AMERICAN ACADEMY OF PEDIATRICS

Committee on Fetus and Newborn

Surfactant Replacement Therapy for Respiratory Distress Syndrome

It is now clearly established that respiratory distress syndrome (RDS) is associated with prematurity-related surfactant deficiency. Since its discovery,[1] there has been a considerable amount of research defining the biochemical composition of surfactant and its relationship to pulmonary function. A considerable amount of research has also been performed on animals to formulate the scientific basis for surfactant replacement therapy in premature infants to prevent or reduce the severity of RDS.

Clinical trials began with the rescue therapy by Fujiwara et al[2] and were followed by several single institution or multicenter trials using bovine, human, or synthetic surfactants. Many of these clinical trials have been published,[3–11] and others have been submitted for publication. Many of these trials were randomized, and the form of surfactant therapy was either prevention (endotracheal instillation of surfactant at birth) or rescue (treatment after RDS is diagnosed). Based on the published data, it appears that in both prevention and rescue trials, there is early improvement in respiratory status as evidenced by decreased inspired oxygen concentration and mean airway pressure requirements during the first 3 days of life. Some, but not all, published series suggest a reduction in mortality rates and incidence of pulmonary air leaks[3,7] during the first 28 days of life, but none of the published series appear to show an improvement in the incidence of such morbidities as bronchopulmonary dysplasia, necrotizing enterocolitis (NEC), infections, patent ductus arteriosus (PDA), and intraventricular hemorrhage (IVH). In fact, one series showed increased incidence of NEC in the surfactant-treated group,[6] the European trial showed an increased incidence of IVH,[12] and one series showed an increased incidence in PDA[9] in the surfactant-treated group.

In summary, it appears that surfactant replacement therapy may improve survival rate and reduce the severity of RDS. On the other hand, the evidence that it improves the overall outcome of low birth weight infants is still evolving.

The Food and Drug Administration has licensed one surfactant and will likely issue a license for the distribution of another surfactant product soon. The prospect of universal availability of surfactant raises concerns regarding potential misuse of this form of therapy. One such concern is that very low birth weight infants treated by surfactants may stay in nurseries that have inadequate facilities and personnel to care appropriately for infants with multisystem disorders. This is a critical issue because the target population for surfactant therapy is those high-risk, low birth weight infants who may have multisystem morbidities that are not affected beneficially by surfactant. Caring for these infants in nurseries that do not have the full range of capabilities required may affect the overall outcome adversely.

RECOMMENDATIONS

1. The surfactant replacement therapy should be conducted by physicians qualified and trained to do so. Qualifications should include experience in the respiratory management of low birth weight infants, including knowledge and experience in mechanical ventilation.
2. Nursing and respiratory therapy personnel experienced in the management of low birth weight infants, including mechanical ventilation, should be available on-site when surfactant therapy is administered.

The recommendations in this publication do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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3. Equipment necessary for managing and monitoring low birth weight infants, including that needed for mechanical ventilation, should be available on-site when surfactant therapy is conducted.
4. Radiology and laboratory support to manage a broad range of needs of very low birth weight infants should be available.
5. There should be an institutionally approved surfactant therapy protocol that should be a mandatory component of the quality assurance program.
6. In those institutions where any of the items in recommendations 2 through 5 are not present, if an emergency situation arises and if indications are present, the surfactant therapy may be given, but only by a physician who is skilled in endotracheal intubation. Infants should be transferred from such institutions as soon as feasible to a center with appropriate facilities and staff trained to care for multisystem morbidity in low birth weight infants.

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