

## Safety of acupuncture for osteoarthritis of the knee: a review of randomized controlled trials

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**Background and Objective:** If we review published case reports on the adverse events that occurred in acupuncture treatment for osteoarthritis of the knee (knee OA) in East-Asian countries, there are some cases of serious infection or arterial injury. However, the frequency of these adverse events in standard acupuncture practice is unknown, and a causal relationship has not been established. Although it is regarded that the evidence from retrospective case reports is weak, the safety of acupuncture is often discussed based only on retrospective case reports or case series studies. Accordingly, we reviewed papers of randomized controlled trials (RCT) on acupuncture for knee OA, focusing on adverse events.

**Methods:** We used two data sources: PubMed and Japana Centra Revuo Medicina (Igaku Chuo Zasshi). The Keywords used were “acupuncture”, “electroacupuncture”, “osteoarthritis”, “knee”, “gonalgia” and “gonarthrosis”. The type of article in PubMed was limited to RCT. We extracted the descriptions and information regarding adverse events in treating the knee. Adverse events which were already judged to have no causal relationship by the authors were excluded.

**Results:** Eleven RCT papers were located, with 6 including information on adverse events. Recent papers published in 2004 and 2005 reported adverse events, while many of the earlier papers and a Japanese domestic paper did not. Some papers reported local bruise (contusion) or subcutaneous hemorrhage as an adverse event, while others did not. Some papers reported adverse events using the number of patients, while others reported them using the number of events. More joint swelling and local inflammation occurred in the control groups which received dummy electroacupuncture or minimal superficial needling.

**Discussion:** Because of the heterogeneity of reporting style, it was impossible to synthesize the data. Nevertheless, we could confirm that almost all of the adverse events or side effects were mild and transient. If the safety of acupuncture is assessed based only on case studies without a control group for comparison, it might be interpreted that insertion of the needles is the cause of all cases of joint swelling or infection. As the present review shows, however, more joint swellings or inflammation occurred in the control groups. This suggests that some of the adverse events in the published case reports are non-specific to the acupuncture needle insertion. Thus, we should assess the safety of acupuncture based on the data from RCTs. We discuss the problems related to this idea and method, and case reports of adverse events from East-Asian countries.

**Key Words:** Acupuncture, Safety, Osteoarthritis of the knee, Randomized controlled trial, Review