Using moxibustion in primary healthcare to correct non-vertex presentation: a multicentre randomised controlled trial

Jorge Vas,[1,2] José Manuel Aranda-Regules,[3] Manuela Modesto,[1]
María Ramos-Monserrat,[4] Mercedes Barón,[5] Inmaculada Aguilar,[1]
Nicolás Benítez-Parejo,[6] Carmen Ramírez-Carmona,[7] Francisco Rivas-Ruiz[2,6]

[1]Pain Treatment Unit, Doña Mercedes Primary Health Care Centre, Andalusian Public Health System, Dos Hermanas, Spain
[2]Carlos III Health Institute, Network of Research in Health Services in Chronic Diseases (REDISSEC), Madrid, Spain
[3]San Andrés Torcal Primary Health Care Centre, Andalusian Public Health System, Malaga, Spain
[4]Registre de Càncer, Servei d'Epidemiologia, Direcció General de Salut Pública, Palma, Spain
[5]El Lugar Primary Health Care Centre, Andalusian Public Health System, Chiclana de la Frontera, Spain
[6]Support Research Unit, Andalusian Public Health System, Costa del Sol Hospital, Marbella, Spain
[7]Doña Mercedes Primary Health Care Centre, Andalusian Public Health System, Dos Hermanas, Spain

Correspondence to
Dr Jorge Vas, Pain Treatment Unit, Doña Mercedes Primary Health Care Centre, Andalusian Public Health System, Dos Hermanas, Sevilla 41700, Spain; jorgef.vas.sspa@juntadeandalucia.es

▶ http://dx.doi.org/10.1136/acupmed-2012-010288

ABSTRACT

Objective To compare the effectiveness of additional moxibustion at point BL67 with moxibustion at a non-specific acupuncture point and with usual care alone to correct non-vertex presentation.

Methods This was a multicentre randomised controlled trial in which 406 low-risk pregnant women with a fetus in ultrasound breech presentation, with a gestational age of 33–35 weeks, were assigned to (1) true moxibustion at point BL67 plus usual care; (2) moxibustion at SP1, a non-specific acupuncture point (sham moxibustion) plus usual care; or (3) usual care alone. The primary outcome was cephalic presentation at birth. Women were recruited at health centres in primary healthcare.

Results In the true moxibustion group, 58.1% of the full-term presentations were cephalic compared with 43.4% in the sham moxibustion group (RR 1.34, 95% CI 1.05 to 1.70) and 44.8% of those in the usual care group (RR 1.29, 95% CI 1.02 to 1.64). The reduction in RR of the primary outcome in women allocated to the true moxibustion group compared with the usual care group was 29.7% (95% CI 3.1% to 55.2%) and the number needed to treat was 8 (95% CI 4 to 72). There were no severe adverse effects during the treatment.

Conclusions Moxibustion at acupuncture point BL67 is effective and safe to correct non-vertex presentation when used between 33 and 35 weeks of gestation. We believe that moxibustion represents a treatment option that should be considered to achieve version of the non-vertex fetus.

Trial registration Current Controlled Trials ISRCTN10634508.

INTRODUCTION

The incidence of non-vertex or breech presentation is 20% at 28 weeks of gestation, although spontaneous version frequently occurs,[1] so only in 3–4% of women with a full-term singleton pregnancy is the fetus in a non-vertex presentation.[2] In Spain, non-vertex presentations represents 3.8% of all births.[3]

Caesarean section is the technique most frequently used in cases of non-vertex presentation.[4] Compared with planned vaginal delivery, caesarean section reduces perinatal or neonatal death and severe neonatal morbidity but causes increased maternal morbidity.[5] Because of the risks associated with both breech delivery and caesarean section, various types of manoeuvres have been proposed to promote the version of the fetus towards a cephalic presentation. Of these, the method most commonly adopted is external cephalic version which reduces the likelihood of non-vertex presentation births[6] without reducing caesarean sections.[7] Methods based on maternal posture or hypnosis and relaxation techniques to promote fetal version have also been recommended; they are widely used but their effectiveness remains unproven.[8]

The application of heat from the combustion of *Artemisia vulgaris* (moxibustion) for therapeutic purposes has long been used in China. Among other effects, it is believed to contribute to correcting the non-vertex presentation of the fetus when applied at a specific acupuncture point (BL67 *Zhiyin*) located at the outer corner of the little toenail.[9] [10] A recent meta-analysis[11] highlighted the effectiveness of this technique in comparison with usual care, reporting a rate of cephalic version among the moxibustion group of

72.5% compared with 53.2% in the control group and a number needed to treat (NNT) of 5 (95% CI 4 to 7). In terms of safety, no significant differences were found in the moxibustion group compared with other techniques. However, the authors advise caution in interpreting these results owing to the high level of heterogeneity among the studies considered. Two later studies have reported conflicting results,[12 13] and in neither case was there a control group in which moxibustion was applied to another non-specific acupuncture point.

The aim of the present study is to assess the effectiveness, specificity and safety of additional moxibustion at a specific point compared with additional moxibustion at a non-specific point and with usual care alone in pregnant women with non-vertex presentation at the gestational age of 33–35 weeks in primary healthcare.

METHODS
Study design and participants
This study was a multicentre randomised controlled trial of the effectiveness and safety of moxibustion applied at a specific acupuncture point (true moxibustión) in conjunction with usual care, in comparison with moxibustion at a non-specific point (sham moxibustion) in conjunction with usual care, and with usual care alone.

The study was carried out at 58 primary healthcare centres belonging to the Andalusia (Spain) Public Health System in the provinces of Sevilla, Huelva, Cádiz and Málaga. In Andalusia, low-risk pregnancy follow-up is carried out by midwives and general practitioners in primary healthcare.

The study population comprised women in week 32 of gestation who revealed a breech presentation of the fetus in the third scheduled obstetric ultrasound examination performed at the hospital. These women were referred to one of the participating healthcare centres and invited to participate in the study if the following inclusion criteria were met: fetus in a non-cephalic position diagnosed by physical examination and ultrasound; age at least 18 years; gestational age 33–35 weeks estimated by ultrasound; normal fetal biometry and no prior treatment with moxibustion to achieve version of the fetus. The following exclusion criteria were applied: multiple pregnancy; bone pelvic defects; previous uterine surgery; fetal malformation or chromosomal disorder; uterine malformations; risk of preterm birth (preterm uterine contractions and/or initial dilatation or shortening of the cervix with a score of 4 on the Bishop scale); uterine fibroids >4 cm; tocolytic therapy; and maternal heart or kidney disease.

All pregnant women who fulfilled the inclusion criteria and did not have any exclusion criteria were invited to participate and, upon acceptance, they received information about the study and were invited to sign the informed consent. Participants were randomised to receive: (1) true moxibustion at point BL67 plus usual care; (2) moxibustion at a non-specific acupuncture point (sham moxibustion) plus usual care; or (3) usual care alone.

Sample size
On the basis of existing documentation, we assumed there would be a difference of at least 20% in the rate of cephalic presentations at term between the true moxibustion group and the usual care alone group.[11] For a significance level of 5% and a statistical power of 90%, 372 women had to be included in the study. As the sample was calculated for two groups (but in fact we compared three groups) and because of drop-outs, we enlarged the sample by 10% so the necessary sample size was estimated to be 406 women.

Random allocation
Randomisation of the three arms of the study was centralised and performed by a statistician not otherwise involved in the study, following a 1:1:1 scheme in blocks of 12 and stratified by centre. A pack of envelopes was prepared for each healthcare centre participating in the study. Each pack contained 12 opaque envelopes, each of which was sealed after the introduction of a card with the letter corresponding to the group to which the patient was assigned, in accordance with the software-generated sequence (true moxibustion, sham moxibustion or usual care). After the baseline assessment and the provision of written informed consent, these sealed and numbered opaque envelopes were used to assign the participants to one of the three study groups in sequence. The midwife collaborating with the study noted on the card the patient's number and that of the healthcare centre. At the end of the study the principal researcher checked each card against the original randomisation list to verify that the participants had received the treatment assigned. The participants assigned to the true and sham moxibustion arms were blinded with regard to the treatment received, as were the analysts of the results.

Procedures
All the midwives participating in the study took a 10 h training course, given by three physicians who were specialists in acupuncture and moxibustion with over 10 years' clinical experience, and were informed about the moxibustion technique, sham moxibustion, usual care and standard criteria for data collection.

True moxibustion
The woman should lie down, face up. Heat is applied for 20 min by means of a moxa stick (herbal preparation with *Artemisia vulgaris*, Huaian Stick Moxa, Changsha, China) at point BL67 (*Zhiyin*), close to the outer angle of the little toenail. The heat is applied

from a distance of 1.5–3 cm. More details are given in the study protocol paper.[14]

Sham moxibustion

This procedure is identical to the moxibustion technique except that the point stimulated is SP1 (*Yinbai*), close to the inner angle of the big toenail, a non-active one according to the principles of Traditional Chinese Medicine.

Usual care

In accordance with the clinical practice guidelines of the Andalusian Public Health System,[15] pregnancy follow-up is shared between the general practitioner and the midwife who perform a minimum of six scheduled visits. Obstetric risk is assessed in every visit, an ultrasound is performed quarterly and a non-stress cardiotocography is performed in week 40. If abnormal fetal presentation is confirmed during the third ultrasound, women receive recommendations for knee-chest postural management. A caesarean section is scheduled when non-vertex presentation confirmed by ultrasound is maintained until the full-term pregnancy.

The pregnant women assigned to the true and sham moxibustion groups were blinded with regard to the type of intervention. Both interventions were applied at home by a family member. During the first visit with the midwife, the woman and the person who was going to apply moxibustion received a practical demonstration and a learning session. They were advised to apply the treatment for 20 min a day for 2 weeks, changing from one foot to the other as soon as the heat became uncomfortable at the point of application. They were told to suspend treatment and to consult the midwife if they noticed a change in the position of the fetus or any adverse effect. They were given sufficient moxibustion sticks for the whole course of treatment.

After 2 weeks of treatment, all the women participating were asked to attend the health centre for an ultrasound evaluation of the position of the fetus.

Outcome assessment

The primary clinical outcome was cephalic presentation at birth. Secondary clinical outcomes were cephalic presentation at the conclusion of the treatment and the mode of birth: caesarean section or vaginal birth (spontaneous cephalic, assisted cephalic or vaginal breech).

Independent measures

At baseline the following information was obtained: (1) age, country of origin, educational level; (2) health measures: height (cm), weight (kg); (3) obstetric-gynaecological variables: parity, gestational age when the woman is included in the study, type of presentation (breech, oblique or transverse), location of the placenta (anterolateral or posterior); and (4) four items related to the women's expectations and confidence in the treatment evaluated on a visual analogue scale (from 0=totally disagree to 10=totally agree).

During the first visit, fetal and maternal heart rates were recorded to assess possible adverse effects of the technique. Data on women's expectations and confidence in the treatment were collected from those in the true moxibustion and sham moxibustion groups.

After each home treatment session the following safety variables were recorded: fetal movements, uterine contractions, maternal pulse and any other possible adverse effect arising from the treatment.

Finally, a number of other variables related to the birth were obtained: gestational age at birth, preterm birth (<37 weeks), sex and weight of the neonate, Apgar score at 2 and 5 min and any perinatal or maternal complications.

Data collection

Most of the data were recorded from the Pregnant Woman's Health Passport by hospital staff who had no connection with the study and who therefore were blinded to the treatment received, from the Child's Health Passport and some of them through interview performed by the midwife. A Data Collection Record was elaborated to collect all this information. Therefore, after each home treatment session, the pregnant women completed a self-report questionnaire.

Statistical analysis

We performed a basal comparative analysis of sociodemographic, health and obstetric-gynaecological variables between the groups using the Student t test and two-sided χ^2 test or non-parametric tests when normality was not met.

The primary (fetal presentation at birth) and secondary (cephalic presentation at the conclusion of the treatment and the mode of birth) clinical outcome variables were analysed by intention to treat. Comparison of these variables in both groups was made using the Student t test and the χ^2 test if normality was met. Otherwise, a two-sided Mann–Whitney test was used. The relative risk (RR), RR reduction and the NNT were calculated for true moxibustion versus usual care and for true moxibustion versus sham moxibustion. The level of statistical significance was set at $p < 0.05$ and included the respective 95% CI. All missing outcomes were computed as non-vertex presentation as recommended.[16]

Finally, we performed a multivariate logistic regression analysis to explore the factors associated with cephalic presentation at delivery adjusting for potential confounders. A forward stepwise method was used with an entry criterion of $p < 0.05$.

Findings with p values < 0.05 were deemed statistically significant. Analysis was performed by a statistician blinded to the study group. SPSS (V.17) was used for all analyses.

RESULTS

Between April 2008 and December 2010, midwives at the participating health centres evaluated 524 women of whom 118 were excluded, so 406 were randomised (figure 1). The baseline characteristics were similar in the three groups (table 1). No significant differences between the true and sham moxibustion groups were observed with regard to expectations and confidence in the treatment (table 2).

Cephalic presentation at birth was present in 58.1% of the women in the true moxibustion group compared with 44.8% of the usual care group (RR 1.29, 95% CI 1.02 to 1.64) and 43.4% of the sham moxibustion group (RR 1.34, 95% CI 1.05 to 1.70) (table 3). The RR reduction of the primary outcome in the true moxibustion group compared with the usual care group was 29.7% (95% CI 3.1% to 55.2%) and the NNT was 8 (95% CI 4 to 72). No significant differences regarding mode of birth were observed between the groups.

During the treatment period, 29.4% of the women reported having felt uterine contractions and 14.6%

experienced palpitations. No significant differences were observed among the groups. Heart rate (maternal and fetal) did not vary in any clinically significant way during the intervention in any of the groups; there was an average increase of 1.30 beats/min (95% CI 0.19 to 2.41) in the maternal heart rate and of 1.02 beats/min (95% CI 0.18 to 2.21) in the fetal heart rate during the application of moxibustion, both true and sham. There were no severe adverse effects during the treatment, although one patient reported a burn caused during combustion of the moxa and another discontinued treatment because of abdominal pain following moxibustion. The most common complaints were gastrointestinal disturbances (heartburn, nausea and vomiting) (2%), dizziness (1.7%), mild hypertensive disorders (1.7%), abdominal pain (1.5%) and fetal hiccups (1.2%), with no significant differences being observed between the three groups.

Furthermore, no differences were observed in neonatal outcomes (weight and sex of the neonate). The adverse events recorded were 1.5% cord pathology, 1.5% did not progress due to lack of uterine
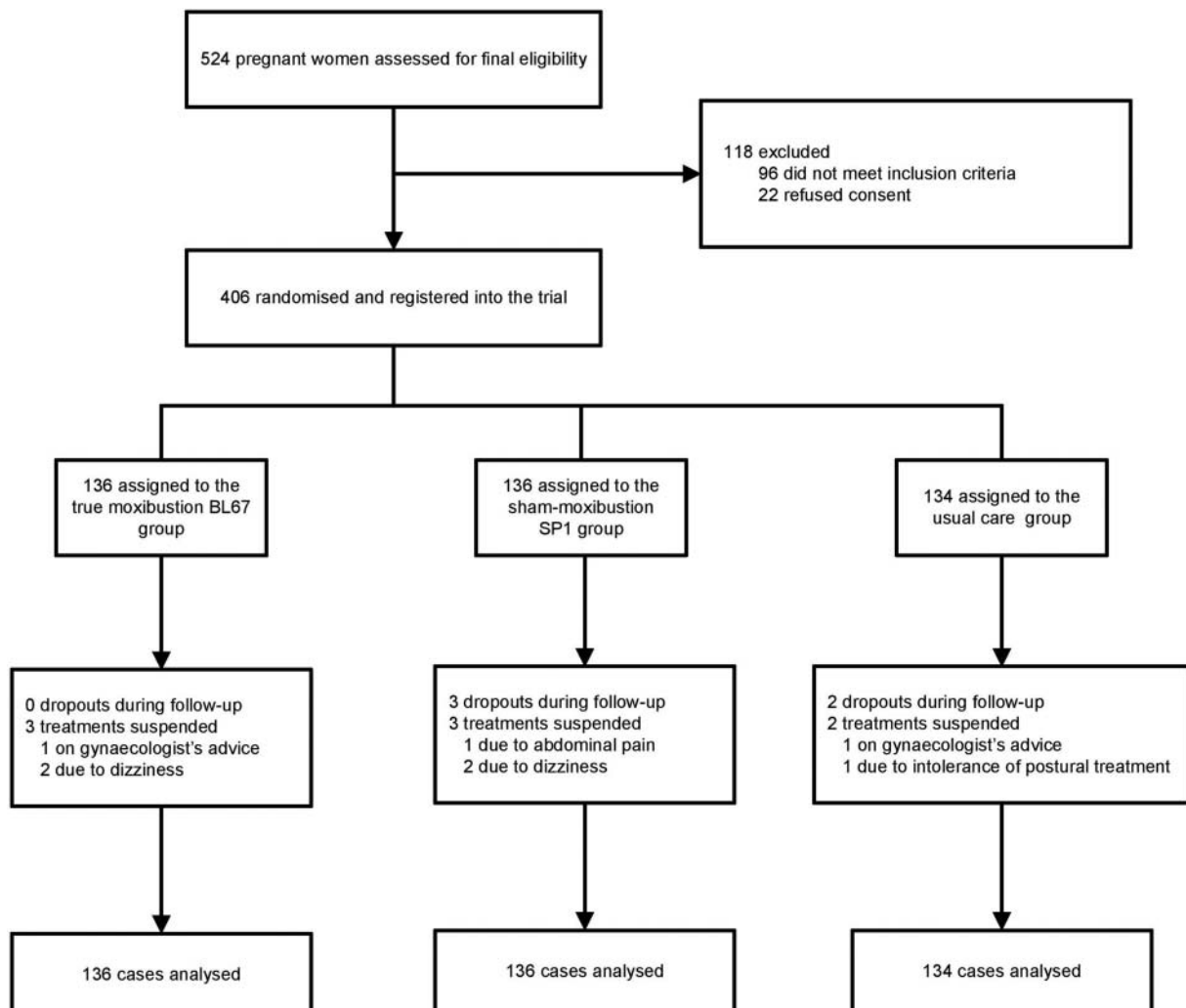

Figure 1 Trial profile.

Table 1 Demographic and clinical characteristics of study participants

Characteristics at randomisation	True moxibustion (n=136)	Sham moxibustion (n=136)	Usual care (n=134)	Total (n=406)
Age (years)	31.5 (22.6, 39.0)	32.0 (24.4, 38.0)	31.0 (24.0, 38.3)	32.0 (23.4, 38.0)
Born in Spain	126 (92.6)	126 (92.6)	128 (95.5)	380 (93.6)
Educational level				
Without studies	4 (2.9)	6 (4.4)	11 (8.2)	21 (5.2)
Primary school	35 (25.7)	27 (19.9)	47 (35.1)	109 (26.8)
Secondary school	49 (36.0)	60 (44.1)	45 (33.6)	154 (37.9)
Higher level	48 (35.3)	43 (31.3)	31 (23.1)	122 (30.3)
Nulliparity	73 (53.7)	77 (56.6)	81 (60.4)	231 (56.9)
Gestational age at start of treatment (weeks)	34.0 (33.0, 35.0)	33.0 (33.0, 35.0)	34.0 (33.0, 35.0)	33.5 (33.0, 35.0)
Maternal height (cm)	162.0 (153.9, 175.2)	162.0 (152.0, 173.2)	164.0 (151.5, 175.0)	162.5 (152.4, 175.0)
Maternal weight (kg)	67.0 (52.0, 99.2)	66.0 (53.0, 92.6)	70.0 (50.8, 94.0)	68.0 (52.0, 94.7)
Type of presentation				
Breech	125 (91.9)	130 (95.6)	130 (97.0)	385 (94.8)
Oblique	2 (1.5)	1 (0.7)	0 (0.0)	3 (0.7)
Transverse	9 (6.6)	5 (3.7)	4 (3.0)	18 (4.4)
Anterior placenta	72 (52.9)	73 (53.7)	61 (45.5)	206 (50.7)

Data are median (5th, 95th centile) or n (%).

contractions, 1.2% premature rupture of the membranes and 0.5% oligohydramnios. None of the neonates had an Apgar score of <7 at 5 min.

In the multivariate model, variables associated with cephalic presentation at birth were true but not sham moxibustion, multiparity, being born outside Spain and fewer gestational weeks at the start of treatment (table 4).

DISCUSSION

To the best of our knowledge, this randomised trial is the first to compare supplemented real moxibustion at a specific acupuncture point with supplemented sham moxibustion at a non-specific acupuncture point and with usual care alone for correcting non-vertex presentation of the fetus in pregnant women with a gestational age of 33–35 weeks. The probability of achieving version of the fetus was found to be 30% higher when true moxibustion was associated with usual care than with usual care alone. Thus, it is

necessary to treat eight pregnant women in order to correct one non-vertex presentation. These results are consistent with those reported both in our systematic review[11] and in other systematic reviews published previously,[11 17 18] as well as with another recent cost-effectiveness study.[19] Two recent studies have reported conflicting results. Guittier et al[12] found no differences in the proportion of versions among pregnant women treated with moxibustion and those in the control group, probably because the gestational age of these women (34–36 weeks) was higher than in our study and there was a higher percentage of nulliparous participants. It is known that higher gestational age and nulliparity versus lower gestational age and multiparity tend to reduce the rate of spontaneous version.[1] Do et al[13] found a trend towards an increase in cephalic version at delivery for women receiving moxibustion compared with usual care, but the study was underpowered to detect statistical differences between groups.

Table 2 Expectation and confidence in the treatment

Items	True moxibustion (n=136) Mean (95% CI)	Sham moxibustion (n=135) Mean (95% CI)	p Value*
I am confident this treatment will correct the position of my baby	7.69 (7.39 to 7.99)	7.32 (6.99 to 7.65)	0.162
I consider the treatment a logical one	7.06 (6.68 to 7.43)	6.99 (6.62 to 7.35)	0.726
I would recommend this treatment to a friend or relative with the same problem	8.21 (7.91 to 8.50)	7.84 (7.51 to 8.18)	0.132
I believe this treatment would be an option to consider for treating other problems	7.40 (7.03 to 7.78)	7.35 (7.02 to 7.67)	0.549

The four items are evaluated on a visual analogue scale of 0–10 cm (0=totally disagree; 10=totally agree).
*Mann–Whitney U test.

Original paper

Table 3 Characteristics and outcomes of pregnancy, labour and birth

Outcome	True moxibustion (n=136)	Sham moxibustion (n=136)	Usual care (n=134)	RR (95% CI) True moxibustion vs usual care	RR (95% CI) True moxibustion vs sham moxibustion
Cephalic presentation at delivery	79 (58.1)	59 (43.4)	60 (44.8)	1.29 (1.02 to 1.64)	1.34 (1.05 to 1.70)
Cephalic version during treatment*	51 (38.3)	28 (21.2)	29 (22.3)	1.42 (1.13 to 1.79)	1.46 (1.16 to 1.84)
Caesarean section†	69 (50.7)	82 (61.7)	78 (59.1)	0.85 (0.67 to 1.07)	0.80 (0.64 to 1.02)
Vaginal birth†					
Spontaneous cephalic	55 (40.4)	42 (30.9)	41 (30.6)	1.32 (0.95 to 1.83)	1.31 (0.95 to 1.81)
Assisted cephalic (vacuum or forceps)	9 (6.6)	8 (5.9)	11 (8.2)	0.81 (035 to 1.88)	1.13 (0.45 to 2.83)
Vaginal breech	3 (2.2)	1 (0.7)	2 (1.5)	1.48 (0.25 to 8.70)	3.00 (0.32 to 28.48)
Gestational age at delivery†	39.0 (37.0, 41.0)	39.0 (37.0, 41.0)	39.0 (37.7, 41.0)	0.871‡	0.386‡
Preterm birth <37 weeks†	4 (2.9)	4 (3.0)	5 (3.8)	0.87 (0.42 to 1.83)	0.99 (0.49 to 2.00)

Data are n (%) or median (5th, 95th centiles).
*Missing data for three women in the true moxibustion group, four in the sham moxibustion group and four in the usual care group.
†Missing data for three women in the sham moxibustion group and two in the usual care group.
‡Two-sided Mann–Whitney test.
RR, relative risk.

Our study confirms the findings of the systematic review in terms of safety, adding more evidence in favour of moxibustion as a safe technique for pregnant women.[11]

Regarding the mode of birth, the percentage of caesarean sections diminished in the moxibustion group (but not significantly), probably due to the lack of potency, although the influence of the gynaecologist's modus operandi cannot be ruled out. The same has been reported with external cephalic version.[7] The fact that 16.2% of the pregnant women with cephalic presentation at term needed a caesarean section is in line with the established prevalence of caesarean sections in deliveries without complications in Andalusia.[20]

The main strength of this study is the robustness of the design used to demonstrate the effectiveness and safety of moxibustion at a specific point for pregnant women with non-vertex presentation. We developed a randomised double-blind study with three arms, with the innovative use of a control group with moxibustion applied at another non-specific point for the purpose of achieving fetal version. The results obtained in the sham moxibustion group are very similar to those for the usual care group, which demonstrates the specific effect of moxibustion applied to the 67BL point.

Some researchers believe that it is difficult to have a control group based on the use of a sham technique in this type of study in view of the participants' easy access to information in this respect on the internet.[11] However, in our study the level of expectations and confidence in the technique was similar in the two groups in which moxibustion was used, and although the procedure was performed at home and the acupuncture point could have been changed, the results obtained in the sham group lead us to believe this was not so.

We also highlight the reliability of this study and its multicentre nature (with the participation of 58 health centres), which enabled us to analyse a heterogeneous sample of pregnant women. The obstetric-gynaecological variables, both primary (cephalic

Table 4 Multivariate analysis of factors associated to cephalic presentation at delivery

	B	p Value	RR	95% CI
Treatment group				
Usual care			1	
True moxibustion	0.65	0.018	1.92	1.12 to 3.29
Sham moxibustion	−0.06	0.832	0.94	0.55 to 1.62
Parity				
Nulliparous			1	
Multiparous	1.29	<0.010	3.63	2.34 to 5.64
Country of origin				
Spain			1	
Foreign	0.97	0.042	2.64	1.03 to 6.75
Educational level				
Higher level			1	
No studies	1.66	0.010	5.28	1.49 to 18.76
Primary school	0.83	<0.010	2.28	1.27 to 4.11
Secondary school	0.23	0.400	1.25	0.74 to 2.12
Gestational age at the start of treatment	−0.46	<0.010	0.63	0.47 to 0.86

RR, relative risk.

presentation at birth) and secondary (version of the fetus during treatment or days of treatment to obtain cephalic version), are easily measurable and not subjective.

No independent effect on version was observed with respect to the mother's height, the weight or sex of the neonate or the location of the placenta, all factors that we had considered might influence the outcome. A striking finding was the occurrence of a reverse gradient between the mother's educational level and fetal position at term. Country of origin presented a similar pattern and, given the high correlation with income level, we consider both variables as a proxy for social class. This finding, which has also been mentioned in another study,[21] reveals the presence of social mediators in the incidence of the problem and in the effectiveness of treatment, which suggests a possible area of interest for future study.

A notable feature of this study was the high rate of acceptance of a technique that is uncommon in Western medicine (only 4.2% refused to participate) and the low voluntary dropout rate (1.23%), which is in contrast with other studies.[21] This circumstance probably arose because the technique was proposed in the context of primary healthcare and probably because it was self-administered, under the supervision of the woman's regular midwife.

There may have been a selection bias in our study, which included only pregnant women who requested treatment within the public health system. The feasibility of this study would have been limited if private clinics had also been included because of the difficulty involved in subsequent monitoring of their patients. However, we believe this possible limitation was minimal because the coverage and acceptance of safe motherhood programmes in the Andalusian public health system is almost universal.

A limitation of the study is that the experimental procedure was applied by a person who was not an expert. However, given the simplicity of the procedure, which enabled it to be quickly learned, and the high degree of motivation of the participants who appreciated the benefits to be obtained from the success of the technique, we consider the mode of administration of this experimental technique was valid. Another limitation is the lack of record of adherence to any of the study interventions, which could be a confounding factor.

The results suggest two areas that should be considered immediately for further research. The first concerns the best gestational age at which treatment should be started. Some authors suggest between weeks 32 and 37,[12 21–23] while others do not apply it after week 35 due to the theoretical risk of inducing contractions leading to premature delivery.[24] There is no empirical basis for either claim. Our data suggest that the application of the technique is not associated with premature birth. The data also suggest that, the earlier the treatment is begun the more effective it is, although we only compared weeks 33–35 and further purpose-designed studies are needed to confirm this hypothesis.

The second question to be considered is whether the application of heat to acupuncture point BL67 by processes other than moxibustion would be equally effective in obtaining version of the fetus. It has been reported that the infrared radiation intensity produced by a traditional moxa stick is different from that produced by other sources of radiation.[25] We do not know if a simple device to apply heat at this point, controlling heat intensity and duration, would have the same effects as *Artemisia moxa*. If this were so, the treatment process would be less cumbersome and its use could be more readily generalised.

> **Summary points**
>
> ▶ We randomised 406 pregnant women with breech presentation to three groups.
> ▶ At term, vertex presentations were 58% for moxa at BL67, 43% for moxa at sham SP1 and 45% for usual care.

CONCLUSIONS

We conclude that moxibustion at acupuncture point BL67 is effective and safe to correct non-vertex presentation when used between 32 and 34 weeks of gestation. Moxibustion is well-accepted by women and the straightforward nature of the procedure means it can be easily applied at home. Moxibustion therefore represents a treatment option that should be considered to achieve version of the non-vertex fetus.

Gámez Requena, Mercedes Acuña, Eugenia Sevilla Blanca, Mª Eugenia Fernández Ruiz, Isabel Moreno Cuevas, Dolores Ponce García, Rosa Girón Zambonino, Mª Isabel Cabezón Robles, Magdalena Rus Ruiz, Rosa Mª Abad Ponce, Carmen Colombo Roquete, Mª Encarnación Báez Perea, Natividad Bernal Guerrero, Esther Ramallo Peón, Angel C Delgado Lucio, Mª Dolores López Cossi, Claudia Kaiser.

REFERENCES

1 Westgren M, Edvall H, Nordstrom L, *et al*. Spontaneous cephalic version of breech presentation in the last trimester. *Br J Obstet Gynaecol* 1985;92:19–22.

2 Cruikshank DP. Breech presentation. *Clin Obstet Gynecol* 1986;29:255–63.

3 Acien P. Breech presentation in Spain, 1992: a collaborative study. *Eur J Obstet Gynecol Reprod Biol* 1995;62:19–24.

4 Goffinet F, Carayol M, Foidart JM, *et al*. Is planned vaginal delivery for breech presentation at term still an option? Results of an observational prospective survey in France and Belgium. *Am J Obstet Gynecol* 2006;194:1002–11.

5 Hofmeyr GJ, Hannah ME. Planned caesarean section for term breech delivery. *Cochrane Database Syst Rev* 2003;CD000166.

6 Hutton EK, Hofmeyr GJ. External cephalic version for breech presentation before term. *Cochrane Database Syst Rev* 2006; CD000084.

7 Hutton EK, Hannah ME, Ross SJ, *et al*. The Early External Cephalic Version (ECV) 2 Trial: an international multicentre randomised controlled trial of timing of ECV for breech pregnancies. *BJOG* 2011;118:564–77.

8 Founds SA. Maternal posture for cephalic version of breech presentation: a review of the evidence. *Birth* 2005;32:137–44.

9 Liu GW. *Clinical acupuncture and moxibustion*. 1st edn. Tianjin: Tianjin Science and Technology Translation and Publishing Corp, 1996.

10 Hou JL. *Acupuncture and moxibustion therapy in gynecology and obstetrics*. 1st edn. Beijing: Beijing Science and Technology Press, 1995.

11 Vas J, Aranda JM, Nishishinya B, *et al*. Correction of nonvertex presentation with moxibustion: a systematic review and metaanalysis. *Am J Obstet Gynecol* 2009; 201:241–59.

12 Guittier MJ, Pichon M, Dong H, *et al*. Moxibustion for breech version: a randomized controlled trial. *Obstet Gynecol* 2009;114:1034–40.

13 Do CK, Smith CA, Dahlen H, *et al*. Moxibustion for cephalic version: a feasibility randomised controlled trial. *BMC Complement Altern Med* 2011;11:81.

14 Vas J, Aranda JM, Baron M, *et al*. Correcting non cephalic presentation with moxibustion: study protocol for a multi-centre randomised controlled trial in general practice. *BMC Complement Altern Med* 2008;8:22.

15 Consejería de Salud. *Embarazo, parto y puerperio: proceso asistencial integrado*. Sevilla: Consejería de Salud, 2005. http://www.juntadeandalucia.es/salud/export/sites/csalud/galerias/documentos/p_3_p_3_procesos_asistenciales_integrados/embarazo_parto_puerperio/embarazo_parto_puerperio.pdf (accessed 12 Sept 2012).

16 Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. *BMJ* 1999;319:670–4.

17 van den Berg I, Bosch JL, Jacobs B, *et al*. Effectiveness of acupuncture-type interventions versus expectant management to correct breech presentation: a systematic review. *Complement Ther Med* 2008;16:92–100.

18 Li X, Hu J, Wang X, *et al*. Moxibustion and other acupuncture point stimulation methods to treat breech presentation: a systematic review of clinical trials. *Chin Med* 2009;4:4.

19 van den Berg I, Kaandorp GC, Bosch JL, *et al*. Cost-effectiveness of breech version by acupuncture-type interventions on BL 67, including moxibustion, for women with a breech foetus at 33 weeks gestation: a modelling approach. *Complement Ther Med* 2010;18:67–77.

20 Márquez-Calderón S, Ruiz-Ramos M, Juárez S, *et al*. Caesarean delivery in Andalusia, Spain. Relationship with social, clinical and health services factors (2007–2009). *Rev Esp Salud Publica* 2011;85:205–15.

21 Cardini F, Lombardo P, Regalia AL, *et al*. A randomised controlled trial of moxibustion for breech presentation. *BJOG* 2005;112:743–7.

22 Habek D, Cerkez HJ, Jagust M. Acupuncture conversion of fetal breech presentation. *Fetal Diagn Ther* 2003; 18:418–21.

23 Cardini F, Weixin H. Moxibustion for correction of breech presentation: a randomized controlled trial. *JAMA* 1998;280:1580–4.

24 Neri I, Airola G, Contu G, *et al*. Acupuncture plus moxibustion to resolve breech presentation: a randomized controlled study. *J Matern Fetal Neonatal Med* 2004;15:247–52.

25 Shen X, Ding G, Wei J, *et al*. An infrared radiation study of the biophysical characteristics of traditional moxibustion. *Complement Ther Med* 2006;14:213–19.

Using moxibustion in primary healthcare to correct non-vertex presentation: a multicentre randomised controlled trial

Jorge Vas, José Manuel Aranda-Regules, Manuela Modesto, et al.

Updated information and services can be found at:

http://aim.bmj.com/content/31/1/31.full.html

These include:

References	This article cites 20 articles, 1 of which can be accessed free at: **http://aim.bmj.com/content/31/1/31.full.html#ref-list-1**
	Article cited in: **http://aim.bmj.com/content/31/1/31.full.html#related-urls**
Email alerting service	Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections	Articles on similar topics can be found in the following collections Editor's choice (15 articles)

Notes