RESPONSIVENESS OF BRAZILIAN VERSION OF OHIP-EDENT FOR APPLICATIONS OF PATIENT-CENTERED APPROACHES IN CLINICAL PRACTICE AND RESEARCH

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Palavras-chave: Boca edêntula. Saúde bucal. Qualidade de vida. Prótese total.

RESUMO

Objetivo: avaliar a capacidade de resposta da versão brasileira do instrumento OHIP-EDENT para aplicações de abordagens centradas no paciente na prática clínica e pesquisa odontológica. **Materiais e Métodos:** cem pacientes edêntulos de até 50 anos atendidos em uma clínica universitária pública foram incluídos neste estudo clínico não randomizado. Todos os indivíduos receberam uma nova prótese total (PT) e responderam a um instrumento de qualidade de vida relacionado à saúde bucal (QVRSB) antes do tratamento (AT) e 3 meses após o tratamento (DT). A capacidade de resposta foi analisada dividindo-se a pontuação média variando de AT a DT pelo desvio padrão dos escores de mudança, considerando que 0,2, 0,5 e 0,8 representam alterações clínicas pequenas, moderadas e grandes, respectivamente. **Resultados:** observou-se diminuição AT e DT das pontuações totais e de todas as subescalas (p<0,001). Os escores de responsividade do OHIP-EDENT caíram 14,46 pontos após o tratamento, demonstrando uma redução positiva das médias, bem como uma melhora na QVRSB do paciente após a nova PT. A capacidade de resposta foi 1,74, representando uma grande responsividade. **Conclusão:** o OHIP-EDENT (versão brasileira) apresenta capacidade de detectar a resposta em pacientes edêntulos. Este instrumento pode ajudar a pesar riscos e benefícios, avaliar a relação custo-eficácia dos tratamentos e influenciar recomendações sobre políticas de saúde que adotem uma abordagem mais holística dos cuidados de saúde.

Keywords: Mouth, edentulous. Oral health. Quality of life. Denture, complete.

ABSTRACT

Objective: to evaluate the responsiveness of the Brazilian version of OHIP-EDENT instrument to applications of patient-centered approaches in dental clinical practice and research. **Materials and Methods:** one hundred edentulous patients up to 50 years old attending a public university clinic were enrolled in this non-randomized clinical study. All subjects received a new CD and answered an oral health-related quality of life (OHRQoL) instrument before treatment (BT) and 3 months after treatment (AT). The responsiveness was analyzed by dividing the mean score ranging from BT to AT by the standard deviation of change scores considering 0.2, 0.5, and 0.8 represent small, moderate, and large clinical changes, respectively. **Results:** There was a decrease in AT and DT in total scores and in all subscales (p<0.001). The OHIP-EDENT responsiveness scores dropped 14.46 points after treatment, demonstrating a positive reduction as well as an improvement in the patient OHRQoL after new CD. The SRM scored as 1.74, representing satisfactory responsiveness. **Conclusion:** the OHIP-EDENT (Brazilian version) presents capacity to detect changes in edentulous patients. This instrument can help weigh risks and benefits, assess the cost effectiveness of treatments, and influence recommendations on health policies adopting a more holistic approach to healthcare.

Submitted: August 19, 2023
Modification: January 17, 2024
Accepted: January 23, 2024

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INTRODUCTION

Oral disease remains a major public health burden worldwide.[1] Data extracted from the Global Burden of Disease Study in 2010 shows that edentulous is one of the most common conditions among oral health disorders and affects 2.3% of the world population, which represents 158 million people worldwide. In most societies, despite aging population, the need for complete dentures is not likely to reduce in the near future.[2] So, therapy with complete denture (CD) will probably not disappear over the next 4 to 5 decades.[3] Complete dentures will continue to play a central role in the rehabilitation of edentulous; thus, research, teaching and specialist training in CD must continue, and in fact be intensified rather than reduced.[2]

According to World Health Organization, the definition of health - "a state of complete physical, mental and social well-being, not merely the absence disease or infirmity" – has not only determined physical disease but appears, even more, looking the patient in a holistic manner.[3-5] Consequently, it is crucial for everyone to contribute to the assessment of oral health by considering both clinical and social-dental indicators to fully align with this comprehensive health definition.[3-5] Some socio-dental indicators are used to evaluate oral health-related quality of life (OHRQoL) and an appropriate shortened version of the Oral Health Impact Profile (OHIP) - OHIP-EDENT - was developed for use in edentulous patients.[6] This instrument has been cross-cultural validated for use in diverse countries[7] including Brazil.[8,9]

In dentistry, the therapeutic approach usually occurs through the implementation of oral health interventions, where the evaluation of the outcome needs to be performed at two distinct times: before and after treatment.[10-12] CD has the strong potential to contribute to OHRQoL in longterm.[10-12] Consequently, it is important to assess the effectiveness of clinical interventions to treat these conditions, using quality of life as one of the key outcomes.[13,14]

A recent systematic review detected the low use of a specific instrument to detect the OHRQoL and also observed a little studies reporting psychometric properties testing for the ability to detect changes when used as results in clinical trials.[10] The responsiveness of OHRQoL instruments has become relevant, given the increasing tendency to use OHRQoL measures as outcomes in clinical trials and evaluation studies.[12,14,15] Thus, as OHIP-EDENT is a specific instrument to detect the impact on edentulous patient and to date the responsiveness property has not been tested, the aim of this study was to assess the responsiveness of the Brazilian version of OHIP-EDENT in measuring edentulous-patient-based outcomes after treatment with CD.

MATERIALS AND METHODS

Ethical issues

All procedures involving human participants were performed in accordance with the ethical standards of the institutional and national research committees, and the 1964 Helsinki declaration, as revised in 2008. Ethical approval was obtained from the local Research Ethics Committee (approval no. 880.827). Written informed consent was obtained from all included patients. This study is part of a non-randomized clinical trial to evaluate the impact of the Use of New Complete Denture on the Oral Health-Related Quality of Life (OHRQoL) registered on http://clinicaltrials.gov under protocol NCT03687047. The findings of this study were reported in accordance with the CONSORT guidelines.[16]

Sample size calculation and psychometric properties

Sample size was determined *a priori* using the mean and standard deviation of the difference in before and post treatment in the experimental group from a pilot study. The statistical program BioEstat 5.0 was used. A 5% level of significance was adopted for a two-tailed test and 80% power. Ten percent more participants were added in order to compensate for any loss. Thus, the sample reached a minimum of 29 participants.

A pilot study (not part of this study) also confirms the internal consistency in each moment (Alpha de Cronbach = 0.90 for before treatment and 0.76 for after treatment) and the reliability (ICC = 0.92). For reability the instrument was applied and reapplied (interval of 2 weeks) only in the group of BT.

Study design

In this non-randomized clinical trial, a consecutive sample was taken from Brazilian edentulous patients who sought treatment for a complete denture attending a public university clinic from 12-month period (from 2016 to 2017). The eligibility criteria included: healthy patients without disabilities; aged up to 50 years; complete upper and or lower jaw edentulous for a minimum 5 years; the presence of adequate healthy tissue to support the prosthesis; adequate cognitive ability and understanding to respond to the questions posed. It was excluded patient with motor disabilities, cognitive impairment and people with special needs.

The oral rehabilitation of patients with CD was performed as previously reported.[15] OHRQoL was measured using OHIP-EDENT. An experienced researcher conduct this process from a theoretical stage, followed by a practical

stage of interviewer training. Finally, proper calibration was carried out. This step was realized with the volunteers who participated in the pilot study stage. The face-to-face interview method was used to decrease possible bias by respondents and increase response rates.[17] OHRQoL before and after treatment was conducted by the same interviewer that did not participate from de oral rehabilitation. OHIP-EDENT has 19 items distributed into seven subscales: Functional Limitation (3 questions); Physical Pain (4 questions); Psychological Discomfort (2 questions); Physical Disability (3 questions); Psychological Disability (2 questions); Social Disability (3 questions); Handicap (2 questions). Scoring was calculated by attributing points to the responses (0 = never; 1 = sometimes; 2 = almost always; 3=always). The instrument scored from zero to 57. The greater the values found are in the summary of the responses, the greater the negative impact of the conditions found on the quality of life of the individual analyzed. This instrument had previously been determined to be valid and reliable in original[6] and the Brazilian version in edentulous patients.[8,9] The OHRQoL assessment was conducted before treatment (BT) and also 3 months after treatment (AT) with CD.

Data management and statistical analysis

The data were inserted into Excel and then statistically analyzed by using the SPSS software (IBM SPSS Statistics for Windows, Version 19.0, Armonk, NY, USA) at a significance level of 5%.

The scores of OHIP-EDENT index were calculated using the additive method, summing the numeric response codes for each item.

Shapiro-Wilk test was performed to evaluate the normality of the data. The normality assumption was violated and the Wilcoxon non-parametric test was used. Mean and median comparisons were made for items in the overall scale and subscale scores for both situations (BT and AT).

Responsiveness was assessed by analyzing the change of scores on scales and subscales. Changes were calculated by subtracting after treatment scores (AT) from before treatment scores (BT). Positive change scores (reduction on mean score) indicate an improvement in OHRQoL, while negative scores (score increase) indicate deterioration. Standardized response means (SRMs) were computed by dividing the mean score ranging from BT to AT by the standard deviation of change scores. SRMs of 0.2, 0.5, and 0.8 represent small, moderate, and large clinical changes, respectively.[18]

RESULTS

A total of 136 patients were invited to participate in this study. From those, 15 did not fulfill the inclusion criteria. A total of 21 were lost (15 patients were lost due to changes of address/telephone number, 4 did not return for the follow up and 2 died) A total loss was 17.4%. Thus, the final sample consisted of 100 edentulous patients (35 male, 65 female, mean age = 62.8 SD9.2 years), as described in Figure 1.

Table 1 shows mean (standard deviation) and median (confidence interval) of results of OHIP-EDENT total and subscales scores before and after oral rehabilitation. Decrease in scores were found after oral rehabilitation for total scores and all subscales (p<0.001). OHIP-EDENT responsiveness overall scores declined 14.46 points, characterized by a large decrease in those scores. The SRM scored as 1.74, representing satisfactory responsiveness. A large responsiveness was observed for total scores, functional limitation, physical pain, psychological discomfort, physical disability and psychological disability subscales. Social disability and handicap subscale presented moderate responsiveness (Table 2).

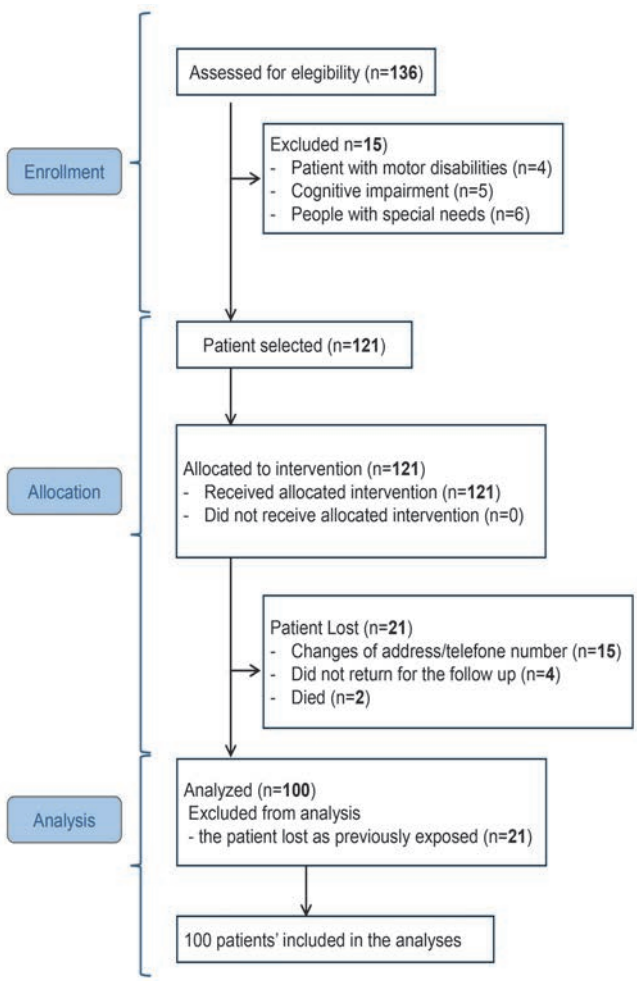

Table 1: *Scores obtained in the OHIP-EDENT questionnaire of patients at baseline and 3 months after oral rehabilitation with complete dentures.*

	Before		After		*p*-Value*
	Mean (SD)	Median (CI)	Mean (SD)	Median (CI)	
Total mean	14.99 (9.97)	13.5 (13.0 – 17.0)	0.53 (1.68)	0.0 (0.2 – 0.9)	<0.001
Functional Limitation	3.44 (2.38)	3.0 (3.0 – 3.9)	0.20 (0.69)	0.0 (0.1 – 0.3)	<0.001
Physical Pain	2.13 (2.59)	1.0 (1.6 – 2.6)	0.12 (0.51)	0.0 (0.0 – 0.2)	<0.001
Psychological Discomfort	2.65 (2.26)	2.0 (2.2 – 3.1)	0.60 (0.31)	0.0 (0.0 – 0.1)	<0.001
Physical Disability	3.36 (2.74)	3.0 (2.8 – 3.9)	0.60 (0.27)	0.0 (0.0 – 0.1)	<0.001
Psychological Disability	1.93 (1.92)	1.0 (1.5 – 2.3)	0.50 (0.26)	0.0 (0.0 – 0.1)	<0.001
Social Disability	0.71 (1.5)	0.0 (0.4 – 1.0)	0.20 (0.14)	0.0 (0.0 – 0.0)	<0.001
Handicap	0.77 (1.39)	0.0 (0.5 – 1.0)	0.20 (0.14)	0.0 (0.0 – 0.0)	<0.001

*Note: * Wilcoxon test; SD: standard deviation; CI: confidence interval.*

Table 2: *Standardized response mean (SRM) and difference of mean scores (BT-AT) obtained in the OHIP-EDENT questionnaire of patients before and 3 months after oral rehabilitation with complete dentures.*

	BT-AT*	SRM
Total Mean	*14.46*	*1.74*
Functional Limitation	*3.24*	*1.91*
Physical Pain	*2.01*	*0.96*
Psychological Discomfort	*2.05*	*1.05*
Physical Disability	*2.76*	*1.11*
Psychological Disability	*1.43*	*0.86*
Social Disability	*0.51*	*0.37*
Handicap	*0.57*	*0.68*

*Note: *Difference of the means of the scores obtained in the OHIP-EDENT; BT: before oral rehabilitation; AT: after oral rehabilitation. **SRM (Standardized response mean) = Difference of mean scores (BT – AT) / Difference of the standard deviation of the scores (BT-AT). SRMs of 0.2, 0.5, and 0.8 represent small, moderate, and large clinical changes, respectively.[18]*

DISCUSSION

Elderly patients present age-related limitations that can affect expressively their social and psychological welfare.[19] The study of quality of life is an important tool that can provide relevant data to report the response to treatments and/or clinical conduct that aim to improve elders' life conditions. Despite the broad scientific basis on which dentistry is based, there is still some lack of understanding how patients feel about their treatment, and usually success rates are based on criteria established by professionals, instead of the patient.[20] Therefore, it is vitally important to understand the real difficulties faced by these patients, to use tools to measure how patients feel about their oral health, which will allow them to indicate failures and to determine the best treatment. The complete dentures are able to give the patient greater confidence to live in a society.[21]

In dentistry, perceiving the change in habits and/or behaviors after performing a clinical treatment is important to evaluate the performance of the therapeutic procedure chosen. The instruments used to measure this change must present good responsiveness, so that the results can be reliable and reproducible. Responsiveness is an important characteristic of OHRQoL instruments that are used to assess the change in pre and post-treatment.[12,14,15] However, this is a psychometric property uncommonly reported when instruments are used to evaluate the quality of life. This methodological failure can be considered a risk of bias, when this property was not previously evaluated, in order to

Antunes et al.confirm its reliability and to allow that results of other studies can be compared. The subscale that presented the greatest impact and higher responsiveness was a functional limitation, followed by physical disability and psychological discomfort. Those domains represent concerns on chewing, food catching under the denture base, pain or discomfort in wearing the denture and embarrassment related to the dentures. These domains were also the ones with the highest impact in previous studies[22-25] and can be due to the difficulty in promoting stability and retention with complete dentures,[3] which can lead to chewing impairment and insecurity in eating and/or speak in public.

The values found for domains social disability and handicap were the smaller for this sample, as well for other research.[22-25] These domains ask about concerns relating to other persons. Considering the social context where these patients are inserted, it is probable that their social cycle is composed of similar individuals, also presenting edentulous or wearing removable prostheses.

This study confirmed the hypothesis that the responsiveness of OHIP-EDENT in detect change before and after treatment in edentulous patients using Standardized Response Mean test for effect size. Compared to baseline, all domains and a total score changed significantly after oral rehabilitation, as well as in previous studies.[7,22-25] In addition, large responsiveness was found for the instruments total score, as previous one[6] and most domains, except for social disability and handicap comparing baseline with after 3 months of treatment. However, these domains showed a low impact with OHRQoL even before treatment was performed, influencing responsiveness results.

The period of 3 months for evaluation after prostheses delivery was adopted due to the need for a neuromuscular adaptation of patient to the complete denture.[26] Previous studies also adopted this period as the minimum for after treatment evaluations with complete dentures, however none of them assessed responsiveness.[22,23]

Despite representing an important psychometric property, responsiveness is uncommonly reported in OHRQoL studies.[27] Although validity and reliability of the Brazilian version of OHIP-EDENT were demonstrated,[8,9] its responsiveness was not assessed before[28] found large responsiveness for OHIP-EDENT. However, the English version was tested and the socioeconomic characteristics of the studied population were different from the Brazilian ones.

The subscale of physical pain, presented a great responsiveness. This could signify a recognition of the complexity and diversity of pain experiences, prompting researchers to delve into the nuances of a particular aspect rather than treating pain as a uniform entity. The responsiveness may be driven by the clinical relevance of the identified subscale. If this dimension of physical pain is known to have significant implications for patients' well-being or requires specialized interventions, it would naturally draw attention and responsiveness from researchers and healthcare professionals.

As limitations, our sample had patient loss. The sample lost can be considered low as reported by CONSORT guidelines[16] once the majority of selected patients returned after the three-month period for reassessment. The sample size calculated based on the mean and standard deviation of the difference in before and post treatment in the experimental group from a pilot study could guarantee that we show sufficient power to detect differences of this study.

The absence of other studies testing responsiveness psychometric property is a strong point, because this study makes a new contribution to literature. Therefore, it is reasonable to infer that this result represents important data that should be discussed in future studies, since this property represents a tool of significant importance for the validation of the results obtained, in addition to making it possible to compare these data with studies which make scientific evidence more consistent and reliable.

Based on our results, we could provide the validity of an important psychometric property: the OHIP-EDENT responsiveness. After the evaluation of the results, the instrument used in this clinical research proved to be valid and can be an important tool to provide reliable information for healthcare professionals when they are faced with clinical situations where the therapeutic choice will have a strong impact on the general well-being of the individual. These measures can help weigh risks and benefits, as well as assess the cost effectiveness of treatments, thus influencing treatment recommendations and health policies. The incorporation of these measures into a professional's daily life not only represents an improvement in professional performance, but also addresses a humanitarian concern.

CONCLUSION

The OHIP-EDENT (Brazilian version) presents capacity to detect changes in edentulous patient. This instrument can help weigh risks and benefits, assess the cost effectiveness of treatments, and influence recommendations on health policies adopting a more holistic approach to healthcare.

ACKNOWLEDGMENTS

We would like to thank Universidade Federal Fluminense - Instituto de Saúde de Nova Friburgo and Fundação de Amparo à Pesquisa do Estado do Rio de Janeiro.

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