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Success rate of Hall Technique for restoring carious primary molars - Systematic review and meta-analysis

Hall Technique for restoring carious primary molar

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Success rate of Hall Technique for restoring carious primary molars - Systematic review and meta-analysis

Abstract

Objectives: The overall pooled success rate of the Hall Technique (HT) in various types of studies has not been investigated. The present study aims to evaluate the success rate of HT to restore carious primary molars. **Methods:** A systematic search was carried out in the MEDLINE/PubMed, Excerpta Medica Database (EMBASE), Scopus, Web of Science, and LIVIVO electronic databases, as well as the ProQuest database for grey literature review. A search was carried out up to September 2023 for studies meeting the eligibility criteria: Randomised Clinical Trials (RCTs) and Non-Randomised Studies of Interventions (NRSIs); children with primary molars treated using HT; and reporting success for at least 1-month post-treatment. Single-arm meta-analysis assessed the pooled proportion (95% CI) of HT success rates. Risk of bias and certainty of evidence using the GRADE approach were assessed. **Results:** Searching identified 665 studies, with 25 (15 RCTs and 10 NRSIs) meeting the eligibility criteria. In meta-analyses of RCTs, the pooled proportion success rate was 98% (95%CI: 97-99%) at 12-month follow-up. For NRSIs, the pooled proportion success rate was 95% (95%CI: 91-100%) up to 89 months. **Conclusions:** HT presents a high success rate, even though the primary studies had “low” to “high” risk of bias and demonstrated “moderate” to “low” certainty of evidence. One of the main reasons for downgrading was related to blinding, which was generally unfeasible due to visibly different restorative materials. The systematic review protocol was registered in PROSPERO (ID: CRD42021204415).

Keywords: Paediatric Dentistry, Hall Technique, Cariology.

Introduction

Dental caries worldwide prevalence is 46.2% in primary teeth and 53.8% in permanent dentition in children¹, making it the 10th most common condition globally². This preventable, biofilm-mediated, lifestyle-driven disease harms children's health

and well-being³, impacting negatively on their quality of life, resulting in pain, early tooth loss along with impaired function, growth, esthetics^{4,5} and loss of time at school⁶.

The evidence suggests that employing less invasive techniques for cavitated, asymptomatic decayed primary teeth can decrease the risk of pulp exposure and restoration failure^{7,8}. Nevertheless, various restorative treatments exhibit a notable high failure rate^{9,11}. The success of treatment is influenced by factors such as the child's age, cognitive development, cooperation, caries risk, cavity size, number of surfaces, adaptation issues, moisture control, and the characteristics of the materials used¹²⁻¹⁴ thereby compromising treatment outcomes.

The **preformed metal crown (PMC)** is more durable and has a higher success rate than direct filling materials¹⁵⁻¹⁷. When used conventionally, they require local anaesthetics and rotary instruments to prepare the teeth and trim the crowns. The Hall Technique uses the advantages of **PMC** and builds on their high success rates¹⁸⁻²⁰ with no anaesthetic needed. The Hall Technique is **a non-invasive**, "child-friendly" technique suitable for restoring primary molars with occlusal or occlusoproximal lesions, without pulp involvement, which seals and inactivates the lesion, with no carious tissue removal¹⁸⁻²¹.

The available systematic reviews²²⁻²⁶ currently focus on evaluating different restorative materials or treatments for restoring caries lesions in children. However, the overall pooled success rate of the Hall Technique in various types of studies has not been investigated. Therefore, this systematic review with single-arm meta-analysis aimed to assess the success rate of **PMC** using the Hall Technique to restore carious primary molars and the certainty of the available evidence. The summary of success rates allows us to establish recommendations for the effective treatment of caries lesions using this technique and demonstrate to the dentists and care providers the advantages of implementing the Hall technique.

Methods

Protocol and Registration

This systematic review was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA Statement) guideline 2020²⁷. The study is registered in the PROSPERO database (International Prospective Registry of Systematic Reviews) with the registration number CRD42021204415. The

detailed protocol manuscript has been published in the Open Science Framework (OSF) platform as a preprint (DOI 10.31219/osf.io/fxvz7)²⁸.

Deviation from protocol

As per our research protocol, we had initially planned to exclude studies that reported less than 12 months of follow-up. However, during the screening process, we found that most reports did not provide a definitive follow-up time but rather reported a median follow-up based on the last visit of each participant, making it difficult to determine the exact follow-up time. Therefore, we revised this criterion to include studies reporting at least one month of follow-up. Another modification to our protocol was regarding the outcome measurement. As most studies did not report survival rates, we considered success rate as our primary outcome. Furthermore, we could not access the OpenGrey literature database as they had officially notified about their cessation of activity. Therefore, we used the ProQuest database as an alternative.

Information sources

A systematic search was carried out in the MEDLINE/PubMed, Excerpta Medica Database (EMBASE), Scopus, Web of Science, and LIVIVO electronic databases, as well as the ProQuest database for grey literature review. In addition, a manual search of the reference lists of selected studies was conducted to identify potentially eligible studies. The final search was completed on September 12th, 2023.

Search strategy

The PICO question used to develop the search strategies was: "What is the success rate of preformed metal crowns using the Hall Technique (HT) for primary molars?" (Participants: primary molars; Intervention: **PMC** using HT; Comparator: Not applied; Outcome: success rate).

Restorative treatment was deemed successful if the crowns were considered satisfactory and showed no signs or symptoms of pulpal pathology, did not require additional intervention after cementation, and the tooth exfoliated without failure²⁹. Minor failures were also considered successes. However, if the crown was lost or there were signs or symptoms of reversible or irreversible pulpitis after the crown was cemented, further treatment was required, it was considered a failure.

The search strategy was initially developed for MEDLINE/PubMed and was then adjusted for the other databases based on their specific syntax rules. SI Table 1 displays the search strategies for each database.

Eligibility criteria

Inclusion criteria:

- Clinical trials investigating the HT in children with carious primary molars;
- Randomised controlled trials (RCTs) and prospective/retrospective nonrandomised studies of interventions (NRSIs);
- Reporting success rates or where this data could be derived;
- At least one month of follow-up.

Exclusion criteria

- Explicitly reported including children without good general health;
- Included treating teeth with clinical or radiographic signs of pulp involvement, such as periapical lesions, swelling, abscess or non-physiological mobility associated with the decayed primary molar to be treated.

There were no restrictions on language or year of publication. The authors are proficient in English, Arabic, French and Portuguese. For articles in other languages DeepL Translate (<https://www.deepl.com/translator>) was used.

Study selection

The references found in the databases were uploaded to the online tool (<https://www.myendnoteweb.com>) to remove duplicates. The remaining articles were then exported to Rayyan software³⁰ for screening.

Potentially relevant studies were selected by two independent, blinded reviewers (CLG and GS), and in duplicate, previously trained and calibrated (Kappa = 0.80 with 92.4% agreement). Calibration was done using a 10% sample of the total identified articles, which were evaluated independently and discussed with a third reviewer to check the discrepancies.

Initially, the reviewers independently screened the titles and abstracts of articles based on the inclusion criteria. After this, the eligible full-text articles were retrieved

and reviewed against exclusion criteria. References without abstracts were evaluated at the full-text level. If there were any disagreements during the screening process, a third reviewer (DPR) was consulted for resolution. Whenever the data was incomplete or unclear, corresponding authors were contacted via email to request the necessary information to determine their eligibility for inclusion in the research. If no response was received, the corresponding authors were contacted three times.

Data extraction

The same reviewers conducted data extraction independently and in duplicate for the pre-specified items using standardised forms created in Microsoft Excel for Mac version 16.35. The following details were collected: publication information (author, year, country, study design), sample information (age of participants, the brand of PMC, the brand of glass ionomer cement, setting, operator qualification), methodological information (registration protocol, blinding, criteria used to assess success), and outcome information (number of successes, minor and major failures, success rate, follow-up).

Risk of bias of included studies

Two reviewers (TKT and TG) independently assessed the risk of bias in duplicate. RoB 2³¹ was employed to evaluate RCTs, focusing on five domains: the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. The overall risk of bias was rated based on the following criteria: low if all domains had a low risk, some concerns if there were concerns in one domain, and high risk if there were concerns in two or more domains or a high risk of bias.

ROBINS-I³² was employed to assess NRSIs, focusing on seven domains: confounding, participant selection, intervention classification, deviations from intended interventions, missing data, outcome measurement, and selection of the reported result. The overall bias rating was determined as low if all domains had a low risk, moderate if one domain had a moderate risk, and serious if two or more domains had a moderate or serious risk.

Statistical analyses and Data synthesis

The I^2 test was conducted to assess heterogeneity among the studies, and τ^2 test was used to estimate within-study variance. Subsequently, single-arm meta-analyses were performed to evaluate the cumulative proportion of success rates for the HT. Subgroup analyses were performed to investigate the impact of the risk of bias on the success rate - “low”, “some concerns” or “moderate”, and “high” risk of bias. In addition, sensitivity analyses were carried out to explore the possible influence of individual studies on the outcome estimates when moderate or high heterogeneity was present. Publication bias was investigated using visual analyses of funnel plot asymmetry and Begg’s test when there were ten or more studies.

The extracted data were analysed using the "meta", "metafor", "metaprop" and "metabias" packages in RStudio Team software (RStudio Team, 2022, Boston, MA). The overall proportion rate and corresponding 95% confidence intervals (95%CI) were then calculated.

Certainty of Evidence Assessment

We evaluated the certainty of evidence using the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach³³. This method assesses five key domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias. Additionally, for the evidence related to NRSIs, three supplementary domains were considered, including effect magnitude, dose-response gradient, and residual confounding. The certainty of evidence was evaluated using GRADEPro (McMaster University, ON, Canada) in collaboration with other assessors (CLG, TG, TKT, DPR). The evidence was adequately classified into four levels: high, moderate, low, and very low.

Results

Study selection

Database search yielded 1,428 potentially relevant articles. One additional reference was included as obtained through personal communication, giving 1,429 articles. After deduplication, 665 underwent title and abstract screening with 38 articles selected for full review. Subsequently, we excluded 13 articles for incorrect outcome

(n=3), article commentary/analysis (n=6), and were part of a more up-to-date included article (n=4) (SI Table 2). There were 25 articles included (Figure 1).

Description of studies

The main information from the included articles is presented in SI Table 3. Of the 25 publications included, 15 were RCTs³⁴⁻⁴⁸, while the remaining 10 were NRSIs⁴⁹⁻⁵⁸. The studies were conducted in 16 countries (Africa, Australia, Brazil, China, Egypt, England, India, Iran, Germany, New Zealand, Scotland, Sudan, Syria, Turkey, United Arab Emirates, and the United States of America). Among the 15 RCTs, nine were registered in a clinical trial open registry databases such as ClinicalTrials.gov, International Standard Randomised Controlled Trial Number (ISRCTN), the Australian New Zealand Clinical Trials Registry, and the Iranian Registry of Clinical Trials^{34,35,37-40,42,46,48}. None of the NRSIs reported registration.

A total of twenty-four articles were published in English, while only one was in Chinese³⁶. The latter was translated using a specialised validated translation tool to obtain the information reported. Thirteen studies were conducted in an academic setting^{35,39-41,43-45,48,51,52,54,55,57}, two in a field setting^{38,47}, one in a medical setting³⁶, four in a private setting^{34,37,49,50}, and five in a public setting^{42,46,53,56,58}.

Participant characteristics

Children were two to twelve years old.

Intervention characteristics

The crown brands used were 3M/ESPE (n=10)^{36,38,39,40,42,43,48,49,53,54}, Kids Crown (n=4)^{37,41,44,45}, while the brand was not reported in the remaining eleven studies. Fifteen studies^{35-44,48,49,53,54,58} reported the brand of the cement used, with six different manufacturers.

Most of the studies employed the HT criteria, as outlined by Innes et al.²⁹, to assess the success of preformed crowns. However, six studies^{36,37,39,44,54,56} used their own criteria. Follow-up treatment was reported in months. The minimum reported follow-up time was one month, while the maximum was 89 months. The full information can be found on SI Table 3.

Risk of bias assessment

The RoB 2 tool (Figure 2) assessed the seven included RCTs (46.7%) as having a high risk of bias^{36,41,43-47}, 40% with low risk^{34,35,37,39,42,48}, and 13.3% showing some concerns^{37,40}. Concerns about the randomisation process (D1) were identified in eight trials^{36,37,41,43-47}, one had some concerns about deviations from the intended intervention (D2)³⁶, none of the trials exhibited a risk of missing outcome data (D3), and two studies had some concerns about the risk of bias in outcome measurement (D4)^{40,45}. In addition, five studies had some concerns about selective outcome reporting^{36,41,43-45}, with two studies rated as high risk (D5)^{46,47}.

In the ten included NRSIs studies, five were identified as a moderate risk of overall bias^{52,54-57}, four with a serious risk^{49-51,53}, and only one study with low risk⁵⁸ (Figure 3). One study was found to have a moderate risk of bias due to confounders (D1)⁵⁰, while two studies showed a serious risk in participant selection (D2) due to issues in the selection process and differences in the start/follow-up of the intervention^{49,50}. All studies were deemed risk-free in terms of classification (D3) and deviations from the planned intervention (D4), with two studies showing serious and moderate risk for missing data (D5), respectively^{51,53}. Nine out of the ten studies presented moderate risk in the domain that evaluated the measurement of outcomes (D6)⁴⁹⁻⁵⁷. Finally, no study presented any risk regarding selective outcome reporting (D7).

Data synthesis

For the data synthesis, RCTs and NRSIs were evaluated separately. Table 1 presents the overall pooled results of the success rate of preformed metal crowns applied according to the Hall Technique on primary molars at different time points corresponding to all included studies. Since the studies measured success at different time points, for RCTs, a 12-month follow-up period was selected as the outcome assessment time point, as this was a standard follow-up period among the studies. For NRSIs, we compiled success data reported in all studies, considering the longest follow-up period since the data were presented as minimal and maximal time points.

Randomised clinical trials

We performed a meta-analysis of 15 RCTs to evaluate the success rate of PMCs applied according to the Hall Technique on decayed primary molars. The overall analysis yielded a pooled proportion of 98% (95% CI 97-99) of success rate (SI Figure

1). Heterogeneity was considered moderate ($I^2 = 32\%$) and not statistically significant ($p = 0.110$). Sensitivity analysis was then performed, and no influence on the heterogeneity was observed.

Subgroup analysis did not show the difference in the pooled proportion of success rate among the risk of bias of the studies ($p = 0.061$; Low risk = 99%; Some concerns = 94%; High risk = 97%) (Figure 4).

Visual inspection of the funnel plot suggested asymmetry (SI Figure 2), and the publication bias analysis (Begg's test) confirmed the asymmetry in the funnel plot ($p = 0.0018$).

Non-randomised studies of intervention

To evaluate the success rate of the Hall technique in primary molars, a meta-analysis was conducted on ten non-randomized controlled trials. The analysis found a pooled proportion of success rate of 95% (95% CI: 91-100), as shown in SI Figure 3. However, high heterogeneity was observed ($I^2 = 96\%$) and found to be statistically significant ($p < 0.01$).

Given the high heterogeneity observed in the meta-analysis, a sensitivity analysis was conducted. One study (Innes et al., 2006) influenced the results significantly. Upon removing this study, the I^2 value decreased to 51%. Subsequently, a new meta-analysis was performed on the remaining studies, which yielded a pooled proportion of success rate of 98% (95% CI: 96-99) as depicted in SI Figure 4. Moderate heterogeneity ($I^2 = 51\%$) was still detected and statistically significant ($p = 0.04$).

A subgroup analysis was conducted to evaluate the influence of risk of bias on the success rate, as shown in Figure 5. The analysis found no significant impact of risk of bias on the success rate ($p = 0.239$), with success rates of 99%, 98%, and 97% for studies with low, moderate, and serious risk of bias, respectively.

While visual inspection of the funnel plot suggested some asymmetry, as shown in SI Figure 5, publication bias analysis (Begg's test) revealed no significant asymmetry ($p = 0.325$).

Certainty of evidence assessment

The certainty of evidence and accompanying explanation for each factor rating is presented in Table 2. The RCTs were downgraded primarily due to limitations in the study design. The overall risk of bias was deemed serious owing to issues in the

randomisation process, deviations from the intended intervention, outcome measurement, and selective outcome reporting. Additionally, publication bias was detected by visual inspection of the funnel plot. The NRSIs were also considered to have a serious risk of bias due to limited analysis information, retrospective data analysis, variations in treatment timings, a high number of dropouts, significant differences in dropouts between groups, and a lack of blinding. Inconsistency was also observed among the studies due to significant heterogeneity, and publication bias was detected in the visual inspection. In contrast, for NSRIs, the quality of evidence was raised by evaluating three additional categories, namely magnitude of effect, confounding factors, and dose-response gradient, resulting in a positive response.

Discussion

This systematic review represents the initial endeavour to consolidate success rates of preformed metal crowns in primary molars following the Hall Technique from both RCTs and NRSIs. Our findings reveal an overall pooled success rate of 98% in both RCTs over a 12-month follow-up period and in NRSIs over a variable period of 1 to 89 months. The high success rate is likely attributed to the sealing of the lesion achieved through the use of preformed crowns, preventing biofilm accumulation, thereby arresting the caries lesion⁴⁹.

The available evidence corroborates that HT surpasses any other type of restorative treatment in terms of failure, retreatment, pain and discomfort in the long term^{22,23,25,26}. Moreover, this minimal intervention approach, which arrests the caries lesion, preserves the dentin pulp complex undamaged and protects the tooth structure until exfoliation, is the most cost-effective option⁵⁹⁻⁶¹.

To assess the influence of each study on the overall effect size of each meta-analysis, we conducted a sensitivity analysis in both study design groups. One NSRI study significantly impacted the overall results due to the high heterogeneity among included studies. Unlike the other retrospective cohorts, the study by Innes et al.⁴⁹ is the first retrospective study to report Hall Technique success data collected from the records of a general practitioner's practice over 13 years. Nevertheless, subgroups analysis in both RCTs and NRSIs showed no difference in the estimated pooled success rate of HT when categories of risk of bias were considered, possibly due to the high success rate and small confidence interval observed.

Upon the assessment of risk of bias, the majority of the RCTs raised concerns about a high risk of bias, emphasising critical aspects in their structure. These concerns included the absence of information on allocation concealment and a lack of protocol registration. In some scenarios, the operator also served as the outcome assessor, and there was a lack of participant blinding, operator blinding, or outcome assessor blinding. For NRSIs, most of the studies showed a moderate to serious risk of bias. During the risk of bias analysis, confounding and participant selection problems were identified due to insufficient information on the analysis performed, retrospective analysis of data, along with differences in baseline time, follow-up, and participants' age, missing data, and issues in the measurement of outcomes due to non-blinding of the outcome assessor. Protocol registration is mandatory before participant enrolment to ensure transparency in the process⁶². To prevent missing information, it is recommended to use a reporting guideline when drafting the report.

Moreover, though blinding is a crucial element to prevent bias in intervention studies, its practical implementation is frequently challenging, particularly when distinct restorative materials are employed in trials. Consequently, it should not be deemed a significant issue within the study. These variables might impact the ultimate risk of bias analysis, potentially resulting in an underestimation of the certainty of evidence. Therefore, prudence and diligence are essential when utilising and evaluating the results⁶³.

However, for randomised trials, it is imperative to adequately justify the randomisation process and allocation concealment. This ensures the prevention of substantial differences between intervention groups and guards against the manipulation of participant enrollment. Ultimately, to bolster the robustness of the evidence, efforts should be made to minimise discrepancies in the available data. Careful handling and, when necessary, analysis should be undertaken to verify that the estimate of effect remains unbiased.

Regarding the certainty of evidence, the rating was low for RCTs and moderate for NRSIs. The lower rating for RCTs was mainly due to biases such as insufficient information on allocation concealment, which reflects bias from the randomization process; inability to blind participants in most studies, indicative of bias from deviations in intended interventions; having the same **operator** performing and assessing outcomes, representing bias in outcome measurement; and the lack of a registered protocol with a predefined analysis plan, highlighting bias in selecting reported

outcomes. For NRSIs, the analysis information was often limited, treatments were administered at varying times (introducing bias in participant selection), and there were significant dropout rates along with notable differences in patient exclusions between groups (resulting in bias due to missing data). Additionally, blinding information was either not reported or deemed unfeasible (affecting bias in result measurement). Moreover, there was substantial heterogeneity among the studies, indicating issues with consistency.

Our study has several limitations. Firstly, we had initially planned to conduct a meta-regression to explore potential associations with HT success. However, this analysis proved unfeasible due to the lack of reported data in the studies. Secondly, the absence of an exact time point in the reported success rates across the primary studies posed a challenge. This variability made it impossible to conduct a standardised assessment using a common time point in NRSIs, as the reported follow-up periods varied significantly. Moreover, the estimation of the pooled success rate at the 12-month follow-up was only feasible for RCTs, as it was the only common follow-up period shared among these studies. Despite these limitations, our review revealed a consistently high success rate in both types of interventional studies (RCTs and NRSIs), offering positive encouragement for the implementation of the Hall Technique. Moving forward, future studies should focus on understanding the barriers and facilitators influencing the adoption of this technique to promote its effective implementation.

Conclusion

HT presents a high success rate, even though the primary studies had “low” to “high” risk of bias and demonstrated “moderate” to “low” certainty of evidence. One of the main reasons for downgrading was related to blinding, which was generally unfeasible due to visibly different restorative materials.

Authors contributions

D.P.R., T.K.T. and N.P.I. were involved in conception and design of the study. D.P.R., C.L.G. and G.S.S. were involved in data acquisition. T.K.T., N.P.I., T.G., M.M.B., M.P.A. and D.P.R. were involved in data analysis and interpretation. T.K.T., N.P.I., W.A. and D.P.R. drafted the manuscript. T.K.T., N.P.I., C.L.G., G.S.S., T.G., M.M.B., M.P.A., J.J., W.A. and D.P.R. revised and gave final approval of the manuscript.

Ethics declarations:

Not applicable

Data availability:

The datasets used and/or analysed during the current study are available in the Appendix.

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FIGURE AND TABLE LEGENDS

Figure 1 - Flowchart of screening and eligibility of the studies.

Figure 2 - Risk of bias assessment of randomized controlled trials.

Figure 3 - Risk of bias assessment of non-randomized controlled trials.

Figure 4 - Subgroup analysis considering the influence of risk of bias on the outcome in randomized controlled trials.

Figure 5 - Subgroup analysis considering the influence of risk of bias on the outcome.

Table 1 - Overview of success results of preformed metal crowns applied following the Hall Technique in primary molars at different time points corresponding to all included studies.

Table 2 - Certainty of evidence and rating explanation according to the GRADE approach.