

## Original Research Article

TITLE – VALIDITY AND RELIABILITY OF REVISED IMPACT OF FAMILY SCALE IN PRIMARY CARE GIVER OF CLEFT LIP AND CLEFT PALATE CHILDREN IN WEST BENGAL, INDIA THE HOSPITAL CONTEXT.

### ABSTRACT

**Aim** –The aim of the study was to check the validity and reliability of revised impact of family scale (RIOFS) in Indian setting among Bengali population in parents or primary care giver of cleft lip and cleft palate children who were hospitalised for their treatment in comprehensive cleft care centre, Kolkata, West Bengal, India.

**Materials & methods** –This study was conducted in a comprehensive cleft care centre which is located at Howrah, Kolkata. Original RIOFS (2019) questionnaire was the assessment tool in this study. The original questionnaire was sent to a bilingual teacher (English – Bengali) for translation into Bengali (Version-V1). V1 was sent to Bengali language teacher for semantic correction and idiosyncratic variants (Version -2). In collaboration with other social and psychiatric professional, V2 was compared to the final version of Bengali. The investigator one used the final scale which was filled by 32 parents/primary care giver of cleft lip and cleft palate children who were admitted to a comprehensive cleft care centre in West Bengal for their treatment. Investigator two was used the same scale in same population within 15 days of administering the previous one. Data are tabulated and analysed and statistical method was used to calculate the content validity ratio, inter-observer reliability (ICC) and Cronbach's alpha.

**Results** –Content Validity Ratio (CVR) was ranged from 0.8 – 1 which is within the acceptable limit. The overall intra-class correlation coefficient (ICC) measures 0.844 during

assessment of inter – observer reliability and of Cronbach’s alpha was 0.771 which indicates that RIOFS has overall good validity and reliability measures.

**Conclusion** – RIOFS (2019) is very simple and valid scale which can be used with respect to the Bengali population as the finding support the psychometric properties of questionnaire.

Key words – Revised impact of family scale, Impact of family scale, Cleft lip and palate children, Cleft lip and/palate parent, Validity, Reliability.

## **Introduction**

Cleft lip and cleft palate are morphological alterations that cause functional problems with psychological implications in the individual's life and wellbeing. Now a days, comprehensive Cleft Care is a benchmark of the of cleft care treatment.<sup>1</sup>This Comprehensive Cleft Care managements including the feeding advice to parents just after the birth of baby, feeding intervention, parental counselling, and primary surgery to speech rehabilitation and orthodontic treatment of cleft lip and cleft palate child from their infancy to early adulthood.<sup>2</sup> This treatment need frequent hospitalization of child and mother/primary care giver in different time for surgery and fallow up.

Functional limitations and long-time hospitalization needed for cleft care treatment which might be affect their family environment, as caregivers usually bear important and multidimensional responsibilities over the time. The effective management of these problems along with the care of their child giving them a big challenge and affecting their physical and psychological health, economical status, that might be compromised whole family function. Thus, Quality of life of these parents influenced by their child treatment. The Quality of Life is an important auxiliary measure for clinical indicators to assess the family impact of this infants.<sup>3</sup>

The Impacton Family Scale (IOFS) is an instrument originally designed to assess family burden in the paediatric ambulatory care context. The actual version of it consisted in 27

items grouped in four factors (financial, familial/social, personal strain and mastery). But, a “Revised version of the IOFS” (RIOFS-Table I) considering only 15 items has shown better psychometric properties than the original IOFS, and it used as a shorter, representative and more reliable single factor solution scale. RIOFS have been developed in different versions like Turkey, Germany, Brazil and France.<sup>3</sup>

The purpose of this study is to measure reliability and content validity of RIOFS scale in Indian setting among Bengali population by parents having cleft lip and/ palate child and coming for hospital treatment for their child in comprehensive cleft care centre Kolkata.

Table –I (English Version of RIOFS questionnaire)

1	Our family gives up things because of my child's illness.
2	People in the neighborhood treat us specially because of my child's illness
3	We see family and friends less because of the illness
4	I don't have much time left over for other family members after caring for my child.
5	We have little desire to go out because of my child's illness.
6	Because of the illness, we are not able to travel out of the city.
7	Sometimes we have to change plans about going out at the last minute because of my child's state.
8	Sometimes I wonder whether my child should be treated "specially" or the same as a normal child.
9	I think about not having more children because of the illness.
10	Nobody understands the burden I carry.
11	Traveling to the hospital is a strain on me.
12	Sometimes I feel like we live on a roller coaster: in crisis when my child is acutely ill. OK when things are stable.
13	It is hard to find a reliable person to take care of my child.
14	I live from day to day and don't plan for the future.
15	Fatigue is a problem for me because of my child's illness.

For each item an answer of four choices should be considered. "1. Strongly agree; 2. Agree; 3 Disagree; 4. Strongly disagree"

## Methodology

- I) Questionnaire**–RIOFS questionnaire is used which is validated Turkey, Germany, Brazil and France. In recent 2019 Jalil et al,<sup>3</sup> did RIOFS Spanish validation. English version of RIOFS included 15 item scales. It is a Likert Scale

questionnaire which value each question 1 (strongly agree), 2 (agree), 3 (disagree), 4 (strongly disagree).

Original English version of the RIOFS (Table – 1)

## **II) Study Setting, Study subjects and Study Duration**

This validation study was conducted in ABMSS comprehensive cleft care centre, Howrah West Bengal. Data was collected from either parent of cleft lip and /palate children coming at ABMSS comprehensive cleft care centre Kolkata for their child treatment in the month of February and March 2022. All the parents of cleft children coming in these time syndromic and non – syndromic were included in this study. RIOFS questionnaire was given to 32 parents by investigator one to be filled by parents and after 15 days investigator two was given same questionnaire to same parents to be filled again.

## **III) Procedure**

### **Assessment of validity**

Face and Content Validity were tested by administering the questionnaire to the domain experts (10 experts). The experts were provided with a 4-point content validity assessment tool to assess the relevancy of the tool. At the same time, the original English version of the questionnaire was sent to a bilingual teacher (English-Bengali) for translation into Bengali (version 1, V1). After that, V1 was given to a Bengali language teacher for any semantic correction and made idiosyncratic variants (version 2, V2). In collaboration with a researcher, social worker and other mental health care professionals, V2 was compared to the final version of Bengali. The scale was then back translated into the original (English) language. In this sense, the intention was to reduce the ambiguity and misinterpretation, to ensure a good adaptation to the Bengali population.

### **Assessment of reliability**

Inter – observer reliability was tested to measure reliability. Data was collected from either parent of cleft lip and/or palate children coming at ABMSS comprehensive cleft care centre Kolkata for the treatment of their child in the month of February and March 2022. All the parents of cleft children who came during this period for both syndromic and non – syndromic were included in this

study. Bengali version (V2) of the RIOFS questionnaire was given to 32 parents by a trained investigator to be filled by parents. Same questionnaire was administered by a second investigator to the same set of parents within 2 weeks of administering the questionnaire by the first investigator.

### **Internal Consistency**

It is assessed by computing Cronbach's alpha for each item, sub scale and for entire study instrument after the data collection from all the study subjects. Cronbach's alpha was computed for each scale to assess internal consistency with 0.7 considered minimally acceptable.

### **Statistical analysis**

Data were tabulated and analyzed using the IBM SPSS version 26 and the statistical methods used were Content Validity Ratio, ICC and Cronbach's alpha. Content Validity Ratio (CVR) measures the essentiality of an item [4]. The formula of content validity ratio is  $CVR = (N_e - N/2) / (N/2)$ , in which the  $N_e$  is the number of panellists indicating "essential" and  $N$  is the total number of panellists. The numeric value of content validity ratio is determined by Lawshe content validity ratio Table. For **validity ratio** the number of experts, who rated 3 and 4 for any item, are considered as  $N_e$ , where 0.8 ratio are considered as acceptable.<sup>4</sup>

Cronbach's alpha intensity was used to assess the internal consistency of the instrument. It is expressed as a number between 0 and 1 (**Figure 1**). Internal consistency describes the extent to which all the items in a test measure a similar concept or construct<sup>5</sup>. If alpha is too high it may suggest that some items are expendable as they are testing the same question but in a different guise. A maximum alpha value of 0.90 has been recommended.<sup>6</sup>

Figure – 1 (Internal consistency interpretation)

The Interclass correlation coefficient (ICC) was used to assess Inter – observer reliability. The ICC is a value measures between 0 and 1, where values below 0.5 indicate poor reliability, between 0.5 and 0.75 moderate reliability, between 0.75 and 0.9 good reliability, and any value above 0.9 indicates excellent reliability. Spearman’s rho was also calculated to measure overall correlation of items during the two investigators. These results were used to evaluate the psychometric properties of the questionnaire and to confirm that each item directly measured what it intended.

## **Results**

### **i) Content validity**

Results of the Content Validity Assessment are presented in (Figure - 2). All the item of RIOFS questionnaire shows CVR from 0.8 to 1. Item 2,3,4,7,9,14,15 have CVR value of 0.8 and Item 1,5,6,8,10,11,12,13 have CVR value of 1 (Figure - 2). For a number of 10 experts, CVR value of 0.8 is considered acceptable.<sup>4</sup> Hence, the RIOFS questionnaire elicited overall acceptable content validity.

Figure– 2(Content validity ratio)

### **ii) Inter – observer reliability**

All the item of RIOFS has ICC value range from 0.35 to 1 in two different group. ICCs were classified as follows: ‘excellent’ ( $\geq .81$ ), ‘good’ (.61 - .80), ‘moderate’

(.41 - .60), 'poor' ( $\leq .40$ )<sup>10</sup>. Item no 6 (because the illness we are not travel out of the city) and 7 (sometimes we have to changed the plan for going out at last minute because of child illness) scored 0.645 and 0.626 which interpreted moderate reliability. Item no 5 (We have little desire to go out because of my child illness) and item no 13(it is hard to found a reliable person to take care of my child) also scored less 0.674 and 0.664 interpreted moderate reliability (Table II). However, overall ICC value for the questionnaire measured 0.84 which indicates that RIOFS (V2) questionnaire is reliable. Spearman's rho was measured as 0.815 which depicts good positive correlation in inter – observer reliability.

	<b>Inter-class (Corelation) Coefficient Values (95% CI)</b>	<b>95%CI</b>	
Item 1	1	1.000	1.000
Item 2	0.892 (0.787 – 0.946)		
Item 3	0.854	0.718	0.927
Item 4	0.83	0.677	0.914
Item 5	0.674	0.424	0.828
Item 6	0.645	0.381	0.811
Item 7	0.626	0.354	0.800
Item 8	1	1.000	1.000
Item 9	0.769	0.574	0.882
Item 10	1	1.000	1.000
Item 11	1	1.000	1.000
Item 12	1	1.000	1.000
Item 13	0.664	0.410	0.823
Item 14	0.783	0.596	0.889
Item 15	1	1.000	1.000
Total	0.844	0.701	0.921
P= 0.000			



during instrument development. Validity is not the property of an instrument, but the property of the values obtained by an instrument used for a specific purpose on a special group of respondents. Therefore, validity evidence should be obtained on each study for which an instrument is used".<sup>5, 6, 9</sup>

"Reliability is tasked with the ability of an instrument to measure consistently.<sup>4</sup> It should be observed that the reliability of an instrument is intimately associated with its validity. If an instrument is not reliable, then it cannot be said to be valid. However, the reliability of an instrument does not depend on its validity"<sup>6, 7, 8</sup>. To ensure reliability, Cronbach's alpha integration and ICC were calculated for the questionnaire. In general, the results were acceptable.

"This adapted version of the RIOFS in the hospital context has been presented as a simple answering tool. The study proved that proposed scale have acceptable psychometric properties of reliability and validity that would validate its application in parents having cleft lip and/palate children or caregiver's population. These results could be explained by the fact that RIOFS is a one-factor solution, unlike the original IOFS which exhibit poorer psychometric properties than the revised version like Jalil et al 2019".<sup>3</sup> "Our results suggest that they remained acceptable after this process. The internal consistency showed acceptable values (0.778 Cronbach's alpha), framed in the category of "good" (values > 0.7), as reported" by Steiner et al.<sup>6</sup>

## **Conclusion**

Cleft lip and **cleft palate** children need treatment from their infancy to early childhood including primary surgery, revision surgery, plastic surgery, speech rehabilitation, etc which required frequent hospitalization both mother and child. Thus parents of these children have a negative effect on their quality of life. This study recommended that RIOFS is a valid and reliable simple, non invasive tool for evaluation of quality of life of parents having cleft lip and /palate children.

## **Limitation –**

This study has several limitations. It was a single centred and small population study. We need to further study with multi-centric and in big population.

## **Ethical Approval**

Requisite ethical clearance & permission to undertake the study was obtained from Gurunanak Institutional ethical committee of Gurunanak Institute of Dental Sciences and Research, Kolkata. Ethical approval no is GNIDSR/IEC/2020-23/04.

### **Consent**

As per international standard or university standard, Participants' written consent has been collected and preserved by the author(s).

### **Acknowledgement –**

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### **Conflicts of Interest**

There are no conflicts of interest.

### **References**

1. Havlik, Robert J. *Comprehensive Cleft Care*. Plastic and Reconstructive Surgery. September 2009; 124(3): 995
- 2.Kharbanda OP, Monga N. Cleft care in India: What is missing?. J Indian Orthod Soc 2018;52:S97-100
- 3.Jalil et al. Journal of Patient-Reported Outcomes (2019) 3:28 <https://doi.org/10.1186/s41687-019-0118-1>.
- 4.Ayre C, Scally A. Critical Values for Lawshes Content Validity Ratio. Measurement and Evaluation in Counselling and Development. 2013; 47:79-86.
- 5.Cronbach L. Coefficient alpha and the internal structure of tests. Psychometrika. 1951;16:297-334.
6. Streiner D. Starting at the beginning: an introduction to coefficient alpha and internal consistency. Journal of personality assessment. 2003;80:99-103.
- 7.Tavakol M, Mohagheghi MA, Dennick R. Assessing the skills of surgical residents using simulation. J Surg Educ. 2008;65(2): 77-83

8. Lynn MR. Determination and quantification of content validity. *Nurs Res.* 1986;35(6): 382-5
9. Waltz CF, Strickland O, Lenz ER. *Measurement in nursing and health research.* 4th ed. New York: Springer Publishing Company; 2010
- 10.** Fleiss, J. L.: *The Design and Analysis of Clinical Experiments.* Wiley, New York – Chichester – Brisbane – Toronto – Singapore 1986, <https://doi.org/10.1002/bimj.4710300308>

