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ACCURACY OF THE DENTAL PULP SENSIBILITY TEST USING COLD SPRAY FOR THE DIAGNOSIS OF PULP DISEASES: AN OBSERVATIONAL CLINICAL STUDY

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Abstract

The dental pulp sensibility test is one of the main auxiliary resources for the diagnosis of pulp pathologies, and its accuracy is still debatable. This cross-sectional observational study evaluated the accuracy of the pulp sensibility test (PST) using cold spray (1,1,1,2-tetrafluoroethane) for the diagnosis of pulp diseases and determined the effect of individual and clinical variables on the reliability of this test. The paper was designed following the STROBE statement. Sixty patients with indications for primary endodontic treatment were selected and examined from August 2017 to July 2018. Data collection was performed through interviews, clinical/radiographic examinations and the PST. The results of the cold test, along with data on sex, age, the tooth type regarding the root number, and the presence of restorations and caries, as well as the recent consumption of analgesics, were recorded. The presence of bleeding within the pulp chamber was used as the gold standard to compare with the clinical diagnosis and to identify the true-positive, false-positive, true-negative, and false-negative responses. The accuracy of PST achieved in subgroups of individual and clinical variables was compared using the chi-square test with a significance level of 5% ($p < 0.05$). The PST with the use of cold spray showed a sensitivity of 0.88, a specificity of 1.00, a positive predictive value of 1.00, a negative predictive value of 0.86, and an accuracy of 0.93. The accuracy of the cold spray was not affected by individual or clinical variables. The PST with the use of cold spray is an accurate and reliable method for determining the diagnosis of pulp diseases, especially in cases of pulp vitality or irreversible pulpitis.

Keywords: Dental Pulp Necrosis. Dental Pulp Test. Endodontics. Oral Diagnosis. Pulpitis.

1. Introduction

The early detection of pulp pathologies prevents the development and/or progression of inflammatory processes in the pulp tissue and the resorption of dental and periradicular hard tissues, thus allowing the tooth to be treated more conservatively (Alghaithy and Qualtrough 2017; Mainkar and Kim 2018; Matos et al. 2020). However, since dental pulp is surrounded by dentin walls and is not clinically visible, determining its real state is quite difficult (Jespersen et al. 2014). Pulp diagnosis depends, in most cases, on the combination of information obtained from the anamnesis, the clinical and radiographic examinations,

and complementary examinations based on neurovascular analysis (Setzer et al. 2012; Jespersen et al. 2014; Alghaithy and Qualtrough 2017; Mousavi et al. 2017; Naseri et al. 2017).

Ideally, the appropriate method for pulp condition assessment should be simple, objective, reliable, reproducible, inexpensive, and noninvasive (Dastmalchi et al. 2012; Villa-Chávez et al. 2013; Alghaithy and Qualtrough 2017, Mousavi et al. 2017). Most of these goals are achieved through pulp sensibility tests (PSTs), such as the cold test, which has been the most clinically used test to assess pulp condition (Jafarzadeh and Abbott 2010; Dastmalchi et al. 2012; Setzer et al. 2012). The diagnosis obtained with this test is established by stimulating the myelinated nerve fibers of the pulp connective tissue, that is, by means of thermal conduction (Dastmalchi et al. 2012; Jespersen et al. 2014).

Many authors agree that the thermal PST associated with anamnesis findings and clinical and complementary examinations is an accurate and reliable method for determining the true condition of the pulp and therefore has a high chance of guiding the correct endodontic therapy in most cases (Setzer et al. 2012; Jespersen et al. 2014; Ricucci et al. 2014; Mainkar and Kim 2018). However, the PST does not directly analyze tooth vitality, as it depends on a patient's subjective response (sensibility or pain) to an external stimulus of the nervous system (Chen and Abbott 2011). Its quantification is based on verbal reports, and its perception is directly related to psychobiological factors influenced by the patient's emotional state and the use of drugs (Levin 2013; Fowler et al. 2014).

Thus, considering that the thermal PST is one of the main auxiliary resources in the diagnosis of pulp pathologies, determine its accuracy and reliability would help clinicians to reach an accurate pulp diagnosis and choose the most effective treatment (Setzer et al. 2012; Fowler et al. 2014; Jespersen et al. 2014). Currently, there is still no consensus on which pulp testing method provides the best diagnostic accuracy (Mainkar and Kim 2018). Therefore, this study aimed to evaluate the accuracy of the PST test using cold spray (1,1,1,2-tetrafluoroethane) in the diagnosis of pulp diseases and to determine the effect of individual and clinical variables on the reliability of the test. The null hypothesis tested was that the accuracy and reliability of the PST is not affected by individual and clinical variables.

2. Material and Methods

This research was developed with a cross-sectional observational study model and followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (https://www.strobe-statement.org). The protocol of the study was approved by the local Institute Review Board (Certificate of Presentation for Ethical Consideration: 46838715.8.0000.5207), and all volunteer patients signed an informed consent form before the clinical tests.

Patients of both sexes with indications for primary endodontic treatment and without any restriction regarding tooth type were recruited in the Department of Dentistry of the Federal University of Sergipe over a 12-month period from August 2017 to July 2018. The number of cases during the study period determined the sample size. After a full general and dental examination, systemically healthy patients aged between 12 to 60 years old whose teeth had mature apices, with or without pain sensation, were included in the study. The exclusion criteria were patients with intellectual disability; those whose teeth were diagnosed as having normal pulp, reversible pulpitis, or periapical disease; those who had been previously treated or who had previously initiated therapy; teeth that were unavailable for evaluation due to a fixed prosthesis, full-surface crowns, large restorations, recent trauma (last 6 months), regressed pulpal chambers or calcified root canals; those with periodontal changes (pockets >3 mm, mobility >I, or gingival edema); and orthodontic treatment.

Data collection was performed by a single examiner through interview, and clinical/radiographic examination. The interview was conducted using a predesigned questionnaire, which included sociodemographic characteristics (sex and age), tooth number, characteristics of previous pain (i.e., spontaneous or elicited, mild or severe, lingering or intermittent), and analgesic consumption in the last 12 hours. The clinical and radiographic examinations were performed to confirm the type and position of the tooth and to evaluate the presence of caries or restorations as well as the tooth or periodontal tissue responses to apical palpation, horizontal and vertical percussion, and mobility tests.

The PST was performed by a different examiner who was blinded to the clinical signs and symptoms, dental histories, and radiographic findings. Before testing, each tooth was isolated with cotton rolls and dried thoroughly. A contralateral healthy tooth was tested as a control before the experimental tooth to observe

the baseline normal response. The examiner sprayed a cotton pellet with cold spray (1,1,1,2-tetrafluoroethane) (Endo-Ice®, Maquira Dental, Maringá, PR, Brazil) for 2 s until it was soaked, and the pellet was then placed onto the crown of the tooth at the middle third of the buccal surface (incisors and canines) or in the center of the occlusal surface (premolars and molars) for 10 s or until the participant raised a hand to indicate cold sensation (Villa-Chávez et al. 2013; Naseri et al. 2017). The severity and duration of the pulpal response to the sensibility test were recorded as mild or severe and short (< 10 s) or lingering (> 10 s), respectively (American Association of Endodontics. Consensus conference recommended diagnostic terminology 2009).

The PST data together with the information obtained from the interview and clinical examination were analyzed together by a third researcher to establish a clinical diagnosis of the pulp condition; pulp was classified as normal pulp, reversible pulpitis, symptomatic irreversible pulpitis, asymptomatic irreversible pulpitis, or pulp necrosis according to the terminology recommended by the American Association of Endodontists (American Association of Endodontics. Consensus conference recommended diagnostic terminology 2009; Levin et al. 2009), as shown in table 1.

Table 1. Signs and symptoms of dental pulp diseases.

Signs and symptoms	Reversible pulpitis	Symptomatic irreversible pulpitis	Asymptomatic irreversible pulpitis	Pulp necrosis
History of pain	Elicited, mild and intermittent	Spontaneous, severe and lingering	Elicited, severe and intermittent	No pain
Response to cold spray	Positive: mild and subsides quickly (< 10 s)	Positive: severe and subsides slowly (> 10 s)	Positive: severe and subsides slowly (> 10 s)	Negative
Response to apical percussion and palpation	Negative	Negative or rarely positive	Negative or rarely positive	Negative or positive
Radiographic findings	Normal	Normal or rarely with periodontal ligament thickening	Normal or rarely with periodontal ligament thickening	Normal or with periodontal ligament thickening and apical lesion

Teeth diagnosed with symptomatic or asymptomatic irreversible pulpitis and pulp necrosis underwent endodontic treatment. After local anesthesia with 2% lidocaine with epinephrine 1:100,000 (Alphacaine; DFL, Indústria e Comércio Ltda., Rio de Janeiro, RJ, Brazil), the access cavity was prepared under rubber dam isolation, and the pulp status (irreversible pulpitis / pulp necrosis) was recorded by observing bleeding within the pulp chamber. The presence (irreversible pulpitis) or absence (pulp necrosis) of bleeding was used as the gold standard to compare with the clinical diagnosis and to identify the true-positive, false-positive, true-negative, and false-negative responses. The patients underwent routine conventional endodontic treatment of the clinic.

Data are described in tables by means of absolute (n) and relative (%) frequencies and measures of sensitivity (true positive / true positive + false negative), specificity (true negative / true negative + false positive), positive predictive value (true positive / true positive + false positive), negative predictive value (true negative / true negative + false negative), and accuracy (true positive + true negative / total). A comparison between the subgroups according to the individual and clinical variables was performed using the chi-square test with a level of significance of 5% ($p < 0.05$), taking into account the accuracy achieved in each subgroup. Additionally, ROC (receiver operating characteristic) curve analysis was performed to assess the overall performance of the diagnostic test. Statistical procedures were performed using IBM SPSS Statistics version 20.0 and MedCalc version 19.0.7 software, considering a 95% confidence interval to obtain the estimates.

3. Results

One hundred and ninety-six patients were initially recruited for the study, but 129 did not meet the inclusion criteria, and seven patients who declined participation were excluded (Figure 1). Thus, 60 patients were analyzed for the accuracy of the PST using cold spray for the diagnosis of pulp diseases. Each participant contributed one tooth to the analysis for a total of 60 teeth. The mean age of the patients was 45 years old.

Table 2 shows the general characteristics of the sample, including the clinical diagnosis and gold standard (bleeding), the tooth types, the clinical evaluations of the teeth, and analgesic consumption. The PST identified 31 of the 35 vital/inflamed pulp tissues as vital/inflamed (true-positives) and 25 of the 25 necrotic pulp tissues as necrotic (true-negatives), and the remaining four teeth had false-negative responses. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy are shown in table 3. The sensitivity was 0.88, and the specificity was 1.00. This result indicates that 88% of the teeth with vital/inflamed pulp tissues were identified as vital/inflamed, whereas 100% of the teeth with necrotic pulp tissues were identified as necrotic. The positive predictive value was 1.00, and the negative predictive value was 0.86. Thus, there was a probability of 100% that positive responses to cold spray represented vital/inflamed pulp and a probability of 86% that negative responses to cold spray represented necrotic pulp. The accuracy was 0.93, indicating that the PST with the use of cold spray had a probability of 93% for determining the correct diagnosis. ROC curve analysis demonstrated high or near-optimal performance (AUC = 0.93, $p < 0.001$) of the PST (Figure 2). The accuracy of the cold spray was not affected by individual or clinical variables ($p > 0.05$; chi-square test) regarding sex, age, tooth type, the presence of restoration or caries, and analgesic consumption (Table 4).

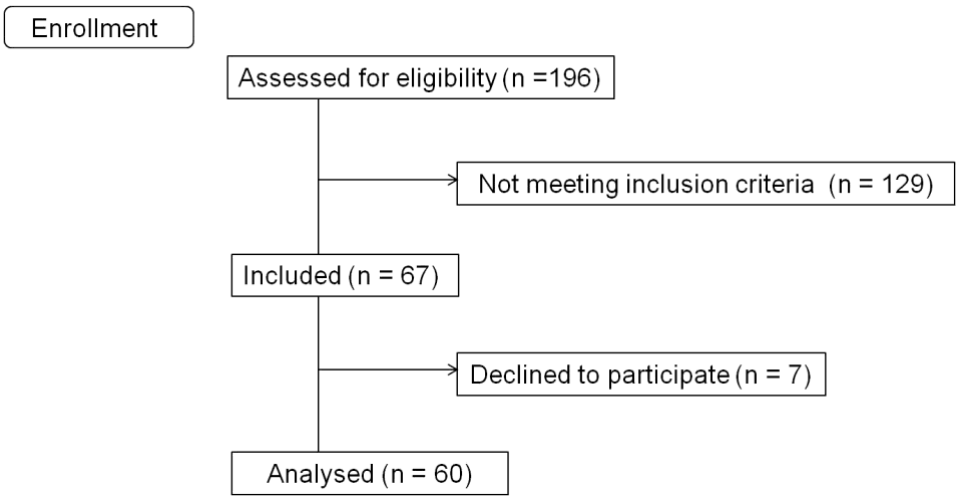

Figure 1. Flow diagram of the cross-sectional observational study.

Table 2. General characteristics of the sample.

Characteristics		n	%
Clinical diagnosis	PN[1]	29	48.3
	AIP[2]	28	46.7
	SIP[3]	3	5.0
Bleeding	Absent	25	41.7
	Present	35	58.3
Sex	Female	39	65.0
	Male	21	35.0
Age	12-18	7	11.7
	19-40	37	61.7
	41-60	16	26.7
Tooth	Single-rooted	26	43.33
	Multiradicular	34	56.67
Restoration	Absent	21	35.0
	Present	39	65.0
Caries	Absent	20	33.3
	Present	40	66.7
Analgesic	No	48	80.0
	Yes	12	20.0

[1]PN – pulp necrosis; [2]AIP – asymptomatic irreversible pulpitis; [3]SIP – symptomatic irreversible pulpitis.

Table 3. Performance of dental pulp sensibility test using cold spray.

Sensitivity	Specificity	PPV[1]	NPV[2]	Accuracy
0.88	1.00	1.00	0.86	0.93

[1]PPV – positive predictive value; [2]NPV – negative predictive value.

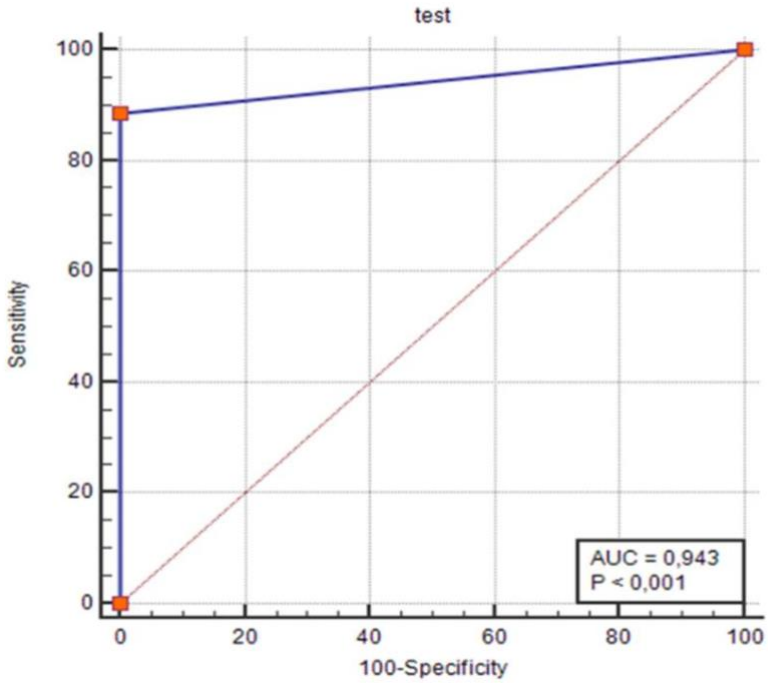

Figure 2. ROC curve demonstrating the diagnostic performance of the cold spray. AUC = Area under the ROC curve.

Table 4. Comparison of cold spray accuracy between subgroups according to the individual and clinical variables.

Subgroup		Sensitivity	Specificity	Accuracy	p
Sex	Female	0.905	1.000	0.949	0.515 ns*
	Male	0.857	1.000	0.905	
Age	12-18	1.000	1.000	1.000	0.264 ns*
	19-40	0.826	1.000	0.892	
	41-60	1.000	1.000	1.000	
Tooth	Single-rooted	0.786	1.000	0.885	0.186 ns*
	Multiradicular	0.952	1.000	0.971	
Restoration	Absent	1.000	1.000	1.000	0.129 ns*
	Present	0.826	1.000	0.897	
Caries	Absent	0.700	1.000	0.850	0.067 ns*
	Present	0.960	1.000	0.975	
Analgesic	No	0.875	1.000	0.938	0.796 ns*
	Yes	0.909	1.000	0.917	

*ns – statistically not significant difference.

4. Discussion

Differential diagnosis in endodontics requires professional scientific knowledge and the ability to analyze and interpret clinical information to achieve proper treatment planning (Setzer et al. 2012; Farias et al. 2016; Naseri et al. 2017). When the pulp tissue suffers from a mainly infectious origin, a reversible or irreversible inflammatory process is initiated as a defense mechanism to maintain the integrity of the pulp. However, if the agent of damage is not removed and persists, pulp inflammation compromises local blood microcirculation, with consequent pulp tissue necrosis and nerve fiber degeneration, which, if not diagnosed and treated early, can cause severe damage to the dental and periodontal hard tissues, such as resorption and periradicular lesions (Hahn and Liewehr 2007; Ricucci et al. 2014). Thus, the determination of tooth vitality is usually based on the PST to indirectly assess the intrapulp blood supply, which is the most accurate

and currently used pulp health status indicator (Jafarzadeh and Abbott 2010; Alghaithy and Qualtrough 2017). In the current study, we investigated the accuracy of the dental PST using cold spray to determine the diagnosis of pulp diseases.

The PST with the use of cold spray works by stimulating myelinated Aδ nerve fibers in the dentin-pulp complex through the flow of cold spray fluid into the dentinal tubules (Jafarzadeh and Abbott 2010; Levin 2013). Although the insulating effects of dental hard tissues do not allow the determination of the degree of pulp disease from this nervous stimulus, the thermal PST evaluates neurovascular changes based on temperature variation, extrapolating its results to the histological condition of the pulp (Dastmalchi et al. 2012; Setzer et al. 2012; Jespersen et al. 2014). However, since this assessment is based solely on the patient's subjective report of pulp nerve fiber stimulation, whose responsiveness may be altered by reduced tissue oxygenation, false-positive and false-negative responses may be found (Jafarzadeh and Abbott 2010; Naseri et al. 2017). The presence or absence of bleeding within the pulp chamber after crown opening has been used as a valid measure to determine pulp status, as most degenerative processes begin in the clinical crown (Villa-Chávez et al. 2013; Jespersen et al. 2014).

The present study showed that the PST with the use of cold spray, associated with the clinical and complementary examinations, had a satisfactory performance for establishing an endodontic diagnosis, with an accuracy of 0.93, a sensitivity of 0.88 and a specificity of 1.00; these values are similar (0.94, 0.88 and 1.00, respectively) to those reported by Villa-Chavéz et al. (2013). The test was applied to teeth that, after interviews as well as the clinical and radiographic examinations, possibly presented some pathological pulp alterations (irreversible pulpitis or pulp necrosis) and, therefore, did not evaluate the diagnostic efficacy of cold spray in teeth with healthy pulp. The sensitivity of the cold spray was not 100% satisfactory, probably because in advanced stages of pulp inflammation, oxygen-dependent Aδ nerve fibers degenerate with no sensitive response when cold spray is applied to teeth (Kataoka et al. 2011; Villa-Chávez et al. 2013). Considering the negative predictive value of 0.86, it can then be suggested that there is a 14% probability that negative responses to the cold test do not represent pulp necrosis, that is, even if responding negatively, there may still be pulp blood flow. On the other hand, positive responses to the cold test are more likely to represent pulp vitality since the positive predictive value was 1.00.

Psychobiological factors associated with the patient's emotional state and drug use (sedatives, tranquilizers or painkillers) may also affect the pulp response and the patient's response to sensibility tests leading to false-positive or false-negative results (Fowler et al. 2014). In this context, the present study evaluated whether individual and clinical variables such as sex, age, type of tooth regarding number of roots, presence of restorations and caries, and recent consumption of analgesics could interfere with the accuracy of the PST using cold spray. The null hypothesis was accepted, as individual and clinical variables did not interfere with the accuracy of the pulp sensibility test. When performing the PST on teeth of patients who had recently used analgesics, it was expected that the response to the test, specifically the negative responses, could be related to the increase in the pulp nerve stimulation threshold caused by the medication (false-negative results). However, when comparing the accuracy of the test between individuals who used analgesics in the last 12 hours and those who did not, no statistically significant difference was found (Table 4), suggesting that recent use of analgesic did not change the accuracy of the thermal PST, which is consistent with other works (Fowler et al. 2014; Jespersen et al. 2014; Mousavi et al. 2017).

Molar and premolar teeth are more likely to exhibit false-positive and false-negative results because they have a larger enamel and dentin thickness, a larger volume of pulp tissue and multiple roots, and they may present regions of necrosis and pulp vitality on at least one of the canals (Setzer et al. 2012; Jespersen et al. 2014). In this study, there was no statistically significant difference in the accuracy level of the thermal PST between uniradicular and multiradicular teeth (Table 2). The cold test was not efficient in determining the pulp condition in four cases of the total sample, three of which were uniradicular premolars and one of which was a multiradicular molar. The response of these teeth to cold spray was negative, suggesting pulp necrosis. However, after crown opening, there was the presence of bleeding, which was then equivalent to false-negative responses. These findings have also been reported in a previous study (Dastmalchi et al. 2012) that observed, through histological analysis of the pulp, progressing coagulation necrosis in the crown pulp and, apically, the presence of living tissue and dystrophic calcification.

Another factor that may interfere with the accuracy of the PST is the age of the patient (Chen and Abbott 2011; Levin 2013; Jespersen et al. 2014). Although some studies state that incomplete root development and pulp innervation influence only the results of the electrical PST, young patients, because they are more anxious, may present inaccurate responses to the thermal PST (Jafarzadeh and Abbott 2010). In older patients, however, decreased pulp innervation and increased dental mineralization with reduced pulp volume may mainly contribute to false-negative responses (Chen and Abbott 2011; Mousavi et al. 2017). The amount of secondary or tertiary dentin acts as a thermal insulator, making it difficult for the tooth to respond to the stimulus provided by the cold spray (Chen and Abbott 2011). In the present investigation, there was no significant difference in the accuracy of the thermal PST when comparing three different age groups (12-18, 19-40 and 41-60) (Table 2). This result is in disagreement with the study by Jespersen *et al.* (Jespersen et al. 2014), in which patients aged 21 to 50 years exhibited a more accurate response to the cold test than patients in other age groups. The absence of a significant difference among the age subgroups in our study may be justified by the fact that the sample size was not large enough to determine a significant difference.

The presence of caries in vital teeth may improve the accuracy of the thermal PST by inducing an inflammatory response in the pulp tissue, which decreases the excitability threshold of Aδ nerve fibers (Hahn and Liewehr 2007; Jespersen et al. 2014). Even so, the positive response to cold should not be interpreted as a true-positive result in the presence of caries, as pulp status cannot be known with certainty at the time of testing (Jespersen et al. 2014). Reinforcing previous studies (Mousavi et al. 2017) and disagreeing with others (Jespersen et al. 2014), in this research, the presence or absence of caries did not interfere with the accuracy of the diagnosis using cold spray (Table 2). Restorative status and sex were also analyzed as possible interference factors in the PST results. Restorative procedures can act as thermal, chemical or mechanical irritants to the pulp and trigger tissue inflammation and alterations of the nerve excitability threshold. It is believed that females suffer more commonly from psychosomatic illnesses than males and that their pain is governed by emotional factors under strong hormonal influence, suggesting that women tend to display lower pain thresholds and pain tolerance than men, which could interfere with the PST results (Wise et al. 2002; Ng et al. 2004). However, neither restorative status nor sex resulted in significant differences with regard to thermal PST accuracy, which is consistent with previous works (Kardelis et al. 2002; Miller et al. 2004; Jespersen et al. 2014).

In addition to sensitivity, specificity and accuracy, the positive and negative predictive values of the cold test were also calculated. Although not commonly used, these measurements provide valuable insight into the diagnostic effectiveness of a test. According to the data presented, the cold spray had a positive predictive value (PPV) of 1.00, which means that a tooth diagnosed with irreversible pulpitis was approximately 100% likely to actually have the condition. The negative predictive value (NPV) was 0.86, which indicates that the probability of a nonsensitive reaction representing a necrotic pulp was 86%. These results are similar to those found by Villa-Chavéz et al. (2013), whose PPV was 1.00 and NPV was 0.90, but the results are different from those reported by Jespersen et al. (2014), whose PPV was 0.862 and NPV was 0.937. Methodological differences and factors related to the general characteristics of the sample may have caused divergences between study results. Although the sample size may compromise the statistical precision of the results, this observational clinical study provides important unpublished information on the accuracy of the thermal PST and its correlation with individual and clinical variables, thereby reinforcing its clinical utility as an important auxiliary resource in the diagnosis of pulp diseases.

5. Conclusions

The dental pulp sensibility test using cold spray is an accurate and reliable method for determining the diagnosis of pulp diseases (vitality vs. necrosis). Positive responses to the pulp sensibility test are more reliable for determining pulp vitality than negative responses for determining pulp necrosis.

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intellectual content; PARANHOS, L.R.: conception and design, analysis and interpretation of data, and critical review of important intellectual content. All authors have read and approved the final version of the manuscript.

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