Systematic Reviews of Selected Dental Caries Diagnostic and Management Methods

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The complete version of this paper can be viewed at :
http://www.nidcr.nih.gov/news/consensus.asp

Abstract:

A systematic review of the English language literature was conducted to address three related questions concerning the diagnosis and management of dental caries: (a) the performance (sensitivity, specificity) of currently available diagnostic methods for carious lesions, (b) the efficacy of approaches to the management of non-cavitated, or initial carious lesions, and (c) the efficacy of preventive methods among individuals who have experienced or are expected to experience elevated incidence of carious lesions. From of 1328 caries diagnostic and 1435 caries management reports originally identified, 39 diagnostic studies and 27 management studies were included in the final evidence tables. Point estimates or reasonable range estimates for the diagnostic validity of methods for the diagnosis of carious lesions could not be established from the literature reviewed. There are insufficient numbers of reports of diagnostic performance involving primary teeth, anterior teeth, and root surfaces. For posterior occlusal and proximal surfaces, quality issues and the variation among studies precludes establishing such estimates. The apparent differences in sensitivity among methods are generally smaller than the variation reported within methods. The literature on the management of non-cavitated carious lesions consisted of five studies describing seven experimental interventions. Because these interventions varied extensively in terms of management methods tested as well as other study characteristics, no conclusions about the efficacy of these methods were possible. The literature on the management of individuals at elevated risk of carious lesions consisted of 22 studies describing 29 experimental interventions. The strength of the evidence for the efficacy of fluoride varnish for prevention of dental caries in high-risk subjects was fair, and the evidence for all other methods as incomplete. Because the evidence for efficacy for some methods,

including chlorhexidine, sucrose-free gum, and combined chlorhexidine-fluoride methods is suggestive but not conclusive, these interventions represent fruitful areas for further research.

Keywords: dental caries, prevention; dental caries, diagnosis; systematic review

Dental caries, a chronic infectious disease, is experienced by more than 90 percent of all adults in the U.S.[1,2] The depth of that experience varies extensively between individuals, however.[1,2] Several strategies for identifying those persons who will experience an elevated incidence of carious lesions have been reported.[3-8] Also, as understanding of the disease process has matured, the range of management strategies for dental caries has broadened to include a variety of interventions to arrest or reverse the demineralization process that characterizes the development of a carious lesion.[9-10]

The growing sophistication in available interventions for prevention and non-surgical treatment of dental caries is matched by a similar increase in the available methods for diagnosis of carious lesions. The diagnosis of carious lesions has been primarily a visual process, based principally on clinical inspection and review of radiographs. Tactile information obtained through use of the dental explorer or "probe" has also been used in the diagnostic process. The development of some alternative diagnostic methods, such as fiberoptic transillumination (FOTI) and direct digital imaging continue to rely on dentists' interpretation of visual cues, while other emerging methods, such as electrical conductance (EC) and computer analysis of digitized radiographic images, offer the first "objective" assessments, where visual and tactile cues are either supplemented or supplanted by quantitative measurements.

This relatively recent growth in alternatives available for both diagnosis and management of dental caries has yet to be fully assimilated by dental practice. Thorough reviews of methods for diagnosis and management of dental caries should assist in that assimilation process.

METHODS

The clinical questions in this report were developed in conjunction with the planning committee for the Dental Caries Consensus Development Conference. They reflect three aspects of the diagnosis and management of dental caries where the committee perceived either that current clinical practice might not reflect current knowledge regarding efficacy and effectiveness, or that a review of current evidence might help stimulate new research.

The first question addresses methods used in caries diagnosis, defined for purposes of this report as identification of the presence of a carious lesion. At issue is the validity of each diagnostic technique. Diagnoses of carious lesions can occur at a variety of sites--primary and permanent teeth, occlusal and smooth surfaces, and coronal and root surfaces. Several diagnostic techniques are available, and the ability of these different techniques to detect carious lesions on specific sites is not widely understood.

The second question addresses the effectiveness of preventive methods among those individuals who have experienced, or are expected to experience, an elevated incidence of carious lesions. Dentists are now being urged to identify individuals with elevated caries

activity,[3-8] but this "risk assessment" strategy has not been complemented by the identification of the most effective interventions to mitigate the expected caries attack.

The third question concerns the effectiveness of non-surgical strategies to arrest or reverse the progress of carious lesions before tooth tissue is irreversibly lost. The relative effectiveness of these conservative treatments is not well-identified.

We conducted two detailed searches of the relevant English language literature from 1966 to October 1999 using MEDLINE, EMBASE, and the Cochrane controlled trials register. Hand searches of current journals updated the search to the end of 1999. The gray literature, i.e., information not reported in the periodic scientific literature, was not examined. One search focused on six diagnostic methods (visual and visual tactile inspection, radiography, fiberoptic transillumination, electrical conductance, laser fluorescence) and combinations of these methods, using keywords for the disease (dental caries, tooth demineralization), diagnostic concepts (oral diagnosis, oral pathology, dental radiography), and study characteristics and design. A second search focused on dental caries preventive or management methods, using keywords for methods (fluorides, pit and fissure sealants, health education, dental prophylaxis, oral hygiene, dental plaque, chlorhexidine dental sealants, cariostatic agents) and study characteristics and design in addition to the disease key words.

Explicit inclusion and exclusion criteria were used to identify the studies to be included in the reviews. We included studies in the diagnostic review that used histological validation of caries status, and either reported results as sensitivity and specificity of the diagnosis, or reported

data from which these measures could be calculated. We excluded reports of diagnostic methods not commercially available. For the review of the dental caries management literature we included only reports concerning methods applied or prescribed in a professional setting. Also, we included only studies performed in vivo and having a comparison group.

The two questions based on the management review each featured additional inclusion criteria. For the management of non-cavitated carious lesions we included only studies where the lesion was the unit of analysis. We accepted several different descriptions of non-cavitated lesions including the terms “incipient” and “initial.” In the literature describing the management of subjects at elevated risk for dental caries, we included only studies where the classification of elevated risk had been made for individual subjects. The classification had to be based on carious lesion experience and/or bacteriological testing. We applied no criteria for what constituted an elevated risk classification. For either method we accepted the classification described in the paper.

We selected studies for inclusion from among 1,407 diagnostic and 1,478 management reports through independent duplicate reviews of titles, abstracts, and, where necessary, full papers, with discussion leading to consensus where disagreement occurred. The two reviewers agreed on inclusion status for 97 percent of the reports at this stage. In addition, we separately identified six studies evaluating preventive methods in patients who had received radiotherapy for head and neck neoplasms, and seven studies evaluating preventive methods in patients with orthodontic bands or brackets, both special high-risk groups. We felt that these studies should be

included in the review but not combined with the main group of studies due to substantial differences in lesions and study methods.

We abstracted data (single abstraction, subsequent independent review) on 39 diagnostic studies and 27 management studies using different forms for the diagnostic and management studies. Four reviewers were involved in the abstraction process, with inter-reviewer agreement rates of 100% for results and 88% for other study descriptors. Quality rating forms were completed by the scientific director for each study, using different items for the two reviews. For the management studies, quality rating items assessed several elements of internal validity, including study design, duration, sample size, blinding, baseline assessments of differences among groups, loss to follow-up, and examiner reliability. Two items also requested the reviewer's subjective assessment of both internal and external validity of the study. Diagnosis study quality rating items included these subjective assessments as well as ratings addressing sample size, selection of teeth and surfaces, study setting, validation method, validation criteria, lesion prevalence, number of evaluators, evaluator reliability, and lesion criteria.

We compiled the abstracted data in a series of six evidence tables, one each for in vivo and in vitro radiographic studies, studies of management of non-cavitated carious lesions and individuals at elevated risk for carious lesions, and studies of special populations of orthodontic patients and patients who received head and neck radiotherapy. We then graded the evidence summarized in the tables.

For the diagnostic question, the strength of the evidence was judged in terms of the extent to which it offered a clear, unambiguous assessment of the validity of a particular method for identifying a specific type of lesion on a specific type of surface. The three possible ratings were:

- Good (A): The number of studies is large, the quality of the studies is generally high, and the results of the studies represent narrow ranges of observed sensitivity and specificity.
- Fair (B): There are at least three studies, the quality of the studies is at least average, and the results represent moderate ranges of observed sensitivity and specificity.
- Poor (C): There are fewer than three studies, or the quality of the available studies is generally lower than average, and/or the results represent wide ranges of observed sensitivities and/or specificities.

For purposes of this question, a narrow range of sensitivity/specificity is defined as no more than 0.15 on a scale of 0.0 to 1.00, a moderate range is no more than 0.35, and a wide range is more than 0.35. High quality is defined as most study scores at or above 60 on a 0-100 scale, and average quality is defined as most study scores at or above 45 but less than 60.

For the management studies we used a scheme based on several considerations including the magnitude of the results reported, the quality rating scores of the studies, the number of studies, and the consistency of the results across studies. The scientific and clinical directors independently rated the interventions, and developed an adjudicated final rating. The four possible ratings were:

- Good (A): Data are sufficient for evaluating efficacy. The sample size is substantial, the data are consistent, and the findings indicate that the intervention is clearly superior to the placebo/usual care alternative.

- Fair (B): Data are sufficient for evaluating efficacy. The sample size is substantial, but the data show some inconsistencies in outcomes between intervention and placebo/usual care groups such that efficacy is not clearly established.
- Poor (C): Data are sufficient for evaluating efficacy. The sample size is sufficient, but the data show that the intervention is no more efficacious than placebo or usual care.
- Insufficient Evidence (I): Data are insufficient for assessing the efficacy of the intervention, based on limited sample size and/or poor methodology.

RESULTS

Caries Diagnosis: We evaluated the strength of the evidence describing the performance of diagnostic methods separately for identifying cavitated lesions, lesions involving dentin, enamel lesions, and any lesions. We also separated the evaluations by the surface and tooth type involved. We found 39 studies[11-50] reporting 126 histologically validated assessments of diagnostic methods. Table 1 summarizes the distribution of diagnostic methods, tooth surfaces, and lesion extent among these assessments. Among these studies there were few assessments of the performance of any diagnostic methods for primary or anterior teeth, and no assessments of performance on root surfaces. The strength of the evidence describing the performance of any method for these teeth and surfaces is *poor*.

Among studies assessing diagnostic performance for proximal and occlusal surfaces in posterior teeth, we rated the strength of the evidence describing the performance of visual/tactile, fiberoptic transillumination (FOTI), and laser fluorescence methods as *poor* due to the small numbers of studies available (Table 1).

We also rated the strength of the evidence for radiographic, visual, and electrical conductance, methods as *poor* for all types of lesions on posterior proximal and occlusal surfaces (Table 1). However, these ratings were due less to inadequate numbers of assessments than to variation among reported results. In one instance the quality of the available studies was the principal reason for the rating.

For all but EC assessments, specificity of a diagnostic method was generally higher than sensitivity. Thus, false negative diagnoses were proportionally more apt to occur in the presence of disease than were false positive diagnoses in the absence of disease. The evidence did not support the superiority of either visual or visual/tactile methods. The number of available assessments was small and there was substantial variation among reports for each method. The evidence suggests, but is far from conclusive, that some digital radiographic methods may offer small gains in sensitivity compared to conventional film radiography on both proximal and occlusal surfaces. The evidence also suggests, but is not conclusive that EC methods may offer heightened sensitivity on occlusal surfaces, but at the expense of specificity.

Management of Caries-Active Individuals: We evaluated the evidence for nine methods; fluoride varnishes, fluoride topical solutions, fluoride rinses, chlorhexidine varnishes, chlorhexidine topicals, chlorhexidine rinses, combined chlorhexidine-fluoride applications, occlusal sealants, and other approaches. We found 22 studies[51-72] describing 29 experimental interventions evaluating these methods in our main review (Table 2). We also examined 13 studies of special at-risk populations (orthodontic and head and neck radiotherapy patients).

We rated the evidence for the efficacy of fluoride varnishes as *fair*, and the evidence for all other methods as *insufficient*. For fluoride varnishes, five assessments all examined effectiveness in children. Reductions in the increment of new carious lesions ranged from seven to 30 percent over 2-5 years in the four studies where the intervention was compared to placebo or no treatment, and the number need to treat ranged from 1.5-5.4. However, only two of these studies reported the reduction to be statistically significant. The general level of quality scores for these studies was reasonably high, although the two studies showing statistical significance had the lowest scores of the group. Too few studies for any other fluoride method were included to permit any assessment.

The evidence for efficacy was suggestive for chlorhexidine varnishes and gels, for combination treatments including chlorhexidine, and for sucrose-free gum, but in each instance the number of studies was too small or the results were too variable to be conclusive. Thus the evidence was rated as *insufficient.*

Among subjects undergoing orthodontic treatment with attached bands or brackets (summary data not shown) we found the evidence for efficacy of fluoride interventions to be suggestive, but *insufficient.* Evidence was also *insufficient* for all other prevention methods for these subjects.

Among individuals receiving head and neck radiotherapy the literature offers *fair* evidence of the efficacy of fluoride-based interventions (summary data not shown). The evidence was

insufficient for any other types of preventive interventions among these subjects. Finally, we found no reports of substantive harms associated with any interventions.

Management of Non-Cavitated Carious Lesions: We found only five studies[73-77] addressing this topic (Table 3). No synthesis of these studies was possible because they differed in the preventive methods studied, in the treatment provided to comparison groups, and in how non-cavitated lesions were defined. The studies were characterized by problems in the identification and control of subjects' exposure to community-based and individual preventive dental procedures, and by high loss to follow-up due in part to limiting analyses only to full participants. We rated the evidence for this question as *insufficient.*

DISCUSSION

The diagnostic performance literature is limited in terms of numbers of available assessments for most diagnostic techniques overall, and especially for primary teeth, anterior teeth and root surfaces, and for visual/tactile and FOTI methods. The literature is further limited by threats to both internal and external validity represented by incomplete descriptions of selection and diagnostic criteria and examiner reliability, the use of small numbers of examiners, non-representative teeth, samples with high lesion prevalence, and a variety of reference standards of unknown reliability.

Research is needed to evaluate the performance of all diagnostic methods currently available to dental practitioners. Such research should focus on in vivo settings to the extent possible, despite difficulties imposed by the requirement for histological validation in that environment. Methods for histological validation should be standardized, and a standard

reporting format for evaluation of diagnostic performance should be formulated. Several aspects of study designs in this literature should be strengthened, including using samples with representative lesion prevalences and presentations, increasing the numbers of examiners whose performance is assessed, and ensuring examiner blinding for determinations of both experimental diagnoses and reference standards. Finally, research should begin to evaluate the "downstream" performance of diagnostic methods, i.e., the appropriateness of treatment provided in response to the diagnosis, and diagnostic performance in detection of changes in lesion volume.

With respect to the prevention and management of dental caries, we found the number of available studies for any specific method to be a serious limitation. Among studies addressing a method, the variety of experimental protocols, comparison groups and other community and individual preventive dentistry exposures further restricted our opportunity to draw conclusions about the efficacy of the method. Finally, generalization from the studies to the broader US population is problematic as nearly all studies included only children, reflected background exposures to preventive dentistry programs rather more extensive than the typical US experience, and evaluated changes only in the permanent dentition.

Additional clinical studies examining outcomes of management strategies for non-cavitated lesions and for caries-active patients are clearly needed. Here investigators must be encouraged to contribute studies that fill identified gaps, that build upon existing findings, and that use methods that facilitate comparison across studies. Funders and editors are important gatekeepers in this respect. Studies should use comparison groups representing the most common alternative treatment whenever possible, and document all professional, community, and

individual preventive dentistry exposures for all subjects. Intention to treat analyses, where all outcomes of all subjects enrolled at baseline are included in the analyses, are to be encouraged as well. Secondary analyses of existing studies of preventive agents might be exploited in the short-term to augment the meager store of knowledge for both non-cavitated lesions and caries-active individuals. However, some additional efforts need to be extended for the development of valid standard criteria for these classifications.

ACKNOWLEDGEMENT

This study was developed by the RTI/UNC Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality (Contract No. 290-97-0011), Rockville MD. The text of this paper is a modified version of the Executive Summary of the full evidence report prepared for the Dental Caries Consensus Development Conference. The tables in this paper are modified versions of tables prepared for scientific manuscripts under the AHRQ contract that have been submitted to *Caries Research* and *Community Dentistry Oral Epidemiology*. We acknowledge the capable assistance of Jacqueline Besteman, EPC Program Offices, Tina Murray, Task Order Officer, and Isabel Garcia, National Institute of Dental and Craniofacial Research laison with AHRQ for the task. We thank the Technical Expert Advisory Committee members, Craig Amundson, Ken Anusavice, Brian Burt, John Featherstone, David Pendrys, Nigel Pitts, and Jane Weintraub, and our consultants, Jan Clarkson, Amid Ismail, Gary Rozier, and Alex White for their helpful comments throughout the review process. Finally we thank Kathy Lohr and Jessica Nelson at RTI and Anne Jackman, Lynn Whitner, Donna Curasi, Sally Mauriello, Teg Hughes, and Jessica Lee at UNC for their invaluable assistance with the project.

DISCLAIMER

The authors of this article are responsible for its contents, including any clinical or treatment recommendations. No statement in this article should be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

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Table 1. Performance Summaries for Various Methods for the Detection of Carious Lesions

Method / *Surface* / *Extent of Lesion*	*number of studies*	*number of examiners* mean	median	*lesion prevalence* mean	median	*quality score* mean	median	*sensitivity* mean	median	range	*specificity* mean	median	range
Visual													
occlusal surfaces													
cavitated	4	1	1	56%	51%	45	42	63	51	53	89	89	22
dentinal	10	9	4	50%	44%	50	45	37	25	92	87	91	59
enamel	2	2	2	21%	21%	48	48	66	66	12	69	69	7
any	4	12	7	78%	75%	48	43	59	62	62	72	74	39
proximal surfaces													
cavitated	1	1	-	nr*	-	50	-	94	-	-	92	-	-
Visual-Tactile													
occlusal surfaces													
cavitated	1	1	-	nr-	-0	50	-	92	-	-	85	-	-
dentinal	2	12	6	29%	29%	45	45	19	19	10	97	97	7
any	2	4	4	40%	40%	45	45	39	39	44	94	94	13
proximal surfaces													
cavitated	3	3	3	5%	6%	62	65	52	32	64	98	99	2
dentinal	1	3	-	nr	-	35	-	50	-	-	71	-	-
Radiographic													
occlusal surfaces													
dentinal	26	4	3	54%	55%	47	45	53	54	79	83	85	50
enamel	4	2	2	18%	18%	48	48	30	28	25	76	76	10
any	7	5	4	82%	84%	49	50	39	27	67	91	95	18
proximal surfaces													
cavitated	7	3	3	13%	9%	63	60	66	66	63	95	97	13
dentinal	8	39	5	27%	25%	53	55	38	40	42	95	96	7
enamel	2	10	10	25%	25%	60	60	41	41	11	78	78	4
any	11	6	3	62%	66%	50	50	50	49	85	87	88	26
Electrical Conductance													
occlusal surfaces													
dentinal	14	2	1	38%	37%	37	45	84	91	39	78	80	38
enamel	1	1	-	24%	-	50	-	65	-	-	73	-	-
any	8	1	1	69%	64%	29	37	73	70	21	87	85	22
FOTI													
occlusal surfaces													
dentinal	1	1	-	36%	-	60	-	14	-	-	95	-	-
enamel	1	1	-	24%	-	55	-	21	-	-	88	-	-
proximal surfaces													
cavitated	1	4	-	6%	-	70	-	04	-	-	100	-	-
Laser Fluoresence													
occlusal surfaces													
dentinal	2	1	-	36%	36%	30	30	80	80	8	86	86	3
Combination Visual/Radiographic													
occlusal surfaces													
dentinal	3	10	10	61%	61%	47	45	67	65	37	75	74	23

*nr=not reported

Table 2. Studies of the Efficacy of Caries Prevention in High Caries Risk Individuals

study reference	*quality score*	*treatment*	*percent reduction*	*p value*	*number needed to treat*
Fluoride Agents					
51	60	0.04% NaF rinse, once per day	15%	>.05	2.5
52	50	2.2% F varnish (Duraphat), twice yearly	30%	<.001	1.6
52	50	0.7% F varnish (FluorProtector), twice yearly	11%	ns*	5.4
53	55	2.2% F varnish (Duraphat), four times per year	7%	>.05	4.3
53	55	0.2% Ferric Aluminum F topical, four times per year	13%	>.05	2.5
54	80	1.23% APF gel, twice yearly	9%	>.05	6.7
55	55	1.1% F varnish (Duraphat), three times per year	0%	--	--
56	60	1% Amine F rinse, twice per year	24%	not rptd[+]	10.2
57	50	0.1% F varnish (FluorProtector), twice yearly	25%	<.05	3.5
ChlorhexidineAgents					
58	40	1% CHX[#] gel, whenever ms > $2.5*10^5$	26%	ns	2.0
59	60	1% CHX gel, four times per year	44%	not rptd	1.5
53	55	1% CHX gel, eight times in two days, whenever ms > $2.5*10^5$	52%	<.001	0.6
60	70	0.05% CHX rinse, twice daily for five days, every third week	3%	ns	27.5
61	25	CHX varnish, three times in eight months	25%	not rptd	--
62	55	CHX varnish twice yearly	33%	<.05	2.8
62	55	CHX varnish twice yearly	-9%	>.05	--
CombinationAgents					
51	60	1% CHX / NaF rinse, once per day	43%	<.001	0.9
63	45	1% CHX gel once per day for two weeks every four months when ms > $2.5*10^5$, and occlusal sealants	81%	<.001	0.2
64	45	1% CHX gel as needed, and NaF topical and NaF gel	89%	<.05	0.7
60	70	0.05% CHX / 0.04 NaF /500 ppm Sr rinse, twice per day for five days every third week	8%	>.05	9.2
60	70	0.05% CHX / 0.04F twice per day for five days every third week	34%	>.05	2.1
65	40	1% CHX rinse, and 0.2%F rinse twice yearly to mothers	13%	ns	33.5
66	65	1%CHX / 0.1% NaF varnish, twice yearly	-26%	ns	--
Other Agents					
67	40	5% Kanamycin gel, twice/day for one week, repeated once	46%	not rptd	1.6
68	65	Occlusal sealants applied as needed, no repair	88%	not rptd	4.4
I9	70	Xylitol gum, 3.5 g three times per day	55%	<.001	1.4
70	60	dentist directed to use high risk protocol	13%	ns	5.9
71	65	0.9% alum rinse, once per day	23%	ns	2.2
72	65	sorbitol / manitol / aspartame gum, three times per day	11%	.003	3.0

*ns=reported as not statistically significant
[+]not rptd= no statistical testing reported
[#]CHX=chlorhexidine

Table 3. Studies of the Efficacy of Treatment for Non-Cavitated Carious Lesions

study reference	*quality score*	*treatment*	*% progression*		*p value*
			treatment	*control*	
73	60	APF solution, once (no conc. rptd.)	51%	82%	<.001
73	60	8% SnF solution, once	67%	82%	<.001
73	60	Ammoniacal silver nitrate, once, (no conc. rptd.)	69%	82%	<.001
74	55	0.5% NaF rinse, every two weeks	24%	16%	not rptd*.
75	40	2% NaF solution, every week for 3 weeks, twice	33%	36%	ns[+]
76	65	5% F varnish+0.2%NaF rinse, every 2 weeks	60%	61%	not rptd.
77	45	Occlusal sealant	11%	52%	<.001

*not rptd= no statistical testing reported
[+]ns=reported as not statistically significant