Are Dental Amalgams Toxic to Children? Comment on 2 Recently Published Randomized Controlled Trials

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When I graduated from dental school in 1987, dental amalgam was essentially the only material available for the direct restoration of carious posterior teeth. Dentin bonding was in its first generation of technological development in restorative dentistry, and composite resin restoration of posterior teeth was carried out with caution by some dentists, but avoided by most.

Even at that time, there was a long history of concern over the biocompatability of dental amalgam, which is 50% mercury by weight. Yet, in dental school, I was taught that amalgam was a safe restorative material and that composite resins were unsuitable for the occlusal surfaces of posterior teeth. I was never given a scientific explanation for these teachings.

Soon after I graduated, I took it upon myself to search the literature to explore the controversy and determine the safety of amalgam in dental practice.

In a review entitled "Mercury and dentistry, the controversy continues,"[1] I summarized then-current evidence on the biocompatibility of dental amalgam. This evidence consisted of results from animal studies, anecdotal reports, cross-sectional studies, case-series reports and some poor-quality retrospective cohort reviews. I concluded that, although the levels of mercury in blood, urine and expired air were positively correlated with the number of amalgam restorations in the oral cavity, these levels were well below the threshold considered to be dangerous. Furthermore, considering its long success in clinical practice in managing the most prevalent disease (dental caries) in western society, there was no clinical or epidemiologic evidence to suggest that dental amalgam posed a public health risk.

In 1990, CBS's highly rated television news magazine *60 Minutes* aired a story on the safety of dental amalgam.[2] It implied that members of the dental profession were knowingly poisoning their patients with amalgam because most simply did not possess the clinical skills to use the newer, better and safer alternative materials. Such an inference only demonstrated the ignorance or bias of the news piece, considering the complex biomechanical cavity preparation required for amalgam restoration compared with that for a posterior composite resin restoration.

In the mid-1990s, Health Canada commissioned Dr. Mark Richardson to review the biologic risk of dental amalgams. He presented his non-systematic review on August 18, 1995,[3] concluding that, "There are insufficient published data on the potential health effects of dental amalgam specifically to support or refute the diverse variety of health effects attributed to it." Nevertheless,

Box 1 Summary of study by Bellinger and colleagues[7]

<table>
<tr><td>Article</td><td>Bellinger DC, Trachtenberg F, Barregard L, Tavares M, Cernichiari E, Daniel D, and other. Neuropsychological and renal effects of dental amalgam in children: a randomized clinical trial. JAMA 2006; 295(15):1775–83.</td></tr>
<tr><td>Clinical question</td><td>Do amalgam restorations pose a health risk to children?</td></tr>
<tr><td>Study design</td><td>Randomized controlled trial, single blinded</td></tr>
<tr><td>Duration of study</td><td>5 years</td></tr>
<tr><td>Population</td><td>6–10 year old children from the New England area (United States)</td></tr>
<tr><td>Intervention</td><td>Dental caries restored with dental amalgam</td></tr>
<tr><td>Comparison</td><td>Dental caries restored with dental composite resin</td></tr>
<tr><td>Sample size</td><td>534 in total, 267 in each group</td></tr>
<tr><td>Outcome</td><td>• Urinary Hg-levels at 5 years
• The difference between baseline and 5-year follow-up in
- IQ (Wechlser intelligence scale for children score [WISC III])
- General memory index
- Visuomotor composite score
• Urine creatinine adjusted albumin at 5 years</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Outcome measure</th><th>Amalgam</th><th>Composite resin</th><th>Significant difference between groups</th></tr>
<tr><td>Urinary Hg level at 5 years (mean); µg/g</td><td>0.9</td><td>0.6</td><td>Yes ($p < 0.001$)</td></tr>
<tr><td>Difference in IQ after 5 years (mean)</td><td>3.1</td><td>2.1</td><td>No ($p = 0.21$)</td></tr>
<tr><td>Difference in memory index after 4 years (mean)</td><td>8.1</td><td>7.2</td><td>No ($p = 0.34$)</td></tr>
<tr><td>Difference in visuomotor composite score after 4 years (mean)</td><td>3.8</td><td>3.7</td><td>No ($p = 0.93$)</td></tr>
<tr><td>Creatinine-adjusted albumin at 5 years (median); mg/g</td><td>7.5</td><td>7.4</td><td>No ($p = 0.61$)</td></tr>
</table>
</td></tr>
<tr><td>Conclusion</td><td>Although this 5-year study shows that children with amalgam restorations presented with significantly higher urinary mercury levels than children treated with composite resin restorations, there was no statistically significant difference in neuropsychologic or renal function between these 2 groups.</td></tr>
</table>

Note: Hg = mercury; IQ = intelligence quotient.

he felt that, if a risk did exist, then the patients most vulnerable to chronic low-level mercury exposure were children, pregnant women and patients with kidney disease. Hence, he recommended that these types of dental patients not have any future carious lesions restored with amalgam. Although an interesting hypothesis, this recommendation was hotly criticized by the scientific community, including the Canadian Dental Association, because there was no scientific evidence at that time to suggest that such a risk existed.[4]

In March 1995, an editorial was published in *Quintessence International* titled "Move over amalgam — at last." The gist of the opinion piece was that amalgams had no place in the restoration of primary teeth when there were better alternatives available.[5] I challenged this conclusion in a letter to the editor, based on the grounds

Box 2 Summary of study by DeRouen and colleagues[8]

<table>
<tr><td>Article</td><td>DeRouen TA, Martin MD, Leroux BG, Townes BD, Woods JS, Leitao J, and others. Neurobehavioral effects of dental amalgam in children: a randomized clinical trial. JAMA 2006; 295(15):1784–92.</td></tr>
<tr><td>Clinical question</td><td>Do amalgam restorations pose a health risk to children?</td></tr>
<tr><td>Study design</td><td>Randomized controlled trial, single blinded</td></tr>
<tr><td>Duration of study</td><td>7 years</td></tr>
<tr><td>Population</td><td>8–10 year old children from Lisbon (Portugal)</td></tr>
<tr><td>Intervention</td><td>Posterior dental caries restored with amalgam</td></tr>
<tr><td>Comparison</td><td>Posterior dental caries restored with composite resin</td></tr>
<tr><td>Sample size</td><td>507 in total (amalgam group = 253, composite resin group = 254)</td></tr>
<tr><td>Outcome</td><td>Annual
• Neurobehavioural test scores
• Nerve conduction velocities
• Intelligence scores</td></tr>
<tr><td>Results[a]</td><td>Figures are 7th year means.
<table>
<tr><th>Test</th><th>Amalgam</th><th>Composite resin</th><th>Significant difference between groups</th></tr>
<tr><td colspan="4">Memory</td></tr>
<tr><td>RAVLT memory</td><td>9.65</td><td>9.73</td><td rowspan="24">No
(p values range from 0.29 to 0.91)[a]</td></tr>
<tr><td>RAVLT total learning</td><td>46.06</td><td>47.36</td></tr>
<tr><td>WMS-II reproduction (delayed)</td><td>33.02</td><td>32.98</td></tr>
<tr><td>WMS-II reproduction (immediate)</td><td>35.15</td><td>35.79</td></tr>
<tr><td colspan="4">Attention, concentration</td></tr>
<tr><td>WAIS-III digit symbols</td><td>9.45</td><td>9.42</td></tr>
<tr><td>WAIS-III symbol search</td><td>9.77</td><td>9.40</td></tr>
<tr><td>WAIS-III digit span</td><td>7.70</td><td>7.64</td></tr>
<tr><td>WAIS-III spatial span</td><td>9.34</td><td>9.03</td></tr>
<tr><td>Adult trials A (seconds)</td><td>28.72</td><td>28.94</td></tr>
<tr><td>Adult trials B (seconds)</td><td>65.34</td><td>63.84</td></tr>
<tr><td>Stroop word</td><td>41.41</td><td>41.70</td></tr>
<tr><td>Stroop colour</td><td>42.67</td><td>41.59</td></tr>
<tr><td>Stroop colour-word</td><td>48.42</td><td>46.99</td></tr>
<tr><td colspan="4">Visuomotor</td></tr>
<tr><td>WASI matrices</td><td>24.83</td><td>24.44</td></tr>
<tr><td>WRAVMA pegs (dominant)</td><td>119.51</td><td>119.76</td></tr>
<tr><td>WRAVMA pegs (nondominant)</td><td>119.01</td><td>119.38</td></tr>
<tr><td>Standard reaction time</td><td>0.77</td><td>0.76</td></tr>
<tr><td>Finger tapping (dominant)</td><td>50.51</td><td>50.50</td></tr>
<tr><td>Finger tapping (nondominant)</td><td>44.48</td><td>44.49</td></tr>
<tr><td colspan="4">Intelligence</td></tr>
<tr><td>CTONI</td><td>81</td><td>81</td></tr>
<tr><td>WASI</td><td>94</td><td>92</td></tr>
</table>
[a]Range of calculated p values using Hotelling's F-test and O'Brien's t-test</td></tr>
<tr><td>Conclusion</td><td>No statistically significant difference in the neurobehavioural assessment, nerve conduction velocity and intelligence observed over 7 years in children treated with amalgam or composite resin dental restorations.</td></tr>
</table>

[a]*The results are reprinted, with permission, from DeRouen and colleagues.*[8]
Note: CTONI = comprehensive test of nonverbal intelligence; RAVLT = Rey auditory-verbal learning test; WAIS = Wechsler adult intelligence scale; WASI = Wechsler abbreviated scale of intelligence; WMS = Wechsler memory scale; WRAVMA = wide range assessment of memory and learning.

that any alternative materials available at that time were simply not as cost-effective as amalgam for restoring teeth "designed to maintain the oral integrity until 10 years of age."[6]

Almost 2 centuries after amalgam was first introduced to North American dentists and 2 decades since I published my review, the controversy continues. It is fuelled by anecdotal claims and theoretical hypotheses cited on the Internet. There was no hard evidence to support or refute these claims until Bellinger and others[7] and DeRouen and others[8] published their results in a recent issue of the *Journal of the American Medical Association* [**Boxes 1** and **2**]. These studies are particularly significant because they are randomized controlled trials (RCTs) comparing the neurobehavioural, neurofunctional, intelligence and renal function risk to children with a follow-up of 5–7 years after treatment with an amalgam or composite resin fillings.

In the field of evidence-based health care, well-designed RCTs represent the highest level of evidential truth. Both of theses studies describe clear methods using well-accepted outcome measures to arrive at similar conclusions, i.e., that there was no statistical difference in physiological, neurological and renal function of children 5–7 years after either amalgam or composite resin material was used to restore a carious lesion.

Although, arguably, a period of 7 years may not reflect long-term chronic mercury exposure, it does provide some valid evidence that, in the short and mid term, amalgams do not pose any greater risk to children than composite resins. Unfortunately, neither of these studies had a no-treatment control group. Such a group would have helped answer the question of whether children exposed to either amalgam or composite resin are at greater health risk than children who are caries free.

These studies will not put the final nail into the anti-amalgamists' coffin because data on long-term chronic exposure into adulthood are still required before we can be absolutely sure that amalgam is safe.

Further, in an editorial commenting on the 2 studies, Needleman[9] points out, "Although these were sufficiently powered to rule out clinically important neurocognitive effects, the statistical power may be insufficient [i.e., the sample size too small] for detecting smaller effects." He argues that the prevalence of tooth decay in children and thus the potential use of amalgam as the material of choice may have had a profound effect if a type II error occurred. Although a theoretically valid point that may deserve further investigation, both these studies are the first of their kind that offer very strong evidence against a neurologic or psychologic risk of amalgam to children.

Hence, these studies lend support to the use of amalgam as the material of choice in primary teeth. Caries in primary teeth continues to be a public health concern, with the poor suffering the largest burden of the disease.[10] Because of dental amalgam's cost effectiveness and now with science to show that it poses no more health risk to children than its alternatives, the argument I made almost a decade ago to the editor of *Quintessence International* still holds. Nevertheless, I expect the controversy will continue.

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The views expressed are those of the author and do not necessarily reflect the opinions or official policies of the Canadian Dental Association.

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8. DeRouen TA, Martin MD, Leroux BG, Townes BD, Woods JS, Leitao J, and others. Neurobehavioral effects of dental amalgam in children: a randomized clinical trial. *JAMA* 2006; 295(15):1784–92.

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