related to the procedure were recorded, classified as major (death, cardiac arrest with successful resuscitation, device embolization) or minor (inguinal haematoma, transient thrombosis of the femoral artery, blood transfusion, haemolysis, LPA and/or significant aortic stenosis).

Catheterization

PDA percutaneous closure was performed in nine French tertiary paediatric cardiac centres, as described previously \([17]\). Procedures were performed under conscious sedation or general anaesthesia. A lateral view aortogram was performed before percutaneous closure to determine duct shape according to Krichenko et al.’s angiographic classification \([21]\) and PDA minimal diameter. The PDA minimal diameter (mm) per patient weight (kg) ratio (PDA/W ratio) was calculated. PDA length and angle were not measured.

In most cases, the device size selected was 1 to 2 mm greater than the PDA minimal diameter, measured by angiography in lateral projection. The lateral view aortogram was repeated after occlusion to assess residual shunting. Procedural and fluoroscopy times, injected iodine volume (ml/kg) as well as venous and arterial catheter sizes were recorded. When measured, a final gradient at the aortic or pulmonary end of the device was considered to be significant if greater than 10 mmHg.

with the ADO in France between October 1998 and June 2007. Informed consent was obtained from legal guardians. The inclusion criteria consisted of clinically symptomatic PDA in infants weighing less or equal to 6 kg without supra-systemic pulmonary hypertension. Symptoms of significant PDA included difficulty in breathing, repeated respiratory tract infections, weight stagnation or failure to thrive and signs of patent heart failure. Indicators of significant PDA on 2D-TTE included left atrial and left ventricular volume overload and signs of pulmonary hypertension. The former was classified as absent, trivial, moderate or severe according to weight-related dimensions; the latter was graded according to duct velocity and flow direction and was classified as absent, infra systemic or isosystemic. PDA minimal diameter was determined on 2D-TTE before the transcatheter procedure. Infants who had undergone PDA closure using the ADO but weighed more than 6 kg and those who had had an attempted PDA closure using coils were excluded.
diac arrest occurred, leading to severe neurological lesions and death 1 month later. The other five patients underwent successful surgical ligation. Table 1 shows the clinical and angiographic characteristics of the six unsuccessful cases.

Major procedural complications occurred in four patients (6.9%): death occurred in one patient (as described earlier), cardiac arrest with successful resuscitation in two patients and device embolization in one patient. Cardiac arrests were presumably due to aortic obstruction by the device; both patients recovered without sequelae. The device that had embolized in the descending aorta was retrieved and reimplemented successfully during the same procedure.

Minor procedural complications occurred in 18 (31.0%) patients. Nine patients had significant aortic and/or LPA protrusion of the device assessed during catheterization or by Doppler TTE measurements after the procedure. One patient also had a blood transfusion and another had an inguinal haematoma. Five other patients required a blood transfusion while four had transient femoral pulse loss.

Technical data were available for 29 (50.0%) patients: mean (SD) procedural time was 66 (33) minutes, mean (SD) fluoroscopy time was 10.0 (6.6) minutes and mean (SD) injected iodine volume was 5.7 (2.3) ml/kg. Catheter sizes were recorded for 38 (65.5%) patients: a 4 French arterial catheter was used in 87.0% of recorded cases and a 6 French venous sheath in 83.0% of recorded cases.

Complete occlusion was demonstrable in the cardiac catheterization laboratory in 20 out of 52 (38.5%) patients. The following day, eight patients continued to have residual flow (grade I in six patients) demonstrated by colour Doppler TTE.

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Age (months)</th>
<th>Weight (kg)</th>
<th>Angiographic minimal PDA diameter (mm)</th>
<th>PDA/W ratio</th>
<th>PDA type</th>
<th>ADO size</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>3.50</td>
<td>4.40</td>
<td>4.50</td>
<td>1.02</td>
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<td>—</td>
</tr>
<tr>
<td>11</td>
<td>2.10</td>
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<td>1.12</td>
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<td>6/4</td>
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<td>28</td>
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<td>4.00</td>
<td>6.00</td>
<td>1.50</td>
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<td>10/8</td>
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<td>5.70</td>
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<tr>
<td>45</td>
<td>9.10</td>
<td>6.00</td>
<td>6.00</td>
<td>1.00</td>
<td>C</td>
<td>10/8</td>
</tr>
<tr>
<td>Mean</td>
<td>4.88</td>
<td>4.49</td>
<td>4.68</td>
<td>1.06</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

ADO: Amplatzer® duct occluder; PDA: persistent ductus arteriosus; PDA/W: persistent ductus arteriosus minimal angiographic diameter (mm)/patient weight (kg).
Amplatzer® duct occluder in infants less or equal to 6 kg

Follow-up

Seven foreign patients were lost to follow-up (12.1%). The remaining 45 patients who underwent successful ADO implantation were followed up for a median of 10 months (range: 0.5–91). Patients showed no recurrent respiratory infections or signs of heart failure and those who had failed to thrive had increased their weight. 2D-TTE showed complete regression of signs of volume overload for all but two patients; one of these patients had a perimembranous ventricular septal defect in addition to the closed PDA. Of the eight patients demonstrating early residual shunt on TTE, five showed complete occlusion at 1 year, two were lost to follow-up and one asymptomatic patient had a moderate (grade II) residual shunt at his 8-month visit, but without echocardiographic signs of volume overload. Of the nine infants demonstrating significant early aortic or LPA stenosis, five were followed up; all showed regression of the stenosis. All minor aortic obstructions (less than 2 m/s) also disappeared with child growth.

Risk factors

Risk factors significantly associated with the occurrence of an unsuccessful procedure were identified, as shown in Table 2. The figure of 3.7 mm was chosen as a cut-off for statistical analysis because it corresponded to the mean angiographic minimal duct diameter in our patients. The limit for the PDA/W ratio of greater than 0.91 was determined after constructing an ROC curve. Patient weight alone (greater or less than 5 kg) was not a risk factor, nor was isolation status (isolated or not isolated) of the PDA. Down syndrome did not have any bearing on outcome. There was no significant ‘centre effect’ when analysing results and complication rates (p > 0.05). For each of the nine centres, the numbers of patients and major and minor complications were as follows: centre A (n = 14, one major and six minor complications); centre B (n = 13, one major and five minor complications); centre C (n = 11, four minor complications); centre D (n = 6, two major and two minor complications); centre E (n = 4, no complications); centre F (n = 3, one minor complication); centres G, H, and I (n = 3, n = 1 and n = 1, respectively, no complications).

Discussion

To our knowledge, our study of percutaneous closure of symptomatic PDA in low-body-weight infants is the largest reported to date. This study demonstrates that percutaneous closure of symptomatic PDA with the ADO in selected infants less or equal to 6 kg is feasible and effective, with a success rate of 89.7%. The occlusion rate at 1 year was 100% for those followed up over this period. Major and minor complications occurred in 6.9 and 31.0% of cases, respectively. Several risk factors were significantly associated with the occurrence of an unsuccessful procedure and/or major complications.

Amplatzer® duct occluder occlusion

Numerous series have reported the successful use of the ADO in adults or adolescents, with a success rate and occlusion rate at 1 year of more than 99% [18–20]. Fewer and smaller studies of ADO implantation in infants have been reported [22–25]. We chose to compare our results with those found in six other selected studies using Pearson’s χ² test (or Fisher’s test) [19,20,22–25]. All six studies report PDA percutaneous closure using the ADO: three are large studies, while the other three have a smaller population size but include mainly infants and are therefore similar to ours. Our success rate was significantly lower than those reported in the six studies mentioned above (p < 0.001), except for the study of Fischer et al. (p = 0.18) [25]. Overall morbidity was significantly higher in our study (p < 0.001) than in the other studies.

Most of these studies agree with the manufacturer’s recommendation not to use the ADO in infants with a body weight less than 6 kg. Nevertheless, many centres perform this procedure, with variable results. The results of the present study may give a clearer view of the outcomes of this procedure in low-body-weight infants, while identifying precise risk factors.

There are two main concerns about using the ADO in low-weight infants: local arterial complications due to the size of the sheath and aortic obstruction due to the size of the isthmus in relation to device size. We encountered five local complications (8.6%). All of these patients recovered ad integrum during follow-up. This rate is similar to the rate of 8.3% reported by Fischer el al. [25] and lower than the rate of 16.7% reported by Butera et al. [24] (two of the series reporting ADO implantation in infants). Compared with previous devices, ADO implantation requires smaller-sized introduction sheaths (5–7 French). Thus, fewer vascular access complications occur, as demonstrated in our series.

The six unsuccessful procedures encountered in our series were related to the occurrence of aortic subocclusion by the device. The size of the aortic isthmus is related to patient weight. The infants included in our series had lower weights than those in other reports [22,24,25] and consequently a
narrower isthmus, thus explaining our higher rate of aortic subocclusion and lower success rate. Table 3 summarizes the data from these six (adult and paediatric) studies.

Other factors may play a role in the occurrence of subocclusion — for example, the angle between the PDA and the aorta, which is usually an acute angle. Unfortunately, few centres in France record this information. When the device is released, there is a rocking motion of the retention disc in the aorta, which is more problematic when the aortic isthmus is narrow. It is even more problematic when there is no ampulla at the aortic end of the PDA, as in PDA types B and C, according to Krichenko’s classification. Thus, the problem of the angle between the PDA and the aorta is linked to the type of PDA. When there is an acute angle and PDA type C, the rocking motion of the retention disc leads to protrusion of the device directly into the aortic isthmus. In our series, PDA type C represented 29.3% of all cases and was significantly associated with an unsuccessful procedure. In previous series reporting the use of ADO in PDA closure in infants [22,24–26], duct shape was not described in relation to the occurrence of device protrusion. Other paediatric series reporting PDA occlusion using coils had a lower incidence of PDA type C [27,28]. Yet, there may be a bias: patients selected for coil occlusion usually have a small PDA, which is more likely to have a restricted pulmonary end. In February 2008, AGA Medical Corporation announced that it had received European ‘Conformité Européenne’ mark approval for the Amplatzer® duct occluder II (ADO II) [29], which is also a self-expanding nitinol mesh device, fabric-free, shaped into a cylindrical waist with retention discs on either end. According to the manufacturer, it can treat (almost) all PDA classifications but, again, only in patients who weigh more than 6 kg and are older than 6 months of age. Further studies will be needed to assess its safety and effectiveness in our patient population.

Duct length may also be a risk factor for aortic subocclusion — particularly the device length/PDA length ratio. Indeed, implantation of a ‘long’ device may cause aortic subocclusion due to protrusion of the device.

These hypotheses concerning aortic subocclusion suggest that PDA is a complex and three-dimensional structure. The mere measurement of the minimal diameter may not be sufficient, especially in this infant population, and other variables such as PDA type, PDA angle and PDA length should be evaluated before performing the procedure. Ideally, there should be a specific device for each PDA, taking into account all of these variables. Performing a non-invasive imaging technique such as three-dimensional TTE, computed tomography or magnetic resonance imaging, before catheterization, may be useful for characterizing the aortic isthmus and detecting those patients more at risk of aortic subocclusion.

Our study also demonstrated that patient weight alone was not statistically associated with an increased risk of failure or complications. However, a PDA/W ratio greater than 0.91 was significantly associated, emphasizing the fact that both factors are important in determining the risk. Ideally, our study should also have included patients with significant PDA treated by surgical ligation in the same centres during the same time period, and those who underwent ADO

### Table 3

<table>
<thead>
<tr>
<th>Study</th>
<th>Median age (range) (years)</th>
<th>Median weight (range) (kg)</th>
<th>No. of patients</th>
<th>Median follow-up (months)</th>
<th>Success rate (%)</th>
<th>Median follow-up (months)</th>
<th>1-year occlusion rate (%)</th>
<th>Overall morbidity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pass et al. [20]</td>
<td>0.2 (0.1—70.7)</td>
<td>3.4 (0.3—23.9)</td>
<td>209</td>
<td>14</td>
<td>100</td>
<td>11 (4.5—164.5)</td>
<td>99.3</td>
<td>99.7</td>
</tr>
<tr>
<td>Masura et al. [19]</td>
<td>0.9 (0.2—30)</td>
<td>6.4 (3.4—63.2)</td>
<td>209</td>
<td>12</td>
<td>99.7</td>
<td>15 (4.9—58)</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Bilkis et al. [23]</td>
<td>0.5 (0.3—1.3)</td>
<td>8.4 (1.3—1.6)</td>
<td>209</td>
<td>6</td>
<td>98</td>
<td>8.4 (1.3—1.6)</td>
<td>83</td>
<td>100</td>
</tr>
<tr>
<td>Butera et al. [24]</td>
<td>0.4 (0.1—0.9)</td>
<td>4.4 (0.3—4.4)</td>
<td>209</td>
<td>7</td>
<td>97.7</td>
<td>4.4 (0.3—4.4)</td>
<td>97.7</td>
<td>100</td>
</tr>
<tr>
<td>Fischer et al. [25]</td>
<td>0.1 (0.1—1.3)</td>
<td>3.9 (0.1—1.3)</td>
<td>209</td>
<td>9</td>
<td>92.1</td>
<td>3.9 (0.1—1.3)</td>
<td>97.7</td>
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<td>Al-Ata et al. [22]</td>
<td>0.4 (0.1—1.3)</td>
<td>11 (4.5—164.5)</td>
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<td>99.7</td>
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<td>99.7</td>
<td>99.7</td>
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<tr>
<td>Our study</td>
<td>0.4 (0.1—1.3)</td>
<td>11 (4.5—164.5)</td>
<td>209</td>
<td>12</td>
<td>99.7</td>
<td>11 (4.5—164.5)</td>
<td>99.7</td>
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</tr>
</tbody>
</table>

NR: not reported.

a Mean value.
b Median follow-up reported; 43% of the patients had a 1-year follow-up.
c Occlusion rate at 6 months.
d Occlusion rate among patients who had a 1-year follow-up.
implantation but weighed more than 6 kg, to compare outcomes and complication rates between the three groups. We have compared our results only with those reported in the literature for similar populations, as shown in Table 3. It appears from our results that before using the ADO for PDA occlusion in symptomatic infants less or equal to 6 kg, one should consider not only patient weight, but also PDA type and PDA/W ratio to identify patients at higher risk of failure or complications. The risk factors identified in this preliminary series need to be validated in a prospective study.

Surgical treatment

For some teams, conventional open surgery remains the treatment of choice [14]. Mavroudis et al. [30] reported their 46-year experience of PDA division and ligation, with a 0% mortality rate and 4.4% morbidity rate, which rose to 14% during the last decade if complications such as blood transfusions were included. This rate would probably be higher for low-weight infants with large PDA. Moreover, absence of residual shunt was confirmed during follow-up by auscultation in more than 50% of patients, and thus may have been underestimated. Concerning video-assisted thoracoscopic surgery, this technique is burdened with a high rate of recurrent laryngeal nerve injuries and chylothorax [31]. No specific reports have been found for PDA surgery in low-body-weight infants.

Nevertheless, conventional surgery may have to be considered as the first-line treatment for some infants weighing less or equal to 6 kg with a symptomatic PDA, especially those with PDA type C, a PDA diameter greater or equal to 3.7 mm and a PDA/W ratio greater than 0.91.

Study limitations

This is a limited series where only selected patients have been offered percutaneous closure with the ADO, according to their paediatric cardiologist’s opinion, formed with or without a multidisciplinary discussion. While this approach certainly introduces a bias, this bias should have favoured the device, as closure using the ADO had been attempted only in ‘favourable PDA anatomies’. If all PDA cases had been included, one can speculate that the results would have shown even more complications.

Missing data and patients lost to follow-up are related to the retrospective nature of our study. Because this was not a controlled study, we did not have a ‘surgical’ group or a ‘percutaneous closure with ADO in infants more than 6 kg’ group to compare our results with and to demonstrate the influence of this technique and of patient weight on the success and complication rates. Thus, we compared our results to those reported in the literature. No statistical difference was found between the nine centres that performed this procedure, but this may be related to a lack of power of the statistical analysis due to the small size of our population.

Conclusion

Our study demonstrated that percutaneous closure of moderate to large PDA using the ADO in selected infants weighing less or equal to 6 kg is effective, with a high success rate. However, the complication rate in this population is high, mainly due to aortic subocclusion related to the use of large devices. Predictors of failure and/or major complications have been identified: PDA type C, an angiographic PDA diameter greater or equal to 3.7 mm and a PDA/W ratio greater than 0.91. These should be taken into account to guide future procedures in this patient population, and even to indicate surgery as a first-line treatment, at least until further studies are carried out to assess the safety and effectiveness of the new ADO II in low-body-weight infants.

Conflict of interests

None.

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