Original Article

Development of Caries Risk Assessment Tool for Iranian Preschoolers: A Primary Validation Study

Abstract

Background: The aim of the present study was to develop a dental caries risk assessment tool for Iranian preschoolers. **Methods:** In a validation and cross-sectional study, a random sample of 150 preschool children was involved. This study was conducted in three phases: questionnaire design (expert panel and peer evaluation), questionnaire testing (pilot evaluation and field testing), and validation study. The initial assessments include interview, dental examination, and laboratory investigations. Validity and reliability indices, content validity index (CVI), content validity ratio (CVR), impact score, and test-retest and Cronbach's alpha were measured. Decayed, missing, filled teeth (dmft) scores were calculated according to the WHO guidelines. **Results:** The Iranian version of caries risk assessment (CRA) questionnaire contained 17 items. Cronbach's alpha coefficient (0.86) indicated a suitable internal consistency. The mean scores for the CVI and the CVR were 0.87 and 0.78, respectively. The prevalence rate of dental caries in the study group was 69.3%, and the mean dmft was 4.57 (range 0–19). **Conclusions:** The Persian version of CRA questionnaire was adapted to the Iranian population. The findings demonstrated overall acceptable validity and also reliability in the application of test-retest. The results of the present study provide initial evidence that the designed CRA form could be a useful tool for CRA in the Iranian preschoolers.

Keywords: *Dental caries, Iran, preschool child, risk assessment*

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Introduction

Dental caries, as a global disease, is a multifactorial, transmissible, and pH-mediated disease with several components caused by interactions of various factors such as acidogenic bacteria, biofilm, and individual caries risk factors.[1-4] Dental caries is one of the most common chronic diseases of childhood. The results of a National Survey in the United States showed that approximately 20% of Americans had untreated caries and about three-quarters of the population had at least one restoration.[5] In an epidemiologic study in four communities, in the province of Manitoba and Canada, the overall prevalence of early childhood caries (ECC) was more than 50%, and the prevalence was similar in all 4 communities.[6]

Dental caries is highly prevalent among populations of low socioeconomic status (SES).[7] It is well known that it can be prevented and arrested, especially in very young children.[8-10] While it is relatively inexpensive to prevent ECC, when left untreated it can cause several dental, medical, and social side effects influencing the children's quality of life.[11] Identification of children, who has a greater chance of developing caries and focusing the preventive and treatment practices on these children, is the basic concept of caries risk assessment (CRA).[12]

CRA is defined as the process of predicting the chance of developing a patient's new carious lesions over a specific period.[13] Early and objective identification of children at high caries risk lead to appropriate and cost-effective interventions and determination of the periodicity of these services.[13,14]

CRA is an important tool which guides the clinician to better determine the patient's caries risk.[15-17] In addition, due to this fact that caries in the primary teeth is strongly associated with carries in permanent dentition, the CRA and its subsequent measures are vital for children.[18]

The prevention of dental caries in children is generally considered as a dental services priority.[7] Since the 1990s, various risk-based caries prevention strategies have been developed.[13,19] On the other hand, the

How to cite this article: Mortazavi S, Enshaei Z, Farajzadegan Z. Development of caries risk assessment tool for iranian preschoolers: A primary validation study. Int J Prev Med 2017;8:92.

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Access this article online

Website: www.ijpvmjournal.net/www.ijpm.ir

DOI: 10.4103/ijpvm.IJPVM_256_17

Quick Response Code:

complex nature of caries risk has led to the expansion of various protocols that are not all validated.[20]

By now, several models of caries-risk assessment have been suggested by professional societies, such as American Academy of Pediatric Dentistry, California dental association, a computerized program – cariogram – and so forth. However, the accuracy of these models has not been proven, or its validity in preschool children was unsatisfactory.[21-25]

As far as we know, there is not any CRA survey or validation study in Iran. The objective of this study was to develop a dental CRA tool for Iranian preschoolers.

Methods

This validation and cross-sectional study was conducted on a random sample of 150 preschool children in Isfahan, Iran, between May 2015 and February 2016. This sample size was defined based on the general recommendation of having at least 100 participants for questionnaire validation studies and applying multivariate analyses.[26] The study protocol was approved by the Ethics Committee of Isfahan University of medical sciences. With parental written consent, participants were recruited from four kindergartens in the Isfahan, Iran. These kindergartens were located in neighborhoods with families of different socioeconomic profiles. The inclusion criteria were: (1) age less than 6 years, (2) at least 2 teeth erupted, (3) permanent residence in Isfahan, and (4) being willing to participate in the study. Children whose parents did not sign the informed consent were excluded from the study.

As shown in Figure 1, the present study was conducted in three phases: questionnaire design (expert panel and peer evaluation); questionnaire testing (Pilot evaluation and field testing); and validation study.

The focus group was established based on a literature review, study objectives, and findings of the previous studies. The A panel of 15 experts including General dentists, specialists in Pediatric Dentistry, Restorative, Dentistry, Orthodontics, Public Oral Health, and Tool Developers judged the face and content validity of the developed questionnaire.

To determine the reliability of tool, the researchers applied developed the form in two stages with an interval of two weeks for 20 children.

The assessment section included: (a) Face-to-face interview with the parents of the child to gather information on their socioeconomic status, child's demographic background, and oral health habits and medication; (b) dental caries registration at the cavitation level according to the World Health Organization criteria; also recording white-spot lesion, dental plaque, developmental defect, and dental appliance; and (c) measuring stimulated salivary flow rate (ml/min), salivary microbial counts (*Streptococcus mutans* and *Lactobacillus*) and buffer capacity. The salivary flow was stimulated by chewing a piece of paraffin wax for 5 min.

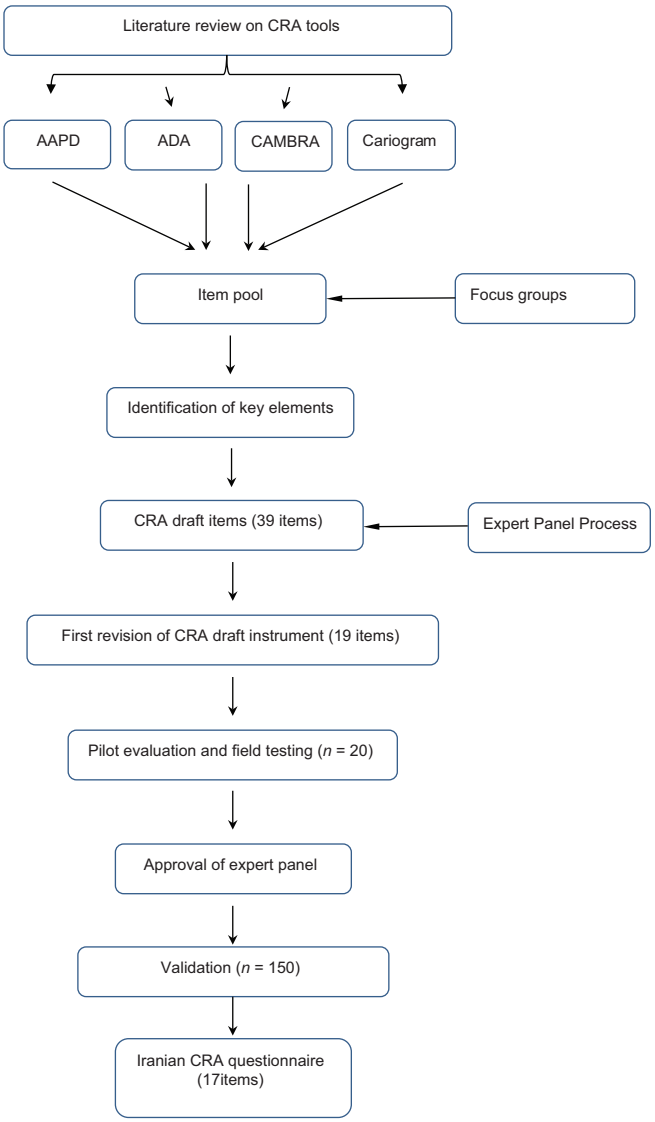

Figure 1: Form development diagram

All children were examined by an experienced dentist, with a sterile mouth mirror. All examinations – after cleaning the teeth – were conducted in the supine position. No dental radiographs were taken.

Collected data included child's age, sex, decayed, missing, filled teeth (dmft), dietary history and habits, SES, oral hygiene, dental care, medical conditions, and laboratory tests. We used the principal component analysis for computing SES. To achieve this, participants were asked to provide family income level, educational degree, and occupation. We combine a number of measures to ensure the credibility of the designed questionnaire. The content validity index (CVI) and the content validity ratio (CVR) were measured and items which acquired least values of 0.51 and 0.79 were considered acceptable, respectively.[27,28]

Impact scores were used to examine the questionnaire face validity with minimum impact score of 1.5.[28] Reliability of the questionnaire was calculated by test-retest and Cronbach's alpha with values >0.70 being considered acceptable.[29] Statistical analyses were done by SPSS software (SPSS, Inc., Chicago, IL, USA, version 23). Descriptive data are reported as a mean ± standard deviation, median (interquartile range), or number (percent) as appropriate. Independent sample *t*-test, Chi-square and Fisher exact tests, and Chi-square for trend was used as appropriate. Multivariable logistic regression was used for identifying predictors of caries risk. The level of significance was considered to be less than 0.05.

Results

During the study, 150 children (52.7% girls, 47.3% boys) were examined. The mean age of studied population was 46.2 ± 19.3 months. Among these children, the prevalence of caries experience was 69.3%, increasing from 8.3% in the youngest age group (under 2 years) to 90% in the 5-year-olds.

Figure 1 shows the form development flowchart. The final version of the questionnaire contained of 17 items. All items showed acceptable lower limits values for CVI and CVR. Overall, the scale CVI was found to be 0.87, and the CVR was 0.78. The reliability of the whole items was estimated using Cronbach's alpha. The mean of test–retest reliability of questionnaire was an acceptable range (Cronbach's alpha = 0.863). The summary results relating to the psychometric properties of Iranian version of CRA questionnaire are shown in Table 1.

As shown in Table 2, the mean dmft score was 4.6 (range 0-19), and the frequency of dmft higher than 1 was 62.7% of the sample. Table 3 provides detailed information about dmft in all participants. As shown in Table 3, the upper age groups, bottle use at bed, mothers' active caries status, visible plaque and white spot lesions, saliva thickness, and levels of MS in saliva; significantly related to caries.

For identifying potential determinants and predictors of dental caries in this study, we performed multiple logistic regression analysis. The variables with a *P* value less than 0.1 on univariate analysis were retained for the multivariate regression tests to identify significant independent factors associated with caries risk [Table 4].

Table 1: Results of the validity and reliability for the Iranian caries risk assessment questionnaire

Aspect	Index	Statistical test	Score or range
Validity	Content validity	CVR	0.78
		CVI	0.87
	Face validity	Impact score	2.1-5.0
Reliability	Internal consistency	Cronbach's alpha	0.86

CVR=Content validity ratio, CVI=Content validity index

Discussion

The main objective of this population-based, randomly selected participant, and cross-sectional study was the development of a dental CRA tool for Iranian preschoolers. The secondary objectives of the study were to determine the prevalence, associated factors, and predictors of dental caries in this population.

To the best of our knowledge, this is the first attempt for the development and validation of such scale to measure caries risk in Iran.

The results of the present study indicate that the Persian version of designed questionnaire is a valid and reliable tool to assess dental caries risk in Iranian preschool children as well as other related tools. A caries assessment tool should be simple and have high specificity.[30] Although the Cariogram was satisfactorily validated for the school-aged children and adults,[25,31] its validity was not acceptable in preschoolers.[25] Recently, CAMBRA has been validated in a population of 12,954 people, and its accuracy has been proven in determining high- and very high-risk people.[32] CAMBRA has higher sensitivity (≥93.8%) and lower specificity (≤43.6%) as compared with computer algorithms of CRA like Cariogram. However, by adding biological tests, its specificity was improved (lower false-positive rate).[33]

The provided form of this study was developed based on existing CRA systems. In general, these systems, differ in total number of studied factors, areas of assessments (e.g., socioeconomic, microbiological, and salivary), and target population. The classification of high- and low-risks varies among systems. However, it seems that there is an overlap in the main known etiologic factors and disease indicators such as caries experience, dental plaque, exposure to fluoride, diet, salivary flow, and general health status.[20]

The prevalence of caries in our study population of children younger than six years, was 69.3% (95% confidence interval: 61.9-76.8) and mean dmft score was 4.6. Although the prevalence of dental caries varies worldwide and is high in most countries,[34] we need to recognize this as a warning sign that caries in the Iranian preschool children is high, and requires special attention. In a national survey on the dental health of California's children, 27% of preschoolers have untreated decay.[35] In a study by Yoon and colleagues,[36] prevalence of ECC was 48.6%. The prevalence of caries in the national average for children of this age, in 2007,[37] was 31.4%; and in a community-prevalence study for 3- and 4-year-old children,[38] was 66.0%.

The univariate analysis demonstrates a fairly significant relationship between caries prevalence and the upper age groups, bottle use at bed, salivary levels of MS, white spot lesions, active caries in the mother/caregiver, saliva thickness, and visible plaque on the teeth ($P < 0.05$).

Table 2: Descriptive statistics of caries status (decayed, missing, and filled teeth index) in 150 Iranian preschoolers

Characteristics	*n* (%)	Mean	Minimum-maximum	Median (IQR)
dmft	-	4.57	0-19	4 (0-8)
Decayed	-	5.65	0-47	3 (0-8)
Missing	-	0.87	0-20	0
Filled	-	3.15	0-40	0 (0-1.25)
dmft=0	46 (30.7)	-	-	-
dmft >0	104 (69.3)	-	-	-
dmft >1/>5/>10	94 (62.7)/59 (39.3)/21 (14)	-	-	-

dmft=Decayed, missing, and filled teeth, IQR=Interquartile range

Table 3: Baseline characteristics of 150 participants under caries risk assessment at first oral evaluation and its association with dental caries (the dependent variables - decayed, missing, and filled teeth - was dichotomized [decayed, missing, and filled teeth=0 vs. decayed, missing, and filled teeth ≥1])

Characteristics	Total	Frequency of DC based on dmft		*P*
		Positive 104	Negative 46	
Age (month)	46.2±19.3	52.6±15.5	31.8±19.2	<0.0001*
Age group (year)				
≤1	24 (16.0)	2 (8.3)	22 (91.7)	<0.0001**
2	25 (16.7)	19 (76.0)	6 (24)	
3	25 (16.7)	18 (72.0)	7 (28)	
4	26 (17.3)	20 (76.9)	6 (23.1)	
5	50 (30.7)	45 (90.0)	5 (10)	
Gender, boy/girl	71/79	47/57	24/22	0.430#
Low socioeconomic status	78 (52)	59 (75.6)	19 (24.4)	0.081#
Bottle use at bed	23 (15.3)	10 (43.5)	13 (56.5)	0.003#
Breastfeed throughout the night	112 (74.7)	80 (71.4)	32 (28.6)	0.339#
Frequent consumption of fermentable carbohydrate	65 (43.3)	47 (72.3)	18 (27.7)	0.490#
Special health-care needs	0	-	-	-
Regular dental care	38 (25.3)	31 (81.6)	7 (18.4)	0.058#
Visible plaque on the teeth	75 (50.7)	62 (82.7)	13 (17.3)	<0.0001#
Orthodontic/intraoral appliance	4 (2.7)	4 (100)	0	0.313$
White spot lesions/enamel defects	106 (71.1)	85 (80.2)	21 (19.8)	<0.0001#
Active caries in the mother/caregiver	84 (56)	64 (76.2)	20 (23.8)	0.040#
Saliva reducing factors (medications/radiation, systemic disease)	10 (6.7)	9 (90.0)	1 (10)	0.285$
Thick or ropy saliva (saliva thickness)	21 (14)	20 (95.2)	1 (4.8)	0.006#
Salivary flow rate (mL/min) (*n*=75)	0.46±0.24	0.47±0.25	0.43±0.23	0.671*
Inadequate salivary flow (<0.5 mL/min)	51 (68)	43 (84.3)	8 (15.7)	0.716#
Buffer capacity of the saliva (*n*=75)				
High	65 (86.7)	54 (83.1)	11 (16.9)	0.708$
Medium	8 (10.7)	8 (100)	0	
Low	2 (2.7)	2 (100)	0	
Salivary levels of MS (*n*=75)				
High	59 (78.7)	54 (91.5)	5 (8.5)	0.009$
Low	16 (21.3)	10 (64.5)	6 (37.5)	
Salivary levels of LB				
High	54 (72)	49 (90.7)	5 (9.3)	0.063$
Low	21 (28)	15 (71.4)	6 (28.6)	
Fluoridated drinking water/fluoride supplements	0	-	-	-
Professional topical fluoride	18 (12)	15 (83.3)	3 (16.7)	0.170#
Daily use of fluoride toothpaste	74 (49.3)	56 (75.7)	18 (24.3)	0.096#

Data expressed as mean±SD (minimum-maximum), *n* (%). *P* values calculated by *Independent sample *t*-test, **χ^2 for trend, #χ^2 and $Fisher exact test. DC=Dental caries, dmft=Decayed, missing, and filled teeth, SD=Standard deviation, MS=Mutans Streptococci, LB=Lactobacilli

In contrast to some previous studies,[39-41] our study failed to provide evidence for significant association between salivary levels of SM, saliva thickness, dental plaque, salivary levels of LB, and dental caries.

Table 4: Multivariable-adjusted odds ratios and 95% confidence intervals for the independent association of various potential caries risk predictors with dental caries (decayed, missing, and filled teeth) obtained from multivariable logistic regression

Variables	β	OR	95% CI for OR	*P*
Age (year)	0.183	1.200	0.294-4.901	0.799
Bottle use at bed	−1.539	0.215	0.009-5.269	0.346
Visible plaque on the teeth	0.712	2.038	0.190-21.888	0.557
White spot lesions/enamel defects	3.496	32.998	1.732-628.694	0.020
Active caries in mother/caregiver	2.809	16.592	0.696-395.387	0.083
Salivary levels of MS	1.257	3.515	0.391-31.560	0.262
Thick or ropy saliva (saliva thickness)	0.343	1.410	0.080-24.875	0.815
Regular use of fluoride	0.813	2.256	0.115-44.336	0.592
Salivary levels of LB	2.342	10.404	0.611-177.159	0.105
Regular dental care	−4.849	0.008	0.000-0.693	0.034
Low socioeconomic status	−1.950	0.142	0.006-3.506	0.233

CI=Confidence interval, OR=Odds ratio, MS=Mutans streptococci, LB=Lactobacilli

Based on multivariate regression analysis, in this study, white spot lesions (P = 0.20), Active caries on mother or caregiver (P = 0.083), and regular dental care (P = 0.034) were independent predictors of dental caries. The interaction of various factors should be considered when analyzing ECC as a multifactorial process. The effects of some risk factors on caries risk seem to be altered in fluoridated communities.[42] Our study was carried done in a non-fluoridated community deprived from caries preventive effects of systemic fluoride. Therefore, the studied children are at higher risk at baseline regardless of other risk factors.[43] Hence, these findings can be partly explained by inaccessibility to systemic fluoride (i.e., water fluoridation and fluoride supplements).

Implications for practice and research

The Persian version of CRA form can be used in educational environments, dental schools, clinical trials, and epidemiological studies. Furthermore, general dentists and specialists can use this tool to better assess the patient's condition and response to therapy.

Limitations and strengths of study

Results of this study need to be considered in the context of its limitations. Given the cross-sectional nature of the present study, we cannot make any causal interpretation; and however, the results must be interpreted with caution. Well-designed and large-scale prospective studies are needed to determine predictors of dental caries. Another limitation of the study is that despite the statistically significant results, the sample size was relatively small. Further research is necessary to replicate the findings on a larger and representative sample.

Despite these limitations, the current study is the first that provides a valid and reliable form for assessing dental carries in Iranian preschoolers and Farsi-speaking community. Further assessment of the reliability and validity of this questionnaire should be undertaken in other studies.

Conclusions

Our study provides evidence that the Persian version of the designed questionnaire is a simple, practical, efficient, reliable, and unbiased tool for dental CRA in this sample of preschool children.

Acknowledgments

This investigation was supported by Health System Research (HSR) Council of Isfahan University of Medical Sciences. Research grants No. 194252.

Financial support and sponsorship

This investigation was supported by Health System Research (HSR) Council of Isfahan University of Medical Sciences. Research grants No. 194252.

Conflicts of interest

There are no conflicts of interest.

Received: 20 Jun 17 **Accepted:** 27 Aug 17
Published: 07 Nov 17

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