



TA pharmacopuncture as a primary and independent treatment for frequent sprains occurring over 9 months in a patient with needle sickness

Case report

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Abstract

Rationale: Sprains, stretching or tearing of ligaments are common injuries. Clinicians should try to prevent acupuncture-associated vasovagal responses (AAVR) when treating patients with such injuries. In this study, we report the treatment of frequent sprains of various body parts in a patient with a history of AAVR using only TA (a 7-herb extract consisting of *Scutellaria baicalensis*, *Phellodendron amurense*, *Pulsatilla koreana*, *Sophora tonkinensis*, *Aucklandia lappa*, *Aquilaria agallocha*, and *Carthamus tinctorius* L.) pharmacopuncture.

Patient concerns: The patient was a 47-year-old woman who was injured 23 times in 9 months. The injuries occurred in the knees, thumb, wrist, ankle, and low back region due to overextension during physical activity or frequent exercise. This patient had great fear of acupuncture after fainting due to her experience with a previous fire needling on an ankle sprain 18 years ago. Therefore, she did not want to undergo conventional acupuncture, including needle retention.

Diagnoses: With the exception of the bruising and sprain of a knee occurring over 1 week after onset at the initial visit, the injuries were diagnosed as acute sprains of grade 1 with pain without range of movement limitation in various parts of the knee, ankle, thumb, and lower back. Time to onset of these injuries was within 3 days.

Interventions: The patients received only TA pharmacopuncture at 4 to 6 ouch points (ashi points). The patient returned to work immediately after the conclusion of treatment without any posttreatment such as infrared and hot pack which can help absorbing the extract and calming the injection site.

Outcome: The treatment was usually completed within 4 sessions, and led to a reduction in pain (visual analog scale [VAS] score of 1). In the absence of mild swelling and warmth or when there was mild pain (VAS score <3) in the affected area, the patient reported reduced pain and smoother joint movement immediately after 1 to 2 sessions.

Lessons: Although our report is a single case study, our results indicate that TA pharmacopuncture can be effective in treating various acute sprains and is a potential acupuncture method for the treatment of patients with AAVR.

Abbreviations: AAVR = acupuncture-associated vasovagal response, ROM = range of motion, TA = a 7-herb extract consisting of *Scutellaria baicalensis*, *Phellodendron amurense*, *Pulsatilla koreana*, *Sophora tonkinensis*, *Aucklandia lappa*, *Aquilaria agallocha*, and *Carthamus tinctorius* L., TCM = traditional Chinese medicine, TKM = traditional Korean medicine, VAS = visual analog scale.

Keywords: clinical study, elderly patients, Korean medicine, needle sickness, pharmacopuncture, sprain, TA

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1. Introduction

Injuries due to participation in sports and physical activity are prevalent. Sprains, stretching, and tearing of ligaments are common injuries. One or more ligaments can be injured during a sprain. The severity of injury can be classified based on the extent of injury to a single ligament and the number of ligaments involved. Sprains can occur anywhere in the upper or lower parts of the body. Sprains often occur in the ankle, knee, wrist, and thumb when walking or exercising on an uneven surface, pivoting during an athletic activity, or landing on an outstretched hand during a fall. They may also occur during skiing or due to overextension when playing racquet sports, such as tennis. [1–3]

Faint during acupuncture treatment (acupuncture-associated vasovagal response [AAVR] or needle sickness) is an adverse reaction to acupuncture comprising feeling faint, dizziness, cold sweating, and nausea during and/or after needling. Although

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patients typically recover without lasting effects, the experience may produce concern and anxiety in both patients and clinicians. Therefore, clinicians attempt to prevent AAVR when treating patients with a history of the condition.^[3,4]

Pharmacopuncture, which is an acupuncture technique involving the injection of herbal medicine, is considered faster and more effective than oral treatment because it can deliver the medicine to the target tissue/organ directly without passing through the digestive system. Therefore, it is often used to target rapid pain relief. [3,5] TA is a polyherbal extract used for pharmacopuncture. It is used to treat musculoskeletal diseases and traffic accident injury syndrome in traditional Korean medicine (TKM) clinical practice. In addition to experimental studies on the anti-inflammatory effects^[6] and safety^[7,8] of TA extract, a clinical study has reported its therapeutic effects on thoracic pain due to seatbelt-induced injuries in traffic accidents. [9] In this study, we report the treatment of frequent sprains of various body parts not related to a traffic accident in a patient with AAVR using only TA pharmacopuncture in 59 sessions over 9 months.

2. Case report

The patient was a 47-year-old woman who climbed and walked frequently for weight control. As a part of her job, she was required to repeatedly use her hands and wrists and sometimes carry heavy things. She was also required to stand for >6 h/d. The patient was injured 23 times in 9 months. The patient's right and left knees, as well as both knees, were sprained 11, 3, and 2 times, respectively, due to frequent climbing or walking exercises. The right and left thumbs and the right wrist were sprained 3, 1, and 1 times, respectively, due to overextension during physical activities such as lifting a heavy object, helping others remove pressure stockings, or opening hard-to-open lids. The patient's left ankle was sprained once when she slipped on water in a restaurant. A low back sprain occurred once after the patient carried a heavy item while working. One week before visiting our hospital, the patient received bruising and sprain to the right knee due to a climbing accident and visited a local clinic. Due to the severe edema, she underwent knee aspiration without X-ray and received a prescription for anti-inflammatory drugs for 3 days. Four years ago, the patient underwent right knee aspiration twice due to the recurrence of fluid accumulation in the affected knee. During her first visit to our hospital, the patient asked for treatment of her symptoms, including severe pain without limit of range of motion (ROM), swelling, warmth, and limp when walking, using TKM to prevent a recurrence of fluid accumulation in the affected knee. She stated that she felt very nervous and had sweating whenever she received a knee aspiration. The patient had a fear of heights and AAVR. She had great fear of acupuncture after fainting during a previous session of fire needling for the treatment of an ankle sprain 18 years ago. Therefore, she did not want to undergo conventional acupuncture, including needle retention, due to the possibility of sweating, nervousness, and pale skin. We suggested the use of TA pharmacopuncture, which can be thought of as a terminal method (quick acupuncture into and out of the patient) wherein one acupuncture therapy needle is inserted into the acupuncture point very quickly and pulled out very quickly to produce a weak stimulus. This technique is most commonly used in children, patients with physical weaknesses, and mentally stressed individuals. [3] In addition, TA, which is a water-soluble extract with a small particle size, can lead to less pain during injection when compared with other pharmacopuncture medicines.^[6] After receiving one treatment, the patient lost much of her fear regarding this treatment and agreed to continue her treatment using the above technique. Sprains of the patient's ankle, thumb, and the lower back, which occurred after the knee injury, were also treated using this technique.

3. Examination

The severity of a sprain can be diagnosed as 1 of 3 stages. In general, first-degree sprains (mild) cause excessive stretching or slight tearing of ligaments with no joint instability, and are characterized by minimal pain, swelling, and little or no loss of functional ability. They are accompanied by no or slight bruising. X-rays are usually not needed for the diagnosis of first-degree sprains. Second-degree sprains (moderate) cause partial tearing of ligaments and are characterized by moderate pain, bruising, and swelling. X-rays might be needed to determine if the pain and swelling are caused by a fracture. Magnetic resonance imaging is sometimes used to distinguish a significant partial injury from complete tearing of a ligament. Third-degree sprains (severe) cause complete tears or rupture of a ligament and are characterized by severe pain, swelling, and bruising. X-rays are usually obtained to rule out a fracture. [3] The damaged area must be inspected against the normal side to check for swelling, bleeding, tenderness, ROM, and joint instability by physical instability examination. In this study, with the exception of the bruise and sprain of the knee occurring over a week after onset at the initial visit, the injuries were diagnosed as acute sprains of grade 1 with pain without limit of ROM in various parts of the knee, ankle, thumb, and lower back within 2 days of onset. The patient's pain intensity was evaluated using the visual analogue scale (VAS) before and after treatment at each visit and the following visit to determine the immediate effects of pharmacopuncture. This case report is one of retrospective chart reviews and the patient signed informed consent for the publication of this case report.

4. Intervention

TA consists of 7 herbs (Table 1). All materials were purchased from a herbal materials company (Jayeondameun; Yangju, Korea) and were verified the quality by the Korean Food and Drug Administration. The TA extract in a sealing vial was provided by Namsangcheon Herbal Medicine Dispensary (an extramural facility meeting Korean Good Manufacturing Practice [K-GMP] standards).

Composition of TA extract.

Herb name	Scientific name	Ratio, mg/mL	
Scutellariae Radix	Scutellaria baicalensis	10	
Phellodendri Cortex	Phellodendron amurense	10	
Pulsatilla Koreana	Pulsatilla koreana	10	
Sophorae Subprostratae Radix	Sophora tonkinensis	10	
Aucklandiae Radix	Aucklandia lappa	5	
Aquilaria agallocha	Aquilaria agallocha	0.5	
Carthami Tinctorii Fructus	Carthamus tinctorius L.	15	
		60.5	

TA=a 7-herb extract consisting of Scutellaria baicalensis, Phellodendron amurense, Pulsatilla koreana. Sophora tonkinensis. Aucklandia lappa. Aquilaria agallocha. and Carthamus tinctorius L.

Table 2
Sites, dates, and dosages of treatment using TA pharmacopuncture.

Site		Treatment			Time from recent onset, d	Symptoms before treatment		Dosage of TA, mL
	Order	No. of treatments	Treatment dates		VAS	Swelling		
Le Bo	Right	1st	4	10/10, 11, 13, and 16	7	8	++	0.3
		2nd	1	11/3	1	3	_	0.3
		3rd	4	11/14, 17, 22, and 24	1	4	+	0.24
		4th	1	12/12	2	2	_	0.24
		5th	3	12/26, 27, and 30	1	4	+	0.3
		6th	3	2/12, 14, and 19	1	4	+	0.3
		7th	2	3/24 and 29	1	3	_	0.3
		8th	4	4/13, 16, and 17	2	3	+	0.3
		9th	4	4/30 and 5/4, 8, and 9	1	4	+	0.3
		10th	1	5/19	1	2	_	0.24
		11th	2	5/26 and 30	3	3	_	0.24
		11	29					
	Left	1st	7	2/28 and 3/2, 3, 5, 6, 7, and 9	3	5	++	0.3
		2nd	2	3/13 and 16	2	3	+	0.3
		3rd	1	6/1	2	2	_	0.24
		3	10					
	Both	1st	1	4/27	1	2	-	0.42
		2nd	1	6/8	0	2	_	0.42
		2	2					
	Total	16	41					
I	Right	1st	5	11/14, 17, 22, 24, and 28	0	5	++	0.15
		2nd	1	5/10	0	2	_	0.12
		3rd	1	5/16	0	2	_	0.12
		3	7					
	Left	1st	4	12/18, 20, 23, and 26	0	4	+	0.15
	Total	4	11					
Wrist	Right	1st	3	6/4, 5, and 8	0	3	+	0.12
Ankle	Left	1st	3	3/30 and 31, and 4/2	1	4	++	0.16
Low back	Both	1st	1	5/23	2	4	_	0.40
Total		23	59					

^{-:} no swelling, +: mild, ++: moderate

TA = a 7-herb extract consisting of Scutellaria baicalensis, Phellodendron amurense, Pulsatilla koreana, Sophora tonkinensis, Aucklandia lappa, Aquilaria agallocha, and Carthamus tinctorius L.

From October 2017 to June 2018, the patient underwent 59 TA pharmacopuncture treatments for various acute sprains. She underwent no other treatment. In clinical practice, 0.1 mL of medication per point is generally used. However, considering the possibility of AAVR in the patient, she was treated with less medicine than usual and the dose to be administered at each point was adjusted according to the treatment site. We administered 0.02 to 0.04 mL of medication per point at sensitive body parts such as the thumb, wrist, and ankle. In contrast, we administered 0.06 to 0.08 mL of medication per point at sites with thick skin, such as the knee and lower back. For each body part, pharmacopuncture treatment was administered at 4 to 6 ouch points (ashi points), which are sites determined based on tenderness or other pathological responses. The total amount of TA extract used for each treatment was between 0.1 and 0.5 mL. Two sites were treated at once in 4 treatment sessions. In those cases, the total amount of TA administered was <0.5 mL (Table 2). The patient returned to work immediately after the conclusion of the treatment.

5. Outcomes

The intervention was performed 59 times from October 2017 to June 2018 at Gachon University Korean Medical Hospital. Outcomes were assessed before and after each treatment session.

The 59 TA sessions were used for the treatment 23 different

The 59 TA sessions were used for the treatment 23 different sprains occurring over 9 months. With the exception of the first

visit, the patient was treated within 3 days after the onset of symptoms. Most of the patient's injuries were treated over one session. The treatment was usually performed over <4 sessions and led to improvements in pain (VAS score of 1). In the absence of mild swelling and warmth, or in the case of mild pain (VAS scores <3) in the affected area, the patient felt that the pain was reduced and movement of the joint was improved immediately after 1 to 2 treatments. Two of the 23 injuries require >5 treatments. When she first injured her right thumb and left knee, the patient had moderate swelling and warmth, as well as moderate pain (VAS scores of 5-6). After the first 3 treatment sessions, the swelling had almost disappeared. Following the last treatment, the pain was improved to a VAS score of 1 (Table 2, Fig. 1). In addition, the patient was active without any problems within 1 to 2 minutes of the treatment without the use of any special treatment for the absorption of the pharmacopunture extracts. The patient stated that she felt little pain or discomfort during and after the treatment.

6. Discussion

Sprain is stretching or tearing of ligaments and is often caused by trauma or the joint being taken beyond its functional ROM. The severity of sprain can range from that in minor injuries resolved within a few days to major ruptures of one or more ligaments requiring surgical fixation and an immobilization period. Sprains typically occur when the joint is taken beyond its functional

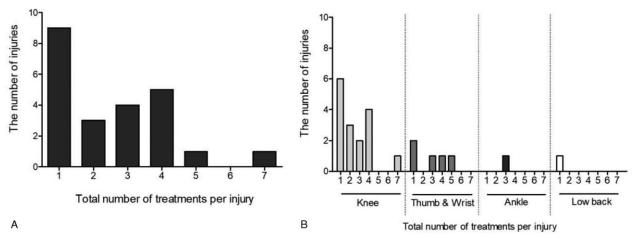


Figure 1. Total number of TA pharmacopuncture treatments per injury (A) and at each site (B).

ROM. The risk for sprains increases with participation in sports and activities that involve lifting and bending. Sprain can often be diagnosed with a good degree of certainty by physical examination while considering clinical symptoms and the method of injury. The basic therapeutic goal when treating sprains is to prevent chronic pain and instability. First- and second-degree sprains are treated with rest, ice, compression, and elevation (RICE). Splinting or surgery may be used in Western medicine to treat severe sprains. The Mark the most rapid treatment measure is acupuncture, followed by physical therapy and medication depending on the type of injury and symptoms.

Fainting during acupuncture treatment (AAVR or needle sickness) is a relatively uncommon adverse event that occurs in 0.02% to 7% of patients. [10-12] A wide range of symptoms can manifest in this condition, including presyncopal symptoms of dizziness, nausea, sweating, pale skin, bradycardia, and, in more severe cases, syncope or convulsions. Although patients typically recover without lasting effects, the experience may be of concern and anxiety-producing for both patients and providers. Clinicians should be well versed in the methods used for prevention and treatment of AAVR to promote safe practice environments, patient satisfaction and comfort, and cost-effectiveness. The risk of AAVR is increased in patients who are nervous or fearful, poorly rested, fatigued, dehydrated, hungry or have not eaten recently, have a weak constitution, or are receiving acupuncture for the first time. In addition, strong stimulation from vigorous needling techniques, electrostimulation, or a large needle count, especially with acupuncture-naive patients, can confer additional risks. [3,4,10-12] It is essential to thoroughly understand the history of the patient receiving initial acupuncture treatment. Clinicians should perform the treatment lightly on the first day. They should also explain the methodology and understand the condition of mentally tensioned patients. In patients receiving acupuncture for the first time, of the use of fewer acupoints is desired. The patient's position during treatment also plays a role in AAVR. Because acupuncture treatment causes vasodilation and subsequently reduced blood pressure, treating patients in a supine or prone position can help prevent AAVR.[3,4]

Pharmacopuncture is a new form of acupuncture therapy in TKM and traditional Chinese medicine (TCM), which can be thought of as combining acupuncture and herbal medicine. To combine the effects of acupuncture and the medicine, pharmacopuncture treatment is generally performed by injecting small

amounts of extract from medicinal materials at acupuncture points or in affected areas. ^[3,5] There are 2 different types of pharmacopunture medicines: aromatic (water-soluble) and oilbased extract. ^[3,5]

TA extract can be used with a thin (30- or 31-gauge) syringe because it is water-soluble. It can be used directly in ligaments and tendons, as well as muscles and joints.^[5] TA extract is therefore effective for the treatment of sprains and bruises, as well as blood stasis, as there is little pain when it is administered. TA pharmacopuncture extract has blood-activating and stasisdispelling effects and frees collateral vessels, relaxes sinews, and activates collaterals in TKM. This medicine consists only of plant-based raw materials that can be produced and supplied stably to replace Calculus Bovis, Fel Ursi, Moschus (BUM or V) pharmacopuncture extract, which is a representative medicine used to treat acute inflammatory and painful diseases in TKM. TA is thus useful because the main animal-based medical ingredients of V or B are difficult to obtain due to the Convention on International Trade in Endangered Species of Wild Fauna and Flora. [6,13] The 7 constituents of TA are as follows: Scutellariae Radix, Phellodendri Cortex, Pulsatilla Koreana, and Sophorae Subprostratae Radix, the heat-clearing medicines Aucklandiae Radix and Aquilaria agallocha, qi-regulating medicines, and Carthami Tinctorii Fructus, which is a blood-activating and stasis-dispelling medicine. TA was named after traffic accidents (TA), because TA pharmacopuncture therapy is mainly used to treat musculoskeletal diseases, especially TA syndrome. This is based on the therapeutic effects of TA on muscle tenderness and pain, and its anti-inflammatory effects in clinical practice. [6-9] TA has been reported to inhibit the production of nitric oxide and the inflammatory cytokines interleukin-6 and tumor necrosis factor- α in in vitro studies. [6] In this study, the patient, who was treated with TA pharmacopuncture, showed improvements in pain and swelling due to her sprains, which were not caused by traffic accidents. After treatment, the patient stated that she noticed improvements in joint movement. In addition, she felt an immediate cooling sensation in the painful area. These findings may be linked to the pharmacological effects of TA extract and its respective constituent herbs.

Ouch points, also called ashi points, are acupuncture points with no specific name or definite location. The location of each ouch point is determined based on tenderness or other pathological responses. These acupoints are commonly used in

treating musculoskeletal problems in TKM and TCM.^[3,5] We therefore used ouch points in this study.

The patient had a fear of acupuncture after fainting due to a fire needling treatment for an ankle sprain about 18 years ago. We were thus unable to keep the needles at the acupoints for long periods due to the possibility of AAVR comprising symptoms such as dizziness, nausea, sweating, and pale skin. Therefore, to prevent AAVR, we performed pharmacopuncture at as few acupoints as possible mainly based on ouch points. Of the many extracts available for pharmacopuncture, TA was selected because it leads to less pain than other medications during injection. Despite the patient's fear of needing, she received 59 TA pharmacopuncture treatments >9 months and showed improvements in her condition. We believe that the short procedure time and the low level of pain during the procedure alleviated the patient's mental tension.

Although here we report the case of only one patient, our results indicate that TA pharmacopuncture can be effective in treating various acute sprains and could be a potential acupuncture method for the treatment of patients with a history of AAVR. This is because the treatment can be performed in a short period of time and the procedure is simple and easy. In further studies, we will consider more case reports in patients with various symptoms treated with TA pharmacopuncture. We also plan to carry out a clinical trial with a larger sample size to verify the therapeutic effects of TA pharmacopuncture.

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