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QUALITY OF LIFE OF CHILDREN WITH CEREBRAL PALSY TREATED WITH BOTULINUM TOXIN

Are well-being measures appropriate?

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Abstract – Aim: To analyze quality of life (QOL) of children with cerebral palsy (CP) treated with botulinum toxin type A (BTXA). **Method:** Two QOL evaluation tools, translated into Portuguese, were used: Pediatric Outcomes Data Collection Instrument (PODCI) and Child's Caregiver Questionnaire (CCQ). Questionnaires were answered by caregivers on two occasions. Patients were divided into 3 groups: I – patients who had been previously treated with BTXA and who underwent a session of BTXA; II – patients who used BTXA for the first time; III – patients previously treated with BTXA but did not in this interval. **Results:** Sixty-eight patients were evaluated. In group I (n=26) the functional ability had improvement for all types of CP (p=0.04), and tetraplegic increased interaction/communication (p=0.02). In group II (n=14) positioning improved (p=0.02). Group III (n=28) showed no change in QOL. **Conclusion:** PODCI and CCQ are able to capture outcome in children with CP.

KEY WORDS: cerebral palsy, quality of life, questionnaires of quality of life, botulinum toxin type A.

Qualidade de vida em crianças com paralisia cerebral tratadas com toxina botulínica: estas avaliações são adequadas ?

Resumo – Objetivo: Analisar a qualidade de vida (QV) de crianças com paralisia cerebral tratadas com toxina botulínica do tipo A (TBA). **Método:** Dois instrumentos de QV, adaptados para a língua portuguesa, foram utilizados: Instrumento para Avaliação de Resultados de Reabilitação em Pediatria (IARRP) e Questionário do Cuidador da Criança (CQC), sendo respondidos pelos cuidadores. Os pacientes foram divididos em 3 grupos: I – já haviam utilizado TBA e foram submetidos à aplicação neste intervalo; II – utilizaram TBA pela primeira vez; III – utilizaram TBA previamente, mas não neste intervalo. **Resultados:** Sessenta e oito pacientes foram avaliados, no grupo I (n=26) houve melhora da capacidade funcional em todos os tipos de PC (p=0.04), e tetraplégicos tiveram ganho também na interação/comunicação (p=0.02). No grupo II (n=14) houve melhora em posicionamento (p=0.02). Não foram observadas mudanças na QV do grupo III (n=28). **Conclusão:** IARRP e CQC são capazes de avaliar resultados em crianças com PC.

PALAVRAS-CHAVE: paralisia cerebral, qualidade de vida, questionários de qualidade de vida, toxina botulínica do tipo A.

Several questionnaires have been developed in an attempt to measure well-being in children with cerebral palsy (CP), major cause of motor deficits in children and adolescents. These patients were submitted a multiple treatment options for a long time and health professionals who care for their need know about patient/families' expectations and perceptions of happiness about physical function[1-3].

At our days botulinum toxin type A (BTXA) is an important modality for the treatment of patients with cerebral palsy (CP)[4]. Several studies using the Ashworth scale and goniometry have shown that BTXA is a useful tool for the management of children and adults with spasticity[5-15]. Assessment of quality of life (QOL) may reflect the effect of clinical intervention[16-18].

The aim of this study is to verify if QOL have the abil-

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ity to detect differences in health states in children and adolescents with CP treated with BTXA.

METHOD

Reference population

The reference population in this study had been seen at the Pediatric Spasticity Outpatient Clinics (PSOC) at the Neuropediatrics Center (CENEP) of the Federal University of Parana General Hospital since the beginning of the year 2001, as a result of a partnership with the Health Department of the State of Parana to supply botulinum toxin type A (BTXA). The PSOC team consists of professionals from the following areas: pediatric neurology, pediatric orthopedics, physical therapy, occupational therapy, nursing, social work, anesthesia, psychology, neuro psychology, pedagogy, pediatrics and pediatric neurology interns, administration, and volunteers. Patients at PSOC participate in a rehabilitation program, which basically consists of 1 to 2 physical therapy sessions per week. In view of this, caregivers received instructions from our team for daily stretching, positioning, and use of extending and polypropylene splints when appropriate in order to optimize results from the therapeutic management.

Injections are performed using electro-stimulation guidance. Selection of the muscles for blockade and its performance is carried out under direct supervision by the PSOC (LHCS) coordinator. The toxin used was botulinum toxin type A (BOTOX®, Allergan, Irvine, CA, USA), and the maximum dose was 15 U/kg per session, up to 500 U, with a minimum interval of three months between sessions.

We evaluated patients from May to September in 2003. There were 68 patients whose caregivers answered the two questionnaires on two occasions – *before* and *after*. They were divided into 3 groups: Group I – patients who were already receiving BTXA at PSOC and who were treated with BTXA injections in the period of time between the questionnaires; Group II – patients who had no previous application of BTXA but who began BTXA therapy between the questionnaires; Group III – patients who were being followed up and had already received BTXA, but were not treated with BTXA in this period. Patients were excluded if their parents refused to participate in the study, were illiterate, or did not answer the second questionnaire. This work was approved by the Scientific Committee of the Department of Pediatrics and the Human Research Ethics Committee of the Federal University of Parana General Hospital. Consent to participate in the study was obtained by signing the Free and Informed Consent Form.

Evaluation of quality of life

Two instruments were used to evaluate quality of life. They are based on self-reports from the guardians while the patients were waiting to be seen at the clinic. Questionnaires were translated into Portuguese (http://www.hc.ufpr.br/acad/pediatria/index.htm), then back into English by a native speaker and, subsequently, both English versions were compared by an arbitrator.[17] Explanations on how to answer the questionnaires were given by the first author (TRSA) that did not know the patients' clinical and therapeutic history and/or classification. All questionnaires were checked upon return to verify if all fields were completed.

The child's caregiver's questionnaire[18] (CCQ, or Questionário do Cuidador da Criança – QCC – in the Portuguese version) has four domains: Personal Care (PEC), Positioning/Transferring (POSIC), Comfort (COMF), and Interaction/Communication (INTER). The Pediatric Outcomes Data Collection Instrument[19] (PODCI, or Instrumento para Avaliação de Resultados de Reabilitação em Pediatria – IARRP – in the Portuguese version) was used in a format to be answered by children's parents and/or tutors, from their birth to their adolescence in this study. Dimensions were Upper Extremity and Physical function (UEP), Transfers and Basic Mobility (TBM), Sports and Physical Function (SPF), Pain and Comfort (PC), Expectations (EXP), Happiness, (HAPP), and Global Function and Symptoms (GFS). GFS is obtained from the variables of the UEP, TBM, SPF, and PC scores. For Groups I and II, questionnaires were administered before blockade with BTXA (*Before* – B), and after a period of time of 30 to 90 days from the blockade (*After* – A). For Group III, consisting of patients not receiving BTXA injections, questionnaires were administered within the same period of time as in Groups I and II.

To perform socioeconomic classification of the families, we used Criterion Brasil 97, from the Brazilian Association of Market Research Institutes (ABIPEME), which takes the family supporter's education level and family's comfort items into consideration. Considering the final score we have 5 classes (A, B, C, D and E), where A is the highest and E is the lowest.

Data obtained from the charts included: age, gender, education, relatedness level of the informer; family supporter's education level, date of the latest BTXA injection, follow-up at PSOC, clinical classification, spasticity etiology and side effects of BTXA injection. Patients were clinically classified into the following groups: hemiplegia, diplegia and tetraplegia.

Statistical analysis

To obtain PODCI scores, we used the SPSS program and the syntax sent to us by the orthopedics clinical research coordinator of the Children's Hospital of New York. For between-group and between-subgroup comparison of scores in each dimension, the non-parametric Mann-Whitney test was applied. For comparison of the two different time points, we used the non-parametric Wilcoxon test. To evaluate the association of variables with one another, Spearman's correlation coefficient was determined. For all tests, a p value <0.05 was considered to be statistically significant.

RESULTS

There were 68 patients (34 male and 34 female) ranging in age from 1 year and three months to 17 years and three months old. Gross Motor Functional Classification System

(GMFCS) were levels II-41, III-7, IV-14 and V-6. Twenty-six were in Group I; 14 in Group II, and 28 in Group III.

Group I (n=26) consisted predominantly of male patients (57.7%). Mean age was 6.15±3.6 years, ranging from 1 year and 8 months to 15 years and 7 months. GMFCS levels II-11, III-4, IV-10 and V-1. Mean follow-up period at PSOC was 12.9±3.9 months, ranging from 6 to 19 months. Previous injection was performed an average of 1.8±0.9 times, 1 to 4. The mean interval between questionnaires and the last injection was 7.3±2.2 months, 3 to 12 months. Mean interval between the answers to the questionnaires was 50.3±15.7 days, 33 to 91 days. Diplegia (10 patients) was predominant, followed by hemiplegia (8) and tetraplegia (8).

Group II (n=14) consisted predominantly of female patients (57.1%). Mean age was 5.8±3.64 years, ranging from 1 year and 3 months to 11 years and 3 months. GMFCS levels II-6, III-2, IV-2 and V-4. The mean follow-up period at PSOC was 3.4±4.3 months, 0.5 to 15 months. The mean period of time between the answers was 52.2±21.1 days, 33 to 97 days. Tetraplegia (6 patients) prevailed, followed by diplegia (4) and hemiplegia (4).

Group III (n=28) predominantly consisted of female patients (53.6%). Mean age was 6.3±3.6 years, ranging from 1 year and 9 months to 17 years and 3 months. GMFCS levels II-24, III-1, IV-2 and V-1. The mean follow-up period at PSOC was 13.3±3.8 months, 6 to 19 months. The mean number of previous injections was 2.2±1.1, 1 to 5. The mean interval between the *before* questionnaire date and the last injection was 4.5±3.3 months, 1 to 12 months. The mean period of time between the answers was 70.1±25.2 days, 25 to 105 days. Hemiplegia (19 patients) prevailed, followed by diplegia (5) and tetraplegia (4).

There social class C prevailed in groups I and III and social class D in group II. In the three groups, the family supporter's education was predominantly incomplete junior high school.

Twenty-six caregivers in group I answered the PODCI and CCQ at *Before* (B) and *After* (A). The means of each di-

Table 1. Global means and standard deviation (SD) of different dimensions of the quality of life questionnaires.

	Group I			Group II			Group III		
	n	mean	SD	n	mean	SD	n	mean	SD
UEPB	5	45.71	25.76	6	12.50	28.62	14	69.05	15.22
UEPA	7	54.17	26.60	6	12.50	28.62	13	75.00	16.84
TBMB	6	19.82	21.26	5	16.06	22.00	12	82.97	19.82
TBMA	5	39.39	29.26	6	14.60	18.83	15	84.33	16.14
SPFB	6	23.09	5.16	5	18.14	6.44	13	69.13	21.51
SPFA	8	26.83	18.60	6	20.09	7.74	15	69.92	19.96
PCB	7	82.38	19.76	6	75.09	22.57	16	85.90	14.90
PCA	8	76.39	22.75	6	81.57	15.93	18	84.63	15.42
EXPB	8	89.24	15.60	4	100.00	0.00	13	83.97	19.65
EXPA	6	94.44	10.09	3	98.15	3.21	15	84.26	18.14
HAPPB	7	94.11	8.86	5	83.00	13.51	12	87.92	14.53
HAPPA	7	90.95	7.87	5	83.00	14.40	14	89.88	10.63
GFSB	2	44.73	4.91	2	45.84	16.20	8	75.03	13.31
GFSA	4	61.25	10.04	2	46.22	16.74	10	77.27	11.07
PECB	8	21.25	10.93	6	40.33	24.74	19	11.84	11.03
PECA	8	22.75	12.04	6	32.00	24.23	19	15.42	11.83
POSIB	8	12.50	6.46	6	30.33	25.35	19	6.11	6.05
POSIA	8	13.13	10.63	6	15.67	12.85	19	6.53	4.53
COMFB	8	18.13	8.48	6	20.83	17.76	19	13.63	3.82
COMFA	8	10.75	5.42	6	17.00	8.56	19	13.42	3.10
INTERB	8	17.00	11.67	6	38.50	12.57	19	16.53	13.50
INTERA	8	13.13	12.46	6	26.00	12.60	19	13.47	10.65

UEP, upper extremity and physical function; TBM, transfers and basic mobility; SPF, sports and physical function; PC, pain and comfort; EXP, expectations; HAPP, happiness; GFS, global function and symptoms; PEC, personal care; POSIC, positioning/transferring; COMF, comfort, INTER, interaction/comunication; B, before; A, after.

Table 2. Comparison between scores before and after in each dimension for each group and for clinical classification.

Subgroups	Group I						Group II						Group III					
	Diplegia		Hemiplegia		Tetraplegia		Diplegia		Hemiplegia		Tetraplegia		Diplegia		Hemiplegia		Tetraplegia	
	n	p	n	p	n	p	n	p	n	p	n	p	n	p	n	p	n	p
UEPB × UEPA	8	0.6	7	0.22	5	0.14	2		3		6		1		12	0.23	2	
TBMB × TBMA	9	0.44	4		5	0.06	2		3		5		4	1.00	10	0.26	3	
SPFB × SPFA	8	0.02	6	0.60	6	0.50	2		2		5	0.28	3	1.00	13	0.85	4	0.06
PCB × PCA	10	0.28	6		7	0.68	4		4	0.42	6		5	0.59	16	0.34	3	
EXPB × EXPA	8	0.34	6	0.68	6	0.59	1		1		3		4		10	0.24	3	
HAPPB × HAPPA	10	0.72	3		7	0.22	2		1		5	1.00	5	1.00	11	0.36	2	
GFSB × GFSA	7	0.73	4	0.14	2		1		2		2		1		6	0.07	2	
PECB × PECA	10	0.17	8	0.05	8	0.39	4	0.46	4	0.71	6	0.91	5	0.07	19	0.07	4	0.06
POSICB × POSICA	10	0.41	8	0.23	8	0.83	4	0.71	4	0.14	6	0.04	5	1.00	19	0.76	4	0.71
COMFB × COMFA	10	0.04	8	0.50	8	0.07	4	0.06	4		6	0.71	5	0.28	19	0.75	4	0.28
INTERB × INTERA	10	0.93	8	0.40	8	0.02	4	1.00	4	0.59	6	0.07	5	0.10	19	0.22	4	0.46

UEP, upper extremity and physical function; TBM, transfers and basic mobility; SPF, sports and physical function; PC, pain and comfort; EXP, expectations; HAPP, happiness; GFS, global function and symptoms; PEC, personal care; POSIC, positioning/transferring; COMF, comfort; INTER, interaction/comunication; B, before; A, after

Table 3. Medians in each subgroup of each group.

	Group I			Group II			Group III		
	Diplegia	Hemiplegia	Tetraplegia	Diplegia	Hemiplegia	Tetraplegia	Diplegia	Hemiplegia	Tetraplegia
UEPB	71.43	72.92	61.90	77.08	58.33	0.00	83.33	68.75	79.16
UEPA	75.00	79.17	61.90	70.84	83.33	0.00	95.24	79.17	70.83
TBMB	59.85	84.85	14.02	52.27	72.63	0.00	74.25	84.85	42.42
TBMA	72.73	87.26	36.36	71.59	93.94	5.56	81.06	85.61	43.94
SPFB	44.70	66.67	21.78	25.95	85.99	18.18	76.52	73.48	22.35
SPFA	54.55	77.91	21.72	18.69	90.91	21.21	48.48	74.07	36.46
PCB	88.89	100.00	82.22	94.44	85.56	80.00	88.89	91.11	73.89
PCA	72.22	100.00	81.11	100.00	88.89	80.00	93.33	88.89	71.11
EXPB	88.89	100.00	91.67	94.44	88.89	100.00	100.00	88.89	94.44
EXPA	97.22	88.89	100.00			100.00	93.06	88.89	100.00
HAPPB	97.50	83.33	95.00	100.00	87.50	75.00	85.00	90.00	90.00
HAPPA	95.00	90.00	91.67	95.00	87.50	80.00	87.50	92.50	87.50
GFSB	64.64	83.71	44.73		85.26	45.84	76.14	77.72	56.72
GFSA	73.33	81.36	57.45		92.05	46.22	84.88	79.24	59.25
PECB	11.00	12.50	21.50	7.00	18.00	47.50	7.00	9.00	31.00
PECA	19.00	22.50	21.50	16.00	13.50	21.50	27.00	13.00	44.50
POSICB	10.00	4.00	13.00	9.00	7.00	30.00	2.00	4.00	20.00
POSICA	5.00	4.50	10.50	7.50	3.00	16.50	5.00	5.00	19.00
COMFB	13.00	13.00	13.00	13.00	13.00	13.00	13.00	13.00	16.50
COMFA	14.00	13.00	13.00	11.50	13.00	17.00	13.00	13.00	22.50
INTERB	7.50	10.00	13.50	11.00	11.00	43.00	7.00	11.00	19.00
INTERA	7.00	13.00	8.00	8.00	9.00	26.00	0.06	10.00	18.50

UEP, upper extremity and physical function; TBM, transfers and basic mobility; SPF, sports and physical function; PC, pain and comfort; EXP, expectations; HAPP, happiness; GFS, global function and symptoms; PEC, personal care; POSIC, positioning/transferring; COMF, comfort; INTER, interaction/comunication; B, before; A, after.

Table 4. Comparison between subgroups in dimensions before and after time points.

Subgroups	Group I			Group II			Group III		
	Diplegia × Tetraplegia	Hemiplegia × Tetraplegia	Diplegia × Hemiplegia	Diplegia × Tetraplegia	Hemiplegia × Tetraplegia	Diplegia × Hemiplegia	Diplegia × Tetraplegia	Hemiplegia × Tetraplegia	Diplegia × Hemiplegia
	p	p	p	p	p	p	p	p	p
UEPB	0.11	0.17	0.60	0.14	0.09	0.80	0.80	0.33	0.19
UEPA	0.12	0.09	0.77	0.14	0.02	0.80	0.10	0.43	0.08
TBMB	0.003	0.004	0.09	0.03	0.01	0.40	0.05	0.01	0.44
TBMA	0.05	0.01	0.11	0.07	0.02	0.40	0.03	0.009	0.61
SPFB	0.007	0.001	0.005	0.19	0.09	0.33	0.01	0.003	0.92
SPFA	0.005	0.002	0.08	1.00	0.02	0.20	0.22	0.01	0.65
PCB	0.96	0.20	0.13	0.25	0.76	0.68	0.14	0.35	0.65
PCA	0.89	0.04	0.01	0.25	0.60	0.48	0.19	0.11	0.85
EXPB	0.60	0.66	0.45	0.53	0.22	0.80	0.14	1.00	0.14
EXPA	0.52	0.36	0.75				0.48	0.35	0.80
HAPPB	0.88	0.43	0.51	0.57	0.57	1.00	0.39	1.00	0.50
HAPPA	0.73	0.83	1.00	0.38	0.85	0.66	0.85	0.70	0.62
GFSB	0.04	0.09	0.17		0.33		0.20	0.17	1.00
GFSA	0.31	0.11	0.23		0.20		0.20	0.02	0.75
PECB	0.35	0.10	0.96	0.06	0.17	0.48	0.28	0.06	0.73
PECA	0.82	0.64	0.89	0.35	0.25	0.68	0.28	0.05	0.16
POSICB	0.89	0.007	0.03	0.17	0.35	0.88	0.06	0.01	0.53
POSICA	0.63	0.04	0.20	0.35	0.17	0.34	0.01	0.004	0.58
COMFB	0.14	0.64	0.45	0.60	0.76	0.88	0.11	0.08	0.94
COMFA	0.06	0.87	0.06	0.17	0.35	0.68	0.19	0.08	0.67
INTERB	0.17	0.64	0.45	0.03	0.01	1.00	0.11	0.50	0.10
INTERA	0.82	0.50	0.27	0.17	0.11	1.00	0.06	0.13	0.48

UEP, upper extremity and physical function; TBM, transfers and basic mobility; SPF, sports and physical function; PC, pain and comfort; EXP, expectations; HAPP, happiness; GFS, global function and symptoms; PEC, personal care; POSIC, positioning/transferring; COMF, comfort; INTER, interaction/comunication; B, before; A, after.

mension were obtained for group I, as can be seen in Table 1. There was a statistically significant difference between *Before* and *After* in the TBM and PEC. Comparison of means of each of the dimensions evaluated in the diplegia and hemiplegia showed statistically significant differences for the SPFB, PCA and POSICB (Table 3 and 4). When comparing the means of the dimensions verified in the diplegia and tetraplegia, statistically significant differences for TBMB, SPFB, SPFA and GFSB were observed. When comparing the hemiplegia and tetraplegia, statistically significant differences for TBMB, TBMA, SPFB, SPFA, PCA, POSICB, and POSICA were observed (Table 3 and 4). Comparison of means of each dimension for *Before* and *After* showed no statistically significant difference for the hemiplegia. In the diplegia, analysis showed a statistically significant difference between *Before* and *After* for the SPF and COMF. In the tetraplegia, there was a statistically significant difference when comparing *Before* and *After* in the INTER (Table 2).

Fourteen caregivers in group II answered the PODCI and CCQ at *Before* and *After*, with a period of time varying from 30 to 60 days. The means of each dimension for group II were obtained, as can be seen in Table 1. There was a statistically significant difference between *Before* and *After* in the POSIC in the tetraplegia (Table 2). Comparison of means of each of the dimensions evaluated between tetraplegia and hemiplegia showed statistically significant differences for the UEPA, TBMB, TBMA, SPFA and INTERB. When comparing the means of each variable evaluated in the tetraplegia with the diplegia, a statistically significant difference was observed for the TBMB and INTERB (Table 4). Comparison of means of each dimension in the *Before* and *After* showed that there was no statistically significant difference for the diplegia and hemiplegia. In

the tetraplegia, there was a statistically significant difference when comparing *Before* and *After* in the POSIC.

Twenty-eight caregivers in group III answered the PODCI and CCQ at *Before* and *After*. The means of each dimension were obtained, as can be seen in Table 1. There was not a statistically significant difference between *Before* and *After* of the dimensions of the PODCI and CCQ (Table 2). When comparing the means of each dimension evaluated in the hemiplegia and tetraplegia, a statistically significant differences were observed for the TBMB, TBMA, SPFB, SPFA, GFSA, POSICB, and POSICA. When comparing the diplegia and tetraplegia, a statistically significant difference was observed for the TBMB, TBMA, SPFB, and POSICA (Table 3 and 4).

There is not correlation between Global Function and Symptoms (GFS) and number of sessions, interval of the last session and follow up period. No side effects were observed in the 40 blockades performed during this study involving 1200 sites of BTXA injection.

DISCUSSION

The use of BTXA for the management of spasticity began a little over a decade ago, with several clinical studies using clinical and functional scales to demonstrate its effectiveness in the rehabilitation of children and adults[5-15]. The major contribution of BTXA is in the management of preschool- and school-aged children who have great potential for growth and a high risk of relapse with the need for frequent surgical re-interventions. With there use increases the chances of reaching the proposal of a single, definitive orthopedic intervention, and may even have better functional results[2,13,20,21].

The majority of the patients' caregivers understood the research goal, promptly signing the commitment form. Most patients were classified into social classes "C" and "D", but the education level verified did not allow assessment of the correlation of social class with QOL. The literature shows that individuals with higher education and income levels tend to have better QOL[22]. Parents are excellent sources of information on their children's QOL issues, although there is some potential for distortion of the information given[18,23]. Caution should be taken when analyzing variables of each individual at *Before* and *After*, because caregiver's perception, in addition to the child's health condition, is influenced by numerous variables, including, but not limited to, economic restrictions, caregiver's mood, relationship with school and community. The analysis of patient groups aims at diffusing these error variables.

The questionnaires used were developed for children; one was general (PODCI), for children with musculoskeletal changes, and the other was specific (CCQ), for children with CP. Although The United Cerebral Palsy Association considers QOL as one of the priorities, there are few tools to evaluate children's quality of life, and even fewer for children with motor disability[18,24,25]. To date, CCQ was the only specific questionnaire focused on quality of life for children with CP. CCQ showed to be a user-friendly, quick, useful tool to evaluate QOL, especially when associated with a questionnaire based on function[18]. In the present study, CCQ was associated with PODCI, which is a general instrument focused on quality of life, with a more elaborate functional focus. PODCI extension was commented by parents, however this did not jeopardize data collection – a fact that is similar to that noticed by Pencharz et al.[26]. Another study that used Child Health Questionnaire (CHQ), PODCI and Pediatric Evaluation and Disability Inventory (PEDI) showed that CHQ was the easiest to administer and is a good general quality of life measure; however, the PODCI or PEDI may be preferred if information about more specific functional activities is desired[16]. Vitale et al.[17] showed that PODCI was more sensitive to differences in the diplegic and hemiplegic but quadriplegics exhibited a ceiling effect on 2 of the 12 domains in that questionnaire; CHQ was more effective is this group of patients. Such a fact was also noticed in this study, in which only 35 patients from a sample of 68 had the global score. Barnes et al.[27] conducted a study in ambulatory patients with CP with GMFCS levels I through III and concluded that PODCI is effective regardless clinical classification. The use of PODCI to evaluate QOL of children with several orthopedic conditions has shown that its indicators, particularly those related to motor function, may be used as monitor for stabilization, deterioration or clinical improvement, and that they are valid to evaluate the benefits from various orthopedic interventions[21]. Those same authors used the PODCI for 57 healthy children and 27 healthy adolescents, and they observed that the scores obtained were high, close to or at 100, and that score of 80 or less means that the child has a lower than expected functional ability[21]. QOL in groups I and III is similar, thus it enabled their comparison. The impact of BTXA injection on Group I can be seen in motor improvement, which became significantly different from improvement noted by Group III at the *After*. Groups II and III were different at the first time point, and became more similar after BTXA session, as observed by the improvement in the scores for motor function and psychosocial functioning. Quality of life in Groups I and II was also different in the beginning of the study; however, after BTXA, they became similar in the upper extremity and psychosocial functions due to a higher gain in these scores in Group II.

The clinical variability existing among spastic patients is directly reflected in QOL and response to therapeu-

tic interventions. This led to the sub-division of patients into hemiplegia, diplegia and tetraplegia[15,28]. Patients with hemiplegia showed better initial scores than those of the diplegia and tetraplegia, and the last one showed worse scores. Following injections, the diplegia was similar to the hemiplegia in motor function. Regarding pain and comfort, the hemiplegia had greater benefits from the use of BTXA, suggesting that pain is more important when the upper limb is affected. However, when looking into the sports domain, the diplegia subgroup showed greater benefit. These results from the fact that the physical functions approached through the PODCI were beyond those expected for a patient with tetraplegia, and the last one had greater benefit in psychosocial function. The psychosocial gain seen in this study, and in clinical practice as well, which is highlighted by parents and/or caregivers, is probably a result of the improvement in motor function – much more debilitating for more severe patients, enabling children to more actively participate in their world, rather than being just spectators. In Group III no change in QOL was seen and we could say that patients remain functionally stable following BTXA injections, if they were submitted to other interventions (positioning and orthesis) in order to maintain such results. These data show that BTXA may be helpful for spastic patients, regardless their clinical classification. Less affected patients improve in functional ability with patients reaching normal global scores. The key for success in the use of this therapy seems to be an appropriate evaluation and selection of patients. It is important to know in which phase of the psychomotor development each individual patient is, and to individually adjust goals and therapeutic plans. The rational use of BTXA can bring benefit for all patients without generating unrealistic expectations or undue burden to the healthcare system and families. Cost-effectiveness assessment should take the therapeutic intervention's efficacy and safety into consideration. The efficacy and absence of side effects in this study lead us to the conclusion that this is a useful and safe tool for the rehabilitation of spastic children.

In conclusion, the instruments used to assess QOL (PODCI and CCQ) were sensitive enough to detect changes over time in children with CP, easy to administrate and inexpensive; and BTXA injections promoted improvement in functional ability mainly in Group I and II, regardless their clinical classification, with tetraplegia also showing gain in psychosocial function. Other studies may be necessary to investigate maintenance of the improvement with a longer follow-up.

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