



Commentary

Does acupuncture increase the risk of bleeding in patients taking warfarin?

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The current study examines a retrospective chart review study previously carried out by Kim et al¹.

1. Focal article

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2. Aim

The aim of the current study is to compare the safety of acupuncture in patients taking warfarin or antiplatelet medications with that in patients who are not taking anticoagulant or antiplatelet medication.

3. Design

In this retrospective chart review, the medical records of inpatients who received acupuncture between November 2010 and April 2012 were evaluated.

4. Setting

The study was conducted at the Department of Korean Internal Medicine, Stroke and Neurological Disorders Center, Kyung Hee University Hospital, Seoul, Korea.

5. Participants

Group A: 42 patients who were taking warfarin and were permitted to undergo antiplatelet therapy. Group B: 100 patients who were taking antiplatelet medication but not warfarin. Group C: 100 patients taking neither warfarin nor antiplatelet

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medication. Patients with no record of side effects associated with acupuncture therapy were excluded.

6. Intervention

All patients underwent general acupuncture therapy for treatment of their condition, with no restrictions on the duration or number of sessions. Disposable needles (diameter, 0.25 mm; length, 30 mm or 40 mm; Dongbang Acupuncture Inc., Boryeong, Korea) were inserted up to a depth of 10–20 mm at the acupoints for 20 minutes; all adverse events were recorded by interns. Patients were allowed to take other types of Western and herbal medicines.

7. Main outcome measures

7.1. Study variables

General characteristics (diagnosis, sex, age, medical history, medication), number of acupuncture sessions, and prothrombin time international normalized ratio (PT INR).

7.2. Side effects (recorded by interns)

(1) Microbleeding: assessed by measuring the time taken for hemostasis 10 seconds after removing the acupuncture needle. Bleeding that stopped within 30 seconds was defined as microbleeding. When multiple bleeding events occurred during one acupuncture session, a single case of bleeding was considered; (2) extensive bleeding (at least 30 seconds to achieve hemostasis); (3) time required for hemostasis; (4) massive hemorrhage influencing vital signs or causing other complications; (5) bruising (checked 1–3 hours after needle removal); and (6) edema, faintness, or dizziness; fatigue or exhaustion; nausea or vomiting; pneumothorax; needle fracture; skin eruption or itching; pain after needling; or other adverse effects.

8. Main results

8.1. Baseline characteristics

Patients in Group C were younger and the prevalence of hypertension and diabetes mellitus was lower than in Groups A and B. Patients in Group A showed the highest prevalence of atrial fibrillation.

8.2. Side effects (the adverse effect data for the three groups are expressed as numbers and percentages)

The total number of acupuncture sessions was 848, 1794, and 2249 in Groups A, B, and C, respectively. The incidences of side effects in the three groups were as follows: (1) bruising: 2.0%, 1.6%, and 1.3%, respectively (no significant intergroup differences); and (2) microbleeding: 4.8%, 0.9%, and 3.0%, respectively (intergroup differences were significant). Microbleeding stopped between 10 seconds and 20 seconds in most cases and did not affect vital signs. In Group A, microbleeding

stopped within 20 seconds in 93% patients; (3) no extensive bleeding or massive hemorrhage was observed; and (4) one patient in Group C reported fatigue. Microbleeding, bruising, and fatigue were the only side effects reported.

8.3. PT INR

The average PT INR in Group A was 2.26 ± 0.46 ; it was 1.0–1.5 in three patients, 1.5–2.0 in eight patients, 2.0–2.5 in 19 patients, 2.5–3.0 in 11 patients, and > 3.0 in one patient.

9. Author's conclusion

This review did not identify any serious adverse events related to treatment with acupuncture for various diagnoses. Acupuncture was found to be safe even for patients taking anticoagulants and those with a high PT INR.

10. Commentary

Research on the safety of acupuncture is increasing. In the study currently being examined, the authors discuss the safety of acupuncture for patients taking antiplatelet and anticoagulant medications. Previous studies have investigated the safety of acupuncture for the general population and concluded that acupuncture therapy provided by well-trained physicians is relatively safe.^{2,3} Similar studies exploring the safety of this technique for vulnerable groups have also been published. Adams et al⁴ published a systematic review about the safety of acupuncture for pediatric patients, concluding that the severity of adverse events (AEs) was mild and that the incidence of mild AEs was 11.8% [95% confidence interval (CI), 10.1–13.5]. Park et al⁵ published a systematic review about the safety of acupuncture during pregnancy, concluding, on the basis of an overall incidence of 1.9%, that acupuncture during pregnancy was relatively safe, with a low incidence of AEs when appropriately administered. However, in clinical practice, the safety of acupuncture is more controversial for patients taking anticoagulant medication than for those taking antiplatelet medication. Therefore, the current study focuses on the safety of acupuncture for patients taking anticoagulant medication.

Warfarin is an oral anticoagulant that inhibits the synthesis of clotting factors, thus increasing the INR. Warfarin is indicated for the prevention of thromboembolic complications caused by atrial fibrillation and is widely used for the prevention of recurrent stroke and transient ischemic attacks.⁶ Acupuncture needles are generally very thin, much smaller than the hypodermic needles used for phlebotomy and injections. Thus, the risk of acupuncture-related bleeding in patients taking anticoagulant medication may be low, although the safety of acupuncture for such patients has not been well investigated. In a case series involving four patients who underwent 51 acupuncture sessions,⁷ no posttreatment bleeding was reported by the physician/acupuncturist or patients. However, this evidence is not adequate. Moreover, some doctors prohibit their patients from receiving acupuncture during anticoagulant therapy, possibly because of the

reported side effects. For example, Kenz et al⁸ reported thigh hematoma after the acupuncture treatment of an 82-year-old woman taking warfarin. Her PT INR was 2.4 at the time of acupuncture treatment. Warfarin was discontinued and oral vitamin K was initiated, following which she showed good recovery. Another case of acupuncture-induced calf hematoma in a patient taking anticoagulant medication was reported by Han et al⁹, while other articles report multiple small hematomas on the inner membrane of the appendix¹⁰ and acute carpal tunnel syndrome with bleeding from the rupture of several extensor tendons in the hand¹¹ after acupuncture.

Although there are several small case series regarding this topic, to our knowledge, this is the first relatively large retrospective chart review on the safety of acupuncture for patients taking anticoagulant medication. In this review, side effects were reported in 6.8%, 2.5%, and 4.4% of the patients in Groups A, B, and C, respectively. The rate of minor AEs was similar to that in a large prospective observational study of 229,230 patients.³ In the present review, microbleeding is defined as bleeding for > 10 seconds and < 30 seconds. Therefore, patients whose bleeding stopped within 10 seconds were excluded. If all patients with bleeding were considered, the rate of AEs would have been higher. Nevertheless, no serious AEs were reported. Therefore, the authors concluded that acupuncture treatment is not a contraindication for patients taking oral anticoagulants. The average PT INR was 2.26 in Group A. In this review, 26 acupuncture sessions were conducted when the PT INR value was > 3.0, and only minor bleeding was observed. In a previous study, Miller et al¹² divided patients with a PT INR of ≥ 2.3 and < 2.3 into two groups and reported that INR does not influence the incidence of bleeding (14.3% vs. 14.6%, respectively). This study was limited by the fact that the authors did not describe their method of assessing the severity and causality of the AEs.

In a study examining the safety of acupuncture for pregnant women,⁵ Common Terminology Criteria for AEs (CTCAE) were used to assess severity, while the World Health Organization–Uppsala Monitoring Center (WHO-UMC) system was used to assess causality. Accordingly, future studies should focus on the assessment of causality and severity. A systematic review on this issue was recently published.¹³ It included seven studies involving 384 patients and 3974 treatment sessions. The rate of minor bleeding was 1.4% (58 events), while serious bleeding occurred in only one patient. This value was much lower than that (12.3%) for patients who underwent total hip or knee replacement while receiving low-molecular-weight heparin or vitamin K antagonists.¹⁴ Unfortunately, the review¹³ did not include the retrospective review discussed here, although the results are consistent and the sample size in this review was relatively large. Further well-designed prospective studies with a larger sample size that focus on severe AEs after acupuncture therapy for patients taking anticoagulant medication are required. In clinical practice, acupuncture therapy administered by a well-trained, licensed physician to patients taking anticoagulant medication is relatively safe, as these physicians are trained with regard to the anatomy of the human body and safe

treatment techniques in long formal education sessions to avoid severe AEs such as pneumothorax, infection, and neuritis, among others. Furthermore, practitioners should always record detailed histories before initiating acupuncture therapy, particularly any history of anticoagulant medication, the last assessed INR value, and any history of AEs during anticoagulant therapy.

Conflicts of interest

The author declares no conflict of interest.

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