Clinical Evaluation of Two Different Prevention Programs in Adults Depending on Their Caries Risk Profile: One-year Results

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Clinical Relevance

The application of preventive protocols in patients with high and moderate caries risk differs. Regarding low-risk patients, the application of oral hygiene instructions is essential.

SUMMARY

The aim of this study was to investigate the management of incipient caries lesions in adults with two preventive protocols. A total of 44 adult patients with high, moderate and low caries risk with 516 incipient caries took part in the study. These patients were assessed for caries with International Caries Detection and Assessment System (ICDAS) criteria and were then divided into three groups depending

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on their caries risk profile: a high-risk group (group A), a moderate-risk group (group B), and a low-risk group (group C). Participants in each group were further divided randomly into two subgroups. In subgroups A1, B1, and C1, an intensive preventive protocol was applied, while in subgroups A2, B2, and C2, the protocol consisted only of instructions in oral hygiene. The invasive-intensive protocol included the topical application of fluoride, brushing with 5000-ppm fluoride toothpaste, use of amorphous calcium phosphate-casein phosphopeptide, applications of sealants for occlusal lesions (ICDAS code 2), and minimal resin restorations for occlusal lesions (ICDAS code 3). There was no statistically significant difference in the number of lesions (baseline and after one year) in the high-risk and moderate-risk groups that received the intensive protocol (groups A1 and B1), while the control groups were statistically significant different (groups A2 and B2). In the low-risk group, there was no statistically significant difference in the number of lesions (groups C1 and C2). The two different preventive protocols in the high- and moderate-risk groups presented dif-

ferences in effectiveness, while in the low-risk group, no significant difference was demonstrated.

INTRODUCTION

The principles of modern caries management include detection and long-term monitoring of incipient noncavitated caries lesions, evaluation of the patient's caries risk, and efforts to reduce the risk, as well as caries management, by applying less invasive treatment options and always according to the caries risk profile of each patient.¹⁻³

The treatment of patients should focus mainly on prevention (using high-fluoride toothpastes, solutions, patient education, and so on) and avoid further invasive treatments, thus achieving the goal of modern dentistry, which follows the philosophy of minimal intervention. The effort of balancing the causative factors of caries with the protective factors, in conjunction with caries risk assessment, offers the ability to focus on the patient for prevention and treatment before irreversible lesions occur in dental tissues. 4

For the application of modern caries management and treatment today, it is necessary to clinically apply a proper cost-effective prevention program on incipient caries lesions, according to minimally invasive principles, that guides the dentist beyond theory in clinical practice. The application of such a protocol to manage incipient caries lesions allows the dentist to stabilize and reverse incipient lesions with minimal "sacrifice" of healthy dental tissues.

Preventive programs on caries lesions in the adult population have been applied since 1970 and include various preventive measures, such as intensive topical application of fluoride, oral hygiene instructions, patient education and advice, and monitoring of lesions, all of which have been effective in reversing and preventing lesions for the past 40 years.⁵⁻⁸

In the dental literature, there are reports of clinical protocols that propose procedures to be followed to avoid caries. Even though such clinical protocols have been proposed, they have been poorly evaluated clinically in adult patients with different caries risk presenting with incipient lesions. Reports of such protocols' preventive programs have been published for adults, children, and adolescents. ⁹⁻¹²

Single preventive measures on incipient caries in the dental literature have been evaluated, such as the application of sealants, $^{13\text{-}16}$ fluoride, $^{17\text{-}19}$ and amorphous calcium phosphate-casein phosphopeptide (ACP-CPP). $^{20\text{-}23}$

With regard to preventive programs, few studies have evaluated protocols (but not for incipient caries), mainly on special needs patient groups, such as the elderly population, ^{24,25} patients with xerostomia, ²⁶⁻²⁸ patients who have undergone head and neck radiation and chemotherapy, ^{24,29-33} and other studies which have not evaluated incipient caries. ^{8,12} Additionally, few studies exist that refer to the patient's caries risk.

The purpose of this clinical study was to evaluate different protocols to treat incipient caries lesions in adults. These protocols were based on their caries risk profiles. Patients received dental treatment immediately after joining the study. The research hypothesis was that the applied protocols, depending on caries risk assessment of patients, do not present any difference. In particular, there is no difference in the number of incipient lesions after the application of these caries protocols, nor is there a difference in the development of incipient lesions compared to the control group.

METHODS AND MATERIALS

This study was conducted on patients attending the postgraduate Department of Operative Dentistry at the National Kapodistrian University of Athens. Specifically, the study included new patients entering the Postgraduate Clinical Program of Operative Dentistry but also patients who have previously been treated in that clinic. The study was approved by the Committee of Ethics of the Dental School of the University (protocol number 170), and all patients who took part in the study were informed and gave their prior written consent.

Inclusion and Exclusion Criteria for the Participants

Selection criteria were for patients to be over 18 years old and to have at least 10 natural teeth, without restorations and cavities. All the different medical conditions of the patients were included, except for those who were pregnant, patients who were in cancer therapy at the time of the study, or those with systematic diseases or who had taken medicines that influence the saliva. Exclusion criteria also included totally edentulous patients and patients with crowns, bridges, and restorations in 50% of more of their dentition.

	Caries Risk Group	
Low Risk	Moderate Risk	High Risk
No caries lesions and/or No proximal caries exceeding D2 (by bitewing X-rays)	Caries lesions 1-3 (ICDAS II) \leq 3 and/or Open cavity \leq 1 and/or Proximal lesions D3 \leq 1 (by bitewing X-rays)	Caries lesions with open cavity ≤ 2 and/or Proximal lesions D4 category < 1 (by bitewing X-rays) and/or Caries lesions 1-3 (ICDAS II) > 3 (by bitewing X-rays)

Baseline Evaluation

Patients were examined clinically with International Caries Detection and Assessment System (ICDAS II) criteria³⁴ by one examiner and were then classified based on their caries risk profile into low-, moderate-, and high-risk groups. The evaluation of caries risk was based on the clinical features of caries risk, as shown in Table 1.

Teeth were coded from 0 to 6 according to the ICDAS II criteria (Table 2). 34,35 Only incipient lesions that were coded ICDAS 0-3 took part in the study, while more extended lesions (into dentin) that were coded ICDAS 4-6 were restored prior.

Each tooth surface was examined and scored under wet- and dry- conditions (air for five seconds) as per the ICDAS II instructions. The clinical examination of the teeth was made midday in a dental unit using the light and the air syringe of the unit by one examiner. The examiner was trained with educational software (ICDAS training software) to use these criteria before the clinical examination of the teeth. Further training was accomplished with a second examiner (also trained and familiar with the ICDAS II criteria). The two examiners were

Table 2: International Caries Detection and Assessment System (ICDAS II) Codes With Direct Visualization of the Teeth First in Moisture and After Drying Them With Air for Five Seconds^{34,35}

	After Drying Them With Air for Five Seconds ^{34,35}
	Visual Examination ICDAS Codes
0	Sound tooth surface
1	First visual change in dry enamel
2	Distinct visual change in moist enamel
3	Localized enamel breakdown due to caries with no visible dentine or underlying shadow
4	Underlying dark shadow in dentine with or without localized enamel breakdown
5	Distinct cavity with visible dentine
6	Extensive distinct cavity with visible dentine

calibrated by pilot scoring 10 teeth independently and then seeking agreement for the scores presenting disagreement. After one week, scoring of 10 other teeth was repeated separately by the two examiners, and the two examiners came to full agreement. Finally, at a different time, the two examiners independently scored 38 teeth, and the agreement was substantial (Table 3).

During the patient's baseline clinical examination, all lesions with code 1, 2, and 3 based on the ICDAS II criteria were photographed by the examiner. For the baseline evaluation of the proximal lesions, digital radiography was used (Vista Scan device and DBSWIN software, Dürr Dental, Bietigheim-Bissingen, Germany).

Application of Protocols

Control Group—Patients in the control group were given only oral hygiene instructions to brush (Caries Protection toothpaste, Colgate fluoride, 1450 ppm, Colgate-Palmolive, Cincinnati, OH, USA) and floss interproximally (waxed dental floss was given to patients; Colgate). All patients (control and intervention groups) were instructed to brush with the Bass technique twice a day and to floss once per day, and for this purpose leaflets with these instructions were given. Additionally, they were instructed with demonstration models and trained with a toothbrush in their mouth. Lesions with the 1-3 ICDAS code were recorded and shown to the patients.

Table 3: Interexaminer Agreement Between the Two
Examiners in ICDAS Criteria (International
Caries Detection and Assessment System) and
Intraexaminer Agreement in Different Time
Interval Examinations

K (ICDAS)	K	Agreement		
Examiners	0.73 ± 0.07	Substantial		
Different time interval examination	0.74 ± 0.04	Substantial		

Table 4: General and Specific Measures Applied to the Patients in the Intervention Group

Patients		HIGH	CARIES	RISK A1		MODERATE CARIES RISK B1			LOW CARIES RISK C1			
Interventi	on group											
Tuestuseut		Enhanc	ed oral h	ygiene instru	ıctions	Enhanced	Enhanced oral hygiene instructions			Oral hygiene instructions		
Treatment	ι.			toothpaste			with 5000ppm F-toothpaste			Oral Hygietie instructions		
General m	easures		• •	nd advice		Dietary ad			Dietary adv	vice		
22	General measures			on of fluoride	/1 220/		olication of 1.23	20/ NaE gola	Dietary advice Topical application of fluoride(1.23%			
							ery 6 months	o war ger,		l time/year	nue(1.25%	
						1 time/eve	ry o monuns		Nar ger), .	r ume/year		
		months	r		and a state	Dit and Car	ures sealants fo					
				ealants for te	eth with							
		deep grooves (mandatory) Recall, 3 months					grooves (option	nai) ————	D 11			
						Recall, 6 m			Recall, eve	ry year		
Treatment	•	CPP-	seal	ICON	Resin	CPP-	Sealan	Resin	CPP-	sealants	Resin	
measures	for each	ACP ^b	ants		restor	ACP ^b	ts	restora	ACP ^b		restor	
lesion					ation			tion			ation	
						3.6						
Lesio	on	High caries risk			Moderate caries risk			Low caries risk				
Occlusal	01 ICDAS											
	02 ICDAS		٧				V					
	UZ ICDAS		V				V					
	03 ICDAS				٧			٧		٧		
Smooth	01 ICDAS	٧				٧						
surfaces	02 ICDAS	٧		√ anterior		V						
	OZ ICDAS	V		teeth		V						
	03 ICDAS				٧	٧			٧			
Proximal	01 ICDAS	٧				٧			٧			
	02 ICDAS	٧				٧			٧			
	03 ICDAS				٧			٧	٧			
Root	1 ICDAS				٧	٧						
caries												

^a C Care, 1.23% NaF gel, APF (Dental Line Ltd, Athens, Greece).
^b Amorphous calcium phosphate-casein phosphopeptide (ACP-CPP) cream, GC Tooth Mousse (GC Corp, Tokyo, Japan).

Intervention Group—In this group, in lesions coded 1, 2, and 3 according to ICDAS II criteria, protocols of caries management were applied. Protocols were applied by the same examiner who conducted the evaluations. Protocols (presented in Table 4) included general preventive measures depending on the patient's caries risk, followed by specific measures for each lesion.

Evaluation Stage—In the control and intervention groups, recalls were performed at time intervals according to the caries risk of each patient. High-risk patients were re-examined every three months, moderate-risk patients every six months, and low-risk patients at one year. At the recalls, each lesion, treated or not, was re-evaluated by the clinical ICDAS criteria (pit and fissure caries, root caries, caries on smooth surfaces, and proximal surfaces). At the recall, the percentages of lesions that had further developed or stabilized were calculated. Finally, each patient was examined for the occurrence of new lesions. Additionally, comparison of the treatment and control groups was performed.

Sample

A total of 50 patients took part in the present study (n=50); however, six patients withdrew from the study before the one-year recall. The final sample that was evaluated consisted of 44 people (9 men and 35 women) aged 20-62 years old with a mean age of 30 years. Before the final selection of the patients, a pilot study was performed with three patients of high caries risk, and the power of the results was higher than 0.8. The results deemed to be clinically relevant and to have that high power were the differences between the number of caries in these three patients at two separate visits. After the ICDAS II examination of the patients and the evaluation of their caries risk, the randomization process was as follows: the first patient who took part in the study of each patient risk group was included in the intervention group and the second in the control group and the sequence continued in this wav.

Statistical Methods

Findings were analyzed as follows:

1) The percentage and absolute number of incipient lesions in all groups at baseline examination and at the one-year recall as well as the $D_{1-3}MFS$ index for each group were calculated (D_{1-3} : for each participant the incipient lesions with 1-2-3 ICDAS code).

2) The changes for each lesion from the baseline examination to the one-year recall were recorded. The nonparametric Wilcoxon test was applied to the two visits (baseline and one year) in each group for comparing the number of lesions. Computer software (SPSS Statistics version 13.7, IBM, Armonk, NY, USA) was used, and the level of statistical significance was 0.05.

RESULTS

Percentage and Absolute Number of Incipient Caries in All Groups at the Baseline Examination and the One-Year Recall by Caries Risk

The results are presented in Tables 5-7.

DMFS Index for Each Group- Wilcoxon Test

The $D_{1-3}MFS$ index for each group is presented in Table 8.

The Wilcoxon test (Table 8) revealed statistically significant differences in the high-risk control group (group A2, p=0.024) with the DMFS index decreasing from 16.83 \pm 1.00 (mean \pm SE) to 14 \pm 1.15 (mean \pm SE) after one year and in the moderate risk control group (group B2, p=0.041) with the DMFS index increasing from 12.43 \pm 1.47 (mean \pm SE) to 14.7 \pm 1.82 (mean \pm SE) after one year. There was no statistically significant difference in the number of lesions among the high-risk and moderate-risk patient groups when preventive protocols were applied (group A1, p=0.786; group B1, p=0.233). In the low-risk group, there was no statistically significant difference in the number of lesions (group C1, p=0.203; group C2, p=0.303).

DISCUSSION

The protocols for the management of incipient caries lesions evaluated in this clinical study include preventive and minimally invasive methods as published in the most recent studies of incipient lesions treatment. Different protocols were applied based on the caries risk of each patient. All caries were identified using the latest modified version of the ICDAS criteria (ICDAS II). 34,35

In the present study, the caries risk of each patient was determined based solely on the clinical examination and the existing number of lesions. Due to the complexity and difficulty of applying the various caries risk evaluation strategies (because of the multiple collection of data), research tends to simplify this procedure so that it can be incorporated

Patient	Baseline	1 year
1 High caries risk	32	26
2	24	19
3 \rightarrow Intervention	12	13
1	18	23
5 group	20	24
6	12	12
1	17	15
2	18	12
3 Control	21	19
4 group	16	14
5	14	11
6	15	13
1	22	23
2 Moderate caries risk	17	10
3	12	10
1 Intervention	17	16
5 group	14	18
	10	9
7	13	6
1	11	16
2	14	19
3 Control	19 14	21
group		
<u></u>	9 7	10
6 7	13	8 12
1	. 4	10
	5	5
Low caries risk	11	14
1	5	4
5 Intervention	6	3
6 group	6	9
7	7	6
8	2	3
9	9	14
1	6	6
2	5	8
3	3	5
4 Control	5	8
5 group	7	4
6	6	7
7	0	1
8 9	10 10	9 10
9 1)	10	10

Table 6: Baseline Incipient Lesions and One-Year Recall Regarding the Changes of the Incipient Lesions With International Caries Detection and Assessment System (ICDAS II) Criteria^a

ICDAS	High	caries ri	isk		Moderate caries risk				Low caries risk			
CODE	Intervention		Control		Intervention		Control		Intervention		Control	
	Baseline	1 year	Baseline	1 year	Baseline	1 year	Baseline	1 year	Baseline	1 year	Baseline	1 year
00		31		30		44		10		1.		
01	14	13	10 <	1	12 <	4	9 <	9	14 5	22	19 <	20
02	64	68	48 🗡	45	80 🗸	76	59	65	35	40	27 🗲	2!
03	40	11	41	28	13	9	19	25	2 🕹	2	7 —	1
04				4				2				
05				¥ 2				1				
	<u>I</u>	ı	ı	I	<u> I</u>	1	1	1	I	1	<u> I</u>	I

easily into the everyday clinical dental practice of caries risk assessment. In a retrospective analysis by Domejean and others, ³⁶ who evaluated the CAMBRA system in 2571 patients, it was concluded that "visible cavities" and cavities with "radiographic penetration into dentin" were significantly associated with the caries risk. Another study evaluated Cariogram and suggested that it is possible for the evaluation of caries risk to find more simplified models using regression analysis for the determination of risk. ³⁷ In another study, Bader and others ³⁸ ranked 45,693 patients, indicating a way to classify each individual by caries activity at the time of

examination. This classification integrates and unifies the entire patient history and is associated with patient behavior and caries risk. Later, Bader and others assessed the subjective evaluation of the dentist in determining caries risk, what additional information dentists examine, and if there is a need for direct involvement of the dentist in caries risk assessment. The subjective evaluations of dentists contributed to further increase of risk evaluation sensitivity. In conclusion, the determination of caries risk based on current dental status is well documented and approaches the clinical reality.

Table 7: Baseline Number of Patients and Lesions and One-Year Recall Regarding the Changes of the Incipient Lesions (Numerically and %) in High-, Moderate-, and Low-Risk Patients

Caries Risk	High-Risk Patients		Moderate-Ris	k Patients	Low-Risk Patients		
Group	Intervention	Control	Intervention	Control	Intervention	Control	
Patients (number)	6	6	7	7	9	9	
Baseline examination (number of lesions)	118	99	105	87	55	52	
1-y recall/lesions							
Increased number of caries (%)	9 (8%)	9 (8%)	7 (5%)	17 (16%)	5 (6%)	9 (14%)	
Decreased number of caries (%)	32 (29%)	45 (39%)	48 (37%)	15 (14%)	18 (22%)	13 (20%)	
Stabilized number of caries (%)	38 (35%)	45 (38%)	45 (34%)	55 (50%)	31 (38%)	30 (46%)	
New caries number of caries (%)	31 (28%)	18 (15%)	31 (24%)	22 (20%)	28 (34%)	13 (20%)	

Table 8	: DMFS Index in the Intervention and Control Groups of High-, Moderate-, and Low-Risk Patients and Wilcoxon Test
	Statistics for Comparison Among Groups in Number of Lesions at Baseline and in One Year

DMFS	DMFS									
	High Ca	ries Risk	Moderate (Caries Risk	Low Caries Risk					
	Intervention	Control	Intervention	Control	Intervention	Control				
	Group A1	Group A2	Group B1	Group B2	Group C1	Group C2				
Baseline	19.66 ± 3.11	16.83 ± 1.00	15.00 ± 1.50	12.43 ± 1.47	6.11 ± 0.88	5.77 ± 1.00				
	(mean±SE)	(mean±SE)	(mean±SE)	(mean±SE)	(mean±SE)	(mean±SE)				
Year	19.50 ± 2.40	14.00 ± 1.15	13.14 ± 2.27	14.70 ± 1.82	7.55 ± 1.46	6.44 ± 2.78				
	(mean±SE)	(mean±SE)	(mean±SE)	(mean±SE)	(mean±SE)	(mean±SE)				
Wilcoxon p	p = 0.786	p = 0.024	p = 0.233	p = 0.041	p = 0.203	p = 0.303				

In the present study, in patients with high or moderate caries risk, the incipient caries lesions with ICDAS code 3 were restored with resin composite after minimal preparation of these lesions. A recent systematic review of 14 studies, including 1440 patients with 3551 lesions, found that conservative treatment (minimal invasive) of incipient lesions required less retreatment compared to lesions that were not treated. The researchers also concluded that the strategy of minimally invasive treatment was the most effective, followed by microinvasive and noninvasive treatment.⁴⁰

In the present study, a statistically significant difference with regard to the number of caries lesions was found only for the control groups of high- and moderate-risk patients. In the other groups, where the preventive protocols were applied, no statistically significant differences were found. Intervention groups of high- or moderate-risk patients were not found to be statistically significant different, although the protocols were quite intensive.

There are no data from studies of the management of incipient caries in adults. For this reason, the results of the present study were compared with relative studies conducted with children. This is not really clinically relevant, but it does present a view of what happens in different age-groups. The results of the aforementioned study could be in agreement with a study that treated high caries risk children with sealants and supervised brushing. In this study, daily supervised brushing was as good as the application of sealant materials in preventing lesions from advancing to cavities. 15 In contrast to the above, Borges and others⁴¹ evaluated the influence of sealants in patients with high or moderate caries risk and concluded that the measure is effective in reversing lesions.

Although the results of these studies 15,41 conflict with those of the present study, they reach similar conclusions. Statistically significant differences were found in the control groups of high- and moderaterisk patients but, when evaluated together with the changes in the DMFS index of these two groups, have opposite results. In high-risk patients, the DMFS index decreased from 16.83 to 14.00 solely by emphasizing oral hygiene (meaning that oral hygiene was effective for this patient group, as the number of carious surfaces decreased). However, the opposite was found for the control group of moderaterisk patients, as the DMFS increased from 12.43 to 14.70 in one year; thus, oral hygiene proved an insufficient measure for these patients as the number of carious surfaces increased.

In the present study, in the intervention group of high-risk patients, no statistically significant difference was found in the recall at one year with regard to the number of caries lesions, and the DMFS index remained stable (from 19.50 to 19.60 in one year). However, in the control group, solely through meticulous oral hygiene, a statistically significant difference was found in the number of lesions, and the DMFS index decreased from 16.83 to 14.00.

Results of the present study are in disagreement with other studies where toothpaste that contains 5000-ppm fluoride was significantly better compared to toothpaste that contains 1450-ppm fluoride in reversing incipient lesions without cavity formation. 42-44 The comparison of the present results with previous studies is difficult, and Bader and others 45 reached the same conclusion in a systematic review of 1435 articles on the effectiveness of preventive methods in high-risk individuals with incipient lesions. They concluded that the main limitations of the literature regarding the treatment of incipient lesions were the small number of studies as well as variation among patients, tooth surfaces, caries

assessment and lesion progression criteria and variation in the experimental and control groups; thus, it is impossible to achieve a comparable conclusion about the effectiveness of any method.

In patients with moderate caries risk in the intervention group, no statistically significant difference was found in the number of lesions before and after the application of the prevention program. The DMFS index decreased from 15.00 ± 1.50 on the baseline examination to 13.14 ± 2.27 at the one-year recall. In the control group, the DMFS increased from 12.43 to 14.70 at one year and had a statistically significant difference (p=0.041).

Pit and fissure sealants materials have been found protective in adolescents, but only in low- or moderate-risk patients. ⁴⁶ Unfortunately, in the literature, studies related to moderate-risk patients are largely missing. Based on all this, a reliable conclusion cannot be drawn from the comparison of the results of the present study for this caries risk group.

In the low-risk group, there was no statistically significant difference in any of the treatment or control groups in the number of lesions. Studies in children and adolescents concluded that this measure is clearly effective. However, for sealants, cost-effectiveness must be taken into serious consideration in low-risk groups because there are other measures, such as the use of fluoride and oral hygiene instructions, that could achieve the same results. 47,48

Moreover, in the present study, in the high-risk patients, the intervention and control subgroups had the same increasing rate of caries lesions (8%), while there was a difference in the intervention group in the occurrence of new lesions (28%) and a reduction of existing lesions (29%) compared with the control group, where the percentages were 15% (new caries) and 39% (reduced caries), respectively. However, in the present study, in the annual recall in the intervention group after the application of the protocols, there were no lesions greater than ICDAS code 3. That means that in this group, the caries lesions remained in the enamel, while in the control group, some lesions progressed further into the dentin since four lesions were identified as ICDAS code 4, one lesion was identified as ICDAS code 5, and a composite resin restoration was placed in a previous recall.

This final result of the present study agrees with the two-year study of Liu and others¹⁷ of 501 patients who applied three different preventive measures in incipient occlusal caries lesions in 1.491 molars with lesions code 2 according to the ICDAS criteria. After two years, dentin lesions in the control group were 4.6% and were statistically significantly higher than in the other three treatment groups (p=0.002).

Regarding the moderate-risk patients, in the intervention group, 37% of the lesions decreased, while only 5% increased. In the control group, 14% of the lesions decreased, while 16% increased. The application of the protocol in patients with moderate caries risk presented differences compared with the control group.

In the low-risk patients in the intervention group, 6% of the lesions increased, 34% new lesions developed, and 38% remained stable, while in the control group, the corresponding rates were 14% (increased), 20% (new caries), and 46% (remained stable).

The duration of the present study was one year. The intensive preventive programs clearly had no favorable results at this one-year period. Longer periods of observation and intervention are probably needed to show effectiveness.

CONCLUSIONS

- In patients with moderate caries risk, the intervention group presented lower caries development rates and a lower DMFS index than the control group; thus, oral hygiene instructions given to the control group are not adequate to control caries.
- In patients with high caries risk, the result of this study is not clear. The control group presented significantly lower DMFS than the intervention group. The control group presented overall better results than the intervention group; however, some incipient lesions further progressed into dentin in the control group, a fact that did not exist in the intervention group. Thus, in high-risk patients due to the above-mentioned result, the dentist must choose whether to apply to the patient an intensive protocol; however, the risk of some incipient lesions to progress into dentin must be considered. In such cases, the final selection should be done in collaboration with the patient, and cost-effectiveness should be taken into account.
- Regarding the low-risk patients, both protocols proved to have no difference in results, meaning that in these patients, the application of only oral hygiene instructions is adequate for the management of incipient lesions.

 Incipient lesions in patients should be monitored regularly, as the present study showed that these lesions may advance in less than a year to a "worse" category (as evaluated with ICDAS II criteria).

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Committee of Ethics of the Dental School of the University. The approval code for this study is protocol number 170.

Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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