

## Septal Artery Embolization with EVOH in Obstructive Hypertrophic Cardiomyopathy Associated with Percutaneous Treatment of Coronary Disease

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### Introduction

Hypertrophic cardiomyopathy (HCM) is the most common genetic heart disease. It has an autosomal dominant inheritance pattern, and to date, 11 genes have been identified among the 1400 mutations involved in its pathogenesis. The most common are the  $\beta$ -myosin heavy chain (MYH7), myosin-binding protein C (MYBPC3), and troponin T (TNNT2), which encode cardiac sarcomeric proteins.<sup>1</sup> Three mutations are involved in its pathophysiology: missense, insertions, and deletions. The most common mutation is missense, which causes a punctual exchange between two nucleic acids, resulting in a change in the nucleotide conformation, leading to the formation of a codon that codes for a different amino acid.<sup>2,3</sup>

HCM promotes changes in cardiac structure, with left ventricular hypertrophy (LVH) without another underlying etiology being the most common anatomical alteration.<sup>4</sup> Its symptomatology varies according to the HCM profiles, and can present asymptotically, with minor symptoms such as dyspnea on exertion, precordialgia, fatigue, presyncope and syncope, or in a severe form, evolving with advanced heart failure (HF), ventricular and atrial arrhythmias, and even sudden cardiac death.<sup>4,5</sup>

The prevalence of HCM is estimated at 0.2% of the adult population, and for this reason, early diagnosis, with echocardiography and cardiac MRI, especially in at-risk groups such as athletes, is essential, since in these patients treatments for septal reduction can be instituted, thus improving their quality of life and allowing them to continue practicing sports.<sup>6</sup>

The presence of other comorbidities along with HCM can occur in some patients, with coronary artery disease (CAD) being one possibility. In this patient profile, which includes both CAD and HCM, simultaneous percutaneous treatment

of both conditions is often necessary.<sup>7</sup> Concomitant coronary angioplasty and septal embolization are known strategies that can be performed together in the same procedure.

Among the proposed treatments for HCM, surgery is the gold standard, but currently, percutaneous intervention proposals have gained ground due to their similar clinical results to the standard treatment in reducing the gradient and thickness of the septum, thus improving symptoms. Non-alcoholic agents such as ethylene-vinyl alcohol copolymer (EVOH - Onyx®, Micro Therapeutics, Inc. ev3 Neurovascular, Irvine, CA, USA), already successfully used in embolization of aneurysms and arteriovenous malformations, have been implemented in septal reduction because they have non-adhesive, less thrombogenic properties, and are capable of penetrating deep arteries. Their safety is based on their higher viscosity and polymerization time compared to alcoholic substances.<sup>8-11</sup>

The objective of this work is to report the case of a patient with symptomatic HCM who underwent septal embolization with EVOH (Onyx®) associated with concomitant percutaneous angioplasty of the left anterior descending artery (LAD). This study was approved by the Ethics Committee of the Hospital de Urgências de Goiás under the number CAAE: 81824624.6.0000.0033.

### Case Report

A 62-year-old female patient with septal HCM in the basal and mid-segments of the interventricular septum, reporting progressive dyspnea and exercise intolerance over the past seven months, was classified as NYHA Class III on admission. The patient was under regular treatment for comorbidities (hypertension, diabetes mellitus, and dyslipidemia).

On physical examination, the patient was hemodynamically stable, eupneic, and without signs of respiratory distress. Heart rhythm was regular in two beats, without murmurs. The pre-procedure electrocardiogram (ECG) showed sinus rhythm, normal PR interval, with signs of left ventricular overload (strain pattern). A pre-operative transesophageal echocardiogram revealed a significant and asymmetrical increase in left ventricular myocardial thickness, more pronounced in the basal and middle segments of the septal wall (measuring up to 20 mm), generating acceleration of systolic flow in the left ventricular outflow tract, with a maximum dynamic gradient of 160 mmHg.

She underwent coronary angiography, which revealed calcifications and an 80% obstructive lesion in the middle

### Keywords

Hypertrophic Cardiomyopathy; Heart Septum; Therapeutic Embolization; Coronary Artery Disease; Angioplasty.

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third of the LAD and at the origin and proximal third of the second diagonal branch. Furthermore, it showed the first and second septal branches originating from the LAD, viable for septal reduction therapy (Figure 1A). Invasive manometry showed an intraventricular gradient of 180 mmHg (Figure 3A).

Due to the refractoriness of symptoms to optimized therapy and the presence of severe obstructive coronary lesions, hospital admission and treatment planning were performed: transluminal coronary angioplasty of the left anterior descending artery and embolization of the first and second septal branches with EVOH (Onyx®) in a single stage.

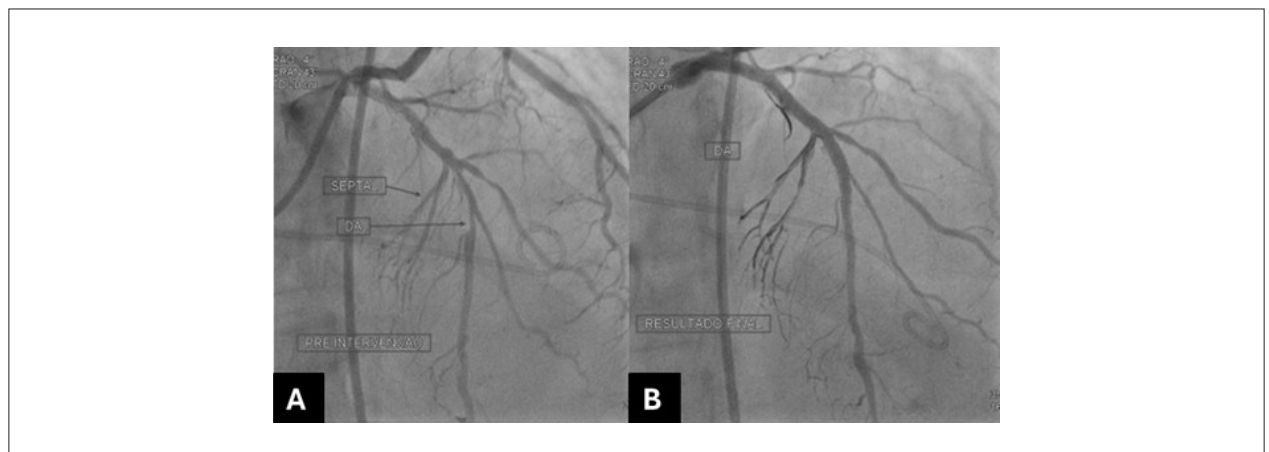
The procedure was performed under sedation and local anesthesia, via the right femoral artery with a 6F introducer (CORDIS AVANTI®+) and placement of a 3.5 6F XB guide catheter (Cordis, Warren, NJ, USA). The right radial artery was punctured with a 5F radial introducer, and a Pig Tail catheter was placed in the apical portion of the left ventricle for simultaneous manometry with the XB catheter already positioned in the aorta. After catheterization of the left main coronary artery (LMCA), a 0.014" Avigo® guidewire was advanced into the first septal branch, and through this, an Echelon® 10" dimethyl sulfoxide (DMSO) compatible microcatheter was inserted. A second 0.014" guidewire was positioned in the distal portion of the LAD, and through this, an occlusive balloon was placed. HyperGlide® Occlusion Balloon System 4.0x20mm (both Micro Therapeutics, Inc. ev3 Neurovascular, Irvine, CA, USA) occluding the segment of origin of the first septal branch. This is a compliant, atraumatic balloon used in the neurovascular territory. It passes over a 0.014" guidewire and requires the presence of this wire inside it to be inflated. A septal branch occlusion test was performed by inflating the HyperGlide® balloon and injecting contrast through the microcatheter, without reflux into the LAD and LCA, and without other connections to the studied vessel. To prevent polymerization of EVOH (Onyx®) within the microcatheter lumen in contact with serum or blood, we injected the DMSO solvent, which is part of the kit, in the exact volume to fill it (0.34 ml dead space). Immediately afterwards, we slowly injected approximately 2 to 3 ml of

EVOH (Onyx®) until total opacification of the septal branch (Figure 2A), preventing reflux into the LAD. At the end, we noted preserved distal TIMI-III flow and total occlusion of the septal branch visualized by EVOH radiopacity (Onyx®) (Figure 2B). Manometry (Figures 3A and 3B) showed a significant improvement in the pressure gradient in the left ventricular outflow tract (LVOT), decreasing from 180 mmHg to 15 mmHg at the end of the procedure.

Following the embolization, a single-stage transluminal coronary angioplasty of the LAD was performed as planned. The guidewire was advanced by 0.014" and the LAD lesion was transposed. Pre-dilation of the lesion was performed with a 3.0x20 mm balloon. A 3.5x38 mm drug-eluting stent was successfully implanted. Post-dilation was also performed with a non-compliant 3.5x8 mm balloon. The lesion of the second diagonal branch remained under medical treatment. At the end of the procedure, the ECG showed the patient in sinus rhythm, without signs of atrioventricular block of any degree and/or ischemic changes, with preserved distal flow TIMI III (Figure 1B). Subsequently, the introducer was removed with manual compression of the puncture site for hemostasis.

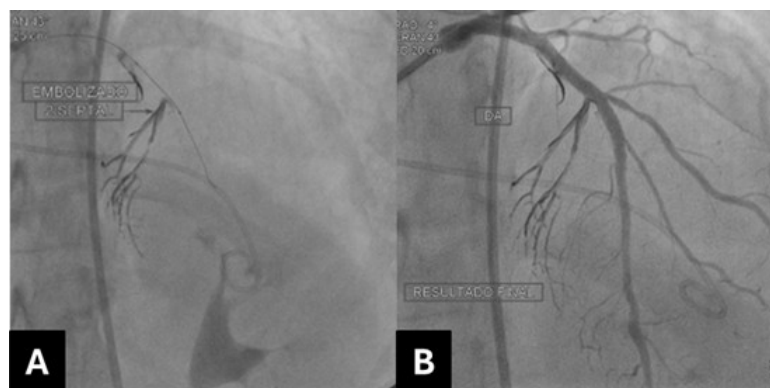
The patient was transferred to the Intensive Care Unit, hemodynamically stable, breathing room air. A transthoracic echocardiogram (TTE) was performed 72 hours after the procedure, which showed a 14 mm septum (-6 mm compared to baseline), dynamic obstruction in the left ventricular outflow tract at rest, resulting in a gradient of 73 mmHg, therefore 110 mmHg less than the pre-procedure baseline value, but 60 mmHg more than the immediate postoperative value. This variation is described in cases of septal ablation as a triphasic response, comprising an abrupt drop in the initial gradient, a "worsening" in the first three to six months, probably due to edema of the ablated muscle, and a return, in the third phase, to lower gradients.

She was discharged from the hospital 72 hours after the procedure, without complaints or complications during her stay, maintaining hemodynamic stability and presenting NYHA functional class II. Outpatient follow-up with the cardiology team was scheduled, along with optimized therapy and a new echocardiogram after adequate heart rate control to assess

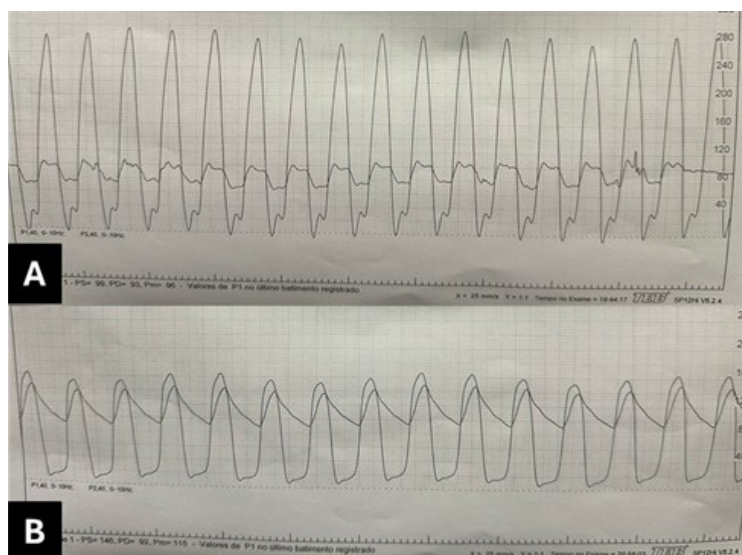


**Figure 1** – Angiography and angioplasty of the left anterior descending artery (LAD). 1A) 80% lesion in the middle third of the LAD, pre-intervention. 1B) After intervention by percutaneous transluminal angioplasty with implantation of a drug-eluting stent.

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**Figure 2 – Septal embolization.** 2A) Opacification of the septal branch preventing reflux into the left anterior descending artery (LAD). 2B) End of the procedure showing preserved distal flow TIMI-III and total occlusion of the septal branch visualized by the radiopacity of the EVOH (Onyx®).



**Figure 3 – Manometries.** 3A) Manometry obtained during the procedure, with a pre-procedure LV/Ao gradient of 180 mmHg. 3B) Improvement in the gradient after septal embolization (15 mmHg).

the intraventricular gradient. A follow-up echocardiogram was performed four months after the procedure, revealing a 14 mm interventricular septum with a 39 mmHg gradient in the left ventricular outflow tract, with mild mitral regurgitation due to anterior systolic motion (ASM) of the mitral valve. In the clinical evaluation, also four months later, the patient was classified as NYHA I, reporting being asymptomatic.

## Discussion

In patients with HCM who are selected for septal reduction therapy, myectomy and alcohol ablation are established therapies.<sup>10,12</sup>

In some selected cases, when HCM and CAD are present concomitantly, septal embolization in conjunction with angioplasty of the affected vessel is a viable procedure, as demonstrated by Honda et al., who described the concomitant performance of septal embolization with ethanol and LAD angioplasty, showing that performing both treatments during the same procedure is safe.<sup>13</sup> In the clinical case reported here, concomitant treatment of HCM with non-alcoholic embolization and CAD was performed. The use of EVOH (Onyx®) as an agent for septal embolization in conjunction with LAD angioplasty has not yet been described. Our report is the first case described in the literature in which septal embolization with EVOH (Onyx®) and LAD angioplasty were performed together.

Non-alcoholic agents have been introduced into clinical practice more recently, reducing the gradient in the LVOT and generating more localized ischemia. However, when compared to alcohol, these agents do not seem to show the same long-term results, due to recurrence of the LVOT gradient caused by return or persistence of fixed (septal thickness) and dynamic (systolic thickening and narrowing of this “tunnel” with accelerated flow and ASM) changes, probably due to new collaterals irrigating the septum.<sup>5,6</sup>

EVOH (Onyx<sup>®</sup>) has become an alternative in the treatment of septal reduction in HCM due to its non-adhesive, less thrombogenic properties and its ability to penetrate deeper septal arteries. This polymer is considered safe due to its higher viscosity and polymerization time compared to other substances. It is worth noting that the visibility of substances like Onyx<sup>®</sup> in embolizations is due to tantalum, which is radiopaque, while EVOH serves only as a carrier for this substance, allowing for better visualization and control during the procedure.<sup>5,6</sup>

Despite the benefits of EVOH, such as Onyx<sup>®</sup>, and the visibility of tantalum, septal embolization in HCM presents significant limitations. Among these, the difficulty in controlling the injection in small and complex vessels stands out, increasing the risk of reaching unwanted areas, a concern also addressed in endovascular treatment contexts, such as intracranial arteriovenous malformations.<sup>14</sup> In addition, EVOH requires specific solvents, such as DMSO, and careful handling. Despite the potential advantages, the use of EVOH for embolization presents certain limitations compared to the established technique of absolute alcohol. The cost of the procedure is significantly higher, since EVOH requires specific DMSO-compatible microcatheters, increasing the cost of materials. Furthermore, the need for a catheter for each septal branch further increases costs in cases of embolization of multiple branches. Another relevant limitation lies in the difficulty of selective catheterization of septal branches with guidewires and microcatheters. This challenge is particularly pronounced in patients with CAD (with or without calcifications) and/or previously implanted stents, as observed in the case reported here. Additionally, there are risks of complications such as heart blocks, which may require pacemaker implantation, and arrhythmias. The technique also has a learning curve, and there is a lack of long-term data to assess its durability and safety compared to other therapeutic approaches.<sup>14</sup>

A study conducted in Turkey by Asil et al. used EVOH (Onyx<sup>®</sup>) for septal embolization in 25 patients with HCM. In this study, two patients developed complete AV block and pacemaker implantation, but without long-term pacemaker dependence, maintaining only a left bundle branch block on electrocardiographic follow-up. There was reflux of EVOH (Onyx<sup>®</sup>) into the diagonal artery in one patient, without clinical or electrocardiographic implications. In addition, two septal arteries were embolized in five patients due to unsatisfactory hemodynamic results.<sup>11</sup> In this study, there was improvement in functional capacity, a decrease in atrial natriuretic peptide (BNP), and an immediate decrease in the LVOT gradient (median from 68 mmHg to 20 mmHg). However, three patients did not show a reduction in the LVOT gradient after six months, despite a drop in this gradient in

the immediate postoperative period.<sup>11</sup> In our case report, there was no manifestation of AV block, in addition to a more significant improvement in the LVOT gradient from 180 mmHg to 15 mmHg (a 91% drop compared to 70% in the Turkish study), and it was also the first reported case with angioplasty performed concomitantly with embolization and with a satisfactory angiographic result after the procedure and without complications.

It is known that the most common factor contributing to the development of LVOT obstruction is mitral valve ASM against the interventricular septum.<sup>15</sup> In our report, we observed a significant improvement in mitral valve ASM. In the preoperative echocardiogram, the mitral valve showed mild thickening, with preserved opening and MAS of the anterior leaflet, generating a marked degree of regurgitation. In the TTE performed on the third postoperative day, the mitral valve still presented ASM of the anterior leaflet and moderate regurgitation at the beginning of the examination, which became mild with the reduction of the heart rate (HR) from 115 bpm to 90 bpm. The new TTE performed four months after discharge once again showed mild ASM, with a HR of 62 bpm.

Follow-up after the EVOH (Onyx<sup>®</sup>) procedure is essential. In the work carried out by Asil et al., there was no evaluation of fibrosis areas after embolizations, and follow-up was performed by TTE, as it is a non-invasive and more readily available method.<sup>11</sup> In our case report, however, gradient measurement was performed by direct manometry, providing greater reliability to the measurements taken.

The significant decrease in pressure gradient after septal embolization, as observed in this case, is the physiological cornerstone for the improvement of HCM symptoms. This effective reduction of LVOT obstruction and the consequent optimization of blood flow provide substantial relief from the debilitating symptoms that previously severely compromised the patient's quality of life.<sup>15,16</sup> This positive response to symptoms manifests as an improvement in functional class according to the NYHA score. In our report, the patient, four months after the procedure, was classified as NYHA I, indicating significant progress compared to her baseline NYHA III status.

This study has limitations that need to be highlighted. Troponin levels were not measured before and after the interventions. The results were monitored using TTE, as it is a non-invasive and more accessible method, and therefore subject to examiner bias. Another factor to mention is the lack of longer-term follow-up. We recognize that ideally, follow-up would be more than 12 months to investigate any changes in gradients and septal anatomy, as well as to document the evolution of the clinical picture using the NYHA score, in addition to other possible clinical events. It is also important to emphasize that this report did not perform a more comprehensive assessment of quality of life using specific questionnaires.

## Conclusion

This case report demonstrates the success of septal embolization in symptomatic HCM using the embolic agent

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EVOH (Onyx®), evidenced by a satisfactory post-procedure angiographic result and the absence of complications, with a marked decrease in the intraventricular gradient. Additionally, this case illustrates the feasibility and success of performing concomitant septal embolization with EVOH (Onyx®) and percutaneous LAD angioplasty in the same patient. Although promising, these findings in a single case reinforce the need for prospective, randomized clinical trials to compare the efficacy and safety of EVOH embolization with conventional septal reduction therapies and to systematically evaluate the safety and benefits of the combined approach in patients with HCM and concomitant CAD.

### Author Contributions

Conception and design of the research: Gardenghi G; Acquisition of data: Trindade VT, Silva NA, Garcia NJM, Gardenghi G; Analysis and interpretation of the data: Trindade VT, Silva NA, Garcia NJM, Souza AL, Gardenghi G; Writing of the manuscript: Trindade VT, Silva NA, Garcia NJM, Souza AL, Prudente ML; Critical revision of the manuscript for content: Trindade VT, Silva NA, Garcia NJM, Souza AL, Prudente ML, Gardenghi G.

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### Potential conflict of interest

No potential conflict of interest relevant to this article was reported.

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### Study association

This study is not associated with any thesis or dissertation work.

### Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Urgências de Goiás under the protocol number CAAE: 81824624.6.0000.0033. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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