

## REVIEW

Spontaneous Bleeding Associated with *Ginkgo biloba*

## A Case Report and Systematic Review of the Literature

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**BACKGROUND:** *Ginkgo biloba* (ginkgo) is a herbal remedy used by over 2% of the adult population in the United States. Several review articles have suggested that ginkgo may increase the risk of bleeding.

**OBJECTIVE:** To report a case of bleeding associated with using ginkgo, to systematically review the literature for similar case reports, and to evaluate whether using ginkgo is causally related to bleeding.

**DATA SOURCES:** We searched MEDLINE, EMBASE, IBIDS, and the Cochrane Collaboration Database from 1966 to October 2004 with no language restrictions.

**REVIEW METHODS:** Published case reports of bleeding events in persons using ginkgo were selected. Two reviewers independently abstracted a standard set of information to assess whether ginkgo caused the bleeding event.

**RESULTS:** Fifteen published case reports described a temporal association between using ginkgo and a bleeding event. Most cases involved serious medical conditions, including 8 episodes of intracranial bleeding. However, 13 of the case reports identified other risk factors for bleeding. Only 6 reports clearly described that ginkgo was stopped and that bleeding did not recur. Bleeding times, measured in 3 reports, were elevated when patients were taking ginkgo.

**CONCLUSION:** A structured assessment of published case reports suggests a possible causal association between using ginkgo and bleeding events. Given the widespread use of this herb and the serious nature of the reported events, further studies are needed. Patients using ginkgo, particularly those with known bleeding risks, should be counseled about a possible increase in bleeding risk.

**KEY WORDS:** herbal medicine; alternative medicine; bleeding.

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**G**INKGO *biloba* (ginkgo) is the fourth most commonly used herbal remedy in the United States, accounting for 4.3% of all single herb sales in 2001.<sup>1</sup> In a recent national telephone survey, 2.2% of the adult U.S. population, or approximately 4.5 million individuals, reported using ginkgo in the past week.<sup>2</sup>

Ginkgo is most commonly used to treat dementia, but has also been used for memory improvement, cerebrovascular and arterial insufficiency, tinnitus, vertigo, asthma, allergies, and many other conditions.<sup>3</sup> While the precise mechanism of ac-

tion of this herb is not completely clear, ginkgo is believed to improve cerebral and peripheral blood flow through nitric oxide-induced vasodilation, possess antioxidant activity that may prevent cellular damage, and inhibit platelet-activating factor.<sup>3</sup> Two systematic reviews evaluating the use of ginkgo to treat dementia concluded that the herb is significantly more effective than placebo in delaying cognitive deterioration.<sup>4,5</sup> While less evidence exists for other indications, a recent review concluded that promising evidence exists for ginkgo in the treatment of tinnitus and intermittent claudication.<sup>6</sup>

Several recent review articles<sup>6,7</sup> and herbal medicine textbooks<sup>3,8,9</sup> have noted that ginkgo may increase the risk of bleeding. Prior research suggests a biologically plausible mechanism for an increased risk of bleeding with ginkgo through interactions with platelet-activating factor and collagen that lead to decreased platelet aggregation.<sup>10,11</sup> Ginkgo appears to inhibit platelet aggregation by increasing concentrations of endothelium-derived thrombolytics, such as nitric oxide and prostacyclin.<sup>12</sup> Ginkgolide B, a component of ginkgo, may also directly inhibit the binding of platelet-activating factor to its receptors on platelet membranes.<sup>11</sup> Other investigators believe that ginkgo primarily affects interactions between platelets and collagen (rather than platelet-activating factor) to inhibit aggregation.<sup>10</sup> However, 3 recent systematic reviews examining the efficacy of ginkgo for dementia found no increased risk of bleeding.<sup>4,5,13</sup>

We describe a case report of a patient who experienced spontaneous bleeding while taking ginkgo. We then present a systematic review of the literature conducted to identify all prior case reports of bleeding in association with ginkgo use, and to determine the quality of published information on this potential side effect.

## METHODS

## Systematic Review

We conducted a search of MEDLINE, EMBASE, IBIDS, and the Cochrane Collaboration Clinical Trials Registry from 1966 to October 2004 for human studies using the title word "ginkgo" with no language restriction. Two authors (S. B. and A. P.) independently reviewed article titles to identify all potential case reports of bleeding in persons using ginkgo. Articles were deemed potentially relevant if the title or abstract included

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the word ginkgo in addition to any mention of bleeding, risk, or complication. All articles that were deemed potentially relevant by either author were located for full manuscript review, and reference lists from retrieved articles were scanned to identify other potentially relevant reports. We then used a structured abstract form to record the author and year of the case report, the age, gender, and race of the patient, ginkgo dose and duration of use, current medications, clinical presentation, laboratory test results, radiographic studies, clinical course of bleeding, and the 5 causality elements described below. Disagreements in the abstracted data were resolved by further review, discussion, and consensus between the 2 reviewing authors.

While there is no consensus on the specific information necessary to determine causality from case reports, many established systems rely on 5 basic data elements: (1) the timing of the event relative to the drug exposure, (2) the presence or absence of other factors that might also cause the event, (3) the result of withdrawing the drug ("dechallenge"), (4) the results of reintroducing the drug ("rechallenge"), and (5) other data supporting an association (e.g., previous cases).<sup>14</sup> We included the first 4 of these data elements on the data abstraction form, and addressed the fifth data element by presenting all cases in tabular form.

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## Case Report

A 73-year-old white man presented complaining of recent episodes of spontaneous bleeding. He had noticed 3 nose bleeds in the prior month, ecchymosis on his hands and arms after very minor trauma, frequent hemorrhoidal bleeding, and bleeding from his ear after striking it with a blunt comb.

The patient was a healthy, retired pediatrician. He had a remote history of bleeding after using aspirin, occasional, mild hemorrhoidal bleeding, and only 1 or 2 previous nosebleeds. The patient had no excessive bleeding after previous surgical procedures. He was taking no prescription medications, but did take vitamins A, C, D, E, and folic acid for preventive care and had used ginkgo, 75 mg per day, for the previous 6 months as an aid to his "failing memory." The ginkgo supplement, which was produced by a large U.S. manufacturer and distributed by a large supermarket chain, was standardized to 27% ginkgo flavone glycosides and 10% terpene lactones. He had never been diagnosed with cognitive dysfunction, but felt that ginkgo improved both his memory and clarity of thought.

He discontinued ginkgo but continued his other supplements and observed that his bleeding stopped. Because the patient perceived a significant benefit from using ginkgo, he decided, after discussion with his physician, to restart the medication while monitoring laboratory tests. After a 6-week washout period, baseline labs, including complete blood count (CBC), prothrombin time (PT)/international normalized ratio (INR), partial thromboplastin time, and bleeding time (5.5 minutes, normal range 2.5–9.5 minutes), were all within normal limits. Laboratory personnel performing all tests were blinded to patient characteristics, including ginkgo use.

The patient then restarted the same ginkgo supplement at the same dose. During the next 10 weeks, he noticed occa-

sional ecchymoses, but no other spontaneous bleeding. Repeat laboratory studies 10 weeks after restarting ginkgo again showed normal CBC and coagulation studies. However, the bleeding time was elevated at >15 minutes. He then discontinued ginkgo and had no further bleeding episodes. Over the next several years, the patient experienced a slow, progressive loss of cognitive function as well as an episode of paranoid delusion. Further neurologic evaluation revealed the diagnosis of a variant of Alzheimer's dementia.

## Systematic Review of Case Reports

**Included studies.** The title word search identified 1,908 articles, of which 33 were selected for full manuscript review. Thirteen reports described bleeding episodes in patients taking ginkgo. One report described 2 separate bleeding episodes in 1 patient,<sup>15</sup> and is therefore shown here as 2 cases. The current report is also included in the total of 15 published case reports of bleeding associated with ginkgo (Table).<sup>15–27</sup>

The identified cases were published between 1996 and 2003. Most cases involved serious medical conditions, including 8 episodes of intracranial bleeding. Of these, 2 patients required surgical evacuation,<sup>16,22</sup> 2 were left with permanent neurologic defects,<sup>19,21</sup> and 1 died.<sup>27</sup> Four cases involved ocular bleeding.<sup>15,17,23,26</sup> Of these, 1 required surgical intervention,<sup>26</sup> and all returned to baseline vision.

## Causality Assessment

**Timing of Event Relative to Ginkgo Exposure.** In 8 of the 12 cases providing information about duration of use, patients reported taking ginkgo for more than 6 months before the bleeding event (shown in the Table as "Duration"). Two cases with intracranial bleeding had used ginkgo for less than 2 months. In both cases of spontaneous hyphema, ginkgo was used less than 2 weeks before the onset of symptoms.

**Presence of other Factors that Might have Caused Bleeding.** Most patients had risk factors for bleeding other than ginkgo (shown in the Table as "Age" and "Clinical Presentation"). Age was the most common risk factor; 13 of the 15 cases were aged 56–78. Five patients were using medications known to increase the risk of bleeding<sup>15,17,19,27</sup> (and current case). Other risk factors for bleeding included a fall before a subdural hematoma,<sup>22</sup> advanced cirrhosis in a patient with postoperative bleeding,<sup>15</sup> and an intracerebral mass.<sup>27</sup>

Two patients had no identifiable risk factors other than using ginkgo. A 33-year-old woman developed a subdural hematoma,<sup>16</sup> and a 34-year-old man developed excessive bleeding after a laparoscopic cholecystectomy.<sup>20</sup>

**Dechallenge.** Only 6 of the 15 case reports explicitly indicated that ginkgo was stopped<sup>15–18,23</sup> (and current case) (shown in the Table as "Dechallenge"). None of the 6 cases had recurrent bleeding, but the follow-up time varied from 3 months to 4 years. All 3 cases that measured bleeding times reported shorter bleeding times when the patient was not using ginkgo<sup>16,18</sup> (and current case). Two cases reported abnormally high bleeding times during ginkgo use<sup>18</sup> (and current case).

**Rechallenge.** Only the current case reintroduced ginkgo after the bleeding episode (because of the mild nature of the initial bleeding). The bleeding time increased from 5 minutes when the patient was not taking ginkgo to >15 minutes (normal

range 2.5 to 9.5) when ginkgo was reintroduced. The patient experienced mild echymosis with reintroduction of ginkgo.

## DISCUSSION

While numerous review articles and texts note that using ginkgo may be a risk factor for bleeding,<sup>3,6-9</sup> there is very limited evidence from clinical research to support this concern. Systematic reviews of randomized controlled trials have not noted any increased risk of bleeding in patients taking ginkgo.<sup>4,5,13</sup> However, because most studies included in these reviews were small and of short duration (24 of 33 included studies included fewer than 100 patients and lasted 12 weeks or less),<sup>13</sup> the individual studies did not have sufficient power to detect even moderate increases in bleeding risk in patients treated with ginkgo, and the systematic reviews did not specifically describe pooling data on bleeding events. Two recent randomized controlled trials designed to detect side effects from ginkgo found no interactions with warfarin<sup>28</sup> or any effect on bleeding time, coagulation parameters, or platelet activity.<sup>29</sup> These studies were similarly limited by a small sample size (24 and 50 patients) and short duration (1 month and 1 week).<sup>28,29</sup> Our search did not identify any case-control or cohort studies examining the association between ginkgo and bleeding.

Given the absence of relevant data from controlled or observational studies, we evaluated case reports for evidence of a causal association between ginkgo use and bleeding. Including the current case, we identified 15 published case reports. Using widely accepted elements of case reports to establish causality, we examined the strength of the association between ginkgo use and bleeding in each identified case. The timing of the bleeding event relative to the ginkgo exposure did not strongly suggest a causal association in most cases since the majority of patients had been taking ginkgo for months or years. Only 1 case of a spontaneous hyphema involved a short interval (1 week) between initiating ginkgo and the bleeding event.<sup>17</sup> However, the lack of a short interval between ginkgo initiation and the bleeding events does not rule out an increased risk from the herb. The risk of bleeding may increase over time, or may require the presence of another risk factor, such as a fall or an operation, to cause a bleeding event.

Most patients had other clinical risk factors, including age and use of other medications, that could have caused the bleeding episode. In 2 cases, involving a 33-year-old woman with bilateral subdural hematomas and a 34-year-old man with excessive postoperative bleeding, risk factors were noticeably absent. Although rare, bleeding events in young, healthy adults do occur, and the ginkgo may not have been the causal factor even in these cases.

Only 6 of the cases specifically noted that ginkgo was stopped, and none of the patients had recurrent bleeding over follow-up periods ranging from 10 weeks to 4 years. However, because major bleeding is a relatively rare event, even in the elderly, it is not surprising that recurrent bleeding was not noted.

Only 3 cases provided information on bleeding times. In all of these, the bleeding times were higher when patients were taking ginkgo, and in 2, they were clearly abnormal while on ginkgo and normal when off of ginkgo. Of note, only the current case indicated that the person performing the bleeding time test was blinded to whether the patient was using ginkgo. Lack of blinding has the potential to introduce substantial bias in the interpretation of this test.

Our study, which seeks to determine whether the use of ginkgo increases the risk of bleeding, is limited by the information presented in the identified articles and by the inherent difficulties in determining causality from case reports. As discussed previously, there are 5 basic data elements that are commonly used to assess causality, only 4 of which come from individual case reports (timing, other risk factors, dechallenge, rechallenge). In many cases, it is not safe to attempt a rechallenge because of the severe nature of the first bleeding event. Therefore, in the case of ginkgo and bleeding, there are only 3 data elements that are typically available to assess causality. Of the 15 cases identified in this review, only 5 gave complete details on these 3 elements. Furthermore, even with very thorough case reporting, it remains controversial whether causality can be determined from case reports, with many experts preferring to surmise some probability that a drug or herb caused an adverse event, rather than making a definitive determination of causality.<sup>14</sup> Finally, while we utilized a broad search strategy in 4 large computerized databases and included publications in all languages, we did not search conference proceedings, and it is possible that we missed some case reports that were never published.

In our view, the published evidence from case reports suggests a possible causal association between ginkgo and bleeding events. The most convincing finding is an increased bleeding time reported in all 3 cases assessing this laboratory parameter. Coupled with prior evidence showing that ginkgo leads to inhibition of platelet aggregation, we believe that ginkgo may increase bleeding times. Because ginkgo is used by 2.2% of the adult population and because the range of reported bleeding events include serious adverse events, the safety of this herb should be further assessed. Suitable research designs for future studies include large cohorts with sufficient follow-up to detect effects that occur only after prolonged use and high-quality case-control studies that include careful assessments of herb use. Until then, we believe that patients using ginkgo should be warned of the possible increased risk of bleeding.

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Table 1. Published Case Reports of Bleeding Associated with *Ginkgo biloba* (ginkgo)

Reference	Age/Gender	Daily Dose (mg)	Duration	Clinical Risk Factor for Bleeding	Clinical Presentation
Rowin and Lewis <sup>16</sup>	33, F	120	2 y	None	3 mo of headache, 2 wk of diplopia, nausea, vomiting
Rosenblatt and Mindell <sup>17</sup>	70, M	80	1 wk	Aspirin 325 mg/d	2 d of blurred vision
Vale <sup>18</sup>	61, M	120 to 160	6+ mo	None	5 d of headache, back pain, nausea, sleepiness
Matthews <sup>19</sup>	78, F	NR	2 mo	Hypertension, warfarin for 5 y	2 d of inability to feed herself and apraxia
Fessenden et al. <sup>20</sup>	34, M	NR	NR	None	Excessive bleeding after laparoscopic cholecystectomy
Benjamin et al. <sup>21</sup>	56, M	120	18 mo	None	Acute confusion, unable to stand, severe pain behind eye
Miller and Freeman <sup>22</sup>	78, M	150	6 mo	Fall 5 d prior to admission	Headache, confusion, right-sided weakness after a fall
Hauser et al. <sup>15</sup>	59, M	NR	NR	Cirrhosis	Peri-hepatic fluid collections after liver transplant
Hauser et al. <sup>15</sup>	59, M	NR	NR	Cirrhosis, 81 mg aspirin	Blurred vision
Schneider et al. <sup>23</sup>	65, M	600	8 wk	None	6 wk of blurred vision
Purroy Garcia et al. <sup>24</sup>	75, M	80	1 mo	NR	Nausea, vomiting
Gilbert <sup>25</sup>	72, F	150	6 to 7 mo	NR	6 mo of memory impairment and dizziness
Fong and Kinnear <sup>26</sup>	65, F	120	2 y	None	Sudden eye pain, proptosis, bruising, reduced vision during injection of anesthetic in inferotemporal region of orbit for cataract surgery
Meisel et al. <sup>27</sup>	71, M	80	2½ y	Ibuprofen	Coma
Bent (2005)	73, M	75	6 to 7 mo	Vitamin E	Spontaneous bleeding from ear and nose, ecchymosis on hands and arm

\*Dechallenge indicates whether the drug was withdrawn, and the length of follow-up after drug cessation.

†Bleeding times were 15.0 and 9.5 minutes when taking ginkgo and 6.5 and 6.5 minutes after 35 days washout; normal range not reported.

‡Bleeding time on ginkgo was 6 minutes; 4 months after discontinuation of ginkgo bleeding time was 3 minutes (normal range 1–3 minutes).

§Bleeding time off of ginkgo was 5.5 minutes (normal range 2.5 to 9.5 minutes). Ginkgo restarted for 10 weeks, and patient had only occasional ecchymoses. Repeat bleeding time on ginkgo was greater than 15 minutes.

M, male; F, female; NR, not reported; NA, not applicable.

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Table 1. continued

Bleeding Event	Clinical Course	Dechallenge* Yes/No/NR, Time	Bleeding Time/ Rechallenge
Bilateral subdural hematomas	Surgical evacuation and full recovery while taking Ginkgo	Yes, 15 mo	Yes <sup>†</sup>
Spontaneous hyphema	Bleeding stopped spontaneously in 5 min	Yes, 3 mo	No
Subarachnoid hemorrhage	Full recovery	Yes, 4 mo	Yes <sup>‡</sup>
Left parietal hemorrhage	Some apraxia remained in 1 mo	No	No
375 mL of bloody fluid from surgical drain in abdomen	Hemoglobin fell 16.5 to 5.4 g/dL, transfused 2 units	NR	No
Right parietal hematoma	Permanent left inferior quadrantanopia	NR	No
Left subdural hematoma	Patient underwent surgical evacuation and uneventful postoperative course	NR	No
Multiple peri-hepatic hematomas	Patient underwent surgical evacuation of hematomas and was discharged	No	No
Vitreous hemorrhage		Yes, time not specified	No
Spontaneous hyphema	Complete resolution	Yes, 18 mo	No
Cerebellar hematoma	NR	NR	No
Subdural hematoma	NR	NR	No
Acute retrobulbar hemorrhage	Surgical decompression with return of baseline vision	NR	No
Intracerebral mass bleeding	Death	NA	No
Ecchymosis, epistaxis		Yes, 4 y	Yes <sup>§</sup>