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Comparing Subjective Scales for Rating Drooling: A Pilot, Bicentric, Study

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Abstract

Purpose: To evaluate the differences among the major subjective scales used to rate drooling in children with neurological disorders.

Patient and Methods: Children with neurological disorders of broad aetiologies were recruited and three different subjective scales were administered: the Drooling Impact Scale (DIS), the modified Teachers' Drooling Scale (mTDS), and the Drooling Severity and Frequency Scale (DSFS). Participants were then divided into 2 groups (A and B) according to the score obtained on the DSFS scale. The Mann-Whitney U test was applied to verify and quantify the difference between the DIS scores obtained in the two groups. The Pearson's correlation was used to verify the correlation between the DSFS score and the DIS total (DIS-tot) score, the DSFS score and DIS (domain 1 to 5) score, and the DSFS score and the mTDS score. Moreover, we analyzed the correlation between age and DSFS/DIS-tot scores, and age and the mTDS score.

Results: 31 children (mean age: 7.3 ± 4.5 years) were enrolled. Group A included 11 (35%) patients with a DSFS score of 2-5; group B included 20 (65%) patients with a DSFS score of 6-9. The Mann-Whitney test highlighted a significant difference between group A and group B with a DIS-tot score of $p = 5 \times 10–5$. We obtained a strong correlation between DSFS and DIS-tot (r = 0.86), between DSFS and mTDS (r = 0.88), and between DIS-tot and mTDS (r = 0.87). No correlation was found between age and DSFS (r = 0.12).

Conclusion: The DIS, DSFS, and mTDS scales are effective in rating drooling, both in terms of severity and frequency. A subjective illustrative approach should, however, include an adequate assessment of the patient as a whole. In light of the impact that drooling has on the quality of life of these patients, the development of a comprehensive method to assess this condition is essential in the future.

What is known?

Drooling recognition and therapeutic management represent a fundamental step in the care of both the patient and his/her caregivers.

The application of subjective scales to measure drooling is suggested in the literature. However, to date, these methods are currently non-validated.

Existing objective approaches do not consider the overall patient's quality of life, which is a fundamental parameter in evaluating treatments' effectiveness.

What is new?

Subjective scales (DIS, mTDS, and DSFS) were effective in the diagnosis of drooling, both in terms of rating its severity and its frequency.

The DIS scale has some defects in its method of administration and interpretation in a language different from English.

Keywords: Cerebral Palsy • Drooling• Neurological Disorders• Pediatrics• Quality of Life• Subjective Scales

Abbreviations: CP: Cerebral Palsy • DIS: Drooling Impact Scale • DIS-tot: Drooling Impact Scale-Total • DIS-d1/5: Drooling Impact Domain 1/5 • DSFS: Drooling Severity and Frequency Scale • Max: Maximum • Min: Minimum • Mo: Months • mTDS: Modified Teachers' Drooling Scale • NRS: Number Rating Scale • P: p-value • r: Pearson Correlation Coefficient • S.D: Standard Deviation • U: Mann-Whitney test • VAS: Visual Analogue Scale • y: Years

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Introduction

Drooling affects up to 58% of children with severe neurological disorders [1] and greatly influences the patient's Quality of Life (QoL) [2]. Drooling recognition and therapeutic management represent a fundamental step in the care of both the patient and his caregivers [1]. Nowadays, novel treatments for pediatric drooling are facing the market, although the methods to assess their clinical utility and efficacy are not experimentally grounded and lack uniformity [1,3]. The lack of reliable metrics to assess efficacy and safety outcomes in drooling limits researchers from identifying the best patient-suitable treatment. Furthermore, existing objective assessment methods do not consider the overall patient's quality of life, which is a fundamental parameter in evaluating treatments' effectiveness. Therefore, the application of subjective scales is

suggested. The main goal is to develop a unique and validated technique to rate drooling, which will allow a reliable and safe assessment, and to carry out a detailed analysis of the effectiveness of the specific anti-drooling treatment [4]. Therefore, a key enabler for new efficient therapies stands in the introduction of accurate and robust scales to measure their effects on drooling. An accurate approach must study the severity, frequency, and all the physical and psychological complications to improve the quality of life of the patients and their families [4]. Sforza and collaborators reviewed the scales used for a comprehensive assessment of drooling; however, they underlined the need for more data to determine validity, reliability, and responsiveness [4]. We performed a pilot experimental study on a group of Italian paediatric patients with neurological disorders of broad aetiologies, to evaluate the adequacy and differences between the three most used subjective scales (DIS, mTDS, and DSFS) in rating drooling.

Methodology

Patients' selection and materials

Pediatric patients with neurological disorders of broad aetiologies were recruited from two tertiary pediatric neurological hospitals from September 2019 to June 2020.

The healthcare worker administered the Drooling Impact Scale (DIS) [5-7] and the modified Teachers' Drooling Scale (mTDS) [6] directly to the parent/caregiver. The Drooling Severity and Frequency Scale (DSFS) [5] were completed by the physician after the patient's examination. Scales were translated into Italian following the "Good clinical practices for the translation, cultural adaptation, and linguistic validation of clinician-reported outcome, observer-reported outcome, and performance outcome measures" [8].

To quantify the three different scales, each question was given a score from one to ten, using a Number Rating Scale (NRS) or a Visual Analogue Scale (VAS). Given the variability of the items, we divided the Drooling Impact Scale (DIS) into five domains, as follows:

Domain 1 (d1) - Severity, items 1 and 2

Domain 2 (d2) - Level of care, items 3, 6 and 8

Domain 3 (d3) - Complications, items 4 and 5

Domain 4 (d4) - Impact on child's life, items 7 and 9

Domain 5 (d5) - Impact on family life, item 10

For each participant, demographic, and clinical data, as well as treatment data, were collected through a standardized clinical sheet.

Statistical analysis

Participants were stratified in: i) patients with DSFS score between 2-5 (mild drooling)[Group A]; ii) patients with DSFS score between 6-9 (moderate/severe drooling) [Group B]. We calculated the absolute and relative frequency of the patients in these two different groups. Afterwards, we applied the nonparametric Mann-Whitney U test [9] to verify and quantify the difference between the DIS scores obtained. Furthermore, the DIS score was divided into two groups: the DIS-total score (DIS-tot), which represents the total DIS score and the DIS domain score (DIS-d1/d5), which represents the score of a single domain, these domains are not part of the original DIS scale. For these data, we analyzed the average, median, and standard deviation (S.D.) for age; the absolute and relative frequency (%) for sex and diagnosis, and the average, median, and standard deviation (S.D.) for DSFS score, DIS-tot score, DIS-d1(severity); DIS-d2 (level of care); DIS-d3 (complications); DIS-d4 (impact on child's life); DIS-d5 (impact on family life), and mTDS score. We used Pearson's correlation [10] to verify the correlation between the DSFS score and DIS-tot score, the DSFS score and DIS-d1/5 score, and the DSFS score and the mTDS score. Moreover, we analyzed the correlation between age and DSFS score, age and DIS-tot score, and age and mTDS score. The r coefficient obtained describes the linear correlation between the two continuous variables. The value of r ranges from -1 to 1. The sign indicates the direction of the linear correlation. The strength of the linear relationship is indicated as follows: $0 < r < 0.3$ weak correlation; $0.3 < r < 0.7$ moderate correlation; $r > 0.7$ strong correlations. Finally, we calculated the absolute number and the percentage of patients with epilepsy in the two groups, to check differences by diagnosis.

Results

Demographics data

We enrolled 31 children (age range: 1-17 years; mean age: 7.3 ± 4.5 years): 10 with an acquired neurological disorder (CP, neurofibromatosis, and encephalitis); 19 with a genetic-malformation disorder; 2 with a muscular disease. As regards comorbidities, we focused on the presence or absence of epilepsy. The characteristics of the participants are reported in Table 1.

Statistical analysis and scale results

Of these 31 patients, 15 underwent DSFS and DIS scales only, while 16 underwent DSFS, DIS, and mTDS scales.

Group-A included 11 (35%) patients, whereas group B included 20 (65%) patients. The Mann-Whitney test allowed to highlight differences between group A and group B for the total impact (assessed by the DIS-tot score) where $p= 5 \times 10^{-5}$ and for each of the domains (assessed by the DIS-d1/5 scores) (Table 2). Furthermore, to verify if there was an association between epilepsy and drooling using all three different scales, a comparison was made between epileptic and non-epileptic patients. Group A included 7 (64%) patients with epilepsy and 4 (36%) patients without epilepsy, whereas Group B included 13 (65%) patients with epilepsy and 7 (35%) patients without epilepsy.

Moreover, we observed a strong correlation between DSFS and DIS-tot (r = 0.86) (Figure 1), between DSFS and mTDS (r = 0.88), and between DIS-tot and mTDS (r = 0.87). The correlation between age and DSFS was weak (r = 0.12) and no linear relationship was found between age and DIS-tot. Age and mTDS score showed a negative linear relationship (r = -0.20). Results are

Table 1. Analysis of age, sex, diagnosis, epilepsy, and therapy in the study group.

Patients' Characteristics		Number	%
Age	Average 7 year 3 months; Median 6 year; S.D. 4 year 5 months	-	-
Sex	Female	10	32%
	Male	21	68%
Diagnosis	Neurological acquired causes	10	32%
	Neurological congenital causes	19	61%
	Muscular causes	2	7%
Epilepsy	Epileptic	20	65%
	Non-epileptic	11	35%
Therapy	With anti-drooling agents	3	10%
	Without anti-drooling agents	28	90%

Table 2. Values that express the difference in DIS scores (total and domains) between patients with mild drooling and those with moderate-to-severe drooling.

Parameter	Group A *vs.* Group B
DIS-tot	U=16
	$p=5 \times 10^{-5}$
DIS-d1 severity	U=21
	$p=1 \times 10^{-4}$
DIS-d2 level of care	U=20
	$p=1 \times 10^{-4}$
DIS-d3 complications	U=45
	p=0.03
DIS-d4 impact on the child's life	U=54
	p=0.006
DIS-d5 impact on family life	U=35
	$p=8 \times 10^{-4}$

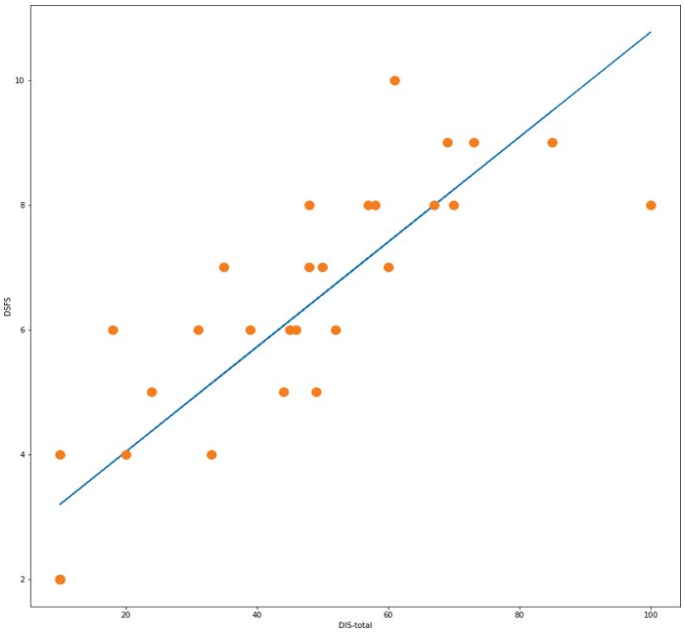

Figure 1. The linear positive relationship between DSFS score and DIS-tot score.

shown in Table 3.

Considering the variability of the scores on the different items of the DIS questionnaire, we calculated the correlations between each DIS-d and the DSFS and the mTDS. Table 4 shows the results obtained in calculating the correlation between DIS-d1/5 and DSFS. We observed a strong correlation between DSFS and Severity (r = 0.87), Level of care (r = 0.84), and Impact on family life (r = 0.77). Unlikewise, there was a moderate correlation between DSFS and Complications (r = 0.53) and Impact on child's life (r = 0.48).

Table 5 shows the results obtained in calculating the correlation between DIS-d1/5 and mTDS. We obtained a strong correlation between mTDS and Severity (r = 0.93) and Level of care (r = 0.82). However, the correlation was moderate between mTDS and Complications (r = 0.60) and Impact on child's life (r = 0.46). Figure 2 shows the correlations between the parameters of the patients, the higher the Pearson index (r > 0.7).

Discussion and Analysis

We provide a primary experimental evaluation of the adequacy and the differences of the three most used subjective scales (DIS, mTDS, and DSFS) in rating drooling in pediatric patients. The strong correlation between the DSFS, DIS, and mTDS scales confirms their validity to assess drooling. Their efficacy has proven to be interchangeable for almost all aspects assessed in the questionnaires. However, given the study being a pilot and having some missing values (not all the patients have been assessed with the mTDS scale) further studies are needed.

Patients with severe drooling deal with physical and psychological complications that negatively affect their quality of life. However, the scales did not analyze how the patient's clinical condition impacts their quality of life. We observed a strong correlation between DSFS and the severity of drooling, the burden of care, and the impact on the family by comparing the DSFS scale with the domains of the DIS scale. Nevertheless, the correlation remains moderate between DSFS and mTDS and complications and the impact on the family.

The condition of patients with mild, moderate, or severe drooling also differed. In comparison to subjects with mild drooling (group A), patients with severe drooling scored higher in each domain of the DIS. Parents' accurate perception of the pathology has been demonstrated by the way they assessed drooling severity and frequency. However, 8 participants in our study were less than 4 years old and, according to Van Hulst K, et al., loss of saliva may still be "normal": about 3-15% of the preschoolers in their cohort did not acquire full saliva control at the age of 4 years [11]. Accordingly, the interpretation of

Table 3. Patients' DSFS, DIS-tot, and mTDS scores and their correlations.

Patient	Age (y, mo)	DSFS (min 2, max 9)	DIS-tot (min 10, max 100)	mTDS (min 1, max 9)
1	6	9	73	-
2	16	9	69	-
3	10	8	48	-
4	14	8	57	-
5	17	7	35	-
6	12	7	60	-
7	5	6	39	-
8	13	6	18	-
9	12	5	44	-
10	4	5	49	-
11	9	5	24	-
12	10	4	10	-
13	8	2	10	-
14	6	2	10	-
15	2	2	-	-
16	1	7	48	5
17	3	6	46	2
18	3	4	33	4
19	5	9	85	9
20	3	4	20	2
21	10	2	10	1
22	7	2	10	1
23	8	9	61	8
24	6	8	100	9
25	2	6	31	5
26	4	8	67	9
27	3	7	50	8
28	2	8	58	9
29	12	6	45	5
30	8	6	52	6
31	4	8	70	9
Average	7.3	6	43.3	5.75
Median	6	6	46	5.5
S.D.	4.5	2.35	24.2	3.1
Pearson		r=0.12		
			r=0.05	
				r=-0.20
			r=0.86	
				r=0.88
				r=0.87

the impact scores (DIS) may be different for these young children and their parents, compared to the older children. Notwithstanding, in our study, age does not seem to have a specific correlation with subjective scales, as shown by the low r values (r < 0.3), more studies are, therefore, needed.

Epilepsy has the same frequency both in subjects with severe drooling and in those with mild drooling. However, considering the small sample size of our cohort, further data are required.

Table 4. Patients' DSFS, DIS-d1/5 scores, and their correlations.

Patient	DSFS (min 2, max 9)	DIS-d1 Severity (min 2, max 20)	DIS-d2 Level of care (min 3, max 30)	DIS-d3 Complications (min 2, max 20)	DIS-d4 Impact on the child's life (min 2, max 20)	DIS-d5 Impact on family life (min 1, max 10)
1	9	20	24	8	11	10
2	9	18	30	13	2	6
3	8	16	20	3	2	7
4	8	18	18	9	2	10
5	7	16	14	2	2	1
6	7	13	21	11	8	7
7	6	13	8	11	2	5
8	6	6	3	2	4	3
9	5	15	16	6	2	5
10	5	15	13	10	2	9
11	5	12	7	2	2	1
12	4	2	3	2	2	1
13	2	2	3	2	2	1
14	2	2	3	2	2	1
15	2	2	3	2	2	1
16	7	10	21	2	8	7
17	6	10	18	6	7	5
18	4	9	8	5	6	5
19	9	20	30	8	17	10
20	4	2	11	2	3	2
21	2	2	3	2	2	1
22	2	2	3	2	2	1
23	9	15	15	6	15	10
24	8	20	30	20	20	10
25	6	13	12	2	2	2
26	8	18	25	5	10	9
27	7	15	18	10	5	2
28	8	18	23	6	2	9
29	6	10	11	6	12	6
30	6	18	12	6	15	1
31	8	20	30	8	2	10
Average	6	12	14.7	5.83	5.64	5.09
Median	6	13	14	6	2	5
S.D.	2.35	6.49	9.11	4.28	5.31	3.59
Pearson		r=0.87				
			r=0.84			
				r=0.53		
					r=0.48	
						r=0.77

Table 5. Patients' mTDS and DIS-d1/5 scores and their correlations.

Patient	mTDS (min 1, max 9)	DIS-d1 Severity (min 2, max 20)	DIS-d2 Level of care (min 3, max 30)	DIS-d3 Complications (min 2, max 20)	DIS-d4 Impact on the child's life (min 2, max 20)	DIS-d5 Impact on family life (min 1, max 10)
16	5	10	21	2	8	7
17	2	10	18	6	7	5
18	4	9	8	5	6	5
19	9	20	30	8	17	10
20	2	2	11	2	3	2
21	1	2	3	2	2	1
22	1	2	3	2	2	1
23	8	15	15	6	15	10
24	9	20	30	20	20	10
25	5	13	12	2	2	2
26	9	18	25	5	10	9
27	8	15	18	10	5	2
28	9	18	23	6	2	9
29	5	10	11	6	12	6
30	6	18	12	6	15	1

31	9	20	30	8	2	10
Average	5.75	12	14.7	5.83	5.64	5.09
Median	5.5	13	14	6	2	5
S.D.	3.1	6.49	9.11	4.28	5.31	3.59
Pearson		r=0.93				
			r=0.82			
				r=0.60		
					r=0.46	
						r=0.75

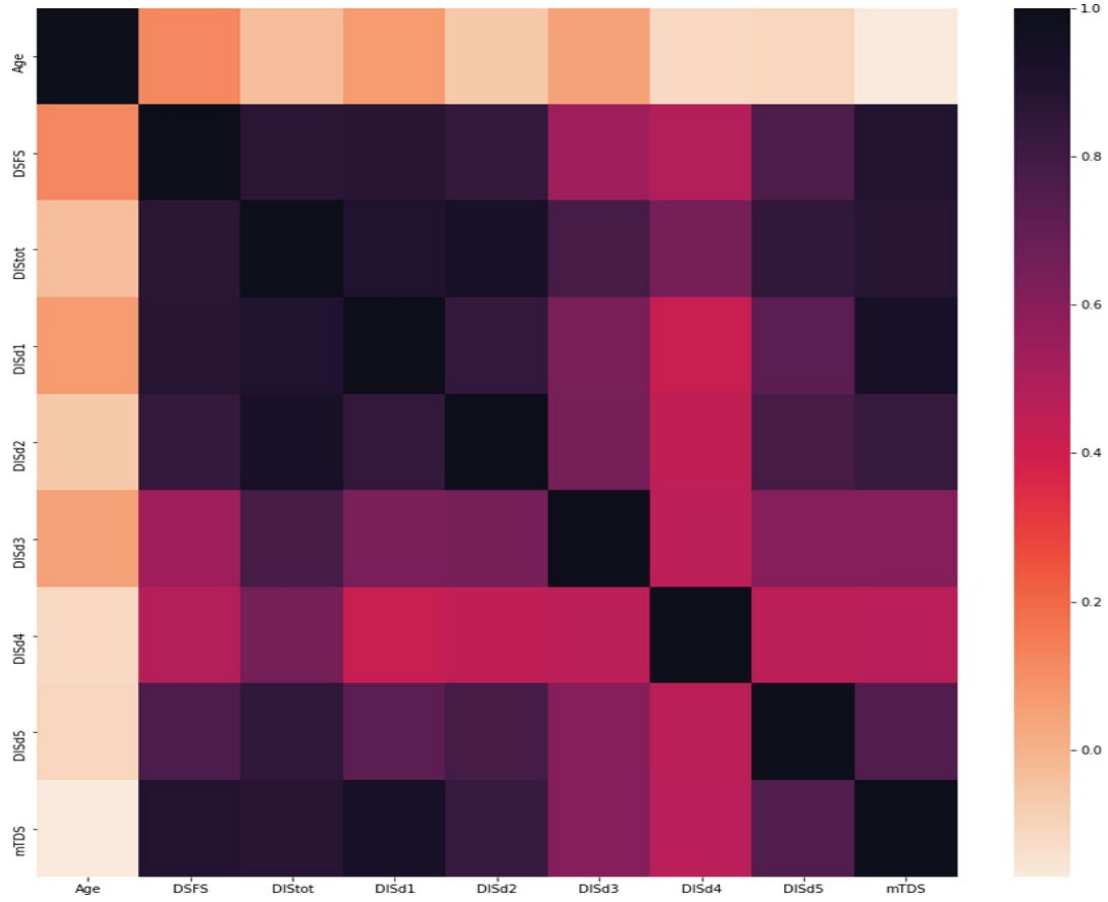

Figure 2. Heat-map showing the correlations between the investigated parameters in our cohort.

Patients with severe drooling are neurological patients with a serious clinical and social disability, well recognized by parents and well suffered by the child and the family. The scales were quick and manageable to administer with only ten minutes required to complete the assessment. The most accomplished subjective scale proved to be the DIS scale thanks to its greater variability and its different subdomains. However, the DIS scale has some drawbacks. First, the questions in the scale refer only to the type of anterior drooling, while there are no questions that investigate posterior drooling, which in terms of complications could be more complex and significantly impact the life of the patient and caregivers. In addition, the questions relating to the psycho-social impact are rather generic and always refer to the parents, not including the patient himself in the evaluation. The items aimed at examining the actual consequences in social interactions, but the psycho-affective experience of the patient and caregivers are missing. This is because the DIS scale was designated to quantify the benefits of a short-medium term intervention. The items included in the scale were chosen based on the property of changing in quickly after an operation/treatment. However, changes in social interaction and self-esteem occur more gradually and may not emerge in the short to medium term. Finally, each question requires a score from 1 to 10, through NRS and parents often reported their difficulty in understanding how "quantify and qualify" the condition with a number. For this reason, the use of the VAS (Visual Analogue Scale) is strongly suggested.

Indeed, it is not possible to correctly evaluate drooling without analyzing its impact on the QoL. An illustrative subjective approach should not be limited to directly assessing characteristics of drooling, such as its frequency and severity. It should include an adequate assessment of the patient as a "whole" by incorporating questions about the impact of drooling on daily life, practical consequences and psycho-social functioning for children and their parents/caregiver(s). Hitherto, aspects such as the number of bibs or clothes changed per day, the level of interpersonal contact, and the stress load of the caregiver become essential parameters in the management of these patients.

Conclusion

Each of the subjective scales (DIS, mTDS, and DSFS) was effective in the diagnosis of drooling, both in terms of rating its severity and its frequency. We found that the DIS scale was the only one that takes into account the physical complications of drooling and its impact on quality of life. From our analysis appeared a strong correlation between these complications and the severity of the condition. Currently, a standardized and objective method has not been developed for assessing sialorrhea. Developing and validating objective methods to address the limitations of the existing scales must be the focus of future studies. For example, the rating scales must be validated and standardized in a language other than English. Moreover, the complications of

posterior drooling must be considered. Complications of posterior drooling can be much more serious and include dyspnea, cough, and aspiration pneumonia. Further, the new questions of the DIS scale should emphasize both the child's and the parent's impact on life to give greater insight into one of the worst aspects of sialorrhea. Additionally, to increase the accuracy of the scale, a question about the effect of the treatment can be added. A different suggestion, albeit longer and more complex, is to assess two questionnaires, one before treatment and one after treatment.

Our study highlights some defects of the DIS scale also in its method of administration and interpretation. When reviewing the questionnaire, the first point to consider is the formulation of the questions, which are always addressed to the parent, regardless of the patient's ability to answer them. Thus, our suggestion is to produce a version of the DIS scale in which each question is addressed both to the parent and the child. Patients' assessments of the problem can improve the scale in a significant way, especially when it comes to aspects of personal life. A simplified version of the scale can be proposed, which is not based on the NRS, nor the VAS, but on a "Faces" Drooling Rating Scale, taking, for example, the existing scale for pain assessment in pediatric or intellectually disabled patients. An objective methodology that takes heed of both its clinical effects and its treatments may help in better and personalized management of these young patients and their families.

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Author Contribution

MGP, AR, CF data collection, interpretation of data, drafting. EV, EA data collection and revision of the manuscript. GT, LS, AV revision of the manuscript. PS, conception and design of the study, revision and final approval of the manuscript. All authors read and approved the final manuscript.

Ethical Standard

This study has been performed following the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Consent to Participate

Written informed consent was obtained from the parents.

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