

Original article

Balloon atrial septostomy under echocardiographic and fluoroscopic guidance in patients with congenital heart disease under 3 months old at a national pediatric referral center

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ABSTRACT

Objective. Balloon atrial septostomy is an emergency procedure used in congenital heart diseases that require interatrial communication to increase cardiac output in right-sided obstructive lesions or to improve mixing in patients with transposition of the great arteries. This procedure is currently performed using both fluoroscopy and echocardiography guidance. The aim of this study is to describe our center's experience in performing balloon atrial septostomy under echocardiographic and fluoroscopic guidance in patients under 3 months of age. **Materials and Methods.** Descriptive, comparative, and retrospective study in patients who underwent balloon atrial septostomy under echocardiographic and fluoroscopic guidance between 2018 and 2023 in a specialized center in Peru. **Results.** 36 patients were analyzed, of which 21 were in the fluoroscopy group and 15 in the echocardiography group. More than two-thirds of the cases were male, and over 60% in both groups had transposition of the great vessels. No significant differences were found in terms of ventilatory support and inotropic support. The procedure success rate was 100% in both groups, with no complications. **Conclusion.** Both balloon atrial septostomy performed by fluoroscopy and by echocardiography were successful and without complications. It should be emphasized that the one performed by echocardiography was done at the patient's bedside, to avoid transferring the patient from the critical care unit to the angiography room and without the use of radiation.

Keywords: Balloon Atrioseptostomy; Atrial Septum; Fluoroscopy; Echocardiography (Source: MeSH-NLM).

RESUMEN

Atrioseptostomía con balón bajo guía ecocardiográfica y fluoroscópica en pacientes con cardiopatías congénitas menores de 3 meses en un centro pediátrico de referencia nacional

Objetivo. La atrioseptostomía con balón es un procedimiento de urgencia en cardiopatías congénitas que requieren comunicación interauricular para aumentar el gasto cardíaco en lesiones obstructivas del lado derecho o para mejorar la mezcla en pacientes con transposición de las grandes arterias. Dicho procedimiento se realiza actualmente tanto con fluoroscopia como con ecocardiografía. El objetivo del estudio es describir la experiencia de nuestro centro en la realización de la atrioseptostomía con balón bajo guía ecocardiográfica y bajo guía fluoroscópica en pacientes menores de 3 meses de edad. **Materiales y métodos.** Estudio descriptivo, comparativo y retrospectivo en pacientes en quienes se realizó la atrioseptostomía con balón bajo guía ecocardiográfica y fluoroscópica entre 2018 y 2023 en un centro especializado en el Perú. **Resultados.** Se analizaron 36 pacientes, de los cuales 21 fueron del grupo de fluoroscopia y 15 del grupo de ecocardiografía. Más de 2/3 de los casos fueron del sexo masculino y más del 60%, en ambos grupos, tenía transposición de grandes vasos. No se encontraron diferencias significativas en cuanto al soporte ventilatorio y soporte inotrópico. La tasa de éxito del procedimiento fue del 100% en ambos grupos, sin presentar complicaciones. **Conclusión.** Tanto la atrioseptostomía con balón realizada por fluoroscopia y la realizada por ecocardiografía fueron exitosas y sin complicaciones, se debe enfatizar que la realizada por ecocardiografía se hizo en la cuna del paciente, para evitar el traslado de la unidad crítica a la sala de angiografía y sin uso de radiación.

Palabras clave: Atrioseptostomía con Balón; Tabique Interauricular; Fluoroscopia; Ecocardiografía (Fuente: DeCS Bireme).

Introduction

Life-threatening congenital heart diseases can be effectively palliated by creating an interatrial septal defect⁽¹⁾. Balloon atrial septostomy (BAS) is an essential interventional procedure for some congenital heart lesions that require interatrial communication to increase cardiac output in right-sided obstructive lesions⁽²⁾; to improve mixing in patients with transposition of the great arteries⁽³⁻⁶⁾; and to relieve left atrial pressure in left-sided obstructive lesions⁽⁵⁾.

Traditionally, the procedure was performed in the catheterization laboratory assisted by uniplanar fluoroscopy, which made it difficult to accurately identify the balloon's position and generated greater risks of cardiac perforation, damage to atrioventricular valves, and laceration of pulmonary and systemic veins, among other complications⁽⁷⁻⁹⁾. These risks decreased with the use of biplanar fluoroscopy; however, in this case, there was a significant increase in exposure to ionizing radiation.

To address these limitations, some protocols were validated using echocardiography to aid balloon catheter positioning in the catheterization laboratory during an invasive procedure. In the study conducted by Savorgnan⁽¹⁰⁾, it was demonstrated that performing balloon atrial septostomy under echocardiographic guidance was as effective as using fluoroscopy alone.

The decision to perform BAS at the patient's bedside is often based on physician judgment or institutional preference⁽¹¹⁻¹³⁾, with the advantage of faster execution, avoiding patient transfer from the ICU to the cardiac catheterization laboratory^(11,14-16); reducing the risk of injury and trauma to atrioventricular valves and vital structures⁽¹⁷⁾; and reducing ionizing radiation exposure time for the benefit of both operators and patients⁽¹⁸⁾.

Although there are international reports of experience in performing BAS using echocardiography and fluoroscopy, in our country we do not have a clear report that allows us to have feedback and thus identify opportunities for improvement in this procedure, considering that almost no patient has prenatal studies and they are referred to the institution late. In this sense, this study aims to describe the experience regarding the effectiveness and safety of BAS under echocardiographic and fluoroscopic guidance in patients with congenital heart diseases under 3 months of age, with indication for atrial septostomy at the Instituto Nacional de Salud del Niño San Borja, Lima - Peru, treated between 2018 and 2023.

Materials and methods

Study design and population

This is a descriptive, observational, retrospective comparative study. Electronic medical records and procedure reports of patients under 3 months of age who underwent BAS between 2018 and 2023 were reviewed. Two groups were evaluated: those performed with fluoroscopy (Siemens Artis Zee biplane arch) and those performed with echocardiography (Aloka Pro Sound Alpha

7 equipment). Patients with heart diseases requiring surgery were excluded (patients going directly to corrective surgery in case of transposition of great vessels, correction of obstructive anomalous pulmonary venous connection in the interatrial septum, or those going directly to palliative surgery in case of pulmonary atresia with intact septum or tricuspid atresia). Moreover, patients with echocardiographic assessment showing thick interatrial septum (due to low possibilities of opening the interatrial septum), and patients with incomplete data in the registration systems were also excluded.

Procedure

The indication for BAS was made after discussion by a cardio-surgical medical board. In cases where only echocardiography was used, the procedure was performed in the intensive care unit where the patient was admitted, while patients in whom fluoroscopy was used were transferred to the angiography room.

The execution of the procedure in the cineangiography room or intensive care unit room was left to the consideration of the operators, according to the patient's hemodynamic state that enables or prevents their transfer and the presence of personnel in the cineangiography room.

All patients were intubated for the procedure, general anesthesia was administered by cardiovascular anesthesiologists in the angiography room, and they were managed by a pediatric/neonatal intensivists in the intensive care unit. In all patients, the left or right femoral vein was accessed by Seldinger technique with a short 4 Fr introducer and then changed to a short 5/6 Fr introducer, according to the atrial septostomy balloon catheter to be used (Z5 - Numed®). After femoral venous access, 50 IU/kg of unfractionated heparin was administered.

In patients where echocardiography was used, subcostal coronal, sagittal, and four-chamber views were taken to locate the atrial septostomy balloon catheter, inflating the balloon with saline solution, visualizing the inflation and the opening of the interatrial communication when pulling the balloon catheter from the left atrium to the right atrium up to three times.

In patients where fluoroscopy was used, the atrial septostomy balloon catheter was observed ascending through the inferior vena cava - right atrium - left atrium, inflating the balloon catheter with 2/3 saline solution and 1/3 contrast solution; subsequently, pulling the balloon from the left atrium to the right atrium, achieving the loss of interatrial resistance. Two sizes of atrial septostomy balloon catheter (Z5- Numed®) were available; the 9.5 mm measure was used in patients under 2.5 kg and the 13.5 mm measure in those over 2.5 kg.

Variables

Both groups were compared in relation to age, sex, weight, ventilatory and inotropic support, comorbidities upon entering the procedure, and the pathology in which BAS was performed. The effectiveness of the procedures was evaluated by measuring the patient's arterial oxygen saturation (SaO₂) pre- and post-procedure, and the size of the interatrial defect pre- and post-procedure. The safety of the procedures was evaluated by the frequency of complications in both groups.

Ethical aspects

This study complies with all requirements contained in the WHO ethical code (Declaration of Helsinki). It was reviewed and approved by the Ethics Committee of the Instituto Nacional de Salud del Niño San Borja and approved according to document No. 045-2023-CIEI-INSN-SAN BORJA.

Statistical analysis

Categorical variables were expressed in frequencies and proportions. After verifying the normal distribution of numerical variables, they were expressed in means or medians with their respective measures of central tendency.

The Mann-Whitney U test was used for comparing medians in quantitative variables and the chi-square test for comparing proportions of categorical variables. A two-tailed alpha error of 5% was considered as statistically significant ($p < 0.05$). Statistical analyses were performed using IBM SPSS Statistics software (version 22, SPSS, IBM Corporation, Armonk, New York).

Results

36 patients under 3 months of age with indication for BAS were included. The median age of patients who underwent BAS by fluoroscopy was 16.5 days, and by echocardiography was 15 days ($p = 0.6997$). The median weight for BAS with fluoroscopy was 3.3 kg, and by echocardiography was 3.2 kg ($p = 0.0878$). Male sex predominated in both groups (80.9% in the fluoroscopy group and 73.3% in the echocardiography group, $p = 0.588$). The most frequent underlying pathology in both groups was transposition of the great vessels with intact interventricular septum (71.4% in the fluoroscopy group and 53.3% in the echocardiography group, $p = 0.265$) (Table 1).

A greater number of patients in the fluoroscopy group entered the procedure with ventilatory support compared to the

echocardiography group (47.6% vs. 20%). Regarding inotropic support, there was no significant difference between both groups. 38% of patients in the fluoroscopy group entered the procedure with comorbidities such as sepsis, bradycardia, or cardiogenic shock, a higher percentage than patients with echocardiography (26.7%), but without significant difference ($p = 0.473$); (Table 2).

Regarding the effectiveness of the procedures, 100% of patients experienced an improvement in SaO_2 . The median pre-procedure arterial oxygen saturation was 59% in both groups, while the median post-procedure saturation was higher in atrial septostomy performed with echocardiography (85%) compared to the fluoroscopy group (82%), ($p = 0.630$). No difference was found between both groups regarding the size of the interatrial communication achieved after the procedures, managing to increase the diameter of the interatrial communication up to 6 mm (Table 2).

There were no complications in the femoral venous access area; after the procedure, patients who underwent BAS with echocardiography remained in the intensive care unit where the procedure was performed; while patients in whom fluoroscopy was used returned from the cineangiography room to the assigned intensive care unit.

In our study, no patient had a prenatal diagnosis of heart disease, they were referred from peripheral neonatal intensive care units, and the definitive diagnosis was made upon arrival at our institution in the assigned intensive care unit.

Discussion

In this study, BAS, both by fluoroscopy and echocardiography, were effective procedures, without complications and without differences between both techniques. The median age of patients who underwent BAS was ≥ 15 days for both methods, unlike studies conducted by Savorgnan⁽¹⁰⁾ and Lopes⁽¹⁹⁾, where

Table 1. General characteristics of the study population

	Total	Fluoroscopy (n = 21)	Echocardiography (n = 15)	p value
Male sex	28 (77.78 %)	17 (80.95 %)	11 (73.33%)	0.588
Age in days, median (IQR)	16.5 (10.5 – 28.5)	17.0 (11.0 – 22.0)	15.0 (8.0 – 30.0)	0.699
Weight in kg, median (IQR)	3.3 (3.0 – 3.7)	3.2 (2.8 – 3.4)	3.5 (3.0 – 4.0)	0.087
Diagnosis				
D-TGA with IVS + PDA + Restrictive PFO	23 (63.9 %)	15 (71.4%)	8 (53.3%)	0.265
Others*	13 (36.1%)	6 (28.6%)	7 (46.7%)	

IQR: interquartile range; D-TGA with IVS: D-transposition of the great arteries with intact interventricular septum; PDA: patent ductus arteriosus; PFO: patent foramen ovale.

*Others: pulmonary atresia, complex D-transposition, pulmonary atresia with intact septum, obstructive anomalous pulmonary venous connection at the level of foramen ovale.

Table 2. Characteristics of treatments and post-procedure results

	Total	Fluoroscopy (n = 21)	Echocardiography (n = 15)	p value
Pre-procedure ventilatory support	13 (36.1%)	10 (47.6%)	3 (20.0%)	0.089
Pre-procedure inotropics	33 (91.7%)	19 (90.5%)	14 (93.3%)	0.760
Pre-procedure SaO ₂ , median (IQR)	59.0 (40.0 – 71.0)	59.0 (51.0 – 71.0)	59.0 (36.4– 83.0)	0.897
Post-procedure SaO ₂ , median (IQR)	83.0 (74.5 – 90.0)	82.0 (76.0 – 90.0)	85.0 (70.0 – 95.0)	0.630
Pre-procedure PFO, mm, median (IQR)	2.0 (1.5 – 2.0)	2.0 (1.5 – 2.0)	2.0 (1.5 – 2.2)	0.374
Post-procedure ASD, mm, median (IQR)	6.0 (5.0 – 6.1)	6.0 (5.0 – 6.0)	6.0 (5.0 – 7.0)	0.498
Comorbidity*	12 (33.3%)	8.0 (38.1%)	4 (26.7%)	0.473

SaO₂: oxygen saturation; ASD: atrial septal defect ostium secundum; PFO: patent foramen ovale; IQR: interquartile range.
*Sepsis, bradycardia or in cardiogenic shock.

the procedure was performed before the first week of life. Given this difference, it should be noted that in none of our cases was a prenatal diagnosis made ⁽¹⁶⁾, which would condition a late diagnosis and referral to our institution.

As in other studies such as Savorgnan's ⁽¹⁰⁾, at least two-thirds of the patients were male. Transposition of the great vessels represented at least 50% of the patients who underwent balloon atrial septostomy, a percentage similar to other studies such as that reported by Lopes ⁽¹⁹⁾.

Both the use of fluoroscopy and echocardiography managed to improve the saturation and hemodynamic stability of patients by increasing the diameter of the interatrial defect; considering it an effective and safe procedure taking into account the late age at which our patients arrive. In our cases, there were no complications from the procedure; however, supraventricular tachycardia and atrial fibrillation are reported ⁽¹⁹⁾, transient events with recovery without impediment to performing the procedure. It is also worth mentioning that other types of complications, such as cardiac perforation or mitral valve injury, with the materials currently available are extremely rare and have not occurred in any case in our institution ^(17,18).

Given the above, balloon atrial septostomy with echocardiography could even be performed in intensive care units of those hospitals from which the neonates come, improving hemodynamic conditions so that at the time of admission to our institution, they have better chances of survival for corrective or palliative surgeries that correspond to them.

In addition to finding no differences between both groups, it is important to emphasize that with the use of echocardiography in the intensive care unit room, patient transport is avoided (which can condition greater hemodynamic

decompensation during transfer), there is no radiation, and less personnel is used, reducing costs, an important fact considering the limited resources available in hospitals belonging to the Ministry of Health.

On the other hand, emphasis should be placed on promoting prenatal diagnosis (in our cases, none had it); unlike what was found by Savorgnan ⁽¹⁰⁾, where in more than 10% of cases with fluoroscopy and up to 40% in cases with echocardiography, the diagnosis was made in the fetal stage. All this to achieve timely and quality care for patients.

This study has the limitations inherent to a retrospective study, from a single hospital center, in a relatively short time (due to the hospital not having many years of operation), so the number of cases is reduced. For the same reason, the results cannot be easily generalized to other hospital centers; for example, due to the differences in resources (medical equipment) that exist in other hospitals.

In conclusion, BAS performed by echocardiography and fluoroscopy were successful and safe procedures without difference between both techniques. The one performed with echocardiography in the intensive care unit at the patient's bedside avoids transport to the cardiac catheterization room, does not generate radiation, and involves fewer healthcare personnel with possible reduction in procedure costs.

Authors' Contributions

ACC, KCA, MMD: conceptualization and data curation. **ACC, KCA:** Formal analysis. **ACC, KCA, MMD:** investigation. **ACC, KCA, MMD, RGA:** Methodology. **ACC, KCA:** Project administration, supervision. **ACC, KCA:** Writing - Original Draft. **ACC, KCA:** Writing - Review & Editing.

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