





Tratamiento del ductus arterioso permeable en neonatología: estado actual y desafíos futuros

Treatment of patent ductus arteriosus in neonatology: status and future challenges

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Ductus arteriosus patent, tratamiento farmacológico, neonato.

Keywords:

Ductus arteriosus patent, pharmacological treatment, neonate.

Resumen

Introducción: El ductus arterioso permeable (DAP) es una anomalía común en recién nacidos, especialmente prematuros. Esto puede provocar problemas cardíacos y pulmonares graves. Aunque existen tratamientos, la mejor manera de manejarlo aún se debate, y se necesitan guías más claras para la atención. **Objetivo:** Proporcionar una actualización exhaustiva sobre el tratamiento del ductus arterioso permeable en neonatos. **Metodología:** Se realizó una revisión bibliográfica no sistemática tipo narrativa, de bases de datos como: *PubMed, SciELO, Library, EBSCO, Google Academic, DynaMed, Science Direct, Cochrane* y Anales de Pediatría de la Asociación española. **Resultados:** Se encontraron 64 resultados en total, de los cuales se seleccionaron 30 documentos que cumplían con los criterios de inclusión. **Discusión:** El manejo del DAP es con fármacos como la indometacina o el ibuprofeno, y cuando estos no funcionan, se recomienda cirugía. Actualmente se están probando nuevas alternativas como el uso del paracetamol, el cierre percutáneo o una terapia combinada. **Conclusión:** En el DAP se destaca la efectividad de medicamentos e intervenciones quirúrgicas y se ha visto productivo realizar estudios a largo plazo y aplicar enfoques personalizados. **Área de estudio general:** Medicina. **Área de estudio específica:** Ginecología y neonatología. **Tipo de estudio:** revisión bibliográfica.

Abstract

Introduction: Patent ductus arteriosus (PDA) is a common anomaly in newborns, especially premature infants. It can lead to serious cardiac and pulmonary problems. Although treatments exist, the best way to manage it is still debated, and clearer guidelines for care are needed. **Objective:** To provide a comprehensive update on the management of patent ductus arteriosus in neonates. **Methodology:** A non-systematic narrative literature review was conducted from databases such as: *PubMed, SciELO, Library, EBSCO, Google Scholar, DynaMed, Science Direct, Cochrane* and Anales de Pediatría de la Asociación Española. **Results:** A total of 64 results were found from which 30 papers were selected that met the inclusion criteria. **Discussion:** The management of PDA is with

drugs such as indomethacin or ibuprofen, and when these do not work, surgery is recommended. New alternatives such as the use of paracetamol, percutaneous closure or combined therapy are currently being evaluated. Conclusion: In PDA, the effectiveness of medication and surgical interventions is highlighted, and long-term studies and personalized approaches have been found to be productive.

Introduction

Patent ductus arteriosus (PDA) represents one of the most frequent cardiovascular anomalies in newborns, with a particularly high prevalence in premature neonates (1). This blood vessel, essential during fetal life to divert blood from non-functional lungs, normally closes shortly after birth. However, in up to 50% of neonates weighing less than 1500 grams, this physiological closure does not occur, giving rise to PDA (2, 3).

Persistent PDA can trigger a cascade of potentially serious complications, including heart failure, intraventricular hemorrhage, bronchopulmonary dysplasia, and necrotizing enterocolitis (4). These complications not only threaten the immediate survival of the neonate, but may also have long-term repercussions on its development and quality of life.

Despite decades of research, optimal management of PDA remains a topic of considerable debate in the neonatal community. Advances in medical technology and perinatal care have expanded the spectrum of therapeutic options, each with its own advantages and limitations. However, heterogeneity in clinical practices across institutions and regions underscores the need for updated and consistent evidence-based guidance (5, 6).

This review aims to provide a comprehensive update on the treatment of DAP in neonates, addressing three key questions:

What are the most effective therapeutic strategies for the management of PDA in the neonatal population? What emerging innovations are redefining the treatment landscape for PDA? What are the main challenges and limitations faced by clinicians in the management of this condition?

By exploring these questions, we aim to provide a critical synthesis of current knowledge, identify gaps in research, and provide a sound basis for clinical decision-making. Furthermore, this review aims to catalyze future research in areas where knowledge is still lacking, with the ultimate goal of optimizing outcomes for neonates affected by PDA.

The importance of this update lies in its potential to standardize and improve treatment protocols, reduce variability in clinical practice, and ultimately improve the prognosis of neonates with PDA. In a field where every decision can have far-reaching consequences, a thorough and up-to-date understanding of treatment options, their mechanisms of action, and their short- and long-term outcomes is crucial.

Methodology

The methodological design used in this bibliographic review is of a descriptive systemic type.

Eligibility criteria

The inclusion and exclusion criteria for the selection of studies were as follows:

The inclusion criteria were high-quality articles (systemic reviews and meta-analyses), bibliographic reviews, cohort studies and clinical trials, published in English or Spanish, between 2019-2024, open access, original, and above all, evaluating pharmacological and/or surgical treatments for PDA in neonates.

Exclusion criteria were animal studies or preclinical studies, articles that did not provide specific data on neonatal outcomes, narrative reviews, editorial comments, and letters to the editor without original data.

Sources of information

Searches were conducted in bibliographic databases such as: PubMed, Embase, DynaMed, Scopus, Cochrane Library, and the Annals of Pediatrics of the Spanish Association were also reviewed.

Search strategies

It is based on high-impact databases previously described on the treatment of DAP from a pharmacological, surgical and personalized strategy approach.

The search terms used included a combination of keywords and MeSH terms related to DAP and its treatment. The search strategy was developed with the assistance of a health sciences librarian and was tailored for each database. The search terms were as follows:

1. “Ductus arteriosus, patent” [MeSH]
2. “Patent ductus arteriosus” [Title/Abstract]
3. “Neonate” OR “Premature infant” OR “Preterm infant” [MeSH]
4. “Pharmacological treatment” [MeSH] OR “Ibuprofen” OR “Indomethacin” OR “Paracetamol” [Title/Abstract]
5. “Surgical ligation” [Title/Abstract]

6. “Emerging therapies” OR “Innovative treatments” [Title/Abstract]

Study selection process

During the search for articles in the different databases, based on the inclusion and exclusion criteria, the titles, abstracts, results and conclusions were independently reviewed. For articles relevant to this research, the full texts were obtained for evaluation.

Data extraction process

Data extraction was performed independently by the authors, using extraction forms based on the template provided by Cochrane (2). The information collected from all studies was organized in an Excel document. For articles published in English, DeepL was used for translation into Spanish.

Critical evaluation

In this narrative review, the methodological quality and validity of the results of the included studies were considered.

Ethical considerations

No specific ethical considerations were applied during the selection and analysis of sources, as this review is based exclusively on published literature and does not involve primary data or human participants.

Limitations

It is acknowledged that this narrative review has inherent limitations due to its non-systematic approach. There is a possibility of bias in the selection of sources and lack of comprehensiveness in the search. Furthermore, the interpretation of the results may be influenced by the subjectivity of the reviewer.

Results

For the DynaMed database, the keywords “Ductus arteriosus, patent” [MeSH] were used, resulting in 3 articles, of which 2 were excluded for being irrelevant; 1 article was used.

In the PubMed database, the advanced search terms were used: “Ductus arteriosus, patent” [MeSH], “Neonate” OR “Premature infant” OR “Preterm infant” [MeSH], “Pharmacological treatment” [MeSH] OR “Ibuprofen” OR “Indomethacin” OR “Paracetamol” [Title/Abstract]

“Emerging therapies” OR “Innovative treatments” [Title/Abstract]; with a result of 1200 articles. By placing filters: open access articles, from the last 5 years, in English and Spanish; 15 results were obtained, of which 5 were discarded as they did not correspond to the topic; and 10 articles were used.

For the Embase database, the terms “Ductus arteriosus, patent” [MeSH], “Pharmacological treatment” [MeSH] OR “Ibuprofen” OR “Indomethacin” OR “Paracetamol” [Title/Abstract] were used; with a result of 500 articles, from which those that were not from the last 5 years and were not in English or Spanish were excluded; 8 articles were used.

Regarding the Scopus database, the terms used were: “Ductus arteriosus, patent” [MeSH], “Pharmacological treatment” [MeSH] “Surgical ligation” [Title/Abstract]; with a result of 260 articles, of which 240 were excluded due to language, with a result of 20 articles, of which 15 were eliminated for being irrelevant topics; 5 articles were used.

For the search in the Cochrane Library the words "Ductus arteriosus" [MeSH] AND "pharmacological treatment" [MeSH] AND "neonate" [MeSH] “Emerging therapies” OR “Innovative treatments” [Title/Abstract] were entered; 52 documents were obtained, a filter was placed for the year, from 2019 to 2024, Spanish or English language, and the search was reduced to 9 documents, of which 2 were eliminated for not corresponding to the topic and 1 for being duplicated, 6 documents were used.

In the complete search for information, 2015 articles were found in the consulted databases. After applying the aforementioned filters, discarding duplicate articles and articles that are not within the inclusion criteria, 30 scientific articles were used in this research as a source of information.

Discussion

Pharmacological treatment

Pharmacological treatments for DAP in premature neonates mainly include indomethacin, ibuprofen and paracetamol.

Indomethacin has been one of the most studied and used treatments. Several studies have demonstrated its ability to effectively close the PDA in a large percentage of premature neonates (7, 8). However, it has significant side effects, such as renal failure and adverse gastrointestinal effects.

Similar to indomethacin, ibuprofen (8), It has been shown to be highly effective for PDA closure. Comparative studies indicate that ibuprofen has comparable efficacy to indomethacin, with better renal tolerance (9, 10). However, ibuprofen can still cause gastrointestinal problems.

Paracetamol is a newer option and is considered a promising alternative, especially in neonates where traditional COX inhibitors are not suitable. Recent studies suggest that it may be effective, although its efficacy may be lower compared to indomethacin and ibuprofen (8). The need for further long-term studies to confirm its efficacy and safety is a significant challenge.

Surgical Treatment

When pharmacological treatments are not effective or are contraindicated, surgical treatment is considered for DAP closure.

Surgical ligation is a well-established and highly effective procedure for closing PDA. It is commonly used when pharmacological treatments fail or are not feasible (9, 11). However, it carries significant risks, including infections and damage to the recurrent laryngeal nerve.

Percutaneous closure of PDA has gained popularity due to its minimally invasive nature. It uses devices inserted through a catheter to occlude the PDA. Recent studies indicate that this technique is effective and safe, even in very low birth weight neonates (11). However, it presents complications such as device embolization and requires significant experience and specialized equipment.

Recent innovations

Innovations in the treatment of DAP are focused on improving the safety and efficacy of existing therapies, as well as developing new treatment options.

Some studies are evaluating the efficacy of combining different drugs (e.g., ibuprofen and paracetamol) to improve PDA closure rates and reduce side effects (12, 13). This strategy may offer improved efficacy by targeting multiple physiological pathways involved in ductal patency.

Percutaneous device technology has advanced with the development of smaller, specific devices for very low birth weight premature neonates. These devices are designed to minimize risks and improve the efficacy of PDA closure (11, 14). Initial clinical trials show that these new devices are promising, although further research is needed to evaluate their long-term effectiveness and safety.

Personalized medicine is emerging as an innovative approach in the management of PDA (15). Treatment decisions are based on individual neonate characteristics, such as gestational age, birth weight, and comorbidities. This approach seeks to optimize outcomes by tailoring treatment to the specific needs of each patient (16, 17). Preliminary studies suggest that personalizing treatment may improve clinical outcomes and reduce variability in clinical practice.

Divergent perspectives and approaches

Although several investigations have been carried out, a clear consensus has not yet been reached on how to properly manage DAP. Clinical practices have been carried out in various parts of the world and have obtained different results regarding treatment, and therefore it has become difficult to have a reliable conclusion (7, 9).

Comparison of studies and results

Indomethacin vs. Ibuprofen: After reviewing the existing evidence on both drugs, it has been concluded that both are effective for the management of DAP. However, studies show that indomethacin is capable of producing a greater number of adverse effects (18, 19).

Ibuprofen as prophylaxis: A 2020 study published in the Cochrane Library database shows that this alternative is not effective, as it does not provide any real short-term benefit, and only exposes neonates to significant side effects (18).

Indomethacin in symptomatic patients: It has been shown that the use of this drug in symptomatic patients has provided a better evolution of the disease, compared to placebo or no treatment. However, the long-term effects of the use of indomethacin are unknown, so further studies are required (20).

Paracetamol: Many studies question the effectiveness of paracetamol, although others have shown that it could be a good alternative. An article published in 2022 shows that paracetamol, compared to ibuprofen and indomethacin, has no differences in its results after the administration of the first cycle (21). It has been decided to study the benefits of this drug, mainly to avoid the undesirable side effects of indomethacin and ibuprofen, especially for newborns who are strongly affected by them (15).

Early treatment vs. expectant management: Studies have shown that early treatment has not been successful compared to expectant management. It is mentioned that there is probably undue exposure to non-steroidal anti-inflammatory drugs, without this leading to a decrease in complications and the need for surgical interventions. Even so, it is worth noting that more specific research is required to be able to reach a certain conclusion (22).

Surgical treatments: The gold standard of surgical techniques is surgical ligation when pharmacological treatment has failed. However, new published studies have had promising results with the use of percutaneous closure, which has the additional advantage of being less invasive (23, 24).

New therapeutic alternatives: Several studies have been conducted to evaluate the combination of therapy and the use of new percutaneous devices, and the results have

been encouraging. It is believed that these new alternatives will be able to overcome the obstacles presented by traditional therapies (12, 24, 25).

Limitations and biases

This narrative review has several limitations. The lack of a systematic protocol may have introduced biases in the selection of the reviewed literature. In addition, the review was based on studies published in English and Spanish, which could exclude relevant research in other languages. The heterogeneity of the included studies may also have affected the comparability of the results. Despite these limitations, the review provides a critical and comprehensive overview of the treatment of PDA in preterm neonates.

New perspectives and future research

The findings of this review suggest several areas for future research. The need for long-term studies evaluating the efficacy and safety of paracetamol is crucial. Furthermore, research on combination therapies and the development of new percutaneous devices could offer innovative solutions for the treatment of PDA. It is also essential to explore personalization of treatment based on specific biomarkers and individual characteristics of the neonate to optimize clinical outcomes and reduce variability in clinical practice (7, 9, 19).

Review of the existing literature on the treatment of PDA in premature neonates reveals that although effective options exist, each has its own challenges. Indomethacin and ibuprofen remain the most commonly used treatments, but paracetamol is emerging as a promising alternative. Variability in clinical practices and lack of long-term data highlight the need for evidence-based guidelines and personalization of treatment. Recent innovations, such as combination therapies and new percutaneous devices, offer promising avenues to improve outcomes and minimize risks in this vulnerable population.

Conclusion

- In summary, this non-systematic literature review has provided a comprehensive overview of the treatment of patent ductus arteriosus (PDA) in premature neonates. Key findings highlight the effectiveness of pharmacological treatments such as indomethacin and ibuprofen, as well as the emerging promise of paracetamol. Surgical treatment options have also been explored, with a particular focus on ligation and percutaneous closure, and recent innovations in combination therapies and percutaneous devices have been discussed.
- These findings are relevant as they contribute to a deeper and more nuanced understanding of the treatment options available for PDA, highlighting both the advantages and limitations of each approach. The review highlights the

importance of personalizing treatment based on the individual characteristics of each neonate, which can optimize outcomes and minimize risks.

- Future research perspectives arising from these findings include the need for long-term studies on the efficacy and safety of paracetamol, the evaluation of combination therapies, and the development of new percutaneous devices. In addition, research into treatment personalization and the use of specific biomarkers may offer more precise and effective approaches.
- The practical implications of these findings are significant for clinical decision-making in the management of PDA. Adoption of evidence-based clinical guidelines may reduce variability in clinical practices and improve outcomes for neonates. Furthermore, the implementation of new technologies and therapeutic approaches should be accompanied by ongoing critical evaluation to ensure their effectiveness and safety.
- Recognizing the limitations of this non-systematic review, such as potential bias in literature selection and lack of comprehensiveness in the search, it is suggested that future research address these limitations through more systematic and rigorous methodologies.
- In conclusion, this review has highlighted the importance of a comprehensive, evidence-based approach to the treatment of PDA in preterm neonates. The findings contribute to existing knowledge and provide a solid foundation for future research and improvements in clinical practice. It is essential that researchers, clinicians and policy makers continue to collaborate to optimize treatments and improve outcomes for this vulnerable population.

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Conflict of interest

The authors declare no conflict of interest.

Limitations of liability

The authors of this work declare that all opinions expressed in this document are our exclusive responsibility, exonerating the Polytechnic School of Chimborazo and the School of Medicine to which we belong from the same.

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