

Reliability and Validation of a Newly Proposed Score-based Criterion for Minimal Invasive Pulpal Diagnosis and Treatment Planning

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ABSTRACT

Introduction: A thorough case history aids in proper diagnosis and treatment planning. Since many years various case history formats or questionnaires have been followed, which are too long as well as they lack any numerical support for the responses. Hence, it makes all of them less precise and less accurate.

Aim: To develop and validate a newly proposed score-based criterion for minimal invasive pulpal diagnosis and treatment planning.

Materials and Methods: The present cross-sectional study was conducted at the Department of Conservative Dentistry and Endodontics, K.M. Shah Dental College, Vadodara, India, from December 2021 to April 2022. Study included 200 subjects with pain in maxillary or mandibular teeth due to primary carious lesion participated. This study included two groups of experts: group I had two experienced endodontists, who examined the patients based on their knowledge and experience using traditional diagnostic methods and a standard treatment plan was advised and group II had two calibrated experts endodontist (primary investigator) and a general dentist (co-investigator)

using this newly proposed score-based evaluation criterion and a minimal invasive treatment plan was suggested. Each patient was examined by both the groups. The statistical analysis for the agreement between standard treatment plan (group I) and suggested treatment plan (group II) was done via Cohen Kappa test.

Results: Of total participants, 108 (54%) were females and 92 (46%) were males and the mean age of participants was 36.26 ± 12.72 years. The mean age of females and males was 34.26 ± 12.17 years and 38.61 ± 13.01 years, respectively. The result of the study showed almost perfect agreement ($\kappa=0.918$, p -value <0.001) between both the groups indicating high accuracy of the newly proposed score-based criterion.

Conclusion: This newly proposed score-based criterion offers a minimal invasive diagnosis and treatment planning with a strong numerical support that can be efficiently used by the general practitioners and the endodontists in their routine clinical practices as well as by the academicians/researchers for case selection for clinical trials/studies in field of endodontics.

Keywords: Endodontist, Minimally invasive endodontics, Root resorption

INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage [1-2]. The pain originating or associated with teeth or their supporting structures i.e, mucosa, gingivae, maxilla, mandible or periodontal membrane is referred as odontogenic pain. Inflammation of pulp is frequently encountered cause of odontogenic pain [3]. Pulpal inflammation is a progressive response to irritants of diverse origin perceived as characteristic signs and symptoms at various stages of inflammation. From an endodontic perspective, accurate pulpal diagnosis based on these signs and symptoms by thorough clinical and radiographic examination is essential before treatment plan is advised [4].

To arrive at a specific diagnosis, clinicians perform some investigatory steps such as checking for tenderness on palpation and percussion, mobility and swelling, commonly used pulp sensibility tests such as thermal and electric pulp test. Radiographic examination is done to study the extent of the caries whether its approaching or involving the pulp and to check the status and condition of periradicular and/or periapical tissues [5].

Recent literature reveals a good correlation between clinical symptoms of pulpitis and the corresponding histological state of a diseased pulp, that means there is strong possibility that in cases on irreversible pulpitis the inflammation can be restricted to coronal pulp itself and not necessarily advancing to the radicular pulp. Based on these studies a newer minimally invasive treatment approach was suggested that can simplify treatment procedures and avoid complex and more invasive treatment modalities [6-8].

The current methods to reach a pulpal diagnosis are case history taking formats or various questionnaires along with radiographic examination, do not have a numerical range of scores according to severity of responses obtained from the patient at the time of routine clinical examination. This observation motivated researchers to design and put forth a new evaluation criterion which is simple, easily applicable, least expensive, non invasive and at the same time highly accurate and has a strong numerical support that not only evaluates the pulpal status closely but also suggests a minimal invasive endodontic treatment based on the over-all scores obtained. Since, no literature is available till date showing any validated chair-side score-based criterion for evaluation of pulpal inflammatory status and a subsequent minimally invasive endodontic treatment plan. Therefore, the aim of the present study was to develop and validate this newly proposed score-based criterion that not only evaluates the status of pulpal inflammation closely but also suggests a minimally invasive treatment plan for the same.

MATERIALS AND METHODS

The present cross-sectional study was conducted at the Department of Conservative Dentistry and Endodontics of K.M. Shah Dental College, Vadodara, India, from December 2021 to April 2022. Prior permission from the Institutional Ethical Committee (Ref no: SVIEC/ON/DENT/RP21026) was obtained and CTRI registration (CTRI/2021/11/038179) of the study was done. The content validation was carried out by the experts from the field of Endodontics and the correlation coefficient of their responses indicated the high validity of the criteria. The study was designed to follow the modified Declaration of Helsinki (2013) [9].

Sample size calculation: A sample size of 200 achieves 80% power to detect an effect size (W) of 0.2335 using three degrees of freedom Chi-square test with a significance level (alpha) of 0.05 (5%) [10]. Patients were informed about the study and the informed consents were taken.

Inclusion criteria: Patients between 18-60 years of age with pain in maxillary or mandibular teeth due to primary carious lesion were included in the study.

Exclusion criteria: Patients with secondary caries, poor periodontal health, open apex, root resorption, endodontic retreatment, vertical root fractures were excluded from the study. Medically compromised, pregnant and lactating women were excluded from the study.

Developing and Designing of the Criterion

This newly proposed criterion contained precisely selected seven questions including six clinical investigatory questions and one radiographical investigatory question collectively involved in pulpal diagnosis. The reasons for choosing this precise seven questions were:

- 1) Simple as it can be performed by any clinicians i.e. general practitioner or specialist.
- 2) Most relevant in terms of evaluating the status of pulpal inflammation.
- 3) Non invasive and highly economical as it uses all chairside diagnostic aids.

The responses to each question were assigned with scores (starting from '0') in an increasing order describing the severity of the response. Lastly, the scores of all individual seven questions were summed together to get a final score. Based on the suggested range of scores in which the final score fits into, a minimal invasive treatment plan would be suggested [Table/Fig-1].

S. No.	Questions	Scores
1.	Since how long patient is experiencing pain (days)?	
	0-5	1
	6-15	2
	>15	3
2.	Onset of pain	
	a. On application of stimulus only	0
	b. Pain on application of stimulus which disappears rapidly	1
	c. Pain lasting for minutes	2
	d. Spontaneous pain associated with changes in postural position	3
3.	Sensitivity to percussion	
	Vertical-No	0
	Yes	1
	Horizontal-No	0
	Yes	1
4.	Response to thermal test	
	a. Positive response as contralateral tooth	0
	b. Short sharp pain disappears rapidly after removal for 20s	1
	c. Pain response lingers even on removal of stimulus	2
	d. No response at all	3
5.	Response to electric pulp test	
	a. Normal response	0
	b. Early response	1
	c. Delayed response	3
	d. No response	3
6.	Effect of pain in daily activity	
	a. No effect	0
	b. Mild discomfort but not disturbing	1
	c. Disturbing but able to carry out the daily activity	2
	d. Highly disturbing cannot concentrate on daily work	3

7.	Radiographic examination	
	a. Radiolucency involving enamel, dentin only	0
	b. Radiolucency approaching pulp	1
	c. Radiolucency involving pulp with no PDL widening	2
	d. Radiolucency involving pulp with PDL widening	3
	e. Radiolucency involving pulp with PDL widening and loss of lamina dura with minimal bone loss	4
	f. Well-defined radiolucency suggestive of periapical pathology with significant bone loss	5
Overall score	Suggested/Advised treatment plan	
≤3	No treatment and follow-up	
4-6	Removal of stimulus/Restoration with sedative base and follow-up	
7-9	Direct/Indirect pulp capping	
10-12	Pulpotomy	
>13	Pulpectomy	

[Table/Fig-1]: Rao and Shah's newly proposed score-based pain evaluation criterion for minimal invasive pulpal diagnosis and treatment planning.

Study Procedure

Initially a pilot study was conducted with a sample size of 20 achieves 80% power to detect an effect size (W) of 0.50 using a 3 degrees of freedom Chi-square test with a significance level (alpha) of 0.05 (5%). The responses of all seven questions were scored with a range of scores initiated from digit/number one ('1') for example in question no.5 the normal response for electric pulp test was given score '1' and an overall score range with an interval of five digits i.e.; 0-5, 5-10,10-15. But the result of the pilot study showed that these ranges showed less accuracy. The possible reason for this could be explained by the fact was the range of score assigned to the responses earlier initiated from digit/number one ('1') instead of zero ('0'). Since the normal response to any diagnostic test is actually the baseline data and therefore should be scored as zero ('0'). Therefore, the entire criterion was revised with important modifications as follows:

- (i) The numbers assigned to the responses were modified and started from number zero (0) in ascending order.
- (ii) The 'overall score range' was narrowed down with an interval of 3 digits instead of 5 digits; i.e, 0-3, 4-6, 7-9,10-12, and ≥13, etc.

The reliability of the criteria was statistically analysed using the Cronbach's Alpha test with a sample size of 20.

Patients Examination and Evaluation

This experimental study was carried out by two groups of experts as follows:

Group I- Each patient included in the study was initially examined by two experienced clinicians (endodontists having experience of more than 10 years). Based on their knowledge and experience, using traditional diagnostic methods, a treatment plan was advised.

Group II- Same patient from group I was then evaluated by two calibrated experts; an endodontist (Primary investigator) and a general dentist (Co-investigator) using this newly proposed score-based evaluation criterion. These experts were blinded regarding the diagnosis and treatment plan suggested by group I.

STATISTICAL ANALYSIS

Data were collected using Microsoft excel software expressed as frequency (percentages) for categorical variables. Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) software version 25.0 (IBM, Chicago, IL, USA). The comparison between treatment plans of both the groups was performed using Fisher's-exact test. The agreement between both the groups was assessed by Cohen's Kappa.

RESULTS

Out of total 200 patients, 108 (54%) were females and 92 (46%) were males and the mean age of participants was 36.26±12.72 years. The mean age of females and males was 34.26±12.17 years and 38.61±13.01 years, respectively.

The results shows that there was almost perfect agreement between both the treatment plans advised by both group I and group II, as the result showed $\kappa=0.918$ with p -value <0.001 [Table/Fig-2].

Treatment	Group I	Group II	Agreement between both the groups for each variable	Cohen Kappa value	p-value
Indirect/ Direct pulp capping	22	22	100%	-	-
Pulpectomy	109	106 (Pulpectomy) 3 (Pulpotomy)	97.2%	-	<0.001
Pulpotomy	46	39 (Pulpotomy) 7 (Pulpectomy)	84.8%	0.918 (91.8%)	-
Removal of caries	23	23	100%	-	-

[Table/Fig-2]: Comparative and agreement analysis between the suggested treatment plans of both the groups using Fischer's-exact test and cohen kappa.

22 out of 200 patients were advised Indirect/direct pulp capping by evaluators of group II, as the overall score was within the range of 7-9 so the suggested line of treatment was indirect/direct pulp capping as per the new criterion, same 22 patients were advised the same treatment plan (Indirect/direct pulp capping) by Group I.

Of all, 109 patients were advised with treatment of pulpectomy/Root Canal Treatment (RCT) for respective teeth according to group I. In these 109 patients, 106 were suggested with pulpectomy according to group II (just like group I); as the score was 13 and above (≥ 13); whereas in three patients the treatment plan differed from the group I.

Forty six out of 200 patients were advised pulpotomy after examination by group I as well as when evaluated by Group II the overall score was within 10-12 and therefore pulpotomy was advised. However, in group II, seven patients out of 46 patients were eventually treated with pulpectomy/RCT. While operating, these seven cases showed failure in achieving haemostasis while doing pulpotomy and hence pulpectomy was opted. For rest 23 patients, the advised line of treatment was removal of caries followed by restoration according to the group I and the group II. The reliability of the criteria was statistically analysed using the Cronbach's Alpha test which gave a value of 0.711 indicating a good level of consistency for our scale with a sample size of 20.

DISCUSSION

The modern endodontics looks forward on the concept of preserving and maintaining the vitality of the pulp, especially in teeth with deep carious lesion. Teeth with symptomatic irreversible pulpitis with/without symptomatic apical periodontitis, till today, are often advised for root canal treatment as the therapy of choice. This preconceived notion is based on the older concept which states that there is a poor correlation between clinical signs and symptoms and the histological state of the pulp in mature teeth [11-12]. But recently, Taha NA et al., revealed a contradictory result that indicated a good correlation between clinical and histological state of the diseased pulp. For example, in cases of irreversible pulpitis, the inflammation and/or necrosis is limited only to the coronal pulp while the radicular pulp could still be viable [13]. Hence, in such cases the vitality of the tooth can be retained with a less invasive treatment modality like pulpotomy procedure (complete/partial) preventing the need for a complete pulpectomy [14-15]. Hashem D et al., presented a modified classification of pulpitis based on the clinical symptoms

[16]. Later Wolter WJ et al., [7] introduced the concept of Endlight and gave a new classification of pulpitis based on the stages of pulpal inflammation emphasising on the minimally invasive treatment plan [7]. This means whenever there is vital pulp tissue, it has the potential to heal if diagnosed and treated correctly and, most importantly, timely. This approach boons to maintain the viability of the pulp, to improve the outcome of vital pulp therapy and to reduce pain and discomfort for the patient [7].

Coronal pulpotomy is an evidence based, safe and predictable treatment that can be offered to adult patients having irreversible pulpitis as a substitute to conventional root canal therapy/Complete pulpectomy [17]. Taha NA et al., studied the outcome of full pulpotomy using Mineral Trioxide Aggregate (MTA) in adult patients with an overall 100% clinical and 97.5% radiographic success during the first year, and 92.7% success at three years. Thus, pulpotomy proved to be a successful treatment option for cariously exposed pulps in mature permanent molar teeth with clinical signs and symptoms indicative of irreversible pulpitis [13].

The present study proposes a new score-based criterion which is basically a set of selected questions assigned with numbers which are basic, essential and, at the same time, are most relevant to evaluate the inflammatory status of the pulp very closely. Although taking a detailed clinical case history for reaching a diagnosis is a routine practice in clinical scenario, but these conventional case histories usually consist of several questions and none of them, by far, have any numerical data support; they don't have a 'score range' describing the severity of the responses obtained from the patients. Basically, by far not a single questionnaire has ever been reported having a score-based evaluation approach for pulpal diagnosis and subsequent treatment planning which is minimally invasive in nature. The objective of designing a score-based criterion was to provide a simple and comprehensive tool for chairside pulpal diagnosis and treatment planning which can be applied and utilised by the endodontists as well as general dentists in routine practice.

In the present study, 200 patients were evaluated under both the groups. As mentioned above, 22 out of 200 patients were advised Indirect/direct pulp capping by evaluators of both groups I and II. One important thing to note here is that the decision of whether to carry out the indirect pulp capping or direct pulp capping was made intraoperatively that is while/after removal of the caries.

Out of total, 109 patients were advised with treatment of pulpectomy/RCT for respective teeth according to group I. Out of these 109 patients, 106 were suggested with pulpectomy according to the group II (just like group I); as the score was 13 and above (≥ 13); but in three patients the treatment plan differed from the group I as they were advised with pulpotomy according to group II because the overall score was within the range of 10-12 which was in contrast with the treatment plan advised by group I. The possible reasons for the discrepancy in these three particular cases can be attributed to:

- 1) Presence of different levels of inflammation in multiple roots; since in these three cases the concerned teeth were molars (multirooted teeth) which might have given a false positive response where the pulp in one of the canals might have been vital or comparatively more inflamed than the others.
- 2) Uncalibrated pulp testing devices, which might have produced variation in the results obtained at that particular moment of examination.

But, ideally, in these three cases, according to the concept of minimally invasive endodontics, the recommended treatment plan should have been Non surgical Endodontic and Vital Pulp Therapy (NSET-VPT) procedure as suggested by Koli B et al., instead of full pulpectomy wherein pulpotomy was performed with the root with no periapical involvement and NSET was performed only with root/roots showing periapical involvement in the same tooth that

had 93.3% success indicating it as biologically acceptable minimal invasive treatment option [18].

Forty six out of 200 patients were advised pulpotomy after examination by group I as well as when evaluated by group II the overall score was within 10-12. Hence, pulpotomy was advised. Somehow, seven out of 46 patients were eventually treated with pulpectomy/RCT. While operating, these seven cases showed failure in achieving haemostasis while doing pulpotomy and hence pulpectomy was opted. The authors suggest that the possible reason for this dissimilarity could be that as these seven patients were not treated on same day after examination and were treated later at an interval of 10-15 days during which the infection from the coronal pulp must have progressed to radicular pulp leading to continuous pulpal haemorrhage. For rest 23 patients, the advised line of treatment was removal of caries followed by restoration according to the group I same was with later suggested as per the group II as the final score was in the range of 4-6.

This newly proposed score-based criterion is simple, numerically supported, precise and a highly economical as it uses all the routinely available chairside diagnostic aids like electric pulp tester, Endo-Frost, intraoral periapical radiographs. Above mentioned qualities make this criterion a reasonable tool for chairside minimally invasive pulpal diagnosis and treatment planning that can be efficiently used by the general practitioners as well as by the endodontists in their routine clinical practices. It can also be used by the academicians/researchers as a reference criterion for case selection in clinical trials/studies in the field of Endodontics.

Limitation(s)

This newly proposed 'score-based' criterion can only be applied to teeth having pain due to primary carious lesions hence this criterion could possibly not be applied to the cases of retreatments, fractures and traumatic injuries of teeth. These are the limitations with the design of this proposed criterion but in the future, hopefully, other score-based tools could be designed for such cases.

CONCLUSION(S)

Within the limitations of the study, it can be concluded that pulpal diagnosis and treatment planning was highly accurate with the newly proposed score-based criterion. This proposed criterion in

the study offers a strong numerical support for each diagnostic step as well as suggests an appropriate treatment plan, thus decreases the incidence of more invasive procedure, maintains the vitality of the pulp and reliable for the case selection in epidemiological studies, specially related to pulpal and periapical diseases.

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