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Review Article

Pulpotomy in primary teeth: Biodentine™ versus calcium hydroxide. A systematic review and meta-analysis

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ABSTRACT

Introduction: Pulpotomy is the total amputation of coronal pulp tissue and subsequent placement of a pulpotomy agent over the root canal orifices, followed by a coronal seal. The most suitable pulpotomy agent for successful treatment outcomes remains controversial.

Objectives: To evaluate and compare the clinical and radiographic success of calcium hydroxide (CH) and Biodentine (BD) in primary tooth pulpotomy at 6 and 12 months.

Materials and methods: An automated search of the PubMed-Medline, Web of Science, and SCOPUS electronic databases was performed to identify scientific articles on primary tooth pulpotomies with either calcium hydroxide (CH) or Biodentine (BD) as a pulpotomy agent, published until January 2024. The software used for meta-analysis was R 4.3.1 (R Core Team, 2023).

Results: Of the 594 potentially eligible articles, 14 met the inclusion criteria: seven articles on CH pulpotomy and seven articles on BD pulpotomy with 6- and 12-months of follow-up. The meta-analysis concluded a mean clinical success rate of 91.8 % at 6 months and 79.0 % at 12 months for the CH group, and 99.2 % at 6 months and 98.8 % at 12 months for the BD group. In terms of the mean radiographic success, the CH group achieved 74.2 % at 6 months and 63.7 % at 12 months, whereas the BD group achieved 99.4 % at 6 months and 98.4 % at 12 months. In comparison, the meta-analysis concluded a marginally significant difference in clinical success in favour of the BD group at 6 months ($p = 0.091$). At 12 months, clinical success was significant in the BD group ($p = 0.023$). Regarding radiographic success, a significant difference in favour of the BD group was observed at 6 ($p = 0.008$) and 12 months ($p < 0.001$).

Conclusion: BD showed significantly higher clinical and radiographic success than CH in pulpotomy.

1. Introduction

Dental caries is still considered a highly prevalent health problem in children worldwide, mainly due to the lack of education and dental care, as well as its symptomatology, which usually goes unnoticed for a large part of its evolution. Symptoms often appear only in the advanced stages of disease progression, frequently leading to deep carious lesions and pulpal affectation (Igna, 2021). Vital pulp therapy (VPT) is a minimally invasive endodontic approach aimed at preserving vital pulp tissue by aiding in the healing and regeneration of the dentin-pulp complex of compromised teeth and maintaining their vitality (Asgary et al., 2018).

In contrast to extraction of primary teeth with pulp exposure, conservation of primary teeth with VPT presents the advantages of lowering the incidence of pain, infection, arch length loss, and subsequent crowding (Ní Chaollaí et al., 2009). Pulpotomy is widely considered to be the most indicated VPT in primary dentition (Guo et al., 2022). Pulpotomy preserves radicular pulp vitality through total amputation of the coronal pulp tissue and subsequent placement of a pulpotomy agent or medicament over the root canal orifices, followed by coronal restoration (Lin et al. 2014; Tewari et al., 2022), taking advantage of the healing capacity of the remaining pulp tissue (Igna, 2021). Calcium hydroxide (CH) is a bactericidal, regenerative, and highly biocompatible

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pulpotomy agent option (Kaya et al., 2022); however, success rates in primary tooth pulpotomy vary greatly and generally decrease over time compared with other pulpotomy agents (Huth et al., 2012; Kalaskar and Damle, 2004; Oliveira et al., 2013). Internal resorption is the most common complication (Schröder, 1978; Waterhouse et al., 2000). Septodont's Biodentine (BD), a next generation tricalcium silicate-based cement, is an exciting alternative for primary tooth pulpotomy, with promising results (Carti and Oznurhan, 2017; El Meligy and Alamoudi, 2016; Mythraiye et al., 2019). Its rapid setting time, antimicrobial activity, and bioactive properties make it a suitable dentin substitute for various endodontic purposes (Wang et al., 2021; Zafar et al., 2020).

With recent concerns about the safety of formocresol (FC) as a pulpotomy agent, despite its proven success, there are now fewer choices of successful pulpotomy agents. The aim of this systematic review and meta-analysis was to determine the clinical and radiographic success rates, at 6 and 12 months of follow-up, of a classic pulpotomy agent with regenerative properties (CH) and a next generation tricalcium silicate-based cement with bioactive properties (BD). The results of the comparison would identify a pulpotomy agent that presents a high degree of success and can be used as an alternative to FC in primary tooth pulpotomy. Additionally, this study aimed to guide professionals from transitioning from established to emerging materials and educate them about the advances made in the development of dental biomaterials.

2. Hypothesis

H0: The null hypothesis of this systematic review and meta-analysis is that Biodentine (BD) has similar clinical and radiographic success rates as Calcium hydroxide (CH) in primary tooth pulpotomy.

H1: The working hypothesis of this systematic review and meta-analysis was that Biodentine (BD) presents higher clinical and radiographic success rates than calcium hydroxide (CH) in primary tooth pulpotomy.

3. Objectives

3.1. General objective

To evaluate the clinical and radiographic success rates of Biodentine (BD) and Calcium hydroxide (CH) in primary tooth pulpotomies.

3.2. Specific objective

To evaluate whether Biodentine (BD) has higher clinical and radiographic success rates than Calcium hydroxide (CH) in primary tooth pulpotomy at 6 and 12 months of follow-up.

4. Materials and methods

This systematic review and meta-analysis was performed according to the PRISMA statement 2020 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) (Page et al., 2021).

The PubMed-Medline, Web of Science, and SCOPUS databases were searched for scientific articles published until January of 2024 on pulpotomies that were performed on primary teeth with CH versus BD as a pulpotomy agent to answer the following question: "In patients undergoing pulpotomy in primary teeth, does Biodentine provide a higher clinical and radiographic success rate than calcium hydroxide as a pulpotomy agent?".

The research questions were established according to the guidelines for the structured PICOS question. The format of the questions was as follows:

- P (population): Patients undergoing pulpotomy in primary teeth
- I (intervention): Biodentine as pulpotomy agent
- C (comparison): Calcium hydroxide as pulpotomy agent

- O (outcome): Clinical and radiographic success rate in pulpotomy
- S (statistical analysis): Forest graphs were plotted to visualise the results with 95 % confidence intervals. Cochran's Q test was used for heterogeneity analysis. The I^2 index was calculated to represent the amount of between-study variability compared to the total variability. Funnel graphs were generated to explore potential publication bias. Egger's test was performed to measure the impact of this type of bias. The significance level was set at 5 % ($\alpha = 0.05$). The software used was R 4.3.1 (R Core Team, 2023).

4.1. Eligibility criteria

The inclusion criteria were the following:

- **Type of study:** Randomised controlled clinical trials, controlled trials, non-controlled trials, prospective and retrospective cohort studies, and case series; in vivo studies on human teeth; publications in English, Spanish, and German; published until January 2024.
- **Type of patient:** Patients undergoing pulpotomy in primary teeth, aged 3–9 years.
- **Type of intervention:** Complete pulpotomy treatment was performed with BD or CH as a pulpotomy agent.
- **Type of variables of results:** Studies that provided data related to the clinical and radiographic success rates of the pulpotomy agents under investigation at 6 and 12 months of follow-up.

The exclusion criteria were the following:

- Systematic reviews, case reports, in vitro studies, animal experimental studies, and studies investigating the outcomes of partial primary tooth pulpotomy or permanent tooth pulpotomy were excluded.

4.2. Sources of information and search strategy

An automatised search of PubMed-Medline, Web of Science and Scopus was carried out using the following key words: "calcium hydroxide," "biodentine," "pulpotomy," and "primary teeth." These keywords were combined with the boolean operators AND and OR, as well as the controlled terms ("MeSH" for the Pubmed-Medline search) to facilitate the search for the best and widest spectrum of results.

The search in **Pubmed-Medline** was carried out as follows: (("calcium hydroxide"[MeSH Terms] OR ("calcium"[All Fields] AND "hydroxide"[All Fields]) OR "calcium hydroxide"[All Fields] OR ("tricalcium silicate"[Supplementary Concept] OR "tricalcium silicate"[All Fields] OR "biodentine"[All Fields])) AND ("pulpotomy"[MeSH Terms] OR "pulpotomy"[All Fields] OR "pulpotomies"[All Fields]) AND ("tooth, deciduous"[MeSH Terms] OR ("tooth"[All Fields] AND "deciduous"[All Fields]) OR "deciduous tooth"[All Fields] OR ("primary"[All Fields] AND "teeth"[All Fields]) OR "primary teeth"[All Fields])) AND (english[Filter] OR german[Filter] OR spanish[Filter]).

The search in **Scopus** was carried out as follows: TITLE-ABS-KEY (((calcium AND hydroxide) OR (biodentine)) AND (pulpotomy)) AND (primary AND teeth)) AND (LIMIT-TO (LANGUAGE, "English")) OR LIMIT-TO (LANGUAGE, "German") OR LIMIT-TO (LANGUAGE, "Spanish").

The search in **Web of Science** was carried out as follows: (((TS = (calcium hydroxide)) OR TS = (Biodentine)) AND TS = (pulpotomy)) AND TS = (primary teeth) and English or German (Languages).

4.3. Study selection process

Study selection was performed in three stages by two reviewers (ML and SMR). In the first stage, articles were filtered according to their titles to eliminate irrelevant publications. In the second stage, abstracts were

screened and selected according to study type, pulpotomy agent, and outcome variables. The third stage was carried out by screening the remaining articles by reading the full text and subsequently applying the eligibility criteria. Articles that did not meet the inclusion criteria were excluded. The remaining articles were included in this systematic review and meta-analysis.

When disagreements arose between reviewers regarding the inclusion or exclusion of articles, discussions were held to resolve them. The degree of inter-examiner agreement regarding the final inclusion/exclusion of articles was obtained using Cohen's kappa test, following the scale proposed by Landis and Koch (1977). The inter-examiner agreement was considered almost perfect ($\kappa = 0.87$).

4.4. Data extraction

The following data were extracted from the articles and arranged in tables: author's name, year of publication, type of study (randomised controlled clinical trials, controlled trials, and non-controlled trials), sample size (total number of teeth treated in the respective studies at each follow-up time point), type of treatment (pulpotomy agents used in the respective studies), clinical success rate (percentage after 6 and 12 months of follow-up), and radiographic success rate (percentage after 6 and 12 months of follow-up).

4.5. Quality assessment

The risk of bias was assessed by two reviewers (MNL and SMR) to analyse the quality of the included articles.

The procedure outlined in the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0, 2011 was used to assess the quality of the randomised controlled clinical trials (<https://training.cochrane.org/handbook/archive/v5.1/>). Studies that met all criteria proposed in the handbook were deemed to have a "low risk of bias." If one or more criteria were not met, the studies were considered "high risk of bias," since this indicated the possibility of the results of the study being unreliable. An "unclear risk of bias" was concluded when there was a lack of information provided by the study or uncertainty regarding the potential bias.

4.6. Data synthesis

To present the results of the different studies for comparison of the success of the two different pulpotomy agents under investigation, the data of the general variables were grouped according to the study group (Biodentine group/calcium hydroxide group). As the studies included in this systematic review were selected based on the homogeneity of their results (presence of 6 and 12 months of follow-up periods for clinical and radiographic success rate evaluations), representative results regarding the two different pulpotomy agents under investigation were obtained.

To carry out the meta-analysis, data on the general variables of only the two pulpotomy agents under investigation were extracted from the selected articles. Each group was assessed in terms of the number of teeth, mean values, and standard deviations.

The following meta-analysis was conducted for each condition (clinical 6 m, X-Ray 6 m, clinical 12 m, X-Ray 12 m):

1. A random-effects model was used to estimate the overall effect measure (raw success rate) for each group (BD and CH). A restricted maximum likelihood estimator of heterogeneity was used.
2. A mixed-effects model (meta-regression) with the moderator variable 'type of material' was used for comparison between the BD and CH groups

Forest graphs were plotted to visualise the results with 95 % confidence intervals. Cochran's Q test was used for the heterogeneity analysis. The I^2 index was also calculated, representing the amount of

between-study variability compared to total variability. Funnel graphs were used to explore potential publication biases. The Egger's test was performed to measure the impact of this type of bias.

The significance level was set at 5 % ($\alpha = 0.05$).

The software used was R 4.3.1 (R Core Team, 2023). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>.

5. Results

A total of 594 articles were obtained from the initial search of PubMed-Medline ($n = 206$), SCOPUS ($n = 208$), and Web of Science ($n = 180$). Among them, 36 were identified as potentially eligible studies after eliminating duplicates and screening by title and abstract. Full-text articles were retrieved and thoroughly evaluated. As a result, 14 articles met the inclusion criteria and were therefore included in this systematic review and meta-analysis (Fig. 1). Of the 14 included, 7 articles provided clinical and radiographic success rates of CH pulpotomy (Alaçam et al., 2009; Costa e Silva et al., 2019; Kaya et al., 2022; Moretti et al., 2008; Odabaş et al., 2011; Uddin et al., 2013; Yildiz and Tosun, 2014) and 7 articles of BD pulpotomy (Bani et al., 2017; Chotitanmapong et al., 2019; Cuadros-Fernández et al., 2016; El Meligy et al., 2019; Eshghi et al., 2022; Guang et al., 2022; Nasrallah et al., 2018) at 6 and 12 months of follow-up. A total of 468 teeth underwent pulpotomy: 183 with CH as pulpotomy agent, 285 with BD as pulpotomy agent.

The Egger's test was performed to assess the potential publication bias of the articles included in the meta-analysis. Egger's test outcomes for CH pulpotomy articles are shown in Fig. 2. Note that the plot suggests relative asymmetry owing to fewer papers in the bottom-right area. It is suggested that this is caused, to some extent, by the fact that the standard errors (SE) for binomial distributions depend on the mean proportion. Therefore, the closer the rate is to 100 %, the lower the estimation of the SE. To correct for this effect, Egger's test was calculated against the sample size instead of SE, with $p = 0.335$. No publication bias was identified. Egger's test outcomes for BD pulpotomy articles are shown in Fig. 3. This plot suggests a high degree of symmetry. Egger's test showed $p = 0.664$. This indicated the absence of publication bias. In the assessment of methodological quality and risk of bias, according to the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0, 2011, for the randomized controlled trials, a low risk of bias was assumed in 3 studies, while for 9 studies, an unclear risk was concluded. In the remaining two studies, a high risk of bias was observed owing to the absence of randomisation.

The meta-analysis concluded the mean clinical success rate at 6 months was 91.8 ± 4.2 % for the CH group and 99.2 ± 0.8 % for the BD group. Mean radiographic success rate at 6 months was concluded at 74.2 ± 8.0 % for the CH group and 99.4 ± 0.8 % for the BD group. Mean clinical success rate at 12 months was 79.0 ± 8.9 % for the CH group and 98.8 ± 0.8 % for the BD group (Fig. 4). Mean radiographic success rate at 12 months was 63.7 ± 9.8 % for the CH group and 98.4 ± 11.0 % for the BD group. Further details of the results of the meta-analysis are presented in Table 1, and the results of the meta-regression of the success rate by group are shown in Table 2.

6. Discussion

With respect to the clinical success at 6 months of the pulpotomy agents under investigation, the results of this systematic review and meta-analysis revealed that BD was a more successful pulpotomy agent. An estimated + 3.21 % higher success rate was observed using BD compared to CH. This result was considered marginally significant ($p = 0.091$). Regarding radiographic success at six months, BD proved to be a more successful pulpotomy agent. An estimated + 20.6 % higher success rate was observed using BD compared to CH. This result was considered statistically significant ($p = 0.008$). Assessing clinical success at 12 months, the results of this systematic review and meta-analysis revealed

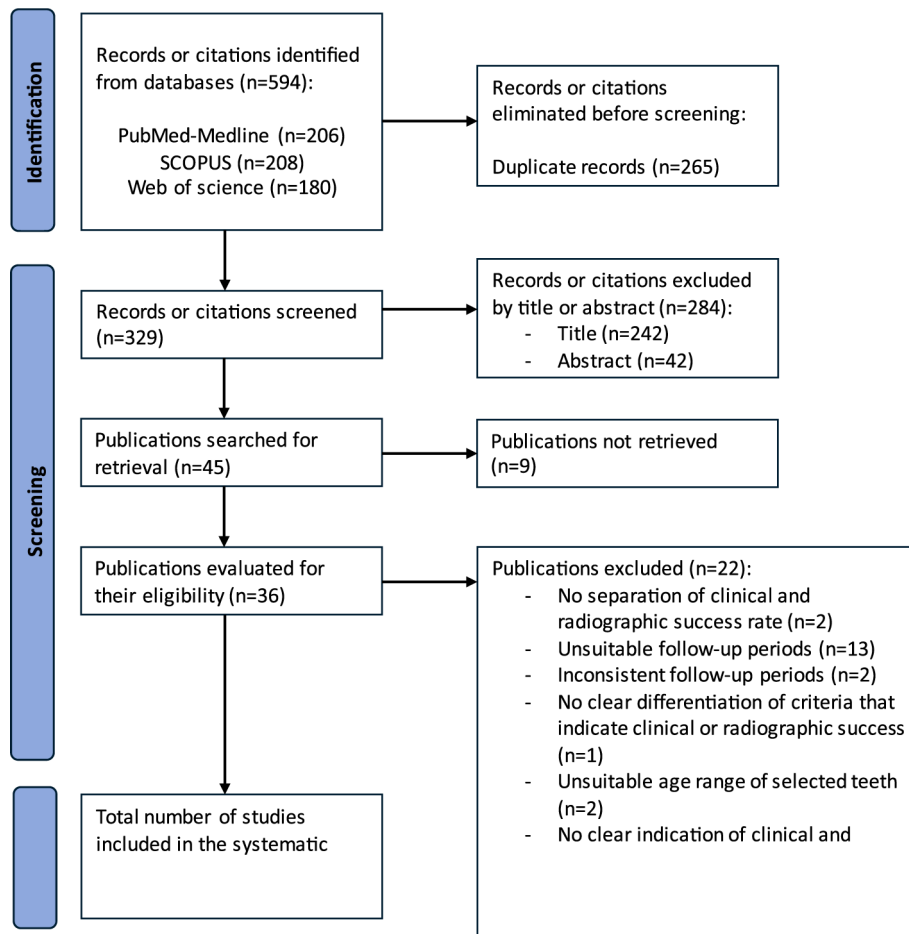


Fig. 1. Flow-chart of search and title selection process during the systematic review and meta-analysis.

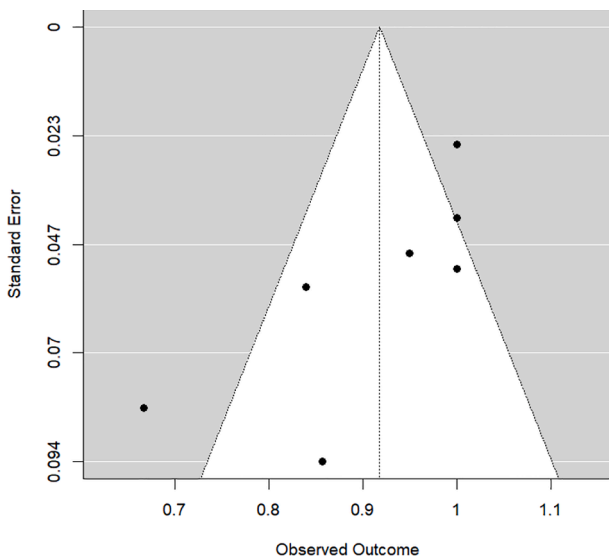


Fig. 2. Funnel plot of Egger's test calculated against standard error (SE) – CH articles.

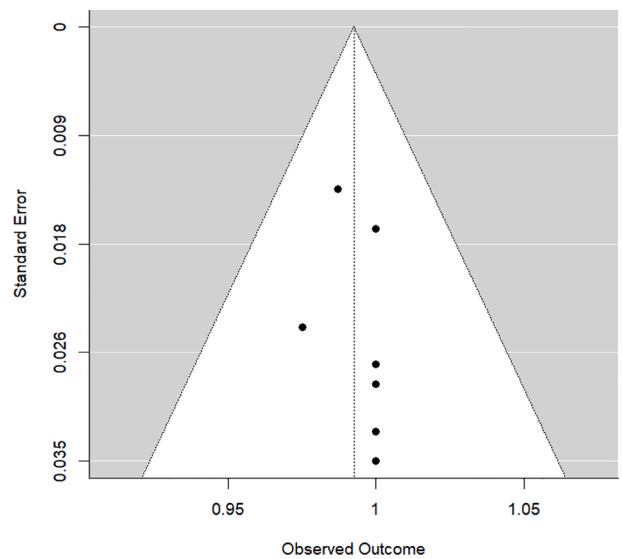


Fig. 3. Funnel plot of Egger's test calculated against standard error (SE) – BD articles.

that BD was the most successful pulpotomy agent. An estimated + 18.3 % higher success rate was observed using BD compared to CH. This result was considered statistically significant ($p = 0.023$). Regarding radiographic success at 12 months, BD proved to be a more successful pulpotomy agent. An estimated + 31.8 % higher success rate was

observed using BD compared to CH. This result was considered statistically significant ($p < 0.001$).

This systematic review and meta-analysis is in agreement with other systematic reviews on the success of BD as a pulpotomy agent for primary teeth. [Nagendrababu et al. \(2019\)](#) and [Stringhini Junior et al.](#)

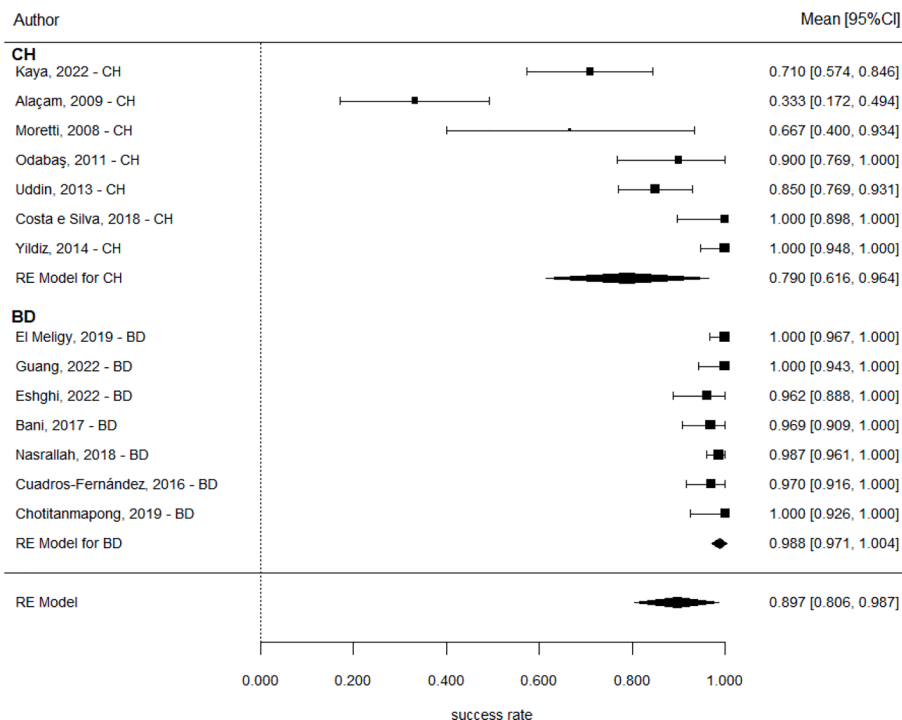


Fig. 4. Forest plot of meta-analysis results of clinical success of CH vs. BD at 12 months.

Table 1

Results of meta-analysis of the **Success rate in the CH and BD group**: mean raw proportion, standard error (SE), 95% confidence interval, z test (p-value), I² index, Cochran's Q statistic (p-value) for heterogeneity; Egger's test (p-value) for publication bias.

CS/RS-Month (Group)	Rate	SE	95 % CI	z (p-value)	I ²	Q _H (p-value)	Egger (p-value)
CS-6 (CH)	0.918	0.042	0.835 1.001	<0.001***	80.1 %	<0.001***	0.335
CS-6 (BD)	0.992	0.008	0.977 1.008	<0.001***	0.0 %	0.979	0.664
RS-6 (CH)	0.742	0.080	0.858 0.900	<0.001***	89.6 %	<0.001***	0.612
RS-6 (BD)	0.994	0.008	0.978 1.010	<0.001***	0.07 %	0.188	0.202
CS-12 (CH)	0.790	0.089	0.616 0.964	<0.001***	94.7 %	<0.001***	0.456
CS-12 (BD)	0.988	0.008	0.971 1.004	<0.001***	0.0 %	0.911	0.789
RS-12 (CH)	0.637	0.098	0.444 0.830	<0.001***	90.2 %	<0.001***	0.611
RS-12 (BD)	0.984	0.011	0.963 1.001	<0.001***	15.9 %	0.386	0.037*

CS, Clinical success; RS, Radiographic success.

*p < 0.05.

**p < 0.01.

***p < 0.001.

(2019), who analysed the clinical and radiographic success rates of MTA and BD, found no statistically significant differences between the MTA and BD groups, and indicated a high success rate for both materials over 6 and 12 months of follow-up. Regarding the success of using CH as a pulpotomy agent in primary teeth, the present results are in concordance with those of other systematic reviews, indicating that other pulpotomy agents present more successes/fewer failures than CH. Shirvani et al. (2014), who analysed the clinical and radiographic success rates of MTA compared to CH, found statistically significant differences at 6 and 12 months in favour of the MTA and CH groups. Similarly, Smail-Faugeron et al. (2018) who compared, among others, the clinical and radiological failure of CH and MTA as well as CH and FC, concluded statistically significant differences at 12 months in favour of the MTA and FC groups and against the CH group. A retrospective study conducted by Caruso et al. (2018) evaluated the clinical and radiographic success of BD versus CH at 9 and 18 months of follow-up and concluded that BD had significantly higher clinical and radiographic success. These results are consistent with the findings of the present systematic review and meta-analysis. One explanation for the lower success rate of CH in primary tooth pulpotomy could be the reported prevalence of internal resorption

in CH pulpotomies (Liu et al., 2011; Moretti et al., 2008; Oliveira et al., 2013). Although internal resorption is the most frequent complication of primary tooth pulpotomy with CH (Schröder, 1978), it is frequently considered a sign of radiographic failure (Costa e Silva et al., 2019; El Meligy et al., 2019; Eshghi et al., 2022). The reason why internal resorption occurs could be attributed to the intense inflammatory responses caused by the high alkaline pH of CH, which triggers macrophage fusion and their subsequent transformation into odontoclasts (Ravi and Subramanyam, 2012). However, Moretti et al. (2008) and Oliveira et al. (2013) observed that most of the teeth in the CH group that presented with internal resorption progressed continually, leading to osseous changes, clinical signs, and symptoms, and ultimately to clinical failure. Other variables that could influence the success of CH pulpotomies are chronic inflammation present in the residual pulp tissue at the time of treatment and haemorrhage control, which can negatively affect the frequency of histologically complete healing due to lack of contact between CH and the vital pulp tissue (Schröder, 1978). However, this level of haemorrhage control is difficult to attain because the manipulation of vital tissues inevitably leads to haemorrhage and exudation (Waterhouse et al., 2000). Even though CH can produce

Table 2

Results of meta-regression of the **Success rate by Group**: Beta coefficient, standard error (SE), 95% confidence interval, z test (p-value), R^2 index.

CS/RS-Month Group	Beta	SE	p-value	95 %CI Beta	R^2	Egger (p-value)
CS-6 CH (ref.)	0					
BD	0.032	0.019	0.091	-0.005 0.0681	20.0 %	0.517
RS-6 CH (ref.)	0					
BD	0.206	0.078	0.008**	0.054 0.358	35.9 %	0.878
CS-12 CH (ref.)	0					
BD	0.183	0.080	0.023*	0.025 0.340	27.0 %	0.614
RS-12 CH (ref.)	0					
BD	0.318	0.090	<0.001***	0.143 0.494	53.4 %	0.936

CS, Clinical success; RS, Radiographic success.

* $p < 0.05$.

** $p < 0.01$.

*** $p < 0.001$.

favourable results, at short-term periods of up to 12 months, as indicated by Costa e Silva et al. (2019) and Yildiz and Tosun (2014), this meta-analysis clearly indicates the inferiority of CH as primary teeth pulpotomy agent, especially with the success of tricalcium silicate-based cement. Additionally, it must be pointed out that the success of the CH pulpotomies notably decreases with time, both in terms of clinical and radiographic success. This leads to the assumption that in pulpotomies requiring success over a longer period of time, for instance, in younger age groups with longer timeframes until the eruption of the permanent successor, CH should not be recommended as a pulpotomy agent. In contrast, BD provided stable success rates in terms of clinical and radiographic success over time, suggesting its use in pulpotomies that require longer timeframes to facilitate favourable eruption. Further high-quality randomised controlled trials (RCTs) comparing BD with other pulpotomy agents are required to confirm these results.

Since all the studies included in this meta-analysis compared either one or the other pulpotomy agents under investigation, the lack of studies comparing the success of both CH and BD as pulpotomy agents in primary teeth could be identified as a limitation of the present meta-analysis, indicating the need for future high-quality RCTs comparing CH and BD in primary tooth pulpotomy to confirm the evidence. Another limitation of the present meta-analysis was the high level of heterogeneity in the results between studies investigating CH pulpotomy (Table 1, Q_H (p-value)). While no individual paper contributed in excess to the overall heterogeneity with respect to radiographic success, the study conducted by Alaçam et al. (2009), stood out as the most heterogeneous paper, in terms of 6- and 12-months clinical success results, compared to the others. A possible explanation for the high degree of heterogeneity in their results could be that Alaçam et al. based their results on pulpotomies conducted by 5th year undergraduate students, with only the supervision of senior staff. A lack of clinical expertise on the part of the dental students, as well as the lack of intervention possibilities for the senior staff in the pulpotomy procedure, could introduce a higher risk of error compared with the rest of the studies, which were conducted by experienced dental professionals only. Therefore, we acknowledge that the results of the present meta-analysis regarding the success of CH as a pulpotomy agent in primary teeth may be less

interpretable and expressive than anticipated. To address the between-study heterogeneity in the results of CH pulpotomies on primary teeth, high-quality RCTs with larger sample sizes are needed. This results in smaller error margins and more interpretable results. All results between the studies investigating BD pulpotomy showed low levels of heterogeneity to absolute homogeneity (Table 1 – Q_H (p-value)), leading to the assumption of a high degree of expressiveness of the meta-analysis results concerning BD pulpotomy.

7. Conclusion

7.1. General conclusion

Both calcium hydroxide (CH) and Biodentine (BD) showed the possibility of producing high rates of clinical and radiographic success.

7.2. Specific conclusions

The use of BD as a pulpotomy agent in primary teeth provided better clinical and radiographic success than CH at 6 and 12 months of follow-up.

- BD presented marginally higher clinical success than CH in primary tooth pulpotomy at 6 months ($p = 0.091$) and significantly higher clinical success at 12 months ($p = 0.008$) follow-up.
- BD presented significantly higher radiographic success than CH in primary tooth pulpotomy at 6 months ($p = 0.023$) and 12 months ($p < 0.001$) of follow-up.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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