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Cost-effectiveness of the Hall Technique in a Randomized Trial

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Abstract

Clinical and patient-reported outcomes have been reported for carious primary molars treated using the Hall Technique (HT) compared with conventional carious tissue removal and restorations (CR) in a 5-year randomized-controlled practice-based trial in Scotland. We have further interrogated this dataset to investigate the cost-effectiveness of HT versus CR. 132 children had two matched occlusal/occlusal-proximal carious lesions in primary molars (n=264 teeth) were randomly allocated to HT or CR, provided by 17 general dental practitioners. Molars were followed up for a mean of five years. A societal perspective was taken for the economic analysis. Direct dental treatment costs were estimated from a Scottish NHS perspective (an NHS England perspective was taken for a sensitivity analysis). Initial, maintenance and re-treatment costs, including re-restorations, endodontic treatments and extractions, were estimated using fee items. Indirect/opportunity costs were estimated using time and travel costs from a UK perspective. The primary outcome was tooth survival. Secondary outcomes were not having pain or needing endodontic treatments/extractions, and not needing re-restorations. Cost-effectiveness and acceptability were estimated from bootstrapped samples. Significantly more molars in HT survived (99, 95% CI: 98-100%) than in CR (92; 87-97%). Also, the proportion of molars retained without pain or requiring endodontic treatment/extraction was significantly higher in HT than CR. In the base-case analysis (NHS Scotland perspective), cumulative direct dental treatment costs of the HT were 24 (23-25) GBP; costs for CR were 29 (17-46) GBP. In an NHS England perspective, the cost advantage of HT (29; 25-34 GBP) over CR (107; 86-127 GBP) was more pronounced. Indirect/opportunity costs were significantly lower for HT (32, 31-34 GBP) than CR (49; 34-69 GBP). Total cumulative costs were significantly lower for HT (32; 31-34 GBP) than CR (49; 34-69 GBP). Based on a long-term practice-based trial, HT was more cost-effective than CR.

Introduction

The expenditures (direct treatment costs) for managing dental diseases have been estimated at 356.80 billion USD globally, and productivity losses (indirect costs) due to dental diseases have been estimated at 187.61 billion USD { ADDIN EN.CITE <EndNote><Cite><Author>Righolt</Author><Year>2018</Year><RecNum>19665</RecNum><DisplayText>(Righolt et al. 2018)</DisplayText><record><rec-number>19665</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrrz5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1521550958">19665</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Righolt, A. J.</author><author>Jevdjevic, M.</author><author>Marcenes, W.</author><author>Listl, S.</author></authors></contributors><auth-address>1 Department of Quality and Safety of Oral Healthcare, Radboud University, Radboud UMC, Nijmegen, the Netherlands.2 Division of Population and Patient Health, King's College London Dental Institute, London, UK.3 Department of Conservative Dentistry, Translational Health Economics Group, Heidelberg University, Heidelberg, Germany.</auth-address><titles><title>Global-, Regional-, and Country-Level Economic Impacts of Dental Diseases in 2015</title><secondary-title>J Dent Res</secondary-title><alt-title>Journal of dental research</alt-title></titles><periodical><full-title>J Dent Res</full-title><abbr-1>Journal of dental research</abbr-1></periodical><alt-periodical><full-title>J Dent Res</full-title><abbr-1>Journal of dental research</abbr-1></alt-periodical><pages>22034517750572</pages><edition>2018/01/18</edition><keywords><keyword>dental public health</keyword><keyword>epidemiology</keyword><keyword>health services research</keyword><keyword>oral health</keyword><keyword>productivity losses</keyword><keyword>treatment expenditures</keyword></keywords><dates><year>2018</year><pub-dates><date>Jan 1</date></pub-dates></dates><isbn>0022-0345</isbn><accession-num>29342371</accession-num><urls></urls><electronic-resource-num>10.1177/0022034517750572</electronic-resource-num><remote-database-

provider>NLM</remote-database-

provider><language>eng</language></record></Cite></EndNote>}. A large share of these costs is generated from managing dental caries, the most prevalent condition of humankind { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}. There is great need for effective and cost-effective interventions for preventing and managing carious lesions.

Partially as a result of increased preventive public health efforts, caries experience in Scottish children has declined over the last 15 years. However, in common with other countries, management of carious lesions continue to be a problem across the UK, the proportion of managed carious lesions in primary teeth remains low at only 15% in Scotland { ADDIN EN.CITE

<EndNote><Cite><Author>NDIP</Author><Year>2016</Year><RecNum>19727</RecNum>

<DisplayText>(NDIP 2016)</DisplayText><record><rec-number>19727</rec-

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>Report of the 2016 Detailed National Dental Inspection Programme of Primary 1 children and the Basic Inspection of Primary 1 and Primary 7 children</title></titles><dates><year>2016</year></dates><pub-

location>http://ndip.scottishdental.org/wp-content/uploads/2016/10/2016-10-25-NDIP-

Report.pdf </pub-location><urls></urls></record></Cite></EndNote>} and 14% in England {

ADDIN EN.CITE

<EndNote><Cite><Author>Davies</Author><Year>2012</Year><RecNum>19755</RecNum

><DisplayText>(Davies et al. 2012)</DisplayText><record><rec-number>19755</rec-

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name="Web Page">12</ref-type><contributors><authors><author>Davies, G.</author><author>Neville, J.</author><author>Rooney, E.</author><author>Robinson, M.</author><author>Jones,

A. Perkins, C. C. National Dental Epidemiology Programme for England: oral health survey of five-year-old-children 2012. <http://www.nwph.net/dentalhealth/Oral%20Health%205yr%20old%20children%202012%20final%20report%20gateway%20approved.pdf>

This might be because providing care for these primary teeth is seen as either not being required or, not feasible as they are in children. Indeed, there is evidence that restoration failure in primary teeth is common when conventional carious tissue removal and direct restorations (CR) are employed { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}. The Hall Technique (HT) has been shown to be a clinically effective treatment option that is considered more acceptable to parents/carers, children and dentists { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}.

Cost-effectiveness considers initial treatment costs, but also costs for re-treatments such as re-restoration, endodontic treatments (pulp therapy) or extractions. Treatments which are initially more costly but also more effective may, eventually, be cost-effective long-term. A recent clinical study found HT more cost-effective than CR and non-restorative cavity control, over 2 years in a German setting (Schwendicke et al. 2018). The study reported here aimed to assess the cost-effectiveness of HT versus CR for managing cavitated carious lesions in primary molars over a longer period of time, building on data from a randomized controlled 5-year practice-based trial in Scotland.

Materials and Methods

Reporting for this study follows the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}. The trial had been

registered (ISRCTN 47267893) and ethically approved (Tayside Committee on Medical Research Ethics approval 108/00). Note that this economic evaluation had not been explicitly planned a priori and is an analysis of an existing dataset. The trial methodology is described in detail elsewhere { ADDIN EN.CITE <EndNote><Cite><Author>Innes</Author><Year>2007</Year><RecNum>345</RecNum><DisplayText>(Innes et al. 2007)</DisplayText><record><rec-number>345</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrz5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="0">345</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Innes, Nicola</author><author>Evans, Dafydd</author><author>Stirrups, David</author></authors></contributors><titles><title>The Hall Technique; a randomized controlled clinical trial of a novel method of managing carious primary molars in general dental practice: acceptability of the technique and outcomes at 23 months</title><secondary-title>BMC Oral Health</secondary-title></titles><periodical><full-title>BMC Oral Health</full-title><abbr-1>BMC oral health</abbr-1></periodical><pages>18</pages><volume>7</volume><number>1</number><dates><year>2007</year></dates><isbn>1472-6831</isbn><accession-num>doi:10.1186/1472-6831-7-18</accession-num><urls><related-urls><url>http://www.biomedcentral.com/1472-6831/7/18</url></related-urls></urls></record></Cite></EndNote>} but given briefly here.

Target population, setting and training

Our analyses are based on a randomized controlled split-mouth trial in General Dental Practice in Scotland, UK, that aimed to compare HT versus CR (defined as General Dental Practitioners' [GDPs] standard carious tissue removal and direct restorations). The target population were children with asymptomatic primary molars matched for tooth type, arch and lesion (for surface and extent), recruited between 2001 and 2004.

All GDPs in Tayside, Scotland (n=143), were invited by mail to take part. From the 41 replies expressing an interest (29% positive response rate), 17 GDPs were selected to obtain a spread of practices from rural, urban and mixed locations. The mean regional d_3mft was 2.47 ($d=1.71$; $m=0.54$; $f=0.22$). Dentists were not required to sequentially screen and invite eligible children but were asked to recruit up to 10 children who met the following inclusion criteria: (1) 4 to 9 years of age, with no medical complications (note that eventually, some dentists had recruited children aged 3 or 10 years, these were retained in the trial); (2) presenting for routine dental care with two unrestored primary molars with carious lesions into dentin that were matched for tooth type, dental arch, and extent of the lesion (radiographically \leq or $>$ $\frac{1}{2}$ way through dentin), and were symptomless, with no clinical or radiographic signs indicating pulpal pathology on bitewing radiographs as assessed by the GDP. The number of recruited participants recruited per dentist varied from 0 to 21 (median 8). The GDPs attended a single, three hour training session at Dundee Dental Hospital and School, which consisted of: a presentation on the study background and aims; instruction by a dental radiographer in obtaining standardized bitewing radiographs, using Rinn dental film holders and size 0 bitewing radiographs; interpretation of bitewing radiographs led by a consultant dental radiologist; observation of the HT being carried out on one child by a consultant in Pediatric Dentistry; and discussion of pre-circulated paperwork, and a brainstorming session to anticipate and problem solve possible hurdles. No additional training was provided on carrying out CR, as the trial was pragmatic in design and testing HT versus CR as usual practice. The trial was eventually conducted with 132 children (264 primary molars), Subgroups of children's gender, dental arch and molar were accounted for during analysis.

Comparators and horizon

There were 264 study molars with carious lesions; 67% were occluso-proximal; 42% had carious lesions extending radiographically over half-way into dentine. Teeth were randomized to either HT (intervention) or CR (control). HT was carried out by removing food debris, if there was any in the cavity, and placing a preformed metal crown over the primary molar, once the

correct size was chosen, using glass ionomer cement. The crown was seated with finger pressure and the child instructed to bite down hard to fully seat the crown and keep pressure on the crown until the cement had set. Local anaesthesia was not used and no attempt was made to remove any of the carious lesion or prepare the molar. For CR, GDPs were asked to carry out their usual treatment and record whether they had removed all of the carious tooth tissue. Ninety-one patients (69%) had 4 years' minimum follow-up; the mean follow-up period was 5 years.

Sample size and randomization

Sample size estimation had been based on a systematic review { ADDIN EN.CITE <EndNote><Cite><Author>Randall</Author><Year>2000</Year><RecNum>19730</RecNum><DisplayText>(Randall et al. 2000)</DisplayText><record><rec-number>19730</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrzr5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1525267949">19730</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Randall, R. C.</author><author>Vrijhoef, M. M.</author><author>Wilson, N. H.</author></authors></contributors><auth-address>3M Dental, Laboratoires 3M Sante, Cergy Pontoise, France.</auth-address><titles><title>Efficacy of preformed metal crowns vs. amalgam restorations in primary molars: a systematic review</title><secondary-title>J Am Dent Assoc</secondary-title><alt-title>Journal of the American Dental Association (1939)</alt-title></titles><periodical><full-title>J Am Dent Assoc</full-title><abbr-1>Journal of the American Dental Association (1939)</abbr-1></periodical><alt-periodical><full-title>J Am Dent Assoc</full-title><abbr-1>Journal of the American Dental Association (1939)</abbr-1></alt-periodical><pages>337-43</pages><volume>131</volume><number>3</number><edition>2000/03/15</edition><keywords><keyword>*Crowns/statistics & numerical data</keyword><keyword>*Dental Amalgam</keyword><keyword>Dental Restoration Failure</keyword><keyword>*Dental Restoration, Permanent/statistics & numerical

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8177</isbn><accession-num>10715925</accession-num><urls></urls><remote-database-
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provider><language>eng</language></record></Cite></EndNote>} where the mean hazard

ratio (HR) was 0.32 in favor of conventionally placed preformed crowns compared to amalgam restorations. Using a two-tailed test ($\alpha = 0.05$) and a power of $1 - \beta = 80\%$, 58 participants were required to show a difference of 50% in the primary outcome, which was clinically and/or radiographically detected failure, at two years. Allowing for loss to follow-up, it was estimated that a minimum of 120 children should be recruited. Following consent, computer-generated centralized randomization was used (accessed by phone call) for treatment allocation (10th generation blocking).

Horizon

The horizon of the present analysis is the follow-up period of the trial; 5 years mean. This period allowed for the exfoliation of many teeth, which is the final survival event (primary teeth cannot survive for longer).

Data

The following data were recorded:

- The time taken to explain each treatment;
- The time taken to provide the initial treatment items (either the HT or CR);
- Children's home postcodes;
- Clinical and radiographic findings (when radiographs were used) annually for routine appointments as well as for any additional non-routine (e.g. emergency) appointments.

Teeth experiencing failed treatments and exfoliation were noted. Diagnosis and treatment outcomes were recorded using standard clinical outcome measures. Radiographs were assessed independently by two calibrated researchers.

In order to measure time and travel costs for the present analysis, the following estimates were used. (1) Times for re-treatments (e.g. restorative, endodontic treatment, extractions) were estimated for each unit of re-treatment from another randomized trial in a similar practice-based setting in Scotland { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}, except for re-treatment involving general anaesthesia, where we assumed – based on expert consensus – a total of 300 minutes to be spent overall (including preparation for surgery, anaesthesia, operating time, and recovery). (2) Travelling times and distances for travel to and from the appointment were calculated, assuming travel from home to the practice, using the postcode data provided by patients and practices. Times and distances were estimated using the Google Distance°Matrix°API, a service that calculates distances and travel times between locations using an HTTP request. Note that we assumed travel by car for distances above 800 m, otherwise travel by foot was assumed.

Currency, price date and discount rate

Costs were calculated in Pound Sterling (Great British Pound, GBP) 2017. Note that the trial was conducted between 2001 and 2007, but using current costs increases the interpretability of possible cost-differences. Future costs (i.e. those experienced during follow-up) were discounted at 1.5% per annum { ADDIN EN.CITE <EndNote><Cite><Author>NICE</Author><Year>2012</Year><RecNum>19710</RecNum><DisplayText>(NICE 2012)</DisplayText><record><rec-number>19710</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrrz5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1524641725">19710</key></foreign-keys><ref-type name="Web Page">12</ref-type><contributors><authors><author>NICE,</author></authors></contributors><titles><title

>Methods for the development of NICE public health guidance (third edition)</titles><dates><year>2012</year></dates><pub-location><https://www.nice.org.uk/process/pmg4/chapter/incorporating-health-economics></pub-location><urls></urls></record></Cite></EndNote>}. Discounting accounts for the lost opportunities when spending money now instead of later.

Health outcomes and effectiveness

Our primary outcome was survival of molars, measures as proportion (in %). Our secondary outcomes were the proportion of molars not causing pain, or needing endodontic treatment or extraction and the proportion of molars not needing any kind of re-restoration. The flow of participants during follow-up is shown in Figure 1.

Estimation of costs

A societal perspective was taken. Direct dental treatment costs were estimated using the NHS Scotland perspective in our base-case analysis. Dental treatments in Scotland for children are reimbursed by the NHS using a capitation and a fee per item system of the British Dental Association (BDA). The out-of-pocket dental expenses for pediatric patients is negligible, and there were unlikely to be substantial out-of-pocket expenses outside of the dental surgery. Also note that costs for over the counter medication are paid for by the government and prescriptions are provided free to the patient.

The BDA item catalogue for Scotland 2017 was used to determine costs for the treatments carried out, as described in the Appendix. All costs were calculated per molar, assuming the split-mouth design to be an element of the trial and not reflecting typical real-life dental care. Note, however, that treating multiple teeth in the same mouth may affect cost-effectiveness. Also note that not accounting for the split-mouth design has likely reduced the statistical power of our analyses to some degree; we accepted these limitations. In a sensitivity analysis, an NHS England perspective was chosen, as described in detail in the Appendix.

Indirect/opportunity costs were estimated based on the data available, ignoring the split-mouth design (assuming the patient visited for only having one molar treated by either HT or CR) as follows. A number of assumptions had to be made: (1) Travel costs were costs for transportation to and from appointments, and derived per mile travelled using the standard UK mileage rate for cars, 0.45 GBP/mile { ADDIN EN.CITE <EndNote><Cite><Author>HMRC</Author><Year>2017</Year><RecNum>19732</RecNum>><DisplayText>(HMRC 2017)</DisplayText><record><rec-number>19732</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrzr5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1525270701">19732</key></foreign-keys><ref-type name="Web Page">12</ref-type><contributors><authors><author>HMRC</author></authors></contributors><titles><title>Travel - mileage and fuel rates and allowances</title></titles><dates><year>2017</year></dates><publication><url>https://www.gov.uk/government/publications/rates-and-allowances-travel-mileage-and-fuel-allowances/travel-mileage-and-fuel-rates-and-allowances</url></publication></urls></record></Cite></EndNote>}. If travel by foot was assumed, no mileage was applied. (2) Time costs measure the value of forgone alternative activities which could have been performed during the time spent for attending the dentist. Time costs were considered for parents, not the child participant { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}. Time costs included travel time, waiting time, and time for appointments, including initial and re-treatment appointments. A mean gross hourly UK wage in 2017 (13.94 GBP) was applied to these times (the hourly wage in Scotland differs minimally, by 0.04 and 0.39 GBP for public and private wages, respectively) { ADDIN EN.CITE <EndNote><Cite><Author>Office for National Statistics</Author><Year>2017</Year><RecNum>19733</RecNum>><DisplayText>(Office for National Statistics 2017; Statista 2018)</DisplayText><record><rec-number>19733</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrzr5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1525272920">19733</key></foreign-keys><ref-type name="Web

Page">12</ref-type><contributors><authors><author>Office for National Statistics,</author></authors></contributors><titles><title>Earnings in Scotland 2016</title></titles><dates><year>2017</year></dates><pub-location>http://www.parliament.scot/ResearchBriefingsAndFactsheets/S5/SB_16-92_Earnings_in_Scotland_2016.pdf</pub-location><urls></urls></record></Cite><Cite><Author>statista</Author><Year>2018</Year><RecNum>19734</RecNum><record><rec-number>19734</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrzr5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1525272978">19734</key></foreign-keys><ref-type name="Web Page">12</ref-type><contributors><authors><author>Statista,</author></authors></contributors><titles><title>Median hourly earnings for full-time employees (excluding overtime pay and hours) in the United Kingdom (UK) from 2006 to 2017 (in GBP)</title></titles><dates><year>2018</year></dates><pub-location>https://www.statista.com/statistics/280687/median-hourly-earnings-for-full-time-employees-in-the-uk-since-2006/</pub-location><urls></urls></record></Cite></EndNote>}. We accounted for possible unemployment { ADDIN EN.CITE <EndNote><Cite><Author>ONS</Author><Year>2018</Year><RecNum>19736</RecNum><DisplayText>(ONS 2018; Scottish Government 2018)</DisplayText><record><rec-number>19736</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrzr5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1525278177">19736</key></foreign-keys><ref-type name="Web Page">12</ref-type><contributors><authors><author>ONS,</author></authors></contributors><titles><title>Unemployment </title></titles><dates><year>2018</year></dates><pub-location>https://www.ons.gov.uk/employmentandlabourmarket/peoplenotinwork/unemployment</pub-location><urls></urls></record></Cite><Cite><Author>Scottish Government</Author><Year>2018</Year><RecNum>19735</RecNum><record><rec-number>19735</rec-number><foreign-keys><key app="EN" db-

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<h3><i>Analytical methods</i></h3>
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<p>Log-rank test was used to explore the level of statistical significance in survival between therapies. Note that for this analysis, the split-mouth design of the study was ignored. Bootstrapping was then performed to construct a sampling distribution of mean costs and effectiveness, yielding 95% confidence intervals (CI) around the mean values. Performance of the HT and the CRs were ranked according to their costs, and the more expensive strategy compared against the less expensive one 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</p>
</div>

per effectiveness loss. The strategy which is less expensive and more effective dominates the other strategy.

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

$$net\ benefit = \lambda \times \Delta e - \Delta c,$$

with λ denoting the ceiling threshold of willingness to pay, i.e. the additional costs a decision maker is willing to bear for gaining an additional unit of effectiveness { ADDIN EN.CITE <EndNote><Cite><Author>Drummond</Author><Year>2005</Year><RecNum>834</RecNum><DisplayText>(Drummond et al. 2005)</DisplayText><record><rec-number>834</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrrz5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="0">834</key></foreign-keys><ref-type name="Book">6</ref-type><contributors><authors><author>Drummond, M</author><author>Sculpher, M</author><author>Torrance, G</author><author>O'Brien, B</author><author>Stoddart, G</author></authors></contributors><titles><title>Methods for Economic Evaluation of Health Care Programmes</title></titles><number>3</number><dates><year>2005</year></dates><publisher>Oxford University Press</publisher><urls></urls></record></Cite></EndNote>}. If $\lambda >$

$\Delta c / \Delta e$, an alternative intervention is considered more cost-effective than the comparator despite possibly being more costly { ADDIN EN.CITE <EndNote><Cite><Author>Briggs</Author><Year>2002</Year><RecNum>935</RecNum><DisplayText>(Briggs et al. 2002)</DisplayText><record><rec-number>935</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrrz5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="0">935</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Briggs, Andrew H.</author><author>O'Brien, Bernie J.</author><author>Blackhouse, Gordon</author></authors></contributors><titles><title>Thinking outside the box: Recent Advances in the Analysis and Presentation of Uncertainty in Cost-Effectiveness Studies</title><secondary-title>Annual Review of Public Health</secondary-

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num>10.1146/annurev.publhealth.23.100901.140534</electronic-resource-num><access-

date>2013/05/15</access-date></record></Cite></EndNote>}. We used the net-benefit

approach to calculate the probability of a strategy being cost-effective for payers with different willingness-to-pay ceiling thresholds.

Statistical analysis was performed using SPSS 22 (IBM, Armonk, IL, USA); bootstrapping was performed in Python using *numpy* and *pandas* modules. Cost-effectiveness acceptability was evaluated using TreeAge Pro (TreeAge, Williamstown, MA, USA)

Results

Effectiveness

The survival curve for both strategies is shown in Figure 2, with significant differences in survival between strategies ($p=0.007$ /Log-rank). Significantly more molars in HT survived (99, 95% CI: 98-100%) than in CR (92; 87-97%). The proportion of molars retained without pain or requiring endodontic treatment/ extraction was also significantly higher in HT than CR (Table 1). Teeth treated with the HT also tended to show fewer re-restorations than CR; however, this difference was not significant in the bootstrapped sample (Table 1).

Costs

In the base-case analysis, initial costs for HT were nearly three times as high as those for CR. However, including re-treatment costs, direct dental treatment costs from an NHS Scotland

perspective found HT (24; 23-25 GBP) to not be significantly cheaper than CR (29; 17-46 GBP). Estimating direct dental treatment costs from an NHS England perspective found HT to be significantly less expensive (29; 25-34 GBP) than CR (107; 86-127 GBP). Indirect/opportunity costs were significantly lower for HT (32, 31—34 GBP) than CR (49; 34-69 GBP), with travel and time costs being significantly lower (Table 1). Total cumulative costs were significantly lower in HT (32; 31-34 GBP) than CR (49; 34-69 GBP).

Cost-effectiveness

HT dominated CRs, being less costly and more effective (Figure 3), with a mean ICER of -2.38 GBP spent additionally while losing 1% of molar survival when choosing CR instead of HT. The probability of HT being cost-effective was 87% at a willingness-to-pay threshold of 0 GBP (Figure 4), and increased to 100% with increasing willingness-to-pay. Hence, HT had acceptable cost-effectiveness regardless of a payer's willingness-to-pay. Also when considering the proportion of molars without pain or endodontic treatment/ extraction (ICER - 1.28 GBP/%) and the proportion of molars without any re-restorations (ICER -0.47 GBP/%), HT was more cost-effective than CR.

Discussion

In this day of limited resources, costs are relevant both for those paying for care and those commissioning it. In this study, we found HT to be significantly less costly than CR when considering direct dental treatment and indirect/opportunity costs. This was mainly because HT was clinically more successful and resulted in significantly fewer re-treatments, some of which are relatively expensive (e.g. treatment under general anaesthesia); these long-term savings compensated for the initially higher costs of providing HT. The cost-ranking holds in our sensitivity analysis, where direct dental treatment costs were estimated from an NHS England perspective. This was despite remuneration being realized very differently in England than Scotland, and direct costs showing a substantially different magnitude in England (being

much higher) than Scotland. Given that a recent study (Schwendicke et al. 2018) found HT to have superior cost-effectiveness under a German healthcare perspective (over a 2 years horizon) compared with CR and non-restorative cavity control, the cost-advantages of HT seem to be generalizable across settings. While this study had only assessed costs of parental absenteeism (for travel and time spent at the dental office), the present study added costs for travelling etc into the estimation. As CR needed significantly more appointments during follow-up, with higher travelling costs, and higher opportunity costs, than HT, we are confident that on multiple cost levels, HT seems advantageous.

Using our primary outcome of molar survival, HT was significantly superior over CR. Also, HT required fewer re-treatments and HT molars experienced fewer episodes of pain, endodontic therapy and extraction; these outcomes are likely to be of high relevance for patients, but also providers. In summary, HT showed high cost-effectiveness, dominating CR. Based on our analysis, HT yields benefits for patients, providers, but also parents of the treated child from a number of perspectives. As HT has also demonstrated high acceptability and applicability { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}, it may be suitable for providing effective, efficient and acceptable care to cavitated carious lesions in children's primary molars.

This study has a number of strengths and limitations. The greatest strength is that the basis of our analysis was a randomized, practice-based, long-term trial, which followed many of the treated molars until exfoliation. The trial thus allowed us to consider not only the initial or short-term aspects of costs and effectiveness, but to capture the long-term impact of HT and CR. Being able to follow teeth from their initial treatment until the final event of "success" (exfoliation) is something which is seldom possible and rarely seen in Dentistry. The trial and its subsequent analyses comprehensively inform decision-makers as to the effectiveness, the subjective impact and the cost-effectiveness of HT and CR in a setting with high external validity. A further strength is that we considered not only direct dental treatment costs (from two perspectives), but also indirect/opportunity costs, i.e. costs resulting from direct dental treatment, and costs placed on the time spent for this treatment or travelling to appointments etc. These costs have been found relevant especially for chronic diseases { ADDIN EN.CITE

{ ADDIN EN.CITE.DATA }}, where costs for absenteeism (e.g. time of work) or presenteeism (e.g. time at work during which one is limited by the disease) are substantial { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}. We also demonstrated the relevance of repeated travelling to and from dental practices, and of the time spent for these appointments on the cost-effectiveness. The main limitation of the study is that it is in parts retrospective in nature. We built on prospectively collected initial treatment times, but needed to make assumptions as to the time needed for re-treatment as well as on travel time and costs. Obviously, these assumptions may not perfectly hold true; and caution is needed when interpreting the generated data. Given the unambiguous ranking of HT and CR, we are confident that our findings are robust, but we highlight that the absolute differences may be over- or under-estimated to some degree. In addition, the study itself is prone to bias by design. For example, operator and also examiner blinding were impossible. Other aspects like attrition and selection bias can be largely excluded given this was a split-mouth study, where imbalanced inclusion or loss-to-follow-up is not an issue. Last, the latter aspect – the study being split-mouth – was ignored in our analysis, as we assumed the pairing of different treatments for the same condition within the same patient to be something artificially introduced by the trial. In daily care, dentists would probably apply the same therapy for similarly affected teeth in the same patient. While obviously, and as mentioned, the clustering of teeth within a mouth, even when treated identically, would affect cost-effectiveness (mainly reducing indirect and opportunity costs), our approach seemed justified to allow a useful comparative analysis of HT versus CR.

A number of recommendations can be made from our study. From a research perspective, future trials should routinely be record efficiency data in detail, including time spent, staff and material needed, and details on travel (mode and distance) as well as patients'/parents' occupational status (to allow assigning monetary values to times). Efficiency data should not only be collected for the initial, but all provided treatments (also during follow-up), as this long-term perspective is relevant; comparing only initial costs would have led to different cost-effectiveness rankings in our study. From a clinical perspective, our study adds another argument supporting HT for managing cavitated carious lesions in primary molars. Currently

and in many healthcare systems, many cavitated primary molars are not treated at all; which may be grounded in parental expectations, dentists' feeling of being unskilled in the management of children, and the polarization of these cavities in a few high-risk children who are complex to manage. HT may allow some of these barriers to be addressed, having been found easy to perform, acceptable for patients and parents, and also cost-effective. Extraction of decayed primary teeth alone, carried out under general anaesthesia, costs an estimated £36 million annually { ADDIN EN.CITE

<EndNote><Cite><Author>NWPH</Author><Year>2014</Year><RecNum>19756</RecNum><DisplayText>(NWPH 2014)</DisplayText><record><rec-number>19756</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrz5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1526198549">19756</key></foreign-keys><ref-type name="Web Page">12</ref-

type><contributors><authors><author>NWPH,</author></authors></contributors><titles><title>NHS England. Improving dental care - a call to action. Secondary Improving dental care - a call to action</title></titles><dates><year>2014</year></dates><pub-location>http://www.nwph.net/dentalhealth/reports/Report_NHS_DEP_for_England_OH_Survey_12yr_2008-09.pdf </pub-location><urls></urls></record></Cite></EndNote>}. Considering the predicted funding gap expected in the NHS (£27 billion by 2029/30) and the associated calls for innovation, efficiency and effective treatments { ADDIN EN.CITE

<EndNote><Cite><Author>Darzi</Author><Year>2017</Year><RecNum>19757</RecNum><DisplayText>(Darzi et al. 2017)</DisplayText><record><rec-number>19757</rec-number><foreign-keys><key app="EN" db-id="p0ftrtrz5vdt5ezpt7xfvzv00p02rzzdf2s" timestamp="1526198621">19757</key></foreign-keys><ref-type name="Web Page">12</ref-type><contributors><authors><author>Darzi, A</author><author>Quilter-Pinner, H</author><author>Kibasi, T</author></authors></contributors><titles><title>The Lord Darzi Review of Health and Care: Interim report</title></titles><dates><year>2017</year></dates><pub-location>The Lord Darzi Review of Health and Care: Interim report</pub-

location><urls></urls></record></Cite></EndNote>}. Considering the predicted funding gap expected in the NHS (£27 billion by 2029/30) and the associated calls for innovation, efficiency and effective treatments { ADDIN EN.CITE

location><urls></urls></record></Cite></EndNote>}, our findings may eventually assist commissioners, clinicians and parents to make informed choices for managing carious lesions in primary teeth.

In conclusion, and within the limitations of this trial, HT was more cost-effective than CR for managing cavitated caries lesions in primary molars. HT teeth were retained for longer and experienced less complication at lower costs.

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References

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Tables

Table 1: Mean (95% CI) effectiveness and costs of different treatment strategies per tooth. HT Hall Technique, CR Conventional Restorative treatment. Bold: statistically significant differences.

Parameter	HT	CR
Effectiveness		
Proportion survived (%)	99 (98-100)	92 (87-97)
Proportion without pain or endodontic/ extraction complications (%)	98 (95-100)	85 (78-91)
Proportion without any re-restoration (%)	96 (92-100)	61 (52-100)
Direct medical costs		
Initial costs (GBP)	22.85 (n/a)	8.75 (n/a)
Costs for endodontic treatment/ extraction re-treatments (GBP)	0 (0-0.95)	13.22 (2.11-27.77)
Costs for restorative re-treatments (GBP)	0 (0-1.12)	8.02 (5.97-9.12)
Subtotal cumulative (GBP)	24.12 (23.04-25.24)	29.26 (17.11-46.42)
Indirect/opportunity costs		
Travel costs (GBP)	5.00 (4.19-5.91)	10.29 (8.40-12.56)
Time costs (GBP)	3.21 (2.79-3.67)	8.83 (7.14-10.86)
Subtotal cumulative (GBP)	8.25 (7.33-9.22)	19.06 (15.87-22.63)
Total cumulative costs (GBP)	32.26 (30.83-33.98)	48.91 (34.40-68.74)

Figure legends



Figure 1: Participant recruitment, follow up and the final dataset flow are shown.

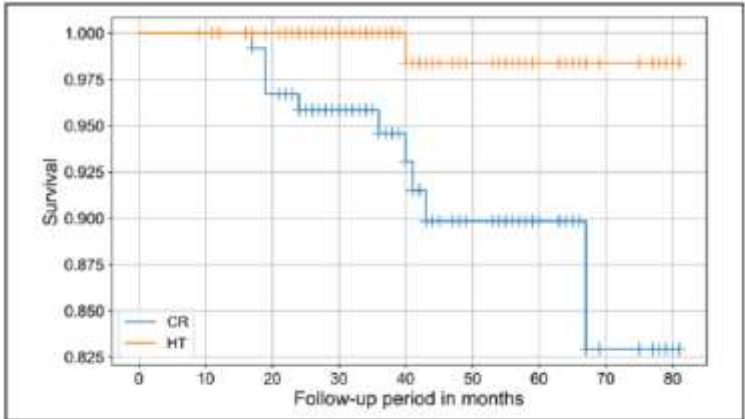


Figure 2: Survival curves for the different strategies. CR: Conventional restorations, HT Hall Technique.

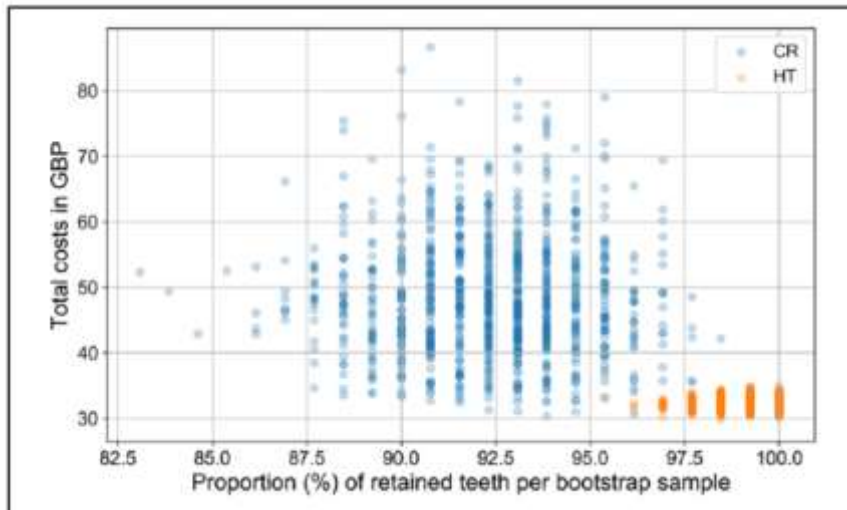


Figure 3: Cost-effectiveness plane. The costs (GBP) and effectiveness (survival, in %) of the HT (Hall Technique) and CR (conventional restorative treatment) were plotted based on bootstrapped sample estimates.

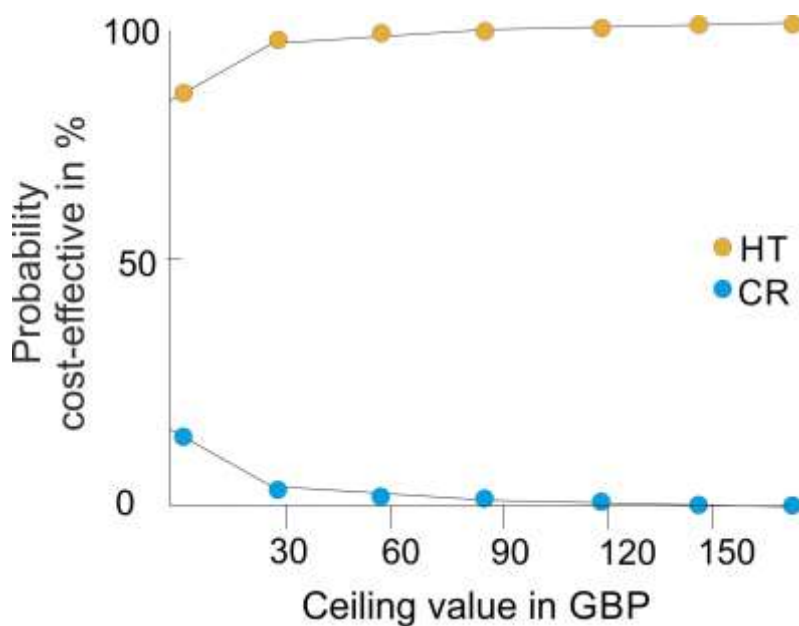


Figure 4: The cost-effectiveness acceptability curve indicates how with increasing willingness-to-pay, the probability of cost-effectiveness of different strategies changes. HT had the highest probability of being cost-effectiveness regardless of a hypothecated payer's willingness-to-pay threshold.

Cost-effectiveness of the Hall Technique in a Randomized Trial

F. Schwendicke, J. Krois, M. Robertson, C. Splieth, R. Santamaria, and N. Innes

Appendix

In the base-case, direct dental treatment costs were estimated from an NHS Scotland perspective. Initial and re-treatment costs were derived from fee items of NHS Scotland dental item fee catalogue. A range of treatment fee items are used for different initial and re-treatments, as indicated in the Appendix Table. For HT, the placement of a stainless steel crown was charged. For CRs, a direct restoration (filling) was charged. Re-treatments involved re-cementation or new placement of stainless steel crowns, pulpotomy or extraction in combination with local anesthesia or under general anesthesia.

Appendix Table: Cost estimation. Costs were derived using the BDA Scotland fees guide. Items were charged as part of different initial treatments (HT Hall Technique, CR Conventional restorative treatment), and also when they occurred as re-treatment items (retreat).

Treatment	Item	GBP	Charged
Direct restoration	4401	8.75	CR
Hall Crown	4402	22.85	HT
Pulpotomy	4403	9.15	Retreat
Stainless steel crown	4402	22.85	Retreat
Re-cementation	1782	11.70	Retreat
Extraction	2102	8.75	Retreat
Antibiotics ⁴	3701	8.45 + 1.29*	Retreat
General anaesthesia (fixed value)	-	719.90**	Retreat

* mean pharmaceutical costs for standard antibiotics, NHS National Services Scotland.

www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Drugs-and-Preparations-with-Tariff-Prices.asp

** { [HYPERLINK "http://www.scottishdental.org/wp-content/uploads/2017/03/SDNAP_Oral-Health-Dental-Services-for-Children-2017.pdf"](http://www.scottishdental.org/wp-content/uploads/2017/03/SDNAP_Oral-Health-Dental-Services-for-Children-2017.pdf) }

In the sensitivity analysis, direct medical costs were estimated within the NHS England perspective. Under this system, treatments are charged within Bands; these Bands cover all treatments falling into it together with any possible treatments in lower Bands regardless of their quantity (placing one filling is paid the same as placing five) as long as they occur during the same course of treatment. Band 1 includes assessment and advice, radiographs etc., Band 2 includes direct restorations including stainless steel/Hall crowns and endodontic treatments (pulp therapies); Band 3 includes lab work. There are additional Bands for urgent treatments (mainly for pain alleviation) and prescriptions. To reflect the different efforts within the Bands, each Band comes with a different number of Unit of Dental Activities (UDAs) being charged (1, 3 and 12 UDAs for Band 1, 2 and 3, respectively). The mean UDA value paid within the NHS England in 2016/17 was 31.63 GBP. Hence, for example, for placing a Hall crown, falling under Band 2, 3 UDAs worth a total of 94.89 GBP would be claimed; this would cover any further direct restorations or assessments etc. needed. Hence, any tooth-based estimations ignoring possible treatments on further teeth may come with distortions, we accepted that. We assumed (in the absence of having claims data for NHS England, given the setting of the trial) the courses of treatment to be completed within two months; i.e. re-interventions in the same or lower Band were charged again once they were provided more than two months after the previous treatment (in line with NHS regulations, treatments within higher Bands were claimed regardless, as these are not covered by a lower Band treatment). Note that this regulation did not apply when the last treatment was an urgent treatment/prescription (as a separate course of treatment is commenced after any urgent treatment has been provided). For GA, children usually received multiple extractions and costs were assumed to be generated accordingly ({ HYPERLINK "https://www.nice.org.uk/guidance/ph55/resources/costing-statement-pdf-69284125" }) at 558 GBP. Note, however, that we again did not distribute these costs among teeth as we did not know the exact number of removed teeth.