Neurobehavioral effects of dental amalgam in children: a randomized clinical trial.


Abstract

CONTEXT:
Dental (silver) amalgam is a widely used restorative material containing 50% elemental mercury that emits small amounts of mercury vapor. No randomized clinical trials have determined whether there are significant health risks associated with this low-level mercury exposure.

OBJECTIVE:
To assess the safety of dental amalgam restorations in children.

DESIGN:
A randomized clinical trial in which children requiring dental restorative treatment were randomized to either amalgam for posterior restorations or resin composite instead of amalgam. Enrollment commenced February 1997, with annual follow-up for 7 years concluding in July 2005.

SETTING AND PARTICIPANTS:
A total of 507 children in Lisbon, Portugal, aged 8 to 10 years with at least 1 carious lesion on a permanent tooth, no previous exposure to amalgam, urinary mercury level <10 microg/L, blood lead level <15 microg/dL, Comprehensive Test of Nonverbal Intelligence IQ > or =67, and with no interfering health conditions.

INTERVENTION:
Routine, standard-of-care dental treatment, with one group receiving amalgam restorations for posterior lesions (n = 253) and the other group receiving resin composite restorations instead of amalgam (n = 254).

MAIN OUTCOME MEASURES:
Neurobehavioral assessments of memory, attention/concentration, and motor/visuomotor domains, as well as nerve conduction velocities.

RESULTS:
During the 7-year trial period, children had a mean of 18.7 tooth surfaces (median, 16) restored in the amalgam group and 21.3 (median, 18) restored in the composite group. Baseline mean creatinine-adjusted urinary mercury levels were 1.8 microg/g in the amalgam group and 1.9 microg/g in the composite group, but during follow-up were 1.0 to 1.5 microg/g higher in the amalgam group than in the composite group (P<.001). There were no statistically significant differences in measures of memory, attention, visuomotor function, or nerve conduction velocities (average z scores were very similar, near zero) for the amalgam and composite groups over all 7 years of follow-up, with no statistically significant differences observed at any time point (P values from .29 to .91). Starting at 5 years after initial treatment, the need for additional restorative treatment was approximately 50% higher in the composite group.

CONCLUSIONS:
In this study, children who received dental restorative treatment with amalgam did not, on average, have statistically significant differences in neurobehavioral assessments or in nerve conduction velocity when compared with children who received resin composite materials without
amalgam. These findings, combined with the trend of higher treatment need later among those receiving composite, suggest that amalgam should remain a viable dental restorative option for children.

**TRIAL REGISTRATION:**
clinicaltrials.gov Identifier: NCT00066118.