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RESEARCH ARTICLE

Tele-Rehabilitation for Boys with Duchenne Muscular Dystrophy in India Amidst the COVID-19 Pandemic: An Implementation Study

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Abstract
Purpose: Duchenne muscular dystrophy (DMD) is X-linked progressive neuromuscular disorder of childhood onset which leads to loss of ambulation, followed by respiratory and cardiac muscle weakness. Physiotherapy is integral to the multidisciplinary care plan for boys with DMD. During the COVID-19 pandemic, Tele-medicine was increasingly used to provide healthcare to patients. The study aimed to assess the efficacy and feasibility of Tele-rehabilitation among ambulatory boys with DMD. Materials and Methods: Ambulatory boys aged 5 to 12 years with DMD were recruited using purposive sampling. The Tele-rehabilitation program was designed by a neuromuscular team and provided by a physiotherapist through telephonic video calls twice a month for three months. A compliance diary was provided to fill out at home after each session. The outcome was measured with a change in Medical Research Council (MRC) sum score and gower's times at 12 weeks using paired t- test. Results: 92 boys with DMD were enrolled and 66 (71%) boys completed the program and had follow-up at 12 weeks. The baseline MRC sum score was 38.2±3.7, and the gower's time was 9.2±6.7 seconds. At 12 weeks MRC sum score was 38.8±4.2, and gower's time was 8.59±7.7 seconds (p-value- 0.03 and p-value- 0.001), respectively. The Vigno's and Brook's scores didn't show a significant change. Compliance of >50% to the Tele-rehabilitation exercise programs was present in 89% of subjects. Conclusion: A short-term Tele-rehabilitation program was feasible with a high compliance rate and efficacious in motor strengthening among boys with DMD.

Keywords
DMD, Tele-rehabilitation, Exercise Program, Compliance, COVID-19

INTRODUCTION

Duchenne muscular dystrophy (DMD) is the most common and X- linked neuromuscular disease, affecting approximately 1 in 3500 male births (Crisafulli et al.2020). This disorder is caused by a mutation in the dystrophin gene on chromosome xp21, leading to formation of dysfunction dystrophin protein, which leads to progressive muscle weakness (Birnkrant et al. 2018). Onset of symptoms typically occurs between 3-5 years of age with delayed walking. In the early stages of

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the disease, there is selective involvement of the pelvic girdles muscles followed by shoulder musculatures (**Giliberto et al. 2014**).

Boys with DMD in their second decade of life became wheel chair bound, and subsequently become dependent for Activities of daily living (**Birnkrant et al 2018**). Lack of mobility; loss of ability to use upper limbs; respiratory muscle weakness, bone weakness, scoliosis, cardiomyopathy and gastrointestinal disturbances are progressive complications of the disease (**Wasilewska et al. 2020**). The cardio-respiratory failure causes death in the second decade of their life.

Despite medical advances, DMD cannot be cured, however, appropriate therapies and multidisciplinary care can improve the quality of life and extend the life expectancy of affected boys to more than 30 years of age (**Passamano et al. 2012**). Multidisciplinary care components includes physiotherapy, orthotics, respiratory support, cardio protective, bone and spine health care and steroids etc. The use of corticosteroids have proven to be effective in reducing the progression of disease and helps in maintaining the mobility of the affected patient. It also delays onset of the respiratory and cardiac complications and reduces the possibility of kyphoscoliosis (**Balaban et al. 2005**)

Physiotherapy is a key component of rehabilitation as it includes stretching of tight muscles structures and postural alignment. The exercises also targets weak muscle structures by mild to moderate strengthening program to improve the muscle strength and endurance (**Hammer et al. 2022**). Thus exercise therapy is an important and integral part of rehabilitation as it maintains overall health, prevent disuse atrophy and improves quality of life.

Tele-rehabilitation is an extended way of rehabilitation that provides specialized treatment far off from hospital settings through remote consultation to patients using telecommunication technology at home or in the community (**Sobierajska-Rek et al. 2020**). Also, providing health care in the home setting could facilitate adherence, improve self-reliability, and adapts to real life domains (**Appleby E et al. 2019**). The biggest advantages of Tele-rehabilitation is that it is efficient and has a potential to deliver therapies in comparison to conventional ways of management especially to neuromuscular patients having ambulation issues, distance obstacles and pandemic barriers (**Akulwar-Tajane and Bhatt 2021**).

In India Tele-rehabilitation is increasingly used to provide care at home during the COVID 19 pandemic. It helped to reduce the risk of exposure to virus and provide quintessential care during the peak phase of pandemic. In addition, Tele-rehabilitation reduced the expenses that are related with receiving care for patients living in rural areas, travel related cost and can provide care to non-ambulatory patients. (**D'Souza and Rebello 2021**). However, there is lack of studies evaluating efficacy and feasibility of Tele-rehabilitation in patients with DMD. We planned this study with the objective to assess the effectiveness and feasibility of Tele-rehabilitation in improving the motor and functional scores of boys with DMD. Additionally, we aim to evaluate the compliance of the participants with the program.

MATERIALS AND METHODS

This pre and post experimental study, conducted between April 2022 to November 2022. Purposive sampling was used to identify the participants for the study, which included ambulatory boy with clinical and genetic diagnosis of DMD between the ages of 5 to 10 years enrolled in a tertiary care hospital's outpatient clinic. The Institute Ethics Committee approved the study protocol (INT/IEC/2022/Study-213). Prior to the inclusion of the children in the study, informed consent from parents and assent from the children was obtained.

Regarding vulnerable groups, the authors took into account the needs and priorities of the groups/individuals in which the study was conducted, in accordance with Articles 19 and 20 of the WMA Declaration of Helsinki, and the situation that the study could not be carried out outside these groups and individuals was taken into account. "In this study, additional precautions were taken by the researcher(s) to protect the volunteers."

Basic Clinical And Demographic Characteristics

Ambulatory boys, having typical signs and symptoms suggesting DMD confirmed with genetic testing or muscle biopsy, free from respiratory tract infections having basic knowledge of attending video call and sending email were included in the study. Baseline evaluation

including Medical Research Council(MRC) sum score, gower's time, Brook's and Vigno's upper and lower limb scores, was performed by physiotherapist and recorded on a case record form.MRC sum score is the most widely used tool for measuring muscle strength having grade 0 to 5 where 0 is "No contraction" to 5 is "Normal power"(**Florence et al.1992**) Gower's time is the time taken to get up from supine position to standing position is a timed function test and is widely used for evaluation of functional performance in clinical trials (**Angelini and Peterle 2012**).

The Vigno's functional scale explained by **Brooke in 1981** grades the severity of lower limbs from grade 1(walks and climbs without assistance) to10 (confined to bed). While the Brooke functional scale grades the severity of the involvement of upper scale from 1 (starting with the arms at the sides, the patient can abduct the arms in a full circle until they touch above the head) to7 (cannot raise hands to mouth and has no useful function of hands). Both functional scales have proven to have good inter and intra rater reliability and are widely used (**Brooke et al 1981**).

A physiotherapy training program was prepared in accordance with DMD care considerations 2018 with thorough discussion among co- authors (**Birnkrant, et al 2018**). Patients and their caregivers were asked to attend a video call demonstrating the exercise program for 30 minutes. Parents were advised to perform muscle stretching and strengthening exercises5times/week for 12 weeks. Exercises were demonstrated and reinforced through a video call after every 2 weeks interval by physiotherapist. Exercise program included six sets of exercises: mild to moderate self-strengthening exercises of target muscle groups: shoulder flexors and abductors, elbow extensors, hip flexors, extensors and abductors, knee flexors and extensors and abdominals (**Lott et al. 2021**). Self stretching of elbow flexors, forearm pronators, wrist and finger flexors; hip flexors, hamstring and plantar flexors. Respiratory exercises included: positive inspiratory pressure and positive expiratory pressure (**Sobierajska-Rek et al. 2021**). After 12 weeks of home physiotherapy program, a physical assessment by same physiotherapist was performed in the clinic. The outcome measures included upper and lower limb functional scores, MRC sum score, gower's time on patients who have completed 12 weeks training program sessions.

Statistical analysis

Data was recorded on a case record form, entered in Microsoft excel program and was analyzed. Statistical Package for the Social Sciences (SPSS version 26.0 Armonk, NY: IBM Corp) was used to analyze the data. Descriptive statistics were presented with mean, standard deviation, and percentages to record baseline demographics and clinical characteristics. To verify the normality of data we have followed two method by graph, the normal bell shaped curve and Kolmogorov-Smirnov test. The Brook's, Vigno's, MRC sum score and Gower's time had skewed distribution according to the Kolmogorov-Smirnov test and Shapiro wilk test. The MRC sum

score and Gower's time were compared using paired t-test. Brookes and Vignos can be presented as mean (SD) if the distribution is normal, but if distribution is skewed median and IQR is the better way to present. Hence for pre post analysis for two related groups, for skewed data Wilcoxson sign rank test is used. Hence Brookes and Vignos were compared using Wilcoxson sign rank test. p value of <0.05 was considered significant.

RESULTS

During the study periods a total of 92 boys with DMD, were recruited into the study and evaluated. The demographic characteristics are presented in the "Table 1". Mean (SD) age of the boys with DMD at enrolment was7.4±1.6 years. Median (IQR) Vigno's lower limb score was 2 (2,2), Brook's upper limb score was 1 (1,2). Mean (SD) MRC sum score was 38.2±3.7 and gower's time was 9.2±6.8 (mean, SD) sec. All 92 children were given telephonic instruction to perform home physiotherapy and fill the compliance diary. Fourteen children (15%) did not respond after few video calls and 12 children (13%) did not come for a follow up visit after 12 weeks.

Post12-week Tele-rehabilitation program (n=66) mean (SD) Brook's score was 1.33±0.51 with mean difference of 0.015 and p value 0.32, Vigno's score was 2.12±0.48(mean, SD) with mean difference of 0.030 and p value 0.15. Post 12-week rehabilitation mean(SD) MRC sum score was 38.77±4.22 with a mean difference of -0.18 and p value 0.03. Post rehabilitation mean (SD)

gower's time was 8.5±7.74second with mean (Table 2). The MRC sum score and Gower's time showed significant improvement ($p< 0.033$ and $p< 0.012$) respectively while there was no significant difference noted between Vigno's and Brook's scores ($p<0.32$ and $p< 0.15$) respectively as shown in "table 2".Patient compliance was measured by using an arbitrary scoring method used by (Malagoni et al. 2011), for evaluating patient's compliance of exercise based rehabilitation for difference of 0.56 second with a p value of 0.012 patients with intermittent claudication, 4 (highest compliance) to 1 (lowest compliance) based on percentage of physiotherapy attempted. A score of 4 was recorded for 13 patients (19.69%); a score of 3 was given to 20 patients (30.30%); a score of 2 was given to 26 patients (39.39%) and score of 1 was given to 7 patients (10.60%) shown in "table 3".

Table 1. Basic clinical and demographic charcteristic of participants (Duchenne muscular dystrophy)

No. of Subjects	N=92 X±SD	Z score
Age, years	7.38±1.62	
Height, cm	117.23±10.69	-1.34±1.68
Weight, Kg	19.38±5.23	-1.59±1.07
Vigno's lower limb score	2.13±0.39	
Brook's upper limb score	1.32±0.49	
MRC sum score	38.25±3.72	
Gower's time, sec	9.17±6.74	

Table 2. The pre and post Tele-rehabilitation outcome measures of boys with DMD at 12 weeks interval

Outcome measures n=66	Pre-intervention X± SD	Post-intervention X±SD	Mean difference	P value*
MRC sum score	38.55±4.2	38.77±4.2	-0.18±0.7	0.03
Gower's time(sec)	9.2±7.6	8.59±7.7	0.56±1.8	0.001
Brooks UL score	1.37±0.51	1.35±0.50	0.02±0.1	0.32
Vigno's LL score	2.15±0.43	2.12±0.48	0.03±0.2	0.16

Table 3.Patient compliance for the home-based Tele-rehabilitation

Compliance Score	No of patients	Percentage	Exercise session performed
4	13	19.7%	<90%
3	20	30.3%	80-90%
2	26	39.4%	50-70%
1	7	10.6%	<50%

DISCUSSION

This pre post experimental study on implementation of Tele-rehabilitation for 12 weeks under supervision of physiotherapist for boys with DMD was feasible with good compliance rate. The efficacy assessed with Vigno's and Brook's score, MRC sum score and Gower's time showed improvement in muscle strength with increase in MRC sum score and reduction in Gower's time over 12 weeks period. Though Vigno's and Brook's score didn't change over 12 weeks period. Tele-rehabilitation can be considered a reliable and promising approach for rehabilitation for children with neuromuscular disorder. Due to the mobility related barriers for boys with DMD, Tele-rehabilitation can deliver equally efficient results comparable to other treatment approaches.

We provided Tele-rehabilitation through video calls with instructions given by trained physiotherapist to parents and boys with DMD for 12 weeks period. In comparisons to other studies that require specialized software to implement rehab in patient's devices, our intervention requires only internet connection with a basic application in the patient's devices that they usually have, allowing its accessibility from remote locations. This is in contrast with several

other studies requiring complex technological platform, and software installation (**Moffet et al.2015**). Ease in administration of the physiotherapy programs allows high compliance and makes it easily applicable to other disease and settings.

One of the most important aspects of DMD is progressive deterioration of muscle strength and thus in functional performance of affected individual. The decline in muscle strength is not linear in boys with DMD, a precipitous decline is observed by the age of 8-10 years manifesting with difficulty in rising from floor of increase in gower's time, and difficulty in walking and subsequently loss of ambulation. Weakness in the pelvic girdle is followed by para-spinal muscles and upper limb weakness, manifesting as difficulty in sitting and postural maintenance, scoliosis, and difficulty in using upper limb for daily living activities. A twelve week rehabilitation program led to a milder improvement in muscle power measured with MRC sum score in response to the exercises and muscular training in antigravity positions such as straight leg raise and dynamic knee extension in supine and sitting positions respectively; similar findings have been reported by Abramson and Rogoff, and Vigno's and Watkins where strengthening exercises have shown improvements in MRC (**Jansen et al.2013; Huijgen e al.2008**). However, active and resisted exercises have been used for the authors in previous studies, whereas our study primarily focuses on active and active assisted exercises which is supported by our findings that MRC improvements are limited to patients with less diseases severity and least severity affected muscle groups (**Cramer et al. 2021; Pastora-Bernal et al. 2021**).

An improvement in Gower's time was observed by active, flexibility and stretching exercises. Similarly in a study by Lutfiye Akkurt et al reported that flexibility exercises of lower limb muscles are correlated with improvements in timed performance test (Gower's test) (**Akkurt et al.2019**). Similarly another study by Alemdaroglu et al found upper extremity exercises by arm ergo meter has improved the timed performance or Gower's test (**Alemdaroğlu et al.2015**).

In this study functional performances measured by the Brook's and Vigno's scales didn't show significant change over 12 weeks. These functional scores strongly correlate with muscle strength (**Lue et al.1992**) since we have found improvements in strength with subjects involving less disease severity and in fewer muscle groups. The baseline vigno's score was 2 and brooks score was 1, suggesting a mild disease severity. There is requirement of considerable muscle strength gain for improvement in vigno's score from 2 to one, which is unlikely in a progressive muscular dystrophy. During the rehabilitation period we have not seen any decline in their functional scales which may be supported by the fact that exercises delay the deterioration in the functional performance as consistent with the findings of Jensen et al in a randomized controlled trial (RCT) that maintaining in the functional performances of the boys with DMD while performing exercise training period in the form of active bicycle exercise program (**Jansen et al 2013**).

Tele-rehabilitation is employed in various other conditions during the COVID 19 pandemic and reported that it is acceptable to patients. In a RCT, Barbara et al studying the feasibility of Tele-rehabilitation reported that it is effective as well as feasible; as it provides satisfaction to the patient by delivering specialized services at their home with ease (**Huijgen et al.2008**). Steven et al studied Tele-rehabilitation in patients with stroke and found it feasible and is a holistic way to provide rehabilitation services (**Cramer et al.2021**). In a similar study Jose-Manual et al reported efficacy of Tele-rehabilitation on low risk cardiac patients and found it is a cost effective and reliable way of providing quality care (**Pastora-Bernal et al.2021**). In a pilot study Chen et al reported chronic stroke patients were highly compliant to the Tele-rehabilitation program and was equally efficacious in comparison to conventional way of providing rehabilitation (**Chen et al. 2021**). Several other studies on Tele-rehabilitation among children with chronic disorders have also documented its potency and feasibility for delivering equally productive care especially to medically fragile children or having any movement constraints (**Tanner et al. 2020; Schlichting et al. 2022**).

Selection of young ambulatory boys with DMD in current study was a potential limitation, since boys with DMD faces mobility constraints with progression of disease when they are wheelchair bound and become non-ambulatory. However, during the pandemic rehabilitation of all chronic neuromuscular disorder was compromised.

Further study targeting rehabilitation of non-ambulatory boys with DMD can be done to understand the acceptability and compliance in advance disease.

In conclusion, our study demonstrated that Tele-rehabilitation is acceptable for dealing motor impairments among boys with DMD from North India. Patients and boys with DMD have high compliance rate to the programs and the efficacy was demonstrated by improvements in MRC sum score and reduction in Gower's time over 12 weeks period. There is a need to conduct larger studies with longer follow up period to understand the efficacy of exercises through Tele-rehabilitation as a substitute of traditional rehabilitation therapies.

Conflict of Interest:

There is no personal or financial conflict of interest within the scope of the study.

Information on Ethics Committee Permission

The Institute Ethics Committee approved the study protocol (INT/IEC/2022/Study-213). Prior to the inclusion of the children in the study, informed consent from parents and assent from the children was obtained.

Author Contributions:

Study conception and design: PG, SB, APS, RS; Data Collection: PG, APS, SB, SSB; Analysis and Interpretation of results: RN, RS, SB, PG; Draft manuscript preparation: PG, APS, SB, SS; All authors reviewed the results and approved the final version of the manuscript.

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