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Correction of nonvertex presentation with moxibustion: a systematic review and metaanalysis

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cupuncture and moxibustion, therapeutic techniques forming part of traditional Chinese medicine, have long been used, and Chinese texts include recommendations for the application of heat (moxibustion) by the combustion of Artemisia vulgaris (moxa) over an acupuncture point to correct podalic presentation^{1,2}; this latter point, known as Zhiyin (BL67) is located in the outer corner of the little toenail.

It has been suggested that this technique might stimulate the production of placental oestrogens and maternal prostaglandin as well as promoting the contraction of the uterus and fetal activity.3 A Cochrane review⁴ concluded that the studies analyzed do not provide sufficient evidence for this hypothesis and commented that there exist very few well-designed studies (only 3 are included in the analysis) and that most studies were carried out using a small sample.

This review spanned the studies published up to August 2004 but excluded those published in Chinese, although the study is most frequently implemented in China.5 Some studies, with a larger sample group, such as that carried out by KaWe searched systematically for randomized controlled trials, comparing moxibustion with a nonmoxibustion control group or other methods such as external cephalic version, postural methods, and acupuncture in databases, both Western and Chinese, up to June 2007. Six studies, with 1087 subjects and a high degree of heterogeneity, compared moxibustion vs observation or postural methods and reported a rate of cephalic version among the moxibustion group of 72.5% vs 53.2% in the control group (relative risk, 1.36; 95% confidence interval, 1.17–1.58); the number needed to treat was 5 (95% confidence interval, 4-7). In terms of safety, no significant differences were found in the comparison of moxibustion with other techniques. Moxibustion at acupuncture point BL67 has been shown to produce a positive effect, whether used alone or in combination with acupuncture or postural measures, in comparison with observation or postural methods alone, for the correction of nonvertex presentation, although these results should be viewed with caution, given the considerable heterogeneity found among studies.

Key words: cephalic version, moxibustion, nonvertex presentation

nakura et al,6 are not randomized. In addition to moxibustion, acupuncture may be used on this or other points, producing similar results.7

The aim of the present review was to assess the available scientific evidence on the effectiveness and safety of moxibustion, compared with a control (ie, either doing nothing or applying a different approach, such as postural methods or acupuncture), to correct the nonvertex presentation of a fetus.

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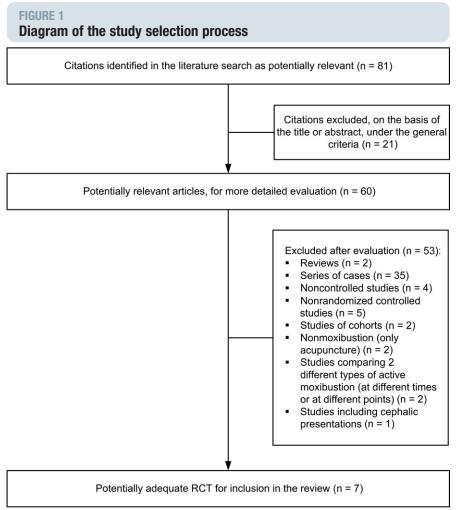
Materials and methods

Search strategy and selection criteria

The protocol was established a priori. Randomized or semirandomized controlled studies were examined in which the effects of moxibustion were compared with those obtained for a control group, with no moxibustion, or were compared with other methods such as external cephalic version, postural methods, or acupuncture for women pregnant with a single fetus in nonvertex presentation. Studies that evaluated the combined effects of moxibustion and another technique were also included.

No restrictions were imposed as to the language of the study. Congress and conference proceedings were excluded. For inclusion, the studies had to report at least 1 of the following outcome measures: position of the fetus after treatment or presentation of the fetus at birth. In addition, data were recorded concerning the safety of the technique applied.

Relevant studies were identified by means of a sequential search procedure of the following databases: Medline (1980-June 2007); Cumulative Index to Nursing and Allied Health Literature REVIEWS Obstetrics www.AJOG.org



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(1982-June 2007); Cochrane Database of Systematic Reviews (Cochrane Collaboration, 1992-June 2007); Excerpta Medica (1980-June 2007); Allied and Complementary Medicine Resources (1985-June 2007); Chinese Biomedical Literature Database (1980-June 2007); Chinese Medical Current Content (1980-June 2007); China National Knowledge Infrastructure (which includes the database China Academic Journals) (1980-June 2007); VIP Information (1980-June 2007); and Wanfang Data (1980-June 2007).

The search terms used (in the English version and/or the corresponding language, to query the databases) were: "breech presentation," "podalic presentation," "version," "moxibustion," "acupuncture," "moxa," "artemisia," "obstetrics," "complementary medicine," and "alternative medicine."

Deciding on inclusion

Eligibility was determined independently by 4 reviewers, 2 for articles in English (J.M.A. and M.B.) and another 2 for languages in Chinese (C.Y.W. and J.P.L.). Articles in languages other than English or Chinese were translated into Spanish and evaluated by the reviewers who had assessed the articles in English. If any conflict arose, consensus was sought between the 2 reviewers, and if the disagreement persisted, C.M. adjudicated. Evaluations were carried out in 2 phases: first, the titles and abstracts were assessed; in the second phase, the complete texts were obtained from the potentially eligible studies. Reasons were given for all exclusions made.

Evaluating the quality of the studies

The methodological quality of the studies was evaluated by the same independent reviewers who had determined their eligibility, and disagreements were resolved by the lead author (J.V.), acting as arbiter.

The assays included in the analysis were classified with a code letter to indicate their quality, in accordance with the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions,8 under the following criteria: randomization (A, adequate; B, unclear, randomization of the study is reported, but the method is not described; C, inadequate [quasirandomization, such as alternation, date of birth, or case history number]; concealment of allocation, A, adequate; B, unclear or not mentioned; C, clearly inadequate or not used; blinding suitable for the evaluation of results, A, evaluator and analyst blinded with respect to allocation; B, not mentioned; documentation on how exclusions were analyzed after allocation to treatment group, A, adequate report (including number and reasons); B, partially reported; C, not reported; baseline comparability, A, comparable; B, unclear; C, noncomparable.

If, for a given study, all the above items were classified as A, it was considered a high-quality study and scored as A; if there were no items classed as C (ie, all were either A or B), the study was classed as B, of moderate quality; if 1 or more items in the study were scored as C, it was considered to be of low quality and classed as C.

Extraction and administration of data

The same reviewers who decided on the inclusion of the studies and who assessed their quality extracted the data on the study design, the characteristics of the women subjects, the interventions performed, and the outcome measures established using a purpose-designed form. Discrepancies were resolved by discussion and consensus. The program Review Manager⁹ was used to situate the data obtained on the forms.

Treatment outcome measures

The principal outcome measure considered was the proportion of versions to cephalic presentation following the period of moxibustion intervention. The relative risks (RRs) and 95% confidence intervals (CIs) were calculated. Whenever possible, study results were combined to calculate the RR together with the 95% CI (significance level of P <.05). In view of the wide variation among the gestational ages of the study populations, sample sizes, duration, and intensity of interventions, random-effects models were applied to compute the pooled relative effectiveness of the studies. ¹⁰ A χ^2 test of heterogeneity and the I^2 statistic were used to detect the heterogeneity of the study results.¹¹

We expected the latter to be derived from the different treatment outcomes between the pregnant women with a gestational age 32 weeks or greater and those with a lower gestational age, from the continent in which the study was carried out, or the methodological quality of the different studies. Therefore, analyses were performed predefined by subgroups for pregnant women with a gestational age of 32 weeks or longer and those with a gestational age less than 32 weeks for studies of low or moderate quality and for studies with subjects recruited in Asia or in Europe. A funnel plot was visually examined to estimate potential publication bias. The statistical analyses were carried out using the program Review Manager.9

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

The literature search identified 81 references. After checking for duplicates and relevance, a total of 60 references were found to be suitable for detailed evaluation. Finally, only 7 studies¹²⁻¹⁸ fulfilled the inclusion criteria and/or provided relevant information. The flow diagram shown in Figure 1 summarizes the selection process applied. Table 1 lists the reasons for exclusion of studies from this review. Of the 7 studies included, 5 were of moderate quality (B)12-15,17 and the

TABLE 1 Reasons for exclusion	n of studies	
Study	Country in which study was carried out	Reason for exclusion
Anderson and Johnson ²²	USA	Review of evidence
Arai ²³	Japan	Noncontrolled study
Beer et al ²⁴	Germany	Noncontrolled study
Budd ²⁵	UK	Series of cases
Cao and Ji ²⁶	China	Series of cases
Cardini et al ²⁰	Italy	Noncontrolled study
Cardini and Marcolongo ²⁷	Italy	Cohorts with retrospective control
Chen and Xu ²⁸	China	Series of cases
Chen ²⁹	China	Series of cases
Chen and Zhang ³⁰	China	Series of cases
Dai ³¹	China	Series of cases
Fang ³²	China	Series of cases
Gao ³³	China	Series of cases
Gong ³⁴	China	Series of cases
Gu and Zhou ³⁵	China	Series of cases
Habek et al ⁷	Croatia	Intervention only with acupuncture, not moxibustion
Jiang and Liao ³⁶	China	Series of cases
Kanakura et al ⁶	Japan	Cohorts with retrospective control
Lai ³⁷	China	Randomized controlled study but comparing moxibustion applied at different times of day
Li and Wang ³⁸	China	Randomized controlled study but including cephalic presentations (occipital-posterior)
Li ³⁹	China	Randomized controlled study but comparing moxibustion applied at 2 different points, SP6 and BL67
Liang et al ⁴⁰	China	Nonrandomized controlled study
Liu ⁴¹	China	Intervention only with acupuncture, not moxibustion
Ma and Gao ⁴²	China	Series of cases
Ma et al ⁴³	China	Series of cases
Mei ⁴⁴	China	Series of cases
Neri et al ⁴⁵	Italy	Noncontrolled study
Qi and Zhou ⁴⁶	China	Series of cases
Qi and Zhou ⁴⁷	China	Series of cases
Raben ⁴⁸	Germany	Series of cases
Shu and Ma ⁴⁹	China	Series of cases
Sun and Guan ⁵⁰	China	Series of cases
Tiran ⁵¹	UK	Descriptive review
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Study	Country in which study was carried out	Reason for exclusion
/ukovic-Bobic and Habek ⁵²	Croatia	Series of cases
Vagner-Pankl ⁵³	Germany	Nonrandomized controlled study
iong and Yang ⁵⁴	China	Nonrandomized controlled study
u and Zhou ⁵⁵	China	Series of cases
′u et al ⁵⁶	China	Series of cases
⟨u ⁵⁷	China	Series of cases
⁄an and Deng ⁵⁸	China	Series of cases
⁄ao et al ⁵⁹	China	Series of cases
/e ⁶⁰	China	Series of cases
∕u et al ⁶¹	China	Series of cases
Zhang ⁶²	China	Series of cases
Zhang ⁶³	Sudan	Series of cases
Zhang ⁶⁴	China	Series of cases
Zhang ⁶⁵	China	Series of cases
Zhang and Lin ⁶⁶	China	Series of cases
Zhang ⁶⁷	China	Nonrandomized controlled study
Zhang and Zhang ⁶⁸	China	Series of cases
Zhou ⁶⁹	China	Nonrandomized controlled study
'hou and Xu ⁷⁰	China	Series of cases
'hou and Han ⁷¹	China	Series of cases

other 2 were of low quality (C). 16,18 Four studies were carried out in China 12,16-18 and 3 in Italy¹³⁻¹⁵ (Table 2). Six studies compared moxibustion (alone or in association with acupuncture and/or postural measures) with no treatment, or with postural measures, 12-14,16-18 whereas 1 compared moxibustion with acupuncture (Table 3).15

To compare moxibustion (alone or in association with acupuncture or postural measures) with mere observation or postural measures, an analysis was made of the percentage of cephalic presentations recorded at the end of the treatment period. This was done combining 6 studies with a total of 1087 pregnant women, 12-14,16-18 with a high degree of heterogeneity and a rate of cephalic version in the moxibustion group of 72.5% vs 53.2% in the control

group (RR, 1.36; 95% CI, 1.17-1.58) (Figure 2). The number needed to treat (NNT) was 5 with a 95% CI between 4 and 7. The funnel plot reflected a symmetrical distribution of the RR for each of the studies in relation to its internal variability of the outcome result.

The only analysis by subgroups that isolated a subset of studies with no significant heterogeneity was that performed with women with a gestational age of 32 weeks or greater (Figure 3); in this case, 4 studies were grouped 12-14,17 with 635 subjects (in 1 of the studies, 17 although women with a lower gestational age were included, as the data were presented in stratified form, it was possible to extract the information on the results for the subgroup of women with a gestational age of ≥32 weeks), and there was seen to be a significant difference between the moxibustion and the control groups (RR, 1.31; 95% CI, 1.03-1.66; NNT of 6, 4-12).

None of the other analyses by subgroups (depending on the study context and overall quality) enabled homogeneous subgroups to be identified. Analysis by subgroups, depending on geographic location of the studies, revealed a RR that was higher for the studies carried out in Asia (RR, 1.40; 95% CI, 1.16-1.68) than those performed in Europe (RR, 1.21; 95% CI, 0.81–1.80). The analysis by subgroups with respect to the overall quality of the studies (with heterogeneity) revealed a higher RR in the low-quality studies (RR, 1.47; 95% CI, 1.07-2.03) than in those classed as moderate quality (RR, 1.30; 95% CI, 1.06–1.59).

To compare moxibustion and acupuncture, an analysis was made of the outcome result "cephalic presentation" from the only study available in this respect,15 which reported a rate of version to cephalic presentation of 80% in the moxibustion group vs 28% in the acupuncture group (RR, 4.0; 95% CI, 1.13-14.17), without specifying whether the measurements were determined after treatment or at birth.

In terms of safety, no statistically significant differences were found in the comparison of moxibustion with any other technique, with respect to rates of caesarean section, premature births, Apgar score less than 7 at 5 minutes, operative deliveries (by vacuum or forceps), or premature rupture of the membranes. Nevertheless, there was found to be a tendency for a lower number of complications in the treatment group. Only 1 study reported statistically significant differences in favor of a reduced use of oxytocin in the experimental group (Figure 4).

Comment

In this review, moxibustion at point BL67, applied as a technique for achieving cephalic version, is found to be more than 30% better than nontreatment or postural methods; it is necessary to treat 4-7 pregnant women with a fetus in nonvertex presentation to achieve an additional version, which represents a clinically significant effect. With respect to

TABLE 2 General chara	cteristics of the	studies included and	methodological quali	ity						
					Met	nodolog	gical q	uality ^a		
Study	Number randomized	Experimental technique	Controls	Moment at which the outcome variable was measured	Randomization	Concealment	Blinding	Exclusions	Baseline comparability	Overall quality
Cardini and Weixin ¹²	260	Moxibustion at BL67 bilateral, once daily (first 87 women) or twice daily (next 43 women), for 30 minutes (n = 130). Technique self-applied at home.	Observation (n = 130)	After treatment	A	В	В	A	A	В
Cardini et al ¹³	123	Moxibustion at BL67 bilateral, twice daily, for 1 or 2 wks, for 30 minutes each time. Technique self-applied at home $^{\rm b}$ (n = 65).	Observation ^b (n = 58)	After treatment	A	А	В	А	A	В
Chen ¹⁸	150	Moxibustion at BL67 bilateral, once daily, for 40 min. Between 5 and 15 sessions ^c (n = 80).	Knee-to-chest posture $^{\rm c}$ (n = 70)	After treatment	В	В	В	С	А	С
Lin et al ¹⁶	122	Moxibustion at BL67 bilateral, twice daily for 30 min plus knee-to-chest position after each session for 10-20 min. Technique performed at the hospital (n = 63).	Knee-to-chest posture (n = 59)	After treatment	В	В	В	С	Α	C
Neri et al ¹⁴	240	Moxibustion at BL67 bilateral, for 20 min, plus acupuncture, twice weekly for 2 wks. Technique performed at the hospital ^d (n = 112).	Observation (n = 114)	After treatment	А	А	В	А	А	В
Neri et al ¹⁵	26	Moxibustion at BL67 twice weekly, for 20 min each time, for 1 wk. Technique performed at the hospital ^e (n = 15).	Bilateral acupuncture at BL67, for 20 min, twice weekly for 1 wk (n = 10)	Not specified	А	В	В	Α	Α	В
Yang ¹⁷	206	Moxibustion at BL67 twice daily, for 15-20 min combined with knee-to-chest posture, for 7 d $^{\rm f}$ (n = 103).	Knee-to-chest posture (n = 103)	After treatment	В	В	В	A	А	В

a Randomization included: A, adequate; B, unclear; C, inadequate. Concealment included: A, adequate; B, unclear; C, inadequate. Blinding included: A, assessor and analyst blinded; B, not stated. Exclusions included: A, adequately reported; B, partially reported; C, not reported. Baseline comparability included: A, comparable; B, unclear; C, noncomparable. Overall quality included: A, high quality; B, moderate quality; C, low quality; b The outcome variable is the rate of cephalic presentations at week 35 because no data are available for the 21 women who were treated by external cephalic version after moxibustion treatment; certain the outcome variable is the rate of cephalic presentations after treatment because in both groups moxibustion was used as the cointervention to achieve reversion to the cephalic position after completing the treatment; ⁴ In the case of 1 woman in the experimental group, version to cephalic presentation took place after the end-of-treatment evaluation had been made; ⁸ It is not stated whether the moment of measurement is after the treatment or at delivery; [†] Rate of cephalic presentation after treatment.

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.

safety, moxibustion, either alone or associated with postural methods, presents no more problems (cesarean section, preterm delivery, premature rupture of membranes, operative delivery by vacuum or forceps, or the use of oxytocin in vaginal deliveries) than do nontreatment or postural methods. In the case of the use of oxytocin, the differences found are statistically significant.

The moment of observation of version to a cephalic position was that of the conclusion of treatment or an equivalent period for the control group because subsequent cointerventions were performed in some of the studies included; moreover, there existed the probability of spontaneous version up to the moment of delivery.¹⁹ This variable is objective and clinically relevant.

It has been hypothesized that heat stimulus on the BL67 acupuncture point might produce adrenocortical stimulation, with a consequent increase in placentary estrogens, and hence a greater sensitivity of the miometrium, and changes in the relationship between the F and E prostaglandins, accompanied by a reduction in type E prostaglandins, whereas type F prostaglandins would remain unchanged; at the same time, there would occur an increase in uterine contractility, which would lead to a stimulation of foetal movements and a higher probability of version of the fetus. 12,20

FIGURE 2
Risk ratio estimates and pooled random risk ratios at end of intervention period

	Moxibus	stion	Contr	ol		Risk Ratio		Risk	Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% C		M-H, Rand	dom, 95% CI	
Cardini ¹²	98	130	62	130	18.6%	1.58 [1.29-1.94]				
Cardini et al13	22	65	21	58	7.2%	0.93 [0.58-1.51]				
Chen ¹⁸	73	80	50	70	21.4%	1.28 [1.09-1.50]				
Lin et al16	58	63	31	59	15.8%	1.75 [1.36-2.26]				
Neri et al14	60	112	43	114	13.7%	1.42 [1.06-1.90]				
Yang ¹⁷	90	103	77	103	23.3%	1.17 [1.02-1.34]			-	
Total (95% CI)		553		534	100.0%	1.36 [1.17-1.58]			•	
Total events	401		284							
Heterogeneity: Tau ² = Test for overall effect:				P = .02)	; I ² = 64%		0.01 0.1	Favore control	1 10	100
			,					Favors control	Favors moxibustion	

Risk ratio estimates and pooled random risk ratios of randomized controlled trials of moxibustion to correct nonvertex presentation at the conclusion of the intervention period are shown.

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.

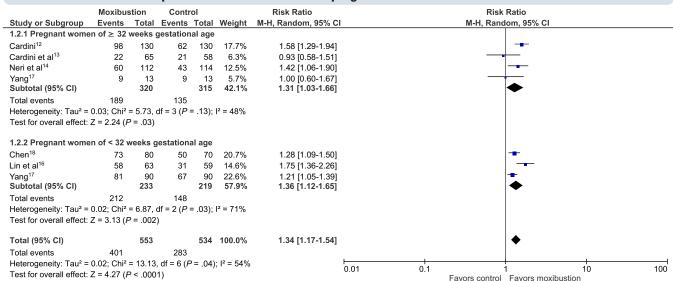
Among the strengths of the present review is the fact that the search is extended without any language limitations, including an examination of Chinese databases, something that had not been done in prior reviews. Thus, a higher number of randomized clinical trials were extracted. The protocols were not standardised, but on the other hand, the same BL67 point was used in every study. The effect size (RR) was the same sign in every study except 1, which had to be in-

terrupted because of noncompliance with the treatment protocol by the medical professionals.¹³

The essays included have an overall moderate degree of internal validity, except with regard to baseline comparability, which was level A in every case. Although the randomization process was not adequate in every study, the baseline comparability for the variables measured was acceptable. In principle, the blinding of the medical

staff in this type of study appears very complicated; although this could have been done for the mother, the result outcome is sufficiently objective for this not to be a problem. Although there do not exist mechanisms by which moxibustion intervention can be simulated, it is unfortunate that there was no study included with a control group given a sham technique because this would have made it possible to examine the specificity of the

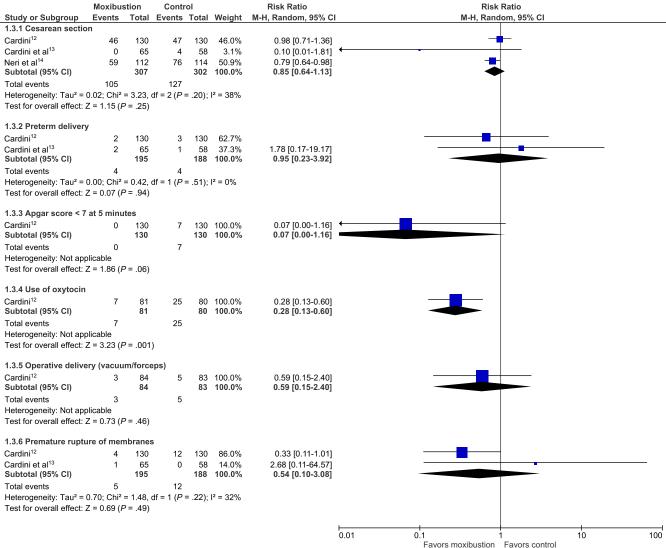
FIGURE 3
Risk ratio estimates and pooled random risk ratios in pregnant women



Risk ratio estimates and pooled random risk ratios of randomized controlled trials of moxibustion to correct nonvertex presentation in pregnant women of <32 weeks' gestational age and in those with a gestational age of \ge 32 weeks are shown.

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.





Risk ratio estimates and pooled random risk ratios of randomized controlled trials on the safety of moxibustion for the correction of nonvertex presentation are shown.

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.

treatment at the BL67 point, as has recently been published in a study protocol.²¹

Another of the limitations of the studies reviewed is the lack of analysis by intention to treat in most cases, although the low number of dropouts means that a sensitivity analysis was unnecessary.

There is no evidence of any publication bias, judging by the symmetry found in the funnel plots, although this possibility cannot be totally rejected, and it should be recognized as a potential limitation. The heterogeneity apparent in the metaanalysis may be due to a selection bias of the clinical, geographic, cultural, and anthropometric characteristics; in fact, when we compared moxibustion alone or associated with another treatment vs no treatment or solely postural measures and analysed by subgroups, on the basis of the country in which the study was carried out, there was found to be a surprising difference between the proportion of cephalic versions obtained in each subgroup: 46.3%

of the studies performed in Europe vs 84.8% of those from Asia, although the subgroups continue to present significant levels of heterogeneity.

There may be noncontrolled explicative variables that influence the risk involved in cephalic version, such as age, parity, week of gestational age in which the intervention is performed, and volume of amniotic fluid or the situation of the placenta. There are clear differences among the studies as concerns the frequency of application of the technique

TABLE 3 Full details o	f the characteristics of the studies included							
STUDY	CARDINI AND WEIXIN ¹²							
Methods	Details of randomization: randomized controlled study. A computer program was used to generate the allocation sequence with sealed envelopes containing the group lists (in groups of 10).							
	Blinding: neither the women nor the medical practitioner were blinded to the treatment, and it is unclear whether the assessor or the analyst were blinded.							
	Exclusions or dropouts during the study: 9 women in the experimental group abandoned treatment (reasons: 3 risks of preterm delivery [increased rate of contractions, abandonment on obstetrician's advice], 1 because of noncompliance, and 5 for unknown reasons). These 9 persons maintained a breech presentation and are included in the analysis.							
	Losses during follow-up: none							
	Type of analysis reported: ITT (data were presented for all the randomized women)							
	Important baseline imbalances in prognosis factors: none							
Participants	Location of study: China							
	Period of study: April 1995 to August 1996							
	Funding: nongovernmental organization and European Community							
	Setting: the Women's Hospital and the Jiujiang Women's and Children's Hospital, in the province of Jiangxi (China)							
	Total number of randomized subjects: 260							
	Mean age: treatment group 25.5 y (± 2.5), control group 25.2 y (± 3.0)							
	Parity: primiparous							
	Single fetus: yes							
	Gestational wk: 33							
	Presentation: breech (diagnosed by echography)							
	Other criteria for inclusion: normal fetal biometry (biparietal and abdominal circumference between percentiles 10 and 90). Informed consent.							
	Criteria for exclusion: pelvic anomalies, previous uterine surgery, pregnancy-related illness, fetal malformation, twin pregnancy, fibroma > 4 cm, uterine malformation, risk of premature delivery (hypercontractility, Bishop 4 or greater, tocolysis during pregnancy.							
Treatment	Treatment group: moxibustion							
	Number of women allocated to this group: 130. First 87 allocated: moxibustion once daily at BL67 for 1 wk. The next 43 women: moxibustion, twice daily for 7 d.							
	Points used and technique: BL67 bilateral (once or twice daily for 30 min each time, 15 min each side). Application of the treatment in the evening was recommended but at the same time, choosing a time when the treatment would not be interrupted.							
	Who applied the technique: self-applied, at home, after an instruction session at the hospital.							
	Criteria for halting the treatment: change to cephalic presentation evidenced by clinical symptoms before d 7; abdominal pain or any other adverse effect.							
	Criteria for continuing moxibustion 1 more week: nonvertex presentation, no adverse effects and agreement by the woman to continue.							
	Control group: observation							
	Number of women allocated to this group: 130							
	Cointerventions in both groups: the women in both groups were offered external cephalic version if the fetus remained in a breech presentation at wk 35.							
Vas. Correction of no	nvertex presentation with moxibustion. Am J Obstet Gynecol 2009. (continued)							

Full details of the characteristics of the studies included (continued)

STUDY

CARDINI AND WEIXIN¹² (continued)

Results

Primary: rate of cephalic presentation at wk 35, rate of cephalic presentation at delivery and fetal motor activity (recorded in a diary)

Cephalic presentation (evidenced by echography) at wk 35 [2 wks after the first visit] 98/130 (75.4%) in the treatment group vs 62/130 (47.4%) in the control group (P < .01; RR, 1.58; 95% Cl, 1.29-1.94). Of the 98 versions in the experimental group. 82 were in the first week and 16 in the second.

External cephalic version (ECV): only 1 woman in the treatment group accepted ECV, but version was not achieved; 24 subjects in the control group accepted ECV, and it was achieved in 19 cases.

Cephalic presentation at term (including ECV): 98/130 (75.4%) vs 81/130 (62.3%) (P = .02; RR, 1.21; 95% CI, 1.02-1.43).

Cephalic presentation at term (excluding ECV): 98/129 (76.0%) vs 62/106 (58.5) (P = .004; RR, 1.30; 95% CI, 1.08-1.57).

Comparison of rates of version at wk 35 and at term: In both groups, the versions produced were maintained until term (except, logically, in the case of the ECV).

Fetal motor activity: During the first week of treatment, fetal movements were recorded for 1 h daily (preferably between 5 and 8 PM. Seven days: 48.45 vs 35.35. Intergroup difference: 13.08; 95% CI, 10.56-15.60; P < .001).

Secondary: compliance with treatment; adverse events; evaluation of the effectiveness of the 2 different doses of moxibustion (ie, once or twice daily); number of ECV after treatment; number and causes of cesareans, spontaneous, or induced deliveries; Apgar score at 5 min.

Differences between moxibustion once or twice daily: no baseline differences were found between the groups concerning the quantity of amniotic fluid during wk 33, frequency of stretching or leg bending during wk 33, location of the placenta, neonatal sex, compliance with treatment or adverse effects attributable to the treatment.

Cephalic presentation at the end of the first week: 34/43 (79.1%) in the twice-daily group vs 48/87 (55.2%) in the once-daily group (P = .007; RR, 1.43; 95% Cl, 1.12-1.83).

Cephalic presentation at the end of the second week (confirmed by echography): 35/43 (81.4%) in the twice-daily group vs 63/87 (72.4%) in the once-daily group. No significant differences. The same percentages were recorded at term.

Cesareans: 46 (35.4%) in the treatment group (20 in cephalic presentation [14 fetopelvic disproportion, 3 postterm pregnancy, 3 fetal distress] and 26 in breech presentation [10 because of premature rupture of the membranes after wk 37, 2 large fetus, 1 fetal distress, 2 oligohydramnios, 11 nonspecific]). Control group: 47 (36.2%) (21 in cephalic presentation [11 fetopelvic disproportion [1 of whom with oligohydramnios], 4 fetal distress [1 in a woman with toxemia], 2 cases of sacral rotation of the occiput, 1 of placental insufficiency, 1 of maternal toxemia, 1 of premature rupture of the membranes, 1 in deep transverse arrest] and 26 in breech presentation [8 cases because of premature rupture of the membranes [with 1 of these cases presenting, additionally, cord prolapse], 3 cases with oligohydramnios, 2 cases of fetal distress, 1 because of the large size of the fetus, 12 for nonspecific causes). In both groups, when the cesarean was performed, 1 case of bicorne uterus, not previously diagnosed, was detected (these 2 cases were retained in the subsequent analysis, despite their circumstance being, a priori, cause for exclusion.

Vaginal deliveries: The only difference was in the use of oxytocin: 7/81 (8.6%) in the treatment group vs 25/80 (31.3%) in the control group (P < .001; RR, 1.33; 95% Cl, 1.13-1.56).

Treatment group: 2 vacuum treatment and 1 forceps vs control group: 2 vacuum treatment and 3 forceps

Apgar 5 min less than 7: treatment group 0/130 vs control group 7/130 (P = .006)

Adverse effects: 3 cases in the treatment group: increased rate of contractions (withdrew from the study, on medical advice)

Adverse events:

None in the treatment group during the treatment. After treatment, there were 2 premature deliveries (at 37 wks), 1 of which was preceded by the premature rupture of the membranes. Premature rupture of the membranes: 4.

Control group: 3 premature deliveries (at 34, 35, and 37 wks, the latter being preceded by placental detachment with fetal distress); 1 intrauterine fetal death (reduced intrauterine growth and oligoamnios, spontaneous delivery at 38 wks; growth within normal limits according to echographic examination at wk 35). Premature rupture of the membranes: 12.

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.

Full details of the characteristics of the studies included (continued)

STUDY

CARDINI ET AL13

Methods

Details of randomization: randomized controlled study. A computer program was used to generate the allocation sequence, with sealed envelopes containing the group lists.

Blinding: Neither the pregnant woman nor the medical practitioner was blinded to the treatment. The assessor was blinded.

Exclusions or dropouts during the study: 14 women abandoned the treatment.

Losses during follow-up: 1 loss from the control group (2 women were included in the analysis of the primary outcome measure but not in that of the secondary outcome measure because 1 woman abandoned the study on becoming aware of her group allocation and was lost during follow-up; in the case of the second woman, it was discovered [at the moment of delivery] that she had a bicorne uterus. For the purposes of the ITT analysis, the data lost from the first of these women were assumed to be positive [version to cephalic presentation].

Type of analysis reported: ITT. An intermediate analysis was scheduled when 40% of the sample had been achieved if any clear-cut result became apparent.

Important baseline imbalances in prognosis factors: the 2 groups were comparable, with no significant differences in the baseline evaluation (maternal age and body weight, educational background, family history of breech presentation, extension of fetal legs, placental location, index of amniotic fluid) or in the delivery (neonatal sex, weight, length, skull circumference, looping of the umbilical cord).

Participants

Location of study: Italy

Period of study: March 2001-February 2003

Funding: University of Turin

Setting: 6 obstetrics services in public hospitals in northern Italy

Total number of randomized subjects: 123

Mean age: 31 y [mean/median age of treatment group? Median age in the control group 26.2]

Parity: primiparous

Single fetus: yes

Gestational week: 32-33 wks plus 3 d (confirmed by echography)

Presentation: breech (diagnosed by echography during the previous 24 h)

Other criteria for inclusion: normal fetal biometry

Criteria for exclusion: nonacceptance of randomization, pelvic anomalies, previous uterine surgery, fetal malformation, uterine malformation, fibroma > 4 cm, twin pregnancy, previous or current tocolysis, other pregnancy-related complications.

Treatment

Treatment group: moxibustion

Number of women allocated to this group: 65

Points used and technique: BL67 bilateral (twice daily, 30 min each time, 15 min each side) for 1 or 2 wks, with the woman comfortably seated or semiseated. Stimulation up to the threshold tolerated (hyperemia without causing any burning). No indication as to the time of day when the technique should be performed. Recommended that it should be performed when the woman was relaxed and when no interruptions would occur.

Who applies the technique: self-applied or by a companion, having received instruction on the first day. Application of the technique at home (except the first time).

Criteria for halting the treatment: change to cephalic presentation evidenced by clinical symptoms before d 7; collateral effects (real or presumed) and adverse events associated with the treatment.

Criteria for continuing moxibustion 1 more week: nonvertex presentation at the intermediate evaluation, no adverse effects, and agreement by the woman to continue treatment.

Control group: observation

Number of pregnant women allocated to this group: 58

Cointerventions in both groups: at clinics at which external cephalic version was carried out, the women in both groups were offered external cephalic version if the fetus remained in a breech presentation after wk 37. Twenty-one of the women in this situation after wk 37 requested ECV, which was successful in 12 cases.

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.

Full details of the characteristics of the studies included (continued)

STUDY

CARDINI ET AL¹³ (continued)

Primary: rate of cephalic presentation at wk 35 (2 wks after randomization) evaluated by echography Results

> Cephalic presentation (evidenced by echography) at wk 35 [2 wks after the first visit] 22/65 (34%) in the treatment group vs 21/58 (36%) in the control group (RR, 0.95; 95% Cl, 0.59-1.5).

Secondary: rate of cephalic presentation at birth and fetal motor activity (recorded in a diary: for 1 h, at 15 min after moxibustion, twice daily, during the first week after randomization), compliance with treatment, adverse events.

Cephalic presentation at term (including ECV): 34/65 (52%) vs 29/57 (51%) [12 cases by ECV and 7 cases by spontaneous version]. No information is available on the number of ECVs in each of the groups, so it was impossible to calculate the proportion of cephalic presentations at term excluding the ECVs.

Fetal motor activity: mean 254 in the moxibustion group vs 220 in the control group (P = .4), median 209 and 121, respectively.

Compliance with treatment (in the moxibustion group, evaluated by the assessors): good 45/65 (69%); acceptable 13/65 (20%); poor 7/65 (11%); 14/65 (22%) women interrupted the treatment, either temporarily or definitively.

Other comparisons:

Fetuses with legs extended in the first (baseline) echography presented a lower percentage of cephalic version than did the fetuses with flexed legs (independently of the group they were assigned to): 18/67 (27%) vs 22/48 (46%).

The median age of the women recruited was 31 y. The women aged younger than 31 y obtained better results than did those in the older age group (independently of the group they were assigned to): 25/56 (45%) cephalic versions at wk 35 among the younger women vs 17/64 (27%) among the older ones.

The cultural level influenced the rate of versions at wk 35: among the women with a low level of cultural background, the rate was 14/30 (47%) vs 26/89 (29%) in those of a higher level (independently of the group they were assigned to).

Adverse effects:

27/65 of the women in the moxibustion group complained that the treatment was unpleasant, associating it with physical disorders: normally, an unpleasant smell, with or without nausea, and throat problems (14 cases), abdominal pain because of contractions (11 cases) and other, less frequent, problems; 14/65 (22%) of the women interrupted the treatment, temporarily or definitively, because of these effects.

Adverse events:

Moxibustion group:

2 preterm births (34 wks), the first because of premature rupture of the membranes after 5 d treatment; the second case was because of uterine contractions on the 10th day of treatment, after sexual activity, and preceded by bleeding and suspected rupture of the membranes.

1 case of bleeding at wk 37, after ECV, probably because of excessive pressure on the rear of the placenta.

Control group:

No cases of premature rupture of the membranes in the control group. 1 case of delivery at wk 37 because of marginal placental abruption.

The 4 cases described were delivered by cesarean section, and these newborn infants did not suffer any adverse consequences.

Notes

The study was interrupted at the decision of most of the participating clinics when 46% of the precalculated sample had been recruited (123/260), so the statistical power of the analysis may be affected. The reasons for interrupting this study were the low degree of compliance with the treatment and the interruptions to it; in consequence, the investigators were led to doubt the suitability of this study for evaluating the effectiveness of the technique.

STUDY

CHEN18

Methods

Details of randomization: randomized controlled study (the abstract states that the subjects were randomized into 2 groups, whereas according to the text, the women were assigned by the order in which they were seen at the clinic, in which case the study should be classified as semirandomized).

Blinding: not stated

Exclusions or dropouts during the study: not stated

Losses during follow-up: not stated

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.

STUDY	CHEN ¹⁸ (continued)						
Methods	Type of analysis reported: it is not stated that the analysis was by ITT, but there was a complete follow-up of all the randomized subjects, and the data for all of them were available.						
	Important baseline imbalances in prognosis factors: the 2 groups were comparable, with no significant differences in the baseline evaluation (maternal age and weight, gestation time, parity).						
Participants	Location of study: China						
	Period of study: 2000						
	Funding: not stated						
	Setting: walk-in clinics. Luo He Higher College of Professional Healthcare Training.						
	Total number of randomized pregnancies: 150						
	Mean age/range: 22-36 y (age range in treatment group 22-36 y; control group 22-35 y)						
	Parity: primiparous and multiparous. Experimental group: 54 primiparous and 26 multiparous. Control group: 49 primiparous and 21 multiparous.						
	Single fetus: yes						
	Gestational week: 28-36 wks (not specified whether gestational age was confirmed by echography). Moxibustion group 28-30 wks (21 cases), 31-32 wks (37 cases), 33-34 wks (19 cases), and 35-36 wks (3 cases). Control group 28-30 wk (20 cases), 31-32 wks (31 cases), 33-34 wks (17 cases), and 35-36 wks (2 cases).						
	Presentation: breech, oblique, transverse, and podalic (not specified whether presentation was confirmed by echography). Moxibustio group: 56 breech, 18 transverse, 4 oblique, and 2 podalic. Control group 49 breech, 16 transverse, 4 oblique, and 1 podalic.						
	Other criteria for inclusion: not stated						
	Criteria for exclusion: not stated						
reatment	Treatment group: moxibustion plus knee-to-chest posture						
	Number of women allocated to this group: 80						
	Points used and technique: BL67 bilateral (once daily, 20 min at each point) with the woman comfortably seated, knees flexed. She was previously recommended to drink 1000 mL of hot water with brown sugar before carrying out the moxibustion session. Five sessions constituted a treatment cycle (range, 5-15 sessions).						
	Who applied the technique: not stated						
	Criteria for halting the treatment: not stated						
	Criteria for continuing moxibustion 1 more week: not stated						
	Control group: knee-to-chest posture once daily (time not stated). Five sessions constituted a treatment cycle (range, 10 20 sessions).						
	Number of women allocated to this group: 70						
	Cointerventions in both groups: The women observed to present cephalic version (whether in the experimental or controgroup) were given moxibustion treatment if the cephalic presentation was reversed.						
Results	Primary: rate of cephalic presentation after treatment						
	Cephalic presentation after a maximum of 15 moxibustion sessions or 20 knee-to-chest postural sessions 73/80 (91.3% in the treatment group vs 50/70 (71.4%) in the control group (RR, 1.28; 95% CI, 1.09-1.50).						
	Secondary: rate of cephalic presentation at delivery (the women who responded to moxibustion or to postural methods were followed up until delivery, and in the case of reversion, moxibustion was applied, for both groups).						
	Cephalic presentation at term (including the women given secondary moxibustion, included in the control group): 73/80 (91.3%) vs 50/70 (71.4%) [5 cases in the experimental group were given moxibustion treatment a second time after reversion of the cephalic position, and version was once again achieved; in the control group, it was necessary to repea moxibustion in 11 cases, for all of whom cephalic version was once again achieved].						
	Mean number of sessions necessary to achieve correction: control group 12.80 (SD, 2.70); moxibustion group 6.99 (SD, 2.97) [control vs moxibustion: difference of the means 5.81; 95% Cl, 4.77-6.86].						
	Adverse effects: not stated						
	Adverse events: not stated						

STUDY	LIN ET AL ¹⁶					
Notes	In cases of insufficiency of Qi and blood, moxa was added at 36E and 23V. In cases of Qi stagnation, dispersion at 3H an 18V (acupuncture, without needle retention).					
Methods	Details of randomization: randomized controlled study, although the allocation method is unclear					
	Blinding: Neither the pregnant woman nor the medical practitioner was blinded to the treatment, and it is not stated whether the assessor and the analyst were blinded.					
	Exclusions or dropouts during the study: not stated					
	Losses during follow-up: not stated					
	Type of analysis reported: It is not stated that the analysis was by ITT, but there was a complete follow-up of all the randomized subjects, and the data for all of them were available.					
	Important baseline imbalances in prognosis factors: The 2 groups were comparable, with no significant differences by baseline evaluation (maternal age and weight, gestation time, parity).					
Participants	Location of study: China					
	Period of study: 2000-2002					
	Funding: not stated					
	Setting: rehabilitation department of the Shi Yan People's Hospital, province of Hu Bei					
	Total number of randomized subjects: 122					
	Mean age/range: 21-38 (age range treatment group 21-38 y; control group 21-37 y)					
	Parity: primiparous and multiparous. Treatment group: 47 primiparous and 16 multiparous. Control group: 44 primiparound 15 multiparous					
	Single fetus: yes					
	Gestational week: 30-37 wks (not specified whether gestational age was confirmed by echography). Treatment group: 30-33 wks (49 cases), 34-37 wks (14 cases). Control group: 30-33 wks (47 cases), 34-37 wks (12 cases)					
	Presentation: breech (presentation confirmed by echography and gynecological examination)					
	Other criteria for inclusion: not stated					
	Criteria for exclusion: organic illness, fetal malformation, uterine malformation, cephalopelvic disproportion					
Treatment	Treatment group: moxibustion plus knee-to-chest posture					
	Number of women allocated to this group: 63					
	Points used and technique: BL67 bilateral (twice daily, 15 min at each point) with the woman comfortably lying down or seated, wearing loose clothing. After moxibustion, she was instructed to remain for 10-20 min in a knee-to-chest posture Every 2 d, the fetal position was examined (not stated whether clinical or echographic examination). Number of sessions not stated					
	Who applied the technique: not stated, but the technique was performed within the hospital					
	Criteria for halting the treatment: cephalic presentation maintained or version not achieved					
	Criteria for continuing moxibustion: persistence of nonvertex presentation after 2 d treatment.					
	Control group: knee-to-chest posture twice daily for 10-20 min. Every 2 d, the fetal position was examined (not state whether clinical or echographic examination). Maximum number of sessions: not stated					
	Number of women allocated to this group: 59					
	Cointerventions in both groups: not stated					
Results	Primary: rate of cephalic presentation after treatment and number of sessions needed to achieve correction					
	Cephalic presentation (not stated whether presentation was confirmed by echography): 58/63 (92.1%) in the treatment group vs 31/59 (52.5%) in the control group (RR, 1.75; 95% Cl, 1.36-2.26)					
	Mean number of days of treatment needed to achieve correction: moxibustion group 3.6 vs 12.8 for the control group					
	Adverse effects: not stated					
	Adverse events: not stated					

Full details of the characteristics of the studies included (continued)

STUDY NERI ET AL14

Methods

Details of randomization: randomized controlled study. A computer program was used to generate the allocation sequence, with central randomization.

Blinding: neither the pregnant woman nor the medical practitioner was blinded to the treatment, and it is unclear whether the assessor and the analyst were blinded.

Exclusions or dropouts during the study: 8 women in the experimental group withdrew from the study (motives: 5 because of uterine contractions observed by the obstetrician, 2 because of the appearance of arterial hypertension, and 1 because of lack of compliance). Six women in the control group withdrew from the study (motives: 2 because of risk of premature delivery, and 4 refused to be assigned to the observation group).

Losses during follow-up: none

Type of analysis reported: The data for the women who withdrew from the study were not included in the analysis, so the ITT analysis was not performed.

Important baseline imbalances in prognosis factors: none

Participants

Location of study: Italy

Period of study: May 2000-June 2002

Funding: not stated

Setting: Departments of Obstetrics and Gynecology at two Italian universities (Modena-Reggio Emilia and Turin)

Total number of randomized subjects: 240

Mean age: not stated (treatment group 31.7 [\pm 4.7], control group 30.1 [\pm 3.6])

Parity: primiparous and multiparous; proportion of primiparous 48.3% in the treatment group vs 59.8% in the control group

Single fetus: yes

Gestational week: 33-35 wks (estimated by echography before wk 12). In the treatment group, the mean gestational age (SD) was 33.5 (\pm 0.6) wks, and in the control group, 33.7 (\pm 0.7) wks.

Presentation: breech (confirmed by echography 24 h before randomization)

Other criteria for inclusion: white race

Criteria for exclusion: gestational age greater than 35 wks, previous uterine surgery (including cesarean), uterine malformation, risk of premature delivery (premature uterine contractions and/or cervical shortening or dilation with a Bishop index > 4), twin pregnancy, fetal malformation or chromosome anomalies, abnormal fetal biometry (biparietal or abdominal diameter below the 10th percentile or above the 90th percentile), maternal kidney or heart disease, transverse or oblique presentation.

Treatment

Treatment group: acupuncture followed by moxibustion

Number of women allocated to this group: 120

Points used and technique: bilateral puncture at BL67 with intermediate manipulation until bilateral Degi was achieved, following which the needles were held in position for 20 min with no further manipulation. After withdrawing the needles, moxibustion was applied for 20 min (alternating every \leq 2 min if the heat caused discomfort). The women were recommended to sit comfortably, with belt unfastened and wearing loose clothing. The session could be repeated twice weekly for 2 wks (maximum of 2 wks). After the first session, a nonstress test was performed for 30 min, during which the maternal arterial pressure and fetal pulse rate were monitored.

Who applied the technique: experienced, qualified acupuncturists, at the hospital

Criteria for halting the treatment: change to cephalic presentation, confirmed by symptoms evaluated by echography

Criteria for continuing the treatment: nonvertex presentation evaluated by echography before each session

Control group: observation

Number of women allocated to this group: 120

Cointerventions in both groups: external cephalic version was not offered. The women in both groups received the same routine attention from their obstetricians.

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.

STUDY	NERI ET AL ¹⁴ (continued)							
Results	Primary: rate of cephalic presentation after treatment							
	Cephalic presentation at birth: 61/112 (54.5%) in the treatment group vs 43/114 (37.7%) in the control group (RR, 1.44; 95% Cl, 1.08-1.93)							
	Secondary: rate of cesareans, cephalic presentation after treatment (2 wks), adverse events.							
	Cephalic presentation after treatment (2 wks): 60/112 (53.6%) in the treatment group vs 43/114 (37.7%) in the control group (RR, 1.42; 95% Cl, 1.06-1.90)							
	Rate of cesareans: the number of cesareans significantly lower in the treatment group (52.3%) vs the control group (66.7%) (RR, 0.79; 95% Cl, 0.64-0.98)							
	Other comparisons:							
	In both groups (except 1 person), the fetuses remaining in podalic presentation were delivered by programmed cesarean during wks 38-39 of gestation. In consequence, the gestational age at delivery varied between the podalic and cephalic presentations, both in the observation group (38.6 \pm 0.8 vs 40.0 \pm 0.9, P < .02) and treatment group (38.7 \pm 0.4 vs 39.8 \pm 0.8, P < .02)							
	The same occurred with the neonate's body weight, which varied between the podalic and cephalic presentations, for both groups (control group 3059 \pm 363 vs 3331 \pm 403 g, P < .02; treatment group 3232 \pm 293 vs 3349 \pm 327 g, P < .05)							
	Adverse effects: no fetal or maternal cardiovascular changes or premature uterine contractions were detected.							
	Adverse events: no							
STUDY	NERI ET AL ¹⁵							
Methods	Details of randomization: open, randomized controlled study, performed in Italy. Funding details not stated. No data provided on the randomization method applied.							
	Blinding: neither the pregnant woman nor the medical practitioner was blinded to the treatment, and it is unclear whether the assessor and the analyst were blinded.							
	Exclusions or dropouts during the study: 2 women did not want acupuncture and refused treatment. Two women were excluded (1 because of previous uterine surgery, 1 because of oligoamnios). Two women were excluded from the analysis because they did not meet the baseline cardiotocographic criteria.							
	Losses during follow-up: none							
	Type of analysis reported: the data for the women who withdrew from the study were not included in the analysis, and so the ITT analysis was not performed.							
	Important baseline imbalances in prognosis factors: none.							
Participants	Location of study: Italy							
	Period of study: not stated							
	Funding: not stated							
	Setting: acupuncture clinic at the Department of Obstetrics and Gynecology at the University of Modena-Reggio Emilia							
	Total number of randomized subjects: 41							
	Mean age: not stated. Range 20-40 y [moxibustion group 34.1 (\pm 5.6); moxibustion plus acupuncture group 32.8 (\pm 4.8) acupuncture group 33.4 (\pm 7.4) y].							
	Parity: primiparous							
	Single fetus: yes							
	Gestational wks: 33-36. Mean gestational age (SD) in the moxibustion group 34.1 wks (\pm 0.7), in the moxibustion + acupuncture group 34.1 wks (\pm 0.9), and in the acupuncture group 35.2 wks (\pm 7.2)							
	Presentation: breech							
	Other criteria for inclusion: not stated							
	Criteria for exclusion: previous uterine surgery, twin pregnancy, oligoamnios, maternal heart-kidney disease, fetal malformation or chromosome disorder, transverse or oblique presentation							

TABLE 3 Full details of the characteristics of the studies included (continued) STUDY NERI ET AL¹⁵ (continued) Treatment group: moxibustion Treatment Number of women allocated to this group: 16 Points used and technique: bilateral moxibustion at BL67 for 20 min, twice weekly for 1 wk. During all sessions, the nonstress test was applied from 20 min before application of the stimulus until 20 min after its conclusion, and the fetal pulse rate, fetal movements, and maternal uterine contractions were monitored. Who applied the technique: not stated, although it was performed at the hospital Criteria for halting the treatment: not stated. Criteria for continuing the treatment: not stated. Control group 1: moxibustion plus acupuncture Number of women allocated to this group: 15 Points used and technique: moxibustion plus bilateral acupuncture at BL67 for 20 min, twice weekly for 1 wk. During all sessions, the nonstress test was applied from 20 min before application of the stimulus until 20 min after its conclusion, and the fetal pulse rate, fetal movements, and maternal uterine contractions were monitored. Not stated whether the techniques were consecutive or applied at the same time. Who applied the technique: not stated, although it was performed at the hospital Criteria for halting the treatment: not stated Criteria for continuing the treatment: not stated Control group 2: acupuncture Number of women allocated to this group: 10 Points used and technique: bilateral acupuncture at BL67 for 20 min, twice weekly for 1 wk. During all sessions, the nonstress test was applied from 20 min before application of the stimulus until 20 min after its conclusion, and the fetal pulse rate, fetal movements, and maternal uterine contractions were monitored. Who applied the technique: not stated, although it was performed at the hospital Criteria for halting the treatment: not stated Criteria for continuing the treatment: not stated Cointerventions in the 2 groups: none Results Primary: data on fetal distress (fetal pulse rate, fetal movements). Presentation at birth

Fetal pulse rate: moxibustion group: no changes in pulse rate, no changes in frequency; moxibustion plus acupuncture group: reduction in frequency; acupuncture group: no changes in frequency (P < .05)

Fetal movements: moxibustion group: no changes in frequency; moxibustion plus acupuncture group: reduction in frequency; acupuncture group: no changes in frequency (P < .05)

Secondary: cephalic presentation (not stated whether this was after treatment or at birth, although follow-up is assumed to have been carried out until delivery)

Cephalic presentation: 12/15 (80%) in the moxibustion group; 8/14 (57%) in the moxibustion plus acupuncture group; 2/10 (20%) in the acupuncture group

Adverse effects: no data Adverse events: no data

STUDY

YANG17

Methods

Details of randomization: randomized controlled study, although the allocation method is unclear

Blinding: neither the pregnant woman nor the medical practitioner was blinded to the treatment, and it is not stated whether the assessors and the analysts were blinded.

Exclusions or dropouts during the study: none

Losses during follow-up: none

Vas. Correction of nonvertex presentation with moxibustion. Am J Obstet Gynecol 2009.

STUDY	YANG ¹⁷ (continued)						
Methods	Type of analysis reported: not stated whether analysis was per ITT, but there was complete follow-up of all the randomized subjects, and the data for all of them were available.						
	Important baseline imbalances in prognosis factors: none						
Participants	Location of study: China						
	Period of study: 2003-2004						
	Funding: not stated						
	Setting: not stated						
	Total number of randomized subjects: 206						
	Mean age/range: not stated (treatment group: 27.6 y [\pm 3.4] in the subgroup with a gestational age of 28-30 wks; 26.2 [\pm 3.6] in the subgroup with a gestational age of 30-32 wks; and 28.1 [\pm 2.2] years in the subgroup with a gestational age of 32-34 wks; control group: 26.7 [\pm 3.6] in the subgroup with a gestational age of 28-30 wks; 25.4 [\pm 4.1] in the subgroup with a gestational age of 30-32 wks; and 27.9 y [\pm 3.1] in the subgroup with a gestational age of 32-34 wks).						
	Parity: primiparous						
	Single fetus: Assumed but not explicitly stated						
	Gestational week: 28-34 wks (not stated if gestational age was confirmed by echography)						
	Presentation: beech (confirmed by echography)						
	Other criteria for inclusion: not stated						
	Criteria for exclusion. not stated						
Treatment	Treatment group: moxibustion plus knee-to-chest posture						
	Number of women allocated to this group: 103 (subgroups: 56 from 28-30 wks, 34 from 30-32 wks, and 13 from 32-34 wks gestation)						
	Points used and technique: BL67 bilateral (twice daily, 15-20 min) while the woman maintained a knee-to-chest posture repeated for 7 d						
	Who applied the technique: not stated						
	Criteria for halting the treatment: not stated						
	Criteria for continuing the moxibustion: not stated						
	Control group: knee-to-chest posture, twice daily for 15-20 min; repeated for 7 d						
	Number of women allocated to this group:103 (subgroups: 56 from 28-30 wks, 34 from 30-32 wks, and 13 from 32-34 wks gestation)						
	Cointerventions in the 2 groups: not stated						
Results	Primary: rate of cephalic presentation after treatment						
	Cephalic presentation (not stated whether presentation was confirmed by echography): 90/103 (87.4%) in the treatmer group vs 77/103 (74.8%) in the control group (RR, 1.17; 95% Cl, 1.02-1.33)						
	Cephalic presentation stratifying by week of gestation at the start of treatment (not specified whether presentation was confirmed by echography):						
	Group 28-30 wks of gestation: 52/56 (92.9%) in the treatment group vs 45/56 (80.4%) in the control group (RR, 1.16; CI, 0.99-1.34)						
	Group 30-32 wks of gestation: 29/34 (85.3%) in the treatment group vs 25/34 (73.5%) in the control group (RR, 1.16; 9 Cl, 0.91-1.49)						
	Group 32-34 wks of gestation: $9/13$ (69.2%) in the treatment group vs $9/13$ (69.2%) in the control group (RR, 1; 95% C 0.60-1.67)						
	Adverse effects: not stated						

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(ranging from once or twice weekly to once or twice daily) and the gestational age at which the technique is initiated; in fact, when we included only the 4 studies with pregnancies of 32 weeks' gestation or more, the heterogeneity was not significant, and the RR remained significant. This suggests that the gestational age at which the women are included in the study may be the most important source of heterogeneity.

Future trials should seek to standardise the frequency and duration of treatment, establish a protocol for the variables related to the safety of the technique, take into account the covariables that influence the prevalence of nonvertex presentation, and consider including a control placebo group.

Although in terms of safety, the results are not statistically significant, except for the reduction in the use of oxytocin, because of the limited statistical power derived from the low level of systematization of the variables, there was seen to be a trend toward fewer problems in this respect arising from nonvertex presentation.

Conclusions

Our systematic review shows that with regard to the correction of nonvertex presentation, there is a beneficial effect of moxibustion applied at the acupuncture point BL67, whether this treatment is applied alone or in association with acupuncture or postural measures, in comparison with mere observation or postural methods alone. The technique has been shown to be safe because there is no increase in the rate of complications typical of nonvertex presentation, although the results are not totally conclusive in this respect. Our results should be interpreted with caution because they may be influenced by differences in the design and quality of the studies considered.

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