Clinical Practice Guideline: **Moxibustion**

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Product: **Specialty**

GUIDELINES

American Specialty Health – Specialty (ASH) considers indirect moxibustion medically necessary for musculoskeletal pain conditions where the application of heat is indicated.
American Specialty Health – Specialty (ASH) considers direct moxibustion not medically necessary due to risk of direct harm.

The potential for direct harm from burns with the use of direct moxibustion and the availability of the safer alternative of indirect moxibustion has led ASH clinical committees to only consider medically necessary the use of the indirect form of moxibustion by contracted practitioners. When indirect moxibustion (e.g., warming needle, moxa box, or placing the moxa on ginger, garlic, aconite, or another appropriate physical barrier) is used, there is no direct contact between the patient's skin and the moxa. Creams, oils, ointments, and other liquid or semi-solid substances are not considered acceptable barriers for adequate patient safety. While techniques such as placing moxa on a needle are considered indirect moxibustion, they still exhibit the potential for heated moxa fragments and/or ash to fall onto the patient causing harm. These techniques should only be performed while using appropriate precautions to prevent moxa from contacting the patient, including physical barriers of sufficient size and composition to prevent injury (e.g., heat shields large enough to capture any falling moxa or ashes). For more information, see the *Techniques and Procedures Not Widely Supported as Evidence Based (CPG 133 – S)* policy.

Patients must be informed verbally and in writing of the nature of any procedure or treatment technique that is considered experimental/investigational or unproven, poses a significant health and safety risk, and/or is scientifically implausible. If the patient decides to receive such services, they must sign a Member Billing Acknowledgment Form (for Medicare use Advance Beneficiary Notice of Non-Coverage form) indicating they understand they are assuming financial responsibility for any service-related fees. Further, the patient must sign an attestation indicating that they understand what is known and unknown about, and the possible risks associated with such techniques prior to receiving these services. All procedures, including those considered here, must be documented in the medical record. Finally, prior to using experimental/investigational or unproven procedures, those that pose a significant health and safety risk, and/or those considered scientifically implausible, it is incumbent on the practitioner to confirm that their

professional liability insurance covers the use of these techniques or procedures in the event of an adverse outcome.

DESCRIPTION/BACKGROUND

Moxibustion involves stimulation of specific acupuncture points and/or meridians (energy pathways throughout the body) by the burning of an herb called *moxa* (dried Artemesia vulgaris or mugwort) or a combination of several traditional Chinese herbs (also referred to as *moxa*) over these points/meridians. The herb(s) are pressed together into cigar-shaped sticks or small cones. Traditionally, there are two approaches to the application of these medicinal herb(s): direct and indirect moxibustion. With *direct moxibustion,* the cone is lit and permitted to burn down to the skin. Some practitioners may also use a thin layer of cream or oil on the skin before applying the moxa to help the cone adhere to the skin. *Indirect moxibustion* involves using a protective barrier such as a slice of ginger, garlic, or a layer of salt between the skin and the moxa, or using a moxa stick held away from the skin. This helps prevent the burning moxa and/or ash from contacting or injuring the skin.

When lit, moxa burns slowly and provides a penetrating heat that enters the meridians to enhance the circulation of blood and *qi* (vital energy). The purpose is to warm, stimulate, and strengthen the blood and *qi* of the body to promote healing or normal functioning of the body.

EVIDENCE REVIEW

Tian, et al. (2020) reviewed seven databases yielding 97 systemic reviews of moxibustion from 2011 to 2019. Reporting quality was assessed based on the Preferred Reporting Items for Systemic Reviews and Meta-Analyses (PRISMA) and moxibustion information per the standards for Reporting Interventions in Clinical Trials of Moxibustion (STRICTOM). 69.1% of reviews did not provide the type of moxibustion. 67% did not include rationale for selection of points for moxa. 28.9% did not list the number or duration of treatments, and 69.1% did not provide information about safety. The authors concluded that, "The reporting quality of SRs of moxibustion need further improvements in terms of adequate reporting of moxibustion interventions and of moxibustion-related rationales. Reporting guidelines of "PRISMA extension for moxibustion interventions" should be developed thus to improve their quality." In 2020, the (PRISMA) guidelines were extended including specific references to the evaluation of moxibustion in systematic reviews (Zhang et al).

To investigate adverse events of acupuncture (including the use of moxibustion), Yamashita et al. (1999) reviewed all relevant cases of adverse events reported by therapists at the Tsukuba College of Technology Clinic in Japan over a six-year period. 84 therapists participated in this study which included a total of 65,482 treatments. Of 94 adverse events (including acupuncture and/or moxibustion related events), seven (7) cases of burn injury and one (1) case of numbness in the extremities were reported. An adverse event was defined as an unfavorable medical event that occurred during or after the treatment

regardless of causal relationships. No serious or severe cases such as pneumothorax, infection, or spinal cord injury were reported by the participants. The results indicate that serious or severe adverse events are rare in standard practice. The reviewers suggest that most severe or serious cases of adverse events caused by acupuncture reported in journals are cases of negligence.

Park et al. (2010) completed a study to identify adverse events of moxibustion as reported in the medical literature. Adverse events related to moxibustion treatment were reported in eighteen studies. The most common adverse events identified were allergic reactions, burns, and infections such as cellulitis and hepatitis C. In clinical trials, various adverse events such as rubefaction, blistering, itching sensations, discomfort due to smoke, general fatigue, stomach upsets, flare-ups, headaches, and burns were also reported. Tenderness and pressure in the epigastric region or in one of the hypochondriac regions, unpleasant odor with or without nausea and throat problems, abdominal pain, premature birth, premature rupture of the membranes and bleeding due to excess pressure on the anterior placenta were reported in pregnant women. The authors concluded that risk is involved in moxibustion with reports of several kinds of potential adverse events such as allergy, burn and infection.

Furuse (2017) conducted a multicenter prospective survey of adverse events related to acupuncture and moxibustion at eight university acupuncture clinics over a 5-7 month period. Moxibustion treatments included many forms including moxa on needle, stick moxa, and box moxibustion. Out of 14,039 acupuncture and/or moxibustion treatments, 847 (6.03%) reported adverse events. Adverse events included subcutaneous bleeding, hematomas, and pain at needle insertion sites. No serious adverse events were reported. 55 of these were small burns due to direct moxibustion. 24 cases of burns from other moxa were noted, 19 of which were first degree burns, 4 superficial second degree burns and 1 burn injury of unknown character.

A case report of adverse reaction to moxibustion was published by Singh (2020). The patient was treated with direct scarring moxibustion on the ankle. Multiple co-morbidities were present likely resulting in non-healing of the burn/blister from the moxa. The area became infected resulting in septic shock and necrotizing fasciitis of the lower leg.

A literature review by Dharmananda (2004) was inconclusive as to whether moxibustion is more effective than acupuncture or other stimulus methods administered for the same condition. In the absence of more detailed studies, moxa is applied primarily on the basis of the traditional acupuncture point therapeutic indications, such as treating syndromes associated with cold, retention of food, spasms, immune deficiency, and local stagnation of fluids with the formation of masses. Moxa may be utilized in some cases of heat syndromes.

Thirty-five stroke patients participated in a study to evaluate the efficacy of electroacupuncture (EA) and moxibustion (Moxa) on spasticity due to stroke (Moon et al., 2003). Fifteen patients were randomized to the EA group, 10 to Moxa, and 10 to the control group. The efficacy of treatment was measured before, immediately, 1 hour, 3 hours, 1 day, 5 days, 10 days, and 15 days after the start of treatment using a modified Ashworth scale (MAS). In the Moxa group, there was no significant change in the MAS scores after the first treatment. In the Moxa and control group, there was no significant change in MAS scores.

Lee et al. (2010) completed a systematic review on moxibustion for treating pain. They concluded that given the limited number of studies and high risk of bias, no conclusions can be drawn.

Choi et al. (2011) completed a systematic review and meta-analysis on moxibustion for rheumatic conditions. A total of 14 RCTs met inclusion criteria. All were of low methodological quality. They concluded that the systematic review fails to provide conclusive evidence for the effectiveness of moxibustion compared with drug therapy in rheumatic conditions. The total number of RCTs included in this review and their methodological quality were low, making it difficult to draw firm conclusions.

In a randomized, controlled study of 70 patients with rheumatoid arthritis, Yu, et al. (2020) monitored pain levels and serological disease markers. Clinical symptoms and serum biomarker levels were significantly improved when moxibustion was added to pharmaceutical treatments. Methods used included both indirect and direct moxibustion on each patient. Direct moxa was performed with moxa cones with small amounts of Vaseline and indirect moxa was performed with gauze and salt under the moxa cone.

In a 2010 systematic review, four (4) randomized controlled trials (RCTs) met all inclusion criteria. Two studies suggested indirect moxibustion provided significant improvements in pain in participants with osteoarthritis when compared with medication for pain management. Choi et al. (2012) also completed a systematic review and meta-analysis on moxibustion and treatment of osteoarthritis (OA). Eight RCTs met inclusion criteria, and most of them had significant methodological weaknesses. The authors concluded that moxibustion may be effective in symptom management among patients with knee OA, however given the low number of RCTs and the high risk of bias, no definitive conclusion could be made.

Zhao et al. (2014) compared the effectiveness and safety of traditional Chinese moxibustion to that of sham moxibustion in patients with chronic knee osteoarthritis (KOA) pain. The WOMAC pain scores showed greater improvement in the active treatment group than in control at weeks 3 and 24 as did WOMAC physical function scores of the active treatment group at weeks 3 and 12 but not 24. Patients and practitioners were

blinded successfully, and no significant adverse effects were found during the trial. The authors concluded that a six-week course of moxibustion seems to relieve pain effectively and improve function in patients with KOA for up to 18 weeks after the end of treatment. Kim et al. (2014) tested the effectiveness of moxibustion on pain and function in chronic knee osteoarthritis (KOA) and evaluated safety. The authors concluded that indirect moxibustion may improve pain, function, and quality of life in KOA patients, but adverse events are common according to this study. Limitations included no sham control or blinding.

Choi, et. al. (2017) completed a systematic review and meta-analysis of the use of moxibustion for osteoarthritis. 19 RCTs met inclusion criteria. Moxa was found to be more effective at pain reduction than sham moxa. Eight RCTs showed superior effects of moxa compared with medication therapies. Three studies noted superior or equivalent effects of moxa on symptom scores when compared with intra-articular or topical medication therapies. The authors reported the levels of evidence as moderate due to high risk of bias and small sample size. However, they also noted the existing evidence was, "sufficiently convincing to suggest that moxibustion compared with sham moxibustion and oral drugs is effective for pain reduction and symptom management in knee osteoarthritis."

A review of systematic reviews was performed by Yin, et. al. (2022) to evaluate previous reviews of moxibustion for knee osteoarthritis. Ten systemic reviews qualified and included fifty-seven randomized, controlled trials and 5149 total participants. Studies included multiple types of moxibustion including traditional, thunder fire, and indirect. A re-meta-analysis demonstrated that moxibustion and moxibustion combined treatments improved the total effectiveness rate in knee osteoarthritis more significantly than the control groups. Eight systematic reviews reported adverse events. No serious effects were reported in the moxa or control groups. Low methodological quality in the reviews and high risk of bias in the original studies reduced the reliability of the results.

Fifteen systemic reviews representing 13,940 participants were evaluated by Jun et al. (2023). Warm needle acupuncture was shown to be more effective than controls (Western Medicine, acupuncture, traditional medicine in various combinations) for treating osteoarthritis in all but two studies that didn't report significant differences between warm needle acupuncture and electroacupuncture. Outcomes included WOMAC score, total effective rate, function, and pain reduction. Most of the studies centered on osteoarthritis of the knee. Methodological quality of the studies was very low to moderate due to issues with reporting of protocols, justifications for excluding studies, and conflicts of interest. Two studies scored greater than 85% compliance with PRISMA guidelines. Adverse events overall were fewer in the warm needle groups and no serious events were noted in these moxibustion groups.

Yuan et al. (2015) reviewed the use of traditional Chinese medicine (TCM) for neck pain (NP) and low back pain (LBP) including 75 trials and 11,077 participants. As part of this larger review, the authors concluded that the efficacy of moxibustion is unknown because no direct evidence was obtained. The authors also noted that, "TCM modalities are relatively safe".

Yao et al. (2023) performed a meta-analysis of randomized controlled trials of moxibustion for lumbar disc herniation. Nineteen studies of 1888 patients were included. Studies showed no difference between moxibustion and acupuncture for response rate, VAS scores or the Japanese Orthopedic Association score. Two studies showed that moxibustion may have similar effects on the VAS score when compared to medication. Evidence level was very low to low. The authors concluded that moxa on its own may not be appropriate for treating lumbar disc herniations but may be used as an adjuvant treatment.

Gadau, et. al. (2014) performed a systematic review of RCTs according to revised STRICTA criteria for treatment of lateral elbow pain. 19 RCTS were included in the review and contained a total of 1,190 subjects. All studies contained at least one domain on the Cochrane risk tool of high or uncertain bias. Three moderate quality studies showed acupuncture to be more effective than sham. 10 RCTs of lower quality demonstrated acupuncture or moxibustion as superior to conventional treatments. Six low quality studies reported acupuncture and moxa were more effective than acupuncture alone. Moxibustion types in these studies included indirect methods such as moxa on the needle or moxa cone on a slice of ginger. Three studies used direct moxa. Adverse events were reported in only four studies. Two of these studies reported no adverse events. Two reported permanent scars with blister-forming moxa treatments. The authors recommend more rigorous study designs to evaluate safety and efficacy.

Liu et al. (2020) showed indirect moxibustion (moxa stick) was an effective treatment for primary dysmenorrhea especially when performed during the premenstrual time in a randomized controlled trial with 208 patients. One adverse event was reported due to overly long moxibustion administration. The reaction resolved in two days and the patient resumed the study.

Two other studies suggested positive effects for *indirect or direct* moxibustion on pain in scleroma or herpes zoster compared with pharmaceutical therapy. Due to only a few studies, most with a high risk of bias, the authors concluded that more rigorous studies are needed to determine the effectiveness of moxibustion (Lee, Choi, Kang, Lee, & Ernst, 2010).

A meta-analysis including 11 RCTs and 927 patients with diabetic peripheral neuropathy was completed in 2020 by Tan, et al. Most of the trials included in the analysis used indirect moxa, but some did not clearly describe moxa methods used. No adverse reactions were

reported in one study and no mention of any adverse reactions was noted in the other 10 studies. Per the author, "attention must be paid to adverse events because moxibustion is not free of risks and generates heat, smoke, and tar that may present a risk of adverse events. The availability of a large amount of safety data will be necessary to standardize the moxibustion therapy".

Wu et. Al. 2021 conducted a systematic review and meta-analysis of moxibustion treatment for postherpetic neuralgia (PHN). A total of thirteen randomized, controlled trials with 798 patients were reviewed. Moxibustion was compared to controls including pharmaceutical and herbal medications, and no treatment. Treatment ranged from 14 to 35 days. The main outcomes were efficacy rate and the Visual Analog Scale (VAS); Secondary outcome measures were adverse events. Moxibustion achieved a significantly higher efficacy rate and lower VAS scores. Five studies reported adverse reactions with moxa including dizziness, abdominal distention, nausea/vomiting, burns, redness/rash/itching, blisters, infection. The authors report that heterogeneity and poor methodological quality (e.g., inappropriate randomization methods, difficulty blinding participants and outcome assessors) impaired the ability to make conclusions about efficacy or safety of moxibustion in the treatment of PHN.

Park et al. (2013) completed a systematic review and meta-analysis evaluating the current evidence on moxibustion for improving global symptoms of irritable bowel syndrome (IBS). A total of 20 RCTs were eligible for inclusion (n = 1,625). The risk of bias was generally high. The authors suggest that moxibustion may provide benefit to IBS patients although future studies are necessary to confirm these results.

Similar results for moxibustion and treatment of inflammatory bowel disease (IBD) were noted in a review by Ji et al. (2013). According to Stein (2017), acupuncture and moxibustion therapy have been shown to reduce inflammation and symptoms in animal and human studies. However, current clinical trials of acupuncture and moxibustion are of insufficient quality to recommend them as alternative therapy.

Ten randomized controlled trials with 760 patients were included in a systematic review and meta-analysis of moxibustion treatment for constipation by Yao, et al. (2020). Any type, duration of moxibustion was permitted in the reviewed trials. Moxibustion was noted to be more clinically effective than controls (other Chinese Medicine Treatments or Western Medical therapies) regardless of the type of moxa therapy used. Four out of ten studies listed adverse reactions due to moxa and one reported no side effects. The authors concluded, "it is not yet possible to assess the safety level of moxibustion therapy, and the quality of the included literature is low, so rigorous studies are warranted."

Lee et al (2010) reviewed five RCTs comparing the effects of moxa with conventional therapies for nausea and vomiting in cancer patients. A meta-analysis showed a

significantly lower frequency of chemotherapy-related nausea and vomiting when moxa was used. The authors reported that all studies had a high risk of bias so there is not enough evidence to draw a conclusion without further research.

A review by Lee et al. (2014) assessed the effectiveness of moxibustion with usual care for cancer-related fatigue vs. usual care alone. Four RCTs with 374 subjects were included in the review. Indirect moxa was used in all four studies, either moxa stick, moxa on ginger or both. Points for moxibustion were chosen according to Traditional Chinese Medicine theory. The moxa treatments ranged in length from 5-30 minutes and in number from 14 to 40. One study reported an adverse effect of burning with a mild blister after moxibustion that resolved in two days. No serious adverse reactions were reported. The authors expressed concern about using moxa with related smoke in patients with lung cancer or other related pulmonary issues, but no pulmonary issues were reported in the trials. The authors concluded that the evidence is limited to suggest moxibustion is an effective supportive cancer care. All studies had a high risk of bias so there was not enough evidence to draw any conclusions.

Coyle et al. (2012) examined the effectiveness and safety of moxibustion on changing the presentation of an unborn baby in the breech position. The inclusion criteria were published and unpublished randomized controlled trials comparing moxibustion (either alone or in combination with acupuncture or postural techniques) with a control group (no moxibustion), or other methods (e.g., external cephalic version, acupuncture, postural techniques) in women with a singleton breech presentation. This updated review now includes a total of eight trials (involving 1,346 women). Meta-analyses were undertaken (where possible) for the main and secondary outcomes. Moxibustion was not found to reduce the number of non-cephalic presentations at birth compared with no treatment. Moxibustion resulted in decreased use of oxytocin before or during labor for women who had vaginal deliveries compared with no treatment. Moxibustion was found to result in fewer non-cephalic presentations at birth compared to acupuncture. When combined with acupuncture, moxibustion resulted in fewer non-cephalic presentations at birth and fewer births by caesarean section compared with no treatment. When combined with a postural technique, moxibustion was found to result in fewer non-cephalic presentations at birth compared with the postural technique alone. The authors found limited evidence to support the use of moxibustion for correcting a breech presentation. Liao, et al (2021) completed a systemic review and meta-analysis to evaluate the effectiveness and safety of moxibustion and acupuncture for correction of breech presentation. Sixteen randomized, controlled trials with 2555 participants were included. All the studies used moxibustion at acupoint Urinary Bladder 67. Moxibustion therapy significantly increased the number of cephalic presentations at birth especially in Asian populations compared with controls. Moxibustion and acupuncture effects were synergistic for correcting breech presentations. Four trials reported on adverse events which included either none, abdominal pain, throat issues, or unpleasant odor with or without nausea. The possibility of publication bias was

noted as well as the small sample sizes of some of the studies and variation of the treatment application time and frequency. The authors suggested more clinical trials "to evaluate whether our estimate of the magnitude of the effect of moxibustion remains constant".

Chen et al. (2023) included 38 RCTs with 4257 patients in a systematic review and meta-analysis of the use of nine moxibustion methods for treating allergic rhinitis. Overall, heat-sensitive moxa (moxa at specifically designated heat-sensitive points) was the most effective. Moxibustion on the needle was more effective than acupuncture alone. Moxibustion combined with medications was more effective at improving VAS scores and regulating serum IgE than medications alone. Adverse effects were mostly related to skin damage from vesiculating moxibustion. The authors note that there were also a few patients with mild skin burns and suggest that this is more of an issue with the provider operation specifications. A small number of participants were allergic to moxa smoke. Limitations of the study included the many types of moxibustion studied, the variation in acupuncture points selected, and the acupuncturist's technique. The conclusion was that heat sensitive moxa can be used for people with allergic rhinitis if traditional medication is not appropriate.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as

appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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