Side-Effects of Moxibustion for Cephalic Version of Breech Presentation

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Abstract

Objectives: Moxibustion, a Traditional Chinese Medicine technique related to acupuncture, was proposed to facilitate cephalic version of breech presentation. Several trials were conducted to evaluate the efficacy, but there are few reports on the safety of moxibustion. Our objective was to assess the side-effects and acceptability of this intervention.

Design: We are conducting a randomized controlled trial to evaluate the efficacy of moxibustion for breech version. The first 12 participants randomized in the moxibustion group had additional fetal surveillance by electronic monitoring.

Subjects: Pregnant women with a fetus in breech presentation are included in the trial between 34 and 36 weeks of gestation.

Interventions: We performed a cardiotocogram during 10 minutes before, 20 minutes during, and 10 minutes after each session. A maximum of 9 sessions were scheduled every other day, and stopped when cephalic version was diagnosed. The recordings were assessed by 3 independent readers using the Fischer scoring system.

Outcome measures: Fetal well-being was evaluated by the cardiotocogram; effect on the mother was evaluated by blood pressure recorded before and after each session; maternal views, contractions, and perceived changes in fetal movements were assessed using a questionnaire.

Results: A total of 65 cardiotocograms were analyzed. All scores were considered as normal, being at 8 or more on a 0–10 scale. Acceptability for the women and compliance to the intervention were good. No significant maternal or fetal side-effect was observed.

Conclusions: We have not detected alterations of fetal and maternal well-being or other side-effects associated with moxibustion applied to the BL 67 for cephalic version of breech presentations. Moxibustion appears to be safe for both the mother and the fetus.

Introduction

Moxibustion is a Traditional Chinese Medicine technique. This consists of stimulating the acupuncture points using the heat produced by burning an herb (common wormwood; Artemisia vulgaris). Moxibustion of the acupuncture point number 67 (BL 67) was proposed to facilitate cephalic version of breech presentation during the third trimester of pregnancy.

A systematic review evaluating the side-effects of acupuncture in various situations concluded that acupuncture can be considered a safe intervention. However, that paper did not report studies including pregnant women and did not discuss the specific concerns during pregnancy or the safety of moxibustion.

A systematic review of the randomized trials on moxibustion concluded that safety of moxibustion in pregnant women still needs to be evaluated.

The main objective of this report was to assess the safety of moxibustion for the fetus. Our secondary objective was to assess the maternal side-effects and acceptability of this intervention.

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Materials and Methods

We are conducting a randomized trial in which the main objective is to evaluate the efficacy of moxibustion to achieve cephalic version. This trial is currently ongoing. The protocol of the trial was approved by the Ethics Committee of the Hospital and all participants give written informed consent. We include women at 34–36 weeks of gestation with a single fetus in breech presentation. In the moxibustion group, the intervention is performed using moxa sticks made from *A. vulgaris* (Shenlong Medical Apparatus Factory, Suzhou, China). These sticks burn without smoke. The burning stick is approached from the BL 67 point, next to the outer corner of the fifth toenail, during a total of 20 minutes (10 minutes on each side). The woman is asked her perception of heat, to adapt the distance between the moxa stick and the skin (Fig. 1). The goal is for her to perceive a sensation of intense heat, but no painful burning. The sessions are scheduled every other day. The intervention is stopped when cephalic version is diagnosed or at 37 weeks of gestation. No specific intervention is performed in the control group.

The first 12 participants randomized in the moxibustion group had a cardiotocogram (CTG), as a nonstress test of fetal well-being, performed 10 minutes before, 20 minutes during, and 10 minutes after each moxibustion session. This assessment was requested by the Ethics Committee to evaluate the need for fetal surveillance during the trial. We used a Hewlett-Packard model 8041A monitoring system, with paper speed set at 2 cm/min. The CTG traces were assessed independently by 3 of the authors (MJG, TJK, MB) using the Fischer scoring system. This score includes the assessment of baseline heart rate, long-term and beat-to-beat variability, presence of accelerations, and absence of decelerations. The score is considered normal when equal to 8 or more on a scale from 0 to 10. Observers were blinded to the results of the other observers. Agreement between observers was assessed using the weighted $\kappa$ coefficient. Cases where disagreement was present were reviewed by the observers and consensus was reached.

Maternal blood pressure was measured before and after each moxibustion session.

Contractions, perceived changes in fetal movements, other perceived side-effects, and some aspects of maternal views were assessed using a questionnaire.

Pain during moxibustion was assessed using two of the three items of the French version of the Short-Form McGill Pain Questionnaire, the Visual Analogue Scale, and the scale from 0 (no pain) to 5 (excruciating pain).

Results

We include in this report the analysis of 65 CTGs performed in the first 12 participants in the moxibustion group. All women were at low risk, but we detected in 2 women obstetrical complications leading to cancellation of the next sessions of moxibustion. One (1) woman had hypertension diagnosed before starting the fifth moxibustion session, later developed preeclampsia, and was delivered by cesarean section at 35 weeks of gestation. The second woman reported signs of premature rupture of membranes to the midwife before starting the third session.

The median number of sessions was 5 (range: 2–9). No cephalic version was observed in these women after the moxibustion sessions. Three (3) CTGs, from 3 different participants, were scored as abnormal. In the 3 cases, only 1 observer gave this score, while the other 2 scored the record as normal. None of these records was classified as nonreassuring when reviewed. Agreement between pairs of observers was moderate. The $\kappa$ coefficient was 37%, 41%, and 50%, respectively, for the three combinations of 2 observers.

Blood pressure was measured before and after each session. No cases of hypertension (blood pressure greater than 140/90 mm Hg) or hypotension (blood pressure less than 90/60) was diagnosed during the sessions. Evaluation of pain during the sessions, using a visual analogue scale from 0 to 100, was in the range from 0 to 15. Eight (8) women reported no contractions, while 4 reported fewer than 10 contractions during the day of the session. Fetal movements were perceived as increased by 7 women, while they were reported as unchanged by 5 women. No women reported a disturbing side-effect during the sessions, and some women described the session as pleasant or relaxing. Most responses on the questionnaire exploring maternal views were either favorable or very favorable (Table 1).

Discussion

The CTG is a simple and widely available method to assess fetal well-being. It is more sensitive to short-term changes following an intervention than measurements of the other markers of well-being, such as amniotic fluid index or fetal growth. The reproducibility of the interpretation of the
recordings, however, was questioned. We have standardized the interpretation using a classical scoring system, to reduce the interobserver variability in the interpretation.

In the previous evaluation of safety of the moxibustion by Neri et al., small modifications of the fetal heart rate were reported. This study showed a small reduction of the fetal heart rate and of the number of accelerations during and soon after the sessions, both being associated with fewer fetal movements and remaining in the normal range. Except for this study, the authors of the other randomized trials on moxibustion did not systematically assess fetal safety using the CTG. Our sample size is small, thus limiting the power to detect rare effects of the intervention. We performed a total of 65 CTGs, thus providing us with a much larger number of recordings for analysis compared with Neri et al., who analyzed only 12 CTGs (one for each woman). Performing a CTG at each session also allows evaluation of any additive side-effect because of repeating the intervention. As the repetition of sessions is advocated to increase the efficacy to obtain cephalic version, we may also hypothesize that this may increase the risk of side-effects.

Previous authors reported either an increase or a decrease of fetal movements during or after moxibustion. The participants in our study reported either no change or an increase in fetal movements, with no woman reporting a decrease. The moxibustion sessions were not associated with pain or changes in blood pressure. Women were very positive about the intervention, despite the apparent lack of efficacy in these few cases. Another finding pointing toward acceptability of the intervention was that no women missed an appointment and none dropped out of the program.

Conclusions

We have not detected short-term alterations of the fetal well-being or other maternal or fetal side-effects associated with moxibustion applied to the BL 67 for cephalic version of breech presentations. Given the reassuring results of the initial surveillance and the lack of reports of unfavorable side-effects in the literature, we decided not to perform fetal monitoring for the other women included in the trial.

Acceptability of the intervention is good in our context, but efficacy still needs to be demonstrated.

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References


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