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Lynn M Jeffries

Alyssa Laforme Fiss

Sarah Westcott McCoy

Lisa Avery

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Title: **Longitudinal Change in Common Impairments in Children with Cerebral Palsy from age 1.5 to 11 years**

Short Title: Change in Impairments

Lynn M. Jeffries, PT, PhD, PCS, Associate Professor, Department of Rehabilitation Sciences, University of Oklahoma Health Sciences Center, Oklahoma City, OK 73117, lynn-jeffries@ouhsc.edu

Alyssa LaForme Fiss, PT, PhD, PCS, Associate Professor, Department of Physical Therapy, Mercer University, Atlanta, GA 30341, fiss_al@mercer.edu

Sarah Westcott McCoy, PT, PhD, FAPTA, Professor, Rehabilitation Medicine, University of Washington, Seattle, WA 98195, westcs@uw.edu

Lisa Avery, B.Eng, M.Sc, Avery Information Services Ltd, Orillia, ON, CAN, lisa@averyinformation.com

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Correspondence: Lynn Jeffries, PT, PhD, PCS, Department of Rehabilitation Sciences, University of Oklahoma Health Sciences Center, 1200 N Stonewall, Rm 3092, Oklahoma City, OK 73117, lynn-jeffries@ouhsc.edu

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Abstract

Purpose

This project aimed to determine if change occurs over time for impairments of balance, range of motion (ROM), endurance, and strength of children with cerebral palsy (CP), by Gross Motor Function Classification System (GMFCS) levels.

Methods

Measurements were completed in 77 children at two sessions (T1, T2) on average 5.8 years apart. Mean ages were 2.9 years (SD .9) and 8.7 years (SD 1.1) at T1 and T2, respectively.

Results

Significant differences were noted from T1 to T2 for some children (GMFCS levels I, II, and III/IV: balance increased, GMFCS levels I and II: strength increased, and GMFCS levels III/IV and V: ROM decreased). Endurance scores were not different. Endurance scores did not change.

Conclusions

Longitudinal changes in most impairments occurred in children with CP. Monitoring and targeted interventions should support each child's development.

Introduction

Children with cerebral palsy (CP) present with impairments of body function and structure.[1,2] Balance is considered a primary impairment since challenges in postural control in both static and dynamic activities are frequently present at the time of diagnosis.[3-5] As children with CP age, secondary impairments often develop including restrictions in joint range of motion (ROM) and decreased endurance and strength.[2,6,7] A primary goal of therapy is to monitor the development of impairments and focus intervention on the reduction of current impairments and prevention of further secondary impairments.

Researchers have documented impairments in children with CP across all functional motor ability levels of the Gross Motor Function Classification System (GMFCS)[8] and as young as 18 months.[2,6,9-11] However, most studies use cross-sectional methodology that provides results related to a cohort of children at one point in time. Based on this cross-sectional data, impairments in children with CP are present and differ by GMFCS levels.[2] A cross-sectional study provides valuable information but does not provide a clear depiction of the development of the impairments over time.

The opportunity occurred to examine longitudinally a sub-set of children with CP who participated in two multi-site, international, prospective studies.[12,13] Using the same clinical measures, we had the ability to examine changes in impairments in a group of children with CP following several years of development. The purposes of this study were to: 1) determine if a change occurs over time for impairments of balance (Early Clinical Assessment of Balance (ECAB)),[17] range of motion (Spinal Alignment and Range of Motion Measure (SAROMM)),[15] endurance for activity (Early Activity Scale for Endurance (EASE)),[16] and strength (Functional Strength Assessment (FSA))[2] in children with CP.

Methods

This study examined results from the Move & PLAY and On Track studies. Movement and Participation in Life Activities of Young Children with Cerebral Palsy (Move & PLAY) aimed to understand the child, family, and service delivery determinants that together explained the motor abilities, self-care, and play of young children with CP.[12,17] On Track: Monitoring Development of Children with Cerebral Palsy and Gross Motor Delay aimed to develop longitudinal developmental trajectories and reference percentiles for impairments, health conditions, and participation variables for children with CP.[13] This current analysis includes children with CP who participated in both studies. Full study protocols have been reported elsewhere.[13,18] All participating institutions and recruitment sites with Institutional Review Boards (IRBs) provided ethics approval. Parents or guardians provided informed consent and children, as appropriate and in compliance with the specific IRB, provided assent for both studies.

Participants

A convenience sample of 77 children with CP participated in both studies, from six provinces across Canada, including British Columbia, Saskatchewan, Manitoba, Ontario, Nova Scotia, and Newfoundland, and four regions of the United States, including areas within and surrounding Georgia, Oklahoma, Pennsylvania, and Washington. Of this sample 52% of the participants were from the United States. Participants were recruited through children's rehabilitation centers in Canada and through physical therapists, occupational therapists, physicians, and hospital systems in the United States. All children had a diagnosis of CP. Children were excluded if their parents were unable to speak and understand English, French, or Spanish.

Measures

Gross Motor Function Classification System (GMFCS)

The GMFCS is a five-point classification system used to describe gross motor function ability including sitting, transfers, walking and wheeled mobility for children with CP. The child's functional abilities, use of assistive technology, and need for care giver assistance differentiates the levels.[8] The GMFCS levels are divided into age bands to clearly describe gross motor function as age. GMFCS content validity,[8] construct validity, and inter-rater reliability have previously been supported.[19-21]

Early Clinical Assessment of Balance (ECAB)

The ECAB provides an estimate of postural stability for children with CP across all GMFCS levels.[14] The assessor examines the child's head and trunk control, protective responses, upright posture in sitting and standing, and postural adjustments during voluntary movements in standing. The ECAB has known-groups validity for children with CP 1.5-12 years of age, with average scores that differ between age groups and all GMFCS levels ($p<0.001$),[14] as well as excellent inter-rater (ICC (2,1) = 0.99) and test-retest (ICC (2,1) = 0.99) reliabilty.[22] The ECAB has a minimal detectible change (MDC_{95}) of 10 points.[14] The total ECAB score out of 100 was used for analysis. The higher the score, the better the balance.

Spinal Alignment and Range of Motion Measure (SAROMM)

The SAROMM provides an overall estimate of *spinal alignment* and *ROM and muscle extensibility* using standard physical therapy measurement techniques.[15] The assessor scores 4 spinal alignment items using a 5-point ordinal score of 0 ("no alignment limitations with active correction") to 4 ("Fixed" – limitation is structural, static, not reducible and severe). For the remaining extremity *ROM and muscle extensibility* items, the assessor scores items using a 5-point ordinal score of 0 ("normal" - no restrictions of ROM on passive testing and no postures typical of some children with CP) to 4 ("fixed" – limitation is structural, static, irreducible and is severe), hence a lower score is better ROM.[15] Researchers report good validity, inter-rater reliability (ICC (2,1) = 0.89), and test-retest reliability (ICC (2,1) = 0.93) when used with children with CP.[15] For the SAROMM, total score the MDC_{90} has been reported as 3.22[23] and MDC_{95} as 9 points,[15] and the minimal clinically important difference (MCID) is 4.53.[23] The mean of all item scores for each child was used for analysis.

4-Item Early Activity Scale for Endurance (EASE)

The 4-item EASE includes four questions of parent perception of the child's endurance for activity.[16] Questions are scored using a 5-point ordinal scale of 1(Never) to 5 (Always) and include the child's (1) physical activity related to peers, (2) physical energy level and their need to take breaks, (3) frequency of breathing quickly and getting flushed during activity, and (4) frequency of daily activities requiring a lot of physical energy. Higher scores indicate greater endurance for activity. The EASE is moderately correlated (Spearman r=0.41, p = 0.01) with the Six-Minute Walk Test[16] and has acceptable inter-rater reliability (ICC (2,1) = 0.79).[16] The EASE does not have a calculated MDC. The mean EASE score was used for analysis.

Functional Strength Assessment (FSA)

The FSA includes an assessment of eight movements against gravity and resistance, providing an estimate of the child's strength in major muscle groups.[2] The assessor rates the child's strength using a 5-point ordinal scale ranging from 1 (only flicker of contraction or just initiates movement against gravity) to 5 (full available range against gravity and strong resistance) for major muscle groups (neck and trunk flexors and extensors, hip extensors, knee extensors, and shoulder flexors).[2] The FSA has excellent inter-rater reliability (ICC (2,1) = 0.996);[2] however, the FSA does not have a calculated MDC. The mean FSA score is used for analysis with a higher score indicating better strength.

The ECAB, SAROMM, EASE, and FSA forms and training protocols can be accessed through the CanChild website (https://www.canchild.ca/en/research-in-practice/current-studies/on-track/on-track-measures).

Procedures

Therapist assessors were physical therapists and occupational therapists, with at least one year experience, from Canada and the United States who completed onsite training prior to data collection. Therapist's also completed videotaped criterion tests of the ECAB, SAROMM and FSA measures and obtained greater than or equal to 80% item agreement with the study investigators providing 'gold standard' responses.

Data from the first assessment of the Move & PLAY study (T1) collected between summer 2007 and spring 2009, and data from the first assessment of the On Track study (T2) collected between spring 2013 and summer 2014 were used for this analysis. Parents completed the EASE and a demographic questionnaire. Therapist assessors completed the ECAB, SAROMM, and FSA. The parent and therapist assessor independently completed the

GMFCS and a consensus rating was determined.[24] For this analysis, we used the GMFCS rating from the On Track study (T2) because some children at T1 were under 2 years old and GMFCS reliability is greater after 2 years of age.[20]

Data Analysis

Data were analyzed using the Statistical Package for Social Sciences (Version 18). Descriptive statistics of participants are in Table 1. Median and minimum/maximum range for impairments (ECAB, SAROMM, EASE, and FSA) are presented in Table 2. Because of the small sample size of children at GMFCS Level III, these children were combined with children at GMFCS Level IV for group comparisons for the impairment measures. The Wilcoxon Signed Ranked test was used for comparison of medians between T1 and T2 for GMFCS level groups (Table 2). Comparisons of median scores for each variable across GMFCS level groups were completed for data at both T1 and T2 using non-parametric, Kruskal-Wallis tests with post hoc pairwise comparisons to determine if significant differences existed across GMFCS levels (Table 3). An alpha level of $p < 0.05$ was used to indicate significance for overall testing.

Results

Children were 1.5 to 4.6 years old (mean 2.9 yrs, SD=.9) at T1 and 6.3 to 11.1 years old (mean 8.7 yrs, SD=1.1) at T2. Participants were 52% males and 79% white. The proportion of children in each GMFCS level in our sample was: GMFCS I – 26.0% (N=20); GMFCS II – 29.9% (N=23); GMFCS III – 9.1% (N=7); GMFCS IV – 13.0% (N=10); GMFCS V – 22.1% (N=17). Table 1 contains demographic information. On average, the time difference between T1 and T2 was 5.8 years (SD .6 yrs).

Comparing ECAB scores over time, significant improvements in balance were noted for children in GMFCS levels I ($p<0.001$), II ($p<0.001$), and III/IV ($p=0.008$), (Table 2). At both T1 and T2 assessments, significant differences were noted on the ECAB across all comparisons with children with more functional mobility demonstrating higher ECAB scores than children with less functional mobility (Table 3).

Overtime SAROMM scores were significantly higher at T2, for children in GMFCS levels III/IV ($p=0.005$) and V ($p<0.001$) indicating greater ROM restrictions (Table 2). At both T1 and T2 assessments, significant differences were noted on the SAROMM across all comparisons, except between children in levels II and III/IV at T1 (Table 3).

No differences in EASE scores within GMFCS levels were noted over time (Table 2). On the EASE, at both T1 and T2 assessments, significant differences were noted across all comparisons, except between children in levels II and III/IV at both T1 and T2 (Table 3).

Comparing FSA scores over time, significant improvements in strength were noted for children in GMFCS levels I ($p<0.001$) and II ($p<0.001$) (Table 2). At both T1 and T2 assessments, significant differences were noted on the FSA across all comparisons, except between children in levels II and III/IV at T1, and between children in levels I and II at T2 (Table 3).

Discussion

This study provided the opportunity to follow 77 children with CP longitudinally over a multiyear period to explore how commonly identified impairments changed over time. Finding for each construct are discussed below.

Significant differences in balance were noted from T1 to T2 for all children with CP except those with GMFCS level V. As expected, children with more gross motor ability demonstrated better balance than children with less gross motor ability. For the majority of children, the amount of change in balance was greater than the minimal amount of change required to differentiate a true change versus a change due to variability in performance.

As balance is correlated to gross motor ability[25] and gross motor skills continue to develop as children with CP age[26] this improvement was expected. For children in level V, the balance median score decreased. Gross motor skills of children at level V plateau on average at 2 years 7 months[19] indicating gross motor skills are not significantly changing, therefore, one could theorize that balance skills will also not change. This longitudinal exploration of balance in children with CP provides a beginning analysis. Continued exploration is needed to determine if differences in service focus and frequency influences a child's balance abilities.

Similar to the results of Ostensjo and colleagues,[9] children with CP in our study presented with some degree of ROM and spinal alignment restrictions regardless of GMFCS level. As expected, children with higher functional mobility presented with fewer restrictions compared to children with lower functional abilities. For the majority of children, the amount of change in ROM scores was greater than the minimal amount of change required to differentiate a true change and they had restrictions beyond what is typically considered a clinical change that influences their daily activities.

When ROM and spinal alignment were measured over time, children at GMFCS levels I and II did not present with a significant change. Based on this study's methodology, direct correlations cannot be examined to determine what prevented the progression of joint restrictions; however, one can hypothesize independent mobility likely facilitates joint and spinal flexibility. Children with higher GMFCS levels rely on assistive devices for mobility (walkers or wheelchairs) and spend a good deal of time seated or even lying down, therefore, these static postures likely contribute to the development of secondary impairments in ROM. This presents as an opportune window for intervention to prevent increases in joint restrictions in children in levels III-V particularly. The challenge is what intervention should be used. Based on a systematic review brief stretching has little to no effect either short-term or long-term on improving joint mobility in persons with neurological conditions.[27] A heightened focus on increasing targeted functional activities and more frequent changes in positions for those at GMFCS Level V may assist to prevent further ROM restrictions. Within our data, however, we do not know the details of interventions to prevent secondary impairments and how increasing environmental modifications may alter the development of ROM restrictions.

As we expected endurance for activity was higher for children with higher functional mobility. Median EASE scores decreased at each GMFCS level but were not significantly different over time. What is unknown is if endurance is relatively constant over time for children with CP in this age range, the tool is not sensitive enough for longitudinal change, or a larger sample of children is needed to identify longitudinal change. We know from physical activity literature that endurance typically decreases in adolescents without disabilities,[28] so tracking children with CP into the future to identify if and when changes in endurance occur is needed. Also since parents report no change in endurance, we hypothesis that maybe this is an area of intervention therapists do not focus on. We recommend in the future therapists should consider targeted interventions focused on endurance at all GMFCS levels and ages.

As expected, strength scores were higher for children with higher motor function. Over time strength scores significantly improved for children in GMFCS levels I and II. This is congruent with literature demonstrating children with CP have the ability to strengthen various muscle groups.[29] Additionally the FSA scores for children in the other GMFCS levels increased but were not significantly different across time. There are varying results in the literature related to strengthening interventions for children with CP and the carry over to functional motor skills.[30] Most literature focuses on children at GMFCS levels I-III since they more often have the ability to demonstrate selective motor control. Given that a focus on services related to secondary impairments increases over time, more details from therapists would be helpful to determine effective strengthening interventions especially for children with lower functional ability.

As most children with CP receive therapy services during their early childhood, therapists have the opportunity to support maturation during this critical period of growth and skill development. Although, we were unable to determine the impact of therapy services nor the child's natural evolution of skill mastery, most children with CP were stronger, had better balance, and their endurance had not significantly declined after almost six years. Based on these results and the knowledge that in adolescents and young adulthood, individuals get heavier and flexibility and endurance decline,[28, 31, 32] therapists should encourage health and wellness programs that focus on strength and cardiopulmonary fitness whether that be in a therapist directed or community program.

Limitations

The primary limitation of this study is the small sample size. To acknowledge this, we used non-parametric statistics for data analysis. **We did not correct for multiple analyses, however as most p values were below <0.001 one could determine this was not a problem**.

We also combined data for children in GMFCS levels III and IV. The EASE and FSA measures do not have MDC or MCID values, which would have provided additional information regarding change over time. This study had a slightly lower proportion of children at GMFCS level I and a greater proportion of children at level V compared to the Reid and colleagues'[33] determination of the GMFCS distribution of CP based on multiple international registries. Finally, a potential sampling bias could be present as parents agreed to participate in two research studies over time which could indicate they are closely linked to rehabilitation providers and potentially engaged in intervention programs more than other children.

Conclusion

The results of this study indicate there are improvements in children with CP within some impairment areas (balance and strength), however greater ROM restrictions and no changes in endurance are noted over an extended time. These changes support the need for physical therapists to monitor and focus interventions on primary and secondary impairments in children with CP, given the hypothesis that each of these impairments can potentially impact the children's ability to perform daily activities and participate in home, school and community environments. Based on this longitudinal study, continued monitoring of impairments and collaboration with families is important for the development of children with CP.

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Table 1. Children’s demographics and clinical characteristics

Child Demographics		
Gender (%)	Male	40 (52)
	Female	37 (48)
Ethnicity (%)	African-American	3 (4)
	Asian or Pacific Islander	3 (4)
	Hispanic/ Latino	1 (1)
	Native American	3 (4)
	White	61 (80)
	Other	4 (6)
	Data not available	2(1)
GMFCS Level (%)	I: Independent self-mobility	20 (26)
	II	23 (30)
	III	7 (9)
	IV	10 (13)
	V: Severe limitations in posture/self-mobility	17 (22)
Distribution of Involvement (%)	Quadriplegia	40 (52)
	Hemiplegia	19 (25)
	Diplegia	14 (18)
	Triplegia	3 (4)
	Data not available	1 (1)

Abbreviation: SD = standard deviation

Table 2: Balance, Range of Motion, Endurance, and Strength comparisons across time by Gross Motor Function Classification System (GMFCS) level

Early Clinical Assessment of Balance (ECAB)			
GMFCS level	**Time 1 Median (min, max)**	**Time 2 Median (min, max)**	**Wilcoxon Signed Ranks Test**
I	87.00 (43.50, 100.0)	100.00 (78.00, 100.00)	**Z=3.62; p < 0.001**
II	45.00 (18.00, 100.0)	86.0 (48.0, 100.00)	**Z=3.90; p < 0.001**
III/IV	21.00 (9.00, 40.50)	32.0 (6.00, 51.50)	**Z=2.66; p = 0.008**
V	5.00 (2.00, 15.00)	3.5.0 (0, 29.00)	Z=-0.57; p = 0.57
Spinal Alignment and Range of Motion Measure (SAROMM)			
I	.23 (.00, .85)	.31 (.08, .96)	Z=1.39; p = 0.17
II	.50 (.00, 1.42)	.85 (.08, 1.85)	Z=1.99; p = 0.05
III/IV	.54 (.12, 1.73)	1.54 (.08, 2.08)	**Z=2.82; p = 0.005**
V	1.38 (.65, 1.77)	2.23 (.96, 2.92)	**Z=3.29; p < 0.001**
Early Activity Scale for Endurance (EASE)			
I	4.25 (3.0, 5.0)	4.00 (2.25, 5.0)	Z=1.28; p = 0.20
II	3.25 (1.75, 5.0)	3.25 (1.75, 4.75)	Z=1.10; p = 0.27
III/IV	3.00 (1.25, 5.0)	2.50 (1.25, 4.25)	Z=1.09; p =0.27
V	1.75 (1.0, 3.5)	1.25 (1.0, 3.25)	Z=0.75; p = 0.45
Functional Strength Assessment (FSA)			
I	3.5 (2.88, 4.00)	4.56 (2.88, 5.00)	**Z=3.69; p < 0.001**
II	3.00 (1.75, 4.00)	4.13 (2.5, 5.00)	**Z=4.17; p < 0.001**
III/IV	2.63 (1.5, 3.75)	3.13 (1.25, 4.25)	Z=1.89; p = 0.06
V	1.25 (.13, 2.5)	1.63 (1.00, 3.38)	Z=1.29; p = 0.20

Table 3: Balance, Range of Motion, Endurance, and Strength pairwise comparisons by Gross Motor Function Classification System (GMFCS) level

Early Clinical Assessment of Balance (ECAB)			
GMFCS level	**Comparison GMFCS level**	**P-value T1**	**P-value T2**
I	II	<.001*	0.003*
	III/IV	<.001*	<0.001*
	V	<.001*	<0.001*
II	III/IV	<.001*	<0.001*
	V	<.001*	<0.001*
III/IV	V	<.001*	<0.001*
Spinal Alignment and Range of Motion Measure (SAROMM)			
GMFCS level	**Comparison GMFCS level**	**p-value T1**	**p-value T2**
I	II	.004*	0.001*
	III/IV	.001*	<0.001*
	V	.000*	<0.001*
II	III/IV	.30	0.02*
	V	<.001*	<0.001*
III/IV	V	.002*	0.002*
Early Activity Scale for Endurance (EASE)			
GMFCS level	**Comparison GMFCS level**	**p-value T1**	**p-value T2**
I	II	.01*	0.01*
	III/IV	<.001*	0.001*
	V	<.001*	<0.001*
II	III/IV	.07	0.07
	V	<.001*	<0.001*
III/IV	V	.001*	0.003*
Functional Strength Assessment (FSA)			
GMFCS level	**Comparison GMFCS level**	**p-value T1**	**p-value T2**
I	II	.002*	0.15
	III/ IV	<.001*	<0.001*
	V	<.001*	<0.001*
II	III/IV	.09	<0.001*
	V	<.001*	<0.001*
III/IV	V	<.001*	<0.001*

*P < 0.05