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ISSUES & OPINIONS

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The care of patients with Duchenne, Becker, and other muscular dystrophies in the COVID-19 pandemic

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Abstract

The coronavirus disease 2019 (COVID-19) pandemic has resulted in the reorganization of health-care settings affecting clinical care delivery to patients with Duchenne and Becker muscular dystrophy (DBMD) as well as other inherited muscular dystrophies. The magnitude of the impact of this public health emergency on the care of patients with DBMD is unclear as they are suspected of having an increased risk for severe manifestations of COVID-19. In this article, the authors discuss their consensus recommendations pertaining to care of these patients during the pandemic. We address issues surrounding corticosteroid and exon-skipping treatments, cardiac medications, hydroxychloroquine use, emergency/respiratory care, rehabilitation management, and the conduct of clinical trials. We highlight the importance of collaborative

Abbreviations: COVID-19, coronavirus disease 2019; DBMD, Duchenne and Becker muscular dystrophy; DMD, Duchenne muscular dystrophy; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

treatment decisions between the patient, family, and health-care provider, considering any geographic or institution-specific policies and precautions for COVID-19. We advocate for continuing multidisciplinary care for these patients using telehealth.

KEYWORDS

BMD, consensus, COVID-19, DMD, muscular dystrophy, recommendations

Coronavirus disease 2019 (COVID-19) is a pandemic and public health emergency caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 symptoms include fever, cough, fatigue, shortness of breath, sore throat, headache, diarrhea, and reduced smell and taste sensations. Severe manifestations, including pneumonia, acute respiratory distress syndrome, cytokine storm, myocardial injury, and death, are more common in older patients and those with medical comorbidities.[1–5] The majority of children with COVID-19 in the United States who have required hospitalization had one or more underlying medical conditions, such as chronic lung disease, cardiovascular disease, and immunosuppression.[6] Management is supportive, as there is no specific antiviral treatment currently available. Social distancing is crucial to limit the spread of COVID-19,[6–8] which has necessitated a reorganization of health-care settings and clinical practice.[9]

Duchenne and Becker muscular dystrophies (DBMDs) are X-linked recessive progressive muscle disorders caused by mutations in the dystrophin gene.[10] There is concern that patients with DBMD may be at increased risk of developing multisystemic and severe complications of COVID-19 due to major comorbidities such as chronic immunosuppression from corticosteroids, respiratory insufficiency leading to poor airway clearance and the need for long-term ventilatory support, and cardiac dysfunction. Providing comprehensive multidisciplinary medical care, genetic testing for early diagnosis, proactive cardiac and respiratory care, and new therapeutic strategies, including targeted treatments such as gene-based dystrophin restoration medications used in conjunction with corticosteroids, are reshaping the natural history of DBMD.[11–13] Currently, there are no data on how the COVID-19 public health emergency and resulting changes in health-care delivery have impacted these patients. We assembled an expert panel of neuromuscular specialists to provide recommendations related to the care of patients with DBMD and other muscular dystrophies during this public health emergency. Expert leaders in DBMD from across the United States were identified and invited to convene for a panel discussion. The primary modes of communication were video/audio conferencing and email for a thorough point-by-point review to reach the consensus. Therefore, this report reflects the consensus opinion of the authors.

Patients with DBMD and their families should follow current national, state, and local guidelines as well as any additional recommendations for people at risk for serious illness from COVID-19.[14,15] Patients and family members should vigilantly practice social distancing, including avoiding public gatherings and public transport, limiting time in stores, and using remote technology platforms in place of in-person meetings and activities, such as use of telehealth for medical care if clinically appropriate.

DBMD patients should continue their current treatments, and specifically should not discontinue existing medications, unless approved by their treating neurologist or neuromuscular specialist. We recommend that patients continue their current corticosteroid treatment. However, should they become ill, they should notify their neurologist or neuromuscular specialist, as their dose (amount or frequency) may need to be adjusted to prevent adrenal insufficiency. Stress dose corticosteroids should be considered in settings of acute sickness or hospitalization.[16] Patients and families should be aware of the risk of adrenal crisis during illness or with sudden cessation of steroid use, and they should discuss this with their health-care providers. Appropriate dosing of stress dose corticosteroids has been described in previous studies.[12,16,17] Consultation with an endocrinologist is recommended when steroid changes are being made during hospitalization. Vomiting is a rare symptom of COVID-19, but patients who cannot tolerate their regular doses of corticosteroids should seek medical attention for clinical assessment and parenteral steroid administration; alternatively, a family member should be prepared to deliver hydrocortisone intramuscularly.

Exon-skipping agents, such as eteplirsen, golodirsen, and viltolarsen, are antisense oligonucleotides that restore expression of a shorter but functional dystrophin. These are given as intravenous infusions over 35 to 60 minutes, once a week. Patients who are receiving these exon-skipping agents are encouraged to continue their medications but should discuss with their neuromuscular specialist the risks vs benefits of continuing infusions during the pandemic. Home infusions should be considered as a potential measure to limit exposure to COVID-19. In the case of home infusions, or other home health care, it would be prudent to limit the number of visits to the necessary minimum, and ensure that providers wear appropriate personal protective equipment and are properly prescreened for symptoms of COVID-19.

Many patients with DBMD are prescribed angiotensin-converting enzyme inhibitors or angiotensin receptor blockers for prophylaxis or treatment of cardiomyopathy. There has been some concern surrounding the use of these drugs due to the interplay of the SARS-CoV-2 virus and angiotensin-converting enzyme 2, which is a coreceptor for the virus. The American Heart Association, the American College of Cardiology, and the Heart Failure Society of America recently issued a joint statement that individuals should continue to take these medications in light of the known benefits to the heart and the uncertain risks of COVID-19.[18]

We emphasize that treatment decisions should be individualized, and made jointly between the patient, family, and health-care provider, considering any geographic or institution specific policies and precautions for COVID-19. Patients should not be labeled as "terminal" and triaged for nontreatment simply on the basis of their disability and diagnosis.

Comprehensive standard of care for patients with DBMD and other muscular dystrophies includes periodic assessments to monitor pulmonary, cardiac, and bone health, as well as side effects from medications or treatments. These can include blood work, echocardiograms, cardiac MRIs, pulmonary function tests, X-rays, and dual-energy X-ray absorptiometry for measuring bone mineral density.[11–13] Surging COVID-19 rates are placing a tremendous burden on health-care systems, resulting in interruption of elective and/or nonemergent services and procedures. During this time, to enhance the safety of our patients, families, and medical staff, we recommend that standard practices be modified and individualized. Alternate options, such as home blood draws and home polysomnography, if clinically appropriate, should be considered to minimize exposure and risk. In some cases, delaying routine laboratory monitoring can be appropriate, but if management decisions necessitate acquisition of clinic-based laboratory studies, such as pulmonary function tests, these can be safely performed with appropriate personal protective equipment. We encourage continuation of comprehensive care using telemedicine, single-provider or multidisciplinary visits, for these patients.

If patients with DBMD develop symptoms of COVID-19, their primary care physician and neuromuscular specialist should be notified. Concerning symptoms include a persistent fever over 103 °F (39.4°C) that does not abate with antipyretics, a reduction in oxygen saturation, increased effort for breathing, and decreased urinary output. Should symptoms warrant assessment in an emergency department, patients/families are advised to bring their home ventilatory support, including ventilators, masks, and mechanical insufflation-exsufflation (cough assist) devices, with them and have their settings and respiratory treatment plans readily available. To prevent spread of infection, ventilation systems should be changed to a full face mask or cuffed tracheostomy with closed tubing systems containing in-line filters.[19,20] Cough assist treatments should not be withheld due to concern for aerosolized particles. We advocate safely continuing frequent and scheduled cough-assist treatments to enhance airway clearance with appropriate personal protective equipment for the caregivers or health-care personnel providing the treatment. Patient/families should remind the treating health-care providers that supplemental oxygenation without adequate ventilation in muscular dystrophy patients may exacerbate underlying chronic hypercapnia. Consultation with pulmonology and/or anesthesiology specialists can be of great value. If intubation is required, neuromuscular blockade should be avoided if possible, and depolarizing agents, such as succinylcholine, are contraindicated.

There has been widespread use of hydroxychloroquine for hospitalized COVID-19 patients. The efficacy of hydroxychloroquine against COVID-19 is unclear with some small uncontrolled studies suggesting benefit, and at least one controlled study showing no benefit.[21] There are potentially serious risks to skeletal and cardiac muscles. Hydroxychloroquine causes a vacuolar myopathy in a minority of patients[22,23] and has also been associated with life-threatening cardiac arrhythmias.[24] Due to the uncertain benefits, and the potential risks to skeletal and cardiac muscle, hydroxychloroquine is not recommended for patients with DBMD.

From a rehabilitation standpoint, the closures of schools and outpatient therapy facilities due to the COVID-19 pandemic has resulted in discontinuation of many therapy services. The clinical urgency of ongoing physical, occupational, and speech/language therapies should be evaluated on a case-by-case basis, and their suspension or continuation agreed upon by therapists, physicians, and patients. Tele-rehabilitation can be successfully implemented by therapy team members, but the ability to perform varies based on local regulatory and compliance requirements. We encourage families and caregivers to use home therapy regimens recommended by their therapy team, if time allows, understanding the impact of added burdens and responsibilities experienced by caregivers. Additional rehabilitation considerations include using intermittent bracing, such as resting ankle-foot orthoses/night splints or hand splints during planned daytime sedentary activities to help maintain a passive range of motion; increasing physical activity and ambulation in the home and neighborhood to prevent worsening contractures and disuse weakness; and therapeutic positioning, such as lying prone or standing with support to provide a passive stretch to the hip flexors, knee flexors, and ankle plantarflexors.[4,25,26] Orthotists and equipment specialists may have limited availability during a pandemic, which can limit necessary attention to bracing and equipment issues. The therapy team and physicians can work together to prioritize issues and recommend in-person vs video appointments or telephone calls with orthotists or equipment specialists.

Children with DBMD have a spectrum of neurobehavioral manifestations, including intellectual disability, learning disabilities, anxiety, attention deficit hyperactivity, and autistic features.[27,28] DBMD patients and their family members are at increased risk of depression and anxiety.[13] Mental health effects can be compounded during this pandemic due to multiple factors, such as interrupted routines, school closures, and anxiety and fear about the situation, as well as limited availability or lack of mental health services. We strongly recommend that psychological care and behavioral support continue via telehealth.

Numerous clinical trials investigating targeted treatments for DMD are currently in progress. The COVID-19 pandemic has impacted the conduct of clinical trials due to a variety of challenges such as quarantines, site closures, travel limitations, and interruptions in supply of investigational products.[29] These challenges affect adherence to protocol-specific procedures, protocol-mandated visits, and testing. Trial sponsors are actively pursuing alternate plans and telemedicine should be encouraged. Clinical trial sites have instituted policies pertaining to research conduct. We strongly recommend that considerations of participant and study staff safety remain the paramount concerns for any decisions regarding the need for in-person visits to the study site. Whenever possible, remote visits should

replace in-person visits without compromising the collection of essential safety data. Decisions around study visits should be made carefully after discussions involving patients, parents if applicable, investigator, study sponsor, and institutional review board. All discussions should be in keeping with institution- and sponsor-specific policies, good clinical practice guidelines, and precautions for COVID-19.

Many of the management recommendations just discussed may also be relevant for patients with other muscular dystrophies, such as some of the limb-girdle and congenital muscular dystrophies.

In conclusion, the COVID-19 pandemic presents tremendous challenges to the health-care community, and disease-specific recommendations are rapidly evolving. For patients with DBMD, we emphasize:

- Corticosteroids should be continued and stress dosing should be considered in the setting of illness and/or hospitalization.
- Exon-skipping medications can be continued after discussing the risks and benefits with the treating neuromuscular specialist.
- Angiotensin-converting enzyme inhibitors and/or angiotensin receptor blockers for prophylaxis or treatment of cardiomyopathy should be continued.
- Those with chronic respiratory insufficiency should be treated in collaboration with pulmonary and/or anesthesiology specialists and should not receive supplemental oxygen without ventilatory support.
- Hydroxychloroquine should not be prescribed.
- Standard-of-care assessments should be individualized and adjusted, balancing patient, caregiver, and staff safety with the need for actionable information affecting important management decisions.

We strongly recommend that health-care providers practice strict adherence to established policies pertaining to the COVID-19 response and work closely with local and institutional authorities to ensure timely and uninterrupted care for patients with DBMD.

ETHICAL PUBLICATION STATEMENT

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

CONFLICT OF INTEREST

A.V. has received support for serving on the advisory boards for Biogen, PTC Therapeutics, and AveXis; is an associate editor for neuromuscular disorders at Medlink Neurology; and serves as principal investigator and subinvestigator at Arkansas Children's Hospital for studies in DMD and spinal muscular atrophy. K.R.W. is a consultant for Sarepta, PTC, Santhera, and Dynacure; served on the data monitoring safety board for Fibrogen; and received research support from the National Institutes of Health, Sarepta, Roche, Pfizer, PTC, and Catabasis. S.A. is a consultant for Sarepta and Biogen, and has received research support from Sarepta, Roche, PTC, Biogen, and Scholar Rock. C.M.M. has received research support from and/or has served as either a paid consultant or as a paid member of scientific advisory boards for Sarepta Therapeutics, PTC Therapeutics, Santhera Pharmaceuticals, Astellas, Bristol-Myers Squibb, Catabasis, Capricor, Eli Lilly, Epirium Bio, FibroGen, Italfarmaco, Marathon Pharmaceuticals Pfizer, Prosensa, and Roche. K.D.M. serves as site principal investigator for the AveXis RESTORE registry for spinal muscular atrophy; received research funding from National Institutes of Health, the US Centers for Disease Control and Prevention, the Friedreich's Ataxia Research Alliance, and the Muscular Dystrophy Association; and was site principal investigator for studies involving Sarepta, Retrotope, Reata, PTC, Italfarmaco, Santhera, Catabasis, CSL Behring, and BMS. J.A.P. received compensation/research support from Biogen, AveXis, Genentech, Scholar Rock, Sarepta, and PTC. B.L.W. has received compensation/research support from Biomarin. K.E. serves as consultant to Ionis, Fulcrum, Acceleron, and Biogen, and participates on an advisory committee adult spinal muscular atrophy for Biogen. P.B.S. has served on ad hoc advisory boards for Genentech, Biogen, AveXis, PTC, and Sarepta; serves as a speaker for Alexion, Grifols, and Biogen; and has research funding from National Instutes of Health/National Institute of Neurological Disorders and Stroke, Biogen, AveXis, Audentes, Pfizer, PTC, Sarepta, Santhera, Roche, and Sanofi/Genzyme. R.J.B. is on the scientific advisory boards of Biogen and Sarepta, and has received research/grant support as principal investigator of studies from Acceleron, AveXis, Biogen, Capricor Catabasis, the National Institutes of Health/National Institute of Neurological Disorders and Stroke, Pfizer, PTC, and Sarepta. V.K.R. has received support for consultation with Avexis, Biogen, Sarepta, and PTC Therapeutics. E.C.S. has received research support and consulting fees from AveXis and Biogen. C.M.P. serves on the advisory boards and as consultant for Biogen, Sarepta, and AveXis; serves as a speaker for Biogen and AveXis; and has research support from AveXis, Astellas, Biogen, Catabasis, CSL Behring, PTC, Pfizer, Sarepta, and Scholar Rock. A.M.C. serves on advisory boards for Sarepta, AveXis, Roche, and Acceleron; serves on a data monitoring safety board for Catabasis; and has worked as a subinvestigator at Nationwide Children's Hospital for studies in DMD for Sarepta and in spinal muscular atrophy for AveXis. E.C. has received personal compensation for serving on advisory boards and/or as a consultant for AveXis, Biogen, Medscape, Pfizer, PTC Therapeutics, Sarepta, Ra Pharma, Wave, the Patient-Centered Outcomes Research Institute, and Strong Bridge Biopharma; has received personal compensation for serving on a speaker's bureau for Biogen and research and/or grant support from the US Centers for Disease Control and Prevention, Cure SMA, Muscular Dystrophy Association, National Institutes of Health, Parent Project Muscular Dystrophy, PTC, Santhera, Sarepta, Orphazyme, and the US Food and Drug Administration; and received royalties from Oxford University Press and compensation from Medlink for editorial duties.

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