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Cost-effectiveness of managing cavitated primary molar caries lesions: A randomized trial in Germany

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ABSTRACT

Objectives: The Hall Technique (HT), Non-Restorative Cavity Control (NRCC) and conventional carious tissue removal and restoration (CR) are strategies for managing cavitated caries lesions in primary molars. A randomized controlled three-arm parallel group trial in a university clinic in Germany was used to measure the cost-effectiveness of these strategies.

Methods: 142 children (HT: 40; NRCC: 44; CR: 58) were followed over a mean 2.5 years. A German healthcare perspective was chosen. The primary outcome was estimated molar survival; secondary outcomes were not needing extraction, not having pain or needing endodontic treatment/extraction, or not needing any re-intervention at all. Initial, maintenance and endodontic/restorative/extraction re-treatment costs were derived from fee items of the statutory insurance. Cumulative cost-effectiveness and cost-effectiveness acceptability were estimated from bootstrapped samples.

Results: HT molars survived longer (estimated mean; 95% CI: 29.7; 26.6–30.5 months) than NRCC (25.3; 21.2–28.7 months) and CR molars (24.1; 22.0–26.2 months). HT was also less costly (66; 62–71 Euro) than NRCC (296; 274–318 Euro) and CR (83; 73–92 Euro). HT was more cost-effective than NRCC and CR in > 96% of samples, and had acceptable cost-effectiveness regardless of a payer's willingness-to-pay. This superior cost-effectiveness was confirmed for secondary health outcomes. Cost-advantages were even more pronounced when costs were calculated per year of tooth retention (mean annual costs were HT: 29, NRCC: 154, CR: 61 Euro).

Conclusions: HT was more cost-effective than CR or NRCC for managing cavitated caries lesions in primary molars, yielding better dental health outcomes at lower costs.

Clinical significance: If choosing between these three strategies for managing cavitated caries lesions in primary molars, dentists should prefer HT over NRCC or CR. This would also save costs for the healthcare payer.

1. Introduction

For managing cavitated carious lesions in primary molars, numerous strategies are available. Conventional, i.e. non-selective carious tissue removal, and restoration (CR) of the cavity using amalgam, glass ionomer cement, resin composite or polyacrylic acid-modified composites used to be the standard treatment [1], although associated with high risk of pulpal complications and restoration failure [2]. If instead, selective carious tissue removal is performed, with some carious tissue being left over the pulp to avoid pulp exposure, success is improved, whilst similar restoration techniques result still in limited survival [3]. The Hall Technique (HT) has been established as an alternative management option, with lower associated risks of pulpal and restorative complications. For HT, carious tissue is sealed within the cavity beneath a stainless-steel crown, without any tissue removal or tooth preparation, preceded only by tooth separation using orthodontic separators, where required, to allow the crown to be fitted where the teeth approximate closely. The sealed bacteria are deprived of carbohydrate and diet; the lesion is inactivated [4–6]. Non-Restorative Cavity Control (NRCC) involves controlling the activity of the lesion by removing overhanging enamel and dentin if needed, followed by repeated and regular biofilm removal and fluoride application [7]. NRCC requires high adherence of patients and/or parents to continuously manage the lesion [8].

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Evidence from randomized control trials supports the use of HT over CR for managing cavitated carious lesions in primary molars [6]. A recent randomized trial in Germany [9,10] compared all three strategies, and found HT to be superior to avoid both major complications (tooth removal, pulpotomy etc.) and minor complications (restoration renewal or repair etc.). There is, so far, no data on the cost-effectiveness of these strategies.

Cost-effectiveness depends on the initial treatment costs, but also costs occurring during follow-up for regular "maintenance" (as for NRCC, where regular re-instruction and re-fluoridation are performed in a dental practice) and costs for re-treatments (required to remedy complications, and including re-restoration, endodontic treatment, i.e. mainly pulpotomy for primary teeth, or tooth removal). Cost-effectiveness also reflects effectiveness, for example measured as tooth survival, avoided pain or avoided complications and re-treatments. In the present study, we compared the cost-effectiveness of HT, NRCC and CR for managing cavitated carious lesions in primary molars based on data from a randomized controlled trial.

2. Materials and methods

Reporting of this study follows the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [11]. The trial had been registered (No. NCT01797458) and ethically approved (Research Ethics Committee of Greifswald University/Germany, BB 39/11). Note that this economic evaluation had not been explicitly planned a priori.

2.1. Target population and subgroups

The target population were children aged 3–8 years with at least one cavitated occlusal-proximal caries lesion (ICDAS 3-5) in a primary molar, who attend the Department for Preventive and Paediatric Dentistry of Greifswald University. Molars presenting with clinical or radiographic signs or symptoms of pulpal or periradicular pathology (including pain) were not included. Subgroups of child's gender, age, and treated tooth were accounted for during analysis.

2.2. Setting and location

Analyses were performed in the context of the German healthcare system. Whilst treatments were provided in secondary (university) care, reimbursement and costs are identical to the primary care settings based on fee items of German item catalogues.

2.3. Comparators and horizon

Two alternative caries management approaches, NRCC and the HT were compared against conventional restorations (CR). The null hypothesis was no difference in the primary outcome parameter "success" (absence of minor or major failures, including secondary caries, lesion progression, loss of restoration, reversible pulpitis, irreversible pulpitis, need for extraction) at 2.5 years among any of the three arms. Participants were assigned to one of the arms using a computer-generated random number list with allocation. Only one molar per child was included in the study. Further study methodology details have been reported [9,10]. Overall, 169 children (mean; SD age 5.6; 1.5 years) participated in the trial. However, only 142 children (HT = 40/52, NRCC = 44/52, and CR = 58/65) of the 169 baseline participants had data for the last follow-up (mean, SD follow-up time was 26.0; 11.2 months). The flowchart of the patients is shown in Fig. 1.

The horizon of the present analysis was this follow-up period. As imbalanced drop-out during follow-up may impact on survival, we used Kaplan Meier estimates to evaluate our primary outcome, survival time, accounting for censoring. Note, however, that these estimates are only valid within the follow-up period; the true survival time may be longer.

Follow-up examinations were performed by two trained examiners (CHS, RMS). Children in the HT and CR arms were recalled twice per year, while those in the NRCC arm were asked to attend once every three months to assess lesion's status, to reinforce oral hygiene, and if needed to assist the caries arrest process including fluoride varnish application.

2.4. Currency, price date and discount rate

Costs were calculated in Euro 2017. Future costs (i.e. those experienced during follow-up) were discounted at 3% per annum [12]. Discounting accounts for the lost opportunities when spending money now instead of later on.

2.5. Health outcomes and effectiveness

Our primary outcome was survival time of molars, i.e. the time until molars needed extraction. Exfoliated molars were assumed to be censored (survived). Our secondary outcomes were (1) the proportion of survived per all treated molars, (2) the proportion of molars not causing pain, needing endodontic or surgical (extraction) treatment during follow-up, and (3) the proportion of molars not needing any kind of re-intervention (note that for NRCC, re-instruction and re-fluoridation were assumed to be planned part of the initial therapy and not counted here).

2.6. Estimation of costs

A mixed public-private-payer's perspective was chosen. Dental treatments in Germany are largely reimbursed by the statutory insurance, with the majority of German patients (89%) being enrollees [13]. For these, most costs, especially in pediatric dentistry, are covered by the statutory insurance, and only very few costs are covered either by the patient or his private additional insurance.

Dental treatment costs within the statutory insurance are estimated using the statutory fee item catalogue, Bewertungsmaßstab (BEMA), or Gebührenordnung für Ärzte (GOÄ). GOÄ costs are related to BEMA, as described in the appendix, where details on the cost calculation are provided. Given that travelling times or times off school (or, for accompanying parents, off work) were not recorded, we could not account for opportunity costs. All costs were calculated per molar and, with only one molar treated per child, patient.

2.7. Analytical methods

Bootstrapping was performed to construct a sampling distribution of mean costs and effectiveness. Kaplan-Meier estimates for mean (95% CI) survival times of different strategies were generated and bootstrapped. In addition, mean (95% CI) proportions of teeth not experiencing extraction, not having pain or requiring endodontic/surgical therapy, and not experiencing any complications were estimated. Mean (95% CI) cumulative total costs and subdivided endodontic/extraction and restorative costs were estimated.

Costs and effectiveness were used to construct a cost-effectiveness plane to depict cost-effectiveness. Strategies were ranked according to their costs, and more expensive strategies compared with less expensive ones using incremental-cost-effectiveness ratios (ICER). ICERs express the cost difference per gained or lost effectiveness; positive ICERs indicate additional costs per additional effectiveness, while negative ICERs indicate additional costs per effectiveness loss. Strategies which were costlier and less effective (i.e. with a negative ICER) were dominated, strategies which were more costly but also more effective were undominated.

Using estimates for costs (c, in Euro) and effectiveness (e, in years), the net benefit of each strategy combination was calculated using the formula

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