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Safety of Acupuncture and Pharmacopuncture in 80,523 Musculoskeletal Disorder Patients

A Retrospective Review of Internal Safety Inspection and Electronic Medical Records

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Abstract: We investigated the range and frequency of significant adverse events (AEs) in use of pharmacopuncture and acupuncture using large-scale, single-center safety data as evidence supporting safety of acupuncture with pharmacopuncture, used extensively in Asia, is scarce. Status reports (nurse records in ambulatory and inpatient care units, and administrative event records) as a part of an internal audit at a Korean Medicine hospital specializing in the treatment of musculoskeletal disorders, patient complaints filed through the hospital website, and medical records of patients visiting from December, 2010 (inception of internal audit) to October, 2014 were retrospectively reviewed. A total 80,523 patients (5966 inpatients and 74,557 outpatients) visited during this period. Inpatients received an average 31.9 ± 20.7 acupuncture, 23.0 ± 15.6 pharmacopuncture, and 15.4 ± 11.3 bee venom pharmacopuncture sessions, and outpatients were administered 8.2 ± 12.2 acupuncture, 7.8 ± 11.5 pharmacopuncture, and 10.0 ± 12.3 bee venom sessions, respectively. AEs associated with acupuncture/pharmacopuncture were forgotten needle (n = 47), hypersensitivity to bee venom (n = 37), presyncopic episode (n = 4), pneumothorax (n = 4), and infection (n = 2). Most cases were mild requiring little or no additional intervention and leaving no sequelae. Although serious AEs including infection (n = 2) and anaphylaxis associated with bee venom treatment (n = 3) were also reported, incidence was rare at 0.002% in infection and 0.019% in anaphylaxis. Incidence of AEs associated with acupuncture/pharmacopuncture treatment was low, and most cases were not serious. Still, however rare, avoidable AEs can and should be prevented through education and corrective action. Further prospective studies on the effect of error reduction strategies on incidence of adverse effects are warranted.

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Abbreviations: CAM = complementary and alternative medicine, CRP = C-reactive protein, ESR = erythrocyte sedimentation rate, FDA = Food and Drug Administration, SR = systematic review.

INTRODUCTION

Musculoskeletal disorders, especially low back and neck pain, are the main reasons for complementary and alternative medicine (CAM) consultation and use.[1,2] According to a 2008 survey,[3] 86% of the South Korean population was estimated to have used Korean medicine treatment at least once, and 45.8% within the preceding 12 months. Among recipients of Korean medicine treatment, 53.4% had received them for musculoskeletal or connective tissue disorders.[3]

Acupuncture is licensed in 39 states in the U.S., and is the 3rd most frequented CAM treatment for back pain.[1] The U.S. Food and Drug Administration estimates that 9 to 12 million acupuncture treatments are performed each year in the U.S., equaling $500 million in annual revenue.[4] Due to heightened public interest in acupuncture, various new methods of acupuncture are being developed and employed. Pharmacopuncture is a relatively new acupuncture technique that combines the 2 most frequently used Korean medicine treatment forms: acupuncture and herbal medicine. Herbal medicine extracts are administered directly to acupuncture points for mechanical and chemical stimulation, thereby maximizing acupuncture point access and expanding the treatment window.[5,6]

Despite paucity of large-scale studies or reports on pharmacopuncture usage in clinical practice, its use can be indirectly gauged from its high production rate and multitude of related research. Approximately 200 herbal preparation types for injection are produced by pharmaceutical companies in China,[7] and pharmacopuncture is covered by some private insurance companies, including traffic accident insurance, in Korea. Most colleges of Korean medicine have incorporated pharmacopuncture into their curriculum, and the government-funded research institution sector has also taken on an active role in pharmacopuncture research.[8] A 2006 review showed that 438 pharmacopuncture studies have been published as of August, 2006 in the Acupuncture, a Korea National Research Foundation-certified journal, which constitutes 34.6% of total 1268 articles published since its foundation.[9] Clinical use of pharmacopuncture for musculoskeletal problems in Korea can be inferred from a retrospective review of medical records of postspine operative pain patients treated at 2 spine-specialty Korean medicine hospitals. Of 702 patients reviewed, 69% were treated with pharmacopuncture. Considering that acupuncture, which is

covered by Korean national health insurance, was used in 88% of patients, it can be deduced that the use of pharmacopuncture is comparable to that of acupuncture.[10]

Most previous studies on acupuncture safety are systematic reviews (SRs) or surveys,[11–14] and U.S., German, British, Korean, and Japanese reports place AE incidence at 0.671% to 11.4%, with the most common acupuncture-related AEs being pain, bleeding, fatigue, and hematoma.[14–17] Two prospective studies of the acupuncture practitioners in the U.K. reported no serious AEs in 66,000 treatment sessions.[11,18] An SR of acupuncture safety investigated nearly a quarter of a million treatments in 9 prospective studies, and the most serious AEs were 2 cases of pneumothorax and 2 of broken needle.[19] Odsberg et al[20] reported no serious AEs in almost 9300 acupuncture treatment sessions conducted by Swedish physiotherapists.

Although acupuncture safety has been rigorously studied in previous literature, there are no such corresponding large-scale clinical investigations on pharmacopuncture safety which is unbefitting to its widespread use. The objectives of this study are, in light of increasing pharmacopuncture use, to determine the range and frequency of significant AEs in combined use of pharmacopuncture and acupuncture compared to acupuncture alone, and to provide large-scale, single-center safety data on bee venom pharmacopuncture, whose safety is already supported by a large body of evidence, as preliminary data for basic clinical safety guidelines of acupuncture and pharmacopuncture practice.

MATERIALS AND METHODS

Study Population and Sampling

Retrospective Review of Electronic Medical Records and Event Reports

We retrospectively reviewed internal audit event monitoring records including relevant status reports (nurse records in ambulatory and inpatient care units, and administrative event records), patient complaints filed through the hospital website, and medical records of all patients treated between December, 2010 and October, 2014 at a Korean Medicine hospital certified by the Korean Ministry of Health & Welfare to specialize in the treatment of spinal disorders.

Data on the number of patients receiving acupuncture/pharmacopuncture treatment and frequency and type of acupuncture/pharmacopuncture treatment sessions were collected from electronic medical records. Audit records were reviewed for AEs that may be associated with treatment (e.g., acupuncture, pharmacopuncture, moxibustion, cupping, Chuna spinal manipulation, herbal medicine, conventional medicine, injection, and physical therapy) and patient management-related accidents (e.g., fall injury, bedsore), and categorized accordingly. Of reported AEs, those related to acupuncture and/or pharmacopuncture were retrieved. Electronic medical records (doctor records, nurse records, lab results, and imaging data such as X-rays and MRIs) of relevant patients were analyzed.

Nurse Records

The nursing staff is divided into 6 outpatient and 5 inpatient units. Each unit consists of 4 to 5 nurses, including a head nurse for each unit, and the outpatient units are staffed with a total 33 nurses (including registered and auxiliary nurses), and inpatient ward with 27. There are additional heads of departments, and of the entire nursing staff. Inpatient ward nurses check patient status 5+ times a day, and ambulatory care unit nurses meet with patients at least twice per visit before and after treatment, permitting close observation of any unexpected or unintended reactions. All significant AEs (regardless of causal relationship with treatments), patient complaints, management records, physician briefings, and transfers to other physicians or institutions are recorded and reported daily. The reports are shared with head nurses and doctors at weekly meetings.

Patients are informed of treatment contents to be introduced to the patient's treatment regimen and related AEs prior to administration by attending physician and attending nurse, and instructions on how to respond to AE occurrence after treatment by counselling (head) nurse. AEs of delayed onset presenting out of hospital grounds can be reported by the patient or guardian using the 24 hour hotline for consultation with the call duty doctor, reported upon visit to the in-hospital ER, or filed through the hospital website, and this information is also compiled by the nursing staff. It can be reasonably inferred that most AEs are covered through extensive exposure and contact means available to patients and a systematic reporting system. A weekly status reports consists of 1380 Korean words on average.

Physician and Nurse Patient Management

The hospital employs a patient management policy where physicians are encouraged to call patients who have been noncompliant with treatment for a prolonged period of time and nurses no-show patients for clinical follow-up and quality assurance means. Although such calls are not specifically for patient safety evaluation, nonreturning patients are so provided with an additional opportunity to report and/or ask about potential AEs.

AE Analysis

Two specially trained Korean medicine doctors individually analyzed AEs associated with acupuncture and/or pharmacopuncture, then reached agreement on difference of opinion through discussion. Demographic information of patients experiencing AEs (inpatient/outpatient department, sex, age, and comorbidities), test type, and results relevant to AE diagnosis were collected in addition to AE symptoms, severity, causality, any concomitant interventions for AE treatment, and additional follow-ups.

AE Frequency

For comparison with previously reported AE incidence of acupuncture and pharmacopuncture/bee venom treatment, frequency was categorized in accordance with the European Commission guidelines for AEs of medicinal products (very common [$\geq$1/10], common [$\geq$1/100 to $<$1/10], uncommon [$\geq$1/1000 to $\leq$1/100], rare [$\geq$1/10,000 to $\leq$1/1000]; very rare [$\leq$1/10,000], and not known).[21]

AE Severity

The severity of the adverse event was classified into 3 levels following Spilker AE classification (mild: does not significantly impair daily activities [function] nor require additional medical intervention; moderate: significantly impairs daily activities [function], and may require additional medical intervention but resolves afterwards; severe: serious AE that requires intense medical intervention, and leaves sequelae).[22]

AE Causality

Causality was determined using the WHO-UMC causality scale.[23] Hypersensitivity to bee venom was classified into local and systemic reactions, and systemic reactions were recategorized using Mueller 4-level classification.[24] Bee venom concentration, total number of bee venom treatments, and vital signs were reviewed through medical charts.

Statistical Analysis

All statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC. In descriptive statistics, continuous variables are given as mean ± SD, and categorical data are given as frequency and percentage (%).

Ethics Statement

The study was approved by the Institutional Review Board (IRB) of Jaseng Hospital of Korean Medicine in Seoul, Korea (IRB approval number: KNJSIRB2016-002).

RESULTS

A total 80,523 patients (5966 inpatients, and 74,557 outpatients) were treated between December, 2010 and October, 2014. The percentage of inpatients receiving acupuncture, pharmacopuncture (including bee venom), and bee venom was 100%, 98%, and 55%, respectively, and that of outpatients was 87%, 81%, and 17%, respectively. Most patients visited the hospital for the disease classification codes M51 (other intervertebral disc disorders), or S33 (dislocation, sprain and strain of joints, and ligaments of lumbar spine and pelvis). Patients received 31.9 ± 20.7 acupuncture treatment sessions for the duration of inpatient care, and 8.2 ± 12.2 sessions in ambulatory care. Inpatients were administered 23.0 ± 15.6 pharmacopuncture sessions, and outpatients, 7.8 ± 11.5 sessions, while bee venom was administered for 15.4 ± 11.3 and 10.0 ± 12.3 sessions in inpatients and outpatients, respectively, showing that inpatients received more intensive treatment within a shorter time frame (Table 1).

The main AEs associated with acupuncture/pharmacopuncture treatment were forgotten needle, presyncopic episode (depression of blood pressure or vertigo), infection, pneumothorax, and hypersensitivity to bee venom. The most frequently reported events were forgotten needle and hypersensitivity to bee venom. All cases of forgotten needle did not require additional medical intervention. Severe AEs consisted of 3 cases of hypersensitivity to bee venom and 2 cases of infection, and were rare. Most AEs were more common in inpatients with the exception of hypersensitivity to bee venom, which had higher incidence in ambulatory care (Table 2).

Eleven males and 16 females, aged 44.5 ± 14.8 years, presented with hypersensitivity to bee venom. The average number of treatment sessions before adverse event presentation was 11.6 ± 9.2 sessions, excluding cases with positive skin tests or not recorded. Of 37 cases of bee venom hypersensitivity, 34 were classified as hypersensitiveness and of moderate AE severity, and 3 cases were classified as anaphylactic and of severe AE severity. Most were prescribed immunosuppressive agents such as phenylamine and dexamethasone, and anaphylactic patients were administered epinephrine. The majority recovered within 24 hours, while 5 were transferred to other hospitals for additional medical attention. Three transfers were for additional medical intervention for anaphylaxis, and 2 were due to delayed onset with symptoms surfacing after operating hours of conventional ambulatory care unit sharing facilities with the Korean medicine hospital. None of the patients expired (Table 3).

Four patients were suspected of infection, all of which were inpatients and mostly geriatrics. Blood tests were conducted upon suspicion of infection, and erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels were elevated in all 4 patients. Imaging results of MRs or ultrasound also confirmed infection in all 4 patients. Most patients presented with severe pain, accompanied with subjective symptoms of fever and chills. All cases were classified as severe, requiring antibiotics and surgery. Whereas causality was rated as probable in 2 of the 4 cases to be nosocomial infections, it was rated unlikely for the other 2 patients. Signs of infection were visible on MRIs taken before admission and acupuncture/pharmacopuncture treatment, and ESR and CRP levels showed elevation in blood tests at admission in the 2 patients for whom attribution was considered unlikely. These cases were therefore judged to be infections occurring prior to hospitalization (Table 4).

All 4 of the pneumothorax cases were slender and female, and most were diagnosed based on clinical symptoms and X-ray. These patients had received acupuncture treatment in the upper thoracic and cervical areas: 2 as inpatients, and 2 as outpatients. Pneumothorax was suspected upon complaints of acute pain shortly after treatment. Dyspnea was not observed in some patients. Most recovered fully within 10 days upon observation and simple oxygen supply without intubation (Table 5).

DISCUSSION

This study reports patterns of use and safety of acupuncture and pharmacopuncture in a population of 80,523 patients with musculoskeletal disorders. Main AEs associated with acupuncture/pharmacopuncture reported over the 4-year period were forgotten needle, presyncopic episode, infection, pneumothorax, and hypersensitivity to bee venom. Of these, the most frequently reported AEs were forgotten needle and hypersensitivity to bee venom, and the most severe were anaphylaxis due to bee venom and infection. However, severe AEs were rare and not fatal, nor did they leave sequelae. The acupuncture/pharmacopuncture safety results of our study are similar to those of a prospective observational study on acupuncture safety in 229,230 patients as shown in Table 2.[25] Presyncopic episode and infection was less common in the current population, while forgotten needle and pneumothorax was slightly more common, but difference was not large. These results imply that incorporation of pharmacopuncture in acupuncture practice does not increase risk of AE.

Hypersensitivity to Bee Venom

Although a literature search was conducted for further information on pharmacopuncture safety, single intervention studies on pharmacopuncture are scarce and most are on bee venom. Clinical symptoms of bee venom hypersensitivity range from minor problems such as skin rashes, hives, and diarrhea to potentially fatal systemic problems such as dyspnea, arrhythmia, and hypotension.[26] A recent SR on risks associated with bee venom therapy using 12 databases from inception to June 2014 without language restriction[27] reported

TABLE 1. Use of Acupuncture and Pharmacopuncture by Patient Disease Classification According to the KCD-6 (n = 80,523)

		n, %		Mean ± SD
Inpatient (n = 5,966)				
	Sex		Age	46.0 ± 14.9
	Female	3,266 (54.7)	Duration of hospital stay (days)	21.8 ± 12.9
	Male	2,700 (45.3)	Number of admissions	1.3 ± 0.7
Outpatient (n = 74,557)				
	Sex		Age	43.4 ± 15.5
	Female	40,121 (53.8)	Duration of outpatient care (days)	111.0 ± 206.1
	Male	34,436 (46.2)	Number of outpatient visits	7.7 ± 12.0

			Acupuncture		Pharmacopuncture		Bee Venom Pharmacopuncture	
	Disease Classification*	n, %	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD
Inpatient	Total	5,966 (100)	5,938	31.9 ± 20.7	5,876	23.0 ± 15.6	3,286	15.4 ± 11.3
	M51	2,462 (41.3)	2,452	33.7 ± 20.5	2,430	24.0 ± 15.0	1,385	16 ± 11.3
	S33	1,242 (20.8)	1,235	28.1 ± 19.3	1,226	20.1 ± 13.9	690	14.3 ± 10.3
	M50	376 (6.3)	376	29.8 ± 19.4	373	21.5 ± 14.7	211	14.2 ± 11.2
	M54	370 (6.2)	368	27.9 ± 18.3	357	21.1 ± 14.9	163	12 ± 9.5
	U63	207 (3.5)	207	30.7 ± 21.0	206	23.6 ± 17.4	115	16.8 ± 11.7
	S13	176 (3.0)	175	28.1 ± 19.5	174	20.3 ± 14.7	93	15.2 ± 10.4
	M47	155 (2.6)	155	35.5 ± 25.5	153	27.4 ± 21.3	84	14.9 ± 12.7
	M48	146 (2.4)	146	37.7 ± 23.8	145	27.4 ± 18.6	86	17.3 ± 13
	U60	104 (1.7)	104	30.0 ± 21.1	104	18.5 ± 13.5	66	16.5 ± 11.7
	M17	77 (1.3)	77	39.6 ± 23.5	76	30.0 ± 19.8	43	18.5 ± 13.8
Outpatient	Total	74,557 (100)	64,515	8.2 ± 12.2	60,266	7.8 ± 11.5	12,497	10.0 ± 12.3
	M51	12,278 (16.5)	11,459	12.6 ± 15.3	11,221	12.5 ± 15.0	4,056	11.8 ± 13.3
	S33	18,275 (24.5)	17,289	7.2 ± 11.3	16,174	6.4 ± 9.5	2,417	9.4 ± 11.1
	M50	3616 (4.8)	3,447	11.8 ± 14.0	3,376	11.7 ± 13.9	1,023	11 ± 12
	M54	11,971 (16.1)	11,051	6.7 ± 10.2	10,294	6.6 ± 9.9	1,879	8.4 ± 11
	S13	6,510 (8.7)	6,179	6.5 ± 10.4	5,720	5.7 ± 8.7	515	8.7 ± 11
	M47	1,351 (1.8)	1,256	10.2 ± 14.4	1,228	10.0 ± 13.8	249	10.8 ± 12.1
	M48	1,500 (2.0)	1,409	12.8 ± 17.1	1,382	13.0 ± 17.3	488	15.5 ± 18
	S83	1,503 (2.0)	1,390	5.9 ± 8.6	1,292	5.4 ± 7.6	221	7.1 ± 7.5
	M25	1,619 (2.2)	1,464	6.5 ± 10.3	1,345	6.4 ± 9.8	419	7.1 ± 8.9
	S93	1,824 (2.4)	1,699	3.4 ± 5.5	1,316	3.5 ± 5.6	148	4.7 ± 6.4

KCD-6 = Korean standard classification of diseases, 6th revision, SD = standard deviation.

*Coded including the 3rd revision of the coding system for Korean medicine diagnosis and pattern differentiation traditional Korean medicine (U codes) which is currently incorporated into KCD-6. M51: Other intervertebral disc disorders; S33: dislocation, sprain and strain of joints and ligaments of lumbar spine and pelvis; M50: cervical disc disorders; M54: dorsalgia; U63: disease pattern/syndrome of fluid and humor; S13: dislocation, sprain and strain of joints and ligaments at neck level; M47: spondylosis; M48: other spondylopathies; U60: disease pattern/syndrome of Qi; M17: Gonarthrosis[arthrosis of knee]; S83: dislocation, sprain and strain of joints and ligaments of knee; M25: other joint disorders, not elsewhere classified; S93: dislocation, sprain and strain of joints and ligaments at ankle and foot level.

that of 6 audits and cohort studies on bee venom pharmacopuncture, 3 studies covered populations larger than 300 and reported AE incidence at 48/374 (12.83%; 48 cases of local reactions),[28] 11/32,000 (0.03%; 11 cases of systemic reactions),[29] and 361/2765 (13.00%; 361 cases of systemic reactions).[30] Also, in a meta-analysis of bee venom AE occurrence compared to normal saline in 4 randomized controlled trials, bee venom showed a 261% increased relative risk. In this study, 37 patients (0.234%) presented with bee venom hypersensitivity, of which 3 were anaphylactic. The relatively low incidence rate of anaphylaxis resulting in no significant sequelae or deaths may be attributed to swift administration of antihistamines such as phenylamine, glucocorticoids such as dexamethasone, or epinephrine as indicated upon presentation of hypersensitivity symptoms.

Infection

Acupuncture and pharmacopuncture are usually administered at acupuncture points in the same region, making differentiation of causal relationship highly difficult. Most invasive treatments for musculoskeletal disorders are administered around the site of the pain, and aggravation of pain may suggest infection or alternatively be a natural progression or fluctuation of disease. Although ESR and CRP are useful indicators of inflammation, many disease processes entail inflammation, and rise in acute phase proteins is not disease-specific (e.g.,

TABLE 2. AEs Associated With Acupuncture or Pharmacopuncture (Out of Total n = 80,523)

	Previously Reported Incidence, %	Frequency Classification†	Total Patients (n = 80,523)			Outpatient Department (n = 74,557)			Inpatient Department (n = 5,966)			AE Severity*				
			n	%	Frequency Classification†	n	%	Frequency Classification†	n	%	Frequency Classification†	Mild	Moderate	Severe	SAE Incidence, %	Frequency Classification†
Forgotten needle[25]	0.01	Very rare	47	0.058	Rare	11	0.015	Rare	36	0.603	Uncommon	47	0	0		
Presyncopic episode[25]	0.038‡, 0.224§	Rare‡, uncommon§	4	0.005	Very rare	3	0.004	Very rare	1	0.017	Rare	2	2	0		
Infection[25]	0.014	Rare	2	0.003	Very rare	0	0.000	Very rare	2‖	0.034	Rare	0	0	2	0.0025	Very rare
Pneumothorax[25]	0.001	Very rare	4	0.005	Very rare	2	0.003	Very rare	2	0.034	Rare	1	3			
Allergic reaction to bee venom¶			37	0.234	Uncommon	31	0.248	Uncommon	6	0.183	Uncommon	0	37	3	0.0190	Rare

AE = Adverse event, SAE = Serious adverse event.
*Classified according to Spilker AE classification.
†Classified according to the European Commission guidelines for AEs of medicinal products (very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to ≤1/100); rare (≥1/10,000 to ≤1/1000); very rare (≤1/10,000), and not known).[21]
‡Depression of blood pressure.
§Vertigo.
‖Excluding cases where causality was rated unlikely to be nosocomial infection.
¶Incidence and type of allergic reaction to bee venom was assessed out of recipients of bee venom pharmacopuncture (total n = 15,783; Inpatient n = 3,286; Outpatient n = 12,497).

infection).[31] For instance, while ESR and CRP values persistently elevated >15 days postsurgery strongly suggest infection, normal ESR and/or CRP values cannot be taken to exclude this diagnosis.[32] Close observation and medical attention is necessary for patients susceptible to infection from immune deficiency or old age. Especially as all infections were serious AEs requiring corrective surgery and avoidable,[12,33] error reduction strategies to prevent infection need to be implemented and tested.

Pneumothorax

Previous investigations on pneumothorax associated with acupuncture report incidence of 0.0014%[34] and 0.001%.[25] Norheim and Fonnebo[33] reported the highest estimate to date with 33 possible cases of acupuncture-induced pneumothorax from questionnaires of doctors and acupuncturists. Pneumothorax was more common in our population than previous clinical observations, with an incidence of 0.005%. Although many patients reporting with this complication are predisposed to secondary pneumothorax,[35] the disparity in incidence of the current population is probably due to difference in chief complaints, as those included were primarily musculoskeletal, especially spinal, and acupuncture was accordingly frequently applied to upper thoracic areas. Although pneumothorax was considered a serious AE in previous studies,[19,25] symptoms were transient and subsided within a week of observation and simple oxygen supply without chest intubation or surgery in most patients in this study.

Presyncopic Episode and Forgotten Needle

Presyncopic episodes were less common in our data, which may be due, at least in part, to widespread prior exposure of Asian patients to acupuncture. As moderate presyncopic AEs were mostly fall injuries following presyncopic episodes, precaution on the part of both staff and patient is needed. Although forgotten needle cases were mild events not requiring additional medical intervention, they were highly common and should be avoided as they indicate malpractice or negligence.

The most significant strength of this study is that it is the 1st large-scale report of AEs associated with acupuncture and pharmacopuncture treatment. Data reliability was enhanced by cross-checking internal audits (status reports) and electronic medical records. Inpatients and outpatients were also separately analyzed as subgroups for distinctive trends by visit type and environment, in addition to AE incidence, severity classification, causality, symptoms, concomitant treatment, and follow-up results for comprehensive evaluation.

Limitations of this study are mainly due to its retrospective nature. This study lacks comparator populations and information on potential confounders such as risk factors were not collected. Data collection relied on voluntary reporting of patient and medical personnel, and considering for efficiency and clarity, the reporting format and range of AEs were kept relatively simple. There is the possibility that less severe events may not have been reported if the patient or practitioner did not regard it to be a problem as Koreans using Korean medicine may be more familiar or lenient toward treatment and regard minor AEs to be part of the treatment process. Due to the possibility of ''missed AEs,'' these results warrant careful interpretation, especially regarding minor AEs which have high incidence in previous reports but may have been underrepresented in this study.

TABLE 3. Adverse Events Associated With Bee Venom Pharmacopuncture

Visit Type	Sex	Age	Concentration, Amount	Treatment Session (s)	Vital Signs*	AE Symptoms	Mueller Classification	AE Severity	Concomitant Treatment	Follow-Up Result	Causality	Diagnosis
Outpatient	M	29	10,000:1 2.0cc (Administered at every visit)	14	Stable	Whole body urticaria, itching	I	Moderate	Peniramin 1A IM injection, PO medication for 3 days (Peniramin 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	F	49	10,000:1 1cc	12	Stable	Whole body urticaria, nausea	II	Moderate	Peniramin 1A, Dexamethasone 1A IM injection	Recovered	Probable	Hypersensitiveness
Outpatient	F	43	10,000:1 0.6cc	13	Stable	Whole body urticaria	I	Moderate	Circulan (over-the-counter drug)	Recovered	Possible	Hypersensitiveness
Outpatient	M	30	10,000:1 1.5cc	28	Stable	Neck urticaria, itching, nausea, chest discomfort	II	Moderate	Peniramin 1A IM injection	Recovered	Probable	Hypersensitiveness
Outpatient	F	54	10,000:1 1cc	25	Stable	Palm itching, facial heat sensation, throat swelling	II	Moderate	Peniramin 1A IM injection	Recovered	Probable	Hypersensitiveness
Outpatient	F	67	10,000:1 0.1cc	24	Stable	Joint pain, right hand swelling	Local reaction	Moderate	PO medication for 3 days (Peniramin 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	F	32	20,000:1 0.3CC	1	Stable	Whole body itching, redness	I	Moderate	Peniramin 1A, Dexamethasone 1A IM injection, PO medication for 3 days (Peniramin 1T, Solondo 0.5T, Almagel 1T #3)	Additional treatment for itching	Probable	Hypersensitiveness
Outpatient	F	65	10,000:1 0.1cc	Test	50/40–66–36.1	General weakness, sweating, drooling, mental status alert	III	Severe	Dexamethasone 1A IM injection, N/S 1L (500 mL full drop, then 500 mL 30gtt/min IV)	Symptom relief after transfer to conventional medicine hospital	Probable	Anaphylaxis
Outpatient	F	32	10,000:1, 0.2cc	5	Stable	Left wrist urticaria, swelling	Local reaction	Moderate	PO medication for 3 days (Peniramin 2 mg 3T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	F	36	10,000:1 0.5cc	2	Stable	Both wrist itching, swelling	Local reaction	Moderate	Peniramin 1A, Dexamethasone 1A IM injection	Recovered	Probable	Hypersensitiveness
Outpatient	F	36	10,000:1 1cc	26	Stable	Urticaria	I	Moderate	Peniramin 1A IM injection	Recovered	Probable	Hypersensitiveness
Outpatient	M	44	10,000:1 0.8cc	13	Stable	Urticaria, itching	I	Moderate	Peniramin 1A IM injection, PO medication for 3 days (Peniramin 2 mg 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	M	29	20,000:1 1cc	15	Stable	Face and neck urticaria, redness	I	Moderate	Peniramin 1A, Dexamethasone 1A IM injection, PO medication for 3 days (Peniramin 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	M	58	10,000:1 0.6cc	5	Stable	Low back itching, redness, swelling	Local reaction	Moderate	Peniramin 1A IM injection	Recovered	Probable	Hypersensitiveness

Visit Type	Sex	Age	Concentration, Amount	Treatment Session (s)	Vital Signs*	AE Symptoms	Mueller Classification	AE Severity	Concomitant Treatment	Follow-Up Result	Causality	Diagnosis
Outpatient	M	38	10,000:1 0.4 CC	2	Stable	Whole body urticaria, itching, facial redness	I	Moderate	Peniramin 1A, Dexamethasone 1A IM injection, PO medication for 2 days (Peniramin 1T, Solondo 1T, Ucerax 1T, Ganakhan 1T #2)	Recovered	Probable	Hypersensitiveness
Outpatient	F	36	10,000:1, 0.4cc	27	Stable	Head, both hand itching, swelling	I	Moderate	Peniramin 1A, Dexamethasone 1A IM injection, PO medication for 3 days (Peniramin 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	F	28	10,000:1 0.5cc	6	Stable	Left wrist swelling	Local reaction	Moderate	Dexamethasone 1A IM injection, PO medication for 3 days (Peniramin 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	F	30	10,000:1 0.5cc	3	Stable	Both ankle swelling	Local reaction	Moderate	Hwangryun pharmacopuncture, 2 Soyeom para-aminosalicylic acid plasters (free of charge), cold pack instructions, Peniramin 1A IM. injection	Recovered	Possible	Hypersensitiveness
Outpatient	M	28	10,000:1 0.7cc	11	Stable	Whole body urticaria, itching, facial swelling	I	Moderate	Peniramin 1A IM injection, PO medication for 2 days (Peniramin 2 mg 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	M	31	10,000:1 0.1cc	Test	Stable	Urticaria, itching,	I	Moderate	Peniramin 1A IM injection	Recovered	Probable	Hypersensitiveness
Outpatient	F	64	10,000:1 0.1cc	1	170/100–95–36.9	Face and upper back urticaria, itching, swelling	I	Moderate	Peniramin 1A, Dexamethasone 1A IM injection	Recovered	Probable	Hypersensitiveness
Outpatient	F	31	10,000:1 0.8cc	10	Stable	Face, palm, and inguinal urticaria, itching, swelling	I	Moderate	Peniramin 1A IM injection, PO medication for 5 days (Peniramin 2 mg 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	M	28	B3-BV (PLA2) 0.5cc	16	Stable	Acupuncture and pharmacopuncture site, scalp, face, palm urticaria, itching, redness	I	Moderate	Peniramin 1A IM injection, PO medication for 3 days (Peniramin 2 mg 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	F	40	B3-BV (PLA2) 0.5cc	3	80/50–112-24	Whole body itching, facial redness, palpitation	I	Moderate	Peniramin 1A, Dexamethasone 1A IM, N/S 500 mL IV (60gtt/min)	Recovered	Probable	Hypersensitiveness
Outpatient	F	77	10,000:1 1cc	Not specified	66/42–56–37.8	Whole body urticaria, itching, redness	I	Severe	Peniramin 1A, Dexamethasone 1A IM injection, cold pack applied	Symptom relief after transfer to conventional medicine hospital	Probable	Anaphylaxis
Outpatient	F	61	10,000:1 0.5cc	1	BP uncheckable	Syncope, mental status drowsy, dyspnea, right shoulder redness	III	Severe	Epinephrine 0.5A, Dexamethasone 1A IM injection,, N/S 500 mL IV failed	Symptom relief after transfer to conventional medicine hospital	Probable	Anaphylaxis

Visit Type	Sex	Age	Concentration, Amount	Treatment Session (s)	Vital Signs*	AE Symptoms	Mueller Classification	AE Severity	Concomitant Treatment	Follow-Up Result	Causality	Diagnosis
Outpatient	F	72	Not specified	Not specified	90/60	Both hand itching sensation, mental status alert, dyspnea, nausea, dizziness	II	Moderate	Peniramin 1A IM injection, N/S 500 mL IV	Recovered	Probable	Hypersensitiveness
Outpatient	F	66	e-BV 0.6cc	Not specified	Stable	Dyspnea, nausea, dizziness	II	Moderate	Peniramin 1A, Dexamethasone 1A IM, N/S 500 mL IV	Recovered	Probable	Hypersensitiveness
Outpatient	F	66	e-BV 1cc	5	80/40–60-36	Mental status alert, mild dyspnea, nausea, vomiting (approx. 300 mL), dizziness, sweating	II	Moderate	Peniramine 1A, Dexametasone 1A IM injection, N/S 500 mL IV	Symptom relief after transfer to conventional medicine hospital	Probable	Hypersensitiveness
Outpatient	F	55	e-BV 1.5cc	33	Stable	Whole body itching, nausea, both hand swelling	II	Moderate	Peniramin 1A IM injection, PO medication for 3 days (Peniramin 2 mg 1T, Solondo 0.5T, Almagel 1T #3)	Recovered	Probable	Hypersensitiveness
Outpatient	F	49	e-BV 1cc	9	Stable	Dyspnea, whole body itching, swelling, redness	II	Moderate	Dexametasone 2A, Peniramin 1A IM injection, N/S 500 mL IV	Symptom relief after transfer to conventional medicine hospital	Probable	Hypersensitiveness
Inpatient	M	37	0,5cc	3	Stable	Itching, dizzness	I	Moderate	Peniramin 1A IM injection, PO medication for 2 days Solondo 2T #2)	Recovered	Probable	Hypersensitiveness
Inpatient	F	45	0.5cc (Administered at every visit)	16	Stable	Face and both arm urticaria	I	Moderate	Peniramin 1A IM injection	Recovered	Probable	Hypersensitiveness
Inpatient	F	45	Not specified	3	Stable	Dyspnea, nausea, dizziness, sweating	II	Moderate	Peniramin 1A, Dexamethasone 1A IM injection, cold pack applied	Recovered	Probable	Hypersensitiveness
Inpatient	F	53	e-BV 1cc	10	Stable	Whole body urticaria, mild eyeball swelling	I	Moderate	Peniramin 1A, Dexamethasone 1A IM injection, N/S 500 mL IV	Recovered	Probable	Hypersensitiveness
Inpatient	M	34	Not specified	19	Stable	Face, shoulder, and abdominal urticaria, itching	I	Moderate	Peniramin 1A IM, PO medication for 3 days (Peniramin 2 mg 3T, Solondo 1.5T, Almagel 3T #3)	Additional treatment for itching	Probable	Hypersensitiveness
Inpatient	F	30	Not specified	10	Stable	Low back urticaria, itching	Local reaction	Moderate	Peniramin 1A IM, PO medication for 3 days (Peniramin 3T, Solondo 1.5T, Almagel 3T #3)	Additional treatment for itching	Probable	Hypersensitiveness

A = ample, IM = intramuscular, gtt/min = guttae/minute (drop factor), IV = intravenous, N/S = normal saline, PO = per os (oral administration), # = daily medication dosage.
*Cases not within normal limits presented as ''systolic blood pressure/diastolic blood pressure – pulse rate – body temperature.''

TABLE 4. Infection Associated With Acupuncture or Pharmacopuncture

Visit Type	Sex	Age	Comorbidity	Treatment	Infection Site	Diagnostic Test Result	AE Symptoms	AE Severity	Causality	Concomitant Treatment and Follow-Up Result
Inpatient	F	72	Osteoporosis, hypertension	Acupuncture, pharmacopuncture	Left shoulder	ESR 28 mm/hour, CRP 20 mg/L; infection suspected on left shoulder MRI	Acute severe pain, chilling, nyctalgia	Severe	Probable	Surgical intervention
Inpatient	F	59	Osteoporosis, breast cancer	Acupuncture	Right thigh	Abscess on sonogram of right thigh	Acute severe pain, no chilling or fever	Severe	Probable	Surgical intervention
Inpatient	M	73	Hypertension	Acupuncture, pharmacopuncture	Low back	ESR 64 mm/hour, CRP 3.54 mg/L; paraspinal abscess size increased on contrast-enhanced lumbar MRI	Severe pain, chilling, fever	Severe	Unlikely	Surgical intervention
Inpatient	M	34	None	Acupuncture, pharmacopuncture	Low back	ESR >80 mm/hour, CPR 11.46 mg/L; myelitis on lumbar MRI	Severe pain	Severe	Unlikely	Not specified

AE = adverse event, CRP = C-reactive protein, ESR = erythrocyte sedimentation rate, MRI = magnetic resonance imaging.

Although in cases where the patient visits an outside clinic/hospital or receives no treatment for AEs it would be difficult for the event to be included in internal audits unless the patient or guardian voluntarily reports to the hospital, it is customary for musculoskeletal treatment to be continued for a period of time as opposed to a one-off session. As shown in Table 1, inpatients received medical care daily for an average hospital stay of 21 days and outpatients visited the hospital 7.7 times over a period of 111 days on average, and as the attending physician and attending nurse check patient condition at each treatment session, AEs associated with the previous visit should be included for internal reporting. In addition, as these records were documented for internal monitoring purposes, and even in cases where patient or medical personnel was reluctant to disclose the event, it is unlikely that significant AEs which require further treatment or may have other consequences for the patient would have gone unrecognized by the patient, guardian, and all staff members. To ensure unbiased systematic reporting of AEs and to be of wider external validity, future studies may consider a regional reporting network of private and public, conventional, and Korean medicine-based health care facilities. An additional limitation is that due to high correlation in method and usage of acupuncture and pharmacopuncture, respective causal relationships of AE are not clear.

Although CAM treatment is generally regarded to be safe, evidence on its safety is lacking. Safety reports hold considerable importance as they may help dictate future practice for AE prevention. Quarterly hospital analyses of AEs displayed a decreasing time-trend (not shown), possibly reflecting error reduction through education and corrective action as a result of internal auditing. For example, a standardized communication system of the number and location of needles between medical personnel was devised to prevent forgotten needles as part of continuous internal quality improvement efforts. Also, education sessions on hand sanitization and alcohol and povidone-iodine use were conducted to lower possibility of infection, as were sessions of appropriate needle retention and removal method in high-risk acupuncture points for pneumothorax. Bee venom skin tests have been shown to be an insufficient indicator of AEs with numerous cases occurring after several treatment sessions, and consequently current clinical instructions focus on regular examination of general patient condition and appropriate course of action upon AE occurrence as opposed to prevention. AE prevention is sought instead through development and manufacture of PLA2- and histamine-free bee venom products.

These results suggest that AEs after acupuncture/pharmacopuncture treatment may have low incidence and reported events were mostly of minor nature. Still, however rare or minor, avoidable AEs can and should be prevented through education and corrective action. Further prospective studies on the effect of error reduction strategies on incidence of adverse effects in a systemized reporting system using standardized terminology such as WHO adverse reaction terminology are warranted.

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TABLE 5. Pneumothorax Associated With Acupuncture or Pharmacopuncture

Visit Type	Sex	Age	Comorbidity	Smoking Status	Acupuncture or Pharmacopuncture Site	Diagnostic Test Result	AE Symptoms	AE severity	Causality	Concomitant Treatment	Follow-Up Result
Inpatient	F	49	None	Non smoker	Back, neck	Pneumothorax on X-ray	Chest pain and constrained feeling, difficulty taking deep breaths, aching pain in right side and back, dizziness	Moderate	Probable	Oxygen supply, observation	Most symptoms relieved after 10 days
Inpatient	F	53	Hyperthyroidism	Current smoker	Shoulder, flank	Pneumothorax on X-ray	Chest pain, dyspnea	Moderate	Possible	Oxygen supply, observation	Most symptoms relieved after 7 days
Outpatient	F	25	None	Not specified	Back, neck	Pneumothorax on X-ray	Severe back pain	Moderate	Probable	Oxygen supply, observation	Most symptoms relieved after 4 days
Outpatient	F	41	None	Non smoker	Back, neck	Pneumothorax on X-ray	Back pain, coughing	Mild	Probable	Observation	Most symptoms relieved after 3 days

AE = adverse event.

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