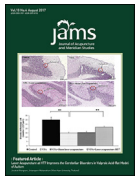
J Acupunct Meridian Stud 2017;10(4):261–275

Available online at www.sciencedirect.com

Journal of Acupuncture and Meridian Studies

journal homepage: www.jams-kpi.com



RESEARCH ARTICLE

Quality Assessment of Randomized Controlled Trials of Moxibustion Using STandards for Reporting Interventions in Clinical Trials of Moxibustion (STRICTOM) and Risk of Bias (ROB)

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Available online 27 July 2017

Received: Feb 16, 2017
Revised: May 31, 2017
Accepted: May 31, 2017

KEYWORDS
moxibustion;
randomized controlled trials;
Risk of Bias;
STandards for Reporting Interventions in Clinical Trials of Moxibustion

Abstract

Objectives: To assess the quality and completeness of published reports of randomized controlled trials (RCTs) of moxibustion.

Method: We searched six databases to retrieve eligible RCTs of moxibustion published from 2000 to December 2015. We used the STandards for Reporting Interventions in Clinical Trials of Moxibustion (STRICTOM) and Risk of Bias (ROB) tool to assess the completeness of reporting of RCTs of moxibustion and evaluate the reporting quality of included RCTs.

Results: Thirty-four studies of moxibustion were analyzed using STRICTOM and ROB. Of the 34 studies, the completeness percentage of STRICTOM varied from 33% to 100% (mean 68%, median 67%). The completeness of STRICTOM items showed a rising tendency along with the publication year. The STRICTOM items of setting and context (14.7%), rationale for the control (17.6%), and response (26.4%) showed incomplete reporting. The number of RCTs that rated a low risk of bias for allocation concealment ($n = 6$), blinding of participants and personnel ($n = 1$), and blinding of outcome assessment ($n = 4$) appeared to be small.

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pISSN 2005-2901 eISSN 2093-8152
http://dx.doi.org/10.1016/j.jams.2017.05.012

Conclusion: The quality of reporting of RCTs of moxibustion remains incomplete according to the STRICTOM and ROB tool at present. Researchers should consider the STRICTOM and ROB for improving not only the completeness of reporting but also the study design. General guidelines for RCTs of moxibustion are also required.

1. Introduction

Moxibustion is a therapeutic form of traditional East Asian medicine making use of moxa (mugwort; *Artemisia argyi* Folium) or other materials to heat, burn, and/or fumigate either acupoints or specific areas on the surface of the body [1]. Traditional East Asian medicine doctors have developed moxibustion therapy through thousands of years of clinical experience. It is thought that the therapeutic effect of moxibustion is a combination of heat, tar, aroma, and psychological reaction [2]. Based on yin and yang, meridian, and qi theory, moxibustion can boost yang qi and remove pathogenic coldness or dampness. Recent studies have suggested that moxibustion can regulate the immune system, stimulate the anti-inflammatory system, improve blood circulation, and release chemicals that can alleviate pain [3]. There are many types of moxibustion including different forms, materials, and techniques. It is used for various diseases such as musculoskeletal, genitourinary, digestive, respiratory, and neoplasmic diseases [4]. Owing to the wide range of applications, a great deal of research has been focused on moxibustion. The number of randomized controlled trials (RCTs) on moxibustion has steadily increased [5], but they appear to have some limitations such as lack of moxibustion detail, unclear randomization, inappropriate control groups. There have been some studies assessing the reporting quality of RCTs, but most of these did not focus on moxibustion. There is a need for guidelines for RCTs on moxibustion to improve the quality and completeness of the study.

The aim of this work is to evaluate the quality of RCTs of moxibustion using the STandards for Reporting Interventions in Clinical Trials of Moxibustion (STRICTOM) [6] and the Risk of Bias (ROB) tool [7]. STRICTOM is developed based on the Consolidated Standards of Reporting Trials (CONSORT), a statement for RCTs, and STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA), a widely used guideline for RCTs of acupuncture [8—10]. We anticipate that this study will provide the current information about RCTs of moxibustion including study setting and protocols, and valuable guidelines to report RCTs in a more evidence-based way.

2. Materials and methods

2.1. Types of studies

Randomized and quasi-randomized (which means the allocation method is not strictly random, such as alternation, date of birth, or case record number) controlled trials were eligible for this analysis. There is no language limitation. Trials that were published from 2000 to December 2015 were included. The studies had to meet the following inclusion criteria as well:

1. Individuals of any age and sex who have any kind of symptoms or disease could be participants. Studies that recruited healthy people were excluded.
2. Studies designed to use moxibustion as a treatment method were included, and moxibustion combined with any other intervention (e.g., acupuncture, herbal medicine, Western medicine, physiotherapy) were also included. Studies adopting self-moxibustion therapy (participants had to practice moxibustion by themselves) were excluded because this is thought to be far from medical practice. Studies using warming needle moxibustion (moxa is lit on the top of an acupuncture needle) were excluded as well because the effect of this type of moxibustion is mixed with that of acupuncture.
3. Studies that had at least one control with any type of intervention (e.g., acupuncture, Western medicine, physiotherapy) or observational control were included. Studies were excluded if moxibustion was used for both the intervention group and the control group.
4. The outcome measure of each study can vary depending on the target symptom or disease.

2.2. Databases and search strategy

Studies in Korean were searched in NDSL, KoreanTK, and Oasis. Studies in English were found in PubMed, Wiley Online Library (Cochrane Library searching engine), and CINAHL. The search was performed based on the results obtained on December 28, 2015. These databases were searched using the following strategy:

[moxibustion OR moxa OR artemisia OR mugwort] AND [randomized OR controlled OR random OR control]

These searching terms were slightly modified depending on the database.

2.3. Data extraction quality assessment

General characteristics of the included studies were extracted systematically by one author including author name, publication year, target disorder, sample sizes of the intervention and control groups, and type of the control. The extraction items are designed not to repeat the items of STRICTOM. To see how each study is designed to show the effectiveness of moxibustion compared with the control, outcome measure and study results were extracted. If there are multiple follow-ups and multiple outcomes, we extracted the last follow-up result.

STRICTOM, modified from STRICTA, was used to analyze the completeness of RCTs of moxibustion [6]. If there was an item that consisted of multiple subitems, we considered