Comparative Evaluation of 30% Ethanolic Extract of Propolis, VivaSens Desensitizer, and Distilled Water for Treating Dentinal Hypersensitivity - A Randomized Controlled Trial

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Abstract

Objective: The aim of the present study was to evaluate and compare the efficacy of 30% ethanolic extract of propolis, VivaSens, and distilled water as placebo in treating dentinal hypersensitivity.

Materials and Methods: A total of 75 teeth with dentinal hypersensitivity were randomly allotted into three groups with 25 teeth in each group. Response to tactile and air stimuli was measured using verbal rating scale initially on the 1st, 14th, 28th, and 60th day, and final assessment was done on the 90th day. A statistical analysis was done using Kruskal–Wallis test and Mann–Whitney U-test for intergroup comparison and for intragroup comparison Friedman test and Wilcoxon signed-ranks test.

Results: The teeth treated with the test groups showed decrease in the mean hypersensitivity values compared to control group, over a period of three months.

Conclusion: It was concluded that propolis and VivaSens were effective in relieving dentinal hypersensitivity and had immediate and sustained effect.

Key words: Dentinal hypersensitivity, Distilled water, Propolis, Verbal rating scale

INTRODUCTION

Dentinal hypersensitivity may be defined as exaggerated response of vital dentin on exposure to chemical, tactile, osmotic, or thermal stimuli, and which cannot be explained by any other form of dental disease. It generally involves the cervical third of facial surface of canines, premolars, and molars as these areas are more prone for exposure due to enamel loss by abrasion, erosion, abfraction, gingival recession, or combination of above-mentioned factors.[1]

While various theories have been proposed to explain the physiology of dentinal hypersensitivity, the most accepted theory is hydrodynamic theory given by Brannstrom. According to this theory, rapid shift in fluid flow in dentinal tubules in response to external stimuli appears to be responsible for causing odontoblastic pain.[2]

In general, 10–30% of the individuals in a given population are afflicted by dentinal hypersensitivity. Greatest incidence of dentinal hypersensitivity is seen in the age group of 20–40 years with females showing greater predilection as compared to males, although this difference is not clinically significant.[3] In spite of being so widespread, it is one of the least successfully treated diseases of the teeth. A plethora of treatment options are currently available in the market for reducing dentinal hypersensitivity. Most of them bring about their therapeutic effect by either partial or complete
obliteration of dentin tubules, anti-inflammatory activity, protein precipitation, or sealing the tubules. Although most of the approaches are quite successful in reducing sensitivity, there is still no consensus as to which product constitutes as the gold standard for the treatment of dentinal hypersensitivity as the duration of relief provided by them varies greatly.⁴

Propolis is a sticky, non-toxic, brown, and resinous substance collected by honey bees from the exudates of trees and plants. It is then modified by the bees by mixing them with their salivary secretions and wax. Several studies have reported it to have antimicrobial, antiviral, anti-inflammatory, and antioxidant properties. Due to these beneficial biological properties, it has found a wide array of uses in dentistry which includes the prevention of dental caries, as direct pulp capping agent, intracanal medicament, and analgesic.⁵,⁶ Recent in vitro studies have shown that propolis had significant effect in reducing dentinal permeability, but to date, only few in vivo studies have been done to test its efficacy as desensitizing agent.⁷,⁸ VivaSens is another resin-based desensitizing varnish that causes the precipitation of calcium ions and proteins in the dentinal fluid, which leads to mechanical obliteration of the tubules. It is mainly indicated for teeth that have hypersensitivity due to exposed dentin in the cervical third.⁹

Therefore, the aim of the present in vivo study is to evaluate the clinical effect of 30% ethanolic extract of propolis, VivaSens topical desensitizer, and distilled water (as placebo) on the reduction of cervical dentin hypersensitivity.

Null hypothesis was proposed that there will be no difference in the change in the level of dentinal hypersensitivity between 30% ethanolic extract of propolis, VivaSens topical desensitizer, and distilled water.

**MATERIALS AND METHODS**

The clinical protocol and written informed consent were reviewed and approved by an Ethical Committee before the start of the study.

**Inclusion Criteria**

1. Patients having a minimum of 24 natural permanent teeth that are free of large restorations or dental prosthetic crowns.
2. Patients having a minimum of three premolars with a pre-operative verbal rating scale (VRS) score of ≥1.
3. Patients with adequate oral hygiene and willing to participate in the study.

**Exclusion Criteria**

1. Patients with a history of any systemic illness and/or psychological disorder.
2. Teeth having dental caries/fractures in the cervical areas of teeth.
3. Patients on analgesics and/or anti-inflammatory drugs.
4. Teeth with extensive unsatisfactory restorations, prosthesis, or orthodontic appliances involving cervical areas.
5. Patients who had taken any treatment for hypersensitivity within the last 6 months.
6. Patients with clinical or radiographic evidence of pulp pathology.
7. Patients allergic to ingredients used in the study.

**Study Procedure**

A total of 75 teeth were randomly allotted into three groups with 25 teeth in each group:

- Group 1 - 30% ethanolic extract of Indian propolis.
- Group 2 - VivaSens desensitizer.
- Group 3 - Sterile distilled water as a negative control.

The tooth was assigned randomly into any one of the groups. The randomization procedure was carried out using sequentially numbered opaque-sealed envelopes prepared with simple randomization.

Each tooth receives two stimuli for measuring dentin hypersensitivity:
- Tactile stimuli (clinical probing).
- Air stimuli (blast from dental unit air syringe).

The probe stimulus was applied under slight manual pressure in the mesiodistal direction on the cervical area of the tooth. The air blast was applied with an air syringe for 1–2 s at a distance of 1 cm from the tooth surface to avoid desiccation after isolating the tooth with cotton rolls and examiner’s finger.

**Criteria for Hypersensitivity Assessment**

The degree of hypersensitivity reported by the participant with each stimulus was determined according to the VRS from 0 to 3, in which:
- 0 = No discomfort
- 1 = Minimum discomfort
- 2 = Mild discomfort
- 3 = Intense discomfort.

**Application Procedure**

- Removal of debris and calculus, if any, around the affected teeth using hand scalers.
- Isolation of the teeth with cotton rolls.
- Drying of tooth surfaces with a cotton pellet.
For Group 1, propolis extract was directly applied onto the site using truncated needle and left to dry for 60 s.

For Group 2, VivaSens desensitizer was manipulated according to manufacturer's instructions and applied with a disposable brush at the cervical region.

For Group 3, sterile water was directly applied on to the site using truncated needle and left to dry for 60 s.

- Care was taken to ensure that none of the products touch other zones of the oral mucosa or adjacent teeth.

The values were collected before the intervention (baseline values) and after each application, on days 1st, 14th, 28th, 60th, and final assessment was done on the 90th day. The patients were instructed not to rinse, eat or drink for 1 h after the treatment and avoid using any other professionally or self-applied desensitizing agent in the course of the investigation.

**RESULTS**

At baseline: There was no significant difference between Group 1 and Group 2 and Group 1 and Group 3. VRS score in Group 2 was significantly higher than Group 3.

At day 1: There was no significant difference between Group 1 and Group 2. VRS score in Group 1 and Group 2 was significantly higher than Group 3.

At day 14 (before): There was no significant difference between Group 1 and Group 2. VRS score in Group 1 and Group 2 was significantly higher than Group 3.

At day 14 (after): There was no significant difference between Group 1, Group 2, and Group 3.

At day 28 (before): There was no significant difference between Group 1, Group 2, and Group 3.

At day 28 (after): There was no significant difference between Group 1 and Group 3. VRS score in Group 3 was significantly higher than Group 1 and Group 2.

At day 60 (before): There was no significant difference between Group 2 and Group 3. VRS score in Group 2 and Group 3 was significantly higher than Group 1.

At day 60 (after): There was no significant difference between Group 1 and Group 2. VRS score in Group 3 was significantly higher than Group 1 and Group 2.

At day 90: There was no significant difference between Group 1 and Group 2. VRS score in Group 3 was significantly higher than Group 1 and Group 2 [Table 1].

At baseline: There was no significant difference between Group 1 and Group 2. VRS score in Group 1 and Group 2 was significantly higher than Group 3.

At day 1: There was no significant difference between Group 1 and Group 2. VRS score in Group 1 and Group 2 was significantly higher than Group 3.

At day 14 (before): There was no significant difference between Group 1 and Group 2. VRS score in Group 1 and Group 2 was significantly higher than Group 3.

At day 14 (after): There was no significant difference between Group 1, Group 2, and Group 3.

At day 28 (before): There was no significant difference between Group 1, Group 2, and Group 3.

At day 28 (after): There was no significant difference between Group 1 and Group 3. VRS score in Group 1 and Group 3 was significantly higher than Group 2.

At day 60 (before): There was no significant difference between Group 1 and Group 2. VRS score in Group 3 was significantly higher than Group 1 and Group 2.

At day 60 (after): There was no significant difference between Group 1 and Group 2. VRS score in Group 3 was significantly higher than Group 1 and Group 2.

Friedman test showed significant difference for tactile sensation between different time intervals in VivaSens group. After this, Wilcoxon signed-ranks test was applied for pairwise comparison which showed following observations:

1. At baseline, VRS for tactile sensation was significantly higher than VRS at day 1, day 14 (before), day 14 (after), day 28 (before), day 28 (after), day 60 (before), day 60 (after), and day 90.
2. There was no significant difference between day 1 and day 14 (before).
3. At day 1 and day 14 (before), VRS for tactile sensation was significantly higher than day 14 (after), day 28 (before), day 28 (after), day 60 (before), day 60 (after), and day 90.
4. There was no significant difference between day 14 (after) and day 28 (before).
5. At day 14 (after) and day 28 (before), VRS for tactile sensation was significantly higher than day 28 (after), day 60 (before), day 60 (after), and day 90.

6. There was no significant difference between day 28 (after), day 60 (before), day 60 (after), and day 90.

Friedman test showed significant difference for tactile sensation between different time intervals in propolis group. After this, Wilcoxon signed-ranks test was applied for pairwise comparison which showed following observations:

1. At baseline, VRS for tactile sensation was significantly higher than VRS at day 1, day 14 (before), day 14 (after), day 28 (before), day 28 (after), day 60 (before), day 60 (after), and day 90.

2. There was no significant difference between day 1 and day 14 (before).

3. At day 1 and day 14 (before), VRS for tactile sensation was significantly higher than day 28 (after), day 60 (before), day 60 (after), and day 90.

4. There was no significant difference between day 14 (after) and D28 (bef.), D28 (aft.), day 60 (bef.), and day 60 (aft.).

5. VRS at D14 (after) was significantly higher than D90.

6. There was no significant difference between D28 (bef.) and D60 (before).

7. VRS at D28 (bef.) and D60 (before) was significantly higher than VRS at D28 (aft.), D60 (aft.), and D90.

8. VRS at D28 was significantly higher than D90.

9. There was no significant difference between D60 (aft.) and D90.

Friedman test showed significant difference for tactile sensation between different time intervals in water group. After this, Wilcoxon signed-ranks test was applied for pairwise comparison which showed following observations:

1. At baseline, VRS for tactile sensation was significantly higher than VRS at day 1, day 14 (before), day 14 (after), day 28 (before), day 28 (after), day 60 (before), day 60 (after), and day 90.

2. There was no significant difference between day 1 and day 14 (before).

3. There was no significant difference between day 1 and day 14 (before).

4. At day 14 (after) and day 28 (before), VRS for air stimuli sensation was significantly higher than VRS at day 14 (after), day 28 (before), day 28 (after), day 60 (before), day 60 (after), and day 90.

5. There was no significant difference between day 14 (after) and day 28 (before).

6. At day 14 (after) and day 28 (before), VRS for air stimuli sensation was significantly higher than VRS at day 28 (after), day 60 (before), day 60 (after), and day 90.

7. At day 28 (after) and day 60 (before), VRS for air stimuli sensation was significantly higher than VRS at day 60 (after) and day 90.

8. There was no significant difference between day 60 (after) and day 90.

Friedman test showed significant difference for air stimuli between different time intervals in propolis group. After this, Wilcoxon signed-ranks test was applied for pairwise comparison which showed following observations:

1. At baseline, VRS for air stimuli sensation was significantly higher than VRS at day 1, day 14 (before), day 14 (after), day 28 (before), day 28 (after), day 60 (before), day 60 (after), and day 90.
2. There was no significant difference between day 1, day 14 (before), day 14 (after), day 28 (before), day 28 (after), day 60 (before), day 60 (after), and day 90 [Table 4].

**DISCUSSION**

Perception of pain is a subjective phenomenon and depending on the factors involved, psychological makeup, level of anxiety, threshold for pain, and past experience with pain; it varies from one individual to another. Due to these individual variations, dentinal hypersensitivity studies are one of the most difficult studies to be conducted in clinical scenario.[4]

Dentinal hypersensitivity is a sharp, acute pain of short duration of exposed dentin in response to external stimuli such as thermal, evaporative, tactile, and osmotic/chemical which cannot be attributed to any other form of dental defect or pathology.[5] There is a high degree of heterogeneity in terms of methods employed to collect data together with high diversity in studied agents making the interpretation of data a cumbersome process.[6]

A simple clinical method of diagnosing dentine hypersensitivity (DH) includes a jet of air or using an exploratory probe on the exposed dentin, in a mesiodistal direction, examining all the teeth in the area in which the patient complains of pain. The severity or degree of pain can be quantified either according to categorical scale (i.e., slight, moderate, or severe pain) or using a visual analog scale. In the present study, VRS was used for the quantification of pain with 4° of intensity. It is widely used in clinical research to assess intensity of acute pain.[7]

Various in-offices, at home products, are currently available in market. In office, approach is generally adopted for localized form, whereas the use of home care products by patients is more for generalized involvement. Effective dentin occlusion offers the greatest prospect for instant and lasting relief of dentin hypersensitivity. Therefore,
there is a need to develop new product which relieves the symptoms in long run.

This study aimed to evaluate and compare the clinical efficiency of 30% ethanolic extract of propolis, VivaSens desensitizer, and distilled water as placebo in treating dentinal hypersensitivity. Propolis is a natural resinous substance collected from sprouts, exudates of tree, and other parts of plant and modified in beehive by addition of salivated secretions and wax. Its composition varies according to its origin. Several biological properties have been reported in the literature for propolis such as antimicrobial, anti-inflammatory, antioxidant, and free radical scavenging action. In 1999, Mahmoud et al. conducted a pioneer study on the effect of propolis on dentinal hypersensitivity in vivo. In this study, propolis was applied twice daily on teeth with hypersensitivity.

**Table 3: Comparison of VRS for tactile sensation between different time intervals in different groups**

<table>
<thead>
<tr>
<th>Time intervals</th>
<th>VivaSens (Group 1)</th>
<th>Propolis (Group 2)</th>
<th>Water (Group 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>1.80±0.65</td>
<td>2.04±0.61</td>
<td>1.48±0.65</td>
</tr>
<tr>
<td>Day 1</td>
<td>1.52±0.51</td>
<td>1.64±0.57</td>
<td>1.16±0.62</td>
</tr>
<tr>
<td>Day 14 (before)</td>
<td>1.20±0.50</td>
<td>0.84±0.69</td>
<td>1.12±0.44</td>
</tr>
<tr>
<td>Day 28 (before)</td>
<td>1.12±0.53</td>
<td>0.92±0.64</td>
<td>1.04±0.61</td>
</tr>
<tr>
<td>Day 60 (before)</td>
<td>0.60±0.58</td>
<td>0.60±0.58</td>
<td>1.04±0.54</td>
</tr>
<tr>
<td>Day 60 (after)</td>
<td>0.48±0.51</td>
<td>1.00±0.41</td>
<td>0.92±0.40</td>
</tr>
<tr>
<td>Friedman test</td>
<td>$\chi^2=127.232$, df=8, $P&lt;0.001$, VHS</td>
<td>$\chi^2=122.882$, df=8, $P&lt;0.001$, VHS</td>
<td>$\chi^2=35.930$, df=8, $P&lt;0.001$, VHS</td>
</tr>
</tbody>
</table>

**Table 4: Comparison of VRS for air stimuli between different time intervals in different groups**

<table>
<thead>
<tr>
<th>Time intervals</th>
<th>VivaSens (Group 1)</th>
<th>Propolis (Group 2)</th>
<th>Water (Group 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>2.00±0.58</td>
<td>1.88±0.60</td>
<td>1.52±0.65</td>
</tr>
<tr>
<td>Day 1</td>
<td>1.60±0.65</td>
<td>1.56±0.58</td>
<td>1.12±0.60</td>
</tr>
<tr>
<td>Day 14 (before)</td>
<td>1.04±0.61</td>
<td>1.08±0.49</td>
<td>1.04±0.46</td>
</tr>
<tr>
<td>Day 28 (before)</td>
<td>0.80±0.50</td>
<td>0.48±0.51</td>
<td>0.96±0.35</td>
</tr>
<tr>
<td>Day 60 (before)</td>
<td>0.60±0.41</td>
<td>0.76±0.44</td>
<td>1.04±0.35</td>
</tr>
<tr>
<td>Friedman test</td>
<td>$\chi^2=120.818$, df=8, $P&lt;0.001$, VHS</td>
<td>$\chi^2=124.792$, df=8, $P&lt;0.001$, VHS</td>
<td>$\chi^2=34.546$, df=8, $P&lt;0.001$, VHS</td>
</tr>
</tbody>
</table>

VRS: Verbal rating scale, SD: Standard deviation, VHS: Very high significant.

Wilcoxon signed-ranks test

Baseline>D1=D14 (before)>D14 (after)>D28 (after)>D28 (before)>D60 (before)>D60 (after)>D90

Friedman test

$\chi^2=120.818$, df=8, $P=0.000$ (<0.001), VHS

$\chi^2=124.792$, df=8, $P=0.000$ (<0.001), VHS

$\chi^2=34.546$, df=8, $P=0.000$ (<0.001), VHS

Wilcoxon signed-ranks test

Baseline>D1=D14 (before)>D14 (after)>D28 (after)>D28 (before)>D60 (before)>D60 (after)>D90

Friedman test

$\chi^2=127.232$, df=8, $P<0.001$, VHS

$\chi^2=122.882$, df=8, $P<0.001$, VHS

$\chi^2=35.930$, df=8, $P<0.001$, VHS

VRS: Verbal rating scale, SD: Standard deviation, VHS: Very high significant
the control of hypersensitivity. The bioflavonoids in propolis may interact with the dentine, thus forming crystals that reduce fluid movement within dentinal tubules and, consequently, reduce dentine sensitivity. This theory was based on the study by Sabir et al., in which direct pulp capping was performed with propolis-derived flavonoids and mild and moderate inflammation was seen in the pulp chamber at weeks 2 and 4, partial dentin bridge formation was detected beneath the pulp capping material at 4th week.\textsuperscript{[8,11]}

The result of the present study demonstrated a significant decrease in mean hypersensitivity in both the test group as compared to control group after 90-day period. Intergroup comparison revealed reduction in mean dentinal hypersensitivity in propolis group which was comparable to VivaSens group. This is in agreement with the study of Madhavan et al. who found a significant reduction in dentinal hypersensitivity after 3 months application of propolis extract casein phosphopeptide-amorphous calcium phosphate F and sodium fluoride.\textsuperscript{[6]} Application of propolis resulted in significant reduction in intensity of pain followed by increase in the efficacy of agent over a period of time with maximum relief from the pain by the end of study period, i.e., 3 months.

Another study by Purra et al. evaluated the efficacy of saturated solution of propolis for the treatment of dentinal hypersensitivity as compared to distilled water and 5% potassium fluoride. There was no significant difference in the immediate host treatment period but showed a significant decrease at the end of 1st and 2nd week. At 4 weeks and 3 months period, a comparison was made and no significant difference was seen. The immediate effect was attributed to tubular sealing which prevented the flow of dentinal fluid in the tubules and sustained effect was attributed to the stable nature of deposit so formed.\textsuperscript{[12]}

VivaSens is a protein precipitate type desensitizer that seals exposed dentin by the precipitation of calcium ions and proteins. It contains polyethylene glycol dimethacrylate which triggers the precipitation of plasma proteins in the dentinal tubules. It also contains glutaraldehyde, which is a cross-linking reagent capable of bonding to amine groups of proteins. Potassium fluoride provides additional protection. In the present study, VivaSens desensitizer was effective in reducing dentinal hypersensitivity when compared to propolis at the end of 3 months. This was in accordance with a study done by Asrani et al. who evaluated the ability of desensitizing agents VivaSens and laser (diode) on dentinal tubule occlusion and its effectiveness over time using scanning electron microscopy. Both VivaSens and diode laser were equally effective in the obliteration of dentinal tubules just after application as well as after 15 days of treatment.\textsuperscript{[13]}

Although when intragroup comparison was made placebo group did not show significant decrease in hypersensitivity when compared to tested group, a strong placebo effect has been reported in the literature concerning dentinal hypersensitivity management which could be attributed to spontaneous healing due to deposition of reparative dentine formation and also other treatment approaches could be present which confound the result.\textsuperscript{[4]}

The main aim in the treatment of dentinal hypersensitivity is to provide a long-lasting relief, but none of currently available treatment modalities fulfill these criteria. In addition to this, there are no standard clinical procedures in the reported literature to test the given study materials making the comparison of data from these studies difficult. Further, research is needed to clarify the mechanism and etiology of this uncomfortable clinical situation.

**CONCLUSION**

Within the limitations of this study, it can be concluded that both desensitizing agent, i.e., propolis extract and VivaSens desensitizer were effective in relieving dentinal hypersensitivity. Their effectiveness was not different from each other but was different from the placebo. Furthermore, expanding the use of propolis for DH treatment in dental clinics will help corroborate its effectiveness and safety may result in this product becoming the treatment of choice for moderate and mild dentinal hypersensitivity.

**REFERENCES**


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