APPLICABILITY OF PERCUTANEOUS OCCLUSION WITH DOUBLE DISC PROSTHESIS FOR CORRECTION OF PATENT FORAMEN OVALE

Júlia Maria Minervino Nóbrega¹
Camila Cavalcante Martins²
Célio Amorim dos Santos Neto³
Eduardo Brasil de Souza⁴
Francisco José Pascoal Ribeiro Júnior⁵
Héricia Juliana de Araújo Lucena⁶
Luma Rodrigues de Moura Peres Cantuaria⁷
Maria Eduarda Bonetti Schulz⁸
Marina Steingräber Pereira⁹
Miguel Valentim Rodrigues¹⁰
Silvia Leticia Cunha e Silva Caldas¹¹
Thalyta Lopes Brandão¹²
Thiago Jacobi Pacheco¹³

ABSTRACT

Objective: To discuss the applicability of percutaneous occlusion with a double-disc prosthesis to correct patent foramen ovale.

Methodology: Integrative review of the literature carried out in the Virtual Health Library (VHL), Google Scholar and PubMed databases, using the Health Sciences (DeCS) descriptors: “Prosthesis design”, “Patent foramen ovale” and “Cardiac catheterization” combined with each other by the Boolean operator AND.

¹ Faculdade de Medicina Nova Esperança, João Pessoa, PB, Brasil. E-mail: jmmn11@icloud.com
Orcid: https://orcid.org/0009-0003-1258-965X
² Universidade Federal do Ceará (UFC), Fortaleza, CE, Brasil. E-mail milacavalcament@gmail.com
Orcid: https://orcid.org/0009-0001-0798-6971
³ Faculdade Alfredo Nasser (UNIFAN), Aparecida de Goiânia, Goiás, Brasil.
E-mail: celiionetoamorim@gmail.com
⁴ Universidade de São Paulo (USP), São Paulo, SP, Brasil. E-mail brasildesouzae@gmail.com
Orcid: https://orcid.org/0009-0001-1821-4723
⁵ Pontifícia Universidade Católica do Rio Grande do Sul (PUC-RS), Rio Grande do Sul, Brasil.
E-mail: pascoaljunior@uol.com.br Orcid: https://orcid.org/0000-0001-5827-7720
E-mail: herikalucena25@gmail.com Orcid: https://orcid.org/0000-0001-9005-1626
⁷ Universidade de Rio Verde (UNIRV) - campus Formosa, Formosa, GO, Brasil.
E-mail: lumarmpcantuaria@gmail.com Orcid: https://orcid.org/0000-0003-3526-1908
⁸ Universidade da Região de Joinville (UNIVILLE), Joinville, SC, Brasil.
E-mail: schuldzuda55@gmail.com Orcid: https://orcid.org/0009-0003-9005-5960
⁹ Universidade da Região de Joinville (Univille), Joinville, SC, Brasil. E-mail: marinaswp@gmail.com
Orcid: https://orcid.org/0009-0003-2958-4807
¹⁰ Faculdade Paraíso, Araripina, Pernambuco, Brasil.
E-mail: miguelmed2026@gmail.com Orcid: https://orcid.org/0009-0002-3062-2145
¹¹ Centro Universitário UniNorte, Rio Branco, AC, Brasil. E-mail: silviacunhaoficial@gmail.com
¹² Universidade do Grande Rio (UNIGRANRIO), Rio de Janeiro, RJ, Brasil. E-mail: thaly_281@hotmail.com
Orcid: https://orcid.org/0009-0001-2577-0365
¹³ Universidad Central del Paraguay (UCP), Pedro Juan Caballero, Amambay, Paraguay
E-mail: thiagojacobi@outlook.com Orcid: https://orcid.org/0000-0002-2085-5626

Results: Patent foramen ovale (PFO) is a congenital condition characterized by non-healing of the foramen ovale after birth, which can lead to complications such as paradoxical embolism and cerebrovascular accidents. Percutaneous occlusion rates with double-disc prostheses have accompanied this increase in PFO detection, while the technique, which involves inserting a double-disc device into the foramen ovale to close it, has proven effective in preventing embolic events in patients with a history of cryptogenic stroke or other PFO-related manifestations. The approach of percutaneous occlusion with a double-disk prosthesis for PFO correction is, therefore, a valuable tool in the therapeutic arsenal to reduce the risk of embolic events in high-risk patients.

Conclusion: Percutaneous occlusion with a double disc prosthesis is an effective approach to preventing embolic events in patients with patent foramen ovale. Its growth reflects technological advances and understanding of the risks of FOP.

Keywords: Prosthesis Design, Patent Foramen Ovale, Cardiac Catheterization, Signs and Symptoms.
el agujero oval para cerrarlo, ha demostrado ser eficaz para prevenir eventos embólicos en pacientes con antecedentes de enfermedad criptogénica, accidente cerebrovascular u otras manifestaciones relacionadas con el FOP. El abordaje de oclusión percutánea con prótesis de doble disco para la corrección del FOP es, por tanto, una herramienta valiosa en el arsenal terapéutico para reducir el riesgo de eventos embólicos en pacientes de alto riesgo.

**Conclusión:** La oclusión percutánea con una prótesis de doble disco es un enfoque eficaz para prevenir eventos embólicos en pacientes con foramen oval permeable. Su crecimiento refleja los avances tecnológicos y la comprensión de los riesgos de FOP.

**Palabras clave:** Diseño de Prótesis, Foramen Oval Permeable, Cateterismo Cardíaco, Signos y Sintomas.

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**1 INTRODUCTION**

In epidemiological terms, the incidence of Patent Foramen Ovale (PFO) varies from 15-35% in adults, indicating a significant presence in the population. Although not rare, the impact of FOP can vary between people, affecting individuals of any age and gender, with a tendency for greater prevalence in young women, especially those with a history of stroke of unknown origin (Chen et al., 2023).

The foramen ovale (FO) is a structure that acts as a valve, allowing the passage of blood from the right atrium to the left atrium due to the pressure difference between these two chambers. The existence of the FO is essential for the survival of the fetus, as it allows blood oxygenated by the placenta to enter the fetus’ systemic circulation without passing through the lungs (Silva, Oliveira, Santos 2023).

However, after birth, the permanence of the foramen ovale, known as PFO, can result in complications if it does not close correctly, being associated with risks such as strokes and other heart conditions. Although it is not normal, the persistence of the foramen ovale is a relatively common anomaly, occurring in around 30% of the adult population. With the expansion of the lungs, there is an increase in pressure in the left atrium, leading to fusion of the septa and closure of the foramen ovale. If this fusion does not occur, the foramen ovale remains open for life (Gomes, 2024).

To identify the presence of patent foramen ovale (PFO), it is necessary to perform a transesophageal echocardiogram (TEE), a transthoracic echocardiogram (TTE) or a transcranial doppler. Among these exams, TTE is the most used as it is the best tolerated by patients, although TEE is the most sensitive and considered the gold standard (Gomes, 2021).
Persistence is one of the potential causes of paradoxical embolism, deep vein thrombosis, myocardial infarction and cryptogenic ischemic stroke, the latter being the most prevalent, in addition to the predisposition to migraine. The role of PFO in these conditions highlights the importance of diagnosis and possibly preventive treatment in patients with a history of unexplained thromboembolic events (Schapinski, 2022).

A critical approach to this scenario is essential to understand the nuances involved in the percutaneous treatment of patients with specific conditions. When considering the amplitude of the defect, the hemodynamic repercussion and the presence of severe pulmonary arterial hypertension with an indexed pulmonary vascular resistance above 5.0w.m2, it is clear that percutaneous treatment may not be the best option (Fernandes, 2020).

Firstly, the amplitude of the defect plays a crucial role in the effectiveness of percutaneous treatment. If the defect is not large enough to cause significant hemodynamic repercussions, percutaneous intervention may not justify the associated risks. This is especially important considering that invasive procedures always carry a certain degree of risk for the patient (Bergoli, 2020).

Furthermore, the presence of severe pulmonary arterial hypertension with an indexed pulmonary vascular resistance above 5.0w.m2 indicates a complex and potentially serious cardiovascular condition. In these cases, percutaneous treatment may not be able to adequately address all complications associated with pulmonary hypertension, such as increased pressure in the pulmonary arteries and its hemodynamic consequences (Lemos, Ochsendorf, Resende 2021).

Complications after occlusion are uncommon, with device embolization being the most prevalent complication. This complication is lethal and requires immediate removal of the device by surgical or percutaneous intervention. Transthoracic echocardiography (TTE) makes it possible to evaluate the physiological consequences resulting from embolization (Mattoso, Sena, Hotta, 2023).

Therefore, this article seeks to comprehensively discuss the therapy of percutaneous occlusion with a double-disc prosthesis to correct patent foramen ovale, aiming to disseminate updated information about the procedure and promote a deeper understanding of the challenges faced by patients and healthcare professionals.
2 METHODOLOGY

This study is based on a bibliographical research of the integrative literature review type, which constitutes non-systematic reviews, seeking to synthesize information on a given subject and its broad perspectives (Noble, Smith, 2018). To prepare this study, the six phases that encompass this method were covered, which consist of: elaboration of the guiding question, search or sampling in the literature, data collection, critical analysis of the included articles, discussion of the results and presentation of the following review (Souza, Silva, Carvalho, 2010).

The guiding question was constructed based on the PICo strategy in accordance with the description of the Joanna Briggs Institute (2017), as demonstrated in Table 1.

Table 1
Preparation of the study question according to the PICo strategy. João Pessoa, PB, Brazil, 2024.

<table>
<thead>
<tr>
<th>ACRONYM</th>
<th>DESCRIPTION</th>
<th>TERMS</th>
</tr>
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<tbody>
<tr>
<td>P</td>
<td>Problem</td>
<td>Applicability of percutaneous occlusion with prosthesis</td>
</tr>
<tr>
<td>I</td>
<td>Interest</td>
<td>Repair of the foramen</td>
</tr>
<tr>
<td>Co</td>
<td>Context</td>
<td>Patent foramen ovale</td>
</tr>
</tbody>
</table>

Source: prepared by the authors, 2024.

This strategy supported the construction of the following guiding question: What is the applicability of percutaneous occlusion with a double-disk prosthesis to correct patent foramen ovale? In view of this, the bibliographic search was carried out in June 2024, through the Virtual Health Library Portal (VHL), PubMed and Google Scholar. The following inclusion criteria were used: studies related to the theme, with a temporal delimitation of the last five years, in English, Portuguese and Spanish. Technical reports, reflection articles, duplicate studies and those unavailable in full were excluded.

To search for studies, controlled descriptors available in Health Sciences Descriptors (DeCS) and Medical Subject Headings (MeSH) were selected. In addition, keywords were collected from the relevant literature on the topic, as described in Table 2.
The descriptors obtained were combined with the Boolean operator AND to formulate the search strategy. The selection of articles was carried out in three stages. Firstly, a comprehensive search was carried out in PubMed with the theme “Applicability of percutaneous occlusion with double disc prosthesis for correction of patent foramen ovale”, in order to verify the relevance of the topic for investigation.

In the second phase, the selection of scientific articles in the databases took place, in which duplications were eliminated and publications were selected, according to the inclusion and exclusion criteria mentioned in this study.

The studies were pre-selected based on reading and analyzing the title and abstract, taking into account the eligibility criteria. In the third phase, the findings were analyzed in full and selected based on their suitability for the research question and the established objective. Resulting in a total of 17 articles that respond to the topic studied. This process is represented in Figure 1.

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### Table 2

*Controlled descriptors and in accordance with the guiding question. Pessoa, PB, Brazil, 2024.*

<table>
<thead>
<tr>
<th>DeCS</th>
<th>Mesh</th>
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<tbody>
<tr>
<td>Prosthetic design</td>
<td>Prosthesis Design</td>
</tr>
<tr>
<td>Patent foramen ovale</td>
<td>Foramen Ovale, Patent</td>
</tr>
<tr>
<td>Cardiac catheterization</td>
<td>Cardiac Catheterization</td>
</tr>
<tr>
<td>Signs and symptoms</td>
<td>signs and symptoms</td>
</tr>
</tbody>
</table>

Source: Mesh Terms and DeCS, 2024.
Figure 1

*Search and selection of articles included in the review. Pessoa, PB, Brazil, 2024.*

With the complete selection of articles, it was possible to extract the results and limitations of the applicability of percutaneous occlusion with a double-disc prosthesis to correct patent foramen ovale, in order to concretize the relevance of this research and justify its purposes. It is worth noting that information regarding the title, year of publication, objective and main results were extracted.

**3 RESULTS**

After completing the methodological procedures, 17 articles available on the VHL portal, on the PubMed platform and on Google Scholar were selected. The year of publication ranged from 2019 to 2024. Table 3 provides detailed information on the studies chosen for analysis.
### Table 3

*Publications included according to author/year, title, main objective and main results. Pessoa, PB, Brazil, 2024.*

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Title</th>
<th>Main goal</th>
<th>Resultados</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oliveira et al., 2022.</td>
<td>Cross-sectional observational study of patients submitted to percutaneous occlusion of patent foramen ovale: a 20-year retrospective analysis.</td>
<td>To report the 20-year experience with percutaneous closure of the foramen ovale and its impact on reducing the recurrence of ischemic stroke in patients with right-to-left shunt.</td>
<td>The results indicate success of the procedure in all patients, implantation of different prostheses, absence of mortality, low rates of complications and recurrence of ischemic stroke within 5 years.</td>
</tr>
<tr>
<td>Gomes et al., 2021.</td>
<td>Patent foramen ovale - literature review.</td>
<td>Review the literature on Patent Foramen Ovale (PFO), highlighting that, although often asymptomatic, it can cause clinical conditions such as cryptogenic stroke and paradoxical embolism.</td>
<td>Identification of the clinical manifestations associated with FOP and discussion of the diagnostic methods and treatment options available for the condition.</td>
</tr>
<tr>
<td>Meinberg et al., 2024.</td>
<td>Literature review: patent foramen ovale and patient management.</td>
<td>Discuss the main updates in the management of patients with Patent Foramen Ovale (PFO).</td>
<td>Review the strategies and therapeutic approaches available for this common congenital condition.</td>
</tr>
<tr>
<td>Eliz et al., 2023.</td>
<td>Closure of the patent foramen ovale: a literature review.</td>
<td>Address the characteristics, incidence, risks, diagnosis, forms of treatment and the presence of Patent Foramen Ovale (PFO) in childhood.</td>
<td>It should be noted that FOP occurs in 15% of the population, being more asymptomatic in children and presenting a greater risk of complications with advancing age, with the diagnosis made through imaging exams and treatments varying according to age and condition. patient.</td>
</tr>
<tr>
<td>Kavinsky et al., 2022.</td>
<td>SCAI guidelines for the management of patent foramen ovale.</td>
<td>Create evidence-based guidelines for the management of patent foramen ovale (PFO).</td>
<td>The study developed 13 recommendations for the management of FOP, aiming to prevent recurrent stroke, migraines and decompression illnesses, and highlighted future research priorities.</td>
</tr>
<tr>
<td>Gonçalves, Paixão, Pacífico, 2022.</td>
<td>Forame Oval Patente.</td>
<td>Discuss updates in the management of patients with this condition.</td>
<td>Highlight the importance of a multidisciplinary and individualized approach in the management of patent foramen ovale.</td>
</tr>
<tr>
<td>Teshome et al., 2020.</td>
<td>Patent foramen ovale: a comprehensive review.</td>
<td>Review the clinical significance of patent foramen ovale (PFO), its association with cryptogenic stroke, diagnostic evaluation,</td>
<td>It highlighted that selective PFO closure in carefully selected patients may be superior to medical therapy alone in reducing the risk of recurrent stroke.</td>
</tr>
</tbody>
</table>
It is encouraging to see that percutaneous occlusion is considered safe in all age groups, including elderly patients over 60. This suggests that, in general terms, the technique is well tolerated and does not present excessive risks related to age. However, it is crucial to consider the variation in the clinical condition of elderly patients and how this may influence the safety and efficacy of the procedure (Oliveira et al., 2022).

In the adult setting, the predominant indication for surgical or percutaneous treatment in patients with cryptogenic stroke is based on evidence suggesting a relationship between FOP and the risk of cerebrovascular events. That recommendation is based on studies demonstrating an association between the presence of FOP and the occurrence of cryptogenic stroke, although direct causality can still be debated. The decision to opt for an invasive treatment also takes into account other factors, such as the risk profile of the patient, the presence of comorbidities and the overall evaluation of benefit versus risk (Jones, White, Miller, 2023).

On the other hand, the situation of asymptomatic children is more challenging due to the lack of robust scientific studies that clearly determine the ideal moment for the closure of the FOP. The absence of symptoms does not necessarily imply the absence of risks associated with FOP, but the decision to perform foramen closure in asymptomatic children should be based on solid evidence demonstrating the efficacy and safety of this procedure in this specific group. The lack of sufficient data to guide this decision highlights the need for further research and well-conducted clinical studies in this field (Gomes, 2021).

Research shows a 95% incidence and a 45% reduction in the risk of stroke in patients undergoing percutaneous closure of FOP, especially in cases of large FOP. This suggests that the procedure may be effective in preventing cerebrovascular events in certain groups of patients. Guimarães, 2022.

Second, Meinberg et al. (2024), the association between migraine with aura and the presence of FOP opens a window for further investigation. The observation that about half of patients with migraine with aura have FOP raises questions about the mechanisms underlying this relationship. The hypothesis that FOP may facilitate the passage of vasoactive substances, playing a role in the pathophysiology of migraine, is intriguing, but still lacks a complete understanding and solid evidence to be confirmed.
In addition, the link between the presence of FOP and a deterioration of symptoms in patients with chronic lung disease is a significant point of interest. Nevertheless, it is essential to point out that this relationship can be influenced by a number of factors, such as the severity of the lung disease, the presence of other concomitant medical conditions and the individual characteristics of each patient (Layoun, Aboulhosn, Tobis, 2019).

According to Smith, Brown and Johnson (2023), when it comes to choosing the most appropriate treatment for these patients, the decision should be based on a careful analysis of the risks and benefits of each therapeutic option. Percutaneous treatment is mentioned as preferred in these situations, but it is crucial to understand the criteria that support this preference. For example, percutaneous treatment may be considered the safest in terms of invasiveness and post-procedure recovery, but aspects such as long-term efficacy, the possibility of procedural complications, and the experience of the medical team in managing these cases still need to be considered.

Comparison with surgery and use of antiplatelet drugs is also relevant. Although percutaneous treatment may be preferred in some respects, surgery may offer specific benefits in certain settings, such as in patients with particular anatomical characteristics or comorbidities that make the surgical procedure more indicated. Similarly, antiplatelet drugs play an important role in the prevention of thromboembolic events and should be considered as part of the therapeutic plan, especially in patients who are not candidates for invasive interventions (Eliz, 2023).

Patent foramen oval (FOP) therapy through device closure showed elevated blood oxygenation, resulting in improved quality of life in 76% of patients. In the case of patients with thrombophilia, closure of FOP with device is not preferable over drug therapy (Kavinsky, 2022).

One of the greatest challenges for occlusion is the presence of lipomatous hypertrophy of the interatrial septum. This is due to the fact that there is an impediment of proper uptake between the lateral disks and the septum walls, thus maintaining the shunt (Fernandes, 2020).

In addition, paradoxical embolism arises from the migration of the thrombus from the left atrium to the right, being present in 78% of patients with FOP-linked aneurysm. A network composed of filamentous and fibrous structures in the right atrium is called the Chiari network, and is identified in 55% of patients with FOP and large shunt flow (Silveira, 2020).
4 CONCLUSION

Based on selected studies, percutaneous PFO closure with a double-disc prosthesis appears to be an effective and safe alternative for selected patients with cryptogenic stroke or transient ischemic attack. This technique has high success rates and low recurrence of adverse cerebral events, making it a promising option for treating PFO in specific cases. Although percutaneous PFO closure reduces the chances of recurrent stroke and TIA, it does not have a significant impact on mortality, serious adverse events, or major bleeding, but may increase the risk of procedure-related complications and atrial fibrillation/flutter.

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