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Original Article

Percutaneous vs. Surgical Treatment of Patent Ductus Arteriosus in Children and Adolescents

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ABSTRACT

Background: Studies comparing percutaneous and surgical methods for the treatment of the patent ductus arteriosus (PDA) are rare in the literature. This study aimed to perform a comparative analysis between both PDA treatment methods with emphasis on efficacy and morbidity. **Methods:** Observational study with 2 cohorts of children and adolescents > 5 kg and < 14 years of age with PDA, treated under a study protocol to assess the incorporation of novel technologies to the Brazilian Public Health System (Unified Health System – SUS) at an excellence hospital, in partnership with the Brazilian Ministry of Health. A prospective analysis was conducted for the percutaneous group from 2009 to 2011 and a retrospective analysis was performed for the surgical group between 2006 and 2011. **Results:** Eighty patients were included in the percutaneous group (60% female) and 39 patients in the surgical group (51% female; P = 0.37). The median age and weight of the percutaneous and surgical groups was 39.4 months vs 25.5 months (P = 0.04) and 14 kg vs 11.1 kg (P = 0.052), respectively. In the percutaneous group, 78 patients (92%) had type A PDA and the minimal ductal diameter at angiography was 2.5 ± 1.2 mm. Amplatzer®, Gianturco coils and Cera™ were the most commonly used devices. Clipping was the most commonly used surgical technique. The success rate of the procedure was 100% in both groups. The surgical group had higher complication rates, including chylothorax, infections, transfusions, systemic arterial hypertension, use of opioids and a greater need for intensive care. The median hospitalization time was 1.3 days in the percutaneous group and 7.9 days in the surgical group (P < 0.01). Upon discharge, occlusion rates were similar in both groups (91% in the percutaneous group and 87% in the surgical group; P = 0.71). **Conclusions:** Due

RESUMO

Tratamento Percutâneo vs. Cirúrgico da Persistência do Canal Arterial em Crianças e Adolescentes

Introdução: Estudos comparando os métodos percutâneo e cirúrgico no tratamento da persistência do canal arterial (PCA) são raros na literatura. Nosso objetivo foi realizar análise comparativa entre os dois métodos de tratamento da PCA, enfatizando os aspectos de eficácia e morbidade. **Métodos:** Estudo observacional com 2 coortes de crianças e adolescentes > 5 kg e < 14 anos, portadores de PCA, tratados durante um projeto de avaliação de incorporação de novas tecnologias ao Sistema Único de Saúde (SUS), realizado em um hospital cardiológico de excelência, em parceria com o Ministério da Saúde do Brasil. Foi feita análise prospectiva no grupo percutâneo entre 2009 e 2011 e retrospectiva no grupo cirúrgico entre 2006 e 2011. **Resultados:** Foram incluídos 80 pacientes no grupo percutâneo (60% do sexo feminino) e 39 no grupo cirúrgico (51% do sexo feminino; P = 0,37). A mediana de idade e de peso dos grupos percutâneo e cirúrgico foi de 39,4 meses vs. 25,5 meses (P = 0,04) e de 14 kg vs. 11,1 kg (P = 0,052), respectivamente. No grupo percutâneo, 78 pa-cientes (92%) tinham PCA do tipo A e o diâmetro mínimo do canal à angiografia foi de 2,5 ± 1,2 mm. As próteses mais utilizadas foram Amplatzer®, molas de Gianturco e Cera™. A técnica cirúrgica mais utilizada foi a clipagem. A taxa de sucesso dos procedimentos foi de 100% nos dois grupos. O grupo cirúrgico apresentou maiores taxas de complicação, incluindo quilotórax, infecções, necessidade de hemoderivados, hipertensão arterial sistêmica e uso de opioides, como também maior necessidade de terapia intensiva. A mediana do tempo de internação foi de 1,3 dia no grupo percutâneo

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to the lower morbidity, the shorter hospitalization time and similar efficacy, percutaneous treatment of the PDA should be considered the modality of choice for selected patients.

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

e de 7,9 dias no grupo cirúrgico (P < 0,01). À alta hospitalar, as taxas de oclusão foram semelhantes nos dois grupos (91% no grupo percutâneo e 87% no grupo cirúrgico; P = 0,71). Conclusões: Em decorrência da menor morbidade, do menor tempo de internação e da igual eficácia, o tratamento percutâneo da PCA deve ser considerado a modalidade terapêutica de escolha para pacientes selecionados.

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

Patent ductus arteriosus (PDA) is one of the most frequent congenital cardiopathies, accounting for up to 7% of all congenital heart disease.[1,2] Its treatment is indicated in the first year of life in the presence of heart failure, or later when there are hemodynamic effects characterized by increased left ventricular dimensions on echocardiography.[3] The timely closure of PDA prevents the appearance of complications such as heart failure, pulmonary hypertension, arrhythmias, and possibly infectious endarteritis.[1,2]

Surgical correction of PDA by lateral thoracotomy without the use of cardiopulmonary bypass was introduced in the late 1930s, and has been used with very good results.[4] However, this approach is associated with significant chest pain and a hospital stay of three to five days and results in a permanent chest scar. In the past 15 years, percutaneous treatment of PDA with latest-generation intracardiac prostheses has been performed with extreme safety and efficacy in various age groups, excluding newborns and young infants weighing less than 4 to 5 kg.

There is a scarcity of comparative studies of percutaneous and surgical treatment of PDA. Although the few published studies have some methodological limitations, they unanimously demonstrate that the percutaneous approach has an efficacy similar to that of the surgical approach and is associated with a lower incidence of complications.[5,6] Thus, percutaneous treatment is becoming the method of choice for the treatment of congenital heart disease in most centers worldwide.

In Brazil, although there are several observational studies reporting excellent results of percutaneous treatment of PDA with different techniques,[3,7–9] studies comparing percutaneous treatment with surgical treatment are nonexistent. This study aimed to compare the safety and efficacy outcomes of percutaneous and surgical treatment of PDA. The study was performed in a cardiology hospital of excellence during the implementation of a project conducted together with the Ministry of Health to review the incorporation of new technologies within the Brazilian Unified Health System (Sistema Único de Saúde – SUS).[10]

METHODS

The present study was an observational clinical trial in which two cohorts of children and adolescents with PDA with hemodynamic consequences were evaluated. The costs of hospitalisation and materials were subsidized by the government project.

For comparison purposes, the patients were divided into two groups: those who received percutaneous treatment with intracardiac prostheses (percutaneous group) and those who underwent conventional cardiac surgery (surgical group). After project approval by the Brazilian Ministry of Health in 2009, each patient was assigned to one of the two groups at the discretion of the attending physician.

Before 2009, the treatment offered to patients by the hospital philanthropic care project was exclusively surgical. The cohort of patients treated with the percutaneous procedure was evaluated prospectively, and the data were compared with data from a historical cohort of contemporary patients undergoing surgical treatment. Data from the latter cohort were retrospectively analysed after data collection from medical records covering the period between 2006 and 2011.

The study was approved by the research ethics committee of the hospital. The patients' parents or tutors were adequately informed of the risks and benefits of the percutaneous procedure and signed an informed consent for the procedure.

Patients selected for this study weighed ≥ 5 kg, were ≤ 14 years old, and had indication for PDA closure, i.e., left chamber overload at echocardiography. The percutaneous group included patients with PDA favorable to prosthesis implantation; these patients had no coexisting intracardiac disease that required surgical treatment. An exclusion criterion for the percutaneous group was PDA with unfavorable anatomy for percutaneous treatment. This was defined by the interventional professional after aortography using a view considered appropriate for assessment of PDA. Patients with low body weight (< 10.8 kg) or with large PDA, in whom the placement of a device could lead to protrusion and