



Original Article

Adverse Events of Electronic Moxibustion Treatment for Knee Osteoarthritis: Case Reports and a Literature Review



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ABSTRACT

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Background: Electronic moxibustion has the advantage of temperature control and maintenance, and overcomes the limitations of the existing moxibustion process without the use of the combustion process. However, as the application of electronic moxibustion in clinical practice has increased, safety issues are emerging.

Methods: Clinical cases of electronic moxibustion treatment for knee osteoarthritis where burns occurred were collected. In addition, adverse events reported in clinical studies using electronic moxibustion for patients with knee osteoarthritis were collected from studies retrieved from Korean and international databases.

Results: There were 3 cases of superficial 2nd degree burns retrospectively collected through chart reviews. Among the selected 5 studies for literature review, 2 studies reported adverse events which were burns milder than those reported in these 3 cases in this retrospective case review.

Conclusion: Since the risk of superficial 2nd degree burn was discovered in the cases reviewed, further research on safe electronic moxibustion treatment is required without compromising the effectiveness of moxibustion.

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Introduction

Knee osteoarthritis is a disease with gradual loss of knee joint cartilage and related secondary changes of knee joint structure. It is more common in elderly individuals, those with injuries, obesity, and women. Typical symptoms include pain, swelling, flexion limitation, joint deformation, and increased pain after activity, especially when climbing the stairs or slopes. It reduces walking distance and interferes with physical activity, which lowers the quality of life of the affected elderly population, and causes financial and social problems such as increased medical costs and loss of productivity [1].

Knee osteoarthritis is treated with anti-inflammatory drugs and intra-articular steroid injections. These treatments are effective in relieving pain and improving motion performance, but have adverse effects on the digestion, urinary, and cardiovascular systems when used over a long period of time. Even replacement surgery (a structural treatment) is not a permanent treatment and further surgery is required when the replacement wears out [2].

Moxibustion is a representative traditional Korean medicine treatment widely used to relieve the symptoms of knee osteoarthritis. A meta-analysis of large-scale clinical studies showed that moxibustion is effective in treating knee osteoarthritis [3-5]. However, despite the effectiveness of moxibustion, harmful

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gases generated during the combustion process, and difficulties in precise temperature control may cause adverse effects such as burns and respiratory discomfort. In a study analyzing the adverse effects of moxibustion, the most frequent adverse effects were allergic reactions, burns, and infection [6].

Despite the effectiveness of moxibustion, its clinical use is limited due to adverse effects, and the type of moxibustion performed; laser moxibustion, smokeless moxibustion, and electronic moxibustion are being developed as alternatives [7-9]. In particular, electronic moxibustion has the advantage of being able to control and maintain the temperature, and it does not generate harmful gases in the process; therefore, the risk of burns and secondary risks caused by inhalation of harmful gases are relatively low.

Although the use of electronic moxibustion for the treatment of knee osteoarthritis is increasing in clinical practice, the safety of electronic moxibustion has not been seriously considered. The purpose of this study was to assess the safety of electronic moxibustion treatment for knee osteoarthritis patients by retrospectively studying case reports reporting 2nd degree burns and performing a literature review of clinical studies reporting adverse events.

Materials and Methods

Patients

Patients who had a radiological diagnosis of knee osteoarthritis, received electronic moxibustion treatment in the Department of Acupuncture and Moxibustion at Pusan Korean Medicine Hospital, and who had burns reported as adverse events were selected for this study.

Ethical consideration

Three patients with knee osteoarthritis were included in this retrospective study. Informed consent was obtained from all included patients for the publication of their photographs and

information from their medical records. This study was approved by the Institutional Review Board of Pusan National University Korean medical hospital (PNUKHIRB no.: 2021-10-006).

Intervention

The patients were treated once a day at 4 standard acupoints [Yanggu (ST34), Hyeolhae (SP10), Naeseulan (EX-LE4), and Dokbi (ST35)] on the affected side of the knee joint (Fig. 1A). Electronic moxibustion (Cettum, K-medical Co., Korea) set at 45°C was attached to the acupoint using a dedicated medical tape, and the treatment time was 10 minutes (Fig. 1B). The practitioner instructed the patients during every treatment session to report any adverse reactions at the attached site. The patients were also treated with acupuncture and herbal medicine. Other hyperthermia treatments were not performed on the affected side of the knee joint. The details of the moxibustion and other interventions are described in Table 1.

Review criteria

To investigate the adverse effects of electronic moxibustion treatment for knee osteoarthritis, all studies in national and international databases were considered. We searched various databases (Medline, Embase, Central, CNKI, and OASIS) for studies published up to August 23, 2021, without restrictions on language. The search keywords and terms were “knee osteoarthritis,” “electronic moxibustion,” and “electrical moxibustion,” which were modified according to each database. The search terms in each database are shown in Table 2.

Results

Case presentation

Case 1

A 67-year-old woman who was taking medications for

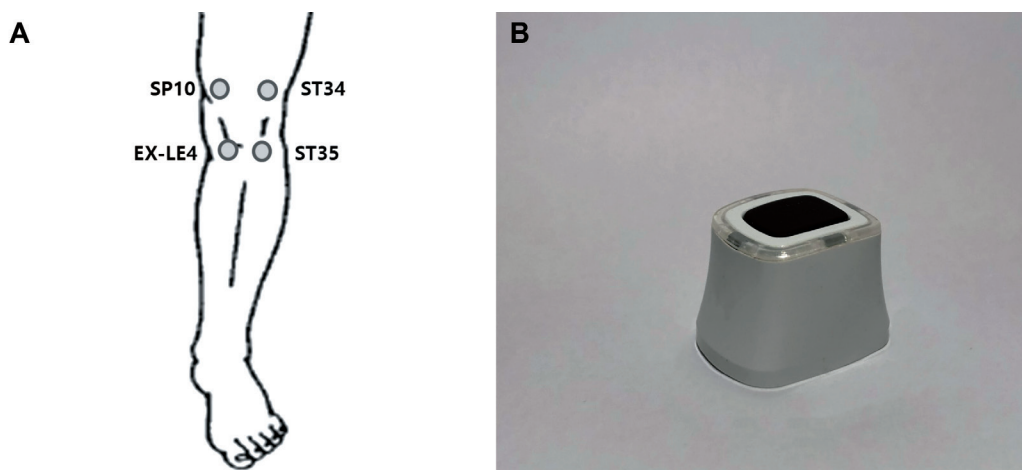


Fig. 1. Electronic moxibustion; (A) The location of acupoints; (B) electronic moxibustion device.

Table 1. Details of Moxibustion.

		Contents
1. Moxibustion rationale	1a) Style of moxibustion	Electronic moxibustion
	1b) Reasoning for treatment provided	Based on historical context and literature sources (e.g., The Textbook of Acupuncture and Moxibustion Medicine)
2. Details of moxibustion	2a) Number of moxibustion per session	4
	2b) Names of points	Yanggu [ST34], Hyeolhae [SP10], Naeseulan [EX-LE4], and Dokbi [ST35]
	2c) Setting temperature	45°C
	2d) Retention time	10 min
	2e) Moxibustion type	Cettum (K-medical Co., Korea)
	2f) Fixed method	Medical tape
3. Treatment regimen	3a) Number of treatment sessions	Based on length of patient's treatment period. 1 session/Day (admission treatment period)
	3b) Frequency and duration of treatment sessions	1 session/d (admission treatment period)
4. Other components of treatment	4a) Details of other interventions	Acupuncture, herbs, self-exercise
5. Practitioner background	5) Description of participating practitioner	Korean medicine doctor (resident trainee in acupuncture and moxibustion medicine with 3 years of experience)
6. Control or comparator interventions	6) No applicable	No applicable

Table 2. Search Keywords or Terms Used for Each Database.

Database	Search keywords or terms
Medline	"Knee osteoarthritis," "Knee arthritis" "Electronic moxibustion," "Electrical moxibustion," "Electromoxibustion"
Embase	"Knee osteoarthritis," "Knee arthritis" "Electronic moxibustion," "Electrical moxibustion," "Electromoxibustion"
Central	"Knee osteoarthritis," "Knee arthritis" "Electronic moxibustion," "Electrical moxibustion," "Electromoxibustion"
CNKI	"Electronic moxibustion," "Knee arthritis" [in Chinese]
OASIS	"Electronic moxibustion," "Knee osteoarthritis" [in Korean].

CNKI, China National Knowledge Infrastructure; OASIS, Oriental Medicine Advanced Searching Integrated System

hypertension and hyperlipidemia, was diagnosed with knee osteoarthritis 7 years ago at a local orthopedics clinic. Although the patient had received hyaluronic acid injection every 6 months, the effect of the treatment was limited, and the extent of pain in the knee joint led to the patient being hospitalized where she received Korean medicine treatment. The pain site was confined to the medial side of the right knee joint. On the 7th day of treatment, a 0.8 × 0.5 cm size blister was observed on the right side

of Naeseulan [EX-LE4], and other adverse event symptoms were not reported (Fig. 2A). The electronic moxibustion treatment was stopped immediately, and the blister resolved 1 week later, without development of infection.

Case 2

A 77-year-old woman suffered from chronic pain in her knee joint which was aggravated while walking up and down the stairs.

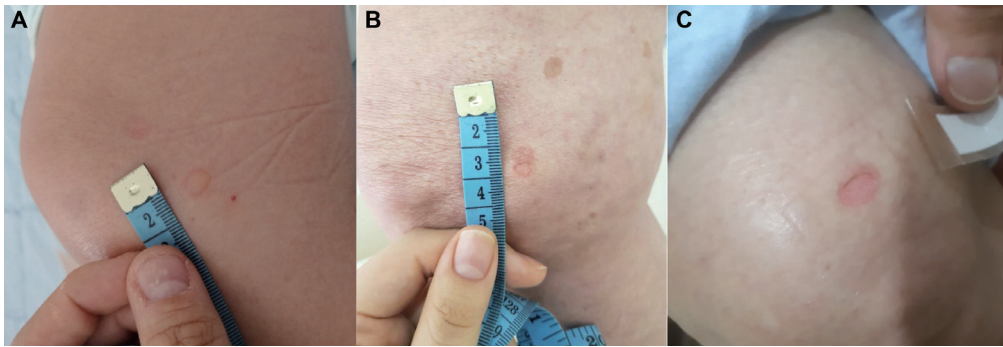


Fig. 2. Adverse events; (A) Case 1; (B) Case 2; (C) Case 3.

She was diagnosed with knee osteoarthritis using X-ray examination of the knee joint. The chief complaint was limping gait caused by pain in the medial side of the right knee joint. After the 20th session of electronic moxibustion treatment, redness with itching occurred in the right Naeseulan [EX-LE4] area (Fig. 2B). The next day, a 0.4 × 0.5 cm size of crust was formed with traces of blister removal. Electronic moxibustion treatment was discontinued with the occurrence of adverse events. Before discharge, the crust was removed without scarring.

Case 3

An 81-year-old woman who had dementia and chronic pain in her knee joint, had swelling and a sensation of heat in her left knee joint, and she had limited flexion in her left knee at the time of admission. She was diagnosed with knee osteoarthritis based on an X-ray of the knee taken on the day after admission. On the 15th day of treatment, redness and a superficial 2nd degree burn (1.0 × 2.0 cm) occurred on the left side of Yanggu [ST34], and she complained of a tingling sensation (Fig. 2C). Electronic moxibustion treatment was stopped, and symptomatic treatment was undertaken to prevent infection. She was discharged with a scar on the burn site.

Results of literature review

Selection process for the literature review

Two researchers independently retrieved, reviewed, and cross-reviewed the literature for the selection procedure. Interventions other than the electronic moxibustion study were excluded, and the target disease was limited to knee osteoarthritis. Only clinical studies including case reports, systematic reviews, and randomized clinical trials (RCTs) were included. Protocol papers were excluded. Adverse events were extracted and summarized from the selected literature.

Amongst the 34 retrieved studies, 5 were duplicates and were excluded. After analyzing the abstracts and titles of the remaining 29 studies, studies not the target disease (1 study), non-clinical research (3 studies), protocol papers (7 studies), and other interventions (8 studies) were excluded from the literature review.

Of the remaining 10 studies, 4 systematic reviews were excluded

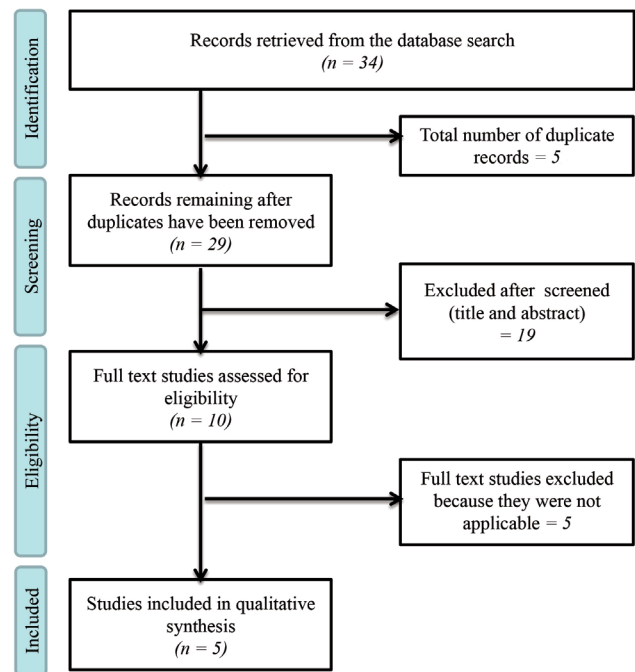


Fig. 3. Flow diagram of study selection and identification.

because electronic moxibustion was not the intervention. One RCT using temperature-controlled moxibustion as an intervention was excluded because it was not the form of electronic moxibustion considered in our study. As a result, 5 studies were included in the analysis (Fig. 3).

Adverse events reported in the selected studies for literature review

All studies included in the qualitative analysis were RCTs. The details of the adverse events reported and intervention details in the selected studies are shown in Table 3 [10-14]. Adverse events were reported in 2 studies, no adverse events were reported in 2 studies, and adverse events were not mentioned in 1 study. The types of

Table 3. The Summary of Induced Studies with Adverse Events.

First author (y) [reference]	n	Temperature	Time	No. of sessions	Electronic moxibustion device	Acupoints	Adverse events (n)	Type of adverse events	Fixed method
Kang (2020) [10]	EM (46) TM (46)	Peak at 45±1°C	15 min	2×/wk for 6 wks	Cettum, (K-medical Co., Korea)	Joksamni [ST36], Dokbi [ST35], Yanggu [ST34], Eumneungcheon [SP9], Naeseulan [EX-LE4] Hyeolhae [SP10]	EM (4) TM (10)	EM: Redness: 5 Crust: 2 TM: Redness: 4 Blister: 4 Crust: 1 Tingling: 1	Medical tape
Tang (2019) [11]	EM (62) TM (62)	46-48°C	30 min	3×/wk for 4 wks	DZWJY-1 (Shanghai University, China)	Naeseulan [EX-LE4] Dokbi [ST 35] Hyeolhae [SP 10] Yanggu [ST 34]	EM (0) TM (0)	No adverse event	Medical tape + 15 cm buckle tape
Xue (2020) [12]	EM (38) TM (34)	46-50°C	30 min	3×/wk for 4 wks	DZWJY-1 (Shanghai University, China)	Naeseulan [EX-LE4] Dokbi [ST 35] Hyeolhae [SP 10] Liangqiu [ST 34]	EM (0) TM (0)	No adverse event	15 cm wide strap
Cheung (2020) [13]	EM (21) Exercise (17)	60°C (high), 52°C (medium) 45°C (low)	20 min	3×/wk for 4 wks	T620 (Mei Fu Ltd, Guangzhou, China)	Total knee area	EM (4)	EM: Redness: 1 Itchiness: 3 Pain: 3	Brace type
Lu (2019) [14]	EM (33) TM (33)	48°C	30 min	3×/wk for 4 wks	DZWJY-1 (Shanghai University, China)	Naeseulan [EX-LE4] Dokbi [ST 35] Hyeolhae [SP 10] Yanggu [ST 34]	Not reported	Not reported	Not reported

EM, electronic moxibustion; TM, traditional moxibustion.

adverse effects caused by electronic moxibustion were redness, crust formation, itching, and pain at the attachment site. The most commonly reported adverse event was redness, and there were no blisters among the reported adverse events. In 2 studies where adverse events were reported, information on the adverse events were collected at every visit. However, in 2 studies where no adverse events were reported, the investigation period for adverse events was not specified.

The temperature of the electronic moxibustion ranged from a minimum of 44°C to a maximum of 60°C. In the case of using electronic moxibustion at 60°C, the temperature was reduced when the patient complained of an intense sensation of heat. The moxibustion time was 30 minutes in 3 studies, 20 minutes in 1 study, and 15 minutes in 1 study. The application time was more than 15 minutes in all the studies. Except for 1 study where it was not mentioned, the selected acupoints were Yanggu [ST34], Hyeolhae [SP10], Naeseulan [EX-LE4], and Dokbi [ST35] located in the knee joint area. Joksamni [ST36] Eumneungcheon [SP9] acupoints were also mentioned.

In 4 studies, electronic moxibustion was placed on the acupoint and medical tape was used to fix the device in place (2 studies used an additional 15-cm wide strap for tight fixation to the skin), and 1 study used electronic moxibustion with a brace which covered the entire knee joint. In addition, 2 studies applied wormwood oil to

the knee joint area before electronic moxibustion treatment.

Discussion

In the 3 cases retrospectively reviewed, all patients experienced superficial 2nd degree burns with redness, blister formation, and tingling after 10 minutes of electronic moxibustion at 45°C. Although all patients received the same intervention, each patient had different symptoms and time of occurrence. Medical tape was used to attach electronic moxibustion to the skin surface, and the treatment was performed once a day during the hospitalization period.

In the literature review, adverse events were reported in 4 studies (8 of 167 patients; 4.79%), and 1 study did not report this information. There were no cases of burns with blisters, but redness, a tingling sensation, itching, crust formation, and pain were reported.

The relationship between moxibustion temperature and burns has been widely researched to determine safety. In an vivo model, burns occurred on the skin of the back of the rat in 4 minutes when electronic moxibustion was performed at 47°C, and burn occurred within 1 minute when the device was set at 49°C [15]. Another study reported that if the temperature of electronic moxibustion was rapidly increased to its maximum within 1 minute, erythema may persist at the application site beyond 24 hours [7]. A heating

temperature of $\geq 42^{\circ}\text{C}$ was reported to be clinically significant, and can have a positive effect on C-fiber receptor activity at $\geq 44.5^{\circ}\text{C}$ [7]. The maximum temperature of electronic moxibustion currently accepted in Korea is in the range of $41\text{-}47^{\circ}\text{C}$, and 2 consecutive treatments are prohibited on the same area of skin. In addition, electronic moxibustion with a maximum temperature of $\geq 45^{\circ}\text{C}$ has been prohibited because of concerns regarding burns on the head and face. Despite electronic moxibustion being performed according to the guidelines, burns occurred in the 3 retrospective cases reviewed. Other factors involved in causing burns during electronic moxibustion need to be considered.

The extent of skin damage from a thermal contact burn is determined by the total thermal energy delivered to the skin and the skin thickness. The amount of transferred thermal energy is affected by the temperature, duration, contact area, and heat capacity of the contact material [16,17]. Studies on the factors except for the temperature and duration of treatment time, involved in the extent of skin damage caused by a thermal contact burn have rarely been researched. It is possible that the occurrence of burns may depend on the patient's age and underlying conditions/diseases. A literature review of 64 moxibustion case reports reported that there was no difference in the incidence of adverse effects according to age, but it is difficult to generalize these results due to the small number of patients analyzed [18].

In the literature review performed for this current study, 2 studies where higher temperatures and longer duration times of electronic moxibustion treatment were used no adverse events were reported [11,12]. In 2 other studies that did report adverse events, burns more severe than 2nd degree burns were not mentioned. It is difficult to determine which factors are associated with preventing burns during electronic moxibustion treatment. However, in the studies by Tang and Xue [11,12], wormwood oil was applied before the attachment of electronic moxibustion device. It is necessary to consider whether the application of oil could prevent burns.

In a study by Kang et al [10] using the same brand of electronic moxibustion device as used in the 3 case reports retrospectively reviewed, similar adverse events such as redness and crust formation occurred, and in the study by Xue et al [11], Tang et al [12], and Lu et al [14] using the same device which was set at $46\text{-}50^{\circ}\text{C}$, no adverse events were reported. This implies the possibility of differences in contact material, contact area, and the rate of temperature change of the device.

There were also differences in the method of attaching electronic moxibustion to the knee joint, including medical tape, brace, and strap. This suggests that the effect on the skin according to the fixation method needs to be considered. In the case of tape, it is also necessary to determine the chemical components within the tape which may affect the skin during thermal stimulation.

In the reporting process of adverse events within clinical studies, the time point when adverse events were collected, and the investigation procedure to inform patients to report adverse effects should be in advance of treatment and is very important. The 2 studies reporting no adverse events did not mention the time point of measurement, and consequently, there may be a possibility of reporting bias.

It has been reported that patients in Eastern Asia tolerate burns

caused by moxibustion because of the symptom relief the treatment provides [19]. The possibility of unreported adverse events due to concerns about discontinuation of treatment should also be considered.

This current study has the following limitations. Firstly, it was difficult to determine the proportion of burns after electronic moxibustion treatment because the clinical charts in this hospital only report 2nd degree burns or more severe burns. Secondly, the exact cause of a burn that occurred after electronic moxibustion treatment could not be identified. However, the factors to be considered were summarized but further research is necessary.

This study is worthwhile as it is the 1st study to focus on superficial 2nd degree burns caused by electronic moxibustion treatment for knee osteoarthritis in clinical practice. Various factors except for the moxibustion temperature and duration of time, are involved in burns occurring. To prevent these burns, if the minimum temperature and treatment time required for moxibustion are not applied, this treatment may not be effective. Besides decreasing the temperature of electronic moxibustion, studies on the heating source, and contact surfaces with the skin should be studied in the future. Electronic moxibustion should be developed and improved as a safe effective treatment to replace existing moxibustion treatment.

Conflicts of Interest

The authors have no conflicts of interest to declare.

Acknowledgments

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Ethical Statement

This research did not involve any human or animal experiment.

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