PEDIATRICS

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

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DOI: 10.1542/peds.2020-1701

Journal: *Pediatrics*

Article Type: Case Report

Citation: Frauenfelder C, Brierley J, Whittaker E, Perucca G, Bamford A. Infant with SARS-CoV-2 infection causing severe lung disease treated with remdesivir. *Pediatrics.* 2020; doi: 10.1542/peds.2020-1701

Infant With SARS-CoV-2 Infection Causing Severe Lung Disease Treated With Remdesivir

Claire Frauenfelder, MBBS, MSurg,[1,2] Joe Brierley MBChB, FRCPCH, FFICM,[1] Elizabeth Whittaker MRCPCH, DTM&H, PhD,[3] Giulia Perucca, MD,[1] Alasdair Bamford MRCPCH, DTM&H, PhD[1,4]

Affiliations:

[1] Great Ormond Street Hospital for Children NHS Foundation Trust, London, UK
[2] Division of Surgery, University of Adelaide, South Australia
[3] Paediatric Infectious Diseases, Imperial College Healthcare NHS Trust, London, UK
[4] UCL Great Ormond Street Institute of Child Health, London, UK

Address correspondence to:

Dr Alasdair Bamford
Department of Paediatric Infectious Diseases
Great Ormond Street Hospital for Children NHS Foundation Trust
Great Ormond Street
London WC1N 3JH
a.bamford@ucl.ac.uk

Funding source: No authors have received any funding for this project, or in any capacity that would influence the study.

Financial disclosure: The authors have indicated they have no financial relationships relevant to this article to disclose.

Conflict of Interest: No authors have potential or real conflicts of interest to disclose.

Abbreviations:

ARDS	Acute respiratory distress syndrome
COVID-19	Coronavirus disease 2019
CT	Cycle threshold
ECMO	Extracorporeal membrane oxygenation
PCR	Polymerase chain reaction
RNA	Ribonucleic acid
SARS-CoV2	Severe acute respiratory syndrome coronavirus 2

Table of contents summary: (max 25 words)

We describe the case of an infant who developed severe pulmonary SARS-CoV2 infection in the 5th week of life and was treated with remdesivir.

Contributors' Statement Page

Drs Frauenfelder, Brierley, and Bamford conceptualized and designed the study, collated the patient data, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr Perucca and Dr Whittaker collected data, revised radiological and infectious disease aspects of the data presented (respectively), and critically reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Abstract

We describe an ex-premature infant presenting with SARS-CoV-2 infection in the 5th week of life. Current reports indicate that acute symptomatic SARS-CoV-2 infection is relatively rare and much less severe than in adults. This case highlights that infection can be associated with life threatening pulmonary disease in young infants and that infection can follow a similar disease course to that described in adults. We provide first data on the use of the novel antiviral remdesivir in a young child and an innovative approach to expedited approval from a multidisciplinary clinical team and bioethics committee for compassionate access to the drug.

Introduction

During the COVID-19 pandemic few children have been infected, and those affected had a typically milder course than adults.[1–8] We describe an ex-premature infant who presented with SARS-CoV-2 infection in the 5th week of life. His clinical course differs from other reported pediatric cases showing only mild respiratory system involvement.[5,8] Severe respiratory distress developed in a short timeframe, following severe airway compromise due to significant glottic swelling. Although his condition initially improved, severe acute respiratory distress syndrome (ARDS) developed at the time prophylactic steroids were given to prepare for extubation. High frequency oscillatory ventilation, nitric oxide and intermittent prone positioning were then required, and following use of the antiviral agent remdesivir, he made a full recovery before discharge home.

Case Report

The patient is a twin born at 32+6 weeks for maternal pre-eclampsia with a small atrial septal defect (<4mm) and cleft palate. He was intubated at birth before weaning off respiratory support within a week. At 37+3 weeks corrected gestational age he developed respiratory distress at home and presented to hospital. Of note, he had been in recent contact with both family members and asymptomatic healthcare workers, who subsequently developed symptoms and were confirmed to have SARS-CoV-2 infection.

In the emergency department progressive hypoxia led to several failed attempts at intubation. Nasopharyngeal aspirate SARS-CoV-2 RNA PCR was positive (CT 20). Oxygenation and ventilation were maintained via laryngeal mask during transfer to a quaternary center for otolaryngologic input. He was successfully intubated in theatre via microlaryngobronchoscopy, using appropriate personal protective equipment for all personnel.[14] Significant glottic swelling and copious airway secretions were noted (Figure 1).

Initial moderate ventilatory pressures and FiO_2 of 0.6 were weaned over 3 days. Initial chest x-ray demonstrated mild bilateral ground glass opacities (Figure 2). CRP was 42 mg/L and he was lymphopenic (1.45x10*9/L) with an otherwise normal blood picture (Figure 3). Serial tracheal aspirates, urine and stool cultures excluded bacterial or fungal co-infection. A line-associated femoral arterial thrombus was treated with therapeutic anticoagulation.

After several days of laryngeal rest ventilation parameters had improved and he was suitable for trial of extubation. The multi-disciplinary team decided to use usual prophylactic steroids to optimize laryngeal conditions for extubation, particularly considering the difficult intubation. Two prophylactic dexamethasone doses were given.

Prior to extubation the patient deteriorated, developing fulminant ARDS with corresponding worsening of chest x-ray findings (Figure 2). He could no-longer be managed with conventional ventilation and required high-frequency oscillatory ventilation, nitric oxide, prone ventilation and inotropic support to maintain oxygenation and ventilation. ECMO was considered but not required. Possible secondary bacterial infection was treated with broad spectrum antibiotics and excluded by bronchoalveolar lavage, using strict personal protective equipment precautions.

Given the life-threatening deterioration, an urgent multidisciplinary meeting was held, followed by an innovative therapy review with the bioethics team and parents via video-link.[15] As there was limited evidence for hyperinflammation (IL6 <50pg/ml, Ferritin 411ug/L), antiviral therapy was preferred to immunomodulation. A compassionate access application for remdesivir was agreed upon and was granted.[16,17]

An intravenous loading dose of 5mg/kg remdesivir was given, followed by 1.25mg/kg maintenance dose for 10 days. IL10 was raised (110pg/ml) but normalized by day 5 of treatment. CRP peaked at 63mg/L on day 6, Ferritin 789ug/L on day 9, and D-dimer 1143ug/L day 10.

Daily SARS-CoV-2 RNA PCR tracheal aspirates became negative after 5 days of remdesivir, excluding an isolated positive on Day 10 of remdesivir. No drug toxicity was observed.

The highest troponin was 138ng/L. There were no clinical or echocardiographic signs of myocarditis. Echocardiogram on day 7 of illness showed only a small patent foramen ovale with left to right shunt, mild dilation left side structures, and mild mitral regurgitation.

Ventilatory and inotropic support were weaned, and extubation was successful on day 18 of illness (Figure 4). He has been discharged home.

Discussion

We describe the clinical course of an infant with severe SARS-CoV-2 infection causing severe airway inflammation and ARDS, who improved following treatment with the novel antiviral remdesivir.

SARS-CoV-2 infection in infants and neonates

No clear explanation has been found as to the different severity of SARS-CoV2 infection in children and adults.[18] A very low proportion of those infected have been children, and even fewer young infants.[1,7,8,10–13] A large Chinese series of 2143 pediatric patients found less than 6% of SARS-CoV-2 infected children developed hypoxia, and <1% progressed to ARDS.[4] A Spanish group reported only 4/41 SARS-CoV-2 infected children (9.7%) required support

beyond nasal prongs, and only a single patient was intubated.[6] An early study reporting infection epidemiology in New York reported fewer than 1% of admissions were children, and none required intensive care.[19]

Airway manifestation in this infant

Cellular composition of airway epithelium is similar between children and adults, and new research indicates little difference in the transcription of genes associated with SARS-CoV2 infection in airway epithelium between children and adults.[20] In a large systematic review of upper airway symptoms observed during the COVID-19 pandemic, stridor and airway compromise are not reported features of SARS-CoV2 infection.[21]

Previous studies comparing ARDS in adults and children indicate different phenotypical disease-courses.[22] This child was on the transition of neonatal[23] to pediatric ARDS,[24] at 2.2 kg and 37 weeks corrected gestational age; however, following secondary lung deterioration all age-specific ARDS definitions were fulfilled. His treatment response interestingly mapped adult ARDS by improving with prone ventilation but only moderately with nitric oxide.

Use of corticosteroids

Large-scale systematic reviews have shown benefit in reducing post-extubation stridor and some reduction in reintubation rates especially in those with high-risk airways or airway abnormalties.[25-28] Early literature recommends against use of corticosteroids for treatment of

SARS-CoV2 infection, unless for other indications, due to concerns about blunting the inflammatory response to viral infection and previous studies of similar viral infections suggesting impaired viral clearance and increased mortality.[29-30] Due to the severity of glottic swelling seen at presentation and the extreme difficulty intubating the child, the highest risk was felt to be from airway swelling so corticosteroids were administered in preparation for extubation.

Given the adult phenotype severe pneumonitis with initial improvement then deterioration in SARS-CoV2 infection, it is unclear if this patient followed the adult pattern of delayed severe disease transition described by Gattinoni and colleagues,[31] or if administration of steroids altered his disease course.

Radiological findings

Ground glass opacification with a bilateral peripheral distribution is the most common finding in COVID-19, mainly based on CT experience in adults.[32] Other findings, such as septal thickening and bronchiectasis may appear later on with disease progression though pneumothorax is uncommon, but is described in later stages[32]. Similar but milder changes are described in children,[32] but CT scanning is reserved for specific indications (e.g. immunocompromised patients, atypical presentations).[33] Chest radiograph may be completely unremarkable in less severe cases. The parenchymal findings seen in our patient's radiographs are particularly prominent considering the age of the child, but consistent with the common description in literature of ground glass opacification and consolidation.

Cardiac involvement

In adults, a history of cardiovascular disease has been associated with higher morbidity and mortality from SARS-CoV2 infection, particularly in elderly patients.[34] 20-30% of patients with severe infection developed infection-related myocarditis and acute ischemic myocardial injury during ARDS, characterized by elevated troponin.[35] This patient's troponin was mildly elevated throughout illness, peaking at 138ng/L on day 10, however no clinical signs of myocarditis or cardiac failure were apparent. Echocaradiography during this admission showed no residual ASD. While there was some left to right shunting via a PFO, it was felt his cardiac anatomy did not play a role in the severity of his illness or his susceptibility to infection.

Remdesivir

Remdesivir (GS-5734) is a nucleotide analogue with broad-spectrum antiviral activity against several RNA viruses developed following emergence of Ebola by Gilead Sciences, Inc. It is as 1′-cyano-substituted adenosine nucleotide analogue prodrug. In animal models remdesivir has demonstrated *in vitro* and *in vivo* activity against other coronavirus strains (SARS-CoV1 and MERS-CoV) by inhibiting replication.[36] Prior to the COVID-19 pandemic it has been used in treatment of Ebola.[29,37] There is a report of an Ebola-infected neonate being treated with remdesivir and surviving.[38] In vitro studies of remdesivir have demonstrated effective SARS-CoV2 inhibition.[16] Early use in humans with SARS-CoV2 has been promising.[39] Currently there are two phase 3 trials investigating efficacy and safety of remdesivir in moderate COVID-19 in adults and children older than 12 years, weighing > 40kg (ClinicalTrials.gov Identifier: NCT04292730), and severe COVID-19 infection in adults (ClinicalTrials.gov Identifier:

NCT04257656). To date there are no published reports of children with COVID-19 treated with remdesivir. It is not possible in a single case report to determine the contribution of remdesivir to clinical recovery, however it is noteworthy that it was well tolerated.

Compassionate access

In view of this patient's disease severity, off-label remdesivir use was proposed. Our institution developed, and published,[40] a bespoke decision-making bioethics framework for such situations, involving children and their families.[41] The case was discussed at an urgent multidisciplinary team including: intensive care, infectious diseases, virology, pharmacy, bioethics team, and the parents. This process includes a mandatory second opinion from another institution. A successful compassionate access application was made for remdesivir.[42]

Conclusion

This case highlights a positive outcome for a critically unwell infant with severe SARS-CoV2 infection. The patient's illness was atypically severe and presentation with severe airway obstruction unusual, compared to other adult or pediatric cases. We describe the intensive care management and decision-making process to treat with remdesivir via compassionate access bioethics pathway. The infant tolerated remdesivir treatment without complication and was discharged home. This information provides urgent first data to inform treatment for children presenting with severe SARS-CoV2 disease as the pandemic affects children across the globe.

Acknowledgments

We thank the following colleagues for their input with the case study: Garth Dixon, Caroline Dalton, Kimberly Gilmore, Mark Gilchrist, Joe Standing, Louis Granjean, Delane Shingadia, Nele Alders, Karyn Moshal, Judith Breuer, the Members of the Great Ormond Street Hospital ethics committee, and Gilead Sciences for access to medication to treat the child.

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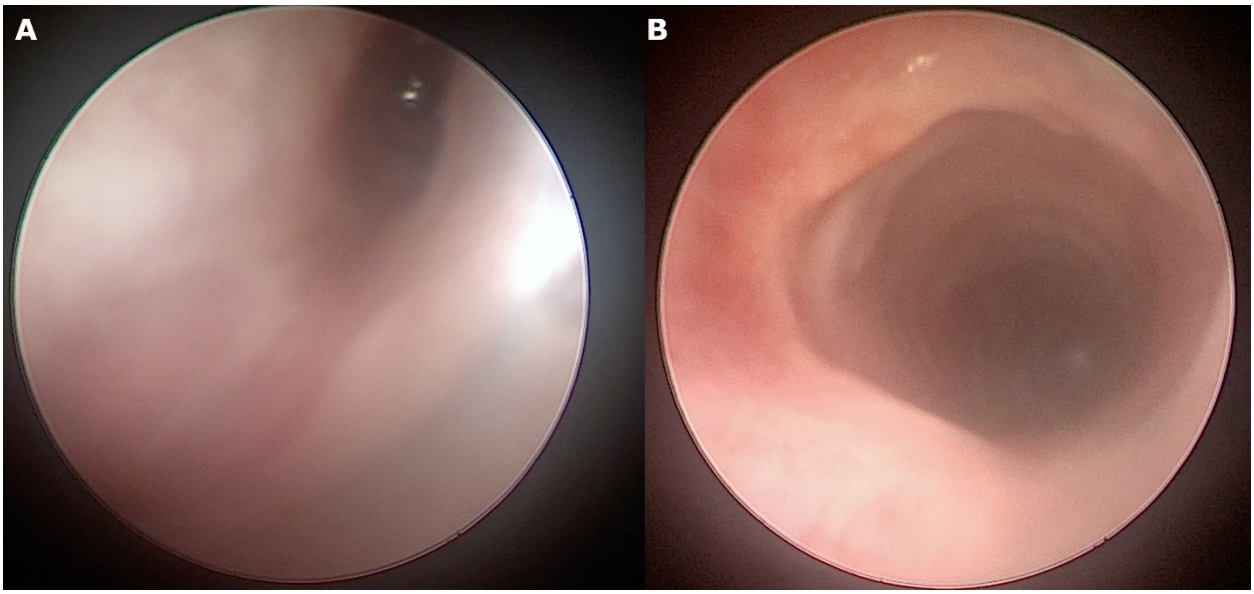

Figure 1: Operative photographs of airway swelling: (A) glottis with grossly swollen vocal folds, and (B) trachea with moderate inflammation and copious distal airway secretions

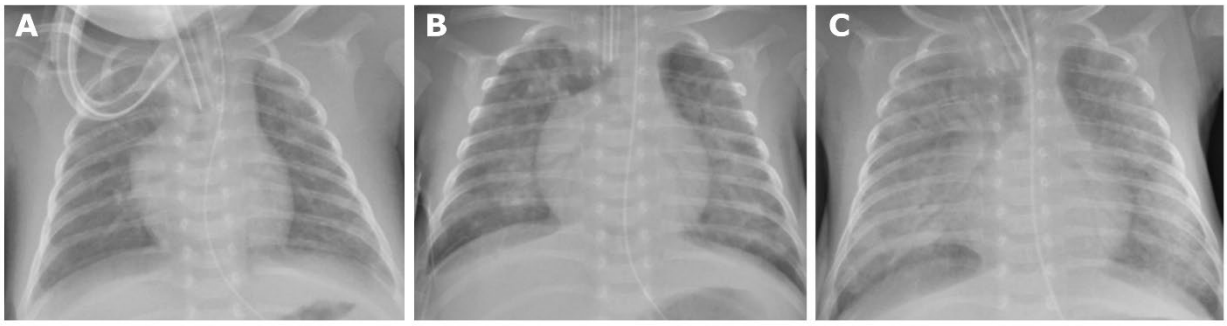

Figure 2: Chest radiographs performed Day 2 (A), 5 (B), and 6 (C). Initially, only mild bilateral ground glass opacities were present. Subsequent radiological worsening is noted with progressive airspace opacification (day 5), and bilateral consolidation with predominant peripheral distribution, lung over-inflation, and right basal pneumothorax (day 6).

	Reference range	Day 2	Day 7	Day 10	Day 12	Day 17	Day 20
SARS-CoV-2 RNA PCR	-	**RNA Detected**	**RNA Detected**	-	RNA not Detected	**RNA Detected**	RNA not Detected
Hb	90-140 g/L	123	100	**73**	92	**73**	100
WBC	6.0-18.0 x10*9/L	**5.63**	11.57	12.05	9.39	7.75	10.68
Neut	1.00-8.50 x10*9/L	4.66	5.99	5.62	4.39	2.53	3.97
Lymph	3.00-13.50 x10*9/L	**1.45**	3.58	5.17	3.45	3.96	5.86
Eos	0.10-0.30 x10*9/L	0.15	**0.04**	0.26	**0.45**	**0.64**	**0.07**
CRP	0-20 mg/L	**42**	-	**36**	**21**	**25**	12
Ferritin	4.2-62.0 ug/L	-	**511**	**568**	**383**	**414**	-
D-Dimer	0-312 ug/L	-	**-**	**1143**	**-**	**1054**	**-**
Troponin	< 34 ng/L	-	**44**	**138**	**54**	-	-
IFNg	pg/mL	-	<50	<50	-	-	-
TNFa	pg/mL	-	<50	<50	-	-	-
IL10	pg/mL	-	110	<50	-	-	-
IL6	pg/mL	-	<50	<50	-	-	-
IL4	pg/mL	-	<50	<50	-	-	-
IL2	pg/mL	-	<50	<50	-	-	-
Creatinine	14 - 34 umol/L	21	26	27	21	16	18
Urea	0.7-5.0 mmol/L	0.9	3.6	2.4	1.3	**<0.7**	**<0.7**
ALT	12 - 47 U/L	29	-	**53**	**53**	36	45
ALP	80-425 U/L	-	-	132	128	-	-
Alb	34 - 42 g/L	**27**	-	**22**	**20**	**<20**	**24**
Bili	<18 umol/L	8	3	6	5	6	<2

Figure 3: Patient results. Laboratory values including SARS-CoV2 RCT PCR results throughout admission. Remdesivir treatment was prescribed from Day 7-17.

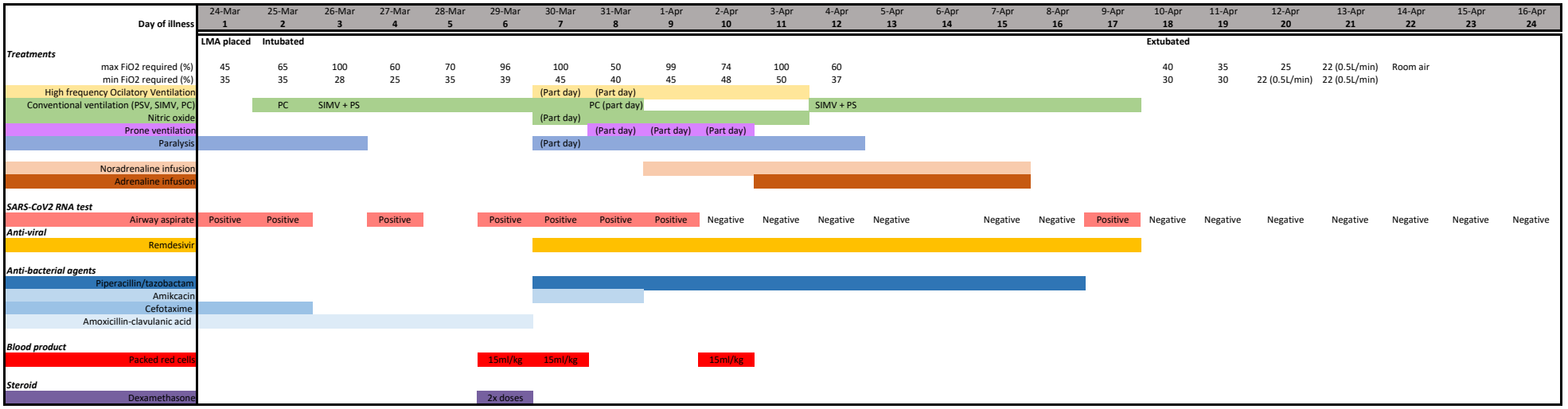

Figure 4: Events and treatments during patient admission. This figure depicts respiratory support requirements, treatment with anti-viral and anti-bacterial agents, and other significant medications.

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