Evaluate the efficacy of an ayurveda treatment regimen on muscular dystrophies – clinical case studies

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Abstract

Duchenne Muscular Dystrophy (DMD) is a severe degenerative, inherited disorder of skeletal and cardiac muscles that affects 1 in 3500 male births. Becker Muscular Dystrophy (BMD) is also an inherited disease with a male distribution pattern and a clinical picture similar to that of DMD. Almost 20 years have passed since the discovery of the gene. Unfortunately, an effective therapy that could mitigate the dystrophic process has not proved. Objective of these case studies was to evaluate the efficacy of an Ayurveda treatment regimen on DMD/ BMD patients. 4 patients were taken for the trial using inconveniant sampling method from the Paediatric Clinic of the Ayurveda Teaching Hospital, Colombo. Treatment period was 45 days. Outcome measures were calf muscle circumference, regularity of falls (per week), time taken for 10 m. walk, Gower's maneuver, climb 4 stairs, rise from chairs, put on a shirt, and Creatine Phosphokinase (CPK) level. They were recorded in a case report forms. These measurements were obtained before starting the treatment and after finishing the treatment regimen. Maximum relief was observed in the signs and symptoms of circumference of calf muscle, frequency of fall (per week), time to climb 4 stairs, time to put on a shirt, CPK level and time to 10 m walk. Time to Gower's maneuver and time to rise from chairs have not revealed the significant p value. Therefore, this study suggests the special Ayurveda treatment regimen can be established as an effective therapy in certain extends for the management of DMD/BMD affected children.

Key words: Duchenne Muscular Dystrophy, Becker Muscular Dystrophy, Mansagatavata.

Introduction

Duchenne Muscular Dystrophy (DMD) is a severe degenerative, inherited disorder of skeletal and cardiac muscles that affects 1 in 3500 male births [1]. DMD patients characteristically display progressive muscle weakness, which begins in early childhood [2]. Although DMD is present at birth, clinical symptoms are not evident until 3-5 years of age [3]. Initial symptoms include leg weakness, lordosis and a waddling gait [3]. Progressive wasting of muscle, reduces muscle power, leads to DMD patients wheelchair bound by the age of 11 or 12 [4]. Respiratory, orthopedic, and cardiac complications emerge, and without intervention, the mean age at death is around 19 years. Non-progressive cognitive dysfunction might also be present [5].

Becker Muscular Dystrophy (BMD) is also an inherited disease with a male distribution pattern and a clinical picture similar to that of Duchenne Muscular Dystrophy. BMD is generally milder than DMD, and the onset of symptoms usually occurs later. The estimated incidence of BMD is 1 individual per 30,000 male births [6]. Almost 20 years have passed since the discovery of the gene. An effective therapy that could mitigate the dystrophic process has not been proved yet. Although numerous methods are currently being explored, there are many drawbacks. In ayurveda system of medicine, among the broad classification of diseases, there is a category known as "*Adhibala Pravurtha*" (Hereditary disorders) diseases. There is no identifiable reference to disease called muscular dystrophy in the Ayurvedic classics. According to the symptoms and signs, "*Mamsagatavata*" can be co-related to certain extent with the muscular dystrophies such as DMD and BMD

In Sri Lanka, during last decade an ayurveda treatment regimen was used to manage the signs and symptoms of DMD/ BMD patients. This treatment regimen was formulated, considering the phamacodynamic properties of medicinal plants, but scientific study has not been reported on this treatment regimen yet. Therefore, the objective of this study was to evaluate the efficacy of the ayurveda treatment regimen on DMD/BMD patients.

Materials and Methods

Patients were diagnosed clinically based on physical examination consisting progressive muscle weakness, muscle strength, calf hypertrophy, positive Gower's sign and reflexes.

Confirmed clinical cases of DMD/BMD and subjects able to sit independently for at least 3 minutes without support and age 3 to 10 years at the time of enrollment

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were included for the clinical trial. Prior to the enrollment, consents was obtained from the parents.

Children were excluded if they were non-ambulatory and /or with other systemic disorders i.e. asthma, cardiac vascular disorders, orthopedic problems and marked cognitive deficits.

Three dystrophic DMD children and one BMD child were selected from the Pediatric Clinic of the Out Patient Department in Ayurveda Teaching Hospital, Colombo, Sri Lanka. Selected participants were admitted to the hospital for indoor treatment consisting 45 days.

Ayurveda treatment regimen and methods of administration of drugs

In first two weeks selected participants were treated internally with 60 mL of *Etamadeduru* decoction [7], *Mahadalu Anupana* [8] 30 mL with 250 mg of *Chandra kalka* [9] twice a day. Participants were applied externally (*Taila Abyanga*) with *Aswaganda* oil [10] on upper limbs and lower limbs in the morning and *Madhu Thakra Abyanga* (two parts of Bee honey mixed with one part of *Thakra*) on the calves in the afternoon.

During the period of third week, the participants were given *Dasamul, Bebila, Amukkara* decoction* (60 mL), one *Yogaraja Vati* [11] and ¼ teaspoon (1.25g.) *Aswaganda* and *Shatawari* powder* with bee honey twice a day. The participants were externally treated with *Pizhichil* (*Kaya sheka*) [11]. *Pizhichil* (*Kaya sheka*) is a procedure where the whole body of patient is oileated and massaged with luke warm *Aswaganda* oil [10] in the morning and then applied *Thilade Lepa* [12] over the calves in the afternoon.

During the period of fourth week, internally 60 mL of *Dasamul, Bebila, Amukkara* milk decoction* along with one *Yogaraja Vati* [13] and ¼ tea spoon of *Aswaganda* and *Shatawari** powder with Bee honey were given twice a day. Externally treated with *Shastikashale Pinda Sweda* [14] in the morning and *Thilade Lepa* [12] in the afternoon.

During the period of fifth week, internally treated with 60 ml of *Danthimoolade* decoction [15] and ¼ tea spoons of *Aswaganda* and *Bintal* powder* with Bee honey twice a day.

Externally patients were treated with *Mamsa pinda sweda* [14] in the morning and applied *Amukkaradhe Lepa** over the calf muscle in the afternoon.

After the fifth week, patients were treated three days with ½ tea spoon *Darthri* powder [16] at night, which has mild purgative action.

During the last 7 days of the treatment regimen, internally used *Mashabalade* decoction [17] and ¼ tea spoons of *Aswaganda* and *Bintal* powder* with Bee honey each twice a day. The participants were administered *Vasti* treatment (Enema) [18, 19] using 30 mL. of *Narayana* oil [20]. They were applied *Amukkaradhe Lepa** over the calf muscle in the afternoon.

* Drug combinations were formulated, considering the phamacodynamic properties of medicinal plants by experience. **Refer-Appendix**

Assessment criteria

The assessment criteria were based on physical activities, signs and symptoms and measurements of the muscle circumferences of the participants. Before starting the treatment the participants were assessed by using the assessment criteria of calf muscle circumference, regularity of falls (per week), time to 10 m walk, time to Gower's maneuver, time to climb 4 stairs, time to rise from chairs, time to put on a shirt, and CPK level. After completion of the treatment, same criteria were assessed (Table.1 and 2).

Table 1: Analysis of the signs and symptoms of DMD/BMD after 45 days treatment

Serial No	*Age (Years)*	*Type of muscle dystrophy*	*Gower's sign*		*Circumference of calf muscles*				*Fall regularly (per week)*	
					Left		*Right*			
			*BT**	*AT***	*BT (cm)*	*AT (cm)*	*BT (cm)*	*AT (cm)*	*BT*	*AT*
1.	6	DMD	Positive	Positive	24	24	24	23.5	6 times	2 times
2.	3	DMD	Positive	Positive	22	21	23	22.5	-	-
3.	8	BMD	Positive	Positive	27	26	26.5	26	4 times	2 times
4.	5	DMD	Positive	Positive	23	22.5	23	22.3	5 times	2 times

Table 2: Analysis of the signs and symptoms of DMD/BMD after 45 days treatment

Serial No.	*Time to 10 m walk*		*Time to Gower's maneuvre*		*Time to climb 4 stairs*		*Time to rise from chairs*		*Time to put on a shirt*		*CPK level (IU)*	
	*BT**	*AT***	*BT*	*AT*	*BT*	*AT*	*BT*	*AT*	*BT*	*AT*	*BT*	*AT*
1.	11s	8s	12s	6s	10s	6s	7s	4s	30s	25s	13540	7850
2.	12s	10s	6s	6s	7s	6s	3s	2s	40s	34s	17670	2343
3.	10s	8s	5s	3s	11s	9s	3s	3s	17s	10s	13540	7850
4.	8s	7s	6s	6s	9s	7s	4s	3s	20s	19s	15210	10334

*Before Treatment **After treatment

Table 3: Statistical analysis of the signs and symptoms

Sign / symptoms	*P value*
Circumference of calf muscle	0.0008044 **
Fall regularly (per week)	0.0503640 *
Time for climb 4 stairs	0.018693*
Time to put on a shirt	0.0182231*
CPK level	0.025085519*
Time to 10 m walk.	0.008138*
Time to Gower's maneuver	0.126107746
Time to rise from chairs	0.070561

P values are significant at $p < 0.05$

Moderately significant* Strongly significant **

Statistical method

Paired- *t* test was used to compare the pre treatment criteria and the post treatment criteria. Findings of $p < 0.05$ were considered to indicate the statistical significance.

Results and Discussion

Trial for DMD an BMD has been done using 4 patients. Recording measurements such as calf muscle circumference, frequency of falls (per week), stiffness of calf muscle, time to 10 m walk, time to Gower's maneuver, time to climb 4 stairs, time to rise from chairs, time to put on a shirt, and CPK level have been used to evaluate the efficacy of the treatment regimen of the pre treatment and post treatment (first round). Paired *t*-test was used to analyze the data.

Sample size of this case study is not sufficient for the above mentioned method of statistical analysis. Since the findings of this study were very encouraging, paired *t*-test was used to analyze the data. Further studies with adequate sample size will be designed.

Out of 4 patients, 3were DMDs and one patient was BMD. Progress levels of the group revealed significant p value ($p < 0.05$) with circumference of calf muscle ($p= 0.0008044$), fall regularly per week ($p= 0.0503640$), time to climb 4 stairs ($p = 0.018693$), time to put on a shirt ($p= 0.0182231$), CPK level (p value = 0.025085519) and time to 10 m walk ($p = 0.008138$). Time to Gower's maneuver ($p= 0.126107746$) and time to rise from chairs ($p = 0.070561$) have not revealed the significant p value.

Maximum relief was observed in the signs and symptoms of circumference of calf muscle, frequency of fall per week, time to climb 4 stairs, time to put on a shirt, CPK level and Time to 10 m walk. Time to Gower's maneuver and time to rise from chairs have not revealed the significant p value. Circumference of calf muscle has shown strongly significant p value. However four of them have remained the sign of Gower's maneuver after the treatment.

Conclusion

Based on the results of these case studies, Ayurveda treatment regimen has the capacity to control some signs and symptoms of BMD/DMD in children. There were some limitations within this study. As these were individual case studies, there were no blinding and controlling. Therefore, it is suggested to conduct Randomized Control Clinical Trial using more children with BMD/DMD.