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AGREEMENT BETWEEN THREE CARIES RISK ASSESSMENT METHODS

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PURPOSE. To evaluate the agreement between the CAMBRA, Cariogram, and ADA caries risk assessment methods in real adult subjects.

MATERIALS AND METHODS. Adult patients were examined at a private dental practice and filled in a questionnaire investigating health self-perception and dietary habits. An objective check-up, including saliva flow rate and buffering capacity (PH) tests, was performed. According to the patients' characteristics, they were classified as at high, moderate or low risk of caries using the CAMBRA, Cariogram, and ADA caries risk estimation methods. The Kappa statistic was used to verify the degree of agreement between the three methods. The difference in risk assessment between the methods was evaluated using the Bhapkar test.

RESULTS. Thirty-one patients were included. The CAMBRA, Cariogram, and ADA methods estimated 24, 17 and four patients at high risk of caries, respectively. The Kappa statistic was 0.19 (95% confidence interval 0.01 to 0.37), indicating poor agreement between the three protocols. In fact, complete agreement was found among the three methods in only three cases (10%, 95%CI: 2; 26). The difference between risks estimated via the three methods was statistically significant (P <0.001).

CONCLUSIONS. There was very low agreement among the three examined methods of estimating the risk of caries in patients.

CONFLICT OF INTEREST STATEMENT
The authors declare that they have completely self-funded the study and that there are no conflicts of interest.

INTRODUCTION

Dental caries is one of the most prevalent chronic diseases affecting people worldwide; individuals remain susceptible to this disease throughout their lifetime[1]. It is a multifactorial pathology that occurs due to an imbalance among the host, their environment and the oral microbiome, which results in the demineralization of the tooth structure[2].
Individual caries risk assessment (CRA) is a clinical process for classifying the probability that caries lesions will appear or progress if the conditions remain the same within a defined period[3,4]. It is carried out as part of a patient-centred caries management strategy to reduce the risk of caries[4]. Dental providers should be skilled in assessing individual patients' risk of dental caries, so that effective and minimally invasive preventative strategies can be deployed to prevent them developing[5,6]. An important first step in managing dental caries is

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assessment of the risk level for their future occurrence, and CRA should therefore be performed periodically to monitor oral health changes over time[7].

There are numerous published methods and guidelines for CRA in caries management[7]. Several CRA are readily available and used internationally, namely CAMBRA (Caries Management by Risk Assessment), Cariogram, and ADA[7]. Recent reviews have attempted to assess the validity of different CRA models/factors[8-10], and several systematic reviews have evaluated the three CRA methods separately[8-12]. In these, the Cariogram was found to be a reliable CRA model for prediction of caries development in both clinical practice for dental patients and communities for general populations[12]. In another systematic review[10]. Cariogram sensitivity and specificity were respectively calculated; sensitivity was low (41.0) to fairly low (75.0), while specificity was higher, ranging from 65.8 to 88.0[10].

However, the scientific evidence on the validity of existing systems is limited[10,11], and standardized CRA models are still lacking; even though Cariogram and ADA (American Dental Association) CRA methods have been tested in children and adults in a few studies of good quality, there is as yet insufficient evidence to state that these methods are effective in caries assessment and prediction[10,13]. Although CAMBRA, Cariogram, and ADA have recently been compared in a study on 26 hypothetical patients, 13 children and 13 adults[14], to date, no study has focused on their agreement in individual CRA of real adult patients. Thus, we do not know how similar the caries risk estimation methods are in real clinical settings.

The aim of the present study, therefore, was to calculate the agreement between CAMBRA, Cariogram, and ADA estimates of individual caries risk in real patients.

MATERIALS AND METHODS

Trial design

This paper was written following the guidelines for reporting reliability and agreement studies (GRRAS)[15]. This was a single-centre, single examiner agreement study between three CRA methods.

The three methods of determining three levels of risk of caries each (high, moderate, low risk of caries) were:

- Caries management by risk assessment (CAMBRA)[16];
- Cariogram[17];
- American Dental Association (ADA) CRA[18].

Eligibility criteria for participants

The investigation was carried out from June to October 2015. During this period, 31 patients seeking oral hygiene procedures at a private clinic located in Campi Bisenzio, Florence, Italy, were consecutively recruited for the study.

The inclusion criteria used for selection were:

- age between 18 and 85 years;
- presence of at least 20 teeth.

Written consent to their inclusion in the study was obtained from all patients.

Interventions

The CAMBRA, Cariogram, and ADA questionnaires were translated into Italian. Each participant underwent an oral hygiene session before the start of the study. Demographic and clinical data were collected.

Data from the following were collected for each patient (see below for details):

- questionnaire featuring questions from CAMBRA, Cariogram and ADA relating to health and nutrition;
- physical examination by an expert operator (UP) to assess for exposed roots, carious lesions, plaque, DMFT (Decayed Missed Filled Teeth), white spots, restorations, orthodontic appliances, deep pits and fissures, and unusual tooth morphology;
- saliva flow rate testing;
- salivary buffering capacity test.

The questionnaire, physical examination and all tests were carried out in a single session. A single operator (UP) performed the physical examination and compiled the questionnaire for all patients. For those applications that required radiographic confirmation of the carious lesion, previous radiographs were examined or new radiographs were taken.

CAMBRA

The CAMBRA risk assessment is the first step in caries prevention and management[16,19], and is performed in two phases: initially the specific disease indicators, risk factors, and protective factors are determined for each patient, while the second step involves determining the level of risk given by the sum of the factors indicated. The risk level can then be used to determine the need for intervention, and is an integral part of treatment planning. The CRA form used in this study was that for "children age 6 and over/adults"[19].

The four specific indicators of caries, clinical observations that inform about the past caries history and activity, considered are:

1. cavities or lesions that are radiologically located in the dentin;
2. radiographic lesions confined to enamel;
3. white spots on smooth tooth surface;
4. dental restorations in the last 3 years.

A positive response to even just one of these categories automatically places the patient at high risk of caries[19].

Caries risk factors, on the other hand, are biological factors that cause or worsen the disease. They include visible heavy plaque on teeth, frequent snacking (>3x daily between meals), deep pits and fissures, and inadequate saliva flow, etc. Protective factors are biological or therapeutic factors or measures that can collectively offset the challenge presented by the previously mentioned caries risk factors. Protective factors include using fluoride toothpaste at least once daily, fluoride mouth rinse (0.05% NaF) daily, xylitol gum/lozenges 4xdaily in the last 6 months, etc.

Determining the caries risk for each individual requires weighing up the number and severity of the disease indicators/risk factors against the protective factors, using the caries balance concept[19]. An individual with carious lesions currently or in the recent past is at high risk of future caries by default. A patient with low bacterial levels would need to have several other risk factors to be considered at moderate risk.

For these reasons, in the present study a patient was classified as at high risk of caries when there was at least one positive response in the disease indicators section. A patient was classified as being at moderate risk when the positive responses in the risk factors column prevailed over the positive responses in the protective factors column. Finally, a patient was classified as at low risk when the positive responses in the protective factors column prevailed over the positive responses in the risk factors column. If the positive responses in the risk

factors and protective factors columns were equal in number, the patient was still placed in the moderate-risk group.

Cariogram

Cariogram® (AppBites, Prishtina, Kosovo) is a software programme and an App for dental health professionals that evaluates an individual's caries risk profile and illustrates it in graphical form[20,21]. Caries-related factors considered by the algorithm are past experience of caries, related general diseases, diet content and frequency, plaque amount, fluoride programme, saliva secretion rate and saliva buffer capacity (the optional *Streptococci mutans* count and clinical judgement were omitted in this study).

The factors included in the Cariogram have been given different "weights". This means that the key factors, which support the development of or resistance to caries, have a greater impact than the less important factors when the software calculates the "Chance of avoiding new cavities". The factors are also weighted in relation to each other. Thus, different factors have different "weights" in different situations, and the number of combinations of factors is enormous[20]. Once the patient's data has been entered into the programme, it yields a pie-chart divided into five coloured sections. In particular, the green sector of the pie-chart shows the estimate of the current "Chance of avoiding new cavities"[20].

For the purposes of this study, the patients were allocated to the low, high and moderate risk groups as follows[20]:

- if the pie-chart was more than 75% green, the patient was considered at low risk of developing caries;
- if the pie-chart was less than 25% green, the patient was considered at high risk of developing caries;
- if the pie-chart was between 25% and 75% green, the patient was considered at moderate risk of caries development.

ADA

The CRA form used in this study was that for patients over age 6[18]. The ADA form investigates three different condition types (Contributing conditions, General health conditions, and Clinical conditions)[18]. Contributing conditions investigated are: fluoride exposure, sugary food or drinks, caries history of parent, caregiver and/or other siblings, and regular dental care. General health conditions include special healthcare needs, and chemo/radiotherapy, etc., while Clinical conditions explored are carious lesions or restorations, teeth missing due to caries in past 36 months, visible plaque, etc.[18]

Thus, the ADA method not only takes into account the general health conditions and the clinical conditions, but also the eating habits, the lifestyle of a person, and the customs and traditions of the country of origin. A patient was classified as being at low risk when only conditions in "Low Risk" column were present; at moderate risk when only conditions in "Low" and/or "Moderate Risk" columns were present, and at high risk when one or more conditions in the "High Risk" column were present[18].

Saliva flow test

The salivary flow rate test was used to evaluate the volume of saliva produced. Specifically, the patient was seated in a relaxed upright position, and given paraffin wax to chew for 5 minutes. The patient was then asked to spit out all the accumulated saliva into a measuring glass. The amount of saliva produced was measured, and the secretion rate calculated (e.g., 3.5 mL in 5 min = 0.7 mL/min). Normal salivary secretion is greater than 1 mL/min[20].

Salivary buffering capacity

Dentobuff Strips (Saliva-Check Buffer, CG Tokyo, Japan) were used to determine salivary buffering capacity. An indicator system incorporated into the test strip changes colour, clearly showing the buffering capacity of the saliva. A pipette was used to apply a drop of stimulated saliva to the test pad, enough to cover the entire pad. When a drop of collected saliva is added to the test pad of the strip, the saliva starts to dissolve the acids dried into the test pad, which also contains pH-sensitive dyes. After a 5-minute reaction time, the operator (UP) compared the colour that had developed on the test pad with the Dentobuff Strip Colour Chart. This test system discriminates between low (yellow), medium (green), and high (blue) buffering capacity.

Sample size

The sample size calculation was performed using the function "CI3Cats" of the package "kappaSize" for R environment for statistical computing[22]. This function provides sample size estimation for k statistic using the confidence interval perspective, and assumes that the outcome has three categories[22]. The anticipated value of k was set at 0.5, the lower bound of the CI95% was set at 0.3, and the upper bound at 0.7. The proportion of patients at high, moderate and low risk of caries were set respectively at 0.25, 0.50 and 0.75. Considering three CRA methods (CAMBRA, Cariogram, ADA), based on the previous parameters, a sample size of at least 30 subjects was necessary.

Statistical methods

Descriptive statistics are expressed as means and standard deviation for quantitative variables and frequency and percentage for qualitative variables. K-statistics with 95% confidence intervals were estimated to assess the agreement among the three methods of risk assessment (CAMBRA, Cariogram and ADA). The k-statistic is a more robust measurement than a simple percentage agreement calculation since it takes into account the agreement occurring by chance. If there is no agreement among the methods other than what is expected by chance, k is equal to 0. Values greater than 0.80 correspond to almost perfect agreement; values between 0.61 and 0.80 correspond to substantial agreement; values between 0.41 and 0.60 correspond to moderate agreement; values between 0.21 and 0.40 correspond to fair agreement; and values equal to or lower than 0.20 correspond to poor or slight agreement[23].

Fleiss k coefficient in the Gwet version using quadratic weight was used to assess the agreement of the three methods of risk assessment[24,25]. Cohen's kappa statistic with quadratic weights was used as a secondary analysis for the pairwise comparison of the three methods. In addition, the Bhapkar test for homogeneity of the marginal distribution and McNemar direction of change test were applied. In essence, the Bhapkar test indicates differences between two methods in general, while the McNemar test on the direction of change indicates whether the two methods differ in one direction.

MedCalc software version 12.7.5.0 (MedCalc Software, bvba, Ostend, Belgium), AgreeStat software version 2013.1 (Advanced Analytic, LLC, Gaithersburg, MD), and MH software version 1.2[26] were used for the calculations.

RESULTS

Thirty-one patients were included in the study. The mean age of the patients was 42.6 years (standard deviation 18.1, range from 19 to 85 years), 12 (39%) were females, and 9 (29%) were smokers.

Mean salivary flow was 1.65 mL/min (SD 0.72) (range from 0.2 to 3.0 mL/min). Nineteen patients (61%) had a salivary pH ≥ 6; 10 patients had a pH >4 and <6; 2 patients had a pH ≤4.

Agreement among the three methods

The distribution of patients in low, moderate, and high risk of caries according to the CAMBRA, Cariogram and ADA, respectively, is reported in **TABLE 1**. CAMBRA estimated that most patients were at high risk of caries, and did not indicate any patients to be at moderate risk of caries. Cariogram, on the other hand, estimated most patients to be at moderate risk of caries, while ADA categorized patients into either moderate or high risk of caries groups, with no patients being classified low risk. As expected from this distribution, the Fleiss k-statistic with quadratic weight, as interpreted according to Landis and Koch[23], indicated a slight or poor agreement among the three risk assessment methods; specifically, the figure was 0.19 (95%CI from 0.01 to 0.37). In fact, complete agreement among the three methods was obtained in only three cases (10%, 95%CI: 2; 26). These three patients were estimated to be at high risk of caries by all three methods.

Agreement between CAMBRA and Cariogram

Agreement between CAMBRA and Cariogram is reported in **TABLE 2**. CAMBRA estimated most patients to be at high risk of caries and did not indicate any patients to be at moderate risk, while Cariogram estimated most patients to be at moderate risk of caries. Cohen's kappa statistic was 0.35 (95%CI: 0.13; 0.57), and the P value was <0.0001 for the Bhapkar test and 0.0011 for the McNemar test. Complete agreement between the two methods was obtained in only seven cases (23%, 95%CI: 10; 41).

Agreement between CAMBRA and ADA

Agreement between CAMBRA and ADA is reported in **TABLE 3**. CAMBRA estimated most patients to be at high risk of caries and did not indicate any patients to be at moderate risk of caries, while ADA did not identify any patients to be at low risk of caries. Cohen's kappa statistic was 0.25 (95%CI: -0.04; 0.54), and the P value was <0.0001 for the Bhapkar test and 0.6171 for the McNemar test. This indicates that the two methods classified patients differently, but did not show a significant difference in the direction of one of the two methods as compared to the other. Complete agreement between the two methods was obtained in 15 cases (48%, 95%CI: 30; 67).

Agreement between Cariogram and ADA

Agreement between Cariogram and ADA is reported in **TABLE 4**. Cariogram estimated most patients to be at moderate risk of caries, while ADA found no patients at low risk of caries. Cohen's kappa statistic was 0.04 (95%CI: -0.18; 0.26), and the P value was 0.0001 for the Bhapkar test and 0.0005 for the McNemar test. Complete agreement between the two methods was obtained in 15 cases (48%, 95%CI: 30; 67).

DISCUSSION

This study aimed to measure the agreement among three CRA methods, CAMBRA, Cariogram and ADA, in individual adult patients. Methods for estimating the risk of caries represent important clinical tools because they are able to influence the treatment plan, the maintenance plan, and the need to predict the diagnosis and prevention of caries[11]. However, this study highlighted statistically significant differences among the three methods. They appear to provide very different estimates of the risk of caries, and the agreement between them is stati-

TABLE 1 DISTRIBUTION OF PATIENTS INTO LOW, MODERATE AND HIGH RISK OF CARIES FOR BY CAMBRA, CARIOGRAM AND ADA, RESPECTIVELY, FREQUENCY (PERCENTAGE)

Method	Low risk	Moderate risk	High risk	Total
CAMBRA	7 (23%)	0 (0%)	24 (77%)	31
Cariogram	3 (10%)	24 (77%)	4 (13%)	31
ADA	0 (0%)	14 (45%)	17 (54%)	31

CAMBRA: Caries Management by Risk Assessment; Cariogram: Cariogram caries risk assessment; ADA: American Dental Association caries risk assessment

TABLE 2 AGREEMENT BETWEEN CAMBRA AND CARIOGRAM

CAMBRA/Cariogram	Cariogram Low risk	Cariogram Moderate risk	Cariogram High risk	Total
CAMBRA Low risk	3	4	0	7
CAMBRA Moderate risk	0	0	0	0
CAMBRA High risk	0	20	4	24
Total	3	24	4	31

CAMBRA: Caries Management by Risk Assessment; Cariogram: Cariogram caries risk assessment

TABLE 3 AGREEMENT BETWEEN CAMBRA AND ADA

CAMBRA/ADA	ADA Low risk	ADA Moderate risk	ADA High risk	Total
CAMBRA Low risk	0	5	2	7
CAMBRA Moderate risk	0	0	0	0
CAMBRA High risk	0	9	15	24
Total	0	14	17	31

CAMBRA: Caries Management by Risk Assessment; ADA: American Dental Association caries risk assessment

TABLE 4 AGREEMENT BETWEEN CARIOGRAM AND ADA

Cariogram/ADA	ADA Low risk	ADA Moderate risk	ADA High risk	Total
Cariogram Low risk	0	1	2	3
Cariogram Moderate risk	0	12	12	24
Criogram High risk	0	1	3	4
Total	0	14	17	31

Cariogram: Cariogram caries risk assessment; ADA: American Dental Association caries risk assessment

stically poor (K = 0.19). In fact, complete agreement among the three methods was found only in 10% of cases. In particular, according to CAMBRA, most patients were at high risk of caries, and none were at moderate risk of caries, while the ADA divided patients into moderate and high risk groups, without selecting patients at low risk of caries. Cariogram, on the other hand, estimated that most patients were at moderate risk of caries.

To our knowledge no other study has investigated the agreement between these three methods on real patients. Featherstone et al. (2021) recently compared the three methods in a study on 26 hypothetical patients (13 children and 13 adults)[14]. However, those authors also used a slightly modified form of CAMBRA, the CAMBRA 123, and the patients were hypothetical, rather than real, patients. Cariogram and CAMBRA categorized their sample into identical risk categories[14]. However, the ADA yielded different results than CAMBRA and Cariogram in several comparison examples. Furthermore, the authors did not perform a quantitative analysis of the results[14]. For the above reasons, it is very difficult to compare our results with those of Featherstone et al. 2021[14].

The agreement between CAMBRA and Cariogram (K = 0.35) in our study was higher than that between CAMBRA and ADA (K = 0.25) and that between Cariogram and ADA (K = 0.04). The reasons for a lack of pairwise agreement between the methods could be related to the fact that CAMBRA mainly evaluates the weight of the recent experience of caries, while the ADA is more focused on diet. In the ADA method, much importance is given to the intake of sugary drinks, such as fruit juices, energy drinks, cordials and soft drinks. If these substances are imbibed between meals or frequently, the patient is classified as being at high risk of caries. The Cariogram, on the other hand, evaluates the risk of caries using different criteria. In this case, the calculation is performed by the software, and so the procedure is less transparent. The chance of not having new caries (green sector) decreases with increasing risk factors represented by diet (dark blue sector), the presence of plaque (red sector), susceptibility (light blue sector) – which is based on a combination of fluoride programme, saliva secretion and saliva buffer capacity – and circumstances (yellow sector), which is based on a combination of past caries experience and related diseases.

The limitations of the present study mainly lie in the fact that, despite having determined that the three methods provided very different results, we were unable to establish which one provided a better estimate of the individual caries risk. The three methods have never been compared to each other in a cohort study to evaluate their differences in sensitivity and specificity. However, given the large discrepancies in agreement among the three protocols that emerged in this study, notable differences in sensitivity and specificity can be expected. It is unknown whether the identification of high-risk individuals can lead to more effective long-term patient management that prevents caries onset and arrests or reverses the progression of lesions. Nonetheless, there is an urgent need to develop valid and reliable methods for CRA that are based on good scientific evidence, rather than the opinions of experts[11].

CONCLUSIONS

Statistically significant differences were highlighted among the three CRA methods. The agreement in estimating risk of caries in the three examined methods was very low. Each method yielded very different estimations of the patients' individual risk of caries.

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