Respiratory Syncytial Virus Prophylaxis in Heart Disease: Indication and Limits of Worldwide Administration

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INTRODUCTION

- Respiratory syncytial virus (RSV) is a common pathogen affecting almost all children by the age of 2 years
- The most severe complications of RSV result in hospitalization among those with known cardiovascular disease
- There is significant congenital heart disease (CHD) due to RSV during the winter season
- Palivizumab (PVZ) is used as standard immune prophylaxis due to the absence of a vaccine against RSV

OBJECTIVE

- To understand global variations in the use of PVZ in immune prophylaxis for severe RSV disease

METHODS

- A systematic Delphi consensus methodology was used to develop questions and recommendations aimed at identifying and addressing the current needs of pediatric patients with congenital heart disease (CHD) at risk for severe RSV disease who require prevention and management strategies
- Strength of evidence (grades and levels) were assessed per standard practice

STERLING COMMITTEE

- A steering committee that comprised 5 international paediatric cardiology expert clinicians and additional faculty composed of international experts (eg, paediatric cardiologists, intensivists, and cardiac surgeons) collaborated (figure 1)

RESULTS

- Through the development process, the group identified 6 questions related to the current need of RSV immunoprophylaxis in paediatric CHD patients

RSV Immunoprophylaxis in children with CHD

Question 1. Who should be involved in developing the standard of care for the use of RSV immunoprophylaxis in children with CHD?

- German, Korea, Spain, and the United States: use prophylaxis in children with
  - hsCHD as defined by Feltes et al14 (Cyanotic stratum, previous cardiac surgery or interventional catheterization, hypercyanotic episode, receiving cardiac medications, evidence of airway obstruction due to cardiovascular causes, and congenital tracheal stenosis
- Japan: Professor Naokata Sumitomo

Question 10. What are the barriers to effective RSV disease prophylaxis in children with CHD, including the delivery of that prophylaxis?

- Barreras to effective RSV immunoprophylaxis in children with CHD include
  - Poor awareness of RSV risks and barriers (eg, nearly unfair RSV prophylaxis)
  - Compliance and completion barriers (eg, fears of injections and AEs; failures of HCPs to understand importance of compliance)
  - Data and experience gaps (eg, paucity of trial data)
  - Not-consilient medically palliative treatment (eg, palliative percutaneous hemodynamic support)
  - Unacceptable RSV seasonality, making it difficult to establish a schedule

Regional variation

- Studies have shown that there is no evidence for giving RSV immunoprophylaxis to those with 22q11.2 microdeletion or insignificant CHD

Question 14. What management strategies could be put in place to overcome these barriers to effective prophylaxis of RSV disease in children with CHD?

- Warning messages to the public by health care professionals do not usually achieve barriers to effective prophylaxis of RSV disease in children with CHD
- Recommended regions (local, regional, national) and important to capture more observational data and experiences of children in different settings
- Provides a feedback loop in RSV epidemiology and potential effectiveness of immunoprophylaxis
- Services and support in regions with specific environment factors

REFERENCES

*Supported by cardiac surgeons; infectious disease, intensive care, primary care, and neonatology specialists; epidemiologists; general paediatricians; cardiologists; infectious disease specialists; intensive care specialists; and neonatologists

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Questions 1-9 are based on the expert opinion of the panel and review of the current evidence. Where there is no evidence, the recommendations are based on expert opinion.

Questions 6-10: On the basis of benefit shown and from your own clinical experience, in which children with CHD do you recommend immunoprophylaxis against RSV infection?

Question 6. During the RSV season, children with CHD

- RSV Immunoprophylaxis for children <1 years of age diagnosed with or being treated for dyspnea or
  - RSV immunoprophylaxis for children with congenital heart disease (CHD) or LHD, or PHS on cardiology consultation

Question 7. During the RSV season, children with cardiopulmonary diseases

- Germany and Mexican consider prophylaxis in patients with cardiopulmonary diseases requiring medical treatment
- Mexican consider prophylaxis in hospitalised infants with uncomplicated cardiovascular disease as well as in infants, unmedicated (in whom infants are aged <1 year)
- United States, Texas, and Korea: Prophylaxis for infants <1 year of age with heart malformations significant (cardiopulmonary) (eg, lyric dysplasia, non-total anomalous pulmonary venous return, tetralogy of Fallot, hypoplastic, turning) or severe (cardiology consultation)

Question 8. During the RSV season, children with complicated CHD

- Consider RSV immunoprophylaxis for children who are on a waiting list for heart transplant or in their first year after heart transplantation

Question 9. During the RSV season, children with CHD

- Germany, Korea, Spain, and the United States: use prophylaxis in children with
- Children with recurrent arrhythmias and channelopathies are not usually candidates for RSV immunoprophylaxis, but it is
- United Arab Emirates: use clinical judgment on a case-by-case basis in patients with hsCHD with partially corrected CHD,
- Colombia and Spain: consider prophylaxis in all children with Down syndrome

Question 11. Based on the benefit shown and from your own clinical experience, in which CHD children do you recommend immunoprophylaxis for the prevention of nosocomial RSV infection, the patient is on cardiologic management?

- In children >1 year of age with CHD, use RSV immunoprophylaxis during a nosocomial RSV outbreak if

Question 12. In which children with CHD <2 years of age should you consider immunoprophylaxis against RSV infection?

- There was general consensus among the panel of international experts that RSV immunoprophylaxis should be used in children
- There is general consensus that RSV immunoprophylaxis should be available more freely in resource-limited countries

Question 13. What are the barriers to effective RSV disease prophylaxis in children with CHD, including the delivery of that prophylaxis?

- Question 11. Based on the benefit shown and from your own clinical experience, in which children with CHD do you recommend immunoprophylaxis against RSV infection?

- Question 12. In which children with CHD <2 years of age should you consider immunoprophylaxis against RSV infection?

- Question 13. What are the barriers to effective RSV disease prophylaxis in children with CHD, including the delivery of that prophylaxis?

- Question 14. What management strategies could be put in place to overcome these barriers to effective prophylaxis of RSV disease in children with CHD?

- Question 15. What are the limits of worldwide administration of RSV immunoprophylaxis in children with CHD?

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- Conclusions

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