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ORIGINAL ARTICLE

Efficacy of biodentine as a direct pulp capping agent in reversible pulpitis.

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ABSTRACT… Objective: To determine the efficacy of Biodentine as a direct pulp capping agent in reversible pulpitis. **Study Design:** Longitudinal Observational study. **Setting:** Department of Operative Dentistry, Ibn-e-Siena Hospital Multan. **Period:** 25th July 2023 to 24th January 2024. **Methods:** A total of 114 patients, aged 18-55 years with reversible pulpitis in permanent teeth were selected through consecutive sampling. Patients with irreversible pulp conditions, developmental anomalies, or handicaps were excluded. Pain was assessed using a visual analogue scale (VAS), and direct pulp capping with Biodentine was performed under local anesthesia. Efficacy was determined 24 hours post-procedure, defined as no pain (VAS=0). Data were analyzed using SPSS version 23. Descriptive statistics were run and factors influencing efficacy were assessed through Fischer's exact at 5% significance level. **Results:** The mean age of participants was 27.4 ± 9.3 years, with 57% males. Pre-operatively, 76.3% had mild pain. Post-operatively, 89.5% of patients reported no pain, with only 10.5% experiencing mild pain. Efficacy was significantly higher in patients ≤25 years (98.5%) compared to >25 years (77.6%, $p<0.001$) and in those with mild to moderate pre-operative pain (98.9% and 65%, respectively) versus severe pain (42.9%, $p<0.001$). **Conclusion:** Direct pulp capping with Biodentine was highly effective in managing reversible pulpitis, particularly in younger patients and those with mild to moderate pre-operative pain. Age and pre-operative pain severity significantly influenced treatment outcomes.

Key words: Biodentine, Dental Pulp Test, Permanent Teeth, Reversible Pulpitis.

INTRODUCTION

Dental caries, an opportunistic infection involving pulp space by routinely present oral microorganisms, is the commonest cause of pulpitis. Other potential sources include trauma, exposure of dentinal tubules, dentinal fractures, and the main apical foramen.[1] There are two clinical types of pulpitis: irreversible and reversible.[2] The main clinical difference is the pulp's response to a heat stimulus. In reversible pulpitis, a cold stimulation results in an elevated but transient response. Irreversible pulpitis is characterized by chronic, spontaneous pain that gives response excessively and persistently to cold stimuli.[1,2] Pulp-capping therapy prolongs the life of exposed pulp or pulp with only a thin layer of dentin covering it by applying material to the vulnerable pulp for strengthening the hard-tissue barrier.[3] Direct pulp capping is used when the pulp is obviously visible owing to trauma, caries or iatrogenic damage, e.g., exposure during tooth preparation or caries treatment procedures.[4] Pulp capping materials should have certain features, e.g., radiopacity, insolubility, dimensional stability, biocompatibility, bioactivity, and appropriate adhesiveness to the dentin and the restorative materials.[5,6] The most commonly used elements are mineral trioxide aggregate (MTA), tricalcium silicate cement (Biodentine), and calcium hydroxide (CH).[7]

A calcium-based silicate material called Biodentine is utilized to repair root perforations and rebuild dentine in big cavities or lesions.[8] Biodentine has exceptional mechanical properties, exceptional biocompatibility, and bioactive behavior in contrast to other materials. It also sets in around 12 minutes. Additionally, it doesn't discolor teeth.[9]

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One of the successful therapeutic outcomes of direct pulp capping is the reduction of the visual analogue scale (VAS)-based human pulpal pain response, which is the same and comparable across various drugs.[10,11] A comparative study by Bokhari SS et al[10] involving 100 subjects aged between 19-50 years showed 4 (8.0%) patients out of 50 reported pain based on human pulpal pain response using VAS on the first day of pulp capping with Biodentine while 46 (92.0%) reported no pain, as compared to 3 (6%) out of 50 in the MTA group. There was no larger difference between the groups (> 0.05).[10]

There is a paucity of data on clinical outcomes for Biodentine alone as a direct pulp capping material in the Pakistani population in terms of human pulpal pain response based on VAS. Biodentine is comparable to MTA in clinical outcomes but has better mechanical properties.[9-11] This study can help inform clinicians whether to select Biodentine for direct pulp capping in reversible pulpitis in terms of simple clinical outcomes such as VAS. Biodentine can decrease the need for complex treatments, improving patient outcomes while reducing healthcare costs.

METHODS

This longitudinal observational study was conducted at Department of Operative Dentistry, Ibn-e-Siena Hospital Multan after approval from ethics review committee (ERC# C-60-1011-01, dated: 13th June 2023) over a period of 6-months from 25th July 2023 to 24th January 2024. A total of 114 patients aged 18-55 years, either male or female gender with reversible pulpitis in any of the permanent, vital teeth (on electric pulp test) without any periapical pathology on radiographs were included through consecutive sampling after informed consent. Patients with uncontrolled pulpal bleeding, internal resorption or pulp calcifications, developmental anomalies of teeth i.e. talons cusp, dens invaginatus, enamel pearls, gemination and handicapped patients were excluded from the study.

Age (year), gender, pre- and post-operative pain score and severity on VAS were recorded. Efficacy was determined after 24-hours of direct pulp capping. Reversible pulpitis was defined as pulp pain of short duration, typically intermittent and brief discomfort initiated by a hot, cold, or sweet stimulus that relieves after removal of stimulus. Pain was assessed using visual analogue scale and classified into mild pain (1 to 4), moderate pain (5 to 7), and severe pain (8 to 10). Direct pulp capping was deemed efficacious if there was no pain (VAS=0) after 24-hours of procedure. In all participants local anaesthesia was administered and tooth isolation was achieved through rubber dam. Caries was completely removed, and cavity was prepared through high-speed handpiece using sterile diamond round bur or spoon excavator. Bleeding was controlled with normal saline moistened cotton pellets. Biodentine was applied at exposure site and final restoration was done with resin composite. Post-operative radiograph was taken in all patients.

A sample size of 114 patients was calculated through OpenEpi online software using formula for single proportion and taking 95% confidence level, 5% margin of error, and efficacy after direct pulp capping with Biodentine as 92%.[10] Statistical Package for social sciences (SPSS) version 23 was used for data analysis. Mean ± SD (median and IQR for non-normal data) were calculated for numerical data and frequency percentages for categorical data. Factors related with efficacy of direct pulp capping were assessed through Fischer's exact test at 5% significance level.

RESULTS

The mean age of the participants was 27.4 ± 9.3 years and 57% (n=65) were 25-years or above. Males constituted 57% (n=65) of the study group. Pre-operative median pain score on Visual analogue scale was 3 (2 – 4) and 76.3% (n=87) were having mild pain [Table-I].

Only 10.5% (n=12) patients felt pain twenty-four hours after direct pulp capping and pain was mild in 11 (91.7%) of these patients. The efficacy of direct pulp capping was 89.5% (n=102) after 24-hours of procedure [Table-II].

Efficacy of direct pulp capping was significantly higher in patients ≤25-years compared to >

25-years (98.5% vs. 77.6%, p-value < 0.001) and in patients with mild to moderate pain compared to severe pre-operative pain (98.9%, 65% vs. 42.9% respectively, p < 0.001) [Table-III].

Age (years), mean ± SD	27.4 ± 9.3
Age Groups ≤ 25-years > 25-years	 65 (57) 49 (43)
Gender Male Female	 65 (57) 49 (43)
Pre-operative pain on VAS, Median (IQR)	3 (2 – 4)
Pre-operative Pain Severity Mild Moderate Severe	 87 (76.3) 20 (17.5) 7 (6.1)

Table-I. Characteristics of patients presenting with reversible pulpitis (N=114)

Post-operative Pain Yes No	 12 (10.5) 102 (89.5)
Post-operative Pain Score on VAS, median (IQR)	0.0 (0)
Post-operative Pain Severity (n=12) Mild Moderate	 11 (91.7) 01 (8.3)
Efficacy of direct pulp-capping Yes No	 102 (89.5) 12 (10.5)

Table-II. Outcomes of Direct pulp-capping in patients presenting with reversible pulpitis (N=114)

Factors Affecting Efficacy		Efficacy of Direct Pulp Capping		P-Value*
		Yes	No	
Age	≤ 25-years	64 (98.5)	1 (1.5)	< 0.001
	> 25-years	38 (77.6)	11 (22.4)	
Gender Male		56 (86.2)	9 (13.8)	0.228
	Female	46 (93.9)	3 (6.1)	
Pre-operative Pain Severity	Mild	86 (98.9)	1 (1.1)	< 0.001
	Moderate	13 (65)	7 (35)	
	Severe	3 (42.9)	4 (57.1)	

Table-III. Factors affecting the efficacy of direct pulp capping in patients presenting with reversible pulpitis (N=114)
***Fischer's exact test**

DISCUSSION

The goal of vital pulp therapy is to preserve pulp tissue that has been damaged but not completely destroyed by trauma, caries, or restorative operations in a healthy condition.[12] Since the existence of vital pulp tissue is a prerequisite for this procedure, it should only be performed on teeth that have reversible pulpitis.

Accurately assessing the pulp's condition, however, becomes difficult. Sensitivity tests and clinical signs and symptoms are not reliable indicators of pulp health. Therefore, in vital pulp therapy, maintaining the healthy pulp tissues and removing the unhealthy part results in the best possible therapeutic outcome.[13] The efficacy of vital pulp therapy is also greatly influenced by the choice of dressing material. When it comes to important pulp therapy, calcium hydroxide has long been regarded as the "gold standard.

Direct pulp capping with CH had variable success rates, from 31.8% after 1 year to 72.7% after 10 years.[14,15] However, this material's drawbacks include inadequate dentin bonding, material resorptions, tunnel defects, and mechanical instability, which means that calcium hydroxide does not prevent micro leakage over time. Furthermore, the pulp tissue's surface develops liquefaction necrosis due to the increased pH (12.5) of calcium hydroxide suspensions.[16]

In recent years, biodentine, a novel cement based on tricalcium silicate (3CaO·SiO2) and marketed as a "bioactive dentine substitute," has gained popularity and been recommended for use in pulp capping treatments. According to studies, biodentine promotes the regeneration of hard tissue and prevents pulp from forming.[16] In their work, Nowicka et al found that full dentinal bridge building occurred without an inflammatory pulp reaction when Biodentine was utilized as a pulp capping material. Additionally, it was discovered that tubular dentin was formed beneath the osteodentin by carefully placed layers of odontoblast-like cells.[17]

In our study, we observed that only 10.5% patients felt pain twenty-four hours after direct

pulp capping. The efficacy of direct pulp capping with Biodentine, was 89.5% after 24-hours of procedure and it was significantly higher in patients ≤25-years.

Our results are comparable with those by Lipski M et al. They found that Biodentine had an overall effectiveness rate of 82.6%. The pulpal survival rate was significantly influenced only by age: the success rate was 73.8% for patients aged 40 and above and 90.9% for those under 40 (P = 0.0480).[18] In several experiments, the ability of Biodentine, MTA, and CH (calcium hydroxide) to directly cap exposed pulp in animals was assessed. They reported positive outcomes while using Biodentine for direct pulp capping.[19,20]

The results of direct pulp capping with MTA and Biodentine in mature permanent teeth with carious exposures were examined in a study by Linu et al. This study demonstrated that the success rates of MTA and Biodentine (with a follow-up period of 18 months following therapy) were 84.6% and 92.3%, respectively. Radiographic results showed evident dentine bridge development in 69.2% and 61.5% of cases where MTA and Biodentine were used.[21] Hegde et al reported similar findings. They stated that the success rates for Biodentine and MTA were 91.7% and 83.3%, respectively, over a 6-month period.[22] Their results are consistent with our findings.

Awawdeh et al assessed the therapeutic efficacy of white MTA and biodentine in individuals aged 16 to 51 whose mature permanent teeth had carious exposure. During three years of follow-up, they found that when utilized as pulp capping materials, Biodentine and MTA exhibited comparable survival probabilities (Biodentine = 91.7% and MTA = 96.0%).[23] The effectiveness of Biodentine and MTA for direct pulp capping in young permanent molar teeth (children between the ages of 7 and 9) was compared by Katge and Patil. Based on clinical and radiographic characteristics, the trial showed 100% effectiveness with both Biodentine and MTA at follow-up after 1 year.[24]

As the pulp's reaction may be hampered by bacterial contamination and inflammation from developing caries, direct pulp capping is unpredictable when used after exposures to carious pulp. However, it has been noted that the method and materials used determine the success rates of direct pulp capping following severe exposures.

The qualities of Biodentine are significantly affected by the absence of bismuth oxide; MTA contains bismuth oxide, which is known to cause discoloration, delay setting, and negatively affect biocompatibility.[25] The fact that the patient must be called back for another visit, the high expense, and the inconvenience of combining two different components are some of the disadvantages of Biodentine.

CONCLUSION

Biodentine is a promising product. With its greater efficacy, it has the potential of producing major contribution to preserve pulp tissue in cases judiciously chosen for direct pulp capping. To increase our understanding and reach a firm conclusion about Biodentine, more extensive in vivo research with a bigger sample size and appropriate clinical settings is necessary.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Qurat Ul Ain:** Conceived the idea, data collection, manuscript writing.
2	**Sheeza Manan:** Critical analysis, data collection,
3	**Ambreen Azad:** Data collection and analysis.
4	**Sharina Naz:** Proof reading, drafting, final approval.
5	**Mustafa Sajid:** Data analysis, proof reading.