Ankle-foot orthosis in patients with Duchenne muscular dystrophy: a retrospective study

Órtese tornozelo-pé em pacientes com distrofia muscular de Duchenne: um estudo retrospectivo

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Abstract

Introduction: Duchenne muscular dystrophy (DMD) is a recessive genetic disease linked to the X chromosome, leading to progressive muscle tissue loss. Initially, there is difficulty getting up from the floor and an increased frequency of falls. Maintaining ambulation as long as possible is essential, and the use of ankle-foot orthosis (AFO) has been investigated as an ally in this process. **Objective:** To verify the prescription and use of an AFO for ambulant boys with DMD. **Methods:** Information was collected using the medical records of 181 patients with DMD from the Neuropediatric Service of the Instituto de Puericultura e Pediatria Martagão Gesteira of the Universidade Federal do Rio de Janeiro. Variables used were: age at the first medical appointment, age at first symptoms, age at loss of independent gait, time between the first symptoms and loss of gait, prescription of orthosis, time of use, and surgical intervention in the lower limbs. **Results:** The orthosis was prescribed for 63.5% of patients and used by 38.1%. The range of orthosis time was 2 to 4 years (62.3%). The night sleep period was the most prescribed for orthosis use, with 67.2%. Patients who used the orthosis for a longer time were older at gait loss. However, the children who arrived earlier for the first appointment had a higher frequency of orthosis prescriptions and later loss of gait. **Conclusion:** The use of AFO can help maintain ambulation for longer in boys with DMD.

Keywords: Duchenne muscular dystrophy. Foot orthoses. Neuromuscular diseases. Walking.

Resumo

Introdução: *A distrofia muscular de Duchenne (DMD) é uma doença genética recessiva ligada ao cromossomo X, que cursa com a perda progressiva do tecido muscular. Inicialmente, observa-se dificuldade para levantar do chão e aumento da frequência de quedas. A manutenção da deambulação pelo maior tempo possível é importante e o uso de órtese tornozelo-pé (OTP) tem sido investigado como aliado nesse processo.* ***Objetivo:*** *Verificar a prescrição e uso de OTP para meninos deambulantes com DMD.* ***Métodos:*** *As informações foram coletadas dos prontuários de 181 pacientes com DMD do Serviço de Neuropediatria do Instituto de Puericultura e Pediatria Martagão Gesteira, da Universidade Federal do Rio de Janeiro. As variáveis utilizadas foram: idade na primeira consulta, idade aos primeiros sintomas, idade na perda da marcha independente, tempo entre os primeiros sintomas e a perda da marcha, prescrição de órtese, tempo de uso e intervenção cirúrgica nos membros inferiores.* ***Resultados:*** *A órtese foi prescrita para 63,5% dos pacientes e utilizada por 38,1%. A variação do tempo de uso foi de 2 a 4 anos (62,3%). O período noturno foi o mais prescrito para uso da órtese, com 67,2%. Os pacientes que a usaram por mais tempo apresentaram maiores idades na perda da marcha. Crianças que chegaram mais precocemente à primeira consulta tiveram maior frequência de prescrição de órtese e perda da marcha mais tardiamente.* ***Conclusão:*** *O uso de OTP pode ajudar a manter a deambulação por mais tempo em meninos com DMD.*

Palavras-chave: *Distrofia muscular de Duchenne. Órtese de pé. Doenças neuromusculares. Caminhada.*

Introduction

Duchenne muscular dystrophy (DMD) is a progressive neuromuscular disorder that leads to the degeneration of muscle fibers and fibrosis of contractile tissues. It has a recessive genetic origin linked to the X chromosome,[1,2] with mutations in the Xp21.2 locus, which leads to the absence of the dystrophin protein and results in irreversible degeneration of muscle tissue.[3,4] Mutations in the gene that produces dystrophin are important to muscle tissue, in addition to the cardiovascular and respiratory systems, thus leading to rapid and progressive degeneration.[2] The incidence is one in every 4,000 male live births.[1] In some countries, the diagnosis happens around the age of 5 years.[5] Araújo et al.[6] found a mean of 7.5 years at diagnosis in Brazil.

Patients with DMD are characterized by progressive loss of muscle strength, with delay in motor development, and some also present intellectual disability. The symptoms can be difficulty of getting up from the floor (presence of the Gowers sign, in which the child climbs to reach a standing position), jumping, climbing stairs, running, and a high incidence of falls when walking.[7] To maintain ambulation for a longer period, thus preventing early complications, it is necessary to understand how each approach used in the treatment will benefit the patient with DMD.

Multidisciplinary follow-up, the use of orthosis, and drug therapy aim at a better quality of life.[4,5] Passive stretching four to six times a week and bracing, especially at the onset of this disorder, will help maintain functionality and delay the limitations caused by DMD. Literature reports the indication of ankle-foot orthosis (AFO) for patients with DMD during the day or at rest.[8-10] Nevertheless, those reports are scarce, with limited number of patients or lacking information about indication and use. The small retrieval of literature in our search prompted us to address this issue.

In addition, despite the evidence of the benefits of using AFO for patients with DMD during the initial phase of the disease,[11] daytime use is unclear. Souza et al.[8] found that the daytime use of articulated AFO had a positive effect on ankle kinematic and kinetic parameters of patients with DMD, but such changes were not maintained when patients removed the device to walk. Early and continuous use of AFO minimizes compensations caused by DMD.[8] Therefore, the nocturnal use of AFO should be prescribed at the beginning of the treatment and maintained throughout to improve results. The early use of AFO during the day and at night minimizes the compensation and prolongs walking ability. Despite these efforts, contractures often develop, and surgery may be required.[12-14]

Due to the need for more information in the scientific literature on the use and prescription of an orthosis, the current study aims to verify the prescription and use of AFO for walking boys with DMD in a cohort followed at a Brazilian neuromuscular center. Our guiding questions about the use of AFO by individuals with DMD were: how are prescription and use occurring? What time of the day is most suitable for using and for how long? What is the relation to the loss of gait?

Methods

This is a retrospective, quantitative, and descriptive study, carried out by collecting information from the medical records of patients with DMD from the database of the Neuropediatric Service of the Martagão Gesteira Institute of Child Care and Pediatrics (IPPMG) of the Universidade Federal do Rio de Janeiro (UFRJ). IPPMG began to provide care for children and adolescents with neuromuscular diseases from 1990 onwards, becoming a reference in Rio de Janeiro. From this assistance activity, it also became a neuromuscular research center from the present century onwards. This study will present data from the appointments performed from 1990 to 2021.

The project was approved by the IPPMG/UFRJ Ethics Committee (CAAE 43515421.8.0000.5264), and data collection took place in February and March 2021. Data was collected using a form prepared by the study authors, including the age at first medical appointment, age at first symptoms, age at loss of independent gait, orthosis prescription, duration of orthosis use, and surgical intervention in lower limbs.

Statistical for the Social Sciences program (SPSS version 22.0) and Microsoft Excel 2007 application were used to analyze the data. The descriptive analysis was based on frequency distributions and calculation of descriptive statistics of the quantitative variables (proportions of interest, minimum, maximum, mean, quartile 1, median, quartile 3, standard deviation, coefficient of variation - CV) and had as objective to synthesize and characterize the behavior of the variables and outline the profile of the participants. The variability of the distribution of a quantitative variable is considered low if CV ≤ 0.20, moderate if 0.20 < CV ≤ 0.40 and high if CV > 0.40.

The distribution of frequencies in classes of a quantitative variable obtained for classes of interest to the authors or for determined classes following the Sturges Method, where the number of classes given by $n_c = 1 + 3.32 \log n$ and the range of classes given by $l = \text{Range}/n_c$ where the range is the maximum data range.

In the inferential analysis, statistical significance tests were performed to analyze whether the differences between distributions of independent groups were significant. The significance of the association between two qualitative factors was investigated using the chi-square or Fisher's exact test. In the inferential analysis of quantitative variables, the normal distribution of variables was investigated using the Kolmogorov-Smirnov and the Shapiro-Wilk tests. For all quantitative variables in this study, the joint analysis of these two normality tests led to the conclusion that the variables did not follow a normal distribution (for at least one of the tests, the resulting p-value was less than 5%). Therefore, the inferential analysis involving the quantitative variables uses a non-parametric approach: the Mann-Whitney test to compare the distribution of two independent groups and the correlation analysis based on the Spearman correlation coefficient (ρ) for the correlation analysis between two quantitative variables - the significance of the correlation coefficient analyzed by the correlation coefficient significance t-Test. The correlation between the two variables is considered vital if $|\rho| > 0.7$ and moderate if $0.6 < |\rho| \leq 0.7$. All discussions about significance tests were conducted considering a maximum significance level of 5% (0.05).

Results

A total of 181 patients with a confirmed genetic diagnosis for DMD listed in our data base had their information collected. Nevertheless, not all variables were available in all medical records. Therefore, the reference sample of each distribution's percentages was calculated differently for each variable without losing the estimated proportions of the generality of the estimated proportions. Table 1 presents the frequency distribution of the variables from included DMD patients, where the most critical frequencies are marked in bold.

Most DMD patients were aged between 15 and 23 years (59.1%) and had achieved independent walking before 1.5 years (71.2%). First symptoms occurred from 1.5 to 4.5 years (54.9%); the patient had the first appointment by the age of 6 to 12 years (69.7%); the loss of gait typically occurred in the age group of 8 to 12 years (70.3%); and the time of appearance of the first symptoms until loss of gait was typically comprised between 3 and 7.5 years (63.4%). Of the total of 181 patients with DMD in our study, 17 (9.4%) had already died, but their data were collected.

AFO was prescribed to 115 boys (63.5% of the patients) but used only by 69 of them (38.1% of the total and 60.0% of those prescribed). Lower limb surgery was performed in only 2.2% of cases. The orthosis use ranged from 2 to 4 years (63.8%) and mostly during the night period (68.1%).

Table 1 - Frequency distribution of variables that characterize patients with Duchenne muscular dystrophy

Variable	Category	F	%*
Chronological age (in years; n = 181)	3 |– 7	8	4.4
	7 |– 11	19	10.5
	11 |– 15	32	17.7
	15 |– 19	**61**	**33.7**
	19 |– 23	**46**	**25.4**
	23 |– 27	8	4.4
	27 |– 31	7	3.9
Independent gait achievement age (in years; n =146)	**0.5 |– 1.5**	**104**	**71.2**
	1.5 |– 2.5	35	24.0
	2.5 |– 3.5	6	4.1
	3.5 |– 4.5	1	0.7
Age at first symptoms (in years; n = 162)	0 |– 1.5	26	16.0
	1.5 |– 3.0	**36**	**22.2**
	3.0 |– 4.5	**53**	**32.7**
	4.5 |– 6.0	23	14.2
	6.0 |– 7.5	18	11.1
	7.5 |– 9.0	6	3.7
Age at first appointment (in years; n =168)	0 |– 3	10	6.0
	3 |– 6	37	22.0
	6 |– 9	**73**	**43.5**
	9 |–12	**44**	**26.2**
	12 |– 15	4	2.4
Age at gait loss (in years, n = 128)	2 |– 4	1	0.8
	4 |– 6	1	0.8
	6 |– 8	25	19.5
	8 |– 10	**58**	**45.3**
	10 |– 12	**32**	**25.0**
	12 |– 14	8	6.3
	14 |– 16	3	2.3
Time between the first symptoms and gait loss (in years; n = 128)	0.0 |– 1.5	4	3.1
	1.5 |– 3.0	7	5.5
	3.0 |– 4.5	**23**	**18.0**
	4.5 |– 6.0	**34**	**26.6**
	6.0 |– 7.5	**24**	**18.8**
	7.5 |–9.0	20	15.6
	9.0 |– 10.5	10	7.8
	10.5 |– 12.0	6	4.7
Observed factors (n = 181)	Bracing prescription	115	63.5
	Use of orthosis	69	38.1
	Lower limb surgery	4	2.2
	Death	17	9.4

Note: F = frequency. A |– B: representation of a numerical interval closed on the left for the value A and open on the right for the value B. *Percentages calculated concerning the size n of the available data sample for each variable. Bold values indicate the most critical frequencies.

Table 1 - Frequency distribution of variables that characterize patients with Duchenne muscular dystrophy (continued)

Variable	Category	F	%*
Time of use of the orthosis (in years; n = 69)	Less than 1	3	4.3
	Between 1 and 2	7	10.1
	2	**16**	**23.2**
	3	**18**	**26.1**
	4	**10**	**14.5**
	5	5	7.2
	6	7	10.1
	7	2	2.9
	8	1	1.4
Period of use of the orthosis (n = 69)	Daytime	14	20.3
	Nighttime	**47**	**68.1**
	Both	8	11.6

Note: F = frequency. *Percentages calculated concerning the size n of the available data sample for each variable. Bold values indicate the most critical frequencies.

Table 2 displays the main statistics of the distributions of the observed variables. According to the values of coefficients of variation, no variable has low variability (all coefficients of variation are more significant than 0.20). The variables "time of use of the orthosis", "age at first symptoms" and "time between first symptoms and loss of gait" showed the most significant variability among patients. When we correlated the quantitative variables with the time of use of the orthosis, we found a moderate and significant correlation between the time of use and age at gait loss ($\rho = 0.62$; $p < 0.001$). Therefore, there is a tendency for patients who use the orthosis for a longer time to be older when they lose their gait, and vice versa (Figure 1).

The distributions of the quantitative variables in without and with orthosis prescription groups were compared to find out if the orthosis prescription was associated with any quantitative variable (Table 3).

Table 2 - Main statistics of the observed variable distributions

Statistics	Variables (in years)						
	CA	AIG	AFS	AFA	TOU	AGL	TBSL
Minimum	3.0	0.7	0.2	0.4	0.0	2.0	0.0
Maximum	30.0	3.5	8.2	12.8	8.0	15.0	12.0
Quartile 1	13.0	1.1	2.0	5.6	2.0	8.0	4.2
Median	**16.8**	**1.3**	**3.0**	**7.3**	**3.0**	**9.0**	**5.7**
Quartile 2	20.0	1.5	5.0	9.3	4.0	10.5	8.0
Average	**16.4**	**1.4**	**3.5**	**7.2**	**3.2**	**9.1**	**5.9**
SD	5.3	0.5	2.0	2.6	1,8	2.0	2.5
CV	0.32	0.35	0.57	0.37	0.56	0.22	0.43

Note: CA = chronological age (n = 181); AIG = age of independent gait (n = 146); AFS = age at first symptoms (n = 162); AFA = age at first appointment (n = 168); TOU = time of use of the orthosis (n = 69); AGL = age at gait loss (n = 128); TBSL = time between the first symptoms and gait loss (n = 128); SD = standard deviation; CV = coefficient of variation. Bold values indicate median and average.

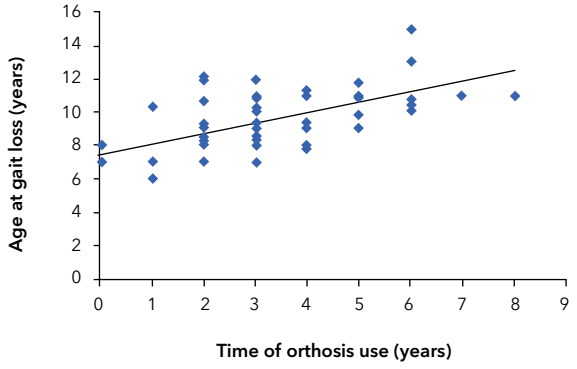

Figure 1 - Conjoint dispersion plot between the time of orthosis use and age at gait loss.

Given the p-values of the statistical significance tests, it was concluded that the groups "without prescription of orthosis" and "with prescription of orthosis" showed a significant difference in the age distributions at the first visit (p = 0.020 of the Mann-Whitney test) and in the age distributions loss of gait (p = 0.001 of the Mann-Whitney test).

Whilst comparing the statistics, it was observed that the patients who had a prescription for an orthosis were younger at the first medical appointment (1.0 years younger, on average) and had a later age at gait loss (1.4 years later, on average) than patients who did not have a prescription for a bracing.

Table 3 - Analysis of the association between orthosis prescription and quantitative variables

Variables (in years)	Group without prescription of orthosis			Group with prescription of orthosis			p-value*
	Average	Median	SD	Average	Median	SD	
CA	15.4	16.0	5.5	16.6	17.0	5.1	0.233
AIG	1.4	1.2	0.6	1.4	1.3	0.5	0.312
AFS	3.5	3.5	2.2	3.5	3.3	2.0	0.895
AFA	7.9	8.0	2.8	6.9	7.0	2.6	**0.020**
AGL	8.1	8.0	2.0	9.5	9.3	1.8	**0.001**
TBSL	5.3	5.0	2.6	6.1	5.9	2.5	0.088

Note: CA = chronological age (n = 181); AIG = age of independent gait (n = 146); AFS = age at first symptoms (n = 162); AFA = age at first appointment (n = 168); AGL = age at gait loss (n = 128); TBSL = time between the first symptoms and gait loss (n = 128); SD = standard deviation. *Mann-Whitney test comparing the distributions of the two groups. Bold values indicate results with a statistically significant difference (p < 0.05).

Discussion

Prescription of AFO for ambulant boys with DMD was made for the majority of individuals, but its actual use occurred for little more than half of these. In this study, we analyzed data from 31 years of care for patients with DMD in a pediatric neurology service, intending to focus on the prescription and use of AFO.

Considering the individuals who used the orthosis, the typical use time was 2 to 4 years. The night period was the most indicated. Data like ours were found by Gupta et al.[9] in a four-year experience in a multidisciplinary clinic. After detailed clinical examination of 126 patients with DMD, including assessment of muscle strength in the limbs and neck, 59 were advised to use AFO (46%).[9] For patients who purchased orthoses, 16 used the AFO as a walking device (27.1%), 40 used it at rest (67.8%), and 3 used it at rest and for walking. Similar results were also found by Kern et al.,[15] who evaluated data on AFOs from 187 boys participating in an international multicenter clinical trial, and found that AFOs were recommended for 54% of them.

The use of the orthosis had an association with the age of gait loss; as such, the patients who used orthosis for a longer period lost their gait later in life. A latter loss of gait represents a delay in the onset of scoliosis, contractures and joint deformities, greater independence for the child, and psychological benefits for both the child and the parents.[16] In this way, prescribing the orthosis use to prolong the gait is an ally to the treatment.

Patients with DMD show pelvic anteversion, hip flexion and lumbar hyperlordosis. These occur due to the extensors' weakness and the hip flexors' shortening. Conjointly, the knee extensors weaken, leading to

hyperextension to bear the body load and compensate for quadriceps weakness. The hip hyperflexion and abduction in the swing phase compensate for the ankle dorsiflexor weakness, generating plantar flexion during swing. To compensate for the lack of stability, the patient with DMD tends to increase the base of support and reduce the stride to perform the gait and increase the base of support while climbing steps.[14, 17-19]

With the alterations presented, the risk of loss of gait and the development of contractures and scoliosis increases. Our results reinforce that the prescription of AFO can help in the delay of gait loss and, as in other studies, we suggest that passive stretching and the use of an orthosis, especially at the beginning of the disorder, can help maintain functionality and delay the limitations caused by DMD.[12-14]

On the prescription of orthoses for walking or for use at rest (at night), AFOs should be indicated for preventive night stretching at a young age and for daytime stretching in more advanced phases/non-ambulatory phase.[14] During the day, AFO can place excessive demands on and further challenge weakened hip muscles. It can further weaken the quadriceps during the eccentric loading phase of gait.[20]

Another interesting fact we found was that children who arrived earlier for the first appointment had a higher frequency of orthosis prescription and later loss of gait. It is assumed that the child who arrives earlier does not have contractures and deformities installed and, therefore, should be easier to adhere to the use of an orthosis. Arriving early to a neuromuscular center might also be a factor to help adherence to treatment recommendations, by having more opportunities to discuss with the health care providers before the rapid decline of DMD phase 3 occurs. Barriers to the use of prescribed devices is an important field to be explored.

In summary, the present study demonstrates that AFOs are recommended for most of the boys with DMD followed at the neuromuscular center from a university setting, that those devices when used might help to delay ambulation loss, but, unfortunately, not all families adhere to the recommendation. This can occur due to several factors, such as the difficulty in creating the AFO; late diagnosis, associated with the presence of foot deformity, generates discomfort; greater importance to drug therapies than therapeutic devices. Therefore, our study strongly recommends that public health management provide greater awareness about DMD so that parents and guardians of children can know the disease, recognize signs and symptoms, and seek appropriate medical care more quickly. Once diagnosed, it is suggested that it be further encouraged and guaranteed to the patient with DMD the viability of production of the AFO.

Limitation on medical records information is a usual problem in cross-sectional studies. Therefore, the different sample sizes according to variable information found in the medical records. However, as a baseline on the subject, we obtained important information, consolidating advice that have been carried on when consulting boys with DMD.

Conclusion

Our results revealed that the use of AFO can help maintain ambulation for longer time in boys with DMD, but not all patients who had a prescription used the orthosis. As in other studies, most patients are prescribed for use during resting time. We reinforce the importance of early diagnosis to make the adopted measures effective. We suggest the focus on orthosis adherence to be further explored in future studies.

Authors' contributions

All authors participated in the study design, analysis and interpretation of data, manuscript drafting and reviewing, and approval of the final version.

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