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Literature review

Efficacy of Surfacen® use in neonatal respiratory distress

Effectiveness of Surfacen® Use in Neonatal Respiratory Distress

Efficacy of using Surfacen® for neonatal respiratory distress

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SUMMARY

Neonatal respiratory distress syndrome (RDS) is a serious illness that contributes to infant mortality. Its cause, surfactant deficiency, has been investigated to develop medications to prevent newborn deaths. This study aims to demonstrate the efficacy of surfacen® in neonatal respiratory distress. A literature review was conducted between June and July 2025, using Spanish-language articles and keywords from the Health Sciences Descriptor. Information from the previous five years was collected using Google Scholar and the SciELO, LILACS, and PubMed databases. Only 20 articles met the inclusion criteria. Analysis and synthesis methods were used to interpret the literature and organize the findings. The use

of surfactant in patients with neonatal respiratory distress promotes oxygenation and reduces the need for mechanical ventilation. The reduction in hospital stay and infant mortality, along with significant improvements in parameters such as exhaled airflow rate, validates its efficacy and safety. Surfacen® is a highly effective medication for treating respiratory diseases such as neonatal respiratory distress syndrome. Its ability to reduce surface tension and facilitate alveolar expansion demonstrates its effectiveness in improving oxygenation and minimizing the use of mechanical ventilation.

Keywords: Respiratory distress; Neonate; Newborn; Pulmonary surfactant; Treatment.

ABSTRACT

Neonatal respiratory distress syndrome is a serious disease that affects infant mortality. Its cause, due to a surfactant deficiency, has been studied to develop medications aimed at preventing newborn deaths. The objective of this study is to demonstrate the effectiveness of Surfacen® use in neonatal respiratory distress. A literature review was conducted between June and July 2025 in Spanish, using keywords from the Health Sciences Descriptors. Information from the last five years was collected through Google Scholar and the SciELO, LILACS, and PubMed databases. Only 20 studies met the inclusion criteria. Analysis and synthesis methods were used, allowing for the interpretation of the literature found and the organization of knowledge. The use of surfactant in patients with neonatal respiratory distress improves oxygenation and reduces the need for mechanical ventilation. The decrease in hospital stay and infant mortality, along with significant improvements in parameters such as the exhaled flow rate, validate its efficacy and safety. Surfacen® is a highly effective drug for treating respiratory diseases such as neonatal respiratory distress. Its ability to reduce surface tension and facilitate alveolar expansion demonstrates its effectiveness in improving oxygenation and minimizing the use of mechanical ventilation.

Keywords: Respiratory distress; Neonate; Newborn; Pulmonary surfactant; Treatment.

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SUMMARY

Neonatal respiratory distress syndrome is a serious condition that influences infant mortality. Its cause, due to surfactant deficiency, has been studied for the development of medications with the objective of avoiding death of newborns. The present work aims to demonstrate the effectiveness of the use of Surfacen® against neonatal respiratory distress. A bibliographic review was carried out between the months of June and July 2025, in Spanish, using key words present in the Descriptor in Health Sciences. Information is collected for the last five years in the databases Google Academic, SciELO, LILACS and PubMed. Only 20 studies will meet the inclusion criteria. We will use methods of analysis and synthesis, which enable the interpretation of the bibliography found and the organization of knowledge. The use of surfactant in patients with neonatal respiratory distress favors oxygenation and reduces the need for mechanical ventilation. The reduction in hospitalization time and infant mortality, together with significant improvements in parameters such as the measured flow rates, validates its effectiveness and safety. O Surfacen® is a highly effective medication to treat respiratory conditions such as neonatal respiratory distress. Its ability to reduce surface tension and facilitate alveolar expansion demonstrates its effectiveness in improving oxygenation and minimizing the use of mechanical ventilation.

Key words: Respiratory discomfort; Neonate; Newborn; Pulmonary surfactant; Treatment.

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Introduction

The United Nations Educational, Scientific and Cultural Organization (UNESCO) has set a

shared goal to end preventable deaths in newborns and children under 5 years of age by 2030. Its main objective is to reduce the mortality rate in premature infants from non-communicable diseases, particularly those that cause respiratory distress. One of the diseases associated with neonatal mortality is hyaline membrane disease, or neonatal respiratory distress syndrome. (1)

Neonatal respiratory distress syndrome (RDS) occurs due to a deficiency of a slippery, protective substance called surfactant, resulting from inadequate surfactant production or inactivation in the context of immature lungs. (2) Oviedo Ramírez (3) and Armas López (4) argue that it is a serious clinical condition affecting premature newborns and, occasionally, those born at term, representing a significant concern in clinical pediatrics. The World Health Organization (WHO) classifies it as diffuse damage to the alveolar capillaries, causing severe respiratory failure with arterial hypoxia and impaired oxygen uptake. (5)

Pathophysiologically, surfactant deficiency increases the surface tension of the airways, which are in a period of immaturity. This causes an increase in pressure to maintain alveolar shape and leads to atelectasis throughout the lung, reducing gas exchange. This results in damage to the respiratory epithelium, accompanied by pulmonary edema and inflammation of the respiratory system. Oxidative stress generated by both the high oxygen tensions of mechanical ventilation and inflammatory processes within the lung also promotes the conversion of surfactant into an inactive form through oxidative damage to proteins and lipid peroxidation. (6)

Its incidence and severity increase with decreasing gestational age, especially in infants born before 32 weeks. It is more common in males, those born by cesarean section and second twins, children of older gestational age born to diabetic mothers with poor metabolic control, and those who have suffered perinatal asphyxia, other intrapartum problems, or problems during the immediate postnatal period. (2)

Millions of babies die each year from this condition. According to the WHO, 2.5 million infants die annually during their first month of life; one million of these deaths occur within

the first 24 hours, and 75% occur during the first week. (7) In Ecuador, the prevalence of cases is higher in babies born before 33 weeks of gestation and in male newborns, due to an epidermal growth factor. (8)

In Cuba, according to the 2022 Statistical Yearbook of Health, 22 newborns died from this condition (18 under seven days old, three from seven to 21 days old, and only one from 28 days to 11 months old), for a rate of 0.2 per 1,000 live births. (9)

Since the first diagnoses, great efforts have been made to prevent newborns from dying at birth or in the first few days from the disease. The development of drugs like Surfacen® in Cuba, which has crossed borders and been recognized for its effectiveness and significant benefits, is an example of this.

That is why the present work aims to show the effectiveness of the use of Surfacen® in neonatal pediatric respiratory distress.

Methods

A literature review was conducted between June and July of 2025, in Spanish using keywords present in the Health Sciences Descriptor.

Information from the last five years was collected using the Google Scholar search engine and the SciELO, LILACS, and PubMed databases. Original articles, review articles, brief communications, theses, letters to the editor, and case presentations were examined.

Selection criteria: full articles with available references that addressed the overall objective of the study, published in the aforementioned language. Only 20 met these criteria. Publications that only included the abstract, did not address the objective of this article, were published in another language, or were unrelated to the types of articles examined were excluded.

The methods of analysis and synthesis were used, which made it possible to interpret the bibliography found and to organize the knowledge.

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Development

The discovery of surfactant, an endogenous substance produced by type II pneumocytes in the alveolar wall, which can be obtained from external sources, marked a milestone in the history of neonatology. Its main function is to reduce the surface tension of the alveolus, thus preventing alveolar collapse and promoting adaptation to the external environment. There are two types: natural (derived from animal lungs) and synthetic (protein-free). Natural surfactants have proven more effective, decreasing mortality and reducing air leaks; among surfactants of animal origin, porcine surfactant offers the greatest benefits. (10)

Surfacen® is an exogenous, porcine-derived, natural pulmonary surfactant developed in Cuba by the National Center for Agricultural Health (CENSA) in what is now Mayabeque Province and registered on April 7, 1995, with sanitary registration number 0800. It is presented in 50 mg vials, and each carton contains four vials, which should be stored at temperatures of 2 to 8 °C. It is indicated for early use in newborns weighing less than 1500 grams at birth with evidence of surfactant deficiency, preferably within the first two hours after birth. It is recommended for rescue treatment of infants with respiratory distress syndrome (RDS) after the first two hours of life. It is only recommended for endotracheal instillation by personnel experienced in intubation, ventilation management, and general patient care. (11)

It was obtained from bronchoalveolar lavage of pig lungs, through a purification process of the active principles, resulting in a composition of phospholipids (95%), mainly dipalmitoylphosphatidylcholine (DPPC), hydrophobic proteins (SP-B and SP-C) constituting 1.5%, and other lipids (3.5%). It was evaluated in immature rabbit fetuses and preterm sheep, demonstrating a significant improvement in pulmonary gas exchange and preventing the typical anatomopathological lesions of RDS. (12)

After being assembled in type II pneumocytes, it is packaged into spherical structures one

to three mm in diameter (lamellar bodies) that are secreted by exocytosis into the extracellular space, a process that can last several hours. In premature newborns, it has a prolonged half-life of 3 days and is quickly catabolized by alveolar macrophages. Term infants have a surfactant storage reserve of approximately 100 mg/kg, while premature infants have 4 to 5 mg/kg. Phospholipids, especially DPPC, are responsible for the surface-active function of surfactant by replacing released water molecules to establish additional interactions. As their surface concentration increases, they produce a progressive reduction in surface tension, which decreases from 70 to 20–25 mN/m, and then to 1 mN/m. (13)

Its creation is a momentous achievement for the country and the international medical community. It exemplifies Cuba's capacity to develop innovative and effective medical technologies, demonstrating the nation's skill and commitment to research and development of solutions to health problems. Its development has had a positive impact on the health of many newborns worldwide, thus recognizing Cuba's potential to produce high-quality pharmaceuticals.

Barrese Pérez and others, (14) stated that its biological origin and composition make it harmless when applied through endotracheal instillation in humans, it has anti-inflammatory and antibacterial action in in vitro and in vivo models and is classified as non-toxic.

At the Guantánamo General Teaching Hospital, (15) a descriptive study was conducted to evaluate the effectiveness and safety of early initiation of Surfacen® use in preterm newborns. The results were favorable: it was effective and well-tolerated, with a marked increase in oxygenation, while monitoring the inspired oxygen concentration to avoid hyperoxia. The authors recommended extending the study to a much larger sample, as only nine patients were included.

López Alfaro et al. (16), analyzing the relationship between the timing of drug administration and the satisfactory or unsatisfactory outcome of patients, found an association between using the drug within two hours of birth and using it after that time,

with a 4.5 times greater probability of death in the latter case. Of the 9 deaths (15.3%), 3 received treatment before 2 hours (33.3%), and 6 (66.7%) after 2 hours.

The author believes that mastering the optimal timing of treatment is crucial. A clinical evaluation before and after treatment will determine if the dosage and application method were correct. Therefore, constant monitoring is a priority, and it's important to remember that treatment should be individualized and supervised by an experienced physician.

Rodríguez Moya et al. (17) consider that the 25 years of routine clinical use of Surfacen® confirms the safety of this medication. Adverse effects such as patent ductus arteriosus and hyperoxia are noted. They state that before its use, the patient must be hemodynamically stable, including their metabolism. If this is not the case, its use is discontinued to initiate measures aimed at stabilization. The lack of reported allergic reactions and infections further reinforces its benefit and usefulness.

At the "Iván Portuondo" General Teaching Hospital in Artemisa province, (18) the use of Cuban surfactant with minimally invasive techniques was reported in three very low birth weight newborns (1100, 1026, and 1354 grams, respectively). A dose of Surfacen® of 100 mg/kg of weight was administered a few minutes after birth (25, 30, and 45 minutes) via tracheal catheterization using an umbilical catheter, maintaining the patient on non-invasive ventilation.

The authors of this research explained the technique used (objectives, necessary materials, and the step-by-step procedure), which provided multiple benefits: rapid and safe administration, clinical, blood gas, and radiological improvement; unnecessary endotracheal intubation; improved oxygenation levels; and a satisfactory outcome without complications. They emphasized that the procedure should be performed by personnel who have previously rehearsed it for better familiarization.

Other advantages to mention include: achieving a synergism that favors the homogeneous dissemination of surfactant in the pulmonary alveoli thanks to the patient's breaths; improving pulmonary compliance and stabilizing functional residual capacity; avoiding

complications of endotracheal intubation such as hypotension, bradycardia and increased intracranial pressure; reducing the incidence of bronchotrauma, bronchopulmonary dysplasia, pulmonary hemorrhage and other severe conditions. (19)

Understanding the above helps optimize time and improve clinical outcomes in a shorter period, minimizes risks associated with the pathological condition, helps take measures to prevent other complications, and assists healthcare professionals in educating family members and anyone interested about the treatment and its expectations.

An aspect that should not be overlooked is the bioethical question, in order to promote the patient's well-being in vulnerable situations, such as this delicate health circumstance. The dilemma that the use of this drug, specifically designed for newborns, may generate must be studied and detailed. The urgency of its administration is emphasized, as is the technical preparation of medical personnel, the availability of resources so that everyone benefits, and, moreover, confidence in its safety and effectiveness to convey to the family the peace of mind they need and avoid the need for highly invasive methods or ill-advised techniques. In general, the above will contribute to ensuring respect for the principles of medical ethics. (20)

In the author's opinion, certain circumstances can affect ethics and the doctor-patient-family relationship. The decision to administer it can be complex when the patient has severe comorbidities and the medical community cannot reach a consensus on its use. A lack of information and research on the subject can generate doubts and even fears in specific cases. On the other hand, a reluctance to use it can limit the therapeutic options available to patients who require it.

Conclusions

Surfacen® is a highly effective medication for treating respiratory conditions such as neonatal respiratory distress syndrome. Its ability to reduce surface tension and facilitate

alveolar expansion has proven effective in improving oxygenation and minimizing the need for mechanical ventilation. It is a valuable drug that requires careful and individualized use.

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Conflict of interest

The authors declare that there is no conflict of interest.

Authorship contribution

Virdanys Flores Alvarez, Cynthia Reyes Flores: conceptualization, formal analysis, research, methodology, visualization, writing - original draft, writing - revision and editing.