SYSTEMATIC REVIEW

Pulpotomy versus pulpectomy in the treatment of vital pulp exposure in primary incisors. A systematic review and meta-analysis. [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

Background: Early childhood caries is a serious public health problem in both developing and industrialized countries. When caries extend to involve the pulp, various forms of pulp treatment are tried to stimulate tooth repair. The choice of proper technique is as important as choosing between different pharmacotherapeutic agents used in treatment of primary teeth. Although pulpotomy is the treatment of choice for vital primary tooth pulp exposure but there is a trend among many dentists to perform pulpectomies for pulp treatment of vital primary anterior teeth. This study aimed to assess the effect of pulpotomy and pulpectomy in treatment of carious vital pulp exposure in primary incisors.

Methods: We searched Pubmed and Cochrane library databases up to March, 2018, OpenGrey for grey literature and ClinicalTrials.gov for ongoing trials. Randomized controlled trials comparing between pulpotomy and pulpectomy in treatment of vital pulp exposure in primary incisors were included. Primary outcomes were clinical failure and radiological failure. Data synthesis was performed with a pair wise meta-analysis using fixed-effect models.

Results: Four trials were identified for qualitative assessment, only three trials were included in meta-analysis after exclusion of one trial due to its high risk of bias. The pooled results of the longest follow up period for clinical and radiographic failure showed no statistically significant difference between pulpotomy and pulpectomy. The relative risk (RR) was 0.74 with 95% CI 0.46 to 1.21 for radiographic failure and RR 2.69, 95% CI 0.76 to 9.58 for clinical failure. The evidence was limited by the small number of trials included in the meta-analysis.

Conclusions: Both pulpotomy and pulpectomy can be used successfully in...
the treatment of vital pulp exposure in primary incisors. Further high quality studies comparing between pulpotomy and pulpectomy in primary incisors with longer follow up period till exfoliation time.

Keywords
Pulpotomy, Pulpectomy, Root Canal Therapy, Primary Incisor, Vital Pulp Exposure

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Author roles: Gadallah L: Methodology, Writing – Original Draft Preparation; Hamdy M: Supervision; El Bardissy A: Investigation; Abou El Yazeed M: Writing – Review & Editing

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Introduction

Dental caries is an international public health challenge, especially among young children. Early childhood caries (ECC) is a serious public health problem in both developing and industrialized countries\(^1\). ECC has been considered to be at epidemic proportions in the developing world\(^2\). Treatment of ECC can be accomplished through different types of intervention. When caries extend to involve the pulp, various forms of pulp treatment have been used to treat and/or remove the pulp or to stimulate tooth repair. The choice of technique is as important as the choice between the different pharmacotherapeutic agents which are used in the treatment of primary teeth\(^3\).

Although pulpotomy is the treatment of choice for vital primary tooth pulp exposure throughout the pediatric dental literature\(^4\), the current trend amongst many dentists is to perform pulpectomies for the pulp treatment of carious vital primary anterior teeth\(^5\).

The most common materials used for pulpotomy are formocresol, ferric sulfate, also calcium hydroxide has been used, but with less long term success and more recently mineral trioxide aggregate (MTA) which is much more expensive\(^6\)\(^7\).

According to the latest recommendations of the American Academy of Pediatric Dentistry, both formocresol and MTA are strongly recommended to be used in pulpotomy with moderate quality of evidence. Ferric sulfate, laser and sodium hypochlorite are conditionally recommended but as for calcium hydroxide there is a recommendation against its use in pulpotomy\(^8\)\(^9\).

In pulpectomy a resorbable material such as nonreinforced zinc/oxide eugenol (ZOE), a combination paste of iodoform and calcium hydroxide (Vitapex, Metapex) or a combination paste of zinc oxide and eugenol, iodoform and calcium hydroxide (Endoflas) are used to fill the canals\(^10\).

According to a Cochrane systematic review there was no conclusive evidence supporting the superiority of one material for use in pulpectomy. Zinc oxide and eugenol, Metapex and Endoflas were found to be equally effective while with low quality of evidence zinc oxide and eugenol may be better than Vitapex but further research is required for confirmation\(^11\).

There are few studies that have compared pulpectomies with pulpotomies in vital primary incisors\(^12\). Therefore the claim that pulpotomies don’t work in primary anterior teeth is not supported by high-quality evidence from research. Moreover two studies recently showed that there was no significant difference in success rates of pulpotomies and pulpectomies in the pulp treatment of asymptomatic vital primary incisors\(^9\)\(^13\).

We therefore aimed to determine in patients with carious vital pulp exposure in primary incisors if pulpotomy is better than pulpectomy in terms of pain, soft tissue pathology, tooth mobility, pathological root resorption, periapical radiolucency, pulp canal obliteration and tooth survival based on evidence from randomized controlled trials.

Methods

Criteria for considering studies for this review

Types of participants. Children with carious vital pulp exposure in primary incisors.

Types of interventions. Pulpotomy and pulpectomy (root canal treatment) techniques with different medicaments.

Types of outcome measures

Primary outcomes. We defined two primary outcomes: clinical failure and radiological failure.

Secondary outcomes. According to the core set of component outcomes as specified by Smaïl-Faugeron et al.\(^16\) these secondary outcomes were considered:

Secondary clinical outcomes: pain, soft tissue pathology (gingival swelling, fistulous tract), pathological mobility and tooth survival.

Secondary radiographical outcomes: pathological radiolucency, pathological root resorption, pulp canal obliteration.

Types of studies

Randomized controlled trials comparing pulpotomy and pulpectomy techniques in the treatment of carious vital pulp exposure in primary incisors were included.

Search methods

Electronic search. We searched the electronic databases as the Cochrane library to 1/3/2018 and Pubmed to 1/3/2018. We developed detailed search strategies for each database searched. We placed no restrictions on the date of publication when searching the electronic databases. The search strategy included appropriate keywords, and Mesh terms when applicable; combined with Boolean operators “AND”, “OR” and “NOT” as shown in Table 1 and Table 2. We also searched OpenGrey for grey literature and ClinicalTrials.gov for ongoing trials.

Hand searching. We hand searched the reference lists of the included full text articles.

Data collection and analysis

Selection of studies. Two review authors (LG and AEB) independently scanned the titles of all reports identified by the search to determine whether the studies were relevant. They independently scanned selected abstracts to determine whether the study was relevant. After obtaining the full report for all relevant articles, they independently scanned the full reports and completed the data extraction form to determine whether the article should be included or excluded. Disagreements at each stage were resolved by discussion. If this did not resolve the disagreement a third author was invited to settle the disagreement. This did not occur over the course of this study.
### Table 1. Index terms used in search with synonyms.

<table>
<thead>
<tr>
<th>PICO item</th>
<th>Item</th>
<th>Synonyms</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>Patients with carious vital pulp exposure in primary anterior teeth</td>
<td>Primary teeth (tooth) Deciduous teeth (tooth) Milky teeth (tooth) Baby teeth (tooth) Incisor(s) Anterior teeth (tooth) Vital teeth (tooth) Pulpally exposed teeth (tooth)</td>
</tr>
<tr>
<td>I</td>
<td>pulpotomy</td>
<td>Pulpotomy Pulpotomies Vital pulp therapy Dental pulp exposure</td>
</tr>
<tr>
<td>C</td>
<td>pulpectomy</td>
<td>Pulpectomy Pulpectomies Root canal therapy</td>
</tr>
</tbody>
</table>

### Table 2. Detailed search strategy for Pubmed and Cochrane library.

<table>
<thead>
<tr>
<th>Item</th>
<th>Pubmed 11/6</th>
<th>Cochrane 11/6</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>Tooth, deciduous (Mesh Term)</td>
<td>10215</td>
</tr>
<tr>
<td>#2</td>
<td>Incisor</td>
<td>22967</td>
</tr>
<tr>
<td>#3</td>
<td>Incisors</td>
<td>28128</td>
</tr>
<tr>
<td>#4</td>
<td>Anterior teeth</td>
<td>11087</td>
</tr>
<tr>
<td>#5</td>
<td>Anterior tooth</td>
<td>8907</td>
</tr>
<tr>
<td>#6</td>
<td>Vital teeth</td>
<td>2445</td>
</tr>
<tr>
<td>#7</td>
<td>Vital tooth</td>
<td>1923</td>
</tr>
<tr>
<td>#8</td>
<td>Pulpally exposed teeth</td>
<td>5</td>
</tr>
<tr>
<td>#9</td>
<td>Pulpally exposed tooth</td>
<td>4</td>
</tr>
<tr>
<td>#10</td>
<td>#2 OR #3 OR #4 OR #5</td>
<td>34393</td>
</tr>
<tr>
<td>#11</td>
<td>#6 OR #7 OR #8 OR #9</td>
<td>2449</td>
</tr>
<tr>
<td>#12</td>
<td>#1 AND # 10 AND #11</td>
<td>22</td>
</tr>
<tr>
<td>#13</td>
<td>Pulpotomy</td>
<td>1416</td>
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<tr>
<td>#14</td>
<td>Pulpotomies</td>
<td>1442</td>
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<tr>
<td>#15</td>
<td>Vital pulp therapy</td>
<td>722</td>
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<tr>
<td>#16</td>
<td>Dental pulp exposure</td>
<td>1564</td>
</tr>
<tr>
<td>#17</td>
<td>#13 OR #14 OR #15 OR # 16</td>
<td>331</td>
</tr>
<tr>
<td>#18</td>
<td>#12 AND #17</td>
<td>11</td>
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<td>#19</td>
<td>Pulpectomy</td>
<td>1277</td>
</tr>
<tr>
<td>#20</td>
<td>Pulpectomies</td>
<td>1291</td>
</tr>
<tr>
<td>#21</td>
<td>Root canal therapy</td>
<td>18604</td>
</tr>
<tr>
<td>#22</td>
<td>#18 OR #19 OR # 20</td>
<td>19281</td>
</tr>
<tr>
<td>#23</td>
<td>#12 AND #22</td>
<td>8</td>
</tr>
<tr>
<td>#24</td>
<td>#18 OR #23</td>
<td>13</td>
</tr>
</tbody>
</table>
**Data extraction and management.** Two review authors (LG and AEB) collected the data independently using a specially designed data extraction form (Dataset 1).

For each trial, the following data were recorded: the year of publication, the country where the trial took place, detailed description of methodology, sample size, mean age of participants, duration of follow-up and reported outcomes. We contacted the authors of randomized controlled trials for missing information if needed.

**Assessment of risk of bias in included studies.** Two review authors (LG and AEB) independently assessed the risk of bias in the included trials. The assessment was according to Cochrane risk of bias tool for quality assessment of randomized controlled trials described in the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 (updated March 2011). Any disagreements between the two authors were resolved by discussion. If this did not resolve the disagreement a third author was invited to settle the disagreement. This did not occur over the course of this study.

**Measures of treatment effect.** Estimated effect size was calculated as risk ratios with 95% Confidence Interval (CI) for dichotomous outcomes. The unit of analysis was the tooth, because teeth were randomly assigned to intervention.

**Data synthesis.** The effect sizes and associated 95% confidence intervals were calculated using the Mantel-Haenszel method. If the results from trials were homogenous then fixed effect model was preferred. The statistical analysis was performed with the Review Manager program v.5.3 (RevMan).

**Results**

By searching the different databases, 14 references were identified after removal of the duplicates. By scanning the titles and abstracts, 4 studies were included as shown in the Prisma flow diagram Figure 1 and data extraction was performed (completed PRISMA checklist is available as Supplementary File 1).

**Study characteristics of included studies**

**Year of publication, setting and operators.** The trials were published between 2004 and 2017. Two trials were in Canada by

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**Figure 1. PRISMA Flow diagram.** A list of included articles is shown in Table 3.
Nguyen et al.\textsuperscript{15} and Casas et al.\textsuperscript{21} one trial in the United states of America by Howley et al.\textsuperscript{9} and one in Iran by Aminabadi et al.\textsuperscript{20}. Operators were dentists in the four trials.

**Participants.** The age range of participants with carious vital pulp exposures in primary incisors varied from 18 to 60 months.

**Number of arms.** All four trials by Nguyen et al.\textsuperscript{15}, Howley et al.\textsuperscript{9}, Aminabadi et al.\textsuperscript{20} and Casas et al.\textsuperscript{21} were two-arm studies.

**Duration of follow up.** Follow up was at 12 and 24 months in two trials, by Aminabadi et al.\textsuperscript{20} and Casas et al.\textsuperscript{21}. Follow up was to 23 months at three intervals: 5–9, 10–14, and 15–23 months in the trial by Howley et al.\textsuperscript{9} and at 12 and 18 months in the trial by Nguyen et al.\textsuperscript{15}.

**Anesthesia.** Three trials, Nguyen et al.\textsuperscript{15}, Howley et al.\textsuperscript{9} and Casas et al.\textsuperscript{21}, were under general anesthesia and one trial was under local anesthesia, Aminabadi et al.\textsuperscript{20}.

**Rubber dam.** All four trials used rubber dam isolation\textsuperscript{3,15,20,21}.

**Treatment.** The following treatments were compared in the included trials:

The Casas et al. trial used ferric sulphate in pulpotomy compared with zinc oxide and eugenol in pulpectomy in \textsuperscript{21}.

Formocresol in pulpotomy was compared with zinc oxide and eugenol in pulpectomy in the Aminabadi et al. trial\textsuperscript{20}.

Formocresol in pulpotomy was compared with vitapex (calcium hydroxide/iodoform paste) in pulpectomy in the Howley et al. trial\textsuperscript{9}.

Ferric sulfate and mineral trioxide aggregate in pulpotomy was compared with zinc oxide and eugenol in pulpectomy in the Nguyen et al. trial\textsuperscript{15}.

**Medicaments**

**Pulpotomy**

Zinc oxide and eugenol was used in three trials by Nguyen et al.\textsuperscript{15}, Aminabadi et al.\textsuperscript{20} and Casas et al.\textsuperscript{21}. One trial, Howley et al., used vitapex (calcium hydroxide/iodoform paste)\textsuperscript{9}.

**Pulp access.** Following caries removal and pulp exposure, the pulp chamber was accessed using a sterile no. 56 bur in a water-cooled high-speed handpiece and was refined using a sterile round bur in a slow-speed handpiece in three trials, Nguyen et al.\textsuperscript{15}, Aminabadi et al.\textsuperscript{20} and Casas et al.\textsuperscript{21}.

In the trial Howley et al.\textsuperscript{9} the pulp chamber was unroofed using a no. 330 sterile bur in a water-cooled high-speed handpiece then the access was refined using a sterile round bur in a slow-speed handpiece.

**Pulpotomy.** The coronal pulp was amputated using a sharp spoon excavator in two trials by Howley et al.\textsuperscript{9} and Aminabadi et al.\textsuperscript{20} and was amputated using a sterile low-speed round bur in another two trials by Nguyen et al.\textsuperscript{15} and Casas et al.\textsuperscript{21}.

**Root canal treatment.** In three trials Nguyen et al.\textsuperscript{15}, Howley et al.\textsuperscript{9} and Casas et al.\textsuperscript{21} pulp tissue was removed en bloc using two or more endodontic files (Hedström files or K files), if the first attempt was unsuccessful, the procedure was repeated until all of the pulp tissue was removed.

In the fourth trial by Aminabadi et al.\textsuperscript{20} an endodontic K file was introduced to the working length after a periapical radiograph was taken, and most of the pulp tissue was removed completely on the first attempt. If the first attempt was unsuccessful, the procedure was repeated and canals were generally enlarged three sizes past the initial file.

**Irrigation.** The irrigation solution was sterile water in Nguyen et al. trial\textsuperscript{15} and saline in the trials by Howley et al.\textsuperscript{9} and Aminabadi et al.\textsuperscript{20} while in the fourth trial by Casas et al.\textsuperscript{21} the irrigating solution was unidentified.

**Final restoration.** Resin restorations was performed in three trials, Nguyen et al.\textsuperscript{15}, Aminabadi et al.\textsuperscript{20} and Casas et al.\textsuperscript{21}. Full coverage crown whether stainless steel crown (SCC) or SCC with white esthetic veneer in Howley et al.\textsuperscript{9}.

**Number of visits.** In the four trials by Nguyen et al.\textsuperscript{15}, Howley et al.\textsuperscript{9}, Aminabadi et al.\textsuperscript{20} and Casas et al.\textsuperscript{21} the intervention was completed in one session, whether they were performed under general or local anesthesia.

**Results of studies**

**Clinical failure.** Clinical failure was reported to be 2% and 3% for pulpotomy at 12 months and 18 months respectively, while for the pulpectomy there were none at 12 months, and 1% at the 18 months follow up period in the Nguyen et al. trial\textsuperscript{15}. No clinical failures were reported for neither pulpotomy nor pulpectomy in this 23 month trial by Howley et al.\textsuperscript{9}. The clinical failure rate was 13.1% for pulpotomy and 4.4% at

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**Table 3. List of included articles.**

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nguyen et al.</td>
<td>2017</td>
</tr>
<tr>
<td>Howley et al.</td>
<td>2012</td>
</tr>
<tr>
<td>Aminabadi et al.</td>
<td>2008</td>
</tr>
<tr>
<td>Casas et al.</td>
<td>2004</td>
</tr>
</tbody>
</table>
2 years follow up for Aminabadi et al. Clinical failure was 22% in the pulpotomy group, with no clinical failures in the pulpectomy group in the trial by Casas et al.

**Radiographical failure.** Radiographical failure was reported to be 3% and 7% in the pulpotomy group at 12 and 18 months respectively, while for the pulpectomy group it was 8% at both 12 months and 18 months follow ups in the Nguyen et al. trial. Cumulative radiographical results showed failure in 11% in the pulpotomy group, and 27% in pulpectomy group in the Howley et al. trial. Radiographical failure was 23.9% in the pulpotomy group, and 8.6% in pulpectomy group at 2 years follow up as reported by Aminabadi et al. Radiographical failure was in 41% in the pulpotomy group and 18% in pulpectomy group at 2 years follow up trial by Casas et al.

**Overall failure.** One incisor was lost early and counted as a failure in the pulpotomy group in the Howley et al. trial. One tooth had to be extracted postoperatively (2.2%) in pulpotomy group in the Aminabadi et al. trial. Only three trials were included in the trial by Casas et al.

**Pain.** One tooth with spontaneous pain (1%) was reported in pulpotomy group in Nguyen et al. trial. No pain was reported in either group in Howley et al. trial. Two teeth were reported as having spontaneous pain (4.4%) in the pulpotomy group, and one (2.2%) in the pulpectomy group in Aminabadi et al. No pain was reported in either group in the Casas et al. trial.

**Soft tissue pathology.** Two teeth showed fistula (2%) in the pulpotomy group, and one tooth had soft tissue swelling (1%) in pulpotomy group in the Nguyen et al. trial. The presence of fistula was reported in 3 teeth (6.6%) in the pulpotomy group of the Aminabadi et al. trial. The presence of gingival swelling or parulis in 9 teeth (22%) in pulpotomy group was reported by Casas et al.

**Pathological mobility.** Pathologic mobility was not reported for any tooth in three trials, Howley et al. Aminabadi et al. and Casas et al. Only one tooth with pathological mobility was reported by Nguyen et al.

**Pathological radiolucency.** The odds ratio for periapical radiolucency was 177.55; 95% CI 20.29 to 1554.01 (P<0.0001; chi-square test) in the Nguyen et al. trial. At 23 months follow up, 7 teeth (23%) showed frank periapical radiolucency in the pulpectomy group, while only 1 tooth (3%) showed frank periapical radiolucency in the pulpectomy group in Howley et al. trial. At 2 years follow up 5 teeth (11.11%) showed periapical radiolucency in the pulpectomy group, while only one tooth (2.17%) in the pulpectomy group showed periapical radiolucency in the Aminabadi et al. trial. At 2 years follow up 7 teeth (58%) showed periapical radiolucency in the pulpotomy group, and 3 teeth (27%) in the pulpectomy group in Casas et al.

**Pathological root resorption.** The odds ratio for external root resorption was 136.41; 95% CI 15.02 to 1238.27 (P<0.0001; chi-square test) in the Nguyen et al. trial. After 23 months follow up, 2 teeth (7%) showed large external root resorption in the pulpotomy group, and 4 teeth (14%) in the pulpectomy group, while for internal resorption one tooth (3%) showed perforating internal root resorption in the pulpectomy group in the Howley et al. trial.

At 2 years follow up pathologic external or internal root resorption occurred in 6 teeth (13.3%) of the pulpotomy group and in 2 teeth (4.34%) of the pulpectomy group in the Aminabadi et al. trial.

At 2 years follow up pathologic external root resorption occurred in 4 teeth (33%) in the pulpotomy group and in 3 teeth (27%) in the pulpectomy group, internal resorption was observed in 17% of the pulpotomy group in Casas et al.

**Pulp canal obliteration.** At 23 months pulp canal obliteration was seen in 18 teeth (60%) in the pulpectomy group in Howley et al. At 2 year follow up no teeth showed pulp canal obliteration in Aminabadi et al. trial. At 2 years follow up 3 teeth (25%) showed pulp canal obliteration in the pulpotomy group in the Casas et al. trial.

**Tooth survival.** The survival rate was 0.94 (95% CI equals 0.89 to 0.97) for pulpotomy and 0.97 for pulpectomy at 18 months in Nguyen et al. trial. The survival rate was 63% for pulpotomy and 85% for pulpectomy at 2 years follow up in Casas et al.

**Risk of bias in included studies.** The risk of bias of included studies is shown in Table 4, Table 5, Table 6, and Table 7. The overall risk of bias was low in two trials, Nguyen et al. and Aminabadi et al. The risk of bias was unclear for clinical assessment in two trials, Howley et al. and Casas et al., and also for random sequence generation in Casas et al. One trial, Casas et al., showed high risk of bias due to high percentage of dropped out cases. The risk of bias of included studies is also summarized in Figure 2.

**Synthesis of results.** Only three trials were included in the meta-analysis by Nguyen et al. Howley et al. and Aminabadi et al. as one trial by Casas et al. was excluded due to its high risk of bias. Data were extractable from all three RCTs totaling 338 teeth.

The data of the longest follow up period was included in the meta-analysis, this was 24 months for Aminabadi et al., 18 months for Nguyen et al., and at 15 to 23 months for Howley et al.

**Clinical failure** At the longest follow up period the pooled results showed no statistically significant difference in clinical failure for pulpotomy compared to pulpectomy (RR 2.69, 95% CI 0.76 to 9.58) as shown in Table 8 and Figure 3.

**Radiographic failure** The pooled results showed no statistically significant difference in radiographical failure for pulpotomy compared to pulpectomy (RR 0.74, 95% CI 0.46 to 1.21) as shown in Table 8 and Figure 4.
### Table 4. Risk of bias in Nguyen et al. 2017.

<table>
<thead>
<tr>
<th>Nguyen et al. 2017&lt;sup&gt;15&lt;/sup&gt;</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bias</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>Computer-generated simple random numbers sequence with a one to one allocation ratio.</td>
</tr>
<tr>
<td>(selection bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Low risk</td>
<td>Quote: Allocation occurred after induction of general anesthesia to ensure allocation</td>
</tr>
<tr>
<td>(selection bias)</td>
<td></td>
<td>concealment. The pediatric dentist, nurse, or assistant directed subjects at the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>time of dental surgery to the appropriate treatment group they had been assigned to</td>
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<tr>
<td></td>
<td></td>
<td>by the investigator.</td>
</tr>
<tr>
<td>Blinding of participants and</td>
<td>Low risk</td>
<td>Quote: All other contributors were blinded to generation and implementation of the</td>
</tr>
<tr>
<td>personnel (performance bias)</td>
<td></td>
<td>treatment assignment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Blinding of clinical outcomes</td>
<td>Low risk</td>
<td>Quote: A single investigator, who did not perform any pulp therapy or participate in</td>
</tr>
<tr>
<td>assessment</td>
<td></td>
<td>radiographic evaluation, performed all clinical assessments.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of radiological</td>
<td>Low risk</td>
<td>Quote: Two experienced pediatric dentists who did not participate in protocol</td>
</tr>
<tr>
<td>outcomes assessment</td>
<td></td>
<td>development or treatment performed radiographic assessments.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It is not possible to blind the assessors due to the nature of treatment received.</td>
</tr>
<tr>
<td>Incomplete outcome data</td>
<td>Low risk</td>
<td>9% drop out of 172 incisors at 12 months, due to loss to follow-up (n=13) and due to</td>
</tr>
<tr>
<td>(attrition bias)</td>
<td></td>
<td>trauma (n=2). 21% drop out of 172 incisors at 18 months, due to loss to follow-up or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>dropout (n =31), exfoliation (n = 3), and trauma (n = 3).</td>
</tr>
<tr>
<td>Reporting bias</td>
<td>Low risk</td>
<td>We revised the protocol that was registered with the ClinicalTrials.gov Protocol and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Registration System (ID no. NCT02019563)</td>
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</tbody>
</table>

### Table 5. Risk of bias in Howley et al. 2012.

<table>
<thead>
<tr>
<th>Howley et al. 2012&lt;sup&gt;9&lt;/sup&gt;</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bias</td>
<td></td>
<td></td>
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<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>An incisor in each pair was randomly assigned by a coin toss.</td>
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<tr>
<td>(selection bias)</td>
<td></td>
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<tr>
<td>Allocation concealment</td>
<td>Low risk</td>
<td>Quote: An incisor in each pair was randomly assigned, by a coin toss to either the</td>
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<td>(selection bias)</td>
<td></td>
<td>experimental group or the control group with the contralateral-paired incisor being</td>
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<td>designated to the other treatment group</td>
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<tr>
<td>Blinding of participants and</td>
<td>Low risk</td>
<td>It is not possible to blind the operator and the participant blinding is ineffective</td>
</tr>
<tr>
<td>personnel (performance bias)</td>
<td></td>
<td>on outcomes</td>
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<tr>
<td>Blinding of clinical outcomes</td>
<td>unclear risk</td>
<td>Insufficient information to make a clear judgement</td>
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<tr>
<td>assessment</td>
<td></td>
<td></td>
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<tr>
<td>Blinding of radiological</td>
<td>Low risk</td>
<td>Quote: The radiographs were evaluated independently by 2 standardized and calibrated</td>
</tr>
<tr>
<td>outcomes assessment</td>
<td></td>
<td>examiners who were not otherwise involved in the study.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It is not possible to blind the assessors due to the nature of treatment received.</td>
</tr>
<tr>
<td>Incomplete outcome data</td>
<td>Low risk</td>
<td>29 study patients, 3 patients failed to return for follow-up.</td>
</tr>
<tr>
<td>(attrition bias)</td>
<td></td>
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</tbody>
</table>

**Pain**
The pooled results showed no statistically significant difference in pain for pulpotomy compared to pulpectomy (RR 2.06, 95% CI 0.31 to 13.8)).

**Soft tissue pathology**
The pooled results showed no statistically significant difference in soft tissue pathology for pulpotomy compared to pulpectomy (RR 3.11, 95% CI 0.54 to 17.7).

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Coin tossing</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: For each patient, by coin tossing, if one tooth was randomly assigned for formocresol pulpotomy then root canal therapy (RCT) was performed on the other incisor.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Low risk</td>
<td>It is not possible to blind the operator and the participant blinding is ineffective on outcomes</td>
</tr>
<tr>
<td>Blinding of clinical outcomes assessment</td>
<td>Low risk</td>
<td>Quote: Two clinicians who did not perform any treatments analyzed the clinical and radiographic outcomes</td>
</tr>
<tr>
<td>Blinding of radiological outcomes assessment</td>
<td>Low risk</td>
<td>Quote: Two clinicians who did not perform any treatments analyzed the clinical and radiographic outcomes It is not possible to blind the assessors due to the nature of treatment received.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>4 subjects were dropped out of 50 patients.</td>
</tr>
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</table>


<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>Insufficient information to make a clear judgement</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Quote: Quality assurance checks were performed by 1 of the investigators (MAL), who did not provide treatment or review postoperative radiographs, to ensure that the investigators who provided treatment complied with the randomization protocol</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Low risk</td>
<td>It is not possible to blind the operator and the participant blinding is ineffective on outcomes</td>
</tr>
<tr>
<td>Blinding of clinical outcomes assessment</td>
<td>unclear risk</td>
<td>Insufficient information to make a clear judgement.</td>
</tr>
<tr>
<td>Blinding of radiological outcomes assessment</td>
<td>Low risk</td>
<td>Quote: Two independent pediatric dentists who were not otherwise involved in the investigation evaluated the radiographs. It is not possible to blind the assessors due to the nature of treatment received.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>Quote: Of the enrolled participants, 64% returned for at least 1 evaluation. 36% drop out in the pulpotomy group and 48% drop out in the root canal treatment group at 2 years follow up</td>
</tr>
</tbody>
</table>

Pathological radiolucency
The pooled results of two trials showed no statistically significant difference in periapical radiolucency for pulpotomy compared to pulpectomy (RR 0.75, 95% CI 0.27 to 2.11).

Pathological root resorption
The pooled results of two trials showed no statistically significant difference in pathologic resorption for pulpotomy compared to pulpectomy (RR 1.5, 95% CI 0.56 to 4.04).
Figure 2. Risk of bias summary of included studies.

Table 8. Risk ratio for clinical failure and radiographic failure.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Studies</th>
<th>Participants</th>
<th>Statistical Method</th>
<th>Effect Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical failure</td>
<td>3</td>
<td>338</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>2.69 [0.76, 9.58]</td>
</tr>
<tr>
<td>Radiographic failure</td>
<td>3</td>
<td>338</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.74 [0.46, 1.21]</td>
</tr>
</tbody>
</table>

Figure 3. Meta-analysis for clinical failure.
Discussion

Pulp therapy is performed to preserve primary teeth and maintain its developmental, esthetic, and functional capabilities. Pulpotomy and root canal therapy have both been performed as techniques for the management of asymptomatic vital primary incisors with large carious lesions where removal of caries will lead to pulp exposure. However, the preference of many pediatric dentists to perform pulpotomy in primary incisors was due to the fact that they were taught to do so in their pediatric dentistry residencies and not due to evidence from high quality research. The aim of this systematic review was to compare between pulpotomy and pulpectomy clinically and radiographically in the treatment of carious vital pulp exposure in primary incisors.

Upon performing our systematic search there were only four randomized controlled trials that have compared pulpotomy and pulpectomy outcomes in vital primary incisors. After exclusion of one trial due to its high risk of bias that left us three trials to be included in the meta-analysis. The data of the longest follow up period was included as the follow ups were close to each other ranging from 15 months to 24 months and they best reveal the efficacy of the performed techniques.

The results were calculated with risk ratio (RR) effect measure and confidence intervals (CIs). The pooled results of the clinical and radiographical failure as the primary outcome showed no statistically significant difference between pulpotomy and pulpectomy, although the relative risk RR was 0.74 with 95% CI 0.46 to 1.21 which means lower risk for radiographic failure in pulpotomy than pulpectomy and the RR was 2.69 with 95% CI from 0.76 to 9.58 for clinical failure which means higher risk for clinical failure in pulpotomy rather than pulpectomy but all the outcomes showed CIs including the number 1 that means that there was no statistical significant difference between pulpotomy and pulpectomy cases.

For the clinical outcomes pain and soft tissue pathology, the pooled results for these outcomes showed no statistically significant difference between pulpotomy and pulpectomy while pathologic mobility was only reported for one incisor in one trial.

The radiographic outcomes included periapical radiolucency and pathologic root resorption, the pooled results also showed no statistically significant difference between pulpotomy and pulpectomy. We considered the tooth to be scored with pathologic root resorption if it showed perforating internal root resorption or large external root resorption while those teeth showing contained internal root resorption or questionable external root resorption were not counted. For periapical radiolucency, only frank radiolucencies were counted and not questionable ones.

Pediatric dentists do not consider the radiographic pathological changes as questionable radiolucencies or limited pathological root resorptions to be an absolute indication for extraction taking into consideration the absence of clinical pathological signs or symptoms.

Overall failure was reported for two pulpotomized incisors in two trials. Regarding tooth survival although it is an important outcome but it is not commonly reported.

This study showed that there is no statistical significant difference in clinical and radiographical success rates of pulpotomy and pulpectomy with different medicaments in the treatment of carious vital pulp exposure in primary incisors and this refutes the misconception among some pediatric dentists that pulpotomy does not work in primary incisors.

The evidence was limited by the small number of trials included in the meta-analysis. The overall risk of bias of primary studies was low for three trials, except for the unclear risk for blinding of clinical assessment which was not effective, we did not have access to all the trial protocols to assess the selective reporting bias except only one trial.

Conclusion

There was no statistical significant difference in the success rates of pulpotomies and pulpectomies in the pulp treatment of carious vital pulp exposure in primary incisors. We recommend teaching of pulpotomy as a treatment option for vital pulp exposure in primary incisors in pediatric dentistry residency programs and further high quality studies comparing between pulpotomy and pulpectomy in primary incisors with a longer follow up period till exfoliation time.
Grant information
The author(s) declared that no grants were involved in supporting this work.

Supplementary material
Supplementary File 1: Completed PRISMA checklist.
Click here to access the data.

References


Open Peer Review

Current Peer Review Status: ✓ ❓

Version 1

Reviewer Report 03 December 2018

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Armin Shirvani
Iranian Center for Endodontic Research, Research Institute of Dental Sciences, Faculty of Medical Education, Shahid Beheshti University of Medical Sciences, Tehran, Iran

The manuscript is well structured and the format of the report on the details of the study is acceptable. There are two points to consider in the Meta-analysis:

1. The results of Hawley’s study should not have been removed because of zero in nominators. They could use 0.01 instead of 0 and continue the analysis.
2. Heterogeneity in time intervals is an important issue and if a significant heterogeneity has been detected the results of the meta-analysis would not be valid.

Are the rationale for, and objectives of, the Systematic Review clearly stated?
Yes

Are sufficient details of the methods and analysis provided to allow replication by others?
Yes

Is the statistical analysis and its interpretation appropriate?
No

Are the conclusions drawn adequately supported by the results presented in the review?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: research methodology and statistical analysis

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.
Dear Dr. Armin,

Many thanks for reviewing our study and for your valuable comments.

Concerning your first comment on the exclusion of Howley et al. study from the clinical failure meta-analysis, we returned to Cochrane handbook for systematic reviews of "intervention that stated that". The standard practice in meta-analysis of odds ratios and risk ratios is to exclude studies from meta-analysis where there are no events in both arms. This is because such studies do not provide any indication of either the direction or magnitude of the relative treatment effect. Actually the Revman program that we used for meta-analysis does not accept any decimals in the events in risk ratio as dichotomous outcomes.

As for the heterogeneity in the radiographic evaluation, we performed a sensitivity analysis and it was due to one outlying study so we performed the meta-analysis both with and without this study and we stated that the results should be interpreted with caution.

**Competing Interests:** No competing interests were disclosed.
4. We, therefore, aimed to determine in patients with carious vital pulp exposure in primary incisors if pulpotomy is better than

Page 6:
- Duration of follow up.
- “Follow up was at 12 and 24 months in two trials, by Aminabadi et al [ref-1] and Casas et al [ref-2].” do you mean that both studies used a 12 and 24 months follow up period or that the first study used 12 months follow up while the second was 24 months? Please clarify.
- Follow up was up to 23 months at three intervals: 5–9, 10–14, and 15–23 months
- Anesthesia: under local anesthesia (by) Aminabadi et al.
- Medicaments -- Pulpotomy: please rewrite this paragraph noting that 2 trials performed formocresol pulpotomy as we don’t achieve hemostasis with formocresol.
- Pulp access: In the trial (by) Howley et al the pulp chamber was unroofed using
- Pulpotomy: in another (the other) two trials by Nguyen et al [ref-4] and Casas et al [ref-2].
- Final restoration: Resin restorations were performed in three..... Full coverage crowns whether stainless steel crown (SCC) or SCC with white esthetic veneer were used in Howley et al (trial) [ref-3].
- Results of studies;
- nor pulpectomy in this trial by Howley et al [ref-3]. The clinical failure rate was 13.1% for pulpotomy and 4.4% (for pulpectomy) at

Page 7:
- radiological failure: was in (remove "in") 41% in the pulpotomy group and 18% in pulpectomy group at 2 years follow up trial by Casas et al [ref-2].
- Pain: No pain was reported in either group(s) in Howley et al [ref-3]. trial9.
- No pain was reported in either group(s) in the Casas et al [ref-2]. trial21.
- Soft tissue pathology: No soft tissue pathology was reported in either group(s) in Howley et al [ref-3]. trial9.
- Pathological mobility: Pathologic mobility was not reported for any tooth in three trials (; Howley et al [ref-3], Aminabadi et al [ref-2].20 and Casas et al [ref-2].21.

Pathological radiolucency:
- At 2 years follow up, 5 teeth (11.11%) showed
- follow up, 7 teeth (58%) showed periapical radiolucency in the
- pathological root resorption: while for internal resorption one tooth (3%) showed perforating
- At 2 years follow up, pathologic external or internal root resorption occurred in 6 teeth (13.3%) (in) the pulpotomy group and in 2 teeth (4.34%) (in) the pulpectomy group in the Aminabadi et al. trial20
- At 2 years follow up, pathologic external root resorption occurred

Pulp canal obliteration:
- At 23 months pulp canal obliteration was seen in 18 teeth (60%) in the pulpotomy group in Howley et al.9 (trial). At 2 year follow up, no teeth showed pulp canal obliteration

Pages 8 and 9:
- Please add reference number to authors names in the titles of tables 4 to 7.

Page 11, discussion section:
- 2nd paragraph: After exclusion of one trial due to its high risk of bias (only) three trials (were left) to be included in the meta-analysis. (were left) to be included in the meta-analysis.
- Overall failure was reported for two pulpotomized incisors in two trials. (on the other hand) tooth survival although it is an important outcome but it is not commonly reported.
The overall risk of bias of primary studies was low for three trials, except for the unclear risk for blinding of clinical assessment which was not effective. We did not have access to all the trial protocols to assess the selective reporting bias except for only one trial.

References

Are the rationale for, and objectives of, the Systematic Review clearly stated?
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Are sufficient details of the methods and analysis provided to allow replication by others?
Yes

Is the statistical analysis and its interpretation appropriate?
Yes

Are the conclusions drawn adequately supported by the results presented in the review?
Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** pediatric dentistry

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 08 Nov 2018

**Lamia Gadallah**, National Research Centre, Egypt, Nasr city, Egypt

Thank you Dr. Mariem very much for reviewing our study. As for the protocol registration, yes it was registered in the Evidence based Committee of Cairo University as the preliminary step of my Ph.D. in 2014.

**Competing Interests:** No competing interests were disclosed.
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