

V. Smail-Faugeron*****, A. Porot**,
M. Muller-Bolla*****, F. Courson*****

*Institut National de la Santé et de la Recherche Médicale,
U1138, Equipe 22, Centre de Recherche des Cordeliers, Paris,
France

**Assistance Publique-Hôpitaux de Paris, Hôpital Bretonneau,
Service d'Odontologie, Paris, France

***Université Paris Descartes - Sorbonne Paris Cité, Faculté
de Chirurgie Dentaire, Unité de Recherches Biomatériaux
Innovants et Interface EA4462, Montrouge, France

****Université de Nice-Sophia Antipolis, Service d'Odontologie,
Faculté de Chirurgie Dentaire, Nice, France

e-mail: violaine.smail-faugeron@parisdescartes.fr

Indirect pulp capping versus pulpotomy for treating deep carious lesions approaching the pulp in primary teeth: a systematic review

ABSTRACT

Aim To assess dental practice regarding the use of indirect pulp capping or pulpotomy in children with deep carious lesions approaching the pulp in primary teeth and to compare the efficacy of the two pulp treatments.

Methods Study design: Systematic review. We searched the Cochrane Library, PubMed via MEDLINE, and EMBASE as well as the reference lists of included reports and ClinicalTrials.gov (for ongoing trials). Eligible studies were surveys of dental practice sent to dentists regarding the use of indirect pulp capping and pulpotomy in children with deep carious lesions approaching the pulp in primary teeth and any type of clinical study. Two review authors independently extracted data and assessed risk of bias in duplicate.

Results Of the 481 potentially eligible articles, 11 were included in the review: 8 described surveys of dental practice, 1 a non-randomised study, and 2 ongoing randomised trials. The surveys of dental

practice showed an overall increase in the teaching and practice of indirect pulp capping in primary teeth. The non-randomised study found a statistically significant difference in favour of indirect pulp capping for clinical and radiological success at 3 years but with high overall risk of bias.

Conclusions Despite the success rate of indirect pulp capping for treating deep carious lesions approaching the pulp in primary teeth, practitioners still hesitate to practice this technique because of lack of evidence and studies on this topic. Thus, for strong evidence, investigators are encouraged to conduct randomised trials comparing the efficacy of indirect pulp capping and pulpotomy for treating deep carious lesions approaching the pulp in primary teeth.

Keywords Carious lesions; Indirect pulp capping; Primary teeth; Pulpotomy.

Introduction

In children, deep carious lesions represent the most common disease of primary teeth; 42% of children aged 2 to 11 have dental carious lesions in their primary teeth, with an average of 1.6 decayed teeth per child [NHANES, 1999-2004]. A recent review described the management of deep carious lesions in permanent and primary teeth. Pulpotomy is the pulp treatment most commonly used for primary teeth with a deep carious lesion approaching the pulp. Complete caries removal often leads to pulpotomy of primary teeth. Partial caries removal is another option that has been recently suggested [Blanchard and Boynton, 2010; Ricketts et al., 2013]. The guidelines of the American Academy of Pediatric Dentistry highlight two pulp treatment techniques available for managing deep carious lesions approaching the pulp in primary teeth: pulpotomy and indirect pulp capping [American Academy of Pediatric Dentistry, 2014-2015]. The primary aim of both is to preserve the vitality of pulp without clinical or radiological signs of failure (e.g., pain, pathologic mobility, pathologic radiolucency or pathologic root resorption) [Camp, 2008].

With pulpotomy, a portion of the pulp is removed: the coronal pulp is removed and the radicular pulp is preserved. After treatment, the cavity is filled with a medicament followed by a final restoration. A recent systematic review found no evidence to clearly identify one superior pulpotomy medicament, although two medicaments seem to be preferable: mineral trioxide aggregate or ferric sulfate [Smail-Faugeron et al., 2014].

With indirect pulp capping, the deepest layer of decayed dentin closest to the pulp is left in place to avoid pulp exposure. Then, it is covered with a medicament

(dentin bonding agent, calcium hydroxide, zinc oxide-eugenol, or glass-ionomer cement), followed by a final restoration [American Academy of Pediatric Dentistry, 2014-2015; Franzone et al., 2007]. Indirect pulp capping is more conservative than pulpotomy because the vitality of coronal and radicular pulp is preserved [Fuks, 2008].

Aim of this study was to assess by a systematic review of the literature current dental practice regarding the use of indirect pulp capping and pulpotomy for treating deep carious lesions in primary teeth. The second objective was to compare the efficacy of the two pulp treatments.

Material and methods

A systematic review of the literature was performed.

Criteria for considering studies for this review

Eligible studies were results of surveys of dental practice sent to dentists regarding the use of indirect pulp capping and pulpotomy in children with deep carious lesions approaching the pulp in primary molars and any type of clinical study comparing indirect pulp capping and pulpotomy (case report or case series, cohort study, comparative non-randomised study or randomised trial).

Search methods for identifying studies

We searched the databases Cochrane Library, MEDLINE, and EMBASE for articles, with no restriction on date or language. Search equations for each database combined free text words and controlled vocabulary pertaining to the condition and interventions (see Supporting Information, Text S1). The last search was conducted in February 2015. We checked the references of all eligible articles for relevant studies and scanned reference lists from identified review articles for further studies. We searched ClinicalTrials.gov for the protocols of included studies and to identify ongoing trials [Chan and Altman, 2005].

Data collection

Two authors independently and in duplicate screened the titles and abstracts of records retrieved by the search, then the selected full-text reports. Finally, we included studies after checking for multiple publications of a given study.

For each survey of dental practice, we collected data on publication year and country, sender, target population, mode of administration, description of the survey, number of surveys sent, and number of responses.

For each clinical study, two authors independently and in duplicate recorded the year of publication and country of origin, inclusion/exclusion criteria specified, number of arms in the trial, treatments compared, detailed description of interventions, number of patients enrolled, number of treated teeth, mean age of participants, duration of follow-up and outcome data. We assessed the risk of bias for each trial by the Cochrane Collaboration

Risk of Bias tool, which includes the following items: selection of participants, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, and selective outcome reporting [Higgins et al., 2011]. For non-randomised studies, we considered the risk of selection bias as high and also assessed the risk of bias related to confounding factors. For each study, each domain was rated as low, high, or unclear risk of bias. Then, each study was assigned an overall risk of bias score: low risk (low for all key domains), high risk (high for one key or more domains), or unclear risk (unclear for one key or more domains). The two review authors compared evaluations and resolved any disagreements by discussion.

Analysis

We did not perform any meta-analysis, but we described the study characteristics and results qualitatively with number, percentage or mean (min-max).

Results

The search yielded 481 potentially eligible articles. We included 11 relevant articles in the review: 8 described surveys of dental practice [Bergoli et al., 2010; Bowen et al., 2012; Dunston and Coll, 2008; Hincapie et al., 2015; Ni Chaollai et al., 2009; Primosch et al., 1997; Seale and Glickman, 2008; Spedding, 1968] and 1 a retrospective

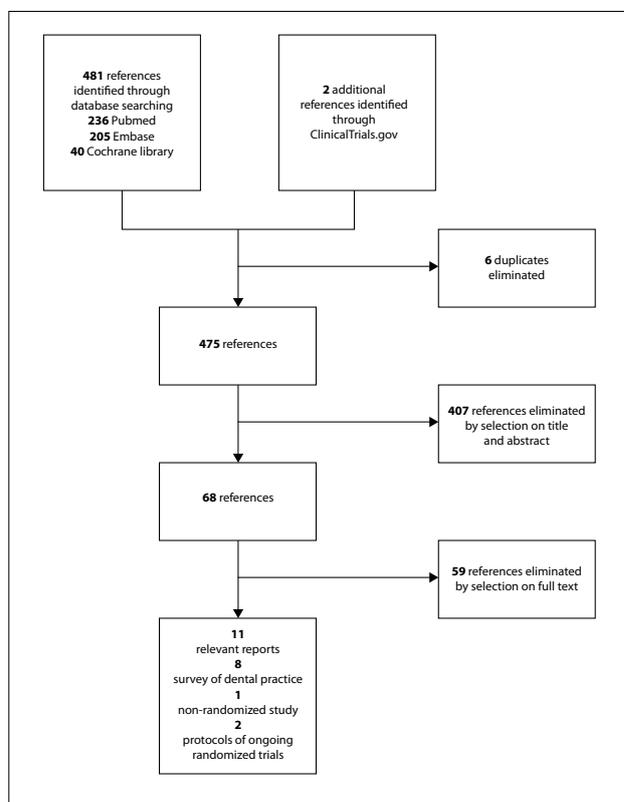


FIG. 1 Flow of studies in the systematic review.

First author, publication year		Spedding 1968	Primosch 1997	Dunston 2007	Seale 2008	Ni Chaollai 2009	Bergoli 2010	Bowen 2012	Hinciapie 2015
Target population	Dental schools-PD	x	x	x		x	x		x
	Dental schools-GP								x
	ABPD diplomates			x	x			x	
	AAE diplomates				x				
	Private GP							x	
Mode of administration	Posted letter	x		x		x			
	E-mail		x		x		x	x	x
Description of the survey	Open-ended questionnaire	x							
	Multiple-choice questions		x	x		x	x	x	x
	5-point Likert-type scale				x				
No. of responses / number of surveys sent (%)	Dental schools-PD	58/58 (100)	53/53 (100)	48/56 (86)		14/18 (78)	83/191 (43)		48/?
	Dental schools-GP								11/?
	ABPD diplomates			690/1200 (57)	252/?			953/3691 (26)	
	AAE diplomates				102/?				
	Private GP							306/3883 (8)	
No. of participants teaching or practicing pulpotomy (%)	Dental schools-PD	57 (98)	53 (100)	48 (100)		14 (100)	82 (99)		48 (100)
	Dental schools-GP								10 (91)
	ABPD diplomates			681 (99)	53%			?	
	AAE diplomates				42%				
	Private-GP							?	
No. of participants using medicament (%)	Formocresol	48 (84)	52 (98)	606 (83)	24%	3 (21)	41 (50)	500 (68)	51 (86)
	Calcium hydroxide	24 (42)				1 (7)			
	Zinc oxide-eugenol	4 (7)							
	Ferric sulfate			138 (19)	1%	13 (93)		156 (21)	3 (6)
	MTA				64%	2 (14)		10 (1)	
No. of participants teaching or practicing indirect pulp capping (%)	Dental schools-PD	51 (88)	37 (70)	40 (83)		10 (71)	79 (95)		40 (83)
	Dental schools-GP								10 (91)
	ABPD diplomates			486 (71)	47%			?	
	AAE diplomates				58%				
	Private GP							?	
No. of participants using medicament (%)	Calcium hydroxide	29 (57)	33 (89)	349 (66)		9 (90)	54 (68)		32 (54)
	Glass ionomer		6 (16)	297 (56)		5 (50)	28 (35)		36 (61)
		31 (61)	8 (22)	54 (10)		1 (10)			

PD: pediatric dentists; GP: general practitioners; ABPD diplomates: diplomates of the American Board of Pediatric Dentistry; AAE diplomates: diplomates of the American Association of Endodontists; MTA: mineral trioxide aggregate

TABLE 1 Surveys of dental practice regarding the teaching or practice of indirect pulp capping and pulpotomy over time.

comparative non-randomised study [Vij et al., 2004]; 2 were protocols of ongoing randomised trials at ClinicalTrials.gov (identification numbers: NCT02298504 and NCT00973089) without reported results. The flow of the article selection is in Figure 1. We found no published randomised trial.

Surveys of dental practice

We assessed trends over time in teaching or using indirect pulp capping and pulpotomy in primary teeth to treat deep carious lesions approaching the pulp (Table 1). Five surveys were conducted in the United States [Bowen et al., 2012; Dunston and Coll, 2008; Primosch et al., 1997; Seale and Glickman, 2008; Spedding, 1968], one in the United Kingdom and Ireland [Ni Chaollai et al., 2009], one in Brazil [Bergoli et al., 2010], and one in Columbia [Hincapie et al., 2015]. All 8 surveys of dental practice investigating taught or practiced pulp treatments were sent to paediatric dentists and general practitioners at dental schools or in private practice. For 75% of surveys, a multiple-choice survey was sent by email. The surveys were returned by a mean of 65% of participants (min-max, 17–100%). Pulpotomy appeared to be the most taught or practiced pulp treatment (mean 92%, min-max 48–100%), and a 1:5 dilution of formocresol applied for 5 min was the preferred medicament (59%). Indirect pulp capping was taught or practiced by a mean of 77% of participants (min-max 53–95%) and calcium hydroxide was the most-used medicament (71%). Before 2000, all participants taught or practiced pulpotomy for treating deep carious lesions in primary teeth as compared with 79% indirect pulp capping. After 2010, all participants taught or practiced pulpotomy as compared with 90% indirect pulp capping. Results showed an overall increase in the teaching and practice of indirect pulp capping in primary teeth.

Retrospective comparative non-randomised study

Vij et al. [2004] conducted a retrospective parallel-arm non-randomised study in the United States comparing indirect pulp capping and pulpotomy for treating deep carious lesions approaching the pulp. Inclusion criteria were caries lesions close to the pulp; no clinical signs of gingival swelling or tooth mobility; no radiolucency; no internal resorption; no pain, or pain compatible with reversible pulpitis that could be relieved by analgesics or brushing after 20 min; adequate pre-operative and postoperative radiographs of at least 1- year recall; and adequate treatment documentation available. The medicament used with indirect pulp capping was glass-ionomer cement and for pulpotomy was formocresol, the pulp chamber then filled with reinforced zinc oxide-eugenol (intermediate restoration). Final restoration was stainless steel crowns, amalgam, glass-ionomer cement, or composite for both treatments. The primary outcome was clinical and radiological success measured by the

absence of fistula or gingival swelling, abnormal mobility, pain to percussion or history of pain, and radiographic signs of internal or external pathologic root resorption or widened periodontal ligament or pathologic radiolucency. The authors retrospectively enrolled 141 children (mean age 5.4 years), including 133 from a previous retrospective parallel-arm non-randomised study [Farooq et al., 2000]. In all, 226 primary molars were treated between 1975 and 1999, including 108 treated by indirect pulp capping and 118 by pulpotomy. Of the 226 teeth, 78 were treated in two stages. First, investigators removed superficial carious tissue and temporarily filled the cavity with reinforced zinc oxide-eugenol or glass-ionomer cement. Then, at a second appointment 1 to 3 months later, they performed indirect pulp capping or pulpotomy. At 3 years, the success rate was 94% with indirect pulp capping and 70% with pulpotomy ($p \leq 0.001$). The authors showed significantly higher long-term success with indirect pulp capping with glass-ionomer cement than formocresol pulpotomy for treatment of deep caries.

The risk of selection bias was high because it was a retrospective non-randomised study. Blinding of participants, personnel and outcome assessors was unclear because of insufficient information for a clear judgment, but blinding was likely absent, given the retrospective nature of the study. The risk of bias related to incomplete outcome data was low because of absence of missing data. The risk of bias related to selective outcome reporting was unclear because authors did not report individual component outcomes assessing the success of pulp treatments defined in the Methods section, and we found no protocol registered in a public registry (consequently, we could not assess whether outcomes were omitted or changed). The risk of confounding bias was high because investigators did not adjust for potential confounders (age, sex, oral health status and caries risk). Overall, this comparative non-randomised study was at high risk of bias.

Protocols of ongoing randomised trials

The ongoing randomised trial NCT02298504 is a 3-arm trial comparing mineral trioxide aggregate pulpotomy, biodentine pulpotomy, and glass-ionomer cement indirect pulp capping for primary teeth in children aged 2 to 9 years. Inclusion criteria defined by the authors are deep dental decay in primary molars, signs and symptoms of reversible pulpitis, no clinical symptoms of irreversible pulpitis or pulp necrosis or acute dental infection and no systemic illness that contraindicated vital pulp treatment such a sickle cell disease or teeth not restorable. The primary outcome is defined as clinical and radiological success measured at 3 years by absence of abscess or any swelling, fistula or other pathology, pathologic mobility, post-operative pain, pain on palpation or percussion, root resorption (internal or external), furcation involvement or periapical radiolucency, loss of lamina dura, or abnormal appearance of periodontal ligament space. The authors

plan to enroll 156 patients. The trial is not yet open for participant recruitment.

The ongoing randomised trial NCT00973089 is a parallel-arm trial comparing indirect pulp capping and complete removal of caries including pulpotomy in primary teeth in children aged 5 to 8 years. Inclusion criteria defined by the authors are healthy children, deep carious lesions reaching the inner half of the dentin, absence of periapical or interradicular alterations detected by radiography, absence of spontaneous pain, ASA I subjects, cooperation, and no clinical or radiographic signs of pathology. The primary outcome is defined as "success" with no more details given. The authors plan to enroll 100 patients. The trial is currently recruiting participants.

Discussion

To our best knowledge, no study has systematically reviewed the existing literature comparing indirect pulp capping and pulpotomy for primary teeth in children with deep carious lesions. On the basis of limited evidence (one retrospective comparative non-randomized study with 226 patients and 141 teeth), we found greater long-term success with indirect pulp capping than pulpotomy for treating deep carious lesions in primary teeth.

The preservation of the vitality of pulp tissue is a new treatment approach in current dentistry [Topaloglu-Ak et al., 2009]. Indirect pulp capping can reduce cavity size and hence preserve tooth structure. Moreover, a more conservative approach is time saving and implies less discomfort for children [Ricketts et al., 2013]. Several studies have reported success rates with indirect pulp capping of > 90% at 1-year follow-up [Rosenberg et al., 2013], 2-year follow-up [Marchi et al., 2006], and 3-year follow-up [Al-Zayer et al., 2003; Falster et al., 2002; Farooq et al., 2000; Vij et al., 2004]. Moreover, recent studies showed that minimal intervention dentistry for managing dental carious lesions in general is increasingly accepted by practitioners [Banerjee, 2013; Freitas et al., 2014]. Our results showed similar conclusions. However, the dental practice is still variable. Among a sample of 1,232 dentists, only 62% stated that they were trained to perform indirect pulp capping in dental school, and among a sample of 738 dentists, 33% stated that they performed pulpotomy but did not perform indirect pulp capping because of lack of sufficient conclusive data to support the use of the technique in primary teeth [Bowen et al., 2012]. The non-inferiority of indirect pulp capping is expected in terms of clinical and radiological success, but the superiority of indirect pulp capping is expected due to the preservation of the vitality of the pulp.

Our study has some limitations. First, we identified only one comparative non-randomised study with overall low quality of evidence and no randomised trial. Thus, the true clinical relevance of the findings is somewhat lacking. Moreover, we did not search "grey" literature,

and we acknowledge that unidentified studies may exist. However, our search strategy was extensive and we consulted the largest trial registry, ClinicalTrials.gov, run by the US National Library of Medicine at the National Institutes of Health [Zarin et al., 2005], to find unpublished randomised trials and hence the risk of publication bias in our study is low [Dwan et al., 2013; Song et al., 2010]. We found two protocols of ongoing randomised trials without reported results. Another limitation is the lack of a clear clinical protocol described in the non-randomised study. For example, the authors gave insufficient information to determine whether a rubber dam was used. Moreover, investigators in the included study did not adequately consider and subsequently adjust for potential confounders, especially patient-related factors of success or failure. For instance, age, sex, oral health status and caries risk were sometimes mentioned but not compared between children receiving active treatment and control treatment. Moreover, the quality of the final restoration could influence the success or failure of treatment, which was discussed by authors but not taken into account in the analysis [Attari and Roberts, 2006; Demarco et al., 2005].

Our remarks could have implications for future research. Decisions about which treatment is best are driven by the results of randomised trials and systematic reviews [Chalmers, 2011]. In this regard, high-quality randomised trials controlling for clinically relevant parameters and constraints are needed to validate whether indirect pulp capping compared to pulpotomy is a worthwhile clinical procedure for treating deep carious lesions in primary teeth. Investigators should be encouraged to define treatment success or failure using the 5 component outcomes retained in the core set of a composite outcomes identified by a Delphi process at 12 and 24 months [Smail-Faugeron et al., 2013; Sinha et al., 2011]. A potential concern with the retrospective study and the ongoing trials is that outcomes do not correspond to the core set defined in this context. Given the limitations of composite outcomes, trialists should analyse only the pre-specified composite and report results for all 5 components as recommended [Cordoba et al., 2010; Montori et al., 2005].

Conclusion

We showed an overall increase in the teaching and practice of indirect pulp capping in primary teeth. However, practitioners still hesitate to practice this technique because of lack of evidence and studies on this topic. Thus, to infer strong evidence, investigators are encouraged to conduct randomised trials comparing the efficacy of indirect pulp capping and pulpotomy for treating deep carious lesions in primary teeth.

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