

Evidence-based Assessment: Evaluation of the Formocresol Versus Ferric Sulfate Primary Molar Pulpotomy

Alex Loh, BSc Polly O'Hoy, BSc Xuan Tran, BSc Rachael Charles, BSc Andrew Hughes, BSc
Kotaro Kubo, BSc Louise Brearley Messer, BSc, LDS, MSc, PhD, FRACDS, FICD

Drs. Loh, O'Hoy, Tran, Charles, Hughes, and Kubo were final year dental students at the time of this study, School of Dental Science, University of Melbourne, Melbourne; Dr. Messer is the Elsdon Storey Professor of Child Dental Health and Director of Graduate Studies, School of Dental Science, University of Melbourne, Australia.

Correspond with Dr. Messer at ljbm@unimelb.edu.au

Abstract

Purpose: Formocresol and ferric sulfate were evaluated as pulpotomy medicaments using evidence-based dentistry principles. Formocresol has been challenged as a potential carcinogen and mutagen, leading to consideration of ferric sulfate.

Methods: The PICOT statement was: (P) In human carious primary molars with reversible coronal pulpitis, (I) does a pulpotomy performed with ferric sulfate, (C) compared with formocresol, (O) result in clinical/radiographic success, (T) in time periods up to exfoliation? Relevant papers (N=894) were identified from databases and inclusion criteria were applied; 94 papers remained (randomized clinical trials [RCTs]=7; clinical trials [CTs]=28; case-control studies=14; opinions, cohort, and cross-sectional studies=4; reviews=22; irretrievable papers=19). Three RCTs and 10 CTs (total teeth: formocresol=753; ferric sulfate=90) were meta-analyzed; 1 RCT and 1 CT were tested for homogeneity (odds ratios; 95% confidence intervals); 3 RCTs and 10 CTs were examined by student's *t* test.

Results: Clinical data indicated ferric sulfate was significantly more successful than formocresol (OR=1.95; CI=1.01-3.80). Radiographic data indicated no difference between medicaments (OR=0.90; CI=0.58-1.39). Medicaments did not differ with *t*-tests of clinical ($P>.10$) and radiographic ($P>.50$) data.

Conclusions: This evidence-based assessment concluded that, in human carious primary molars with reversible coronal pulpitis, pulpotomies performed with either formocresol or ferric sulfate are likely to have similar clinical/radiographic success. (*Pediatr Dent.* 2004;26:401-409)

KEYWORDS: EVIDENCE-BASED DENTISTRY, PRIMARY MOLAR, PULPOTOMY MEDICAMENTS, FORMOCRESOL, FERRIC SULFATE

Received February 27, 2004 Revision Accepted June 22, 2004

Evidence-based practice (EBP) is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."¹ The success of EBP depends upon the quality of the available evidence.¹ The practice aims to provide the current best answer to the clinical question (which may not necessarily be the best possible procedure) and is useful in resolving clinical questions about etiology, prognosis, and treatment.

Traditionally, clinical decisions were based upon experience, advice from colleagues, and continuing education courses.¹ EBP, however, is an intellectual evolution in clinical practice, where decisions are based on evidence rather than opinion. In 1972, a British physician/epidemiologist,

Dr A. Cochrane, published *Effectiveness and Efficiency*, emphasizing scientific evidence rather than intuition, expert opinion, or anecdotal experience.¹ In 1992, the British National Health Service created the Cochrane Centre to facilitate the preparation and maintenance of systemic reviews in health care.¹ Other journals now publish evidence-based literature in the health disciplines. In 1998, *The Journal of Evidence Based Dentistry* commenced as a supplement to *The British Dental Journal*.

Clinical practice guidelines are published by professional associations and regulatory authorities, assisting clinicians and patients to make appropriate decisions on health care. In 1999, the Canadian Collaboration on Clinical Practice Guidelines in Dentistry planned the development of

clinical guidelines utilizing the principles of EBP, now known as evidence-based dentistry (EBD), and clinicians are now placing increasing reliance on EBD.¹

Conduct of research using EBD

Research using the principles of EBD utilizes the following 5 steps:

1. define the clinical research question;
2. search all available literature for evidence;
3. select (sieve) studies for possible inclusion;
4. appraise and rank the evidence in the selected studies and establish a final set of selected studies;
5. compile and analyze data from the studies to produce a statistically based conclusion.²

The first step defines the clinical research question of interest. Clinical questions need to be delineated clearly so that the intended audience is not confused by a vague topic. The acronym "PICOT" constructs the clinical research question to ensure that findings from the investigation provide a practical outcome. The letters define the 5 elements of the question as follows:

1. "P" represents the clinical problem;
2. "I" represents the intervention;
3. "C" represents a comparison;
4. "O" represents an outcome;
5. "T" represents time.

The second step involves a comprehensive search of available literature for all relevant studies and reports. Published papers and unpublished materials (eg, theses, conference proceedings, special reports, etc.) and materials in languages other than English are included. Strategies include searching journal databases, manual searching, checking reference lists, contacting researchers in the field, locating unpublished literature, and, using Internet search engines. Although much of the literature located may be unusable, this step is necessary to avoid literature bias. Peer-reviewed journals may be challenged as biased in only publishing papers that report a statistically significant result. Papers concluding no difference between treatments may, therefore, be harder to find but are relevant.

The third step involves selecting (sieving) all studies for inclusion in the statistical analysis. Inclusion criteria should reflect the requirements of the research question. It is advocated that more than one reviewer independently apply the inclusion criteria to each piece of evidence to eliminate human error and individual bias.³ All included papers are evaluated and ranked, with randomized controlled trials as the strongest evidence, followed in order by: (1) cohort studies; (2) case-control studies; (3) case series; (4) case reports; and (5) expert opinion.^{6,7}

The fourth step requires extraction and synthesis of data from the selected papers. This is time consuming, as vigilant screening for numerical or factual errors is essential in deriving data. It may not be appropriate to combine some data from particular studies. Several statistical techniques, known collectively as meta-analysis in EBD, are used for

evaluation of clinical results.⁷ L'Abbe plots may be used for a qualitative presentation of findings.⁸

The fifth and final step correlates findings of the aforementioned analyses with clinical relevance and makes clinical recommendations.

EBD's value in dental practice

Practicing dentists can use EBD to assess recent literature for new advances and opinions, and to reject new or previously accepted techniques that do not have scientific support. While a literature review summarizes a body of knowledge, EBD provides an enhanced literature review that places importance on evidence based on sound research principles. Given the broad nature of EBD reviews, time-poor practitioners can also use it as a literature filter.

Following sieving of papers, only a few may remain for inclusion in meta-analysis, even for an apparently widely researched topic. Consequently, conclusions from EBD are based on the few studies of sufficient merit for inclusion. Since EBD is based upon defined but arbitrary criteria, excluded articles of potential value will have no input into the EBD process. If no articles fulfill the inclusion criteria, EBD is unable to provide a conclusion other than stating the need for further research on the topic. The shift to the dental practice approach brought about by EBD effectively allows clinicians to review a large amount of literature and draw their own conclusions.⁶ This approach will often result in sound clinical decisions. Clinicians, however, must still determine the validity of the conclusions for themselves.

EBD's application to selection of pulpotomy medicaments

The pulpotomy technique for preserving vital primary teeth with carious or mechanical pulpal exposures was established in the early 1920s,⁹ and has undergone little change. Recently, formocresol (FC) has been challenged as a carcinogen and a mutagen.¹⁰ Other medicaments such as calcium hydroxide and glutaraldehyde have been proposed.¹¹ Teeth treated with calcium hydroxide, however, have shown internal resorption,¹² and glutaraldehyde is not permitted as a therapeutic agent in some countries, including Australia.

More recently, ferric sulfate (FS) has been introduced as a pulpotomy medicament, and shows promise.¹³ It is unlikely, however, that prospective clinical trials would now be permitted by ethics committees to compare the relative efficacy of different medicaments. Therefore, maximum information must be obtained by an evidence-based approach, using defined criteria for literature selection, in order to make recommendations on medicaments.

The aims of this study were to:

1. use the principles of evidence-based dentistry to examine the relative efficacy of formocresol and ferric sulfate as pulpotomy medicaments in primary teeth;
2. produce recommendations on medicament selection for clinicians.

Table 1. Distribution of Search Results From Medline Library and Cochrane Library Databases

Search strings, keywords, and Boolean operators used	Citations in Medline Library	Citations in Cochrane Library
Formocresol	126	25
Formocresols	136	15
Formocresol AND formocresols*	111	14
Incomplete endodontic treatment	1	0
Pulp therapy	72	8
Pulpotomy	435	38
Pulpotomy AND* combined	86	12
Pulpotomy OR* combined	460	10
Dental pulp exposure	184	12
Dental pulp exposure AND* combined	9	4
Deciduous teeth	0	37
Ferric sulfate	77	3
Ferric sulphate	42	5
Ferric sulfate AND pulpotomy	8	4
Ferric sulphate AND pulpotomy	1	2
Ferric sulfate AND pulp therapy	4	1
Ferric sulphate AND pulp therapy	1	1
Total citations identified (1,944)	1,753	191

*Refers to keywords and the search string “formocresol AND formocresols.”

The PICOT statement used for the study was:

1. (P) in human carious molars with reversible coronal pulpitis
2. (I) does a pulpotomy performed with ferric sulfate
3. (C) compared with formocresol
4. (O) result in clinical/radiographical success
5. (T) in time periods up to exfoliation

The criteria for clinical/radiographical success were:

1. tooth remained asymptomatic until normal exfoliation;
2. successor tooth was unaffected;
3. no periapical pathology or internal resorption;
4. tooth did not exfoliate prematurely.

Methods

Searching the literature

Relevant literature was identified using 6 search engines as follows: (1) Medline Ovid Library¹⁴; (2) Cochrane Library¹⁵; (3) PubMed¹⁶; (4) EMBASE¹⁷; (5) Science Citation Index (SCI)¹⁸; and (6) System for Information on Grey Literature in Europe (SIGLE).¹⁹ Many related citations were found via the first 3 search engines; EMBASE, SCI, and SIGLE did not locate any relevant citations.

Therefore, the search was limited to Medline Ovid Library and Cochrane Library. The Boolean operator words

AND and OR were used to narrow and broaden searches respectively; the operator NOT was avoided, due to the risk of excluding relevant articles.²⁰ The same search strings and keywords (including both spellings of ferric sulfate/sulphate) were applied to both search engines, with results limited to: (1) human studies; and (2) written in English. The search generated a total of 1,944 citations (Tables 1 and 2).

Preliminary sieve

Preliminary sieving of these papers was conducted by examining the paper title and selecting for inclusion only those papers fulfilling the following criteria: (1) studies addressing FC and/or FS (2) related to pulpotomy, and (3) performed on primary (deciduous) molar teeth. The sieving resulted in a total of 894 papers (Table 2).

Secondary sieve

Secondary sieving was more specific, focussing more precisely on the PICOT statement by adding 2 further criteria to limit the search to:

1. actual investigations/experiments;
2. study duration for individual teeth up to exfoliation.

Consequently, papers were included which were reviews, full reports, or research abstracts of prospective, retrospective, comparative, and/or radiographic studies. Excluded were case reports, letters, and studies irrelevant to the PICOT statement. This sieving resulted in a total of 104 papers (Table 2).

Appraisal and ranking of evidence

The 104 papers were examined by title and abstract (from the database) and classified tentatively by each pulpotomy medicament and study type according to the following ranked hierarchy of evidence: (1) experimental studies; (2) cohort studies; (3) case-control studies; (4) cross-sectional studies; (5) opinion articles; (6) reviews; and (7) undetermined studies due to current inadequate information. The distribution is shown in Tables 2 and 3. All experimental studies and undetermined studies (29+46=75 papers, Table 3) were sought, and 56 papers were retrieved, examined, and classified on the basis of title, abstract, and methodology. Ten papers were excluded, as they were found to not

address primary (deciduous) molar teeth, and 19 papers were irretrievable (known hereafter as gray papers), resulting in 94 papers for further appraisal and ranking.

Studies were classified as clinical trials if the paper did not mention how subjects were recruited or how treatments were assigned, or if treatment assignment was nonrandom. The 94 papers at this second appraisal of evidence were ranked as follows: (1) randomized clinical trials; (2) clinical trials; (3) cohort studies; (4) case-control studies; (5) cross-sectional studies; (6) opinion articles; (7) reviews; and (8) gray papers (Table 3).

Detailed examination of the 7 randomized clinical trials and 28 clinical trials showed that:

1. Two randomized clinical trials were irrelevant to the PICOT statement.
2. Two randomized clinical trials were actually clinical trials, leaving 3 randomized clinical trials suitable for meta-analysis.

Due to this low number, the clinical trials were also considered for inclusion in the meta-analysis. Of the 30 clinical trials (28+2), 20 were deemed unsuitable (papers addressing glutaraldehyde, permanent teeth, histology, or papers irrelevant to the PICOT statement), leaving 10 clinical trials suitable for meta-analysis. A total of 13 studies (3 randomized clinical trials and 10 clinical trials) were then analyzed statistically via meta-analysis (Figure 1).

Application of meta-analysis

Meta-analysis includes direct and indirect techniques. In the direct technique, trials directly comparing test and control therapies are used. Homogeneity tests are used to describe consistency of outcomes between studies using chi-squared tests and odds ratios.²¹ The odds ratio (OR) is defined as:

$$OR = \frac{P_1 / (1 - P_1)}{P_2 / (1 - P_2)}$$

Table 2. Sequence of Steps, Procedures, and Results of Evidence-based Assessment of Formocresol and Ferric Sulfate (or Ferric Sulphate) as Primary Molar Medicaments

Sequence of steps	Procedure	Limitation criteria applied	Results of search and sieve
1. Initial search using 2 search engines: Medline Library, Cochrane Library	Search strings, keywords, and Boolean operators used	1. Human clinical studies; 2. written in English language.	1,944 citations identified
2. Preliminary sieving	Titles of papers examined	1. Formocresol or ferric sulfate (or ferric sulphate); 2. related to pulpotomy; 3. primary (deciduous) molar teeth.	894 papers selected
3. Secondary sieving	Titles and available abstracts of papers examined	1. Actual investigations or experiments; 2. study duration reported.	104 papers selected
4. Appraisal and first ranking of evidence	Titles, abstracts, and methodology of papers examined	1. Primary (deciduous) molar teeth reapplied.	94 papers selected
5. Appraisal and second ranking of evidence	Complete papers examined in detail	1. Randomized controlled trials; 2. (RCTs) selected clinical trials (CTs) selected.	13 papers selected

where P_1 and P_2 refer to event probability for the test and control therapies, respectively.²² Proportional data from 2 trials are combined into a common OR by pooling the success/failure values from both trials and applying this formula. A value exceeding 1 for the common OR implies

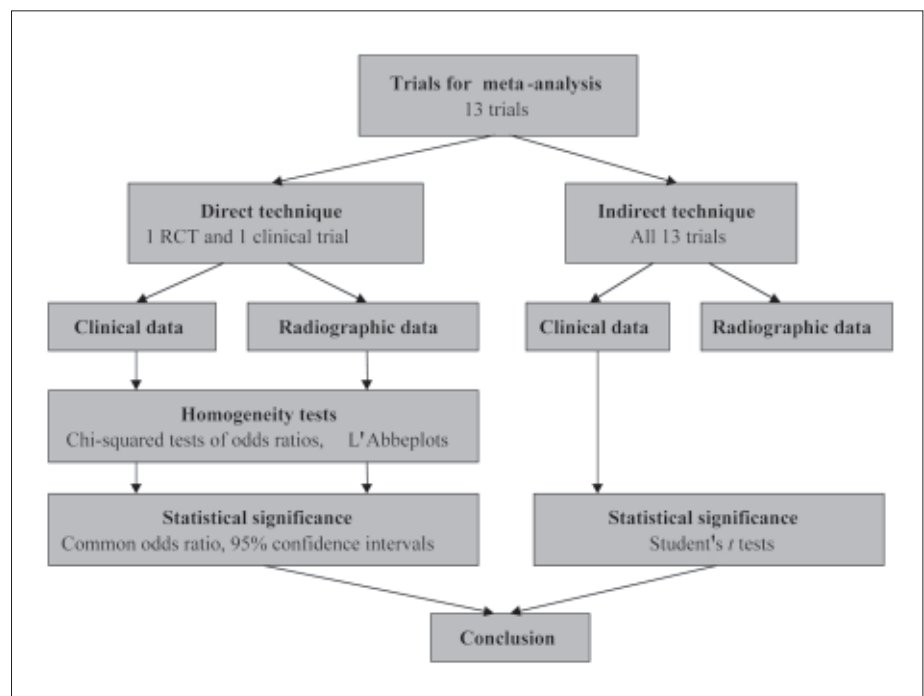


Figure 1. Flow chart of meta-analysis.

Table 3. Ranking of Evidence in Papers Addressing Formocresol or Ferric Sulfate (or Ferric Sulphate) as Primary Molar Pulpotomy Medicaments

Hierarchy of evidence	Appraisal and first ranking of evidence (N=104 papers)	Hierarchy of evidence	Appraisal and second ranking of evidence (N=94 papers)
Experimental studies*	29	Randomized clinical trials (RCTs)	7
		Clinical trials (CTs)	28
Cohort studies	1	Cohort studies	1
Case-control studies	9	Case-control studies	14
Cross-sectional studies	1	Cross-sectional studies	1
Opinion articles	1	Opinion articles	2
Reviews	17	Reviews	22
Undetermined*	46	Grey papers	19

*Papers examined further and reassigned in second ranking of evidence.

that the test therapy is significantly more successful than the control therapy; a common OR less than 1 implies that the control therapy is significantly more successful than the test therapy. The standard error (SE) for the common OR is computed to assess if it differs significantly from 1, within 95% confidence intervals (CI; assuming a normal distribution).²³ L'Abbe plots are used for qualitative presentation of homogeneity, with the proportional successes plotted on the vertical axis for test groups and on the horizontal axis for control groups.⁸

In the indirect technique, data are selected only from the relevant arms of the trials (part of the trial regarding either test or control therapies), pooled for analysis, and the student's *t* test is applied to the means and standard deviations of the success rates. A diagonal line describes equivalent values of proportional success in both groups, aiding subjective comparisons. A point above the line implies that the test therapy is more successful; a point below the line implies that the control therapy is more successful.

Of the 13 trials with useable information for meta-analysis, 1 randomized clinical trial and 1 clinical trial were analyzed by the direct technique, and all 13 trials were analyzed by the indirect technique (Table 4). Data from trials were divided into clinical and radiographic data, and separate statistical analyses were conducted using the direct technique. Odds ratios (ORs) were used to compare the relative success of FS and FC. Data homogeneity was tested using the chi-squared test of consistency on the ORs for each trial.²² Since only 2 trials were compared, the power of these tests was low.

Data from the relevant arms (part of the trial regarding FS or FC) of all 13 trials were examined using the indirect technique. For example, the paper by Eidemann et al¹⁰ described a 2-armed trial comparing mineral trioxide aggregate and FC as pulpotomy medicaments. For the indirect technique, data from the arm of the trial regard-

ing FC was selected, but not that from the arm of the trial regarding mineral trioxide aggregate. For papers with 2 relevant arms (1 regarding FS and 1 regarding FC), both arms were included. Homogeneity tests were not conducted in the indirect technique, since a single arm of data does not provide comparative information.

Data from the relevant arms in all 13 trials were combined as an overall success rate for each medicament. All successful cases in each arm were summed, divided by the total number of cases in the same arm, and the percentage com-

puted. The standard deviation of the overall success rate was computed for each medicament. Trials not including clinical data were excluded from computations of overall clinical success. Similarly, trials not including radiographic data were excluded from computations of overall radiographic success. The student's *t* test was used to determine whether the means and standard deviations for the 2 groups of data differed significantly (using an alpha level of 0.05).²⁴

Results

Application of direct technique to 1 RCT and 1 CT

Table 4 shows the distribution of trials (in chronological order) with respect to type of trial, clinical and radiographic data, medicament, number of teeth studied, follow-up time period, and percent success.^{10,25-36}

Applying the direct technique of meta-analysis to the 2 trials that directly compared FC and FS, the ORs were computed as previously described (allocating FS data as P₁ and FC data as P₂); clinical and radiographic data for success were analyzed separately. The ORs for the clinical data from the 2 trials were as follows: 1.00 (SE=4.47; 95% CI=0.01-88.10) for the trial by Ibrecevic and Al-Jame³⁴; and 2.46 (SE=0.68; 95% CI=1.24-4.89) for the trial by Fuks et al.³² The clinical data were deemed to be homogeneous (chi-squared value for consistency=0.04, df=1; 0.80<*P*<.90). Examination of the clinical data based on total teeth summed from both trials (ie, 35+37=72 teeth treated by FC; 35+55=90 teeth treated by FS) indicated that FS was significantly more successful than FC (common OR=1.95; SE=0.66; 95% CI=1.00-3.80).

The ORs for the radiographic data from the 2 trials were as follows: 1.00 (SE=1.43; 95% CI=0.23-4.20) for the trial by Ibrecevic and Al-Jame³⁴; and 1.08 (SE=0.48; 95% CI=0.66-1.76) for the trial by Fuks et al.³² The clinical data were deemed to be homogeneous (chi-squared value for

Table 4. Distribution of 13 Papers Examined by Meta-analysis for Clinical and Radiographic Success of Formocresol and Ferric Sulfate (or Ferric Sulphate) as Primary Molar Pulpotomy Medicaments

Pulpotomy medicament and paper	Clinical data: no. of primary molars	Clinical data: successful (%)	Radiographic data: no. of primary molars	Radiographic data: successful (%)	Follow-up time period
Formocresol:					
Berger (1965) ²⁵	—	—	31	30 (97)	22-263 d
Redig (1968) ²⁶	40	35 (87)	40	35 (87)	18 mos
Morowa et al (1975) ²⁷	125	123 (98)	125	123 (98)	To exfoliation
Magnusson (1978) ²⁸	84	84 (100)	84	45 (54)	36 mos
Mejare (1979) ²⁹	74	41 (55)	74	41 (55)	2.5 yrs
Alacam (1989) ³⁰	23	21 (91)	23	19 (83)	12 mos
Roberts (1996) ³¹	142	141 (99)	142	141 (99)	2.5 yrs
Fuks et al (1997) ³²	37	31 (84)	37	27 (72)	35 mos
Farooq et al (2000) ³³	78	58 (74)	78	58 (74)	23 mos
Ibrevecic and Al-Jame (2000) ³⁴	35	35 (100)	35	34 (97)	20 mos
Waterhouse et al (2000) ³⁵	44	37 (84)	44	37 (84)	To exfoliation
Eidelman et al (2001) ¹⁰	—	—	15	14 (93)	13 mos
Dean et al (2002) ³⁶	25	25 (100)	25	23 (92)	11.5 mos
Total teeth (753):	707	631 (89)	753	627 (84)	
Ferric sulfate:					
Fuks et al (1997) ³²	55	51 (93)	55	41 (74)	35 mos
Ibrevecic and Al-Jame (2000) ³⁴	35	35 (100)	35	34 (97)	20 mos
Total teeth (90)	90	86 (97)	90	75 (86)	

consistency=0.003, df=1; $P>.95$). Examination of the radiographic data based on total teeth summed from both trials (ie, 35+37=72 teeth treated by FC, and 35+55=90 teeth treated by FS) indicated no significant difference between FS and FC (common OR=0.90; SE=0.43; 95% CI=0.58-1.39).

The L'Abbe plots for the clinical and radiographic data also indicated homogeneity, and particularly for the radiographic data, since the straight line drawn from the origin to the data approximated the 2 data points very closely (Figures 2 and 3).

Application of indirect technique to 13 trials

The number of primary molar teeth studied in the relevant arms of the 13 trials ranged from 15 to 142 (Table 4). The total numbers of teeth compiled from the 13 trials were as follows:

1. 753 teeth treated by FC (radiographic data available for 753 teeth and clinical data for 707 teeth);
2. 90 teeth treated by FS (radiographic and clinical data available for all 90 teeth).

The number of teeth assessed radiographically in each arm of the trials ranged from 15 to 142.

The clinical success rates for treatment with FC or FS in the 13 trials (as shown in the papers) ranged from 55% to

100%, and the radiographic success rates ranged from 54% to 99%. The overall success rates based on the clinical data from the trials were as follows: FC (11 trials)—mean=88.5±14.1%; FS (2 trials)—mean=96.5±4.9% (Table 4). These values did not differ significantly ($P>.10$), implying that the 2 medicaments did not differ with statistical significance based on the clinical data. The overall success rates based on the radiographic data from the trials were as follows: FC (13 trials): mean 83.5±15.5%; FS (2 trials): mean 85.5±16.3%. These values did not differ significantly ($P>0.50$), implying that the 2 medicaments did not differ with statistical significance based on the radiographic data.

Discussion

Evidence-based dentistry is being used increasingly as a tool to synthesize, evaluate, and interpret research to produce clinical guidelines and conclusions. Use of the principles of EBD is particularly relevant in establishing new clinical recommendations for pulpotomy medicaments for primary teeth based on data currently available from the literature.

Since selection of papers to include in the statistical analysis in EBD is based upon defined but arbitrary criteria, bias can occur at several steps in the procedure. Database searches employing computer search engines are limited by the words entered and the Boolean operators

used. Therefore, it is possible that some important and relevant papers are not retrieved. For example, indexing in Medline Ovid Library commenced in 1966.³⁷ While this commencement date would not have hindered the retrieval of FS citations, it could have limited the retrieval of FC citations.

In addition, gray papers cannot be included if they are not available via manual searching, computer databases, or accessible library holdings. Since preliminary sieving excludes papers based on titles only, titles not correctly reflecting paper content will lead to inadvertent exclusions. Similarly, in secondary sieving, vague titles or very brief abstracts could lead to incorrect classification of papers. Such biased information could well influence an EBD study's final conclusions.

A rating system modified from that of Chalmers et al was used originally in the present study to assess quality of the clinical trials, emphasizing sample size and endpoints.³⁸ Rating systems can assist in excluding papers of lesser quality, or can be used in meta-analysis to increase statistical power. Since a total of only 13 papers were available at the end of the appraisal and ranking process in the present study, however, papers of lesser quality were not excluded and rating scores were not incorporated into the meta-analysis. The decision to not use a rating system could decrease the strength of evidence supporting a given conclusion.

Clinical and radiographic data from the indirect technique and radiographic data from the direct technique, showed no significant difference between FS and FC, although FS trended towards higher clinical success. It cannot be concluded, however, that FS is a better pulpotomy medicament for several reasons, as follows. Only 2 trials were included in the direct technique, indicating low statistical power and possible skewing, as outlying data may

not be detected by homogeneity tests. Meta-analysis typically uses a pooled *P* value obtained from several trials, which determines the strength of the analysis.³⁹

In the present study, the *P* values observed exceeded .05, suggesting inadequate evidence to conclude that FS is more successful than FC. Secondly, publication bias was not considered in the present study. Noting that the lower 95% CI for the OR is close to 1, only a few unpublished trials would be needed to make the result statistically insignificant.

In the present study, 1 randomized clinical trial and 1 clinical trial were meta-analyzed by the direct technique. It has been demonstrated that nonrandomized trials could have an effect exaggerated by up to 40%.³⁷ Exaggeration of results from randomized clinical trials is also possible because of deficient examiner blinding,⁴⁰ which was not specified in the trial analyzed in the present study. In addition, the follow-up time periods differed between the 2 trials (20 months vs 35 months). Further long-term randomized and controlled clinical trials are required to confirm the present findings.

The indirect technique has low statistical power in comparison with the direct technique, since there is usually little correlation of variables between studies. In the direct technique, correlation of confounding variables is eliminated because trials compare relative successes of treatments under similar criteria for inclusion, pretreatment status, follow-up, etc. This does not occur in the indirect technique, due to the pooling of studies of differing designs.

In deriving recommendations from meta-analyses, it is noted that odds ratios cannot indicate how much better one material is over another, nor the size of the effect or the clinical significance. The present study indicates that, based on clinical and radiographic data, similar success of a primary molar pulpotomy can be expected with either

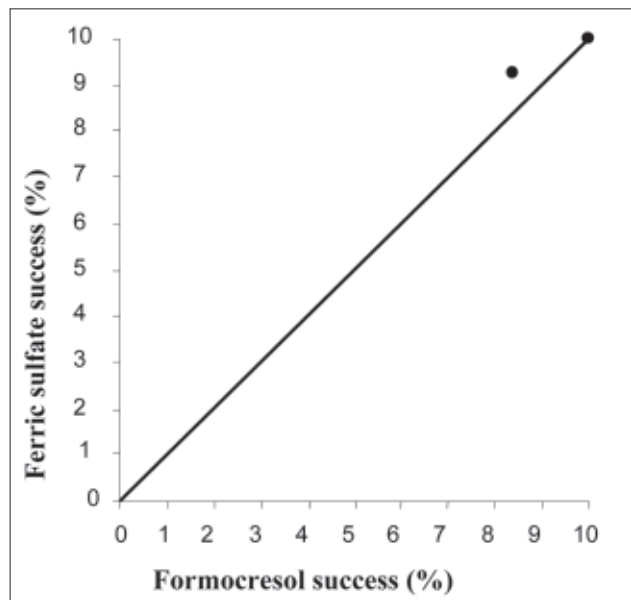


Figure 2. L'Abbe plot of clinical data using the direct technique of meta-analysis to analyze 1 randomized controlled trial (Ibrevic and Al-Jame³⁴) and 1 clinical trial (Fuks et al³²) for homogeneity.

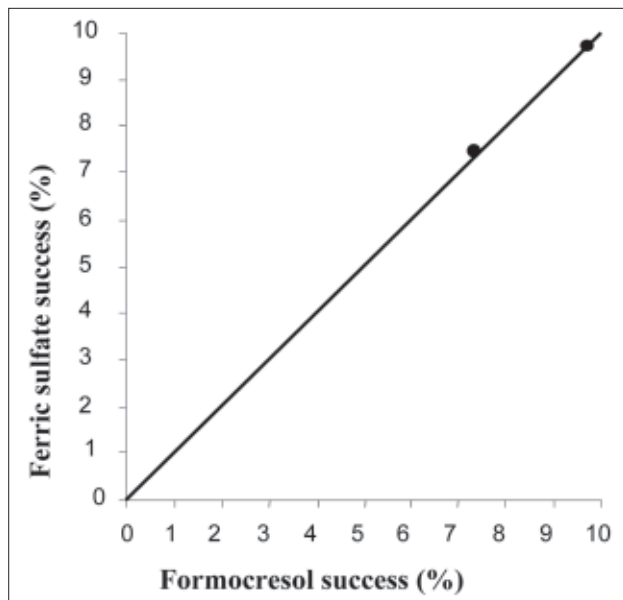


Figure 3. L'Abbe plot of radiographic data using the direct technique of meta-analysis to analyze 1 randomized controlled trial (Ibrevic and Al-Jame³⁴) and 1 clinical trial (Fuks et al³²) for homogeneity.

FC or FS. This agrees with a recent brief EBD report on this subject by Nadin et al who stated that “there is no reliable evidence supporting the superiority of one particular treatment method for pulpally involved primary molars.”⁴¹ Further prospective RCTs should be conducted on this clinical procedure.

Conclusions

Based on available information at present, this evidence-based assessment concludes that, in human carious primary molars with reversible coronal pulpitis, a pulpotomy performed with either ferric sulphate or formocresol is likely to have a similar clinical and radiographic success.

References

- Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: What it is and what it isn't. *Br Med J*. 1996;312:71-72.
- Chiapelli F, Prolo P. Evidence-based dentistry for the 21st century. *Gen Dent*. 2002;50:270-273.
- Abt E. Evidence-based dentistry: An overview of a new approach to dental practice. *Gen Dent*. 1999;47:369-373.
- Cochrane AL. Effectiveness and efficiency: Random reflections on the health services. *Control Clin Trials*. 1989;10:428-433.
- Cochrane Library. Available at: <http://www.cochrane.org>. Accessed August 2003.
- Sutherland SE. Evidence-based dentistry: Part IV. Research design and levels of evidence. *J Can Dent Assoc*. 2001;67:375-378.
- DUMC Library. Available at: www.mclibrary.duke.edu/respub/guides/studies.html. Accessed August 2003.
- L'Abbe KA, Detsky AS, O'Rourke K. Meta-analysis in clinical research. *Ann Intern Med*. 1987;107:224-233.
- Jordan ME. *Operative Dentistry for Children*. Brooklyn, NY: Dental Items of Interest Publishing Co; 1925:74-84.
- Eidelman E, Holman G, Fuks AB. Mineral trioxide aggregate versus formocresol in pulpotomized primary molars: A preliminary report. *Pediatr Dent*. 2001;23:15-18.
- Schroder U. A 2 year follow-up of primary molars, pulpotomized with a gentle technique and capped with calcium hydroxide. *Scand J Dent Res*. 1978;86:273-278.
- García-Godoy F, Ranly DM. Clinical evaluation of pulpotomies with ZOE as the vehicle for glutaraldehyde. *Pediatr Dent*. 1987;9:14-146.
- Burnett S, Walker J. Comparison of ferric sulfate, formocresol, and a combination of ferric sulfate/formocresol in primary tooth vital pulpotomies. *J Dent Child*. 2002;69:44-48.
- Medline Ovid Library. Available at: gateway1.ovid.com/ovidweb.cgi. Accessed August 2003.
- Cochrane Library. Available at: buffy.lib.unimelb.edu.au:2333/cochrane/. Accessed August 2003.
- PubMed. Available at: <http://buffy.lib.unimelb.edu.au:2139/PubMed/>. Accessed August 2003.
- EMBASE. Available at: gateway1.ovid.com/ovidweb.cgi. Accessed August 2003.
- SCI. Available at: <http://www.columbia.edu/cu/libraries/indexes/science-cit-ind.html>. Accessed August 2003.
- SIGLE. Available at: <http://www.york.ac.uk/services/library/guides/sigle.htm>. Accessed August 2003.
- Greenhalgh T. How to read a paper: The Medline database. *Br Med J*. 1997;315:180-183.
- McQuay HJ, Moore RA. Combining data and interpreting the results. In: *An Evidence-based Resource for Pain Relief*. Oxford, UK: Oxford University Press; 1997:32-38.
- Chi square: Testing for goodness of fit. Available at: <http://physics.ucsc.edu/~drip/133/ch4.pdf>. Accessed August 2003.
- Multiple contingency tables and correlation. Available at: <http://www.biostat.harvard.edu/~bio200/sections/labs2002/Lab10.htm>. Accessed August 2003.
- Student *t* test for two independent samples. Available at: <http://www.uvm.edu/~dhowell/gradstat/psych340/Lectures/t-tests/Class15.html>. Accessed August 2003.
- Berger JE. Pulp tissue reaction to formocresol and zinc-oxide eugenol. *J Dent Child*. 1965;32:13-27.
- Redig DF. A comparison and evaluation of two formocresol pulpotomy technics utilizing “Buckley's” formocresol. *J Dent Child*. 1968;35:22-29.
- Morowa AP, Straffon LH, Han SS, Corpron RE. Clinical evaluation of pulpotomies using dilute formocresol. *J Dent Child*. 1975;42:28-31.
- Magnusson BO. Therapeutic pulpotomies in primary molars with the formocresol technique. *Acta Odontol Scand*. 1978;36:157-165.
- Mejare I. Pulpotomy of primary molars with coronal or total pulpitis using formocresol technique. *Scand J Dent Res*. 1979;87:208-216.
- Alacam A. Pulpal tissue changes following pulpotomies with formocresol, glutaraldehyde-calcium hydroxide, and glutaraldehyde-zinc-oxide eugenol pastes in primary teeth. *J Pedod*. 1989;13:123-131.
- Roberts JF. Treatment of vital and non-vital primary molar teeth by one-stage formocresol pulpotomy: Clinical success and effect upon age at exfoliation. *Int J Pediatr Dent*. 1996;6:111-115.
- Fuks AB, Holan G, Davis JM, Eidelman E. Ferric sulfate versus dilute formocresol in pulpotomized primary molars: Long-term followup. *Pediatr Dent*. 1997;19:327-330.
- Farooq NS, Coll JA, Kuwabara A, Shelton P. Success rates of formocresol pulpotomy and indirect pulp therapy in the treatment of deep dental caries in primary teeth. *Pediatr Dent*. 2000;22:278-286.

34. Ibrecevic H, Al-Jame Q. Ferric sulfate as pulpotomy agent in primary teeth: Twenty month clinical follow-up. *J Clin Pediatr Dent.* 2000;24:269-272.
35. Waterhouse PJ, Nunn JH, Whitworth JM. An investigation of the relative efficacy of Buckley's formocresol and calcium hydroxide in primary molar vital pulp therapy. *Br Dent J.* 2000;188:32-36.
36. Dean JA, Mack RB, Fulkerson BT, Sanders BT. Comparison of electrosurgical and formocresol pulpotomy procedures in children. *Int J Pediatr Dent.* 2002;12:177-182.
37. Felson DT. Bias in meta-analytical research. *J Clin Epidemiol.* 1992;45:885-892.
38. Chalmers IC, Smith H, Blackburn B, Silverman B, Schroeder B, Reitman D. A method for assessing the quality of randomized control trial. *Control Clin Trials.* 1981;2:31-49.
39. Olkin I. Statistical and theoretical considerations in meta-analysis. *J Clin Epidemiol.* 1995;48:133-146.
40. Schulz KF, Chalmers IC, Hayes RJ, Altman DG. Empirical evidence of bias: Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *J Am Med Assoc.* 1995;273:408-412.
41. Nadin G, Goel BR, Yeung CA, Glenny AM. Pulp treatment for extensive decay in primary teeth. *Cochrane Database of Systemic Reviews.* 2003;1:CD003220.

ABSTRACT OF THE SCIENTIFIC LITERATURE



EFFECT OF CHIN-CAP THERAPY ON TEMPOROMANDIBULAR JOINTS

The purpose of this study was to evaluate the long-term effects of chin-cap therapy on temporomandibular disorder (TMD) symptoms. The treatment group consisted of 32 individuals with Class III malocclusions who were treated with chin-cap therapy for an average of 1.8 years. Two control groups consisted of: (1) 39 untreated individuals with skeletal Class III malocclusion; and (2) 53 dental students with normal occlusion. Subjects were classified as symptomatic if one positive sign or symptom was found upon examination. The distribution of symptomatic subjects was higher in the normal occlusion group than the treated and untreated Class III groups. The pain occurrence was significantly higher in the normal occlusion group than the treated Class III group. The main conclusion is that chin-cap therapy is not a risk factor for TMD.

Comments: The normal occlusion group consisted of dental students whose mean age was 19.2 years (range=18-21.4 years), while the treatment group had a mean age of 18.4 years (range=13.9-22.5 years). The dental students tended to be older and to likely have a more stressful lifestyle. As stress has been shown to be a significant risk factor for TMD, the authors could have selected a more suitable normal occlusion control group. LDK

Address correspondence to Professor Mirzen Arat, Ankara Universitesi, Dis Hekimligi Fakultesi, Ortodonti AD, Besevler, Ankara 06500, Turkey.

Arat ZM, Akcam MO, Gokalp H. Long-term effects of chin-cup therapy on the temporomandibular joints. *Eur J Orthod.* 2003;25:471-475.

43 references