

Efficacy and Tolerance of Papain Gel with Conventional Drilling Method: A Clinico-Microbiological Study

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Background: Conventional methods of caries removal are commonly associated with pain, fear and discomfort. Chemomechanical methods were introduced to instill a positive dental attitude. Agents like GK-101, Caridex, Carisolv did not prove effective alternatives owing to their high cost, need of special instruments and taste of chlorine. A new chemomechanical agent, Papacarie®, has been introduced to overcome these deficiencies. **Objective:** This study was aimed to compare the effectiveness and tolerance of Papacarie® with the conventional method. **Method:** 25 children with at least two primary teeth with broad cavitated occlusal or cervical lesion were selected. One carious tooth from each patient was randomly treated with each of Papacarie® and conventional drilling method, one after the other. Time taken for caries excavation, child's pain perception, change in anxiety levels, microbial flora and child's preference of treatment were recorded separately for both the methods. **Result:** Although the mean time taken for caries removal by the Papacarie® method was slightly longer ($P > 0.05$) but it led to reduction in pain and anxiety ($p < 0.05$). The viable bacterial counts were significantly reduced by either of the two methods ($P < 0.0001$). More patients preferred Papacarie® over conventional method of treatment ($P < 0.05$). **Conclusion:** Papacarie® method seems to be a better alternative to conventional method of caries removal.

Key words: Caries, Papacarie®, Chemomechanical caries removal, Conventional method

INTRODUCTION

The quest for caries removal with minimal pain and more tissue preservation has given rise to inventions of newer techniques in place of the conventional drilling instruments, more so in children and patients with dental anxiety.¹ Techniques using air abrasion, ultrasonics, sonoabrasion and lasers led to lesser tissue removal and patient discomfort but required costly equipment, making their use expensive.² A viable alternative could be the use of chemomechanical agents which softens the carious dentin and thus may facilitate its removal with gentle excavation. Chemomechanical caries removal (CMCR) methods were likely to eliminate infected tissues while preserving healthy dental structures, prevent pulp irritation and avoid patient discomfort.³

Out of several agents like GK-101, Caridex, Carisolv and enzymes used in CMCR methods, only Carisolv was found to be effective in removing infected carious tissue⁴⁻⁷ but it failed to be a practical alternative to the conventional drilling method due to its high cost, need of special instruments and more time consumption. Further, children disliked its chlorine taste and odor.⁸

A new formula has been developed by Bassadori *et al.*, namely Papacarie® (Fórmula and Ação (F and A), São Paulo (SP) –Brazil) for removal of caries. It has been patented, registered and approved by ANVISA in Brazil. It contains papain, chloramine, toluidine blue, salts and a thickening vehicle to obtain a synergistic action from each of its components and thus facilitate removal of the decayed tissue but papain, the basic component of Papacarie®, is responsible for its bactericidal, bacteriostatic and anti-inflammatory properties. Ease of application and no need for special devices is the added advantage.⁹ Cytotoxic studies on Papacarie® have suggested that Papacarie® is safe for use in pediatric patients¹⁰ But only a few studies have been carried out to demonstrate its efficacy and tolerance,¹¹⁻¹⁵ necessitating the need for further studies, more particularly in Indian patients.

This study was undertaken to evaluate the efficacy and tolerance of Papacarie® caries removal method as compared to conventional drilling method in terms of reduction in microbial flora, pain and anxiety and overall patient acceptance and thereby to assess its application and scope in the field of pediatric dentistry.

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MATERIALS AND METHOD

This randomized, controlled and cross over clinico- microbiological study was carried out at the Department of Pedodontics and Preventive Dentistry, Government Dental College, Kozhikode, India. Clinical criteria for inclusion were patients in age between 5-9 years, normal development for age, no defects in tooth formation and at least two primary teeth with broad cavitated occlusal or cervical lesion with dentinal involvement (Black’s class I and class V cavities), consistency of carious lesion being medium hard and color being light yellow to brown and cavities having open access. Radiographic criteria included a lesion with clearly visible radiolucency extending into, but confined to outer dentine. Exclusion criteria for the study included presence of spontaneous pain, use of antibiotics within two weeks prior to study, teeth with pulpal involvement, furcation or periapical pathology and/or inter-proximal caries and presence of any systemic disease.

The study design, objectives and the potential benefits of the trial were explained to the selected children and their parents and written consent was obtained prior to the study. The ethical committee clearance was also obtained prior to the study.

Caries removal was performed using either of these two methods randomly. In Group A (Conventional drilling method), caries was removed using a high speed hand piece (NSK, Japan) under water spray cooling system with a spherical diamond bur (No. 008). Cavity was examined by visual inspection and tactile sensation using a mirror and an explorer to assess caries removal. Cavity was judged as caries free when the explorer did not stick in dentin and did not give a tug-back sensation. In Group B (Chemomechanical method), the carious cavity was first filled with papain gel Papacarie® (Fórmula and Ação (F and A), São Paulo (SP) –Brazil). After 30 to 40 sec, softened decayed dentin was scraped using opposite side of the excavator in a pendulum motion. The procedure was repeated until a light color was observed but the cavity was not washed between the gel applications. At the end of the procedure, the remaining gel was removed with a cotton-pellet soaked in water. The cavities were checked for complete caries removal using the same criteria as used for the conventional method. The

caries excavation in both methods was carried out under rubber dam isolation to avoid contamination of the dentine samples with saliva and without use of local anesthetics to avoid alteration of pain perception of the patient.

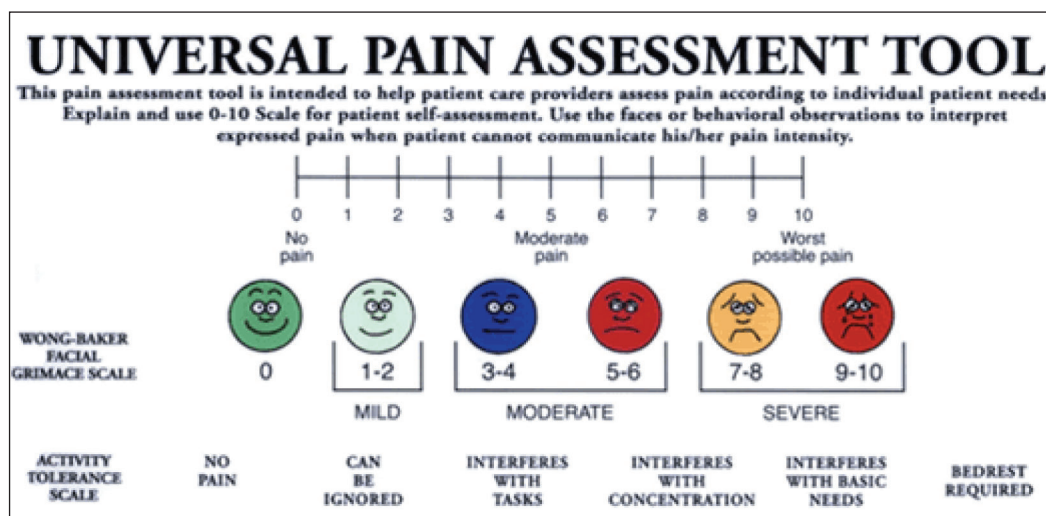
The time taken for caries removal by each procedure was recorded with the help of a stop watch. Pain perception by patients were recorded as Wong-Baker-FACES (WBF) scores using the WSF Pain Rating Scale before, during and at the end of procedure (Figure 1).¹⁶ Pulse rate was also recorded before, during, and after the procedure with a finger pulse oximeter (Make: Nidex Medical India). It was used as a surrogate marker for anxiety. Dentine samples were taken both prior to and after complete caries removal with the help of the sterile and sharp spoon excavator and immediately transferred to sterile vial containing 1ml saline and transported to microbiological laboratory within 1 hour. Each sample was vortexed for about 30 seconds to dislodge the bacteria from the dentine and then serially diluted in blank buffer to make it 10ml. 0.01 ml volume was then spread on different agar plates. Blood agar plates were incubated both aerobically and anaerobically in a candle jar 37°C in 5% CO2 atmosphere. MS agar and Rogosa agar plates were incubated aerobically at 37 °C for 3 days. Growth on different media was recorded as colony forming units (CFU) and the number of CFU/ml was calculated for each sample. Counting the microbial colonies was done manually. The same clinical and microbiological procedures were repeated on the other carious tooth of the patients but using the other method of caries removal (cross over design).

After completion of the caries removal procedure by both the methods, each child was interviewed regarding the preferred caries removal method and his choice was recorded. The obtained data were tabulated and statistically analyzed by Student’s t test and Chi-square test.

RESULTS

A total 50 teeth from 25 Patients were selected for this study. Fourteen of the patients were boys and the remaining 11 were girls. Teeth included consisted of 6 maxillary and 19 mandibular in group A and 5 maxillary and 20 mandibular in group B (p>0.05).

Figure 1 Wong-Baker FACES Pain Rating Scale (WBF)



A repeat application of Papacarie® gel was required in 6 patients only. Mean time taken for caries removal was 6.99±1.7 min. in conventional method as compared to 7.41±1.62 min. in Papacarie® method (p>0.5).

Table 1 shows mean pulse rates and WSF scores for the 2 groups. Prior to the procedure the mean pulse rates were similar for the 2 groups (p>0.5). In group A there was a slight rise in mean pulse rate during the procedure (p>0.1). The pulse rate there after declined but it did not reach to base line levels (p>0.1). On the contrary, the mean pulse rate significantly declined in Papacarie® method, both, during and after the procedure (p<0.001). In absolute terms, none of the patients in Papacarie® method had a rise in pulse during or after the procedure but it was evident in as many as 19 and 16 patients respectively during and after the conventional method (p<0.001). Prior to procedure, scores on WBF Scale were similar for the 2 procedures (p>0.5). There was a slight rise in mean WBF scale score, both, during and after the procedure in group A (p>0.5) but it significantly declined in Papacarie® method, both, during and after the completion of procedure (p<0.01). In absolute terms as many as 16 and 13 patients had a rise in WBF Scale score during and after the conventional method respectively but it was seen in only 1 patient during Papacarie® method. A decline in WBF Scale score was recorded in 21 and 22 patients on Papacarie® method as compared to only 4 and 7 patients respectively on the conventional method (p<0.001). This shows that the pain that existed prior to procedure declined during and after caries removal by Papacarie® method but pain increased, both, during and after the procedure in the conventional method.

Table I: Mean Pulse rate and WBF scores before, during and after the procedure in the two groups.

Parameter	Group A (N=25)	Group B (N=25)
Mean pulse/min		
Before	96.52 ± 14.32	98.24 ± 14.12
During	102.2 ± 14.12	89.64 ± 14.12
After	100.4 ± 12.49	85.12 ± 14.12
Mean WBF score		
Before	5.12 ± 2.01	5.28 ± 1.28
During	6.16 ± 1.91	3.44 ± 1.36
After	5.76 ± 1.76	2.24 ± 1.45

Table II shows the mean colony counts on various media for the samples collected before and after the procedure in the 2 groups. Prior to the procedure, the total viable counts, Lactobacilli counts,

Table II: Colony counts before and after the procedure in Group A and B.

	Group A		Group B	
	Before (CFU/ml)*	After (CFU/ml)*	Before (CFU/ml)*	After (CFU/ml)*
Blood agar Aerobic	226.2 ± 114.0	26.48 ± 14.9	221.6 ± 114.3	25.56 ± 16.2
Blood agar Anaerobic	241.6 ± 120.7	24.8 ± 13.9	243.2 ± 120.3	30.56 ± 15.8
M S agar Aerobic	24.0 ± 14.6	03.64 ± 3.6	28.16 ± 15.7	05.88 ± 5.1
Rogosa agar Aerobic	22.8 ± 11.8	04.32 ± 4.7	26.56 ± 14.4	04.42 ± 4.7

* ×10³

and Streptococci counts were similar for the two methods (p>0.5). After the procedure the various bacterial counts were significantly and equally reduced in the two methods (p<0.001).

Only 2 children preferred Conventional method as compared to 20 children who had preferred Papacarie® method. Three children were not sure, which method to choose.

DISCUSSION

For both the groups in the present study, the primary teeth had a similar degree of decay and distribution (maxillary and mandibular teeth) (p>0.5). The mean total viable count, lactobacilli count and streptococci count in the samples collected prior to the procedure were similar for both the methods. Caries removal was performed randomly by either of the two methods in each patient and then the same patient was crossed over to the other method. Hence the data of the study are valid for statistical comparison as there was no selection bias in the 2 treatment groups.

The time taken for caries removal by Papacarie® method was about the same as that taken by the conventional method in the present study (7.41 min. and 6.99 min., p>0.5). This is consistent with the results obtained by Kotb *et al*¹² but Singh *et al*¹⁵ had reported that the time taken for caries removal with Papacarie® was three times more than the conventional method. The time taken for child’s behavior management was included in the procedure time in this study. This could account for longer time taken for caries removal by conventional method in the present study as compared to that by Singh *et al*¹⁵. Requirement of multiple applications of gel to complete caries removal could also account for longer time.¹⁷ Most of the present study patients required only one gel application, thus reducing the mean procedure time.

Anxiety is an important issue when delivering dental treatment to children¹⁸ but objective measurement of anxiety is often difficult. Yelderman¹⁹ used pulse rate as an indirect index of patient’s response to dental stimuli. Accordingly, a finger pulse oximeter was used in this study to measure pulse rate at different times to assess the level of anxiety, this being the first study to measure anxiety to assess tolerance to Papacarie® method. It was found out that mean pulse rate reduced both during and after caries removal in Papacarie® method (from 98.24 to 89.64/min and from 89.64 to 85.12/min respectively, p<0.05). In contrast, there was a rise in pulse rate during the conventional procedure (from 96.52 to 102.2/min, p>0.05). This shows that anxiety level that existed prior to procedure was lowered in majority of patients when the caries excavation was carried out with Papacarie® method but it continued during and after the conventional method. This reduced anxiety may

have led to a positive behavior by the patients, leading to less time to complete the procedure in group B patients. Patients may also be content by the absence of anesthesia and need for drill. Chourio *et al*²⁰ also noted the positive behavior while using CMCR method. Ansari¹⁸ while reporting similar results had concluded that CMCR is well suited for dental treatment of anxious patients. Contrary to the above studies, Inglehart *et al*²¹ found that the subject's fear of the dentists increased in the CMCR group.

There was a significant decline in the mean WSF scores both during and after caries removal with Papacarie® method (from 5.28 to 3.44 and from 3.44 to 2.24 respectively, $p < 0.05$). By contrast, there was a rise in the scores during caries removal in the conventional method (from 5.12 to 6.16, $p > 0.05$). These findings are in accordance with those of Silva *et al*²² and Kotb¹² who demonstrated that caries removal using Papacarie® was significantly less painful as compared to the conventional method. This proves that Papacarie® acts only on the dead infected tissue, reduces the risk of pulp exposure, and does not cause damage to healthy tissues. Way back in 1987, Anusavice and Kindhloe had shown that removing carious dentin generally elicits little or no painful sensation, while removing sound dentin often results in some level of pain.²³ Contrary to the above studies, Inglehar²¹ found that a substantial percentage of the subjects in their study had reported pain in the CMCR method. Longer treatment time could account for negative behavior in their patients.

In the present study, the mean total viable count, lactobacilli count and streptococci count declined significantly in samples taken after caries removal by both the methods. Singh¹⁵ found similar results when Papacarie® was used to compare with the conventional method.

Majority (80%) of the children in the present study preferred Papacarie® method. Less pain and anxiety could account for positive behavior in our patients. Further, none of our patients reported distaste as a problem. Ansari *et al*¹⁸ have reported similarly.

CONCLUSION

From the results of this study, it can be concluded that Papacarie® is safe and efficient method of caries removal from open and accessible occlusal lesions and can be recommended for caries removal in patients seeking an alternative to conventional treatment. However these results need to be confirmed with more longitudinal studies on a larger number of patients.

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