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Authors

Featherstone, JDB
Chaffee, BW

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The Evidence for Caries Management by Risk Assessment (CAMBRA[®])

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J.D.B. Featherstone¹ and B.W. Chaffee¹

Abstract

A system for Caries Management by Risk Assessment (CAMBRA[®]) has been developed in California. The purpose of this article is to summarize the science behind the methodology, the history of the development of CAMBRA, and the outcomes of clinical application. The CAMBRA caries risk assessment (CRA) tool for ages 6 y through adult has been used at the University of California, San Francisco (UCSF), for 14 y, and outcome studies involving thousands of patients have been conducted. Three outcomes assessments, each on different patient cohorts, demonstrated a clear relationship between CAMBRA-CRA risk levels of low, moderate, high, and extreme with cavitation or lesions into dentin (by radiograph) at follow-up. This validated risk prediction tool has been updated with time and is now routinely used at UCSF and in other settings worldwide as part of normal clinical practice. The CAMBRA-CRA tool for 0- to 5-y-olds has demonstrated similar predictive validity and is in routine use. The addition of chemical therapy (antibacterial plus fluoride) to the traditional restorative treatment plan, based on caries risk status, has been shown to reduce the caries increment by about 20% to 38% in high-caries-risk adult patients. The chemical therapy used for high-risk patients is a combination of daily antibacterial therapy (0.12% w/v chlorhexidine gluconate mouth rinse) and twice-daily high-concentration fluoride toothpaste (5,000 ppm F), both for home use. These outcomes assessments provide the evidence to use these CRA tools with confidence. Caries can be managed by adding chemical therapy, based on the assessed caries risk level, coupled with necessary restorative procedures. For high- and extreme-risk patients, a combination of antibacterial and fluoride therapy is necessary. The fluoride therapy must be supplemented by antibacterial therapy to reduce the bacterial challenge, modify the biofilm, and provide prevention rather than continued caries progression.

Keywords: dental caries, fluoride, chlorhexidine, disease indicators, caries risk assessment, dental plaque

Background

For decades, there have been numerous attempts to provide methodology to predict future dental caries or to assess caries risk and to manage the disease (Krasse 1985; Disney et al. 1992). There are many publications related to these topics. It is not the aim of this article to review these published works. The purpose of the present article is simply to review the history of the development of a system for caries risk assessment and caries management that has been developed in California and used for 14 y in the teaching clinics of the School of Dentistry at the University of California San Francisco (UCSF). The procedures and philosophy are known as “Caries Management by Risk Assessment” and abbreviated to CAMBRA. This article will briefly summarize the science behind the methodology, the history of the development of CAMBRA[®], and the outcomes of 14 y of clinical application in thousands of patients.

Caries Mechanism and Its Application to Caries Risk Assessment and Caries Management

There are hundreds of articles that have contributed to our understanding of the overall mechanism of dental caries and

the roles of fluoride and other agents in the management of the disease. Based on decades of research on dental caries by many investigators, we published a clinically oriented summary that described the balance between pathological factors and protective factors and how this might be dealt with in the clinical setting (Featherstone 1999, 2000, 2003). In summary, dental caries is demineralization of tooth mineral caused by acid generated when cariogenic bacteria in the plaque (biofilm) on the teeth metabolize fermentable carbohydrates. The demineralization can be inhibited by salivary components, antibacterial agents, and fluoride or reversed by remineralization that requires calcium, phosphate, and fluoride. We proposed that the progression or reversal of dental caries was driven by the “caries balance,” namely, the balance between the pathological factors, primarily (1) cariogenic bacteria, (2) fermentable carbohydrates, and (3) salivary dysfunction, and protective

¹Department of Preventive and Restorative Dental Sciences, School of Dentistry, University of California San Francisco, San Francisco, CA, USA

Corresponding Author:

J.D.B. Featherstone, School of Dentistry, University of California at San Francisco, 513 Parnassus Avenue, San Francisco, CA 94143-0430, USA.
Email: john.featherstone@ucsf.edu

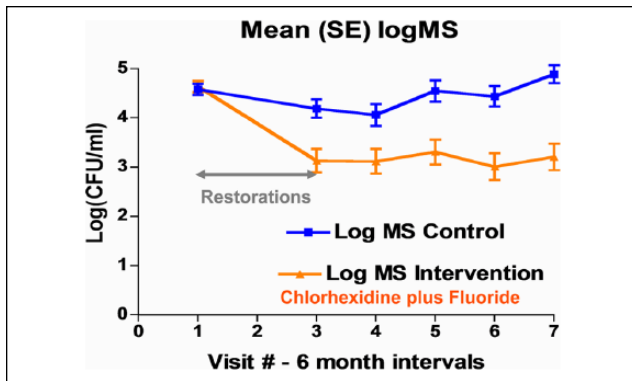


Figure 1. Mean (SE) log of mutans streptococci counts in saliva (colony-forming units per milliliter) at baseline and at follow-up visits every 6 mo in a randomized controlled clinical trial that examined caries management by risk assessment using chemical intervention therapy (Featherstone et al. 2012). Between sampling visits 1 and 3, all restorative work was completed. Visits 3 to 7 represent the 2-y period between “restorations complete” and the final examination. The upper line is the control group (conventional dental and restorative treatment). The lower line is the intervention group that received chlorhexidine rinse and fluoride toothpaste.

factors, primarily (1) sufficient saliva; (2) remineralization that requires calcium, phosphate, and fluoride; and (3) antibacterial agents.

Randomized Controlled Clinical Trial on Caries Management

A randomized controlled clinical trial was conducted during 1999 to 2005 that examined the concept of the caries balance and whether altering that balance could reduce new dental caries (Featherstone et al. 2012). This controlled clinical trial was conducted in the predoctoral teaching clinic at UCSF. The study included adults aged 18 to 65 y who had 1 to 7 cavities. Details are given elsewhere (Featherstone et al. 2012). The control group was patients who continued with conventional treatment, and the test group had an intervention that consisted of a combination of fluoride mouth rinse, fluoride toothpaste, and 0.12% chlorhexidine gluconate mouth rinse.

The trial produced several key results.

1. The trial demonstrated a statistically significant 24% reduction in 2-y caries increment in initially high-caries-risk patients provided with the combined therapeutic intervention.
2. The study also showed that placing restorations had no statistically significant effect on mean bacterial levels in the whole mouth, either initially or over a 2-y follow-up period after the restorative work was complete. In the control group, approximately 70% of the subjects returned within 2 y with new cavities.
3. High numbers of decayed surfaces at baseline were strongly related to a combination of high levels of mutans streptococci and lactobacilli.

4. Preliminary studies that used detailed microbiological assessments over short periods had established that the chlorhexidine rinse should be used once a day for 1 wk every month. This regimen was then used in the clinical trial and was shown to markedly reduce the levels of cariogenic bacteria in the patients (Fig. 1). Other studies that reported no effect on dental caries by chlorhexidine used very different regimens, such as rinsing daily for 2 wk every 3 mo. The sustained marked reduction in cariogenic bacterial levels in the intervention group in this high-risk population coincided with the reduction in caries increment.
5. A reanalysis of the trial findings (Cheng et al. 2015) showed that caries reduction was mediated by combined action of changes in salivary bacterial levels and fluoride concentration, as well as additional unmeasured factors.
6. The results of the study clearly showed the need for antibacterial therapy as well as fluoride therapy in order to alter the balance in these high-risk individuals.

Development of the CAMBRA Philosophy and Practice

The Caries Management By Risk Assessment (CAMBRA) philosophy was developed in California following 2 consensus conferences (Featherstone et al. 2003, 2007). The full proceedings, including all manuscripts, of these 2 conferences are available online at <http://www.cdafoundation.org/education/resources-library>. Representatives from most of the California dental schools and several others across the United States were present and contributed to these proceedings. The newly designed caries risk assessment form was piloted in several dental schools. UCSF and University of the Pacific implemented particularly comprehensive, large-scale pilots, starting in 2003. The forms and procedures were modified over time, and the modified versions were published in the California Dental Association Journal in 2007 (Featherstone et al. 2007; Jenson et al. 2007) in 2 special issues (available online as described above).

The following summarizes the steps in the caries management process that were implemented and remain in place in these university clinics:

1. Take dental and medical history.
2. Conduct clinical examination.
3. Detect caries lesions early enough to reverse or prevent progression.
4. Assess the caries risk as low, high, moderate, or extreme using data from 1, 2, and 3 and a short questionnaire.
5. Produce a treatment plan that includes chemical therapy appropriate to the caries risk level.
6. Use chemical therapy that includes fluoride and/or antibacterial agents based on risk level.
7. Use minimally invasive restorative procedures to conserve tooth structure and function.

Table. Cross-Tabulation of Disease Indicators, Caries Risk Factors, and Protective Factors with Cavitation or Caries into Dentin by Radiograph at Baseline for 2 Studies (Doméjean-Orliaguet et al. 2006; Doméjean et al. 2011).

	Odds Ratio	
	Doméjean et al. (2006), N = 2,351	Doméjean et al. (2011), N = 12,954
Disease indicators		
Approximal lesions in enamel, by radiograph	13.6	8.2
Restorations in the past 3 y	1.6	1.5
White spot lesions	3.3	2.8
Risk factors/pathological factors		
Visible heavy plaque on the teeth	2.8	2.6
Frequent snacking	1.9	1.8
Inadequate saliva	1.4	1.3
Deep pits and fissures	1.9	1.8
Recreational drug use	2.0	2.0
Protective factors		
Fluoride toothpaste	0.67	0.81
Fluoride mouth rinse	0.74	0.80
Fluoridated community	0.81 (not statistically significant)	0.85

^aOdds ratios are for the relationship of each individual item. All items shown here were statistically significantly related. Odds ratios greater than 1.0 indicate a positive relationship and odds ratios less than 1.0 a negative relationship.

8. Recall and review at intervals appropriate to the caries risk status.
9. Reassess caries risk level at recall and modify the treatment plan as necessary.

studies showed that in our clinics, approximately 5% of our patients are at extreme risk (Doméjean et al. 2011).

An example of a patient at extreme risk would be the following:

Caries Risk Assessment Procedure Development and Validation

Following the pilot introduction of caries risk assessment procedures into our clinics in early 2003, we made the decision to conduct caries risk assessments on all new UCSF patients starting in July 2003. As time progressed, the caries risk assessment items included in the form were paired with the goal of retaining only risk items that were the strongest predictors of caries outcomes and clinically relevant to disease progression and management (Doméjean-Orliaguet et al. 2006). Outcomes studies specifically related to the predictive validity of the caries risk assessment form were conducted and published in 2006 and 2011 (Doméjean-Orliaguet et al. 2006; Doméjean et al. 2011). As a result of these outcomes studies, the items used in the caries risk assessment for patients aged 6 y through adult were grouped into (1) disease indicators (clinical observations), (2) biological risk factors (expanded to pathological factors), and (3) protective factors. These are shown in the Table, together with the odds ratios relating each risk factor to visible cavities or caries into dentin by radiograph for the 2006 and the 2011 studies. The number of patient records used was 2,351 in the 2006 study and 12,954 in the 2011 study.

The caries risk level was determined by the individual providers based on an assessment of the balance between the disease indicators, the risk factors, and the protective factors, as per detailed instructions previously published (Featherstone et al. 2007). Risk levels were assigned as low, moderate, high, or extreme. Extreme was defined as high risk plus hyposalivation, as assessed by visual inspection, medical history, and, if in doubt, measurement of salivary flow rate. Our outcomes

Disease indicators: Visible cavity, numerous approximal lesions by radiograph, numerous restorations in the past 3 y.

Biological risk factors: Visible heavy plaque on the teeth, frequent snacking, inadequate saliva flow by measurement and signs of dry mouth, more than 1 medication that has hyposalivatory side effects.

Protective factors: Once-daily fluoride toothpaste use.

In this case, the assessment would be 7 disease indicators and pathological factors, including hyposalivation and only 1 protective factor, leading to a definite extreme risk patient assessment.

The 2011 outcomes assessment (Doméjean et al. 2011) clearly showed a relationship between assessed risk level and new cavities at follow-up, as illustrated in Figure 2 for 2,571 returning patients. Although 24% of patients classified at low risk had cavities at follow-up, 76% did not. Refinement of the tool, such as addition of accurate chairside microbiological assessment in the future, may further improve the negative predictive value of a designation of low caries risk. Close to 70% at high risk had new cavities at follow-up, and 88% at extreme risk had new cavities, demonstrating very good predictive validity. These numbers were similar to those observed in a smaller patient cohort in the 2006 outcomes assessment (Doméjean et al. 2006) and were repeated recently in a new cohort of patients (Chaffee et al. 2015a, 2015b). Undoubtedly, the tool can be further refined and improved, but in its current form, it is an excellent predictor of low, high, and extreme caries risk.

One recent modification to the caries risk assessment (CRA) form clarifies the item about recent restorations. For new patients (6 y through adult), we use “restorations in the

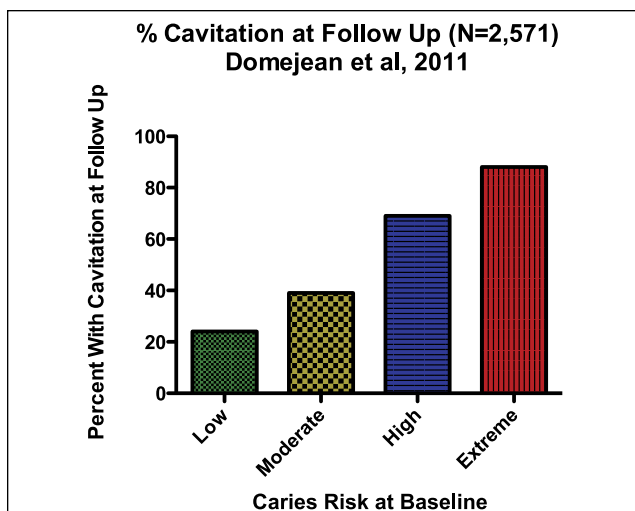


Figure 2. Percentage of adult patients with evident cavitation or caries into dentin (by radiograph) at follow-up, stratified by risk level assessed at baseline: $n = 12,954$ at baseline and $n = 2,571$ at the follow-up examination.

past 3 years,” whereas for patients of record, we use “new caries-related restorations in the past 12 months.” This allows the compliant patient to get “out of the penalty box” in that a patient under continuing care is not relegated to high-risk status for 3 y following restoration placement if the balance of risk and protective factors is otherwise favorable. The fact that caries risk level can be lowered with behavior change and therapeutic intervention may be motivating for patients. The feasibility of lowering caries risk was illustrated in a practice-based research study reported by Rechmann et al., as reported in the present publication (Rechmann et al. 2017), where the authors demonstrated dramatic reductions in caries risk status within 18 to 24 mo.

A second CAMBRA caries risk assessment tool (Ramos-Gomez et al. 2007) was developed in parallel with the age 6 y to adult form for use with young children aged 0 to 5 y. This form was introduced in the UCSF postgraduate pediatric teaching clinics in 2009. An outcomes assessment was conducted (Chaffee et al. 2016) to assess the predictive validity of this additional CRA tool. Very few extreme-risk children were identified, so this assessment was confined to low-, moderate-, and high-risk patients. Very similar results to the adult studies described above were found and are summarized in Figure 3. As was the case with older patients, approximately 70% of patients assessed as high risk had new decay at follow-up visits.

Caries Management Outcomes

Under the CAMBRA philosophy, minimal intervention dentistry is carried out as needed, and invasive restorative treatments may be delayed and performed at more advanced caries lesion stages if they develop over time (Vidnes-Kopperud et al. 2011; Doméjean et al. 2015; Rechmann et al. 2016). A central tenant of CAMBRA is that patient risk assessment levels dictate appropriate, patient-tailored noninvasive therapy: the most

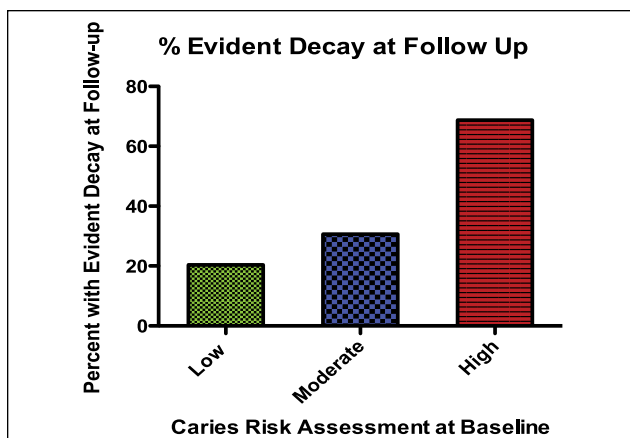


Figure 3. Percentage of children, aged 0 to 5 y, with evident dental decay at follow-up, stratified by caries risk status at baseline (Chaffee et al. 2016): $n = 3,810$ at baseline and $n = 1,315$ at the follow-up examination.

intensive preventive interventions are targeted at high-risk and extreme-risk patients, delaying or preventing decay and restorative treatment needs.

Over the first decade of CAMBRA implementation at UCSF, we had accumulated meaningful data on caries risk assessment and caries management based on risk assessment. The age 6 to adult multicomponent CAMBRA caries risk assessment tool, described above, was confirmed as strongly associated with future treatment needs (Chaffee et al. 2015a), and the first CAMBRA clinical trial had yielded promising results (Featherstone et al. 2012). Less information was available regarding the effectiveness of risk-based caries management in practice. We recently conducted an outcomes assessment (Chaffee et al. 2015b) based on patient records for 18,004 eligible patients from 2007 to 2012 in our predoctoral teaching clinic. Caries risk assessment was conducted at baseline as a routine part of clinical care using the CRA methodology summarized above (Featherstone et al. 2007). At their initial visit, 11,900 adult patients were assessed as high risk by student providers under the supervision of faculty dentists. Of these patients 2,724 were examined at follow-up after an average of 18 mo. Full details of the methodology, patient characteristics, statistical analyses, and so forth are given elsewhere (Chaffee et al. 2015b).

The recommended chemical therapy for these high-caries-risk patients consisted of (1) fluoride varnish at the initial visit, (2) twice-daily use of prescription fluoride toothpaste (5,000 ppm F), (3) chlorhexidine gluconate 0.12% mouthrinse (once daily for 1 wk every month), and (4) xylitol gum or mints daily. All patients were offered this therapy, but many opted not to receive or use the anticaries products.

To assess the efficacy of the regimen, caries outcomes in 3 patient groups were compared, namely, (1) never received the anticaries products ($n = 1,501$), (2) took the products once and never returned for refills ($n = 900$), (3) took the anticaries products and returned at least once for more ($n = 323$). Although

this was a retrospective study and not a controlled randomized clinical trial, these 3 groups provide evidence whether or not the regimen worked to reduce caries increment.

The results of this outcomes assessment, reported as adjusted decayed, filled teeth (DFT) increment, after 18 mo of follow-up were as follows:

1. Never took the products: DFT increment = 1.82.*
2. Took the products only once: DFT increment = 1.78.*
3. Took the products twice or more: DFT increment = 1.47.**

Groups 1 and 2* were not statistically significantly different, but group 3 was statistically significantly** less than groups 1 and 2 by approximately 20%. This lesser DFT increment represents a major change in caries increment for a university clinic that serves a largely high-caries, mostly poorly compliant, mostly low socioeconomic status population.

A subgroup of these patients was on a public assistance program, and their products were available at no cost to them. Even then, many did not accept or use the anticaries products, or took them only once, which presumably indicated they did not use them regularly. Comparing the same 3 groupings of none, 1, and 2 or more times, the group that took the products twice or more had 38% lower DFT increment than the group that never received the products. However, because of relatively small numbers ($n = 335, 238, \text{ and } 167$, respectively, for the 3 groups), this difference was not statistically significant.

The next question is whether these reductions in caries increment in an academic teaching clinic setting can be achieved, or improved upon, in a private practice setting. A practice-based research network clinical trial was recently completed, and the preliminary results are reported elsewhere in this issue (Rechmann et al. 2017). The study used 18 private practices, 3 community clinics, and 460 patients, each patient followed for up to 2 y. Marked reductions in caries risk status were observed.

The evidence for the CAMBRA approach includes the 2 randomized, controlled, clinical trials summarized above as well as several outcomes studies involving thousands of patients. In the ideal world, further randomized clinical trials should be conducted that include other possible chemical therapeutic regimens, perhaps with lower dropout rates and pediatric participants as well as adults. However, it is very challenging to get funding for such studies that are expensive and take several years to conduct.

Summary and Conclusions

Caries Risk Assessment Tools

The CAMBRA (Caries Management by Risk Assessment) CRA procedure for the age group 6 y through adult (Featherstone et al. 2007) was developed over a period of years and followed the suggestions of a consensus conference. These CRA procedures have been used in the predoctoral teaching clinics at UCSF for 14 y, and several outcome studies have

been conducted (Doméjean-Orliaguet et al. 2006; Doméjean et al. 2011; Chaffee et al. 2015a). These 3 outcomes assessments, each on different cohorts of thousands of patients, demonstrated a clear relationship between CAMBRA-CRA risk levels of low, moderate, high, and extreme with cavitation or lesions into dentin (by radiograph) at follow-up. This risk prediction tool has been updated with time and is now routinely used in these clinics as part of normal clinical practice. The CAMBRA-CRA tool for 0- to 5-y-olds (Ramos-Gomez et al. 2007) has demonstrated similar predictive validity (Chaffee et al. 2016) and is in routine use in the UCSF postgraduate pediatric dentistry clinics. These CRA tools can be used with confidence. Additions and modifications should not be made unless there is evidence to support such changes.

Caries Reduction

Implementation, assessment, and utilization of the CRA tool took several years to fully embrace in the UCSF teaching clinics. Addition of chemical therapy to the traditional restorative treatment plan, based on caries risk status, has been shown to reduce the caries increment by about 20% in high-caries-risk adult patients. The biggest barriers are the need for patients to pay for the therapy, coupled with patient and provider acceptance. In a subset of these patients, a group whose therapy was covered by insurance showed a 38% reduction in caries increment.

The chemical therapy used for high-risk patients (6 y through adult) is a combination of antibacterial therapy (0.12% w/v chlorhexidine gluconate mouthrinse) and high-concentration twice-daily fluoride toothpaste (5,000 ppm F), both for home use. The chlorhexidine is used as a daily rinse for 1 wk each month and is continued until the risk level has been reduced for 1 y. Looking ahead, chlorhexidine products can be substituted by equivalent, or better, antibacterial agents as these become available and are clinically proven to be effective. As our understanding of the microbiome, and the best ways to modify the biofilm, evolves and improves, there will undoubtedly be better therapies that can be substituted for chlorhexidine so that altering the caries balance can be even more effectively done. Modifications to diet may also be shown to be powerful ways to positively alter the biofilm in the future. All of these approaches together will provide more successful caries management of high- and extreme-risk patients.

The results of the clinical trial described above (Featherstone et al. 2012), together with the several years of outcomes assessment results summarized here, clearly show that for high-caries-risk individuals, even with access to community water fluoridation and topical fluorides, new cavities will continue to develop. The fluoride therapy must be supplemented by antibacterial therapy to reduce the bacterial challenge, modify the biofilm, and swing the caries balance (Featherstone 2000) to provide prevention rather than caries progression.

Author Contributions

J.D.B. Featherstone, contributed to conception, design, data analysis, and interpretation and drafted and critically revised the

manuscript; B.W. Chaffee, contributed to conception, design, data analysis, and interpretation and critically revised the manuscript. Both authors gave final approval and agree to be accountable for all aspects of the work.

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