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

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Abstract

The corona virus disease 2019 (COVID-19) pandemic has resulted in the reorganization of healthcare 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 paper, 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 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.

Key words: COVID19, muscular dystrophy, BMD, DMD, consensus, recommendations

Corona virus disease 2019 (COVID-19) is a pandemic and public health emergency caused by the SARS-CoV-2 virus. 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 co-morbidities[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 healthcare settings and clinical practice[9].

Duchenne and Becker muscular dystrophies (DBMD) are x-linked recessive progressive muscle disorders caused by mutations in the dystrophin gene[10]. There is a concern that patients with DBMD may be at an increased risk of developing multi-systemic 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 chronic 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 USA were identified and invited to convene for the panel. The primary modes of communication were video/audio conferencing and email for a thorough point-by-point review to reach the consensus. This report, therefore, 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, including the 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

discuss this with their health care providers. Appropriate dosing of stress dose corticosteroids has been published[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 the medications but should discuss with their neuromuscular specialist the risks versus 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 pre-screened 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 co-receptor 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 non-treatment 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 healthcare systems, resulting in interruption of elective and/or non-emergent 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 multi-disciplinary 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 degrees Fahrenheit (39.4 degrees Celsius) that does not abate with antipyretics, a reduction in oxygen saturation, increased work of breathing, and decreased urinary output. Should symptoms warrant assessment in an emergency department, patients/families are advised to bring their home ventilatory support including ventilator, masks, and mechanical insufflation-exsufflation (cough assist) device with them and have their settings and respiratory treatment plans handy. To prevent spread of infection, ventilation systems should be changed to a full facemask 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 healthcare personnel providing the treatment. Patient/families should remind the treating healthcare 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 out-patient 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 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 plantar flexors[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 versus 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, anxiety and fear about the situation as well as limited availability or lack of mental health services. We highly 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 discussed above 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 healthcare community, and disease-specific recommendations are rapidly evolving. We emphasize that for patients with DBMD:

- 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 healthcare 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.

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Abbreviations

COVID-19 Corona virus disease 2019

DBMD Duchene and Becker muscular dystrophy

DMD Duchenne muscular dystrophy

MRI Magnetic resonance imaging