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## Abstract of the paper

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**Title:** Liver-related safety assessment of green tea extracts in humans: a systematic review of randomized controlled trials

**Objective:** There remain liver-related safety concerns, regarding potential hepatotoxicity in humans, induced by green tea intake, despite being supposedly beneficial. Although many randomized controlled trials (RCTs) of green tea extracts have been reported in the literature, the systematic reviews published to date were only based on subjective assessment of case reports. To more objectively examine the liver-related safety of green tea intake, we conducted a systematic review of published RCTs.

**Methods:** A systematic literature search was conducted using three databases (PubMed, EMBASE and Cochrane Central Register of Controlled Trials) in December 2013 to identify RCTs of green tea extracts. Data on liver-related adverse events, including laboratory test abnormalities, were abstracted from the identified articles. Methodological quality of RCTs was assessed.

**Results:** After excluding duplicates, 561 titles and abstracts and 119 full-text articles were screened, and finally 34 trials were identified. Of these, liver-related adverse events were reported in four trials; these adverse events involved seven subjects (eight events) in the green tea intervention group and one subject (one event) in the control group. The summary odds ratio, estimated using a meta-analysis method for sparse event data, for intervention compared with placebo was 2.1 (95% confidence interval: 0.5–9.8). The few events reported in both groups were elevations of liver enzymes. Most were mild, and no serious liver-related adverse events were reported.

**Conclusion:** Results of this review, although not conclusive, suggest that liver-related adverse events after intake of green tea extracts are expected to be rare.

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