Treatment of RSV Lower Respiratory Tract Infection in Two Immunocompromised Children with Polyclonal Immunoglobulin Containing Standardized Levels of Neutralizing Antibodies to RSV

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Background
- Respiratory syncytial virus (RSV) can cause severe lower respiratory tract infection (LRTI) in immunocompromised patients.
- No standard, effective therapy for severe RSV LRTI currently exists.
- Use of ribavirin (inhaled or oral), pooled donor intravenous immunoglobulin (IVIg), and monoclonal anti-RSV antibodies (palivizumab) have been described.
- RI-002 (ADMA Biologics) is a pooled human polyclonal IVIg containing standardized levels of neutralizing anti-RSV antibodies that is prepared via a patented process.
- The predecessor of RI-002 was used for compassionate treatment in RSV LRTI in stem cell transplant patients.
- RI-002 was FDA-approved in 2019 for prophylaxis in primary immunodeficiency patients.

Methods
- Two children with T-cell lymphoblastic lymphoma and neuphtonia secondary to chemotherapy were included.
- Both patients had RSV LRTI.
- Both received PO ribavirin and IVIG.
- Both were treated with RI-002 under an emergency FDA Investigational New Drug application

Patient #1: Clinical Course
- Admitted (Day 0) with fever, neutropenia, and respiratory symptoms. RSV positive.
- RI-002 started (Day 1) with 15 mg/kg dose IVIg, followed by 5 mg/kg on Day 2, 3, 4.
- High frequency oscillatory ventilation, and prone sedation. Mechanical ventilation
- Discharged home (Day 44) with 90 days of RI-002

Patient #2: Clinical Course
- Patient 2 admitted (Day 1) with fever, cough, and respiratory distress. RSV positive.
- RI-002 started (Day 2) with 15 mg/kg dose IVIg, followed by 5 mg/kg on Day 3, 4.
- Mechanical ventilation
- Discharged home (Day 16) with 90 days of RI-002

Patient #3: Microbiology Data
- RSV (positive)
- Day 3: RSV not detected
- Day 7: RSV not detected

Patient #4: Microbiology Data
- RSV (positive)
- Day 3: RSV not detected
- Day 7: RSV not detected

Conclusions
- Polyclonal immunoglobulin (RI-002) contains high levels of neutralizing anti-RSV antibodies.
- In immunocompromised children:
  - RI-002 may be useful in the treatment of severe RSV LRTI
  - RI-002 may be useful in preventing RSV infection or its progression to severe LRTI
- Future studies on the role of RI-002 in the treatment and prevention of RSV LRTI in immunocompromised children are warranted.

References

Mayo Clinic’s Center for Individualized Medicine