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Original Article

# Percutaneous Closure of a Patent Ductus Arteriosus with the Cera™ PDA Occluder: Another Good Option in the Toolbox

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## ABSTRACT

**Background:** The percutaneous closure of a patent ductus arteriosus (PDA) has been considered the treatment of choice by most authors, and several devices with different structural characteristics have been used. The initial experience with the novel Cera™ PDA Occluder is reported. **Methods:** From March of 2010 through December of 2011, patients weighing over 5 kg with a PDA diagnosed by transthoracic echocardiogram (TTE) with colour Doppler flow mapping and no associated defects underwent the procedure. Follow-up was performed by TTE one, three, and six months after the procedure, and yearly thereafter. **Results:** Overall, 18 patients were referred for percutaneous occlusion; 61.2% were female. The mean age and weight were 13.7 ± 9.3 years and 42.9 ± 20.1 kg, respectively. Regarding morphology, 11 were type A, six were type E, and one had a residual postoperative defect. The mean diameter was 4.2 mm. Implantation was possible in all patients. Ten 6-4 mm, one 8-6 mm, three 10-8 mm, and four 12-10 mm devices were used. All defects were completely closed by the first follow-up TTE. Deaths or complications were not observed in this series. **Conclusions:** The Cera™ prosthesis may be used for the occlusion of small or large defects, and delivers to excellent results in children and adults. The procedure is easy, safe, has a high efficacy and low morbidity, and may be an excellent option for the percutaneous closure of a PDA. Due to its flexibility, oversized devices greater than 2 mm should be used.

**DESCRIPTORS:** Ductus arteriosus, patent. Heart catheterization. Prostheses and implants. Heart defects, congenital.

## RESUMO

### Fechamento de Canais Arteriais com o Dispositivo Cera™ PDA Occluder: Mais uma Boa Opção na Caixa de Ferramentas

**Introdução:** O fechamento percutâneo de persistência dos canais arteriais (PCA) tem sido considerado tratamento de escolha pela maioria dos autores, e diversos dispositivos com diferentes características estruturais têm sido utilizados. Apresentamos a experiência inicial do grupo com a nova prótese Cera™ PDA Occluder. **Métodos:** Entre março de 2010 e dezembro de 2011 foram submetidos ao procedimento pacientes com mais de 5 kg de peso, com PCA diagnosticada por meio de ecocardiograma transtorácico com mapeamento de fluxo em cores (ETT), sem defeitos associados. O seguimento foi feito com ETT no primeiro, no terceiro e no sexto meses subsequentes, e, a seguir, anualmente. **Resultados:** No total, 18 pacientes foram encaminhados para oclusão percutânea, dos quais 61,2% eram do sexo feminino. As médias das idades e dos pesos foram, respectivamente, de 13,7 ± 9,3 anos e 42,9 ± 20,1 kg. Quanto à morfologia, 11 canais foram do tipo A, 6 foram do tipo E, e 1 pertuito residual após cirurgia. A média dos diâmetros foi de 4,2 mm. O implante foi possível em todos os casos. Foram utilizadas 10 próteses 6-4 mm, 1 prótese 8-6 mm, 3 próteses 10-8 mm e 4 próteses 12-10 mm. Todos os canais estavam completamente fechados por ocasião do primeiro ETT de controle. Não houve óbitos ou complicações nesta casuística. **Conclusões:** A prótese Cera™ pode ser utilizada para o fechamento de canais de pequeno ou grande calibres com excelente resultado, em crianças e adultos. O procedimento é fácil, seguro, com alta eficácia e baixa morbidade, e pode ser excelente opção para o fechamento percutâneo de PCA. Suas características de flexibilidade sugerem que sejam utilizadas próteses superdimensionadas acima dos 2 mm habitualmente recomendados.

**DESCRITORES:** Permeabilidade do canal arterial. Cateterismo cardíaco. Próteses e implantes. Cardiopatias congênitas.

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The percutaneous closure of a patent ductus arteriosus (PDA) represents an established alternative to surgical ligation and has been defined as the treatment of choice by most authors. To this end, several devices have been used.[1–15]

At the end of the 1990s, the first metal mesh prosthesis, the Amplatzer® Duct Occluder I (ADO I), capable of occluding larger diameter channels was developed as an alternative to embolisation coils.[16] Universally used, it has occlusion rates of nearly 100%, with very low short- and long-term complication rates.[17–20] Despite the success, new devices with different structural characteristics have been produced.

The objective of the present study was to present an initial experience with a new prosthesis, the Cera™ PDA Occluder (Lifetech Scientific Co. Ltd., Shenzhen, China), and to examine its role as another option for the occlusion of medium and large calibre PDA.

**Figure 1** – Two details of the Cera™ PDA Occluder. The retention disc can be observed in the aortic extremity and the thread in the opposed extremity connected to the releaser cable. The presence of expanded polytetrafluorethylene inside the prosthesis to increase its occlusive capacity can be noticed.

## METHODS

### Study design

This was a prospective, single-arm study performed at two centres. All patients underwent closure of PDA with the Cera™ prosthesis between March 2010 and December 2011. Characteristics of the device and the immediate results are described.

### Selection criteria

All consecutive patients weighing more than 5 kg with PDA, and without any other associated defects that required surgical correction, were included in this study. Cases were chosen by transthoracic echocardiograms (TTEs) with colour flow mapping. The dimensions and morphology of the defects did not constitute exclusion criteria.

### The prosthesis

The Cera™ occluder is a self-expansible prosthesis with a nitinol fragmented cone and ceramic coating. The proximal (pulmonary) extremity has a female thread, measuring 2 mm less than the distal (aortic) extremity of the cone, and connects to the delivery system. There is a retention disc in the aortic extremity that measures 4 mm more than the distal extremity (Figure 1).

The device is available in 2-mm increments from 6 mm to 24 mm in diameter (distal extremity). The central portion measures 7 mm in 6- to 14-mm prostheses, 8 mm in 16- and 18-mm prostheses, 9 mm in 20- and 22-mm prostheses, and 10 mm in 24-mm prostheses.

The delivery system is composed of a 5 F to 12 F long and flexible sheath, a small loader of compatible size, a haemostatic valve, and a distal extremity with a metallic cable with threads.

### Implant technique

The implant and follow-up protocols have been previously described and are the same protocols used for the ADO I prosthesis study.[20]

### Statistical analysis

Continuous variables were expressed as mean and standard deviation, while categorical variables were expressed as numbers and percentages. The objective of this article was to present the initial experience with the new Cera™ prosthesis for the treatment of PDA in a single-arm registry; therefore, comparisons were not made.

## RESULTS

Eighteen patients were referred for percutaneous closure with the Cera™ prosthesis; 61.2% were female. Their ages ranged from 1 to 33 years (13.7 ± 9.3 years), and their weights ranged from 10 kg to 72 kg (42.9 ± 20.1 kg).

Two patients had recent onset of exertional dyspnoea (cases 17 and 18). Regarding the morphology, 11 channels were type A, six were type E,[21] and the other was a residual channel after surgical ligation.

The smaller channel diameters, measured at the pulmonary extremity, ranged from 1 mm to 8.6 mm (4.2 ± 2.4 mm) (Table).

The systolic pulmonary pressure was higher than 30 mmHg in 50% (9/18) of patients and ranged from 18 mmHg to 45 mmHg (31 ± 7.9 mmHg).

Implantation of the device was possible in all cases. Ten 6-4 mm, one 8-6 mm, three 10-8 mm, and four 12-10 mm prostheses were used.