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CASE SERIES

Palivizumab for Severe Respiratory Syncytial Virus Infection in Immunocompetent Adults: A Case Series

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Background: Respiratory syncytial virus (RSV) is a significant cause of lower respiratory tract infections in adults, particularly the elderly, and can lead to severe outcomes, including respiratory failure. Current treatment options for RSV in immunocompetent adults are limited to supportive care.

Objective: This case series aims to describe the clinical course and outcomes of two immunocompetent adults with severe RSV infection treated with Palivizumab, a monoclonal antibody against RSV.

Methods: We report two cases: a 92-year-old female with a history of hypertension and a previous meningioma resection, and a 42-year-old female with no significant past medical history. Both presented with severe respiratory symptoms, were diagnosed with RSV infection via PCR, and received a single dose of intramuscular Palivizumab (approximately 12–13 mg/kg) after initial clinical deterioration despite supportive care and empiric antibiotic therapy.

Results: Following Palivizumab administration, both patients exhibited clinical improvement, including resolution of fever and improvement in oxygenation and radiographic findings. Both patients were discharged in stable condition without the need for supplemental oxygen.

Conclusion: These cases suggest that Palivizumab may be a potential therapeutic option for severe RSV infection in immunocompetent adults. Further research, including randomized controlled trials, is needed to confirm these preliminary findings and establish optimal dosing and treatment protocols.

Keywords: respiratory syncytial virus, palivizumab, immunocompetent adults

Introduction

Respiratory syncytial virus (RSV) is a major cause of respiratory illness globally, responsible for significant morbidity and mortality in both infants and adults. While RSV is well-recognized as a leading cause of bronchiolitis and pneumonia in young children, its impact on adult populations, particularly the elderly and those with underlying comorbidities, is increasingly appreciated. In immunocompetent adults, RSV infection can lead to severe lower respiratory tract infections, requiring hospitalization and resulting in respiratory failure and death in some cases. A recent retrospective study conducted in France focused on 104 immunocompetent adults, of whom 93% had at least one comorbidity. Among these patients, 26 (25%) required ventilator support, and 14 (13%) died within one month of hospital admission.[1] RSV remains one of the most common respiratory viruses even after the emergence of SARS-CoV-2. Despite the potential for severe outcomes, treatment options for RSV infection in adults, particularly immunocompetent individuals, remain largely

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limited to supportive care.[2] The absence of effective antiviral therapies represents a significant unmet need in the management of this increasingly recognized clinical entity.

Palivizumab, a monoclonal RSV antibody preparation, which is composed of humanized immunoglobulin IgG antibody that binds to the highly conserved epitope of the F protein of RSV,[3] is currently approved for the prevention of severe RSV disease in high-risk infants and young children. In terms of therapeutic use, several retrospective studies have explored its off-label application in adults, primarily among patients with hematologic malignancies or those who have undergone organ or stem cell transplantation.[4–9] However, its potential as a therapeutic agent for established RSV infection, particularly in immunocompetent adults, has not been thoroughly investigated. This report presents two cases of severe RSV lower respiratory tract infection in immunocompetent adults who received Palivizumab as a compassionate treatment, aiming to shed light on its potential efficacy and safety in this understudied population.

Cases 1

A 92-year-old female with a history of hypertension and previous T6-T7 intraspinal meningioma status post hemilaminectomy and semilaminectomy, presented to the emergency department with productive cough over 5 days. Accompanying symptoms included a sore throat, fever with chills. She also reported poor appetite and generalized weakness. Her husband, who lived with her, reported similar respiratory complaints.

In the emergency department, her vital signs were notable for hypertension (BP 164/69 mmHg) and mild tachypnea (RR 21 breaths/min), with a body temperature of 36.9°C. Initial oxygen saturation was 95% on room air. Physical examination revealed bilateral rhonchi on lung auscultation. Laboratory investigations showed leukocytosis (WBC 12,670/uL), elevated CRP (20.3 mg/dL). Chest X-ray revealed increasing interstitial and alveolar infiltration over both lung fields, predominantly in the left lower lung field, suggestive of pneumonia (Figure 1A). RSV infection was confirmed via nasopharyngeal swab polymerase chain reaction (PCR) and the Multiplex PCR respiratory and pneumonia assay (bioMérieux, Utah, USA). She was admitted for further management with a diagnosis of RSV bronchitis and pneumonia.

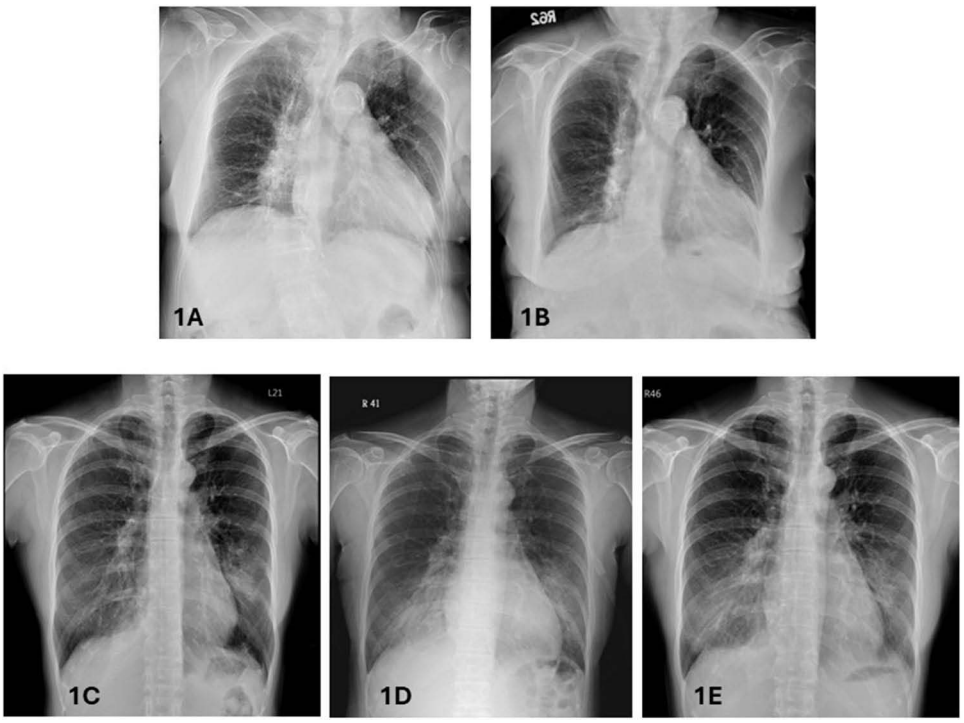

Figure 1 Serial chest plain film of two cases. (**A**) Case 1 chest X-ray at emergent department; (**B**) Case 1 chest X-ray on day 4 of admission; (**C**) Case 2 chest X-ray at emergent department; (**D**) Case 2 chest X-ray on day 3 of hospitalization; (**E**) Case 2 chest X-ray on day 5 of hospitalization.

On the first day of admission, the patient was started on supportive therapy, including anti-tussive medication for symptom relief. Ampicillin/Sulbactam was prescribed empirically for suspected bacterial pneumonia.

On day 2 of admission, fever and productive cough persisted. Oxygen saturation on room air dropped to 91%. After discussing the pros and cons of Palivizumab administration with the patient and her family, the patient agreed with compassionate use of Palivizumab administration. Palivizumab 600 mg (13 mg/kg of ideal body weight) was administered intramuscularly as a single dose. Following sputum bacterial culture yielded no bacteria growth. The fever subsided by day 4 of admission. Serial laboratory tests showed gradual improvement in inflammatory markers. Follow-up chest X-rays demonstrated improvement in bilateral lung infiltrates, correlating with clinical recovery (Figure 1B). After 7 days of hospitalization, a mild productive cough remained but no supplemental oxygen was required. She was discharged under relative stable conditions on day 7.

Case 2

A 42-year-old woman with a history of tension headaches presented with a high fever (up to 40.5°C) lasting two days, accompanied by generalized weakness and headaches. She also reported a productive cough for several days. Notably, her son, who lived with her, experienced fever, cough, and rhinorrhea. Concerned about her symptoms, she sought medical attention in our emergency department.

In the emergency department, her vital signs revealed a body temperature of 39.2°C and tachycardia, with a heart rate of 111 beats per minute. Physical examination showed no specific findings. A chest radiograph revealed the right lower lung infiltration and patchy consolidation in the left lower lung (Figure 1C). Laboratory tests demonstrated an elevated C-reactive protein (CRP) level of 17.01 mg/dL and a white blood cell (WBC) count of 7650/μL with 89% neutrophils. A nasopharyngeal swab was tested using PCR for rRSV, which revealed positive. COVID-19 and influenza tests were negative. The patient was subsequently admitted with a diagnosis of RSV pneumonia, with a suspected bacterial co-infection.

From days 1 to 3 of hospitalization, supportive treatments, including hydration and antipyretics, were administered. Empiric antibiotics, including intravenous ampicillin/sulbactam and oral doxycycline, were initiated. Despite treatment, intermittent fever persisted, and her oxygen saturation remained between 92–95% on room air. A chest X-ray on the third day of admission showed progression of right lower lung consolidation and the appearance of an air-bronchogram (Figure 1D). A sputum sample was analyzed using the multiplex PCR (bioMérieux, Utah, USA) pneumonia assay, which detected *Mycoplasma pneumoniae*.

Following a detailed discussion, the patient consented to the administration of Palivizumab. A single intramuscular dose of 600 mg (11.5 mg/kg) was given on the fourth day of hospitalization. By day 4, the patient's fever had resolved. A chest X-ray on day 5 showed improvement, with resolution of the right lower lung consolidation, although the left lower lung infiltrate persisted (Figure 1E). Sputum cultures revealed no bacterial growth, and her oxygen saturation on room air improved to 98%. The patient was discharged in stable condition on the sixth day of hospitalization with an additional one-week course of oral doxycycline to complete treatment.

Discussion

This case series presents two immunocompetent adults with severe RSV lower respiratory tract infection who demonstrated clinical improvement following the administration of Palivizumab. This is significant as it represents the first documented use of Palivizumab as a treatment for RSV infection in non-immunocompromised patients. In our report, the term "immunocompetent" is used to indicate the absence of major immunocompromising conditions such as malignancy, end-stage liver or renal disease, or HIV infection. In our cases, Palivizumab was prescribed due to clinical deterioration in Case 1 and persistent fever with progression of imaging findings in Case 2.

Current treatment options for RSV infection in adults are primarily limited to supportive care. Ribavirin, an antiviral agent, has been used in some cases, particularly in immunocompromised individuals. However, its efficacy remains controversial. Oral or aerosolized ribavirin has been widely used as a treatment for RSV infection in adults. The potential effect of ribavirin in preventing the progression of upper respiratory tract infection (URTI) to lower respiratory tract infection (LRTI) in immunocompromised and immunocompetent patients has been documented in several observational

studies and meta-analysis.[10–14] However, ribavirin was not prescribed in the two reported cases due to its unavailability in this region.

Three previous case reports have documented the use of palivizumab in patients with severe RSV infection accompanied by respiratory failure.[15–17] In all reported cases, both clinical symptoms and imaging findings showed marked improvement following treatment. In Table 1, we summarize the currently published reports on the use of palivizumab for treating patients with RSV infection. Most of the previous reports have focused on patients with relatively immunocompromised conditions, particularly those with hematological malignancies, hematopoietic stem cell transplantation (HSCT), or heart and lung transplantation. This focus is partly attributable to the high cost of palivizumab and the limited data on its efficacy as a treatment for RSV infection. In 2001, a Phase 1 clinical study

Table 1 Case Reports and Retrospective Studies of Using Palivizumab as Treatment of RSV Infection

Author (Year)	Patients	Diagnosis Method	Type of Infection	Treatment	Follow Up Duration; Mortality or Outcome
Labay et al (2023)[15]	50, Female, Post-liver transplantation	PCR, Nasopharyngeal swab	LRTI, with respiratory failure and mechanical ventilation	Palivizumab 11 mg/kg, IM, once; Ribavirin PO 400 mg BID x 7 days; Methylprednisolone 40 mg/day IV x at least 4 days, followed by tapering dose	Improvement of chest image and successful wean from ventilator 5 days after therapy and transition to room air after 6 days.
Banna et al (2004)[16]	56, Female, Hodgkin's disease	Immunofluorescence	LRTI	Palivizumab 8 mg/kg, IV, once; Betamethoasone 4mg BID	Resolution of fever following Palivizumab; oxygen therapy withdrawn 10 days after therapy; radiological improvement after 15 days
Grodin et al (2012)[17]	70, Male, Post-heart transplantation	Direct fluorescence antibody (DFA)	URTI and LRTI, with requirement of BiPAP	Palivizumab 7.5 mg/kg, IV, once; Aerosolized ribavirin (2 g Q8H) x 5 days; IVIG 400 mg/kg, once; Methylprednisolone (40 mg daily) x 3 days	Weaned off BiPAP; Radiological and PFT improvement at 3-month follow-up
McCoy et al (2011)[5]	26 patients (58% male); Hematological malignancies (6), HSCT recipients (20); Mean age 51.5	Rapid antigen detection, cell culture	31 URTI, 13 LRTI	Palivizumab 15mg/kg Aerosolized Ribavirin	90 days; 2 deaths (both unrelated to RSV)
Liu et al (2010)[9]	23 patients (20% male); Bilateral lung (15) and single lung or heart-lung transplant recipients (10); Mean age 42	DFA, cell culture	13 URTI, 10 LRTI	Palivizumab 15mg/kg Aerosolized Ribavirin; IV methylprednisolone 500mg/day for 3 days; IVIG	1 year; 2 deaths (both unrelated to RSV)
Boeckh et al (2001)[4]	15 patients* (47% male); HSCT recipients; Mean age 36	DFA, shell vial centrifugation, tube culture	3 URTI, 12 LRTI	Palivizumab 15mg/kg Aerosolized Ribavirin;	28–45 days; 2 deaths (both related to RSV IP)
Fontbrune et al (2007)[8]	40 patients; HSCT recipients; Mean age 16	Immunofluorescence	18 URTI, 22 LRTI	Palivizumab 15mg/kg (9 URTI, 3 LRTI patients); IV Ribavirin (7 URTI, 3 LRTI patients)	1 year; 9 deaths (1 death is related to RSV pneumonia),
Khanna et al (2008)[6]	34 patients (59% male); Hematological disease; Mean age 41.7	Culture, antigen testing, PCR	22 URTI, 12 LRTI	Palivizumab 15mg/kg Aerosolized or oral Ribavirin; IVIG	5 years; 6 deaths (5 deaths related to LRTI)
Tsitsikas et al (2009)[7]	8 patients; HSCT recipients; Mean age 41	Immunofluorescence, PCR	2 URTI, 6 LRTI	Palivizumab 15mg/kg Aerosolized Ribavirin;	30 days; 2 deaths (unrelated to RSV)

Note: *Only include the patient infected by RSV in the study.
Abbreviations: URTI, Upper respiratory tract infection; LRTI, Lower respiratory tract infection; HSCT, Hematopoietic stem cell transplantation; DFA, Direct fluorescence antibody.

demonstrated that palivizumab was safe and well-tolerated in HSCT recipients.[4] Subsequent studies have also reported minimal adverse events following palivizumab administration (Table 1).

The mechanism by which Palivizumab may exert a therapeutic effect in established RSV infection is not fully understood.[5,6] The effectiveness of palivizumab in preventing the progression of RSV from URTI to LRTI remains inconclusive. A case series involving eight HSCT recipients suggested that a combination of palivizumab and aerosolized ribavirin might help prevent RSV progression.[7] However, contradictory findings were reported in another small retrospective cohort study.[8] Another potential benefit of palivizumab was its role in preventing lung function decline in patients undergoing lung or heart transplantation.[9] It is worth noting that the reported benefits of palivizumab therapy primarily stem from retrospective studies with small sample sizes. Furthermore, most treatment regimens in these studies included additional therapies such as ribavirin, steroids, or IVIG. As a result, the observed benefits may have been attributable to these adjunct therapies rather than to palivizumab alone. In contrast, in our two cases, palivizumab was used as monotherapy for RSV treatment (aside from concurrent antibiotic use), and both patients showed clinical improvement. However, to clarify the efficacy of palivizumab, larger randomized studies are needed in the future.

In our cases, palivizumab was prescribed at a dose of 13 mg/kg in Case 1 and 11.5 mg/kg in Case 2. The reported doses of palivizumab vary across studies, ranging from 7.5 mg/kg to 11 mg/kg. Notably, all six retrospective studies we reviewed reported using a dose of 15 mg/kg (Table 1). Currently, there is no established data on the optimal dose of palivizumab for the treatment of RSV infection. The timing of administration may also be crucial, with earlier intervention potentially yielding better outcomes.

In summary, this case series provides preliminary evidence that Palivizumab may be a potential therapeutic option for severe RSV infection in immunocompetent adults. Although limited by the small sample size and observational design, our findings underscore the need for larger randomized trials to evaluate its efficacy, safety, and optimal dosing in this population.

Ethics Approval and Informed Consent

The report was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board of Taichung Veterans General Hospital (CE20004B). Written informed consent for publication of their details was obtained from the patients.

Author Contributions

All authors made a significant contribution to the work reported, whether in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; Jun-Yu Zhong, Ting-Kuang Yeh, Po-Yu Liu, and Yun-Ching Fu conceptualized the study; Ting-Kuang Yeh, Hsien-Po Huang, Chun-Mei Ho, and Po-Yu Liu developed the methodology; formal analysis was performed by Jun-Yu Zhong, Ting-Kuang Yeh, and Po-Yu Liu; the investigation was carried out by Jun-Yu Zhong, Ting-Kuang Yeh, Po-Yu Liu, and Yun-Ching Fu; data curation was undertaken by Jun-Yu Zhong, Ting-Kuang Yeh, Hsien-Po Huang, and Chun-Mei Ho; the original draft was prepared by Jun-Yu Zhong, Ting-Kuang Yeh, and Po-Yu Liu; writing—review and editing were completed by Ting-Kuang Yeh, Po-Yu Liu, and Yun-Ching Fu. All authors have given final approval of the version to be published, have agreed on the journal to which the article has been submitted, and agree to be accountable for all aspects of the work. Jun-Yu Zhong and Ting-Kuang Yeh contributed equally to this work as co-first authors.

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Disclosure

The authors declare that they have no conflict of interest.

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