

THE STUDY OF QUALITY OF LIFE BEFORE AND AFTER ADMINISTRATION OF *BOTULINUM* TOXIN TO CHILDREN WITH CEREBRAL PALSY VERSUS CONTROL GROUP

IULIANA ȘTEFANIA DINU¹, HOUSSEIN TOUFIC SEBLANY^{1*},
MONICA SAFER², DOINA ANCA PLEȘCA²

¹*University of Medicine and Pharmacy „Carol Davila”, Dionisie Lupu
37 street, 2nd district, Bucharest*

²*Department of Pediatrics and Pediatric Neurology, „Victor Gomoiu”
Children Clinical Hospital, University of Medicine and Pharmacy „Carol
Davila”, Dionisie Lupu 37 street, 2nd district, Bucharest*

** corresponding author: housseinovici@yahoo.com*

Abstract

Cerebral palsy (CP) refers to a group of disorders in the development of motor control and posture, occurring as a result of a non-progressive impairment of the developing central nervous system. CP is a permanent disease which cannot be cured, but the consequences can be minimized and thus the negative impact can be reduced and the quality of life improved.

Using Family Quality of Life Survey (FQOLS) – the version addressed to the main caregiver of the child with disability translated in Romanian language, the present study aimed to explore the quality of life (QoL) and to identify the areas of life that are affected for a CP child treated with *botulinum* toxin and child's family compared to CP children who did not receive pharmacologic treatment, initially and after the follow-up period.

The scores were statistically analyzed with the non-parametric Mann-Whitney U test for independent samples.

Rezumat

Paralizia cerebrală (PC) este o afecțiune neurologică cronică ce se caracterizează prin tulburări ale motilității și posturii care apar ca o consecință a unei/unor leziuni cerebrale non-progresive apărute în timpul dezvoltării prenatale, perinatale sau postnatale a creierului. PC reprezintă o afecțiune cronică, care nu poate fi vindecată, dar care printr-un tratament susținut (kinetoterapie, terapie medicamentoasă, tratament chirurgical, logopedie, terapie ocupațională, etc.) conduce la o ameliorare evidentă a consecințelor.

Studiul de față a avut ca scop compararea calității vieții în grupul copiilor cu PC tratați cu toxină botulinică față de grupul de control al copiilor cu PC care nu au primit tratament farmacologic, inițial și după o perioadă de urmărire și identificare a domeniilor influențate.

Scorurile au fost analizate statistic cu testul neparametric Mann-Whitney pentru eșantioane independente.

Keywords: cerebral palsy (CP), quality of life (QoL), area of life.

Introduction

Cerebral palsy (CP) refers to a group of disorders in the development of motor control and posture, occurring as a result of a non-progressive impairment of the developing central nervous system [1, 9]. CP is characterized by abnormal motor control which can impact fine motor skills, gross motor skills and oral motor functioning and/or abnormal posture and can involve communication difficulties. Every case of CP can be considered as unique due to the type of injury and the timing of the injury to the developing brain. CP is a non-progressive condition and the injury and damage to the brain is permanent [3, 4, 5, 7].

Children with CP face many social and developmental challenges including, but not limited to, restricted physical activity and motion, poor socialization, limited recreational activities and leading as a direct consequence to stigmatization and thus to an obvious impairment of the quality of life (QoL) [3, 4, 5, 7, 13]. This impairment reflects in family' QoL also as the family plays a key role in supporting the child with CP to adapt to a life on which this medical condition puts its mark [2, 8, 9, 11].

CP is a permanent disease which cannot be cured, but the consequences can be minimized and thus the negative impact can be reduced and the QoL improved [6, 12].

Materials and Methods

The patients included in the study were selected from the database of the Pediatrics and Pediatric Neurology Department of „Victor Gomoiu” Children Clinical Hospital, Bucharest, Romania. The study was approved by the Ethics Committee of „Victor Gomoiu” Children Clinical Hospital. For all the children in the study, the written consent was obtained from children's parents for using the medical data, ensuring also privacy and identity protection of the subjects.

This paper included data from 72 patients diagnosed with CP. The treated group included 40 patients treated with *botulinum* toxin, female (42.5%) and male (57.5%), the mean age ($\pm$ SD) 6.00 ± 2.34 years. The control group included 32 patients who did not receive medical treatment, female (53.1%) and male (46.9%), mean age ($\pm$ SD) 6.19 ± 1.23 years.

Exclusion criteria: patients with severe spasticity, mixed forms of CP, children who underwent orthopedic surgery, patients whose parents didn't understand the items from questionnaire.

This paper presents the results regarding the QoL in CP children before and after administration of *botulinum* toxin compared with control

group and another aim of this work was to identify the areas of life that are affected for a family that has a child with CP.

Questionnaire Management

In order to assess the QoL, it was employed Family Quality of Life Survey (FQOLS) – the version addressed to the main caregiver of the child and translated in Romanian language.

FQOLS is structured as follows:

1. About Your Family chapter which introduces the family members.
2. The next nine chapters address specific areas of life: health, financial well-being, family relationships, support from others, support from services, influence of values, careers, leisure and recreation and community integration.

Each of these nine chapters has two sections: Section A providing the context and containing questions that collect some general information and Section B which contains questions related to six key concepts: importance, opportunities, initiative, attainment, stability and satisfaction.

3. The final part asks for overall impressions on Family QoL [10].

The FQOLS was completed by the health professional with the main caregiver (face-to-face administration) so that the parent to have the possibility to ask any questions that might arise.

The questionnaire meets a score from 1 (minimum) to 5 (maximum) for each question.

Results and Discussion

The patients included in the study were primarily diagnosed with CP. For both treated and control groups, the scores assigned to the satisfaction as key concept were statistically analyzed for the nine areas of life. Descriptive statistics for the scores determined at the initial assessment and at the follow-up assessment are presented in Table I and Table II.

Table I
Descriptive statistics of the scores for satisfaction in the nine key areas of QoL at
the *initial assessment*

#	Area of life	GROUP	N	Mean	Std. Deviation
Initial assessment	Health of the family	1	40	1.68	0.694
		2	32	1.31	0.471
	Financial well-being	1	40	1.93	0.616
		2	32	1.16	0.369
	Family relationships	1	40	2.43	0.781
		2	32	1.66	0.602
	Support from other people	1	40	2.10	0.672
		2	32	1.59	0.615

	Support from disability related services	1	40	2.08	0.616
		2	32	3.44	0.669
	Influence of values	1	40	2.90	0.900
		2	32	3.59	0.560
	Careers and preparing for careers	1	40	2.18	0.675
		2	32	1.31	0.471
	Leisure and recreation	1	40	2.03	0.620
		2	32	1.19	0.397
	Community interaction	1	40	2.08	0.526
		2	32	2.47	0.761
	Overall QoL	1	40	2.05	0.389
		2	32	2.06	0.619
	Overall satisfaction on QoL	1	40	1.98	0.530
		2	32	1.78	0.553

Group 1 = treated group

Group 2 = control group

Table II

Descriptive statistics of the scores for satisfaction in the nine key areas of QoL at the *follow-up assessment*

#	Area of life	GROUP	N	Mean	Std. Deviation
Follow-up assessment	Health of the family	1	40	4.10	0.496
		2	32	1.34	0.483
	Financial well-being	1	40	3.50	0.679
		2	32	1.47	0.621
	Family relationships	1	40	4.10	0.591
		2	32	1.97	0.782
	Support from other people	1	40	3.75	0.588
		2	32	1.63	0.660
	Support from disability related services	1	40	3.70	0.516
		2	32	3.22	0.706
	Influence of values	1	40	3.55	0.639
		2	32	3.38	0.660
	Careers and preparing for careers	1	40	3.45	0.639
		2	32	1.34	0.545
	Leisure and recreation	1	40	3.85	0.580
		2	32	1.28	0.457
	Community interaction	1	40	3.50	0.506
		2	32	2.50	0.803
	Overall QoL	1	40	3.48	0.751
		2	32	1.88	0.609
	Overall satisfaction on QoL	1	40	3.58	0.636
		2	32	1.88	0.660

Group 1 = treated group

Group 2 = control group

The non-parametric Mann-Whitney U test for independent samples was applied for comparing the CP treated group with the CP control group scores assigned to satisfaction regarding each area of life. The test was applied independently, both for the initial assessment scores and for the follow-up scores. The results are presented in Table III and Table IV.

Table III

Mann-Whitney test applied for comparison between CP treated group and CP control group scores regarding each area of life at the *initial assessment*

#	Area of life	Mann-Whitney statistic U	p
Initial assessment	Health of the family	463.000	0.023
	Financial well-being	218.000	< 0.001
	Family relationships	309.000	< 0.001
	Support from other people	392.500	0.002
	Support from disability related services	118.500	< 0.001
	Influence of values	339.000	< 0.001
	Careers and preparing for careers	225.000	< 0.001
	Leisure and recreation	208.000	< 0.001
	Community interaction	442.500	0.011
	Overall QoL	629.000	0.869
	Overall satisfaction on QoL	532.500	0.132

Mann-Whitney statistic U applied to the satisfaction scores for comparison between the two groups in each area of life associated a probability $p < 0.05$ for all the areas of QoL, which shows a statistical significant difference between the treated group and control group at the initial assessment. Based on these results, we can conclude that the perception on QoL is different between the treated and control groups.

Regarding overall QoL and overall satisfaction on QoL, Mann-Whitney statistic could not highlight a significant difference ($p > 0.05$) between the two CP groups at the initial assessment which suggests that the global satisfaction was similar for the two groups at this time point.

Table IV

Mann-Whitney test applied for comparison between CP treated group and CP control group scores regarding each area of life at the *follow-up assessment*

#	Area of life	Mann-Whitney statistic U	p
Follow-up assessment	Health of the family	0.000	< 0.001
	Financial well-being	37.500	< 0.001
	Family relationships	33.000	< 0.001
	Support from other people	25.000	< 0.001
	Support from disability related services	398.500	0.002
	Influence of values	569.000	0.370
	Careers and preparing for careers	20.500	< 0.001
	Leisure and recreation	4.500	< 0.001
	Community interaction	220.000	< 0.001
	Overall QoL	94.000	< 0.001
	Overall satisfaction on QoL	69.500	< 0.001

Mann-Whitney statistic U applied to the comparison between the two groups scores for satisfaction in each area of life at the follow-up assessment, associated a probability $p < 0.01$ for all the areas, except "Influence of values", which shows a strong statistical significant difference

between the treated and control groups at the follow-up assessment. These results confirm the hypothesis that administration of treatment improves satisfaction on QoL.

For each group, treated and control, independently, the scores assigned to satisfaction in each area of life, including global satisfaction on QoL, at the initial assessment, were compared with those measured at the follow-up assessment. This was done using the non-parametric Wilcoxon signed ranks test for dependent samples. The results are presented in Table V and Table VI.

Table V

Non-parametric Wilcoxon test in *CP treated group* applied for the *initial and follow-up assessment scores*

Group	Area of life	Wilcoxon statistic Z	p
CP treated	Health of the family	-5.650	< 0.001
	Financial well-being	-5.221	< 0.001
	Family relationships	-5.245	< 0.001
	Support from other people	-5.650	< 0.001
	Support from disability related services	-5.504	< 0.001
	Influence of values	-3.963	< 0.001
	Careers and preparing for careers	-5.410	< 0.001
	Leisure and recreation	-5.772	< 0.001
	Community interaction	-5.542	< 0.001
	Overall QoL	-5.297	< 0.001
	Overall satisfaction on QoL	-5.496	< 0.001

For CP treated group, the non-parametric Wilcoxon test highlighted a statistical significant difference ($p < 0.001$) between scores of satisfaction in each area of life, including overall QoL and overall satisfaction on QoL, measured at the initial and follow-up (after administration of pharmacologic treatment) time points. This significant change in satisfaction expressed from parent's point of view in all areas of QoL sustains the hypothesis that administration of botulinum toxin improves patient's and his family QoL.

Table VI

Non-parametric Wilcoxon test in *CP control group* applied for the *initial and follow-up assessment scores*

Group	Area of life	Wilcoxon statistic Z	p
CP control	Health of the family	-0.577	> 0.05
	Financial well-being	-2.236	< 0.05
	Family relationships	-2.132	< 0.05
	Support from other people	-0.447	> 0.05
	Support from disability related services	-2.111	< 0.05
	Influence of values	-2.333	< 0.05
	Careers and preparing for careers	-0.577	> 0.05
	Leisure and recreation	-1.732	> 0.05
	Community interaction	-0.447	> 0.05
	Overall QoL	-2.121	< 0.05
	Overall satisfaction on QoL	-1.342	> 0.05

In CP control group, the non-parametric Wilcoxon test could highlight a statistical significant difference ($p < 0.05$) only in some areas like “Financial well-being”, “Family relationships”, “Support from disability related services” and “Influence of values”. In other fields like “Health of the family”, “Support from other people”, “Careers and preparing for careers”, “Leisure and recreation” and “Community interaction” the Wilcoxon test values were not associated to a statistical significant difference ($p > 0.05$). The non-parametric Wilcoxon test showed a slight statistical significant difference ($p = 0.34$) regarding overall QoL.

CP is a medical condition with major implications on QoL. CP can't be cured, but the consequences can be relieved with administration of pharmacologic treatment. In our opinion, the results confirm the hypothesis that the perspective remains unchanged on long-term if we think of health improvement, the support that the family might receive from other people, the opportunity of a carrier or the recreation activities of the family that is also influenced in the absence of an improvement of health condition of the family member with CP.

Conclusions

There is a difference in expressing satisfaction in the nine considered areas of life between the cerebral palsy treated group and cerebral palsy control group even before administration of *botulinum* toxin. In our opinion, the perspective of pharmacologic treatment alternative influences satisfaction on QoL from parent's point of view expressed in the treated group.

Analysis of satisfaction before and after administration of pharmacological treatment revealed a statistical significant difference between assessments before and after treatment. Thus, we may conclude that pharmacological treatment administration alternative improves quality of life and perception upon it expressed by satisfaction as key point.

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Manuscript received: November 2013