

Efficiency of new custom-made pulse oximeter sensor holder in assessment of actual pulp status

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ABSTRACT

Aim: This study aims to assess the diagnostic accuracy of new custom-made pulse oximeter sensor holder in assessment of actual pulp status with three pulp sensibility tests. **Materials and Methods:** Seventy-nine single canal teeth requiring endodontic therapy was included in the study. The tooth that was requiring root canal treatment was tested with heat test, cold test, electric pulp test, and pulse oximeter. Between each test, a time period of 2 min was allowed. The response from three pulp sensibility tests and the reading from pulse oximeter were recorded. Following which root canal treatment was performed. The result obtained from four pulp tests were correlated with the clinical finding after access cavity preparation. The data obtained was statistically assessed. Receiver operator characteristic (ROC) curve analysis was performed to assess the efficacy of the pulp tests. In the above statistical tools, the probability value .05 is considered as significant level. **Results:** The overall diagnostic accuracy was found to be significantly higher with pulse oximeter when compared with other three pulp sensibility tests. The ROC curve demonstrates the results obtained from pulse oximeter was found to be more reliable than other pulp tests. **Conclusion:** Within the limitation of the study, diagnostic accuracy of pulse oximeter with custom made sensor holder was reliable and accurate in assessment of actual pulp status.

Keywords: Cold test, electric pulp test, heat test, pulse oximeter

Introduction

Primary care is the essential need for a human population where they receive care for most of their everyday health needs. Accurate diagnosis of clinical condition, treatment of symptomatic illness, disease prevention, health maintenance, counselling, and patient education are the various bodies which the primary care includes.^[1] It is the foremost duty of a dental clinician to accurately diagnose the clinical condition in case

of symptomatic patients who report to dental clinic with pain. When we introspect the role of dentistry, it is a known fact that the practice of general dentistry is primary care.

Diagnosis of the clinical condition plays a decisive role in dental treatment plan. Accurate and reliable diagnosis of the actual condition of the tooth plays a significant role in the prognosis of the treatment. In order to achieve this there should be appropriate, accurate, reliable, and objective pulp test that can identify the actual status of pulp whether healthy (vital), symptomatic irreversible pulpitis, or pulp necrosis.^[2]

The pulp tests, which are traditionally used in endodontic practice, are the pulp sensibility tests. There are numerous studies in the literature, which had reported the diagnostic accuracy of heat test, cold test, and electric pulp test. At different clinical situations

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Received: 12-01-2020

Revised: 12-03-2020

Accepted: 26-03-2020

Published: 30-07-2020

Access this article online

Quick Response Code:



Website:
www.jfmpc.com

DOI:
10.4103/jfmpc.jfmpc_73_20

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How to cite this article: Janani K, Ajitha P, Sandhya R, Subbaiyan H, Jose J. Efficiency of new custom-made pulse oximeter sensor holder in assessment of actual pulp status. J Family Med Prim Care 2020;9:3333-7.

one cannot rely on these pulp tests to arrive at a diagnosis especially in traumatic injuries. These pulp sensibility test may not always translate the actual clinical condition of pulp.^[3] Also, we know that the diagnosis cannot be made only by performing the pulp test, it requires a combined assessment of clinical and radiographic examination. These pulp tests are based on patient's subjective response, so the reliability of these tests is questionable. Because there might be possibility for an apprehensive patient to misinterpret and provide an inappropriate result to the operator.

Pulse oximeter, a non-invasive device has been introduced into endodontics for assessing the vascular response in the pulp. This device has pulse oximeter monitor, sensor holder, and sensor holding probe. The blood supply to the pulp can be assessed based on the oxygen saturation levels to the tooth. This serves to be a reliable indicator and objective test in assessing the actual status of the pulp.^[4]

The authors of the present study have designed a custom-made pulse oximeter sensor holding device, which aids in effective positioning of the sensor in order to record the pulpal status of the tooth.

Therefore, the aim of this study is to design a customized pulse oximeter sensor probe holder in determining the vitality of permanent teeth and to evaluate the diagnostic accuracy of pulse oximeter, heat test, cold test and electric pulp test to identify the actual status of pulp in the teeth requiring root canal treatment.

Materials and Method

It is a prospective observational diagnostic trail. Approval for the study was obtained from the Institutional Review Board of Saveetha Institute of Medical and Technical Sciences, Chennai, India [SRB Ref No: SRB/SDMDS11/17ODS/11]. Institutional ethical committee approval has been obtained and approval number has been mentioned as (SRB Ref No). Date of approval 28.11.2017. The sample size was determined from the previous study^[5] using G power 3.1 version. The sample size of 79 single rooted teeth was arrived by assuming alpha error- 0.05 and power of the study as 0.95. Single rooted teeth requiring endodontic therapy, teeth that require intentional root canal treatment for prosthodontic considerations and teeth with deep carious lesions were included in the study.

Patients with systemic complications, inability to respond to pulp testing (Intellectual disabilities), presence of developmental defects, presence of resorption, pulp canal obliteration were excluded from the study.

Seventy-nine single rooted teeth matching the inclusion criteria were included in the study. The study participants were recruited from the pool of patients in the Department of Conservative Dentistry and Endodontics at Saveetha Dental College, Saveetha Institute of Medical and Technical Sciences, Chennai, India. 18 to 56-year-old male and female patients were included in the study.

Three blinded operators were involved in the study. First operator recorded the clinical and radiographic examination, second operator performed all the pulp vitality tests, and the third operator performed the access cavity preparation. The order of testing was the cold test, heat test followed by electric pulp tester, and then the pulse oximeter, with a time lag of 2 minutes between each test for the central sensitization to occur. In every patient all 4 pulp tests were performed i.e. cold test, heat test, electric pulp tester, and pulse oximeter.

Pulp testing

Cold test: Double ended ear bud was saturated with 1, 1, 1, 2- tetrafluoroethene spray outside the range of subject's vision. The bud was held back until it was frosty, following which, it was applied on the middle third of the labial surface of the tooth. An interval of 2 minutes was allowed to minimize the influence of one test over the other.

Heat test: Following isolation and drying the tooth a layer of petroleum jelly was smeared on the labial surface of the tooth to avoid sticking of gutta percha to the surface. One end of the gutta percha stick was heated on the flame out of the subject's sight to the point till it gets softened and just begins to glisten. Heated gutta percha stick was gently applied on middle third of the labial surface for 10 seconds or until a sensation was felt, which ever was earlier.

Electric pulp tester: After cleaning the probe of electric pulp tester with alcohol, an electrolyte was applied and placed on middle third of the labial surface of the tooth. Tip of the probe was placed on the tooth and lip clip was placed. The contra lateral tooth was used as control. If the current required to gain a response from the test tooth was the same as needed to excite the control, the pulp of the test group was considered normal, and was recorded as a positive response. The pulp of the test group was considered to be degenerating when much more current was required to gain a response compared to the control and was recorded as a negative response. Lack of response was also recorded as a negative response. Two readings were taken for each tooth, with an interval of 5 min, and the average was recorded.

Pulse Oximeter: Pulp testing was carried out with pulse oximeter using the probe. Reading for oxygen saturation was noted on the index finger of each subject, which was kept as a gold standard for comparison of the readings obtained on teeth. Probe was placed on the labial surface in middle third of the crown in order to fit closely to the tooth surface. Care was taken to place the sensor on the palatal surface so that the red - infrared rays pass from labial to palatal surface through the middle of the crown thereby, creating a long axis that was perpendicular to the axis of the crown. Each tooth was evaluated for 30 seconds following which the readings obtained on the pulse oximeter were recorded. After performing pulp vitality test, access cavity preparation was performed and presence or absence of bleeding from the canal orifice was noted. Bleeding from the canal orifice is inferred to be vital and absence of bleeding was considered to be pulp necrosis.

The response was tabulated and was analyzed statistically.

Statistical analysis

The collected data were analyzed with IBM.SPSS statistics software 23.0 Version. To describe about the data descriptive statistics, frequency analysis and percentage analysis was used. To analyze the diagnostic accuracy of pulp tests Receiver Operator Characteristic (ROC) curve analysis, Sensitivity, Specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) was performed. In the above statistical tools, the probability value. 05 is considered as significant level.

Results

Sensitivity, Specificity, Positive and Negative predictive value of pulse oximeter, thermal and electric pulp test was performed [Tables 1-4]. Outcome results of all the pulp tests was compared with clinical finding (i.e direct visual examination of access cavity) [Table 5, Figure 1]. ROC curve analysis was performed [Graph 1]. From the results of the present study it can be interpreted that, pulse oximeter is more reliable in diagnosing the actual pulpal status and was in correlation with the actual clinical finding. The results were found to be highly significant with $P < 0.01$ level [Table 6].

Discussion

The assessment of pulp vitality plays a crucial role in deciding the treatment plan. It is the well-known fact that it is not always advisable to decide the treatment plan only on the basis of pulp sensibility tests, which most of the dentists practice in their routine clinical scenario. The authors of the present study keep a standpoint that the major reason for most of the clinicians who are not using pulp vascularity test in day to day dental practice is due to difficulty in procuring the device as it has been not commercialized yet.

Based on the recent systematic review^[6] it was evident that previously published articles had high risk of bias. Most of the studies did not incorporate reference standard in their article.^[7]

Over the recent years, clinical trial performed on paediatric age group did not mention the type of sensor and sensor holder used in their study^[8]

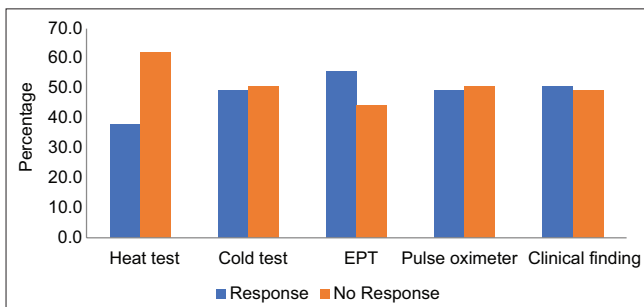


Figure 1: Outcome comparison

There are previous reports on the usage of pulse oximeter device for the assessment of oxygen saturation levels in pulpal diseases.^[2,5,9-17] Different studies used different sensor and sensor holding probes. Sensor and sensor holding probes varied among different studies.

There were many drawbacks in all the previously mentioned studies. Therefore, the present study was performed to address the existing lacunae. Though the previous authors have

Table 1: Heat test- % of accuracy

Sensitivity	55.00
Specificity	79.49
PPV	73.33
NPV	63.27
Accuracy	67.24

Table 2: Cold test- % of accuracy

Sensitivity	80.00
Specificity	82.05
PPV	82.05
NPV	80.00
Accuracy	81.03

Table 3: EPT- % of accuracy

Sensitivity	77.50
Specificity	66.67
PPV	70.45
NPV	74.29
Accuracy	72.08

Table 4: Pulse oximeter - % of accuracy

Sensitivity	97.50
Specificity	100.00
PPV	100.00
NPV	97.50
Accuracy	98.75

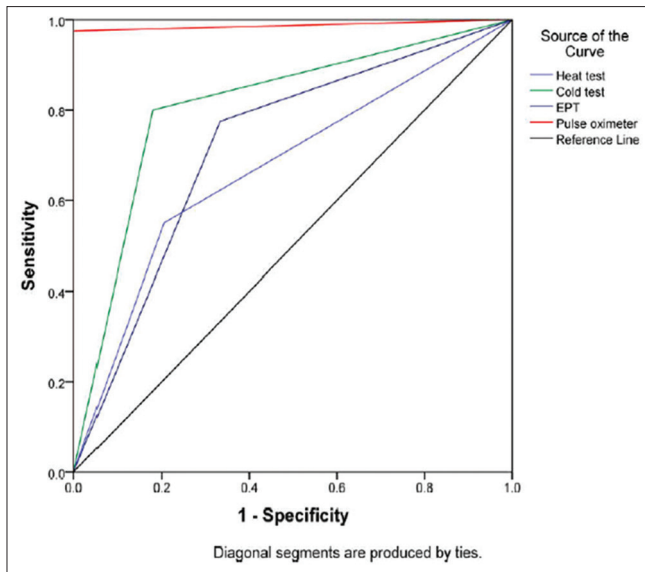
Table 5: Outcome comparison of pulp tests

	Heat test	Cold test	EPT	Pulse oximeter	Clinical finding
Response	38.0	49.4	55.7	49.4	50.6
No Response	62.0	50.6	44.3	50.6	49.4

Table 6: Area under the curve

Test Result Variable(s)	Area Under the Curve			
	Area	P	95% C. I	
			Lower Bound	Upper Bound
Heat test	0.672	0.008 **	0.552	0.793
Cold test	0.810	0.0005 **	0.710	0.911
EPT	0.721	0.001 **	0.606	0.836
Pulse oximeter	0.988	0.0005 **	0.959	1.000

** Highly significant at $P < 0.01$ level



Graph 1: ROC Curve

customised their own pulse oximeter device to assess the actual pulp status, few studies failed to assess its accuracy along with the other sensibility tests,^[10,13] It is not possible to assess the accuracy of the device without comparing other pulp tests. Therefore, the present study was designed to test the accuracy of pulse oximeter in comparison with thermal and electrical pulp tests.

Moreover, correlating the results of the pulp tests with the actual clinical finding is considered to be the gold standard method in assessing the accuracy of the device. Due to ethical constraints, it is not always possible to correlate with the direct inspection of the access cavity, especially in conditions with vital pulp, which does not require an endodontic treatment. The authors of the present study correlated the findings of pulp tests to the direct examination of the access cavity. The teeth that showed vital response with pulse oximeter were not included for the direct visual examination of access cavity assessment.

An important part of this study was to make a specific dental probe for utilizing the pulse oximeter in endodontic diagnosis. Special dental probes have not been manufactured for the dental market, and this is a major limitation of the use pulse oximeter in endodontics. Noblett *et al.*^[18] designed an invitro model to assess the pulpal circulation using pulse oximeter. He used a rubber dam clamp as the sensor. Kahan *et al.*^[17] and Gopikrishna *et al.*,^[5] Karayilmaz *et al.*^[19] used innovative probes in their studies. Finger or ear sensors has been used in few previous studies.^[5,9,15,20] The authors of this study keep a standpoint that though finger or ear sensors are been employed, the size of these sensor are much larger, so when these are embedded in the sensor holding probe its total size becomes larger to adapt to the external tooth surface.^[9,12] In the present study neonatal sensor was used and the sensor holder was designed and custom made to aid in accurate placement on the tooth surface. 3D printing method was used to fabricate the flexible sensor holder, which facilitated the ease of placement on the tooth surface.

There are so many factors which influence the results of the pulp vitality. They are the type of the sensor and sensor holding probe, the age of the patient, gender of the patient, and general systemic conditions. Gender to a certain extent influence the interpretation of pulp sensibility tests as it is based on patient's subjective response. Apprehensive female patients fail to interpret the exact response, which might eventually lead to misdiagnosis. When it comes to the use of pulse oximeter, there is also probability that patients with systemic disorder (cardiovascular disease, high venous pressure, low peripheral perfusion and hypotension) might have correlation with oxygen saturation level.^[20] The results of Goho *et al.*^[21] reported that patient's systemic circulation does not has any correlation with oxygen saturation levels.

The author of the study strongly opines that age of the patients influence the oxygen saturation levels of the pulp. It is a well known that as age advances, pulp volume decreases with increased deposition of mineralized tissue.^[22] The above-mentioned mechanism leads to atherosclerotic changes in the blood vessels.^[18] Therefore, in older patients the oxygen saturation reading of a healthy normal pulp tends to be a reduced value. Under such instance the dentists should not falsely interpret and perform unnecessary endodontic management. Keeping this in focus, the authors of this study interpreted the results of pulse oximeter values when performed on older individuals.

In the present study the overall diagnostic accuracy of four pulp tests were assessed. Amongst all the pulp tests, pulse oximeter showed highest diagnostic accuracy. Receiver operating characteristic curve was plotted against sensitivity and specificity. The test is said to be accurate when the ROC curve originates from the left handed border and reaches the top border of ROC space, away from 45-degree diagonal line. This shows pulse oximeter test to be reliable in assessing the actual pulp status.

The other interesting point is that three investigators were involved in the present study, which was not employed in the previous studies. This reduces the operator induced bias and review bias. Therefore, the authors of this study strongly opine the reliability and accuracy of the results obtained from the pulp tests.

Future implication

The efficiency of pulse oximeter in assessing the pulpal status of the tooth that had undergone revascularization treatment would bring about revolution and change the future scope of endodontics.

Conclusion

Within the limitations of the study, it can be concluded that customized pulse oximeter sensor holder proves to be accurate, reliable, and objective in assessing the actual condition of the tooth.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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