

Initial assessment of responsiveness of the P-CPQ (Brazilian Version) to describe the changes in quality of life after treatment for traumatic dental injury

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Abstract – This study aimed to assess the responsiveness of the Brazilian version of the Parental–Caregiver Perception Questionnaire (B-P-CPQ) to describe changes in quality of life (QoL) after treatment for traumatic dental injury (TDI). After eligibility criteria were applied, 42 of 255 patients who went to a dental trauma center for TDI treatment were included. QoL was evaluated in two different appointments: A1 (after TDI) and A2 (after TDI treatment). The B-P-CPQ scores were calculated using the additive method. Psychometric properties like internal consistency (Cronbach's Alpha), test–retest reliability, intraclass correlation coefficient (ICC), and construct validity (Spearman's correlations) were assessed, and, mainly, the responsiveness was analyzed by standardized response means (SRM). Mean B-P-CPQ scores were 30.05 (1.74 SD) and 2.67 (4.05 SD), while the median scores were 17.39 and 2.00 ($P < 0.01$), respectively in A1 and A2. Cronbach's Alpha was 0.87 in A1 and 0.66 in A2. ICC was 0.90. B-P-CPQ scores were correlated with overall well-being ($P < 0.01$; rho: 0.71). The B-P-CPQ responsiveness scores declined 27.38 points, and a perfect SRM of 1.76 was achieved. The B-P-CPQ scores indicated changes in QoL following TDI. The change was observed as an impact decrease after TDI treatment, demonstrating positive reduction and improvement on QoL. The responsiveness of the P-CPQ (Brazilian version) in detecting change on QoL after TDI treatment was confirmed by SRM assessment. The findings represent an evidence of the importance of professional care and treatment of TDI.

Traumatic dental injuries (TDI) constitute a public health problem that affects the population, leading in some cases to tooth loss. Thus, their impact involves not only physical damage, but psychological damage as well; esthetic issues are also involved. Moreover, TDIs mobilize the whole family structure, with impacts on the child's parents (1).

The American Academy of Pediatrics defines child health as the social functioning, physical and emotional development of children and children's family. Therefore, the contemporary concepts of child health consider the quality of life from the perspective of the child and the family (2). The approach to a child with a dental trauma should be taken in a holistic manner to control not only the local consequences of TDI such as sequels to the dentition, but also the impact on child's oral health related to quality of life (OHRQoL). The solution of the disease's signs and symptoms alone does not allow a patient to enjoy full health.

According to Jokovic et al. (3), although mothers are often treated as representatives of children/adolescents,

in some situations both opinions (child/adolescent and parent) should be obtained. The use of parental reports is a controversial point. It is not entirely clear that parents are always the most appropriate adults to answer a questionnaire, because their reports are usually based on knowledge about how they are affected (4), and furthermore, there are children/adolescents who spend more time with teachers, caregivers, or other family members than with their parents. Therefore, another person could have greater knowledge about the social and psychological functioning of a child, and this should be taken into consideration (5). It is important to include the assessment of the person, or people, who spend the most time with a child/adolescent, such as caregivers.

A set of instruments known as the Child Oral Health Quality of Life (COHQoL) Questionnaire measures the perception of the oral health of children by parents or caregivers (6). Within this group is the Parental–Caregiver Perceptions Questionnaire (P-CPQ), which is the most suitable with proven reliability, validity, and reproducibility in its original version (7) and in other

versions, such as those of the United Kingdom (8, 9), China (10), and Brazil (11).

Measures of OHRQoL are useful in clinical trials, and they evaluate outcomes of treatments. Thus, treatment related to dental trauma is another point that can affect the quality of life of the individual concerned and must also be evaluated.

There are innumerable epidemiological surveys on the prevalence of dento-alveolar traumas in Brazilian children. These studies generally examine the more common traumas, discussing the prevalence according to dentition, age range, and gender, and they list the more common causal and predisposing factors, relating such factors with socio-economic level. In the literature, however, there is a scarcity of studies that use instruments to evaluate the (QoL) impact on the parents/caretakers of patients who have suffered dental trauma (12–15), or even the impact of the treatment of patients on the QoL of the children and their families. Thus, works searching for such answers are of extreme relevance.

To aid the investigator, who wishes to use a measure of OHRQoL in research or clinical practice, it is essential to assess the technical properties of all the measures. The property by which the change pre- and post-treatment is assessed is the responsiveness. Establishing this property could assist health professionals in interpreting the meaning of changes in scores derived from measures (16). The purpose of this study was to assess the responsiveness of the Brazilian version of the P-CPQ (B-P-CPQ) to describe the change in QoL after TDI treatment.

Materials and methods

Study sample

Data from all cases that arrived at the dental trauma center (DTC) at the Federal University of Rio de Janeiro – Brazil from June 2009 to November 2010 were obtained in an operational way.

The eligibility criteria consisted of the following: (i) parents/caregivers of children and adolescents aged between 8 and 14 years; (ii) health patients without disabilities; (iii) TDI affecting permanent teeth; (iv) TDI that occurred in the last 3 months before questionnaire application; and (v) TDI treatment completed up to 3 months before questionnaire application. If the parents/caregivers refused to answer the questionnaire at any point or if they did not sign the consent terms, they were excluded from the present study.

Ethical issues

Ethical approval was obtained from the local Human Ethics Committee of Clementino Fraga Filho Hospital at Rio de Janeiro Federal University, Brazil. Informed consent was obtained from all participating individuals or parents/legal guardians.

Study design

This study was prospective with clinical interventional, analyzing changes in child QoL following TDI treatment

as perceived by parents/caregivers. The study was designed to obtain sample and TDI characterization, as well as to evaluate the impact of TDI on the QoL of children through the evaluation of the parents' perception before (appointment 1–A1) and after TDI treatment (appointment 2–A2).

Data collection

All children were examined, diagnosed, and treated by seven dentists, previously trained to assess TDI. The kappa scores on intra- and inter-examiner reliability were taken to analyze the TDI clinical examination, previously standardized, that was carried out by the dentist participants. Calibration results for the TDI clinical examination were between good to excellent; weighted kappa scores were between 0.66 and 1.00 for intra-examiner reliability (0.68–0.89 for support tissue; 0.66–1.00 for dental tissue) and between 0.77 and 0.89 for inter-examiner reliability (0.84–0.89 for support tissue; 0.77–0.88 for dental tissue).

Sample and trauma characterization

The following data were obtained: socio-demographic data; interviewee's age, kinship, education level (years of study); child's age and gender and TDI history (when, where, and how the trauma occurred; which tooth and dentition were affected; and tissue and type of TDI more prevalent).

Clinical examination (TDI diagnostic and severity classification according to type of TDI)

Clinical examination of the patient was carried out to diagnose the problem (TDI classification), to collect data about the prevalence and extent of dental TDI (severity classification), and to plan the treatment.

The classification of TDI was performed following Andreasen's criteria (17) considering dental tissue (fracture of the crown – enamel only, enamel and dentin with or without pulp exposure; crown-root fracture; crown-root fracture with pulp exposure; root fracture) and support tissue (concussion, subluxation, lateral luxation, intrusive luxation, extrusive luxation and avulsion).

The extent of dental TDI was classified into levels of severity according to Glendor et al. (18). This classification takes into consideration the tooth injuries according to degree. The same classification was used to determine the group ('uncomplicated', 'complicated') in which the individual was assigned according to injury severity as follows:

- 1 'uncomplicated' (those in which the pulpal tissue was not exposed, and the tooth was not dislocated);
- 2 'complicated' (those involving exposure of the pulpal tissue and/or tooth dislocation);
- 3 one or more diagnoses could be included, the classification on the individual level being determined by the most complicated diagnosis.

Quality-of-life assessment

Quality of life was measured using the B-P-CPQ (11), which has 31 items distributed into four subscales: oral symptoms, functional limitations, emotional well-being,

and social well-being. The questions refer only to the frequency of events in the previous 3 months. The items have five response options: never (0), once or twice (1), sometimes (2), often (3), and every day or almost every day (4). A response of 'don't know' was also permitted and scored as 0, in accordance with Goursand et al. (11). Global ratings of the child's general health, oral health, and trauma impact on his or her well-being were obtained from the parents/caregivers. The global ratings had a 5-point response format ranging from excellent (0) to poor (4) for general and oral health, and from not at all (0) to very much (4) for trauma impact.

The measurement of QoL was assessed by one trained interviewer at two different stages:

- 1 A1 (baseline): parents/caregivers were instructed to answer the B-P-CPQ questionnaire within 3 months of the occurrence of the TDI.
- 2 A2 (after TDI treatment): the parents/caregivers were instructed to answer the same questions from between 2 weeks and 3 months after the TDI treatment.

Data management and statistical analysis

Data were analyzed using the statistical software SPSS 16.0 (SPSS Inc., Chicago, IL, USA). The level of statistical significance was set at $P < 0.05$.

The relative frequency (%) of variables such as socio-economic data, TDI history, and diagnoses from children and their families was obtained. The scores of the B-P-CPQ index were calculated using the additive method, summing the numeric response codes for each item. Psychometric properties were assessed through internal consistency, test-retest reliability, construct validity, and mainly the responsiveness.

Internal consistency reliability was assessed by means of Cronbach's Alpha and test-retest reliability by means of the intraclass correlation coefficient (ICC). A new convenience sample of parents/caregivers of children who had suffered dental trauma were recruited from the same clinical locations ($n = 9$). As test-retest reliability analysis requires individuals to be stable between the two administrations of the questionnaire, the second sample was selected after asking parents/caregivers if the child's condition had changed since recruitment.

Construct validity was assessed by means of associations between scale scores and the two global indicators of health status (general and oral) and well-being (the impact of dental trauma and its treatment) using Spearman's correlations.

Mean and median comparisons were carried out for items in overall and subscale scores for the two situations (A1 and A2). As the items were scored using the ordinal scale, nonparametric statistical procedures (Wilcoxon's test) were used.

TDI severity was qualitatively and quantitatively described in both appointments to correlate with the B-P-CPQ scores changes.

The responsiveness was assessed by analyzing the change of the scores on the scales and subscales, calculating the subtraction of post-treatment scores (A2) from pre-treatment scores (A1). Consequently,

positive change scores indicate an improvement in OHRQoL, while negative scores indicate deterioration. Standardized response means (SRMs) were computed by dividing the mean score range from A1 to A2 by standard deviation of change scores. To facilitate interpretation, as proposed by Zou (19), an SRM of 0.5 denoted null responsiveness and 1.0 perfect responsiveness.

Results

From 255 patients who came for TDI treatment, 46 satisfied the inclusion criteria. There were no refusals to participate. There were no reports of side effects or treatment dissatisfaction. After treatment, however, four patients did not return for follow-up. As we could not reach these patients because of address changes or mistakes, they were considered lost. Thus, the final sample consisted of 42 children and their parents/caregivers.

Tables 1 and 2 show the sample and the trauma characteristics, respectively. The mean age of parents/caregivers was 40 years (11.6 SD); 35.7% had 9–11 years of study and 64.3% of the respondents were mothers. The mean age of the children was 10 years (1.9 SD), and the majority (54.8%) were boys. The prevalence of TDI was higher in the mixed dentition (88.1%). The tooth most affected was the right maxillary central incisor (41.2%). The type of tissue most injured was dental tissue (54.8%). The most prevalent type of TDI was fracture of enamel and dentin (48.9%).

The psychometric properties of the instrument gave a satisfactory reliability with 0.87 and 0.66 for Cronbach's alpha, respectively, in A1 and A2, and 0.90 in test-retest. When the scores of the B-P-CPQ were correlated with global indicators, there was no statistical relationship to oral and general health. The TDI well-being, however, showed satisfactory construct validity ($P < 0.01$, rho: 0.71, correlation Spearman).

The mean B-P-CPQ scores were 30.05 (1.74 SD) and 2.73 (4.05 SD), while the median scores were 17.39 and

Table 1. Sample characterization

Parents/caregivers	<i>N</i> = 42
Mean age (SD)	40 (11.6) years
Guardian	<i>n</i> (%)
Father	8 (19.0)
Mother	27 (64.3)
Grandmother/father	7 (16.7)
Guardian's Education Level – years of study, <i>n</i> (%)	
≤4	2 (4.8)
5–8	9 (21.4)
9–11	15 (35.7)
12–15	14 (33.3)
≥16	2 (4.8)
Children	<i>N</i> = 42
Mean age (SD)	10 (1.9) years
Gender, <i>n</i> (%)	
Female	19 (45.2)
Male	23 (54.8)

Table 2. Trauma characterization

Traumatic dental injury (DTI)	<i>n</i> (%)
When happened? (<i>n</i> = 42)	
1 day	6 (14.3)
2–7 days	17 (40.5)
8–30 days	14 (33.3)
31 days to 2 months	5 (11.9)
Where happened? (<i>n</i> = 42)	
House	13 (30.9)
Street	23 (54.8)
School	4 (9.5)
Park	2 (4.8)
How happened? (<i>n</i> = 42)	
Fall from own height	24 (57.2)
Bike accident	8 (19.0)
Dash	7 (16.7)
Car accident	3 (7.1)
Dentition affected (<i>n</i> = 42)	
Mixed	37 (88.1)
Permanent	5 (11.9)
Type of tissue affected (<i>n</i> = 42)	
Support tissue	5 (11.9)
Dental tissue	23 (54.8)
Support and dental tissue	14 (33.3)
Teeth affected (<i>n</i> = 80)	
11	33 (41.2)
12	5 (6.2)
21	32 (40.0)
22	6 (7.5)
13	1 (1.3)
42	3 (3.8)
Type of traumatic dental injury (<i>n</i> = 92)	
Concussion	4 (4.3)
Subluxation	9 (9.8)
Lateral luxation	14 (15.2)
Intrusive luxation	4 (4.4)
Avulsion	5 (5.4)
Fracture of enamel	9 (9.8)
Fracture of enamel/dentin	45 (48.9)
Fracture of enamel/dentin with pulp exposure	2 (2.2)

2.00 ($P < 0.01$ Wilcoxon's test), respectively, in A1 and A2 (Table 3). When the subscales (symptom oral functional limitation, emotional well-being, and social well-being) were analyzed in the present study, the oral symptoms had the lowest score impact average of 3.36 (3.10 SD) for A1 and 0.48 (0.31 SD) for A2, while functional limitations, emotional well-being, and social well-being showed the greatest impact with numbers very close to a significant reduction in A1 to A2.

The B-P-CPQ responsiveness scores declined 27.38 points. The SRM scored as 1.76, corresponding to perfect responsiveness. This could also be observed for all subscales, with emotional well-being and functional limitations showing the most benefit. These high SRM values for total scale and for all subscales indicated the B-P-CPQ as a good instrument to detect changes over time (Table 4).

Table 5 qualitatively describes the mean B-P-CPQ scores related to the DTI type and severity. More than half the population evaluated in our study presented uncomplicated (59.52%) classification of DTI severity. It could be observed that the highest levels of impact and its reduction after treatment were in the group of

Table 3. Comparison of the mean and median in A1/A2 in total scale and subscales of B-P-CPQ scores

B-P-CPQ (variation)	A1		A2		<i>P</i> -value ¹
	Mean (SD)	Median	Mean (SD)	Median	
Total scale (0–124)	30.05 (17.39)	27.50	2.67 (4.02)	2.00	<0.01
Subscales					
Oral symptoms (0–24)	3.36 (3.11)	3.00	0.05 (0.31)	0.00	<0.01
Functional limitations (0–32)	9.83 (6.50)	9.50	1.38 (2.78)	0.00	<0.01
Emotional well-being (0–28)	9.12 (6.60)	10.00	0.17 (0.70)	0.00	<0.01
Social well-being (0–40)	7.74 (6.41)	7.00	1.07 (1.63)	0.00	<0.01

¹Wilcoxon Test.

Table 4. Responsiveness and standardized response mean (SRM) evaluation

B-P-CPQ	Score A1–A2 ¹	SRM ²
Total scale	27.38	1.76
Subscales		
Oral symptoms	3.31	1.09
Functional limitations	8.45	1.38
Emotional well-being	8.95	1.40
Social well-being	6.67	1.15

¹Responsiveness formula.

²Standardized response mean (SRM)

= $\frac{\text{mean score change (A1–A2)}}{\text{Standard Deviation of change scores (A1–A2)}}$

trauma affecting both dental and support tissue. However, noticeable change over time could be identified (positive reduction) for all types of DTI, which denotes 100% of the population benefiting from trauma treatment.

Discussion

Questionnaires designed to assess the impact of OHR-QoL are specific instruments for application in various areas, including political action, research, and public health clinics, which makes their use extremely important (20–22). To measure the perception of parents/caregivers of the oral health of their children/adolescents, the P-CPQ proved to be valid and reliable (7, 9–11). In these studies, the P-CPQ score was able to discriminate between different perceptions of parents/caregivers concerning the oral conditions of their children/adolescents (dental caries and malocclusion). In our study that evaluated DTI, this instrument was also considered valid and reliable when applied to parents/caregivers to provide satisfactory internal consistency and test–retest reliability, and good validity of construct and discriminant validity.

Table 5. Mean and standard deviation of B-P-CPQ scores in A1 and A2, according to classification of TDI severity proposed by Glendor et al. (18)

Type of tissue affected (<i>n</i> = 42)	Classification of TDI (<i>n</i> = 42)	Severity	Score			
			A1		A2	
			Mean	SD	Mean	SD
Support (<i>n</i> = 5)	Luxation without dislocation (<i>n</i> = 2)	UC	16.50	6.37	0.00	0.00
	Luxation with dislocation (<i>n</i> = 3)	C	26.00	20.52	6.66	9.86
Dental (<i>n</i> = 23)	Fracture without pulp exposure (<i>n</i> = 23)	UC	29.13	13.48	1.91	2.59
Support and dental (<i>n</i> = 14)	Luxation without dislocation/fracture without pulp exposure (<i>n</i> = 6)	UC	33.00	23.55	4.33	6.12
	Luxation with dislocation/fracture without pulp exposure (<i>n</i> = 7)	C	39.14	23.23	3.14	2.34
	Luxation with dislocation/fracture with pulp exposure (<i>n</i> = 1)	C	9.00	–	0.00	–

UC, uncomplicated; C, complicated.

In our work, the impact caused by TDI felt by parents/caregivers (A1) showed a much higher mean total (30.05) than when compared to those results of other different groups in other studies such as groups of caries and malocclusion (11), or pediatric and orthodontic (10). However, in Jokovic et al.'s (7) study, the group of orofacial problems showed an even higher average impact detected by the P-CPQ (31.83). The findings of the present study demonstrate that dental trauma is one of the oral conditions that generates the worst impact on OHRQoL, so it deserves more attention from the clinician when it happens.

Some studies are found in the literature which evaluate the impact of TDI. Cortes et al. (13) evaluated Brazilian children with and without fractures using Daily Oral Impact Performance (OIDP). Ramos-Jorge et al. (15), also using OIDP, analyzed impact on the QoL of adolescents with TDI restoration and with no history of trauma. Fakhruddin et al. (14) compared children with and without TDI, treated and untreated. Thus, as noted, these works present a comparison of different groups as a methodological outline, but without observing the change in QoL within the same group as in our work. These articles have found generally that trauma creates greater impact in untreated children or that the fracture restorations reduced the impact, which shows a tendency to change detection by the instruments used. However, in these studies, it was not possible to determine the sensitivity to change (responsiveness) of the applied instruments.

The sensitivity to change should be performed in studies evaluating the same population in different moments (before and after interventions). Based on this, our study evaluated the ability of the B-P-CPQ instrument to detect change after receiving treatment in Brazilian children who had undergone a TDI. The property to assess the change pre- and post-treatment (responsiveness) is not well established in many studies that measured OHRQoL. This is a significant omission, given the increasing tendency to use OHRQoL measures as outcomes in clinical trials and evaluation studies. Different measures of responsiveness lead to different conclusions because such measures have different purposes (23). Terwee et al. (23) found in the literature 25 definitions and 31 indices for measuring responsiveness.

Two popular indices to analyze a single group in a pre-post study design are the effect size and SRM. They are related to be conceptually similar. However, Zou's (19) examination comparing the two indices for measuring responsiveness showed there is a growing understanding that it may be misleading to apply the effect size, as defined by Cohen (24), to QoL studies, in which the objective is to quantify the responsiveness of instruments. Therefore, in our study, we made the option of using SRM evaluation to enhance the interpretability of our findings with the most informative presentation approach. In accordance with SRM assessment, the responsiveness of the P-CPQ (Brazilian version) in detecting change on QoL after TDI treatment was confirmed and presented perfect responsiveness. It could leave us to consider the B-P-CPQ as a good instrument to detect changes over time and suggest its application.

Considering our sample, in accordance with the eligibility criteria, a large amount of participants who arrived for TDI treatment were excluded, mainly because they were below 8 years of age and the instrument used is indicated for child/adolescents between 8 and 14 years of age. We did not observe refusal on follow-up because of side effects, experience of treatment or because of dissatisfaction in relation to the treatment. The four losses detected in our study were because of loss of contact because of address changes or mistakes.

Still considering the sample size area, it is important to emphasize that our study presented convenience sample obtained from all cases that arrived at the dental trauma center from a period of time in an operational way. Although Agou et al. (25) describe that a larger sample size will allow the sensitivity to change of the QoL instrument to be explored more fully, the results reported here suggest that the B-P-CPQ is a suitable instrument to measure the changes in child oral health-related quality of life. Furthermore, the SRM and the estimate of the minimal important difference can also provide the basis for sample size calculations for treatment efficacy studies in future studies.

In this study, the mean B-P-CPQ score for the group that suffered TDI (A1) was approximately seven times higher when compared with the treated group (A2). Thus, using the B-P-CPQ, an instrument with proven ability to detect change over time, the population

affected by TDI had an improved quality of life after treatment. This advantage could benefit all patients, independently of the severity of TDI, as observed in our results. It also could be observed in children who were affected by more than one type of TDI as they had the highest level of reduction.

As a measurement instrument, the P-CPQ was used in a further analysis by assessing the condition before and after treatment, only in the analyses of treatments under general anesthesia (26, 27) and orthodontic treatments (25). The provision of dental treatment under general anesthesia for young children with severe dental caries is associated with significant and substantial improvement in the three instruments of OHRQoL analyzed, among them the P-CPQ (26). Malden et al. (27) also noted that the child OHRQoL improved after treatment under general anesthesia, according to their parents. The Agou et al. (25) preliminary results provided evidence of the sensitivity to the change of child OHRQoL questionnaires (CPQ₁₁₋₁₄, FIS, P-CPQ) when used with children under orthodontic treatment. All studies cited previously confirmed the sensitivity of the P-CPQ instrument to detect change, as in the present study using the Brazilian version.

Generalizing our results, in which the ability of the B-P-CPQ instrument to detect the change after treatment could be observed, one can conclude that it could be used in other studies with pre-post design analyzing dental trauma in other populations. It could potentially help clinicians understand the magnitude of the benefits associated with the treatment of Traumatic Dental Injury (DTI).

Conclusion

The B-P-CPQ scores indicated changes in QoL following TDI. The change was observed as an impact decrease after TDI treatment, demonstrating positive reduction and improvement on QoL. The responsiveness of the P-CPQ (Brazilian version) in detecting change on QoL after TDI treatment was confirmed by SRM assessment. The findings represent evidence of the importance of professional care and treatment of TDI.

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