DOI: https://doi.org/10.53350/pjmhs2023173558

ORIGINAL ARTICLE

Comparison of Postoperative Sensitivity in Class I Amalgam Restorations using Copal Varnish Versus Dentin Bonding Agent: A Randomized Control Trial

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ABSTRACT

Objective: To compare the efficacy of Copal varnish versus dentin bonding agent for the prevention of postoperative sensitivity in amalgam restorations with the help of Visual auditory score (VAS).

Study Design: Comparative clinical study.

Place and Duration: A randomized control trial was conducted in the Department of Operative Dentistry after approval from the Institutional Review Board (IRB) of Fatima Memorial Hospital (FMH-03-2020-IRB-752-M).

Methodology: A randomized control trial was conducted in which sample size of 60 was calculated, 30 in group. A (copal varnish) and 30 in group B (dentin bonding agent) with 95% confidence level and 80% power of test, 5 % level of significance. Non-probability consecutive sampling was used using lottery method. Inclusion criteria included both male and female patients with age range 18-40 years and no significant signs and symptoms of pain prior to treatment. Teeth which were previously restored and deep cavities with less than 2mm of remaining dentin thickness on periapical radiograph, with reference to GV Black's class I were excluded from the study.

Results: The study subjects were 60 patients requiring restorations for class I cavities. Each treatment group had 30 patients. A single operator evaluated all the patients at baseline and performed the procedure. The patients were recalled at 24 hours and 7th day, for postoperative evaluation. No significant difference was found in the mean sensitivity score of both the classes. Chi-square test was analyzed to find out the frequency of postoperative sensitivity and efficacy among males and females. No significant difference was found among both males and females.

Practical implication: Current study can help dentists choose the right materials for restorative procedures, reducing postoperative discomfort. It also highlights the importance of regular dental check-ups and early intervention to prevent invasive procedures and promote oral health for the community.

Conclusion: Copal varnish and dentin bonding agents are equally good in terms of their efficacy and reduction of postoperative sensitivity, in class I amalgam restorations. The effect of cavity depth and amount of tooth reduction greatly affect the result of postoperative sensitivity in class I lesions confined to outer 1/3rd of dentin.

Keywords: Copal varnish, dentin bonding agents, Amalgam, dentinal tubules

INTRODUCTION

Pain, sensitivity, food impaction and discoloration are the most common reasons to seek dental treatment. Sometimes the diagnosis of caries is accidental finding specially where lesions are not very deep and reaching the dentin and they hardly cause any symptom. Such teeth after restorations, usually remain symptom free, where as those teeth having preoperative signs and symptoms are in greater chance of postoperative symptoms.

Amalgam is one of the most popular restorative materials used in posterior teeth for over 150 years.[1-3] It has remained a very popular restorative material due to its superior qualities, such as easy manipulation, good wear resistance, low technique sensitivity, acceptable life expectancy and low cost. However, there are some disadvantages including inferior aesthetic appearance, local degradation, occasional allergic responses to some of its components, toxicity of mercury and most importantly, postoperative sensitivity, which greatly affect the patient's satisfaction.[4]

Dental amalgam can withstand high masticatory forces that is why it is preferred mostly in posterior teeth.[5,6]. One of the biggest drawbacks of amalgam restoration is it needs mandatory cutting of the tooth substance for its retention. Conventional amalgam derives its retention from mechanical preparations such as undercuts, grooves, locks, slots and coves.[7] Due to such aggressive mechanical cutting of tooth the issues of postoperative sensitivity are greatly seen among the patients. Some other causes of postoperative sensitivity are microleakage at tooth-restorative interface, cusp deflection, abrasion and tooth wear etc. Studies have shown that the primary cause of the post operative sensitivity is microleakage at the interface of tooth structure and restoration.[8]

Micro leakage is considered to be one of the main causes of the postoperative sensitivity in amalgam restorations.[9] Dentin sensitivity is seen as a result of dentinal tubules exposed to external stimuli. It is characterized by pain of short duration but sharp in nature when a stimulus is applied.[10] The mechanism was explained with the help of hydrodynamic theory of pulpal sensitivity by Brannstrom.[11] According to this theory, fluid movements with in the dentinal tubules stimulate pulpal mechanoreceptors resulting in pain. He made the conclusion that sealing of the dentinal tubules in the cavity walls, should prevent microleakage, thereby reducing or eliminating postoperative sensitivity.

When amalgam is initially applied, there is a micro space between the restoration and the cavity walls. The size of this space and the permeability of dentin are the main factors that allow free movement of fluid within the dentinal tubules, which is interpreted as pain by the pulpal mechanoreceptors. However, there is reduction in sensitivity following amalgam placement due to the possible sealing of the margins of the restoration by corrosion products.[12] According to Ben-Amer et al, there is significant reduction in postoperative sensitivity after the application of Copal Varnish on freshly prepared dentinal walls.[13] Copal vanish is routinely used under non-insulating amalgam as barrier against bacteria, toxins and temperature. Varnishes are considered to be unstable in oral environment and demonstrate some breakdown in oral fluids. But they still worked well with the traditionally used low copper amalgam alloys which have inherited tendency for increase corrosion.

The corrosion products fill the gap which is created by the evaporation of varnish and thus prolongs the seal of the restorations. In the present-day dentistry, high copper amalgam alloys are used due to superior properties and low corrosion

tendency, that would eventually produce a partial seal at the tooth restoration interface.[14] A vast variety of materials are available, other than Copal Varnish, which include calcium hydroxide cements, zinc oxide eugenol bases, zinc phosphate bases.[15-17]More recently, dentine bonding agents (DBA) have increasingly gained popularity and are introduced as a new way of sealing dentinal tubules.[18] Dentine bonding agent has the benefits of bonding to enamel and dentin as well as amalgam, and is considered to be more effective in the treatment of postoperative sensitivity, sealing the tubules under amalgam restorations than copal varnish.[19]

Rationale of Study: To compare the efficacy of Copal varnish versus dentin bonding agent for the prevention of postoperative sensitivity in amalgam restorations with the help of Visual auditory score (VAS).

METHODOLOGY

A randomized control trial was conducted in the Department of Operative Dentistry after approval from the Institutional Review Board (IRB) of Fatima Memorial Hospital (FMH-03-2020-IRB-752-M). Sample size of 60 was calculated, 30 in group A (copal varnish) and 30 in group B (dentin bonding agent) with 95% confidence level and 80% power of test, 5 % level of significance. The study was initiated and data collection was completed in 6 months.

Non-probability consecutive sampling was used using lottery method. The selected patients had no other sensitivity problem and were having good oral hygiene and periodontal health

Inclusion Criteria: It included both male and female patients with age range 18-40 years and no significant signs and symptoms of pain prior to treatment. The proposed thickness of remaining dentin was taken as 2.5mm, which was evaluated on periapical radiograph. Only molars with GV Black's class I cavity design were included in the study.[32,33]

Exclusion Criteria: All the operative procedure was done under rubber-dam isolation. Patients were educated and advised to mark on a visual analogue scale according to their sensitivity in test tooth upon the application of cold stimulus (ethyl chloride spray on cotton pellet)

Analysis: Teeth which were previously restored and deep cavities with less than 2mm of remaining dentin thickness on periapical radiograph, with reference to GV Black's class I were excluded from the study. Subjects were randomly divided into two equal groups with the help of computer-generated table of random numbers. Odd numbers were given to group A and even numbers to group B. Group A signifying copal varnish & group B signifying dentin bonding agent. Effect modifiers like age, gender and base line pain were controlled by stratification. All the operative procedure was done under rubber-dam isolation. Patients were educated and advised to mark on a visual analogue scale according to their sensitivity in test tooth upon the application of cold stimulus (ethyl chloride spray on cotton pellet). The stimulus was applied for about 5 seconds using digital stop watch. Patients were said to have postoperative sensitivity if he presents with moderate or severe (A value of more than 4 on VAS) assessed after 24 hours and 7 days. Class 1 cavities according to the inclusion criteria radiograph showing remaining dentin thickness of 2.5mm was prepared by the same operator with 245 carbide bur in high-speed handpiece with copious irrigation. Cavity depth of 1.5mm +/- 0.3mm was preferred.

Enamel and dentine surfaces of Group A preparation were lined with copal varnish (Copalite, Cooley & Cooley Ltd. USA.) Two coats were applied with the help of applicator brush. After each coat, the cavity was gently air dried and restored with amalgam (high copper alloy). In group B preparation enamel and dentin surfaces were acid etched for 15 seconds, followed by rinsing with water for 10 seconds. Fifth generation dentin bonding agent (Adper TM Single Bond Plus Adhesive 3M ESPE) was then applied, followed by gentle drying with air using triple syringe. It was then exposed to light for curing for 10 seconds. Amalgam (high copper alloy) was placed. All the standards of carving, burnishing and occlusion were taken in to consideration.

Statystical Analysis: The data was analyzed by SPSS-25. Categorical variables like gender and groups were presented in form of frequency and percentages. Mean and standard deviation were calculated for quantitative variables like age and VAS score. Independent sample t test was used to compare mean pain score of both groups at baseline, 24 hours and 7 days' time period. Chi-square test was used to compare the postoperative sensitivity and efficacy of both groups. Data was stratified for age and gender. To compare gender-based pain score difference within a group, independent sample t test was used. P-value less than 0.05 was considered to be significant.

RESULTS

The study subjects were 60 patients requiring restorations for class I cavities. Each treatment group had 30 patients. According to the laid-out protocol, a single operator (principal investigator; An operative dentist) evaluated all the patients at baseline and performed the procedure. The patients were recalled at 24 hours and 7th day, for postoperative evaluation by the same operator. Data was stratified in terms of age and gender. In this study age range was from 18 to 42 years with mean age 30.73±6.05 years. Out of 60 patients, 30 (50.0%) were females and 30 (50.0%) were males a female to male ratio of 1:1 (Table 1).

Table 1: Demographics

Demographics		Descriptive Statistics
Age (Mean ± SD)		30.73 ± 6.05
Gender N (%)	Male	30(50%)
	Female	30(50%)

Class I amalgam restorations done with copal varnish had mean score of 1.10 ± 1.09 whereas class I amalgam restorations done with dentin bonding agent had mean score of 1.30 ± 0.91. No significant difference was found in the mean sensitivity score of both the classes (p=0.446). Independent sample t test was used for evaluating postoperative sensitivity scores at 24 hours and at 7 days. No significant results were found among both groups as shown in table (Table 2)

Table 2: Sensitivity score with Copal varnish Versus Dentin bonding agent at baseline, 24 hours and 7 days

Technique	Baseline	24 hours	7 days
Class I amalgam restoration done with copal varnish	1.10 ± 1.09	1.70 ± 1.57	1.26 ± 1.81
Class I amalgam restoration done with dentin bonding agent	1.30 ± 0.91	1.50 ± 1.45	1.00 ± 1.59
P-value	0.44	0.612	0.54

Chi Square test was run in order to assess the comparison of postoperative sensitivity and efficacy among the two groups. In class I amalgam restorations done with copal varnish; 5 patients (8.3%) showed post-operative sensitivity while 25 patients (41.7 %) showed efficacy. In class I amalgam restorations done with dentin adhesive liner; 3 patients (5.0%) experienced postoperative sensitivity whereas 27 patients (45.0%) summed up with positive efficacy. The overall comparative results were insignificant (p=0.706). (Table 3)

Chi-square test was analyzed to find out the frequency of postoperative sensitivity and efficacy among males and females. In comparison of postoperative sensitivity among males and females, 4 male patients (13.3%) had sensitivity in group A and 3 male patients (10.0) had sensitivity in group B with no significant difference (p=1.000). Whereas in females only 1 patient (3.3%) had sensitivity in group A and none of the patient, felt sensitivity in group B respectively, with no significant result (p=0.433). (Table 4)

In comparison of efficacy among males and females, 13 male patients (43.3%) had shown efficacy in group A and 10 male

patients (33.3%) reported positive efficacy results in group B with no significant difference (p=1.000). Whereas in females 12 patients (40%) had shown efficacy in group A and 17 patients (56.7%), gave positive efficacy results in group B respectively with no significant result (p=0.433). (Table 4)

Table 3: Comparison of postoperative sensitivity and Efficacy of Copal varnish Versus Dentin bonding agent

		Class I amalgam restoration done with copal varnish	Class I amalgam restoration done with dentin bonding agent	Total	P-value
Postoperative sensitivity	Yes	5(8.3%)	3(5)	8(13.3)	0.70
	No	25(41.7)	27(45)	52(86.7)	
Efficacy	Yes	25(41.7)	27(45)	52(86.7)	0.70
	No	30(50)	30(50)	60(100)	

Table 4: Comparison of postoperative sensitivity and Efficacy of Copal varnish Versus Dentin bonding agent among males and females

			Technique			P-value
Gender			Class I amalgam restoration done with copal varnish	Class I amalgam restoration done with dentin bonding agent	Total	
Males	Postoperative sensitivity	Yes	4 (13.3)	3(10)	7(23.3)	1.0
		No	13(43.3)	10(33.3)	23(76.7)	
Females	Postoperative sensitivity	Yes	1(3.3)	0(0)	1(3.3)	0.43
		No	12(40)	17(56.7)	29(96.7)	
Males	Efficacy	Yes	13(43.3)	10(33.3)	23(76.7)	1.0
		No	4 (13.3)	3(10)	7(23.3)	
Females	Efficacy	Yes	12(40)	17(56.7)	29(96.7)	0.43
		No	1(3.3)	0(0)	1(3.3)	

DISCUSSION

Effect of microleakage on pulp was first investigated by Brannstrom and Nordenvall. They made a conclusion that pulp could get damaged by infection which may occur from two sources: Bacteria in the smear layer and the ingress of bacteria via microleakage. Thus, an emphasis was made on the removal of smear layer which would eliminate the bacteria present at tissue restoration interface.[20]

Proper seal of the cavities after restorations is very important in terms of longevity and prognosis of the restoration and tooth. According to some scholar's proper adaptation of the restorative material to the cavity walls and intact marginal seal are the important factors for the long-term performance of the restoration.[21] Failure to achieve this seal can result is gap formation and microleakage which can lead to postoperative pain, recurrent caries, marginal staining and in advanced cases, possible pulpal pathology.[14]

"Liners and bases are commonly used under different restorations for sealing the dentinal tubules and protection of pulp.[22] Cavity liners are placed with minimal thickness, usually less than 0.5 mm, and provide some type of therapeutic benefit, such as fluoride release, dentinal seal through adhesion to tooth structure, and/or antibacterial action that promotes pulpal health.[22] The most commonly used lining material under amalgam restoration is Zinc phosphate, which is usually preferred when the cavity depth is more than or equal to 2mm.

Our results are in agreement with Mahler where use of bonding agent failed to demonstrate any advantage in reducing postoperative sensitivity.[23] We infer that amalgam bonding agents are not protective against postoperative sensitivity. Lack of sensitivity in Class I cavities in both groups can simply be explained by less amount of tooth reduction and hence less microleakage around restorations.

However, there is convincing evidence that have shown that there is no difference in postoperative sensitivity in cases with and without bonding agents thus have seriously questioned the benefits of using bonding agents for sensitivity management.[24] Previously one study has shown an adhesive to be inferior to varnish in the seal it provides,[25] others have shown adhesives and varnishes to exhibit similar degrees of microleakage. [26,27]

Our Study also is in line with one of the studies carried out in Agha Khan University, Karachi, showing that there was no difference in the postoperative sensitivity in the conventional and the bonded amalgam restorations in the Class I preparations.[28] According to a study conducted by Sepetcioglu F and Ataman BA tested and compared the sealing ability of a cavity varnish and dental bonding agents for reducing the microleakage when used with high copper amalgam restorations. They concluded that employing dentin bonding agent as an inter-facial sealer had significant advantages to decrease microleakage when compared with conventional Copal varnish which ultimately helped in reducing postoperative sensitivity.[29]

According to research conducted by Hajizadeh H, et al, in 2008 both copal varnish and dentin bonding agent reduced postoperative sensitivity to cold in amalgam restorations as compared to the control group where no sealer was applied (p0.05). The most probable reason could be the fact that Hajizadeh H et al included teeth with a cavity no deeper than 2mm, which is comparable to our study in which the depth of cavity was no more than 2mm. In such superficial cavities, the huge amount of remaining dentin acts as a confounding factor in reducing postoperative sensitivity.[30]A study conducted by Schwartz compared dentin bonding agent and cavity varnish under amalgam restorations in class V carious lesions in 16 patients. The study concluded that there was less sensitivity in the dentin bonding agent group as compared to the copal varnish group at 24 hours, 2 weeks and 4 weeks.[31] With respect to our study there was follow up testing 24 hours and 7 days only which showed insignificant results.[29,30]

The aim of this study was to assess the comparison of efficacy of Copal varnish and dentin bonding agent in class I amalgam restorations since the cavity depth prepared were not more than 1.75mm. Our initial hypothesis is disapproved since the overall results showed insignificant values[28]. According to observational analysis in this study the overall comparative results were insignificant because all of the cases selected in this study had class I cavity with the depth of no more than 1.75 mm. Radiographically this indicates the carious lesions were confined to outer 1/3rd of dentin, due to which the patients had not significant sensitivity complain at baseline. However, there were some patients who had more sensitivity at baseline due to which there was less reduction in post op sensitivity comparatively. From which we can incur there is role of pain threshold as well despite the depth of cavity.[30,31]

CONCLUSION

According to the results of our study Copal varnish and dentin bonding agents are equally good in terms of their efficacy and reduction of postoperative sensitivity, in class I amalgam restorations. The effect of cavity depth and amount of tooth reduction greatly affect the result of postoperative sensitivity in class I lesions confined to outer 1/3rd of dentin.

Acknowledgements: I as corresponding author acknowledged the contribution of all co-authors and those who participate in this study directly or indirectly

Conflict of Interest: The authors say they have no competing interests. The study's design, data collection, analysis, or interpretation; the preparation of the paper; or the choice to publish the findings were all made independently.

Funding: No external funding was received.

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