

Double “dynamic” balloon atrial septostomy. New modification of Dr. Rashkind’s technique for cases with thickened interatrial septum

Septostomía atrial con doble balón “dinámico”. Nueva modificación de la técnica del Dr. Rashkind para casos con septum interatrial engrosado

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Abstract

Objective: Balloon atrial septostomy (BAS) is a palliative procedure mainly for newborns with transposition of the great arteries, currently, this procedure has a class IA recommendation. However, in some cases, this procedure does not achieve an adequate interatrial defect, due mainly to a thickened interatrial septum, this situation led to the development of various techniques to tackle this problem. Therefore, we made a modification to the original technique using two balloons simultaneously instead of one. The objective of this study is to analyze the results of this new modification to the traditional technique (with one balloon) as an alternative for cases with thickened interatrial septum. **Methods:** A retrospective and descriptive study from May 2010 to December 2022 was conducted in three pediatric centers. **Results:** Six patients were identified (median age 35 days, median weight 3.4 kg, median size of atrial septal defect before procedure 2.6 mm). All patients underwent to this modification of the BAS with good results and without complications. The modification has some advantages: including to avoid the using of cutting devices or stent placement. In addition, we share the description of this new technique, titled: double “dynamic” BAS. **Conclusion:** This brief evidence shown that this modification of de original technique is easy, safe, and cost-effective for cases with a thickened interatrial septum.

Keywords: Balloon atrial septostomy. Transposition of great arteries. Thickened interatrial septum. Atrial septal defect.

Resumen

Objetivo: La septostomía auricular con balón (SAB) es un procedimiento paliativo principalmente para recién nacidos con transposición de las grandes arterias, actualmente, este procedimiento tiene una recomendación clase IA. Sin embargo, en algunos casos, este procedimiento no logra un defecto interauricular adecuado, debido principalmente a un septum interauricular engrosado,

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esta situación llevó al desarrollo de diversas técnicas para abordar este problema. Por ello, realizamos una modificación de la técnica original utilizando dos balones simultáneamente en lugar de uno. El objetivo de este estudio es analizar los resultados de esta nueva modificación de la técnica tradicional (con un balón) como alternativa para los casos con septum interauricular engrosado. **Métodos:** Se realizó un estudio retrospectivo y descriptivo desde mayo de 2010 hasta diciembre de 2022 en tres centros hospitalarios pediátricos. **Resultados:** Se identificaron seis pacientes (mediana de edad 35 días, mediana de peso 3,4 kg, mediana de tamaño de la comunicación interauricular antes del procedimiento 2,6 mm). Todos los pacientes se sometieron a esta modificación del SAB con buenos resultados y sin complicaciones. La modificación presenta varias ventajas, así mismo evitar el uso de dispositivos de corte o la colocación de stent. Además, compartimos la descripción de esta nueva modificación a la técnica, titulada: septostomía atrial con doble balón “dinámico”. **Conclusiones:** Esta breve evidencia demuestra que esta modificación de la técnica original es; fácil, segura y económica para los casos con septum interatrial engrosado.

Palabras clave: Septostomía atrial con balón. Transposición de las grandes arterias. Septum interatrial engrosado. Defecto septal interatrial.

Introduction

Dr. William J. Rashkind and Dr. W.W. Miller published percutaneous balloon atrial septostomy (BAS) in 1966¹. The technique was developed at Children’s Hospital of Philadelphia and first presented at The Hospital for Sick Children of Toronto. In 1968, they presented the result of its application in 31 patients². Since then, the technique has become essential and recognized as a palliative procedure for patients with transposition of the great arteries (TGA)^{3,4}. From then on, the development of interventional cardiology has globally expanded.

At present, BAS is a class IA recommendation of the American Heart Association to palliate the physiology of patients with TGA. In addition, it is used for the same purpose in other congenital heart diseases (CHD) such as classic tricuspid atresia and pulmonary atresia with intact ventricular septum (PA-IVS) that require an obligatory interatrial shunt, as well as, in other complex CHDs needing a non-restrictive interatrial defect.

The procedure is practically performed with the same technique as originally described, with only minimal modifications. Likewise, the balloon used has evolved over time. However, in some cases, BAS may not be entirely satisfactory or may be suboptimal, especially when the interatrial septum is thickened. In Addition, the atrial septal defect (ASD) may even partially reclose after a few days or weeks. Due to these problems, other techniques such as Park’s blade septostomy⁵, cutting balloon septostomy⁶, wire septostomy⁷, static atrial septostomy (septoplasty), and stent placement have been developed. In addition, an improvised technique was recently reported due to the shortage of septostomy balloons worldwide⁸.

The aim of this study is to share the description and shown the results obtained of this new modification of the original technique of Dr. W.J. Rashkind and W.W.

Miller in patients based on simultaneous use of two balloons instead of one. This technique, titled: double “dynamic” BAS has not been reported in the literature.

Methods

A retrospective and descriptive study of all patients who underwent double “dynamic” BAS was conducted from May 1st, 2010, to December 31st, 2022.

Inclusion criteria: all patients who underwent double “dynamic” BAS in three pediatric centers during the study period. Exclusion criteria: patients who underwent BAS with a single balloon, static atrial septostomy (septoplasty) (with one or two balloons), cutting balloon septostomy, and Park’s blade septostomy.

In the study period, the database of the three pediatric hospitals was reviewed in search of all cardiac catheterizations. This study was approved by the Ethics Committee from the three hospitals.

Results

From May 1st, 2010, to December 31st, 2022, a total of 6 patients from the database of the three pediatric hospitals who underwent cardiac catheterizations fulfilled the inclusion criteria.

The patient’s median age was 35 days (range 1-180 days); the median height, 52 cm (range 48-71 cm) and median weight, 3.4 kg (range 2.8-8.5 kg). There was a predominance of females (4 girls and 2 boys) with a ratio of 2:1.

The diagnoses were TGA in 4 cases (66.6%), hypoplastic left ventricle with mitral atresia and double outlet right ventricle (DORV) without pulmonary stenosis in one case (16.7%), and PA-IVS in one case (16.7%).

Transthoracic echocardiography (TTE) was performed in all patients on admission to measure the size of the ASD before the procedure, recording a median size of 2.6 mm (1-6 mm). After the procedure, the median size of the ASD was 7 mm (6 to 9 mm). The maximum gradient recorded before the interventional procedure had a median of 7.0 mmHg (range 5-31 mmHg). The maximum gradient after atrial septostomy with two balloons had a median of 1.0 mmHg (range 0-2).

The procedure time recorded a median of 161 min (range 60-270 min), and a median hospital stay of 93 days (range 5-46 days).

The reported bleeding during the procedures showed a median of 46 mL (range 15-60 mL).

The contrast medium used had a median of 30 ml (range 0*-60 mL), and fluoroscopy time had a median of 17 min (range 0*-37 min) (*in one patient the procedure was exclusively guided by TTE). The median time in hours from admission to the hospital until septostomy was 21 h (range 2-96 h).

Description of cases (Table 1)

Case 1

Female 51 days-old and weight: 4.3 Kg. Diagnosis: TGA. BAS: single balloon performed at another hospital; type and balloon size, unknown with apparent improvement for 2 weeks. Progressive desaturation in her led to a referral to one of the hospitals in the study. On admission: cyanosis and SpO₂ 52% (4.1 mm ASD and maximum gradient of 6 mmHg). A new BAS was performed using a Z-5 balloon catheter (Numed®) of 13.5 mm. However, the patient did not show any clinical improvement, not increase in the size of the ASD nor oxygen saturation. On these observations and since cutting balloon or a Park's blade catheter were not available, an improvisation to the original technique was performed. This consisted in the use of two balloons (a Z-5 balloon of 9.5 mm and another of 13.5 mm) in a simultaneous way. The balloons were passed through the same 7 Fr. sheath introducer (11 cm of length) and five septostomies with double "dynamic" balloon were performed. This resulted in an improvement in saturation until 90% and ASD to 8.1 mm with a residual gradient to 1 mmHg. Procedure time: 172 min, bleeding: 48 mL, contrast medium: 27 mL, fluoroscopy: 14.6 min.

The patient improved, was extubated, and at the age of 65 days was subjected to pulmonary banding for

left ventricular preparation. Arterial switch operation was performed 3 weeks later; however, complications during the weaning from cardiopulmonary bypass led to death in the immediate post-operative period.

Case 2

Male 48 days-old and weight: 3.4 Kg. Diagnosis: TGA with small ventricular septal defect. He was hospitalized for respiratory distress and cyanosis. On admission; lower respiratory infectious disease, oxygen saturation of 78%, and signs of low cardiac output (3.5 mm ASD with a maximum gradient of 6 mmHg) were observed. Conventional atrial septostomy was performed with a Z-5 balloon (9.5 mm), followed by another one (13.5 mm), without improvement in saturation or gradient. Following this observation, an atrial septostomy with a double "dynamic" balloon (Z-5 of 9.5 mm and the other of 13.5 mm) was performed for 6 times (Fig. 1). With this, a saturation (84%), an interatrial gradient (1 mmHg) and an ASD size (6 mm) were achieved. Procedure time was 150 min, bleeding 60 mL, contrast medium 40 mL, and fluoroscopy 37 min.

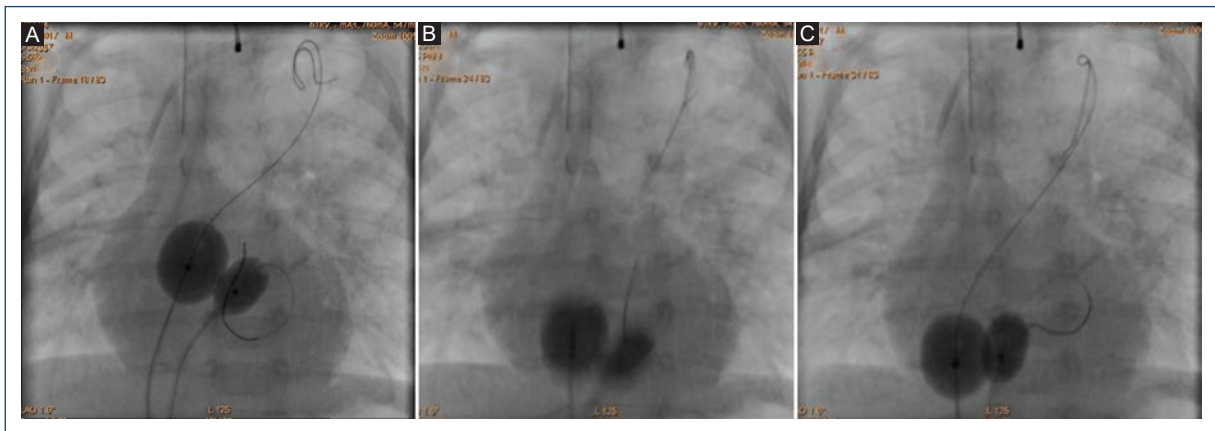
Subsequently in pediatric intensive care unit, his pulmonary infectious process was resolved, and he underwent an arterial switch operation 30 days after his intervention. He was discharged 3 weeks later. His follow-up 6 years later remains with good evolution with mild gradient in the neo-pulmonary artery.

Case 3

Female 17 days-old and weight: 3.3 Kg. He was referred to one of the hospitals in the study from another hospital due to cyanosis and desaturation (50%). Classic TGA with an ASD of 1.8 mm and 5 mmHg gradient was diagnosed. BAS, exclusively guided by TTE was performed in the neonatal intensive care unit (NICU). This 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 double "dynamic" balloon technique was performed with Z-5 balloons of 9.5 mm and 13.5 mm (Fig. 2). Following this procedure, 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 the operation. After 2 years, she is found to have appropriate evolution without residual lesions.

Table 1. Case series

Case	Aged (days)/ Wt (Kg)	Diagnostic	ASD Pre (gradient)	ASD Post (gradient)	Oximetry pre and post (%)	Size of Z-5 Balloons	Complications	Evolution
1	(51) (4.3)	TGA	4.1 (6)	8.1 (1)	52-90	13.5 mm + 9.5 mm	No	Pulmonary banding, arterial switch. Death after surgery
2	(48) (3.4)	TGA with small VSD	3.5 (6)	6.0 (1)	78-84	13.5 mm + 9.5 mm	No	Arterial switch Alive Mild neo-pulmonary stenosis
3	(17) (3.3)	TGA	1.8 (5)	6.0 (0)	50-88	13.5 mm + 9.5 mm	No	Guided by TTE Arterial Switch Alive
4	(1) (3.4)	Mitral atresia/LV hypoplastic and DORV without pulmonary stenosis	1.0 (31)	6.1 (2)	85-94	13.5 mm + 9.5 mm	No	Pulmonary Banding Alive Waiting Glenn
5	(180) (8.5)	AP-IVS	6.0 (9)	9.0 (1)	45-86	13.5 mm + 13.5 mm	No	Glenn Good Alive
6	(22) (2.8)	TGA	1.0 (8)	8.0 (0)	79-90	13.5 mm + 9.5 mm	No	Arterial switch Alive

**Figure 1. A-C:** double “dynamic” BAS (simultaneous Z-5 balloons of 13.5 mm and 9.5 mm) with saturation increase to 84% and a residual gradient between both atria of 1 mmHg.

Case 4

Male, age: 1 day-old and weight: 3.4 Kg. Diagnoses: hypoplastic left ventricle, mitral atresia, and DORV without pulmonary stenosis. He was admitted

with hemodynamic instability. A TTE-guided BAS was attempted in NICU without success due to a very small ASD (< 1 mm). In the catheterization laboratory, it was possible to cross the defect with a peak-to-peak gradient record of 31 mmHg between both atria. A coronary

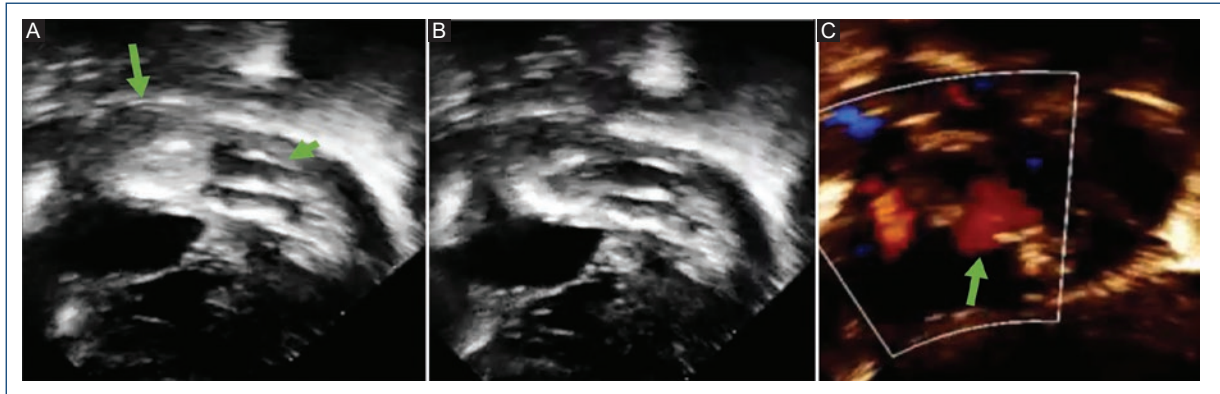


Figure 2. TTE. Subcostal view. **A:** a Z-5 balloon of 9.5 mm (arrowhead) and another of 13.5 mm (arrow) during inflating. **B:** both balloons have been inflated in the LA ready to perform the double “dynamic” BAS. **C:** a wide ASD is observed (arrow), and the interatrial septum is thickened (see supplementary material, video 1).

angioplasty guide wire (“0.014”) was successfully passed through; however, the orifice was so small that a Z-5 septostomy balloon catheter of 9.5 mm could not cross. Therefore, static atrial septostomy (septoplasty) was performed with an 8 × 20 mm minityshak balloon catheter, followed by classical BAS with Z-5 balloon catheter of 13.5 mm. It was observed that the ASD was insufficient (3.3 mm) and the interatrial septum was very thick. It was decided to perform double “dynamic” BAS (Z-5 balloons of 13.5 mm and 9.5 mm) 7 times (Fig. 3). TTE showed an interatrial defect measuring 6.1 mm at the highest part of the septum with left-to-right laminar flow. A new pressure withdrawal trace showed a residual peak-to-peak gradient of 2 mmHg. Procedure time: 270 min, bleeding: 30 mL, contrast medium: 30 mL, fluoroscopy: 24 min. Pulmonary banding was performed 33 days later and he was discharged 113 days after surgery. Seventeen months later, the patient is currently stable with good evolution. He is awaiting bidirectional cavopulmonary shunt.

Case 5

Female, age: 180 days-old and weight: 8.5 Kg. She was admitted for hypercyanotic spells, saturation 45%. Diagnosis: PA-IVS with restrictive ASD (6 mm), and small patent ductus arteriosus. Ductal stent placement was performed without complications, resulting in an immediate increase of saturation. Left atrium (LA) to right atrium (RA) pressure withdrawal trace showed a peak-to-peak gradient of 9 mmHg, prompting atrial septostomy with a Z-5 balloon catheter of 13.5 mm in four times. The ASD was found to be insufficient, and

the gradient decreased to 4 mmHg, leading to double “dynamic” BAS (both Z-5 balloons of 13.5 mm) through an 8 Fr. sheath introducer (Fig. 4). This resulted in achieving a residual gradient of 1 mmHg and an interatrial defect of 9 mm, with a final saturation of 86%. Procedure time: 180 min, bleeding: 50 ml, contrast medium: 60 mL, fluoroscopy: 20 min. The patient was discharged 5 days after the procedure. Bidirectional cavopulmonary shunt (Glenn procedure) was performed 3 months later. Her follow-up at 15 months is with good evolution.

Case 6

Female 22 days-old and weight: 2.8 Kg. She was referred to one of the hospitals in the study for desaturation (79%) and hemodynamic instability. Diagnosis: TGA with a patent foramen ovale (PFO) < 1 mm. BAS was first performed with a Z-5 balloon catheter of 9.5 mm and subsequently with another of 13.5 mm for several times. TTE showed an ASD of 3.8 mm and a thickened interatrial septum. With this observation, it was decided to use the double “dynamic” BAS technique (Z-5 balloons of 9.5 mm and 13.5 mm) simultaneously for 5 times (Figs. 5 and 6). The result was the achievement of 90% saturation and ASD size of 8 mm with bidirectional shunt without residual gradient. Procedure time: 140 min, bleeding: 45 ml, contrast medium: 30 mL, fluoroscopy: 10 min, without complications. Arterial switch surgery was performed 12 days later with good evolution, she was discharged 140 days after the operation, and 1 year later no complications were reported.

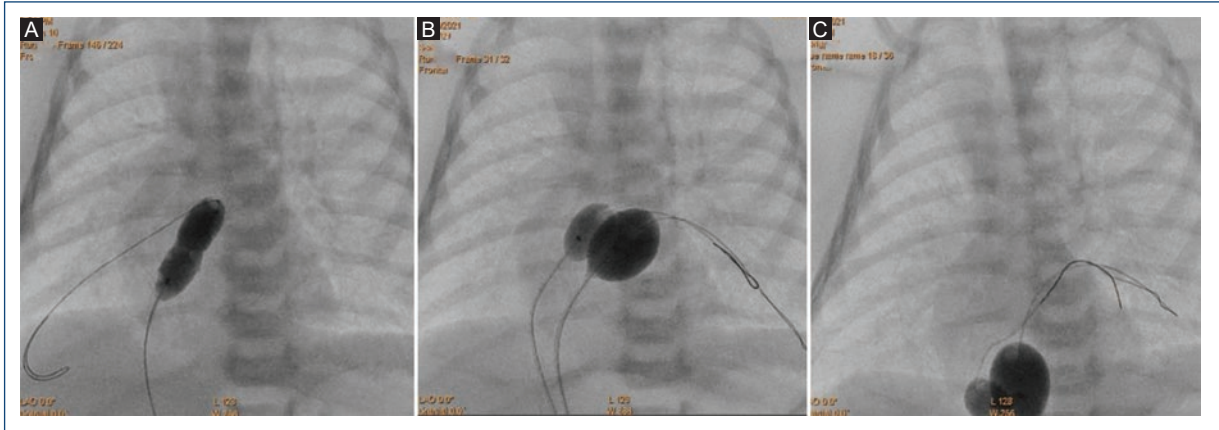


Figure 3. A: atrial septoplasty with minityshak balloon catheter 8 × 20 mm. **B and C:** double “dynamic” BAS (Z-5 balloons of 13.5 and 9.5 mm).

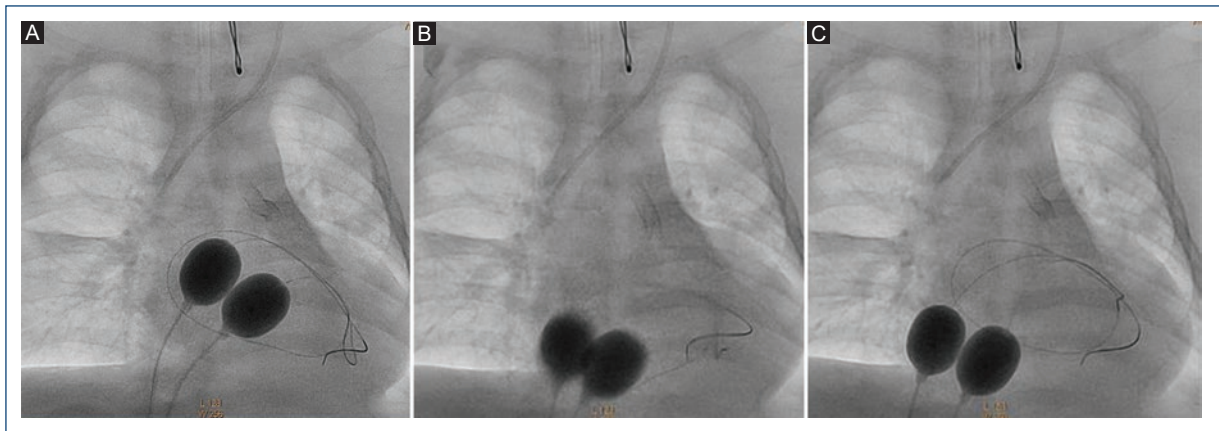


Figure 4. A-C: sequence of atrial septostomy with double “dynamic” balloon, both Z-5 balloons of 13.5 mm (see supplementary data, video 2).

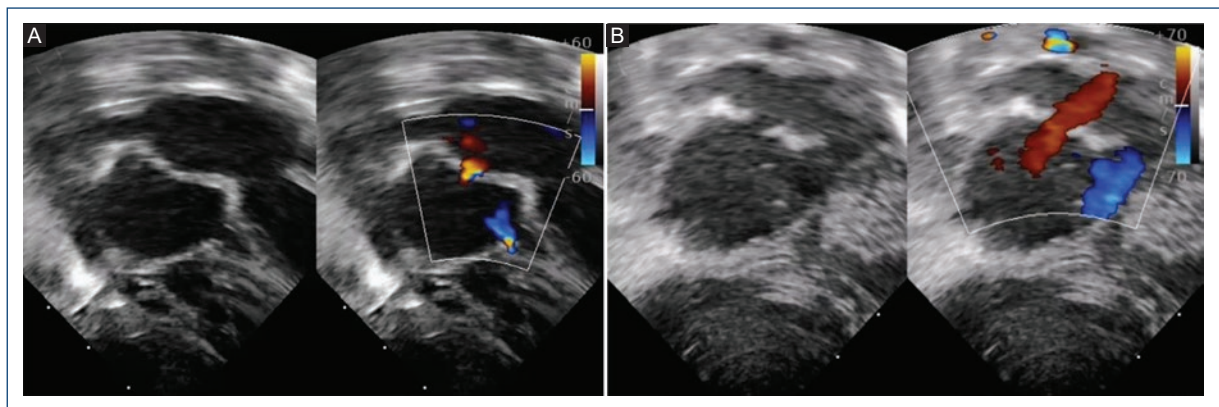


Figure 5. A: we can see a thickened interatrial septum with a very restrictive PFO. **B:** interatrial septum after septostomy with a single Z-5 balloon of 13.5 mm, ASD measures 3.8 mm with bidirectional shunting, the patient remains hypoxemic.

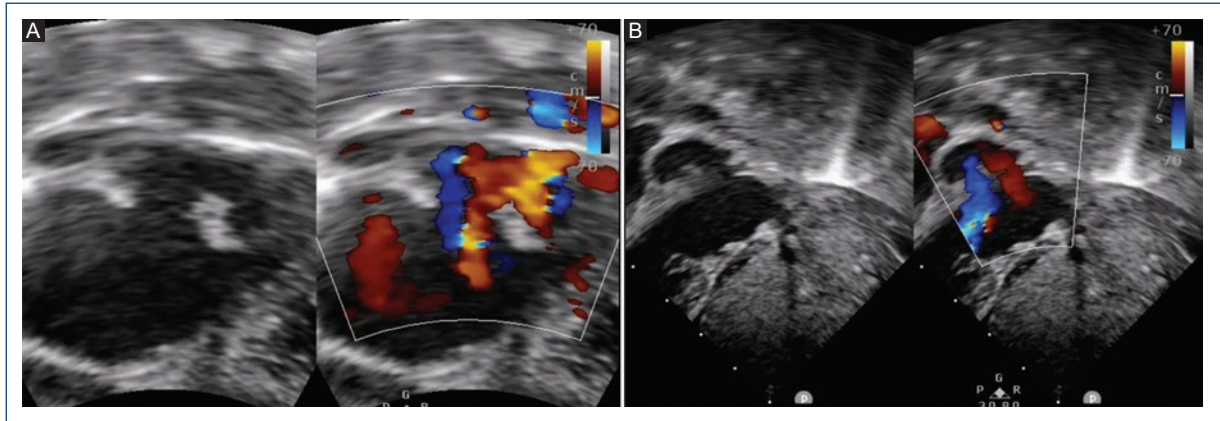


Figure 6. A and B: interatrial septum after double “dynamic” BAS (Z-5 balloons of 9.5 mm and 13.5 mm), ASD measures 8 mm with bidirectional shunt without gradient (see supplementary data, video 3).

No immediate or late complications related to the procedures were registered in any of the cases.

Discussion

In all cases, ASD was restrictive. The indication to perform double “dynamic” BAS, in all cases was the lack of clinical improvement or saturation, as well as, the presence of an insufficient or suboptimal ASD following septostomy with a Z-5 balloon catheter of 13.5 mm. The goal was to improve systemic oxygenation in patients with TGA, as well as, to increase the size of the ASD in the other two patients and decrease the trans-atrial gradient in all cases.

In patients with thickened interatrial septum, several points are worth noting:

- The first point is: that a thickened interatrial septum can occur at any age, although it is more common after 2 months of age. There are recommendations for the use of cutting devices from this age afterward.
- The second point: is that in developing countries, immediate access and costs of Park’s blade catheter or cutting balloon are extremely high (due to importation and distribution processes), also the stent placement can be an option, but in our pediatric hospitals this device is not available immediately. In this situation and in any case, where BAS (with a single balloon) is not entirely satisfactory or optimal, our only viable and rapid option is the static atrial septostomy (septoplasty), which in our setting are usually low-pressure rupture balloons (compliant balloons), and medium or high-pressure balloons

(non-compliant) are often too long to be used in newborns and infants. Thus, many cases of failure in BAS with a single balloon, when the interatrial septum is thickened have been reported⁵⁻⁷.

- The third point is: that in our country, the diagnoses of these critical CHD in the neonatal period are not made prenatally; thus, many of the patients are seen several days or months after birth, when they have already had severe hemodynamic conditions. In addition, in the cases with a thickened interatrial septum the BAS with a single balloon may not optimally tear it. Therefore, in the hemodynamically unstable patient, immediate access to cutting devices is extremely important; however, this is not feasible due to logistics in the provision and costs of the Park’s blade catheter or cutting balloon.

Finally, the Z-5 balloon catheter (Numed®) is the only balloon of septostomy routinely available in our country.

Description of double “dynamic” BAS technique

- Technique for newborns or infants weighing up to 5 kg: Two Z-5 balloons (9.5 mm and 13.5 mm sizes) (Figs. 7 and 8, Videos 4, 5, and 6).

Procedure: first the patient is monitored and under general anesthesia is intubated, after that; Insert a 7 Fr. sheath introducer through a femoral vein, then; place two 0.014” coronary angioplasty guide wires in the LA or in the pulmonary veins. First, introduce the smaller balloon and temporarily leave it at the caval-atrial junction, then, advance the second



Figure 7. Technique to introduce both balloons through introducer sheath. Step by step (part 1).

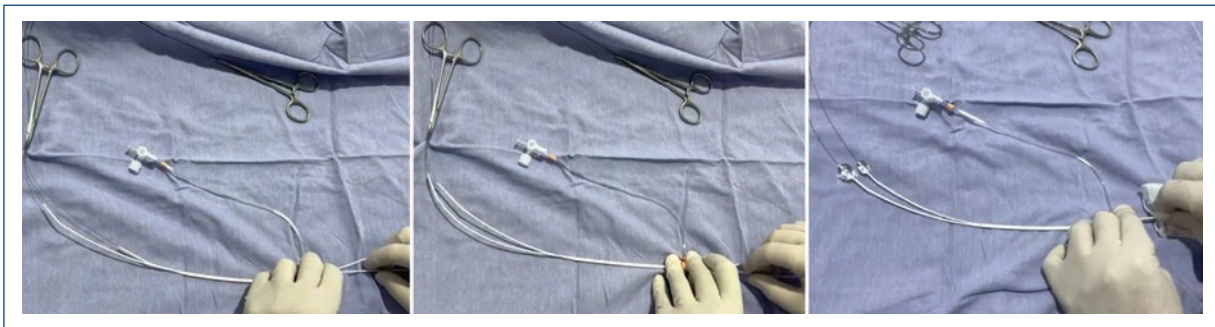


Figure 8. Technique to introduce both balloons through introducer sheath. Step by step (part 2).

(larger) balloon through the other coronary angioplasty guide wire until the caval-atrial junction. After, advance it (the “larger” balloon) forward to the LA and position it above the mitral valve (near the interatrial septum). Next; pass the small balloon to the LA and also position it above the mitral valve (near the interatrial septum). After; insufflated both balloons and take both profiles of the two balloons with a dry gauze and perform atrial septostomy in the habitual manner (at least 4 septotomy is recommended or more if the ASD continues restrictive). After that, TTE is made to confirm the ASD and residual gradient.

- Technique for newborns and infants weighing more than 5 KG: Two Z-5 balloons (both of 13.5 mm). Procedure: The procedure is exactly the same as above, except that an 8 Fr. sheath introducer is used instead of 7 Fr. And that both balloons are of the same size (13.5 mm).

No immediate or late complications related to the procedure occurred in any patient. The only eventuality encountered was slight bleeding through the hemostatic valve of the sheath introducer placed in the

femoral vein when both balloons were introduced simultaneously. This can be avoided by using a sheath introducer with hemostatic valve which has better competence. If this is not possible, the sheath introducer can be withdrawn 2 or 3 cm, and the distal part can be elevated at 45° to stop the slight bleeding through the hemostatic valve of the sheath introducer.

Another relevant point to mention is that this technique has various benefits: one is: that its use can prevent inherent risks associated with the use of cutting devices (Park’s blade catheter or cutting balloon) as: injury to the mitral valve, or perforation, laceration or rupture of any of the atrial chambers or inferior caval vein. The second benefit is that its use avoids the potential complications inherent with the mechanism of Park’s blade catheter; where it may become stuck. Which in any of the situations above-mentioned can be fatal or require an emergency cardiac surgery.

This modification to the original technique is also feasible under TTE guidance in the neonatal or pediatric intensive care unit, with the advantage of avoid the risk on patient transfer to the catheterization laboratory (see case 3).

The evidence obtained with our study using the double “dynamic” or dual BAS indicates that this modification of the original technique is easy, safe, cost-effective, and currently a viable option for cases with thickened interatrial septum. In addition, using the technique leaves behind the use of cutting devices with their inherent risks.

Limitations of the study are: the brief number of cases, so that, more patients who need a septostomy with a balloon Z-5 of 13.5 is sufficient to reach an optimal ASD to increase saturation or decrease the pressure of one of any atrium, even, in some patients with thickened interatrial septum and is unknown if this new modification of the original technique can be used as first intention procedure in cases with thickened interatrial septum.

Conclusion

Double “dynamic” or dual BAS is a modification of the original technique of Dr. W. J. Rashkind and Dr. W.W. Miller. It presents itself as a useful and lower-risk alternative for patients with thickened interatrial septum who require an adequate-sized ASD. The brief evidence of this modification indicates that it is effective, safe, cost-effective, and can even be performed in the intensive care unit under TTE guidance with good results and without complications.

This new modification to the original technique can help to avoid the inherent risks associated with the use of cutting devices such as the Park’s blade catheter and cutting balloon. It is necessary more studies utilizing this new modification to supporting it with a higher level of evidence.

Supplementary data

Supplementary data are available at DOI: 10.24875/ACM.24000128. These data are provided by the corresponding author and published online for the benefit of the reader. The contents of supplementary data are the sole responsibility of the authors.

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Conflicts of Interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution’s confidentiality protocols, obtained informed consent from patients, and received approval from the Ethics Committee. The SAGER guidelines were followed according to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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