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Research Article

Balloon Atrial Septostomy Guided by Echocardiography Versus by Fluoroscopy in Newborns

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Abstract

Introduction: Balloon atrial septostomy (BAS) has the objective to create or to increase in size an atrial septal defect to improve the shunt between both atria or reduce the pressure in one of them, which can be guided by echocardiography or by fluoroscopy.

Materials and Methods: We conducted a quantitative, observational, analytical, cross-sectional, retrospective cohort study at the neonatal intensive care unit, from September 2010 to March 2023. The study included newborns who underwent BAS guided by echocardiography (group A) or fluoroscopy (group B).

Results: 43 patients were included: Group A: 25 patients and group B: 18 cases. Atrial septa defect (ASD) and oxygen saturation increased similarly in both groups. The procedure time and bleeding were higher in the group B. There were two complications in group A and four complications in group B. In one patient (of group A) the BAS was performance with "dual" BAS technique (previously not described).

Discussion: Both groups were similar in relation of characteristics about the patients and there was not significance statistical. The complications in our study were similar to other authors. In the group B; 3 mayor complications were presented (group A had not fatal complications), which was statistically significant (p = 0.034).

Conclusion: In our setting; BAS performed under echocardiographic guidance is safer and such as effective as BAS under fluoroscopic guidance,

Keywords: *Balloon Atrial Septostomy; Atrial Septal Defect; Echocardiography; Fluoroscopy; Complications*

Introduction

Balloon atrial septostomy (BAS) was introduced by W. Rashkind in 1966 [1,2], since then, this palliative procedure is essential in pediatric cardiology. The interventional procedure consists to create or increased the size of the atrial septal defect (ASD) to improve the shunt between both atria or to reduce the pressure in one of them [1-5].

It is usually performed in the neonatal period by fluoroscopy guided in all over the world and also in some centres in the neonatal intensive care unit (NICU) by echocardiography guidance [3-8]. The complication rate is usually less than 1% of all procedures performed [3-8]. When it is necessary to perform the procedure in older patients, the difficulty is higher, because; the presence of a thicker and less tearing interatrial septum, thus; the complications are usually higher [8-11].

The BAS was originally created for newborns with transposition of great arteries (TGA) with severe hypoxia due to a restrictive interatrial septum (RIS). This procedure changed the survival for this congenital heart disease (CHD) and allowed the development of subsequent corrective techniques for many pathologies. Currently; BAS has an indication IA (newborns or infants with TGA and RIS) and also it can be useful in another critical CHD in the neonatal stage.

The success rate of the BAS is up to 98% and the mortality rate is less than 0.5 - 1% [3-11]. The original technique is similar until nowadays, but the balloons and imagen modalities have improved over the time and subsequently the results have been much better.

However; in some cases, BAS may not be satisfactory or may be suboptimal, especially when the interatrial septum is thickened, with this problem; other techniques, such as; Park´s blade septostomy [9], cutting balloon septostomy [10], wire septostomy [11], static atrial septostomy (septoplasty) and stent placement have been developed.

Baker EJ., *et al*. (1984) conducted a study in 8 patients with TGA and BAS was performed in the NICU only under cross-sectional echocardiographic control. This technique eliminated the fluoroscopy exposition for the procedure, is quicker and causes little discomfort to the patient during the procedure; so; the baby does not have to be moved from the incubator [12].

Beizke A., *et al*. (1991) reported their experience on performing echocardiographically guided BAS in 44 newborns in NICU without complications, with good results in terms of post-procedure ASD size and oxygen saturation [13].

Zellers TM., *et al*. (2002) published a retrospective study, where they analysed the outcomes from 1996 to 1999 in a total of 38 septostomies in patients with TGA, of which 21 cases were performed by fluoroscopy and 17 cases by echocardiography. in both groups they found an increase in oxygen saturation. They concluded that echocardiography-guided is much less expensive and a safer technique, in which the waiting time for the procedure was reduced [3].

Martin., *et al*. (2003) published a study of 5 patients with TGA in who septostomies were performed by echocardiography. The patients could not be transported to the Royal Brompton Hospital in England. They found that it is a safe procedure in patients who cannot be transported due to their haemodynamic conditions, with adequate results and without complications [14].

Marchi CH., *et al*. published in 2005 a study from August 1997 to January 2004 in which 31 patients were underwent at the procedure guided exclusively by echocardiography. The size of the ASD and arterial oxygen saturation increased. It was concluded that BAS monitored with echocardiography is a safe and effective procedure. It can be performed at the bedside, avoiding patient transport, observe the catheter balloon location reduces the occurrence of severe complications and assess the immediate outcome of the procedure [6].

Lopes LM., *et al*. (2010) conducted a study between January 1997 and July 2008, where 102 Rashkind´s procedure ultrasound-guided were made. Only 98 patients found inclusion criteria: group A; 90 patients (preoperative procedure) and 8 cases in group B (postoperative

procedure). The procedure was effective in 95 of the 98 cases, in 3 patients where the procedure failed; it was due to the impossibility of advancing the catheter through the inferior caval vein in one patient, in another case due to the impossibility of reaching the left atrium and in the last patient due to the difficulty of achieving adequate balloon position within a very small left atrium. Two complications related to the procedure were reported, one of them presented with atrial fibrillation followed by ventricular tachycardia and tamponade secondary to probable right atrial tear and the other complication was bradycardia in a 46-day-old infant. A total of 8 deaths were reported prior to the surgical treatment; the cause of death was cardiogenic shock (65%), septic shock (21%) and not related to the procedure [5].

Kumar N., *et al*. (2018) published a prospective study conducted in Pakistan; 40 patients with TGA with BAS echocardiography-guided were included and they described: post ASD diameter, oxygen saturation and complications. It was concluded, that; there was sufficient evidence that BAS at the bedside is a safer, more effective and saves significant time and resources that would otherwise be required to transport these patients to the cardiac catheterisation laboratory. Therefore, it is time-saving, easier, cost-effective and provides immediate results [8].

Aim of the Study

The aim of this study is to share the results and complications of this procedure guided by echocardiography versus guided by fluoroscopy in our centre, since that; this comparation has been performance just once in the literature [3].

Materials and Methods

We conducted a quantitative, observational, analytical, cross-sectional, retrospective cohort study at the NICU from September 2010 to March 2023. The study included newborns who underwent BAS guided by echocardiography or fluoroscopy.

Variables measured included gestational age (evaluated at birth using the Capurro or Ballard Test), age in days, birth weight in grams, height in centimeters, gender, procedure time in minutes, pre and post atrial septal defect (ASD) size in millimeters, pre and post BAS oxygen saturation in percentage, diagnosis post-catheterization, trans and post BAS complications, bleeding in milliliters, and death defined as irreversible cessation of cardiorespiratory functions.

Data analysis was performed using SPSS 25, with descriptive statistics and univariate analysis for group comparisons using Chi-squared tests for nominal variables and Student's T-test for numerical variables, considering $P < 0.05$ as statistically significant.

Inclusion criteria: To have a complete medical record from the NICU of the hospital, age between 1 day and 28 days, have a congenital heart disease that warrants BAS, having had an echocardiography or fluoroscopy guided BAS.

Exclusion criteria: Patients who underwent BAS with stent ductal placement, having undergone any other surgical procedure prior to BAS.

Elimination criteria: Patient records that do not contain at least 90% integration for correct analysis.

Results

In the period of study 61 BAS were performed in our hospital. 18 patients were excluded due criteria. A total of 43 cases were included for analysis: 25 patients were guided by echocardiography (group A), and 18 patients guided by fluoroscopy (group B). Comprising 23 males (53.5%) and 20 females (46.5%).

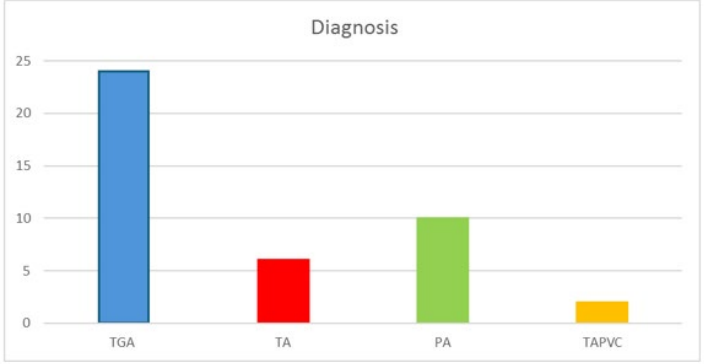
The analysis for total population of the study is the follow: the mean gestational age was 38.2 weeks (± 1.6 weeks), median 38 weeks, range 31 - 41 weeks. The mean age at the procedure was 13.5 days (± 10.3 days), median 11 days, range 1-28 days. Mean admission weight

was 3.12 kg (± 0.75 kg), median 3.16 kg, range 1.56 - 4.9 kg. Mean height was 50.16 cm (± 3.6 cm), median 50 cm, range 41 - 60 cm (Table 1).

	Gestational Age	Age	Weight	Height
Mean	38.28	13.56	3.12616	50.16
Median	38.00	11.00	3.16000	50.00
Std.Dev.	1.817	10.356	0.751912	3.612
Minimum	31	1	1.560	41
Maximum	41	28	4.900	60

Table 1: *Gestational age, age, weight, and height of the both groups.*

The diagnosis most frequent was TGA in 24 patients (55.8%), followed by; pulmonary atresia with intact ventricular septum (PA-IVS) in 10 patients (23.3%), tricuspid atresia (TA) in 7 patients (16.3%) and total anomalous pulmonary venous connection (TAPVC) in 2 patients (4.7%) (Graphic 1).



Graphic 1: *Diagnosis of the CHD of the both groups.*

In Group A (25 patients: 13 males, 12 females), the mean gestational age was 38.2 weeks (± 2.11 weeks), median 39 weeks, range 31 - 41 weeks. Mean age was 14.7 days (± 10.2 days), median 15 days, range 1 - 28 days. Mean weight was 3.06 kg (± 0.74 kg), median 3.15 kg, range 1.56 - 4.9 kg. Mean height was 50.76 cm (± 3.6 cm), median 52 cm, range 41 - 60 cm. TGA was the diagnosis most frequent:16 patients (64%), followed by; 6 cases with TA (24%), 2 patients with PA-IVS (8%), and 1 case with TAPVC (4%) (Table 2 and 3).

	Gestational Age	Age	Weight	Height
Mean	38.28	14.76	3.06540	50.76
Median	39.00	15.00	3.15000	52.00
Std.Dev.	2.112	10.236	0.740514	3.643
Minimum	31	1	1.560	41
Maximum	41	28	4.900	60

Table 2: *Gestational age, age, weight, and height for group A.*

Diagnosis	Frequency	Percentage
Transposition of the great arteries	16	64.0
Tricuspid atresia	6	24.0
Pulmonary atresia with IVS	2	8.0
Total anomalous pulmonary venous connection	1	4.0
Total	25	100.0

Table 3: *Diagnosis of the CHD in group A.*

In group B (18 patients: 10 males, 8 females), the mean gestational age was 38.2 weeks (± 1.2 weeks), median 38 weeks, range 36 - 40 weeks. Mean age was 11.9 days (± 10.5 days), median 7.5 days, range 1 - 28 days. Mean weight was 3.21 kg (± 0.78 kg), median 3.2 kg, range 1.785 - 4.8 kg. Mean height was 49.33 cm (± 3.49 cm), median 50 cm, range 42 - 55 cm. TGA in 8 cases and PA-IVS in 8 patients (each one with 44.4%), followed by; TA with 1 patient and TAPVC also with 1 case (each one with 5.6%) (Table 4 and 5).

	Gestational Age	Age	Weight	Height
Mean	38.28	11.89	3.21056	49.33
Median	38.00	7.50	3.20000	50.00
Std.Dev.	1.364	10.582	0.780816	3.498
Minimum	36	1	1.785	42
Maximum	40	28	4.800	55

Table 4: *Gestational age, age, weight, and height for group B.*

Diagnosis	Frequency	Percentage
Transposition of the great arteries	8	44.4
Tricuspid atresia	1	5.6
Pulmonary atresia with IVS	1	5.6
Total anomalous pulmonary venous connection	8	44.4
Total	18	100.0

Table 5: *Diagnosis of the CHD in group B.*

In all the patients at least, a Z-5 balloon of 13.5 mm (Numed®) was used, except in one patient in group A with TGA, who underwent to BAS with "double" balloon technique without complications (see below for details).

Female 17-days-old and weight: 3.3 Kg. He was referred to our hospital due to cyanosis and desaturation (50%), an ASD of 1.8 mm and 5 mmHg gradient was observed. BAS exclusively guided by TTE was performed in the NICU. The procedure was initially done with a Z-5 balloon of 13.5 mm which resulted in an ASD of 4 mm and a restrictive gradient. Therefore, a dual balloon technique was performed with Z-5 balloons of 9.5 mm and 13.5 mm simultaneously (Figure 1). Following this technique, the saturation increased to 88%, the ASD was increased to 6 mm and no gradient was observed. Procedure time: 60 min, bleeding: 15 ml, contrast medium: 0 ml, fluoroscopy: 0 min. Arterial switch operation was performed 3 weeks later with a good outcome. He was discharged at 47 days after surgery. After three years, she is with appropriate evolution without residual lesions.

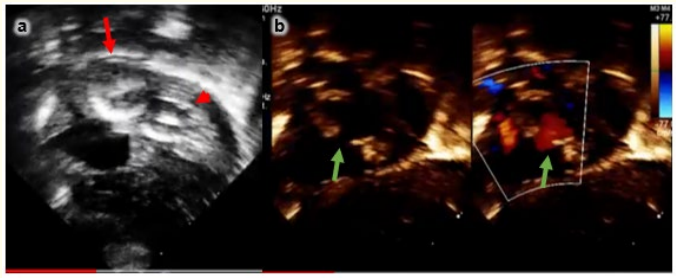


Figure 1: *TTE. Subcostal view. A): we can see a Z-5 balloon catheter of 9.5 mm (red arrow head) and other one of 13.5 mm (red arrow) can see in the left atrium. B): we can see a wide ASD (green arrow) and interatrial septum is thickened.*

The procedure time in group A was significantly shorter (57.6 minutes ± 41.6) compared to group B (111.1 minutes ± 51.9), with statistical significance ($p < 0.05$) (Table 6 and 7). Pre-procedure ASD size in group A was 2.45 mm (± 1.18 mm) compared to 2.22 mm (± 1.24 mm) in group B. Post-procedure ASD size was 8.02 mm (± 1.52 mm) in group A and 7.93 mm (± 2.16 mm) in group B. The increase in ASD size was similar between groups, without statistical significance ($p = 0.795$).

	Overall Procedure Time	Group A Procedure Time	Group B Procedure Time
Mean	80.02	57.64	111.11
Median	60.00	50.00	110
Std.Dev.	52.857	41.629	51.921
Minimum	15	20	15
Maximum	240	240	190
T		-3.746	
Sig (2-tailed)		0.001	

Table 6: *Procedure time in both groups.*

	Procedure time
T	-3.746
Sig (2-tailed)	0.001

Table 7: *T-test analysis of procedure time.*

Bleeding in group A averaged 22 ml (± 7.36 ml), compared to 26.39 ml (± 18.3 ml) in group B ($p = 0.285$). pre-procedure oxygen saturation in group A was 63% (± 11.74%), while in group B was 68.89% (± 9.38%). post-procedure saturation was 84.36% (± 6.006%) in group A and 85.05% (± 6.15%) in group B. The increase in saturation between both groups was not statistically significant ($p = 0.107$).

In group A, procedure-related complications included two cases: one patient with TGA experienced ventricular fibrillation, which was reverted with defibrillation, returning to sinus rhythm and another patient with TA developed supraventricular tachycardia, which was reverted with intracavity stimulation; both patients had no further complications. In group B, there were four complications: two patients

with TGA developed hemopericardium and subsequent cardiorespiratory arrest, resulting in death in both cases in the catheterization laboratory room; one patient with PA-IVS had sudden cardiac arrest and died in the catheterization room and finally other one patient with PA-IVS presented bradycardia which was improved with amine support. The chi-square test for complications was 0.184 (Table 8 and 9). When comparing procedure-related deaths, none occurred in group A, while three deaths occurred in group B, with a statistically significant chi-square of 0.034 (Table 10 and 11).

		Procedure		Total
		Echocardiography	Fluoroscopy	
Complications Trans	Yes	2	4	6
	No	23	14	37
Total		25	18	43

Table 8: *Cross table trans procedure complications.*

	Values	fd	Asymptotic significance (bilateral)
Pearson Chi-square	1.763[a]	1	0.184

Table 9: *Chi-square test complications trans.*

Ultrasound		Procedure		Total
		Fluoroscopy		
Death	Yes	0	3	3
	No	25	15	40
Total		25	18	43

Table 10: *Cross table trans-procedure death.*

	Values	fd	Asymptotic significance (bilateral)
Pearson Chi-square	1.763[a]	1	0.184

Table 11: *Chi-square tests death trans.*

Eleven patients in group A and eight in group B underwent surgical intervention post BAS (p = 0.977). The mean hospital stay was 24.88 days (± 20 days) for group A and 25.72 days (± 54 days) for group B.

Discussion

In our study; male is the gender predominated with an average gestational age of 38.2 weeks of gestation ± 1.6 for the total patients. When divided into groups, we found that group A had an average gestational age of 38.2 ± 2.11, while group B had an average of 38.2 ± 1.2. Other variables analysed included; age (13.5 days ± 10.3 days) and weight at admission (3.12 kg ± 0.75 kg). TGA was the most frequent CHD, occurring in 64% of group A and 44.4% of group B.

The procedure time; we found that group A had a significantly shorter time compared to group B ($p < 0.05$). About the bleeding; group A had lower bleeding, although the result was not statistically significant (p = 0.285).

Various criteria have been proposed to consider BAS successful; including an increase in ASD size at least of 6 mm and improved oxygen saturation [3-5]. According to the study by Marchi CH., *et al*. [6], the ASD size increased from 1.8 ± 0.8 mm to 5.8 ± 1.3 mm, and in the Kumar N., *et al*. [8] reported an increase in ASD size from 1.4 - 2.8 mm to 5.4 ± 0.4 mm, in our study the findings were similar: final ASD size increase in group A until 5.56 mm ± 1.76 mm and in group B until 5.71 mm ± 1.87 mm.

The oxygen saturation before and after the procedure; Group A had a pre-procedure oxygen saturation of 63% ± 11.74%, while group B had 68.89% ± 9.38%. Post-procedure, group A showed an oxygen saturation of 84.36% ± 6.006%, and group B had 85.05% ± 6.15%. Despite the lack of a statistically significant difference between the groups, both procedures yielded favorable results. These results were similar to those reported by Marchi CH., *et al*. [6], where oxygen saturation increased from 64.5 ± 18.9% to 85.1 ± 9.2%, Kumar N., *et al*. [8], who reported an increase from 46 ± 6% to 81 ± 3%, and finally in the study of Zellers TM., *et al*. [3], where oxygen saturation increased from 66% ± 4% to 89 ± 3%, in the group with echocardiography-guided, and from 56% ± 4% to 87 ± 2% in the group with fluoroscopy-guided.

In our study; group A, a total of 11 patients underwent surgery following the BAS compared to 8 patients in group B ($p = 0.977$). This is clinically relevant, because the objective of BAS is to improve; the oxygenation and hemodynamics conditions until optimal conditions have come for definitive surgical treatment ensue. There were not statistically significant differences.

It is worth noting that; in one patient of group A, the BAS was performance with dual balloon technique (this new modification from the original technique has not been reported before in the literature). This case was undergone at the beside BAS, because her hemodynamic instability, first a Z-5 balloon catheter of 13.5 mm was used, however; the ASD was suboptimal, for this reason; we decide to use the "dual" BAS technique with improved of oxygen saturation and ASD, the procedure without complications.

Our study has limitations; to be performance in a single centre, also, missing to compare the post BAS evolution in both groups, considering hospital staying time, because; hospital staying depends on clinical evolution, which depends on many factors in the patient himself and other factors in the evolution as; infections, complications associated with mechanical ventilation, nosocomial issues, among others, as; hemodynamics status previous at BAS and serum lactate level.

The complications had been reported to occur in less than 2% of cases including; transient bradycardia, hematoma at the puncture site, venous insufficiency of the lower extremity and less frequently; femoral venous thrombosis, cardiac perforation, inferior caval vein avulsion, systemic thromboembolism, and severe arrhythmias and death [3-12].

The complications observed in our study were similar at the study of Lopes LM., *et al*. [5], which included atrial fibrillation, cardiac tamponade, and bradycardia. Marchi CH., *et al*. [6] reported balloon rupture, supraventricular tachycardia, atrial flutter, and right femoral vein injury. In our study, there were 2 complications in group A (ventricular fibrillation and supraventricular tachycardia) and 4 in group B (cardiac arrest and bradycardia), with 3 of these complications resulting in death. Importantly, group A had no deaths, while group B had 3 deaths, with a statistically significant p-value of 0.034.

It is possible that the complications were more in patient in groups B, maybe because of a worst status hemodynamics before the BAS and these patients were underwent to the BAS under fluoroscopy guidance.

Finally; echocardiography guided BAS has proved to be an effective and safe procedure with significantly shorter duration and fewer severe complications compared to fluoroscopy-guided [3]. Both methods, even with their modifications have provided comparable improvement in ASD size and oxygen saturation and give the opportunity to the patients for definitive surgical interventions in the better hemodynamics and oxygenation conditions [1-14].

Conclusion

In our study BAS performed under echocardiographic guidance is safer and such as effective as BAS performed under fluoroscopic guidance.

The BAS guided by echocardiography reduces the risk associated with transferring critically ill patients to a tertiary care unit or even to the haemodymics laboratory room and eliminates radiation exposure for the patient and the sanitary staff.

In addition; the evidence in our centre and in the other centres with the procedure performance under echocardiography guidance has the same cost-effective option for the healthcare system, but; is safer and both points are very important in developing countries.

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